An exploration of the medication related experiences of community dwelling adults with learning disabilities.

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An exploration of the medication related experiences of community dwelling adults with learning disabilities

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ABSTRACT

The purpose of this study was to explore the medication related experiences of community dwelling adults with learning disabilities (LD). A narrative review was undertaken and found that current literature focused on measuring the prevalence of particular drug related issues, rather than on the views and experiences of the adult with LD.

A qualitative methodology was adopted with a pragmatic case study approach in which each case study focused on a community dwelling adult with LD. The Patients Lived Experience with Medicines (PLEM) conceptual model was used as a theoretical framework for data collection and analysis. Data were collected from: semi-structured interviews with the adult with LD, where possible; semi-structured interviews with relevant carers and care workers; available documents; and unstructured indirect observations of relevant artefacts by the researcher. Ethical approval was gained.

One pilot and ten case studies were identified by local care providers. Using the PLEM conceptual model, the following medication related experiences were reported:

1. Medication related burden: drugs adversely affecting cognitive ability and mental wellbeing are often intolerable, the daily routine can itself be a burden, changes to routine can be challenging, and the burden with medication is often assumed by the carers or care workers;
2. Medication related beliefs: medication is seen as both beneficial and necessary, carers and care workers of adults with severe LD are the experts on the person being prescribed for, and enabling the coping skills of adults with mild-moderate LD is important;
3. Medication taking practice: acceptance of medication was never truly unconditional.

In conclusion, the medication related experiences of community dwelling adults with LD are multifaceted and often shared by or transferred to, any carer or care worker. The outcomes of this research could help support the education and training of health care professionals.

Key words: *learning disabilities; medicines; medication; patients lived experience with medicines (PLEM); medication related burden; medication related beliefs; medication taking practice*

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OUTPUT AND IMPACT SUMMARY

Poster Abstracts

NHS Education for Scotland –Achieving Excellence in Pharmacy Education conference - Edinburgh (27th April 2018)

'Undertaking a professional doctorate'

NHS Grampian's Quality and Safety in Healthcare event - Aberdeen (1st May 2018)

'Adults with learning disabilities and medication – what are their experiences?'

RGU Pharmacy and Life Sciences Research Day - Aberdeen (28th May 2018)

'Adults with learning disabilities and medication – what are their experiences?'

European Society of Clinical Pharmacy conference, Belfast (24th-26th Oct 2018)

'Medication related experiences of adults with learning disabilities'

NHS Scotland Research conference, Perth (30th Oct 2018)

'Medication related experiences of adults with learning disabilities'

Workshops

European Society of Clinical Pharmacy conference, Oslo (5th-7th Oct 2016)

'Tackling inequalities in access to clinical pharmacist led healthcare: recognising and overcoming ethical issues of inclusion in research'

European Society of Clinical Pharmacy conference, Belfast (24th-26th Oct 2018)

'Understanding medication-related experiences of adults with learning disabilities; the challenges they often face; and how pharmacists can personalise their pharmaceutical care'

Additional Local and National Impact

- Increased professional links with LD care providers, LD service managers, LD charities and NHS LD nurse consultant.
- Inclusion of a section for LD services in the local medication management guidance.
- Undertaking national project work for NES using doctoral research skills; creation of a training programme for Educational Supervisors.

Other Planned Outputs

- Journal publications (2019) – Journal of Applied Research in Intellectual Disabilities:
    - *People with intellectual disabilities and their experience of medication: a narrative literature review;*
    - *Adults with intellectual disabilities and their experience of medication.*
- Oral presentation of work at International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) conference (August 2019).
- Summary of the research for the Scottish Commission for Learning Disabilities (2019).

FOREWORD

For the last 8 years I have been employed by NHS Grampian as a primary care Lead Pharmacist within Aberdeen City Health and Social Care Partnership (previously Community Health Partnership). Prior to that I worked for 10 years as a clinical pharmacist across a variety of GP practices within NHS Grampian where I advised the GP practice team on medication related issues, participated in multi-disciplinary meetings, and ran clinics for patients with respiratory conditions as an independent prescriber. Whilst the core aspect of my current role is to work with GPs to ensure safe and cost-effective prescribing, a significant part of my role is also spent working with social care colleagues on medication management issues. Over the years I have been involved in: producing an online resource (www.medicinemanagement.org) for medication administration training; rewriting our local medication management guidance (version 3 launched June 2017); and assisting our Adult Support and Protection team with some cases involving medication. Some of my work with social care colleagues has involved me working with several LD care providers to create medication management policies and review current practices. During these times I was struck by some of the complex and unique challenges that LD care providers faced with regards to supporting their clients with medicines. It was the lack of literature on the subject that then prompted me to undertake research that would document some of these challenges and therefore increase awareness amongst health and social care professionals and so improve the support for this group of patients/clients. At the same time, I was working with academic colleagues to undertake local, practice-based research in the areas of multi-compartment compliance aids[1] [2] [3] [4] and the homeless population[5] [6].

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[1] Stewart D, Smith KG, MacLeod J, Strath A, Paudyal V, Forbes-McKay K, Cunningham S, MacLure K. The experiences and beliefs of older people in Scottish very sheltered housing about using multi-compartment compliance aids. International journal of clinical pharmacy. 2018 Apr 1;40(2):394-402.

[2] Stewart D, McDonald C, MacLeod J, MacLure K, Gray G, McIntosh T. The behaviors and experiences of the community pharmacy team on the provision of multi-compartment compliance aids. Research in social and administrative pharmacy. 2018 Apr 1;14(4):347-55.

[3] Counter D, Stewart D, MacLeod J, McLay JS. Multicompartment compliance aids in the community: the prevalence of potentially inappropriate medications. British journal of clinical pharmacology. 2017 Jul;83(7):1515-20.

[4] MacLure K, MacLeod J, Forbes-McKay K, Paudyal V, Cunningham S, Strath A, Lynch R, Stewart D. A case study investigation into the use of multi-compartment compliance aids in older people resident in very sheltered housing. The Patient-Patient-Centered Outcomes Research. 2016 Dec 1;9(6):583-90.

[5] Smith KG, Paudyal V, MacLure K, Forbes-McKay K, Buchanan C, Wilson L, MacLeod J, Smith A, Stewart D. Relocating patients from a specialist homeless healthcare centre to general practices: a multi-perspective study. Br J Gen Pract. 2018 Feb 1;68(667):e105-13.

[6] Paudyal V, MacLure K, Buchanan C, Wilson L, Macleod J, Stewart D. 'When you are homeless, you are not thinking about your medication, but your food, shelter or heat for the night': behavioural determinants of homeless patients' adherence to prescribed medicines. Public health. 2017 Jul 1;148:1-8.

As I was developing my knowledge of research processes and opportunities through this collaborative work, the option of undertaking a Doctorate of Professional Practice (DPP) arose. Whilst a traditional PhD was also an option, the DPP had a greater focus on the impact of the research and was therefore of greater value to me as a clinician, and to the service I work within. Accordingly, the DPP was chosen as a means of developing personal research skills but with the expectation that the results could be of benefit to the local service.

This thesis has been structured as follows:

- Chapter 1 is a general introduction to the thesis including a narrative literature review and the aim and objectives of the research;
- Chapter 2 outlines the methodology, research governance, theoretical framework and study design;
- Chapter 3 summarises the ten cases which were studied in the research;
- Chapters 4, 5 and 6 contain the results, structured under the three research objectives which reflect the conceptual model adopted as a theoretical framework;
- Chapter 7 continues the results by outlining the newly identified sub-themes that were not listed within the aforementioned theoretical framework;
- Chapter 8 summarises the outcome of the dissemination panel check which was employed to enhance the credibility of the results;
- Chapter 9 discusses the overall results in terms of the theoretical framework used and then considers the reflexivity, transferability, strengths and limitations of the research;
- Chapter 10 considers the impact of the research before providing a conclusion.

ABBREVIATIONS

ADR	Adverse Drug Reaction
AED	Anti Epileptic Drug
AREC	Adults with incapacity Research Ethics Committee
ASD	Autistic Spectrum Disorder
BP	Blood Pressure
BPS	British Psychological Society
CASPA	Care And Support Providers Aberdeen
CPAP	Continuous Positive Airway Pressure
CQC	Care Quality Commission
DD	Developmental Disability
DPP	Doctorate of Professional Practice
EFT	Enteral Feeding Tube
GDPR	General Data Protection Regulation
GP	General Practitioner (doctor)
HCP	Health Care Professional
HL	Health Literacy
HRA	Health Research Authority
HrQoL	Health-related Quality of Life
IASSIDD	International Association for the Scientific Study of Intellectual and Developmental Disabilities
ID	Intellectual Disability
IQ	Intelligence Quotient
LA	Local Authority
LD	Learning Disability
MAR	Medication Administration Record
MCA	Multi-compartment Compliance Aid
MRC	Medical Research Council
NHS	National Health Service
NBM	Nil By Mouth
NES	NHS Education for Scotland
NG	Nasogastric
OTC	Over The Counter
PAMIS	Promoting A More Inclusive Society
PEG	Percutaneous Endoscopic Gastrostomy

P&LS	Pharmacy and Life Sciences
PLEM	Patient's Lived Experience with Medicine
PMLD	Profound and Multiple Learning Disabilities
POM	Prescription Only Medicine
PRUK	Pharmacy Research UK
RGU	Robert Gordon University
TDF	Theoretical Domains Framework
UK	United Kingdom

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CHAPTER 1: GENERAL INTRODUCTION

'You never really understand a person until you consider things from his point of view – until you climb into his skin and walk around in it.'

Atticus Finch in 'To Kill a Mockingbird' – Harper Lee

1.1 CHAPTER INTRODUCTION

This chapter provides an introduction to the thesis. First of all, the concept of learning disabilities (LD) is explored through describing the current definitions and classification of LD; citing the estimated prevalence of LD; and outlining the models for understanding LD. Current UK and Scottish policies relating to LD are described as well as the recognised health needs of people with LD. A brief summary of social care provision, the role of carers and care workers, and of medication and polypharmacy within Scotland is then provided. Following on from this, the current evidence within the literature relating to adults with LD and medication is presented in six themed sections: general medication; antipsychotic medication; practical challenges to medication administration and management; carers, care workers and medication; pharmacist input to care; and clinical issues. Gaps within the literature are then noted and discussed. Finally, the aim and objectives of the research are stated.

1.2 LEARNING DISABILITIES

1.2.1 Definition- Learning Disability (LD)

Learning disability (LD) is the term used in the United Kingdom (UK) to describe an individual who: has significant impairment of intellectual functioning (generally recognised as Intelligence Quotient (IQ) <70); and who has significant impairment of adaptive functioning; and where the age of onset was before adulthood (British Psychological Society 2000). The British Psychological Society (2000 p.6) defines adaptive functioning as being impaired when, *'The individual requires significant assistance to provide for his/her own survival (eating and drinking; keeping himself/herself clean, warm and clothed) and/or with his/her social/community adaptation (e.g. social problem solving and social reasoning).'* However, Emerson and Hatton (2014) do highlight that the definition of LD has varied hugely over time due to it being a profoundly social construct.

Intellectual disability (ID) is the internationally recognised term for LD. It too is defined in terms of significant impairment to both intellectual functioning and adaptive functioning with symptoms beginning in childhood or adolescence (American Psychiatric Association 2017; American Association on Intellectual and Development Disabilities 2015). The definitions of LD and ID are so similar that those working and conducting research within this field see the terms as synonymous (Bhaumik *et al* 2015). As this research was conducted solely in the UK, the term learning disability (LD) will be used throughout this thesis.

It should also be noted that the term 'learning difficulties', used within the UK educational system, is not synonymous with ID and LD. 'Learning difficulties' refers to those issues that can affect education such as: speech and language impairments; sensory impairments that give rise to learning problems, physical disabilities, medical problems or general behavioural difficulties; and specific learning problems such as dyslexia (Bhaumik *et al* 2015). Furthermore, the term developmental disability (DD) is an umbrella term that refers to both physical and/or learning disabilities that originated at birth or early childhood; will last throughout life, and; will severely restrict the individual's functioning in several major life activities (Center for Disease Control and Prevention 2017). The term 'learning difficulties' and 'developmental disabilities' are therefore broader categories than LD or ID.

1.2.2 Causes of LD

Not all the causes of LD are known (British Institute of Learning Disabilities 2011). Some of the more common causes are listed by the Foundation for People with Learning Disabilities (Mental Health Foundation 2017) and include: genetic conditions such as Fragile X; chromosomal abnormalities such as Down's syndrome; very premature delivery; illness of mother during pregnancy; brain damage or abnormal development of the brain before, during, or after birth such as Cerebral Palsy; foetal alcohol syndrome; teratogenic drugs; neglect or a lack of mental stimulation early in life.

1.2.3 Classification of LD

Traditionally in the UK, LD was classified on the basis of intelligence: mild (IQ 50-70); moderate (IQ 35-50); severe (IQ 20-35); or profound (IQ <20) (British Institute of Learning Disabilities 2011; British Psychological Society 2000). Due to the challenges of accurately measuring IQ, and recognising adaptive functioning as a key issue, the British Psychological Society (BPS) recommended that LD classification should refer not just to the IQ but also to the required adaptive or social functioning support that person requires (British Psychological Society 2000). The BPS states that intellectual functioning should be classified as either significant (IQ 55-69) or severe (IQ<55); and the level of support required in relation to adaptive functioning should then be referred to as intermittent (episodic), limited (consistent over time, time limited, but more regular than intermittent), extensive (regular and not time limited), or pervasive (high intensity across more than one environment). However, accurate classification of LD remains a challenge for health care professionals (HCPs) and likely to change in the future (Webb and Whitaker 2012). Furthermore, in practice it is often difficult to ascertain how any classification being used by carers, care workers or HCPs to describe an individual with LD was actually determined.

1.2.4 Prevalence of LD

The 2011 Scottish Census recorded that 26,300 (0.5%) people in Scotland reported that they had a learning disability: 15,100 males and 11,200 females (National Records of Scotland, 2011). Public Health England (2016) estimated that in 2015 in England there were 1,087,100 (1.7%) people with learning disabilities, including 930,400 adults. The Royal College of Nursing (2013) cited a higher figure of ~1.5 million (2.3%) people having LD in the UK. From these data sources it can be estimated that 0.5-2.3% of the UK population has LD. This can be compared to a meta-analysis undertaken by Maulik *et al* (cited by Emerson and Hatton 2013) which calculated global prevalence of LD to be 1.03%. This differences in prevalence data is most probably due to the heterogeneity of the population to which it refers and whether or not people with mild LD see, or declare, themselves as having LD (British Psychological Society 2000). The Scottish Government noted that research studies that tried to more accurately determine the prevalence of LD have been challenging, expensive and unsuccessful (Scottish Government 2013).

1.2.5 Models of LD

Emerson and Hatton (2014) outline the three main models for understanding LD: the medical model; the social model; and the biopsychosocial model.

1. The ***medical model*** is deficit based and aims to first reduce the deficit and then care for this population. The goal is to reduce the poor health of people with LD whilst accepting that they will always be in poorer health than the remainder of the non-LD population.
2. The ***social model*** makes a conceptual distinction between impairment and disability, and views experienced inequalities as an expression of societal oppression and exclusion. This then provides a framework for political change, achievement of civil rights, and empowerment.
3. The ***biopsychosocial model*** was developed by the World Health Organization (World Health Organization 2001). It is more complex than the medical or social models and some consider it to be the medical model with the social model just grafted on. The biopsychosocial model is neutral on the goals of policy and practice.

Furthermore, within social care, the work of both Sen and Nussbaum has encouraged a shift of focus from disability to capability (Nussbaum 2011; Sen 1999). Capabilities are not to be considered merely as skills or abilities but as a combination of personal attributes and the environment with a particular emphasis on what that person is able to do and to be (Nussbaum 2011; Sen 1999). Giving due consideration to capability, inclusion and empowerment is, therefore, important for both HCPs and researchers (Nind 2009; Dalton and McVilly 2004; Stalker 1998).

1.2.6 UK National Health Service (NHS)

In 1948, the publicly owned National Health Service (NHS) was founded in each of the four home nations of the UK (England, Northern Ireland, Scotland and Wales) and to this day continues to provide health care to all UK citizens (GIG Cymru NHS Wales 2017; Health and Social Care Northern Ireland 2017; NHS Choices 2017; Scotland's Health on the Web 2017; Scottish Government Health Directorates 2008). Although the NHS has evolved differently in the four home nations, each nation adheres to the central principle of the NHS being available to all through a taxation system where people pay into it according to their means (GIG Cymru NHS Wales 2017; Health and Social Care Northern Ireland 2017; NHS Choices 2017; Scotland's Health on the Web 2017).

1.2.7 UK Government Health Policies

The National Health Service and Community Care Act (National Health Service and Community Care Act 1990) was the first major reform of the NHS since its inception (Emerson and Hatton 1994). The Act attempted to bridge the gap between health care services and local council social services and, where possible, move these services away from institutions and into communities. Emerson and Hatton (1994) noted that this meant that people with LD were no longer to be consigned to mental handicap hospitals for their lifetime, but instead included in the community and housed in smaller units of residential care. In Scotland these smaller units of residential care are known as independent living supported housing (Scottish Government 2017a). In 2001, the UK Department of Health issued a strategic White Paper with the four key principles of rights, independence, choice, and inclusion, and covered issues ranging from health to advocacy (Department of Health 2001).

However, in May 2011, despite this clearly articulated strategy for improving the lives of people with LD, the British Broadcasting Corporation (BBC)'s Panorama television documentary revealed the shocking, criminal abuse of people with LD at a privately owned hospital in Winterbourne (BBC News 2011). Many of the employees were subsequently prosecuted and an investigation into the abuse was led by the Care Quality Commission (CQC). One of the key recommendations from the CQC investigation was that only when it was clinically necessary should any person with LD live in a hospital setting (Department of Health 2012). Whilst medication was not a primary factor in the Winterbourne scandal, the subsequent reports highlighted concerns over the use of antipsychotic and other psychoactive medicines being used as a chemical restraint:

> *'We have heard deep concerns about over-use of antipsychotic and antidepressant medicines. Health professionals caring for people with learning disabilities should assess and keep under review the medicines requirements for each individual patient to determine the best course of action for that patient, taking into account the views of the person if possible*

and their family and/or carer. Services should have systems and policies in place to ensure that this is done safely and in a timely manner and should carry out regular audits of medication prescribing and management, involving pharmacists, doctors and nurses.' (Department of Health 2012 p.45)

'…antipsychotics and antidepressants are often prescribed in the absence of recorded diagnosis for which they are known to be effective...relatively few of the patients would have taken the initiative themselves to seek initial or continuing treatment. It is likely that carers would have been influential both in arranging consultations and in procuring and administering medications.' (Public Health England 2015 p.7 & p.48)

Within Scotland, *'The Keys to Life'* is the current strategy document for improving the lives of people with LD (Scottish Government 2013). It relates to the United Nations Convention of the Rights of People with Disabilities (United Nations General Assembly 2007) and lists four outcomes for people with LD in Scotland: a healthy life; choice and control; independence; and active citizenship. The strategy notes that, *'Independent living does not mean living by yourself, or fending for yourself. It means rights to practical assistance and support to participate in society and live an ordinary life.'* (Scottish Government 2013 p.54)

The Scottish Chief Medical Officer's three most recent reports, *'Realistic Medicine'* (Scottish Government 2016); *'Realising Realistic Medicine'* (Scottish Government 2017b); and 'Practising Realistic Medicine' (Scottish Government 2018), have begun a new conversation in health and social care on personalising care, managing clinical risk, reducing harm and waste and innovating to improve. Two key points are noted below:

'You should expect the doctor (or other health professional) to explore and understand what matters to you personally and what your goals are, to explain to you the possible treatments or interventions available with a realistic explanation of their potential benefits and risks for you as an individual, and to discuss the option and implications of doing nothing. You should expect to be given enough information and time to make up your mind. You should consider carefully the value to you of anything that is being proposed whether it be a treatment, consultation or diagnostic investigation and be prepared to offer challenge if you feel it appropriate.' (Scottish Government 2017b p.4)

'We fail to measure what really matters in producing value-based care because we've been trained in a reductionist environment where people don't trust measures that aren't highly

> *objective and generalisable, when most things that contribute to value at the level of the individual are highly subjective and context specific, including their preferences. If we don't measure whether services delivered are concordant with people's preferences, we can't measure that value creation.'* (Scottish Government 2017b p. 11)

These views have been echoed by the Scottish Chief Pharmaceutical Officer in, *'Achieving Excellence in Pharmaceutical Care – a Strategy for Scotland'* (Scottish Government 2017c). Adopting a person-centred approach to improving the quality of care and achieving better health outcomes, in particular for people with multiple and complex long term conditions, is a key focus. Within the strategy, a specific commitment was made to support patients who are resident in care home settings or who require support from care workers and involve their carers, family or care workers in key decisions.

1.2.8 Health Needs of People with LD

People with LD are known to have increased medical needs and a higher incidence of: visual impairment; hearing impairment; epilepsy; dementia; psychiatric disorders; cardiovascular disease; gastro-intestinal problems; major physical disabilities of mobility; faecal and urinary incontinence; and obesity (Bhaumik *et al* 2015; O'Dwyer, Mestrovic and Henman 2015; Paton *et al* 2011; Van-Schrojenstein, Lantman-De Valk and Walsh 2008; Peate and Fearns 2006; Munk and Repp 1994). Garvey and Vincent (2006) highlight that people with LD are 58 times more likely to die before 50 years of age and are 2.5 times more likely to have a condition requiring medical attention than people without LD. Furthermore, people with LD encounter all the major life threatening diseases 5-10 years earlier than the rest of the population (Scottish Government 2013). Baxter *et al* (2006 p.95) also highlight that even minor health issues, *'may be more significant for these people than the general population because of their impact on already limited social, communicative, and practical abilities.'*

Swallowing difficulties (dysphagia, difficulties in chewing and swallowing, difficulties in maintaining a safe posture for eating and drinking) are often prevalent in people with severe LD and insertion of either a nasogastric (NG) tube or a percutaneous endoscopy gastrostomy (PEG) tube for feeding and medicine administration is often required (Bhaumik *et al* 2015; Shah 2008).

Although it is known that people with LD have increased health needs, the Royal College of General Practitioners (2010) highlight the potential for diagnostic overshadowing as a result of attributing symptoms to the overall LD condition. Furthermore, people with LD can often have difficulty in

relating illness to dysfunction in their body, recognising relevant signs and symptoms, or communicating these to a HCP (Davis *et al* 2016; Van Schrojenstein Lantman-De Valk and Walsh 2008; Straetmans *et al* 2007). Another key issue to note is that any person with severe LD relies completely on their carers to communicate and advocate their health needs (Scottish Government 2013).

1.2.9 Care Provision, Carers and Care Workers

In Scotland, Local Authorities (LAs) and the NHS are the two public bodies primarily responsible for providing formal services to adults with LD (Scottish Government 2013). Whilst the NHS is responsible for providing an appropriate health care service, the LA is responsible for assessing the need for social care services. If social care support is then required, the LA will either commission the provision of that service or provide a direct payment to the adult or their carer in order for them to commission their preferred services (Social Care (Self-directed Support) (Scotland) Act 2013). Whilst LAs may also provide the commissioned support to some adults with LD, care is often delivered by private care providers and third sector organisations such as community groups, voluntary organisations, charities, social enterprises, and co-operatives (Scottish Government 2017d; Scottish Government 2017e).

People who are employed by the LA, care providers or third sector organisations to provide care and support are referred to as care workers (Scottish Government 2010). However, much of the care provided to adults with LD, is provided by unpaid carers. The Scottish Government (2010) estimated that 7,793 adults with LD and autism known to LAs in Scotland lived with a carer. In their 'Caring Together' strategy, the Scottish Government (2010 p16) notes that, '*a range of terms is used to describe a person who cares for another including: "unpaid carer", "carer", "family carer", and "informal carer" …It is important that carers are not confused with paid workers, who are sometimes incorrectly called carers too; paid workers are care workers'.* Whilst this distinction is clear to those who work in the care sector it is not as clear to HCPs and the general public, and it is common to hear both groups referred to collectively as 'carers'. Within this thesis every attempt will be made to refer to both carers and care workers and differentiate between them where appropriate.

Locally, the Aberdeen Care Provider forum, previously known as Care And Support Providers Aberdeen (CASPA), is linked with Aberdeen Council of Voluntary Organisations (ACVO), a third sector interface organisation (ACVO 2018). This forum includes LD care providers and LD charities, all of

whom support community dwelling adults with LD in the local area where this research was undertaken.

1.3 MEDICINES, MEDICATION and POLYPHARMACY

In the UK, the 2012 Human Medicines Regulations use the term ‘medicinal product’ to define: (a) any substance or combination of substances presented as having properties of preventing or treating disease in human beings; or (b) any substance or combination of substances that may be used by or administered to human beings with a view to restoring, correcting or modifying a physiological function by exerting a pharmacological, immunological or metabolic action, or making a medical diagnosis (The Human Medicines Regulations 2012).

However, the term ‘medicinal product’ is rarely used by HCPs or patients; instead the terms medicine or medication are used. The Oxford English dictionary defines medicine as, *‘a drug or other preparation for the treatment or prevention of disease’*, and medication as, *‘a drug or other form of medicine that is used to treat or prevent disease’* (English Oxford Living Dictionary 2018a; English Oxford Living Dictionary 2018b). Whilst it can be argued that there is a distinction between the terms, the two will be used interchangeably within this thesis to refer to substances that are legally defined as ‘medicinal products’.

According to the National Institute for health and Care Excellence (NICE), medicines are the most common intervention in healthcare and are used to prevent, treat or manage many medical conditions (National Institute for Health and Care Excellence 2015b). Within Scotland, 103.4 million prescription items were dispensed in primary care between April 2016 and March 2017 at a gross ingredient cost of £1.3 billion (National Services Scotland Information Services Division 2017). Guthrie *et al* (2012) noted that in Scotland the number of people prescribed multiple medicines is growing year on year. They calculated that in 1995, 12% of patients were prescribed 5 or more drugs and 1.9% were prescribed 10 or more drugs and that by 2010 these figures had risen to 22% patients being prescribed 5 or more drugs and 5.8% bring prescribed 10 or more drugs. The term used to define this phenomena of multiple medicine use is ‘polypharmacy’ and within Scotland this is understood to refer to patients who take five or more medicines (Scottish Government Model of Care Polypharmacy Working Group 2015). However, as noted by Duerden, Avery and Payne (2013), there is a distinction between appropriate polypharmacy (when medicines use has been optimised and prescribed according to best evidence) and problematic polypharmacy (when the use of multiple medications is inappropriate, or where the intended benefit of the medication is not

realised). In addition, Straetmans *et al* (2007) noted that people with LD are prescribed more medication than the general population due to their increased health needs.

1.4 LITERATURE REVIEW

1.4.1 Aim

To provide an overview, in the form of a narrative review, of the current literature relating to people with LD and their experience of medication and/or pharmaceutical care. As such, the included studies have not been critically appraised. However, key limitations of each study have been noted in Table 1.2.

1.4.2 Process

Several electronic databases were searched for articles relating to LD and medication administration, or LD and pharmaceutical care, including: Medline (medicines, pharmacy, and biomedical and forensic sciences); Cumulative Index of Nursing and Allied Health Literature (nursing and allied health care professionals); and International Pharmacy Abstracts (pharmaceutical sciences). Articles had to be readily available, written in English and published in an academic journal. No time restriction was placed on the articles. These searches were set up to run on a monthly alert basis throughout the time of the research project to highlight new journal articles. Relevant papers from these ongoing searches and other relevant papers identified from included article reference lists were also incorporated into the review. Associated terms were used for LD, medication and pharmaceutical care which are summarised in Table 1.1. American spellings were also included.

Table 1.1 Summary of search terms

Key Term	Terms Used in Search
Learning Disability	Learning disabilit*, difficult*, impairment Intellectual disabilit*, difficult*, impairment Developmental disabilit*, difficult*, impairment Mental retard*
Medication Administration	Med* organisation, adherence, compliance, optimisation Drug organisation, adherence, compliance, optimisation Prescription organisation, adherence, compliance, optimisation
Pharmaceutical Care	Pharma*

1.4.3 Results of Literature Searches

Searching for LD and medication administration terms in July 2015 initially yielded 58 results. Furthermore, searching for LD and pharmaceutical care terms in July 2015 initially yielded 272 results. A total of 330 potential studies were therefore initially identified in the electronic databases. However, 17 of these were duplicates and 264 were found to not be relevant to the topic of people with LD and medication. Furthermore, 25 articles were not available from the RGU library and 1 was

only available as an abstract. This provided a total of 23 studies for initial review. Over the course of the research, a further 6 papers were identified from the searches and incorporated into the literature review and a summary of these 29 papers can be found in Table 1.2. Other relevant papers identified from the article reference lists were also incorporated into the narrative review.

Table 1.2 Summary of papers included in the literature review

Section 1: LD & General Medication						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
TOBI, H., SCHEERS, T., NETJES, K.A., MULDER, E.J., DE BILDT, A. and MINDERAA, R.B., 2005	Netherlands	To investigate the chronic drug utilisation in children with 'mental retardation'	N=912 Children (4-18y) with 'mental retardation' attending a school for people with LD (or known to LD services)	Comprehensive structured interview with parents/caregiver – no medical records accessed	• ~22% used regular medication • 47% used two or more drugs • 9.6% used an antipsychotic • Prevalence of drug use increased with severity of mental retardation from about 17% to 49% *(exception was the 6% of children with borderline LD- medication prevalence was 27%)*	Dependence on carers providing accurate information; only regular medicines included; exclusion of children with LD who did not attend specialist LD schools
ZAAL, R.J., VAN DER KAAIJ, A.D., EVENHUIS, H.M. and VAN DEN BEMT, P.M., 2013	Netherlands	To determine the prevalence of older individuals with LD with at least one prescription error and identify potential risk factors for these prescription errors	N=600 Older (≥50 years) people with LD using one or more drugs (randomly selected from the study cohort of another study)	Cross-sectional study; screening of medication for errors using consensus methodology; use of multivariate logistic regression to identify potential risk factors	• 47.5% had prescription errors • 26.8% of these errors required a change of therapy • Age, level of LD, BMI, and frailty index are potential risk factors for errors • Polypharmacy and drugs for the nervous system are also associated with errors	Instances when clinicians made an informed decision to continue with therapy despite an 'error' were not taken into account
HAIDER, S.I., ANSARI, Z., VAUGHAN, L., MATTERS, H. and EMERSON, E., 2014	Australia	To analyse the prevalence of polypharmacy (5 or more medicines) and to evaluate the role of different factors associated with polypharmacy	N=897 Adults with LD living in the community in Victoria, Australia	Telephone questionnaire with proxy of person with LD	• 76% of adults with LD used prescribed medicine • ~21% were exposed to polypharmacy in the last two weeks • Polypharmacy was significantly associated with older age, unemployment and inability to	All information is self-reported; no mention of literacy issues in recruitment; those with mild LD and no carer could not participate; whether the polypharmacy was

					get help from family and friends	appropriate or not was not determined
FISH, R., HATTON, C. and CHAUHAN, U., 2017	UK	To ask people with LD how they felt about the information they got with their medicines	N=58 Adults with LD (self-advocates) attending a self advocacy conference in the north of England, UK	Written questionnaire (easy-read) – option of carer assistance to complete	• 55% people received helpful info from health care professionals about their medicines; 29% people did not receive helpful information • Frequent themes: information not accessible; only given basic information; information only given to carer	Not representative of general LD population; may have excluded those with lower health literacy
Section 2: LD & Antipsychotic Medication						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
LOTT, I.T., MCGREGOR, M., ENGELMAN, L., TOUCHETTE, P., TOURNAY, A., SANDMAN, C., FERNANDEZ, G., PLON, L. and WALSH, D., 2004	USA	To describe the longitudinal prescribing practices for psychoactive medications	N=2344 People with LD and DD (resident in community settings)	Descriptive study; computerised pharmacy records were accessed and reviewed over 17 months	• 52% of all prescriptions were for psychoactive medications • 62% were given prescriptions for more than one psychoactive medication; 36% received three or more	No comparison to the general population; 'psychoactive' includes antiepileptic medication and antidepressants as well as antipsychotics

PATON, C., FLYNN, A., SHINGLETON-SMITH, A., MCINTYRE, S., BHAUMIK, S., RASMUSSEN, J., HARDY, S. and BARNES, T., 2011	UK	To determine if people with LD prescribed an antipsychotic had: the indication noted; the need for the antipsychotic reviewed annually; and side-effects checked for annually	N=2319 Person with LD under the care of an LD consultant and prescribed an antipsychotic	Data collection from the clinical records of individuals with LD	• Indication in notes – 95% • Annual review done – 96% • Annual review inclusion of check for side-effects – 69%	Not a true audit as standards did not include a stated target (only the criteria)
DOAN, T., WARE, R., MCPHERSON, L., DOOREN, K., BAIN, C., CARRINGTON, S., EINFELD, S., TONGE, B. and LENNOX, N., 2014	Australia	To investigate prevalence of, and factors associated with, psychotropic medication	N=176 Adolescents (11-19y) with LD living in the community & attending a special LD school or LD unit	Cross-sectional, self-reported information	• 20% taking psychotropics • 9% taking psychostimulants • Male gender and major behaviour problems are associated with use of psychotropic medication	Medication use was self-reported (recall bias); possibility that incorrect indication was attributed by researcher
MURRAY, M.L., HSIA, Y., GLASER, K., SIMONOFF, E., MURPHY, D.G., ASHERSON, P.J., EKLUND, H. and WONG, I.C., 2014	UK	To investigate the incidence and prevalence of psychotropic medication prescribing and neuropsychiatric related co-morbidities of <25s with autism spectrum disorder (ASD) diagnoses	N= 561 People <25 years with ASD	A descriptive cohort study	• 9.7% prescribed hypnotics; 7.9% psychostimulants; 7.3% antipsychotics • 12.6% of the cohort had LD and/or DD	Not all people with ASD have LD and not all people with LD have ASD; completeness of data set being used; measures prescription and not compliance
SALDANA, S.N., KEESHIN, B.R., WEHRY, A.M., BLOM, T.J., SORTER, M.T., DELBELLO, M.P. and STRAWN, J.R., 2014	USA	To identify demographic and/or clinical predictors of antipsychotic prescribing in psychiatrically hospitalised children and adolescents	N= 1427 Children and adolescents discharged from an urban psychiatric service in a hospital over 9 months (not all had LD)	Retrospective review of medical records; sub-analysis to determine predictors of antipsychotic	A diagnosis of LD was predictive of antipsychotic prescribing at discharge; for 56% of the admission for people with LD was due to significant violence and aggression	Only 4% participants had LD so sub-analysis potentially limited; lack of information in medical records

Section 3: LD and Practical Challenges to Administration						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
SHAH, T., TSE, A.P.Y., GILL, H., WONG, I.C.K., SUTCLIFFE, A., GRINGRAS, P., APPLETON, R. and TULEU, C., 2008	UK	To assess the compatibility and short-term stability of melatonin capsules mixed in various foods and liquids	n/a	Measurement of melatonin concentration (mcg/ml) over a 6 hour time period	Melatonin mixed in either water, orange juice, semi-skimmed milk, strawberry yoghurt, and strawberry jam is stable for up to 6 hours	Only applicable to melatonin and those food substances listed
BUELOW, J.M. and SHORE, C.P., 2010	USA	To describe some of the factors associated with LD and epilepsy; to address the management challenges associated with these diagnoses	Children with LD and epilepsy	Description of challenges from personal experience	Parental concerns: • Children cannot describe precisely how the medicines affect them • Difficulty in differentiating the cognitive adverse drug reactions from the actual anti-epilpetic drug (AED) itself • the need to develop strategies to manage and remember to give medicines • interactions with health care professionals can be stressful	Practical and insightful information but limited evidence base for statements
HUNEKE, N.T., GUPTA, R., HALDER, N. and CHAUDRY, N., 2012	UK	To audit current practice concerning consent to treatment in patients with LD	N=45	Questionnaire (easy-read format) sent to person and completed with the help of a carer.	Overall, the patients' knowledge of their medications was poor; doctors are providing information but delivery needs to be improved, and patients' understanding and recall need to be checked more thoroughly	Not a true audit as standards did not include a stated target (only the criteria); results filtered through the carer-acquiescence?
EPITROPAKIS, C. and DIPIETRO, E.A., 2015	USA	Design and implementation of a medication compliance protocol for paediatric patients with severe LD	N=6 Paediatric patients with severe LD in a neurobehavioural unit	Implementation of medication compliance protocol based on applied	Medication administration success rate of 83.3% after 4 weeks with the compliance protocol	Small study; hard to follow the intervention details; no before and after so claim of success

				behavioural analysis framework		is unverifiable; few references to literature
FLOOD, B. and HENMAN, M.C., 2015	Ireland	Case report – to provide insight into the difficulties of insulin administration and diabetes self-management for a man with mild LD	N=1 Person with LD & diabetes	Case report– but used a grounded theory approach to review the data	Details of the medicine challenges faced	No results section; very little info from the actual case study – more in intro and discussion; unsure of how grounded theory was actually used in the approach
DAVIS, S.R., DURVASULA, S., MERHI, D., YOUNG, P.M., TRAINI, D. and ANTICEVICH, S.Z.B., 2016	Australia	To explore the level of understanding of people with LD in relation to their asthma medication	N=17 People with mild LD who self-administer their asthma medicines	Face-to-face interviews	Level of autonomy for medication use varied, with motivation to self-manage asthma influenced by the level of support that was practically available to individual participants	Specific to asthma management; small numbers; limited to those who self-managed and were able to participate in an interview
Section 4: Family or Carer Effect on Medication						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
RASARATNAM, R., CROUCH, K. and REGAN, A., 2004	UK	To investigate the influence of attitudes of carers of people with LD towards giving medication	N=93 Carers of people with LD (where the person with LD attends an outpatient clinic)	Interview using the Rating of Attitude to Medication Scale interview schedule	A disproportionate number of parents express a negative attitude in comparison with professional carers (46% vs. 11%)	Many people with mild LD do not attend an LD outpatient clinic – so exclusion of this group in the study
VAN DEN BEMT, P.M., ROBERTZ, R., DE JONG, A.L., VAN ROON, E.N. and LEUFKENS, H.G.M., 2007	Netherlands	To identify the frequency of drug administration errors and determinants for these errors in an institutional setting	N=46 Children and adults with LD, resident in institutional setting	Prospective, disguised, observational study with a case control design for identifying determinants for errors; each resident observed for 2 weeks	• 953 drug administrations observed • 25% administrations had least one error • Determinants associated with errors were: 'oral by feeding tube' and 'inhalation'; the units 'adult full-time care' and	Short study period for each person; observations made during weekdays and only during the day; potential for participants to have modified their

					'children daytime care'; and the absence of a distribution robot	behaviour knowing that they were being watched
ERICKSON, S.R. and LEROY, B., 2015	USA	To measure health literacy (HL) of caregivers of adults with LD; to determine the association between HL and a medication administration task (MAT) assessment; to identify caregiver characteristics associated with higher HL and MAT scores	N=47 Adult caregivers of people with LD	Cross-sectional study	The lower the HL, the lower the medication administration ability; higher education was associated with greater HL	Small sample and potential selection bias; sub-analysis on very small numbers; potential lack of instrument sensitivity
HOM, C.L., TOUCHETTE, P., NGUYEN, V., FERNANDEZ, G., TOURNAY, A., PLON, L., HIMBER, P. and LOTT, I.T., 2015	USA	To determine factors affecting non-adherence with antiepileptic drugs (AED) medication in people with LD and epilepsy	N=793 People with LD and epilepsy who have been prescribed AEDs for >6 months.	Retrospective examination of pharmacy records; calculation of medication possession ratio	Compared with those living in group homes, individuals with LD living in family homes or in semi-independent settings were significantly less adherent to AEDs ($p < 0.0003$)	Did not note that measuring adherence through prescriptions ordered may not be the same as medicines actually taken
JOOS, E., MEHUYS, E., VAN BOCXLAER, J., REMON, J.P., VAN WINCKEL, M. and BOUSSERY, K., 2015	Belgium	To collect direct observational data on drug administration practices to residents with LD and enteral feeding tube (EFT)	N=48 People with LD living in a residential care facilities (RCF)	Cross-sectional observational study of 862 drug preparations and 268 administrations in 48 residents with EFT	Deviations from medication preparation and medication administration guidance were observed	Deviations not graded with respect to harm; potential for participants to have modified their behaviour knowing that they were being watched; observations limited to daytime weekdays
JOOS, E., MEHUYS, E., VAN BOCXLAER, J., REMON, J.P., VAN WINCKEL, M. and BOUSSERY, K., 2016	Belgium	To investigate knowledge of EFT guidelines among staff of RCF for people with LD	N=356 Formal carers of people with LD living in RCF	Self-administered questionnaire	Mean self-perceived knowledge of medication administration via EFT was 6.7 (on a 0–10 scale); on average, 5.7 (SD 1.9) of 13 questions were answered correctly; identification of a substantial lack of guideline knowledge	Self selection of respondents (potential selection bias); questionnaire not formally validated

Section 5: Pharmacist Input to Care of People with LD						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
BROWN, R.O., DICKERSON, R.N., HAK, E.B., MATTHEWS, J.B. and HAK, L.J., 1997	USA	To assess the impact of a pharmacy service (for enteral feeds) on patient body weight	N=24 Non-ambulatory patients (children and adults) with severe LD receiving long term enteral feeding	Review of the impact of pharmacist led interventions (educational and clinical); comparison to a control group	Month 4: body weight had increased from 101 ± 6% of baseline to 109 ± 7% ($p<0.05$). Month 7: body weight had increased to 116 ± 12% of baseline ($p<0.0001$).	Small sample; unmatched groups; extreme dosages; all weight gain was fat; weight gain not linked to improved outcome
BRAHM, N.C. and BROWN, R.C., 2004	USA	Description of a pharmacist-based consulting service for the developmentally disabled	n/a	n/a	A pharmacist-based drug therapy consulting program provides valuable services to clinicians and patients.	Lack of objective measurement; limited transferability
BELL, J.S., KIRKPATRICK, C.M. and ALDERMAN, C.P., 2015	n/a	n/a – editorial comment on paper by O'Dwyer, Meštrović, and Henman (2015)	n/a	n/a	*'There is an urgent need for the pharmacy profession to develop a research agenda to promote the quality use of medications in vulnerable patient groups.'*	Editorial comment only
O'DWYER, M., MEŠTROVIĆ, A. and HENMAN, M., 2015	n/a	To explore what type of pharmaceutical care interventions were being undertaken for people with LD and how pharmacists' contributed to the care of people with LD as part of multidisciplinary teams	n/a	Narrative review of 8 papers – found from systematic searches of electronic databases	Some limited evidence to suggest benefit of pharmacist input but more research required. *'…little is known about their (people with LD) attitudes to medicines, their interactions with pharmacists and their ability to engage in the health care process in primary care.'* *'There were no studies of patients' or carers' views of pharmacists' contribution to care.'*	Focus was on pharmacist interventions only but no other limitations of note

Section 6: Clinical Issues						
Author(s) and Publication Year	***Country***	***Aim of Study***	***Population***	***Intervention***	***Key Findings***	***Key Limitations Identified by Study and/or Researcher***
BRAHM, N.C., FAST, G.A. and BROWN, R.C., 2008	USA	Case study of a patient with LD and ASD whose behavioral problems were improved with buspirone	N=1 33-year-old, white, nonverbal, profoundly intellectually-impaired woman	Addition of buspirone after discontinuation of: sertraline, aripiprazole, clozapine, risperidone and naltrexone	Described therapy changes led to a reduction in target behaviors of self-injury, property destruction, and physical aggression	No case study methodology referenced; limited transferability
CARPAY, J.A., AALBERS, K., GRAVELAND, G.A. and ENGELSMAN, M., 2009	Netherlands	To assess the long-term usefulness of new AEDs (lamotrigine, topiramate, levetiracetam, gabapentin and pregabalin) in institutionalised patients with LD	N=118 People with LD (resident in institutions) with epilepsy and current/past use of AEDs	Retrospective study using data from the medical files and the pharmacy databases	• The most frequently used new AEDs were lamotrigine (68%) and levetiracetam (58%) • The 3-year retention rate was highest for lamotrigine (70%), and lowest for gabapentin (33%) • Discontinuation due to lack of efficacy was: 61% - topiramate; 60% - lamotrigine; 42% - levetiracetam • Discontinuation due to adverse events was: 42% - levetiracetam; 33% - topiramate; 28% - lamotrigine	Retrospective, open, non-randomised design makes definite attribution of the effect or side-effect to the drug and comparison between AEDs impossible
FERGUSON, L. and MURPHY, G.H., 2014	UK	To investigate the capacity of individuals with LD to make decisions about their medications, and to evaluate whether the provision of training (information) sessions on medications would increase their capacity	N=28 Adults with mild-moderate LD on regular Epilim (valproate), metformin or haloperidol.	Evaluation of three training sessions (using validated tools)	Training had improved the capacity of the participants to give informed consent to taking their medications; increased levels of receptive language ability correlated with greater ability to give informed consent to taking medication	Small numbers; no control; not blinded for assessors

ERICKSON, S.R. and KORNEXL, K., 2016	USA	To characterise and compare the screening, treatment, and control of BP in patients with DD to patients without DD	N=183 Adults with DD living in a community setting	Retrospective cross-sectional study from existing database	Both groups had similar outcomes for hypertension therapy; those with uncontrolled BP in the DD group tended to have higher systolic BP; significantly more DD patients had a history of stroke	Groups not equal with respect to gender; sub-analysis with respect to type of DD not possible

1.4.4 Analysis

In their recent literature review on a similar subject, '*Pharmacists' medicines-related interventions for people with intellectual disabilities: a narrative review',* O'Dwyer, Mestrovic and Henman (2015) noted that a systematic review was precluded because of the heterogeneity of published studies. A scoping review of the 29 papers identified in this review against Critical Appraisal Skills Programme (CASP) checklists resulted in a similar conclusion (CASP UK 2016). As shown in Table 1.2, each paper was reviewed by considering the population, the intervention, the outcome and the key limitations. Six main themes within the literature were then identified by the researcher: general medication issues; antipsychotic medication; practical challenges to medication administration and management; carer and care worker issues; and general clinical issues. A narrative review of the literature was then undertaken to provide a foundation for the proposed research.

1.4.5 Narrative Review

General Medication Issues

People with LD are often on medication that was initiated in childhood (Tobi *et al* 2005). It is estimated that people with LD are 27% more likely to be prescribed regular medication than the general population and that people with LD are prescribed four times more regular medicines than the general population (Straetmans *et al* 2007). In their study of community dwelling adults with LD in Australia (n=897), Haider *et al* (2014) estimated that 76% of adults with LD had used prescribed medication and that ~21% off adults with LD in their study were exposed to polypharmacy (5 or more medicines) in the last two weeks. This contrasts to a similar sized study by O'Dwyer *et al* (2016) where it was estimated that 53.7% of Irish adults with LD (aged 40 years and over) were exposed to polypharmacy (five or more medicines). Both these figures can be contrasted again with a study conducted in Scotland by Payne *et al* (2014) which found that 21.6% of the general adult population were receiving four or more medicines and incidence of polypharmacy increased with age (36% in those aged 60-69 years; 70.4% in those aged ≥ 80 years). It should be noted that none of these studies ascertained if the polypharmacy was inappropriate or appropriate. However, in their study of people ≥50 years with LD who were taking one or more medicines, Zaal *et al* (2013) noted that 47.5% had prescription errors with 26.8% requiring a change of therapy.

In addition to being prescribed more medicines than the general population and experiencing similar, or indeed higher, rates of polypharmacy, Bhaumik *et al* (2015) suggested that compared with the general population, people with LD have: altered sensitivities to drugs; different effects from drugs; different optimum doses; and more adverse drug reactions. This issue was also raised

by Saldana *et al* (2014) in relation to polypharmacy in the LD population and by Hefti and Blanco (2017) in respect to individuals with Down's syndrome.
Fish, Hatton and Chauhan (2017) highlighted that people with LD are often not receiving information about their medicines in a way that they can understand. In addition, the participants highlighted a desire for more direct involvement in consultations, whilst still involving their carer(s).

Antipsychotic Medication

Antipsychotic drugs are licensed for the short term management of severe anxiety or disturbance, and for the long term management of schizophrenia and other psychoses (Joint Formulary Committee 2016). Antipsychotics have often been used in patients with LD to treat challenging behaviour, sometimes in the absence of a diagnosis of psychoses (Bhaumik *et al* 2015; National Institute for Health and Care Excellence 2015a).

However, the prescribing of antipsychotics for challenging behaviour is now a contentious ethical issue due to them being perceived as a 'chemical straitjacket' (Bhaumik *et al* 2015; Public Health England 2015; Department of Health 2012). Best practice now dictates that antipsychotics should only be considered if: psychological or other interventions alone do not produce change within an agreed time; or treatment for any co-existing mental or physical health problem do not lead to a reduction in the behaviour; or the risk to the person or others is very severe (National Institute for Health and Care Excellence 2015a). As a result of this intensified focus on antipsychotics, much of research on people with LD in relation to medication has therefore focused on the use of antipsychotic medication for challenging behaviour (Ferguson and Murphy 2014).

Public Health England (2015), using a database that included 7.8% of the English population, estimated that 16.6% of people with LD in England were being prescribed an antipsychotic between April 2009 and March 2012. Another recent UK study by Sheehan *et al* (2015), noted that the rate of prescription of antipsychotics in people with LD was almost twice that of the general population. They also noted that of the people with LD who had a record of challenging behaviour, 47% had been prescribed antipsychotic medication yet only 12% had a concurrent diagnosis of severe mental illness. Furthermore, in a study of psychiatrically hospitalised children and adolescents in the USA, Saldana *et al* (2014) noted that a diagnosis of LD was actually a predictor of antipsychotic prescribing.

A further two studies also estimated the prevalence of psychoactive (antipsychotics, antidepressants and antiepileptic) medication: Lott *et al* (2004) determined that 52% of people with LD and

developmental delay were prescribed psychoactive medication; Doan *et al* (2014) determined that 20% of adolescents with LD were prescribed psychoactive medication.

Practical Challenges to Medication Administration and Management

Bhaumik *et al* (2015) and Crossley and Withers (2009) noted that people with LD can encounter problems in taking oral medicines for a variety of physical, medical and psychological reasons, some of which are noted below:

- Physical: oral palate malformations, dry mouth, unpleasant taste, and texture of medicines;
- Medical: dysphagia, reflux;
- Psychological: concern over size of tablet and choking, dislike for tablets, reaction to changes in tablet appearance, unwillingness to embrace changes to medicines or the medicine routine.

