



## **Living with Medicines for Dementia – Patient and Carer Perspectives**

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FINAL REPORT October 2009

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## Acknowledgements

This study was supported by a Galen Award granted in 2005 by the Pharmacy Practice Research Trust, a research charity based at the Royal Pharmaceutical Society of Great Britain. I am very grateful for their continued support and faith in me after a very difficult journey.

I also wish to thank my supervisor Professor Marjorie Weiss for her patience and understanding and the rest of my work colleagues who have given me time and space in which to complete this work.

My deepest love and thanks also to my partner Alec Lawless who has been unstinting in his support and faith in me. I would not be here without him

Published by the Pharmacy Practice Research Trust  
1 Lambeth High Street,  
London, SE1 7JN

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First Published 2009  
© Pharmacy Practice Research Trust 2009  
Printed in Great Britain by the Pharmacy Practice Research Trust  
ISBN 9780956332318

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## Foreword

The care of patients with Alzheimer's disease and dementia is complex and distressing and it must include the needs and support of the carer. More often than not, patients with early to moderate signs of the illness will be cared for at home by spouses or other family members and the effect of dramatic behaviour changes associated with dementia can be devastating to these carers. This research highlights the need for care to be more holistic in its approach and the need for healthcare professionals to take into account the behaviour and coping mechanisms of the immediate carer and the impact that these may have on patients.

It is easy to see why carers become desperate for the hope that medication may bring to the lives of sufferers. The expectations the carers have and the management of these in real terms is a crucial element of healthcare practice. The research emphasises the extent to which medication is often not a treatment option and how important support for patients and carers outside of medication is. The study also shows that these patients often did not fit the assessment measurements dictated by NICE in their guidance for the treatment of Alzheimer's disease<sup>1</sup> when determining access to specific medications particularly where mild forms of the disease are present. The author considers that they are not sensitive enough for patients with higher intellect who often scored highly and therefore were not eligible for medication even though this was in contrast with evidence from the carer of deteriorating function. In addition it is thought that scores could fluctuate day by day according to a multitude of factors that influence the behaviour of patients with dementia such as stimulation, other co-existing conditions and or co-prescribed medication.

This research highlights some of the real issues experienced by all those involved in the care of patients with dementia. From the devastation of diagnosis to the dearth of treatment options to the different coping mechanisms of carers and the impact that these have on patients. The further issue of problems arising with existing co-morbid conditions especially those that result in reduced stimulus for patients such as hearing or eyesight problems make things much more difficult for the carer and must be a real consideration in the development of care plans for patients.

For prescribers, the advice that they give and its possible misinterpretation by patients, managing patient and carer expectation around drug therapies, using professional judgement in titrating medication and monitoring side effects and the plateau stages of therapies are all crucial issues. The study demonstrates the impact that prescribing behaviour and individual professional judgements have on patient and carer lives. This is notable in the differences observed across prescribing for the treatment of side effects. Some prescribers advocated prescribing to ameliorate the worse side effects to allow titration to therapeutic levels whilst others withdrew medication in the presence of extreme side effects. Cessation of medication due to intolerance or lack of efficacy, or even when quality of life would be better in the absence of medication, are all difficult medication decisions faced by practitioners and must be made in partnership with patients and carers.

The study also notes the impact of continuity of care on assessments, support and prescribing when healthcare teams change and the impact on relationships with healthcare professionals when delays in treatment occur.

Overall what is clear from the research is the individuality of the needs and expectations of patients and their carers. The term 'patient-centred care' is often used but here it truly comes into focus in the understanding of the need to deliver care that is specific to patients and their individual carers. To achieve this, professional judgements over and above standard guidelines must be brought to the fore. For some carers even in the knowledge that the medication may not be tolerated or effective it is better than doing nothing. It also appears carers find it easier to cope with other problems such as coping with short term memory loss,

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<sup>1</sup> NICE Technology Appraisal Guidance 111. Donepezil, galantamine, rivastigmine (review) and memantine for the treatment of Alzheimer's disease. National Institute for Health and Clinical Excellence November 2006. [www.nice.org.uk](http://www.nice.org.uk).

than living with a person who can no longer converse. Although this may well be due to a placebo effect of the drug in the initial period, the impact on the lives of carers must be acknowledged.

The lack of pharmacy involvement in the study and indeed in the care of patients with Alzheimer's disease or dementia is highlighted by the author as disappointing and I can only agree with their conclusion that more work is needed around the role that pharmacists could play in improving the lives of patients and carers.

Marshall Davies  
Chair, Pharmacy Practice Research Trust

## **Executive Summary**

Dementia is 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 in those people who have this condition.

There are two different types of medicines for dementia which can help with these symptoms. They are not a cure but they help to stop the progression of the illness and restore some normal functioning such as sociability, motivation and completing tasks. These medicines are the cholinesterase inhibitors (donepezil, rivastigmine and galantamine) and the NMDA receptor antagonist (memantine). There is a wealth of information on the effectiveness of these medicines for people with dementia and their prescribing is controlled by NICE (The National Institute for Health and Clinical Excellence).

NICE in 2001 originally recommended the cholinesterase inhibitors for use in people with mild and moderate Alzheimer's disease (the most common form of dementia). In 2006, NICE published revised guidance with the result that the medicines could no longer be prescribed in mild disease as it considered there was not enough evidence to show cost effectiveness. A number of organisations continue to canvass for the reversal of this decision as they consider that effective medicines are not able to be prescribed.

NICE also gives guidance on how the response to these medicines is measured and it recommends an assessment tool called the mini mental state examination (MMSE) which tests short and medium term memory as well as problem solving and following commands. It does not however assess for responses in other areas of cognition such as language, visuospatial and perceptual ability, or personality.

### **Research Aims and Objectives**

The aim of this study was to explore the patient and carer perspective, over time, on the use of medicines for dementia and their impact on day-to-day life.

The objectives of this phase of the study are to explore:

1. The attitudes that carers, people with dementia and the associated healthcare professional(s) may hold about medicines for dementia.
2. Whether there was agreement on perceived efficacy of these medicines.
3. An individual's criterion for initiation, continuation, swapping and/or withdrawal of these agents.
4. The relevance of clinical outcome measures of efficacy of these agents in day-to-day life.
5. The issues associated with continued use of these medicines.

### **Methods**

The study used a case study approach to establish the actual impact that the prescribing of these agents may have on the lives of the people studied. Case study research 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; their carer and important healthcare professionals associated with the prescribing process. The intervention was 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.

A maximum variation sampling technique was employed to explore in greater depth whether the effect of a particular medicine or indeed no medicine had any discernible outcomes.

There would be 8 possible case studies in all:

- one where the medicine for dementia is donepezil;
- one where the medicine for dementia is rivastigmine;
- one where the medicine for dementia is galantamine;
- one where the medicine for dementia is memantine;
- one where a medicine for dementia has been withdrawn due either to adverse effects or lack of efficacy or has been swapped to another agent;
- one where there is co-prescribing of medicines for dementia;
- one where the person refused treatment and
- one where the person was ineligible for treatment (e.g. because it was for a condition where these agents are not licensed such as mild cognitive impairment).

Participants were recruited from three different memory clinic locations across one large mental health trust in the Southwest of England.

Local Research Ethical Committee Approval was given in April 2006 but memory clinic staffing problems delayed recruitment until October 2006. In total 7 case studies were filled (there was no recruitment for the case study with donepezil), totalling six people with dementia or a memory problem, six carers, four different prescribers and two other healthcare professionals. Participants were followed from 1 to 13 month periods depending on the emergence of new data.

