

The use of antipsychotic medication for people with dementia:

Time for action

**A report for the
Minister of State for Care Services
by
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An independent report commissioned and funded by the
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Letter to the Minister of State

Dear Minister of State

I was asked last year to examine the use of antipsychotic medication for people with dementia in the NHS in England, and this is my review.

There have been increasing concerns over the past years about the use of these drugs in dementia. The findings of my review confirm that there are indeed significant issues in terms of quality of care and patient safety. These drugs appear to be used too often in dementia and, at their likely level of use, potential benefits are most probably outweighed by their risks overall. This is a problem across the world, not one just restricted to the NHS. It is positive that, with action, we have the means with which to sort out this problem, quickly and safely.

Looking at the use of these drugs in dementia, it is clear that this is a specific symptom of a general cumulative failure over the years in our health and social care systems to develop an effective response to the challenges posed by dementia. So, it is positive that the National Dementia Strategy provides a framework for us to deal with the specific problem of the overuse of antipsychotic medication. As requested, this review presents clear, practical solutions.

In the course of this review, I have sought to understand the current evidence base, the law, and practice relating to prescription of these drugs in dementia. I have investigated the situation in other countries and sought the views of as many stakeholders as possible, including the public, people with dementia, carers, clinicians, NHS managers and the pharmaceutical industry, among others. This has taken place as part of the consultation and development process for the National Dementia Strategy and, following its publication, as a separate, specific line of enquiry.

Antipsychotic drugs are used for the management of behavioural and psychological symptoms in dementia. The development of such symptoms is a core part of the syndrome of dementia. They can cause major problems for people with dementia and their carers and are a legitimate focus for intervention to decrease distress and harm, and increase quality of life. However, the assessment and management of such behaviours in dementia can be complicated. The systems that we have for dementia treatment and care have grown by chance rather than by active planning or commissioning, and there are important gaps in services and skills. The consequence of this is that while some people

with dementia receive excellent care, for the large majority it appears that current systems deliver a largely antipsychotic-based response. Good practice guidelines are readily available but they do not appear to have been translated into clinical practice.

The evidence base includes gaps, contradictions and complexity but there is an emerging consensus with respect to the level of use and risk of antipsychotic drugs for people with dementia. There is uncertainty in any calculation where the data are incomplete, as in this case, and there is a need to be cautious about inferences made. However, reviewing the evidence, these drugs appear to have only a limited positive effect in treating these symptoms but can cause significant harm to people with dementia. Clearly, some people do benefit from these medications and there are groups (eg where there is severe and complex risk) where trials have not been completed but where there may be particular value in using these medications. Using the best available information, I estimate that we are treating 180,000 people with dementia with antipsychotic medication across the country per year. Of these, up to 36,000 will derive some benefit from the treatment. In terms of negative effects that are directly attributable to the use of antipsychotic medication, use at this level equates to an additional 1,620 cerebrovascular adverse events, around half of which may be severe, and to an additional 1,800 deaths per year on top of those that would be expected in this frail population.

Quality is the overarching principle for the NHS, with “quality at the heart of everything we do”. *High Quality Care for All* stressed the importance of patient safety, stating that “...safety must be paramount for the NHS. Public trust in the NHS is conditional on our ability to keep patients safe when they are in our care”. It is clear from this review that the current level of use of antipsychotics for people with dementia presents a significant issue in terms of quality of care, with negative impacts in patient safety, clinical effectiveness and the patient experience.

A positive finding of this review is that there are actions that we can take to address this problem. In doing so we would provide international leadership in this complex clinical area as well as improving the quality of life and quality of care for people with dementia and their carers in England. This report contains 11 recommendations that will, if implemented, reduce the use of these drugs to the level where benefit will outweigh risk and assure us that patients are being managed safely and effectively.

We need to make reduction in the use of these medications a clinical governance priority across the NHS, with strong national, regional and local leadership from the Department of Health, the Care Quality Commission, strategic health authorities, primary care trusts (PCTs), mental health trusts and acute trusts. We need a cycle of audit that will deliver good quality information on the use of these drugs in dementia and that can be used to drive down the use of these drugs in dementia safely and drive up the quality of initiation, monitoring and maintenance of these medications when they are needed. Leadership is

needed to enable the modest investment and service development needed to achieve this quality improvement.

I estimate that we can reduce the rate of use of antipsychotic medication to a third of its current level. I believe that it is realistic for us to seek to do this safely over a 36 month period.

At the heart of the action is the recommendation that each PCT should commission from specialist older people's mental health services a service that supports primary care in its work in care homes and the community. We will solve this problem by services working together, and there is need for extra capacity to enable a programme of in-reach work to all care homes with people with dementia resident and to GPs in the community. We can build on our existing nationwide network of specialist community older people's mental health services to deliver this.

To achieve and sustain this we also need to extend research on the clinical and cost effectiveness of non-pharmacological methods of treating behavioural problems in dementia and of other pharmacological approaches as an alternative to antipsychotic medication. Training and building skills are at the heart of the sustainability of this plan, and recommendations are made concerning improving the curriculum and skills in primary care and in care home settings, where a national vocational qualification in dementia is proposed.

I have tried to generate a broad practical plan of action with recommendations about how, on the balance of evidence, the Government should proceed. We can make these positive changes with a modest increase in investment coupled with re-designing existing structures to ensure that specialist input is available where needed into key decisions in care planning. I believe that the recommendations presented here offer a consistent, fair and affordable way forward.

I hope that the Government will feel able to accept and implement them.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Sube Banerjee', with a stylized, cursive script.

Sube Banerjee
Professor of Mental Health and Ageing
The Institute of Psychiatry, King's College London

3 October 2009

Summary

1. Dementia is one of the most severe and challenging disorders we face. There are approximately 700,000 people with dementia in the UK; in 30 years, the number of people with dementia will double to 1.4 million. The national cost of dementia is about £17 billion per year; in 30 years, the cost will treble to over £50 billion.
2. The development of behavioural and psychological difficulties (eg agitation, aggression, wandering, shouting, repeated questioning and sleep disturbance) is common in dementia. These cause problems in themselves, which complicate care, and they can occur at any stage of the illness. They are a legitimate object for intervention to decrease distress and harm, and increase quality of life for the person with dementia and their carers. The systems that we have in place to manage behavioural problems in dementia have grown by chance rather than by specific planning or commissioning and there are important gaps in services and skills. Current systems appear to deliver a largely antipsychotic-based response. The first antipsychotic drugs were produced as a treatment for schizophrenia in the 1950s. This first generation is known as the 'typical' antipsychotics. This is to differentiate them from the 'atypical' antipsychotics, which became available from the 1990s. The atypical antipsychotics, have become much more commonly used than the typicals due to their favourable side effect profile. It is clear that these medications are being prescribed to deal with behavioural and psychological symptoms in dementia rather than just for psychosis.
3. The evidence includes gaps, contradictions and complexity but there is emerging consensus with respect to the level of use and risk of antipsychotic drugs for people with dementia. Reviewing the evidence, these drugs appear to have only a limited positive effect in treating these symptoms but can cause significant harm to people with dementia. However, some people do benefit from these medications and there are groups (eg where there is severe and complex risk) where trials have not been completed but where there may be particular value in using these medications. However, it appears that they are too often used as a first-line response to behavioural difficulty in dementia rather than as a considered second-line treatment when other non-pharmacological approaches have failed.
4. There is uncertainty about estimates of risk and benefit where the data are incomplete, and there is a need to be cautious about inferences made. However, on balance, it appears that around 180,000 people with dementia are treated with

antipsychotic medication across the country per year. Of these, up to 36,000 may derive some benefit from the treatment. In terms of negative effects that are directly attributable to the use of antipsychotic medication, use at this level equates to an additional 1,800 deaths, and an additional 1,620 cerebrovascular adverse events, around half of which may be severe, per year. The proportion of these prescriptions which would be unnecessary if appropriate support were available is unclear and will vary by setting, but may well be of the order of two-thirds overall.