Often a personalised medicine administration plan is required to maximise the success of medicine administration, as demonstrated by Epitropikas and Dipietro (2015).

Monitoring the side effects of medication is another challenge as patients with LD do not usually volunteer such information due to their communication difficulties, or are only able to express the information in idiosyncratic ways (Bhaumik *et al* 2015; O'Dwyer, Mestrovic and Henman 2015; Stenfert-Kroese, Dewhurst and Holmes 2001). Furthermore, side-effects can be mistaken for challenging behaviour or just a part of the disability (Buelow and Shore 2010; Raghaven and Patel 2010).

Health literacy is defined as, *'the cognitive and social skills which determine the motivation and ability of individuals to gain access to, understand and use information in ways which promote and maintain good health'* (Nutbeam 1998 p.263). It is a known issue for the general population and relevant to the LD population (Ngoh 2009; Schwartzberg *et al* 2007; Davis *et al* 2006). People with LD often have poorer health literacy and so rely on their caregivers, family, respite staff or HCPs for appropriate (and ongoing) support and education, as demonstrated in the studies by Davis *et al* (2006) and Flood and Henman (2015). In one study, lack of medication knowledge resulted in a belief amongst people with milder LD that because their carers knew more about their medicines than they did, then their carers should make all the decisions on their behalf (Crossley and Withers 2009). In addition, for people with milder LD, problems with memory and understanding of time were highlighted as having the potential to adversely affect their ability to independently manage their medication (Bond and Hurst 2010; Arscott, Stenfert Kroese and Daganan 2000).

Williams and Evans (2013) raised the interesting point that society has a tendency to overprotect people with LD even though this has the potential to damage their development, self-esteem and community participation. They noted that, *'…it will be an even greater safeguard of the person's welfare if they can learn to practise safety themselves, and to learn this there must be some exposure to the hazards' (*Williams and Evans 2013 p.91). Whilst written generally, it is applicable to the area of medicine administration and management for people with milder LD.

Carer and Care Worker Issues

Support with medication administration and decision-making is often necessary for people with LD (Hom *et al* 2015; Ferguson and Murphy 2014; Haider *et al* 2014; Rasaratnam, Couch and Regan 2004). However, as highlighted by Christian *et al* (1999), the skills, knowledge and decision-making ability of the caregiver is then crucial. Donley, Chan and Webber (2012) also noted that care workers, who often have limited training and qualifications, are expected to be able to interpret and communicate the complex needs of the person with LD that they are supporting.

Van der Bemt *et al* (2007) noted that 25% of all drug administrations in an institution for people with LD were associated with at least one error. Joos *et al* (2015) observed deviations from medication preparation and medication administration guidance by care workers administering medicines via PEG tubes for people with LD in a residential facility. In a later study they identified a substantial lack of guideline knowledge amongst staff with regards to administration of medicines via a PEG tube (Joos *et al* 2016).

Rasaratnam, Couch and Regan (2004) found that parents were more likely than care workers to express a negative attitude towards medication. In addition, carers and care workers highlighted that communication with HCPs was often stressful, they often felt excluded from decision-making, and that concerns were often ignored (Redley *et al* 2013; Buelow *et al* 2006). This issue was summarised succinctly by Keywood and Flynn (2006 p. 360), *'People with learning disabilities frequently experience unnoticed deteriorating health and suffering, they report considerable difficulty in gaining access to health services and are frequently reliant on relatives and support staff who have little option but to become battle-weary health advocates.'*

Pharmacist Input to Care

In their narrative literature, O'Dwyer, Mestrovic and Henman (2015) concluded that there was limited available evidence to suggest the benefit of pharmacist input within the care of people with LD and therefore more research was required. This echoed the conclusion of Davis (2014) who concluded there was a lack of published evidence to support pharmacist-led medication reviews for people with LD living in the community. Flood and Henman (2015 p.235) commented that people with LD, *'…are a complex group of patients who may be "invisible" to pharmacists. Pharmacists may have little knowledge or experience of the challenges faced by this group...'.* Blasi, Kendall and Spark (2006) cited that a lack of inter-professional collaboration may also inhibit the input of pharmacists in the care of people with LD.

General Clinical Issues

Bhaumik *et al* (2015) noted the challenges doctors often face in diagnosing psychiatric and behavioural problems in people with LD (due to different presentations and communication difficulties) and the feeling of vulnerability when prescribing an antipsychotic for the unlicensed indication of challenging behaviour.

Van Schrojenstein Lantman-De Valk and Walsh (2008) noted the problem of unrecognised and untreated physical and mental health problems for people with LD. This was quantified in a study by Baxter *et al* (2006) who found that 51% of people with LD included in their study had new needs recognised during a pro-active health check. Baxter *et al* (2006) also highlighted that because of their already impaired social, communicative, and practical abilities, even relatively minor conditions such as blocked ear wax or vision difficulties had a significant impact on quality of life for a person with LD.

O'Dwyer, Mestrovic and Henman (2015) also noted that little is actually known about people with LD's attitudes towards their medication. Furthermore, ascertaining the real level of capacity and understanding, and being assured of truly shared decision-making is a challenge for all HCPs and prescribers when caring for people with mild to moderate LD (Ferguson and Murphy 2014; Stenfert Kroese, Dewhurst and Holmes 2001; Arscott, Stenfert Kroese and Dagnan 2000).

1.4.6 Summary of the Narrative Literature Review

In summary, the published literature relating to people with LD and their experience of medication and pharmaceutical care noted that people with LD:

- are prescribed more medicines and experience more polypharmacy than the general population;
- are more likely to be prescribed antipsychotic medicines than the general population;
- have poorer health literacy than the general population;
- are more vulnerable to experiencing clinical and practical problems with their medication;
- experience more challenges in communicating their views on medication;
- may have sub-optimal medicine regimens;
- often rely on carers to support them with their medication.

In addition, the literature notes how medication related pressures and challenges are transferred to the carers of people with LD or their HCPs. Only two identified studies explored the views of people with LD in relation to medication (Bond and Hurst 2010; Crossley and Withers 2009); a further two studies explored their level of understanding about their medication (Davis *et al* 2006; Arscott, Stenfert Kroese and Dagnan 2000). Four studies explored the views of carers of people with LD in relation to medication (Redley *et al* 2013; Donley, Chan and Webber 2012; Buelow *et al* 2006; Rasaratnam, Crouch and Regan 2004).

1.4.7 Gaps in the Literature and Reason for this Research

The Scottish Government's Realising Realistic Medicine (Scottish Government 2017b), Achieving Excellence in Pharmaceutical Care – a Strategy for Scotland (Scottish Government 2017c), and Keys to Life (Scottish Government 2013) policy documents all ask HCPs to provide care in more meaningful and personalised ways. In order to do this, HCPs require an increased understanding of the reality for patients in incorporating medication into their lives (Mohammed, Moles and Chen 2016; O'Dwyer Mestrovic and Henman 2015). Despite people with LD experiencing more polypharmacy and medication related problems (O'Dwyer *et al* 2016; Bhaumik *et al* 2015; Haider *et al* 2014; Zaal *et al* 2013; Straetmans *et al* 2007), the majority of studies from the literature review focused on quantifying drug related issues, not understanding the experiences of the person with LD in relation to medication. In order for both prescribers and pharmacists to provide tailored and meaningful support to people with LD in relation to medication, and thereby improve patient care, a greater understanding of the experiences of medication of people with learning disabilities is required (Bell, Kirkpatrick and Alderman 2015; Flood and Henman 2015; Hollins and Tuffrey-Wijne 2013). The results of this review echo the conclusion of the narrative review, '*Pharmacists*'

medicines-related interventions for people with intellectual disabilities: a narrative review', by O'Dwyer Mestrovic and Henman (2015).

1.5 RESEARCH AIM AND OBJECTIVES

1.5.1 Aim

The purpose of this study is to explore and describe the medication related experiences of community dwelling adults with LD.

1.5.2 Objectives

1. To explore and describe the medication related burden experienced by adults with LD;
2. To explore and describe the medication related beliefs of adults with LD;
3. To explore and describe the medication taking practice of adults with LD.

1.6 CHAPTER SUMMARY

This chapter provided an introduction to the thesis. First of all, the concept of learning disabilities (LD) was explored through describing the current definitions and classification of LD; citing the estimated prevalence of LD; and outlining the models for understanding LD. Current UK and Scottish policies relating to LD were described as well as the recognised health needs of people with LD. A brief summary of social care provision, the role of carers and care workers and of medication and polypharmacy within Scotland was provided. Following on from this, the current evidence within the literature relating to adults with LD and medication was presented in six themed sections: general medication; antipsychotic medication; practical challenges to medication administration and management; carers, care workers and medication; pharmacist input to care; and clinical issues. Gaps within the literature were then noted and discussed. Finally, the aim and objectives of the research were stated.

CHAPTER 2: METHODOLOGY, RESEARCH GOVERNANCE AND STUDY DESIGN

'For us truth is always partial, fragmentary, the view from somewhere and not, as philosophers sometimes say, "the view from nowhere".'

The View from Nowhere - Thomas Nagel

2.1 CHAPTER INTRODUCTION

First of all, this chapter provides a brief outline of research worldviews; epistemology, ontology, axiology and methodology within these worldviews; and the most common methodological approaches. A general overview of qualitative methodology and then a more specific overview of case study methodology will then be provided. Strategies for qualitative data collection, data analysis and for promoting trustworthiness, reflexivity and transferability throughout the research process are then evidenced. Then, this chapter will consider both the general then the specific research governance requirements when involving adults with incapacity in research. Issues of pertinent legislation, informed consent, inclusion, literacy, health literacy, involvement of significant others, capability and establishing relational boundaries will be discussed. Legislation surrounding the storage of data will also be outlined. Following on from this overview of theory and legislation, this chapter will outline how this theory has been applied within the design of this study and outline how this study has sought to adhere to the various methodological and research governance requirements.

2.2 RESEARCH WORLDVIEWS

Underpinning all research is the belief and approach of the researcher which is referred to in various, and often interchangeable, terms: worldview (Creswell 2014); paradigm (Bowling 2014; Denzin and Lincoln 2013; Kuhn 2012; Lincoln and Guba 1985); philosophical assumptions (Creswell 2013; Creswell and Clark 2011); interpretive framework (Creswell 2013). Creswell (2014 p.6) describes a worldview as, *'…a general philosophical orientation about the world and the nature of research that a researcher brings to a study*'. Many worldviews have been defined (Denzin and Lincoln 2013), and Creswell (2013) notes that the number is ever expanding. However, Creswell (2013) cites post-positivism, constructivism, the transformative framework and pragmatism as being the four most commonly used within health and social sciences:

- Post-positivism, also known as the scientific or traditional quantitative approach, is deterministic and reduces ideas to variables that can be tested; knowledge is developed through careful observation and measurement and laws, theories or hypotheses are tested and verified.
- Constructivism, also known as the qualitative approach, seeks an understanding of the lived world and looks for complexity of participants' views; meanings are negotiated historically and socially and a theory (or pattern of meaning from the data) is generated.

- The transformative framework is intertwined with politics and addresses issues of power and justice; the researcher(s) work with participants at all stages of the research and ultimately seek to make a change that benefits the group being researched.
- Pragmatism is orientated to the 'real world' and will use quantitative or qualitative or mixed (quantitative and qualitative) methods, as required and focuses on finding solutions to problems.

2.3 ONTOLOGY, EPISTEMOLOGY, AXIOLOGY and METHODOLOGY

However, worldviews are better described in terms of their ontology (the nature of reality); their epistemology (what counts as knowledge and how knowledge claims are justified); their axiology (the role of values in research); and their methodology (the process of research), (Creswell 2014; Creswell 2013). A summary of the four common worldviews found within health and social sciences (taken and adapted from Creswell 2013, and Creswell and Clark 2011) can be found in Table 2.1.

Table 2.1 Four common worldviews within health and social sciences

	Post-Positivism	Constructivism	Transformative	Pragmatism
Epistemology	Objective; approximation of reality through research and statistics; minimal interaction with participants	Subjective evidence from participants; enters world of researched; co-constructs reality with participants	Multiple ways of knowing reality; collaboration	Gather data in the way that best answers the question(s)
Ontology	Single reality; reject or fail to reject a hypothesis	Multiple realities constructed through lived experiences	Political reality; negotiated with participants	Single and multiple realities
Axiology	Researcher bias must be minmised (if not eliminated) and controlled	Biased; researcher is open about their bias	Biases are negotiated with participants	Uses multiple stances (biased and unbiased)
Methodology	Quantitative, deductive logic; testing of theory	Qualitative, inductive logic; emergent theory	Emphasis on collaboration, participating politically, questioning of methods, highlighting of concerns and issues	Mixed qualitative and/or quantitative approaches in data collection and analysis

2.4 METHODOLOGICAL APPROACHES

There are three main methodological approaches within research: quantitative, qualitative and a combination of both quantitative and qualitative known as mixed methods.

2.4.1 Quantitative

Quantitative approaches seek to explain the relationship between variables or predict the results of related variables following from *a priori* theory (Bowling 2014; Creswell and Clark 2011). The predicted relationship is then presented as a hypothesis (null or directional) which the research proceeds to test through experimental designs (randomised controlled trials or quasi-experiments) or through non-experimental designs (surveys - cross-sectional or longitudinal), (Creswell 2014). It is reductionist, logical and empirical and the numerical data is analysed using appropriate statistical procedures (Creswell 2014).

2.4.2 Qualitative

In contrast, qualitative research focuses on exploring phenomena in their natural setting and seeking to understand the meanings that people attribute to their world (Creswell 2013; Denzin and Lincoln 2013). In doing so, the researcher explores and gains detailed understanding of the experiences or meanings of an individual or a particular group (Bowling 2014; Ritchie and Lewis 2003). Lincoln and Guba (1985) note that the natural setting is essential because the phenomena of study take their meaning not just from themselves but from their context. Giangreco and Taylor (2003 p.135) state that, *'Qualitative methods are ideally suited to providing an understanding of context and a detailed description of how practices actually work'.* Rather than approaching the topic with a theory, qualitative research seeks to generate or develop a theory through interpreting the meaning(s) that others have of the world (Creswell 2013; Ritchie and Lewis 2003). Interestingly, Creswell (2013) notes that researchers can actually approach qualitative methodology through a post-positivist interpretive framework and view qualitative inquiry as a series of logically related steps, adhere to rigorous methods of data collection and analysis, and present findings in a structure similar to quantitative studies.

Within a qualitative approach there are many methodologies that can be employed and Creswell (2014) highlights the following as the most common in health and social sciences: narrative (describing the experiences of individuals through story); phenomenology (describing the common meaning of a concept or phenomenon through the lived experience for a group of people); grounded theory (building a theory from the constant comparison, in depth repeat interviewing,

coding and analysis of layers of observational data); ethnography (describing the shared culture of a group through long term observation and conversation); and case study (providing in-depth understanding of a single unit or entity such as a person, process, organisation).

2.4.3 Mixed Methods

A mixed methods approach employs both quantitative and qualitative approaches in the research process and would be considered appropriate when either: one data source is insufficient; results require explanation; exploratory finding require generalisation; the study requires enhancement with a second method; a particular theoretical stance is required; and/or multiple phases or projects would best address the research questions (Creswell and Clark 2011). Creswell and Clark (2011) continue to detail six recognised mixed methods designs, each of which detail the approach (qualitative and/or quantitative) for each phase and then how each phase of data collection and analysis informs the next: convergent parallel, explanatory sequential, exploratory sequential, embedded, transformative, and multiphase.

2.5 CASE STUDIES

Case studies are described by Luck, Jackson and Usher (2006 p.104) as a, '*detailed, intensive study of a particular contextual, and bounded, phenomena that is undertaken in real life situations.'* Yin (2014) notes there are three key aspects to case studies: a clearly defined focus; looking at a phenomenon in depth; and looking at this phenomenon within the real world. According to Thomas (2011), case studies can be classed according to subject, purpose, approach and process as detailed in Table 2.2.

Table 2.2 Case study classification (Thomas 2011)

Subject	Purpose	Approach	Process
Special (or outlier) Key Local knowledge	Intrinsic Instrumental Evaluative Explanatory Exploratory	Testing a theory Building a theory Illustrative Descriptive Interpretative Experimental	Single *(retrospective, snapshot or diachronic)* Multiple *(nested, parallel or sequential)*

How researchers select their cases will depend on the subject, purpose, approach and process, but as with all research, case selection will be restricted by available resources, including access and time (Yin 2014; Stake 1995). Case study methodology allows the researcher to collate multiple case studies or to merely select one case that is either extreme, critical or paradigmatic (Flyvbjerg 2006). Due to the strong connection with quantitative methodology, both Yin (2014) and Thomas (2011)

advise that case study researchers avoid using the term 'sample'. Instead, Yin (2014) and Thomas (2011) recommend the use of the term 'selection' to prevent confusion and unfounded criticism. Eisenhardt (1989) also highlights that for case studies it is neither necessary,, or even preferable, to choose cases randomly. However, Yin (2014) does note that non-random selection has the potential to create bias. Meyer (2001) stresses that case study researchers must be aware of the possible accusation of lack of rigour in case selection and therefore the need to be explicit about the choices made and the justification behind them.

If considering multiple case studies, Yin (2014) stresses the importance of focusing on replication and not sampling logic. He states that each case must be carefully selected so that it either predicts similar results (literal replication), or contrasting results for anticipated reasons (theoretical replication). Yin (2014) also recommends 2-3 case studies for literal replication; 4-6 cases studies for theoretical replication; and 6-10 case studies as an aggregation to allow for convincing support for the original propositions. As an alternative strategy, Eisenhardt (1989) suggests that researchers should stop adding cases when theoretical saturation is reached.

Establishment of boundaries in case study design is essential (Yin 2014; Baxter and Jack 2008). Boundaries are similar to quantitative inclusion and exclusion criteria for sample selection; the difference is that the breadth and depth of the study is also referred to in the boundaries.

Yin (2014); Thomas (2011); Baxter and Jack (2008); and Luck, Jackson and Usher (2006) all note that one of the strengths of a case study approach is the inclusion of a variety of data sources. Luck, Jackson and Usher (2006) list some of these data sources as: direct observations; participant observations; survey, questionnaire; documentation; archival records; interviews (both structured and unstructured); written accounts by participants; physical artefacts; and researcher description of the context. It is the researcher's responsibility to identify and incorporate the available and most appropriate data sources into the research design. As with all methodologies, case studies have noted advantages and disadvantages which are summarised in Table 2.3.

Table 2.3 Advantages and disadvantages of case studies

Advantages of case studies	Can be used within any worldview because all methods are acceptable (Luck, Jackson and Usher 2006)
	Can incorporate multiple sources of evidence (Baxter and Jack 2008; Yin 2014)
	Research design and data collection procedures can be tailored to the research questions (Meyer 2001)
	Allows for single or multiple realities (Yin 2014)
	Can be conducted in real-life settings (Luck, Jackson and Usher 2006)
	Has the flexibility to combine seemingly contradictory methods, allow for differing views and enable complex interrelated phenomena to be interpreted (Luck, Jackson and Usher 2006)
	Can be used to accomplish a wide variety of aims including providing description, testing theory and generating theory (Eisenhardt 1989)
	Takes a holistic approach to understanding phenomena as opposed to reducing it to a set of interrelating variables (Baxter and Jack 2008; Thomas 2011)
	'Context-dependent knowledge and experience are at the very heart of expert activity…It is only because of experience with cases that one can at all move from being a beginner to being an expert.' (Flyvbjerg 2006 p.223)
Disadvantages of case studies	Cases studies cannot assess prevalence of a phenomena (Yin 2014)
	No case study research design requirements have been stipulated and so there are no predefined standards of what constitutes a good case study (Meyer 2001; Yin 2014)
	Case studies are only generalisable to theoretical propositions and not to populations or universes. They do not represent a sample; only analytical and not statistical generalisations can be made (Jenson and Rodgers 2001 as cited by Luck, Jackson and Usher 2006; Yin 2014)
	Case studies are often considered to lack rigour (Meyer 2001; Luck, Jackson and Usher 2006)
	The result of a case study can be a long and potentially unreadable document (Yin 2014)

2.6 QUALITATIVE DATA COLLECTION

Unlike quantitative data, qualitative data is non-numerical data from a variety of sources such as observations, documents and interviews (Bowling 2014; Creswell 2013; Merriam 2009).

2.6.1 Observations and Field Notes

Bowling (2014) notes that in natural science, systematic observation is the classic method of enquiry. The author stresses that observation is not just merely watching but the gathering of information through use of the senses. This additional data on behaviour, actions and inactions, activities and interactions can provide the researcher with greater insight into more complex situations which may not always be articulated or even understood by the participants. Eisenhardt (1989) recommends that field notes be a running commentary and include the researcher's impressions, learning points, cross-case comparison thoughts, hunches and anecdotes. Thomas

(2011) notes that researchers may choose to observe in a structured manner (systematically looking for particular kinds of behaviour) or in an unstructured manner (informally from within the situation). Bowling (2014) recommends the following to researchers planning to incorporate observations into their fieldwork: decide what to observe and the clear definition of all variables of interest; keep separate observational notes; organise observations by time and keep in chronological order; record raw behaviour, not just the interpretation of the behaviour; write field notes up in full at the end of each observational session to prevent memory bias; and record feelings or impressions separately. Referencing Merriam (1988), Bowling (2014) suggests the following structure for observational notes: setting; participants; activities and interactions; frequency and duration; and subtle factors.

As well as the time consuming nature of observation, another significant drawback of observational data is the effect of being studied upon those being studied. This is commonly known as the 'Hawthorne effect', as described by Roethlisberger and Dickson 1939, cited by Bowling 2014. Furthermore, as noted by Gillham (2000), research has shown that observation can be both fallible and highly selective. However, Stake (1995) stresses the need for qualitative researchers to find the uniqueness and complexity of the case. Accordingly, the case study researcher must exert discipline and effort to become an accurate and balanced observer whose observations enrich the case study. Regardless of whether the researcher chooses to include observations in the case study, field notes must always be created. Merriam (2009) states that field notes should include three things: verbal descriptions of the setting, the people, the activities; direct quotations or at least the substance of what people said; and the observer's comments.

2.6.2 Documents

Including the analysis of available documents within the case study allows the researcher to include records of activity that the researcher could not observe directly and to relate formal reality to the informal reality (Gillham 2000; Stake 1995). Meyer (2001) also comments on the practical advantage of using documents to save time in interviews with regards to ascertaining certain facts. Thomas (2011) highlights the need to carefully read each document for meaning and substance and Gillham (2000) notes that the importance of the document will ultimately depend on the relevance to the research question. The potential issues Yin (2014) associates with documents are: problems with retrievability; biased selectivity if collection is incomplete; reporting bias; and the fact that access may be withheld. However, Stake (1995) also points out that it is also possible that the person recording may have been a better observer of the situation than the researcher.

2.6.3 Interviews

A research interview is not to be considered a conversation between equal partners but an interaction defined and controlled, to varying degrees, by the researcher (Kvale and Brinkmann 2009). Merriam (2009) notes that interviewing becomes necessary because observation alone does not allow the researcher to understand their feelings and interpretation of the world around them. Whilst technique is important, Kvale and Brinkmann (2009) note that interview mastery is achieved when the interviewer thinks less of the technique and more of the interviewee and the knowledge sought. Baxter and Jack (2008), Ritchie and Lewis (2003), and Meyer (2001) all stress the importance of the researcher creating and maintaining trust and rapport with the interviewee in order to elicit accurate information in an interview.

Interviews can be conducted in person, over the phone or through digital technology such as Facetime and Skype; interviews can be one-to-one or in a group. The interview itself can be described as: structured (set questions); semi-structured (set questions to give rise to more in depth probes); or unstructured (few, if any, set questions), (Bowling 2014; Thomas 2011). In addition, Yin (2014) describes case study interviews as being either: prolonged (two or more hours); shorter (approximately one hour, more focused, and following case study protocol); or a survey (structured questionnaire). Furthermore, Khan *et al* (1991) highlight that within the interview, the actual questions themselves can also be described as: structured; semi-structured; or unstructured. However, Nind (2009) highlights four potential issues with interviews for people with LD: inarticulateness, linked to low self-esteem, anxiety and language skills; unresponsiveness in open questioning; difficulty generalising from experience; and conceptual difficulty around time. In addition, Atkinson (2004 p696) notes that for some people with LD there is the issue of memory and that, *'Some areas of life have been forgotten – some were never known'.*

2.7 QUALITATIVE DATA ANALYSIS

2.7.1 Strategies

Within qualitative research there is no one particular way to approach data analysis (Bradley, Curry and Devers 2007); instead it must be custom-built (Creswell 2013). Hsiu and Shannon (2005) present three general strategies for approaching content analysis in qualitative data: conventional content analysis where categories flow from the data (inductive); directed content analysis in order to validate or extend conceptually a theoretical framework or theory; and summative content analysis with the counting and comparison of keywords or content followed by interpretation of the underlying content. In comparison, Miles and Huberman (1994) define their strategies according to

how the researcher decided upon their coding lists: *a priori* - creation of a provisional 'start list' of codes (master and sub) prior to fieldwork from a conceptual framework; inductive - no pre-coding until all the data is collected; and partway between *a priori* and inductive - creation of a general accounting scheme for codes that is not content specific but points to the general domains in which codes can be developed inductively. Whether one researcher undertaking all the coding alone is sufficient, or preferable, to a team of coders is debated within the literature (Bradley, Curry and Devers 2007).

Gale *et al* (2013) recommend the framework method (thematic analysis) as a systematic and flexible approach that can be used inductively or deductively and note that is not aligned to any particular worldview. The deductive approach involves using themes and codes that are pre-selected from previous literature, theories or specifics of the research questions (Gale *et al* 2013). Using a deductive framework approach to content analysis is easy to follow, allows for inclusion of non-interview data and demonstrates a systematic approach to analysis (Gale *et al* 2013). However, researchers may be tempted to begin quantifying results, find evidence that is supportive rather than non-supportive of the theory, or be blinded to contextual aspects of the phenomenon (Gale *et al* 2013; Hsui and Shannon 2005).

2.7.2 Procedure for Analysis

Patton (2002 p.433) notes that within qualitative data analysis, *'no absolute rules exist except perhaps this: Do your very best with your full intellect to fairly represent the data and communicate what the data reveal given the purpose of the study.'* Whilst there is no one procedure for analysing qualitative data, Gale *et al* (2013) recommended a 7-step procedure for qualitative data analysis within a framework approach which is detailed in Figure 2.1.

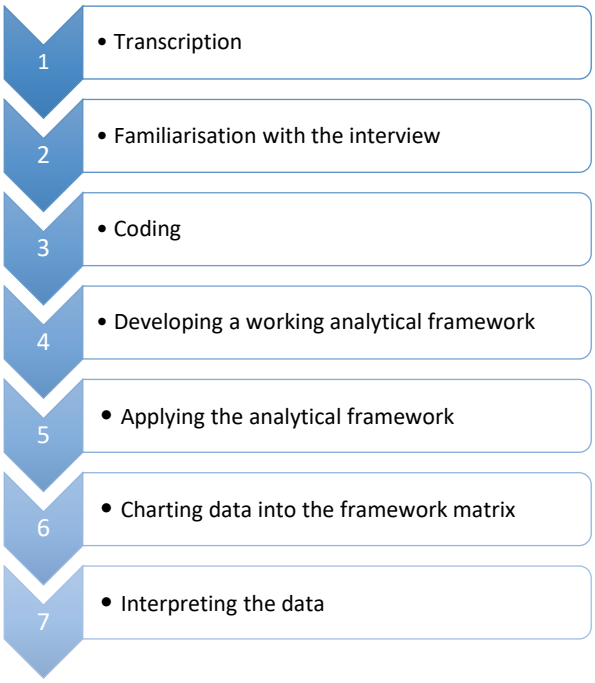


Figure 2.1 Qualitative data analysis procedure within a framework approach

Transcription, the act of changing audible talk to written words, requires reduction, interpretation and representation in order to make the data both readable and meaningful (Bailey 2008). Gale *et al* (2013) also note that within framework analysis, whilst it is ideal to transcribe the interview verbatim, it is not necessary to record all the conventions of dialogue transcription because it is what is said, rather than how it is said, that is of greatest interest. They further note that throughout the procedure the researcher must, *'strike a balance between reducing the data on the one hand and retaining the original meanings and "feel" of the interviewees' words on the other'* (Gale *et al* 2013 p5). Oliver, Serovich and Mason (2005) highlight the complexities of interview transcription and note that when the informational content is the main interest, it can be considered appropriate to 'denaturalise' data through correcting of grammar and the removing of involuntary noises.

2.7.3 Timing

Gale *et al* (2013), Merriam (2009), and Silverman (2005) highlight that, in contrast to quantitative researchers, qualitative researchers must see data collection and analysis as a simultaneous activity in order to produce more trustworthy findings. As such, data analysis must begin immediately after the first interview, occur throughout data collection and then be finally refined once data collection is complete. Qualitative researchers must constantly remind themselves of the explicit purpose of the study and the conceptual lens that is being used whilst at the same time being open and responsive to the unexpected (Miles and Huberman 1994).

2.8 MAXIMISING THE QUALITY OF QUALITATIVE RESEARCH

2.8.1 Trustworthiness

Within quantitative research, validity and reliability are the criteria used to judge the quality of the research (Creswell 2014; Gray 2013; Silverman 2005). For research to be considered valid, it must have measured what it was intended to measure and various types of validity can be measured (internal, external, criterion, construct, content, predictive, statistical) and presented as evidence of the quality of the research (Gray 2013). For research to be considered reliable, the means of measurement within the research must be consistent. Reliability can also be measured in many ways such as stability, equivalence, internal consistency, inter-judge reliability, and intra-judge reliability (Gray 2013). Preventing bias and errors during conceptualisation of the research idea, and then during the design and process of the study, is paramount to ensuring validity and reliability (Bowling 2014). Some of the more common types of bias and error, as outlined by Bowling (2014), are listed in Table 2.4.

However, Shenton (2004) and Lincoln and Guba (1985) propose alternative terminology for use within qualitative work that is different to, and distanced from, the positivist paradigm. These terms are credibility, transferability, dependability and confirmability and are detailed in Table 2.5.

Case study research can be used under a variety of paradigms and within quantitative, qualitative and mixed methods approaches, and so it is prudent to maintain a degree of flexibility when deciding on the terminology and approach to assessing quality. Furthermore, Birt *et al* (2016), Barbour (2001), and Sandelowski (1993), all caution on the over-zealous and uncritical adoption of trustworthiness strategies because of the potential to cause as many problems as they solve. Carlson (2010 p.1110) suggests that, *'…trustworthiness is gained when researchers show that their data were ethically and mindfully collected, analysed, and reported'.* Birt *et al* (2016), Barbour (2005), and Sandelowski (1993) also warn of potential problems with member checking (validation) of data because of: participants forgetting the information they provided; the changing nature of interpretations of phenomena over time by participants; the potential ethical issue of returning data to participants; the dilemma of anticipating and assimilating the disconfirming voices; and deciding who has ultimate responsibility for the overall interpretation. Barbour (2005) also suggests the use of dissemination focus groups as a possible alternative to member checking. This involves the researcher convening a group, providing feedback about the preliminary findings, and using the opportunity not just to validate the existing data but to generate more data.

Table 2.4 Common types of bias and error (Bowling 2014)

Origin	Bias or Error	Description or example
Researcher	Conceptual bias	Faulty logic in relation to the research problem, interpretations and conclusions
	Design bias	Faulty design, method, sampling, procedures or analysis
	Handling of outliers	Failure to discard an unusual value in a small sample or excluding unusual values inappropriately
	Interviewer bias	Consciously or subconsciously causing participants to respond in a certain way e.g. asking leading questions
	Measurement decay	Changing the way a measurement is taken throughout the research process
	Observer bias	Difference between the actual situation and the one recorded
	Response set	Having a lack of variety in questions that cause the participant to just say yes regardless of content; linked to participant response style bias
	Sampling bias	The sample does not represent the population being studied
	Selection bias	The characteristics of the sample differ from those of the wider population
	Systematic error	All the various biases or errors in a study resulting in an estimate not being a true value
Participant	Acquiescence	Participants are most likely to endorse, rather than disagree, with a statement
	Evaluation apprehension	Participants giving answers they think are expected, rather than what they actually think, as a result of 'exam anxiety'
	Mood bias	Participants with depression may not accurately describe their situation
	Reactive 'Hawthorne' effect	Participants changing their behavior due to the knowledge that they are being studied
	Recall (memory) bias	Participants selective memory in relation to past events
	Reporting bias	Participants failing to provide the information requested
	Response style bias	Saying yes to items regardless of content; linked to researcher response set bias
	Social desirability bias	Participants wanting to present themselves at their best
Other	Non-response bias	Differences in the characteristics between the responders and the non-responders not being known or accounted for
	Publication bias	Results demonstrating a statistically significant outcome are more likely to be published than those that do not; positive results more likely to be published than negative

Table 2.5 Trustworthiness in qualitative research (Shenton 2004; Lincoln and Guba 1985)

Term	Description	Similar to	Examples of how this can be achieved
Credibility	The level to which the findings accurately reflect (are congruent with) reality	Internal validity	• Use well recognised research methods • Develop familiarity with individuals or organisation being researched • Random sampling of individuals serving as informants • Employ tactics to ensure honesty in informants • Triangulation - noted as fundamental to case study research *(Yin 2014; Thomas 2011; Stake 1995; Eisenhardt 1989)* • Frequent debriefing • Peer scrutiny of project • Reflective commentary • Member checks of data (validation) • Description of the background, qualifications and experience of researcher • Rich, thick description of phenomenon
Transferability	The level to which the findings of the research can be applied (by the reader) to another group	External validity (generalisability)	• Provide background data • Establish context of study • Provide detailed descriptions of phenomenon (to allow for comparison)
Dependability	The level to which the research could be replicated accurately by another researcher	Reliability	• Use 'overlapping' methods • Provide a detailed description of methodology (to allow study to be repeated)
Confirmability	The level to which the findings are the result of the experiences and ideas if the informants (rather than that of the researcher)	Objectivity	• Use of triangulation (to reduce investigator bias) • Admission of researcher's beliefs and assumptions • Acknowledge shortcoming(s) in methods and their effect(s) • In-depth descriptions of methods • Provision of an audit trail

2.8.2 Reflexivity

Mays and Pope (2000) define reflexivity as the awareness of the researcher to the ways in which both they personally, and the research process generally, shaped and influenced the collected data; Malterud (2001) uses the metaphor, '*the knower's mirror*'. Within qualitative research, this issue is not whether the researcher has affected the process or indeed how to prevent any influence. Instead reflexivity is about acknowledging and sharing the effect of the researcher, on all aspects of the research. Encouraging dialogue between researchers so beliefs are made transparent; writing a reflexive journal to record logistics, decisions and reflections of values and interests; and reporting beliefs and values pre and post data collection are all considered ways to enhance reflexivity (Silverman 2005; Ahern 1999). When reviewing qualitative research Malterud (2001 p.485) suggests

assessing reflexivity by asking the question, *'Are the researcher's motives, background, perspectives and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?'*

2.9 RESEARCH GOVERNANCE – GENERAL CONSIDERATIONS

NHS Research Scotland (2017) defines research governance as the setting of standards to improve research quality and to safeguard the public. Enhancing ethical and scientific quality, promoting good practice, reducing adverse incidents, ensuring lessons are learned, and preventing poor performance and misconduct are all considered (NHS Research Scotland 2017). Within their policy framework for health and social care research, the NHS Health Research Authority (HRA) outline the principles that apply to all health and social care research and the responsibilities of those involved (NHS Health Research Authority 2017a). These principles and responsibilities are summarised in Table 2.6. In addition, the Medical Research Council (MRC) provides online guidance on consent and how to prepare documents to support the process (Medical Research Council 2016). Finally, the university's policies on research governance and integrity, and research ethics, support students in ensuring that the safety, rights, dignity and well-being of the participant and themselves are maintained; and that the research adheres to all relevant codes of good practice and policy (Robert Gordon University 2016a). As part of the research governance and integrity policy, all research involving human participants must be referred to the university's Research Integrity and Ethics Sub-committee for review before research can proceed (Robert Gordon University 2016a). It should also be noted that if any research involved NHS Grampian then approval from the North of Scotland Research Ethics Committee would also be required (Robert Gordon University 2016a).

Table 2.6 Principles and responsibilities in research (NHS Health Research Authority 2017a)

Principle	Summary
1	The safety and well-being of the individual prevail over the interests of science and society.
2	All the people involved in managing and conducting a research project are qualified by education, training and experience, or otherwise competent under the supervision of a suitably qualified person, to perform their tasks.
3	Research projects are scientifically sound and guided by ethical principles in all their aspects.
4	Patients, service users and the public are involved in the design, management, conduct and dissemination of research, unless otherwise justified.
5	Research is designed, reviewed, managed and undertaken in a way that ensures integrity, quality and transparency.
6	The design and procedure of the research are clearly described and justified in a research proposal or protocol, where applicable conforming to a standard template and/or specified contents.
7	The researchers and sponsor familiarise themselves with relevant legislation and guidance in respect of managing and conducting the research.
8	Before the research project is started, any anticipated benefit for the individual participant and other present and future recipients of the health or social care in question is weighed against the foreseeable risks and inconveniences once they have been mitigated.
9	A research project is started only if a research ethics committee and any other relevant approval body have favourably reviewed the research proposal or protocol and related information, where their review is expected or required.
10	In order to avoid waste, information about research projects (other than those for educational purposes) is made publicly available before they start (unless a deferral is agreed by or on behalf of the research ethics committee).
11	Other than research for educational purposes and early phase trials, the findings, whether positive or negative, are made accessible, with adequate consent and privacy safeguards, in a timely manner after they have finished, in compliance with any applicable regulatory standards, i.e. legal requirements or expectations of regulators. In addition, where appropriate, information about the findings of the research is available, in a suitable format and timely manner, to those who took part in it, unless otherwise justified.
12	Research participants are afforded respect and autonomy, taking account of their capacity to understand. Where there is a difference between the research and the standard practice that they might otherwise experience, research participants are given information to understand the distinction and make a choice, unless a research ethics committee agrees otherwise. Where participants' explicit consent is sought, it is voluntary and informed. Where consent is refused or withdrawn, this is done without reprisal.
13	Adequate provision is made for insurance or indemnity to cover liabilities which may arise in relation to the design, management and conduct of the research project.
14	All information collected for or as part of the research project is recorded, handled and stored appropriately and in such a way and for such time that it can be accurately reported, interpreted and verified, while the confidentiality of individual research participants remains appropriately protected. Data and tissue collections are managed in a transparent way that demonstrates commitment to their appropriate use for research and appropriate protection of privacy.
15	Sanctions for non-compliance with these principles may include appropriate and proportionate administrative, contractual or legal measures by funders, employers, relevant professional and statutory regulators, and other bodies.

2.10 RESEARCH GOVERNANCE CONSIDERATIONS SPECIFIC TO THE INCLUSION OF ADULTS WITH INCAPACITY

2.10.1 Introduction

According to the British Medical Association's Medical Ethics Department (2009 p.4), a person is considered to lack capacity if, *'he or she is incapable of acting, making decisions, communicating decisions, understanding decisions or retaining the memory of decisions due either to a mental disorder or to a physical disability which prevents communication.'* Furthermore, incapacity is not to be viewed as an 'all-or-nothing' concept but dependent on the nature of the decision that needs to be made (British Medical Association Medical Ethics Department 2009). In their policy framework for health and social care research, the NHS HRA state that persons, *'who are not able to consent for themselves should be included in research, provided that you do this in line with relevant legal frameworks and ethical principles'* (NHS Health Research Authority 2017a). The following section outlines the relevant legislation and ethical issues noted in the literature that require consideration when undertaking research inclusive of adults with LD who lack capacity or have only limited capacity.

2.10.2 Adults with Incapacity Legislation (Scotland)

The Adults with Incapacity (Scotland) Act (2000), provides a framework for safeguarding the welfare, and for managing the finances, of adults who lack capacity due to mental disorder or inability to communicate (Adults with Incapacity (Scotland) Act 2000). The Act sets down five general principles which must underpin any intervention, that is, any decision being taken on their behalf by other people:

1. The intervention must benefit the adult;
2. The adult's wishes, so far as they can be ascertained, must be taken into account;
3. The views of relevant others, so far as it is reasonable and practical to do so, must be taken into account;
4. The adult's freedom should be restricted as little as possible while still achieving the desired benefit;
5. The adult must be encouraged to use any residual capacity.

The Adults with Incapacity (Scotland) Act 2000 makes provision for a legally recognised proxy decision maker to be appointed by one of three routes: power of attorney; guardianship; and person appointed by a court order (The Office of the Public Guardian in Scotland, 2016):

Power of Attorney – Continuing and Welfare

Continuing power of attorney gives power over the granter's property and finances. Continuing power of attorney may start immediately and continue in the event of the granter's incapacity, or the granter may stipulate that it only begins when they become incapable. Welfare power of attorney gives power over decisions that need to be taken about the granter's welfare and health care. In contrast to continuing power of attorney, welfare power of attorney can only begin when the granter becomes incapable and has been medically certified as such. In order to grant either continuing or welfare power of attorney, the granter must have capacity.

Guardianship

Someone who has already lost capacity, or who has never had capacity, cannot appoint a power of attorney (welfare or continuing). Guardianship is a court appointment that authorises a person to act and make decisions on behalf of someone over the age of 16 years with incapacity who is not able to look after their own affairs. The Court will agree the powers to be included in the guardianship order and these can be financial, welfare-related or a combination of both.

Person Appointed by a Court Order

Anyone with an interest can make an application for an intervention order. This is a court appointment which authorises a person to act and take a one-off action or make decisions on behalf of an adult with incapacity. The order allows the person appointed to do certain one-off things such as sign legal documents or sell the adult's house or sign forms agreeing where someone can live. If powers are required on an on-going basis then guardianship would be more appropriate.

Section 51 of the Adults with Incapacity (Scotland) Act 2000 outlines the authority for research and states that all research involving adults with incapacity must: have been approved by an ethics committee; entail no foreseeable risk, or only a minimal foreseeable risk, to the adult; impose no, or minimal, discomfort on the adult; and obtain consent from any guardian or welfare attorney who has power to consent to the adult's participation in research, or where there is no such guardian or welfare attorney, from the adult's nearest relative. Of note, is the fact that research involving adults with incapacity is not prohibited. When undertaking research that involves an individual who lacks

capacity, all aspects of Section 51 of the Adults with Incapacity (Scotland) Act 2000 must be adhered to.

2.10.3 Informed Consent

For consent to be considered both legal and ethical it must be given voluntarily with no undue influence, by an individual with capacity, who has been adequately informed (NHS Health Research Authority 2017b). In addition, consent must be seen not as a one-off event but an iterative and on-going process (NHS Health Research Authority 2017b). The Medical Research Council (2007) states very clearly that a person is deemed unable to consent to take part in research if they cannot: understand the information relevant to the decision; retain the information long enough to make the decision; use or weigh that information as part of the process for making the decision; and communicate their decision. When considering consent in people with LD there will be two groups of individuals: those who lack the capacity to consent; and those who are able enough, possibly with a degree of support, to provide their own consent.

If an individual lacks capacity to consent then, as per Section 51 of the *Adults with Incapacity Act (Scotland) 2000*, the person's legal representative (welfare power of attorney or welfare guardian or person appointed by a court order) or relative can be approached and be asked to provide consent. When this occurs, the NHS Health Research Authority (2017b) stipulates that the legal representative must be given sufficient information about the research and then be told that they: are being asked to give consent on behalf of the incapacitated adult; are free to decide whether or not they wish to make this decision; and are being asked to consider what the adult would want; and should set aside their own personal views when making this decision. Dalton and McVilly (2004 p.63) recommend that, *'…where a nominated family member of legal guardian does not have regular contact with the potential participant, collective decision making processes, involving a number of advocates, can be more effective in safeguarding the potential participant's best interests'*.

The issue of ensuring informed consent, and not just acquiescence, has been raised in the literature (Stalker 1998). To ensure consent is indeed informed, it is recommended that researchers give due consideration to: the quality of information provided; who they provide information to; what format they provide the information in; how they will arrange for adequate support for the individual to consider the information; ascertaining and adapting the research process to the previous experience and familiarity with making choices of that individual (Raghavan and Patel 2010; Nind 2009; Keywood and Flynn 2006). For Clinical Trials of Investigational Medicinal Products (CTIMPs), consent

is only legal if it is provided in writing, but for other types of research consent may be provided verbally, non-verbally or in writing (Health Research Authority 2017b). Dalton and McVilly (2004) recommend that if only verbal consent can be given then it should be witnessed by at least one independent individual and formally documented.

When undertaking research involving adults with LD, ascertaining their level of capacity to consent and participate will be essential. In addition, ensuring that written information is adapted for people with LD and that the process of obtaining consent and data collection is adapted to support the individual whilst still adhering to all the principles and requirements laid down by the HRA is also essential (NHS Health Research Authority 2017a).

2.10.4 Inclusion in Research

The need to, and the benefits of, involving people with LD in projects designed to promote health and research in their community are well documented (Medical Research Council 2007; Dalton and McVilly 2004; Walmsley 2004; Atkinson 2004; Stalker 1998; Ward and Simons 1998). Dalton and McVilly (2004 p.59) also state that people with LD, *'…should not be excluded (discriminated against) as potential participants in generic research and every effort should be made to include their perspectives, priorities and needs in generic research activities'.* However, due consideration must be given to the fact that intellectual impairment does limit the extent and means to which people with LD can be involved in certain research activities (Walmsley 2004), and that not everyone with LD will be able or want to be involved (Ward and Simons 1998). Ward and Simons (1998) also note that doing research with people with LD instead of research about them, takes time, thought and energy. However, enabling them to be an authority on their own lives (Stalker 1998), and controlling the stories of their lives (Atkinson 2004) can bring people with LD enormous benefit. It also strengthens, enriches, appropriately focusses and produces more effective outputs within research (Ward 1998). Finally, Arscott, Stenfert Kroese and Dagnan (2000) remind us that many people, not just those with LD, are content to rely on their doctor's recommendations and adhere to medication with very little knowledge of that medication. All of these issues must be incorporated into any research involving adults with LD.

2.10.5 Literacy and Health Literacy

The definition of the term 'literacy' is constantly evolving but is generally understood to refer to an individual's ability to read; sometimes to read and write; and sometimes to read, write, speak and listen (Cambridge Assessment 2013). More specifically, the term 'health literacy' refers to the

degree to which an individual has the cognitive and social skills to obtain, process, and understand basic health information and need for services in order to make appropriate health decisions (US Department of Health and Human Services 2000; Nutbeam 1998). As a consequence, people with limited health literacy often lack knowledge or are misinformed about the body and the nature and causes of disease (US Department of Health and Human Services 2000). The diagnosis of LD is only given to an individual whose IQ is known to be less than 70 (British Psychological Society 2000). It therefore follows that within the LD population, both literacy and health literacy are either challenging, limited or impossible. Considering the potential for reduced literacy and health literacy in the LD population, amending materials and processes is essential. Another issue that further compounds this is the increased incidence of visual impairment within the LD population (Scottish Government 2013; Royal College of General Practitioners 2012).

'Easy-read' is one way of making information more accessible to people with milder LD as it limits information, simplifies concepts, uses larger font size text, and uses pictures to accompany any text (Department of Health 2010). Some of the practical recommendations from the Department of Health (2010) are highlighted in Figure 2.2.

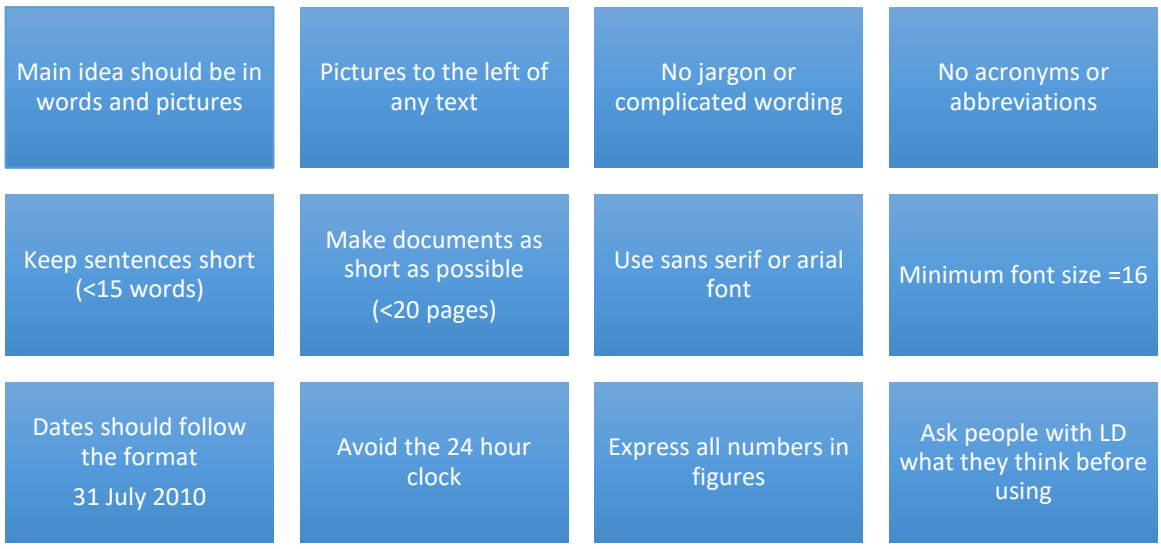


Figure 2.2 Practical recommendations for easy-read (Department of Health 2010)

2.10.6 Involvement of Significant Others

Citing Walmsley 2004, Nind (2009) recommends that those who wish to undertake research in the LD population, work closely with those who know the individuals well. These people can then advise on the unique ways to maximise communication with each individual and therefore enhance participation. Nind (2009) also notes that some people with LD may need the support of a familiar person in the interview who can help them communicate their ideas or act as a translator when required. Nind (2009) also notes that for many people with profound LD, interviews are just not possible. Involving significant others in the research process is therefore essential.

