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Doctoral Thesis:

Ethical Decision Making: Advance Directives and Electroconvulsive Therapy (ECT)

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Word Count Statement

Thesis Section	Text	Tables, figures, references and appendices	Total
Abstract	221	-	221
Literature Review	7,614	4,724	12,338
Research Paper	7,931	3,039	10,970
Critical Appraisal	3,823	3,215	7,038
Ethics Section	5,401	12,637	18,038
Totals	24,990	23,615	48,605

Abstract

This thesis comprises a literature review, a research paper and a critical review of the research process.

In the literature review, a meta-ethnography was conducted in order to identify and synthesise 17 studies that explored a person's experience and understanding of advance directives in physical health care. Four themes emerged: 'hope and fears for the family'; 'the trust between the participant and the doctor'; 'the communication of advance directives by health care staff' and 'hope and fears for the individual's future. The findings are discussed in terms of culture and identity, affective forecasting and the notion of 'conditional autonomy'.

The empirical paper used a grounded theory informed methodology with ten participants who were all mental health professionals with experience of making a decision to give someone ECT or not. The ten participants were interviewed in order to develop a model that explained how this process occurred in clinical practice.

The critical review discusses my own epistemological position in relation to the research process and how it influenced my choice of methodology. The limitations of the research will then be reviewed specifically focusing on the challenges of involving expert by experience consultants (EbE) and recruiting service users and family to the research. The paper is concluded by linking the two research papers together by discussing the role of advance directives in ECT.

Declaration

This thesis records work undertaken for the Doctorate in Clinical Psychology at Lancaster

University's Division of Health Research between September 2015 and June 2016.

  The work presented here is the author's own, except where due reference is made.

The work has not been submitted for the award of a higher degree elsewhere.

Name: Anna Duxbury

Signature:

Date

Acknowledgements

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Section 2: Research Paper

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Section One: Literature Review

A metasynthesis investigating how people experience and understand advance directives in physical health care

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[1] The manuscript was prepared in line with author guidelines for Psychology & Health (see Appendix 1-A). Where these guidelines have not been followed, Lancaster University thesis guidelines have been followed. Of note, the word count is in line with University guidance.

Abstract

Background: Previous research has highlighted that clinicians' positive regard for advance directives does not always translate practically into the completion of an advance directive written by the patient. Many of the recent systematic literature reviews performed in the area of advance care planning and advance directives has focused on professional understandings of why positive regard has not been translated into action. This study focuses on the perspective of the patients to understand their experiences and views of advance directives. Exploring the experiences and understandings from both the clinicians' and the patients' points of view should help illuminate the process of advance directives and highlight areas for improvement and future research.

Aims: The aim of this meta-ethnography was to identify and synthesise qualitative research in order to understand how people experience and understand advance directives. This enabled the identification of key learning points for health care professionals working in physical health care settings and further research recommendations.

Method: A systematic search of qualitative articles was conducted using six databases, identifying 17 studies that met the inclusion/exclusion criteria. These articles were synthesised according to the method of meta-ethnography.

Results: Four themes emerged from the meta-ethnography; 'hopes and fears for the family'; 'doctor-patient trust; 'the communication of advance directives by health care staff' and 'hopes and fears for the individual's future.

Conclusions: People want to have a personally measured acceptable quality of life in end of life care and reduce the burden on their loved ones. Advance directives are written when people trust their clinician to understand and then respect their personal values. However this process can take time and a commitment. The views expressed in an advance directive may change over time as illness progresses and it is therefore important that advance directives are

not seen as 'a one off'. Honest conversations about views changing over time should happen

between clinicians and the patients.

Declaration of Interests: None.

Keywords: advance directive; meta-synthesis; meta-ethnography

Advance care planning (ACP) is a process whereby adults, who have the capacity to do so, can communicate their preferences about future treatment for a time when they lose the capacity to make a decision (Brinkman-Stoppelenburg, Rietjens, & van der Heide, 2014). Advance directives[2] are a key component of ACP of which there are two main types: the first simply designates a substitute decision-maker and the second, which is the subject of this paper, is the legal mechanism for documenting instructions regarding how future health care decisions should be made (Schmidt, 2015).

Internationally, there are different legal requirements related to advance directives depending on the country's specific jurisdiction (e.g. Bundesministerium der Justiz, 2010; Department of Health (WA), 2010; Law regarding Palliative Care 2002; O'Connor & Purves 2009; Patient Self Determination Act, 1990). In most countries, legal requirements for a valid advance directive are "a written form that is personally signed by a person who is of legal age, has decision-making capacity, is informed about the decision to be taken (including alternatives to the chosen action), and is able to make and communicate a non-coerced choice" (Trachsel, Mitchell, Biller-Andorno, 2013, p.5).

Patient Autonomy: Context and paradigms

Coleman (2012) suggests advance directives are an "American concept" driven by an ethical stance of the importance of autonomy (p. 697). Indeed, the principle of autonomy is widely regarded in Western bioethics as the "intellectual and moral foundation of the discipline" (Bowman, 2004, p. 666): however, when making future life care decisions there are other ethical perspectives, such as justice and beneficence, that a clinician may prioritise over 'autonomy' (Sanchez-Gonzalez, 1997). Coleman (2012) conducted a systematic review

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[2]The terminology surrounding advance directives in the United Kingdom (UK) is unclear and has been said to lead to confusion at the practical level of making and recoding different decisions: in particular, differentiating between legally-binding and other general documents (Kitzinger & Kitzinger, 2016). For the purpose of this paper the term advance directive will be used to describe the legal document that gives specific instructions regarding end-of-life care.

looking at the attitudes of physicians, from different countries, towards advance directives.

He suggested that although health care professionals had unanimously positive attitudes to

respect patient autonomy regarding advance directives, this did not always translate into

physician adherence to patients' advance directives in practice. Coleman found that there

were many variables that influenced the application of advance directives in practice. These

included: legal problems, culture, religion, family influence, fear of increased assisted suicide

and paternalism.

Recent controversies regarding physicians and pharmacists who refuse to prescribe or

dispense emergency and other contraceptives in the USA, sparked debate about

"conscientious objection in health care" (Curlin, Lawrence, Chin & Lantos, 2007, p.593).

This debate centres on whether health care professionals should have to offer or engage in

treatments that go against their personal moral stances. Curlin et al. (2007) found that

although 86% of doctors would always discuss all options with a patient, they concluded that

14% of patients may be cared for by physicians who did not believe they were obligated to

disclose information about medically available treatments they personally considered

objectionable. Such findings highlight the ongoing debate between medical paternalism and

patient autonomy. Paternalism arguments are based on the assumption that due to their

expertise, physicians know what is best for their patients and may therefore make decisions

without informing their patients of all the facts, alternatives, or risks. However, as Curlin et

al. (2007) found, these decisions may also be based on moral stances. Furthermore, if a

clinician has themselves completed advanced directives, they are more likely to introduce

discussions about advanced directives with their patients. Such clinicians also have an

improved ability to assist with the process than those who have not (Hall & Grant, 2014).

In addition to clinician views, research has also shown that some patients do not want

to engage in discussions about their future care and treatment, and that 'forced' conversations

may cause people harm (Sanders, Rogers, Gately & Kennedy, 2008). Horne, Seymour and

Shepherd (2006) showed that while some patients welcomed discussions about the future,

others felt that future decisions were up to the individual and that discussions with others

were not necessary. This was said to lead to a decline in the patient- clinician relationship if

the conversation was pushed.

Internationally, current policy and practice on advance directives (e.g. the Mental

Capacity Act [MCA], 2005 and Patient Self Determination Act [PSDA], 1990) emphasise a

rational and individual approach. This is said to reflect ideological biases of Western culture,

ignoring the influence of family members and the larger social networks that are perhaps

more dominant in Eastern culture (Hicks & Lam, 1999).   Bito et al. (2007) found that in

Japanese cultures family members viewed advance directives as an "intrusive legal

mechanism that interferes with their responsibilities as family members to care for their loved

ones" (p. 260). Instead of experiencing autonomy as empowering, some cultures see it as

isolating and burdensome (Johnstone & Kanitsaki, 2009) and believe that health care systems

insistent on patients making advance directives at the point of admission may be acting in a

hostile and racist way (Candib, 2002). On the other hand, Detering et al. (2015) in their cross

sectional study suggested that people from Western and non-Western, non-English speaking

backgrounds think positively about ACP and completing advance directives. They concluded

that ACP is a complex intervention with multiple components that varies considerably

throughout the world.

Synthesising the patients' perspectives

Clinicians' positive regard for advance directives does not always translate practically

into the completion of an advance directive for the patient (Coleman, 2012), as indicated by

recent systematic reviews (Coleman, 2012; De Vleminck et al. 2013; Ke, Huang, O'Connor

& Lee, 2015). Wilson et al. (2013) looked at advance directive completion amongst the

general population in Canada, and identified a need for more research to understand the many

and varied lived experiences and viewpoints on advance directive completion. Current

understandings focus on the professional perspective when in reality it is the patient that has

to write the advance directive. Being able to understand the experiences from clinicians and

patients should help to ascertain what the difficulties are in implementing advance directives.

This study will therefore synthesise research focusing on people's experiences and

understandings of advance directives.

A metasynthesis of patient views will enable identification of new insights and

understanding of the previous qualitative literature (Walsh & Downe 2005) which would

highlight how people understand the use of and experience advance directives. The current

study will draw upon previous findings of culture differences to ensure a deeper analysis

(Bito et al., 2007; Johnstone & Kanitsaki, 2009); a recommended element of fully developed

metasyntheses (Thorne, 2015).

The present review is a synthesis of how people experience and understand advance

directives in order to identify key learning points for health care professionals working in

physical health care settings. It was decided to include studies that explored both people who

had experienced writing an advance directive and the views of those who did not have direct

experience in order to understand both perspectives. The study will also syntheses studies

with participants at different life stages and different health statuses to ensure all views are

captured. Specifically, the research question for this review is how do people experience and

understand advance directives in regards to physical health care?

Method

Searching for the Studies

Literature searches took place in October 2015. Six databases (Academic Search

Online Complete, 1989-2015; MEDLINE, 1983-2015; PsychInfo, 1947-2015; PsyArticles,

1947-2015; CINAHL, 1990- 2015; Web of Science, 1945-2015) were searched for papers to include in the review after consultation with a topic specialist librarian. The search terms can be seen in Table 1. Where the search term was recognised in the EBSCO host thesaurus, the thesaurus tool was utilised to search the databases.

TABLE 1 HERE

Inclusion/ Exclusion Criteria

The following inclusion criteria were used to select papers for review: (a) the paper was published in English; (b) the paper made specific reference to exploring or understanding advanced directives in the results or discussion section; (c) data gathered via an interview or focus group; and (d) an inductive method of qualitative analysis was used.

As this study is the first attempt to synthesise literature specific to peoples' experiences and understandings of advance directives, it was decided to include articles that used a range of methodologies and epistemologies, as long as an inductive approach to analysis was used. This would enable a richer representation of qualitative research in the area. Papers that did not use an inductive approach were excluded. Papers were also excluded if they were set within a mental health context. This is because the Mental Health Act (1983) can often overrule advance directives and so people's experience and understandings of them is therefore likely to be very different from those in physical health care settings. Studies that looked to evaluate an initiative or pilot an initiative to increase advance directives uptakes were also excluded, as such studies focus on a different experience than that which the current study is aiming to address. Studies were also excluded if they were specifically about 'do not resuscitate' orders, as these are written by the doctor and not the patient. Examples of excluded studies can be seen in Table 2.

The search terms used for all six databases resulted in 1901 papers (PsychInfo, 214;PsyArticles: 7; Web of Science, 833; CINAHL, 350; Academic Search Complete, 98;

MEDLINE, 399). All the papers were reviewed by reading the title and abstract. Where it

was unclear if the paper met the inclusion criteria, the method section was also reviewed. In

cases where it was difficult to clarify whether the paper looked specifically into

understanding advance directives, the entire paper was read. A hand search of references in

the included papers identified no extra papers. The majority of the studies were excluded

because they did not have a qualitative methodology or they were set within a mental health

context. The search resulted in 17 papers to be included in the synthesis (Figure 1).

FIGURE 1 HERE

TABLE 2 HERE

Appraising the Quality of the Selected Studies

The use of critical appraisal tools for qualitative studies is readily debated

(Dixon-Woods, Agarwal, Young, Jones & Sutton, 2005). Some authors have noted that, for

them, appraising qualitative studies became an exercise in judging the quality of the written

report rather than the research procedure itself (Atkins et al., 2008); while others have

suggested that the evaluation of the quality of qualitative research is to a significant extent a

matter of "taste" (Sandelowski, 2015, p. 86). Whilst I agree with these comments, my

epistemological stance means that whilst fully acknowledging that the world is seen through

the subject lens of the person, there are common laws of causation that will lead to accounts

having an underlying commonality. Commonalities can be critiqued using a critical appraisal

tool, but must still be understood in the context of the subjective way they were written.

The Critical Skills Appraisal Programme (CASP) (Public Health Research Unit,

2006) was therefore followed to allow for critical reflections of the reporting quality of the

articles. The CASP is comprised of ten items that seek to understand three main principles

(or underlying commonalities) of the research: credibility, rigour and relevance of the

research. These three recurring principles are said to be the underpinning concepts of quality

in qualitative research (Spencer & Ritchie, 2012).

All the studies passed the CASP screening items. Each study was then scored as

either "1" weak, "2" moderate or "3" strong for each of the remaining eight items, as

suggested by Duggleby et al. (2010). For each study, the scores were totalled, with a

maximum possible score of 24 (Table 3). The quantitative scoring was used mainly to allow

the author to follow the same step by step guide for each paper, promoting a deeper critical

reflection and so that readers of the meta-ethnography could have an accessible and

simplistically presented insight into how the author had reviewed the studies. Scores were

not used to exclude studies because there is no consensus on markers of quality in qualitative

research (Sandelowski & Barroso, 2003). Instead, the scores highlighted areas of strengths

and weaknesses for each paper. These strengths and weaknesses were reflected upon in the

analysis stage. For example, it was noted which studies contributed the most quotes and how

that related to CASP scores. In addition, it was recorded how many themes were present in

each paper and if the number of themes represented was linked to the CASP score. CASP

scores are inevitably influenced by journal criteria, as indicated by the lowest scoring paper

(Lau et al., 2010) appearing in a journal with a word limit of 3000 words, whereas one of the

higher scoring papers (Seymour, Gott, Bellamy, Ahmedzaic & Clark, 2004) was in a journal

that had an 8000 word limit.

TABLE 3 HERE

Characteristics of the Selected Studies

The final papers included data from 547 participants. The papers were published

between 1998 and 2013 and came from eight different countries: Australia, United States of

America, UK, Canada, The Netherlands, Malaysia, Belgium and Germany. All these

countries have legal directions about advance directives that seek to emphasise the principle

of individual autonomy and empowerment: thus there is a commonality between the countries included. Further demographic and descriptive data regarding the participants and methods within the studies is presented in table 4.

TABLE 4 HERE

Data Analysis

A meta-ethnographic approach was used in order to synthesise the 17 papers. The method followed was that described by Noblit and Hare (1988). Noblit and Hare detail seven stages which the researcher must follow in order to conduct the meta-ethnography. These stages can also "overlap" (p.26). The first two stages include identifying a research question and carrying out literature searches which have been described in detail above. The final four stages are described in table 5. Table 6 demonstrates an example of the codes which led to one of the final concepts; 'hopes and fears for the family'.

TABLE 5 HERE

TABLE 6 HERE

Findings

The aim of the meta-ethnography was to synthesise qualitative research exploring peoples' experiences and understandings of advance directives. The meta-ethnography drew on the experiences of 547 participants as reported in 17 studies from eight different countries. The analysis led to four themes: seven of the seventeen studies contained all four concepts. The remaining ten studies contained at least two of the themes (Table 7).

TABLE 7 HERE

The four themes developed through the analysis are: 'hopes and fears for the family'; 'doctor-patient trust; 'the communication of advance directives by health care staff' and 'hopes and fears for the individual'.

Hopes and Fears for the Family

The first theme represents the family's role in the experience and understanding of advance directives. Participants stated they wanted to cause as little distress to their families as they could. The participants voiced different ways in how they actioned this. At times this was interpreted as being culturally dependant.

Participants in the studies voiced that they did not want to be a **"**burden to the family" (Crisp, 2007, p. 185; Dupree, 2000, p.14; Htut, Shahrul & Poi, 2007, p. 60; Jezewski & Meerker, 2005, p. 324; Perkins, Geppert, Gonzalez, Cortez & Hazuda, 2002, p.51; Piers et al., 2013, p.326; Sessanna, 2007, p. 38; Lambert et al., 2005, p. 631; McMahan, Knight, Fried & Sudore, 2013, p. 361; Singer et al., 1998, p.881). Being a burden to the family was seen as impacting on: (1) families financial expenses: " I just can't see people costing their families all that money" (White, 2005, p. 17) which is of particular relevance to the participants from countries where they had to pay for health care; (2) their time: "in such conditions, family will take care of you the first few months but after a while you become a nuisance to them" (Htut et al., 2007, p. 60) which was of particular concern to those families in the studies where it was culturally expected for families to care for their relatives at home; (3) the emotional burden placed on the family: "for the rest of their lives, these people will ask themselves if they should have tried a little longer or if they hadn't stopped too soon. I don't want that" (Piers et al., 2003, p.326) and; (4) the quality of life of their family members: "if I had to die, it would make me happy knowing [my daughter] was ending my life to make her life better" (Perkins et al., 2002, p.51).

For some, writing an advance directive was perceived to increase family distress and so they opted to not complete one. There was a sense that writing an advance directive was akin to explicitly saying you wanted to die, which some families found too distressing to easily tolerate: "I don't want to make my family miserable by making a decision [to complete

an advance directive]. I mean I'm quite willing to suffer a little more if my family's happy

about that" (Sinclair, Auret & Burgess, 2012, p 361). Others wanted to write an advance

directive but avoided them due to the difficult conversations they would invoke: "I wanted to

show him [fiancé] all 3 of them [advance directives]… so that he could see what I could

choose from, but it's very hard to talk about death with him, because he's just lost his dad, and

it was kind of a hard subject, so I didn't pursue it. I just kind of dropped it" (Singer, 1998, p.

882). The combination of a perceived increase in family distress, plus a perceived lack of

family support in writing the advance directive was a factor in why people did not complete

the advance directive.

Writing an advance directive did not always result in increased distress for family

members. For some participants writing an advance directive was a way to cease the

perceived burden placed on the family; especially if there was an awareness of the advance

directive being written: "my family were all for me doing [an advance directive]. They said

'righto, you go ahead and do as you please'" (Sinclair et al., 2012, p.361). This support was

seen as an important enabling factor in writing the advance directive.

There were some participants for whom perceptions of being a burden on the family

was not the driver of their decision making process. Instead was the idea of trusting their

family member to make a decision for them. This trust and the giving of the decision to the

family was a way to alleviate the distress that the death may cause. Those participants felt

less need to write an advance directive:

> Yeah, I think if I were asked how come I don't do an advance directive I think it is
>
> because I trust that my wife could make a good decision. I mean the problem with
>
> doing an advance directive is that it takes it out of their hands which is also not good
>
> because they should be able to say what happens to me. (McMahon et al., 2013, p.
>
> 360)

Moreover, filling in an advance directive was viewed by some as a sign of distrust towards

your family: "If you fill out those papers [advance directives], it shows so little trust in your

fellow men [family members]. Uh, it's like you don't believe that they [husband and

children] will make it happen (Piers et al., 2013, p. 26). The implication was that not trusting

your family members would cause them distress.

In addition to trust, participants also seemed to have a cultural understanding that their

families would take care of sick relatives and make decisions on their behalf. Indeed, some

participants (Searight & Gafford, 2005) described advance directives and patient-centred

decision making in general as "contrary to their cultural norms" (p. 201). There seemed to be

a common thread amongst participants from non-white European or American ethnicities that

they trusted their family to make decisions and therefore did not need advance directives.

Doctor-Patient trust

Participants' understandings of advance directives seemed to centre on the trust they

had for doctors and the trust they had that their advance directive would be followed.

Participants varied in the amount of trust they had for the doctors involved in their

care and the amount of trust they had that their advance directive would be followed. Those

that trusted their doctor appeared to also trust that the advance directive would be followed

too. This varying level of trust affected their decision whether to make an advance directive

or not. For some, the lack of trust that an advance directive would be followed meant there

was no point writing it: "well what's the good of it [advance directive]? [Doctors] just do

what they like" (Sinclair et al., 2013, p. 361). Others trusted that the advance directive would

be followed. They saw the advance directive as a way of ensuring their wishes were

followed by doctors who they otherwise might not trust: "Interviewer: Do you think the

doctors are more likely to do … what you want if you sign the directive to physicians than if

you don't? Participant: They [doctors] honour a man's agreement and his will." (Perkins et

al., 2002, p. 51). Moreover, the advance directive was seen as being more likely to be honoured if it was in the hands of a doctor: "well, I thought it will be given more importance when falling into the hands of a doctor' 'that it [the advance directive] will be taken more serious [sic]" (Becker et al., 2010, p. 623).

For others, a lack of trust in the doctor meant that they had to write an advance directive as a means to protect their own wishes: "If they don't have a [Living] Will, [the doctors] might do everything possible and humanly and medically technologically try [sic]" (Perkins et al., 2002, p. 53). This lack of trust seemed to stem from the participants believing that the doctor had different values to their own. Indeed, there was a worry for some participants that the doctors would not take into consideration individual wishes and so an advance directive was important to ensure that their values were respected:

> The doctor was playing God, telling me what I had to do about Daddy. It is important
> for them to understand that because they have specialized training doesn't mean they
> are specialists in understanding how people feel. They are qualified to judge
> individual situations. Their training should be for indicators, not for absolutes.
> (Dupree, 2000, p. 14).

Whilst those that did trust their doctor felt no need to write an advance directive: "I figure the doctors that I have right now, they know what they're doing. They want to get me well." (Perkins et al., 2002, p. 53). In these situations the participants viewed the doctor's values as similar to their own.

Culture seemed to play a role in how participants viewed doctors. In addition to the influence of the perception of different cultural values between the doctors and themselves, there was also the influence of socio-political factors. The extent to which the doctor could be questioned and trusted was dependant on cultural expectations. In addition, the extent to which the participants believed they had the right to aspects of medical care: "there are a lot

of things that we have been denied for so long and we begin to feel that we shouldn't have

them [certain treatments] and subsequently begin to refuse them" (Dupree, 2000, p. 14). In

this sense, sometimes advance directives were being refused because there was a sense of

participants feeling, perhaps unconsciously, unentitled to an advance directive.

The Communication of Advance Directives by Health Care Staff

Throughout the studies there seemed to be a constant theme that many of the

participants were unaware of what advance directives were and that professionals did not

communicate information about advance directives to them: "like I said, I didn't know what

it [advance directive] was before coming here [support group]" (Jezeweski & Meeker, 2005,

p. 324). The papers suggested that this lack of awareness about advanced directives was

because participants either misunderstood the information they received about advance

directives, were not retaining the information they were receiving, or that they were not being

told the information. Some participants perceived this to be due to issues with staff resource:

> [did you talk to staff about Advance directives] No, not at all. . . . They're always
>
> passing. . . . Why bother? It's too much of a turnover, they're here for maybe a couple
>
> of months and then they transfer into another type of field or another job and then
>
> they're always moving all the time. So it's not worth it" (Singer, 1998, p. 882).

Other people attributed it to not paying attention to what was being said: "she told me I had to

have a doctor or a nurse understand something [advance directive]. And be sure that he gets

it [advance directive] or signs it… or I don't know. I didn't pay too much attention" (Perkins

et al., 2002, p. 51).

Misunderstanding that an advance directive was a means of stating only care to keep

a person alive meant some people did not make one: 'I didn't need it [advance directive]. I

knew what I wanted. Because I have seen my sister dying a wretched death, and this is

absolutely not what I want for myself.' (Becker et al., 2010, p. 623). Others made an advance

directive but later regretted the decision. They blamed the wrong decision on not having

enough information: "It was shocking…because I didn't realize that this tube would be down

my throat until I had made my decision. They should have taken time and explained more"

(White, 2005, p. 17). The lack of information was about not only the advance directive

process itself, but also information about the treatment options that would be covered by an

advance directive "I don't know all of the extreme measures you can take nowadays [about

treatment in general]" (Lambert, et al., 2005, p. 629).

The participants did, on the whole, want clear information about what options they

had: "Give them [patients] as much information as possible. And have the forms available for

them right away. And be willing to take the time, maybe individually, with someone who is

having problems filling out the forms" (Jezeweski & Meerker, 2005, p. 325). There was,

however, a paradox in wanting this information, as some participants feared what might

happen in relation to their illness and so wanted to avoid such information:

> You know, [we don't always have] enough information… to make the decisions.
>
> Having said that I am in a cleft stick. I don't want that information…because I'm,
>
> you know I've been faced with a situation like that, you know oh God I'm really ill
>
> here, will I survive until tomorrow, so I don't want anyone to give me that
>
> information. But the other side of me says hold on, you know, this is me, it belongs to
>
> me this body. (Seymour et al., 2004, p.65)

Hopes and Fears for the Individual's future

The experiences and understanding of advance directives were shaped by the

participants' past experiences and imagined idea of their futures. As the previous theme

suggested, many people were fearful of what their future would be like and this influenced

their understandings of advance directives. Some would avoid conversations and thus

decisions around death, whereas others would un-fearfully engage in such activities.

Imagined future quality of life was a common influencer across the papers on participants' understandings of advance directives: "I have always thought that when your quality of life has gone, whether it's mentally or physically, I really don't care about being kept alive, just to be alive" (Crisp, 2007, p. 185). There was a sense that keeping people alive for the sake of a low quality of life was morally wrong, "but to keep a person alive as such, he couldn't talk, he couldn't drink, he couldn't eat… that is cruel. And that's where these [advance directive forms] should be" (White, 2005, p. 18). An advance directive was a way to ensure that a participant did not have to endure a life that was below their threshold of acceptable quality. This threshold of an acceptable quality of life varied across participants and was summed up as an individual choice by one participant: "the quality of life to one person is one thing and to another person it's another thing and that ought to be part of this advance directive" (McMahon et al., 2013, p. 358).

 Quality of life was often associated with age, with the majority of older participants in the studies (Crisp, 2007; Lambert et al., 2007; Piers et al., 2013; Sessanna, 2008; Seymour et al., 2003; White, 2005) discussing how their older age played a part in deciding whether to write an advance directive or not:

> I say to myself 'you are old'. Yes, that is what I say to myself. You don't, if you are
> 91, you don't have to think, 'what is waiting there for me?' Nothing, isn't it. Death,
> ah yes, death. (Piers et al., 2013, p. 324)

Many of the papers cited that the past experience of a family member or friend dying influenced their views on advance directives. Some papers discussed the death as a way of forcing the participants to think of their own mortality. Participants with a chronic illness discussed the experience of seeing a "lingering death" and "hooked up to machines" (Jezeweski & Meerker, 2005, p. 324). Healthy adults shared similar thoughts "her agony dragged out over a period of months and I just don't intend to go through the same

experience if I can prevent it" (Crisp, 2007, p. 186). An advance directive was the way to ensure they too did not experience that same fate. In this sense their past experiences of seeing others in their situation shaped how they imagined their future death.

The uncertainty of death versus the certainty of death was an influencer in whether someone completed an advance directive or not. Participants whose cause of death were more certain were more likely to have made an advance directive "but when I got the secondaries you know they only go in remission they don't go away and so that's when I went and did [advance directive form] (Sinclair et al., 2013, p. 361). This was even more pronounced for those whose deaths were more imminent. For example a participant in the pre-manifest stage of Huntington's disease stated "of course you can't say now how you will think in 10, 15, 30 years' time." (Booij et al., 2013, p.326) whereas a participant in stage four of the disease said "and I filled in an advance directive…then we talked about it, saying if it is like this, end it" (Booij et al., 2013, p.326).

Some participants did not fear death, and this often appeared linked to religious or spiritual reasons:

I don't understand what there is to be afraid to talk about. I'm one of those people who don't believe that dying is it. I understand that when I'm absent from this body I'll be present with the Lord. That gives me great comfort while I'm living. (Dupree, 2000, p. 15).

This meant that it was easier to discuss options for death and write an advance directive because there was no fear associated with doing so. For others, although not scared of death, they believed it was pre-determined by God and for this reason there was no need to write an advance directive: "It is life over which we rule, but it isn't ours. We don't own our life. We have somebody above us and I don't have a say in it. You have to be a God to decide" (Piers et al., 2003, p. 326).