Semi-structured, face-to-face interviews and diary records were used to collect participants' perspectives about the medicines for dementia and the effects on their day-to-day lives. Resultant data was triangulated with objective data from medical records and from observed consultations between prescriber and participants with a memory problem due to dementia.

### **Overview of Findings**

With respect to the perceived overall efficacy of the cholinesterase inhibitors and memantine, it was a very complex picture. It is pertinent to remind ourselves that dementia is a progressive syndrome and each person is affected differently by the disease process. This means that participants noticed responses to their medication in areas of concern to them, for example, improved motivation or self initiative or the ability to complete practical tasks or engage in social activities with family and friends. It is relevant that we note memory is only one consideration in an assessment process and that by necessity perhaps the assessment should be individualised to the person with the dementia in terms of target symptoms and not the generic MMSE as proposed. (Target symptoms are those relevant to the individual and their carer, for example, to reduce repetitive behaviour or speech or to reduce the loss of personal items such as keys or glasses).

Living with dementia can have an enormous impact on the relationships that the person with dementia holds and so the positive effects of these medicines of sociability; initiative and motivation has the potential to improve the quality of life of those affected and also to increase the time the person is cared for in their own home rather than admission to a care facility.

### **Brief Description of Case Studies**

NB All names have been anonymised to protect confidentiality

#### **Case Study One: Mr & Mrs Black**

Recruited from Location One. Mr Black was not eligible for treatment with a cholinesterase inhibitor because the memory loss was diagnosed as being mild cognitive impairment possibly attributed to the effects of a heart bypass surgery event. He lived with his wife 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. The subject'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 him being made redundant as he could no longer keep up with his work.



The case study also included his wife. The following healthcare professionals were recruited to the study: a psychologist who had performed all the cognitive diagnostic testing and the potential prescriber, a consultant in dementia.

#### **Case Study Two: Mr and Mrs Smith**

Recruited from Location Two. Mr Smith was eligible because he had not been able to tolerate the side effects of a cholinesterase inhibitor and this had been withdrawn. He actually was tried on two agents to see if a change may help but he was unable to tolerate the side effects of either agent. His prescriber, did not believe in co-prescribing for iatrogenic illness and so the cholinesterase inhibitors were considered intolerable. He lived with his wife, who herself had arthritis of long standing who needed assistance on stairs (they had a chairlift fitted about 10 years previously because of her increasing immobility). As the subject became increasingly frailer and less mobile it became more of a struggle for his wife and he eventually needed a wheelchair for mobility. He needed a (hip/knee) replacement but was not considered eligible because of his dementia and concomitant cardiovascular problems.

This case study also included his wife and the prescriber. They received no other home assessment in relation to the dementia.

#### **Case Study Three: Mr and Mrs Jones**

Recruited from Location Three. Mr Jones had been prescribed a cholinesterase inhibitor (rivastigmine) off-licence for a vascular dementia. He lived with his wife who had found it very difficult to account for her husband's increasingly withdrawn state. This case study included his wife and his prescriber. They had no other home visits in relation to his care.

#### **Case Study Four: Mr and Mrs White**

Also recruited from Location Three. Mr White had been diagnosed with Alzheimer's disease in 2003 and had memantine co-prescribed when he was already stable on rivastigmine. He had started to deteriorate quite markedly in terms of verbal fluency and cognitive functioning and it was decided to add in memantine. He lived with his wife who was the main carer and looked after him on her own. She was a very organised person and believed in keeping a routine in order to keep the subject functioning as well as possible.

This case study included his wife, a community psychiatric nurse who visited them on a three-monthly basis and his prescriber.

#### **Case Study Five: Mr and Mrs Green**

Also recruited from Location Three. Mr 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 very well spoken with good social skills enabling him to seemingly function at quite a high level on casual observation. He lived with his second wife, 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 after the death of their mother and although they were (the children) now near to retirement age; they declined to have further contact with him.

This case study included his wife and his prescriber. They had been assigned a community psychiatric nurse but had refused them entry to the house because they did not think they were needed yet.

### **Case Study Six: Mr and Mrs Johnson**

Also recruited from Location Three and was originally recruited because Mr Johnson had refused to take any medicines for his memory problems. The subject had even had all his mercury dental fillings replaced in order to reduce the risk of this being the cause of his problem. However, between the time of consenting to participate in the study and the interview taking place his wife had convinced him that he should take the medication being offered.

This case study included his wife and his prescriber but no CPN visit as the subject had dismissed this as being "a waste of time."

### **Case Study Seven: Mr and Mrs Smith**

This was the original case study two. Mr Smith had not been deemed suitable for memantine at the time of these being withdrawn because his dementia was only mild to moderate. However, at the time of the observed consultation his condition had progressed and it was decided with the agreement of himself and his wife and son-in-law, to start him on memantine.

This case study included his wife and his prescriber.

### **Common Findings**

For the people with a memory problem or dementia and their carers there were four main themes that they talked about. These were:

- Living with Dementia;
- Relationship Dynamics;
- Interacting with Healthcare Professionals; and,
- Medicines for Dementia.

In general when people are living with a dementia or a memory problem they experience increasing levels of frustration and stress at not being able to do the things that they could before. The case studies illustrated that they also became increasingly withdrawn and quiet and didn't join in or initiate conversations, leading to the increasing dissatisfaction and upset of their carers who felt that they were no longer married to the person they fell in love with. It must be understood that this is not deliberate on the behalf of the person with the memory problem, they have no understanding or awareness that it is actually happening.

The medicines for dementia were perceived to improve the ability of the person with dementia to take part in social and family activities. Participants spoke of improved levels of alertness, initiative and the ability to actively take part in conversations.

### **Prescribers**

In total there were four prescribers with one 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.

The prescribers of people with a memory problem or dementia talked about three main themes. These were:

- Decision Making in Prescribing;
- Medicines for Dementia; and,
- The Therapeutic Relationship.

In general, the prescribers wanted what was best for their patients and tried very hard to ensure that they remained on effective medication as long as possible as long as there were no distressing side effects. They reported being constrained by the NICE guidance as it meant they were unable to offer effective licensed treatment which they knew were available.

They were also aware that the medicines do not work for everyone, with a third experiencing a dramatic effect, another third experiencing a response and the remaining third not responding at all. For these non-responders they always offered the trial of a second medication. They also tried to be realistic and honest with their patients in the study so that hopes were not built up unrealistically as the medicines are not a cure, they only help with some of the symptoms.

They spoke about how the assessment tools were often not effective enough to capture all improvements and this meant they had to use at least two if not more tests to check a response objectively. However, they said they always asked the person with the problem and their carer about benefits that they have seen because this subjective assessment seemed just as important.

### **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 and one psychologist interviewed in their workplace.

These participants' narrative settled into two themes:

- Procedural issues; and,
- Medicines for dementia.

They either assessed the extent of the problem in order for a prescriber to make a diagnosis or they monitored the effects of the medicines to check for response.

They perceived that, in their experience, the medicines helped most people in some way. They knew that all people benefited in some way, but those that they worked with had experienced improvements in the quality of their day-to-day life. The CPN spoke of how it was difficult just to use assessment tools and she always relied on her eyes and ears to find out what else was going on. She also measured target symptoms that the people with dementia and their carers thought were important and they wanted the medication to help with. An example of a target symptom is not losing things so often.

### **Observed Consultations**

Four consultations were observed in total: case study two, three, four and five, with three different prescribers.