5. The high level of use of antipsychotics means that the potential benefit of their use in specific cases is likely to be outweighed by the adverse effects of their use in general. This overuse of antipsychotic medication is a clear, specific example of the general set of problems in the way our health and social care systems serve people with dementia and their carers. We currently have systems that often work poorly; improving the quality of dementia services for all is the aim of the National Dementia Strategy and the findings of this review are complementary to its implementation.
6. Quality has been identified as the overarching principle for the NHS, with “quality at the heart of everything we do”. *High Quality Care for All*, Lord Darzi’s NHS Next Stage Review, stressed the importance of patient safety, stating that “...safety must be paramount for the NHS. Public trust in the NHS is conditional on our ability to keep patients safe when they are in our care”. It is clear from this review that the current level of use of antipsychotics for people with dementia represents a significant issue in terms of quality of care, with negative impacts in its three main underpinning factors: patient safety, clinical effectiveness and the patient experience.
7. The review makes the positive finding that there are clear actions that can be taken to address this problem. In doing so we would be providing international leadership in this complex clinical area as well as improving the quality of life and quality of care for people with dementia and their carers in England. However, there are some simple actions which need to be avoided, such as prohibition or wholesale cessation of these medications. Such actions may themselves compromise patient safety, causing considerable harm and leading to a paradoxical increase in distress for people with dementia and their carers. A measured, planned approach is needed.
8. In this report there are 11 recommendations that will, if implemented, reduce the use of these drugs to the level where benefit will outweigh risk and where we can be assured that patients are being managed safely and effectively. Reduction in the use of these medications needs to be made a clinical governance priority across the NHS with strong national, regional and local leadership from the Department of Health, the Care Quality Commission, strategic health authorities, primary care trusts (PCTs), mental health trusts and acute trusts. We need a cycle of audit that will deliver good quality information on the use of these drugs in dementia and that can be used, over a

two-year period, to drive down the use of these drugs in dementia safely and drive up the quality of initiation, monitoring and maintenance of these medications where they are needed. This leadership is needed to enable the modest investment and service development needed to achieve this quality improvement. This means that decisive local action should be taken, using relevant local data on use of these drugs from the audit, to generate local goals and action planning.

9. A core recommendation is that each PCT should commission from specialist older people's mental health services a service that supports primary care in its work in care homes and the community. This will enable services to work together for the benefit of people with dementia and their carers. There is need for extra capacity in specialist dementia services that can work in all care homes where there are people with dementia and with GPs in these homes and in the community. We can build on the existing nationwide network of specialist community older people's mental health services to deliver this.
10. To achieve and sustain this we also need to extend research on the clinical and cost effectiveness of non-pharmacological methods of treating behavioural problems in dementia and of other pharmacological approaches as an alternative to antipsychotic medication. Training and building skills are of paramount importance in terms of sustainability of good practice, and recommendations are made concerning improving the curriculum and skills in primary care and in care home settings, where a national vocational qualification in dementia is proposed.
11. Making these changes will require modest extra investment in the system of dementia care; without this, the system will not be able to change to deliver the required quality improvements and improvements in patient safety identified. Throughout the review there was a clear message from clinicians, people with dementia and their carers, and commissioners alike that there was a need for an explicit vision of where we should aim to inform and invigorate local action. The following specific recommendations are made. These are presented in the order in which they appear in the structure of the text of the report. The order does not indicate priority – they should all be considered to have equal priority – neither does it indicate the sequence for their implementation.

Recommendation 1: Reducing the use of antipsychotic drugs for people with dementia and assuring good practice when they are needed should be made a clinical governance priority across the NHS. Using their existing clinical governance structures, Medical Directors (or their equivalent) in all primary care trusts, all mental health trusts and all acute trusts should review their level of risk in this area and ensure that systems and services are put in place to ensure good practice in the initiation, maintenance and cessation of these drugs for people with dementia.

Recommendation 2: National leadership for reducing the level of prescription of antipsychotic medication for people with dementia should be provided by the National Clinical Director for Dementia, working with local and national services. He or she should report on a six-monthly basis to the Minister of State for Care Services on progress against the recommendations in this review.

Recommendation 3: The National Clinical Director for Dementia should develop, with national and local clinical audit structures and leads, an audit to generate data on the use of antipsychotic medication for people with dementia in each primary care trust in England. This audit should be completed as soon as possible following the publication of this report, generating baseline data across England. It should be repeated one, two and three years later to gauge progress.

Recommendation 4: People with dementia should receive antipsychotic medication only when they really need it. To achieve this, there is a need for clear, realistic but ambitious goals to be agreed for the reduction of the use of antipsychotics for people with dementia. Explicit goals for the size and speed of this reduction in the use of antipsychotics in dementia, and improvement in their use where needed, should be agreed and published locally following the completion of the baseline audit. These goals should be reviewed yearly at primary care trust, regional and national level, with information published yearly on progress towards them at each level.

Recommendation 5: There is a need for further research to be completed, including work assessing the clinical and cost effectiveness of non-pharmacological methods of treating behavioural problems in dementia and of other pharmacological approaches as an alternative to antipsychotic medication. The National Institute for Health Research and the Medical Research Council should work to develop programmes of work in this area.

Recommendation 6: The Royal Colleges of General Practitioners, Psychiatrists, Nursing and Physicians should develop a curriculum for the development of appropriate skills for GPs and others working in care homes, to equip them for their role in the management of the complexity, co-morbidity and severity of mental and physical disorder in those now residing in care homes. This should be available as part of continuing professional development.

Recommendation 7: There is a need to develop a curriculum for the development of appropriate skills for care home staff in the non-pharmacological treatment of behavioural disorder in dementia, including the deployment of specific therapies with positive impact. Senior staff in care homes should have these skills and the ability to transfer them to other staff members in care homes. A national vocational qualification in dementia care should be developed for those working with people with dementia.

Recommendation 8: Each primary care trust should commission from local specialist older people's mental health services an in-reach service that supports primary care in its work in care homes. This extension of service needs the capacity to work routinely in all care homes where there may be people with dementia. They may be aided by regular pharmacist input into homes. This is a core recommendation of this report and it requires new capacity to be commissioned by primary care trusts in order that the other recommendations can be met.

Recommendation 9: The Care Quality Commission should consider using rates of prescription of antipsychotic medication for people with dementia, adherence to good practice guidelines, the availability of skills in non-pharmacological management of behavioural and psychological symptoms in dementia and the establishment of care home in-reach from specialist mental health services as markers of the quality of care provided by care homes. These data should be available by analysis of local audit data and commissioning decisions.

Recommendation 10: The Improving Access to Psychological Therapies programme should ensure that resources are made available for the delivery of therapies to people with dementia and their carers. Information and support should be available to carers to give them the skills needed to spot behavioural problems quickly, to seek help early and to deploy elements of non-pharmacological care themselves in the home.

Recommendation 11: Specialist older people's mental health services and GPs should meet in order to plan how to address the issue of people with dementia in their own homes who are on antipsychotic medication. Using practice and patient-level data from the completed audits on the use of these medications, they should agree how best to review and manage existing cases and how to ensure that future use follows best practice in terms of initiation, dose minimisation and cessation.

