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Informed consent for pharmacogenomic testing in people with a learning disability

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**INFORMED CONSENT FOR PHARMACOGENOMIC
TESTING IN PEOPLE WITH A LEARNING DISABILITY**

LESLEY GOLDSMITH

PhD 2010

**INFORMED CONSENT FOR PHARMACOGENOMIC TESTING IN
PEOPLE WITH A LEARNING DISABILITY**

by

LESLEY GOLDSMITH

A thesis submitted to the University of Plymouth in partial fulfilment
for the degree of

DOCTOR OF PHILOSOPHY

School of Nursing and Midwifery
Faculty of Health

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Abstract

Informed consent for pharmacogenomic testing in people with a learning disability

Lesley Goldsmith

Background

Advances in genomic healthcare will enable medication to be tailored to each individual's needs, based on subtle genetic variations. This will result in individuals being asked to consent to genetic testing for this purpose. The recent political agenda for social change has emphasised the right of people with learning disabilities to have more autonomy and make their own decisions. There have also been significant changes in the way healthcare practitioners relate to their patients, with a shift away from paternalism towards shared decision-making.

Research Aim

The aims of the study were (1) to explore the information needs of people with mild to moderate learning disabilities with respect to pharmacogenomic tests and (2) to identify ways of facilitating informed consent.

Methods

An integrative literature review was conducted to identify research on informed consent to healthcare interventions in people with learning disabilities (Phase 1). Subsequent phases (Phases 2-4) of the study were conducted using an ethnographic approach.

Phase 2 involved observation of six participants with learning disabilities undergoing a routine blood test consultation in general practice. This was followed by Phase 3, in which semi-structured interviews with 14 participants with learning disabilities were conducted. In Phase 4, three different methods were used: focus groups with carers (four paid carers, five family carers), an on-line bulletin board for healthcare professionals (five participants) and interviews with six key informants from the field of learning disability.

Findings

The data showed consent procedures were often inadequate and there was inconsistent knowledge of mental capacity law amongst health professionals. Provision of information to patients prior to a blood test was variable, but interviews with people with learning disabilities revealed the fact that this information may not be wanted by them. People with learning disabilities viewed pharmacogenomic tests as similar to other blood tests and would want access to them. The attitudes of paid carers and family carers differed in terms of decision-making opportunities for people with learning disabilities.

Conclusions

Healthcare practitioners, carers and people with learning disability need to be familiar with the principles of the Mental Capacity Act to facilitate valid consent in the healthcare context. Healthcare practitioners also need to be made aware of developments in pharmacogenomics if it is to become part of routine health care. Finally, this study demonstrated the value of qualitative research in exploring the knowledge and attitudes of people with learning disability.

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List of abbreviations used in this thesis

ACQ	Ability to Consent Questionnaire
BMA	British Medical Association
BPVS	British Picture Vocabulary Scale
CASP	Critical Appraisal Skills Programme
CTLD	Community Team for Learning Disability
DES	Direct Enhanced Services
GMC	General Medical Council
GP	General Practitioner
HCP	Health Care Practitioner or Professional
IQ	Intelligence Quotient
LD	Learning Disability
MCA	Mental Capacity Act (2005)
MDT	Multi-disciplinary Team
NHS	National Health Service
PWLD	People with learning disability or a person with a learning disability
QOF	Quality Outcomes Framework
RCT	Randomised controlled trial
RBMT-C	Rivermead Behavioural Memory Test for Children

Acknowledgements

The journey towards this PhD probably started many years ago when I decided to embark on a degree with the Open University. Having completed about two-thirds of the degree, life intervened in the form of marriage and the birth of two lovely children and my priorities changed. It was not until I was taking my 18-year old daughter around university open days in 2001 that the idea of continuing my higher education re-surfaced. I was at a stage in my life where I needed a new challenge, so in 2002 I moved to Plymouth to study for a BSc (Honours) Human Biology and Psychology as an undergraduate. Having gained first class honours, I was lucky enough to be offered a six-month post as research assistant working on the GeneSense project at the University of Plymouth. At the end of that contract, I was made aware of some forthcoming PhD studentships in what was at that time known as the Peninsula Postgraduate Health Institute. I was encouraged to apply by the very supportive team I worked for, and was offered a studentship which commenced in January 2006.

I have a particular interest in genetics and learning disability, as my son has Down syndrome; the topic area suggested for the PhD was therefore something I knew would motivate me. I am grateful for the opportunity and funding provided to me by both the Peninsula Postgraduate Health Institute and latterly the Faculty of Health at the University of Plymouth. I feel privileged to have had this chance to further widen my knowledge of subjects of such interest to me.

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Author's Declaration

At no time during the registration for the degree of Doctor of Philosophy has the author been registered for any other University award without prior agreement of the Graduate Committee.

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A. Haddow 7 March 2011

Chapter One

Introduction

1.1 Setting the scene

In the provision of health care, as in many other contexts, valid consent to any intervention is essential. Individuals have a fundamental right to decide what happens to their bodies (Department of Health, 2001a). This principle applies whether the procedure is a simple one, such as screening urine for sugar to exclude diabetes, or a major complex procedure such as surgery for breast cancer. Medicine has become increasingly sophisticated, with a wide range of diagnostic and screening tests available – for example, ultrasound scanning, computerised tomography (CT) and magnetic resonance imaging (MRI) scans, newborn cystic fibrosis screening and more recently, diagnostic maternal blood tests for Down syndrome. These vary in complexity from simple screening or diagnostic tests to procedures that carry a greater degree of risk, all of which entail careful explanation and preparation on the part of the healthcare professional. Detailed discussion of the terms consent and capacity will follow later in this chapter; however, the requirement for the patient to understand any procedure and the risks and benefits involved is universal.

Increasingly, people in the general population will be asked to consent to genetic testing for the purposes of identifying predisposition to common diseases and to personalise drug and other therapies. These tests will not be confined to specific groups in the population, and so should be routinely available to people with learning disabilities (LD). People with learning disabilities, however, are only one of several sectors of the general population

who are classed as vulnerable with respect to gaining valid consent. Research has been conducted into the ability of people with cognitive impairment (Collier, 1998; Fisk, Beattie & Donnelly, 2007; Howe *et al.*, 2005), Alzheimer disease (Karlavish *et al.*, 2005) and various psychoses (Jeste *et al.*, 2003; Palmer & Jeste, 2006) to consent to both treatment and research. The consensus from these and other similar papers is that neither age nor diagnosis should be used to make judgements of capacity. Fisk and colleagues (2007) state that:

“Competency is not a unitary or static construct and must be considered as the ability to make an informed decision about participation in the particular context of the specific treatment or study” (p 411)

The functional approach to assessing capacity acknowledges that understanding can be partial and often fluctuates (Collier, 1998). In contrast to people with dementia or mental health problems, capacity in people with learning disabilities is less likely to fluctuate with time, but is likely to differ depending on context and complexity of the decision to be made (Department of Health, 2001b). Capacity may also be affected by any co-existing mental health problems.

The aims of this programme of study were to explore the needs of people with learning disabilities with respect to consent for new types of genetic tests used for health care management, focusing on pharmacogenomic testing, and to identify ways of facilitating informed consent. The rationale was to inform the development of effective ways of facilitating informed consent in people with learning disabilities to ensure that they have equity of access to advances in genetic health care.

Ensuring that the client has a full understanding of the purpose of a blood test and its benefits and risk is a challenge in any context. It has been shown that the general public find the science of genetics difficult to understand, although there is much 'lay' perception of inheritance within families (Henderson & Maguire, 2000; Richards, 1996). Little research has been carried out into what people with learning disabilities understand about genetics, or indeed genetic testing. Researchers based at the Norah Fry Centre in Bristol explored the knowledge and understanding of people with learning disabilities in relation to prenatal screening and diagnosis (Ward, 2001). This work illustrated the importance of not only making new knowledge accessible to people with learning disabilities, but also involving them in policy discussions. With the rapid advances taking place in the field, it is important for this type of exploratory work to be done so that as pharmacogenomic testing moves from the research field into clinical practice, the benefits can be made available to all.

Before describing the background to this study, I will clarify some of the terminology used in this thesis. I will then outline the general topic of consent and how it relates to people with learning disabilities, the genetics White Paper "Our inheritance, our future" (Department of Health, 2003c), its implications and the advances in genetics (the 'new' genetics) which made it necessary, and previous research relevant to this study. To conclude this introduction, I will describe some theories and models that I consider may have relevance to this study.

1.1.2 Terminology used in this thesis

Learning disability

A person with a learning disability can be said to have intellectual impairment and social or adaptive dysfunction, both of early onset (British Institute of Learning Disabilities, 2004). The term used to describe someone with a learning disability has changed over the last few decades. In the 1980s the term in common use in the United Kingdom (UK) was *mental handicap*. By the 1990s the term *learning disability* came into common use (British Institute of Learning Disabilities, 2004). The term *intellectual disability* is also used – widely in Australasia and by some academics in the UK (Burton, 1997). More recently some people with learning disabilities and organisations prefer the term *learning difficulty* (for example, People First, 2010). In the US the term *mental retardation* is still used in some academic papers, although this is increasingly being replaced by *intellectual disability* (AAIDD, 2010). In this thesis I shall use the term *learning disability* except when citing research in which alternative terms are used.

Pharmacogenomics

The original title of this thesis included the term *pharmacogenetic testing*. There are various definitions of the terms *pharmacogenetics* and *pharmacogenomics*:

“pharmacogenetics starts with an unexpected drug response result and looks for a genetic cause”

“pharmacogenomics on the other hand begins with looking for genetic differences within a population that explain certain observed drug responses to a drug or susceptibility to a health problem”

(Centre for Genetics Education, 2007)

The Australian Centre for Genetics Education (2007) uses these terms interchangeably. However, the term *pharmacogenomics* now seems to be

accepted when describing the tailoring of medication and the reduction in adverse drug reactions based on individual genotype (Human Genome Project, 2008). Pharmacogenomics implies an awareness of environment as well as genes, and this is the term I will use in this thesis, except when citing literature or quoting participants using different terminology.

People

I would also like to clarify the terms used for the various participants in this study. People with learning disabilities can be patients, clients or service-users depending on the context. People caring for them can be parents, carers (paid or unpaid) or support workers. I will use the term *carer* unless there is a need to be specific. Another term used in this study is 'supporter', which has a literal meaning and could be applied to parents or other carers. In the context of the consent process for this study, and for interviews, the supporter was someone the participant with learning disabilities chose to support them on that occasion. Terminology varies from organisation to organisation, and from time to time, so it is difficult to be consistent. I consider that use of the various terms will be self-explanatory in context.

1.2 Concepts of informed consent and capacity

Consent to treatment lies at the heart of the relationship between patient and healthcare professional (UK Clinical Ethics Network, 2008). The historical background to the development of consent law is of relevance to this study. The publication of the Nuremberg Code (1947) and the Helsinki declaration (World Medical Association, 1964) reflected the growing concern about the unethical treatment of vulnerable groups such as those with 'mental handicap'.

To some extent, these measures were a response to eugenic practices, for example the unethical medical experimentation carried out in Nazi Germany (Harper, 2008). However, Harper considered that the concerns of the medical genetics community in relation to unethical eugenics practice reflected issues that were relevant to medical practice as a whole. With increasing emphasis on person-centred health care (Department of Health, 2009c), it is important that the patient understands the decision they are making when they give consent to any form of healthcare intervention. Obtaining informed consent involves, amongst other things, giving patients sufficient information to ensure that they understand the concepts involved and any possible risks and future implications of testing or treatment. Professional bodies such as the General Medical Council (2008) and the British Medical Association (2009), alongside UK government departments such as the Department of Health (2001c, 2009d), have published guidelines to facilitate best practice.

To set this study into context, the concepts of consent and capacity have evolved differently in the UK and United States of America (USA). Arscott *et al* (1999) quote the UK Law Commission's (1991) definition of capacity as 'an understanding in broad terms of the nature and likely effects of what is to take place' (p 29). Murphy and Clare (1997) state that in England and Wales there is an assumption of capacity (to make decisions) in anyone over the age of 18. In the UK, prior to the implementation of the Mental Capacity Act (2005) in 2007, if there was any doubt about an individual's capacity decisions about that capacity were based on previous common law decisions. For example, Mr Justice Thorpe, in *re C (Adult: Refusal of Treatment)* in 1993 stated that there were three stages involved in the patient's decision whether or not to consent to

surgery – ability to understand and retain the relevant information, to believe it, and to weigh up the risks and benefits and any other relevant information to make the decision (Medical Law and Research Online, 1995). This judgement is commonly quoted in research and guidance on consent, for example by the UK Clinical Ethics Network (2008). The Law Commission subsequently produced a report in 1995 that reiterated the following criteria for capacity to consent: ability to understand and retain relevant information including the consequences of any decision made, and to weigh that information when making a decision (Law Commission, 1995). This report was not implemented as law, but at this time there were three approaches to the assessment of capacity, according to Murphy and Clare (1997):

- The *status (or diagnostic) approach* in which capacity or lack of it is based on a person's diagnosis;
- The *outcome approach*, where people make what is considered by the healthcare professional as an unwise or irrational decision and this is seen as a sign of mental incapacity;
- The *functional approach*, which involves assessment of the three criteria outlined above – the ability to understand and retain the information relevant to the decision to be made, and to weigh up that information in the process of making a choice.

In England and Wales, the functional approach to assessment of capacity has now been adopted following the consultation paper 'Who decides?' (Department for Constitutional Affairs, 1997) and the subsequent government report, 'Making decisions' (Department for Constitutional Affairs, 1999). In 'Making Decisions', it was stated that The Law Commission recommended a 'functional approach' to

determining capacity. The main rationale behind the functional approach is that capacity only relates to the particular decision to be made, at the time the decision is made, and that the individual has to understand the nature and effect of the decision; it also implies that individuals may be considered to have capacity in some contexts and not others because the level of capacity will depend on the complexity of the decision to be taken, and also on other factors such as the patient's current health status or anxiety levels. By using the functional approach, according to this report, the individual is able to exercise the 'maximum decision-making powers possible'. This is now the approach encapsulated in the Mental Capacity Act 2005, alongside the assumption that there is capacity unless proven otherwise. The Mental Capacity Act (Department of Health, 2005c) in England and Wales has formalized the procedures relating to assessment of capacity in those cases where capacity is in doubt, and is designed to protect vulnerable adults without capacity.

According to the Mental Capacity Act (2005), where any doubt exists, the capacity of the person to take the decision in question must be assessed, using the assistance of specialists (such as speech therapists) to make the information accessible. No specific assessment tool is identified; the onus is on the healthcare professional involved in the decision to make a judgement - for example, by exploring a person's ability to paraphrase what has been said (Department of Health, 2001b).

Much work has been carried out in the USA on mental capacity; in the 1980s by Appelbaum and Roth (1982) and Appelbaum and Grisso (1988). Grisso and Appelbaum (1998) distinguished between competence and capacity by considering that a person's competence (a legal term) depends on assessment

of functional abilities or 'capacities'. The following standards for assessing functional capacity emerged as a result of research by the above authors:

- Ability to express a choice
- Ability to understand relevant information
- Ability to appreciate the significance (of the decision) and consequences for self
- Ability to reason with relevant information to weigh up the options.

Having outlined the various components of capacity, valid consent requires three elements to be satisfied. These are disclosure of information relevant to the decision, capacity (or competence) to make that decision, and the ability to make that decision in a voluntary manner, free from coercion. These three criteria appear to be fairly universal – certainly they are applied in the USA, the UK, Ireland and Australia, for example (Department of Health, 2001c; Grisso & Appelbaum, 1998; Hillery *et al.*, 1998; Iacono & Murray, 2003).

Genetic testing, like other medical procedures, requires informed consent, and individuals with learning disabilities should not be presumed unable to consent (Williams, Skirton & Masny, 2006). Consent in medical genetic practice is given special consideration in a report produced by the Joint Committee on Medical Genetics (Royal College of Physicians, 2005). It is acknowledged that whilst the general principles of consent apply for genetic tests, it is essential that consent should be obtained prior to any test with genetic implications, and also before genetic information is disclosed. The possible distinction between non-genetic and genetic tests will be discussed later in this chapter.

Factors such as the patient's level of education and their attitude to genetic testing will influence their perception that they have given informed consent. Who provides the information, the time allowed and the setting will also have an effect (Lea, Jenkins & Francomano, 1998). Research has shown that, by using the functional approach in assessing capacity and thus identifying ways of maximising capacity, it is possible to achieve capacity in some people with learning disabilities (Arscott, Dagnan & Kroese, 1998; Arscott, Dagnan & Kroese, 1999; Cea & Fisher, 2003; Fisher *et al.*, 2006; Morris, Niederbuhl & Mahr, 1993; Wong *et al.*, 2000). The range of abilities within the population of people with learning disabilities is wide, and adults should always be presumed to be capable of taking healthcare decisions, unless the opposite has been demonstrated (Department of Health, 2001b). However, the International Society of Nurses in Genetics (ISONG) (2005), in a position statement on informed consent and decision-making, states that information should be tailored to the ability of the individual.

1.3 Health care for people with learning disabilities

According to a recent report approximately 985,000 (2% of the adult general population) in the UK have a learning disability (Emerson & Hatton, 2008). However, less than 20% of these use services for people with learning disabilities. In Scotland, a report by one of the largest social care charities has stated that a significant proportion of adults with learning disabilities constitute an 'invisible' population, particularly if they are living with family at home (Johnston, 2008). It is therefore likely that the prevalence of learning disability in the population in the UK (approximately 2%) is an underestimate, in view of

the fact that there are many people with learning disabilities living 'invisibly' in the community.

Research has shown that people with learning disabilities and people with mental health problems are more likely to have significant health risks and major health problems than the general population (Disability Rights Commission, 2006). *Healthcare for All*, a report written in response to 'Death by Indifference' (Mencap, 2007) describes how 'the 'most vulnerable members of our society', including many of those with learning disabilities, have 'significantly worse health than others' (Michael, 2008, see Executive Summary p8). Evidence provided for the purpose of this report confirmed that it is harder for people with learning disabilities to access assessment and treatment for conditions not directly related to their learning disability. Factors such as diagnostic overshadowing, limited communication skills on the part of the healthcare staff and limited knowledge of learning disability have all contributed to this inequality. Among the recommendations outlined in 'Healthcare for all' is the requirement to make 'reasonable adjustments' (p10) to the services provided to vulnerable groups. It is also suggested the healthcare professionals are made more aware of the greater risks of premature death in people with learning disabilities.

1.4 Recent advances in healthcare genetics

1.4.1 Background

The new generation of genetic testing differs from testing for rare single gene disorders or chromosome anomalies in terms of those who might utilise it. New molecular genetic tests may provide a tool for health management, compared to

diagnosis and antenatal screening. People with learning disabilities are as susceptible as anyone else, and sometimes more than others (Michael, 2008), to common diseases such as coronary heart disease and diabetes. As such they should be adequately informed and supported to make their own choices. This is necessary in the context of rapid advances being made in screening, diagnosis and prediction of disease, and in particular pharmacogenomic testing (see below). As part of the background to this study, I will outline the genetics White Paper, its implications and the advances in genetics (the 'new' genetics) that made it necessary, together with the nature of 'genetic tests' and how this can affect the consent process.

1.4.2 The UK context

One of the main objectives of the genetics White Paper, 'Our inheritance, our future' (Department of Health, 2003c), was to increase *public* and *professional* understanding of genetics. It is important to consider not only the general public and health professionals, but also those who may be considered not to have the capacity to understand such concepts –such as those with learning disability. In the White Paper it was claimed that the 'new genetics' would facilitate:

- more personalised prediction of risk
- more precise diagnosis
- more targeted and effective use of drugs
- new gene-based drugs and therapy
- preventive regimes tailored to a person's individual genetic profile.

Progress is already being made in the hunt for susceptibility genes for diseases, such as Type 2 diabetes and schizophrenia, which will facilitate future management of patients (Carlson *et al.*, 2004; Emery & Hayflick, 2001).

In recognition of the potential of the new genetics, the White Paper states:

'the greatest impact of genetics on healthcare in the shorter term is likely to come from pharmacogenetics'

(Department of Health, 2003c, Summary p4)

The basic concept in pharmacogenetics is that a patient's genotype can affect the way he or she responds to drug therapy. Pharmacogenomics is the use of genetic or genomic techniques to determine individual differences in drug effectiveness and toxicity (Williams, Skirton & Masny, 2006). Variants in the cytochrome P450 multigene family are the focus of much current research, and enzymes encoded by these genes are responsible for metabolising most drugs used today, including many for treating psychiatric, neurological and cardiovascular diseases (US Department of Energy, 2003). The rapid advances in genetic testing over the past decade or so mean that it may be feasible for drug treatments and dosages to be tailored to an individual's genotype in the foreseeable future (Corrigan, 2005). In the USA the Food and Drug Administration (FDA) has authorised the first genetic test for warfarin sensitivity (based on variants of the CYP2C9 and VKORC1), and some drug labels incorporate genetic information (Jones, 2007). These advances should result in increased therapeutic efficacy and fewer adverse reactions (The Royal Society, 2005), and it is essential that people with learning disabilities should be in a position to benefit from them.

1.4.3 Genetic exceptionalism

Having considered consent and the criteria for obtaining it, I will now consider the nature of the 'genetic test' itself. What is a genetic test, and does it differ from a routine screening blood test, such as a cholesterol level? There is no clear definition of what can be considered a 'genetic test'. One such definition is 'a test of anything that is, or potentially can be, inherited according to Mendelian laws' (Godard *et al.*, 2003). However, these authors go on to state that if the test result has no predictive value for the subject or family members, it has no features that distinguish it from other tests. They also suggest that even if the test is predictive for the subject, it can be considered as ethically similar to some other ('non-genetic') tests. Skirton and Patch (2009) describe the difficulty in distinguishing a genetic test from a 'routine' one, but consider that a useful definition of a genetic test is one for which the results may have implications for the wider family as well as the patient being tested. Most of the debate about genetic exceptionalism – which considers genetic tests as different from other screening tests on healthy patients – relates to predictive genetic tests (see for example, Green & Botkins, 2003). These include genetic tests for disease susceptibility or specific late-onset diseases such as Huntington disease or BRCA1/BRCA2 testing for risk of breast cancer. The information obtained from both non-genetic screening tests and predictive genetic tests can be used to advise both patients and healthcare professionals on future management and lifestyle changes (Green & Botkins, 2003). However, predictive genetic tests often have implications for other family members. Pharmacogenetic testing is an interesting anomaly, because this type of test is used to identify genotype at a specific gene location, (for example the

CYP2C9 gene for warfarin metabolism (Rieder, 2007), its application is in the health management of the individual patient and it has been considered not have implications for other family members. In this way, it could be said to be no different to any other screening or monitoring blood test. However, recent research has shown that this is not necessarily the case, and that 'ancillary information' such as disease risk information could also be identified (Henrikson, Burke & Veenstra, 2008). Two important reports provide guidance for healthcare professionals when obtaining consent for genetic tests. The Human Genetics Commission, 'Inside Information' (2002) and a report from the Joint Committee on Medical Genetics (2005) describe the different types of genetic tests, and contain guidance on sharing genetic information with wider family members. The authors of the latter document also discuss the amount of sensitive information provided by a genetic test, and state that the amount of information provided in order to obtain informed consent needs to take this into account. For the purposes of this study, I will consider pharmacogenomic tests as belonging to the wider category of blood tests used in the screening or health monitoring of healthy patients – for example, blood cholesterol, blood glucose or serum levels of various medications. The issue of how much information is needed for a patient to give consent to this type of test is a debatable one. Patients should not be given more detail than they need, as this might confuse them - a simple, broad explanation may well be enough, as suggested in the Code of Practice for the Mental Capacity Act (2005)(Ministry of Justice, 2007). Recent professional guidance included a clause that information given to the patient should be tailored to the complexity of the treatment (General Medical Council, 2008). A general principle is that any significant

risks must be understood by the patient for consent to be valid (Department of Health, 2001c). When health professionals are sharing information with their patients for the purposes of obtaining informed consent, it is acknowledged that the amount of information needed can vary with the individual circumstances of the patient. A tailored approach should take into consideration factors such as the patient's wants and needs, their level of knowledge about, and understanding of, their condition and the complexity of the proposed treatment (General Medical Council, 2008).

1.5 Previous research relevant to this thesis

When considering previous research relevant to this thesis, it is necessary to look further afield than the topic area being researched. Research carried out in the field of consent for genetic screening and testing has mainly been on antenatal screening and diagnosis, and has identified problems in obtaining *informed* consent (Green *et al.*, 2004; Rostant, Steed & O'Leary, 2003; Williams, Alderson & Farsides, 2002). Most studies have tended to focus on two aspects:

- a) the knowledge, understanding and attitudes of the healthcare professionals involved
- b) the knowledge, understanding and attitudes of the patients themselves.

Research into lay understanding of inheritance and genetics (Henderson & Maguire, 2000; Henneman, Timmermans & van der Wal, 2004; Richards & Ponder, 1996) has shown levels of genetic knowledge that would appear to be low, although this was mainly applied to knowledge of single gene disorders or chromosomal anomalies. Such a level of knowledge would also be inadequate

to understand the concepts and associated implications of the myriad of genetic screening and tests currently available (or likely to be available) in the foreseeable future.

Looking at the wider picture, there is a body of evidence on the subject of consent in people with learning disabilities, covering issues such as financial decision-making (Suto *et al.*, 2005a), housing choices (Bowey, McGlaughlin & Saul, 2005), consent to a sexual relationship (Murphy, 2004) and health care interventions (Arscott, Dagnan & Kroese, 1999; Wong *et al.*, 2000). Much of this work includes empirical data and discussion about capacity to consent. In addition to the previously discussed increased health risks and inequities of access to health care for people with learning disabilities, evidence also suggests that informed consent to screening can be problematic. For example, coverage in the cervical screening programme in the UK is lower for women with learning disabilities (Stein & Allen, 1999). The authors suggest that one of the contributing factors to this could be perceived difficulty in obtaining informed consent. This view is supported by a review of the literature carried out by Broughton (2002) who suggests that women with learning disabilities need the appropriate knowledge and support from health professionals in order to make an informed choice about screening. This problem is not unique to the learning disabled population – the concept of fully informed consent has been questioned in the general population of women eligible for cervical screening (Philips, Avis & Whyntes, 2005; Slater, 2000).

1.6 Need for further research

There is currently an emphasis on person-centred care in the UK, as evidenced by publications such as 'Our health, our care, our say' (Department of Health,

2006b), and it is important that this principle includes, as far as practically possible, people with learning disabilities. Authors of White Papers such as *Valuing People* (Department of Health, 2001d) and the Disability Rights Commission's report, *Equal Treatment – Closing the Gap* (2006) have stressed the need for equity of access for people with learning disabilities. It is important that these people benefit from the recent advances in medical knowledge, including those in genetics. The challenge will be to facilitate informed consent in these individuals. In order to obtain informed consent, there should be meaningful communication between healthcare professionals and patients. It will therefore be useful to assess the attitudes of healthcare professionals involved in the care of people with learning disabilities. There is evidence that some healthcare professionals make an assumption that people with a learning disability lack understanding when having to make decisions about their treatment (Carlson, 2004; Keywood, Fovargue & Flynn, 1999). There is also evidence, however, that capacity can be optimised by tailoring presentation of information to the needs of the individual (Cea & Fisher, 2003; Wong *et al.*, 2000). Pharmacogenomics is a developing field in health care, and in anticipation of the introduction of such tests in primary and secondary care settings, research is needed to explore what support and information people with learning disabilities need to facilitate capacity and thus valid consent to pharmacogenomic tests.

Wong's (2000) quantitative study provides useful data on the level of capacity to consent to a blood test. Qualitative research involving people with learning disabilities and consent and their experiences in the primary healthcare setting is rarely reported. In the UK, health action plans for people with learning

disabilities have been introduced in some parts of the country as the result of a new primary care contracting framework (National Health Service Primary Care Contracting, 2007). It is likely that annual health checks on all people with learning disabilities will soon be common practice in the UK, as the Department of Health has now incentivized these as part of Direct Enhanced Services (DES) in general practice (Cobb, Giraud-Saunders & Kerr, 2008; NHS Confederation (Employers) Company, 2008). These health checks are now part of NHS services in Wales (Felce *et al.*, 2008) New Zealand (Webb & Rogers, 1999) and Scotland (Cooper *et al.*, 2006) and are likely to include screening blood tests such as serum cholesterol. Wong *et al* (2000) state that the decision about whether or not to have a blood test is a common healthcare decision for people with and without a 'mental disability', and that this allows direct comparison between groups. Arscott *et al* (1999) suggested that it would be useful to study the ability of people with learning disabilities to consent when they undergo 'real life' interventions, rather than relying on hypothetical vignettes. This has now been done in several studies using quantitative methods (Dye, Hare & Hendy, 2007; Wong *et al.*, 2000).

The conclusion from the research into consent in various populations and the wealth of guidance for healthcare professionals on how to obtain it, in users with and without learning disabilities, suggests the challenging nature of obtaining *informed* consent in people with learning disabilities. In particular, with reference to consent to genetic testing, it is important to consider the question of how much information is needed, and the best methods of providing it – taking into account the views and attitudes of not only the service-users, but also their carers and the healthcare professionals involved in their care.

1.7 Relevant theories and models

When exploring the subject of consent in people with learning disabilities, there are several relevant theories and models that should be examined first. A secondary aim of this research was to facilitate a greater level of informed consent in this group of people by exploring the experiences and attitudes of not only the people themselves, but also of those around them. There have been major changes in the way people with learning disabilities are cared for and educated in the past few decades and this is the result of various sociological theories and subsequent government policies in the UK. It is difficult to be selective – strategies such as normalisation, social role valorisation, empowerment or personalisation have all been written about by academics, policy-makers, healthcare professionals, sociologists and politicians in an attempt to improve the everyday lives of people with learning disabilities (and other vulnerable groups). Examples of these include such publications as 'Valuing People' and 'Valuing People Now' (Department of Health, 2001d; Department of Health, 2009c), 'Improving the Life Chances of Disabled People' (Prime Minister's Strategy Unit, 2005), 'Independence and Opportunity' (Department for Communities and Local Government, 2007) and 'Promoting Equality' (Department of Health, 2007b).

It is not only in the field of learning disability that changes have occurred. There has been a movement in healthcare from the paternalistic model of care to shared decision-making, culminating in guidance from the General Medical Council on how doctors and patients should make decisions together (General Medical Council, 2008). The approach to health care is changing; patients are being given more power. The UK Government White Paper 'Our health, our

care, our say' (Department of Health, 2006b) illustrates the government's response to the public's wishes to be more involved in their health care – to make choices and take control, but a subsequent paper, 'Independence, choice and risk: a guide to best practice in supported decision making' (Department of Health, 2007c) warns of the 'practicalities of managing risk in relation to choice' (p2, Executive summary).

I will focus here on three key theories or approaches– those of empowerment, the social model of disability and shared decision making. To put these theories into context, I would also like to conclude by outlining some aspects of role theory that may be of relevance to this study.

1.7.1 Empowerment

The act of empowerment can be defined in two ways:

- To give (someone) the authority or power to do something
- To make (someone) stronger and more confident, especially in controlling their life and claiming their rights.

The fact that empowerment implies the giving of power from someone in authority to someone with less power is stressed by Steve Dowson (1997). The Green paper, 'Independence, Well-being and Choice' (Department of Health, 2005b) was written with the aim of giving more control to adults in social care, but there is evidence of the practical problems involved in attempts to achieve this aim (Finlay, Walton & Antaki, 2008; Jingree & Finlay, 2008). These authors note the conflicts that staff can experience when attempting to follow the principles of empowerment; these include risk versus choice, the demands of

the organisation that employ them and the influence of family members, who may have views on the choices of the individual with a learning disability.

I would like to add a personal reflection here; I have experienced this conflict personally as the parent of a son with learning disabilities living in 'supported living' accommodation. I have witnessed the constant conflict between the difficulties of *allowing* the individual to have choice and make their own decisions and the benefits of doing so to that person. The procedures for risk assessment are time-consuming and labour intensive, and I consider that *giving* the person with learning disability power and control over their own lives is indeed difficult to achieve in practice. Alongside this, even if choice is *allowed*, the choices are probably limited by the organisation or society as a whole.

Following consultation, the Green paper led to the publication of 'Our Health, our care, our say' (Department of Health, 2006b) which stated that there would be a radical shift in the way services were delivered, making them more personalised and giving people more voice in driving improvement in services. This is made clear in the Easy Read version of this White Paper (Department of Health, 2006a):

You will be in charge of your own health. You will get better information so you can make choices about staying healthy and well.
(p 7)

It is interesting to note, however, that in a progress report (Department of Health, 2007a) published a year later there is little mention of participants with learning disabilities. Although it is stated that excluded groups were given extra weight in this report, it included people in black and minority ethnic groups, unemployed, people with no qualifications, carers, single parents,

people in poor health and people with long term conditions – but there is no mention of people with learning disabilities.

In 'Empowerment in everyday life: Learning Disability' (Ramcharan *et al.*, 1997), Steve Dowson comments that in reality, people with learning disabilities have very little choice about whom they see, what they do and what they eat, for example. He suggests that as the drive for empowerment has come from social and healthcare professionals and policy makers, there is good reason to suppose that their interests may not be served by 'allowing' this power. I consider that empowerment is of relevance to this study, as it is implicit in the changing approach to people with learning disabilities in the UK. It is difficult to conduct research involving people with learning disabilities without considering the concept of empowerment.

Having considered empowerment from the point of view of the person with learning disability, I would now like to describe the social model of disability which came to the forefront of the disability movement in the 1990s and how it might have relevance for people with learning disabilities in terms of their position in society.

1.7.2 The social model of disability

Mike Oliver coined the phrase 'the social model of disability' in 1983 and has written much subsequently (for example, Oliver, 1990). The theory of normalisation (later to evolve into social valorisation) originated mainly from the work of Wolfensberger (1983). This approach had dominated the learning difficulty agenda, but was losing support by the late 1980's and early 1990's, to be replaced by the idea of the social model of disability (Chappell, 1998).

Walmsley (2001) considered that although normalisation contributed to the empowerment of people with learning difficulties, it was an idea which had been developed without any input from the people with learning difficulties themselves. This view is supported by a more recent contribution from Oliver (2009), who stated that normalisation theory was:

"trying to impose 'normality' on disabled people - whereas 'empowerment' is a collective process of transformation on which the powerless embark as part of the struggle to resist the oppression of others, as part of their demands to be included and/or to articulate their own views of the world." (p 102)

The social model of disability, which originated from the arguments of the Union of Physically Impaired Against Segregation (UPIAS), states that people with *impairments are disabled* by society, and therefore considers disabled people as an oppressed group (Shakespeare, 2010). It is interesting to note the term '*physically impaired*'. Chappell (1998) considered that the experiences of people with learning difficulties were marginal to the social model of disability because this model assumes that disability is physical. Tom Shakespeare, in a recent essay (Shakespeare, 2010), explained that the social model of disability was constructed by a group of people who mainly had *physical* impairments and did not appear to be in any minority social group. He considered that had UPIAS included people with learning difficulties, people with mental health problems or complex physical problems, their definition of disability would have been quite different.

How people with learning disabilities view their own identity may affect their ability to make decisions; as such, exploring this model in relation to the findings may be illuminating. Finally I would like to outline the ideology of shared

decision-making and consider power from the point of view of the healthcare professional.

1.7.3 Shared decision-making

Many people with learning disabilities are not involved in decisions concerning their healthcare (Fovargue, Keywood & Flynn, 2000). Research conducted prior to the implementation of the Mental Capacity Act (2005) in 2007, revealed that there were still a number of vulnerable people who felt powerless when it came to decision-making, and the authors concluded that there was variation in the levels of knowledge of mental capacity amongst health and social care providers and that service users expressed the need to be heard and wanted support in making decisions for themselves (Myron *et al.*, 2007). In parallel to the developments designed to give vulnerable people, such as those with learning disabilities, more control over their lives, there has been a move in the area of healthcare towards shared decision-making. This policy is obviously aimed at the public as a whole, but how will it affect those with learning disabilities?

Angela Coulter (1999) considered that although 'paternalism is endemic in the NHS' (p 719), there was a growing movement to making relationships between health professionals and their patients more equal. She also comments that little is known about patients' desire for this change. In particular, she states that younger people are more likely to be critical of the paternalistic attitude of doctors, in contrast to older people or people with serious illnesses who may be more likely to prefer the doctor to make the decision. It may also be difficult for doctors to adopt this change in role; a focus group study with general practice registrars (Elwyn *et al.*, 1999) found that these health professionals, who were

at the start of their career as General Practitioners (GPs), had a wide range of attitudes towards the role they played in decision making. Some still preferred the paternalistic role while others were happy to embark on shared decision making. The authors considered that any developments in shared decision making would rely upon the skills and attitudes of the health professionals involved. Interestingly, they also stressed the importance of reliable information, appropriate timing and the willingness of patients to be involved in the decision. In a later study from the same research centre, focus groups of experienced GPs were conducted and the authors concluded that although the participants' views were that the ethos of shared decision making should be adopted by all, there were challenges to the interpersonal skills and information requirements which needed to be overcome (Elwyn *et al.*, 2000). Eight years later, the General Medical Council (GMC) published a guidance document for doctors on how shared decision making should be approached (General Medical Council, 2008); can it now therefore be assumed that this ethos has been accepted into common practice? The reality of this in relation to the findings will be explored in the discussion chapter.

The combination of this change in the way doctors are supposed to consult and the demands of the new Mental Capacity Act (2005) provided a useful background to this study, and how people with learning disabilities might be affected. In this study, I have collected data from 'patients' and healthcare professionals; therefore it will be useful to relate developments in shared decision-making policy with the findings.

1.7.4 Role theory

To conclude this chapter, I would like to give a short account of role theory. There are five approaches to role theory rather than one integrated theory (Biddle, 1979). The first two are based on the sociological perspectives of functionalism and symbolic interactionism. Functional role theory is exemplified by such sociologists as Talcott Parsons, who analysed social systems by considering actions and interactions of individuals in a stable society. Parsons concluded that these social systems included cultural symbols that were understood by all (Parsons, 1991).

Parsons' approach, commonly known as 'structural functionalism', according to Biddle (1986) was on the decline by the mid 1970's. Biddle points out some of the pitfalls of functional role theory – in particular, that not all roles are associated with a particular social position, and also that social systems are not necessarily stable. Functionalism has a 'macro' approach to society and views society as a stable structure. In contrast, the other sociological perspective, symbolic interactionism "*emphasises the small-scale interactions of individuals, not society as a whole*" (Giddens & Griffiths, 2006). Biddle lists three other approaches to role theory. Firstly, structural role theory in which the influence of society on roles is more important than the individual, and which uses mathematic symbols. Biddle is dismissive of this approach. Secondly, he cites organisational role theory, which is concerned with roles in organisations and the effect of role conflict. Of particular interest to this study is work by Allen and van de Vliert (1984) which explores the effect of changes in social position or expectations. Finally, a role theory that emanates from cognitive social psychology – cognitive role theory. This approach also contains several

subfields of research, for example role playing (Moreno, 1934), and norms (Sherif, 1936). Biddle considers that cognitive role theory is the most useful in terms of a broader research base (Biddle, 1986)

Having looked at the different theoretical perspectives which can be applied to role theory, I do not consider it necessary to focus on one particular approach. There is consensus about certain basic elements of role theory. Biddle states that *role* is related to notions such as social position, expectations and context, and that "*many roles are embedded in social systems*" (p 7) Despite the lack of unity in role theory mentioned above, Biddle (1979) states that there are several propositions on which there is agreement; some of these may be relevant to this study:

"Roles are often associated with sets of persons who share a common identity"

"Persons are often aware of roles, and to some extent roles are governed by the fact of their awareness (ie by expectations) (p8)

According to Biddle (1986) it is common belief among role theorists that experience will influence a person's expectations, which will in turn generate a particular role. Shared identity in relation to role behaviour in people with learning disabilities is a difficult concept to explore, as there may be some conflict about identity as a learning disabled (or intellectually disabled) person (for example, Craig *et al.*, 2002). Organisational role theory suggests that roles in organisations are linked to certain social positions, and problems can arise when the roles, or the expectations related to them, change (Biddle, 1986).

In the context of this study, I am interested in the role of both the person with learning disability, the healthcare professional, and of equal importance, the

carer and how these may have changed over the last few decades. I will therefore return to the above theoretical approaches in the discussion chapter, in relation to the findings.

In this chapter, I have described recent advances in genetics which may lead to improved health management. In order for these advances to be made available to the whole population, including those with a learning disability, attention should be paid to the issues of informed consent and access to health care which relate to this group of people. I have also described some theoretical approaches which may be of relevance to this study.

In the next chapter, I describe the findings from a systematic review of the literature on informed consent to healthcare interventions in people with a learning disability.

Chapter Two

Informed consent to healthcare interventions in people with learning disabilities – an integrative review (Phase 1 of study)

2.1 Aim of this review

Consent to treatment lies at the heart of the relationship between patient and healthcare professional and 'the focus on patient centred care and shared decision- making highlights the importance of informed consent' (UK Clinical Ethics Network, 2008) . In order for people with learning disabilities to have equity of access to health care, they need to be able to give informed consent to health interventions – or be assessed as incompetent to give consent. Although the law concerning consent varies, it is now widely accepted that there should be presumption that an individual has capacity to give consent unless proved otherwise (Keywood, Fovargue & Flynn, 1999); this presumption can be overturned if it can be shown that the patient is not able to comprehend and retain information that is material to the decision, including the likely consequences of having or not having the proposed treatment, or is unable to use the information and weigh it in the balance as part of the process of arriving at the decision. Wong *et al* (2000) state that in English law there is a presumption that adults aged 18 or over have capacity. The Mental Capacity Act (2005) in England and Wales, which attempts to clarify issues of consent and capacity, became law in 2007 (Department of Health, 2005c), and is underpinned by five principles, three of which are relevant for this review –

- Presumption of capacity

- The right for individuals to be supported to make their own decisions
- The right for individuals to make what might be seen as eccentric or unwise decisions

In the United States also the law presumes patients' competence – or decision-making capacity - unless for some reason this is questioned (Appelbaum & Grisso, 1988). It should be noted here that in the United States there is distinction between the terms '*capacity*' and '*competence*'. According to Gunn *et al* (1999), the former is a general concept and the latter a specific one. Grisso and Appelbaum (1998) refer to '*competence*' as a legal concept, explaining that an assessment of (legal) competence should include an investigation into an individual's functional abilities or capacities in any particular situation; these include ability to express a choice, to understand relevant information, to appreciate the context and significance of the information, and to reason with the information to make a choice.

In the UK, various guidelines and government reports have been produced in an attempt to facilitate equity of access to health care and other services for people with learning disabilities, and to address the problem of informed consent (Department of Health, 2001b; Department of Health, 2001d). Much has been written about the situations in which there may not be capacity (Appelbaum & Grisso, 1988; Dimond, 2001; Hutchinson, 2005; Keywood, 1998); and the various approaches to assessing capacity (Arscott, 1997; Grisso & Appelbaum, 1998; Morris, Niederbuhl & Mahr, 1993). When investigating informed consent, it is important to consider users' perspectives and healthcare professionals' perspectives, as well as those of carers or anyone else involved

in the process of gaining informed consent for healthcare interventions. In this integrative review, I will assess empirical evidence relating to informed consent (to include assessment of mental capacity) to healthcare interventions for people with learning disabilities. In order to gain a comprehensive picture, I will include research involving participants with learning disabilities as well as that including healthcare professionals or carers.

2.2 Objectives

Whittemore and Knaff (2005) stress the importance of identifying the problem and purpose of the review in order to focus the integrative review process. The objectives of the review were:

- to familiarise myself with relevant background material and previous research in this field
- to clarify the research question(s) to be answered, and the focus of the proposed empirical research project
- to ascertain the range of methods being used in this research field to enable me to make informed and appropriate choices in my own research.

2.3 Methods

2.3.1 Searching the literature

A clear definition of what is meant by an integrative review was not easy to locate. In the 1980s, such a review was described as 'a synthesis of separate empirical findings into a coherent whole' (Cooper, 1982); Ganong (1987) stated that integrative reviews are conducted to identify, analyse and synthesise

results from independent studies to determine the current knowledge in a particular area and he considered them a valuable part of the process of creating and organising a body of literature.

Polit and Beck (2006, p 502) define the integrative review as 'a review of research that amasses comprehensive information on a topic, weighs pieces of evidence, and integrates information to draw conclusions about the state of knowledge.' Whitemore and Knafl (2005), in an article outlining updated methodology for the integrative review, state that the integrative review method is an approach that allows for the inclusion of diverse methodologies and contributes to the presentation of varied perspectives on a phenomenon of concern. One of the distinct advantages of the integrative review approach is the ability to combine data from different types of research design (Whitemore, 2005). In this review, I will assess empirical evidence relating to informed consent to healthcare interventions in people with learning disabilities.

According to Cooper (1982) there are five possible techniques to retrieve information – the "invisible college" approach, the ancestry approach, the descendency approach, the use of abstracting services and, finally, on-line computer searching. I used two of these – searching on-line bibliographical databases and ancestry searching, which involves retrieval of relevant papers cited in papers found in initial searches of databases.

Following consultation with a specialist subject librarian, the following bibliographic databases - British Nursing Index (BNI), CINAHL, MEDLINE, Social Care Online and PsycINFO - were used to search for research articles or reviews using the following search terms:

Preliminary search terms: Informed consent or informed choice or mental capacity or consent to treat* or consent to examin*

AND

learning disab* or intellectual* disab* or mental* retard* or learning difficult* or mental* handicap* or developmental delay or Down* syndrome.

Care was taken to include the various terms used – e.g. learning disability (UK), mental retardation (USA) and intellectual disability (Australasia and academic circles in the UK) (Burton, 1997) and to use truncation (*) – e.g. mental* handicap* - to ensure retrieval of all relevant papers.

The limitations set were:

Limitations: Publication date: between January 1990 and March 2007

Population: Human

Age: Adult

Language: English

Title only.

When possible, searching was limited to research or review papers. This option was not available in all cases, and so papers were filtered manually to identify those based on primary or secondary research. The initial yield was ten papers in total, after eliminating duplicates.

Re-running the CINAHL search, which originally yielded no papers, and omitting 'research or review', one paper was retrieved. This related to antenatal

screening for Down syndrome. I made a decision to omit Down syndrome from subsequent searches. I considered that this would yield many papers on antenatal screening and that any research involving people with Down syndrome would include the term 'learning disability' or a similar term; thus, it was unlikely that any papers would be lost by omitting 'Down syndrome'. None of the papers identified had 'developmental delay' as a keyword, and so this was also omitted. The term 'developmental delay' could relate to conditions other than learning disability, and might also identify research concerning children rather than adults.

Thus, preliminary searches, limited to title only and omitting Down syndrome and developmental disability, yielded ten possibly relevant papers. Due to these low numbers, I decided to repeat these searches as 'full text' searches. The yield was as follows:

BNI:	-	15 (including previous 2)
CINAHL:	-	33
Social Care Online	-	7 (no further papers found)
MEDLINE	-	77
PsycINFO	-	44 (including previous 4)
Total number	-	176

Following discussion with supervisors, the search strategy was finalised:

search terms were amended to 'consent' in place of 'informed consent' (I considered that 'consent' implied 'informed consent'), and 'capacity' in place of 'mental capacity' for similar reasons. I considered this should maximise the

number of papers retrieved. 'Developmental delay' and 'Down syndrome' were omitted. I decided that an appropriate period for the search would be ten years, as I could not identify any significant health or social legislation prior to that period which would have affected the results. The resulting final search parameters were:

Keywords: Consent or informed choice or capacity or consent to treat* or
consent to examin*

AND

Learning disab* or intellectual* disab* or mental* retard* or
learning difficult* or mental* handicap*

Limitations: Publication date: January 1996 – March 2007

Publication language: English

Age: Adult

Using this search strategy, 380 papers were found, including those previously identified. On a brief scan through these, 273 papers were discarded initially for one of the following reasons:

- they reported research involving consent to sex, sexual abuse, sexual offences
- they were policy documents or statements
- they were books or other educational resources
- the papers consisted of guidelines, editorials, 'comments', letters.

It was interesting to note that by carrying out a 'full-text' search and using the keywords 'capacity' and 'consent', many irrelevant papers were retrieved, eg 'endurance capacity', 'secretory capacity', but I considered this necessary to ensure retrieval of the maximum number of appropriate papers. It was immediately obvious that these papers were irrelevant and they were discarded. Full text versions of papers were obtained where either an abstract was not available, or it was unclear from the abstract whether the paper reported research or a review. From reading the remaining papers, a total of 22 papers were identified as either research or review papers that satisfied the inclusion criteria.

On further in-depth reading of these papers, I decided to add two new keywords to the previously-run searches: intellectual impairment and developmental disability; these occurred in the text of some papers, and I felt that their inclusion might result in identification of more papers. For completeness, I also decided to run further searches using this new search strategy in two additional databases – ERIC and ASSIA. Following these two new searches and the re-running of the previous searches, one new paper was identified. At this point, I was satisfied that 'saturation' had been achieved, the searches in the new databases having yielded many duplicates from other databases.

2.3.2 Appraisal of the results

I identified various tools or checklists for use in appraising quantitative studies (Greenhalgh, 2006; Kmet, Lee & Cook, 2004; Polit & Beck, 2006; Public Health Resource Unit, 2007) and qualitative studies (Greenhalgh, 2006; Kmet, Lee & Cook, 2004; Polit & Beck, 2006; Public Health Resource Unit, 2007; Seale, 1999; Walsh & Downe, 2006). There are many others available, but in view of

time constraints I restricted the search to what appeared to be commonly used tools, or to authors such as Walsh and Downe (2006) who had conducted a review of tools and checklists themselves.

In view of the relatively small number of papers retrieved, it did not seem appropriate to exclude any on grounds of quality. However, I considered it would be useful to have some kind of grading system (which would incorporate both kinds of research), and for this reason I selected the appraisal tool outlined by Kmet *et al* (Kmet, Lee & Cook, 2004).

The Kmet tool (Kmet, Lee & Cook, 2004) is designed for quantitative and qualitative papers; for reviews I decided to use the Critical Appraisal Skills Programme (CASP) tool "10 questions to help you make sense of reviews" (Public Health Resource Unit, 2007) which appeared accessible to the user and is one of a few commonly-used tools designed specifically for use with reviews.

Using these tools not only enabled me to grade papers according to quality, but also gave the opportunity to read them several times, looking in detail at the criteria commonly used to assess quality. In this way, I 'immersed' myself in the detail of these papers, whilst at the same time being able to look critically at various methodological features such as research design, recruitment and sampling and statistical analysis.

Having carried out the appraisals, the scores obtained confirmed my original impression about the quality of the papers, but I considered it would be wise to check the reliability of my scores. Despite using a specific checklist, there is still room for subjectivity and, in addition as an inexperienced researcher, I needed confirmation that my judgements were in line with those of more experienced

researchers. I produced a chart showing the range of scores obtained, and selected the two papers with the lowest score, the two with the highest score and the one with the median score and I asked my supervisor and another researcher to appraise those papers using the same checklist. The researcher ranked papers in the same order as me, but with consistently lower scores. I attribute this to my caution and lack of confidence in my ability to critically appraise much-cited authors. I did notice, however, that the papers cited most often tended to be those of higher quality. Following discussion with my supervisor, I revisited several of the papers, bearing in mind her comments, to see if I agreed with her score, or wished to retain my original score.

I had scored the top two papers equally, but my supervisor ranked one of them less highly. This prompted me to re-appraise these two papers – Arscott *et al* (2000) and Wong *et al* (2000) and when directly comparing them, I considered that the research question was less well described and possibly the sample size not as well considered in the former. Both authors acknowledge in their discussion that their sample sizes are small, and that generalisation would therefore be difficult. Kmet *et al* (2004) state that with statistically significant results for major outcomes, appropriate sample size can usually be assumed. The statistically significant results described by Arscott *et al* (2000) are not for major outcomes, thus reducing the quality. The re-appraisal resulted in the same score for the Wong *et al* paper, but a lower score (17/22 compared with 22/22 originally) for Arscott *et al*. For the purposes of this part of the review, this is not a problematic issue, as no papers are being excluded on grounds of quality. However, when considering the application of the results of these papers in practice, factors such as sample size and confounding must be taken

into account. There were two other papers that my supervisor and I scored in reverse order, and on re-reading these papers and further discussion, I agreed with her ranking.

Having used the Kmet *et al* (2004) tool to appraise these papers, it was useful to note that ethical issues were not included on the checklist for either quantitative or qualitative research; this meant that papers without any discussion of the ethical issues involved in research (particularly with people with learning disabilities) did not 'lose points' in the scoring process. Polit and Beck (2006, p442) state that "in performing a comprehensive critique, you should consider whether there is evidence of ethical violations" and that this might have an impact on the scientific merit of the research. The CASP appraisal tool for qualitative research lists ethical issues as a criterion, but this is lacking in the checklist for quantitative research. In Whitemore (2005) in a table of constructs believed to affect the quality of primary studies, there is no mention of ethics. The issue of ethics in the context of this review is a fundamental one, and will be discussed in detail later.

This exercise undertaken to check the reliability of my appraisals was useful in several ways. Firstly, it served to reassure me that, in general, my assessment of these primary studies was in line with more experienced researchers. All three appraisers were in agreement on the 'best quality' papers. Secondly, it demonstrated that appraisal, despite using formal tools, is a subjective process open to discussion – for example, in one of the papers, my supervisor considered that there was inadequate description of the methods, while in my opinion they were adequately described.

Finally, I learned several important things about my own judgement. I found myself influenced by how prolific an author was, or more precisely, how often work was cited by other authors – making the assumption that a much-cited author would produce papers of a higher quality. Generally, this proved to be the case, but I learnt that it is important to approach a paper with an open mind. The results of my appraisals might have been different had they been carried out in the same way as papers are peer-reviewed for journals, without details of authorship. Both my experienced co-appraisers produced lower scores for the papers they appraised, although *ranking* was the same with the researcher, and following re-appraisal was also the same with my supervisor.

2.3.3 Analysis of the findings

The search strategy identified papers reporting both qualitative and quantitative research. In order to draw meaningful conclusions about current knowledge pertaining to informed consent to health interventions in people with learning disabilities, these need to be analysed and synthesised.

Whittemore and Knaf (2005), in a paper outlining updated methodology for integrative reviews, describe the stages involved. Following the 'data evaluation stage' is the 'data analysis stage', in which the same methods used for primary research can be utilised. Miles and Huberman (1994) describe three stages of qualitative data analysis – data reduction, when primary data is refined, summarised, grouped or organised; data display, which can involve matrices, graphs, tables etc; and 'conclusion drawing and verification', when patterns, explanations or propositions begin to emerge. Table 1 represents the first of these stages, and summarises the papers identified, outlining the methodology, sample size, data collection methods and main findings. Some

of these papers were difficult to categorise – by methodology, research design, or even as 'quantitative' or 'qualitative' research. Much research in the 'real world' does not fit into neat categorizations of 'qualitative' and 'quantitative', according to Harden and Thomas (2005), who state that both types of research can, for example, use numbers or words, test or generate hypotheses or use methods that are ethical or unethical, for example. Thomas *et al* (2004) when integrating qualitative and quantitative studies, used three separate syntheses – one for controlled trials, one for qualitative, and then a synthesis of the two. The methodology for this is described in a later paper (Harden & Thomas, 2005). Dixon-Woods *et al* (2005) analyse a range of strategies for synthesising qualitative and quantitative evidence, many of them based on existing qualitative methods for the analysis of primary data.

Both qualitative and quantitative research papers were identified by my search, and this was further complicated by the fact that there was little consistency in type of population used, research method, type of analysis or even rationale for the studies. Dixon-Woods *et al* (2005) describe thematic analysis as the identification of prominent or recurring themes in the literature, and the summarisation of findings of different studies under thematic headings. I considered that this was the best method of analysis to use, bearing in mind the range of literature I had identified. I had already found some common themes present in both qualitative and quantitative studies and decided that there were no identifiable advantages to synthesising the types of study separately. The themes and categories within them were identified by repeated readings of the papers – in particular the results sections. Many of the studies involved

quantitative methodology, and in practice many of the variables that emerged from these studies became categories in the analysis.

2.4 Findings

There were 23 studies reviewed. Of those, ten were based on quantitative methodology – including a randomized controlled trial (RCT), quasi-experimental studies, surveys and one case study. There were ten qualitative studies using interviews or a case study approach, two literature reviews and one study where a combination of qualitative and quantitative methods was used. For clarity and to facilitate ease of reading through the text of the chapter, I have included the table of studies at the end of this chapter (Table 1).

The over-arching aim of the studies identified for this review was to gain more knowledge about the concept of informed consent in people with learning disabilities. For brevity, any reference to informed consent in this section will be in the context of people with learning disabilities. The majority of research involved people with learning disabilities as participants, but some also involved healthcare professionals or carers. The authors of some studies explored assessment of capacity to give informed consent and the factors that influence that capacity (or lack of it); some approached the question from the point of view of the healthcare professional – their understanding of the concept of informed consent and its application in practice. For the purposes of this analysis, 'ability to consent' includes the terms 'competence', 'functional ability', and 'mental capacity'. I make no distinction between mental capacity and competence, although these terms have slightly different definitions – in the USA, capacity is regarded as a general concept, in contrast to competence being a specific one (Gunn *et al* 1999). Functional capacities are assessed

leading to a judgement about legal competence. Gunn *et al* (1999) state that in England the terms are more likely to be used interchangeably.

I will now describe the themes that emerged from the research.

2.4.1 Psychometric properties

Intelligence

Morris *et al* (1993) had a hypothesis that what they termed 'capability to consent' would be more likely for individuals with higher intelligence. They did not formally test the IQ of their participants, but used the results of recent psychometric tests and adaptive behaviour scales to allocate 15 to the 'mild mental retardation' and 15 to the 'moderate mental retardation' groups. Although detailed results are not given, only six out of fifteen participants were deemed capable of consent in the 'mild retardation' group, and one out of fifteen in the moderate group.

In the study by Cea and Fisher (2003), 'level of functioning' was assessed using two instruments –Wechsler Adult Intelligence Scale-Revised (WAIS-R) and adaptive behaviour scales (Vineland). The IQ scores for the participants were taken from assessments during the previous three years, and were not carried out specifically for the study; the scores ranged from 55-80 (mild mental retardation) and 36-54 (moderate mental retardation). The only exception to this was the IQ of the comparison group, measured for the study using the Kaufman Brief Intelligence Test – these scores ranged from 80-117. The results of this study showed that the ability of adults with and without 'mental retardation' decreased with the complexity of the information presented and the concepts involved.

In contrast to the Cea and Fisher (2003) study, Fisher *et al* (2006) assessed intelligence using the Kaufman Brief Intelligence Test for all participants at the time of the study; of 150 adults, 50 comparison subjects had a mean IQ of 106, 50 with mild 'mental retardation' a mean of 60.3, and 50 with moderate retardation a mean of 48. Vineland Adaptive Behaviour scales were also used, with 86% of the mild and 96% of the moderate mental retardation groups scoring in the low range. The findings showed that overall intelligence score predicted total score on the capacity assessment.

Verbal ability

In the earliest study in this review, Morris *et al* (1993) simply state that all participants had adequate hearing and at least moderate expressive language abilities, but they do not assess any association between this and the ability to consent.

Two studies by Arscott *et al* (1998, 1999) investigated consent to psychological research and treatment respectively. In the first study using 40 participants, receptive language ability was measured using the British Picture Vocabulary Scale (BPVS) and correlation with the number of correct answers on the 'ability to consent' questionnaire was calculated, producing a Pearson's correlation coefficient of 0.50 (df=38, $p<0.01$), showing that people with higher receptive language scores were more likely to score better on the ability to consent questionnaire. In the second study by Arscott, using the same 40 participants, the scores on each ACQ question were analysed separately and tested for correlation with receptive language ability, which again had been assessed using BPVS. All the answers were significantly correlated with verbal ability – all at $p<0.01$ with the exception of the 'ability to indicate a choice' question, which

was $p < 0.05$. Independent *t* tests were carried out to see whether the influence of verbal ability varied according to the vignette used. The result showed a significant difference ($p < 0.05$) in verbal ability across all vignettes between those able and unable to consent.

Wong *et al* (2000), although investigating the capacity of people with a range of 'mental disability' to make a health care decision, did not measure verbal ability in isolation. Learning disability was assessed using verbal IQ (VIQ) from the Vocabulary, Comprehension and Similarities subtests of the Wechsler Adult Intelligence Scale-Revised (WAIS-R) and Digit Span subtests to measure short-term memory retention. Their results, using a staged assessment of decision-making capacity, with each successive stage being less verbally demanding, showed that capacity improved as the decision-making task (and the way the information was presented) was simplified.

Dye *et al* (2007) adapted the ACQ from Arscott *et al* (1998, 1999) for their study of consent to take part in a research study and BPVS was used to assess receptive vocabulary. The aim was not only to assess the capacity of people to give consent, but also to assess the impact of different ways of presenting the consent information. Dye *et al* recruited 85 participants for this study and ACQ scores were significantly correlated with verbal ability (Pearson's correlation coefficient = 0.510, $p < 0.01$) thus reinforcing the findings of Arscott *et al* (1998) and Wong *et al* (2000).

Memory

As well as verbal ability, memory (particularly short-term) has been found to influence the ability to consent. Arscott *et al* (1999) used the route recall and

story recall memory items taken from the Rivermead Behavioural Memory Test for Children (RBMT-C) to assess memory as well as verbal ability when studying ability to consent to treatment. Memory ability was found to be correlated with the questions relating to understanding the treatment, the alternatives and the impact of choices ($p < 0.01$) and to understanding the risks and benefits, the rights and options available and the ability to indicate a choice ($p < 0.05$). Memory ability was not correlated with the question relating to understanding the nature of the problem; it was, however, correlated ($p < 0.01$) to the total score for each treatment vignette. Overall, memory scores were significantly higher ($p < 0.05$) for people assessed as able to consent (to the surgical and medical vignettes, but not for the restraint vignette).

The same memory test (RBMT-C) was used by Dye *et al* (2007) when assessing capacity of individuals to take part in a research study, following the method used by Arscott *et al* (1999). The mean memory score for the 85 participants who completed the study was 24.27 out of a maximum possible score of 72 (range 3 - 53.5). This is comparable with the Arscott *et al* (1999) study findings in which the mean score was 23.31 (range 0 - 40.5). The ACQ scores were significantly correlated with an aggregated memory score (Pearson's correlation coefficient = 0.616, $p < 0.01$). The results from this study, unexpectedly, did not show that capacity to consent increased with reduced demand on memory (presenting information in 'chunks' or with photographs).

2.4.2 Life experience

One of the themes that emerged from the literature was that of life experience; within this are four sub-themes –residential status of the participant, experience of decision-making, acquiescence and health experience. These have all been mentioned in one or more studies, not as part of the research question or hypothesis, but as a subject included in the discussion of results. Experience of decision-making and acquiescence, although possibly associated with each other, have been treated as separate themes.

Residential status

The place of residence of the person with learning disability is considered by several studies in the discussion, rather than being treated as a variable in any quantitative sense. Descriptions of participants' place of residence are provided by several authors (Arscott *et al* 1999; Dye *et al* 2007; Fisher *et al* 2006) without any further investigation into its possible effect. However, there appear to be certain assumptions made by researchers. Dean *et al* (1998), when developing a functional approach to capacity assessment, discuss the fact that there was a group of participants who were not considered able to give fully informed consent. Members of this group had problems communicating and had often been institutionalised therefore making choices had never been an option or they were unable to hypothesise. Dean *et al*'s assessments illustrated that some people were in situations in which their preferences were not taken into account. Hart (1999), in a qualitative study on consent to treatment in general health care settings, described how Ellen, with a mild to moderate learning disability, lived in a 'life-style sharing placement with a family', and the author made certain assumptions when she stated that "there must be concern,

however, for the many persons with learning disabilities who do not have such expertise (access to learning disability nurses) to hand, as they live independently”.

Fisher *et al* (2006), exploring capacity to consent to a randomized clinical trial, stated that “the expectation that adults with mental retardation living in community residential settings would find the concept of voluntarism difficult met with mixed results.” This is difficult to interpret, as the term ‘community residential settings’ has not been clearly defined, and this study took place in the United States. In a study into the knowledge people with learning disabilities and their carers have about their medication, Heslop *et al* (2005) recruited participants receiving different levels of support in the community. They concluded that most people in the study expected their carer to “know all about their medication”, and that in general neither the carers nor the people themselves were aware of the alternatives available, so were unlikely to be giving informed consent to their treatment. Although not specifically stated in the results, it seems that place of residence has an influence on how much information is available to an individual with learning disabilities.

Arcscott *et al* (1999) in a study of ability to give informed consent to treatment, stated in their discussion that questions regarding the rights, options and impact of choices were the most difficult for the participants to answer and that it would be interesting to explore whether any characteristics of an individual or their *lifestyle* made people more likely to answer these questions adequately. This question about lifestyle is closely linked with the next category of decision-making.

Decision-making opportunity

The opportunity to make decisions in everyday life appears to be associated with where a person lives – at home with parents, in supported living accommodation, in a residential home or semi-independently. This fact is alluded to by several authors, but never formally tested as a hypothesis.

There appears to be consensus that people with learning disabilities lack experience in decision-making, and that this will affect their functional capacities with regard to informed consent. Arscott *et al* (1999) attributed the fact that participants found questions concerning their legal rights and options regarding treatment difficult, to the fact that they may not be allowed to, or be familiar with making lifestyle decisions. Cea and Fisher (2003), looking at health care decision-making, concluded that “adults with mental retardation” who may not have experience in decision-making, would not be able to understand the concept of a risk-benefit analysis, and thus would be denied the freedom of choice.

Dye *et al* (2007), investigating capacity to take part in a randomized controlled trial, cited Jenkinson (1999) and Suto *et al* (2005b) who stated that limited decision-making opportunities in the life of people with intellectual disabilities limited their capacity to consent. They also questioned whether the ‘Ability to Consent Questionnaire’ (ACQ) used in their own study is a valid measure of the decision-making processes in people with intellectual disabilities, and suggested that further research into the process of decision-making in this population might be useful.

Morris *et al* (1993) in an earlier paper on the capability to give informed consent, speculated that people with 'mental retardation' have never been given much choice over what happens to them, and that going along with what others suggest has become a way of life for them. He suggested that these individuals may need education on their rights to make decisions which will affect their treatment, and to be aware that alternatives may be available to them.

In a study of health care decision-making by Keywood *et al* (1999), the majority of parents and carers identified themselves as the main decision-makers for the adults with learning disabilities, and indeed "some parents struggled with the idea that their learning-disabled sons and daughters could take part in decisions about their health". Similarly, Heslop *et al* (2005), when investigating how much people knew about the medication they were prescribed, found that little information was provided to the people themselves or even their carers – implying that the decisions were actually taken by the prescribers.

Both residential status and experience of decision-making are illustrated by a case study on the palliative care needs of people with intellectual disabilities. Jim, the sole participant in this study, was a man with Down syndrome living in a residential home. Tuffrey-Wijne (2002) felt that Jim was capable of making decisions, but that there was reluctance on the part of the staff to accept this. She also felt that people with learning disabilities were routinely denied the opportunity to make decisions for themselves.

Finally, Fisher *et al* (2006) stated that people with 'mental retardation' are characterized by an impaired capacity to make adaptive decisions in daily life. It may be this assumption that denies this group of people the opportunity to make these decisions.

Acquiescence

Acquiescence (defined as acceptance without protest) is a concept that may well be associated with residential status and decision-making opportunity. Keywood *et al* (1999) in their report, 'Best Practice?' found much evidence of acquiescence among the participants with learning disabilities they interviewed – especially with regard to female contraception, pregnancy testing and sterilisation; it was often the carer, the doctor or the parents who were making the healthcare decision, and the individual simply went along with it. Similarly, in the study by Morris *et al* (1993) many participants were said to consider that they had no choice in any treatment and felt that whatever they said would make no difference. This caused Morris to question the concept of voluntariness - which is an essential element of valid consent, in these participants. The two studies by Arscott *et al* (1998, 1999) utilised methodology based on the Morris *et al* (1993) study and looked at informed consent to take part in research, and to have medical treatment. The authors concluded that many participants did not understand that they could withdraw from a study, and may have been keen to please the researcher. With regard to health interventions, many may not perceive that they are able to make a decision that does not match that of the healthcare professional caring for them. A study by Dunn *et al* (2006a) reinforced the findings of Arscott *et al* (1998, 1999) – only two out of nineteen participants understood that they could decide whether or not they continued seeing a psychologist; in fact, one participant, when asked if he would tell a psychologist he did not want to continue attending, asked, "Are you allowed to say that?" Dunn *et al* (2006a) warned

that clinicians need to be aware of this tendency to a high level of acquiescence in people with learning disabilities.

Dye *et al* (2007) found that although the majority of their participants were assessed as being unable to consent, they were all very willing to take part in the research. Dye *et al* cite Bybee and Zigler (1999) who stated that people with learning disabilities will often follow the lead of more able people without learning disabilities, rather than decide on their own course of action. Fisher *et al* (2006), investigating consent to participate in randomized clinical trials, found although many of their participants understood the concept of voluntarism, fewer understood that they could subsequent withdraw from a study once they had agreed to take part. The authors considered that adults with 'mental retardation' are more likely than others to make decisions that they feel will please the researchers.

The same problem of acquiescence has been found in consent to taking medication. Heslop *et al* (2004) found that most of the people with learning disabilities interviewed felt they had no choice in taking their psychotropic medication and took it because they were told to; the same applied to carers, who felt that the people in their care had no real choice when it came to taking medication. The authors commented that this attitude on the part of the carers bordered on coercion, and certainly did not represent valid consent.

Previous health experience

The use of vignettes or scenarios in research is sometimes the only way to investigate a phenomenon, due to ethical or practical problems in using real-life situations. However, participants' personal experience of health-related issues

such as medication or dental treatment, or any other topic presented in a vignette, may influence the findings. In a study investigating the capability of individuals with 'mental retardation' to give informed consent, Morris *et al* (1993) developed three vignettes – consent to surgery, a restrictive behavioural intervention and psychotropic medication; individuals were allowed to choose their vignette, and if there was no choice, vignettes were assigned to participants on the basis of their histories. The authors considered that this 'non-random' allocation of vignette would maximise the likelihood of an individual having the relevant experience and knowledge to facilitate consent.

Arcott *et al* (1999), contrary to their expectations, found that having experience of taking medication did not render participants more able to consent in their study, using a vignette of a proposed medical intervention. Cea and Fisher (2003) however, in their study of health care decision-making, stated that factual understanding was based on the degree to which the participant had experienced the treatment for which consent is being sought. It is not clear from the results of their study how this conclusion has been reached, as there are no details of the participants' medical histories. It is also important to note that personal experience may only affect certain components of capacity to consent – for example, 'factual understanding' in the study by Cea and Fisher. In a later study, Fisher *et al* (2006), found no association between medical or consent history and level of capacity to consent to a clinical trial. They did comment, however, that the fact that participants were able to appreciate the context of the clinical trial they were consenting to, as well as understand it, could have been due to the fact that the content of the vignettes may have been familiar to them.

It is difficult to compare those studies investigating informed consent to treatment with those studying informed consent to research. However, previous experience is still considered a factor. Dye *et al* (2007) compared the results of their study (in which only 5.9% were deemed able to consent to participate in research) with those by Arscott *et al* (1999) and Wong *et al* (2000). This led them to suggest that because the latter studies were concerned with consent to treatment (rather than research), it may have been that prior experience with the treatment increased the level of consent. In the study by Wong *et al* (2000), all but one participant had previous experience of having a blood test, which may well have had a positive influence on the outcome.

In a study investigating the effect of presenting information about psychological services using video materials, Dunn *et al* (2006a) were aware that none of their participants had psychological problems, and would have been unfamiliar with the concept of psychological services. It was suggested that it would be useful to carry out further assessments on patients who had already been referred to psychology services to see if their comprehension was better, or whether questions could be presented in a less complex way.

2.4.3 Interaction between healthcare professional and participant

Attitude to consent

When exploring the concept of informed consent in people with learning disabilities, it is important to find evidence to illustrate the attitude of healthcare professionals, as well as looking at the capacity of people with learning disabilities to give consent. Carlson (2004) identified 171 referrals to the Community Team for Learning Disability (CTLTD), then sent out questionnaires

designed to establish referrers' awareness of and attitude to consent. Approximately two-thirds of all the referrers were aware of guidelines produced by the Department of Health, General Medical Council (GMC) and British Medical Association (BMA), but only 44% of general practitioners (GPs) were aware of those guidelines. Paradoxically, although 52% of referrers said that they always discussed the referral beforehand with the patient, two-thirds went on to give reasons for not always obtaining consent. Various reasons were given: consent was obtained from someone other than the patient; the patient was unable to understand; they 'did not realise they had to'; they forgot, or there were time constraints. The majority (79%) considered that simply telling the patient that they were going to make the referral constituted informed consent. The authors suggest that perceived difficulty in communicating with people with learning disabilities may be a contributory factor, particularly with GPs, who see few people with learning disabilities. However, 46% cited the patient's probable inability to understand as a reason for not obtaining consent. The findings of this study show that there may be an educational issue involved in ensuring that informed consent is obtained, as "being aware of guidelines appeared to result in better practice".

Hart (1999), in her qualitative study of the experiences of people in hospital, found very little consistency in the practice of consent, despite the hospitals all being in the same region. One participant, despite being able to attend her follow-up hospital appointments on her own after a hysterectomy, described how she was not allowed to sign her own consent form, but that the doctors insisted on her mother signing it. Another less able participant described a

situation where, as far as possible, a full explanation of the procedure was given, and she was able to sign a form giving her informed consent.

Green and Nicoll (2001), using a case study approach for a reflective account of their treatment of an individual with learning disabilities using therapeutic touch, constantly stress the need to obtain informed consent at various stages of the treatment:

"Prior to this encounter with Oscar, we had always gained his consent by walking with him into the lounge and then by observing any subtleties which occurred between us." (p 183)

This paper illustrates clearly that informed consent can be obtained in a variety of ways, and in this particular case, resulted from the intense and sensitive relationship the healthcare professional had built up with the patient.

A survey of off-label prescribing¹ (Haw and Stubbs 2005) found that only 6% of patients with learning disabilities being prescribed off-label psychotropic medication had been informed of this fact; the main reason given by the psychiatrists for this obvious lack of informed consent to take the medication was that the patient lacked capacity to understand the 'off-label' concept. The authors found similar results in a study using mental health patients without learning disabilities, so this finding is not confined to people with learning disabilities. It is not clear from this paper whether a proper assessment of capacity was carried out, but the findings suggest that valid consent was not obtained in the majority of cases. Another study concerning knowledge of medication by Heslop *et al* (2004) found that prescribers expressed doubt about how much the patient or their carer understood - but still prescribed. Arscott *et*

¹ Off-label prescribing is defined as the prescription of medicines for purposes for which they are not licensed. (General Medical Council, 2008)

al (2000) investigated the knowledge that people with intellectual disabilities had about their prescribed medication, and although informed consent was not the focus of the study, their results lead to the conclusion that participants had insufficient understanding of their medication to give informed consent. Just over half the participants answered 'knowledge' questions well enough to obtain the maximum score of two. However, questions on side effects, contraindications and alternatives were most difficult for them to answer; for example the mean score on a question concerning contraindicated medication was 0.4, where participants could score 0 for an incorrect response, 1 for partially correct and 2 for a correct response. The standard deviation was 0.7 and 73% scored zero.

Keywood *et al* (1999) reported that many participants and interviewees were not given basic information by healthcare professionals that might enable them to make a fully informed choice. They also found evidence of parents and carers being asked to consent on behalf of adults with learning disabilities and people with learning disabilities being asked to pass consent forms to their parents or carers. These findings also illustrate the attitude of the healthcare professional towards informed consent.

Tuffrey-Wijne (2002) in a case study found that despite everybody involved in Jim's care agreeing that he had a right of choice with medication, nurses and carers still attempted to hide his tablets in his food in an attempt to get him to comply. In another case report, on ethical issues raised in a treatment programme for an individual with a 'moderate intellectual disability', Iqbal (2002) showed that concerns by the care staff concerned about the ethical issues – in particular, the lack of informed consent, led to inconsistent application of the

programme. In a literature review on the palliative care needs of people with learning disabilities Tuffrey-Wijne (2003) found that consent was not always obtained for tests and treatment, and that there was a likelihood that more invasive treatments were avoided due to issues around informed consent.

In another literature review, Broughton (2002) concluded that one of the reasons why uptake for cervical screening in the UK was low among women with learning disabilities was that professionals and carers found it difficult to assess capacity to consent; she further commented that the issue of consent caused problems for not only GP's, but also nurses and that this may have kept healthcare providers from providing the gynaecological care that women with learning disabilities should have been able to access.

On a more positive note, a case study by Hunt *et al* (2004) described a 34 year old man with learning disabilities who needed surgery on a hernia. He was given detailed information by the community nurse and surgeon about the surgery, the benefits and possible risks; using communication methods designed to maximise his understanding, He was also made aware of his right to change his mind or withdraw his consent.

Method of presentation

When considering the information necessary to obtain informed consent for any intervention, whether treatment or research, two factors should be considered – the content of the information, and the way it is presented. Some studies assessed informed consent to *research* (Arscott *et al* 1998, Dye *et al* 2007), some consent to *treatment* (Arscott *et al* 1999, Cea and Fisher 2003, Dunn *et al* 2006a, Morris *et al* 1993, Wong *et al* 2000) and some consent to *medication*

(Haw and Stubbs 2005, Heslop *et al* 2004). In some, vignettes were used (Arscott *et al* 1999, Cea and Fisher 2003, Morris *et al* 1993) and some the authors used real life situations (Dean *et al* 1998, Dye *et al* 2007, Wong *et al* 2000).

Morris *et al* (1993) used three different vignettes, which were read out loud to participants, who were then interviewed to assess capability to consent. The authors commented that interviewers had a tendency to "teach" participants in an effort to maximise capability and that this may have influenced the results.

Arscott *et al* (1998, 1999) adapted the vignettes from the Morris *et al* (1993) study by increasing the Flesch reading score (Flesch, 1948) to 'easy to read' (Morris used 'fairly easy'), by replacing American terminology and by producing simple line drawings to accompany each vignette. They concluded from their studies that verbal and memory ability influence ability to consent, and that this information should guide professionals in the way information is presented. They identified 65% of the sample as able to consent to at least one vignette, compared with Morris *et al* (1993), who only assessed 23% of individuals with mild or moderate learning disabilities as able to consent.

Cea and Fisher (2003), in a study of health care decision-making, used three different treatment vignettes which were read to participants using a 'single unit disclosure format' first described by Grisso and Appelbaum (1991). This entailed reading each paragraph singly, followed by questions after each one to assess understanding – thus 'chunking' the information. They confirmed previous findings that factual understanding is not simply dependent on intellectual capacity, but linked to the type of information and the way it is presented. In a later study, Fisher *et al* (2006) again used the single unit

disclosure format to assess ability to consent in a hypothetical RCT. They described the format of the vignette in some detail – for example, 19 paragraphs, 1-4 lines each, story-like, brief sentences and simple, concrete terms. Their results suggested that many adults with mild and some with moderate 'mental retardation' were able to grasp some of this information when it was tailored to their general deficits in language, memory and attention. This point had been well illustrated in a previous study by Dean *et al* (1998), who developed a functional approach to assessing capacity. For the purpose of that research, comprehension levels were assessed by speech therapists and patients with a high level of comprehension but poor communication skills, and those who had no verbal communication received intensive input and several interviews. Speech therapists advised on appropriate materials and methods, such as using cards or Makaton.

Wong *et al* (2000) used the 'real life' situation of needing a blood test to carry out their study of capacity to make a health decision. An information sheet was produced, using a large font and simple language analysed using Flesch (Flesch, 1948) and described as 'less complex than the UK's best-selling tabloid'. Different ways of testing understanding were then used – 'uninterrupted disclosure where questions were asked at the end of the verbal reading of the information sheet or questions after each 'element'. The study demonstrated the impact of simplifying the decision-making task; capacity increased as the task was simplified, and Wong *et al* concluded that these findings have implications about the way consent is sought from people with a 'mental disability'.

Dye *et al* (2007) in a study of consent to 'real life' research, confirmed the findings of Wong *et al* (2000), Cea and Fisher (2003), Fisher *et al* (2006) and Arscott *et al* (1999) that ability to consent would correlate positively with verbal and memory ability, but interestingly failed to show the impact of different forms of information provision. They used a similar method to Arscott *et al* (1999) – a control condition where the consent passage was read through and questions asked at the end, a 'section' condition where questions were asked in 'chunks', and a 'photograph' condition. Their mean consent score (using a tool adapted from Arscott *et al*) was also lower; only 5.9% of participants with learning disabilities were deemed able to consent to take part in the research, compared with higher levels achieved by Arscott *et al* (1999) and Wong *et al* (2000). However, this may not be a valid comparison, as the latter two studies were studying consent to treatment rather than consent to research, and previous experience may have affected the results.

Dunn *et al* (2006a), citing the UK Department of Health document 'Valuing People' (Department of Health, 2001b) as the rationale for their study, stated that there should be more thought about the way choices are offered, and how information about choice and decision-making is presented. The authors cite both Arscott *et al* (1999) and Wong *et al* (2000), who stressed that there should be 'enough information' and it should be in an accessible form in order for there to be informed consent. This study explored the use of video format to provide information to participants and showed that there was a significant increase in knowledge (of psychology services) after the video. The capacity was maximised by presenting the video in 'chunks' as the information was understood and maintained. These findings replicated those of Wong *et al* that

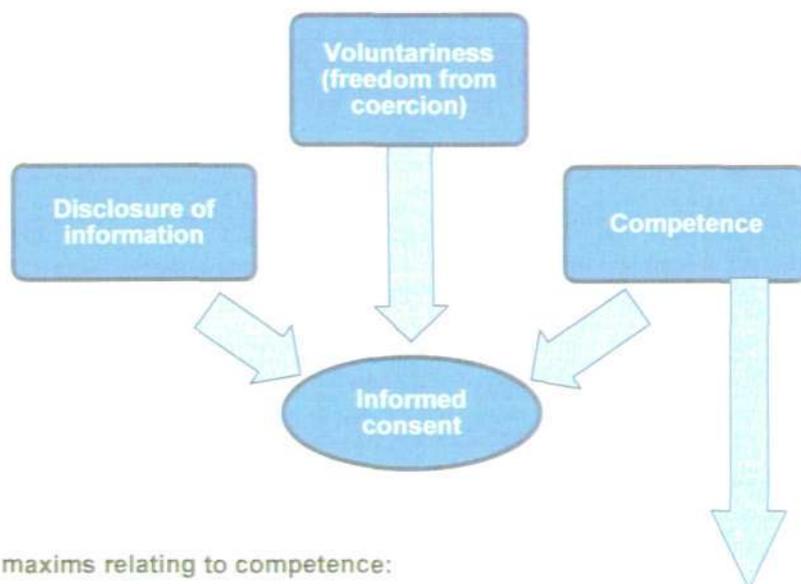
capacity to consent is increased when information is broken down into separate elements.