Without exception the prescribers were warm and empathic to the people they were caring for. The styles of consultation were generally very relaxed and open and all tried to be very honest and direct with each couple. The assessment procedure was different in each consultation and reasons for this change seemed dependent on whether it was an issue of the licensed use of a medication or whether it fitted with local or national policy.

The participants in the consultation held the prescriber in high regard and were all supportive and accepting of the consultation outcomes.

### **Objective Data**

The comparison of objective data with the subjective arising from the interviews supported the continuation of medicines in all those being prescribed them because of the demonstration of continued response in both objective and subjective outcomes.

### **Implications for Practice**

There were no pharmacists recruited to this study, and they were only mentioned in two case studies in relation to the mislabelling of medicines which caused some concern and panic for those concerned. No pro-active advice or support seemed to be offered by pharmacists but this may be due to unfamiliarity with the appropriate doses and dosing schedule of these medicines. All of the participants had concomitant medication and had managed to establish their own methods of remembering how to take the medication. However, this population group would seem to be an ideal group for inclusion in medication review schemes to ensure the most effective use of medication.

## 1. Background

### 1.1 Literature Review

Dementia is an insidious and progressive neurodegenerative disorder, which has a major impact on both the patient 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 relatively recently there was no licensed pharmacological treatment available for the relief of dementia syndromes. This meant that carers generally provided the majority of primary care healthcare provision. With the licensing of the cholinesterase inhibitors, Donepezil (Aricept®) in 1997, Rivastigmine (Exelon®) in 1998, and Galantamine (Reminyl®) in 2000 and the NMDA Receptor Antagonist Memantine (Ebixa®) in 2002, the possibilities of symptomatic treatment for dementia were greatly improved. However, due perhaps to an unfamiliarity with treating people with dementia and misconception of the beneficial therapeutic effects of these agents, prescribing rates were poor until the National Institute for Clinical Excellence (NICE) just produced prescribing guidance in January 2001, recommending them for mild and moderate stages of Alzheimer's disease.<sup>1</sup>

Controversy still continues with the updated NICE guidance published in 2006 which suggests that although these agents are clinically effective in controlling the symptoms of Alzheimer's disease they should not be prescribed until the moderate stages of the illness due to a lack of clear cost effectiveness data in the mild stages.<sup>2</sup>

Medicines management is an umbrella term for the responsible provision of medication for the purpose of achieving definite outcomes, which improve the patient's quality of life.<sup>3</sup> However, many medicines may actually have a deleterious effect on a patient's self-assessed quality of life to the extent that they may eventually stop taking the medicine.

Indeed it is well documented that the adverse effects of the licensed medicines for the symptomatic treatment of dementia, the cholinesterase inhibitors, exhibit frequent adverse events in the recipients of these agents. (See table below for the most common).<sup>4</sup>

**Table One: Common Gastrointestinal Adverse Effects**

<b>Gastrointestinal Adverse Effects</b>	<b>Placebo n=2296</b>	<b>Donepezil n=1209</b>	<b>Galantamine n=1040</b>	<b>Rivastigmine n=1188</b>
Nausea	9%	14%	24%	47%
Vomiting	4%	8%	13%	31%
Diarrhoea	7%	12%	9%	19%

A recent article suggests that up to 25% of all patients started on a cholinesterase inhibitor in a clinical trial withdraws from the trial because of adverse effects.<sup>5</sup> This would suggest that perhaps the withdrawal rate from these agents due to adverse effects is even higher in a community-based setting where the support facilities are often less than those offered to patients participating in a clinical trial.

Often the initial choice of agent is dependent on clinician experience and patient tolerance of and to side effects. Donepezil is most often prescribed first-line because of its once daily dosing profile and also its propensity to cause less gastro-intestinal side effects than other cholinesterase inhibitors. However, there is anecdotal evidence in the literature that Donepezil may have a shorter duration of efficacy than either of the other two agents and that switching to another cholinesterase inhibitor may be beneficial in some patients.<sup>6</sup> Exacerbating this finding is that each of these agents has linear dose pharmacokinetics, which means that the best therapeutic effect is seen with the maximum licensed dose. (The NNT's or numbers needed to treat fall from 13 with low dose therapy to between 3 and 7 with high dose therapy).<sup>7</sup> However, many patients remain on the dose that they can tolerate or are even withdrawn from treatment before a therapeutic dose is reached. Pre-emptive treatment of side effects in this group of patients seems to be rare.

A local audit<sup>8</sup> highlights that up to 33% of patients receiving cholinesterase therapy withdraw or change agents due to intolerable side effects. The frequency of this withdrawal is dependent on the agent initiated, occurring less frequently in patients started on donepezil.

Historically, patients with end-stage Parkinson's disease who qualify for the prescription of apomorphine, a highly emetogenic dopamine agonist that has to be given parentally, are pre-emptively treated with domperidone (an anti-emetic which does not cross the blood brain barrier).<sup>9</sup> It would seem sensible that prior to initiation and at dose titration stages of treatment with the highly emetogenic cholinesterase inhibitors, that domperidone is used pre-emptively to reduce nausea and vomiting in dementia patients. This would then allow patients to be titrated to a therapeutic dose more rapidly, or allow patients to stay on therapy longer.

There is now increasing evidence to demonstrate that the longer that treatment initiation with cholinesterase inhibitors is delayed the less effective it becomes.<sup>10</sup> Therefore once initiated, it would seem logical to titrate as rapidly as possible to the maximum therapeutic dose of the agent selected.

Findings published in the 'Forget me Not' report<sup>11</sup> 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.

An audit to investigate the use of and funding of cholinesterase inhibitors in dementia, was published by Mace and Taylor in 2002.<sup>12</sup> The findings demonstrated that only 76% of the 91 prescribing advisers of health authorities in England and Wales had identified formal funding for their use. However, since these reports, the responsibility for the prescribing budget for medicines for dementia has been transferred to Primary Care Trusts (PCTs). Indeed the volume of prescribing of these agents has now become a Performance Indicator for Mental Health Service provision in England and Wales. The performance indicators suggest that the prescribing rates of these agents should increase as the identification of patients with probable Alzheimer's disease increased.<sup>13</sup>

On being presented with a diagnosis of a particular medical condition, many patients will hold a belief about how medication may ameliorate or totally cure their medical condition.<sup>14,15</sup> This may or may not coincide with their carers, or prescriber's viewpoint or indeed the dispensing pharmacist's viewpoint.

For patients diagnosed with probable Alzheimer's disease NICE<sup>1</sup> has suggested that pre-agreed cessation points of treatment must be agreed between the patient, their carer and the physician, prior to the patient receiving medicines for dementia. It is possible that the viewpoints of all those concerned with use of these anti-dementia agents will change over a period of time. Also if patient, carer and physician expectations are 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.

In fact in the second survey report by the Alzheimer's Society in 2004,<sup>16</sup> 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 *improved concentration / speech*." That is the end points of successful treatment in the eyes of a carer seems at odds from those endpoints proposed by NICE.<sup>1</sup>

It is therefore important to explore both people with dementia and carer perspectives in the use of medications for dementia.

## 1.2 Aims and Objectives

The aim of this phase of the study is to explore the patient and carer perspective, over time, on the use of medicines for dementia and their impact on coping with day-to-day life.

These objectives of this phase of the study are to explore:

6. The attitudes that carers, people with dementia and the associated healthcare professional may hold about medicines for dementia.
7. Whether there is agreement on perceived efficacy of these medicines.
8. An individual's criterion for initiation, continuation, swapping and/or withdrawal of these agents.
9. The relevance of clinical outcome measures of efficacy of these agents in day-to-day life.
10. The issues associated with continued use of these medicines.