2.10.7 Capability, Not Disability

When discussing the transformative paradigm, Mertens (2004) highlights the need for researchers who work with populations different to their own to be culturally competent, that is: to be aware of their assumptions regarding human behaviour, values, biases; to actively attempt to understand the worldview of the group of people they are researching; and to develop and practice appropriate, relevant and sensitive strategies and skills for working with that research population. After describing the medical, social and biopsychosocial models for ID, Emerson and Hatton (2013) highlight the tension between the medical and social models. The medical model views LD as a series of functional deficits whereas the social model is concerned with achieving civil rights and empowerment. As a result, conducting research that only seeks to highlight deficits within the LD community would not be considered culturally competent. Emerson and Hatton (2013) promote working within the capabilities framework that was begun by Sen (1999) and Nussbaum (2011) which focusses on what individuals are able to do and be, rather than what they cannot do nor be.

2.10.8 Establishing Relational Boundaries

A survey of 2898 people with LD by Emerson *et al* (2005) reported that 19% of people with LD never saw members of their family; 31% said they did not have any contact with friends; and 5% had no friends and did not see anyone from their family. As a result, there is the potential issue of the person with LD coming to misinterpret multiple visits from a researcher as a new friendship. In addition, there is also the potential for the blurring of lines between the research and current medical or pharmaceutical issues when the researcher also a local HCP. This will be both from the point of view of the participants who may wish to discuss and action current pharmaceutical issues, and from the researcher who may wish to intervene to resolve a current pharmaceutical issue. Both issues required to be addressed within the research plans to ensure that, wherever possible, appropriate relational boundaries between the researcher and the participants are established and

maintained. This would ensure that the focus and integrity of the research would be retained whilst not neglecting the wellbeing and safety of the participant.

2.10.9 Adult Support and Protection Legislation (Scotland)

According to the Adult Support and Protection (Scotland) Act 2007, 'adults at risk' are adults who are unable to safeguard their own well-being, property, rights or other interests; are at risk of harm; and because they are affected by disability, mental disorder, illness or physical or mental infirmity, are more vulnerable to being harmed than adults who are not so affected (Adult Support and Protection (Scotland) Act 2007). These adults would be considered at risk of harm when either another person's conduct is causing, or is likely to cause, the adult to be harmed; or when the adult is engaging, or is likely to engage, in conduct which causes, or is likely to cause, self-harm. Where a public body or office-holder knows or believes that a person is an adult at risk, and that action needs to be taken in order to protect that person from harm, the public body or office-holder (including all HCPs) must always report the facts and circumstances of the case to the LA. The NHS HRA (2017a) clarifies the potential clash of clinical and research priorities by stating that, *'If an unmanageable conflict arises between research and patient interests, the duty to the participant as a patient prevails.'*

2.11 DATA PROTECTION

From 25th May 2018 the European Union General Data Protection Regulation (GDPR) has become the governing data protection legislation within the UK (Council of the European Union 2016). However, at the time of research, the governing legislation for data storage within the UK was still the Data Protection Act 1998 (Data Protection Act 1998).

The eight principles in Schedule 1 of the Data Protection Act (1998) are listed below:

1. Personal data shall be processed fairly and lawfully and, in particular, shall not be processed unless (a) at least one of the conditions in Schedule 2 is met, and (b) in the case of sensitive personal data, at least one of the conditions in Schedule 3 is also met;
2. Personal data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes;
3. Personal data shall be adequate, relevant and not excessive in relation to the purpose or purposes for which they are processed;
4. Personal data shall be accurate and, where necessary, kept up to date;
5. Personal data processed for any purpose or purposes shall not be kept for longer than is

necessary for that purpose or those purposes;

6. Personal data shall be processed in accordance with the rights of data subjects under this Act;
7. Appropriate technical and organisational measures shall be taken against unauthorised or unlawful processing of personal data and against accidental loss or destruction of, or damage to, personal data;
8. Personal data shall not be transferred to a country or territory outside the European Economic Area unless that country or territory ensures an adequate level of protection for the rights and freedoms of data subjects in relation to the processing of personal data.

In addition, the Research Council UK provides an overarching framework to reflect two key principles about publicly-funded research data: they are a public good and produced in the public interest; and they should be openly available to the maximum extent possible (Research Councils UK 2015). Finally, RGU has a guide for students on managing and sharing research data to ensure best practice (Robert Gordon University 2016b).

2.12 STUDY DESIGN

2.12.1 Worldview and Methodological Approach

From a pragmatic worldview, a predominantly qualitative design, as outlined by Creswell (2013) and Denzin and Lincoln (2013), was adopted. This was because the intention of the research was to explore, and not quantify, the medication related experiences of adults with LD in order to identify ways in which these experiences might be improved by HCPs. This resonates with Koelsch (2013 p. 170) who states that the purpose of qualitative research, *'…is not to achieve representation, but rather to change problematic social conditions, institutions, thoughts, behaviours, and so forth.'* However, using a framework approach, as detailed by Gale *et al* (2013), with *a priori* coding as detailed by Miles and Huberman (1994) detracts from a purely constructivist study design.

2.12.2 Qualitative Methodology – Case Studies

As the purpose of the research was not to build theory, grounded theory was not an appropriate choice of methodology. The potential for negatively impacting on the participants when withdrawing from their world after the research period ended made ethnography less suitable; the potential for limited recall from adults with LD made a narrative approach also less suitable. Although phenomenology was considered, case study methodology was chosen in preference for this research because it allowed for real-life study of the defined phenomena (medication

experience in adults with LD); inclusion of multiple 'cases'; and inclusion of a variety of data sources (Yin 2014; Thomas 2011; Baxter and Jack 2008; and Luck, Jackson and Usher 2006).

Using the case study classification as defined by Thomas (2011) in Table 2.2: the subject (an adult with LD) will be selected through the knowledge of local care providers and support charities; the purpose will be exploratory; the approach will be illustrative; and the process will be to include multiple case studies in a parallel manner. Local care providers and charities will be asked to identify potential suitable participants. As recommended by Yin (2014), 6-10 case studies will be included in order to allow for an aggregation of evidence.

The boundaries, or inclusion criteria, for each case will be as follows: the adult with LD must be aged 18 years or more; have taken more than one regularly prescribed medicine for more than 6 months; and be living in a community setting. The case will include any aspect of medication experience for that adult with LD from any point in their life. Consideration will not be given to any adult with LD where: participation would be stressful or inappropriate for the adult with LD and their carers or care workers; there are current adult protection issues for that individual or housing unit; adult protection issues involving medication were experienced in the past. Whilst the view of associated HCPs would add a further dimension to the case study evidence their views will not be sought so that the voice of the adult with LD is heard.

As described in Chapter 1, care providers and charities are often involved in supporting adults with LD, and are therefore ideal to involve in the recruitment process. The Care and Support Providers Aberdeen (CASPA) forum, mentioned in Chapter 1, will be asked to support recruitment and identification of suitable cases by disseminating invitations to participate in the research. In order to promote the recruitment, the researcher and supervisor will attended a scheduled meeting of CASPA. A presentation will be made to the assembled representatives including relevant study information. Subsequently, a request for participants will be emailed to CASPA, including an easy-read information sheet and consent form. CASPA will be asked to send this information and request on to the affiliated care provider companies, charities, and the local LD support group

2.12.3 Data Collection

The primary data source for each case study will be semi-structured interviews with the adult with LD and/or their carers and care workers. However, where possible, information from available documents such as medicine administration records and client records, and unstructured indirect

observations by the researcher will also be collected. Neither the medical not the pharmaceutical records of each individual adult with LD will be accessed so all information pertaining to medication, medical conditions, and medical history, must be obtained through interview and through observations of the actual medication, repeat prescriptions re-order slips, and other written records.

Interviews

Wherever possible, interviews will be conducted face-to-face at a time and location convenient to the participant. However, a telephone interview will be conducted if preferred. With prior consent, all interviews will be audio-recorded. Depending on what the participants and their carers or care workers are most comfortable with, interviews may be one-to-one, with a carer or care worker present (for an interview with an adult with LD) or as a group (for care workers).

Interviews will be semi-structured and the interview schedule will be developed to reflect the PLEM conceptual model (see Section 2.12.4). The first part of the interview will be an opportunity for the participants to discuss the experiences most important to them; following on from this structured questions, based on the PLEM conceptual model, will be asked.

Prior to data collection, interview questions in standard and easy-read format will be peer reviewed by the researcher's supervisory team, by senior LD care workers, and by an adult with LD, to ensure the wording is as clear and understandable as possible. In addition, a pilot interview will be conducted to refine interview technique and process.

A simplified, easy-read version of the interview questions (see Appendix 2.1) will be provided to participants at least 48 hours before the interview. The adult with LD (if capacity allows), and current care workers and carers will all be invited to participate.

A small financial reimbursement, to cover out-of-pocket expenses, was provided to all participants.

Observations, Documentation and Field Work Notes

Direct observation of medication taking practice was not incorporated into the study design because of the inherent problem of the participants amending behaviour as a result of being observed (commonly known as the 'Hawthorne effect' as described by Roethlisberger and Dickson 2003, cited by Bowling (2014)). General indirect observations of the setting, the actual medication, the medication storage, dynamic between carers and overall impressions will be noted in the field work note book. Medication storage, and information in written records will be photographed, if anonymity could be preserved, or noted in the field work note book.

2.12.4 Theoretical Framework

Introduction

Birken *et al* (2017) cite twelve different ways in which theory is used by researchers within their area. This is summarised in Figure 2.3.

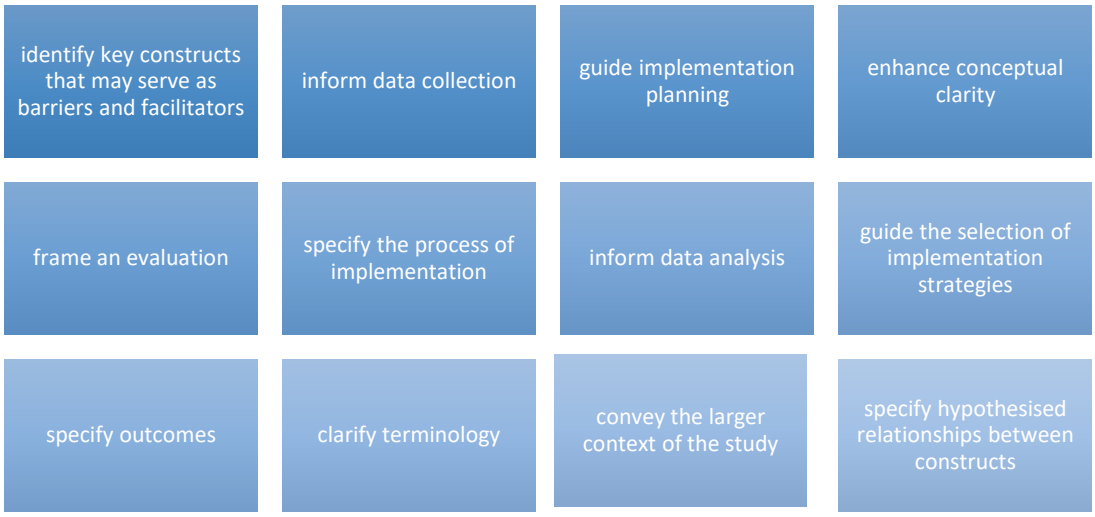


Figure 2.3 Use of theory by researchers (Birken *et al* 2017)

Within the literature these theories are referred to in a variety of terms: theoretical lens; theoretical perspective; theoretical framework; conceptual framework; and conceptual model (Grant and Osanloo 2016; Creswell 2014; Maxwell 2012). However, within the literature there is not yet consensus on the definitions and interchangeability of the various terms, as noted on discussion threads on Researchgate (Researchgate 2014a; Researchgate 2014b). To prevent any unnecessary confusion by interchanging terminology, 'theoretical framework' will be the term used to describe

the underpinning theory within this research although when referring to other work, the term used by those authors will be used.

Choice of Theoretical Framework for this Research

The challenge of selecting a suitable theoretical framework is highlighted by Birken *et al* (2017) who cite the various criteria used by researchers when selecting theory which is summarised in Figure 2.4. For this research, ensuring that the theory had a logical consistency and plausibility relating to medication experience, and could be used within a qualitative research method, were of primary importance.

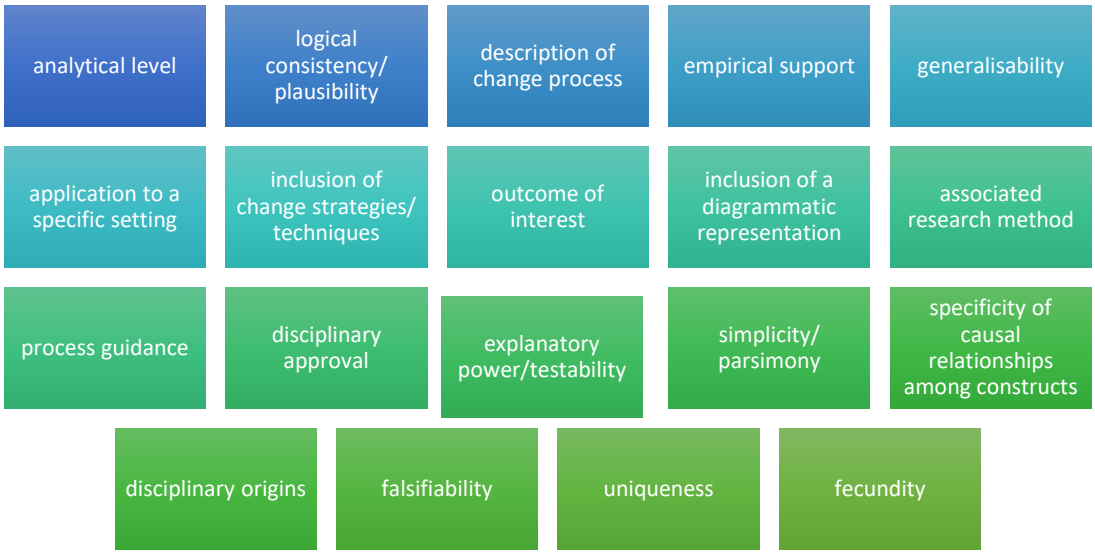


Figure 2.4 Criteria used to select theory (Birken *et al* 2017)

Existing validated instruments for measuring beliefs about medicines (Horne, Weinman and Hankins 1999); treatment burden (Tran *et al* 2014); and experiences with medication (Krska *et al* 2014), were considered. However, all these instruments quantified experience and did not lend themselves to an explorative qualitative approach.

Consideration was also given to using the Theoretical Domains Framework (TDF). The TDF was developed by Michie *et al* (2005) to make behavioural change theory more easily understood and accessible to non-psychologists. It simplifies and summarises 33 theories and 128 key theoretical constructs related to behaviour into 14 domains (knowledge; skills; role and identity; beliefs about capabilities; optimism; beliefs about consequences; reinforcement; intentions; goals; memory,

attention and decision process; environmental context and resources; social influences; emotion; and behavioural regulation). Whilst the TDF might have been used as a means of describing the behaviours of people with LD or their carers and care workers, the purpose of the study was not actually to identify areas of behavioural change and therefore the TDF was limited in its applicability.

In early 2016 (whilst the research proposal was being drafted), Mohammed, Moles and Chen (2016) identified and meta-synthesised 34 studies (from an initial 4063) to create a new conceptual model describing the Patient's Lived Experience with Medicine (PLEM) (see Figure 2.5).

Descriptions of Patients' Lived Experience with Medicines (PLEM) Conceptual Model

This new PLEM conceptual model incorporated the three major and inter-related themes that emerged from the studies: medication related burden; medication related beliefs; and medication taking practice. The authors intended medication related burden to be considered an antecedent factor and medication taking practice the target behavior or outcome within the model. Under each of these three themes, sub-themes were identified. The sub-themes for medication related beliefs were developed using the Theory of Planned Behaviour (Ajzen 1991). This theory proposes that an individual's behavioural intentions are a combination of their attitude toward that behaviour, subjective norms, and perceived behavioural control (Ajzen 1991). Furthermore, within the PLEM model, the combination of medication related burden, medication related beliefs, and medication taking practice were shown to influence the patient's wellbeing or health-related quality of life (HRQoL) and negative therapeutic outcomes as well as determining the patient's lived experience with medicine. Citing Cipolle, Strand and Morley (2004), Mohammed, Moles and Chen (2016 p.1) define patients' medication experience as, *'the sum of all events involving drug therapy that a patient encounters in his/her lifetime'.*

Use of PLEM in the Literature

At the point of research planning and data collection (2016), the PLEM model had only just been published so there was no additional literature where the PLEM model had been used, critiqued or validated. In October 2017, eight citations of Mohammed, Moles and Chen (2016) were identified through Google Scholar but none of these studies were found to have used, critiqued or validated the PLEM model.

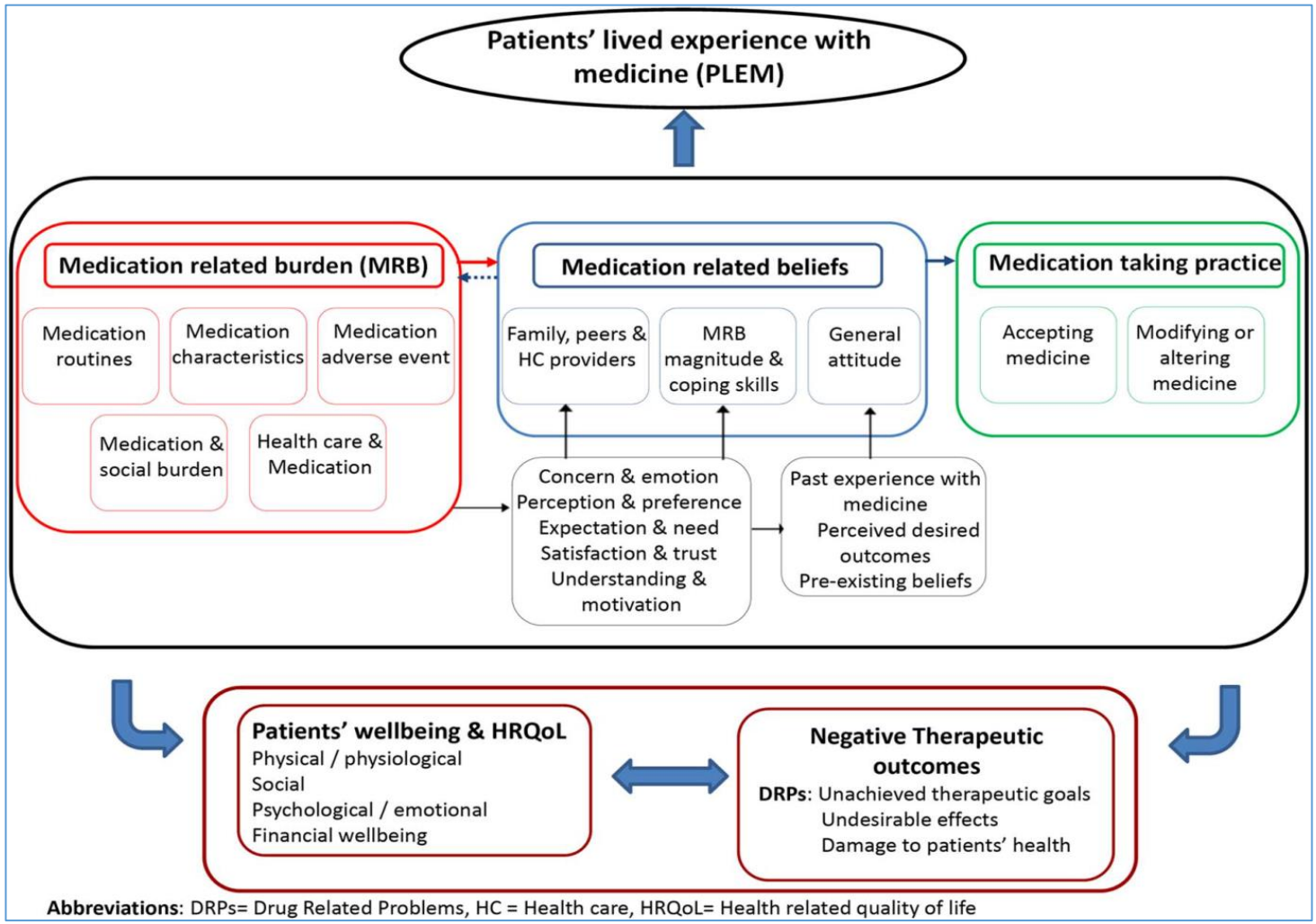


Figure 2.5 Patient's lived experience with medicines (Mohammed, Moles and Chen 2016)

Strengths and Limitations of PLEM Conceptual Model as a Theoretical Framework

Although the PLEM model may require refinement through validation, it had a high degree of logical consistency and plausibility, could be used within a qualitative research method, and had the required outcome of interest (experience with medication). Furthermore, it resonated with my experience and knowledge as a practising pharmacist. Maxwell (2012 p45) argues against ignoring knowledge gained from experience about the settings or issues that are proposed to be studied and cites Wright Mills (1959 p.195) as saying *'The most admirable scholars within the scholarly community . . . do not split their work from their lives. They seem to take both too seriously to allow such dissociation, and they want to use each for the enrichment of the other.'* Furthermore, no other theoretical framework was found that was as specific to medication experience as the PLEM model. However, there are some limitations of note:

- The PLEM conceptual model has not yet been validated and so elements of the model may be disputed in the future;
- Although the burden and negative aspects of medicines are conceptualised, the positive aspects of medicines are not as clearly conceptualised and this may result in an imbalance within the model;
- The depth of disease related burden was not accounted for in the model as an issue that affecting the extent and impact of any medication related burden;
- The minor themes of '*Patients' wellbeing &HRQoL'* and '*Negative Therapeutic Outcomes*' were not as clearly defined, linked and described as the major themes;
- Attempting to cover all aspects of the model within an interview would be resource and time intensive for both the researcher and the participants;
- None of the studies included in the metasynthesis included adults with LD;
- The term, 'lived experience' is closely associated with phenomenological enquiry where the researcher seeks to describe how an individual experiences a phenomenon in their everyday world (Sadala and Adorno 2002). Mohammed, Moles and Chen (2016) have not linked their use of the phrase 'lived experience' to this phenomenological term and there is therefore potential for misunderstanding about the term.

How the PLEM Conceptual Model will be used as a Theoretical Framework in this Research

The three major and interrelated themes of medication related burden, medication related beliefs and medication taking practice, and their individual sub-themes will be used to structure data collection and analysis. Furthermore, within their published paper Mohammed, Moles and Chen (2016), cite examples of each sub-theme and these examples will also be used to explore

participants' experience with medicines. In addition, these themes, sub-themes, and examples will be used as *a priori* codes for data analysis. The final framework with *a priori* codes for data collection and analysis, adapted from the PLEM conceptual model by Mohammed, Moles and Chen (2016) can be found in Appendix 2.2.

The minor themes of *Patients' wellbeing & HRQoL* and *Negative Therapeutic Outcomes* will not be used as these were not as clearly defined, linked and described. Furthermore, to accurately assess HRQoL would involve the use of validated instruments and quantitative methodology and methods; this would detract from the constructivist approach of exploring the experiences of adults with LD in relation to medication.

2.12.5 Data Analysis

Interviews will be transcribed in a denaturalised manner by the researcher as outlined by Oliver, Serovich and Mason (2005). Conversational data not relating to the research topic, pauses or 'stumblings', involuntary vocalisations such as sniffing or laughing and movement will therefore be excluded, unless to do so would prevent understanding of the verbal data. Audio recordings, transcripts, fieldwork notes, photos and information from any formal files will be added to the study database in the relevant case file. The transcripts will be checked for accuracy against the audio recording by the researcher's principal supervisor of doctoral studies.

Analysis of all the collected data will therefore be undertaken through a deductive framework approach using the PLEM conceptual model *a priori* codes; these codes can be found in Appendix 2.2. Any data not fitting the *a priori* coding system will be assigned a new code. All coding will be undertaken by the researcher with regular check by, and discussion with, the researcher's principal supervisor of doctoral studies.

Data analysis will begin at the individual case study level but will then be collated and presented at a multiple case study level. A summary of the 7-step process for data analysis, as outlined by Gale *et al* (2013) in Figure 2.1, has been amended for this study to allow the framework to structure data collection and accommodate multiple case study methodology. See Figure 2.6 for this amended process for data analysis.

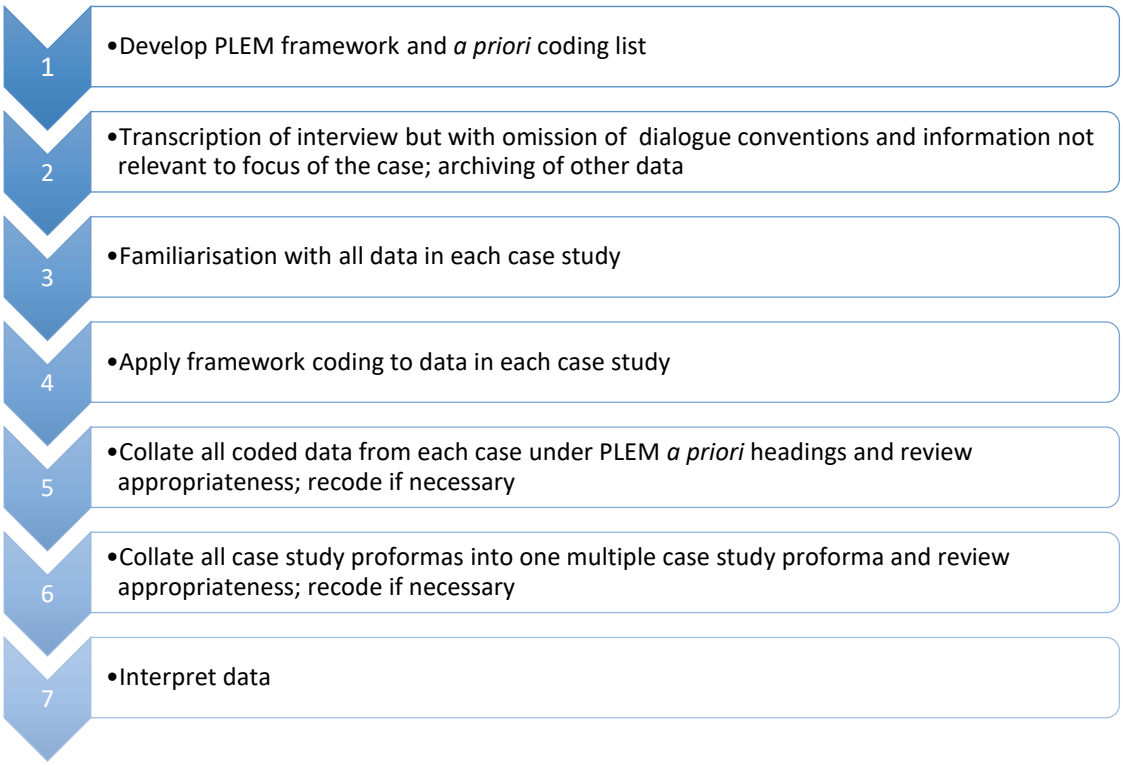


Figure 2.6 Amended process for data analysis based on the 7-step process by Gale *et al* (2013)

2.12.6 Maximising the Quality of this Research

Trustworthiness

As advised by Shenton (2004), strategies to promote the credibility, transferability, dependability and confirmability of the research have been adopted and are outlined in Table 2.7.

Table 2.7 Strategies to promote trustworthiness within this research

Term	Strategy within this research
Credibility	• Adoption of best practice methods for arranging and conducting interviews • Scrutiny of questions and processes by the academic supervisor and the Aberdeen Provider Forum (previously CASPA). The chair of the local LD support group (who has mild LD) helped to further refine the questions into easy-read format. This enhanced both academic rigour and suitability for the intended participant group. • Familiarity with LD services and key people had already been established prior to the research being researched • Individuals were not selected by the researcher but identified by the services involved • Adopting a relaxed attitude in the interview in a time and location of the participant's choice to promote honesty in informants • Information from multiple carers or care workers and use of documents to aid triangulation of data sources • Frequent debriefing with supervisor • Written reflective diary kept during research and issues discussed with supervisor • Checking of transcription and coding accuracy by supervisor • Dissemination focus group-like approach in preference to member checking- described in more detail in next section • Description of the background, qualifications and experience of researcher within the thesis • Rich, thick description of the cases in Chapter 3 and Appendices 3.1 – 3.11
Transferability	• Background data to cases provided in Chapter 3 and Appendices 3.1 – 3.11 • Context of study established in Chapter 2 • Quotes and evidence from all cases included in Chapters 4 - 7 and Appendices 3.1 – 3.11
Dependability	• Methodology described to allow study to be repeated in Chapter 2
Confirmability	• Triangulation used to reduce investigator bias • Researcher's beliefs and assumptions described in the introduction to the thesis, Chapter 2 and Chapter 9 • Methods described in Chapter 2 • Limitations of study acknowledged in Chapter 9 • Audit trail of all aspects of research process kept

Dissemination Check

Although member checking of the data after transcription is a potential strategy for enhancing credibility, concerns of memory and recall for participants with LD and then who holds the ultimate responsibility for overall interpretation of group interviews, limited the value of this strategy. However, it was important to explore whether the findings resonated with the LD community, ascertain if any key issues had been missed, and explore future dissemination strategies. This concept has been described as a 'dissemination focus group' in the literature and describes a situation where new participants explore and clarify research findings together, with a particular focus on how the findings could be disseminated (Barbour 2005). Focus groups typically involve 4-10 participants (Morgan 1996; Kitzinger 1995). However, in order to ensure an interview that could fully

explore the views of people experienced in the LD sector it was decided to only invite two people (a local LD Service Manager and LD Charity Manager) to formally participate in the research. Although this reduced the breadth of views it enhanced the depth of views from two experts in the field. However, as there were only two participants, it cannot be termed a focus group. Both participants were emailed a copy of the key findings, asked to read through and consider the following before meeting together with the researcher:

Q1 Are the results credible and do they ring true with your experience?

Q2 From your perspective, what are the most important point(s) about adults with LD's experience of medication?

Q3 Are there any important points about medication experience in adults with LD that you think are missing?

Q4 What issues raised in the research would be most applicable to your current place of work?

Q5 How do you think health care professionals could better support adults with LD with respect to their medication?

Q6 How do you think this information could be best used to improve adults with LD's experience of medication?

The dissemination check was not audio-recorded. Extensive notes of the discussion were taken by the researcher. The wording of the key points for each question were agreed by the group during the meeting.

Reflexivity

The research was undertaken in the 'real world' so the research was anchored in a pragmatic worldview. Approaching the research as both a HCP and researcher and focusing on the impact the research might have in the 'real world' has significantly shaped and influenced the research process, particularly the practical aspects. As highlighted by Maxwell (2012), using knowledge of settings and issues gained from prior clinical experience about the settings to optimise the research process and maximise the impact from the research can be viewed positively. However, it does have to be acknowledged that this may conversely cause bias and negatively impact the quality of the research. A more detailed background to the researcher and motivation for the research is provided in the introduction to this thesis. Ensuring transparency was a key focus throughout the research process and so a reflexive diary was kept throughout; thoughts and experiences were to be discussed regularly with the academic supervisor in order to minimise any bias. A final reflexive account is given in Chapter 9.

2.12.7 Research Governance within this Research

Review of Research Proposal and Plans

The Scientific Officer linked to the Adults with Incapacity Research Ethics Committee (AREC) in Edinburgh advised that it was not necessary to seek ethical approval from the North of Scotland Research Ethics Service or from the AREC because the participants were not being recruited as NHS patients; and also because there was no involvement of NHS staff as participants, NHS facilities or NHS data. It was, therefore, only the RGU School of Pharmacy and Life Sciences (P&LS) Ethical Review Panel that reviewed and approved the proposed research. This review checked that all appropriate safeguards for participant and researcher were in place and that the research would be in accordance with the RGU Research Governance and Integrity policy (Robert Gordon University 2016a). At the time of research, the active legislation governing data management was the Data Protection Act (1998) and the RGU School of P&LS Ethical Review Panel ensured that processes for acquiring, storing and managing data were all in accordance with the Act.

However, in addition to review by RGU School of P&LS Ethical Review Panel, the research proposal (aims and objectives; recruitment options; procedures and paperwork; and interview questions) were also reviewed for suitability by representatives of CASPA (now the Aberdeen Provider Forum), the research team and the Chair of the local LD support group (an individual with LD) who was keen to be involved throughout the research process. Questions were worded positively and a capability focus was retained in order to maximise acceptance of the research in the LD community. Ensuring all information and consent forms were available in easy-read, and adapting processes to ensure that adults with LD were included as far as is possible, were integral to the research proposal.

Safeguarding Vulnerable Adults

If during the course of the fieldwork, a participant raised an issue indicative of abuse (physical, emotional, financial, or sexual) the following protocol was agreed:

- Fieldwork will cease;
- The researcher will listen to what the individual says and will not ask any more research-based questions;
- The relevant LA's Adult Support and Protection team will be contacted by the researcher (the contact number for each LA's Adult Support and Protection team was added to the researcher's mobile phone);
- Depending on the allegation and advice from the Adult Support and Protection team, the legal welfare guardian or family or carer may need to be notified by the researcher;

- The issue, intervention and outcome will all be recorded in fieldwork notes whilst protecting identities of participants throughout;
- A discussion of the event with the supervisory team will take place and agreement reached on how to proceed and whether the case should be excluded from the research. If the team agrees that it can be included, the researcher will ask for formal consent for the data to be included from all relevant participants.

If during the course of the interview or fieldwork, a participant with LD became notably aggressive, distressed or distracted the following protocol was agreed:

- The interview or fieldwork will be suspended and a note made of this in the proforma;
- If not already present, carers will be contacted and the researcher will step back to allow the situation to be addressed and resolved;
- Advice will be taken from the carers as to whether to recommence, reschedule or terminate the interview and fieldwork;
- If fieldwork is to recommence or be rescheduled, advice will be taken from the carers on how to minimise a reoccurrence of the aggression, distress or distraction;
- The issue, intervention and outcome will all be recorded in fieldwork notes. A discussion of the event with the supervisory team will take place and agreement reached on how to proceed and whether the case should be excluded from the research.

Consent – Amended Process and Documentation

All information and consent forms were created in line with Health Research Authority (2017b) advice and with the input of LD charity representatives and an individual with LD. Easy-read versions of the information and consent forms for participants with LD were also created and used where appropriate. A selection of these information and consent forms can be seen in Appendices 2.3 – 2.8.

The following protocol for consent was agreed:

- Consent for the research to be obtained from the person with LD (if they had capacity) or from their welfare guardian, family representative, primary carer or care worker;
- If the person with LD had the capacity to consent:
    - Easy-read information sheets and consent forms were provided to the adult with LD and their primary carer or care worker;
    - The person with LD was able to discuss the research with whoever they chose;
    - Written or audio-recorded verbal consent was obtained a minimum of a week later;

    - Written or audio-recorded verbal consent was taken in the presence of a witness if the person with LD was not independently managing their medication;
- Written, signed consent from the senior manager of any formal Care Provider to access their medication-related documentation and to ask their staff to be interviewed was obtained;
- Written, signed consent from any care worker or carer participating in the research was obtained prior to interview and in the standard manner.

Inclusion, Making Choices and Involvement of Significant Others

Throughout the research process, advice on many aspects of the research was sought from a local LD service manager, an LD charity manager and from the chair of the local LD support group (an individual with LD). Wherever capacity and capability permitted, the person with LD who was the focus of the case study was asked to participate in the research and provide consent. Information was provided to participants with LD in easy-read format and more time taken to explain the project. In addition, the person with LD was given the option of having a known carer or care worker sit in with them during the interview to aid communication and provide support when required. Care was taken not to ask questions to which participants with LD would just acquiesce. If the person with LD lacked capacity, then their welfare guardian, family representative, main carer or care worker provided consent and was invited to participate in the research.

Boundaries

From the outset of fieldwork, the researcher emphasised to the person with LD and their carer or care worker that they were only going to be visiting once or twice to ask them questions about their medicines. This was to provide clarity about the reason for the researcher in their life and about the temporary nature of the involvement.

If during the course of the fieldwork, a medication issue is identified requiring intervention from the researcher as a HCP, the following protocol was agreed:

- The researcher will make a note during the interview or time of observation to deal with afterwards unless there is the potential for immediate harm;
- If there is the potential for harm, the researcher will intervene immediately to ensure the safety of the person;
- Whether or not fieldwork will continue or be postponed will depend on the situation;
- The issue, intervention and outcome will all be recorded in fieldwork notes;

- A discussion of the event with the supervisory team will take place and agreement reached on the effect of this on the data collected and how to highlight this in the formal write up;
- If required, the researcher will follow the incident up with the individual, relevant HCP, social care professional and care provider.

Data Protection

All data were collected, stored and handled in accordance with the RGU Research Governance and Integrity Policy (Robert Gordon University 2016a), the Research Council UK Common Principles on Data Policy (Research Councils UK 2015) and the data legislation which was active at the time of research, the Data Protection Act (1998).

All case studies were assigned a number and a pseudonym; other participants were assigned an identification number linked to the case study. Suitable folders were created on the researcher's secure 'R' drive on RGU password protected servers only accessible to the research team. All data files were named to include the case identification number, the data source, the participant identification number and the date of data collection.

Paper consent forms were scanned into an electronic version and stored in a separate password protected file in the researcher's 'R' drive in RGU and the paper versions shredded and disposed of in confidential waste. Digital data (audio recordings and photos) were uploaded directly into the researcher's 'R' drive in RGU and saved into the appropriate case study folder. Written information from care provider records and any written observations were scanned into an electronic version and then uploaded into the researcher's 'R' drive in RGU and saved into the appropriate case study folder. Typed interview transcripts were uploaded into the appropriate case study folder. The researcher's reflective diary was scanned at the end of the research process and the paper version shredded and disposed of in confidential waste. After uploading, photos were then deleted from the original device; digital audio recordings were deleted from the recording device after transcription was completed. All the data is archived in the researcher's RGU folders in password protected files for 10 years.

Once data were redacted of any person identifiable information, it was held temporarily on the researcher's password protected personal laptop or tablet in a password protected file for data analysis; it was deleted from this laptop once analysis was complete.

All data within this research will be presented anonymously; only pseudonyms will be used. References to named health and social care professionals, places and local services have been redacted from the data. In addition, care has been taken to balance the methodological requirement for 'rich, thick description' with the need to ensure all participants retain their anonymity.

2.13 CHAPTER SUMMARY

First of all, this chapter provided a brief outline of research worldviews; ontology, epistemology, axiology and methodology within these worldviews; and the most common methodological approaches. Following on from this, qualitative methodology and then case study methodology were outlined. Strategies for qualitative data analysis and for promoting trustworthiness, reflexivity and transferability throughout the research process were then evidenced.

Then, this chapter considered both the general research governance requirements and the more specific research governance requirements when involving adults with incapacity in research. Issues of pertinent legislation, informed consent, inclusion, literacy, health literacy, involvement of significant others, capability, safeguarding and establishing relational boundaries were discussed. Legislation surrounding the storage of data was also outlined.

Finally, this chapter described the design of this study and outlined how it has been shaped by the methodological and research governance requirements and is appropriate for the research focus and population.

CHAPTER 3: CASE STUDIES SUMMARY

"A conversation where it is the desire for truth itself—on the part of both participants—that is truly listening and speaking... So, listen, to yourself and to those with whom you are speaking. Your wisdom then consists not of the knowledge you already have, but the continual search for knowledge, which is the highest form of wisdom... Assume that the person you are listening to might know something you don't."

12 Rules for Life: An Antidote to Chaos - Professor Jordan B. Peterson

3.1 CHAPTER INTRODUCTION

This chapter provides a brief summary of each individual adult with LD who was the focus of each of the ten case studies; full summaries are available in Appendices 3.2 - 3.11. The name used for each case is a pseudonym.

3.2 CASE STUDIES SUMMARY

Eleven community-dwelling adults with LD or their care worker or carer volunteered to participate in the research; all eleven adults with LD met the pre-determined case study inclusion criteria and were recruited as detailed in Section 2.12.2. Consent to participate in the research was obtained from all participants as outlined in Section 2.12.7.

Each case study was allocated a unique case identifier which consisted of a number, the letter C or N, and a pseudonym for the adult with LD. The C or N was to indicate whether the adult with LD who was the focus of each case study had **C**apacity to consent or **N**ot to the study. With the first case study, Case01N, the care workers were not able to participate at the time of the research. As there was no opportunity to triangulate the interview data from the parent of Case01N, and because the structure of the interview was altered, the interview was considered a pilot and accordingly, data from that interview were not included in the full study results. This resulted in ten cases providing data for the study: 02N-Anna; 03N-Paul; 04N-Jamie; 05N-Rob; 06C-Mark; 07C-Fiona; 08C-Ruth; 09C-Donald; 10C-Susan; and 11C-David. As noted in Section 2.12.2, within case study methodology, ten cases are accepted as allowing for aggregation of evidence.

For all presented data in the thesis, the type or source of the data follows the case identifier except if the source was from the interview with the adult with LD. In this instance the data source will just be labelled with the case identifier. Carers and care workers have been differentiated as 'Carer' and 'CareW' respectively, and then allocated a number which was appended to the case study identifier.

Data were collected as outlined in Section 2.12.3. All interviews were conducted face-to-face except for Case04N-Jamie-CareW02 and Case05N-Rob-CareW03 where the interviewee indicated their preference for a telephone interview. With interviewee permission, all interviews were audio-recorded; interviews ranged in length from 20 - 80 minutes. Although the research was based on the PLEM conceptual model, as detailed in Section 2.12.4, and participants were provided with a list of proposed interview questions, as detailed in Appendix 2.1, a neutral stance was maintained and participants were not pressed to provide answers for all sub-themes covered in the model.

Accordingly, there are some areas of PLEM where none of the participants provided data and this has been noted in the results. As outlined in Chapter 2, other case study data were gathered either before or after interviews, depending on what was most convenient to the participants. Dependent on the number of participants being interviewed and the availability of written records, data collection times for each case study took between one and four hours.

A summary of all data and identifiers for each case study can be found in Table 3.1. As noted in Section 2.12.3, all medical and pharmaceutical information was gathered from interview, observation or written record. Only prescribed medication has been noted within the table. Within the results and discussion, bought (OTC) medicines are, however, referenced. Written records included Care Provider records, MAR charts, and repeat prescription re-order slips. The majority of data were from interviews. If inconsistencies with data, e.g. current dose of a medicine, were discovered, every attempt to resolve the issue with the relevant participants. If this was not possible, the inconsistency was noted.

Appendices 3.1 - 3.11 contain a detailed summary of each adult with LD who has been included as a case study in this research. As previously discussed in Section 2.12, every care has been taken to balance the methodological requirement for 'rich, thick description' with the need to ensure all participants retain their anonymity.

Table 3.1 Summary of case study identifiers and data sources

Case and pseudonym	*Age (years)*	*Gender*	*Severity of LD*	*No. of prescribed medicines (regular)*	*Living arrangements*	*Who is responsible for ordering medication?*	*Who is responsible for administering medication?*	*Interviews*		*Observations/other Data Sources*		
								Adult with LD	*Carers and Care Workers*	*Photos*	*Written records*	*Fieldwork notes*
01N-Pilot	*46*	M	Severe	Not confirmed	Small care home	Care workers	Care workers	no	Carer01-PILOT	no	no	no
02N 'Anna'	26	F	Severe	8	Shared care: 1 month in family home & 1 month in residential accommodation	Parents	Parents and care workers	no	Carer01 CareW02 CareW03 CareW04 CareW05	yes	yes	yes
03N 'Paul'	31	M	Severe	6	Small care home	Care workers	Care workers	no	CareW01 CareW02 CareW03 CareW04	yes	yes	yes
04N 'Jamie'	21 (at time of death)	M	Severe	20	Family home	Parents	Parents and care worker	no	Carer01 CareW02	no	yes	yes
05N 'Rob'	20	M	Severe	12	Shared care: home of formal carer ('adoptive parents') with some weekends & holidays with family	'Adoptive parents'	'Adoptive parents'(care workers); parents; additional care worker	no	CareW01 Carer02 CareW03	yes	yes	yes
06C 'Mark'	54	M	Moderate	5	Room in residential accommodation	Care Workers	Mark (but under supervision of care worker)	yes	CareW01 CareW02 CareW03 CareW04	yes	yes	yes

Case and pseudonym	*Age (years)*	*Gender*	*Severity of LD*	*No. of prescribed medicines (regular)*	*Living arrangements*	*Who is responsible for ordering medication?*	*Who is responsible for administering medication?*	*Interviews*		*Observations/other Data Sources*		
								Adult with LD	*Carers and Care Workers*	*Photos*	*Written records*	*Fieldwork notes*
07C 'Fiona'	46	F	Mild-moderate	4	Flat in residential accommodation	Care Workers	Fiona (but under supervision of care worker)	yes	CareW01 CareW02	yes	yes	yes
08C 'Ruth'	55	F	Mild-moderate	14	Flat in supported accommodation	Care Workers	Ruth (care workers supervise administration of one drug)	yes	CareW01 CareW02 CareW03 CareW04	yes	yes	yes
09C 'Donald'	29	M	Mild	4	Flat	Donald	Donald	yes	no	yes	no	no
10C 'Susan'	59	F	Mild-moderate	7	Flat in supported accommodation	Care Worker attached to supported accommodation	Susan	yes	no	yes	no	no
11C 'David'	68	M	Mild	5	Flat in supported accommodation	David	David	yes	no	yes	no	no

3.4 CHAPTER SUMMARY

This chapter provided a summary of the process for the identification of case studies, data collection and data analysis. Full summaries of the case studies are available in Appendices 3.1 - 3.11.

CHAPTER 4 RESULTS – MEDICATION RELATED BURDEN

'In God we trust, all others must bring data'

W. Edwards Deming

4.1 CHAPTER INTRODUCTION

This section will focus on medication related burden - the first section of PLEM as outlined in Figure 4.1 below:

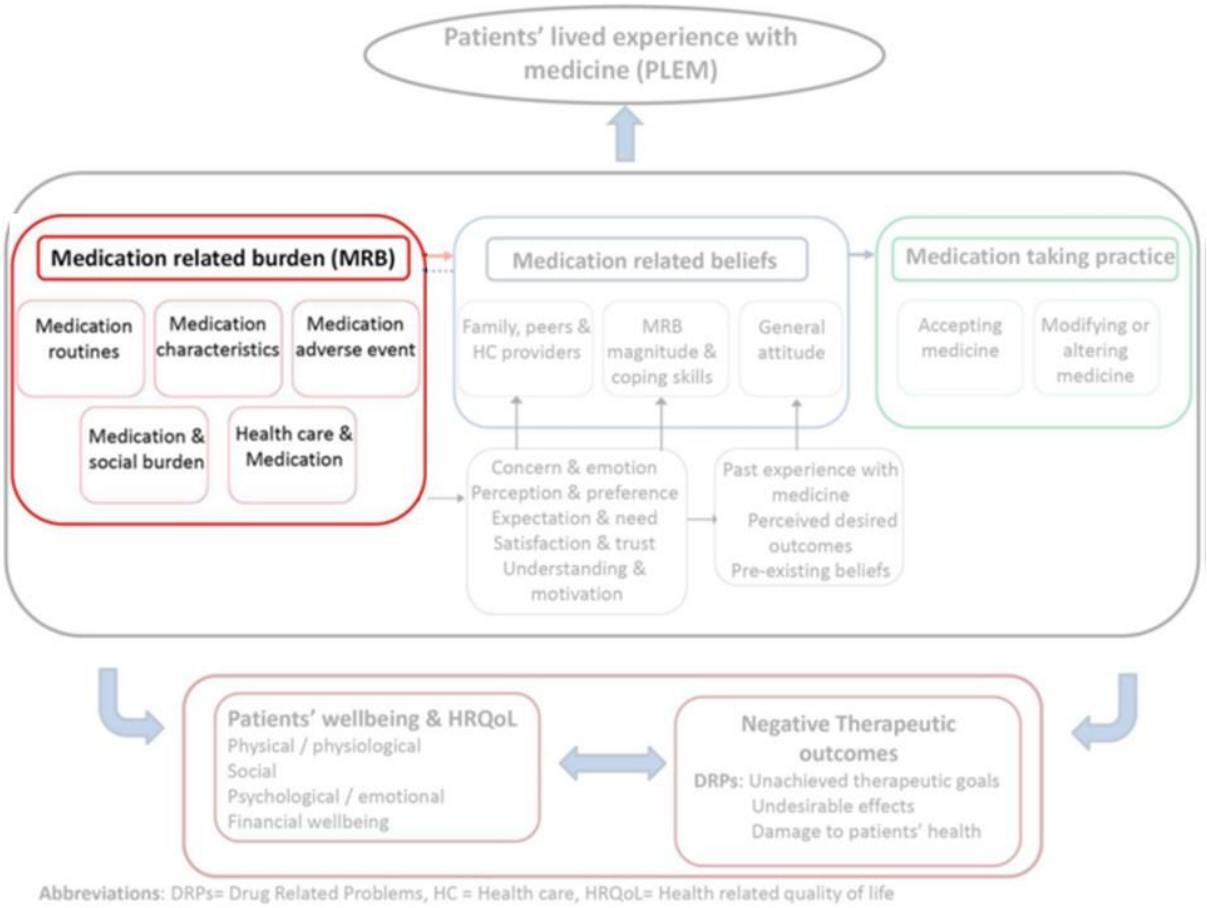


Figure 4.1 PLEM - medication related burden

As can be seen within the conceptual model, the first section of PLEM (medication related burden) contains five themes: medication routines; medication characteristics; medication adverse event; medication and social burden; and health care and medication. Within the study by Mohammed, Moles and Chen (2016) examples (or sub-themes) of each of these five themes were also listed and these are detailed in Table 4.1. These themes and sub-themes were used to structure the results that will now be presented within this chapter.

