Lay Perspectives of Medicines for Dementia: a qualitative study

Denise Ann Taylor

A thesis submitted for the degree of Doctor of Philosophy

University of Bath

Department of Pharmacy & Pharmacology

September 2009

COPYRIGHT

Attention is drawn to the fact that copyright of this thesis rests with its author. A copy of this thesis has been supplied on condition that anyone who consults it is understood to recognise that its copyright rests with the author and they must not copy it or use material from it except as permitted by law or with the consent of the author.

This thesis may be made available for consultation within the University Library and may be photocopied or lent to other libraries for the purpose of consultation.

Signed:                               Dated:
AUTHOR’S DECLARATION

I certify that I have read and understood the entry in the Student Handbook for the Department of Pharmacy and Pharmacology on Cheating and Plagiarism and that all material in this assignment is my own work, except where I have indicated with appropriate references. I agree that, in line with Regulation 15.3(e), if requested I will submit an electronic copy of this work for submission to a Plagiarism Detection Service for quality assurance purposes.

Signed: 

Dated: 

Word Count: 89,176
ACKNOWLEDGEMENTS

I have a lot of people to thank for their continued support and love over the time this research took place.

Firstly I would like to acknowledge the generosity of all the participants in sharing with me their lived experience pertaining to the medicines for dementia. I would also like to acknowledge all the research gateway keepers including the branch leads of the Alzheimer’s Society in Phase One and the memory clinic staff in Phase Two.

Receiving the Galen Award allowed phase Two to be pursued and my thanks goes to Beth Allen and her great team at the Pharmacy Practice Research Trust. I would also like to thank the Swindon LREC panel and Tony Soteriou and his Research and Development team for their empathy and support when the study was delayed further by my accident in 2007.

I would like to thank Professor Marjorie Weiss, for her unfailing support and encouragement throughout the research and for her understanding of my need to undertake a qualitative piece of research that hoped to reach the lived experiences quantitative research could not.

My colleagues within the Department of Pharmacy & Pharmacology have been amazing in their love and support and encouragement in helping me to get back on track after my accident in 2007. I thank them from the bottom of my heart as without each one of their prayers and good wishes, there could have been a very different outcome. Thank you.

The writing up of this thesis has been helped greatly by Dr Jane Sutton and Ms Hannah Dawson’s unstinting generosity in covering my data collection slots on another study. Thank you so much.

Next I need to express my gratitude and love for Dr Jenny Scott’s unflattering support in the worst of times; it made things bearable.

Finally I thank my loving partner Alec Lawless for his unstinting care and attention when it was most needed and for always being there when the times got tough. His care of me has been the most extraordinary gift that I could ever have hoped to receive and his wonderful cooking has nurtured me nutritionally throughout. Thank you my darling.
# TABLE OF CONTENTS

AUTHOR’S DECLARATION .................................................................................... 2

ACKNOWLEDGEMENTS ......................................................................................... 3

TABLE OF CONTENTS .......................................................................................... 4

TABLE OF FIGURES AND TABLES ....................................................................... 11

ABSTRACT ................................................................................................................ 12

LIST OF ABBREVIATIONS AND GLOSSARY .................................................... 13

CHAPTER ONE: INTRODUCTION ............................................................................. 15

1.1 An Introduction to the Ethos of the Research .................................. 15

1.2 A Guide to the Thesis ...................................................................................... 18

1.3 Reflexivity on Starting .................................................................................... 18

CHAPTER TWO: LITERATURE REVIEW ............................................................... 20

2.1 An Introduction to Dementia ................................................................. 20

2.1.1 Definition, Epidemiology and Symptomatology ................. 20

2.1.2 The Diagnosis of Dementia ............................................................. 21

2.1.2.1 Ageism ................................................................................. 21

2.1.2.2 Ageing or dementia .............................................................. 22

2.1.2.3 Screening .............................................................................. 22

2.1.2.4 Diagnosis of dementia .......................................................... 24

2.1.3 Classification of the dementias ......................................................... 24

2.1.3.1 Mild Cognitive Impairment ............................................... 24

2.1.3.2 Alzheimer’s Disease ................................................................ 25

2.1.3.3 Vascular Dementia (VaD) .................................................. 25

2.1.3.4 Dementia with Lewy bodies ............................................... 26

2.1.4 Medicines for Dementia .................................................................. 26

2.1.4.1 The Acetylcholinesterase Inhibitors .................................. 26

2.1.4.2 Memantine: a N-Methyl D-Aspartate (NMDA) Receptor Antagonist ..................................................... 28

2.1.5 Monitoring Response .......................................................................... 28

2.2 The Effect of Dementia on Individuals .............................................. 29

2.2.1 Perception of Self .............................................................................. 29

2.2.2 Behavioural Changes ......................................................................... 30

2.2.3 Effect on Carers and Families of Dementia ................................ 31

2.3 NHS Health and Social Care for Dementia ......................................... 35

2.3.1 Services for Dementia ....................................................................... 35

2.3.2 Therapeutic Relationships ................................................................. 36

2.3.2.1 The Pharmacist’s Role in Dementia Care ........................................... 37

2.3.3 NICE Guidance .................................................................................. 37

2.3.3.1 NICE Guidance and Acetylcholinesterase Inhibitors ................................................................. 37
2.3.3.2 NICE and the Prescribing of Memantine .................................................. 39
2.3.4 Perceptions Of Response To Treatment 39
2.3.4.1 Predicting response ................................................................. 41

2.4 The Aims and Objectives 41

CHAPTER THREE: METHODOLOGY & METHODS PHASE ONE ................... 43

3.1 Introduction 43

3.2 Aims and Objectives 43

3.3 Ethical Considerations 43
3.3.1 Consent issues 44
3.3.2 Participant Emotional needs 44
3.3.3 Researcher Safety 45
3.3.4 Data Protection and Confidentiality 45

3.4 Methodology 46
3.4.1 Methods 47
3.4.1.1 Focus group methodology .......................................................... 47
3.4.1.2 Semi-structured Interview Methodology ...................................... 48
3.4.1.3 Development of the Topic Guides .............................................. 49
3.4.2 Sampling and Recruitment 49
3.4.2.1 Branch selection ................................................................. 49
3.4.2.2 Participant recruitment .......................................................... 50
3.4.2.3 Inclusion and Exclusion Criteria .............................................. 50
3.4.3 Data Handling 50
3.4.3.1 Recording and Transcribing .................................................. 50
3.4.3.2 Methods for Coding and Analysis ........................................... 51

3.5 Recruitment 52
3.5.1 Recruitment of Local Alzheimer’s Society Branches 52
3.5.1.1 Location One ................................................................. 53
3.5.1.2 Location Two ................................................................. 53
3.5.1.3 Location Three ............................................................... 53
3.5.1.4 Location Four ................................................................. 54
Factor 55
3.5.1.5 Non-participating Branches .................................................. 56
3.5.2 Study Participants 56

CHAPTER FOUR: RESULTS AND DISCUSSION PHASE ONE ................... 58

4.1 Data Coding 58
4.1.1 Coding for Carer Participants 59
4.1.2 Coding for People with Dementia 60
4.1.3 Cross Coding for All Participants 62

4.2 On Being A Carer 62
4.2.1 Generalities of Caring 62
4.2.1.1 The Day-to-Day Experience ................................................. 62
4.2.1.2 Gender Role Changes ....................................................... 64
4.2.1.3 Keeping Loved Ones Safe .................................................. 64
4.2.1.4 Uncertainty and Decision-making in Caring .......................... 66
4.2.1.5 Information Seeking Behaviour .......................................... 67
4.2.1.6 Sharing Information .......................................................... 69
4.2.1.7 Misinformation and Bureaucracy ....................................... 70
4.2.2 Caring: Darkness and Light 71
4.2.2.1 Supportive Structures ....................................................... 71

5
4.3 Interaction with Healthcare Professionals 76
4.3.1 Consultation Etiquette 76
4.3.1.1 Differing Approaches .................................................. 77
4.3.1.2 Lack of Knowledge ...................................................... 77
4.3.1.3 Carer Involvement ...................................................... 78
4.3.1.4 People with Dementia and Consultations ......................... 79
4.3.1.5 Consultations: together or apart? ................................... 80
4.3.1.6 Conflict with Healthcare Professionals .............................. 82
4.3.2 Ageism 83
4.3.2.1 Recognition and Diagnosis ........................................... 83
4.3.2.2 Complexity and Duration ............................................. 85
4.3.3 Accessing Medicines for Dementia 86
4.3.3.1 Hopes and Fears of Medication .................................... 86

4.4 Living With A Degenerative Illness 90
4.4.1 The Lived Experience 90
4.4.1.1 Sense Making and Acceptance ....................................... 90
4.4.1.2 Living with a Poor Memory .......................................... 91
4.4.1.3 Changing Relationships ............................................. 93
4.4.1.4 Progression and Behavioural Changes ............................ 94
4.4.2 After Medicines for Dementia 97
4.4.2.1 Effects on People with Dementia .................................. 97
4.4.2.2 Effects on Care-givers ............................................. 102
4.4.3 Issues with Medicines 105
4.4.3.1 Managing Side Effects ............................................. 105
4.4.3.2 Monitoring and Assessment of Response ......................... 106
4.4.3.3 Uncertainty of response ............................................ 108
4.4.3.4 Stopping treatment .................................................. 109
4.4.3.5 Concomitant Illness and Medication ............................. 110
4.4.3.6 Ensuring Compliance ........................................... 111

4.5 Summary of Key Findings 114

CHAPTER FIVE: METHODOLOGY & METHODS PHASE TWO .............. 116

5.1 Introduction 116

5.2 Case Study Methodology 116
5.2.1 Case Study Methodology in Health Service Research 116
5.2.2 Quality Issues in Case Research Methodology 117
5.2.2.1 Construct Validity ................................................... 118
5.2.2.2 Internal Validity (for explanatory and causal design) .......... 118
5.2.2.3 External Validity .................................................... 119
5.2.2.4 Reliability .......................................................... 119
5.2.2.5 Alternative Quality Structures ................................. 120
5.2.3 Case Study Design for Phase Two 120

5.3 Aims and Objectives 121

5.4 Methodology 122
5.4.1 Methods 122
5.4.1.1 Face-to-face Interviews ........................................... 122
5.4.1.2 Observation of Consultations .................................... 123
5.4.1.3 Diary Records ..................................................... 124
5.4.1.4 Patient Shared Care Records .................................... 124
5.4.2 Recruitment 125
5.4.2.1 Selection of Recruitment Sites ................................... 125
5.4.2.2 Participant Recruitment ................................................................. 125
5.4.2.3 Inclusion and Exclusion Criteria....................................................... 125
5.4.3 Data Collection and Management ....................................................... 126
  5.4.3.1 Interview data ............................................................................. 126
  5.4.3.2 Observation Data .......................................................................... 126
  5.4.3.3 Diary Data .................................................................................... 127
  5.4.3.4 Patient Shared Record Data .......................................................... 127

5.5 Ethical Considerations ........................................................................... 128
  5.5.1 The Process ...................................................................................... 128
  5.5.2 Research and Development Approval ................................................. 129
  5.5.3 Potential Ethical Dilemmas ............................................................... 129

5.6 Recruitment ......................................................................................... 130
  5.6.1 Description of Recruitment Locations ................................................. 130
    5.6.1.1 Location One ............................................................................. 130
    5.6.1.2 Location Two ............................................................................ 130
    5.6.1.3 Location Three ................................................................. 131

5.7 Reporting Case Study Findings .............................................................. 131

CHAPTER SIX: RESULTS AND DISCUSSION OF PHASE TWO .............................................................................. 132

6.1 Description of Case Studies ................................................................... 132
  6.1.1 Case Study One: Ineligible for a medicine for dementia ...................... 132
  6.1.2 Case Study Two: Intolerable side effects ........................................... 132
  6.1.3 Case Study Three: Rivastigmine ..................................................... 133
  6.1.4 Case Study Four: Co-prescription of Memantine and an Acetylcholinesterase Inhibitor ............................................................. 133
  6.1.5 Case Study Five: Galantamine ......................................................... 133
  6.1.6 Case Study Six: Refused to take Medication ....................................... 133
  6.1.7 Case Study Seven: Memantine ......................................................... 134

6.2 DATA COLLECTION and ANALYSIS ..................................................... 134
  6.2.1 The Data .......................................................................................... 136
    6.2.1.1 Interviews of Participants and their Carer .................................... 136
    6.2.1.2 Interviews with all Healthcare Professionals ................................ 136
    6.2.1.3 Observed Consultations ............................................................. 136
    6.2.1.4 Diary Records ............................................................................ 136
  6.2.2 Data Analysis .................................................................................... 136
    6.2.2.1 Thematic Taxonomy from Individual Case Studies ....................... 137
    6.2.2.2 Cross-case Analysis .................................................................. 138

6.3 Living With A Memory Problem Or Dementia ....................................... 141
  6.3.1 Personal Changes ............................................................................. 141
    6.3.1.1 Ageing and Concomitant Illness ................................................ 141
    6.3.1.2 An elusive memory .................................................................... 144
    6.3.1.3 Fluctuations and progression ..................................................... 145
  6.3.2 Comparative Changes ..................................................................... 147
    6.3.2.1 Behaviours ............................................................................... 147
    6.3.2.2 Activities ................................................................................... 152
  6.3.3 Relationship Dynamics ..................................................................... 153
    6.3.3.1 Perspectives of day-to-day living ................................................. 153
    6.3.3.2 Communicating with a memory problem ..................................... 156
    6.3.3.3 Effects on Others ....................................................................... 157
    6.3.3.4 Acceptance and Living Together ............................................... 159

6.4 Interacting With Healthcare Professionals .......................................... 161
6.4.1 The Therapeutic Relationship ................................................................. 161
6.4.1.1 Consultation Etiquette ........................................................................... 161
6.4.1.2 Expectations within the Consultation .................................................. 163
6.4.1.3 Beliefs and Expectation of Medication ............................................... 164
6.4.2 Therapeutic Decision-making ............................................................... 165
6.4.2.1 Diagnostic Processes ........................................................................... 165
6.4.2.2 Prescribing Decisions ......................................................................... 168
6.4.2.3 Predicting Response ............................................................................ 170
6.4.3 Assessment, follow-up & support ........................................................... 171
6.4.3.1 Testing for response ............................................................................ 171
6.4.3.2 Assessing the response ....................................................................... 172
6.4.3.3 Follow-up and Support ....................................................................... 175

6.5 Medicines For Dementia ........................................................................... 177
6.5.1 Prescribing Hindrances ........................................................................... 177
6.5.1.1 Access to Acetylcholinesterase Inhibitors ............................................. 177
6.5.1.2 Prescribing and Co-prescribing of Memantine .................................... 179
6.5.2 Responding to a Medicine for Dementia .................................................. 180
6.5.2.1 Response Rate and Duration ................................................................ 180
6.5.2.2 Beneficial Response .......................................................................... 181
6.5.2.3 Sociability and Returning to Old self ................................................... 183
6.5.2.4 Perceived Quality of Life ..................................................................... 186
6.5.3 Medication Issues ................................................................................... 187
6.5.3.1 Experiencing Side Effects ................................................................... 187
6.5.3.2 Getting the prescription and the medication ....................................... 190
6.5.3.3 Mislabelling ...................................................................................... 191
6.5.3.4 Compliance and Titration Problems ..................................................... 191

6.6 Summary of Findings ................................................................................ 194

CHAPTER SEVEN: OVERARCHING DISCUSSION AND CONCLUSIONS ..... 195

7.1 Summary of Findings ............................................................................. 195
7.1.1 Phase One Summary ............................................................................ 195
7.1.2 Summary of Phase Two ......................................................................... 196

7.2 Limitations of the Research ...................................................................... 196

7.3 Key Findings ............................................................................................ 198
7.3.1 The Burden of Caring ........................................................................... 198
7.3.2 Accessing Medicines for Dementia ....................................................... 200
7.3.3 Perspectives of Responses .................................................................... 202
7.3.4 Educational Issues ................................................................................ 206
7.3.5 Pharmacists and Medicines Management Issues .................................... 207
7.3.6 Variability ............................................................................................ 209

7.4 Implications for Practice and Research .................................................... 213
7.4.1 Implications for Practice ....................................................................... 213
7.4.2 Implications for Future Research ............................................................ 214

7.5 In Conclusion ........................................................................................... 215

CHAPTER EIGHT: REFLEXIVITY ON RESEARCH ........................................ 216

REFERENCES ............................................................................................... 219
APPENDICES

Appendix A1-1: Abbreviated Mini-mental Test 251
Appendix A1-2: Mini-Mental State Examination 252
Appendix A3-1: Phase One Internal Ethical Review 254
Appendix A3-2: LREC Approval Phase One 255
Appendix A3-3: Information Sheets 258
Appendix A3-4: TOPIC GUIDE Phase One 261
Appendix A3-5: Patient Consent forms 263
Appendix A3-6: Branch Letter 264
Appendix A3-7: Advertising Flyer 266
Appendix A4-1: Categorisation of Carer Themes Phase One 267
Appendix A4-2: Explanation of Superordinate Themes 276
Appendix A5-1: Case Study Protocol 277
Appendix A5-2: Topic Guide for Phase Two 284
Appendix A5-3: Consent for Observation of Consultation 286
Appendix A5-4: Consultation Observation Tool 287
Appendix A5-5: Study Information Sheet Phase Two 288
Appendix A5-5: Joint Recruitment letter 291
Appendix A5-5: Consent Form for Interviews 293
Appendix A5-8: Shared Cared Record Data Collection Form 294
Appendix A5-9: Internal Ethical Review 295
Appendix A5-10: LREC Approval Phase Two 298
Appendix A5-11: LREC Approval of Changes to the 300
Appendix A5-12: LREC Approval Amendment 1 301
Appendix A5-13: LREC Approval Amendment 2 303
Appendix A5-14: LREC Approved Study Extension 1 305
Appendix A5-15: LREC Approved Study Extension 2 306
Appendix A5-16: LREC Approved Study Extension 3 308
Appendix A5-17: Case Study Report 309
Appendix A6-1: Coding Taxonomy for Phase Two  
Appendix A6-2: Description of Superordinate Themes  
Appendix 8-1: Publications and Dissemination
TABLE OF FIGURES AND TABLES

Table 1.1: Common Gastrointestinal Adverse Effects * ........................................... 16
Table 2.1: The Changing Clinical Features of Dementia ............................................. 23
Figure 2.1: Pearlin’s Conceptual model of Alzheimer’s caregivers’ stress ................. 32
Figure 2.2 Theoretical framework for well-being and relationships .......................... 34
Table 3.1: Local Branch Specifications* ..................................................................... 55
Table 3.2: Participants in Phase One ........................................................................... 57
Figure 5.1: Overview of Case Study Methodology .................................................... 128
Table 6.1: The Case Studies ...................................................................................... 135
Table 6.2: Comparison of Taxonomy Between Individual Case Studies ................. 139
Figure 6.1: Interaction of Superordinate Themes ....................................................... 140
Figure 6.2: Diagrammatic Representation of Living with a Memory ................. 141
Problem or Dementia .............................................................................................. 141
Table 6.3: Improving Memory Deficits to Aid Communication ......................... 151
Figure 6.3: Diagrammatic Representation of Interacting with Healthcare ............... 161
Professionals .............................................................................................................. 161
Figure 6.4: Harry’s MMSE Timeline ........................................................................ 173
Figure 6.5: David’s MMSE Timeline ....................................................................... 174
Figure 6.6: Diagrammatic Representation of Medicines for Dementia ............... 177
Table 6.4: Diary Notes by Judy Jones ....................................................................... 185
Figure 7.1 Postulated mediation of medicines for dementia on carer ability to live
with dementia ........................................................................................................... 199
Table 7.1 Impact of Pharmacists’ activities on improving care for people with AD
......................................................................................................................................... 208
Table 7.2 Linking Study Findings to the National Dementia Strategy Objectives 211
ABSTRACT

Lay Perspectives of Medicines for Dementia: a qualitative study

This was a two phase study exploring lay perspectives of medicines for dementia. In phase one, participants were recruited from 4 local branches of the Alzheimer’s Society in the southwest to take part in a single focus group or interview. In total 5 people with dementia and 23 carers participated. The aim was to explore perceptions of medicines on day-to-day life. Findings fell into 3 superordinate themes: On Being a Carer; Interacting with Healthcare Professionals and Living with a Degenerative Illness. Participants described great variability in access to medicines and in outcomes of consultations with healthcare professionals. Ageism and therapeutic nihilism were commonly encountered.

Phase Two was a longitudinal study exploring the impact of medicines for dementia in early stage disease using a case study approach. Seven case studies were recruited via memory clinics; with four receiving a medicine for dementia and three not. Case study participants were followed over a 13-month period. The superordinate themes were: Living with a Memory Problem or Dementia; Interacting with Healthcare Professionals and Medicines for Dementia. Even in the early stages of a dementia spousal relationships were negatively affected. Medicines for dementia enabled renegotiation of spousal relationships and adjustment and acceptance to take place. The Mini-Mental State Examination was perceived to tell only half the story and was insensitive to improvements in alertness, initiative, engagement with the individuals’ lifeworld and ability to maintain and engage in social relationships.

Overall both phases found access to medicines for dementia a complicated and long procedure. The methods for assessing response were perceived as threatening and unrealistic. There was a perceived need for greater education about dementia and its treatment for healthcare professionals, people with dementia and their carers. It was identified that pharmacists could take a more proactive role in providing a pharmaceutical care service.

Word Count: 298
LIST OF ABBREVIATIONS AND GLOSSARY

- Acetylcholinesterase inhibitors = AChEIs
- Alzheimer’s disease = AD
- Appendix = A
- Code = a narrative excerpt from the data which depict a particular meaning
- Coding = this process is to organise or manage data for analysis
- Dementia with Lewy bodies = DLB
- Descriptor Code = This term is used to describe the ethos or the underlying meaning of the code. That is, it is like a definition of the code and helps to aid robustness of the coding process
- Focus Group = FG
- Healthcare Professional = HCP
- Interview = IV
- Location = L
- Mild Cognitive Impairment = MCI
- Mini-Mental State Examination = MMSE
- National Dementia Strategy = NDS
- National Institute for Health and Clinical Excellence = NICE
- N-Methyl D-Aspartate Receptor Antagonist = NMDA Receptor Antagonist
- Parkinson’s disease dementia = PDD
- Participant with dementia = PaWD
- People with dementia = PWD
- Primary care Trust = PCT
- Share care Record = SCR
- Sub-code delineator = A code may cover a number of minor codes and a ‘sub-code delineator’ is a definition of this level of analysis.
- Summary of product Characteristics = SPC
• Super-ordinate Theme (Delineator) = This is an over-arching term used to describe a clumping of themes and sub-themes which describe in their totality the phenomenology or understanding of the data.

• Theme = A theme is an term used to describe a number of codes and/or sub-codes. For example ‘problems with diagnosis’ could cover codes and sub-codes such as time to diagnosis; access to specialists etc.

• Vascular dementia = VaD
CHAPTER ONE: INTRODUCTION

This chapter will give a short introduction to the background behind the research area which will be expanded on in Chapter Two. Following this introduction will be a short guide to the thesis and then an explanation of how researcher reflexivity will be presented throughout the thesis.

1.1 An Introduction to the Ethos of the Research

Dementia is an insidious and progressive neurodegenerative disorder, which has a major impact on both the person with dementia and their carers’ health and quality of life. As the disease progresses and the person with dementia declines, the accompanying mood and personality changes can be profoundly upsetting to loved ones. Until 1997 there was no licensed pharmacological treatment available for treatment of dementia syndromes in the United Kingdom (UK). With the licensing of the acetylcholinesterase inhibitors (AChEIs), [Donepezil (Aricept®)\(^1\) in 1997, Rivastigmine (Exelon®)\(^2\) in 1998, and Galantamine (Reminyl®)\(^3\) in 2000 and the NMDA Receptor Antagonist Memantine (Ebixa®)\(^4\) in 2002], the possibility of symptomatic treatment for dementia was realised.

However, there seemed reluctance\(^5\)-\(^7\) to use these treatments even though robust trial evidence\(^8\)-\(^14\) demonstrated statistically significant improvements in validated assessment scales including the mini-mental state examination (MMSE).\(^15\)-\(^19\) Healthcare professionals (HCPs) and those involved in the acceptance of these agents onto local prescribing formularies had difficulty translating improved MMSE scores into actual clinical benefits for people with dementia (PWD).\(^20\),\(^22\) Although there have been attempts to explain why these treatment effects may not be seen as useful by clinicians’ rating them.\(^23\) There was also unfamiliarity with prescribing pharmacologically effective treatments for dementia as the previous licensed agents had either been withdrawn due to liver toxicity\(^24\) or inefficacy.\(^25\),\(^26\) In 2001 the then National Institute for Clinical Excellence (NICE) produced prescribing guidance for the AChEIs.\(^27\) This guidance stated that the AChEIs were effective in the treatment of mild and moderate Alzheimer’s disease (AD) and should be prescribed once a diagnosis had been made by a specialist.\(^27\)

On being presented with a diagnosis of a particular medical condition, many people will hold a belief about how medication may ameliorate or totally cure their medical condition.\(^28\),\(^29\) This may or may not coincide with the viewpoint of the persons’ carer, the prescriber or other healthcare professionals (HCPs) involved in their care, who may hold different views of efficacy.\(^30\)

However, prior to treatment being started, NICE guidance stated that compliance needed to be ensured and an end date when the treatment would be withdrawn, discussed.\(^27\) It is possible that the viewpoints of all those concerned with use of AChEIs may change over a period of time. Also if the person with dementia, their carer and the physician expectations were widely different, then it may be impossible to agree on, and get informed consent for, an endpoint for cessation of treatment prior to starting treatment.

Controversy still continues with revised guidelines published by the now National Institute for Health and Clinical Excellence (NICE) in 2006\(^31\) (since revised in
2009) suggesting that although these agents are clinically effective in controlling the symptoms of AD they should not be prescribed in the mild stages of the disease due to questionable cost effectiveness.  

Medicines management is an umbrella term for the responsible provision of medication for the purpose of achieving definite outcomes, which improve a patient’s quality of life. However, many medicines may actually have a deleterious effect on a patient’s self-assessed quality of life to the extent they may eventually stop taking the medicine. Indeed it is well documented that the adverse effects of AChEIs can cause frequent adverse events in the recipient. (See Table 1.1 below for the most common).

**Table 1.1: Common Gastrointestinal Adverse Effects** *

<table>
<thead>
<tr>
<th>Gastrointestinal Adverse Effects</th>
<th>Placebo n 2296</th>
<th>Donepezil n 1209</th>
<th>Galantamine n 1040</th>
<th>Rivastigmine n 1188</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nausea</td>
<td>9%</td>
<td>14%</td>
<td>24%</td>
<td>47%</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4%</td>
<td>8%</td>
<td>13%</td>
<td>31%</td>
</tr>
<tr>
<td>Diarrhoea</td>
<td>7%</td>
<td>12%</td>
<td>9%</td>
<td>19%</td>
</tr>
</tbody>
</table>

*(Adapted from Wilkinson)*

Evidence suggests that up to 25% of all people started on an AChEI in a clinical trial withdraw because of adverse effects. This could suggest that perhaps withdrawal rates due to adverse effects may be higher in a community-based setting where support facilities may be less than those offered to clinical trial participants.

Often the initial choice of an AChEI is dependent on clinician experience and individual tolerance of side effects. Donepezil is commonly prescribed first-line because of its once daily dosing profile and also its propensity to cause less gastro-intestinal side effects than the other two agents. However, there is some evidence that donepezil may have a shorter duration of effect than the other two agents and that switching to another AChEI may be beneficial in some patients. A further complication is that each of these agents has linear dose pharmacokinetics, meaning the best therapeutic effect is seen at the maximum licensed dose. This is confirmed by the numbers needed to treat falling from 13 with low dose therapy to between 3 and 7 with high dose therapy.

A local audit in 2003 highlighted that nearly 33% of patients receiving an AChEI withdrew or changed agents due to intolerable side effects. The frequency of this withdrawal was dependent on the agent initiated, occurring less frequently in those people started on donepezil. However, many people remain on the dose they can tolerate or may be withdrawn from treatment before a therapeutic dose is reached. Pre-emptive treatment of side effects in this population group seems to be uncommon due to the risk of further iatrogenic disease from another pharmacological agent being introduced.

Historically, patients with end-stage Parkinson’s disease who qualify for the prescription of apomorphine, a highly emetogenic parenteral dopamine agonist, are pre-emptively treated with domperidone (an antiemetic which does not cross the blood brain barrier). It would seem sensible that prior to initiation and at dose titration with the highly emetogenic AChEIs, that domperidone could be...
used pre-emptively to reduce nausea and vomiting. This would then allow a more rapid titration.

It has been suggested that the longer that treatment with AChEIs was delayed the less effective it became.\textsuperscript{35} Therefore once a person is diagnosed with AD, it would seem logical to titrate as rapidly as possible to the maximum tolerated therapeutic dose of the agent selected.

The results of a questionnaire aimed at assessing the depth of service provision for PWD was published in the \textit{Forget me Not 2002} report.\textsuperscript{45} The findings demonstrated an inequity of service provision throughout England and Wales, with some health authorities having well established service provision for older people with mental health problems and others having much less.\textsuperscript{45} There has since been almost a plethora of other reports documenting the same shortcomings in service provision\textsuperscript{46-50} prior to the publication of the National Dementia Strategy (NDS) in 2009.\textsuperscript{51}

An audit in 2002 investigated the prescribing and funding of AChEIs in dementia and findings demonstrated that only 76\% of the 91 prescribing advisers of health authorities in England and Wales had identified formal funding for their use.\textsuperscript{5} Since this report, the responsibility for the prescribing budget of medicines for dementia has been transferred to Primary Care Trusts (PCTs). Indeed the volume of prescribing of AChEIs has now become a Performance Indicator for Mental Health Service provision in England and Wales.\textsuperscript{52} The performance indicators suggest that the prescribing rates of these agents should increase as the identification of patients with probable AD increased.\textsuperscript{52} However prescribing rates are still low with a recent study showing little change to that of 2002.\textsuperscript{53} The NDS highlighted that even in the best geographical areas of prescribing; the United Kingdom (UK) was still performing less effectively than most countries in Europe.\textsuperscript{51} The question of why these medicines are not being funded sufficiently or prescribed for appropriate people remains unclear.

In the second survey report by the Alzheimer’s Society in 2004, carers of people taking medicines for dementia were asked to describe the positive effects of these medicines on the person that they cared for. Descriptions included: “seems brighter / happier/ more aware / more active” to “calmer / less aggressive” to \textit{improved concentration / speech.}”\textsuperscript{30} That is, the end points of successful treatment in the eyes of a carer seemed at odds from those endpoints proposed by NICE as improvement in terms of increases or stability in MMSE scores.\textsuperscript{27,31}

It is therefore important to explore the perspectives of PWD and their carer’s in the use of medicines for dementia and the lived experience of response. Perhaps only PWD and their carers can describe what is important for them. Frank states “\textit{some treatment effects are known only to the patient}” and “\textit{patients provide a unique perspective on treatment effectiveness.}”\textsuperscript{54} Why is it then that NICE\textsuperscript{55} and HCPs can take such little account of patient reported outcomes?

In summary evidence suggests there may be a case for improved prescribing of AChEIs by co-prescription of preparations for gastrointestinal side effects; trying a different AChEI if the first is ineffective and making greater efforts towards equity in dementia services. In addition the differing perceptions of efficacy need to be
investigated with an aim of understanding the benefits of these medicines from the experiences of people with dementia, their carers and their families.

1.2 A Guide to the Thesis
In this chapter I have introduced a brief background to the perceived need for the research and this will be expanded in the literature review (Chapter Two). Chapter Three describes the methods and methodology used in phase one; including interpretative phenomenological analysis as the underpinning method of analyses and the use of focus group and semi-structured interview methodology. The results and discussion of phase one are outlined in Chapter Four. In Chapter Five the philosophy of using case study methodology as an approach to research in phase two is discussed and the findings are presented and discussed in Chapter Six. This is followed by Chapter Seven with an overarching discussion and conclusions of the key findings. Following this short guide to the thesis is a brief section on how researcher reflexivity will be used and presented throughout the thesis; and overall reflexivity will be summed up in Chapter Eight. Throughout this thesis an appendix will be represented by A, followed by the number of the chapter and then the number of the appendix. For example A2-1 means the first appendix of Chapter Two.

1.3 Reflexivity on Starting

“Reflection can be defined as ‘thinking about’ something after the event. Reflexivity, in contrast, involves a more immediate, dynamic and continuing self-awareness.” Linda Finlay and Brendan Gough, page xi).

I don’t completely agree with the definition above of reflection, as one can reflect in action as one is in the process of decision-making and many HCPs would be familiar with this experience; as I myself am. Reflecting on an event is something we all do; some perhaps better than others and we each have our different styles. As a pharmacist I was experienced at using reflection within my professional role and as an educator I also incorporated a reflective approach within my teaching units. This is because I strongly believe that reflection can positively impact on personal and professional growth. Reflection or reflexivity as a researcher; or the appreciation “that research is co-constituted – a joint product of the participants, researcher and their relationship” was something I was less familiar with. However, I had not been involved in qualitative research before or particularly shared meaningful life discussions with patients as part of my previous research.

My career as a pharmacist started in New Zealand (NZ) where I qualified and first worked in community pharmacy for two and a half years before heading out for the big OE (Overseas Experience). My original plan was to travel around before returning to NZ; funding this travel by working as a locum pharmacist. It was the mid 1980’s and I discovered hospital pharmacy and the new concept of clinical pharmacy and attachments to clinical teams. I was appointed Priority Care Pharmacist at the Dulwich Hospital in 1986 with responsibility for clinical input to the mental health and elderly care wards. I then moved to pharmacy lead for elderly care services at Gloucestershire Royal Hospital where I had clinical
attachments to three consultant wards and responsibility for prescribing budgets and improving patient pharmaceutical care. I also completed a Masters by Research which was a randomised controlled trial on whether medication counselling by a pharmacist improved adherence in older people. (A8-1) As part of the consent process I had to use the Abbreviated Mini Mental State Examination (AMMT) (A1-1). I was trained in the use of the AMMT and the Folstein MMSE (A1-2) as part of my ward duties by the teams’ clinical psychologist as I routinely helped to care for people with cognitive impairment and delirium.

In 1999 I became lead for Pharmacy Clinical Services at the Royal United Hospital in Bath and found myself providing services to the intensive and coronary care units as well as the mental health wards before being recruited to my current position at the University of Bath in June 2000.

I had written several educational pieces for pharmacists on the dementias and associated pharmacological treatments. (See A8-1) I had become increasingly interested in the use of medicines for dementia in practice and made contact with a local research memory clinic to see if we could undertake joint research and by June 2003 I had secured funding with a collaborant for a national survey of prescribing habits of AChEIs as part of my doctorate studies. However there were a few hiccups including a new supervisor; luckily for me with experience in qualitative research. Professor Marjorie Weiss (my new supervisor) was someone who understood my need to undertake a qualitative piece of research in pharmacy practice. After completing my Masters I was aware that although processes within the hospital changed in terms of improving information given to patients and their general practitioners after discharge; I was really unclear about the true affect it had on participants. Consequently I designed the research around an exploratory focus group study (Phase One) to gain an idea of people’s experiences of living with these medicines and then went on to design Phase Two to explore these effects in early dementia in greater depth over time.

In my thesis I use reflexive points throughout as a means of conveying what was happening to me as a researcher and how this affected progression or my attitude. As mentioned earlier, reflexivity of the entire thesis will be discussed further in Chapter Eight.
CHAPTER TWO: LITERATURE REVIEW

This chapter will introduce the background literature in dementia as it relates to this research in terms of access to treatment; assessment of response and the effects that dementia has on all those involved in the care of a person with dementia.

Overview of Search Strategy
PubMed, (the then Medline), PsycINFO, the Cochrane Data Base and Web of Science were accessed as databases throughout the period of this research; the ability to save search strategies and have regular update feeds emailed directly has been a great help. Other access to data was from the follow-up of references found in relevant articles; conference proceedings, involvement in responding to calls from the Nuffield Council on Bioethics ‘Dementia: Ethical issues’ consultation, and Transforming the Quality of Dementia Care. Also general reading updates from RSS feeds and the updating of previously written educational tools kept my knowledge and reference bank current.

2.1 An Introduction to Dementia

This section will give an overview of the current definitions of dementia; its epidemiology, diagnosis and classification as well as the wider effects not only to the individual but their carer, wider family and society. A brief overview of how societal and institutionalised ageism may affect care services in this area will also be presented.

2.1.1 Definition, Epidemiology and Symptomatology

The dementias are arguably the most insidious and cruel of all diseases, with a seemingly relentless progression from mild memory impairment through to behavioural and personality changes, to a complete inability for the individual to complete any activities of daily living or to communicate effectively within their surrounding environment.

Dementia has been described as a syndrome where there is progressive impairment in two or more areas of cognitive function (these include memory, language, visuospatial and perceptual ability, thinking and problem-solving or personality) with the result that work, social function and relationships are affected. This impairment occurs in the absence of delirium (acute confusional state) or other psychiatric disorders such as depression or schizophrenia. Dementia is generally irreversible except for a small number of so-called ‘pseudo-dementias’ (about 1% of all dementias).

The dementias are primarily a disease of the elderly, with prevalence of 2% between the ages of 65 and 69 years rising to 20% in the 85 to 89 year-old age group. The incidence is estimated at 1 new case per 100 population per year, with the prevalence being higher in men until the age of 74 years, but higher in women thereafter. In 2009, the NDS stated the number of PWD in England and Wales was 700,000 and that in 30 years this would double to 1.4 million.
Due to the heterogeneity of the disease and the areas of the brain that are affected, presenting features of dementia in individuals are many and varied, with the clinical picture affected by the individual’s pre-morbid personality. Individuals with good social skills can maintain a social façade despite gross intellectual impairment, however individuals in social isolation or with visual or hearing impairment are less likely to compensate so well. Clinical features change over the time-course of the disorder, and are often subdivided into early, mid and late symptomatology (see Table 2.1).

### 2.1.2 The Diagnosis of Dementia

Diagnosis is a complex process, generally requiring specialist knowledge and application; however the NDS highlighted that many more frontline healthcare professionals (HCPs) such as general practitioners (GPs); nurses and pharmacists could be able, with appropriate training and education, to recognise early symptoms and refer appropriately. It is estimated that there are approximately 700,000 people with a dementia but only 20-40% of these receive a formal diagnosis. The NDS highlights a 30-fold variation in practice between primary care trusts (PCTs) in the provision of services for dementia which seems to highlight a backdrop of inequity and ignorance. The following section will discuss the possible reasons for this discrepancy and poor recognition.

#### 2.1.2.1 Ageism

A difficulty in diagnosis seems to be a misunderstanding that dementia is not a normal part of ageing and that there are non-pharmacological and pharmacological options which can improve the ability of a person to live with dementia. Ageism seems to be an inherent part of our society and a study in 2009 suggested that 47% of the sampled clinicians from the British Geriatrics Society believed that the National Health Service (NHS) is “institutionally ageist” with 55% concerned about how they themselves would be treated by the NHS in the future. A spokesperson from the British Medical Association suggested that “Institutional and unconscious ageism is not just a problem for the health service but for society as a whole.” The charity Help the Aged has been campaigning for age to be included as an equality in current discrimination legislation changes. It is also a telling indictment that the abuse of older people has no underpinning legislation to support reforms in health and social care in this country.

The National Service Framework for Older People (NSFOP) published in 2001 was an attempt to overhaul the ageist attitude to patient access to health services and ensure equity. However evidence suggests that access to appropriate care is still denied many older people. Terence Blacker, a journalist, describes ageism as “our most popular prejudice” and goes on to use the results of an American study as an example of inherent ageism within the NHS.

Langa and colleagues studied 8,299 Americans and 5,276 Britons aged over 65 and found higher rates of depression and lower rates of cognitive capacity in the Britons. The authors suggest this may be due to more aggressive
treatment of cardiovascular risks in middle age Americans in comparison to Britons.  

In 2006 the Healthcare Commission reported on their evaluation of the NSFOP in terms of access to care and ageism. Their results highlighted a decline in explicit ageism in access to physical healthcare services, but not in access to mental health services.

Ageism in mental health services and in access to medicines for dementia are well documented as is the stigma of a mental illness. There have been several key reports which described the poor progress made in the provision of integrated and holistic services for older people with mental health issues such as dementia. These culminated in the publication of joint guidelines on supporting PWD and their carers in 2006. Perhaps the most important document relating to improving dementia services has been the publication of Living Well With Dementia, the National Dementia Strategy (NDS) in February 2009. (See 2.3.1 for further information).

2.1.2.2 Ageing or dementia
Ageing is thought to arise from to a complex interaction of molecular damage which eventually overwhelms the bodies defence, maintenance and repair systems. It is important to understand that age in years is a chronological marker for what is occurring at a biological and social level and there is great heterogeneity in people of any age.

It is well known that in the normal ageing process there are cognitive changes which present over time and the difficulty for frontline HCPs is understanding how these are different from those individuals presenting with a possible dementia. It has been suggested there should be a low threshold for referral to specialist services if a dementia is suspected.

2.1.2.3 Screening
It has been identified that GP’s felt they were under-skilled in recognition and management of dementia and a significant minority thought that this role was the responsibility of specialist services. It was also suggested that that older male GP’s and those with less knowledge about dementia and local services were more pessimistic about care. Furthermore when GPs perceived specialist services were absent or unresponsive, this limited the recognition of dementia and was perceived as therapeutic nihilism by those seeking services. The NDS suggests that front-line professionals such as GPs should receive better training to enable them to recognise symptoms of dementia and refer earlier.

The trend for primary care clinicians to recognise and screen for dementia has resulted in a series of new, validated measures which take less time than the MMSE (See A1-2 for a copy) or ADAS-cog scales used in research and specialist services. These include a 6-item cognitive impairment test (6CIT) the Memory Impairment Screen (MIS) the Mini-cog, the General Practitioner Assessment of Cognition, and the seven minute screening test. A review of the efficacy and quality of the MIS, Mini-Cog and GPCOG in comparison to the MMSE in 2008 found the briefer tests more appropriate and robust for routine use in general practice.
# Table 2.1: The Changing Clinical Features of Dementia

<table>
<thead>
<tr>
<th>Feature</th>
<th>Early clinical features</th>
<th>Mid stage clinical features</th>
<th>Late stage clinical features</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mood</td>
<td>• Anxious</td>
<td>• Emotions and responses to events blunted. Sudden mood changes occur, often with explosive angry outbursts with no cause.</td>
<td>• Often stuporous</td>
</tr>
<tr>
<td></td>
<td>• Irritable</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Depressed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thinking</td>
<td>• Slowed with impoverished content</td>
<td>• Syntactical errors (getting words with a sentence in the wrong order)</td>
<td>• Grossly fragmented and incoherent</td>
</tr>
<tr>
<td></td>
<td>• Concrete thinking with decreased flexibility &amp; perseveration.</td>
<td>• Nominal dysphasia (impaired content, order and/or understanding of speech)</td>
<td>• Speech often meaningless, unintelligible or the patient is mute</td>
</tr>
<tr>
<td></td>
<td>• Impaired judgement</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• False ideas, especially persecutory, gain ground easily</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Speech – searching for words</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Behaviour</td>
<td>• Disorganised, distractible, restless &amp; inappropriate.</td>
<td>• Self neglect</td>
<td>• Disorientated</td>
</tr>
<tr>
<td></td>
<td>• Loss of interest &amp; initiative</td>
<td>• Neglect of social conventions</td>
<td>• Incoherent</td>
</tr>
<tr>
<td></td>
<td>• Personality changes – neurotic traits exaggerated</td>
<td>• Behaviour often aimless, with stereotypes and mannerisms occurring.</td>
<td>• Double incontinence</td>
</tr>
<tr>
<td></td>
<td>• Hallucinations or delusions common</td>
<td>• Wandering</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Antisocial behaviours</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>• including sexual disinhibition and shoplifting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cognitive function</td>
<td>• Impaired memory</td>
<td>• Impaired attention</td>
<td>• Disorientation in time, place and person</td>
</tr>
<tr>
<td></td>
<td>• Difficulty in new learning</td>
<td>• Impaired concentration</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Memory loss for recent events rather than remote. Excuses or confabulation.</td>
<td>• Disorientation in time</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.1.2.4 Diagnosis of dementia
The most important part of the diagnostic procedure seems to be an accurate and detailed history, paying particular attention to cognitive functioning as well as physical and neurological symptoms. A key part of this diagnostic process is information gained from informants (i.e. the individuals’ carer or family) who may be able to give more explicit details of symptom onset. In essence it remains a process of exclusion so that potentially remediable conditions can be identified and treated if appropriate.

In general practice it has been estimated that it takes a person 18 months to present to their GP after first experiencing a related symptom and a further 18 months for the requisite tests to be completed and a diagnosis of dementia made. An educational software intervention aimed at improving ‘diagnostic and management thinking’ has been developed and distributed to every general practice in England and has been incorporated into the general practice clinical software tool EMIS. It is unclear whether there is ongoing support for this intervention and/or the effect it is having on diagnostic rates.

An early diagnosis allows people to receive supporting information; and access to appropriate care services and pharmacological and non-pharmacological treatments. Another important reason for early diagnosis is the ability for individuals to initiate Advanced Directives and Lasting Power of Attorneys to guide future care needs. The Royal College of Physicians has suggested that GPs discuss advance planning with their patients at each annual review to ensure preferences are known.

2.1.3 Classification of the dementias
The aim of an early diagnosis is not only to identify possible remedial causes but also to classify the type of dementia and its severity. The actual diagnosis is dependent on key features of a particular dementia being present and the severity rated by the MMSE, which is scored out of a possible 30 points (A1-2). It has been suggested that a score ≥27 equates to normal cognition; between 25 to 27 associated with mild cognitive impairment (MCI); between 20 and 25 mild dementia, between 10 and 20 moderate dementia and less than 10 severe dementia.

AD is the most common form of dementia with some sources stating it accounts for about two-thirds of all cases of dementia. However Burns and Iliffe propose it accounts for 50% of cases, with vascular dementia (VaD) accounting for a further 25%. The authors propose that included within these two categories 25% will have a mixed AD and VaD picture; dementia with Lewy bodies (DLB) accounts for 15% of all diagnoses and all other dementias account for the rest.

2.1.3.1 Mild Cognitive Impairment
Mild cognitive impairment (MCI) may or may not progress to a dementia; recent findings suggest that individual’s with predominantly memory problems (amnestic MCI) on presentation will. It has been proposed that the prodromal period of AD is typically a 9-year decline in cognitive function, and part of that decline may possibly include a diagnosis of amnestic MCI. It is unknown
whether taking active steps to reduce personal risk factors for dementia will affect this progression.

None of the three AChEIs are licensed for the symptomatic treatment of MCI or now recommended for mild AD, which means there is currently no pharmacological treatment to offer until a person is in the moderate stages of AD. (See 2.1.4)

### 2.1.3.2 Alzheimer's Disease
AD, which includes an early onset and a late onset variant, was first described by Dr Lois Alzheimer in 1917. Key features include an insidious onset of symptoms (predominantly memory loss in the early stages) and emergence of aphasia and agnosia (failure of recognition).

Established risk factors include increasing age and family history, depression (although it has been proposed that depression may be part of the prodromal period), cardiovascular risk factors and low mental and physical activity as well as a specific apolipoprotein E4 status and genetic risk factors.

The pathophysiology of AD is associated with an excess of intracellular neurofibrillary tangles (NFTs) and extracellular β-amyloid plaques. NFTs occur as a normal process of ageing, but have greater formation and deposition in AD. These depositions are thought to be responsible for the dramatic loss in cholinergic neurones, which result in reductions in neurotransmitters; mainly acetylcholine and enzymes such as choline acetyltransferase (CAT).

The cholinergic system is critical to normal memory and other cognitive functions. In AD there is selective loss of cells in the basal forebrain. These cells produce acetylcholine (ACh) and project diffusely into the hippocampus, basal nucleus of Meynert and the entorhinal cortex. The depletion of neurons in this area correlates with memory and cognitive decline in AD.

### 2.1.3.3 Vascular Dementia (VaD)
Vascular dementia (VaD) generally presents with sudden onset and the dementia follows a step-wise progression. This means there are periods of stability followed by periods of rapid decline. Generally there is a history of hypertension, stroke or transient ischaemic attack (TIA). There are focal neurological signs (which describe the physical or psychological symptoms directly related to the area of brain damage) which are absent in AD, and often emotional lability and depression. Common associated clinical features are early memory problems, apraxia, agnosia, dysarthria and dizziness. Generally insight is more preserved than in AD, but this often leads to increasing distress for the person, as they can be more aware of the prognosis of the disease. Risk factors for VaD include: family history; male gender; hypertension; history of stroke or TIA; diabetes mellitus; smoking or atrial fibrillation (AF).

A number of health policy documents propose public health education programmes aimed at improving the treatment and prevention of cardiovascular risk factors in primary care. An improvement in these...
areas may result in a decrease in the proportion of vascular dementia observed in future years. If the hypothesis of Langa and colleagues is correct, they may also help to improve the general cognitive function of older people if tighter control of vascular disease becomes more widespread.69

2.1.3.4 Dementia with Lewy bodies
Dementia with Lewy bodies (DLB) is a progressive, fluctuating dementia associated with hallucinations, periods of confusion and other psychiatric symptoms.107,108 It is also associated with early gait disturbances, extrapyramidal features such as rigidity, bradykinesia, tremor and fixed posture (signs of parkinsonism).107,108 Sufferers demonstrate an extreme sensitivity to the extrapyramidal side effects of antipsychotic medication.107,108 This may be explained by deficits in nigrostriatal dopamine neurones.

DLB is characterised by the histological feature of the presence of Lewy bodies (an intracellular inclusion of a round hyaline mass) in the cerebral cortex and substantia nigra and a disorder of alpha-synuclein metabolism.107-109 Senile plaques may also be present, but NFTs are absent. Lewy bodies are also found in the post-mortem brains of people with Parkinson’s disease (PD), Pick’s disease and Huntington’s chorea. However, in people with PD without dementia, Lewy bodies are predominantly found in the subcortical regions and the loss of choline acetyltransferase (CAT) in the cortex is modest.107-109 In PD with dementia (PDD), Lewy bodies are present in the cortex and there is pronounced loss of CAT.109 There has been some controversy about the diagnosis of LBD and the overlap it has with PDD, and this is now linked to the timing of the appearance of a dementia syndrome in relation to symptoms of PD.109

2.1.4 Medicines for Dementia
Medicines for dementia are enshrouded in controversy, mainly related to their perceived lack of cost-effectiveness by NICE31 even though clinical effectiveness has been well established.9-12,27,31,110,111 This section will briefly describe the medicines licensed for dementia in the United Kingdom and mentioned within the study findings.

2.1.4.1 The Acetylcholinesterase Inhibitors
These agents are licensed for the symptomatic treatment of mild to moderate AD and exert their pharmacological activity by inhibiting the enzyme acetylcholinesterase (AChE) to increase the concentration of acetylcholine (ACh) at sites of neurotransmission.1-3 Galantamine also enhances the action of ACh on nicotinic receptors.3 Although these agents belong to the same group they all produce their pharmacological effect in a slightly different way, so if a response to one agent is not seen, it is justifiable to try another.38-41

Anecdotal clinical evidence suggests that approximately one-third of people treated respond well; another one-third respond to a degree and the remaining third seem to have no discernible response. However evidence shows that stopping AChEIs can result in decline in individual functioning and behaviour, even in areas where the medicine was not thought to be affecting.111,112
The associated common side effect profiles of AChEIs have been illustrated previously in Figure 1.1 and care needs to be taken when prescribing with concomitant illness such as bradycardia or atrial fibrillation. The individual Summary of Product Characteristics should always be consulted prior to prescribing.1-3

**Donepezil**

Donepezil (Aricept®) is once daily dosing with only two licensed dose increments (5 and 10mg).1 This makes it an ideal choice for someone who lives on their own or when a complex titration process may not be appropriate. It has a half life of 70 to 80 hours meaning that a therapeutic level can be reached in about 350 hours (14 days and 14 hours).1 Clinical response can take longer than this and for some people improvement continues or is maintained over many years.1 Further improvements can also be seen by increasing the dose to 10mg if tolerated.1

**Galantamine**

Galantamine (Reminyl®) is available as twice daily or a long acting once daily preparation, both of which require titration to achieve maximal clinical benefit.3 The half life of regular galantamine is 7 to 8 hours so theoretically effective serum levels can be reached at about 40 hours.3 However increased clinical benefit is seen at higher doses of 8 to 12mg twice daily (although actual dosing may start at 4mg twice daily).3 The long acting form of galantamine (available in 8mg, 12mg and 24mg strengths) has a half life of 8 to 10 hours which theoretically means that therapeutic levels are achieved at about 50 hours.3 However the Summary of Product Characteristics indicates that the plasma level is not linked to the level of clinical benefits or side effect profile so increased dose titration should occur until maximum benefit is reached at the maximum tolerated dose.3,27

Because donepezil and galantamine can be administered as once daily preparations, findings from the AHEAD study demonstrated that these agents reduced the overall management costs of AD.113 The authors went on to postulate that it seemed galantamine had a greater cognitive affect than donepezil which delayed admission to full-time care services.113 However there are no head-to-head trials which compare all three agents within the same study so these results need to be interpreted with caution.113,114

**Rivastigmine**

Rivastigmine (Exelon®) has a twice daily dosing regimen, with a dose range of 1.5mg to 6mg twice daily; or a 24-hour transdermal patch (maximum 9.5mg/24 hours) again with the proviso that the maximum tolerated dose should be aimed for to achieve maximum clinical benefit.2,27 Its half life is between 1 and 2 hours (meaning steady state will be reached in about 10 hours) but with an enzyme inhibitory response duration of 9 hours.2,27 Rivastigmine is also licensed for the treatment of mild to moderate symptoms of PDD.2,27

**Choice of Agent**

Key considerations are patient factors such as concomitant illness or gastrointestinal sensitivities which may preclude a certain agent. For example these agents can worsen respiratory problems such as chronic obstructive
airways disease or asthma, but if thought appropriate a trial with a short acting agent such as rivastigmine could be an option. Increasing evidence is accruing for the use of the AChEIs in the management of behavioural and psychological symptoms associated with dementia as a safer alternative to antipsychotics.\textsuperscript{110,115-117}

2.1.4.2 Memantine: a N-Methyl D-Aspartate (NMDA) Receptor Antagonist

Memantine was the first NMDA-receptor antagonist to be licensed in the United Kingdom (September 2002) for treatment of moderately severe to severe AD.\textsuperscript{4} NMDA is involved in the regulation of glutamergic transmission. An excess of glutamate causes overstimulation of NMDA receptors which allows free-flow of calcium into the cell.\textsuperscript{4,118} Sustained levels of excess glutamate lead to a chronic overexposure of calcium, which in turn leads to cell degeneration and ultimately cell death. Memantine binds to NMDA receptors to block the glutamate-gated receptor channels.\textsuperscript{4,118} It allows the physiological activation of the receptors (which are involved in memory formation) but it blocks the pathological activation (which is involved in cell degeneration).\textsuperscript{4,118}

Memantines may cause significant improvements in cognitive function, behavioural disturbance\textsuperscript{118-120} and global outcomes.\textsuperscript{110,118} A Cochrane review\textsuperscript{118} highlighted its possible usefulness in treating VaD, mixed dementias and AD with increased efficacy and safety demonstrated when used concomitantly with AChEIs.\textsuperscript{121}

Dosing starts at 5mg once daily increasing to a maximum of 10mg twice daily, but is reduced in moderate renal impairment. The main side effects are hallucinations (5\% versus 2.1\% in placebo); confusion (1.3\% versus 0.3\%); dizziness (5\% versus 2.8\%); headache (5\% versus 3.1\%) and tiredness (1\% versus 0.3\%).\textsuperscript{4}

2.1.5 Monitoring Response

There are two types of scales used to monitor response to treatment, subjective and objective. Subjective responses are those outcomes that are reported as being important to the individual receiving or the clinician monitoring treatment; whereas objective responses are those which are measured using validated rating scales such as the MMSE.\textsuperscript{(A1-2)}

The Folstein MMSE was designed by Marshall Folstein in the early 1970’s as a ‘mini’ or quick tool to assess “cognitive mental status.”\textsuperscript{81} It was designed to concentrate only on cognition and not to take account of “mood, abnormal mental experiences and the form of thinking.”\textsuperscript{81} The MMSE is a two part scale consisting of eleven questions which cover orientation, memory, attention, the ability to follow verbal and written commands, write a sentence and copy a drawing.\textsuperscript{81} (See A1-2) The original validation process was completed with a total of 206 people including 38 people with dementia; 63 normal subjects and the remaining with some form of affective disorder, personality disorder or schizophrenia.\textsuperscript{81} The scores demonstrated segregation at <20/30 for those people with dementia, delirium, schizophrenia or affective disorder.\textsuperscript{81} The authors recognised that people
with impaired vision were disadvantaged and the tool was not diagnostic but one which rated changes in cognition over time. 81 These limitations in practical application of the MMSE were supported by a review of its use in practice in 1992.112 A statistically significant correlation between the MMSE and ADAS-cog in term of assessment of severity of dementia was demonstrated by Doraiswamy and colleagues in 1997. 113

The limitations of the MMSE are well documented122,123 including: environment, people with high or low levels of education/intellect, income, race/ethnicity, age and gender.124-128 The incidence of false negative and positives when the MMSE has been used as either a screening or diagnostic tool in primary care has been reported as high by some researchers127,128 yet a meta-analysis on the accuracy of the MMSE suggested the MMSE achieved less than 3 false negatives in every 100 screened.129

For people of previously low intellect it is an inadequate reflection of cognitive status as individuals may end up with a score that reflects mild or even moderate dementia because they had never known the information.126 Interestingly the use of the MMSE in people of low intelligence was ruled as discriminatory in England and Wales and not to be used as a basis for the prescribing of medicines for dementia.126 It is unclear why its use in people of high intellect is still countenanced when it can give false negatives also.124-128

When the relationship between the MMSE, a person’s quality of life (QoL) and their instrumental activities of daily living (IADL) were explored the authors found no significant relationship between cognitive or psychological function and social relationships.130 Perhaps these also support the MMSE’s inability to successfully monitor changes in softer outcomes such as improved behaviours, initiative and sociability.

In spite of the above limitations the MMSE continues to be chosen by NICE as the validated tool to classify severity and monitor response to treatment.27,31

2.2 The Effect of Dementia on Individuals
This section will briefly discuss the known effects of living with dementia on people with the disease and those that care for them.

2.2.1 Perception of Self
Historically there has not been a great deal of research into the experience of dementia from the point of view of the individual with dementia. However this is changing with a research emphasis on how the individual perceives the effect of dementia on relationships,131-133 on awareness of dementia as an illness134,135 acceptance of dementia136 and sense of self or personhood.134,137-141 Li and Orleans suggest that because of the current biomedical viewpoint of dementia as a disease “characterised by losses, inabilities and deterioration we lose sight of the concept that the individual is still a person.” 141 The authors also suggest that “respect for persons is predicated upon seeing individual’ as rational, self-motivated and self-aware.”141 Perhaps this is the reason that patient reported outcomes (PROs) are not routinely sought in PWD as there is an inherent disrespect for the person with dementia.
Findings from qualitative carer research suggests that for carers their biggest distress is the person they care for is no longer themself; their self has changed in someway in which they no longer recognise.\textsuperscript{131,141,142}

What is ‘self’ and is it really different in PWD or are they just adjusting to being themselves but different?\textsuperscript{142} Basting\textsuperscript{143} describes this process of adjusting to living with the symptoms of dementia as “a self in transition” and this sense of continually adjusting and re-adjusting of self in reaction to dementia has been described by others.\textsuperscript{132,136,142} For people learning to live with chronic illness there needs to be acceptance at a physical level but also in terms of their own self identity.\textsuperscript{135} Western culture places a great deal of importance on intellect and memory; almost to the point that without complete memory you can no longer be a person.\textsuperscript{141} This seems to be a very inhumane stance. Memories are shared and interwoven and bind people together in someway but not remembering does not make an individual a non-person. Li and Orleans argue that by appreciating PWD for the things they still are rather than what they once were can enable and empower a more harmonious relationship.\textsuperscript{141}

2.2.2 Behavioural Changes

Behavioural changes in dementia are very common with up to 90% of individuals displaying these in such a way as to cause distress and concern for their carer and family.\textsuperscript{119,144,145} Jost and Grossberg tabulated the evolution of these behaviours in 1996 in terms of their appearance (in months) prior to a diagnosis of AD being made.\textsuperscript{146} First to appear at about 34 months prior to diagnosis was social withdrawal, followed by suicidal ideation and depression at about 25 months; then paranoia (about 16 months), followed by disturbances in diurnal rhythm and anxiety (at 5 to 7 months) with accusatory behaviour and mood changes occurring about the time of diagnosis.\textsuperscript{146}

From this we could surmise that a person living with dementia makes both behavioural and psychological adaptations in response to lived changes within that disease. It has been postulated that perhaps behavioural and psychological symptoms of dementia (BPSD) are a direct response of the individual trying to reconstruct their own sense of self within a neurodegenerative process.\textsuperscript{147,148} It has also been suggested that unresolved and unremembered traumatic events from the past contribute to expressed aggression and agitation in PWD.\textsuperscript{149,150} Evidence suggests that PWD rely more on non-verbal methods of communication as their verbal skills reduce and carers need to be aware of this to help PWD to express themselves more completely.\textsuperscript{151}

Behavioural changes are well known to increase carer stress and carer burden and are the prime factor for early institutionalisation.\textsuperscript{49-51,61,119,144,145} Historically BPSD have been treated routinely with antipsychotics even though these are not licensed; there is little evidence of efficacy\textsuperscript{97,119,152} and an associated increase in morbidity and mortality.\textsuperscript{153,154} In 1999 the Ombudsman Reconciliation Act (OBRA) legislation in America\textsuperscript{155} made it illegal to prescribe antipsychotics to older people without informed consent, but practice continued in this country. In March 2004, the then Committee of Safety of Medicines (CSM); issued advice on the use of atypical antipsychotics in PWD in
England.\textsuperscript{156} This was followed by professional guidance on the risks of cerebrovascular and cardiovascular complications with the prescribing of risperidone and olanzapine for the treatment of BPSD.\textsuperscript{157} Since then many studies have outlined the increased risk of morbidity and mortality of typical and atypical antipsychotics when used to treat BPSD.\textsuperscript{158-162} However the practice continues perhaps as a response to poorly trained and/or low staffing levels which contribute to a less than patient-centred approach to care.\textsuperscript{164}

2.2.3 Effect on Carers and Families of Dementia

As previously mentioned dementia can have catastrophic effects on carers and family as each adjusts to their individual perception of what is happening.\textsuperscript{165} It has been suggested that perhaps carers’ biggest distress is when the person they care for is no longer themself; that is their self has changed in someway in which they no longer recognise.\textsuperscript{131,141,142}

In this section early theoretical models which outline the possible causes of carer stress and carer burden will be discussed briefly. Later research exploring how couples make sense of the illness and learn to cope and live with it will also be considered.

Caring becomes a full-time job which includes supervision and changes in autonomy and relationship with the person with dementia.\textsuperscript{143} Changing spousal relationships as a result of living with a person with dementia mean a renegotiation of the whole relationship including roles, authority and autonomy.\textsuperscript{166-169} The quality of the pre-care giving relationship seems important in how well adjustments are made in response to the changing roles.\textsuperscript{167,168} These changing roles may cause difficulties in coping which can be exacerbated by poor knowledge or understanding of dementia.\textsuperscript{167}

Pearlin et al in 1990 outlined a theoretical model of caregiver stress resulting from a number of interconnected factors that the caregiver was exposed to.\textsuperscript{170} These could be primary or secondary stressors; with primary stressors being those directly related to the care-giving process and hardship. Secondary stressors were described as those occurring outside the role of care-giver (e.g. from family or life circumstance) or psychological stress, which ultimately led to the diminishment of self-concepts. The authors described these primary stressors as:

- The ability to complete activities of daily living;
- The level of cognitive impairment, and
- The frequency of behavioural problems.\textsuperscript{170}

The full model is illustrated in the table below as it shows the interconnectedness between primary and secondary stressors and how these influenced carer outcome.\textsuperscript{170} The possible impact of ‘mediators’ or interventions for caregivers are linked to primary and secondary stressors as well as carer outcomes.\textsuperscript{170} This simple model illustrates well the complexity of the caregiving process.
Figure 2.1: Pearls' Conceptual model of Alzheimer's caregivers' stress. (Adapted from Pearl 170)
Others such as Dumarche et al reasoned that primary objective stressors then
directly presented as or led to primary subjective stressors which were:

- Role overload,
- Role captivity, and
- Relational deprivation between caregivers and care recipients as
  perceived by the care givers.  

A dementia carer’s survey published in 2008 found that the most problematic
symptoms associated with caring were the inability of PWD to complete
activities of daily living (68%) and behavioural problems (50%). As
mentioned earlier the contribution of behavioural problems to the premature
institutionalisation of PWD is well known.  
Research into
how stress affects the physical and mental health of care-givers
demonstrates the chronicity of stress is a major determinant in the
psychological morbidity of the caregiver.  

Li and Orleans proposed that due to the negative biomedical image of dementia
and dementia care which is projected to the public, carers and PWD see and
experience mainly negative aspects to living with dementia and caring for a
person with dementia. Support and/or resources offered to carers have been
proposed as key variables which decrease negative psychological stress
perceived by individual carers. These resources and support mechanisms
have been proposed by Pearlín’s model of carer stress as variables, which
mediate the stress-health relationship. That is they help to lessen some of the
care burden and associated psychosocial stresses of caring.

This is an important aspect of supporting carers as several studies suggest that
carers respond differently to the stress associated with care-giving.  
Campbell’s findings supported a multifactorial role and interdependence of
stressors and suggested that “caregiver overload, carer-patient relationship
quality, the experience of adverse life events, caregiver gender, caregivers’ level
of neuroticism, caregiver role captivity and the level of caregiver confidence
accounted for over 80% of the variance in caregiver burden.”  

Etters et al proposed that individualised multicomponent care interventions are
needed in order to ease caregiver burden of those caring for PWD. More
importantly such interventions improved health and well-being of the carer, which positively affected the health and well-being of the person with dementia
and reduced rates of institutionalisation. Aneshensel et al and McCleod et al’s findings suggest that unrelieved carer stress results in
poorer outcomes for the care-receiver (physically and mentally) and frequently
led to institutionalisation and decreased longevity of the care-
recipient. More importantly is that sustained stress and lack of understanding of how to
deal with behavioural problems in a caring role or an inability to accept an
unwanted caring role can lead to abuse of PWD and perhaps reduced
survival. It then becomes an important part of a GPs role to actively support
carers in terms of maintaining their own physical and mental health to not
only prevent further distress but also prevent harm to the person being cared for.
In 2002 Nolan et al brought together key principles needed for caregiving in dementia from Aneshensel, Pearlin and others' work\textsuperscript{187} to develop the Carers’ Assessment of Managing Index (CAMI).\textsuperscript{187} The most important aspect of this work was that the ability of the caregiver to cope and how they coped by use of their own caregiving strategies was assessed from their own perspective.\textsuperscript{187} Nolan et al’s findings suggested that coping tactics of caregivers included problem-solving; cognitive approaches to reconsider a particular scenario and strategies to minimise stress.\textsuperscript{187} Caregivers were proactive in terms of problem-solving; seeking information and valuing their own expertise in a given situation.\textsuperscript{187} Non-recognition of caregiver expertise has important consequences for service providers because if the coping strategies of the caregiver are not appropriately recognised by social and healthcare services; then inappropriate service provision may occur.\textsuperscript{187}

A systematic review by Abllit on the effect of dementia on spousal relationships showed there were 3 key factors involved in the ability to live with dementia.\textsuperscript{188} These were the way in which dementia impacted on relationship; affected the quality of the previous and present relationship and how relationships changed.\textsuperscript{188} The authors proposed a model for well-being and relationships as illustrated below. They suggest that the quality of the previous relationship will influence the ability to learn to cope with the associated effects of living with dementia which can be perceived as both negative (increased carer burden) and positive (increased intimacy and mutual well-being).\textsuperscript{188} The implications for practice are that those with previously good quality relationships will experience the caring role as less distressing and less onerous. Those with previously less positive relationships will experience high levels of distress, carer burden and resentment.\textsuperscript{188} By understanding these concepts, healthcare professionals supporting caring relationships could perhaps increase carer support and education as appropriate but be aware that all caring relationships are associated with emotional and physical exhaustion.\textsuperscript{188}

**Figure 2.2 Theoretical framework for well-being and relationships** (adapted from Abllit)\textsuperscript{186}
It then becomes an important part of a GP's role to actively support carers in terms of maintaining their own physical and mental health\textsuperscript{189,190} to not only prevent further distress but also prevent harm to the person being cared for.\textsuperscript{183}

2.3 NHS Health and Social Care for Dementia

2.3.1 Services for Dementia

It is estimated that informal carers save the UK taxpayer some £6 billion per year in terms of delayed admissions to care homes; the cost of which is equivalent to about 40% of the overall £17 billion per year spent on dementia care services.\textsuperscript{192} However, it seems that dementia care services for many are not individualised or sufficiently proactive to prevent carer distress, breakdown of the caring relationship, and/or early institutionalisation.\textsuperscript{49-51,61,119,144,145,171-177} It has been proposed for the effective delivery of mental health services that there are four key principles which should drive the intervention:

- **Positivity and inclusiveness** of the HCPs involved to enable shared decision-making with those receiving care;
- **Flexible and individualised** person-centred care provision,
- **Accessible and responsive** services which offered rapid response and an out of hours approach, and
- **Integrated and co-ordinated** services which are embedded within the mainstream service provision.\textsuperscript{192}

This review went on to report that although service interventions such as: working directly with families; educational programmes and offering breaks from caring were common; it was less common to find evidence of carer assessment and support packages; information available by telephone or computer-based packages or care services which were multi-dimensional or changed according to progression of the illness.\textsuperscript{192} Qualitative evidence suggests that carers appreciate integrated care services and proactive access to supporting information.\textsuperscript{193} The early provision of respite and day care services has long been recognised as a means of relieving carer stress and/or burden and decreasing institutionalisation by as much as 29%.\textsuperscript{193} Multidimensional psychosocial interventions aimed at PWD\textsuperscript{194-196} and their carers\textsuperscript{196-198} all demonstrate improvements in cognitive functioning, coping, and quality of life with one showing a delayed rate of institutionalisation over 5 years.\textsuperscript{196}

There has been a growth in dementia care mapping services based on the philosophy of delivering person-centred care.\textsuperscript{199-203} In AD person-centred care was first proposed by Tom Kitwood and involved seeing the person with dementia as an individual who was still able to experience life and relationships but whose personality was increasingly concealed by the disease as it progressed.\textsuperscript{199} He also proposed that person-centred care should take account of the individuals personal history and should focus on the individuals current ability to do things rather than what they could no longer do whilst supporting their individual values, beliefs and rights.\textsuperscript{199} Dementia care mapping supports
shared decision-making, preserving relationships and recognising behaviour from the perspective of the person with dementia.\textsuperscript{201,202} A cluster-randomised trial demonstrated that person-centred care and dementia care mapping both reduced agitation in PWD in residential care compared to usual care.\textsuperscript{203} This suggests that greater importance should be placed on adequately training formal and informal carers in these approaches to caring for a person with dementia.

The NDS maps out a series of proposed reforms to dementia care service provision over the next five years; with funding for the next two.\textsuperscript{51} These reforms have been seen as necessary\textsuperscript{204} and also as less than evidence-based.\textsuperscript{205} However a key proponent of the NDS from inception argues that cost savings will only be generated by spending money to improve service provision and education of HCPs and service users\textsuperscript{206} It is unclear how integrated services will arise to support the 17 objectives of the NDS\textsuperscript{51} but it is hoped that findings from the current pilot project aiming to integrate health and social care service provision in 16 sites across England may help.\textsuperscript{207} Just as important to consider is the possible impact on workforce priorities in the next 5 years as much of the NDS is based on improved educational input to those providing dementia care services.\textsuperscript{208} On a more strategic level is the need for units in dementia care to be included in all relevant undergraduate and postgraduate curricula.\textsuperscript{208}

\section*{2.3.2 Therapeutic Relationships}
Therapeutic relationships are built by on-going mutual involvement in addressing the needs of the person with an illness and using shared decision-making to arrive at a mutually acceptable treatment plan. These interactions are built on trust and mutual respect of each other’s needs. The current biomedical consultation preserves the rights and confidentiality of the individual with the medical problem, with no information being shared with others unless the patient gives explicit consent. This seems to be the root of some of the problems within consultations for PWD and their carers.\textsuperscript{209} It has been suggested that although the therapeutic relationship needs to still focus on the needs of the person with dementia, the implications of the diagnosis and associated treatment and support package needs also to include the spouse/main carer and implications for the wider family.\textsuperscript{210}

In primary care medicine there has been a move towards patient centred therapeutic relationships with a shared decision-making process. The Calgary-Cambridge approach typifies this process where the relationships are about building mutual trust and respect in order to achieve concordant outcomes in terms of therapeutic recommendations for treatment.\textsuperscript{211} As mentioned previously the more paternalistic biomedical approach may protect patient confidentiality but may actually fail both the person with dementia and their carer if a holistic and inclusive approach not fully adopted.\textsuperscript{79,80,209,210}

Evidence suggests that there is a perception of therapeutic nihilism amongst GPs and specialists involved in dementia care and that this negatively impacts on shared decision-making.\textsuperscript{79,80} A study found when psychiatrists actively ignored patient’s attempts to describe their psychotic symptoms it resulted in unsatisfactory consultation outcomes for the patient.\textsuperscript{212} This negative outcome was also proposed as the reason for lack of long-term engagement with mental
health services. Interestingly two survey studies which explored doctors' attitudes towards the meaning of good medical practice found that poor interpersonal skills were not viewed as seriously as failures in technical skills even though service user complaints were mainly based around deficiencies in poor manner and communication. As mentioned earlier, person-centred care which takes account of values and outcomes important for the person with dementia and their carer seems to be the best way forward.