Discussion

The meta-ethnography found four key themes across the papers that highlighted how people understand and experience advance directives in physical health care: 'hopes and fears for the family'; 'doctor- patient trust'; 'the communication of advance directives by health care staff' and 'hopes and fears for the individual's future. The themes highlighted that people wanted to make their own decisions about their future but that these decisions looked very different for different people. For some, the writing of an advance directive was a way to ensure their wishes were respected, but for others there was an active decision to not make an advance directive. Often the decision to write or not write an advance directive was centred on ensuring the least amount of distress was caused to either themselves or their families. Some people may have wished to communicate their autonomy by writing an advance directive, but were not being supported or given the necessary information to write it. Halpern (2012) suggests that to complete an advance directive a person must be able to "(1) be willing to think about and plan for death, (2) find value in the purported benefits of completing an advance directive, and (3) believe that attaining these benefits requires an active step such as completing an advance directive, rather than their having already been attained in some other way". The findings from the meta-ethnography would support these three requirements.

Culture and Identity

Fear of the imagined future for the individual and for their families played an influential role in whether an advance directive was discussed and indeed completed or not. A fear that either the individual's quality of life was going to be below their personal threshold of acceptability and/ or that they would become a burden to their families often drove people to want to make a decision about their future. Clinicians' understandings of advance directives therefore need to be pitched very closely to the person's views of quality

of life and perceived notion of being a burden: The person focuses on these two issues and therefore so too should the clinician.

Death is said to be understood and experienced as part of a complex combination of cultural and social meanings (Kagawa-Singer, 1994). Indeed, Koenig and Williams (1995, p. 246) discussed how an elderly "bed ridden and demented" person could be said to be subject to a form of social death which precedes the biological death. The participants in the current meta-ethnography talked about the ending of their lives in a similar way as if they had constructed that their social death "being hooked up to machines" came before their biological death.

In a Western world where media often reports that there is an "increasing global burden of an ageing population, both financially and in care provision"(Conway, 2010) it is not surprising to see how these narratives become internalised. It has been suggested that groups such as "the elderly, those who are disabled by society and the physically or mentally distressed" who often need support to live, will be especially prone to these internalised thoughts of being a burden to others (Gorvin & Brown, 2012, p.1). A quantitative study conducted by Chochinov et al., (2007) showed 60% of terminally ill participants felt distressed because they thought they were a burden to others. This distress was suggested to be caused by hopelessness, depression and a negative outlook of the future. The researchers found that levels of distress was not correlated with physical dependence and concluded that psychological factors influence the perception of being a burden.

Low mood and hopelessness are linked to suicidal ideation (Joiner, 2005) and thus feeling like a burden is linked to wanting to die. A person feeling they were a burden has also been shown to have negative effects on self-identity (Galvin, 2005) and an inability to fulfil social roles (Brenner et al., 2008). The vast amount of research on being a burden has been carried out in Western settings where the human body is seen in its ideal form as being

self-contained and autonomous (Lupton, 2000) and, where it could be argued, to be

dependent on others is not in keeping with those ideals. In terms of the ramifications for

advance directives, making a decision to not have life-saving treatment may have been

influenced by the psychological factors influencing the perception of being a burden. In

addition, the concept of an advance directive to be autonomous is slightly contradicted by an

underpinning that a person *should not* be dependent on others in Western societies.

Therefore the decision is not really an autonomous one but one that is conditional on social

ideals.

In many societies, ideas about the sense of self differ from the western ideal of an

autonomous individual (e.g., Gilbar & Miola, 2014; Roche et al., 2014). This is at odds with

the idea of being a burden and so this concept may not necessarily resonate with individuals

from non-Western cultures. Previous research on this topic is limited, however, the meta-

ethnography synthesised that although people from non-Western groups did still talk about

being a burden, there was a sense from families that there was a role to look after 'sick'

relatives, which perhaps would alleviate some of the feelings of being a burden.

Furthermore, those people who do not identify as being an autonomous individual will be at

odds with the notion of completing advance directive. However, as the meta-ethnography

highlighted there is a problem with blank statements about cultural identities and the notion

that an individual can be mapped onto a cultural norm based on their demographics (Koenig

& Williams, 1995). The findings highlighted that although it should be considered, a

person's cultural demographics cannot lead you to a conclusion about how they make

decisions around death.

Affective Forecasting

Often at the start of a progressive illness people cannot comprehend being able to

cope with a certain disability and so opt not to have aggressive treatments in fear that their

quality of life will be too poor to live with (Halpern & Arnold, 2008). However, often once patients have experienced such health states they are more willing to accept aggressive treatment choices, even with limited benefits (Fried et al., 2006). Furthermore, previous research has suggested that people's preferences about future treatment are not consistent over time (Halpern & Arnold, 2008; Koch, 2001; Loewenstein, 2005). A study interviewing older people with advanced chronic illness showed that many of the participants became more, and then less willing (or vice-versa), over time to undergo future high-burden therapy or to risk severe disability (Fried, O'Leary, Van Ness & Fraenkel, 2007). This is consistent with the findings from the current meta-ethnography and suggests that a one off advance directive is not sufficient.

Ethicists have criticised advance directives by suggesting they do not carry the same moral weight as a person's in the moment autonomous choice (Furberg, 2012). One reason for this was posed by Wrigley (2007) who suggested decisions concerning the future often involve imagining future problems to be worse than they are. Affective forecasting errors, as this is known, has been said to be particularly relevant when thinking of the unlikely benefit of healthy adults making advance directives since their views are likely to change over time (Halpern & Arnold, 2008). However, not offering advance directives to healthy adults could be said to undermine the entire notion of advance directives (Halpern, 2012). Halpern (2012) suggests that targeting advance directives to those people with incurable illnesses may increase the probability that people's stated preferences in advance directives will stably predict what they want if they lose the capacity to make the decision. This would fit with the findings of the current meta-ethnography which found that people were more able to think about advance directives and decisions around death the nearer they came to dying. Alternatively, the advance directive needs to be re-addressed over time. In addition, open conversations had about the possible changes in views over a time that a person may have;

which specifically focuses on imagined quality of life and perceived notion of being a burden.

Affective forecasting errors have also been found to increase due to defective, misunderstood or absent information about the future, as seen by the findings in this meta-ethnography (Wrigley, 2007). Indeed, the findings highlighted that at times there was poor communication about advance directives from health care professionals and that there was a lack of trust that advance directives would be followed even if they were written. These findings would support quantitative literature in the area which has indicated that a lack of knowledge about advance directives was a primary barrier to people completing them (Ko & Lee, 2010). In addition, Redmann, Brasel, Alexander and Schwarze's (2012) findings from a national survey of surgeons in USA showed 46% of doctors would still operate if there was advance directive in place, highlighting why there may be distrust in the use of advance directives.

Some groups, such as African Americans, with a complex history of limited access to services, most notably in the USA, may not trust physicians to act in their best interest (Adler, Boyce, Chesney, Folkman & Syme, 1994). It is therefore of upmost importance that trust is established between the doctor and patient. This is both in terms of trust that the doctor understands and respects the patient's wishes, and that they will continue to respect those wishes after the person no longer has capacity to make those decisions themselves.

It takes time to establish and develop trust and to share personal views about fears for the future, however, this time should be prioritised in order to ensure the patient's continued autonomy. A further reason for taking time to understand the personal values and future hopes and fears of the patients come from the area of decision psychology or behavioural economics. This field suggests that in contrast to traditional concepts of autonomy (Swindell,

McGuire & Halpern, 2011) peoples' 'preferences 'are frequently constructed in the moment and are greatly influenced by how options were presented to them (Slovic, 1995).

Advance directives are centred on the principle of autonomy, yet if autonomy is not a meaningful concept, advance directives become flawed which perhaps helps to understand why the uptake of them is low (Lang & Wagner, 2007; Rao, Anderson, Feng-Chang & Laux, 2014; YouGov Poll, 2013). The action of writing an advance directive has been found by the meta-ethnography to be seen as 'conditional autonomy' based upon the influence of hopes and fears for the future, cultural identity and the trust and communication of professionals involved in their care. An individual's history and experiences cannot be changed; however, it may be useful to find a way to formulate how personal experiences affect a person's autonomy in regards to making an advance directive, especially if the person is feeling distressed about the future.

Limitations

It must be noted that the studies were conducted in a number of different countries under different legal systems and so current political agendas and documentation may have influenced the findings. The political and legal status of advance directives in these countries, although briefly touched upon, was beyond the scope of this meta-ethnography. All the countries in the study did however place an importance on patient autonomy within their legal frameworks. Despite the differences in specific legal policy, it should be noted that the themes remained similar throughout the papers.

Separating out the experience and understandings of advance directives from ACP was not easy and a lot of time was spent at each stage of the meta-ethnography process doing this. For instance, some papers on ACP contained themes that were similar to the ones found in this study; however as they were not about advance directives specifically they were excluded from the data. This could also been seen through some of the quotes in the studies

where ACP and advance directives often seemed to be talked about interchangeably. The complexity and interconnectedness of ACP and advance directives should be noted.

Future Research

Future research should look to explore how much time health care professionals dedicate to understanding patient's values based on their fears for imagined quality of life and imagined burden on their families. The potential barriers and pitfalls to allocating this time could also be explored. Such research could include a qualitative methodology exploring the process of how people made an advance directive and the interactions they specifically had with health care professionals. The findings have also shown how conversations about advance directives and the documenting of an advance directive cannot be a one off. Future research should look to focus on ways to put this into practice. The understandings in regards to advance directives were seen to centre on minimising distress for both the individual and the families, and future research would benefit from understanding if supporting conversations between family members about imagined burden alters understandings of advance directives.

<div align="center">

Conclusion

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People want to have a personally measured acceptable quality of life in end of life care and reduce the burden on their loved ones, and advance directives can be an effect way to do this. If people are to write advanced directives, they must trust the clinician to understand and respect their personal values. This process takes time and commitment. The views expressed in an advance directive may change as illness progresses and so it is important that completing advance directives is not a single event which once written, is considered 'done'. Honest conversations about views changing over time should be had between clinicians and the patients. Over 20 years ago Koenig and Gates-William (1995) wrote "the challenge for clinical practice is to allow ethical pluralism-a true engagement with

and respect for diverse perspective". The findings from this meta-ethnography show that this

challenge remains today and will continue if we are to remain to be progressive.

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Table 1

Search Terms

Search Term	AND
"advance directive*" OR	"Qualitative Research" OR
"advanced directive" OR	"experience" OR
"advance decision*" OR	"narrative" OR
"advance care plan" OR	"thematic analysis" OR
"advance health care plan" OR	"interviews" OR
"advance medical plan" OR	"grounded theory" OR
"living will" OR	"phenomenolog*" OR
"advanced care planning" OR	"audio record" OR
"advanced care plan" OR	"discourse" OR
"advanced health care plan"	"IPA" OR
	"interpretative phenomenological analysis"

Table 2

Examples of Studies Excluded from the Meta-ethnography

Author	Title	Reason for Exclusion
Davison (2006)	Facilitating advance care planning for patients with end stage renal disease: the patient perspective.	The study does not address ADs explicitly in the findings.
Horne, Seymour & Shepherd (2006)	Advance care planning for patients with inoperable lung cancer	The study looked to pilot and evaluate an ACP interview guide. There was also no explicit mention of ADs in the findings.
Rosenfeld, Wenger, Kagawa- Singer (2000)	End of life decision making. A qualitative study of elderly individuals	No specific mention of ADs
Reilly, Magnussen, Ross, Ash, Papa & Wagner (1994)	Can we talk? Inpatient discussions about advanced directives in a community hospital.	Quantitative methods of analysis used.
Morrison, Zayas, Mulvihill, Baskin & Meier (1998)	Barriers to completion of health care proxy forms: a qualitative analysis of ethnic difference	deductive method of content analysis
Eliott&Olver, (2008)	Choosing between life and death: patient and family perceptions of the decision not to resuscitate the terminally ill cancer patient	Study is specifically about Do not resuscitate orders.

Table 3

CASP Scores

Study	Research Design	Strategy	Data Collection	Reflexivity	Ethical Considerations	Data Analysis	Findings	Value of the Research	Total Score
Becker et al. (2010)	1	3	2	1	2	1	2	2	14
Booij et al, (2013)	2	2	3	1	1	2	2	2	15
Crisp (2007)	2	2	2	1	2	3	3	2	17
Dupree (2000)	2	2	3	1	1	2	2	2	15
Htut, Shahrul& Poi (2007)	2	3	3	1	1	2	2	2	16
Jezeweski & Meeker (2005)	1	2	2	1	2	2	3	3	16
Lambert et al. (2005)	3	3	3	1	2	3	3	3	21
Lau et al. (2010)	1	2	2	1	1	1	2	2	12
McMahan et al. (2013)	1	2	3	1	2	3	3	2	17
Perkins (2002)	1	2	2	1	1	3	3	3	16
Piers et al. (2013)	2	3	3	`1	3	3	3	3	22
Searight & Gafford (2005)	3	2	3	1	1	2	2`	2	16
Sessanna (2008)	3	2	3	1	2	3	3	3	20

Seymour et al. (2004)	3	3	3	2	3	2	3	3	22
Sinclair et al. (2012)	2	2	3	1	2	3	3	3	19
Singer et al. (1998)	2	2	3	1	3	3	3	3	20
White (2005)	3	3	3	1	3	1	2	3	19

Table 4

Characteristics of the Included Studies

Paper	Research Aims	Methodology	Participants
Becker, Jaspers, King, Radbruch, Voltz & Nauck (2010) Did you seek assistance for writing your advance directive? A qualitative study	To analyse whether or not individuals approached advisors for the completion of their advance directive, whom they chose, and which reasons were given for seeking or foregoing assistance	Inductive category development from semi structured open ended interviews	N=53 (healthy n = 20, chronically ill n = 17, palliative care patients n = 16). Location: Germany.
Booij, R¨odig, Engberts, Tibben&Roos (2013) Euthanasia and Advance Directives in Huntington's Disease: Qualitative Analysis of Interviews with Patients	To obtain in-depth information about patients' thoughts on and attitudes to euthanasia, physician-assisted suicide and the use of advance directives in Huntington's Disease. To assess the difficulties patients encounter when thinking about end-of-life wishes	Semi-structured in-depth interviews followed by qualitative analysis of the interviews based on grounded theory.	n=14. Unselected HD patients from out-patient clinic based on a topic list. Location: The Netherlands
Crisp (2007) Health older adults' execution of advance directives: a qualitative study of decision making	To understand how health adults execute advance directives	Thematic analysis	n=8. Healthy adults who had experience of disease, surgery, hospitalisation. Location: USA

Dupree (2000) The Attitudes of Black Americans Toward Advance Directives	To describe how some Black Americans view advance directives.	Inductive content analysis from semi structured interviews.	n=17. Black Americans who had contact with the health care system Location: USA.
Htut, Shahrul& Poi (2007) The Views of Older Malaysians on Advanced Directive and Advanced Care Planning: A Qualitative Study	To describe views of elderly Malaysians on advanced care planning and advanced directives and explore factors influencing these views.	Thematic Analysis from semi structured interviews	n=15 elderly Malaysians who had been on a ward or outpatient clinic between a certain time period. Location: Malaysia
Jezeweski & Meeker (2005) Constituting Advanced Directives from the Perspectives of People with Chronic Illness	To investigate the end of life decision making from the perspectives of people with chronic illness.	Grounded Theory from either focus groups or individual semi structured interviews	n=76. Participants had chronic illnesses. Location USA.
Lambert, McColl, Gilbert, Wong, Murray &Shortt (2005) Factors Affecting Long-Term-Care Residents' Decision-Making Processes as They Formulate Advance Directives	To describe factors contributing to the decision-making processes of elderly persons as they formulate advance directives in long-term care	Open and axial coding based on grounded theory of interview transcripts were carried out and the factors contributing to the decision process were defined.	n=9. Residents of a long-term-care facility. Location: Canada
Lau, Kirkpatrick, Merchant, Perman, Abella, Gaieski, Becker, Chiames & Reitsma(2010)	To better understand sudden cardiac arrest survivors' beliefs about complex issues that arise in the immediate post-	Themes are presented in a narrative format with illustrative quotes. Semi structured telephone interviews	n=9. Participants were recruited from a non-profit, national organization for cardiac arrest survivors in Location: USA.

Experiences of sudden cardiac arrest survivors regarding prognostication and advance care planning	arrest period and explore advance care planning. Specifically, we wished to explore four themes: (1) patient and family perception of medical providers' prognostication in the immediate post-arrest phase; (2) patient definitions of death; (3) use of advance directives and (4) perceptions of health and organ donation.		
McMahan, Knight, Fried & Sudore (2013) Advanced care planning beyond advanced directives: perspectives from patients and surrogates	To understand what steps best prepare patients and surrogates in decision making	Thematic content analysis from focus groups	N= 69 (n= 38 patients n=31 surrogates). Location: USA
Perkins, Geppert, Gonzales, Cortez &Hazuda(2002) Cross-cultural Similarities and Differences in Attitudes About Advance Care Planning.	To characterise relevant cultural attitudes in enough detail to enable health care professionals to conduct culturally specific advance care planning.	Content analysis from structured open ended interviews.	n=58. From two general medicine wards. Location: USA

Piers, van Eechoud, Van Campa, Grypdonck, Deveugele, Verbeke& Van Den Noortgate(2013) Advance Care Planning in terminally ill and frail older persons	To gain insight into the views of elderly on advance care planning.	Thematic analysis from semi structured interviews.	n= 38. Participants were from three different end-stage trajectories (malignancy, organ failure, frailty). Location: Belgium
Searight & Gafford, (2005) "It's Like Playing With Your Destiny": Bosnian Immigrants' Views of Advance Directives and End-of-Life Decision-Making	To understand perspectives on advance directives, doctor–patient communication, and proxy decision makers among individuals from the Bosnian community	Grounded theory from focus groups.	n=12. Bosnian immigrants living in the USA. Setting: USA
Sessanna (2008) The Role of Spirituality in Advance Directive Decision Making Among Independent Community Dwelling Older Adults	To investigate the meaning, definition, and needs regarding the role of spirituality in end of life care among independent community dwelling older adults in relation to advance directive decision making	Grounded theory from semi structured interviews	n= 12 independent community dwelling older adults, aged 65 years and older. Location: USA.
Seymour, Gott, Bellamy, Ahmedzaic, Clark (2004) Planning for the end of life: the views of older people about advance care statements	To explore older people's views about advance statements and the role these might play in end of life care decisions.	Unnamed qualitative methodology	n= 32 older people or their representatives who belonged to six diverse community groups. Location: UK

Sinclair Auret, & Burgess(2012) The balancing point: understanding uptake of advance directive forms in a rural Australian community	To explore perceptions towards newly legislated advance care planning documents. This study explored baseline awareness and perception of advance directive forms and factors relevant to their utilisation	Thematic analysis from semi structured interviews.	n=62. Adults recruited from residential aged care facilities, community care organisations, general practice, an oncology service and a law firm. Location: Australia.
Singer, Martin, Lavery, Thiel, Kelner & Mendelssohn (1998) Reconceptualising advanced care planning from the patients perspective	To examine the traditional academic assumptions by exploring advance care planning from the perspective of the participants actively in the planning process.	Grounded theory from semi structured interviews.	n=38. Participants were undergoing haemodialysis. Location: Canada
White (2005) An Exploration of Decision-Making Factors Regarding Advance Directives in a Long-Term Care Facility	To explore the experiences of residents who had signed an advance directive on admission to a long-term care facility	Thematic analysis using qualitative grounded theory from semi structured interviews	n=13 older adults in long term care facility. Location: Mid-West, America

Table 5

The stages of meta-ethnography analysis

Stage 3: "reading the studies".	The author spent a lot of time reading the papers and becoming familiar with the content. Contextual details such as the sample size, demographics and country of origin were recorded and collated (Table). Themes, subthemes and quotations that highlighted the themes relevant to the research question were selected and highlighted in each article.
Stage: 4 "determining how the studies are related".	Noblit and Hare (1998) state that at this stage researcher should make a list of the key metaphors, phrases, ideas and or concepts from the data and then juxtapose them. This was done in two ways. First, the author went to the original data or 1st order constructs. The author logged the quotes into a database and wrote down a key idea (which was named initial code) that was "interpreted" from the quote. Second, the author made use of the original authors' interpretations or second order constructs (e.g. concepts, themes from primary qualitative studies as data. Due to the fact that the paper was looking specifically at advance directives only quotes in the papers that were relevant specifically to advance directives were logged.
Stage 5: "translating the studies into one another".	This step involved a constant comparison of the papers which worked towards interpreting themes within and between articles or "translating the interpretations of one study into the interpretations of another" (Noblit & Hare, 1988, p. 32). The studies were compared the studies in chronological order. The studies stretch over 17 years and in that time Laws have been brought in and changed around advance directives and so it seems sensible to start with the earliest paper first. The first order constructs of the first two studies were compared and contrasted. This included all quotes relevant to advance directives. The main themes, discussions and conclusions were compared and contrasted also so that second order constructs

	were utilised too. The next paper in chronological order was then compared to the findings off the previously compared papers until all the papers had been compared.
Stage 6: "synthesising themes into higher order themes that preserve and represent the meaning in the individual studies".	The overall concepts found in the meta-ethnography were scrutinised to see how well the reflected the original themes from each paper (Table7)
Stage 7: "expressing the synthesis".	The findings were written up in this meta-ethnography.

Table 6

A table to show an example the theme 'hopes and fears for the family' was formed.

1st and 2nd order constructs	Codes	Theme
Family duty to look after someone till they die.	Trust family to make decision	'hopes and fears for the family'
Advanced directives not necessary if family there to carry out wishes.		
Family members not physicians should make decisions		
Advance directives stops family members making decisions		
Decision lies with the family not them		
Filling out advance directives shows distrust in family.		
Trust that family would follow wishes so no need for advance directives		
Make families life better	Individual makes decision so as not to burden the family	
Put family's happiness before theirs.		
Does not want family to see them in certain way		
Does not want their care to cost their family money		
Would not put family through the trauma of battling to keep patient alive/death.		
The advance directives takes pressure of the family to decide		
People don't want to cause family members to be affected mentally and emotionally by having to making a decision. That would cause more pressure and torment on patient		
Family/ someone who knows the person should be the decision maker	Family support the individual to make the decision but can be conflict.	
Family supporting autonomy of patient		
No family to help decide so person has to make decision.		

Table 7

Description of which studies contributed to each of the key concepts, which are: (1)'hope and

fears for the family'; (2)'doctor- patient' trust; (3) 'the communication of advance directives

by health care staff'; (4) 'hopes and fears for the individual's future'.

Papers	1	2	3	4
Becker, Jaspers, King, Radbruch, Voltz & Nauck (2010) Did you seek assistance for writing your advance directive? A qualitative study		x	x	x
Booij, R¨odig, Engberts, Tibben & Roos (2013) Euthanasia and Advance Directives in Huntington's Disease: Qualitative Analysis of Interviews with Patients	x	x	x	x
Crisp (2007) Health older adults' execution of advance directives: a qualitative study of decision making	x			x
Dupree (2000) The Attitudes of Black Americans Toward Advance Directives	x	x		x
Htut, Shahrul & Poi (2007) The Views of Older Malaysians on Advanced Directive and Advanced Care Planning: A Qualitative Study	x	x		x
Jezeweski & Meeker, (2005) Constituting Advanced Directives from the Perspectives of People with Chronic Illness	x	x	x	x
Lambert et al. (2005) Factors Affecting Long-Term-Care Residents' Decision-Making Processes as They Formulate Advance Directives	x	x	x	x
Lau et al. (2010) Experiences of sudden cardiac arrest survivors regarding prognostication and advance care planning		x	x	x
McMahan, Knight, Fried & Sudore (2013) Advanced care planning beyond advanced directives: perspectives from patients and surrogates	x			x
Perkins et al. (2002) Cross-cultural Similarities and Differences in Attitudes About Advance Care Planning.	x	x	x	x
Piers et al. (2013) Advance Care Planning in terminally ill and frail older persons	x	x		x
Searight & Gafford, (2005) "It's Like Playing With Your Destiny": Bosnian Immigrants' Views of Advance Directives and End-of-Life Decision-Making	x	x		x
Sessanna (2008) The role of spirituality in advance directive decision making among independent community dwelling older adults	x			x

Seymour et al. (2004) Planning for the end of life: the views of older people about advance care statements	x	x	x	x
Sinclair et al. (2012) The balancing point: understanding uptake of advance directive forms in a rural Australian community	x	x		x
Singer et al. (1998) Reconceptualising advanced care planning from the patients perspective	x	x	x	x
White (2005) An Exploration of Decision-Making Factors Regarding Advance Directives in a Long-Term Care Facility	x	x	x	x

Figure 1

Flow Diagram for Inclusion of Articles in the Metasynthesis

MedLine	PsyArticles	PsychInfo	Web of Science	CINAHL	Academic Search Complete
399 results	7 results	214 results	833 results	350 results	98 results

1901 records screened for eligibility

37 full-text articles assessed for eligibility

17 studies suitable for inclusion

Hand-searching of references – 0 further eligible studies

17 studies included in qualitative meta-ethnography

Appendix 1-A
Authors' notes for *Health & Psychology*

Manuscript Preparation

1) General Guidelines

Manuscripts are accepted in English. British English spelling and punctuation are preferred. Please use single quotation marks, except where 'a quotation is "within" a quotation'. Long quotations of 40 words or more should be indented without quotation marks.

A typical manuscript will not exceed 30 pages including tables, references, captions and endnotes. Manuscripts that greatly exceed this will be critically reviewed with respect to length. Authors should include a word count with their manuscript.

Manuscripts should be compiled in the following order: title page; abstract; keywords; main text; acknowledgements; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).

Structured abstracts of 200 words are required for all manuscripts submitted. Primary headings should be: Objective, Design, Main Outcome Measures, Results, Conclusion.

Each manuscript should have 3 to 6 keywords.

Search engine optimization (SEO) is a means of making your article more visible to anyone who might be looking for it. Please consult our guidance here.

Section headings should be concise.

All authors of a manuscript should include their full names, affiliations, postal addresses, telephone numbers and email addresses on the cover page of the manuscript. One author should be identified as the corresponding author. Please give the affiliation where the research was conducted. If any of the named co-authors moves affiliation during the peer

review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after the manuscript is accepted. Please note that the email address of the corresponding author will normally be displayed in the article PDF (depending on the journal style) and the online article.

All persons who have a reasonable claim to authorship must be named in the manuscript as co-authors; the corresponding author must be authorized by all co-authors to act as an agent on their behalf in all matters pertaining to publication of the manuscript, and the order of names should be agreed by all authors.

Biographical notes on contributors are not required for this journal.

Please supply all details required by any funding and grant-awarding bodies as an Acknowledgement on the title page of the manuscript, in a separate paragraph, as follows:

For single agency grants: "This work was supported by the [Funding Agency] under Grant [number xxxx]."

For multiple agency grants: "This work was supported by the [Funding Agency 1] under Grant [number xxxx]; [Funding Agency 2] under Grant [number xxxx]; and [Funding Agency 3] under Grant [number xxxx]."

Authors must also incorporate a Disclosure Statement which will acknowledge any financial interest or benefit they have arising from the direct applications of their research.

For all manuscripts non-discriminatory language is mandatory. Sexist or racist terms must not be used.

Authors must adhere to SI units. Units are not italicised.

When using a word which is or is asserted to be a proprietary term or trade mark, authors must use the symbol ® or TM.

Reports of statistical tests should include an indication of effect size whenever possible. Reports of randomised controlled trials should state any registration details of the trial and should follow CONSORT guidelines where relevant (see Moher, D., Schulz, K.F. & Altman, D.G. for the CONSORT group, 2001. The CONSORT statement: Revised recommendations for improving the quality of reports of parallel-group randomized trials. Annals of Internal Medicine, 134, 657-662).

2. Style guidelines

Font: Times New Roman, 12 point. Use margins of at least 2.5 cm (1 inch). Further details of how to insert special characters, accents and diacritics are available here.

Title: Use bold for your article title, with an initial capital letter for any proper nouns. Authors' names: Give the names of all contributing authors on the title page exactly as you wish them to appear in the published article.

Affiliations: List the affiliation of each author (department, university, city, country). Correspondence details: Please provide an institutional email address for the corresponding author. Full postal details are also needed by the publisher, but will not necessarily be published. Anonymity for peer review: Ensure your identity and that of your co-authors is not revealed in the text of your article or in your manuscript files when submitting the manuscript for review. Advice on anonymizing your manuscript is available here.

Abstract: Indicate the abstract paragraph with a heading or by reducing the font size. Advice on writing abstracts is available here.

Keywords: Please provide five or six keywords to help readers find your article. Advice on selecting suitable keywords is available here.