Table 4.1 Medication related burden themes and sub-themes

Theme	Sub-theme
Medication routines	General strategies to manage medication routines
	Time required to manage medication
	Adapting life to suit medication routine (intentional)
	Adapting life to suit medication routine (unintentional)
	Adapting medication routine to suit life (intentional)
	Adapting medication routine to suit life (unintentional)
Medication characteristics	Complexity of the number of medicines
	Pill size and shape
	Exchange of medication brands
	Challenges of packaging
	Additional instructions
Mediation adverse event	No experience or not recognised
	Previous negative experience
	Anxiety of future occurrence
	Impact on belief and behaviour
Medication and social burden	Medication impacting social life (positive)
	Medication impacting social life (negative)
	Influence of 'significant others' (positive)
	Influence of 'significant others' (negative)
	Stigma from medication use
Health care and medication	Time spent dealing with healthcare appointments or services to get medicines
	Practicalities of accessing, obtaining or adhering to medicines
	Inadequate, conflicting or contradicting medication information
	Lack of consideration for patient's lived experience from health care professionals
	Lack of continuity or co-ordination of prescribing

4.2 MEDICATION ROUTINES

4.2.1 General strategies to manage medication routines

Carers and care workers cited using visual or audio reminders to remember to give the required medication:

> *'We've got the medication board with the times. And if there's a time that's new – say an antibiotic – we'll set an alarm or something.'* Case02N-Anna-CareW03

> *'They [medicines] live in the kitchen cupboard and the boxes that are in use live on the window sill [see Figure 4.2] which is perhaps not ideal but if I leave them hiding in the cupboard I will forget.'* Case02N-Anna-Carer01

Figure 4.2 Case02NPhoto08 Storage of medicines in use at home (kitchen window sill)

Adults with mild LD often highlighted their capability with respect to remembering when and how to take their medication:

> *'I think I just must remember. I don't need to set reminders or nothing.'* Case09C-Donald

> *'I get up, answer my front door, they give me a key, I open my cabinet, I take out my box of cocodamol, my fluoxetine, my lactulose. 'Cause I know that's the three that I take in the morning. I fill my glass with water, put my two cocodamols in it. It makes a hissing noise which is good. I take my two fluoxetine at the same time 'cause it's easier to swallow. Then my lactulose.'* Case07C-Fiona

One care worker of an adult with moderate LD commented on his capability to remember and administer his medicines:

> *'He actually even reminds us about his 1pm meds. He'll come through… And automatic first thing in the morning – he's out of bed and he knows to himself that's what he does – he gets his tablets before he'll sort of go for a wash or whatever in the morning.'* Case06C-Mark-CareW01

Medicine routines were often simplified or amended to maximise the chances of successful administration:

> *'Well I eventually got them into a blister pack [pharmacy-filled] so it's easier for me taking them so I know which day I've taken them…I'm quite happy with the blister pack 'cause I can handle it better.'* Case10C-Susan

> *'The morning routine when he has his first lot of medicine and his gagging with his reflux – I don't like that but that's just Rob so we've learnt to sit him up, don't rush him.'* Case05N-Rob-Carer02

Sometimes medication was taken or administered in a specific order:

> '*She takes her tablets the same way every day. It's the same tablets…just say it's the blue one first, and then the green ones and then the white ones. She does that every day. That's the way she takes her tablets…She has to take them in that certain [way] – she can't take the green one first 'cause that would be out of sync.'* Case08C-Ruth-CareW04

> *'So I went in and I was using the MAR [medicine administration record] sheet. And then I just go down, one by one – so I do it one at a time… And then I have my own kind of order for putting them in [the PEG tube]…'* Case03N-Paul-CareW04

Two carers stated the way in which the medicine routine is just seen as a normal part of life:

> *'To be truthful, his younger brother can help us – the kids like being involved in Rob's care. And it makes it a normal part of life. There's no scariness. "Oh, can I do his meds tonight?" – of course you can, c'mon then. It's not a big deal.'* Case05N-Rob-Carer02

'But it's just part of what she does, it's just part of routine, it's part of life…it's what she does, it's the same as getting your hair brushed and teeth brushed, it's just what happens.' Case02N-Anna-Carer01

4.2.2 Time required to manage medication

In general, time required to manage medication was not cited as a burden except by one care worker:

'So, maybe I took a lot longer because obviously Carer01 and her husband were a lot more adept at it and quite confident about what they were doing. I was a bit slower; and Jamie was very patient with me!' Case04N-Jamie-CareW02

One carer commented on the time benefits of administering medicines via a PEG tube, demonstrating the positive impact of a change of route of administration:

'It's a five min job, not even five mins – a squirt here and there, 'cause there's only four or five medications that he has and it's done in seconds.' Case05N-Rob-Carer02

4.2.3 Adapting life to suit medication routine (intentional)

Working the day's activity around the medicine routine was noted:

'… Out and then make sure you're back at this time for medication.' Case03N-Paul-CareW04

'Well, like I was saying, a Monday morning I've to take the, the what do you call it, 30 mins before I start eating…[then] through to the toilet, manage a shave, come back and well I'll have my cereal then…I have my lamotrigine, aye, just before I start eating and once I've had, I take my…, that's it, that's the order...' Case11C-David

In addition, the need to ensure the daily routine adhered to the same medicine routine was highlighted for one adult with LD:

'He doesn't like change does he?...He likes the normal routine…He's got a structure he's to follow – like a weekly timetable. If that's not followed right down to the tee then it'll knock him and it'll increase his anxieties as well.' Case06C-Mark-CareW03

4.2.4 Adapting life to suit medication routine (unintentional)

No data with this theme was provided by any of the cases during the research.

4.2.5 Adapting medication routine to suit life (intentional)

One carer gave two examples of how she adapted the manner of medicine administration to suit:

> *'So yeah, they may go into a spoonful of yogurt or something…if you feed someone yogurt it tends to go down as a one-er, as a gulp so if you put the tablets in that it's not like you're having to get them over so they will go down….'* Case02N-Anna-Carer01

> *'I got a leaflet [for midazolam]…It's like, "open the mouth and put it into the cheek". Well the teeth are clamped firmly shut 'cause she's in a seizure and "drizzle a little in either side". No, just whack it in and hope for the best. I know that if she swallows it, it doesn't work as well but you have to realise that you are probably wrestling her around the carpet at this point so you're not worried about the niceties really!'* Case02N-Anna-Carer01

Care workers for another adult with severe LD highlighted how they adapted the timing of the medicines to suit:

> *'The debate is whether we should actually give him it once he's up and washed and dressed. I know he's meant to get it at 8 o'clock and it's sometimes a case of let sleeping dogs lie – leave him to sleep and once he's wakened and if the bathroom's busy, give him his meds. Or whether you should say, right, let's just leave him and once he's upright. 'Cause like this morning he had to wait, got his meds and then he spewed them all back up again. And you think, well that's defeating the purpose 'cause how much is still inside you?!'* Case03N-Paul-CareW03

> *'Because if you're holding the [PEG] tube and he starts to kick off he can hit it and bang it about…you're kind of in a dilemma…you've just got to kind of soothe him at that time – to soothe him and calm down…if he's still kicking off then you have to stop at that moment until he's calmed down. There's no point in carrying on while he's in that mood.'* Case03N-Paul-CareW04

4.2.6 Adapting medication routine to suit life (unintentional)

No data with this theme was provided by any of the cases during the research.

4.3 MEDICATION CHARACTERISTICS

4.3.1 Complexity of the number of medicines

None of the carers or care workers in the cases found the complexity of the medicines an issue for themselves. One care worker was aware of the impact of additional medicines for one adult with mild-moderate LD:

> *'As long as it's one tablet – he couldn't do it with heaps – but with one or two I think he would cope with knowing what it's for.'* Case06C-Mark-CareW01

For one adult with LD the complexity of her medicines necessitated a multi-compartment compliance aid (MCA), commonly referred to as a blister pack:

> *'If they're not in a blister pack I can't manage them – if they're in boxes.'* Case08C-Ruth

4.3.2 Pill size and shape

Pill size and shape was only cited an issue for one adult with severe LD; possibly due to the fact that the other three cases received their medicines via a PEG tube (so pill size and shape were not an issue):

> *'…she doesn't have any manipulation issues for too small; too big can be an issue particularly when people think they are doing us a favour by reducing the number [of tablets] we have to take without consultation.'* Case02N-Anna-Carer01

However, for one of the cases with a PEG tube, the need to accurately halve and then administer this half tablet (crushed) was cited as a challenge:

> *'He's got baclofen now which is tablet form and it's got to be crushed. And because he's only on a half it's the tiniest – to crush it (to be quite honest) the powder – where is it?!'* Case03N-Paul-CareW01

Swallowing difficulties with larger tablets were cited as an issue by adults with mild-moderate LD:

> *'I'm not good at swallowing tablets… The fluoxetine are the only size of capsule that I can take.'* Case07C-Fiona

> [When asked about size of tablets being an issue]:
> *'Yes. Sometimes I can't get it down so they've got to change it to another method.'* Case08C-Ruth

4.3.3 Exchange of medication brands

In two cases, having the prescription for an epilepsy medicine changed by the prescriber from a branded product to a generic product was noted to adversely affect clinical control of the adult with LD's epilepsy in two cases. Of note is the contrasting timescales in resolving the situation.

> *'…we had been on Lamictal for ages, and then we just started getting lamotrigine but it was never the same lamotrigine twice... her control went off and she was having a lot more seizures. I spoke to the consultant and she…wrote to the GP. So it took a few months to get it but we got it back.'* Case02N-Anna-Carer01

> *'I was very careful about using the named brand against the generic brand because I did find differences with him with the epilepsy medication and immediately had to go back onto the named brand.'* Case04N-Jamie-CareW01

Changing the brand or presentation of medicine boxes also caused a degree of confusion:

> *'I think sometimes when you get the own brands people aren't aware and they think, "Oh! That's not the same!" But then you think no, that is the same, it's just the own brand…it's the same stuff but just a different company they are using – or a cheaper tablet.'* Case03N-Jamie-CareW03

> [When asked about the boxes of medicines looking different each time]:
> *'I get confused.'* Case08C-Ruth

4.3.4 Challenges of packaging

Sometimes the packaging was noted to affect the ease of access to the medicines by adults with mild LD:

> *'I've got my new box of cocodamol but I don't like the foil paper. It's too sharp. It's still the same, it's still the same name – cocodamol – it's just in foil….The one that I'm using now is easier to open* [See Figure 4.3] *…'* Case07C-Fiona.

Figure 4.3 Case07CPhoto08 Two brands of cocodamol

> *'I don't like taking them out of that [compliance aid] packet. They're fiddly and sometimes you lose the tablet.'* Case08C-Ruth

One carer noted the impact of a change of packaging to ease of administration:

> '*I don't like how they've changed the domperidone bottle. It used to be a plastic bottle so you could put the syringe in it. And they've put it to a glass bottle so the syringe doesn't go into it…So before I would take the bottle and tip it up 'cause a 20ml syringe would fit into the bottle without leaking but now you've got to tip it into a container and suck it up [into the syringe].'* Case05N-Rob-Carer02

Within one case, packaging was not perceived to be an issue by the adult with LD, but the care workers had noticed a potential problem:

> *'The only thing we have to keep an eye on sometimes is the fluoxetine packets. He'll think it's empty sometimes. You've to check it 'cause he will be quite rushed and think oh it's finished so I'll put it in the bin. So that's the only thing you've really got to watch for.'* Case06C-Mark-CareW02

An instance of packaging causing a challenge was observed when Susan (Case 10C), attempted to demonstrate how she was able to puncture the back of her MCA pack. Instead of opening an empty blister she inadvertently opened a future blister containing medicines.

4.3.5 Additional instructions

No data with this theme was provided by any of the cases during the research.

4.4 MEDICATION ADVERSE EVENTS

Throughout the cases, carers and care workers of adults with severe LD would mention, unprompted, numerous adverse events including adverse drug reactions (ADRs), that is unwanted or harmful effects. However, when asked specifically if the adult with LD had experienced ADRs they would often respond to say this was not the case. Furthermore, these events did not necessarily translate into an associated burden or adversely affect their view of medicines. Specific side-effects, withdrawal, allergy or other negative experience with medication were rarely cited by adults with mild-moderate LD.

4.4.1 No experience or not recognised

In three cases (Case 05-Rob; Case 08-Ruth; Case 09-Donald) it was cited that adverse effects had not been experienced yet at another point in the interview, adverse effects were highlighted.

4.4.2 Previous negative experience

For the adults with severe LD, multiple instances of adverse effects from different medicines were noted and examples were provided to illustrate the issues encountered:

> ***Case 02N-Anna***
>
> *'…when she was given phenytoin [Anna] became very flushed.'* Case02N-Anna-Letter from neurologist 2012 (care workers' documentation)
>
> *'…mum said to me that she thought she knew what had caused [Anna]'s extreme breakdown in behaviour… rapid withdrawal of tramadol and dihydrocodeine.'* Case02N-Anna-Letter from neurologist 2011 (care workers' documentation)
>
> *'…but the Epilim [sodium valproate] turned her into a – she was terrified of the world, terrified of everything- she just lived in a corner, back to the wall – was just terrified of everything.'* Case02N-Anna-Carer01
>
> *'To begin with she was fine but then as the dose [of levetiracetam] increased she got very anxious, very agitated, very easily pushed to the point of lashing out and reducing it took that away so obviously it was [the problem].'* Case02N-Anna-Carer01

'She has been on topiramate at higher doses in the past (200mg twice daily) but by that dose we felt it was affecting her cognition…' Case02N-Anna-Letter from neurologist 2012 (in formal care workers' file)

Case03N-Paul

'…he used to sweat profusely and we'd be changing his clothes constantly and washing him down…But that did actually dope him up – that did dope him up and he were really sleepy on haloperidol.' Case03N-Paul-CareW02

'… just recently we had a bit of a mix up and started to wean him off the risperidone. It were [sic] a confusion…and the sweating came back – profuse sweating came back and it exacerbated his behaviour as well – the screaming got worse until we got him back on it and everything was sorted out.' Case03N-Paul-CareW02

Case04N-Jamie

'I got the midazolam in its infancy...and what I discovered at that point was that his heart rate was slowing down when I was using it that method.' Case04N-Jamie-Carer01

'…they started him on baclofen for his muscle tone - which at the first was oral baclofen. And yes, it helped but it's also a drowsy - it makes them drowsy. So yes, for a period he was very stable but for a period we saw issues with his cognitive abilities – he seemed to slide a bit.' Case04N-Jamie-Carer01

'They then thought they need to replace the baclofen implant – they thought there must be something. And it was withdrawal of baclofen. He was suffering terrible withdrawals from the baclofen because he was in distress for the whole five weeks he was in hospital.' Case04N-Jamie-Carer01

'…he was getting this baclofen implant…but what we didn't know was that he was developing a very rare syndrome through it…arachnoiditis…it's adhesions up the spinal canal and it causes adhesions. And it causes a multitude of symptoms because of course it's affecting all the nerves that come out of the spine.' Case04N-Jamie-Carer01

'Epilim [Sodium Valproate] …It was the one that worked –it was working well for him. But obviously we were working on tablets because as I'd spoken to you before, we discovered he had a rare allergy to red colouring in medications…' Case04N-Jamie-Carer01

'The only thing I used to recognise was that when you used the nebules, salbutamol of course, his heart rate would go up.' Case04N-Jamie-Carer01

Case 05N-Rob

'Started him on Epilim [Sodium Valproate]. His mood went down…' Case05N-Rob-Carer02

'I actually called the paramedics out because I thought I'd OD'd [overdosed] him…because he was so drowsy [from the midazolam].' Case05N-Rob-CareW01

In addition, other negative experiences of medicines were noted for adults with severe LD in relation to the route of administration:

'The old omeprazole when I had the tablet form of it – which was little tiny balls. And that was a flaming nightmare!... I did manage to unblock [the PEG tube] but what I found was, that a couple of times it actually damaged the thing.' Case05N-Rob-CareW01

'But one carer that we had thought that he got a sexual thrill out of that [insertion of suppositories].' Case03N-Paul-CareW02

'…somebody thought it would be a good idea to give him a barium meal…I gave him this barium drink and then laid him down. Immediate emergency! They had to pump him out and he lived with tiny flecks of barium in his lungs all his life.' Case04N-Jamie-Carer01

'The nurses were coming in and doing the pen drive [syringe driver] every day. The only thing that I was a bit upset about was that he got an ulcer or something where it was in the thigh…so they swapped to the other leg.' Case04N-Jamie-Carer01

For one case (Case 08C-Ruth), an adult with mild LD, several ADRs were highlighted:

'I was on a cream for my back. It was called Voltarol [diclofenac]. And they put it all over my back twice a day and I had side-effects there. I could hardly breathe. I was feeling sick and everything. They had to get the doctor out I think.' Case08C-Ruth

'Ibuprofen was in it. And she was like [mimics gasping for breath] So we got the paramedics in.' Case08C-Ruth-CareW04

'She was on that sleeping tablet [zopiclone] and it really made her angry and withdrawn and when she didn't get it [during a trial stop] she was quite aggressive.' Case08C-Ruth-CareW04

'She was the same on Sevredol [morphine] with the spike in morphine. If she didn't get that she became quite angry…She was falling asleep on the Sevredol…Initially when she would take it she would be zonking out and she was falling asleep at her daughter's through the day and then in the afternoon just falling asleep on the chair.' Case08C-Ruth-CareW01

'Aye, I stopped it [all painkillers including morphine]. I paid for it because I was sick and everything. Cold sweats and I had to go back on it after two days.' Case08C-Ruth

'But then it's kind of ruined the lining of her stomach all these years taking all these medications without eating properly. She's kind of made herself ill with doing it and persisting with it.' Case08C-Ruth-CareW02

Addiction to opiates was also noted to be an issue for another adult with mild LD (Case07C-Fiona):

[Cocodamol] '…you can get addicted to cocodamol. And she was wanting it more and more sometimes…She used to always come down before we managed to cut it to twice. She could get it four times a day was it? And she kept coming down, "I'm sore, I'm sore", and we were wondering if she was getting addicted to it?' Case07C-Fiona-CareW02

4.4.4 Anxiety of future occurrence

Despite the multiple instances of negative experiences of medicines, anxiety about future occurrence was not expressed.

4.4.5 Impact on belief and behaviour

The occurrence of negative experiences with medicines, even those that had impacted more severely on the adult's quality of life, did not appear to significantly affect beliefs and behaviours in relation to medication. As noted previously, potential side-effects from medication, affected the beliefs of Susan (Case10C), an adult with mild LD:

'If you change a tablet, you can get side-effects and I don't want that.' Case10C-Susan

4.5 MEDICATION AND SOCIAL BURDEN

Throughout all the cases there was little reference to medicines having a negative impact on the adult's social life. Instead medication had a largely positive effect on the adult's social life.

4.5.1 Medicines impacting social life (positive)

The positive impact that medicines have on the social life of adults with LD was stated implicitly in one case:

> *'Obviously it [medication] gave him a good quality of life in that he was able to go out and do the things he needed to do. He was never in the house. He was always out and about. It gave him strength. It allowed him to overcome some of the difficulties that other people I have met have had.'* Case04N-Jamie-CareW02

> [In reference to the medicines given during the palliative stage of his life]:
> *'It gave him more time and he was comfortable. We got the impression he didn't want to go anyway. He enjoyed his life. And it allowed him – he was at home for the last while- but it allowed him to receive visitors and people would come and say hello for a short time and he enjoyed all that social side of things. It just let him do that for him. He had his 21st birthday and then after that he kind of went downhill. And the end was fairly peaceful.'* Case04N-Jamie-CareW02

The supervision of medicine administration for adults with mild-moderate LD by care workers was seen not just as a necessary task but as a means of positively impacting the social life of the adult with LD:

> *'That's when she sees staff really…We only see her at medication time. Apart from when she's going out and she'll come down and sign the book to say she's going out to her activities and stuff. And I suppose it's probably she's lonely as well. So I suppose she likes the thought that the staff are going up.'* Case07C-Fiona-CareW02

4.5.2 Medication impacting social life (negative)

The negative impact of a medicine on a social outing was cited:

> [In reference to midazolam administration]:
> *'And I was with a couple of friends and I said, I'm going to have to take him home – he's gone really drowsy and I'm not sure what's going on.'* Case05N-Rob-CareW01

In one case, it was actually **not** having a suitable medication to help moderate behaviour that was impacting negatively on one adult with LD's social life:

> *'I think that if he was on something that made him calmer. …We try and keep it all about him but our staff team too are getting very stressed by it so you find that the behaviour escalates for him and people are withdrawing in a way 'cause they just can't cope. I mean some of us can cope and others really can't cope… I think people are frightened too because when he does go into a huge paddy [tantrum] it's like his blood vessels bulge, his heart races.'* Case03N-Paul-CareW01

> *'It's quite hard because our whole ethos of here is to be part of the community, be out there, doing normal things and it's harder and harder to take him now…we are vulnerable to the perception of the public.'* Case03N-Paul-CareW02

4.5.3 Influence of 'significant others' (positive)

For adults with severe LD, their 'significant others' are their only advocates and examples of how that was a positive influence were apparent in the cases studied:

> *'I thought it was worth going and seeing my GP and going and having a chat about his regime... I don't worry about speaking to my GP. And the neurologist I've known for years – I wouldn't hesitate to get advice from her either. I'm lucky in that way.'* Case05N-Rob-CareW01

> *'They [doctors] tried to reduce it [fluoxetine] a few years ago and I was at the GP appointment and I kind of disagreed and said it wouldn't have a very good effect if we were to reduce it. So we kept it as it is and it seems to be working.'* Case06C-Mark-CareW02

4.5.4 Influence of 'significant others' (negative)

However, the influence of 'significant others' also has the potential to be negative for adults with LD:

> *'But I know when he stayed in the family home, his sister – they weren't giving him his medication. So per chance he remembers the hard times he went through because of that. And that's the reason he was moved out. I think they were drinking quite a lot and he wasn't getting his medication. And they had to get him somewhere where they could be better organised.'* Case06C-Mark-CareW04

One adult with mild LD (Case 10C-David) described the influence of friends with regards to buying OTC products which could be considered potentially positive or negative depending on the knowledge and intention of those friends:

> *'Well, I've a few friends that recommended something for me…I would have gone in and bought the Strepsils on the strength of just doing what I've heard.'* Case11C-David

4.5.5 Stigma from medication use

No data with this theme was provided by any of the cases during the research.

4.6 HEALTH CARE AND MEDICATION

Carers and care workers of adults with LD cited numerous examples of health care burden in relation to the medication of the adult with LD. However, none of the adults with mild LD (who were all self-administering) made any reference to medication being a burden to them with regards to time, practicalities, accompanying information, consideration of their experience or lack of prescribing continuity.

4.6.1 Time spent dealing with health care appointments or services to obtain medicines

Although there was no reference made to the time spent dealing with health care appointments or services to obtain medicines, reference was made to the time required to obtain an answer to medication queries:

> *'Sometimes it's quite a while before the GP actually manages to get back to us.'* Case07C-Fiona-CareW02

> [In reference to contacting the pharmacist]:
> *'And at least that's a faster response than having to wait for phoning the doctor, get the doctor to phone back - or somebody to phone back. At least if we can phone the pharmacist, we've got an answer more or less right away.'* Case07C-Fiona-CareW02

4.6.2 Practicalities of accessing, obtaining and adhering to medicines

Although the practicalities of accessing and obtaining medicines were rarely mentioned by carers and care workers, the practicalities of adhering to medicines were frequently cited. General administration practicalities, practicalities associated with administering medicines via a PEG tube, practicalities faced by care workers in particular, and other issues were noted within all the cases:

General administration practicalities

The adult with LD not being well was cited as an issue for adhering to medication:

'…if she's had a prolonged seizure – she then obviously feels nauseous and then she won't take anything – she refuses everything so we have to get it down her…, someway or other.' Case02N-Anna-Carer01

Paul's reflux and vomiting were so severe that a PEG tube had to be inserted for feeding. Despite the PEG tube, Paul still vomits. Staff had kept a record of the number of instances of vomiting in the last 8 months up to October 2017: March (n=11); April (n=13); May (n=16); June (n=15); July (n=20); August (n=8); September (n=17); October (n=9). There were four recorded instances of medicines being visible in the vomit in the last eight months. Case03N-Paul-Fieldnotes

The issue of the adult with LD not being able to swallow medication safely was noted by one carer:

'It was very hit and miss in those early stages of getting his drugs down [orally, pre-PEG tube] and then obviously what we didn't know was how much was going into his tummy and how much he was aspirating.' Case04N-Jamie-Carer01

For one adult with mild LD, the size and visibility of the measuring cup graduations was an issue:

'I keep the same glass and the little medicine cup with the bigger letters, no numbers, so I can see how much I am putting in [for lactulose]. 'Cause I've got that little caps that you get on fluoxetine [sic – meant lactulose] bottles and I can hardly see the numbers on that. So the bigger [cup] I can read 'cause their numbers are better.' Case07C-Fiona

Administration practicalities of adhering to medicines administered via a PEG tube

Administering medicines via a PEG tube requires additional skills and can cause problems unique to that route of administration:

'The crushable tablets [Epilim] were a problem. They used to get stuck in the tube and it was sometimes a bit of an effort to try without distressing Jamie.' Case04N-Jamie-CareW02

[In reference to the PEG tube coming out of the stoma]: *'…one of the times it happened I had to give him all his medication orally which was hugely difficult and stressful for me. I*

managed to get the medication down him very slowly, very carefully… But it was stressful because I just knew I didn't want his stomach upset, I didn't want the epilepsy medication upset too much.' Case05N-Rob-CareW01

However, the PEG tube also aided adherence in one situation:
'…the only thing I can say with the gastrostomy more would be fluids - so if he's had a tummy bug at least I can get Dioralyte into him instead of having to stress over his mouth. Or if he's not wanting to swallow, at least I've got that.' Case05N-Rob-Carer02

Practicalities of adhering to medicines faced by care workers in particular
Care workers cited their issue of having to maintain skills for administering emergency medication for epilepsy seizures:
'If we haven't been the one that's been administering buccal [midazolam] for a while, it can be quite nerve-wracking you know. It's something that if you're not often doing, you start getting apprehensive…' Case02N-Anna-CareW03

Ensuring clarity of prescribed instructions was another practical issue they had to deal with:
'…if it says take Epilim 100mg twice a day, we have to put times for staff to follow 'cause obviously there's different shifts. So, we'll say 8am, 8pm. If staff miss giving it at 8am, and then we do a med count and we find at med count time that she hasn't had the morning meds, we have to get medical advice. And some of the GPs, well I've had them say, "As far as I'm concerned it's prescribed twice a day, I'm not caring what time – that's your company policy and procedures", and they won't give advice. And some of them are really good at giving advice.' Case02N-Anna-CareW03

Care workers also found themselves having to balance the needs of several service users all working to fixed timetables:
'Because if the residents and service users go to day centres. Our policy is two staff to administer meds whenever possible. Staff start at 7:30 and the service users will be picked up at 8:30/8:45. So we have a very short window to get four service users up, dressed, washed, breakfasted and medication.' Case02N-Anna-CareW03

Care workers also noted that only being able to follow the prescriber's instructions with regards to the administration of medicines sometimes caused problems between them and carers:

'We've had families go to the Care Inspectorate because we're following best possible practice (as in social care medication) and they've went to the Care Inspectorate 'cause they think we're being difficult.' Case02N-Anna-CareW03

Other practicalities

Care workers noted that having the responsibility to judge whether a 'when required' medicine should be administered is a practical issue for them:

'There's a conflict all the time…Yeah, you doubt yourself…It's your own judgement.' Case03N-Paul-CareWs01+02

4.6.3 Inadequate, conflicting or contradicting medicine information

Through experience, carers and care workers build their knowledge and understanding of medication. However, carers were able to recollect when this was not the case:

[In reference to the first prescription of rectal diazepam]:

'…and one of the GPs…said, "Oh well, we'll need to give you some of that to have at home…You stuff it up her arse and squeeze", I believe were the instructions I was given…I later discovered she should have been on her side with her knees folded up and I could have punctured her bowl. I didn't know.' Case02N-Anna-Carer01

[In reference to learning about medicines]:

'I mean it was a learning curve for us. As you say – very much a learning curve for parents.' Case04N-Jamie-Carer01

The problem of ambiguous dosage instructions was cited:

'You can have various difficulties in ensuring that it's easy for staff to follow and that there's no grey areas. Like, are we doing half or one and a half? It has to be clear. Staff, if they've been involved in med errors, they can end up having disciplinaries. So, we need to have it as clear as possible for staff to follow… It's just about ensuring everybody's clear and making sure that it reads clear on the labels.' Case02N-Anna-CareW03

Contradicting information was also noted:

> *'But there's some tablets if you read the instructions it says don't crush and yet we're being asked to crush them.' Case03N-Paul-CareW02*

> *'The only thing I remember was getting ear drops once and reading the leaflet and it said not to be given in a burst ear drum and of course he did have a burst ear drum.'* Case05N-Rob-Carer02

4.6.4 Lack of consideration for patient's lived experience from health care professionals

Carers cited instances of when their knowledge and lived experience was ignored:

> *'And also, sometimes having to stand up to professionals which I did have to. On a number of occasions, I had to be quite brave and stand up knowing that I was doing right by him… Ok you're the one with the qualifications but I know how his body works and I know him and I need to say this…I got the midazolam in its infancy...and what I discovered at that point was that his heart rate was slowing down when I was using it that method. I stood my ground in the hospital because they wanted to give him another dose and I said no. And I said his heart rate's reducing.'* Case04N-Jamie-Carer01

> [In reference to pain control during a hospital admission]:
> *'…and the nurses were doing their own thing with the medication… They couldn't get him, they could not get him – terrible!'* Case04N-Jamie-Carer01

> *'…ask any family carers and they'll tell you, there's a link between increased seizure activity and severe constipation. Doctors will say but there's no reason for that. And you say, but you're not living it. You speak to family carers and they'll tell you we see it; we absolutely live it.'* Case05N-Rob-CareW01

In addition, a response for a request for help was dealt with in a way which failed to appreciate the impact this might have on the care workers:

> *'So, he's got about six pages of proactive strategies and six pages of reactive strategies…and when we said we really do need help again, the psychiatrist got back to us and said do you want the psychology involved again? And it was like oh I don't know. That felt like they condemned us a wee bit – are you all working to this 100%?'* Case03N-Paul-CareW01

4.6.5 Lack of continuity and co-ordination of prescribing

The complexity of prescribing when both the GP and Specialist(s) were involved resulted in a lack of co-ordination with prescribing:

> *'I think sometimes too with medication we think we'd really like to try something else… but because we're going through psychiatrists and learning disability nurses and doctors, no change takes place really quickly…so you have your appointment with the psychiatrist and he might say, "Ok, we're going to introduce baclofen or pain relief or something…" Then we've got three or four weeks 'til it gets communicated down to start. So, he goes to a psychiatrist's appointment, and then two weeks later and like I say, everything's on computer so our doctor's looking at it – the letters are not physically coming to them now they're all [electronic].'* Case03N-Paul-CareW01

> '*But it's quite a delay now between a psychiatry appointment … and actually a change taking place. It's three or four months each time.'* Case03N-Paul-CareW01

> *'That's another thing that's changed you see. We used to get whatever letter was sent to the doctor [from the Specialist], we'd get a copy of but we don't get that now, it just goes to the doctor [GP].'* Case03N-Paul-CareW02

Within one case, the lack of a consistent approach to the prescribing of a hypnotic was noted:

> *'…the doctor that she has presently - another doctor had said this shouldn't happen – we had to do a sleep chart on her to not have the zopiclone but to get it reduced. But the doctor that said this isn't right, Ruth got angry with that doctor and they then also gave her it. And this was the doctor that said she shouldn't get this, this is outrageous – but then gave her it. It just seems strange – like she was the one saying no, why has she ever been allowed this? And then when it became her dealing with her, she gave her it as well in the end!'* Case08C-Ruth-CareW01

However, a positive example of communication regarding prescribing changes from health care professionals was also noted:

> *'We used to go to the doctor with her, but now she does it herself. If she got a prescription from the GP it would get kept at the GP practice and the pharmacy would come and pick it up… and we would get the information back from them and it would go into her dossette.*

But just recently, because we're not going down, she came with a letter telling us that her medication had been reduced so that we knew about it.' Case08C-Ruth-CareW02

4.7 CHAPTER SUMMARY

This chapter explored the medication related burden experienced by adults with LD in relation to the first section of PLEM (medication related burden) under the five themes of: medication routines; medication characteristics; medication adverse event; medication and social burden; and health care and medication.

CHAPTER 5 RESULTS – MEDICATION RELATED BELIEFS

'Life is choices, and they are relentless. No sooner have you made one choice than another is upon you'

Being Mortal: Medicine and What Matters in the End - Dr Atul Gawande

5.1 CHAPTER INTRODUCTION

This section will focus on medication related beliefs - the second section of PLEM as outlined in Figure 5.1 below. Due to the often limited ability to articulate belief, and the involvement of carers and care workers in many aspects of their life, beliefs of carers and care workers involved in supporting adults with LD with their medication have been included instead of, or alongside, the beliefs of adults with LD.

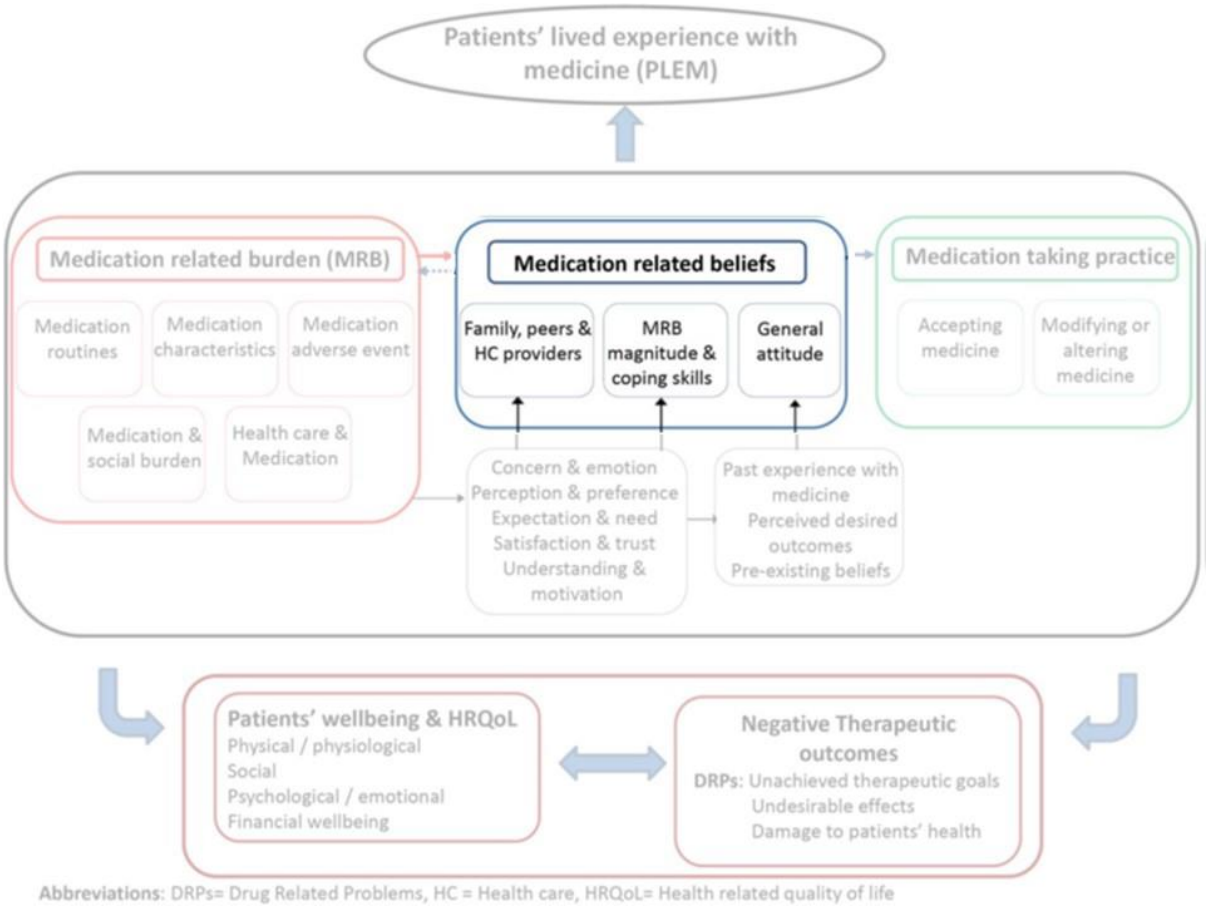


Figure 5.1 PLEM - medication related beliefs

As can be seen within the conceptual model, the second section of PLEM (medication related beliefs) contains three themes: family peers and health care providers; medication related burden magnitude and coping skills; and general attitude. Within the study by Mohammed, Moles and Chen (2016) examples (or sub-themes) of each of these three themes were also listed and these are detailed in Table 5.1. These themes and sub-themes were used to structure the results that will now be presented within this chapter.

Table 5.1 Medication related burden themes and sub-themes

Theme	Sub-theme
Family, peers, health care providers (normative beliefs)	*n/a*
Magnitude and intensity of medication related burden and coping skills (control beliefs)	Intensity of medication related burden
	Self-awareness of coping skills
	Ability to develop problem solving strategies
	Lack of medication information
	Lack of comprehension
	Unmet need or expectation
	Response to negative aspects of medication
General Attitude	Weighing up the burden and benefits
	Controls illness or disease
	Hope
	Prevents consequences of illness or disease
	Allows them to fulfil social roles
	Negative past experience
	Lack of perceived desired outcomes
	Preconceived negative attitudes

5.2 NORMATIVE BELIEFS OF FAMILY, PEERS AND HEALTH CARE PROVIDERS

5.2.1 Cases 02N-05N (adults with severe LD)

The belief that medication was needed by, and of benefit to, adults with severe LD was expressed by their carers and care workers:

> *'…as I added another drug on it sort of reinforced the fact that, oh gosh, you know this is how it's going to be and you think you're coming to terms with the fact that you're dealing with an individual who's got a lot of medical needs and it's about coming to terms with that.'* Case04N-Jamie-Carer01

> *'…it's medication and it's not something you're having for fun. It's something you have to have to make you better.'* Case02N-Anna-Carer01

> *'I enjoy doing the medication, I like doing the medication. You feel and hope that the medication is quite important to them. It's helping them, it's keeping them healthy. So, I think it's quite an important task throughout the day to do the medication. I think it's one of those things that you feel are really important, that it's got to be done. It's the one thing you always remember - medication time, medication time.'* Case03N-Paul-CareW04

> *'I think it [medication] is giving him a good quality of life.'* Case05N-Rob-CareW03

However, some care workers did express some doubts about medication:

> *'And whether he needs them all is debateable. If we could get one that did the job it would be easier but no that's about it. For me, too many for the same thing and I think they're counteracting each other.'* Case03N-Paul-CareW02

> *''Cause I'm finding as I'm doing this kind of job that doctors are reluctant to remove a medication but they just keep adding to them. Yeah – that has worked in the past – we'll not touch that. But we'll give you this on top just to see how that works!'* Case04N-Jamie-CareW02

Carers and care workers also expressed views on the extent to which they believed the adult with severe LD was aware of their need for, and benefit of, their medicines:

> *'I don't know if he really knows he's getting medicines.'* Case03N-Paul-CareW03

'He had the ability to think through I need this to feel, you know – I think he realised that medication was something he needed.' Case04N-Jamie-Carer01

'I'm sure he knows what it is because if he doesn't want to open his mouth to a yoghurt and you take over the Gaviscon because you think he's gulpy, he'll open his mouth for that. So, he definitely knows he gets relief from it.' Case05N-Rob-Carer02

'He doesn't know he's taking them [medicines] does he – with the gastrostomy? He's happy with it.' Case05N-Rob-Carer02

Care workers also expressed their views on the limitations to their knowledge on medicines and deference to HCPs:

'We're not pharmacists, we're not nurses, we know nothing, we're being guided by them.' Case03N-Paul-CareW03

'…but I'm not a doctor, I don't know – but that's just my thought.' Case07C-CareW02

In addition, the belief that the way medicines may work for the general population may not extend to those adults with severe LD was stated:

'It's about looking at how things work on people whose bodies are working full tilt may not be how a drug will work on people's bodies who are not working full tilt.' Case04N-Jamie-Carer01

5.2.2 Cases 06C-11C (adults with mild – moderate LD)

Care workers of adults with mild-moderate LD expressed views on the extent to which they believed the adult knew and understood what their medicines were for and the extent of the adult's capability to manage and organise their medicines:

'He knows what medication he's on too!' Case06C-Mark-CareW03

'She was down at the doctor one day and the doctor was offering her a 2.5 and she says, "No, that doesn't work. And you discontinued the 6.3 so can I have the 7.5?" And I'm like [mimes jaw open]. How do you know these things?!' Case08C-Ruth-CareW04

[In response to whether Case07C would make good decisions about her medicines if the care workers were not there]:

'Yeah, I don't think she would really.' Case07C-Fiona-CareW01

'I think he would recognise if you gave him something different – he would know a different colour.' Case06C-Mark-CareW02

'At the beginning we did her tablets in the dossette. And as time's progressed we've realised that Ruth's capable of doing more. So we've carried on with that over time.' Case08C-Ruth-CareW01

'I don't think she'd be able to do it herself would she, and order [her medicines]. No, she's a very reliant person. She relies on us for a lot more than we actually think she should – emotional support and things... She likes people to do things for her rather than do it herself.' Case08C-Ruth-CareW04

For Case08C-Ruth, the relationship that the adult with mild-moderate LD had with their medicines was of concern to the care workers:

'She just relies on the tablets. That's her sole way of coping with life I think.' Case08C-Ruth-CareW02

'It's a shame – she thinks a pill will cure everything for her.' Case08C-Ruth-CareW04

'It's an obsession is it? She's got to have them… She's always got creams for her back pain as well. She's had so many different creams and it's an obsession. She even went and bought one over the counter which went against her tablets one time. So, it's an obsession really is it – the cream for the back.' Case08C-Ruth-CareW02

5.3 MAGNITUDE AND INTENSITY OF MEDICATION RELATED BURDEN AND COPING SKILLS (CONTROL BELIEFS)

In all cases, the extent (or perceived extent) of the medication related burden in combination with coping and problem solving abilities of the individuals involved in managing the medication, was cited.

5.3.1 Intensity of medication related burden

Getting the medication 'right' was cited as a concern for care workers:

> *'I suppose because it was polypharmacy it was a concern about getting the doses right.'* Case04N-Jamie-CareW02

For Case08C-Ruth, the problem and intensity of medication related burden was of concern to her care workers:

> *'Because it domineers her life. If they're going to reduce her medication in any way she gets in a panic. I think she thinks that pills fix everything: I'll get a pill and that'll fix this and that.'* Case08C-Ruth-CareW02

> *'She does get annoyed I would say slightly because if the doctor didn't give her what she wants. If the doctor tries to encourage her to change or decrease, then she gets very annoyed with that. She just wants to go to the doctor and say, "I need this, give it to me".'* Case08C-Ruth-CareW02

However, medication was also just accepted as a normal part of life for Case09C-Donald:

> [In response to how he thought his life would be without medicines]:
> *'Em, I'm not sure because it's something that I've known most of my childhood life and most of my adult life. I don't really know how life would be without them.'* Case09C-Donald

5.3.2 Self-awareness of coping skills

An awareness of their coping skills was expressed by carers of adults with severe LD:

> *'It was just something you got because from when he was tiny then he was only on one or two meds. But it was a gradual process. So, by the time he was 20, 21 [years old] the fact that he had half a pharmacy morning, noon and night – you just took in your stride.'* Case04N-Jamie-Carer01

'I'm quite organised – I think you've got to be. I've never had an issue where I've forgotten.' Case05N-Rob-Carer02

A self-awareness of coping skills was also expressed by adults with mild LD:

'I would say I find it all pretty easy. You know, it's just a case of popping them out of the pack when you can and just sticking them down your throat.' Case09C-Donald

'I know what I'm taking, I watch what I'm taking…No. I'm used to taking them myself 'cause I know what I'm taking.' Case10C-Susan

'Ah well, it's fairly easy now. I've been in a daily routine for years now so it's fairly easy to fit in the other ones [medicines]...I've been doing this routine so long it's second nature... Aye, I've a pretty good idea about what's effective.' Case11C-David

'When I'm at my mum's I remember the stuff, right down what I take with me but I know what I take at what time in the morning and what I take at night. I'm pretty good… Say *I'm at my mum's tomorrow, I'd take my own medication with me. And I'd look out what I need to take at night. I'd organise myself!'* Case07C-Fiona

5.3.3 Ability to develop problem solving strategies

Adults with mild-moderate LD, and the carers and care workers of adults with LD, demonstrated a wide variety of problem-solving strategies in relation to medicine including: shared and informed decision making; how to solve practical administration issues; gaining and sharing medication knowledge; knowing how and where to seek advice and support.

Shared and informed decision making

Shared and informed decision making was apparent as a problem solving strategy for adults with LD and their carers and care workers:

'…she [his care worker] was also his citizen advocate…My husband and I felt we had this balance – somebody who knew him well but who could look on…on his behalf as an outsider and say yes or no. And on a couple of occasions she said, 'Do you think he would really want that?' and I'd go no, you're right. It was really good to have her there alongside us.' Case04N-Jamie-Carer01

'We always take her meds sheet up to the hospital so they know exactly what she's on – what she can get, what she can't get.' Case02N-Anna-CareW04

See Figure 5.2 and Figure 5.3 below for written permission for care workers (from GP) to administer bought medicines:

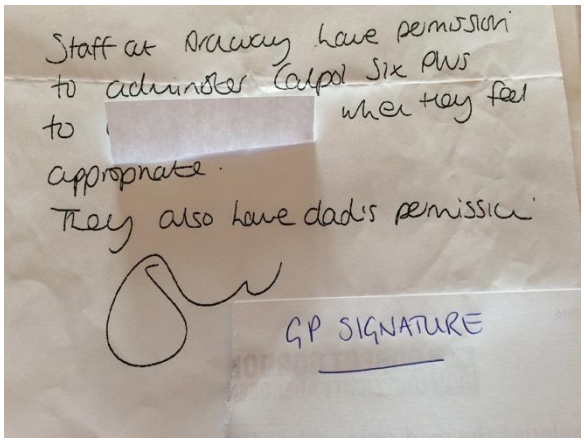


Figure 5.2 Case02NPhoto04 GP authorisation to administer bought paracetamol suspension

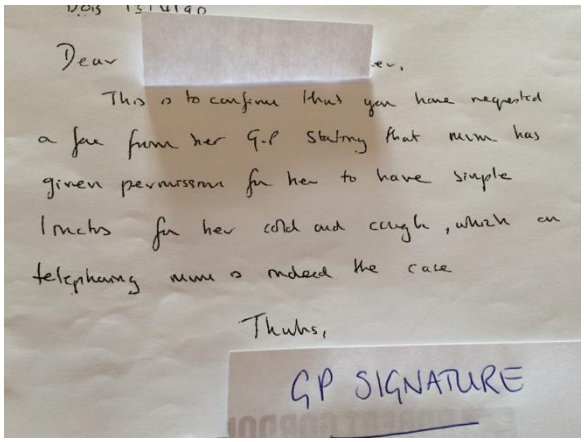


Figure 5.3 Case02NPhoto05 GP authorisation to administer bought simple linctus

A topical product aide memoire, see Figure 5.4, was used by care workers to communicate the site of application for a cream to all care workers.

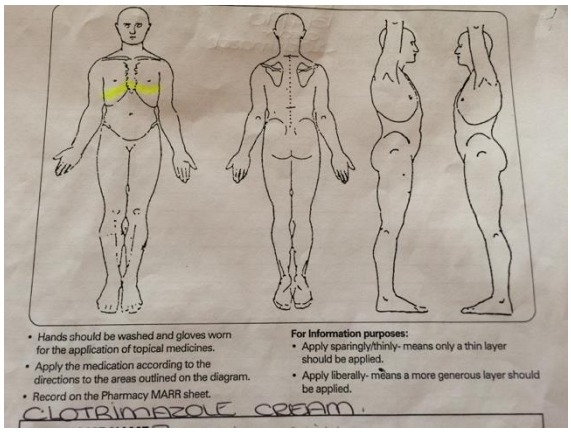


Figure 5.4 Case02NPhoto03 Topical product aide memoire

Solving administration issues (practicalities)

Strategies from carers and care workers to solve practical administration issues were noted: *'So yeah, they [the tablets] may go into a spoonful of yogurt or something…Suprax [cefixime] liquid…it's foul, it's like sand in milk, it's gritty, it's disgusting – serious bribery required here but I would recommend you have a glass of something that they love to bits that they don't get very often (for example coca cola or chocolate buttons) ready.'* Case02N-Anna-Carer01

'If there's a tendency to get [medicines] stuck [in the PEG tube] I usually leave that until last which possibly should go down first – I'm not quite sure. But because of the difficulty getting it down I always leave that until last so that I know that he's got his other medication.' Case03N-Paul-CareW02

Adults with mild-moderate LD also shared how they solved practical administration issues: *'I keep the same glass and the little medicine cup with the bigger letters… Sometimes I've missed! But if I [put on] my kitchen light, put the cup there and put my finger on the actual number. So I know how much I'm putting in – it's a good tip.'* Case07C-Fiona

[In response to finding tablets hard to swallow]:
'I hide them in breakfast or I just bite the bullet and take them…Sometimes it can be cereal. But it seems to be the one that gets it over at the moment.' Case09C-Donald

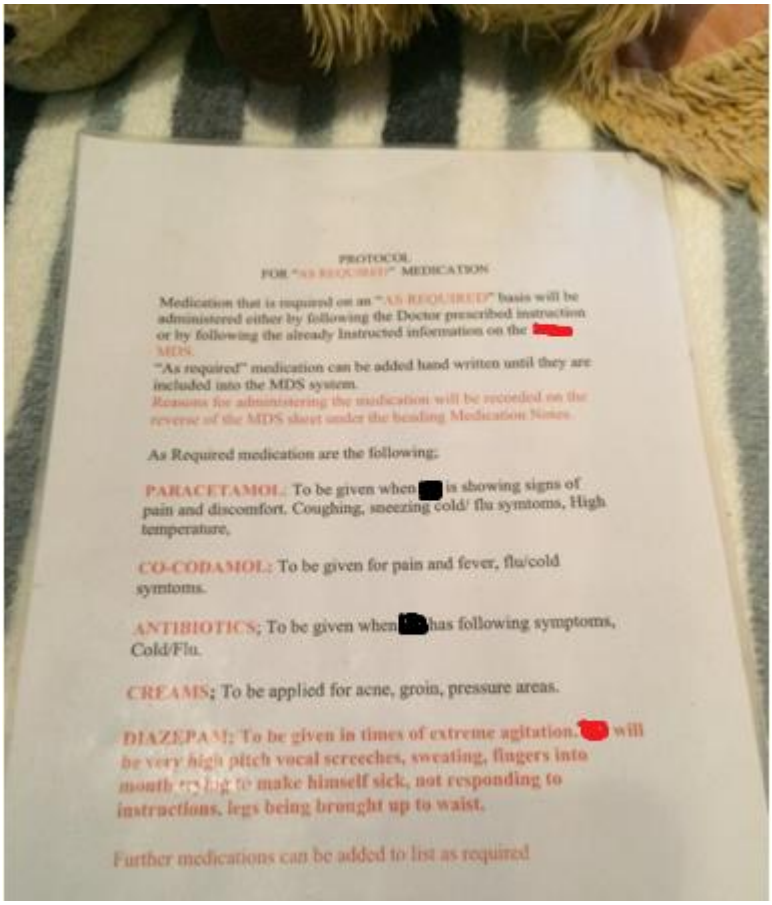
'… you see I did consider putting all the daily tabs in the one box but then I says, no, no, at least if I have them separately I'll be able to keep track better.' Case11C-David

Gaining and sharing knowledge

Carers and care workers also shared strategies on gaining knowledge about the medication: *'I think because we're pretty involved in taking him to the doctor's and speaking to the doctor's we know what they're [medicines] for.'* Case03N-Paul-CareW04

'…we used to read through the side-effects and be aware of them – if he was given anything new. So, we were always on top of that.' Case04N-Jamie-CareW02

'In front of their medication sheets we've got our own sheet that the Care Inspector advised us to have a wee bit of guidance [see Figure 5.5] *as to what 'as required' means.'* Case03N-Paul-Carer01.