2.3.2.1 The Pharmacist’s Role in Dementia Care
Pharmacists have been pronounced as the ‘medicines expert’ in a number of key health policy documents in the last 10 years, with many focussing on how pharmacists can support people with medicines. In secondary care the emphasis of pharmacist input has been one of improving the safer and more cost-effective and evidence-based use of medicines. In 2003 legislation changes allowed the advent of pharmacist supplementary prescribers and then pharmacist independent prescribers in 2006. This has been viewed as a method of improving patient access to healthcare in a more timely and effective manner allowing medical colleagues to concentrate on more complex cases. In 2004 the community pharmacy contract changed and proposed there were three levels of services for delivering medicines associated healthcare from community pharmacists. These have been described as essential services (e.g. dispensing and checking prescriptions, provision of health promotion leaflets etc); enhanced services (minor ailment schemes; smoking cessation services, physical health clinics) and advanced services (medication usage reviews or prescription interventions). Medication Usage Reviews (MURs) are a planned review of an individual’s medication regimen which assesses appropriateness, compliance issues, side effect management and other aspects such as provision of information. In 2008 the government pharmacy White Paper highlighted the success of pharmacist independent prescribers in community and primary care and also proposed that community pharmacies could become the hub of healthcare information and service provision. The report went on to suggest that pharmacists could provide vascular assessments to support the delivery of health policy aims of reducing cardiovascular disease in the UK; and perhaps incidence of VaD in the future.

With respect to dementia services the current community pharmacy contract is well placed to support the provision of medicine management services for PWD and their carers. However there is little evidence of proactive provision of medication management services for people with any mental illness in community. It is hoped that the publication of the Mental Health Pharmacy Toolkit will support service development.

2.3.3 NICE Guidance

2.3.3.1 NICE Guidance and Acetylcholinesterase Inhibitors
The original NICE guidance in 2001 supported the prescribing of AChEIs for mild to moderate stages of Alzheimer’s disease subject to limitations as follows.
- A specialist diagnosis of AD with a MMSE >12.
• The carers' views of the patient's condition are sought before and during treatment with 6-monthly follow-up. Compliance with medication is confirmed.
• The medication is only continued when further assessment shows an increase or no decrease in MMSE scores, together with improvements in behaviour and/or functioning.\textsuperscript{27}

The revision of NICE 2001 guidance was originally due in December 2003, but in 2005 there were conflicting media releases about the original guidance\textsuperscript{27} being changed.\textsuperscript{225} This was denied by NICE who then requested further evidence from pharmaceutical companies.\textsuperscript{226} However in 2006 NICE announced their decision to limit the prescribing of AChEIs for moderate AD only.\textsuperscript{227} The new economic model used quality adjusted life years (QALY) which NICE linked to improvements in MMSE and ADAC-cog scales at mild, moderate and moderately severe stages of the disease. The latter two groups demonstrated greater improvements in the rating scales and this was perceived by NICE to mean the agents were more effective in moderate and moderately severe stages.\textsuperscript{114} However there are well argued and evidenced hypotheses that current rating scales are not actually measuring what needs to be measured and that it is inappropriate to use the same scale across the continuum of dementia.\textsuperscript{228}

Further more NICE did not include any costs related to carer quality of life and perceived benefits of the medicines because “the effect of the drug would be to delay progression of the condition, in which case the carer would still be faced at some time in the future with the same difficulties caused by disease progression.” (Section 4.3.10.2 NICE HTA)\textsuperscript{31} This is not evidence-based decision-making this is a value-based judgment based on the values of the decision-makers not the people living with disease and their carers.\textsuperscript{114} Various groups responded,\textsuperscript{229} with a joint position statement from the Royal College of Psychiatry (RCPsych) Faculty of Old Age Psychiatry, RCPsych Faculty of the Psychiatry of Learning Disability and the British Geriatrics Society\textsuperscript{230} and concerned pharmaceutical companies applying for a judicial review.\textsuperscript{231} The joint position paper reminded doctors of their duties under the General Medical Council (GMC) as follows:

“... Whilst doctors have to be mindful of issues of equity and cost-effectiveness, they should also consider an individual patient's needs and the circumstances that might warrant a departure from the general policy of NICE guidance.”\textsuperscript{230}

Each published guideline from NICE contains a written disclaimer, part of which follows next:

“...The guidance does not, however, override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.”\textsuperscript{31}

This has been taken to mean that “NICE clearly therefore does not expect its guidance to override a clinician’s duty as a doctor.”\textsuperscript{230}
Ultimately NICE’s decision was backed by the High Court which resulted in a warning that the decision had created “new ethical dilemmas about allocation of scarce resources” for older people and that “prescribing drugs according to cost effectiveness may be the opposite of the rights based approach.” Due to increasing use of NICE guidance worldwide the 2006 revision has provoked widespread debate. It has been suggested that NICE was “failing to take patients’ opinions into consideration when rationing healthcare interventions” and that these should be considered as part of the appraisal mechanism.

Interestingly economic analyses of AChEIs by others have demonstrated economic benefit for PWD, their carers and wider society and reduced time to institutionalisation especially for galantamine. Consequent to this controversy prescribing rates of medicines for dementia in the United Kingdom remain low, in fact in the lowest quartile of prescribing in Europe. A survey in2003 demonstrated the main reason these agents were not prescribed was due to lack of funding from health authorities. An audit of prescribing rates in the north-west of England in 2006 demonstrated lower than expected rates of prescribing from known prevalence rates perhaps related to poor funding and poor access by ethnic minorities.

2.3.3.2 NICE and the Prescribing of Memantine

The prescribing of memantine was not considered in NICE 2001 guidelines and in the 2006 guidelines it made a statement that memantine should only be prescribed in moderately severe to severe disease within the confines of a well designed clinical trial. This caused controversy as the clinical effectiveness of memantine had been well established Positive cost benefits have been demonstrated using a resource utilisation in dementia scale and adaptations of a Markov model. The potential use of memantine as an ‘add-on’ agent to AChEI prescribing to improve cognitive function and activities of daily living had also been demonstrated. This was seen as a missed opportunity for clinicians to help stabilise people in the moderately severe to severe stage of the disease and help reduce carer burden.

NICE however, did not make a ruling on prescribing in mild or moderate dementia, whilst giving audit criteria that 100% of people should be offered a treatment for moderate dementia if appropriate. The side effect profile of AChEIs can exclude many people from receiving these medicines and clinicians were advised that memantine could be an alternative choice for select patients. There is now increasing evidence that memantine is safer and more effective to use to treat aggression and agitation in people with AD than antipsychotics.

2.3.4 Perceptions Of Response To Treatment

Results from randomised controlled trials suggest benefits of AChEIs over a wide range of reported outcomes such as mood, cognitive function, activities of daily living and behavioural symptoms Supporting this is increasing evidence that treatment effects seem small but are consistent over time. Other authors suggested that even though measured responses were statistically significant their translation into meaning in actual clinical
practice was difficult and therefore the place of these medicines in therapy should be reviewed.  

The findings of the Alzheimer’s Society Report in 2004 suggested that carers used descriptors such as: “seems brighter / happier/ more aware / more active” to “calmer / less aggressive” to improved concentration / speech” rather than specific responses such as memory or cognitive improvement. It has been suggested that the outcomes used in randomised controlled trials were a requirement of statutory organisations for licensing of the medication rather than measurement of the effect of treatment on day-to-day functioning. Since 2000 there have been suggestions that current measures are not addressing the outcomes important for PWD and their carers. More globally in terms of treatment for older people, it has been suggested that PWD and carers wanted more individualised goals but physicians wanted more distant, policy-oriented goals. A further suggestion has been that the assessment of treatment benefits in randomised controlled trials should include both clinical data and patient-based measures in terms of benefits and outcomes.

There has been little qualitative research with people with dementia and their carers specifically about the effects of medicines for dementia on day-to-day experiences within relationship. Some prescribers’ of these medicines had previously voiced concerns about the ethical issues associated with prescribing such as: whether they issued false hope to those that cared for PWD and whether the regained insight by PWD was detrimental to their well-being. An interview study of 12 carers by Huizing et al found that all participants felt a delay in the decline of cognitive function was beneficial; however those who cared for a person who experienced side effects of the medication felt these problems enhanced the time needed for caring.

Another study by Traynor and Derring endeavoured through consensus agreement between people who took medicines for dementia and their carers and prescribers to develop a series of statements, which could be used to assess effectiveness of treatment. Problems arose when clinicians rated improvements differently from people who took the medicines and those that cared for them. This discrepancy has been noted in other studies and it raises the need for greater research for outcome assessments for treatment in dementia which satisfy criterion from PWD, their carers and prescribers.

In 2001 Rockwood called for prescribers monitoring the effects of medicines for dementia to use the Clinician Interview-Based Impression of Change - Plus Carer Input (CIBIC-Plus) and annotate rigorously the positive changes reported by PWD and their carer’s on the CIBIC-Plus. Rockwood reasoned that clinicians’ narrative could form the basis of “widespread, systematic qualitative studies” to provide greater insight into the treatment effects of medicines for dementia and perhaps also illuminate the ‘clinical meaningfulness’ of these effects for clinicians. Although Rockwood continues to explore treatment effects which are meaningful to PWD and their carers these studies are not qualitative in design or analyses.
2.3.4.1 Predicting response
There seems to be no consensus of predicting which individuals may respond better to AChEIs. An Italian study measured the short latency afferent inhibition (SAI) as a means of predicting response to AChEIs.²⁵⁴ Findings suggested that if individuals with an abnormal baseline measure were given a single dose of rivastigmine and their SAI level improved then these individuals did better on rivastigmine than those with a normal SAI on baseline.²⁵⁴ A retrospective study over 4 years demonstrated that people with LBD or PDD did better on AChEIs than other diagnoses including AD.²⁵⁵ Interestingly they also found that people with mild dementia had a ‘cognitive’ response (as measured by a 2 point improvement on the MMSE) but not a ‘clinical’ response (defined as “those patients in whom the prescribing clinician decided that their response at reassessment was sufficient to recommend the GP took over prescribing.”)²⁵⁵

Treatment with AChEIs and memantine remains a controversial issue, although much of this controversy is centred on cost and conflicting opinion on what is indeed a valid response.²⁴³,²⁴⁵-²⁵⁰ It has long been established that AChEIs delay disease progress by about six months, but there is increasing evidence that some individuals may benefit for periods up to four years.²⁵⁶-²⁵⁸

Interestingly a post mortem necropsy study in 2007 has shown possible benefits at a pathophysiological level in terms of reducing the amount of beta-amyloid protein being deposited in the brains of people with a dementia.²⁵⁶ In the brains of people who had been treated with AChEIs there was a 70% reduction in parenchymal deposition of cortical β-amyloid.²⁵⁹ This implies that there is actual change at a neuronal level perhaps resulting in a neuroprotective effect of these agents in the brains of people with dementia.

In summary it is clear that the treatment and support of PWD and their carers is very complex and possibly one requiring a quantum shift of thought as to what a useful response actually is from the perspective of the person taking it and those that care for them. This may mean an acknowledgement that successful outcome criteria for PWD and their carers may be different than those of HCPs.

2.4 The Aims and Objectives
The proposed research was a two-part study, where the overall aim was to explore lay perspectives of the efficacy of medicines for dementia and how they impacted on living with a dementia.

The objectives of phase one were to explore:

1. the lay perspective of the use of these medicines in practice.
2. lay perceptions of the outcomes of medicines for dementia and their affect and effects on living with a dementia.
3. if participants perceived they were involved in decision-making and prescribing processes.
4. the experience of the provision of support and information from healthcare professionals.
The second phase was a longitudinal study designed to explore the effects of medicines on people with early dementia and their carers over time. The objectives of this part of the study were to:

1. explore lay and healthcare professional perceptions of the outcomes of medicines for dementia.
2. explore whether there was consensus on perceived efficacy over time.
3. explore perceptions on how medicines for dementia should be used in early dementia.
4. to highlight the potential role of the pharmacist in supporting medication use in people with early dementia and their carers.
5. to identify possible areas of educational need for healthcare professionals.
CHAPTER THREE: METHODOLOGY & METHODS
PHASE ONE

3.1 Introduction
The first phase of the study was designed to explore what the attitudes and
concerns of people that were taking or had taken medicines for dementia and
the carers of these people may hold about these medicines.

3.2 Aims and Objectives
This phase of the research study was designed to provide qualitative evidence
of the perceived effectiveness of medicines for dementia in a community setting
(as compared to a clinical trial setting) by the person with dementia and their
carer. The study proposed to recruit a number of local branches of the
Alzheimer’s Society from the Southwest to invite members to take part in either
a focus group or face-to-face interview to share their views and beliefs on
medicines for dementia. It was hoped results would provide valuable information
to aid in the education and training of healthcare professionals involved in the
provision of a medicine for dementia in primary care settings.

The aim of this phase of the research was to explore lay attitudes and concerns
about medicines used for dementia.

The objectives of phase one was to explore:

1. the lay perspective of the use of these medicines in practice.
2. lay perceptions of the outcomes of medicines for dementia and their
   affect and effects on living with a dementia.
3. if participants perceived they were involved in decision-making and
   prescribing processes.
4. the experience of the provision of support and information from
   healthcare professionals.

3.3 Ethical Considerations
Both people with dementia and their carers can be described as vulnerable
subjects in research, therefore multi-centred research ethics approval was
needed before the study started. Prior to this application the research protocol
had to satisfy the local University of Bath research ethics procedures for
research protocols. The study protocol was submitted to the Department of
Pharmacy and Pharmacology’s peer review process and reviewed by Dr Jenny
Scott and a photocopy of her comments can be found in Appendix A3-1. The
outline of the study was presented at the Department of Pharmacy and
Pharmacology’s Research Seminar on the 6th April 2005 and discussed at a
Carer Meeting at a local memory clinic, on the 13th June 2005. At this meeting
carers suggested that separate interviews and focus groups should be held for
the person with dementia so that shared sensitive information would not cause
upset. They also thought the person they cared for (in the early stages of
dementia) would be able to make the decision on whether to participate or not in
an interview or a focus group on their own.
An application was submitted to the Central Manchester Local Research Ethics Committee (LREC) for multi-centred approval in June 2005 and final approval was granted 15th August 2005. (A3-2) The participant information sheet, the topic guide and the consent form can be found in Appendix A3-3 to A3-5 respectively. Ethical considerations are outlined in further detail below.

### 3.3.1 Consent issues

People with mild dementia that are taking medication are often able to give informed consent. In order to be able to give informed consent the capacity of the person to do so must be assessed. Basically there are 4 main stages in assessing the capacity of a person to give informed consent these are:

1. The person must be given sufficient jargon-free information in a format which they prefer (this could mean verbal, written, or audiovisual). The information must be presented to the person in a way in which they can understand it. Often people require a verbal explanation as well as a written information leaflet.
2. The time to weigh up and consider the meaning of the information and to ask questions if appropriate
3. The ability to take any risks and/or benefits into account when making their decision,
4. Be able to convey their decision to another.  

Once a potential participant contacted the lead researcher for further information, the reason for the study was explained in further detail and what their involvement would be if they decided to take part. That is, it was explained they could either be part of a small group of people who met once only to discuss various issues about these medicines; or they could have a one-to-one interview. It was explained that if they were to get upset during the session by one of the questions, then they would be able to leave the group or stop the interview. It was also explained that the group session and/or the interview would be tape-recorded to help the researcher to gather all the information accurately.

At this stage the potential participant was asked if they could summarise the information they had received and make a decision as to whether they wished to continue or not. If the person seemed able to do this process; then this demonstrated capacity to give informed consent.  

Jan Dewing has called for a “person-centred approach” to gaining consent from PWD to ensure that each individual has the consent process tailored to their individual needs without losing the replicability of the process.  

This is emphasised by McKillop and Wilkinson who also argue that time, place of consent; the communication style and the comfort of the individual are all important factors to gaining truly informed consent at any stage of the dementia process.

### 3.3.2 Participant Emotional needs

Focus groups were to be held at the local branch meeting area and face-to-face interviews could also take place here or at the individual’s home. This was to ensure that participants felt able to make a choice about where they would feel most comfortable to take part.
Although participants freely enter their thoughts and opinions within an interview or focus group it is recognised that perhaps issues may be discussed or be reflected upon in a different way after an interaction with a researcher. This has important issues for the continued well-being of the participant so it was agreed with each branch lead if there were any incidences of emotional distress during the course of an interview or a focus group, then the following would occur:

- The interview or focus group would be suspended until the participant was able to recollect themselves
- During this time the tape recording would be stopped
- The researcher would ask about any input that was needed
- The participant could then decide whether to withdraw or continue

If a participant were to become distressed the local branch manager would be telephoned by the researcher and informed of the event. The local branch lead would then contact the participant to offer advice and support.

### 3.3.3 Researcher Safety

Participants who requested interviews took place in their own home were informed they could have a friend or relative present if they wished. This was so they would feel as relaxed as possible during the interview. As the researcher I also had to account for my safety and as such agreed to inform my supervisor of when such interviews would take place and agreed to telephone prior to entering the home and on leaving the home to ensure an audit trail was available. A designated research phone number was used on all information sent out for the study in response to a request from the MREC approval decision.

### 3.3.4 Data Protection and Confidentiality

The Data Protection Act\(^{265}\) and the NHS Confidentiality Code of Practice\(^{266}\) guided the development of the ethical approval application and the development and the design of the research in terms of patient confidentiality and the management and utilisation of all data collated. Underpinning this important legislation were the Data Protection guidelines of the University of Bath\(^{267}\) which were also followed to ensure the safety of potentially sensitive information. The written and recorded versions of the focus groups and interviews will be kept in a locked secure cupboard within the locked office of the lead researcher for a period of 10 years when they will be destroyed appropriately.

During transcribing each recording was transcribed as Focus Group (or Interview) 1 or 2 for example, as appropriate and all potentially identifiable names and places were removed in order to protect the confidentiality of the participant. However when using quotations all participants were assigned a pseudonym to protect their identity and to facilitate the narrative to depict a lived experience by real people.

All names and addresses and contact telephone numbers of participants requesting an interview at home were destroyed after each interview as were names and addresses of participants requesting a summary of key findings once these were sent. At all other times sensitive data were stored in a locked and secure environment according to data protection guidance.\(^{265,267}\) Data was
stored on and analysed on University computers and/or laptops which were password protected and kept in locked offices.  

3.4 Methodology

Qualitative methodology and methods were appropriate for this study as the aim was to explore in greater depth the way in which the medicines for dementia affected the day to day lives of people who took them and their carers, therefore quantitative methodology would be inappropriate as this would only result in numerical information.  

Linda Finlay describes the process of qualitative research as “rather like going on a journey” and it seems that this journey takes place outside of the constraints of figures and statistics and in the realm of experienced phenomena. Of course there is a multitude of methodologies under the umbrella term of ‘qualitative research’ so it became important to understand very clearly the focus of the research question.

The underlying supposition was that if we knew how these medicines could change or affect behaviours and lifestyles of both the person taking them and those caring for them then healthcare professionals may be better placed to support these people. So this was about the philosophy of phenomenology. How did taking these medicines affect day-to-day lives of each participant; how was this experienced in terms of their ability to take part in usual daily activities such as relationships or completion of tasks? These points of interest were not existential or descriptive but idiographic in that they were more about the individual participants’ physical, cognitive and affective responses. This can also be termed Interpretative Phenomenological Analysis.

Phenomenological approaches to qualitative research support the use of in-depth semi-structured interviews and focus groups as they allow the participant(s) to talk about and describe their experience in their own words and relate importance to the experience or not as relevant to themselves. These methods also allow greater insight into the phenomena being explored (medicines for dementia) and the resultant effects (phenomenon) within the relationship and their lives. In terms of a philosophical position; phenomenology is generally seen to be one of a “constructivist-interpretive paradigm”. This is because phenomenology recognises that there may be multiple meanings and that experiences and realities are all subjective (that is events are interpreted by the person experiencing them who then makes sense of them using their own experience, knowledge and life history in order to come to an understanding of what actually happened).

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>What was interesting was that as the researcher I would be going through the same process when interviewing or facilitating a focus group and listening to resultant narratives and so I needed to be aware of this double hermeneutic experience.</td>
</tr>
</tbody>
</table>
3.4.1 Methods
As mentioned earlier it had been decided that carers and PWD would be interviewed on their own or attend a separate focus groups. This was an attempt to reduce possible participant distress if sharing potentially sensitive and personal information in front of others which may have led to discord.

Point of Reflexivity
With greater than 16 years experience of working with older people and completing a Masters by Research in this population group I felt able to handle possible incidents of participants becoming upset or fractious. However, the local branch contact member would also be on standby in case a participant needed to be taken somewhere private or needed to talk to someone after an interview had finished.

3.4.1.1 Focus group methodology
Focus groups for carer participants were chosen as the original methodological basis of the study as they promote discussion and interaction on the subject of importance and allow participants to almost converse with each other as they describe their experiences and/or beliefs.277 This process is ‘naturalistic’ in that it allows participants to communicate in a more natural manner and often includes a variety of processes such as teasing; explanation; story telling and often heated debate or the sharing of personal experience.277,278

Although focus group methodology has been used for many years as a marketing tool to try and define public opinion on a specific item,277 they were originally used in the 1920’s to support the development of survey instruments.278 In the 1940’s Robert Merton’s research team implemented ‘focussed group interviews’ to explore public response to radio programmes of the day.275

Focus group methodology seemed an ideal way for participants to explore individual questions from the topic guide and share with others their own experiences and comment on and learn from those of others. This is almost like facilitating a group discussion in a semi-structured way; whilst encouraging each member of the group to express their own opinion and to steer conversation back on track if a side road is taken.

Focus groups should ideally consist of 6 to 10 participants in order to promote conversation and productive interaction, without the risk of the session becoming unmanageable if too many people speak at the same time.277 I was the group facilitator and aimed to follow the topic guide for each session (A3-4). The aim of the facilitating style was to be non-directional and to encourage participation from all members. However the order of introducing the topics was flexible in response to the dynamic interaction of the group and dependent on the narrative that the participants were following. Flexibility was needed in order to ensure that participants were not interrupted in such a manner that could impair their interaction within the focus group members.277,278
It was anticipated that each session would last approximately 40 to 60 minutes and would be recorded, with the written consent of all participants, using a cassette-type recording device with multi-directional microphone.

On the day of the focus group session, participants were asked to sign a consent form (A3-5) agreeing to take part and for the session to be recorded. Participants were reminded about the confidentiality of any personal information that was shared during the session. They were also reminded that if they became upset, they would be asked if they wished to continue or to leave the group and that during this time the recording device would be stopped. Participants were also informed that if they wished to leave during the focus group session for any reason then they were welcome to do so.

3.4.1.2 Semi-structured Interview Methodology

It was envisaged that some people taking medicines for dementia, may have insight into their disease and therefore give valuable reflection on receiving medicines for dementia. Therefore if they wished to participate in the research and were able to give informed consent they were eligible to participate. Semi-structured interview methodology was originally chosen for participants with dementia as my previous experience suggested that PWD may prefer an interview in preference to attending a focus group. This is because even in mild dementia people may have difficulty in concentrating on the conversations of greater than one person at a time. Although this approach was intuitive at the time of designing this part of the study, McKillop and Wilkinson support the reduction of background noise and the use of face-to-face interviews. However, at location 4 the participants with dementia expressed a wish to be interviewed together in the same place at their support group meeting. On reflection this seemed a reasonable request and was supported by McKillop and Hutchinson who suggest that if several people wish to be interviewed together it should be considered and should take place in a setting where they all feel safe.

Pre-study communication with local branches of the Alzheimer's Society also raised the issue that some carers were not able to drive and that they also wanted to express their viewpoints via a face-to-face interview.

As well as the above reasons, people may have personal or confidential concerns as to why they do not wish to take part in a focus group. For this reason carers and people with mild dementia who wanted to participate and who were able to give informed consent, were offered a face-to-face interview with the researcher, either at the local branch or in their own home.

The interviews were semi-structured in that although they were based on the same topic guide used for the focus group sessions (A3-4), questions would not be asked in any particular order but rather as a response to where the narrative had led from a previous question. Also depending on a participants response further questions could be asked to explore interesting responses. The interview itself was informal and the questions asked in a language that was comparable to the participant. It was intended that each interview would last 20 to 30 minutes and would be tape-recorded (with informed written consent) to ensure accuracy of any findings. It was also reiterated to potential participants
they may wish to be interviewed away from the person they cared for or correspondingly the person that cared for them.

On the day of the interview participants were assessed as for capacity to give consent. In the cases of people with dementia, this process was observed by the local branch representative or their carer. Participants able to give consent to take part in the research were asked to sign a consent form as detailed above (Appendix A3-5).

3.4.1.3 Development of the Topic Guides
The topic guide (also referred to as an interview guide) is a means of ensuring that all potential areas of interest to the aims of the research question are covered.

The Topic Guide can be found in Appendix A3-4 but ultimately aimed to explore attitudes and beliefs about:

- the efficacy of the medication
- perception of the success of treatment
- medicine management issues e.g. adverse effects, compliance, dosing or titration problems; positive and negative effects on their day-to-day life
- whether the medication taken by the person they care for effects their own day-to-day life (and in what way)
- when they feel these agents should be withdrawn
- their role in the decision-making process with the prescribing team and their perceived rights to be involved in this process
- to determine views on outcome measures to determine efficacy of treatment

3.4.2 Sampling and Recruitment
The sampling framework was determined by the desire to recruit participants who would reflect the general population living in the community of people taking medicines for dementia and those that cared for them. Rather than advertise through newspapers or via outpatient clinics it was decided to use the local branches of the Alzheimer’s Society as the sampling frame. The potential population sample were all people attending their local Alzheimer’s Society branch living in the South-West of England. The actual sample was those that agreed to take part in the study. Sample size therefore was to be determined by the recruitment procedure at participating branches.

3.4.2.1 Branch selection
Alzheimer’s Society local branches were chosen as recruitment sites as they offer support to PWD and those that care for them, and therefore would have a local membership which was likely to include carers and PWD who took medicines for dementia. As lay perspectives were the focus of the study, recruitment was not held via local memory clinics or Old Age Psychiatry organisations because there was a chance that people selected from these centres may be part of a research study where they might not know if they were taking an active medication. There was also a desire to gain a broader population than those attending a memory clinic, who may have a more severe
illness or other factors which might influence their experience of medicines used for dementia.

The details of all Alzheimer’s Society local branches in the Southwest in 2005 were obtained via the internet\textsuperscript{261} and at the time of recruitment there were ten branches with named local branch managers and a local branch office.

All branches were approached by letter describing an outline of the proposed study (Appendix A3-6). They were asked whether they would be willing support the study if felt appropriate for their local branch. This resulted in recruitment being dependent on the local branch managers’ decision. If branch managers felt able to support the study they were asked to complete and return the enclosed expression of interest form to the lead researcher.

3.4.2.2 Participant recruitment
The local branches agreeing to host the study were asked to advertise the study via a short announcement at one of their carer support days and/or placing advertising flyers on their notice board. (Appendix A3-7) For those who agreed to support the study discussions were held about the best way of notifying potential participants of the event with two local branch leads expressing the wish to contact people directly who they thought would be willing to take part in the study. This would be especially useful in identifying people with mild dementia within the local region as it was the intention to interview at least one person with dementia at each of the recruitment sites.

Local branch leads suggested they would only offer participant information to those people they thought would be suitable. (A3-3) It was decided that the participant’s General Practitioner need not be informed of their inclusion in the study as it was for a one off event and no medical information would be accessed. The information leaflet explained the study in further detail and also directed potential participants to contact the lead researcher directly if they wanted to take part and/or if they required further information. People had at least one month to decide whether or not they wanted to take part, as dates were determined in advance by the activities of the local branch.

3.4.2.3 Inclusion and Exclusion Criteria
All people who attended a participating branch of the Alzheimer’s society and were taking or who had taken a medicine for dementia and who were able to give informed consent were eligible to take part. The carers of people who were taking or who had previously taken medicines for dementia were also eligible to take part in the study. People who were unable to give informed consent were not eligible to take part in the study.

3.4.3 Data Handling
Data handling, storage and analysis was guided by the Data Protection Act\textsuperscript{262} the NHS Code of Confidentiality\textsuperscript{266} and the University of Bath’s Data Protection Policy.\textsuperscript{267}

3.4.3.1 Recording and Transcribing
Focus groups and interviews were audiotaped, with participants’ written consent and then transcribed verbatim whilst protecting confidentiality of each
participant. The recording devices used were two cassette recorders with multidirectional microphones to collect as much detail as possible.

Recorded sessions were initially transcribed by Departmental secretaries with some experience in transcribing. However, all transcriptions were checked by the researcher at least once because of the secretaries’ unfamiliarity with the research area and some of the terminology and language being used. This meant that the researcher could clarify any ambiguities and edit areas where sound quality was poor. This enabled the researcher to relive the interview or focus group experience and gain greater depth of understanding from actually listening to the tonality and expressions of the participant/s and relate this to the narrative arising from the transcription. During the transcribing process all identifying names, places and organisations were removed to ensure participant confidentiality. After transcribing, each recorded piece was converted into rich text format in order for processing by NVivo® a qualitative computer data package software system designed to facilitate data handling and analysis.

3.4.3.2 Methods for Coding and Analysis
The analysis of the transcriptions was explored using Interpretative Phenomenological Analysis (IPA). This methodological philosophy was chosen because of the nature of the relationship between the researcher and the research area. With many years of experience of working with older people and nearly 8 years in the field of dementia I needed to allow participants to tell their own story with their own words. IPA recognises that the interpretation of this could be influenced by personal and professional experience in this area. By acknowledging this potential conflict and potential for researcher bias IPA demands constant reassessment of the analytical process in relation to the experience of the individuals’ experience and not that of the researcher.

The aim of IPA is for the researcher to explore the way in which participants make sense of a life experience (i.e. receiving a medicine for dementia). An idiographic approach to analysis takes place where each interview is analysed for particular examples before moving on to categorisation. This is done several times to ensure new insights are not lost before then moving on to naming emerging theme titles. These titles should clearly illustrate the theoretical connection with the original experience. Emergent themes are then sorted into clusters and superordinate concepts. Recurrent themes, common links, patterns of experience, internal differences are then mapped and tested to create categories that transcend the individual experience and capture what it means to be engaged in taking medicines for dementia or caring for those that do.

Subsequent interview analyses builds on repeating patterns and allow emerging themes which may be divergent or convergent. This iterative and interpretative stance allows the recognition that participant accounts may be similar but different which in turn enhances the richness of the findings as the researcher returns to previously analysed transcripts and reviews these in light of new findings.

The aim of IPA has been described by the School of Psychology Birkbeck University of London as “trying to understand lived experience and with how participants themselves make sense of their own experience.” This means
that the researcher is trying to understand the meanings that those experiences may hold for the individual. This process is phenomenological because it aims to explore this understanding without producing an objective record of the event itself. It is also interpretative because as stated above, the researcher has their own conception’s through which they make sense of the world and experiences and they therefore use these concepts in an interpretative manner to explore the experiences of the participants lived experiences.²⁷³

IPA is a relatively new qualitative research philosophy which was developed specifically for the area of psychology.²⁷³,²⁷⁴ However with the emphasis of biomedical care shifting more towards patient-centred care this process lends itself to researchers in health and social care. Phenomenology originated from work by Husserl²⁷² at the start of the twentieth century, who attempted to construct a philosophical science of consciousness. His work was taking place at the same time that psychology was being founded as “the study of consciousness.”²⁷² From this early start phenomenological research has developed into a means of exploring an individuals’ experience of a phenomena in the actual context in which it occurred. This is often termed the “life world” of the individual.²⁷³

Phenomenology then became linked with the theory of interpretation or hermeneutics which allow greater exploration of an individual’s experience or life world. In the 1930’s symbolic interactionism emerged which allowed the exploration of an individual’s sense of meaning from a particular life experience to be interpreted via social engagement.²⁷²

Each transcript was coded in NVivo® using an inductive process. This means that prior to the coding process the final transcription was reread at least twice to update the setting of the participant and the interaction between the participant and the researcher.²⁷³,²⁷⁴ This allowed the coding to occur with a background understanding of the session. Then each sentence was explored for coding as appropriate. The process of analysis and coding will be described in greater depth in section 4.1.

3.5 Recruitment

This section will discuss the recruitment process of local branches of the Alzheimer’s Society in the Southwest and the resultant participating branches.

3.5.1 Recruitment of Local Alzheimer’s Society Branches

A total of ten local branches of the Alzheimer Society in the Southwest were contacted by letter and/or telephone to ascertain their interest in supporting the study. Of these there was one outright refusal; two branches who expressed an interest but were unable to support the study because of local branch re-organisation commitments; two branches who agreed to organise focus group meetings but had to cancel these due to unforeseen operational difficulties, one branch who advertised the study in their local newsletter but received no replies and four acceptances.
It became apparent throughout this phase of the study that each branch operated slightly differently in accordance with local health and service organisations in place. This also meant that there was also different service provision and information available to local branch members. Table 3.1 outlines service provision in greater detail. The effect of this on access to medicines or support services by both PWD and their carers is discussed in further detail in section 4.2. Also dependent on the local circumstances, branches were able either to assist with hosting a focus group or in contacting people thought appropriate for and/or who might be interested in participating.

3.5.1.1 Location One
This branch was very interested in supporting the study and rang as soon as they had received the letter and prior to ethics approval being obtained. This branch is set in a village in a rural part of the southwest with some interconnecting bus service; but a high reliance on personal transport. Because of this issue and in organising a focus group at the local branch, individuals wishing to participate indicated a request for a one-to-one interview to be held in their own home. Anecdotal comments from the manager of the local branch also indicated that they did not wish to talk about their views and beliefs in front of other people. Five people were identified who wished to participate in the study; four female carers and one male person with dementia.

All wished to participate in one-to-one interviews. Except for the first interview where the male participant with dementia and his carer were interviewed at the same address, in separate interviews; all other interviews occurred when the person they cared for was at a day centre.

3.5.1.2 Location Two
This branch also covered a large rural area and provided services from the nearest largest town. In the time leading up to this study the local Mental Health Trust had closed the one specialist ward at the local hospital for PWD. This included some day services. This had resulted in carers not having access to support as usual and it was not possible to organise a carer focus group meeting because there was an inability to buy in sitting services for the people that they cared for whilst they took part in a focus group. Hence this locations participant’s all opted for one-to-one interviews in their own homes, with two of the 4 participants having the person that they cared for present during the interview. These people had moderate to moderately severe dementia and sat relatively quietly during the interview process with no contribution to the interview itself. One participant had her cousin in attendance as a means of moral support. There were no people with mild dementia identified as being suitable to take part in the study at this location.

3.5.1.3 Location Three
This branch covered a large area and were keen to be involved. The branch lead supported the organisation of a carer focus group, which originally had 7 participants taking part. Unfortunately due to a number of unforeseen circumstances on the day, (illness; a fall resulting in a fracture neck of femur; a social service review and a consultant appointment) only 3 people took part on the day. The branch lead was in attendance for about 10 minutes at the start of the session as she wanted to know exactly what was going on. Participants who were unable to attend gave their permission to be contacted at home for an
interview, but due to timing only one further carer and a person with mild dementia participated in the study.

3.5.1.4 Location Four
This branch supported the organisation of a separate focus group for carers and for people with mild dementia who wanted to participate. The original focus group for carers was cancelled due to unforeseen circumstances and was rescheduled. There were 12 participants including the branch lead.
<table>
<thead>
<tr>
<th>Factor</th>
<th>Demographics</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Location One</td>
</tr>
<tr>
<td>Total population</td>
<td>157,800</td>
</tr>
<tr>
<td>Predicted Number of People with Dementia in this area</td>
<td>Don’t know</td>
</tr>
<tr>
<td>Registered Members at Local Branch</td>
<td>Carers and PWD</td>
</tr>
<tr>
<td>Main Client group e.g. all ages, &gt;65years</td>
<td>All ages are welcome but no under 65’s at present</td>
</tr>
<tr>
<td>Is there a local memory clinic?</td>
<td>Two, about 20miles apart</td>
</tr>
<tr>
<td>Is there Day Centre provision locally?</td>
<td>Three places provide 4 days per week; two places provide one day per week</td>
</tr>
<tr>
<td>Is Consultant access readily available?</td>
<td>Yes</td>
</tr>
<tr>
<td>Local services/support offered by local branch</td>
<td>Carers support group; including PWD</td>
</tr>
<tr>
<td>Local services/support offered by local MH services</td>
<td>Carers support workers attached to GP surgeries for ALL carers. Not sure but I think all are available. I am unaware of a problem now.</td>
</tr>
<tr>
<td>Local prescribing issues e.g. are all dementia medicines available or just one or two</td>
<td>Unsure</td>
</tr>
</tbody>
</table>

*Taken verbatim from responses from local branch leader*
There were 3 participants in the focus group for PWD. Each person with dementia was informed of the study by the branch lead, (with permission of their main carer) and was given the information leaflet (A3-3) to read and then discuss with her and/or their carer. Originally four PWD had indicated they would like to take part; but one had become so anxious about participating he had not slept the night before and was quite troubled. He was reassured that he didn’t have to take part and could just resume his usual activities at the group event.

3.5.1.5 Non-participating Branches
Branch 5 declined any interest in the study, with branches 6 and 8 offering to support the organisation of a focus group for carers, but due to changes in the national management of the Alzheimer’s Society branches were unable to support them to completion. Each was cancelled a few days before the event. Branch 7 placed an advertisement for the study in their local newsletter but no expressions of interest were returned and branches 9 and 10 had changes of local management which precluded their ability to take part.

3.5.2 Study Participants
In all, five PWD took part in the study; two participated in face-to-face interviews (one in location one and the second in location 3) and the remaining three took part in the focus group at location 4. The branch at location 2 was unable to identify any PWD who would be suitable for the study. The local services had recently been cut for PWD and those that cared for them so there was also difficulty in general communication with and support of these people. In total twenty-three carers of PWD participated; 9 had face-to-face interviews in their own homes and 14 took part in one of two focus groups.

The demographic details of the participants are laid out for clarity in table 3.2. Although two branch members observed sessions (location 3 and 4); their comments and details are not included in the results due to their observational role in the focus group. Where age ranges are given, these were supplied by the local branch lead for missing data.
Table 3.2: Participants in Phase One

<table>
<thead>
<tr>
<th>Location Number</th>
<th>Study Name</th>
<th>Participant Number</th>
<th>Person with Dementia</th>
<th>Carer</th>
<th>Gender</th>
<th>Age</th>
<th>Date of Session</th>
<th>Focus group</th>
<th>Interview</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Jack</td>
<td>1</td>
<td>Male</td>
<td>65</td>
<td></td>
<td></td>
<td>21.09.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ann</td>
<td>2</td>
<td>Female</td>
<td>65</td>
<td></td>
<td></td>
<td>21.09.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pat</td>
<td>3</td>
<td>Female</td>
<td>67</td>
<td></td>
<td></td>
<td>21.09.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jill</td>
<td>4</td>
<td>Female</td>
<td>80</td>
<td></td>
<td></td>
<td>22.09.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Doris</td>
<td>5</td>
<td>Female</td>
<td>72</td>
<td></td>
<td></td>
<td>22.09.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Mavis</td>
<td>6</td>
<td>Female</td>
<td>Early 70's</td>
<td>60</td>
<td></td>
<td>05.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sue</td>
<td>7</td>
<td>Female</td>
<td>mid 60's</td>
<td>74</td>
<td></td>
<td>05.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Lyn</td>
<td>8</td>
<td>Female</td>
<td>Early 80's</td>
<td>72</td>
<td></td>
<td>05.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Jenny</td>
<td>9</td>
<td>Female</td>
<td>Late 70's</td>
<td>77</td>
<td></td>
<td>05.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Jane</td>
<td>10</td>
<td>Female</td>
<td>Early 50's</td>
<td>63</td>
<td></td>
<td>12.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mary</td>
<td>11</td>
<td>Female</td>
<td>74</td>
<td></td>
<td></td>
<td>12.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Wendy</td>
<td>12</td>
<td>Female</td>
<td>78</td>
<td></td>
<td></td>
<td>12.10.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Peter</td>
<td>24</td>
<td>Male</td>
<td>60</td>
<td></td>
<td></td>
<td>04.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Thomas</td>
<td>28</td>
<td>Male</td>
<td>77</td>
<td></td>
<td></td>
<td>01.02.06</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Andrea</td>
<td>13</td>
<td>Female</td>
<td>79</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Liz</td>
<td>14</td>
<td>Female</td>
<td>79</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Bob</td>
<td>15</td>
<td>Male</td>
<td>85</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Diane</td>
<td>16</td>
<td>Female</td>
<td>80</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mandy</td>
<td>17</td>
<td>Female</td>
<td>63</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Steve</td>
<td>18</td>
<td>Male</td>
<td>86</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fred</td>
<td>19</td>
<td>Male</td>
<td>82</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sarah</td>
<td>20</td>
<td>Female</td>
<td>79</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Angela</td>
<td>21</td>
<td>Female</td>
<td>68</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Paul</td>
<td>22</td>
<td>Male</td>
<td>77</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Helen</td>
<td>23</td>
<td>Female</td>
<td>61</td>
<td></td>
<td></td>
<td>03.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Tim</td>
<td>25</td>
<td>Male</td>
<td>76</td>
<td></td>
<td></td>
<td>17.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sandy</td>
<td>26</td>
<td>Female</td>
<td>72</td>
<td></td>
<td></td>
<td>17.11.05</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Philip</td>
<td>27</td>
<td>Male</td>
<td>73</td>
<td></td>
<td></td>
<td>17.11.05</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
CHAPTER FOUR: RESULTS AND DISCUSSION PHASE ONE

This chapter will briefly explain the analytical process using Interpretative Phenomenological Analysis and then discuss key findings from phase one in each of the three identified superordinate themes.

4.1 Data Coding

After the final transcription was passed as complete by the researcher it was time to start the data analysis. Analysis started in order with the very first interview before moving on to the next transcript. The transcripts of carers and PWD were analysed separately to explore any differences in attitudes and beliefs arising from the data. Once data analysis was completed for carers and PWD, superordinate themes were compared and interrogated across both groups.

The process was methodical and time consuming. The first interview was read through twice by the researcher prior to starting any analytical process. Then it was read a third time and notes were made about concepts arising out of the data that seemed of interest. At all times the underlying philosophy of Interpretative Phenomenological Analysis (IPA) was referred to in order to ensure that the phenomenon being explored was being described by the researcher in terms of the effect on the life experience of the participants. By doing this it became clearer to see the actual effects of medicines for dementia on participants’ day to day lives. The transcript was read a further time and then an attempt to code these concepts into themes was made. The difficulty became actually ensuring that the theme descriptor reflected accurately the life meaning to the participant.

After the first transcript was completed the codes and themes were grouped together in historical order prior to a further arrangement under descriptive codes. Then the second transcript was analysed as above with new themes and descriptor codes being added to the master list. At the end of the final transcription analysis the master code list was arranged into descriptor code headings and themes sorted accordingly. At this point all transcripts were reviewed and re-analysed against the final master list to ensure that all relevant data was highlighted. Following this, there were five further data sorting sessions where each theme was reviewed and questioned by the researcher to ensure that it was appropriately described by the superordinate or sub-code delineator.

NVivo® was used only as a means of coding and managing thematic data. Ongoing questioning and interrogation of the data took place by the writing of each theme on a ‘post-it’ note and then placing these on large pieces of paper titled with the superordinate theme. Visual exploration allowed a greater internalisation process of the data to occur, resulting in the cross interrogation of sub-codes across each superordinate theme. Coding validation was achieved by sharing the thought processes behind the analysis and the development of the superordinate themes with a colleague,
Dr Jane Sutton, who has a wealth of experience in IPA. Further details of this process can be found in Appendix A4-1.

4.1.1 Coding for Carer Participants

There were 18 female carers and 5 male carers involved in the carer interviews or focus group sessions. (See Table 3.2 for further information). The age range was from 60 to the late 70’s. It is unclear why more female carers participated in the study, but this seemed to be a reflection of the branch membership activity in terms of gender and attendance at local meetings.

Coding for carer participants was completed separately from PWD to ensure that analysis was specific to the participant group. A total of 131 codes emerged from the data and on exploration, as described above in 4.1; data was sorted into 5 superordinate codes, each of which had sub-code analyses.

These were:
1. Carer Expertise
2. On Being a Carer
3. Living with a Degenerative Illness
4. Interaction with Healthcare Professionals
5. Trials and Tribulations of Medicines

The original coding process took place in January 2007 and due to a period of suspension from June 2007 to February 2008 required a re-analysis of the results as a means of re-familiarisation with the data. During the re-analysis I had a moment of absolute clarity of the difference between IPA and modified grounded theory (another analytical method used frequently in our department). IPA is the interpretative analysis of the phenomena being studied (in this case the experience of taking medicines for dementia or living with those that do so) that is the psychological effect on the persons self or inner world as interpreted by the researcher whilst always relating this to the narrative used. Modified grounded theory is the interpretation of themes that arise from the data but which are constructed by the researcher. Both processes are iterative and arise from the data but IPA is looking for effect of this on the lifeworld (subjective experience) of a person and how they make sense of this. It requires a subtle shift in mindset or approach by the researcher so that the results are seen as experienced by the participant not as experienced by the researcher.

The original superordinate themes for carer participants were:
1. keeping loved ones at home.
2. accessing the appropriate medication
3. diagnostic communication processes (healthcare professional consultation process)
4. access to information.
5. quality of life benefits
6. being a carer.
My original coding for the carer data really reflected my own interests as the researcher; that it was the medication and its benefits which allowed the carer to keep their loved one safe at home for as long as possible. Whereas on re-analysis the medication was still important but it was just one of the key support structures for effective care-giving to take place enabling the carer to continue living with a person with a degenerative illness and cope with being a carer. One could argue that it is the same finding; however I feel that the second re-analysis is more from the participants’ unique experiential perspective of being someone who is living with a degenerative illness and all that entails.

An overall summation of how these themes affected day-to-day lives of carers of people with dementia follows.

The over riding concern of carers seemed to be the need to find the appropriate information, medication and/or support in order to keep their loved one at home. In their role of being a carer they developed expertise in some areas but for many there was an uncertainty in how they should care for a person with a degenerative illness. This affected decision-making in many areas of caring and also highlighted areas which they had less expertise and required more information. Information seeking behaviour generally arose from a lack of proactive information given within a therapeutic relationship and this resulted in further interactions with healthcare professionals, not all with perceived acceptable outcomes. The perceived beneficial effects of the medicines for dementia on their loved one and the resultant quality of life benefits enabled them to continue living with a person with a degenerative illness and in their role of being a carer. The medicines however, were not without their own trials and tribulations as carers battled with ensuring compliance and continuation of prescriptions. Carers also needed a framework of support for caring in order to be able to continue in this role, which required further access to information and interaction with healthcare professionals.

4.1.2 Coding for People with Dementia
Of the five participants who had dementia and were taking medication for it, four were male and one female. This does not depict the prevalence of dementia where it is commonly understood to have a greater female to male ratio. A proposed reason for this is that the incidence of dementia peaks in the eighties age range, where it is more common for people to be of the female gender than male in that population group. Perhaps the findings of this study reflect the incidence of dementia in the younger age group (60 to 70’s).

The participants with dementia were all capable of giving informed consent to take part in the study but were probably all at different stages in the continuum of dementia. What was interesting about the three PWD taking part in the focus group was their narratives could be linked to supporting statements from their carers who had a separate focus group two weeks later. Tim was married to Liz; Philip was married to Mandy and Sandy was married to Paul.
Four of the five participants were cared for by their spouse in their own home and the spouse was also responsible for the day-to-day organisation of living and caring arrangements. Thomas was the only one living independently, but he also had appointments to see the nurse at the local hospital and had made contact with the local Alzheimer’s Society branch but did not regularly attend any meetings or receive support. He was quite happy with this arrangement as he felt he was coping quite well at the present time and he had many friends in the local church.

As a researcher it was interesting facilitating a focus group with people with dementia for many reasons; the first was the ability to observe how they interacted together and were able to support each other with their experiences and knowledge; the second was to note how well they could function socially and as part of a group with fairly impaired memory. They joked with each other and also explained concepts if a participant seemed to be floundering in their comprehension. It is often said that PWD who have good social skills can hide behind this façade for some time (in terms of evading recognition and diagnosis) so it was interesting to see their social communication skills. One could argue that there was less depth and breadth to their conversation but it was still enjoyed by all participants.

As mentioned previously, coding for participants with dementia was completed separately from carer participants and a total of 32 codes emerged from the data. On further interrogation, data was sorted into 5 superordinate codes, each of which had sub-code analyses.

These were:
1. Living with Dementia
2. Perceptual Processing
3. Interactions with Healthcare Professionals
4. Relationships with Close Others/Carers
5. Trials and Tribulations of Medicines.

People with dementia were able to speak about what it was like to live with dementia and how they felt this affected their relationships with close others. For some their carer was seen as the main support in day-to-day life and helped them with the interface at interactions with healthcare professionals and also to deal with the trial and tribulations of medicines. The medicines however were viewed as a very important part of their lives and some remembered distinctly the difference between their day-to-day abilities prior to and after starting them. It was interesting how people with dementia still retained their ability for perceptual processing and how this was independent of memory.
4.1.3 Cross Coding for All Participants
Some of the superordinate themes were similar for both participant groups and all superordinate themes will be discussed together as appropriate to explore the same theme from each perspective.

The final themes for carers and participants with dementia (PaWD) were as follows:

1. On Being a Carer (Carer Expertise and supporting data from PaWD)
2. Interactions with Healthcare Professionals (Carers and PaWD)
3. Living with a Degenerative Illness (Carers and PaWD, and includes Perceptual Processing and Relationships with Close Others/Carers and Trials and Tribulations of Medicines (Carers and PaWD))

The explanation or definition of each superordinate theme can be found in Appendix 4-2.

When quotes are used to describe the participant experience, their assigned pseudonym is used (see table 3.2), followed by their location. The location area will be referred to as L for location and the number of the site e.g. L1 for Location 1. If a quotation includes a question from the interviewer; this is represented by “I” for interviewer and the narrative in bold font. Phrases to aid sense of the quotation (if used) will be in non-italic font and contained inside brackets. A … indicates a section of the quote is has been deleted to aid clarity and understanding.

4.2 On Being A Carer
Being a carer seemed to involve stepping out of a usual life role and taking on a new persona. Duties and responsibilities included becoming the person who: made all the household decisions and completed many of the household tasks as well as taking on a caring role. Carers needed to learn how to access supportive mechanisms, such as service organisations, peer support groups and specialist healthcare professionals. What was more unexpected was the experience of the darker side of caring and associated emotions of recognising their inability to continue as a carer.

4.2.1 Generalities of Caring
Caring required undertaking tasks to enable routine and daily activities to be completed, helping their loved one with personal activities and taking on new relationship and supervisory roles.

4.2.1.1 The Day-to-Day Experience
Carers described a complete change in their loved ones ability to perform the most simple of tasks and how this affected their caring role.

“He doesn’t do anything for himself. Well he can eat with a spoon; he has got a special plate. He is all right still with a cup; mind you don’t fill it right up. But other than that he can’t put his shoes on or if he manages to get
his slippers on its just luck really that he has got them on the right feet. He couldn’t do his laces up or buttons, he can’t do anything. I have to take him to the toilet and he has got a catheter.” Pat, L1

Carers perceived there was a need for routine to orientate loved ones and establish a sense of normality. Many included daily walking in this routine to keep loved ones as active and fit as possible. The second carer focus group linked a change in routine to possibly worsening an already variable mood status.

Angela: “They still have bad mood swings, don’t they and days when they’re very low their memory’s worse than other days.”

Helen: “Yes, yes.”

Liz: “And if it’s out of routine then they get very agitated.”

Sarah: “(Husband)... whenever we go out anywhere, when we go home he is always very lost he never knows where he is. And he is always asking to go home.”

Carer Focus Group 2, L4

Thomas had a greater level of insight and general functioning than other participants with dementia. At the time of the interview he still travelled within Europe to visit one of his daughters and took winter sun breaks. What he showed most insight into was the maintenance of his current level of functioning and interaction was dependent on his weekly routine. His main area of cognitive loss was in short term memory; corroborated by his forgetting the interview which eventually took place on the fourth date it was arranged.

“I go out for a walk and spend a fair bit of time round at the church either doing the garden, looking after the presbytery and I go to mass one day a week and on Sunday. I realise that it’s easy to hibernate and not see anybody and once you start doing that I feel that you hesitate to go out and start not interacting with people and you’re isolated. I’m not as daft as a brush.” Thomas, L3

These changes associated with living with a person with dementia and resultant full-time caring role meant an acceptance of change in their own life circumstance. Their previous life had gone and a new life was being shaped by the changing daily demands of a degenerative illness.

“I mean your whole life revolves about caring for that person, actually you haven’t got another life at all anymore, so all you do all you think about is how that can be improved and how the person is on that day and how it worries you.” Jane, L3
There seemed to be little information available for carers on how best to support the continued integration of their loved one in daily activities and engagement with previous interests and prolonging mental stimulation. In 2003 the *Alzheimer’s Society Book of Activities* was published which may have helped many of the carers.284

### 4.2.1.2 Gender Role Changes

In the two carer focus groups there was discussion about the effect of role changes with the consensus that it was “worse for men” to be a carer than it was for women. Sue also thought it was worse “for a man to have to cope and to get a woman dressed and take her to the toilet and do all the things for her.” This is supported in the literature where males perceived daily caring activities such as washing and dressing as diminishing their wife as a female person and resulted in reduced intimacy within the relationship.131 Paul explained below his frustration at an almost complete reversal of roles.

“I mean when I was young, I was the breadwinner in our house and I used to go to work. And the wife used to do all the cleaning and all the cooking and everything, I done hardly anything. But now it’s changed; now I’m doing all the lot! Not only the cooking, I mean she can’t even make a cup of tea or do anything properly.”

Paul, L4

Ann (L1) also explained that she had “turned out to be a DIYer, shelve, cut the grass, change light bulbs, everything” kind of person but admitted that this was more to do with Jack having left-sided weakness following transient ischaemic attacks, than his dementia. Although there is a wealth of research on female aspects of caring as it is perhaps more accepted for females to have caring roles,285 there is little research on male gender role reversals in caring. Hirst has suggested that men over the age of 65 years were more likely to be caring for their spouse than were women.286 This is an interesting point because the response rates in this study do not reflect this. However research suggests that men “are often reluctant to use services”285 and other authors comment this may be related to masculinity and its negative effect on seeking help.284 They go onto to state that if men did not seek and/or use support services they would be less likely to be recruited in gender-related research (or one could argue, any research).287 It has been proposed that male carers were more likely to give up their caring roles and institutionalise their spouse due to “relational deprivation.”171 The author’s hypothesis was that men receive all of their emotional support from their wives and as the disease progressed, this integral support for their intimate relationship diminished and caused underlying feelings of deprivation within and about their relationship.171 Interestingly in this study, all male care givers had or were considering admitting their spouse to a long-term care organisation.

### 4.2.1.3 Keeping Loved Ones Safe

An observed caring role was the need to keep loved ones safe; a finding supported by Aneshensel et al who found it could also be linked to carer burden if the supervisory role was too great.177 This included trying to protect them from adverse medication effects or from getting lost in public or from admission to a nursing home. It has been suggested that 60% of all PWD
wander or “feel compelled to walk about” with 40% getting lost.\textsuperscript{288} Unfortunately wandering can also lead to disappearance of the individual and/or accidental death.\textsuperscript{289} Recently the Alzheimer’s Society, supported by the Department of Health have called for safer walking schemes for PWD which could include tagging with satellite monitoring.\textsuperscript{290} Tagging for PWD is relatively common in care home facilities\textsuperscript{291} but up until recently not used extensively in community settings. Possible tagging of PWD could enable people who get lost to be quickly found and hopefully before putting themselves at risk. However, there are several ethical issues associated with this proposal such as possible deprivation of liberty and whether this makes it easier for carers or PWD.\textsuperscript{290}

Ann (L1) had lost Jack in a strange town the previous year and described how the medication made her feel “not so worrying that I’m going to lose him.”

Due to PWD losing insight into their own safety, carers spent a lot of their time in a supervisory role. As Doris (L1) explained this could get very time consuming as “The only time I can leave him for a moment is when he’s fast asleep.” This obviously limits a carer’s ability to complete any of their own personal activities. A recent survey illustrated how the numbers of hours per day for this supervisory role increased in line with increasing severity of dementia.\textsuperscript{172}

Another concern was the adverse effects of medication; with Jill (L1) explaining that the medication used to help her husband sleep were actually dangerous because they had “such a long effect and I think it is more dangerous for him because he staggers when he gets up to go to the bathroom.” Jill had been a nurse before she retired and she knew that unsteadiness could result in a fall and possibly unnecessary admission to hospital.\textsuperscript{292} The reduction in falls experienced by older people is one of the Department of Health’s major focuses for improving long-term care outcomes for older people.\textsuperscript{66,292}

As well as keeping loved ones safe, carers needed to consider the safety of others in terms of the person with dementia continuing to drive. Tim was unusual as he was the only participant with dementia who was still driving. He never drove without his wife in case he got lost but said “If I didn’t have that thing to do, my wife wouldn’t get very far” as she didn’t drive. He thought his ability to still drive safely was because “it’s just ingrained, which I’m glad to say” from driving since he was 17 (at the time of the focus group he was 76).

“But I suppose that goes back for many many years. I’ve driven all my life. I was an instructor you know a driving instructor in the army and out in civvy street. And it just comes natural.”

Tim, L4

Some tasks which are ingrained and habitual can be retained for some time. Problems arise when the person is no longer able to recognise where they are but the actual mechanical process involved with driving may be still be being performed relatively well. There are also associated problems of an ageing driver such as delayed reaction; difficulty in assessing distance and speed and
reduced hearing and visual acuity. However Morgan proposes that older drivers may actually be safer because they take fewer chances; they drive more slowly and consider their decisions more carefully.\textsuperscript{77}

For PWD there may be major emotional attachments to driving such as independence and self-determination even in view of an increased risk of road traffic accidents. It is important that these factors are addressed within the consultation process.\textsuperscript{293-295}

But perhaps the biggest concern for nearly all carers was the need to continue to care for their loved one at home as Angela (L4), expressed as “long as possible.”

“I know I probably will need some help later on as the disease progresses but I don’t want him comatosed in the chair, not now anyway, not at the moment because he likes the garden, he likes to go for a ride in the car, he enjoys that. And while he can enjoy things like that, I want to stay here as long as we can.”

Jill, L1

Generally carers did their utmost to continue caring for the person they loved at home as long as possible. This was made possible by good supporting structures for the carer to reduce overall burden.

\textbf{4.2.1.4 Uncertainty and Decision-making in Caring}

A key theme was how carers held uncertainty about the illness and associated caring issues and this affected decision-making. Overall they were keen to do the right thing but uncertainty about past decisions persisted for many years.

Lyn didn’t see any medical clinicians (including her husband’s GP) but thought she might be able to if there was a real need. It is unclear how this lack of knowledge of key members of a healthcare team can exist and perhaps could be addressed by the carer having a written document outlining the team members, their contact details and their role.

“I haven’t sort of asked who’s on this board that meets and discusses each case. I don’t know if there are any difficulties in seeing (GP) again, you know to talk to. But I don’t think he can do anything more than any of the others.”

Lyn, L2

This uncertainty also extended to the actual diagnosis of a dementia as for some carers the signs and symptoms of dementia were noted in relation to an unrelated hospital admission. Lyn described how her husband had been hospitalised with encephalitis which seemed to be the trigger.

“I wondered if that might have been the start of it. Cos he went very peculiar as you would; you know he didn’t know where he was and couldn’t remember what he was doing in hospital. I often wonder if it’s really what they say it is, vascular dementia. That’s different from Alzheimer’s disease. We don’t know.”

Lyn, L2
This doubt and uncertainty about diagnosis was also expressed by Thomas (L3) a participant with dementia. He described himself as “just old and a bit dilapidated that’s the way I see it.”

Mostly carers’ expressed retrospective self-doubt of previous decisions and whether they still held up to scrutiny.

“Cos then I wonder you see, should I have taken him sooner? If we’d gone sooner and accepted some drugs would we have been a bit better off? I often think should I have done it sooner.” Lyn, L2

However decision-making on the behalf of others is a difficult situation to be in and clarity gained from hindsight is not something we have access to at the time of making a decision. The Alzheimer’s Society published a useful guide for all carers of PWD in 2005 which covered caring-related decisions from early to later stages of the illness.296

Pat had been asked to be involved in a decision that was unexpected and she had been less than prepared for. The local research memory clinic that her husband had attended while he was on a trial medication had telephoned to ask her if she would agree to donate his brain once he died.

“If when anything happened to (husband) if I would be prepared to let them look at his brain and then I said ‘well I didn’t really know, he can’t make the decision so it’s going to have to be up to me.’ Umm and then she was looking at her paperwork she said ‘I really shouldn’t be ringing you because he was on the placebo.’” Pat, L1

The impact of such a telephone call cannot be underestimated; firstly the call could be taken to imply her husband was going to die imminently; secondly she had been given very little information or time in order to make an informed decision; thirdly she now knew her husband had been on placebo and this may be why his condition was now so advanced and finally the caller was unprepared and if she had read the notes thoroughly prior to dialling she would have realised there was no need to call.

In summary carers and participants with dementia experienced uncertainty in their day-to-day lives and for carers this was also compounded by having to make decisions on behalf of others, which affected their own lives as well as challenged their health beliefs and ethical principles.

4.2.1.5 Information Seeking Behaviour
Carers held an individual repertoire of knowledge, which they added to and checked the validity of. This concept of carer expertise has been commented on by Nolan et al who also established that carers proactively sought information if they felt there knowledge was lacking.187 An important consideration was the content and depth of knowledge, changed from individual to individual and topic to topic; that is being knowledgeable in one area did not imply being knowledgeable in others. Because of their membership to the Alzheimer’s Society, carers were privy to sharing information and received Living with
Dementia from the Society.\textsuperscript{297} When information was not forthcoming from HCPs people accessed the following sources: libraries, the internet, newspapers, television, the Alzheimer’s Society and people in a similar situation to their own. Previous research suggests that non-sharing of or vague information was experienced as confusing and upsetting.\textsuperscript{298} It could also be suggested that this can also undermine the therapeutic relationship and creates one of co-dependency or paternalism; not one of person-centred care. Seeking information and support was perceived as ‘a battle’ or ‘struggle’ by carers.

Jane: “So you are constantly thinking ‘am I doing the right thing? Am I upsetting the person in the memory clinic because I am now seeing Dr X?’ You know nobody told me anything else so you, I feel you are constantly fighting, trying to get information. It’s just a constant struggle to do the right things”

Mary: “It’s a battle isn’t it?” Jane & Mary, L3

In general participants spoke about a lack of information at the point of prescribing which resulted in them having to actively seek out further information.

“No information at all was given when (husband) was put on to Aricept®. We had been going to the memory clinic for 3 or 4 months maybe and this particular doctor said ‘Well I think we will try him on Aricept®’ but no information about it whatsoever he just went on it, but there was a distinct improvement.” Mary, L3

Both Jack (L1) and Thomas (L3) commented that they had sufficient information on the medicines and in Jack’s case he said “I am not afraid of asking questions; from my point of view it’s necessary.” Thomas couldn’t remember anyone telling him what was wrong with him so he had to find out for himself.

“Obviously I knew they were for my brain function. Then of course you get the bit of paper in the back and I always read things like that and I look them up in the medical book.” Thomas, L3

On being recommended any new treatment, part of the decision-making process is being given sufficient information about potential risks and benefits to make an informed decision about whether to take them or not. This has been well described in the Mental Capacity Act\textsuperscript{299} and also in the NICE guidance on medication adherence.\textsuperscript{300} As carers were responsible for the compliance to medication regimens and they were making decisions on behalf of loved ones, it could be argued that they were poorly informed due to the paucity of information received. In a national survey only 50\% (n=2030) of all respondents said they received sufficient information about medicines and the disease at the time of diagnosis, a finding supported by these results.\textsuperscript{30} The variability in the provision of information even in the same location implied it would be hard to recommend a particular level or standard of information provision because the experience of participants was so different.
4.2.1.6 Sharing Information
Several interactions within focus groups illustrated that carers used local branch meetings as opportunities to share knowledge with others. In this example below, group members discussed that medicines were a help but not a cure.

Angela: “But we went on umm Exelon®, which did no good whatsoever, so we went back on that (Aricept®) and he seems to be fine. But as people are saying, he’s going down hill with certain things, so I just don’t know whether the tablets stopped working, or whether (pause) ....... if you asked him he’d say ‘oh no the tablets are working’”

Paul: “They don’t stop it though love, do they?”
Angela: “It doesn’t stop it, it slows it, (lots of agreement) so you don’t really know....”
Andrea: “What they’d be like without”
Sarah: “Yes. The trouble is once they’re stopped you would then notice a difference and quickly they go down hill. You don’t know until you stop them, do you?” (General agreement)
Angela: “They’d never recover then would they?”
Sarah: “No, no they don’t not according to research anyway. Once they go down hill they can’t put them back on them because it doesn’t bring them back up to the level they were.”

Carer Focus Group 2, L4

Evidence suggests that if a medicine for dementia is withdrawn, then the person needs to be closely monitored for the next two weeks and if signs of deterioration occur the medication is reinstated as soon as possible to halt further decline.111,112 Because the medicines act on all cholinergic functioning, it is not just memory that is affected but behaviour, activities of daily living, problem solving and communication. These positive effects are often not attributed to the medication especially if carers may be more focussed on memory or behavioural issues.

It has been identified that all carers want information on dementia, how to get help and the best way to interact with services.79 The authors recommended that the best information was related to the specific needs of the individual,79 a finding also endorsed by others.182,301 Lyn, in her early 80’s described a situation of only finding out support services were available after talking to a neighbour who had respite and sitting services. When she asked the professional involved in her care (the same professional as her neighbour) why she didn’t have these services she was told that she had never asked for them.

“I said, ‘they came after me, how come they have a good sitter and I haven’t?’ She looked me in the eye and said ‘you never asked’. So now I ask for what I want, for what I need, that’s more like it.”

Lyn, L2.
Jane and Mary spoke of their lack of knowledge of basic support service such as memory clinics or day centres and how they could access care in the first place. Not knowing the availability of services precluded people from asking for them. As mentioned above, it seemed that information was often only given in a response to a carer’s lack of ability to cope rather than in a proactive manner, which would be supportive to carer health and caring ability.

4.2.1.7 Misinformation and Bureaucracy

There were many shared experiences of carers receiving incorrect information. This resulted in loss of confidence in the HCP but also a reluctance to speak out in case they were seen to be ‘rocking the boat’ and were removed from patient lists. Most commonly carers were told that all AChEIs were the same or that memantine was the same as an AChEI. This provision of misinformation could also seriously undermine trust within a therapeutic relationship as illustrated by Mary (L3) when she said “But when I asked him about Ebixa® he told me it was the same drug (previously on Aricept®) and it isn’t. And I knew that it wasn’t.”

A continued lack of information can result in great frustration and anger for carers who described their days as being completely absorbed by caring for another and worrying continually whether they were doing the right thing.

“Why do we have to fight? I mean dementia is just, is an illness just like any other. Why do we have to fight for everything and why do we get so little information and why do GP’s really know so little about this illness, and how it affects people and carers?”

Jane, L3

Perceived misinformation or a complete lack of information received from HCPs’ forced people to access other organisations such as support groups or the internet. In this study, the internet was used by most carers and by Thomas (L3) as an information source. People with dementia often require further information as demonstrated in a study where all calls to the Alzheimer’s Society were logged to explore the nature and frequency of calls. The authors were surprised to find PWD regularly called help lines to ask for information or practical help. A large internet study in America highlighted that support seekers (carers) were the second largest group of people to access the internet for medical advice about the person they were supporting.

It seemed that relevant, individualised information presented in a suitable format and repeated at various stages throughout the illness was necessary for carers to feel they had sufficient to make informed decisions. The NDS suggests that information provided should be both verbal and written and supported by an information co-ordinator for each person so there is always an open line to relevant and timely information and support. This seems to be an imminently useful proposal if sufficient workforce resources are allocated. Most important is the need for access to specialist services at an early stage of the disease to
allow for greater planning of the inevitable with on-going access to support and information as the illness progresses. One of the problems with current access to specialist services being limited to people on a medicine for dementia is that it creates inequity, as only generalist care seems the option for many.

4.2.2 Caring: Darkness and Light
Carers recognised that they had to be aware of their own needs and develop coping strategies to support this new role. They were able to recognise when they were coping and when they needed support from the local branch, GPs, respite care and from specialist services.

4.2.2.1 Supportive Structures
What carers appreciated most was the provision of proactive support, even if as Ann (L1) shared, it was just a question from the clinician such as ‘how are you coping?’ Carers recognised when they could cope but also realised there would come a time when they might not. Some felt that the ability to cope may be age-related and although they could cope now they surmised they may not in the future.

“I mean if I was 80 it would be different you probably can’t feel like it you know? I am 67 so I still feel as though I can do what I need to do.”

Pat, L1

Peter explained that caring for someone with dementia “can be lonely, quite truthfully and I think that’s what a lot of people find.” This is often exaggerated when the person being cared for is younger because most services are aimed at the 70plus age group and the activities may not seem suitable for those people in their fifties with dementia. Peter’s wife was first diagnosed with dementia when she was 55 and they found there were few activities available for this age group and consequently had set up an informal support group called the “Half Dozen Club.” (A group of 6 younger carers and their spouses who met at each other’s houses once every month or so to share food and company).

“Especially in the early days it was a very good release valve because you’ve all got same or similar problems and it was marvellous. Ringing each other up, so on and so forth.”

Peter, L3

The participants also valued the support they received from the local branch of the Alzheimer’s Society. As Andrea opined, it was “absolutely invaluable” for both themselves and the person they cared for. At these carer support events there was the ability to spend time away from the person they cared for and also a joint refreshment event where activities were done together.

Liz: “I think this is the only thing that Tim remembers, coming here. Definitely; that this is where he comes. He loves coming here.”

Paul: “They all do don’t they?”

Polly: “(Husband) does remember every time he’s coming.”

71
Mandy: “It something they all enjoy.”

These joint sessions were enjoyed by both and allowed a semblance of normality of shared social interaction within their relationship. It is an important point that shared enjoyable activities can reduce the carer from feeling undermined as a person and undervalued within the relationship.\(^\text{131,166,167,171,177,304}\)

**Support from Family and General Practitioners**

Family was also a great support to many, with children of carers providing extra free time by having their loved one for an afternoon or evening once a week, or taking them out food shopping. Many however did not like to bother their children too much because as Mavis suggested, “they have got their own lives anyway haven’t they?”

Although it has been proposed that wider family relationships could cause conflict for the caregiver and become a secondary stressor in the care-giving process; this was not supported from the findings of this study.\(^\text{170,171}\)

Generally carers’ first point of call was their spouse’s General Practitioner (GP) who in some locations, seemed to be able to arrange support more directly than in others.

> “I went to my GP and sat down with him and said ‘Look I can’t cope any longer like this.’ He wrote a letter to the Consultant, because that’s all he can do he can’t do anything, and said ‘look this woman is at the end of her tether she is beginning to hate her husband and something needs to be done about this.’ Nothing happened. No response at all, nothing. (silence)“  

Sue L2

Other carers, like Lyn (L2), explained that although they had asked their GP for practical and medical help “letters got lost” and help was not forthcoming for over a year. Lyn expanded “I was a bit peeved by that, I couldn’t really work it out” but now “someone comes every morning to wash him and dress him.”

**Respite and Day Care**

Respite care provision was seen as a key element of support in order to give the carer a sustained break over a number of days rather than hours. This did not mean that it was without problems with many speaking of how guilty they felt sending their loved one away. As Jenny (L2) shared “I don’t like to see him go, you know. But you got to think about yourself as well.”

Frequently it took some crisis in care in order for day or respite care services to be initiated. Day care was provided according to individual needs of the carer however some carers of people with moderately severe dementia received no day care whereas other participants in the same location received up to four days a week. This discrepancy was also observed in the provision of respite care, where some received a weekend every few months, with others receiving
one or two week respite session every six week to thirteen weeks. The provision of day and respite care is dependent on local availability and individual needs; however on reflection those carers who were able to vocalise their needs seemed to have a greater influence on receiving a service.

“I think in this area we’re probably a lot luckier than a lot of areas. Some areas I know are really bad and there aren’t day care places. You get two days a week. I was lucky. (Sue received four days a week)”

Sue, L2

Sue had received the greatest amount of support in both day and respite care services prior to her husband being admitted to a care home. She was the youngest of the carers in this location and seemed to have found it more difficult than others to sustain a caring role. Other participants in the same location seemed more stoical. This difference may be due to secondary subjective pressors such that the subjective experience of caring was one of relational deprivation. As Baker and Robertson propose it may be the perception of the stress of caring rather than the amount of support that is involved which results in care-giving breakdown. Perhaps in Sue’s experience the role reversal was so great and she was receiving so little reciprocation of care and support from her husband in return for her perceived personal sacrifices as a care-giver that it became too difficult for her to sustain a caring role. This would be supported by Pearlín’s model of caregiver stress which indicates that the different characteristic backgrounds’ of carers plus their psychological response to caring are key components in the experience of carer burden and stress.

It seems services were generally only provided in response to crisis and crisis management is a poor option in the provision of quality healthcare services. Evidence suggests that crisis management leads to greater institutionalisation and greater spending on health and social care and that proactive care and holistic support can result in cost savings in the long-term.