Part 1: Background

Chapter 1: Introduction

1.1 Dementia – a definition

‘Dementia’ is a term used to describe a syndrome that may be caused by a number of illnesses in which there is progressive decline in multiple areas of function, including decline in memory, reasoning, communication skills and the ability to carry out daily activities. Alongside this decline, individuals may develop behavioural and psychological symptoms in dementia (BPSD) such as agitation, aggression, wandering, shouting, repeated questioning, sleep disturbance, depression and psychosis. These cause problems in themselves, which complicate care; they can occur at any stage of the illness.

The causes of these illnesses are not fully understood but they all result in structural and chemical changes in the brain, leading to the death of brain tissue. The main sub-types of dementia are Alzheimer’s disease, vascular dementia, mixtures of these two pathologies (mixed dementia) and rarer types such as Lewy body dementia, dementia in Parkinson’s disease and frontotemporal dementia. The term ‘Alzheimer’s disease’ is used sometimes as a shorthand term to cover all forms of dementia. Here, the term ‘dementia’ is used to cover all forms of dementia, since they share more in terms of symptoms and management, than divide them.

The dementias all share the same devastating impact on those affected and their family carers. Dementias affect all in society irrespective of gender, ethnicity and class. They can affect adults of working age as well as older adults. People with learning disabilities are a group at particular risk. This review is designed to address the use of antipsychotic medication in all people with dementia, no matter the type or their age, ethnic origin or social status.

1.2 The impact of dementia

Dementia is one of the most challenging and complex set of disorders we face. It is also very common. Key data for the UK were calculated and brought together for the

Alzheimer's Society in its report, *Dementia UK: The Full Report*,¹ these include the following:

- There are approximately 700,000 people with dementia.
- In 30 years, the number of people with dementia will double to 1.4 million.
- The national cost of dementia is about £17 billion per year.
- In 30 years, the cost will treble to over £50 billion.
- The incidence of dementia (the number of new cases per year) and the prevalence of dementia (the number of cases at any one time) rise exponentially with age.
- Dementia affects men and women in all social groups.
- Dementia is predominantly a disorder of later life, but there are at least 15,000 people under the age of 65 with the illness.
- People from all ethnic groups are affected by dementia. The current number of people with dementia in minority ethnic groups is around 15,000 but this is set to rise sharply.

Dementia not only has a major impact on those with the disorder, but also has profound, negative effects on family members who provide the majority of care. Family carers are often old and frail themselves and have high levels of carer burden, depression and physical illness, and decreased quality of life. Dementia is a terminal disorder, but people may live with their dementia for 7 to 12 years after diagnosis.

1.3 Current state of dementia services

Dementia UK: The Full Report examined markers of the current state of service provision for people with dementia and this was followed up by investigations by the National Audit Office (NAO)² and the Committee of Public Accounts.³ Taken together they provide a clear picture of the strengths and weaknesses of current systems.

1 Knapp M, Prince M, Albanese E, Banerjee S, Dhanasiri S, et al. *Dementia UK: The Full Report*. London: Alzheimer's Society, 2007.

2 NAO. *Improving Services and Support for People with Dementia*. London: TSO, 2007.

3 Committee of Public Accounts. *Improving Services and Support for People with Dementia*. London: TSO, 2008.

The level of UK diagnosis and treatment of people with dementia is generally low, with international comparisons suggesting that the UK is in the bottom third of European performance in terms of diagnosis and treatment, with less than half the activity of France, Sweden, Ireland and Spain.⁴ *Dementia UK: The Full Report* presented data that demonstrated that there is also high variation in assessment and treatment within the UK with a 24-fold difference between highest and lowest activity by primary care trust (PCT). Work carried out by the NAO for their Value for Money report confirmed that currently only a third of people with dementia receive a formal diagnosis or have contact with specialist services at any time during their illness. Also, such diagnosis and contact often occur late in the illness and/or in crisis, when opportunities for harm prevention and maximisation of quality of life have passed. If dementia is not diagnosed, then the person with dementia and their family carers are denied the possibility of making choices themselves. They are unable to make informed plans for their future and do not have access to the help, support and treatments (social and psychological, as well as pharmacological) that can help them.

All the reports confirm that, contrary to social misconception, there is a very great deal that can be done to help people with dementia, with a major problem being that people are not offered interventions of known effectiveness, such as those summarised in the National Institute for Health and Clinical Excellence (NICE)/Social Care Institute for Excellence (SCIE) Clinical Guideline on Dementia.⁵ The reports conclude that the current care pathways for dementia are failing most people with dementia and their carers. Services need to be re-engineered so that dementia is diagnosed early and well and so that people with dementia and their family carers receive the treatment, care and support following diagnosis that can enable them to live as well as possible with dementia.

One specific area consistently identified as being of major and growing anxiety has been the use of antipsychotic medication for people with dementia, with the apparent high level of its use within care homes of particular concern.

1.4 Improving dementia care – the National Dementia Strategy

These factors together led the Department of Health (DH) to declare in July 2007 that dementia was a national health and social care priority, a commitment confirmed in the 2008/09 NHS Operating Framework. Work to develop a National Dementia Strategy was announced and, following a two-phase formal consultation, this was published in February 2009. The Strategy is an ambitious five-year plan which, if implemented, will result in the positive transformation of health and social care for dementia in England. It presents a comprehensive critical analysis of the current systems of providing health and social for

4 Waldemar G, Phung TT, Burns A, et al. Access to diagnostic evaluation and treatment for dementia in Europe. *International Journal of Geriatric Psychiatry*, 2007, 22, 47–54.

5 NICE/SCIE. *Dementia – Supporting People with Dementia and Their Carers in Health and Social Care*. London: NICE/SCIE, 2006.

people with dementia and their carers and sets out the actions needed to enable people to live well with dementia. It is structured into three broad themes:

- improving public and professional awareness and understanding;
- providing early specialist diagnosis and support for all people with dementia; and
- improving the quality of care from diagnosis right through to the end of life.

It has 17 specific objectives:

Objectives of the National Dementia Strategy

1. Improving public and professional awareness and understanding of dementia.
2. Good quality early diagnosis and intervention for all.
3. Good quality information for those with diagnosed dementia and their carers.
4. Enabling easy access to care, support and advice following diagnosis.
5. Development of structured peer support and learning networks.
6. Improved community personal support services.
7. Implementing the Carers' Strategy.
8. Improved quality of care for people with dementia in general hospitals.
9. Improved intermediate care for people with dementia.
10. Considering the potential for housing support, housing-related services and telecare to support people with dementia and their carers.
11. Living well with dementia in care homes.
12. Improved end-of-life care for people with dementia.
13. An informed and effective workforce for people with dementia.
14. A joint commissioning strategy for dementia.
15. Improved assessment and regulation of health and care services and of how systems are working for people with dementia and their carers.
16. A clear picture of research evidence and needs.
17. Effective national and regional support for implementation of the Strategy.

All of these could have a positive effect on the quality of care provided for those with BPSD and might impact to reduce the use of antipsychotic medication, but objective 11 is of particular importance to this review, for it is within this that the discussion of the use of antipsychotic drugs for people with dementia is placed. The text following the objective identifies that improved quality of care for people with dementia in care homes includes: "Only appropriate use of anti-psychotic medication for people with dementia." One suggested way of achieving this is through the commissioning of specialist in-reach services from older people's community mental health teams to work in care homes, so

providing specialist support for primary care and the home in the prevention, initiation, dose reduction and cessation of these medications. This will be considered in detail later in this report.