Broughton (2002) carried out a literature review specifically looking at capacity to consent to cervical screening in women with learning disabilities. It was found that the way information was presented to women was crucial, and influenced their ability to understand the procedure and therefore give informed consent. Language appropriate to level of disability, short clear text, the use of alternate media such as video or audio-tapes or preparatory visits to the department were suggested by one of the studies reviewed.

2.4.4 Ability to consent

For the purpose of this review, the terms 'ability to consent', 'capacity' and 'competence' will be interchangeable. This theme is difficult to sub-divide, although there are different elements involved. The concept itself has been defined using different criteria depending again on location - United States of America (USA) or United Kingdom (UK), or date of study. It will be necessary later to discuss the various definitions and criteria used when conducting research into capacity and informed consent, and also the relationship between capacity and consent. However, for clarification, please see Figure 1.

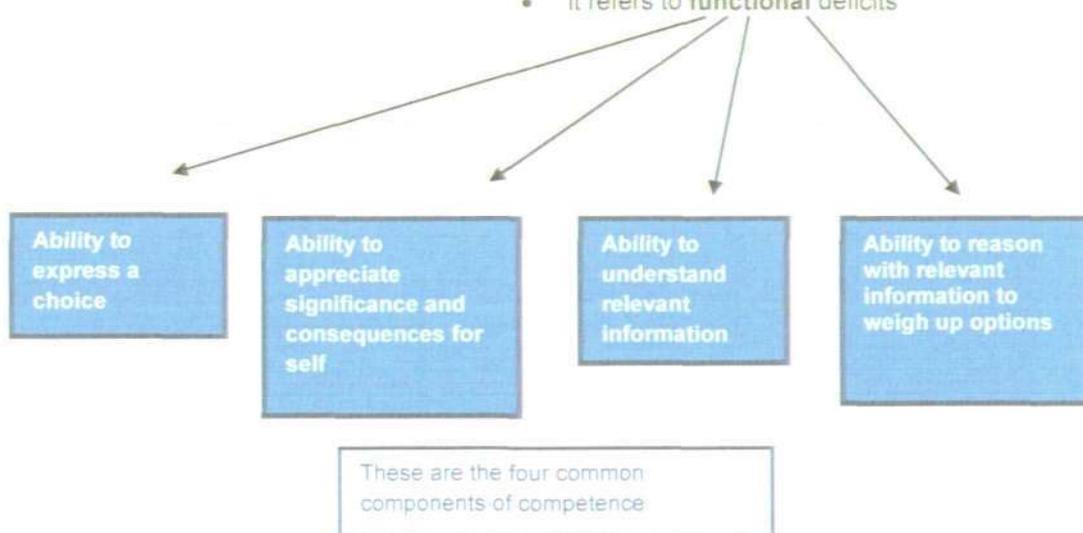
Figure 1 Informed consent and capacity



There are 5 maxims relating to competence:

“the question of individuals’ competence requires an enquiry into their actual capacities, incompetence being determined on the basis of a demonstrated lack of the requisite functional abilities for the specific individual in question” (Grisso and Appelbaum 1998)

- it is related to, but **not** the same as, impaired mental states
- it can change
- it depends on consequences (benefits/risks)
- it depends on functional demands (domain, case specific, situation(context))
- it refers to **functional** deficits



(based on Grisso & Appelbaum, 1998)

Morris *et al* (1993) based in the USA, used three legal criteria previously described by Grisso (1986) to determine capability to consent; knowledge' (understanding the facts), 'intelligence' (ability to weigh the risks and benefits of the treatment or any alternatives) and 'voluntariness' (free from coercion or any other influence). Arscott *et al* (1999) adapted the assessment tool used by Morris *et al* using the same criteria. Both assessment tools used questions on understanding the nature of a problem or treatment, understanding of risks, benefits and alternative options, understanding of rights, options and choices and their impact. Participants are asked to make a choice and give their rationale for making it. Cea and Fisher (2003, researching in the US, based their research on the four psycholegal standards defined by Appelbaum and Roth (1982), as suitable to evaluate ability to consent:

- Ability to communicate a choice concerning treatment
- Ability to understand factual information about the nature of the disorder and risks and benefits of the proposed treatment
- Ability to understand the cognitive and emotional implications of the treatment for the individual's own circumstances
- Ability to weigh the risks and benefits of the proposed treatment when making a choice and to arrive at a "reasonable" outcome of choice.

Wong *et al* (2000), working in the UK, used the criteria for evaluating capacity from the draft Mental Capacity Act (UK) – defining incapacity as being unable by reason of mental disability to make a decision on the matter in question, that is, if the disability is such that, at the time the decision needs to be made, he or she is unable to:

- Understand relevant information and/or
- Retain this information and/or
- Make a decision based on the information given
- Communicate that decision.

Considering the above variation, the following sub-themes were used to synthesise the results of this review within the 'ability to consent' theme – communicating a choice, understanding and retaining information, appreciation of the situation/context and finally, rational manipulation of information. By using these categories, the data can be synthesised in a way that will facilitate useful discussion of the major findings.

Communicating a choice

Various studies have investigated ability to consent in people with learning disabilities – some using consent to take part in research, some consent to medication, and some consent to treatment. If the four standards of Appelbaum and Roth (1982) are used, the first one – ability to communicate a choice concerning treatment – has consistently been shown to be the most easily achieved by people with learning disabilities.

Arcott *et al* (1998) investigated ability to consent to take part in their larger research study and found that although all 40 participants were able to communicate their decision to take part in the subsequent study, none of them correctly answered all five questions designed to assess their understanding and reasoning ability. In a subsequent study on ability to consent to treatment Arcott *et al* (1999) found the same – that communication of a decision was the easiest element. Using a tool adapted from Morris *et al* (1993), six questions

were asked to obtain data on the various elements such as understanding, reasoning etc. The mean score for the 'indicates a choice' question across all three vignettes used for this study was 5 (out of a possible score of 6) – with a standard deviation of 0.99. Of the 40 participants with learning disabilities, almost 70% across the three vignettes achieved the maximum available score on this question. Cea and Fisher (2003), also investigating consent relating to health care, found that compared with participants with no 'mental retardation', 95% of whom were able to communicate a choice: the percentage for those with mild and moderate 'mental retardation' was 81% and 47% respectively. Again, the 'choice' question was the easiest to answer, ahead of understanding factual information, appreciation of the situation and rational manipulation of the information. Cea and Fisher concluded that with increasing complexity of the four 'standards', the ability to consent was reduced. In a later study into consent to take part in an RCT, Fisher *et al* (2006) found that most participants with 'mental retardation' were able to make a choice; this was a quasi-experimental study and they found that the comparison group and the two groups with 'mental retardation' did not differ in their ability to communicate a choice.

Using a sample of 102 people with intellectual disabilities, Dye *et al* (2007) investigated their capacity to take part in a research study. They were investigating the influence of different forms of information provision, and found no differences between them, but they also looked at each aspect of ability to consent in detail, and found that all of the participants could make a choice, despite over 30% not understanding the impact of that choice. Even fewer than that (55%) understood the risks and benefits. These findings reinforce those of

Cea and Fisher (2003) and Fisher *et al* (2006) that as the complexity of the 'standard' being assessed increases, the ability to consent (as a whole) is reduced.

Wong *et al* (2000) in a UK study assessed the capacity of people with a 'mental disability' to make a health care decision. The assessment tool used in this study used the criteria for 'incapacity' adopted in the draft Mental Capacity Bill (now the Mental Capacity Act 2005), as outlined above. For this reason, it is difficult to compare the results of this study with those previously described; studies based on Grisso and Appelbaum's 'psycholegal standards' refer to separate elements such as 'appreciation' or 'manipulating information', whereas the criteria used in this study are not so detailed – the relevant one here being the ability to make a decision based on the information given. In their results, Wong *et al* simply produced a percentage of each group (mental illness, learning disability, dementia, general population) who were assessed as having capability to make a decision about a blood test, but do not give detailed results for each element of capacity.

Understanding and retaining information

Synthesising the evidence relating to understanding relevant information is difficult, as the complexity of the information varies between studies, and can involve information about research, treatment or medication. Different categories of information have been presented to participants: factual information about the topic, the risks and benefits, or the individual's rights – for example, right to withdraw.

Arscott *et al* (1998) found that a high percentage (92.5%) of participants were able to describe the study outlined to them; this level of understanding decreased with the complexity of the information, for example, only 2.5% could describe any disadvantages of taking part in the research. However, this could be seen not as 'understanding', but as 'rational manipulation' of the information, and will be discussed later. In a later study relating to treatment (Arscott *et al* 1999), an average of over 70% participants (across three different vignettes) understood the nature of the problem, compared with 54% who understood the proposed intervention. Full understanding diminished as questions became more cognitively demanding. Arscott's later study used a more flexible scoring system – rather than simply scoring 0 for inadequate understanding or 1 for adequate, they used an interim score to indicate partial understanding. Cea and Fisher (2003), also studying consent to treatment, found that 81% of participants with mild (IQ range 55 – 80) and 56% of those with moderate (IQ range 36 – 54)'mental retardation' had at least partial understanding of the proposed treatment choices (across three vignettes), which is comparable with Arscott's earlier findings. Statistically significant differences ($p < 0.001$) were found among all three of their groups (no 'mental retardation', mild and moderate 'mental retardation) on the understanding of factual information. Cea and Fisher suggested that these findings were not dependent simply on intellectual capacity, but on previous experience, the type of information and how it was presented.

Fisher *et al* (2006) investigating consent to a hypothetical RCT, found that understanding of research *procedures* (mean 1.41/2 in mild and 0.96/2 in moderate 'mental retardation') was greater than understanding of the *purpose*

of research (0.61/2 and 0.26/2 respectively) – which would indicate that understanding of 'concrete' facts such as procedures is easier than abstract concepts such as purpose of research. This difference is also present in Fisher's comparison group. Fisher and colleagues also found that for questions on understanding of research procedure, 68% of participants with mild and 34% with moderate 'mental retardation' scored within the range of the comparison group. In another study of consent to take part in research, Dye *et al* (2007) investigated each aspect of ability to consent (using the same criteria as Arscott's earlier studies in 1998 and 1999) and showed that although all the participants could make a choice, only 69% understood the impact of that choice. Half of the participants understood the facts about the study procedures, but only 13% the nature of the study. This study further illustrates the hierarchical nature of the information presented to participants and how it relates to their level of understanding.

In a study that aimed to assess the effectiveness of video as a means of information provision to people with learning disabilities, Dunn *et al* (2006a) found that participants gained a greater knowledge of psychology services after seeing the video, and also that factual information was understood and maintained more efficiently when questions were presented after each section of the video. The study, however, does not compare the level of, or retention of information following video presentation compared with other methods of presentation.

In a qualitative study, Hart (1999) described a patient with moderate learning disabilities who had signed his own consent form and apparently demonstrated an understanding of his problem; however, he later wished to withdraw his

consent and was not permitted to do so. This raised the question of whether his capacity was properly assessed at the time; had he received enough information to permit full understanding of not only his problem, but the proposed treatment. In a study of patients' knowledge of their medication, Heslop *et al* (2004), found that prescribers had not assessed patients' knowledge or understanding of medication before prescribing it. Iqbal (2002) in a case study about a differential reinforcer for a client with behavioural problems and moderate intellectual disability found that there was lack of informed consent as the client understood neither the issue in question nor the treatment objectives and reason for trying to decrease his problem behaviour.

In a literature review on capacity to consent to cervical screening, Broughton (2002) found one study in which 75% of the sample had very little or no understanding of the purpose of the cervical smear test, apparently causing anxiety and inability to relax for the procedure. There is no comment as to whether the people in this sample were deemed capable of giving consent. Carlson (2004) investigating consent for referral by healthcare professionals found that one of the many reasons they failed to obtain consent was that they considered the patient would be unable to understand. In contrast, Morris *et al* (1993), carrying out research using hypothetical vignettes, described a problem his team experienced in assessing understanding in participants with learning disabilities – that the researchers, as clinicians, tended to attempt to 'teach' the participants, or impart their own knowledge to them. It is difficult to say whether this factor may have arisen in the studies mentioned above.

Appreciation of context

Only two papers specifically assess this factor – both studies were conducted in the US. Cea and Fisher (2003) used questions designed to assess participants' understanding of the personal consequences for them when they either gave consent for a healthcare procedure or declined it, as opposed to understanding the risks and benefits *per se*. For example, participants were asked *why* they would want to take the medication (having had the risks and benefits explained to them). One of the objectives of the study by Fisher *et al* (2006) was to assess whether adults with 'mental retardation' appreciated the situation of being a patient, and the consequences of whether or not they chose to take part in a hypothetical clinical trial. Both of these studies used what they term the 'four-abilities' model of Grisso and Appelbaum (see Figure 1). All three groups in the 'treatment' study performed less well on this 'standard' than those of 'understanding' and 'communicating a choice'. An average of 90% of the comparison group achieved partial or full scores; this compared with 68% of those with mild and 18% of those with moderate 'mental retardation'. In the latter 'clinical trial' study, the percentage of participants with mild 'mental retardation' performing within the range of the comparison group was 74% for appreciation of the consequences of participation, and 32% for the moderate group, achieving a mean score of 1.68/2 (mild) and 1.36/2 (moderate) respectively.

Rational manipulation of information

The study by Morris *et al* (1993) described this factor as '*intelligent*' - defined as the ability to consider or weigh the risks and benefits of a proposed procedure and any alternatives. Morris worked with three groups: mild and moderate

'mental retardation' and a comparison group with no retardation, and created three treatment vignettes. In the protocol relating to each vignette, one question was designed to establish whether the participant could express a clear decision, with a rationale. Unfortunately, Morris does not provide a detailed breakdown of results, but simply tabulates how many participants have been assessed as capable to consent in each group. There is a comment, however, that cognitive limitations such as memory impairment and limited comprehension seemed to underlie the ability to express a rational decision – most frequently for those with moderate 'mental retardation'.

Cea and Fisher's (2003) study found that over half the participants with mild 'mental retardation' scored partial or full points on the standard of 'rational manipulation of information', but that this dropped to less than 20% in the moderate group. In the comparison group, 81% scored partial or full points. The figures confirm Cea and Fisher's statement that ability to consent decreases with the complexity of the 'standard' being measured, even in the comparison group. 'Rational manipulation of information' was the most difficult standard to achieve in all groups; for example over 95% scored partial or full points on 'choice', 'understanding' and 'appreciation of context' in the comparison group. Fisher *et al* (2006), investigating consent to research, found that questions on reasoning were more difficult than other ability categories for all three groups, as illustrated by the mean scores of 1.80/2 for the comparison group, 0.65/2 for the mild and 0.23/2 for the moderate retardation groups. Arscott *et al* (1998), although not specifically testing 'rational manipulation' as in the Cea and Fisher (2003) study, found that understanding the advantages and disadvantages of taking part in the research was particularly difficult ;

understanding of these is one of the main features of manipulating information to come to a decision.

2.5 Discussion

Integrative literature reviews are a relatively new form of systematic review, and may summarize research findings or theoretical literature (Whittemore, 2005). In an integrative review, the author seeks to combine evidence from qualitative as well as quantitative research. Due to the evolving nature of this type of review, there is little consistency in the way one is produced. Traditional systematic reviews of evidence, such as those published by the Cochrane Collaboration, have been reviews of quantitative research, usually carried out to assess the effectiveness of a clinical intervention. In contrast, qualitative research usually provides rich information about experiences, attitudes or interactions. Evans (2007) considers that combining both quantitative and qualitative research in an integrative review provides a more robust overview of evidence, particularly in the healthcare field.

Carrying out this type of review is challenging: evidence from studies that involve different methodological approaches is difficult to compare and synthesise effectively. In addition, in this review, even those studies *within* the quantitative group have included different methods – experimental, quasi-experimental or case study. It was important that evidence was sought from studies focusing upon people with learning disabilities and healthcare professionals involved in their care. The need for a broad approach was demonstrated when, having constructed the search strategy, a wide range of relevant studies were identified, albeit a fairly small number. There were also a

few studies identified which did not have consent in PWLD as the focus, but nevertheless produced useful evidence.

I have described the historical context of consent and capacity in the UK and the US in Chapter 1 and briefly earlier in this chapter. However, it is important to state here that the research identified in this integrative review was conducted prior to the implementation of the Mental Capacity Act (2005) in England and Wales in 2007.

I will now clarify the definitions of learning disability. As mentioned in the Methods section, I used a range of search terms to identify research involving people with learning disabilities. In the papers identified, the following terms were used to describe the samples: people with learning disabilities, intellectual disabilities or mental retardation. The level of disability was described in most cases as mild, moderate, severe or profound.

There was a range not only of methodological approaches used, but also the type of samples used and the aims of the studies. However, there was a common rationale for all the research, namely to explore the concepts of capacity and consent using certain classes of vulnerable adults or their healthcare professionals and in some cases to identify ways of maximising capacity and therefore consent.

Despite this broad range of studies, it was possible to identify some important findings that 'cut across' these studies.

2.5.1 The functional approach to assessing capacity

The current emphasis, both in the UK and the USA, on a functional approach to assessing capacity in PWLD is illustrated by several studies (Arscott, Dagnan &

Kroese, 1998; Arscott, Dagnan & Kroese, 1999; Cea & Fisher, 2003; Fisher *et al.*, 2006; Morris, Niederbuhl & Mahr, 1993; Wong *et al.*, 2000). By considering and measuring the individual elements of capacity as defined above by Appelbaum and Grisso, researchers identified the areas of weakness. The functional approach was shown to be appropriate in the study using cohorts of patients with mental illness or dementia alongside those with learning disabilities (Wong *et al.*, 2000); this is because some participants in each experimental group were assessed as able to consent. Wong *et al.* considered that this should lead to a rejection of the 'status' approach, in which would the patient's capacity would be judged based on their diagnosis. Those studies using comparison groups when studying ability to consent (Cea & Fisher, 2003; Fisher *et al.*, 2006; Morris, Niederbuhl & Mahr, 1993; Wong *et al.*, 2000) also produced evidence to support the functional approach to capacity, as they showed that as the cognitive demands of the 'capacity' standard increased, capacity decreased and this was also the case for people without learning disabilities. This establishes a 'hierarchy' of complexity that can be used in future assessments. The conclusion by Wong *et al.* (2000) reflects the findings of most of the research in this review, and summarises the functional approach to assessment of capacity:

"Consistent with current views, capacity reflected an interaction between the decision-maker and the demands of the decision-making task" (p295)

The scoring system for 'understanding' appears to have evolved. Researchers in earlier studies (Arscott, Dagnan & Kroese, 1998) used a definitive score of 0 for lack of understanding to 1 for understanding, however, in later studies an intermediate score was used for partial understanding (Arscott, Dagnan & Kroese, 1999; Cea & Fisher, 2003; Wong *et al.*, 2000). This greater flexibility is

useful when considering the application of the research findings as, when using a functional assessment of capacity, the level of understanding required to indicate capacity may depend on the balance of risk and benefit of the treatment to be undertaken.

In the research described, the ability to express a choice appears to be the easiest functional ability. In practice, this could be misleading, because ability to express a choice does not necessarily imply an understanding of the factual material presented, or its consequences for the individual. This was illustrated in the study by Dye *et al* (2007), when 100% of participants indicated a choice to take part in the research, but the level of understanding of its various aspects ranged from approximately 12.9% of participants to 69.4%.

2.5.2 Professional attitudes to consent

Several of the papers provide evidence of professional attitudes to consent, even if not specifically investigating them. There appears in some cases to be an assumption of *incapacity* in people with learning disabilities rather than the now universally accepted assumption of *capacity* (Murphy & Clare, 1997). Carlson (2004) found inconsistency in what healthcare professionals stated was their attitude to consent and what happened in practice. Forty six per cent of professionals believed that the patient was unable to understand and therefore did not attempt to obtain consent. Similarly, Haw and Stubbs (2005) found that psychiatrists prescribing psychotropic drugs 'off-label' had only notified 6% of patients of this fact, citing as their reason that the patient would be unable to understand. By implication, informed consent had not been given for this use. Green and Nicoll (2001), as healthcare professionals, however, pay detailed attention to the issue of informed consent when describing their case study.

These findings suggest that awareness of the legal requirements for valid consent, and the way healthcare professionals practise, is not consistent. The new Mental Capacity Act (2005) in England and Wales, which came into effect in 2007, seeks to bring together previous case law rulings and guidelines in an effort to ensure both that people without capacity are protected and that assessments of capacity are carried out before making assumptions of incapacity. This obviously has major training implications for healthcare professionals, but should lead to better practice and more people-centred health care for those with learning disabilities.

2.5.3 Facilitating informed consent in people with learning disabilities

Some studies, as well as measuring functional abilities of PWLD as part of the research, also investigated ways of maximizing capacity by testing various methods of presentation such as 'chunking' the information or using photographs or videos (Dunn *et al.*, 2006a; Dye, Hare & Hendy, 2007; Wong *et al.*, 2000). It is clear from these findings that the ability to give informed consent can be facilitated by using the functional approach, and ensuring that the required information for each decision is presented in a format tailored to the individual concerned and to the decision to be made. However, the findings have been inconsistent on this point; some showing the capacity could be increased (Arscott, Dagnan & Kroese, 1999; Cea & Fisher, 2003; Wong *et al.*, 2000) while others (Dye, Hare & Hendy, 2007) did not support this finding. Dye *et al* consider that this unexpected finding may have been due to the fact that their study involved consent to research, while others have involved consent to treatment; previous health experience may have been a confounding factor in these studies. The fact that some researchers investigated consent to take part

in research while others focused on consent to treatment makes it difficult to compare findings, although the consensus appears to be that making information less cognitively demanding will improve capacity.

2.5.4 Factors influencing ability to consent

All the quantitative research identified has shown evidence that verbal and memory capacity and general IQ have an impact on capacity, and thus on ability to give consent (Arscott, Dagnan & Kroese, 1998; Arscott, Dagnan & Kroese, 1999; Dye, Hare & Hendy, 2007; Fisher *et al.*, 2006; Morris, Niederbuhl & Mahr, 1993). However, there are other factors that may influence this ability; several authors concede that there may have been confounding factors in their research. Arscott *et al* (1999) and Dye *et al* (2007) mention the potential differences between vignettes and real life situations that may induce feelings of stress, nervousness and powerlessness. The possible lack of decision-making opportunity in people with learning disabilities is also mentioned (Arscott, Dagnan & Kroese, 1999; Dye, Hare & Hendy, 2007). Cea and Fisher (2003) suggest that previous experience with proposed treatment, and the way in which the information is presented will also affect findings.

2.5.5 Limitations of the research findings

Although it has been possible to identify useful findings from this review, there are important limitations, especially when applying these findings to clinical practice. Although the studies used people with learning disabilities (in some cases together with comparison groups or other 'mental disability' groups), the focus of the research varied, together with the detailed methods used. Some researchers investigated consent to research; others consent to treatment or

(indirectly) consent to taking medication. Within these groups, some researchers used hypothetical vignettes, some 'real life' situations. Regardless of which method was used, participants' life experiences may influence their responses and confound the results. Even the reports that contained details of participants' residential status, for example, did not link this factor to the findings. Samples in each study differ in characteristics such as residential status, employment status and health experience thus, unless these are taken into account, it is difficult to ensure that they have not influenced the findings. Samples were recruited differently, using different criteria – Wong *et al* (2000) for example, excluded participants without verbal expressive communication or who required a complex explanation of their blood test. Staff in day centres were asked to judge potential participants' ability to take part, for example Dye *et al* (2007) asked key workers to identify potential participants who had an attention span of up to 30 minutes and who could communicate verbally. Studies involving comparison groups have provided useful evidence, although the fact that 'comparison' participants may have greater experience of decision-making and also of health treatments may have skewed the results.

2.5.6 Strengths and limitations of the review

One of the possible limitations of this review is the choice of bibliographical databases used. Having taken the advice of a specialist librarian, five databases were used to retrieve suitable papers. Ancestry searches from these papers were carried out, which yielded further material. I believe that the duplication which occurred between databases suggests that coverage was fairly comprehensive. I did not include unpublished material, as I considered that if research was of sufficient importance and/or quality, it was likely to have

been published; unpublished material would not have the benefit of peer review. Due to the relatively small number of papers found, none were excluded on the grounds of quality and this may weaken the conclusions.

Another limitation is the fact that some of the papers contained little or no information on the ethical issues concerned in obtaining consent for the study. As mentioned, recruitment sometimes involved access via 'gatekeepers' or assent was obtained rather than informed consent. These factors may have led to less reliable findings.

2.5.7 Implications for clinical practice or use of current guidelines

Overall, the findings of this review support the functional approach to assessing mental capacity for the purpose of obtaining valid consent. This is in line with the approach of the Mental Capacity Act (2005), which became fully operational in 2007 in England and Wales. The review also illustrates the fact that whether or not capacity to consent is achieved may depend on the effort made to 'tailor' the relevant information to the abilities and needs of the individual concerned. This has implications for clinical practice – particularly in general practice, where considerable time constraints exist. Healthcare professionals are legally obliged to comply with the requirements of the Mental Capacity Act; in practice this may cause problems due to the time needed to maximise the potential for capacity in many individuals.

2.5.8 Future research

Based on the findings of this review, I concluded that there was a need for research exploring consent in people with learning disabilities using real life

situations. In the following chapters I will report on such a study conducted as part of the programme of work for this PhD.

Table 1 Summary of papers from literature review

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Arscott <i>et al</i> (1998)	To investigate the ability of PWLD to consent to psychological research	Quasi-experiment	Adults with a LD from various social educational centres in 2 towns in W. Midlands. n=40	Assessment of receptive vocabulary using the BPVS. Interview using scoring protocol to assess ability to consent	Scores were produced for ability to consent. The reliability of the scoring protocol was tested using a second rater (Kappa 0.95 across all questions)	None of the participants answered all 5 questions correctly. Questions about the advantages and disadvantages of the research were the most difficult to answer, and 42.5% did not understand that they had the right to withdraw at any time. Further analysis using association with BPVS score showed that people with higher receptive language scores tended to answer more questions correctly.
Arscott <i>et al</i> (1999)	To investigate the assessment of capacity of PWLD to give informed consent to treatment, and the influence of verbal and memory ability on this capacity	Quasi-experiment	Adults with a LD from various social educational centres in 2 towns in W. Midlands. n=40	Interview using scales to measure receptive vocabulary, verbal and spatial memory. Interview using questionnaire to assess ability to consent.	Scores for each parameter were produced and tested for association using SPSS software.	Verbal scores were positively correlated with ability to consent (for all 3 vignettes); memory scores were positively correlated with the ability to consent to the surgical & medical vignettes, but not the restraint vignette. 65% of the sample was able to consent to at least one vignette. BUT 35% had insufficient understanding of all factors associated with capacity to consent on ANY of the vignettes.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Arcott <i>et al</i> (2000)	To investigate the amount of knowledge that people with ID have about their medication, including the name of the medication, why it is being taken, the amount taken, the frequency and possible side-effects.	Quantitative	Adults with a LD from various social educational centres in 2 towns in W. Midlands. n=30	Questionnaire survey	A score for knowledge of medication was produced, using a 'Knowledge of Prescribed Medication Questionnaire'. Scores for individual questions were compared using one-way ANOVA, and Sheffe's procedure to determine significant differences.	People with ID have a poor knowledge about some aspects of their medication - in particular, the side effects and possible alternatives. This conclusion leads the author to question the issue of informed consent in this population. The reasons for this are not clear from this study (as the results are comparable with other similar studies using other populations) - the participants may not have received information, or alternatively may have not remembered it. The author suggests further research to address the amount of knowledge retained following the provision of information.
Broughton (2002)	To give a general overview of the literature available about women with learning disabilities and cervical screening.	Literature review	5 databases, published and electronic journals, library and world wide web.	Databases systematically searched from 1990's to present. Specific search strategy not stated.	Not stated	With regard to informed consent, women with learning disabilities need to have knowledge and information about the cervical smear test and its relevance to them. Women with LD need to gain some control through appropriate preparation; education, knowledge and support from appropriately trained professionals in order to be able to make an informed decision about cervical screening.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Carlson <i>et al</i> (2004)	To investigate present practice, in relation to consent to treatment, of those who refer to an adult learning disability service	Questionnaire survey	ALL referrers to a CTPWLD. n= 171	Postal questionnaires. 79/171 responded - response rate 46%.	Not stated. Awareness of consent guidelines by referring agencies analysed, plus prior discussion of referral with client.	68% of all referrers but only 44% of GPs are aware of guidelines. 52% of referrers always discuss referral with client beforehand; 33% usually do; 6% rarely, 5% never. Reasons for not obtaining consent: obtained consent from another (60%); patient unable to understand (46%); did not realise I had to (13%); forgot (4%); time constraints (4%). Results showed that those who were unaware of guidelines were less likely to give information to the patient on what would happen following referral and less likely to keep written records of consent. This suggests that increased awareness of guidelines on consent results in better practice.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Cea and Fisher (2003)	To examine the ability of adults with mild and moderate mental retardation living in residential facilities, as well as those with no retardation, to understand the elements of informed consent for health related treatments within the 4 psycho-legal standards proposed by Appelbaum & Roth (1982)	Quasi-experimental. Interviews.	3 equal groups: No MR, mild MR, moderate MR. Those with MR recruited from local residences, those without from a local community college n=90	Individual interviews using 'Assessment of Consent Capacity-Treatment' instrument developed for this study. 15 mins per vignette-total 45 mins session for each ppt.	All interviews audiotaped, transcribed and independently scored by 2 trained raters using a 3-point coding system. Inter-rater agreement high. Univariate analysis of variance (ANOVA) comparing differences between groups in each context (vignette) and each psycho-legal standard.	The ability of adults with and without MR to provide full-credit responses to questions decreased as level of cognitive complexity of the standard associated with the question increased. Significant differences between a) groups in each treatment context and b)groups in each psycho-legal standard: 1.Communicating a choice - majority of ppts with mild MR and almost half with moderate MR provided adequate responses. 2. Understanding factual information - most ppts with mild MR able to adequately or partially understand factual info, and half of those with moderate MR. 3. Appreciation of the situation & consequences - ppts in all 3 groups showed lesser capacity on this standard, but majority with MR showed at least partial grasp. 4. Rational manipulation of info - adequate responses to this were lowest across all 3 groups. This research shows that many adults with mild MR and some with moderate MR do have the ability to provide informed consent. Consent capacity could be enhanced with supportive decision making or educational techniques.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Dean <i>et al</i> (1998)	To identify difficulties in assessing the capacity to give consent	Qualitative using structured interviews	People with LD living informally in Severn NHS trust buildings. n=67	Interviews carried out by registered LD nurses. All interviewers trained in same format. Interviews tailored to individuals.	Developed a graphic method to summarise results of each assessment - 'circle of consent'.	Only 4 could give valid consent to their care & treatment. 2 could not do so due to mental health problems. The other 61 - could not, mainly due to communication problems. Therefore, it was considered that some people could not exercise control due to communication problems, or situations in which people's preferences were not taken into account. There were a number of people who could give some level of consent, but did not meet criteria for valid consent. The findings of this study illustrate that consent and decision making have long been a neglected area of practice in LD services.
Dunn <i>et al</i> (2006)	To investigate whether a video presentation is a useful tool in helping PWLD to gain sufficient knowledge to make an informed decision about treatment	Within-participant comparison'. Experimental design: self-controls (Fink p94)	n=19 people with mild or moderate LD, from social education centre in West Midlands	Administration of a set of 3 comprehension tests prior to, during, and after the showing of a video about psychology services. Comprehension tests carried out individually with the researcher; questions and responses verbal.	Data analysis carried out using related t-tests.	Ppts knowledge of psychology significantly increased following video. Test before video (CT1) < CT2 (tested at 3 points during video, following each section). CT3 (end of video) still significantly greater than CT1. Info understood & maintained more efficiently if presented (& assessed) in sections, ? due to memory problems in PWLD. Replicates findings of Wong (2000) - capacity to consent increases when information is presented in chunks.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Dye <i>et al</i> (2007)	To investigate the different forms of information provision when assessing capacity to consent in people with LD	Randomised controlled trial	Recruited from 3 day services for people with mild to moderate LD. Inclusion criteria: Attention span of up to 30 mins; Able to communicate verbally. n=102 initially, 85 eventually completed study	Interview using 'ability to consent' questionnaire (ACQ) and instruments to measure receptive vocabulary (BPVS), memory and reasoning abilities.	One-way ANOVA between experimental conditions and Pearson's correlation between ACQ and other measures.	Experimental manipulation of reducing demand on memory, or providing additional visual info did not result in an increase in ability to consent. ACQ scores correlated with aggregated memory score, reasoning score and BPVS score. Only 5.9% of ppts were assessed as able to consent, although all ppts could indicate a choice.
Fisher <i>et al</i> (2006)	To examine the capacity of persons with MR to consent to participate in RCT's.	Quasi-experimental. Interview study using consent questions for a hypothetical RCT	Adults - 50 with mild MR, 50 with moderate MR and 50 'comparison' subjects without MR. Recruited from community residences and day facilities. Around 50% had psychiatric co-morbidity. n=150	Assessment instruments: IQ was assessed for the purpose of categorising ppts as mild or moderately retarded. The Assessment of Consent Capacity-RCT was used to assess consent capacity.	ACC-RCT items grouped into 4 'consent categories' - understanding, appreciation, communicating a choice, reasoning. Univariate and multivariate methods - correlation tests, t tests, ANOVA, regression analysis, MANOVA all using SPSS.	Adults with MR strongest in communicating participation choice, weakest in providing reasons for or against. Understanding, appreciating and reasoning about RCT - Adults with MR < those without, adults with moderate < those with mild MR. BUT proportion of adults with MR whose performance on certain consent categories was comparable to 'controls' with normal IQ was unexpected. Data suggest that consent capacity may be enhanced when disclosures and consent assessment for RCT's are individualised for adults with MR. Obtaining meaningful assent from adults with mild to moderate MR is feasible in most cases. Within each MR group, IQ score predicted ACC-RCT score, BUT lack of

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
						association with consent experience, history of aggressive disorders and psychiatric symptom severity in general. This underlines major role of IQ.
Green & Nicoll (2001)	To describe how the process of reflection facilitated insight into the therapeutic and caring relationship. Issues relating to informed consent were discussed.	Case study	One case study	Reflective diaries	N/K	Issues relating to informed consent were complex and required special consideration.
Hart (1998)	To describe the experiences of PWLD in a hospital setting	Qualitative – semi-structured interviews	It is not stated how these participants were recruited. n=13 from 7 different general hospitals.	Interviews tape-recorded and transcribed verbatim.	Grounded theory to identify a series of key concepts.	Key concepts – 'fears about treatment', 'communication', 'general nursing', 'consent to treatment' and 'doctors'. Much of the content was critical of service provision. 'Consent to treatment' is further investigated in Hart (1999) below.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Hart (1999)	To describe the problems of obtaining informed consent in PWLD in the health care setting	Qualitative - Semi-structured interviews	It is not stated how these participants were recruited. n=13 from 7 different general hospitals.	Interviews tape-recorded and transcribed verbatim.	Grounded theory, using constant comparative analysis	With regard to consent to treatment, the management of PWLD in general hospitals was diverse. Professional attitudes and practice varied.
Haw and Stubbs (2005)	To determine the frequency of 'off-label' prescribing of psychotropics for in-patients with mild intellectual disability and mental illness resident in a large psychiatric hospital, the nature of the off-label clinical indications and details about patient consent and case note documentation of the off-label usage.	Cross-sectional survey plus interviews.	Patients in the Adult Unit of a hospital offering specialist in-patient treatment for a wide variety of mental health problems. All patients suffered with mild or borderline ID and mental illness or personality disorder. n=56 Final sample n=26 (patients being prescribed off-label psychotropics)	Structured interviews with consultant psychiatrists (caring for the sample)	Not stated.	(related to informed consent) For 29/32 off-label prescriptions, the psychiatrist was aware that the prescription was off label. The psychiatrists believed that in only 21/32 off label prescriptions, (66%) had the capacity to understand about medication. In only 2 (6%) had the patients been told the drug was being used off-label. The reason cited was that the patient lacked capacity to understand the off-label concept. Because the patients studied had ID and mental illness, the findings cannot be generalised to community or hospitalized patients with ID alone.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Heslop <i>et al</i> (2004)	To ascertain whether PWLD on psychotropic medication are being informed about the benefits, risk and alternative to treatment.	Qualitative -a descriptive study	Adults with learning disabilities from 4 regions of England, with their closest carer and the prescriber. n=21	Semi-structured Interviews of individuals themselves, plus closest carer and professional prescribing the medication	Not stated	Most ppts could articulate the benefits of their medication; very few were aware of possible side effects or risks. A number of prescribers said they had not assessed the person's knowledge, or that the person's understanding was not recorded. Most interviewees thought PWLD should be given the same information as anyone else. PWLD generally made an assumption that their carer would, or should know all about their medication. Both ppts & carers felt patients were given no choice re. whether to take the medication or not. Key strategies were produced to facilitate informed choices.
Heslop <i>et al</i> (2005)	To explore what knowledge PWLD and their carers had about the person's treatment with psychotropic medication.	Qualitative - Interview. Research team consisting of 3 researchers and 5 co-researchers with learning disabilities.	As above (Heslop 2004) n=21 Inclusion: learning disability on psychotropic medication. Further purposive sampling to include both M and F, a range of ages & backgrounds & differing levels of support.	Semi-structured, face to face interviews. Interviews by co-researchers based on an accessible interview schedule. Carers and prescribers also invited to take part (with consent of ppt)	Grounded theory approach. Thematic analysis supported by the use of MAXqda qualitative data analysis software.	Sketchy knowledge about why medication was prescribed. Lack of knowledge about possible side-effects, their recognition and what effective action to take. Discrepancy between what PWLD thought their carers knew and what the carers actually knew. Poor provision of information for carers. Need for more information. Limited access to alternatives to medication. Key strategies identified.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Hunt <i>et al</i> (2004)	To provide evidence of mainstream health staff and LD professionals working together and breaking down barriers to provide a seamless service	Case study	One case study	N/K	N/K	Health professionals, by reflecting on past experiences and working seamlessly as a multi-disciplinary team, enabled the patient being studied to have an operation and give informed consent.
Iqbal (2002)	To describe the application and ethical issues pertaining to a differential reinforcement of inappropriate behaviour programme in a patient with ID and ? Autism? OCD	Case study	One case study	N/K	N/K	With regard to consent, there was lack of informed consent from the subject, as he did not understand the issues in question, nor the treatment objectives and reasons for decreasing his ritualization and social isolation.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Keywood <i>et al</i> (1999)	To examine how decisions are made on behalf of adults with LD; the role that adults with LD play in decisions about their health; the views and expectations of adults with LD as to how their role should develop in the future.	Qualitative, based on values of participatory research	2 groups of adults with LD. One group working in a small workshop (N=15); one group attending a large day centre (N=11). A further 11 adults with LD who attended a different day centre, plus relatives and carers	Workshop focus groups recorded and transcribed. Interviews with members of an advocacy group and members of a day centre not involved in the workshops.	Data analysed using qualitative research methods. Not specifically stated.	<p>Limited health care decision-making; people are often asked to make decisions on the basis of inadequate information; people's limited knowledge of their own health needs limits their freedom to make health care decisions; there are exaggerated legal concerns surrounding the signing of consent forms.</p> <p>Dialogue between health professionals & care-givers, excluding adults with LD, obscures consideration of people's capacity to give consent. Some customs & practices of health professionals impede facilitating health care decision-making. Health care practice broadly favours proxy decision-making, most particularly in respect of reproductive choices. Asserting people's autonomy in the guise of 'choices' has to be scrutinised carefully.</p> <p>The law fails to offer guidance on best practice in health decision-making in adults with LD; typically, focus of decision-making does not reside with adults with LD; there is scope for developing models of support decision-making which recognise the <i>interdependence</i> of our decision-making.</p>

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Morris <i>et al</i> (1993)	1. To test an instrument for assessing capacity to consent 2. To test the hypothesis that capacity to consent increases with intelligence. 3. To test the hypothesis that capability would vary according to vignette.	Quasi-experimental	3 groups - without MR, mild MR and moderate MR. Selected on basis of 'availability and willingness' from various day and residential facilities. n = 45	Interviews using 3 protocols, matched to 3 hypothetical treatment vignettes. Scoring based on understanding of presenting problem, of intervention, of risks, benefits and alternatives, of rights and options and expression of decision with rationale. 3 interviewers; inter-rater reliability tested.	Inter-rater reliability was assessed and deemed highly significant. Descriptive statistics only - apart from a Jonckheere test to show relationship between capacity and level of intellectual functioning.	Experimental findings showed the likelihood of being determined capable to provide informed consent was directly related to level of intellectual functioning. The interviewing process provided reliable determinations about capability. Problems with level of information-giving - interviewers may have varied in their level of disclosing or teaching information. Stress the need for further research, in particular, situation specific. Need to balance need for autonomy and protection - risks and benefits are relevant. Express doubt about there ever being a universally accepted standard for capability to consent.
Tuffrey-Wijne (2002)	To describe a case study that aimed to consider the unique needs of a client who has Intellectual disabilities and a terminal illness	Case study	One case study	Not stated	N/A	The client refused medication and this raised the issue of informed consent to treatment/medication, as on occasions the staff had tried to hide his medication in his food. The nature of learning disability can also affect the assessment/recognition of symptoms etc as described in the literature review by the same author.

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
Tuffrey-Wijne (2003)	A literature review to answer the following question: What are the palliative care needs of people with intellectual disabilities?	Literature review	3 databases	Accessing computer databases - CINAHL (1983 - present), Medline (1980 - present) and PsychINFO (1984 - present)	Not stated	Literature review suggested some potential problems: late presentation of illness, difficulties in assessing symptoms, difficulties in understanding the illness and its implications and ethical issues around decision making and consent to treatment.
Wong (2000)	1. To investigate & compare the performance of 3 groups of ppts - 'mental disability' (MI/ LD /dementia) on a decision making task using same assessment methodology. 2. To assess whether by simplifying information & modifying response to become less dependent on verbal ability,	Quantitative. ? Quasi-experimental	Convenience samples of the 3 'mental disability' groups recruited through local clinical services. Control group recruited from phlebotomy clinic of local district general hospital. Mental illness group n=21; LD group n=20; dementia group n=21. General population group n=20 (screened first to exclude a 'mental disability'.	Standardized semi-structured interview for decision-making assessment. Assessment of severity of 'mental disability' using: Mental illness - BPRS; LD - verbal IQ using WAIS-R; Dementia - MMSE.	Inter-rater reliability for scoring on the level of 'mental disability', and decision making assessment was tested using kappa coefficient or Spearman correlation. SPSS was used to compare the 4 ppt groups with ANOVA for continuous variables and chi-squared or Fisher exact test for categorical variables. Ppts were compared across 2 stages of assessment using the McNemar test, and Cochran's Q test for comparison across 4 stages - to establish which items of information were most difficult to understand.	Compared with the 'general population' group, significantly smaller proportions of LD and dementia groups were judged as having capacity. Nevertheless, in both these groups, some ppts had capacity to make a decision re a blood test even at the initial (spontaneous) stage of the staged assessment of capacity. No significant difference between mental illness and 'general population' group. Regardless of experimental group, the main difference between individuals with and without capacity lay in their ability to 'make a decision based on the information given'. Across the 3 'mental disability' groups, there was a broadly similar pattern in understanding and retaining particular elements of the

Reference	Purpose of study	Methodology	Sample & size	Data collection method	Method of analysis	Main findings
	capacity might improve; (they expected that performance of each group would be significantly poorer than that of counterparts in the general population"					information sheet. Risks of procedure and 'risks of saying no' appeared difficult. Likely that these elements were too cognitively demanding. For all groups except 'dementia', capacity increased with progressive simplification of the task. This supports a 'functional approach' to obtaining informed consent.

In this chapter, I have described the process and outcomes of a systematic review of the literature on informed consent to healthcare interventions in people with learning disabilities. I identified the major themes which relate to the functional approach to capacity, the professional attitude to consent and the ways consent can be facilitated in people with learning disabilities. These informed the design and scope of the research project I planned to conduct.

The planning and methodology of the study is described in the next chapter.

Chapter Three

Methodology

3.1 Introduction

In the last chapter, I reported the findings from an integrative review of the literature on informed consent to healthcare interventions in people with learning disabilities. The review indicated a need for research on consent in people with learning disabilities in a 'real life' context rather than presenting participants with vignettes. The evidence from this review informed the aims and objectives of my study, and enabled me to identify gaps in the knowledge in the field of consent in people with learning disabilities.

In this chapter, I outline the aims of the study, the research design and discuss some of the ethical challenges.

3.2 The aims of the study

The aims of this qualitative study were to 1) explore the information needs of people with learning disabilities with respect to consent for new types of genetic test and 2) identify ways of facilitating informed consent. For the purposes of this study, the focus will be on pharmacogenomic tests used for health care management.

The objectives were to:

- examine the ways in which obtaining informed consent (from people with learning disabilities) for screening blood tests is currently achieved
- assess the attitudes of healthcare professionals and carers towards the provision of pharmacogenomic testing for people with learning disabilities

- assess the potential understanding of and attitude to pharmacogenomic testing in people with learning disabilities
- make recommendations to ensure appropriate practice in obtaining informed consent for pharmacogenomic testing from people with learning disabilities.

Research Questions

1. What is the current practice in obtaining consent for a blood test in people with learning disabilities?
2. What are the attitudes of healthcare professionals and carers to offering pharmacogenomic tests to people with learning disabilities?
3. What information would people with learning disabilities wish to have when making a decision about having a pharmacogenomic test, and does this differ from blood tests for other purposes?

3.3 Research Design

The general topic area of informed consent to healthcare interventions in people with learning disabilities is one in which there has been a limited amount of research (Goldsmith, Skirton & Webb, 2008). This integrative review, in which consent to healthcare interventions was explored, also indicated the need for research in a 'real life' setting. The aim of this programme of study was to explore the information needs of people with learning disabilities with respect to pharmacogenomic testing. Qualitative research is an appropriate paradigm to adopt when a new area is being explored, or when little is known about a topic area (Morse & Field, 1996). Because I wished to explore participants' attitudes and experiences, I considered that a qualitative study was appropriate. Qualitative research involves collection of data that cannot be adequately

expressed numerically and that describes people's behaviours and ideas in their social world (Murphy *et al.*, 1998.). Patton (2002) considered that one of the functions of qualitative data is to take the reader into the world that has been described by the researcher so that they can envisage it. Before exploring the views of people with learning disabilities on consent to pharmacogenomic testing, it was necessary to investigate and describe current practice in obtaining consent to *general* health care, to establish a 'baseline'. Building on this foundation, the feelings, beliefs and attitudes of people with learning disabilities and the people who have responsibility for their health and social care were explored. Lincoln and Guba (1985) distinguish 'naturalistic' enquiry from the positivist paradigm, describing the fact that research is conducted in a natural setting, using purposive sampling, qualitative methods and inductive data analysis. As a novice researcher, I experienced difficulty in identifying an appropriate theoretical approach within the qualitative paradigm. My starting point was the research questions, and what type of data would be required to answer them. In considering which methodological approach to adopt, I also had to take into account both the purpose of the research, and the study population. As a theoretical base, I explored the use of grounded theory, phenomenology and ethnography.

One of the principles of the grounded theory approach as described by Glaser and Strauss (1967) is that it is inductive in nature, and the theory 'emerges from the data'. However, more recently it has been acknowledged that with the increasing amount of published knowledge in certain fields, this emphasis is changing, and pre-existing concepts from the literature are often used to guide data collection, usually by informing the construction of semi-structured

interview schedules (Corbin & Strauss, 2008). The controversy between Glaser and Strauss (1967) the original proponents of the grounded theory approach, and Strauss and Corbin (1990) who modified the approach to incorporate the use of pre-conceived concepts in data analysis is described in a comprehensive review of qualitative research methodology (Murphy *et al.*, 1998). However, my proposed research was primarily exploratory - to identify current practice and explore the attitudes and perceptions of participants in the topic areas of consent, and in particular consent to pharmacogenomic testing in people with learning disabilities. Thus, although several features of the grounded theory approach appeared suitable, in particular the inductive nature of the analysis, the fact that there was no intention to produce a theory made it less so.

The phenomenological approach often involves data collection via lengthy unstructured interviews, and seeks to identify the "essence of how people attend to the world" (Richards & Morse, 2007). In view of the fact that some of the participants would have a learning disability and possibly limited concentration span, I felt that this approach would be unsuitable for practical reasons, if nothing else. Patton (2002) considers that researchers need to be pragmatic in their approach –

"being pragmatic allows one to eschew methodological orthodoxy in favour of methodological appropriateness as the primary criterion for judging methodological quality, recognising that different methods are appropriate for different situations". (p72)

Finally, I explored the possible use of an ethnographic approach. Ethnography has an interesting history, having its roots in anthropology, and being previously associated with studies of cultures very different, and often distant, from the researcher's own. Early ethnographers spent long periods living within the

culture they were studying. Margaret Mead's 'Coming of Age in Samoa', despite subsequent criticism, can be considered a classic ethnography of this type. In the first half of the 20th century there were two parallel developments. Sociologists in the 'Chicago School' were carrying out ethnographical studies of urban and rural cultures closer to home. These were described by Mary Jo Deegan (2001) as the core Chicago ethnographies and the author cites such studies as '*The Gang*' (Thrasher, 1927) and '*The Ghetto*' (Wirth, 1928). The tradition of ethnography continued from the Chicago School, with seminal works such as '*Street Corner Society*' by William Whyte (1943), in which the author spent several years living in an Italian slum area of Boston and immersing himself in the local culture. In the UK in the early 1920's, the movement known as British social anthropology was becoming established by Bronislaw Malinowski as a "discipline based on what he called 'scientific ethnographic fieldwork'" (Macdonald, 2001). Malinowski's work *Argonauts of the Western Pacific* (1922) again illustrates the nature of ethnographic fieldwork – he spent two years in the Trobriands conducting his research. Hammersley and Atkinson (2007) confirm that the main focus of ethnography is field research involving a range of methods. These authors also consider that although the use of ethnography is no longer restricted to naturally occurring populations or isolated communities, the basic principles such as the importance of participant observation still apply.

This emphasis on participant observation in 'traditional' ethnography (Hammersley & Atkinson, 2007) initially presented me with a methodological problem. As a non-healthcare professional, participant observation would be impossible for me. However, Richards and Morse (Richards & Morse, 2007)

state that one of the assumptions of ethnography is that it is better carried out by people who are not part of the culture being studied, as it is difficult for those immersed in that culture to identify embedded beliefs and attitudes. In addition, in the field of health care research, a new type of ethnography has emerged. This is the focused ethnography, which is conducted with a specific question and a clear purpose in mind and is applied in intent. Focused ethnographies, as defined by Roper and Shapira (2000), have a shorter timescale than traditional anthropological ethnographies, and focus on a specific problem in a particular context. The findings are intended to be applied by healthcare professionals. Muecke (1994, p199) defines them as "*time-limited exploratory studies within a fairly discrete community or organisation*".

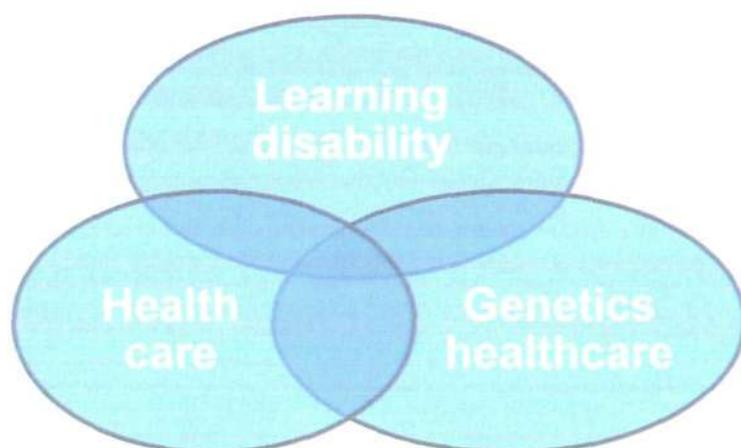
Early examples of focused ethnography include a study by Janice Morse on the cultural context and current practice in infant feeding in Fiji (Morse, 1984) and Pamela Brink's work on the custom of the 'fattening room' in a rural Nigerian culture (Brink, 1989). A more recent study investigating injury to children in a low-income neighbourhood in Southern California (Mull *et al.*, 2001) uses the term 'focused ethnography' explicitly in the title, and the authors stress the appropriateness of using ethnographic methods to investigate the underlying cultural factors that may influence the topic under investigation.

It is interesting to note that although the above studies are cited as examples of focused ethnographies by Roper and Shapira (2000), the length of time spent 'in the field' can still be relatively long. Mull *et al.* (2001), for example, spent over a year collecting data, and in another focused ethnography cited by Roper and Shapira, the research extended to ten years (Lipson & Omidian, 1997). I decided, however, that regardless of time spent 'in the field', the focused

ethnography should be the approach of choice for my study, as I would be looking at a specific concept (informed consent) among a specified group of people (people with learning disabilities), with pre-defined research questions to be answered.

One of the core characteristics of the ethnographic approach is that data collection takes place in natural rather than experimental settings and usually focuses on a few cases, perhaps a single setting or group of people (Hammersley & Atkinson, 2007). Roper and Shapira, when discussing ethnography in nursing research considered two conceptualisations of 'culture' – the behavioural and materialist concept which looks at a group's behaviour and customs, and the cognitive concept which considers ideas, beliefs and knowledge of the group. These authors state that by using these two concepts of culture, ethnographers can identify "what people know and believe and what they do" (Roper & Shapira, 2000, p3). Ethnography has been defined as "a branch of human inquiry, associated with anthropology, that focuses on the culture of a group of people, with an effort to understand their world view" (Polit & Beck, 2006, p499). Units and settings within nursing have been considered as cultures – for example, a neonatal intensive care unit as a culture (Hutchinson, 1984, cited in Roper and Shapira, 2000). I considered it legitimate, therefore, to consider the settings of health care and learning disability as cultures, together with the field of genetics healthcare, as in each of these areas there are likely to be a set of common beliefs, written and unwritten rules and attitudes. The following diagram represents, in simple terms, the relationship between the three 'cultures'. At the centre is the person with learning disabilities.

Figure 2 The relationship between three cultures



To answer the research questions, I considered that a combination of methods would be required; observation of current practice, individual interviews to explore feelings and attitudes of participants with learning disabilities, and focus groups with carers and healthcare professionals. One of the main features of ethnographic research is that it involves the use of several different methods of data collection (Hammersley & Atkinson, 2007). As well as using non-participant observation in the first phase of the study, and individual, semi-structured interviews for the second phase, I decided to use a combination of focus groups and an online bulletin board to collect data from participants in the final phase. In a comparison between face to face focus groups and 'computer mediated' focus groups, Reid and Reid (2007) found that, subjectively, participants in the latter group preferred the anonymity, lack of intimidation and lack of inhibition that this forum offered. In view of the potentially sensitive nature of the topic area, in particular when healthcare professionals were discussing their attitude towards healthcare provision for people with learning disabilities, I decided to use the online method for data collection from healthcare professionals. Participants could register with a pseudonym, thus ensuring that their

contribution remained anonymous. Another reason for choosing an online form of data collection was for the convenience of participants who may have found it difficult to travel to a face-to-face focus group. I should note here that I chose an online bulletin board (asynchronous) rather than an online focus group which would be synchronous. The method chosen had the advantage of enabling participants to register and log in at their convenience, rather than having to log in at a pre-arranged time to participate. In contrast to the data collection method selected for healthcare professionals, it has been shown that when the focus group is used as a method of collecting data from carers, participants value the opportunity to discuss problems with their peers, and gain benefit from the empathy of other participants (Chambers & Connor, 2001).

During the final stages of data collection, due to problems recruiting to the carers' focus groups and the small number of participants in each group, I conducted interviews with 'key informants' in the learning disability field to gain supplementary data and to triangulate the findings of the previous phases.

3.4 Ethical Issues

In order to protect research participants, safeguards are needed and most professions have guidelines to ensure that ethical principles are adhered to in both research and clinical practice. For example, the Department of Health states that "the dignity, rights, safety and well-being of participants must be the primary consideration in any research study" (Department of Health, 2005a, p7), while the Economic and Social Research Council (ESRC) used six core principles to inform their Research Ethics Framework (Economic and Social Research Council, 2005). Several of these are particularly relevant when

conducting research involving people with learning disabilities. Participants need to be fully informed about the purpose, methods and intended uses for the research. In this study, great care was taken to ensure that participant information sheets and consent forms for participants with learning disabilities were in a format that would be accessible to them. Further core principles from the framework include those of confidentiality, anonymity and freedom from coercion to participate. Participants should also have the right to withdraw at any time. All these concepts need to be explained to participants at the time of gaining informed consent, which needs to be in place before any research can proceed.

Attitudes, feelings and perceptions can be measured by using quantitative or qualitative methods. A feature of qualitative methodology – as described by Miles and Huberman (1994), is that the researcher is trying to identify perceptions and understand the ways people come to “understand, account for, take action, and otherwise manage their day-to-day situations” (p7). The use of qualitative methodology, with data collection via observation or interview, results in data in the form of text, and can include many direct quotations that are used when presenting the results. Goodwin (2006) describes three ethical issues that she considers particularly important in qualitative research: anonymity, confidentiality and informed consent. It was important in this study to ensure that participants with learning disabilities understood that, although quotations from interviews might be used in my report, these extracts would not render the individuals identifiable.

Given the high propensity for ethical problems in a vulnerable research population such as those with learning disabilities, it was essential to ensure

firstly that information sheets and consent forms were accessible to people with learning disabilities, and secondly that *valid* consent was obtained. In the UK, any research involving participants in the NHS is approved and monitored by NHS Research Ethics Committees. As with any participants, the problems associated with ethical research in vulnerable populations such as those with learning disabilities were reflected in the care taken both in applying for NHS ethics approval, and in the detailed consideration by the committee. This resulted in the submission of two sets of amended supplementary material. The Mental Capacity Act 2005 contains clear guidelines on carrying out research involving people who *may* lack capacity. For example, it states that:

"researchers should assume that a person has capacity, unless there is proof that they lack capacity to make a specific decision. The person must also receive support to try to help them make their own decision. The person whose capacity is in question has the right to make decisions that others might not agree with, and they have the right not to take part in research" (Ministry of Justice, 2007, p 202)

However, for this study, I decided only to include participants who were judged as having capacity to consent to the study. There were several reasons for this. Firstly, as this was an exploratory study in a topic area which has been little researched before, I felt it was important for me to involve participants who could be defined informally as having a mild to moderate degree of learning disability rather than severe or profound. This would maximise the likelihood of obtaining useful interview data. Secondly, the inclusion of participants without capacity would immediately involve the researcher in identifying 'consultees' under the Mental Capacity Act (2005) in order to discuss the 'best interests' of the potential participant. Both these factors could have resulted in delays in the

progression of the research, which would have been problematic in view of the time constraints inherent in an academic programme of study.

Recruiting participants directly would have been difficult for me to achieve in an ethical manner, as I was not in a position to judge whether potential participants would have the capacity to consent to research. Had I approached them directly, there could have been a risk that they were agreeing to take part simply to please me. They could also have subsequently given their consent without full understanding of the research. For this reason, I considered it safer to use the experience of nurses working in the field who would have a much more detailed knowledge of their patients. The use of gatekeepers is common in learning disability research (for example, see Young and Chesson, 2007) so in this study participants were recruited via gatekeepers. Initially the plan was to use learning disability nurses as gatekeepers. These nurses have extensive experience of judging capacity to consent for a wide range of clinical activities, and should therefore be able to make a judgement on an individual's capacity to consent to research. However, it soon became clear that the majority of people with learning disabilities do not have regular contact with a learning disability nurse. For this reason, an amendment was submitted to the NHS Research Ethics Committee, and approval was given to also include care workers and support staff working in the community as gatekeepers. People with learning disabilities are a vulnerable group, and it is known that there are problems obtaining informed consent from them, in particular for participation in research (Arscott, Dagnan & Kroese, 1999; Dye, Hare & Hendy, 2007). Potential participants were nominated by gatekeepers (see section 3.5), who were provided with information about the study, and detailed inclusion and exclusion

criteria. The nominated participants were then sent a letter, with information about the research in accessible format. Following the methods used by Young and Chesson (2007) each participant was asked to choose a 'supporter' (someone they knew and trusted) to accompany them to a face-to-face meeting arranged specifically to obtain consent. This meeting was not part of the study. The supporter was someone who knew the participant well; if there was any doubt about either a participant's capacity to consent to the research, or the fact that they had given their consent voluntarily, they were not recruited. Participants were given the opportunity to ask questions after the research had been explained to them to ensure capacity. This meeting was video-recorded in order to provide a visual record of any non-verbal cues that may have contradicted or supported the verbal or written consent given. The supporter was given information regarding consent and a study information sheet, and following the meeting was asked to judge a) if consent had been freely given or withheld, and b) if they considered the participant had the capacity to make the decision. As a final safeguard, just prior to the observation (Phase 2) and the interview (Phase 3), this consent was confirmed in the following way:

- The participant had indicated consent
- The supporter agreed that consent was valid
- The researcher believed consent was valid.

All three criteria needed to be fulfilled for there to be valid consent, and this decision was recorded in writing (Young & Chesson, 2007). Having discussed the issue of accessible information with a speech and language therapist specialising in learning disability, it was felt that there was too much information

to take in when both Phase 2 and 3 were included in the information sheet. It was therefore decided to consider Phase 2 and Phase 3 separately in terms of participant information sheets and consent processes for the participants with learning disability. This meant it was possible for participants to consent to Phase 2 and then decide not to participate in Phase 3. This 2-stage process made it less likely that participants would feel they had been coerced into consenting to take part in the research, and may also have enhanced their understanding of the information. There were some disadvantages to this method, however, as it entailed two separate consent interviews – one for each phase. Some of the participants appeared to find this confusing, and on reflection I consider that consent for both phases could have been obtained at the same time, with the use of a combined information sheet. In two cases, I obtained consent for both phases in one session, using the two separate information sheets and consent forms. In the first case, I considered this was necessary due to short notice of the participant having a blood test, and also for the convenience of the 'supporter' who accompanied the participant to the consent interview. In the second case, it was likely that the participant might be moving away in the near future, and I wished to ensure that consent for both phases was obtained. In both cases, I only took this action after giving due consideration to whether or not this action would cause any harm or distress to the patient, and took the action in consultation with the supporter.

There are several other ethical principles to which all research studies should adhere. The information sheets for participants with learning disabilities outlined the nature and purposes of the proposed research, and the participant's right to withdraw from the study at any time. Although the risk to

participants was minimal in terms of physical harm, it was possible that they may have experienced distress due to unfamiliarity with interview procedures, and unfamiliarity with the researcher. They were offered the opportunity to have their 'supporter' available in case any problems should occur. There was also reassurance about anonymisation of data from interviews and focus groups by using participant codes or numbers, not names. Only the researcher was involved in transcription of data, and both data and transcripts were kept in a locked drawer or a password-protected computer file.

It is important to clarify the issues of consent and capacity in this study. First, only participants who were judged by gatekeepers to have the capacity to consent to participate in research were included. However, the primary aim of the study was to explore the needs of people with learning disabilities with respect to giving informed consent to pharmacogenomic testing. A participant who was able to give consent to participate in the study would not necessarily be able to understand the concepts involved in genetic testing, as these are more cognitively demanding. Paradoxically, however, it is also possible that giving informed consent to research is cognitively more demanding than consent to a simple blood test. This may have resulted in potential participants being excluded from the study. I will discuss consent and capacity and the ethical issues arising during recruitment in further detail in the next chapter.

3.5 Methods

3.5.1 Introduction

In this section I will outline the different phases of the study:

- (Phase 1 – Integrative review of the literature described in Chapter 2)

- Phase 2 – Observation
- Phase 3 – Interviews
- Phase 4 – Focus groups, online bulletin board and interviews with key informants

In preparation for the study, two learning disability teams in the South West of England were approached to support recruitment of people with learning disabilities. Gatekeepers were identified from each learning disability team, from local community groups and from local GP surgeries. I also canvassed possible members of the advisory group.

3.5.2 Phases 2 and 3

3.5.2.1 Recruitment

In Phase 2, it was necessary to recruit participants who require some form of regular blood test. Following discussion with the senior community learning disability nurse from the advisory group, the researcher ascertained that these were likely to be either people with diabetes, epilepsy or Down syndrome. For Phases 2 and 3, because a specific group of participants were required to answer the research questions (mild to moderate learning disability, requiring a blood test), purposive sampling (Patton, 2002) was used. I aimed for a maximum variation sample in terms of residential status, age and ability (Patton, 2002). Consideration was given to the range of abilities involved, and different client groups such as those living in the community, in supported accommodation or in residential care homes. However, due to the emerging nature of naturalistic inquiry (Lincoln & Guba, 1985), sample numbers and

recruitment needed to be flexible. The aim was to recruit between 12-20 participants.

Inclusion criteria:

People with learning disabilities were eligible for this study if they were:

- Aged 18 years old or over
- Able to consent to participate in research
- Not affected by any acute physical health problems
- Not currently under the care of the Mental Health team
- Requiring a routine blood test within approximately two months of recruitment. This criterion was modified with the approval of the NHS Research Ethics Committee, such that there was no maximum time requirement. This was necessary due to the low number of participants requiring a blood test within two months.

Exclusion criteria:

People with learning disabilities were not eligible to participate in the study if they were:

- Judged by gatekeepers as unlikely to have capacity to consent to participate in research.

Recruitment for Phase 3 was carried out alongside Phase 2. It became apparent that I could not rely only on recruitment of the participants I observed during Phase 2; some participants were willing to be interviewed but did not have the requirement for a blood test within the timeframe of the study (14 percent), or were registered with practices that were not willing to allow access

to the researcher (14 percent). Ideally, participants should have been involved in both phases, but in view of the recruitment and access problems, I decided to conduct Phase 3 interviews regardless of the need for a blood test. This decision necessitated the submission of another substantial amendment to the relevant ethics committee. Therefore, some participants I interviewed in Phase 3 had already participated in Phase 2, others had not.

3.5.2.2 *Procedures*

1. The researcher presented an outline of the proposed research to members of the relevant professional teams in the relevant trusts. These were the local NHS trusts providing services for people with learning disabilities, together with local providers of social care.
2. The researcher clarified inclusion and exclusion criteria and the nature of a maximum variation sample with gatekeepers
3. When the participants had been identified:
 - a. An invitation letter was given to the gatekeeper for passing to participant.
 - b. One-to-one contact was arranged with the participants identified to explain the project and obtain their consent to take part.
 - c. In some cases, arrangements were made to speak to each participant's carer (paid or unpaid) to describe the study to them.
 - d. It was established where potential participants spent time during the week.

e. The requirement for a blood test and how the observation should be arranged was discussed with the participant's GP practice.

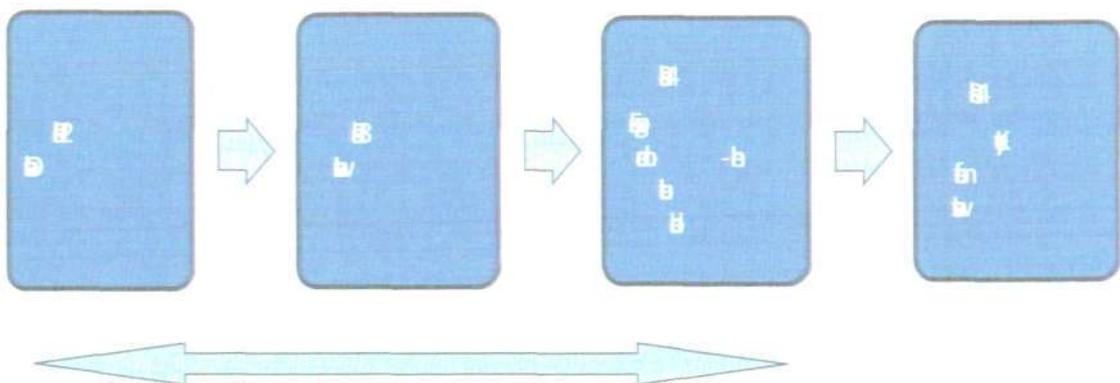
f. Interviews for Phase 3 were arranged at a venue of the participant's choice; participants from Phase 2 were interviewed subsequent to the observation of a blood test, others were interviewed at a mutually convenient time.

4. The relevant GP surgery was contacted to discuss proposed research with the primary health care team.

3.5.2.3 Data collection

One of the characteristics of ethnographic research is the use of multiple methods of data collection. One advantage of using several different methods to collect data is that findings from previous phases can be utilised in subsequent interview schedules or other data collection guides. Phases 2, 3 and 4 were conducted concurrently; this was necessary due to the low level of recruitment for Phases 2 and 3, which were therefore extended.

Figure 3 Data 'flow' between subsequent phases of the study



I describe in each findings chapter how the themes developed from phase to phase; in some cases themes were extended to include new sub-themes, and in some cases new themes were identified.

Hammersley and Atkinson (2007) state that data can be obtained from a range of sources, but that "participant observation and/or relatively informal conversations are usually the main ones" (p3). Ethnographic research has become popular in the medical setting, and Pope (2005) describes the continuum between participant and non-participant observation. In her research in an anaesthetic department, as a 'non medic' she was unable to assume a fully participant role in her research, but still became an integral part of the setting she was studying. I considered that the best method of identifying current practice in obtaining consent for a blood test in general practice was by non-participant observation. This was combined with a detailed reflexive diary that included an account of the reactivity between the researcher and the participants – both those with learning disabilities and those involved in their care. In selecting an ethnographic approach, I considered that despite not being a healthcare professional, I would have the opportunity to familiarise myself with health and learning disability settings, become known to the participants with learning disabilities, their carers and healthcare professionals and thus not be seen as a total stranger when conducting data collection. This became an essential element of my research, and I became a regular visitor to local organisations where people with learning disabilities spent their time, for example a 'drop-in' centre for people with learning disabilities.

According to Britten *et al.* (1995), semi-structured or in-depth interviews have become one of the most common qualitative methods of data collection used in

medical research. Qualitative methods are being increasingly used in the health field, either to complement quantitative research such as clinical trials, or independently (Pope, 2006), and interviews have been used in studies of both patients and doctors (Britten, 2006) to collect data on the feelings and attitudes of participants. I therefore considered that semi-structured interviews were an appropriate method of data collection to elicit the views and feelings of the participants with learning disabilities. These interviews were conducted in a safe environment familiar to participants, with a supporter present (if required by the participant) to provide reassurance.

Data collection: Phase 2 – Observation

Arrangements were made to observe a consultation for a blood test for each participant; these observations were audio-recorded and video-recorded (with the consent of all the participants, including the health professionals). This was non-participant observation as the researcher is not a healthcare professional and took no part in the process. The main focus of the observation was the communication between the participants – the service-user with learning disabilities, the healthcare professional involved and any paid or unpaid carer present at the consultation. This was important when considering the requirements for consent, in particular the autonomous nature of the decision. Field notes were taken to supplement the audio-recording of the consultation; these provided a rich description of the context, together with reflexive notes. The consultation took place at the participant's GP surgery.

Data collection: Phase 3 –Semi-structured interviews

This phase of the study was an iterative one. As interviews progressed, the interview schedule was refined to reflect data collected from earlier participants.

Early participants were interviewed to explore the information needs of participants when making a decision about a blood test. Later participants were shown resource materials based on findings from the first five interviews, as part of the interview. Feedback was sought from these participants. Subsequent interviews and/or presentations were modified based on the previous interview data. Interviews were semi-structured, and because of the possible short attention span of participants, were limited to 30 minutes. Participants were invited to have a supporter present during the interview should they so wish, but it was made clear that the supporter should only take an active part in the interview should the participant request it. Each interview was audio-recorded (with the consent of the participant).

3.5.3 Phase 4

3.5.3.1 Recruitment

Focus groups (carers)

The composition of these focus groups could not be finalised until the participants for Phases 2 and 3 had been selected. Ideally the parents or paid carers of the participants from Phases 2 and 3 would have been involved. However, this proved impractical and it was necessary to take a pragmatic approach and recruit carers via the local carer development officer. I gave her details of the study and the inclusion criteria, and she was able to suggest suitable participants for the family carer's focus group. Participants for the paid carers' focus group were recruited via the houses where the Phase 2 and 3 participants lived, with the agreement of the providers of support to those houses.

Inclusion criteria:

Carers were eligible for inclusion if they were:

- Paid or unpaid carers of people with learning disabilities
- Aged 18 years or over
- Able to give informed consent

Bulletin boards (healthcare professionals)

Healthcare professionals were recruited via the community teams and general practices during the course of Phases 2 and 3, and via an on-line learning disability forum (Foundation for People with Learning Disabilities).

Inclusion criteria:

Individuals were eligible to be included if they were:

- Healthcare professionals - GPs, practice nurses, learning disability nurses and other specialist healthcare professionals such as speech and language therapists.

Interviews (key informants)

Key informants were recruited in various ways; some by networking and some from contacts made in Phases 2 and 3. The criterion for inclusion was that a key informant had experience in the field of learning disability.

3.5.3.2 Data collection - Focus groups, bulletin boards and interviews

In Phase 4 of this study, I decided to use a combination of face-to-face focus groups, an on-line bulletin board and interviews to collect data. The aim of these was to identify the views, feelings and attitudes of healthcare professionals,

paid and unpaid carers involved in the care of people with learning disabilities and key informants from the field.

Focus groups

For focus groups to be successful, the topic area needs to be of interest to participants as well as researchers (Morgan, 1998). Morgan also considers that in contrast to popular belief, focus groups are appropriate for sensitive topics, as participants have a common interest, and are often willing to divulge their inner thoughts to people they may never see again. I considered that there would be a range of views on the topic of obtaining informed consent and decision-making in the area of health care – depending on the degree of learning disability and the family background, which would be stimulated in a focus group situation. Kitzinger supports Morgan's view, and states that "group work can actively facilitate the discussion of difficult topics because the less inhibited members of the group break the ice for shyer participants" (Kitzinger, 2006).

Focus groups were arranged in venues convenient for the participants and light refreshments provided at the start of each focus group. Each focus group was audio-recorded (with the consent of the participants). The focus groups were relatively unstructured, with the use of a topic guide rather than specific questions. There was a moderator (myself) and an observer for each focus group. Due to unforeseen circumstances, two participants from the family carers' focus group were unable to attend. Data were subsequently collected from these two participants in a joint interview utilising the same topic guide. Although not ideal, this decision was made for practical reasons in the context

of recruitment problems and the need to collect data from a range of family carers.

Bulletin board

The rationale for using a bulletin board was as follows: Firstly, healthcare professionals have time constraints and recruitment for focus groups may therefore be poor; secondly, due to the anonymous nature of a bulletin board, more candid answers may be given than in the face-to-face context of a focus group. Consent was obtained from the participants via email; participants were then given a link to the website, and instructions on how to register and contribute. Questions were posted to the bulletin board at regular intervals and reminder emails sent to those participants who had either not registered or not contributed. After the final question had been posted, the transcript was downloaded for data analysis.

Key informant interviews

In order to supplement the data from the focus groups and online bulletin board, it was decided to conduct semi-structured interviews with key informants in the learning disability field. The topic guide from the online bulletin board was used, with some additional questions designed to obtain feedback on key findings. The interviews were conducted either face-to-face or on the telephone, according to participant preference and location.

3.5.4 Data analysis – Phases 2, 3 and 4

It has been stated that there are three broad approaches to consider when analysing qualitative data (Pope, Ziebland & Mays, 2006), the first of these being thematic analysis. These authors consider thematic analysis as possibly

the simplest form of analysis and for this reason, the most commonly used method of analysis in health care research. Thematic analysis has also been described as “the basic form of qualitative analysis” (Hayes, 2000, p 171). However, Braun and Clarke (2006) consider that thematic analysis should be a method of analysis in its own right rather than, as is often the case, being seen as merely a process within a methodological approach such as grounded theory.

In their description of qualitative data analysis in health care (Pope, Ziebland & Mays, 2006), the authors describe an iterative cycle of initial reading and re-reading of data to identify initial themes or categories, coding of these categories to facilitate later retrieval and subsequent refining of categories into larger ‘key’ themes, possible with sub-themes.

Depending on the methodological approach adopted, thematic analysis can vary from inductive, using themes identified solely from the data, through to deductive, whereby pre-existing codes, for example from a literature review, are used as a framework for coding (Pope, Ziebland & Mays, 2006). Hayes (2000) distinguishes between themes ‘emerging from the data’ (data-driven) and pre-determined themes (theory-driven). An integrative review of the literature was conducted as part of this study; this was felt necessary in order to establish the current level of research knowledge in this topic area. However, analysis of the empirical data was approached in an inductive way, considered appropriate for such an exploratory, descriptive study.

Interview and focus group data were transcribed verbatim. Using what is known as ‘interim analysis’ (Miles & Huberman, 1994), the transcripts were read and

re-read during the data collection phase, and further enriching of the record (Richards, 2005) took place with the addition of reflexive memos and comments; initial attempts at identifying themes from the data were then made by further re-reading of the transcripts. Hammersley and Atkinson (1995) describe the iterative nature of analysis involving several steps, which involves repeated, detailed reading and coding of the data leading to the identification of concepts or themes. NVivo 8 (QSR International, 2008) specialist software was used to record and store this data for coding. Observations of the health checks were also video-recorded and supplemented by note-taking, using NVivo 8 software for storage and coding of the resulting data. The visual data were used to identify behavioural cues and check any incongruence between speech and expression. No formal method of analysis was used for video data; they were simply used to supplement audio data. Demographic data – including age, gender and residential status of the participants with learning disabilities were obtained during the interviews in Phase 3. Due to the small number of participants, it was not appropriate to analyse these data statistically; however, the data obtained facilitated a detailed (thick) description of participants and their context, which is necessary for 'transferability' (Lincoln & Guba, 1985).

3.5.5 Ensuring rigour

3.5.5.1 Advisory group

In order to guide the conduct of the study, an advisory group was formed prior to the fieldwork. I planned for the advisory group to include representatives from the following groups: people with learning disabilities, healthcare professionals involved in their care, paid and family carers. Potential members of the advisory group were identified and recruited by talking to members of

local learning disability teams, who later acted as 'gatekeepers' (Hammersley & Atkinson, 1995) in suggesting suitable participants. The first member of the advisory group to be recruited was the senior community learning disability nurse from one of the care trusts to be involved in the research. The senior speech and language therapist from the other learning disability team was then recruited, and acted in an advisory capacity during production of the participant information sheets and consent forms for participants with learning disabilities. Following this, a key member of one of the learning disability teams agreed to join the advisory group; this person had been my initial contact with that particular team, and had been very helpful in supplying useful contacts and facilitating my access to the team members. During subsequent meetings, she suggested suitable venues for meeting and interviewing participants. The advisory group played a role in discussing suitable settings for fieldwork and identifying local user groups, support groups and possible informants. Due to the fact that two separate geographic areas were used for this research, and that some members of the advisory group were busy healthcare professionals, the advisory group became 'virtual' in nature, with communication via email. Regular contact with members of the advisory group served to increase the level of trust between researcher and participants, particularly in view of the fact that I am not a healthcare professional. Although the plan was to include a person with learning disabilities in an advisory role, this became impractical: due to slow progress with recruitment of people with learning disabilities, I considered it advisable to include any people fulfilling the inclusion criteria in the study, and was reluctant to exclude any participant to be an advisor. In practice, my informal contact with people with learning disabilities and their

supporters during the lengthy recruitment and data collection period enabled me to familiarise myself with their lives, thus facilitating the planning of my research.

3.5.5.2 *Quality issues in qualitative research*

Rigour in qualitative research is a widely and fiercely debated topic, one of the problems being whether or not quality criteria traditionally used in quantitative or 'scientific' research should even be applied to qualitative research. The argument is clearly summarised by Spencer *et al* (2003), at one pole is the extreme view which states that there can be no quality criteria applied to qualitative research because social reality is 'constructed' (idealism) and there is no one 'truth'. Discounting this view, there are then two opposing viewpoints, firstly that because qualitative research is philosophically distinct from quantitative, a different set of criteria should be applied (Lincoln & Guba, 1985), known as the 'anti-realist' approach. Lincoln and Guba replace what they term 'conventional' criteria for rigour (which they re-name 'trustworthiness') as follows: internal and external validity are replaced with the concepts credibility and transferability respectively, and reliability and objectivity are replaced by dependability and confirmability. Regardless of the terms used, this still represents an attempt to ensure that there is some kind of 'quality assurance' when research is conducted and published.

The second approach, put forward by Hammersley (1992) appears to support a 'middle ground' solution. In his approach, commonly known as 'subtle realism', he considers the role of qualitative research as attempting to represent some underlying reality, rather than insisting on 'one truth' (Mays & Pope, 2006). In this approach, criteria common to both quantitative and qualitative research are used. Hammersley (1992) considers that the two most important factors when

judging the quality of qualitative research are validity and relevance, and defines validity as an accurate representation of those features of the phenomena that it is intended to describe.

Hammersley and Atkinson (2007) concede that the goals of qualitative research can be not only different from quantitative, but can also differ depending on which qualitative approach is adopted. Accordingly, Rolfe (2007) considers that there is no place for universal criteria in ensuring rigour in qualitative research, but that each qualitative paradigm should have its own criteria.

In my research, I have approached the issue of rigour from the 'subtle realism' approach, using Hammersley's (1992) criteria of validity and relevance. I find it difficult to accept the approach that states that there is no place for assessment of quality in qualitative approach. Although I agree that it is up to the *reader* of the research report to judge credibility in relation to their own context, I also feel that the *researcher* has a responsibility to strive for validity (as defined by Hammersley). Although my research was intended to be exploratory in nature, I considered it important for potential readers of the research report to have confidence that the research was conducted in a rigorous manner. There are several ways to try and achieve this, which I will now outline.

Validity

The objectives were to observe and describe current practice, and to explore the attitudes and opinions of participants, both of those with learning disabilities and those involved in their care. All the data (from observation, interviews and focus groups) were transcribed by me, which I considered was the best way to represent the data as accurately as possible. For analysis, recorded data were combined with field notes written at the time, and notes from the reflexive diary

which I kept. There are various approaches to keeping a research diary; Burgess (1981) suggests including autobiographical details about the research in a methodological account and Pope and Mays (2006) discuss the use of a personal research diary to record the researcher's reactions during the course of the research, together with personal and intellectual biases. Hammersley and Atkinson (1995) advise the recording of reflexive data alongside field notes. Although being guided by these approaches, I adopted an informal approach to the 'reflexive diary' and made ad hoc notes throughout the data collection and analysis period. These notes were used to inform the reflexive account included in the thesis. The use of a video recorder in Phase 2 provided valuable visual evidence to corroborate verbal data obtained. The analysis of the data, as described above, was by thematic analysis. Independent coding of several transcripts from each phase was carried out by two of my supervisors, who are experienced researchers, to maximise the validity of my analysis. This was useful, as there was congruence of the themes identified.