Specialist Services
Access to memory clinics was seen as one of the greatest supports because of the expertise available and central co-ordination of support services including access to medication. As Mavis (L2) explained “they are so nice and they are so helpful and they are there, I know they are there if I need them.” Sometimes a CPN was assigned for routine monitoring of the person with dementia in their own home, which then saved arranging transport to attend assessment clinics. Some consultants were held in great regard when they provided carers with a telephone number to call if they were ever worried as illustrated by the narrative below.

“But you can ring them at anytime He said ‘you must ring at anytime if you’re worried about anything at all I’m on the end of the phone’. I mean they can’t do anything more than that really, can they?”

Angela, L4.
Unfortunately this was not common and other carers present felt deprived because they had not been offered the same sort of support. This variability in experiences of living with and caring for a person with dementia was prevalent throughout phase one findings.

4.2.3.2 The Darker Side of Caring
As previously mentioned, the caring role has more frequently been thought of as a female role, although this did not mean that it sat easier with either female or male carers. A caring role which is not asked for and is unrelenting and demanding on emotional, physical and psychological levels can seriously damage ones health.\(^\text{173-175,178-181}\) The darker side of caring was associated with the care-giver reaching the end of their resources.

**The Struggle of Caring**
This relentless nature of caring was perhaps expressed best by Jenny who at the time of the interview qualified for a respite break once every 13 weeks but had her last break cancelled due to a cut in local service provision.

> “*When they come and talk they (local social worker) say ‘we finish at 5 o’clock’. I got it 24 hours a day 7 days a week. I think they’ll probably set it up again, (the respite break) they said probably getting him in once every five or six weeks which would be better*”

Jenny, L2

This struggle was enhanced by the continual need carers had to find out more information about the care-giving structure. As discussed previously much of this information or support was not pro-actively offered and so had to be actively sought out by carers.

> “*Everyday is a struggle dealing with people with dementia and if you have to struggle with the medical profession as well to get the right medication or to at least try the medication it is just another thing that you don’t need.*”

Jane, L3

It is unsurprising that carers expressed their darker feelings within narratives; in fact one could argue it would be less healthy if they did not. Sue struggled hard to adapt to her caring role even though HCPs had intimated to her that “*others were good at caring*” which left her feeling even more inadequate.

> “*I mean I kept thinking ‘I’m a failure I’m a failure’ because I can’t do this and some people they’re good at it. There are people, and they told me, there are people that do not like doing it but are very good at nursing their partners and I’m not.*”

Sue, L3

It may be that the severity or the stage of the illness and/or the duration of the carer coping on their own affected the intensity of these feelings. Perhaps as others suggest, it is even more complex and includes prior relationship issues.\(^\text{167,170,171,177}\) For whatever reason Sue started to hate her husband and admitted this on tape (see below); hoping I think that her distress and experience would perhaps aid detection in others at an earlier stage.
“To cut a long story short he (husband) went in the next day (to a care home) and has been in ever since. I felt really really guilty for a month or so. I mean I still do now but he’s in the best place because I was beginning to hate him. Not only was I beginning to hate him, but I admit and I admit it on the tape that I had thoughts going through my mind ‘can I push this man down the stairs?’ I really couldn’t cope but nobody was helping me and there must be hundreds of people out there that are in the same situation.”

Sue, L3

The above narrative depicts just how destructive continual caring can be for some people and their relationships and of course for the person with dementia. What was interesting was that these feelings of despair and anguish were not seen in carers older than Sue, who seemed to adopt a more stoical/philosophical approach as reflected by Lyn below:

“I don’t want too much detail as long as I have the facts and know how to deal with them, that’s all. So we have a situation we can’t alter, so no good fussing about. Accepting what you have and get on with it. That’s my angle anyway.”

Lyn, L2

It was difficult to say whether these differences were related to the older age of the carers, who came from a generation with perhaps fewer expectations from life and healthcare from those ten to twenty years younger. However, secondary stressors associated with the caring process include psychological responses such as role captivity.170,171,177,188,285 Role captivity is the response to a role that was not asked for, not wanted and yet has to be done. Seen from this perspective it becomes easier to understand that even basic caring roles could seem cumbersome and onerous to a carer with such a response.

The adverse effects of a full-time caring role are well recognised and the Carers Act of 2005305 was an attempt to ensure that carers’ own needs were assessed and taken into account as part of the total care package for an individual patient. A healthier carer can support the patient longer in the community and there is then less of a financial burden placed on the wider health and social care budget.51,206 However many carers struggled to gain any support at all and the majority had not received individual care needs assessment.

4.2.3.3 Asking for Help

The perceived adverse social stigma associated with caring for PWD was raised by one carer. Fundamentally it meant admitting that the person being cared for has a problem considered to be a mental illness. Dementia has double stigma in reality as it embraces ageism and mental illness; two concepts that the NDS and memory clinics may be able to reduce by educating both the public and HCPs.51,204 This double stigma can negatively influence successful access to medical care perhaps due to the institutionalised ageism embedded within the NHS.64-68

Sue shared that it had taken her some time to realise that she needed help as she had been embarrassed and too proud to admit this to others.
“I was too proud and not only proud but embarrassed because you’ve got a husband or a husband has got a wife that’s not quite right in the head, you’re embarrassed about it and you want to hide it and you don’t want to admit to anybody that you can’t cope.”

Sue, L2

Before you can ask for support for caring duties, you first have to recognise that you are a carer and not a spouse or a child of the person being cared for. This can be a defining moment as described by Sue when she read a poster at her GP surgery which asked “Are you a carer?”

“I saw a notice (in the GP surgery) that said “are you a carer?” and it said “carers coffee evening where you can discuss your problems.” So I said to the receptionist ‘I don’t know if I’m a carer or not’ and she said ‘well what do you do?’ and I said ‘I have to look after my husband’ and so she said ‘you are a carer’ so I went to that coffee and that actually started it.”

Sue, L2

The majority of participants in this study perceived that proactive information improved coping ability and prevented a crisis in care. In 1995 it was observed that services often arrived too late to avoid carer distress and some were counter productive. In 2002 Bailey reflected that services were few and that you needed to fight for them if you were a carer, as still seems the case with these findings. The consequences of carer needs not being assessed can have major negative impact on their physical and mental health and this distress is associated with increased morbidity, mortality and rates of institutionalisation for PWD.

4.3 Interaction with Healthcare Professionals

This section describes how participants, both PWD and carers, experienced interactions with healthcare professionals (HCPs) when they sought advice and/or support. They described less than person-centred therapeutic relationships and their frustration at the complexity and duration of the diagnostic process.

4.3.1 Consultation Etiquette

Consultation etiquette is a descriptor for relationship dynamics within a consultation. Increasingly more emphasis is placed on HCPs having good communication skills to ensure satisfactory outcomes of consultations. All carers were involved in the day-to-day care of their loved one so by default were perhaps the best informed on the persons condition. However some were able to make more of a contribution than others within a consultation whereas others felt excluded. Carers often perceived their views and concerns were ignored or of no interest to the clinician, which unsurprisingly resulted in carers feeling isolated.

76
4.3.1.1 Differing Approaches
Communication within a consultation can be a very difficult process to get right, and this can be reflected in the lack of therapeutic engagement by people not establishing successful relationships with their prescriber. Compounding this perceived lack of effective communication from HCPs was the experience that it changed with individual clinicians. Within locations it was clear that carers shared their experiences of good and less effective experiences with HCPs and within each location identified the HCP with the perceived best approach. This resulted in carers switching clinicians and then becoming anxious about associated politics and possible negative outcomes for the person they cared for. More importantly it illustrated inequity and variability of resultant care offered from different HCPs and the potential for stress this had on the carer, and therefore potentially the person with dementia.

There were examples of very supportive HCPs which left some listeners feeling less satisfied with their own.

Helen: “A lot of doctors ignore us don’t they?”

Angela: “I think Dr X is, the Consultant, is very good because he does say to you ‘if you’re worried about anything at all I’m on the end of the phone. All you have to do is ring and somebody will come.’ They can’t do more than that can they?”

Paul: “No, they can’t.”

Steve: “No, but I suppose different consultants are different. We don’t ever get that. We never.”

A bit later

Steve: “Our GP is very good.”

Andrea: “So’s ours.”

Liz:” When we’ve needed help.”

Helen: “We’ve had two GP’s over the last few years and they’ve both been excellent.”  
Carer Focus Group, L4

This variability in responses from HCPs in therapeutic consultations has been commented on by others who found that people consulting a GP rated the interaction dependent on the amount of information given and the manner in which it was delivered.

4.3.1.2 Lack of Knowledge
As mentioned previously GPs were generally the first port of call for information and support in order to seek out the reason for their loved one’s behavioural changes. However there was a perceived sense that the GP lacked appropriate training and knowledge.
“I just feel the GP, if we were just in the GP’s hands we would get nothing at all because they haven’t got a clue really, what’s going on.”

Mary, L3

Depending on the setting carers were offered either no or insufficient information about medication or support services. GPs were seen as being useful for the management of other medical conditions but generally not helpful for dementia care. For those people on medicines for dementia this meant 3 to 6 monthly reviews with a specialist service and perhaps telephone contacts in case of emergency. For people who had been withdrawn from or were never suitable for medication there was no regular support offered.

“We don’t go to the memory clinic any more because when he was taken off Aricept® and I enquired about further medication and I was told no it wasn’t possible. The doctor said ‘and I shan’t need to see you any more’ and that was it, I was finished, we were finished.”

Wendy, L3

4.3.1.3 Carer Involvement

Carers perceived they had a very good idea of what was going on due to their full-time caring role. However if they felt excluded from the consultation they perceived that the clinician was getting an incomplete picture on which to base decision-making.

Mary: “Well I used to go in with him when he was having this memory test and the doctor would start off by saying ‘so how are things?’ And I mean to begin with I was saying ‘a tremendous improvement.’ But there was nothing, I don’t know he just didn’t seem terribly interested in that side of it. He seemed to be more anxious to get on with giving him the memory test again and I don’t know it was a, it was a difficult situation.”

I: “And how did that make you feel?”

Mary: “It made me feel very angry actually, yes in fact I mentioned to (branch lead) several times. I said ‘I am very, very upset with doctor … he is giving (husband) the Aricept®, but I don’t feel he is taking the interest in what is happening with (husband) since taking it.”

Mary, L3

Interestingly the experience of therapeutic relationships varied within and across locations and age groups. Carers often described situations where their thoughts and viewpoints were ignored. This finding is supported by others who described carers as feeling squeezed out of the consultation process due to the traditional medical orientation which focuses on the patient.191

Carers were asked whether they felt they had sufficient input into decision-making processes within a consultation and the majority thought they would like the chance to have more input. They viewed themselves as the expert on the
day-to-day life of the person they cared for and therefore their views should be sought and respected.

“I think that we should have a big part in the decision-making because I mean we know the person that we are caring for don’t we? And I think that we should be allowed a big decision but obviously the ultimate decision is the doctor’s of course, the medical one. But yes I think we should be given more chance of a decision than we get at the moment.”

Mary, L3

The consultation is a complex undertaking for any HCP and it requires excellent person-centred communication skills to ensure that both patient and carers’ agenda is voiced and understood. This may be very different from the agenda of the HCP who may want to complete specific tasks within the allotted timeframe. Somehow a mutually agreeable outcome needs to be negotiated within the consultation period. Interestingly a qualitative study in 2005, established that what mattered most for people with chronic mental illness in primary care consultations was not specific knowledge of an illness but the ability to communicate the following: optimism in the treatment; continuity of care and demonstration of listening skills. These are key communication skills for every HCP consultation delivering a patient-centred focus.

Other carers felt they had good relationships with HCPs and had good input into care-related decisions, as Lyn explained:

“I think I get plenty of input into his care anyway. When we go to the doctor I go in as well, you know. I have to ‘cos he can’t, he doesn’t know what he’s gone for sometimes.”

Lyn, L2

The three younger carers (Sue, Helen and Peter) seemed very adept at interacting with HCPs to get the treatment and/or care support that they wanted. This age-related difference is an interesting finding within this study. Perhaps highlighting the difference in expectations of patient and doctor relationships from those people born in the 1920’s as compared to those born in the 1940’s. The concept of ageism in service provision has been discussed in 2.1.2.1.

4.3.1.4 People with Dementia and Consultations

Carers described the fluctuating changes of their loved ones’ behaviour in many dimensions and interestingly, some of this demonstrated retention of insight as they changed their social skills and usual behaviours in company or within a consultation. This perception of self-preservation was demonstrated beautifully by this next quote, which described what happened on the day of a visit to the memory clinic for a routine assessment.

Wendy: “I will tell you what I do find with the memory clinic, he seems to get geared up somehow and he will answer questions there that he wouldn’t answer at home, like what day is it, what month is it, it is as if he is putting on a bit of an act.”

Jane: “They always put on a front don’t they?”
Wendy: “As if he is trying to do something so clever and I think well you wouldn’t have said that at home. He might have said it before we went there, what month is it and as soon as they ask him he will say the month you know. You know I can’t believe it, I can’t believe this, it is like two different people talking.” Wendy & Jane, L3

Jack’s opinion was that HCPs involved in consultations with PWD needed to develop their communication skills in order to pass on relevant information to the individual.

“The difficulty there is actually whether the interviewer can actually put things over properly, without talking down and without leaving things out or without complicating it…the best ones have an understanding to ask the right questions at the right level (but) most of them can’t seem to.”
Jack, L1

This was an insightful comment, as many people do have difficulty communicating with a person with dementia. There seems to be a perception that PWD cannot understand anything, but this is not explored within the consultation. HCPs need to simplify sentences, ask one question at a time and wait for an answer to be constructed and then spoken. Often communication takes longer with PWD and more time and patience is needed. To complicate things people with advanced disease often lose verbal fluency and use more non-verbal communication skills. HCPs may need to increase observation skills of the person and their body language and facial expressions to communicate effectively.

4.3.1.5 Consultations: together or apart?
Carers expressed concern about having to talk about the activities and behaviour of their loved one in front of the person themselves within a consultation. They felt this upset the person that they cared for and their behaviour was more subdued afterwards. What carer participants wanted, was a chance to talk with the HCP on their own either before or after the consultation with the care-recipient in order to give a realistic picture of the day-to-day. In this study only four carers had the person that they cared for present at the time of the interview. Jack and Ann were interviewed in their own home and Jack was able to give informed consent to participate. Mavis, Jenny and Penny had their respective spouse’s present on the day but this was because they were at the stage where there was little or no insight into the content of conversation. The remaining carer participants took part because their loved one was at a respite or day care facility and they would not have to speak in front of them.

Helen: “Sometimes when the nurse comes to talk to us and occasionally, well I did last week, I’d had a bad week, and I rang the nurse and chatted to her when my husband was out for the day somewhere. Specifically because I just hate talking in front of him.”

Lots of agreement
Helen: “I do think he’s a little bit down after I’ve talked about things in front of him.”

(Lots of agreement)

Helen: “And after we’ve been to the specialist there is just something that he’s not quite so bright, if you could say bright, but, as usual, as if he’s absorbed something from the conversation and it’s affected him.”

Mandy: “I think they resent the fact that you are saying something about them.”

The above comments typify carer experience and it seemed there was a need for a change in the way in which consultations are managed for PWD and their carers.

Interestingly there were opposite views of who should be included in the consultation process from the participants with dementia. Thomas, who was widowed and lived on his own, normally saw his youngest daughter once every two or three months for a few hours at a time. The first consultation with a consultant had been organised by this daughter and as he described below, he had little input to the consultation or any decisions.

“I was sat beside his desk…and my daughter stood behind me and he was firing questions at me - I can’t remember how many questions it was … but every time I answered, his eyes went over my head and my daughter was signalling to him ‘Oh God no’ that kind of thing. And then he said ‘right okay Mr X you can go now.’”

Thomas, L3

For subsequent consultations he had been told he needed “to have somebody with me,” but he had since decided it was not going to be his daughter but someone who knew him on a day-to-day basis because he experienced the consultation as “annoying the way it was done.” This was in contrast to Jack who thought it was good that his wife Ann accompanied him into consultations as it helped to get the most accurate information.

“It is important as well, sort of to have both sides because if I suddenly can’t think of the next word that I am going to use, then Ann sometimes knows what I’m going to say.”

Jack, L1

This seems an area that HCPs working with PWD and their carers need to address within their own consultations; whether the patient and carer should be seen together or apart or both. Fundamental to this decision is the need to explore how the person with dementia would like to be involved, who else they would like to be involved and who they trust to take those decisions on their behalf. Obviously any agreement needs to be flexible to respond to the changes brought about by disease progression. The Mental Capacity Act 299 and Dementia Care Mapping 199-203 supports the concept that PWD should always be
considered as having capacity to make or be involved with decisions about their own care.

4.3.1.6 Conflict with Healthcare Professionals

Due to the nature of full-time caring and wanting what was perceived as the best treatment and support for your loved one; carers often came into conflict with HCPs. Examples centred on access to support or medication. Mary (L3) was trying to get her husband prescribed memantine as the AChEIs had been withdrawn 12months previously. Since then her husband had become increasingly restless, wanting to walk outside for hours and he had lost sense of the night-day cycle. This is a common behavioural change exhibited by PWD sometimes referred to as ‘sun-downing’ or diurnal variation. Mary was not sleeping either as she kept her husband company on his nightly walks; she was literally exhausted.

“And at night he gets up and he wanders, and he wants to go out and he wants to go walking and he wants to know where his mother is and all these usual sort of things...I have got another appointment with Doctor X (specialist) in the first week in November, and he said if the sleeping is stabilised then he will start him on Ebixa®.”

This specialist supplied her with Zimovane® (a non-benzodiazepine hypnotic) to try and establish a day-night cycle. It seemed to work effectively for two weeks before tolerance was seen; the dose increased and again tolerance resulted. The risks of tolerance and addiction are well known pharmacological effects as are the risks to the person in terms of confusion and possible falls. It is perhaps an inappropriate treatment for sun-downing; but one that Mary felt she had to give to possibly receive memantine. It also seems inappropriate that therapeutic trade offs are being made for people at this stage of the illness. If an asthmatic were kept awake at night by their wheeze or cough they would not be prescribed a hypnotic in order to make them sleep; they would have the appropriate treatment for their symptoms prescribed. As mentioned in 2.1.2.1 the clinician should feel able to prescribe in the patients’ best interest and it would seem that evidence would support the prescribing of memantine ahead of Zimovane®.

Because most carers felt that the medicines were positively effective in many areas of daily living they often had difficulty accepting judgements obtained from clinic assessment tools. Pat's husband was taken off an AChEI because his MMSE score stayed the same. Another way of looking at a static MMSE score is the medication is holding the neurodegenerative process, and preventing further deterioration at this particular point.

“Well I thought he sort of stayed the same when he was on that. He didn’t seem to get any worse. But I suppose he didn’t improve either so they said it wasn’t doing him any good.”

Others ignored well meant advice from HCPs that the person they cared for was potentially dangerous and they should not take them home. Sue explained that this occurred twice; once after her husband had an inpatient stay (for an
unrelated medical problem) where he had become very confused, disorientated and aggressive with staff when they had tried to restrain him and the second after his first admission to a respite service.

“(They said) ‘I don’t know whether you should have him back he’s very aggressive.’ And I said well I’ve been married to him for 49 years he’s not going to do anything to me I know. So anyway then we went and got him and he walked in the front door and he said ‘It’s all right I’m home.’”

Sue, L2

In reality these behavioural changes displayed by PWD when moved from a familiar environment to one that is less so are well documented as triggers to agitated and aggressive behaviour.310 People with dementia need familiar objects in their environment to help orientate them to time, place and/or space. Without familiar objects, orientation is lost, sometimes on all three levels and this can be a frightening and confusing experience. It seems that more formal carers are less able to help orientate people without specific training and this lack of skilling increases agitation and anxiety of the transposed person.50,51

These interactions with HCPs, for many carers, were an interaction with a powerful other. That is, someone who was perceived as having control over their ability to care and their loved ones day-to-day mood and behaviour. This powerful other held the possibility of information, appropriate medication, and carer support.

4.3.2 Ageism

Carers’ generally recognised subtle prodromal changes in their partner, such as uncharacteristic behaviour, fuzzy heads; difficulty in telling the time, mood changes and/or loss of interest in usual hobbies. This prodromal period lasted from 5 to 12 years and carers’ related stories of frustration at the lack of response from GPs and other HCPs when they sought advice and/or guidance and their concerns were dismissed as being age-related.

4.3.2.1 Recognition and Diagnosis

Carers experienced the disinterest and dismissal of concerns displayed by HCPs as therapeutic nihilism, which compounded the feeling of not being heard. As Wendy described in the narrative below, this lack of concern for the effects of symptoms on the lives of carers could be distressing and lead to mental and physical stress.

“As far as my own GP is concerned it was a case of well he is 80, he is doing quite well in getting to 80 and that was it you know. No matter what goes on it was nothing really because of his age, you know. I thought there was a line drawn because he was 80 years of age and as long as he was on his feet it didn’t matter about what else was going on or how I was coping that sort of thing.”

Wendy, L 3

“So I knew sometime really before he was diagnosed and before the doctors really took it up because I even mentioned it to one doctor and he said ‘oh well that’s old age’ you know, because it wasn’t that much.

Doris, L2
As mentioned previously in 2.1.2.1, for older PWD there was a double stigma, with it being perceived as a mental illness and affecting older people. Dementia continues to be one of the most under funded and under-supported of the major therapeutic conditions in today’s health services. Although it is hoped that funding of £150million in support of the NDS implementation may help to address issues such as stigma and therapeutic nihilism.\textsuperscript{51,79,80} Currently many services are attached to Old Age Psychiatry units and continued and/or adequate funding may be dependent on local resources for Mental Health services. The Cinderella of modern medicine, Mental Health services are well known for being inadequately funded and also having funding taken from their budgets in order to support debt ridden general medical services.\textsuperscript{311}

\begin{table}[h]
\centering
\begin{tabular}{|c|c|}
\hline
\textbf{Point of Reflexivity} & The branch lead from location one and each of the participants had asked to be kept informed about the findings from the study. Two of the interim findings had been around the variability in the provision of information, medication and/or services and the experience of ageism in this aforementioned process. The carer participants’ age range was between 65 and 80 in this location and each asked the branch lead to feed back to me that this was something they had found upsetting and frustrating when seeking help from healthcare services. \\
\hline
\end{tabular}
\end{table}

Non-recognition of symptoms by frontline HCPs meant that many PWD were not referred to specialist services for some years. Not only did this preclude the usefulness of an early diagnosis in terms of allowing the person to prepare for the time they would no longer have insight into their treatment and perhaps complete an Advanced Directive, but it meant useful treatments, services and educational interventions were not accessible.\textsuperscript{192,194-8} Patients and their families need time to understand what is going on before it is too late and prepare in advance for potential financial, social and mobility issues.

Ann had recognised something was not quite right with Jack over 12 years before the diagnosis was finally made. They bounced from GP to GP to specialist GPs to consultants before a diagnosis was finally made. Jack, had been a University lecturer, with previous high intellect and she had been sure that this was the reason for the delay in her husbands’ diagnosis as illustrated below.

\begin{quote}
\textit{“So you know she (the consultant) confirmed what I’d been saying all along that yes there was a problem and she actually sent an email to this GP Specialist to say ‘you’ve got to look for the very intelligent patients to see what their drop is’ because he’s had a massive drop but because he started at a higher level.”}
\end{quote}

Ann, L1

Often getting the diagnosis was not actually seen as helpful by carers as it didn’t actually change anything.
“(Husband) did have a brain scan though to see if it was anything. They say, if it’s Alzheimer’s the brain shrinks or something and if it’s vascular there’s other signs, you know. It still doesn’t alter the fact of how you are does it?” Lynn, L2

Many people find it very difficult to take a lot of information on board at the time of diagnosis and perhaps even forgetting they have been told certain facts. In fact, the diagnosis given in an off-hand manner can cause distress, humiliation and anger at the process of diagnosis, the lack of support and “the system of so-called ‘care.’” Pat described the off-hand way in which she and her husband received his diagnosis, when there had been no expectation of such a prognosis.

“We had to see the consultant and he said to me “You must have guessed he’s got Alzheimer’s?” I said well I hadn’t because I thought with Alzheimer’s once it had gone it had gone and (husband) would remember another time and it didn’t sort of cross my mind.” Pat, L1

4.3.2.2 Complexity and Duration
As mentioned in 2.1.2.4, diagnosis of dementia is one of exclusion with no routinely available simple blood or tissue tests. Unsurprisingly, this resulted in a large number of visits to different HCPs, often in different healthcare settings. One could predict that there would be miscommunication; lost results, incorrect procedures being undertaken; all of which delayed time to diagnosis further. This diagnostic process was experienced as being time consuming and frustrating.

Ann: “It was frustrating for me, I got very uptight. They lost the CAT scan from (the hospital). At that time he had what seemed to be a stroke which now turns out to be several TIA’s but when we went to see the specialist about that he hadn’t got the figures to hand because the scan was missing. It’s a long cycle of things that went wrong.” Ann, L1

This diagnostic process was also associated with a large time commitment for both the carer and the person with dementia as Jack related below:

“I don’t think we went really a day, a week rather, when we weren’t seeing somebody, we are more used to that than anything else. That was normal.” Jack, L1

The duration of time between the initial contact with a HCP with respect to presenting memory problems and a confirmed diagnosis, was counted in years rather than months. These experiences contrasted with the proposal that the duration of the diagnostic process in primary care took 18 months, which did not seem to take into account the years of delay from an ageist response at first presentation.
This delay in access to services and active treatment was perceived by carers to have negatively affected their loved ones current health status.

“In all the years and she (her mother) has been here, six and a half years and it is only this year she has gone there (memory clinic). If she had taken Aricept® five to six years ago she may have been you know in a much better state than she is now.”

Jane, L3

Jane’s comment above illustrated the extreme desire that carers had to hold the disease in a specific timeframe and halt further progression so that the person they remembered and loved was kept safe in the present. It was very moving to witness the emotions displayed by the participant carers and their perceived impotence to contribute to this yearning.

4.3.3 Accessing Medicines for Dementia
As mentioned previously, carers were reasonably well informed as they received the quarterly magazine Living with Dementia which enabled them to form their own opinions on efficacy and use of medicines for dementia. Consequently there were associated hopes and fears associated with these treatments.

4.3.3.1 Hopes and Fears of Medication
There were four main fears or hopes associated with medicines for dementia. These were:
1. the chance for their loved one to try a perceived effective treatment,
2. how to overcome the barriers to accessing a medicine for dementia,
3. being able to start the medication sufficiently early to ensure a good and prolonged response, and
4. the hope it would not be discontinued if they felt the medication was helping.

A Chance to Try
Receiving a diagnosis of Alzheimer’s, vascular or a mixed dementia, did not guarantee access to medicines for dementia. Prescribing criteria between locations was different, with two of the four sites not routinely prescribing memantine. This meant that those people who were not eligible for AChEIs because of concomitant medical problems or because their MMSE score were too low, were not eligible for any medicine for dementia. In locations 3 and 4 some people were prescribed memantine but others were not; this variability resulted in inequity in access to treatment and another thing a carer felt they needed to fight for.

“I think they should be given the chance even if it is not going to work, I feel that they should be given the chance. I mean it may not work for (husband) but you know I shall feel happy that he has been given the chance to try which hopefully he will but as you say, you fight every step
There was great frustration expressed that the treatment of dementia was not regarded in the same way as which physical health conditions were and this raised undercurrents of feeling neglected by the NHS. This could also be linked to institutionalised ageism having possibly pervaded the auspices of NICE in terms of the inappropriate use of QALYs as an outcome measure for a terminal illness in older people.  

“I mean if somebody has some sort of other physical illness like angina the doctor wouldn’t think about not giving him the right medication which might help that person.”  

Jane, L3

When carers spoke of their hopes for a medicine for dementia to be prescribed for their loved one there were always mixed emotions present. Some were very anxious about it, not wanting to push too hard and the rock the boat; whereas others were angry and saw it as their loved ones’ right to be able to try a treatment that was available. Listening to the benefits seen in some PWD, carers experienced great hope tempered by the knowledge that it might not be effective for their loved one.

Mary: “I know I am sat hear almost drooling over the improvements.”

Wendy: “We have tears. I am so worried…we are told aren’t we, we mustn’t pin our hopes on it. I must be realistic, it may not work and I think to myself ‘well the Aricept worked I am sure it will if he ever gets on Ebixa®.”

Mary & Wendy, L3

Barriers

As outlined in 2.3.3.1 the review of the NICE guideline was overdue and a draft suggested reduced availability of AChEIs and although it was not a question on the topic guide; carers expressed their disapproval of the impending decision. This decision-making process was seen as long and arduous, resulting in many participants feeling anxious about the effect of the impending decision on their own situation but also the effect it would have on others not currently receiving treatment. It all added to their sense of disempowerment and helplessness within the current biomedical framework.

“That’s why I’m so angry about this NICE proposal. Because they say ‘well you haven’t got a worry because (wife) is already on it she’ll carry on.’ That’s not the thing. It’s people not been given the opportunity because it’s so dramatic, altered every one of our lives. Anyone even remotely connected with (wife), it’s so totally different even her sister who only sees (wife) probably once a month; she wouldn’t have anything to do with her, now she strokes her and everything.”

Peter, L3
Another point of concern was the perception that the prescribing of these medicines was rationed locally and that somehow, they and the person they cared for had to pass an unknown test before a prescription was written.

“Well he did come out here and see me in our own home before prescribing the medicine...So he came out here and he saw us and chatted to us and was very pleasant. And probably deciding whether it was worth spending the money. Oh God isn’t it awful? But maybe their hands are tied and they’re told you can only have so many patients that are allowed to be prescribed it.” Sue, L2

Some carers were concerned that their continued demands on behalf of their loved one would end with them being removed from surgery lists as a patient.

“I do feel like I have been making waves for quite a while about this Ebixa® and I mean when the, my husband’s GP said well I don’t think they’re, any of these things are any good anyway, you know that really got me going (pause) not to him. I don’t want to be taken off the list.” Mary, L3

It could be considered that memantine’s place in therapy would be once the AChEIs were no longer effective; or if they had been an inappropriate choice due to concomitant illness. Many carers had difficulty accepting the NHS could refuse to prescribe a medicines costing £2.50 per day to enable PWD to be cared for at home for longer, but were willing to pay £400 per week for the same person to go into a care home. Carers were quite open that they wouldn’t be able to contribute much if at all to the care home costs as explained by Mavis (L2) “we couldn’t do it, which would mean it would be on the NHS” and Peter below:

“I’d swear I’d never do it, I can’t say you will never do it but I was reaching the end of my tether with her (his wife). It was going to cost somebody a lot of money because I couldn’t carry on looking after (wife), bearing in mind I’d done if for 8 years. But there is no problem now, she’s fine, aren’t you (wife since starting memantine)?” Peter, L3

Others looked at it from a slightly different viewpoint and thought the government was making money out of informal carers and by implication the government should be more prepared to prescribe medicines for dementia. This became a debated point in the second carer focus group (L4).

Paul: “Well if the governments got all this money what they’re making out of all of us sick people; the millions of pounds that they’re making.”

Diane: “With us caring for them?”

Paul: “Yeah with us caring for ‘em like.”

General: “Yes, yes”
Paul: “They’d spend a lot more if they had to go in a home wouldn’t they?”

General Agreement: “Yes” “Yes” “True”

As mentioned earlier, Informal carers have been estimated to save the government £6 billion pounds each year by bypassing the need to implement more formal caring arrangements. 51,191 Although the Carers Act 305 outlines the legal rights of informal carers; it is not widely publicised and local health organisations struggle to assess individual carer needs. 48-50,192 Many carers feel undervalued and unsupported; leading to increased carer burden, stress and ultimately institutionalisation of the person they care for and increased health and social care costs. 192

Participants realised that money in the health service was limited and that NICE was there to “sort out the good from the bad” but they felt the decision was hasty to stop access when the medication actually caused improvement in some people.

“I wrote when we had the big push for the latest drug I wrote to the MP because I thought it was important that when you could see what it could do for some people. It doesn’t suit everybody, not everybody it works for. I feel that they were a bit hasty. I know money is a problem but it seemed rather hard to just sort of stop.”

Lynn, L2

Starting Medicines Early
A number of carers voiced opinions that ‘they were not keen on tablets’ and that this influenced their decisions on whether to start recommended medication for their loved one. This also raised an interesting ethical dilemma in terms of what the best interests of the person with dementia actually were. In the following example it was unclear whose beliefs were being addressed and whether the best interests of the patient were being protected.

“I can’t remember which one it was it was, but it was one of the three main ones. And it was quite clear it was all experimental. They wanted to monitor so on and so forth. I’ve never been keen on drugs, we’ve never been keen, so we didn’t actually do it.”

Peter, L3

Who has the best interest of the person with dementia at heart? Can there ever be true concordance with a medication regimen when PWD may not be given the chance to voice their opinion?

In terms of starting a medicine for dementia carers generally felt the medicines were not started soon enough. Evidence 8-12,23,27 supports that starting AChEIs in mild dementia can be beneficial for some people; but larger differences in response from baseline measurements are witnessed when the medicines are started at moderate stages. 31
“Perhaps if they had been a year earlier, you don’t know. But I think they do pick up on it more now. I mean it’s, I don’t know, maybe its seven years (since first symptoms appeared).”

Pat, L1

All the participants with dementia knew that they had been started a medication for “brain function” and Jack (L1) believed that the medicines should be started as soon as possible as long as the diagnosis was correct.

“ASAP except you should maybe be sure that they are appropriately prescribed, and identification of the condition.”

Jack, L1

In summary HCPs were perceived as powerful gatekeepers to the access of medicines for dementia and support services. Variability in communication skills and knowledge across and within locations demonstrated a resultant inequity in support and service provision.

### 4.4 Living With A Degenerative Illness

Living with a degenerative illness as a carer meant the daily witness of a loved ones’ decline in cognitive; social, psychological and physical functioning. Section 4.3.1 discussed the general role changes and associated challenges of caring. This section will discuss the lived experience of participants and how they perceived the medicines for dementia supported this.

#### 4.4.1 The Lived Experience

This section describes how dementia affected and shaped the lives of those involved. The lived experience was the daily recognition that what once was had changed forever. Participants expressed sadness and frustration at perceived individual losses, but there were some signs of illness acceptance.

##### 4.4.1.1 Sense Making and Acceptance

Both care-givers and recipients expressed difficulties in understanding why people were affected and many narratives described participant’s sense-making of their lived experience. A large part of this process was trying to establish exactly what dementia was.

“…what started this originally has got nothing to do with what this is about. He had one of those TIA’s. And they say that’s what caused this.”

Doris, L1

There were contrasting views on whether dementia was a disease or an illness as illustrated below:

“They still don’t know what it is really. Because it’s not an illness is it?”

Jenny, L2
“I mean it is an illness. If you have got cancer you go in hospital and you have your treatment free. I mean I know they don’t need to be in hospital but they still need care if they are in a (their) home.” Pat, L1

The concept of whether dementia is an illness or a disease is one I struggled with as well. Disease is defined as “any alteration of the normal vital processes of man, any disorder or morbid condition.” Illness as “the state of being ill, sickness, physical indisposition.” The signs and symptoms seemed to traverse across the two descriptors as cognition negatively impacted on physical health. It seemed carers felt an illness was taken more seriously in terms of the treatment proffered.

A common narrative from carers was incomprehension of how dementia could occur in someone who was otherwise fit: almost as if it would be easier to bear if a loved one had some other medical condition.

“It’s just the mental part, I mean actually he’s well in his self and he eats ever so well I mean he’s 82 but he eats well and that, there is nothing wrong with him really. (Husband interjects; non-sensical) This is the part; (the distress of living with a person with dementia) when you can’t hold a conversation with him.” Jenny, L2

As with any chronic illness there needs to be adjustment and acceptance made by those living with it that the situation cannot be changed and therefore need to be accepted in order to move on. Tim (L4) had experienced difficulty dealing with the frustration of his poor memory on daily activities and stated “you’ve got to be I suppose philosophical is the right word. You can’t let it bother you too much otherwise you’d go bonkers wouldn’t you?”

Philip (L4) talked about how his ability to complete tasks was “all right for a while now, then it dies away” and how frustrating this was. He expanded saying the hardest thing “I found was you couldn’t do what you were capable of doing, that’s what was the worst bit of the lot, you know. But I got over it.”

It is interesting to consider whether these illustrate a true acceptance of living with memory problems or whether participants forgot to get concerned about not remembering, or as the disease progressed their insight into previous abilities lessened. However the frustration was still evident as they remembered the extent of their cognitive limitations.

4.4.1.2 Living with a Poor Memory
Poor short-term memory is a prominent factor of most dementias, and especially those diagnosed with an Alzheimer-type. The participants with dementia described how this symptom affected them and their daily routines. Thomas
found it difficult to accept his diagnosis of AD because he felt that there was not a great difference in his memory from when he was a younger man. He said that he had always been absent minded as “my brain was away up in the sky somewhere.” He continued with the following explanation:

“My wife always reckoned I had a bad memory. There were lots of things she liked to trot out like ‘What’s your name, Mary Jane, where do you live, down the lane.’ So, it still is that, but a little bit worse.”

Thomas L3

In the focus group for PWD (L4), participants shared their frustration about being able to remember distant but not recent events.

Tim: “It’s just the memory at times, you want to remember, and it’s always the things you want to remember you can’t!”

Philip: “And the more you try the worse it is.”

Tim: “The worse it is! So I go into my memory bank, my wife. Most people find it very hard, people like us. They’ve sort of lost their memories and yet you can go back years ago, I can remember all that.”

I: It’s all there, so it’s just the recent sort of things

Tim: “Yes, you can walk down the road and if you ask me tomorrow ‘what did we do?’ I can’t tell you we walked down the road. Strange isn’t it? It used to frustrate me a lot…”

Philip: “It used to with me as well.”

Tim: “but the wife said ‘forget it, I know what you’ve done’”

PWD Focus Group L4

Some carers accepted short term memory problems as part of the condition and adjusted conversational content to more distant shared memories.

“His long term memory is excellent but you ask him about something that happened yesterday and he can’t remember but that is one of the symptoms anyway but apparently he is not doing too badly so I have got nothing really to complain about have I?”

Wendy, L3

Participants with dementia acknowledged their reliance on carers to confirm their memories but Jack found it difficult that sometimes he could not remember a shared memory at all causing him some frustration as he explained:

“It’s not only that I forget what’s been said I forget that it was said. It’s irritating and exasperating.”

Jack, L1
Although Jack said that he sometimes felt “over dependent” relying on Ann to do things, he accepted that this was necessary and qualified it by saying “I don’t believe in shooting myself.” He continued by saying that “we’re quite good friends. And always have been.” This seems to be an important factor in the caring relationship, the maintenance of friendship and social intimacy through talking and social contact. This concept about the quality of the previous relationship influencing the quality of the subsequent caring relationship is well known and perhaps should also help to shape support packages for the person with dementia.  

4.4.1.3 Changing Relationships

Participants with dementia generally spoke warmly and with affection and gratitude for the support of their carer as Jack shared “Imagine, it would be impossible to work things out at all without help of a carer.” Carers felt a sense of loss for the person they loved and the associated deterioration in their personality. As has been suggested, if there are unresolved issues or disappointments then it may become increasingly difficult for caring to continue and/or the relationship to survive. For the person with dementia this can obviously present a number of difficulties especially as the illness progresses and dependence increases.

Sandy (L4) was an anxious lady who knew her poor memory was causing her husband Paul great irritation; although she said “He’s been very good though; my husband has. Really, very good.” Paul was finding it increasingly difficult to care for her and she shared “he’s getting a bit frustrated.” Other statements were repeated during the focus group creating a dilemma as to whether Sandy was safe at home.

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a researcher this was cause for ethical deliberation. Sandy repeatedly stated how her husband was frequently irritated with her and that she thought she needed some more of the medicines for dementia as she thought these may help her and by inference, her husband. She became quite anxious through the latter stage of the group session and I became concerned for her well-being at home. Did I break the confidentiality of the sharing within the group? Was I picking up incorrect information? Was it any of my business as the researcher? In the end I asked to speak to the lead social worker at the branch and shared my concerns. They were well aware of the increasing irritation and frustrations experienced by Paul in response to Sandy’s inability to complete simple tasks and were doing their best to support them both. However, Paul was proceeding with enquiries to have Sandy admitted to a care home and Sandy was very anxious as she did not want this to happen.</td>
</tr>
</tbody>
</table>

Jack (L1) spoke about his concerns of his behaviour and memory before the diagnosis was made as he realised that “everything was going wrong, physically and mentally and I was a bit concerned. It affected other people as well.”
On a more personal and emotional level for carers intimacy was lost within the relationship, as the person they had fallen in love seemed to disappear, resulting in profound sadness.

“He doesn’t even remember when we were courting or anything. We’ve just had our 60th wedding anniversary and he’d completely forgotten about that; he didn’t even know what it was all about. It’s pretty awful really.” 
Doris, L2

This loss of being able to share personal, intimate relationship memories has been proposed as a key subjective stressor affecting the ability for caring to continue.131,166,177

“There is something to be said from a heart attack. I know it is a shock for people left behind but there’s a lot to be said for it. I had a friend and, her husband died of cancer and he had in about four months and she said ‘well at least you still got him,’ but you haven’t, you haven’t got him at all.”
Pat, L1

Sue experienced such a complete change in the relationship with her husband that there was almost a felt sense of the anger, loss and perceived unfairness of the resultant situation.

“I had a husband that did pay the bills, made the arrangements in our lives, looked after me and suddenly he went and I didn’t have that person any more. He couldn’t make the decisions, he couldn’t pay the bills, he couldn’t talk to me at all and it was absolutely appalling to live with somebody…who isn’t that person anymore. It’s been the worst time in my life I would say, it was terrible absolutely terrible.” 
Sue, L2

This perceived loss of the person carers’ loved can be distressing resulting in increased carer burden131,166,177,285 however it has been suggested that perhaps this is due to the inability of the carer to live with the person as they are now rather than the person they once were.141

4.4.1.4 Progression and Behavioural Changes
Dementia is an insidiously progressive disease and it has been suggested carers want to be forewarned of possible outcomes61 as Jenny stated:

“Oh no I think it was the right thing (being told about progression). You know it gets worse don’t you? I mean when he first had it, it’s no good saying he’s going to get better from it. You really hope that he is.”
Jenny, L2

On or off a medicine for dementia PWD exhibited fluctuations in cognition and behaviour as Jill voiced “you see their condition changes so much I find you know, every week is something different.” Others like Helen Mary, Bob, Steve
and Fred (L4) observed a decrease in confidence which was experienced as their loved ones “becoming more clingy.” Fred shared “she’s (his wife) always looking for me. She gets quite obsessed.”

Fluctuations in mood impacted greatly on care-givers as Jane described below:

“I always think the worst thing for carers, it is not so much that people get more and more forgetful or do strange things, it’s to see when they are unhappy and when they are miserable because that really pulls on the heart strings and you’re sort of living with this unhappiness in the house all day long.”

Jane, L3

Communication became increasingly difficult both for the person with dementia and for the care-giver trying to adjust to and live with these changes. This was illustrated by a discussion at the second carer focus group (L4).

Bob: “You can’t tell from day to day where she’s at. If you argue about things you may as well forget about it but if you agree and go along with the flow then it’s ok. Strange.”

Mandy: “I think we’re all like that aren’t we? Don’t argue, you can’t argue with them, because they’re never wrong.”

Bob: “That’s it they’re never wrong.”

Polly: “Never wrong.”

Bob: “And don’t tell me what to do.”

Mandy: “Not their fault.”

Steve: “Don’t tell me what to do.”

Mandy: “That’s right.”

Bob: “Strange.”

Steve: “Yes that seems to be the case of male and female. You daren’t sort of try and correct them, because if they’re in a state where you’d call them apparently normal, they can flip over to being aggressive.”

Carer Focus Group, L4

Good communication skills become increasingly important when caring for someone with dementia. If a person can no longer reason or understand logic then no amount of debate will shift their viewpoint. Guidance suggests that agreement and then distraction from the topic may be the best way to handle these situations.\textsuperscript{151,316,317} The person with dementia does not become frustrated in their ability to understand and the carer does not become embroiled in an argument that can never be won.\textsuperscript{151,316,317} Interestingly Pat linked this decrease in communication skills to progression of the illness.
“I think he is getting into another stage now, he’s not so amenable as he used to be, he’s not violent or anything like that but he gets very, he gets frustrated because he wants to say things and he can’t communicate, he gets cross about it.”

Pat, L2

Carers described aggression as being either internally or externally directed. Internally directed behaviour was described as “jittery” and externally directed behaviour was often associated with people lashing out or hitting others.

“The aggression went (after memantine started) because he was getting very aggressive and agitated all the time, sort of jittery and wanting to run away from himself.”

Sue, L2

“...if you came with in striking distance, you’d get a biff. You weren’t allowed to touch her or anything (before memantine).”

Peter, L3

Other carers such as Helen experienced disease progression as increasing resistance to completing small tasks or their approach becoming more aggressive.

“I would say it (Aricept®) held the position as it was for about a year at least without any deterioration at all and then gradually things started to deteriorate with doing tasks, that sort of thing and then after about 3 years or so I suppose, he started becoming a little bit more aggressive himself.”

Helen, L4

Another change experienced in people with advancing dementia was the inability to orientate to time and place in terms of their environment and/or in recognition of their loved ones and family. This has been described as one of the most difficult things for carers to accept as illustrated by Jill below:

“He doesn’t live in the here and now and you know he sees things. He thinks I am his mother most of the time, or I can be his father sometimes, if I’ve been in the garden working he thinks I am his father. I can be sitting watching him and we’re having tea and he’ll say ‘when’s Jill coming home?’ and I say ‘I am Jill.’ You know, and then I’ll say ‘well who do you think I am?’ “Well you’re my father.” You know, it’s very weird.

Jill L1

In summary the lived experience of degenerative illness challenged care givers and receiver on many levels; completely changing the previous relationships and lives they once shared.
4.4.2 After Medicines for Dementia

Carer participants described wide-ranging effects of medicines for dementia. Because dementia causes progressive impairment in areas of memory, language, visuospatial and perceptual ability, thinking and problem-solving or personality; it could perhaps be foreseen that these agents could have a more global affect than just improving memory. More important was how these effects were experienced by carers and by those who took them and resultant effects on mood, functioning, daily activities and carers’ ability to cope.

4.4.2.1 Effects on People with Dementia

In terms of effect on memory there was variability; with carers reporting improvement, holding or no effect. More important seemed to be global improvements in functioning. Sue for example perceived the main effect was improved behaviour.

“It would say mostly behaviour, but I don’t think he was on them early enough. I think it probably did hold it sort of stop the memory getting quickly worse which it would have done without them, but I wouldn’t say it improved the memory.”

Sue, L2

“It didn’t help his memory but it helped him in other ways. … again he’d stopped being quite so outgoing, but he’s back to that again and he’s much more friendly and talking to everybody in there (day centre) and he has little jokes now and that sort of thing.”

Mandy (about Philip), L4

Behaviour was a generic term used to include anything from perceived aggression, agitation, repeated questioning to increased sociability and friendliness.

“And he had been becoming more aggressive and really questioning everything that we did ‘why?’ ‘Why do I have to do this?’ ‘Why do we have to do that?’ and this (memantine) controlled that. And it was really mood enhancing it’s not so much the tasks that these drugs help altogether, so much as the mood and the way they approach things and how much easier that makes it for me.”

Helen, L4

Participants described a wide range of improvements on mood including: the return of a sense of fun or humour; improved mood or mood stability; or mood alerting or calming affects. Many carers were pleased to see loved ones happier and more cheerful in themselves; this obviously helped to improve social interactions within the caring process as humour returned. Jane shared what she felt were the most important benefits of the treatment below.

“Now I think there is a purpose for her because she gets up and she’s cheerful and she laughs and we have a joke and she does something silly, she has got a great sense of humour, she always had which disappeared for a while and it has come back and this is really very special to me.”

Jane, L3
Prior to starting memantine Jenny’s husband was up all night and displayed very agitated and driven behaviour. He was unable to sit quietly and was always on the go, which was exhausting for Jenny, as she wasn’t sleeping well at night trying to get him upstairs to bed.

“...this is the one that has calmed him down a bit. Where he used to be on the go and would never sit down and he’d be up and down and moving about and I don’t know never rest, but now this is great we sit like this (quietly side by side) in the evening, he really likes a sit down.”

Jenny, L2

Helen described how the introduction of memantine had enabled her husband to attempt every day tasks that Helen would normally be doing for him.

“He had started being a bit more confident and for instance, I’d started shaving him just prior to that (starting memantine) everyday and he said ‘oh I’ll try that, I’ll do that’ even though he couldn’t complete it properly he was having a go at some of the smaller tasks.”

Helen, L4

Jack described how the medicines made him feel more confident and therefore able to complete his usual daily activities.

“I think the best way of putting it is to say that I feel more confident in going about my daily doings and there has been occasions where I haven’t been safe to be walking home on the side of the road, but I’m safe to take the dogs out (now) and so on but you know that’s where I’ve been feeling more confident and I don’t think it’s getting any worse.”

Jack, L1

In terms of the effects of the medicines on daily activities, the responses were varied both in terms of capabilities but also in terms of importance to the carer. For example Ann reported improvement in activities such as making a cup of tea and using the dishwasher but more important to her was the fact that Jack could now spend time on a previous hobby of railway modelling.

“Well we still have a short-term memory loss. I don’t think it is as bad as it was. We’ve actually got Jack to start modelling again. He has a railway model and… before he would not have been able to do what he’s been doing now. Although what he is doing now is very simple.”

Ann, L1

Other carers reported a return to previously enjoyed activities such as crosswords; reading and listening to music, but for others it was toileting issues that were of more importance.

“He likes listening to his music he has got all these videos that I put on because he likes all music. Irish, Scottish ones he’s got there. If there is nothing on the television I’ll put that on, even if you think he is asleep he
isn’t because you can see his foot tapping.”

Pat, L1

“So far as regards toilet that’s fine and that’s where I think this is helping him. I do think maybe I might have had more problems that way.”

Mavis, L2

The participants with dementia described daily activities which ranged from helping with household chores, to dog walking or collecting newspapers, to driving under supervision, and then on to arranging own travel and accommodation and cooking and cleaning for oneself. So a wide range of capabilities were demonstrated and this may reflect different individual’s stage of the illness and/or include a contribution from their prior capabilities and personal aptitudes.

As Thomas (L3) explained, “Except for being a bit forgetful I think I’m coping alright. I keep myself clean, I keep the flat reasonably clean and tidy, I cook proper meals, I walk and get a lot of exercise.” However he confessed to forgetting to shower at one stage but had written reminders on the calendar to ensure that he showered regularly. He was also doing all his own laundry and ironing; although he admitted “I don’t iron the sheets very well mind you.”

Tim (L4) liked to walk out for the paper when he could, as he liked the exercise. At this stage he felt safe enough to do that without getting lost as he explained, “I think, the roads round where we live are imprinted in me mind anyway.”

Philip spoke frequently of his disbelief about how quickly and how well the Aricept® worked for him and comments such as “I couldn’t believe it; I can still remember it today, the day I took them for the first time” were common. He described them as a “magic pill” and how he felt “completely new and better” after taking the medication which more than anything perhaps gives an indication of how badly he felt before.

“When they first told me, before I had took it, (the medicine for dementia) I didn’t know what planet I was on or anything, you know. I was just a dead loss you know.”

Philip, L4

Mary (L3) described her husband as being “more alert, his speech was more coherent as it were and this went on for about a year.” In comparison Sarah (L4) had experienced her husbands slip into dementia as almost like a sleeping sickness, and after starting an ACHeI she described him as having “been sleeping and suddenly he was more aware and he changed.” For Jill this increased alertness without improved insight decreased her ability to cope and as there were side effects of treatment it was decided to withdraw the medication.

“I did notice he was brighter and you know more responsive and probably at the time I thought that I don’t want him that bright because he’ll want to go out and do Parish work, when he isn’t it, you know. He doesn’t, he has no self-awareness at the moment.”

Jill, L1
All participants with dementia described episodes of insight into their own
behaviour or needs, this included Sandy (L4) who commented, “I think I could
do with some” after she heard about the dramatic benefits of the medication that
Philip had experienced. Before starting the medication Philip described himself
as “very contrary and things like that you know which I didn’t even know I was
doing.” It seemed these medicines could also improve self awareness and
insight into previous and present behaviour. As Jack told Ann in her interview,
the “effects of stress on you made me upset as well” clearly demonstrating that
PWD can be very much aware of how their illness may affect the health and
well-being of others. This finding is supported by an observational study of PWD
interacting with their carers in their own home with interview follow-up which
noted how the effects of dementia on the spousal relationship were of great
concern for some of the participants with dementia.133

Also noted were positive benefits on visual perception, communication, retention
of personality and ultimately quality of life. The changes in thought processing
and communication were often seen as remarkable by carers as their loved one
demonstrated greater insight and understanding than previously. It seemed
unclear whether this insight and understanding was already present but just
could not be accessed prior to a medicine for dementia.

“Well with the Aricept® she had brief moments where I thought ‘where
does that come from?’ … Did I tell you what she said one day? It was a
nice sunny day and she said “oh isn’t this a lovely sunny day can you
freeze it?” So I thought that was really sweet you know. You just think
what a complicated thought pattern you know, to keep something sort of
frozen and then you can keep it safe.” Jane, L3

What was interesting from participants’ narratives was that PWD engaged more
with visual stimuli which improved engagement in the world of their carer.

“Well within a month of going on to memantine she was doing things she
hasn’t done for yonks. Like for instance if a hot air balloon went by she
wouldn’t even see it but now ‘oh oh’ and the birds come down and will fly
by and she notices that. We used to have the television on she’d look at it
and go to sleep, (now) she argues with the television. She loves watching
the kiddies programmes c-beebies, wildlife with animals, things with
movement, she loves watching it.” Peter, L3

An unexpected response for carers was observed improvements in mobility in
two PWD. Prior to taking the medication they were either limited in walking by
pains in their feet (Philip L4) or perceived discrepancies in the surface on which
they were walking (Peter’s wife, L3). The latter perception is commonly
associated with falls in older people and there is guidance on the types of
flooring that should be used in care facilities to reduce risk of falls.292 For
example, flooring with lined patterns are more frequently associated with falls as
people with poor vision may mistake these for steps or changes in floor heights
and hence trip or fall.292 So these observed improvements may be related to
improved visuospatial awareness, vision and/or physical and manual dexterity.
“We do a lot of walking in the woods and if she saw a leaf she’d be trying to pick it up and wouldn’t be able to pick it up and would keep missing it. Now she bends down and picks it up no trouble at all. She was starting to find trouble going from different colour surfaces, ‘cos it obviously was going to be a different height, all gone.”

Peter, L3

“Within a couple of days, he (Philip) could hardly walk before that (Aricept® being prescribed) because he felt his shoes were filled with gravel, and his feet were hurting, and he walked sideways all the time off the pavement and within a couple of days that stopped completely.”

Mandy, L4

Many carers spoke of improvements in clarity and content of speech and the resulting ability of their loved one to participate in conversations and become more sociable and friendly. Diane shared “people who came in said how much friendlier he was and chattier and all this sort of thing.” It is difficult to understand how these changes arise as they are quite complex interactions and it may be that this is the combination of increased confidence; clarity of thought processing and a deeper understanding of what is being said and/or awareness of their environment. Again this type of improvement helped the caring process, as they were then able to communicate on a deeper level with their caregiver than prior to treatment starting. The sharing of conversation is a core part of relationship building and it is a sorely missed aspect by carers in relationships as the illness progresses.133,166,167,177,304

“Well he wasn’t taking anything else until he started on the Aricept® so I know quite well that the Aricept® was a great help for him. The change was really wonderful, you know with his speech and clarity and he was much more alert and asking me questions for a while which was unheard of. It was good. I was thrilled with it.”

Mary, L3

Carers frequently expressed their sadness at living with a person who was ‘not them’ and did not engage with life or their family as they had previously. An important experience for some carers was the return of ‘them’ and preservation or return of previous personality traits. Helen was a younger carer and had experienced her husbands’ loss of his former personality as ‘losing him as he was.’

“With the Aricept® I did feel it kept his personality somehow, I felt once or twice prior to taking it that I was sort of losing him, I can’t explain why, but that’s about losing him as he was. And I think that that retained his personality for a long, long time.”

Helen, L4

Obviously these are important experiences for carers to have: the perception of the person they now care for still being the person they fell in love with and not an empty shell. If we relate this as being a reduction in subjective stressors in the care-giving process170,171,177, we can see then that these medicines reduce
caregiver burden by decreasing the subjective experience of stress related to the caring process.  

### 4.4.2.2 Effects on Care-givers

Consensus opinion was that the medicines for dementia were an integral part of the care structure support system enabling caring to continue. Positive effects included the perception that the care-recipient was easier to care for and improved sociability impacted positively on relationships and quality of life. However sometimes carers felt it difficult to describe exactly how the medicines had helped as Ann expressed

> “I feel there’s been a slight improvement but I can’t actually specifically say what that improvement is except that life is not quite so bad.”

---

Ann (L1)

Others were much more aware of how the medication had affected their ability to cope with caring as Jane noted below;

> “She is happy, she sleeps well which is wonderful as a carer to get a decent night’s sleep and she is just really happy and cheerful.”

---

Jane, L3

Peter, who had been caring for his wife since she was 55, described his life after memantine was prescribed for his wife at age 63 as having “been cushy.” The eight years he had been caring for his wife prior to memantine had become increasingly stressful to the point where his GP was concerned for Peter’s cardiovascular health.

> “But if I tell you now that my blood pressure is normally about 137 over 70 something and I don’t think that’s just the drugs (bendroflumethiazide). That is I’m feeling better, I’m not under pressure. I feel better enough to do exercise. I go on the bike, which I was doing anyway, trying to do. But I’m losing weight again, you know, I don’t mind admitting I was comfort eating. I was absolutely worn out”

---

Peter, L3

This finding of being less worn out was supported by Ann who felt although she was still tired she wasn’t so weary and she put this down to not having to watch Jack to the same extent. His increased awareness meant that she could leave him alone at home for short periods “as long as I’m on the end of the phone it tends to be alright.” These are important and significant improvements in the quality of a carer’s life and the resultant positive effects on their own physical and mental health. Caring has long been associated with negative health outcomes for carers and interventions that minimise these stressors have an important role in supporting continued caring. Educational, respite, day care and formal care service interventions have also shown to improve the quality of life and associated levels of stress related with caring. It is important that any support package addresses all relevant needs to enable caring to continue.
Another consensus was how the medicines affected not only their lives but also the lives of others. PWD have interactions with healthcare and related professionals as well as family and friends. Peter thought the wider circle of people involved with caring for a PWD should be consulted in any monitoring process monitoring efficacy.

“I think it’s two pronged. It’s on the person it’s been given and also the people caring for them because I, people say I look younger now than I have for years. I was worn out. I feel better now than I’ve felt for the last five or six years. I know I keep using the work dramatic but it is. So no I think both the carer or carers and the person having the drug need to be monitored see how it’s affecting their lives.”

Peter, L3

As mentioned earlier carers described loved ones as calmer, more relaxed and less aggressive; this helped day-to-day caring at home but also interactions at day and respite care facilities. This is an important concept to take in to consideration when measuring the benefits of these medicines; the improvements in behaviours, mood and cognitive functioning benefit all those involved; not just the carer and the person with dementia but wider family and caring support networks.

“I haven’t noticed her doing any more better things or being brighter at all but her attitude has changed and, like she went to respite care for a week and they said that she is just a different person and it just makes such a difference.”

Jane, L3

Others spoke of how prior to starting the medication they could see the progression of the illness in their loved one and how this halted on the start of the medication.

“…at the very beginning I could see quite a difference, because you could see it, you could see it progressing, going down hill and then suddenly that stopped when he went on to this drug.”

Wendy, L3

The overall value or worth of these medicines was talked about by a number of participants, mainly with respect to delaying the progression of the illness. This in itself is an interesting concept; that carers would prefer to have their loved ones with them longer even at a moderate to moderately severe stage rather than not treated at all. This is in contradiction to NICE who see medicines for dementia as an inevitable delay in the terminal outcome. These highlight the need for decision-makers rationing access to treatments to take greater account of the values that people taking medicines and those that care for them believe are important.

“I think it’s important for quality of life to remain on them for as long as possible. I think if he hadn’t gone on them he would have dropped off. You don’t know do you because you don’t have control. I think they
should be on it for as long as possible to maintain that quality of life.”

Ann, L1

“I: So would you say that your quality of life as well as your mother’s quality of life has improved?

Oh god yes, oh it’s so much better. I mean if you cared for someone who was constantly unhappy and unwell you would think what is the purpose of their life if they are this unhappy? But now I think there is a purpose for her because she gets up and she’s cheerful and she laughs and we have … she has got a great sense of humour, she always had which disappeared for a while and it has come back and this is really very special to me.”

Jane, L3

The way in which the participants with dementia spoke about the positive effects of their medicines on their day-to-day lives implied quality of life benefits. When Jack (L1) was asked what he understood by the term ‘quality of life’ he replied that it was “When you can do the things you want to be able to do” and that in relation to the tablets he felt this was “immeasurably better.” He went on to say that it was “especially the confidence, presumably this is mostly due to the Aricept.® I don’t know what state I’d be in without them.”

A qualitative study proposed the hypothetical introduction of a new medicine for dementia to 102 caregivers of PWD in the severe stages of dementia and described that it wasn’t a cure and it may also cause gastrointestinal side effects in 3% of people who took it. Carers expressed their opinion that they would risk these side effects if it had beneficial effects on the care-recipient’s quality of life (QoL); even if it prolonged time spent in a particular stage of the illness. This is an important viewpoint for NICE to consider when it next reviews the guidance on the use of AChEIs, as their value-based decision-making is not reflected by PWD and their carers.

Overall carers believed that the medication had positively affected their quality of life; however for some it was difficult to accept that the illness and associated symptoms had not been completely removed. When Jenny (L2) was asked if the medication had affected her own quality of life she replied that it had but “it is still hard for me because I have got it all the time you are never rested either.” However Helen thought any improvement helped, even if it was for a short period of time.

“It’s still that five or six months that he was more confident a bit more confident and so on it was a big help. I mean anything that helps, for any period of time, is just wonderful really when you’re in this situation.”

Helen, L4

Previous research has demonstrated the ability to undertake activities of daily living is strongly associated with improved QoL scores for both PWD and their carers. This is an important consideration for decision and policy makers who act as gateway keepers to these medicines.
In summary the medicines for dementia were seen to be a positive part of the process of living with a degenerative illness; improving the ability to care and also the ability for people with dementia to take part in daily activities.

4.4.3 Issues with Medicines

Although carers and participants with dementia perceived the medicines to have positive benefits on their lives and those supporting them, medicines were not without their problems. These included the experience of adverse effects, being assessed for response to treatment, the complications of concomitant medications and ensuring compliance.

4.4.3.1 Managing Side Effects

As previously mentioned in 2.1.4 the medicines for dementia are associated with many side effects.1-3,33 Interestingly people either experienced no side effects or they were severe enough to warrant co-prescribing of other medicines. Jack (L1) experienced a continually streaming nose and cramps in his feet which were severe enough for him to be prescribed concomitant medication to help alleviate these. Jack felt that “mostly the effects are now positive and you don’t mind side effects if they (the medicines) are working.”

For some though the adverse effects experienced were sufficient for the medication to be stopped. Pat (L1) spoke of how her husband had felt so sick that “he couldn’t lift his feet up, you know he was quite disorientated.” Her husband then said “if this is what they are going to make me feel like I don’t want to take them” so they were stopped and subsequently Reminyl® (an alternative AChEI) was prescribed.

Jill (L1) described how she decided to stop her husband’s medication after he had 3 months of gastrointestinal side effects and “he was feeling stressed and feeling really ill.” Many prescribers are reluctant to prescribe medicines for side effects in elderly people as it can lead to a cascade effect and resultant polypharmacy.319 Supporting evidence from the literature demonstrates that when side effects or lack of response to one AChEI is experienced then a trial with one or both of the remaining agents could lead to an improvement without adverse effect. This allows both carer and the person with dementia to possibly experience the benefits from treatment.

There was variability in how prescribers managed side effects associated with AChEis; some locations offered an alternative agent and others did not. Steve (L4) explained that his wife had been started on Aricept® but could not tolerate the associated nausea and vomiting however when “she was prescribed Reminyl® that didn’t upset her at all.” An experience supported by Mavis (L2) who said “when this one came through it was okay, he has no side effects at all.”

Diane described a severe reaction by her husband, to the starting of Reminyl®, a medication that takes some time to titrate up to an effective dose. What is unclear from her description of the event was whether this panic, anxiety and fear experienced by her husband was due to some return of insight into his illness.
“My husband can’t take them, they put him on Reminyl® and he just went out of his mind completely. He was almost normal before that, just a little memory problem. He’d done the first month, ‘cos there were three stages wasn’t there? As soon as he went on to the second one he was suicidal. He was crying, he was frightened, he couldn’t breathe and very ill, they had to take him off them so he’s on nothing now”.

Diane, L4

This overarching theme of variability in provision of care, medication, information and services is prevalent throughout the data. Each participants’ experience was individual and therefore it became increasingly apparent that generalisations within and across locations could not be made as service provision was so variable.

Peter had a very pragmatic approach to risks of medication; he balanced these with potential benefit in quality of life for himself and his wife for whom he cared, as well as relating these to his concepts of how the illness progressed. This is illustrated in the narrative below when I asked if he had received any information about side effects of the memantine or when it might be withdrawn:

“No she mentioned that there were possibly side effects, well the same with risperidone, the thing of possibly strokes. You know and my argument was that in theory that is what is happening all the time, strokes, little mini strokes, so my attitude is and I made it very clear that it’s quality of life when we’ve got it. You know it’s no good going on forever in hell you might as well as have perhaps a shorter period of time, a very pleasant time, which is what we’ve got but touch wood there doesn’t appear to be any side-effects for (wife) at all.”

Peter, L3.

4.4.3.2 Monitoring and Assessment of Response
A medicine for dementia can only be prescribed with regular monitoring and assessment; with NICE guidance placing an emphasis on the use of the Folstein MMSE. However in practice there is often a battery of tests used to gain a more holistic assessment of response. Carers soon learned the potential limitations and implications of the tests. For example that answers may be easier depending on where the test actually took place and they also knew at what score their loved one was at risk of being taken off the medication.

“But he had one of those mini-mental tests on Monday (3 days previous), the nurse came and did it at home, and he’d gone down to 12 and I know if he had had that done at (Day Hospital) where the consultant is, he wouldn’t have answered as well, cos she said ‘where are you? Do you know what this place is called?’ Well he knew it was his home and that sort of thing but if you go to (Day Hospital) and he never knows where he is or what level, you know, so that was a good score. Because I then said to her ‘well 12 is the borderline, isn’t it for stopping Aricept®’ but she said ‘well they wouldn’t do because its doing him, good, everybody can see that it is.”

Mandy, L4
Mandy’s quote above, highlights a limitation of the MMSE being dependent on where the assessment takes place and not reflecting improvements observed by others. Carers were distressed to think that the decision to continue a medicine could be based on a memory or psychological test score on a specific day as a snapshot when PWD fluctuated on a daily basis.

“People with dementia can have very bad days. If they have a really bad day when they go to the memory clinic; you know they (the prescriber) might not do anything. My mother has been very confused this morning, I got up this morning and she is stuffing all her stuff down the toilet and she has never done this before and this is a very odd thing to do you know and these things just happen on the day. So it’s, this memory clinic is every 6 months don’t really tell you an awful lot I don’t think.”

Jane, L3

Of the participants with dementia, only Thomas could remember the test he had completed. He remembered being told the names of three objects and told he would have to repeat those names back at the end of the consultation.

“When I go down there, well he said “I want you to remember three words and I’ll ask you them at the end” and he forgot to ask me. And he also asked me to draw some shapes and….he asked me about them; “which is the top, which is the bottom,” and he turned it upside down and said “where is the top now” and things like that… I’m not quite sure what he was trying to prove but I think I got them all right and didn’t have a problem with them.”

Thomas, L3

Of the remaining participants with dementia Philip (L4) could not remember what kind of test he had received but he knew that he had to have his dose of Aricept® increased because of the results. Jack and Ann (L1) felt the tests were not appropriate for his level of intelligence.

Ann: “Jack actually got one more point out last time on the short-term memory part of it, so she (psychologist) was quite pleased, but it’s too easy a test for him.”

Jack: “Especially for me ’cos I found them too simple and straightforward.”

Ann: “I think he should be having at some stage the tests he had at the beginning to see the improvement I mean there has been.”

Ann & Jack, L1

It is an interesting concept to consider whether people with higher intellect prior to their diagnosis of dementia, should have a different set of tests during diagnostic and assessment. It has been suggested by others that the MMSE is not an appropriate tool for the continuum for a neurodegenerative illness as it is not sufficiently sensitive in the earlier stages to pick up changes.124-128,130
4.4.3.3 Uncertainly of response
Due to the heterogeneity of dementia PWD exhibit different signs and symptoms which are prominent or problematic for them. For whatever reason not everyone responds overtly to these medicines. Although the benefits of medicines for dementia on care-giver and recipient have been discussed earlier, some carers were unable to clarify exactly how and in what way the medicines were effective. This uncertainty seemed to arise from trying to make a judgement in improvement on a background of disease progression. Was the rate in decline due to the disease or the medication or was it a combination of both?

“Well what I did for a while is wrote everything in my diary and see how she (mother) was on the day. Things that I noticed that were better or worse and I think perhaps they should just give you a piece of paper really and ask you to write something down everyday or whatever to help you along with that. You know I think that is the only way.”

Jane, L3

“But it’s difficult to know what action it does have on the patient, because unless you give it them for x number of months and then stop it, and note any difference, you can’t really tell. Because I mean there’s a downward trend.”

Fred, L4

This latter perception was one that Thomas agreed with when he was asked about how effective he thought his medicine for dementia was.

“I can’t make a comparison on that. The only way I could do that would be say to go a fortnight without and make notes and a fortnight back on again.”

Thomas, L3

Perhaps the difficulty when talking about the effectiveness of a medicine is that it depends on an individuals’ definition of ‘effective’. For many people a medication is seen as a cure, an agent that will fix the problem. For example antibiotics and analgesics are commonly considered to be ‘cures’ for a particular condition. Medicines that ameliorate symptoms are more difficult to judge, especially if the symptoms they ameliorate change on a daily basis. This concept is an interesting one as NICE suggested that as the medicines were not a cure and just delayed the inevitable then perhaps any utility value associated with their use should not be applied. This viewpoint is difficult to uphold when the majority of pharmacological treatments available for cardiovascular disease (for example) are not a cure either; they ameliorate symptoms and improve outcomes.

Jenny (L2) and others however, voiced opinions that “it’s not a cure though is it? I suppose in time they will find one but not in our time. I don’t think there will be a cure for it really, not a complete cure.” This was an interesting concept for some who compared the treatment of dementia to cancer treatment twenty years ago.
“I suppose eventually they might find a cure or at least be able to help more like they do with cancer. So many people survive that now; you know eventually they will won’t they? At one time there was nothing for cancer.”

Mavis, L2

The NDS highlighted the national lack of research co-ordination and funding and suggested it was a similar position to that of cancer research in England in the mid nineties.51 This theme has been expanded in the NDS for greater linking of research on the three key care strategies that have been laid out. These are:

1. Ensure better knowledge about dementia and remove the stigma
2. Ensure early diagnosis, support and treatment for people with dementia and their family and carers
3. Develop services to meet changing needs better.51

4.4.3.4 Stopping treatment
The thought of stopping these medicines left the majority of participants feeling anxious. Mavis described the medicines as a support ‘helping even when they say it isn’t.’ However NICE 2001 guidance suggests that the concept of stopping the medication should be discussed at the point of prescribing.27 The excerpt below from a carer focus group (L4) illustrated the reservations participants held about stopping the medication.

I: “When do you think that these agents should be stopped?”

Sarah: “Never, they go down hill so fast, they are deteriorating all the time and without them their memory will go so much quicker. They’re going down hill with the drug and if that was stopped…”

Paul: “They should keep on ‘em”

Sarah: “You know, we’d never cope. We want to keep them home with us long as possible, don’t we?”

And later

Helen: “It is related isn’t it? Because if we don’t get the support and we go down hill then that worries my children. They’re worried and their families and they’re more involved and so on and it just goes down through the family, affecting everybody involved. Unfortunately it affects everybody’s health really.”

Carer Focus Group 2, L4

It seemed that the medicines were seen as a core part of the support structure to enable caring. As the medicines were perceived to improve activities of daily living, behaviours, mood and communication these were all improvements which could mitigate the associated stressors of caring170,171,177 and the sense of loss experienced as a carer.166,304 Although carers were aware that the medication had to be stopped at some stage there was great uncertainty and fear associated with this thought.
“I’m too terrified to stop it because of the adverse effects. I’m quite happy for it to carry on.”

Doris L1

Ann felt that stopping the medication would adversely affect both Jacks’ and her quality of life as she narrated below:

“I think it’s important for quality of life to remain on them for as long as possible. I think if he hadn’t gone on them he would have dropped off. You don’t know do you because you don’t have control. I think they should be on it for as long as possible to maintain that quality of life.”

Ann, L1

When participants with dementia were asked how they felt about the possibility of having their medication for dementia stopped Thomas (L3) replied that he would “probably do a test on myself by stopping it for a week to see if there was any difference in my behaviour and then go back on them perhaps.”

Jack thought the medication should only be stopped “when you die. They should ask other people as well.” He went on to explain that all those involved in the support of PWD should be involved in any decision to stop medication.

“Carers, friends and family. Other people that are involved like grandchildren, and our children and I hope they will be asked as well.”

Jack, L1

This is a very interesting comment because without exception, all participants with dementia recognised that their behaviour affected other people as well as their carers and that this was, or could be, modified by the medication. Again an important concept for policy and decision-makers to consider in the next guidance review.31

4.4.3.5 Concomitant Illness and Medication

With concomitant illness came concomitant medication and when there were a number of medicines being taken together it was difficult for carers and participant with dementia to know which agent was causing which effect.