Headings: Please indicate the level of the section headings in your article: • First-level headings (e.g. Introduction, Conclusion) should be in bold, with an initial capital letter for any proper nouns. • Second-level headings should be in bold italics, with an initial capital letter for any proper nouns. • Third-level headings should be in italics, with an initial capital letter for any proper nouns. • Fourth-level headings should also be in italics, at the beginning of a paragraph. The text follows immediately after a full stop (full point) or other punctuation mark.

Tables and figures: Indicate in the text where the tables and figures should appear, for example by inserting [Table 1 near here]. The actual tables and figures should be supplied either at the end of the text or in a separate file as requested by the Editor. Ensure you have permission to use any figures you are reproducing from another source. Advice on artwork is available here. Advice on tables is available here.

Running heads and received dates are not required when submitting a manuscript for review. If your article is accepted for publication, it will be copy-edited and typeset in the correct style for the journal.

References: APA (American Psychological Association) references are widely used in the social sciences, education, engineering and business. For detailed information, please see the Publication Manual of the American Psychological Association, 6th edition

3. Figures

Please provide the highest quality figure format possible. Please be sure that all imported scanned material is scanned at the appropriate resolution: 1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour.

Figures must be saved separate to text. Please do not embed figures in the manuscript file.

Files should be saved as one of the following formats: TIFF (tagged image file format), PostScript or EPS (encapsulated PostScript), and should contain all the necessary font information and the source file of the application (e.g. CorelDraw/Mac, CorelDraw/PC).

All figures must be numbered in the order in which they appear in the manuscript (e.g. Figure 1, Figure 2). In multi-part figures, each part should be labelled (e.g. Figure 1(a), Figure 1(b)).

Figure captions must be saved separately, as part of the file containing the complete text of the manuscript, and numbered correspondingly.

The filename for a graphic should be descriptive of the graphic, e.g. Figure1, Figure2a.

Appendix 1-B
Example of step 4 and step 5 of analysis using Microsoft Excel

Sinclair 2012		
I don't think I would want to talk about it. Because again it is accelerating the inevitable and the less you think about it, the easier you get through the day.		Forgetting about the illness makes it easier to get through the day.
No one else has had any say in the rest of my life so why should they have a say when I'm down at the last block, there's only one person and that's me.		It should be an indiviudal decision only.
And [nominating a guardian] would make it easier for whoever has to look after me but by the same token I don't believe in giving away my authority or anything.		Always getting ultimate responsibily but allowing a guardian to make the process easier
But when I got the secondaries you know they only go in remission they don't go away and so that's when I went and did [AD form].		When death became an imminent certainity
but to keep a person alive as such, he couldn't talk, he couldn't drink, he couldn't eat… that is cruel. And that's where these [AD forms] should be		Cruel to keep people alive in some circumstances.
You know your children are leaving you and you're going to be left on your own, why don't you go and make some arrangements		Making an AD when no one else there to help you.
The way [doctor] put it, if you fell down dead out there now do you want me to resuscitate you?		Doctor being very direct and asking directly for an AD
I've been nursing for years and years… and seen some bloody horrendous things happen. And I made up my mind early in the piece that I would… be in control of my destiny.		Negative experiences affecting AD decision Being in control
I am conscious that things really need to be put in some sort of order, and this was just another… document that helped tie up everything together.		AD creates order in the person's life
Well what's the good of it? [Doctors] just do what they like.		Doctors just do what they like.
… but once you come here [care home] you got no choice what doctor you get… and the one that was here… said I well get the other doctor…to print (AD) out and she said she'll get him to print it out. So you know it just hasn't arrived.		No access to AD form reliant on doctors.
…we often talked about it because I've heard there's a living will and… we asked the doctor once and he said as a joke "have another wine at night and… enjoy life".		Doctor not giving information on AD
my family were all for me doing [an AD]. They said 'Righto, you go ahead and do as you please'.		support of family to do as you want.
– I don't want to make my family miserable by making a decision [to complete an AHD]. I mean I'm quite willing to suffer a little more if my family's happy about that.		Family's happiness over their own.
"Well, they oughtn't try to resuscitate me. Because, ah, it'd be coming back to a lot more pain and a lot more suffering… but, ah, my family isn't very happy about that… So where it'll finish up I have no idea."		own views conflicting with family's view so uncertainty of what will happen.

Study (author first initial)	S+D+P+W+L+B+L	S+D+P+W+L+B+M	S+D+P+W+L+B+M+S	S+D+P+W+L+B+M+S+B
	Themes to compare	Themes to compare	Themes to compare	Themes to compare
				QUALITY OF LIFE
	QUALITY OF LIFE	HARD TO PRDICT FUTURE	QUALITY OF LIFE	STATE OF MIND WHEN YOU WRITE IT
	NOT WANTING TO BE BURDEN ON FAMILY	STAYING ALIVE	INDIVIUDAL DECISION	FOR WHEN YOU LOSE ABILITY TO DECIDE- CONTROL
	LACK OF COMMUNICATION	CONFUSING HOW ADs work	ULTIMATE DECISION WITH PERSON BUT WANTING SUPPORT	SUPPORT FROM FAMILY
	SHARING IMPORTANCE OF ADs WITH OTHERS		AD WHEN DEATH IS A CERTAINITY	IMPORTANT TO SPEAK TO RIGHT PROFESSIONALS
			CONTROL	AMBIVALENCE OF DISCUSSION
			ORDER	HARD TO KNOW OPTIONS OF FUTURE DON'T WANT TO MAKE CONCRETE DECISION
			ROLE OF DOCTORS -CAN BE DIRECT	HARD TO PREDICT FUTURE
			DOCTORS CONTROL THE PROCESS	
			PAST NEGATIVE EXPERIECNES OF PEOPLE DYING	
			LACK OF COMMUNICATION	
			ROLE OF FAMILY	
			SUPPORT OF FAMILY	
			PUTTING FAMILY FIRST	
			CONFLICTING VIEWS WITH FAMILY	

Section Two: Empirical Research Paper

What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.

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[1] Please note this manuscript was prepared in line with author guidelines for *Social Psychiatry and Psychiatric Epidemiology (See Appendix 2-A).* Where these guidelines have not been followed, most notably the word count, Lancaster University thesis guidelines have.

Abstract

Background: A recent report highlighted that 84% of detained patients did not consent to the ECT treatment they received. This is despite the Mental Health Act (2007) stating that if a person has capacity and is detained under the Act they cannot be given the treatment unless two Consultant Psychiatrists deem the treatment to be life-saving. The decision-making process taking place in regards to deciding if ECT is given or not is complex and unclear. It is, therefore, important for the development of clinical care, to understand how the decision making process is taking place so mental health professionals can ensure that as many people as possible are consenting to the treatment

Aims: To develop a grounded theory informed model that explains the decision making process different stakeholders go through in regards to ECT.

Method: A grounded theory informed methodology was used to analyse the data offered by ten participants who had all been involved in the process of deciding if someone has ECT or not.

Results: The core categories, described as 'layers' in this research, '*personal and professional identity';' a person's general view on ECT'; 'when does ECT become a treatment option for an individual?';' who has the power to make the decision?' and 'the decision in action'* was constructed from the data. Findings are discussed in relation to previous research; in particularly to concepts of recovery.

Conclusions: The findings of the study enabled a model of decision making in regards to ECT to be developed. The model highlights that the decision to give ECT includes many different layers including professional identity, how a person understands the evidence base, past experiences and the amount of power they have in the process. The Consultant Psychiatrist and the patient were seen as holding most power in the process depending on whether the Mental Capacity Act (2005) or Mental Health Act (2007) was being followed.

Patients were seen to experience a very different decision making process dependant on the

professionals involved in their care and especially depending on the Consultant Psychiatrist

involvement in their care. Future research should look to extend the model to understand the

decision making process from the perspective of the patient and families.

Declaration of Interests: None.

Keywords: Grounded theory; staff; electroconvulsive therapy

Electroconvulsive therapy (ECT) involves passing an electric current briefly through the brain which then induces generalised seizure activity [1]. The opening chapter of the Royal College of Psychiatrists (RCoP) ECT Handbook states that "75 years after its introduction, ECT remains the most effective treatment for severe depressive disorder" [2 p.1] and in the United Kingdom (UK), policymakers and many psychiatrists regard ECT as an effective intervention [3]. Although ECT has been used since the 1930s, there is still no universally accepted theory that explains its mechanism of action [1]. Many possible mechanisms of actions have been suggested including alterations in serotonin sensitivity, direct effects of convulsions, increased secretion of hormones, neurogenesis, and glial changes [4]. Not explicitly knowing how ECT works is an often cited criticism of ECT. This, however, is not just specific to ECT and could be true for most biological treatments in psychiatry [2].

ECT remains relatively under researched compared with other biologically based treatments [2]. Possible reasons for this include the negative public image ECT has, funding priorities, the interests of researchers and the practical and ethical difficulties in studying a treatment that is usually prescribed for severely distressed people. For Anderson and Fergusson [2] the lack of research is concerning and acts as a potential barrier to understanding the high number of people who experience severe distress after undergoing what was deemed to be "successful ECT treatments" as well as understanding the adverse cognitive effects that are reported following ECT treatment [5,6]

Due to the unknown mechanisms of ECT works, the high rate of (what is called in the literature) relapse, and the adverse cognitive effects, ECT is said to be one of the most controversial interventions within mental health services[7]. The literature surrounding ECT is often polarised, as highlighted by systematic literature reviews in the area [7,8,9]. For example, Read and Bentall's [7] meta-analysis concluded that ECT caused "significant

increased risk of death" and that "the cost-benefit analysis for ECT is so poor that its use

cannot be scientifically justified" [7, p.333]. On the other hand, the UK ECT group [8]

concluded in favour of ECT, stating it was significantly more effective than "simulated ECT"

and significantly more effective than pharmacotherapy. Furthermore, Sienaert [9] concluded

that ECT is highly effective in the treatment of experiences that may be categorised as "major

depressive disorder".

The National Institute for Health and Care Excellence (NICE) recommends that ECT

only be used for experiences that are categorised by the International Classification of

Diseases 10 as "severe depressive illness, a prolonged or severe episode of mania, or

catatonia" [10, p.3]. The ECT Minimum Dataset Activity Data Report 2015 [11] and the

Scottish ECT Accreditation Network (SEAN) Annual Report 2015 [12], however, show ECT

is used for other forms of psychological distress, including experiences categorised as:

"adjustment disorder, anxiety, atypical anorexia nervosa, borderline personality disorder,

emotionally unstable personality disorder, peri-natal depression, anti-natal depression, post-

natal depression, persistent delusional disorder, psychosis, schizoaffective disorder,

schizophrenia and schizophrenia-mood disorder".

ECT Policy and Legislation

The ECT Minimum Dataset Activity Data Report (2015) [11] capturing ECT

administration data in the UK concluded that 81.6% people who received ECT whilst

detained under the Mental Health Act [MHA] (2007) in 2014-15 did not consent at the start

of the treatment. In the 2013- 2014 report, 84% of people who were detained under the MHA

did not consent to treatment [13].

According to MHA (2007), if a person is capable of understanding the nature, purpose

and likely effects of the treatment, i.e. they have capacity to make the decision, then ECT

cannot be given without his/her consent. ECT can only be given to a person who is deemed

to not have capacity when an independent, specially approved psychiatrist has authorised it. If a person who is deemed as having capacity refused treatment, then the only circumstance in which ECT can still be administered is under section 62 (1A & 1B) of the MHA (2007) which is an emergency treatment usually because there is a fear that the person will die if they do not have the treatment.

The Mental Capacity Act (MCA) (2005) runs alongside the MHA in England and Wales, and provides a statutory framework for decision-making in relation to adults who may lack the capacity to make specific decisions for themselves. The core purpose of the MCA is to empower individuals to make their own decisions wherever possible, as well as protecting vulnerable individuals who lack decision-making capacity. The MCA (2005) specifically includes ECT within it, to ensure that there is a safeguard in place for people that lacked capacity to consent to ECT, but who were not detained under the MHA. It is, however, said to be unusual for someone to be given ECT under the MCA, as the MHA provides the best protection for a service user's rights [1]. The MCA can only be used if the patient lacks capacity and a "decision maker" (usually the consultant in charge of their care) decides that ECT is in the service user's "best interest".

According to NICE guidelines [10, p.32], the consent process for ECT should involve: the individual's advocate and/or carer where possible; provide full and appropriate information in a suitable format and language to enable an informed decision; explain and discuss the general risks of ECT, risks specific to the individual and potential benefits to the individual; does not pressure or coerce the individual into consent to the treatment; and, reminds the individual that he or she has the right to withdraw consent at any point. NICE [10] guidelines, however, do not detail what would constitute appropriate information and/or guidance on the suitable format or language use, nor does it detail what constitutes coercion or how to ensure the capacity of the service user to make and communicate a decision[14].

The decision making process for ECT

Rose, Wykes, Bindmann and Fleischmann [15] concluded from their meta-analysis that approximately half of UK mental health service users felt they had not been given enough information about ECT before consenting to the procedure and that one-third of service users did not feel they had freely consented to ECT treatment. This was also found in a more recent study published six years after that meta-analysis [14].

Research has suggested that many people who received ECT felt it was a "last resort" [14, p.350]. Morrison [16] also discussed the idea of ECT being a "last resort" in her personal account of receiving ECT. Fisher et al. [14] suggested that the idea of ECT being a "last resort" is further reinforced by NICE [10] guidelines, which explain ECT should be used "only in life-threatening situations or when medication and other interventions have failed". Johnstone [17] stated that this will impact on a person's ability to consent, as they will feel unable to refuse treatment that is seen as their last chance, and furthermore, will deem there to be no other treatment options.

Fisher et al. [14] concluded that future research should investigate how service users make sense of and prioritise multiple sources of information when deciding whether to have ECT. They also stated, however, that such research needed to be sophisticated enough to take into account the "complex interpersonal and systemic context in which patients make this decision" [14, p.353]. Research that includes the understanding of both professionals and service users involved in the consent process, will seek to take into account the interpersonal and systemic context. In addition, Fisher et al. [14] suggested that future research with people who refuse to consent to ECT would provide more insight into the ECT decision making process.

There has been little research involving staff and the use of ECT. One study whose sample was staff members, found that there were significant differences in attitudes towards

ECT between those in different job roles [18]. The study concluded that there is a need for

awareness of differences of opinion within multidisciplinary teams towards the treatment, and

that teams should be aware that there might be strong differences of opinion amongst

members. These differences were said to be likely to affect the decision making process

about ECT. As of yet, no research has investigated staff members views on the process of

ECT.

Fisher [19] states that clinical psychologists, given their training in qualitative

methods, can continue to inform best practice guidelines within the area of ECT. Fisher [19]

also recommended that such research should aim to work collaboratively with service users

and other mental health professions involved in ECT; particularly psychiatry and nursing.

The Current Study

It can be seen from the policy and research highlighted above, that the decision-

making process taking place in practice is not just a mechanistic one, but one that is complex

and unclear. It is, therefore, important for the development of clinical care, to understand

how the decision making process is taking place so mental health professionals can ensure

that as many people as possible are consenting to the treatment. The current study will look

to address the following research question: what is the current decision making process, with

regards to ECT administration, from the different perspectives involved?

Method

Design

A qualitative design was used to enable an in-depth exploration of participants'

experiences of the decision making processes in relation to ECT treatment. The study

adopted a grounded theory informed methodology in order to go beyond just the meaning of

lived experiences of phenomena, and instead develop an explanatory theory based on social

processes [20]. There are different approaches to grounded theory and this study adopted

Charmaz's [21] approach. This approach is underlined by constructivist epistemology. This assumes that theories are not discovered, but rather constructed through the research process, and that the model created will map perceptions of processes in its theories, rather than the underlying realities.

Ethical Considerations

The study was reviewed and gained ethical approval by North West Greater Manchester South NHS REC (see Ethics Section). In addition, local NHS Research and Development guidelines were adhered to where appropriate.

Sampling and Participants

Participants were recruited primarily from two large NHS Trusts in the North West of England, across multiple sites. In order to gain access to a wider pool of participants three amendments were sought (approval granted 26/01/16; 21/03/16 & 10/05/16) to also recruit participants via social media platforms and to interview participants via telephone as well as in person (see figure 1). A total of 10 participants were recruited. Further demographic information can be seen in table 1.

Interview Procedures

Each participant was interviewed once, using a flexible topic guide. The topic guide developed as the analyses progressed in line with Charmaz [21]. Interviews lasted between 28 minutes (final interview) and 80 minutes.

Prior to interview, each participant was given the information sheet, allowing for at least 48 hours to consider participation in the study. Any questions raised were answered and each participant signed a consent form. All interviews occurred at the participant's workplace or a local NHS site that was convenient for them. Interviews were recorded using a voice recorder.

One of the interviews was listened to by the research supervisor to help inform the development of the researcher's interviewing technique.

Data Collection and Analysis

Initially, individual interviews were undertaken with four participants; one psychologist, one consultant, one ECT lead nurse and one ward manager. Memos and reflective notes were written after each interview to capture the ideas the researcher had about initial codes that were emerging from the data. The initial four transcripts were then line to line coded [21]. This involved assigning codes to every line of the transcripts. Memos were again written at this stage to ensure the researcher was analysing the ideas early on in the research process and to increase the level of abstraction in the ideas [21]. These codes were then amalgamated to form focused codes and then further amalgamated, utilising the researcher's memos, to form conceptual codes. The findings were then used to adapt the interview schedule [21]. Both the research supervisor and field supervisor informed this process. The process also highlighted participant demographics that should be focused on, in line with theoretical sampling [21], to develop the emerging conceptual codes further.

A further six participants were recruited and the analysis was repeated in constant comparison with the initial codes and conceptual categories. If the data emerging in the interviews did not fit with the existing initial codes, then new codes were developed. Eventually, all data were then collated to contribute to a grounded theory informed model of the process. The study data fits with the description of data sufficiency provided by Dey [22]. The conceptual categories that already exist did not require revision or alteration in respect of new data (see figure 2).

Reflexivity

Reflections were made on the author's perspective of, and experience of conducting the ECT research, on an Internet blog site (https://ectresearch.wordpress.com/). Reflections

were also made and discussed in monthly research supervisions. Reflecting on these

experiences enabled acknowledgement of assumptions and biases within the research

process.

Findings

These findings should be read alongside the diagrammatic summary in Figure 3. The

diagram shows the stages involved in making a decision to give ECT or not. This is

represented by a pyramid metaphor with the decision in action at the pinnacle of the pyramid.

Each layer of the pyramid shapes the layer above it. If a person thinks ECT should be given

then they progress to the next layer. At each layer are exits from the decision making model

which would result in a decision not to give ECT. The first layer offers insight into the

boundaries of the model. The personal and professional identity of the individuals shaped

their decision making process; however, a detailed understanding of this layer was outside the

remit of this research. The process of how the layers are formed and how they connect with

the adjoining layers will be discussed in further detail below. At the end of the discussion is

another version of the model which includes a specific example of the decision making

process using the experience of participant 3 (figure 4).

Figure 3 here

What is a Person's General View of ECT?

All the participants, whose professional identity had exposed them to considering

ECT as a potential treatment option, talked about their general thoughts on both the

effectiveness and harmfulness of ECT. Effectiveness for the participants was if the treatment

"worked" and if they could observe that the patient had got "better". Most participants talked

about the treatment working in terms of mood improvement. Harmfulness was described in

terms of side effects to ECT (nausea, vomiting, headaches), contraindications (such as

cardiac problems) that may result in serious harm or death for the patient if they were to be given ECT and cognitive impairments as a result of the ECT.

The views that a person had about the effectiveness of ECT came from two sources; the research evidence base: "I am yet to come to an evidence base that says ECT is not equal, superior or sometimes the only method of treatment" (P4) and the experience of seeing it work for someone "I have never known it not to work for anybody" (P5). This is linked to the previous layer in that the participants had different experiences based on their professional training and professional job roles. All the participants in the study had witnessed some form of "dramatic" improvement in terms of how a person presented and this undoubtedly influenced how they made their decisions. Seeing such an improvement meant some difficulties they perceived that might be potentially caused through the process of giving someone ECT, particularly against someone's will, were often mitigated against.

> Even though it is horrible at first and you do have to put hands on and take someone
>
> round there you can justify it in your head because you think I know it will get better
>
> for that person and so that's how I have rationalised it before (P5)

On the other hand, participants said some professionals would never give ECT: "we know that there are certain Consultants within the Trust who don't like ECT…some Consultants just don't prescribe ECT at all" (P7). Some participants felt this was harmful to patients as they were being deprived of a treatment that could potentially help before they had even had chance to consider it. Whilst one person, therefore, thought their decision making was acting in the best interest of patients (withholding a harmful treatment) another decided that this was harmful to patients (withholding an effective treatment without giving opportunity for the patient to choose what they thought was the best option).

When does ECT Become a Treatment Option for an Individual?

All but one of the participants felt that ECT should only be given after other options had been tried first: "I mean I don't think we should jump straight to ECT" (P6). The majority of the participants spent most of the interview discussing ECT in regards to life-threatening situations or in regards to severely distressed people that were "stuck" in their distress. It was difficult to prompt conversations about what happened before people reached this point:

> Not to sound like a broken record but it's the lifesaving thing. It is the only thing that I think we can do to genuinely save a life. For most other things [diagnoses] you can contain and eventually you will get there but for that group of people you have to do something" (P10).

When asked why ECT was not considered in the first instance the participants cited examples of side effects such as memory loss, confusion, headaches and nausea. There was also an idea of ECT being seen as "invasive", "intrusive", or even considered "barbaric". This intrusive element left participants feeling uncomfortable yet it was very difficult for the participants to elaborate on this feeling.

> I tended to think and maybe I still do that it was given to elderly people and by default those people at the time were subservient to doctors; they would do what the doctor said and that made me a little uncomfortable about that. There also seemed to me, people who were disenfranchised in some ways got ECT sooner than other people, so people without advocacy, people without family, they got ECT sooner than other people. So that made me uncomfortable. (P10)

However this uncomfortable feeling could be alleviated if there was trust in the effectiveness of the treatment.

> I know that it works and that the moral and ethical arguments against it are almost
>
> academic in some respects because we have got an established treatment that we
>
> know works, that we know the efficacy of to a large part, we know the side effects
>
> and we can explain those, and we can adjust for them. (P10)

When the participants described the people who they felt should be considered for ECT they described the person as being "catatonic" or "severely depressed". The participants spoke mainly in diagnostic language, however they explained further what that diagnoses would look like in practice: "not eating", "not drinking" and "just existing" were common narratives in how people were described.

Some of the participants made reference to guidelines (NICE & Electroconvulsive Therapy Accreditation Service [ECTAS]) that supported their decision of who was appropriate to receive ECT. However, in the main, people stated the decision came from clinical observation.

> We don't go off that [guidelines] I think as staff nurses what we'd be looking for is
>
> observational signs. So if we see somebody come in and you know and we are a ward
>
> that does preserve and we try and get them motivated, try and get them to do things
>
> and if we just, if those signs and those alarms bells are going that's when we would
>
> bring it to the table. (P5)

People talked about relying on their experience, understood within what appeared to be a scientific framework, to judge if someone would benefit from ECT or not.

> Well it's usually the same presentation i.e. if they are, especially if they have had it
>
> before, then I know it is going to work that they'll get better. But if it's a new person
>
> it's more that they are agitated, if it's clinical depression, you know if they are a
>
> certain age you know what I mean. I don't know you just get to know that this person
>
> it will work well for because usually the presentation is exactly the same. (P7)

Another, again scientific, factor that was taken into consideration was if the person had ECT

before or not and if it had been deemed to be successful in the past. If it was deemed to have

been successful in the past, then it was used again: "so people who have had ECT and were

successful with it we would never replace it with anything else" (P4).

In addition to thinking why people would benefit from the treatment all the

participants talked about weighing the benefits against the harm that ECT may cause. All the

participants voiced concerns about the safety of analgesia first and how analgesia use was

more unsafe with some people than others. If there was any fear that ECT was

contraindicated and could cause severe harm or death then it was not an option.

Although many participants focused on physical harm some also considered

psychological harm. This seemed to be explained by the training that a person had: those

whose training had a focus on psychological perspectives to mental health spoke about

psychological harm more:

> I knew that that was a particular difficult topic for him [having ECT] because his dad
>
> had ECT around the same age and so that was part of the formulation. There was a
>
> lot of that feeding in to like a feeling of a self-fulfilling prophecy really. (P9)

The predicted psychological harm ECT could cause was therefore something that could cause

a person to want to not give someone ECT. There was a common theme, however, that if life

was in danger then ECT should always be used regardless of psychological harm caused by

the treatment. In this sense, some participants appeared to see psychological distress as

something different from the "illness" the ECT was treating. Effectiveness for these

participants was ECT treating the person so that they started eating or drinking again.

Effectiveness was boosting a person's motivation to, at a basic level engage with life again.

The psychological harm caused by the treatment (i.e. abuse of power, feelings in relation to

being restrained) was something that needed to be addressed, but at a later stage. It was also

something that was not being addressed enough according to some participants:

>I think at the time it probably is the right treatment to do from a life-saving point of
>
>view but then we have also got to consider that it is quite, I'd say, parental. It is going
>
>back to the old days of strapping them to the bed and giving them a treatment and all
>
>the ensuing memories that that could dredge up. I don't necessarily think that we
>
>address that. (P10)

The feelings associated with nursing or caring for a person in so much distress was

also distressing for the participants and this appeared to be a factor that influenced how

people made their decision. When describing what it was like, one participant summed it up

as "well it is awful. It's awful… this job it will emotionally pull you. We are only human."

(P5). There was a real drive to get people better because it was hard to see a person in so

much distress, and because that was the main aim of coming into a health care profession. As

P5 concluded:

>We have come in to this job to help people…so you have to sort of , you've got to be
>
>hopeful that everyone who comes in that there is, you know, that things are going to
>
>get better, we will reduce risk and we'll get them out as soon as we can.

Who has the Power to make the Decision?

The participants in the study weighed up their own opinions on whether ECT should

or should not be given. By this layer in the process, some participants may have exited from

the layer, concluding that ECT was not the best option for the patient. The participants,

however, held different amounts of power that their own decision would be followed. There

was no doubt in all of the participants' accounts that if a patient had capacity then it was for

the patient to make the decision to have ECT or not. "If they are informal [and don't want

ECT], they don't get it. We don't treat. It's as simple as that". (P2). This view of capacity

was the same even if the person was detained under the Mental Health Act (2007) "then they don't have it. If they are under a section and they have capacity and they are not consenting then they will not be having it!" (P7). This view was driven by an inherent respect for the patient's right to autonomy "if I am in any doubt, I will choose what the patient has the right to" (P4). This right to autonomy is reflected legally by the Mental Capacity Act (2005) and by the amendment to the Mental Health Act (1983) that says a person can refuse ECT treatment specifically if they have capacity.

> I mean it [MHA] tends to help us because then we can say the Mental Health Act says this so we can't give it. 'Cause maybe, possibly, in the past they did just bring them down and they would have the treatment no matter what, you know what I am saying?" (P7)

If the patient did not have capacity then the participants described that a multidisciplinary team (MDT) decision should then occur to decide if the patient was to receive ECT or not. Ideally, in line with the model this would be a discussion that took into account all the layers of decision making that each member of the MDT had gone through. This MDT decision, however, was described not to happen in practice: "yeah it has to be a team decision. Well it has to be a team discussion, I'm not saying it is a team decision but it has to be team discussion" (P5). The team decision was said to be dependent on the Consultant who all ten participants described as having ultimate power in the process (when the patient did not have capacity):

> I think it comes down to the personality of the Consultant and whether that is someone who values the skill, experience, opinion of their team because my experience of working on the wards is that some Consultants really appreciate and absorb that and other don't. (P9)

The participants felt that the main factor in what drove Consultants to make the decision was the fear of judgement and blame if a patient was to die. This is because under the Mental Health Act (2007) the Consultant Psychiatrist is named as the Responsible Clinician. This could force the Consultant to rely on their own decision making process and not listen to others.

> I think the problem that we have got is that our Consultant had a few like serious incidents where people have gone and killed themselves so his anxieties is, it's awful when you are standing in front of a coroner…but the way that he sees it is that [they] have to do everything that [they] can in order so that if someone does then they have tried everything. (P5)

All the Consultants in the study stated that they were ultimately responsible for the decision. All of them, however, expressed making the decision to give ECT or not with their multi-disciplinary team and felt there were never disagreements around the decision "I don't think we have ever had a case where I wanted ECT and the nursing staff hasn't." (P6). There was a also a sense that other members of the team looked to the Consultants for answers.