## 2. Study Design and Methodology

### 2.1 Case Study Methodology

This phase of the study is designed to establish the actual impact that the prescribing of these agents may have on people's lives using case study research methodology. Case study research is designed to explore a *situation* in which an *intervention* being evaluated has no clear single set of *outcomes*.<sup>17</sup> In this research the *situation* is the day-to-day lives of the person taking the medication; their carer and important healthcare professionals and/or other support workers associated with the prescribing process. 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.

### 2.2 Sampling Technique

A maximum variation sampling technique was employed to explore in greater depth whether the effect of a particular medicine or indeed no medicine had any discernible outcomes.

It was proposed that there would be 8 case studies in all:

- one where the medicine for dementia is donepezil;
- one where the medicine for dementia is rivastigmine;
- one where the medicine for dementia is galantamine;
- one where the medicine for dementia is memantine;
- 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;
- one where there is co-prescribing of medicines for dementia;
- one where the person refused treatment, and
- 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).

### 2.3 Recruitment

Originally it was proposed to recruit people with newly diagnosed mild<sup>1</sup> dementia and their carers from two local memory clinics with an active interest in clinical research. Unfortunately within months of the study starting one of the proposed recruitment sites decided to withdraw and a further three memory clinics were approached and agreed to host the recruitment of possible participants.

The potential participant members of each case study group included: the person with dementia, their carer, the prescriber and the healthcare professional providing support (e.g. the community psychiatric nurse, psychologist or pharmacist as appropriate).

These case study groups were to be followed up for a period of up to 6 months (depending on the emergence of new findings) to assess whether attitudes to the medication change; how the carer and the person with dementia deal with the experience of side effects, monitoring requirements, withdrawal issues and impacts (if any) on self and carer-perceived quality of life.

## 2.4 Data Collection

Interviews were the main method used to collect data in order to explore in greater depth the subjective experience of taking medicines for dementia (or not) and how these produce affects and effects in daily life. Participants would be offered the option of recording their thoughts in a diary on their feeling and possible responses in relation to the medication.

Interview data would be triangulated with objective data from memory clinic assessment sessions to see if there were comparable findings.

It was planned to also observe a consultation to explore the level of input into the decision-making process that a person with dementia or memory problem had.

The following information was to be collected:

- The person with dementia, their carer, prescriber and/or healthcare professional beliefs or attitudes toward the efficacy of the medication throughout the 6-month period (interview)
- The person with dementia, their carer, prescriber and/or healthcare professional perception of the success of treatment (interview)
- In-house measurement scales of success of treatment (objective scale)
- The effect on quality of life as self-perceived by the person with dementia, their carer, physician and/or healthcare professional (interview and objective scale used at clinic)

Interviews with each case study participant were proposed to take place at baseline, at 3 to 4 weeks after the start of the medication to explore how side effects may affect day to day life, then at 3 and/or 6 months from baseline. It was the intention to also observe at least one consultation with the prescriber to determine the level of process.

Interviews (with carer and person taking medicines for dementia)

Baseline interview prior to or very close to start of medication

Interview about 3 to 4 weeks of therapy (to explore experience of side effects)

Interview at 3 months (observe consultation if possible)

Interview at 6 months

Interviews (with prescriber)

Baseline interview prior to or very close to start of medicine for dementia

Interview at 3 or 6 months and/or observe consultation if possible

Interviews (with other support worker as appropriate)

Baseline interview prior to or very close to start of medicine for dementia

Interview at 3 or 6 months or observe consultation if possible)

A consultation would only be observed with each participant's permission in order to explore the involvement of the patient and carer in any decision-making processes about prescribing of medicines for dementia.



## **2.5 Research Ethics**

Both people with dementia and their carers can be described as being vulnerable subjects in research. Ethical considerations of importance to this study included:

### **2.5.1 Peer Review**

The research committees at both of the original recruitment sites had been informed about this study and had input to the design and methodology. It had been accepted as part of the research portfolio at each establishment to aid recruitment to the study. Further more it has been discussed at the quarterly Carer Group Meeting at Location One's Memory Clinic on the 13<sup>th</sup> June 2005. Feedback from this group has also informed the study design. The carers present were very keen to ensure that the beliefs and views of both patients and carers is more widely understood. They particularly agreed with the inclusion of a consultation observation session as they thought that generally they were not asked to participate in any decision-making process.

The Department of Pharmacy and Pharmacology Ethics Approval of Research Proposals - Peer Review Process was also undertaken a review of the proposal and it was externally reviewed by the Galen Award panel of the Royal Pharmaceutical Society of Great Britain in August 2005.

### **2.5.2 Recruitment Issues: How are potential participants to be identified and informed of the research?**

Acceptance of the study into the current research portfolio at recruitment sites meant that all staff were aware of the study and would inform potential participants of it. Advertising flyers were also be posted on the clinic waiting room walls or in the waiting room research file. This meant that potential participants will have the chance to ask for further information from memory clinic staff if they wish to do so.

Patients and their carers were to be recruited to the study via the agreed memory clinics across one mental health trust in the Southwest. Newly diagnosed people with dementia in each of the 8 variant sampling frames were be informed of the study by the memory clinic staff and asked if they would like to receive further information about the study. If they answered affirmatively they were given an information sheet and details of how to contact the lead researcher via telephone or an enclosed form to be returned to the lead researcher by prepaid envelope. At some clinic sessions the lead researcher was available to answer any questions about the study directly. The lead researcher did not approach potential participants directly but was highlighted by clinic staff involved in the recruitment process as the person to talk to if further information was needed. For those potential participants responding by telephone or completion of the notification of interest form, the lead researcher was to contact the potential participants and give them further information about the study and discuss the need for informed consent as appropriate. Further information and the consent form was posted to the potential participant and once this had been signed and returned the participants were contacted to arrange a time and date for the baseline interviews. This recruitment process took place at either the assessment visit or the follow-up prescribing visit. At the assessment visit, the psychologist leading research recruitment approached potential participants and at the prescribing visit the prescriber approached potential participants. Potential participants had between one and three weeks to decide whether or not they wished to participate, as this was the time interval between the initial assessment and the follow-up prescribing appointment.

Participants were informed at each contact that they were free to withdraw from the study at any stage without needing to give a reason.

### **2.5.3 Interview Location**

The interviews were at the participant's own home following the University of Bath's *Research in Private Residence* Policy; and the consultations will be observed at the appropriate memory clinic.

### **2.5.4 Consent Issues**

People with mild dementia that are taking medication are often able to give informed consent. 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. The lead researcher is skilled at tailoring the approach according to the needs of the individual. Once the potential participant contacts the lead researcher for further information, the reason for the study will be explained to the person and then what their involvement would be if they decided that they wanted to take part.