“But it is a concoction of tablets, the things they take now you don’t know whether they are working against one another.”

Wendy, L3

Concomitant medication was a problem for Jack because three other medicines had been started at the same time as his medicine for dementia. To add further difficulty there had been subsequent changes to his medication regimen as well.

“It is difficult to know which ones are the side effects of the condition and which ones are side effects of the medication. They have actually
changed medication. It’s sort of evolved since we started. There are certain ones we don’t take now.”

Jack, L1

In summary the presence of concomitant illness and associated medication complicated not only knowing which medication was causing which good or adverse effect but also affected the overall physical frailty of the individual and carer workload.

4.4.3.6 Ensuring Compliance

Before a medication can be taken, a prescription needs to be generated so that it can be cashed at a pharmacy. Obtaining a repeat prescription could be a very complex task as in most locations the medicines for dementia had to be ordered via a specialist prescriber. There was great variability in how these were accessed; some prescriptions were posted directly to peoples’ homes, others had to be collected from specialist services and yet others from their GP.

In terms of keeping track of medication, prescriptions from hospital consultants invariably had insufficient quantities ordered to last until their next appointment. Some carers newly started on medicines were unsure about how to get further supplies and other carers spoke of how they had to telephone the consultant’s secretary to ensure sufficient supply.

“Luckily I kept the appointment card and on the appointment card it says the consultant’s secretary’s name. So I had to ring her and get her to send me a prescription through the post and then it didn’t come. So then I would have to ring again and she was on holiday so you would have to talk to somebody else and they’ve huge huge files because otherwise he would have no tablets and this happened, I would think, at least half a dozen times and that is so bad, just unbelievable.”

Sue, L2

Thomas was the only participant with dementia who had responsibility for ordering and cashing in his own prescriptions for his medicines. His experience was that even once you had a prescription it didn’t necessarily mean it could be filled. He had to remember to order at least a week in advance so his local pharmacy could order the medicines in.

“I just go down to the surgery and get a prescription, take it round and they say come back, because they take four or five or 5 days to get, because they don’t keep them in stock, my little chemist.”

Thomas, L3

NICE 2001 stated that the issue of compliance needed to be discussed with the patient and their carer prior to an AChEI being prescribed.27 This guidance does not speak of adherence, a term which suggests that the person taking a medication is fully informed of the treatment and able to ensure continued self administration; rather it talks of compliance which is a more paternalistic approach where a medication is prescribed and the directions have to be complied with.300 Carer participants spoke about a general assumption that they would take responsibility to supervise medication taking and the whole process
involved with this; for example the ordering, collection and cashing of prescriptions.

In most relationships there is generally one partner who takes care of the medication associated responsibilities and as Wendy (L3) explained “it’s just as we are together, yes they assume that” carers will ensure compliance with the medication regimen. Mary stated “I have always done his tablets” and continued she had to take responsibility for compliance to ensure the medicine was actually taken.

“He doesn’t remember to take anything at all, he wouldn’t take any drugs if I didn’t give them to him, you know they have got no idea about drugs, he wouldn’t know he was on this drug unless I give it to him at night before he goes to bed.”

Mary, L3

Thomas lived alone and had developed a system of having a piece of paper with a weekly grid on as a medicine reminder. (Thomas took three medicines in total and could remember their names and the dosing frequency.) As he took each of his medicines, he would put a tick in the appropriate weekday next to the medication name.

“I have a piece of paper on the kitchen table. I take three pills. Aricept®, and aspirin; that I’ve been taking since I had a TIA many years ago, I was told to keep on taking it for life, it won’t do you any harm, and omega-3 (fish oil). And a piece of paper in the kitchen and there is Monday, Tuesday, Wednesday, Thursday, Friday, three different columns and as I take them I tick them off. I know I don’t take them twice and I know I don’t miss them.”

Thomas L3

A medication regimen becomes more complex with concomitant illness. It is well known that many older people have greater than one medical condition and consequently take a number of regular medicines each day. Some of these medicines have a narrow therapeutic range, for example digoxin and warfarin as highlighted in the transcript below, and adverse effects can be potentially life threatening if the correct dose is not given.

“I would say probably two years ago I started putting them in those little boxes for the day and I would leave them on top of the fridge and he would take them. Then I discovered he was taking double lots in one day and he was taking none for two days. So then I had to start leaving them on top of the fridge and me doing it. Then I found that he would find them so then I had to hide them and I had to keep hiding them in different places. Oh dear, and I couldn’t remember where I put them myself. Anyway we did cope; we did cope with administering them, so that was ok.”

Sue, L2

Ensuring the correct medication was taken became an onerous duty for some carers and Ann explained that even by using compliance devices for medication did not ensure the person gets the right medication at the right time.
“I wasn’t told I had to do it (administer the medicine) but Jack was having such trouble opening all the packets in the morning and in the end we’ve been on this tablet tower* now for nine months or something.”

Ann, L1

* (compliance-aid type device with daily slots for taking medicines at four different times during the day)

Jack said he found the tablet tower very helpful and added “I generally remember them but I have to get her to check sometimes.” However filling the tablet tower was time consuming taking an hour and a half every week. Ann viewed this as a negative effect of the medication for dementia, although to be fair Jack was on ten medicines in total; only three of those related to the dementia. Further complications arise if concomitant prescriptions have not been started at the same time as they will then be out of sync with each other and not ordered at the same time each month. The ability to deal with these issues can become quite taxing for some people and as Jane explained,

“Now I am capable to do this but there are a lot of elderly partners caring for their spouses they might lose track somewhere along the line.”

Jane, L3

As dementia progresses people may lose their ability to swallow solid forms of medication and so carers were given liquid options and/or they decided to crush medication in food.

“No, we have got a lot now in liquid because it was beginning to get where he wouldn’t swallow them and so what we can we get in liquid. …The quetiapine and these; I got a grinder now and I put it in, so I grind the two together and put them into yoghurt, smooth yoghurt because he’ll even find a pip and go puh (spits it out).”

Pat, L1

As can be ascertained from the above examples there is a large responsibility associated with compliance; but one that was seen as important by both carers and PWD. A study of people with chronic illness found that if people perceived a higher necessity for the medicine (in terms of potential benefits) then they were more likely to also report higher rates of adherence to a treatment regimen. What was interesting from my perspective was that there had been no proactive advice from pharmacists on either medication administration or managing adherence to the prescribed regimen. Some of these situations, especially the crushing of medication into food can have negative effect on the efficacy of the medication and possible adverse effects for the individual.
From the narratives of carers the following practice areas could be helped or supported by community and primary care pharmacists becoming involved in the provision of medicines for dementia.

These were:
- The appropriateness of concomitant medication,
- swallowing difficulties and the safe administration of medicines,
- helping compliance issues proactively, addressing repeat prescribing problems, and
- ensuring proactive provision of information.

4.5 Summary of Key Findings

What was striking was the sheer hard work that being a carer entailed. It seemed to be a life changing event which was all encompassing. The most distressing part of this was the variability in support, access to treatment or information and/or specialist services all of which were complicated by the variability in response by healthcare professionals. The objectives of phase one are discussed in relation to the findings next.

Delayed access to support services such as respite or day care led to a breakdown in the carers’ ability to continue coping. Support and information needs to be offered earlier and at frequent intervals throughout the caring process as the experienced burden does change over time in response to the degenerative process and its effect on the person being cared for. There also needs to be some method of ensuring equity in treatment access, services and information offered.

Participants reported a diverse range of improvements to medicines for dementia including: effects on personality, mood and behaviour and quality of life. There were also improvements in activities of daily living, mobility, socialisation and communication skills and engagement in their environment. There was a perception that these benefits were apparent for some time before lessening.

People with dementia were, in the main, able to talk about the benefits of the medication and how it had enabled them to take part in life again. Important outcomes for them and their carers seemed to be an increase in sociability and taking part in daily routine activities around the house. Carers experienced the medicines as making it easier to care for their loved one because of improved mood, sociability and attitude. Even though memory did not seem to improve much overall, this seemed mitigated by the ability of PWD to take part in conversations and interact with people. These perceptions were endorsed by family, friends and healthcare professionals.

It also seemed that healthcare professionals required education and training in the very basic skills of consultation etiquette and determination of whether
consultations needed to be together or apart or both. The expectations and needs of both the person with dementia and their carer need to be addressed within a consultation to ensure that the therapeutic relationship can develop and be trusted and also that all parties arrive at a mutually agreeable decision. However there is a need for healthcare professionals to be proactive in providing support and information. Findings suggest that community pharmacists could have a role in supporting medicine management issues such as the management of side effects; compliance, administration of medicines and ensuring the appropriateness of concomitant medication. Provision of general information on maintaining good physical and mental health as well as information about local dementia services would also be appropriate.

There was a perception of incomprehension of the methods used to monitor the effects of the treatment and the environment in which this took place. This was compounded when carers felt their viewpoints were ignored or not sought within a consultation especially if the person they cared for fluctuated in ability on a daily basis. It seems that further research is needed to agree outcomes to treatment that are important to the person with dementia, their carer and the prescriber.

Caring can be an onerous and lonely task; good supportive therapeutic relationships can help ease the perception of this burden by the carer and support the continued ability for caring at home.

The findings from this phase of the study were paramount in designing the second phase of the study, which explored the longitudinal affect and effects of medicines for dementia in people with early disease. This will be explained in greater depth in Chapter Five.
CHAPTER FIVE: METHODOLOGY & METHODS PHASE TWO

5.1 Introduction

Findings from phase one suggested that the effects produced by a medicine for dementia were similar for all agents and that key concerns were side effects, withdrawal and access to treatment and information. Concerns were also raised about the appropriateness of the objective measures used to assess efficacy and the perceived poor level of participation in decision-making.

The second phase of the study was a longitudinal study which aimed to explore what happened in actual clinical practice in mild dementia when any medicine for dementia was started, with-held or withdrawn. Case study research methodology is designed to explore a situation in which an intervention being evaluated has no clear single set of outcomes. In this research the situation was the day-to-day lives of the person taking the medication and their carer. The intervention was the initiation of a medicine for dementia (or not). The outcomes were multifactorial, as these medicines are known and were shown in the previous chapter to affect a range of domains including: the physical, mental, social and behavioural health of the person taking these agents and those of their carer. These domains can also affect quality of life and the wider social environment such as interaction with family and friends.

5.2 Case Study Methodology

Case study methodology allows a combination of methods to be used to explore a given situation; for example data resulting from both qualitative and quantitative methods can be used to triangulate results. Historically triangulation with quantitative methods has been used in qualitative research as an attempt to justify the robustness of findings and improve transferability or generalisability of findings. Another perspective is that methodological triangulation can offer “a more holistic perspective” of findings in complex situations.

Case study methodology can be explanatory, descriptive or exploratory. This flexibility is one of the reasons why it has been used for a diversity of research subjects as it can support investigation and interrogation of events within contexts such as large organisations; individual case events; or political and historical events. However it is increasingly being used in educational research and health services research.

5.2.1 Case Study Methodology in Health Service Research

At the focus of any healthcare intervention is a patient and in the delivery or monitoring of the intervention is a HCP. So from the start there may be at least two viewpoints on outcome success or failure. As with any healthcare intervention; there are ripple effects of the treatment as experienced by family, carers, relatives, friends and other HCPs. Healthcare research can be very complex and by using different methodologies within a case study framework;
complexities of healthcare interventions can be explored from a number of perspectives. This enables a holistic interpretation of the findings and may improve transferability of findings.\textsuperscript{321} It has been suggested that a case study approach is suitable for palliative care research because it “is a realistic study of practice” and that it “has the potential to contribute to knowledge accumulation.”\textsuperscript{325} This ethos could be applied to most healthcare specialties.

The majority of studies published using single case study design attempted to develop a greater understanding of the reasons behind why a particular process,\textsuperscript{330} event,\textsuperscript{327} or care intervention,\textsuperscript{328} worked effectively or otherwise within a single environment. Multiple case study design was used when differences in behaviours and attitudes towards the intervention being studied was suspected.\textsuperscript{331-333} However case study methodology should not be viewed as a “catch all,” for a mixed methods approach but as the best choice after a rigorous investigation of other potential methodologies has been made by the researcher.\textsuperscript{320,322-324}

There are at least three views on the methodological implications of case study research: those proposed by Yin,\textsuperscript{326} Walsh,\textsuperscript{325} and Mayes and Pope\textsuperscript{331} will be briefly outlined here. Yin holds the view that case study research is a methodology in its own right stating that qualitative and quantitative techniques “are part of the case study arsenal.”\textsuperscript{326} Mays and Pope\textsuperscript{331} suggest case study research falls under the umbrella of qualitative methodology, with Walsh\textsuperscript{325} describing it as “an approach or strategy, not a methodology.” This viewpoint enables researchers to use a number of different data collection methods as long as they are appropriate to the study question.\textsuperscript{325}

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can see the different perspectives outlined above with their associated benefits and theoretical constructs. To me, Yin seems to want to replicate theory and if opposite theories are found he suggests changing criteria and/or sites until there is one theoretical truth.\textsuperscript{320,326} However the ethos of qualitative methodology is to explore all truths, not just one. I don’t believe that case study research falls into just the qualitative or quantitative camp as an entirety either\textsuperscript{331} and perhaps favour Walsh’s\textsuperscript{325} hypothesis that case study research is an approach rather than a methodology. With this approach I can as the researcher choose the most appropriate methods and methodologies for the research question whilst still being aware for the need for quality throughout the research process.</td>
</tr>
</tbody>
</table>

5.2.2 Quality Issues in Case Research Methodology

Interestingly a widespread misunderstanding of the validity and quality of findings from case study methodology has been reported\textsuperscript{320,326,334} with Yin\textsuperscript{326} calling for increased attention to the need for quality in case study design. It is therefore important to ensure that the underlying principles for improving the quality of research are followed. These principles have been well defined by
many and research design should include attention to: construct validity, internal validity, external validity and reliability.

5.2.2.1 Construct Validity
In case study design, construct validity requires the researcher to ensure they employ the most appropriate tool (or set of) to measure outcomes being investigated. Criticism can arise if all measures are completely subjective as findings can be experienced as having no real tangible objective standpoint. In fact, there has been misunderstanding of the value of qualitative methodology in health services research. It has been proposed that qualitative data can describe and explain behaviours behind results of randomised controlled trials to improve understanding of findings. That is the use of methodological triangulation can improve construct validity of the research design and understanding of findings.

Point of Reflexivity

It is my belief that if the views and beliefs of a healthcare, educational or social intervention is required then a qualitative methodology is the most appropriate. Unfortunately for some readers of such research there are few numbers to compute relevance in a way which is meaningful for them. It is interesting that I now feel that every randomised controlled trial or clinical study needs a qualitative arm to actually explore things that are important to the subject receiving the intervention, as well as those outcome measures important to the researcher or prescriber.

In this study, there were 4 sources of evidence which could be linked to one of the study objectives (see 5.3). These were:

1. Interview data from up to four participant sub-groups.
2. Observation of consultations to observe the extent of shared decision-making.
3. Patient shared care records to access objective documentation.
4. Diary records of participants.

5.2.2.2 Internal Validity (for explanatory and causal design)
Internal validity in case study design is to ensure that the method of analysis is decided prior to starting data collection to ensure data collection is focussed. Yin has suggested that the use of pattern-making (thematic analysis); explanation building (theory building) or logic models can help to ensure internal validity.

These suggestions can be viewed as equivalent to the inductive thematic analytical process involved with interpretative phenomenological analysis. In IPA findings are interrogated and re-analysed until an overall thematic picture of the findings evolves. These findings are described in the narrative of the research participants and can be linked to individuals’ life experience. The
subsequent layers of analysis results in a taxonomy (classification system) of superordinate and subordinate themes (see 3.4.3.2 and 4.1). \(^{277,278}\)

Each individual case was to be analysed separately to ensure that there was both descriptive and explanatory discussion on the findings. This taxonomy or thematic overview also in a sense uses ‘pattern-making’ as a form of analysis in that it looks for ‘patterns’ (i.e. themes), which emerge from the data as a result of the participant experience. \(^{278}\) This in turn leads to a synthesis and discussion of the findings to offer an explanation of the participant perspective. \(^{323,329,337,338}\)

**5.2.2.3 External Validity**

If the internal validity processes are robust then there is the generation of analytical theory which can lead to an understanding of which contexts and/or domains the study findings can be generalised or applied to. \(^{320,337,338}\) Yin states that single case studies are like experiments, in that the results cannot be generalised to population groups but they can be generalised in terms of the analytical theory developed. \(^{320}\) This analytical theory if replicated in one or more case study sites with similar findings could lend itself to supporting the theory and by inference may be generalisable to other similar contexts. (i.e. ‘replication logic’ as termed by Yin). \(^{320}\) This stance is heavily dependent on using replication logic (which could possibly be perceived as interrogating data for supportive and/or deviant themes). Other researchers \(^{339}\) believe that qualitative findings cannot be generalisable because they relate to a specific group of participants at a specific point in time. However Lewis and Ritchie \(^{340}\) propose that qualitative findings can have ‘inherent transferability’ (i.e. that one could infer findings would be similar in a similar population group. Similarly the term ‘naturalistic generalisation’ by Lincoln and Guba \(^{311}\) has been used to describe generalisability as dependent on the location or site findings are being transferred from and then to.

**5.2.2.4 Reliability**

An important principle for ensuring the validity and quality of the results is to ensure that the approach to data collection and the process of data collection is the same within and across each case study. If data collection procedures are the same for each it means that the study can theoretically be repeated and the same results obtained. However in qualitative analysis much is dependent on the background and life experience of the researcher involved in the interpretation of findings, so this is not always the case.

In case study research it has been recommended that a Case Study Protocol is produced prior to starting data collection to ensure a thorough investigation of the proposed data collection and analytical methodologies has occurred. \(^{320,326,330}\) The Case Study Protocol should provide an overview of the case study project; the procedures for field work; the research questions and an outline for the preparation of the Case Study Report. \(^{320}\) The Case Study Protocol for this study can be found at Appendix A5-1.

Another recommendation to improve quality of case study research is to keep a clearly defined Case Study Database. \(^{320,326,329}\) Theoretically this is so that any researcher with access to the Case Study Database could replicate the ethos of the study in different locations. \(^{317,339}\)
The Case Study Database for this study includes; taped interview recordings; digital recordings of interviews; all interview transcripts (anonymised); the observation tool; the observation data recorded as field notes; diary records and relevant anonymised data accessed from patient shared records in tabular format. Where possible the electronic data is in a separate folder on the University hard drive and also backed up on a password protected data stick. Written data is filed in a secure and locked cupboard within a locked room along with the original tape recordings to fulfil Data Protection Act requirements.\textsuperscript{265,267}

\subsection*{5.2.2.5 Alternative Quality Structures}
An alternative method of assessing the quality of qualitative research in its independent components (i.e. the interview or observational data) has been described by Mays and Pope.\textsuperscript{331,342} They suggest that "systematic and self-conscious research design, data collection, interpretations and communication" will ensure rigour and quality.\textsuperscript{331,342} The authors suggest that an account of the method, process and data should also be kept (akin to the Case Study Protocol).\textsuperscript{343} Interestingly in 2000 they debate the relativist criteria for quality and suggest that triangulation, respondent validation, an account of the process of the data collection and analysis, attention to negative cases and reflexivity as a researcher can all contribute to improving the validity of findings.\textsuperscript{342}

\begin{table}[h]
\centering
\begin{tabular}{|c|}
\hline
Point of Reflexivity  \\
\hline
Researcher reflexivity defines the process of continually acknowledging the dynamic between the researcher, data collection and interaction with participants of the study. IPA demands that the researcher views findings from the perspective of the lived experience of the participant and not from their own perspective. This can be challenging as it means being aware of your own lived experience and ensuring this does not colour interpretation of the participants.' \\
\hline
\end{tabular}
\end{table}

\subsection*{5.2.3 Case Study Design for Phase Two}
In 4.5 the findings from phase one were briefly discussed with relation to how they influenced the study design for phase two. The findings were diverse and what was wanted was to explore these in greater depth within a set context; the context of taking (or not) a specific pharmacological agent for dementia.

\begin{quote}
"A case study is an empirical inquiry that; investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident."\textsuperscript{320}
\end{quote}

People with newly diagnosed mild dementia were to be recruited from participating memory clinics using purposeful sampling\textsuperscript{332} to complete the proposed case study framework. It could be argued that in case study methodology, there is no real sampling process as the design of the case study itself is pre-determined by theory development (i.e. the unanswered research
questions). Theory development in turn leads to case selection to fulfil the specific aims of the research.

In this phase the underlying premise was that the effect on daily life (phenomenon) of the person taking the medicine for dementia was similar no matter which of the four licensed medicines were taken (context). The remaining 3 cases were purposefully selected to represent common care scenarios described by clinicians working within memory clinics which challenged decision-making and clinical management. It was proposed the case study framework would consist of 8 case studies in total:

1. one where the medicine for dementia was donepezil;
2. one where the medicine for dementia was rivastigmine;
3. one where the medicine for dementia was galantamine;
4. one where the medicine for dementia was is memantine;
5. one where a cholinesterase inhibitor was taken in combination with memantine;
6. one where the medicine for dementia has been withdrawn due either to adverse effects or lack of efficacy;
7. one where the person refused treatment, and
8. one where the person was ineligible for treatment (perhaps due to an unproven condition such as mild cognitive impairment).

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Originally it was proposed to recruit to 7 case studies; the extra one was case study 5 which was suggested by a clinician as an area which challenged prescribing decisions and also an area where there was limited evidence of efficacy.</td>
</tr>
</tbody>
</table>

The potential participant members of each case study group included: the person with dementia, their carer; the prescriber of the medicine for dementia and a HCP providing dementia-related support if appropriate (e.g. a community psychiatric nurse, psychologist).

### 5.3 Aims and Objectives

The second phase was a longitudinal study designed to explore the effects of medicines on the daily lives of people with early dementia and their carers over time. The objectives of this part of the study were to:

1. explore lay and healthcare professional perceptions of the outcomes of medicines for dementia.
2. explore whether there was consensus on perceived efficacy over time.
3. explore perceptions on how medicines for dementia should be used in early dementia.
4. to highlight the potential role of the pharmacist in supporting medication use in people with early dementia and their carers.
5. to identify possible areas of educational need for healthcare professionals.

It was proposed that findings from this study would provide qualitative and quantitative evidence of perceived effects of medicines for dementia in a naturalistic setting. It might also establish insight into the perceived effect on carer's ability to cope. The results could also provide information to aid in the education and training of HCPs involved in the prescribing process.

5.4 Methodology

As previously mentioned a case study approach was chosen as a means of being able to explore and describe the contextual event of a medicine for dementia being prescribed (or not) on the phenomenon of day-to-day life. Eight case studies were to be recruited to and the participants of each case study group were to be followed-up over a period of up to 12 months (dependent on the emergence of new findings).

5.4.1 Methods

In this case study qualitative data would be gained from face-to-face interviews; observation of prescribing consultations and diary entries. Quantitative data would include objective measurements of neuropsychiatric testing found in the shared care record.

5.4.1.1 Face-to-face Interviews

The participants with dementia or a memory problem were the hub of the case and in all there were up to four units of analysis in terms of the interviews, embedded in each case study. These were data from people with the memory problem; their carers; their prescriber and if appropriate a HCP involved in dementia-related care.

The purpose of the interviews with prescribers and HCPs was to explore whether findings from lay participant interviews were supported and to explore HCP viewpoints on medicines for dementia. This group were to be interviewed on a single occasion. Interview methodology was the most suitable for this part of the study as it would allow greater exploration of the individuals experience and beliefs. Qualitative research has been described as “reaching the parts other methods cannot reach” so that greater understanding of people’s experiences within healthcare may be gained. 343

Timeframe of Interviews for People with Dementia and their Carers

Originally interviews were planned at:

- Baseline: to explore expectations and hopes associated with taking a medicine for dementia
- At 3 to 4 weeks after starting a medicine for dementia: to explore occurrence of side effects; severity and management if appropriate. This time period was chosen as it can take at least 3 to 4 weeks to titrate to an effective dose and often people taking these medicines experience side
effects at this time. Also at the start of the study people were recalled at this time for follow-up and monitoring.

- At 3 months: to explore effects on day to day life
- At 6 months: to explore effects over time.

However the actual number of interviews completed per participant would be dependent on new findings arising from the data.

**Development of the Topic Guide**

The Topic Guide can be found in Appendix A5-2 and was designed to explore the following:

- Expectations of the medication
- Information given about the medication
- Any compliance issues
- Positive and negative effects on day-to-day life
- Any other concerns or thoughts

The Topic Guide was a tool used to cover the research area of interest rather than a didactic process of interaction. Questions could be reworded according to understanding and arrive in any order dependent on the flow of the current conversation. Case study research is focussed on what is happening in context; i.e. in real life so an open, semi-structured approach was proposed to facilitate a conversational style of interaction.  

### 5.4.1.2 Observation of Consultations

It has been suggested observational research methods provide us with insight into *why they (people) do what they do.* As part of the data collection, the intention was to observe one consultation with the prescriber to explore the level of decision-making and involvement lay participants had. This was an area which participants from phase one had reported as being a challenge. Rather than accepting individuals accounts of behaviours and events that occur within a consultation; an observation study allows the researcher to observe and document those that actually happen. It was proposed to use a non-participant observer approach to directly (but discreetly) observe behaviours and social interactions within the consultation to develop an explanation of what behaviours were exhibited by each participant.

It is important to note that participants may naturally change their behaviour when they know they are being observed, however it is increasingly common in healthcare settings that there is an observer present as a matter of routine. It seems that patients and HCPs seem less disturbed by a non-participant observer than individuals in other settings. Dallos suggests that it may be difficult for some observers in naturalistic settings to remain wholly non-participant or wholly participant. To reduce the risk of this occurrence I would be seated in a discrete position out of eye contact of each of the consultation participants.

It was proposed that 3-months into the case study, participants would be asked for their consent and written permission to be observed in a consultation with their prescriber. (A5-3) Once this had been established the next appointment would be ascertained and then the prescriber approached separately for written consent. (A5-3)
The observations were not to be audio-recorded but an observation tool (See Appendix A5-4) and field notes were to be used to collect data on shared decision-making and patient-centredness of the consultation.

**Development of the Observation Tool**

One of the pivotal frameworks for measuring and teaching patient-centred consultations with an emphasis on shared decision-making has been the Calgary Cambridge Guide (CCG). This was primarily introduced as a teaching aid in primary care general medicine\(^\text{211}\) but is now used in undergraduate medical and some postgraduate pharmacy curricula’s.

There has been one tool designed to capture shared decision-making within primary care consultations for people with a mental illness.\(^\text{348}\) The OPTION tool contains questions which both observer and the patient use to rate perceived level of shared decision-making at the end of the consultation.\(^\text{348}\) However the phrases were difficult to define meaning in a reliable manner so it appeared an inappropriate tool for this study. The study observation tool drew on content from the CCG, and an assessment tool for patient-centredness of a consultation used in postgraduate communication skills teaching. It can be found in A5-4).

**5.4.1.3 Diary Records**

A finding from phase one (4.4.2.2) highlighted that it was difficult for carers to identify exactly what had changed after medication was started. It seemed appropriate to suggest that participants kept a written record of their progress soon after starting a medicine for dementia. At the first interview carer participants were given the option of using a diary in between interviews to record thoughts and feelings of medication effects.

The use of diary records has frequently been used in qualitative research as a means of attempting to develop explanatory accounts for behaviours and events and/or evidence to support an intervention.\(^\text{349,350}\) They are increasingly being used in health services research as a means of recording patient responses to care interventions such as surgery\(^\text{351}\) or asthma,\(^\text{352}\) with evidence to show that people prefer electronic diaries for ease of access.\(^\text{349,350}\)

The advantages of using diary records is their flexibility in design, their ability to be used in combination with other methods and that they can minimise memory problems if used immediately after event.\(^\text{349}\) The limitations have been described as cost, selection and inaccuracy biases.\(^\text{349}\)

In this study the diaries were to be offered to carers as a means of recording response to any pre-selected goals of the treatment they may have chosen.

**5.4.1.4 Patient Shared Care Records**

Patient shared care records would be accessed at the end of the qualitative data collection and objective data such as the results from neuropsychiatric testing and comments made by the data entrant would be collated. As memory clinics use validated tests to measure an objective response a method of substantiating claims of lay participants would be to access these data and relate these objective findings to the subjective phenomenon experienced.
5.4.2 Recruitment

5.4.2.1 Selection of Recruitment Sites
It was proposed to recruit people newly diagnosed with dementia from specialist memory clinics. This was because at the time of the study all diagnostic and prescribing decisions had to be made by a specialist at a specialist centre and these were often made at memory clinics.

I had already been involved in some collaborative grant proposals at a local research memory clinic and attended a number of their Carer Advisory Group meetings as a consequence. The staff at the centre were supportive of the proposed research and their increased activity into recruitment was seen to be as a trade off (if you like) for my involvement in study steering groups and in design of research proposals. I had also made links to another local memory clinic where staff positively encouraged a qualitative approach as they felt this was an area which was under-represented in dementia research. It seemed that these would be appropriate sites for recruitment of potential participants for Phase Two.

Unexpectedly slow recruitment necessitated an increase in the number of locations to recruit from; finally resulting in a total of 6 sites (see 5.7). Three sites provided memory clinic services from community hospitals and two from general hospital sites as part of the local Mental Health Trust and one was a charity-based memory clinic.

5.4.2.2 Participant Recruitment
Participants with dementia and their carers were to be recruited from one of the above sites. At each site a gatekeeper to the research was responsible for identifying possible participants who attended their clinic and informing them of the study and providing an information pack if appropriate. (See A5-5). This process meant the gatekeeper could identify people with capacity for informed consent and who fulfilled inclusion and exclusion criteria. If people were interested in the study they were invited to contact the lead researcher directly. Alternatively gatekeepers could opt to recruit possible participants via a joint letter from themselves and the researcher. (See A5-6)

Once contacted either after receiving an expression of interest the lead researcher would then speak directly to the potential participant and give further information and discuss the need for informed consent. If participants agreed to take part then an interview was arranged.

5.4.2.3 Inclusion and Exclusion Criteria
All people who attended a participating memory clinic with newly diagnosed mild dementia and satisfied the inclusion criteria of being able to give informed consent were eligible to take part. The carers, prescribers and dementia-related
HCPs who supported the person agreeing to participate were also eligible to take part; but approached after the person with dementia or a memory problem had been recruited.

Memory clinic staff excluded potential participants who they felt did not fulfil inclusion criteria, or who did not speak English or who were deaf as the use of interpreters and/or signers would have brought an added dimension we did not wish to pursue.

5.4.3 Data Collection and Management
In summary both subjective and objective data was to be collected. Subjective data included:
  - the experiences and viewpoints of the person with dementia, their carer, prescriber and/or HCPs about the efficacy of the medication and/or treatment success over time (interviews and diary records), and
  - the observational findings from a consultation between the prescriber and the person with the memory problem or dementia.

The objective data would be the results of in-house measurement scales of treatment efficacy accessed via the shared care record.

5.4.3.1 Interview data

**Recording and Transcribing**
All interviews were to be recorded with informed signed consent and transcribed verbatim removing identifiable phrases and organisations. (A5-7) If consent for recording was not given then hand written notes would be taken. Interviews were intended to be completed separately to minimise any possible negative effect of narrative spoken in front of others. The recording devices used were a cassette and digital recorder with multi-directional microphone.

The transcribing, verification and confidentiality processes followed the same process as outlined in 3.4.3.1.

**Coding and Analysis**
After transcription the data was to be sorted, organised and indexed into categories. These categories would be further interrogated and grouped together in order to clarify the relationships between categories and to refine emerging ideas. The emerging theory was to be tested for deviant (that is data, ideas or relationships that did not fit the emerging pattern) and common themes arising. The analysis of the qualitative data analysis would be via the same process as outlined in 4.1.

5.4.3.2 Observation Data

**Recording of Observed Data**
Although an observation tool was developed; the data collection would mainly be in narrative form so that a description of the event could be made and the behaviours associated with shared decision-making explored in greater detail. One drawback was the consultations were not to be audio or visually recorded and this could mean observer selectivity and perhaps missing salient points.
As a means of reducing this risk, I spoke into the recording device immediately after a consultation in order to note down feelings, thoughts and findings from the observed session before the event reduced in clarity in my mind. Dallos describes this process as “self-reflection” and feels that this may aid the researcher to understand what the experience of being the observer felt like and associated atmospheres and behaviours before they were lost in time.\(^{347}\)

**Analysis of Coded Data**

Although the process of self-reflection described above is an important aspect of supporting field notes; the researcher must not start making interpretative inferences about the nature of the observation before all data has been gathered and the analytical process started.\(^{347}\) This is so that memorable events within the observed period (for example distress; or disagreements) do not cloud the perspective of the rest of the session which may have been based on sound and appropriate social and psychological interaction.\(^{347}\)

The data from the observed consultations would arise from the narrative within the observation tool to provide a descriptive and explanatory account of how individual behaviours supported (or otherwise) a shared decision-making focus.

**5.4.3.3 Diary Data**

Small A5 sized notebooks would be offered to all participants for them to record any thoughts or feelings about their experiences of a medicine for dementia throughout the study. Notebooks were used as diaries as the delayed recruitment process affected the proposed start and the use of a dated diary format.

As the diary would form a naturalistic approach to data collection the text or narrative would be appropriate to support qualitative findings from other parts of the study. The narrative could be seen as a means of adding depth and explanation to findings. Narrative within diaries can be transcribed verbatim and then analysis aided by a qualitative data handling package such as NVivo\(^\text{®}\) so that thematic interpretation can occur as another level of data enquiry.\(^{282}\)

**5.4.3.4 Patient Shared Record Data**

A data collection form was prepared (see Appendix A5-8) to collect relevant participant data from the specific time frame of the study. All data collected was anonymised and to take place at the appropriate study site. Access to shared care records was possible because participants signed a consent forms requesting their permission (see A5-7) and the researcher had an honorary contract with the healthcare trust.

An application process had to be made to gain access to the records and this stage of the data collection was completed once all qualitative data from interviews and consultation observations was concluded. Data findings would be tabulated and used as a strand within the case analysis to lend depth and description to the qualitative findings. A diagrammatic overview can be found in table 5.1 below.
**Figure 5.1: Overview of Case Study Methodology**

![Diagram of Case Study Methodology]

**KEY**
- **CS** = Case study
- **PWD** = Participant with dementia
- **Rx** = Prescriber
- **HCP** = Dementia-related healthcare professional
- **SCR** = shared care record
- **IVs** = interviews
- **Obs.** = observed consultation

### 5.5 Ethical Considerations

As discussed in 3.3, both people with dementia and their carers are described as vulnerable subjects in research, and as NHS HCPs were to be recruited, research ethics approval was needed.

#### 5.5.1 The Process

The study protocol had been submitted to the Department of Pharmacy and Pharmacology Ethics Approval of Research Proposals - Peer Review Process and reviewed by Dr Jenny Scott and a photocopy of her comments can be found in Appendix A5-9]. The study proposal had also been successfully submitted for funding as a Galen Award managed by the Pharmacy Practice Research Trust (PPRT) at the Royal Pharmaceutical Society of Great Britain (RPSGB) in August 2005. This process of application provided for an external review of the study design and methodology by the PPRT panel.

The study was discussed at the Swindon LREC meeting on 1st December 2005 and eventual approval was granted on 1st February 2006. (A5-10) In the intervening period procedural changes in the two original recruitment sites required a substantial amendment to approve changes to revised information...
leaflets and recruitment process. This was granted on 21st April 2006 allowing recruitment to begin. (A5-11). Subsequent to this recruitment was poor and one of the recruitment sites dropped out requiring further substantial amendments to allow for 4 further sites and changes in recruitment procedures. (A5-12, A5-13). Due to the delay in starting and recruitment three further substantial amendments were needed to extend the study duration. (A5-14 to A5-16). A more detailed outline of this process can be found in the Case Study Report. (A5-17)

5.5.2 Research and Development Approval

Research and development approval (R&D approval) was needed for the proposed recruitment sites. Of the two original sites one had clear R&D application processes but for the second it was less clear as it was a charity. The charity clinic felt it did not need R&D approval as it had its own research governance processes but the local primary care trust (PCT) thought otherwise. Three weeks later the PCT agreed it had no research governance jurisdiction.

Similarly for another proposed recruitment site there was also confusion about which NHS Trust it actually belonged to. Three weeks after first contact it was decided the site came under the umbrella of the trust which already held R&D approval for the study. It transpired that all three recruitment sites were part of the same R&D Trust. These also required amendment to the original agreement.

R&D approval allowed the researcher to receive an honorary research contract for the period of the study and to enter NHS property and be involved in research activities. It also meant the researcher could access patient shared records with the patient's permission.

There were times when it has seemed this part of the study would never be completed. I was fortunate that I had an encouraging supervisor and supportive clinicians to work with who suggested further routes to enhance recruitment and also an understanding sponsor of the research. The Swindon LREC and the R&D trust have also been very supportive and responsive to requests for change.

5.5.3 Potential Ethical Dilemmas

Due to the nature of this research there were a number of ethical considerations that were documented and explained within the research ethics application. The recruitment method has been explained earlier and was designed to ensure the researcher could not potentially coerce people to take part.

Participant interviews were to be held in the participant’s own home following the University of Bath’s Research in Private Residence Policy and needed informed signed consent at each interview.261 (See A5-7) Consultations were
observed at the appropriate memory clinic, with informed signed consent from all participants (See A5-3), and interviews with HCPs and prescribers occurred at their place of work. (See A5-7)

As explained in 3.3.1, people with mild dementia are often able to give informed consent. The same process of assessing capacity for consent was followed in this phase of the study and potential participants were informed of their potential involvement.

5.6 Recruitment

As explained earlier recruitment was slow and the first participant was recruited in October 2006, some six months after the study first started (and eleven months after the original LREC submission). Although it had been proposed that there would be eight potential case studies, only seven were recruited to by April 2007, and as the agreed study extension was until September 2007 (at that time point) it was decided to stop any further recruitment activity.

5.6.1 Description of Recruitment Locations

Case study participants were recruited from three of six potential sites, with a total recruitment of six people with dementia or a memory problem (one individual fulfilled the requirements of two case studies); six carers; four different prescribers and two different HCPs. These locations were actually in three different health authorities but services were provided by one mental health trust. A round trip from location one to three to two (in a direct line) totalled 52 miles.

5.6.1.1 Location One

This memory clinic ran from a hospital unit providing health services for older people, near to the centre of a large city. People could self refer or be referred by their GP or another medical clinician. People had an initial meeting for a brief assessment and then were brought to a session where they had a full neuropsychiatric workup; physical examination and referral for other clinical examinations as appropriate. At the time of the study psychologists performed all the neuropsychiatric testing which were then analysed by a senior psychologist who made a decision based on probability related to findings. This was then discussed with the appropriate psychiatrist and a probable diagnosis made. The individual would then be brought back to the clinic to be given the diagnosis and treatment started if appropriate. At the time of the study there were three psychiatrists (one at consultant level) providing this service.

5.6.1.2 Location Two

This memory clinic ran from a small community hospital providing general healthcare services for the local population. It included service provision for older people with mental health problems. Patients could be referred by their GP or another medical clinician. The memory clinic staff included a psychiatrist; a junior doctor and a psychologist (who complete the neuropsychiatric testing).
5.6.1.3 Location Three
This memory clinic ran from a small community hospital providing general healthcare service for the local population. Service provision included that for older people with mental health problems. Generally people were referred by their GP or another medical practitioner. This service was provided by a consultant psychiatrist and a rotational junior doctor with the support of community psychiatric nurses as appropriate.

5.7 Reporting Case Study Findings

It was decided that each case study would be analysed and described separately in its entirety before a cross-case synthesis occurred. This would ensure that thematic frameworks were finalised and interrogated within each case study before comparing findings across case studies.

This would allow comparison of findings across the proposed case studies 1 to 5 (see 5.2.3) and findings from the experimental case studies 6 to 8. Negative and positive findings could be seen as a means of gaining a more holistic overview of the complexities associated with prescribing a medicine for dementia. 320,321,326

The Case Study Report (Appendix A5-17) presents a discussion and analysis of each individual case study and was submitted to the PPRT in June 2008. A detailed analysis and discussion of cross-case thematic findings will be presented in Chapter Six.
CHAPTER SIX: RESULTS AND DISCUSSION OF PHASE TWO

This chapter will present a brief description of individual case studies, followed by cross-case analysis of all findings. The full description of individual case studies can be found in the Case Study Report in Appendix A5-17. Phase two was a longitudinal study exploring the effects of a medicine being prescribed (or not) in the early stages of a dementia. In comparison phase one highlighted associated chronicity and severity of dementia and its affects and effects on carers and caring.

6.1 Description of Case Studies
The following section gives a brief description of the seven case studies and participants. In total six people with dementia or a memory problem (one individual fulfilled the requirements of two case studies); six carers; four different prescribers and two different HCPs were recruited. Interestingly all people with a dementia or memory problem were male; a similar finding to phase one. It is unclear why this was but may be related to male carers being less likely to take part in research\(^{287}\) as discussed previously in 4.2.1.2. The case study not recruited to was the prescribing of donepezil, which was unexpected as donepezil has been viewed as the first-line AChEIs because of its duration on the market and resultant familiarity of use by clinicians.

The demographic data of the case study sites can be found in Table 6.1. Please note ALL participants have received a pseudonym to protect anonymity and confidentiality. Narratives from the interviews and observed consultations will be quoted as outlined in 4.1.3.

6.1.1 Case Study One: Ineligible for a medicine for dementia
Mr George Black was not eligible for treatment with an AChEI because the memory loss was diagnosed as being mild cognitive impairment possibly attributed to the effects of heart bypass surgery. He lived with his wife (Mildred) who was known for her poor memory and had relied on her husband as almost a walking memory bank for most of their married life. George’s problems were recognised because he could no longer remember people’s names or telephone numbers; things that he was previously very good at. This resulted in George being made redundant as he could no longer keep up with his work. George and his wife lived on a council estate on the outskirts of a large city. In George’s case study there was his wife Mildred and the following healthcare professionals: James, a psychologist who performed the diagnostic and routine follow-up neuropsychiatric testing at location one and the potential prescriber Dr North a specialist registrar in dementia.

6.1.2 Case Study Two: Intolerable side effects
Mr Harry Smith was eligible because he had not been able to tolerate two different AChEIs. Harry lived with his wife Joan, who herself had arthritis of long standing and needed assistance on stairs (they had a chair lift fitted about 10 years previously because of her increasing immobility). As Harry became
increasingly frail and less mobile it became more of a struggle for Joan and he eventually needed a wheelchair for mobility. He needed knee replacements but was not considered eligible because of his dementia and concomitant cardiovascular problems. Harry was long retired and he and his wife lived on the outskirts of a medium-sized country town. In Harry’s case study there was his wife Joan and the prescriber Dr South as they received no other home assessment in relation to the dementia.

6.1.3 Case Study Three: Rivastigmine
Mr Robert Jones had been prescribed rivastigmine (off-license) for vascular dementia. He lived with his wife Judy who had found it very difficult to account for her husband’s increasingly withdrawn state. Robert’s ability to communicate and socialise had greatly decreased which had caused great friction within the relationship. Robert and Judy lived in a small town on a private estate in a semi-rural area. In Robert’s case study there was his wife Judy and his prescriber Dr West; they had no other home visits in relation to his care.

6.1.4 Case Study Four: Co-prescription of Memantine and an Acetylcholinesterase Inhibitor
Mr David White had been co-prescribed memantine when he was already stable on rivastigmine. He had been diagnosed with Alzheimer’s disease in 2003. Prior to the memantine being started he had begun to deteriorate quite markedly in terms of cognitive functioning and verbal fluency. He lived with his wife Annabel, who was the main carer and looked after him on her own. Annabel was a very organised person and believed in routine to keep David functioning as well as possible. David and Annabel lived on a residential caravan park on the outskirts of a large city. Mr White’s case study included his wife Annabel, Mary a community psychiatric nurse (CPN) who visited them on a three-monthly basis to monitor progress and his prescriber, Dr West.

6.1.5 Case Study Five: Galantamine
Mr Chris Green was prescribed galantamine for Alzheimer’s disease. After retiring from a high powered engineers post it became increasingly obvious that his memory was causing severe impairment in his ability to carry out day-to-day activities. He was well spoken with good social skills and this enabled him to seemingly function at quite a high level on casual observation. He lived with his second wife, Vicky who did all the caring duties and found this increasingly difficult because of the social isolation it incurred. His children from his first marriage had not accepted him remarrying and now declined to have any further contact. Chris and Vicky lived in a small village in a rural area. Mr Green’s case study included his wife Vicky and his prescriber Dr East. They had been assigned a CPN but had refused them entry to the house.

6.1.6 Case Study Six: Refused to take Medication
Mr John Johnson was originally recruited because he had refused to take any medicines for his memory problems. He had even had all his mercury dental fillings replaced in order to reduce the risk of Alzheimer’s disease being the
cause of his problem. However between the time of consenting to participate in
the study and the interview taking place his wife Janet had convinced him that
he should take the medication being offered (galantamine).

John and Janet lived on the edge of a busy rural town in their own home. In Mr
Johnson’s case study there was his wife Janet and his prescriber Dr West, but
no CPN visit as Mr Johnson had dismissed this as “a waste of time.”

6.1.7 Case Study Seven: Memantine
Case study seven was the original case study two participant; Mr Harry Smith
who had not been able to tolerate AChEIs. He had not been deemed suitable for
memantine at the time of these being withdrawn because his dementia was
classified as mild. However at the time of the observed consultation his
condition had progressed and it was decided with the agreement of himself, his
wife and son-in-law, to start memantine. In this case study there was Mr and
Mrs Smith and his prescriber Dr South.

6.2 DATA COLLECTION and ANALYSIS
As described in 5.4.1, data collection comprised of qualitative data from
interviews with patients, carers, prescribers and appropriate HCPs and
observational data from consultations. Patients and carers had been asked if
they would be willing to keep a small diary to write pointers in to discuss at the
next interview and any changes that they had noticed after the medicine was
started.

Quantitative data collected by the memory clinic staff which ‘formally’ monitored
patient’s progress (objective data) was collated from participant’s medical record
(with consent) as a comparator with the qualitative picture (subjective data).

In total 22 interviews were completed; 16 patient and carer sessions; four
prescriber sessions and two healthcare professional sessions. Four observed
consultations took place with three different prescribers.

All interviews of the person with dementia or a memory problem and their carer
took place in the participants own homes. All the HCPs and prescribers were
interviewed at their place of work.
<table>
<thead>
<tr>
<th>Case</th>
<th>Type</th>
<th>Participant</th>
<th>Carer</th>
<th>Contact</th>
<th>Time in Study</th>
<th>Prescriber</th>
<th>HCP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Not suitable (has mild cognitive impairment)</td>
<td>George Black Age 60 Recruited from location 1</td>
<td>Mildred (Wife)</td>
<td>1st IV: 4.10.06 2nd IV: 15.01.07 3rd IV: 14.06.07 Consult: 24.08.07*</td>
<td>10 months</td>
<td>Dr North</td>
<td>James (Psychologist) IV: 15.12.06</td>
</tr>
<tr>
<td>2</td>
<td>Withdrawn due to adverse effects</td>
<td>Harry Smith Age 83 Recruited from location 2</td>
<td>Joan (Wife)</td>
<td>1st IV: 13.12.06 2nd IV: 04.04.07 Consult: 11.04.07</td>
<td>10 months</td>
<td>Dr South</td>
<td>None involved</td>
</tr>
<tr>
<td>3</td>
<td>Rivastigmine</td>
<td>Robert Jones Age 70 Recruited from location 3</td>
<td>Judy (wife)</td>
<td>1st IV: 19.12.06 2nd IV: 08.03.07 3rd IV: 18.01.08 Consult: 5.4.07</td>
<td>13 months</td>
<td>Dr West</td>
<td>None involved</td>
</tr>
<tr>
<td>4</td>
<td>Co-prescribing of rivastigmine and memantine</td>
<td>David White Age 80 Recruited from location 3</td>
<td>Annabel (Wife)</td>
<td>1st IV: 21.12.06 2nd IV: 09.03.07 3rd IV: 31.01.08 Consult: 5.4.07</td>
<td>13 months</td>
<td>Dr West</td>
<td>Mary (CPN) IV: 27.02.07</td>
</tr>
<tr>
<td>5</td>
<td>Galantamine</td>
<td>Chris Green Age 81 Recruited from location 3</td>
<td>Vicky (Wife)</td>
<td>1st IV: 17.01.07 2nd IV: 10.04.07 3rd IV: 28.01.08 Consult: 12.04.07</td>
<td>12 months</td>
<td>Dr East</td>
<td>None Involved (Refused)</td>
</tr>
<tr>
<td>6</td>
<td>Refused</td>
<td>John Johnson Age 76 Recruited from location 3</td>
<td>Janet (wife)</td>
<td>1st IV: 11.06.07</td>
<td>1 month</td>
<td>Dr West</td>
<td>Refused CPN visit</td>
</tr>
<tr>
<td>7</td>
<td>Memantine</td>
<td>Harry Age 84 Recruited from location 2</td>
<td>Joan (Wife)</td>
<td>1st IV: 19.06.07 Consult: 11.04.07 RIP: 15.10.07</td>
<td></td>
<td>Dr Q</td>
<td>None involved</td>
</tr>
<tr>
<td>8</td>
<td>Donepezil</td>
<td>Did Not Recruit To</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Researcher unable to attend

IV = Interview; Consult = Consultation
6.2.1 The Data

6.2.1.1 Interviews of Participants and their Carer
Although it was intended to interview the person with dementia or memory problem and their spouse separately, all participants wished to be interviewed together. In the case of Mr and Mrs Black (Case 1), there was a very frank exchange of what was going on in terms of the affect and effects of the memory problems on his life and how that made him feel and it was the first time his wife had heard him really talk about it. So there was a sharing of each others experience, which resulted in a deeper understanding of what it was like for each other. This was the case for each of the other case studies as well, with the person with dementia and their carer expressing a wish to be interviewed together. For all but one there were similar sharing experiences as with Mr and Mrs Black, but for Mr and Mrs Green (Case 5) it seemed they were afraid of what their other half may say about them if they were interviewed apart.

6.2.1.2 Interviews with all Healthcare Professionals
Although it had been expected that each person recruited would possibly have a HCP other than a psychiatrist or a medic involved in their monitoring; because of the differences in the way in which locations were organised this was not the case. (See 5.5.1.1 to 5.5.1.3) Each of the HCPs participating expressed a wish not to talk explicitly about the person they cared for, but to express their views in a more generic way and use the participant as a reference if and when appropriate. By engaging in the study in this manner they felt they were best able to protect the confidentiality of their relationship with the patient even though they understood the patient and their carer had given consent for the interview to be about their care.

6.2.1.3 Observed Consultations
Four observed consultations took place at two different locations. The consultation arranged for location one was not able to be attended by the researcher due to unforeseen circumstances. The findings presented here focus mainly on data from interviews with all participants; however the observation findings are presented in greater detail in the Case Study Report (A5-17). The reason for this is that findings from phase one (see 4.3.1.3) indicated participant dissatisfaction with consultations and their involvement in decision-making processes. This was not supported by phase two findings; however one could propose that HCPs working from specialist memory services may have greater awareness of consultation etiquette.

6.2.1.4 Diary Records
All participants were asked if they would like to record their thoughts and feelings in a notebook in between planned interviews. Only Judy Jones (Case 3) completed this on behalf of her husband Robert (see 6.5.2.3).

6.2.2 Data Analysis
Each interview was transcribed verbatim by a departmental secretary and then checked and edited by the researcher in order to clarify confidentiality and sound quality issues and problems arising with unfamiliar medical jargon. The data was
(See Case Study Report A5-17) then formatted for import to NVivo® and coded using interpretative phenomenological analysis. Themes arising from the data were sorted and then categorised into over-arching superordinate themes. Case study sites were analysed separately before being analysed across sites. Healthcare professionals and prescribers were analysed separately linking relevant data to the cross-case analysis as appropriate.

Qualitative data was enhanced by accessing participant’s medical records and comparing objective findings from the clinician with subjective findings arising from the data (see 6.4.3.1). Observational data from the observed consultations was analysed in a descriptive manner linking to the use of consultation skills and the way in which responses to medication were assessed in both a subjective and objective manner.

6.2.2.1 Thematic Taxonomy from Individual Case Studies
Descriptive information on each of the individual case studies in A5-17 outlines the overall nature of each case study, including findings from interviews; observed consultations, diary records (where appropriate) and from the shared care records. Following these descriptive case studies is an overview of findings from the prescribers and then the HCPs involved in the study. Prescribers were analysed separately as they did not wish to make specific comments on individual patients but on general prescribing issues. The HCPs were analysed separately from prescriber data as their roles in follow-up patient care were so different.

In Table 6.2 the superordinate themes from each case study are listed for visual comparison. It was found that living with a memory problem or dementia had a profound effect on the relationship dynamics between the couple, their families’ and friends. For some, interacting with healthcare professionals was arduous but others found it very supportive. There were contrasting experiences of medicines for dementia; with some being very positive; one experiencing intolerable side effects and yet another resisting the need to take them for some time.

Prescribers perceived their therapeutic relationship with their patients and carers as being very important and to be protected. It was via this relationship that they learned about how people lived with dementia and that there was a need for careful decision-making in prescribing a medicine for dementia either on stopping, starting or continuing a prescription. They realised that careful and holistic monitoring of response was important but often felt constrained in their decision-making in prescribing by national and local policy.

The healthcare professionals involved (a community psychiatric nurse and a psychologist) were interesting in that their findings settled into two superordinate themes of medicines for dementia and procedural issues. Although obviously competent at their own role within the prescribing pathway of medicines for dementia; theirs was a role that did not make final decisions but just contributed to these. This was reflected in much of their discussion and narrative focusing on procedural issues and how this related in their experience to medicines for dementia.
6.2.2.2 Cross-case Analysis

In terms of cross-case analysis it was first proposed to compare those cases where a medication for dementia was prescribed (Case 3 Robert Jones; Case 4 David White and Case 5 Chris Green) with findings from those cases who were not prescribed a medicine for dementia (Case 1 George Black; Case 2 Harry Smith and Case 6 John Johnson). This was to follow Yin’s guidance that theoretical analysis should be transferable across sites. However the individuality of experiences described by participants precluded just contrasting findings between two arbitrarily defined groups as originally planned (see 5.7). As a result thematic findings were interrogated across all cases. As appropriate; findings from the prescribers’ and HCPs were incorporated into the analysis to support and/or contrast findings from the people with a memory problem or dementia and their carers.

The inductive process of interpretative phenomenology was used as described earlier in 4.1 with overall themes described in Table 6.2 resulting in a final thematic taxonomy for the results and discussion as:

1. Living with a memory problem or dementia  (including relationship dynamics)
2. Interacting with healthcare professionals (including therapeutic relationships; decision-making in prescribing and procedural issues)
3. Medicines for memory problems or dementia

The individual case analysis took place in May and June 2008 for the Final Report to the Pharmacy Practice Research Trust who funded phase two. The first cross-case analysis took place in May 2009 and the original superordinate themes for carer participants were:

1. Living with a memory problem or dementia
2. Relationship Dynamics
3. Interacting with Healthcare Professionals (including therapeutic relationships; decision-making in prescribing and procedural issues), and
4. Medicines for memory problems or dementia

As the analysis progressed it became clear that ‘Relationship Dynamics’ was a sub-code analysis of ‘Living with a memory problem or a dementia.’
### Table 6.2: Comparison of Taxonomy Between Individual Case Studies

<table>
<thead>
<tr>
<th>Superordinate Themes</th>
<th>Case 1</th>
<th>Case 2</th>
<th>Case 3</th>
<th>Case 4</th>
<th>Case 5</th>
<th>Case 6</th>
<th>Case 7</th>
<th>Rx</th>
<th>HCPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total number of themes</td>
<td>69</td>
<td>31</td>
<td>66</td>
<td>65</td>
<td>61</td>
<td>59</td>
<td>0*</td>
<td>85</td>
<td>41</td>
</tr>
<tr>
<td>Living with a memory problem or dementia</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Relationship Dynamics</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interacting with Healthcare Professionals</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medicines for Dementia</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Therapeutic Relationship Dynamics</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decision-making in Prescribing</td>
<td>✔️</td>
<td>✔️</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Procedural Issues</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>✔️</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**KEY**
- Rx = Prescriber
- HCP = Healthcare Profesional

---

*Point of Reflexivity*

On the 11<sup>th</sup> April 2007 at a follow-up consultation with their prescriber, Mr Harry Smith agreed to try memantine for his dementia. The couple had previously expressed a wish to try another medicine to see if that might help them cope. Because they knew me they were happy to continue with the study but as a new case where Mr Smith became a person with dementia taking memantine. A follow-up interview was arranged for the 19<sup>th</sup> June 2007 as by then they would have been able to titrate the medication up to an effective dose. I was on my way to the interview when I was involved in a road traffic collision which resulted in an extended period of sick leave. Unfortunately by the time I was capable of returning to work-related activities Harry had passed away and his wife no longer wished to take part in the study. May he rest in peace.
The final coding sheet can be found in Appendix A6-1 and an explanation of each superordinate theme can be found in Appendix A6-2.

The overarching theoretical analysis was that **living with a memory problem or dementia** opened Pandora’s Box in terms of its effect on relationship dynamics. Changes in behaviours, roles, activities and social interactions stressed relationships to almost breaking point. Acceptance that there was a problem which required attention resulted in **interacting with healthcare professionals** for advice, support and information. The ultimate hope was for access to **medicines for memory problems or dementia** which were perceived as a means of controlling or holding the disease. Healthcare professionals were empathic and positive about the possible effects of **medicines for memory problems or dementia**. These medicines also improved relationship dynamics which resulted in an increased ability for both the person with the memory problem or dementia and their carer to **live together with the memory problem or dementia**.

**Figure 6.1: Interaction of Superordinate Themes**

![Interaction of Superordinate Themes Diagram]

- **MEDICINES FOR DEMENTIA**
  - Prescribing hindrances
  - Responding
  - Medication issues

- **INTERACTING WITH HEALTHCARE PROFESSIONALS**
  - Therapeutic relationship
  - Therapeutic decision-making
  - Assessment, follow-up and support

- **LIVING WITH a MEMORY PROBLEM OR DEMENTIA**
  - Personal changes
  - Comparative changes
  - Relationship dynamics
6.3 Living With A Memory Problem Or Dementia

Figure 6.2: Diagrammatic Representation of Living with a Memory Problem or Dementia

6.3.1 Personal Changes
There were many personal changes attributed to the dementia or the memory problem with resultant changes in behaviours and activities. Living with these personal changes challenged both the sense of self\textsuperscript{131,134,137-143} and also personal and social relationships.\textsuperscript{166-169} This section will explore these changes in further detail.

6.3.1.1 Ageing and Concomitant Illness
The age range of the participants with a memory problem or dementia was 60 to 84 years. Dr West described three age ranges when providing care for older people; “the young old, the old and then the old old.” He went on to define the age ranges as “young old is 65 to 75; old is 75 to 85 and old old is 85 plus.” So George Black, the youngest at 60 fell outside even the ‘young old’ category; (which Robert Jones was a member of) and the remaining participants were in the ‘old’ category. This age difference was interesting in terms of the results because participants had an increasing package of concomitant medical conditions and associated medication as well as increasing physical frailty associated with older age.

As mentioned in 6.1.2, both Joan and Harry experienced reduced physical capacity. As a result they were confined to the house and relied on family for help for outings and hospital appointments. This also meant that what Harry wanted from his medication was more focused on his physical pain than his cognition.

Harry: “The medicines for my knee that’s the most important thing to me.”

Joan: “I think he’d be completely lost without them to be perfectly truthful, just at the moment.”

Harry & Joan, Case 2
John had worked hard all his life and Janet shared “work was his life” and he had only in the last couple of years handed his business completely over to his son.

“He doesn’t take old age easily, he doesn’t. What I say to him is he is lucky to have got to this age (75). Lots of his friends died of cancer, heart attacks and that’s life isn’t it? But he’s still here so you have to be thankful for that.”

Janet, Case 6

A lack of mental stimulus can lead to poor engagement in the external world and a decreased level of functioning so the reduced stimulus from fewer social interactions with friends and relatives can be a negative factor in maintaining and improving social functioning. Many of the carers in phase two were aware of and tried their best to increase opportunities for mental stimulus (see 6.3.2.2).

Chris had cardiovascular problems, diabetes and about 18months prior to the study had suffered a major stroke which had required removal of a brain clot to preserve arm and leg function. He said that “old age never comes easy” and what upset him most was the macular degeneration which in his view had robbed him of being able to drive and play golf at a level he was happy with.

Sometimes it was difficult for the participants to know whether it was the dementia or their age slowing them up; which was reflected by Robert below.

“But I still don’t have to me I don’t have the power I would like. Whether that is because of the age I’ve got to I don’t know.”

Robert, Case 3

This experience of ageing and its associated medical conditions resulted in trips to hospital and for some, operations and procedures. For all couples except George and Mildred, there had been gradual decline in mental functioning over time as reflected by Judy below.

“I don’t now how much it’s been coming on like this. I think over the last couple of years I’ve compensated by talking and he’s just given up.”

Judy, Case 3

Janet commented that they had been told by their GP that John had been having “mini strokes that he wouldn’t have known that he had them” and continued with “we didn’t notice it too much at first.” Vicky reiterated this perception when she said they had first noticed problems after the brain surgery but added “I suspect it had been building up for a long time without us being aware.” These possible prodromal changes will be discussed further in Section 6.3.2.1.
Robert and John were treated for depression prior to being formally assessed for possible dementia because of their increasing social withdrawal. Depression may cause some symptoms associated with dementia, although it may be part of the dementia prodromal period. Robert never thought he was depressed but his GP prescribed an antidepressant anyway where as John put his low mood down to not being able to “go go go” all the time.

“Then first of all he started going quiet and our GP thought he was depressed, we didn't think he was depressed but they put him on antidepressants.”

Judy, Case 3

These concomitant medical problems muddied the waters for people in terms of knowing what was actually causing what in terms of day-to-day experience.

“Some days can be quite bad, I get tired that is another thing I mean there are so many things going on with me personally you know health wise as well.”

George, Case 1

Not only were there physical effects of concomitant illness, but participants also spoke about the effects of concomitant medication. All participants took between 6 and 10 medicines per day and I could only wonder at the different pharmacodynamic and pharmacokinetic interactions that could negatively effect their cognitive functioning. The elderly are susceptible to experiencing medication-induced delirium with estimates ranging from 11 to 30% of hospital inpatients. Medicines that are centrally active with a high anticholinergic load are well known to cause confusion and delirium so regular medication review and assessment of continued need should occur This was not an activity that I witnessed or I was informed of.

The burden of concomitant illness and medication is illustrated by Robert below who tried to make sense of the number of medicines.

“I feel I've got to the stage now where I take approximately 20 tablets a day; you know shake me I rattle. You don't mind a joke but I just hope and I keep asking 'am I benefited by these or can I reduce them?’ ‘Oh no not at the minute sir,' they turn to me and say ‘oh have you tried these?’”

Robert, Case 4

Harry summed up the associated frustration of medicine taking well when he said: “I have been taking so many bloody tablets.” This concept of taking too many medicines is also referred to as polypharmacy which describes the situation of taking more than one medication regularly. Multiple users of medicines have described a dichotomy of feelings; gratitude that they were still
alive because of the medication but concern about whether it was actually good for their body. Interestingly, it has been suggested that different forms of dementia may be related to higher rates of polypharmacy and co-morbidities. These findings suggest that many people with dementia may require an overall holistic assessment of co-morbidities and medication to reduce associated negative cognitive effects of medication and promote overall well-being.

6.3.1.2 An elusive memory
George Black, had a past history of a heart attack followed by a heart bypass with a seemingly devastating effect on his memory. Previously he had prided himself on his memory and his ability to remember complex numbers; appointments and tasks that needed completing. Mildred, his wife, described it as a “brilliant, brilliant memory” and their relationship roles were built around this fact as her memory had never been good. George took care of business, all the paperwork and remembering historical and current events.

George: “But it is, I don’t know what all these different factors what they are doing to me, what they are doing to my mental state I haven’t got a clue. All I know is that my memory has been getting chronic. For me it is, you know. I am not getting senile I am not getting…”

Mildred: “He had such a brilliant, brilliant memory.”

George: “That is the annoying thing.”

Mildred: “You know it was like opening a book. Ask him and it was there instantly and he knew you know. And now if I asked him something he snaps because he tends to do that. It’s his way of saying he don’t know.”

George & Mildred, Case 1

Prior to the bypass George had been warned that his memory might be affected but it was not until he started back at work that he realised the extent of the change.

“I was missing appointments; I was not doing the things I was asked to do…You know sometimes I had to be quite truthful and say ‘sorry, it completely slipped my mind.’ I didn’t do this, I didn’t do that. So I got to the state where every time I spoke to someone I had to carry my book around with me, (and) write it down.” George, Case 1

The other gentlemen in the study were aged between 70 and 84 years of age, so it seemed that the impact of a poor memory on their sense of self was less devastating for them than it was for George. In this age group the key concerns were the day-to-day and sometimes hour-to-hour fluctuations in their ability to access their memory.

Chris: “I know I’m losing my memory, that’s what worries me but it comes back after probably an hour or two hours but sometimes it is a nuisance actually.” Chris, Case 5
A common source of irritation for carers\textsuperscript{167,169} is the continued repetition of questions; stories or phrases. This was experienced by Vicky, who shared that when she understood the reason it no longer became a problem.

“First of all, which would be about two years ago when I started having to say things twice. I got terribly annoyed about that ‘I just told you that’. Then of course I understood.”

Vicky, Case 4

Both carers and people living with a memory problem or dementia spoke about the differences in long and short term memory, but overall seemed puzzled by how one memory retrieval system could be so good and yet the other was so poor. This was perhaps best summed up by David below:

“My short-term memory is very bad. Long-term is quite good, but a person will say something to me and two or three minutes later it’s gone but not all the time. It’s peculiar. Things come back from the past which I haven’t been thinking about at all and my wife asks me something and two or three days later I’ll suddenly come out with a name. It’s odd and it’s nothing to do with what I’m thinking about you know in the brain (at the time).”

David, Case 4

Of greater concern for three participants was when their memories differed to those of their spouse or were completely nonexistent for a given event. As Robert stated “I couldn’t remember doing things.” George experienced his poor memory as frustrating and it completely shook his belief of what he thought was truth.

“...that is when it really gets frustrating when I am told about things and I hope to me, it has never happened. I have never said it, never done it, no one has done it for me or given it to me or said it to you know. I thought black was black and white was white and now I am not sure, now I am not sure at all.”

George, Case 1

An observational study recorded the progression of dementia symptoms over a 12-month period in 58 patient-carer dyads. A major problem experienced by participants was the inability to “rely upon the memory of, or consciously recollect and relive, a past experience.”\textsuperscript{357} The authors went on to argue that “memory is simultaneously individual and social, and that memorabilities are shared co-constructed events and experiences.”\textsuperscript{357} This viewpoint perhaps explains why carer frustration can be so great when stories are mixed up or incorrect because these ill-remembered memories could be experienced as unpicking shared history and experiences as a couple.

6.3.1.3 Fluctuations and progression

David and Annabel in their first interview described how the time of day and different days affected David’s ability to function and cope with daily activities as narrated below.
Annabel: “We had a slightly dodgy Monday and Tuesday didn’t we of this week…but then from Wednesday and today he is so much brighter you really can’t tell from one day to the next.”

David: “Yes and it varies what time of day. I don’t know why this should be ‘cos I’m not very good after 11 o’clock …It’s the same time each day and I am all right at the moment. We were in Asda and my head was constantly spinning and I couldn’t focus on anything at all…Then it wears off and by the afternoon and evening I’m fine.”

Annabel & David, Case 4

Mary (CPN) had been to check David’s blood pressure and pulse after the event but had found nothing unusual. David described it more as ‘turmoil’ in his head than actually feeling dizzy, which resulted in him not being able to concentrate or focus.

Both carers and people with a memory problem or dementia spoke about their fears of progression and for the future. For David it was a fear of nursing home admission after friends of his had been admitted on a permanent basis.

“I’ve got three friends …they all moved into a home recently they are all our age with the same problem and they won’t come out again. I think to myself how lucky I am that I am not in a home.”

David, Case 4

In contrast, at his first interview George had not seen Dr North for the possible diagnosis. His concerns included not being diagnosed as senile and wanting to be told that his memory would not get any worse.

“I would like to know what he has come up with you know. Is it my memory has gone or is it just me just bloody ga ga you know? I don’t think it is me going ga, ga either.”

George Case 1

This fear of progression has been highlighted in a previous study which investigated what the perceived threats to self were for people living with early dementia. The two overarching themes were “It will get worse” and “I want to be me” and these were linked to the participant wishing to retain their own sense of identity or self-hood. After his first appointment with Dr North, George received a diagnosis of mild cognitive impairment and was told there may be some improvement in the future.

“He ruled out a lot of things but he said, the short term memory might improve but there is no guarantee to it and I must admit it hasn’t yet.”

George, Case 1

Mild cognitive impairment (MCI) has been postulated as being a stepping stone in the continuum of dementia for some of those diagnosed; especially those with
It has been proposed that 44% of people with amnestic MCI will proceed to a diagnosis of AD over 19 months. The possible implications of giving a diagnosis of amnestic MCI to people and its effect on their resultant health behaviours is unclear at present. For George there was no recognition of a possible link to dementia in the future or any information on reducing possible risk factors.

Interviewing people with a memory problem or a dementia is an interesting experience. It requires great attention to the way in which a question is formed and what kind of questions need to be directed to the carer and not the individual with the problem. For example I was reminded of this when I asked Harry Smith in his first interview if he could remember taking his medicines for dementia and just received a blank expression and withdrawal. His wife, Joan tried to explain his reaction by saying

“I don’t think he took a lot of notice of them quite truthfully himself, you know but, he doesn’t remember very much, his memory is not very good at the best of times.”

But really it was my gaffe and I learned to adapt my questions so that they related to their personal experience in the moment. This was made difficult when some people like David who had a great memory for things that he was interested in such as current or family-related affairs but could not remember things he perceived as less important. David could tell me about the benefits of the co-prescribing of rivastigmine and memantine but when I asked him how long he had been taking his rivastigmine he replied:

“I can’t remember when that was. I would have thought it was about 2 years but that is the sort of thing I can’t remember.”

In a way there was a need to explore an individual’s ability to remember and learn the areas in which their memory was less functional.

6.3.2 Comparative Changes
In this section the changes in behaviours and activities of the individual with a memory problem or a dementia will be presented. From the narratives an insight into the effect and affect of these changes on the day-to-day relationship of each couple can be seen as well as resultant affects on their personal relationship.

6.3.2.1 Behaviours
Chapter Two introduced the concept of a prodromal period for people with dementia with resultant behavioural or personality changes. Interestingly John exhibited many of these earlier symptoms such as depression, anxiety, worry
and suspicion (paranoia) as related by his wife and own narrative throughout the interview.

“Before we had a problem, you were very anxious and very worried about everything and that is where the citalopram that helps. You did get a bit down sometimes didn’t you?”  

Janet, Case 6

The following excerpt demonstrated how John tried to make sense of his own anxiety and tendencies towards low mood; as well as sharing how difficult it was for him to contain ‘the man inside.’

John: “…my anxiousness is based probably on a bit of temper do you know what I mean? An anxious person can become down and down and down because you are anxious.”

Janet: “Oh you don’t get in a temper at all you are very..” (Interrupted by John)

John: “You don’t know what the man inside is saying do you?”

Janet: “No but..” (Interrupted by John)

John: “And nor does anyone else.”  

John & Janet Case 6

From Janet’s interruptions to and comments on her husbands narrative it was clear that she was very worried at the start of the interview about how I might feel about him being bad tempered and angry; trying to deflect him from admitting this. At one point she said to John “But I don’t want Denise to think that you get in a temper and you get nasty.” By my response I tried to allay her fears that I thought any less of her husband or her as his wife and that such reactions to dementia were relatively common. This was in great contrast to the first interviews with George and Mildred, and Robert and Judy who shared openly their frustrations and anger about each other, throughout the interviews.

John also had a great dislike of being on his own, and was not keen on going out (present prior to starting medication). This put a great strain on Janet’s activities and ability to function as an independent person.

Janet: “The biggest draw back is he doesn’t want to be far away from me, that’s the..(Interrupted by John)”
John: “No I always cuss and grunt when I am sat on my own and that is the truth I don’t make any bones about that, I say ‘I think I might go down Lyme and see if there is a bird about’ (to pick up a woman).”

And a little later

Janet: “The thing I notice, I can’t have a private telephone conversation. If I am in one room he will come in ‘who’s that, what were they saying, what did they want? Don’t you?”

John: “Well yes. But it’s probably some crony running me down or something like that. You might as well find out mighten you?”

Janet & John, Case 6

These early behavioural changes can cause great disruption of the spousal relationship and result in increased carer stress. As mentioned previously heightened carer stress can also result in heightened stress in the person with the memory problem.\(^{180,181,183}\) It has also been described how in early stages of memory impairment carers may feel any or all of the following: irritated, frustrated, angry, impatient, argumentative, amused, unloved and under-appreciated.\(^{61,168-167}\) Again these can be seen as secondary stressors which increase the carer burden.\(^{170,171,177,186,285}\) It has been suggested that what needs to happen is a psychological adjustment to the actual lived experience of living with dementia.\(^{141,142}\) This adjustment includes jointly trying to make sense of the experience and developing ways of coping together.\(^{142}\)

Another early change for some was social withdrawal and Judy became very agitated about this in the first interview as she felt Robert was “just sitting there not doing anything” and “it was getting me depressed.” Robert tried to explain his feelings about this but Judy dismissed these as excuses.