PROTOCOL
FOR "AS REQUIRED" MEDICATION

Medication that is required on an "AS REQUIRED" basis will be administered either by following the Doctor prescribed instruction or by following the already Instructed information on the [redacted] MDS.
"As required" medication can be added hand written until they are included into the MDS system.
Reasons for administering the medication will be recorded on the reverse of the MDS sheet under the heading Medication Notes.

As Required medication are the following;

PARACETAMOL: To be given when [redacted] is showing signs of pain and discomfort. Coughing, sneezing cold/ flu symtoms, High temperature,

CO-CODAMOL: To be given for pain and fever, flu/cold symtoms.

ANTIBIOTICS; To be given when [redacted] has following symptoms, Cold/Flu.

CREAMS; To be applied for acne, groin, pressure areas.

DIAZEPAM; To be given in times of extreme agitation. [redacted] will be very high pitch vocal screeches, sweating, fingers into mouth so big to make himself sick, not responding to instructions, legs being brought up to waist.

Further medications can be added to list as required

Figure 5.5 Case03NPhoto02 'When required' medicine protocols

Adults with mild LD also noted how they relied on their care workers to support them in solving problems:

> *''Cause when they do the medication [check] on a Sunday, I do sometimes ask [the care workers], sometimes I forget. I don't know whether to keep my Daktacort or throw it out.'* Case07C-Fiona

> [In response to what she would do if she forgot to take any of her medicines]:
> *'I'd tell the staff and then I'd have to miss that dose out.'* Case08C-Ruth

Adults with mild LD also demonstrated their own ability to problem solve:

> [In response to what he would do if he realised he had forgotten to take his medicines]:
> *'I would probably just wait until the next dose.'* Case09C-Donald

> *'Depending on what time of day it is. Say in the morning if I didn't take it first thing, I would just take it when I remembered. Much the same in the evening. If I didn't take it along with my tea, I would make sure I took it before I went to bed.'* Case11C-David

5.3.4 Lack of medication information

In one case, the care workers noted concerns about the source(s) of information for the adult with LD:

> *'I think she talks to people because she'll come back and say, "Betty's on such-and-such; I want that"… So she must talk to other people about it because I'm not sure how she comes up with these.. She'll come back and say, "I've got a friend and she took this in 1986…".'* Case08C-Ruth-CareW01

5.3.5 Lack of comprehension

A logical, but incorrect, belief in respect to multiple medicines being used to treat the same indication was expressed by one care worker:

> *'That's debateable – 'cause it's all for reflux – Gaviscon, domperidone, omeprazole - all for reflux…For me, too many for the same thing and I think they're counteracting each other.'* Case03N-Paul-CareW02

Care workers for one adult with mild LD knew the names of the medicines but not the indications for the medicines:

[In response to the question about what health problems Case07C has]:
'Well she takes omeprazole… I'm not really sure.' Case07C-Fiona-Carer02

[In response to the question about what health problems Case07C has]:
'I'm not 100% sure. She is on fluoxetine.' Case07C-Fiona-Carer01

For one adult with mild LD, a care worker noted her concern about the extent and depth of knowledge that she was perceived to have regarding her medicines:

'And she doesn't always understand what would coincide [interact] with the medication she already takes. So, she has an idea in her head: I could get this and this will give me pain relief, I know someone who gets it. But it might not necessarily work with what she already has, or the dosage or the strength of it. So, she doesn't always link that part together. She has an idea and she's going in with that idea.' Case08C-Ruth-CareW01

During an interview with Susan (Case10C), sometimes she provided information in a muddled way that made it difficult to know if there was underlying lack of comprehension or just a struggle with the articulation of information:

[In response to being asked if she took medicines or called the doctor out when she was unwell the previous night]:
'No, no, no. I took my laparozone [sic] – the ones over there that you were looking at.'

[In response to being asked if it was the loperamide]: *'That's it. loperamide is for my stomach.'* Case10C-Susan

[In reference to when a change in medication was going to happen]:
'I don't know yet; I won't know until I get them [compliance aid] on Friday. No, no, they've already done it, I think they've already done it. No, no, I've to finish that ones that's there.' Case10C-Susan

[When asked to explain what a side effect was]:
'Is this yours and I'd be going – no, that's not mine.' Case10C-Susan

A lack of understanding regarding indications for medication was expressed by some of the adults with mild LD, which may have been due to limited recall and/or understanding:

[When asked if she knew what her mirabegron and solifenacin were for]:

'No. It'll tell you on there – on the packet…They give me tablets for it [urinary incontinence]. They give me a brown tablet. Can you tell me what it's for?' Case10C-Susan

[When asked what his OTC medicines were for]:

'Tyrozets, ah no, I couldn't say… [Strepsils and other lozenges] I can't remember having bought any of these…[Ibuprofen] I couldn't say…[Senna] Is that a painkiller?...Bonjela? On my face – somewhere round my mouth, nose?' Case11C-David

5.3.6 Unmet need or expectation

Care workers of Paul (Case03N) highlighted the frustration of medication not meeting Paul's needs:

'…we are trying everything…I think ultimately people think there must be a magic pill...' Case03N-Paul-CareW01

'It needs something a bit more extreme because in my opinion it's gone on too long and I think there needs to be some kind of [medication] detox and strip back and start again and really test what it is. I don't think it's good for him to have to deal with this day in, day out either.' Case03N-Paul-CareW04

Unmet expectation was also raised in Case08C-Ruth:

'She would just like the ultimate tablet to cure how she feels, day in, day out. If she's unhappy she wants that tablet to make her be happy. If she's over-happy she wants that tablet not to be over-happy.' Case08C-Ruth-CareW04

Recognition that the medication was not controlling a particular condition was highlighted by Susan (Case10C):

'Well how's it [incontinence] not under control? 'Cause I've been on that tablet a long time now.' Case10C-Susan

5.3.7 Response to negative aspects of medication

Unwanted or intolerable side-effects resulted in medicines being altered or never prescribed in the first place to adults with severe LD:

'Keppra [levetiracetam] rage is what they call it because they just become angry and short fuse…I eventually said to the neurologist that I'm prepared to put up with more seizures if

she goes back to being a happy bunny because this is no life for anybody, it's just not right.' Case02NCarer01

[In response to why haloperidol treatment was stopped]:
'We didn't want him to be sedated.' Case03N-Paul-CareW02

However, in other instances the negative aspects of the medicines were accepted and rationalised:

'What they said was it [arachnoiditis – side-effect of intrathecal baclofen] isn't in itself fatal, but …because of the powerful drugs that are needed to control it, it can actually shorten the life - which is exactly what happened to him. What comfort I got was that they'd been using the right medication.' Case04NCarer01

[In reference to Epilim (sodium valproate) causing a lowering of mood]:
'But that was maybe about the time as well of the bad winter so it's all tying in together.' Case05N-Rob-Carer02

The care workers of Ruth (Case08C) articulated Ruth's confused response to the negative side-effects of one of her medicines:

'But she did know about what those tablets [zopiclone] were doing to her in the morning 'cause she said she didn't like speaking the way she was speaking to staff – so she knew. She still wanted them but I think by that time she was addicted to them. She knew things were changing inside her because she would often snap at you and then say, "I'm really sorry, I can't help it." So, she knew things were changing inside her, but she still wanted it.' Case08C-Ruth-CareW02

5.4 GENERAL ATTITUDE

The general attitude of carers and care workers of adults with LD towards medication is affected by a mixture of their experience and then the specific circumstances and history of the adult with LD. For adults with mild-moderate LD, their circumstances and history affected their attitude.

5.4.1 Weighing up the burden and benefits of medication

Compliant medication taking practice masked a variety of underlying views on the burden and benefits of medication for that individual. Sometimes positive views were expressed about the notable benefits of medication to the adult's life:

'[Without medication] She wouldn't have a life I don't think…She needs her medication.' Case02N-Anna-CareW04

'As they get older you're seeing it as this is maintaining a quality of life or this is improving their quality of life so you just accept it – that's another one [medicine] in, you know!... It really was acceptance… 'cause you're then coming to terms with it and looking at what's in their best interest really.' Case04N-Jamie-Carer01

'And I would rather have that [hyoscine for excess salivation] than him with a sore chin or looking a bit awkward for people to look at him – personal dignity I think would be the word…' Case05N-Rob-Carer02

A considered understanding and acceptance of risk was also articulated:

'Now the domperidone – they've for a long time known that that can cause heart issues for long term use. And again, he's on a reasonable dose morning and night as well… On the domperidone she [mum] said she knew (being a nurse) about the heart and they had tried to bring him off - no luck. It caused a huge amount of issues with him. So, she thought it wasn't worth it for the slight risk of maybe some heart issues. And knowing he has such massive problems with his reflux. So, we've decided leave well alone with that.' Case05N-Rob-CareW01

'And my cocodamol – I take two in the morning and two at night. It was 9[am], 1[pm], 5[pm] and 10[pm]. But they cut it down as there's only so much you can have. It's not good for your liver and kidneys and that. So, it's the morning and at night – two in the morning and two at night… 'Cause I'm not like putting too much, I'm keeping my liver and kidneys healthier. I'm glad. 'Cause you get some druggies that take too much and they destroy, their liver's destroyed - like damaged. I'm glad I cut down mine…' Case07C-Fiona

However, conflicted views were also expressed:

'I don't like taking the water ones [solifenacin and mirabegron] because I feel they're not helping… If I didn't take them, that would be worse. I'm dry at the moment.' Case10C-Susan

'As I say, the impact of too many for the same thing - we're wondering what it's doing to him. You know – is it actually helping him or is it making him worse… He makes himself sick so I mean in a sense us putting that down – is that upsetting things?' Case03N-Paul-CareW02

Interestingly, the weighing up of the benefits and burden of medication often resulted in care workers expressing informed concerns over the efficacy and safety of medication:

'One of them – omeprazole – that's supposed to dissolve in the gut but he has it all day in his PEG tube so it goes into his stomach and we have to crush the tablet so it's being digested by the stomach – so is it doing any good?' Case03N-Paul-CareW02

'But the psych, the ones, the magic one we want, that helps his behaviour. Because we really don't know, because we don't know other people that have it - I don't know what affect it really should be having to be honest. Should it be – what's it doing to him? I don't know what it's doing to him…' Case03N-Paul-CareW02

'I used to think that if he didn't have them, what would happen to him – did he really need as many?' Case04N-Jamie-CareW02:

5.4.2 Medication controls illness or disease

The purpose of medication being to control illness or disease was generally taken for granted but was sometimes expressed explicitly by care workers:

'They [medication] do the job they're supposed to do. They must do because I've not seen him without them and I wouldn't want to. So, they obviously do the job they're supposed to.' Case05N-Rob-CareW01

[In response to a question about the benefits of fluoxetine]:

'Outbursts – he had a lot of them before. And although he'll still have them, they're more controlled now and there's a lot of things in place with other health professionals that have been involved to make things better for him…I think he'd just be as high as a kite if he wasn't taking his tablets to be honest with you…' Case06C-Mark-CareW02

The control of illness or disease was articulated clearly by adults with mild-moderate LD too:

'It took a while but the fluoxetine – I'm more relaxed. Having two fluoxetine helps me more than having just 20[mg] fluoxetine… I wouldn't want to stop that. That really helps me be

more relaxed and everything 'cause I'm not so anxious like I used to be. I'm not so, 'C'mon!' I'm just more laid back and it helps a lot.' Case07C-Fiona

'…they [duloxetine] take the pain away. They keep me ok… They keep me on an even keel and everything. I don't get depressed so often…At least I don't end up in hospital…I would never be out of my bed. I wouldn't care about myself or nothing.' Case08C-Ruth

'I suppose to keep my mood up, keep me healthy. You know, I'm able to do stuff. So, it's pretty good actually.' Case09C-Donald

5.4.3 Hope

For Case03N (Paul), the hope that there was a medicine that might help reduce or resolve the escalating behavioural problems was expressed several times:

'I don't know – I still feel there must be something that would really help, that would cause him less distress than he's experiencing 'cause I think that sometimes the focus always come away from him and it's how it's affecting others and we're not forgetting but he must be in chaos and we just want to try and help him and it's very difficult 'cause I don't know what is out there that could help him.' Case03N-Paul-CareW01

'So, it just seems to be a cycle of trying things over and over and over. Seems to be that new people coming in bring up the same ideas to try and they do get tried and I think we're always hopeful that it will work this time, it will work this time.' Case03N-Paul-CareW04

The fact that the adult with mild-moderate LD expressed hope that the medicine will make them better was cited by care workers:

'And he'll just keep saying, "That'll make me better now, that'll make me better".' Case06C-Mark-CareW02

'I think she believes it though. She believes these things will make her better.' Case08C-Ruth-CareW01

5.4.4 Medication prevents consequences of illness or disease

The role of medication in preventing the consequences of illness or disease was noted:

> *'The seizures – we'd be concerned that there'd be an increase and the length of time she was actually having in an actual seizure.'* Case02N-Anna-CareW03

> *'I think it's the fact that when you're caring for someone like Jamie that this was keeping him safe, keeping him well, keeping him alive.'* Case04N-Jamie-Carer01

> *'It'd be really hard for him just for daily life I think without his medications.'* Case06C-Mark-CareW02

> *'I think without them [painkillers] it would be a lot, lot worse. Even though she's still in pain at times, without them I think the pain would be a lot worse for her.'* Case08C-Ruth-CareW03

> [In response to why she chose to take her medicines]:
> *'Well it's to keep you better. If I didn't take them I would be ill.'* Case10C-Susan

5.4.5 Medication allows them to fulfil social roles

The independence that medication conferred was important to one adult with mild LD:

> *'Well it stops me from having the fits when I'm out, and still my own boss as I like to think!'* Case11C-David

5.4.6 Negative past experience

No data with this theme was provided by any of the cases during the research.

5.4.7 Lack of perceived desired outcomes

Failing to achieve the perceived desired outcome has had a significant impact on the beliefs of the care workers of one adult with severe LD (Case03N-Paul) in relation to the efficacy of medication:

> *'He was getting diazepam, fluoxetine, risperidone and none of them seemed to do whatever it was meant to do. And we've been giving him the paracetamol regularly since the weekend and that's not even calming him…And I don't know if there's any medical tablet. We've tried medicine, he's been on medicines, we've reduced medicines…'* Case03N-Paul-CareW03

'And then it was decided to wean him off fluoxetine because he's on risperidone and fluoxetine. It's not made – in fact it's exacerbated his issues – it's not made it any better at all.' Case03N-Paul-CareW01

5.4.8 Preconceived negative attitudes

Preconceived negative attitudes to medication were related to efficacy and the negative impact of change:

'Medication is a waste of time for me – for him.' Case03N-Paul-CareW02

'If you change a tablet, you can get side effects and I don't want that.' Case10C-Susan

5.5 CHAPTER SUMMARY

This chapter explored the medication related beliefs of adults with LD, or of their carers and care workers, in relation to the second section of PLEM (medication related beliefs) under the three themes of: family peers and health care providers; medication related burden magnitude and coping skills; and general attitude.

CHAPTER 6 RESULTS – MEDICATION TAKING PRACTICE

"You can only find out what you actually believe (rather than what you think you believe) by watching how you act."

12 Rules for Life: An Antidote to Chaos - Professor Jordan B. Peterson,

6.1 CHAPTER INTRODUCTION

This section will focus on medication taking practice - the third section of PLEM as outlined in Figure 6.1 below:

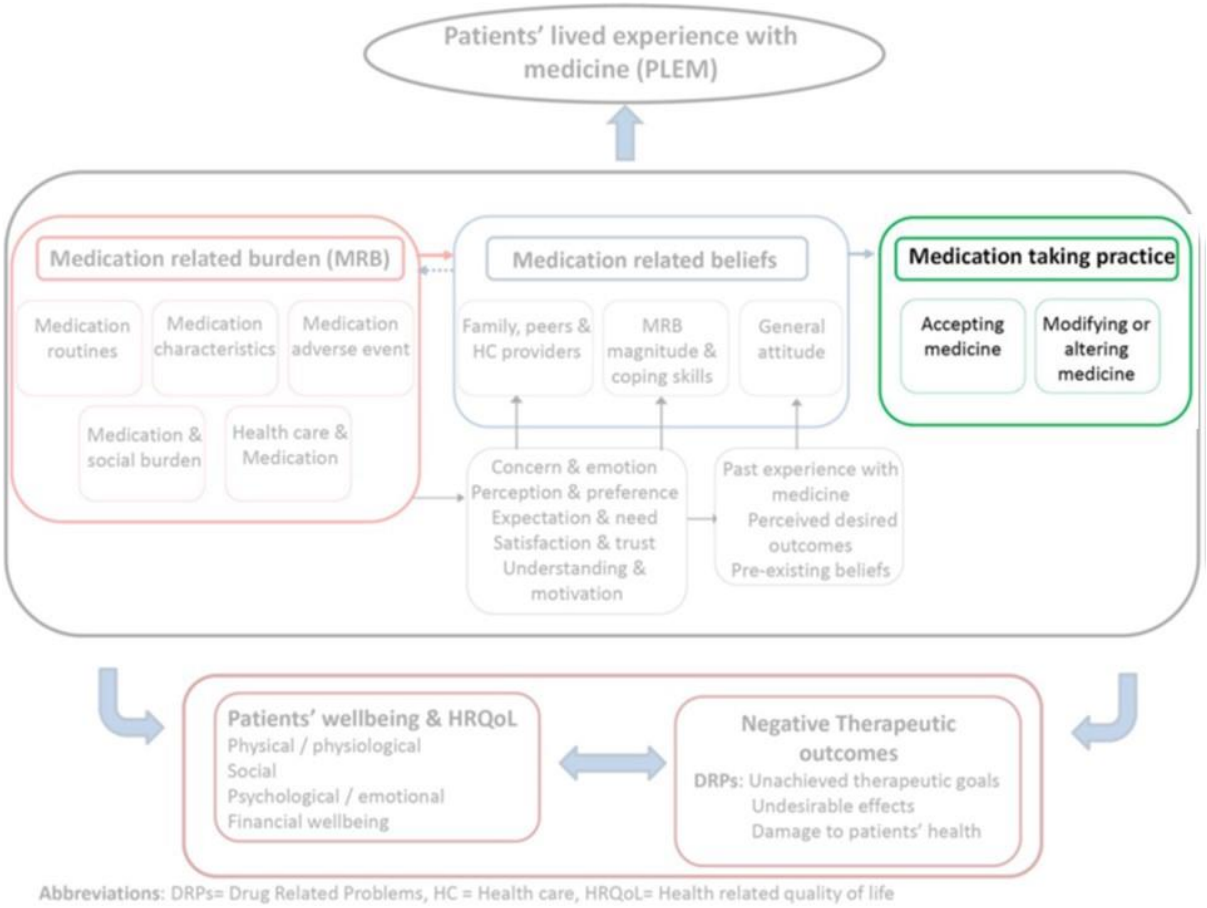


Figure 6.1 PLEM - medication taking practice

As can be seen within the conceptual model, the third section of PLEM (medication taking practice) contains two themes: accepting medicine; and modifying or altering medicine. Within the study by Mohammed, Moles and Chen (2016) examples (or sub-themes) of each of these three themes were also listed and these are detailed in Table 6.1. These themes and sub-themes were used to structure the results that will now be presented within this chapter.

Table 6.1 Medication taking practice themes and sub-themes

Theme	Sub-theme
Accepting medicine	Unconditional acceptance
	Forced into it by underlying illness
	Aiming to please family
	After experiments or consequences non-adherence
Modifying or altering medicine	Intolerable medication related burden
	To evaluate effect of own medication or to discover optimal doses
	Lack of perceived outcome
	Fear of potential side effects
	Peer pressure

6.2 ACCEPTING MEDICINE

Adults with LD or their carers and care workers cited a few examples of unconditional acceptance of medication and acceptance of the regimen after experiments with the medication.

6.2.1 Unconditional acceptance

Truly unconditional acceptance was rarely verbalised as acceptance was generally linked to efficacy and the absence of side-effects. However, unconditional acceptance of the medication routine by the adult with LD was noted by care workers:

> *'I've seen her when she's really tired actually come through for the tablet…and I thought you're tired - you're wanting your tablets – that's at 7 o'clock instead of 8. So, she does let us know!'* Case02N-Anna-CareW05

> *'He actually even reminds us about his 1pm meds. He'll come through… And automatic first thing in the morning – he's out of bed and he knows to himself that's what he does – he gets his tablets before he'll sort of go for a wash or whatever in the morning.'* Case06C-Mark-CareW01

> *'And come dinner time, she's asking if we'll go up maybe half past seven/quarter to eight to give her her last tablet. She's always asking.'* Case08C-Ruth-CareW04

Unconditional administration of medication by care workers was actually seen as a potential problem by one carer:

> *'Come hellfire or high water…people won't necessarily use their discretion because if they're in a care home situation, what it says on the label is what happens– even if it's wrong, that is what happens…'* Carer02N-Anna-Carer01

6.2.2 Forced into it by underlying illness

One adult with LD (Case 08C-Ruth) did express the view that she only took her medicines out of a need to control her illnesses. This was in contradiction to the views of her care workers who noted an obsession and reliance on medication.

6.2.3 Aiming to please family

No data with this theme was provided by any of the cases during the research.

6.2.4 After experiments or consequences of non-adherence

The worsening of a condition upon cessation of the medicine resulted in an acceptance of the medicine:

> *'Domperidone – we tried him off it, it didn't work. He had to be put back on it - his symptoms got worse. So, we did try it, but it didn't work.'"* Case05N-Rob-Carer02

> *'Aye. I stopped it [all painkillers including morphine]. I paid for it because I was sick and everything. Cold sweats and I had to go back on it after two days.'* Case08C-Ruth

6.3 MODIFYING OR ALTERING MEDICINES

Adults with LD or their carers or care workers cited examples of how they modified or altered medicines.

6.3.1 Intolerable medicine related burden

A key factor in medicines becoming intolerable was if they had a detrimental effect on already reduced cognitive abilities or on the behaviour of adults with severe LD, previously detailed in Section 4.4 for Case02N-Anna, Case03N-Paul, Case04N-Jamie and Case05N-Rob. In addition, oral administration of medicines if swallowing difficulties were an issue also caused a degree of burden:

> [In reference to giving medicines orally as a child]:
> *'Obviously it was a nightmare when he was little, before he got the PEG. That was a nightmare!'* Case04N-Jamie-Carer01

6.3.2 To evaluate the effect of their own medicines or discover optimal doses

Although the medicine itself was accepted, several instances of dose optimisation were recounted. However, it was not always stated whether these changes were authorised by the prescriber beforehand:

> *'Epilim – we got him down on to the minimum dose that he needed…He had to be kept on a tiny amount of that [clonazepam]. We tried to take him off it but it's such a powerful medication. I weaned it down to the absolute minimum but when I tried to take him [off it] - we had some really bad effects.'* Case04-Jamie-Carer01

> *'And one of the things that she'd looked at and asked about was about the once a day of the omeprazole…I'm giving a large dose but once a day. So, I thought, okay- I'll have a look at …splitting the dose to work with his overnight feed and with the food that he takes during the day.'* Case05N-Rob-CareW01

'She used to get it three times a day. Then it got reduced to two and all of a sudden she started feeling sick again and it got back up to three. I'm not saying she wasn't sick but it's like every time they take something away she finds another replacement of some other make or name or whatever. So, we've got to the stage when we just stop trying. Because it was like up and down, up and down.' Case08C-Ruth-CareW01

6.3.3 Lack of perceived outcome

Carers and care workers could cite instances of when medication did not achieve their desired outcome for that adult with LD:

[In reference to epilepsy treatment]:

'We gradually had everything up as far as it would go to try and prevent all these seizures but it just wasn't working…Carbamazepine didn't seem to do very much…' Case02N-Anna-Carer01

'*He still suffers really badly from reflux. We're thinking that the new medication omeprazole to lansoprazole swap is not working very well. He is getting more – he was retching two days ago. So, we're not absolutely sure if it's that that's causing the problem.'* Case05N-Rob-CareW03

6.3.4 Fear of potential side effects

Only in two cases was an aversion to potential side-effects noted:

'It's like this. Everything is conflicting with each other. If she takes the iron tablet then she's constipated. And if she's constipated she's unhappy about that. But then the lack of iron makes her sleepy. So, it's this whole mismatch.' Case08C-Ruth-CareW01

'I don't want to change them [blood pressure tablets] because you can get side effects.' Case10C-Susan

6.3.5 Peer pressure

Within the cases, two instances of care workers being pressured to administer medicines (in an acute situation) were cited:

'He had a massive paddy [tantrum] while they were here … and my colleague got a phone call the next day saying, "You must be able to sedate him – you have to sedate him"...' Case03N-Paul-CareW01

'…when he took the turn in the daycentre, it was very difficult to decide whether I should give him his midazolam. Basically because it would have conflicted with the medication that he'd had in the morning. So, what I did was, I waited with a lot of stress around me saying, "You've got to give him it! You've got to give him it!"' Case04N-Jamie-CareW02

6.4 CHAPTER SUMMARY

This chapter explored the medication taking practice of adults with LD, or of their carers and care workers, in relation to the third section of PLEM (medication taking practice) under the two themes of: accepting medicine; and modifying or altering medicine.

CHAPTER 7 RESULTS – SUB-THEME EXAMPLES NEW TO PLEM

'To see what is in front of one's nose requires a constant struggle'

George Orwell

7.1 CHAPTER INTRODUCTION

This chapter highlights the new sub-theme examples from the case study data that were not identified within the PLEM conceptual model paper by Mohammed, Moles and Chen (2016) which are summarised in Table 7.1.

Table 7.1 New sub-theme examples for PLEM

Theme	New Sub-Theme Examples Identified
Medication related burden	Medication Routines • Specialist administration issues related to PEG tube
	Medication Characteristics • Formulation • Palatability
	Adverse Events • Recognised but not considered negative
	Health Care and Medication • Carer and care worker responsibility • NHS policy
Medication related beliefs	Magnitude and intensity of medication related burden and coping skills (control beliefs) • Magnitude and intensity of medication related burden and coping skills unique to care workers • Challenge of communication between adult with LD and their carer or care worker
	General Attitude • Informed questioning of safety • Querying the benefit of medication
Medication taking practice	Accepting Medicines • Proven efficacy and clear benefits • Lack of side effects • Deferring to health care professionals • Perceived norm or reliance
	Modifying or Altering Medicines • Non-compliance (reason unknown) • Lack of side effects

7.2 NEW SUB-THEMES - MEDICATION RELATED BURDEN

7.2.1 Medication Characteristics: specialist administration issues related to PEG tube

The administration of medicines via a PEG tube can affect the medication related burden – both positively and negatively. The formulation of the medicines was a key issue:

> *'If there's a tendency to get [medicines] stuck [in the PEG tube] I usually leave that until last which possibly should go down first – I'm not quite sure. But because of the difficulty getting it down I always leave that until last so that I know that he's got his other medication.'*
>
> Case03N-Paul-CareW02

'The omeprazole – that dissolves in water and you've got to make sure that it is totally dissolved. Of course it's little balls as I call them – they can get stuck and that's the one thing that I find very difficult getting down his tube. If you don't leave it to dissolve enough…' Case03N-Paul-CareW02

'Because it's easy because of the gastrostomy you're not stressing anybody.' Case05N-Rob-Carer02

7.2.2 Medication Characteristics: formulation

The prescribed formulation of the medicine was noted by care workers of adults with severe LD as another medication characteristic that impacted on the ease of administration and, as a result, the associated burden:

'I much prefer the dissolvable ones.' Case03N-Paul-CareW02

'Omeprazole – yes. And we'd gone on to the solution 'cause we'd started off on the tablets which kept clogging up the gastrostomy.' Case05N-Rob-CareW01

'Now that it's buccal [midazolam] we find that it's much easier to administer. We haven't got the same concerns …when it was rectal [diazepam].' Case02N-Anna-CareW03

7.2.3 Medication Characteristics: palatability

Carers and care workers also cited the taste, and associated palatability, as another medication characteristic that impacted on ease of administration and, as a result, the associated burden:

'I've seen her with the lacosamide and the Topamax [topiramate] lately - I think she's taken it out of her mouth…I think it's the taste.' Case02N-Anna-CareW05

'Midazolam. It's vile, absolutely vile. So if she's only half out she won't let you give it to her which is difficult 'cause it's disgusting…it's very sweet.' Case02N-Anna-Carer01

'She wouldn't take the medicine – she didn't like the taste of it…' Case08C-Ruth-CareW01

7.2.4 Adverse Effects: recognised but not considered negative

For one adult with mild LD (Case07C-Fiona), the side-effect from a medicine was noted but not considered to be negative:

'They [hyoscine travel sickness tablets] make me nod off…I have a sleep…it doesn't bother me…If I didn't have my travel pill I probably would be sick. I just nod off.' Case07C-Fiona

7.2.5 Health Care and Medication: carer and care worker responsibility

The responsibility associated with making ongoing decisions on behalf of the adult with LD was consistently noted as an area of burden for carers and care workers:

'If we forget [to give medication], she's oblivious but mum and dad panic!' Case02N-Anna-CareW01

'And the other thing which I think I need to say which is extremely hard is that I had to make decisions on behalf of somebody who would normally make decisions for themselves…I was always conscious of that as a young man of that age what would he want, what would his choice be? And acting in his best interest…' Case04N-Jamie-Carer01

'Also, when you get her medication box, it's checked twice here. We do two checks, two different people to make sure that her medication's correct because sometimes mistakes can be made.' Case08C-Ruth-CareW02

7.2.6 Health Care and Medication: NHS policy

The UK's health care system removes financial pressure for medicines from the patient or their carer. However, the system's policies on cost-effective medicine choices mean that sometimes certain drugs, or formulations of drugs, are less easy to obtain:

'I'd gone online to see if there was anything else and I couldn't find anything else but mum said, "Yes there is – there's a medicine… but it's not broadcast about because it's very expensive…". I went to the GP and I said I know it's expensive but it keeps clogging up his gastrostomy – that's a hundred odd pounds a time. I said okay, you've got an expensive med but it would save £100 a time every time that clogs up. And also, a great deal of problems 'cause I have to take him to the hospital now – I'm not allowed to change it myself.' Case05N-Rob-CareW01

[In reference to why they couldn't get clonazepam liquid]:

'We did – it was all down to financial [sic] wasn't it?' Case06N-Mark-CareW02

'Even just a smaller tablet. 'Cause that's what the GP said, "No, it's too expensive".' Case06N-Mark-CareW04

7.3 NEW SUB-THEMES - MEDICATION RELATED BELIEFS

7.3.1 Magnitude and intensity of medication related burden and coping skills: burden unique to care workers

The standards of care set by their employer and their regulatory body generates additional medication related burden for care workers:

'…What's on the pharmacist's label is what we have to follow. So, if mum comes in and says, "Oh we're at such-and-such [a dose]", but that's not what's on the pharmacist's label I have had to get in touch with GP surgeries. And I can't accept verbal instructions over the phone so we have to get a fax stating what stage we're at 'cause sometimes if somebody comes in and there's changes with meds we have to have that really clear in writing as to what staff are following. Sometimes we can get labels that come in and mum or dad have scored out bits which is unacceptable for us as well. So, again sometimes we've had to speak to mum and say would you be able to get the pharmacist to issue a current label.' Case02N-Anna-CareW03

'We can only give the set dose within the times.' Case03N-Paul-CareW02

'So we're trying baclofen at the moment – but a very small dose. And then they mentioned pain relief as well because of the ...but they never said to start one with the other. And because of the Care Inspectorate you've got to be so careful…' Case03N-Paul-CareW01

7.3.2 Magnitude and intensity of medication related burden and coping skills: challenge of communication between adult with LD and their carer or care worker

Being able to determine how an adult with severe LD and no verbal communication is responding to a medicine and/or if they require a particular medicine is challenging for carers and care workers:

'Because he can't tell you I'm not feeling great or…you read the side effects and you think is he experiencing the side effect, is he not?' Case03N-Paul-CareW01

'Rocking. Which obviously is a sign in a non-verbal person that they're getting discomfort. He… gets a look on his face of, "Uugghh - there's a nasty taste in my mouth", so immediately I'll give him Gaviscon.' Case05N-Rob-CareW01

7.3.3 General Attitude: informed questioning of safety

The negative impact of medication on a condition was raised by one care worker:

> *'Maybe she's got the hiatus hernia- could that be to do with the amount of tablets she takes maybe?'* Case08C-Ruth-CareW01

7.3.4 General Attitude: querying the benefit of medication

The actual benefit of one particular medicine was queried by Ruth (Case08C):

> *'I don't know if that [paracetamol] helps really. I've got a sore head and it still doesn't put that away.'* Case08C-Ruth

7.4 NEW SUB-THEMES - MEDICATION TAKING PRACTICE

7.4.1 Accepting Medication: proven efficacy and clear benefits

Acceptance of medication was strongly linked to whether the drug was perceived as necessary and whether the benefits were apparent:

> *'As they get older you're seeing it as this[medication] is maintaining a quality of life or this is improving their quality of life, so you just accept it – that's another one in, you know!'* Case04NCarer01

> *'Oh no, they're all there for my benefit. Like I say, years ago, I was a bit unsure on the effects they were having…So, like I say, I've just accepted it and well, that accounts for the routine.'* Case11C-David

> *'I suppose because it keeps me a bit, you know, it keeps me well, it keeps me happy.'* Case09C-Donald

One carer also demonstrated an acceptance of 'higher risk' medicines because of the benefit:

> *'She had been under Dr X and he had started her on lamotrigine even though she was too young, she shouldn't have been on it and it was off-licence but, by god, did it work – we were pretty much seizure free.'* Case02N-Anna-Carer01

7.4.2 Accepting Medication: lack of side effects

Acceptance of a medicine was also linked to a lack of side-effects:

> *'And what's great is that he's not got drowsy [on lamotrigine] – which you don't want.'* Case05N-Rob-Carer01

'The [morphine] MST's better 'cause that doesn't knock me out. I mean, 'cause the other ones did. I was falling asleep on buses and everything. My worker was worried about it – so I got taken off it.' Case08C-Ruth

7.4.3 Accepting Medication: deferring to health care professionals

Care workers outlined their doubts but deferred to the expertise of health care professionals:

'I would maybe be trying to cut back that cocodamol and instead of having two a day, one a day. Just to actually see if...'cause I think maybe psychologically, the fact that she's taking them – that's just my opinion, I don't know… If she was taking one instead of two, would she still think I'm getting my tablets? You know? Because it is addictive, then if we cut…but I'm not a doctor, I don't know – but that's just my thought.' Case07C-Fiona-CareW02

'Like I don't personally think she needs all that but I'm not a professional doctor. So, when I take her down and the doctor says, "Ok we'll easily increase your pregabalin." I'm like, ok. But because I'm not medically trained, I think well, I can't say anything.' Case08C-Ruth-CareW01

7.4.4 Accepting Medication: perceived norm and reliance

One care worker expressed the view that the adult with LD relies heavily on her medicines to cope with life and perceives them as the norm:

'She probably doesn't remember what it was like to not have as many meds. So that worries her if the slightest tablet is reduced. It worries her and she gets angry. But it's a good thing. And you tell her it's a good thing. I think she's had it for so long it's now a norm. This is the norm having all these. That's normal, that's what she's used to so that's what she wants to stick to 'cause she knows it.' Case08C-Ruth-CareW03

7.4.5 Modifying or Altering Medication: non-compliance (reason unknown)

For adults with profound LD, the decision surrounding whether to accept, amend or reject a medication rests with the carers or care workers. However, an instance of the adult with LD choosing to refuse a medicine for a period of time was cited:

''Cause he gets Gaviscon as well – the Gaviscon is by mouth. Now he takes it quite well. There was a period last month where he was just letting it drool out – he just wasn't taking it.' Case03N-Anna-CareW04

Unknown compliance with salbutamol in Case08C (Ruth) was raised by one of her care workers:

> *'But she won't use her puffer [inhaler].'* Case08C-Ruth-CareW04

7.4.6 Modifying or Altering Medication: lack of side effects

In one instance of increased dosage it was the absence of side-effects that ensured acceptability:

> *'So, we upped it a wee bit – just one tablet for the day for lamotrigine and definitely it hasn't changed his mood. He's still the same ….'* Case05N-Rob-CareW02

7.5 CHAPTER SUMMARY

This chapter highlighted the sub-theme examples from the case study data that were not identified within the original PLEM conceptual model paper by Mohammed, Moles and Chen (2016).

CHAPTER 8 DISSEMINATION CHECK

'However beautiful the strategy, you should occasionally look at the results'

Sir Winston Churchill

8.1 CHAPTER INTRODUCTION

This chapter is a summary of the collated key responses from the participants of the dissemination check to a first draft of the discussion in Chapter 9; these responses have also been incorporated into Chapter 9.

8.2 BACKGROUND

As noted in Chapter 2, enhancing the credibility of data through member checking would have been problematic in this study because of: the potential problems for participants with LD recalling the information they provided; the changing nature of interpretations of phenomena over time by participants; potential ethical issues of returning collated data to participants; the dilemma of anticipating and assimilating the disconfirming voices; and deciding who has ultimate responsibility for the overall interpretation.However, there remained a need to maximise the credibility of the findings of the study and potential for impact through a dissemination focus group approach, as outlined by Barbour (2005). The process for this dissemination check was outlined in Section 2.12.6. The two participants were selected as independent advisors with extensive practical experience of adults with LD who had been involved with the research project from the outset. It should be noted that the answers to each question are not quotes from one individual, but a mutually agreed summary of the discussion.

8.3 RESULTS FROM THE DISSEMINATION CHECK

1. Are the results credible and do they ring true with your experience?

Yes, and yes (both participants).

2. From your perspective, what are the most important points about adults with LD's experience of medication?

- *Care workers and carers are the experts about the adult with LD:*
    - *Inclusion of carers and care workers in decisions about medication for the adult with LD are so important;*
    - *Too often there is an issue of 'professional power';*
    - *Asking for and listening to the views of carers or care workers would be so helpful and diffuse feelings of exclusion.*
- *Significance of medication routine for an adult with LD:*
    - *It has a direct impact on the adult's everyday life;*

    - *It has the potential to dictate routine and delay social activities (especially in group settings);*
    - *There is then a ripple effect on the family and other residents;*
    - *Some adults with LD have a tendency to obsess about medication;*
    - *Some adults with mild-moderate LD will obstruct medication changes just because it is change.*
- *The responsibility and demands placed on care workers in the formal care setting in relation to medication:*
    - *Time and resource is required to ensure medication is administered, recorded and stored in accordance with regulatory body's standards;*
    - *Day centre staff and travel escorts also impacted;*
    - *Care workers are really fearful of making medication errors; disciplinary action and suspension are real concerns;*
    - *Care workers in day centres have had to turn service users away because carers or care workers have not supplied them with all the required medication (including rescue medication for epileptic seizures).*
- *Medication can be a flashpoint between family carers and care workers:*
    - *Care workers can only follow the prescriber's instructions; carers often amend the dose or timing and then request that this change is followed by care workers;*
    - *Views of the family often outweigh views of care workers even when the family are not involved in the day-to-day care of the adult with LD.*

3. Are there any important points about medication experience in adults with LD that you think are missing?

- *The impact of prescribers deciding unilaterally to reduce antipsychotic medication. Dose reductions have caused an increase in behavioural problems in some adults with LD which then impacted negatively on social activity. The loss of social activity then impacted negatively on behaviour, and a vicious circle was created.*
- *Medication refusals by adults lacking capacity:*
    - *Spitting out of tablets – should this be seen as the adult with LD communicating that they don't want their medication and should that decision be respected?*
    - *Administration via PEG– is that technically covert administration as the person has no idea you are administering medication?*

- *Using food to make it easier for adult with LD to swallow – is that technically covert medication even when you show the adult you are putting the medication in the food?*

- *Hospital:*
  - *Care workers not allowed to administer medication to the adult with LD in hospital even though the HCPs are busy and some wards have prevented carers or care workers from even being present;*
  - *Support for adults with moderate-severe LD is so individualised and HCPs are often out of their depth trying to work out the adult's needs during a hospital stay;*
  - *The adult with LD often can't communicate their medication needs to strangers and behaviour can worsen as a result;*
  - *Medication being administered late often causes problems because of the importance of routine to the adult with LD.*

4. What issues raised in the research would be most applicable to your current place of work?

- *The power relationship between HCPs and carers or care workers - HCPs have more status;*
- *Impact of medication on social activity and the wider family and service such as delaying a group outing because of the need to medicate one person at a particular time;*
- *Lack of flexibility with medication administration causing problems.*

5. & 6. How do you think health care professionals could better support adults with LD with respect to their medication? How do you think this information could be best used to improve adults with LD's experience of medication?

- *General education of HCPs about some of the common challenges faced by adults with LD and their carers or care workers in relation to medication;*
- *Ask HCPs to work in partnership more with carers or care workers in all aspects of care but also in relation to prescribing decisions;*
- *HCPS to listen to the lived experience of adults with LD and/or their carers or care workers;*
- *Proactively ask care workers and carers about medication issues, procedures or routines so these are known and understood by everyone;*
- *More holistic care from prescribing professionals for adults with LD so that polypharmacy is minimised; often specialists in different areas don't speak to each other and it's the carer or care worker who has to link them up.*

8.4 CHAPTER SUMMARY

This chapter detailed the results of the dissemination check that was undertaken after all data had been gathered, collated and analysed.

CHAPTER 9 DISCUSSION OF RESULTS

'Discussion and argument are essential parts of science; the greatest talent is the ability to strip a theory until the simple basic idea emerges with clarity'

Albert Einstein

9.1 CHAPTER INTRODUCTION

This chapter will first of all discuss the collated case study findings for the three research objectives, as set out in Chapter 1, which were:

1. To explore and describe the medication related burden experienced by adults with LD;
2. To explore and describe the medication related beliefs of adults with LD;
3. To explore and describe the medication taking practice of adults with LD.

Then this chapter will discuss the use of the PLEM conceptual model as a theoretical framework within the research before discussing the reflexivity, transferability, and strengths and weaknesses of the research.

9.2 MEDICATION RELATED BURDEN EXPERIENCED BY ADULTS WITH LD

The following key themes emerged from the data: desensitisation to the burden of medication; the impact of drugs affecting cognitive ability and mental wellbeing; burden from the medication routine and any change to routine; reduction of burden through optimisation of the routine; the social benefit of medication; the transfer of burden to carers or care workers. Each of these themes will now be discussed, relating the case study findings to existing literature, and noting comments from the dissemination check.

9.2.1 Desensitisation to the burden of medication

All of the cases, to varying degrees, contained examples of burden that medication had placed on the adult with LD or their carers and care workers. However, the burden that was attached to the medication was often downplayed or not perceived to be a burden; medication, and by default medication related burden, was just the norm and perceived to be part of everyday life. This correlates with Bhaumik *et al* (2015) who suggest that people with LD experience altered sensitivities to drugs, different effects from drugs, different optimum doses, and more adverse drug reactions. Furthermore, desensitisation to the burden of medication was also notable through the absence of expressed anxiety of future problems or burden from medication. A possible explanation for this desensitised view of medication related burden is that carers and care workers of adults with moderate-severe LD have developed a higher threshold of what constitutes a burden. This is because there is a general, everyday burden that exists in caring for a person with multiple medical and social needs and the burden or risk of not controlling certain medical conditions is greater than any medication-associated burden or risk.

Whilst it is not possible to comment on whether the case studies had similar or different experiences with medication to the general population, there was evidence of numerous adverse drug reactions and potentially increased sensitivity to medication, as evidenced in Chapter 4.

Davis *et al* (2016); Van Schrojenstein Lantman De Valk and Walsh (2008), and Straetmans *et al* (2007), note the challenges that adults with LD have relating illness to dysfunction in their body, recognising relevant signs and symptoms, and then being able to communicate these to a HCP. It could then be argued that adults with LD would also have problems in recognising side effects, relating them to their medication and then communicating these to an HCP, or indeed recognising when they might benefit from a medicine. Furthermore, Bhaumik *et al* (2015), and Stenfert-Kroese, Dewhurst and Holmes (2001) also note that adults with LD who have communication difficulties may not volunteer information on side effects or only be able to express the information in idiosyncratic ways. This was noted in Case05N-Rob when his care worker noted how he rocked when he was in discomfort from heartburn and within the dissemination check when they noted that worsening behaviour of an adult with LD in hospital may be related to their inability to communicate their needs to strangers. In the cases within this research which focused on people with mild-moderate LD, none of the adults with mild LD were able to provide an answer about experience of general side effects. However, when asked about specific side effects, they were better able to answer.

General issues with memory and perception of time were highlighted as having the potential to adversely affect ability to independently manage medication for people with mild-moderate LD (Bond and Hurst 2010; Arscott, Stenfert Kroese and Daganan 2000). Several case studies within this research (Case09C-Donald; Case10C-Susan; Case11C-David) demonstrated how impairment of memory and recall adversely affected the adult's ability to provide a complete medication related history with description of medication related burden.

9.2.2 Burden of medication adversely affecting cognitive ability and mental wellbeing

Although medication in totality was not cited as an area of burden, adverse effects on cognitive ability or mental wellbeing from medication, or indeed from cessation of medication, were highlighted by carers and care workers as an intolerable burden. Within the case studies, psychoactive medicines were most frequently referred to as the cause of impaired cognitive ability or mental wellbeing (Case02N-Anna; Case03N-Paul; Case04N-Jamie; Case05N-Rob).

In recent years, there have been moves to address the over-use of psychoactive medication in people with LD (Public Health England 2015; Department of Health 2012) and published studies have often sought to identify the prevalence in various LD populations (Murray *et al* 2014; Doan *et al* 2014; Paton *et al* 2011; Lott *et al* 2004). Whilst carers and care workers cited instances of how side effects from psychoactive medication had impacted negatively on learning potential, social opportunities, daily living and quality of life for both the adult with LD and their carers or care workers, many of the case studies highlighted the positive impact of psychoactive medication (Case02C-Anna; Case06C-Mark; Case07C-Fiona; Case08C-Ruth; Case09c-Donald). Furthermore, for one case (Case03N-Paul), the hope for a psychoactive drug that would help with behavioural challenges, and by default the quality of life, was cited several times by different care workers. This issue resonated in the dissemination check where one participant cited recent experiences of antipsychotic dose reductions causing an increase in behavioural problems and adversely affecting mental wellbeing.

9.2.3 Burden from medication routine and change to routine

All the cases highlighted that for the adult with LD, medication and the associated routine was just a normal part of daily life. In most of the cases studied, medication administration was strongly associated with particular times of day and adhering to the set routine was important to the adult with LD and their carers or care workers. Interestingly, it was the disruption of, or change to, a routine which had the potential to cause anxiety for the adult with LD and thereby increase the anxiety for the carers or care workers (Case06C-Mark; Case08C-Ruth). There was also the potential for medication routines to dictate, or limit, social activities, and as a result cause a degree of burden (Case02N-Anna; Case03N-Paul). This view was echoed within the dissemination check and the potential for obsessive behaviour in relation to medication routine from some adults with LD resonated with them.

Self-management of the daily medication routine was important to adults with mild LD (Case 07C-Susan; Case09C-Donald; Case10C-Susan). For one adult with moderate LD (Case06C-Mark), enabling him to self-administer under supervision had been viewed positively by his care workers. This reflects the view of Williams and Evans (2013) that personal development, self-esteem and community participation are achieved when adults with LD are not over-protected and are given opportunities, where appropriate, to be involved in activities where there is a degree of risk.

However, for formal care workers, ensuring that medication was routinely given in accordance with the prescriber's instructions generated its own burden. Belief in the importance of medication for the wellbeing of the adult with LD was cited (Case02N-Anna; Case03N-Paul) but also the fear of making medication 'errors' by deviating from the established routine (Case02N-Anna; Case03N-Paul). The literature reviewed in this research did not identify this particular issue.

9.2.4 Reducing burden by optimisation of medication

Within all the cases it was apparent that carers, care workers, or the adult with LD had optimised the routine to maximise the chance of successful administration. Examples of this optimisation included: refining the timing of administration in the wider morning routine (Case03N-Paul); requesting formulation changes (Case02N-Anna; Case 05N-Rob); refining the order of medicine administration (Case 03N-Paul); enhancing palatability of medication (Case02N-Anna); refining administration technique during illness or in an acute behavioural situation (Case02N-Anna; Case03N-Paul; Case05N-Rob); using multi-compartment compliance aids (Case10C-Susan; Case11C-David); refining level of carer support (Case05C-Mark).

As medication had been tailored to optimise successful administration and provide assurance of necessity, it follows that even seemingly insignificant changes by prescribers or pharmacists have the potential to significantly affect the related burden of medication – both positively and negatively. The instance of changing from multiple lower strength tablets to fewer higher strength tablets was cited in Case02N-Anna as a potential problem, due to their larger size. Carers and care workers were not automatically averse to changes, but expressed the need for their involvement in any decision to ensure practicalities were considered and concerns allayed. Within the dissemination check, the view that the carer or care worker was the expert on the adult with LD and that asking for, and listening to, the views of carers or care workers would help diffuse feelings of exclusion in decisions. The literature reviewed in this research did not identify this particular issue in relation to medication.