That is, it would be explained that they would have a one-to-one interview with the lead researcher on 3 to 4 different occasions to see if their views on their medicines changed over time. It would also be explained that the lead researcher would like to observe a consultation that they have with the prescriber of the medicines for dementia. The researcher then needs to ensure that the person seems able to understand the information given and to weigh up this information in order to make a decision about whether they wish to continue or not. At this point if the person had understood the process so far, they would be given the content sheet (topic guide) outlining the items to be discussed within the interview and asked if they thought that they would be able to participate further. It would be explained that if they wished to withdraw from the interview or the study at any time then they would be able to do so without giving a reason. It would also be explained that the interview would be tape-recorded to help the researcher to record all the information accurately. At this stage the potential participant would be asked if they could summarise the information they had been given so far and asked to make a decision as to whether they wish to continue or not. If the person seemed able to do this process; that is receive the information; ask appropriate questions, understand the risks that may occur and make a decision that they either wanted to participate in the study or not; then this would demonstrate a persons capacity to give informed consent. Generally it is not necessary to complete a Mini Mental State Examination (MMSE) when assessing an individual's capacity to give consent, as it is the process of information handling by the individual, which is the key factor.<sup>18</sup>

At a Carer Group meeting on the 13<sup>th</sup> June 2005 held at Location One's memory clinic, the carers present said that they thought that generally that the person that they cared for (in the early stages of their treatment) would be able to make the decision on whether to participate or not in an interview on their own.

## **2.6 Data Analysis**

All interviews were to be audiotaped using a cassette device and transcribed verbatim if consent was given for this process. The analysis of the transcriptions was to be both descriptive and explanatory. After transcription the data was to be sorted, organised and indexed into categories. The qualitative data handling package NVivo® was to be used to facilitate this organisation and sorting of the data.<sup>19</sup>

These categories would be further interrogated and grouped together in order to clarify the relationships between categories and to refine emerging ideas. The emerging data will then be assessed for deviant (that is data, ideas or relationships that do not fit the emerging pattern) and superordinate themes arising.<sup>20</sup>

The analysis will evaluate and compare each case participant individually, but also then cross compare with each of the other cases to allow the emergence of patterns. Analysis can also help to explain why people may have the attitudes or beliefs that they do.

### **3. Results**

#### **3.1 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 approved 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's 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 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 three 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 three 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.

#### **3.2 Recruited Participants**

The first participant was recruited in October 2006, some six months after the study first started (and eleven months after the LREC submission had originally been made). Although it was proposed that there would be eight potential case studies, only seven were recruited to by April 2007, and as the agreed extension was September 2007 it was decided to stop any further recruitment activities.

Case studies were recruited from three different recruitment sites, with a total of four different prescribers being interviewed and two different healthcare professionals.

The summary, duration and timings of the case study sites and respective interviews can be found in Table Two.

Please note ALL names have been anonymised to protect the participant confidentiality.

**Table Two: The Case Studies**

	Type	Participant	Carer	Contact	Time in Study	Prescriber	HCP
<b>Case 1</b>	Not suitable (has mild cognitive impairment)	George Black Age 60	Mildred (Wife)	1 <sup>st</sup> IV: 4.10.06 2 <sup>nd</sup> IV: 15.01.07 3 <sup>rd</sup> IV: 14.06.07 Consult: 24.08.07*	10 months	Dr North IV: 23.01.07 Consult: 24.08.07	James (Psychologist) IV: 15.12.06
<b>Case 2</b>	Withdrawn due to adverse effects	Harry Smith Age 83	Joan (Wife)	1 <sup>st</sup> IV: 13.12.06 2 <sup>nd</sup> IV: 04.04.07 Consult: 11.04.07	10 months	Dr South IV: 18.01.07 Consult: 11.04.07	None involved
<b>Case 3</b>	Rivastigmine	Bob Jones Age 70	Judy (wife)	1 <sup>st</sup> IV: 19.12.06 2 <sup>nd</sup> IV: 08.03.07 3rdIV: 18.01.08 Consult: 5.4.07	13 months	Dr West IV: 15.02.07 Consult: 5.04.07	None involved
<b>Case 4</b>	Co-prescribing of rivastigmine and memantine	Peter White Age 80	Annabel (Wife)	1 <sup>st</sup> IV: 21.12.06 2 <sup>nd</sup> IV: 9/11.03.07 3rdIV: 31.01.08 Consult: 5.4.07	13 months	Dr West IV: 15.02.07 Consult: 5.04.07	Mary (CPN) IV: 27.02.07
<b>Case 5</b>	Galantamine	Chris Green Age 81	Sue (Wife)	1 <sup>st</sup> IV: 17.01.07 2 <sup>nd</sup> IV: 10.04.07 3rdIV: 28.01.08 Consult: 12.04.07	12 months	Dr East IV: 16.05.07 Consult: 12.04.07	None Involved (Refused)
<b>Case 6</b>	Refused	John Johnson Age 76	Janet (wife)	1 <sup>st</sup> IV: 11.06.07	1 month	Dr West	Refused CPN visit
<b>Case 7</b>	Memantine	Harry Age 84	Joan (Wife)	1 <sup>st</sup> IV: 19.06.07* Consult: 11.04.07 RIP: 15.10.07		Dr Q	None involved
<b>Case 8</b>	Donepezil	Did Not Recruit To					

\* Researcher unable to attend

IV = Interview; Consult = Consultation

## **3.2.1 Description of Recruitment Locations**

### **3.2.1.1 Location One**

Location one is a memory Clinic which runs from a hospital unit providing mental health services for older people. Attached to the unit is a clinical trials research unit. This operates near to the centre of a large city.

### **3.2.1.2 Location Two**

Location two is a memory clinic which runs from a small community hospital providing healthcare service for the local population. It includes service provision for older people with mental health problems.

### **3.2.1.3 Location Three**

Location three is a memory clinic which runs from a small community hospital providing healthcare service for the local population. It includes service provision for older people with mental health problems.

### **3.2.1.4 Comment**

These locations were actually in three different health authorities but the services were provided by one mental health trust. A round trip from location one to three to two (in a direct line) totalled 52miles.

## **3.2.2 Description of Case Studies**

### **3.2.2.1 Case Study One**

Mr George Black was recruited from location one and was not eligible for treatment with a cholinesterase inhibitor because the memory loss was diagnosed as being mild cognitive impairment possibly attributed to the effects of a heart bypass surgery event. 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.

In George's case study there was also his wife Mildred and the following healthcare professionals were recruited to the study: John, a psychologist who had performed all the cognitive diagnostic testing and the potential prescriber Dr North a consultant in dementia.

### **3.2.2.2 Case Study Two**

Mr Harry Smith was recruited from location two and was eligible because he had not been able to tolerate the side effects of a cholinesterase inhibitor and this had been withdrawn. He actually was tried on two to see if a change may help but he was unable to tolerate the side effects of either agent. His prescriber, Dr South, did not believe in co-prescribing for iatrogenic illness and so the cholinesterase inhibitors were considered intolerable. He lived with his wife Joan, who herself had arthritis of long standing and needed assistance on stairs (they had a chairlift fitted about 10 years previously because of her increasing immobility). As Harry became increasingly frailer and less mobile it became more of a struggle for Joan and he eventually needed a wheelchair for mobility. He needed a (hip/knee) replacement but was not considered eligible because of his dementia and concomitant cardiovascular problems. 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.

### **3.2.2.3 Case Study Three**

Mr Bob Jones was recruited from location three and he had been prescribed a cholinesterase inhibitor (rivastigmine) off-license for a vascular dementia. He lived with his wife Judy who had found it very difficult to account for her husband's increasingly withdrawn state. In Bob's case study there was his wife Judy and his prescriber Dr West involved as they had no other home visits in relation to his care.

### **3.2.2.4 Case Study Four**

Peter White was also recruited from location three and 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 started to deteriorate quite markedly in terms of cognitive functioning and it was decided to add in memantine. 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 keeping a routine in order to keep Peter functioning as well as possible. Mr White's case study included his wife Annabel, Mary a community psychiatric nurse who visited them on a three-monthly basis and his prescriber Dr West.