Robert: “I walk down to the paper shop post office and there’s quite a number of people in there that I talk to and I see on a regular basis, but at the same time once I’ve left there and come back I’m on my own. I admit I should see more people in a 24hr period, I accept that but until recently I have felt that I had work to do around the house which I’ve not achieved and I can take more on but of course at the minute don’t want to push myself too hard.”

Judy: “I just think that you don’t want to get involved in anything outside Robert. This excuse of jobs having to be done in the house and this that and the other it’s just an excuse. If you wanted to go out and do something else you would do.”

Robert & Judy, Case 3

Anger and frustration in response to changes in memory or abilities was common. Chris said “it makes me so cross at times really” but George was quite open as he shared how it turned him into a ‘nasty person.’
“Initially it was making me very bad tempered you know it really made me bad tempered I was a nasty person…(continued later)...I noticed it and frustration started getting in and the more I was getting frustrated, I was getting stressed, I was getting tense, the worse it became.”

George, Case 1

This impacted on carer functioning as well. Mildred had always been known for her poor memory and found it very distressing when she knew that George had said or done something which he later denied knowledge of.

“So I would say to him that you did say that and he would deny it and I would think to myself ‘well alright fine I am not going to argue with you.’ but then George was getting angry, really, really angry with me and I am thinking ‘I am near to tears here because I would stake my life on it that he said it or done it.’”

Mildred, Case 1

Judy frequently described her husband Robert as being agitated in response to every day situations which tested him, saying “he soon gets agitated” continuing with “he’s got a very short fuse” Robert agreed saying “I do, well it’s frustration really,” and perhaps frustration was a better term to use.

Another concern mentioned (6.3.1.1) was the associated slowing down of ageing, but David perceived this as AD itself with Annabel reflecting it affected everything that David did.

David: “And it slows me down a lot.”

Annabel: “That is very significant very, very slow yes.”

I: “Is this the tablets do you think or the disease?”

David: “I would have thought it was the disease actually.”

And a little later

Annabel: “I would say so, I think it’s because it is somehow there being a lack of concentration and he seems to me he’s slowing down and trying to work out what’s to be done next. It’s almost as if each step is a deliberate effort…he doesn’t do anything at even remotely normal speed now.”

David & Annabel, Case 4

This is an interesting finding as it highlights the need for HCPs, carers and family members involved in the care of PWD to allow time for individuals to think and respond to questions and/or to complete tasks and activities. This was highlighted in 4.4.1.4 as an important concept in developing good communication skills with PWD. HCPs need to be aware that the slowing in mental processing is caused by a reduction in the short term memory capacity for new information. This means there is less available capacity for processing and sense-making, which sometimes can be interpreted as the
person having lost conceptual knowledge. Bayles argues that it is the reduction in the available working memory which can affect information processing and retrieval. If the capacity is diminished this can result in a wrong or incomplete answer. The author goes on to suggest there are seven steps which can improve memory and conversation with PWD and these are outlined in the Table 6.3 below.

### Table 6.3: Improving Memory Deficits to Aid Communication

<table>
<thead>
<tr>
<th>Step for Improving Linguistic Memory</th>
<th>How to do This</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Work within memory span capacity</td>
<td>Use a series of short commands in order to complete an instruction; only giving the next when the patient has completed the first command.</td>
</tr>
<tr>
<td>2. Simplify language</td>
<td>Reduce syntactical constructions and use simple, active and declarative sentences and speak at a moderate rate. Rephrase if the person is confused. Don’t use open-ended questions in people with poor searching memory</td>
</tr>
<tr>
<td>3. Put Conversation into Context</td>
<td>Photographs or toys or models can be used to increase meaningful utterances</td>
</tr>
<tr>
<td>4. Provide Repetition if Recall is needed</td>
<td>This has been found to improve picture and story recall, sentence comprehension</td>
</tr>
<tr>
<td>5. Ensure Learning is errorless</td>
<td>If a person cannot remember do not make them guess as this will be the word that they remember next time.</td>
</tr>
<tr>
<td>6. Priming</td>
<td>A prior stimuli can result in the facilitation of s response (this is known as priming and is considered an unconscious form of memory)</td>
</tr>
<tr>
<td>7. Reducing Cognitive Load</td>
<td>Reducing task complexity and thereby the cognitive effort needed to complete a task can be successful. Multitasking is more demanding and can be frustrating for the individual; so eliminate distractions, provide written instructions to support oral instructions</td>
</tr>
</tbody>
</table>

**Point of Reflexivity**

The first interviews with each couple were very much a getting to know each other event, but also a chance for many of the couples to share with each other how it had really been for them over the past months. Harry and Joan were very self contained and of few words and seemed very accepting of their situation. Interactions with the other participants were often very frank and honest to the point I felt for each person and their own individual suffering. Much of the friction was built on the misunderstanding of what living with a dementia or a memory problem entailed and the damage of this to their own perception of their identity, independence and their relationship.
6.3.2.2 Activities

As might be expected participants with the dementia or a memory problem spoke of their past prowess on the cricket pitch, golf course, or about the house or as a do-it-yourselfer. The lament was really a yearning for past times and past enjoyment and satisfaction.

“I played golf extremely well. I was a cricketer from the age of 7. I went all over the world playing cricket. The moment they saw me they said you’ve got to play for us you’ve got to play for us which was great.”

Chris, Case 5

David described the confusion and frustration arising from living with a dementia well in the following narrative:

“I felt very frustrated (before the medication) and as my wife says I used to be quite keen at do it yourself, after that I couldn’t have tackled a job at all. I would just sit and look at it and think ‘well what on earth am I meant to be doing’”

David, Case 4

More distress can also arise when simple tasks become problematic. Prior to starting memantine David went through a phase of not being able to dress properly. He was always particular about being dressed in a shirt and tie with a jumper and trousers, but this fell apart when he could no longer remember how to tie a tie.

Annabel: “You referred to the fact that you couldn’t work out how to tie a tie. You were also at that point, dressing in a most odd fashion. He was putting on trousers upside down and that sort of thing. So it was an overall situation with dressing together with the tying of the tie wasn’t it?”

David: “Yes, putting my pyjamas on top of my trousers.”

Annabel: “It got to that sort of situation which was very distressing really but that is all behind us now (since memantine).”

David & Annabel, Case 4

Robert found it very difficult to cope with having to change from one plan to another and described it as “frustration, you know diversifying” and it caused great friction within his relationship with Judy.

Robert: “Invariably I’ve been in the garage and I’ve been getting things ready to take out into the garden. The good lady will say ‘have you a minute’ (interrupted).”

Judy: “You keep saying that I always interrupt you.”

Robert: “No just a minute, let me finish before you go on. Oh dear. Umm, that distracts me to a given degree not because I want to get in the garage but because I want to do what she wants so I’m torn if you will and as I said she has priority.”
This was quite amusing because Judy did actually interrupt Robert frequently; probably due to her lack of understanding for the need to give a person with dementia time to think about a subject, formulate a response and then vocalise it. This was illustrated again in an excerpt between Janet and John below

Janet: “Can I step in there a minute?”

John: “Well you seem to be, I don’t know.”

Janet: “Because I know when it started.”

John: “Well I am not having a chance to think.”

Janet: “Well you think a minute and I’ll say when it started.”

John: “Well you carry on now.”

Janet & John, Case 6

This is also an important concept for HCPs working with PWD; to give them sufficient time to respond and even longer if an adaptation to a plan or task is needed (see 6.3.2.1). This perception of slowed processing has been explained in terms of reduced working memory span and that account of this deficit needs to be considered when communicating with any person with dementia or memory problem. 359

6.3.3 Relationship Dynamics
This section describes how living with a memory problem or dementia can affect spousal and family relationships as well as the ability to cope on a daily basis.

6.3.3.1 Perspectives of day-to-day living
Both the participants with a memory problem or dementia and their spouses had to learn to live with this problem and develop coping and sense-making strategies. (This was similar to participant experiences presented in 4.4). These changes affected all communication and social interactions. In the first interview, Judy explained her frustration with what she perceived as lack of initiative which
resulted in Robert’s inactivity and perhaps suggested Judy thought it was deliberate.

Judy: “You don’t seem to activate something, seems you’ve got to the stage where you react on somebody saying something asking you to do something but you don’t do it on your own.”

Robert: “I just feel that at the minute I’ve been going round in ever decreasing circles and not knowing anything so ever. You could argue I used to be very bright, positive in what I did, but now I’m quite sort of lethargic. Just hoping I can get back on track.”

Judy & Robert, Case 3

This perception of “not knowing anything” was also experienced by David and Chris. This inability to be pro-active or take initiative in conversation, tasks and their relationships is probably what made respective carers frustrated. The machinations of the mind are so complex it seems almost dramatic that a medication could help improve these complexities to an extent perceived as beneficial by both the individual and their carer (see 6.5.2.2 to 6.5.2.4).

Roles changed in response to the dynamics of living with a memory problem or dementia. As could be expected this inability to think or initiate activity impacted on their relationships especially spousal interactions. Judy had set up a number of lists around the house to prompt Robert to do or remember things; however these only worked if Robert remembered to look.

“You could help yourself by just referring to it (the list) before you went out but I have to do it at the door, I say ‘have you got this, have you got that, have you got your tablets, have you got?’ everywhere we go… So it’s like a constant checking all the time.”

Judy Case 3

This depth of frustration seemed linked to a lack of understanding about what having dementia actually meant and how roles had had to change in response to Robert’s behaviours as well as a yearning for things to be as they were so that normality could return.

In order to combat this lack of initiative or inertia, Judy, Annabel and Vicky tried hard to provide stimulus and activities which improved mental stimulation and be interesting. These were not always successful and depending on the individual spouse finding new ideas for activities was hard work.

“I tried to get you to do crosswords, showed you how to do that sudoku, but just everything mentally to make your brain hurt you won’t do.”

Judy, Case 6

“The dominos is good yes that was a brilliant idea on my part, it is trying to have these ideas, that is only one, I need dozens more.”

Vicky, Case 5
Vicky felt that she was unable to give Chris the stimulation he needed as in her experience Chris became more socially interactive in male company. She explained how her brother’s visit had resulted in Chris being animated and involved with conversation and tasks. She believed this was because her brother “was able to give you a stimulus that I can’t, you know being female.” She continued “So that’s really what Chris needs but I don’t know how to supply it to him.”

This need to find stimulating activities was a different aspect to findings in 4.2.1.1 where carer participants tried to involve their loved one in routine activities of daily living rather than in mind stimulation.

Coping Strategies
There are many strategies to support a poor memory, ranging from writing lists; using diaries, calendars, mobile phones as alarms etc and increasingly computer or handheld programmes to stimulate brain function. Interestingly none of the participants had any formal direction on this from their respective memory clinics and so had adopted various strategies that worked for them.

George at interview one was writing everything down saying “I am having to adapt everything you know” and by interview he described his “normal code of practice in the morning is getting up looking at the calendar see what is on.” Judy had three lists on the go saying “I think you have to do it, it’s a lot of organisation really.” Robert added they also used a diary to enable them to work together.

“We have a diary in there and that’s the only way to do it to put things in the diary …you know what I mean cos we’ve got to work together.”

Robert, Case 3

Annabel believed strongly in motivation and routine stating that “we have quite a regime here, we have a set pattern for our day otherwise things don’t work out.” She believed that this approach was “good for both of us actually” as it gave her time to do things on her own whilst David had been taken to either his camera club or art class by friends. When asked whether he liked the routine David said “yes I enjoy it” although Annabel appreciated that “it must be very frustrating to be told or asked if you like to do this or that...” She did confide that she wasn’t trained at all and often worried if she had the right approach.

“When you are looking after somebody in this situation and you are not experienced in it you do what you think is the right thing and I talk over with Mary or when Doctor West comes and they haven’t yet told me ‘you shouldn’t be doing that or the other’ and so we keep going and with me rather driving is a too strong a word but motivating David I think is better and if I find that he’s going down a little bit and a bit lethargic then I try to give him something else to concentrate on. And I personally think the combination of the drugs and how I contend with things works.”

Annabel, Case 4
6.3.3.2 Communicating with a memory problem
One of the main areas of distress for Judy in the first interview was the inability of Robert to initiate or take part in a conversation. It also highlighted Judy's lack of knowledge and/or understanding about why this might be so. Robert tried to explain why he felt unable to maintain a conversation, but he had also been trying to tell Judy that he wasn’t able to remember recent events sufficiently well enough to put these into conversation. The narratives below highlight their frustration with the other not being able to see their point of view.

Robert: “Sometimes I feel that I’m in a conversation and I suddenly dry up because I feel I’ve run out of things to say, I need a digit pressing to sort of get back on track.”

Judy: “Robert what I want is your conversation to be about present and future not things about (interrupted).”

Robert: “I was just saying what I was capable of; not present day and I admit that (vehemently)!”

Robert & Judy Case 3

The EUROCARE study highlighted that two of the most difficult experiences as a carer of a person with dementia was the “loss of companionship through diminished quality of communication” and changes in social behaviour.381 (See Section 6.3.1.4) A finding that Judy’s narratives support.

What most annoyed George was the effect that his poor memory for names had on his ability to take part in conversation. He was so busy trying to remember a person’s name that he wasn’t able to concentrate on what was being said and then had no idea how to respond.

“…I can contend with not being at work, I contend with not having the money that I used to have, but all that doesn’t really bother me you know what bothers me is not being able to go out in that street meeting somebody, knowing who I am talking to and not being stressed out because I can’t remember what they had said five minutes ago because my mind is trying to work on something else.”

George Case 1

David and Robert both had hearing problems and needed bilateral hearing aids. However hearing aids tend not to be selective in what they make louder and the wearer can find themselves “bombarded from all sides and you can’t really pick out anything” as David explained. Annabel observed that this made communicating as part of a large group quite difficult.

“He does have a problem with fairly largish groups of people and I can appreciate that obviously because with his hearing problems as well he finds it difficult.”

Annabel, Case 4

This finding was supported by Judy who at the second interview thought that Robert still tended “to be quiet in company I don’t think you’ve got these hearing
aids sorted well enough yet.” Chris had no problem hearing but had very poor vision. There is evidence that reduced visual acuity can affect communication due to reduced visual clues. However both visual and hearing impairment can negatively effect cognitive function so such people may need greater support. These are important concepts for HCPs to take into account when communicating with PWD with visual or hearing impairments as these will also exacerbate the slowing in mental processing.

6.3.3.3 Effects on Others
A change in mood of the person experiencing the memory problem can affect everyone around them and result in damaged relationships between spouses and other family members. Mildred recounted below how George’s bad temperedness had caused her embarrassment and stress and had also affected his relationship with their sons.

“I am not normally a nasty person you know I don’t normally bite the boys head off but I have been… one of my sons he took me aside and said ‘that was out of order dad.’ I don’t even remember what I have done you know…I mean at first I didn’t realise how bad I was. It is only because of just everyone threatening to leave me two or three times…I have had to rethink myself and the way I behave and try to control myself it is hard, it is hard.”

George, Case 1

Mary commented that on her home visits she often perceived evidence of discord in a relationship but it was hard to get to the bottom of things if there was not the opportunity to speak to people on their own.

“Sometimes you get a clue that they’re going to be defensive or they will say things are fine if they can’t talk in front of the individuals, some kind of scheme (is needed) where you can talk to them separately.”

Mary, CPN

As mentioned earlier Robert and Judy; George and Mildred spoke very frankly about their relationship difficulties, but for Chris and Vicky this was a very different story. The first interview with them was very difficult as they were both so careful about what they were saying; plus also I was a stranger to them. Vicky seemed very agitated and fidgety during the interview and at the end as she walked me to my car she said that she found it very hard, very distressing and very awful and that she would like to talk to me on her own but she would upset Chris by doing so. In the end she actually wrote her thoughts to Dr West in a private letter. In the subsequent interviews they were both much more relaxed; perhaps some of this due to Chris improving slightly; and also because they felt they knew me a bit better. Interestingly Chris shared his worries about Vicky with me and her future in interview 3 when she was out of the room and he thought she couldn’t hear. I felt so much for them both.
and perhaps their relationship was best summed up by Dr West who said “the couple shared a special relationship and one gets the impression that one would be lost without the other.”

Another issue for carers was how the changes associated with the memory problem resulted in the person changing from the person they fell in love; a finding also highlighted in 4.4.2.1. This is reflected by Judy and Robert’s narrative below.

Judy: “Sometimes you think you’ve lost the person that you married, don’t say you’ve been like this all the time.”

Robert: “I appreciate I haven’t been like this all the time, don’t ask me why.”

Judy: “No I just wish sometimes it was like that (before).”

Judy & Robert, Case 3

The participants spoke of their appreciation for their respective spouses’ care and concern as reflected by Robert’s comments below.

“I married a good lady, my mentor, that’s all I live for really plus the family. Whilst I’ve been in this state I’ll admit I haven’t felt right, don’t know why just something that happens and …I’m gratified that I’ve now got to this stage with the help of good lady.”

Robert, Case 3

George had more to reflect on and his response below is perhaps indicative of one of the differences between male and female acceptance of living with dementia and associated relationship changes.¹³¹,²⁸⁵

“I have sat down and thought about what has happened in the last year 18 months and if I had been Mildred I would have been gone a long time ago and would have left me.”

George, Case 1

However the illness didn’t just affect spouses but also family as Janet described how prior to the medicine for dementia she needed extra help around the house in order to care for John and that his increasing social withdrawal made it difficult for family events.

“This time last year, John was entirely different. My sister used to come everyday, my son used to come twice a day, my niece used to come and help do the housework and things were difficult…John, last year come 9 o’clock he wants to go home, he was quite agitation. Christmas we got there at 1 o’clock we had to leave at 4 he wanted to come home.”

Janet, Case 6
For Chris it wasn’t the dementia which caused friction with his children but his marriage to Vicky some twenty years earlier, twelve years after his first wife died. At the first interview he said “unfortunately my children…we just fell out. They didn’t get on with Vicky…so my two children don’t keep in contact.” It is very difficult to make sense of family histories as they are always more complex than they first seem. His adult children refused to see him in hospital when he had his stroke telling Vicky “they were too busy.” Chris said that he found the situation “very difficult actually.”

At the third interview, while Vicky was out of the room he shared “I have a problem is that my children which are all very good but they don’t have anything to do with Vicky” and “what I’m worried about is her.” Vicky entered the room shortly afterwards and said “Chris’s great tragedy is that his children won’t have anything to do with him, was he telling you that? It is a huge, huge sadness.”

Unresolved issues can cause a great deal of suffering and distress for people and it has been linked to the presence of behavioural changes in advanced disease. Problems within the family can act as secondary stressors to the caring and coping process, thereby increasing carer burden. Interestingly this family discord seen in second marriages in older couples where the step-mother is caring for a person with AD has been described by others. They describe the findings from nine ‘late-life remarried women’ as encompassing rejection from their partner’s adult children and a general disinterest in them wanting to be involved in care-giving. The authors reflected that these women also inherited unresolved issues which were increasingly difficult to address and suggest such couples may need greater social input and support.

6.3.3.5 Acceptance and Living Together
Although developing coping strategies seemed to improve relationships and the ability to live together; this had to be underpinned by acceptance of the memory problem or dementia by both.

George: “I accepted it there and then, I knew I had a problem before but I hadn’t said to myself ‘oi you have got a problem get it sorted.’”

Mildred: “But he is coming back to it, he is coming back to the person that I used to know and I love that person. I didn’t love the person that took over from him if you get my drift. …and I couldn’t even nail it down to why he was like it to begin with until I realised that he did have a problem and he said he was waiting for this thing so hopefully fingers crossed we will go forward. We both understand it a bit now.”

George & Mildred, Case 1

Acceptance of chronic illness is perhaps one of the most difficult things for individuals to do especially if it is associated with progression and few treatment options. The concept of acceptance of the diagnosis and then the consequences of living with its symptoms was commented on by Dr South below.

159
“Often I think people get the diagnosis and they first realise that there is a significant problem and they get very worried that things are going to change very quickly… and then actually a year down the line things aren’t necessarily that different they settle in to a sort of acceptance, you know realisation that actually things usually happen fairly slowly and you have time to adjust.” Dr South

This acceptance enabled couples to relate to each other with understanding and empathy as reflected by Janet.

“When John couldn’t remember things I used to try desperately hard to get him to remember, sometimes I would get a bit irritated because I couldn’t get through to him. The minute he (Dr West) said what it was I saw things completely differently, I didn’t get so cross, don’t ask me why but I seemed to know there was a reason.” Janet, Case 6

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a researcher building increasing rapport with the participants over a period of time, it was clear that couples became more relaxed and perhaps shared increasingly more personal views. It seemed at times I was almost put in a role of mediator or therapist and I needed to work hard at objectivity and not becoming involved. After each interview I off-loaded all my feelings and concerns into the recording device so that I cold regain a sense of perspective as a researcher. As a human being caring about others, I found this more challenging.</td>
</tr>
</tbody>
</table>

Living with a memory problem or dementia will severely test the strength of any relationship and this is reflected well by the excerpt from the second interview with Chris and Vicky.

Chris: “But it’s all in the past we’ve got to live together and get on with ourselves, have we not Madame?”

Vicky: “Absolutely.”

Chris: “Cause there’s nobody else; it’s just the two of us. Cos Vicky is on her own.”

Vicky: “I never had any children so.”

Chris: “Well it’s a problem. But we get on with it, we’re friends aren’t we?”

Both cackle with laughter

Vicky: “It’s a case you have to be or all else.” Both laugh
Chris: “I have to say that don’t I? You know me. We have mini fights occasionally don’t we?”

Vicky: “We do, we do have an argument. We break it down very quickly.”

Vicky & Chris, Case 5

In summary the effects of living with the changes associated with a memory problem or a dementia tested social and personal relationships to the full. Improved understanding of the problem including carers realising that things were not being done deliberately done helped acceptance and empathy toward the person they cared for. These are important concepts for those providing healthcare that more information is needed about the reasons why people exhibit the behaviours that they do and how these could best be managed.

6.4 Interacting With Healthcare Professionals

Figure 6.3: Diagrammatic Representation of Interacting with Healthcare Professionals

6.4.1 The Therapeutic Relationship

This section describes the interaction between communication skills, different consultation styles and how lay participant expectations and beliefs of medication could affect dynamics within the therapeutic relationship.

6.4.1.1 Consultation Etiquette

The therapeutic relationship was a concept which prescribers and healthcare professionals (HCPs) participating in the study found important and protected in terms of confidentiality. As mentioned in 6.2.1.2 prescribers and HCPs expressed a wish to talk generically about prescribing medicines for dementia to maintain patient confidentiality. They also re-checked consent for the researcher’s attendance at the consultation before the consultation took place.

Consultation Types

A total of four consultations with three different prescribers were observed. In the main there were two different styles in terms of eliciting information from the
person with the memory problem and their carer. Drs West and East had both 
the person with the memory problem and respective spouse in the consultation 
together at the same time. Dr South consulted with Joan and her son-in-law first 
whilst Harry completed his neuropsychiatric testing with the psychologist. Then 
Harry joined everyone once he had finished his tests.

In both of the above scenarios there are benefits and possible problems; when 
sleeping people together there is the risk that the dominant person gets to do all 
the talking and the more reticent participant's story remains untold. It takes a 
skilful practitioner to redirect questions and pick up on non-verbal clues and 
changes in body language. Obviously there is the risk that people may feel 
inhibited about speaking their truth in front of the other in case there is resultant 
discord and also in theory breach of confidentiality for the individual being seen. 
In all consultations there was no prescriber time spent only with the person with 
dementia. In Harry’s case he joined his wife and son-in-law and was asked his 
view on the decision to start memantine previously made by Dr South, Joan and 
their son-law.

**Communication**
The style of each prescriber was formal, with patients and carers being greeted 
in the waiting area using formal titles and in direct conversation using the word 
‘sir’ when addressing the individual. This possibly reflected the age group being 
seen but also rooted the consultation in formality and implicitly set boundaries.

Drs West and East had similar consultation styles in that they started the 
consultation with general every day questions to put participants at ease before 
moving on to the main reason for the consultation which was to assess the 
response to the medicine for dementia using a series of neuropsychiatric tests. 
Dr West saw Robert and Judy Jones plus David and Annabel White on the 
same day. Dr West varied his assessments depending on the person he saw. 
With David; he was interested in evaluating how the combination of memantine 
and rivastigmine was holding David’s cognitive functioning. Because one of 
David’s problem areas was speech and language, Dr South started off a 
conversation with David about what he had been doing recently in the garden 
and around the home. As an observer this seemed like quite a random piece of 
conversation. But Dr South explained afterwards that actually he was testing 
memory; his ability to interpret what was being said; think and formulate an 
answer and then interact within and maintain a conversation. When viewed in 
this manner the interactive dialogue made complete sense and also meant that 
the person was being assessed to do a reasonably complex task without ever 
feeling they were. This is important because in comparison Chris and Robert 
both reacted to more formal testing with increasing anxiety and distress both of 
which exacerbate memory dysfunction. The tests had to be stopped in Chris’s 
case to avoid him becoming even more distressed.

Dr West commented that in Robert’s case he was using more formal and in-
depth tests because Robert had been prescribed rivastigmine off-license for 
vascular dementia. In order for Dr West to justify continued expenditure he 
needed to demonstrate continuing improvement. Although it was clear Robert 
had ‘holes’ in his memory he scored better than previously and it transpired that 
Robert had only been taking 3mg once daily (sub-therapeutic), due to an
incorrectly written prescription. This problem in the titration of medication doses is discussed further in 6.5.3.5.

**Communication Processes**
All prescribers spoke more clearly and slowly, using simple words and phrases when talking to the person with the dementia. This makes imminently sense in allowing time for mental processing to occur as mentioned in 6.3.2.1. However Bayles warned that if the rate of speech was too slow it became more difficult to understand as PWD had to keep more information in their compromised working memory for longer and therefore may forget earlier information. Interestingly Vicky had a problem with this slowed speech pattern used by Dr West and thought this slowness was a reflection of Dr West’s inability to converse with them. (Chris had originally been assessed and diagnosed by Dr West but in the observed consultation had been seen by Dr East).

“He was very slow but he tried to explain things you could tell he would be swimming around in the dark, he didn’t know what on earth to say to these strange people on the other side of the room.”

Vicky, Case 5

Janet thought Dr West was “so nice, so easy to talk to” and Chris said that “I could talk to him and he would understand (what I meant)” so it is interesting how perspectives differ. It was also interesting observing the participants within the consultation. In the observed consultation with Vicky, Chris and Dr East, Vicky’s body language was very tense and she became tenser as the consultation went on. This was in response to Dr East exploring how they were coping on a day-to-day basis and trying to ascertain if they needed extra support at home. Vicky became quite agitated at the thought of a ‘stranger’ coming into the house. Dr East had to repeat several times they would leave this for now but would revisit this in the future, before she visibly relaxed. She also became very annoyed (not verbally but demonstrated amply by her body language) when Dr East suggested to Chris that it didn’t matter if he couldn’t drive as he had “someone (nodding to Vicky) to take you around wherever you want.” Being a taxi driver appeared not to be a role Vicky had any aspirations for.

**6.4.1.2 Expectations within the Consultation**
At the time of the first interview all but George had met their prospective prescriber and received a diagnosis. For George a lot hinged on this future appointment; as since his consultation with James both he and Mildred had realised there may be something wrong which could possibly be treated. This realisation in itself had improved their relationship, however George remained anxious. Mildred however was hopeful about the results of the consultation with Dr North the following week.

George: “Just wait and see what Doctor North (says), hopefully something positive will come out but I just, my fears I just don’t want to get any worse. I take pride in myself in a lot of things but now (shrugs).”
Mildred: "If George can come out being the person that I married and not the person he turned into our quality of life will be perfect but if he goes back to being that person I don’t think we’d have a life."

George & Mildred, Case 1

When prescribers and HCPs spoke about their consultations in general, it was clear they also held perceptions about the expectations of their patients. The consultation was perceived as a gateway to a medication people felt would help them in their daily struggle. The perceived expectations of the medication were eloquently described by Dr West below.

“I do think the hardest bit is balancing its (the medication) expectations and not giving too much hope, where some people will expect the drugs to perform miracles. Interestingly older old people are more happy with anything that helps; younger old people are expecting more of the magical hit. In my expectations, older old are just happy you know their expectations are much lower; younger old are more assertive.”

Dr West

This perception of differing expectations dependent on age is interesting and perhaps reflects findings in 1.4.2.2 where younger old participants seemed to struggle more with coping as a carer and the older old participants were more stoical and accepting. It is unclear whether these findings reflect societal changes and expectations of health delivery and well-being.

Mary felt there was also an expectation or hope on the carer’s behalf that the medicines would bring their old familiar way of life back as she explained below:

“I would think that they would want to be released from a carer role that they would really rather be a spouse a daughter a son to the person that gives the drugs that they would rather have a different relationship rather than a carer.”

Mary, CPN

6.4.1.3 Beliefs and Expectation of Medication
John, George and Mildred expressed reservations about taking medication. George had refused to take any form of medication as a young man and had only started to take them to control angina and related heart conditions. Mildred had similar views and felt that medication should be a last option to keep a person alive.

George: “It is like being experimented on, like these tablets every time we get tablets now we sit and read.. (Interrupted by Mildred)”

Mildred: “Read what it says because I have had two really bad experiences from tablets. My attitude towards medicine is it is fine to give a person the medicine if it is their life line, if they have got to keep that medicine to keep them alive then fine they have got to take it but if they can get by without having to have that thing then it is not important for them to have it.”

George & Mildred Case 1
In terms of medicines for dementia, John initially refused medication (and possibly refuted the diagnosis) and had all his mercury fillings replaced in an attempt to lessen his worsening memory. John had only agreed to take medication if it was going to help.

“I think it was just as plain as that for me on any subject, if it is doing me good I am all for it and that’s it really. I can’t elaborate on that because I mean it and if it weren’t doing me good I would be saying to him quickly ‘here this stuff isn’t any good at all to me I am getting bloody worse!”

John, Case 6

At the time of the first interview, Robert, Chris and John had fairly recently started their AChEIs so it was early days in terms of noticing a response to the medication. Robert had become increasingly quiet and socially withdrawn and this had negatively affected his relationship with Judy who desperately missed their conversations and social activities. Consequently her expectations of the medication were quite different to Robert’s who was more concerned about his perceived lack of “power.”

“Well for him to join in more, with the family things rather than sitting there quietly and watching things….I wish he had more interest in things and do more…He doesn’t go out and join in to anything, he hasn’t got any conversation about him so his whole world is sat watching television so he doesn’t talk about anything.”

Judy, Case 3

However the prescribers and HCPs also had expectations of how medicines could help their patients as a result of their clinical experience. James (psychologist) said his “impression (was) that they seem to have mood improvement.” Dr South thought that people mainly commented on “the improvement that they see is a sort of increased motivation a sort of improvement in the apathy.” Whereas Mary (CPN) said that “Some people I’ve seen live entirely on their own and are enabled to live on their own because they’ve taken cognitive enhancers.”

6.4.2 Therapeutic Decision-making

This section will briefly describe the processes involved in therapeutic decision-making related to medicines for dementia. This includes the processes of a diagnosis and how prescribing decisions were made.

6.4.2.1 Diagnostic Processes

The National Dementia Strategy highlights the importance of early detection and diagnosis of a dementia so that appropriate treatment options with supportive educational interventions can be offered.51

Across the case studies there was a variation in time to diagnosis; with George receiving a diagnosis of mild cognitive impairment (MCI) within months of his referral and investigation; but 2 years after the bypass which was suspected of
causing this. John had been followed up for 5 years by his memory clinic after his initial diagnosis of MCI before a diagnosis of Alzheimer’s disease was made and at this point he refused medication and tried other avenues.

Robert, David and Chris were investigated in response to memory deficits noticed after a cerebral haemorrhage (Chris) and cerebral ischaemia (Robert and David). Harry did have atrial fibrillation but his diagnosis of Alzheimer’s disease was not thought to be linked to this. However it is interesting that in all case studies there is damage to the cerebral vasculature system. It can only be hoped that the Department of Health’s drive to reduce cardiovascular disease by preventative methods and public health initiatives will reduce incidence in the future.103-106

As previously mentioned in 2.1.2.4 the diagnostic process of AD is fundamentally one of exclusion and the duration of the process can seem infuriatingly slow to those involved. This is reflected by Vicky who described a series of consultations over an 18 month period before a diagnosis was made and a possible treatment offered.

“Four times if not five I can’t quite remember and the last time brought us to the beginning of August when he finally gave a prescription. Inside myself without saying anything; ‘why this hesitation for heaven’s sake? Get on with it you know the sooner you’ve got the medication the better. Why are you hesitating? Why all this?’”

Vicky, Case 5

Neuropsychiatric testing can be quite an involved procedure sometimes lasting for an hour or longer. Individuals can find the tests quite threatening and can become quite nervous. For some, the actual questions involved seemed a little ridiculous and non-sensical and made people feel dismissive of the results. One of the Folstein questions involves asking the person to draw two intersecting pentagons (A1-2), the usefulness of which was questioned by John below.

Janet: “When he first went up to Dr West and he had to do some drawings and things well he…thought it was absolutely ridiculous what they asked him to do and he more or less told them as well, ‘what the hell have I got to do that for?’”

John: “Well yes I think that would be me because some of these things, to be a free hand I am no good drawing; what’s good drawing from bad ones? And I never once, I never had the patience to be able to do good free hand drawings I would always get a wiggly line come somewhere.”

Janet & John, Case 6

This is an interesting point as the ability to draw the face of a clock has been shown to have increased sensitivity and specificity at demonstrating higher executive dysfunction in people with normal MMSE scores than the replication of intersecting pentagons.365
Chris had difficulty with questions which were specifically oriented to memory and comprehension such as remembering shopping lists or series of numbers, or even what he had to do next, leaving him feeling flustered and unsure.

“I have to think about it and eventually I get there but when they were asking me once or twice I just couldn’t understand what they were asking me. That’s where I felt I wasn’t (sigh) I wasn’t in the system and eventually after not saying anything I realised that I should have been doing something.”

Chris, Case 5

As previously mentioned, the MMSE is recommended to classify severity of AD and response to medication. Dr North thought it was probably better as a screening tool to be used in conjunction with other assessment scales.

“It’s a good screening instrument but…although my study guidance does say MMSE assesses all the skills. It’s alright. I just use it, (as) a reasonable reflection. I think in a way needs to be used with other scales rather than just use it on its own in isolation.”

Dr North

The limitations of the MMSE in detecting dementia in people of previously high intellect is well known. This was illustrated by David who scored between 27 and 30 (indicating normal cognitive function) throughout the period of the study, yet it was plain to see that he was not functioning well (see 6.4.3.1 Figure 6.5). Dr West suggested (6.4.2.3) that people with a previously high level of intelligence seemed to have a more aggressive illness; but perhaps this is due to the insensitivity of current diagnostic tools to identify the presence of dementia at an earlier stage.

“I mean obviously MMSE is not the tool to do on somebody with high intellectual functioning. They could still get thirty and still have really gross functioning…It does let them down and goes against them to a point.”

Dr North

The three AChEIs (see 2.1.4.1) are licensed for the symptomatic treatment of mild to moderate AD but since 2006 are only recommended for treatment of moderate disease (i.e. when the MMSE score is between 10 and 20). For prescribers this meant there was no licensed treatment for people in the milder stages of dementia or those with mild cognitive impairment.

“With people who we think have MCI we have to say to them ‘I don’t feel a diagnosis of Alzheimer’s is appropriate at the moment, come back in 6 months.” Really what you’re saying is we’ll have to see if it gets worse then maybe we’ll give that diagnosis and then give the treatment.”

Dr South
6.4.2.2 Prescribing Decisions

Once a diagnosis and a decision to prescribe was made there needed to be a decision about which of the agent was most suitable. Each of the prescribers had their own selection process encompassing a wide number of variables. Decisions seemed dependent on the need for once daily dosing, adverse effects and concomitant illness.

“I suppose I often start donepezil, because in our experience we found it easier in terms of plotting the dosing partly that it’s only two different dose levels. And that I think we feel that people tend not to have side-effects but … whether that would actually be the case (shrug) but I guess because we’ve used donepezil probably more we kind of feel we know it better.” Dr South

As mentioned key considerations such as concomitant illness or gastrointestinal sensitivities may preclude a certain agent. For example these agents can exacerbate respiratory problems such as chronic obstructive airways disease or asthma, but if it was thought appropriate a trial with a short acting agent such as rivastigmine may be an option.

“There have been instances where people have had quite bad asthma or chronic obstructive airways disease and we’ve maybe then started with rivastigmine because it has a shorter half life so that if people do get side effects of exacerbating their airway problems that it obviously washed out quicker.” Dr South

“Somebody where you predict that because they are quite frail they may have problems with their balance, potential side effects of drugs then we might lean to donepezil.” Dr West

Drs North, South and East felt that AChEIs were equal in terms of efficacy with Dr North proposing that “all three are fairly similar but just with minor variations.” However Dr West had been a researcher involved in clinical trials of AChEIs prior to becoming a Consultant and his views and experience were quite different. He maintained there was a difference in toxicity and duration of effect between the three agents.

“I think there is differences in tolerance you know rivastigmine most toxic galantamine middle. I do think there is a difference in the length. I mean galantamine works for a longer duration particularly (compared) with donepezil. It’s hard to judge but it’s my perception over the years, comparing the three together there is a difference there as well.” Dr West

Discussions with individuals and their carers prior to starting a treatment for dementia are very important as they need to be warned not only of the possible side effects and how to deal with these but also that these medicines do not help everyone.
“I do talk about there is a one in three chance (of responding well) and I do also say that if they do not respond to the first one there is still fifty-fifty to respond to the second and make it clear about that you don’t just have one shot.”

Dr West

The different perceptions of the prescribers about the efficacy of AChEIs were interesting with Dr South stating that “the drugs aren’t wonder drugs by any means” in contrast with Dr East’s comments below.

“I think overall, in the initial stages at least it does have an effect on the person’s ability to manage his own work or the carer’s ability to cope. … I think there is a lot of things which these medications help rather than just orientation in time place and person.”

Dr East

It has been suggested that the evidence to date “is overwhelmingly in favour of the benefits of AChEIs” with the authors discussing the uncontrolled evidence available which support the earlier use of these agents in AD. The authors suggest the evidence base “would favour an early diagnosis and prompt treatment to maximise the cognitive and functional abilities” of people with AD for as long as is possible.

Participant and carers perceived that more information could have been given at the time of prescribing about possible side effects or what to expect. Joan stated “I just read the leaflet right through and that’s all more or less” and Janet could not remember receiving any particular information either. In contrast Robert and Judy could remember being told about possible side effects, but then there was some concern about whether they may not be working effectively if there wasn’t a side effect.

Robert: “I’m alright on them. The doctor said ‘you might feel nausea or a little sick.’ I don’t, whether that’s a good thing I don’t know.”

Judy: “I was worried about side effects, but touch wood you haven’t seen any side effects.”

Robert & Judy, Case 3

Dr West explained that he “would always give them the common side effects and they always have our phone number to phone me if they have any concerns” and this was corroborated by Vicky who said “he talked to us for a long time.”

However, Annabel probably summed it up best below when she put the perceived lack of information into context of the gratitude of receiving the medication.

“I wouldn’t have said there was any in-depth discussion about each one (medication for dementia), it’s just we were so grateful at the time I think to get something that was going to possibly do some good.”

Annabel, Case 4
This is an interesting comment as evidence suggests that patients’ prefer to be given a positive explanation about their treatment which improves their satisfaction rating. Provision of negative information was associated with decreased compliance to treatment and decreased satisfaction with the information. This is the perception of what Dr West’s thought people actually remembered from a consultation as he related below:

“The problem is the difference of what comes out of my mouth and what the patient and carer hear and can take a day later. The reality you are only going to take three points from a consultation and so you may well take the three best ones, so I do my best but sometimes it’s hard to judge the difference between mine and the judgement of patients and carers.”

Dr West

6.4.2.3 Predicting Response
Prescribers were asked if they were able to predict which individuals would respond to treatment because anecdotal evidence suggests that one-third of those treated respond very well and one-third respond somewhat. In terms of medicine budgets and the risks of exposing people to medication unnecessarily it may be useful to know which people not to start on treatment.

“That is a difficult one, I would say no to that because it is very, very difficult to pinpoint a great response from individual patients until you start them on a monitor…with some people you get a brilliant response and others it doesn’t change it doesn’t make a difference so it is difficult to say.”

Dr North

Although the general consensus was that a clinician could not predict responders, Dr North indicated he thought age affected depth of response and Dr East proposed that people who were highly anxious fared worse. Dr West’s experience indicated that those people with higher pre-morbid intelligence responded less well.

“I think …the slightly younger patients, not totally young not under 65’s but I would say in their early 70’s they seem to respond slightly better at least initially.”

Dr North

“I don’t know if it is just observation by me or it is just a coincidence but people who are anxious as a sort of personality…it seems that it might not be that effective.”

Dr East

“I think we realise that highly educated people diagnosed with dementia have a more aggressive course, so that group I’d still treat with a bit less optimism. But no I still find it hard to know whether the person will respond well or not.”

Dr West:

In summary there was a great deal dependent on these consultations for participants because the outcome dictated whether they would gain access to a medication with perceived potential of improving daily functioning. Prescribers
and HCPs held their own perspectives on treatment outcome and how these were measured but were in favour of treating the disease at an earlier stage.

### 6.4.3 Assessment, follow-up & support

This section describes how the response to a medicine for dementia was tested and assessed and the resultant follow-up options of care that were available.

#### 6.4.3.1 Testing for response

Once a medicine for dementia was prescribed there began a process of routine follow-up to measure any clinical response and assess for the presence of side effects. The first follow-up appointment was generally led by the prescriber and Dr West thought this was probably the most important consultation.

> “The follow up after 3 to 4 months you would normally be able to gauge if the person’s better, stable or still deteriorating and that's often most, in just pure medical side that’s the most important consultation of all.”

Dr West

A very interesting concept raised was that of a possible placebo response to treatment at the first follow-up appointment. This was explained by Dr South as perhaps due to the high expectations of the individual and their carer; Dr West thought it may be due to the fact that finally something was being done and also the differing pharmacokinetic profiles of the medicines prescribed. If the rivastigmine and galantamine doses were still being titrated, the person may not have reached an effective dose, so a clinical response may not be expected. Another perspective is that the variability of response is well known as are the limitations of the assessment tools; perhaps these need accounting for as well within the term ‘placebo response?’

> “It is difficult because that becomes a very subjective thing and obviously that again depends a lot on the mind-set of the patient and their relative or friend because you know, if they are hoping against hope that this is going to do something then it’s positive thinking and they come back and say ‘oh he’s much better’ and yet all testing’s worse you have to think ‘well is that just wishful thinking?’...Because you can't deny what people are telling you. You can't say well if they feel better and the relatives they say ‘oh yes things have been much easier and other people have commented’ you can’t say ‘oh well no they haven’t.’ So it is quite hard and I often feel that are we just, is this just placebo? Is this just a response that ‘yes that having the tablets we must be better’ but you know that’s hard to say.”

Dr South

> “I think there’s a danger in that first follow up consultation, there may well be a degree of placebo effect within that something’s getting cracking in the pot and is therapeutic and the original trials show this. The placebo group improved as well at 6 months, that’s when the placebo and treatment group really separated...Sometimes with older patients their
conditions and expectations (are less) and actually those are the people that I think have less of a placebo effect.”

Dr West

These are interesting comments and perhaps some credence can be given to each as people who have been worrying over an undiagnosed condition may feel relief and some sense of hope when a diagnosis has been made and a treatment offered. As Dr West implied by ‘something cooking in the pot’ people feel that people are being taken seriously, something is indeed wrong and more importantly something is being done about it. It is interesting that in many studies evaluating the efficacy of medicines in psychiatry such as antidepressants or AChEIs, there is a high placebo response. Many different explanations have been proposed for this; better supportive care from trial arrangements; regular follow-up with concerned HCPs and the positive expectations of a new treatment. Nunn proposes that if the actual interventions were described in greater detail there would be increased transparency into what actually happened and what was responsible for causing the so-called ‘placebo’ effect. Perhaps a better term to use if improvements are temporary (that is they are not apparent on next measurement) is the Hawthorne effect. Perhaps also the limitations of current measurement tools fail to capture the personal and social improvements that PWD and their carers’ find so important.

George’s comments below reflect his feelings since he realised there was a chance that Dr North may be able to help him.

“I think for me since I actually came up to the hospital and the tests and all that I think that is when something in the mind suddenly said ‘maybe there is something going to get done now’ and I wasn’t just waiting in limbo.”

George, Case 1

This sense of being helped by an expert seems a powerful driver for people to seek help and information perhaps leading to unrealistic expectations of the expert and any provided treatment. However there may also be some incorrect use of the word ‘placebo’ as implied by the comment below from Dr West. What he is really saying is that rivastigmine and galantamine have not reached a therapeutic dose in the majority of cases by the first follow-up consultation because of titration difficulties. This is not a ‘placebo’ dose; it is an ineffective dose.

“The other time when we donepezil first line is when we need a quicker speed of onset because the 5 milligrams the initial dose of donepezil is a working dose where for the other two the first month is a placebo dose.”

Dr West

6.4.3.2 Assessing the response

There were many different tests used for assessing response to a medicine for dementia and/or to stage severity. The Folstein MMSE was only part of this assessment process as the prescribers and Mary all felt that it did not give a complete picture of the clinical response. These findings are similar to those found in 4.4.3.2 and highlighted in the literature review.
“Daily-activity scales are not very good. They don’t pick up changes very well and on the first follow-up visit, when they’ve been on them four months or so, we don’t just do the mini-mental we do camcord which has more in it than the mini-mental. The mini-mental doesn’t capture things and often you see that some areas have improved and others have dropped and again people vary from day to day so I think one has to take a little bit of license with it and yes, yeah sure testing doesn’t necessarily pick up the slight thing that maybe has improved, or a bit of initiative.”

Dr South

“I don’t think MMSE is the perfect set of tests at times we do have patients who have scored more than 20 but you have the gut feeling that their cognitive ability is much worse than that.”

Dr East

In this study data from the participants shared care record (SCR) was accessed to establish findings from objective measures of response. This was to explore further whether the subjective findings from interviews and observation were supported by objective scores. Two figures follow Figure 6.4 and 6.5 which depict the change of the MMSE score over time, with comments from interviews and the prescriber for Harry Smith and David White respectively.

Figure 6.4: Harry’s MMSE Timeline

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE</th>
<th>SCR:</th>
<th>Interview 1: Joan: “he doesn’t talk an awful lot, he talks to me but he doesn’t hold the conversation he ever used to hold.”</th>
<th>SCR: Increasing memory problems, lack of initiative &amp; conversation. Start memantine.</th>
<th>Observed Consultation: Harry: “no sense in being miserable”</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.04.06</td>
<td>17</td>
<td>Memory not improved, diarrhoea a problem, donepezil stopped</td>
<td>SCR: Probable AD; donepezil started</td>
<td>SCR: Confused &amp; disorientated, start galantamine (stopped after 2 doses)</td>
<td></td>
</tr>
<tr>
<td>26.07.06</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>04.11.06</td>
<td>14</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>28.11.06</td>
<td>20</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20.03.07</td>
<td>18.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>08.05.07</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Harry’s changing MMSE scores indicated the fluctuating nature and increasing severity of his disease and were probably an accurate reflection of his capabilities at home.
For David; his behavioural changes such as poor speech, problems with washing and dressing occurred with a MMSE score of 27; the NICE definition of which is ‘mild cognitive impairment’. In fact for the whole of this study David’s scores were 27 or above. This finding supported the limitations of the MMSE used in people with higher intellect and potentially it can discriminate access to medicines and services for dementia until the disease, for that individual, is at a very advanced level.

Further information on other individual assessment scores in relation to their daily abilities can be found in the Case Study Report in A5-17.

As an alternative approach, Mary often agreed target symptoms that individuals would like to see respond to the medication rather than use a standardised tool. These have also been referred to as goal assessments and could also form the basis of patient reported outcomes for dementia.

“I guess it’s classed as subjective really but we check with the carer or the individual…and how they’re progressing; they’re either the same, they’re improved or obviously they deteriorate.” Mary CPN

Lay experiences of completing these tests differed with David being able to remember how he had improved in some of the questions over time and Judy being able to tell that even by the way her husband answered the question he was never going to get it right.

David: “When he came to do those tests which he does, there were two of them I got 30 out of 30 and another one I got 28 out of 30.” (MMSE)

Annabel: “And he said you’re doing very well.”

David: “Yes and there was a distinct sign of improvement.”

David & Annabel, Case 4
*These scores were for the two methods of completing the MMSE; one where the question is to subtract serial seven’s from a 100 and the other version is to spell world backwards.

Judy: “It was quite interesting those test things that Dr West did like; ‘how many things can you name in a supermarket in a minute’ and you just got stuck after half a dozen things and I could tell the way his (Robert’s) mind was working by what he said.”

Robert: “I was going round the shelf.”

Judy: “No no you weren’t going around the shelves. The things that you were saying were the things that have been on a shopping list recently (at home).”  

Judy & Robert, Case 3

Another problem with objective assessment scores such as the MMSE being taken on a particular day was that it did not account for fluctuations in people’s functioning. Drs North and West commented that many PWD had ‘bad’ days and this meant that readings from the subjective tests probably did not reflect a true account. This resulted in greater emphasis being placed on what the individual’s and their carers thought were important in terms of change or response.

“…the same with memory it might have been a hard day when they are doing the mini-mental or the ADAS-cog and it probably is not the same results testing at that point in time and I tend to go by what the carers and the patients feel important as well.”  

Dr North

When pressed as to his actions if a person scored poorly on the MMSE, (and according to the guidance it should be withdrawn) but the individual and carer both reported improvements, Dr North replied:

“I would be inclined to continue the medication because obviously the functionality is maintained and the quality of life is maintained and I wouldn’t go by an objective testing at that point in time, the MMSE, I wouldn’t go by that mentality. It’s just more an augmentation tool.”  

Dr North

As mentioned in 2.3.4.1 there seems no consensus on the prediction of which individuals may respond more overtly to a medicine for dementia, or agreement on how to measure response. However it is not just the overt response of the PWD but also the impact on carer quality of life that allows PWD to be cared at home for longer that needs to be accounted for. 49,51 It seems that this very complex area of response may need further research and ultimately redefinition.

6.4.3.3 Follow-up and Support

Once it had been decided that there had indeed been a clinical response and the medication was to be continued then follow-up was arranged. This differed in each location and was also dependent on the complexity of the case. Generally people were followed up annually by the prescriber (unless there was
a problem or a complex issue and in-between at 6-monthly intervals by the clinic nurse or psychologist.

“The then it would all depend on the service capacity; if the person is stabilised on treatment it may well be taken over by one of the memory monitoring nurses or junior doctors. If they haven’t got capacity, I’d still take them and if anybody’s on a quite a complex combination of medication and diagnoses I would then carry on with treating them.”

Dr West

The participants found this system worked well and in-between times there were calls to or from the memory clinic about repeat prescriptions

John: “What we have been able to achieve now is to keep it rolling and to go and see Doctor West however often, is it twice a year? I don’t know.”

Janet: “Probably more than that.”

John: “But to be able to go there and sit and have a discussion with him and then go off, it’s good.”

John & Janet, Case 6

In terms of disease severity, perhaps Harry was the most advanced, followed by David, then Chris, Robert and then George. Over the time of the study Harry had progressed from needing healthcare assistants to help him get up and dressed in the morning to needing assistance twice daily. It must be said that at the start Harry’s main problem was his physical mobility and because of Joan’s rheumatoid problems she was unable to physically help him with some tasks. As the disease progressed Harry also became increasingly lethargic and recalcitrant. (Further details can be found in the Case Study Report A5-17).

Joan: “We have a carer comes every morning and in the evenings, help get him up or to be put into bed again….they are very pleasant all the carers are lovely to him really nice. I’d be lost without them. I can’t cope every day, push around pull around you know.”

Joan, Case 2

Mary visited David and Annabel every three months to complete assessments, but apart from that they had no other care support. John and Chris had been offered CPN support but had refused.

“Somebody offered to come but it was a strange voice that I’d never heard before and didn’t know anything about it and I thought rather than I let strange people in the house I want to know something about them and we didn’t see them that time. …So I suppose at some time or another it would be nice to talk to him now that I know who he is”

Vicky, Case 5

This is quite interesting because although Vicky felt she didn’t want a stranger coming to their home related to the hospital memory clinic; she initiated a
cleaning person to ease the pressure on her household tasks, explaining “we have got a cleaning lady now to my huge relief she’s coming tomorrow afternoon.” In contrast to phase one findings (4.2.2.3) it seemed the participants were not as severe and/or their carers had yet to be weighed down by the chronicity of caring as there was only positive comment about support services. This was from Joan who had perhaps had more exposure than the other spouses participating in the study.

“...I don’t think there is anything anybody else can really do for us. Everyone has been very very good, we haven’t any complaints about anybody at all or the NHS. I wouldn’t run them down for the world. “

Joan, Case 2

In summary the healthcare professionals involved in the care of the participants were caring and empathic towards their daily predicament and where possible helped as much as they could in terms of access to medicines and information.

6.5 Medicines For Dementia

Figure 6.6: Diagrammatic Representation of Medicines for Dementia

6.5.1 Prescribing Hindrances
The study participants were interviewed between October 2006 and the end of January 2008, and the NICE revised guidance was published in November 2006.31 There was frequent coverage by the media both on local and national television as well as local radio and newspapers. So for some participants there was the worry that the revised guidance would mean they came off the medicines they were already on or that other people at the same stage of illness would be denied access.

6.5.1.1 Access to Acetylcholinesterase Inhibitors
Janet had eventually begged Dr West for the chance for John to try a medication for dementia and she related that “I know it’s not easy for him (Dr
West) to get” but they felt lucky they had a chance to try them because “I think anybody with that problem, they do want them but they can’t get them. “

Judy agreed with the above sentiment saying “I think it’s a shame when they start doing this not letting people have tablets that are available.” To which Robert replied that he felt “I’ve been very lucky to get on that road” and Judy replying “Dr West was good wasn’t he because it was just before they got taken off.” Anecdotally many clinics screened more people prior to the final NICE decision so they could start people who satisfied the old criteria of having mild disease.

The NICE decision to withdraw recommendations for the use of the AChEIs in the mild stages of Alzheimer’s disease really wound David up in particular who was very animated and cross as he spoke about how he felt about this decision.

David: “What I find is so bad that and bureaucracy gone mad really. I have two hearing aids and they supply all the batteries; now they’re expensive batteries and I only have to send off a pack of used ones and they’ll send me back a brand new pack. Why don’t they charge for it? They say they’ve got no money and yet they’re giving them away! …Ridiculous! They’re not organised with things like that and somebody said “it would cost too much to collect.”

Annabel: “Yes, I think it boils down to the admin doesn’t it?”

David: “I think they want to get it sorted out, they say they can’t afford these tablets and yet they give batteries out like…”

David & Annabel, Case 4

But David still felt aggrieved about his perceived injustice of it all and went on to mention “the bonuses some of these directors are getting at the end of each year are phenomenal” implying this was not right if there was insufficient money in the health service. His perception was that if public sector monies were re-organised there could be money available for treatment.

“We were reading an article the other day, weren’t we? Somebody in the paper and it quoted the price it costs to keep a prisoner in jail for a week and how much it costs for these tablets and there’s no comparison.”

David, Case 4

Annabel thought David’s discourse was marvellous and indicative of how well he was doing on both the rivastigmine and memantine in combination.

“This is what is so good, David wouldn’t have been able to remember or think or converse on a particular subject like that. I find it amazing when he comes out with something like that.”

Annabel, Case 4
It wasn’t just the participants with dementia and their spouses who felt aggrieved, the prescribers felt at times hampered in their clinical decision-making.

“I think with the recent NICE guidelines, I feel that it should be provided at an earlier stage rather than the moderate at least to an extent where we could help some of the proportion of these people to maintain this for a longer period of time rather than giving it when their MMSE is 20.”

Dr East

“The treatments are licensed for Alzheimer’s; you think once you’ve made the diagnosis you should be able to use them.”

Dr South

The concept of rationing healthcare is not a new one and NICE was implemented to help prevent postcode lottery of access to medication and healthcare in England. Whether this has been a success or not is yet to be proven. The NDS clearly highlights a continuing postcode lottery for access to medicines for dementia. 51 It has been proposed that NICE “can make or break a drug – and, consequently, make or break the lives of many people who may benefit from the drug.” 65 The authors continue that NICE does not sufficiently take into account patients opinions or costs outside of the NHS and implications for the wider population. 55

6.5.1.2 Prescribing and Co-prescribing of Memantine
The prescribers had clinical experience in the use of memantine either as a single agent or more commonly in combination with an AChEI (as in David’s case).

“Most clinicians would say it seems to be useful for, in earlier people is expressive language … the memantine coincides with them being able to speak clearer and that was chosen partly for that reason (in David’s case).”

Dr West

David was started on memantine when functionally he started deteriorating, even though his MMSE scores reflected a seemingly high level of cognitive ability at 27. Annabel described the combination as “brilliant really marvellous” and that he now seemed to be “more or less sort of holding his own.” She went on to say “the change is remarkable.” (See section 6.4.3.1 Figure 6.5).

Although the NICE guidelines are only guidelines PCT Prescribing Advisors work hard to ensure that implementation and associated audit takes place. However, guidelines cannot be applied to every individual; there is always someone who does not fit the criteria because of individual idiosyncrasies; concomitant illness, allergy or clinical need. As mentioned earlier, clinician’s had been guided to make treatment decisions based on what was in their patient’s best interest even if this was outside NICE guidance. 230 However prescribers in this study felt that their ability to make clinical decisions on the needs of the patient may be compromised by the new decision as narrated below.
“Just that it’s going to be hard if we do have to follow the NICE guidelines but we’ll see what happens. Because you know it is nice that there is something to offer and basically you know if we’re not allowed to use memantine then there is nothing to offer the more severe people and to be only able to treat people once they reach a certain level of dysfunction seems very wrong as a clinician.”

Dr South

In terms of noted response rate to memantine the clinicians varied in their assessment with Dr East claiming “probably about 80% of the people have benefited at least to an extent.” Whereas Dr North thought it was “about 60%” as an add on therapy and “about 30-40% pushed” as a single agent for moderate cognitive impairment. His narrative demonstrates the heterogeneity of observed response to memantine.

“Doesn’t happen with everybody, it is really hard to give a statistic but some people respond brilliantly and you can’t rate the response and others it doesn’t make a difference and you use it for awhile, (and) if it doesn’t make a difference stop it.”

Dr North

6.5.2 Responding to a Medicine for Dementia

This section will discuss findings related to the actual type of responses observed and/or experienced by lay participants and the duration.

6.5.2.1 Response Rate and Duration

One of the controversies of the use of AChEIs is the interpretation of a response. What does an improvement of two points on the MMSE mean (or any other scale for that matter?) For those measuring a response on an objective scale such as the MMSE there is no inherent experience or understanding of what this means for the person taking the medicine and those caring for that person. This is where the experiential (subjective) effect of these medicines on daily lives seems to differ widely from the clinical (objective) assessment of the effect. The response rate was best described by Dr West below.

“I’d say it’s the rule of thirds; a third of people improve the third people stabilise and a third of people don’t benefit. The improvement can go from really dramatic to mild, but mild can be just the one straw that breaks the camels back, but mild can be just the one straw that breaks the camels back, the remaining one straw is the camels back (that is) sometimes a mild improvement in function can still be the difference between staying at home and being in care.”

Dr West

Prescribers spoke about an average duration of sustained response, of 2 years but shared experiences of individuals still responding to the medicines at 4 to 7 years.

“I would normally tell people that if they are in the two-thirds who are benefiting I would normally try and achieve 2 years of stability…”

The max
at the moment is about 7 years so we’ve got quite a few patients who are on four years.”

Dr West

6.5.2.2 Beneficial Response
Dr West previously described the follow-up consultation at 3 to 4 months as probably “the most important consultation of all” but continued with:

“that often at 2 months you can begin to see signs not improving so much in cognition but in the attention, concentration…it sounds very trite but sometimes the early sign is that you just see the person looks more alert and bright.”

Dr West

Interestingly Dr West’s observations support findings from the Alzheimer survey in 2004 where respondents described people as being “brighter / happier/ more aware / more active” to “calmer / less aggressive” to improved concentration / speech.”

This increased alertness and interest in their environment was mentioned by many of the carers. Judy at their first interview shared “at least his interest is coming back in things. It affects every part of your life.” This was endorsed by Joan who felt that the Aricept® (donepezil) had somehow lifted Harry out of his shell he had withdrawn to.

“I would say that the Aricept was one tablet that did sort of bring him out of himself more, you know because he is back in his shell and doesn't say very much but that one Aricept® it was (a) wonderful tablet.”

Joan, Case 2

Increased alertness was also highlighted by phase one findings as improving the ability of carers’ to cope. This increased alertness in Robert’s case seemed to be still improving at the third interview when he told me “last time you called I’d tend to be a bit more lethargic.” He went on to say that he felt “more alert for the want of it” and that when he woke in the morning he was able to plan his day.

“I wake up in the morning and I come round and I’m thinking ‘what day is it? How am I going to do it?’ like that. If I’m here (in the living area) then I’m thinking ‘well that needs doing’ but I’m more alert.”

Robert, Case 3

This improved alertness translated into improved awareness of their environment and recognising what needed doing and the initiative to complete tasks without being asked.

“I was able to see a job in the house and go and do it and before that I wouldn’t even think about it, I would walk past it and not know there was anything to do anyway, but I even made the bed this morning.”

David, Case 4
Robert had also been a very keen handyman and had always been painting, repairing and gardening prior to the onset of dementia. He then withdrew and sat watching television, not able to complete any tasks. At interview one about 3 weeks after the medicines had been started he had been out mowing the lawn and doing other garden activities without prompting. Judy was pleasantly surprised as she said "so he’s going back to how he was, you know wanting to do things which has been amazing really."

For some participants the changes were less dramatic but were seen in improved behaviour or return to previous activities. Janet described "John is better on these" and then went on to explain that he knew what day it was when he woke up and that there were "lots of little things I notice like that, you know, they are really nothing very much but I think 'oh that's good.'" John endorsed this general improvement when he said:

“I am 75 and I am functioning quite well amongst people much younger, so I think in that respect and I am quite satisfied with what is happening now with (what) Doctor West's supplied. And I am going along quite well I think.”

John, Case 6

People also spoke in more general terms about how they felt since the medication was started. Robert said "life’s fantastic now" and Janet said that there had been "a vast improvement, everybody can see it and not only that he looks better." To which John replied "Blimey they are doing well aren’t they?" I felt this was a nice indicator of attention to the conversation and appropriate processing with a sense of humour in the response. He went on to say that "because the memory, the mind is better, you (meaning himself) are not a miserable old devil.”

Many of the participants also became more involved with household tasks now that they were at home full-time. John drove down to the local shops to do the shopping, and helped out with peeling vegetables; emptying dishwashers and changing the beds. David had been involved in spring cleaning and Chris had regular household chores that he helped with.

Chris: “Well I do the washing and the ironing don’t I, all the time?”

Vicky: “Yes you do dear yes you do you’re very good at it.”

Chris: “And the cooking.”

Vicky: “Yes and he does washing up and drying, you don’t actually do the cooking. But you do the ironing.”

Chris & Vicky, Case 5

Chris also thought the medication was helping him to cope with living with his memory problems, saying “I feel I can cope now whereas at one time I couldn’t but now I can. I can cope now.” However, Vicky seemed unsure whether there had been progression since the medicines had been started.
Vicky: “Well as I understood it it’s supposed to stabilise Chris’s situation and it’s not going to cure it but it will prevent it getting worse, that’s what I understand and I’d say that’s what’s happened as far as I can tell”

Vicky, Case 5

This uncertainty remained at interview 3 and in some respects it was easy to see her predicament. Since the medication had started about 14 months previously, Chris had become blind in one eye due to macular degeneration and was partially sighted in the other; this had increased her supervisory role enormously and also curtailed any independent activities such as walking or golf that Chris used to do.

“They seem to be as far as, I mean I don’t know how to judge but I can’t find anything to say yay or nay. I mean you could be feeding him talcum powder for all I know. I mean how do you judge? He just carries on as he always does carry on.”

Vicky, Case 5

David was taking other medication for concomitant illness as well so had problems knowing which was responsible for what.

“If you were to put the tablets out in a line I couldn’t tell you which was which. I find it difficult to say about a particular drug is doing a particular job (pause) but overall it’s improving and it’s better than before.”

David, Case 4

This very general level of improvement is perhaps the reason why objective assessment of response is so difficult. This may also be why the non-specialist viewpoint is that the medicines are not cost-effective as they are not appreciative of the unmeasured benefits on daily lives. The response seemed to be different for each person and the importance of that response to individuals was also different.

As outlined earlier the prescribers all had different ways of measuring response and some of the most important were just the ability to continue with usual every day tasks as outlined by Dr North below.

“I tend to ask of the general activities of daily living; in more sort of things they can do for themselves and how independent they are, maybe shopping finances, do they drive, do they manage to pay their own bills, how is their personal care, using the telephone, how do you manage various things like that you get a good feel for things.”

Dr North

6.5.2.3 Sociability and Returning to Old self
Perhaps the most remarked upon improvement for spouses was the increased ability of their loved one to take part in conversations and social activities again.
They shared how their husbands were getting back to their old self and the improvements this had on their lives and the wider family.

Social interactions are important as part of a couple continuing their own personal relationship and if people can no longer converse it can cause great friction between them. In their first interview Judy was quite fraught about the situation and she mentioned how Robert would previously “just sit there silent you now, wouldn’t speak to me, wouldn’t speak if we went out” but that now “he’ll actually have a conversation instead of just sitting there and watching TV.”

At the second interview things had improved even more and they were back to going out to dinner or away for the weekend and having fun together. Robert tried to explain the difference in his behaviour.

Judy: “That was really nice because it was a nice restaurant and a nice meal and it was really sociable whereas we got out of that because it was no fun going to anything like that.”

Robert: “I would sit I would not talk, I don’t know why I can’t say I was struck dumb but I just didn’t want to talk and that was it, now I talk the hind leg of a donkey.”

Judy & Robert, Case 3

Janet mentioned how John’s impatience to be back at home had lessened and when they had been out recently at a family event he was happy to stay and take part in the conversation.

“Last Friday when we went (to family function) he didn’t even mention coming home; we were still there at half past ten and he was quite happy and joined n the conversation.”

Janet, Case 6

Along with this improvement in conversation and perceived sociability was the perception of the person returning to their old self again. This was related to personality, previous activities and interactions with family. These improvements seemed to impact positively on quality of life and carer well-being.

In interview one Robert said he felt “that these tablets have helped quite dramatically” and Judy replied that “since he’s taken these tablets he’s getting back to how he was.” Robert went on to describe his thoughts of how he had been after taking the tablets below.

“I came back. Sat down there for a while (pointing to sofa) until these tablets decided to take effect and then I thought ‘yes I can do things,’ which I’m grateful for because I’m usually a do-it-yourself’ fiend and I just lost me nerve hadn’t been doing that much at all.”

At the second interview Robert said

“I would say I think the presence they’ve given me for want of a word have brought me back into the world really.”

Robert, Case 3
In section 6.5.5.1 David had been talking with knowledge and passion about his feelings of the NICE decision on the access to medicines for dementia and he attributed his ability to do so to the medicines. He said “when I am talking like that I feel everything is normal and as I used to be.”

In the first interview Judy was asked what key things she hoped the medicines would improve in terms of Robert’s behaviour on a day-to-day basis. Firstly she wanted Robert to “join in with family things rather than sitting there quietly and watching things” and also that he “took more interest in things and do more” as well as converse more with her. Robert just felt he needed more power in order to be able to do things.

At the second interview Judy was thrilled that he was interacting more with the family; especially the grandchildren.

Judy: “And the children have said ‘goodness sake what’s up with him he won’t shut up’. He keeps going on so much they’d noticed. And he actually takes more interest in the grandchildren now; he’ll sit and play with them now where he wouldn’t before.”

Judy Case 3

In her diary recordings Judy had listed a number of things she hoped would improve and then later on had given examples of activities that Robert was now involved with. These were not tabulated or linked together; but presenting in a tabular format demonstrates clearly the improvements in sociability; initiative and self motivation which were lacking prior to taking the medication. See table 6.4 below.

**Table 6.4: Diary Notes by Judy Jones**

<table>
<thead>
<tr>
<th>Symptoms Noted after First Interview</th>
<th>Improvement Since taking Exelon®</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of conversation</td>
<td>Went to hotel with relatives over New Year and held conversations at table over meals</td>
</tr>
<tr>
<td>Quietness</td>
<td></td>
</tr>
<tr>
<td>Wanting to sit quietly</td>
<td>Repaired water barrel pump which has been broken for over a year Visited Coventry cathedral and went shopping</td>
</tr>
<tr>
<td>Not going to bowling club</td>
<td>Has shown interest in starting to play bowls again next season</td>
</tr>
<tr>
<td>Aggressiveness</td>
<td></td>
</tr>
<tr>
<td>Stopped gardening</td>
<td>Has mowed the lawn and done some gardening. Has raked the path</td>
</tr>
<tr>
<td>Can’t have a discussion without arguing</td>
<td></td>
</tr>
<tr>
<td>Doesn’t join in conversations with friends &amp; family prefers to sit quietly</td>
<td>Makes more effort talking with family</td>
</tr>
<tr>
<td>No conversation on a car journey</td>
<td></td>
</tr>
<tr>
<td>No interest in money/family/finances etc</td>
<td></td>
</tr>
<tr>
<td>Doesn’t play with grandson (age 2)</td>
<td>Now plays with two grandsons</td>
</tr>
<tr>
<td>Bad memory of recent things</td>
<td></td>
</tr>
<tr>
<td>Keeps raking up the past</td>
<td></td>
</tr>
</tbody>
</table>
6.5.2.4 Perceived Quality of Life
These improvements also affected perceived quality of life with David saying “It’s affected me very well, it’s made me think in a way how lucky I am” and John saying that he did “not feel too bad for an old chap” Mary described quality of life nicely as the perceived ability of people to be able to do every day things.

“I mean yes it does improve their quality of life I think the hope sometimes as well improves their self esteem that they’re able to do little things.”

Mary, CPN

It is a complex thing to measure a person’s perceived quality of life (QoL). There are a number of dementia-specific QoL measures available, but controversy still remains about whether these scales should be completed by the individual or by proxy. This is because PWD generally rate their QoL higher than proxy informants. However it has been suggested that this lack of insight and disagreement with their caregivers’ rating perhaps reflected a “legitimate self-perception of mood and function that are associated with co-morbidities rather than AD.”

This is an interesting point, because all participants had at least two other co-morbidities which affected their QoL; physically, emotionally and psychologically. How can it be decided which concomitant illness or medication is responsible for what? There are also many external events that impact on a person’s perception of their QoL that perhaps in a sense makes disease or medicine-specific measurement meaningless. For example George spoke about his distress over his concomitant medical and memory problems and how these were adversely affecting him in terms of health. At the second interview he had received a court summons due to a loan non-payment as a result of his redundancy. The worry and anxiety of that event took precedence over all his other worries to the extent that he was having angina pains during the interview. (The interview was terminated early while George took a nitrate spray successfully and was then sent off to the medical centre with his wife).

One proxy measurement for the value that people place on medicines for dementia is whether they would purchase them themselves if they could.

John: “Well what I was going to say was I would if I could get hold of what I wanted, I would go and buy it if I could.”

I: “Would you?”

John: “I mean you can’t go on for ever like that you’d go bust wouldn’t you but saying that I mean if I have got something which is doing me good I would try very hard even if it cost money to keep it going. (To interviewer) I don’t want a bill from West next week.”

John, Case 6

There was an issue raised by Judy about how she felt they had been robbed of quality time together because of the time it took to get the medicine for dementia prescribed.
“If he could have gone on these instead of the antidepressants straight away we just feel as though we’ve had 12 months taken away you know which could have been avoided if these tablets had been prescribed sooner. I suppose they have to eliminate certain things but I think they certainly make a difference.”

Judy, Case 3

This is interesting because according to the current NICE guidance John, David, Robert, David and Chris would not have been eligible for an AChEI as they had mild disease. These medicines were perceived to have produced positive effects on the person taking them which in turn meant improved relationships with their spouse and families. These improvements helped the carer to be able to cope with their new caring role. It is hard and perhaps inappropriate to reflect on what may have happened to these already straining relationships if a medication had not been started. I find it difficult to think about people in the early stages of dementia who now have no access to an effective treatment.

However medication is a double-edged word, there are always negative aspects and these will be discussed next in 6.5.3 Medication Issues.

6.5.3 Medication Issues

This section will describe the experience and management of medication-related issues such as side effects associated with treatment; obtaining stocks of the medication; dispensing errors and concerns around compliance.

6.5.3.1 Experiencing Side Effects

As previously mentioned the most common side effects of AChEIs are cholinergic, affecting mainly gastrointestinal, cardiovascular and respiratory systems.\(^1\)\(^-\)\(^3\)\(^,\)\(^9\)\(^-\)\(^8\) Prescribing another medicine for the side effect of one already prescribed brings added risks for the individual;\(^3\)\(^1\)\(^9\)\(^,\)\(^3\)\(^7\) the reason why many clinicians do not co-prescribe for adverse effects but instead slow the titration rate. There are a number of ways of viewing this; firstly the reduction in exposure to any medication is beneficial to the patient; secondly co-prescribing and/or slowing the titration may alleviate initial symptoms until tolerance occurs; thirdly not prescribing for symptoms may mean the person has to stop taking the medication and forgo any benefits to cognition. As more people are being prescribed these medicines; bradycardia and possible effects on balance are increasingly being recognised with some people having pacemakers fitted so that the benefits of the medication are continued.\(^3\)\(^7\) The HCPs, prescribers and participants all described their experience of side effects and how these affected day-to-day lives.

“I would think the gastrointestinal side effects are the most common. But we do have people who have more vivid dreams and don’t sleep as well
and then we would change the timing they take to the morning and that often helps. But I would think that diarrhoea would probably be the most common.”