However, the issue of the use of these medications in dementia is wider than just the care home population. There needs to be attention to their use in all settings. This includes the community, where people with dementia may be living with a family carer or alone in their own household, in sheltered and other supported housing, in general hospitals, in mental health units and in NHS continuing care settings. This is the broad remit set for this review.

Part 2: Findings

“My mother was prescribed these while I was living at home with her. They were given because she was anxious...from that day onwards her speech diminished and she suffered with the shakes. I haven’t been happy with the drugs for some time. The dose was reduced at my request and Mum started to talk a little more, but then I went on holiday and while I was away the dose was upped again to higher than the original. I do not feel these drugs have benefited my mother in any way and I have seen plenty of negatives.”

Carer of a person with dementia living at home

“While there is a lot of evidence showing the negative effects of taking these drugs, little is written about the sometimes positive effects when a person is very frightened and agitated. It may mean that the person can remain with their carer for a lot longer when taking a small amount of antipsychotic medication.”

Admiral Nurse

“I hold them responsible for his rapid loss of speech, the constant drooling, his mask-like frozen expression, the constant jerking of his right foot that stayed with him for the rest of his life, and rapid onset of incontinence. While still able to walk, he would walk leaning over sideways or backwards at an alarming angle, and no doubt it was this ‘unbalancing’ that caused the hip fractures. Soon he developed epileptic fits and I cannot be sure that it was not related to the antipsychotics.”

Carer of a person with dementia living in a care home

“At 5pm precisely I have to give her medication: warfarin and [an antipsychotic]. Within half an hour the change in her is drastic. On one occasion she has slumped sideways and fainted. She cannot move or talk properly and we virtually have to carry her into the car to take her back. I only found out yesterday just exactly what these [antipsychotics] are for. They had been described previously as ‘to take the edge off the Alzheimer’s’. To be frank I am now worried to death at the consequence of them, considering that [before] she started taking them she never had any trouble with her chest whatsoever.”

Carer of a person with dementia living in a care home

Chapter 2: Use of antipsychotic medication for people with dementia

2.1 What are antipsychotics?

The first antipsychotic drugs were produced as a treatment for schizophrenia in the 1950s; a large number of different drugs were tested and developed in the next three decades and their use became widespread for those with psychotic illnesses. This first generation of antipsychotic medication is now generally known as the 'typical' antipsychotics. This is to differentiate them from the 'atypical' antipsychotics, which became available from the 1990s. Examples of typical antipsychotics include chlorpromazine, haloperidol and trifluoperazine; examples of atypical antipsychotics include risperidone, olanzapine and quetiapine. The clinical differences between the two groups are largely in terms of their side effect profile.

Typical antipsychotics are associated with common and serious adverse effects, including over-sedation, hypotension, involuntary movements (including irreversible late onset tardive dyskinesia), Parkinsonian symptoms (rigidity, tremor and problems with walking) and the rare occurrence of cardiotoxicity (damage to the heart), high fever and vascular collapse (neuroleptic malignant syndrome). Since their introduction, the use of the atypical antipsychotics has become much more common than the typicals due to their generally favourable side effect profile, with the incidence of Parkinsonian side effects and tardive dyskinesia much lower for atypical antipsychotics.

2.2 Why are antipsychotics used in dementia?

The main licensed use for antipsychotics is for the treatment of schizophrenia or bipolar disorder where there is psychosis. Psychosis is not a condition in itself; it is a symptom of other conditions. Psychosis is a term that is used to describe a mental condition where somebody is unable to distinguish between reality and their imagination. Most commonly people with psychosis experience hallucinations – where you hear or see things that are not there – and/or delusions – where you believe things that are untrue.

In Chapter 1, mention was made that people with dementia may develop BPSD which cause problems in themselves, which complicate care and which can occur at any stage of the illness. These include agitation, repetitive questioning, depression, aggression,

wandering and psychosis. BPSD are very common, with point prevalence estimates (ie the proportion having any problem at a single time point) ranging between 60% and 80%, and a cumulative risk of 90% across the course of the illness.⁶ They also cluster together, so people with dementia are commonly affected by multiple,^{7,8} and recurrent, behavioural problems.⁹ BPSD are distressing and problematic for carers as well as the person with dementia; they make a large and independent contribution to caregiver strain¹⁰ and are a common precipitating factor for institutionalisation.

There are questions about whether the psychosis associated with dementia is exactly the same as the psychosis in other illnesses, but one of the reasons for the prescription of antipsychotics in dementia is to treat such psychosis. However, psychosis is relatively rare in dementia compared with the absolute level of prescribing and it is clear that these medications are being prescribed to deal with BPSD in a more general sense, for behaviours including agitation, aggression, wandering, shouting, repeated questioning and sleep disturbance.

Relatively soon after their introduction in the 1950s, the typical antipsychotics became the medications most used for the pharmacological treatment of BPSD. Up to the turn of the century, the use of such drugs as haloperidol, thioridazine and promazine to treat BPSD was relatively common. However, people with dementia are generally much older, are more frail and have greater levels of co-morbid physical illness (ie having a mental disorder and one or more physical disorders at the same time) than the working-age adults these drugs were designed for and tested on. This means that people with dementia are much more sensitive to the side effects of typical antipsychotics such as Parkinsonism, disorders of movement and QT prolongation (interference with conduction in the heart) and that these are more disabling. Particular concerns about the adverse effects on the heart attributed to thioridazine and the severity of side effects from other typical antipsychotics, such as haloperidol and promazine, meant that once the atypical antipsychotics had become available and people had become used to their prescription for psychosis there was a switch to the use of atypical antipsychotics and away from the older medications. The consequence of this is the current situation, where atypical antipsychotics are the most commonly used drugs for the pharmacological treatment of BPSD.

- 6 Parnetti L, Amici S, Lanari A, Gallai V. Pharmacological treatment of non-cognitive disturbances in dementia disorders. *Mechanisms of Ageing and Development*, 2001, 122(16), 2063–9.
- 7 Lyketsos CG, Steele C, Galik E, et al. Physical aggression in dementia patients and its relationship to depression. *American Journal of Psychiatry*, 1999, 156(1), 66–71.
- 8 Levy ML, Cummings JL, Fairbanks LA, et al. Longitudinal assessment of symptoms of depression, agitation, and psychosis in 181 patients with Alzheimer's disease. *American Journal of Psychiatry*, 1996, 153(11), 1438–43.
- 9 Holtzer R, Tang MX, Devanand DP, et al. Psychopathological features in Alzheimer's disease: course and relationship with cognitive status. *Journal of the American Geriatrics Society*, 2003, 51(7), 953–60.
- 10 Black W, Almeida OP. A systematic review of the association between the behavioral and psychological symptoms of dementia and burden of care. *International Psychogeriatrics*, 2004 16(3), 295–315.

Such treatment (principally with risperidone, olanzapine, quetiapine and aripiprazole) is largely unlicensed or 'off-label'; in most countries, few or no treatments have been given regulatory approval for such use. In the UK the only drug with a relevant licence is risperidone, which is indicated for the "short-term treatment (up to six weeks) of persistent aggression in patients with moderate to severe Alzheimer's dementia unresponsive to non-pharmacological approaches and when there is a risk of harm to self or others".