### **3.2.2.5 Case Study Five**

Mr Chris Green was also recruited from location three and was prescribed galantamine for Alzheimer's disease. After retiring from a high powered engineering post it became increasingly obvious that his memory was causing severe impairment in his ability to carry out day to day activities. He was very well spoken with good social skills and this enabled him to seemingly function at quite a high level on a casual observation. He lived with his second wife, Sue 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 after the death of their mother and although they were (the children) now near to retirement age; they declined to have further contact with him. Mr Green's case study site included his wife Sue and his prescriber Dr East. They had been assigned a community psychiatric nurse but had refused them entry to the house because they did not think they were needed yet.

### **3.2.2.6 Case Study Six**

Mr John Johnson was also recruited from location three and 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 this 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. 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 being "a waste of time."

### **3.2.2.7 Case Study Seven**

Case study seven was the original case study two participant, Mr Harry Smith who had not been able to tolerate cholinesterase inhibitors. He had not been deemed suitable for memantine at the time of these being withdrawn because his dementia was only mild to moderate. However at the time of the observed consultation his condition had progressed and it was decided with the agreement of himself and his wife and son, to start him on memantine. In this case study there was Mr and Mrs Smith and his prescriber Dr South.

## **3.3 Data Collection**

Data collection comprises of qualitative data from interviews with patients, carers, prescribers and appropriate healthcare professionals and also observational data from the 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' monitors patients progress was collated from the participants medical record (with consent) in order to use as a comparator with the qualitative picture.

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 and their carer took place in the participants own homes. All the healthcare professionals and prescribers were interviewed in their place of work.

The summary and timings of the case study sites and respective interviews can be found in Table Two.

### **3.3.1 Interviews of Participants and their Carer**

Although it was intended to interview the person with dementia or memory problem and their spouse individually, all participants wished to be interviewed together. In the case of Mr and Mrs Black, 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 Mrs and Mrs Green it seemed they were afraid of what their other half may say about them if they were interviewed apart.

### **3.3.2 Interviews with all Healthcare Professionals**

Although it had been expected that each person recruited would possibly have a healthcare professional 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. People with dementia or mild cognitive impairment in location one were monitored by the psychologists and then were seen by the clinician once the results were calculated. In location two the prescriber met with the carer while the person with dementia was assessed by the psychologist and then all decisions were made together. In location three the medical and psychological testing was completed by the consultant in dementia services and follow-up was devolved to a community psychiatric nurse (CPN) once the medication was stabilised. However if the patient and their carer refused a CPN visit the follow-up was completed by the consultant or senior house officer once every 3 to 6 months depending on need.

Each of the healthcare professions participating expressed a wish not to talk expressly about the person they cared for in specific terms, but to express their views in a more generic way and use the study patient 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.

### **3.3.3 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.

### **3.3.4 Diary Records**

All participants were asked if they would like to record their thoughts and feelings in a notebook in between planned interviews. Only one couple agreed to do this. Generally it was seen as yet another thing that needed to be done and many of the participants felt they wrote more things down already than they ever used to.

### 3.4 Data Analysis

Each interview was transcribed verbatim by a departmental secretary and then was checked and edited by the researcher in order to clarify confidentiality issues; sound quality issues and problems arising with unfamiliarity with medical jargon. The data was 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 and then across sites. Healthcare professionals and prescribers were analysed separately linking relevant data to the specific case study site as and if appropriate.

Qualitative data was enhanced by accessing medical records of the participants and comparing the objective findings from the clinician with subjective findings arising from the data. 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.

### 3.5 Case Study Results and Discussion

#### 3.5.1 Case Study 1: Mr and Mrs Black

In total five interviews comprised this case study with three involving Mr and Mrs 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 2008 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.”*

Mr Black Interview One page 2

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.”*

Mr Black, Interview One page 6

*“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.”*

Mrs Black Interview One page 14

Mrs Black 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.'"*

Mr Black Interview One page 3

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 Mr and Mrs Black 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. Mr Black 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."*

Mr Black Interview One page

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 Mrs Black 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?'"*

Mrs Black Interview One page 25

Dr North expressed that he found it difficult that there was currently no treatment options available for people like Mr Black and 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

Mr Black and his wife 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.

Mr Black 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. Mr Black'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 persons' prior knowledge or ability can affect the score achieved and perhaps bear no relation to heir functional ability in day to day activities. At the time of collation of results Mr Black's medical notes were unable to be found so feedback from the consultation with the prescriber was not available.

### 3.5.2 Case Study Two: Mr and Mrs Smith

There were three recorded interviews in total for this case study with two from Mr and Mrs 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 Mr Smith 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."*

Mrs Smith Interview One page 5

Although the local community hospital provided support for Mr Smith 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. Mr Smith expressed "we're both no good" and Mrs Smith 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."*

Mrs Smith Interview Two page 3

They spoke of their disappointment of Mr Smith 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. Mr Smith 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 Interview One page 3

However this also meant that there were no further pharmacological options for Mr Smith at this time as memantine was only licensed for moderate dementia. At the observed consultation Mr Smith had deteriorated 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

Mr Smith 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 Mr Smith's MMSE scores is depicted in table three below

**Table Three: Clinic Results for Mr Smith**

Date	MMSE Score (out of 30)	Description of Mr S
12.04.06	17	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
26.07.06	20	MMSE improved, memory not, diarrhoea a problem donepezil stopped
21.10.06	17	
04.11.06	14	
28.11.06	20	Confused and not recognising he is at home; start galantamine
30.11.06		Galantamine stopped after two doses because of diarrhoea
20.03.07	18.5	
08.05.07	12	Increasing memory problems, lack of motivation and poor initiation and conversation. Memantine started

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 Mr Smith. This was also reflected in his physical mobility.

### **3.5.3 Case Study Three: Mr and Mrs Jones**

There were four recorded interviews in total; three with Mr and Mrs 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 Mr and Mrs Jones 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."*

Mrs Jones Interview One page 4

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.”* (Interview Two page 1)

The following excerpt from interview two page 11 illustrates this positive response on improved socialisation very well.

Mr Jones: *“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.”*

Mrs Jones: *“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.”*

Mr Jones: *“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.”*

Mrs Jones: *“And got to the point saying shall we go home?”*

Mr Jones: *“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.”*

Mrs Jones Interview One page 2

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 Mrs Jones was how to increase the mental stimulation of her husband in order to help preserve what cognitive function he had. This conflicted with Mr Jones 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 page 16 was part of a heated discussion on this subject.

Mrs Jones: *“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”.*

Mr Jones: *“No I’ve never sat long enough to read a book”*

Mrs Jones: *“But you could do now.”*

Mr Jones: *“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 Jones**

<b>Symptoms Noted after First Interview</b>	<b>Improvement Since taking Exelon</b>
Lack of conversation	Went to hotel with relatives over New Year and held conversations at table over meals
Quietness	
Wanting to sit quietly	Repaired water barrel pump which has been broken for over a year
Not going to bowling club	Has shown interest in starting to play bowls again next season
Aggressiveness	
Stopped gardening	Has mowed the lawn and done some gardening. Has raked the path
Can't have a discussion without arguing	
Doesn't join in conversations with friends & family prefers to sit quietly	Makes more effort talking with family
No conversation on a car journey	
No interest in money/family/finances etc	
Doesn't play with grandson (age 2)	Now plays with two grandsons
Bad memory of recent things	
Keeps raking up the past	
	Visited Coventry cathedral and went shopping

These were not tabulated by Mrs Jones or linked together as a before and after; 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

Mr and Mrs Jones 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. Mr Jones's short term memory was still poor and they developed a system of prompts to support this but this was outweighed by the benefits to their relationship that the sociability and increased initiative brought.