For three of the cases where the adult had severe LD, medicines were administered via a PEG tube (Case03N-Paul; Case04N-Jamie; Case05N-Rob). Whilst there is some associated burden for carers and care workers with PEG tubes, such as having to ensure that medicines are crushed adequately and knowing what to do if the tube blocks, this is less of a burden than having to take responsibility for administering medicines orally when aspiration and choking is likely. It was also noted in Case05N-Rob that administration of medicines via a PEG tube was less disruptive to the adult with

LD and that the time required to administer medicines was reduced as a result of the PEG tube. The level of expertise in administering medicines via a PEG tube was not a focus of this study so data were not specifically gathered to ascertain competency – as was done by Joos *et al* (2016) and Joos *et al* (2015). However, of interest was the fact that carers and care workers did not make reference to any formal written guidance when discussing medicine administration via PEG tubes. The dissemination check also queried whether administration of medication by PEG tube and the use of food to make swallowing easier should be considered covert administration in those adults with LD who lack capacity.

9.2.5 Medication has the potential to be either a benefit or a burden socially

Medication which improved mental wellbeing resulted in the adult with LD being able to better engage in social activity which then improved their quality of life. These medicines were viewed positively and defended as both essential and beneficial within the case studies (Case04N-Jamie; Case05N-Rob; Case06C-Mark; Case07C-Fiona; Case09C-Donald). In addition, medicines which addressed physical conditions that limited mobility or wellbeing such as medicines for epilepsy or heartburn, were viewed as allowing the adult with LD to have more social opportunities within the case studies (Case02N-Anna; Case04N-Jamie; Case05N-Rob).

Within supported housing, it was interesting to note that medication administration times were viewed as an opportunity for social contact between the carers and the adults with LD (Case06C-Mark; Case07C-Fiona). Care workers noted that the arrangement of them supervising self-administration provided the adult with LD with an acceptable level of independence but also served as daily social contact to check how they were doing in general, and that this was of mutual benefit. The literature reviewed in this research did not identify this benefit to medication.

In the majority of cases, medication was not collected from the pharmacy by the adult with LD but was instead collected by carers or care workers or delivered by the pharmacy. This lack of contact with pharmacy services may be the reason for Flood and Henman (2015 p.235) commenting that people with LD are invisible to pharmacists and that, *'…Pharmacists may have little knowledge or experience of the challenges faced by this group...'.*

Conversely, any medication or change to medication that reduced the ability of the adult with LD to engage in social activities was viewed as a burden. For one case (Case03N-Paul) the limited effect of any psychoactive medication in helping manage his challenging behaviour to enable increased social activity was a notable disappointment. Maximising the quality and quantity of social engagement

was viewed, by case study and dissemination check participants, as an essential outcome of therapy for adults with LD.

9.2.6 Burden of medication decisions being transferred to carers and care workers

Adults with moderate-severe LD are dependent on their carers and care workers to make the vast majority of their health decisions, including medication related decisions (Davis *et al* 2016; Flood and Henman 2015). Within the case studies focusing on an adult with moderate-severe LD, carers and care workers often highlighted the burden of having to make decisions on behalf of another adult. Aspects of that burden included: making decisions that the adult would want (Case05N-Rob); living with decisions that had resulted in an adverse event (Case04N-Jamie); weighing up the benefits and problems associated with medication (Case03N-Paul); ascertaining if medication was actually having a benefit (Case03N-Paul); the 'panic' when a dose was missed (Case02N-Anna); and having to 'battle' with HCPs to have their views heard (Case04N-Jamie). This last issue linked to the issues raised in the literature of exclusion from decision-making and an ignoring of raised concerns (Redley *et al* 2013; Buelow *et al* 2006; and Keywood and Flynn 2006).

Whilst there was a lesser transfer of burden to care workers in Case07C-Fiona and Case08C-Ruth because the adult with LD had sufficient capacity and capability with respect to medication management, concern about the adult's ability to make informed decisions about medication and retain relevant information was expressed. For Case09C-Donald, Case10C-Susan, and Case11C-David, who were all managing their medicines independently, little medication burden was expressed. It was not possible to determine if this was due to a lack of awareness or if it was an informed view. However, having no support with medication from care workers and little contact with their community pharmacy potentially makes these adults with LD more vulnerable than those adults with LD who have support from carers or care workers. The literature reviewed in this research did not identify this as an issue for community dwelling adults with LD.

9.3 MEDICATION RELATED BELIEFS OF ADULTS WITH LD

The following key themes emerged from the data about medication related beliefs: beliefs and influence of significant others; medication being viewed as both beneficial and necessary; carers and care workers of adults with severe LD being the experts on the person being prescribed for; maximising the coping skills of adults with mild-moderate LD; and recognition of the coping skills of carers and care workers. Each of these themes will now be discussed, relating the case study findings to existing literature, where available, and noting comments from the dissemination check.

9.3.1 Beliefs and influence of significant others

Within the case studies of adults with moderate-severe LD, both positive and negative beliefs about medication were expressed by the carers and care workers. Some of these beliefs were medicine specific and related to the efficacy or tolerability of the medicine. However, sometimes conflicting beliefs were expressed, such as in Case03N-Paul where there was a desire for a 'magic pill' to resolve the current behavioural challenges, despite past drugs being ineffective.

For adults with mild LD (Case07C-Fiona; Case08C-Ruth; Case09C-Donald; Case10C-Susan; Case11C-David) there was variation in their level of capacity and capability, their living arrangements, the number of significant others in their life, who their significant others were, and the involvement or influence of significant others with medication. The influence of significant others, both current and past, was rarely mentioned by the adult. If care workers were involved it was they who articulated their current level of influence in relation to medication. Whether the lack of reference to the influence of others in relation to their medication was due to there being an absence of any influence, a lack of recall, or lack of insight into this influence is debateable. This situation may in part relate to the results of a survey of 2898 people with LD by Emerson *et al* (2005) where it was found that 19% participants never saw members of their family, 31% said they did not have any contact with friends and 5% had no friends and did not see anyone from their family.

Care workers sometimes expressed a view and then downplayed the importance of that view by highlighting that they were only a care worker and not a HCP (Case03N-Paul; Case07C-Fiona; Case08C-Ruth). This latter issue was noted by the participants in the dissemination check who commented that there is often a perceived 'power relationship' between HCPs and carers or care workers. The literature reviewed in this research did not identify this as an issue for carers and care workers of adults with LD although reference was made to carers and care workers having to become 'battle weary health advocates' (Keywood and Flynn 2006).

9.3.2 Belief that medication is both beneficial and necessary

Whilst some burden was attached to medication, this burden was most commonly perceived to be less than the burden that would have been experienced without it. Therefore, the belief that medication reduced morbidity or mortality was expressed within all the cases. For adults with moderate-severe LD, any benefit that the medication was able to confer was believed worthwhile by their carers and care workers. However, two situations caused belief in the benefit and necessity of medication to be questioned by the carers: intolerable side-effects, in particular side-effects relating

to cognitive ability or mental wellbeing (see Section 4.2.2); and failure to control, manage or reduce symptoms of a condition (Case03N-Paul). Within the case studies focusing on adults with mild LD it was more difficult to explore the reasons for believing their medication to be beneficial and necessary. A factor to consider in the acceptance of medication is an issue highlighted by Stalker (1998): some adults with LD tend to acquiesce, not because of their LD, but because they are so used to having other areas of their life controlled by others.

9.3.3 Belief that carers and care workers of adults with severe LD are the experts on the person

All the cases of an adult with severe LD highlighted the conflict and tension that arises when HCPs did not involve the carers and care workers in key decisions, including prescribing. The stress and frustration of medicines being prescribed in inappropriate formulations, excessive doses and with little accompanying communication about any changes was a recurring theme. Carers and care workers did not describe themselves as experts in prescribing or medication – although their knowledge of past medication, and particularly medicines that had caused adverse events, would be invaluable to prescribers. They did, however, consider themselves an expert on the adult they were caring for, and this was evident in the detail they provided during the interviews. Their belief was very much that their expertise and views were often not consistently taken into consideration, to the detriment to the adult with LD. In the dissemination check, the participants highlighted this as a key issue and reiterated the importance of involvement of the carers and care workers in prescribing decisions and using their enhanced knowledge of the adult with LD in the decision making process. The literature reviewed in this research did not identify this particular issue.

9.3.4 Beliefs in maximising the coping skills of adults with mild-moderate LD

Care workers of adults with mild-moderate LD often expressed a degree of concern regarding the extent of the adult with LD's capability to make informed medication related decisions or their capability to manage their medication. Beliefs of care workers about the adult with LD's capability affected the level of support provided (Case06C-Mark; Case07C-Fiona), and seeing the adult with LD making poorer decisions in relation to their medicines was a source of stress (Case08C-Ruth). Ascertaining capacity, capability, level of health literacy and then ensuring ongoing understanding in people with mild to moderate LD, has been noted as a challenge for all clinicians and prescribers (Ferguson and Murphy 2014; Stenfert Kroese, Ngoh 2009; Schwartzberg *et al* 2007; Davis *et al* 2006; Arscott *et al* 2003; and Dewhurst and Holmes 2001).

Managing their medication with minimal support from carers or care workers was a source of pride to adults with milder LD as it evidenced their capability (Cases07C-11C). This confidence in their own capability contrasts to the study by Crossley and Withers (2009) where people with milder LD expressed the belief that because their carers knew more about their medicines than they do, then their carers should make all the decisions on their behalf. The care workers in Case06C-Mark and Case07C-Fiona also expressed their belief in the benefits of increased self-esteem through an enablement approach to medication. There were, however, some concerns about removing all support, and the importance of routine for the individuals was stressed.

Donald (Case 09C), Susan (Case 10C), and David (Case 11C) had no care worker supporting them with their medicine administration and expressed no concerns about their ability to manage their medication. However, during the interview there was sometimes evidence to the contrary. For example, Donald (Case 09C) could not explain why he received his medication on a weekly basis; Susan (Case 10C) did not correctly identify an empty blister in her MCA and was confused about when a medication change was occurring; and David (Case 11C) was not able to recall the indication for bought medicines. Accepting some degree of risk in relation to self-management of medication is challenging for carers, care workers and HCPs. However, Williams and Evans (2013) raised the interesting point that it is important for people with LD to be exposed to some level of hazard so they learn how to be safe and this in turn aids their development, self-esteem and community participation.

9.3.5 Carers and care workers' beliefs of their own coping skills

Supporting adults with LD to take their medication was seen by carers and care workers as part of their role. Care workers received some formal training from their employer on administration and record keeping. However, family carers developed these skills through trial and error over the years. Both carers and care workers demonstrated a person-centred approach to administration as they adapted the medication routine (Case03N-Paul; Case06C-Mark; Case07C-Fiona), formulation (Case04N- Jamie; Case05N-Rob; Case06C-Mark) or route (Case04N- Jamie; Case05N-Rob) to best suit the adult with LD and optimise the chances of successful administration.

Administering medication was not the only skill noted in the case studies. For carers and care workers of adults with moderate - severe LD, recognising how the adult with LD would communicate medication related issues such as the need for a 'when required' medication, was important. This was particularly important when the adult with LD was non-verbal. Bhaumik *et al* (2015), and

Stenfert-Kroese, Dewhurst and Holmes (2001), highlighted the challenges associated with monitoring side effects in patients with LD because of their limited or idiosyncratic ways of communication. The dissemination check noted that these challenges are heightened in the hospital setting where the surroundings and HCPs are all unknown to the adult with LD.

Also highlighted in the case studies was the unique burden faced by care workers because of their employer's and regulatory body's policies. Care workers highlighted that family carers can adopt a more flexible approach to medication whereas care workers must always administer medication in exact accordance with the prescriber's instructions and any deviation would be considered a reportable error. As highlighted in one case (Case02N-Anna), where both carers and care workers care for an adult with LD, tension over medication can arise and become a flashpoint. The participants of the dissemination check echoed this issue as being one they encountered frequently yet there was no evidence of this issue in the literature identified for this research.

9.4 MEDICATION TAKING PRACTICE OF ADULTS WITH LD

The following two key themes emerged from the data: conditional acceptance of medication; and compliant medication taking or administration. Each of these themes will now be discussed, relating the case study findings to existing literature where available, and noting comments from the dissemination check.

9.4.1 Conditional acceptance of medication

Whilst there was evidence to suggest that some adults with moderate-severe LD accepted the medication unconditionally, several case studies suggested that it may have been the routine itself that was accepted unconditionally (Case02N-Anna; Case06C-Mark). This unconditional acceptance of medication as a routine may explain why changes to medication can be so problematic; not only do the clinical implications need to be understood and consented to, but the impact on routine and change to the familiar need to be considered. For adults with milder LD, understanding of their medication was perhaps more simplistic. However, it was still conditional on it making them feel better, not making them feel worse, being acceptable in terms of palatability and also being easy to take.

Within the majority of cases, carers and care workers of adults with moderate-severe LD demonstrated an acceptance of medication that was conditional on tangible benefits or the absence of significant side effects. Acceptance of a medication regimen, particularly from carers, was also generally only after experimentation with doses and timings or alternative medicines to find the

optimal regimen. However, some care workers accepted medication for the adult with LD that they were caring for with fewer conditions and a lesser desire for experimentation. This was not due to them being less concerned about the adult with LD's welfare, but because they saw the doctor or prescriber as the expert and did not feel it appropriate for them to question or influence decisions made by a HCP. This was even more acute for care workers of people with mild LD because of the greater ability of the adult with LD to deal directly with their clinicians and make independent decisions about their medication. The result was often that care workers were left in a position of accepting the medication and supporting the adult with LD to take their medication as prescribed despite having unvoiced or unanswered concerns. This issue of perceived 'power' was again echoed by the dissemination check participants but not noted within the literature identified within this research.

9.4.2 Compliant medication taking or administration

Acceptance of medication, whether conditional or unconditional, in the lives of people with LD is not actually synonymous with medication taking or administering practice. Within the case studies, despite any doubts, medication was taken or administered in accordance with the prescriber's instructions. Any non-adherence was either unintentional or for a legitimate reason, such as challenging behaviour. Whilst unintentional non-adherence generated anxiety for both carers and care workers, there were additional employment consequences for care workers. The Human Medicines Regulations (2012) state that prescription only medicines (POMs) can only be given in accordance with the directions of an appropriate practitioner. Having to ensure that medication was administered only as per the prescriber's instructions meant that care workers would not consider any change to the medication regimen without written instruction from the prescriber. In most instances this restriction will safeguard the adult with LD from potentially dangerous decisions. However, as demonstrated in one of the cases (Case02N-Anna), this lack of permitted flexibility for care workers can generate a flashpoint between themselves and family carers. In another case (Case03N-Paul) it prevented the timely trial of potentially helpful changes of dose to assist in managing challenging behaviour. A desire for more flexibility with medication for care workers in similar situations was also expressed within the dissemination check. The literature reviewed in this research did not identify this particular issue.

9.5 THEORETICAL FRAMEWORK

The Patient's Lived Experience with Medicine (PLEM) conceptual model by Mohammed, Moles and Chen (2016) was adopted as a theoretical framework for this study. A description of this model and an initial discussion of the strengths and limitations of the model was provided in Chapter 2. As the purpose of this research was not to formally validate or critique this model, only a brief discussion on the experience of using this model will now be undertaken with some recommendations for improvement. In addition, it is recognised that this study only included a small number of participants, and from a very particular population, and so a comprehensive critique of the model is therefore limited.

As noted by Birken *et al* (2017) the ultimate purpose of a theoretical framework is to act as a 'synthesizing architecture'. PLEM was chosen because it had a high degree of logical consistency and plausibility, could be used within a qualitative research method, and had the required focus of interest – experience with medication. However, a key limitation was the lack of validation or critique of the model within the literature. To date, no work has been published critiquing the PLEM model.

In general, the PLEM conceptual model facilitated systematic data collection and analysis. However, as advised by Maxwell (2012), the researcher was mindful not to confine interview questioning to the framework, or to force insights into the framework, or to overlook data which did not fit into the framework. Participants were provided with the interview questions before the interview but in the interview were encouraged, through an open question, to tell their story. Often this yielded information that direct questioning from the framework might not have done. It also allowed the participants to talk about what mattered most to them as opposed to what the researcher thought might matter most.

The framework approach to analysis, as detailed by Gale *et al* (2013), promotes systematic and consistent handling of qualitative data. The PLEM conceptual model was easily used to create a deductive list of themes, sub-themes, and sub-theme examples, but care was taken to allow other sub-theme examples to emerge from the data. Table 7.1 lists the new sub-theme examples identified within the data that had not been identified within the PLEM framework.

From the outset of the research, the absence of a section with the PLEM model that accounted for the benefit of medicines due to the reduction of disease burden was noted as a potential limitation. Within this study there were several instances where the medicines, despite any burden that they brought, were accepted because the disease burden was in comparison much greater:

> [In response to a question about the benefits of fluoxetine]:
> *'Outbursts – he had a lot of them before. And although he'll still have them, they're more controlled now…I think he'd just be as high as a kite if he wasn't taking his tablets to be honest with you…'* Case06C-Mark-CareW02

> *'[without medication] She wouldn't have a life I don't think…She needs her medication.'* Case02N-Anna-CareW04

Imbalance towards the negative aspects of medicines can also be seen in that there was only a *Negative Therapeutic Outcomes* element within the model; to truly describe lived experience, a positive therapeutic outcomes element should be included. Whilst it could be argued that the *Patients' wellbeing & HRQoL* element within the model addresses this, I would argue it does not provide the required balance or neutrality within the model. An element on medication related benefits needs to be included alongside medication related burden. In addition, wellbeing and health related quality of life is linked to more than just medication, and the relationship between the two is more complex than that indicated within the model. In fact, it could be argued that your wellbeing and quality of life will influence your lived experience with medicine as much as medicine will influence your wellbeing and quality of life.

As both a researcher and clinician I was unclear as to whether a side-effect or adverse event from a medicine (a 'drug related problem (DRP)') was to be classed as a *Medication Related Burden* or a *Negative Therapeutic Outcome* or both. Double weighting should not be given to DRPs within the PLEM model so clarification or refinement of this particular aspect of the model is recommended.

Finally, the relationships between all the themes require review and refinement. Relationships are often only annotated as one way and feedback loops missing. For example, medication taking practice is not linked back to medication related burden yet, it is clear that how and when a person actually takes a medicine will affect the potential burden. It would also appear from the model that the *Patient's wellbeing and HRQoL* and *Negative Therapeutic outcomes* do not influence the three

major themes of medication related burden, medication related beliefs, and medication taking practice. Further research to specifically review and refine this model would be recommended.

9.6 REFLEXIVITY

'Are the researcher's motives, background, perspectives and preliminary hypotheses presented, and is the effect of these issues sufficiently dealt with?' Malterud (2001 p.485)

Motives for the research and the researcher's background were outlined in the introduction to this thesis and the impact of being both a local HCP and researcher acknowledged. As detailed in Chapter 2, the methodology and methods employed have been outlined and made as transparent as possible to the reader. It is acknowledged that a more experienced researcher, with more honed skills, may have yielded a different data set. It is also possible that my being a practicing clinician inadvertently affected participants' responses – potentially both negatively and positively. Data from the study has been presented in Chapters 3-8, before discussions in Chapter 9 to allow the reader to decide if the findings reached are reflective of the data gathered. During the entire research process an open dialogue with my primary supervisor occurred to ensure that my actions and decisions were checked regularly. However, whilst every attempt has been made to acknowledge the impact of the researcher on the research, it is possible that, as outlined in the Johari Model of self-awareness, I have unknowingly influenced the research and not accounted for that influence (Luft and Ingham 1961). Undertaking this research has enhanced my ability to project manage and my attention to detail, extended and improved my listening and questioning skills, and also developed my writing skills.

9.7 TRANSFERABILITY OF RESEARCH FINDINGS

As detailed in Table 2.3, the transferability of a study, is the level to which the findings of a qualitative research study can be applied to another group by the reader. This can only be achieved when the researcher provides background data, establishes the context of study and provides detailed descriptions of phenomenon in order to allow for comparison. The context of the study was established in Chapter 1 and included a background to: LD; health and social care service in the UK; medicines, medication and polypharmacy; and a summary of the literature relating to adults with LD and medication. Full descriptions of all the cases and background data are included in Appendices 3.1 – 3.11. As will be discussed in Section 9.8.2, the lack of geographical diversity in the cases may limit the degree of transferability. Another issue is that health care in Scotland, including provision of medication, is free at the point of delivery. This is different to so many other countries and will affect the degree of transferability of data relating to financial burden from medication.

9.8 STRENGTHS AND LIMITATIONS OF THIS RESEARCH

As with all research studies, this study has both strengths and limitations which will now be considered:

9.8.1 Strengths

First and foremost, this study was designed to involve and include both adults with LD, and those who are actively involved in their care. As detailed in Chapter 2, methodology and methods which were sensitive to the needs and challenges of the LD population were chosen and an adult with mild LD was involved in ensuring materials and questions were appropriate for the LD community. In addition, appropriate professional and academic governance and safeguarding were established and adhered to throughout the study thus prioritising the wellbeing of any participant.

Situated in a pragmatic 'real life' worldview, methodology and methods best suited to answering the research questions were chosen. The use of a new conceptual model could be considered a strength but, as it was not validated, it could also be considered a potential limitation. Contact was made with the corresponding author of PLEM before data collection to ensure as full an understanding of the model as was possible. The PLEM model was discussed in more detail in Section 9.5.

As detailed in Table 2.7, as far as was possible, the study was designed to be transparent and to maximise the credibility, transferability, dependability and confirmability of the data gathered and analysed. Reflexive practice was employed throughout the study.

Finally, local care providers and charities were involved from the outset to help shape and influence the research. This improved the quality of the research methodology and methods, maximised acceptability of the research in the LD community, helped in recruitment, checked the credibility of the results and aided in the local dissemination of the study outcomes.

9.8.2 Limitations

Firstly, the study was limited to a local geographical area in the north of Scotland. All the cases studied were born and lived their lives in north east Scotland and this may therefore limit the transferability of results to other populations.

As noted by Meyer (2001), non-random selection of cases may give rise to a possible accusation of lack of rigour or indeed bias. The cases were not chosen by the researcher, and all cases who

volunteered were included. There is always the possibility that these volunteers were those who were most interested in and engaged with medication, and that participants with less interest in medication were not included. However, the purpose of the study was to allow a small number of participants to share their unique experiences with medication and not to reflect all 'types' of people in respect to their engagement with medication.

Engagement and communication with those participants who had mild LD and no carer or care worker involved in medication management was a challenge for the researcher. Without the guidance of carers or care workers it was more challenging to gain rapport and to ensure that information and questions were provided in a manner which maximised the understanding of the participant. Of note was Donald (Case09C) who provided little information in response to the interview questions. Furthermore, it was difficult to verify and triangulate data in cases focused on an adult with mild LD where no carer or care worker was involved (Case 09C-Donald; Case10C-Susan; Case11C-David). However, this in and of itself highlighted the opportunity for HCPs, including community pharmacists, to develop and maintain the coping skills of adults with LD in relation to medication.

As with all studies, the degree of participant biases, as outlined in Table 2.4, cannot be verified. However, throughout the research process, every attempt was made to minimise participant bias by encouraging honesty and reassuring anonymity.

Another potential limitation was the lack of data from other sources, notably interviews of significant others, in the cases focusing on adults with mild LD, as was recommended by Yin (2014), Thomas (2011), Stake (1995) and Eisenhardt (1989). Inclusion of data from health care records (medical or pharmacy) and the inclusion of views of significant HCPs would have enhanced triangulation of data. Furthermore, the noted issue of recall and memory has meant that there are potentially significant events relating to medication that the participants, particularly those with LD, were unable to recall and so the data in these cases are potentially incomplete. Whilst inclusion of HCP views and records would have provided additional data and perspective, it also had the potential to detract from the key focus of the research – to understand the lived experience of adults with LD in relation to medication and to give them, their carers and care workers a voice.

Finally, the data used in analysis was heavily weighted to the interview(s) undertaken in each case. Additional observational data from the researcher may have yielded greater insight into current

situations that were not properly understood or articulated by the participants, as noted by Bowling (2014). However, due consideration would have had to be given to the time commitment required to make this successful, the potential for the Hawthorne effect (as detailed in Chapter 2), and the impact on participants with LD of having the researcher becoming part of their life and then leaving.

9.9 CHAPTER SUMMARY

This chapter discussed the collated case study findings for the three research objectives, as set out in Chapter 1, which were:

1. To explore and describe the medication related burden experienced by adults with LD;
2. To explore and describe the medication related beliefs of adults with LD;
3. To explore and describe the medication taking practice of adults with LD.

Then this chapter discussed the use of the PLEM conceptual model as a theoretical framework within the research before discussing the reflexivity, transferability, and strengths and weaknesses of the research.

CHAPTER 10 IMPACT AND CONCLUSION

'We must go on and take the adventure that comes to us'

The Last Battle - C.S.Lewis

10.1 CHAPTER INTRODUCTION

Before providing a conclusion to this thesis, this chapter will discuss the potential impact of the research, and possible future work identified within this research.

10.2 POTENTIAL IMPACT OF THE RESEARCH

Impact from research has to be defined as more than just academic knowledge creation; it has to also include the influence or effect out with of academia (Denicolo 2014). The Research Councils UK (RCUK) defines impact as academic or as being economic and societal (Research Councils UK 2018). RCUK also notes the importance of engaging the public with research in order to improve both the quality and impact (Research Councils UK 2018). Rivera *et al* (2017), identified the current frameworks used to demonstrate impact from health research and recognising the common concepts and themes. The collective summary of pathways to health research impact from Rivera *et al* (2017) is detailed below in Figure 10.1:

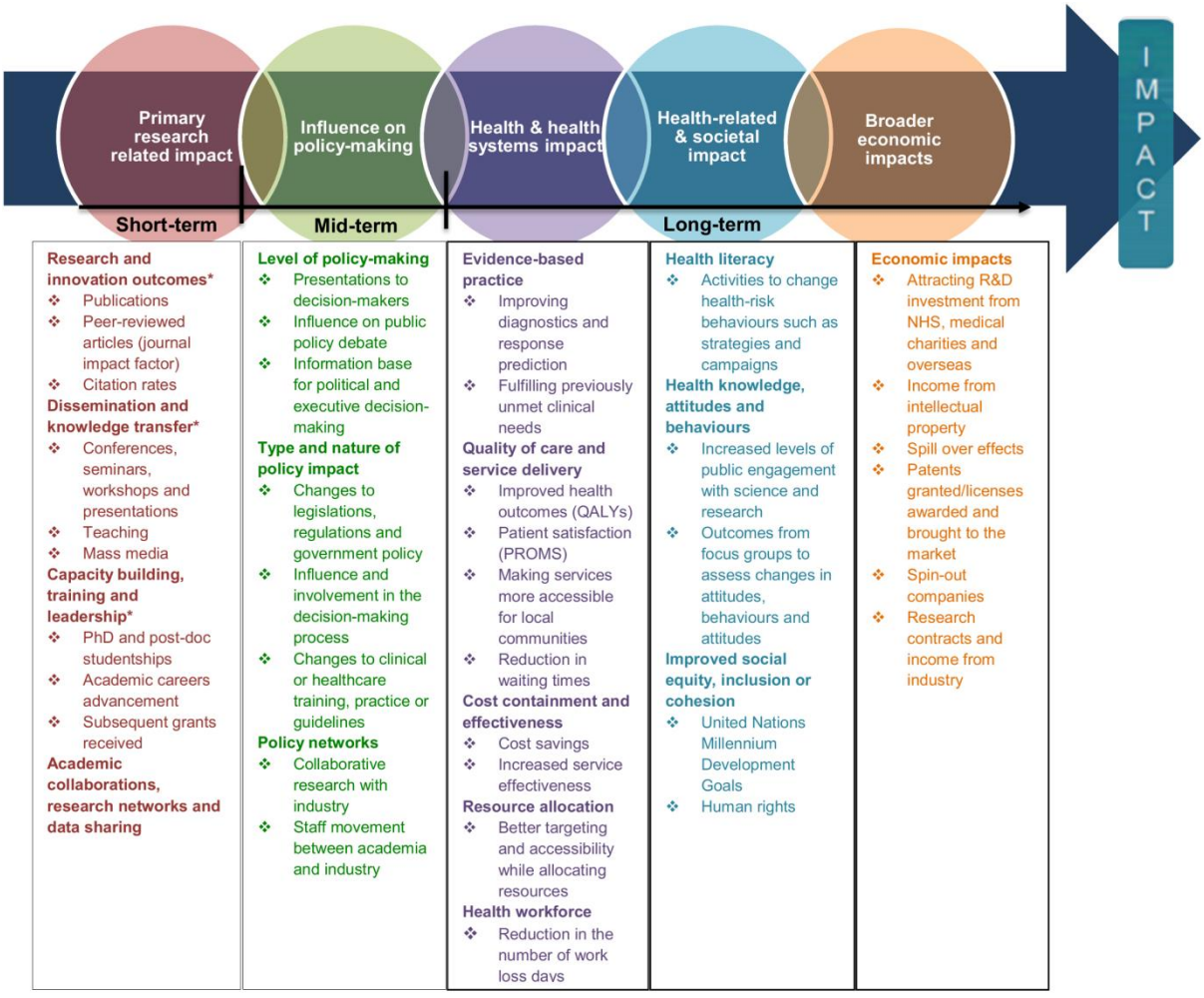


Figure 10.1 Pathways to research impact (Rivera *et al* 2017)

10.2.1 Primary Research Related Impact

Using the pathways to research impact framework by Rivera *et al* (2017), the following is a description of the potential key categories of impact for this research:

Research and Innovations Outcomes

It is the intention to publish aspects of this research in both a pharmacy and an LD peer-reviewed journal so that the learning can be shared and accessed by all researchers and clinicians interested in this area.

Dissemination and Knowledge Transfer

- A workshop entitled, *'Tackling inequalities in access to clinical pharmacist led healthcare: recognising and overcoming ethical issues of inclusion in research'*, was delivered at the European Society of Clinical Pharmacy conference in Oslo (5th-7th October 2016).
- A further workshop entitled, 'Medication related experiences of adults with learning disabilities', was delivered at the European Society of Clinical Pharmacy conference in Belfast (24th-26th October 2018).
- Poster abstracts have been presented at:
    - NHS Grampian's Quality and Safety in Healthcare event, Aberdeen (1st May 2018);
    - RGU's Pharmacy and Life Sciences Research Day, Aberdeen (28th May 2018);
    - European Society of Clinical Pharmacy conference, Belfast (24th-26th October 2018);
    - NHS Scotland's Research conference, Perth (30th October 2018).
- Local participation in Scotland's national Learning Disability Week (14th – 20th May 2018).
- Feedback to the Aberdeen Provider's Forum, formerly CASPA (27th June 2018).
- Meeting with NHS Grampian's newly appointed Nurse Consultant for LD to discuss how to disseminate and apply research locally (31st July 2018).
- A summary of the research will be sent to the Scottish Commission for Learning Disabilities (SCLD) in Glasgow.
- Planned participation (poster and/or oral abstract) for the International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) conference in Glasgow (6th – 9th August 2019).

Capacity Building, Training and Leadership

This research study has been part of the doctoral training for the researcher. As a result of this training, project work for NES was undertaken January-June 2018.

10.2.2 Influence on Policy-Making

Level of Policy Making; Type and Nature of Policy Impact; Policy Networks

> This research will influence local medication management policies, procedures and training which can then be shared nationally. However, as Rivera *et al* (2017 p.18) noted, *'The outcomes of research may emerge slowly and be absorbed gradually. Consequently, it is difficult to determine the influence of research in the development of a new policy, practice, or guidelines.'*

10.2.3 Health-related and Societal Impact

Health Knowledge, Attitudes and Behaviours

It is hoped that this research involving adults with LD will encourage other researchers to include adults with LD in research design and also encourage other adults with LD to participate.

10.3 POSSIBLE PRACTICAL KEY LEARNING POINTS FOR HEALTH CARE PROFESSIONALS

A key element of the Doctorate of Professional Practice is to focus on the impact of the research. The following section was created by the researcher to demonstrate how the emerging themes from medication related burden; medication related beliefs; and medication taking practice might be summarised into practical key learning points for HCPs. It is important to stress that these learning points have not been validated and would require such a process before they could be disseminated within the academic sphere. The possible practical key learning points for HCPs are first of all summarised in Table 10.1 before being expanded upon. Evidence from the case studies and, if applicable, relevant UK Government health polices as outlined in Chapter 1, illustrate or evidence the issue.

Table 10.1 Summary of proposed practical key learning points for health care professionals

Proposed Learning Point	Description
#1	For adults with LD, medication is generally viewed to be both beneficial and essential in respect to morbidity and mortality; a perceived lack of efficacy or intolerable side-effects challenges this belief.
#2	Maximising cognitive ability and mental wellbeing is essential for adults with LD so adverse effects on cognitive ability or mental wellbeing from medication or medication withdrawal are often unacceptable.
#3	Carers and care workers of adults with LD, particularly those of adults with severe LD, are the expert on the person; they want to work with HCPs but are often excluded from discussions and decision making.
#4	Medication has the potential to both enhance and hinder the quality of life for adults with LD; enhanced social ability or experiences and quality of life is an important outcome and small gains are valued.
#5	Medication routine is an important aspect of life for adults with LD and altering it can have unexpected impact on their life.
#6	HCPs need to be mindful of the practical issues surrounding medication administration for carers, care workers of adults with LD, and of self-medicating adults with LD.
#7	The coping skills of adults with mild-moderate LD in relation to medication should be developed and maintained by carers, care workers and HCPs; but their potential limitations of capability and responsibility remembered.

Proposed learning point #1	For adults with LD, medication is generally viewed to be both beneficial and essential in respect to morbidity and mortality; a perceived lack of efficacy or intolerable side-effects challenges this belief.

HCPs might improve the medication related experiences of adults with LD by:

- being aware that medication for adults with LD is viewed as beneficial and essential in respect to both morbidity and mortality;
- considering that even seemingly small benefits from medicines may be of value to the adult with LD and their carers or care workers;
- being aware that sensitivity to the effects and side-effects of medication may be increased in adults with LD;
- considering the possible side-effects and the impact on the adult with LD, particularly before prescribing new medicines;
- counselling adults with LD or their carers and care workers about potential side effects of new medicines;
- reviewing all medication on a regular basis and amending doses or discontinuing medication where efficacy is lacking or side-effects are considered intolerable.

'She wouldn't have a life [without medication] I don't think…She needs her medication.' Case02N-Anna-CareW04

'It'd be really hard for him just for daily life I think without his medications.' Case06C-Mark-CareW02

'Epilim – we got him down on to the minimum dose that he needed…He had to be kept on a tiny amount of that [clonazepam]. We tried to take him off it but it's such a powerful medication. I weaned it down to the absolute minimum but when I tried to take him [off it] - we had some really bad effects.' Case04-Jamie-Carer01

'You should expect the doctor (or other health professional) to explore and understand what matters to you personally and what your goals are, to explain to you the possible treatments or interventions available with a realistic explanation of their potential benefits and risks for

you as an individual, and to discuss the option and implications of doing nothing.' (Scottish Government 2017b p. 4)

Proposed learning point #2	Maximising cognitive ability and mental wellbeing is essential for adults with LD so adverse effects on cognitive ability or mental wellbeing from medication or medication withdrawal are often unacceptable.

HCPs might improve the medication related experiences of adults with LD by:

- ensuring that optimal cognitive ability and mental wellbeing is a primary focus of care;
- being aware that any adverse effect on cognitive ability or mental wellbeing from medication, or medication withdrawal, is likely to be considered intolerable;
- prescribing drugs with the least potential negative impact on cognitive ability or mental well being;
- involving the adult with LD, their carers, or care workers before initiating any change to medication which may impact negatively on cognitive ability or mental wellbeing;
- considering the impact on the adult's quality of life from adverse effects on cognitive ability or mental wellbeing when reviewing medication or changes to doses of medication.

'I suppose to keep my mood up, keep me healthy. You know, I'm able to do stuff. So it's pretty good actually.' Case09C-Donald

'It took a while but the fluoxetine – I'm more relaxed. Having two fluoxetine helps me more than having just 20[mg] fluoxetine… I wouldn't want to stop that. That really helps me be more relaxed and everything 'cause I'm not so anxious like I used to be. I'm not so, 'C'mon!' I'm just more laid back and it helps a lot.' Case07C-Fiona

'…some of them are fairly sedative and obviously that has a knock-on effect to people's development… the impact on their cognitive abilities…' Case04N-Jamie-Carer01

'… we've been trained in a reductionist environment where people don't trust measures that aren't highly objective and generalisable, when most things that contribute to value at the level of the individual are highly subjective and context specific, including their preferences…' (Scottish Government 2017b p. 11).

Proposed learning point #3	Carers and care workers of adults with LD, particularly those of adults with severe LD, are the expert on the person; they want to work with HCPs but are often excluded from discussions and decision making.

HCPs might improve the medication related experiences of adults, particularly those with severe LD by:

- viewing the carers and care workers as the experts on the adult with LD whilst remaining the experts on clinical care and medication;
- being aware that it is the carers and care workers of adults with LD, particularly adults with moderate-severe LD, who carry the responsibility and any associated burden related to medication;
- always involving the carers and care workers of adults with severe LD in any medication related decision or change;
- respecting the lived experience of carers and care workers and valuing the expertise they can bring;
- listening to the wishes and concerns of carers and care workers about the medication or the administration practicalities;
- reaching a mutually acceptable decision for medication provided this would promote the wellbeing of the adult with LD;
- retaining awareness of the potential for medication to become a flash point between carers and care workers, so encourage proactive and ongoing communication between them.

'…[tablets that are] too big can be an issue particularly when people think they are doing us a favour by reducing the number [of tablets] we have to take without consultation.' Case02N-Anna-Carer01

'And the other thing which I think I need to say which is extremely hard is that I had to make decisions on behalf of somebody who would normally make decisions for themselves…I was always conscious of that as a young man of that age what would he want, what would his choice be? And acting in his best interest…' Case04N-Jamie-Carer01

'And also sometimes having to stand up to professionals which I did have to. On a number of occasions, I had to be quite brave and stand up knowing that I was doing right by him… Ok you're the one with the qualifications but I know how his body works and I know him and I need to say this.' Case04N-Jamie-Carer01

'Health professionals caring for people with learning disabilities should assess and keep under review the medicines requirements for each individual patient to determine the best course of action for that patient, taking into account the views of the person if possible and their family and/or carer.' (Department of Health 2012 page 45)

Proposed learning point #4	Medication has the potential to both enhance and hinder the quality of life for adults with LD; enhanced social ability or experiences and quality of life is an important outcome and small gains are valued.

HCPs might improve the medication related experiences of adults with LD by:

- being aware that seemingly small improvements to quality of life are valued;
- enabling increased social activity and enhancing quality of life through medication;
- using enhanced social activity or experiences as an outcome measure for certain medicines;
- involving carers and care workers of adults with LD in discussions and decisions as outlined in learning point #3.

'Well it stops me from having the fits when I'm out, and still my own boss as I like to think!' Case11C-David

'Keppra [levetiracetam] rage is what they call it because they just become angry and short fuse…I eventually said to the neurologist that I'm prepared to put up with more seizures if she goes back to being a happy bunny because this is no life for anybody, it's just not right.' Case02N-Anna-Carer01

'As they get older you're seeing it as this is maintaining a quality of life or this is improving their quality of life so you just accept it – that's another one [medicine] in, you know!... It really was acceptance… 'cause you're then coming to terms with it and looking at what's in their best interest really.' Case04N-Jamie-Carer01

Proposed learning point #5	Medication routine is an important aspect of life for adults with LD and altering it can have unexpected impact on their life.

HCPs might improve the medication related experiences of adults with LD by:

- working with the adult with LD and their carers or care workers to optimise their regimen so it maximises quality of life (see learning point #4) but also minimises disruption to everyday life;
- supporting carers and care workers to alter the routine appropriately to minimise disruption;
- being aware of the practical issues surrounding medication administration (see Key Finding #6);
- involving adults with LD and their carers or care workers when making any change to medication – no matter how small;
- recognising the importance of medication routine for many adults with LD and maintaining that routine in other settings such as a hospital;
- being aware of the possibility for medication and medication routine to become an obsession for some adults with mild-moderate LD.

'He doesn't like change does he?...He likes the normal routine…He's got a structure he's to follow – like a weekly timetable. If that's not followed right down to the tee then it'll knock him and it'll increase his anxieties as well.' Case06C-Mark-CareW03

'Yeah, the day's built... I mean even the social activities that go on – like going out. You have to be out and then back for meds. Out and then make sure you're back at this time for medication.' Case03N-Paul-CareW04

'Because it domineers her life. If they're going to reduce her medication in any way she gets in a panic. I think she thinks that pills fix everything: I'll get a pill and that'll fix this and that.' Case08C-Ruth-CareW02

Proposed learning point #6	HCPs need to be mindful of the practical issues surrounding medication administration for carers, care workers of adults with LD, and of self-medicating adults with LD.

HCPs might improve the medication related experiences of adults with LD by:

- giving due consideration to the formulation and practicalities of administration when prescribing new medicines;
- seeking the views of carers and care workers regarding the practicalities and timings of administration for the adult with LD;
- ensuring all 'when required' medication prescriptions have details of the dose, maximum daily dose, minimum time interval between doses and a description of the indication;
- specifying the timing of doses to breakfast, lunch, teatime or bedtime, where possible;
- enabling carers and care workers of adults with moderate-severe LD a degree of 'experimentation' with doses and timings to ascertain optimal regimen; for care workers these instructions must be given in writing;
- remembering that for care workers all changes to medication must be provided in writing; verbal direction is insufficient;
- encouraging regular and timely communication between carers and care workers about any changes to medication or administration.

'She wouldn't take the medicine – she didn't like the taste of it…' Case08C-Ruth-CareW01

'…What's on the pharmacist's label is what we have to follow... And I can't accept verbal instructions over the phone…Sometimes we can get labels that come in and mum or dad have scored out bits which is unacceptable for us as well…You can have various difficulties in ensuring that it's easy for staff to follow and that there's no grey areas...It's just about ensuring everybody's clear and making sure that it reads clear on the labels.' Case02N-Anna-CareW03

'The debate is whether we should actually give him it once he's up and washed and dressed. I know he's meant to get it at 8 o'clock and it's sometimes a case of…leave him to sleep and once he's wakened and if the bathroom's busy, give him his meds. Or whether you should

say, right – let's just leave him and once he's upright. 'Cause like this morning he had to wait, got his meds and then he spewed them all back up again. And you think, well that's defeating the purpose 'cause how much is still inside you?!' Case03N-Paul-CareW03

Proposed learning point #7	The coping skills of adults with mild-moderate LD in relation to medication should be developed and maintained by carers, care workers and HCPs; but their potential limitations of capability and responsibility remembered.

HCPs might improve the medication related experiences of adults with LD by:

- encouraging the collection of medication from the pharmacy and establishing a relationship with the pharmacy staff so that they are another support for the adult with LD and their carers or care workers;
- encouraging carers and care workers to consider enabling an adult with mild-moderate LD to self-administer medication under supervision and then, if safe and appropriate, unsupervised;
- involving adults with mild-moderate LD in medication related decisions, where appropriate;
- providing medication information in easy-read format, where possible; the University of Birmingham has easy-read medication leaflets and accompanying audio recordings for the majority of medicines used in behavioural problems (University of Birmingham 2018);
- retaining awareness that adults with LD may have reduced or variable levels of memory and recall and/or limited ability to articulate information, worries and problems and in these situations, the involvement of carers or care workers should be encouraged;
- allowing more time for counselling, using simple terminology, reinforcing key information and providing regular review of their medication;
- checking what prescribed and OTC medication the adult with LD has in their home and what they understand it to be for.

'Ah well, it's fairly easy now. I've been in a daily routine for years now so it's fairly easy to fit in the other ones [medicines]...I've been doing this routine so long it's second nature... Aye, I've a pretty good idea about what's effective.' Case11C-David

'I keep the same glass and the little medicine cup with the bigger letters, no numbers, so I can see how much I am putting in [for lactulose]. 'Cause I've got that little caps that you get

on fluoxetine [sic – meant lactulose] bottles and I can hardly see the numbers on that. So the bigger [cup] I can read 'cause their numbers are better.' Case07C-Fiona

'At the beginning we did her tablets in the dossette. And as time's progressed we've realised that Ruth's capable of doing more. So we've carried on with that over time.' Case08C-Ruth-CareW01

10.4 FURTHER WORK

As noted in Chapter 1, a greater understanding of the experiences of medication of people with LD is required (Bell, Kirkpatrick and Alderman 2015; Flood and Henman 2015; Hollins and Tuffrey-Wijne 2013). This study has begun that conversation and further research will continue to inform HCPs how they can provide optimal person-centred care in relation to medication to this group of patients. Future research, identified within this research study, might include the validation of the proposed learning points suggested in Section 9.5 and then investigating the medication related experiences of: children with LD and their carers or care workers; children and adults with LD within an acute care setting; and children and adults with LD and their carers or care workers in relation to the dose reduction of antipsychotic medication. Such research would continue to build the knowledge base of the experiences of medication of people with LD.

10.5 CONCLUSION

Anchored in a pragmatic worldview and using qualitative case study methodology, this programme of research has explored the medication related experiences of ten adults with LD living in a community setting. Using the PLEM conceptual model, their medication related burden, medication related beliefs, and medication taking practice were investigated, documented, collated, and analysed. The data were presented in Chapters 3 through to 8 and discussed in Chapter 9. The key medication related experiences of community dwelling adults with LD within this study were found to be:

- a general desensitisation to the burden of medication due to it being perceived as a normal, beneficial and necessary part of life;
- the impact on cognitive ability and mental wellbeing being as an important consideration for acceptance of long term medication;
- the burden from the medication routine itself, and also any change to an established routine;
- adapting the medication regimen and routine to optimise therapy;
- the social benefits provided by medication;
- the impact of the medication related beliefs and influence of their significant others, including family and carers;
- a general acceptance of their medication on the condition that there were tangible benefits or an absence of significant side effects.

In addition, the carers and care workers of adults with moderate- severe LD noted the transfer of medication related burden to themselves. However, they often felt excluded from medication related decisions related to the adult with LD that they were caring for.

All these experiences were further considered in this chapter and proposed learning points for HCPs were outlined in Table 10.1. Whilst not without its' limitations, this study it will contribute to the evidence base and aid HCPs' engagement in understanding and improving the medication related experiences of community dwelling adults with LD.

10.6 CHAPTER SUMMARY

This chapter discussed the potential impact of the research, and possible future work identified within this research. The chapter also provided a conclusion for the research undertaken and presented within this thesis.

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APPENDICES

Appendix 2.1 Interview Questions Provided to Participants Before the Interview

You and your medicines

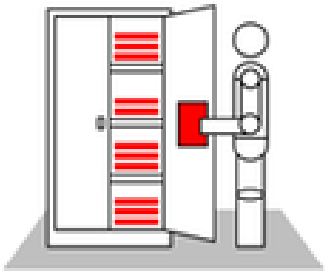
What medicines do you take just now?
[Take your medicines with you to the interview]

What is the reason for taking them?

Have you had to take any other medicines?

Do you have any other health problems that you don't take medicines for?

Do you have to see the doctor or nurse regularly? Tell me more about this.



Organising your medicines

How do you organise your medicines in your home?

Do you look after your medicines or does someone help you?

What part(s) of organising and taking your medicines do you find easy?

What part(s) of organising and taking your medicines do you find hard?

Where do you store your medicines?

How do you manage your medicines if you are going out on a day trip or on holiday?

Remembering to take your medicines

How do you remember to take your medicines?

What do you do if you forget?

How medicines affect your life

How do you think your medicines(s) affect your life in good ways?

How do you think your medicines(s) affect your life in bad ways?

Have you ever had a row or got cross about having to take your medicines with your carers or family?

	How do you manage your medicines if you are going out on a day trip or on holiday?
	Side Effects Every medicine is given for a particular reason (e.g. to stop your knee from hurting). However, medicines can also end up doing things we don't always want them to do. So they might stop your knee from hurting but then they cause your stomach to hurt or your skin to itch. These are called **side effects**. Do you think any of your medicines have ever caused you side effects?
	**Taking your medicines** How do you feel about having to take regular medicines? Why do you choose to take your medicine? Why do you choose not to take any medicine?

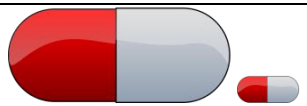
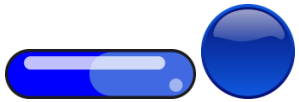
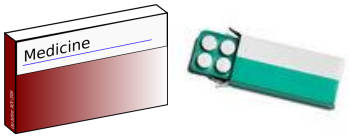
Do you ever change when or how you take your medicines?

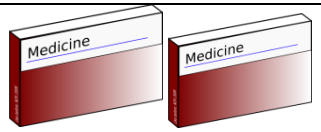
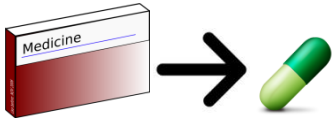
Have you ever experienced any of the following problems with medicines?

Complicated instructions on your medicines

Example: "Five tablets in the morning reducing by one tablet every other week until taking one tablet in the morning then take one tablet alternate days for two weeks"

Too many medicines to manage

	**Size** of tablet – too big? – too small?
	**Shape** of tablet - Hard to swallow?
	**Colour** of tablet - Hard to see? - Keeps changing?
	**Taste** of medicine
	The **box** my medicine comes in **looks different** each time

 	I have **different medicines that come in similar looking boxes** It is **hard to get the medicine out of the packaging** **Other?**

Pharmacists and pharmacies

Do you collect your medicine from the pharmacy?

Do you speak to anyone working in the pharmacy?

Have you ever discussed your medicine(s) with your pharmacist?

Is it easy to go into a pharmacy and ask the pharmacist about your medicines?

Who gives you advice on your medicine?