Reflexivity, one of the key elements in ethnographic research according to Hammersley and Atkinson (2007) requires an awareness by the researcher of several factors including his or her own background, prejudices and attitudes that may have affected any part of the research process, from research design through data collection to data analysis. From the outset of this study, I was aware that as the parent of a person with a learning disability my natural inclination was to consider myself as a 'champion' for people with learning disabilities. When observing current practice in taking a blood sample from a person with learning disability, I was on some occasions surprised by the lack of knowledge on the part of the healthcare professional. However, not being a

healthcare professional, it was easy for me to be critical of their practice, without understanding the problems they encounter in everyday practice. Keeping a reflexive diary, in whatever format, helped me to be aware of my own assumptions and prejudices. I found myself using self-disclosure as a means of increasing my credibility with some of the healthcare professionals, and indeed parents of people with learning disabilities. I felt that by identifying myself as the parent of someone with learning disability, I was demonstrating that I had some background knowledge and familiarity with some of the issues involved in this context. Similarly, when approaching practices to negotiate entry as a researcher, I found that disclosing the fact that I had worked as a practice manager for ten years, and in general practice for much longer, helped to establish some degree of rapport with the practice managers, who were usually the 'gatekeeper' of the practice.

Secondly, there needs to be an awareness of the 'reactivity' which could be present during observation or interview – the effect of the researcher on the participant. I was constantly aware of the effect my presence was having on the participants (people with learning disabilities or healthcare professionals). In Phase 2 (Observation) it was apparent in some cases that the way the consultation was being conducted was being influenced by my presence. In some cases, this was explicit, and I was addressed by the participant with learning disability. The presence of the video camera appeared to have an effect on participants in two ways. Some participants with learning disabilities made efforts to turn and smile at the camera periodically. One healthcare professional even admitted that she thought she would have trouble taking blood because she was being observed and this turned out to be the case.

Thirdly comes an awareness of the effect of context on the research findings. The other value of a reflexive diary is that it facilitates the 'thick description', which is so often referred to in qualitative methodology texts (Geertz, 1973; Hammersley, 1992; Lincoln & Guba, 1985; Patton, 2002). Thick description should enable the reader to understand the phenomenon being described and make their own judgements about its significance in their own context.

Another element of validity is transparency when describing the methods of data collection and analysis, so that readers can make their own judgements about the quality of the research. Koch (2006) argued that the "trustworthiness (rigour) of a study may be established if the reader is able to audit the events, influences and actions of the researcher "(known as the decision trail).

Hammersley and Atkinson (2007) list two other issues when looking at validity – respondent validation and triangulation of methods. Bloor (1997), however, considered that although these techniques cannot validate findings, they can be relevant in terms of providing new data.

I did not consider that respondent validation of raw data was appropriate in this study. Sandelowski (1986) suggests several strategies for ensuring rigour in qualitative research. These include checking for representativeness of the data as a whole and of coding categories, and also obtaining validation from the subjects themselves. However, the fact that the observations and interviews were video-recorded enabled me to check the accuracy of the data and I considered little would be gained by asking participants to check the transcripts. However, it was important to check my *interpretation* of the data in terms of validity of the themes, and this was achieved by summarising the findings and

incorporating them into the key informant interview schedule. I also incorporated some of findings from previous stages into the focus group guides to stimulate discussion. Any data produced is only a 'snapshot' of the context being studied, whether it is by observation, interviews or focus groups, so it was useful to put this 'snapshot' into context by discussing the findings with key informants and using the outcome to produce a richer and more rounded description.

Tobin and Begley (2004, p393) state that in qualitative research, triangulation is not used by researchers to confirm existing data, but as a means of enlarging the "landscape of their enquiry, offering a deeper and more comprehensive picture." Using an ethnographic approach usually involves several different methods of data collection, which could be described as a type of methodological triangulation. By utilising different methods of data collection (observation, interview, on-line bulletin board and face-to-face focus group), analysing the data and comparing the findings with a relevant body of literature, I consider that I achieved some degree of triangulation (Hammersley & Atkinson, 2007) to maximise the credibility (Lincoln & Guba, 1985) of the analysis. Although different methods were used to address different aspects of the overall research questions, many of the findings were consistent in terms of themes. For example, there was evidence for an increased level of acquiescence in people with learning disabilities in all phases of the study. Overall the data obtained will contribute to a detailed description of the phenomenon of informed consent in people with LD obtained from multiple perspectives.

Relevance

For me as a researcher, this was a much easier criterion of rigour to address than validity. In a practical sense this research was relevant in the following ways. The recent emphasis on ways of giving people with learning disabilities a voice, for example 'Valuing People' (Department of Health, 2001d), 'Our health, our care, our say' (Department of Health, 2006b) and evidence that people with learning disabilities do not have equity of access to health care (Disability Rights Commission, 2006), together with the Mental Capacity Act 2005 (Department of Health, 2005c) which stresses the functional approach to assessment of capacity, all make this research relevant.

However, Hammersley and Atkinson (2007) consider that for findings to be relevant, they need to add to current knowledge, or increase confidence in existing knowledge. The findings of this research add to current knowledge in the field, as will be demonstrated in the chapters following. It is also important to consider the extent to which findings can be transferred beyond the setting – and again, thick description seems to be the key. Providing a rich description of the context of my study should facilitate transferability to other settings. The relevance of research also depends on the 'audience' – in the case of this research, I consider that as well as other researchers in the field, the research needs to be relevant to practitioners involved in the care of people with learning disabilities. Mays and Pope (2006) described Hammersley's (1990) case for assessing relevance of research in terms of its capacity to help practitioners with identified problems. In line with this, Roper and Shapira's definition of focused ethnography describes how knowledge learned is expected to be useful and have practical application for healthcare professionals (Roper & Shapira, 2000).

In this chapter, I have outlined the aims of this study and described how I chose my methodological approach. The ethical issues to be considered when conducting research involving people with a learning disability have been discussed, together with a detailed account of data collection and analysis. Finally, I have described the methods I used to ensure the rigour of the study.

In the next chapter, I will focus on the ethical issues, in particular relating to recruitment and consent, which need to be considered when conducting research involving people with learning disabilities.

Chapter Four

Recruitment and the consent process – ethical considerations

Having described the methodology of this study in the previous chapter, I would now like to explore the issues that arose during the early stages, namely the recruitment process and obtaining valid consent from potential participants. This will be done by firstly describing the nature of the population and their potential vulnerability, and secondly by relating the challenges I faced to the three elements which constitute valid consent – freedom from coercion, disclosure of information and competence.

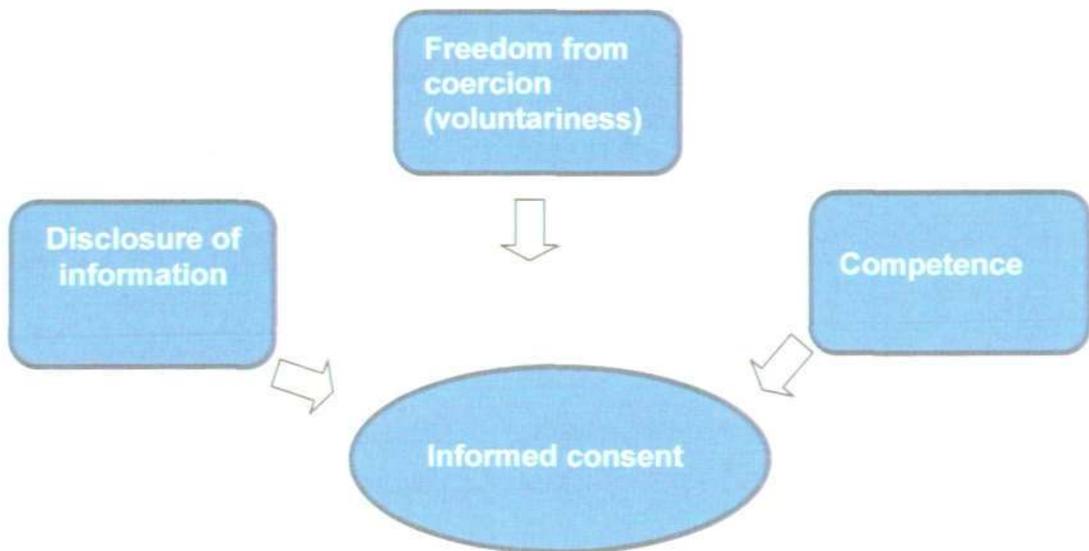
For the purposes of this thesis, it is worth considering the ethical issues surrounding the research study in greater detail. Evidence received by the Joint Committee on Human Rights confirms that adults with learning disabilities are particularly vulnerable to a lack of respect for their human rights (Joint Committee on Human Rights, 2008). In the UK, the government has now acknowledged the health inequalities experienced by people with learning disabilities, and states that “people with learning disabilities are entitled to be treated with the same dignity and respect as any other member of the community” (Department of Health, 2009c, p6). People with learning disabilities are thus considered to be vulnerable, and careful measures are needed to avoid any breach of their human rights. Potential problems when embarking on research involving people with learning disabilities include doubt about capacity to consent to participate in research, problems arising from institutional care, the tendency to acquiesce to the wishes of others and the unequal power relationship between researcher and participant (Dalton & McVilly, 2004;

lacono, 2006). lacono (2006), writing in Australia, considered that ethics committees are becoming more conservative in their approach to granting approval for research involving people with learning disabilities in order to avoid exploitation and potential harm to this group of people. However, lacono questioned this trend and considered that it could result in “non-inclusive and discriminatory decisions” (lacono, 2006, p173). Excluding people with learning disabilities from participating in research can be seen not only as denying them their right to choose to take part and have their opinions heard, but perhaps more importantly, their non-inclusion in research may lead to incomplete evidence. Lennox *et al* (2005), when considering recruitment to clinical trials, stated that excluding people with learning disabilities from trials of new medicines or clinical interventions may lead to an evidence base which is not fully representative of the population. This principle can also be applied to the recruitment of people with learning disabilities to qualitative studies – the attitudes, experiences and views of this population need to be explored in order to ensure that their needs are being met when services are being planned. The Mental Capacity Act in England and Wales (Department of Health, 2005c) includes a code of conduct for researchers wishing to carry out research involving people with learning disabilities. In line with the basic principles of the Act, researchers should assume capacity unless proven otherwise, and potential participants should receive support to enable them to make the decision whether or not to participate. If potential participants are assessed as lacking capacity, researchers have to fulfil certain criteria such as:

“The aim of the research must be to provide knowledge about the cause of, or treatment or care of people with, the same impairing condition – or a similar condition.” (p207)

They also have to ensure that the risks are negligible. If, however, the potential participant has capacity to consent to participate in the research, the usual criteria for valid consent apply. These can best be summarised graphically:

Figure 4 The requirements for informed consent



4.1 Ethical issues

When considering application to the NHS ethics committee, these criteria were challenging to me as a novice researcher, in particular as a non-healthcare professional. I will describe my attempts to satisfy the three criteria in turn, as each has been associated with interesting dilemmas.

4.1.1 Freedom from coercion

Coercion, defined as persuading (an unwilling person) to do something by using force or threats – is perhaps too strong a word to use when applied to obtaining consent from a research participant. However, consent has to be voluntary – in other words, it has to be given of the participant's own free will. When recruiting potential participants with learning disabilities, this element of valid consent

needs to be considered carefully for several reasons. Firstly, participants will have varying experience of decision-making in their everyday life. This could be related to their residential status, for example. It has been suggested that living environments have an effect on self-determination and choice. Wehmeyer and Bolding (1999) found evidence to show that adults with mental retardation (learning disabilities) who lived or worked in community settings made more choices for themselves and had greater autonomy than those who were segregated. Research also suggests that those living in smaller residences with fewer staff and fewer other residents had more opportunity to make choices (Stancliffe, 1997). The above evidence would suggest that adults with learning disabilities living independently with support, and thus comparatively integrated into the community, would develop a greater degree of self-determination and control over many of their everyday decisions. When recruiting, I therefore aimed for a maximum variation sample in terms of residential status, from those living at home with parents to those living alone in flats with minimal support.

Secondly, coercion involves the use of power by one individual over another, and in the process of recruiting participants, I needed to ensure that there was no element of coercion involved. For this reason, I did not recruit directly, but identified gatekeepers working in the field who could assist me in finding suitable participants. This is a method commonly used in learning disability research, and was explained in Chapter 3. It was interesting to note that initially some gatekeepers were reluctant to take part because of their own concerns about the individual's freedom of choice. As one staff member explained, "She would do anything if we asked her to". The two-step process of recruitment

(also described in Chapter 3) needed to be explained fully, and reassurance given that there was minimal risk of harm to the participant. By visiting the settings where the gatekeepers worked, and making myself familiar to both staff and potential participants, I felt that I had gained the trust of all concerned. The concept of coercion is a difficult one in this context; I was recruiting people who may have had little experience of decision-making and also a tendency to acquiescence when dealing with carers and other professionals. Evidence has shown that people with learning disabilities have higher levels of acquiescence than those without (Clare & Gudjonsson, 1993; Keywood, Fovargue & Flynn, 1999; Murphy & Clare, 1995). Heal and Sigelman (1995) suggest that acquiescence can be a problem when there is a power or status difference between the researcher and the respondent, and that in general, people with learning disabilities demonstrate an exaggerated acquiescence bias (i.e. the tendency to say 'yes') when being interviewed. When considering the problem of coercion, I was not convinced by the argument that potential participants were less likely to be coerced by gatekeepers than by a researcher. However, Fisher *et al* (2006, p 108) consider that "adults with mental retardation are more vulnerable than others to acquiescing to requests to please the investigator". I consider that the original views expressed above by the gatekeeper were pertinent and that the members of staff were in a more powerful position than I would be as they had the potential to influence the everyday life of the participant. However, it was reassuring that several of the potential participants nominated by the gatekeepers subsequently expressed their desire *not* to participate. Cameron and Murphy (2007) suggest that it is useful to record these decisions to show evidence that there has been no coercion in the

recruitment process. When participants had expressed an interest in taking part in my study, I then arranged to conduct a consent interview. During this period, I made the observation that each participant was keen for me to know that they wanted to help me, and this led me to reflect on their motivations. It is well documented that people with learning disabilities do not have the same opportunities or social skills to make friendships as those without learning disabilities (Chappell, 1994; Fish *et al.*, 2006). As the participants in the centre became familiar with me during subsequent visits to arrange consent interviews and research interviews, I was greeted in a very friendly manner. On an individual level, I also felt that I was viewed as a friend rather than as a researcher; the participants seemed to be expressing pride in the fact they were helping me – “its good to help each other, isn't it?” This comment was made by my first participant, who was requesting a lift following an observation of her blood test consultation in the first phase of the research. This situation also made me consider my role as a researcher with great care: would I be contravening any ethical principles by giving the participant a lift in my car? On discussion with my supervisor, we agreed that this action was ethically acceptable, but it illustrated the care that needs to be taken with regard to possible coercion.

4.1.2 Disclosure of information

The provision of appropriate information is essential when obtaining informed consent. However, deciding what or how much is appropriate is not simple. The code of practice for the Mental Capacity Act (2005) states that it is sometimes sufficient to give a broad explanation using simple language, but also stresses that the information needs to be appropriate to the needs and

circumstances of the person making the decision (Ministry of Justice, 2007). The General Medical Council recommends that information should be tailored to the individual's circumstances – including their priorities, wants and needs and level of knowledge about their condition (General Medical Council, 2008). The Mental Capacity Act (2005) states that it is important not to give more detail than the person needs, which might confuse them (Ministry of Justice, 2007). The above statements relate to a range of decisions, from everyday decisions such as where to spend time during the day, deciding where to live, decisions about sexual relationships, through to decisions about medical interventions or taking part in research.

Having compiled the necessary information relating to my study, I then had to ensure that it was in a format that would be accessible to the participants, who would have a range of intellectual abilities and communication impairments. There is a range of specialist software available for this purpose – for example Widgit ('Widgit,' 2008), a symbol-based software used in many schools, colleges and in social care. There is also a body of knowledge to guide the production of accessible information, for example, the use of simple language, short sentences and large, simple font, together with pictures if appropriate (Mencap, 2005; Social Care Institute for Excellence, 2005). Having considered the options available to me and the available evidence, I decided that I would compile information sheets and consent forms using large font text, simple language and short sentences combined with images from ClipArt ('Clip Art,' 2008) and my own digital photographs. I then sought the advice of the Chief Speech and Language Therapist from one of the local learning disability trusts, who made some useful suggestions. Once the final draft had been produced, I

then asked for comments from two other speech and language therapists, who also gave some helpful feedback.

I then conducted a small pilot study with a group of three young men with learning disabilities (who would not subsequently be participating in the study). This reinforced some advice that I had received from an experienced researcher in the field of learning disability, that the most important element when communicating research information to participants with learning disabilities is the *verbal* explanation, supported by the information in accessible written format.

4.1.3 Competence (capacity)

The final component of valid consent is that of competence or capacity. Definitions of these concepts vary, and in the United States (US) the term competence tends to be used in a legal context, whereas capacity is a clinical judgement (Appelbaum & Grisso, 1988). These authors describe the legal standards for competence as the related skills of communicating a choice, understanding relevant information, appreciating the current situation and its consequences, and manipulating information rationally. In England and Wales, the Mental Capacity Act (2005) has formalised common law relating to capacity, and the Code of Practice outlines the two-stage test of capacity:

- “Does the person have an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works?”
- “Does that impairment or disturbance mean that the person is unable to make the decision in question at the time it needs to be made?” (Department of Health, 2005c; Ministry of Justice, 2007).

If there *is* an impairment likely to render the person unable to make any decision at a particular time, then the following criteria need to be fulfilled before capacity can be confirmed:

- Does the person have a general understanding of what decision they need to make and why they need to make it?
- Does the person have a general understanding of the likely consequences of making, or not making, this decision?
- Is the person able to understand, retain, use and weigh up the information relevant to this decision?
- Can the person communicate their decision (by talking, using sign language or any other means)?

These criteria reflect those related to 'competence' above, suggested by Appelbaum and Grisso (1988) and for this reason, I consider the two terms can be used interchangeably.

As mentioned above, potential participants were nominated by gatekeepers working in the field, using the inclusion criteria for the study (see section on recruitment, Chapter 3). I explained to the gatekeepers that the second inclusion criteria was not a strict clinical assessment of capacity, but simply a judgement on their part that the person was *likely* to have capacity to consent to participate in the research. Once participants had been nominated, an interview was arranged to obtain consent. This process is explained fully in Chapter 3. In effect, this is a two-stage process for consent. However, in line with the Mental Capacity Act (2005), consent was also confirmed immediately prior to

data collection, as it needs to be valid at the time of the procedure or intervention to which consent has been given.

4.2 Capacity and its assessment

This stage of the research was an interesting one, causing me to reflect deeply on the meaning of capacity, and its relevance to the everyday life of people with learning disabilities. It was also useful to reflect on how capacity can be interpreted in different ways by different people.

4.2.1 The nature of capacity and its assessment

At the beginning of the recruitment process, when using only learning disability nurses as gatekeepers, I was sent an email by my contact on the learning disability team giving me a list of service-users at the drop-in centre who had been nominated as having capacity to consent to research. Unfortunately, this email was sent to an alternate email address and did not come to my attention until I had conducted four consent interviews at the drop-in centre. From these four consent interviews, three participants gave valid consent, with capacity being confirmed by the supporter; a fourth participant was considered by both myself and the supporter *not* to have capacity to consent to research and was therefore not recruited to the study. Interestingly, this participant was on the list of service-users nominated by the learning disability nurses as having capacity. As a non-healthcare professional, my first impression was that this particular service-user would have capacity to consent to the research. This illustrated to me how easy it is to assume understanding in a person who has good verbal skills and is seemingly articulate. This phenomenon applies particularly to certain groups of people with learning disabilities, whose communication

abilities may be well ahead of their overall cognitive profile. Bellugi and St. George (2001) described how adolescents and adults with Williams syndrome can appear articulate, which may surprise people who encounter them. The situation described above also reinforced, for me, the fact that capacity is specific to a particular decision and to the time that decision is being taken. It is possible that this person may well have had capacity in different situations – possibly less complex than consenting to research. Research probably presents as an abstract concept, and it has been shown that people with learning disabilities are more capable of understanding ‘concrete’ facts than abstract ones. For example, Fisher *et al* (2006) found that participants with a learning disability found it easier to understand the *procedures* involved in research than the *purpose* of research.

4.2.2 Lack of capacity – the implications

The consequences of choosing to conduct research with participants with mild to moderate learning disability rather than severe or profound, and having a rigorous method to ensure valid consent to participate may have had unforeseen consequences. Most of the participants I recruited to the study were relatively independent – travelling around the city without support and living alone with support or in shared housing (receiving varying levels of support). My aim was to recruit a maximum variation sample in order to observe and interview people with a range of abilities. This is particularly relevant to the observation of a blood test consultation, as I wished to observe the communication between the triad of healthcare professional, patient and carer. I only recruited two participants who had a carer present in the consulting room, and I have concerns that by ensuring capacity to consent to

research, this may result in exclusion of this group of service-users. Paradoxically, it may be the case that service-users I have come into contact with may have capacity to consent to a simple blood test, but not to consent to the research study.

In this chapter, I have explored the complex issues relating to consent and capacity in vulnerable populations such as people with learning disabilities, and the criteria that are necessary for informed consent. I have reflected on the effects that these ethical issues may have had on the conduct and outcomes of this study.

In the next chapter, I will present the findings of Phase 2 of the study, the observation of people with learning disabilities having a routine blood test in general practice.

Chapter Five

Findings – Observation (Phase 2 of the study)

5.1 Introduction

In Phase 1 of this study I conducted an integrative review of the literature on informed consent to healthcare interventions in people with learning disabilities. The findings of the review were described in Chapter 2. In this chapter I will present findings from the second phase of the study, which consisted of observation of participants with learning disabilities in a blood test consultation in general practice. Observations of these consultations were conducted in local practices and were video- and audio- recorded.

Although the focus of this study was informed consent to genetic testing in people with learning disabilities, it was essential initially to establish a 'baseline' of current practice with regard to obtaining consent when taking blood from a person with a learning disability. In the process of documenting the observations, and reading the transcripts, it became obvious that there were several factors influencing the way consultations were conducted. I will describe these findings in a narrative fashion, as the order in which things occur in the consultation could be relevant to the process of obtaining fully informed consent. In the UK, the General Medical Council (2008) published a document that illustrated the shift from paternalism to shared decision making. For example:

“you should explore these matters (the information) with patients, listen to their concerns, ask for and respect their views, and encourage them to ask questions. You should check whether patients have understood the information they have been given, and whether or not they would like more information before making a decision.” (p10-11)

When considering consent, there needs to be a logical progression in the consultation in order for the various criteria to be fulfilled. For example, the first step should be provision of information relevant to the decision to be made; there should then be an assessment of the person's understanding of that information, and their ability to weigh up the risks and benefits in order to make a decision based on that information (Ministry of Justice, 2007). The consent process, however, does not always conform to a straightforward sequence; for example initial information may need to be repeated if there is a doubt about the patient's understanding. Following these steps, consent should then be sought by the healthcare professional and expressed either verbally or in writing by the patient.

I will outline the main themes that were identified from this phase of the study and relate them in more detail to the findings of the literature review.

In any quotations which follow, I have used bold font to indicate data from the healthcare professional, who may have been a qualified nurse, a healthcare assistant or a phlebotomist. I have therefore not distinguished between the different grades of staff. By doing this, I can ensure the anonymity of those health professionals who were observed.

5.2 Demographics of participants and context

5.2.1 *Description of the participants*

Six participants with learning disabilities participated in Phase 2 of the study. They ranged in age from 34 to 59 years. One participant lived at home with parents; the others lived independently with support – either in shared houses or in individual flats. Two of the participants had support from family members –

parents or siblings, one had no formal support but had ad hoc help from work placements he attended, and three had paid carers in the form of support workers in their supported living accommodation (see Table 2)

Table 2 Participants in Phase 2 (Observation)

<i>Participant</i>	<i>Age</i>	<i>Residential status</i>
A	35	Living in a shared house (supported living)
B	51	Lives alone with informal family support
C	59	Living independently in a flat with support
D	50	Living independently in a flat with support
E	34	Living at home with parents
F	41	Living in a shared house (supported living)

Some participants were having blood tests as part of the management of chronic diseases such as diabetes or hypothyroidism, others were having tests as part of the requirements of the GP contract (Department of Health, 2003b), Direct Enhanced Services (DES) (Department of Health, 2009a) or Quality Outcomes Framework (QOF) (Department of Health, 2003a).

5.2.2 *The participants in the health context*

Blood tests had been ordered for the participants for a range of reasons. Two of the participants had diabetes and were recalled to see the practice nurse at the surgery for their annual blood tests as part of their routine diabetic management (measuring parameters such as HbA1c, random blood glucose and tests of renal function is part of this care). The frequency of intermittent appointments depends on the stability of their diabetes (National Institute for Health and Clinical Excellence, 2008). Practice nurses who have been trained in the

management of chronic diseases such as diabetes or coronary heart disease often conduct these annual reviews, sometimes jointly with the general practitioner (Pierce, Agarwal & Ridout, 2000). Blood is often taken by a healthcare assistant or phlebotomist prior to the annual review. In the case of the two participants with diabetes, one had blood taken by the practice nurse, one by a healthcare assistant. Because having these blood tests is part of the routine healthcare management, in practice they are not ordered by a doctor, it is the nurse who orders them as part of that care.

The other four participants were offered blood tests for thyroid monitoring or as part of Department of Health initiatives under the Direct Enhanced Services scheme (DES) (Department of Health, 2009a). These blood test consultations were conducted by a member of the nursing team. The patients then returned to see their doctor to discuss the results.

It was apparent that all six participants were well known to the health professionals who performed the blood test; the data from the observations were therefore a 'snapshot'. This will be discussed further in Chapter 8.

5.3 The findings

I will describe these in chronological order to reflect the progress of the consultation – the opening stage, the consent process and finally the procedure itself. In Table 3 the themes are summarised and at the end of this chapter I will review them in a short discussion section.

Table 3 Themes and categories Phase 2

Theme	Sub-theme
Patient in healthcare context	Attitude to having a blood test
	Relationship and communication with the healthcare professional
Information and knowledge	Presentation of health information
	Purpose of blood test and procedure
Consent	Seeking consent
	Expressing consent
Behavioural	Anxiety
	Bravado
	Fear
	Pain
	Relief
	Resistance
Strategies/coping mechanisms	Distraction tactics
	Establishing rapport
	Reassurance
	Use of humour or teasing

5.3.1 Theme 1 – Patient in the healthcare context

Having observed and analysed the opening stages of the consultation, this first theme was identified as a result of observing the processes that influenced the patient being invited for a blood test, and the context in which the relationship between the patient and healthcare professional developed. It was difficult to define this theme, but in simple terms it relates to how the participants see themselves in relation to their healthcare team - how they feel about going to see the doctor, about having blood tests, about their relationship and communication with the healthcare team.

The 'lead-up' to the actual venesection was in most cases lengthier than the procedure itself, but varied in content. The exchange of news and general conversation in some cases led up to an explanation of the procedure and sometimes the reason for the blood test itself. This, in some cases, signalled the start of the consent process.

The opening stages of the consultations varied. In some cases, the consultation was brief and 'business-like', with no preliminary chat or social niceties involved. Due to the nature of the participants, their responses to questions were in many cases brief, and there was therefore often little substance to the conversation.

So, we're gonna take some bloods from you this morning, B. Is that all right?

Yes, it is, yes. (E, line 5)

In contrast to this, some of the consultations appeared quite informal, starting with a social chat, with the patient relaying news to the nurse about a forthcoming move to a new house.

So you're moving into a new place?

Yes, I'm waiting, yeah

Yeah, so have you got a date yet to go, or not?

No, no, nothing's happening

Right, so you get to go and have a look at your new room?

Yeah (A, line 1)

This continues to include discussion of what colour she would like her room painted – eventually leading up to a question from the nurse asking if the patient knows why she is there that day:

Yeah, for my blood test. (A, line 16)

In most cases, there were obvious efforts by the healthcare professional to put the patient at ease – by the use of simple social conversation:

Yes, so... that's Mondays, that's from half-past nine till four, and then eight times out of ten me sister picks me up, cos she works at C, so that's um. You know, it breaks the week up and all that.

Yeah, don't want the same old thing all the time, do ya? (B, line 9)

The use of humour was also evident in several cases. In one case, immediately prior to the nurse trying to find a good vein, with needle 'poised for action', the participant made a joke and the nurse responded.

I get the point

Sorry?

I get the point (laughs at own joke)

(both laugh).

You're on form today, aren't you (both laugh again). (D, line 55)

The following exchange between the nurse and the participant during the blood test procedure illustrates the rapport between patient and health professional

Ah, he's a lovely chap. I like him.

Like him, do you?

Yeah, he's very.... Especially with me stump and all that, he's helped me a lot.

Oh, good.

Yeah, he has. He's writ some good letters to some nursing homes and all that for me, last year.

Yeah?

Which I must, um, yeah, I must praise him for cos he was very good.

Oh, good. That's what you need though

Yeah, well, that's it, yeah, you need support. (B, line 55)

This theme was more evident when interviewing participants, in most cases subsequent to their blood test, and will be discussed in the next chapter. How the patients see themselves within the healthcare context is a theme which links well to the theme of 'life experience' identified in the literature review. Under this broad theme, I identified factors from the literature such as the patient's residential status, their previous health experience, their experience of decision-

making and acquiescence. Research has shown that many people with learning disabilities are denied the opportunity to make choices or decisions (for example, Keywood, Fovargue & Flynn, 1999; Morris, Niederbuhl & Mahr, 1993) or there is simply an assumption that they do not have the ability to do so (Fisher *et al.*, 2006; Tuffrey-Wijne, 2002). Linked to this inexperience of decision-making is the acquiescence exhibited by many people with learning disabilities; researchers have found that participants with learning disabilities are unaware that they have a choice regarding their own health (for example, Arscott, Dagnan & Kroese, 1999; Dunn *et al.*, 2006a). Any or all of these may influence the patient's attitude to and feelings about their health and the people who care for them. Before a patient can make a decision of any kind, it is necessary to have knowledge to support that decision, and this leads to the next main theme identified from the observation data.

5.3.2 *Theme 2 - Information and knowledge*

From observation of a number of blood test consultations, it can be seen that the amount of knowledge imparted to patients (or indeed demanded by them) is variable. When identifying the categories within this theme, I have considered them from both the information-giving and the information-receiving perspective. In some cases, the healthcare professional attempts to establish the level of understanding of the patient; for example, does the patient know why he or she has come to see the nurse or why the blood test is advisable? It is also necessary to distinguish between a) communicating information about the procedure itself – the strapping of the cuff around the patient's arm or how it will feel when the needle is inserted, and b) informing the patient why having the planned blood test is advisable and what the consequences might be. For

example, one participant (F) who has diabetes was obviously objecting to the cuff being inflated by the nurse; an explanation as to why this measure was necessary was not given. In contrast to this, another nurse who was having problems finding a suitable vein explained this procedure as she went along. The patient was sighing loudly, seemingly losing patience with the length of time this was taking:

Mmm, right. I'm gonna put my blood pressure cuff on, cos that's not coming up very well.

Sorry (smiles)

It's not your fault, is it? Obviously knew you were coming in here today, so they're hiding. This'll just give them a bit more pressure on there, make the veins come up better. (A, line 75)

The previous extracts from the transcripts have illustrated the variation in the amount of information provided to patients prior to taking a blood sample.

For one participant (F), no information was given prior to the blood being taken, but once the procedure was over, the nurse took the patient over to the computer screen and showed her the previous blood sugar and cholesterol results, commenting that the patient's cholesterol level of 3.7 was better than her own. She then gave an explanation of target values for blood sugar readings, and informed the patient that the results would be available for the doctor to review at the appointment the following week.

It is interesting to note that although I have identified examples of information-giving prior to and following the blood test procedure, it was not obvious during the consultations, or from reading of the transcripts how much information, or indeed understanding, the participants possessed, either as pre-existing knowledge or as knowledge gained from that particular consultation. This is particularly important when considering the validity of consent. The themes from the literature review: experience of decision-making, health experience

and acquiescence, may all influence how much information, if any, is given to a patient. For example, two of the participants had diabetes (B and F) and attend the surgery regularly for management of this chronic disease. There may be an assumption on the part of the health professional that knowledge about the nature and purpose of routine monitoring blood tests has previously been explained fully to the patients.

A theme from the literature review that is relevant to the findings of this phase of the study is the method of presentation of information relating to the decision to be made. This will be discussed in more detail in the next chapter, describing interview findings. However, I can report that all information given during the blood tests consultations was verbal and there were no examples of any alternative presentation such as a leaflet in accessible format. There may be several reasons for this, which will be outlined in the discussion chapter. However, if information *is* given to the patient, the way it is presented is important and this leads to the next theme – seeking and expressing consent.

Having described some of the preliminary stages of the consultation, which in some cases contained some information-giving, but also included examples where this was absent, I am now going to look at the consent process itself.

5.3.3 *Theme 3 – Seeking and expressing consent*

One of the essential criteria for valid consent is provision of relevant information in a format accessible to the patient (Ministry of Justice, 2007).

The amount of information provided for participants prior to obtaining consent for taking blood ranged from none at all to a detailed description of why the blood test was required and what tests were being conducted on the blood. In

some cases, consent appeared to be sought for the *procedure* rather than for the *testing of the blood sample*. This was illustrated by the example previously given, a simple statement that blood was going to be taken (E).

Some healthcare professionals, however, gave a very detailed description of the purpose of the blood test, for example:

Do you know why you are here today?
Yeah, for my blood test. Cos I was, I was ill
Yes, but the one that we're taking is to check your thyroxin levels
...
You know, cos you're on medication for your thyroid, so that's why I was, but I've come off now
Have you stopped taking your medication then, for that? Oh, let me just have a look. It might be for them to just check, though. (A, line 15)

Sometimes both elements (procedure and purpose) were mentioned, and the patient indicated understanding using non-verbal communication:

So, we're gonna take some bloods this morning
Yeah
If that's alright?
Yeah, yeah
Now, we'll check your kidney function and your [liver]
[Yeah]
(pats his upper abdomen in the region of his liver, indicating understanding)
[function]
Right
And your cholesterol and a full blood count, OK?
Yes (D, line 16)

After the preliminary conversations and explanations, if any, were over, then this may have been the appropriate time for obtaining consent, before the procedure. As mentioned above, in one case, an attempt to gain consent was made at the beginning of the consultation (E), with no preceding conversation or information-giving. In others, there appeared to be little or no explicit attempt to obtain consent from the patient. For example (F):

Do you watch those? (referring to 'Carry On' films)

Yes. *Ooh, this, ooh* (nurse still pumping up cuff)

Arm nice and straight for me now please D.

(Whistles)

Only two bottles

Oh that's alright then (grunts)

Ever so still

Just stick it in there

Are you ready?

Yeah.

Ever so still

(Big gasp!)

Well done. Brilliant. (F, line 23)

However, the patient's responses could be interpreted as giving some degree of consent. In another case, the nurse requested the patient's arm after preliminary social conversation:

You good at computers, are you?

Oh no, [no]

[Cos I can] just about manage what I have to here

[No, no] I know, but they don't, they put a few figures in, and that ain't too bad, you know. I'm a [bit slow]

[No, I dunno], I'm very good at breaking 'em

[But then]

Can I have your arm a minute? (B, line 1)

There were then another two or three minutes of conversation while the nurse prepared her equipment and identified a suitable vein. At the point of the attempt to take the blood, the conversation continued. As the nurse is about to insert the needle, the participant grimaces and looks down at her arm:

Ooh, I don't like this.

Don't [like it]?

[This], no. (B, line 25)

The nurse then tries to distract her by suggesting other things for her to focus upon, but continues with the procedure:

you could look at – that's Dr X and [his wife and his children] (raises voice)

(Both raising voice - nurse trying to distract B)

[No, no] (loudly) – no, I'll a I'll a (pulls a more severe face – obviously in

pain)

[Alright, scratch] coming now

Aah

(silence while nurse continues procedure) (B, line 31)

The participant then looks away from her arm at the noticeboard. As illustrated, there was a lengthy preamble to the blood being taken, and an obvious rapport between the patient and healthcare professional, but no information was given to the patient (B) about the procedure or its purpose. At no point in this consultation was explicit consent sought or given.

In the case of A, who was given a full explanation of the reasons for the blood test, there is a clear request for consent:

Yeah, it's to make sure that the level is still staying OK, because at the moment your levels are alright so you don't actually need the medication, but that could change, so they'll probably check it, I think at the moment it's going to be every six months

(A listens intently to the explanation)

Yeah

until they get a pattern and see whether it stays level, and if it stays ok, it will be every year for them to do the level. Is that alright? (A, line 24)

A then goes on to talk about an unrelated health problem and the topic of conversation changes. Once that has been dealt with, the nurse prepares for the procedure. The patient then raises an objection, says she hates this and asks for a local anaesthetic:

I hate it, I hate this bit (but smiles at me and camera)

I know

You're going to dead it first, aren't you?

No

(shouts) Don't!

Don't what? (gently)

Going to deaden it first?

You can't deaden it before you do this, love. Only just one sharp scratch, and that's it – and that's all you'll feel. Is that alright?

Yeah, I'll try (A, line 93)

Again, the nurse is asking for consent before she proceeds and obtains only a

tentative response.

The responses from the participants, as illustrated above, when expressing consent are fairly minimal, and not particularly convincing. In the case of F, after she has expressed the fact that she hates needles, and the nurse has attempted to reassure her, she then objects to the blood pressure cuff being applied to her arm, prior to the blood being taken:

*(Pulls face) Wait till I see the needle, I kinda flinches. Hate the bloody things
Actually you are good at this
Don't
I'm just gonna pump this one up to start with. (F, line 15)*

She then simply says:

That's alright, love, just carry on. Carry on nursie. (line 19)

It appeared to me in this case that her comments were simply 'token' objections to both the pumping up of the cuff and the needle itself, but this is open to interpretation.

The patients' ability to make a decision for themselves, and indeed their experience of doing so in the health context, varies – and the healthcare professional should make a judgement about their capacity to do so. This is not always straightforward; for example some patients will attend with carers or support workers and others will be more independent. The patients may also be well known to the healthcare staff, as they were in this study, and if the patient has previously accepted having the procedure without objection (i.e. assenting rather than consenting), then repeating the information may seem superfluous. It is also possible that healthcare professionals may make assumptions about

the situation – for example, a nurse may assume that the doctor requesting the blood test has obtained consent.

Once patients have been provided with information pertinent to the decision to be made, the next logical step is for the healthcare professional to obtain the patient's consent for the procedure. In some health contexts, this consent would be in the form of a signed consent form, but in general practice consent for a blood test is usually expressed verbally, or in some cases implied. A guidance document for doctors produced by the General Medical Council (2008) states, when listing expressions of consent:

"Patients can give consent orally or in writing, or they may imply consent by complying for example, by rolling up their sleeve to have their blood pressure taken."

"In the case of minor or routine investigations.... it is usually enough to have oral or implied consent" (p20)

The implementation of the Mental Capacity Act in England and Wales (Department of Health, 2005c) in 2007 means that more attention needs to be paid to the individual elements of consent, and in particular to the capacity of the patient to give consent.

One of the major themes identified from the literature was that of the interaction between the patient and the healthcare professional, and this is very relevant to the seeking and giving of consent. Firstly, one of the major influencing factors in the consent process was found to be the attitude of the healthcare professionals towards the consent procedure and how it was conducted. Research has identified examples of family members being asked to consent to procedures inappropriately (Hart, 1999), lack of informed consent due to the assumption by the healthcare professional that the patient would lack

understanding (Haw & Stubbs, 2005), and problems with assessment of capacity to consent affecting the uptake of cervical screening in women with learning disabilities (Broughton, 2002). The other factor was the way that information relevant to the decision was presented to the patient. The attitude of the healthcare professional will affect whether or not capacity to consent is assessed; whether it is the patient or their carer who is asked to give consent; or even whether consent is sought at all. Assuming that the consent process is followed, the method of presenting the relevant information to the patient is also important in view of the fact that for informed consent, the patient needs to understand that information.

I have illustrated various examples of seeking consent by the healthcare professional and expressions of consent from the participants. It appears that not only is there a range of ways this is done, but in most cases, not much attention has been paid to the process and indeed to the legal requirements under the Mental Capacity Act (Department of Health, 2005c). I found evidence in the literature review of poor practice with respect to gaining informed consent to healthcare interventions, but most of the literature was published before the implementation of the Act, so this is perhaps not surprising. For example, Keywood and colleagues (Keywood, Fovargue & Flynn, 1999) found that people were asked to make decisions based on inadequate information, and that often, dialogue in the consultation did not include the adult with learning disability. In a more recent article, Keywood and Flynn (2006) describe the challenges in ensuring the people with learning disabilities are involved in healthcare decisions, and state that even with the future publication of a code of practice for the Mental Capacity Act (Ministry of Justice, 2007),

"the health needs of people with learning disabilities present challenges that require health and social care providers to work against the flow of fast-track initiatives" (p362)

The authors stress the need for adequate time to facilitate and support patients' decision-making and consent.

Although the focus of the observation phase in this study was on the consent process as described above, I should also describe other themes which I identified from the data, which may have relevance to the overall picture, and certainly link well with the subsequent interview data. These were the behavioural characteristics displayed by the participants during the consultation, and the strategies and coping mechanisms that appeared to be employed by both the patients and their healthcare professionals to deal with them.

To summarise so far, there was a range of ways in which the healthcare professionals approached the blood test consultation, and inconsistency in the level of information giving and seeking of consent.

5.3.4 *Theme 4 – Behavioural characteristics*

The benefit of using video recording has been that body language such as facial expressions or other 'emotional' signals have been recorded for analysis. In many cases, the body language contradicted the verbal evidence; in some cases it supported it. It was interesting to record the visual behavioural cues exhibited by participants during the blood test consultation as well as their verbal expressions, both before and after the procedure. These included expressions of fear and anxiety, resistance, relief and resignation, the appearance of being in pain and even bravado. Some of this behaviour was verbal, but there were many non-verbal clues to how the participants were

feeling. One participant (D) exhibited signs of anxiety while awaiting the test, his facial muscles were tense, his respiratory rate increased and his legs were constantly jogging up and down. His anxiety did not wane following the drawing of the blood, and he expressed anxieties about the after-effects of having blood taken:

You OK?

Mmm. Will I have to sit down for a minute, will I have to take a rest cos I have had some blood taken out? (seems anxious again)

Well, no, it's a very small amount, you'll be fine. (D, line 88)

He appeared to need much reassurance from the nurse, as he continued:

I won't have to rest?"

No

Rest, no? I might feel a bit dizzy afterwards, anyhow?

Despite the anxiety and fear described above, there was much evidence of bravado prior to and during the procedure – again sometimes visual, sometimes verbal. Eventually, participants appeared to resign themselves to having the procedure, despite their apprehension. This acceptance was often combined with the use of humour. Expressions such as “Just stick it in there” (F) and “Just stick the needle in and do it” (A) illustrate both acceptance of the situation and an element of ‘putting on a brave face’. One participant whistled, and I noticed that despite obvious anxiety, some participants were alternating between grimacing and smiling, again showing evidence of bravado. It is difficult to be sure whether this apparent bravado was a reaction to my presence as researcher or part of the participants’ normal behaviour.

Some participants expressed token resistance to the procedure. Some appeared to find the inflating of a cuff as painful as the drawing of blood. Others obviously experienced pain during the procedure – illustrated mainly by

their facial expressions and sighs and gasps, or simply "Ow!" (A). Comments such as "Don't" (F, A), did not seem to be intended as literal commands, simply as objections. This again is obviously open to interpretation by the healthcare professional. Two of the participants specifically expressed relief that the procedure was over:

Ah well, that was quick, just a little (laughs) – yeah, alright (B, line 71)

The second one was even more emphatic in response to the nurse's comment:

All done. Needle out, all finished
Oh, thank God for that. Phew (whistles) (F, line 48)

There was evidence of fear and anxiety that manifested as muscular twitching, leg jogging, facial muscular tension or even the cracking of jokes. Similarly, pain was expressed sometimes verbally, or sometimes by facial expressions. Bravado is a difficult characteristic to define, but I considered that much of the smiling and attempts at humour were veiling anxieties beneath the surface. There were obvious attempts by some of the patients to appear quite blasé, as if taking of blood presented no problem to them, but on occasions the smiles looked a little forced, and the body language 'gave them away'. It is possible that the study itself, or the presence of the researcher had a reactive effect, known as the Hawthorne effect (Roethlisberger & Dickson, 1939) on the participants. There was what appeared to be 'token' resistance to the procedure in some cases, followed by a degree of resignation expressed simply as sighs, or comments such as "just stick it in there".

I have listed these characteristics as a theme to illustrate the complex problems that can occur when considering consent and capacity to a procedure. It is important for the healthcare professional to be aware of these behaviours and

react to them, which is the subject of the final theme I shall be describing – that of the strategies and coping mechanisms adopted by both the healthcare professionals and their patients with learning disabilities.

5.3.5 Theme 5 – Strategies and coping mechanisms

Throughout the consultations there were various strategies used by both parties to deal with what appeared to be the nervousness and apprehension of the participant. In the case of A, who was expecting a local anaesthetic for the procedure, the nurse dealt with this by repeated, gentle reassurance. Another way of helping the patient relax appeared to be to involve them in the procedure itself. One nurse, who was having a problem finding a good vein, explained how she did it –

How do you know which vein it is?

By feeling. You have a good feel around

I don't know which one – that one, is it?

Yeah, that one feels better than the other – feel that? (D, line 76)

Most of the patients were well known to the nurses taking the blood, and humour appeared to be a feature of their meetings – as with E:

Almost there, I won't take it all, I promise (laughs)

That's ok.

I'll leave you with some.

Oh, good! (both laugh) (E, line 27)

One nurse, having been told to –

Carrie on nursie (F line 19),

chatted to the participant about the 'Carry On' films. In another case, the participant needed constant reassurance and this was reinforced with humour:

It's not your fault, is it? Obviously knew you were coming in here today, so they're hiding. This'll just give them a bit

more pressure on there, make the veins come up better.

(A looks a bit nervous and breathing a bit faster)

You alright?

Just stick the needle in and do it! (smiles at camera)

(laughs) **"I've got to feel something to stick it into first. I can't just shoot blind you know.** (A, line 79)

Once the procedure had commenced, various ways of distracting a nervous patient were used by healthcare professionals. One asked the patient to have a look at the photos of the doctor and his family on the notice board:

I've got nothing brilliant for you to look at, but

No

You could look at – that's Dr X and his wife and his children (B, line 29)

Another handed the pressure dial (she was using a blood pressure cuff as an aid to finding a vein) to the patient –

Now you look after that one for me- you're in charge (F, line 25)

Sometimes the patients needed reassurance that they were not going to come to harm, or that they were doing well:

(Pulls face.) **Wait till I see the needle, I kinda flinches. Hate the bloody things.**

Actually you are good at this (F, line 15)

Having tried to bolster up the patient's confidence in this way, the nurse then praised her once the procedure was successfully underway:

Well done, brilliant (line 37)

During the procedure, there were constant checks to ensure that the patients were 'all right', even if they had exhibited no signs of anxiety or pain:

There we go. Little sharp sting there, OK? Well done. There we are, I'll just loosen that one off. Alright?

Yes, thank you, I am.

Excellent. (E, line 20)

Followed later by:

Lovely. Right, how's that doing? (looks at arm). **Let's have a look-lovely.**

Yep

Are you alright with Elastoplast, you're not allergic to it, are you?

No, I'm not (E, line 36)

In another case, the patient was asked four times if she was 'alright', and another was asked three times if he was 'OK'.

The use of various strategies by the healthcare professionals was obvious in each consultation. It appeared that attempts to establish rapport with the patient, the use of distraction tactics and a sense of humour were all used in the consultations. What is of interest is that these were not only used by the healthcare professionals to ease patients' anxieties and apprehension, but also by the patients themselves in an attempt to make light of their concerns. In most cases the blood test procedure was preceded by some social conversation and catching up with the patients' news. I considered that this was a strategy used by the healthcare professionals to relax the patients, although the fact that they already knew the patients well could have contributed to the 'chatty' atmosphere. Despite the fact that this tactic was used in most cases, the nurses appeared aware that the patient was still nervous about the procedure itself, and at this point, distraction tactics were employed, such as suggesting that the patient look at the photos of the doctor's family or keeping an eye on a pressure monitor for the nurse. Even in the briefest consultation, the use of humour by both the nurse and the patient was evident and produced laughter from both parties, thus reinforcing the rapport in the patient-nurse relationship. In some cases, it was necessary to reassure the patient that the procedure would not be painful and that there would be no after-effects and this was done in a gentle, caring way in each case. Finally, having

established rapport with the patient and made an attempt at distraction if necessary, I noted many instances of reassurance throughout the consultations, evidence that the healthcare professionals were constantly aware of the patients' anxieties and concerns.

5.4 The themes reviewed

The themes were identified from the observation data. I adopted an inductive approach to data analysis, by repeatedly reading the transcripts and identifying what I considered were the main themes. I have attempted to relate them to those from the literature review, and I will summarise this at the conclusion of this chapter. I have used the same coding frame for the observation phase (this chapter), the interview phase (next chapter) and subsequent phases. This was not a pre-defined framework, but has been guided by my reading of the data. For this reason, the themes have been added in some cases 'layer by layer'. I have tabulated the themes and categories (Table 3). It is clear that some of the categories can be defined both from the point of view of the participant with learning disabilities and from that of the healthcare professional – for example 'purpose of blood test and procedure'. This can obviously be understood *by* the patient, or communicated *to* the patient.

5.5 How these findings relate to the literature

I have already described how each theme may relate to the findings from the integrative review of the literature conducted in Phase 1. The four themes identified from Phase 1 were:

- *Life experience* – residential status, decision-making opportunity, acquiescence, previous health experience;

- *Interaction between healthcare professional and participant* – attitude to consent, method of presentation;
- *Ability to consent* – communicating a choice, understanding and retaining information, appreciation of context, rational manipulation of information;
- *Psychometric properties* – intelligence, verbal ability, memory.

During Phase 2, some of these were clearly demonstrated – for example, acquiescence in the consultation, the variation in the healthcare professionals' attitude to consent, the communication of choice. Others were less obvious, for example assessment of a person's ability to consent (their capacity). New themes were uncovered by observation of a 'real life' situation such as the behaviour exhibited by the participants during the consultation and the use of strategies or coping mechanisms by both patient and healthcare professional.

In this chapter, I have given a demographic description of the participants and the context in which observations for Phase 2 took place. I have then written a narrative description of the consultation that takes the reader through the different stages. Within this, I have discussed the themes identified from the data and related them to findings from the systematic review of the literature (Phase 1).

In the next chapter, I shall describe the findings from the interviews with the participants with learning disabilities (Phase 3). Not all patients who were interviewed were observed having a blood test; some were observed having a blood test subsequent to being interviewed. Some of the themes identified from Phase 2 are reinforced by the interviews in Phase 3 but there are some interesting paradoxes that will be discussed.

Chapter Six

Interviews with people with learning disabilities (Phase 3 of study)

6.1 Introduction

In the previous chapter, I described the findings from the observation phase of this study. In this chapter, I will describe those from the next phase, in which I interviewed fourteen people with learning disabilities. Firstly I will outline the context; in addition, I will explain the role of the supporter and the effect the supporter may have had on data collection. I will then describe the themes identified from the data and finally relate them to those previously identified from Phases 1 (Literature review) and 2 (Observation).

6.1.1 Demographics of the participants

I interviewed fourteen people with learning disabilities in this phase of the study. They ranged in age from 27 to 65 and varied in their level of independence. Some of the participants had been observed during Phase 2; others had been recruited for this phase as described in Chapter 3.

See Table 4 below.

Table 4 Participants in Phase 3 (Interviews)

<i>Participant</i>	<i>Age</i>	<i>Residential status</i>
C*	59	Living independently in a flat with support
E*	34	Living at home with parents
G	38	Living in a shared house (supported living)
H	N/K	Living in a shared house (supported living)
I	27	Married, living independently in a flat with support
J	65	Living in a shared house (supported living)
F*	41	Living in a shared house (supported living)
A*	35	Living in a shared house (supported living)
K	46	Living independently in a flat with support
D*	50	Living independently in a flat with support
L	56	Living in a shared house (supported living)
M	55	Married, living independently in a flat with support
B*	51	Lives alone with informal family support
N	33	Living in a shared house (supported living)

** indicates participants who were also observed in Phase 2*

6.1.2 Setting the scene

The original plan was to conduct the observation of each participant having a blood test in general practice (Phase 2) and then follow this with an interview (Phase 3) as soon as possible. I considered that doing this would maximise the likelihood of the participant recalling the experience of their blood test. In practice, however, this was not always possible. I interviewed some participants as planned – after a blood test in general practice. Those participants who were not due a blood test were interviewed, and in some cases a subsequent blood test was observed. One participant consented to Phase 2; access was denied by her GP surgery so she was simply interviewed for Phase 3. Because of these issues, and the way the data was collected, this meant that some participants who were interviewed could not recall ever having had a blood test. Although this could be seen as a disadvantage, it resulted in some

useful data concerning the lack of understanding or problems with recall in some people with learning disabilities.

Participants were given the choice of venue for their interviews. Some were carried out at a drop-in centre attended by people with learning disabilities. I was permitted the use of a small, private room at this venue, and I felt that this worked well as the participants were relaxed in this environment. It also meant that if the participant had requested a supporter to be present for the interview, there was someone who knew them well immediately to hand. Similarly, I was permitted to use a room at the office of one of the local providers of support for people living independently, with members of the support staff acting as supporters for the interviews if required. Occasionally there was a problem when there was not a member of staff free, or it was not possible to arrange a time that was convenient to all parties concerned – the staff, the participant and myself. On these occasions, I offered to conduct the interview at the participant's own home, ensuring that a member of the support staff was available if appropriate. Again, this meant that the participant was familiar with their surroundings and more likely to relax. Due to the range of residential accommodation arrangements for people with learning disabilities, and the fact that accommodation is usually shared with others, there were some practical problems in conducting these interviews. Privacy and a quiet environment do not always feature in these situations, and any interruptions had to be dealt with tactfully.

Before I describe the themes identified from the data, I would like to explain a process that may be specific to my research population, or other vulnerable groups. People with learning disabilities are considered a vulnerable population,

and for this reason it was decided that they should have the opportunity to ask for a supporter of their choice to be present during the interview. This mirrors much of the rest of their life, in which a supporter is often needed for some activities.

6.1.3 The role of the supporter in the interview

It is necessary at this stage to explain the possible effect of having a supporter present during an interview. Although this is not a theme from the data, it is useful to illustrate the context by using short quotations from interviews. When it was decided to offer the participant with learning disability the opportunity to have a supporter present during the interview, this was intended as a measure to ensure that any problems such as distress during the interview could be dealt with immediately, and also simply to ensure that the participant felt supported during the interview with me, a comparative stranger. In reality, although this was indeed the prime function of the supporter, their presence had other effects on the interview.

Firstly, participants with limited verbal communication used the supporter to clarify their answers to my questions. The supporters, knowing the participants well, were 'tuned in' to their speech patterns and were in a better position to understand what the participant was saying than I was. Equally, supporters were used to by some participants who had poor recall of names or places, to 'plug the gap'. In the following excerpts, S = supporter.

For example:

You said, well, you said your doctor's name, you said it was Dr R?

Yeah

Do you know where their surgery is?

...

I've forgotten the ..
On the corner near the C shop?
Yes
S *It will be in her records*
Is it Dr B and Dr W?
Yes (N, 3)

Sometimes the supporter contributed to the discussion, despite being told at the beginning of the interview that the role of supporter was to support if necessary, but that it was the participant who should respond to my questions. In some cases, this simply enabled the interview to flow more smoothly – a facilitative role.

For example:

So in most cases, then, when people explain things to you, they just talk to you and explain things slowly.
Yeah (hesitates) – appears tired, starting to rub eyes etc
Do they, do people explain things to you when you go to the doctors?
Sometimes the staff come with me sometimes, sometimes on my own, is that right, S?
S *Mm*
So
S *Sometimes you ask for support, other times you don't. (G, 255)*

In other cases, when the supporter prompted the participant, this resulted in useful data, which I felt might not have been forthcoming had there been no interruption by the supporter. For example:

So, what do you like about going to the doctor's?
Eh, check me, health eh
(S Check my health)
...
Yeah, good. And is there anything that's difficult for you about going to the doctor's?
...
No
...
(S Ooh, D, tell her about the doctor that you did see, honey.)
Lady doctor
Ooh, you look as if you are a bit doubtful about that one.

Aaah, awful.

(S She - was very rude about D's learning disability)

...

You didn't like that very much [then?]

[No, no]

(S I've made his point clear to the surgery haven't you, cos they will NOT put him in with that doctor now.)

...

So what was it you didn't like, what was it that...?

Umm...

(S She called him mentally [retarded])

[Yeah]

Oh, that's very rude

(Indecipherable, but obviously angry about this). (J, 25)

This participant had very indistinct speech, which may have contributed to the greater input from the supporter. In some instances, the 'interpretation' of his speech was helpful. For instance:

Have you heard of genes?

Yes

And what do you think genes are? Do you know what they do?

Cancer – you get cancer.

(S He thinks it's to do with cancer.) (J,113)

Overall, despite unsolicited interruptions by some supporters, I considered that the role was a positive one, enabling the participant to feel safe and relaxed, and also supporting me as a researcher in communicating with participants I had only known for a short time. Having discussed the role of the supporter, I will now describe the themes I identified from the interview data.

6.2 The Themes

Observations and interviews were being conducted concurrently, and on reading the transcripts prior to data analysis, it became clear that there were themes common to both. Data collection and analysis proceeded in parallel during these two phases, and coding was an iterative process. I have used the same coding framework as for Phase 2 (see Table 3, Chapter 5), but analysis

of the rich data from the interviews not only reinforced and developed the themes identified from Phase 2, but also produced a new theme - that of 'The Self', comprising self-identity, self-image and self-determination. The theme of information and knowledge was also expanded in this phase, as it was possible to explore the level of understanding and relate it to the blood test consultation if appropriate. The topic of pharmacogenomic testing was introduced to the participants with a brief, simple explanation. The theme of genetics and pharmacogenomic testing, therefore, is different from the other themes; it was a theme introduced by me, which enabled me subsequently to identify any concerns that participants had, to comment on their level of genetic knowledge, and to be made aware of their attitudes to this new type of test. In this chapter, I have therefore separated the theme of genetics and pharmacogenomic testing from that of information and knowledge.

I consider that the expansion and development of these themes was due to the fact the participants were given the opportunity to think about their experiences at the doctor's surgery, about how they were treated, and about how much they knew and understood about their visits to the doctor. For some participants therefore, the findings from the observation and subsequent interview can be related to each other. One theme (consent) from Phase 2 was absent in the subsequent interview stage. This is due to the fact that consent was a *process* being observed and was not identified from the subsequent interview data.

For clarity, I now include a table of the themes identified in this phase, which includes some from Phase 2 (Table 5)

Table 5 Themes and categories Phase 3

Theme	Sub-theme
Patient in healthcare context	Attitude to having a blood test
	*Feeling about going to the doctors
	*Knowledge of healthcare system
	Relationship and communication with the healthcare professional
Information and knowledge	*Role of supporter
	Presentation of health information
	*Knowledge of blood tests in general
Behavioural	Purpose of blood test and procedure
	Anxiety
	Bravado
Strategies and coping mechanisms	Fear
	Distraction tactics
*The self	
	*Self-identity
	*Self-image
	*How I would like to be treated
*Genetics and pharmacogenomic testing	*Decision-making
	*Knowledge and understanding of genetics and pharmacogenomics
	*Attitude to having a new kind of blood test (pharmacogenomics)

* indicates a theme or category new to Phase 3

The next section contains detailed description of the themes, and is followed by table 6 illustrating the cumulative list of themes identified from Phases 2 and 3.

6.2.1 Theme 1 – The patient in the healthcare context

6.2.1.1 Feeling about going to the doctors (to have a blood test)

Within this group of participants, there was a wide range of attitudes to visiting the doctor, for any reason. Several participants (for example E, A, J) insisted that they had no worries either about going to see a doctor, or having a blood test:

So, how do you, how do you feel when you go to the doctor's?
I just feel normal.
Feel normal?
Yes, I feel nothing after all that.
No, you didn't look, you looked quite, um
Calm and all that
Yeah, you looked calm actually.
Yes. (E, 14)

Another participant was more emphatic:

And so, can you tell me how you feel when you go to the doctor's to have a blood test?
Fine
Fine?
Yeah, it don't bother me
...
What about going to the doctor's generally?
What, on my own?
How do you feel about going to the doctors for anything?
Fine, fine (pause). Not afraid of nothing, me not...I'm brave. (A, 9)

I will comment on the last sentence, implying bravado, later in this chapter.

Can you tell me a bit about how you feel when you go to the doctor's to have a blood test?
OK, ye-es.
OK?
Yes, yes.
You don't mind?
No, no – me, needle, needle, yeah, no bother me.
Needles don't worry you?
J No, no. (J, 16)

For some, having a blood test has simply become accepted as part of their life, particularly those with conditions requiring regular monitoring (for example, C.):

but can you tell me a bit about how you feel when you go to the doctors or the hospital to have, to have a blood test?
I'm so used to it now
Are you?
I've had it for ages. Cos I've got thyroid trouble and they do it every so often. (C, 2)

Some participants, in contrast, expressed a fear of 'the needle' and this affected their relationship with healthcare professionals, as illustrated in the next section.

6.2.1.2 Relationship with the healthcare professionals

Some participants were ambivalent about a visit to the doctor and saw it as part of everyday life, although in the following extract, a certain standard was expected, and when it wasn't provided, the participant made the decision to change her doctor:

Mmm, is there anything hard about going to doctors, anything you don't like, or you find difficult?

No (pauses) – well, not this doctors, nothing.

So, do you think it, you say “this doctors” – have you had doctors that weren't so good, then?

Well, when I went to one place, and um he said “Well, what are you here for?”. I thought crikey, that's not a very, thing, you don't ask, say that to somebody, do you?

No, no.

So I moved doctors' surgery then. (C, 22)

One participant expressed the view that despite the fact that she did not like some of the procedures she had to undergo at the doctors (in particular anything involving needles!), she still felt it was a good idea to go:

Eh, well, sometimes you have misgiving, cos you wonder, you know, but really and truly it's just a matter of course, sort of thing you know, a matter of just going and um as long as you get the appointment, cos sometimes you has misgivings and all that, to think if anything else could... I never like needles or anything like that, like I've had over the years [and that...]

[I could see that from your face] – you went (pulls a face)

Yeah, yeah, that's it, but when you think, I've had a leg amputated and all that, but then you are put off all that, ain't you, but anaesthetics are terrible. Anyway, I've never liked anaesthetics or anything like that, but you know, this is just a matter of um..

So a blood test is quite routine for you then

Yeah, yeah, quite routine. (B, 17)

Others (for example, J) simply acknowledged that it is a good idea to go to the doctors:

So, what do you like about going to the doctor's?

Eh, check me, health eh

S check my health

Check your [health? That's a good thing, then.]

[Yes, yes]

Yeah, good. And is there anything that's difficult for you about going to the doctor's?

No (J, 25)

One participant recalled her feelings when having blood tests done at the hospital:

I'm not very good with needles, so I had to cope with it. So I had to, like, I had to like, um, put up with it and just think about all the nice stuff for T, think about my future, future that I am going to have now, not think about the past, and it works.

So, you thought about the good things, and that took your mind off it?

Yeah. (I, 18)

One participant (B) demonstrates a viewpoint that was expressed by several participants, that of trust in the healthcare system, in particular the surgery she was registered with and the local hospital:

Whether or not it be a blood test or whatever, and you want to make yourself better, don't you?

Yes, yeah.

This is the main thing, so I think, I don't mind going,

No.

And providing, cos you put your faith in the doctors and nurses.

Yes, and you trust them.

Which, and you trust them.

Yeah.

Cos it's your health they're dealing with, innit,

Yeah.

And if you didn't have your health, you wouldn't be living today, would you sort of thing, would you? (laughs) (B, 88)

Several participants associated a visit to the surgery with unpleasant experiences, in particular needles. It is interesting to note the confusion that often occurs between immunisation and venepuncture - there seemed to be no

distinction made between injection of vaccine and the drawing of blood, for example:

When you go and have things like a blood test at the hospital or the doctors, do people explain to you why you are having them?

Ah, if people have flu's or anything, and I had, I went to the doctors with a lady called D. She took me up the surgery

Yeah

And said I got to come back to have a flu jab and injection, but I don't like that. (H, 40)

In either case, the experience seems to have influenced the feelings of a number of participants (G, F) about going to the visit their doctor:

What do you think about having a flu jab, then?

Sometimes I don't like it, sometimes I don't like the needle. (but smiles)

Is it the needle?

Yeah

So when you have a blood test, then, is that what would worry about having a blood [test]

[Yes] (nods vigorously) (G, 60)

And:

Now, can you tell me a bit about how you feel when you go to the doctor's to have a blood test?

OK, but I'm very, I'm very petrified of needles, cos I hate the damn things. (F, 5)

Although the fear of needles was expressed by several participants, in some cases (for example H) this fear seems to have been extended to include a general fear of anything medical:

No, I don't like any needles at all, nothing, or a flu jab or anything, I don't like it.

So you still go, though, do you, if you have to.

Yeah, but I don't like it.

What about going to the doctors, just, you know, to find out if there is something wrong with you, or anything like that. Does that, are you quite, you don't mind going for something like that then?

Nooo – I don't like going anyway.

...

So you don't really like the idea of going to the doctor's at all?

No, no I don't. (H, 9)

On the positive side, several participants appreciated certain features of the service they received at the surgery, such as the environment and the attitude of the staff. For example, one participant (N) with diabetes who said she was quite happy about having blood tests, also expressed positive feelings about the care she received:

To find out what's wrong with you, if there's anything wrong with ya.

And they, you go because you've got diabetes

Yeah

so they make sure you're staying healthy then

Yeah

So that's why you think it's a good idea

Yeah

...

They're good friends to me as well. (N, 101)

Another liked the new surgery:

Yeah, or whenever you go to the doctors – any bits you don't like very much?

Well, the thing is, no, no – the surgery is nice, cos they've got a new surgery down there now – before it was portacabins and all that you know, and it was a bit of a shambles sort of thing, but now this, this is nice. This is nicer to go, but the thing is, when you go the doctors, you go for a reason, don't you – (B, 82)

Finally, one participant appeared to admit that he enjoyed going to the doctor's surgery to see the nurse:

Nothing you don't like?

No, not really?

(You don't mind going?)

I don't mind

(You're happy when you go?)

Yeah

(There's nothing you don't like?)

Umm. ... the nurses?

You like the nurses?

No

(I think probably 'Yes')

You like the nurses

Nah, no (laughing)

You had a twinkle in your eye when you said that R; I'm making him blush now look (all laughing). So you like going just so you can see the nurses, do you?

Not really (but see his face)

(Laughs) – Tell the truth! (L, 38)

The supporter's comments are in brackets, and it was interesting in this interview how she adopted the role of 'interpreter' or even interviewer, as she teased out answers from the participant. Despite the fact that this participant was not very vocal, in some instances his facial expressions definitely told a story.

This participant, however, is a good example of a situation where it was difficult to be sure that there was understanding of the question asked. When trying to ascertain how L felt about having a blood test, his responses were somewhat ambiguous:

Cos you go quite often, don't you , to have your cholesterol checked, A said, so how does that make you feel when you go to the doctors for a blood test?

Alright (very quietly)

Alright?

No

Are you sure about that, you don't look quite sure?

(Both laughing) Not really?

Yeah, yeah

Yeah?

(Do you feel nervous?)

Nervous, no.

(Do you worry about it?)

Nope

No?

(You don't seem to worry, do you?)

No, not really (L, 8)

Again, note the intervention of the support worker using her knowledge of the participant to enhance the communication between us.

Having described the way the participants feel about the surgery they attend, having a blood test, and their relationship with the healthcare professionals, there are two more categories in this theme that relate to each other, and indeed to the next theme, which concerns information and knowledge. These are the role of the supporter and communication with the healthcare professional.

6.2.1.3 Knowledge of the healthcare system

Some participants displayed a good level of knowledge of how the health system, in particular their surgery and the local hospital worked.

So you have to go into the surgery, and they take your blood, so is it the nurses that do it?

The nurses do it for the doctor

So you have your blood taken, and then you have go back when they have got the results, do you?

Um

Sometimes?

Yeah, and then you gotta see the doctor and that, and the doctor tells you if the results have come out alright and that.

(K, 92)

And

Yeah, the nurses, but this is just to help the nurses

Yes

And help the nurses, and help the doctors, like the nurses help the doctors. They know quite a bit, like K who I'm seeing Thursday. She's got names, letters after her name and all that. But I think these health care assistants are to help the nurses sort of thing because there's more people living longer these days and that.

Right, that's true.

And that... we need... and they're busier and they need more people to um, to assist them. (B, 51)

6.2.1.4 The role of the supporter

Several participants stated that they found it difficult to understand or communicate with healthcare professionals, and this is where the role of the supporter is often essential. A support worker or family carer sometimes

accompanied the participants to healthcare appointments, and they described how this helped them (for example, C, E.)

If I, I would take my carer with me, because she knows and understands, and then she would sort of talk to me afterwards and explain.

OK, so she would listen to the doctor...

Yeah.

and then she would put it in a different way when she explains it to you?

Yeah, she would, sort of, for a little while and then she would come back and say it again to me, cos I, cos part of my dyslexia I have got a very short term memory. (C, 127)

And:

Do you think it's, is it a good idea to have someone with you, do you think, when you go to the doctor's?

Yes.

Yeah, OK. How do you think that helps then, by having someone with you? How does it make you feel, then, when..

It makes me feel very happy, and enjoy, and (pauses to think), and I just find it helpful. (E, 38)

Some participants, despite normally going to the doctor unaccompanied, acknowledged the important role of the supporter for some people. For example, D:

I think if I wanted to know, I would take somebody with them so they could write it down.

That's a good idea.

You know.

Do you take someone with you when you go?

No, I always go on my own. (308)

...
So if someone had to take a carer with them, or a supporter, then do you think, so would the supporter help them understand it?

I say they would be more confident in themselves (316)

...
Yeah. And somebody would, what would the supporter do then?
Probably just sit there with them, and make sure they talk to them properly.

Yes – and explain

You know. They could ask the doctors questions, cos he knows more.

Yes.

The doctors could tell them, and they could perhaps tell the person. (321)

Having considered the role of the supporter, in particular when facilitating understanding between the healthcare professional and the patient with learning disabilities, I would now like to describe the final category in this section: communication with the healthcare professional. This, of course, is often intimately linked with the role of the supporter, as illustrated in the previous examples.

6.2.1.5 *Communication with the healthcare professional*

This category is a thread that runs through every interview, and is difficult to consider in isolation. However, there are some useful quotations that illustrate the frustrations of some of the participants with learning disabilities.

How do you find it at the doctors? Do you understand everything that they are saying to you?

Um, I find a little bit difficult cos I have to say to the doctor, "Can you repeat that please?" But yeah, they say it again, I understand that, and they are really good, my doctors. (I, 81)

Communication may be difficult if the patient perceives that they have been treated wrongly, as the previous case where J objected to being called 'mentally retarded' illustrates.

Some just find it all rather daunting:

Yeah, and then you gotta see the doctor and that, and the doctor tells you if the results have come out alright and that.

Yeah, so – is there anything that's difficult for you about going to the doctors – anything you don't like?

It's when they ask you the questions and that, and they write the forms down and that (laughing – looks quite relaxed about this)

Mm. Are they difficult, some of the questions they ask?

Yeah, a little bit. (K, 99)

I asked K how the doctors could 'make it better':

Well, people who have got learning difficulties and that, like me and that, um, got problems with their words and that, and explaining it to the doctors and that.

Mm. So sometimes you can't explain what YOU want to say to the doctor, and sometimes you don't understand what THEY are saying.

Sometimes, yeah.

So how could they make that better, do you think?

...

Well, could they talk a little bit slower?

Mm,mm

Not too quick. (gesticulating) (K, 402)

I will discuss some of the communication issues in more detail in paragraph 6.2.2.2, under the heading of 'Presentation of health information'. The themes described so far, and the ones I will describe next cannot be considered in isolation. Information is one of the essential requirements for valid, informed consent, and for this information to be understood, it has to be presented at a level appropriate to the individual concerned. For example, do patients understand why they attend the surgery, what a blood test is for and so on? It is equally as important that any information they are given in a format they can understand. I will now describe the findings relating to information and knowledge that I identified from the interview data.

6.2.2 Theme 2 - Information and knowledge

6.2.2.1 The purpose of the consultation and/or blood test

In some cases, the participants appeared to be unaware of why they were having a blood test, or at least did not have any recall of being told (for example, E, N, J):

So, do you know what your blood test, the blood test you had at the surgery, do you know what that was for?

Umm. I don't know that. No, I don't.

...

...when you saw the doctor, she asked you if you could have a blood test, did she?

Yes

Did she tell you what it was for?

Ummm
Can you remember?
(Long pause for thought)
It doesn't matter if you can't.
No, no, I can't remember now. No. (E, 55)

It is difficult to say whether at the time this participant was aware of the purpose of the blood test. This participant had a blood test as a follow-up from an annual health check, which I observed and recorded. There was no information given at the time of the blood test, but it is not known whether the doctor requesting the test gave an explanation at the time of the health check. This participant had a family carer with him for both the health check and the blood test, and it is possible that the information was given to the carer at the health check. It is interesting to note, however, that this participant was not concerned at the lack of information:

So perhaps when you went to have the blood test, you didn't know what it was for, but obviously it didn't worry you. You were quite happy to have it done
Yes
without knowing.... What do you think? If you, if they told you exactly what the blood test was for, would that make any difference.
E Not really, no. No. (E, 70)

And:

Good. So, obviously you have to have blood tests quite often, don't you, at the surgery?
Four times, and then, um, uh (). Yeah, I do, yeah.
Do you know what, do you know exactly what the blood tests are for?
No (N, 118)

Later in the interview:

OK. So, when you have your blood tests then, the nurses just come and say they are going to do the blood test, but you don't know exactly what they are taking the blood for?
No
But you're quite happy because you think it's because they are trying to keep you healthy – is that right?
Yeah (N, 140)

Similarly, J stated that he did not know why he had had a recent blood test in hospital, but stated that if he went to have a blood test at his doctor's surgery, he would want to know what the test was for and how it would help him:

So, um – can you tell me about any of the blood tests that you've had? You told me just now you had one at the hospital.

Yes

Do you know what that one was for?

Don't know

So..

(S That was a full blood count wasn't it?)

Yes

Did they, did they explain it to you when you were in hospital?

J No, no, say no, no dear, no (J, 71)

Later on in the interview, having been given a simple explanation about pharmacogenomic tests, the participant was asked what he needed to know about a blood test:

If you went to see your GP at the surgery, and he said he would like to do a blood test, what do you think you need to know?

Would you want to know anything [about it]

Yes, yes.

What kind of things would you like to know about it?

Um (indecipherable) She, she, same doctor, got it right?

Would you want to know what the test was for?

Yes

And would you want to know how it might help you?

J Yes, yes. (J, 211)

Some patients appeared to make assumptions about the tests they had, despite allegedly not having been given an explanation:

So, when you had the blood taken at the hospital, do you know what that blood test was for?

It was all to find out if the medicines I take are working, I suppose (shrugs)

Mmm. So, did they, did the nurse – was it a nurse that took your blood?

Yes.

Did she explain, did she sit down and explain to you what the blood tests were for?

No.

No. No, but you guessed that it was to do with your medicines, did you ?

Yes. (C, 61)

Later on in the same interview, when we were again discussing the procedures involved in blood tests, it appeared that on reconsideration, the participant did know what her blood tests were for:

What they did, they take three lots of blood, three, I thought it would be one, but it's three.

...

That was at the hospital?

Yeah.

Mmm.

You get, uh, with the um, I suppose its – ah, one I think they said it was for my liver and see if my kidneys are working properly.

...

So that's good – so you did know what they were, that's good. (C, 190)

There were other examples of participants being aware of why they were having their blood taken (H, 1) although again in the case of H, there seems to be some confusion between vaccination and venepuncture.

So perhaps you had to have blood tests when you were epileptic to make sure that you were taking right medicine, did you

Yeah

...

So, did they ever explain why they took the blood from your arm?
(shakes head)

No?

One lady, a long time ago, said that I was anaemic, and I don't know, but they had to do it cos I'm anaemic.

Oh, cos you were anaemic?

And they said I was low on sugar or something.

Oh, so they did tell you a bit [about]

[Yeah]

...do you think that's a good idea to have the blood test even if it hurts, then, if they explain?

Yes, they said I've got to come to the doctors and do I have to have injection and a flu jab, and they said, yes, because you don't want to be poorly with the flu and that. (H, 63)

And:

Do you know what the ones that you had in hospital were for, when you had your baby? Did they explain what they were for?
They took 3 vials out of me, out of arm, of blood. One for my iron, one for my cholesterol and the other one was for my, just a normal blood test, routine really. And I realised that, well, I didn't know before, that I had something wrong with my iron, so I am taking iron tablets, folic acid for my iron and all that. Every day I take it.

Mm (1, 57)

Several participants (F, A, B) appeared to have a reasonably good knowledge of why blood tests were necessary:

OK, so those blood tests that you had at the surgery last week. Um, do you know what they were?

Uuuh....

...

(laughs). I think one's for my cholesterol, I think, I'm guessing, and the other one was for, I can't remember. ... Yeah, I can't remember what the other one was for, sorry (laughs) (F, 79)

Or:

Well, sometimes she explains what my blood test is for – like saying, 'Oh, it's for your diabetes' and then she will tell me what my blood is tested for, like my liver, my kidneys, or my cholesterol. (F, 285)

However, earlier in this interview, this is more dubious:

Cos, I took two, you know those containers, like gallon [containers]

[Oh, yeah]

I took two of them when I had to do two lots of 24 hour piss test

Mmm

I done one, and a few days later I had to do another one for 24 hours, and then they took it to make sure I didn't have any cushions in my blood

Mm,mm

Cos if, cos I know what would happen if I did. If I had cushions in my blood, I would have to go to hospital for two days, and I would have to have blood tests every six hours.

...

Yeah, it was good news. Didn't have any cushions in my blood

(laughs)

In my urine. You know, like little, you know what I mean, like little things whatever you call it (laughing) (F, 173)

In this case, the participant appears to be talking about a test for Cushings disease, and is confusing a urine test with a blood test.

A appeared to understand the nature of her thyroid function tests:

Now, those blood tests that you had, do you understand what they were for, the ones?

Yeah, I was poorly at one time. I was losing so much weight that they done a blood test and ()Thyroid problem. (A now very fidgety, moving about a lot in her chair)

Mmm Mmm. Thyroid problem?

Yeah

OK. So then, what happened, when they decided you'd got a thyroid problem, did they start you on some medicine?

Yeah

OK, so what do you think this blood test was for, then?

To make sure it hadn't come back. (A, 134)

B also appeared to understand the need for her blood tests:

So do you know what , the blood tests that you had on... on...um - when I saw you...Do you know what those blood tests were for? Do you..?

They're for, they're for diabetes. And to see (pause), to see, you know, like your tablets, to see about, if, or else if I need to be increased the tablets, else if I need to go on the insulin, you know.

*...
And that, this is it, yeah. This is what the review will be about Thursday.
(B, 127)*

Finally, one participant (L) illustrates the problems involved in interviewing people with learning disabilities, and the difficulty in interpreting their responses:

Umm – so do you know, when you go and have your blood test, do you actually know, do they tell you what the blood test is for, when you go to the surgery?

Yes

They do? So what do they tell you it's for – can you remember?

No

No?

(S You can't remember what it's called?)

And do they explain why they are doing the blood test?

No

Not really?

No (L, 79)

And later in the interview:

And then she just gets you ready to take the blood, so she doesn't tell you why she's taking the blood?

(S No?)

No

Even if she did you probably can't remember

(S He couldn't remember) (L, 106)

Having considered whether there has been understanding of the purpose of the consultation, the nature of the blood test and the reason for having it, I would now like to describe what the participants had to say about how they wanted information (if any) presented to them.

6.2.2.2 *Presentation of health information*

Several problems seem to arise in the health consultation with a person with learning disability. Firstly, there appears to be the problem of communicating at a *level* that is inappropriate to the person with learning disability. For example:

So what is it about the way, about the way that doctors explain things that is difficult for a lot of people, do you think?

The sort of long words they use sometimes.

Mmm.

Cos some people can't, you know, don't know what they're saying, talking about. (C, 135)

Another participant (E), whilst echoing what the previous participant felt about long words, also mentioned the fact that the size of the lettering was important:

What do you think makes leaflets easy to read, then? What, what sort of things.

If it's big print.

Big print, yeah. And what about the kinds of words that are used? Do you think? Cos some leaflets might be difficult to read, mightn't they? So what kind of words do you think people should use for someone like you, or any of the people here?

A magnifying glass

Sorry, say that again.

A magnifying glass, to see.

Oh, a magnifying glass

Yes

To see, to make the words bigger.

Yes. (E, 189)

One participant (H) expressed this very concisely:

I can't see when they're little, I like it when they are big. I can read then, but not long words. (208)

Another participant, when asked about how information should be presented, raised the subject of the type of language used –

OK. So how do you, how do you think, how do you like to be told about things, or given information?

Just... me, me...advice . Tell me what it's for.

They need to tell you what it's for?

Yeah

OK

And explain to me

Mmm

S l o w l y, [not] (gesticulates)

...

[Not] in a load of jargon. (A, 256)

These issues were raised by the majority of participants who wanted explanations for health procedures they were undergoing, commenting on the length, the complexity of the words and the font size to enable easier reading. Secondly, the *format* for information was mentioned. Alternatives were suggested, either in the form of a CD or DVD (A, M):

I can't read

No [so that (a leaflet) wouldn't be much help to you]

[I can't read] No. It would have to be on a CD.

...

Someone filming it, do you know what I mean, that I can watch it.

So, something that you could take away and put in a computer,

Yeah (smiling)

or watch on television

Yeah (smiling)

or DVD or something

Yeah. (A, 305)

And:

I can read, yeah.

So, if a doctor was trying to explain this kind of test to you.

Yeah.

***Do you think, would you understand it best if he talked to you, or if he gave you a leaflet, or any other way?
Sometimes even a DVD to watch, you know, on the telly. That would be one way of doing it. (M, 139)***

In the later stages of Phase 3, if a participant was able to use a computer, I offered to show them a DVD that I had produced, as an interactive tool designed to give a simple explanation of the process involved in having a pharmacogenomic test. This was received well and participants appeared to enjoy using it. However, the details of this will be described in the next section when exploring the participants' knowledge of genetics and pharmacogenomics. As discussed in paragraph 6.2.1.4, the role of the support worker or any other 'supporter' who accompanies the patient was considered central by most participants who were interviewed. Even if they generally preferred to attend medical appointments alone, there were some occasions when they felt it advisable to have a supporter present to facilitate better communication.