The comparison of findings from the interviews and information from the medical notes can be found in the table on the following page.

**Table Five: Clinic Results for Mr Jones**

Date	MMSE (out of 30)	Comments in Record
01.11.06	DEMTEC low score (7);	Dementia diagnosed; loss in memory domain (concentration, short term memory & executive function). Off license use of cholinesterase inhibitor
05.04.07	DEMTEC 9	Cognitive testing improved significantly, slowness in processing & short term memory. Motivation and socialisation improved
15.09.07	26	Wife depressed about her increasing duties e.g. organising builders
17.01.08	26	Deficits in orientation and recall. Wife prompts tasks by using lists. Suggest increase in dose to 4.5mg twice daily

Mr Jones 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 by 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.

### 3.5.4 Case Study Four: Mr and Mrs White

There were five recorded interviews in total; three with Mr and Mrs 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 years; 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."*

Mr White Interview One page 1-2

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."*

Mr White Interview One page 2

Although Mr White was at the mild to moderate stage of the illness and also suffered from continuing strokes, they received no extra home help and Mrs W coped with her husband on her own. She strongly believed in the powers of motivation and being organised and Mr White

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”*

Mrs White Interview One page 11

They lived in a residential park and the organisers of the local newsletter relied on Mr White 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 Mrs White gets a break as well.

Mr White had been co-prescribed memantine when Dr West had decided he had “fallen off the plateau” induced but the 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 Mr White 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.”*

Mr White Interview Two page 6-7

However over the course of the study Mr White 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 Mr White 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 Mr White would fall off his plateau once more and there would be very little they could do 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 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 Interview One page 6

#### Over the Course of the Study

Mr and Mrs White remained in the study for 13 months. Mr White 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 very worried and concerned and she used it as more of a session to speak to someone about her concerns about his tiredness which seemed to be greatly increased since prior to the admission. 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**

Target Symptoms	06.12.06	19.12.06	19.02.07	04.09.07	05.10.07
Confidence	Some	Improving	No change	decreased	No change
Visual hallucinations	After infection	No	Decreased	Two events but not distressed	Decreased
Losing items	Wife supervises				
Restless nights	Wife says no, Mr H says sometimes	Sleeps better	More sleepy after TIA January	Mr W yes Mrs W No	No change

**Table Seven: Clinic Results for Mr White**

Date	MMSE (out of 30)	Comments
10.04.03		Alzheimer’s disease diagnosed; rivastigmine started
February 2005	29	Rivastigmine 6mg twice daily
16.02.05	27	Memantine introduced
16.12.06	28	
19.12.06	30	
19.02.07	27	
04.09.07	29	NB Consultant left at this point, no follow-up
13.02.08		Nocturnal agitation clonazepam prescribed. Gradual decline in memory, word finding difficulties
08.05.08		Gradual deterioration over last 2 months; slower and lower in mood. Admits to being depressed as can’t get on top of pain. Sleeps well, good appetite

In the above table, the MMSE scores indicate a mild stage of dementia, however functionally and cognitively Mr White thought the dementia was increasing. Again the MMSE seemed not to reflect the true nature of the individuals cognitive functioning.

### 3.5.5 Case Study Five: Mr and Mrs Green

This case study composed of Mr and Mrs 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. Mr Green 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".*

Mrs Green Interview One page 4

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. Mr Green 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 Mrs Green's ability to drive them anywhere in terms of household related tasks and social outings. Mr Green felt very 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. Mr Green seemed quite insecure at time 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 page 4

Mrs Green 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 and Mr Green explained it such *"I'm quite pleased about it. I can get round quite happily and it's important."* (Interview Two page 2). 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".*

Mrs Green Interview Two page 1

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 his second wife Mrs Green and even refused to meet at a neutral place where she would not 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”*

Mr Green Interview Three page 4

The medication was seen as enabling Mr Green 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 Sue, we have a good laugh at times.”*

Mr Green Interview Three page 5

### Over the Course of the Study

Mr and Mrs Green remained in the study for just over 12 months and over this time there was an improvement in their relationship with less anxiety and irritation displayed by Mrs Green in interviews two and three. Mr Green 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 Green**

Date	MMSE (out of 30)	Comment
06.06.06	18	Diagnosed with Alzheimer’s disease (early stage). Short term memory problems, muddled with dates; function greater than MMSE
01.09.06		Started galantamine XL 8mg once daily, to increase to 16mg once daily after two weeks
30.11.06		Recruited to study
11.11.06		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
03.05.07		Memory stable since last appointment, better since on medication, better activities of daily living
August 2007		Prescriber left and no follow-up
06.06.08	20	MMSE unremarkable, repetitive speech and obvious cognitive impairment

Again the results demonstrate that functionally Mr Green operates at a higher level than his MMSE score might predict, and how the loss of a prescriber can mean reduced patient follow-up.

### **3.5.6 Case Study Six: Mr and Mrs Johnson**

This case study comprised of Mr and Mrs Johnson and his prescriber Dr West. There was no other healthcare professional involved as Mr Johnson 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 Mr Johnson 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 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 Mr Johnson's memory problems were considered to be mild cognitive impairment and the chances of this developing into a dementia had been discussed with him. Mr Johnson 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 amalgams 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 cant 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!"*

Mr Johnson Interview One page 1

Mr Johnson 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."*

Mrs Johnson Interview One page 13

His wife at this stage 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 Mr Johnson on an increasingly closer basis. Her daughter-in-law 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.

Mrs Johnson: *"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?"

Mrs Johnson: *"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.

Mr Johnson 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 from interview one page 15.

*Mrs Johnson: “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?’*

*Mr Johnson: “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.”*

Mr Green Interview One page 15

### 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 Johnson**

Date	MMSE (out of 30)	Comment
12.04.00	24	
08.06.06		Mild cognitive impairment diagnosed
14.12.06		Alzheimer’s disease with vascular component diagnosed
08.03.07	25	Bristol activities of daily living improved by two points and MMSE by one point. Wife more relaxed and willing to smile
19.06.07		Anxiety and tension decreasing, high level of memory, both smiling
14.06.08	23	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

### 3.5.7 Case Study Seven: Mr and Mrs Smith

On the 11<sup>th</sup> April 2007 at a follow-up consultation with their prescriber, Mr 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 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 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 Mr Smith 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

**Table Ten: Clinic Results for Mr Smith**

Date	MMSE Score (out of 30)	Description of Mr H
08.05.07	12	Increasing memory problems, lack of motivation and poor initiation and conversation. Memantine started
18.05.07		Started Day Hospital for stimulation and respite for wife
22.05.07		Mr H well, no further mobility issues at present
05.06.07		Happy with care at present
13.07.07		Increasing pain in legs and difficulty with mobilising and transferring (e.g. from bed to chair)
23.07.07		Mobility and transfer assessment and training completed,
31.07.07		Transferred improved, now has electric wheelchair which he copes with well.
21.08.07		New problem, Mr H refusing to respond to requests
06.09.07		Admitted DGH with cardiac problems
03.10.07		Medically fit for discharge
15.10.07		Suddenly unwell, RIP
No further memory assessments completed		

This table demonstrates the general deterioration over time and how this is also reflected in physical activities and mobility.