Dr South

“Nausea, followed by decreased appetite. There’s a toss up between whether it’s a slight balance disorder or whether it is the medication ... Now that we’ve got people on more we tend to see more bradycardias or slowing of pulse or something.”

Dr West

Harry had experienced almost continuous diarrhoea when he was started on Aricept® and this continued until his follow-up appointment at 3 months with Dr South who stopped the medication. Harry had continued with the medication in spite of diarrhoea because the leaflet had “said that diarrhoea was one the side effects.” Because of this Joan thought Harry just needed to carry on taking them and it may resolve. This stoicism was remarkable, but not always the case as Dr South commented below.

“People often after a fortnight three weeks of taking it say ‘I’m not taking this anymore and I don’t want to try another one because I felt so ill,’ so some people really do feel quite ill, that’s unusual but it does happen.”

Dr South

As mentioned earlier some people experienced severe side effects which eventually necessitated withdrawal of the agent; as in Harry’s case. All prescribers agreed they would use non-pharmacological methods first-line for side effects and only co-prescribe if they were severe and cognitive benefits were present. Dr South said “I really don’t want to go on adding more and more tablets in to treat side effects” which was supported by Dr East when he said “I do discuss but prefer not to prescribe just because, another tablet, another side effect you know.”

This reluctance to prescribe another medicine for a side effect is common for clinicians caring for older people as it can start what is commonly termed a ‘prescribing cascade’ and end with polypharmacy, all of which may cause an increase in the morbidity and mortality of the older person. With this knowledge in mind, the prescribers were very careful about taking a decision to prescribe for a side effect with the majority deciding to withdraw the agent and try another AChEI, as Dr South summed up below.

“The feeling is that we would try people on two but not usually on three; so if they haven’t had a good response on two of them we wouldn’t even try a third one. But we have some people who have side effects with one and not with another so yeah it does happen.”

Dr South

This ‘switching’ of agents can also be a treatment strategy if there has been poor response to an agent, with evidence supporting that different people respond to or tolerate different agents within the same class. At some point AChEIs need to be withdrawn and discontinued; sometimes for lack of response; or intolerable side effects or when it is obvious they are no longer
holding disease progression. NICE 2001 suggested that end points should be discussed prior to starting the medication, but it seemed this was not explicit during consultations. 27

The participants all had different understandings of when the medicine would be withdrawn or stopped with Janet saying that they hadn’t been told when it would be stopped but “what he said was they could work for 2 years, they could work for longer but there is no set time but he did say that we have got stronger ones.” This unknown about the duration of response was a fear echoed by Annabel who said “how long it will last I don’t know but I hope it continues.”

The prescribers and HCPs expressed some interesting thoughts on when these medicines should be withdrawn or stopped; with Dr North seeming the most reluctant due to his experience of witnessing a worsening of cognitive function in people who had stopped treatment.

“I have seen this before. Some of the carers feel that they may not be working and they think let’s try and stop it and with the patient being lower in their mental state you say try and stop it and you can see a dramatic difference in the people and you (need to) reinstate it back.”

Dr North.

Now when Dr North withdraws an AChEI he warns carers that “if there are any differences come back to me straightaway so I can put it back on.” In Harry’s case because the diarrhoea was so severe it seemed that stopping the tablets as suggested by Dr South was a good idea, but Joan reflected “I thought it was better when he was on Aricept®; definitely he went down hill after he stopped taking it.”

The clinicians expressed sadness about not being able to offer treatment at the later stages of the disease with Dr North outlining that all they could do was to “just put an extra social support and get social interventions, we make sure they have a support package.”

“I feel very sad basically knowing that they would deteriorate if they stop but eventually we have to stop because of all the other aspects of duty of care. It’s sad but at some point of time we do accept this.”

Dr East

An important observation from these interviews was that the prescribers and HCPs strived for a holistic approach to the assessment of response to medication and disease progression. Where possible they involved PWD and their carers in the decision-making process but often felt sad at the lack of options available for caring for people in the later stages of the disease. These findings seemed in great contrast from participant perspectives described in 4.3.1.3.
6.5.3.2 Getting the prescription and the medication
Once the medication was prescribed and a decision was made to continue it, the prescriptions had to be obtained from the various memory clinics, with Annabel, Vicky and Judy telephoning the secretary for further prescriptions.

“Most of David’s drugs come from our GP which is local, but those which Dr West prescribed came as a result of being in (Location 3). So I have a number where I can ring through and say I am down to the last month as it were. I like to be well prepared I don’t want to run out.”

Annabel, Case 4

However this was not without problems as often the prescriptions were incorrectly written and this meant that there was a need for further prescriptions so medication did not run out before the next appointment. In the narrative below Judy explains how she managed to get a prescription written for three months (3 stroke12) but only for once daily dosing instead of twice daily.

“It (the prescription) said 3 stroke12, 3mg, so they look at it at the Chemist and (say) ‘I’ll give you 3 months of 1 tablet for 1 a day’ so he didn’t say twice a day, so you only get one.”

Judy, Case 3

The second time it happened they complained to the psychologist completing Robert’s neuropsychiatric testing who said to Judy she would “sort it out.” Judy continued “I mean they ought to put twice a day.” These echoed similar findings from phase one in 4.4.3.5.

**Point of Reflexivity**

This may be an incorrectly written prescription but the dispensing pharmacist also has a role to play in stopping these errors from being perpetuated. The licensed dose is twice daily; Judy told the pharmacist it was twice daily and yet the prescriber was not contacted to check the prescription was correct. This happened twice and is not reflective of demonstrating a duty of care by the pharmacist to the patient in that they receive an appropriate prescription.32

Once the prescription was attained by Robert and Judy it was often difficult for the full supply to be received at the original point of dispensing or indeed for them to find a dispensary which stocked the medication as Judy shared below.

“I think he’s been better on them; the only thing that concerns me is getting the prescription and getting it right from the chemist as well. Do you know why they won’t stock them?”
I: “Do you go to the same chemist every time?”

Judy: “Well we try different ones to see if they’re any better...if you go into town, Boots down at (local village) don’t have them, we’ve tried Lloyds they didn’t have them at all, we tried the chemist in (another local village) and we had to go back because they sold out and this last time I said ‘let’s try the surgery at (local village).’ Well they said ‘well we’ll have to send away for them.’”

Judy, Case 3

6.5.3.3 Mislabelling

Of more concern as a pharmacist was the extent of mislabelling errors reported in such a small study. Both Vicky and Judy reported labelling errors and highlighted their concerns for people with memory problems who may be trying to keep track of things on their own.

“When he goes for his tablets they never have enough of them so they keep the prescription and at one point we had a box of tablets that said 3mg twice a day and the other box said 3mg once a day and they were dated about a week apart and I thought somebody with a memory problem this is. It’s not good, obviously I’m keeping tracks on it, but they shouldn’t get this sort of thing wrong for people with memory, should they?”

Judy, Case 3

In the first interview Vicky had shown me a box of Robert’s medication which had just been issued after their 4-week follow-up appointment. When I read the label it said “Take two a day” whereas Chris had been telling me he took one a day (long acting galantamine). There was consternation about what the correct dose was which could only be ascertained by a telephone call to the prescriber and then the pharmacy; at the next visit Vicky recalled:

“Well it was the Pharmacist’s fault as soon as you’d gone I phoned (local) hospital and they put me in touch with the doctor...and he checked in Chris’s notes and Chris was on the right dose it was the right medication so I went back to the Pharmacy and said ‘do you realise you’ve got it wrong?’”

Vicky, Case 5

Point of Reflexivity

This is actually quite a serious error in the eyes of the law. Earlier in 2009 a pharmacist was struck from the register and received a 3month jail term suspended for 18months for a similar error.³³³ This was also experienced by Robert and Judy and for a small study indicates poor knowledge about the license prescribing indices of medicines for dementia.

6.5.3.4 Compliance and Titration Problems

Robert had been started on rivastigmine and because of his cardiovascular problems and the increased risk of gastrointestinal effects with rivastigmine had
been put on an increasing dose to be titrated upwards from 1.5mg twice daily for two weeks, increasing by 1.5mg once daily every four weeks to 4.5mg twice daily over the next couple of months. No written information was given to Robert and the increasing dosage was not written on the prescription so it didn’t get put on the label. Hence there was a lot of confusion about Robert’s dose and what he was supposed to be on. To complicate matters Robert still looked after his own medication and transferred medication from packets to a medication compliance device every week. He also was responsible for remembering to take his medication during the day.

At interview one Robert reported that “this week I take two in the morning and one in the afternoon” with the aim of getting up to twice daily in a few weeks time. Between the first and second interview Robert had passed out in the kitchen, banged his head and spent two days in hospital while tests were done to see if it was a side effect of the medication or to do with his cardiovascular problems. (He was also on Warfarin which meant his head injury had bled profusely and needed stitching). So the medication had been reduced back to one in the morning and one at night. But somehow when the next prescription arrived from the memory clinic it had been written for 3mg for 3 months and this had been interpreted by the dispenser as 3mg once daily instead of 1.5mg twice daily (see Case Study Report A5-17). Dr West had been very apologetic and explained that Robert should now take 3mg in the morning and 1.5mg in the evening and increase to 3mg twice daily in two weeks. He was then to stay on this dose for 6 weeks when he would increase the dose to 4.5mg twice daily. However he did not explain why he wanted to increase the dose (for increased cognitive response) and because they had read in the literature that they could only go up to 6mg twice daily they didn’t want to reach it too soon in case they ran out of options; so they stayed at 3mg twice daily.

“It’s a shame that Dr West left because we had faith in him. He didn’t sort of explain why he wanted to put them up and we were a bit frightened because of what had happened and if you get used to the increased dose you can only go up to 6 twice a day can’t you?”
Judy, Case 3

This is an important reminder for HCPs involved in the prescribing of any medication for PWD to always provide an explanation of what is happening and supporting written information.

In terms of actually taking the medicine John thought that if the medication was “doing you some good you’d be a bit of a fool not to” take them. He added:

“Well to do the best you can, what’s the point in going to see Doctor West years ago to see what can be done if you get the treatment not to do it justice? I am very positive and very certain that that requires to be done at all times as instructed. It would be just crazy not to, wouldn’t it? Just absolutely crazy.”
John, Case 6

This was quite an interesting stance after he had refused medication for so long, but as he experienced the medicines as being effective he felt they should be
taken. Judy mentioned in two interviews that she was concerned that Robert still
had control of his medicines and that he couldn’t tell you what the name or
strength of his medicines were, but Robert was adamant that he had them all
under control.

Judy: “One thing I’m not sort of happy with, Robert does his own tablets,
which he wants to do and he puts them in his box but he couldn’t tell you
what tablets he’s on.”

Robert: “I could tell you quite a lot of them.”

And later

Judy: “But you can’t remember the names of them you see, that’s what
worries me.”

Robert: “Well they’ve all got packets or boxes or bottles up there so that’s
it. I don’t think there’s any problem, I’m not going to take too many of
one.”

Robert & Judy, Case 3

The absence of any pro-active input from a pharmacist for
these people with concomitant medical problems as well a
dementia has been quite shocking. One would expect that
basic advice would include information about titration issues;
reminder cards to emphasise medication routine and perhaps
a Medication Use Review session to see if there was any
other help and information that people needed. I also found it
difficult that healthcare professionals working with people with
a memory problem or a dementia did not routinely provide
written information to back-up dosage changes or titration
information. Relying on carers’ memory cannot be an option
as they are also taking on board much new information within
a consultation.

In a recent paper the authors discussed their concerns for a lack of evidence-
based strategies to promote medication adherence in PWD. 384 Although there is
a large literature base on general aspects of medication adherence, compliance
and concordance; with national generic guidance published February 2009390
there seems to be little pro-active involvement by community pharmacists in
helping these people to take their medicines successfully. I would argue that as
a clinician you could rarely achieve true concordance (definition of a shared
decision between prescriber and individual to start a medication and agree to
take it) with a person with dementia unless they were in the early stages of the
illness and normally had full control of their medication. More often than not
medicines are looked after by one person in a relationship and they ensure
medicines are re-ordered; re-dispensed and taken. This is not concordance this
is probably best described as compliance (complying with a direction), or if they
agree with taking the medication, adherence. 385
6.6 Summary of Findings

In summary this section has discussed the expectations of and responses to the medicines for dementia from both lay and healthcare professional perspectives. The more important responses of efficacy from the lay perspective seemed to be increased sociability, initiative and interaction with others. These seem at direct odds to those responses measured by the MMSE.

In Chapter Five it was proposed that findings from this study would provide qualitative and some quantitative evidence of the perceived effectiveness of medicines for dementia in a naturalistic setting. There was also the possibility that findings could inform information educational strategies for HCPs about communicating with PWD and their carers when starting a medicine for dementia.

In relation to the objectives of the study the medicines for dementia were associated with global improvements in personality, quality of life; social skills, orientation and improved initiative which positively affected personal and wider relationships. These improvements were seen to outweigh lesser improvements in memory. Experiences of lay participants and healthcare professionals supported the use of these medicines in early stages of dementia, although heterogeneity in response was raised by prescribers. Of more interest was the heterogeneity in the type of response and at times the very generality of it, resulting perhaps in a perception that the effect was in fact a 'placebo' response. However the longitudinal nature of this study demonstrated sustained efficacy over time in some cases.

The MMSE recommended by NICE, was seen to tell only 'half the story' and did not accurately reflect for some participants; the true impact of the medication on day to day life; especially interactions and relationships with spouses, family and friends. For people like David the MMSE seemed not to accurately reflect the extent of functional impairment. NICE was seen to hinder appropriate access to medicines by lay participants, prescribers and HCPs. It seems that a wider range of patient reported responses may be important in determining efficacy of treatment.

Of key importance is the need for education and information about the disease; its associated behaviours and how these progress over time at the early stages of the illness. As reflected by Vicky and Judy much of their frustration and associated negative effects on their respective relationships was related to not understanding common symptoms such as repetition and poor short term memory. Carers need to understand these are part of the disease and not a deliberate action on the part of the affected person.

Pharmacists can be more involved in the support of people with dementia and their families. Key areas include provision of information, clearer labelling, provision of medication reviews and support with compliance and titration regimens. Inadequate knowledge about the correct prescribing for these agents was also highlighted which indicates an urgent need for educational input.
CHAPTER SEVEN: OVERARCHING DISCUSSION AND CONCLUSIONS

This chapter will briefly summarise findings from both research phases and discuss the study limitations. Key findings will be presented and discussed and the implications for practice and future research will be explored.

7.1 Summary of Findings

Participants for phase one were recruited from four different branches of the Alzheimer's Society in the South-west and for this reason the findings were more diverse in terms of the range of severity and chronicity of the disease and the effect of these on carer burden and personal relationships. Participants with early dementia or a memory problem in phase two were recruited from three different memory clinics. Findings illustrated longitudinal effects of the medicines prescribed for dementia on alertness, initiative, communication and improved relationships.

Although there were surveys\textsuperscript{30,253} and clinical trials\textsuperscript{245,247,248} detailing the perspectives of people with dementia and their carers about the medicines for dementia, only one study incorporated a qualitative study which explored these findings in greater depth.\textsuperscript{253} Traynor et al have since outlined the importance of incorporating lay perspectives of treatment effects into measurements of medication response.\textsuperscript{386} In phase two of the aforementioned study there seemed to be a willingness of the HCP study participants to take account of subjective lay perceptions of response in some areas but not all,\textsuperscript{253} however this doesn’t seem to have filtered through to policy decision-makers. Leibig has suggested that the incorporation of lay perspectives of important outcomes has been encompassed in the prescribing of medicines for dementia by specialist geriatricians but there remains an element of doubt because of the international controversy.\textsuperscript{387}

7.1.1 Phase One Summary

The objectives of the study were to explore lay participant experiences of the use and effects of medicines for dementia; the experience of support and information provision and involvement in shared decision-making. What was striking was the sheer hard work that being a carer entailed. The most distressing part of this was the variability in support, access to treatment or information and/or specialist services all of which were complicated by the variability in response by HCPs. Delayed access to support services such as respite or day care led to breakdown in carers’ ability to continue coping. Findings suggested that support and information needs to be offered earlier and at frequent intervals throughout the caring process as the experienced burden changes over time.

Not only was there variability in the aforementioned areas but also in the effects of the treatment in terms of efficacy; side effects and monitoring issues. Important outcomes for participants seemed to be an increase in sociability and taking part in daily activities around the home. These perceptions were corroborated by family, friends and supporting HCPs.
It seemed there was a need for some HCPs to complete further education and training in the very basic skills of communication and consultation etiquette. There was also a perceived need to explore whether consultations need to be conducted together with both patient and carer or apart or both. From pharmacists there was a paucity of proactive involvement but findings suggested there were many issues associated with medicines management and the illness that pharmacists could help support.

7.1.2 Summary of Phase Two
In summary this phase was a longitudinal study which explored the effects of the medicines for dementia from lay, prescriber and HCP perspectives in a naturalistic setting. Important outcomes noted from lay perspectives were increased sociability, initiative and interaction with others and the associated effects on acceptance and adjustment.\(^{36,142,143}\) These seem at direct odds to those responses measured by the MMSE with the MMSE perceived as only telling ‘half the story’ of the true impact of the medication on day-to-day life. Other key findings included a need for information and/or education for carers about how a dementia affects an individual and how this can result in changed behaviours. Other information required included suggestions for managing behaviours and support in suggestions for activities. Community pharmacists could be more proactively involved in the support of people with dementia and their families in the community especially in the areas of maintaining compliance and adequate and accurate medication supplies.

7.2 Limitations of the Research
In terms of actual participant numbers these were both small studies and the implications for transferability or generalisability of findings will be discussed later. In phase one, participants were recruited from local branches of the Alzheimer’s Society, but it could be argued that participants self-selected in order to tell their story. With the implication that those with the most grievances were those that signed up. However this is not reflected by the overarching variability in the provision of support, information, services and access to medication. These participants may also have had greater knowledge on treatment availability, current research and accessing support services, because of their membership. However again there was great variability in all of these areas and there seemed to be a paucity of support services in some locations. It could also be said that by recruiting from local branches there would be inherent bias in the participants’ perception that the local branch was a positive support. Participants in phase two were recruited from specialist memory clinics so perhaps findings of improved knowledge and communication skills from the prescribers and HCPs involved was not surprising. This was in contrast to interactions with HCPs by phase one participants which were variable and often unsatisfactory.

In terms of the importance of medication-related responses such as improved communication and relationships, it is unclear whether these would have been different if there had been more male carer participants in each phase of the study. In phase one all male carers were or had contemplated placing their loved one in long-term care compared to one female participant. It has been
suggested that the daily completion of intimate caring tasks for their spouses by male carers could destroy their own perception of the spousal relationships such that it ended in institutionalisation. ¹⁷¹,¹⁸²,²⁸³ This seems in stark contrast with the female participant carers of this study who seemed to place greater emphasis on communication and sociability.

In qualitative research and especially in face-to-face interviews the personal qualities of the researcher can have a direct effect on the interaction with participants and their involvement with the process. That is researchers’ can vary in their ability to form a relationship with the participant and this may affect shared narrative and therefore findings. ⁵⁷,²⁶⁸,²⁷⁰ It was evident that a number of interviews over a period of time can result in a relationship which may no longer be perceived as strictly participant and researcher. Participants may perceive the researcher more as an interested acquaintance rather than an objective researcher. ⁵⁷,²⁶⁸,²⁷⁰ This has implications for the resultant behaviour of the researcher which needs to remain objective. ²⁷²,²⁷³ The participant invitation letters introduced me to potential participants as a pharmacist and this could also have affected the participant perception of the relationship.

The design of phase two included attention to quality and validity with production of a Case Study Protocol (A5-1), a study database and generation of a Case Study Report (A5-17). The inherent use of multiple data sources in a case study approach can be seen as methodological triangulation to ensure all truths are discovered. ³²¹ The multiple data sources included; diary recordings from one participant willing to complete these; patient shared records; interview data and consultation observational data. Generally when multiple methods are used it is hoped that they will all produce the same results to improve the robustness and transferability of findings. The diary findings of this participant couple supported findings from the interviews, observed consultation and the patient shared record. However, the limitations of diary research such as inaccuracy of entry biases are well known. ³⁴⁹ It is also a limitation that only one couple felt able to record their responses over time. However it could also be perceived that this could be a time consuming request for a carer who’s time is already constrained by caring responsibilities. ¹³²,¹⁶⁷,¹⁶⁹ This supposition has been supported by Välimäki et al who found that although some caregivers perceived diary writing as ‘therapeutic,’ others felt it was “an extra source of stress.” ³⁸⁸

The different data collection methods in phase two indicated that some objective findings from disease rating scales did not actually reflect accurately what was happening in the real life-world of the individual. Does this matter? Others argue that disparate findings help to increase the depth and relevance of findings as they reflect more accurately the complexities of healthcare interventions and the heterogeneity of people. ³²¹,³⁸⁹ I would also agree with the complexity of healthcare interventions but more importantly on the heterogeneity of those involved and the individual reactions that people can have. The sheer interconnectedness of life implies that any intervention will have a myriad of effects and not just on the individual receiving it but those caring for and living with that individual. Although there were only six HCP participants in total in phase two their perspectives of the value of medicines for dementia generally reflected those of lay participants in phase two and other studies ³⁰,²⁵ and
perhaps this could be explored in a larger study, looking at patient-reported outcomes.

Are the findings of these small studies transferable or generalisable? Yin\textsuperscript{20} argues it is not the transferability of results but the transferability of theory from findings that can be transferred. Perhaps the superordinate themes from each study phase could have ‘inferential transferability’ as proposed by Lewis and Ritchie so that one might infer the same findings could be found from a similar population group.\textsuperscript{340} Similarly if the context where the findings were being transferred to was similar to the context the findings came from then they would hold ‘naturalistic generalisation.’\textsuperscript{341} It could also be proposed that the findings would be likely to resonate with other PWD and their carers attending local branches of the Alzheimer’s Society and/or attending memory clinics for treatment of mild dementia.

7.3 Key Findings

This section will present the key findings from the study in order of importance and also link to the key healthcare policy literature.

7.3.1 The Burden of Caring

As a researcher an over-riding perception was of the sheer hard work that caring entailed. It completely changed any previous concepts of daily activities; roles and personal identity within that relationship. This was especially apparent in phase one where the chronicity of caring by participants seemed to have been longer than in phase two. In phase two came a personal recognition of the potentially devastating effects that mild dementia and cognitive impairment had on personal relationships. The improvements in spousal communication and social interactions that medicines for dementia and acceptance of illness brought were in some cases dramatic.

Key pointers in reducing carer stress and sense of burden seemed to be the medicines’ for dementia’s affect on mood and initiative of the person with dementia and resultant affect on their ability to complete daily tasks. As mentioned in 2.2.2 behavioural changes and decreased ability to complete activities of daily living can be key factors which result in early institutionalisation of PWD by their carer.\textsuperscript{49-51,81,119,144,145} So it seemed the medicines for dementia by improving mood and initiative reduced the experienced burden of daily caring activities for some carers. Also a key part of this was the provision of appropriate support in terms of regular day and respite care. This is supported by Pearlin’s conceptual model of carer stress (see 2.2.3 Figure 2.2) which demonstrates a connection between the provision of an interventional programme and an experience of mediation in the stressors associated with caring.\textsuperscript{170}

Coping with caring was also linked to perceptions of grief and anger at the loss of previous relationship dynamics between spouses and a taking on of an unwanted and unasked for role. This has been described by others as role captivity.\textsuperscript{170,177} The roles of stressors and secondary stressors in the magnitude of carer burden experienced have been well described\textsuperscript{170,171,188} and the perception of these stressors by individual carers seems important in how a
caring role is perceived. Pearlin suggested that the psychological experiences (intrapsychic strains) were shaped by the individual characteristics of the carer and these associated reactions by individual carers to caregiver burden were demonstrated within both phases of the study. Sue (location 2, phase 1) and Judy (Case 3, Phase 2) both struggled with their new roles and having to take on activities that had previously been performed by their respective husbands. It is important to note that the improvements in social skills after a medicine for dementia was prescribed made caring more bearable by mitigating other perceived dysfunctions such as memory loss. That is these medicines seemed to improve the ability to cope with everything else if there was a sense of gained relationship for the female carer. For many the concept of not being able to converse as usual with their partner was very distressing for both participants with dementia and carers and experienced as a major stressor within their own sense of self. This is entirely understandable, as Sue described it must be terrible to live with someone who you no longer know and recognise on a personal level. A return to a person’s former self or regaining their personality was also an important aspect of medication for some carers. It is however interesting that the older couples, and those with perhaps healthier relationships prior to the onset of dementia seemed to fare better with coping than others who were younger or who had previously more dependent roles on their respective spouse.

This of course relates well to Ablitt’s theoretical framework for well-being and relationships as depicted in Figure 2.3. It seems that the medicines for dementia could mediate the effect of living with dementia of the carer by improving relationship quality and as a result improving emotional well-being. As a result the proposed addition of a medicine for dementia taken by a PWD may mediate the well-being and relationships experience by the carer as postulated below in Figure 7.1.

![Diagram](image_url)

**Figure 7.1 Postulated mediation of medicines for dementia on carer ability to live with dementia.** (Adapted from Ablitt)
Whatever the relationship dynamic it was clear that people needed individualised support packages which were also backed up by written information and details of contacts for services in a crisis. These services needed to be offered proactively rather than in response to crisis so that relationships could be preserved and institutionalisation avoided.\textsuperscript{171,174,175,177,180,181,183} Once a carer has started to hate the person they are caring for, institutionalisation seems inevitably to be the next step.\textsuperscript{185,186}

Although there have been a number of government directives on the support of carers\textsuperscript{45-51} it was clear from phase one findings that carer support was not equitable, generally not proactive and varied across and within locations. In July 2009 the government published ‘Shaping the Future of Care Together’ which is an attempt to drive forward a more equitable care system across all areas where care and support is needed.\textsuperscript{391} It is hoped that this will improve carer experiences in the future. However if medicines for dementia are a positive mediating effect on the experience of caregiver burden and stress then a revised policy on how medicines for dementia are provided and the efficacy of these within the dyad of the PWD and the carer is urgently needed. (See later 7.3.2)

7.3.2 Accessing Medicines for Dementia

Both lay and healthcare professional participant perceptions of the medicines for dementia were they had proven efficacy and beneficial effects were generally preserved for up to two years. Prescribers in phase two described how they felt their professional decision-making was compromised by the revised NICE guidance of 2006, in terms of caring for people at the mild and moderately severe to severe stages of the illness.\textsuperscript{31} The new economic costing model were upheld by Judicial Review\textsuperscript{232} even though discrepancies were noted such as the appropriateness of using QALY evaluations in older people and the decision not to include carer burden into the cost-effectiveness model\textsuperscript{31,114,230} These decisions point to a misunderstanding on the behalf of NICE of what PWD and their families feel are important outcomes.\textsuperscript{30,55,247-250,253}

Point of Reflexivity

Interestingly I was at an ESRC Economic Evaluation seminar in pharmacy practice in June 2009 where one of the members of the health economic modelling team for HTA 19\textsuperscript{27,31} and another from the recent review of cancer therapies were presenting. I found it very difficult to understand the complete lack of compassion they had about the effects of the decisions their new cost models had on people’s lives. One of the comments went something like this:

‘...if I have to listen to another bleating patient group about how these drugs help people to spend more time with their families when they are going to die anyway (I will be very angry).’

It is very easy to make decisions when you have complete disregard for the effect these might have on peoples’ lives.
We are all going to die at some point and if a medication can ease the pain of leaving this world for the next from the perspectives of patients, carers and families then there should be some real recognition of this. People need to have time with better levels of cognition and insight to plan in advance for their future care and end of life care plans. In great contrast was a wonderful presentation by Dr Jason Leitch (the National Clinical Lead for Safety and Improvement, Scottish Government) who presented at the 2009 Health Services Research conference. He presented statistical data on a graph as patients’ names, ages and cause of death; making it personalised so the impact of these hospital acquired infections or accidents could be seen on the whole of the family and society.

The participants of both phases held anxiety about whether the medications they or their loved one was taking may be withdrawn because of the impending NICE decision and/or their access to medication for the later stages of the disease would be closed. Participants from phase one described their perceptions of it being ‘a battle’ or a ‘fight’ to access what was perceived as the relevant medication, information or support. Those in phase two felt lucky they had been prescribed the medicines prior to the decision being made to limit prescribing. Perhaps a more eloquent indication of the perceived value of these medicines and the benefits they brought to the person taking them and those supporting them was participant’s anger about other people not being eligible for treatment after the final NICE decision (see Peter’s comments in 4.3.3 and David’s in 6.5.1.1)

The media obviously has a great role in how the public view many things including healthcare and so another problem for HCPs and prescribers was how to manage expectations of these medicines. Medicines for dementia are only part of the treatment available for dementia, but they seem to be a part that helps support and ease the burden of caring through some of their more global improvements other than improved memory and cognition. Some of the prescribers talked about perceived placebo responses to treatment in the early follow-up consultations. This is interesting but perhaps raises more questions than can ever be answered; what exactly is the placebo? The medication? The fact that something is being done? The prescriber themselves? Does it really matter? Robin Nunn argues that once we describe the placebo it is no longer a placebo; it is a tangible effect and that perhaps we need to throw out all our own preconceptions and perceptions of what placebo is and look at what really is happening.367

NICE guidance31 is actually due for a further review at the end of 2009; it will be interesting to see the approach taken. It has been proposed that the recognition of quality improvements in healthcare for older people may not best be reflected using QALYs. An interesting article by the researchers who developed the Assessment of Health Economics in Alzheimer’s Disease (AHEAD) model which NICE based their new economic model showed a great disparity in the cost per QALY.393 NICE 2006 estimated £46,000 per QALY for galantamine compared to £9000 per QALY in 2001.393 The authors reflect that NICE used incorrect and unsubstantiated evidence to base their new economic
modelling and did not take into account the uncertainty in the estimates that they used.  

At present there seems to be a great mismatch between lay perspectives of the efficacy of these medicines and the biomedical viewpoint gained from rating scales such as the MMSE, ADAS-cog and others.  

The improvements in sociability, initiative and attitude seem to be perceived by the current biomedical emphasis on memory retention as ‘soft’ outcomes for these medicines. As Woodarczyk et al pointed out the MMSE does not capture psychological and quality of life improvements; and just because it does not, does not mean improvements are not present or indeed that they should be ignored. Perhaps we need to revisit the attitude of Western culture which places an emphasis on memory and intelligence above all else and concentrate on social and relational outcomes associated with being human.  

It should be considered unethical now to have further placebo-randomised controlled trials with any of these medicines for dementia as their efficacy has been proven in certain groups of people beyond doubt.  

However placebo-controlled trials continue in new research placing those on placebo at disadvantage in regaining lost cognitive function and preventing early progression. Perhaps what is needed is to revisit the way in which these response rates are measured and trust PWD and their carers to give PROs that reflect their response to medicines for dementia? (See 7.3.4 for further discussion).  

7.3.3 Perspectives of Responses  
What was apparent in both phases of the research was that the medicines for dementia had a diverse range of affects and effects with generally positive outcomes on activities of daily living; including those important to social relationships. Humans are basically a very social being who want/need to share experiences and thoughts with others, primarily through conversational interaction. Once this ability to converse declines or fades the resultant effect on personal relationships can be catastrophic.  

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>What I found interesting in phase two interviews was the depth of anger and frustration displayed by both the person with the memory problem and the carer as a result of cognitive impairment. The early social withdrawal displayed by those with a memory problem or dementia had an effect on social relationships; interactions with friends, family and grandchildren as well as the ability to socialise within a relationship in terms of just simple conversation. Participants with dementia spoke about how they were unaware of why they were behaving like this and that it wasn’t until they received a medicine for dementia they actually gained insight into their previous behaviour. Observing couples interacting together in their own homes over a period of up to 13months was very interesting as you could witness a range of responses not only to the medication but also the acceptance</td>
</tr>
</tbody>
</table>
and understanding of the illness itself. Observing the
difference in insight and awareness of some of those taking
the medicines and the resultant effects on their conversation,
social skills and interactions with their grandchildren was very
humbling. Dementia care is a very complex business
requiring thoughtful, holistic and individualised support to
those affected and their wider social circle of family and
friends.

This diverse range of improvements included: global effects on personality,
mood and behaviour; quality of life; improved socialisation skills;
communication; activities of daily living; mobility and engagement in their life
world; and that these were apparent for some time before lessening.
Participants commented on the fact that memory did not seem to improve that
much but this was outweighed by other perceived benefits in day-to-day living.
On the whole participants felt the medicines should be continued as long as
they were perceived to be beneficial, the side effects were tolerable or when it
was definitely proved they were no longer working.

The findings from phase two suggest there is indeed a role for medicines for
dementia in early disease, if just to ease the suffering associated with living with
a memory problem and its resultant effects on communication and relationship
dynamics and to decrease institutionalisation. (These are very important positive
outcomes as they help to reduce carer burden and stress and these are well
known to increase rates of institutionalisation). I believe that the
decision to ration these medicines has increased unnecessary suffering for
people with dementia and their families in early disease; a situation which
seems grossly inappropriate in a so-called developed nation. This increased
level of suffering can only grow and perhaps by the time moderate disease is
reached permanent damage may be done to the spousal relationships and
continued ability to care. It is indicative of institutionalised ageism, and
associated stigma and misunderstanding of what it is to have to dementia. Li
and Orleans proposed that the negative value-based judgments of HCPs
prevaded all parts of the dementia treatment continuum and that a person with
dementia became a non-person (just because they cannot remember what they
did that morning). This ethos resulted in a complete disrespect for the
individual with dementia and those caring for them. It is as if once a person
has a diagnosis of dementia their opinion is no longer valuable, relevant or
pertinent and not to be trusted.

In both phases of the research, lay perceptions of the usefulness of the current
tools available for rating the severity of dementia and response to
pharmacological treatment were doubtful. Participants could not understand why
a series of assessments testing their loved ones ability in areas where they had
always been very good at; or alternatively very poor at were useful at all. The
MMSE seemed to be associated with the most anxiety as this was also linked to
the continuation of the medication. People with previously higher intellect
generally scored highly whereas their actual functionality in terms of day-to-day
activities and social interactions was grossly impaired. Prescribers and HCPs in
specialist services were generally aware of the limitations of the MMSE in
clinical practice and did not rely on it as a single rating tool. This resulted in a
battery of tests used to assess efficacy in some people whereas in others a more global and possibly subjective assessment of improvement was taken. This variability will be discussed further in 7.2.6.

In June 2009 the 2006 guidance was updated again, not with respect to the economic costing model which was upheld (even in view of irregularities) but in terms of the use of the MMSE.\textsuperscript{31} It points out that the MMSE does not fairly reflect the diagnosis or staging of severity in those people with learning disability; sensory disability (such as hearing or blindness problems), or have English as a second language. It did not comment on the inappropriate use of this tool in people of higher intellect. In view of the fact that many of NICE decisions are based on trials using MMSE in all people (where pre-morbid level of intellect unknown) perhaps this underestimates treatment effects shown in studies and has implications for their next revision.

Questions within the MMSE are location dependent\textsuperscript{126-128} with people scoring more highly in their own home than within an institutional setting. Perhaps as they are living in their own home, this is where the assessment should take place? Although many of the tools for assessing response to medicines were developed for use within a clinical trial setting it is less than clear of their usefulness in a naturalistic setting. It was also clear in both phases that many carers had little knowledge of the symptoms of AD (other than a poor memory) and how they manifested in day-to-day life. For example repetition and lack of initiative were seen almost as deliberate behaviours designed to annoy the carer. This ignorance points to a need for greater education for carers and PWD to inform them of the more global affects and effects of AD. This would enable them to understand more clearly how the medicines for dementia were affecting their loved one and perhaps reduce uncertainty in the area of response.

It may therefore be more useful to develop a set of patient reported outcomes (PROs) for use in clinical settings which reflect the importance of response to these medicines from patient and carer perspective. As Frank reports “some treatment effects are known only to the patient” and “patients provide a unique perspective on treatment effectiveness.”\textsuperscript{54} One could argue that this is common sense as the patient is living with the disease and is far more aware of the effects of change brought about by a treatment intervention than a medical observer.

This research has provided the basis for a series of PROs which could be developed further and validated as a means of a more patient and carer-centred focus on measuring outcomes that are important in daily life. For example key PROs seem to be: social interaction; initiative; involvement in the environment/world and a returning or retention of self (personality). As mentioned in 7.3.1 and 7.3.2 these soft outcomes are important in their own right as the resultant improvements in social interaction seem to mitigate carer response to dealing with other aspects of caring, lessening burden and allowing adjustment to living with dementia.

Currently the main use of PROs in dementia research is in the measurement of health-related quality of life (HRQOL) which suggest good correlation between PROs and those found on other QOL measurement tools in dementia.\textsuperscript{371-374} They have also been used as a measure of the patient perspective in mild
cognitive impairment with some success. However there seems to be a reluctance to trust PROs in dementia as frequently their reporting differs from carer informant reporting in the same areas. Studies show that carers consistently rate HRQOL lower than PWD do, but this also occurs in other areas such as cardiac disease and breast cancer. However another perspective is that QoL PROs are also a valid perspective of the truth as experienced by the person with dementia. It has also been suggested that carers rate PROs lower if their carer burden and stress levels are high. This suggests to me that perhaps carers are rating their own QoL rather than that of the care-recipient. Lohr argues that as health is such a complex dynamic then perhaps more than one perspective is needed and that outcomes should be triangulated from the carer, patient and clinician perspective as well as other members of the multidisciplinary team if appropriate. This seems imminently sensible, but what if the results are all different? More importantly does it matter if the person with dementia and their carer are happy?

In terms of consistency NICE guidance can be construed as conflicting. Although they suggest the use of MMSE and ADAS-cog tools in diagnosis, rating severity and response to treatment and base their cost models on these outcomes; in section 7.4 they go on to state that “surrogate measures of disease progression such as cognition do not correlate with clinically relevant outcomes such as behaviour, function and carer well-being…” This could be interpreted as mitigating reliance on such tools and encouraging clinicians’ to use their own clinical judgement, or just abdicating responsibility for the possible impact of supporting tools with acknowledged limitations.

However this is an important statement which should be read by all decision and policy makers in PCTs in conjunction with key guidance points as it can directly affect patient and carer outcomes if medication is stopped or not started because of an arbitrary score on a rating scale.

<table>
<thead>
<tr>
<th>Point of Reflexivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>As a clinical ward pharmacist in a previous career path I have completed many audits primarily looking at appropriate prescribing. I know of colleagues working in dementia services that routinely audit MMSE scores of PWD on AChEIs and recommend treatment withdrawal on the basis of a low score. Without a real understanding of the relevance of these scores and an understanding that these can fluctuate on a daily basis and may not truly reflect responses that are important to PWD and their carers; well meaning HCPs can actually do a lot of damage to a patients (and their carers’) well-being. This type of audit does not just occur in hospitals nationwide but also in outpatients and PCT as a means of cost-saving. I find the thought distressing in terms of the potential for increased suffering for PWD and their families.</td>
</tr>
</tbody>
</table>

There is recognition that there is limited health funding but if overt rationing by NICE is to be upheld then greater acknowledgement of these treatments on family members and carers should be taken into account. It could be suggested that the NICE 2006 decision was based on personal value
judgements of the economic advisory panel involved and did not adequately reflect those of PWD and their families.31 Having licensed medicines available with proven efficacy yet not being able to prescribe them seems non-sensical in the 21st century. The fact that health and social care costs are separate makes it easier to target medicines expenditure as a soft option. It is far more palatable to ration medication than make redundancies or perhaps address the inadequacies of mismanaged and inequitable service provision (in both health and social care). It has been suggested that as soon as the current licensed medicines come off patent and there are generic alternatives the decision will change; but for many this will be too late.235 Too many people will have suffered unnecessarily and for too long in the intervening period.

7.3.4 Educational Issues
A number of findings pointed to the need for greater educational resources and training to be made available for HCPs; carers and PWD. The educational need of HCPs at the front-line (GPs) was one not only of knowledge but also in the best ways of communicating with PWD and their carers.30,31 GPs may not be experts in diagnosing dementia but there should be an awareness of the associated symptom pattern and an understanding of the difference from normal ageing. One of the underpinning tragedies of findings reported in the NDS was that although there is an estimated 700,000 people in the United Kingdom with dementia, only 400,000 of these are formally diagnosed and less than this number are receiving appropriate treatment and/or health and social service support.41 This information indicates there are a great many families and relationships suffering in silent despair from the effects of living with this disease.

Findings from these two small studies highlight the anguish and burden of caring for a person with dementia that had been able to access treatment and support; what must it be like for those that have not? It is hard to tell if this lack of identification and referral to appropriate services is due to an underpinning ethos of ageism,67,68 the stigma of a mental illness and/or therapeutic nihilism seemingly engrained in many front-line practitioners.80,81 Lay participants in phase one commented on these attitudes being less than helpful and generally obstructive in their search for information and support.

In terms of communication skills and consultation etiquette it seems that some HCPs have a lot to learn about how to support people asking for help. There is also a need to revisit the structure of the consultation for PWD and their carers and to ascertain what type of engagement best suits participants needs. There is a need to protect the best interests of the person with dementia and maintain confidentiality where possible and this may best be done apart from their carer at times. However to ensure a complete picture of what the clinical situation is at home, carer views need to be explored, and again this may need to be completed alone to prevent discord or upset for those PWD retaining insight. To complicate things further shared decision-making may need to be negotiated between all parties together. This obviously could be seen as time consuming for the HCP involved but findings suggest that if carers' viewpoints are not heard this builds resentment which ultimately negatively impinges on their continued ability to care. Interestingly a simple phrase like ‘how are you coping’ was seen
by Ann (L1) as making all the difference to how she felt within the consultation and in her role as a carer.

People with dementia and their carers also needed information about the illness, its progression and what to expect in terms of changed behaviours and activities and how best to cope with these. This information needed to be also provided in a written format so that it could be referred to at a later date and the information needed to be tailored to the individual so that it helped their sense-making processes of what was actually happening. It was evident that some carers did not understand that the behaviours they found most annoying (repetition; lack of initiative; lack of conversation and mood changes) were in fact part of the dementia syndrome and not a deliberate attempt to annoy them. Being aware of disease-related changes with guidance on how to manage these can reduce frustration and anger in both care-giver and care-recipient.

7.3.5 Pharmacists and Medicines Management Issues

Results from both phases of the research highlighted a large number of medicines management concerns for PWD and their carers. These included: difficulties in managing compliance and accessing the full supply of a prescription; problems with medicines administration, incorrectly labelled prescriptions, managing titration regimens and advice, information and support about side effects and disease management.

All of these problems or difficulties could be covered by the pharmacist offering a medication usage review (MUR) service for PWD and their carers but there was no evidence of any proactive help or support by pharmacists. Bob and Judy’s and Chris and Sue’s experience in phase two of receiving incorrectly labelled medication and the lack of the dispensers initiative in checking an incorrectly written prescription are examples of levels of very poor knowledge in the area of medicines for dementia in community pharmacy. It also indicates a very poor level of duty of care by the pharmacist for the individual which conflicts directly with the professional practice guidance for pharmacist.

After presenting an oral paper at the British Pharmaceutical Conference in 2006 about lay perspectives on the medicines for dementia I was commissioned to write an article on how to undertake a MUR in dementia for a national pharmacy magazine aimed primarily at community pharmacists. The article was also linked to the national CPD competency framework for pharmacists. However it remains unclear how effective these sorts of publications are and whether they actually change practice by enhancing knowledge.

In terms of supporting people to achieve compliance the study findings showed no active input by pharmacists into the management of monitored dosage boxes (compliance aids) with these being filled either by the person with dementia or carers. As described in the findings, many PWD had concomitant illness and medication and were taking anywhere between one and 10 different medicines.
This can make for a very complex pharmacological cocktail with the potential for interactions, side effects and iatrogenic disease.\textsuperscript{397} It would seem that when dispensing a prescription for a medicine for dementia there was no active thought process by the pharmacist involved about giving advice on the medication or compliance, checking possible interactions with concomitant medication or obtaining repeat supplies. A compounding factor was that often these prescriptions were supplied by the specialist service and therefore would not be on the same prescription form as the person’s regular medication. This makes it important for pharmacists to check concomitant medication and illness if they do not have a record of it on pharmacy medication records. There perhaps is also a need for individuals to make a relationship with a specific pharmacy in order to maintain continuity of care.

There are very few publications of the role of the pharmacist in dementia care and the majority are from the United States.\textsuperscript{384,398-400} In 1998 the potential for pharmacist involvement in medication review; input into care of people with behavioural symptoms and the promotion of AChEIs as an effective treatment was proposed.\textsuperscript{385} In 2008 the American Pharmacists Association published a ‘White paper on the expanding role of the pharmacist in caring for individuals with Alzheimer’s disease.’\textsuperscript{399} It went on to give guidance for better education and training at undergraduate and postgraduate levels.\textsuperscript{399} They authors described the top eight pharmacist roles and rated these out of a 100 in terms of perceived improvement to the care of people with AD.\textsuperscript{399} These are listed in the Table 7.1 below.

<table>
<thead>
<tr>
<th>Pharmacist Activity</th>
<th>Impact of Care on People with AD (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Providing general medication therapy review</td>
<td>69.2</td>
</tr>
<tr>
<td>Incorporating pharmacists into support groups and education programmes</td>
<td>69.2</td>
</tr>
<tr>
<td>Counselling individuals with AD on medication</td>
<td>53.8</td>
</tr>
<tr>
<td>Improving adherence and compliance to medication regimens</td>
<td>53.8</td>
</tr>
<tr>
<td>Delivering community education programmes</td>
<td>46.1</td>
</tr>
<tr>
<td>Conducting memory services</td>
<td>38.4</td>
</tr>
<tr>
<td>Serving as a source of referrals to other healthcare practitioners and local resources</td>
<td>38.4</td>
</tr>
<tr>
<td>Directing individuals with AD to pharmaceutical maintenance programmes</td>
<td>23</td>
</tr>
</tbody>
</table>

* Adapted from Skelton 2008\textsuperscript{399}

In the United Kingdom there is currently no guidance from the Royal Pharmaceutical Society of Great Britain (RPSGB) on the role of the pharmacist in the care of people with dementia or specific advice for training at undergraduate or postgraduate level. However in 2008, representing the United Kingdom Psychiatric Pharmacy group (UKPPG) I collaborated with the RPSGB to develop the response to the National Dementia Strategy (NDS) consultation for potential pharmacist input to the objectives of the NDS.\textsuperscript{401} I have also written Practice Guidance documentation for the Pharmaceutical Care of People with Dementia and the monitoring of medicines for dementia as part of a toolkit.
aimed at enabling primary and community care pharmacists to support people with mental health problems. For each mental health area (including dementia) the toolkit links possible pharmacist roles at the essential, enhanced and advanced levels (see 2.3.2.1) as well as at pharmacist prescribing level. These correlate well with those suggestions proposed by the American White paper. However it is clear that there is a real need for increased education for UK pharmacists across all sectors in the recognition and management of dementia and their potential input. Two recent CPD papers published in the Pharmaceutical Journal (the mainstream publication of the RPSGB) outlined the background to AD and other dementias but there was no information about how best to support people and/or their carers and families. Perhaps the best indication of the narrow medication-related focus some pharmacy practitioners hold. There is a need to re-address this pharmacist-medication focus to a more holistic patient-focussed care if the aims of the Pharmacy White paper are to be fulfilled.

There also needs to be recognition of the need for specific education on dementia and the associated public, social and healthcare impacts at undergraduate level as well. This lack of knowledge may be reflected in a lack of proactive service provision to PWD and their families. A study in 2003 highlighted that pharmacists were commonly involved in referral of people with concerns about probable dementia to dementia services. However there was no indication of further involvement in multidisciplinary team working or at a specialist level in terms of medication review even though Wagner had previously highlighted the role of clinical pharmacists in secondary care in medication review services.

**7.3.6 Variability**

In phase one the results highlighted great variability across and within locations in a number of areas. These variability’s included:

- access to treatment, information, support and/or specialist services,
- differing responses and attitudes from HCPs,
- differing effects of treatment, side effect rates, monitoring methods and follow-on treatment.

In terms of variability in carer support it is hoped that the six key objectives of ‘Shaping the Future of Care Together’ document; which follow, will help to address this experienced inequity:

1. the right for people to have support and care needs addressed to stay as independent for as long as possible
2. access to an equitable care and support needs assessment
3. a care service package that is seamless and holistic
4. that people can find their way through the care and support system easily
5. that services are based on personal circumstances and need, and
6. people will have a say in how their own funding for care services is decided.

The implementation of the NDS will hopefully improve the awareness of dementia, lessen associated stigma, promote the need for holistic care and result in a more informed workforce with a better ability to support PWD and
their families. However more training is perhaps needed in communication and consultation skills needed to relate effectively with both PWD and their carer and also within wider health and social care services to address the issue of ageism that is currently perceived and experienced by many.

The variability in access to treatment is something that will need greater input in terms of earlier recognition by frontline HCPs and increased awareness of the perceived benefits of these medicines by people who take them and those that care for them. The NDS highlighted the presence of postcode prescribing and this perhaps reflects the misunderstanding of the perceived benefits of these medicines by policy and decision-makers at a local level. However it may be difficult to address this issue when the value-based judgements of NICE are couched within a so-called evidence-based framework.

The NDS has 17 objectives which it claims will improve dementia care services within England. These are outlined in Table 7.2 and linked to the findings from both phases of this research. Only objectives 9 (relating to intermediate care provision), 10 (relating to technology) and 12 (relating to palliative care) were not mentioned by participants. This may be because they had no experience in these areas rather than no viewpoint.

In terms of a national strategy the proposed NDS seems both comprehensive and far-sighted. It is also supported by government funding over the next two years which is a first for dementia care services. As mentioned earlier what will be needed is a change in the ethos of local PCTs and organisations supporting PWD and their families on how best to implement initiatives to achieve the 17 objectives locally. This will need planning and coordination plus buy in from all stakeholders.

What would seem imminently sensible would be the appointment of a champion trained in dementia care mapping (DCM) or patient-centred care to promote a patient-centred and holistic approach to care provision in each PCT and organisation providing dementia-related services. Along with this is the need to ensure that HCPs and related staff supporting PWD and their families are also adequately trained in the DCM approach.

It is also important that as part of the NDS there is a concurrent drive to increase the general publics’ awareness of how they can best reduce their own risk of dementia in the future. This includes public health issues being addressed such as healthy eating and exercise for the mind and body and reduction of modifiable risk factors such as cardiovascular disease. It is also important that people understand that some protective factors such as drinking red wine are health risks in themselves. Community pharmacists would be ideally placed to support public health initiatives which should accompany the implementation of the NDS.
### Table 7.2 Linking Study Findings to the National Dementia Strategy Objectives

<table>
<thead>
<tr>
<th>NDS Objective</th>
<th>Research Findings &amp; Implication for Practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Raise awareness of dementia and encourage people to seek help</td>
<td>Training of frontline staff is needed to achieve this and also increased knowledge of referral and support systems for diseases management (pharmacological and non-pharmacological) as the therapeutic nihilism experienced by many carers and PWD in phase one actually put people off seeking help.</td>
</tr>
<tr>
<td>2. Good-quality, early diagnosis, support and treatment for people with dementia and their carers, explained in a sensitive way.</td>
<td>Again phase one had many examples of people with diagnoses taking many years, then a perceived lack of access to effective treatment and support. Two carers spoke of their distress at the way in which the diagnosis was given.</td>
</tr>
<tr>
<td>3. Good-quality information for people with dementia and their carers</td>
<td>Participants generally found this information from the Alzheimer’s Society or specialist services; with very little being available in general practice.</td>
</tr>
<tr>
<td>4. Easy access to care, support and advice after diagnosis</td>
<td>In phase two the participants were linked to specialist memory clinics so had ready access to advice and support. In phase one many participants had little or no access to advice and support because the person they cared for was not on a medicine for dementia.</td>
</tr>
<tr>
<td>5. Develop structured peer support and learning networks</td>
<td>The Alzheimer’s Society did this very well with participants from phase one developing other support groups for younger PWD which involved greater physical activity and social interaction.</td>
</tr>
<tr>
<td>6. Improve community personal support services for people living at home</td>
<td>There was evidence in phase one this was needed.</td>
</tr>
<tr>
<td>7. Implement the New Deal for Carers</td>
<td>There was evidence in phase one this was needed.</td>
</tr>
<tr>
<td>8. Improve the quality of care for people with dementia in general hospitals</td>
<td>Evidence from phase one indicated that perhaps earlier signs and symptoms could have been picked up in hospital for unrelated admissions so that referral and</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th></th>
<th>investigation could occur.</th>
</tr>
</thead>
<tbody>
<tr>
<td>9.</td>
<td>Improve intermediate care for people with dementia</td>
</tr>
<tr>
<td>10.</td>
<td>Consider how housing support, housing-related services, technology and telecare can help support people with dementia and their carers</td>
</tr>
<tr>
<td>11.</td>
<td>Improve the quality of care for people with dementia in care homes</td>
</tr>
<tr>
<td>12.</td>
<td>Improve end of life care for people with dementia</td>
</tr>
<tr>
<td>13.</td>
<td>An informed and effective workforce for people with dementia</td>
</tr>
<tr>
<td>14.</td>
<td>A joint commissioning strategy for dementia</td>
</tr>
<tr>
<td>15.</td>
<td>Improve assessment and regulation of health and care services and of how systems are working</td>
</tr>
<tr>
<td>16.</td>
<td>Provide a clear picture of research about the causes and possible future treatments of dementia</td>
</tr>
<tr>
<td>17.</td>
<td>Effective national and regional support for local services to help them develop and carry out the Strategy.</td>
</tr>
</tbody>
</table>
7.4 Implications for Practice and Research

In relation to the key findings summarised in 7.3 there are also important implications for practice and research and these will be briefly outlined next.

7.4.1 Implications for Practice

For those professionals working with and/or supporting PWD and their families there were a number of key implications for future practice; some of these have also been outlined in 7.3. These were related to support, medicines for dementia, therapeutic relationships, reducing carer burden, proactive input from HCPs and pharmacists especially, education and training and public health.

The public in general and HCPs in particular need greater education about the signs and symptoms of dementia and the need for early referral and support. This support can be physical in terms of respite and day care or can be in the form of tailored information. This support and information needs to be offered proactively to prevent crisis and reflect the changing nature of the disease. (See 7.3.1 and 7.3.4)

Caring can be experienced and perceived as an onerous and lonely task; good supportive therapeutic relationships can help ease the perception of this burden by the carer and enable them to continue to care for the person with dementia at home for longer. Carers need individual assessment of needs so that identified stressors can be addressed and hopefully lessened. It is important that the individuals’ perspective of the carer burden is assessed as this seems to have the greater impact on the ability to continue caring. These have implications for reduced rates of institutionalisation. (See 7.3.1 and 7.3.4)

The medicines for dementia are associated with global improvements impacting on sociability, relationships, mood and imitative all of which seem to mitigate the caring burden. Even though memory did not seem to improve much overall, this seemed less important than improvements in socialisation and the ability to complete tasks and activities of daily living. (See 7.3.1 and 7.3.3)

The expectations and needs of both the person with dementia and their carer need to be addressed within a consultation to ensure that the therapeutic relationship can develop. There is a need for good communication skills with people with dementia and this may need to be addressed in further training. (See 7.3.4)

The findings suggest there is a need for increased and proactive input from pharmacists to ensure PWD and their carers have all their medicines management issues addressed. Pharmacists need to gain an increased awareness of the safer prescribing of these medicines and how to support compliance.

For the above to occur there is a need for greater training and education in the awareness; the course of and the management (pharmacological and non-pharmacological) of dementia. This needs to be across all sectors of the health
and social care service; the general community and embedded in undergraduate and postgraduate training of all HCPs.

7.4.2 Implications for Future Research

The findings from this research have highlighted a number of areas that could be pursued further and these are explained in brief detail below:

1. I would like to explore the perceived effects of NICE 2006 on prescriber decision-making in dementia and the impact in terms of patient care. I would like to do this as a national study which uses both qualitative and quantitative methodologies. Qualitative methods such as focus groups and interviews would be used to explore perceptions and experiences and from these a series of research questions could be developed. These could be tested quantitatively as a national survey to investigate consensus of opinion and geographical differences.

2. There is a part of me that since 2006 has wanted to interview each of the participants involved in the revision of NICE guidance; especially the economic modelling panel. I would like to explore in greater depth individual participant perceptions of evidence-based decision-making; value-based decision-making, and quality of life in relation to economic modelling. From a psychological perspective I would also be interested to explore their perceptions of the effect of their decisions on individuals.

3. I would like to take forward preliminary patient and carer reported outcomes and explore these in relation to developing PROs as a means of understanding the experienced response to a medicine for dementia. This would involve a multi-centred study involving patient and carer user groups in the development and validation of this process alongside supportive clinicians.

4. I would like to be involved with an educational intervention for community pharmacists to help improve the recognition of PWD and initiate proactive medicines management support services as appropriate. In reality the Centre for Postgraduate Pharmacist Education (CPPE) already host a learning event on dementia care in community pharmacy (which I helped to produce) however it seems not to have been reflected in findings from this research. However CPPE events are optional and if pharmacists do not have an interest they do not attend. Also due to stretched finances and time to deliver services pharmacists may not have viewed dementia as a priority in the past. However an enhanced educational event which links to key NDS objectives and commissioned service objectives from PCTs has the potential to support the implementation of the NDS and improve the provision of pharmaceutical care services to PWD and their carers.

214
7.5 In Conclusion

The findings of this research present a qualitative picture of the lived experience of the perceived benefits of medicines for dementia and they support those from the literature which suggest that not enough consideration is given to the perspectives of PWD and their carers in terms of important outcomes of pharmacological treatment.\textsuperscript{253,386} What is surprising though is the seemingly institutionalised response of the inability to understand the importance of these global improvements in social skills, initiative; alertness, and maintaining relationships by policy makers. It is well known that dementia is a syndrome affecting many abilities such as speech; thinking, problem-solving and visuospatial and perceptual ability, as well as memory.\textsuperscript{59} It seems less than compressible why the MMSE is still used as a means of deciding whether a medicine should be started, increased or withdrawn, when sensitivity to these softer improvements has not been demonstrated.\textsuperscript{31} Greater attention to the ‘softer’ global improvements is needed as these seem more important than improvements in memory and seem also to mitigate carer distress and perceived carer burden. In terms of the NDS objectives of reducing the stigma of dementia and the all pervading ageist response to older people presenting to services, it seems that there is a need for a national educational strategy which encompasses the community and all health and social care professionals related to dementia care service provision. It is also distressing to see that evidence-based decision-making is couched in such value-based judgements of the economic modelling panel.\textsuperscript{31} It seems outrageous that such a viewpoint can be held by policy decision makers who influence the lives and associated morbidity and mortality of people with dementia and their carers.

Phase two is the first case study approach used in the exploration of the perceived benefits of medicines for dementia by people with dementia, their carers, prescribers and associated healthcare professionals. The findings supported a longitudinal and positive benefit of these medicines in the early stages of dementia and importantly enabled participants to salvage and repair relationships before the associated carer stress and burden became too great.
CHAPTER EIGHT: REFLEXIVITY ON RESEARCH

In terms of my own reactions to designing and leading qualitative research studies; it has been a formidable learning curve. In Phase One I designed a qualitative study based on the use of interview and focus groups methods and IPA as an analytical methodology. As I had not led a research interview or a focus group before I had some learning to do. I attended a study day on designing and leading focus groups on campus and a study day on qualitative interviewing at the University of Surrey. I remember being very nervous for my first interviews. Luckily they were with Jack and Ann from location one and they were such lovely people it (the process of interviewing) became as natural as almost talking to them as old friends. I remember thinking that was probably a good thing to have happened as from an IPA perspective I was interested in their experiences and their interpretation of it and how this affected their own lifeworld. Throughout each of the interviews I was also aware of the possible affects of questions on the participant in terms of perhaps making them upset by reliving previously difficult experiences. However when people faltered or were tearful they were asked if they were alright to continue or wanted to stop; all of them continued. I understood that actually what was happening was a sharing of their experiences in terms of hurt, anger, frustration and disbelief so that perhaps their stories may be heard by someone who could possibly put a stop to it happening to others. I was also aware that because of who I am and the way I interact with people that possibly people opened up to me with a more frank response. But then again maybe they just wanted their story heard.

At times I have found it very hard to contain my anger and frustration at health and social care policy and some of the professionals working in it after being privy to some of the stories that I was privileged to be told. I have struggled at times to maintain objectivity and not get emotionally or personally involved. In phase one there were times when I felt strongly there had been an injustice committed against both carers and PWD. My other half showed great patience with my post-interview or focus group ranting, but at times it was too much for us both.

Phase Two was a more involved piece of research which my bench fee would not have been able to cover. I was fortunate to be awarded the Galen Award in July 2005 by the Pharmacy Practice Research Trust at the Royal Pharmaceutical Society of Great Britain which enabled the study to go ahead. Phase Two has seemed at times like it would never be completed; the first indication being the 4-month period it took for LREC approval. This was then followed by very slow recruitment with the first patient being recruited after the study had been open 6 months. Prior to this two other people had expressed an interest but one had withdrawn because ‘the doctor had said there was nothing wrong with him’ and the second person withdrew because he became very anxious about having to talk to someone he did not know. In Phase Two I learnt to speak about my feelings after an interview or observation into the recording device as it seemed to help more than off-loading to another person. It also has enabled me to track my thoughts and feelings about the changing relationship between the PWD and their carer over time; not something which always came through in the narrative.
However it has been an absolute privilege to be invited into the lives of the people in phase two and gain an insight of how things have progressed over time. I recently spoke to a friend of mine who is a Consultant psychiatrist who has refused to do outpatient clinics for twenty years as he always felt he got to know much more about the patient by visiting them in their own home. I couldn’t agree more.

I found it incredibly interesting how some of the couple just carried on with their conversations (and arguments) with each other as if I wasn’t there; and in the first interviews almost used it as a means of sharing what things were like for each of them for the first time. I am very grateful for all the participants’ ability and willingness to share their experiences with me, as may of these were painful and distressing. Again I am also aware that by interviewing people three times over a 13month period, a sense of rapport was built up and at times it was difficult for them to still see me as a researcher. For me, it was difficult sometimes to not answer questions that were asked of me and respond as a clinical pharmacist (and at times as a therapist) but to direct them to their specialist or their GP because it was evident they actually needed the information then. I think the NDS objective of having a key contact person for information will be a great help in building continuity in information sharing but also strengthening a therapeutic relationship by familiarity.

I have found that I have loved the face-to-face research contact with people and have also enjoyed the adventure into the world of IPA as a means of analysing qualitative data. I think because IPA is always asking you to view the narrative from the participant perspective I have gained a greater understanding and insight of what it is to live with someone with dementia. I find myself not understanding whether dementia is an illness or a disease; and perhaps feeling that it is more of a continuum of symptoms which ebb and change over a period of years. In some ways I feel a pejorative labelling of someone having a specific type of dementia is not really helpful; we should be thinking more of it being a degenerative process and where possible attempting to slow or halt progression and treat signs and symptoms appropriately as they occur (using pharmacological and/or non-pharmacological approaches).

As a pharmacist I have gained a greater insight into the actual effect of dementia on communication and relationships and how this can totally destroy a carer’s ability to love the person they once did. I think it is a terrible thing that we cannot support carers earlier and more effectively so that this stage is not reached. In terms of the medicines for dementia, they are not a cure; but they seem associated with global improvements for many. These may not be easily recognised at the time; perhaps because some have been living with the degenerative process over a long period of time and have less feeling for how things were. What was clear was the experience of progression of one of these medicines was withdrawn. For other people these medicines were like ‘magic pills’ and impacted positively in all areas of their lives. For me the greatest impact was watching people being able to initiate and contribute to conversation and observe the relationship between the person with dementia and their family improve. Seeing how Bob’s interaction with his grandson improved over the time of the study was inspiring and hammered home how many people this disease actually affects. It is like a stone being thrown into a still pond; with the resultant
ripples being people affected by the loss of a person’s social and communication skills as well as the effects of the resultant behavioural and mood changes.

Reflecting on my reflexivity I see that I have written it as a reflective piece on my journey from novice to more experienced qualitative researcher. But I am aware that my reflexivity has shaped and directed the flow of this research and the interpretation of the findings. My epiphany in the use of IPA has been previously described in Chapter 4 as a reflexive point and I can see that it has really driven my interpretation of the findings and ensured that they have been driven by the experience of the participants and not my interpretation of that.

I feel a strong sense of responsibility for disseminating the results of both phases of this research in journals that will be read both by HCPs and those involved with policy change as it is important that the associated suffering of living with dementia is reduced. I have presented a number of oral and poster presentations on findings plus one commissioned article. Please see Appendix A8-1 for further details.
REFERENCES


37. Raskind, AM; Peskind, ER; Truyen, L; Kershaw, P; Damaraju, CV. The cognitive benefits of galantamine are sustained for at least 36 months. Arch Neurol2004;61(2):252-256.


46. Holmes, J; Bentley, K, Cameron, I. A UK survey of psychiatric services for older people in general hospitals. Int J Geriatr Psychiatry 2003;18:716-721


53. Matthews, FE; McKeith I; Bond, J; Brayne, C; CFAS, M. Reaching the population with dementia drugs: what are the challenges? Int J Geriatr Psychiatry 2007;22(7):627-31


55. Speight, J; Reaney, M. Wouldn’t it be nice to consider patients’ views when rationing health care? BMJ 2009;338:b85


74. Kirkwood, T. The most pressing problem of our AGE. *BMJ*. 2003, 326:1297-1299


79. Turner, S; Iliffe, S; Downs, M; Wilcock, J; Bryans, M; Levin, E; Keady,J; O’Carroll, R. General Practitioners’ knowledge confidence and attitudes in the diagnosis and management of dementia. *Age Ageing*. 2006;33:461-467


84. Buschke, H; Kuslansky, G; Katz, M; Stewart, W.F; Sliwinski, M.J; Eckholdt, H.M; Lipton, R.B. Screening for dementia with the Memory Impairment Screen. *Neurology* 1999;52:231


88. Milne, A; Culverwell, A; Gss,R; Tuppen, J; Whelton, R. Screening for dementia in primary care : a review of the use, efficacy and quality of measures. *Int Psychogeriatr* 2008;20(5):911-26


96. Ownby, R L; Crocco, E; Acevedo A; John, V; Loewenstein, D. Depression and risk for Alzheimer’s disease. *Arch Gen Psychiatry* 2006;63(5):530-538


107. McKeith, I.G. Dementia with Lewy bodies. Psychiatry 2008;7:20-23

108. McKeith, I.G; Dickson, D.W; Lowe, J; Emre, M et al. Diagnosis and management of dementia with Lewy bodies. Third report of the DLB consortium. Neurology 2005;65:1863-1872


111. Cummings, J L. Use of Cholinesterase Inhibitors in Clinical Practice: Evidence-Based Recommendations. Focus 2004;2:239-252


116. Holmes, C; Wilkinson, D; Dean, C; Vethanayagam, S; Olivieri, S; Langley, A; Pandita-Gunawardena, N D; Hogg, F; Clare, C; Damms, J. The efficacy of donepezil in the treatment of neuropsychiatric symptoms in Alzheimer disease. Neurology 2004;63:214-219


125. Scacufca, M; Almeida, O P; Vallada, H P; Tasse, W A; Menez, P R. Limitations of the Mini-Mental State examination for screening dementia in a community with low socioeconomic status. Eur Arch Psychiatry 2009;259:8-15


127. Hensel, A; Luck,T; Lappa, M; Glaemer, H; Angermeyer, M C; Riedel-Heller, S G. Does a reliable decline in Mini Mental state Examination total score predict dementia? Diagnostic accuracy of two reliable change indices. Dement Geriatr Cogn Disord 2009;27(1):50-8

128. White, N; Scott, A; Woods, R T; Wenger, C; Keady, J D; Devakumar, M. The limited utility of the Mini-Mental State Examination in screening people over the age of 75 ears for dementia in primary care. Br J Gen Pract 2002;52:1002-1003


132. Clare, L. We’ll fight it as long as we can: coping with the onset of Alzheimer’s disease. Aging Mental Health 2002;6(2):139-148

133. Norman, I; Redfern, S; Briggs, K; Askham, J. Predictions and management of change by people with dementia and their cares living at home. Dementia 2004;3(1):19-44


138. Rankin, K P; Baldwin, E; Pace-Savitsky, C; Kramer J H; Miller, B L. Self awareness and personality change in dementia. J Neurol Neurosurg Psychiatry 2005;76:632-639


144. Andersen, K; Kragh-Sørensen, P. Ability to perform activities of daily living is the main factor affecting quality of life in patients with dementia. BMC Health and Quality of Life Outcomes 2004;2:52. doi:10.1186/1477-7525-2-52


162. Liporoti, R. Starting a conventional antipsychotic increases risk of death more than an atypical antipsychotic in elderly people with dementia. *Evid. Based Ment. Health* 2009;12:58


166. Adams, K B; McClendon, M J; Smyth, K A. Personal losses and relationship quality in dementia caregiving. *Dementia* 2008;7:301-319


171. Dumarche, F; Lévesque, L; Lachance, L; Gangbè, M; Zarit, S H; Vézina, J; Caron, C D. Older husbands as caregivers: factors associated with health and the intention to end home caregiving. Research on Aging 2007;29(1):3-31


173. Hermann, N; Lanctôt, K L; Sambrook, R; Lesnikova, N; Hébert, R; McCracken, P; Robillard A; Nguyen, E. The COSID Investigators. The contribution of neuropsychiatric symptoms to cost of dementia care. Int J Geriatr Psychiatry 2006;21:972-976


177. Aneshensel, C S; Pearlin, L I; Schuler, R H. Stress, role captivity, and the cessation of caring. J Health & Social Behav 1993;34(1):54-70

178. Campbell, P; Wright, J; Oyebode, J; Crome, P; Bentham, P; Jones, L; Lendon, C. Determinants of burden in those who care for someone with dementia. Int J Geriatr Psychiatry 2008;23:1078-1085


180. Lund, D A; Wright, S D; Caserta, M S. Respite services: enhancing the quality of daily life for caregivers and persons with dementia. Geriatr & Aging 2005;8(4):60-65

181. Mossello, E; Caleri, V; Razzi E; Di Bari, M; Cantini, C; Tonon, E; Lopilato, E; Mainin, M; Simoni, D; Cavallini, M C; Marchionni, N; Biagini, C A; Masotti, G. Day care for older dementia patients: favorable effects on behavioural and psychological symptoms and caregiver stress. Int J Geriatr Psychiatry 2008;23:1066-1072


184. Schulz, R; Belle, S H; Czaja, S J; McGinnis, K A; Stevens, A; Zhang, S. Long-term care placement of dementia patients and caregiver health and well-being. *JAMA* 2004;**292**(8):961-967

185. Selwood, A; Cooper, C; Owens, C; Blanchard, M; Livingston, G. What would help me stop abusing? The family carer’s perspective. *Psychogeriatr* 2009;**21**(2):209-13

186. Cooper, C; Selwood, A; Blanchard, M; Walker, Z; Blizard, R; Livingston, G. Abuse of people with dementia by family carers: representative cross sectional survey. *BMJ* 2009;**338**:b155 doi:10.1136/bmj.b155


191. Butler, R. The carers of people with dementia want high quality health services and have compelling reasons to get them. *BMJ* 2008;**336**:1260-1261


193. Savard, J; Leduc, N; Lebel, P; Béland, F; Bergman, H. Caregiver satisfaction with support services. *J Aging & Health* 2006;**18**(1):3-27

194. Burgener, S C; Buettner, L L; Beattie, E; Rose K M. Effectiveness of community-based nonpharmacological interventions for early-stage dementia: conclusion and recommendations. *J Gerontol Nurs* 2009;**35**(3):50-7

195. Burgener, S C; Yang, Y; Gilbet, R; Marsh-Yant, S. The effects of multimodal intervention on outcomes of persons with early-stage dementia. *Am J Alzheimers Dis Other Demen* 2008;**23**:382-394

196. Signe, A; Solve, E. Effective psychosocial intervention for family caregivers lengthens time elapsed before nursing home placement of individuals with dementia: a five-year follow-up study. *Int Psychogeriatr* 2008;**20**(6):1177-92

197. Charlesworth, G; Shepstone, L; Wilson, E; Reynolds, S; Mugford, M; Price, D; Harvey, I; Poland, F. Befriending carers of people with dementia: randomised controlled trial. *BMJ* 2008;**336**:1295-1297
198. Robinson, L; Brittain, K; Lindsay S; Jackson, D; Olivier, P. Keeping In Touch Everyday (KITE): developing assistive technologies with people with dementia and their caregivers to promote independence. *Int Psychogeriatr* 2009;21(3):494-502


201. Fossey, J; Lee, L; Ballard, C. Dementia Care Mapping as a research tool for measuring quality of life in care settings: psychometric properties. *Int J Geriatr Psychiatry* 2002;17:1064-70

202. Brooker, D; Foster, N; Banner, A; Payne, M; Jackson, L. The efficacy of Dementia Care mapping as an audit tool: report of a 3-year British NHS evaluation. *Aging & Ment Health* 1998;2(1):60-70

203. Chenoweth, L; King, M T; Jeon, Y; Brodaty, J; Stein-Parbury, J; Norman, R; Haas, M; Luscombe, G. Caring for Aged Dementia care Resident Study (CADRES) of person-centred care, dementia-care mapping, and usual care in dementia: a cluster randomised trial. *Lancet Neurol* 2009;8:317-25

204. Jolley, D; Moniz-Cook, E. Memory clinics are all about stigma no screening. *BMJ* 2009;338:557-8


206. Bannerjee, S; Wittenberg, R. Clinical and cost effectiveness of services for early diagnosis and intervention in dementia. *Int J Geriatr Psychiatry* 2009;24:748-754

207. Mooney, H. Sixteen sites in England will try to integrate health and social care. *BMJ* 2009;338:849


209. Downs, M; Ariss, S M B; Grant, E; Keady, J; Turner, S; Bryans, M; Wilcock, J; Levin, E; O’Carroll, R; Iliffe, S. Family carers’ accounts of general practice contacts for their relatives with early signs of dementia. *Dementia* 2006;5(3):353-373


212. McCabe, R; Heath, C; Burns, T; Priebe, S. Engagement of patients with psychosis in the consultation: conversation analytic study. BMJ 2002;325:1148-51

213. McManus, I C; Gordon, D; Winder B E Duties of a doctor: UK doctors and Good Medical Practice Qual Health Care 2000;9:14-22; doi:10.1136/qhc.9.1.14


220. The Department of Health webpage on pharmacist independent prescribing


233. Gulland A. NICE guidelines create ethical dilemmas in care of elderly people says international report. BMJ 2007;335:791


238. François, C; Sintonen, H; Sulkava R; Rive B. Cost effectiveness of memantine in moderately severe to severe Alzheimer’s disease: a markov model in Finland. *Clinical drug investigation* 2004;24(7):373-84.