Appendix 2.2 *A Priori* Coding from PLEM Conceptual Model

MEDICATION RELATED BURDEN			
Code	**Description**	**Sub-Code**	**Description**
MRB-ROUT	Medicine ROUTINES	A	General strategies to manage med routines
		B	Time required to manage meds
		C	Adapting life to suit med routine (intentional)
		D	Adapting life to suit med routine (unintentional)
		E	Adapting med routine to suit life (intentional)
		F	Adapting med routine to suit life (unintentional)
		X	Other
MRB-CHAR	Medicine CHARACTERISTICS	A	Complexity of the number of medicines
		B	Pill size and shape
		C	Exchange of medication brands
		D	Challenges of packaging
		E	Additional instructions
		X	Other
MRB-ADVE	ADVERSE EVENTS	A	No experience/not recognised
		B	Previous negative experience
		C	Anxiety of future occurrence
		D	Impact on belief & behaviour
		X	Other
MRB-SBURD	SOCIAL BURDEN from medicines	A	Meds impacting social life (positive)
		B	Meds impacting social life (negative)
		C	Influence of 'significant others' re: meds (positive)
		D	Influence of 'significant others' re: meds (negative)
		E	Stigma from meds use
		X	Other
MRB-HBURD	HEALTHCARE BURDEN from medicines	A	Time spent dealing with healthcare appts/services/issues to get medicines
		B	Practicalities of accessing/obtaining/adhering to medicines
		C	Inadequate/conflicting/contradicting meds information
		D	Lack of consideration for patient's lived experience from health care professionals
		E	Lack of continuity/co-ordination of prescribing
		X	Other

MEDICATION RELATED BELIEFS			
Code	**Description**	**Sub-Code**	**Description**
BEL-PEER	FAMILY, PEERS, HEALTHCARE PROVIDERS (Normative beliefs)		
BEL-SKILL	MAGNITUDE/INTENSITY of medication related burden & COPING SKILLS (Control beliefs)	A	Intensity of medication related burden
		B	Self-awareness of coping skills
		C	Ability to develop problem solving strategies
		D	Lack of meds information
		E	Lack of comprehension
		F	Unmet need/expectation
		G	Response to negative aspects of medicines
		X	Other
BEL-ATTIT	GENERAL ATTITUDE	A	Weighing up the burden and benefits
		B	Controls illness/disease
		C	Hope
		D	Prevents consequences of illness/disease
		E	Allows them to fulfil social roles
		F	Negative past experience
		G	Lack of perceived desired outcomes
		H	Preconceived negative attitudes
		X	Other
PRA: MEDICATION TAKING PRACTICE			
Code	**Description**	**Sub-Code**	**Description**
PRA-ACCEPT	ACCEPTING medicines	A	Unconditional
		B	Forced into it by underlying illness
		C	Aiming to please family
		D	After experiments/consequences non-adherence
		X	Other
PRA-ALTER	MODIFYING/ALTERING medicines	A	Intolerable medicine related burden
		B	To evaluate effect of own meds/discover optimal doses
		C	Lack of perceived outcome
		D	Fear of potential side effects
		E	Peer pressure
		X	Other

Appendix 2.3 Participant Information Sheet (LD)

ROBERT GORDON UNIVERSITY ABERDEEN

Exploring the medication related experiences of adults with learning disabilities.

Researcher: Joan MacLeod

email: j.m.macleod1@rgu.ac.uk
phone: xxxxxx

PARTICIPANT INFORMATION SHEET

Dear

You are invited to take part in a research study to find out about your experience of taking regular medication.
Please read this letter so you understand why the research is being done and what it will involve.
If anything is unclear, or if you would like more information, please just ask.

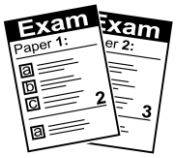
Who is the researcher?

My name is Joan and I am a pharmacist who works in Aberdeen.
I am also studying at the Robert Gordon University.

What is the purpose of the study?

To find out more about people with learning disabilities' experience of taking regular medication.

	**Why have I been chosen?** I asked local Care Providers to think of people with learning disabilities who take regular medication and who might want to take part.
	**Do I have to take part?** You only have to take part if you want to. You can pull out at any time without giving a reason.
   	**What will happen if I take part?** With your permission I will: • come to your home • look at your medicines and take a photo of them • ask you some questions about your medicines • use a tape recorder to record your answers • write some notes • arrange to speak to any family members and carers who help you with your medicines

	If you have formal (paid) carers I will also look at the records they keep in relation to your medicines and make some notes.
	**When will this happen?** The day and time will be agreed with you and any carer(s) or family.
 	**Is this an exam?** No – this is not an exam. I just want to hear your views on your medicines. There are no right or wrong answers.
No change to your medicines	**You are a pharmacist - will you change my medicines?** No - but if I see a problem with your medicines I will help arrange for you (or your carer) to speak with your doctor.
	**What are the possible benefits of taking part?** There is no direct benefit to you but hopefully you will enjoy speaking with me. It is possible that the findings will allow pharmacists, doctors and carers to help other people with learning disabilities in the future
	**Will my contribution to this study be kept confidential?** Yes - but it is okay for you to talk about it. Your name (or any information that would identify you) will not be used in any report.

	Only if you tell me about something bad that is happening to you will I tell someone. This is so that they can help you.
	**What will happen to the results of the research study?** I will send you a short report of the findings. The full findings of the study will be written up as a report for the Robert Gordon University. The findings may also be published in a health care journal and presented at a conference.
NHS Education for Scotland Pharmacy Research UK	**Who is organising and funding the research?** I am organising this research as part of my Doctorate of Professional Practice at the Robert Gordon University. It is funded by NHS Education for Scotland (NES) and Pharmacy Research UK (PRUK).
	**Who has reviewed the study?** The wording of this information sheet and the consent form have been reviewed by CASPA, the Chair of Aberdeen and Aberdeenshire's Learning Disability Group, and the Robert Gordon University's ethical review panel. The aims and intentions of the study have been reviewed by academic experts and approved by the Robert Gordon University's ethical review panel.

	**What do I do now?** • Talk to your friends or family or carers about this and show them the information. • Let them know if you would like to take part or not. • I will then get back in touch and get a consent form completed.

Thank you for your time and consideration in reading this information sheet. If you have further questions about this study please contact me on:

☎ xxxxxx 💻 j.m.macleod1@rgu.ac.uk

Joan MacLeod, Pharmacist and Research Student, RGU

Supervisors: Dr Katie MacLure k.m.maclure@rgu.ac.uk
Prof Derek Stewart d.stewart@rgu.ac.uk

Appendix 2.4 Consent Form (LD)

ROBERT GORDON UNIVERSITY ABERDEEN

Exploring the medication related experiences of adults with learning disabilities.

Researcher: Joan MacLeod

email: j.m.macleod1@rgu.ac.uk
phone: xxxxxx

CONSENT FORM

Area of Consent		Participant tick/initials	Carer (advocate) initials
  	**The researcher has:** • described the study to me • left me written information v1.3 dated 15thJuly2016 • asked me if I had any questions • answered any questions I had		

	I understand that I only need to take part if I want to and I can change my mind at any time.		
    	I am happy for the researcher to • see my medicines and take a photo of them • ask me questions about my experience taking medicines • record my answers • take notes • [If applicable] read the notes my carers keep about my medicines • speak to my carers and/or family about their experience of my medicines		
	I understand that my name (or any information that would identify me) will not be used in any report, journal article or conference.		

	**The researcher has confirmed that everything I say is confidential UNLESS the researcher knows that she has to tell someone to keep me safe and well.**		
	**I understand that there may be a need for information collected by the researcher to be seen by a regulatory authority (e.g. Local Authority; RGU exam board)**		

AGREEMENT TO PARTICIPATE IN RESEARCH

	Name	Signature	Date
Participant			
Witness			
Researcher			

Appendix 2.5 Guardian Information Sheet

ROBERT GORDON UNIVERSITY ABERDEEN

Exploring the medication related experiences of adults with learning disabilities.

Researcher:
Joan MacLeod

Email:
j.m.macleod1@rgu.ac.uk

Phone: XXXXXX

RELATIVE/ WELFARE GUARDIAN INFORMATION SHEET

Dear [relative/ welfare Guardian]

You are being invited to consider giving your permission for your relative to take part in a research study. The study explores the impact of medication on the lives of people with learning disabilities and their carers (formal and unpaid). Please read this information sheet so you understand why the research is being done and what involvement would be required. If anything is unclear, or if you would like more information, please just ask.

What is the purpose of the study?

I [Joan] am a pharmacist and am interested in finding out about the experiences of people with learning disabilities with their regular medication. I am doing this by generating case studies of 6 -10 individuals with learning disabilities. In each case study I plan to detail the medication related experiences of that individual.

Why has your relative been chosen?

Care and Support Providers Aberdeen (CASPA) were approached by myself to identify people with learning disabilities on regular medication who may be suitable for inclusion in the study. Your relative was one of the clients identified but they lack the capacity to make an informed decision about whether they can take place in a research study. I am therefore asking you as their nearest relative/welfare Guardian if you will give consent on their behalf to join this study. This is permissible under the Adults with Incapacity (Scotland) Act 2000.

Does my relative have to take part?

Taking part is voluntary. It is up to you to decide whether they are included within the study. If you do agree that they can be part of the study, you are free to change your mind at any time and without giving a reason. This will not alter their care in any way, now or at any stage in the future.

What will happen to your relative if they take part?

- I will arrange to visit your relative in their home in order to record their current medication and storage/administration arrangements – this will be in the presence of a carer (formal or unpaid).
- If formal carers are involved, records relating to medication administration will be accessed (with the consent of the care provider)
- Their carers will be interviewed (interview questions attached)

Can I participate in the research?

If you have current or past experience of managing the medication for your relative and/or seeing the impact on them then your participation would be most welcome - this can be noted on the consent form.

Will the research result in changes to my relative's medication?

Although I am a pharmacist, I am not wishing to access medication information with the purpose of undertaking a medication review.
However, if in the course of the research I notice an issue (or an issue is highlighted to me) I will ensure that you and any formal carer are made aware and that appropriate action is then taken (e.g. appointment made with the GP).

What are the possible benefits of taking part?

There is very little known about the impact medication can have on the lives of people with learning disabilities and their carers. It is possible that the findings will allow pharmacists, doctors and carers to better help other people with learning disabilities in the future.

There is no direct benefit to the individual participants. However, I hope that all the participants will enjoy the experience of being involved with, and contributing to, local research.

Will our contribution to this study be kept confidential?

All the information collected during the course of the research will be kept confidential. All raw data will only be stored in password protected files within the Robert Gordon University. Once the data is anonymised the information will be held on the researcher's laptop in password protected files until the thesis is completed. At this stage it will be deleted from the researcher's laptop.

All participants' responses will be anonymised.

Confidentiality will only ever be breached is if any information indicating an adult protection issue is revealed. As required by law, adult protection concerns would be passed on to a suitable manager of the formal Care Provider organisation and/or the appropriate Local Authority's Adult Protection team who would then assess the situation. After discussion with yourself and other relevant parties, a decision would be reached about the appropriateness of including some or all of the data gathered in the case study or whether the person (and therefore all associated data) should be withdrawn from the study.

What will happen to the results of the research study?

- I will send you a short report of the findings.
- The full findings of the study will become the researcher's thesis and selected sections may be published in a health care journal and presented at a conference.

Who is organising and funding the research?

I am doing this research as part of my Doctorate of Professional Practice at the Robert Gordon University which is funded by NHS Education for Scotland (NES) and Pharmacy Research UK (PRUK).

Who has reviewed the study?

- The wording of this information sheet and the consent form has been reviewed by CASPA and the Robert Gordon University's ethical review panel.
- The aims and intentions of the study have been reviewed by academic experts and approved by the Robert Gordon University's ethical review panel.

What if there is a problem?

If you have any concern about this study and/or the researcher please contact:

Dr Katie MacLure (Senior Research Fellow and Lecturer)
School of Pharmacy and Life Sciences
Robert Gordon University -Aberdeen
k.m.maclure@rgu.ac.uk
xxxxxx

Thank you for your time and consideration in reading this information sheet. If you have further questions about this study please contact me on xxxxxx or j.m.macleod1@rgu.ac.uk

Supervisors:Dr Katie MacLure k.m.maclure@rgu.ac.uk ; Prof Derek Stewart d.stewart@rgu.ac.uk

Appendix 2.6 Guardian Consent Form

ROBERT GORDON UNIVERSITY ABERDEEN

Exploring the medication related experiences of adults with learning disabilities.

Researcher: Joan MacLeod
Email: j.m.macleod1@rgu.ac.uk
Phone: xxxxxx

RELATIVE/WELFARE GUARDIAN CONSENT FORM

Area of Consent	Initials
1. I confirm that I have read the information sheet v1.2 dated 11thOct2016for the above named study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that participation in this study is voluntary and that I am free to withdraw my relative/ward from the study at any time, without giving any reason, without my or their care or legal rights being affected	
3. I understand that the researcher will be: interviewing carers involved in the care of my relative; accessing my relative's medication; accessing any medication records kept by formal carers (with their consent) for my relative; taking a photo of the medicines and how they are organised. In addition, data collected during the study may be looked at by the researcher and her supervisors and I grant them permission to do so.	
4. I understand that anonymised data from the study may be looked at by regulatory authorities (e.g. Local Authority; RGU Exam Board) if appropriate.	
5. I understand that data collected during the study will be used for research purposes including publication of anonymised findings and quotations. I grant copyright permission on the understanding that the confidentiality of my relative will be protected.	
6. I agree to allow my relative to be included in the study.	

I would like to be interviewed as part of the research study: YES / NO **If yes, please provide details of how you would prefer to be contacted below:**
Please now complete the appropriate section
For Relatives ***I confirm that as [insert relationship]*** **……** ***I am the nearest relative for [insert name of person]*** **…….** ***and that no other nearest relative or welfare Guardian exists.***

Name:	**Date:**
Signature:	**Contact Number:**

For Welfare Guardians ***I confirm that I am the welfare Guardian for [insert name of person]*** **…….**

Name:	**Date:**
Signature:	**Contact Number:**

Researcher Signature:	**Date:**

Appendix 2.7 Carer Information Sheet

Exploring the medication related experiences of adults with learning disabilities.

Researcher: Joan MacLeod
Email: j.m.macleod1@rgu.ac.uk
Phone: XXXXXX

CARER (Formal or Unpaid) INFORMATION SHEET

Dear [carer name]

You are invited, as the carer of a person with learning disabilities, to take part in a research study to find out about the impact of regular medication on the lives of people with learning disabilities and their carers (formal and unpaid). Please read this letter so you understand why the research is being done and what involvement would be required. If anything is unclear, or if you would like more information, please just ask.

What is the purpose of the study?

I [Joan] am a pharmacist and am interested in finding out about the experiences of people with learning disabilities with their regular medication. I am doing this by generating case studies of 6 -10 individuals with learning disabilities. In each case study I plan to detail the medication related burden, the medication related beliefs and medication taking practice of that individual.

Why have I been chosen?

You are/were a regular carer for one of the people with learning disabilities included in this study.

Do I have to take part?
Taking part is voluntary. If you do agree to take part, you are free to change your mind at any time and without giving a reason.

What will happen if I take part?

- I will interview you with regards to your experiences of your client/relative's experience with medication (questions attached)
- If your client/relative has capacity, you may be asked to be present [as an advocate] while I interview your client/relative
- Formal Carers: Only information relating to the individual participating will be requested and included in the study i.e. you will not be asked to provide information on other clients in your service.

Will the research result in changes to the person's medication?
Although I am a pharmacist, I am not wishing to access medication information with the purpose of undertaking a medication review. However, if in the course of the research I notice an issue (or an issue is highlighted to me) I will ensure that the person and their primary carer is made aware and that appropriate action is then taken (e.g. appointment made with the GP).

What are the possible benefits of taking part?
There is very little known about the impact medication can have on the lives of people with learning disabilities and their carers. It is possible that the findings will allow pharmacists, doctors and carers to better help other people with learning disabilities in the future

There is no direct benefit to the individual participants and to you as an organisation. However, I hope that all the participants will enjoy the experience of being involved with, and contributing to, local research.

Will our contribution to this study be kept confidential?

All the information collected during the course of the research will be kept confidential. All raw data will only be stored in password protected files within the Robert Gordon University.

Once the data is anonymised the information may also be held on the researcher's laptop in password protected files until the thesis is completed. At this stage it will be deleted from the researcher's laptop.

All participants' responses will be anonymised.

Confidentiality will only ever be breached if current or previously unknown adult protection issue(s) are revealed and/or the safety of the person was at risk.

As required by law, adult protection concerns would be passed on to a suitable manager of the formal Care Provider organisation and/or the appropriate Local Authority's Adult Protection team who would then assess the situation. After discussion with all relevant parties, a decision would be reached about the appropriateness of including some or all of the data gathered in the case study or whether the person (and therefore all associated data) should be withdrawn from the study.

What will happen to the results of the research study?

- I will send you a short report of the findings.
- The full findings of the study will become my doctoral thesis and selected sections may be published in a health care journal and presented at a conference.

Who is organising and funding the research?

I am doing this research as part of my Doctorate of Professional Practice at the Robert Gordon University which is funded by NHS Education for Scotland (NES) and Pharmacy Research UK (PRUK) are funding the research.

Who has reviewed the study?

- The wording of this information sheet and the consent form have been reviewed by CASPA and the Robert Gordon University's ethical review panel.
- The aims and intentions of the study have been reviewed by academic experts and approved by the Robert Gordon University's ethical review panel.

What if there is a problem?

If you have any concern about this study and/or the researcher please contact:

Dr Katie MacLure (Senior Research Fellow and Lecturer)
School of Pharmacy and Life Sciences
Robert Gordon University -Aberdeen
k.m.maclure@rgu.ac.uk

Thank you for your time and consideration in reading this information sheet. If you have further questions about this study please contact me on XXXXXX or j.m.macleod1@rgu.ac.uk

Supervisors: Dr Katie MacLure k.m.maclure@rgu.ac.uk ; Prof Derek Stewart d.stewart@rgu.ac.uk

Appendix 2.8 Carer Consent Form

ROBERT GORDON UNIVERSITY ABERDEEN

Exploring the medication related experiences of adults with learning disabilities.

Researcher: Joan MacLeod
Email: j.m.macleod1@rgu.ac.uk
Phone: XXXXXX

CARER (FORMAL OR UNPAID) CONSENT FORM

Area of Consent	Initials
1. I confirm that I have read the information sheet v1.2 dated 11thOct2016for the above named study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2. I understand that my participation is voluntary and that I am free to withdraw from the study at any time, without giving any reason, without my care or legal rights being affected	
3. I understand that data collected during the study may be looked at by the researcher and her supervisors and I grant them permission to do so.	
4. I understand that data from the study may be looked at by regulatory authorities (e.g. Local Authority; RGU Exam Board) if appropriate.	
5. I understand that data collected during the study will be used for research purposes including publication of anonymised findings and quotations. I grant copyright permission on the understanding that my confidentiality will be protected.	
6. I agree to take part in the study.	

	Name	Signature	Date
Participant			
Researcher			

Appendix 3.1 CASE 01N - PILOT

Case01N-Pilot is a 46-year old Caucasian male who has severe LD. He is described by his carer as having profound and multiple learning disabilities (PMLD). He is deaf and non-verbal as a result of Usher syndrome and requires help with all tasks of daily living. He is also diagnosed with epilepsy.

His carer was willing to participate in the research but the care workers were unable to participate throughout the duration of the planned fieldwork. The interview was therefore used as a pilot for the interview schedule and the data not included in the study. No further information was obtained.

Appendix 3.2 CASE 02N - ANNA

Personal Details

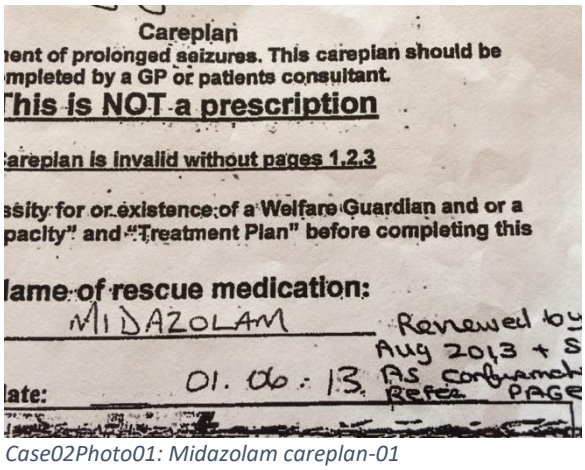
Anna is a 26-year-old Caucasian female who has severe LD and is almost non-verbal. She was diagnosed with Global Development Delay of unknown cause as a baby. Although she is independently mobile she requires help with all tasks of daily living. She alternates month about between living with her parents and living in a respite home with around the clock care worker support. Her carers/care workers gave the following descriptions of her: *cheeky monkey; understands more than we give her credit for; happy; content; sweet; child-like; likes to help; sometimes difficult to interpret; knows what she wants from her life.*

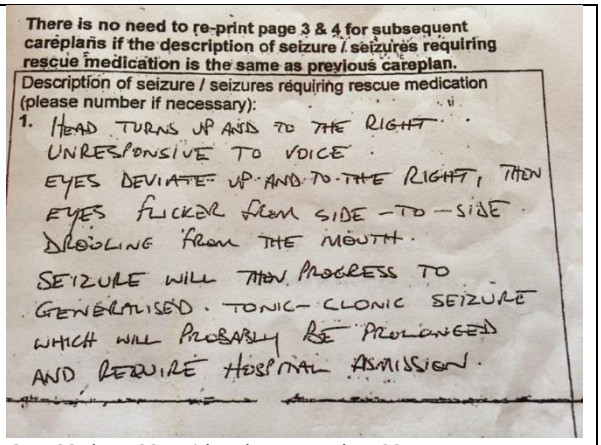
Medical History

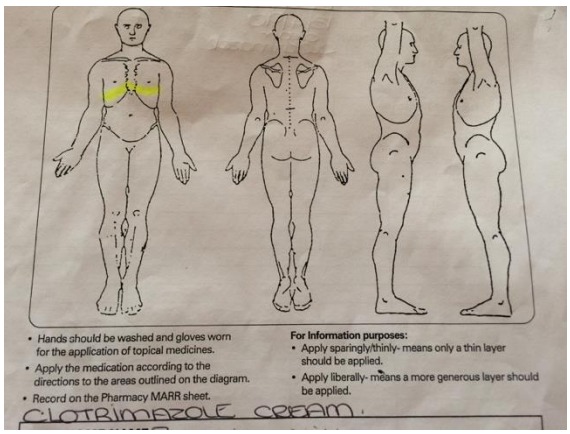
Active Medical Conditions	Comments/Notes
Epilepsy (tonic-clonic)	• *First seizure at 9 months; started properly age 5-6 years* • *Seizure frequency is increasing (~3 per month)*
Dysplasia of front temporal lobe (stroke damage) and right-sided weakness	• *Diagnosed at 9 years of age* • *A scarred area in the left temporal lobe is the focal point for her seizures but as she has prolonged seizures, the area of damage gets bigger*

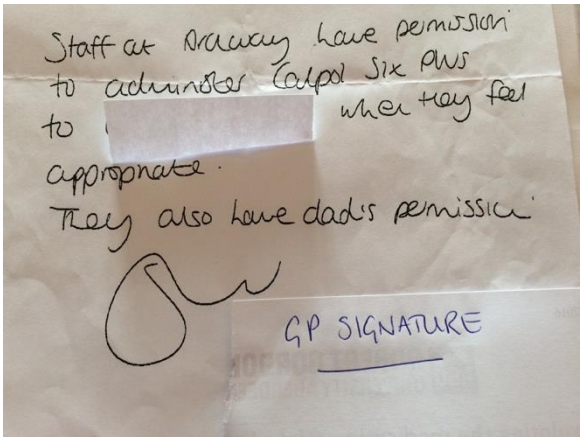
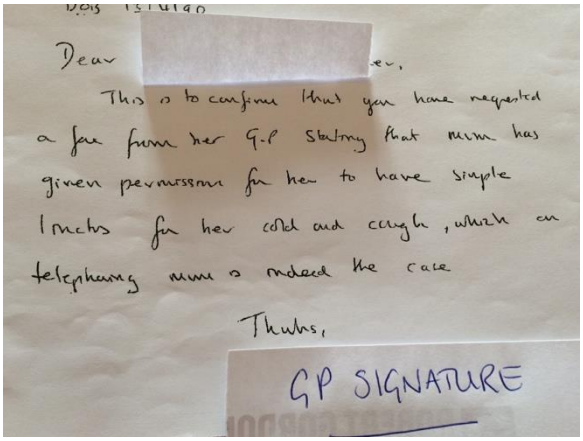
Past Medical Conditions	Comments/Notes
Dental extractions	
Pityriasis versicalor	
Urinary tract infections	

Medication History

Current Prescribed Medication	Indication	Comments/Notes
Midazolam *(Epistatus)* 10mg/ml oromucosal solution 1ml as per protocol	Acute epileptic seizure	• To be given as detailed in her care plan • See Case02NPhoto01 and Case02Nphoto02 for excerpts of that care plan  Careplan ent of prolonged seizures. This careplan should be mpleted by a GP or patients consultant. This is NOT a prescription areplan is invalid without pages 1,2,3 ssity for or existence of a Welfare Guardian and or a pacity" and "Treatment Plan" before completing this lame of rescue medication: MIDAZOLAM Renewed by Aug 2013 + S 01.06.13 late: PAGE *Case02Photo01: Midazolam careplan-01*

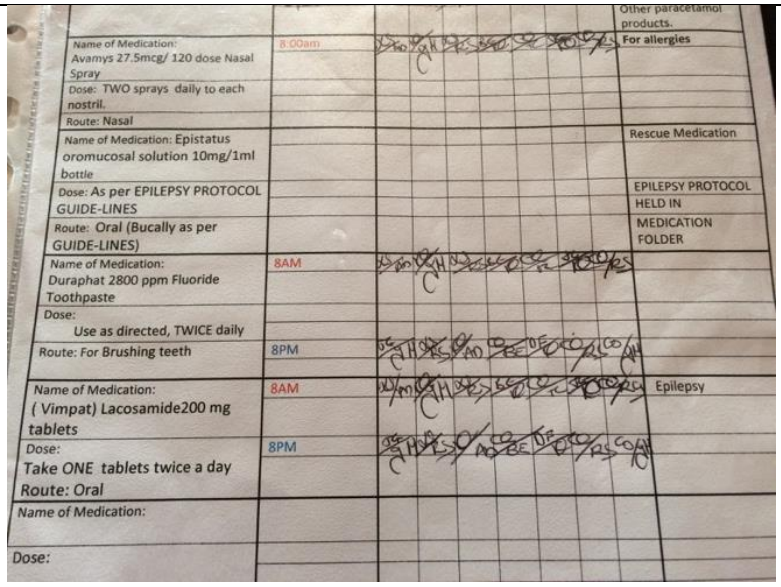
		 There is no need to re-print page 3 & 4 for subsequent careplans if the description of seizure / seizures requiring rescue medication is the same as previous careplan. Description of seizure / seizures requiring rescue medication (please number if necessary): 1. HEAD TURNS UP AND TO THE RIGHT UNRESPONSIVE TO VOICE EYES DEVIATE UP AND TO THE RIGHT, THEN EYES FLICKER FROM SIDE-TO-SIDE DROOLING FROM THE MOUTH. SEIZURE WILL THEN PROGRESS TO GENERALISED. TONIC-CLONIC SEIZURE WHICH WILL PROBABLY BE PROLONGED AND REQUIRE HOSPITAL ADMISSION. *Case02Photo02: Midazolam careplan-02*
Lamotrigine *(Lamictal)* dispersible tablets 250mg (2x100mg + 2x25mg) morning and night	Epilepsy	
Topiramate *(Topamax)* 100mg tablets One in the morning and night	Epilepsy	• Case02N Letter from neurologist 2012 (in care workers' file): *'She has been topiramate at higher doses in the past (200mg BD) but by that dose we felt it was affecting her cognition…'* • Also, querying side-effect of hair loss
Lacosamide *(Vimpat)* 200mg tablets One in the morning and night	Epilepsy	
Evra patch *(ethinylestradiol 33.9 microgram per 24h + norelgestromin 203 microgram per 24h)* One patch weekly for 3 weeks then one week patch free	Control of menstrual cycle	• Addition of Evra adversely affected epilepsy control • Led to the addition of topiramate and lacosamide
Fluticasone furoate *(Avamys)* 27.5 micrograms/dose nasal spray Two sprays in the morning	Sinus problems	
Duraphat *(fluoride 5000 ppm)* toothpaste Use morning and night	To strengthen tooth enamel	
Paracetamol 250mg/5ml suspension 20ml when required up to four times a day	Pain	

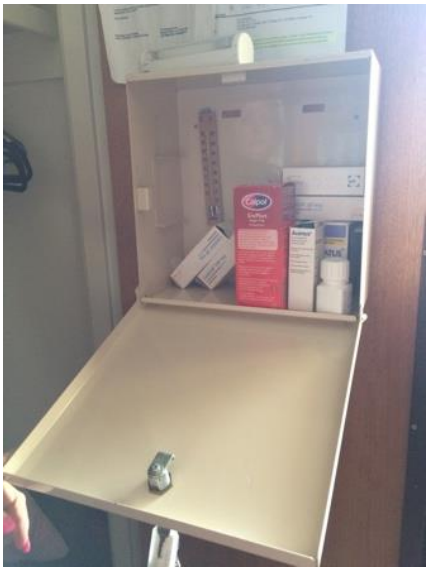
Past Prescribed Medication	Indication	Comments/Notes
Diazepam rectal tubules	Acute epileptic seizure	• Replaced by midazolam
Phenytoin	Epilepsy	• Case02N Letter from neurologist 2012 (in care workers' file): *'…when she was given phenytoin [Anna] became very flushed'*
Carbamazepine *(Tegretol)*	Epilepsy	• Stopped as it was ineffective
Sodium Valproate *(Epilim)*	Epilepsy	• Stopped because of side-effects: increased terror and fear
Levetiracetam *(Keppra)*	Epilpesy	• Controlled the epilepsy but had to be stopped because of side-effects: increased anxiety, agitation, anger
Antibiotics	Infections	
Ibuprofen liquid	Short term pain/fever	
Tramadol	Impacted wisdom teeth/extraction	• Abrupt withdrawal caused behavioural problems that resulted in short term use of riperidone • Case02N Letter from neurologist 2011 (in care workers' file): *'…mum said to me that she thought she knew what had caused [Anna]'s extreme breakdown in behaviour… rapid withdrawal of tramadol and dihydrocodeine'*
Dihydrocodeine	Impacted wisdom teeth/extraction	
Risperidone	Breakdown in behaviour	• Associated with rapid withdrawal of tramadol and dihydrocodeine
Miconazole shampoo	Pityriasis versicalor	• Used as a lotion on the body. Left on overnight according to prescriber's instructions but caused serious skin irritation
Fexofenadine tablets	Skin sensitivity from miconazole	• Used until skin desensitised
Doublebase gel	Skin sensitivity from miconazole	• Used until skin desensitised
Clotrimazole (Canesten) 1% cream	Sweat rash under the breasts	• Care workers used a topical product aide memoire to help administration – see Case02NPhoto03  • Hands should be washed and gloves worn for the application of topical medicines. • Apply the medication according to the directions to the areas outlined on the diagram. • Record on the Pharmacy MARR sheet. For Information purposes: • Apply sparingly/thinly- means only a thin layer should be applied. • Apply liberally- means a more generous layer should be applied. CLOTRIMAZOLE CREAM. *Case02NPhoto03: Topical product aide memoire*

Over the Counter (OTC) Medication	Indication	Comments/Notes
Paracetamol 250mg/5ml suspension (Calpol Six Plus) 20ml when required up to four times a day	Pain	• Care workers require written permission from GP to administer any paracetamol that was not prescribed – see Case02NPhoto04 below  *Case02NPhoto04: GP authorisation to administer bought paracetamol suspension*
Simple Linctus	Sore throat/cough and cold	• Care workers require written permission from GP to administer any simple linctus that was not prescribed – see Case02NPhoto05  *Case02NPhoto05: GP authorisation to administer bought simple linctus*

Medication Management

Ordering of prescriptions	• Parents order repeat prescriptions
Taking prescriptions to pharmacy	• Local pharmacy collects repeat prescriptions from surgery • Parents or care worker would take acute prescription to pharmacy
Collecting medication from pharmacy	• Parents or care worker collect medication from local pharmacy
Administration	• Responsibility for administration lies with parents when at home and with care workers when in respite home • Care workers are required to have Medication Administration Record (MAR) charts to record all administration – see Case02NPhoto06

	 Other paracetamol products. Name of Medication: Avamys 27.5mcg/ 120 dose Nasal Spray — 8:00am — For allergies Dose: TWO sprays daily to each nostril. Route: Nasal Name of Medication: Epistatus oromucosal solution 10mg/1ml bottle — Rescue Medication Dose: As per EPILEPSY PROTOCOL GUIDE-LINES — EPILEPSY PROTOCOL HELD IN MEDICATION FOLDER Route: Oral (Bucally as per GUIDE-LINES) Name of Medication: Duraphat 2800 ppm Fluoride Toothpaste — 8AM Dose: Use as directed, TWICE daily Route: For Brushing teeth — 8PM Name of Medication: (Vimpat) Lacosamide200 mg tablets — 8AM — Epilepsy Dose: Take ONE tablets twice a day — 8PM Route: Oral Name of Medication: Dose: *Case02NPhoto06: Medication administration record chart* • Midazolam has a specific protocol for administration – see Case02Photo01 and Case02Photo02
Storage in family home	• Extra boxes of medicines are stored in a kitchen cupboard above the worktop and the medicines in use are stored on the kitchen window sill - see Case02NPhoto07 and Case02NPhoto08  *Case02NPhoto07: Storage of extra medicines at home (kitchen cupboard)*

	 *Case02NPhoto08: Storage of medicines in use at home (kitchen window sill)*
Storage in respite home	• Medication is stored in Anna's bedroom in a locked cabinet – see Case02NPhoto09  *Case02NPhoto09: Storage of medicines in respite home (bedroom cupboard)*
Other	Travel bag for emergency midazolam – see Case02NPhoto10.  *Case02NPhoto10: Travel bag for emergency midazolam*

Appendix 3.3 CASE 03N - PAUL

Personal Details

Paul is a 31-year-old Caucasian male who has profound and multiple learning disabilities (PMLD) as a result of oxygen deprivation at birth. He is visually impaired, non-verbal and unable to mobilise independently. He lives in a small residential unit with other adults with PMLD where there is around the clock care. His care workers gave the following descriptions of him: *cheeky; unpredictable; challenging; vocal; charming; lovable; sad scamp; complicated; frustrating; knowing – he knows what is going on.*

Medical History

Active Medical Conditions	Comments/Notes
Cerebral Palsy	• Has contractures which are painful
Behavioural problems – agitation/rage, screaming vocalisation, making himself sick	• At the point of data collection, Paul's behavioural problems were of such a severity, it was putting his placement at risk • There were concerns that if he was hospitalised and in a shared ward environment he would require to be heavily sedated for his own wellbeing and to allow staff to cope • Case03N Letter from Clinical Psychologist, 2013 (in care workers file): *'[Paul]'s level of learning disability means that he requires a clear and predictable routine…Constipation can be linked to challenging behaviour…It is unlikely that his behaviour is caused by one factor'*
Reflux/vomiting	• His reflux/vomiting was so severe that a PEG tube required to be inserted for feeding • Despite the PEG tube, Paul still vomits • Staff had kept a record of the number of instances of vomiting in the last 8 months: March (11); April (13); May (16); June (15); July (20); August (8); September (17); October (9) • The vomit varies in volume; often just a small amount of phlegm; sometimes blood present • Sometimes the vomiting is linked to agitation; Paul often calms down quickly afterwards • There were four recorded instances of medicines being visible in the vomit in the last eight months • Case03N Email from Dietician, 2016 (in formal care workers file): *'The reason he is NBM [nil by mouth] in the first place is because of the reflux/agitation.'*
Has PEG (percutaneous endoscopic gastrostomy) tube in situ	• Paul is fed overnight (Nutrison) and has all his medication administered via the PEG tube except for his Gaviscon which is administered orally
Constipation	
Heart valve problems	

Past Medical Conditions	Comments/Notes
None mentioned	

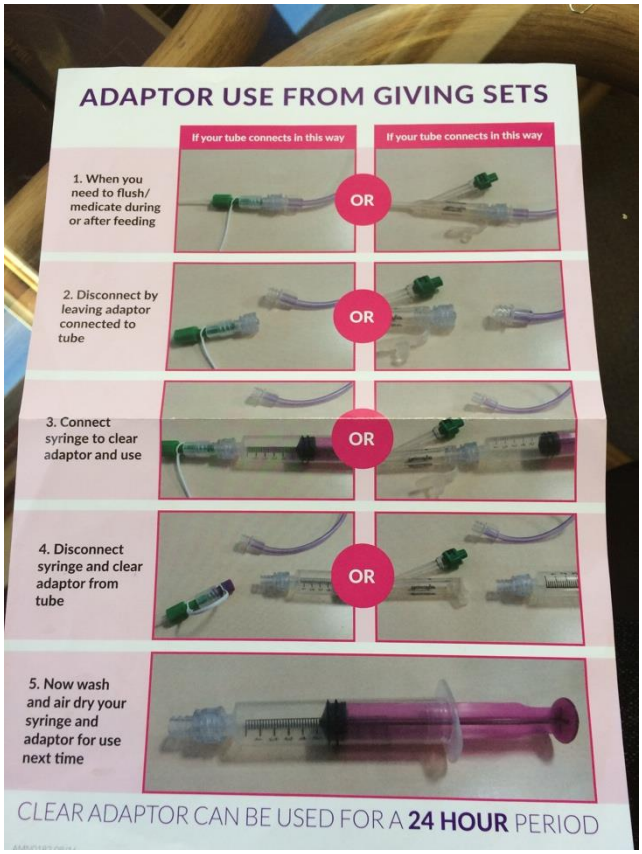
Medication History

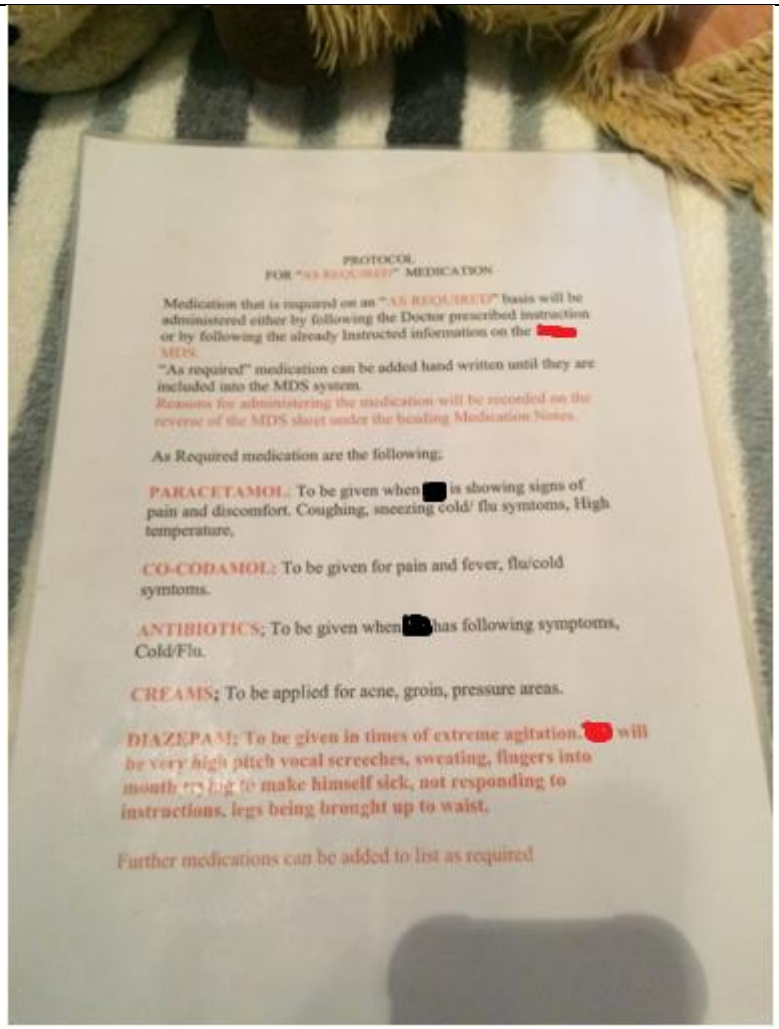
Current Prescribed Medication	Indication	Comments/Notes
Omeprazole 40mg dispersible tabs One at breakfast and bedtime via PEG tube	Reflux	
Gaviscon Advance liquid 20ml up to four times daily ORALLY	Reflux	• From the administration records, it is nearly always given in the morning and at bedtime and given ~33% of the time at lunch and tea times.
Macrogol (*Laxido*) sachets One sachet at breakfast and bedtime via PEG tube	Constipation	
Paracetamol 500mg soluble tabs One or two tablets up to four times a day when required via PEG tube	Pain/fever	• Rarely required
Risperidone 1mg/ml liquid 1ml at breakfast and bedtime via PEG tube	Behavioural issues	• Paul's behaviour has been a serious issue for ~10 years
Baclofen 10mg tabs Half a tablet three times daily via PEG tube	Cerebral palsy – contractures and muscle spasticity	• New – had only been started on this a month previously

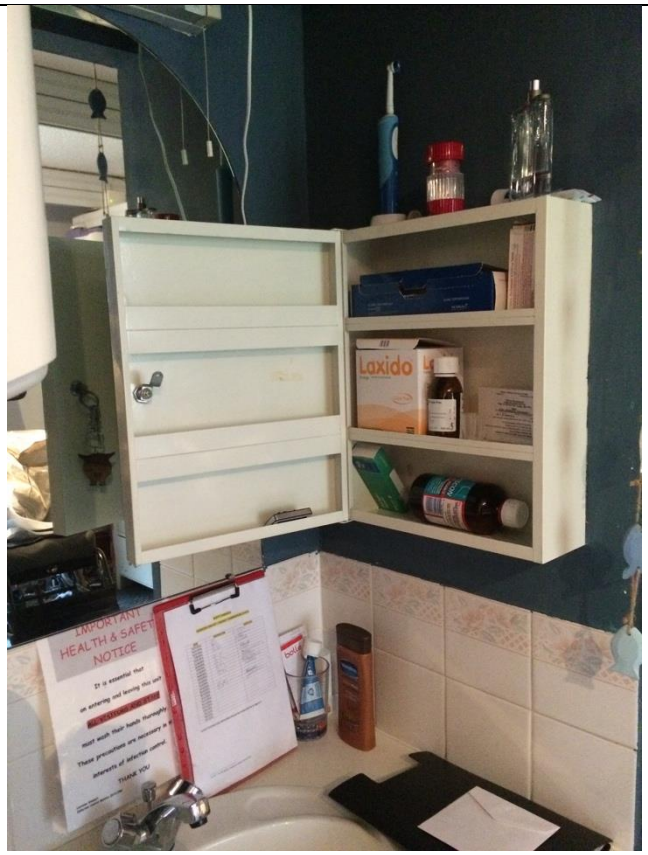
Past Prescribed Medication	Indication	Comments/Notes
Fluoxetine	Depression	
Haloperidol	Behavioural issues	• Stopped because of side effect of profuse sweating and no benefit to behaviour
Diazepam liquid (as part of a wider de-escalation procedure)	Behavioural issues	• Case03N Letter from Consultant Psychiatrist 2016 (in formal care workers file): *'Currently on diazepam 4mg a day…staff however reported that the introduction of diazepam has not made much of a difference…nor the recent increase in the dose of risperidone.'*
Domperidone	Reflux	
Laxative suppositories	Constipation	
Senna liquid	Constipation	
Cocodamol dispersible tablets	Pain	

Over the Counter (OTC) Medication	Indication	Comments/Notes
None		

Medication Management

Ordering of prescriptions ***Taking prescriptions to pharmacy*** ***Collecting medication from pharmacy***	• Manager or depute manager are responsible for ordering, organising and collecting all medication
Administration	• All care workers are trained to administer Paul's medicines via his PEG tube (and Gaviscon orally) • Senior care workers will train new care workers; information resources available in Paul's folder – see photo Case03NPhoto1  *Case03NPhoto01: Information available to care workers (PEG administration)* • Written protocol for administration of 'when required' medicines availabe to carers – see Case03NPhoto2

	 PROTOCOL FOR "AS REQUIRED" MEDICATION Medication that is required on an "AS REQUIRED" basis will be administered either by following the Doctor prescribed instruction or by following the already Instructed information on the [redacted] MDS. "As required" medication can be added hand written until they are included into the MDS system. Reasons for administering the medication will be recorded on the reverse of the MDS sheet under the heading Medication Notes. As Required medication are the following: PARACETAMOL: To be given when [redacted] is showing signs of pain and discomfort. Coughing, sneezing cold/ flu symtoms, High temperature. CO-CODAMOL: To be given for pain and fever, flu/cold symtoms. ANTIBIOTICS; To be given when [redacted] has following symptoms, Cold/Flu. CREAMS; To be applied for acne, groin, pressure areas. DIAZEPAM; To be given in times of extreme agitation. [redacted] will be very high pitch vocal screeches, sweating, fingers into mouth trying to make himself sick, not responding to instructions, legs being brought up to waist. Further medications can be added to list as required *Case03NPhoto02: 'When required' medicine protocols*
Storage	• All medicines in use are stored in a locked cabinet in Paul's room – see Case03NPhoto3 • If there is any excess medication, it is stored in a locked cabinet in the general office

	 *Case03NPhoto03: Medicine storage (bedroom)*
Other	

Appendix 3.4 CASE 04N - JAMIE

Personal Details

Jamie was a Caucasian male who had PMLD; at the time of his death he was 21 years of age. He was adopted at the age of 8 months and lived with his adoptive parents (his primary carers) all his life. His regular care worker also acted as his Citizen Advocate. His carer and care worker gave the following descriptions of him: *a people person; insightful and understanding; he soothed people and he made people feel good in his company; loving; caring.*

Medical History

Active Medical Conditions	**Comments/Notes**
Quadriplegic cerebral palsy	• Loss of muscle tone; contractures; dystonia (occasional); scoliosis; instances of aspiration; excess salivation • His distorted body shape exacerbated health issues
Epilepsy (absence, partial and tonic-clonic)	• Had seizures from birth
Chronic gastrointestinal issues including: gagging, reflux and constipation. *[PEG tube in situ]*	• Serious digestive issues from birth and feeding as a young child was a slow process • A PEG tube was put in place age 6 years – from this point all medicines were given via the PEG tube • Fundoplication occurred age 6years and was repeated again later in life
Asthma and general breathing problems from scoliosis	• Nearer the end of his life, Jamie required oxygen and a continuous positive airways pressure (CPAP) ventilator
Hayfever	
Carnitine deficiency	• Diagnosed in his teens
Electrolyte imbalance	
Excess salivation	
Kidney stones	• Had regular scans

Past Medical Conditions	**Comments/Notes**
Widespread herpes infection age 6 years	• Caused gastro-intestinal ulceration which confirmed the requirement for a PEG tube
Depression	• Circles of discontent – physical illness affecting mental wellbeing which then causes increased physical illness • Caused restless sleep

Medication

Regular Prescribed Medication (in last 3 months of life)	**Indication**	**Comments/Notes**
Sodium Valproate *(Epilim)* 100mg crushable tablets 5 tablets twice daily via PEG tube	Epilepsy	• Allergic to the red dye in Epilim liquid
Clonazepam 500mcg tabs 2 in the morning and 1 at night via PEG tube	Epilepsy	• Had reduced down to this dose • Stopping had been unsuccessful
Midazolam *(Epistatus)* 10mg/ml oromucosal solution 1ml as per protocol when required	Epilepsy	• Had trialled original formulation of midazolam but the dose/delivery caused bradycardia
Omeprazole *(Losec)* 40mg MUPS tablets One in the morning via PEG tube	Reflux	
Ondansetron *(Zofran)* 4mg/5ml 5ml twice daily via PEG tube	Reflux/sickness	
Gaviscon Advance liquid 5-10ml up to four times a day when required via PEG tube	Reflux	
Macrogol *(Movicol)*sachets One sachet in the morning via PEG tube	Constipation	
Benefiber powder 15ml to be added to Ketocal feed	Constipation	
Paracetamol 500mg soluble tablets One and a half tablets up to four times a day when required via PEG tube	Pain	
Diclofenac *(Voltarol)* 50mg suppositories One to be inserted rectally when required	Dystonia- pain	• Only required in last year of life
Cetirizine 5mg/5ml solution 5ml twice daily via PEG tube	Hayfever	
Hyoscine *(Scopolamine)* 1.5mg patch One patch to be applied every 48 hours	Excess salivation	
Sando K 1000mg effervescent tablets Two at night via PEG tube	Body salts	
Sodium Chloride 50mg/5ml solution 5ml in the morning via PEG tube	Body salts	
Budesonide *(Pulmicort) [strength not specified]* nebules One to be inhaled in the morning	Asthma	
Salbutamol *[strength not specified]* nebules One to be inhaled when required	Asthma	• Caused tachycardia
Carnitor 30% solution 3.3ml in the morning via PEG tube	Carnitine deficiency	
Ketocal powdered food 200mg +500ml boiled water +500ml filtered water 250ml bolus at night the 900ml overnight	Food	• For the last 7 years of his life he was on a ketocal (high fat) diet

Midazolam via syringe driver	Palliative care	• An ulcer developed around entry site of needle
Morphine via syringe driver	Palliative care	

Past Prescribed Medication	Indication	Comments/Notes
Baclofen – oral and intrathecal	Loss of muscle tone/contractures	• Side effect of excess drowsiness/reduced cognition at one point • Intrathecal baclofen (via a continuous pump) was installed in Jamie's mid-teens • Long term side effect was arachnoiditis (adhesions up the spinal canal)
Oxygen	Breathing problems from distorted body shape	• Also had CPAP ventilator
Variety of anti-epileptic medication including lamotrigine	Epilpesy	• Was careful to stick to a brand as generics affected seizure control
Rectal diazepam	Epileptic seizure	• Replaced with buccal midazolam

Over the Counter (OTC) Medication	Indication	Comments/Notes
None noted		

Medication Management

Ordering of prescriptions	• Parents
Taking prescriptions to pharmacy	
Collecting medication from pharmacy	
Administration	• Mainly parents but carer (employed under direct payments) would administer medication if required
Storage	• A locked box/medication chest where current medication was stored • Excess medication was stored in his bedroom • Emergency medication was stored in the chest and in his bedroom • Toolbox converted to medication box for travel
Other	

Appendix 3.5 CASE 05N - ROB

Personal Details

Rob is a 20-year-old Caucasian male who has PMLD as a result of Emanuel syndrome, a chromosomal disorder. He has hearing impairment and wears a hearing aid in one ear; visual impairment and wears glasses; and is non-verbal. As part of a formal shared care agreement, Rob now lives with his 'second parents' in his 'second home' but returns to his family home every other weekend and for some holidays. His carer and care workers gave the following descriptions of him: *cheeky; strong-willed; determined; quirky; very loving; an absolute joy.*

Medical History

Active Medical Conditions	**Comments/Notes**
Emanuel Syndrome *(also known as chromosome 11/22 translocation or partial trisomy 11/22)*	• Emanuel syndrome is a chromosomal disorder; most affected individuals have severe to profound intellectual disability (US Department of Health and Human Services 2017)
Chronic gastrointestinal issues including: gagging, reflux and constipation *[PEG tube in situ]*	• Started at puberty. PEG tube was put in place mid teens • All medication administered via the PEG tube but Jamie still takes some food orally • Small amount of liquid Nutrison feed given overnight to maintain weight • Lack of mobility and fluid intake contributing factors to constipation
Epilepsy	• Started at puberty. Initially tonic-clinic; now mainly complex partial • Photosensitive
Scoliosis and muscoskeletal issues	• Multiple operations to hip, leg, ankle, feet to improve mobility
Excess salivation	

Past Medical Conditions	**Comments/Notes**
Cleft palate (sub-mucosal)	• Caused drainage problems from ears
Ear infections	• Has had grommets inserted several times • Attends audiology clinic regularly and has ears cleaned out
Stomach ulcer	• From stress of routine change – having to stay indoors during a prolonged winter.
Meningitis	
Rotavirus	

Medication History

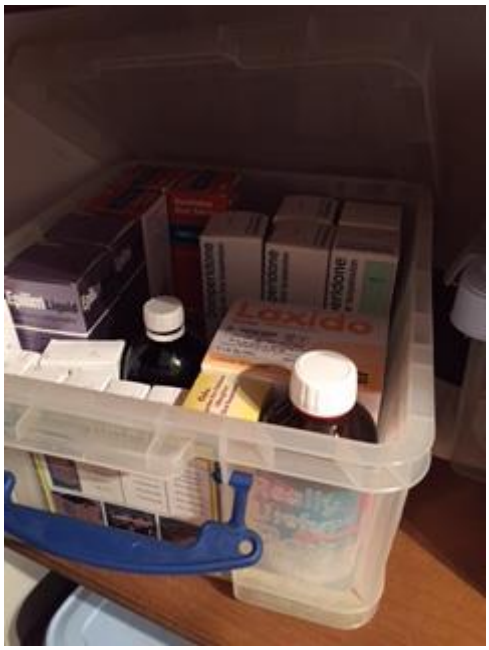
Current Prescribed Medication	Indication	Comments/Notes
Sodium Valporate *(Epilim)* 200mg/5ml liquid 15ml twice daily via PEG tube	Epilepsy	
Lamotrigine *(Lamictal)* 25mg dispersible tablets Four tablets twice daily via PEG tube	Epilepsy	
Midazolam *(Epistatus)* 10mg/ml oromucosal solution 1ml as per protocol	Epileptic seizure	
Lansoprazole 15mg fastab One tablet twice daily via PEG tube	Reflux	• Recently changed from omeprazole 20mg/5ml liquid – 10ml in the morning • Omeprazole tablets had clogged up the PEG tube
Ranitidine 150mg/10ml liquid 10ml twice daily via PEG tube	Reflux	
Domperidone 1mg/ml liquid 20ml twice daily via PEG tube	Reflux	• Had tried to reduce and stop but had to restart for symptom control
Gaviscon Advance liquid 5ml twice daily via PEG tube	Reflux	• Often used after mealtimes
Macrogol *(Movicol)* sachets One at night via PEG tube	Constipation	
Lactulose liquid 10ml twice daily via PEG tube	Constipation	
Paracetamol 250mg/5ml liquid 15ml up to four times a day when required via PEG tube	Occasional pain	
Hyoscine *(Scopalamine)* 1.5mg patch One patch to be applied every 72h	Excess salivation	• Less effective on day 3
Maxitrol eye ointment Apply round stoma area when required	Over-granulation of stoma tissue	• Maxitrol contains 1 ml suspension contains 1 mg dexamethasone, 6000 IU polymyxin B sulfate, 3500 IU neomycin sulfate (as base)

Past Prescribed Medication	Indication	Comments/Notes
Antibiotics (liquid)	Ear infections	
Senna	Constipation	
Dioralyte	Hydration during illness	

Over the Counter (OTC) Medication	Indication	Comments/Notes
None noted.		