An aspect of autonomy that challenged the participant's decision making was for people who had capacity and requested ECT. The pyramid model described here for the professionals also fits for these patients who will have started their decision making with their own views on ECT and their own ideas on when they felt they should have ECT. In situations where patients requested ECT the participants would follow the same decision making model, weighing up their own views on ECT, and weighing up if the person should have ECT or not:

> So I and one of my patients she said wanted ECT as it helped her to block her thoughts of abuse when she was a child but that is not really the function of ECT so in

that case a discussion was whether ECT was appropriate or not and we didn't proceed

with it because I felt that she would benefit more from trauma therapy (P10)

The previous quote highlighted that Consultants felt a paternalistic approach could be taken

in these situation to avoid the person coming to harm from the treatment. When there was a

fear of the consequences of risk, however, it pushed some people to give the power to the

patient to decide to have the treatment. This was because the fear of blame and judgement if

the person was to die was too overpowering.

but she will go into a review and say I want to kill myself and if you discharge me I

will kill myself… because if she goes out and kills herself, [if he gives ECT], [talking

as the Consultant] "I can say to a coroner that I have done everything in my power to

help this girl". (P3)

The Decision in Action

Once it had been decided who held the power to make the decision, i.e. the patient or

the Consultant, the decision was put into action.

Advocating. The participants talked about times when the patient did not have

capacity or when the patient compliantly went along with the Consultant's decision that they

did not agree with.

I want to do the best job that I can. Doesn't everybody? And if that means standing

up to a Consultant because we have been advocates for patients in the past and it

hasn't all been smooth. (P2)

The participants also talked about how some patients, particularly older patients, would

typically never challenge the views of the psychiatrists and so even if they did have capacity

would often go along with what the Consultant was saying. In these situations the

participants felt they had to advocate on behalf of the patient. This was driven by a need to

either empower that patient's autonomy, or empower the participant's opinion over the

decision that was made because they felt that their own decision making was in the best

interest of the patients and not the decision that had been made.

       Reassure/persuade. A patient may have held the power to say no to the treatment;

however sometimes the participants still believed that the treatment was the best option for

the patient. In these situations, many of the participants saw a main part of their role was to

reassure patients that ECT was a good treatment choice. This reassurance was done in many

ways including showing people around the ECT suite "we also facilitate patients coming

down to the unit before they are treated so that they can have a look around if necessary"

(P2); alleviating stigma "well first off it is trying to alleviate the stigma of ECT: the myth

about it being a painful process which it is not" (P4), and talking people carefully through the

process:

> Tell them [the patient] what the treatment entails, probably what will happen, going
>
> through the process so that they know. We try to give them as much reassurance as
>
> possible. That also is, it's like, a face to face so that they will have, so that they will
>
> know us when they are here. (P2)

The majority of the professionals that engaged in these types of actions labelled it specifically

as reassurance and maintained that it was ultimately the patient that made the final decision;

however this seemed to come only after the patient had been presented with potentially

biased information. The participants reasoned that this reassurance was necessary because

just like the participant's scales were not balanced at the start of the decision making process,

neither were the patients'. The participants believed that the patients started the process with

a very negatively biased image of ECT. This bias came from what the participant's believed

was a very negative image of ECT in the media and through historic legacy. They believed

that if they did not reassure the patient, then the patient would not have the treatment due to

predominantly negative social beliefs about ECT and that this would not enable an informed,
autonomous decision.

> I think there is a lot of stigma around it and I think especially with films and what
> they have seen. It's completely different and they can go and have a look around the
> ECT suite if they want to, they can have all that information so they can see it's not
> this barbaric treatment (P5).

Some professionals saw this reassurance as persuasion; "and they would discuss the risks,
wouldn't they, but they were basically trying to persuade him to… from what he says it was
kind of like pressure, and pressure really to have it" (P9) and

> They didn't pursue ECT while he was on the ward because he didn't want it…he said
> from the word go that he didn't want it but they kept sending junior doctors with
> leaflets to talk to him about it…"oh you know it used to be like this but now it is like
> this and it's OK now because we anaesthetised people" or "we use analgesia" (P9).

One participant specified that they felt his role was to convince people to have ECT if they
felt the treatment was in the patient's best interests "but I think it is my job to convince even
those who might not want it if I think in my view they might benefit from ECT." (P6). This
seemed to come from a paternalistic view point that he knew what was in the best interest for
the patient to promote their wellbeing, despite the patient having the capacity to make their
own decision. Participants that held such views tended to see ECT as a "solution" that would
eliminate the suffering of the patient. Other participants that felt that distress should be "sat
with" and would not just be solved, leaned away from feeling the need to persuade a person
to have the treatment.

> **Supporting the patient to make an informed and autonomous decision.** The final
option for action that came as a consequence of the decision making process was supporting
the patient to make an authentic, informed, autonomous decision. This was when the person

held the power to make their own decision. This action was difficult to tease apart from the previous action, as many of the participants believed that they were doing this when they were offering reassurance to a client. It was very important to all the professionals, at least on the surface, that the patient was allowed to make an informed choice. This was most notably important for the participants in the study who had experienced times when the patient was not as informed in their care:

> I started off my career with a fairly negative view of it [ECT] really. I tended to think and maybe I still do that it was given to elderly people and by default those people at the time were subservient to doctors; they would do what the doctor said and that made me a little uncomfortable about that. There also seemed to me, people who were disenfranchised in some ways got ECT sooner than other people so people without advocacy, people without family, they got ECT sooner than other people so that made me uncomfortable. (P10)

Ways to ensure that patients had more of a say in their treatment was to offer advocacy and to have more family carer involvement. Psychological support was rarely offered to the patient. Having a psychological formulation that supported a patient to understand why they were "stuck" in their distress was discussed as being important in order to help a patient make an informed, autonomous decision about whether they wanted ECT or not.

Figure 4 here

Discussion

The findings have begun to explore the process that an individual goes through when deciding whether to give ECT or not. Individuals go through stages of decision making represented by the layers of the grounded theory model (figure 3). Each layer is advanced when a person decides, through consideration of numerous factors, that ECT is the best option for the patient. Each layer can be advanced up until the "who holds the power layer".

This layer can only be progressed by the Consultant or the patient as legally stated by the MHA (2007) and the MCA (2005). If the patient has capacity, only they can theoretically progress through this layer unless they are deemed to be in a life threatening situation, in which case they can be overruled by two psychiatrists under the MHA (2007). At each layer of the model is the potential to exit from the model after deciding to not give ECT. After exiting from the layers the individual will re-join the process at the "who holds the power" layer. Their decision to not give ECT will then depend on who they are and their status of power. This means that the MDT is involved in their own personal decision making up until the "who holds the power" layer, at which point their involvement is less influential and depends upon the Consultant or the patient. When a person does not have power to legally make the decision, they can attempt to influence the decision in action to change in three other ways; advocating, reassuring/persuading and supporting/informing.

The exits from the decision making layers show reasons as to why a person may decide that they do not think ECT is the best option for a person. The findings highlighted that sometimes patients were not even being given the option of ECT due to the professionals understanding of the effectiveness and harmfulness of ECT, who were involved in the patient's care. NICE guidance [10] recommends the use of ECT in certain situations however some patients were not able to access this treatment option, due to professionals not offering it. On the other hand, some people could be potentially "persuaded" to have ECT based on the professionals understanding of ECT or could be more likely to have a potentially forced treatment. This highlighted that at times the process is not fair or standardised across patients and that patient's treatment choices are dependent upon the views of ECT that, namely, a Consultant had.

Friedberg [24, p.1013] wrote:

Assuming free and fully informed consent, it is well to reaffirm the individual's right to pursue happiness through brain damage if he or she so chooses. But we might ask ourselves whether we, as doctors sworn to the Hippocratic Oath, should be offering it. Consultants are perhaps utilising the current UK's working version of the Hippocratic Oath [24] in different ways to either decide to give or not give ECT. Some doctors utilise the evidence base and experience to offer ECT thinking it is in keeping with the Hippocratic Oath. Whereas others, who utilise the evidence base and previous experience, conclude that ECT is harmful and follow the Hippocratic Oath by not offering ECT. Indeed the General Medical Council's [24] guidance states that Doctors "must use your judgement in applying the principles to the various situations you will face as a doctor".

The findings highlighted that the participants often decided to give ECT because they rationalised that ECT would make the person "better" and therefore "recover" from their "episode of illness". In 2008, Pilgrim [25] stated that the concept of 'recovery' was central to hopes for progress in mental health policy. Indeed in 2011, the government's mental health strategy for England was published with one of six main objectives being that "more people with mental health problems will recover" [26, p.6]. In 2014, a government mental health strategy was to ensure "high-quality mental health services with an emphasis on recovery" [27, p.10]. Recovery is said to a "poly-variant" concept with understandings offered from biomedical, social and disenfranchised service user led group perspectives [25]. Within Western societies recovery is crudely suggested to be interventions that result in a meaningful life that includes factors such as hope, personal choice, self-determination, links with social networks and flexible resources rather than purely medical approaches [28]. There are, however, service user led groups that are critical of recovery centred approaches arguing, amongst other reasons, they are used as a way to discharge people prematurely from an underfunded and over-subscribed NHS [29]. Such groups argue for the concept of

"unrecovery" which politically stipulates that those in caring roles should not just pay attention to the individual distress of a person but also the problems that exist in wider society [30]. Other service user groups argue that recovery is reclaiming control over life and finding value and satisfaction with the world [31]. In this sense, recovery can be seen as both an individual and social process [32]. What is apparent from the understandings of recovery and "un-recovery" from the service user perspective is that a person's own meaning and understanding of (un)recovery is crucial.

ECT is, however, a dominantly biomedical approach. Indeed, some participants in the study said that the decision to give ECT was a wholly medical decision that did not need to include non-medics. From the findings, participants suggested that this biological recovery is an increase in mood from the result of excitation of the nervous system and a reduction in the risk of dying from not eating or drinking. The biomedical approach to recovery has been said to offer value in containing some people's distress; however, long term rates of recovery are disputed [33]. This is especially when considering social recovery; the ability to lead full and contributing lives as active citizens [34]. Read, Haslam, Sayce, and Davies [35] furthermore suggested that biomedical approaches may also take away control and initiative from a person therefore counteracting ideas of recovery and, inadvertently, increasing social exclusion.

For those that do not understand their (un)recovery within a biological framework, this prescribed idea of recovery may not be one that they identify with. Unless a patient understands their recovery from a biomedical approach, a personal meaning of recovery from the other stances on recovery is not offered from ECT alone. This perhaps suggests an argument that if ECT is going to be used then an understanding from other approaches (e.g. social approaches) may need to be taken into consideration alongside ECT too.

In the current study, participants described how the power was always with the patients to decide if they wanted ECT or not, if they had the capacity. In legal terms, at this point ECT is not being considered as a mental health treatment that can be given without consent under the MHA (2007). Patients with capacity are able to decide if ECT fitted into their own ideas of recovery or not under the MCA (2005). As soon as capacity is lost, however, then the autonomy to make their decision is lost and ECT can be given under the MHA (2007) as a "treatment" for a "mental disorder". Considerations are then no longer allowed for personal understandings of recovery. That is unless, the person has an advance directive; which no one in the current study had ever experienced. If there is an advance directive in place then the patient's decision is respected until their mental health deteriorates to a point where they are at risk of death. When there is a risk of death the MHA (2007) means that Consultant Psychiatrists become responsible for keeping the person alive.

This responsibility for keeping someone alive: someone who is deemed not to be able to make rational decisions because they are said to have a mental disorder clouding their judgement, seemed to bring with it a culture of fear. Many of the participants spoke about the fear of judgement and blaming and specifically named the traumatic nature of attending coroner's court. This fear of judgement and blame and the onus on one person being legally responsible for the patient seemed to lead the Consultants described in this study to make more individualistic decisions. The Consultants were, at times, said to rely on their model of decision making as opposed to incorporating other people's in the overall decision too.

Limitations

The sample was biased towards people who often did decide to give ECT and so there is missing data about how people came to the stance that they would never give ECT. The model is, however, still valid in that these views would likely be shaped by their personal and

professional identity and through their own interpretations of their experiences and the evidence base.

The study had a small sample size due to practicalities of recruiting and there were no service users or carers in the sample. The lack of service users and carers will be discussed further in the critical appraisal. This is a qualitative study with a relatively small sample and so the findings cannot be widely generalised. The study does, however, offer a useful insight into the layers of the decision making process that could be further considered in clinical settings.

Future Research

Future research should look to explore the decision making process from the view of the patient and the carers involved in the process. This research would help build on the current model to show how the professional's decision making impacts on the patients. It will also show if patients and carers agreed with the current models suggestion that advocating, reassuring/ persuading and informing occur and how they influence a patient's decision making.

Given that this was the first study looking to explore the decision making process involved in ECT it looked to cover all aspects of the decision making process. This was so a model that captured all possibilities in ECT decision making could be built. The data collected highlighted that this was a complex decision making process which appeared to have related but distinct processes for if a patient had capacity compared to if they were deemed not to, or if the patient was detained under the MHA versus informal. The processes for each of those categories should be further explored.

<div align="center">**Conclusion**</div>

The findings of the study enabled a model of decision making in regards to ECT to be developed. The model highlights that the decision to give ECT includes many different

layers including professional identity, how a person understands the evidence base, past

experiences and the amount of power they have in the process. The Consultant Psychiatrist

and the patient were seen as holding most power in the process depending on whether the

Mental Capacity Act (2005) or Mental Health Act (2007) was being followed. Patients were

seen to experience a very different decision making process dependant on the professionals

involved in their care and especially depending on the Consultant Psychiatrist involved in

their care. Future research should look to extend the model to understand the decision

making process from the perspective of the patient and families.

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Table 1
Demographic information of participants*

Name	Age	Ethnicity	Job Role	Gender
Participant (P) 1	35	-	Clinical Psychologist (older adults)	Female
P2	54	White British	Specialist ECT nurse practitioner	Female
P3	50	White British	Team Manager (acute mental health ward)	Male
P4	-	-	Consultant Psychiatrist (acute mental health ward)	Male
P5	24	White British	Deputy Ward Manager (acute mental health ward)	Female
P6	42	Indian	Locum Consultant Psychiatrist (acute mental health ward)	Male
P7	51	White British	Lead ECT nurse	Male
P8	35	White British	Support time recovery worker (community mental health)	Male
P9	29	White British	Clinical Psychologist (acute mental health ward)	Female
P10	-	White British	Advanced Practitioner (acute mental health ward)	Male

*It was also intended to ask about reason for referral, mental health act status at time of ECT and number of ECT treatments however as these were not applicable for any of the recruited participants they have not been added to the table.

Where data is missing this is either because the data was not provided by the participant or as a safeguard to protect anonymity

Figure 1

Recruitment and sampling strategy

| Recruitment | | Sampling |

Email clinical leads of inpatient care from recruiting trusts (psychologists and consultant psychiatrists). Email to CMHTs in two trusts. Present at those interested

Clinical leads forwarded email on to all consultants in their team.

Consultants forwarded onto ward managers

Meet with all ECT clinics with the recruiting trusts. Clinics to advertise study and give PIS to patients and carers.

Advertise study via social media platforms

Participants expressed interest in the study

Confirm interest after participant reviewed the participant information sheet

Sample participants and purposively recruit

All participants invited to interview

Interview

Analyse

Note. Red line depicts the planned sampling method and the blue arrows depict the actual sampling method.