2.3 Concerns regarding the safety of antipsychotic drugs in people with dementia

All drugs have side effects (or adverse effects) as well as intended effects; their impact depends on their nature, their severity and the likelihood of experiencing them. However, not all people are affected equally. Generally, fit young people are less troubled by side effects than older frail people. As noted above, people with dementia may well fall into a high-risk group for side effects on the basis of age, frailty, physical co-morbidity and interactions with other drugs being taken. However, increased risk may also apply to particular groups. It has become clear that people with dementia as a whole are at higher risk of potentially serious adverse effects from antipsychotic medication.

In October 2002 the manufacturer of risperidone notified Canadian healthcare professionals that in drug-sponsored clinical trials, risperidone users had been found to have a higher rate of cerebrovascular adverse events (CVAEs) relative to those receiving placebo. In 2003, the US Food and Drug Administration (FDA) and other authorities published warnings and required changes to the prescribing information for risperidone.¹¹ In 2004 the European Medicines Agency (EMA) also issued public advice about an increased risk of CVAEs and mortality in elderly patients with dementia receiving olanzapine. In March 2004, the UK Medicines and Healthcare products Regulatory Agency (MHRA) informed clinicians that risperidone and olanzapine should not be used to treat BPSD because of increased risk of strokes with both drugs. Similarly, in 2005 the FDA issued warnings for aripiprazole regarding the risk of CVAEs, including stroke, in elderly patients with dementia.¹² In April 2005 the FDA informed health professionals of the results of an independent, pooled analysis of 17 randomised controlled trials (RCTs)¹³ reporting a 1.7 times increased risk of all-cause mortality associated with atypical antipsychotic use compared with placebo.

11 Black W, Almeida OP. A systematic review of the association between the behavioral and psychological symptoms of dementia and burden of care. *International Psychogeriatrics*, 2004 16(3), 295–315.

12 Food and Drug Administration. *Patient Information Sheet. Aripiprazole*. Center for Drug Evaluation and Research, 2005.

13 Schneider LS, Dagerman KS, Insel P. Risk of death with atypical antipsychotic drug treatment for dementia: meta-analysis of randomized placebo-controlled trials. *JAMA, the Journal of American Medical Association*, 2005, 294(15), 1934–43.

2.4 The extent of use of antipsychotics in the older population, and among those with dementia

These are worrying findings; however, their impact depends not only on the large numbers of people with dementia but also on the proportion of those that are given these medications. In reviewing the data available it is striking how poor the evidence base is, with few data routinely collected with which to judge the extent of the potential problem.

There are surprisingly few published data on the level of use of antipsychotic medication among older people in general or people with dementia in particular in the UK. Censuses of the residential and nursing home populations in Leicestershire indicated a stable prevalence of antipsychotic prescribing for cognitively impaired residents between 1990 (29.1%) and 1997 (30.7%).¹⁴ A more recent study in 12 nursing homes across 3 English cities (London, Newcastle and Oxford) found 168 (48%) of 348 people with dementia to be on an antipsychotic.¹⁵ A recent report from IMS Health, a provider of pharmaceutical market information, based on data capture from suppliers and anonymised patient records, suggested that 20.3% of prescriptions for the treatment of people with a recorded diagnosis of dementia included an antipsychotic drug, a similar proportion to Italy and Spain.¹⁶ However, these data are limited in their generalisability because up to two-thirds of people with dementia in the UK do not have a formal diagnosis made and so it will not be on their notes.

In the USA 2004 National Nursing Home Survey, 24.8% of all nursing home residents received antipsychotic medication; 23.5% received atypical antipsychotics and 1.9% typical antipsychotic medication.¹⁷ As an index of the large number of potential indications for antipsychotic medication, its use was independently associated with diagnoses of schizophrenia (odds ratio (OR) 11.2), bipolar disorder (OR 4.0), dementia (OR 2.2), anxiety (OR 1.7), Parkinson's disease (OR 1.3) and depression (OR 1.2). Some 33.1% of residents with dementia had been prescribed antipsychotic medication. Complete population prescription data from the Canadian province of Manitoba¹⁸ indicates that the prevalence of antipsychotic use among those aged over 65 years increased between 1996 and 2006 from 2.9% to 4.3% in men and from 4.1% to 6.0% in women. The prevalence of antipsychotic use in older adults was two to three times higher than among those under

14 Lindsay J, Matthews R, Jagger C. Factors associated with antipsychotic drug use in residential care: changes between 1990 and 1997. *International Journal of Geriatric Psychiatry*, 2003, 18(6), 511–9.

15 Fossey J, Ballard C, Juszcak E, et al. Effect of enhanced psychosocial care on people with severe dementia: cluster randomised trial antipsychotic use in nursing home residents. *British Medical Journal*, 2006, 332, 756–76.1

16 IMS Health, 2009. Issues Bulletin: The Use of Medicines in Dementia Care. London: IMS, 2009.

17 Kamble P, Chen H, Sherer J, Aparasu RR. Antipsychotic drug use among elderly nursing home residents in the United States. *American Journal of Geriatric Pharmacotherapy*, 2008, 6(4), 187–97.

18 Alessi-Severini S, Biscontri RG, Collins DM, et al. Utilization and costs of antipsychotic agents: a Canadian population-based study, 1996–2006. *Psychiatric Services*, 2008, 59(5), 547–53.

65 years of age. Although not quantified precisely, it was stated that “the majority” of antipsychotic prescriptions among older people were atypicals for people with dementia.

In Ontario, Canada, numbers and rates of older people with dementia who were prescribed antipsychotic drugs increased over the period 2000–07¹⁹ – from 1.1% to 1.8% of the whole over-65-year-old population (roughly a quarter to a third of all people with dementia). Of the people with dementia receiving antipsychotic prescriptions, 41.8% were aged over 85 years and 70.5% were nursing home residents. The evidence from Ontario suggests only a modest impact of the several pharmaceutical company and regulatory authority warnings regarding serious adverse events on prescribing behaviour. Despite these warnings there was an overall increase in prescriptions of antipsychotics to people with dementia over the period 2000–07; there was evidence of a slight slowing in the rate of increase of antipsychotic prescriptions temporally linked to the warnings. For older people with dementia, the market share of risperidone (45.5% in 2000 and 45.8% in 2007) and olanzapine (21.2% in 2000 and 22.3% in 2007) remained fairly stable, but there was a switch away from typical antipsychotics (35.0% in 2000 and 5.2% in 2007) and a large increase in the use of quetiapine (2.4% in 2000 and 31.9% in 2007).

In support of this review the NHS Information Centre for Health and Social Care completed analyses using the IMS Disease Analyzer. The sample includes practices from England, Wales, Scotland and Northern Ireland and has a representative UK sample by age and sex. This analysis is based on a sample of 1,098,627 patients available in their practice for the whole of the 12-month period from 1 April 2007 to 31 March 2008. This yielded 192,190 people (17.5%) over the age of 65, of whom 10,255 (5.3%) received a prescription for an antipsychotic. This overall proportion is similar to that reported for Manitoba, Canada (4.3% in men and 6.0% in women). In the Canadian data, the inference is made that up to two-thirds of these prescriptions are likely to be for other indications (eg schizophrenia and bipolar disorder). However, in the UK context, where these other indications for antipsychotic use are relatively rare in those over the age of 65 and where the prevalence of dementia in this population would be predicted to be around 6%, this is a worryingly high prescription rate, equating to at least 50% of people with dementia overall who may be prescribed an antipsychotic in a particular year. No information is available from this dataset to enable an estimation of the numbers in care homes and in the community.