Medication Management

Ordering of prescriptions	• Care worker
Taking prescriptions to pharmacy	
Collecting medication from pharmacy	
Administration	
Storage – Care Worker's home	• Medicines stored in locked cabinet in kitchen – see photos Case05NPhoto1 and Case05NPhoto2  *Case05NPhoto01 – Closed medicine cabinet (kitchen)*  *Case05NPhoto02 – Open medicine cabinet (kitchen)*

	• Extra boxes and new supplies are stored in a bedroom, in plastic boxes, at care worker's home – see Photos Case05NPhoto3 and Case05NPhoto4  *Case05NPhoto03: Storage of extra boxes/new supplies-01*  *Case05NPhoto04: Storage of extra boxes/new supplies-02* • Case05NCareW01: *'When I take him away…on holiday what I've got is…a big toolbox and I put all the medicines in that… omeprazole liquid, we had to keep it cool. And what we did was, we had a cool box that we could plug into the car…'*
Storage – family home	• Case05NCarer02: *'We've got a utility room so they're in a shelf above in the utility room away from everybody else.'* • Case05NCarer02[in reference to travel]: *'Everything goes into a bag. Basically, we've got a plastic tub with all the syringes in it and it'll go into a separate carrier bag with all the stuff. And then I lay out his medication.'*
Other	

Appendix 3.6 CASE 06C - MARK

Personal Details

Mark is a 54-year-old Caucasian male with moderate LD caused by Fragile X syndrome, a genetic condition. His capacity is limited but he is able to communicate verbally. He has his own room in a housing support facility and there are always care workers available. He receives scheduled support from care workers for most of his daily activities (washing, dressing, eating, activities). His carers gave the following description of him: *sociable; likeable; happy; good sense of humour; great memory; loves Star Wars and the Welsh rugby team.*

Medical History

Active Medical Conditions	Comments/Notes
Fragile X syndrome	• Fragile X syndrome is a genetic condition that causes a range of developmental problems including learning disabilities and cognitive impairment (US Department of Health and Human Services 2017)
Anxiety	
Eczema	

Past Medical Conditions	Comments/Notes
None noted	

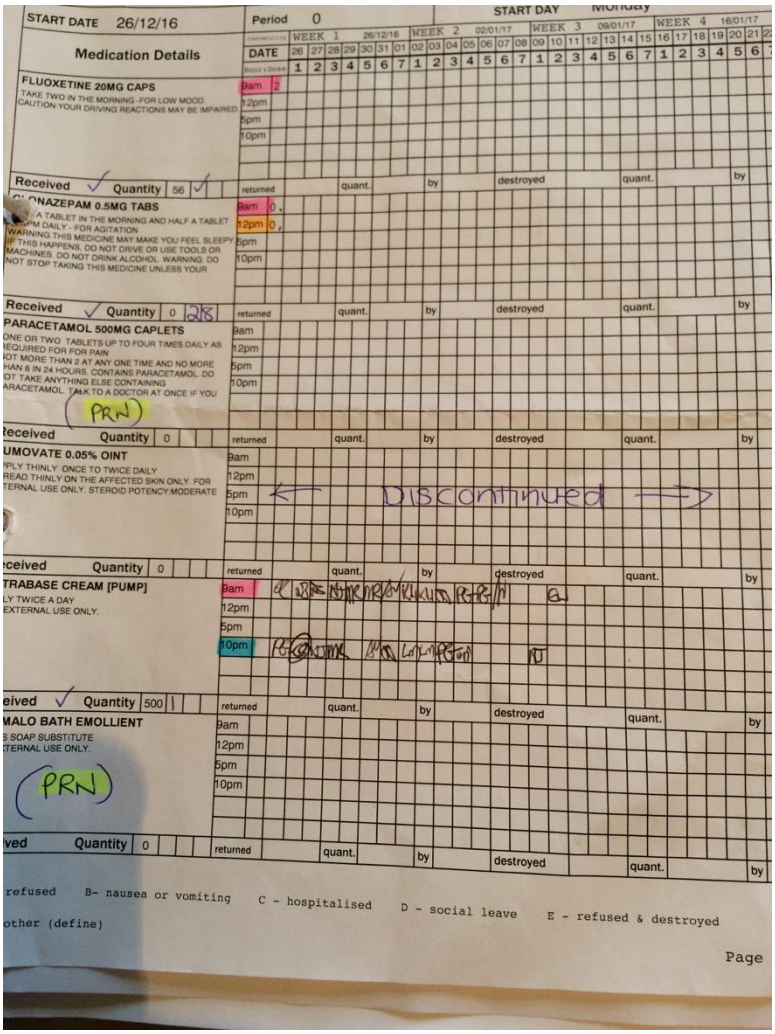
Medication

Current Prescribed Medication	Indication	Comments/Notes
Fluoxetine 20mg capsules Two in the morning	Anxiety and mood	• Has successfully controlled his outbursts
Clonazepam 0.5mg tablets Half a tablet in the morning and at lunchtime	Anxiety/agitation	• Will also take a dose before he has to attend the doctor or dentist
Paracetamol 500mg tablets One or two tablets up to four times daily when required	Pain	
Deramalo bath emollient Use in the bath when required	Eczema	• Flare-ups possibly linked to anxiety
Ultrabase cream Apply morning and night	Eczema	

Past Prescribed Medication	Indication	Comments/Notes
Clobetasone butyrate *(Eumovate)* 0.05% cream Apply once or twice daily when required	Eczema	• Moderately potent steroid

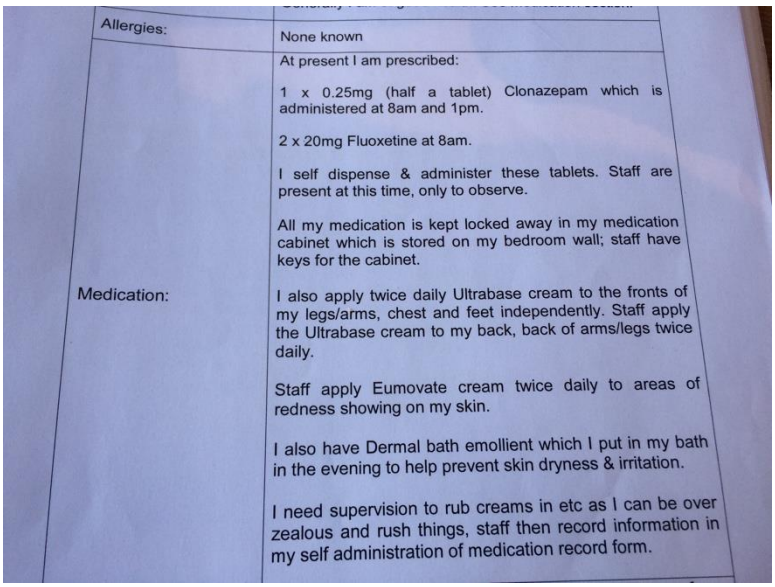
Over the Counter (OTC) Medication	Indication	Comments/Notes
None noted		

Medication Management

Ordering of prescriptions	• Key worker or another care worker
Taking prescriptions to pharmacy	
Collecting medication from pharmacy	• The pharmacy delivers medication to the residential unit
Administration	• Routine is very important to Mark and he will remind the care workers to help him with his medicines if they are ever late • Mark self-administers as his care workers supervise. Care workers only help Mark apply his Ultrabase cream and record this on a MAR chart – see Case06CPhoto1  *Case06CPhoto01: MAR chart* • Mark's routine is included in his care plan – see Case06CPhoto2 and Case06CPhoto3

	Breakfast Time
Monday	Staff prompt me with my medication I then get myself washed and shaved at the sink in the bathroom. I collect my clean clothes from the laundry get dressed and then have toast, cereal and tea/coffee for my breakfast.

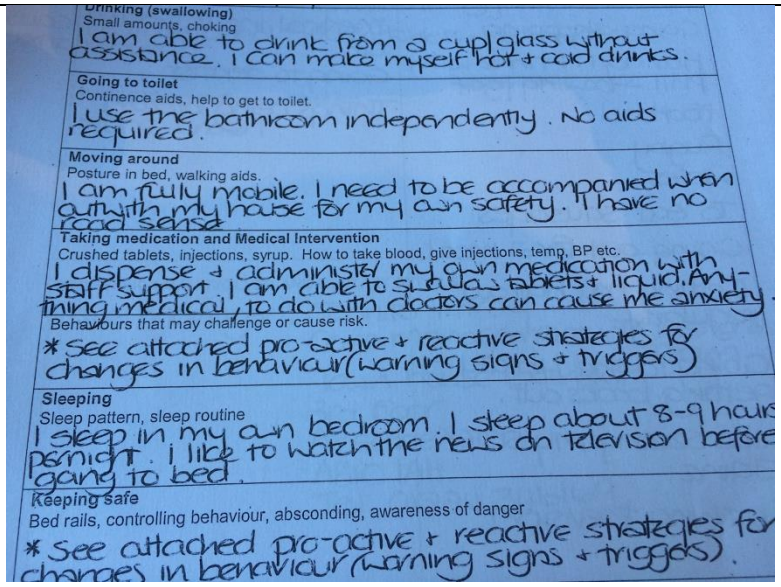
Case06CPhoto02: Care plan excerpt-01



Allergies:	None known
Medication:	At present I am prescribed: 1 x 0.25mg (half a tablet) Clonazepam which is administered at 8am and 1pm. 2 x 20mg Fluoxetine at 8am. I self dispense & administer these tablets. Staff are present at this time, only to observe. All my medication is kept locked away in my medication cabinet which is stored on my bedroom wall; staff have keys for the cabinet. I also apply twice daily Ultrabase cream to the fronts of my legs/arms, chest and feet independently. Staff apply the Ultrabase cream to my back, back of arms/legs twice daily. Staff apply Eumovate cream twice daily to areas of redness showing on my skin. I also have Dermal bath emollient which I put in my bath in the evening to help prevent skin dryness & irritation. I need supervision to rub creams in etc as I can be over zealous and rush things, staff then record information in my self administration of medication record form.

Case06CPhoto03 - Care plan excerpt-02

- His ability to self-administer is also noted in his hospital passport – see Case06CPhoto04

	 **Drinking (swallowing)** Small amounts, choking I am able to drink from a cup/glass without assistance. I can make myself hot + cold drinks. **Going to toilet** Continence aids, help to get to toilet. I use the bathroom independently. No aids required. **Moving around** Posture in bed, walking aids. I am fully mobile. I need to be accompanied when out with my house for my own safety. I have no road sense. **Taking medication and Medical Intervention** Crushed tablets, injections, syrup. How to take blood, give injections, temp, BP etc. I dispense + administer my own medication with staff support. I am able to swallow tablets + liquid. Anything medical, to do with doctors can cause me anxiety. Behaviours that may challenge or cause risk. * See attached pro-active + reactive strategies for changes in behaviour (warning signs + triggers) **Sleeping** Sleep pattern, sleep routine I sleep in my own bedroom. I sleep about 8-9 hours per night. I like to watch the news on television before going to bed. **Keeping Safe** Bed rails, controlling behaviour, absconding, awareness of danger * See attached pro-active + reactive strategies for changes in behaviour (warning signs + triggers). *Case06CPhoto04: Hospital passport excerpt*
Storage	• Medication stored in a locked cupboard in Mark's bedroom – see Case06CPhoto5  *Case06CPhoto05: Medicines storage (bedroom)*
Other	Carers keep Patient Information Leaflets (PILs) for reference – see Case06CPhoto06

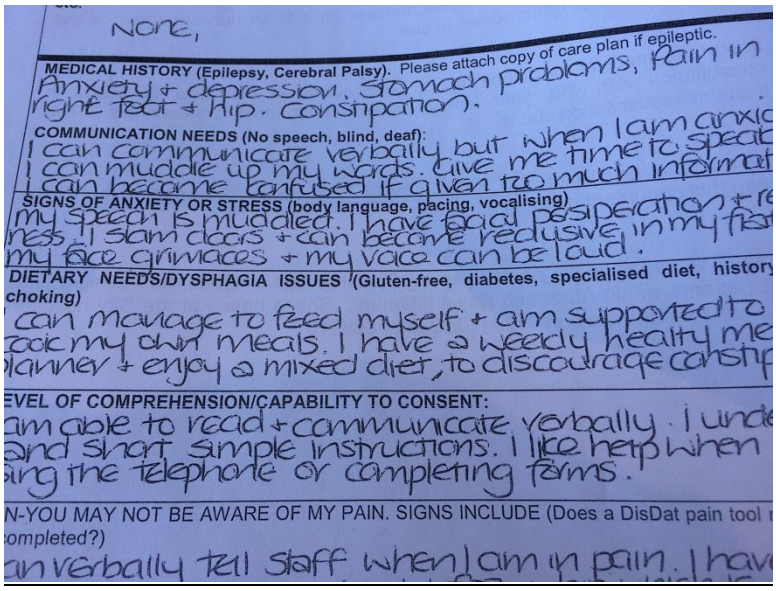
	 *Case06CPhoto06: Referenced PILs*

Appendix 3.7 CASE 07C - FIONA

Personal Details

Fiona is a 46-year-old Caucasian female who has mild-moderate LD (cause unknown). For the majority of everyday decisions, including medication, she is deemed to have capacity but the Local Authority has guardianship for particular decisions. Her mum lives locally and they have regular contact. She lives in her own flat within a small housing support unit for adults with LD; a care worker is always available around the clock. Care workers supervise her self-administering her medicines twice daily and support her with her finance. Fiona describes herself as enjoying her independence but needs company. She also enjoys craft work, decorating and going to the bingo with her mum.

Medical History

Active Medical Conditions	Comments/Notes
Pain (hip) Depression/anxiety Constipation Dry skin	• See information from care plan in Case07CPhoto1  None, MEDICAL HISTORY (Epilepsy, Cerebral Palsy). Please attach copy of care plan if epileptic. Anxiety + depression. Stomach problems, Pain in right foot + hip. Constipation. COMMUNICATION NEEDS (No speech, blind, deaf): I can communicate verbally but when I am anxio I can muddle up my words. Give me time to speak I can become confused if given too much informat SIGNS OF ANXIETY OR STRESS (body language, pacing, vocalising) my speech is muddled. I have facial perspiration + re ness. I slam doors + can become reclusive, in my fac my face grimaces + my voice can be loud. DIETARY NEEDS/DYSPHAGIA ISSUES (Gluten-free, diabetes, specialised diet, history choking) I can manage to feed myself + am supported to cook my own meals. I have a weekly healty me planner + enjoy a mixed diet, to discourage constip EVEL OF COMPREHENSION/CAPABILITY TO CONSENT: am able to read + communicate verbally. I unde and short simple instructions. I like help when sing the telephone or completing forms. N-YOU MAY NOT BE AWARE OF MY PAIN. SIGNS INCLUDE (Does a DisDat pain tool ompleted?) an verbally tell staff when I am in pain. I hav *Case07CPhoto01: Care plan*

Past Medical Conditions	Comments/Notes
Indigestion/heartburn	
Fungal infections (skin)	• Possibly linked to not washing and drying properly

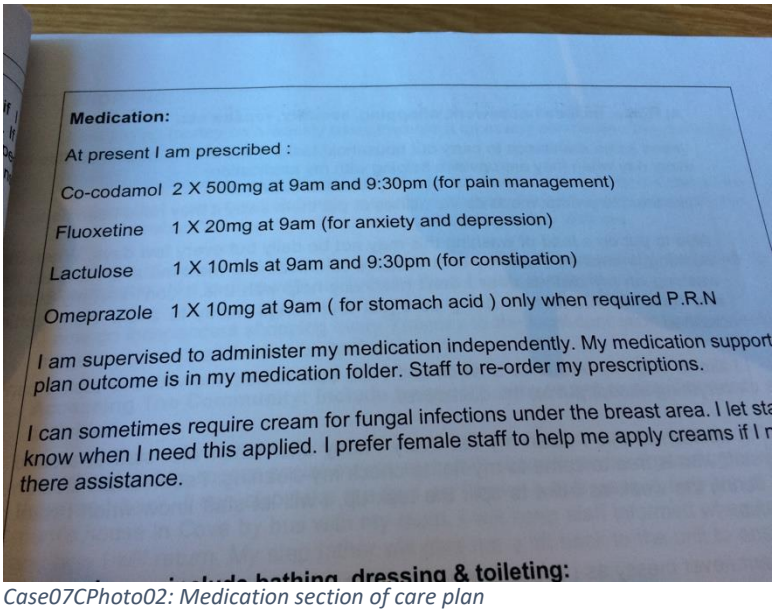
Medication History

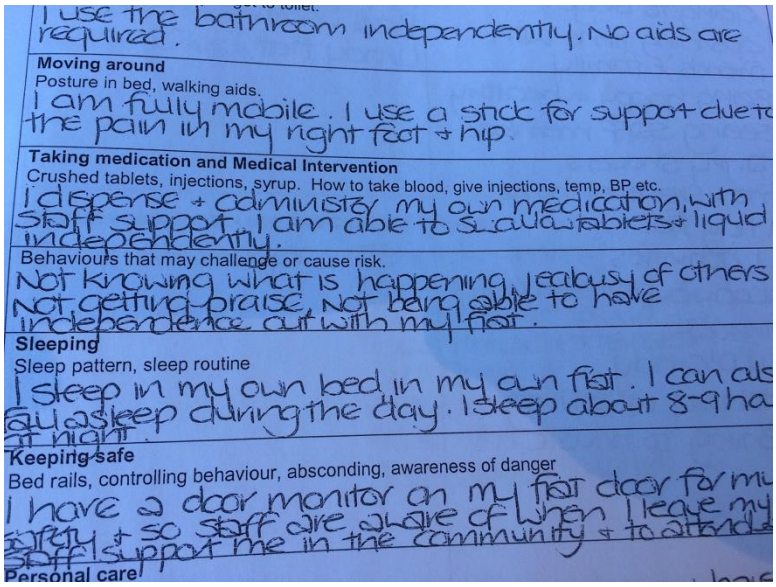
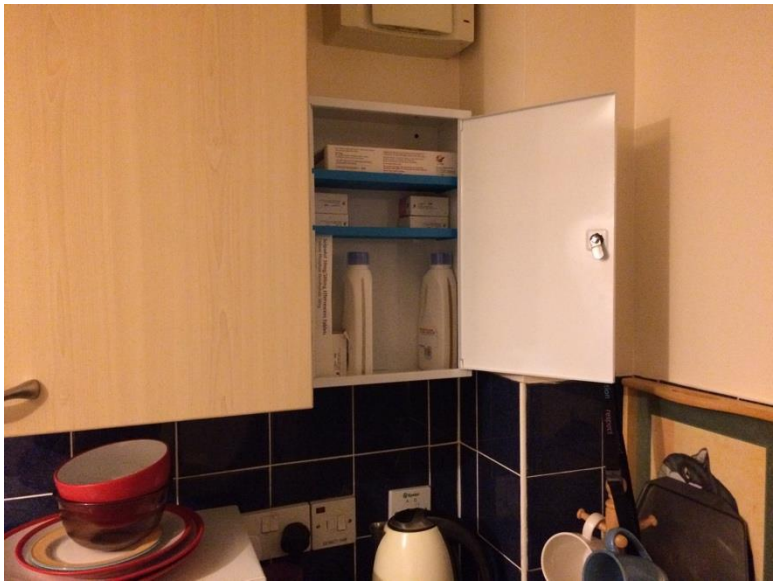
Current Prescribed Medication	Indication	Comments/Notes
Cocodamol 30/500 effervescent tablets Two tablets twice daily	Hip pain	• Had previously been prescribed as two tablets four times daily • Concerns over dependence raised and dose reduced to twice daily
Fluoxetine 20mg capsules Two in the morning	Depression and anxiety	• Initially prescribed as 20mg daily; then increased to 40mg
Lactulose solution 10mls twice daily	Constipation	
Doublebase cream Apply after shower	Dry skin	

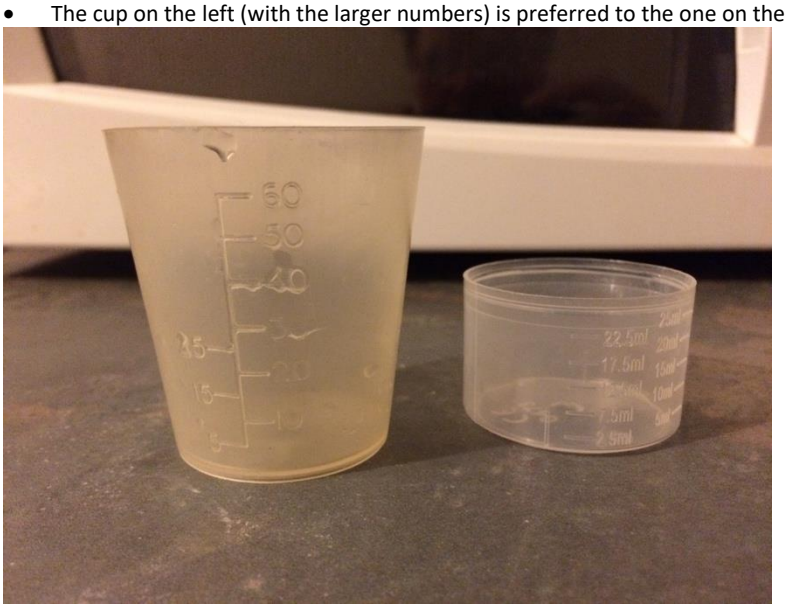
Past Prescribed Medication	Indication	Comments/Notes
Omeprazole 10mg capsules One in the morning when required	Indigestion	
Fexofenadine 120mg tablets One in the morning when required	Skin irritation	
Daktacort cream Apply twice a day when required	Sweat rash beneath breasts	

Over the Counter (OTC) Medication	Indication	Comments/Notes
Hyoscine *(Kwells)* 300mcg tab	Travel sickness	

Medication Management

Ordering of prescriptions ***Taking prescriptions to pharmacy***	• Care Workers
Collecting medication from pharmacy	• Pharmacy delivers medication to the care workers at the residential unit
Administration	• Her care workers keep the key to the locked cupboard containing her medication but Fiona self-administers all her medication as detailed in her care plan (see Case07CPhoto2) and hospital passport (see Case07CPhoto3)  *Case07CPhoto02: Medication section of care plan*

	 I use the bathroom independently. No aids are required. **Moving around** Posture in bed, walking aids. I am fully mobile. I use a stick for support due to the pain in my right foot + hip. **Taking medication and Medical Intervention** Crushed tablets, injections, syrup. How to take blood, give injections, temp, BP etc. I dispense + administer my own medication, with staff support. I am able to swallow tablets + liquid independently. Behaviours that may challenge or cause risk. Not knowing what is happening, jealousy of others Not getting praise, Not being able to have independence out with my flat. **Sleeping** Sleep pattern, sleep routine I sleep in my own bed in my own flat. I can als fall asleep during the day. I sleep about 8-9 ha at night **Keeping safe** Bed rails, controlling behaviour, absconding, awareness of danger I have a door monitor on my flat door for mi safety + so staff are aware of when I leave my staff support me in the community + to attend **Personal care** *Case07CPhoto03: Medication section of hospital passport* • Fiona has a set routine for taking her medicines: *'I get up, answer my front door, they give me a key, I open my cabinet, I take out my box of co-codamol, my fluoxetine, my lactulose. 'Cause I know that's the three that I take in the morning. I fill my glass with water, put my two co-codamols in it. It makes a hissing noise which is good. I take my two fluoxetine at the same time 'cause it's easier to swallow. Then my lactulose. That's in the morning. And at night I've only my lactulose and co-codamol at night-time.'*
Storage	• Fiona has her oral medicines stored in a locked cupboard in her kitchen – see Case07CPhoto04  *Case07CPhoto04: Medication storage in kitchen* • Her Daktacort is stored in her fridge • Fiona has a particular glass that she uses for her cocodamol – see Case07CPhoto5

	 *Case07CPhoto05: Dedicated glass for taking dispersible co-codamol* • Fiona also has particular measuring cups for her liquid medicines – see Case07CPhoto07 • The cup on the left (with the larger numbers) is preferred to the one on the right.  *Case07CPhoto07: Measuring Cups*
Other	• Two different types of packaging for cocodamol – see Case07CPhoto08 • Fiona finds the foil ones easier to open

Case07CPhoto08: Two brands of cocodamol

- Care workers do a stock check of all medicines on a Sunday

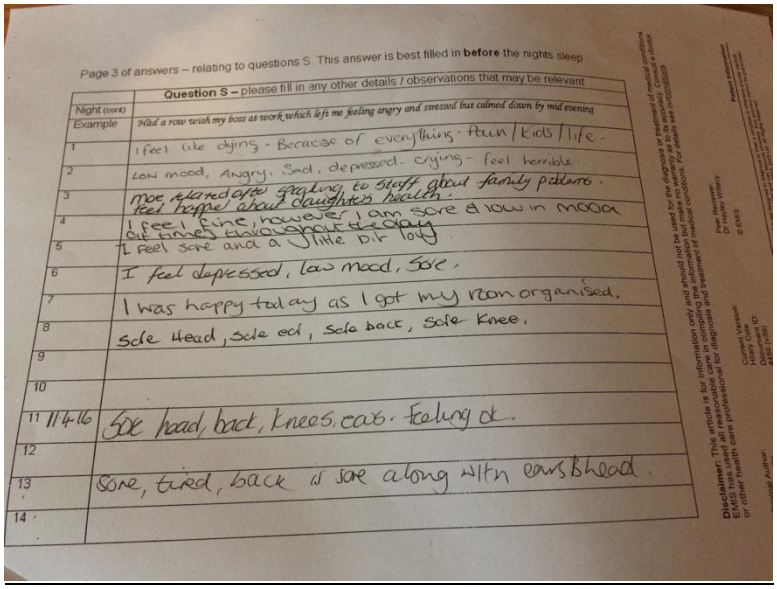
Appendix 3.8 CASE 08C - RUTH

Personal Details

Ruth is a 55-year-old Caucasian female with mild LD and has capacity to make decisions for herself (including medication). She lives alone in a flat that is part of a supported housing complex for adults with LD; children and grandchildren live locally and she has contact with most of them. Although she has worked previously she does not at present. Care workers supervise her taking her morphine tablets twice daily but Ruth is responsible for all her other medicines. Care workers also support her in arranging activities and with some aspects of personal care; support is minimal compared with other residents in the complex. Ruth enjoys going to the cinema, seeing her grandchildren and daughter, and going out for coffee.

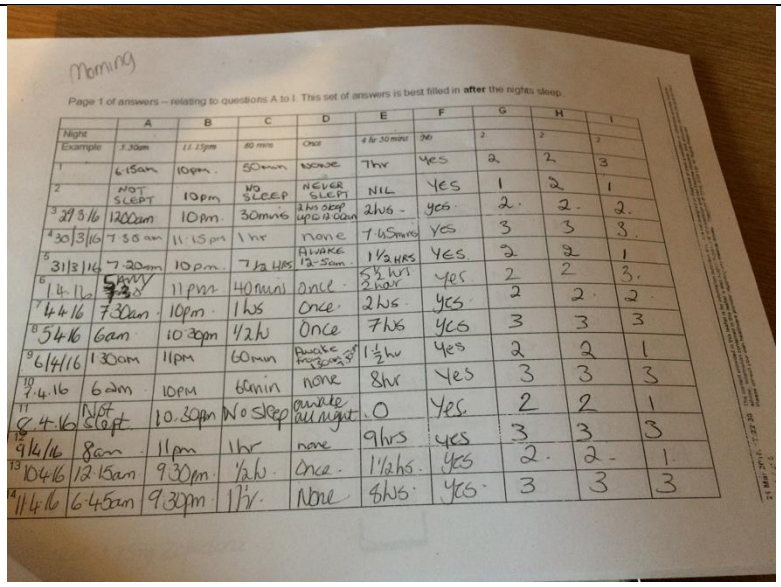
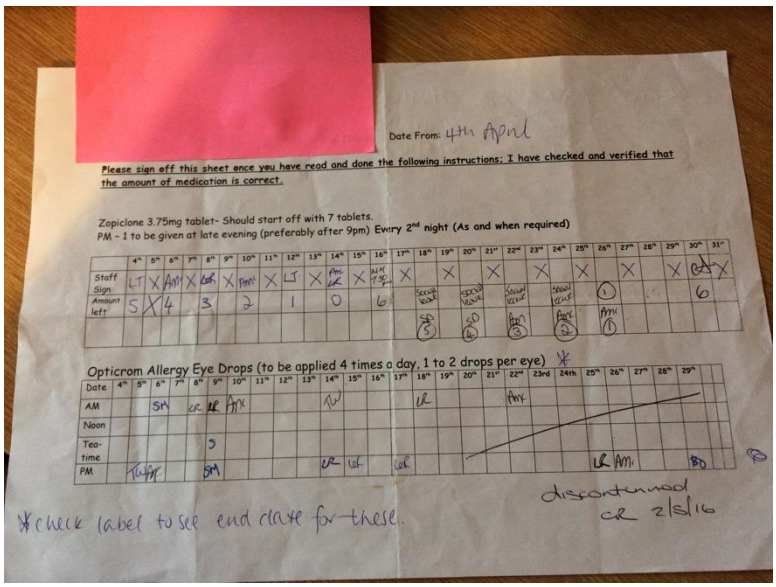
Medical History

Active Medical Conditions	Comments/Notes
Depression/anxiety	• Admitted to hospital for 2 years due to suicidal ideation before coming to current flat • Potential for self-harm when feeling stressed or anxious • Problems with low mood and pain recorded in sleep diary in previous 12 months– see Case08CPhoto01
Insomnia	• Evidence of attempts to gain insight into sleep patterns (see Case08CPhoto02) and to regulate hypnotic use (see Case08CPhoto03) over last 12 months


Page 3 of answers – relating to questions S. This answer is best filled in **before** the nights sleep

Night (cont)	Question S – please fill in any other details / observations that may be relevant
Example	Had a row with my boss at work which left me feeling angry and stressed but calmed down by mid evening.
1	I feel like dying - Because of everything - Mum / kids / life -
2	Low mood, Angry. Sad, depressed. crying - feel horrible
3	me stressed after speaking to staff about family matters.
4	I feel fine, however I am sore & low in mood but happy throughout the day
5	I feel sore and a little bit low
6	I feel depressed, low mood, sore,
7	I was happy today as I got my room organised.
8	Sore Head, Sore ear, Sore back, Sore knee.
9	
10	
11 11/4/16	Sore head, back, knees, ears. feeling ok.
12	
13	Sore, tired, back is sore along with ears & head.
14	

Case08CPhoto01: Problems with low mood evidenced in sleep diary

	 Morning Page 1 of answers – relating to questions A to I. This set of answers is best filled in after the nights sleep *Case08CPhoto02- Information on sleep pattern*  Date From: 4th April Please sign off this sheet once you have read and done the following instructions; I have checked and verified that the amount of medication is correct. Zopiclone 3.75mg tablet- Should start off with 7 tablets. PM – 1 to be given at late evening (preferably after 9pm) Every 2nd night (As and when required) Opticrom Allergy Eye Drops (to be applied 4 times a day, 1 to 2 drops per eye) discontinued CR 2/5/16 *Case08CPhoto03: Attempt to regulate/reduce hypnotic use*
Osteoarthritis & chronic pain	• Back, pelvis and knees
Hiatus hernia	• Had endoscopy and colonoscopy done within last 12 months
Constipation	
Irritable Bowel Syndrome (IBS) and intestinal polyps	
Hypothyroid	
Iron deficiency	
Asthma	• Quiescent
Allergy to diclofenac *(Voltarol)* gel and ibuprofen gel	• Caused bronchospasm and skin irritation

Past Medical Conditions	Comments/Notes
UTIs	• Infrequent
Impacted wax	

Medication History

Current Prescribed Medication	Indication	Comments/Notes
Duloxetine 60mg capsules One in the morning and bedtime	Depression/pain	• About to begin dose reduction as requested by specialist
Pregabalin *(Lyrica)* 200mg capsules One capsule three times daily	Pain	
Morphine *(MST)* MR tablets [1x10mg + 1x30mg] twice daily	Pain	
Paracetamol 500mg tablets Two tablets four times daily	Pain	
Zopiclone 7.5mg tablets One at night	Insomnia	• Has been on 3.75mg and 15mg in the past
L-thyroxine tablets [1x25mcg + 1x50mcg] in the morning	Hypothyroid	
Ranitidine 300mg tablets One tablet twice daily	Hiatus hernia	• Had been 150mg twice daily
Metoclopramide 10mg tablets One tablet three times a day	Hiatus hernia	• Tried and failed to reduce dose
Gaviscon Advance liquid 10ml up to four times a day	Hiatus hernia	
Docusate 100mg capsules Two capsules twice daily	Constipation	• Exacerbated by MST and iron
Ferrous sulfate *(Ferrograd)* 210mg tablets One in the morning	Anaemia	• Didn't like the taste of liquid preparation
Hyoscine *(Buscopan)* 10mg tablets One tablet three times daily	IBS	
Piroxicam gel	Sore muscles/joints	• Mentioned by carers but not seen or mentioned by Ruth
Sodium hyaluronate *(Clinitas)* eye drops	Dry eyes	• Seen in bedroom but not mentioned by Ruth

Past Prescribed Medication	Indication	Comments/Notes
Cerumol ear drops	Impacted wax	
Ibuprofel topical gel	Back pain	• Adverse drug reaction
Omeprazole capsules	Hiatus hernia	• Changed to ranitidine
Macrogol *(Laxido)* sachets	Constipation	
Diazepam tablets	Anxiety	
Dihydrocodeine tablets	Pain	
Tramadol capsules	Pain	
Amitriptyline tablets	Pain	• Replaced with pregabalin
Peppermint oil capsules	IBS	

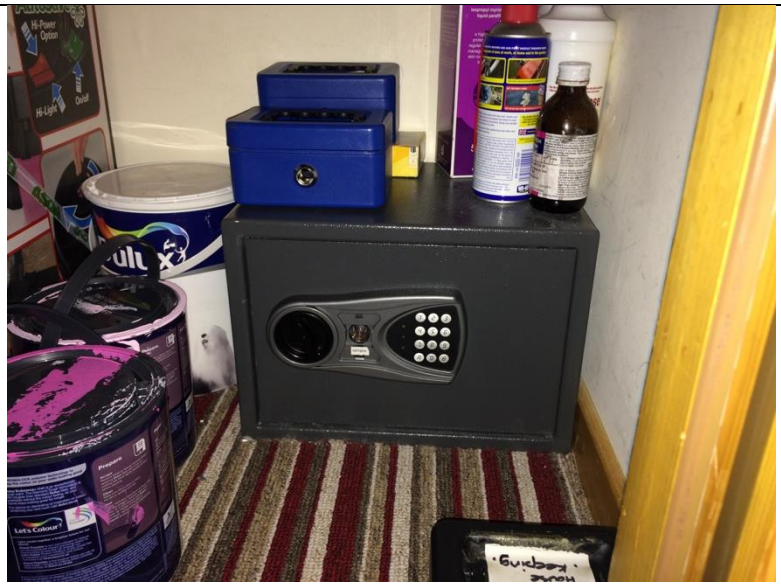
Salbutamol inhaler	Asthma	
Beclometasone inhaler	Asthma	
Simple linctus	Sore throat	
Doublebase cream	Dry skin	
Sodium Cromoglycate *(Opticrom)* allergy eye drops	Sore eyes	
Antibiotics	UTIs	

Over the Counter (OTC) Medication	**Indication**	**Comments/Notes**
Tums tablets	Indigestion	
Deep Freeze gel	Back pain	

Medication Management

Ordering of prescriptions	The supplying pharmacy.
Taking prescriptions to pharmacy	Pharmacy collect from the surgery.
Collecting medication from pharmacy	Pharmacy deliver to the care workers at the supported housing unit.
Administration	• Ruth self administers all her medicines except the MST without any supervision by the care workers • The majority of medicines are packed in a pharmacy filled MCA – see Case08CPhoto04  *Case08CPhoto04: Pharmacy-filled MCA* • In the morning, Ruth moves all these tablets into her own pillbox (see Case08CPhoto05) and self-administers from this

	 *Case08CPhoto05: Ruth's own pill-box* • Ruth has a particular routine with her medicines as described by her carers, Case08CCarer04: *'She takes her tablets the same way every day. It's the same tablets go – just say it's the blue one first, and then the green ones and then the white ones. She does that every day. That's the way she takes her tablet.'* • Case08CCarer02: *'She's got a lined-up routine thing going on I've noticed. Sometimes she's got them lined-up waiting for the time to take the.'* • Ruth's MST is stored in a medisafe and the carers supervise her access to the MST • Even though it is not legally required, the carers maintain a CD register
Storage	• Ruth stores all her medicines (except for her MST) in her bedroom – see Case08CPhoto06  *Case08CPhoto06: Storage of medicines (bedroom)* • MST is stored in a locked safe in her hall cupboard – see Case08CPhoto07

	 *Case08CPhoto07: Storage of MST (hall cupboard)*
Other	

Appendix 3.9 CASE 09C - DONALD

Personal Details

Donald is a 29-year-old Caucasian male who has autism and mild LD. He lives alone in a tenement flat; in that tenement other flats are rented out to adults with LD. His parents live on the other side of the city and he sees them at least once a week. Donald works for 2 hours/week in a nearby office. He receives 20 hours of care worker support each week and it fits around what he has on that week. His care worker makes sure he is eating properly, budgeting appropriately and general housekeeping; his care workers are not involved with any aspect of his medication. Donald states that what is important to him is volunteering with a number of groups, working, and getting enough sleep.

Medical History

Active Medical Conditions	Comments/Notes
Autism	
Depression/ seasonal affective disorder	• Diagnosed age 18/19y
Anxiety	
Asthma	• Diagnosed age 14y
Eczema	• From birth
Hayfever	• From birth

Past Medical Conditions	Comments/Notes
None mentioned	

Medication

Current Prescribed Medication	Indication	Comments/Notes
Mirtazapine 30mg tablet One at night	Depression	• Weekly dispense
Venlafaxine *(Efexor)* 75mg XL capsule One in the morning	Depression/anxiety	• Weekly dispense
Salbutamol 100mcg inhaler Two puffs when required	Asthma	
Beclometasone 100mcg and salmeterol 6mcg *(Fostair)* inhaler Two puffs morning and night	Asthma	

Past Prescribed Medication	Indication	Comments/Notes
Co-codamol 30/500 tablets Two tablets up to four times a day when required	Pain	

Over the Counter (OTC) Medication	Indication	Comments/Notes
None mentioned		

Medication Management

Ordering of prescriptions	• Donald will order his prescriptions
Taking prescriptions to pharmacy	• The pharmacy collect the prescriptions from the GP surgery
Collecting medication from pharmacy	• Donald goes to the pharmacy himself to collect the medication
Administration	• Donald self-administers without any supervision from care workers
Storage	• Medicines stored in drawer in kitchen – see Case09CPhoto01  *Case09CPhoto01: Medicines storage (kitchen)*
Other	

Appendix 3.10 CASE 10C - SUSAN

Personal Details

Susan is a 59-year-old Caucasian female who lives in a flat in a supported housing complex (city location); she had been in at least 5 other places before that. She has mild-moderate LD (cause unknown) and has visual impairment from only having one working eye. Both her parents have died and she only has contact with one of her siblings. She receives scheduled care worker support once a fortnight to assist her with shopping and general activities. She has capacity for everyday decisions and self-manages her medication. For Susan, the things that are important to her are: feeling secure (as she does in her current accommodation); going to her drama group on a Wednesday; and dolphins – she swam with dolphins on a trip to Florida.

Medical History

Active Medical Conditions	Comments/Notes
Hypertension	
Heartburn/ indigestion	
Urinary frequency, urgency, and urge incontinence	• Despite medication, still has to wear incontinence pads
Irritable bowel syndrome?	• Complains of stomach pains, wind and occasional diarrhoea
Hip pain/ mobility issues	• Requires a frame to walk
Visual Impairment	• Only has one eye

Past Medical Conditions	Comments/Notes
Hormonal/uterine problems	• Problems with bleeding; had a hysterectomy
Urinary tract infections (UTIs)	

Medication History

Current Prescribed Medication	Indication	Comments/Notes
Aspirin 75mg dispersible tablets One in the morning	Primary prevention?	• No recollection of a myocardial infarction or stroke
Amlodipine 10mg tablets One in the morning	Hypertension	
Ramipril 2.5mg capsules One in the morning	Hypertension	
Lansoprazole 30mg capsules One in the morning	Heartburn/ indigestion	
Mirabegron MR 50mg capsules One in the morning	Urinary frequency, urgency, and urge incontinence	• Still suffers from urinary incontinence despite medication

Solifenacin 5mg tablets One in the morning	Urinary frequency, urgency, and urge incontinence	
Loperamide 2mg capsules One when required after loose stool	Diarrhoea	

Past Prescribed Medication	**Indication**	**Comments/Notes**
Hormonal therapy	Pre-hysterectomy	
Antibiotics	UTIs	

Over the Counter (OTC) Medication	**Indication**	**Comments/Notes**
Gaviscon double action sachets	Indigestion	
Hyoscine 0.3mg tabs	Travel sickness	
Vitamins (cod liver oil)		
Aspirin tablets	Pain	

Medication Management

Ordering of prescriptions	• Care Worker in housing support unit orders Susan's prescriptions
Taking prescriptions to pharmacy	• Pharmacy collects prescriptions from the GP surgery
Collecting medication from pharmacy	• Pharmacy delivers medication to Susan
Administration	• Susan self-administers her medication without formal carer support; she gets all her regular medication in an MCA
Storage	• Susan keeps her MCA on a pull out shelf in the kitchen (see Case10CPhoto01) and original packs of medicines in a plastic container beside the microwave in the kitchen (see Case10CPhoto02)  *Case10CPhoto01: Medicine storage-01 (kitchen)*

	 *Case10CPhoto02: Medicines storage-02 (kitchen)*
Other	

Appendix 3.11 CASE 11C - DAVID

Personal Details

David is a 68-year-old Caucasian male who describes himself as having LD. However, his learning disability actually came about from a motorbike accident when he was a teenager that left him partially paralysed and brain damaged. He has memory problems and described himself as 'dead slow'. Although it can be argued that he does not have LD as defined by the British Psychological Society (2000), he identifies with that sub-group of the general population and so has been included. David worked as a handyman for most his life but had to retire early because of an increasing frequency of epileptic seizures. He has lived alone in a flat in a supported housing unit for the last 30 years. David receives support several times a week from a support worker; he manages his medication independently**.** Of most importance to David are: his security; his art – he enjoys sketching and painting and would like to attend a local art class; and being fit and independent.

Medical History

Active Medical Conditions	**Comments/Notes**
Epilepsy (petit mal)	• Started after his motorbike accident • Was controlled earlier on in his life but not in his later working life – resulted in him having to take early retirement
Osteoporosis	
Low body weight	• Involvement of dietitian

Past Medical Conditions	**Comments/Notes**
Brain injury/ haemorrhage after motorbike accident	• Right-sided causing left-sided weakness
Fractured neck of femur	• Fell in a local shop

Medication History

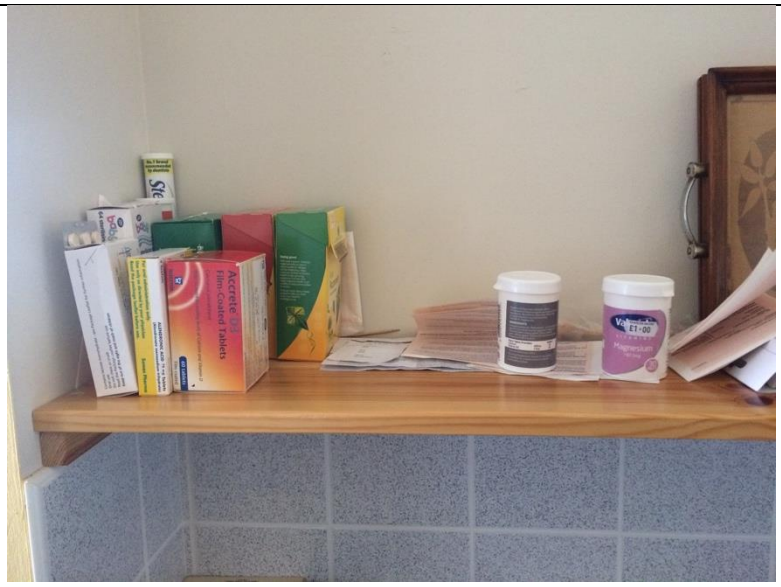
Current Prescribed Medication	Indication	Comments/Notes
Alendronate 70mg tablet One tablet weekly	Osteoporosis	• Takes on a Monday
Accrete D3 tablet One tablet twice daily	Osteoporosis	
Lamotrigine 200mg tablet One tablet twice daily	Epilepsy	
Ensure Plus Two drinks daily	Low body weight	
Paracetamol 500mg tablets Two tablets when required	General aches/pains	• David decants his paracetamol from a pack into a tub that was previously for vitamins – see Case11CPhoto01 Paracetamol storage  *Case11CPhoto01 Paracetamol storage*

Past Prescribed Medication	Indication	Comments/Notes
Senna 7.5mg tablets Two tabs morning and night	Constipation	• Not required regularly
Aqueous cream	Dry skin	• On repeat prescription list but David never mentioned
Other anti-epileptic medication		• Couldn't remember the names

Over the Counter (OTC) Medication	Indication	Comments/Notes
Calcium and vitamin D tablets	Supplement	• Knew that he now had prescribed calcium and vitamin D so was no longer taking
Magnesium 187.5mcg tablets	Supplement	• Couldn't remember why he had bought these
Strepsils lozenges	Sore throat	
Propolis lozenges		
Tyrozet lozenges		
Lemsip Max sachets	Cough/cold	
Ibuprofen 200mg tablets	Pain relief	
Paracetamol 500mg tablets		
Bonjela oral gel	Sore mouth	

Medication Management

Ordering of prescriptions	• Orders his own medication
Taking prescriptions to pharmacy	• Pharmacy collects the prescriptions from the GP surgery
Collecting medication from pharmacy	• Pharmacy delivers his medication to his flat
Administration	• David self-administers his own medication • He has his own system for organising his medication • He puts his twice daily lamotrigine into his own medication box and keep a strip of his Accrete D3 beside it (see Case11CPhoto02)  *Case11CPhoto02: David's system for organising his lamotrigine and Accrete* • He then uses his old medication box (see Case11CPhoto03) for other medication/vitamins he needs to take that day  *Case11CPhoto03: David's system for organising other medicines/vitamins*
Storage	• David stores his medicines in the kitchen in two locations – see Case11CPhoto04 and Case11CPhoto05

	 *Case11CPhoto04: Medicine storage-01 (kitchen)*  *Case11CPhoto05: Medicine storage-02 (kitchen)*
Other	