Figure 2

The process of analysis

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                                    ┌──────────────────────┐
                   ┌───────────────→│ Interview            │──────────┐
                   │                └──────────────────────┘          │
                   │                           │                      ↓
                   │                           ↓          ┌──────────────────────┐
                   │                ┌──────────────────────┐         │ Memos and            │
┌──────────────────────┐           │ Transcribe interview │         │ reflective diary     │
│ Interview topic guide │          └──────────────────────┘         └──────────────────────┘
│ revised based on     │                      │                              │
│ category             │                      ↓                              │
│ development          │           ┌──────────────────────┐                  │
└──────────────────────┘          │ Initial coding       │                  │
                   │                └──────────────────────┘                  │
                   │                           │                             │
                   │                           ↓                             ↓
                   │                ┌──────────────────────────────┐
                   └───────────────│ Focused codes and            │
                                    │ category development,        │
                                    │ constant comparisons         │
                                    └──────────────────────────────┘
```
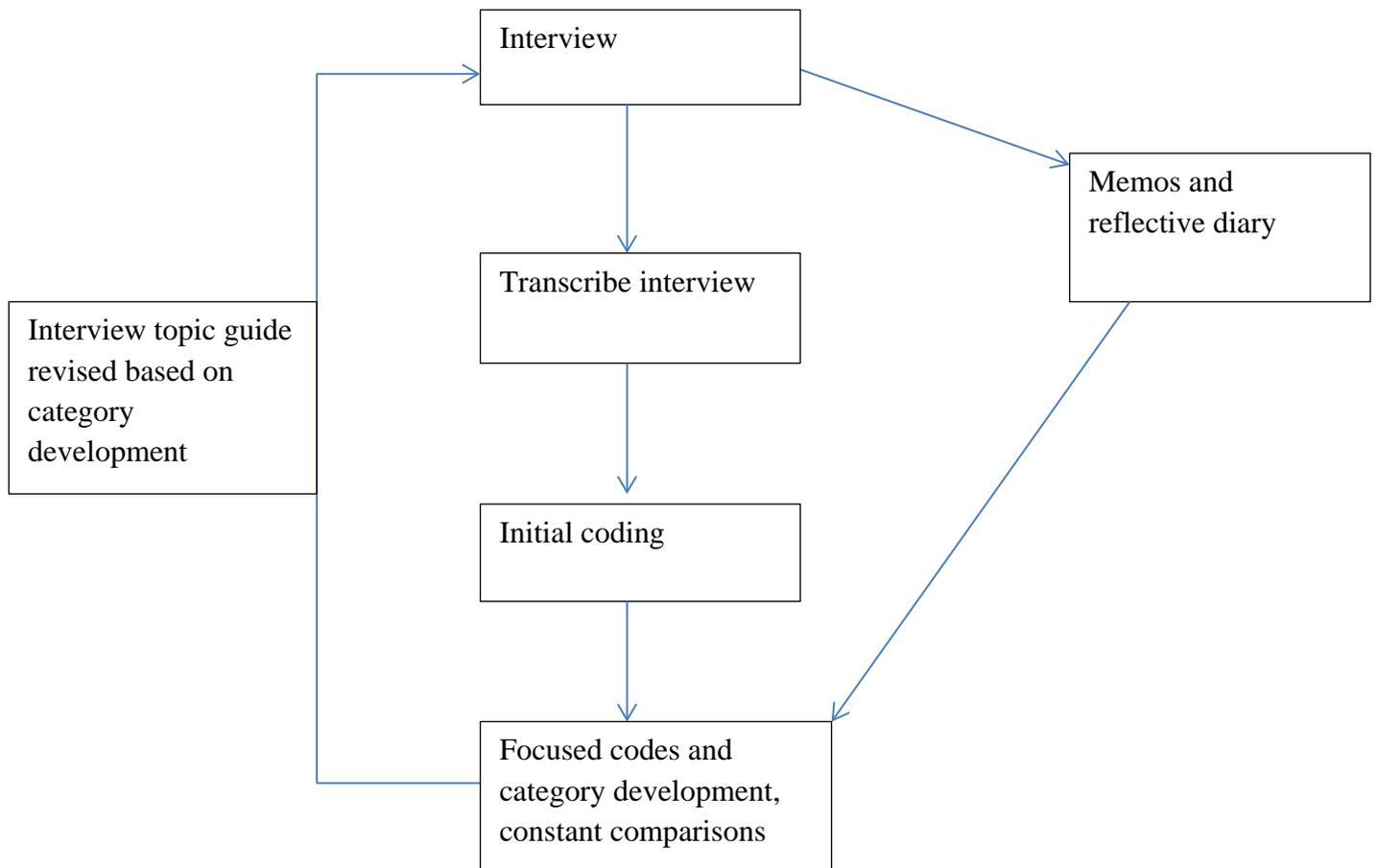
Figure 3

The grounded theory informed model of decision making in ECT
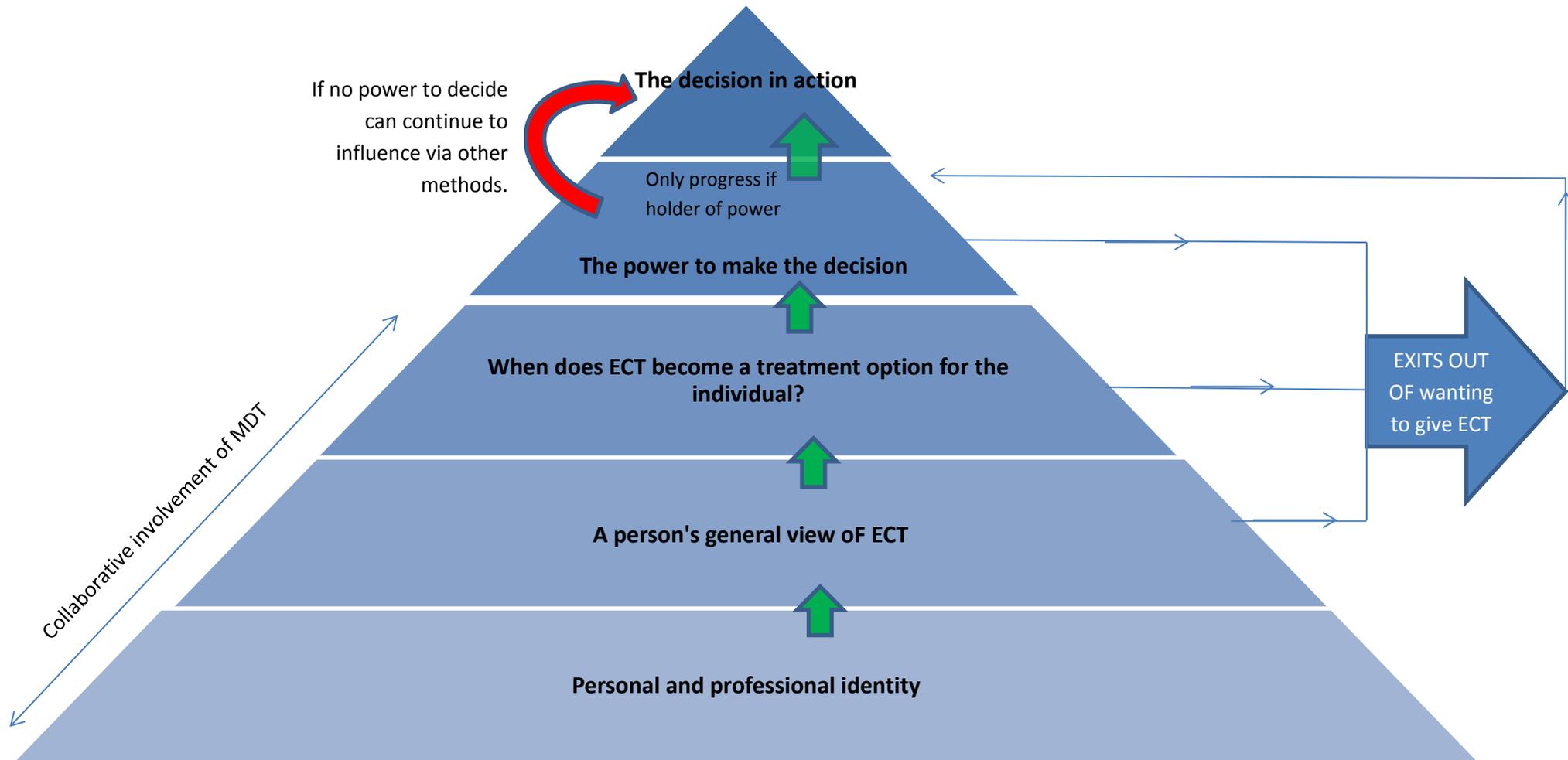
Figure 4

The grounded theory informed model of decision making in ECT using P3's experiences

Advocate: "So I have already booked another professionals meetings… then we will hopefully say well actually no we are not going to give her ECT. And I can then look at the correct pathways for her.

"It's a team meeting but the final decision the consultant still believe that they are the one or this consultant does and this consultant still believes that the book stops with him"

The decision in action

Not holder of power

The power to make the decision

e.g EXIT- not holder of power

When does ECT become a treatment option for an individual?

""based on her presentation 6 months ago she might have warranted ECT but based on her presentation now she doesn't"

e.g. Exit out of wanting to give ECT

A person's general view on ECT

"it might be they [patient] need that bit of a boost bit of a jolt so to speak erm that they need the ECT"

Personal and professional identity

Appendix 2-A

Author's notes for *Social Psychiatry and Psychiatric Epidemiology*

For full version of authors note see:

http://www.springer.com/medicine/psychiatry/journal/127?detailsPage=pltci_1890267

For ease of reading the following notes are of importance:

- Papers must be written in English.

- Accepted article types: Original Papers, Reviews, Invited Reviews, Brief Reports, Editorials, Commentaries (invited), Correspondence articles and Study Protocols and Samples.

- Original Papers or Reviews must not exceed 4,500 words, not including references, plus 5 tables or figures. An abstract (150 to 250 words) and 4-6 keywords are required (please see also section 'title page').

- Submissions for Study Protocols and Samples are welcome which describe the rationale, the design, procedures, and sample characteristics of large epidemiological studies in the context of existing research. Papers must not exceed 4,500 words. An abstract (150 to 250 words) and 4-6 keywords are required.

- Brief Reports should not contain more than 1,500 words plus 1 figure or table. Please submit a short abstract of max. 100 words and 4-6 keywords.

- Editorials and Correspondence articles will be considered for publication; they should not contain more than 1,500 words.

- Commentaries should not contain more than 10,000 characters and less than 10 references. Please do not include an abstract or keywords

- Exceptions to the word limits can be made only with the agreement of the Editor-in-Chief.

- Authors are required to state the word count of their paper when submitting the manuscript

Text Formatting

Manuscripts should be submitted in Word.

- Use a normal, plain font (e.g., 10-point Times Roman) for text.

- Use italics for emphasis.

- Use the automatic page numbering function to number the pages.

- Do not use field functions.

- Use tab stops or other commands for indents, not the space bar.

- Use the table function, not spreadsheets, to make tables.

- Use the equation editor or MathType for equations.

- Save your file in docx format (Word 2007 or higher) or doc format (older Word versions).

Citation

- Reference citations in the text should be identified by numbers in square brackets.

  Some examples:

- 1. Negotiation research spans many disciplines [3].

- 2. This result was later contradicted by Becker and Seligman [5].

- 3. This effect has been widely studied [1-3, 7].

Reference list

- The list of references should only include works that are cited in the text and that have been published or accepted for publication. Personal communications and unpublished works should only be mentioned in the text. Do not use footnotes or endnotes as a substitute for a reference list.

- The entries in the list should be numbered consecutively.

Appendix 2-B

Example of Memo written after Interview with P1

P1

This was my first ever grounded theory interview and so I felt a little hesitant and also unsure as to if I was asking the right questions about "the process". I found myself really thinking about what question to ask next and was unable to actively listen as much as I normally would in these sorts of interviews. It is perhaps interesting to note that my first interview is with a clinical psychologist and so that is perhaps providing some safety or certainty for me.

I am struck by the participants uncertainty on the topic they are very keen to keep pointing out that they do not have that much experience in this area in general, that they are new to the team that everything is "just their opinion". Is this just a reflection of this persons experience of Clinical Psychology's involvement in ECT decision making or is this an experience that many clinical psychologists have? It would be interesting to interview more clinical psychologists and get their view on this.

The participant is clearly feeling a sense of unfairness for the service user that she is talking about. There is an underlying feel or coercion and overpowering yet this seems to be in the context of in the "best interest of the client". There is a clear sense that the nursing team really do think this is in the best interest, but that the participant maybe isn't quite as on board. There seems to be a drive to reassure the patient to agree with the decision to have ECT? I need to find out more about the reassurance and what drives that need to convince a patient to their point of view? The participant's view does not appear to be as influential to the process as other voices.

The participant feels a real sense of following the guidance and making sure medication is tried first. Evidence doesn't say give ECT first. She feels a real sense of unfairness that just because the ECT was tried in the past it should be tried again. There is a strong sense that ECT, although she thinks in some circumstances is OK to use, should be a last resort. She personally deems the side effects of ECT to be worse than those of medication. Although she does say "if the person wants it and can weigh up the pros and cons great, give it them." Patient autonomy choice over guidance?

The participant would really like staff to have extra psychologically informed training; this would hopefully provide them with other options than just having to rely on ECT. A sense that the ward she is talking about doesn't have a good enough understanding of "functional" diagnosis because it is a ward that primarily cares for people with organic disorders. They therefore do not know what other interventions there are in mental health. Is this just to the setting of this ward or is this a more general theme across different ward specialities?

Participant talks about the older patients just going along with what the doctor says because they trust the doctor's opinion and would never challenge it. How do doctors see this? Do they think about the notion of compliancy? How does this fit in with the idea of autonomy and mental capacity act?

Appendix 2-C
Transcript extract with coding (P1)

Data	Initial Code	Focused Code	Category Code
Participant (P):…in those ECT discussions when he refused it erm and you know again she was encouraging him to have it really because she just wanted him to get better I think and that is very much how it was packaged in my opinion. Researcher (R): You know when you said you had this plan, there was this kind of formulation to say you know it might take a little bit longer with this guy. These are the reasons why people can't sit with that and that people just need to get people better. Like, would that be your experience here? P: Yeah definitely. That would be my experience throughout my career and I have, I've seen people have it and be well and you know seen that myself erm before I did training I was a social worker, I worked in the community and I saw that then, more than once erm what I also saw was that it wasn't long lasting change a lot of the time erm and I am not blanket against ECT but with that particular patient on the ward I just felt like there was more that could have been done. And like what you were saying it was going to be hard work and it was going to be slow but there was work that we could be doing. I didn't feel the risks were high enough really to offer ECT. R: What risk would you be like, would you be	ECT packaged as a way to get better. ECT effects are short lived	Reassurance that ECT will make a person better Knowledge of effectiveness of ECT from experience	Decision in Action Stance on ECT

looking for then? P: I think for me, erm when so they talk about catatonic, catatonia, catatonic state erm which again is just a label but I think again for me when I have seen it work or be beneficial or when the risks are things like someone is so low they are not eating, they are not drinking, that level of depression honestly reduced cognitive functioning, when someone is just erm on the floor really for me that is the time when it should be used although you know I'm not great fan of ECT but I think that is it's place. Not, as with this case with this person, they're getting up, they're getting dressed, they're probably not depressed in the you know diagnostic sense but there is something about them that means they are not getting better and it is a psychological issue that's not what it [ECT] is for. R: And did the team discuss in those meetings what they hoped ECT would achieve? P: I think they hoped that it would kind of you know lift his motivation erm lift his motivation to engage basically and I think a lot of it was driven by fear of risk and I guess seeing that now, now that he has come back after another serious suicide attempt people are scared. I mean they are now talking about residential care now for this person and you know again I don't think he's there, I don't think that's what he needs erm but that is driven by fear of risk and he's very impulsive both suicidal attempts have been impulsive and so. R: So there is a fear that he will kind of go and I don't know take his own life or something like that	Not all options being considered. Risk should be high to give it Catatonia reason to give ECT Not eating, not drinking, reduced cognitive function ECT has a place in extreme presentations ECT not for psychological issue Team hoped ECT	Options/ alternatives to ECT High risk only Presentation that warrants ECT Presentation that warrants ECT Extreme presentations Psychological issues vs medical issues	Weighing up individual factors When do you start weighing up decision Individual factors Individual factors when do you start weighing up decision. Individual factors

and that is driving the need for him to get better. If he was like to do that, they they hadn't given him ECT and he was then to go and to that. What would be the consequences for those clinicians? Like is there something about that that drives it that there is a fear of… P: I think that there is something more generally about the consequences for clinicians of a suicide definitely. Whether, I don't think there would be any questions asked about not considering ECT I might be wrong about that erm obviously there are questions asked about that when someone dies, what treatment has been tried erm but I think again, I'm not you know I'm not sure whether it will be glaringly obvious that ECT should have been tried erm but it is something that psychiatrists have in their armoury isn't it?	would increase motivation Driven by fear of patient risk to self Fear of impulsive suicide Consequences for clinicians RE suicide ECT is in armoury of psychiatrist	What ECT does Fear Fear Fear	Weighing up individual factors Who has the power?

Section Three: Critical Appraisal

A critical appraisal of the research process

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I have been keeping a blog throughout the research process and it may be useful to read that blog (contained in Appendix 3-A) before reading this critical appraisal to give context to the thoughts discussed below. I began writing the blog because it became increasingly apparent during the thesis process that I was researching a controversial area, which was continuously pulling me in opposing ethical directions. I wanted to be able to reflect and critique the position I was taking in relation to my research. I had never written a blog prior to this research and was surprised by the positive experience I had from writing it. People who read the blog commented and emailed me with their reflections and questions. It allowed for live informal conversations of the issues with people who had experienced Electroconvulsive Therapy (ECT) in many different capacities. Blogs are generally much more accessible than academic papers, and provide a way to bring empirical research much more into the public sphere (McMahon, 2015). It opened my eyes to a new world of information and a potential new way for me to be conducting research with a wealth of personal testimonies that offer insight into life experiences.

I have struggled throughout the Doctorate with trying to fit into a space I perceived to be one of academic intellect, holding knowledge and expertise, with output placed behind a pay wall that others are often not privileged to have. Social media seems to reduce some of that constructed power and gives greater space for people's voices in sharing their own lived knowledge and expertise. A recent briefing paper from Psychologist Against Austerity (PAA) highlighted the importance of clinical psychologists considering how the information they wish to share can be targeted to avoid being missed or ignored by the public (PAA, 2015); dissemination through the media seems to be an effective and feasible way to do this. Indeed, there are highly regarded clinical psychologists who currently disseminate and share their ideas via social media (e.g. Kinderman). In keeping with accessibility and inclusivity, blogs are usually written in a style authentic to the author, not one that has been dictated by

journal expectations. Accordingly, I have chosen to write this critical appraisal in the style that I would my blog posts.

I will first summarise my research before discussing my epistemological position in relation to the research process and how it influenced my choice of methodology. I will then review the limitations of the research, specifically focusing on the challenges of involving expert by experience (EbE) consultants and recruiting service users and family to the research. I will conclude by linking my two research papers together by discussing the role of advance directives in ECT, before offering some final reflections on the research process.

Summary of Research

My thesis consists of three papers (the third being this critical appraisal). The first paper was a meta-ethnography which explored people's experience and understanding of advance directives in physical health care. Four themes emerged from this paper: 'hope and fears for the family'; 'the trust between the participant and the doctor'; 'the communication of advance directives by health care staff' and 'hope and fears for the individual's future. These themes highlighted the issues that needed to be taken into consideration to initiate and maintain the process of someone writing an advance directive.

The second paper was the empirical paper which used a grounded theory informed methodology (Charmaz, 2006) with ten participants to explore the decision making process of deciding if someone has ECT or not. The participants were all mental health professionals with experience of making a decision to give someone ECT or not. Originally, I had planned to include service users and carers who had been involved in the decision making process however recruitment was not successful. The ten participants were interviewed in order to develop a model that explained how this process occurred in clinical practice.

My Epistemological Position

Articulating how I understand what reality is and how I can know what reality is, is a very useful starting point in exploring epistemology, and has been one of the most difficult parts of this research project. I know what I think, but finding the language to share my stance with someone else has been a challenge. I have looked to previous philosophical work for examples; however, there is no book, article or blog post that I have read on ontology or epistemology where I have not had to research the meaning of words. I experienced that language as inaccessible and excluding. I can only write this in words I have access to, understand and can connect with. If I tell you I am a critical realist, which my reading would suggest that I am aligned to (Bhaskar, 2016) then you will have your own assumptions and meaning to that definition; maybe it will take you further away from the 'truth' of how I see the world.

There is a 'truth' in how I see the world; language just takes you away from that truth. That is the reasoning I used throughout this research. There was a decision making process about whether to give ECT or not to uncover; a truth so to speak. The process happened; everyone that I interviewed went through a process of decision-making, however, each one of the participants had different meanings, influences and values that guided it. That is what I was interested in discovering. I also had my own meaning, influences and values as a researcher that I brought to the interviews. I was not a neutral bystander; I was very much active in negotiating the direction of the interview. What developed, therefore, was an understanding of the process constructed and grounded mainly by the participants but also with the influence of myself. I believe had another researcher conducted the research there would be similar findings. The actual decision making happened, so there was a truth to be discovered, but how that truth is found will be constructed differently for each researcher.

Using Grounded Theory Methodology

My epistemological position, in addition to my research question, seemed to lend itself to a grounded theory informed methodology. I decided to use Charmaz's (2006) version of grounded theory to inform my methodology. Charmaz (2006) specifically discussed the concept of "process" cited as "consisting of unfolding temporal sequences that may have identifiable markers with clear beginnings and endings and benchmarks in between" (p.10). She stated that even the most regimented processes "contain surprises" that can be uncovered (Charmaz, 2006, p.10). This seemed very appropriate for my research question which was looking specifically at a process that occurred within rigid systems, particularly when acknowledging the active role of the researcher in the interviewing process (Charmaz, 2006). I was keen to be able to do this because such a controversial and emotive topic was never going to allow for me to stay separate from the data. Charmaz (2006) also questioned and examined the role of power in the interview process. I was aware that power was going to be an important influencing factor in the interviews.

When designing the research I thought that this would be most apparent when interviewing potentially disempowered participants i.e. the service users. My experience, however, was that there appeared to be a slight distrust of my research from participants in relatively 'powerful' positions within their organisation context. It highlighted how even people who are powerful in other contexts can become disempowered when they are a participant in a research study. I found myself having to repeatedly clarify the aims of the research and how my findings would be used. I felt a real sense of distrust from some participants at the start of the process that my thesis was aiming to support "anti ECT" research and at times I felt like they were trying to 'sell' ECT to me.

It has been said that sociological analyses are more inclined to problematize services, as opposed to psychiatry that emphasise the inherently beneficent role of services (Pilgrim &

Rodgers, 2005) and this, perhaps, explains the worries of some of the participants. I tried to overcome this by being open about possible criticism of both the research and the method (Bravo-Moreno, 2003) and giving participants the opportunity and time to discuss their objections (Brinkmann & Kvale, 2005).

Expert by Experience Involvement

The term 'experts by experience' (EbE) emphasises the value that individuals with experiential knowledge are able to bring to the research process. It was very important for me to be able to work alongside EbE on this project. The experiential knowledge of living with a condition is said to provide relevance and credibility to a research project (Thompson et al., 2009). At the start of the project my thesis supervisor invited EbE involvement via the social media platform Twitter. This resulted in two self-identified EbE being involved in the research process. The EbE decided the extent of their involvement in the process. It was agreed that their participation would be flexible, offering as much as they felt they could whilst ensuring that they would collaborate at every stage of the process.

On reflection, when I am collaborating with EbE in the future, there are a few things I will do differently. I think first and foremost, the issue I did not account for was the time it took to arrange telephone meetings and draft reads. In hindsight, a simple timetable of a telephone meeting on a certain day at a certain time each month would have worked better than trying to arrange it as we went along. This would have kept communication consistent and people much more involved in every detail of the project. As it stands, I think a lot of the decisions about the project were made by me and my supervisors. My expectation that the EbE would be able to read my drafts in the same time frame as my supervisors was also something that I should have considered more. There were occasions where I would send over a draft of a document and want it back within a couple of days in order to reach a deadline. Communication with the EbE concluded that they felt happy and included in the

project, however, for EbE consultation to be considered meaningfully, trainee's need to be

flexible with how they work and mindful that more time needs to be afforded to certain

periods of the project.

Project timelines and the sharing of power between researchers and EbE have been

said to create difficulties within research teams (Gradinger et al., 2013). I am also mindful,

however, that the constrictions of the thesis framework meant that deadlines were often tight.

Furthermore, the EbE were the only people in the research team that volunteered their time

and so had to fit draft reads and meeting times around their own day to day lives. Perhaps if

there was funding available for EbE participation, their involvement would feel more

meaningful.

Recruitment

The initial idea of this research was generated after reading the ECT Minimum dataset

(Royal College of Psychiatrists, 2014) which showed that 84% of people detained against

their will did not consent to the treatment. As people who are detained and have capacity are

allowed by Law (Mental Health Act, 2007) to refuse the treatment (unless it is deemed as

life-saving and the decline is over-ruled by two psychiatrists) this must mean that those 84%

were deemed not to have capacity and were given the treatment against their will. These

were the voices that needed to be heard, in order to see if there were any improvements for

clinical practice in this area to be made.

I proposed to ethics that I would recruit people who potentially did not have the

capacity, so long as they wanted to take part and their responsible clinician consented on their

behalf. The specialist ethics committee (that approved research studies wishing to recruit

adults deemed not to have capacity) explicitly told me that I was not permitted to recruit such

individuals. Their belief was that the study could recruit adults who did have capacity and

had been through the ECT process; therefore there was no need to recruit those that did not.

Their rationale was that potential harm could happen to people taking part that did not have capacity. Indeed, there is a notion that research "needs to protect vulnerable participant groups" (British Psychological Society, 2010; Iacono & Murray, 2003, p.49).

The research, which was originally commenced to aid clinical practice with people who did not have the capacity to consent to ECT, was therefore excluding them at the very first stage of the process in order to not cause 'harm'. Whilst I would of course advocate that research should not cause harm to participants, I do not assume that harm will be automatically caused to potentially 'vulnerable' adults by taking part in research and that a blanket rule should therefore be applied. For me, it makes more sense that being involved in research makes people less vulnerable to harm from the potential results of research that only includes the voices of those people who are consistently more powerful than them.

The research progressed with me simply being able to recruit service users and family that were deemed to have capacity to participate; however, I completely underestimated how difficult this would be. Professionals still seemed to act as gatekeepers to people they felt were and were not able to participate. Every service I went to suggested that one person would be potentially able to take part whereas another was not. It was very difficult to get past this 'unofficial' gatekeeping. I therefore tried to widen my search by posting on social media sites; however, this too was to no avail. My amendment for recruitment via social media was granted in March 2016 when I had one study day a week to recruit, interview and analyse my data. I am confident that that my success at recruiting participants through this means was not as high as they could have been had I started off with this strategy when I had more dedicated research hours. In future research, I will focus on considering all possible avenues of recruitment at the outset of the process to make sure recruitment is as effective as possible.

Advance Directives

I chose to conduct my systematic literature review on advance directives in the context of physical health as I thought it would offer me insights into how they can best be used in ECT decision making. Under the Mental Health Act (MHA) (2007) ECT is the only mental health treatment for which a person can write an advance directive (under the Mental Capacity Act, MCA, [2005]) to refuse future treatment for a time when they do not have capacity to make the decision. This only stands, however, if the person is deemed to not be in a life threatening situation or that their mental health will not deteriorate severely if they were not to have the treatment (MHA, 2007). There is, therefore, a complex interplay between the promotion of autonomy through the MCA and the potentially overriding paternalism of the MHA.

The participants in the empirical study only talked about advance directives when I prompted them; explicitly asking about the role of advance directives in ECT. Many of the participants had never encountered an advance directive and furthermore did not see a role for them. This was mainly due to the fact that the MHA would overrule the advance directives in the life threatening situations they felt ECT was currently, in the vast majority of times, being given for. Participants valued saving a person's life over their autonomy to refuse the treatment, as demonstrated by the quote below:

> I can't see how it (advance directive) would help us because if I felt somebody was at risk and we were running out of options then I would be saying we need to be doing this ECT, and we have been in positions where we have said "that needs to be done today, book it in and have it done emergency ECT rather than planned", so we have done that because of the risks and if someone stuck an advanced directive in amongst it I'd be pulling my hair out. (Participant 3)

Participants felt they had to save the life of a person because the responsibility was legally

(MHA. 2007) left with them to keep the person alive.

> I personally struggle between a system where you have the autonomy to make an
>
> advanced directive but the responsibility [of dying] does not lie with you. So, if you
>
> have an advanced directive…and your instruction in the advanced directive is that
>
> someone will not call 999, but the person [with you and doesn't ring 999 even though
>
> you are dying] could be prosecuted for not calling. So how does that work? It works
>
> well in countries or in systems where either the law is not involved at all so you don't
>
> have that legal responsibility or the legal responsibility decision lies with the
>
> individual. (Participant 4)

There was a consistent view from the participants that at the point where a person no longer

had the capacity to consent to the procedure, was the point where their life was in danger and

in these situations autonomy had to be overruled for the sake of saving a life. There was not

only fear of blame and judgement of the death, but also a moral stance that life was sacred

and always worth preserving in these situations.

The findings suggested that an advance directive, stating ECT should not be used if

the person was deemed not to have capacity to make the decision, was not needed.

According to the findings, in the vast majority of situations where ECT was being considered,

life was always threatened and, therefore, the advance directive would be overruled. For me

this raises an interesting question about how 'life threatening' is conceptualised. The

participants described a simple system whereby a person either has capacity or not and that

usually, by the time the person does not have capacity, there is too much 'risk' to life to not

give ECT. To me, this simplistic view mirrors the simplistic decision making that is taking

place on the ground and ignores the complexity of autonomous and paternalistic practice.

For me an interesting comparison to make between the literature review on physical health care and the opinions in regards to advance directives in a mental health setting, was the reasoning and acceptance of the concept 'right to die'. The literature review highlighted that patients in physical health settings want to have a personally measured and acceptable quality of life in end of life care and, in addition, reduce the burden on their loved ones. This idea, in the main, seems to be understood and accepted by health care professionals and is a valid reason to make an advance directive about future care, even if that involved refusing life sustaining treatment. These ideas are not mirrored in mental health settings.

The literature review's findings highlighted that in order to make an advance directive, people must trust their clinician to understand and respect their personal values, and that the health care professionals communicate and support a person to make an advance directive. It is not surprising then that from the evidence given by participants in the empirical paper, people do not make advance directives in regards to ECT. Mental health professionals were not promoting the use of advance directives in ECT nor did they value their use. I have been unable to find research that investigates how many advance directives have been written in regards to ECT, when they are completed, and what proportion are overruled. This is potentially an interesting quantitative study for future research.

There is a clear contradiction with ECT being cited in both the MCA (2005) and MHA (2007). We either need to empower people to make a fully informed decision when they have capacity about future treatment in regards to ECT and accept that this may result in death, or stop giving people false hope of autonomy only to then take that autonomy away.

Final Reflections

I undertook this research because I am interested in the interplay of psychiatry and clinical psychology. ECT is arguably one of the most controversial treatments in a psychiatrists' tool box (Read & Bentall, 2010) and I was intrigued to see if and how clinical

psychology fits with it. Two years ago, I came at the research from a more or less neutral stand point. Today, I am struggling to pinpoint where I am.

In relation to my epistemological stance, I believe that we cannot explain everything in terms of what we mean by psychological distress. Whilst I believe that mental health difficulties are caused, in part, by societal factors, for me there is something individualistic about that distress. The distress needs to be intervened with on both a societal level and an individual level. I do not want to label this distress as an illness because I think the word "illness" has too many negative connotations and personal meanings attached to it which I certainly do not agree with. In line with my epistemological position I believe the word "illness" will take you away from the truth of what I think psychological distress is.

For me, people need individual support measures and there is a wide spectrum of individual intensity of what those support measures potentially could be. I would argue, however, for a person to be autonomous in deciding what that individual intervention is. I wish that people's level of need did not get to a stage whereby they cannot eat or drink and I am ashamed that as a society we let this happen. On the one hand, I think if we continue to resource and research treatments, as indeed this thesis has done, then we are just colluding with a system that says it is OK for someone to be left to become so distressed. Yet on the other, I pragmatically think this is the society we live in and that there are people who are that distressed. If there is a possibility that ECT does 'kick-start' something (and if we are to go off the testimonies from participants in my empirical study then this would be true), then should we not be looking to research how we can do that in the most ethical and inclusive way?

Ultimately, I think I would identify as wanting to be a social practitioner. I have seen time and time again in my relatively short career in mental health, that society causes mental health distress. It is at a societal level that I believe change should occur (Harper, 2016). In

the meantime, however, there are people who are currently living society's oppression and

we cannot just ignore them whilst we work on making society more equal.

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Appendix A

Blog Posts from https://ectresearch.wordpress.com/

Introduction Blog

Hello, my name is Anna and I am third year trainee clinical psychologist at Lancaster University. In August last year one of the clinical tutors at Lancaster University, Ste Weatherhead (@SteWeatherhead), circulated an email to second year Lancaster DClinPsy trainees that highlighted figures from the Electroconvulsive Therapy (ECT) Minimum Data Activity Report (2012/2013). The figures suggested that of the 832 people who received Electroconvulsive Therapy (ECT) whilst detained, 695 were found to lack the capacity to consent to that treatment. Similar figures were found in their most recent 2014-2015 report, albeit less visible and requiring a bit of additional mental arithmetic to work out! Ste stated that the figures suggested to him that clinical practice in the area could be improved so that more people were able to make the decision to have ECT themselves. In order to speak the 'evidence' language of decision-makers, suggesting improvements in clinical practice would need to be underpinned by good research: and so Ste requested if any trainees were interested in conducting their thesis on the subject.

I have previously worked as a research assistant at the Neuroscience and Psychiatry Unit at The University of Manchester were another group of researcher were investigating whether the use of Ketamine would alleviate some of the cognitive difficulties experienced as a side effect of ECT. Being part of the same department I was able to attend CPD events that included presentations on ECT. I was incredibly interested (although I'm not quite sure if "interested" quite covers it- more a contradictory mix of "shocked, curious, concerned, fascinated") in the procedure. The talks suggested such radical improvements in people's mental health but also suggested that improvements were often not long standing and could cause negative effects on cognitive functioning. As I went away and read up further on the

procedure I saw just how polarised people's views on ECT were. Some professionals and service users avidly supported ECT stating it had transformed their lives (see Sherwin Nuland's TED talk), whilst others talked about a barbaric and truly invasive procedure (see the comments section of Sherwin Nuland's TED talk!)

So when Ste suggested the research, I jumped on the opportunity to investigate ECT more: especially because it involved looking at issues of consent. At the time, I felt that I was in a "middle place" in regards to my views on ECT and so I would be able to produce unbiased research in an area filled with polarised views. Now 15 months later from Ste's original request, I am through ethics and have just started recruiting for the study. I have decided to start a blog on my research because, even at this early stage, I am beginning to come across issues that I think I have to reflect on and process in my mind. I remember Ste at the start of the study warning me that this was a controversial area of research that would make me questions my own views and the systems we work in and I guess it wasn't till very recently that I have really started to recognise that fact! I figured it might also be quite interesting for others to read about and offer other opinions while I try to get to grips with this subject.

So my disclaimer for this blog is that my thoughts on ECT are not fully formed; I'm figuring this out as I go along the process! I'm pretty certain that what I write one day, I probably won't agree with the next: I've certainly found this so far on my research journey! I probably should also say that whatever I write on here is not representative of the views of the other people who are involved in supervising and offering consultation to my thesis: this is all based on my own personal experiences of the research. Also apologies for any spelling, grammar mistakes! They are not my forte.

This is my first attempt at a blog- so any comments; suggestions about how/what I post will be gratefully received! Thanks for checking it out and yeah speak soon…….

Trying to understand my position on ECT….

Like I said in my introduction blog, I wanted to write this blog to help me understand and process some of the thoughts I was having in regards to ECT and the research I'm conducting. When I analyse the data that I collect from this study I'll be using Charmaz's grounded theory methodology. This methodology utilises a constructivist epistemology which takes the stance that the beliefs and views of the researcher will influence the model that is finally created. It is important therefore to name those beliefs and views. The problem is I'm not entirely sure what my beliefs and views are. So in line with grounded theory it seems important to write about some of the thoughts going round in my head! This blog is therefore an honest and frank account of those thoughts. Think of it like a diary. If you want to read a blog for references and up to date theory, this probably isn't the blog for you (but you can read my final empirical paper)!

It's fair to say that the journey of my evolving views in regards to ECT has mirrored my journey of understandings towards mental health interventions in general. I started the DClinPsy course in September 2013 with the rather rare experience of having only met one clinical psychologist in my life and with no real understanding of what clinical psychologists actually did beyond "help people to understand and cope with mental health difficulties". You know that imposter feeling that every trainee has? I definitely had it!

What I did have though was a bit of (negative) life experience that I could reflect on at interview. At the Lancaster DClinPsy interview I had to do a presentation entitled "how I have developed the strength and personal maturity to prepare me to be a trainee clinical psychologist". Amongst many other reflections, I talked about my own experiences and how I wanted to use those experiences to help other people to not feel like I had done: to be there to help think though strategies and interventions and to essentially help them get through tough times. I recall reflecting on the fact that because I had my own experiences of mental

health difficulties I would strive not to impose my understandings of "recovery" on the people I was working with. Little did I realise that just in thinking that everyone had the same chance of recovery as me I was doing that very thing I said I wouldn't.