### 3.6 Comparison across Case Studies

Interestingly all the participants with a memory problem or a dementia were male. The reason for this is unknown. It could be speculated that female carers make more time to engage with

others, or that male carers feel that they have enough to do without taking part in a research study. However speculation does not really help and this could perhaps be the focus of a study in itself on why people participate in research and others do not.

**Table Eleven: Commonality between Case Studies**

Case Study	Themes	Superordinate Themes
1	69	Living with a Memory Problem, Relationship Dynamics Interacting with Healthcare Professionals.
2	31	Living with Dementia Medicines for Dementia
3	66	Living with Dementia. Relationship Dynamics Interacting with Healthcare Professionals Medicines for Dementia.
4	65.	Living with Dementia; Medicines for Dementia Relationship Dynamics
5	61	Living with Dementia Relationship Dynamics Medicines for Dementia Interacting with Healthcare Professionals
6	59	Living with Dementia Relationship Dynamics Medicines for Dementia Interacting with Healthcare Professionals.
7	0	

### 3.6.1 People with a Memory Problem or a Dementia

People living with a memory problem, whether it be classified as a dementia or mild cognitive impairment without exception found it a frustrating experience and were aware of their sometimes resultant aggressive responses to their spouse. Although there was insight into their behavioural changes after taking the medication, this was not apparent before in six of the seven cases. Mr T only realised he was being a “nasty” person when his son spoke of his concerns to him and his wife of nearly 40 years threatened to leave. This was the jolt he needed to seek referral to a memory clinic via his GP and after being assessed and speaking to healthcare professionals at the clinic he realised that actually there were things he could do about it, and the first one was to accept and admit that he had a problem with his memory.

Many of the participants were very open and honest about their love and high regard for their spouse and how much they owed to their support and care. They also spoke of “being good friends” and how well they got on in their day to day activities.

This acceptance came to all other participants as well summing it up by saying “there’s no point in being miserable” and that they just try to now get on and do what they can do. Although Mr Black was adamant he was “not going senile” for Mr White it was a great fear that he would deteriorate to the point he had be admitted to a nursing home

The medicines for the four people interviewed after start of a medicine for dementia noted the effects in terms of being able to do things that they wanted to do and realising that they needed to converse with their spouse. Many spoke of the fun that they had experienced on social events with friends or family and attributed this to the medication. These were all very positive improvements in quality of life.

They held their prescriber in high regard and all felt relaxed and comfortable when speaking to them. They also felt that they were listened to.

### 3.6.2 The Carers of these People

The spouses of the participants all described in various ways how difficult they found it living with this different person who wasn’t the person that they married and wondering whether it was the end of their lives as they knew it. The accompanying role changes where they had to

become the one that organised and scheduled trips; holidays visits to the shops for example as well as look after the financial matters, all came as a bit of a shock to some. One carer expressing that it was now “too much hassle” to go holiday any more because her husband was “too much of a liability.” She had also begun to realise the full responsibility for caring for someone 24 hours a day was exaggerated when you were holidaying abroad as you always wondered if you would lose them or they would fall ill.

This change in their spouses' behaviour impacted on their own relationship and also on their interaction with friends and wider family. One carer described how all their friends seemed to “disappear out of the woodwork” after the diagnosis and others became embarrassed going out with a partner who just sat beside or across from them and said absolutely nothing.

All carers noted positive response to the medication and in the case of Mrs Smith, the extent of this was only fully appreciated when the medication was withdrawn because of intolerable side effects. The experience of response seemed to be that the memory probably did not improve that much but the motivation, initiative and sociability of their spouses all improved. What was dreadfully missed by all was the lack of conversation that they used to share as a couple and this returned to some extent after the medication had been prescribed.

Interacting with healthcare professionals became a routine part of their lives, especially at the beginning prior to a diagnosis being made when there were regular assessments and checkups, all of which seemed to them delay the time to prescribing and the delay the time to the return of the person they fell in love with.

### 3.6.3 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 Interview One page 1

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 2007<sup>2</sup> which stated that cholinesterase inhibitors should no longer be offered to people with mild Alzheimer's disease (when the 2001<sup>1</sup> 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 Interview One page 7

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 Interview One page 3

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 North Interview One page 3

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 Interview One page 2.

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 Interview One page 6

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 Interview One page 3

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 Interview One page 2-3

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; it’s 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 Interview One page 8

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 for and not being able to understand her husband’s 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 Interview One page 4

### **3.6.4 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 diagnosis into that and that goes to a consultant to look at and that forms part of the assessment.”*

James (psychologist) Interview One page 1

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.”*

Mary CPN Interview One page 3

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) Interview One page 2

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 misplacing 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) Interview One page 6

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 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) Interview One page 6

### **3.7 Observed Consultations**

Four consultations were observed in total: case study two, three, four and five, with three different prescribers.

#### **3.7.1 Case Study Two: Mr and Mrs Smith**

This consultation took place on the 11<sup>th</sup> 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 his 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 on 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. 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.

### **3.7.2 Case Study Three: Mr and Mrs Jones**

The consultation took place in a small room at the memory clinic of location three on the 5<sup>th</sup> 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 and 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.

Dr 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's "not as good as what I want it to be."

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 Mr and Mrs Jones on how the damage by the stroke had affected his speech a little and his speed of processing information. This explanation seemed to encourage Mr and Mrs Jones.

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.

### **3.7.3 Case Study Four: Mr and Mrs White**

This consultation took place at location three and on the same day (5<sup>th</sup> 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.

### **3.7.4 Case Study Five: Mr and Mrs Green**

This interview occurred in location three as described previously but on the 3<sup>rd</sup> 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 his wife] 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 any; might come a time when there is” and that 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 Mr and Mrs Green.

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 and then closed the consultation and made his goodbyes.

### **3.7.5 Commonalities of the Consultation**

Without exception the prescribers were warm and empathic to the people they were caring for. The styles of consultation were generally very relaxed and open and all tried to be very honest and direct with each couple. The assessment procedure was different in each consultation and reasons for this change seemed dependent on whether it was an issue of the licensed use of a medication or whether it fitted with local or national policy.

The participants in the consultation held the prescriber in high regard and were all supportive and accepting of the consultation outcomes

### **3.8 Summary of Findings and Conclusion**

With respect to the perceived overall efficacy of the cholinesterase inhibitors and memantine, it was a very complex picture. It is pertinent to remind ourselves that dementia is 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.<sup>21</sup> It seems obvious therefore that memory is only one consideration in an assessment process

and that by necessity perhaps the assessment should be individualised to the person with the dementia.

Rockwood *al*<sup>22</sup> have been proponents for the monitoring of target symptoms to assess the response to cholinesterase inhibitors and memantine since 2002 explaining that there is such wide inter-variation in response in people that a blanket tool seemed a less robust mechanism.

Living with dementia can have an enormous impact on the relations that the person with dementia holds and so the positive effects of these medicines on sociability; initiative and motivation has the potential to improve the quality of life of those affected.

### **3.9 Implications for Practice**

There were no pharmacists recruited to this study, and they were only mentioned in two case studies in relation to mislabelling of medicines which caused some concern and panic for those concerned. It may be because pharmacists had unfamiliarity of the appropriate doses and dosing schedule of these medicines but no pro-active advice or support seemed to be offered. All of the participants had concomitant medication and had managed to establish their own methods of remembering how to take the medication. However this population group would seem to be an ideal group for inclusion in medication review schemes to ensure the most effective use of medication. Guidance on undertaking medication use reviews for people with dementia was published using my experience in this and earlier research exploring the views of people who take medicines for dementia and their carers.<sup>23</sup>



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