Taken together these data suggest that, as a conservative estimate, up to a quarter of people with dementia in the UK may be on antipsychotics at any time. This equates to 180,000 people with dementia being treated with antipsychotic medication by the NHS. This is a high level of prescription of these medications that have potentially harmful

19 Valiyeva E, Herrmann N, Rochon PA, et al. Effect of regulatory warnings on antipsychotic prescription rates among elderly patients with dementia: a population-based time-series analysis. *Canada Medical Association Journal*, 2008, 26, 179(5), 438–46.

effects on this vulnerable population. Given the nature of the NHS, the large majority of the medications will be prescribed by GPs, with a strong suggestion that people with dementia in care homes may be at particular risk. However, in order to understand the risk properly we need to understand and quantify the risks and benefits of this medication. In the next chapter, the evidence for the positive and negative effects of antipsychotics in dementia is summarised.

Chapter 3: Positive and negative effects of antipsychotic medication for people with dementia

3.1 Introduction

Examining the literature, there is a clear emerging consensus about the positive and negative effects of antipsychotic drugs. This review has benefited from being able to access the results of up-to-date, well-conducted and authoritative systematic reviews of the scientific literature and meta-analyses of the data available.^{20,21,22} In addition, for this review, a further systematic review estimating the aggregate public impact of antipsychotic use in dementia was commissioned from Professor Martin Prince and his team in the Centre for Public Mental Health at the Institute of Psychiatry, King's College London. Summaries from this review are presented below; the review is available in full via the Department of Health (DH) Dementia Information Portal at www.dementia.dh.gov.uk/.

3.2 Methodological considerations and limits to inference

Well-conducted RCTs provide the strongest possible evidence for assessing the efficacy, tolerability and safety of drug treatments. Randomisation effectively removes the possibility of confounding, and blinding limits information bias. All things being equal, observed differences between the drug treatment and placebo arms can be **causally** attributed to the drug being evaluated. However, there are several limitations to this source of evidence, some of which are of particular relevance to the trials conducted in this area.

Many of the individual trials are small in size, and are hence underpowered (not big enough) to detect small, but still important, differences in the rates of relatively uncommon adverse events. This is particularly the case with regard to mortality and CVAEs, where the associations only began to become apparent following meta-analytical synthesis of findings

20 Ballard, C, Howard R. Neuroleptic drugs in dementia: benefits and harm. *Nature Reviews Neurosciences*, 2006, 7, 492–500.

21 Schneider L S, Dagerman K, Insel, P S. Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. *American Journal of Geriatric Psychiatry*, 2006, 14, 191–210.

22 Ballard C G, Gauthier S, et al, Robert P, Lyketsos CG. *Nature Reviews Neurology* 2009, 5, 245–55.

(ie looking at all the data together in the same way) from all available published and unpublished trials. Meta-analysis is an appropriate technique where the drugs being evaluated, the patients recruited, the trials designed and the outcomes studied are fairly homogeneous. Since, with the exception of the effect of risperidone on CVAEs, no statistically significant effect on mortality or CVAEs was observed for any individual atypical antipsychotic agent, we need to assume that any genuine effect of these agents is a class effect that applies in the same way across risperidone, olanzapine, quetiapine, aripiprazole and all others, to justify the pooling of data across trials.

The trials were generally of short duration (two to four months) and do not therefore provide information on the effects of longer-term prescribing of these agents. There are some areas of interest that trials have simply not covered in any detail, such as the use of antipsychotics for sleep disturbance in dementia, and so no conclusions can be drawn from the literature in these important areas. In statistical terms, intention-to-treat (ITT) analyses (counting all those randomised to a particular treatment at the beginning of the trial as having been on that treatment no matter what happened in terms of the use of the medication over the life of the trial) are the 'gold standard', as an appropriately conservative approach to establish efficacy. However, many participants will not take their allocated medication, or may switch from placebo to active medication. Protocol analyses, in which the exposure reflects what the patient actually took, may also be useful when considering possible adverse effects, the size of which may be underestimated in ITT analyses.

Selection criteria for RCTs are often stringent, with multiple exclusions both for reasons of safety and to ensure a relatively 'pure' assessment of the potential efficacy of the drug. As such, trial participants may not reflect the generality of older people with dementia who may be prescribed antipsychotic drugs. In many cases, these people may have more severe dementia and BPSD, more general medical co-morbidity and hence a higher baseline risk of CVAE and mortality. The trials therefore generate data on the efficacy (its use in ideal circumstances) of the medications, when what is needed for accurate risk assessment and clinical decision-making are data on the clinical effectiveness of the drugs (ie their effects when deployed in normal clinical populations, not the highly selected subgroup recruited into trials).

Evidence from observational epidemiological studies can be used to complement the evidence from RCTs. Epidemiological studies can potentially provide important information from large and representative samples of 'real-world' patients. There is more scope to study multiple pharmacological exposures together with lifestyle and clinical risk factors. Most of the studies cited are based on a longitudinal design (either prospective or retrospective cohort studies, or case-control studies with contemporaneous records of historical exposures), which reduces the possibility of information bias and allows consideration of direction of causality. Follow-up periods are generally much longer than for clinical trials.

The main challenge to the validity of observational pharmacoepidemiological research in this area is confounding. Put simply, the decision to prescribe antipsychotic medication to a person with dementia is based on the presence of an indication (BPSD) and the absence of a contraindication (eg a severe heart problem). Confounding by indication or contraindication occurs when **these factors, rather than a direct action of the drug itself**, are associated with the outcome of interest. Thus, people with dementia and BPSD may be more likely to die (and to be prescribed antipsychotic drugs) than people with dementia and no BPSD. None of the observational studies reviewed control directly for BPSD. Some studies have attempted to control for this; nevertheless, residual confounding by indication and contraindication is likely to be significant in most of these studies, severely limiting their utility. Having accepted these important caveats, it is notable that the evidence from observational studies is, on the whole, consistent with that from RCTs (where such residual confounding is not possible due to randomisation) in indicating an increased risk of mortality and CVAEs, and no effect of antipsychotic use on fractures.

For this review the evidence pertaining to the balance of benefits and risks associated with the use of these medications was re-appraised in order to present it in a single, accessible way. Specifically, with respect to benefits, the evidence from randomised, placebo-controlled trials on the efficacy of typical and atypical antipsychotics for the treatment of behavioural disturbance and psychosis in dementia was systematically reviewed. With respect to harm, the aim was to update and systematically review the available randomised and non-randomised evidence for the relationship between antipsychotic use in dementia and:

- all-cause mortality;
- CVAEs; and
- falls and fractures.

While there is extensive literature on other important side effects of antipsychotic drugs, these three outcomes are among the most serious, impactful and irreversible, and hence are salient to a risk–benefit analysis.

The overall strategy in presenting the findings was:

- To report effect sizes for possible treatment benefits in standardised form to compare directly the effects of different antipsychotic agents and their clinical relevance (standardised mean differences for continuous outcomes and numbers needed to treat (NNT) for dichotomous outcomes).

- To report effect sizes for adverse event outcomes in a way that allows risk–benefit analysis (numbers needed to harm (NNH)).

NNH is the estimated number of patients who need to be treated with the new treatment rather than the control condition for one additional patient to experience the adverse outcome, and is calculated as the reciprocal of the absolute risk increase. NNT is the number needed to obtain one favourable outcome beyond that which would have been achieved by the placebo; it is obtained by taking the reciprocal of the absolute risk reduction.