It soon became apparent to me on training that despite going through a pretty difficult time I had been in a privileged position. I had a wealth of support around me; I had an education, I had no money worries, I had never experienced any other form of trauma, I had internal coping skills that I had been taught, I am white, heterosexual, cisgender… the list goes on. For the majority of the people I have worked with, many of these things weren't in place and I soon realised that not having these systemic protective factors was a real barrier to developing change.   I became increasingly frustrated with the idea of 1:1 therapy: the idea that I was meant to be helping someone change individually when they were oppressed in a system of poverty, abuse and inequality.   I guess that's when I started to become more influenced by community psychology ideas. For me the root problems seemed to always lay in society not the individual. I wanted to prevent mental health difficulties instead of just reacting.

I tried to get involved in more community activities; helping organising #walkthetalk2015 and the developments since; marching at demonstrations; attending conferences with community psychology themes etc. My view went from being more individually focused to completely society focused.

My stance on this research therefore changed. If I was starting to disbelief the notion of 1:1 therapy then I was certainly starting to think that ECT was not something that I ever wanted to be associated with. I started getting nervous about what conducting this research would mean. Would people start to think I was agreeing with ECT? Was I somehow part of a colluding process to make ECT more accessible by creating a model of decision making? The clinical psychologists that had inspired my transition to more community psychology

approaches had also published papers that were hugely not in favour of ECT. What would they think about a trainee with a seemingly accepting view of ECT? If I did want to venture down the more community psychology route was this research going to somehow taint how people saw me?

Hesitantly, I carried on with the research. At this point I was ready to start conducting interviews with people about the process of their decision making in regards to ECT. I met with some fantastic professionals: nurses, psychiatrists, psychologists, ward managers. Each and every one of them so incredibly committed to the service users in their care and who all talked about just wanting to relieve some of the distress that the service user was facing. It took me back to my own experiences and it made me realise something: I had somehow lost the individual.

Due to being on a study block, I hadn't been on placement for a couple of months and so I had lost that day to day interaction of working with service users. I had lost the idea that it is an individual that has to cope with the never ending running commentary in their heads about how worthless they are; the never ending thoughts to not be here. It's the individual that has to go through the torment of listening to a voice tell them they are useless; the individual that has to cope with the obsessive rituals, the anxiety, the soul destroying low mood. And it is that individual that presents to clinics or on the wards. It made me forget how incredibly hard it is working in a professional capacity to feel hopeless for someone and the pressure and responsibility we can put on ourselves to help make someone's life better. It made me remember how you want to do everything you can for that person. That you use everything you have in your training tool box to try and help. For some professionals, they have ECT in their toolbox.

So yes of course I still want to tackle the social issues and prevent mental health difficulties but I also want to be there for the individuals that have to try and live with the

distress. Do I think that can be done via ECT? Not without other forms of systemic support/change, no. But in some circumstances alongside that? I'm not sure. Maybe.

Yet, there is a part of me that hates that I have just written that. I have to acknowledge and find out where that comes from. The fact is there are professionals that believe in ECT, more importantly perhaps there are service users that believe in it. If I can help to find a way to make that process as safe and as empowering for the service user as possible then, I don't know, to me that's a useful thing?

I have stated to realise though that because people have such polarised views on ECT it can be really hard to come to my own nuanced opinion on it. Sometimes I feel that as a (trainee) psychologist if I don't take a hard stance that ECT is wrong then I'm going to be judged negatively. It forces you to take a position that you may not have really thought about thoroughly. It can make you attend to only arguments that support that position and miss opposing arguments entirely. I guess this is the point of this blog really. To be transparent about the journey that is going on in my head, and for me not to just regurgitate a position on something because I think it's what people want to hear.

I read somewhere blog posts should be about 600- 900 words?! I've gone over. To be continued…

ECT, Advance Directives and Self-Determination to die.

TW: This blog post talks about themes relating to end of life

As part of my doctorate, in addition to the empirical paper looking at the decision making processes in deciding whether someone has ECT or not, I also have to complete a systematic literature review on a topic area that is related to my empirical paper. I have chosen to look at the use of advance directives in physical health care settings.

Under the Mental Health Act (1983) someone can make an advance directive to say they do not want ECT in the future. This has to be honoured unless two doctors believe that not having the treatment would result in the person dying or deterioration in mental health. Last week in supervision, Ste asked me a tough question: do I think that advance directives should be used for ECT as they are in physical health settings? I.e. Do I think that somebody should be able to say in advance, when they have capacity to make the decision, that they do not want ECT regardless of how they present, and that ultimately they would rather die than have the treatment. I was stumped. I had always thought that my answer to this was "yes, of course I think that!" but it wasn't. (You can read more about this dilemma here from a blog by Ste and @theagentapsley here.)

I used to volunteer as a listener for the Samaritans. Self-determination is fundamental to their ethos. If someone wants to die you do not convince them otherwise, you don't offer advice, you just listen. I did that but it always made me feel uncomfortable. What if me suggesting something, no matter how small, put them on a path that completely changed their view of the world? What if it saved their life? Egotistical that I thought I could do that? Hopeful? Am I paternalistic? Do I think that I know what is better for someone's life then they do? I guess, when it gets to life or death decision making, I am. That doesn't sit well. I've always framed it as hopeful, striving to do all I can for someone, but actually as I write this, it sounds pretty damn paternalistic.

Maybe it's the years of Sunday school telling me that life was sacred. Maybe it's because my own life is worth living and that dying is my greatest fear. Maybe it's because I'm not convinced of an afterlife that will make things better for people. Maybe I just impose all that on others. I talk to people with overwhelmingly distressing lives every day and I know that for some people life isn't worth living, it never has been. But there is that hope inside me that I can change that. I cannot tolerate the feeling that we (as individuals, as a society) have made this life so unbearable for people that they would want to die. I want to do all I can to rectify that.

So when I think of a hypothetical situation of working on a ward with someone that is not eating or drinking that is dying a distressing and painful death, and I know they have an advance directive specifically instructing that that is what they want, could I let it happen? I'm pretty certain my answer is no.

This feels different from say someone refusing to have physical treatment based on religious beliefs or refusing life sustaining treatment as part of end of life care. I just can't succinctly articulate why that is. I think it has something to do with the fact that I assume that person is happy, that they have lived an OK life and that this choice isn't based on the fact that their life isn't worth living but because there are other reasons. If a Jehovah witness told me they didn't want to have a life saving blood transfusion after, I don't know the birth of their child say, then I would respect that. I would feel OK with that. It's not what I would want for me or them but it sits OK. Maybe it's because I couldn't change their mind. There is not that desperate need to change their mind. I wouldn't feel like I had let them down. It suddenly feel so selfish, this is potentially about containing my own distress.

So why do I respect someone's autonomy in a physical health setting but not in the case of ECT in a mental health setting? What is that difference? Is it an inability to contain my own distress? Whatever that difference is I think it needs to be understood because it is

potentially why paternalism exists more in mental health than physical health. It has something to do with me as person: something to do with other individuals that think like this. Something to do with how we all come together and create something like The Mental Health Act. I know not everyone would come to the same (working) conclusion as me. Some would advocate that advance directives should be used the same in ECT as they are in physical health. I'm not sure if it would be "better" to think like that or not. Maybe we need aspects of paternalism. I need to keep thinking…

Section Four: Ethics Section

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Research Protocol

Title: What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.

Chief Investigator (referred to as "researcher in this document): Anna Duxbury

Academic Supervisor: Dr Ian Smith

Field Supervisor: Dr Stephen Weatherhead

Professor Ian Anderson (The University of Manchester)

Introduction

What is Electroconvulsive Therapy?

Electroconvulsive therapy (ECT) is said to be one of the most controversial interventions within mental health services (Read & Bentall, 2010). However, in the United Kingdom, policymakers and many psychiatrists regard ECT as an effective intervention (Singhal, 2011). The National Institute for Health and Care Excellence (NICE) recommends that ECT be used for experiences that are categorised by the International Classification of Diseases 10 as "severe depressive illness, a prolonged or severe episode of mania, or catatonia" (NICE, 2003, p. 3). However, the ECT Minimum Dataset Activity Data Report (Royal College of Psychiatrists, 2013) shows ECT is used for other forms of psychological distress, categorised as "anxiety, mixed affective psychosis, neuroleptic malignant syndrome, peri-natal depression, post-natal depression, persistent delusional disorder, psychosis, schizoaffective disorder –depression, schizoaffective disorder, schizophrenia and schizophrenia-mood disorder".

ECT involves passing an electric current briefly through the brain which induces generalised seizure activity (Royal College of Psychiatrists [RCoP], 2014). Although ECT has been used since the 1930s, there is still no generally accepted theory that explains its purported mechanism of action (RCoP, 2014).

The debate around ECT is often polarised; as highlighted by systematic literature reviews in the areas (see Read & Bentall, 2010; The UK ECT group, 2003; Sienaert, 2011). Read and Bentall's meta-analysis concluded that ECT caused "significant increased risk of death" and that "the cost-benefit analysis for ECT is so poor that its use cannot be scientifically justified" (Read and Bentall, 2010 p. 333). On the other hand, the UK ECT group concluded in favour of ECT, stating it was significantly more effective than 'simulated ECT' and significantly more effective than pharmacotherapy. Furthermore, Sienaert (2011) concluded that ECT is highly effective in the treatment of experiences that may be categorised as 'major depressive disorder'.

ECT Policy and Legislation

The ECT Minimum Dataset Activity Data Report (Royal College of Psychiatrists, 2013) concluded that 84% people who received ECT whilst detained under the Mental Health Act (2009) in 2012-13 did not consent to the treatment at the start of the treatment. Of those who were defined as informal patients, 92% were reported to consent to treatment.

According to The Mental Health Act (2009), if a service user is "capable of understanding the nature, purpose and likely effects of the treatment" then ECT cannot be given without his/her consent. Furthermore, in section 58a the code of practice which "applies to detained patients and to all patients over 18 years of age (whether or not they are detained)" states that ECT cannot be given to a detained patient unless they consent and are deemed to have the capacity to consent

ECT can therefore only be given to a patient who is deemed to not have capacity when an independent, specially approved psychiatrist has authorised it. If a person who is deemed as having capacity refused treatment then the only circumstance in which ECT can still be administered is under section 62 (1A & 1B) of the Mental Health Act (2007).

In addition to the Mental Health Act is the Mental Capacity Act (2005) which provides a statutory framework for decision-making in relation to adults who may lack the capacity to make specific decisions for themselves. The core purpose of the MCA is to empower individuals to make their own decisions wherever possible, as well as protecting vulnerable individuals who lack decision-making capacity   The Mental Capacity Act 2005 specifically includes ECT within it. This was to ensure that there was a safeguard in place for people that lacked capacity to consent to ECT but who were not detained under the Mental Health Act. Under the Mental Capacity Act 2005 a "decision maker" decides that ECT is in the patient's "best interests".

According to NICE guidelines (2003), the process should involve:

> the individual's advocate and/or carer where possible; provides full and appropriate information in a suitable format and language to enable an informed discussion; explains and discusses the general risks of ECT, risks specific to the individual and potential benefits to the individual; does not pressure or coerce the individual into consent to the treatment; reminds the individual that he or she has the right to withdraw consent at any point.

However NICE (2003) guidelines do not detail what would constitute appropriate information, guidance on suitable format or language use; it does not detail what constitutes as coercion or how to ensure the capacity of the patient to make and communicate a decision (Fisher, Johnstone & Williamson, 2011)

The Decision Making Process for ECT

Rose, Wykes, Bindmann and Fleischmann (2005) concluded from their meta-analysis that approximately half of United Kingdom mental health patients felt they had not been given enough information about ECT before consenting to the procedure.   Furthermore,

Fisher, Johnstone and Williamson (2011) also found half of their participants reported not having enough information about ECT before consenting to the treatment. Rose, Wykes, Bindmann and Fleischman (2005) reported that one-third of patients did not feel they had freely consented to ECT treatment. In addition, research has suggested that many patients who received ECT felt it was a "last resort" (Fisher, Johnstone & Williamson, 2011, p. 350). Morrison (2009) also discussed the idea of ECT being a "last resort" in her personal account of receiving ECT. Fisher, Johnstone and Williamson (2011) suggested that the idea of ECT being a "last resort" is further reinforced by NICE (2003) guidance which says ECT should be used should "only in life-threatening situations or when medication and other interventions have failed''. Johnstone (1999) stated that this will impact on patient's ability to consent as they will feel unable to refuse treatment that is seen as their last chance and furthermore will deem there to be no other treatment options.

Fisher, Johnstone and Williamson (2011) concluded that future research should investigate how patients make sense of and prioritise multiple sources of information when deciding whether to have ECT. However, they also stated that such research needed to be sophisticated enough to take into account the "complex interpersonal and systemic context in which patients make this decision" (p, 353). Including the understanding of both professionals and patients involved in the consent process will seek to take into account the interpersonal and systemic context. In addition, Fisher, Johnstone and Williamson (2011) suggested that future research with people who refuse to consent to ECT would provide more insights into the decision making process

There has been little research into ECT that involves staff. Amongst those that have, one study found that there were significant differences in attitudes towards ECT between those in

different job roles (Lutchman, Stevens, Bashir & Orrell, 2001). The study concluded that

there is a need for awareness of differences of opinion towards the treatment in

multidisciplinary teams and that the teams should be aware that there may be strong

differences of opinion amongst members. These differences were said to be likely to affect

the decision making process about ECT. As of yet, no research has investigated staff

members views on the process of ECT.

Relevance to Clinical Psychology

Clinical psychologists work alongside professionals involved in the administration of

ECT and furthermore have recently begun to act as Responsible Clinicians under the UK

Mental Health Act. They will therefore be increasingly involved in decisions to administer

ECT or not (Gillmer & Taylor, 2011). In addition, Fisher (2012) stated that clinical

psychologists "need to be actively involved in consent procedures, use clinical formulation to

understand the perspective of patients, and empower patients to share their views of ECT

with mental health professionals and service developers" (p, 590). Fisher (2012) went on to

recommend that future research should investigate how patients experience ECT, particularly

using qualitative methodologies.

Clinical Psychologists are also often involved in conducting capacity assessments as they are

trained to assess the cognitive abilities underlying judgement and decision-making capacities,

as well as being skilled in formulating the psychological processes influencing capacity, and

identifying mechanisms to enhance decision-making abilities (Walji, Fletcher &

Weatherhead, 2014)

Research Aims

It can be seen from the policy and research highlighted above, that the decision making

process that is taking place on the ground is not just a mechanistic one but one that is

complex and not clear. The data suggests that people are not following best practice guidance

and are not going beyond the minimum that is required of them. It is therefore important for developing clinical care to understand how the decision making process is taking place. The research will specifically ask.

1. What is currently happening on the ground in regards to ECT decision making?

2. How does current ECT decision making fit with the Mental Capacity Act and the Mental Health Act guidance?

3. What do people think need to change in regards to ECT decision making?

This will be done by qualitatively exploring the views of all people who are involved in the process of deciding if ECT is prescribed or not. Grounded Theory will be used to develop understandings as it will allow for the generation of a model. The model will give detailed information regarding examples of how the decisions process is seen to be happening from the perspectives of different stakeholders. This could include psychiatrists, patients, family and any other ward staff involved in the process. The research will ask the question what is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made?

Rationale

Utilising a grounded theory informed approach will allow for the development of a model to explain the process stated in the research aims section. The approach will add to the under researched area of consent in ECT. The study will inform future clinical practice and inform research progression in the area.

Method

Research Design

A qualitative methodology will be utilised for the study. Semi- structured individual interviews will be used to explore the experience of participants in the process of ECT decision making. In accordance with grounded theory principles, the topic guide (Appendix

4-B) will be amended and adapted to capture the inductive nature of the research project at each stage of stage collection (e.g. before each interview).

Participants

The participants will include anyone who has been involved in the process of deciding whether ECT will be used as treatment or not in the past twelve months. This may include consultant psychiatrists, clinical psychologists, patients, family and any other ward staff involved in the process.

Participants will be recruited from one of two NHS Trusts; Lancashire Care Foundation Trust or 5 Boroughs Partnership Foundation Trust. Participants may also be recruited via the social media platforms Twitter and Facebook. Due to limitations of time, face to face interviews will be limited to people who can be interviewed in Cumbria, Lancashire, Greater Manchester, West Yorkshire, Merseyside, Cheshire. This will be stated on the social media adverts (Appendix 4-C). If participants not in those counties still request to take part then a telephone interview will be arranged. If professionals are recruited from social media they will be asked to either complete the research in their own time or get permission from their line manager. The total number of participants will be dependent on "theoretical sufficiency" (Dey, 1999, p. 117). Theoretical sampling means that once existing categories do not require revision or alteration in respect of new data then no new participants need to be recruited.

Inclusion criteria:

- Person has been involved in the decision making process of whether ECT is administered or not.

- Person has been involved in the process of decision making in the past twelve months

- Has capacity to take part in the study.

- Consent to providing certain demographic information about themselves.

- Patients consent to their case managers/care co-ordinators/keyworkers being contacted in regards to any risk issues.

Exclusion Criteria

- Does not meet all the inclusion criteria

- Is under the age of 18.

Purposive sampling will be used to select who takes part in the study. Purposive sampling is when decisions concerning the individuals to be included in the sample are taken by the researcher, based upon a variety of criteria. For this study that may include job role, whether they are a service user, whether they are a family member etc. This will allow the researcher to make decisions about the individual participants who would be most likely to contribute appropriate data, both in terms of relevance and depth.

Demographic Information

A table of demographic information will be included within the research paper to provide context for the sample. This is in line with the Grounded Theory approach.

- Demographic information will be a requirement for taking part in the study and so all participants will need to consent to this within the procedures outlined above.

Demographic information for each individual participant will be collected in order to be incorporated into the analytical process. This will include:

- Role in the process i.e. service user, family or professional role Profession

- Age

- Gender

- Ethnicity

- Reason for referral*

- Mental Health Act Status at time of ECT treatment*

- Number of ECT treatments*

*This information specific to their ECT procedure is being asked because as the current study will have a small sample size this information will help map against the larger sample in the ECT minimum data set (RCoP, 2013)

Setting

Interviews will be mostly undertaken within the NHS trust where the participant has been recruited from. They will be conducted in a space that is private and ensures confidentiality. The researcher will be responsible in making sure they are aware of all policies and procedures and that all procedures are carefully followed. This includes any local policies that are related to risk. The researcher will liaise with the site contacts about all the relevant procedures that need to be followed.   If family members are recruited for the research, then they may wish to be interviewed in their home. For participants recruited via Twitter, the researcher will try to book a room for the interview in a NHS, GP, or University that is local to the participant. If this is not possible then the researcher will arrange to conduct the interview at the participant's home. In these instances, the researcher will adopt the Lancaster University's Lone Worker Guidance (Section 3.5 of the field work guidance). The guidance states that "a safe system of work should then be devised in order, as far as is reasonably practicable, to safeguard the health and safety of the worker as required by Section 2 of the HSW Act and reduce risks from foreseeable hazards to an acceptable level". The following has been devised based on the recommendations of the guidance and the researchers based experience of research in lone working settings:

- Prior to conducting the interview, the researcher will try to find out as much as possible about the characteristics of the people they will be interviewing and their housing and living environments. The area will be reconnoitred first; if this is not possible then a map of the area will be studied to help to evaluate its character - e.g. rural, suburban or inner city, plan car parking and to plan routes for leaving dense housing areas to prevent getting lost.

- Researcher will designate a personal contact that is able to action the lone worker plan. The guidance above notes that this should be the researcher (students) supervisor however, this is not possible in this instance.

- Researcher will make sure this person is aware of i) Who they are going to see ii) Where the visit is taking place iii) What time they will be going to place iv) What time they plan to leave the place v) Contact number. However, to protect anonymity of the participant these details will be kept in a sealed envelope that will be instructed only to be opened if either point 5 in this list occurs or if the researcher rings and uses the safe phrase, "I am going to be late for Bob's appointment".

- Researcher will telephone the designated person before entering the house. They will remind them of how long they plan to be and that the person should expect a call from then.

- Once the visit is over the researcher will call the designator person to say they are save.

- If they do not call, the designator person will ring researcher to see if they are OK.

- The researcher will keep their phone on loud mode throughout the visit so that they will hear this call.

- If no response from that call, designator person will call 999.

- If on the visit a risk arises the researcher will leave the house immediately.

- The researcher's car will be parked facing the route of exit.

Whilst conducting the interview the researcher be aware of cultural norms and appreciate (amongst others) the use of body language, the acceptability or not of body contact and establishing the right social distance.

Procedure

The researcher will advertise the study to anybody in the Trusts who the study may be relevant to. This will be discussed with the site contacts but may include inpatient wards, CMHTs and ECT clinics. For example, this may take the form of posters, presentations at team meetings and patient meetings. Participant Information Sheets (PIS) and response slips (Appendix 4-D) will be available for all staff, service users and family. The research will also be advertised via Twitter. The chief investigator has a professional twitter account (@trainee_Anna) which will be used to recruit people. The tweet will say "Have you been involved in deciding whether someone has ECT? Participants needed for study". The tweet will have an advert attached to it that will give further details of the study. The researcher will tweet other twitter accounts that are relevant to the area of mental health (e.g the Rethink account) and request that they retweet the request for participants. When using Facebook to recruit, the researcher will ask somebody else to post on their behalf (so this research will not to be linked to their personal facebook page) the same document used for the twitter advert to any appropriate groups that may have potential participants in them. People who have been involved in the decision making process can then self-select to be involved in the study. These people, if recruited from the Trusts, can either contact the researcher directly using the contact details on the PIS or they can leave their details on a supplied response slip which they can put into a response box, left with the team contact, to be collected by the researcher. If recruited from Twitter they can contact the research directly using the details supplied in

the tweet. The response slip will also ask (only applicable for service users) for contact details for a case manager/care co-ordinator/ keyworker so that the researcher can be aware of any relevant risk issues. If the participant directly contacts the researcher then the researcher will ask for the contact details of the case manager/care co-ordinator/ keyworker. The case manager will only be contacted if an interview date is arranged. This will be explicitly discussed with the participant and if they do not agree to this, they will not take part in the study.

The researcher will then contact the person and discuss the PIS with them. If the person does not have a PIS then this will be sent to them either via post or electronically. If the person expresses a wish to take part in the study, a date will be arranged for the interview. This will always take place at least 48 hours after the person originally took the PIS to ensure that they have sufficient time to ensure they fully understand the study requirements, and can fully consider their decision to take part. At any time the person can contact the researcher to further clarify or withdraw from the study. The participants will be told that they have one week to withdraw from the study and that after then, although the research will make every effort to withdraw their date, data removal will not be guaranteed. This is due to Grounded Theory methodology which means that the data collected is used to inform the recruitment of the next participant and so taking out one set of data would impact on those collected after. Furthermore, the interviews will be transcribed and analysed after that one week time frame. This will be made clear in the information sheet and on the consent forms. They will be able to withdraw from the study via text if they wish, which will offer a less pressured way to withdraw from the study. This will all be stated in the PIS.

At the time of interview the researcher will again go through the PIS and recap the nature of the study. If the participant still wishes to continue with the study written consent to take part

will be gained from the participant (Appendix 4-E). If interviewing by telephone the consent

form will be emailed/posted prior to the interview according to participant preference and

discussed before beginning the interview. A paper copy of the consent form will be sent to

participants with a stamped addressed envelope for the participant to return a signed copy to

the researcher. The researcher will explain to telephone participants that they will be on loud

speaker in a private and safe setting and that the conversation is being audio recorded to

transcribe later.

According to the British Psychological Society (BPS) (BPS, 2008) guidelines for conducting

research with people who do not have capacity to consent, researchers should assume that a

participant or potential participant does have the capacity to decide whether to consent or not

to their participation, unless there is evidence that questions the person's capacity to reach

this decision. If the researcher has any doubts that the person does not have capacity to

consent then they will utilise the University of California, San Diego Brief Assessment of

Capacity to Consent (UBACC) in order to ensure that the participant has capacity to consent

(Jeste, Paul, Appelbaum, Golshan, Glorioso, Dunn et al., 2007). The researcher will also use

the guidance of the Mental Capacity Act (2005) to ensure capacity.

If the researcher finds that the participant has capacity then the interview will commence.

Alternatively, a further date can be arranged to conduct the interview if need be. If the person

does not have capacity time will be taken to discuss with the participant that they are not

currently eligible to take part in the study. However, if the participant wants, the researcher

will suggest that they will come back in 3 weeks' time and re-assess their capacity to take

part in the study. If the participant wishes for this to happen, the researcher will arrange a

date to return and see the person. The day before that planned meeting, the researcher will

get in contact with the potential participation and check that they still wish to be considered

to take part in the study. If at the second meeting the person still does not have capacity to

consent to the study, they will be excluded. If they do have capacity they will be invited to

take part in an interview.

Prior to the interview, the researcher will again ensure that the participant wishes to take part

in the interview; they will then run through the PIS again taking particular to contact details

on the researchers and ways to withdraw from the study should the participant choose.

Qualitative Methodology; informed by Grounded Theory

The individuals will initially meet with the researcher on one occasion to conduct the

interview however, in line with Grounded Theory techniques they may be asked if can be re-

interviewed at a later date to further clarify or gather extra information. The interview topic

guide will include semi structured open ended questions which will aid participants to give

their personal accounts and views. This topic guide may change in line with grounded theory

which allows for the researcher to adapt the topic guide based on the themes they have

already collected. The interviews will last approximately 60 minutes.

The interviews will be digital recorded and transcribed by the researcher as soon as possible.

The digital recordings will then be destroyed and the anonymised transcripts will be used for

the analytic process.

Data Analysis

The aim of grounded theory is 'to generate or discover a theory' (Glaser & Strauss,

1967). This is done by the researcher initially having a general research topic to explore: for

this study the 'decision making processes regarding the administration of ECT"? A

theoretical understanding is then made from the data that is generated through the research.

The data is analysed at every point of data collection (i.e. after every interview) so that

further data collection can be informed. This is achieved through theoretical sampling.

The study will use the approaches to grounded theory offered by Charmaz (1990; 2006). Like Charmaz, the research will take a constructivist approach that assumes that theories are not there to be discovered but are constructed through the research process. Grounded theory thus sees the final research conclusions as an interpretative portrayal of the world, rather than a 'true' picture.

Grounded Theory involved a process of coding the data and also memo writing to further analyse the data (Glaser, 1978; Charmaz, 1990). The initial stage of coding consists of indexing from the interviews all topics that are considered to be important or interesting. These are then labelled according to their possible relevance to the subject of the study. This will create a list of relevant topics that have arisen from the interviews and that are considered important for the research aims.

After thoroughly indexing the interviews a series of categories, concepts or codes are built up which start to explain the phenomena that are emerging from the study. This process continues as data is collected -the analysis of data within the grounded theory context is very much a dynamic process. Codes and concepts are added, amalgamated, or removed as new data emerges.

The codes and concepts identified in the initial coding analysis will then be refined, extended, and cross-referenced to see how they can be integrated to form a theory (Glaser, 1978) The ongoing memo writing should contain hypotheses and ideas that have been recorded during the analysis process. The memo writing will also constitute an audit trail of how the theory was developed.

Dissemination

In order to reach the maximum number of people from many different contexts there will be several levels to dissemination. The researcher will create an accessible report that will be feedback to all participants. In addition, the researcher will also prepare a power point to feedback to staff members at all the research sites. This may include people who did not participate in the study but work within ECT decision making and who the results may affect. The researcher plans to write up the report for submission to a suitable journal for dissemination to the wider mental health field. The researcher will also disseminate the results of the study via a professional twitter account, and any relevant conferences in the field.

Practical and Ethical Information

Confidential Information and Research Data

Prior to the participants consenting to the study the researcher will have no access to any personal information; after consent demographic information will be collected as outlined in the method section.

Audio recordings will be erased from the digital recorder as soon as they have been transferred securely. The digital recordings will be stored on the researcher's University encrypted password protected network drive, and the researcher will be responsible for deleting them after the thesis has been submitted. Where any data has sensitive material or identifiable personal information the individual files will be password-protected as an additional security measure. All paper data will be scanned as soon as possible to be stored on the University of Lancaster Server (as above) and will then be destroyed. Whilst still in the paper format the data will be stored securely in a locked cabinet.

The academic and field supervisor will have access to all data in its anonymised format, including the audio data. The chief researcher will be the only person who is able to see identifiable information. The research consultants will not have any access to raw data.

Transcription will take place at either the researcher's home address or within the Clinical Psychology Department at Lancaster University. This will be completed on a personal laptop that is password protected. The electronic data will be stored by the Department of Clinical Psychology Research Coordinator in an encrypted password-protected file space on the university server. The Data Custodian i.e. the person who has ultimate responsibility for managing the usage and safety of the data is the programme Research Director, Dr Jane Simpson.

Direct quotes from the participants will be used in the write up of this report. A pseudonym will be used to make sure that the participant is anonymous. Participants will be invited to choose their pseudonym.

Expenses

All costs of photocopying, printing and free post envelopes will be covered by Lancaster University.

As the interviews will be taking place either where someone is residing or where someone works it is not anticipated that travel expenses will be needed. If a participant makes a specific trip to a location for the purpose of the research then the participant will be able to claim up to £20 for travel to and from the interview providing they have a receipt for their travel. The participants will be given a business expense claim form and a freepost envelope to be returned to the Admin Department of the Doctorate of Clinical Psychology. The admin team, once they have received the completed form from the participant will authorise it and send it to the Finance Office to be processed for payment. Participants who have travelled by car can claim to be reimbursed for their total mileage at the 45p/mile rate.

Ethical Concerns

The proposed study will be approved by the Examinations Board of the Doctorate in Clinical Psychology at Lancaster University. Ethical approval will be sought from the National Research Ethics Service and through the Trust R&Ds of the recruiting sites.

Although the research does not involve any invasive procedures, there is the risk that recalling significant memories may evoke emotional reactions from the participants. The cost and benefit to taking part in the study will be specifically addressed in the PIS and the researcher will discuss this with all participants. The researcher will ensure that there is a procedure in the field site that will be followed if there are signs of emotional distress for the participants. For staff members this will mean supporting them to access support from their line management or through anonymous helplines. The PIS will also contain contact details for Samaritans and local site counselling services. For the service users this will involve liaising with support staff and care coordinators.

The staff will be advised in the participant information sheet and verbally at the start of the interview that any confidentiality will be breached if there is a safeguarding concern. Best efforts will be made to this in collaboration with the participant but in some instances this may not be possible. If any potential safeguarding concerns arise the researcher will not investigate the area but will ask questions that deem whether this is an actual concern or not. Any safeguarding concerns will be discussed with either academic or field supervisor and acted on accordingly following local policies and procedures.