243. Pelosi, A J; McNulty, S V; Jackson, G A. Role of cholinesterase inhibitors in dementia care needs rethinking. *BMJ* 333:491-493


245. Rockwood, K; Jeffries C. Improving clinical descriptions to understand the effects of dementia treatment: consensus recommendations. *Int J Geriatr Psychiatry* 2001;17:1006-1011

246. Winblad B; Brodaty, H; Gauthier, S; Morris, J C; Orhogojo, J; Rockwood, K; Schneider, L; Toleda, M; Tariot, P; Wilkinson D. Pharmacotherapy of Alzheimer’s disease: is there a need to redefine treatment success *Int J Geriatr Psychiatry* 2001;16:653-666


249. Rockwood, K; Black S; Bedard M; Tran, T; Lussier, L. Specific symptomatic changes following donepezil treatment of Alzheimer’s disease: a multi-
centre, primary care, open-label study. *Int J Geriatr Psychiatry* 2007;22(4):312-319

250. Bradley, E H; Bogardus, S T; van Doorn, C; Williams, C S; Cherlin, E; Inouye, S K. Goals in geriatric assessment: are we measuring the right outcomes? *Gerontologist* 2000;40(2):191-196

251. Campbell, R; Quilty, B; Dieppe, P. Discrepancies between patients’ assessments of outcome: qualitative study nested within a randomised controlled trial. BMJ 2003;326:252-3

252. Huizing, AR; Berghmans, RLP; Widdershoven, GAM; Verbey, FRJ. Do caregivers’ experiences correspond with the concerns raised in the literature? Ethical issues relating to anti-dementia drugs. *Int J Geriatr Psychiatry*. 2006;21:869-875

253. Traynor, V; Dewing, J. Alzheimer’s Society and RCN Gerontological Nursing programme “Drugs for dementia” Project Stage two: “To identify user and carer-defined outcomes that can be used to evaluate the effectiveness of drugs for dementia.” April 2002. Royal College of Nursing Institute.

254. Lazzaro, V D; Oliviero, A; Pilato, F; Saturno, E; Dileone, M; Marra, C; Ghiurlando, S; Ranieri, F; Gainotti, G; Tonali, P. Neurophysiological predictors of long term response to AChE inhibitors in AD patients. *J Neurol Neurosurg Psychiatry* 2005;76:1064-1069

255. Van der Putt, R; Dineen, C; Janes, D; Series, H; McShane, R. Effectiveness of acetylcholinesterase inhibitors: diagnosis and severity as predictors of response in routine practice. *Int J Geriatr Psychiatry* 2006;21:755-760


259. Ballard, C; Chalmers, K; Todd, C; McKeith, I G; O’Brien J; T; Wilcock, G; Love, S; Perry, E. K. Cholinesterase inhibitors reduce cortical Aβ in dementia with Lewy bodies. *Neurology* 2007;68:1726-1729


264. McKillop, J; Wilkinson, H. Make it Easy on Yourself!: Advice to researchers from someone with dementia on being interviewed. Dementia 2004;3:117-125


290. Hughes, J C; Louw, S. Electronic tagging of people with dementia who wander. *BMJ* 2002;325:847-8


293. Breen, D A; Breen D P; Moore, J W; Breen, P A; O’Neill, D. Driving and dementia. *BMJ* 2007;334:1365-9


313. Sonnen, J A;Montine, K S; Quinn, J F; Kaye, J A; Breitner, J C S; Montine, T J. Biomarkers for cognitive impairment and dementia in elderly people. Lancet Neurol 2008;7:704-14


318. Karlawish, JH; Cassarett, D J ; James, B D; Trenhave, T; Clare , C M; Asch, D A. Why would caregivers not want to treat their relative’s Alzheimer’s disease? *Am Geriatr Soc* 2003;51(10):1391-7


344. Smith, F. Health services research methods in pharmacy: Focus groups and observation studies. *Int J Pharm Pract*; 1998;**6**:229-42


348. Elwyn, G; Edwards, A; Wensing, M; Hood, K; Atwell, C; Grol, R. Shared decision making: developing the OPTION scale for measuring patient involvement *Qual Safet Health Care* 2003;**2**:93-99; doi:10.1136/qhc.12.2.93


351. Begg, A., Drummond, G; Tiplady, B. Assessment f postsurgical recovery after discharge using a pen computer diary. *Anaesthesia* 2003;**58**:1101-1118


354. Wilson, RS; Mendes de Leon, CF; Barnes, LL; Schneider, JA; Bienias, JL; Evans, DA; Bennett, DA. Participation in Cognitively Stimulating Activities and Risk of Incident Alzheimer Disease. *JAMA* 2002;**287**:742-748.

355. Moen, J; Bohm, A; Tillenius, T; Antonov, K; Nilsson, JLG. “I don’t know how many of these [medicines] are necessary..” - A focus group study among elderly users of multiple medicines. *Patient Educ Counsell* 2009;**74**(2):135-141

356. Formiga, F; Fort, I; Robles, M J; Riu, S; Sabartes, O; Barranco; E; Catena, J. Comorbidity and clinical features in elderly patients with dementia:
Differences according to dementia severity  *J Nutr Health Aging* 2009;13(5):423-427


358. Lingler, JH; Nightingale, MC; Erlen, JA; Kan, AL; Reynolds, CF; Schulz, R; DeKosky, ST. Making sense of mild cognitive impairment: a qualitative exploration of the patient experience. *Gerontol* 2006;46(6):791-800


361. Murray, J; Schneider, J; Bannerjee, S; Mann, A. EUROCAR: a cross-national study of co-resident spouse carers for people with Alzheimer’s disease: II-a qualitative analysis of the experience of caregiving. *Int J Geriatr Psychiatry* 1999;14:662-667

362. Lawrence, V; Murray, J; Ffytche, D; Bannerjee, S. “Out of sight, out of mind”: a qualitative study of visual impairment and dementia from three perspectives. *Int Psychogeriatr* 2009;21(3):5118


364. Sherman, CW; Boss, P. Spousal dementia caregiving in the context of late-life remarriage. *Dementia* 2007;6:245-270


366. Berry, DC; Michas, IC; Gillie, T; Forster, M. What do patients want to know about their medicines, and what do doctors want to tell them?: A comparative study. *Psychol Health* 1997;12:467-480

367. Nunn, R. It’s time to put the placebo out of our misery. *BMJ* 2009;338:b1568


374. Scocco, P; Fantoni, G; Caon, F. Role of depressive and cognitive status in self-reported evaluation of quality of life in older people: comparing proxy and physician perspectives. Age Aging 2006;35:166-171


376. Mozey, CG; Huxley, P; Sutcliffe, C; Bagley, H; Burns, A; Challis, D; Cordingley, L. ‘Not knowing where I am doesn’t mean I don’t know what I like’: cognitive impairment and quality of life responses in elderly people. Int J Geriatr Psychiatry 1999;14:776-783


378. Gill, SS; Mamdani, M; Naglie, G; Stener, DL; Bronskill, SE; Kopp, A; Shulman, KI; Lee, PE; Rochon, PA. A prescribing cascade involving cholinesterase inhibitors and anticholinergic drugs. Arch Intern Med 2005;165:808-813.

379. Gill, SS; Anderson, GM.; Fischer, HD.; Bell CM.; Li P; Normand T.; Rochon PA. Syncope and Its Consequences in Patients With Dementia Receiving Cholinesterase Inhibitors: A Population-Based Cohort Study. Arch Intern Med 2009;169:867-73

380. Treloar, A; Bech, S; Paton, C. Administering medicines to patients with dementia and other organic cognitive syndromes. Advanc Psychiatric Treatment 2001;7:444-452

381. Ellul, J; Archer, N; Foy, CML; Poppe, M; Boothby, H; Nicholas, H; Brown, RG; Lovestone, S. The effects of commonly prescribed drugs in patients with Alzheimer’s disease on the rate of deterioration. J Neurol Neurosurg Psychiatry 2007;78:233-239
382. Hilmer, SN; Mager, DE; Simonsick, EM; Cao, Y; Ling, SM; Windham, BG; Harris, TB; Hanlon, JT; Rubin, SM; Shorr, RI; Bauer, DC; Abernethy, DR. A drug burden index to define the functional burden of medications in older people. Arch Intern Med 2007;167:781-787


386. Traynor, V; Pritchard, E; Dewing, J. Illustrating the importance of including the views and experiences of users and carers in evaluating the effectiveness of drug treatments for dementia. Dementia 2004;3:145-159


393. Gettsios D; Migliaccio-Walle K; Caro J.J. NICE cost-effectiveness appraisal of cholinesterase inhibitors: was the right question posed? Were the best tools used? Pharmacoeconomics. 2007;25(12):997-1006.


397. The Author 2006 on behalf of the British Geriatrics Society. Pharmacist-led medication reviews can reduce patient morbidity? *Age and Aging* 2006;35:555-556


407. Antilla, T; Helkala, E; Viitanen, M; Kåreholt, I; Fratiglioni, L; Wnblad, B; Soininen, H; Tuominen, J; Nissinen, A; Kivipelto, M. Alcohol drinking in middle age and subsequent risk of mild cognitive impairment and dementia
in old age: a prospective population based study. *BMJ* 2004;329:539-;
doi:10.1136/bmj.38181.418958.BE
APPENDICES

Appendix A1-1: Abbreviated Mini-mental Test

Hodkins – an example of an Abbreviated Mini-mental Test Scale (AMTS)

The following questions are asked:

1. Age
2. Time (to nearest hour)
3. Address for recall at the end of the test e.g. 42 West Street. This address should be repeated by the patient, to ensure that it has been heard correctly.
4. Year
5. Name of the hospital
6. Recognition of 2 persons (doctor/nurse), or 2 objects (watch and pen)
7. Date of birth
8. Year of First World War
9. Name of present monarch
10. Count backward from 20 to 1

A score of 7 or greater is indicative of normal cognitive function.
Appendix A1-2: Mini-Mental State Examination
(adapted from Folstein et al.)

Patient Name .................................................................
Date of birth............................................................... Date of test..............................

Section Questions: Max Pt

1. Orientation
a) Can you tell me today’s date/month/year?
   Which day of the week is it today?
   Can you also tell me which season it is? 5
b) What city/town are we in?
   What is the county/country?
   What building are we in and on what floor? 5

2. Registration
I should like to test your memory.
   (name 3 common objects: e.g. “ball, car, man”)
   Can you repeat the words I said?
   (Score one point for each word) 3
   (repeat up to 6 trials until all three are remembered)
   (record number of trials needed here)

3. Attention & Calculation
   a) From 100 keep subtracting 7 and give each answer:
      stop after 5 answers. (93-86-79-72-65-).
      Alternatively
   b) Spell the word ‘WORLD’ backwards. (D-L-R-O-W). 5

4. Recall
What were the three words I asked you to say earlier? 3
(Skip this test if all three objects were not remembered during registration test)

5. Language
   Naming: Name these objects (show a watch) (show a pencil) 2
   Repeating: Repeat the following: “no ifs, ands or buts” 1

6. Reading:
   (show card or write “CLOSE YOUR EYES”)
   Say “Read this sentence and do what it says” 1
   Writing: Now can you write a short sentence for me? 1

7. Three stage
   (Present a piece of paper)
   Command: Take this paper in your left (or right) hand,
   fold it in half, and put it on the floor. 3

8 Construction Will you copy this drawing please? 1

Examiner: Max Score
Notes Patient Score
Scoring the Mini-mental State Examination (adapted from Folstein et al.)

1. Orientation 10 points
   a) Ask for specific facts omitted until a response has been given to all 10 parts of the question. Score one point for each correct response.
   b) Ask each question in turn. Score one point for each correct response.

2. Registration 3 points
   Name a sequence of three unrelated objects e.g. (apple, table, penny) or (ball, car, man) taking about a second to say each word. Ask the patient to repeat all three words. Score one point for each word remembered at first attempt. If response is incorrect after repeating the test five more times, recall cannot meaningfully be tested - skip section 4.

3. Attention & Calculation 5 points
   a) Serial sevens: score one point for each correct subtraction of seven.
   OR
   b) Spelling backwards: one point is deducted if a letter is missing and one point is deducted for each remaining letter out of sequence (e.g. DLRW = 4; DLORW or DLW = 3).

4. Recall 3 points
   Score one point for each word recalled.

5. Language - naming/repetition 3 points
   Score one point for each correct response. One trial only for the sentence.

6. Language – reading/writing 2 points
   a) Score one point only if patient actually closes their eyes. Score one point if sentence contains a subject and a verb and is sensible. Ignore mistakes such as grammar or punctuation.

7. Language - three stage command 3 points
   Give the patient a piece of plain blank paper and follow the command. Score one point for each part correctly executed.

8. Construction 2 points
   Score one point if each pentagon has five angles and two angles intersect. Ignore tremors or rotation of pentagon.

The possible relationship between the MMSE and the progression of AD
It has been suggested that the rate of cognitive decline as measured by the MMSE score also correlates with the progression and severity of the disease itself.
Scores range from 0-30. (the lower the score the greater the impairment).
A score of 24 or greater is considered indicative of normal cognitive function. However, a score of 27 in an individual with previously high intellect may be indicative of quite severe intellectual impairment.

Table 1-1a: Interpreting MMSE scores

<table>
<thead>
<tr>
<th>Score</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>27-30</td>
<td>Normal</td>
</tr>
<tr>
<td>25-26</td>
<td>Possible dementia</td>
</tr>
<tr>
<td>10-24</td>
<td>Mild-moderate dementia</td>
</tr>
<tr>
<td>6-9</td>
<td>Moderate-severe dementia</td>
</tr>
<tr>
<td>&lt;6</td>
<td>Severe dementia</td>
</tr>
</tbody>
</table>
APPENDIX A3-1: PHASE ONE INTERNAL ETHICAL REVIEW

University of Bath

Ethics approval of Research Proposals – Peer Review Process

Name of Applicant: Deirdre Taylor
Email address: deir@bath.ac.uk
Title of Project: Management of Antidepressant Algorithms: Work with Depression (ADs)
Name of peer reviewer: Dr Jenny Searl
Position and Department/School: Lecturer in Pharmacy Practice/Pharmacology

Comments of Peer Reviewer:

This study has the potential to inform how medicines are discussed with people newly treated with ADs: the inform healthcare professional training - therefore it has clear benefits. The methods have been well considered are sensitive to the population being studied. The safety of the participants is the preeminent concern. The ethical issues have been considered. The researcher has very good experience with these patient groups. The analysis is clear and appropriate. I consider it a suitable work of the participant is included. I support this work being undertaken.

Approved by:

Name: ____________________ Signature: ____________________
Position: ____________________ Date: ____________________
Appendix A3-2: LREC Approval Phase One

Central Manchester Local Research Ethics Committee
Room 181
Gateway House
Piccadilly South
Manchester
M60 7LP
Telephone: 0161-237-2153
Facsimile: 0161-237-2383

15 August 2005

Miss Denise A Taylor
Senior Teaching Fellow
Department of Pharmacy and Pharmacology
University of Bath
Claverton Down
Bath
BA2 7AY

Dear Miss Taylor

Full title of study: Medicines Management of Antidementia Agents in People with Dementia (MAPD)

REC reference number: 05/Q1407/161

Thank you for your letter of 03 August 2005, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

The Committee has designated this study as having “no local investigators”. There is no requirement for other Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td>4.1</td>
<td>03 June 2005</td>
</tr>
<tr>
<td>Investigator CV</td>
<td>1.0 - Denise Taylor</td>
<td>02 June 2005</td>
</tr>
<tr>
<td>Investigator CV</td>
<td>1.0 - Marjorie Cecilia Weiss</td>
<td>03 June 2005</td>
</tr>
<tr>
<td>Protocol</td>
<td>5 - Phase One</td>
<td>03 August 2005</td>
</tr>
<tr>
<td>Summary/Synopsis</td>
<td>2 - FG</td>
<td>03 June 2005</td>
</tr>
</tbody>
</table>

An advisory committee to Greater Manchester Strategic Health Authority
Management approval

You should arrange for all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain management approval from the relevant care organisation before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Notification of other bodies

The Committee Administrator will notify the research sponsor that the study has a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.
With the Committee's best wishes for the success of this project,

Yours sincerely

K. Osborne

D Mandal (Dr)
Chair

Email: kath.osborne@gmsha.nhs.uk

Enclosures:

Standard approval conditions

SF1 list of approved sites

An advisory committee to Greater Manchester Strategic Health Authority
Appendix A3-3: Information Sheets
(Patient only versions will be presented throughout to maintain brevity)

(Patient Information Sheet Version 3 25th July 2005)

Determining Attitudes to the Prescribing of Medicine for Dementia

Lead Investigator: Miss Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath, BATH BA2 7AY
Telephone: 01225 383677 (work)
Telephone: 07891790025 (mobile)
Email: prsdtpath.ac.uk

Information for People who take Medicines for Dementia on the Interview or Focus Group Study

Dear Sir or Madam,

We are inviting people who take (or have taken in the past) medicines for dementia to take part in a study. The study is to help us to find out what the attitudes and beliefs are of people that take these medicines may be. In the study we will use interviews and/or focus groups to help us find out this information. Focus groups are when 6 to 10 people take part in a group discussion to share ideas, thoughts and beliefs about a particular subject. Interviews are when a person talks one-to-one with a researcher about their thoughts and beliefs on a particular subject. You are only being asked to take part in either a one-to-one interview or in a focus group; not both.

You are being invited to take part in this study. Please take time to read the following information carefully. Please ask if there is anything that is not clear or if you would like more information.

Thank you for reading this.

1. Why are we doing this?
We want to know your views on the medicines that you take for dementia including how effective you think these medicines are. We would also like to know your views on how these medicines affect your day-to-day life.

2. Why do we ask you?
You are being invited to take part in the study to give your views because you are a person who currently takes or has taken medicines for dementia. You also attend a local Alzheimer Society branch for support. We are planning to interview up to 6 people in total who take medicines for dementia. Alternatively you may choose to attend a focus group session for people with dementia, which will be held at your local branch. If you agree to take part in the research, you would only be taking part in one interview session or attend one focus group session. We would expect an interview to last about 20 to 30 minutes and the focus group may last between 40 and 50 minutes.

3. Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do take part you can keep the information sheet and will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide not to take part, any support that you receive at the local Alzheimer Society branch will not be affected.
4. What will happen during the study?
If you agree to take part in the study, you will be contacted by Miss Denise Taylor, the person doing the research, who will explain things to you in further detail. She will ask you if you would prefer to have a face-to-face interview or to be part of a focus group session.

If you would prefer to be part of a focus group session, Miss Denise Taylor will meet you at the local branch before the focus group begins. The researcher will explain what you have to do and if you agree to take part in the study you will then be asked to sign a consent form. The focus-group session will be tape-recorded and you will be asked for your consent for this to happen. When the tape is being written up, you will not be able to be identified in anyway from the recording. There may be up to 9 other people taking part in the focus group session and you will be introduced to the other participants before it starts. During the focus group the lead researcher will follow a guide in order that the aims of the research are met. We expect the session to last between 40 and 50 minutes.

If you decide that you would prefer an interview, the researcher will arrange a suitable time and place for the interview to occur. This could be in your own home or at the local Alzheimer Society branch. The interview will be tape-recorded to ensure the information is recorded accurately and you will be asked your consent for this to happen. You will be asked to sign a consent form if you agree to participate in the study and if you agree for this recording to take place. When the tape is being written up, you will not be able to be identified in anyway from the recording. During the interview the researcher will follow a guide so that the aims of the research are met. We expect the interview to last between 20 and 30 minutes.

5. What are the possible disadvantages and risks of taking part?
Taking part in the study is unlikely to put you at any risk. If you were to get upset by a question asked in the interview or focus group session, the researcher will deal with these sensitively. You may ask to discontinue the interview or to leave the focus group at any time. If this happens then Mr/Mrs X from the local branch and/or the lead researcher will contact you the next day to ensure that you are okay.

6. What are the possible advantages of taking part?
We do not expect there to be any advantages to you in taking part. However the information you give us will help us to understand what people who take medicines for dementia think and believe about their treatment. These findings will help us to educate healthcare professionals involved in the prescribing of these medicines.

7. What if something goes wrong?
In the unlikely event that you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone’s negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the Lead Researcher; Miss Denise Taylor, Department of Pharmacy and Pharmacology, University of Bath, Bath BA2 7AY. Telephone: 01225-383677, or her supervisor Dr Marjorie Weiss at the same address on telephone 01225-386787.

8. Will my taking part in the study be kept confidential?
All information coming from the interview or focus group will not have your name on it and will not be shared with anyone else who is not part of the study. The Alzheimer’s Society will not know what you have said. The interviews will be typed up by a secretary who will not know who you are. If your name is mentioned on the tape-recording it will not be typed up in the written report. Once the study is completed the interview tape will be kept in a secure place for 10 years and then destroyed. You can see the written report of your participation at any time.
9. **What will happen to the results of the research study?**
We may have some quotes of what you say printed in a journal or magazine. If this happens your name and details and the local branch details will always be taken off, so that nobody will know whose words they are or where they came from. If you are interested to know more about the results, you should contact the Lead Researcher for further information.

10. **Who is organising and funding this research?**
The study is being organised as part of a doctoral thesis (PhD) by Miss Denise Taylor, the lead researcher. The study is funded by the University of Bath.

11. **Who has reviewed this study?**
This study has been approved by a research ethics committee (the Central Manchester Local Research Ethics Committee) and by the University of Bath.

12. **Who do I contact for further information?**
If you have any other questions, please contact Miss Denise Taylor at prsdat@bath.ac.uk, Department of Pharmacy and Pharmacology, University of Bath, Bath, BA2 7AY. Telephone 01225-383677 (office) or 07891-790025 (mobile).

13. **What do I do now?**
If you would like to take part, please complete the reply slip below and return it in the stamped addressed envelope provided. The researcher will contact you over the next few days to discuss the research with you. If you do not wish to take part you do not need to do anything. You will not be contacted again.

**Thank you for your time in reading this information**

---

I would be interested in helping with this research study about the prescribing of medicines for dementia.

Name:
Address:
Alzheimer Society Local Branch:
Telephone: (please indicate when the best time to contact you is)

**Thank you for your help!**

Please return to:
Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath
Claverton Down
Bath BA2 7AY
Telephone: 01225 383677

---

260
Appendix A3-4: TOPIC GUIDE Phase One
(Only patient version will be presented)


Determining Attitudes to the Prescribing of Medicines for Dementia

PATIENT VIEWS ON MEDICINES TO TREAT DEMENTIA

TOPIC GUIDE

We are interested in finding out your views and beliefs about the medicines that are used to help treat the symptoms of dementia or Alzheimer’s disease. We would like to find out about your involvement in the prescribing process of these medicines and how effective you think they are. We are also interested in how these medicines may affect your day-to-day life.

All information from the interview will be treated in the strictest confidence – so we will not use your name or refer to any people you might mention directly by their name. The tapes from this interview will be assigned a number and that is how we will refer to you when we present this information to other people.

1. Background/Personal Information
   - Tell us the name of medicine for dementia that you are taking
   - Tell us about when you started taking it and how long you have taken it for now

2. The prescribing process
   - Were you given sufficient information about the medicine prior to starting
   - Were you told about the effectiveness of the medicine?
   - How do you remember to take the medicine every day?
   - How do you monitor the effects of the medicine? For example for adverse effects; effectiveness of treatment etc
   - Before you were started on this treatment, did you discuss an end or withdrawal date with the prescriber?

3. The effect of these medicines on day-to-day life
   - Tell us about how these medicines affect your day-to-day life in the following areas:
     - Adverse effects
     - Remembering to take the medicines
     - Problems with increasing the dose
     - Ordering and supply issues
     - General effects on day-to-day life

4. How effective are these medicines?
   - Tell us about the effects these medicines have on the ability for you to lead life as per your usual routine. For example what are the:
     - Positive effects
     - Negative effects
     - Important improvements to you?
     - Important effects for the person you care for?
5. **When should they be stopped/withdrawn?**
   - Tell us about when you think these medicines should be stopped or withdrawn? For example:
     - Adverse effects?
     - No further improvements?
     - Other?

6. **Role in decision-making process?**
   - Tell us about your involvement with any decision-making about the medicine when you go to your clinic visits;
   - Is anyone who helps to care for you involved in any decision-making?
   - Do you think you get sufficient information to make decisions?

7. **Any other issues?**
   - Is there anything else you would like to tell us about which is important to you and/or the person that may care for with respect to these medicines?

THANK YOU FOR YOUR HELP

If you would like to receive a summary of interview findings, please complete the reply slip below and return it in the stamped addressed envelope provided. The researcher will send you the summary details once they have been compiled.

**Thank you for your time**

I would like to receive a summary of the findings of this interview about the prescribing of medicines for dementia.

Name:

Address:

Alzheimer Society Local Branch:

**Thank you for your help!**

Please return to:

*Denise Taylor*
*Department of Pharmacy & Pharmacology*
*University of Bath*
*Claverton Down*
*Bath BA2 7AY*
*Telephone: 01225 383677*
Appendix A3-5: Patient Consent forms

(Only patient versions will be presented)


Determining Attitudes to the Prescribing of Medicines for Dementia

Lead Investigator: Miss Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath, BATH BA2 7AY
Telephone: 01225 383677 (work)
Telephone: 07891790025 (mobile)
Email: prsdat@bath.ac.uk

Please initial the box

1. I confirm that I have read and understood the information sheet dated 25th July 2005 for the above study

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

3. I am happy to have the interview audio-tape recorded

4. I agree to take part in the above study

Name of participant ___________________________ Date __________ Signature ______________________________

Name of witness to Consent process ___________________________ Date __________ Signature ______________________________

Name of researcher ___________________________ Date __________ Signature ______________________________

1 for participant; 1 for researcher
Appendix A3-6: Branch Letter

Branch letter, version 2 3rd June 2005

Dear

I am a clinical pharmacist and Senior Teaching Fellow at the Department of Pharmacy and Pharmacology at the University of Bath. I am currently registered to complete a PhD as a part-time student.

My area of interest for some time has been the treatment and care of people with dementia. I am particularly concerned about the role that the medicines used to treat the symptoms of dementia have on the day-to-day lives of the people who take them and the carers who care for these people. Also of interest is the fact that the carers of people with dementia have to agree (according to NICE guidance 2001) to ensure these medicines are taken by the person they care for and agree in principle to a time when these medicines will be withdrawn.

My research study consists of three phases; the first of which is a series of 5 or 6 focus group sessions to be run with carers of people taking medicines for dementia. I would like these focus group sessions to be run in local branches of the Alzheimer Society in the South-West who agree to participate in the study. I hadn’t wanted to organise carer focus group sessions that were attached to a memory or research clinic because of the possibility carers may feel that they ‘had to’ participate or felt that their views may some how affect the treatment and support that they receive.

At this stage I hadn’t intended to invite people taking these medicines to the focus group sessions because of possible problems in assessing capacity to consent. Plus I feel that these people probably do better in face-to-face interviews with one person rather than in a large group as it is easier to concentrate on one person speaking rather than many. So I will be asking people with mild dementia who are taking medicines for dementia if they would like to participate in the study by having a semi-structured interview. I would expect to complete 5 interviews in total, perhaps one at each of the participating branches.

What I am asking for is the opportunity for me to run a focus group session and perhaps an interview (although these can also take place at the persons home if that is more convenient) at one of your local branch meetings at some point over the next 3 to 4 months. A focus group lasts for about an hour and involves about 6 to 10 people being asked to give their views and beliefs on a certain topic.

To help you understand more clearly the content of this session, I enclose a copy of my research protocol, a copy of the information sheet and topic guide for both the interview and the focus group sessions plus an advertising flyer for the event.

The research is currently going through a MREC application at the Central Manchester Research Ethics Committee, which considers whether any possible ethical dilemmas have been considered by the researcher.

The ethical dilemmas as I see them are:

1. I can advertise the event but I cannot actively seek participants. To this end I need to ask for a contact person at the local branch who would be able to hand out information sheets to those people expressing an interest in joining the
session. (See attached). If the person does want to join the session they need to read the sheet and send me their contact details in a supplied stamped addressed envelope. I will then contact them and ensure they understand the study.

2. I will need informed consent of the participants because I will be (with their permission) audio-taping the sessions to allow exact representation of their views to be made. All transcriptions will be anonimised and any identifiable factors removed. In any publications the branch name will also be removed and the session referred to as a number, e.g. focus group (or interview 1) one. Any audio-tapes and their transcripts will be kept in a locked cupboard in a secure room at the University of Bath for 10 years when they will be destroyed as appropriately.

3. I am happy to supply a summary of the information obtained from the focus group to participants on their request and to enable me to do this I have asked for their addresses. The addresses will be stored separately to the transcripts. Again once this information has been sent to those requesting it, the addresses will be destroyed appropriately.

4. It may be possible that a member of the focus group could become upset when recounting personal information about how these medicines have affected their lives and the life of the person for whom they care. I have worked with the elderly for some 16 years and feel that I should be able to deal with these instances in a sensitive manner. However, if possible it would be beneficial if there were a local branch representative who would be available during the session if the participant wanted to leave the focus group.

I would be happy to fund refreshments (coffee, tea and biscuits for example) perhaps at the start of the event to enable people to relax prior to the session. I would also be happy to talk at a branch meeting if felt appropriate to discuss the outcomes of the wider study.

I would be very happy to talk this through with you either face-to-face or on the telephone. My contact details follow at the end of this letter. Thank you for your time in reading this letter and I hope that it is something that you feel you would be able to support.

Looking forward to hearing from you.
Best wishes
Denise Taylor
Senior Teaching Fellow
Telephone: 01225-383677 (work)
Telephone: 07787717126 (mobile)
Email: prsdat@ bath.ac.uk
Appendix A3-7: Advertising Flyer

Interview Advertising Flyer for Carers

We, at the University of Bath would like a chance to interview you about your experience of caring for someone who takes or has taken medicines for dementia.

_An interview? What is that?_
It’s a one-to-one chat about your experiences of the effects of medicines for dementia on the person that you care for.

_How long will it take?_ About half an hour

_Where will it take place?_
Either here or in the comfort of your own home

For further information please ask (contact name) from your local branch for an information leaflet.
Appendix A4-1: Categorisation of Carer Themes Phase One

After IPA of the carer transcripts there were 131 themes generated. It then became a process of inductive and time consuming analysis of these. The process is described in 4.1.

In the first analysis the themes seemed to settle into 8 superordinate themes; these were:

1. Dealing with Uncertainty
2. Seeking and Receiving Information
3. Carer Expertise
4. Living with a Degenerative Illness
5. Dilemma in Decision-making
6. Consultation Etiquettes
7. Problems with diagnosis
8. Trials and Tribulations of Medication

Photocopies of the penned working of these superordinate themes in terms of critical analysis can be found next (pages Axx to Axx). These illustrate an initial attempt to understand how each of the themes interacted together as a whole explanation of the carer experience.

On page A4xx a scan of one of the original pieces of working paper from the wall (Interaction with Healthcare Professionals) illustrates the eventual listing of three sub-ordinate themes. These were: Seeking information and help; Consultation etiquettes and Diagnostic issues. Further copies of the workings and organisation of these sub-sub themes are shown in pages Axx to Axx.

This type of analytical process continued for each of the super-ordinate themes listed above until the (at that time) final super-ordinate themes presented in 4.1.1 (and below) were settled.

1. Carer expertise
2. On Being a carer
3. Living with a Degenerative Illness
4. Interaction with Healthcare Professionals
5. Trials and Tribulations of Medication.

At this point I had to present to my colleague Dr Jane Sutton, the large pieces of paper with the sticky notes attached and explain my rationale for coding and analysis.
On Being a Carer

Living with a Degenerative Illness

Caregivers

Seeking & Learning Info

Doing the Right Thing - Uncertainty & Dilemmas

Interaction w/ HCPs (Consult etiquette & Diagnostic Issues)

Trials & Tribes of Medication

Feedback w/ HCP

C.M.H.P

College of Mental Health Pharmacists
Living with a Degenerative Illness

- Causes
- When to report
- Approach and methods

- Early detection
- Outcome

CMHP
College of Mental Health Pharmacists
Interaction with NCP's ideas (Seek 'Help')

- Seeking info / help
  - The Known
  - Misinformation
  - More direction
  - Inaccurate of access info
  - laugh (bad)
- Seek (constantly) yes
- Timing of info
- NICE
- Sharing of bear support
  - NICE

Consult - quarterback

Different Drs
- Involvement
- Case / involvement
- Do / pt involvement
- (from dilemmas)

Diagnostic Process
- Conflict
- Memory
- Rivalry (doubt)
- Prediction (know something wrong)
- Diagnosis
- diagnosis

NICE
- NICE
- Medication (get buy?)
Interaction W HCP

1. Seeky Info + Help
- Seeky
- Missy
- Can we
- Query
- NICC
- The known
- What known
- Searching wrong
- Query
- Trees
- More details
- Reach not previous
- Missing
- Trees

2. Consultation Etiquette
- Diff 1 s
- Children can
- 3rd mandates
- Snapshot assets
- Diff mandate
- Not informed of HCP
- Change vs the progression

3. Diagnostic issues
- Something wrong
- Process issues
- Diagnostic complications
- Test
- Medical
tell
- Conflict
- NICE
- Feeling + quantity
- Confusion of family

C M H P
College of Mental Health Pharmacists
Interaction with HCPs/Others

Seeking Info and Help

The Known
Known facts 2.4a,c, 3.5a, 10.8a

More Direction
Want/need more direction 3.6ce

Incorrect Information/Misinformation/no information
Being told TIA's can be seen on CT scan when need an MRI (effect on duration of diagnostic process and carer stress levels) 1.2
Incorrect info 10.3h, 6.9b, 10.21g
NO INFORMATION ON MEDICINES 11.10d (seeking info)CEts

Carer seeking information/support
lack of info from professional results in searching internet and contacting AS 1.1
General 2.4b, 10.2d, 10.3a, 11.7kl (progression)
not told about stopping or withdrawal leads to supposition 1.10
reason for lack of information/Perception of reason for lack of information 11.7
pvd comment 1.12 the stigma of mental health problems (talked about in dark corners)
on starting a new medicine 5.3a
perseverance 6.7ce
‘if you don’t know how can you ask?’ 6.9a
Lack of knowledge local practice/custom 6.12d
Getting care 8.5f, 8.5g
Pushing really hard for adm 10.2b
Different GP/prescribers different outcome 10.8c, 10.16a, 10.21h,
11.6i, 11.11c, 11.0b
Fighting 10.16c, 10.21n, 10.21l
Anger/upset/frustration at lack of interest 10.15bc.
Not Making waves 10.20a, 10.20c (holding back response)
On mms score & stopping 1.7b
Best source info/support (AS) 11.11a
PWD dislikes GP 11.19c
Confirmation from researcher 11.4c
Access to Specialist Support
Off ADM to access 10.7e, 10.7g, 11.16a (proactive use of GP to keep in touch)
Waiting on appointments 10.13a, 10.20e
To preferred clinician 10.20d
Positive help 11.19ab

Powerful other opinion
‘they warned me’ 8.3g
Lack of knowledge of dementia 6.9c, 11.11b (superficial)
Lack of knowledge local practice/custom 6.12d
GP lack of knowledge 10.22a, 10.23a
On starting 9.1f
Disinterest 9.4a, 10.15a, 11.19c
Unsympathetic hcp 10.3
Making trade offs 10.4b
Therapeutic nihilism 10.20b
Ageist response 10.22b
GP only deals with non adms/non dementia illness 11.19d

Reactive Support/Information
Reactive 6.8h
No proactive info on D 10.2hj
No proactive info on SE/medication 10.5b, 10.8b, 10.17b, 11.10b

Bureaucracy of Access to Information
‘not allowed to tell you’ 8.7b
Politics of care 9.1a, 9.3h, 9.6b

Timing of Information
had the information in a carer group session but ’I didn’t twig’ 1.3

Something’s Wrong
knew something was wrong; outlined prodroma period (greater than 12 years)
1.4
reasons why people should stay on treatment 1.9
reasons when medication should be withdrawn 1.9
thoughts on future involvement in therapeutic decision-making 1.10
thoughts on efficacy; without he would have ‘dropped off’ 1.10
views on what it must be like to live with memory problems 1.11
The timing of medication withdrawal 1.11
Other 2.1

Sharing/Peer Support
sharing knowledge/sense making in FG 11.5b (on carer support) 11.10c
(prescribing)

NICE
It’s a decision about a decision /NICE 1.10

Consultation Etiquettes

Different doctors 11.8b
Carer Involvement in decision making 6.12a, b, 1.20f, 10.21a, 11.16c, Not
being asked 6.11a
Decision-making (from seeking)
Involvement in 4.4d
None in decision to start 10.1d
More involvement b carer 10.20f, 10.21a
Snapshot assessments 10.21bd, Carer expertise on day-to-day 10.21f
Different monitoring services 11.15d
Not in front of the patient 11.16de, 11.17d, 11.18a, PWD different after shared consultation 11.7abc
PWD involvement 11.17d, PWD different story to C 11.18c, PWD changes behaviour in different settings 11.18d, Patient involvement in DM 2.4g, 2.7d

Diagnostic Issues

Diagnostic Issues
higher intelligence of partner 1.2, 6.11a
number of professionals involved (complex) 1.2
incompetence (long cycle of things gone wrong) 1.2
stress/frustration on carer of duration of process 1.11
problems 6.2d, 11.8f
delays in process 6.3a duration of diagnostic process 1.2, 1.11
dismissal of symptoms 11.18c
getting the diagnosis 6.14e, 1.15b
lack of recognition or referral by HCPs 6.16de
waiting on a decision 6.17a
Ageist response 0.16h, 5.65
Nobody listening (not being heard)
I knew there was a problem; he's doing this doing that etc 1.2
Not being heard 2.8b
Disinterest in effect on lives 10.16i
Receiving the diagnosis Deliver 2.8d Seeking to Diagnostic issues HCP pick up 3.4b
Concomitant illness Non-recognition 10.6d

Prodroma (Something's wrong)
uncharacteristic behaviour 2.8c, 3.3m, 3.4a
general 2.8a, 3.3i, 4.2h, 5.6b, 6.5a, 7.1d, 11.15a

Testing, Making sense of memory testing 2.5a

Medication (getting it)
Getting the medication 6.15b
waiting on a decision 6.17a

Conflict
Conflict with professional OR hcp opinion hereditary component dismissed by HCP 1.2
non-acceptance of diagnosis by a HCP 1.2
(ON INVOLVEMENT IN THERAPEUTIC RELATIONSHIP) 'no real involvement at all' makes proactive prompts to HC assessor of PWDs progress 1.9
Others 2.1, 2.1b, 2.2h, 2.47i, 3.1b, 3.4c

NICE It's a decision about a decision (NICE) 1.10
Appendix A4-2: Explanation of Superordinate Themes

Superordinate Theme: On Being A Carer

Becoming a carer resulted in a whole new persona and the perception that a life outside of caring was lost to them. This theme encompasses the associated role changes as well as the darker side of caring when the burden became overwhelming.

Superordinate Theme: Interaction With Healthcare Professionals

Many carer participants perceived that a major barrier or aid to their ability to care for a person with dementia was dependent on the successful interaction with a healthcare professional. However the perception for some was there was some unwritten test they needed to pass to receive the information, support or treatment they needed. Therefore many interactions' with healthcare professionals were fraught with less than successful outcomes.

Superordinate Theme: Living With A Degenerative Illness

The term degenerative illness has been used in place of dementia or Alzheimer’s disease as the findings highlighted a chronicity of care and suffering associated with a continued and in many case unchecked progression in symptoms. Learning to live with this as a carer or a person with dementia was often dependent on the successful access to pharmacological treatment.
Appendix A5-1: Case Study Protocol

Case Study Protocol

Living with Medicines for Dementia

– Patient and Carer Perspectives

Denise Ann Taylor,
Department of Pharmacy and Pharmacology
University of Bath
1. Introduction to the study

Living with Medicines for Dementia - Patient and Carer Perspectives.
The research proposes to explain whether the effect of a particular medicine for
dementia on the day-to-day lives of people who take that medicine and those that care
for them is different if a different medicines is. The possible effects and perceived
and/or experienced outcomes will be explored over time. The case study approach is to
explain and explore whether a different medicine for dementia is associated with
different outcomes.

This study will compare patient outcomes with those perceived by carers; the prescriber
of the medication and if appropriate a healthcare professional also supporting dementia
care. Findings will also be compared with objective psychometric testing results recorded
in the patients shared record.
1.1. The Study Research Team

**The Chief Investigators**

**Miss Denise Taylor**
Senior Teaching Fellow, Programme Lead for Pharmacist Prescribing
Department of Pharmacy and Pharmacology at the University of Bath.

**PhD Supervisor**

**Professor Marjorie Weiss**
Department of Pharmacy and Pharmacology
University of Bath

1.2. The Sponsors of the Study

This study was funded by a GALEN award managed by the Pharmacy Practice Research Trust (PPRT) at the Royal Pharmaceutical Society of Great Britain (see later). The GALEN award is a research bursary awarded annually by the PPRT to support the development of research capacity in pharmacy practice research. It is made as a result of an annual bequest from Rowland Henry Williams for monetary support for research up to £10,000.

**The Pharmacy Practice Research Trust**

The Pharmacy Practice Research Trust (the PPRT) was established in July 1999, by the Royal Pharmaceutical Society of Great Britain, as an independent research charity, with a broad objective to promote and develop the field of pharmacy practice research. “We aim to support and promote the professional practice and performance of pharmacists and the delivery of safe, patient focused services by the pharmacy workforce. We are committed to disseminating the results from research to ensure that the knowledge is used to inform evidence-based changes to policy, practice and services.”

For more information please visit the website: [www.pprt.org.uk](http://www.pprt.org.uk)

2. Introduction to case study methodology and the purpose of the case study protocol

The development of an appropriate case study protocol facilitates consistency in data collection between case study sites and is instrumental in maintaining the focus of the case study research to ensure reliability and ultimately quality of the findings. (Yin, 2003).

This case study protocol includes:
- An Introduction to the Study and the Purpose of the Study
- Data Collection Procedures
- Case Study Questions
- Outline of Case Study Report

2.1. An Overview of the Case Study

Case study methodology was chosen as a research strategy for this project as it enables the researcher to make a thorough investigation of what actually happens in a given situation, and chronicles events that happen over time. Case study methodology allows the validation of quantitative data through the addition of qualitative information to
acheive triangulation of results in order to construct an overall robust picture of service provision (Yin, 2003).

This study will use in-depth comparative case study methodology as a means of exploring a situation in which an intervention being evaluated has no clear single set of outcomes (Yin, 2003). In this research the situation is the day-to-day lives of people taking a medication for dementia and those that care for them. The intervention is the initiation of a medicine for dementia. The outcomes are multi-factorial, as these medicines are known to affect a range of domains including: the physical, mental, social and behavioural health of the person taking these agents and those of their carer. These domains can also affect quality of life and the wider social environment such as interaction with family and friends.

It was proposed that here would be 8 case studies to investigate if there were differences between the cholinesterase inhibitors (donepezil, rivastigmine and galantamine); and the NMDA-receptor antagonist (memantine). Two other cases were chosen; the first to explore issues about how not being appropriate and/or refusing a medicine for dementia affected day-to-day life experiences; the second to explore the effect of the medication classes in combination.

These are detailed in full, below:

1. one where the medicine for dementia is donepezil;
2. one where the medicine for dementia is rivastigmine;
3. one where the medicine for dementia is galantamine;
4. one where the medicine for dementia is memantine;
5. one where an medicine for dementia has been withdrawn due either to adverse effects or lack of efficacy or has been swapped to another agent;
6. one where there is co-prescribing of medicines for dementia;
7. one where the person refused treatment, and
8. one where the person was ineligible for treatment (e.g. because it was for a condition where these agents are not licensed such as vascular dementia).

These case studies were chosen due to the issues in clinical practice when patients were first initiated on a medicine for dementia and to explore the dilemmas of when issues became complicated by things such as adverse effects of the reduction of efficacy after a period of time. Further information can be found in the study protocol.

2.2 Data Collection Procedures

2.2.1 Access to Proposed Case Studies

Potential patients were to be identified by clinic staff at a variety of locations to try to maximise the opportunities of recruitment. An aim was to attempt to recruit the person who might be eligible to take a medicine for dementia, before they actually started so expectations hopes and fears of the medicine could be explored and then compared with actual events and effects of the medicines over time. The researcher would not have access to the patients so recruitment was dependent on local clinicians identifying patients; giving them information about the study and then providing the actual patient information pack. (NB: originally there were only two recruitment sites; but when after 3 months there had been no successful recruitment, two more were added (with LREC approval). Shortly after this one of the first two sites withdrew due to changes in their organisational policy so the lead clinicians agreed to help recruit from two further
<table>
<thead>
<tr>
<th></th>
<th>Healthcare Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Research charity with a specialist interest in dementia</td>
</tr>
<tr>
<td>2</td>
<td>Research memory clinic attached to care of the elderly wards in a large city</td>
</tr>
<tr>
<td>3</td>
<td>Memory clinic as part of older people services at a community general hospital</td>
</tr>
<tr>
<td>4</td>
<td>Memory clinic provided as part of a Community Mental Health Trust</td>
</tr>
<tr>
<td>5</td>
<td>Memory clinic provided as part of a Community Mental Health Trust</td>
</tr>
<tr>
<td>6</td>
<td>Memory clinic provided as part of a Community Mental Health Trust</td>
</tr>
</tbody>
</table>

memory clinics. Each site had at least one research gatekeeper; these have been deleted for confidentiality purposes.

2.2.2 Data to be Collected

Patient and carers would be interviewed using a semi-structured interview technique to explore perceptions, experiences and viewpoints. They would be interviewed up to 4 times over a 12 month period. (NB: initially participants were to be followed up for a period of 6-months, however external events resulted in an increase to 12-months. Interviews were originally proposed prior to the start of the medication; 3 to 4 weeks after the start of the medication (to explore the incidence and severity and effects of possible adverse effects of the medication prescriber; again at 3 months to explore any titration issues and then at 6-months to establish if there were changes once an effective dose level was reached. Again the protocol needed to change as the procedures within each of the clinics change din response to concerns about the delays in access to treatment. Originally the clinics had seen patients at time 1 for physical and psychological investigation and they were also referred for other tests such as MRI or CT scans that were not available on site. Prior to time 2 the lead psychologist and the appropriate psychiatrist would discuss the possible diagnoses and the patient invited to attend at time 2. At this visit the patient would receive their diagnosis and be able to ask for further relevant information before being invited back for a third visit where the medication would be explained and initiated.

It had been planned that at time 2 the patient would be introduced to the study and invited to take part prior to straying the medication; however both original clinics reduced the process to two visits to reduce the time to initiation of therapy. This was because the literature supported findings that suggested delays in treatment represent lost function that may not be retrievable. Patients were then recruited at time 2 visit and the ability to explore perceptions and expectations of medicines prior to starting was lost. Prescribers and healthcare professionals were to be interviewed once during the life of the case study and with informed consent of all concerned an observation of a consultation between the prescriber and the patient (with/without carer would take place).

Objective data from patient shared records would be accessed to see if documented findings supported claims by patients and their carers of the effects of the medicines for dementia.
Field Procedures
This section explains procedures to be undertaken by the researcher when visiting case study sites. Following these procedures are important to ensure researcher and participant safety, as well as rigorous data collection.

Lone working
Lone work presents a greater potential for harm and may require more stringent precautions to comply with the law. Ideally researcher should work in pairs, but if this is not possible the following procedures must be followed.

- The participant may wish for another person (that they know) to be present. The participant and researcher before hand must agree this.
- The researcher must carry a dedicated mobile phone (which should be fully charged) that remains turned on during the visit so that they remain in constant contact with the research supervisor.
- The researcher must ensure that the research supervisor has the address that they will be visiting.
- The researcher must inform the research supervisor as they arrive at this address and as they leave this address.
- If the researcher does not get in contact with the research supervisor after a specified time (1 ½ hours) the research supervisor must try to get in contact with them on the mobile phone or the phone number for the address supplied.

2.3 Case Study Questions
The research generally asks how and why questions about the effects of medicines for dementia on the day-to-day lives of those people who take them and those people who care for them. The second phase was a longitudinal study designed to explore the effects of medicines on the daily lives of people with early dementia and their carers over time. The objectives of this part of the study were to:

1. explore lay and healthcare professional perceptions of the outcomes of medicines for dementia.
2. explore whether there was consensus on perceived efficacy over time.
3. explore perceptions on how medicines for dementia should be used in early dementia.
4. to highlight the potential role of the pharmacist in supporting medication use in people with early dementia and their carers.
5. to identify possible areas of educational need for healthcare professionals.

It was proposed that findings from this study would provide qualitative and quantitative evidence of perceived effects of medicines for dementia in a naturalistic setting. It might also establish insight into the perceived effect on carer’s ability to cope. The results could also provide information to aid in the education and training of HCPs involved in the prescribing process.

Questions to be addressed by the case studies

(1) Do the medicines produce the same perceived effects?
(2) How are these medicines perceived to effect the day-to-day lives of those that take them and those that care for them?
(3) Are these findings supported by healthcare professionals and prescribers?
(4) How do the objective measures used at routine monitoring clinics compare with those observed in the field?

These will also be guided by the content of the relevant interview topic guide.

2.4 Guide for the Case Study Report

Audience:
RPSGB, Basis of doctoral thesis.

Format
An overview and description of the case studies recruited to as an appendix to an in-depth cross-case analysis of the findings. Interview data will be analysed using Nvivo as a support tool and using interpretative phenomenological analysis as the analytical methodology.

Appendix
Annotated Bibliography (itemized list of all documents used for documentary review)

3 References
Appendix A5-2: Topic Guide for Phase Two
(Only patient versions will be presented)


Living with Medicines for Memory Problems: Patient and Carer Perspectives

PATIENT VIEWS ON MEDICINES FOR MEMORY PROBLEMS

TOPIC GUIDE

We are interested in finding out your views and beliefs about the medicines that are used to help treat memory problems. We would like to find out how you think these medicines affect your day-to-day life. We are also interested in finding out how effective you think they are and what changes they may make to every day activities.

All information from the interviews will be treated in the strictest confidence – so we will not use your name or refer to any people you might mention directly by their name. The tapes from this session will be assigned a number and that is how we will refer to you and the other members of the group, when we present this information to other people.

8. Background/Personal Information
After a brief introduction at the start of the interview by the researcher, participants will be asked to think about the following as an ice-breaker: “What do you think about these medicines? Are they good? Do they work? Did you have any problems with these?” Responses will be explored and then this will lead into the major content of the interview.

- Tell us the name of any medicine for memory problems you are familiar with

9. Medicine Taking

- What expectations do you have about these medicines being able to treat your condition?
- What are you expecting to see?
- Could you identify 3 or 4 key things you would like them to achieve (e.g. help you remember where you place keys or glasses; help you to be able to concentrate on reading or television or music etc)
- Is there anything else you are hoping they may help with?

10. The prescribing process

- Were you given sufficient information about the medicine prior to starting
- Were you told about the effectiveness of the medicine?
- How are you managing to take the medicine every day?
• Are you involved with the monitoring of the medicine? For example for adverse effects; effectiveness of treatment etc
• Did you discuss an end or withdrawal date issues prior to the medicine being started?

11. The effect of these medicines on day-to-day life
• Tell us about how these medicines affect your day-to-day life in the following areas:
  - Adverse effects
  - Compliance issues
  - Dosing or titration problems
  - Ordering and supply issues
  - General effects on day-to-day life

12. How effective are these medicines?
• Tell us about the effects these medicines have on the ability for you to lead a life as per your usual routine. For example what are the:
  - Positive effects
  - Negative effects
  - important improvements to you?
  - important effects for the person who cares for you?

13. Any other issues?
• Is there anything else you would like to tell us about which is important to you and/or the person you care for with respect to these medicines?

THANK YOU FOR YOUR HELP

If you would like to receive a summary of your case group interviews, please complete the reply slip below and return it in the stamped addressed envelope provided. The researcher will send you the summary details once they have been compiled.

Thank you for your time

I would like to receive a summary of the findings of my case study group about the living with the medicines for memory problems.

Name:
Address:

Thank you for your help!

Please return to:
Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath
Claverton Down
Bath BA2 7AY
Telephone: 01225 383677
Appendix A5-3: Consent for Observation of Consultation
(Only patient versions will be presented)

(Patient Consent Form, Version 4 21st April 2006)

Living with Medicines for a Memory Problem: Patient and Carer Perspectives

Lead Investigator: Miss Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath, BATH BA2 7AY
Telephone: 01225 383677 (work)
Telephone: 07981790025 (mobile)
Email: d.a.taylor@bath.ac.uk

Observation of Consultation

Please initial the box

5. I confirm that I have read and understood the information sheet dated 14th March 2006 for the above study

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

7. I am happy to have the consultation observed

8. I agree to take part in the above study

Name of participant          Date          Signature

Name of witness to Consent process          Date          Signature

Name of researcher          Date          Signature

1 for participant; 1 for researcher
Appendix A5-4: Consultation Observation Tool

Feedback Form on Pharmacist-Patient Communication

(1) Explores patient’s ideas, concerns and expectations. Identifies the reasons for the consultation and explores how the problem affects the patient’s life. Facilitates patient’s responses through verbal prompts. Probes wider social issues impacting upon health.


Appendix A5-5: Study Information Sheet Phase Two
(only the patient version will be presented)


Living with Medicines for Memory Problems:
Patient and Carer Perspectives

| Lead Investigator: Miss Denise Taylor |
| Department of Pharmacy & Pharmacology |
| University of Bath, BATH BA2 7AY |
| Telephone: 01225 383677 (work) |
| Telephone: 07891790025 (mobile) |
| Email: d.a.taylor@bath.ac.uk |

Information for Patients

Dear Sir or Madam,

We are asking people to take part in a research study who may need to take a medicine for a memory problem. The study is designed to help us find out what people may think about taking these medicines and how people may think they can help in day to day life. The research uses interviews to help us to do this. We would also like to interview your carer, your doctor and (if you have one) your clinic nurse. We would like to interview each of you one at a time. We will not share any information that you tell us with anyone else.

You are being asked to take part in a research study. Please take time to read this information carefully. If you would like more information or if there is anything that is not clear, then please contact Denise Taylor. (Contact details above).

Thank you for reading this.

1. What is the purpose of this study?
The purpose of this study is to find out what people who take medicines for memory problems think about them and whether you think these medicines work and how they may affect your day-to-day life. We would like to find out if what you think about these medicines will change over time. To do this, we would like to visit you at home and interview you and your carer for a maximum of 3 visits over a 6-month period.

2. Why have I been chosen?
You have been chosen because you have recently attended a clinic about the memory problems you have been experiencing. You are being asked to take part in the study to tell us about your experiences of taking medicines. We are planning to talk to up to 7 groups of patients and carers.

At this stage we do not know what your diagnosis will be. If following the diagnosis, you do not meet the inclusion criteria of our study there will be no need for you to continue to take part. The researcher will contact you and let you know that there will be no need for any further interviews.

3. Do I have to take part?
No. It is up to you to decide whether or not you want to do this research. If you do take part you can keep this information sheet and you will be asked to sign a consent form. If you decide to take part you are still change your mind later, without giving a reason. If you decide not to take part, any care or treatment you receive will not be affected.
4. What will happen during the study?
If you agree to take part in the study, you will be contacted by the lady doing the research, who will explain things to you in further detail. She will arrange a suitable time and place for the first interview to occur. This could be in your own home or at the memory clinic. You will also be asked to sign a consent form. During each interview the researcher will follow a list of questions, which cover the issues in the research. We expect the interview to last between 20 and 30 minutes each time.

The interviews will be recorded and you will be asked your consent for this to happen. When the tape is being written up, you will not be able to be identified in any way from the recording.

5. What are the possible disadvantages and risks of taking part?
Taking part in the study is very unlikely to put you at any risk. In the unlikely event that the interview brings up difficult issues for you, the researcher will deal with these sensitively. You may ask to stop the interview at any time.

6. What are the possible advantages of taking part?
We do not expect there to be any advantages to you in taking part. However the information you give us will help us to understand how these medicines can affect the day-to-day lives of people who take these medicines. This information will also help us to understand how your opinions of these medicines may change over time. These findings may help us to educate people involved in the prescribing of these medicines.

7. What if something goes wrong?
In the unlikely event that you are harmed by taking part in this study, there are no special compensation arrangements. However, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you can contact the Lead Researcher; Miss Denise Taylor, Department of Pharmacy and Pharmacology, University of Bath, Bath BA2 7AY. Telephone: 01225-383677, or her supervisor Dr Marjorie Weiss at the same address on telephone 01225-386787.

8. Will my taking part in the study be kept confidential?
No information coming from any of the interviews or the consultation will have your name on it and will not be shared with anyone else who is not part of the study. The interviews will be typed up by a secretary who will not know who you are. Once the study is completed the interview tape will be kept in a secure place for 10 years and then destroyed. You can see the written report of your participation at any time.

9. What will happen to the results of the research study?
We may have some of what you say printed in a journal or magazine. If this happens your name and details will always be removed, so that nobody will know whose words they are. If you are interested to know more about the results, you should contact the Lead Researcher for further information.

10. Who is organising and funding this research?
The study is being organised as part of a doctoral thesis (PhD) by Miss Denise Taylor (the lady researcher). The study is supported by a grant from the Royal Pharmaceutical Society of Great Britain.

11. Who has reviewed this study?
This study has been reviewed by the Swindon Ethics Committee, and also has been internally reviewed by Dr Jenny Scott at the University of Bath and also peer reviewed by the Royal Pharmaceutical Society of Great Britain.
12. Who do I contact for further information?
If you have any other questions, please contact Miss Denise Taylor at
d.a.taylor@bath.ac.uk, Department of Pharmacy and Pharmacology, University of
Bath, Bath, BA2 7AY. Telephone 01225-383677 (office) or 07891790025

13. What do I do now?
If you would like to take part, you can telephone the lead researcher on the number
below. Or complete the reply slip below and return it in the stamped addressed
envelope provided. The researcher will contact you over the next few days to discuss
the research with you.

Thank you for your time

I would be interested in helping with this research study about living with medicines
for memory problems.

Name:
Address:

Telephone: (please indicate when the best time to contact you is)

Thank you for your help!

Please return to:
Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath
Claverton Down
Bath BA2 7AY
Telephone: 01225 383677
Appendix A5-5: Joint Recruitment letter

Patient Invitation Letter version 1 8th August 2006

To be on Clinic Headed paper

Name of potential participant
Address of potential participant
Date

Dear [Name of Potential Participant]

We are writing to ask your help with a research project exploring people’s views on the medicines they use for memory problems. The aim of this study is to find out how you think these medicines work and how they help in your everyday life. The study is being led by a pharmacist called Denise Taylor, who works at the University of Bath, as part of her doctorate studies.

The reason why this study is being done is because some people who take these medicines describe benefits that are not seen by staff at the memory clinic, so the study would like to find out more about these issues. The study also wants to ask the people who care for you the same questions. So we would like to ask whether you would be interested in helping with this study to talk about the medicines you are taking for memory problems and whether your main carer would also be interested in taking part.

The study involves being interviewed on up to 3 occasions over a 6-month period. Each interview will last about 20 to 30 minutes and Denise will ask your views on how well you think the medicine has worked. Denise would prefer to talk to you separately from your carer, although they or a friend can be present during the interview if you wish.

The interview will be quite informal. The interview can either be held here at the clinic or Denise can visit you in your own home if that would be more convenient.

The interviews will be tape recorded, if you are happy for this to happen. Denise will produce a report but you will not be able to be identified in anyway from the written record. All identifying names and markers will be removed. You can ask for a copy of your interview if you would like one. The tape will be kept in a secure place so no one else has access to it and then it will be destroyed after 10 years.

If you would like to take part in this study [please return the attached form directly to Denise in the FREEPOST envelope or you can contact her directly by telephone] you can read the enclosed information sheets or you can contact Denise directly by telephone (her number is at the end of this letter). Thank you very much for your time in reading this letter. Please feel free to contact us for further information.

Enclosed are the following documents:

1. The Patient Information Sheet: please read this carefully as it explains in further details what the research is about and what your involvement will be. The section at the end is what you return to Denise if you are interested in helping with this study.

2. The Patient Topic Guide: this outlines the sort of things you will be asked to give your views on in the interview.

3. The Patient Consent Form: this is the form you will need to sign on the day of the interview. It needs to be signed because it is a record that you have read.
and understood the information and consented to take part in the study. It also states that we would like to record the interview session and we need your permission to do this. It is very important that you do not feel pressured into participating in the study and we need to be sure that you have understood the information and have had sufficient time to make up your own mind whether you would like to be interviewed. For this reason we ask another person (perhaps your main carer) to witness this.

4. A stamped addressed return envelope

Yours sincerely                                Yours sincerely
Appendix A5-5: Consent Form for Interviews
(Only the patient version will be presented)

Patient Interview Consent Form; Version 3 14th March 2006.
Living with Medicines for Memory Problems:
Patient and Carer Perspectives

Lead Investigator: Miss Denise Taylor
Department of Pharmacy & Pharmacology
University of Bath, BATH BA2 7AY
Telephone: 01225 383677 (work)
Telephone: 07981790025 (mobile)
Email: d.a.taylor@bath.ac.uk

Interviews

Please initial the box

1. I confirm that I have read and understood the information sheet dated 4th November 2005 for the above study

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

3. I am happy to have the interviews audio-tape recorded

4. I understand that relevant sections of my medical notes and Data collected during the study may be looked at by the Researcher. I give my permission for the researcher to have access to my records.

5. I agree to take part in the above study

Name of participant                      Date                      Signature

Name of witness to Consent process       Date                      Signature

Name of researcher                      Date                      Signature

1 for participant; 1 for researcher
Appendix A5-8: Shared Cared Record Data Collection Form

Data Collection Form: Shared Care Record

Name:
D.O.B:

Date of Recruitment:

Date of Interview 1:
Date of Interview 2:
Date of Interview 3:
Date of Interview 4:

Date of Observed Consultation:

<table>
<thead>
<tr>
<th>Date</th>
<th>Clinician</th>
<th>Results &amp; Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix A5-9: Internal Ethical Review

University of Bath

Ethics approval of Research Proposals – Peer Review Process

Name of Applicant: Miss Denise Ann Taylor

Email address: d.a.taylor@bath.ac.uk

Title of Project: Living with Anti-dementia Medicines: Patient and Carer Perspectives (Phase II of PhD project)

Name of peer reviewer: Dr Jenny Scott

Position and Department/School: Lecturer in Pharmacy Practice, Dept of Pharmacy & Pharmacology

Comments of Peer Reviewer:

The research team and resources:
The lead applicant is well qualified to undertake this study. She has extensive clinical experience of working with the patient group and with carers. She also has had training in and experience of using qualitative research methods. She is supported by an appropriate supervisory team. This study has received external funding and therefore undergone external peer review also (RPSGB Linstead Fund Practice Research Awards Panel).

The rationale for study:
The rationale for the study appears to be sound. Patient and carer involvement in the development of healthcare is an increasingly important factor and this area is one often neglected.

Design:
This is a longitudinal study which will follow up over time patients and carers to establish how their views on anti-dementia medicines change over time. The follow up is important in this study as views are unlikely to remain static. It adds depth to establish how these views change over time rather than to take a snapshot which, as illustrated by the applicant in the protocol, has shortfalls when used to inform future care. Opinions and expectations at the onset of treatment or clinical diagnosis are likely to change with the lived experience. The data will be collected using semi structured interview. Analysis using N-Vivo is appropriate and the research has experience of using this package.

Consent:
This study uses opt-in methodology, which therefore protects the right of the individual to make an active choice in participating minimising the risk of coercion. The researcher will not have access to potential participant names or other details until the person makes contact to share these. The patients at this stage of their disease are considered able to make informed decisions
and the advice of the clinicians is recommended prior to follow up to ensure that this view is still held about the individual.

The healthcare professionals involved will also opt-in to the study.

Comments on consent taking:
Consent to observe consultations must be taken as a separate discreet consent. It must be made clear to the patient, their carer and the clinician that the study can continue without observed consultation.

The rights of all participants to withdraw at any time must be made explicitly clear and due to the interactive nature of the relationship between the participants it must be made clear that should any party withdraw (e.g. patient, carer or clinician/support worker) then the involvement of that patient, carer and clinician/support worker 'unit' in the study will end (i.e. ongoing involvement is dependent on all three/four parties consenting to participate). This must be done in such a way as not to be coercive.

Participant information sheets are needed for all four parties to potentially be involved.

Confidentiality
The data will be stored securely and kept for the required time stipulated by the data protection act. Participant ID numbers will be used to protect identity on tapes and transcripts.

Indemnity
The research will adhere to the Research Governance Framework and the University (the research sponsor) has indemnity cover in place.

Summary
In summary, this is a well designed study that has paid attention to the sensitive issues that working in this clinical area and with this client group can raise. The extensive experience of the researcher with older people during her previous clinical practice is reassuring. Participants are free to opt-in to take part and free to withdraw at any time. This is a worthwhile study which uses follow up to explore this important area which could potentially influence prescribing practice in this clinical area.

Approved by:

Name: J. Scott Signature: [signature]
Position: Lecturer in Date: 5-10-05
Pharmacy Practice
University of Bath

Ethics approval of Research Proposals – Peer Review Process

Name of Applicant: Miss Denise Ann Taylor

Email address: prsdat@bath.ac.uk

Title of Project: Living with Antidementia Medicines: Patient and Carer Perspectives

Name of peer reviewer: Dr Jenny Scott

Position and Department/School: Lecturer in Pharmacy Practice
Dept of Pharmacy and Pharmacology

Comments of Applicant:

Thank you for the comments made on the above project. They are highly valued. After discussion with my supervisor we have decided that there is no reason why the continuation of the case study is dependent on one of the participants withdrawing from the case study group. This is because the aim of the study is to explore the experiences that participants have with the medicines. Experiences and reflections will be specific to the individual and not dependent on whether a particular party remains a member of the study group. It is not intended to set up a coercive dynamic to the study groups where individual participation is dependent on the continuing participation of others. Each case study participant may still have valuable perspectives and contributions that they wish to make. Because of the complexity and multifactorial components of living with dementia and with medicines for dementia it is important that people have the option to tell their story. This is one of the reasons case study methodology was selected.

However, participants are able to withdraw at any stage from the study, without needing to give an explanation. Each participant at each interview will be asked if their consent is still valid for continuation in the study and/or will be assessed for capacity to continue to give informed consent.

Name: Denise Taylor
Position: Applicant
Signature: 
Date: 14-11-2015

Name: H. C. West
Position: Supervisor
Signature: 
Date: 15/11/2015
Appendix A5-10: LREC Approval Phase Two

Swindon Research Ethics Committee
Unit B
Valentines
Epsom Square
White Horse Business Park
Trowbridge
BA14 0XG

Telephone: 01225 766752
Facsimile: 01225 754648

01 February 2006

Miss Denise Ann Taylor
Senior Teaching Fellow
Department of Pharmacy and Pharmacology
University of Bath
Claverton Down
BATH
BA2 7AY

Dear Miss Taylor

Full title of study: Medicines Management of Antidementia Agents in People with Dementia (MAPD)
REC reference number: 05/Q2004/82

Thank you for your letter of 22 December 2005 and the letter from your Supervisor dated 24 January 2006, responding to the Committee’s request for further information on the above research and submitting revised documentation.

The further information was considered by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has designated this study as exempt from site-specific assessment (SSA). There is no requirement for [other] Local Research Ethics Committees to be informed or for site-specific assessment to be carried out at each site.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application</td>
<td></td>
<td>15 November 2006</td>
</tr>
<tr>
<td>Investigator CV</td>
<td>D Taylor</td>
<td>14 November 2005</td>
</tr>
<tr>
<td>Investigator CV</td>
<td></td>
<td>03 November 2005</td>
</tr>
<tr>
<td>Protocol</td>
<td>3</td>
<td>15 November 2005</td>
</tr>
<tr>
<td>Advertisement</td>
<td>2</td>
<td>13 November 2005</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>5</td>
<td>15 December 2005</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>2</td>
<td>21 December 2005</td>
</tr>
<tr>
<td>Letter from Statistician</td>
<td></td>
<td>22 December 2005</td>
</tr>
</tbody>
</table>

An advisory committee to Avon, Gloucestershire and Wiltshire Strategic Health Authority

298
<table>
<thead>
<tr>
<th>Summary of Phase One</th>
<th>21 December 2005</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carer Interview Topic Guide</td>
<td>2 13 November 2005</td>
</tr>
<tr>
<td>Prescriber Interview Topic Guide</td>
<td>2 13 November 2005</td>
</tr>
<tr>
<td>HCP Interview Topic Guide</td>
<td>2 13 November 2005</td>
</tr>
<tr>
<td>Letter from Medicines &amp; People</td>
<td>24 August 2005</td>
</tr>
<tr>
<td>Letter from Supervisor</td>
<td>24 January 2006</td>
</tr>
<tr>
<td>Carer Information Sheet</td>
<td>3 13 November 2005</td>
</tr>
<tr>
<td>Prescriber Information Sheet</td>
<td>3 13 November 2005</td>
</tr>
<tr>
<td>Healthcare Professional Information Sheet</td>
<td>3 13 November 2005</td>
</tr>
<tr>
<td>Carer Consent Form</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Prescriber Consent Form</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>HCP Consent Form</td>
<td>2 14 November 2005</td>
</tr>
<tr>
<td>Patient consent Form C</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Carer Consent Form C</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Prescriber Consent Form C</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Patient Invitation Letter</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Carer Invitation Letter</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Prescriber Invitation Letter</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>HCP Invitation letter</td>
<td>1 04 November 2005</td>
</tr>
<tr>
<td>Patient interview Topic Guide</td>
<td>2 13 November 2005</td>
</tr>
</tbody>
</table>

**Research governance approval**

You should arrange for the R&D department at all relevant NHS care organisations to be notified that the research will be taking place, and provide a copy of the REC application, the protocol and this letter.

All researchers and research collaborators who will be participating in the research must obtain final research ethics approval before commencing any research procedures. Where a substantive contract is not held with the care organisation, it may be necessary for an honorary contract to be issued before approval for the research can be given.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**REC reference number 05/Q2004/82 please quote this number on all correspondence**

With the Committee’s best wishes for the success of this project

Yours sincerely

[Signature]

p/t Dr Elizabeth Price
Chair
Swindon Research Ethics Committee

Ensue: Standard approval conditions

cc: Department of Pharmacy and Pharmacology University of Bath
     Claverton Down BATH

An advisory committee to Avon, Gloucestershire and Wiltshire Strategic Health Authority
Appendix A5-11: LREC Approval of Changes to the Information Leaflet

Swindon Research Ethics Committee (REC)
c/o West Wiltshire PCT
Unit B, Valentines
Epsom Square
White Horse Business Park
Trowbridge
Wiltshire
BA14 0XG

Direct Line: 01225 756752
Fax: 01225 754648

21 April 2006

kp/05/Q2004/82

Denise Taylor
Senior Teaching Fellow
Department of Pharmacy and Pharmacology
University of Bath
Claverton Down
Bath
BA2 7AY

Dear Miss Taylor

Rec ref: 05/Q2004/82
Study title: Living with antidementia agents – patient and carer perspectives

Thank you for your letter of 14 March 2006 enclosing a copy of the patient Information Sheet version 7 dated 14 March 2006 which has been given a favourable opinion.

I refer to your comments in the last paragraph of your letter. You had written to the Committee asking it to consider modifications which you wished to make to the document (your letter of 17 February 2006 refers) and the suggestions made in the Committee's letter to you of 8 March 2006 came about as a result of this review and were intended to be helpful and constructive. The amendment was considered at a full committee meeting and several members were present and commented or made suggestions. I can assure you therefore that it is not just one person who considers whether documents are acceptable or not. I understand that you considered these modifications minor but would remind you that you must seek the Committee's approval before modifying or altering any documents which have been reviewed by the Committee or indeed any new documents which you wish to introduce. I hope this clarifies matters for you and assure you again that these decisions are not just the whim of one Committee member.

Any amendments which you wish to make to the study should be submitted on the appropriate Amendment Form. The Committee would then consider the amendment at the first available meeting.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

Kirsten Peck
Kirsten Peck (Mrs)
Co-ordinator
Swindon Research Ethics Committee

An advisory committee to Avon, Gloucestershire and Wiltshire Strategic Health Authority
Appendix A5-12: LREC Approval Amendment 1

Swindon Research Ethics Committee
Unit B
Valentines
Epsom Square
White Horse Business Park
Trowbridge
BA14 0XG

Tel: 01225 756762
Fax: 01225 754948

11 August 2006
Miss Denise Ann Taylor
Senior Teaching Fellow
University of Bath
Claverton Down
BATH
BA2 7AY

Dear Miss Taylor

Study title: Medicines Management of Antidementia Agents in People with Dementia (MAPD)
REC reference: 05/Q2004/82
Amendment number: 1
Amendment date: 21 July 2006

Thank you for your letter of 21 July 2006 enclosing a notice of substantial amendment.