3.3 Conclusions on the positive and negative effects of antipsychotic medication on people with dementia

Antipsychotic drugs show minimal efficacy for the treatment of BPSD. Effect sizes for most atypical antipsychotic drugs on the outcome measures that assess global behavioural disturbance are in the range of 0.1 to 0.2, which is very low. There is some evidence to support slightly greater efficacy for risperidone for the treatment of aggression, as opposed to non-aggressive agitation, with effect sizes in the region of 0.3. NNT to achieve clinically significant improvement in one additional behaviourally disturbed patient range from 5 to 11.

The few direct randomised comparisons of haloperidol with risperidone suggest no, or minimal, difference in efficacy on behavioural outcomes. Although the evidence base for haloperidol is much more limited than for atypical antipsychotic drugs, it seems to have a similar minimal efficacy for the treatment of global behaviour disturbance, and aggression. Use of haloperidol is, however, associated with a higher incidence of extrapyramidal and other side effects.²³

There is very limited evidence for the efficacy of atypical or typical antipsychotic drugs for the treatment of symptoms of psychosis in dementia. A clinically significant degree of improvement has only been demonstrated for aripiprazole, with NNT of 13.8.²⁴

There is evidence from randomised, placebo-controlled trials of increased mortality associated with the use of atypical antipsychotic drugs. The pooled relative risk is 1.41 (95% CI 0.99–2.03) and the absolute risk difference is 1.0% (95% CI +0.1% to +1.8%). NNH suggest that 100.0 people with dementia would need to be treated to result in one additional death over the typical 6–12-week follow-up period. The suggestion of an

23 Chan WC, Lam LC, Choy CN, et al. A double-blind randomised comparison of risperidone and haloperidol in the treatment of behavioural and psychological symptoms in Chinese dementia patients. *International Journal of Geriatric Psychiatry*, 2001, 16(12), 1156–62.

24 Schneider L S, Dagerman K Insel, P S. Efficacy and adverse effects of atypical antipsychotics for dementia: meta-analysis of randomized, placebo-controlled trials. *American Journal of Geriatric Psychiatry*, 2006, 14, 191–210.

increased mortality risk is supported by a number of large observational studies (retrospective cohort design) that consistently indicate a similar relative risk. These observational studies indicate that the increased mortality risk persists for at least six months after initial prescription.

There is insufficient evidence from RCTs to establish an increased mortality risk associated with the use of haloperidol and other typical antipsychotics in dementia. However, data from observational studies that either compare all older users of atypical and typical antipsychotics or restrict these comparisons to older people with dementia consistently suggest a higher mortality (around 30%) among users of typical antipsychotics. Some of the higher risk observed among those prescribed haloperidol may arise from the common use of this drug for the treatment of delirium. Nevertheless, it seems reasonable to conclude that the increased mortality risk is at least as high for typical as for atypical antipsychotic drugs, and may be higher.

There is consistent evidence from RCTs of risperidone and olanzapine that use of these drugs in dementia is not associated with an increased incidence of falls, at least over the typical 6–12-week duration of these studies. There is limited and inconsistent evidence from observational studies regarding the association between antipsychotic use and falls. The two available studies were not limited to people with dementia and did not control adequately for the clinical indication for antipsychotic prescription. The more extensive observational evidence on antipsychotic use and fractures tends to suggest an absence of association, once dementia and cognitive impairment (each independently associated with risk of fracture) have been controlled for. It is unclear why gait disturbance, which is much more common in placebo-controlled trials among those allocated to atypical antipsychotics, should not translate into a higher incidence of falls and fractures, other than if concomitant reductions in agitation and mobility offset this risk factor.

Meta-analysed evidence from 15 randomised placebo-controlled trials of atypical antipsychotics provides robust evidence for an increased risk of CVAEs, with a pooled relative risk of 2.57 (95% CI 1.41-4.66) and an absolute risk difference of +1.7% (95% CI +0.9% to +2.5%). NNH suggest that 58.8 people with dementia would need to be treated to result in one additional CVAE over the typical 6–12 week follow-up period. Similarly large increases in risk have been observed consistently in two retrospective cohort studies from Italy, an incident case-control study from the Netherlands and a self-controlled case series study from the UK. One null finding from a nursing home case-control study in the USA²⁵ is most probably explained by clear selection bias, and the

25 Liperoti R, Gambassi G, Lapane KL, et al. Cerebrovascular events among elderly nursing home patients treated with conventional or atypical antipsychotics. *Journal of Clinical Psychiatry*, 2005, 66(9), 1090–6.

other, from a retrospective cohort study among US veterans²⁶ by lack of power and the relatively long 18-month follow-up period. There is evidence to suggest that the increased risk of CVAEs may be concentrated in the first few weeks of use, and that those with a past history of cerebrovascular events may be particularly at risk.

3.4 Summary of risks and benefits at a population level of the use of atypical antipsychotics for BPSD in people with dementia

Summarising the risks and benefits using NNT and NNH, the data here suggest that treating 1,000 people with BPSD with an atypical antipsychotic drug for around 12 weeks would result in:

- an additional 91–200 patients with behaviour disturbance (or an additional 72 patients of 1,000 with psychosis) showing clinically significant improvement in these symptoms;
- an additional 10 deaths;
- an additional 18 CVAEs, around half of which may be severe;
- no additional falls or fractures; and
- an additional 58–94 patients with gait disturbance.

It is important to recognise that this balance of risks and benefits might alter markedly with longer periods of treatment. While it is unlikely that incremental treatment benefits would accrue over time, there is evidence, at least for mortality, that adverse events are likely to accumulate. Thus, in the DART-AD trial,^{27,28} continuation compared with cessation of antipsychotic medication was associated with increased mortality; NNH were 21.9 at one year but down to 6.0 at two years. This may suggest, under the scenario described in the paragraph above, that longer-term treatment may result in up to 167 additional deaths among 1,000 people with dementia treated with antipsychotics over a two-year period. So, these data suggest that mortality may increase with length of time taking antipsychotics.

26 Barnett MJ, Wehring H, Perry PJ. Comparison of risk of cerebrovascular events in an elderly VA population with dementia between antipsychotic and non antipsychotic users. *Journal of Clinical Psychopharmacology*, 2007, 27(6), 595–601.

27 Ballard C, Hanney ML, Theodoulou M, et al. The dementia antipsychotic withdrawal trial (DART-AD): long-term follow-up of a randomised placebo-controlled trial. *The Lancet Neurol*, 2009, 8(2), 151–7.

28 Ballard C, Lana MM, Theodoulou M, et al. A randomised, blinded, placebo-controlled trial in dementia patients continuing or stopping neuroleptics (the DART-AD trial). *PLoS Medicine*, 2008, 1;5(4), e76.

Conversely, there is evidence from observational studies to suggest that the increased risk of CVAEs may be more or less confined to the two to three-month period typically encompassed in an RCT follow-up; as such, the extrapolation in the meta-analysis conducted by the Committee on Safety of Medicines²⁹ that NNH of 37 from the 8–12-week trial data would translate into NNH of 6.3 over one year (an additional 159 CVAEs per 1,000 prescriptions) may be unduly pessimistic.

Summary of negative impacts of antipsychotics for those with dementia

If, at any one time, we are treating approximately 180,000 people with dementia with antipsychotic medication in any year, and we make the conservative assumption that the average treatment episode is the 6–12 weeks used in trials, this equates to the following:

- an additional 1,800 deaths per year; and
- an additional 1,620 CVAEs, around half of which may be severe.