At the end of the interview, the participant's will be de-briefed verbally. This will include reminding them of the purpose of the study, reminding them that they can withdraw from the study at any time and a reminder of the researchers contact details.

Timescale

- Liaise with field contacts at the research sites - May 2015.

- Apply to ethic and R&D committees- September 2015

- Data Collection- December- April (inclusive) 2016

- Data Analysis- April/May 2016

- 1st Draft of induction and Method- December 2015

- Complete 1st Draft- April 2016

- Complete 2nd Draft- May 2016

- Submit Thesis- May 2016.

- Formal dissemination/ feedback of results to participants- June 2016

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Appendix 4-A
IRAS Application

Full Set of Project Data   **IRAS Version 5.3.0**

Welcome to the Integrated Research Application System

IRAS Project Filter

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

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

Please enter a short title for this project (maximum 70 characters)
The decision making process of ECT administration

1. Is your project research?

◉ Yes ○ No

---

2. Select one category from the list below:

○ Clinical trial of an investigational medicinal product

○ Clinical investigation or other study of a medical device

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

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

○ Basic science study involving procedures with human participants

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

◉ Study involving qualitative methods only

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

○ Study limited to working with data (specific project only)

○ Research tissue bank

○ Research database

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

○ Other study

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

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

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

c) Will you be using existing human tissue samples (or other human biological samples)? ○ Yes ◉ No

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

☑ England
☐ Scotland

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☐ Wales
☐ Northern Ireland

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

◉ England

○ Scotland

○ Wales

○ Northern Ireland

○ This study does not involve the NHS

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4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☐ IRAS Form
☑ NHS/HSC Research and Development offices
☐ Social Care Research Ethics Committee
☑ Research Ethics Committee
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

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

◯ Yes ⦿ No

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

⦿ Yes ◯ No

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

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

◯ Yes ⦿ No

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

⦿ Yes ◯ No

Please describe briefly the involvement of the student(s):
The student will be the Chief Investigator and will be carrying out the research as part of their thesis for a Doctorate in Clinical Psychology

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

⦿ Yes ◯ No

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

◯ Yes ⦿ No

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

◯ Yes ⦿ No

Integrated Research Application System
Application Form for Research involving qualitative methods only

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
The decision making process of ECT administration

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made?   A grounded theory informed study of the perspectives of those involved.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Miss	Anna C	Duxbury

Address	Clinical Psychology - Division of Health Research
	Furness College
	Lancaster University, Lancaster
Post Code	LA1 4YG
E-mail	a.duxbury@lancaster.ac.uk
Telephone	07506145169
Fax	

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Lancaster University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Ian	Smith

Address	Clinical Psychology - Division of Health Research

Full Set of Project Data   IRAS Version 5.3.0

Furness College
Lancaster University, Lancaster
Post Code   LA1 4YG
E-mail   i.smith@lancaster.ac.uk
Telephone   +44 1524 592282
Fax

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Miss Anna C Duxbury	☑ Dr Ian Smith

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

◉ Student

◯ Academic supervisor

◯ Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Miss Anna C Duxbury
Post	Trainee Clinical Psychologist
Qualifications	BSc (Hons) Neuroscience MSc Psychology
Employer	Lancashire Care Foundation Trust
Work Address	Clinical Psychology - Division of Health Research
	Furness College
	Lancaster
Post Code	LA1 4YG
Work E-mail	a.duxbury@lancaster.ac.uk
* Personal E-mail	
Work Telephone	
* Personal Telephone/Mobile	07506145169
Fax	

* This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

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Full Set of Project Data

IRAS Version 5.3.0

	Title Forename/Initials Surname
	Miss Debbie Knight
Address	Research Support Office
	B58 Bowland Main,
	Lancaster University,
Post Code	LA14YT
E-mail	ethics@lancaster.ac.uk
Telephone	01524 592605
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):

Sponsor's/protocol number:

Protocol Version: Version 1

Protocol Date: 01/06/2015

Funder's reference number:

Project website:

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes   ⦿ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Previous research has suggested that 80% of people who have been administered ECT whilst detained in hospital did not consent to the treatment. In addition, research has found that service users felt they had not been given enough information about ECT before consenting to the procedure and that many service users felt it was a "last resort". The idea of treatment being a last resort will potentially impact on a patient's ability to consent as they will feel unable to refuse treatment that is seen as their last chance and furthermore will deem there to be no other treatment options.

There has been little research into ECT that involves staff. Among those that have, one found that there were significant differences in attitudes towards ECT between those in different job roles (Lutchman, Stevens, Bashir &

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Orrell, 2001). The study concluded that there is a need for awareness of differences of opinion towards the treatment in multidisciplinary teams and that the teams should be aware that there may be strong differences of opinion among members. These differences were said to be likely to affect the decision making process about ECT. As of yet, no research has investigated staff members views on the process of ECT.

It is clear that the decision making process that is taking place on the ground is not just a mechanistic one but one that is complex and not clear, therefore it is important for developing clinical care to understand how this is taking place. Grounded Theory is a helpful approach because it will allow the generation of a model giving detailed information regarding examples of how the decisions process is seen to be happening from the perspectives of different stakeholders

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A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

As there is a potential difficulty in recruiting for this study, 2 research sites will be used in the study to recruit from. 2 research sites will also prevent collecting data that relates to only one service. Field contacts will be used at each site to support access to participants.

As the research will be recruiting from, but not limited to, inpatient ward settings, there are potential risk issues that have been accounted for in the methodology. The researcher will be confident in her knowledge of the risk policies and procedures at each of the research sites. These will be strictly adhered to when the researcher is on site and conducting the interviews. All rooms were the interviews will take place will be selected with the guidance of the field contacts to minimise any risk issues. Any individual person risk plans will be followed also.

The researcher will have no access to confidential information about the participants prior to giving consent for the study. The only information that the researcher will know is their job role/if they are a service user/family member etc. However, there is an exception to this when there is a possible risk involved. Participants who are inpatients will consent to their case manager being contacted about their participation. The case manager will only comment to the researcher about any relevant risk there is to the research being conducted. After consent has been given, demographic information will be given (as specified in the protocol). Throughout the research pseudonyms, chosen by the participants, will be used and any identifiable information altered.

Audio recordings will be erased from the digital recorder as soon as they have been transferred to securely encrypted storage. The digital recordings will be stored on the researchers University password protected network drive, and the researcher will be responsible for deleting them after the study has been submitted. Where any data has sensitive material or identifiable personal information the individual files will be password protected as an additional security measure. All paper data will be scanned as soon as possible to be stored on the University of Lancaster Server (as above) and hard copies will then be destroyed. Whilst still in the paper format the data will be stored securely in a locked cabinet. During the analysis process the storage will be at the chief investigators home address; however long term storage will be stored electronically Department of Clinical Psychology Research at Lancaster University. The Data Custodian i.e. the person who has ultimate responsibility for managing the usage and safety of the data is the programme Research Director, Dr Jane Simpson. This will be done by following a procedure that has been developed by the Department of Clinical Psychology and can be found at http://www.lancaster.ac.uk/shm/study/doctoral_study/dclinpsy/onli nehandbook/ethics_and_data_storage_advice/

There are potential risks to the participants' emotional wellbeing when conducting research. The interviews may evoke difficult memories and emotions for some participants. This has been accounted for in the protocol and advice on how to contact appropriate forms of support has been explicitly stated. The costs and benefits of the research will be clearly stated within the participant information sheet. For the participants who are inpatients, their case managers will be contacted if the participant is at any form of risk.

There is a potential for some of the participants to not have capacity to consent for the study. The protocol clearly states the ways in which the chief investigator will assess capacity. The researcher has had training via her university doctorate course on the Mental Capacity Act and will utilize her knowledge throughout the process. The researcher will also be mindful of guidance given the British Psychological Society on the Mental Capacity Act, specifically about minimising the risk of coercion. If loss of capacity occurs at any stage the participant will be withdrawn immediately from the study, however any data they have given up to that point will remain in the study.

The researcher although employed by Lancashire Care Foundation Trust has no affiliations or ties with the specific wards being recruited from. This is the same for the other sites. The research will therefore be minimising any influence they have over the participant group.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The aim of the research is to generate a model that captures the process by which a decision to administer ECT or not is made, by the different stakeholders that are involved in the process.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

1. What is currently happening on the ground in regards to ECT decision making?
2. How does current ECT decision making fit with the Mental Capacity Act and the Mental Health Act guidance?
3. What do people think need to change in regards to ECT decision making?

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

Rose, Wykes, Bindmann and Fleischmann (2005) concluded from their meta-analysis that approximately half of United Kingdom mental health patients felt they had not been given enough information about ECT before consenting to the procedure. Furthermore, Fisher, Johnstone and Williamson (2011) also found half of their participants reported not having enough information about ECT before consenting to the treatment. Rose, Wykes, Bindmann and Fleischman (2005) reported that one-third of patients did not feel they had freely consented to ECT treatment. In addition, research has suggested that many patients who received ECT felt it was a "last resort" (Fisher, Johnstone & Williamson, 2011, p. 350). Morrison (2009) also discussed the idea of ECT being a "last resort" in her personal account of receiving ECT. Fisher, Johnstone and Williamson (2011) suggested that the idea of ECT being a "last resort" is further reinforced by NICE (2003) guidance which says ECT should be used should "only in life-threatening situations or when medication and other interventions have failed". Johnstone (1999) stated that this will impact on patient's ability to consent as they will feel unable to refuse treatment that is seen as their last chance and furthermore will deem there to be no other treatment options.

Fisher, Johnstone and Williamson (2011) concluded that future research should investigate how patients make sense of and prioritise multiple sources of information when deciding whether to have ECT. However, they also stated that

such research needed to be sophisticated enough to take into account the "complex interpersonal and systemic context in which patients make this decision" (p, 353). Including the understanding of both professionals and patients involved in the consent process will seek to take into account the interpersonal and systemic context. In addition, Fisher, Johnstone and Williamson (2011) suggested that future research with people who refuse to consent to ECT would provide more insights into the decision making process

There has been little research into ECT that involves staff. Amongst those that have, one study found that there were significant differences in attitudes towards ECT between those in different job roles (Lutchman, Stevens, Bashir & Orrell, 2001). The study concluded that there is a need for awareness of differences of opinion towards the treatment in multidisciplinary teams and that the teams should be aware that there may be strong differences of opinion amongst members. These differences were said to be likely to affect the decision making process about ECT. As of yet, no research has investigated staff members views on the process of ECT.

Relevance to Clinical Psychology
Clinical psychologists work alongside professionals involved in the administration of ECT and furthermore have recently begun to act as Responsible Clinicians under the UK Mental Health Act. They will therefore be increasingly involved in decisions to administer ECT or not (Gillmer & Taylor, 2011). In addition, Fisher (2012) stated that clinical psychologists "need to be actively involved in consent procedures, use clinical formulation to understand the perspective of patients, and empower patients to share their views of ECT with mental health professionals and service developers" (p, 590). Fisher (2012) went on to recommend that future research should investigate how patients experience ECT, particularly using qualitative methodologies.
Clinical Psychologists are also often involved in conducting capacity assessments as they are trained to assess the cognitive abilities underlying judgement and decision-making capacities, as well as being skilled in formulating the psychological processes influencing capacity, and identifying mechanisms to enhance decision-making abilities (Walji, Fletcher & Weatherhead, 2014)

Research Aims
It can be seen that the policy and research highlighted above, that the decision making process that is taking place on the ground is not just a mechanistic one but one that is complex and not clear. It is therefore important for developing clinical care to understand how this taking place.

This will be done by qualitatively exploring the views of all people who are involved in the process of deciding if ECT is prescribed or not. Grounded Theory is a helpful approach to develop understandings, because it will allow the generation of a model giving detailed information regarding examples of how the decisions process is seen to be happening from the perspectives of different stakeholders. This could include psychiatrists, patients, family and any other ward staff involved in the process. The research will ask the question what is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made?

Rationale
Utilising a grounded theory informed approach will allow for the development of a model to explain the process stated in the research aims section. The approach will add to the under researched area of consent in ECT. The study will inform future clinical practice and inform research progression in the area.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

All participants will be recruited from one of two NHS Trusts; ████████████████████████████████
██████████████████

The researcher will advertise the study to anybody in the Trusts who the study may be relevant to. This will be discussed with the site contacts but may include inpatient wards, CMHTs and ECT clinics. For example, this may take the form of posters, presentations at team meetings and patient meetings. Patient Information Sheets (PIS) and response slips will be available for all staff, service users and family. People who have been involved in the decision making process can then self-select to be involved in the study. These people can either contact the researcher directly using the contact details on the PIS or they can leave their details on a supplied response slip which they can put into a response box, left with the team contact, to be collected by the researcher. The response slip will also ask for contact details for a case manager/care co-ordinator/ keyworker so that the researcher can be aware of any relevant risk issues. The case manager will only be contacted if an interview date is arranged. This will be explicitly discussed with the participant and if they do not agree to this, they will not take part in the study.

The researcher will then contact the person and discuss the PIS with them. If the person expresses a wish to take part in the study, a date will be arranged for the interview. This will always take place at least 48 hours after the person originally took the PIS to ensure that they have sufficient time to ensure they fully understand the study requirements,

and can fully consider their decision to take part.   At any time the person can contact the researcher to further clarify or withdraw from the study.   The participants will be told that they have one week to withdraw from the study and that after then they will not be able to withdraw their data as it will have been transcribed and anonymised.   This will be made clear in the information sheet and on the consent forms.   They will be able to withdraw from the study via text if they wish, which will offer a less pressured way to withdraw from the study.   This will all be stated in the PIS.

At the time of interview the researcher will again go through the PIS and recap the nature of the study.   If the participant still wishes to continue with the study written consent to take part will be gained from the participant. For those who express an interest, the nature of the study will be recapped.

The interviews will take place within the NHS trust where the participant has been recruited from or if it is a family member they may request the interview to be at their home. The interviews will be conducted in a space that is private and ensures confidentiality.

According to the British Psychological Society (BPS) (BPS, 2008) guidelines for conducting research with people who do not have capacity to consent, researchers should assume that a participant or potential participant does have the capacity to decide whether to consent or not to their participation, unless there is evidence that questions the person's capacity to reach this decision.   If the researcher has any doubts that the person does not have capacity to consent then they will utilise the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) in order to ensure that the participant has capacity to consent (see appendix).   The researcher will also use the guidance of the Mental Capacity Act (2005) to ensure capacity.

If the researcher finds that the participant has capacity then the interview will commence. Alternatively, a further date can be arranged to conduct the interview if need be.   Prior to the interview, the researcher will again ensure that the participant wishes to take part in the interview; they will then run through the PIS again taking particular to contact details on the researchers and ways to withdraw from the study should the participant choose.

Given the nature of the research and that it is important to ensure that as many people have access to be heard in the study, if the researcher thinks that the participant does not have the capacity to consent AND the participant still wishes to take part in the research then Section 32 of the Mental Capacity Act (2005) will be used.   This will mean that an appropriate person will act as a consultee on behalf of the participant. This will ensure that the decision to involve the participant is in the best interest of the participant. A letter will be sent inviting someone to act as a consultee.   This will be either a personal appointed consultee   or the responsible clinician (RC) involved in the patients care.   The letter will explain the role of the RC or consultee and the study.   If the invitation is accepted then the researcher will arrange to meet with the person to discuss the research study and if appropriate complete a RC/consultee declaration form.   If consent is given, an interview will be arrange a minimum of 48 hours later to ensure that the RC/consultee has enough time to consider their decision.   Details of how to withdraw consent will be discussed with the consulte

The individuals will initially meet with the researcher on one occasion to conduct the interview however, in line with Grounded Theory techniques they may be asked if can be re-interviewed at a later date to further clarify or gather extra information.   The interview schedule will include semi structured open ended questions which will aid participants to give their personal accounts and views.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

☑ Design of the research

☑ Management of the research

☑ Undertaking the research

☑ Analysis of results

☑ Dissemination of findings

☐ None of the above

Give details of involvement, or if none please justify the absence of involvement.
The project management team for this study includes two members o
f the public who are considered experts by experience, with a par
ticular interest in research in ECT. They also have experience of
 publishing in academic journals, acting as lay and peer reviewer s and contributing to research ethics committees.

The experts b y experience have been involved in the study from the initial stages. They were recruited via a social media request for people interested in the title to collaborate on the project. I have meetings with the service user group once every months to discuss the next plans for the research and to get feedback from them on issues we have already discussed. The service user group have reviewed and fed back comments on every document that has been written for the ethics process and for the study.

The service users will not not see any of the raw data but will support the generation of the grounded theory model by discussing themes that have risen from the anonymised   analyse the data directly, but they will draft read and feedback on my anonymised data.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☑ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☐ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender: Male and female participants

Lower age limit: 18   Years

Upper age limit: No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

- Person has been involved the process of decision making process of whether ECT is administered or not.
- Person has been involved in the process of decision making in the past twelve months
- Has capacity to take part in the study or a responsible clinician or a personal appointee consents that the person can take part in the study.
- Consent to providing certain demographic information about themselves.
- Patients consent to their case managers/care co-ordinators/keyworkers being contacted in regards to any risk issues.

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Person doesn't meet all of the inclusion criteria.
Person is under the age of 18.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.

2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?

3. Average time taken per intervention/procedure (minutes, hours or days)

4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Telephone call to arrange interview	1	n/a	10-15 minutes	The participants will get in touch with Anna Duxbury via information on the Patient Information sheet
Filling in response slip	1	n/a	5 minutes	If the participants do not want to or cannot phone Anna Duxbury they can leave their contact details in a response box that will be provided. Anna Duxbury will then call them
Seeking Consent	1	n/a	10 minutes	Anna Duxbury will seek consent. This will take place at the arranged interview location
The interview	1/2	n/a	60 minutes	Anna Duxbury will conduct the interview. This will take place immediately following taking consent. The participant may be asked to do a second interview

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A21. How long do you expect each participant to be in the study in total?

The study is planned to take approximately 5 months to complete.

The participants will be directly participating in the study for, an approximate, one hour interview.   The researcher may ask them to take part in a second interview to expand on their original answers.   This interview is also estimated to last for approximately one hour.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

There is a possibility that the interviews may cause participants to reflect on potentially emotional topics with regards to their experiences of ECT.   This may cause participants to experience some distress.   The researcher will remind the participant at the start of the interview that they may stop at any time if

they wish, either to take a rest break or to stop the interview completely. The researcher will take steps to minimise distress by allowing comfort breaks if needed.

If the researcher becomes concerned for the welfare of the participant during the interview, they will stop the interview process and discuss with the participant options for supporting their well being.   These options potentially include giving advice for support networks such as the Samaritans.

When interviewing service users, the interviews will always take place in NHS premises and so there will be a member of their care team there to support if needed.   The researcher will have permission of the participant to call their case manager if they need further support.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

◉ Yes   ◯ No

If Yes, please give details of procedures in place to deal with these issues:

The aim of the study is to explore participants' experiences of decision making in ECT. It is therefore possible that the researcher could be made aware of unethical practice.   If this happens, the researcher will seek advice from their research and field supervisors. The research will escalate the concern further if it is necessary for the protection of service users, staff or the public. If concerns are identified that do not require escalation but would be helpful for the services to be aware of then this will be fed back to the appropriate services as part of the dissemination process on completion of the research.   This feedback will be in a general form that is anonymised with no reference to specific individuals or teams.

A24. What is the potential for benefit to research participants?

There are no direct benefits to participants taking part, although they may find it positive to be contributing to a research study that aims to improve clinical practice in this area.

A26. What are the potential risks for the researchers themselves? *(if any)*

All efforts will be made to arrange an interview at a NHS site however, if this is not possible then the researcher may interview at the participant's homes.   In these instances, the researcher will adopt the Lancaster University's Lone Worker Guidance (section 3.5 of the field work guidance).   The guidance states that "a safe system of work should then be devised in order, as far as is reasonably practicable, to safeguard the health and safety of the worker as required by Section 2 of the HSW Act and reduce risks from foreseeable hazards to an acceptable level". The following has been devised based on the recommendations of the guidance and the researchers based experience of research in lone working settings:

• Prior to conducting the interview, the researcher will try to find out as much as possible about the characteristics of the people they will be interviewing and their housing and living environments. The area will be reconnoitered first; if this is not possible then a map of the area will be studied to help to evaluate its character - e.g. rural, suburban or inner city, plan car parking and to plan routes for leaving dense housing areas to prevent getting lost.
• Researcher will designate a personal contact that is able to action the lone worker plan. The guidance above notes that this should be the researcher (students) supervisor however, this is not possible in this instance.
• Researcher will make sure this person is aware of i) Who they are going to see ii) Where the visit is taking place iii) What time they will be going to place iv) What time they plan to leave the place v) Contact number.   However, to protect anonymity of the participant these details will be kept in a sealed envelope that will be instructed only to be opened if either point 5 in this list occurs or if the researcher rings and uses the safe phrase, "I am going to be late for Bob's appointment".
• Researcher will telephone the designated person before entering the house. They will remind them of how long they plan to be and that the person should expect a call from then.
• Once the visit is over the researcher will call the designated person to say they are save.
• If they do not call, the designated person will ring researcher to see if they are OK.
• The researcher will keep their phone on loud mode throughout the visit so that they will hear this call.
• If no response from that call, designated person will call 999.
• If on the visit a risk arises the researcher will leave the house immediately.
• The researcher's car will be parked facing the route of exit.

Whilst conducting the interview the researcher be aware of cultural norms and appreciate (amongst others) the use of

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body language, the acceptability or not of body contact and establishing the right social distance.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

Participants will opt in themselves to the study by contacting the researcher directly either by telephone or via an opt in sheet.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

◯ Yes   ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

◉ Yes   ◯ No

If Yes, please give details of how and where publicity will be conducted, and enclose copy of all advertising material (with version numbers and dates).

A poster will be put up in any relevant service or department in the NHS trusts.

A29. How and by whom will potential participants first be approached?

The researcher will leave Patient Information Sheets in all relevant areas of the NHS trusts where the participants are being recruited from. Potential participants may also see a recruitment a poster and contact the researcher via details on the poster. The participants will then make initial contact with the researcher via telephone or an opt in sheet. If opt in sheet then researcher will contact the participant.   The researcher will then arrange a time and date to conduct the research.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes   ◯ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Anna Duxbury, chief investigator will obtain consent from the participants.

The researcher will then contact the person and discuss the PIS with them on the initial phone call.   If the person expresses a wish to take part in the study, a date will be arranged for the interview. This will always take place at least 48 hours after the person originally took the PIS to ensure that they have sufficient time to ensure they fully understand the study requirements, and can fully consider their decision to take part.

The researcher will again go for through the PIS with the participant before the interview and answer any questions they may have.   The researcher will then obtain consent, using a consent form as a guide.   The participant will need to consent to several points on the consent form (See consent form).

According to the British Psychological Society (BPS) (BPS, 2008) guidelines for conducting research with people who do not have capacity to consent, researchers should assume that a participant or potential participant does have the capacity to decide whether to consent or not to their participation, unless there is evidence that questions the person's capacity to reach this decision.   If the researcher has any doubts that the person does not have capacity to consent then they will utilise the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC) in order to ensure that the participant has capacity to consent (see appendix).   The researcher will also use the guidance of the Mental Capacity Act (2005) to ensure capacity.

If the researcher finds that the participant has capacity then the interview will commence. Alternatively, a further date can be arranged to conduct the interview if need be.   Prior to the interview, the researcher will again ensure that the participant wishes to take part in the interview; they will then run through the PIS again taking particular to contact details on the researchers and ways to withdraw from the study should the participant choose.

Given the nature of the research and that it is important to ensure that as many people have access to be heard in the study, if the researcher thinks that the participant does not have the capacity to consent AND the participant still wishes to take part in the research then Section 32 of the Mental Capacity Act (2005) will be used.   This will mean that an appropriate person will act as a consultee on behalf of the participant. This will ensure that the decision to involve the participant is in the best interest of the participant. A letter will be sent inviting someone to act as a consultee.   This will be either a officially recognised personal appointed consultee (appendix X) or the responsible clinician (RC) involved in the patients care (appendix XX).   The letter will explain the role of the RC or consultee and the study.   If the invitation is accepted then the researcher will arrange to meet with the person to discuss the research study and if appropriate complete a RC/consultee declaration form (appendix XXX).   If consent is given, an interview will be arrange a minimum of 48 hours later to ensure that the RC/consultee has enough time to consider their decision.   Details of how to withdraw consent will be discussed with the consultee.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

⦿ Yes   ◯ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will have at least 48 hours between receiving the PIS and taking consent for the interview.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

An interpreter will be requested to help translate the patient information sheet and consent form.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

◯ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.

⦿ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.

◯ The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◯ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

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It is not envisaged that the participant will lose the capacity to consent during the one hour interview however if this were to happen, before being withdrawn from the study the researcher, using section 32 of the Mental Capacity Act, would request consent from a personal consultee or responsible clinician.   This would only be done if the participant lost capacity but wanted to remain in the study. The procedure outline in this application for gaining consent from a responsible clinician or personal consultee would be followed.

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

☐ Access to medical records by those outside the direct healthcare team

☐ Access to social care records by those outside the direct social care team

☐ Electronic transfer by magnetic or optical media, email or computer networks

☐ Sharing of personal data with other organisations

☐ Export of personal data outside the EEA

☑ Use of personal addresses, postcodes, faxes, emails or telephone numbers

☑ Publication of direct quotations from respondents

☐ Publication of data that might allow identification of individuals

☑ Use of audio/visual recording devices

☑ Storage of personal data on any of the following:

    ☑ Manual files (includes paper or film)

    ☐ NHS computers

    ☐ Social Care Service computers

    ☐ Home or other personal computers

    ☑ University computers

    ☐ Private company computers

    ☑ Laptop computers

Further details:
Personal addresses will only be taken if a family member wishes to conduct the interview at their home address. Interviews at people's homes will be a last resort option.

All work relating to the research will be completed on a personal laptop or a university computer that is both password protected and encrypted.

Any electronic data will be uploaded an encrypted password-protected file space on the university server and then deleted from the personal laptop or university computer storage space.   The Data Custodian i.e. the person who has ultimate responsibility for managing the usage and safety of the data is the programme Research Director, Dr Jane Simpson.

A37. Please describe the physical security arrangements for storage of personal data during the study?

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Consent forms and any other paper documentation with personal information on will be stored separately from any data collected. The paper documents will be stored for the duration of the study in two separate locked filing boxes at the home of the researcher.

In regards to the use of the recorder, any identifiable data (including recordings of participants' voices) will be deleted from the recorder as quickly as possible. This will be done as soon as the recordings have been transferred to the researcher's University encrypted password protected network drive, and the researcher will be responsible for deleting them after the thesis has been submitted. Where any data has sensitive material or identifiable personal information the individual files will be password-protected as an additional security measure.

The audio recordings will be transcribed verbatim by the researcher into an electronic Word document. The electronic document will not contain any identifying information or demographic information and will be saved only with the anonymised participant number as a password protected file on the secure university server. In instances where a paper copy of the transcription is required (e.g. for supervision purposes) the paper copy will be destroyed immediately following its use.

All work relating to the research will be completed on a personal laptop that is password protected and encrypted. The electronic data will be stored by the Department of Clinical Psychology Research Coordinator in an encrypted password-protected file space on the university server. The Data Custodian i.e. the person who has ultimate responsibility for managing the usage and safety of the data is the programme Research Director, Dr Jane Simpson.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All participant quotes will be anonymised in the final report in order to protect the identity of participants. Participants will be asked to choose a pseudonym so that their quotes can be appropriately referenced in the main report. Any identifying information about the participants will also be anonymised.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The chief investigator will be the only person to see personal data during the study

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Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The researcher will transfer the audio recordings to a password protected file on the secure University server as soon as is reasonably possible following the interview. The audio recordings will be deleted from the audio device as soon as this has been done.

The transcripts and notes generated during the analysis will be analysed by the researcher electronically on an password protected and encrypted laptop. They will be saved onto the secure University server.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title	Forename/Initials	Surname
	Dr	Jane	Simpson
Post	Research Director, Doctorate in Clinical Psychology, Lancaster University		
Qualifications	PhD		
Work Address	Division of Health Research		
	Furness College, Lancaster University		
	Lancaster		
Post Code	LA1 4YG		
Work Email	j.simpson2@lancaster.ac.uk		
Work Telephone	01524 592858		

Fax

A43. How long will personal data be stored or accessed after the study has ended?

- ◉ Less than 3 months
- ◯ 3 – 6 months
- ◯ 6 – 12 months
- ◯ 12 months – 3 years
- ◯ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. Say *where data will be stored, who will have access and the arrangements to ensure security.*

The data that will be retained for storage after the study is completed will include the consent forms, interview transcripts and any coded data produced during analysis. All data will be stored in electronic form and transferred to the Lancaster DClinPsy Administration team via secure file transfer software, ZendTo. Any paper copies held by the chief
investigator will be destroyed following this transfer.

The research data will be stored by the Lancaster University DClinPsy administration team for ten years following completion of the study. The Lancaster University DClinPsy administration team will be responsible for destroying these records once ten years has passed.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

◉ Yes   ◯ No

If Yes, please give details. For monetary payments, indicate how much and on what basis this has been determined.
For participants who need to travel to a base to attend the interview, travel expenses up to the value of £20 will be offered by the Lancaster University Clinical Psychology Doctorate programme. No other financial incentives or payments will be offered for taking part in the study.

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes   ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes   ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes   ⦿ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

◯ Yes   ⦿ No

Please give details, or justify if not registering the research.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

☑ Peer reviewed scientific journals

☑ Internal report

☑ Conference presentation

☐ Publication on website

☐ Other publication

☐ Submission to regulatory authorities

☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be used in the final report.
Any quotes used in published documents will be assigned a pseudonym to ensure anonymity.

A53. Will you inform participants of the results?

⦿ Yes   ◯ No

Please give details of how you will inform participants or justify if not doing so.
The researcher will create an accessible report that will be feedback to all participants if they would like.   The researcher will ask the participant for a means of contact at the end of the interview (email/postal address) if they would like the report.   In addition, the researcher will also prepare a power point to feedback to staff members at all the research sites.   This may include people who did not participate in the study but work within ECT decision making and who the results may affect.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi–centre research group

☑ Review within the Chief Investigator's institution or host organisation

☑ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The research team compromises of two supervisors (academic supervisor and field supervisor) and a service user involvement group.   All have read through the ethics documents and commented on the content of the documents. The academic supervisor has reviewed the full IRAS application.

The IRAS application and all ethics documents have been reviewed and commented on by the Research Ethics Officer at Lancaster University. There is not a written review available to attach to the application.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 12
Total international sample size (including UK): 0
Total in European Economic Area: 0

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

The participant size is estimated to be 12.   Grounded Theory does not dictate how many participants a study should have however does say that the total number of participants can depend on "theoretical sufficiency" (Dey, 1999, p. 117).   Theoretical sampling means that once existing categories do not require revision or alteration in respect of new data then no new participants need to be recruited. Based on previous grounded theory informed studies that impose theoretical sufficiency an estimation of 12 has been suggested.
12 is also the maximum number of participants that is feasible   within the scope of a   student doctoral project of this type

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A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

The aim of grounded theory is 'to generate or discover a theory' (Glaser & Strauss, 1967).   This is done by the researcher initially having a general research topic to explore: for this study the 'decision making processes regarding the administration of ECT"?   A theoretical understanding is then made from the data that is generated through the research.   The data is analysed at every point of data collection (i.e. after every interview) so that further data collection can be informed.   This is achieved through theoretical sampling.

The study will use the approaches to grounded theory offered by Charmaz (1990; 2006).   Like Charmaz, the research will take a constructivist approach that assumes that theories are not there to be discovered but are constructed

through the research process.   Grounded theory thus sees the final research conclusions as an interpretative portrayal of the world, rather than a 'true' picture.

Grounded Theory involved a process of coding the data and also memo writing to further analyse the data (Glaser, 1978; Charmaz, 1990).   The initial stage of coding consists of indexing from the interviews all topics that are considered to be important or interesting. These are then labelled according to their possible relevance to the subject of the study. This will create a list of relevant topics that have arisen from the interviews and that are considered important for the research aims.

After thoroughly indexing the interviews a series of categories, concepts or codes are built up which start to explain the phenomena that are emerging from the study. This process continues as data is collected -the analysis of data within the grounded theory context is very much a dynamic process. Codes and concepts are added, amalgamated, or removed as new data emerges.

The codes and concepts identified in the initial coding analysis will then be refined, extended, and cross-referenced to see how they can be integrated to form a theory (Glaser, 1978)

The ongoing memo writing should contain hypotheses and ideas that have been recorded during the analysis process.   The memo writing will also constitute an audit trail of how the theory was developed.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Ian	Smith
Post	Clinical Psychologist		
Qualifications	DClinPsy		
Employer	Lancaster University		
Work Address	Doctorate in Clinical Psychology,		
	Division of Health Research Furness Building,		
	Lancaster University, Lancaster		
Post Code	LA1 4YG		
Telephone	01524292282		
Fax			
Mobile			
Work Email	i.smith@lancaster.ac.uk		

	Title	Forename/Initials	Surname
	Dr	Stephen	Weatherhead
Post	Clinical Psychologist		
Qualifications	DClinPsy		
Employer	Lancaster University		
Work Address	Doctorate in Clinical Psychology,		
	Division of Health Research, Furness Building,		
	Lancaster University, Lancaster		
Post Code	LA1 4YG		
Telephone	01524592974		
Fax			
Mobile			
Work Email	s.weatherhead		

	Title	Forename/Initials	Surname
	Ms	Bethan	Mair-Edwards

Post	
Qualifications	
Employer	
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	

	Title	Forename/Initials	Surname
	Mr	Gerry R	Bennison

Post	
Qualifications	
Employer	
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	

	Title	Forename/Initials	Surname
	Dr	Suzanne	Hodge

Post	Lecturer
Qualifications	PhD
Employer	Lancaster University
Work Address	Doctorate in Clinical Psychology, Division of Health Research Furness Building, Lancaster University
Post Code	LA1 4YG
Telephone	01524592712
Fax	
Mobile	
Work Email	s.hodge@lancaster.ac.uk

	Title	Forename/Initials	Surname
	Professor	Ian	Anderson

Post	Professor of Psychiatry
Qualifications	MRCP(UK), MD, FRCPsych
Employer	The University of Manchester
Work Address	Room G.810/811 Stopford Building The University of Manchester

	Oxford Road
Post Code	M13 9PL
Telephone	0161 275 7427
Fax	0161 275 7429
Mobile	
Work Email	ian.anderson@manchester.ac.uk

	Title Forename/Initials Surname
	Miss Kerry Irvine
Post	Trainee Clinical Psychologist
Qualifications	BSc (Hons) Psychology
Employer	Lancashire Care Foundation Trust
Work Address	Doctorate in Clinical Psychology
	Division of Health Research Furness Building,
	Lancaster University
Post Code	LA1 4YG
Telephone	
Fax	
Mobile	
Work Email	a.duxbury@lancaster.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:　○ NHS or HSC care organisation　　　　　Commercial status:　Non-Commercial

　　　　 ○ Academic

　　　　 ○ Pharmaceutical industry

　　　　 ○ Medical device industry

　　　　 ○ Local Authority

　　　　 ○ Other social care provider (including voluntary sector or private organisation)

　　　　 ○ Other

If Other, please specify:

Contact person

Name of organisation	Lancaster University
Given name	Debbie
Family name	Knight
Address	B58 Bowland Main, Research Support Office
Town/city	Lancaster
Post code	LA1 4YT
Country	UNITED KINGDOM

Telephone   01524 592605
Fax
E-mail   ethics@lancaster.ac.uk

Is the sponsor based outside the UK?
○ Yes   ○ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

☐ Funding secured from one or more funders

☐ External funding application to one or more funders in progress

☑ No application for external funding will be made

What type of research project is this?

◉ Standalone project

○ Project that is part of a programme grant

○ Project that is part of a Centre grant

○ Project that is part of a fellowship/ personal award/ research training award

○ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes   ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes   ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

                  Title Forename/Initials Surname
Organisation
Address   Research and Development

Post Code   █████████

Work Email   ███████████████

Telephone   █████████

Fax

Mobile

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

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A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2015

Planned end date: 01/06/2016

Total duration:

Years: 0 Months: 8 Days: 1

A71-1. Is this study?

◯ Single centre

◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England

☐ Scotland

☐ Wales

☐ Northern Ireland

☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

◯ Yes   ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England   2

☐ NHS organisations in Wales

☐ NHS organisations in Scotland

☐ HSC organisations in Northern Ireland

☐ GP practices in England

☐ GP practices in Wales

☐ GP practices in Scotland

☐ GP practices in Northern Ireland

☐ Joint health and social care agencies (eg community mental health teams)

☐ Local authorities

☐ Phase 1 trial units

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☐ Prison establishments

☐ Probation areas

☐ Independent (private or voluntary sector)
organisations

☐ Educational establishments

☐ Independent research units

☐ Other (give details)

Total UK sites in study: 2

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes   ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The research will be monitored by the academic supervisor and the field supervisor in the first instance. The supervisors will check study documents to ensure they are appropriate. They will also listen to an audio recording of at least one of the interviews to ensure that the content of the interviews is appropriate.
There will be monthly meetings with the project management team where the chief investigator will update on the research. The team will provide support and guidance
As the research will take place within NHS settings, audit and mo
nitoring of the research will also take place locally within the Research and Development Departments of the relevant NHS trusts. The researcher will comply with any requests for information from these Trusts.

A76. Insurance/ indemnity to meet potential legal liabilities

Note: in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland

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A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management **of the research?** *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design **of the research?** *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☐ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☑ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Lancaster University legal liability cover will apply

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ◯ No ◯ Not sure

B. All research other than CTIMPs

In this sub-section, an adult means a person aged 16 or over.

B1. What impairing condition(s) will the participants have?

The study must be connected to this condition or its treatment.

The ECT Minimum Dataset Activity Data Report (Royal College of Psychiatrists, 2013) concluded that 84% people who received ECT whilst detained under the Mental Health Act (2009) in 2012-13 did not consent to the treatment at the start of the treatment due to the people experiencing distress in relation to their mental well being. The participants being recruited to this study may also be experiencing   distress in relation to their mental well being.

B2. Justify the inclusion of adults unable to consent for themselves. It should be clear why the research could not be carried out as effectively if confined to adults capable of giving consent.

The research is looking at the decision making processes of deciding whether ECT is given or not, as this is is often done with people who cannot consent it is important that the research does all it can to represent the people who are involved in the decision making process. These people are not usually given a voice in research and it is important that their opinions are listened to.

It is important to note that the researcher will only look to recruit the participant if they do not have the capacity to consent AND they actively want   to take part in the research.   In this case, Section 32 of the Mental Capacity Act (2005) will be used.   This will mean that an appropriate person will act as a consultee on behalf of the participant. This will ensure that the decision to involve the participant is in the best interest of the participant.

To reiterate, this will only be done if the participant has a strong interest to take part in the study, they will not be recruited to the study if they do not have capacity and do not want to take part in the study.

B3. Who in the research team will decide whether or not the participants have the capacity to give consent? What training/experience will they have to enable them to reach this decision?

The chief investigator will be the initial person to decide if the person has capacity to consent or not. The chief investigator is a trainee clinical psychologist who has attended training on the Mental Capacity Act. The chief investigator has two supervisors who are qualified clinical psychologists and they will be able to advise on any

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decisions in regards to capacity.

The chief investigator will then ask the responsible clinician or a personally appointed consultee for consent for the person to take part in the research. If this consent is not gained then the participant will not take part in the research.

B4. Does the research have the potential to benefit participants who are unable to consent for themselves?

◉ Yes   ○ No

If Yes, please indicate the nature of this benefit. You may refer back to your answer to Question A24.

The potential participant who lacks capacity will only be considered to take part in the research if they have a strong interest to take part. Enabling them to take part in something they have a strong interest in, will be a benefit to them as it is fulfilling their wishes and may improve well being.

The participant will be contributing to research that is looking to improve the clinical practice of decision making in ECT.

B5. Will the research contribute to knowledge of the causes or the treatment or care of persons with the same impairing condition (or a similar condition)?

◉ Yes   ○ No

If Yes, please explain how the research will achieve this:

The research is looking to improve the clinical practice of decision making in ECT. Other people experiencing distress in regards to their well being may be involved in the decision making process of whether they should have the treatment in the future,

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B6. Will the research involve any foreseeable risk or burden for these participants, or interfere in any way with their freedom of action or privacy?

◉ Yes   ○ No

If Yes, please give an assessment below. Highlight any risk, burden or discomfort specific to these participants and say what will be done to minimise it. You may refer back to your answers to Questions A22 and A23.

The participants will be asked to talk about their experiences of deciding whether to have ECT or not; this may evoke some difficult feelings for the participant.   The case manager for the participant will be informed that the person is taking part in the research and will be informed if the participant experiences any distress from the research. The participants who are potentially unable to consent to the research will all be based on an inpatient mental health ward and so they will have support around them 24/7 following the interview.

The chief investigator, who is conducting the interviews, is a third year trainee clinical psychologist and has clinical experience of managing distress.   The chief investigator will look out for any signs of distress in the interview and the interview will be terminated if appropriate.   The participant will be offered chances to break throughout the interview.   If at any point they say they do not want to continue to interview then the interview will be stopped.

Questions B7 and B8 apply to any participants recruited in England and Wales.

B7. What arrangements will be made to identify and consult persons able to advise on the presumed wishes and feelings of participants unable to consent for themselves and on their inclusion in the research?

A letter will be sent inviting someone to act as a consultee.   This will be either an officially recognised personal appointed consultee or the responsible clinician (RC) involved in the patients care. The letter will explain the role of the RC or consultee and the study.   If the invitation is accepted then the researcher will arrange to meet with the person to discuss the research study and if appropriate complete a RC/consultee declaration form.   If consent is given, an

interview will be arranged a minimum of 48 hours later to ensure that the RC/consultee has enough time to consider their decision.   Details of how to withdraw consent will be discussed with the consultee.

Please enclose a copy of the written information to be provided to consultees. This should describe their role under section 32 of the Mental Capacity Act and provide information about the research similar to that which might be given to participants able to consent for themselves.

B8. Is it possible that a participant requiring urgent treatment might need to be recruited into research before it is possible to identify and consult a person under B7?

○ Yes   ⦿ No

If Yes, say whether arrangements will be made instead to seek agreement from a registered medical practitioner and outline these arrangements. Or, if this is also not feasible, outline how decisions will be made on the inclusion of participants and what arrangements will be made to seek consent from the participant (if capacity has been recovered) or advice from a consultee as soon as practicable thereafter.

B9. What arrangements will be made to continue to consult such persons during the course of the research where necessary?

The chief investigator will advise the consultee on whether the interview happened or not.   They will not share the contents of the interview but will report if any significant distress occurred. If a second interview is required then capacity will be assessed again and the consultee informed if necessary.

B10. What steps will you take, if appropriate, to provide participants who are unable to consent for themselves with information about the research, and to consider their wishes and feelings?

The researcher will go through the information sheet and consent procedure as they would any other participant.   The participant will only take part if they wish to take part in the study. Their wishes and feelings will therefore vital to whether they are recruited in to the research or not.

B11. Is it possible that the capacity of participants could fluctuate during the research? How would this be handled?

In most cases there will be only one interview that capacity is assessed for. If a second interview is required then the process of assessing for capacity will commence again as the Mental Capacity Act states capacity should be assumed for every specific decision. To take part in a second interview will be a specific decision.

B12-1. What will be the criteria for withdrawal of participants?

The participant will be able to voice that they want to withdraw from the study at any point during the interview.   The interviewer will check throughout the interview that the participant is happy to go on with the interview.

Participants or the RC/personal consultee can withdraw consent from the study by contacting me on 07852516697 or a.duxbury@lancaster.ac.uk. Participants will be able to withdraw from the study up to one week after the interview. None of your data will be used if you withdraw in this one week period.   However, if they withdraw consent at any other stage any data collected will be used in the study.

B13. Describe what steps will be taken to ensure that nothing is done to which participants appear to object (unless it is to protect them from harm or minimise pain or discomfort).

The participant will only take part in the research if they want to.   If they object at any point during the research they will be withdrawn from the study.   As above, if it is one week after the interview then their data will still be used.

B14. Describe what steps will be taken to ensure that nothing is done which is contrary to any advance decision or statement by the participant?

The responsible clinician or personal consultee who will consent on behalf of the participant will be asked if there has been an advance decision or statement made in the past that would imply the participant would not wish to take part in the research.

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Research site	Investigator/ Collaborator/ Contact
Institution name	Title
Department name	First name/ Initials
Street address	Surname
Town/city	
Post Code	
Institution name	Title
Department name	First name/ Initials
Street address	Surname
Town/city	
Post Code	

Appendix 4-B

Topic Guide

1.   What is currently happening on the ground in regards to ECT decision making?

- How successful do you think the process is?

- How collaborative is the process?

- If not successful or collaborative, why not?

- Who is involved in the process?

- What are the positive/ negatives of those people being involved?

- Is there anyone else you think should be involved?

- What happens if someone doesn't consent?

2.   How does current ECT decision making fit with the Mental Capacity Act and the Mental Health Act guidance?

- How does the MH Act impact on the decision making in ECT?

- How does the MCA impact on the decision making in ECT?

3.   What do people think need to change in regards to ECT decision making?

- What are the strengths/ weaknesses of the process

- How would you like ECT decision making to look?

- What prevents the decision making from looking how you want it to?

Appendix 4-C
Example of Social Media Advert (Twitter)

Lancaster University

ECT and Decision Making

Study title: What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.

My name is Anna Duxbury and I am a trainee clinical psychologist conducting this research as a student on the Doctorate in Clinical Psychology programme at Lancaster University.

What is the study about?
The purpose of this study is to understand what the process is to making a decision about whether ECT is given or not. The study is looking to recruit anyone who has been involved in this decision making in the last 12 months. You may be anyone (service user, family member or professional who has been involved in making the decision.

What does the study involve?
If you decide you want to take part in the study, you would be asked to attend an interview that would last around 1 hour. The interview would be audio recorded and later transcribed. During the interview we would talk about the decision you made to have ECT or not. This may include asking you questions like "who was involved in the decision to have ECT or not", "do you think the process could be improved in anyway" and "what are the positives and negatives of the process?"
The interview would take place at a NHS site near to you or at your home.

Due to time and resource limitations of the study I am only able to recruit people who can be interviewed in Cumbria, Lancashire, Greater Manchester, West Yorkshire, Merseyside or Cheshire.

To receive a participant information sheet with more information about the study or if you have any queries or questions about the study please contact me on 07852 516 697 or a.duxbury@lancaster.ac.uk

Appendix 4-D
Participant Information Sheet

Participant Information Sheet
ECT and Decision Making

Study title: What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.

My name is Anna Duxbury and I am a trainee clinical psychologist conducting this research as a student in the Doctorate in Clinical Psychology programme at Lancaster University.

What is the study about?
The purpose of this study is to understand what the process is to making a decision about whether ECT should be given or not.

Why have I been approached?
You have been approached because I want to talk to people who have made a decision about whether you or someone else should have ECT or not, in the last 12 months.

Do I have to take part?
No. It's completely up to you to decide whether or not you take part. Not taking part will not affect your care or your work with the service. There are no negative consequences to not taking part in the research.

What will I be asked to do if I take part?
If you decide you would like to take part in the study, you may be asked to take part in an interview with me. As I can only recruit up to 15 people, I may not be able to interview everyone who is interested in taking part, but I will let you know by April 2016 if you are not needed to be in the study.

If you are service user than I will ask you if I can contact your case worker to let them know you want to participate in the study. I will phone them and then send them a copy of this information sheet. If you do not agree to me contacting them, then I'm sorry but unfortunately you will not be able to take part in the research.

If you are asked to attend an interview, I will answer any questions you have before the interview. The interview will take about 1 hour, but it doesn't have to last this long. The interview will stop when you want it to stop. We can have breaks throughout the interview

too if you want. We will talk about the decision you made to have or give ECT or not. This may include asking you questions like "who was involved in the decision to have ECT or not", "do you think the process could be improved in anyway" and "what are the positives and negatives of the process?" The interview will take place in an NHS Trust building where you are based. This may be in a room on a ward, an office, or a room at the ECT clinic.

I might ask if I can interview you a second time to further explore some of the ideas we discussed in the first interview. It is up to you if you want to do that second interview or not.

Will my data be Identifiable?

Your data will not be identifiable. Nobody but me will know what you say in the interviews. I will ask you if I can use quotes of what you said for when I write up the research. Any quotes I use will be anonymised. This means that I will not use your name next to the quote, but will ask you to choose a name that I can use instead.

The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:
   o Audio recordings will be deleted as soon as I have transcribed them.
   o The files on the computer will be encrypted (that is no-one other than the researcher will be able to access them) and the computer itself will be password protected and encrypted.
   o The typed version of your interview will be made anonymous by removing any identifying information including your name.
   o All your personal data will be confidential and will be kept separately from your interview responses.

There are some limits to confidentiality: if what is said in the interview makes me think that you, or someone else, are at significant risk of harm, I will have to break confidentiality and speak to my supervisors about this. I might then have to take action to stop anyone from getting hurt. If possible, I will tell you if I have to do this.

What will happen to the results?

The results will be summarised and reported in a thesis and may be submitted for publication in an academic or professional journal. I will present the results back to the services that I have recruited from. I will also send you a summary report of the results at the end of the study.

Are there any risks?

There are no risks anticipated with participating in this study. However, the interviews may involve you talking about an experience that was distressing to you. If you do feel distressed at the end of the interview you are encouraged to let me know and we can discuss options to help support you. If you have accessed services, this may include me talking to your case worker about how you are feeling. I would always aim to do this after talking to you about it first. There are also services listed at the end of this information sheet that you can contact should you feel distressed.

Are there any benefits to taking part?
Although you may find participating interesting, there are no direct benefits to you in taking part. This research is intended to finds way to improve clinical practice around ECT decision making processes.

Who has reviewed the project?
The proposed study was approved by the Examinations Board of the Doctorate in Clinical Psychology at Lancaster University. Ethical approval has been granted by the National Research Ethics Service and through the Trust's Research and Development Department.

Where can I obtain further information about the study if I need it?
If you have any questions about the study, please contact the main researcher:
Name: Anna Duxbury
Address: Lancashire Care Foundation Trust/ Lancaster University
Faculty of Health & Medicine
Clinical Psychology - Division of Health Research
Furness College
Lancaster University
Lancaster, Lancashire
LA1 4YG

Telephone: Research mobile (9am- 5pm) **07852516697**
Email: **a.duxbury@lancaster.ac.uk**

How do I decide to take part in the research?

If you want to take part in the research then please contact me on **07852516697.** You are welcome to send me a text or leave a voice message. Alternatively, you can email me **a.duxbury@lancaster.ac.uk.**

Alternatively, if you are based in a ward setting or at the ECT clinic you can leave your details in the confidential research box and I will contact you. There is a details section at the bottom of this information sheet than you can fill in and leave in the box.

How do I withdraw from the study?

You can withdraw from the study by contacting me on **07852516697**
or a.duxbury@lancaster.ac.uk. You will be able to withdraw from the study **up to one week** after the interview. None of your data will be used if you withdraw in this one week period. However, if you withdraw consent at any other stage any data I have collected from you will be used in the study.

Complaints
If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researcher, you can contact:

Name: Dr Jane Simpson
Research Director, Doctorate in Clinical Psychology

Address: Lancaster University
Faculty of Health & Medicine
Clinical Psychology - Division of Health Research
Furness College
Lancaster University
Lancaster, Lancashire
LA1 4YG
Email: j.simpson2@lancaster.ac.uk

If you wish to speak to someone outside of the Clinical Psychology Doctorate Programme, you may also contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Thank you for taking the time to read this information sheet.

Resources in the event of distress
Should you feel distressed either as a result of taking part, or in the future, the following resources may be of assistance.

NHS staff can contact the Occupational Health Service by emailing {insert site specific information}

You can contact Samaritans on 08457 90 90 90 or email jo@samaritans.co.uk

Or service users may wish to speak with their care co-ordinator or named nurse.

Contact Details for the researcher if you wish to be contacted about the study. Please place in research box when you have filled this in. This will be located at the place you got this information sheet from.

Name:………

Role in ECT decision making i.e. service user, family member, nurse, psychiatrist etc:

……….

If a Service User, please provide the name and contact details of your care co-ordinator, keyworker or case-manager.

……

How would you like to be contacted?

……

How would you like to be contacted?

Appendix 4-E
Consent Form

Lancaster University

Consent Form

Study Title: What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.

Please initial each

statement

1. I confirm that I have read the information sheet and understand what I am being asked to do in the study

2. I confirm that I have had the opportunity to ask any questions and to have them answered.

3. I understand that my interview will be audio recorded and then made into an anonymised written transcript.

4. I understand that audio recordings will be deleted as soon as they have been transcribed into a written document.

5. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.

6. I understand that I have **one week from my interview date to withdraw from the study.** After that date, the researcher will make their best efforts to remove the data but this cannot be guaranteed.

7. I understand that the information from my interview will be put together with other participants' responses, anonymised and may be published.

8. I consent to information and quotations from my interview being used in reports, conferences and training events.

9. I understand that any information I give will remain strictly anonymous unless it is thought that there is a risk of harm to myself or others, in which case the principal investigator will need to share this information with her research supervisor and take appropriate action to prevent anyone from harm.

10. I consent to Lancaster University keeping written transcriptions of the study for 10 years after the study has finished.

11. I consent to my case worker being informed of my involvement in the study (if applicable)

12. I consent to take part in the study.

Name of Participant_____ **Signature**_____ **Date**_____

Name of Researcher _____**Signature** _____**Date**_____

Appendix 4-F
REC Approval

NHS
Health Research Authority
Research Ethics Service

North West - Greater Manchester South Research Ethics Committee
3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Telephone: 0207 104 8002

05 November 2015

Miss Anna C Duxbury
Clinical Psychology - Division of Health Research
Furness College
Lancaster University
Lancaster
LA1 4YG

Dear Miss Duxbury

Study title:	What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.
REC reference:	15/NW/0756
IRAS project ID:	183213

Thank you for your letter of 30 October 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair and Ms Kathryn Fellows.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Assistant, Miss Ewa Grzegorska, nrescommittee.northwest-gmsouth@nhs.net.

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, subject to the conditions specified below.

Mental Capacity Act 2005

The committee did not approve this research project for the purposes of the Mental Capacity Act 2005. The research may not be carried out on, or in relation to, a person who lacks capacity to consent to taking part in the project.

A Research Ethics Committee established by the Health Research Authority

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

<u>Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.</u>

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

<u>Registration of Clinical Trials</u>

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (catherineblewett@nhs.net), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable). Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS sites

The Committee has not yet completed any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to

any non-NHS site at present. We will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	Version	Date
Copies of advertisement materials for research participants [Recruitment Poster]	1.0	02 June 2015
Covering letter on headed paper [Cover Letter for revised documents]	1.0	30 October 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Insurance]		13 August 2015
Interview schedules or topic guides for participants [Topic Guide]	1.0	02 June 2015
Letter from sponsor [Sponsor Letter]		28 August 2015
Letters of invitation to participant [Consultee Invitation Letter]	1	22 June 2015
Other [Lancaster University Guidance on Lone Working]		
Other [Case Worker Participant Information Sheet]	1.0	30 October 2015
Participant consent form [Consultee Consent]	1	22 September 2015
Participant consent form [Participant Consent Form]	2.0	30 October 2015
Participant information sheet (PIS) [Consultee PIS]	1	22 September 2015
Participant information sheet (PIS) [Participant Information Sheet]	2.0	30 October 2015
REC Application Form [REC_Form_22092015]		22 September 2015
Research protocol or project proposal [Protocol]	2.0	30 October 2015
Summary CV for Chief Investigator (CI) [Anna Duxbury CV]		10 September 2015
Summary CV for supervisor (student research) [Ian Smith CV]	1.0	16 April 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review
Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

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The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0756	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely
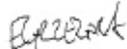
[signature]

On behalf of
Professor Sobhan Vinjamuri
Chair

Email: nrescommittee.northwest-gmsouth@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: ███████████████████████
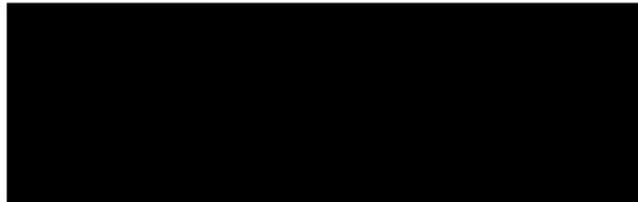
Appendix 4-G

An Example of REC Amendment Approval

NHS
Health Research Authority

North West - Greater Manchester South Research Ethics Committee

3rd Floor, Barlow House
4 Minshull Street
Manchester
M1 3DZ

Tel: 0207 104 8002

21 March 2016

Miss Anna C Duxbury
Clinical Psychology - Division of Health Research
Furness College
Lancaster University, Lancaster
LA1 4YG

Dear Miss Duxbury

Study title:	**What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved.**
REC reference:	15/NW/0756
Amendment number:	**Amendment 4**
Amendment date:	**22 February 2016**
IRAS project ID:	183213

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

Approval was sought for the request to include the recruitment of professionals to the study.

The researchers would also like to extend recruiting to Facebook.

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Copies of advertisement materials for research participants [Twitter Advert]	2.0	22 February 2016
Copies of advertisement materials for research participants [Twitter Post]	2.0	22 February 2016
Copies of advertisement materials for research participants [Facebook Advert]	1.0	22 February 2016
Copies of advertisement materials for research participants [Facebook Post]	1.0	22 February 2016
Notice of Substantial Amendment (non-CTIMP)	Amendment	22 February 2016

A Research Ethics Committee established by the Health Research Authority

	4	
Research protocol or project proposal	4.0	22 February 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/NW/0756:	Please quote this number on all correspondence

Yours sincerely
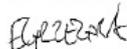
[signature]

**On behalf of
Professor Sobhan Vinjamuri
Chair**

E-mail: nrescommittee.northwest-gmsouth@nhs.net

Enclosures: List of names and professions of members who took part in the
                         review

Copy to: ██████████████████████████

                         Miss Debbie Knight

Appendix 4-H

An Example of Trust Amendment Approval

Our Ref: 15/22

23rd March 2016

Miss Anna C Duxbury
Clinical Psychology - Division of Health Research
Furness College
Lancaster University
Lancaster, LA1 4YG

Dear *Miss Duxbury*,

Study Title: *What is the process by which a decision to administer Electroconvulsive Therapy (ECT) or not is made? A grounded theory informed study of the perspectives of those involved*
REC No: 15/NW/0756

Thank you for sending details/documents of the following amendment to the R&D Office.

Document	Version	Date
Ethics Approval Letter	Amend 4	21 March 2016
Notice of Substantial Amendment	Amend 4	22 February 2016
Twitter Advert	V2	22 February 2016
Twitter Post	V2	22 February 2016
Research Protocol	V4	22 February 2016
Facebook Advert	V1	22 February 2016
Facebook Post	V1	22 February 2016

I am pleased to confirm that the amendment has been noted and approved by the R&D Department. Please keep us informed of any future amendments.

Please ensure that you forward to the R&D department the necessary progress reports when submitting these to the Ethics Committee or when requested by the R&D department. On completion of the study you are required to submit a 'Declaration of End of Study' form and Final Report to the main REC, which should also be copied and forwarded to the R&D office at the address shown above.

Yours sincerely

R&D Director