I have described the way participants prefer information to be presented and the problems they can encounter in the health consultation. I will consider how much knowledge, if any, the participants have about genetics in particular, and to what degree my explanation of pharmacogenomics was understood in section 6.2.6.

6.2.3 Theme 3 – Behaviour or emotions

When talking about having a blood test, many participants described the fear and anxiety they experienced. Some of these comments related to recent experiences, some to those in the past. Some related to hospital experiences, some to those in primary care. When describing these factors in Phase 2, I considered fear and anxiety separately, as these had been identified from

observing the participants' behaviour. However, for this phase, I regarded them as two factors that participants had described as contributing to a negative feeling about undergoing blood tests, or even further, that resulted in a dislike of any contact at all with the medical profession. For this reason, I will describe them together.

6.2.3.1 *Fear and anxiety*

One of the major reasons for fear and anxiety was 'the needle':

and you don't sound TOO keen about doing to the doctors, but you don't mind it that much, do you?

Not very much

Not too much. Just the needles you don't like, is it?

No, Yeah, I don't like needles

But you quite like the people

Yeah, the people are alright, it's the needle. I don't like it. (G, 290)

And:

Nooo – I don't like going anyway.

Don't like it. Why's that?

I'm frightened of injections, or operations or anything, I'm frightened of it.

So you don't really like the idea of going to the doctor's at all?

No, no I don't.

...

It's not what the results are gonna show

No

It's not that, it's just the needle that you don't like

Yeah, I don't like the needle (H, 22)

And:

I had it on the couch because I feel faint. At one stage up there they thought they might need an ambulance because I didn't come round very quick after it.

Mm

They were worried.

That would worry you a bit, if you know you are going to feel faint

Same with dentists, too. When she comes at me with the needle – agh. (M, 41)

Some participants did not reveal any fear of needles, but explained that they were sometimes anxious about hearing the results from the blood tests. A, who

was having her thyroid function monitored, had demonstrated her anxiety during the consultation when she asked the nurse "if it might have come back." She reiterated this in the interview:

Were you worrying at all about what the result might show?

No, the first time when I had that thyroid problem, it was worrying.

Mmm, so [you were]

Yeah

A bit [worried]

Yeah, yeah.

it might come back. I think when you had the blood test, you said to the nurse that, you asked her if she thought it had come back, didn't you?

Yeah

So, perhaps that was when you were waiting for the result?

Yeah

Were you wondering [if]

[Yeah]

it had come back?

Yeah

And you must have been pleased

Yeah (A, 165)

D, who at the time of interview had not been observed having a blood test, recalled a blood test he had undergone in the past, and how waiting for the result caused him anxiety:

So – can you remember what the blood test, it was a long time ago, so – do you know what they were for?

Uh

Cos you said they were for...

I think it was just checking me over, so I had a brain tumour a while back. Just checking to be sure I was staying healthy. Yeah.

So you went back to get the results, you were a bit worried, you said didn't you?

Yeah, a little bit

But um

It was alright.

So the doctor told you it was all...

It was fine, you know

It was all fine.

I worried over nothing. (D, 86)

This participant assured me in the interview that he didn't worry about the procedure itself. However, at the subsequent observation of his blood test consultation, he exhibited signs of anxiety before and after the procedure (previously described in Chapter 5).

One participant (A), who hadn't particularly expressed a dislike of needles, finally admitted that the procedure "hurt a little bit". Another, despite admitting that she "never liked needles or anything like that", had accepted the fact that having a blood test was part of her life:

Well, well, yeah, not too bad, you know, what with me operations and all that, years ago, and the accident and all that, I've been really through the hospitals, been through it a lot meself really, you know, so really and truly, just a bit of a needle in me arm 'n all that in't too bad really, but the (smiles) thought of it's not very nice as you know from my dear face as you saw last week (smiles) (B, 35)

Having listened to the fears and anxieties about blood tests and seeing a doctor, I recognised one other feature that was exhibited by some participants during the interviews – that of bravado.

6.2.3.2 *Bravado*

When asked how she felt about going to the doctors, A was emphatic –

What about going to the doctor's generally?

What, on my own?

How do you feel about going to the doctors for anything?

Fine, fine (pause). Not afraid of nothing, me not... I'm brave. (A, 16)

I, although admitting dislike of hospitals, resigned herself to have to "cope with it":

And can you remember how you felt about having a blood test?

Um, well

It was a long time ago

I'm not very good with needles, so I had to cope with it. So I had to, like, I had to like, um, put up with it. (I, 15)

This characteristic of bravado, or alternatively passive acceptance of the situation could be considered as associated with the final theme from this phase, that of 'the self'. This concept includes related factors such as self-esteem, self-identity, self-image and self-determination.

6.2.4 Theme 4 – Strategies and coping mechanisms

This theme was mainly evident in Phase 2, the observation phase, but there was one example in this phase.

One participant (I) described how she employed distraction tactics whilst attending hospital for a blood test, which she admitted she found difficult:

I'm not very good with needles, so I had to cope with it. So I had to, like, I had to like, um, put up with it and just think about all the nice stuff for T, think about my future, future that I am going to have now, not think about the past, and it works.

So, you thought about the good things, and that took your mind off it.

Yeah (I, 18)

6.2.5 Theme 5 – The Self

In this section the different categories I identified when analysing the data were:

- Self-identity
- Self-image
- How I would like to be treated
- Decision making

The first two are related, so I will describe them together, and I consider the term which best describes them is 'self image'.

6.2.5.1 *Self-image*

One participant (C) had described how she thought it was 'babyish' to be given information in accessible format, for example with images. In her case, there was also a certain degree of disdain about other people with learning disabilities who are unable to read:

So do you feel that, you are being, when that happens, you are given things with pictures, it is treating you, like, you think it's babyish – so you'd [rather be treated...]

[Yes, but]I, I can see L's (the manager) point of view, so he's got to do it that way, cos of people that can't read.

Mmm.

As I feel that people that can't read ought to go and learn to read. (C, 176)

Others felt that it was quite acceptable to be given information in a pictorial format, and acknowledged that for some other people with learning disabilities, this was useful:

And of course a lot of people with learning disabilities can't read.

Or as you say, they have got hearing problems. They just find different ways of, you know, presenting. Some people might like.

I mean, I did these sheets with pictures because some people find it difficult to read.

That's right, yeah.

What do you think about... I mean, someone else I spoke to said that they thought that was babyish. But

No, that's not babyish.

You think it helps people?

Yes, I think it would. Help people a lot, yeah. Yeah, yup.

I mean, you don't need it, but some people do.

Some people do, yeah. Yeah. (M, 219)

The need for a support worker was another topic in which opinions seemed to be somewhat polarized. As previously stated, some participants wanted the security that a support worker represented; others valued the support worker as an 'interpreter' or 'facilitator' in the health consultation. In some cases,

however, people who needed the presence of a support worker were seen as inferior:

Do you think you need to be brave to go the doctor's?

No. I'm not like the rest of them that need support worker ...

If I need to go to the doctors..... They want their support worker to go with them all the time. I'm not like that (scratches head, looks emotional) I just go on my own.

And that's being brave?

I'm not a baby, I'm an adult (shrugs) (A, 22)

One person (M), despite appreciating the security that a support worker provided in the consultation, also considered that attending the doctor without a support worker represented a step towards independence:

When you said that sometimes you take someone with you for your blood test, um, if there is anything.... Does the support worker sometimes explain things to you, if there are things that you don't understand at the doctors. Would a support worker help you?

They would help me, but if I can go in the doctors and explain myself, then that is going more forward. (M, 196)

Some of the participants (B, D) were keen to demonstrate their knowledge, confidence or even their ability to give me the answer they thought I wanted.

And if you didn't have your health, you wouldn't be living today, would you sort of thing, would you? (laughs)

(laughs)

No, that's true really. Maybe sounds strange, but when you really think, and you do your research, Lesley, and that, I think you'll find that what I'm saying will be adequate to answer (B, 99)

And:

Mm, mm. So how do you feel about going to the doctor's generally?

Alright. (nods, smiles)

Does it make you feel..

I'm quite confident, you know. (D, 18)

In one case, it is possible that I was being patronising in the way I interviewed this participant, and he made it clear to me that he knew what I was talking about:

Do you know, have you ever heard of things called genes? I don't mean jeans you wear.

Yeah, I know. Genes in your... (points to own body) (D, 110)

...

Cos everybody's different.

Yeah, I know that, yeah. (D, 159)

M was keen to agree with my statement that he seemed quite able, when discussing the need for accessible information:

I mean, you don't need it, but some people do.

Some people do, yeah. Yeah.

Cos you seem quite able really.

I am, yeah. (M, 229)

6.2.5.2 *How I would like to be treated*

In some interviews, people expressed how they did, or did not want to be treated. This related generally to the healthcare context, but their comments could be interpreted to include most other areas of life. One participant (C) spoke several times about not wanting to be treated as a child:

So that, really then, what you are saying is that the most important thing is that you know, that people are friendly and talk to you in a way that you would want to be talked to?

Yes, not like children.

And that makes going to the doctors easier?

Yes, cos you're just like anybody else, then.

...

I don't like pictures very much, because I can read.

Mmm.

You know, I know people that can't read, then you've got to have pictures. I think it's a bit babyish (pulls a face), I think. (C, 38)

Several participants had experienced what they considered to be rude or aggressive treatment from the health care team:

And I saw one doctor, and she was a bit nasty to me, she upset me and the support worker come with me

Yes

And he got me in tears, crying.(looked distressed)

...

Oh, she wasn't very kind to you, then?

No, I didn't like that.

It was a good thing you had a support worker in with you, then, did you?

Oh, yeah.

...

Happen she was rude

Mm. So you think, it's quite important...

She said to me "What do you come here for" (in a loud, aggressive voice)

Did she?

Yeah

That's certainly not the way to treat people, is it?

Not when people got learning difficulties and that. (K, 418)

Another example is the case of J, described earlier, who was upset that he had been called mentally retarded by a doctor at his surgery. Two participants made comments that reflected how they liked to be treated at the doctors' surgery:

Yeah? And do they – how do you find talking to them. Do they – are they friendly, and treat you well?

Yeah, they listen to you, you know.

They do?

Yeah. (D, 39)

M, when describing how he liked information presented to him, made the following observation:

Yeah. Cos usually the appointments are quite quick, aren't they?

They are, yeah. I think, as well, the doctors these days are giving more time to explain to people too. They've got more time for people, you know? (M, 172)

Finally, some participants had something valuable to say about their opportunities to make their own choices.

6.2.5.3 *Decision-making*

One participant was not happy with the way she was treated at her previous surgery, and appeared proud to have made the decision to change her GP surgery:

Well, when I went to one place, and um he said "Well, what are you here for?". I thought crikey, that's not a very, thing, you don't ask, say that to somebody, do you?

No, no.

So I moved doctors surgery then.

Yeah.

So I don't want this, I'll go somewhere else. (C, 27)

Participants appeared to find satisfaction in having made decisions for themselves. For example, (I), when telling me that she did not require information prior to having a blood test, agreed that it was her choice:

I just tell him to get on with it, that's all. I don't really want to know about what kind of blood test its for, really.

And that's your choice, if you don't WANT to know, then

I just tell him to get on with it, you know. (I, 301)

However, the same participant (I), when describing her experiences with regard to another situation, considered that she had been given no choice:

So I had a choice, of, nobody didn't want me to make any choices, so I had a choice of still battling with social services, or give up, put T up for adoption, and that made my depression, cos I suffer with depression as well, that made my depression worse. I am on medication for that. It made me worse. So, I didn't know, my mind was confused, the final hearing, and I don't know what I was thinking, but I had no choice but to put T up for adoption. I am now regretting it. (I, 113-119)

She also later described how where she and her husband live is their decision to make. These examples illustrate how important the issue of choice and self-determination are for people with learning disabilities.

A described a difficult situation she had encountered in her life that had influenced her decision not to undergo certain procedures in the surgery:

So, that, you've made the [choice]
[Yeah] (shifting in her chair, looking uncomfortable and anxious)
and you've got a good [reason]
Yeah. (A, 100)

In contrast, one participant (H) implied that she was given no choice when being told that she 'had to have' a vaccination at the surgery:

So did they say to you, did they give you the chance to say yes or no for that one?
She said, I asked the doctor, do I have to have it, he said yes.
He said yes, you had to have it?
Yes, he said I've got to come up, I don't know when, but he said I got to come up and have that S W I N E (spells out the letters) flu
Oh, yes
and one of them, but I don't like.
But he said you've got to have it, did he?
Yeah. (H, 85)

Having described the experiences and attitudes of people with learning disabilities in the health context, together with how they feel about themselves and how they should be treated, I would now like to conclude with the final theme of pharmacogenomic testing. This theme is somewhat different from the others – because pharmacogenomics is a topic which needed to be introduced during the general discussion about blood tests, it did not 'emerge from the data' in the normal process of inductive analysis. Before I could identify the participants' attitude about this kind of genetic test, I needed to give them a brief, simple description. This enabled me to explore their understanding of the topic.

6.2.6 Theme 6 – Genetics and pharmacogenomic testing

6.2.6.1 Knowledge and understanding of genetics and pharmacogenomics

Before I attempted to give participants a simple explanation of pharmacogenomic testing, it was important to first establish their current level of knowledge with regard to genes and genetics. Of the participants interviewed, five said that they had heard of 'genes' or 'genetics' and some of these were able to illustrate this understanding by examples:

So, if I can explain, have you heard of, do you know what genes are? I don't mean the jeans like I am wearing, but do you know what genes are?

Isn't it some sort of thing you get passed down from your parents?

That's right, yeah, good answer (laughs)– that's just what I was going to say. Yes, so we all have genes in our bodies, and they are in every part of your body, and yes, you are quite right, they are passed down from your parents, and they affect all kinds of things – how your body works, how you behave, what you look like – you might look like more like your mum or more like your dad. I think I take after more like my dad's side, cos they were all rather plump. (C, 78)

One participant had obviously received some kind of education about genetics and possibly an explanation of what may have caused her learning disability:

Now have you heard of things called genes, or genetics?

Yeah

... So, tell me what you know about genes and genetics then.

Well, genes is like a um, well it's made like a group of circular things in your body (puts her arms up to demonstrate the circular shape), and they connect together, and if one of those genes falls apart, I think that would be it, you're in trouble. Well, I would be in trouble if that happens. And of course, with myself, for me, unfortunately, I'm missing a gene in my body. (I, 133)

Two participants linked cancer with genetics:

But sometimes, this test is so the doctor can find out... it's a test that looks at – have you heard of things called genes (I don't mean jeans that you wear). Have you heard of genes?

Yes

And what do you think genes are? Do you know what they do?

Cancer – you get cancer.

(S He thinks it's to do with cancer.)

Oh, that's interesting, cos someone else thought. So you think, well, you think that genes, depending on what kind of genes you've got, that will decide whether you are going to get cancer or not?

Yes, yes. (J, 111)

And:

This is going to be in the future. It's a new kind of test which is based on, it's about genetics. Genetics is a difficult thing to explain, cos a lot of people don't understand it

Yeah, genes and all that

Yeah, genes. Genes are things that are in every cell in your body really, that are passed down from parents to children, and it affects

Yeah

you know, what you look like and how your body works, And cancer, it's like cancer and all that. We've all got cancer in us, innit – and only summat that triggers it up (B, 226)

In some cases, there was an apparent awareness of genetics, but this knowledge was somewhat inaccurate and confused:

If you had, and sometimes, and genetics is, so if you had, some conditions are called genetic conditions, so they can do tests to find out what you've got wrong with you, like Down Syndrome or something like [that]

Oh, yeah, yeah, I have heard of it, yeah.

So that's what genetics is all about

Yeah, like if someone's got Downs Syndrome, spina bifida or, or if they're paraplegic. F, 153)

This participant, however, when asked earlier in the interview about genes and genetics, answered with a description of the sex education she had received at school, and later on she went on to associate genetics incorrectly with a 24 hour urine test she had recently undergone.

Over half of the participants, however, had never heard of genes or genetics. It was a challenge to give these in particular, and to a certain extent, the others, a simple explanation of pharmacogenomic testing. The first stage was to try and give a basic description of genetics, and then focus on pharmacogenomics. Despite my scientific background, I found providing an easy to understand account of genetics challenging. I considered that some participants who had

no previous knowledge of genetics were either unable to understand, were not interested, or simply diverted the conversation onto themselves. For example:

...and they work out what kind of gene you've got, what sort of gene to do with this, how your body reacts to drugs, and it'll help the doctor to decide the best medicine for you, and um what kind of dose you had, so if you had to have a high dose of painkiller, or a low dose of a painkiller.

Um, I can't remember what painkiller I'm on

No

(S - Co-codamol)

Yeah, cos I gets pain in my back all the time (G, 200)

And:

Mm. So, do you think the way I've explained it, which is not easy to explain anyway, do you think you understand what this blood test will do? Can you just tell me in your own words what you think?

Yeah

What do you think it's going to do then?

Um, it sounds like it. It's gonna be another version of having a needle, but without having the needle. It'll be like, no what I'm trying to say, is it's like a new invention for the future

True

So, it's a bit like using a needle

It will use a needle, because it takes blood

I Ah (I, 202)

Two participants seemed to have a basic understanding of what I had told them:

So, I've explained that test to you. Can you tell me what you think that test was about. Do you think? I have tried to explain it to you, and it is difficult for me to explain.

Yeah, about genes, you said, isn't it?

And

And see, the doctors see what medication you need to take, other tablets, drugs, you know? Yeah. (M, 233)

And:

And then the doctor can say, oh well, you know – I don't think we should put her on this medicine. So they don't have to keep trying different medicines – the test would tell them, would be...

More accurate

Yes, that's exactly it, more accurate

More accurate, oh yes. (B, 241)

For some participants, as described in the previous section, I showed an interactive DVD to several participants to see if this was successful in facilitating understanding. The following accounts are taken from participants who either used the DVD or had it shown to them:

I like the funny faces. They are fun. Especially that one. Mm. OK, so that's the end. So, do you think that would be a good way to explain to someone if they hadn't had a blood test before, or? Yeah. Then they know what's coming up. Then they know what actually..

...
And it does technically say....it helps them to decide if they want it or not. Really, and it helps them to understand what they are preparing for. (I, 258)

Another participant, although not computer literate, could read and was interested in seeing the DVD. I operated the laptop and she read the text from the screen. She appeared to enjoy the process and found it interesting:

OK, so –

(both reading from screen) **"What was this all about?"**

"The way our body works is passed down from your parents"

"Some people may need to tell/take more medicine than others". Some medicines will suit you, some medicines may take (smiling again) not suit you"

Ooh, a bit miserable (referring to face on screen, both smiling)

OK, that's the end really, just to say that "Blood tests may help the doctor decide which medicine is best for you." So that's what that new kind of blood test is like. So, that was one way of explaining it, wasn't it, using the computer, um

Yeah

– so, if you were, so now I've shown you that, do you think you now what that blood test is about, can you tell me?

Yeah.

Can you tell me a bit, what do you think that blood test is for?

Uh, the nurse put the needle into your arm and that

Yeah

And then they write it down on this glass thing, and it sends all the way up to D Hospital.

Yeah. And what will the result of that blood test show, do you think? When the doctor..

And then the results will come back to your doctor, and doctor will tell you what you are allergic to and that.

So you understand that it will help about choosing the best kind of medicine for you?

Yeah, and if you are anaemic, what medicine to have and that, what tablets to have and that. (K, 336)

Another participant, again not computer literate, but able to read, was shown the DVD and read the text from the screen:

(reading from screen) "How are bodies work can be passed down from our parents" "Some people need to take more medicine than others" "Some medicines will suit you, some may not suit you" "My blood tests may help the doctor decide which medicine is best for you".

So what do you think? It needs a bit of tidying up, perhaps, and a bit more, but do you think that kind of thing would help people understand?

Yes, I think so. Yeah, a lot, yeah. (M, 295)

6.2.6.2 Having a new kind of blood test (pharmacogenomics)

Having given participants a simple explanation about the new kind of pharmacogenomic tests which might be available in the future, they were asked how they would feel about consenting to this kind of test. Some appeared to understand the nature of the test, and the fact that it could be viewed as subtly different from tests they had undergone in the past:

But if it was this new kind of test, would you see that as anything different? No?

Not really, because its, like, you know – just be like exactly the same blood test, nothing different really.

Just a different way of helping the doctor to decide something, you think?

Yeah, exactly the same, I mean,

So

It's totally different, but at the end, I understand what you are saying, about totally different blood tests, but mainly, we need something new to get us into the future, you know, and our health. (I, 283)

Another (C) felt that she should accept anything 'new' as it was a sign of progress.

So if the doctor said he wanted to put you on a new medicine for something, perhaps for your thyroid, if he said, "Well, I've got a blood test that might, you know, mean we can sort out the right

**dose straight away, or see if this new medicine would suit you",
how would you feel about having a blood test for that?**
I wouldn't mind, because they've got to learn and got to find out, haven't they? You don't just sit back and let, you know, let uh new uh things go, go by.
No.
Because they might find a cure for things.
So you think it would be a good idea
Yes,
To have that to see if there is a better medicine.
Yeah. (C,107)

Some participants did not regard a pharmacogenomic test as anything different from any other routine blood test used in the management of their health, although in making this statement, I am assuming that there was a certain level of understanding of my explanation:

So you wouldn't have any worries about someone suggesting this kind of blood test.
No, no
So, um it wouldn't really seem different to any other blood test?
[No, no.]
[For you] just a blood test is a blood test
Yes, yes. (J, 204)

The issue of whether genetic tests are 'exceptional' in terms of consent, and in particular whether pharmacogenomic tests differ from diagnostic genetic tests will be discussed later in Chapter 8.

Some participants felt that they would accept this new kind of test without any information:

So really, then, if a doctor said to you that he wanted to do a blood test just to check what was the best kind of medicine for you, you would be quite happy, if he didn't explain it, you would still be quite happy to have it done, would you?
Yes (E, 142)

Others stated that they would want to know more before they consented (for example, G, B)

OK, so how would you feel, and if it was one of these tests about medicines and things?

(yawns widely – bored??)

How do you think you would feel about that, would you say yes, or do you think you would want to know more about it?

I gonna more about it, first afore deciding it. (G, 225)

And:

But if you had to have a different blood test that was for something else, then do you think you would rather have it explained to you before..

Oh, yes, because you don't know what averse (sic) reaction there may be. Though I know this is alright, and you've got to believe in the doctors and nurses, like I've said before, and I have said to people, you've got to, you know, you've got to believe. (B, 332)

Interestingly, B, although stating that she wanted the test explained, also then went on to refer to her 'belief' in the doctors. For some people, the worry was not about the nature or outcome of the pharmacogenomic test, but simply related to their needle phobia:

What would worry you about it?

Uh (laughing) – just the needle

The needle! (both laughing) So it's not actually the, it's not the, wouldn't be the result of the blood test or anything

No

It's just actually HAVING the blood test.

Yeah, just the needle part. I do hate needles.

So that blood test, to you, wouldn't feel any different to any other blood test?

No (F, 242)

I have previously described how these themes were identified from the data, and how this new interview data revealed not only further examples, but also a new set of themes based on the individual person with learning disabilities. The themes identified in Phases 2 and 3 are summarised in Table 6.

Table 6 Themes and categories Phases 2 and 3

Theme	Sub-theme	Phase 2 (Observations)	Phase 3 (Interviews)
Patient in healthcare context	Attitude to having a blood test	✓	✓
	Feeling about going to the doctors		✓
	Knowledge of healthcare system		✓
	Relationship and communication with the healthcare professional	✓	✓
	Role of supporter		✓
Information and knowledge	Presentation of health information	✓	✓
	Knowledge of blood tests in general		✓
	Purpose of blood test and procedure	✓	✓
Consent	Seeking consent	✓	
	Expressing consent	✓	
Behavioural	Anxiety	✓	✓
	Bravado	✓	✓
	Fear	✓	✓
	Pain	✓	
	Relief	✓	
	Resistance	✓	
Strategies and coping mechanisms	Distraction tactics	✓	✓
	Establishing rapport	✓	
	Reassurance	✓	
	Use of humour or teasing	✓	
The self	Self-identity		✓
	Self-image		✓
	How I would like to be treated		✓
	Decision-making		✓
Genetics and pharmacogenomic testing	Knowledge and understanding of genetics and pharmacogenomics		✓
	Attitude to having a new kind of blood test (pharmacogenomics)		✓

To conclude this chapter, I would like to discuss how some of the themes identified in the literature review (Phase 1), have been reinforced by my own research, but also how some of the findings have raised further questions.

6.3 How the findings from Phases 2 and 3 relate to the literature

Having analysed the data from the interviews, I found myself relating the findings not only to the observations I conducted, but also to the themes I identified from my reading of the literature in Phase 1. I consider that the most useful data has been gained from participants in whom I conducted both an observation of a blood test consultation and a subsequent interview. This enabled me to evaluate the findings from the interviews in light of what I had personally observed. For example, some participants exhibited anxiety in the consultation but subsequently informed me that they had no worries about attending for a blood test. All except one participant attended for a blood test with no support; however, on being interviewed several conceded that support was useful on some occasions, when complex issues were involved. However, it became clear to me that the findings from both empirical phases described so far, in most cases, confirmed those from the literature review. In particular, the themes of life experience and interaction between the healthcare professional and participant were prominent in the data.

In this chapter I outlined the relationship between themes from Phase 2 (Observation) and Phase 3 (Interviews); I also explained the role of the supporter in the interview and how this may have affected the data. I then described the findings in detail, giving more illustrations of existing themes from Phase 1, but also adding a new theme, that of 'The Self'.

In the next chapter, I will describe the findings from the final phase of the programme of study, in which I explore the views of carers, healthcare professionals and key informants from the field of learning disability.

Chapter Seven

The views of carers and healthcare professionals (Phase 4 of study)

7.1 Introduction

In the previous chapter I described findings from Phase 3, which involved collecting data via interviews with participants with learning disabilities. I will now describe the findings from Phase 4, in which I conducted two focus groups, and an on-line (asynchronous) bulletin board. Data were collected from:

- Paid carers (face-to-face)
- Unpaid (family) carers (face-to-face)
- Healthcare professionals (HCPs) (online).

Finally I conducted semi-structured interviews with key informants from the field of learning disabilities. Table 7² shows the participants involved in Phase 4.

Table 7 Participants in Phase 4

Focus group 1 (FG1)	Paid carers – four participants from two different providers of social care (4)
Focus group 2 (FG2)	Family carers – three parents, one sibling, one sister-in-law (5)
Online bulletin board (OBB)	A range of healthcare professionals: one general practitioner (GP), two speech therapists, one phlebotomist and one learning disability (LD) nurse (5)
Key informants (KI)	Six participants: one LD nurse, manager of organisation providing support to PWLD, co-director of national LD charity, genetic counsellor, training co-ordinator/health action planner on local LD team, senior speech and language therapist on local LD team (6)

² The abbreviations in Table 7 are used to identify the source of any quotations that follow

7.2 The themes

In each stage of this phase, data were transcribed and analysed separately, but because many of the themes are common to all three, I have synthesised the findings and will present them together under themes. As there is overlap between the various sub-themes, I will describe them together within each theme rather than individually, to avoid duplication. I will provide a list of themes and sub-themes from all three phases (observation, interviews and focus groups) at the end of this section (see Table 9). However, for clarity, as in previous chapters, Table 8, which follows, illustrates the themes and categories from Phase 4 only. It should be noted that in addition to the themes from Phases 2 and 3, new themes and categories have been identified during this final phase and some existing themes have been extended to include new categories.

Table 8 Themes and categories Phase 4

Theme	Sub-theme
Patient in healthcare context	*Attitude of HCPs and staff
	*Attitude of others (non-HCPs)
	Relationship and communication between healthcare professionals, support worker and participant
	*Equity of access
	*Health experience
	Role of supporter
Information and knowledge	Presentation of health information
Consent and capacity	*Assessment of capacity
	Seeking consent
	Expressing consent
	*Best interest
	*Professional knowledge & understanding of MCA
	*Supporting/facilitating informed consent and facilitating understanding
	*Barriers to obtaining informed consent
	*The knowledge of the assessor/decision-maker
Behavioural	*Acquiescence
The self	Self-determination/decision-making
	How I would like to be treated
	*Abilities of person cared for
	*Personal qualities of person cared for
	*Visibility of learning disability

Theme	Sub-theme
Being a carer	*Being a carer
	*Carers' assumptions
	*Feeling of identity with other carers
Genetics and pharmacogenomic testing	*Are genetic tests different?
	Attitude to pharmacogenomics testing
	*Lay knowledge of genetics
	*Professional knowledge of pharmacogenomics
Miscellaneous codes	Understanding of my explanation of pharmacogenomics
	Transition of care status
	How different are people with LD? The spectrum of learning disability

* indicates a theme or category new to Phase 4

7.2.1 Patient in the healthcare context

This theme emerged as a common thread, following on from Phases 2 and 3, and it was useful to obtain data from differing perspectives – that of the paid carer, the family carer and the healthcare professional.

There was much discussion concerning the attitude of healthcare professionals and their teams, and the relationships and communication between healthcare professionals, supporters³ and patients with learning disabilities.

The support workers had a range of experiences in supporting their clients in the health setting. Some reported negative, unhelpful attitudes from staff:

I had a lady years ago, and I asked her why she was going to the doctors. She said, "I don't know, cos they tell me I'm too stupid to know". I said "No, you're not, you are going for you, you need to know." She was going to go unsupported as well, but she didn't – I went with her. It was just a well woman check in the end, but this is what she had been told years prior –that she was too stupid to know why they were doing things. She had to be told because she was NOT a stupid lady. Not in the slightest. (FG1,S, 339-345)

One family carer expressed her anger at the attitude of a hospital doctor when treating the person she supported:

³ Supporters in this context: paid support workers, parents or other family carers

The specialist up there said to me, looking straight at me, P is in the wheelchair to the left of me, pushed back a bit, and said to me "If we find cancer, considering Mr H's present condition would you still want us to go ahead and treat?... And that was 18 months ago. If I could have hit him there and then I would (laughing) (FG2, L, 369-375)

The attitude of healthcare professionals can sometimes cause support staff to become frustrated on behalf of their clients. This is illustrated by an example from secondary care:

And I think also, when you ARE supporting somebody in the surgery you still would hope that the doctor would actually talk to the client and NOT to... I had an experience where, it was at the hospital, and the specialist completely blanked my client out and started talking to me, and I kept referring back to him to try and give her the pointers to try and make ... You know, speak to my client. But she wouldn't, she just. And he was very verbal and able. He wasn't, you know, he didn't have any major complex issues, but she wouldn't speak to him. (FG1, P 209-217)

I asked the paid carers if they had thought about why this happens. There were several responses to this:

- P Well, I think it's about time, isn't it?*
A Yeah
P They think it's quicker to talk to the support worker, let's get this one out of the way, I'll speak to them. Perhaps they feel they are going to be drawn in too much if they are talking to the client/service user.
A I think it's a fear of communicating
P [Yeah]
A [with] people.
C Yeah, I think I would agree with that.
Mm. Perhaps they haven't had experience.
S A touch of ignorance
All Yeah, Mm etc (FG1, 225-236)

Frustration is not limited to support workers; several healthcare professionals expressed similar views:

I feel a lot of the time decisions are made over the head of the person with a learning disability and between professionals and family members where the person with learning disability is still regarded as either a 'child'

or someone who will just not be able to make any kind of decision for themselves. (OBB, GG, 88-91)

Not all experiences were negative, however, and some participants also reported examples of good practice and illustrated how some general practices and hospitals provide an excellent service to people with learning disabilities:

and they were very good and very understanding, cos he's verbal, but limited verbal communication and DS, so quite complex, and they were very understanding with him, and at one point they had to do a skin biopsy and of course, they did explain it clearly to him. I could see the fear come in his face when he thought about what... and you know, they gave him a chance to think about it, and I said, "Are you sure you really want this done?" Cos he had a choice, so – and he said, "Yes, I will", (FG1, P, 410-416)

Having described some of the experiences of people with learning disabilities in the health context as related by their carers or healthcare professionals, I would now like to give some examples of the perceived role of the supporter.

7.2.2 The role of the supporter

Support workers appear to see themselves in a somewhat protective role with regard to their 'clients' or 'service users', the people with learning disabilities. This can be related to equity of access to health care. The relationship between the healthcare professional, supporter and the patient in the health consultation can be complex. In some cases, the support workers saw their role as that of ensuring that the client received the care they were entitled to, and were treated equitably:

A *but there does seem to be a resentment, especially if there is a support worker there, and you wonder what would go on if you weren't there. Would it be worse, or would it be better? Um, and I think in the past, people at TH have gone unsupported to medical professionals. I think now, we tend to always to go with the tenants, because we are not quite sure whether they are gonna get equal treatment.*

S *Mm*

A *And, you know, especially if there is a communication barrier as well, um I think a lot of the time the tenants tend to be fobbed off. What do you think MIGHT happen if you know, if they DID go unaccompanied.*

A *Well, I think, at worst, nothing. (FG1, 124 - 138)*

I explained to the family carers that some support workers felt that their presence in the consulting room was not welcome:

R *I can see that possibly. We don't experience that, but I can see it from the point of view of someone coming in as a paid support worker, possibly the professional would look at them with some suspicion.*

J *Well, I find that they do that much more with a relative...they feel that you are going to be too overpowering and too over-protective and try to speak up too often (FG2, 860-866)*

This point was clarified succinctly by one of the key informants:

Mm. I think that it's something that the support worker and the person they are supporting ought to talk about beforehand and be clear about why the support worker might go in with them, and then the answer, if the health professional queries it, the answer is that they have talked about it and agreed that that's what the person with learning disabilities wants. (KI, AA, 335-339)

Participants in the family carers' group gave examples of what can or might happen when a person with learning disabilities attends a medical appointment without support:

Well, one woman, one woman, the story was very sad because she had gone to the doctor on her own, and without any support, and she had heard that women were supposed to have a smear test. When she went to the doctor, the doctor told her – "Well, it's not for you".... "It's not for you, I mean you are not in a relationship, you don't need a smear test." So she went back to her support worker at the drop-in and um obviously there was uproar (laughs) (FG2, L, 945-952)

BH *I am sure he could go in on his own, and have no problems, but we go every time, don't we (looking at wife)*

VH *Yes, because I think if he was told something, he probably wouldn't be able to relate it back to us if we weren't there.*

BH *That's the problem. (FG2, 46-50)*

Support workers also see themselves acting as interpreters when their clients have difficulty understanding what the healthcare professional is saying:

... they may want support in a doctor's surgery because they don't have the confidence to go in alone, and only yesterday a lady asked me to accompany her to a doctor's surgery, cos she said "I just can't understand when they start saying all the long words, so can you come in and support me?" (FG1, P, 69-74)

This view of the supporter as an interpreter is reinforced by comments from several key informants, confirming that supporters not only help the person to understand what the healthcare professional is saying, but also ensure that the healthcare professional has a full understanding of the presenting problem. For example:

And so mostly, what I hear from GPs is that they would appreciate having a well informed supporter there so that they (the GP) can be sure that they understand what the problem is and can have some confidence that what they say will be remembered and acted on. (KI, AA, 349-352)

Taking this idea further some participants stressed that they themselves need to understand information that is being imparted to their clients; one participant described a situation where he was expected to gain consent from the client for a particular procedure (with no healthcare professional present). His concern was that he may not have had a sufficient level of understanding to ensure that the client was making an informed choice:

A Yeah, we rely quite a lot on the medical professional's giving out enough information to explain it.

All Mmm, yeah

A Cos I mean, you know, if we're not aware of what a procedure is for, or what a medical problem means, then it's very difficult for us to impart that information. I mean, we could get it wrong and scare somebody. (FG1, 285-290)

Family carers see themselves in a similarly protective role, giving support and reassurance when necessary and ensuring that information is presented in an appropriate way and acting as interpreters if not:

Well that's why we go in really, we make sure he's, because we want to make sure he's alright and understands, and that's it. (FG2, BH, 361-362)

I noted that family carers without exception felt that they were the best people to support their (adult) children:

So, um, but I don't think anything helps anybody to deal with any individual person more than genetic familiarity. You know, the fact that he is your son, the fact that my brother is my brother, means that I have an intuitive understanding of him, um, as I am sure you do (to R), and it's quite hard that he's actually under the care of people that, through no fault of their own, can't understand him terribly well, and that causes problems. (FG2, J, 125-131)

However, there was a comment from someone in the on-line group of healthcare professionals relating to the role of the 'supporter'. When asked about the challenges to obtaining consent from a person with learning disability, this participant appears to believe that family members or professionals can obstruct the process:

Opinions of family members/professional not allowing the person with a learning disability being fully involved in the decision making process (OBB, GG, 186-187)

This view was reinforced by one of the key informants, who commented about potential problems when parents accompany a person with learning disabilities:

And they probably do know their child best and that is about getting the balance right between the GP saying "I really appreciate that you are here, and I think it's great that we've got this chance to meet, so we can share information, but I am here for your son today, and I'm gonna get the information from your son, and then we can look at the whole information, we can look at the whole picture". Because before, they

have been ignored, the person with LD has been ignored. Now it's about bringing them into that picture and having the whole thing, rather than just a little segment. (KI, BB, 393-400)

The same participant also stressed the need for the supporter to make a judgement on the degree of support that a person needed:

I think we have to be careful as carers not to over-emphasise our role because it's very easy to take on a protective role when it should be a supportive role. ...Why should we be de-skilling that individual and taking it away? On the other hand, if that individual is likely to get confused or may need prompting and support in the future, if they need that support, then by all means a carer can be a very useful asset. (KI, BB, 417-427)

Having considered the person with learning disabilities in the health context and relationships with supporters, I will now describe the theme of information and knowledge, which should be an essential part of any informed consent process.

7.2.3 Information and knowledge

In this section, I will discuss how information is presented to people, and also participants' views on how that information is understood (or not, as is often the case). Appropriate and accessible information is a requirement for the informed consent process.

The emphasis in all groups was that information needed to be at a level appropriate to the patient. Two of the challenges identified by one healthcare professional were:

*Ensuring that the information they receive is accessible and informative.
Ensuring that they have the time and support to digest the information
and have it explained to them in a way they understand. (OBB, GG, 171-173)*

Healthcare professionals talked about the ways accessible information can be achieved:

For the person in their everyday life. Trying to enable people to use strategies if that's appropriate. So that's things like signed back up speech, pictures. Pictures are nearly always helpful to some degree – so helping people understand how they can be used. Um, helping people to modify their language and to use things in the environment, objects and demonstrating things to help the person understand. (KI, CC, 28-33)

Both the paid carers and family carers concurred with this opinion, and as evidenced in the previous section, if information was not presented in an appropriate format, the role of the supporter was to make the information understandable:

C I think, the thing is, if they needed any treatment for anything, it would be a matter of explaining it at their level...so, if it needs simplifying, explaining it so they understand what is going on so that they can say this is what's happening, so then they can make an informed decision. I mean, at best of times, we all go to doctor's, and they are talking to us, um, about things, and you've not got a clue, and you are asking questions, and you still don't understand what, you know, what's what. So it's about researching, and letting somebody really understand just what is going to happen

A Mm

C And this is why they are doing it. At my level of understanding, or at anybody's level of understanding, so that they can then say, "Yes, I want this" or "No, I don't want this". (FG1, 268-282)

The concept of accessible information can be a difficult one. Each person with learning disability is an individual, and there were examples where the appropriateness of information was questioned:

And why are they being given that information when they are able to read? Or the verbal spoken word, you know, or you know, there's ways of doing it that empower people as opposed to disempowering them, isn't there? (KI, BB, 221-223)

Another aspect of information provision to consider is how much information a person needs to make a specific decision. This will be considered in more detail under the next theme of consent and capacity.

And I suppose the amount of explanation that people are given varies as well and um if it's a thing like a blood test, yeah, I think, I suspect the reason for the blood test, the explanation of the reason for the blood test, is probably quite broad – so "We need to find out whatever". Um, and "that might mean we can give you some medicine to make you feel better" or something like that. So it's quite a broad explanation rather than going into the specifics. (KI, CC, 65-71)

In some situations it is unclear whether a person with learning disability has full understanding of information they have been given, because linguistic ability may not reflect the level of cognitive ability. For example, research has suggested that in general, people with Williams syndrome have a relative strength in their language which is in contrast with their general cognitive impairment (Bellugi & St George, 2001).

The focus here is whether the purpose of a consultation or a procedure such as a blood test has been understood. This usually relates to how much information they have been given or the appropriateness of that information. In other words, was the information at a level appropriate to that person's cognitive ability?

In the family carers' focus group, it appeared that the carers took on the responsibility of ensuring that the person in their care understood the nature of the consultation, if indeed they felt that was necessary:

I usually explain that sort of thing, because you know, I say they want the bloods just to see if there is anything wrong with you, to check whether your liver works, whether your kidneys work or all the rest of it. I did explain to him before we did it last time, and he didn't mind, you know. (FG2, BH, 197-200)

When asked if information was given prior to blood test procedures, some support workers commented that explanations were often not forthcoming:

- P *Generally (some murmuring yes!) it has been in my experience, yes.*
A *Not in my experience.*
S *No*

A *We have to dig for it. We will find out, but we're not told as a matter of course. (296-299)*

A *For an investigation – they don't say what they are investigating, or explain what the implications are. (FG1, 337-338)*

Some healthcare professionals considered that if information is provided, it should be appropriate and only sufficient for the patient to gain enough understanding to make the decision concerned:

I would also question how much of the information provided is necessary or understood (for example what is a "full blood count"). . . I think it is important to establish how much information is required to ascertain consent. (OBB, DD, 292-298)

The last quotation was in response to data I provided from my observation of participants with learning disabilities having a routine blood test in primary care. Healthcare professionals among the key informants also expressed the need for clear information to be given to patients, and for that information to be given in a suitable way:

Yeah, it's giving them the information and advice, we take them on the tours so that they can see, you know, what is actually used in the process of the screening, and then after they have had that information, and they have digested it, and they have taken leaflets away, if they then want to pursue the screening process, then they get in contact with me or the service, and then we support them. (KI, DD, 37-41)

Having considered information and knowledge, I will now describe the findings from the next theme I identified. This was the consent process itself, of which the provision of appropriate information is an essential part.

7.2.4 Consent and capacity

This section of Chapter 7 needs to be read in the context of the Mental Capacity Act (Department of Health, 2005c), implemented in 2007. This Act is described in detail in Chapter 4, but to recap, it concerns decision-making for those who

are unlikely to be able to make decisions for themselves. It is stated quite clearly in the Act that people should be assumed to have capacity to make a decision unless proven otherwise. There is a two-stage test that establishes whether there needs to be test of a person's capacity. If a person is assessed as not having capacity to make a decision, then a decision is made in the person's 'best interest' by a group of people who know that person best. Although my research has involved participants with learning disabilities, they have been able to participate in this research because they were judged as having capacity to make that decision for themselves. The decision I am considering in this study is consent to a routine blood test and consent to a new kind of blood test, a pharmacogenomic blood test. Mental capacity is always specific to a time and decision, and should not be applied to an individual as a 'blanket' judgement.

In the previous section, the importance of giving appropriate information to facilitate informed consent was explained. In this section, I will be considering the nature of consent to a health intervention, in particular a blood test and how it is viewed by carers and healthcare professionals.

The sub-themes were 'assessment of capacity', 'facilitating informed consent', 'best interest', 'barriers', 'seeking consent', 'expressing consent', and 'professionals' understanding of the Mental Capacity Act (2005)'. However, as with the previous themes, because there is much overlap, I will not consider them individually.

The knowledge that healthcare professionals and carers hold about the Mental Capacity Act (2005) appears to be inconsistent, with some healthcare professionals commenting that some of their peers or colleagues have

insufficient knowledge of the Act and others demonstrating their own knowledge of the Act:

I find that one of the challenges is ensuring that all of the professionals involved understand and assess capacity in the same way. There, unfortunately, appears to remain a residual 'paternalistic' approach, regardless of the Mental Capacity Act, which says that if a person is refusing treatment then they must lack capacity. (OBB, DD, 150-153)

This inconsistency was confirmed by one of the key informants:

I have heard mixed reports. I have heard some stories of health staff clearly having taken on board the Act and thinking hard about how they can help someone to get all the information they need in the way that they want it, and make their own decision. Equally, I have heard of health staff making assumptions that somebody doesn't have capacity, and that they will just make decisions for them. (KI, AA, 43-48)

It appears that sometimes 'best interest' decisions are made when in fact the patient had the capacity to make the decision:

... without any information as to why, what the vaccination was for and side effects – 5 minutes would have covered this and enabled that lady to take some ownership of her health care and decision making without relying on the nurse doing something for her that was in her interests but inadvertently preventing her from making an informed decision. (OBB, GG, 92-97)

The following quotation from a healthcare professional illustrates the complexities of the consent process under the Mental Capacity Act and the problems that can arise:

The mums had become court appointed deputies and were very cross because they were finding health professionals still insisting on going through a best interest procedure. That was an interesting one, and I was saying to them that if the health professionals were doing it um just because they didn't understand what a court appointed deputy was, and the power that you have as a deputy, to stand for the person, that was one thing. If I was a deputy, um, I thought that there might be occasions where I would find it helpful and comforting to go through a best interest procedure/process in order to reassure ME that I was um making the best possible decision. (KI, AA, 56-64)

Knowledge of mental capacity and consent law should evolve in time; there is a policy that healthcare professionals and social care staff should receive training on the Mental Capacity Act (2005), and it appears that this is slowly starting to influence the way these people communicate with both patients and the people who care for them. Following some discussion about the Mental Capacity Act, one family carer explained that his son's dentist had a suggestion to make:

His dentist, challenged us with the fact that, should we be making the decision for P to have any work. She is quite happy, cos we do a 6-month check up with him, and she is quite happy to do that, but she said if we came to an extraction or something, then who makes that decision? And she suggested that we should look at lasting power of attorney. (FG2, R, 394-399)

Another described a recent experience she had with her brother:

I am sure you have come across this R (addressing other participant) when you go with P to the doctor, and these days the doctor will try and ignore your presence and try and talk directly to P... the pressure is on them to try and deal directly, but learning disability I believe should always have support with them. (FG2, 818-832)

It should be noted that in the family carers' group, there was consensus that healthcare decisions were devolved to the carer:

P is like a 3-year old, so in the same way you would treat a 3 year old, you treat him. You accompany him, you make the decision for him, he isn't cognitively able to do that AT ALL. He wouldn't know, he thinks going to the hospital is a trip out (FG2, L, 336-339)

It's assumed, it's assumed that I make decisions (FG2, L, 358-362)

One of the participants was trying to clarify what my research was really about, and in doing so, clearly expressed his assumption that he, as carer, was responsible for making decisions for his son, and this was reinforced by other participants:

R And who gives that consent? That's what you, that's what the consideration has to be

- Mm, yes**
R *Whereas around the table here, we are going to give that consent*
J *Of course (FG2, 632-636)*

When considering the decision-making of a person with learning disabilities in the healthcare context, each individual has different experience of the healthcare system and a different medical history. It appears that healthcare professionals consider that a person's health experience will have an influence on their ability to give consent:

Experience is usually a good indicator of someone's ability to give consent, particularly around things like giving blood. (OBB, DD, 231-232)

I posted some quotations from Phase 2 (Observation) onto the online bulletin board for comment by the healthcare professionals, and their replies indicated that a patient's experience or lack of it could influence the consent process:

Again are they happy to give 'consent' as they have had blood taken regularly in the past and it is a 'normal' occurrence for them? (OBB, GG, 314-315)

Healthcare professionals identified what they considered as problems and challenges when assessing capacity to make a decision or obtaining informed consent:

It is often difficult to be sure that the Patient has understood and able to understand. To be sure that you as a health care professional have gained the appropriate consent. Sometimes I feel that a patient might have just put their trust in your judgement to do what is right for them as a health care professional and give consent by just putting out their arm to draw blood from them but not really understanding why. (OBB, II, 132-137)

Healthcare professionals working in secondary care reinforced some of the above points, for example:

So, I think for GPs, they are only ever going to have a few people with learning disabilities.... it takes a little while to judge – well, how much

does this person understand, in the context of a GP consultation realistically they haven't got much time to make that decision. (KI, CC, 196-202)

The fact that GPs are unlikely to see many people with learning disabilities is also mentioned by another healthcare professional when talking about assessment of capacity:

I think the training for learning disability awareness is very different from general practitioners training, and they are used to dealing with people that have capacity, so when someone is presenting that lacks capacity, then it presents a whole new ball game for them, because they don't really know. They don't see it enough to know how to deal with it. So it is raising awareness more than anything else. (KI, BB, 67-72)

One of the participants put the assessment of capacity in simple terms:

And that's how you need to treat that person – as an individual, so you and I, if we go into the opticians, I could understand it. Right, OK, these glasses are just for reading. But it's down to the skills of the people that are actually doing the examinations, in any profession, you know, whether they can ascertain what is the capacity of this person that I'm actually, that I've got sat in front of me? (KI, DD, 450-454)

Having illustrated some of the challenges, it is important to consider how carers and healthcare professionals feel they can facilitate the informed consent process. Some were very clear about the way forward, for example:

I think that the challenge is how we go about ensuring that the patient with a learning disability is provided with accessible information and time to help them understand as much as they can so that the consent that they give is as informed on their part as possible. I don't think we need to supply in depth descriptions or reasons but to make sure the information delivered to them is coherent to them. (OBB, GG, 319-324)

It is clear from the above quotations that obtaining valid consent from a person with learning disabilities can involve time and effort, and the following quotations reinforce what others have said about the value of teamwork:

...with a good MDT⁴ working together with the service user, and with the appropriate amount of planning and preparation I think we can support a wider range of service users to give or withdraw consent. (OBB, DD, 159-162)

In a way, it's about trying to explain it to the service-user, but then everybody working together. (KI, EE, 24-26)

The Mental Capacity Act Code of Conduct (Ministry of Justice, 2007) states that people should receive 'sufficient' information to enable them to make a decision. One of the healthcare professionals related this to a blood test decision:

And I suppose the amount of explanation that people are given varies as well and um if it's a thing like a blood test, yeah, I think, I suspect the reason for the blood test, the explanation of the reason for the blood test, is probably quite broad – so "We need to find out whatever". Um, and "that might mean we can give you some medicine to make you feel better" or something like that. So it's quite a broad explanation rather than going into the specifics. (KI, CC, 65-71)

Despite the best efforts of healthcare staff or a multi-disciplinary team, informed consent will not always be feasible. According to one healthcare professional:

It does depend on the level of disability and the choice to be made (KI, CC, 148)

The idea of a 'middle group' of people who fall between those who are unlikely to ever be able to consent despite the best efforts of all concerned and those who will be able to understand information given in the right quantity and at an appropriate level, was discussed:

So, there are some people for whom it doesn't matter how you give the information, they wouldn't understand it. Um, but then at the opposite end, I guess there are people who can understand most of the information provided you don't give too much at a time. And then you've got people in the middle, and those are the people I suppose that myself and my colleagues, we often get quite frustrated in that not necessarily every effort is made to help the person understand. (KI, CC, 157-163)

⁴ Multi-disciplinary team

In summary, I have illustrated in this section how inconsistencies both in the knowledge of the MCA (2005) and in attitudes of staff working with people with learning disabilities can influence whether or not these people make their own choices in the health context. Variation in factors such as time available, resources, communication skills, experience in dealing with this 'client group' have all been shown to affect the level of consent gained. In the next section, I will be describing the personal qualities of the people with learning disabilities, as seen through the eyes of people who work with them or care for them. This will include aspects of their behaviour, their abilities and their perceived limitations.

7.2.5 *The person with a learning disability*

Having described some of the behaviours which people with learning disabilities demonstrated in both the observation phase and also when being interviewed, I would now like to include comments from carers and healthcare professionals, which confirm the findings from earlier phases.

The characteristics that have been apparent throughout this study are those of acquiescence and passivity, and this is expressed in different ways. Family carers said:

VH I don't think B would ask

No

BH No, I don't think he would. He would just say, "Well, that's it." You know, you say, you know – he'd completely trust 'em. (FG2, 241-244)

There is also the tendency to want to give the desired response, or in other words, to please the other person:

J *and it is not clear to him very often whether he is saying what he conceives to be the right thing or not. He is very biddable, he is very anxious to please. If he believes that he can understand what the person would like him to say, that's what he'll say. (FG2, 102-105)*

Healthcare professionals described their experiences of this acquiescence and some attributed it to the power imbalance:

I agree that it can be very difficult to assess someone's level of consent, particularly with the passive nature of many people with learning disabilities who have been encouraged to go along with the suggestions of people in 'power'. (OBB, DD, 226-228)

I think at times it can be very easy to get consent from someone with a learning disability as the power is usually with the person with the knowledge and the equipment. I think that deference to the medical and nursing profession as well as carers etc can ensure that consent is obtained. (OBB, GG, 316-319)

When I asked about the challenges in obtaining informed consent:

.....Deference and acquiescence on the part of the person with a learning disability who may consent immediately with very little/no information being provided to them. (OBB, GG, 184-185)

One healthcare professional, talking about patients in general, rather than just people with learning disabilities, described the attitude of some patients:

the difficulty we have is that when patients come to hospital, um, they expect to be told what's going to happen to them. I mean, in good medicine, there usually is a dialogue, but there is still a paternalistic approach. (KI, FF, 222-225)

Having described the level of acquiescence displayed by people with learning disabilities, I will go on to consider some of their personal qualities, abilities and limitations. Acquiescence is a personal quality or behavioural characteristic that is described by those who care for people with learning disabilities, and a quality which has been illustrated to me while both observing and interviewing my participants. However, I identified other sub-themes discussed by both

carers and healthcare professionals, such as 'how people with learning disabilities like to be treated', 'decision-making', together with other topics such as the abilities of the person cared for, and their qualities as seen by others. Some of these have already been described in Chapters 5 and 6.

When I interviewed participants with learning disabilities, they provided me with many examples of how they liked to be treated, of how independent they considered themselves and what help they sometimes needed in terms of support. In this section, I will describe these issues from the point of view of people caring for, or treating people with learning disabilities.

When talking to family carers, it was apparent to me that there are many assumptions made by those closest to people with learning disabilities. There are inconsistencies in their judgements; there is praise and even pride in their family members, but alongside this there is an acknowledgement of their limitations. Firstly, there is praise for their personal qualities and abilities:

But, you know he doesn't, uh, he will now do dishes and make tea, and the look on his face when he has made tea for you is terrific, you know – he lights up...."I've done the dishes, Dad" (FG2, BH, 25-29)

...but we fought through all sorts of things and he is now a really entertaining character. (FG2, R, 20-21)

Then, acknowledgement of their lack of ability in certain areas:

He needs care and supervision constantly, but he does sleep at night, and he is unable to do his personal care without supervision. (FG2, R, 35-37)

you know, he can't actually dress himself, he is not classifiable in any way, he is not Downs, he is not autistic, he is, you know – so all those things. (FG2, J, 85-87)

I have previously shown evidence of family carers' assumptions about the capacity of the person for whom they care. For example, they assume that it is

their (the carer's) role to make decisions or give consent. In contrast to this, however, in one case there was some acknowledgement that the person they care for may be capable of making choices:

- BH ... He's getting better at this sort of thing. It's surprising what he comes out with sometimes. He knows more than you think he knows... And sometimes, it's humour he comes out with and it's very very good.*
- VH He is getting more independent, I think. Um, I mean he will sort of, if we are going out and he doesn't want to go, he would say, "Oh no, I'll stay at home today", which he never used to. So, he's making his own choices.*
- VH He's making choices, yeah. (FG2, 396-405)*

When I probed a bit further into the issue of capacity, or the ability to make decisions, and asked how easy it was to allow the person with learning disabilities to make their own decisions in some situations, the answers in this case were quite illuminating:

- VH Quite difficult really.*
- ...*
- VH I mean, I can't think of any examples of where he has actually done anything off his own initiative.*
- BH No, he needs encouragement from us [all the time]*
- VH [Yeah]*
- BH To do things*
- VH But whether that's our fault, cos we are always around to do it*
- BH Could well be (151-159)*
- ...*
- BH I always believe in everybody making their own decisions if they can, and as long as he makes the right one, then, you know. (FG2, 134-135)*

Another family carer expressed the problems that may arise when asking a person with learning disabilities to make their own choices:

He understands being asked to decide between 2 things – do you want to go out, do you not want to go out, but this phrase, and it is a phrase "It's your choice, E, what you want to do" – it can't be answered by him without prompting, without additional language being used to understand exactly what someone is trying to ascertain, and it is not clear to him very often whether he is saying what he conceives to be the right thing or not

... He also suffers from something called, I think it's echolasia⁵, where if you ask him, if you give him a choice of 2 things, he will almost invariably choose the second one of the choice, the last one he has heard. (FG2, J, 97-109)

The personal characteristics mentioned earlier in this chapter, and in the last participant's comments, those of acquiescence and passivity together with a wish to please others, led me to consider to what extent people with learning disabilities differ from the general population. Each group consists of individuals who vary a great deal in their ability and I began to question the degree of difference.

7.2.6 *How different is a person with a learning disability?*

I have previously discussed the person with learning disabilities in the health context, the role of the supporter, the information they require to make decisions and also considered the issues of capacity relevant to the consent process. During data collection, I became aware of many statements and comments that could equally have been applied to any member of the general population. I would therefore like to give some views expressed by carers and healthcare professionals which illustrate this.

When discussing the fact that patients who are regular attenders may well not be asked for their consent, as they are familiar with the tests being conducted:

And a lot of those faults in the process and the approach and so on would apply probably to a lot of people not just people with learning disabilities (K1, AA, 228-229)

Several participants also felt that there were other areas in which some people with learning disabilities did not differ from people without learning disabilities:

⁵ Probably means echolalia

I know so many younger people who wouldn't question, and would say, "Oh well, you know, if the doctor says it, that must be right" and wouldn't feel able to confident to question or speak up... and I think sometimes in the learning disability world we've not done ourselves any favours by making out that people with learning disabilities are a special case. (KI, AA, 268-273)

Whoever they are – whether they have got a learning disability, mental health problem, elderly dementia, whoever they are, that person then should have extra support to understand that communication process and what's been happening to them, so regardless of whether they've got a learning disability or not. (KI, BB, 337-345)

The next theme is choice and decision-making and how these processes may be compromised in people with learning disabilities.

7.2.7 Choice and decision-making

Government policy in the UK in recent years has stressed the importance of person-centred care. White papers such as 'Valuing People' (Department of Health, 2001d), 'Valuing People Now' (Department of Health, 2009c) and 'Independence, choice and risk' (Department of Health, 2007c) have made the empowerment of people with learning disabilities an issue to be considered by all those working in this field. Data from this phase of the study has illustrated that this is not always a straightforward process. The influence of 'others' could emanate from parents, siblings, support workers or healthcare professionals.

Support workers had the following comments to make:

- P Well, parents can also have an influence, can't they?
... It can be worse at times, can't it, when – especially the older generation have very set ideas on certain things, and they may say "Oh no, don't go and have that", you know, without giving them the choice or allowing them to make that choice, or influencing them. If they say "Don't do that, it's not good", they will probably listen to their parents.*
- C They do, from my experience. Certain parents have a lot of influence, and say "You don't want that, do you" and the person goes "No, I don't want that", or "You want that, don't ya"
(laughter) (FG1, 629-69)*

One parent, acknowledging that their child might understand, still stressed the parental role:

BH Yes, I think he would be able to understand. He would have to be, he would rely on us to say it was alright, though. You know, he would be nervous probably.

Mm

BH But if we said it was alright, that would be it, wouldn't it? (FG2, 71-75)

Family carers may have had years of assuming the role of decision-maker for the people they care for. Healthcare professionals also concede that it is not easy for carers or healthcare professionals to remain 'neutral' when assisting someone in making an informed decision:

Yeah, and I think, it's a fair point that carers aren't particularly given training to help people make choices, and quite a lot of people that I've been aware of, um, it's kind of a natural tendency, I suppose, you stress the benefits of the option, but if it's something you want the person to have, and you think it would be good, you stress the benefits, you don't say so much about the risks of the (KI, CC, 336-341)

You know, it's only your own self-insight that enables you to make a choice. Some people can live very secluded lives, you know, they are doing that. They might NOT know that there are choices out there. It's really difficult not to impose your feelings onto other people, because it's only the experiences that we have had in our lifetimes that make OUR choices what they are. (KI, BB, 294-298)

One of the support workers mentioned the changes that have occurred since supported living has been introduced. Supported living is a strategy originating in the United States that gathered momentum in the UK in the 1990's. It is first formally mentioned in legislation in Valuing People (Department of Health, 2001d). People living in 'supported living' accommodation have appropriate support to make their own choices, the goal being to achieve their potential in terms of independent living. This change has not been an easy transition for some:

Yeah, I think some of the service users aren't really aware of the change. They see things happening around them and as much as we might try to make people aware of what the changes mean, um, for them, and what it means to us, and what it means legally as well, some people just aren't interested, they want things to stay the same. (FG1, A, 260-264)

This topic is also mentioned by one of the key informants:

Um, I suppose it goes back to what support, what type of support they had within the residential setting. Do you know what I mean, there are some good companies out there that choice is given to each individual, but there are some archaic ones that obviously, do you know what I mean, it's just not thought about...choice and individuality isn't thought about. (KI, DD, 309-313)

There is one more sub-theme which relates to 'choice and decision-making', but which I feel merits a separate section.

7.2.8 *Being a carer*

At this point, I should like to introduce a theme which is naturally related to several others – that of 'being a carer'. This theme was present mainly in the family carers' group, but the issue was also raised by two healthcare professionals. I believe it is useful to discuss it now, as it can impact on the consent process. As stated earlier, the family carers in this study felt very responsible for ensuring the safety of the people they care for, for making decisions on their behalf, and for ensuring that they received the treatment they deserved. There was also a feeling that they are the right people to provide this support:

The more support anybody with LD gets, the better they are, and that is the problem these days. Unless WE were there, I don't think B would get very much support, and that is the problem. It's employing the people to do it and uh getting those people to be really enthusiastic about their job and not just walk around doing very little. (FG2, BH, 346-350)

Family carers appear to make certain assumptions about the abilities of the person they care for, and this may affect the extent to which they are permitted to make their own choices:

- L *Um so there are many um situations that these people find themselves in, and the only, as far as I am concerned, the only person that speaks for them is.... You speak for your son, I speak for Pa, and you speak for your brother, and if something happens to them, I know I've got three sons who understand him and have been brought up with him. Um, so he's got another [network]*
- J *[support network] yeah.*
- L *But we've created that, and I think we are the only ones who really care (FG2, 1065-1072)*

At one point, the family carers were almost speaking with one voice, when discussing the limitations of their relatives and making certain assumptions, and this is summed up by J:

And I would debate whether anyone with LD can rationalise, can differentiate, can understand consequential things. You know, they can't, they can't. We are never going to completely generalise but we are all very defensive people about what's going on by the sound of things already, and it is so frustrating... (FG2, 734-750)

The findings so far from this phase of the study have provided information about capacity and consent, information requirements and people's attitudes and experiences in the health context. Finally, I will outline the final theme of pharmacogenomics – which includes knowledge of genetics and of pharmacogenomic testing; it also illustrates the views of carers and healthcare professionals on this new area of genetics, together with their opinions on how it should be offered to people with learning disabilities in the context of concerns about capacity and consent.

7.2.9 **Genetics and pharmacogenomic testing**

No participant from either of the carers' groups had heard of pharmacogenomic testing. Having been given a simple explanation of the purpose of this type of testing, it appeared to me that the assumption was that if they understood what the test was for, they would make the decision. One participant felt that she would be able to explain this to her relative in simple terms:

Why are we worrying about it, because it is so obviously going to help them, it's so obviously going to be beneficial for them to have this test, and I have thought since looking at this, of ways that I would explain it to my brother. And thought of things that I would use to explain it, like you know, that everybody in our family likes liquorice, don't they, and everybody in our family likes music, and everybody in our family, or most people in our family are artistic, and explaining to him that when you are all related, you have things that are the same. (FG2, J, 609-612)

Others simply felt that if they understood the test, and felt it would be beneficial to the person, then they (the carer) would make that decision in the person's 'best interests':

R *Whereas around the table here, we are going to give that consent*
J *Of course*
R *You know, and [that's the issue]*
J *Of course, and I don't have any doubt that if we could explain it very fully to them, but I think in terms of explaining it in terms of genes and genetics and da di da, certainly in our cases, you know, it wouldn't work going along that line, but there ARE methods of simplifying the technology of genetics*
R *[This is where I]*
J *[I mean they have a level of understanding]*
R *[This is where I now] say, you know, why do we need to be able to do [all these things], when we have the [best interests]*
L *[Exactly]*
J *[Best interests]*
R *Of the individual concerned and [we should make those choices, make those decisions] (FG2, 635-650)*

It would appear from the above extract that, as outlined earlier in this chapter, some family carers assume that it is their duty to make a decision because they

have that person's best interests at heart. Furthermore, the dialogue illustrated how a carer can influence outcomes:

- J *It's so frustrating, all that sort of stuff, but you know, at a point of sense, this test can only help anybody and I think one of the first things you, or doctors, or anybody should convey to a person with LD is "This is something that's going to [help you]*
- R *["Its good, is good"]*
Mm
- J *If you pre-empt any conversation with that, with one of these two, you know I was talking about choices, having a right or wrong. If you pre-empt anything with a positive statement, "This is going to help you" then – and I don't think that is being biased because it is, [it's gonna help anybody in the world] (FG2, 687-697)*

Similarly, paid workers felt that if a blood test was going to be beneficial to a patient, regardless of whether it was a pharmacogenomic test or any kind of routine screening or monitoring blood test, then they should encourage the patient to have the test. They also, having listened to my simple explanation, constructed ways of explaining the test to their service-users:

- C *If it's gonna benefit somebody, how you explain it, "If you have this blood test, they can tell which would be the best medication for you to take, and you might not have to take all the medication you are taking now, what do think of that?"*
- A *I think you have to have a positive approach.*
- C *Yeah. (FG1, 569-581)*

One participant said that when she read the participant information sheet she was 'indignant':

Well, my reaction when I read THIS (PIS), I got quite indignant, so I, you know, I think you just explained then, you know, to me when I first read it, I thought, "Well, they're gonna take a blood test to look at my genetic make-up, so they're gonna know just about everything about me, and I said, "No, I would never agree to that". You know, um, although it might benefit me in some way, I still don't, at the moment, I don't agree with it. But you're saying it's only a certain part.... (FG1, P, 516-522)

I then explained to her that this type of test would only be investigating one group of genes involving in drug metabolism, and that no other genetic information would be identified. Another participant said that he appreciated the benefits of the new type of test, but explained that initially he had reservations due to the connotations he associated with genetics, agreeing with the previous participant:

- A *Um, and if this test could reduce or tailor that cocktail, then I can see it as a good thing, but I feel the same way as you – as soon as people say “genes”, “testing genes”, (laughter)[then I think there is a sort of]*
- C *[You see I’m totally the opposite way]*
- A *Some paranoia about it, I think, yeah. (FG1, 555-560)*

This concern about other genetic information being identified and divulged to patients and their families was not just expressed by support workers, but also by some healthcare professionals. I had posted a comment on the bulletin board stating that a pharmacogenomic test would only be identifying variations in the group of genes responsible for drug metabolism (for example, cytochrome P450):

... it is difficult to ignore the wider implications of genetic testing. It might be difficult only to test people for the pharmacogenetic characteristics without coincidentally diagnosing or increasing the likelihood of other conditions. This could have both positive and negative effects. Early diagnosis or knowledge of say, diabetes may help prevent complications but early diagnosis of progressive untreatable conditions like Huntingdon’s could have a negative effect. Even if the test was purely drug related it might be difficult to reassure patient that this was the case. (OBB, JJ, 362-368)

The level of awareness or knowledge of pharmacogenomic testing ranged from none at all to a little in the healthcare professionals. For example:

I had heard of it and I recall a little information about it but I don’t know that much about it. (OBB, GG, 29-30)

There has been some information about this in the medical and popular press but little has yet filtered down into day to day general practice.(OBB, JJ, 39-40)

In the interviews with key informants, I was able to give a simple explanation of pharmacogenomics testing to those who had no knowledge of it. Again, there was concern from some participants about the level of genetic information that would be identified or divulged following this type of test, and this had to be explained:

Um, I suppose um I don't feel clear whether this test for this purpose would uncover information about their genetic make-up that might tell you other things about them. (KI, AA, 141-143)

...it's slightly different than someone turning up at the doctors and you've got some symptoms, so these are the symptoms, so this is OK why we are going to do some blood tests. Whereas this, you are just looking, sorry not just looking, into the genetics. I suppose you are also going to go into the family, so the family would also be consenting, wouldn't they?

[No]

[No?]

... The group of genes that are involved in drug metabolism – that test specifically looks at those, and wouldn't look at anything else. It wouldn't be a thing that would affect the family, [so]

[Right, right], I understand (KI, DD, 223-240)

One participant did have professional knowledge of pharmacogenomics:

... they will often say to us, um, are you testing for other things, because I think there is a perception among the general public that we have this all powerful, all seeing DNA test which will tell us about all sorts of things. Um, often, I suspect about paternity, which is why people get concerned – and looking for other genes. I always say, no, we are going to be specifically looking for this gene, and I guess in terms of a pharmacogenetics approach we could say that we are actually looking, that these are going to be targeted at particular genes in order to hopefully improve somebody's health, or you know, help them get over an episode of ill health. (KI, FF, 115-127)

Having considered the degree of knowledge and understanding of pharmacogenomics testing in the various participants, I would finally like to describe their attitudes on the topic. Although the consensus was that if there was evidence that the tests would be beneficial, they should be offered as part

of good practice, and in best interests if patients lacked capacity, some participants had reservations:

To a certain extent we already make assumptions about some genetic characteristics for example in the prescription of ACE inhibitors. There would be significant cost implications not only in terms of the test, the drug but also the time to test a patient, time taken to explain the test and allaying of fears that this might test for other conditions. Some of that cost may be balanced against fewer prescriptions of ineffective drugs. Only time would tell if this would be economic. (OBB, JJ, 354-360)

I think these are quite, at the moment, these are quite, uh, involved concepts and I guess in genetics we are very fortunate in the fact that we have time to explain things to patients in a way that your average GP or doctor in an outpatient clinic doesn't have. And so, my experience in general genetics is that often patients will come having had previous consultations with a health professional, who may not fully understand or hasn't had the time, um, and then you end up with a confused patient. (KI, FF, 128-140)

This participant had more to say about the level of genetic knowledge in healthcare professionals:

There obviously are some very clued up clinicians, um, but I think there is a general lack of understanding even about basic inheritance patterns. Um, and so that is worrying, and I think once you get into.... and I think then you know, you really are having to make up ground to try and let the patient know that actually you do have that knowledge, and giving them the right piece of information. (KI, FF, 146-157)

As stated earlier in this chapter, one of the main points which was illustrated from the data was that if a test was evidence-based and likely to be beneficial to a patient's health, then it should be offered:

I think if you are looking at genetic testing for people just to find out what is wrong with them, you know, there's an almost – "Well, why do we need to know?".... but if it's going to be beneficial to their health because it means they are taking less medication, or they are taking the appropriate medication that responds well to them, then, yeah, I personally wouldn't think that there is a problem with that. I think you could argue in the best interest, because you are looking at weighing up the benefits the outweighing the negatives. (KI, BB, 146-154)

I would like to end this chapter with a final comment from a social care manager, which expresses the attitude of many of the participants from this phase:

It doesn't matter whether they've got a learning disability or not, to be honest, Lesley, does it? If it's gonna benefit somebody then why shouldn't they have it, in a way?

No

And, you know, they should consent, you know

Yes

But they should be told why, that's the thing (KI, EE, 274-280)

7.3 The development of themes

Finally in this chapter I have included an updated table of themes (Table 9), indicating yet again the way themes have been identified with successive phases, using different methods and participants. It can be seen that some of details differ from those in earlier tables of themes; this is due to the iterative nature of thematic analysis and coding. Constant re-reading of the data with each successive findings chapter has clarified some of the themes and led me to re-organise others, whilst new themes have been identified and included.

Table 9 Themes and categories from Phase 2, 3 and 4

Theme	Sub-theme	Ph. 2	Ph. 3	Ph. 4
Patient in healthcare context	Attitude to having a blood test	✓	✓	
	Attitude of HCPs and staff		✓	✓
	Attitude of others (non-HCPs)			✓
	Feeling about going to the doctors		✓	
	Knowledge of healthcare system		✓	
	Relationship & communication between HCPs, support worker & participant	✓	✓	✓
	Equity of access			✓
	Health experience		✓	✓
	Role of supporter		✓	✓
Information and knowledge	Presentation of health information		✓	✓
	Knowledge of blood tests in general		✓	
	Purpose of blood test and procedure	✓	✓	
Consent	Assessment of capacity			✓
	Seeking consent	✓		✓
	Expressing consent	✓		✓
	Best interest			✓
	Professional knowledge & understanding of MCA (2005)			✓
	Facilitating informed consent			✓
	Barriers to obtaining informed consent			✓
	The knowledge of the assessor/decision-maker			✓
Behavioural	Anxiety	✓	✓	
	Acquiescence		✓	✓
	Bravado	✓	✓	
	Fear	✓	✓	
	Pain	✓		
	Relief	✓		
	Resistance	✓		
Strategies/ coping mechanisms	Distraction tactics	✓		
	Establishing rapport	✓		
	Reassurance	✓		
	Use of humour or teasing	✓		
The self	Self-determination		✓	✓
	How I would like to be treated		✓	✓
	Identity		✓	
	Self-image		✓	
	Abilities of person cared for			✓
	Personal qualities of person cared for			✓
	Visibility of learning disability		✓	✓
Being a carer	Being a carer			✓
	Carers' assumptions			✓
	Feeling of identity with other carers			✓
Genetics and pharmacogenomic testing	Are genetic tests different?		✓	✓
	Attitude to having a new kind of blood test		✓	
	Attitude to pharmacogenomics testing			✓
	Lay knowledge of genetics		✓	✓
	Professional knowledge of pharmacogenomics			✓
	Understanding of my explanation of pharmacogenomics		✓	✓
Miscellaneous codes	Transition of care status			✓
	How different are people with LD?			✓
	The spectrum of learning disability			✓

Key:

Phase 2 – Observation

Phase 3 – Interviews

Phase 4 – Focus groups, online bulletin board and key informant interviews

In this chapter, I have described the findings from focus groups of family carers and paid carers, an online bulletin board for healthcare professionals and key interviews with people working in the field of learning disability or genetics.

In the next chapter, I will summarise and discuss the findings from all the phases of the study, including the integrative review of the literature and how they relate to each other. I will then relate these findings to relevant theories.

Chapter Eight

Discussion

8.1 Introduction

In previous chapters, I have described findings from the successive phases of this study, commencing with an integrative review of the literature on informed consent to healthcare interventions in people with learning disabilities (Chapter 2). In this review, I identified various factors that could influence the outcome of the consent process in the health context. These included professional attitudes to informed consent and how information is presented to people with learning disabilities. I also discussed the topics of consent and capacity, together with the functional approach to assessing mental capacity, which has now been encapsulated in the Mental Capacity Act (2005c, p 58). I concluded from this review that it would be useful to conduct research into informed consent in people with learning disabilities using a 'real-life' situation rather than vignettes.

In Chapter 5, I described the findings from the observation phase of the study – observing people with learning disabilities having a routine blood test in general practice; the focus of this phase was the consent process and the way it was approached. In Chapter 6 the themes identified from interviewing people with learning disabilities were outlined, and I was able to build on the themes identified from the observation phase as well as to identify new themes. Findings from the final phase are included in Chapter 7, in which I describe themes identified from various focus group and interview data collected from carers, healthcare professionals and key informants. Throughout these

chapters, I have briefly related the emerging themes to those identified from the literature. In this chapter I will synthesise the themes from all phases to produce a rich description of the process of gaining consent from people with learning disabilities, focusing on the factors that may influence this process. I will then re-introduce the theories I described in Chapter 1 and discuss their relevance to the findings of this study. Firstly, however, it is important to relate these findings to the original research questions and the aims and objectives of the study.

8.2 The research questions revisited

As stated at the beginning of Chapter 3, the aims of this study were to explore the information needs of people with learning disabilities, with particular reference to pharmacogenomic testing. A second aim was to identify ways of facilitating informed consent. To achieve this, the objectives were to:

- Examine the ways in which obtaining consent (from people with learning disabilities) for screening blood tests is currently achieved
- Assess the attitudes of healthcare professionals and carers towards the provision of pharmacogenomic testing for people with learning disabilities
- Assess the potential understanding of and attitude to pharmacogenomic testing in people with learning disabilities
- Make recommendations to ensure appropriate practice in obtaining informed consent for pharmacogenomic testing from people with learning disabilities.

By conducting an ethnographic study using four different data collection methods, I set out to answer the following research questions:

1. What is the current practice in obtaining consent for a blood test in people with learning disabilities?
2. What are the attitudes of healthcare professionals and carers to offering pharmacogenomic tests to people with learning disabilities?
3. What information would people with learning disabilities wish to have when making a decision about having a pharmacogenomic test, and does this differ from blood tests for other purposes?

As I progressed through the study, I became increasingly aware of my own prejudices and attitudes with regard to both people with learning disabilities and people working in the health and social care services. My own background, both as someone who has worked in general practice as a manager, and also as the mother of a son aged 29 with Down syndrome caused me to reflect constantly on my role as researcher, the researcher effect and the ethical issues involved in conducting research with people with learning disabilities and their families. I will enlarge on this when appropriate in this chapter, referring to reflexive notes I made throughout the course of the study.

Having re-stated the research questions, I will now discuss each one in turn, in relation to the major themes identified during the course of this study that may help to answer them. It has become apparent to me that in the course of attempting to answer these research questions, my familiarisation with the data has revealed much about the lives of both people with learning disabilities and the people who care for them in their everyday lives, and those who are responsible for their health care. After discussing the research questions, therefore, I will elaborate on some of the findings which have emerged from the study which, although not directly answering the research questions, may have

relevance to the care of people with learning disabilities and help to inform healthcare professionals and policy makers.

8.3 Current practice in obtaining consent for a blood test in people with learning disabilities

Six participants were observed having a blood test in general practice; two of whom attended with support. The elements of valid consent are voluntariness, disclosure of information and capacity. In practice, this means that a patient should be given sufficient information about the decision to be made, in a format which they will understand; they should have the capacity to make that decision (consent to the procedure) and they should give that consent voluntarily without coercion (Grisso & Appelbaum, 1998): this would include family as well as the health professionals involved. The first thing to note is that the consent process was not fully followed in any of the six consultations I observed in Phase 2, but there may be valid reasons for this, which I will discuss later in more detail.

In the integrative review of the literature I found evidence of personal qualities and experiences that influence the consent process. Factors such as a person's place of residence (for example, see Dean, Turner & Cash, 1998; Fisher *et al.*, 2006), their previous health experience (Cea & Fisher, 2003) and opportunities to make their own life choices (Arscott, Dagnan & Kroese, 1999) all contribute to the individual's likelihood to be able to give informed consent to healthcare interventions.

It is difficult to say if these findings were confirmed during observations of blood test consultations; the consent process was inadequate – either there was little or no provision of information, or consent was not sought or expressed explicitly. However, there were a few examples of good practice in which

nurses gave appropriate information, tailored to the ability of the participant and checked basic understanding prior to proceeding. Some of the participants certainly had previous health experience and were regular attenders at the surgery; several had chronic diseases such as diabetes or hypothyroidism. This may have been the reason for the lack of information given, with the nurses assuming a pre-existing level of knowledge about the blood test being requested. It is also possible that the person taking the blood made the assumption that information relating to the blood test had been given by the person requesting the blood test. These assumptions would not be sufficient to fulfil the requirements of the Mental Capacity Act (2005), as it is the responsibility of the person carrying out the procedure to ensure that valid consent is in place, and this would include provision of relevant information. Consent is specific to the time of the procedure. This is particularly important in the case of people with learning disabilities, who may not have the cognitive ability to retain information given previously. Information given, if any, was brief and I did not observe any attempts to confirm that there was understanding. In the majority of cases, patients were simply asked if it was 'okay' to take blood. These findings reinforce those from the literature, which describe the effect that a healthcare practitioner's attitude can have on whether or not valid consent is obtained (Carlson, 2004; Haw & Stubbs, 2005)

Most of the participants were in supported living accommodation, either living alone or sharing with others, and had a limited amount of support. These participants attended the surgery unaccompanied and travelled independently – thus having the opportunity to make some of their own decisions. There is evidence to show that the ability to exercise self-determination is influenced by

"one's living, working and educational environments and the actions of significant others in these environments" (Stancliffe, 2001, p 96). Although the focus of this study is on informed consent, this is not unrelated to the concepts of decision-making, autonomy and empowerment, which are thought to contribute to the multi-dimensional concept of choice (Stalker & Harris, 1998). Those authors state that choice-making is inhibited by several factors, one of which is the beliefs and attitudes of staff. Acquiescence was identified in the integrative review as a factor affecting the consent process and research has shown a higher level of acquiescence in people with learning disabilities (Clare & Gudjonsson, 1993; Heal & Sigelman, 1995). It was present to a certain extent in the interview data when participants talked about allowing doctors to make decisions for them, and certainly reinforced when talking to key informants. The possibility of limited opportunity to make choices, combined with a certain level of acquiescence is likely to have an effect on the ability of a person with learning disabilities to give consent – *if they are offered the opportunity.*

In each observation I was aware of the rapport that existed between patient and healthcare professional; the patients in some cases were well known to the healthcare team, and from the interview data it was also apparent that the healthcare team had the trust of the patients. Despite the fact that the consent obtained in some cases could not be considered as fully informed, the patients were clearly assenting to the procedure, and although some made it obvious that they did not like the needle, or found it painful, they complied and appeared to accept the blood test as a necessary part of the health care they were being offered. During the procedure, the healthcare staff made every effort to ensure

the comfort of the patient and minimise any anxiety. Although in some cases, detailed information was not forthcoming, there was sometimes an explanation afterwards of why the blood was taken, what the results could mean, and the importance of attending subsequent appointments.

The code of practice for The Mental Capacity Act (2005) states that "every adult has the right to make their own decisions if they have the capacity to do so" (Ministry of Justice, 2007, p19). This is interesting when applied to the interview finding that many people with learning disabilities do not wish to have information about a blood test, but are happy to allow the healthcare professional to make the decision for them. Does this constitute autonomy, and are they therefore within their rights to decline information (or simply assent when it is not given)? It is useful here to refer to two documents which provide guidance to help healthcare professionals in shared decision making. 'Consent: patients and doctors making decisions together', published by the General Medical Council (2008) includes guidelines on how doctors should approach the consent process if the patient declines information:

"If a patient insists that they do not want even this basic information, you must explain the potential consequences of them not having it, particularly if it might mean that their consent is not valid" (p 12).

This would imply that if a person with learning disability has capacity, but declines information, consent may not be valid, because only two of the three requirements for valid consent would be present. The same document states that patients can give implied consent by complying with the proposed treatment or investigation, but this has to be subsequent to provision of information. It also states that how much information is shared with a patient will vary, and that the approach should be tailored to the patients 'needs, wishes

and priorities', to the 'complexity of the condition' and to the 'nature and level of risk associated with the investigation or treatment.'(p 9-10). Considering the lack of information provided in the majority of the consultations I observed, I would consider that this advice is open to interpretation; it is possible that a routine blood test is considered to be a very simple, low risk procedure and that, coupled with the patient's lack of desire to have information, explains what I would consider to be a lack of valid consent. It is also possible, of course, that there is limited knowledge of these guidelines.

Secondly, the code of practice for the Mental Capacity Act (Ministry of Justice, 2007), when considering what information should be considered as relevant to a decision, advises:

'Try not to give more detail than the person needs – this might confuse them. In some cases, a simple, broad explanation will be enough. But it must not miss out important information.' (p 28)

These findings raised the following questions:

1. How different would this process be in a person without a learning disability?
2. Considering the Mental Health Act Code of Practice (Ministry of Justice, 2007), what level of information is 'sufficient' for purpose for a routine blood test?

Participants who were interviewed had some pertinent comments to make about communication with healthcare professionals – that they often found it difficult to understand information given to them due to the complex terminology used, and often had to rely on support of some kind to interpret this information. They asked for simple, short words with no use of jargon. This was reinforced

when talking to carers, both paid and family carers. Research conducted in the field of learning disability has shown that communication between general practice staff and people with communication disabilities of any kind is problematic, with patients listing better GP staff communication skills as a priority (Murphy, 2006; Jones *et al*, 2008). It is also acknowledged that there is a 'health literacy gap' between physicians and patients, with patients' understanding being improved with slower speech, simpler words and a limited amount of information (Safeer & Keenan, 2005). A report produced for the Institute of Medicine in the US on health literacy stated that most people, even those who are well educated, will encounter health information they cannot understand, and stressed the importance of making information accessible (Institute of Medicine, 2004).

One of the main elements of supporting a person with learning disabilities was 'interpreting' information and ensuring that it was understood. Paid carers also felt it was important for the healthcare professional to address the person with learning disabilities, rather than the carer. Lack of experience in communicating with this group of patients, lack of time or lack of knowledge of the Mental Capacity Act were all put forward as possible reasons for this not happening. It is difficult to know why the majority of people with learning disabilities I interviewed were not concerned about receiving information prior to a blood test. This may have simply been due to the fact that they were not aware of their right to information, or even their right to give consent. There is evidence to show that self-determination in people with learning disabilities is associated with factors such as intelligence, environment, social abilities and the opportunity to make choices (Nota *et al.*, 2007). Re-visiting the interview data, it

is interesting to note that the majority of participants with learning disabilities who said that they would require information for a new type of blood test were members of a self-advocacy group. In a study in accident and emergency departments, some nurses made the assumption that consent was implied by the patient's presence in the department; other nurses in the same study, who were aware of the need for valid consent admitted difficulty in communicating information to people with learning disabilities (Sowney & Barr, 2007). It is possible that practice nurses or healthcare assistants might exhibit similar lack of knowledge or difficulties in communication. At several points in the study (while collecting and analysing data), I reflected on the fact that I did not consider the findings would be essentially different using a research population without learning disabilities. I will come back to this important point later in this chapter.

I would like to make a distinction here between the views of the paid carers and those of family carers. Paid carers had knowledge of the Mental Capacity Act (2005) as they had received compulsory training; parents did not appear to have a similar level of knowledge or simply did not acknowledge the rights of the person with learning disabilities to make their own choices. One parent acknowledged that it was difficult to allow her son to make his own decisions and questioned her role in the development of his independence. It is difficult to come to a clear conclusion here, as every person with a learning disability is unique in terms of their cognitive and communication abilities. Even within the 'mild to moderate learning disability' group there is wide variation, with some people travelling independently on public transport, carrying out everyday tasks such as shopping or visiting the doctor independently and others always

accompanied and not making many of their own decisions. In the family carers' focus group, the participants all expressed the fact that they made decisions for the person they cared for; this may have been due to the nature of the learning disability or possibly the way the learning disability was perceived by the family carers. In most cases I only met the carers and not the people they cared for. However, regardless of the level of learning disability, family members do not have the right to make a decision on behalf of the person with learning disabilities; in the case of proven lack of capacity, a 'best interest' decision must be made by consulting with a number of people, depending on the decision to be made.

Comments from key informants also reinforced the findings about healthcare professionals' attitudes and knowledge with regard to consent. It was acknowledged by some that there was inadequate knowledge of the Mental Capacity Act (2005); this would tend to deny people with learning disabilities the right to make their own decisions, and to be given the appropriate support to do so. The Mental Capacity Act Code of Practice (Ministry of Justice, 2007) states that every effort should be made to facilitate informed consent by providing accessible information. Some participants also considered that decisions are often made 'over the heads' of people with learning disabilities; it is not only the healthcare professionals that play a part in this, but also some parents and carers who, acting in what they think is the best interest of the person they are caring for, make decisions for them. Keywood and colleagues (1999) identified that:

"the majority of parents and carers identified themselves as the primary decision-makers for adults with learning disabilities" (p 27).

This report was based on a study conducted in 1998, which involved adults with learning disabilities, their families and paid carers, and the foreword states that *"carers, especially relatives, go on acting as though the individual were still a child"* (p 6)

To conclude this section, a picture emerges of people with learning disabilities being satisfied with the care they are receiving when they have a blood test, having trust in the healthcare team, and requesting support should they feel they need it. Jones *et al* (2008) collected data from people with learning disabilities and paid support staff and found that service-users were satisfied with the service they received in primary care, but support staff raised issues of poor communication skills and in some cases negative attitudes to PWLD. The knowledge that health and social care professionals hold about the Mental Capacity Act (2005) appears to be patchy, resulting in a consent procedure which is not wholly consistent with the Act, but which seems to satisfy the patients themselves. Paid carers and family carers appear to have differing ideas on the importance of the person-centred approach in healthcare – and this may result in some people with learning disabilities being denied the right to make their own health decisions.

As stated earlier, one of the important issues arising from this research question is whether the situations I observed were any different from those that might be observed in *any* consultation for a routine blood test, i.e. for patients without learning disabilities. This merits more exploration later in this chapter. The next research question is a difficult one to answer in view of the fact that despite the hopes expressed in the genetics white paper (Department of Health, 2003c) and subsequent reports both in the UK and the US (Department of Health,

2008; Department of Health and Human Services, 2008), pharmacogenomics has not yet been integrated into everyday clinical services in the UK, despite much research being conducted in the drug development field.

8.4 The attitudes of healthcare professionals and carers to offering pharmacogenomic tests to people with learning disabilities

This research question was posed on the assumption that there would be some level of knowledge of pharmacogenomics within the healthcare community. Although one of the aims of the White Paper, 'Our inheritance, our future' (Department of Health, 2003c) was to develop pharmacogenomic services, and to spread knowledge of genetics throughout the NHS (Department of Health, 2008), in reality, barriers such as cost, complexity, and lack of evidence base have been identified (Martin *et al.*, 2006). A report by the Royal Society (2005) investigating the current situation regarding pharmacogenetic testing in clinical practice, concluded that:

"Until studies of the clinical and cost effectiveness of its value on a drug-by-drug basis have been carried out, its role in clinical practice will remain uncertain". (p 29)

In this section, therefore, I will first discuss the level of knowledge and then describe the attitudes to this kind of test.

8.4.1 Knowledge of pharmacogenomic testing

Data from the focus groups, the online bulletin board and interviews with key informants enabled me to assess how much knowledge of pharmacogenomic testing existed in these participants, and illustrated one example of the many assumptions I had made prior to embarking on this study. Because I have an interest in genetics, both following my undergraduate degree and simply as the parent of a person with a learning disability, I was surprised by the low level of

knowledge of this area present in healthcare workers. However, it is evident that staff working in general practice are by nature generalists (NHS Choices, 2010). Emery and Hayflick (2001) described how genetic medicine will be extending into primary care in the form of screening for cystic fibrosis and haemoglobinopathy carrier screening, with the possibility of the future introduction of tailored prescribing in the form of pharmacogenomic testing. They suggested that general practice staff did not perceive genetic education as relevant to them. Before genetics can be introduced into primary care, there is a need for education of healthcare professionals (Fargher *et al.*, 2007). Studies have been conducted to explore attitudes to genetic testing in primary care. For example, in a study to evaluate the integration of genetics into mainstream clinical services in the UK, which was one of the aims of the genetics White Paper (Department of Health, 2003c), Martin and colleagues found a lack of interest in clinical genetics among primary care staff, compounded by the demands of national health targets (Martin, Currie & Finn, 2009). McCahon *et al* (2009) suggested that GPs' attitudes to providing genetic health care were influenced by lack of training and lack of evidence of benefit to patients. It is the aim of the UK government to spread knowledge of genetics more widely throughout the NHS (Department of Health, 2008) and to this end, genomic medicine should be included in undergraduate medical education (Department of Health, 2009b). One of the key informants considered that general practitioners do not have the time to explain complex genetic concepts to patients, and because of their inadequate knowledge, they risk giving inaccurate information which then has to be corrected by a genetic health specialist. One healthcare professional, having stated that she had little

knowledge of pharmacogenomics, went on to express concern that in the process of conducting pharmacogenomic testing, other conditions or pre-dispositions might be identified. This concern has also been identified as a possible barrier to progress in the literature (for example, Fargher *et al.*, 2007) No-one in the carers' focus groups had any knowledge of pharmacogenomics, although there appeared to be some lay knowledge of genetics. However, having received a brief explanation from me, participants in the paid carers' focus group and some of the key informants also expressed their concerns about identification of other genetic information, and one carer felt that there was an unspoken fear about 'genes' and 'testing genes'. As one key informant said, sometimes there is a general perception among the public that a 'DNA' test is an all-powerful test that will tell us everything about a person.

8.4.2 Offering pharmacogenomic tests to people with learning disabilities

Following my explanation of what a pharmacogenomic test involved and how it would be used in the management of a patient's medication, there was consensus among the carers that such a test would probably benefit the patient. However, there was a general feeling that anything that a carer (whether a family carer or a paid carer) felt would benefit the person they cared for should be encouraged. This was an interesting point, as there was some discussion among the paid carers concerning the way ideas are presented to the person with a learning disability. One family carer felt that if you 'pre-empted' any conversation with a positive statement, that would encourage the person to agree to a procedure. A paid carer felt that a positive approach was necessary when obtaining consent for something that *the carer* felt would benefit the person was acceptable. These comments raise the possibility of coercion,

albeit gentle, which would invalidate consent under the Mental Capacity Act (2005). The idea of 'best interest' (UK Clinical Ethics Network, 2010) was expressed by some carers as a lay concept, saying that they had their relative's best interests at heart when they made decisions on their behalf. As I stated earlier, there was no doubt in these carers' minds that they had the right to make these decisions, despite the fact that no formal assessment of capacity had been made to confirm that the person *lacked* capacity. This is distinct from the legal use of the term 'best interest' which is one of the five principles of the Mental Capacity Act (2005c):

An act done, or decision made, under this Act for or on behalf of a person who lacks capacity must be done, or made, in his best interests.
(Office of Public Sector Information, 2005, p1)

This clarifies the fact that 'best interest' decisions in the legal sense should only be taken when a person *lacks capacity*.

Most of the participants with learning disabilities, perhaps unsurprisingly, stated that they would be willing to have this kind of test and would not consider it as different from any other kind of blood test. This was after I had given them a simple explanation of inheritance, genetics and pharmacogenomics, in some cases using an interactive DVD. In the same way as the carers, they felt that anything that would help the doctor in the management of their health care was acceptable (in the case of carers, to be encouraged). Having been given a simple explanation, the people with learning disabilities would not have had the background knowledge which caused some of the health professionals and carers concern – namely the possible identification of other genetic information.

One key informant expressed uncertainty as to whether GPs would offer this kind of test unless they were incentivized, and also questioned the level of

genetic knowledge in primary care. Although I only recruited one GP to the online discussion, I consider that comments made demonstrated the barriers that may arise when offering a new kind of genetic test to a person with a learning disability. These included not only taking the blood, but time taken to explain the nature of the test, and to allay any fears about the test revealing genetic conditions in addition to the specific pharmacogenomic test.

8.5 The information requirements of people with learning disabilities

This section is related to the final research question which asks:

“What information would people with learning disabilities wish to have when making a decision about having a pharmacogenomic test, and does this differ from blood tests for other purposes?”

There are two important issues that arise as a result of asking this research question, leading to two subsidiary questions for discussion. Firstly, how difficult is it for a person with a learning disability to answer this question, which is essentially a hypothetical one, as pharmacogenomic tests are not clinically available in the UK? Secondly, should a pharmacogenomic test be considered as conceptually different from a genetic test that offers diagnosis of a genetic disorder or information about predisposition to certain diseases?

8.5.1 Are hypothetical questions difficult for a person with a learning disability?

In order to explore the information needs of people with learning disabilities when they are considering a routine blood test or a pharmacogenomic blood test, it is important to discuss the difference between the two. The debate concerning the possible differences between routine screening blood tests and genetic tests is discussed in the next section. However, there is another equally

important issue here. The fact that pharmacogenomic blood tests are not yet clinically available to the public in the UK meant that before assessing attitude, I had to explain the nature of the test. Genetics and pharmacogenomics are complex subjects; in essence having a pharmacogenomic test had to be presented by me as a hypothetical situation. In Chapter 2, when suggesting future research, I concluded that it would be useful to conduct research using real life situations rather than vignettes. I based this suggestion partly on comments made in some of the studies I identified about the difficulties people with learning disabilities had with hypothetical situations. For example, Fisher *et al* (2006) reported that:

as expected, adults with mental retardation as compared to those without, and adults with moderate mental retardation as compared to those with mild mental retardation, had greater difficulty understanding, appreciating, and reasoning about a hypothetical randomized clinical trial (p 1818)

I also based this suggestion on a personal assumption that people with learning disabilities, in view of various functional deficits, might find imagining hypothetical situations, or other abstract concepts difficult.

In Phase 3, when interviewing participants with learning disabilities, I was really presenting them with a hypothetical situation when talking about pharmacogenomic testing, so I need to question the validity of their responses. For this reason, I now need to explore research in this area.

Despite extensive searching, using terms such as 'abstract concepts', 'abstract thoughts', 'abstract reasoning', I found very little primary research on this topic, and have concluded that there may be *assumption* that people with learning disabilities have a problem with abstract reasoning. Evidence I did find was in the field of cognitive psychology, investigating whether cognitive behaviour

therapy is appropriate in people with learning disabilities. Kroese (1997) concludes that in the context of cognitive behavioural therapy, people with learning disabilities can deal with abstract concepts, but their knowledge and understanding has to be assessed, and they need teaching and instruction from the therapist. In the same text, Jones *et al* (1997), when considering theoretical and practical issues relating to cognitive behavioural therapy in this population, note an increased probability that cognitive deficits may include concrete thinking. These authors quote Vygotsky (1978) who claimed that ignoring abstract thoughts in the teaching of children, and only teaching them concrete concepts based on their level of development can lead to learned helplessness and a dependency on others. They suggest that many people with learning disabilities may have had this kind of educational disadvantage. It has also been suggested that deficits in analogical reasoning (applying analogies to different domains in order to learn) may be caused not simply by level of IQ, but by problems caused by memory overload (Buchel, 2006).

It is difficult to evaluate how much understanding of the concept of pharmacogenomics the participants gained from my explanation although some participants were able to feedback a reasonable version of explanation to me. However, it is more difficult to establish whether they could really imagine themselves in the situation of having such a test. Participants focused more on the information requirements for *any* blood test rather than the new type of blood test I had explained to them. I simply wish to draw attention to the possible limitations involved in this part of the study, which will be discussed later in this chapter.

8.5.2 Genetic exceptionalism

The debate about the nature of genetic tests was introduced in Chapter 1. In the context of this study, I consider it relevant to discuss firstly whether *any* genetic test should be viewed as essentially different from a routine screening blood test and secondly whether the same argument should be applied to a *pharmacogenomic* test. Having read the arguments for and against genetic exceptionalism (for example, Godard *et al.*, 2003; Green & Botkins, 2003), I would agree that predictive genetic tests such as those which identify the genes in late-onset diseases such as Huntington disease, or disease susceptibility genes such as BRCA1/BRCA2 for breast cancer need to be treated differently from routine screening or monitoring blood tests. The reason for this is that the results of these specific genetic tests are likely to have implications for the health of the wider family, and also if the person wanted to apply for health or life insurance. This makes them different from routine blood tests. In the case of pharmacogenomic tests, although some research has shown that other genetic information might be identified when conducting pharmacogenetic tests (Henrikson, Burke & Veenstra, 2008), the consensus appears to be that this is not the case. As pharmacogenomic testing would be used in the health management of the patient, to optimise and possibly personalise medication, I am treating it as another routine tool to be used by a general practitioner in the care of the patient. By doing this, when discussing the information needs of the person with a learning disability with regard to pharmacogenomic testing, they can be considered alongside those for a routine blood test.

The Mental Capacity Act Code of Conduct (Ministry of Justice, 2007) states that any information given to a patient must be sufficient for them to understand the

implications of the procedure being undertaken. In other words, information should be proportional to the complexity of the test or procedure for which consent is being sought.

8.5.3 What information do people with learning disabilities want or need?

Having discussed the ability of people with learning disabilities to understand abstract concepts, and the nature of a pharmacogenomic test, I will now attempt to look at the evidence from the literature and from my empirical data to answer this question. Firstly, I would like to state how important I consider it is to ask the people themselves. Without such evidence it is difficult for policy makers to decide what people need or want. I would compare it to making a 'best interest' decision when a person has capacity.

From the literature review there is some qualitative evidence that people with learning disabilities are often not given sufficient information to make health decisions (Keywood, Fovargue & Flynn, 1999). However, the reasons for this are complex. Keywood and her colleagues described certain misconceptions held by people with learning disabilities, for example, that family members have the right to consent on their behalf, or that health workers can impose unwanted treatment on a patient. People with learning disabilities who have lived most of their lives having decisions made for them, and without the opportunity to make their own choices, may not be aware of their rights in relation to provision of information before giving consent – so may not express a wish for such information. The majority of participants with learning disabilities, when recalling having had blood tests in the past, said that they were not aware of the reason for these tests; this could be due to their poor recall. However, it could also be due to the fact that they were given no information. If patients are

regular attenders at a surgery, are well known to the health team, and have never requested information, it will be interesting to see if practice changes in response to the introduction of legislation designed to facilitate consent in a vulnerable population. It may be that further measures such as ongoing education for health practitioners in the field of consent and capacity may be necessary.

The participants I interviewed fell into several groups with regard to information provision. Firstly there were those who had received no information about past blood tests, and were emphatic that they did not want or need it, but were simply happy for the blood to be taken. This group display the acquiescence that is common in people with learning disabilities. Then there were several who admitted to not knowing what previous blood tests were for, but told me that they would like information in future. Some participants were guessing what the blood tests were for, some were perhaps using knowledge they had gained over many years of attending the surgery for blood tests. Some of the participants whom I both observed and interviewed appeared to have some knowledge of their blood tests that had not been presented to them during the consultation, which might confirm the idea that the nurses were assuming prior knowledge.

On reflection, I was unsure about the truth of the participants' answers about the provision of information. There appeared to be a paradox in that, despite not being given, or requesting information about blood tests in practice, some participants told me that if they were going to have a new kind of blood test, they would want information about it. I wondered if this was a case of participants giving me the answer they thought I expected. The main body of

research on acquiescence in people with learning disability was conducted by Sigelman and colleagues in the 1980s and 1990s (Heal & Sigelman, 1995; Sigelman *et al.*, 1981) and the findings question the validity of responses when interviewing people with learning disabilities, in whom acquiescence is commonly observed. One of the features of acquiescence as they define it is the tendency to say 'yes' (known as yea-saying). These authors also comment that people with a lower level of education are more likely to be influenced by the way questions are asked (Heal & Sigelman, 1995). Using conversation analysis, Rapley and Antaki (1996) concluded:

"the traditional notion of submissive, willing-to-please acquiescence is probably unsustainable on current evidence, and ought to be replaced by a more respectful account of the linguistic and interpersonal competence of people with learning disabilities." (p 207)

Rapley and Antaki also concluded that people with learning disabilities were likely to treat the research interview as a form of test. I would suggest that the data from the current study support this contention; as I reflected at the time, the participants I interviewed appeared keen to 'do well' in the interview, as illustrated by one enthusiastic participant:

and you do your research ,Lesley, and that, I think you'll find that what I'm saying will be adequate to answer. (B, 103-104)

I was aware of the possible pitfalls when I interviewed the participants, and attempted not to lead them or use closed questions, but inevitably as a novice researcher this was a challenge. I will discuss this in more detail in the section on limitations later in this chapter.

Regardless of whether or not participants wanted information about blood tests, or had received it during their consultation, they were keen to tell me how they

liked information presented to them. Their comments reinforced the recommendations made by many organisations providing advice on accessible information: that it should be simple with short words, short sentences and large font (for example, Mencap, 2002; Social Care Institute for Excellence, 2005). These data also reinforce some of the findings from the integrative review of the literature about the nature of accessible information which should be provided for people with learning disabilities: that capacity is maximised when information is broken down into simple elements (Wong *et al.*, 2000) or with brief sentences and simple, concrete terms (Fisher *et al.*, 2006).

Having discussed the research questions, I would now like to discuss some of the other major themes I identified in the course of this study, which I consider are relevant to the topic of informed consent in people with learning disabilities, despite not directly answering the research questions as stated above. For clarity I am combining some of these themes together, as they are conceptually linked and also have relevance to the topics introduced in Chapter 1: empowerment, shared decision making and the social model of disability.

8.6 The person with a learning disability

On reading and re-reading the transcripts from the observations and the interviews, I was impressed by what appeared to be attempts by the participants with learning disabilities to boost their self-image, and to impress upon me how capable and independent they could be. From these data I identified such sub-themes as self-image, identity, decision-making and personal qualities, as included in Table 5, Chapter 6. As outlined in the findings chapters, participants were also keen to tell me how they liked to be treated and gave me examples of incidents they found upsetting or patronising.

This led me to reflect on how difficult it is to consider people with learning disability as a homogeneous group of people; the variation *within* the learning disability population must surely be as large as that in the population as a whole.

8.6.1 Finding a voice

Alongside the ideologies of normalisation and social role valorisation mentioned in Chapter 1 (and which will be evaluated later in this chapter), there have been developments in the way people with learning disabilities can be heard. One of the policy objectives of Valuing People Now (Department of Health, 2009c) was to promote advocacy in its various forms; self-advocacy, citizen advocacy, and peer advocacy, as well as various forms of paid advocacy. People First is an organisation that supports people with learning difficulties (their preferred terminology) in setting up and running their own organisations, including self-advocacy groups. Several of the study participants were members of a People First self-advocacy group and expressed their views clearly.

A recently published Disability Studies Reader (Davis, 2010) contains a chapter written by people with learning disabilities, which confirms the findings of the current study in terms of the way people with learning disabilities feel they are treated, or how they would like to be treated. The first point of interest in this article is that there is discussion about the medical model and the social model; the authors critique both, but make the valid comment that they would like to read more about the social model of disability, but cannot do so *“because it isn’t accessible. It should be in pictures and large print.”* (Docherty *et al.*, 2010, p 434). However, they do list certain barriers that they consider make them ‘disabled’, and consider that people with learning disabilities should be included

in the social model. Among these barriers are offensive terminology, people's negative attitudes and people being patronising.

I would now like to discuss these barriers, and the effect they might have on people with learning disabilities.

8.6.2 The 'wounded' identity

Wolfensberger used the word 'wound' to describe the negative experiences of 'devalued' people in his social valorisation theory (Race, 1999), which does not relate solely to people with learning disabilities, but to any group of people considered as vulnerable, and who have been 'socially devalued'. There were examples of this in my findings, such as when participants received what they considered offensive comments from healthcare professionals or when they were patronised. Historically there have been examples of this in health care: women with learning disabilities being excluded from the cervical smear programme due to assumptions made about their lives (Broughton, 2002) or patients with learning disabilities receiving discriminatory or negative comments in hospital (Gibbs, Brown & Muir, 2008).

The question of identity in people with learning disabilities is complex. There has been research showing that some people with learning disabilities do not see themselves as 'learning disabled' (Craig *et al.*, 2002) and find it difficult to accept this label. People with learning disabilities may be considered as 'stigmatised' as defined by Goffman (1963) in terms of blemishes of character. Goffman includes mental disorder as one such blemish and although he does not specifically discuss learning disability, he discusses the use of disparaging terms such as 'moron' when applied to these stigmatised individuals. Goffman

also describes how individuals who are stigmatised can adopt different perspectives according to their situation – in other words, in some contexts they will accept the label and in others they will adopt a strategy of distancing themselves from those with the same stigma as a way of preserving their own identity. An example of the former is when people involved in self-advocacy, by definition, have to accept the learning disabled label in order to improve life for their less able peers. This point is expressed clearly by members of a People First Group who contributed to a chapter for “The Disability Studies Reader” (Davis, 2010):

‘Learning disabled’ is the name we have chosen for ourselves, it widens it more than us, to other disabled people. (p433)

This is an interesting point, as the People First website (2010), which supports the social model of disability, states that the preferred term is *learning difficulties*, which reflects the fact that peoples’ learning needs change and considers that people with *learning difficulties* are *disabled by society*.

There are, of course, ways in which people with learning disabilities cannot avoid their ‘categorical’ identity – such as using a disabled bus pass or having a discounted ticket at the cinema. Antaki and colleagues (2007) have suggested that the way in which an activity is suggested to a person with learning disabilities can have an effect on their identity in a positive or a negative way. It has also been found that people with learning difficulties gain their self-identities from different sources, from discourse, from experience and from power relationships, and there can sometimes be incongruence between their ‘categorical’ identity and their self-identity (Davies & Jenkins, 1997).

8.7 Being a carer

Although the aim of this study was to explore the information needs of people with learning disabilities, data were collected from not only the people themselves, but also the professionals responsible for their health care and the people who cared for them. Healthcare professionals stressed the individuality of the people they care for, and how important it was to consider each and every one as an individual in terms of their needs, preferences and abilities. With regard to carers, a distinction has to be made between paid carers or support workers and family carers; as the data have shown, unsurprisingly, that the views, experiences and attitudes of these two groups can be different. Members of a family may make assumptions, not only about the abilities of the person they care for, but also their rights in terms of decision-making. In contrast to this, people who are employed to care for people with learning disabilities are more likely to be aware of current law such as the Mental Capacity Act (2005) and the rights it confers on learning disabled people. The data from the paid carers' focus group illustrated the carers' views that people should be treated as individuals and encouraged to make their own choices and decisions whenever possible; it was more difficult to recognise this attitude in the family carers.

There was, however, real evidence of the warmth of the relationship when family carers spoke about the people they cared for, and indeed the paid carers also spoken with great affection about the people they supported. It was clear that both family and paid carers had the best interests of the person at heart. However, it is also apparent that the level of independence achieved by that person and their level of personal development differs according to their

situation. The family carers generally considered that it was their duty to make decisions on behalf of their family member, although one parent did acknowledge the possibility of some responsibility for not allowing a greater degree of independence. In this particular case, I felt that by discussing the subject I was to a certain extent playing 'devil's advocate'; this was a difficult situation for me as the parent of a person with a learning disability. I have had many discussions with friends and acquaintances who have children with learning disabilities about the risks and benefits of 'letting go'. The relationship between an adult with a learning disability living at home and his or her family carers can be complex. Grant and Ramcharan (2001) wrote about the experiences of families which included a child or adult with a learning disability, from the caring perspective, and described the positive and negative aspects of caring. A pertinent finding for this study is the reciprocal relationship between people with intellectual disabilities and their ageing carers, and the fact that some parents experience caring as having some positive aspects with many rewards. Walker and Walker (1998) describe the emotional and social interdependence that can develop between older people with learning difficulties and their family carers. It is possible that the influence of these factors on family carers may have an adverse effect on the development of independence in their family member, and thus the choices and decision-making activity.

Paid support workers, however, tend to adopt, or are probably *expected* to adopt, the ethos of the organisation that employs them, and there is much emphasis on person-centred planning, health action plans and encouraging and

allowing the person with a learning disability to make his or her own choice (with appropriate support).

Government publications such as *Valuing People* (Department of Health, 2001d) stress the importance of independence:

“Valuing People sets out how the Government will provide new opportunities for children and adults with learning disabilities and their families to live full and independent lives as part of their local communities.” (Executive summary, p 2)

Family carers, on the other hand, are not governed by such values, and simply rely on their own judgement and experience. The findings from the paid and family carers' focus groups show how influential those close to the individual with a learning disability can be when it comes to making decisions.

8.8 The relevance of various theories to this study

I consider that the best way to understand these findings about people with learning disabilities is to explore the context in which they are happening, and how this context has changed over the past few decades. I suggested some relevant theories or ideologies in Chapter 1: empowerment, the social model of disability and shared decision-making. I would now like to revisit them in relation to the findings of this study.

8.8.1 Normalisation and social role valorisation

Before reconsidering empowerment, I will describe two ideologies that have had great influence over the last few decades. Normalisation (Nirje, 1969; Wolfensberger, 1983) and social role valorisation (Wolfensberger, 1983) underpinned the planning of care for people with learning disabilities for over two decades. Normalisation was criticised by some as *imposing* ideas of

normality onto people with learning disabilities by people who were non-disabled (Oliver, 2009). It has also been considered to ignore the power differences between learning disabled people and the people who care for them (Gilbert, 1993). According to Walmsley (2001), normalisation had its roots in academia in the work of Nirje and Wolfensberger, and research in the field was conducted by non-disabled researchers. Nirje (1969) described the normalization principle as giving people who were 'mentally retarded' an everyday life as close as possible to that of mainstream society. Social role valorisation had a different emphasis in that it stressed the fact that certain vulnerable groups had been socially 'devalued' by society, and sought to 'revalue' those roles. There was some confusion between the two terms amongst professionals, with some considering social role valorisation as a new, distinct philosophy (Barr, 1995). By the 1990s, social role valorisation had become less influential, despite the fact that Wolfensberger had cited it as a social science theory (Race, 1999) and the social model of disability, first described by Oliver (1990) was gaining in acceptance.

8.8.2 *The social model of disability*

There has been much debate about the validity of the social model of disability, both in terms of how the model views *impairment* and how it relates to those with learning disabilities. Tom Shakespeare has written prolifically about the strengths and weakness of this model, which asserts that disability is a construct of society (Shakespeare, 2010). He acknowledges, along with others (for example, Crow, 1996), however, that the physical and emotional effect of the *impairment* can remain even if the social barriers are removed; impairment should not be ignored in the social model of disability.

With regard to people with learning disabilities, the social model of disability is generally considered not to have real relevance to people with learning disabilities (Barnes & Mercer, 2003; Chappell, 1998), as it relates mainly to people with physical disabilities. There is an interesting comment from a group of learning disabled researchers:

"Disabled for us means information problems, but when we're talking about the social model, if information was accessible, then we wouldn't be disabled" (Docherty *et al.*, 2010, p437)

For this group of learning disabled people, the social model of disability is considered relevant. They considered inaccessible information as a barrier to their inclusion in society, and by the production of accessible information they consider themselves 'not disabled'. However, this illustrates how people with learning disabilities cannot be considered as a homogeneous population; information cannot be made accessible to everyone and there will always be a section of the learning disabled community who will be excluded from accessible information due to the level of their intellectual deficits. Secondly, the above quotation reinforces a finding from this study: that people with mild learning disabilities, those with the kind of qualities which drive them to join self-advocacy groups, for example, may have little understanding of the needs of those less able than themselves. One participant felt that because she could read, everyone else with learning disabilities should learn to read. This is reinforced by Craig *et al* (2002) who found that people with learning disabilities tended to think of themselves as 'non-disabled', and compared themselves favourably with other less able people with learning disabilities; another of the participants in this study explained how she helped someone less able than herself to use a computer, thus conveying a positive image of herself.

8.8.3 Empowerment

Having considered the background to the development of the social model of disability, I would now like to briefly discuss the relevance of empowerment. In Chapter 1 I stated that the concept of empowerment was implicit in the developments in services for people with learning disabilities. Oliver (2009) distinguished between the process of normalisation, which he considered was imposed on people with learning disabilities and that of empowerment, a collective process which involved those who were powerless resisting oppression by others.

It is difficult to conclude from this programme of studies whether empowerment is an appropriate concept to relate to the evidence. As stated earlier, several of the participants with learning disabilities were members of a local self-advocacy group; in fact one had attended national self-advocacy events as a representative. For these participants, empowerment would seem an issue and self-advocacy groups are certainly fora in which people with learning disabilities collectively put their views forward. There is evidence that being a member of a self-advocacy group can lead to empowerment at both an individual and collective level (Gilmartin & Steven, 2009). However, I am not convinced that at the individual level, any of the participants saw themselves as 'oppressed' as defined by Oliver (2009); in fact many of them took pride in their independence and ability to make decisions. A good example of this is the two participants who told me they had changed their GP due to what they felt was a poor attitude.

One aspect of oppression could be related to control:

"All of us struggle with issues of control in our lives... yet for many people with learning disabilities, this struggle is continuous and oppressive. Others who are more powerful make decisions about where they live, with whom, how they spend their days, how they dress....." (Brewster & Ramcharan, 2005)

Another possible source of oppression is the label of learning disability and the constant struggle to overcome it (Llewellyn & McConnell, 2005). Oliver (1990) concludes that the oppression experienced by people with learning disabilities, in common with others with disability, is caused by barriers created by society that deny them the same opportunities as everyone else, for example in work and education.

I consider that the use of empowerment, as defined by Oliver (2009) in relation to the position of *some* people with learning disabilities may be inappropriate, in that the majority of them will need some kind of support in their lives. Documents such as Valuing People Now (Department of Health, 2009c) for example, illustrate this, although the ethos behind the strategy is empowerment, there are many references to the support that people will need, to find work, to live healthy lives, to have relationships and become parents, so it is difficult to see them as embarking on a struggle, or taking the initiative to do so. In other words, it is difficult to view these changes as true empowerment. However, I will now describe changes which may affect the power balance between patient and doctor; the move towards shared decision-making.

8.8.4 Shared decision-making

As I described in Chapter 1, healthcare professionals are being encouraged to adopt a shared decision-making model in their consultations. Shared decision-making, according to the General Medical Council (2008) is based on the following principles:

"Whatever the context in which medical decisions are made, you must work in partnership with your patients to ensure good care. In so doing, you must:

- a. listen to patients and respect their views about their health*
- b. discuss with patients what their diagnosis, prognosis, treatment and care involve*
- c. share with patients the information they want or need in order to make decisions*
- d. maximise patients' opportunities, and their ability, to make decisions for themselves*
- e. respect patients' decisions."* (p 10)

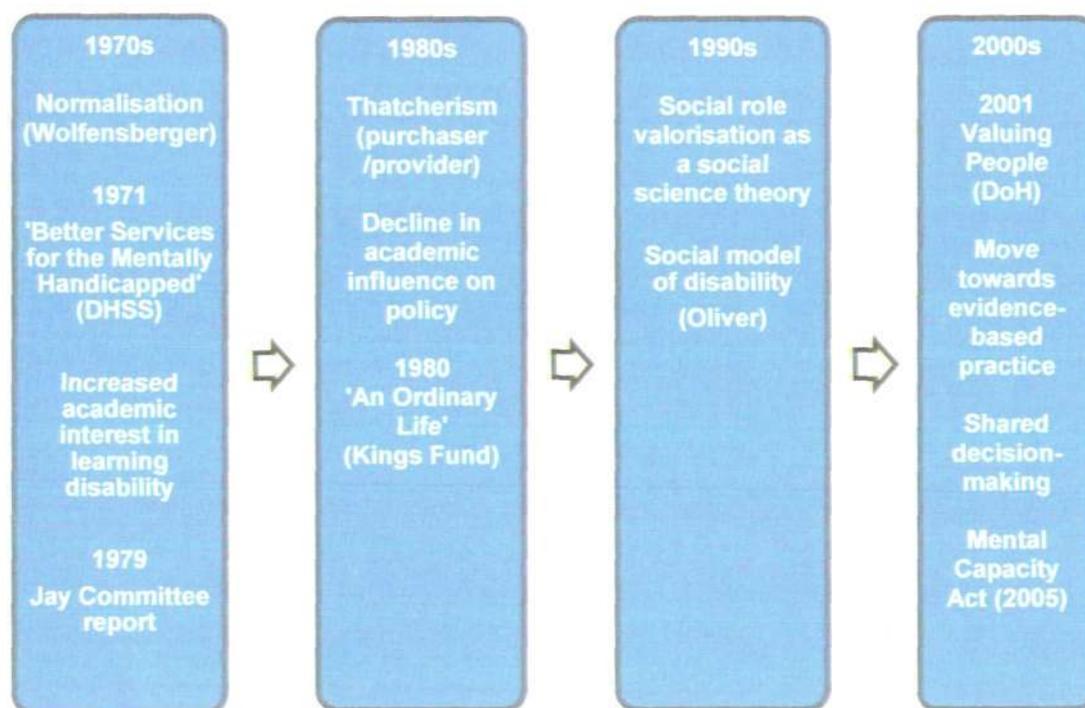
Each of these principles needs careful consideration when applied to a person with a learning disability, as they may require extra time and effort on the part of the healthcare professional. In fact, the requirements above of sharing information and maximising patients' opportunities and ability to make decisions for themselves are exactly those also required by the Mental Capacity Act (2005). I would question, in view of the data obtained, whether these requirements are being followed in practice.

Having considered various theories of relevance to this study, I think it would be helpful to summarise the historical context of care for people with learning disabilities over the last few decades, before concluding with what I consider to be the theory that has most relevance to the findings of this study.

8.9 Summary of the context of this study

Changes in attitude, policy and behaviour are not quick processes, but in Figure 5 I have attempted to put the recent developments into context. I would like to briefly comment on some of the points in this figure, which I have adapted from Race (Race, 1999, Table 1, p4) (see next page).

Figure 5 Significant changes in ideology and policy since the 1970s



(adapted from Race, 1999)

I have already described normalisation and the work of Wolfensberger (1983) culminating in the concept of social role valorisation. In the UK, the Department of Health and Social Security (as it was known then) produced a White Paper in response to the scandalous conditions that people with 'mental handicap' were having to tolerate in hospitals and large institutions (Department of Health and Social Security, 1971). The publication of this White Paper prepared the way for progressive movement of people with learning disabilities (and mental health problems) from hospitals into community care so that by 1990, under the National Health Service and Community Care Act (Department of Health, 1990), community care had been established for the majority under the auspices of local social services departments. The policy of normalisation was still very

much in evidence by 1980 with the publication of 'An Ordinary Life: comprehensive locally-based residential services for mentally handicapped people' (King's Fund Centre, 1980) and the Jay Committee report (Jay Committee, 1979), both of which had normalisation as the underpinning ideology. The Jay Committee report, into the care of mentally handicapped people was never implemented and Race (1999) considered that by the late 1970s and early 1980s, with the rise of the Thatcher administration, academic influence on government policy had decreased, with an emphasis on a purchaser/provider economy (this became evident in the way that health and social care became organised). Despite this, the social model of disability was implicit in the Jay Committee report and gained favour by the 1990s (Race, 1999).

In the first decade of the twenty-first century came the publication of 'Valuing People' (Department of Health, 2001d), described as a "New Strategy for Learning Disability for the 21st Century". This was the first White Paper on learning disability since the publication thirty years previously of "Better Services" (Department of Health and Social Security, 1971) The principle that people with learning disabilities should have the same rights under disability discrimination legislation and human rights legislation as every member of the public underpins this document and it covers all aspects of life, including health, housing and employment.

To conclude this part of the chapter, I would like to discuss what I now consider the most relevant theory that relates to the lives of people with learning disabilities, their carers and the healthcare professionals who look after them.

8.10 Role theory and its relevance to the findings of this study

The roles, expectations and identities of people with learning disabilities, healthcare professionals and carers are constantly evolving. The lives of people with learning disabilities are being influenced by legislation designed to give them more say in the way they live; providers of social care are being given guidance make their care 'person-centred' and to facilitate higher levels of independence in the people they support (Department of Health, 2010a; Department of Health, 2010b). In view of the previous discussion about empowerment, it is interesting to note the following explanation that appears in the above Department of Health document on person-centred planning:

Person-centred planning is both an empowering philosophy and a set of tools for change, at an individual, a team and an organisational level. It shifts power from professionals to people who use services .(2010b, p3)

The '*empowering*' in this case is policy driven, not issuing from the people who are seen as disempowered. In other words, this power is being *given*, not *taken*.

Healthcare staff are receiving instruction on how to comply with the new Mental Capacity Act (2005); there is also a published Code of Conduct (Ministry of Justice, 2007). Doctors have been issued with guidance on how to conduct shared decision-making in their consultations (General Medical Council, 2008) . Each of these developments is likely to disturb the established dynamics within relationships. For example, establishing a greater level of independence for the person with a learning disability will inevitably change the balance of power in the relationship between 'supporter' and 'supported'. This process is not always easy for either party, as some of the paid carers explained, there needs to be an awareness of the right to individual decisions and choices, and this in itself is

a learning process. Someone who has lived their whole life being deprived of personal choices such as where to live, what activities to enjoy, who to see, may find it difficult to accept this new responsibility of making a choice. Paid carers referred to this when describing how some of their residents had come from 'institutional' care to supported living and found making their own decisions difficult, as did the staff who supported them. Barr (1995) describes the way learning disability nursing staff should respond to what he sees as the challenges in implementing normalisation, for example, and concedes that there may be risks involved. This is not the only challenge in 'normalising' people's lives; Barr describes simple day to day activities such as making a cup of tea rather than having one made for you, but again, this is a learning process and is more labour-intensive on the staff involved in the teaching of the task.

The current situation in the learning disabled healthcare field is complex in that roles are changing for everyone involved. The role of the person with a learning disability is developing, with emphasis on choice, decision-making and greater independence; alongside this, the role of the carer is changing to adapt to the person-centred approach and the greater involvement of the person with learning disabilities in everyday choices. This was seen earlier when considering the social policy context. What of the role of the family member who cares for a relative with a learning disability? How have they been affected by the above changes? I would suggest that this is a difficult question to answer, the data showed possible ignorance of the principles of the Mental Capacity Act (2005) among family carers, although the changes mentioned above may gradually become apparent to families. One of the family carers, for example, had noticed that the family GP had started to address his son directly

rather than via him as carer. Finally the role of the healthcare professional is changing in terms of a change from the paternalistic approach to medical decision-making to that of a very much person-centred decision process, in which decision-making is shared (General Medical Council, 2008). Rather than doctors holding the balance of power in terms of their medical knowledge and expertise, there has been a policy change to that of the patients presenting as the 'lay expert' in the consultation and having an equal say in the outcome (Barnes, Mercer & Shakespeare, 1999). Pendleton *et al* (2003) state that although there has been a move away from paternalism to informed choice, there are external factors that might influence the doctor to obtain consent without the patient being fully informed.

This study has been conducted in the context of significant changes in policies, government strategies and living conditions for people with learning disabilities since the 1960s. Biddle's statement that people's expectations generate their behaviour, and that people are likely to conform if other people have power and can 'exercise sanctions' (Biddle, 1986, p79) perhaps explains why it is sometimes difficult for people with learning disabilities to change their role and adopt a new, more independent way of life: their expectations do not allow it. It has been difficult to identify recent research on the changing roles of people with learning disability (and of those around them). However, with any change in roles there is likely to be a learning process involved (Boyanowsky, 1984).

From the literature on organisational role transitions, where the word 'normalization' is used in a different sense, that of becoming comfortable in a new role, comes the view that when someone's role changes, they need to be familiar with their new role (and organisation) to feel comfortable and perform

well (Ashforth, 2001). This principle could be applied to the healthcare professionals' new role of 'shared decision-maker' and that of the person with learning disability with a newly developed role in decision-making. Each is adopting a subtly different 'role' in the healthcare system and the findings from this study show that the transition is not necessarily successful.

8.11 How different is a person with a learning disability?

Before describing the strengths and limitations of this study and concluding this chapter, I would like to return to a theme which was a feature of several phases of this study, and which was a question I constantly returned to in my reflections. Some of the participants were quite clear that they wanted to 'be normal', and considered themselves as such – certainly in the context we were discussing. Looking at the data about the consent process, provision of information and the nature of consultations, I found myself wondering how different the answers would be if I were to conduct the same study in a population without learning disability. Questions about how much information people want or need prior to a blood test may well produce the same answers in any population. Is the apparent vulnerability of a population the important issue here? Would similar findings be identified in a population of older people? The Mental Capacity Act (2005) should be applied to everyone whose capacity is in doubt, using the two-stage test referred to in Chapter 4, and information should be in an accessible format for *anyone* who would have difficulty understanding it in a regular format. This point was mentioned regularly by key informants when interviewed. The fact that some of the participants said that they did not require information was also discussed as well as the fine line between autonomy and protection. In summary, I conclude that in the context of consent to a routine

blood test, people with mild to moderate learning disabilities are not significantly different from people without learning disabilities, apart from the need for extra support (if required) to achieve optimum communication and understanding to facilitate informed consent. However, as stated earlier, information may not be required, and this situation may apply to people with or without learning disabilities.

This theme of 'How different is a person with a learning disability?' leads me into the discussion of the strengths and limitations of this study.

8.12 Strengths and limitations of the study

8.12.1 Strengths

Asking people with learning disabilities

I consider that one of the strengths of this study was the fact that people with learning disabilities were asked to relate their experiences, their attitudes and their opinions.

By the late 1990s, researchers were acknowledging the importance of including people with learning disabilities as participants in research exploring decision-making (Stalker & Harris, 1998) and healthcare decision-making (Keywood, Fovargue & Flynn, 1999). Although there is now an increased interest in conducting research involving people with learning disabilities (for example, Abell *et al.*, 2007; Garbutt *et al.*, 2010), in the past much research has utilised quantitative methods (for example, Arscott, Dagnan & Kroese, 1999; Cea & Fisher, 2003), and has been *on* rather than *with* people with LD. Researchers investigating consent or capacity in people with learning disabilities have used vignettes and quantitatively analysed the findings (for example, Arscott, Dagnan

& Kroese, 1999; Morris, Niederbuhl & Mahr, 1993), or used tools such as a hypothetical study to assess the level of consent quantitatively (for example, Fisher *et al.*, 2006). Wong *et al* (2000) conducted their study in the 'real life' context of a routine blood test, but again this was analysed quantitatively, so was not accessing the views of the people with learning disabilities.

Grant and Ramcharan (2007) in a review of research conducted as part of the Learning Disability Research Initiative, found a significant increase in people with learning disabilities involved as participants in research, and refer to the fact that they are "*experts by experience*" (p40).

Methodological triangulation

One of the strategies for increasing validity, as defined by Hammersley (1992), is triangulation of methods (Hammersley & Atkinson, 2007). By using different methods of data collection in this study, observation, interviews, focus groups and an online bulletin board, I consider that I have maximised the validity of the data. In addition to this, an integrative review of the literature was conducted, which provided evidence of the current state of the research in this area.

Participant triangulation

I considered it essential to get the views of all concerned in the consent process, the people with learning disabilities, their carers (paid or family) and a range of healthcare professionals. Finally, the views of some key informants in the field of learning disability was sought to add more depth to the data. Jones *et al* (2008) stressed the importance of obtaining a wide range of views when researching ways of improving access of primary care for people with intellectual disabilities. By collecting data from not only the people themselves,

but also carers and healthcare professionals, I consider that I have maximised trustworthiness (Lincoln & Guba, 1985) and relevance of the study for healthcare professionals and carers and obtained a '360 degree' view of the topic being explored.

Using an ethnographic approach

I consider that this was the appropriate approach to adopt for this study. This was an exploratory study and qualitative methods are considered suitable when little is known about a subject. Morse and Field (1996) describe how qualitative researchers approach a topic or setting to find out what goes on, and how they explore the topic in a systematic way.

Based on the findings of the integrative review, I planned to observe 'real life' situations in this study rather than using vignettes. By familiarising myself with their everyday lives and making myself known to participants and making regular visits to places frequented by them, they relaxed in my presence and I believe this resulted in a willingness to be recruited and interview and observational data that was authentic.

The use of video recording

I consider that the use of both audio- and video-recording in the consent interviews and when interviewing people with learning disabilities in Phase 3 has benefited the study in two ways. In the consent interview, the use of a video-recorder enabled me to ensure that the participant's body language showed congruence with their apparent understanding and consent to participate in the research. In the Phase 3 interviews, the video- data was used to supplement the audio- data when transcribing; this was particularly useful in

the context of the sometimes indistinct speech patterns exhibited by the participants. The video- data also provided visual clues to reinforce the spoken word, for example, seeing a smile provided me with an indication of humour or positive feelings, depending on the question asked. Using both audio- and video- recordings to transcribe the data resulted in a richer set of data.

8.12.2 *Limitations*

Recruitment

Participants with learning disabilities

From the outset of this study, decisions had to be made with regard to the sampling strategy. Firstly, I had to decide whether to include people who lacked capacity; this would have involved a justification to the NHS Ethics Committee that the research would benefit the population of people with learning disabilities as a whole. This in itself would not have been a problem, but the complexities of the Mental Capacity Act (2005) with regard to conducting research in vulnerable populations were daunting to me as a novice researcher. I also considered that, again as a novice researcher with little experience of collecting data from people with learning disabilities, that interviewing people with severe or profound learning disabilities would be extremely challenging. A decision was therefore made to include only people with mild to moderate learning disability as participants. At this stage I made the assumption that the local Learning Disability Team would have their clients classified in this way. I was later informed that this was not the case, although the majority of patients with Down syndrome had been categorised. This decision has had an effect on the transferability of these findings. The majority of participants attended the surgery unaccompanied, so observation of the consultation did not include the

presence of a carer. Many participants were at the more 'able' end of the continuum of learning disability and this caused me to reflect on the differences between what I observed in the study, and what would be observed in *any* routine consultation for a blood test. In contrast, what would I have observed in a consultation involving a patient with profound or severe learning disability?

Secondly, due to the vulnerable nature of the participants, I used gatekeepers to introduce me to participants, as it is not considered ethically acceptable to recruit directly. This process not only caused delay in recruitment, but it is possible that many suitable participants were excluded due to judgements made by gatekeepers. In any future study involving people with learning disabilities, I think it would be worthwhile to ensure that every avenue is explored to get to know local populations of people with learning disability and the staff who work with them. It was only towards the end of the study that I found I was meeting new people who could act as gatekeepers, and who could probably have been very helpful in recruiting participants had I conducted more preparatory work and met them earlier in the study.

Both of the above factors: the decision to recruit only mild to moderate learning disability and use of gatekeepers for recruitment, will limit the transferability of the findings. The intention at the outset of the study was to obtain a purposive sample with maximum variation in terms of age, gender and residential status. There is evidence to show that factors such as residential status and the nature of support received have an effect on decision making opportunities (Nota *et al.*, 2007; Standliffe, 2001); there is also evidence to link the level of decision making opportunity with capacity to consent (for example, Dye, Hare & Hendy,

2003). For this reason it would have been useful to recruit a greater number of young participants, and also more who lived at home with family.

Thirdly, I would like to mention a paradox in the way I planned the recruitment and consent process for this study. As described in Chapter 3, I used a two stage process which involved gatekeepers being given inclusion criteria for the study and suggesting suitable participants whom they considered would have capacity to consent to participate in the study. I then conducted a consent interview, where I explained the study, using an information sheet in accessible format, and used a 'supporter' to confirm that the participant had capacity to consent to participate. On reflection, it is likely that consent to research is a more difficult concept to understand than consent to something 'real' like a blood test, and for this reason, it may well be that participants who were excluded by both the gatekeepers and myself for this reason would have been useful contributors to the research. I have not questioned the gatekeepers about their choice of participants, although in one case a participant was excluded due to her current social problems, not on the basis of her capacity.

Carers

Recruiting carers was difficult. The plan was to recruit carers via the participants in Phase 2 (the observation). Despite efforts on my part, such as giving letters for participants to take home, this only resulted in two participants. Two participants told me that their relatives were unable to take part due to work commitments. The outcome of this was that I then had to recruit carers via a different route, a local carer support group. This resulted in three more participants. Again, had I contacted this carer support group at an earlier stage in the study, I may have been more successful. I was told that members of this

carer support group were currently being consulted by the local council, which meant that there were few who had the time to help me with my research. I was slightly more successful with paid carers, but I was very dependent on the goodwill of their employers; two of them attended during their paid working hours, two others came in their spare time. One participant failed to turn up at the focus group.

Healthcare professionals

I considered that the choice of an asynchronous online discussion forum for healthcare professionals would maximise the number of participants, as they could participate at their convenience and would not have to find time to attend a focus group. I also made the assumption that their computer literacy would be at a level able to use this technology. Several potential participants had problems returning my consent form via email, and then logging onto the website. Despite being sent detailed, simple instructions on how to do this, I lost these participants. Several who had promised to participate did not even attempt to register on the website. Careful consideration needs to be given when trying to access a busy working group of participants; NHS staff certainly seem to be in this group and I had to constantly remind participants to continue with the study.

Having reflected on the strengths and limitations of this study, I would like to conclude this chapter with a short account of how I might have approached the study differently.

8.12.3 *Lessons learned from the conduct of this research project*

Recruitment

Recruitment of people with learning disability in this study was a challenge; not only participants with learning disabilities, but also healthcare professionals and carers. It might therefore have been beneficial to recruit via different routes.

In view of the fact that annual health checks are now established for people with learning disabilities, I think I would have recruited via GPs and observed health checks and follow-up blood tests if requested. This would have several advantages over the method I used. Firstly, I would have been able to observe GP consultations, which may have been revealing in terms of communication. Secondly, I would have identified more people who were having blood tests, as it is likely that the majority would be asked to have routine bloods such as full blood count, thyroid function etc as part of the annual health check. By doing this, I could have observed any differences between nurses, healthcare assistants, phlebotomists and doctors in the consent process, or indeed identify who was obtaining consent. Recruiting via GP practices would entail the use of GPs as gatekeepers; assuming this is a role they would accept, it is possible that more participants would have been recruited. However, there is some evidence that higher research participation among people with learning disabilities occurs where the researcher can make direct contact with the potential participant, rather than relying on gatekeepers (Cleaver, Ouellette-Kuntz & Sakar, 2010). These authors surmised that:

"investigators would be able to present a more convincing case to potential participants than could an individual less directly involved" (p 191)

It is worth re-considering here whether this could be construed as coercion; I think this is unlikely in view of the low risk nature of this qualitative study. By

accessing people with learning disabilities via their GP, I also consider this would have resulted in access to a greater number of healthcare professionals. In order to do this, closer liaison with the local primary care trust (PCT) would have been essential, and it may also have been necessary to enlist the support of certain staff at the PCT in order to encourage practices to participate.

In retrospect, I could have spent more time familiarising myself with the local learning disability organisations, both statutory and voluntary. I felt that I was only getting part of the picture, as illustrated by not finding a useful gatekeeper until I had almost finished data collection.

Methodology

On reflection, I wonder if focus groups would have been equally as effective as interviews when collecting data from people with learning disabilities. By utilising existing groups such as self-advocacy groups, recruitment might have been more straightforward. My only reservation about this is that I might have found it difficult to facilitate such a group – although in the case of People First, I could possibly have asked the paid facilitator there to help. I did note when I visited one self-advocacy group to talk about my research that there was a lot of ‘overtalking’ and interrupting going on, so it might have been difficult to enforce the ground rules of allowing people to speak. Focus groups have been used successfully in research involving people with learning disabilities, (for example, Barr, McConkey & McConaghie, 2003; Fraser & Fraser, 2001) but with acknowledgement that this method may exclude people with communication difficulties and also that such groups need well trained and prepared moderators. One potential problem with accessing self-advocacy groups could be limited variation in the sample, as only the more articulate and independent

people are likely to join these groups. Other issues can also arise, such as the role of any supporters or facilitators present and their effect on the data, and the fact that some of these groups are 'over-researched' (Kaehne & O'Connell, 2010). However, a benefit would be that this would avoid the problem that gatekeepers expressed about not wanting to 'rock the boat' with parents. Both gatekeepers mentioned the fact that they should ask parents' permission for the service user to participate; maybe if I had accessed a group, this might not have been considered necessary or appropriate (compared with an individual interview that might seem more threatening to an overprotective parent).

With regard to the data collection method used for healthcare professionals, I consider it might have been better to have accessed pre-existing groups as focus groups, for example, practice nurse groups or primary healthcare team meetings. My reservations about this were the time constraints, which is one of the reasons why I chose an online method. However, the online method had limited success due to the technical problems/lack of IT literacy among healthcare professionals recruited.

In this chapter I have discussed the findings of the study in relation to the research questions, and discussed other important themes which were identified. I have linked the study findings to those of the literature review, to the policy context and to wider theories I considered relevant to this area of study. I have also identified the strengths and limitations of the study.

In the final chapter, I will outline the final conclusions and what these will contribute to the body of knowledge in the fields of healthcare for people with learning disabilities and genetic healthcare. I will also describe the implications for practice and suggest further lines of research.

Chapter Nine

Conclusions

9.1 Introduction

In the previous chapter I discussed the findings of this study in relation to the research questions. I also described findings that, although not directly answering these, were relevant as they illustrated some of the issues involved in conducting research in the field of learning disability, and could also help explain some of the findings. I then attempted to place this study into the historical and ideological context of the healthcare of people with learning disabilities over the last forty or so years.

In Chapter 3, I explained why this study could be defined as a focused ethnography; it had a shorter timescale than a traditional anthropological ethnography, it focused on a specific problem in a particular context and the findings could be applied by healthcare professionals. In this chapter, therefore, I will make some recommendations for clinical practice. I will also suggest how this study has contributed to theory and what it has contributed to methodological knowledge in the field of learning disability research. Finally I will make some recommendations for future research and describe how the findings of this research will be disseminated.

9.2 Implications for practice

9.2.1 *The need for education about the Mental Capacity Act (2005)*

It was clear from the findings of this study that knowledge of the MCA (2005) was inconsistent in healthcare professionals; paid carers appeared to have a

greater knowledge of the rights of people with learning disabilities in relation to consent, but family carers did not seem to be fully aware of these. The topic of informed consent was not explicitly discussed with people with learning disabilities, but the data showed little awareness of the process of consent to healthcare interventions.

9.2.1.1 *Healthcare professionals*

Training on the Mental Capacity Act (2005) was made available to all HCPs following its implementation in 2007. However, attendance for training is not likely to have been compulsory. General Practitioners and their staff have only a small number of patients with learning disability and it may therefore be the case that the information provided during training is not retained (although of course it relates to all patients). In the case of a blood test, it may be that the consent process is not considered relevant, as in patients without learning disability, their presence in the consulting room is taken as implied consent. Without reiterating the complexities of consent and capacity, I would just like to stress the importance of valid consent being in place for *any clinical procedure*, and thus the requirement for primary care staff to be fully cognisant of its implications in the case of people with learning disabilities.

9.2.1.2 *Paid carers*

As mentioned above, the data demonstrated that paid carers have good awareness of the rights of people with learning disabilities. This is likely to be because the organisation that employ them specialise in the care and support of people with learning disabilities, and adopt the current political ethos of person-centred planning along with awareness of the MCA (2005).

9.2.1.2 *Family carers*

Family carers need to be made aware of the rights of the people they care for (and indeed their rights as family members). Most importantly, they need to be aware of the concept of mental capacity, its definition and criteria; if the person they support has capacity then they should be allowed to make their own decisions, with appropriate support and information. If, however, that person does not have capacity, the carers need to understand the concept of 'best interest' and how family members should be involved in making decisions, alongside others such as HCPs and possibly paid carers. This training could be provided at local carers' groups or via providers of support in the community.

9.2.1.3 *People with learning disabilities*

Finally, I need to consider the people at the centre of this study, those with learning disabilities. Because the focus of this study was not on the provision of information or education on mental capacity and consent for people with learning disabilities, I cannot state with certainty that they are *not* receiving this information. However, in view of the known characteristic of acquiescence and possible inexperience in decision-making, it is essential that people with learning disabilities are made aware that it is their right to be given information in a format accessible to them (if they want it), and to make decisions for themselves with appropriate support. They need to know that they can say "No".

9.2.2 *Genetic education for healthcare professionals*

The majority of the HCPs in this study, whether working in general practice or for specialist learning disability services had little knowledge of pharmacogenomics. This is understandable as it is not yet widely available

outside of secondary care in the UK. However, as described in Chapter 8 there is evidence to show not only a low level of genetic knowledge in primary care but also inadequate genetic education in medical schools and the attitude that genetics is not really of concern to primary care. If pharmacogenomic tests are going to be valuable as a tool to tailor patients' medication to their genotype, then there needs to be an increased awareness of developments in this field. This is likely to happen; a recent communication on the US National Institutes for Health (NIH) website announced a \$15 million dollar investment over the next five years to expand the Pharmacogenomics Knowledge Base (2010), one of the aims being to develop guidelines for doctors to customise dosages of certain medications using genetic information. Whether similar investment will follow in the UK remains to be seen.

9.2.3 The provision of accessible information at the appropriate time

If the requirements for informed consent are to be fulfilled, information should be provided in a format appropriate to *each individual*. The format could be printed material, in large font, with simple short words and sentences and no medical jargon. This could include images if required. Alternatively, information could be in the form of a CD-ROM or video. In any of these cases, it would be useful for the information to be provided in advance so that the patient has time to read (or view) it at their own pace, with support if necessary. By doing this, informed consent should be facilitated, as the patient will attend the surgery having already benefited from information about the procedure to be carried out. This should also help to reassure the healthcare practitioner that the patient has good understanding of what they are being asked to consent to. The procedure

could then be discussed, with carer support if necessary, and any questions answered.

In the case of a pharmacogenomic test, the underlying basis of the test should be explained; the test is not a routine genetic test, nor does it have the same basis as a routine biochemical or haematological test. However, an in-depth explanation of the science involved in pharmacogenomics should not be necessary or required. The Mental Capacity Act states that a patient should be given information sufficient to have a *broad* understanding of what they are consenting to, including any risks and benefits (Ministry of Justice, 2007). Patients (and HCPs) should be reassured that there would be no implications for family members or identification of factors which would predict disease.

9.2.4 Continuity of care

One of the themes repeatedly identified from the data was that of trust between patient and HCP, in particular the doctor. Carers who were satisfied with the care their service-users obtained from their primary healthcare team were those who said that the staff knew the patient well. It has been suggested that patients who are well known to healthcare professionals receive better care (Jones *et al*, 2008). Evidence has shown that staff in primary care have little knowledge of learning disability and often do not appreciate the complex communication problems experienced by people with learning disability (Michael, 2008). It is important, therefore, for a person with learning disability to receive continuity of care, seeing the same GP or nurse on each visit if possible, so that communication can be optimised as patient and doctor or nurse come to understand each other.

9.3 Contribution to theory

In Chapters 1 and 8, I outlined the theories that I considered were relevant to this study. It is difficult to restrict this discussion to one theory in particular, as they are all to a certain extent inter-related and cannot be considered in isolation. For example, in the social model of disability, disability is seen as socially constructed and it is considered that removing the barriers that cause the disability will remove the disability. This has been a subject for debate, with writers like Shakespeare stressing that impairment cannot be left out of the social model, and will remain after removal of barriers (Shakespeare, 2010). It also appears to be the consensus that the social model of disability cannot really be applied to people with learning disabilities, as it based on physical impairments (Chappell, 1998).

It has been said that people with learning disabilities experience oppression in a similar way to other oppressed groups (Goward & Gething, 2005). Oliver (1990) suggests that this oppression is based on the barriers in society as described in the social model. Oppression is also a component of empowerment theory. As described in Chapter 8, Oliver (2009) describes the struggle that the powerless (in this case, people with learning disabilities) face to get their views heard, in the context of oppression by others.

The key question here is whether individuals with learning disability see themselves as oppressed, or even identify themselves as having a learning disability. As discussed previously, there is some debate about whether people with learning disabilities identify with the learning disabled label or make positive efforts to be seen as 'non-disabled' (for example, Craig *et al.*, 2002; Walmsley, 2005). However, the increased emphasis on involving people with

learning disabilities in research as co-researchers as well as participants as described by Stalker (1998) and more recently Grant and Ramcharan (2009) would imply a certain level of self-awareness of disability. If people with learning disabilities are offered education on consent, capacity and their right to make their own decisions, together with being offered the opportunity to participate in and plan research in the field of learning disability, I consider that this is when real empowerment will occur. Whether or not oppression is a prerequisite for this empowerment is debatable; I view empowerment simply as the opportunity for people with learning disabilities to live their lives as they choose rather than their lives being dictated by 'non-learning disabled' policy makers.

9.4 Contribution to methodology

9.4.1 Recruitment

The initial decision to include only participants who were judged as having capacity to consent to research, together with the use of gatekeepers to identify them, has limited the transferability of the findings. On reflection, I would suggest that it is essential to recruit a maximum variation sample for this type of study, and to do this would necessitate the inclusion of people whose capacity might be in doubt. As a novice researcher, I was wary of both the complexities of obtaining NHS Ethics approval for research involving people without capacity, and also collecting data from people that I may not have had the communication skills to interview. Despite these reservations, in view of the fact that the research was low risk and had the potential to be of benefit to the population of people with learning disabilities as a whole, I would recommend widening the inclusion criteria.

9.4.2 Introduction of new health technologies

I have demonstrated in this study that it is of value to clinical practice to explore the needs and attitudes of people with learning disabilities (and possibly other vulnerable populations such as older people) prior to introducing any new health technologies. By so doing, healthcare practitioners can be made aware of these needs and thus provide an appropriate service for people with learning disabilities. However, further research may need to be conducted to establish the feasibility of using vignettes in research involving people with learning disabilities; researchers may need training in specialist techniques in assessing the understanding gained when vignettes are used.

9.4.3 The use of video- recording

The use of video in the consent interview minimises the likelihood of the researcher being viewed as coercive in the recruitment process, as there is visual evidence of any incongruence between spoken and body language. It is also a valuable addition to the ethnographic 'toolkit', as body language is recorded and can be viewed throughout the data analysis stage to supplement the observation or interview transcript. This is particularly useful when conducting researching involving people with learning disabilities, as communication can often be difficult, and speech indistinct. The video data in this study served to clarify doubtful passages of speech and was sometimes quite illuminating; for example, it would illustrate whether a comment was meant as a serious one or whether the participant was teasing. I would, however, make one caveat: the researcher effect may be more pronounced when using video as well as audio-recording and this must be considered when analysing the data.

9.5 Further research

9.5.1 Replicating the same study with non-learning disabled participants and other vulnerable populations

Replication of this study with different participants (patients) such as older people or those with dementia would provide additional evidence to show whether or not the findings in people with learning disabilities were unique or whether they simply represented 'normal variation' in the population.

9.5.2 Conducting a large scale study, with a maximum variation sample

The numbers recruited for this study and the variation in participants, although adequate for the purpose of doctoral research, may limit the transferability. In order to obtain data from people with a wider range of learning disability and having different personal circumstances, it would be advisable to conduct a large scale study, recruiting people with and without capacity, of a wider age range. In Wong *et al* (2000), the real situation of needing a blood test was used; this is likely to be a familiar scenario for people with learning disabilities – and should become more so, with the development of health action plans as advocated in the new primary care contracting framework for people with learning disabilities in the UK (National Health Service Primary Care Contracting, 2007). I consider that this development not only makes a larger scale study feasible, but also might facilitate the use of a mixed methods approach in which the influence of such factors as residential status, opportunity for decision-making and health experience on ability to consent could be assessed.

9.5.3 Further research with healthcare practitioners on attitude to people with learning disabilities

This study illustrated the inadequacy of the consent process in general practice; the reasons for this are not clear. For this reason, I would recommend a qualitative study exploring the views of health professionals and staff working in general practice about the health care of people with learning disabilities and how they approach it.

9.6 Summary

To conclude: the aims of this study were to explore the information needs of people with learning disabilities with respect to pharmacogenomic tests and to identify ways of facilitating informed consent. This was achieved by observation of current practice in obtaining consent for a blood test for a person with learning disability in general practice, by exploring the attitudes of health care staff and carers to offering pharmacogenomic blood tests to people with learning disabilities, and by ascertaining the information requirements of people with learning disabilities prior to having a new kind of blood test. As the study progressed, the emphasis changed and I found myself focusing more on capacity and consent issues, as these are relevant to the introduction of *any* new health procedure. As well as answering the research questions, therefore, I consider that I have been able, in this study, to identify ways to approach and implement research involving people with learning disabilities.

Appendices and references

Appendices

Appendix 1	Introductory letter to participants with LD
Appendix 2*	Participant Information sheet (PIS) Phase 2 (LD)
Appendix 3*	PIS Phase 3 (LD)
Appendix 4	PIS All phases – healthcare professional (HCP)
Appendix 5	PIS All phases (Carer)
Appendix 6	PIS Phase 4 (HCP online)
Appendix 7	PIS Phase 4 (Key informant)
Appendix 8	PIS (Supporter)
Appendix 9	Consent form Phase 2 (LD)
Appendix 10	Consent form Phase 3 (LD)
Appendix 11	Consent form All phases (non LD)
Appendix 12	Consent form Phase 4 (HCPs on line)
Appendix 13	Consent form Phase 4 (Key informants)
Appendix 14	Phase 3 Interview schedule
Appendix 15	Phase 4 Focus group guide (carers)
Appendix 16	Phase 4 Online bulletin board questions
Appendix 17	Sample transcript Phase 2
Appendix 18	Sample transcript Phase 3
Appendix 19	Transcript from Phase 4 online bulletin board
Appendix 20	Transcript from Phase 4 carers focus group

Appendix 21	Sample transcript from Phase 4 (Key informant)
Appendix 22	Approval letter from Frenchay NHS Research Ethics Committee (REC) 6 August 2008
Appendix 23	Approval letter from Frenchay NHS REC 1 st substantial amendment 11 November 2008
Appendix 24	Approval letter from Frenchay NHS REC 2 nd substantial amendment 13 March 2009
Appendix 25	Approval letter from Frenchay NHS REC 3 rd substantial amendment 17 September 2009
Appendix 26	Approval letter from Frenchay NHS REC 4 th substantial amendment 1 March 2010
Appendix 27	Published paper: Goldsmith, L., Skirton, H. & Webb, C. (2008) 'Informed consent to healthcare interventions in people with learning disabilities - an integrative review'. <i>Journal of Advanced Nursing</i> , 64 (6). pp 549-563.

* Images of blood test procedure in Appendix 2 and Appendix 3 were used with the permission of the authors of an accessible blood test leaflet produced by Hull and East Yorkshire hospitals NHS trust and Humber Mental Health Teaching NHS trust



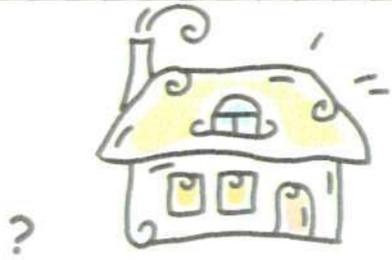
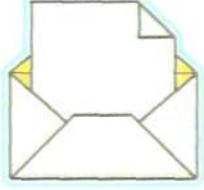
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Dear

	<p>My name is Lesley Goldsmith .</p> <p>I work at the University of Plymouth.</p>
	<p>I would like to talk to you about some work you might be able to help me with.</p>
	<p>You can say 'Yes' or 'No' to seeing me.</p>

	<p>You can choose where to see me - this could be where you live, or somewhere you go during the day.</p>
	<p>You can have someone with you if you like. This could be your key worker or one of your family.</p>
	<p>Could you please fill in the form attached to this letter?</p>
	<p>I have given you an envelope to put it in.</p>
	<p>Please ask someone to help you with this if you like.</p>
	<p>Thank you.</p>

Dear Lesley

My name is (Please print your name)

I agree for you to come and talk to me about your work. I would like to talk to you at:

.....
.....
.....
.....
.....

(Please write the address in this space)

You can get in touch with me at the following phone number:

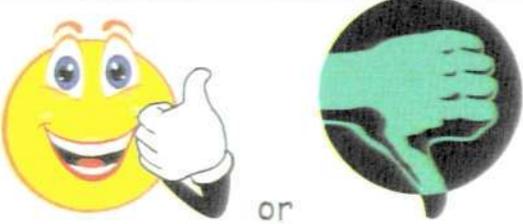
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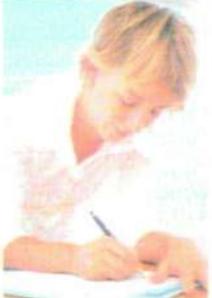
(Please write the phone number where I can talk to you)

Signed:

(Please sign your name here)

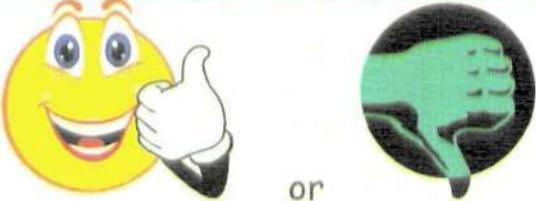
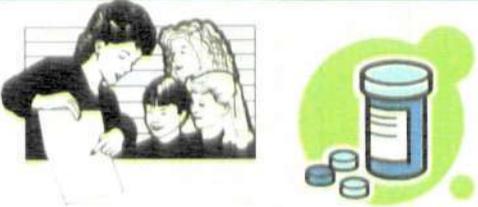
Information sheet for service users
Making choices about health (Phase 1)

 <p>or</p>	<p>It is good for everyone to decide what happens to them when they see a doctor or a nurse. Everyone should be able to say 'Yes' or 'No'.</p>
	<p>I want to find out what happens when you go to the doctor's for a blood test.</p>
	<p>I would like to sit in the room at the doctor's when you have your blood test.</p>

 or 	<p>You can say yes or no to this.</p> <p>If you say no, you do not have to say why.</p>
	<p>If you say yes, I would like to video what happens so I know what people said.</p>
	<p>If you say yes and then change your mind, this will be OK.</p>
	<p>What happens at the doctor's will be kept private.</p>
	<p>I will write a report about the study, but will not use anyone's name.</p>
	<p>I would like to tell your doctor that you are helping me with this project.</p>

Information sheet for service users

Making choices about health (Phase 2)

 <p>or</p>	<p>It is good for everyone to decide what happens to them when they see a doctor or a nurse. Everyone should be able to say 'Yes' or 'No'.</p>
	<p>I would like to hear what you think you need to know when you decide if you are going to have a blood test.</p>
	<p>I would also like to tell you about a kind of blood test that might help the doctor choose the right medicine for you.</p>
	<p>I hope you will tell me some good ways that I could explain blood tests to you.</p>
	<p>We can do this at a place you know, and I will arrange it for you.</p>

	<p>You can have someone with you if you like.</p> <p>This could be your key worker or one of your family.</p>
	<p>If you say ok, I would like to video our chat so I can be sure what you said.</p>
 <p style="text-align: center;">or</p>	<p>You can choose whether to say yes or no. You do not have to say why.</p>
	<p>If you say yes and then change your mind, this will be OK.</p>
	<p>I will write a report about the study, but will not use anyone's name.</p>

How will the study make things better?

Most people think that people should be able to decide things for themselves.

People can decide for themselves to have a blood test, or not to have a blood test.

How will the study make things better?

Most people think that people should be able to decide things for themselves.

People can decide for themselves to have a blood test, or not to have a blood test.

To decide, a person needs to have some information about the blood test.

I want to find out what information a person should have about a blood test, to help make a decision.

What will happen when the study finishes?

I will be writing a report about what I find. If you are interested, I can come and talk to you about my report.

To decide, a person needs to have some information about the blood test.

I want to find out what information a person should have about a blood test, to help make a decision.

What if there is a problem?

If you have any worries at any time during this study, you should talk to your key worker, or you can contact me (Lesley Goldsmith) by phone on 01752 586715 or 07866 560762.

What will happen when the study finishes?

I will be writing a report about what I find. If you are interested, I can come and talk to you about my report.

Research Study Information Sheet

Making choices about health:

Supporting people with learning disabilities

I would like to invite you to take part in this study. Please take time to read the following information carefully before you decide whether or not you are willing to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is not clear, and take your time to decide whether to participate.

Part 1

What is the study about? This is a study to find out about how people with learning disabilities could give their consent to having a genetic test. It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup. The aim of my study is to explore the needs of people with learning disabilities to help them understand these new genetic tests. To do this, I am interviewing people with learning disabilities, people who support them and health professionals.

Why am I being asked to take part in this study? As a health professional involved in the care of people with learning disabilities, I am interested in hearing your views and experiences.

Do I have to take part? No, it is entirely your choice whether you take part or not. Even if you agree to take part, you can still change your mind at any time.

What will happen if I agree to take part? In the first part of this study I would like to make a video of your patient attending the surgery for a routine blood test. This will involve making a video during the consultation, in which the participant themselves, the healthcare practitioner taking the blood and any carer present will be recorded.

The aim of this study is to facilitate ways of enabling people with learning disabilities to give informed consent to new genetic tests, in particular pharmacogenetic tests, which may be available in the future. This first part of the study will identify current practice of obtaining informed consent to a blood test in general practice - in particular the way information is given. The observation will focus on the communication between the parties in the consulting room.

In the second part of the study, I would like to invite you to take part in an on-line bulletin board discussion. This will involve you answering simple questions which the researcher will be posting on the board. Other participants will see your comments when they log in to the bulletin board, and you will be able to respond to each other's comments - in effect, an on-line focus group. This part of the study is designed to stimulate discussion between healthcare professionals, and topics will include informed consent, your views on the way health care is provided for people with learning disabilities, and your thoughts on pharmacogenetic testing. Your input to the bulletin board will be anonymous, and the data will be analysed as part of the study. You will be supplied with details on how to access the bulletin board.

What are the benefits of this study? We hope that the results of this study will help us to make sure people with learning disabilities are given the same opportunity as others to make up their own minds about whether they want to have these new genetic tests when they are available.

What are the possible disadvantages or risks of taking part? In the unlikely event that practice that may harm the patient is identified during the study, this will be discussed with the professional concerned, and may be reported to the patient's general practitioner.

What will happen when the study finishes? A report of the study will be produced as part of my PhD course, and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it.

What if there is a problem? Any complaints about the conduct of the study will be addressed (further details below).

Will my taking part in this study be kept confidential? Yes, I will follow ethical and legal guidelines, and all information about you will be handled in confidence (further details below).

If the information in Part 1 has interested you, and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study? You are free to withdraw from the study at any time. You can decide whether you will allow data collected up to the time of your withdrawal to be retained and analysed for the purposes of the research.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do her best to answer your questions (Lesley Goldsmith, tel: 01752 586715, mobile 07866 560762)). If you remain unhappy and wish to complain formally, you can do this through my supervisor at the Faculty of Health and Social Work, University of Plymouth (Dr Heather Skirton, tel: 01823 366911).

Will my taking part in this study be kept confidential? All data collected during this study will be kept confidential. Both the video and the corresponding transcripts from Phase 1 will be kept either in a secure file on the researcher's computer at the University of Plymouth, or in a locked cabinet. Participants will be given pseudonyms, and will not be identifiable. In Phase 3 (online bulletin board), participants will choose a user name for themselves, which will ensure anonymity. Only the researcher and other participants will have access to the bulletin board during its operation. It will be the responsibility of you as a participant to ensure that you do not inadvertently identify yourself once using the bulletin board. The researcher's academic supervisor will have access to the subsequent transcripts from the bulletin board, for educational purposes. You have the right to check the data obtained and correct any inaccuracies.

What will happen when the study finishes? As outlined previously, I will produce a report of my research for my PhD thesis and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. All recordings will be destroyed after the PhD award is given.

Who is organising and funding the research? This research is being sponsored by the Faculty of Health and Social Work, University of Plymouth.

Who has reviewed the study? This study has been reviewed and approved by Frenchay Research Ethics Committee.

What do I do if I have questions about the study? You can contact me to ask questions by phoning me on 01752 586715 or on my mobile 07866 560762, or you can email me at lesley.goldsmith@pms.ac.uk.

You will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to read this information sheet.

Research Study Information Sheet

Making choices about health

I would like to invite you to take part in this study. Please take time to read the following information carefully before you decide whether or not you are willing to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is not clear, and take your time to decide whether to participate.

Part 1

What is the study about? This is a study to find out about how people with learning disabilities could give their consent to having a genetic test. It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup. The aim of my study is to explore the needs of people with learning disabilities to help them understand these new genetic tests. To do this, I am interviewing people with learning disabilities, people who support them and health professionals.

Why am I being asked to take part in this study?

As the carer of someone with a learning disability, you are likely to have valuable experience that I would like to hear about.

Do I have to take part? No, it is entirely your choice whether you take part or not. Even if you agree to take part, you can still change your mind at any time.

What will happen if I agree to take part? In the first part of this study, I will be making a video of the person you support having a blood test (with their consent). As you may be present, I will need your consent for you to be included in this video.

In the second part of the study, I may invite you to take part in a focus group with other carers (discussion involving 6-8 people). It will take between 45 and 90 minutes and the discussion will be tape recorded.

What are the benefits of this study? We hope that the results of this study will help us to make sure people with learning disabilities are given the same opportunity as others to make up their own minds about whether they want to have these new genetic tests when they are available.

What are the possible disadvantages or risks of taking part? Difficult issues may arise during the focus group discussion. If at any time you feel you would prefer to withdraw from the discussion, you will be free to do so. If you need to talk to someone, you should contact your GP or local carer support worker (details available separately).

What will happen when the study finishes? A report of the study will be produced as part of my PhD course, and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it.

What if there is a problem? Any complaints about the conduct of the study will be addressed (further details below).

Will my taking part in this study be kept confidential? Yes, I will follow ethical and legal guidelines, and all information about you will be handled in confidence (further details below).

If the information in Part 1 has interested you, and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study? You are free to withdraw from the study at any time. You can decide whether you will allow data collected up to the time of your withdrawal to be retained and analysed for the purposes of the research.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do her best to answer your questions (Lesley Goldsmith, home tel: 01752 606596, mobile 07866 560762)). If you remain unhappy and wish to complain formally, you can do this

through my supervisor at the Faculty of Health and Social Work, University of Plymouth (Dr Heather Skirton, tel: 01823 366911).

Will my taking part in this study be kept confidential? All data collected during this study will be kept confidential. Only the researcher and her academic supervisors will have access to the video tapes and subsequent transcripts from the observations of the consultation, and to the transcripts from the focus groups, for educational purposes. You have the right to check the data obtained and correct any inaccuracies.

What will happen when the study finishes? As outlined previously, I will produce a report of my research for my PhD thesis and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. All recordings will be destroyed after the PhD award is given.

Who is organising and funding the research? This research is being sponsored by the Faculty of Health and Social Work, University of Plymouth.

Who has reviewed the study? This study has been reviewed and approved by Frenchay Research Ethics Committee.

What do I do if I have questions about the study? You can contact me to ask questions by phoning me on 01752 586715 or on my mobile 07866 560762, or you can email me at lesley.goldsmith@pms.ac.uk.

Thank you for taking the time to read this information sheet.

Research Study Information Sheet

Making choices about health:

Supporting people with learning disabilities

I would like to invite you to take part in this study. Please take time to read the following information carefully before you decide whether or not you are willing to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is not clear, and take your time to decide whether to participate.

Part 1

What is the study about? This is a study to find out about how people with learning disabilities could give their consent to having a genetic test. It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup. The aim of my study is to explore the needs of people with learning disabilities to help them understand these new genetic tests. To do this, I am interviewing people with learning disabilities, people who support them and health professionals.

Why am I being asked to take part in this study? As a health professional involved in the care of people with learning disabilities, I am interested in hearing your views and experiences.

Do I have to take part? No, it is entirely your choice whether you take part or not. Even if you agree to take part, you can still change your mind at any time.

What will happen if I agree to take part? I would like to invite you to take part in an on-line bulletin board discussion. Your input to the bulletin board will be anonymous, and the data will be analysed as part of the study. You will be supplied with details on how to access the bulletin board.

What are the benefits of this study? We hope that the results of this study will help us to make sure people with learning disabilities are given the same opportunity as others to make up their own minds about whether they want to have these new genetic tests when they are available.

What are the possible disadvantages or risks of taking part? There are no identifiable risks in taking part in this study.

What will happen when the study finishes? A report of the study will be produced as part of my PhD course, and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it.

What if there is a problem? Any complaints about the conduct of the study will be addressed (further details below).

Will my taking part in this study be kept confidential? Yes, I will follow ethical and legal guidelines, and all information about you will be handled in confidence (further details below).

If the information in Part 1 has interested you, and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study? You are free to withdraw from the study at any time. You can decide whether you will allow data collected up to the time of your withdrawal to be retained and analysed for the purposes of the research.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do her best to answer your questions (Lesley Goldsmith, tel: 01752 586715, mobile 07866 560762)). If you remain unhappy and wish to complain formally, you can do this through my supervisor at the Faculty of Health and Social Work, University of Plymouth (Dr Heather Skirton, tel: 01823 366911).

Will my taking part in this study be kept confidential? All data collected during this study will be kept confidential. When registering for the online bulletin board, participants will choose a user name for themselves, which will ensure anonymity. Only the researcher and other participants will have access to the bulletin board during its operation. It will be the responsibility of you as a

participant to ensure that you do not inadvertently identify yourself once using the bulletin board. The researcher's academic supervisor will have access to the subsequent transcripts from the bulletin board, for educational purposes. You have the right to check the data obtained and correct any inaccuracies.

What will happen when the study finishes? As outlined previously, I will produce a report of my research for my PhD thesis and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. All recordings will be destroyed after the PhD award is given.

Who is organising and funding the research? This research is being sponsored by the Faculty of Health and Social Work, University of Plymouth.

Who has reviewed the study? This study has been reviewed and approved by Frenchay Research Ethics Committee.

What do I do if I have questions about the study? You can contact me to ask questions by phoning me on 01752 586715 or on my mobile 07866 560762, or you can email me at lesley.goldsmith@pms.ac.uk.

Thank you for taking the time to read this information sheet.

Research Study Information Sheet

Making choices about health:

Supporting people with learning disabilities

I would like to invite you to take part in this study. Please take time to read the following information carefully before you decide whether or not you are willing to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is not clear, and take your time to decide whether to participate.

Part 1

What is the study about? This is a study to find out about how people with learning disabilities could give their consent to having a genetic test. It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup (pharmacogenetics). The aim of my study is to explore the needs of people with learning disabilities to help them understand these new genetic tests. To do this, I am interviewing people with learning disabilities, people who support them and health professionals.

Why am I being asked to take part in this study? As a health or social care professional involved in the care and support of people with learning disabilities, or with other relevant experience, I am interested in hearing your views and experiences.

Do I have to take part? No, it is entirely your choice whether you take part or not. Even if you agree to take part, you can still change your mind at any time.

What will happen if I agree to take part?

I would like to conduct a one-to-one interview with you. Topics will include informed consent, your views on the way health care is provided for people with learning disabilities, and your thoughts on pharmacogenetic testing. The interview

data will be anonymous, and will be analysed as part of the study. The interview may take place face-to-face or by telephone, at a time convenient to you, and will be audio-recorded.

What are the benefits of this study? We hope that the results of this study will help us to make sure people with learning disabilities are given the same opportunity as others to make up their own minds about whether they want to have these new genetic tests when they are available.

What are the possible disadvantages or risks of taking part? I consider that the only risks or disadvantages of your participation in this study will be the time commitment on your part.

What will happen when the study finishes? A report of the study will be produced as part of my PhD course, and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. Having been transcribed, the digital audio-recordings will be deleted on completion of the study.

What if there is a problem? Any complaints about the conduct of the study will be addressed (further details below).

Will my taking part in this study be kept confidential? Yes, I will follow ethical and legal guidelines, and all information about you will be handled in confidence (further details below).

If the information in Part 1 has interested you, and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study? You are free to withdraw from the study at any time. You can decide whether you will allow data collected up to the time of your withdrawal to be retained and analysed for the purposes of the research.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do her best to answer your questions (Lesley Goldsmith, home tel: 01752 606596, mobile 07866 560762)). If you remain unhappy and wish to complain formally, you can do this

through my supervisor at the Faculty of Health and Social Work, University of Plymouth (Dr Heather Skirton, tel: 01823 366911).

Will my taking part in this study be kept confidential? All data collected during this study will be kept confidential. The researcher's academic supervisor will have access to the interview transcripts, for educational purposes. You have the right to check the data obtained and correct any inaccuracies.

What will happen when the study finishes? As outlined previously, I will produce a report of my research for my PhD thesis and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. All recordings will be destroyed after the PhD award is given.

Who is organising and funding the research? This research is being sponsored by the Faculty of Health, University of Plymouth.

Who has reviewed the study? This study has been reviewed and approved by Frenchay Research Ethics Committee.

What do I do if I have questions about the study? You can contact me to ask questions by phoning me on 01752 586715 or on my mobile 07866 560762, or you can email me at lesley.goldsmith@plymouth.ac.uk.

You will be given a copy of this information sheet and the signed consent form to keep.

Thank you for taking the time to read this information sheet.

Research Study Information Sheet

Making choices about health

I would like to invite you to take part in this study. Please take time to read the following information carefully before you decide whether or not you are willing to take part.

Part 1 tells you the purpose of this study and what will happen if you take part.

Part 2 gives you more detailed information about the conduct of the study.

Please ask if anything is not clear, and take your time to decide whether to participate.

Part 1

What is the study about? This is a study to find out about how people with learning disabilities could give their consent to having a genetic test. It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup. The aim of my study is to explore the needs of people with learning disabilities to help them understand these new genetic tests. To do this, I am interviewing people with learning disabilities, people who support them and health professionals.

Why am I being asked to take part in this study?

You have been chosen byto act as his/her 'supporter'.

Do I have to take part in the focus group if asked? No, it is entirely your choice whether you take part or not. Even if you agree to take part, you can still change your mind at any time.

What will happen if I agree to take part?

The participant will have received an invitation to a face-face meeting for me to explain the study and obtain consent. As you have been chosen by this participant to be their supporter, they have asked you to attend this meeting with them. At this meeting, I will explain the first part of the study in detail. I will then ask the participant a few questions to assess whether they have understood this information and are capable of giving their consent. I will then ask you, as someone who knows this person well, to confirm that they have capacity to give

their consent, and that they have given consent voluntarily. You will both be asked to sign a consent form. If you feel that the participant is not able or willing to consent, it would not be ethical for me to include them in the study.

What will happen next? In the first part of the study, I will be making a video of the person you support having a blood test (with their consent). As you may be present, I will need your consent for you to be included in this video.

In the second part of the study, I will be inviting the participant to meet me for a one-to-one interview which will last no longer than 30 minutes. Just prior to this interview, I will again confirm that they give their consent, which I will ask you to confirm.

Finally, if you are also this person's carer, I may invite you to take part in a focus group with other carers (discussion involving 6-8 people). It will take between 45 and 90 minutes and the discussion will be tape recorded.

What are the benefits of this study? We hope that the results of this study will help us to make sure people with learning disabilities are given the same opportunity as others to make up their own minds about whether they want to have these new genetic tests when they are available.

What are the possible disadvantages or risks of taking part? There are no significant risks or disadvantages apart from the time commitment involved.

What will happen when the study finishes? A report of the study will be produced as part of my PhD course, and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it.

What if there is a problem? Any complaints about the conduct of the study will be addressed. The detailed information on this is given in Part 2.

Will my taking part in this study be kept confidential? Yes, I will follow ethical and legal guidelines, and all information about you will be handled in confidence. The details about this are given in Part 2.

If the information in Part 1 has interested you, and you are considering participation, please read the additional information in Part 2 before making any decision.

Part 2

What will happen if I don't want to carry on with the study? You are free to withdraw from the study at any time. You can decide whether you will allow data collected up to the time of your withdrawal to be retained and analysed for the purposes of the research.

What if there is a problem? If you have a concern about any aspect of this study, you should ask to speak to the researcher who will do her best to answer your questions (Lesley Goldsmith, home tel: 01752 606596, mobile 07866 560762). If you remain unhappy and wish to complain formally, you can do this through my supervisor at the Faculty of Health and Social Work, University of Plymouth (Dr Heather Skirton, tel: 01823 366911).

Will my taking part in this study be kept confidential? All data collected during this study will be kept confidential. Only the researcher and her academic supervisors will have access to the video tapes and subsequent transcripts from the observations of the consultation, and to the transcripts from the focus groups, for educational purposes. You have the right to check the data obtained and correct any inaccuracies.

What will happen when the study finishes? As outlined previously, I will produce a report of my research for my PhD thesis and you can request a summary if you wish. Although your comments might be included in the report, your name will be changed and you will not be able to be identified by anyone reading it. All data will be destroyed after the PhD award is given.

Who is organising and funding the research? This research is being sponsored by the Faculty of Health and Social, University of Plymouth.

Who has reviewed the study? This study has been reviewed and given favourable opinion by Frenchay Research Ethics Committee.

What do I do if I have questions about the study? You can contact me to ask questions by phoning me on 01752 586715 or on my mobile 07866 560762, or you can email me at lesley.goldsmith@pms.ac.uk.

Thank you for taking the time to read this information sheet.

Title of Project: Making choices about health (Phase 1)

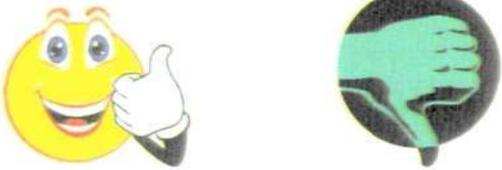
Name of researcher: Lesley Goldsmith

	<p>I have read the information sheet about this project or someone explained it to me.</p>
	<p>I was able to speak to Lesley Goldsmith and ask her any questions about the project.</p>
	<p>I agree to take part in the first part of this project. I know that I can change my mind and pull out at any time. This will be OK.</p>
	<p>I agree that when I have my blood test, a video will be made.</p>
	<p>I know that later on I can ask for anything I said to be taken out of the video recording. I can ask for my video recording not to be used at all in the report.</p>
	<p>I understand that this study is about finding ways that people with learning disabilities can take control of their own health.</p>

Appendix 10

Title of Project: Making choices about health (Phase 2)

Name of researcher: Lesley Goldsmith

	I have read the information sheet about this project or someone explained it to me.
	I was able to speak to Lesley Goldsmith and ask her any questions.
	I agree to take part in the second part of this project. I know that I can change my mind and pull out at any time. This will be OK.
	I agree that when I talk to Lesley Goldsmith she will make a video-recording of our talk.
	I know that later on I can ask for anything I said to be taken out of the recording. I can ask her not to use the video recording in the report.
	I understand that this study is about finding ways that people with learning disabilities can take control of their own health.

Appendix 11

Title of Project: Making choices about health: supporting people with learning disabilities.

Name of researcher: Lesley Goldsmith

Please tick each box

I confirm that I have read and understand the information sheet Version 3. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I confirm that I consent for my involvement to be audio or video-recorded as appropriate.

I agree that the researcher may use anonymised quotations, either for subsequent stages of the research study, or in reports for publication.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and ask for the data to be destroyed.

I understand that data collected during the study may be looked at by the researcher and her academic supervisor.

I agree to take part in the above study.

Name of Participant **Date** **Signature**

Name of Person taking consent **Date** **Signature**

When completed: 1 for participant, 1 for researcher file.

Appendix 12

Title of Project: Making choices about health: supporting people with learning disabilities.

Name of researcher: Lesley Goldsmith

Please place an X in each box

I confirm that I have read and understand the information sheet Version 3. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I agree that the researcher may use anonymised quotations, either for subsequent stages of the research study, or in reports for publication.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and ask for the data to be destroyed.

I understand that data collected during the study may be looked at by the researcher and her academic supervisor.

I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person taking consent

Date

Signature

When completed: 1 for participant, 1 for researcher file.

Appendix 13

Title of Project: Making choices about health: supporting people with learning disabilities.

Name of researcher: Lesley Goldsmith

Please tick each box

I confirm that I have read and understand the information sheet Version 1. for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

I confirm that I consent for the interview to be audio –recorded.

I agree that the researcher may use anonymised quotations, either for subsequent stages of the research study, or in reports for publication.

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and ask for the data to be destroyed.

I understand that data collected during the study may be looked at by the researcher and her academic supervisor.

I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person
taking consent

Date

Signature

When completed: 1 for participant, 1 for researcher file.

Consent to genetic testing in people with a learning disability

Phase 2 Interview schedule

In view of the participants' learning disabilities, and the fact that there will be a range of abilities with regard to communication and understanding, it is difficult to provide an interview schedule in advance.

The interviews will be semi-structured.

Today I would like to tell you about a new kind of blood test which will help the doctor decide on the best medicine for you – but first:

Possible questions:

- Can you tell me a bit about how you feel when you go to the doctor's to have a blood test?

Prompts: What do you like about going to the doctor?

What is the hardest thing for you about going to the doctor?

- There are different kinds of blood test. Some are to find out what is wrong with you if you feel ill. Some are to make sure you are staying healthy. Some are to find out you are taking the right amount of medicine.

Prompts: Would you like to tell me about blood tests you have had?

Do you understand what these were for?

- So now I will tell you about this new kind of blood test. Everyone is different – so we all react to medicines in a different way. This new test helps us find out how you would react to a medicine, so if you had this test in future, it would be to find out how you might react if the doctor thought you needed a particular kind of medicine.

I will be using visual aids such as photographic images, cartoons etc, if appropriate to support this explanation.

Prompts: So, could you please explain to me what you think this test is about?

Now I have told you about it, if the doctor wanted you to have this kind of test, do you think you would say yes?

Do you have any worries about this kind of test?

- What would you like to know before you decide to have a blood test like the one I've just talked about?

Prompts: What is this test for?

How will it help you?

Will it be painful?

Do you have any worries about this kind of test?

- When people explain things like blood tests to you, there are different ways they can do this. Which way do you find the easiest to understand?

Prompt: Written information sheet, information sheet with symbols, information sheet with photos, video – show examples of each.

Consent to genetic testing in people with a learning disability

Focus group guide (Carers)

- I would like you to introduce yourselves (first name only), and tell the group a little about your role as a carer
- You are carer for a person with a learning disability. How much involvement do you have with your their medical care?
- To what extent are they able to make their own decisions about their own medical or health care?

Prompt: Does it depend on the circumstances?

- Do you think they should be encouraged to make their own decisions?
- If they are making decisions, what helps? If they are not making decisions, what hinders this?
- I would like to hear about your experiences of attending the surgery with the person you care for, for a blood test

Prompts: Is it explained to the person you care for?

If so, how is it explained?

Are they asked if they agree to the blood test?

Sufficient time?

Method of presenting the relevant information?

Particular communication issues?

- I would like to share some comments made by people with learning disabilities about having a blood test

Prompts: Would any of you like to make any comments about this comment?

- It is likely in the future that we will be able to have a genetic test that shows which medicines are best for us, according to our genetic makeup.

Prompts: Do you see this kind of blood test as being any different from those already in use?

How easy is it to understand?

- How would you feel about the person you care for being offered a test to help health professionals to prescribe for him or her in the future?

Prompts: Do you envisage any particular issues arising with regard to informed consent in this context?

Do you think they would have the capacity to understand this type of test?

How could they be helped to understand this type of testing?

There will be two focus groups of carers – one for paid, one for family (unpaid) carers.

Appendix 16

Consent to genetic testing in people with a learning disability

Bulletin board question guide (Healthcare professionals)

- Could you start by saying something about your current professional role?

- What is your experience of involving patients with learning disabilities in decisions about their own medical or healthcare?

- What do you find are the particular challenges to gaining informed consent from people with learning disabilities for their medical or healthcare?

- How do you personally deal with obtaining informed consent for minor procedures such as blood tests?

- There has been a lot of talk about pharmacogenetic testing in the media. Before today, how aware were you of this?

- What are your thoughts about offering pharmacogenetic testing (when available) to your patients?

Anonymised quotes from the data obtained in Phase 1 of the study (observation of a consultation for a blood test) may be used in this question guide to stimulate discussion.

Appendix 17 (B transcript 20 February 2009)

- 1 N You good at computers, are you?
- 2 B Oh, no[no]
- 3 N [Cos I can] just about manage what I have to here
- 4 B [No, no] I know, but they don't, they put a few figures in, and that ain't too
5 bad, you know. I'm a [bit slow.]
- 6 N [No, I dunno], I'm very good at breaking 'em
- 7 B [But then]
- 8 N Can I have your arm a minute?
- 9 B Yes, so... that's Mondays, that's from half-past nine til four, and then
10 eight times out of ten me sister picks me up, cos she works at C, so
11 that's um. You know, it breaks the week up and all that.
- 12 N Yeah, don't want the same old thing all the time, do ya?
- 13 B No, so um Tuesdays, three times, three mornings a week I'm up at R, up
14 at where Lesley's met me, you know
- 15 N Yeah
- 16 B up at M-P, the drop-in centre.
- 17 N Ohhhh, right.
- 18 B So these groups and all that up there. We have advocacy on a Tuesday,
19 and I'm involved in.
- 20 N Right
- 21 B I help the chap who's blind with the computer and that, read it out to 'im.
- 22 N Wow!
- 23 B But you know..
- 24 N You're really busy, aren't you?
- 25 B Yeah, (N laughs loudly). Well, I try to be, you know. (*pulls a face*) Ooh, I
26 don't like this.
- 27 N Don't [like it]
- 28 B [This], no.
- 29 N I've got nothing brilliant for you to look at, but
- 30 B No

31 N you could look at – that's Dr W and [his wife and his children] (raises
32 voice)

33 B [No, no] (loudly) – no, I'll a , I'll a (*pulls a more severe face – obviously in*
34 *pain*)

35 N [Alright, scratch] coming now

36 N Aah

37 (*silence while nurse continues procedure*)

38 B Where's Dr W, then - in the picture? (*smiling, looking a photos on*
39 *board*)

40 N No, that, oh I bet he wishes. He's a bit older than that now.

41 B Yeah?

42 N I think that's his children underneath, and that's his wife

43 B Oh, yeah?

44 N In the top picture. (*Long silence while blood is being taken*)

45 B Nice. Dr W – isn't he here today?

46 N No, not today.

47 B He's here a few times a week, in he?

48 N He is, yeah, he works more up at W Surgery

49 B Do he?

50 N Mmm.

51 B ... () Dr A

52 N Dr A is shorter than Dr W.

53 B Yeah, and he's normally here, in he?

54 N Yeah, downstairs

55 B Yeah. You got the locum in today, haven't you – the locum?

56 N Yeah, Dr S?

57 B Ah, he's a lovely chap. I like him.

58 N Do you?

59 B Yeah, he's very.... Especially with me stump and all that, he's helped me
60 a lot.

61 N Oh, good.

62 B Yeah, he has. He's writ some good letters to some nursing homes and
63 all that for me, last year.

64 N Yeah

65 B Which I must, um, yeah, I must praise him for cos he was very good.

66 N Oh, good. That's what you need though

67 B Yeah, well that's it, yeah, you need support.

68 N Yeah (emphatically) – well that's what we're all here for, innit?

69 B Yeah, that's right.

70 N Yeah, that's that job done

71 B Is it all done?

72 N Yeah

73 B Ah well, that was quick, just a little ha ha, (*smiles*) yeah, alright.

74 N That's that for another [six months now, is it?]

75 B [You got enough?] Yeah, and now you've got me specimen there,

76 N [Yeah]

77 B [you can just] say I've got me period and that

78 N Yeah, I'll put that on your notes when I put the results, alright?

79 B Yeah, alright, just in case something comes up like it did..

80 N I'll put it on there, cos, yeah it has got blood in it, which is expected

81 B Yeah, yeah, yeah that's right.

82 N Unfortunately, though, it's also got sugar in it, so you know K's going to
83 tell you off, don't you? (*peers into B's face and laughs kindly*)

84 B Has it? (*N continues to laugh*) Has it, have you noticed that?

85 N Yeah

86 B You tested it? Yeah, yeah, well (*long pause, looks down and a bit*
87 *'sheepish'*)... we'll have to wait and see next Thursday.

88 N What have you been eating that you shouldn't have been? (*laughs*)

89 I can see that smile (*laughs loudly again*)

90 B No well, you can't always... I try to be good, you know, but

91 N I think it's called being human, S, isn't it? You got to have a treat,
92 haven't ya?

- 93 B Yeah, that's right (*smiles at N – they have a good rapport and*
94 *understanding*)
- 95 N (*laughs again*)
- 96 B Yeah, so – you knows all about it, then, yeah
- 97 N Well, not all about it, a little bit.
- 98 B Yeah
- 99 N There we go – alright?
- 100 B Yeah, cos you go on courses and that, still?
- 101 N Yeah, going on one next week actually
- 102 B Are you?
- 103 N Up in E (name of city)
- 104 B Oh well, all the best, yeah.
- 105 N But luckily K used to live in E, the other healthcare assistant
- 106 B Oh, yeah?
- 107 N And she's gonna drive
- 108 B Oh, lovely.
- 109 N Cos she knows where we're going
- 110 B Oh yeah, good, oh.
- 111 N Alright with that?
- 112 B Yeah
- 113 N And you've got your appointment booked with K for next week?
- 114 B Yeah, twenty, half past nine
- 115 N Half past nine
- 116 B Half past nine, that's all done.
- 117 N Yeah, cos your bloods will be back then for that.
- 118 B Yeah, and then, then I'll have a review with her and talk about a few
119 other things.
- 120 N Alright then
- 121 B Well, alright?
- 122 N Yeah, that's fine

123 B Is that alright, Lesley?

124 L That's fine, thank you.

Appendix 18 (D transcript 2 April 2009)

- 1 LG Right, OK – right. We'll just.. and this won't take very long. I just want to..
- 2 D Right
- 3 LG So, no I think, I was gonna ask you how you feel about when you have to
- 4 go to the doctors for a blood test, but – tell me, how long is it since you
- 5 have had a blood test?
- 6 D About six, about five or six years ago.
- 7 LG Can you remember what that was like?
- 8 D Uh, it was alright.
- 9 LG Was it at the doctors' or the hospital?
- 10 D Doctor, doctors – GPs. I got the flu and he was checking blood pressure
- 11 to see if I was getting better.
- 12 LG Oh, it wasn't um – cos a blood test is when you have um, they put a
- 13 needle in there (*points to inner surface of elbow*)
- 14 D I know
- 15 LG And they wrap something round and take the blood out with a needle, so
- 16 Would you have had that done then, or?
- 17 D A long time ago.
- 18 LG Mm, mm. So how do you feel about going to the doctor's generally?
- 19 D Alright. (nods, smiles)
- 20 LG Does it make you feel..
- 21 D I'm quite confident, you know.
- 22 LG So what's the most difficult thing you, is there anything you don't like
- 23 about going to the doctor's?
- 24 D Hearing the results.
- 25 LG Hearing results?
- 26 D Hearing results.. when he does take the blood test and you go and find
- 27 out what is wrong with you. That's what I don't like about going to the
- 28 doctor's. Cos he always says "Come back to me".
- 29 LG So does that worry you then, going back?
- 30 D A little bit, yeah.
- 31 LG Mmm.
- 32 D So (undecipherable)

33 LG Mmm.

34 D That's alright.

35 LG So, is there anything you LIKE about going to the doctor's?

36 D Yeah, it's alright. Cos they're all friendly, friendly bunch.

37 LG Are they? Nice people?

38 D Yeah, they're alright. (*both nodding*) sees me girls and I'm OK.

39 LG Yeah? And do they – how do you find talking to them. Do they – are

40 they friendly, and treat you well.

41 D Yeah, they listen to you, you know.

42 LG They do

43 D Yeah

44 LG Good

45 D Sometimes the nurse comes in and talks to me – the nurse?

46 LG Mmm Mmm

47 D The only thing, I, I think I had my blood done when I was seeing the

48 nurse.

49 LG Yeah, you would have seen the nurse.

50 D Yeah, some things taken. The nurse does it, doesn't she?

51 LG Yeah, the nurse takes the blood.

52 D Yeah, that was, that was when I, that was the last time I was in.

53 LG That was the last time.

54 D Mmm.

55 LG Mmm. So it doesn't sound as if you worry too much about

56 D No, no, no.

57 LG a blood test?

58 LG Well, I was just going to say, there's different kinds of blood tests. I

59 mean some blood tests are to find out if you are ill, if there is something

60 wrong with you.

61 D That's what I mean.

62 LG Aren't they? Some of them are just to make sure you are staying healthy,

63 so, um to make sure you haven't got too much fat in your blood, or too

64 much sugar in your blood – and that's just to make sure your body is

65 working properly.

66 D They tell you to calm down if you do that

67 LG Yeah (laughs), yeah, yeah. And some people have to have blood tests,
68 like people who are diabetic or [people]

69 D [Anaemic?]

70 LG who have fits.

71 D What about anaemic.

72 LG Or, yes, well anaemic, yes – a blood test will tell you if you are anaemic.

73 D Or diabetic?

74 LG Yes, a blood test would also tell you if you were diabetic.

75 D Mmm. (*nodding repeatedly*)

76 LG And if you were...

77 D What about cancer?

78 LG Um, yes, I think some do, some do.

79 D Yes.

80 LG So there's lots of different tests, blood tests that can do that, and there
81 are some blood tests – if you were taking some kind of medication or
82 medicines, um there are some blood tests to make sure you are taking
83 the right amount.

84 D Yeah.

85 LG So that would, so there are all kinds of reasons, aren't there?

86 D Yeah, mmm.

87 LG So – can you remember what the blood test, it was a long time ago, so –
88 do you know what they were for?

89 D Uh

90 LG Cos you said they were for...

91 D I think it was just checking me over, so I had a brain tumour a while back.
92 Just checking to be sure I was staying healthy. Yeah.

93 LG So you went back to get the results, you were a bit worried, you said
94 didn't you?

95 D Yeah, a little bit

96 LG But um

97 D It was alright.

98 LG So the doctor told you it was all...

99 D It was fine, you know
100 LG It was all fine.
101 D I worried over nothing.
102 LG So what do you think they were, when you had those blood tests – did
103 you really understand? As far as you were concerned, that they were to
104 check that you were staying healthy – is that what you mean?
105 D Yeah, to make sure I wasn't, anything was not wrong with me.
106 LG And it might have come back. Is that what you were worried about?
107 D Yeah, yeah. Cos sometimes it's something, you think you are alright....
108 LG Umm, OK, so umm now I am just going to tell you about, there's this new
109 kind of blood test which may be coming in. At the moment, they are just
110 doing research on it, so it's not available to everybody, but it's kind of...
111 um, now where can I start explaining? Do you know, have you ever
112 heard of things called genes? I don't mean jeans you wear.
113 D Yeah, I know. Genes in your...*(points to own body)*
114 LG Genes in your blood. *(mirrors pointing to body)*
115 D In your blood, yeah,
116 LG In your body cells.
117 D Is that to do with your heart and things?
118 LG Yeah, genes
119 D Yeah
120 LG Genes are things, that, they are in every part of your body, they're inside,
121 they're tiny – we can't see them
122 D It's like a little uh
123 LG They're inside your blood
124 D I know
125 LG inside your cells, your skin, everywhere.
126 D You've got to go for a what's it called?
127 LG Yeah, well you can see, you can have a blood test that looks at your
128 genes.
129 D Yes.
130 LG And genes are things that get passed down from your parents (D nods in
131 agreement), that make you like you are, you know.

132 D Is it to do with if you have an eye test?

133 LG Umm – well, genes affect all parts of your body. They're what gives your
134 body instructions how it's going to work.

135 D Yeah, like your brain and heart.

136 LG Yeah, and they come down, and they are passed down, you know, from
137 your parents. So genes affect what you look like – so I don't know if you
138 look more like your mum or your dad.

139 D Mum, mum.

140 LG More like your mum? So it's the genes that affect how you look.

141 D Yeah (*lots of nodding*)

142 LG And, and sometimes how you behave.

143 D Yeah.

144 LG And there are some genes in your body that affect how your body reacts
145 to different medicines.

146 D Yeah

147 LG So some people, some medicines might suit some people and different..

148 D Some medicines don't.

149 LG Some medicines might suit different people. Some people have nasty
150 reactions. Do you know, do you know of anybody who has, you know,
151 they might take a medicine that might make them poorly.

152 D H's had a reaction before, you know, H my young lady. She
153 had a reaction with taking medicine – she was very sick.

154 LG So what happens if she's taking, if you take a medicine that makes you
155 sick, then what would the doctor do?

156 D They would have to tell you to take them off it, or change it.

157 LG Yeah, yeah. So this new test, new kind of test that might be available is
158 a sort of test that, it will check before a doctor starts someone on
159 medicine, it will check what's the best sort of medicine for that person.

160 D Yeah

161 LG Cos everybody's different.

162 D Yeah, I know that, yeah.

163 LG So, I mean, um, and also it will stop the doctor prescribing a medicine
164 that might make you ill

165 D So you know when that medicine will hurt you.

166 LG Yeah, so it's a sort of test that's really to help the doctor to give you the
167 best medicine, and the best medicine for YOU in particular, which might
168 be different medicine from what they might give me, or Heather. So you
169 know, everyone is different, so that's the sort of blood test it is. Umm –
170 it's just to find out how you might react to certain medicines, and it's
171 based on... you know, they take the blood, and they look at the genes
172 with a very strong microscope.

173 D Yeah

174 LG And they work out what kind of gene you've got for the medicine.

175 D How do they know what gene you've got?

176 LG Well, they're very tiny, they look at very strong microscopes and they...

177 D They must be a funny shape to see what gene you've got

178 LG Yeah, they're.

179 D A funny shape?

180 LG Yeah, they're, they're part of what's called the chromosome, which is.
181 Everybody's got the same number of chromosomes in their cells, you
182 know, but we can't, only really clever scientists can see them, with
183 microscopes. They're trained specially to look at them.

184 D Yeah.

185 LG And they can look and say "Oh, you've got such and such a gene", but
186 there are, as I say, genes give your body instructions how to work, and
187 how to react to medicines.

188 D Mmm.

189 LG So – do you think you have understood what this new kind of blood test
190 is about? What do you think, I just, tell me what I just said to you.

191 D You've explained to me about the new blood tests, have you?

192 LG What have I just said this new blood test might do? How might it help the
193 doctor?

194 D Is it to do with the microscope?

195 LG Yeah, but how will it help?

196 D It's to do with the genes, innit?

197 LG Yeah, that's right, the genes in your blood?

198 D Yeah

199 LG And how will it, how did I say it would help the doctor? How could it help
200 the doctor look after you?

201 D He knows what the problem is. He knows what medication to give you.

202 LG That's right, yes. Yes, so it's quite a different kind of blood test. So if
203 this type of blood test came in, then,

204 D Yes?

205 LG Um, do you think, if your doctor said to you, "Oh, I'm going to do this test
206 on you to see" – say you needed medicine for your heart or something.

207 D Yeah, he would want to try a new medicine

208 LG Would you be willing to have that kind of blood test, do you think, if it
209 meant that you could go on the right medicine?

210 D If it was going to help me, yes, yeah. Then if it's going to help me. If I
211 knew it was going to help me.

212 LG Mmm, yeah, good – OK. So is there anything that would worry you
213 about this kind of test, any different from any other kind of blood test?

214 D Eh, not really, no.

215 LG No, no. So, if the doctor said, you know, I'm gonna give you this blood
216 test (the one that I just explained to you), what do you think you would
217 need to know from the doctor? Is there any information that you think
218 you would ask him before you had the blood test?

219 D Yeah, is it going to uh, how's it going to affect me? Am I going to have
220 uh side effects afterwards.

221 LG Have?

222 D Side effects.

223 LG Side effects – from the blood test?

224 D Yeah, cos some people do, don't they? Is it going to be OK? Will I feel
225 alright?

226 LG That's the main thing, is it, how it's going to affect you, having the blood
227 taken?

228 D Yeah

229 LG And do you think he needs to explain in lots of detail what it's for?

230 D He needs to tell me properly. If it's going to have side effects, then I will

231 know, yeah.

232 LG So, do you think, um, so really, is there anything that would worry you,
233 um – I think I've just asked you that, you said that wouldn't really worry
234 about it any more than any other kind of blood test.

235 D No.

236 LG So, when people explain things to you – if the doctor said he was going
237 to do this kind of blood test, um, what do you think is the best way to
238 explain it?

239 Do you think just talking to someone, or um, there is different ways aren't
240 there, of giving information.

241 D Yeah, I think about writing it down.

242 LG Yeah, would that be helpful to you, do you think?

243 D Writing it down and things?

244 LG Mmm.

245 D And show me some pictures how it looks like.

246 LG Yeah, what do you think is the best way for YOU? How do you like
247 things explained? Not just blood tests, but other things. How do you find
248 it best?

249 D If it's written down for me, I suppose.

250 LG Written down. Do you read?

251 D Yes.

252 LG And do you need pictures, or do you not need pictures when you?

253 D Not really, no.

254 LG No.

255 D It's just that I like to understand properly.

256 LG So if it was written down in words.

257 D I could ask the doctor.

258 LG So if he gave you something to read and then you could ask him
259 questions?

260 D Yeah, yeah.

261 LG What about, can you read anything, or does it need to be quite big print,
262 or are there any special...

263 D I can't see small print very well.

264 LG No. What about the words?
265 D The words? I can't read long words.
266 LG So they need to be..
267 D More that I can understand them properly.
268 LG So, short words and not too complicated.
269 D Yeah, so
270 LG But then, from that, you are quite happy.
271 Is there any other way, I mean what about things like, if there was a
272 video about the new kind of blood test, or
273 D That's a good idea, yeah.
274 LG Or um,
275 D Yeah, video would be better.
276 LG And do you ever go on the computer?
277 D I used to go on the WorkAble computer.
278 LG Did you?
279 D And sometimes in here.
280 LG So have you ever gone onto a computer and looked at something, you
281 know, on the internet or anything like that?
282 D No.
283 LG Or, on CD-ROM for a bit of information?
284 D Sometimes I go on it for the music.
285 LG Yeah. You remember on Monday, L was telling everyone about the
286 D Oh, about the eh,
287 LG Digital television.
288 D Digital television, yeah.
289 LG Well that was on a DVD wasn't it?
290 D I know.
291 LG And he put it in there – so do you think that's a good way to give people
292 information?
293 D Yeah, I think it would be a good idea if you made one for those, then...
294 what to expect.
295 LG Mm. And it would tell you what it was about as well.
296 D Yeah, yeah.

297 LG Yeah, OK.

298 D You'd need someone to help you to do that, wouldn't you?

299 LG Yes, yeah, it's just an idea. I think, because everyone's different, aren't
300 they, and I mean.

301 D Have you asked L about that?

302 LG No, I haven't, but I could talk to L about that, that's yeah, so.

303 D Or N.

304 LG Mm. So you, as far as you're concerned, you would be quite happy with,
305 you know, when you are at the doctor's, you would be quite happy with
306 written information.

307 D Yeah.

308 LG But you think that perhaps other people might, you know
309 D Get confused.

310 LG You know, do you think it is a good idea to have a range of ways of
311 explaining?

312 D I think if I wanted to know, I would take somebody with them so they
313 could write it down.

314 LG That's a good idea.

315 D You know.

316 LG Do you take someone with you when you go.

317 D No, I always go on my own.

318 LG But you think some people might need to take someone.

319 D Take the carers, if it's really bad, you know.

320 LG So if someone had to take a carer with them, or a supporter, then do you
321 think, so would the supporter help them understand it?

322 D I say they would be more confident in themselves

323 LG Mmm.

324 D If they had someone writing, wouldn't they?

325 LG Yeah. And somebody would, what would the supporter do then?

326 D Probably just sit there with them, and make sure they talk to them
327 properly.

328 LG Yes – and explain

329 D You know. They could ask the doctors questions, cos he knows more.

330 LG Yes.

331 D The doctors could tell them, and they could perhaps tell the person.

332 LG Yeah, that's. Because they know the person well, they would know how
333 much the person would understand.

334 D Yeah, yeah.

335 LG Well, I think we've um, yeah, I think we've um.

336 D They might get afraid of the doctor, see, and they might not understand
337 the doctor. Cos sometimes they're foreign doctors.

338 LG Yes.

339 D That's the trouble if you don't understand their language. You don't
340 understand what they're talking about .

341 LG No.

342 D He might be telling you about this drug, it might be in his language or
343 something.

344 LG So in that case the supporter would be helpful because they might
345 understand.

346 D Understand his language.

347 LG Yeah.

348 D Some people can't lip (?) very well cos they're deaf.

349 LG Well, a lot of people with learning disabilities have hearing problems,
350 don't they?

351 D Yeah, mmm.

352 LG Is your hearing alright?

353 D Yeah, it's OK. It was damaged when I had a brain tumour, that's all.

354 LG Mmm.

355 D But only slightly.

356 LG And it's OK now?

357 D Only slightly, I can hear.

358 LG So you've got one good ear and one bad ear?

359 D Yes, it's only slightly.

360 LG Yeah, so OK – well, I think probably that's, we've finished. I think that's
361 really interesting. You've told me.

Appendix 19 (Transcript from online bulletin board)

1 **Informed consent to genetic testing in people with a learning disability⁶**

2 The aim of this discussion forum is to explore the experience, views and
3 attitudes of healthcare professionals involved in the care of people with learning
4 disabilities. We will focus on consent, health care for people with a learning
5 disability, and the new genetic tests. Questions for discussion will be posted on
6 the forum at regular intervals over a period of about six weeks.

7 **Could you start by saying something about your current professional**
8 **role?**

9 **HH**

10 Currently I am a clinical lead Speech and Language Therapist for adults who
11 have a learning disability. Within this role I support individuals to communicate
12 in the most effective way for them and also support their communication
13 partners to understand and support their communication methods. In terms of
14 consent my role often involves assessing the consent of individuals with
15 communication difficulties and supporting people to increase their capacity to
16 consent around a wide range of topics.

17 **KK**

18 I am currently a Speech and Language Therapist working with adults with
19 learning disabilities. I have been involved in several assessments around
20 capacity to consent regarding a variety of issues; moving house, having an
21 operation, etc. On one occasion, I worked alongside a genetic counsellor to
22 assess an individual's capacity to consent to having genetic tests for
23 Huntington's disease.

24 **LG (researcher)**

25 What I find interesting is the misconception among some professionals that
26 'capacity' is an 'all or nothing' state rather than being context, decision and time-
27 specific. I look forward to hearing people's experiences of maximising capacity
28 in various contexts to achieve informed consent.

29 **II**

30 I work as a HCA/Phlebotomist within a general practice. My job often involves
31 taking blood from people with LD and also other monitoring of their general
32 health ie monitoring their weight and blood pressure and ECGS etc.
33 Also to give advise in regards to giving up smoking.

⁶ This transcript was extracted from the online bulletin board; spelling errors and typographical errors have not therefore been corrected.

34 **GG**

35 I currently work as Primary Care Liaison Nurse – one of the main functions of
36 my role would be to assist health professionals to help people with learning
37 disabilities make informed decisions on their health care by providing support,
38 information and advice.

39 **JJ**

40 I am a GP.

41 **What is your experience of involving patients with learning disabilities in
42 decisions about their own medical or health care?**

43 **HH**

44 I have been involved in both increasing individuals' understanding of what the
45 proposed treatment is and also in assessing someone's capacity regarding
46 specific medical treatment in a number of cases.

47 At the moment I am involved with a lady with severe hearing impairment and
48 learning disabilities who requires dental treatment. The dentist (who we have
49 worked with many times before) has proposed that she requires at least one
50 tooth extraction, she appears to have no pain from this at present and is
51 refusing to enter the dental surgery or private hospital where the treatment is
52 proposed to take place.

53 Myself as the SLT and her health facilitator have been working on informing her
54 of the consequences of not undergoing treatment, as well as the possible
55 consequences of having the tooth extraction. We have also been working with
56 the other professionals involved regarding her capacity to make this decision.

57 I have also been involved in other cases in the past whereby where 'life saving'
58 treatment is proposed assessment regarding someone's capacity to make a
59 decision (even if viewed by some as unwise) has been overruled by consultants
60 and a best interest decision has been made on their behalf. ☺

61 **II**

62 I have often been involved in trying to gain consent for a blood test where I have
63 been unsure of the understanding of the procedure by the patient. In this
64 instance it has been necessary to involve the requesting Dr and the carer as to
65 the necessity as to what's in the best interest of the patient. i.e the patient was
66 a diabetic and there was a need for the procedure to take place in the patients
67 best interest due to the medication being taken and the instability of the
68 patients diabetes at that time.

69 **LG**

70 I find both these posts interesting. I wonder if, as you imply, Kanny, that 'best
71 interest' decisions are often made by healthcare professionals when there is a
72 distinct possibility that the patient does actually have capacity to consent for
73 themselves (and thus has the right to refuse treatment)? Equally, I think it might
74 often be the case that although a patient with LD has said 'yes' to a procedure,
75 there is no attempt to ensure that they fully understand what they are
76 consenting to. In one case, a lack of capacity is assumed, and in the other
77 there is assumption of capacity.

78 Would anyone like to comment on this, or give more examples? 😊

79 GG

80 I am currently involved in looking at women whose recall for cervical smear test
81 has been deferred for 3 years at the request of their gp practice and this
82 decision consented to by the primary care nurse and a family member. I am
83 unsure of the process taken to arrive at this point – re information, capacity
84 assessment, best interest checklists, and hope to look at this further – it would
85 appear that there are women out there with a learning disability who are being
86 discriminated against by being denied the opportunity to consent to or decline a
87 smear test without being involved in this decision at all.

88 I think it is important to involve the person from the very beginning by working
89 together as a healthcare team to facilitate informed consent as far as possible
90 and to ensure that the human aspect of this is not removed when they are
91 deemed not to have capacity and a decision is then made in their best interests.

92 I feel a lot of the time decisions are made over the head of the person with a
93 learning disability and between professionals and family members where the
94 person with learning disability is still regarded as either a 'child' or someone who
95 will just not be able to make any kind of decision for themselves. i have also
96 seen a lady who would appear to be perfectly capable to consent to a
97 vaccination being offered it but with out any information as to why, what the
98 vacc was for and side effects – 5 minutes would have covered this and enabled
99 that lady to take some ownership of her health care and decision making
100 without relying on the nurse doing something for her that was in her interests
101 but inadvertently preventing her from making an informed decision.

102 KK

103 Myself (SLT) and a Genetic Counsellor worked with a lady who was suspected
104 to have Huntingdon's disease. We aimed to assess whether she had the
105 capacity to consent to having a blood test and genetic counselling. We worked
106 with her for several weeks over a number of sessions; it was eventually decided
107 that she was able to consent to this. She was then booked in for a blood test
108 and counselling session for the next month. While waiting for the appointment,
109 we received a letter from her Neurologist stating that he had given her a blood
110 test and she did not have Huntingdon's disease. We then wrote a letter to the
111 Neurologist saying that we were disappointed that he had carried out a blood
112 test without gaining her consent, we also said that we were willing to work with

113 him in the future if he had any more clients with LD in the same/similar
114 situation. He wrote back stating that he had assessed her as not having the
115 capacity to consent to having a blood test, so had acted in her best interests
116 and gone ahead with it. (U)

117 There was also a slight twist in the case; the lady had 6 children that had been
118 adopted by the same family. She no longer had contact with them. Thinking
119 ahead, we discussed whether the children would be told if she did have
120 Huntington's disease. It was decided that as our concern was with the lady in
121 question, if she did have the capacity to consent to telling the children, then it
122 would be her decision whether to tell them or not. If she did not have the
123 capacity to consent to telling the children, then it would be a best interests
124 decision, but it would be what was in her best interests, and not the childrens
125 best interests. So it was decided that it would not be in her best interests for
126 the children to know, as it was her private medical information.

127 **JJ**

128 In general it is rewarding to involve people in their care as much as possible. As
129 capacity is a decision specific ability many people are able to consent to some
130 extent even if their ability to understand complex problems is limited. Given time
131 and appropriate tools it is often possible to establish what people want and
132 then incorporate that into a best interests meeting if the patient lacks full
133 capacity.

134

135 **What do you find are the particular challenges to gaining informed**
136 **consent from people with learning disabilities for their medical or health**
137 **care?**

138 **II**

139 It is often difficult to be sure that the Patient has understood and able to
140 understand ? To be sure that you as a health care professional have gained the
141 appropriate consent.

142 Sometimes I feel that a patient might have just put their trust in your judgement
143 to do what is right for them as a health care professional and give consent by
144 just putting out their arm to draw blood from them but not really understanding
145 why.

146 You should not always assume that just because the patient is brought to clinic
147 by their carer without any objection from the patient that the patient is going to
148 automatically give consent to the procedure that you are about to carry out.
149 Trying to assess a patient with LD that you don't really know is very difficult.

150 **LG**

151 Thank you for that informative reply, Jessie. I agree that it is often difficult
152 to assess whether a person with LD has fully understood what they are
153 consenting to. I have experienced this when interviewing people with LD for
154 this study, and despite the fact that they have been assessed as having
155 capacity to consent to being interviewed, I find myself questioning the level of
156 understanding when I am actually interviewing them.

157 **HH**

158 I find that one of the challenges is ensuring that all of the professionals involved
159 understand and assess capacity in the same way. There, unfortunately,
160 appears to remain a residual 'paternalistic' approach, regardless of the Mental
161 Capacity Act, which says that if a person is refusing treatment then they must
162 lack capacity. I've even worked with someone who ruled a person to lack
163 capacity because they don't understand the concept of 'death', a tricky concept
164 at the best of times!

165

166 I agree that things like blood tests are difficult because the benefits are not
167 immediately obvious, but a lot of people with LD are encouraged to passively go
168 along with them because 'the doctor knows best'. However, with a good MDT
169 working together with the service user, and with the appropriate amount of
170 planning and preparation I think we can support a wider range of service users
171 to give or withdraw consent.

172 **LG**

173 Thank you for your comments, Kanny. I agree that there is a tendency to
174 assume that a person is lacking capacity if their choice differs from that of the
175 healthcare professional (often a GP) – at which point a decision is made 'in their
176 best interest'. An interesting example is the 'flu jab. Some people with LD have
177 been telling me that they have been told by their GP that 'they have to have it' –
178 even when the patient specifically asks them if they have to have it.

179 **GG**

180 1.Ensuring that the information they receive is accessible and informative.

181 2.Ensuring that they have the time and support to digest the information and
182 have it explained to them in a way they understand.

183 3.Determining understanding on the part of the person with a learning disability
184 around the decision or care needed.

185 4.Communication difficulties on the part of the health professional trying to
186 support someone to give informed consent. Also understanding around
187 difficulties their patient might have in understanding, processing information and
188 making it meaningful to them.

189 5. Professional understanding around the Mental Capacity Act and consent can
190 be poor and often family members or professionals will be asked for consent on
191 behalf of the person with no attempt to assess capacity or consideration for the
192 fact that as adults they cannot be consented for.

193 6. Deference and acquiescence on the part of the person with a learning
194 disability who may consent immediately with very little/no information being
195 provided to them.

196 7. Opinions of family members/professional not allowing the person with a
197 learning disability being fully involved in the decision making process.

198 **KK**

199 A challenge that I've found is trying to assess the clients' knowledge of a
200 specific medical treatment that you are not expert in. The person carrying out
201 the treatment (e.g. surgeon) is not always available to be present for sessions
202 where the procedure is explained to the client in an accessible way. If the client
203 has specific questions about the procedure, the person carrying out the capacity
204 assessment may not know the answer. It is difficult to assess the clients'
205 understanding of the procedure/test if the assessor is not expert in the
206 procedure/test themselves.

207 **LG**

208 Thanks for your interesting contributions, Sam. I agree with what you say here
209 – for example, in general practice, you might have a GP who fully understands
210 the procedure they are trying to obtain consent for, but who has neither the
211 knowledge about mental capacity/informed consent procedures nor the skills or
212 time to present that information in a way that will facilitate consent! Ideally, of
213 course, there would be a 'triad' – the healthcare professional (medical), the
214 healthcare professional who is an expert at communicating knowledge to
215 people with learning disabilities and assessing capacity, and the patient! Fairly
216 unrealistic, I would say – given the time constraints in general practice.

217 Would anyone else like to comment on this? 😊

218 **JJ**

219 Communication, history taking, explanation

220 Assessing the patients needs rather than that of families or carers

221 Time pressures for health professionals

222 Access to appropriate tools eg diagrams to aid explanation

223 Apathy on the part of carers "he doesn't want anything"

224 Acquiescence on part of patient "anything you say Doc"

225 Lack of knowledge on part of health professionals in mental capacity act.

226 **How do you personally deal with obtaining informed consent for minor**
227 **procedures such as blood tests?**

228 **II**

229 Gaining informed consent is sometimes very difficult depending on the patients
230 capability of understanding. I feel that it is very important that time is spent to
231 explain the procedure before any attempt is made to perform venepuncture or
232 any other procedure. This is a good way of giving time to assess the patients
233 capabilities of giving consent and also to gain confidence from the patient to
234 give consent.

235 It is often necessary to gain physical consent rather than verbal consent
236 depending on the patients communicative skills.

237 **HH**

238 I agree that it can be very difficult to assess someone's level of consent,
239 particularly with the passive nature of many people with learning disabilities who
240 have been encouraged to go along with the suggestions of people in 'power'.

241 I think it is possible to assess consent by physical means, we have a lady who
242 refuses to enter the dentist surgery and as an MDT we have agreed this is her
243 withdrawing her consent to dental treatment. Experience is usually a good
244 indicator of someone's ability to give consent, particularly around things like
245 giving blood. In terms of informing people of minor procedures we have used a
246 wide range of materials including showing someone the objects prior to the
247 investigation, watching a video of it being done, a sequence of pictures and not
248 just relying on verbal cues.

249 We worked with one lady about taking her blood pressure by putting it on
250 ourselves and encouraging her to press the button to start it, to demonstrate
251 how it worked. Following this she was quite happy (and even keen) to put it on
252 for her own test.

253 **JJ**

254 There is an organised way of assessing capacity to consent as set out in the
255 mental capacity act. If the person lacks capacity, then the reasons behind
256 carrying out such a procedure would usually be discussed at a best interests
257 meeting. If at that meeting the procedure was felt to be in the persons best
258 interests then the procedure should be carried out with the least distress
259 possible. This may require a trusted other person attending, reassurance,
260 desensitisation to medical procedures or even sedation in the hospital setting. I
261 would normally initiate a best interest meeting if there was any doubt about the
262 appropriateness of testing.

263 **LG**

264 Thank you for your responses to your question. I would like to give you a
265 couple of quotes from my research and would be interested in your comments
266 on the consent process in these: (N=Nurse, P=Patient)

267 Example 1:

268
269 N So, we're gonna take some blood this morning
270 P Yeah
271 N If that's alright?
272 P Yeah, yeah
273 N Now, we'll check your kidney function and your [liver]
274 P [Yeah]
275 N function
276 P Right
277 N And your cholesterol and a full blood count, OK?
278 P Yes
279 N Um, just to make sure everything is OK, we try and do them every year
280 P Right, OK (nods in acceptance)

281

282 Example 2:

283

284 N Arm nice and straight for me now please.
285 P (Whistles)
286 N Only two bottles
287 P Oh that's alright then (grunts)
288 N Ever so still
289 P Just stick it in there
290 N Are you ready?
291 P Yeah.
292 N Ever so still
293 P (Big gasp!)
294 N Well done. Brilliant.

295

296 II

297 In example 1 I feel that the nurse has used good communication to gain the
298 consent from the patient. Patient probably not understanding the blood samples
299 that are being taken due to the "yeah" before the sentence was finished ! But
300 physical consent was certainly given by patient.

301 In example 2 I felt that there was not enough explanation as to what the
302 procedure involved and therefore did not give any time for consent to be
303 withdrawn from the patient.

304 There was also a risk of injury to nurse and patient as not enough time was
305 given to assess the patients capabilities of understanding and consent.

306 HH

307 That's interesting. From that information I would question the understanding of
308 the patient in example 1. Experience says that many people with learning
309 disabilities are likely to say "yes" to people who are perceived as in power. I
310 would also question how much of the information provided is necessary or
311 understood (for example what is a "full blood count"). I would like to think that
312 the second example that physical prompting was encouraged. I think it is
313 important to establish how much information is required to ascertain consent.

314 GG

315 In the first example verbal consent was certainly obtained but whether or not it
316 was actually informed consent is a different matter. The patient maybe
317 understands the procedure of having bloods taken but I agree that the
318 conversation would suggest that s/he does not understand what the blood tests
319 are actually for – the clinician does not attempt to explain kidney function, liver
320 function, full blood count or cholesterol. There is no discussion around what
321 implications of not having this done are. The patient agrees but is s/he taking
322 the word of the nurse and acquiescing to the power holder? Has the patient
323 had blood taken before, is familiar with the procedure and therefore would be
324 happy to consent without information? The nurse does not attempt to assess
325 patients understanding in any way.

326 For example 2 (is this the same patient?) this appears to be a relaxed
327 procedure – the patient implies consent by giving their arm to the nurse and
328 gives verbal consent by stating 'just stick it in there'. What information was
329 given to the patient prior to this? Was there work done with them around
330 venepuncture – they appear familiar with procedure? Again are they happy to
331 give 'consent' as they have had blood taken regularly in the past and it is a
332 'normal' occurrence for them.

333 I think at times it can be very easy to get consent from someone with a learning
334 disability as the power is usually with the person with the knowledge and the
335 equipment. I think that deference to the medical and nursing profession as well
336 as carers etc can ensure that consent is obtained. I think that the challenge is
337 how we go about ensuring that the patient with a learning disability is provided
338 with accessible information and time to help them understand as much as they
339 can so that the consent that they give is as informed on their part as possible. I
340 don't think we need to supply in depth descriptions or reasons but to make sure
341 the information delivered to them is coherent to them.

342

343 **There has been a lot of talk about pharmacogenetic testing in the media.**
344 **Before today, how aware were you of this?**

345 GG

346 I had heard of it and I recall a little information about it but I don't know that
347 much about it.

348 **KK**

349 I am not that aware of the current issues surrounding pharmacogenetic testing
350 and have not heard/seen much in the media around this.

351

352 **II**

353

354 Know very little about this subject. Too little to make any real relevant
355 comments.

356 **JJ**

357 There has been some information about this in the medical and popular press
358 but little has yet filtered down into day to day general practice.

359 **HH**

360 No I know nothing of pharmacogenetic testing.

361 **What are your thoughts about offering any of the new type of genetic tests**
362 **which, in future, might assist in the health management of your patients?**
363 **By this, I mean pharmacogenetic testing, tests for predisposition to**
364 **certain common diseases etc, NOT diagnostic tests for single gene**
365 **disorders or chromosome anomalies.**

366 **JJ**

367 I understand that pharmacogenetic testing may allow drugs to be more targeted
368 to people who would benefit from them by means of analysing their genetic
369 make up. This in principle sounds great. It would stop futile trials of drugs that
370 are unlikely to work for some genetic reason or other. However, it may be
371 limited to certain drugs and might skew prescribing to those drugs for which
372 there is a test. This is not to say other drugs may not be equally efficacious. To
373 a certain extent we already make assumptions about some genetic
374 characteristics for example in the prescription of ACE inhibitors. There would be
375 significant cost implications not only in terms of the test, the drug but also the
376 time to test a patient, time taken to explain the test and allaying of fears that this
377 might test for other conditions. Some of that cost may be balanced against fewer
378 prescriptions of ineffective drugs. Only time would tell if this would be economic.

379 I note your last comment on the post, but feel it is difficult to ignore the wider
380 implications of genetic testing. It might be difficult only to test people for the
381 pharmacogenetic characteristics without coincidentally diagnosing or increasing
382 the likelihood of other conditions. This could have both positive and negative
383 effects. Early diagnosis or knowledge of say, diabetes may help prevent
384 complications but early diagnosis of progressive untreatable conditions like

385 Huntingdons could have a negative effect. Even if the test was purely drug
386 related it might be difficult to reassure patient that this was the case.

387 HH

388 Much as I don't have involvement with genetic testing around pharmacological
389 issues, is this offered to other people? Within the right circumstances I can't
390 see why this wouldn't be offered if it were offered to other people with similar
391 pre-dispositions.

392 Regarding progressive conditions, I have been involved in the case of offering a
393 service user the opportunity to undergo tests for possible Huntington's Disease,
394 which was actually very positive. The service user was not unaware of her
395 deteriorating condition and wanted answers about why this was happening. I
396 can understand this may not always be the case and it was felt in this
397 circumstance that she had capacity to make that decision.

398 I think proving best interest in these cases would be difficult but certainly where
399 someone is appropriate assumed or assessed to have capacity I would be
400 supportive of individual's being given all the information and opportunities

Appendix 20 (Focus group, family carers 25 January 2010)

- 1 LG Well, first of all, I would like to go round and if you could introduce
2 yourselves and tell everyone else a bit about your role as a carer. So,
3 who would like to start? Roy? As you were here first?
- 4 R The perks of being here first?
- 5 LG Yeah
- 6 R I, or we, my wife and I have been a carer for 36 years, 35 years – our
7 son will be 36 in November. Um, and of course, I worked during that
8 time, so I suppose my wife has been the main carer for that period of
9 time. I retired in 2002, having worked in personnel for some years. I
10 took early retirement, not really to support the caring issue, but really
11 the opportunity was there, which did help with the care for our son.
12 Um, his issues were really, um, he was born with the cord round his
13 neck and therefore he was brain dead for 2-3 minutes at birth, and due
14 to negligence of the hospital , which we were unable to uh – in those
15 days you didn't actually [really look at]
- 16 J [question it]
- 17 R And therefore, it didn't really come to light until he was 9-10 months,
18 not sleeping, not eating and everything else. At that particular time I
19 was away, but we fought through all sorts of things and he is now a
20 really entertaining character. He lives at home with us; he has a
21 placement for 5 days a week in a centre (they are not called day
22 centres any more, I am not sure what they are called these days). Um,
23 but he has 5 days there from 9-3, which is very good for him, it keeps
24 his interest. He has an infectious character, and he is able at this
25 moment in time to do some supported work placement.
- 26 LG Good
- 27 R Again, that's something which has been in the last couple of years, but
28 there are levels that he can achieve. Apart from that, he is a very
29 sociable and possibly, Fran and I are identified as his parents, rather
30 than Fran and Roy, out and about with our son – everybody says,
31 "Hello, Fran", you know – and he knows more people than we do, I
32 think – through actually the circle of friends he has and where he goes.
- 33 LG Mm
- 34 R Although he lives at home, he is not a He needs care and
35 supervision constantly, but he does sleep at night, and he is unable to
36 do his personal care without supervision. He can clean his teeth, I
37 suppose, with
38 [some prompting]
- 39 L [prompting]
- 40 R But the other bits and pieces, he doesn't want to get his hands dirty at
41 all, so we still care for him in that respect, and actually I guess he
42 doesn't have the ability to dress himself. Although if the clothes are put
43 on the bed for him, he will be able to dress then, but to take from the
44 wardrobe and [decide]
- 45 J [choose]
- 46 R [which] was which
- 47 J [choices]

48 R he would be unable to do that. Um, I have had this conversation with P
49 City Council over and over again about the level, and unfortunately his
50 level cannot be identified. Um, he is on the spectrum, but where on the
51 spectrum, we haven't been able to identify. He is not Downs, but he is
52 on that spectrum. He is an anomaly really, and he's really good
53 company, as I say he is an infectious individual that's got two nephews
54 now and unfortunately Max who is only 4, is far more able than he is.
55 And Max is not yet able to identify his issues.

56 (All : Mmm, understanding)

57 R So that's a problem we have at the moment, which we will grow
58 through that I am sure, and Max will identify what he has to do and
59 what he can't do.
60 Um I rambled on there a bit – is that enough?

61 J [enough]

62 LG [No, that's] very interesting, thank you.

63 J Can I go next?

64 LG Of course you can

65 J Simply because it is such a pleasure, and I have to say it's a pleasure
66 to meet somebody who, I could sit here and say almost word for word
67 what you have said, in terms of, you know, your son and your
68 involvement and the problems. I have a brother who was brain
69 damaged at birth. My mum had what's called placenta praevia, which
70 meant that they assumed he was dead when he was born because
71 they assumed he had drowned in her blood literally. Um, he was put
72 aside and he let out a cry after something like 4 minutes. So, he has
73 brain damage consequently. He lived at home with my parents until he
74 was 38; my mother died and my dad was not able to take care of him
75 and he went into a home in C. He was there for 18 years and that
76 place was closing down. He moved somewhere inappropriate for a
77 year in C, and I endeavoured from the point that I knew the home he
78 had been in for 18 years was closing down, to get him moved down
79 here. I succeeded in that a year ago, and he is in a home down
80 here, but I am there almost every day and I spend a lot of time
81 with him and he quite often spends the weekends with me, because it's
82 a supported living home and it doesn't fulfil his needs. It's debatable
83 whether he should be in supported living or not, because of the
84 same kinds of problems as yours (to R) – you know, he can't actually
85 dress himself, he is not classifiable in any way, he is not Downs, he
86 is not autistic, he is, you know – so all those things. Um, he has
87 settled, is resistant to change, and so I am battling through, trying to
88 make him living in a home that is supported living, um, work. I don't
89 know if you know about, you know there is residential care and
90 supported living, and he is in a ... middle ground place. It's a home
91 that's what's called de-registered, so it used to be a residential home,
92 but it now calls itself 'supported living'. But in fact it now doesn't fall
93 under any of the headings, a bit like our respective relatives (laughs),
94 so that has its problems. A lot of them are to do with choice and the
95 fact that supported living means people are given choices, and E in
96 essence doesn't understand choice. He understands being asked to

97 decide between 2 things – do you want to go out, do you not want to go
98 out, but this phrase, and it is a phrase “It’s your choice, E, what you
99 want to do” – it can’t be answered by him without prompting, without
100 additional language being used to understand exactly what someone is
101 trying to ascertain, and it is not clear to him very often whether he is
102 saying what he conceives to be the right thing or not. He is very
103 biddable, he is very anxious to please. If he believes that he can
104 understand what the person would like him to say, that’s what he’ll say.
105 He also suffers from something called, I think it’s echolasia, where if
106 you ask him, if you give him a choice of 2 things, he will almost
107 invariably choose the second one of the choice, the last one he has
108 heard. Um, he has the potential to be very content and very cheery,
109 but he does have bipolar, and he has powerful medication that was
110 only introduced when he was 38 and when this home that he
111 had been in for 18 years started talking about closing down. The
112 anxiety around that meant that he went downhill, and loads of different
113 drugs have been introduced. They are a problem, they limit his ability
114 to get up each day, and they have a very sedatory effect on him. They
115 have lots of negative effects. He is on lithium which works very well for
116 the bipolar, but the other drugs, I believe, and most consultants that
117 see him believe that he should be withdrawn from them, but the
118 question is, how, you know because of the consequences and all
119 that. Um, he, my role is just to sort of be there all the time, in terms of
120 that he knows I am nearby, which is a vast improvement on where he
121 was with no relatives were nearby. I am also an advocate for people
122 with learning disabilities and my most recent work before I retired, was
123 working with children with Down syndrome in a mainstream school.
124 So, um, but I don’t think anything helps anybody to deal with any
125 individual person more than genetic familiarity. You know, the fact that
126 he is your son, the fact that my brother is my brother, means that I
127 have an intuitive understanding of him, um, as I am sure you do (to R),
128 and it’s quite hard that he’s actually under the care of people that,
129 through no fault of their own, can’t understand him terribly well, and
130 that causes problems.

131 LG It must be frustrating for you.

132 J Yes, and this whole issue of choices is very very difficult, very difficult.
133 They will tell me something they have asked him, and I will say, well E
134 doesn’t have the cognitive skills to understand the consequences of
135 what you are asking him to reply to, or sign, or anything like that. Um,
136 so, it’s complex and I’ve often thought about, would it work better if he
137 came and lived with me. Um, it’s very very difficult to know, and we’re
138 still a work in progress, really, to decide what, how much more
139 improvement can be done to his quality of life. I believe his quality of
140 life has improved down here, and he agrees that he is doing more
141 things, he has met more people. He comes to a choir with me, he
142 comes, I take him to the gym twice a week, I take him to church. Um,
143 he interacts in all those situations. The home doesn’t actually take him
144 out many places and they don’t actually integrate him anywhere. He
145 goes to college a couple of days a week, but that’s a C College with a

146 group of special needs learning disability people. So, between the two
147 of us, we are getting to know very many people locally, um, far more
148 than he knew in C or C where has lived previously, and he um, as I say
149 is a work in progress.

150 LG Mmm. Can I stop you there?

151 J Yes

152 LG And we can we get on to.... Lisa's looking as if she has got things to
153 say too,

154 J She's [bursting as well]

155 L [Well], I suppose I reflect the other side of that. For the past 17 years I
156 have looked after my brother-in-law who is mentally and physically (as
157 I see him) handicapped. That's not PC, but that's the way it is, and
158 people understand it. Um, he was born with a form of cerebral palsy,
159 um but was a protracted birth, [oxygen deprivation]

160 J (whispers) [that's interesting]

161 L So we've got all the other things. It was a home birth, third child, um
162 and he wasn't diagnosed until he was two. He is 55, [will be 55]

163 J (whispers) [same age as my brother]

164 L Um, he lived with his mum up until she died in 1993. In 1993 he came
165 to live with us, um at the time we had three children, we still have three
166 children (laughs) One 12, one 6 and one 3.

167 LG Mmm

168 L Pa used to be able to walk, but as he has got older, in fact he is now
169 wheelchair bound. Um, he is treated for epilepsy, although he hasn't
170 had a fit in years. Um, he is somewhere in between the age, as I say,
171 55, but mentally he is somewhere between the age of 3 and 4, so he
172 repeats everything, he is into everything, Father Christmas will never
173 die in our house, which is wonderful.

174 J Does he come all the year round in your house?

175 L Yeah! Yes, and I'm his main carer. I get respite care, and we get day
176 care.

177 LG Good

178 L Um, I could haven't done it with the boys as they were growing up if I
179 hadn't had help, but now he has taken over what would be a dining
180 room is now his bedroom, has been now, as I have said, for 17 years.

181 J So, does he go, like your son (R), does he go to 5 days a week care?

182 L Because he lives at home and because of the situation then he gets 5
183 days day care

184 J At W or somewhere, yeah?

185 L No, he goes to I* three days a week and 2 days he's at S*, and we get
186 around about 6/7 nights a month of respite, because he's 24/7.

187 LG Mm

188 J Gosh

189 L Um, and he is, last year, he went into nappies (I call them nappies)
190 because his incontinence grows as you get older (It does for all of us, it
191 does for P!) – (laughs)

192 J (whispering again) – such a lot of work, my goodness me.

193 L Um, yeah, but on the other hand, he is a fantastic character. I have
194 known Pa since I was 18 when I met my husband, um, so we have

195 grown up together. When his mum died, he had never been in a, well
196 he had, he had been to CS*, which was a bad experience for him. In
197 those days, they were told to send them to an institution, and I think
198 from about the age of 13 to around about 18/19, over those teen years
199 he went, but he hated it. He hated it – he came back looking like
200 something out of Belsun.

201 J Oh, no.

202 L And so she couldn't take it any more, so she had him home. She had
203 three herself, when the other two got married, she had him home and
204 he stayed with her for the last 12 years of her life, and then he came to
205 stay with us. And, I could, there was no way I could have put him into,
206 put him back into that situation, not just for him, but for my husband
207 as well, because their elder brother has a daughter, one daughter who
208 had childhood leukaemia, he automatically felt responsible for Pa,
209 always had anyway, even before that situation occurred, so to have
210 said "No, I couldn't do it"

211 LG Mm

212 L Would have given us extra pressure on top of the family, so I said I'd
213 have him, and 17 years later, it was the best thing I ever did.

214 All: Mmm

215 R Well, that's what we find actually, we've had P from the beginning and
216 now we are coming into our dotage, what's gonna happen to him

217 J It's scary

218 R You know, I keep telling my wife we've got another 30 years to go yet,
219 but she says, "Yeah, but what happens when we're 90, how can we
220 look after him when we're 90?"

221 J I know, it's so sad

222 R But we have friends, or we know friends, that P goes to different
223 centres with, and one of the Dad's there is 90 and he [still]

224 LG [Yeah]

225 L Yeah, I know them, yeah

226 R He still brings....

227 J (interrupting) but at the point my mother died and my brother went into
228 care, my dad was 80 you see, he couldn't take care of him.

229 LG It is a problem, isn't it?

230 J Yes

231 R Yeah

232 J And we all, my other two brothers and I had young children of our own,
233 and E was happy in the home he was in for 18 years, but it's NOW,
234 and it's having, oh goodness me, it's having choices. I mean, having
235 choices of 'does he stay in care' or 'does he...', you know, um, it's very
236 very difficult. I do frequently kind of ask him um, but I think in lots of
237 ways he'd like to still keep his independence in terms of being
238 surrounded with a peer group a lot of the time. But what I didn't realise
239 is that it is possible for the people you are caring for to spend 5 days a
240 week somewhere where they ARE with their peer group, you know.

241 L You should be able to get a care plan

242 J Mm

243 R Oh, yes, respite would um, yeah, although we [don't take respite]

244 J [Anyway, that's going]
 245 L [Of course, you need to go on to the next question!]
 246 LG [Yes] Sounds like, I'm aware
 247 J [We could]
 248 L You could start a carers' forum
 249 R Yeah
 250 LG There is a, but you're part of a carers' group, you two, aren't you?
 251 R Well, I go to...
 252 LG Isn't that how A found you?
 253 L I'm the carer rep on the LD Partnership Board
 254 R Oh, you are the 'L'. She mentions you quite often at the meetings...
 255 J Where have I seen you then....?
 256 LG Cos, A, it sounds like there is a group that you could access, cos
 257 you...
 258 J Mm
 259 R Well, through A
 260 J Who is A?
 261 L AM – she looks after carers in the city. She's at DH.
 262 J Yes
 263 R But P's at – you mentioned W, across the road from W, was the FEC,
 264 which is now H
 265 J Yes, that I work from as an advocate, yeah.
 266 R You work for them as an advocate?
 267 J Yes
 268 R Oh, right. Well, P goes to the centre there 5 days a week.
 269 J Right. Does he come to the Friendship Club, the Disco
 270 R On a Friday night?
 271 J Yeah
 272 R Yeah
 273 J Oh, well I inevitably know P
 274 R You will know him
 275 J I know P
 276 R If you met P once, you would never forget him
 277 J No
 278 LG Can I suggest that perhaps we can put you three in touch with each
 279 other? You [know]
 280 J Yes, yes
 281 L I think my biggest complaint about carers' organisations in the city is
 282 that they are too disparate, that they are fragmented and that nobody
 283 comes together.
 284 All: Mm, yeah
 285 L And that the Partnership Board is supposed to be, and quite honestly
 286 it's been a shock to Social Services and P City Council that, you know,
 287 we've got people like us out there doing this, and they have, under the
 288 new, what's it, the paper "Valuing People" (sings this in a mocking
 289 fashion!).
 290 R People, yeah
 291 J Is P "happy I am"?
 292 R Yes, yes

293 J He's the lad that goes round the whole time saying, "I'm happy, I am".
 294 R Yeah
 295 (all laughing)
 296 J He's absolutely lovely.
 297 L Let's hear Lesley's next question!
 298 LG Can I, [I am concerned]
 299 L [I've got to be gone by 12]
 300 LG [We've got some very interesting things] for me to ask you. I mean if
 301 you are happy for me to, you know, put you in touch with each other,
 302 L Yes, absolutely
 303 J If you don't mind, you've got enough to do by the sound of it.
 304 R To be honest, we are happy with, you are doing sterling work on this
 305 partnership (to L), and the meetings that have been held at Highbury
 306 that [this is where I've talked with A]
 307 L [that's where I have seen you] Did you do the direct payments one?
 308 R Yes
 309 L Yes, that's right
 310 R So, you know, I'm quite happy with the situation at the moment
 311 LG Would it be a good idea to give J A's details, [A's contact details]
 312 R [Oh, definitely I think]
 313 LG Cos she'd be the person who cares for the carers –
 314 Would you be interested in having her contact details
 315 J If you don't mind. Because I can't make the decision about stuff
 316 without hearing the pro's and con's of it, and nobody... There doesn't
 317 seem to be one place that you can go, like I've been at Highbury for the
 318 last couple of days talking to L and the main advocates, I mean I'm a
 319 voluntary advocate, but the main advocate, and you are then trying to
 320 piece together odd bits everybody has said, I still can't get the picture
 321 of how things function if E were to come and live with me, so it would
 322 be really helpful to...
 323 L Well, that's me, because, I have taken over, well I've become a new
 324 trustee
 325 J Right
 326 L Because the day centre where my brother in law goes was failing, so
 327 they kept the So anyway, that's another story.
 328 LG OK, if we could just move on a bit – so you obviously are all carers in
 329 slightly different ways, but I would like to ask how much involvement
 330 you have in their medical care. By that I mean, you've touched on that
 331 anyway – in terms of a) do you accompany the person you care for to
 332 medical appointments, and b) how much involvement do you have in,
 333 are they in any way able to make their own decisions as to whether or
 334 not they consent to treatment, that kind of thing. So...
 335 L Shall I go first, because Pa is like a 3-year old, so in the same way you
 336 would treat a 3 year old, you treat him. You accompany him, you make
 337 the decision for him, he isn't cognitively able to do that AT ALL. He
 338 wouldn't know, he thinks going to the hospital is a trip out
 339 LG Right

340 L Or going to the doctor is the best thing ever because usually they give
341 him something. Um, he loves needles, so he loves having his blood
342 taken

343 LG Really? (laughing)

344 L Yep

345 J He's going to be your dream client

346 L He stays still as anything. He just loves it. He loves the attention.

347 J Yes, I think that's [part of it]

348 LG [That's an] interesting comment.

349 L He loves being the centre of attention. Um, he had to have his
350 gallbladder removed, oh about five years ago. Luckily it was done by
351 keyhole, thank God, so we were in and out within 24 hours, but I would
352 not allow, I wouldn't feel comfortable letting him be in there, I stayed
353 there the whole 24 hours, um because nobody understands him. He
354 speaks like a 3yr old. Once you've got used to him, you know
355 exactly what he is saying, like any other baby.

356 LG Can I ask you a question, and obviously I completely understand what
357 you are saying, but since the Mental Capacity Act came in, has there
358 ever been any mention when you have seen healthcare professionals,
359 about his capacity, or is it just assumed that you make decisions on his
360 behalf?

361 L It's assumed, it's assumed that I make decisions

362 LG Because you know the people, presumably you know the GP.

363 L The GP is, yes, has been in the family for about 30 years, but the
364 interesting thing is when you go the hospital, for example, he presented
365 with symptoms which looked like prostate cancer about 18 months ago,
366 so we took him to the C* - is it the C* (up in D Hospital)

367 R Yeah, the C*

368 L The specialist up there said to me, looking straight at me, Pa is in the
369 wheelchair to the left of me, pushed back a bit, and said to me "If we
370 find cancer, considering Mr H's present condition would you still
371 want us to go ahead and treat?"

372 LG Really?

373 L And that was 18 months ago. If I could have hit him there and then I
374 would (laughing)

375 LG Mm. I would say that is shocking, but it doesn't surprise me

376 J No

377 L It isn't, most people ARE surprised by it, um, most people.

378 J I am surprised at the lack of subtlety.

379 L Well, I mean, he, they're too busy

380 J [Mm]

381 R As well as the subtlety, it's [the]

382 J [Sensitivity]

383 R We've encountered this in the dentist.

384 LG Yes

385 R P luckily doesn't go to the doctors very often and he's not on any
386 medication, I meant to add that when you talked about yours, so
387 dentistry seems to be the thing we have with P. And we have, when
388 we have been to the dentist, at TT,

389 L ST
390 R ST or whatever it's called
391 J TT is a home
392 (all laughing- discussion about the name of the place where the dentist
393 is!)

394 R J, his dentist, challenged us with the fact that, should we be making the
395 decision for P to have any work. She is quite happy, cos we do a 6-
396 month check up with him, and she is quite happy to do that, but she
397 said if we came to an extraction or something, then who makes that
398 decision? And she suggested that we should look at lasting power of
399 [attorney.]

400 J/L Mm
401 R [for that]. So that we can [make the decision]
402 J Yes, somebody's just mentioned that
403 R Make decisions for P, cos choices and decisions are the things that he
404 can't do, um.

405 LG That's why I asked, because with the new Mental Capacity Act, it has
406 changed the way health care professionals [are supposed]
407 R [Yeah, oh she was]
408 LG [to deal with these kinds of things]
409 R She was very, very, you know she said "We need to sort something
410 out", and we are at the moment trying to do that, but she is still treating
411 him. We were there 3 or 4 weeks ago. But she wants to be able, in her
412 position, if anything goes wrong during that surgery or extraction, then
413 she has got that permission correctly from whoever it should be given
414 by.

415 J Mm, a GP has recently done exactly the same thing to me, has said
416 "You know, what would happen if E needed something serious done,
417 you know, you need to sort it out". But I didn't quite [understand how
418 he meant to sort it out]
419 R [Well, we] have gone back to our GP and explained this to him now,
420 but he was, you know, perhaps we ought to consider this...
421 J So [I said]
422 R [It is the message getting to the professionals]
423 J Everybody – they're talking about power of attorney, they're talking
424 about all the people we care for, us three I mean, and all of the rest,
425 talking about them having wills and sorting out wills, andit's quite
426 mindblowing because, you know, you can't believe the priorities when
427 they should be....

428 LG Mm, so you, going to the doctors, you say that your son (R) doesn't go
429 to the doctors very often, have you, but presumably you have
430 accompanied him to the doctors in the past?
431 R Yes, [we accompany our... it's very similar]
432 LG [So what happens when] – has he ever had to have a blood test or
433 anything like that?
434 R He has had his blood taken. The other thing that's happened within the
435 disability group is that they now have a yearly
436 LG [Health check]
437 R [Health check]

438 L Yes, [learning disability assessment]
 439 J That's fun
 440 R That's fun. Yes, it was actually. Well, I didn't go, my wife took him to
 441 that, which was in October last year, and I think it went well, you know
 442 at that particular time we didn't know about the permissions and such
 443 like, so he was given a clean bill of health really. His heart is as strong
 444 as anybody else's according to the GP, his anxiety issues are a thing.
 445 He will have his blood taken quite easily, he's not afraid
 446 J (interrupting again) E's the same. I think it has happened to them so
 447 much that they become....
 448 R Yeah, the dentist thing, she is brilliant with him – you can imagine
 449 dentists, and once upon a time, I don't know whether it's with age or
 450 whatever, but he is now quite chilled when he goes to see J
 451 LG Yeah
 452 R Whether that's that relationship that's built up
 453 L P goes to see A, and he's quite happy, but he loves it, as I say, it's a
 454 day off!
 455 LG To go back to thinking about blood tests and you know, your
 456 experiences, I don't know whether you've ever accompanied E
 457 J E, I always accompany him because him, yeah. [He has to have
 458 regular blood tests]
 459 LG [So when they have blood] tests, um, have you experienced there
 460 being any kind of explanation from the nurse as to what the blood test
 461 is for?
 462 J No, I mean in E's case it's a blood test for the lithium levels, the
 463 absorption of lithium in his bloodstream. Um, he knows he's got to
 464 have it, he understands it's something to do with the big white tablet,
 465 but beyond that, you know....
 466 LG So, how, would that have [been explained to him] at some point do you
 467 think?
 468 J [the complexities] I doubt it very much, other than, "We're just
 469 checking that.." – because they will say to me, "the blood test should
 470 also indicate any damage to organs that's going on". I can't quite
 471 see how it does that, but...
 472 LG Yeah, mm
 473 J [Uh]
 474 L [So as far as you are concerned]
 475 J [No, I mean], he is just told, we have to give you regular blood tests to
 476 make sure, I think I may have heard, or one GP has tried to say
 477 something to him, and I have interpreted it to E as, they are just trying
 478 to make sure that the tablet is working properly, [that's]
 479 LG [And he puts] his arm out and
 480 J Oh, he's perfect.. As everybody has said
 481 LG [he complies]
 482 R Yeah
 483 J They are quite, let's equate it to 'it's something that makes them feel
 484 like everybody else' on one level, and on another level, they're getting
 485 attention, on another level, it's something that they feel brave about. I
 486 don't know [if Pa does but]

487 L I think with Pa it is also another thing about – this is my body, it's
488 almost
489 J [attention]
490 L [“Oh, look], this is mine, this is my arm.” And so, you know, when the
491 pillow comes underneath, and they put the tourniquet strap thing
492 R Well, we haven't ever viewed it, we've never looked at it that way, I
493 guess. You know, it's a blood test and P says OK and down we go,
494 um, as I say, he's far more cool with it now than he was years ago. I
495 used to take him years ago because F was worried about him fighting
496 for it, but he has that. But, I don't know what's going through his mind,
497 um, apart from the fact that he has to have it done. Yes, we go for a
498 reason, his thyroid, I think there was some issue with his thyroid
499 All: Mm
500 R With his yearly check, so his blood was taken and we were explained
501 why it was being taken
502 LG So that was, so you did get an explanation?
503 R Oh, yes, and the reason why, but as far as Paul [understands]
504 J [it's trying to explain to somebody what their thyroid does]
505 L They explain to us what the tests are for, but there is no way Pa would
506 understand
507 J No
508 R And I don't think P would either, and I am not sure why he goes. It's
509 not a thing about being the centre of attention, it's the fact that he's
510 gotta go.
511 L Mm
512 R It's a bit like going to the dentist, or going out, you know, you've got to
513 go for a blood test this morning, OK
514 J I have tried to explain, cos E has a problem with his thyroid that's come
515 to light recently. Um, you know, we all, in Pa's case it may not be
516 possible at all, but you know, I will always kind of simplify language, try
517 and relate it to something else. There are ways, obviously, we have
518 learnt ways
519 LG Mm, mm
520 J Of making, putting E at ease about something. Assuring him that he
521 doesn't need to worry about it. But I mean, trying to explain what the
522 thyroid does, is
523 LG Oh, no
524 J Is very difficult (laughing)
525 LG I think basically, what they, under the Mental Capacity Act, what they
526 are supposed to have is information *sufficient* to enable them to make
527 that decision. Well, I mean that's a very broad statement
528 L Very broad
529 J Mm, incredibly
530 LG You know, I think you are right, I don't actually feel that they need to
531 have the science behind, [you know]
532 J No, they can't [if it's too high level]
533 LG [If it's simply] something that's going to keep them healthy or make
534 sure they are staying healthy, then I think that's probably sufficient, but
535 um, if I could just – this research is actually about consent to a new

536 kind of genetic test, which is, and the thinking behind the research is
537 that if this test is going to be offered to the general public, will PWLD be
538 able to understand it, and in other words, give consent to it, and will the
539 fact that it may be difficult for them to understand it, prevent doctors
540 offering it to them?

541 J It shouldn't.

542 LG But in view of what we have been saying, I think, if I could just tell you
543 briefly about the test, it's, in a nutshell, it's looking a particular group of
544 genes that are responsible for drug metabolism, so it's a very small
545 group of genes, and the test just looks at that group of genes, it doesn't
546 look at any other

547 J (whispering) – [that's fantastic]

548 LG [you know], it won't diagnose genetic disorders, it won't tell people
549 whether they have got a predisposition to cancer or heart disease, it's
550 literally looking at that [group]

551 J [metabolic]

552 LG So, because what happens is, depending on the type, on someone's
553 genetic make-up, they might metabolise drugs more quickly, so that will
554 affect the dosage, or they might have an adverse reaction to a
555 particular drug. These tests aren't available at the moment, but they
556 possibly could be available in the next 10 years. They are using them
557 a bit in the States, for – do you know about Warfarin, which is for blood
558 thinning

559 J Mm

560 LG They use it to monitor people's dosage for that to look at people's
561 genotype. So, when I interviewed people with LD and explained this
562 kind of test to them

563 J (whispering again) how do you do that?

564 LG With difficulty! I first had to establish whether they had ever heard of
565 genes or genetics.

566 J No

567 LG No, I was quite surprised that some had.

568 R Sure it's not the ones I am wearing?

569 J Yeah

570 LG Well, I had to say that, I had to say "Have you heard of genes, NOT the
571 ones I am wearing" (laughing) – in nearly every case I said that, but
572 actually, no some – and some said "Well, it's to do with whether you
573 are going to get cancer or not"

574 J Mmm, that's

575 LG And someone else said, I can't remember, but [you know]

576 R [Yeah, I'm sure there's ...]

577 LG [There was some knowledge]

578 L [There's a level at which

579 LG There was some knowledge, and the people I interviewed were sort of
580 mild to moderate LD, so you may not be able to identify with those, but
581 more interesting to me, was when I asked them how much information
582 they needed a) about general kinds of blood test and b) what did they
583 think they would need to know about this kind of blood test, it was
584 about 50:50. Some said that they would like to know about a test

585 before they had it, others said that, you know, - this one here said "You
586 know, I could trust my doctor 100%"
587 L/J Yeah
588 LG I've got my own doctor, he's a marvellous man, he knows my family, I
589 trust him, and if he says ah, blood test to check up on your bloods, for
590 example, I sit and do it, you know, I trust him"
591 J Yes
592 LG [So]
593 J [That's common] I would say
594 LG And some people positively said they didn't want the information.
595 J Umm
596 LG Or didn't need it and were happy to have it done. So what's your, do
597 you have any comments on that?
598 J I think that this test (sorry, jumping in first), you know, there is no doubt
599 that this would be incredibly beneficial to anybody, everybody, to know
600 exactly genetically how they absorb or don't absorb medication. It will
601 be an incredible breakthrough when it comes through. I don't think
602 there's any doubt that it will be positive knowledge, in other words it will
603 improve the care and therefore the health of every single person with
604 LD, so I don't quite understand the fear around getting consent, do you
605 know what I mean?
606 L Yeah
607 J [Why]
608 L [Yeah, I understand] It would seem obvious
609 J [Why] are we worrying about it, because it is so obviously going to help
610 them, it's so obviously going to be beneficial for them to have this test,
611 and I have thought since looking at this, of ways that I would explain it
612 to my brother.
613 LG Mm
614 J And thought of things that I would use to explain it, like you know, that
615 everybody in our family likes liquorice, don't they, and everybody in our
616 family likes music, and everybody in our family, or most people in our
617 family are artistic, and explaining to him that when you are all related,
618 you have things that are the same. E and I look identical, we've both
619 got curly hair, we look like twins almost, and so I [don't think']
620 LG [You can explain] it in that way, you are right
621 J [I don't think] it would be difficult. It's obviously much more difficult for
622 you (addressed at L), but I don't think you would ever doubt that it
623 would be something that could benefit Pa.
624 L I think anything that could help Pa could help anybody else
625 J Yes, I [don't think there's a doubt] that it's going to help everyone
626 L Is the main aim
627 R This is all based around
628 L consent
629 R Yes, that's what you are looking at, isn't it?
630 LG Mm
631 J And you are forced to consider consent
632 R And who gives that consent? That's what you, that's what the
633 consideration has to be

634 LG Mm, yes
635 R Whereas around the table here, we are going to give that consent
636 J Of course
637 R You know, and [that's the issue]
638 J Of course, and I don't have any doubt that if we could explain it very
639 fully to them, but I think in terms of explaining it in terms of genes and
640 genetics and da di da, certainly in our cases, you know, it wouldn't
641 work going along that line, but there ARE methods of simplifying the
642 technology of genetics
643 R [This is where I]
644 J [I mean they have a level of understanding]
645 R [This is where I now] say, you know, why do we need to be able to do
646 [all these things], when we have the [best interests]
647 L [Exactly]
648 J [Best interests]
649 R Of the individual concerned and [we should make those choices, make
650 those decisions]
651 J [Exactly, that's what I was trying to say]
652 L Yes, because it comes down to individual rights
653 J You see so [many] (R laughing loudly)
654 R Yeah, exactly
655 (all laughing)
656 R Legislation, yeah, isn't it
657 J You see so many [remember]
658 R [Yeah, it's you know]
659 L But sometimes individual right is compromised by the law [because..]
660 R [We can go round and round in circles]
661 L Yeah, exactly.
662 J Roy, what you have to remember is, that a huge percentage of people,
663 including my brother, if I wasn't around, is in care, in a home, there are
664 20 staff taking care of 12 people and no one of those 20 staff know my
665 brother well enough to enable him to [understand something like this]
666 at any level. So
667 R Yeah
668 J If, on the one hand, and they are all getting told, you've got to try, and
669 you've got to get consent, and you've got to make it a choice, you
670 know, this is all going off on a weird tangent that's you know, a misuse,
671 I think, of energy and time and everything.
672 LG Mm
673 J But there's nothing we can do about, this is the way the whole world,
674 the whole system is going. Um, and I can only say that you have to
675 endeavour to utilise any family member that's available and anybody
676 that considers themselves to be, say the key worker or something, but in
677 so many situations they do not hold enough information, personal
678 information about the person and records are very badly kept.
679 L Yes
680 J My brother was described to a new advocate that has been assigned to
681 him, she said "I was told he has got bipolar and schizophrenia". He's
682 55 years old and he does not have schizophrenia. I mean, and she

683 has been told by the home that he's in that he has schizophrenia. You
684 know, it makes you want to.....
685 (murmurs of agreement from all)
686 L I think we all fight for them
687 J It's so frustrating, all that sort of stuff, but you know, at a point of sense,
688 this test can only help anybody and I think one of the first things you, or
689 doctors, or anybody should convey to a person with LD is "This is
690 something that's going to [help you]
691 R ["Its good, is good"]
692 LG Mm
693 J If you pre-empt any conversation with that, with one of these two, you
694 know I was talking about choices, having a right or wrong. If you pre-
695 empt anything with a positive statement, "This is going to help you"
696 then – and I don't think that is being biased because it is, [it's gonna
697 help anybody in the world]
698 R [But this advocacy], advocates I've written down, I'm sorry I didn't
699 realise you were one, because when we're talking about my pet hates
700 J Advocates could be [one of them]
701 R [Yes, they could] because [they're]
702 J [I, I find it]
703 R They're going to approach something with their view, like we approach
704 things with our view, but [we know the individual]
705 J [we have a knowledge] [I know, I don't]
706 R [We know the individual] and these advocates [come along] with
707 J [I shout all the time, Roy] about, you know, what am I supposed to do
708 for this person, I can see, I can only help with practical things that I can
709 see are going wrong. Most of the people that I do advocacy for have
710 no communication skills whatsoever, very few, but having said that
711 about somebody you spend some time with them and [you find that of
712 course]
713 R [Well they will identify those, yes.]
714 J But, certainly for my brother an advocate who has seen him once has
715 told me that he has told her he doesn't ever want to move again, and
716 she has written that down as gospel, and I just, I am not getting
717 [involved in this]
718 R Yeah, but Paul's [been]
719 J [Please give it time]
720 R [But Paul's been to one group]
721 J [Don't assume one comment means something] emphatic
722 R Paul's been to some groups, I can't remember when that was or where
723 it was, but he was asked whether he'd like to move out, cos he's been
724 living at home for so long, whether he'd like to move out and join his
725 friends
726 J Of course
727 R Um
728 J Of course he would say, [ooh, yeah]
729 R [Yeah, of course he would]
730 J Yeah, I would be happy!
731 R Yeah

732 L They always are, they [always]
 733 J [(It is mindblowing)]
 734 L They always answer normally in the positive
 735 J Positive, exactly.
 736 L So if you ask them a question, they'll always [say yes]
 737 J [(Of course)] They've learnt reaction skills, they've learnt response
 738 skills, you know.
 739 L Mm
 740 J You know, and [they will]
 741 R [I believe Paul] can't rationalise to say "No, I'm [happy though]"
 742 J [(No of course)]
 743 L [(That's right, I agree with you on)]
 744 J [(I believe E can't rationalise)]
 745 L Of course
 746 J And I would debate whether anyone with LD can rationalise, can
 747 differentiate, can understand consequential things. You know, they
 748 can't, they can't. We are never going to completely generalise but we
 749 are all very defensive people about what's going on by the sound of
 750 things already, and it is so frustrating, and yes I understand what you
 751 are saying: "An advocate comes in – how does an advocate know or
 752 even begin to understand P?" You know.
 753 LG Can I just say, I mean, an advocate is only brought in when that
 754 person has been assessed as not having capacity.
 755 J No, no, no
 756 R No
 757 LG That's what the Mental Capacity Act says – you only need an advocate
 758 when someone lacks [capacity]
 759 R [(Possibly because), sorry in line with the blood test, the subject we are
 760 talking about?
 761 LG Well, if there was a decision that has to be made, that that person
 762 hasn't got the capacity to make, well that's what the Mental Capacity
 763 Act says.
 764 L I think you will find that anyone who has LD automatically get, there's a
 765 doctor, a dentist, there's the advocate.
 766 J No, we're aiming at that, [but]
 767 LG Can I just, before, [can we change]
 768 R [(Highbury would go)] out of business if they didn't have the advocacy
 769 service
 770 J (laughs)
 771 LG Can I just tell you a bit about paid carers, cos I had a paid carers' focus
 772 group
 773 L Right
 774 LG I had a similar group with paid carers and I would just be interested, so
 775 that we don't miss out on this, to hear your opinions on this, that – and I
 776 thought there would be differences between how the paid carers feel,
 777 and looking at the role of the SW in consultation, there was a concern
 778 among the support workers that if they didn't go in with the person they
 779 were supporting, that they may not be treated properly, they may not
 780 get equity of access, and I actually said to one "What do you think

781 would happen if you didn't go in with that person?" – and he said, well,
782 at the worst, nothing. Meaning, you know, if he didn't go in and support
783 that person, then that person wouldn't get the treatment they should
784 get.

785 L Is that person being supported by a member of the family or
786 LG No, this is a paid care support worker. So, you know, they, I think all
787 felt like this, that they were in a way championing the, [you know]
788 J [That's right]
789 R Yeah
790 LG So I think they have the same, you know, they are coming from the
791 same point [of view]
792 J [In a way] Yes
793 LG But equally the people that are paid carers are also very aware of the
794 transition. I mean there has been, as you mentioned J, the transition
795 between residential care, from residential care to supported living. So
796 their ethos in any supported living [place]
797 J [Is stand back]
798 LG [Is to give] people choices, so they want, they are really trying to
799 encourage these people to be able to make their own decisions, and
800 obviously we are talking about people with mild to moderate LD, so
801 perhaps it may not apply to you three, but... You know, there are
802 people who may well be judged by a GP not to be able to make their
803 own decisions, but were they given the information in a better format
804 J In a better format
805 LG And having it explained to them or interpreted, if you like, by a support
806 worker, they could actually make that decision for themselves.
807 J Mm
808 LG And I think the worry is that some people, we know that there could be
809 informed consent gained from them, but it's not happening because
810 there is an assumption that they don't understand. Or equally, there is
811 an assumption that they DO understand. I mean, in many cases,
812 people will, for example with a blood test or any small procedure at the
813 doctors, the patient will say "Yes", but they don't actually understand
814 what they are saying "Yes" too
815 J No
816 LG And the GP will make an assumption because they have said "Yes"
817 that they are understanding [what they are consenting to.]
818 J [Yes, that they are understanding]. I am sure you have come across
819 this R when you go with P to the doctor, and these days the doctor will
820 try and ignore your presence and try and talk directly to P
821 R Yes
822 J It's astonishing some of the things (laughing), talking about this will
823 thing. The last time I took E to a GP it was to have this annual health
824 check. It was a GP that hadn't ever met E before, so you know, you
825 start off thinking, "Oh my God", you know. And we went in, and he said
826 to E – "What if something happened to you, E, who would you want to
827 have power of attorney?" I said "My brother doesn't understand that
828 phrase at all" and he said, "Well, if something was wrong, who would
829 you want to help?" And they are trying, bless them, but

830 LG Mm
831 J The pressure is on them to try and deal directly, but learning disability I
832 believe should always have support with them. We have just had a
833 situation with my brother where when he moved into the home it turns
834 out, without any support, he signed a document, a tenancy agreement.
835 That tenancy agreement I believe, and it has been accepted that I am
836 right, that tenancy agreement is totally invalid
837 R Null and void
838 J Null and void, because E has no understanding of the consequences of
839 it, the implications of it. So, the danger when you do that, you try and
840 get a direct answer from the person themselves, that's dangerous, it's
841 dangerous. They will always need support and somebody to support
842 and interpret for them, and to reassure them. My brother.... And I am
843 sure P would be the same, would be very uncomfortable, very unhappy
844 about going into see a doctor, a nurse, anybody by himself.
845 LG Mm
846 J He does go with the staff sometimes if I don't know about the
847 appointment. If I do know, I go, and I insist on going because I know all
848 his medical history and stuff. But um, it's very dangerous for
849 [somebody]
850 R [Do I understand] then, the comment from the paid carers is the same,
851 that their concerns are the same as ours
852 LG Um
853 R Or not
854 LG Their concerns are yes, that they feel that [they need to be there]
855 R [Need to go in]
856 LG To give equity of access, in that way. They also commented, well one
857 commented, that he felt, and probably you would agree with this, that
858 there was some resentment of the support worker being there.
859 J Yes, yes.
860 R I can see that possibly. We don't experience that, but I can see it from
861 the point of view of someone coming in as a paid support worker,
862 possibly the professional would look at them with some suspicion.
863 J Well, I find that they do that much more with a relative. [Because]
864 LG [You feel that too]
865 J They feel that you are going to be too overpowering and too over-
866 protective and [try to speak up too often]
867 L I think it depends on your relationship with the doctor. If you've only
868 just come into the city
869 J Yes
870 L [Then that's] and your doctor is new
871 J We're in a practice and [We actually see a different] doctor every time
872 we go
873 R Well
874 J And I just try to
875 L Pa's only memory is of the surgery where [we go]
876 R [Yes] P is in a similar situation
877 J [Yes] I am trying to establish that we see one GP because I've
878 explained that it's important for E's trust, but E, yes, if a doctor even

879 without any intervention, if the doctor said something to him, like a
880 doctor explained to him that he needs to have this tablet for his thyroid.
881 He didn't know what it was, but he said "I trust you, if you say I need it,
882 OK, I'll take it". They are very trusting of somebody in a role like that –
883 a GP, a doctor. Um.

884 LG Can I just tell you a bit about, I mean, the first phase of my study was
885 actually to observe people, some people with LD having a blood test.
886 I only did 5 because it was very very difficult to actually find the people
887 who were due to have a blood test, also a couple of GP surgeries didn't
888 allow me access, although the participants themselves [had]
889 J [agreed]
890 LG [consented], but they wouldn't allow me to observe. Um, but only in
891 one case did that person have someone with them. And that was
892 someone who lived at home with his parents, and his father
893 accompanied him for the blood test. In the other cases, um, the, and
894 obviously I assume from what, they must be at the milder end of the
895 scale, but nevertheless they were classed as people with LD because
896 they receive all the services, and that's how I recruited them, via a
897 drop-in centre. And they were, and interviewing them afterwards, they
898 were very, they wanted to be independent. Um, they wanted to go on
899 their own, and you know, but they did equally, they said that if there
900 was a particularly difficult decision they had to make, that they would
901 want someone in with them,
902 J Mm
903 LG So, it's a level of, you know, it's a sort of hierarchy of
904 J Mm
905 LG Whether they would want someone in with them or not, but someone
906 else, yeah, one chap said, I said you know, "Does the support worker
907 sometimes explain things to you, if there are things you don't
908 understand at the doctors, would a SW help you?" And he said "Well,
909 they would help me, but if I can go into the doctors and explain
910 myself, then that's going more forward. And he is someone who
911 wants to be more independent. So there are
912 R [You knocked the nail on the head] there, you know
913 J [Yes, of course]
914 R That's the [spectrum] we're in
915 J [spectrum]
916 LG Mm
917 L That's why LD is a total () term for everything [that..]
918 J And as you said, and [I have said]
919 L Cos you can go from dyslexia to somebody who can't manage anything
920 J You know, it's so difficult to categorise, you know
921 LG Mm
922 L They're all individuals
923 J Everybody [wants]
924 LG [Exactly]
925 J People to be on, in a [box]
926 R [Yes]
927 J And they're [not]

928 LG [labels]
929 J And they're not, they're not in a box. P and [my brother]
930 R [P got involved] in a, in um, and I think they're not called Shooting
931 Stars, I think is it,
932 J All Stars
933 R All Stars, that's right. So that group first started many many years ago,
934 as the FEC as it was then, and P being musical, he was part of that
935 group. Now the people who were in that group were far more able than
936 P. I see them in town. They travel on the buses on their own.
937 J Yes
938 R They know, but they are classed as learning disabilities, as similar to P.
939 L We have people on the board, who, they call them service-users, who
940 are
941 R Great, well, able.
942 L Yes
943 J Yeah, they can [go out]
944 R [And I'm sure] they can go to the doctors
945 L Well, one woman, one woman, the story was very sad because she
946 had gone to the doctor on her own, and without any support, and she
947 had heard that women were supposed to have a smear test. When
948 she went to the doctor, the doctor told her – "Well, it's not for you"
949 LG Common, that's common
950 L "It's not for you, I mean you are not in a relationship, you don't need a
951 smear test." So she went back to her SW at the drop-in and um
952 obviously there was uproar (laughs)
953 LG Can I ask you how long ago this was?
954 L This was within the last year.
955 LG Mm.
956 L Do you know the person I am talking about?
957 LG No, I don't , but that's interesting, because I work in a practice one day
958 week, and I am aware that since the Mental Capacity Act, they are re-
959 thinking their, because in the past, you are right, it was assumption that
960 "you don't need to have a smear", but they are now actually re-thinking
961 that and realising that...
962 L It's a woman's right to have one. So, yes, and obviously the person
963 who chairs the board was totally distraught that something along that
964 line could happen.
965 LG Mm. So, the health care professionals do tend to making sweeping
966 generalisations about people with LD as a whole group?
967 L Yeah, I think there's something like 49 GP surgeries in Plymouth,
968 something along those lines. I think only 47 have actually signed up to
969 doing the LD assessments (medical assessments). There are still 2 or
970 3 that haven't.
971 J That refuse to do it?
972 L Um, that would see it as being um
973 J That they don't have the expertise to do it?
974 L Or they don't have the time to actually come in and do the extra
975 training. Because it does take another, I mean they do child protection,
976 they do this, they do that, they do the other. They've got to update

977 themselves on medical stuff all the time. We understand their position.
 978 So then it will get lowered down to the practice manager, then the
 979 practice nurse will take care of it.
 980 LG Mm
 981 L So, it's how it's done and how people are assessed within the surgery
 982 that I am more interested about – how this one really takes off,
 983 because if you've got somebody there who doesn't really understand it,
 984 who's just got to tick a box and say, "Oh, I've seen Pa".
 985 LG Are you talking about the health checks
 986 L [Yes]
 987 J [They've only been introduced this year]
 988 L But then if you apply that to anybody going in, so they don't actually
 989 see the doctor, they go in to see that nurse, or they're going to see the
 990 manager, or somebody else that's been assigned.
 991 LG Do you have any comments to make about the skills, the
 992 communication skills of the healthcare professionals, whether it's
 993 nurses or doctors, when they are dealing with people with LD? Do you
 994 – although it may be difficult for you to answer because of the nature of
 995 your, the people you care for, but um – what do you think about their
 996 communication skills?
 997 J Well, invariably they don't get it right. They try their best, or some try
 998 very hard, but how can they get it right, because we're not...
 999 R I think it depends on the frequency of visit, I think
 1000 J Yes, [they have to]
 1001 R [Because once] you get to know P, I think some people make an effort
 1002 to talk to him, and he can reply, you see. He can speak quite clearly.
 1003 The rationalisation of it all is the issue, but he can actually talk quite
 1004 clearly and they can understand what, how he is replying, but when
 1005 they first would meet him possibly they would talk to us (which you
 1006 experienced) rather than P.
 1007 LG Yeah
 1008 R But now, as you said, they are now directing their questions to P with
 1009 an eye to us, and in fact, a number of times, I can't remember actually,
 1010 () an example, but P has been asked a question and has answered it,
 1011 and the person looks at me and I, and [I just]
 1012 J [and go ahead, exactly, yeah]
 1013 R shake my head, and look, I sort of stay back
 1014 J [try your best to stay back]
 1015 R So I shake my head and then ask him again
 1016 J Yeah
 1017 R And he might well then say a different answer
 1018 J Yep
 1019 R And that's, you know, that's how we communicate really
 1020 LG Mm
 1021 R Without, giving, I think we need to develop him in being able to answer,
 1022 but he would say [anything that]
 1023 J [He thinks is, yeah]
 1024 LG So that reinforces your point about, that you know the person [best]

1025 J [Yes] but this thing of desperate to please is learned behaviour, though.
1026 You know, they will always do that. But I mean, if, as R says, you
1027 know, if a doctor does gradually get to know him, the way in for E is a
1028 sense of humour. You know, if they start to joke around with him and
1029 gets a bit of banter going, he then feels relaxed with them, and then
1030 you know. So, but I think, they obviously feel pressurised to try and
1031 speak directly

1032 LG/R Yeah

1033 J To the person with LD, but I do think it's very unfair that pressure on
1034 them, it's very unfair for them to do that completely cold, you know,
1035 when they've not met them before, they've not spoken to the person
1036 that's caring for them, be it a staff member or a relative, you know, it's
1037 pressure on them to try their best to speak directly, and it's dangerous
1038 again, because of all the situations where.... I don't think it is
1039 particularly our relatives, it's, I see it a lot with all of them at the
1040 Friendship Club and the discos and things – they will answer in a way
1041 that they think you want.

1042 LG Yes. I did hear a very interesting example of a GP apparently
1043 someone turned up on a Monday morning, a person with LD with a
1044 SW, but neither the person with LD nor the support worker, who was
1045 an agency SW, actually knew or could express why they were there.
1046 So obviously the appointment had been made, but the person didn't
1047 know, you know the carer didn't know the person

1048 L Scary

1049 J That's a regular occurrence if staff [that's what I was trying to say]

1050 L [That's what I mean] Everybody who works with people who've got LD
1051 must know them. Not just by virtue of the fact that you are a relative,
1052 but if they are a paid worker, then it takes time. It would take, I reckon
1053 to know Pa, a good year.

1054 LG Mm

1055 L Of one to one. Otherwise, what you are going to get back isn't going to
1056 be true. They won't [understand]

1057 J [Yes] but supported living isn't one to one, supported living is standing
1058 back and just kind of being around them, and this is what so [terrible
1059 about it]

1060 R [It's a bit scary]

1061 L [It's very very scary]

1062 J [Because they're around but they're not intervening]

1063 L [I know people who are in supporting living who can't talk, who can't
1064 speak, who only react to light and shade, who are in supported living,
1065 it's one to one. Um so there are many um situations that these people
1066 find themselves in, and the only, as far as I am concerned, the only
1067 person that speaks for them is.... You speak for your son, I speak for
1068 Pa, and you speak for your brother, and if something happens to them,
1069 I know I've got three sons who understand him and have been brought
1070 up with him. Um, so he's got another [network]

1071 J [support network] yeah.

1072 L But we've created that, and I think we are the only ones who really care

1073 J I know

1074 L I don't think anybody
 1075 R I don't know whether this breakdown of the family is identifying lots of
 1076 these people who now haven't got that privilege, not privilege, wrong
 1077 word, but that support network
 1078 J Of relatives living nearby or anything, yes.
 1079 L Or the community. But when you've got, say, the child who is
 1080 orphaned who has got an LD, then they should be able to stay within
 1081 the same environment for their life, in order that people know them. If
 1082 you were going to give security, you would want total support for these
 1083 people.
 1084 J Supported living is creating, you know, monumental problems.
 1085 LG It looks as if there are people waiting, we are going to have to wind up,
 1086 yes, we are going to have wind up now.
 1087 L Have you hit your main target?
 1088 LG It's been very interesting. You very much seem to think with one voice,
 1089 you three, so that's interesting, and you've also got a lot in common, I
 1090 think with, shall we say, conscientious paid workers, you know, paid
 1091 workers who care about what they are doing, I think you again, there
 1092 are things in common.
 1093 L And that continuity, it's essential
 1094 J I know, I can't have that
 1095 L And with paid workers you are not going to get it. Absolutely not.
 1096 J You see with the supported living home that E is in, there are 20 staff.
 1097 Those 20 staff also care for a couple of people who live in their own
 1098 flats, so they might only be in the home a couple of times a fortnight.
 1099 You know, how are they going to, how's E going to get to know them,
 1100 and how are they going to get to know E terribly well? They have an
 1101 assumption that because people have LD they can't be all that
 1102 complex.
 1103 LG Yes
 1104 J Do you agree with that, R?
 1105 L [No] I don't agree with that
 1106 R No
 1107 L No, I don't agree with that one, no
 1108 J They think that they are simple in their abilities, and they are simple in
 1109 their make-up; they don't accept... I am always saying that my brother
 1110 is incredibly complex, and I am sure you were kind of saying that in the
 1111 very beginning when you said P isn't categorisable, he's got a little bit
 1112 of this and a little bit of that, so
 1113 LG I think we are really going to have to stop now, sorry J.
 1114 J We could go on

Appendix 21 (Sample transcript from key informant interview, Phase 4, BB)

- 1 LG So, I mean you know what my research is about – about informed
2 consent to genetic testing.
- 3 BB Yep.
- 4 LG So, can you tell me your role in terms of decision making and consent,
5 can you tell me how you get involved in..
- 6 BB Gosh, it's huge now because my role has changed.
- 7 LG Cos you are primary care liaison now, aren't you?
- 8 BB I am now, yeah – I was acute services to begin with, but now primary
9 care liaison, so that's changed greatly. We do a lot of capacity
10 assessments now, in regards to capacity and cervical screening mainly.
- 11 LG Mm.
- 12 BB So it's the 4-stage test based on the MCA, and it's whether somebody
13 understands the information, can weigh it up, can use it as part of the
14 decision making process and also communicate a decision.
- 15 LG Mm.
- 16 BB So not only are we assessing that area of their need, but also what is the
17 best method of communication to present that individual with. So if they
18 LACK capacity, then you go down the 'best interest' route.
- 19 LG Yes, yes.
- 20 BB And it's understanding what would be best for that individual and what is
21 the individual's need.
- 22 LG Mm. So, who do you get called in by? Is that mainly from GPs you get
23 called in?
- 24 BB Practice nurses mainly now.

25 LG So they are obviously aware of your, of what you can do for them now.

26 BB Trying to build it up now, yeah – we're going out to all the GP surgeries.
27 I have probably covered about a quarter of the surgeries in Plymouth so
28 far.

29 LG That's interesting about the cervical smears, although that's not what my
30 research is about

31 BB Screening!

32 LG Sorry *(both laughing)*

33 BB Cervical screening

34 LG OK, not smears any more, sorry!

35 BB That's alright.

36 LG So I would imagine then, that GPs are now offering, aware that they have
37 to offer that to people. A lot of people who haven't ever been offered it
38 before, is that ?

39 BB No, what happens is that there is a new recall system, so that everybody
40 that was priorly taken off the list has now been put back on the list. So
41 even those that lack capacity, whose parents or carers have decided
42 that they didn't need that service, have now been completely
43 removed and they have been put back on the list, so that everyone in P
44 with a learning disability has now been re-invited, and that's where the
45 best interest and capacity decisions are being made now.

46 LG Mm. Do you ever get called in for anything else in terms, I mean for
47 example if , with regard to blood tests, what do you think happens, or
48 have you had any experience of consent to blood tests.

49 BB Yeeess *(laughing)*. There's been a lot. I had one this morning actually.
50 What we tend to do now is that there's always an issue with people that
51 lack capacity, cos if somebody says 'No', then it seems that they won't
52 now do a blood test on somebody that's saying 'No', rather than using

53 the 4-stage capacity assessment. So what I am doing is advocating
54 that you do the 4-stage capacity assessment and then you look at what
55 is in that person's best interest. So if somebody is on medication for
56 a specific disorder, then is that person symptomatic, showing signs and
57 symptoms of that disorder, and therefore then you can look at
58 maybe a MINIMUM restraint, cos it would be minimum restraint, or
59 admission to D hospital for that blood test under sedation.

60 LG Mm.

61 BB Cos it's in their best interest. If someone is suffering from thyroxin, you
62 know, hypothyroidism and they haven't had a regular blood test, that
63 could leave, you know, inevitably to death. So it's about weighing up
64 the benefits and the risks.

65 LG So do you think the GPs, or the practice nurses I suppose you say, are
66 turning to you for advice on that. Is that because they feel unable to deal
67 with that themselves, do you think, or....?

68 BB I think the training for learning disability awareness is very different from
69 general practitioners training, and they are used to dealing with people
70 that have capacity, so when someone is presenting that lacks
71 capacity, then it presents a whole new ball game for them, because
72 they don't really know. They don't see it enough to know how to deal
73 with it. So it is raising awareness more than anything else.

74 LG What about the people that sort of fall into, I was just talking to M about
75 this – the people that fall into a sort of middle group, where possibly
76 they could understand the information if it were presented

77 BB Yup

78 LG in a more accessible way. What do you think happens to those in
79 general practice, if there has been no attention paid to whether or not
80 they have capacity, do you think it would probably be assumed that they
81 lack capacity?

82 BB Yes

83 LG So, in terms, so therefore for example, someone going in to have a blood
84 test, and the nurse just simply says "I'm going to take some bloods from
85 you today, is that OK?" and the person says "Yes", it's not really
86 informed consent is it?

87 BB Not at all

88 LG You think that will carry on happening, or is there going to be sufficient
89 awareness of that, do you think, for that to change?

90 BB I think even if you haven't got informed consent, if somebody is assenting
91 to a procedure, that's fine. But if they say "No", or they pull away, then
92 you must stop and look at doing it in their best interests as opposed
93 to doing it because you think they've got capacity.

94 LG Yes, that's interesting, so you're saying that if they are assenting, they're
95 implying consent

96 BB Yes

97 LG But they haven't – so it's consent, but not really informed consent.

98 BB It's not informed consent, I think informed consent

99 LG Do you think it matters, how important do you think the 'informed' bit is?

100 BB It depends what you are doing the test for.

101 LG Mm. So it's, that's another thing we've been talking about, that the
102 majority, the people I have been observing having blood tests have been
103 having, you know, routine screening tests, maybe for cholesterol, thyroid
104 function, sometimes for cardiovascular disease – you know, the new
105 DES or LES or whatever it is.

106 BB Yeah, they all do that.

107 LG So screening bloods, for lipids or whatever – um, those can be seen as
108 sort of blood tests that are used in the management of a person's

109 health. When you are looking at the pharmacogenetic testing, um –
110 now tell me how much you understand about pharmacogenetic
111 testing?

112 BB Very limited (*laughing*)!

113 LG Cos we did, I recently did a webcast with my supervisor, and she is a
114 genetic counsellor, so she was able to explain it to people that were
115 listening in a very easy way. I mean I am not a geneticist, I'm a lay
116 person – I'm not even a nurse. So, but basically pharmacogenetic
117 testing is looking at a particular set of genes that are responsible for drug
118 metabolism. It is not available in this country yet, but they are using it in
119 the States for things like, cos depending on which type of gene you've
120 got, or what version of the gene you've got, you might metabolise drugs
121 more quickly or more slowly, [so it]

122 BB Yeah, the uptake

123 LG So it affects the dosage, also it will detect [adverse]

124 BB Half-lives

125 LG Adverse reactions. Basically, it's tailoring the medication to the
126 genotype. So, would you see that kind of blood test as being, in terms of
127 consent, informed consent, would you see that as being any different, ie
128 would there be a problem in getting consent from people for that kind of
129 test.

130 BB Gosh, it would have to depend on evidence, wouldn't it, that was
131 presented? There would have to be research and it would have to be, it
132 would become part of good practice, wouldn't it? Because what you've
133 got is, at the moment, you've got guesswork whether a drug works or
134 not.

135 LG Mm.

136 BB So if there is enough research to say "This is beneficial to this specific
137 person because...", then I don't think that would be a problem personally.

138 I think it's improving their health care then, isn't it, cos you are going to
139 know that if somebody's got epilepsy and they need a specific, you know
140 there are a lot of people out there that have polypharmacy, so they have
141 anti-psychotics, anti-emetics, they have a huge amount of different drugs
142 going into their system, which obviously can lead to kidney disorders and
143 liver failure later on in years, but if there is something that could be
144 identified to say, "Right this drug is more suitable for that individual"

145 LG Mm.

146 BB So the ultimate aim is, if you know something is going to benefit that
147 individual and there's research to back it up, and it's evidence based, cos
148 it would have to be evidence based wouldn't it?

149 LG Yes

150 BB Then it would become part of best practice.

151 LG So it wouldn't really be seen as any different from any other blood test in
152 terms of consent.

153 BB I wouldn't have thought it would have. I think if you are looking at genetic
154 testing for people just to find out what is wrong with them, you know,
155 there's an almost –"Well, why do we need to know?". Why do we need to
156 put a label on that person? But if it's going to be beneficial to their
157 health because it means they are taking less medication, or they are
158 taking the appropriate medication that responds well to them, then, yeah,
159 I personally wouldn't think that there is a problem with that. I think you
160 could argue in the best interest, because you are looking at weighing up
161 the benefits the outweighing the negatives.

162 LG Yes, yes.

163 BB So the benefits of having a blood test, as long as the blood test wasn't
164 too traumatic and didn't involve a general anaesthetic, which is a risk,
165 you know, you are weighing up the risks against the benefits aren't you?

166 LG Mm, yes, I agree. Um, as well as observing people, I have to say when I
167 did my observations, I only did five because it was quite difficult

168 BB Mm

169 LG to get into surgeries, but um, there was a great range of amount of
170 information given, if any, when someone was having a blood test, so
171 sometimes there was none, sometimes there was explanation that "we
172 are just going this to check that your kidneys are working properly", and
173 there was sort of an attempt at getting consent, but in most cases the
174 patient were well known to the nurses, so it's understandable I suppose
175 that there wasn't a particular effort to get consent. Um, when I actually
176 spoke to people – I interviewed 14 people with LD, some of whom I have
177 also observed, um, some of them were quite clear that they didn't
178 particularly want information about what the blood test was about,

179 BB Mm

180 LG They didn't need it. So, I found that interesting because, then you are
181 looking at how different is someone with a learning disability to someone
182 without a learning disability.

183 BB No different

184 LG Cos that choice

185 BB There shouldn't be any difference

186 LG would apply to anyone

187 BB Absolutely

188 LG So, with regard to

189 *(Recording interrupted, someone came into the room. Resumed in a different*
190 *room)*

191 LG Oh, yes people who said they don't want information

192 BB Yeah

193 LG Um

194 BB No different at all from the general public, why should it be?

195 LG No, no.

196 BB Yeah, my dad doesn't want to know when he has his bloods done, what
197 it's for, and I say to him, "What have you had done?"

198 LG Mm. So , in that way someone with LD is no different, so in terms of what
199 you have been experiencing, you know, with the people with LD, if they
200 say that,

201 BB Mm

202 LG You just accept that, that they don't

203 BB Absolutely

204 LG That they don't need to know, and there would be no question of ..

205 BB I would question to make sure that I got the appropriate feedback from
206 them, you know, but is it important for you not to know, or maybe give
207 the carer some information so that if they wanted to know in the future, or
208 give them information to say, if you did change your mind, you know,
209 ask...

210 LG Cos, I can't remember, I looked at a paper recently, I can't remember
211 who it was, but they actually said that really in a way, that person saying
212 they don't want the information, they are exercising autonomy, aren't
213 they?

214 BB Yeah, of course they are.

215 LG Cos it's their choice not to know

216 BB Absolutely

217 LG So, that's you know, interesting.

218 BB But it might be that they haven't been offered the information in a form
219 that they understand in the first place, so when they are given
220 information that they don't understand, it's almost, "Well, don't give me
221 that information cos I won't understand it anyway, it's too complex for
222 me".

223 LG Maybe that's why they say

224 BB Yeah

225 LG they don't want it, because they are afraid of being shown up, of, you
226 know, it's very important for them to feel that they are not being made to
227 look stupid.

228 BB Yeah

229 LG You know, I think some of them.... I certainly got the impression from
230 talking to all of the people, that their self-esteem is so important to them.
231 I mean, some of them said, "I don't want anything with pictures cos that's
232 babyish".

233 BB Absolutely

234 LG So you [have to be careful]

235 BB And why are they being given that information when they are able to
236 read? Or the verbal spoken word, you know, or you know, there's ways
237 of doing it that empower people as opposed to disempowering them, isn't
238 there?

239 LG And isn't that about knowing the person. In a way, possibly, I have to
240 say I haven't seen anyone in a surgery being given accessible
241 information, but I am sure, I suppose it does happen. Not for a blood
242 test.

243 BB We've got a blood test pathway. It's photographic, that we can show
244 people who might have visual difficulties or difficulties understanding,
245 and we do a desensitisation process with somebody. But for those who
246 lack capacity, that wouldn't be offered because they don't understand the

247 information. The majority of them wouldn't be able to retain the
248 information anyway, which is why we are doing the best interest in the
249 first place.

250 LG Mm. Um, Ok, so we've talked about the pharmacogenetic testing. So in
251 terms of the fact that you really don't see there is any difference to any
252 other sort of screening or any other routine blood test, then really there
253 are no specific problems that would arise in terms of explaining it
254 because they would give them all the information that they need, which
255 would be

256 BB "We are testing your blood to find out if it matches what tablets we want
257 to give you".

258 LG Mm, yeah. And most of them, again, when I tried to explain um
259 pharmacogenetic testing to them – you know, if you establish that they
260 have never heard of genes or they've never heard of genetics, then
261 there's no point in just going down that pathway

262 BB Oooh, why not? Why couldn't you describe it some way different, like,
263 your body is made up of....

264 LG Oh, yeah

265 BB You know, it's how you describe it, cos we use medical terminology
266 can confuse the best of us.

267 LG Mm

268 BB And it's about breaking that down into a formula, you know, you say a
269 gene and they might think, oh well, I wear jeans on a Friday

270 LG Well, I think that's what I....

271 BB It's about finding the right way of communicating [what]

272 LG Well, I think that's what I meant; I probably didn't express that very well.
273 I did, I started off by saying "Have you heard of genes, not the jeans that
274 you wear, but genes" And some of them have and some of them said

275 "Oh yes, it's to do with whether you are going to get cancer", which I
276 thought was very interesting.

277 BB OK (*sounded surprised*)

278 LG And someone else said "Is it to do with your heart or your brain" – but
279 they knew it was

280 BB Yes

281 LG And then someone said, "Isn't that something that's passed down from
282 your parents.

283 BB Wow!

284 LG So I was quite surprised.

285 BB Yeah, no, that's good.

286 LG But as you say, the ones who hadn't heard of , I then went on and
287 explained about, I mean I used eye colour and hair colour because that
288 was the first thing I could think of that would, and the fact that you might
289 look a bit like your mother or your father, and sort of, so as you say, it
290 doesn't need to be scientific language. You don't need to express it as
291 'genetics' or 'genes', but it needs to be in a way that they can
292 understand. I think that certainly they don't need the science behind it.
293 That's what I was trying to say.

294 BB Yeah.

295 LG To go onto something slightly different in terms of decision making. Um,
296 I had a focus group with paid carers and they were saying that they
297 found the move, the transition from people in residential care changing
298 over to supported living was quite difficult because people hadn't had
299 previous opportunities for making a decision for themselves, and weren't
300 even aware that they could have a choice. Have you noticed that in
301 your, you know, is that something you have been aware of – this lack
302 of....

303 BB Not residential to supported living, but I think generally

304 LG That they're not aware that they have a choice?

305 BB Just generally, it's very difficult to enable choice because you need to
306 know there is a choice presented before you can make one (laughs).
307 You know? So if you say to somebody I am going to give you a choice
308 now between fish and chips and pizza, if you've never tasted either of
309 those, how can you make a choice? So to suddenly change from
310 supported living to residential care (*she got this the wrong way round*)
311 without knowing what's out there, without experiencing it previously, it
312 depends on the background. But that goes not just for people with
313 learning disabilities, but for any of us.

314 LG Mm

315 BB You know, it's only your own self-insight that enables you to make a
316 choice. Some people can live very secluded lives, you know, they are
317 doing that. They might NOT know that there are choices out there. It's
318 really difficult not to impose your feelings onto other people, because it's
319 only the experiences that we have had in our lifetimes that make OUR
320 choices what they are.

321 LG Yeah, mm. So, I was saying to M that because it's becoming obvious to
322 me that a lot of the work I've done, you could relate it to people without a
323 learning disability.

324 BB Of course

325 LG So, I'm trying to establish in my own mind what is it about people with
326 learning disability that makes it more important for them to have, give an
327 informed choice. What would you say about that?

328 BB Historically, people with LD have not been accepted as part of the
329 community because they are not valued, because a lot of the individuals,
330 maybe with a more severe learning disability, will never be able, in some

331 people's eyes, to contribute to society, and therefore they are not valued
332 like they should be.

333 LG Mm.

334 BB That is changing. We are trying to enable change. Through people living
335 in the community, they are no longer in huge institutions in the middle of
336 the country in their own little villages, you know, they are, there is a
337 process of normalisation going on where we are trying to enable people
338 to feel more valued and more accepted in the social.... but that's not
339 about changing the person with a learning disability's mind, it's about
340 changing society's minds, and that's huge.

341 LG Yeah

342 BB And that's where the specialist services come in, to promote that and say
343 "Why should these people be treated any differently?" There's no reason
344 for it. Stop doing it. They are HUMAN BEINGS at the end of the day;
345 they might need a little extra support and they might need direction,
346 but why shouldn't they be offered the same opportunities that the rest
347 of us make. Who says they are not capable of doing that?

348 LG Oh, yes.

349 BB You know, there are people on the more severe end of the spectrum that
350 maybe will never attain goals in their life like you or I would, but there are
351 other people that, with a bit of support, why can't they?

352 LG Mm. So if you were a GP and you, or a practice nurse, when you offer
353 someone a blood test, you don't normally give them the information then,
354 what you're saying, in a way then, why should a person with a learning
355 disability be given information that perhaps somebody else might not be
356 given? Do you see what I mean?

357 BB I think it's completely individual.

358 LG [You think it's irrelevant then?]

359 BB [If that person comes in] Yeah, I think it's completely irrelevant. If
360 somebody comes in and starts asking questions, then you give that
361 information. If somebody comes in, who you can see is struggling with
362 the communication process, then you need to do a communication
363 assessment [to support that]

364 LG Whoever they are?

365 BB Whoever they are – whether they have got a learning disability, mental
366 health problem, elderly dementia, whoever they are, that person then
367 should have extra support to understand that communication process
368 and what's been happening to them, so regardless of whether they've
369 got a learning disability or not.

370 LG Mm. What about, now the other thing, I've also had a group of family
371 carers – I had one with paid carers and one with family carers.

372 BB OK

373 LG What about the parents that come in (BB smiling) with their child, their
374 adult son or daughter and assume that they can make the decisions for
375 that person. Have you encountered that as a problem?

376 BB Yes, I think it's just about educating the individuals, because they've
377 gone through their life, and it's a protective nurture, isn't it?

378 LG Yes, Mm.

379 BB This is my son, we want what's best for them. But also it's about
380 enabling those parents and carers to see that the person is an adult in
381 their own right.

382 LG How do you get over the problem, though, that, I mean one father said to
383 me – he had noticed that the GP, whom the family has known for a long
384 time, whereas previously he had addressed the father, the GP has
385 suddenly started to address the [son]

386 BB [Brilliant, brilliant!]

387 LG But, his attitude to that was "Well, that's a waste of time because he
388 doesn't understand"

389 BB Aww

390 LG I couldn't comment on, obviously I couldn't comment on that. I am also a
391 parent, so I couldn't comment on it in the group, but do you think that
392 could be a common reaction in that, you know, it would be difficult for
393 GPs to, and that people would be deprived of being able to make a
394 choice for themselves? Or do you think that in fact, the parents DO know
395 their child best, and are actually accurate in the fact that they wouldn't
396 able to understand? You know, how do you deal with that?

397 BB I think that's on an individual basis again. I mean, we're professionals,
398 so our practice is evidence-based. So if we've got government
399 documents coming out, they've been led from research, so we've got the
400 evidence base to say that the majority of people with a learning disability
401 haven't had the chances. There might be adults out there, parents out
402 there that have advocated very strongly for their children all their life and
403 have a very good sound moral basis, and they are very evidence based
404 and they see the rationale behind it. There are other people that are
405 doing it on a wing and a prayer (both laugh) and just hoping they are
406 doing the right thing for their son or daughter. As a professional, we
407 have standards, we have a duty to care, and we have to make sure that
408 our practice is evidence based. So we can then say to the parents,
409 "Look, historically, this is how people have been treated, now we are
410 trying to do this BECAUSE this is what we have learned works, and it's
411 right, and it makes people feel valued, and we're trying to....

412 LG A sensitive issue to deal with, though, with parents

413 BB Exceptionally sensitive, and I think it would have to be taken on an
414 individual basis, because it's about looking at who that individual is, what
415 the dynamics are within that relationship, and how much that individual
416 benefits from that situation.

- 417 LG Mm. Cos there's definitely a feeling – well, I know my child best, you
418 know, anyone else coming in.....
- 419 BB And they probably do know their child best and that is about getting the
420 balance right between the GP saying "I really appreciate that you are
421 here, and I think it's great that we've got this chance to meet, so we can
422 share information, but I am here for your son today, and I'm gonna get
423 the information from your son, and then we can look at the whole
424 information, we can look at the whole picture". Because before, they
425 have been ignored, the person with LD has been ignored. Now it's
426 about bringing them into that picture and having the whole thing,
427 rather than just a little segment.
- 428 LG Mm, yes, that's a difficult one. Some of the paid carers, the support
429 workers, whatever role they are in, actually felt that were they not
430 present, that the person might not get the care that they merited. Now,
431 you know, talking to the people with LD, they very much appreciated the
432 support worker's role as an interpreter sometimes, you know, with the
433 language the GP was using, and they would act as a go-between in
434 terms of explaining the procedures when consent was obtained, and they
435 said they felt safe and it was helpful. Some of them felt that they wanted
436 to be more independent and they wanted to go in on their own, but from
437 the supporter's point of view, they, some of them felt, it was almost as if
438 they were seeing themselves as 'champions' for people with LD, that if
439 they didn't go in and make sure that that person got the treatment. One
440 of them actually said, I said "Well, what do you think would happen if you
441 didn't go in with that person?" And he said "Well, at best, nothing", well,
442 at worst ,nothing. You know, I think they very much feel they've got to go
443 in there and make sure that things are done properly. Have you come
444 across that, do you have any comments on that?
- 445 BB I think we have to be careful as carers not to over-emphasise our role
446 because it's very easy to take on a protective role when it should be a
447 supportive role.

448 LG Mm

449 BB Again, it's looking at the individual and how that individual is able to
450 communicate their own need. If they are able to express how their
451 feeling and the difficulties they are having, and what's wrong with them,
452 then why should the carer be involved in that process? Why should we
453 be de-skilling that individual and taking it away? On the other hand, if
454 that individual is likely to get confused or may need prompting and
455 support in the future, if they need that support, then by all means a carer
456 can be a very useful asset.

457 LG The same person also said that he felt that in some cases, there was
458 resentment on the part of the healthcare professional that they were in
459 with them, you know, almost as if they felt that the healthcare
460 professional was seeing them as interfering, sort of, you know,
461 perhaps it was appropriate that they felt the carer shouldn't have been
462 there? That they felt they should be dealing directly?

463 BB I think advocacy has a big role to play there now, doesn't it, in that, yeah
464 if the individual is being cared for in supported living or residential
465 environment, then it may be that they have additional needs and maybe
466 that care worker is a supportive role, but there is also a role for advocacy
467 in there, in that that person then has nothing to gain from that, and it
468 should be seen as a supportive interaction as opposed to a negative one.
469 Cos GPs or maybe at D Hospital or somewhere like that, there's no need
470 to be defensive about extra support, you know, it's about transparency
471 isn't it, and we are all here to help this individual rather than a hindrance.

472 LG Ok, I think probably we've covered everything now. There were some
473 comments from the people with LD about the visibility of the LD – that
474 sometimes people didn't recognise that they had a learning disability.

475 BB Isn't that a good thing?

476 LG But then they felt that they weren't getting the support that they needed
477 from, you know, people weren't understanding that they had extra
478 needs.

479 BB Yeah

480 LG So, it's a bit of a [paradox]

481 BB [Catch-22] Yeah. You know, again, it is, what you've got is learning
482 disabilities is such a broad spectrum. You've got people who have got
483 profound and severe LD that couldn't survive without the support of
484 another, and on the other end of the spectrum you've got someone with
485 a very mild LD, who is very able, able to communicate, but may just get
486 a little bit muddled every now and then – don't we all? (both laugh) You
487 know, and it's about the whole spectrum, it's not about putting people
488 into boxes, it's about looking at what their individual need is, and being
489 dynamic and versatile enough to change to meet the needs from the
490 person with a profound and severe LD to meeting the needs of
491 somebody who may just need a little bit more reassurance and extra
492 communication.

493 LG Mm. You obviously know far more about the MCA than I do. A court-
494 appointed deputy – now, one GP apparently suggested to a parent that
495 they should make themselves, get themselves appointed as a deputy
496 for that person. Does that only happen when there is lack of capacity?

497 BB Mm,mm.

498 LG Right, that's interesting, cos that's happened too.

499 BB You can have an advanced decision when there is somebody who HAS
500 capacity chooses that person to deal with their affairs.

501 LG Mm

502 BB But if it's a lack of capacity, then somebody should be appointed for
503 financial reasons.

504 LG But what about health decisions?

505 BB Yep, health decisions as well.

506 LG So

507 BB You can then involve an IMCA as well.

508 LG Yeah, so that's a different, So basically, that GP would have been
509 asking for that so that he felt he could communicate with the parent
510 legitimately, do you think?

511 BB That doesn't come into it really, [because by being next of kin now]

512 LG [I just wondered why it was requested]

513 BB Yeah, no, I don't know – maybe they are getting a bit confused, but by
514 having an appointee, it's a legal power, but as a next of kin now the new
515 MCA (2005) has now enabled the next of kin, you must have discussions
516 with the next of kin, but ultimately the decision lies with the person who is
517 proposing the treatment. And if you have no next of kin, then it falls to an
518 IMCA. If the treatment is thought to be life-threatening. Interesting one,
519 that.

520 LG So, if someone's got an appointee then, does that mean that there
521 doesn't have to be, cos with best interest decisions, you involve lots of
522 people, don't you? So does that still happen?

523 BB It's best practice, yes.

524 LG Right, well I think we've just about covered everything really – you know,
525 there's so much to talk about, but that's given me a lot of information,
526 thanks very much A.

Frenchay Research Ethics Committee

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06 August 2008

Mrs Lesley Goldsmith
PhD student
University of Plymouth
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Drake Circus
PL4 8AA

Dear Mrs Goldsmith

Full title of study: Informed consent for genetic testing in people with a learning disability
REC reference number: 08/H0107/49

The Research Ethics Committee Chair reviewed the above application at the meeting held on 06 August 2008.

Ethical opinion

The chair of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Ethical review of research sites

Site-specific assessment is not required. There is no need to complete the Site-Specific Information Form or to inform other Research Ethics Committees about the research. However, all researchers and local research collaborators who intend to participate in this study at NHS sites seek approval from the R&D office for the relevant care organisation.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission at NHS sites ("R&D approval") should be obtained from the relevant care organisation(s) in accordance with NHS research governance arrangements. Guidance on applying for NHS permission is available in the Integrated Research Application System or at <http://www.rdforum.nhs.uk>.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>	
Application		15 May 2008	
Investigator CV		06 May 2008	
Protocol		13 May 2008	
Covering Letter		21 May 2008	
Covering Letter		03 July 2008	
Covering Letter		29 July 2008	
Summary/Synopsis		15 May 2008	
Letter from Sponsor		15 May 2008	
Letter from Sponsor		29 July 2008	
Compensation Arrangements		17 July 2007	
Interview Schedules/Topic Guides	1	15 May 2008	
Interview Schedules/Topic Guides	2	30 June 2008	
Interview Schedules/Topic Guides	3	28 July 2008	
Advertisement		15 May 2008	
Letter of invitation to participant	1	15 May 2008	

GP/Consultant Information Sheets	1	15 May 2008	
Participant Information Sheet: Carers	1	15 May 2008	
Participant Information Sheet: LD nurses	1	15 May 2008	
Participant Information Sheet: Healthcare professionals	1	15 May 2008	
Participant Information Sheet: Phase 2 (LD)	1	15 May 2008	
Participant Information Sheet: Phase 1 (LD)	1	15 May 2008	
Participant Information Sheet: Supporter	2	30 June 2008	
Participant Information Sheet: Supporter	3	28 July 2008	
Participant Information Sheet: Healthcare Professionals	3	28 July 2008	
Participant Information Sheet: Phase 2 LD	3	28 July 2008	
Participant Information Sheet: Phase 1 LD	3	28 July 2008	
Participant Information Sheet: Carer	2	30 June 2008	
Participant Information Sheet: LD nurses	2	30 June 2008	
Participant Information Sheet: Healthcare Professionals	2	30 June 2008	
Participant Information Sheet: Phase 2 LD	2	30 June 2008	
Participant Information Sheet: Phase 1 LD	2	30 June 2008	
Participant Consent Form: Phase 2 LD	2	30 June 2008	
Participant Consent Form: Phase 1 LD	2	30 June 2008	
Participant Consent Form: Non LD	2	30 June 2008	
Participant Consent Form: Phase 2 (LD)	1	15 May 2008	
Participant Consent Form: Phase 1 (LD)	1	15 May 2008	
Participant Consent Form: Non LD all phases	1	15 May 2008	
Participant Consent Form: Non LD	3	28 July 2008	
Response to Request for Further Information			
Response to Request for Further Information			
Bulletin board question guide	1	15 May 2008	
Focus Group Guide Carers	1	15 May 2008	
Supporters PIS	1	15 May 2008	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Now that you have completed the application process please visit the National Research Ethics Website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

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
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

08/H0107/49

Please quote this number on all correspondence

With the Committee's best wishes for the success of this project

Yours sincerely

Dr Mike Shere
Chair

Frenchay Research Ethics Committee

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11 November 2008

Mrs Lesley Goldsmith
PhD student
University of Plymouth
Centre Court
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PL4 8AA

Dear Lesley

Study title:	Informed consent for genetic testing in people with a learning disability
REC reference:	08/H0107/49
Amendment number:	1
Amendment date:	27 October 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 07 November 2008.

Ethical opinion

The members of the Committee present 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	
Notes to accompany amendment			
Notice of Substantial Amendment (non-CTIMPs)	1	27 October 2008	

Membership of the Committee

The members of the Committee who were present at the meeting 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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0107/49: Please quote this number on all correspondence

Yours sincerely

Mr Anthony Sack

Committee Co-ordinator

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13 March 2009

Mrs Lesley Goldsmith
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PL4 8AA

Dear Lesley

Study title: Informed consent for genetic testing in people with a learning disability
REC reference: 08/H0107/49
Amendment number: 2
Amendment date: 09 March 2009

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 11 March 2009.

Ethical opinion

The members of the Committee present 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	
Notice of Substantial Amendment (non-CTIMPs)	2	09 March 2009	
Covering Letter			

Membership of the Committee

The members of the Committee who were present at the meeting 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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0107/49: Please quote this number on all correspondence

Yours sincerely

Mr Anthony Sack

Appendix 25

Frenchay Research Ethics Committee

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Tel: 0117 323 5211

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17 September 2009

Ms Lesley Goldsmith
PhD student
University of Plymouth
Centre Court
Drake Circus
PL4 8AA

Dear Lesley

Study title:	Informed consent for genetic testing in people with a learning disability
REC reference:	08/H0107/49
Amendment number:	3
Amendment date:	11 September 2009

The above amendment was reviewed by the Sub-Committee in correspondence on 17 September 2009.

Ethical opinion

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	
Participant Consent Form: Carer (online)	1		
Participant Information Sheet: Carer info sheet (online)	1	02 September 2009	
Notice of Substantial Amendment (non-CTIMPs)	3	11 September 2009	

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0107/49:

Please quote this number on all correspondence

Yours sincerely

Mr Anthony Sack

Committee Co-ordinator

Appendix 26

Frenchay Research Ethics Committee

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01 March 2010

Ms Lesley Goldsmith
PhD student
University of Plymouth
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Dear Lesley

Study title:	Informed consent for genetic testing in people with a learning disability
REC reference:	08/H0107/49
Amendment number:	4
Amendment date:	26 January 2010

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

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	
Participant Consent Form	1	26 January 2010	
Notice of Substantial Amendment (non-CTIMPs)	4	26 January 2010	
Covering Letter			
Proposed participants		22 February 2010	
Participant Information Sheet: key informant	2	22 February 2010	

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

08/H0107/49:

Please quote this number on all correspondence

Yours sincerely

Mr Anthony Sack
Committee Co-ordinator

Informed consent to healthcare interventions in people with learning disabilities – an integrative review

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GOLDSMITH L., SKIRTON H. & WEBB C. (2008) *Informed consent to healthcare interventions in people with learning disabilities – an integrative review. Journal of Advanced Nursing* 64(6), 549–563
doi: 10.1111/j.1365-2648.2008.04829.x

Abstract

Title. Informed consent to healthcare interventions in people with learning disabilities – an integrative review.

Aim. This paper is a report of an integrative review of informed consent to healthcare interventions in people with learning disabilities.

Background. Consent to treatment lies at the heart of the relationship between patient and healthcare professional. In order for people with learning disabilities to have equity of access to health care, they need to be able to give informed consent to health interventions – or be assessed as incompetent to give consent.

Data sources. The British Nursing Index (BNI), CINAHL, MEDLINE, Social Care Online, ERIC and ASSIA and PsycINFO databases were searched using the search terms: Consent or informed choice or capacity or consent to treat* or consent to examin* AND Learning disab* or intellectual* disab* or mental* retard* or learning difficult* or mental* handicap*. The search was limited to papers published in English from January 1990 to March 2007.

Review methods. An integrative review was conducted and the data analysed thematically.

Results. Twenty-two studies were reviewed. The main themes identified were: life experience, interaction between healthcare professionals and participants, ability to consent, and psychometric variables. A consensus seemed to emerge that capacity to consent is greater in people with higher cognitive ability and verbal skills, but that the attitudes and behaviour of healthcare professionals was also a crucial factor.

Conclusion. The findings support use of the functional approach to assessing mental capacity for the purpose of obtaining informed consent. Future research into informed consent in people with learning disabilities is needed using real life situations rather than hypothetical vignettes.

Keywords: cognitive disabilities, informed consent, integrative review, learning disabilities, nursing

Introduction

Consent to treatment lies at the heart of the relationship between patient and healthcare professional and 'the focus on patient centred care and shared decision-making highlights the importance of informed consent' (UK Clinical Ethics Network 2006). In order for people with learning disabilities (LD) to have equity of access to health care, they need to be able to give informed consent to health interventions – or be assessed as incompetent to give consent. Although laws concerning consent vary, it is now widely accepted that there should be presumption that an individual has capacity to give consent unless proved otherwise (Keywood *et al.* 1999); this presumption can be overturned if it can be shown that the patient is not able to comprehend and retain information that is material to the decision, including the likely consequences of having or not having the proposed treatment, or is unable to use the information and weigh it in the balance as part of the process of arriving at the decision. As the law varies slightly in the different countries making up the United Kingdom (UK), we refer only to England and Wales in this paper. The *Mental Capacity Act* (Department of Health 2005), which attempts to clarify issues of consent and capacity, includes the following key principles:

- Presumption of capacity.
- The right for individuals to be supported to make their own decisions.
- The right for individuals to make what might be seen as eccentric or unwise decisions.

The law in the United States of America (USA) also presumes patients' competence – or decision-making capacity (Appelbaum & Grisso 1988), but there is distinction between the terms *capacity* and *competence*. According to Gunn *et al.* (1999) the former is a general concept and the latter a specific one.

When investigating informed consent, it is important to consider the perspectives of users' and healthcare professionals', as well as those of carers or others involved in the process of gaining informed consent for healthcare interventions. In this integrative review, we assess empirical evidence relating to informed consent (to include assessment of mental capacity) to healthcare interventions for people with LD.

The review

Aim

The aim of this integrative review was to examine the literature on obtaining informed consent to healthcare interventions from people with LD.

Design

An integrative review of both quantitative and qualitative research was undertaken (Whittemore & Knafl 2005).

Search methods

The British Nursing Index (BNI), CINAHL, MEDLINE, Social Care Online, ERIC and ASSIA and PsycINFO databases were searched using the following search terms:

Consent or informed choice or capacity or consent to treat* or consent to examin* AND Learning disab* or intellectual* disab* or mental* retard* or learning difficult* or mental* handicap*

The limits set were:

Publication date: between January 1990 and March 2007

Population: Human

Age: Adult

Language: English

The definition of adult used was 16 years because in the UK those over 16 can take medical decisions independently of their parents (Ministry of Justice, 1969). When possible, searching was limited to research or review papers. Where this option was not available papers were filtered manually to identify those based on primary or secondary research.

Search outcome

Twenty-two studies were found: 10 quantitative, eight qualitative, one mixed methods, one with unclear methodology and two literature reviews. All relevant papers were included, regardless of quality. Four papers were mentioned in both the literature reviews and the empirical studies. However, as no meta-analysis was conducted the problem of double counting did not arise.

Quality appraisal

A grading system was adopted to facilitate quality appraisal. For quantitative and qualitative papers the tool described by Kmet *et al.* (2004) was used. For reviews, the CASP tool '10 questions to help you make sense of reviews' (Public Health Resource Unit 2007) was used.

A chart was produced by the first author (LG) showing the range of scores obtained, and then the two papers with the lowest score, the two with the highest score and the one with the median score were selected and a blind appraisal was made by the second author. The papers were ranked in the same order by both appraisers.

Data synthesis

The data were synthesized using the approach of Miles and Huberman (1994), involving data reduction (primary data are refined, summarized, grouped or organized), data display (using matrices, graphs, tables etc), and conclusion drawing and verification (based on emerging patterns, explanations or propositions). The papers identified are shown in Table 1, which outlines the methodology, sample size, data collection methods and main findings.

Results

The over-arching aim of the studies identified for this review was to gain more knowledge about the concept of informed consent in people with LD. The majority of research involved people with LD as participants, but some also involved healthcare professionals or carers. For the purposes of this review, 'ability to consent' includes the terms 'competence', 'functional ability' and 'mental capacity'. No distinction is made between mental capacity and competence although these terms have slightly different definitions: in the USA, capacity is regarded as a general concept, with competence being a specific one, whereas in England the terms are often used interchangeably (Gunn *et al.* 1999).

Life experience

One of the themes which emerged from the literature was that of life experience; within this are four sub-themes – residential status of the participant, experience of decision-making, acquiescence and health experience.

Residential status

The place of residence of the person with LD is considered in several studies in discussions (Arscott *et al.* 1999, Fisher *et al.* 2006, Dye *et al.* 2007) without any further investigation into its possible effect. Authors who do consider residential status conclude that people with LD living in residential care settings will have few opportunities to exercise choice (Dean *et al.* 1998) or that those living independently will not have access to assistance, such as from learning disability nurses, to help them make choices.

Decision-making opportunity

There appears to be consensus that people with LD lack experience in decision-making, and that this will affect their functional capacities with regard to informed consent (Morris *et al.* 1993, Cea & Fisher 2003, Dye *et al.* 2007). For example, Arscott *et al.* (1999) attributed the fact that par-

ticipants found questions about their legal rights and options regarding treatment difficult to the fact that they may not be allowed to, or be familiar with making lifestyle decisions.

In relation to consent to taking part in a randomized controlled trial, Dye *et al.* (2007), also suggest that limited decision-making opportunities in the lives of people with intellectual disabilities will limit their capacity to consent. Similarly, in a study of healthcare decision-making by Keywood *et al.* (1999), the majority of parents and carers identified themselves as the main decision-makers for the adults with LD, while Heslop *et al.* (2005), investigating how much people knew about their medications, found that little information was given to the people themselves or their carers – implying that the decisions were actually taken by the prescribers.

Acquiescence

Acquiescence (defined as acceptance without protest) is a concept that may be associated with residential status and decision-making opportunity. Keywood *et al.* (1999) found much evidence of acquiescence among the participants with LD they interviewed, especially with regard to female contraception, pregnancy testing and sterilization; it was often the carer, doctor or parents who were making the healthcare decision, and the individual simply went along with it. Similarly, in the study by Morris *et al.* (1993) many participants were said to consider that they had no choice in treatment and felt that whatever they said would make no difference. The two studies by Arscott *et al.* (1998, 1999) looked at informed consent to take part in research, and to have medical treatment. The authors concluded that many participants did not understand that they could withdraw from a study, and may have been keen to please the researcher. With regard to health interventions, people with LD may not perceive that they are able to make a decision that does not match that of their healthcare professional. Dunn *et al.* (2006) reinforce these findings, with only two out of 19 of their participants understanding that they could decide whether they continued seeing a psychologist. These authors warn that clinicians need to be aware of this tendency to a high level of acquiescence in people with LD, and Dye *et al.* (2007) found that although the majority of their participants were assessed as being unable to consent, they were all very willing to take part in the research.

Previous health experience

Several workers have considered the influence of previous experience on ability to give consent by people with LD, but findings have varied.

Arscott *et al.* (1999), contrary to their expectations, found that having experience of taking medication did not render

Table 1 Summary of papers

Reference	Purpose of study	Methodology	Sample and size	Data collection method	Method of analysis	Main findings of relevance
Arscott <i>et al.</i> (1998)	To investigate the ability of people with LD to consent to psychological research	Quasi-experiment	Adults with LD from various social educational centres in two towns in England. $n = 40$	Assessment of receptive vocabulary using the BPVS. Interview using scoring protocol to assess ability to consent	Scores were produced for ability to consent. Reliability was tested using a second rater (Kappa 0.95 across all questions)	Participants able to understand nature of research, but little understanding of risks, benefits or their rights. Higher receptive language score associated with ability to consent Researchers need to be aware that participants may agree to take part in research without fully understanding the implications
Arscott <i>et al.</i> (1999)	To investigate the assessment of capacity of people with LD to give informed consent to treatment, and the influence of verbal and memory ability	Quasi-experiment	Adults with LD from various social educational centres in two towns in England. $n = 40$	Interview using scales to measure receptive vocabulary, verbal and spatial memory. Interview using questionnaire to assess ability to consent	Scores for each parameter were produced and tested for association	Verbal and memory ability influenced capacity to consent. Questions concerning participants' rights, options and impact of their choices most difficult to answer. Sixty-five per cent of participants were assessed as having capacity to consent to at least one vignette
Arscott <i>et al.</i> (2000)	To investigate the amount of knowledge that people with intellectual disability have about their medication	Quantitative	Adults with ID from various social educational centres in two towns in England. $n = 30$	Questionnaire survey using a 'Knowledge of Prescribed Medication Questionnaire'	A score for medication knowledge was produced. Scores for each question were compared using one-way ANOVA	People with ID have poor knowledge about some aspects of their medication. The author questions the issue of informed consent in this population, although this lack of knowledge is not specific to people with ID. Participants may not have received information, or may have not remembered it
Broughton (2002)	To give a general overview of the literature available about women with LD and cervical screening	Literature review	Five databases, published and electronic journals, library and world wide web	Databases systematically searched from 1990's to present. Specific search strategy not stated	Not stated	With regard to informed consent, women with LD need to gain some control through appropriate preparation; education, knowledge and support from trained professionals in order to be able to give informed consent about cervical screening
Carlson <i>et al.</i> (2004)	To investigate present practice, in relation to consent to treatment, of those who refer to an adult learning disability service	Questionnaire survey	All referrers to a Community Team for Learning Disability in England. $n = 171$	Postal questionnaires. 79/171 responded – response rate 46%	Not stated. Awareness of consent guidelines by referring agencies analysed, plus prior discussion of referral with client	Sixty-eight per cent of all referrers (but fewer GPs) were aware of guidelines. Those unaware of guidelines were less likely to give information to patient on what would happen following referral and less likely to keep written records of consent. This suggests that increased awareness of guidelines on consent results in better practice

Table 1 (Continued)

Reference	Purpose of study	Methodology	Sample and size	Data collection method	Method of analysis	Main findings of relevance
Cea and Fisher (2003)	To examine the ability of adults with mild and moderate mental retardation (MR), to understand the elements of informed consent for health related treatments within the four psycho-legal standards proposed by Appelbaum and Roth (1982).	Quasi-experimental interviews	Three equal groups: No MR, mild MR, moderate MR. Those with MR recruited from local residences, those without from a local community college in USA. n = 90	Individual interviews using 'Assessment of Capacity-Treatment' instrument developed for this study	All interview transcripts independently scored by two raters. Inter-rater agreement high. ANOVA to compare differences between groups in each context (vignette) and each psycho-legal standard	Capacity in all groups decreased with increased complexity of questions. This study shows that many adults with mild MR and some with moderate MR have the ability to give informed consent. Consent capacity could be enhanced with supportive decision-making or educational techniques
Dean <i>et al.</i> (1998)	To identify difficulties in assessing the capacity to give consent	Unclear 'qualitative' but using structured interviews	People with LD living informally in NJS buildings in England. n = 67	Interviews carried out by registered LD nurses. All interviewers trained in same format. Interviews tailored to individuals	Developed a graphic method to summarize results of each assessment - 'circle of consent'	The majority could not give valid consent, mainly due to communication problems. A small number could give some level of consent, but did not meet criteria for valid consent. The findings of this study illustrate that consent and decision-making have long been a neglected area of practice in LD services
Dunn <i>et al.</i> (2006)	To investigate whether video presentation is of use in helping people with LD to gain sufficient knowledge to give informed consent to treatment	Within-participant comparison. Experimental design: self-controls	People with mild or moderate LD, from social education centre in England. n = 19	Administration of three comprehension tests prior to, during, and after the showing video about psychology services. Tests carried out individually with the researcher. Questions and responses verbal	Data analysis carried out using related <i>t</i> -tests	Knowledge of psychology significantly increased following video. Information understood and maintained more efficiently if presented (and assessed) in sections. This may relate to memory problems in people with LD
Dye <i>et al.</i> (2007)	To investigate the different forms of information provision when assessing capacity to consent in people with LD	Randomized controlled trial	Adults with mild to moderate LD in England with an attention span of up to 30 minutes; able to communicate verbally. n = 85 at completion	Interview using 'ability to consent' questionnaire (ACQ) and instruments to measure receptive vocabulary (BPVS), memory and reasoning abilities	One-way ANOVA between experimental conditions and Pearson's correlation between ACQ and other measures	Experimental manipulation of reducing demand on memory, or providing additional visual info did not result in increased ability to consent. ACQ scores correlated with aggregated memory score, reasoning score and BPVS score. Only 5.9% of participants were assessed as able to consent, although all participants could indicate a choice

Table 1 (Continued)

Reference	Purpose of study	Methodology	Sample and size	Data collection method	Method of analysis	Main findings of relevance
Fisher <i>et al.</i> (2006)	To examine the capacity of persons with MR to consent to participate in RCT's	Quasi-experimental. Interview study using consent questions for a hypothetical RCT	Adults – 50 with mild MR, 50 with moderate MR and 50 'comparison' subjects without MR. Recruited from community residences and day facilities in USA. Around 50% had psychiatric comorbidity. $n = 150$	Assessment instruments: IQ was assessed for the purpose of categorizing participants as mild or moderately retarded. The Assessment of Consent Capacity-RCT (ACC-RCT) was used to assess consent capacity	ACC-RCT items grouped into four categories – understanding, appreciation, communicating choice, and reasoning. Univariate and multivariate methods – correlation tests, <i>t</i> -tests, ANOVA, regression analysis, and MANOVA	Adults with MR strongest in communicating choice, weakest in providing reasons for or against. Lower scores for understanding, appreciating and reasoning in adults with MR. Many adults with MR achieved capacity scores comparable with comparison group. Consent capacity may be enhanced when disclosures and consent assessments are individualised for adults with MR. Within each MR group, IQ score predicted capacity score, but there was no association with consent experience. This underlines the major role of IQ
Green and Nicoll (2001)	To describe how the process of reflection facilitated insight into the therapeutic relationship. Issues relating to informed consent were discussed	Case study	One case study in England	Reflective diaries	Not known	Issues relating to informed consent were complex and required special consideration
Hart (1998)	To describe the experiences of people with LD in a hospital setting	Qualitative – semi-structured interviews	It is not stated how these participants were recruited. $n = 13$ from seven different general hospitals in England	Interviews tape-recorded and transcribed verbatim	Grounded theory to identify a series of key concepts	Key concepts – 'fears about treatment', 'communication', 'general nursing', 'consent to treatment' and 'doctors'. Much of the content was critical of service provision. 'Consent to treatment' is further investigated in Hart (1999) below
Hart (1999)	To describe the problems of obtaining informed consent in people with LD in the healthcare setting	Qualitative - Semi-structured interviews	It is not stated how participants were recruited. $n = 13$ from seven general hospitals in England	Interviews tape-recorded and transcribed verbatim	Grounded theory, using constant comparative analysis	With regard to consent to treatment, the management of PWLD in general hospitals was diverse. Professional attitudes and practice varied
Haw and Stubbs (2005)	To determine the frequency of 'off-label' prescribing of psychotropics for inpatients with mild ID and mental illness (MI) in a psychiatric hospital; the nature of off-label clinical indications and details about patient consent and case note documentation of the off-label usage	Cross-sectional survey plus interviews	Inpatients receiving treatment for MH problems. All patients had mild/borderline ID and MI or personality disorder. Final sample $n = 26$ (patients treated with off-label psychotropics)	Structured interviews with consultant psychiatrists (caring for the sample)	Not stated	For most off-label prescriptions, the psychiatrist was aware that the prescription was off-label. The psychiatrists believed that 21 patients on 'off-label' medication had capacity to understand about medication, but only two had been told the drug was being used off-label. The reason cited was that the patient lacked capacity to understand the off-label concept. Because the patients studied had ID and MI, the findings cannot be generalised to community or hospitalized patients with ID alone

Table 1 (Continued)

Reference	Purpose of study	Methodology	Sample and size	Data collection method	Method of analysis	Main findings of relevance
Heslop <i>et al.</i> (2005)	To explore what knowledge people with LD and their carers had about the person's treatment with psychotropic medication	Qualitative - interview. Research team consisting of three researchers and five co-researchers with learning disabilities	Adults with LD on psychotropic medication, from four regions of England, with closest carer and prescriber. Purposive sampling to include both M and F, a range of ages and backgrounds and differing levels of support. $n = 21$	Semi-structured, face to face interviews. Interviews by co-researchers based on an accessible interview schedule. Carers and prescribers also invited to take part (with consent of ppt)	Grounded theory approach. Thematic analysis supported by the use of MAXqda qualitative data analysis software	Sketchy knowledge about why medication was prescribed. Lack of knowledge about possible side-effects, their recognition and what effective action to take. Discrepancy between what people with LD thought their carers knew and what carers actually knew. Poor provision of information for carers. Limited access to alternatives to medication
Hunt <i>et al.</i> (2004)	To provide evidence of mainstream health staff and LD professionals working together and breaking down barriers to provide a seamless service	Case study	One case study in England	Not known	Not known	Health professionals, by reflecting on past experiences and working seamlessly as a multi-disciplinary team, enabled the patient being studied to have an operation and give informed consent
Iqbal (2002)	To describe the application and ethical issues pertaining to a differential reinforcement of inappropriate behaviour programme in a patient with ID and possible autism or OCD	Case study	One case study in England	Not known	Not known	With regard to consent, there was lack of informed consent from the subject, as he did not understand the issues in question, nor the treatment objectives and reasons for decreasing his ritualization and social isolation
Keywood <i>et al.</i> (1999)	To examine how decisions are made on behalf of adults with LD; the role that adults with LD play in decisions about their health; the views and expectations of adults with LD as to how their role should develop in the future	Qualitative, based on values of participatory research	Two groups of adults with LD in England. One group working in a small workshop ($n = 15$); one group attending a large day centre ($n = 11$). A further 11 adults with LD who attended a different day centre, plus relatives and carers	Workshop focus groups recorded and transcribed. Interviews with members of an advocacy group and members of a day centre not involved in the workshops	Data analysed using qualitative research methods. Not specifically stated	People's healthcare decision-making range is limited; people are often asked to make decisions with inadequate information and knowledge; there are exaggerated legal concerns surrounding the signing of consent forms. Healthcare professionals often do not communicate directly with people with LD, or consider their capacity. Some healthcare practices get in the way of facilitating healthcare decision-making. The law fails to offer guidance on best practice in healthcare decision-making in adults with LD. Typically, the focus of healthcare decision-making does not reside with adults with LD; there is scope for developing models of support decision-making which recognise the <i>interdependence</i> of decision-making

Table 1 (Continued)

Reference	Purpose of study	Methodology	Sample and size	Data collection method	Method of analysis	Main findings of relevance
Morris <i>et al.</i> (1993)	To test an instrument for assessing capacity to consent and to test the hypothesis that capacity to consent increases with intelligence. To test the hypothesis that capability would vary according to context	Quasi-experimental	Three groups – without MR, mild MR and moderate MR in USA. Selected on basis of 'availability and willingness' from various day and residential facilities. <i>n</i> = 45	Interviews using three protocols, matched to three hypothetical treatment vignettes. Scores based on individual criteria for capacity. Three interviewers; inter-rater reliability tested	Inter-rater reliability assessed as highly significant. Descriptive statistics – apart from Jonckheere test to show relationship between capacity and level of intellectual functioning	Experimental findings showed that capacity to give informed consent was directly related to level of intellectual functioning. The interviewing process provided reliable determinations about capability. Authors stress need for further research, in particular, situation specific. Authors express doubt about there being a universally accepted standard for capability to consent
Tuffrey-Wijne (2002)	To describe a case study that considered the unique needs of a client who has ID and a terminal illness	Case study	One case study in England	Not stated	Not applicable	The client refused medication; this raised the issue of informed consent to treatment, as on occasions staff had tried to hide medication in his food
Tuffrey-Wijne (2003)	A literature review to answer the following question: What are the palliative care needs of people with intellectual disabilities?	Literature review	Three databases	Accessing computer databases – CINAHL (1983 – present), Medline (1980 – present) and PsychINFO (1984 – present)	Not stated	Literature review suggested potential problems – difficulties in understanding the illness and its implications and ethical issues around decision-making and consent to treatment
Wong <i>et al.</i> (2000)	To investigate and compare the performance of three groups of participants (MI, LD or dementia) on a decision-making task using the same assessment method. To assess whether, by simplifying presentation of information & making the response less dependent on verbal ability, capacity might improve	Quantitative. Quasi-experimental	Convenience samples were recruited through local clinical services in England. Control group recruited from local phlebotomy clinic. MI group <i>n</i> = 21; LD group <i>n</i> = 20; dementia group <i>n</i> = 21. General population group <i>n</i> = 20 (screened first to exclude a 'mental disability')	Standardized semi-structured interview for decision-making assessment. Assessment of severity of 'mental disability' using: Mental illness – BPRS; LD – verbal IQ using WAIS-R; Dementia – MMSE	Inter-rater reliability tested using kappa coefficient or Spearman correlation. ANOVA, chi-squared or Fisher exact test for relationships between variables. McNemar test and Cochran's Q test for testing which items of information were most difficult to understand	Capacity to make a particular decision was significantly more impaired in the LD and dementia groups compared with 'normal population group', but not more impaired in the MI group. The risks of the procedure and the risk of 'saying no' appeared difficult to understand in all groups and may have been too cognitively demanding. Capacity increased with progressive simplification of the decision-making task. This supports a 'functional approach' to obtaining informed consent

ID, intellectual disability; ACQ, 'Ability to consent' questionnaire; BPVS, British Picture Vocabulary Scale; BPRS, Brief Psychiatric Rating Scale; GP, General practitioner; IQ, intelligence quotient; LD, learning disability; MMSE, Mini Mental State Examination; MR, mental retardation; RCT, randomized controlled trial; WAIS-R, Wechsler Adult Intelligence Scale-Revised.

participants more able to consent in their study using a vignette of a proposed medical intervention. Cea and Fisher (2003), however, found that factual understanding was based on the degree to which the participant had experienced the treatment for which consent was being sought. In a later study, Fisher *et al.* (2006), found no association between medical or consent history and level of capacity to consent to a clinical trial.