Ethical opinion
The Chair of the Committee has considered the amendment and given a favourable ethical opinion on the basis described in the notice of amendment form and supporting documentation.

Approved documents
The documents reviewed and approved were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>4</td>
<td>21 July 2006</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>3.1</td>
<td>21 July 2006</td>
</tr>
</tbody>
</table>

Research governance approval
All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

An advisory committee to South West Strategic Health Authority
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number 05/Q2004/82 Please quote this number on all correspondence

Yours sincerely

Kirsten Peck
Mrs Kirsten Peck
Coordinator
Swindon Research Ethics Committee
Appendix A5-13: LREC Approval Amendment 2

Swindon Research Ethics Committee
Unit B
Valentines
Epsom Square
White Horse Business Park
Trowbridge
BA14 0GG

Tel: 01225 750752
Fax: 01225 754948

08 September 2006
Miss Denise Ann Taylor
Senior Teaching Fellow
University of Bath
Claverton Down
BATH
BA2 7AY

Dear Miss Taylor

Study title: Medicines Management of Antidementia Agents in People with Dementia (MAPD)
REC reference: 05/Q2004/82

Amendment number: 2
Amendment date: 10 August 2006

The above amendment was reviewed at the meeting of the Committee held on 07 September 2006.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol</td>
<td>5</td>
<td>08 August 2006</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>3.1</td>
<td>08 August 2006</td>
</tr>
<tr>
<td>Letter of invitation to participant</td>
<td>1</td>
<td>08 August 2006</td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

An advisory committee to South West Strategic Health Authority
Research governance approval

All investigators and research collaborators in the NHS should notify the R&D Department for the relevant NHS care organisation of this amendment and check whether it affects research governance approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number 05/Q2004/82 please quote this number on all correspondence

Yours sincerely

Mrs Kirsten Peck
Co-ordinator
Swindon Research Ethics Committee

Enca \(\text{List of names and professions of members who were present at the meeting and those who submitted written comments}\)
Appendix A5-14: LREC Approved Study Extension 1

Appendix A5-14: LREC Approved Study

Extension 1

Swindon Research Ethics Committee (REC)
Room 11
John Apley Building
Royal United Hospital
Combe Park
Bath
BA1 3NG

Direct Line: 01225 821031
Fax: 01225 825725
11 December 2006

Denise Taylor
Senior Teaching Fellow
Department of Pharmacy and Pharmacology
University of Bath
Claverton Down
Bath
BA2 7AY

Dear Ms Taylor

05/Q2004/82 (SSS)
Living with antidementia agents – patient and carer perspectives

Thank you for your letter of 1 November 2006 notifying the Committee of an amendment on this study to the end of May 2007.

The amendment was considered at the meeting on 7 December 2006 and received a favourable ethical opinion.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number 05/Q2004/82 please quote this number on all correspondence

Yours sincerely

Kirsten Peck
Coordinator
Swindon Research Ethics Committee

An advisory committee to South West Strategic Health Authority
Appendix A5-15: LREC Approved Study Extension 2

National Research Ethics Service

Wiltshire Research Ethics Committee
Room 11
John Apley Building
Royal United Hospital
Combe Park
Bath
BA1 3NG

Tel: 01225 824355
Fax: 01225 825725

12 June 2007
Miss Denise Ann Taylor
Senior Teaching Fellow
University of Bath
Claverton Down
BATH
BA2 7AY

Dear Miss Taylor

Study title: Medicines Management of Antidementia Agents in People with Dementia (MAPD)
REC reference: 05/Q2004/82
Amendment number: 3
Amendment date: July 2007

The above amendment was reviewed at the meeting of the Committee held on 07 June 2007.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

No new documents were approved. End date of study has been extended to August 2007.

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority
The National Research Ethics Service (NRES) represents the NIHR Directorates within the National Patient Safety Agency and Research Ethics Committees in England.
Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number 05/Q2004/82: Please quote this number on all correspondence

Yours sincerely

[Signature]

Mrs Kirstan Peck
Co-ordinator
Wiltshire Research Ethics Committee

Enclosures

List of names and professions of members who were present at the meeting and those who submitted written comments
Appendix A5-16: LREC Approved Study Extension 3

National Research Ethics Service

Wiltshire Research Ethics Committee
Room 11
John Apley Building
Royal United Hospital
Combe Park
Bath
BA1 3NG

Tel: 01225 824255
Fax: 01225 829725

20 July 2007

Miss Denise Ann Taylor
Senior Teaching Fellow
University of Bath
Claverton Down
BATH
BA2 7AY

Dear Miss Taylor

Study title: Medicines Management of Antidementia Agents in People with Dementia (MAPD) 05/Q2004/82
REC reference:
Amendment number: 4
Amendment date: July 2007

Further to an exchange of e-mails between Kirsten Peck, the Coordinator, and Professor Marjorie Weiss, Katrina Brockbank, Co chair of the Committee, has considered the request to extend the end date of the project as you have been in a very serious car accident. In the circumstances it was felt that a realistic end date would be December 2008 and this has been approved by the Co chair. Please do not hesitate to contact me again should you feel that I can be of any assistance to you.

I hope this finds you well on your way to a full recovery.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

REC reference number 05/Q2004/82: Please quote this number on all correspondence

Yours sincerely

[Signature]

Kirsten Peck
Co-ordinator
Wiltshire Research Ethics Committee

This Research Ethics Committee is an advisory committee to South West Strategic Health Authority
The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England
Appendix A5-17: Case Study Report

Single Case Study Results and Discussion

(This has been taken from the final report to the Pharmacy Practice Research Trust on completion of the Galen Award, which supported this phase of the study).

Case Study 1: Mr and Mrs Black

In total five interviews comprised this case study with three involving Mr George and Mrs Mildred Black, one with John the psychologist involved with the psychological assessment and one with the consultant in charge of the diagnosis and decision to prescribe, Dr North. Although it had been planned to observe the follow-up consultation in August 2007 this had not been possible due to unforeseen circumstances.

In total there were 69 themes from the interviews with Mr & Mrs Black, but these settled into three superordinate themes; Living with a Memory Problem, Relationship Dynamics and Interacting with Healthcare Professionals. The main theme was living with a memory problem and the resultant effect and affects this had on day to day life and relationships and how this had been tempered in some way by his interaction with healthcare professionals.

“my memory has always been very good, I have trained my memory, I mean my memory was like, well my brain was like a computer. I would log it file it, put it in a folder and then I could access it anytime I wanted.”

George

Mr Black spoke of his increasing frustration with his memory loss for short term events. He found this particularly frustrating as he had prided himself as having a great memory and had in fact taken over the role of being the knowledge font in the relationship.

“that is when it really gets frustrating when things, when I am told about things and I hope to me, it has never happened I have never said it, never done it, no one has done it for me or given it to me or said it to me you know I thought black was black and white was white and now I am not sure, now I am not sure at all.”

George

“I like him to be very good with his memory and I don’t like him being stressed over it I don’t mind having to help and doing my bit that don’t bother me. I just sometimes do worry about him when he really do forget something and I and thinking how can he forgotten something so important that bit worries me you know.”

Mildred

Mildred described him as having a “brilliant, brilliant memory” which was not like hers where she typically could not remember peoples’ names. This lack of short term memory was described by George as being as if “it had never happened or never been said” and had resulted in many arguments with his wife which had culminated with her threatening to leave because of his aggressive response. These aggressive interactions also occurred with other family members and it
wasn’t until one of his sons “pulled me up on it” that he realised he had become “a nasty person.”

“It has caused us major problems you know we have had arguments, it gets her stressed you know… I told her to be bloody blunt about it, excuse my expression……I tell my boys if I am out of order tell me because sometimes I do get out of order because frustration again that is what it is. I am not normally a nasty person you know I don’t normally bite the boys head off but I have been and the boys have told me one of my sons he took me aside and said ‘that was out of order Dad.’”

George, Interview One

At this point he had gone back to his GP and after a period of about six months wait received an outpatient appointment to be assessed at the local memory clinic. Just the process of admitting that there may be something wrong and then being assessed resulted in George and Mildred accepting that there was actually something wrong with his memory and they both had to come to some agreement on how this would be managed. George had had a heart bypass nearly two years previously and he had been told that some people experience some short term memory loss. However, for him it seemed to be getting worse and it also challenged his own self identity as the ‘memory bank’ of the relationship.

“My memory has always been very good, I have trained my memory, I mean my memory was like, well my brain was like a computer. I would log it file it, put it in a folder and then I could access it anytime I wanted.”

George, Interview One

His psychological assessment showed that he had mild cognitive impairment and not a degenerative illness such as dementia, however up to 20% of people with MCI can go on to develop a dementia and for this reason he was to be followed up for a period of about 12 months by the memory clinic. He did not believe he was “going senile” and took comfort from this diagnosis that nothing was really wrong he just had a mild memory problem that may improve with time. This acceptance had a great effect on their relationship as described by Mildred below.

“If I have got to be really, really truthful this past month or so has been really, really good quality of life I don’t feel stressed I don’t feel on the edge that he is going to blow. I feel that I can get through a day and look forward to the next day and not get through a day and think ‘oh God what is tomorrow going to be like?’”

Mildred Interview One

Dr North expressed that he found it difficult that there was currently no treatment options available for people like George as he knew there was little supportive evidence for prescribing cholinesterase inhibitors for people like George. James thought it was a pity that they no longer had the resources to do the 10-week memory training educational interventions that they used to hold for people with MCI or early dementia. This was because they helped people develop the skills and resources to cope with a failing memory and also promote the use of memory exercises to improve cognitive functioning. George had purchased an educational video for training your memory which he found very helpful and he had also started to use techniques such as word association with a visual prompt in order to help him to remember names.
Change Over Time
George and Mildred remained in the study for ten months and over this time period his relationship with his wife improved. In joint interviews there was a decrease in the friction and frustration between them on subsequent visits and at the final interview they both seemed very happy with each other.

George had been practising memory training activities and he felt that his memory was starting to improve again and that more importantly it wasn’t getting worse. George’s original MMSE was 26 out of 30 using ‘serial sevens’ and 28 out of 30 using ‘world.’ In the MMSE there is an option where people are asked to subtract seven from 100 and repeat serially to as far as they can go without making a mistake. The other choice is to spell ‘world’ backwards. This latter option is to account for people who always had poor mathematical skills. 26 out of 30 is a ‘mild’ cognitive impairment whereas 27 and above are classified as ‘normal.’ This disparity demonstrates how a person’s prior knowledge or ability can affect the score achieved and perhaps bear no relation to their functional ability in day to day activities. At two years follow-up George scored 29 out of 30 on his MMSE.

Point of Reflexivity
There had been a planned observation of a follow-up consultation with Mr Black and his potential prescriber Dr X in August 2007. However prior to this appointment I was involved in a serious road traffic accident and I was on extended sick leave at the time. By the time that the project resumed the original prescriber had left the clinic and it was not possible to arrange another observation.

Case Study Two: Mr and Mrs Smith
There were three recorded interviews in total for this case study with two from Mr Harry and Mrs Joan Smith and one with Dr South the prescriber. There was also an observed consultation with Mr and Mrs Smith, their son-in-law and Dr South.

There were 31 themes arising from the transcribed data from these interviews and the following superordinate themes arose: Living with Dementia and Medicines for Dementia. For this couple it was becoming an increasing “struggle” living with dementia on a day to day basis and this they thought was exacerbated by the fact that Harry had been unable to tolerate Medicines for Dementia.

“I would say that the Aricept was one tablet that did sort of bring him out of himself more, you know because he is back in his shell and doesn’t say very much but that one did make Aricept it was wonderful tablet.”

Joan, Interview One

Although the local community hospital provided support for Harry in terms of helping him to wash and dress morning and night, they managed mostly on their own and with the help of two daughters who lived locally. They were both in their eighties and thought that this was a part and parcel of the ageing process. Harry expressed “we’re both no good” and Joan responded that you “Can’t expect much else for 85 can you really?”

They also spoke of their admiration and gratitude for the support and help that they had received from the NHS and local carer groups.
“They are very pleasant all their carers are lovely to him really nice. I’d be lost without them I would be I can’t cope every day, push around pull around you know.”

Joan Interview Two

They spoke of their disappointment of Harry not being able to tolerate the medicines for mild dementia and this was especially sad because for the three months he had tried to tolerate the diarrhoea associated with donepezil they had noticed some improvements with his memory and social interaction which disappeared on withdrawal. Harry had been prescribed a second cholinesterase inhibitor but the symptoms of diarrhoea and nausea appeared on the first dose and only two doses in total were taken.

Dr South did not believe in prescribing for side effects of medication as she thought that this was not good practice, especially in the older person.

“I personally feel you don’t want to keep on adding in, unless it’s like a life saving drug that they’re on you know obviously people who have a knee operations then they have to take anti emetics for it but not that, although you do get improvements in cognition.”

Dr South

However this also meant that there were no further pharmacological options for Harry at this time as memantine was only licensed for moderate dementia. At the observed consultation Mr Smith had deteriorate further according to the results of the various cognitive assessments that he had undertaken. This meant that he was now in the moderate stage of the illness and could be prescribed memantine if he and his wife thought this was the best way forward.

Change over Time

Harry remained in the study for 10 months and he became more conversant with the researcher over time, but this was probably due more to increasing familiarity than any other reason. He had tried two cholinesterase inhibitors without being able to tolerate the side effects and both were anxious to try something else if possible because they recognised the beneficial response of the medication once it had been stopped. The course of his MMSE scores is depicted in Table Three next.

**Table Three: Clinic results for Mr Harry Smith**

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE Score (out of 30)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.04.06</td>
<td>17</td>
<td>Referred to memory clinic by GP. Short term memory problems-poor recall; gets muddled with names; difficulty with practical tasks. Full assessment done. Diagnosed probable Alzheimer’s disease, started donepezil</td>
</tr>
<tr>
<td>26.07.06</td>
<td>20</td>
<td>MMSE improved, memory not, diarrhoea a problem donepezil stopped</td>
</tr>
<tr>
<td>21.10.06</td>
<td>17</td>
<td></td>
</tr>
<tr>
<td>04.11.06</td>
<td>14</td>
<td></td>
</tr>
<tr>
<td>28.11.06</td>
<td>20</td>
<td>Confused and not recognising he is at home; start galantamine</td>
</tr>
<tr>
<td>30.11.06</td>
<td>19</td>
<td>Galantamine stopped after two doses because of diarrhoea</td>
</tr>
<tr>
<td>20.03.07</td>
<td>18.5</td>
<td></td>
</tr>
<tr>
<td>08.05.07</td>
<td>12</td>
<td>Increasing memory problems, lack of motivation and poor initiation and conversation. Memantine started</td>
</tr>
</tbody>
</table>
The results demonstrate the fluctuations in cognitive functioning that may be seen on a day to day basis. A three point increase was seen in response to donepezil but the side effect of three months of continual diarrhoea was seen to outweigh its benefit. It also shows deterioration over time in the general overall cognitive functioning for Harry. This was also reflected in his physical mobility.

**Observed Consultation Mr and Mrs Smith**
This consultation took place on the 11th April 2007 in a small community hospital memory clinic. Mr and Mrs Smith and Dr South all gave informed written consent for the consultation to be observed.

At the start of the consultation the prescriber came out into the waiting area and greeted Mr and Mrs Smith and was introduced to their son-in-law. Mr Smith then went though to another room on is own with a psychologist who performed the neuropsychiatric assessments. While this was taking place Dr South met with Mrs Smith and their son-in-law and discussed the current status of Mr Smith in terms of cognitive functioning and activities of daily living. The set up of the room was quite informal, with Dr South sat to the side of a desk and Mrs Smith opposite her and her son-in-law across from her all facing each other. The researcher sat out of their visual range behind the carer and her son-in-law.

Dr South opened the consultation by asking how her husband was and she responded that his walking was much worse and his legs were very painful and that he now needed to use a wheelchair to get around in the house. The prescriber then asked how he had been apart from his physical health. Mrs Smith explained that “today’s not quite so good, he has his days” and went on to give an example of how good his long term memory was when he helped the driver from the Alzheimer’s society find his way back to the town centre. However she went on to say that “when he was taking Aricept he was much better. That was a really good drug that was.” At this point the son-in-law interrupted with his reading about a new medication that might help Mr Smith and there was a discussion period where Dr South put the research into context for them with other results from clinical studies. She then went on to explain that there was one option that she could try with Mr Smith but that it was only licensed for moderate to severe disease and she was unsure if this was Mr Smith but that she “could probably get away with it” in terms of prescribing. The prescriber then explored his daily activities and noted he still enjoyed reading his paper and football and motor racing n the television but did tend to get bored.

When asked what Mrs Smith found the most difficult in caring for him she replied “If I want him to do anything he needs to be told what to do and to do it he needs a lot of prompting and encouragement.” Dr South then said she would see how Mr Smith did on his memory tests but thought that memantine could be an option for him as it may help “with him taking more initiative.” She then explained briefly about the low risk of side effects and how there was a need to titrate the dose carefully up to the full dose. The process was quite complicated and Dr South got confused in explaining the titration regimen.

At this point Mr Smith joined the consultation and he had not performed very well on the memory tests scoring 13/20 on the MMSE (moderate dementia). She welcomed him to the consultation and asked him how he had been getting on with things to which he replied “It’s one of those sort of things you got to remember
things." When she asked how he was in himself he replied that there was “no sense in being miserable” and that he felt that “some people made it worse for themselves than is necessary.” At this point she asked Mr Smith if he would be prepared to try another tablet to help his dementia that it “was pretty well tolerated and might help.” He responded “Yep, I’m game for anything” and that he didn’t “mind taking a few more.”

Dr South then explained the dosing schedule again and advised them that she would give them a six week prescription and that they should see an improvement by week four and that she would see them again in clinic in four months time. She emphasised that they must let her know if there were side effects and that she would like to know how they got on with them. She then asked if there was “anything else you want to ask me at the moment?” and finally produced a written instruction for the medication dosing schedule at their request. She then bade them goodbye and escorted them to the waiting room.

Throughout the consultation the prescriber held a relaxed posture, using open body language and encouraging empathy and rapport by nodding her head and making verbal acknowledgements (mmm, yes) of any responses. Dr South opened the consultation well to establish rapport; asked appropriate questions to determine what the underlying wants of the participants were, involved Mr and Mrs Smith in the decision making process and then summed up the consultation and provided a written reminder.

After the consultation Dr South shared her thoughts on how it had gone; being very annoyed with herself for confusing the carer about the dosing schedule. She also confided that it was almost good that Mr Smith had had a bad day because he then produced a score which supported her clinical decision to prescribe memantine and this could be used as justification on cost grounds if challenged at a later time.

Case Study Three: Mr and Mrs Jones
There were four recorded interviews in total; three with Mr Robert and Mrs Judy Jones and one with his prescriber Dr West. There was no home support involved. There was also one observed consultation with Mr and Mrs Jones and Dr West. Mr and Mrs Jones were also the only participants who agreed to keep a diary between interview one and interview two recording their thoughts on response to treatment.
There were 66 themes arising from the interviews with Robert and Judy and these settled into four superordinate themes: Living with Dementia. Relationship Dynamics; Interacting with Healthcare Professionals and Medicines for Dementia. The distress of living with dementia had resulted in changes within their relationship which were becoming increasingly intolerable for Mrs Jones. Interaction with Healthcare Professionals resulted in Mr Jones being prescribed a medicine for dementia which had helped to ease the friction within their relationship and his relationship with his grandchildren.

“ It affects every part of your life because we go, I go to to the little ones, they come over here and he’ll be quiet and not join in with the little grandson and I’d say “well why?” and he’d say “I don’t know why” and then he said “let’s go out for a meal” and I said “what’s the point of going out for
a meal if you’re going to sit there and not speak all through the meal.”

Judy, Interview One

Mr Jones had become increasingly quiet and withdrawn over the previous 12 to 18 months and forgetful about recent events and conversation. This had resulted in a serious blow to their relationship with both parties becoming increasingly frustrated with the situation and an increase in severity and frequency of arguments. Over the time of the study this became less of a problem as Mr Jones became able to increasingly participate in conversations; family events and the environment around him on the prescribing of rivastigmine. He described the medication as “I would say I think the presence they’ve given me have brought me back into the world really.”

The following excerpt from interview two illustrates this positive response on improved socialisation very well.

Robert: “I married a good lady, my mentor, that’s all I live for really plus the family. Whilst I’ve been in this state er I’ll admit I haven’t felt right, don’t know why just something that happens and er you sit and you think, but you want to put it all in little boxes and I’m gratified that I’ve now got to this stage with the help of good lady.”

Judy: “It had got to the stage where we weren’t going out because I mean it was too embarrassing to go and sort of sit he’d sit there and not speak.”

Robert: “We’d go and have a meal in the pub and I’d just sit there and have a meal and I wouldn’t say a word.”

Judy: “And got to the point saying shall we go home?”

Robert: “So I get a nudge to say ‘eh are you talking’. Pardon you know and I’d think why is she saying that but reality eventually comes back to me and sort of says, get switched on.” (now after the medication)

However this then resulted in dissatisfaction with interactions with healthcare professionals as the delay in being prescribed the effective medication was perceived as a loss of 12 months and damage to their relationship and Mr Jones’s cognitive health.

“If he could have gone on these instead of the antidepressants straight away he would have, we just feel as though we’ve had 12 months taken away you know which could have been avoided with if these tablets had been prescribed sooner. I suppose they have to go, eliminate certain things but um I think they really make a difference.”

Judy Interview One

The medication was seen as the reason for the return of the former Mr Jones in terms of interest in daily activities and social interaction. His short term memory remained poor but they developed systems of supporting this in terms of increased use of calendars and prompt lists. A continuing area of concern for Judy was how to increase the mental stimulation of her husband in order to help preserve what
cognitive function he had. This conflicted with Robert who had always been a practical man keen on gardening and DIY activities around the house and resulted in frequent heated discussions on the types of activities that he should engage with. The following excerpt from Interview One was part of a heated discussion on this subject.

Judy: “But you’re not stimulating your brain doing that. That’s what I think, ok you’ll read the paper but you won’t read a book”

Robert: “No I’ve never sat long enough to read a book”

Judy: “But you could do now.”

Robert: “Right, yes but invariably if I do that I’ll fall asleep.”

This was solved somewhat by Mr Jones taking up bowls again at the local club and receiving social stimulation from this group.

**Diary Recordings**

These were written by Mrs Jones who made a list after the first interview about the symptoms she had noticed her husband displaying. The day before the second interview she made a list of things that had changed. These are displayed in the table below.

**Table Four: Diary Notes by Mrs Judy Jones**

<table>
<thead>
<tr>
<th>Symptoms Noted after First Interview</th>
<th>Improvement Since taking Exelon</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of conversation</td>
<td>Went to hotel with relatives over New Year and held conversations at table over meals</td>
</tr>
<tr>
<td>Quietness</td>
<td></td>
</tr>
<tr>
<td>Wanting to sit quietly</td>
<td>Repaired water barrel pump which has been broken for over a year</td>
</tr>
<tr>
<td>Not going to bowling club</td>
<td>Has shown interest in starting to play bowls again next season</td>
</tr>
<tr>
<td>Aggressiveness</td>
<td></td>
</tr>
<tr>
<td>Stopped gardening</td>
<td>Has mowed the lawn and done some gardening. Has raked the path</td>
</tr>
<tr>
<td>Can’t have a discussion without arguing</td>
<td></td>
</tr>
<tr>
<td>Doesn’t join in conversations with friends &amp; family prefers to sit quietly</td>
<td>Makes more effort talking with family</td>
</tr>
<tr>
<td>No conversation on a car journey</td>
<td></td>
</tr>
<tr>
<td>No interest in money/family/finances etc</td>
<td></td>
</tr>
<tr>
<td>Doesn’t play with grandson (age 2)</td>
<td>Now plays with two grandsons</td>
</tr>
<tr>
<td>Bad memory of recent things</td>
<td></td>
</tr>
<tr>
<td>Keeps raking up the past</td>
<td>Visited Coventry cathedral and went shopping</td>
</tr>
</tbody>
</table>

These were not tabulated or linked together as a before and after by Judy; but presenting in a tabular format demonstrates clearly the improvements in sociability; initiative and self motivation which were lacking prior to taking the medication.

**Change over Time**

Robert and Judy remained in the study for 13 months and over the course of this time there was great improvement in Mr Jones’s sociability; interaction with friends and family and motivation and initiative in task completion. They had had several
holidays and trips away with each other and had enjoyed these increasingly over
time. Robert’s short term memory was still poor and they developed a system of
prompts to support this but this was outweighed by he benefits to their relationship
that the sociability and increased initiative brought.
Te comparison of findings from the interviews and information from the medical
notes can be found in the table below.

Table Five: Clinic Results for Mr Robert Jones

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE (out of 30)</th>
<th>Comments in Record</th>
</tr>
</thead>
<tbody>
<tr>
<td>01.11.06</td>
<td>DEMTEC low score (7);</td>
<td>Dementia diagnosed; loss in memory domain (concentration, short term memory &amp; executive function). Off license use of cholinesterase inhibitor</td>
</tr>
<tr>
<td>05.04.07</td>
<td>DEMTEC 9</td>
<td>Cognitive testing improved significantly, slowness in processing &amp; short term memory. Motivation and socialisation improved</td>
</tr>
<tr>
<td>15.09.07</td>
<td>26</td>
<td>Wife depressed about her increasing duties e.g. organising builders</td>
</tr>
<tr>
<td>17.01.08</td>
<td>26</td>
<td>Deficits in orientation and recall. Wife prompts tasks by using lists. Suggest increase in dose to 4.5mg twice daily</td>
</tr>
</tbody>
</table>

Robert was originally assessed in the regional memory research centre and they
prefer the use of DEMTEC and other tests. After the initiation of rivastigmine Mr
Jones improved on his cognitive functioning and his later assessments with the
MMSE indicate a ‘mild’ stage of the illness. Although a dose increase was
suggested b the prescriber they declined as they thought everything was going the
right way on the lower dose. It had not been explained that the higher dose can
actually result in greater improvements in function. They were going to request an
increase at the next consultation.

**Observed Consultation: Mr and Mrs Jones**
The consultation took place in a small room at the memory clinic of location three
on the 5th April 2007. Dr West walked out to the general waiting area and greeted
the couple before ascertaining once again whether they were still in agreement
about the consultation being observed. All participants gave informed written
consent. He then led Mr ad Mrs Jones down a long corridor to the consultation
room, where he sat side onto a desk and the couple sat side by side in front of
him. He was quite formal in his approach “How are you sir?” But there was an
obvious rapport with Mr and Mrs Jones. He went through Mr Jones’s recent head
injury from a fall and his latest medication and then asked Mr Jones “How do you
feel in yourself?” Mr Jones explained that previously he had a “lack of drive,
motivation or get up and go” but that “I’ve overcome that…been mowing the lawn
today.” On talking to Mrs Jones Dr West established that he was socialising better
and that his memory was a day to day problem with Mr Jones explaining that he
“felt better than others on some days” and that word finding was a problem.

D West then did a SET and the TE4D COG test which aim to test short term
memory, orientation, co-ordination and problem solving using lists of common
objects and numbers. Although his response was not very good it was better than
four months previously to which Mr Jones responded that it was “not as good as
what I want it to be.”

317
The prescriber was very honest and direct at this point saying “my own feeling is that you’ve shown some response but it’s like you’re half way there.” He continued “the picture I’ve got of you in my mind is that you’re on auto pilot. You’re good but under the surface there’s holes. I feel there is room for improvement.”

Following this was an explanation to Robert and Judy on how the damage by the stroke had affected his speech a little and his speed of processing information. This explanation seemed to encourage them both.

He then asked them how the medication was going and what dose they were currently on. Mr Jones replied that he took 3mg once a day as directed on the label and that before that he had taken 1.5mg twice a day. This was described as a “cock up bluntly” by Dr South as he should be taking 3mg twice daily. There then followed an explanation of the new schedule and the issue of a new prescription so that Mr Jones took 3mg each morning and 1.5mg at night for two weeks before increasing to 3mg twice daily. He emphasised that he should stay on this until he saw them again in six weeks time when he would like to increase the dose again to 4.5mg twice daily.

At this point the consultation was brought to a close and the couple were escorted out of the clinic to the main reception area. At all times Dr West was polite but also very honest with the couple about his thoughts. Although he directed most of the questions to Mr Jones he also sought Mrs Jones’s qualification of what was said.

After the consultation the prescriber shared his feelings on the medication error and that the highest dose would be most appropriate if it could be tolerated by Mr Jones. He then went on to explain that he had used more searching tests than is usually required because he was prescribing rivastigmine off license for vascular dementia. He therefore felt that he had to justify Mr Jones staying on the medication by demonstrating objective improvement at each follow-up consultation.

Case Study Four: Mr and Mrs White
There were five recorded interviews in total; three with Mr David and Mrs Annabel White, one with his prescriber Dr West and one with Mary the community psychiatric nurse who visited every 3 months in order to monitor the effects of the medication. Mr White was on a combined prescription of rivastigmine as well as memantine. There was also an observed consultation with Mr and Mrs White and Dr West.

In total there were 65 themes emerging from the data but these settled into three superordinate themes: Living with Dementia; Medicines for Dementia and Relationship Dynamics. Mr and Mrs White had been living with dementia since his diagnosis in 2003 and medicines for dementia had enabled them to continue to interact with society and also consolidate their relationships with each other.

Prior to medication Mr White explained how things had been for him.

“I felt very frustrated and as my wife says I used to be quite keen at do it yourself, after that I couldn’t have tackled a job at all I would just sit and
look at it and think’ well what on earth am I meant to be doing?’ Frustration
more than anything really and as my wife said I got up and talked at the
camera club for 25 year’s; I would be half way through a sentence and I
would stop and think what on earth, I’d have no idea. I couldn’t go on.”
David Interview One

For Mr White there was an expressed dread of the prospect of nursing home care
and he felt that the medication was the main reason that he hadn’t deteriorated to
that particular stage of the illness.

“Well it’s affected me very well it’s made me think in a way how lucky I am.
I’ve got three friends one of them has developed a (mumbled) they all
moved into a home recently they are all our age with the same problem and
they won’t come out again. I think to myself how lucky I am that I am not in
a home. How long it will last I don’t know but I hope it continues.”
David Interview One

Although David was at the mild to moderate stage of the illness and also suffered
from continuing strokes, they received no extra home help and Annabel coped
with her husband on her own. She strongly believed in the powers of motivation
and being organised and David had a weekly schedule to ensure he also engaged
with external activities such as his art club and his camera club.

“When you are looking after somebody in this situation and you are not
experienced in it you do what you think is the right thing and I talk over with
Mary or when Doctor West comes and they haven’t yet told me ‘you know
you shouldn’t be doing that or the other and so we keep going and with me
rather driving is a too strong a word but motivating Peter I think is better and
if I find that he’s going down a little bit and a bit lethargic then I try to give
him something else to concentrate on. And I personally think the
combination of the drugs and that and how I contend with things works”
Annabel Interview One

They lived in a residential park and the organisers of the local newsletter relied on
David to deliver any mailings and he was supported in this by other residents who
called his wife if he stayed for a cup of tea or a rest. The medication was perceived
as being a great help in his socialising activities and he was able to converse with
other parties when they went out on social events. He also suffered from hearing
difficulties and found this also affected his communication in a different way from
the dementia. Their sons visited regularly and organised joint holidays to ensure
that Annabel gets a break as well.

David had been co-prescribed memantine when Dr West had decided he had
“fallen of the plateau” induced but he cholinesterase inhibitor rivastigmine that he
had been taking. They had noticed an increase in social withdrawal, memory
problems, speech and lethargy. With the addition of the memantine all of these
areas improved; in fact David appeared on local television and in local
newspapers talking about how the medicines had improved his daily activities and
quality of life. He was also able to continue to give small talks at his local camera
club without forgetting what he was talking about. He was a very keen proponent
of medicines for dementia and spoke about articles he had read in the newspapers
at two of the interviews. In the second one he was trying to make sense of why the
government said there was not enough money to fund the medicines when they seemed to be wasting it else where.

“What I find is so bad that and er you’re, bureaucracy gone mad really. I have two hearing aids and they supply all the batteries, now they’re expensive batteries and I only have to send off a pack of used ones and they’ll send me back a brand new pack. Why don’t they charge for it, they say they’ve got no money and yet they’re giving them away? …Ridiculous. They’re not organised with things like that and somebody said “it would cost too much to collect.” David, Interview Two

However over the course of the study David experienced a further mini stroke and an admission to hospital with a severe infection, the later of which was in January 2008 and he became increasingly tired and frail over this time. He also expressed a fear that “the Alzheimer’s was creeping in” which also left him with periods during the day when he felt fuzzy headed and unable to communicate or think properly. Both Dr West and Mary were very supportive of David and the progress he had made on the co-prescription of medicines for dementia but knew that the inevitable would have to be faced at some time and that David would fall off his plateau once more and there would be very little they could to in order to help him. And at this point the memantine would probably be withdrawn. Mary described her feelings when a decision was made to withdraw medication in people that she cared for.

“You always feel sad if somebody is coming towards the end of life of mobility and so forth because you know in her situation the history is all around the photographs are all around her, her family, it’s quite sad that you feel as if you can’t do anymore and so on.” Mary, CPN

Over the Course of the Study
David and Annabel remained in the study for 13months. David was a highly intelligent man who struggled with the longer term consequences of the illness. His wife was a devotee to motivation and timetabled activities which stimulated him mentally and physically. There seemed no doubt that this was an effective supporting structure. Just prior to interview two he had experienced a minor stroke and seemed a bit quieter than the first interview but he conversed about recent articles in the newspaper and where they had been with friends. Unfortunately just before the third interview he had a hospital admission for a serious infection and he was very much quieter at this interview and said how he felt that the “Alzheimer’s was increasing.” At this interview his wife was obviously worried and concerned and she used it as more of a session to speak to someone about her concerns. We eventually agreed that he may need an extended period of rehabilitation before he got back into his stride.

Mary who came to assess is cognitive functioning regularly had helped Mr and Mrs White to agree a set of target symptoms that they hoped the medication would improve over time. These are outlined in the table below.

Table Six: Monitoring Target Symptoms for Mr & Mrs White

<table>
<thead>
<tr>
<th>Target Symptoms</th>
<th>06.12.06</th>
<th>19.12.06</th>
<th>19.02.07</th>
<th>04.09.07</th>
<th>05.10.07</th>
</tr>
</thead>
<tbody>
<tr>
<td>Confidence</td>
<td>Some</td>
<td>Improving</td>
<td>No change</td>
<td>decreased</td>
<td>No change</td>
</tr>
<tr>
<td>Visual</td>
<td>After</td>
<td>No</td>
<td>Decreased</td>
<td>Two</td>
<td>Decreased</td>
</tr>
</tbody>
</table>

320
Table Seven: Clinic Results for Mr David White

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE (out of 30)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.04.03</td>
<td></td>
<td>Alzheimer’s disease diagnosed; rivastigmine started</td>
</tr>
<tr>
<td>February 2005</td>
<td>29</td>
<td>Rivastigmine 6mg twice daily</td>
</tr>
<tr>
<td>16.02.05</td>
<td>27</td>
<td>Memantine introduced</td>
</tr>
<tr>
<td>16.12.06</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>19.12.06</td>
<td>30</td>
<td></td>
</tr>
<tr>
<td>19.02.07</td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>04.09.07</td>
<td>29</td>
<td>NB Consultant left at this point, no follow-up</td>
</tr>
<tr>
<td>13.02.08</td>
<td></td>
<td>Nocturnal agitation clonazepam prescribed. Gradual decline in memory, word</td>
</tr>
<tr>
<td></td>
<td></td>
<td>finding difficulties</td>
</tr>
<tr>
<td>08.05.08</td>
<td></td>
<td>Gradual deterioration over last 2 months; slower and lower in mood. Adm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>its to being depressed as can’t get on top of pain. Sleeps well, good a</td>
</tr>
<tr>
<td></td>
<td></td>
<td>ppetite</td>
</tr>
</tbody>
</table>

In the above table, the MMSE scores indicate a mild stage of dementia, however functionally and cognitively David thought the dementia was increasing. Again the MMSE seemed not to reflect the true nature of the individuals cognitive functioning.

**Observed Consultation: Mr and Mrs White**

This consultation took place at location three and on the same day (5th April 2007) and with the same prescribers described in case study three above. Again Dr West went to the waiting area to greet the couple and again confirmed that they agreed to my presence in the consultation and showed them into the room with the same layout as described above. Dr West spoke slowly and clearly as Mr White had a hearing problem and wore two hearing aids. Mr White had recently been visited by Mary who completed his quarterly cognitive assessments and he scored very well attaining 27/30 on the MMSE. (Indicative of a very mild stage). Mr White and his wife were dressed smartly; with Mr W wearing a shirt, tie and jacket.

The opening narrative was “I’ve had a nice report from the CPN about your assessment in February, how are you sir?” At this point Mr White was more concerned about the increasing pain in his legs more than anything else and this was responded to by the prescriber explaining that he just needed to take the “pain killers” regularly as he had only been taking them when he needed them.

At this point the consultation seemingly became much less structured than the previous one with Dr West asking Mr White what he had been doing recently and what activities he had completed. Mr White began talking about their fish pond which he had been cleaning and also looking after the fish and there was some discussion about this. The prescriber explained afterwards that by asking about activities and how they have been done a clinician can get a better impression of
how they are functioning at a higher level as they bring things into the conversation, respond to questions and formulate sentences. It also demonstrated that his speech had clearly improved (this had been a major effect of the disease for Mr White).

Mr White then went on to explain how they had been cleaning all the brasses in the front room while listening to a trilogy of CDs and he found that he could remember all the words but he had recently experienced “loss of memory in blocks” and he found this difficult to understand. An explanation of the differences in how short term and long term memories were laid down followed. The difference being that in short term memory if there was a lack of full attention or concentration then the information may never enter the memory pathway, just going straight in and straight out again whereas in long term memory there is often repetition (for example you sing along to a song and this reinforces the content) or an emotional content which enables it to be recalled more clearly.

Dr West then went on to ask Mrs White how things were and she replied that they were “coping well with things during the day” and that he was “socialising very much more at ease.” Dr West then completed activities of daily living assessment first asking Mr White what he could do and then confirming this with his wife. Mr White no longer read very much because he fell asleep; and he didn’t write much because the writing just peters out at the end of a sentence.

Dr South then asked him if he was still “seeing things that were not there” and he replied that he did but they “were brief and rare.” He sometimes saw a cat or “the girl from the Wizard of Oz.” As they were not causing him or his wife any distress and they were infrequent, no other intervention was thought to be necessary.

The consultation was drawn to a close by Dr West asking Mr White how he thought he was doing. Mr White replied “pretty well. If my legs were better I’d feel a 100% better I’m sure.” Dr West then said that he thought Mr White was “doing brilliantly; technically in the mild stages.” He then seemed to qualify this statement by adding “I’m not saying everything is good and perfect; I think it’s brilliant. All down to you.” This last statement also seemed to acknowledge the role of the activities schedule that Mrs White used to keep her husband active and mentally stimulated. The interview closed with farewells and the couple being escorted to the waiting room.

After the interview Dr West emphasised how well Mr White was doing because of the co-prescribing of memantine with rivastigmine and still felt clinically that both were warranted. Once there was no sign of benefit then the memantine would be withdrawn.

Case Study Five: Mr and Mrs Green
This case study composed of Mr Chris and Mrs Vicky Green, and his prescriber Dr East. Originally there had been a community psychiatric nurse assigned to their case (who also consented to take part in the study) but after her first visit the Green’s decided they did not need anyone coming to their home. The data set included four interviews; three with Mr and Mrs Green and one with Dr East.

There were 61 themes arising from the data and these fell into four superordinate themes: Living with Dementia; Relationship Dynamics; Medicines for Dementia
and Interacting with Healthcare Professionals. Chris had been being assessed for memory problems for some time and had received a diagnosis of mild cognitive impairment. However he then suffered a major cerebral haemorrhage which worsened his cognitive functioning such that his score on the MMSE was congruent with a diagnosis of Alzheimer’s disease.

“First of all which would be about a year ago or more, two years ago when I started having to say things twice. I got terribly annoyed about that ‘I just told you that’. Then of course I understood so that I can’t really say how far back whether it was 18 months or 2 years. So to me it’s not just memory really”.  

Vicky, Interview One

There was a long history of interacting with healthcare professionals whilst living with dementia before a medicine for dementia was prescribed. This had led to some conflict within their relationship of which they were both very guarded. Chris said he worried about his wife because she had no children and would be on her own when he went and she worried that her husband confabulated and this would not be recognised. She refused however to be interviewed on her own as she saw this as a betrayal of her husband. Dr East commented that “the couple shared a special relationship and one gets the impression that one would be lost without the other.”

The Green’s lived in a rural area and relied on Vicky’s ability to drive them anywhere in terms of household related tasks and social outings. Chris felt angry that his license had been taken from him and this settled only slightly when on assessment at a DVLA centre he was taken outside in preparation for a driving assessment and he could not read a car number plate at the appropriate distance. He suffered from macular degeneration and was already functionally blind in one eye and the other deteriorated over the course of the study. Chris seemed quite insecure at times and generally always confirmed what he was saying with his wife. When asked how he felt before the medication began he said “sometimes or another I just don’t know where I am and that does annoy me intensely. That’s right isn’t it?” (to wife)

Both Mr and Mrs Green found it difficult to say exactly how the medication helped at the start of treatment because Mrs Green’s abilities fluctuated so much from day to day and in response to stimulus.

Mrs Green: “I’ve been trying to see if I can make any constructive points on that score but I can’t honestly. If I had more knowledge myself I might find subtle differences but in everyday life, I mean recently when (Mrs Greens’ brother) came for Christmas you were marvellous weren’t you? Laughing and remembering things and chatting about things”

Mr Green: “Yes, this is the stupidity of it all.”

Mrs Green: “It depends on the stimulus he’s given.”

Excerpt Interview One

Vicky found it very difficult to find activities to engage her husband who preferred to live in the past telling stories about the days he was in the Navy and later as a leading dam building engineer, or on his cricket or golf playing career. She felt that
what he needed was the stimulation of male company as this seemed to enable him to engage more with his external environment. During the summer month this was augmented by people from the local golf club including him in their weekly activities. Chris explained “I’m quite pleased about it. I can get round quite happily and it’s important.” (Interview two). The long winter months seemed a problem to find other activities to do together other than dominos and listening to old records.

“The last what couple of months you’ve been brilliant you’ve been far (laughs) more able to say what you want to say. You’re going to play golf tomorrow he’s got a new golf trolley so you’re going to use it for the first time”. Vicky Interview Two

They experienced an increasing social isolation as previous friends stopped calling once the diagnosis had been made. This was exacerbated by a conflict between Mr Green’s children from his first marriage (now in their late fifties) who had not forgiven their father for remarrying 12 years after his first wife died. They refused to come to the house in case they had to have contact with Vicky and even refused to meet at a neutral place where she wouldn’t be present. He spent many hours ruminating on this conflict and worrying about the future of his children and his second wife.

“I have a problem is that my children which are all very good but they don’t have anything to do with Sue…. Well it makes me sad because they are very good children and we looked after, I looked after almost most of all of them when they were young. It is a funny place, funny place but what can you do, I try to keep going” Chris Interview Three

The medication was seen as enabling Chris to “get on with things” more effectively and his wife thought that they were working but couldn’t really say how. He said he was more engaged with her and tasks about the house even though his memory hadn’t seemed to change very much.

“There down in the garden I have been doing all those things down there, building up those things there. Keeping myself going all the time, but there we are, she works very hard, she does look after me Felicity, we have a good laugh at times.” Chris Interview Three

**Over the Course of the Study**

Chris and Vicky remained in the study for 13 months and over this time there was an improvement in their relationship with less anxiety and irritation displayed by Vicky in interviews two and three. Chris was increasingly able to participate in tasks and activities such as golf and gardening but his deteriorating eyesight hindered his enjoyment of television and reading.

**Table Eight: Clinic results for Mr Chris Green**

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE (out of 30)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>06.06.06</td>
<td>18</td>
<td>Diagnosed with Alzheimer’s disease (early stage). Short term memory problems, muddled with dates; function greater than MMSE</td>
</tr>
<tr>
<td>Date</td>
<td>Event</td>
<td></td>
</tr>
<tr>
<td>-----------</td>
<td>----------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>01.09.06</td>
<td>Started galantamine XL 8mg once daily, to increase to 16mg once daily after two weeks</td>
<td></td>
</tr>
<tr>
<td>30.11.06</td>
<td>Recruited to study</td>
<td></td>
</tr>
<tr>
<td>11.11.06</td>
<td>Letter sent to prescriber saying that she couldn’t talk in front of her husband as it would be unkind. Previously he was nervous anxious and highly strung; covering his memory problems by bluff and exaggeration</td>
<td></td>
</tr>
<tr>
<td>03.05.07</td>
<td>Memory stable since last appointment, better since on medication, better activities of daily living</td>
<td></td>
</tr>
<tr>
<td>August 2007</td>
<td>Prescriber left and no follow-up</td>
<td></td>
</tr>
<tr>
<td>06.06.08</td>
<td>20 MMSE unremarkable, repetitive speech and obvious cognitive impairment</td>
<td></td>
</tr>
</tbody>
</table>

Again the results demonstrate that functionally Mr P operates at a higher level than his MMSE score might predict, and how the los of a prescriber can mean reduced patient follow-up.

**Observed Consultation: Mr and Mrs Green**

This interview occurred in location three a described previously but on the 3rd May 2007 and was led by Dr East. Dr East was the Senior House Officer for the memory clinic and it was going to be the first time that he met Mr and Mrs Green. Dr East went to the waiting room and introduced himself to the couple and then confirmed with them again whether they were happy for the consultation to be observed. Informed consent was given by all attending.

Once in the consultation room (with the same layout as above) he introduced himself again and then apologised that he had an accent that was “a bit fast” and that he would try to slow down and speak more clearly but they should ask if they needed anything repeating. He sat in a chair facing the couple and was very relaxed with open body language. Mr Green was in a suit, shirt and tie and said that he “always felt it was appropriate to dress in tie and suit” for appointments. Mr Green seemed to be more engaged and ready to converse whereas Mrs Green seemed to me much quieter than on previous meetings.

Dr East asked Mr Green what his main problem was and he replied “I lose my memory very quickly; I don’t know whether I’m coming or going” but went on to say “I feel extremely well; playing a lot of golf.” Dr East explored this further establishing that Mr Green also found it difficult to express himself and that he got frustrated and sometimes a bit down by this. He then asked them both if they had noticed any difference since starting the medication. Mrs Green replied that “he’s been remarkably well with it, and able” but that “he does need someone there as back-up.” Mr Green then talked about his golf and cricket again and this was explored further by Dr East who asked him about recent televised games in order to further test recall.

The conversation then turned to his macular degeneration and loss of vision in one eye and poor vision in the other and the anger which followed the loss of his driving license. Dr East explained about insurance policies and then went on to say “to be honest you have someone [nodding to Vicky] to take you around wherever you want” which was not received very well by Mrs Green.
In time Dr East said to Mr Green “Can I ask you a few silly questions” who responded “by all means.” Then Dr Green completed the SET test but mid-way through Mr Green became increasingly anxious and Dr East stopped the test and said that if you are “anxious it makes your memory impaired” so he needed to try and relax in future.

He then asked if the couple “had any concerns on your side that had not been addressed.” Mrs Green wondered if there was a group for men that her husband could join for some added stimulus, but this was an unknown fact and it was agreed that it would be answered outside of the consultation. He then asked if they needed any help at home noting they had refused home visits from the CPN. Mrs Green responded “at the moment we don’t actually need anything; might come a time when there is” and so she would ask then. She then went on to explain “but we’ll need to know a person to get confidence in them” with her demeanour (very tight and quiet) suggesting that strangers were not welcome in their home. Dr East suggested that he or someone would ask them each time they came for follow-up just to make sure everything was alright still. This was agreeable to them both.

Dr East told them that “I will continue the same as I think it’s appropriate” and that he would make an appointment for them to be seen again in six months time. He reminded them of how to order a repeat prescription ad then closed the consultation and made his goodbyes.

Case Study Six: Mr and Mrs Johnson
This case study comprised of Mr John and Mrs Janet Johnson and his prescriber Dr West. There was no other healthcare professional involved as John had dismissed them as being “a waste of time.” There were only two interviews associated with this case; one with Mr and Mrs Johnson and one with Dr West. This was because John had been recruited to explore why people refuse medication when it has been offered, but once the interview had been arranged his wife had persuaded her husband that he should take a medicine for dementia and he had started on galantamine.

There were 59 themes arising from the data and these settled into: Living with Dementia; Relationship Dynamics: Medicines for Dementia and Interacting with Healthcare Professionals. Mr Johnson had been being assessed for cognitive impairment since 2000 when problems with his memory had first been noted by his family so again there was a long history of interacting with healthcare professionals. Living with a dementia had put strain on their and family relationships and his son had eventually persuaded Mrs Johnson to take a more active role in the prescribing of a medicine for dementia.

At first John’s memory problems were considered to be mild cognitive impairment and the chances of this developing into a dementia had been discussed with him. John had no intention of taking any medication that couldn’t be proved would benefit him and had previously objected to the prescribing of a medication. He had researched the area into memory problems and had found a possible relationship to memory loss and mercury dental fillings. He consequently had all his dental fillings replaced with non-mercury amalgates with no great results.

“The strong beliefs would have been I do want to take them if they are doing me good, I think it was just as plain as that for me on any subject, if it
is doing me good I am all for it and that’s it really I can’t elaborate on that because I mean it and if it weren’t doing me good I would be saying to him quickly here this stuff isn’t any good at all to me I am getting bloody worse!”

John, Interview One

John also became quite low and depressed and agreed to take an antidepressant which helped a great deal. He still however refused to accept that he had a memory problem as Mrs Johnson explains.

“John sometimes used to say his memory wasn’t what it used to be, but he also thought it was better than what it was at the same time. Where he used to if he couldn’t remember something and he was getting a bit crotchety because he couldn’t remember he said ‘my memory is not what it used to be’, then in a different context he would say ‘for my age my memory is very good isn’t it?’ I don’t think he realised how it really was.”

Janet Interview One

Janet admitted that she had not taken an active role because she was struggling with the implications of the future if a dementia was diagnosed. She was also struggling to keep on top of household activities and look after John on an increasingly closer basis. Her son, niece and sister came to help her cope with increased caring activities two to three days a week. Consequently she let her son deal with taking her husband to be assessed at the memory clinic for some years. It wasn’t until her son expressed his concerns to her that she decided that she would attend the next appointment with her husband.

Janet: “I don’t know why I didn’t like going in but somehow I, and I thought back, perhaps I didn’t want to accept (pause)”

Interviewer: “What it means?”

Janet: “I think that must have been why I didn’t, I went up to the hospital but (their son) always went in with him and I didn’t. But in December I thought right and I more or less begged for them and then Dr West said I am almost sure I will be able to get them for you. I know it’s not easy for him to get is it?”

At this appointment she was told that he had probable Alzheimer’s disease and she expressed that this then in some way made it easier for her to accept the behaviours of her husband as something outside of his control.

John had previously been a man “who lived for his work” and had only recently retired (some 5 years past real retirement age) and found it increasingly difficult to occupy his time, getting bored easily and becoming very anxious when his wife left him on his own at home while she continued in her social and household activities. He said that he had always been a person with “go go go go” and he found it difficult to calm his mind and had difficulty in sleeping. For this reason his GP had prescribed olanzapine which they both thought helped to calm him and also helped him to sleep and when Dr West had experimented with taking him off this medicine because of the risk of stroke they found other alternatives ineffective and requested to go back on a small dose.
They found the assessments required to be prescribed a medication very difficult to understand the concept of and this is illustrated in the excerpt below.

Janet: “When he first went up to Dr West and he had to do some drawings and things well he, what did you say to the lady there? He thought it was absolutely ridiculous what they asked him to do and he more or less told them as well, ‘what the hell have I got to do that for?’

John: “Well yes I think that would be me because some of these things, to be a free hand I am no good drawing what’s good drawing from bad ones and I never once, I never had the patience to be able to do good free hand drawings I would always get a wiggly line come somewhere and that …Don’t use them any more anyhow do they it is all, all electronic.”

Many of his close friends had died over the past few years “from heart attacks or cancer” and he found it increasingly difficult to know where to go to meet people. He said that it was exacerbated because he was very “straight” and this may not be acceptable to some and that he liked people with “a bit of punch.” He had been offered a place at the local health authority’s men’s group but was struggling to accept it because he dreaded large groups and what he might think about the people there.

“I am not, you know I would willingly go unless it is too far away and I might be no good at it at all because my patience can, can umm you know cause me to say ‘oh God what am I doing here?’ sort of thing.”

John, Interview One

**Over the Course of the Study**

After the first interview it was decided not to follow this gentleman up as he had already started medication, so in terms of the actual study he was signed up for about one month in total. His MMSE scores are depicted in the table below.

**Table Nine: Clinic Results for Mr John Johnson**

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE (out of 30)</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>12.04.00</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>08.06.06</td>
<td></td>
<td>Mild cognitive impairment diagnosed</td>
</tr>
<tr>
<td>14.12.06</td>
<td></td>
<td>Alzheimer’s disease with vascular component diagnosed</td>
</tr>
<tr>
<td>08.03.07</td>
<td>25</td>
<td>Bristol activities of daily living improved by two points and MMSE by one point. Wife more relaxed and willing to smile</td>
</tr>
<tr>
<td>19.06.07</td>
<td></td>
<td>Anxiety and tension decreasing, high level of memory, both smiling</td>
</tr>
<tr>
<td>14.06.08</td>
<td>23</td>
<td>Declining memory, irritability and low mood (when left on own); socialises and has return of good humour. Olanzapine 2.5mg for sleeping, citalopram for mood. MMSE loss in orientation and recall</td>
</tr>
</tbody>
</table>

**Case Study Seven: Mr and Mrs Smith**

On the 14th April 2007 at a follow-up consultation with their prescriber, Harry agreed to try memantine for his dementia. The couple had previously expressed a wish to try another medicine to see if that might help them cope. Because they
knew me they were happy to continue with the study but as new case where Mr Smith became a person with dementia taking memantine. A follow-up interview was arranged for the 19th June 2007 as by then they would have been able to titrate the mediation up to its most effective dose. With memantine the dose starts at one at night for one or two weeks increasing to two twice daily as a maximum. Because Harry had showed great sensitivity to cholinesterase inhibitors in terms of side effects it was decided to increase by one dose every fortnight to reduce the risk of adverse effects with memantine.

I was on my way to the interview when I was involved in a road traffic collision which resulted in an extended period of sick leave. Unfortunately by the time I was capable of returning to work-related activities Mr Smith had passed away and his wife no longer wished to take part in the study.

Information from his medical records indicated that he was “much brighter and responsive” and had agreed to attend a local Day Hospital in order to give his wife respite time once a week. He also started to respond better to the carers who helped him get washed and dressed each morning and those who came to get him ready for bed. Unfortunately Mr Smith developed a heart rhythm problem and became increasingly unwell. He was admitted to a District General Hospital where his physical health was stabilised and he was transferred to a rehabilitation unit in preparation for discharge. The afternoon of his multidisciplinary team meeting to plan discharge he became acutely unwell again and passed away. May he rest in peace.

Over the Course of the Study
This table demonstrates the general deterioration over time and how this is also reflected in physical activities and mobility.

Table Eleven: Clinic Results for Mr Harry Smith

<table>
<thead>
<tr>
<th>Date</th>
<th>MMSE Score (out of 30)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>08.05.07</td>
<td>12</td>
<td>Increasing memory problems, lack of motivation and poor initiation and conversation. Memantine started</td>
</tr>
<tr>
<td>18.05.09</td>
<td></td>
<td>Started Day Hospital for stimulation and respite for wife</td>
</tr>
<tr>
<td>22.05.07</td>
<td></td>
<td>Mr H well, no further mobility issues at present</td>
</tr>
<tr>
<td>05.06.07</td>
<td></td>
<td>Happy with care at present</td>
</tr>
<tr>
<td>13.07.07</td>
<td></td>
<td>Increasing pain in legs and difficulty with mobilising and transferring (e.g. from bed to chair)</td>
</tr>
<tr>
<td>23.07.07</td>
<td></td>
<td>Mobility and transfer assessment and training completed,</td>
</tr>
<tr>
<td>31.07.07</td>
<td></td>
<td>Transferred improved, now has electric wheelchair which he copes with well.</td>
</tr>
<tr>
<td>21.08.07</td>
<td></td>
<td>New problem, Mr H refusing to respond to requests</td>
</tr>
<tr>
<td>06.09.07</td>
<td></td>
<td>Admitted DGH with cardiac problems</td>
</tr>
<tr>
<td>03.10.07</td>
<td></td>
<td>Medically fit for discharge</td>
</tr>
<tr>
<td>15.10.07</td>
<td></td>
<td>Suddenly unwell, RIP</td>
</tr>
</tbody>
</table>

No further memory assessments completed

The Prescribers
In total there were four prescribers with Dr West being common to three case studies. Because of the generality of the discussion within the interviews about
their thoughts and perceptions of the medicines for dementia and how they are
prescribed, the transcript data were analysed together. There were a total of 85
themes arising from the data and these settled into three superordinate themes:
Decision Making in Prescribing; Medicines for Dementia and the Therapeutic
Relationship. Prescribers’ perceived their therapeutic relationship with their
patients and their carers as being very important and one that should be protected.
It was via this relationship they learned about what it was like for people to live
with dementia and after making a decision to prescribe a medicine for dementia
they then witnessed the value of this in their patients and their carers on follow-up.

“I’d say it’s the rule of thirds, a third of people improve the third people
stabilise and a third of people don’t um benefit, the improvement can go
from really dramatic to mild, but mild can be just the one straw that breaks
the camels back, the remaining one straw is the camels back, sometimes a
mild improved in function can still be the difference between staying at
home and being in care”  
Dr West

Obviously all prescribers wanted to be able to offer an effective pharmacological
treatment for their condition and they experienced this as being hampered by the
NICE guidance issued in 200631 which stated that cholinesterase inhibitors should
no longer be offered to people with mild Alzheimer’s disease (when the 200127
guidance stated they were effective in this area) and that memantine was not to be
prescribed for people with moderate disease. The fact that both agents have a
license for those indications and research and clinical experience both
demonstrate efficacy in those areas resulted in clinicians feeling sad about the
future of their patient’s care.

“It’s going to be hard if we do have to follow the NICE guidelines but um
we’ll see what happens. Um because you know it is nice that there is
something to offer and basically you know if we’re not allowed to use
memantine then there is nothing to offer the more severe people um and to
be only able to treat people once they reach a certain level of dysfunction
seems very wrong as a clinician…The treatments are licensed for
Alzheimer’s you think once you’ve made the diagnosis you should be able
to use them but, there you go.”  
Dr South

Prescribers made decisions routinely about prescribing a particular medication for
an individual patient and these became almost second nature as they shared their
own practice skills in this area. The decision on which agent to prescribe was part
of a prescribing choice pathway for all of the prescribers who used clinical
experience and the known side effects of the medications and concomitant illness
of their patient when selecting a first line cholinesterase inhibitor.

“As for my knowledge is concerned of the three probably donepezil or even
galantamine are sort of the first choice I would think about these two
medications before starting. Again the recent researches on rivastigmine in
dementia its good in Lewy body type of dementia or even Parkinson’s so
sort of prescribe that for that category but overall if a person comes with no
other problems just sort of cognitive impairment then probably I would be
prescribing donepezil which has a better side effect profile than any
others.”  
Dr East

330
They generally thought the medication was of great benefit in up to 60% of those in which it was prescribed; however they were unable to predict which people it would help most. The response rate was described as the rule of thirds; that is a third improved dramatically a third responded and a third seemed to show no response. However if the medication was withdrawn in non-responders carers and people with dementia often experienced a deterioration in their condition which necessitated a reinstatement of the medication.

“On the whole if the functionality is reasonably maintained and they are still at home with carer support then I would be reluctant to do it if it can be avoided because the trouble is that I have seen this before. Some of the carers feel that they may not be working and they tell them and think lets try and stop it and with the patient being lower in their mental state you say try and stop it and you can see a dramatic difference in the people and you reinstate it back on, back on in time just as long as you do it fairly soon you know.”

Dr West was the prescriber with the most years experience in prescribing for dementia and he felt that by the three-month follow-up he could see indicators that demonstrate a good response. He was also emphatic that people prescribed these medicines needed to be up to the maximum therapeutic dose that could be tolerated to gain best effect. He said that if people were monitored whilst they were still in their titration phase (galantamine and rivastigmine) then any response seen was probably a placebo response because they were not yet at a therapeutic dose. (When agents have a longer half life and they are being titrated up slowly in order to reduce the chance of side effects then it takes longer for the full potential of the medication to be demonstrated). He explained that a response to treatment was often seen at this stage but he termed this as being a placebo response i.e. the fact they were now on active treatment; something was being done and that they had been able to absorb and accept the diagnosis to a greater extent. He contrasted this with donepezil which rapidly reaches therapeutic effect and that the response seen at 3-months follow-up was a true reflection of response.

“I think there’s a danger in that first follow up consultation, there may well be a degree of placebo effect within that something’s getting cracking in the pot and is therapeutic and the original trials show this the placebo group improved as well at 6 months that’s when the placebo and treatment group really separated I do think there is a degree, the hardest bit is balancing it expectations and not giving too much hope.”

Dr West.

This was one of many examples of how difficult prescribers found it to actually assess the efficacy of the treatment. The assessment of response was performed by “a battery of tests” in order to obtain an objective account of improvement; however what was often needed was the subjective experience from the person with dementia and/or their carer. Although NICE recommends the MMSE as the preferred test prescribers experienced it as a tool which only told half the story and did not account for improvements in socialisation skills, activities of daily living and engagement in their environment in terms of being able to see things that needed to be done and contribute more to their personal relationships.

“Um same with memory it might have been a hard day when they are doing the mini mental or the ADAS-cog and it probably is not the same results
testing at that point in time and I tend to go by what the carers and the patients feel important as well so that gives me a part of this.”

Dr North

The therapeutic relationship was one that was developed over time between both parties and was valued by the people with dementia and their carers as a place where they could ask questions and receive information that was relevant to them. Prescribers talked about the usual information they would discuss with the patient prior to making any prescribing decisions and this included talking about concomitant illness, the possible response to medication and duration of that response. However Dr West shared how this was often difficult to judge on what was actually heard in that people generally did not remember all the facts they were told in a consultation and a few days later tended to have developed their own précis of the interview.

“The problem is the difference of what comes out of my mouth and what the patient and carer hear and can take a day later. The reality you are only going to take three points from a consultation and so you may well take the three best ones, so I do my best but sometimes it’s hard to judge the difference between mine and the judgement of patients and carers.”

Dr West

Interestingly the age of the person with dementia and their carer seemed to influence their attitude and/or acceptance of the illness and the outcomes of treatment. Older people were described as being more realistic about the possible effects of treatment and less likely to demonstrate a placebo response in the early stages. This attitude also affected the services provided with younger patients being experienced as more demanding in their requests.

“The hardest bit is balancing it expectations and not giving too much hope where some people will expect the drugs to cure it; interestingly older old people are more happy with anything that helps, younger old people are expecting more of the magical hit...In my expectations older old are just happy you know their expectations are much lower, younger old are more assertive.”

Dr West

Occasionally there were conflicts within the therapeutic relationship and prescriber Dr South thought that these generally related more to the siblings of their patients who could not come to terms with a diagnosis. She went on to explain that considering there was potentially a huge impact on receiving a diagnosis of depression, on the whole people received and seemed to accept this very well. She perceived that people seemed to relax after a year or so on treatment because things stabilised and nothing was progressing as fast as they thought it might have done.

“You know people are lovely on the whole and you can talk about things and come to an agreed decision about things; its not usually an issue. I’m amazed how well people take you know being given a diagnosis you expect people to have catastrophic reactions much more often than they do but I suppose they’ve been having problems for a long time usually, it’s not something that happens one week and they come and see you the next. So they’ve probably had a bit of an inkling.”

Dr South
Prescribers felt they were making decisions all the time, some which came naturally without any thought and then others which challenged them on deeper personal and ethical levels. Prescribers shared how they felt when they diagnosed somebody as having mild cognitive impairment when there was nothing within the guidelines or in the evidence base to offer these people as an effective treatment. The conversion rate from MCI to dementia is about 20% so for many of these people it became a “watch and wait” follow-up so that if necessary they could offer appropriate treatment when they deteriorated further.

Dr West described a difficult decision he made when one of his patients was admitted to a nursing home when her carer could no longer cope. She had been on medication for dementia on admission and this was kept on, however she had insight into her situation and became very distressed in the care home, not liking the way she was being cared and not being able to understand her husbands unavailability. It was decided in collaboration with the care staff and the community psychiatric nurse involved that the medication would be withdrawn in order to reduce her distress levels by reducing her insight.

“I would not automatically stop because somebody had gone into care we have to look at the needs of that person in that care environment. If somebody is in a grotty home aware of their environment it might be a good place to stop where somebody is in a residential home and liking it and we are trying to place them in residential rather than going to EMI nursing still carrying on the medication.”

Dr West

Other Healthcare Professionals
There were two community psychiatric nurses (CPNs) recruited to the study originally but one withdrew when the person she was supposed to be monitoring decided they no longer wished anyone to come to their home. At the end of the study there was one CPN Mary and one psychologist James interviewed in their workplace.

There were a total of 41 themes arising from the data and these settled into two superordinate themes of: Medicines for Dementia, and Procedural Issues. James and Mary were part of a team delivering supporting care to an individual and generally did not have autonomy. All decisions and findings were to be discussed with either their manager or the relevant prescriber. This meant that narratives consisted of Procedural Issues which they followed in order to deliver their service which was either to provide the neuropsychiatric or the response assessment details to the relevant clinician in order for a medicine for dementia to be prescribed.

James’s remit was to perform all the neuropsychiatric assessments for the initial diagnosis to be made and these would be repeated on an annual basis if the diagnosis was mild cognitive impairment. He generally only spoke to people with a memory problem or dementia and their carers as part of doing his assessments and was not involved in any prescribing decisions.

“I would give the results to my manager who would then score up the memory assessments and interpret it and then she would allocate the
Mary followed-up people who had been stabilised on a medicine for dementia in their own home at three or six monthly intervals dependent on their perceived need. In this respect she had a better idea of how medicines for dementia affected people’s day to day lives as she witnessed their functional and cognitive ability in their own homes.

“Well the people I see who are already stabilised on them at home and I dare say there are some people who may have done well but the majority and all of those I see they are effective as I said before they have helped people who they’ve enabled people to stay in their own homes for much longer periods than they would have done at all.”

Mar CPN

The assessment was a complex process for both, notably more scale driven for James whereas Mary described how there also needed to be some subjective measure and that you had to “use your eyes” in order to actually see what else was going on. She described how the following issues could be picked up in this manner and that in order to maintain stability of the caring process they all needed to be addressed: an underlying infection; relationship issues; the need for extra support for the carer or a possible dose increase for the person taking the medicine.

There was some discussion on the assessment scales available both at a diagnostic level and at a monitoring level. The MMSE has been designated as the preferred tool by NICE but both outlined difficulties they had with it. Mary described how it only gave part of the picture and that she usually used it in combination with one or two other tests (e.g. SET or HALF SET). James thought that it was not a sensitive tool in those people of previous high intellect as they often scored highly (i.e. supposedly demonstrating no cognitive impairment) but had gross functional ability.

“I guess they’re as objective as we can be mostly because it’s an acknowledged and evidenced tool/trait if you like, so it can be quite useful but sometimes we see people who have deteriorated and clearly they’ve deteriorated because there are other ways of seeing I mean you use your eyes and yes you’re right it is subjective but you use your eyes you look around you and you look at the state of the patient, their dress, their demeanour you can check and the state of the home they’re living in if you like or just generally how they’re responding to you and all of those things are part of it as well. So yeah I guess some of it subjective.”

Mary CPN

The importance of a reliable informant (i.e. the carer) was referred to by both as being a necessary part of the assessment procedure to ensure that a greater depth of understanding was ascertained and also the level of carer distress or carer burden. To help support this process there were often target symptoms agreed by both the person with dementia and their carer which they hoped the medication would improve. This also gave a greater means of assessing the
efficacy in terms of the individuals concerned. A target symptom could be
something like not misplaced or losing objects such as car keys or glasses or
repetition of questions to the carer.

Mary experienced the medicines as “without exception” producing some form of
response in people who took them. Both described improvements in mood,
behaviour, speech, sociability, quality of life and maintaining independence and
Mary perceived that they helped to maintain facets of personality.

“I mean yes it does improve their quality of life I mean I think the hope
sometimes as well improves their self esteem that they’re able to do little
things more.” Mary CPN

Mary also described occasions where she had found it difficult in being included in
the decision to stop a medication when there was no other option available and
knowing that there would be a sudden decline in functioning. Her practice involved
an element of clinical supervision which meant that she had the facility to offload
her experiences in order to carry on working.

“I have the option to opt in we do do clinical supervision so as part of my
clinical supervision is that I do talk about it. I mean after a long time, in
nursing I feel as no one is forever you know that and it can be as
comfortable as it can be and that’s fine.” Mary CPN

Recruitment Issues
As discussed in the interim report the start of the study was delayed due to a
series of correspondence with the Local Research Ethics Committee LREC),
which finally approve the study. However by this time the process of prescribing
for newly diagnosed people with dementia had changed on both originally
proposed study sites. (Instead of people being assessed physically and
psychologically on visit one and then a diagnosis being decided prior to their next
visit in three weeks time where prescribing also occurred; the assessment,
diagnostic and prescribing were all to take place on the initial assessment visit.
This was because the delay of three weeks in prescribing these medicines was felt
to be deleterious to the person cognitive function).

This meant that a further substantial amendment had to be made to the LREC and
also the changing of all patient and carer information leaflets and consent forms.
These received approval from LREC and then one of the study sites dropped out
due to increased workload and staffing pressures. At this stage a further four
potential study sites were approached for their agreement to be a recruitment site
for the study. These sites agreed and this meant a further substantial amendment
being made to LREC for their approval which was granted. As well as the addition
of the four new recruitment sites, approval was also sought for two changes to the
recruitment process as this was not going very well. Approval was given for:

1. the lead researcher to be on site at new patient clinic days and for the
healthcare professional leading the consultation to briefly explain to them
about the study and ask if they would like to speak to the person who could
talk to them immediately after the consultation, and/or

2. For the study site consultant to invite people to take part in the study by a
joint letter from them and the lead researcher.
Appendix A6-1: Coding Taxonomy for Phase Two

Superordinate Theme: Living With A Memory Problem Or Dementia

Personal Changes
  Ageing and Concomitant Illness
  An elusive memory
  Fluctuations and progression

Comparative Changes
  Behaviours
  Activities

Relationship Dynamics
  Perspectives of day-to-day living
    Communicating with a memory problem
  Effects on Others
    Acceptance and Living Together

Superordinate Theme: Interacting With Healthcare Professionals

The Therapeutic Relationship
  Consultation Etiquette

Therapeutic Decision-making
  Diagnostic Processes
  Prescribing Decisions
  Predicting Response

Assessment, follow-up & support
  Testing for response
  Assessing the response
  Follow-up and Support

Superordinate Theme: Medicines For Dementia

Prescribing Hindrances
  Access to Acetylcholinesterase Inhibitors
  Prescribing and Co-prescribing of Memantine

Responding to a Medicine for Dementia
  Response Rate and Duration
  Beneficial Response
  Sociability and Returning to Old self
  Perceived Quality of Life

Medication Issues
  Experiencing Side Effects
  Getting the prescription and the medication
  Mislabelling
  Compliance and Titration Problems
Appendix A6-2: Description of Superordinate Themes

Superordinate Theme: Living With A Memory Problem Or Dementia

This theme describes how a memory problem or early stages of a dementia impairs memory and effects personal behaviours and activities which in turn impact on relationships. The spousal relationship required renegotiation with an adaptation and acceptance of new roles and lifestyles.

Superordinate Theme: Interacting With Healthcare Professionals

Both carers and participants with dementia or a memory problem had therapeutic relationships which required interacting with healthcare professionals. In this phase of the study there seemed to be a more acceptable consultation etiquette which participants found supportive.

Superordinate Theme: Medicines For Dementia

Medicines for dementia were perceived to improve relationships by aiding the participant with dementia to engage more fully in their life word and with other people. The result was improved social skills and relationships. There was also a negative charge for the medicines in terms of pharmaceutical issues related to supply and correct labelling.
Appendix 8-1: Publications and Dissemination

From Chapter 1-3

From Chapter 8

Dissemination of Findings from Phase One and Two
I have been able to present the findings of Phase One at a number of conferences; these were:
- An oral presentation at the Health Services Research in Pharmacy Practice in April 2006,
- A poster presentation at the annual British Association of Psychopharmacology in July 2006,
- An oral presentation at the British Pharmaceutical Conference (BPC) in September 2006, and
- An oral presentation at the United Kingdom Psychiatric Pharmacy (UKPPG) Conference in October 2006 where it also won the UKPPG Travel Award (£1500).

After the BPC I was approached by the Editor of the Pharmacy Magazine to write an article on how to complete a Medication Usage Review for PWD. (Ref) A summary of the findings has also been sent to the branch lead of each of the Alzheimer’s Society branches that took place and those participants who expressed a wish to receive it.

I was also approached by BBC Points West and BBC Radio Bristol to comment on various aspects of dementia as outlined below:
- BBC One Points West Television interview Medicines for dementia 6.30pm and 10.30pm 2nd April 2007
- Radio Bristol Live Interview Medicines for dementia 7am 2nd April 2007
- BBC One Points West Television Interview The effect of antipsychotics on older people 7th June 2007
- Radio Bristol Live Interview Antipsychotics in care Homes 7am Friday 8th June 2007

I have had some of the findings of Phase Two accepted for oral presentations at two conferences so far; these were: