JAN REVIEW PAPER

Informed consent to healthcare interventions in people with learning disabilities – an integrative review

Lesley Goldsmith, Heather Skirton & Christine Webb

Accepted for publication 30 July 2008

Correspondence to L. Goldsmith:
e-mail: lesley.goldsmith@pms.ac.uk

Lesley Goldsmith BSc
PhD Student
Faculty of Health and Social Work,
University of Plymouth, UK

Heather Skirton PhD RN Reg
Genetic Counsellor
Deputy Head (for Research, Innovation and Enterprise)
School of Nursing and Community Studies,
University of Plymouth, UK

Christine Webb PhD RN FRCN
Professor of Health Studies
School of Nursing and Community Studies,
University of Plymouth, UK

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 participants 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 *et al.* (1998)	To investigate the ability of people with LD to consent to psy chological 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 *et al.* (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 *et al.* (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 *et al.* (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 Consent 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 *et al.* (1998)	To identify difficulties in assessing the capacity to give consent	Unclear 'qualitative' but using structured interviews	People with LD living informally in NHS 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 *et al.* (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 *t*-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 *et al.* (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 *et al.* (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 co-morbidity. 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, t-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 *et al.* (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 back-grounds 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 *et al.* (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 *et al.* (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 *interdependence* 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 *et al.* (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. $n = 45$	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 *et al.* (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 $n = 21$; 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 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) ($P < 0{\cdot}01$). 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 ($P < 0{\cdot}05$) 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, $P < 0{\cdot}01$).

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. & 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), 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/conscent/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.