Interaction between healthcare professional and participant

Attitude to consent

When exploring the concept of informed consent in people with LD, it is important to consider the attitude of healthcare professionals as reflected in their behaviour towards people with LD. Several examples were found where assumptions were made that they would not be able to consent, despite the publication of government and professional guidelines to the contrary.

Carlson (2004) in the UK identified 171 referrals to a Community Team for Learning Disability, then sent out questionnaires designed to establish referrers' awareness of and attitude to informed consent. Approximately two-thirds of referrers were aware of existing government and professional guidelines but only 44% of general practitioners (GPs) were aware of these guidelines. The majority (79%) considered that simply telling the patient that they were going to make the referral constituted informed consent.

Hart (1999), in a study of people's experiences in hospital, found little consistency in the practice of obtaining consent. One participant, despite being able to attend follow-up hospital appointments on her own after hysterectomy, described how she was not allowed to sign her own consent form and that the doctors insisted on her mother signing it. Another less able participant reported a full explanation of the procedure was given, and she was able to sign to give informed consent.

In relation to medication, Haw and Stubbs (2005) found that only 6% of patients with LD being prescribed off-label psychotropic medication had been informed of this fact; however, they found similar results with mental health patients without a learning disability. Arscott *et al.* (2000) investigating the knowledge of people with intellectual disabilities about their prescribed medication concluded that participants had insufficient understanding to give informed consent. Tablets may be hidden in food to gain compliance (Tuffrey-Wijne 2002) or application of a treatment programme may be inconsistent (Iqbal 2002). Consent may also not always be obtained for tests and treatment, and more

invasive treatments may be avoided due to issues around informed consent (Tuffrey-Wijne 2003).

On a more positive note, Hunt *et al.* (2004) describes the use of communication methods designed to maximize understanding and awareness of the right to withdraw consent. Similarly, Green and Nicoll (2001) stress the need to obtain informed consent at various stages of the treatment and illustrate how informed consent can be obtained in a variety of ways when a healthcare professional has built up a sensitive relationship with the patient.

Method of presentation

When considering the information necessary to obtain informed consent the content of the information and the way it is presented should be considered.

Various approaches have been used in an attempt to increase capacity. For example, vignettes may be read aloud to participants (Morris *et al.* 1993) or adapted to improve readability as verbal and memory ability influence ability to consent (Arscott *et al.* 1998, 1999). Breaking down information into 'chunks' has been shown to improve understanding (Dean *et al.* 1998, Wong *et al.* 2000, Cea & Fisher 2003, Dunn *et al.* 2006, Fisher *et al.* 2006).

Dean *et al.* (1998) developed a functional approach to assessing capacity in which comprehension levels were assessed by speech therapists with patients with a high level of comprehension but poor communication skills, and those who had no verbal communication received intensive input and several interviews to enable them to express their wishes.

Wong *et al.* (2000) used the 'real life' situation of needing a blood test to assess capacity to make a health decision. A large font, simple language information sheet was produced and different ways of testing understanding were used, including 'uninterrupted disclosure where questions were asked after reading the whole information sheet or after each 'element'. Capacity increased as the task was simplified, suggesting the importance of the way informed consent is sought from people with a 'mental disability'. However, whilst Dye *et al.* (2007) confirmed previous findings that ability to consent to research correlates positively with verbal and memory ability, they failed to show the impact of different forms of information provision.

Broughton (2002), in a literature review looking at capacity to consent to cervical screening in women with LD, also found that the way information was presented to women was crucial, and influenced their ability to understand the procedure and therefore give informed consent. Language appropriate to the level of disability, short clear text, and use of alternate media such as video or audio-tapes or preparatory visits to the department were also suggested.

There seems to be consensus, therefore, that capacity to consent is increased when information is broken down into separate elements and presented in a way that is appropriate to the people concerned.

Ability to consent

In an attempt to clarify the situation concerning capability to consent, Morris *et al.* (1993) in the USA used three legal criteria previously described by Grisso (1986): 'knowledge' (understanding the facts), 'intelligence' (ability to weigh the risks and benefits of the treatment or any alternatives) and 'voluntariness' (free from coercion or any other influence). Arscott *et al.* (1999) adapted the assessment tool used by Morris *et al.* using the same criteria. Both tools used questions on understanding the nature of a problem or treatment, understanding of risks, benefits and alternative options, understanding of rights, options and choices and their impact. Cea and Fisher (2003), also in the USA, based their research on the four psycholegal standards defined by Appelbaum and Roth (1982) as suitable to evaluate ability to consent:

- Ability to communicate a choice concerning treatment.
- Ability to understand factual information about the nature of the disorder and risks and benefits of the proposed treatment.
- Ability to understand the cognitive and emotional implications of the treatment for the individual's own circumstances.
- Ability to weigh the risks and benefits of the proposed treatment when making a choice and to arrive at a 'reasonable' outcome of choice.

Wong *et al.* (2000) in the UK used the criteria for evaluating capacity from the draft Mental Capacity Act 2005, defining incapacity as being unable by reason of mental disability to make a decision on the matter in question due to inability to:

- Understand relevant information and/or.
- Retain this information and/or.
- Make a decision based on the information given.
- Unable to communicate that decision.

Communicating a choice

In several reports it is stated that people with LD are able to communicate a choice but do not necessarily understand what the choice involves (Morris *et al.* 1993, Arscott *et al.* 1998, 1999, Cea & Fisher 2003, Fisher *et al.* 2006).

The work of Dye *et al.* (2007) illustrates these issues. Recruiting a sample of 102 people with intellectual disabilities, they investigated the influence of different forms of

information provision on capacity to take part in research. There were no differences between the forms, and they also found that all participants could make a choice, despite over 30% not understanding the impact of that choice and (55%) not understanding the risks and benefits. These findings reinforce those of Cea and Fisher (2003) and Fisher *et al.* (2006) that, as the complexity of the 'standard' being assessed increases, the ability to consent (as a whole) is reduced.

Wong *et al.* (2000), in a UK study, assessed the capacity of people with a 'mental disability' to make a healthcare decision and used the criteria for 'incapacity' adopted in the draft Mental Capacity Bill (now the Mental Capacity Act 2005), as above. For this reason, it is difficult to compare their results with those based on Grisso and Appelbaum's 'psycholegal standards', which are more detailed.

Understanding and retaining information

Synthesizing the evidence relating to understanding relevant information is difficult, as the complexity of the information varies between studies, and can involve information about research, treatment or medication. Different categories of information have been presented to participants: factual information about the topic, the risks and benefits, or the individual's rights (for example, the right to withdraw from research). The general finding is that understanding decreases with greater complexity of the information being given (Arscott *et al.* 1998, 1999, Cea & Fisher 2003). However, Cea and Fisher (2003) suggest that these findings may not be dependent simply on intellectual capacity, but on previous experience, type of information and how it was presented.

In terms of consent to research participation, Fisher *et al.* (2006) found that understanding of research *procedures* was greater than understanding of the *purpose* of research, indicating that understanding 'concrete' facts is easier than understanding abstract concepts. In another study of consent to take part in research, Dye *et al.* (2007) investigated each aspect of ability to consent (using the same criteria as in Arscott *et al.* 1998, 1999 studies) and showed that, although all participants could make a choice, only 69% understood the impact of that choice. Half of the participants understood the facts about the study procedures, but only 13% the nature of the study. This further illustrates the hierarchical nature of the information presented to participants and how it relates to their levels of understanding.

Rational manipulation of information

Morris *et al.* (1993) described 'rational manipulation of information', defined as the ability to consider or weigh the

risks and benefits of a proposed procedure and any alternatives. They consider that cognitive limitations such as memory impairment and limited comprehension seemed to underlie the ability to express a rational decision, most frequently for those with moderate 'mental retardation' ('MR').

Cea and Fisher (2003) found that over half the participants with mild 'MR' scored partial or full points on the standard of 'rational manipulation of information', but that this dropped to less than 20% in the moderate group. In the no 'MR' comparison group, those scoring partial or full points rose to 81%. Thus, ability to consent decreased with the complexity of the 'standard' being measured, even in the comparison group. Fisher *et al.* (2006), investigating consent to participate in research, found that questions on reasoning were more difficult than other ability categories for all three groups. Arscott *et al.* (1998), although not specifically testing 'rational manipulation' as in the Cea and Fisher (2003) study, also found that understanding the advantages and disadvantages of taking part in research was particularly difficult; this is one of the main features of manipulating information to come to a decision.

Psychometric properties

Intelligence

Consideration of the relationship between intelligence and capacity to give consent is impeded by the fact that researchers have used difference measures of IQ or have not used any formal measure (e.g. Morris *et al.* 1993).

The findings of Cea and Fisher (2003) are confusing because they used different measures for their two study groups. 'Level of functioning' in people with LD was assessed using two instruments: the Wechsler Adult Intelligence Scale-Revised (WAIS-R) and adaptive behaviour scales (Vineland). However, the Kaufman Brief Intelligence Test was used for the group without 'MR'. The results showed that the ability of adults with and without 'MR' decreased with the complexity of the information presented and the concepts involved.

In contrast to the Cea and Fisher (2003) study, Fisher *et al.* (2006) assessed intelligence using the Kaufman Brief Intelligence Test for all participants at the time of the study. Vineland Adaptive Behaviour scales were also used, with 86% of the mild and 96% of the moderate MR groups scoring in the low range. The findings showed that overall intelligence score predicted total score on the capacity assessment.

In general, therefore, there seems to be positive relationship between IQ and capacity to give consent.

Verbal ability

Several researchers have investigated the link between verbal ability and ability to consent, but not all measured verbal ability as a distinct variable.

In the two studies by Arscott *et al.* (1998, 1999), consent to research and treatment respectively were investigated. In the first study, people with higher receptive language scores were more likely to score better on the Ability to Consent Questionnaire (ACQ) ($P < 0.01$). In the second study with the same 40 participants and using the same instruments, all responses were statistically significantly correlated with verbal ability. Independent *t*-tests to assess whether the influence of verbal ability varied according to the vignette showed a statistically significant difference ($P < 0.05$) in verbal ability across all vignettes between those able and unable to consent.

Wong *et al.* (2000), although investigating the capacity of people with a range of 'mental disability' to make a healthcare decision, did not measure verbal ability in isolation. Learning disability was assessed using verbal IQ from the Vocabulary, Comprehension and Similarities subtests of the WAIS-R, and Digit Span subtests were used to measure short-term memory retention. Their results, using a staged assessment of decision-making capacity, with each successive stage being less verbally demanding, showed that capacity improved as the decision-making task (and the way the information was presented) was simplified.

Dye *et al.* (2007) adapted the ACQ from Arscott *et al.* (1998, 1999) for their study of consent to take part in a research study and the British Picture Vocabulary Scale was used to assess receptive vocabulary. The aim was not only to assess the capacity of people to give informed consent, but also to assess the impact of different ways of presenting the consent information. Eighty-five participants were recruited and ACQ scores were found to be significantly correlated with verbal ability (Pearson's correlation coefficient = 0.510, $P < 0.01$).

In summary, therefore, studies show that capacity is reduced with lower verbal ability.

Memory

As well as verbal ability, memory (particularly short-term) has been found to influence ability to consent. Arscott *et al.* (1999) used the route recall and story recall memory items from the Rivermead Behavioural Memory Test for Children (RBMT-C) to assess memory and verbal ability when studying ability to consent to treatment. Memory ability was found to be correlated with understanding the treatment, the alternatives and the impact of choices; understanding the risks and benefits, rights and options available; and with

the ability to indicate a choice. Memory ability was not correlated with understanding the nature of the problem, however.

The RBMT-C was also used by Dye *et al.* (2007) when assessing capacity to take part in a research study, following the method used by Arscott *et al.* (1999). The findings were comparable but, unexpectedly, did not show that capacity to consent increased with reduced demand on memory (presenting information in 'chunks' or with photographs).

Thus, in general, verbal ability has a positive influence on ability to consent.

Discussion

Strengths and limitations of the review

Although it has been possible to identify useful findings from this review, there are important limitations, especially when applying these findings to clinical practice. Although the studies involved people with LD (in some cases together with comparison groups or other 'mental disability' groups), the focus of the research varied, together with the detailed methods used. Some researchers investigated consent to research; others consent to treatment or (indirectly) consent to taking medication, while some used hypothetical vignettes and some 'real life' situations. Regardless of the method used, participants' life experiences might influence their responses and confound the results. Even reports containing details of participants' residential status, for example, did not link this factor to the findings. Samples in each study differ in characteristics such as residential status, employment status and health experience; thus, unless these are taken into account, it is difficult to ensure that they have not influenced the findings. Samples were recruited differently, using different criteria. Studies using comparison groups have provided useful evidence, although the fact that 'comparison' participants may have greater experience of decision-making and also of health treatments may have skewed the results.

One of the possible limitations of this review is the bibliographical databases used. Having taken the advice of a specialist librarian, seven databases were used to retrieve suitable papers. Ancestry searches from these papers were carried out, yielding further material. The duplication between databases suggests that coverage was comprehensive. Due to the relatively small number of papers found, none were excluded on the grounds of quality and this may have introduced bias. However, conducting the quality appraisal was a useful way of gaining in-depth understanding of the papers.

Another limitation is the fact that some of the papers contained little or no information on the ethical issues concerned in obtaining consent for the study. As mentioned, recruitment sometimes involved access via 'gatekeepers' or assent was obtained rather than informed consent. These factors may have led to less valid findings.

It is also important to note that research carried out on informed consent from people with LD in different contexts, such as financial decision-making (Suto *et al.* 2005), may inform practice in the health sector. Furthermore, some of the issues identified, such as ability to understand explanations, are not specific to people with LD.

Despite this broad range of studies identified, it was possible to identify some key common themes.

Functional approach to assessing capacity

The current emphasis, both in England and Wales and the USA, on a functional approach to assessing capacity in people with LD is illustrated by several studies (Arscott *et al.* 1998, Arscott *et al.* 1999, Cea & Fisher 2003, Fisher *et al.* 2006, Morris *et al.* 1993, Wong *et al.* 2000). This approach was shown to be appropriate in the study involving patients with mental illness or dementia alongside those with LD (Wong *et al.* 2000) because some participants in each group were assessed as able to consent. Wong *et al.* considered that this should lead to a rejection of the 'status' approach, in which a judgement about capacity is based on diagnosis. Including comparison groups (Morris *et al.* 1993, Wong *et al.* 2000, Cea & Fisher 2003, Fisher *et al.* 2006) when considering ability to consent also produced evidence to support the functional approach to capacity, showing that as the cognitive demands of the decision increased, capacity decreased; this was also the case for people without LD. This establishes a 'hierarchy' of complexity which can be used in future assessments. The conclusion by Wong *et al.* (2000) reflects the findings of most of the research in this review, and summarizes the functional approach to assessment of capacity:

Consistent with current views, capacity reflected an interaction between the decision-maker and the demands of the decision-making task. (p. 295)

Scoring systems for 'understanding' appear to have evolved. The greater flexibility of later methods is useful as the level of understanding required to indicate capacity may depend on the balance of risk and benefit of the treatment to be undertaken.

In the research described, the ability to express a choice appears to be the easiest functional ability. In practice, this could be misleading, because ability to express a choice does

What is already known about this topic

- Consent to treatment lies at the heart of the relationship between patient and healthcare professional.
- For people with learning disabilities to have equity of access to health care, they need to be able to give informed consent to health interventions – or be assessed as incompetent to give consent.
- There should be presumption that an individual has capacity to give consent unless proved otherwise.

What this paper adds

- The functional approach to assessing mental capacity should be used for the purpose of obtaining informed consent.
- Whether or not capacity to consent is achieved may depend on the effort made to ‘tailor’ the relevant information to the abilities and needs of the individual concerned.
- Future research into informed consent in people with learning disabilities is needed using real life situations rather than hypothetical vignettes.

not necessarily imply understanding of the factual material presented or its consequences for the individual.

Professional attitudes to informed consent

Several reports illustrate professional attitudes to consent, even if not specifically investigating them. There appears in some cases to be an assumption of *incapacity* in people with LD rather than the now universally-accepted assumption of *capacity*. These findings suggest that awareness of the legal requirements for informed consent, and the way healthcare professionals practise, is not consistent.

The assessment of competence in children in England and Wales was clarified by the ‘Gillick judgement’ in relation to parental consent to prescribing contraception for teenagers. This suggests that children aged under 16 can give consent if they:

have the legal capacity to consent to medical examination and treatment, providing they can demonstrate sufficient maturity and intelligence to understand and appraise the nature and implications of the proposed treatment, including the risks and alternative courses of actions. (Wheeler 2006, p. 807)

This should mean, after the passage of the Mental Capacity Act 2005, that there is no contradiction between giving consent below and above the age of 16 years in all cases.

The new Mental Capacity Act (2005) in England and Wales seeks to bring together previous case law rulings and guidelines in an effort to ensure both that people without capacity are protected and that assessments of capacity are carried out before making assumptions of incapacity. This obviously has major training implications for healthcare professionals, but should lead to better practice and more people-centred health care for those with LD.

Facilitating informed consent in people with LD

It seems that ‘chunking’ of information, making it less cognitively demanding and tailoring it to the individual concerned and to the decision to be made will improve capacity to give informed consent. However, findings have been inconsistent, perhaps because some studies involved consent to research, while others involved consent to treatment; previous health experience may have been a confounding factor in the latter.

Factors influencing ability to consent

All the quantitative research identified has shown evidence that verbal and memory capacity and general IQ have an impact on capacity in people with LD, and thus on their ability to give informed consent. However, other factors may influence these findings: there may have been confounding factors in their research, and there are potential differences between vignettes and real life situations, with their accompanying features of stress, nervousness and powerlessness. Previous experience with a proposed treatment and with decision-making may also have affected findings.

Conclusion

The review findings support the functional approach to assessing mental capacity for the purpose of obtaining informed consent. However, as identified above, the complexity and nature of the decision need to be taken into account. Therefore, whether or not capacity to consent is achieved may depend on the effort made to ‘tailor’ the relevant information to the abilities and needs of the individual concerned. This has implications for clinical practice, particularly in general practice, where considerable time constraints exist. Healthcare professionals are obliged to comply with their country’s legal requirements; in practice, however, this may cause problems due to the time needed to maximize the potential for capacity in many people with LD.

Future research into informed consent in people with learning disability is needed using real life situations which are more likely to be familiar to the participants than hypothetical vignettes. Larger samples are needed, preferably

recruited through multi-centre studies. A mixed method approach may be useful when assessing the influence of such factors as residential status, opportunity for decision-making and health experience. Until these potentially-confounding factors are included in any analysis, it may not be possible to move forward in the effort to facilitate a greater level of informed consent for people with LD.

Author contributions

LG, HS and CW were responsible for the study conception and design. LG performed the data collection. LG and HS performed the data analysis. LG and CW were responsible for the drafting of the manuscript. LG, HS and CW made critical revisions to the paper for important intellectual content. HS and CW supervised the study.

References

Appelbaum P.S. & Grisso T. (1988) Assessing patients' capacities to consent to treatment. *The New England Journal of Medicine* 319(25), 1635-1638.

Appelbaum P.S. & Roth L.H. (1982) Competency to consent to research: a psychiatric overview. *Archives of General Psychiatry* 39(8), 951-958.

Arscott K., Dagnan D. & Kroese B.S. (1998) Consent to psychological research by people with an intellectual disability. *Journal of Applied Research in Intellectual Disabilities* 11(1), 77-83.

Arscott K., Dagnan D. & Kroese B.S. (1999) Assessing the ability of people with a learning disability to give informed consent to treatment. *Psychological Medicine* 29(6), 1367-1375.

Arscott K., Kroese B.S. & Dagnan D. (2000) A study of the knowledge that people with intellectual disabilities have of their prescribed medication. *Journal of Applied Research in Intellectual Disabilities* 13, 90-99.

Broughton S. (2002) A review of the literature: interventions to maximise capacity to consent and reduce anxiety of women with learning disabilities preparing for a cervical smear test. *Health Services Management Research* 15, 173-185.

Carlson T. (2004) Referrals to a learning disability service and consent to treatment. *Learning Disability Review* 9(2), 11-17.

Cea C.D. & Fisher C.B. (2003) Health care decision-making by adults with mental retardation. *Mental Retardation* 41(2), 78-87.

Dean E., Turner S. & Cash J. (1998) Assessing the capacity to give consent. *Nursing Times* 94(40), 58-60.

Department of Health (2005) *Mental Capacity Act 2005-Summary*. Retrieved from www.dh.gov.uk/en/Publicationsandstatistics/Bulletins/theweek/chiefexecutivebulletin/DH_4108436 on 8 September 2008.

Dunn A., Kroese B.S., Thomas G., McGarry A. & Drew P. (2006) 'Are you allowed to say that?' Using video materials to provide accessible information about psychology services. *British Journal of Learning Disabilities* 34(4), 215-219.

Dye L., Hare D.J. & Henty S. (2007) Capacity of people with intellectual disabilities to consent to take part in a research study. *Journal of Applied Research in Intellectual Disabilities* 20(2), 168-174.

Fisher C.B., Cea C.D., Davidson P.W. & Fried A.L. (2006) Capacity of persons with mental retardation to consent to participate in randomized clinical trials. *American Journal of Psychiatry* 163(10), 1813-1820.

Green C. & Nicoll L. (2001) Therapeutic caring: a learning disability experience. *Complementary Therapies in Nursing & Midwifery* 7(4), 180-187.

Grisso T. (1986) *Evaluating Competencies: Forensic Assessments and Instruments*. Plenum Press, New York.

Gunn M., Wong J.G., Clare C.H. & Holland A.J. (1999) Decision-making capacity. *Medical Law Review* 7, 269-306.

Hart S.L. (1998) Learning disabilities. Learning-disabled people's experience of general hospitals. *British Journal of Nursing* 7(8), 470-477.

Hart S.L. (1999) Meaningful choices: consent to treatment in general health care settings for people with learning disabilities. *Journal of Learning Disabilities for Nursing, Health and Social Care* 3(1), 20-26.

Haw C. & Stubbs J. (2005) A survey of off-label prescribing for inpatients with mild intellectual disability and mental illness. *Journal of Intellectual Disability Research* 49(11), 858-864.

Heslop P., Folkes L. & Rodgers J. (2005) The knowledge people with learning disabilities and their carers have about psychotropic medication. *Learning Disability Review* 10(4), 10-18.

Hunt C., Flecknor D., King M. & Ashman L. (2004) Access to secondary care for people with learning disabilities. *Nursing Times* 100(3), 34-36.

Iqbal Z. (2002) Ethical issues involved in the implementation of a differential reinforcement of inappropriate behaviour programme for the treatment of social isolation and ritualistic behaviour in an individual with intellectual disabilities. *Journal of Intellectual Disability Research: JIDR* 46 (Pt 1), 82-93.

Keywood K., Fovargue S. & Flynn M. (1999) *Best Practice? Health Care Decision-Making By, With and For Adults with Learning Disabilities*. National Development Team, Manchester.

Kmet L.M., Lee R.C. & Cook L.S. (2004) *Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields*. Alberta Heritage Foundation for Medical Research. [Online]. Retrieved from <http://www.ihe.ca/documents/HTA-FR13.pdf> on 8 September 2008.

Miles M.B. & Huberman A.M. (1994) *Qualitative Data Analysis: An Expanded Sourcebook*, 2nd edn. Sage Publications Inc., Thousand Oaks, CA.

Ministry of Justice (1969) *Family Law Reform Act 1969 (c46,s8)*. HMSO. [Online]. Retrieved from http://www.opsi.gov.uk/RevisedStatutes/Acts/ukpga/1969/cukpga_19690046_en_1 on 8 September 2008.

Morris C.D., Niederbuhl J.M. & Mahr J.M. (1993) Determining the capability of individuals with mental retardation to give informed consent. *American Journal on Mental Retardation* 98(2), 263-272.

Public Health Resource Unit (2007) *Critical Appraisal Skills Programme*. 2 January 2007. [Online]. Retrieved from <http://www.phru.nhs.uk/Pages/PHD/resources.htm> on 8 September 2008.

- Suto W.M.I., Clare I.C.H., Holland A.J. & Watson P.C. (2005) Capacity to make financial decisions among people with mild intellectual disabilities. *Journal of Intellectual Disability Research* 49, 199–209.
- Tuffrey-Wijne I. (2002) The palliative care needs of people with intellectual disabilities: a case study. *International Journal of Palliative Nursing* 8(5), 222.
- Tuffrey-Wijne I. (2003) The palliative care needs of people with intellectual disabilities: a literature review. *Palliative Medicine* 17(1), 55–62.
- UK Clinical Ethics Network (2006) [Online]. Retrieved from <http://www.ethics-network.org.uk/ethical-issues/consent/introduction> on 8 September 2008.
- Wheeler R. (2006) Gillick or Fraser? A plea for consistency over competence in children. *British Medical Journal* 332, 807.
- Wong J.G., Clare C.H., Holland A.J., Watson P.C. & Gunn M. (2000) The capacity of people with a 'mental disability' to make a health care decision. *Psychological Medicine* 30(2), 295–306.

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References

Abell, S., Ashmore, J., Beart, S., Brownley, P., Butcher, A., Clarke, Z., Combes, H., Francis, E., Hayes, S., Hemmingham, I., Hicks, K., Ibrahim, A., Kenyon, E., Lee, D., McClimens, A., Collins, M., Newton, J. & Wilson, D. (2007) 'Including everyone in research: The Burton Street Research Group'. *British Journal of Learning Disabilities*, 35 pp 121-124.

Allen, V. L. & van de Vliert, E. (eds.) (1984) *Role Transitions: Explorations and Explanations*. New York: Plenum.

American Association on Intellectual and Developmental Disabilities (AAIDD) (2010) 'Definition of intellectual disability'. [Online]. Available at: http://www.aaid.org/content_100.cfm?navID=21 (Accessed: 2 December 2010).

Antaki, C., Walton, C. & Finlay, W. M. L. (2007) 'How proposing an activity to a person with an intellectual disability can imply a limited identity'. *Discourse and Society*, 18 pp 393-410.

Appelbaum, P. S. & Grisso, T. (1988) 'Assessing patients' capacities to consent to treatment'. *The New England Journal of Medicine*, 319 (25). pp 1635-1638.

Appelbaum, P. S. & Roth, L. H. (1982) 'Competency to consent to research: a psychiatric overview'. *Archives of General Psychiatry*, 39 (8). pp 951-958.

Arcott, K. (1997) 'Assessing the Capacity of People with Learning Disabilities to Make Decisions about Treatment'. *Tizard Learning Disability Review*, 2 (2). pp 17-28.

Arcott, K., Dagnan, D. & Kroese, B. S. (1998) 'Consent to psychological research by people with an intellectual disability'. *Journal of Applied Research in Intellectual Disabilities*, 11 (1). pp 77-83.

Arcott, K., Dagnan, D. & Kroese, B. S. (1999) 'Assessing the ability of people with a learning disability to give informed consent to treatment'. *Psychological Medicine*, 29 (6). pp 1367-1375.

Arcott, K., Kroese, B. S. & Dagnan, D. (2000) 'A Study of the Knowledge that People with Intellectual Disabilities have of their Prescribed Medication'. *Journal of Applied Research in Intellectual Disabilities*, 13 pp 90-99.

Ashforth, B. E. (2001) *Role transitions in organizational life: an identity-based perspective*. Mahwah, New Jersey: Laurence Erlbaum Associates.

Barnes, C. & Mercer, G. (2003) *Disability. Key Concepts*. Cambridge: Polity Press.

Barnes, C., Mercer, G. & Shakespeare, T. (1999) *Exploring disability: A sociological introduction*. Cambridge: Polity Press.

Barr, O. (1995) 'Normalisation: what it means in practice'. *British Journal of Nursing*, 4 (2). pp 90-94.

Barr, O., McConkey, R. & McConaghie, J. (2003) 'Views of People with Learning Difficulties about Current and Future Accommodation: the use of focus groups to promote discussion'. *Disability & Society*, 18 (5). pp 577 - 597.

Bellugi, U. & St George, M. (eds.) (2001) *Journey from cognition to brain to gene: perspectives from Williams Syndrome*. Cambridge, Massachusetts: The MIT Press.

Biddle, B. (1979) *Role Theory: Expectations, Identities, and Behaviors*. London: Academic Press Inc.

Biddle, B. (1986) 'Recent Developments in Role Theory'. *Annual Review of Sociology*, 12 pp 67-92.

Bloor, M. (1997) 'Techniques of Validation in Qualitative Research: a Critical Commentary.'. in Miller, G. and Dingwall, R. (eds.) *Context and Method in Qualitative Research*. London: Sage.

Bowey, L., McGlaughlin, A. & Saul, C. (2005) 'Assessing the Barriers to Achieving Genuine Housing Choice for Adults with a Learning Disability: The Views of Family Carers and Professionals'. *British Journal of Social Work*, 35 (1). pp 139-148.

Boyanowsky, E. O. (1984) 'Self-Identity Change and the Role Transition Process'. in Allen, V.L. and Van de Vliert, E. (eds.) *Role Transitions. Explorations and Explanations*. New York: Plenum Press.

Braun, V. & Clarke, V. (2006) 'Using thematic analysis in psychology'. *Qualitative Research in Psychology*, 3 pp 77-101.

Brewster, J. & Ramcharan, P. (2005) 'Enabling and supporting person-centred approaches'. in Grant, G., Goward, P., Richardson, M. and Ramcharan, P. (eds.) *Learning Disability: A Life Cycle Approach to Valuing People*. Maidenhead: Open University Press.

Brink, P. (1989) 'The fattening room among the Annang of Nigeria'. *Medical Anthropology*, 12 (1). pp 131-143.

British Institute of Learning Disabilities (2004) 'Factsheet - what is a learning disability?' 6 January 2004. (Accessed: 4 March 2008).

British Medical Association (2009) 'Consent toolkit, 5th edition'. British Medical Association. [Online]. Available at:

http://www.bma.org.uk/ethics/consent_and_capacity/consenttoolkit.jsp
(Accessed: 2 September 2010).

Britten, N. (2006) 'Qualitative interviews.'. in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford: Blackwell Publishing Limited.

Britten, N., Jones, R., Murphy, E. & Stacy, R. (1995) 'Qualitative research methods in general practice and primary care'. *Family Practice*, 12 (1). pp 104 - 114.

Broughton, S. (2002) 'A review of the literature: interventions to maximise capacity to consent and reduce anxiety of women with learning disabilities preparing for a cervical smear test'. *Health Services Management Research*, 15 pp 173-185.

Buchel, F. (2006) 'Analogical reasoning in students with moderate intellectual disability: Reasoning capacity limitations or memory overload?'. *Educational and Child Psychology*, 23 (3). pp 61-80.

Burgess, R. G. (1981) 'Keeping a research diary'. *Cambridge Journal of Education*, 11 (1). pp 75 - 83.

Burton, M. (1997) 'Intellectual disability: developing a definition'. *Journal of Learning Disabilities*, 1 (1). pp 37-43.

Bybee, J. & Zigler, E. (1999) 'Outerdirectedness in Individuals with and without Mental Retardation: A review'. in Bennett-Gates, D. and Zigler, E. (eds.) *Personality Development in Individuals with Mental Retardation*. Cambridge: Cambridge University Press.

Cameron, L. & Murphy, J. (2007) 'Obtaining consent to participate in research: the issues involved in including people with a range of learning and communication disabilities'. *British Journal of Learning Disabilities*, 35 (2). pp 113 - 120.

Carlson, C. S., Eberle, M. A., Kruglyak, L. & Nickerson, D. A. (2004) 'Mapping complex disease loci in whole-genome association studies'. *Nature*, 429 (6990). pp 446-452.

Carlson, T. (2004) 'Referrals to a learning disability service and consent to treatment'. *Learning Disability Review*, 9 (2). pp 11-17.

Cea, C. D. & Fisher, C. B. (2003) 'Health care decision-making by adults with mental retardation'. *Mental Retardation*, 41 (2). pp 78-87.

Centre for Genetics Education (2007) 'The Australasian Genetics Resource Book: Pharmacogenetics/Pharmacogenomics'. [Online]. Available at: <http://www.genetics.com.au/factsheet/fs25.asp> (Accessed: 5 September 2010).

Chambers, M., Ryan, A. A. & Connor, S. L. (2001) 'Exploring the emotional support needs and coping strategies of family carers'. *Journal of Psychiatric and Mental Health Nursing*, (8). pp 99-106.

Chappell, A. L. (1994) 'A Question of Friendship: Community Care and the Relationships of People with Learning Difficulties'. *Disability and Society*, 9 (4). pp 419.

Chappell, A. L. (1998) 'Still out in the Cold: People with Learning Difficulties and the Social Model of Disability'. in Shakespeare, T. (ed.) *The Disability Reader: Social Science Perspectives*. New York: Cassell.

Clare, I. C. H. & Gudjonsson, G. H. (1993) 'Interrogative suggestibility, confabulation, and acquiescence in people with mild learning disabilities (mental handicap): implications for reliability during police interrogations.'. *British Journal of Clinical Psychology*, 32 pp 295-301.

Cleaver, S., Ouellette-Kuntz, H. & Sakar, A. (2010) 'Participation in intellectual disability research: a review of 20 years of studies.'. *Journal of Intellectual Disability Research*, 54 (3). pp 187-193.

'Clip Art'. (2008). [Online]. Available at: <http://office.microsoft.com/en-gb/clipart/default.aspx> (Accessed: 10 March 2008).

Cobb, J., Giraud-Saunders, A. & Kerr, M. (2008) 'Health checks and people with learning disabilities'. *Tizard Learning Disability Review*, 13 (3), pp. 38-40

Collier, E. H. (1998) 'The concept of consent and cognitive impairment - nursing issues'. *Reviews in Clinical Gerontology*, 8 pp 53-63.

Cooper, H. M. (1982) 'Scientific Guidelines for Conducting Integrative Research Reviews'. *Review of Educational Research*, 52 (2). pp 291-302.

Cooper, S.-A., Morrison, J., Melville, C., Finlayson, J., Allan, L., Martin, G. & Robinson, N. (2006) 'Improving the health of people with intellectual disabilities: outcomes of a health screening programme after 1 year'. *Journal of Intellectual Disability Research*, 50 (9). pp 667-677.

Corbin, J. & Strauss, A. L. (2008) *Basics of qualitative research*. 3rd edn. Thousand Oaks: Sage.

Corrigan, O. P. (2005) 'Pharmacogenetics, ethical issues: review of the Nuffield Council on Bioethics Report'. *Journal of Medical Ethics*, 31 (3). pp 144-148.

Coulter, A. (1999) 'Paternalism or partnership?'. *British Medical Journal*, 319 pp 719-720.

Craig, J., Craig, F., Withers, P., Hatton, C. & Limb, K. (2002) 'Identity Conflict in People with Intellectual Disabilities: What Role do Service-providers Play in

Mediating Stigma?'. *Journal of Applied Research in Intellectual Disabilities*, 15 pp 61-72.

Crow, L. (1996) 'Including all of our lives: renewing the social model of disability'. in Barnes, C. and Mercer, G. (eds.) *Exploring the Divide*. Leeds: The Disability Press, pp 55-72.

Dalton, A. J. & McVilly, K. R. (2004) 'Ethics Guidelines for International, Multicenter Research Involving People with Intellectual Disabilities'. *Journal of Policy and Practice in Intellectual Disabilities*, 1 (2). pp 57-70.

Davies, C. A. & Jenkins, R. (1997) 'She Has Different Fits to Me': how people with learning difficulties see themselves'. *Disability and Society*, 12 (1). pp 95-109.

Davis, L. J. (ed.) (2010) *The Disability Studies Reader*. 3rd edn. Abingdon: Routledge.

Dean, E., Turner, S. & Cash, J. (1998) 'Assessing the capacity to give consent'. *Nursing Times*, 94 (40). pp 58-60.

Deegan, M. J. (2001) 'The Chicago School of Ethnography'. in Atkinson, P., Coffey, A., Delamont, S., Lofland, J. and Lofland, L. (eds.) *Handbook of Ethnography*. London: Sage.

Department for Communities and Local Government (2007) *Independence and Opportunity. Our strategy for supporting people. Executive summary*. Wetherby, West Yorks: Communities and Local Government Publications.

Department for Constitutional Affairs (1997) 'Who decides? Making decisions on behalf of mentally incapacitated adults. A consultation paper'. [Online]. Available at: <http://www.dca.gov.uk/menincap/meninfr.htm> (Accessed: 22 October 2007).

Department for Constitutional Affairs (1999) 'Making decisions: the government's proposals for making decisions on behalf of mentally incapacitated adults: a report issued in the light of the consultation paper "Who decides" (1997). [Online]. Available at: <http://www.dca.gov.uk/family/mdecisions/indexfr.htm> (Accessed: 23 October 2007).

Department of Health (1990) *National Health Services and Community Care Act (1990)*. London: Her Majesty's Stationery Office.

Department of Health (2001a) 'Good practice in consent implementation guide: consent to examination or treatment'. [Online]. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4005762 (Accessed: 7 September 2007).

Department of Health (2001b) 'Seeking consent: working with people with learning disabilities'. Her Majesty's Stationery Office. [Online]. Available at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4007861&chk=a3qncs (Accessed: 12 March 2007).

Department of Health (2001c) 'Reference guide to consent for examination or treatment'. Department of Health. [Online]. Available at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4006757&chk=snmdw8 (Accessed: 12 March 2007).

Department of Health (2001d) *Valuing people: a new strategy for learning disabilities for the 21st century*. London: The Stationery Office.

Department of Health (2003a) 'New GMS and PMS contract : calculation of aspiration payments for the quality and outcomes framework'. [Online]. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4072478 (Accessed: 5 November 2009).

Department of Health (2003b) 'General Medical Services (GMS)'. [Online]. Available at: <http://www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/index.htm> (Accessed: 5 November 2009).

Department of Health (2003c) 'Our Inheritance, Our Future. Realising the potential of genetics in the NHS'. Her Majesty's Stationery Office. [Online]. Available at: http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4005485&chk=KG7Q38 (Accessed: 12 March 2007).

Department of Health (2005a) 'Research Governance Framework for Health and Social Care'. [Online]. Available at: http://www.dh.gov.uk/en/Researchanddevelopment/A-Z/Researchgovernance/DH_4002112 (Accessed: 20 August 2008).

Department of Health (2005b) 'Independence, Well-being and Choice'. [Online]. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4106477 (Accessed: 31 July 2010).

Department of Health (2005c) 'Mental Capacity Act 2005 - Summary'. 8 February 2007. [Online]. Available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Bulletins/theweek/Chiefexecutivebulletin/DH_4108436 (Accessed: 8 September 2008).

Department of Health (2006a) 'Our health, our care, our say: a new direction for community services (Easy Read version)'. Her Majesty's Stationery Office.

[Online]. Available at:
http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_4127637.pdf (Accessed: 21 August 2010).

Department of Health (2006b) *Our health, our care, our say: a new direction for community services. A brief guide*. London: Department of Health. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4127453 (Accessed: 3 July 2008).

Department of Health (2007a) 'Our health, our care, our say - one year on: making it happen'. [Online]. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_075491 (Accessed: 5 August 2010).

Department of Health (2007b) 'Promoting equality. Response from Department of Health to the Disability Rights Commission Report, "Equal Treatment: Closing the Gap"'. [Online]. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_072955 (Accessed: 3 July 2008).

Department of Health (2007c) 'Independence, choice and risk: a guide to best practice in supported decision making - Executive Summary'. [Online]. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_074773 (Accessed: 3 July 2008).

Department of Health (2008) 'Our inheritance, our future. Realising the potential of genetics in the NHS. Progress review'. Department of Health. [Online]. Available at:
http://www.dh.gov.uk/en/PublicHealth/Scientificdevelopmentgeneticsandbioethics/Genetics/DH_084147 (Accessed: 7 October 2008).

Department of Health (2009a) 'The Primary Medical Services (Directed Enhanced Services) (England) (Amendment) Directions 2009'. [Online]. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_094165 (Accessed: 5 November 2009).

Department of Health (2009b) *Government response to the House of Lords Science and Technology Committee Inquiry into Genomic Medicine*. London: Her Majesty's Stationery Office.

Department of Health (2009c) 'Valuing People Now: A New Three-Year Strategy for people with learning disabilities'. [Online]. Available at:
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_093377 (Accessed: 23 June 2009).

Department of Health (2009d) 'Reference guide to consent for examination or treatment, second edition 2009'. [Online]. Available at:

http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_103653.pdf. (Accessed: 4 October 2010)

Department of Health (2010a) 'Person Centred Planning. Advice for Providers'. [Online]. Available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_115248.pdf. (Accessed: 20 September 2010)

Department of Health (2010b) 'Personalisation through person centred planning'. [Online]. Available at: http://www.dh.gov.uk/dr_consum_dh/groups/dh_digitalassets/@dh/@en/@ps/documents/digitalasset/dh_115249.pdf. (Accessed: 20 September 2010)

Department of Health and Human Services, U. S. A. (2008) 'Realizing the Potential of Pharmacogenomics: Opportunities and Challenges'. [Online]. Available at: http://oba.od.nih.gov/oba/SACGHS/reports/SACGHS_PGx_report.pdf (Accessed: 19 November 2008).

Department of Health and Social Security (1971) *Better Services for the Mentally Handicapped*. London: Her Majesty's Stationery Office.

Dimond, B. (2001) 'Legal aspects of consent, part 5: how to judge mental capacity'. *British Journal of Nursing*, 10 (9). pp 614-615.

Disability Rights Commission (2006) *Equal Treatment: Closing the Gap. A formal investigation into physical health inequalities experienced by people with learning disabilities and/or mental health problems*. Disability Rights Commission, Stratford upon Avon.

Dixon-Woods, M., Agarwal, S., Jones, D., Young, B. & Sutton, A. (2005) 'Synthesising qualitative and quantitative evidence: a review of possible methods.'. *Journal of Health Services Research and Policy*, 10 (1). pp 45-53.

Docherty, D., Hughes, R., Phillips, P., Corbett, D., Regan, B., Barber, A., Adams, M., Boxall, K., Kaplan, I. & Izzidien, S. (2010) 'This is What We Think'. in Davis, L.J. (ed.) *The Disability Studies Reader*. Third edn. Abingdon: Routledge.

Dowson, S. (1997) 'Empowerment within Services: A Comfortable Delusion'. in Ramcharan, P., Roberts, G., Grant, G. and Borland, J. (eds.) *Empowerment in Everyday Life: Learning Disability*. London: Jessica Kingsley.

Dunn, A., Kroese, B. S., Thomas, G., McGarry, A. & Drew, P. (2006a) "Are you allowed to say that?' Using video materials to provide accessible information about psychology services'. *British Journal of Learning Disabilities*, 34 (4). pp 215-219.

Dye, L., Hare, D. J. & Hendy, S. (2003) 'Factors impacting on the capacity to consent in people with learning disabilities'. *Tizard Learning Disability Review*, 8 (3). pp 11-20.

Dye, L., Hare, D. J. & Hendy, S. (2007) 'Capacity of people with intellectual disabilities to consent to take part in a research study'. *Journal of Applied Research in Intellectual Disabilities*, 20 (2). pp 168-174.

Economic and Social Research Council (2005) 'Research Ethics Framework'. [Online]. Available at: http://www.esrc.ac.uk/esrcinfocentre/images/esrc_re_ethics_frame_tcm6-11291.pdf (Accessed: 20 August 2008).

Elwyn, G., Edwards, A., Gwyn, R. & Grol, R. (1999) 'Towards a feasible model for shared decision making: focus group study with general practice registrars.'. *British Medical Journal*, 319 pp 753-756.

Elwyn, G., Edwards, A., Kinnersley, P. & Grol, R. (2000) 'Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices.'. *British Journal of General Practice*, 50 pp 892-897.

Emerson, E. & Hatton, C. (2008) *People with Learning Disabilities in England*. Centre for Disability Research, Lancaster University. Available at: <http://lancashirecare.wordpress.com/2008/06/16/people-with-learning-disabilities-in-england/>.(Accessed 14 October 2010)

Emery, J. & Hayflick, S. (2001) 'The challenge of integrating genetic medicine into primary care'. *British Medical Journal*, 322 (7293). pp 1027-1030.

Evans, D. (2007) 'Integrative Reviews: Overview of Methods'. in Webb, C. and Roe, B. (eds.) *Reviewing Research Evidence for Nursing Practice. Systematic Reviews*. Oxford: Blackwell Publishing Limited.

Fargher, E. A., Eddy, C., Newman, W., Qasim, F., Tricker, K., Elliott, R. A. & Payne, K. (2007) 'Patients' and healthcare professionals' views on pharmacogenetic testing and its future delivery in the NHS'. *Pharmacogenomics*, 8 (11). pp 1511-1519.

Felce, D., Baxter, H., Lowe, K., Dunstan, F., Houston, H., Jones, G., Grey, J., Felce, J. & Kerr, M. (2008) 'The Impact of Checking the Health of Adults with Intellectual Disabilities on Primary Care Consultation Rates, Health Promotion and Contact with Specialists'. *Journal of Applied Research in Intellectual Disabilities*, 21 (6). pp 597-602.

Finlay, W. M. L., Walton, C. & Antaki, C. (2008) 'Promoting choice and control in residential services for people with learning disabilities'. *Disability and Society*, 23 (4). pp 349 - 360.

Fish, T. R., Rabidoux, P., Ober, J. & Graff, V. L. W. (2006) 'Community literacy and friendship model for people with intellectual disabilities'. *Mental Retardation*, 44 (6). pp 443-446.

Fisher, C. B., Cea, C. D., Davidson, P. W. & Fried, A. L. (2006) 'Capacity of persons with mental retardation to consent to participate in randomized clinical trials'. *American Journal of Psychiatry*, 163 (10). pp 1813-1820.

Fisk, J. D., Beattie, B. L. & Donnelly, M. (2007) 'Ethical considerations for decision making for treatment and research participation'. *Alzheimer's and Dementia*, 3 pp 411-417.

Flesch, R. (1948) 'A new readability yardstick.'. *Journal of Applied Psychology*, 32 pp 221-233.

Fovargue, S., Keywood, K. & Flynn, M. (2000) 'Participation in health care decision-making by adults with learning disabilities.'. *Mental Health Care*, 31 (101). pp 341-344.

Fraser, M. & Fraser, A. (2001) 'Are people with learning disabilities able to contribute to focus groups on health promotion?'. *Journal of Advanced Nursing*, 33 (2). pp 225-233.

Ganong, L. H. (1987) 'Integrative Reviews of Nursing Research'. *Research in Nursing and Health*, (10). pp 1-11.

Garbutt, R., Tattersall, J., Dunn, J. & Boycott-Garnett, R. (2010) 'Accessible article: involving people with learning disabilities in research'. *British Journal of Learning Disabilities*, 38 pp 21-34.

Geertz, C. (1973) 'Thick description: Toward an interpretive theory of culture.' in Geertz, C. (ed.) *The Interpretation of Cultures*. New York: Basic Books.

General Medical Council (2008) 'Consent: patients and doctors making decisions together'. [Online]. Available at: http://www.gmc-uk.org/guidance/ethical_guidance/consent_guidance/part1_principles.asp (Accessed: 6 November 2008).

General Medical Council (2008) 'Good practice in prescribing medicines - guidance for doctors'. [Online]. Available at: http://www.gmc-uk.org/guidance/ethical_guidance/prescriptions_faqs.asp (Accessed: 5 October 2010).

Gibbs, S. M., Brown, M. J. & Muir, W. J. (2008) 'The experiences of adults with intellectual disabilities and their carers in general hospitals: a focus group study.'. *Journal of Intellectual Disability Research*, 52 (12). Pp 1061-1077.

Giddens, A. & Griffiths, S. (2006) *Sociology*. Cambridge: Polity Press.

Gilbert, T. (1993) 'Learning disability nursing: from normalization to materialism - towards a new paradigm'. *Journal of Advanced Nursing*, 18 pp 1604-1609.

Gilmartin, A. & Steven, E. (2009) 'Being a member of a self-advocacy group: experiences of intellectually disabled people'. *British Journal of Learning Disabilities*, 38 pp 152-159.

Glaser, B. G. & Strauss, A. L. (1967) *The Discovery of Grounded Theory*. Chicago: Aldine.

Godard, B., Raeburn, S., Pembrey, M., Bobrow, M., Farnon, P. & Ayme, S. (2003) 'Genetic information and testing in insurance and employment: technical, social and ethical issues'. *European Journal of Human Genetics*, 11 (Supplement 2). pp S123-S142.

Goffman, E. (1963) *Stigma. Notes on the management of spoiled identity*. New Jersey: Prentice-Hall.

Goldsmith, L., Skirton, H. & Webb, C. (2008) 'Informed consent to healthcare interventions in people with learning disabilities - an integrative review'. *Journal of Advanced Nursing*, 64 (6). pp 549-563.

Goodwin, D. (2006) 'Ethical Issues'. in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford: Blackwell Publishing Limited.

Goward, P. & Gething, L. (2005) 'Independence, reciprocity and resilience'. in Grant, G., Goward, P., Richardson, M. and Ramcharan, P. (eds.) *Learning Disability: A Life Cycle Approach to Valuing People*. Maidenhead: Open University Press.

Grant, G. & Ramcharan, P. (2001) 'Views and Experiences of People with Intellectual Disabilities and Their Families. (2) The Family Perspective'. *Journal of Applied Research in Intellectual Disabilities*, 14 pp 364-380.

Grant, G. & Ramcharan, P. (2007) *Valuing People and Research: The Learning Disability Research Initiative. Overview report*. London: Department of Health.

Grant, G. & Ramcharan, P. (2009) 'Valuing People and research: outcomes of the Learning Disability Research Initiative'. *Tizard Learning Disability Review*, 14 (2). pp 25 - 34.

Green, C. & Nicoll, L. (2001) 'Therapeutic caring: a learning disability experience'. *Complementary Therapies in Nursing & Midwifery*, 7 (4). pp 180-187.

Green, J. M., Hewison, J., Bekker, H. L., Bryant, L. D. & Cuckle, H. S. (2004) 'Psychosocial aspects of genetic screening of pregnant women and newborns: a systematic review'. *Health Technology Assessment (Winchester, England)*, 8 (33). pp iii.

Green, M. J. & Botkin, J. R. (2003) "Genetic Exceptionalism" in Medicine: Clarifying the Differences between Genetic and Nongenetic Tests'. *Annals of Internal Medicine*, 138 (7). pp 571-575.

Greenhalgh, T. (2006) *How to read a paper. The basics of evidence-based medicine*. 3rd edn. London: Blackwell Publishing Limited.

Grisso, T. (1986) *Evaluating competencies: Forensic assessments and instruments*. New York: Plenum Press.

Grisso, T. & Appelbaum, P. (1991) 'Mentally ill and non-mentally ill patients' abilities related to competence to consent to treatment'. *Law and Human Behavior*, 15 pp 377-388.

Grisso, T. & Appelbaum, P. S. (1998) *Assessing Competence to Consent to Treatment. A Guide for Physicians and Other Health Professionals*. New York: Oxford University Press.

Gunn, M., Wong, J. G., Clare, C. H. & Holland, A. J. (1999) 'Decision-Making Capacity'. *Medical Law Review*, (7). pp 269-306.

Hammersley, M. (1990) *Reading ethnographic research*. New York: Longman.

Hammersley, M. (1992) *What's wrong with ethnography?* London: Routledge.

Hammersley, M. & Atkinson, P. (1995) *Ethnography. Principles in Practice*. 2nd edn. London: Routledge.

Hammersley, M. & Atkinson, P. (2007) *Ethnography. Principles in practice*. 3rd edn. Abingdon: Routledge.

Harden, A. & Thomas, J. (2005) 'Methodological Issues in Combining Diverse Study Types in Systematic Reviews'. *International Journal of Social Research Methodology*, 8 (3). pp 257-271.

Harper, P. S. (2008) *A short history of medical genetics*. New York: Oxford University Press.

Hart, S. L. (1998) 'Learning disabilities. Learning-disabled people's experience of general hospitals'. *British Journal of Nursing (BJN)*, 7 (8). pp 470-477.

Hart, S. L. (1999) 'Meaningful choices: consent to treatment in general health care settings for people with learning disabilities'. *Journal of Learning Disabilities for Nursing, Health and Social Care*, 3 (1). pp 20-26.

Hastings, A. & Redsell, S. (eds.) (2006) *The Good Consultation Guide for Nurses*. Oxford: Radcliffe Publishing Limited.

Haw, C. & Stubbs, J. (2005) 'A survey of off-label prescribing for inpatients with mild intellectual disability and mental illness'. *Journal of Intellectual Disability Research*, 49 (11). pp 858-864.

Hayes, N. (2000) *Doing Psychological Research: gathering and analyzing data*. Buckingham: Open University Press.

Heal, L. W. & Sigelman, C. K. (1995) 'Response biases in interviews of individuals with limited mental ability'. *Journal of Intellectual Disability Research*, 39 (4). pp 331-340.

Henderson, B. J. & Maguire, B. T. (2000) 'Three lay mental models of disease inheritance'. *Social Science & Medicine* (1982), 50 (2). pp 293-301.

Henneman, L., Timmermans, D. R. M. & van der Wal, G. (2004) 'Public Experiences, Knowledge and Expectations about Medical Genetics and the Use of Genetic Information'. *Community Genetics*, 7 (1). pp 33 - 43.

Henrikson, N. B., Burke, W. & Veenstra, D. L. (2008) 'Ancillary risk information and pharmacogenetic tests: social and policy implications'. *The Pharmacogenomics Journal*, 8 pp 85-89.

Heslop, P., Folkes, L. & Rodgers, J. (2004) 'Why medication matters'. *Learning Disability Practice*, 7 (9). pp 10-12.

Heslop, P., Folkes, L. & Rodgers, J. (2005) 'The knowledge people with learning disabilities and their carers have about psychotropic medication'. *Learning Disability Review*, 10 (4). pp 10-18.

Hillery, J., Tomkin, D., McAuley, A., Keane, V. & Staines, M. (1998) 'Consent to treatment and people with learning disabilities.'. *Irish Journal of Psychological Medicine*, 15 (4). pp 117-118.

Howe, V., Foister, K., Jenkins, K., Skene, L., Copolov, D. & Keks, N. (2005) 'Competence to give informed consent in acute psychosis is associated with symptoms rather than diagnosis'. *Schizophrenia Research*, 77 pp 211-214.

Human Genetics Commission (2002) 'Inside Information. Balancing interests in the use of personal genetic data'. Department of Health. [Online]. Available at: http://www.hgc.gov.uk/UploadDocs/DocPub/Document/insideinformation_summary.pdf (Accessed: 21 February 2007).

Human Genome Project (2008) 'Pharmacogenomics'. 19 September 2008. [Online]. Available at: http://www.oml.gov/sci/techresources/Human_Genome/medicine/pharma.shtml (Accessed: 26 November 2008).

Hunt, C., Flecknor, D., King, M. & Ashman, L. (2004) 'Access to secondary care for people with learning disabilities'. *Nursing Times*, 100 (3). pp 34-36.

Hutchinson, C. (2005) 'Addressing issues related to adult patients who lack the capacity to give consent'. *Nursing Standard (Royal College Of Nursing (Great Britain): 1987)*, 19 (23). pp 47.

Hutchinson, S. H. (1984) 'Creating meaning out of horror: How NICU nurses survive and work productively in a stressful environment.'. *Nursing Outlook*, 32 pp 86-90.

Iacono, T. (2006) 'Ethical challenges and complexities of including people with intellectual disability as participants in research'. *Journal of Intellectual and Developmental Disability*, 31 (3). pp 173-179.

Iacono, T. & Murray, V. (2003) 'Issues of informed consent in conducting medical research involving people with intellectual disability'. *Journal of Applied Research in Intellectual Disabilities*, 16 (1). pp 41-51.

Institute of Medicine (2004) 'Health literacy: A prescription to end confusion.'. [Online]. Available at: <http://www.iom.edu/Reports/2004/Health-Literacy-A-Prescription-to-End-Confusion.aspx> (Accessed: 13 September 2010).

International Society of Nurses in Genetics (2005) 'Informed Decision-Making and Consent: The Role of Nursing'. International Society of Nurses in Genetics. 4 April 2005. [Online]. Available at: http://www.isong.org/about/ps_consent.cfm (Accessed: 22 October 2006).

Iqbal, Z. (2002) 'Ethical issues involved in the implementation of a differential reinforcement of inappropriate behaviour programme for the treatment of social isolation and ritualistic behaviour in an individual with intellectual disabilities'. *Journal Of Intellectual Disability Research: JIDR*, 46 (Pt 1). pp 82-93.

Jay Committee (1979) *Report of the Committee of Enquiry into Mental Handicap Nursing and Care*. Command 7468-1 London: Her Majesty's Stationery Office.

Jenkinson, J. C. (1999) 'Factors Affecting Decision-Making by Young Adults With Intellectual Disabilities'. *American Journal on Mental Retardation*, 104 (4). pp 320-329.

Jeste, D. V., Dunn, L. B., Palmer, B. W., Saks, E., Halpain, M., Cook, A., Appelbaum, P. S. & Schneiderman, L. J. (2003) 'A collaborative model for research on decisional capacity and informed consent in older patients with schizophrenia: Bioethics unit of a geriatric psychiatry intervention center'. *Psychopharmacology*, 171 pp 68-74.

Jingree, T. & Finlay, W. M. L. (2008) "You can't do it... it's theory rather than practice": staff use of the practice/principle rhetorical device in talk on empowering people with learning disabilities'. *Discourse and Society*, 19 pp 705 - 726.

Johnston, L. (2008) 'Missed Out, Missing Out'. Quarriers. [Online]. Available at: <http://www.quarriers.org.uk/documents/QuarriersMOMOReport.pdf> (Accessed: 22 September 2008).

Joint Committee on Human Rights (2008) 'A Life Like Any Other? Human Rights of Adults with Learning Disabilities'. [Online]. Available at: <http://www.publications.parliament.uk/pa/jt200708/jtselect/jtrights/40/4002.htm> (Accessed: 23 March 2009).

Jones, D. (2007) 'Steps on the road to personalized medicine'. *Nature Reviews*, 6 pp. 770-771 [Online]. Available at: www.nature.com/reviews/drugdisc (Accessed: 12 February 2008).

Jones, M. C., McLafferty, E., Walley, R., Toland, J. & Melson, N. (2008) 'Inclusion in primary care for people with intellectual disabilities. Gaining the perspective of service user and supporting social care staff.'. *Journal of Intellectual Disabilities*, 12 (2). pp 93-109.

Jones, R. S. P., Miller, B., Williams, H. & Goldthorp, J. (1997) 'Theoretical and practical issues in cognitive-behavioural approaches for people with learning disabilities'. in Kroese, B.S., Dagnan, D. and Loumidis, K. (eds.) *Cognitive-behaviour therapy for people with learning disabilities*. Abingdon: Routledge.

Kaehne, A. & O'Connell, C. (2010) 'Focus groups with people with learning disabilities'. *Journal of Intellectual Disabilities*, 14 (2). pp 133 - 145.

Karlawish, J. H., Casarett, D. J., James, B. D., Xie, S. X. & Kim, S., Y.H. (2005) 'The ability of persons with Alzheimer disease (AD) to make a decision about taking an AD treatment'. *Neurology*, 64 pp 1514-1519.

Keywood, K. (1998) 'Hobson's choice: reproductive choices for women with learning disabilities'. *Medicine And Law*, 17 (2). pp 149-165.

Keywood, K. & Flynn, M. (2006) 'Healthcare decision-making by adults with learning disabilities: ongoing agendas, future challenges'. *Psychiatry*, 5 (10). pp 360-362.

Keywood, K., Fovargue, S. & Flynn, M. (1999) *Best Practice? Health Care Decision-Making By, With and For Adults with Learning Disabilities*. Manchester: National Development Team.

King's Fund Centre (1980) *An ordinary life: comprehensive locally-based residential services for mentally handicapped people*. London: King's Fund Centre.

Kitzinger, J. (2006) 'Focus groups'. in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford: Blackwell Publishing.

Kmet, L. M., Lee, R. C. & Cook, L. S. (2004) 'Standard Quality Assessment Criteria for Evaluating Primary Research Papers from a Variety of Fields'.

Alberta Heritage Foundation for Medical Research. [Online]. Available at: <http://www.ihe.ca/documents/HTA-FR13.pdf> (Accessed: 8 September 2008).

Koch, T. (2006) 'Establishing rigour in qualitative research: the decision trail'. *Journal of Advanced Nursing*, 53 (1). pp 91-100.

Kroese, B. S. (1997) 'Cognitive-behavioural therapy for people with learning disabilities: conceptual and contextual issues'. in Kroese, B.S., Dagnan, D. and Loumidis, K. (eds.) *Cognitive-behavioural therapy for people with learning disabilities*. Abingdon: Routledge.

Law Commission (1991) *Mental Incapacitated Adults and Decision-Making: An Overview*. London: Her Majesty's Stationery Office.

Law Commission (1995) *Mental Incapacity (Report No. 231)*. London: Her Majesty's Stationery Office.

Lea, D. H., Jenkins, J. F. & Francomano, C. A. (1998) *Genetics in clinical practice*. London: Jones and Bartlett.

Lennox, N., Taylor, M., Rey-Conde, T., Bain, C., Purdie, D. & Boyle, F. (2005) 'Beating the barriers: recruitment of people with intellectual disability to participate in research'. *Journal of Intellectual Disability Research*, 49 (4). pp 296-305.

Lincoln, Y. S. & Guba, E. G. (1985) *Naturalistic inquiry*. Newbury Park, CA.: Sage.

Lipson, J. G. & Omidian, P. A. (1997) 'Aghan refugee issues in the U.S. social environment'. *Western Journal of Nursing Research*, 19 pp 110-126.

Llewellyn, G. & McConnell, D. (2005) 'You have to prove yourself all the time'. in Grant, G., Goward, P., Richardson, M. and Ramcharan, P. (eds.) *Learning Disability: A Life Cycle Approach to Valuing People*. Maidenhead: Open University Press.

Macdonald, S. (2001) 'British Social Anthropology'. in Atkinson, P., Coffey, A., Delamont, S., Lofland, J. and Lofland, L. (eds.) *Handbook of Ethnography*. London: Sage.

Malinowski, B. (1922) *Argonauts of the Western Pacific. An Account of Native Enterprise and Adventure in the Archipelagoes of Melanesian New Guinea*. London and New York: Routledge and Kegan Paul.

Martin, G., Currie, G. & Finn, R. (2009) 'Bringing genetics into primary care: findings from a national evaluation of pilots in England'. *Journal of Health Services Research and Policy*, 14 (4). pp 204-211.

Martin, P., Lewis, G., Smart, A. & Webster, A. (2006) 'False positive? The clinical and commercial development of pharmacogenetics'. [Online]. Available

at: <http://www.york.ac.uk/res/pgx/publications/FalsePositive2006.pdf> (Accessed: 19 November 2008).

Mays, N. & Pope, C. (2006) 'Quality in qualitative health research'. in Mays, N. and Pope, C. (eds.) *Qualitative research in health care*. Oxford: Blackwell Publishing Limited.

McCahon, D., Holder, R., Metcalfe, A., Clifford, S., Gill, P., Cole, T., Sleightholme, H. V. & Wilson, S. (2009) 'General practitioners' attitudes to assessment of genetic risk of common disorders in routine primary care'. *Clinical Genetics*, 76 pp 544 - 551.

Medical Law and Research Online (1995). [Online]. Available at: http://www.medreslaw.com/capacity.php#_ftn7 (Accessed: 10 October 2007).

Mencap (2002) 'Am I making myself clear?'. [Online]. Available at: <http://november5th.net/resources/Mencap/Making-Myself-Clear.pdf> (Accessed: 27 July 2010).

Mencap (2005) 'Make it clear'. Mencap. [Online]. Available at: <http://www.mencap.org.uk/document.asp?id=1579> (Accessed: 17 March 2009).

Mencap (2007) 'Death by indifference'. Mencap Campaigns. [Online]. Available at: <http://www.mencap.org.uk/document.asp?id=284> (Accessed: 22 September 2008).

Michael, J. (2008) 'Healthcare for all: Report of the independent inquiry into access to healthcare for people with learning disabilities'. [Online]. Available at: <http://www.oldt.nhs.uk/documents/Healthcareforall.pdf> (Accessed: 22 September 2008).

Miles, M. B. & Huberman, A. M. (1994) *Qualitative data analysis: an expanded sourcebook*. 2nd edn. Thousand Oaks: Sage.

Ministry of Justice (2007) 'Mental Capacity Act 2005. Code of Practice'. The Stationery Office. [Online]. Available at: <http://webarchive.nationalarchives.gov.uk/+http://www.justice.gov.uk/docs/mca-cp.pdf> (Accessed: 2 September 2010).

Moreno, J. L. (1934) *Who shall survive?* Washington D.C.: Nervous and Mental Disease Publishers.

Morgan, D. L. (1998) *The Focus Group Guide Book*. eds. Morgan, D.L. and Krueger, R.A., The Focus Group Kit. Thousand Oaks: Sage.

Morris, C. D., Niederbuhl, J. M. & Mahr, J. M. (1993) 'Determining the capability of individuals with mental retardation to give informed consent'. *American Journal on Mental Retardation*, 98 (2). pp 263-272.

Morse, J. M. (1984) 'The cultural context of infant feeding in Fiji'. *Ecology of Food and Nutrition*, 14 pp 287-296.

Morse, J. M. & Field, P. A. (1996) *Nursing Research. The application of qualitative approaches*. 2nd edn. London: Chapman and Hall.

Muecke, M. A. (1994) 'On the Evaluation of Ethnographies'. in Morse, J.M. (ed.) *Critical Issues in Qualitative Research Methods*. Thousand Oaks: Sage.

Mull, D. S., Agran, P. F., Winn, D. G. & Anderson, C. L. (2001) 'Injury in children of low-income Mexican, Mexican American, and non-Hispanic white mothers in the USA: a focused ethnography'. *Social Science and Medicine*, 52 pp 1081-1091.

Murphy, E., Dingwall, R., Greatbach, D., Parker, S. & Watson, P. (1998) 'Qualitative research methods in health technology assessment: a review of the literature.'. *Health Technology Assessment*, 2 (16), [Online]. Available at: <http://www.hta.ac.uk/fullmono/mon216.pdf> (Accessed: 30 July 2008).

Murphy, G. H. (2004) 'Capacity of adults with intellectual disabilities to consent to sexual relationships'. *Psychological Medicine*, 34 (7). pp 1347-1357.

Murphy, G. H. & Clare, C. H. (1997) 'Consent Issues'. in O'Hara, J. and Sperlinger, A. (eds.) *Adults with Learning Disabilities: a practical approach for health professionals*. Chichester: John Wiley & Sons.

Murphy, G. H. & Clare, I. C. H. (1995) 'Adults' capacity to make decisions affecting the person: Psychologist's contribution.'. in Bull, R. and Carson, D. (eds.) *Handbook of Psychology in Legal Contexts*. Chichester: John Wiley & Sons.

Murphy, J. (2006) 'Perceptions of communication between people with communication disability and general practice staff'. *Health Expectations*, 9 (1). pp 49 - 59.

Myron, R., Gillespie, S., Swift, P. & Williamson, T. (2008) *Whose decision? Preparation for and implementation of the Mental Capacity Act in statutory and non-statutory services in England and Wales*. London: Mental Health Foundation, (Report No. ISBN 1-906162-14-6). Available at: <http://www.mentalhealth.org.uk/publications/?EntryId5=59839&char=W> (Accessed: 14 October 2010).

National Health Service Primary Care Contracting (2007) 'Primary Care Contracting 2007'. [Online]. Available at: <http://www.primarycarecontracting.nhs.uk/204.php> (Accessed: 22 October 2007).

National Institute for Health and Clinical Excellence (2008) 'CG66 - Type 2 diabetes: full guideline'. [Online]. Available at:

<http://guidance.nice.org.uk/CG66/Guidance/pdf/English> (Accessed: 3 September 2010).

National Institutes for Health (2010) 'NIH expands key pharmacogenomics resource'. [Online]. Available at: <http://www.nih.gov/news/health/sep2010/nigms-07a.htm> (Accessed: 7 September 2010).

NHS Choices (2010) 'NHS General practitioners - Frequently asked questions'. [Online]. Available at: <http://www.nhs.uk/nhsengland/aboutnhservices/doctors/pages/gp-faqs.aspx> (Accessed: 30 August 2010).

NHS Confederation (Employers) Company (2008) 'Clinical Direct Enhanced Services (DES) guidance for GMS Contract 2008/2009'. [Online]. Available at: <http://www.nhsemployers.org/pay-conditions/primary-893.cfm> (Accessed: 6 November 2008).

Nirje, B. (1969) 'The normalisation principle and its human management implications.' in Kugel, R. and Wolfensberger, W. (eds.) *Changing patterns in residential services for the mentally retarded*. Washington, D.C.: President's Committee on Mental Retardation.

Nota, L., Ferrari, L., Soresi, S. & Wehmeyer, M. (2007) 'Self-determination, social abilities and the quality of life of people with intellectual disability'. *Journal of Intellectual Disability Research*, 51 (11). pp 850 - 865.

Nuremberg Code 1947 (1949) *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law*. Washington D.C: U.S. Government Printing Office.

Office of Public Sector Information (2005) 'Mental Capacity Act 2005'. Queen's Printer of Acts of Parliament. [Online]. Available at: http://www.legislation.gov.uk/ukpga/2005/9/pdfs/ukpga_20050009_en.pdf (Accessed: 19 August 2010).

Oliver, M. (1990) *The politics of disablement*. Basingstoke: MacMillan.

Oliver, M. (2009) *Understanding disability: from theory to practice*. 2nd edn. Basingstoke: Palgrave Macmillan.

Palmer, B. W. & Jeste, D. V. (2006) 'Relationship of Individual Cognitive Abilities to Specific Components of Decisional Capacity Among Middle-Aged and Older Patients With Schizophrenia'. *Schizophrenia Bulletin*, 32 (1). pp 98-106.

Parsons, T. (1991) *Social System*. 2nd edn. London: Routledge.

Patton, M. Q. (2002) *Qualitative research and evaluation methods*. 3rd edn. Thousand Oaks: Sage.

Pendleton, D., Schofield, T., Tate, P. & Havelock, P. (2003) *The New Consultation. Developing doctor-patient communication*. Oxford: Oxford University Press.

People First (2010) 'Why learning difficulty and not learning disability?'. [Online]. Available at: <http://www.peoplefirstltd.com/why-learning-difficulty.php> (Accessed: 6 September 2010).

Philips, Z., Avis, M. & Whyntes, D. K. (2005) 'Knowledge of cervical cancer and screening among women in east-central England'. *International Journal of Gynecological Cancer*, 15 (4). pp 639-645.

Pierce, M., Agarwal, G. & Ridout, D. (2000) 'A survey of diabetes care in general practice in England and Wales'. *British Journal of General Practice*, 50 pp 542 - 545.

Polit, D. F. & Beck, C. T. (2006) *Essentials of Nursing Research*. 6th edn. Philadelphia: Lippincott Williams and Wilkins.

Pope, C. (2005) 'Conducting ethnography in medical settings'. *Medical Education*, 39 pp. 1180-1187 *Blackwell Synergy*. (Accessed: 27 January 2008).

Pope, C. (2006) 'Qualitative methods in health research'. in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford: Blackwell Publishing Limited.

Pope, C., Ziebland, S. & Mays, N. (2006) 'Analysing qualitative data'. in Pope, C. and Mays, N. (eds.) *Qualitative research in health care*. 3rd edn. Oxford: Blackwell Publishing Limited.

Prime Minister's Strategy Unit (2005) 'Improving the life chances of disabled people'. [Online]. Available at: <http://www.cabinetoffice.gov.uk/media/cabinetoffice/strategy/assets/disability.pdf> (Accessed: 31 July 2010).

Public Health Resource Unit (2007) 'Critical Appraisal Skills Programme'. 2 January 2007. [Online]. Available at: <http://www.phru.nhs.uk/Pages/PHD/resources.htm> (Accessed: 6 June 2007).

QSR International (2008) *NVivo 8*

Race, D. G. (1999) *Social Role Valorization and The English Experience*. London: Whiting and Birch Ltd.

Ramcharan, P., Roberts, G., Grant, G. & Borland, J. (eds.) (1997) *Empowerment in everyday life: Learning disability*. London: Jessica Kingsley Publishers Ltd.

Rapley, M. & Antaki, C. (1996) 'A Conversational Analysis of the 'Acquiescence' of People with Learning Disabilities'. *Journal of Community and Applied Social Psychology*, 6 pp 207-227.

Reid, F. J. M. & Reid, D. J. (2007) 'Online focus groups: An in-depth comparison of computer-mediated and conventional focus group discussions.'. in Bryman, A. (ed.) *Qualitative Research 2*. London: Sage.

Richards, L. (2005) *Handling qualitative data. A practical guide*. London: Sage.

Richards, L. & Morse, J. M. (2007) *Readme first for a user's guide to qualitative methods*. 2nd edn. Thousand Oaks: Sage.

Richards, M. (1996) 'Lay and professional knowledge of genetics and inheritance'. *Public Understanding of Science*, 5 pp 217-230.

Richards, M. & Ponder, M. (1996) 'Lay understanding of genetics: a test of a hypothesis'. *Journal of Medical Genetics*, 33 (12). pp 1032-1036.

Rieder, M. J. (2007) 'Pharmacogenetics of warfarin treatment for potential clinical application'. *Current Cardiovascular Risk Reports*, 1 (5). pp 420-426.

Roethlisberger, F. J. & Dickson, W. J. (1939) *Management and the worker*. Cambridge, MA: Harvard University Press.

Rolfe, G. (2007) 'Validity and the fabrication of truths: a response to Porter'. *Journal of Advanced Nursing*, 60 (1). pp 108-109.

Roper, J. M. & Shapira, J. (2000) *Ethnography in Nursing Research*. ed. Brink, P., Methods in Nursing Research. Thousand Oaks: Sage.

Rostant, K., Steed, L. & O'Leary, P. (2003) 'Prenatal screening and diagnosis: A survey of health care providers' knowledge and attitudes'. *The Australian and New Zealand Journal of Obstetrics and Gynaecology*, 43 (4). pp 307-311.

Royal College of Physicians, Royal College of Pathologists & British Society for Human Genetics (2005) 'Consent and confidentiality in genetic practice: guidance on genetic testing and sharing genetic information. Report of the Joint Committee on Medical Genetics'. London: RCP, RCPATH, BSHG. Available at: [http://www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21\[1\].8.06.pdf](http://www.bshg.org.uk/documents/official_docs/Consent_and_confid_corrected_21[1].8.06.pdf).(accessed 15 October 2010)

Safeer, R. S. & Keenan, J. (2005) 'Health Literacy: The Gap Between Physicians and Patients'. *American Family Physician*, 72 (3). pp 463 - 468.

Sandelowski, M. (1986) 'The problem of rigor in qualitative research'. *Advances in Nursing Science*, 8 (3). pp 27-37.

Seale, C. (1999) *The Quality of Qualitative Research*. ed. Silverman, D., Introducing Qualitative Methods. London: Sage.

Shakespeare, T. (2010) 'The Social Model of Disability'. in Davis, L.J. (ed.) *The Disability Studies Reader*. Abingdon: Routledge.

Sherif, M. (1936) *The Psychology of Social Norms*. New York: Harper.

Sigelman, C. K., Budd, E. C., Spanhel, C. L. & Schoenrock, C. J. (1981) 'When in doubt, say yes: Acquiescence in interviews with mentally retarded persons'. *Mental Retardation*, 19 (2). pp 53-58.

Skirton, H. & Patch, C. (2009) *Genetics for the Health Sciences*. Oxford: SCION Publishing.

Slater, D. N. (2000) 'Are women sufficiently well informed to provide valid consent for the cervical smear test?'. *Cytopathology*, 11 pp 166-170.

Social Care Institute for Excellence (2005) 'How to produce information in an accessible way'. [Online]. Available at: <http://www.scie.org.uk/publications/misc/accessguidelinespublications.pdf> (Accessed: 10 March 2008).

Sowney, M. & Barr, O. (2007) 'The challenges for nurses communicating with and gaining valid consent from adults with intellectual disabilities within the accident and emergency care service'. *Journal of Clinical Nursing*, 16 pp 1678 - 1686.

Spencer, L., Ritchie, J., Lewis, J. & Dillon, L. (2003) *Quality in quality evaluation: A framework for assessing research evidence*. Government Chief Social Researcher's Office London: National Centre for Social Research,.

Stalker, K. (1998) 'Some ethical and methodological issues in research with people with learning difficulties'. *Disability & Society*, 13 (1). pp 5-19.

Stalker, K. & Harris, P. (1998) 'The Exercise of Choice by Adults with Intellectual Disabilities: A Literature Review'. *Journal of Applied Research in Intellectual Disabilities*, 11 (1). pp 60-76.

Stancliffe, R., J. (1997) 'Community living-unit size, staff presence, and residents' choice-making'. *Mental Retardation*, 35 pp 1-9.

Stancliffe, R., J. (2001) 'Living with support in the community: Predictors of choice and self-determination'. *Mental Retardation and Developmental Disabilities Research Reviews*, 7 pp 91-98.

Stein, K. & Allen, N. (1999) 'Cross sectional survey of cervical cancer screening in women with learning disability'. *British Medical Journal*, 318 p. 641 (Accessed: 17 November 2008).

Strauss, A. & Corbin, J. (1990) *Basics of qualitative research: grounded theory procedures and techniques*. Newbury Park, CA.: Sage.

Suto, W. M. I., Clare, I. C. H., Holland, A. J. & Watson, P. C. (2005a) 'Capacity to make financial decisions among people with mild intellectual disabilities.' *Journal of Intellectual Disability Research*, 49 pp 199 - 209.

Suto, W. M. I., Clare, I. C. H., Holland, A. J. & Watson, P. C. (2005b) 'The relationships among three factors affecting the financial decision-making abilities of adults with mild intellectual disabilities'. *Journal of Intellectual Disability Research*, 49 (3). pp 210 - 217.

The Royal Society (2005) *Personalised medicines: hopes and realities*. London: Royal Society. Available at: <http://www.royalsoc.ac.uk/displaypagedoc.asp?id=15874> (Accessed: 16.2.2007).

Thomas, J., Harden, A., Oakley, A., Oliver, S., Sutcliffe, K., Rees, R., Brunton, G. & Kavanagh, J. (2004) 'Integrating qualitative research with trials in systematic reviews'. *British Medical Journal*, 328 pp. 1010-1012 (Accessed: 19 March 2007).

Thrasher, F. M. (1927) *The Gang*. Chicago: University of Chicago Press.

Tobin, G. A. & Begley, C. M. (2004) 'Methodological rigour within a qualitative framework'. *Journal of Advanced Nursing*, 48 (4). pp 388-396.

Tuffrey-Wijne, I. (2002) 'The palliative care needs of people with intellectual disabilities: a case study'. *International Journal of Palliative Nursing*, 8 (5). pp 222.

Tuffrey-Wijne, I. (2003) 'The palliative care needs of people with intellectual disabilities: a literature review'. *Palliative Medicine*, 17 (1). pp 55-62.

UK Clinical Ethics Network (2008) 'Consent - Introduction.' [Online]. Available at: <http://www.ethics-network.org.uk/ethical-issues/consent/introduction> (Accessed: 8 September 2008).

UK Clinical Ethics Network (2010) 'Determining best interests'. [Online]. Available at: <http://www.ethics-network.org.uk/educational-resources/mental-capacity-act-2005/best-interests> (Accessed: 31 August 2010).

US Department of Energy (2003) 'Human Genome Program: *Genomics and Its Impact on Science and Society: The Human Genome and Beyond: Gene Testing, Pharmacogenomics, and Gene Therapy*'. US Department of Energy. [Online]. Available at: http://www.ornl.gov/sci/techresources/Human_Genome/publicat/primer/index.shtml (Accessed: 22 October 2006).

Vygotsky, L. S. (1978) *Mind in Society: The Development of Higher Psychological Processes*. Cambridge, MA: Harvard University Press.

- Walker, A. & Walker, C. (1998) 'Normalisation and 'Normal' Ageing: The social construction of dependency among older people with learning difficulties'. *Disability and Society*, 13 (1). pp 125-142.
- Walmsley, J. (2001) 'Normalisation, Emancipatory Research and Inclusive Research in Learning Disability'. *Disability and Society*, 16 (2). pp 187 - 205.
- Walmsley, J. (2005) 'Research and emancipation: Prospects and problems'. in Grant, G., Goward, P., Richardson, M. and Ramcharan, P. (eds.) *Learning disability: A life cycle approach to valuing people*. Maidenhead: Open University Press.
- Walsh, D. & Downe, S. (2006) 'Appraising the quality of qualitative research'. *Midwifery*, 22 pp 108-119.
- Ward, L. (2001) *Considered Choices. The new genetics, prenatal testing and people with learning disabilities*. Kidderminster: BILD Publications.
- Webb, O. J. & Rogers, L. (1999) 'Health screening for people with intellectual disability: the New Zealand experience'. *Journal of Intellectual Disability Research*, 43 (6). pp 497-503.
- Wehmeyer, M. L. & Bolding, N. (1999) 'Self-Determination Across Living and Working Environments: A Matched Samples Study of Adults With Mental Retardation'. *Mental Retardation*, 37 (5). pp 353-363.
- Whittemore, R. (2005) 'Combining Evidence in Nursing Research'. *Nursing Research*, 54 (1). pp 56-62.
- Whittemore, R. & Knafl, K. (2005) 'The integrative review: updated methodology'. *Journal of Advanced Nursing*, 52 (5). pp 546-553.
- Whyte, W. F. (1943) *Street Corner Society*. Chicago and London: The University of Chicago Press.
- 'Widgit'. (2008) Logotron Educational Software. [Online]. Available at: <http://www.widgit.com/index.htm> (Accessed: 10 March 2008).
- Williams, C., Alderson, P. & Farsides, B. (2002) 'What constitutes 'balanced information in the practitioners' portrayals of Down's syndrome?'. *Midwifery*, 18 (3). pp 230-237.
- Williams, J. K., Skirton, H. & Masny, A. (2006) 'Ethics, Policy, and Educational Issues in Genetic Testing'. *Journal of Nursing Scholarship*, 38 (2). pp 119-125.
- Wirth, L. (1928) *The Ghetto*. Chicago: University of Chicago Press.
- Wolfensberger, W. (1983) 'Social role valorisation: a proposed new term for the principal of normalisation'. *Mental Retardation*, 21 pp 395-413.

Wong, J. G., Clare, C. H., Holland, A. J., Watson, P. C. & Gunn, M. (2000) 'The capacity of people with a 'mental disability' to make a health care decision'. *Psychological Medicine*, 30 (2). pp 295-306.

World Medical Association (1964) 'Ethical principles for medical research involving human subjects'. [Online]. Available at: <http://www.wma.net/en/30publications/10policies/b3/index.html> (Accessed: 11 January 2010).

Young, A. F. & Chesson, R. A. (2007) 'Determining research questions on health risks by people with learning disabilities, carers and care-workers'. *British Journal of Learning Disabilities*, 36 pp. 22-31 DOI: doi:10.1111/j.1468-3156.2007.00444.x (Accessed: 4 February 2007).