29 www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON1004298

Chapter 4: Analysis of the use of antipsychotic medication in dementia

4.1 Good practice in the use of antipsychotics for people with dementia

In conducting this review submissions were received from a number of organisations and individuals, listed at Annex 1. Taking all the data provided together, a clear picture emerges with respect to good practice in the prescription of antipsychotic medication for people with dementia who suffer BPSD. This picture is in accord with that presented in the NICE/SCIE clinical guideline on dementia.³⁰ It can be summarised as follows:

- Antipsychotics should not be a first-line treatment except in circumstances of extreme risk and harm.
- The first line of management should be detailed assessment to identify any treatable cause of the BPSD (eg delirium, pain, depression); this should include taking the history of the problem, having the behaviour described by the carer/team, discussing current and past behaviour with the carer/team.
- All treatable causes should be treated with the correct specific treatment (eg antibiotics for infection or antidepressants for depression).
- An analysis should be made of whether the behaviour (eg reversal of sleep–wake cycle so that the person with dementia is awake at night) is a problem primarily for the person with dementia, or for their carers (be they paid carers or family carers).
- There is a high rate of spontaneous recovery (or placebo effect) in trials, so watchful waiting may be useful in the case of less severe problems since up to half of all cases may be self-limiting.
- Benign complementary approaches may be used.

30 NICE/SCIE. *Dementia – Supporting People with Dementia and Their Carers in Health and Social Care*. London: NICE/SCIE, 2006.

- Where intervention is needed, psychological approaches such as structured social interaction should be used in the first instance.
- Where medication is considered, the person to whom it is to be given should be as involved as possible in decision-making, although many will lack the capacity to consent. In all cases relatives, particularly the main family carer, and other carers or advocates should be involved in discussions about the use of the medication. They should be given information on the possible positive and negative effects of the medication and be invited to contribute fully to the discussion. Ultimately the decision on whether to prescribe the medication or not will be a 'best interests' decision.
- Where behaviour is severe and complicated and medication is indicated, then an atypical antipsychotic is to be preferred over a typical one.
- The medication should be used at the lowest possible effective dose, for the shortest possible time, ideally less than 12 weeks.
- Once initiated, the drug's continuation should be reviewed regularly (at least monthly); at review, reduction or cessation of the medication should be actively considered.

4.2 Current practice in use of antipsychotics for people with dementia

From the evidence available, it is clear that there are particular risks associated with the use of antipsychotics in people with dementia. Antipsychotics appear to be used all too often, in secondary as well as primary care, as a formulaic first-line response to any behavioural difficulty in dementia rather than as a considered second-line treatment when other approaches have failed. The data suggest that antipsychotics are used too often in dementia. The high level of initiation and maintenance of these medications in this vulnerable group means that any potential benefit of their use in specific cases is likely to be outweighed by the serious adverse effects of their use in general. This situation is compounded by our not knowing which cases might respond best.

So why is this happening? There are clear guidelines and the risks have been communicated widely, and yet clinical behaviour appears not to have changed. In order to generate a plan that will really work we need to understand the determinants of this behaviour and the reasons for its persistence. The analysis here is that this is a clear specific example of the general set of problems that have become evident in the way our health and social care systems serve people with dementia and their carers. At present, these systems work only poorly for people with dementia. There is little in the way of specialist care available, and what there is is generally restricted to high risk groups with a

high threshold for referral from primary care. So, old age psychiatric services will cater for people whose behaviour is severe or life-threatening, but are not resourced to help primary care services manage all those with dementia in the community and in care homes. Geriatric medicine services have to deal with those with complex physical co-morbidity, but activities outside their general hospital wards are limited by their resourcing and organisation. Neurology services will make diagnoses of those with atypical and complex neurological symptomatology, often younger individuals, but they are in no way resourced to provide a diagnostic or management service for all with dementia. The system is not geared to early intervention, to provide specialist help for primary care, or to the possibility of the prevention of harm in the later stages of dementia.

These findings are in accord with the conclusions of the National Dementia Strategy and the reports from the Alzheimer's Society, the NAO and the PAC discussed above. This widespread acknowledgment of the overall problem is potentially helpful since it enables the formulation of a sustainable effective response to the specific issue of the use of antipsychotic medication.

4.3 Fundamental issues in the use of antipsychotics for people with dementia

The fundamental issue here is that the vast majority of dementia healthcare in the current system is devolved, by default, to primary care staff with little training in the management of dementia and with little support commissioned from secondary care services, except in the most extreme circumstances. The same is true in the social care context, in settings such as care homes where a third of people with dementia live. This skill and knowledge gap has been acknowledged by GPs themselves in successive studies completed by the Audit Commission and the NAO. Only 31% of GPs believed they had received sufficient basic and post-qualification training to diagnose and manage dementia,³¹ a decrease since the same question was asked for the *Forget Me Not* report³² some eight years before. This apparent decrease in confidence is understandable, as the world of dementia diagnosis and therapy is moving very quickly in terms of new knowledge and treatments.

Current knowledge is moreover based on very thin foundations, since the current and past undergraduate and postgraduate curricula for all doctors and nurses have to date included very little on dementia, so that basic levels of knowledge are low. This unpreparedness must be seen in the context of there often not being sufficient time to communicate with people with dementia and their carers so as to understand the issues and to formulate

31 NAO. *Improving Services and Support for People with Dementia*. London: TSO, 2007.

32 Audit Commission. *Forget Me Not*. London: TSO, 2000.

plans. Finally, there is a lack of ability across the primary care workforce to advise on or deliver the non-pharmacological care that might be of benefit.³³

These shortcomings are set against a backdrop of a rapidly increasing number of people with dementia in primary care. The number of people in the UK with dementia is growing exponentially, with a doubling expected in the next 30 years, from 700,000 to 1.4 million. Part of the reason for health and social care systems not being geared up to dementia is that this recent rapid growth in numbers has not been matched by service changes to accommodate different need. Just a generation ago there were far fewer cases of dementia and far less that could be done; yet the system has not changed in terms of workforce or training to help primary care staff to diagnose and treat people with dementia. Consequently, there is a widespread flight from diagnosis in primary care and the stigma of dementia is felt strongly. Societal misconceptions concerning the normality of dementia as a part of ageing and the idea that there is nothing positive that can be done may be as strong in primary and social care staff as they are in the general population.

One of the areas where primary care services are particularly likely to be in contact with people with dementia is in care homes. Here there has been almost no acknowledgement, in commissioning or service provision terms, of the massive changes in case mix that have occurred in the past 20 years. Overall, there has been a widespread and largely successful move to managing people in their own homes rather than admitting them to care homes. Health and social care services working together now enable the large majority of those who wish to remain in their own homes, even those with complex and brittle medical conditions. The exception to this appears to be those with dementia.

The proportion of people with dementia in care homes has now risen to the point that fully one-third of people with dementia in the UK (over 230,000) live in care homes. Between 66% and 100% of people living in individual care homes have dementia, depending on the type of care home. Into these homes have become concentrated those people with dementia with the highest need, in terms of BPSD and physical co-morbidity. This is a population of very high need and clinical complexity, yet it is also one in which the individuals receive less in the way of community healthcare than their counterparts in the community. When this is coupled with other quality issues in care homes and in managing people with dementia in their own homes, is it any wonder that in the current system primary care clinicians often initiate seemingly simple antipsychotic treatment for BPSD?

Good quality health and social care can transform the quality of life of people with dementia and their carers. However, few receive the care that would be of most benefit

33 Ballard C G, Gauthier S, Cummings JL, et al. Management of agitation and aggression associated with Alzheimer disease. *Nature Reviews Neurology* 2009, 5, 245–55.

to them in our current systems. The development of BPSD in dementia is a core part of the syndrome. They cannot be wished away any more than the symptoms of any other devastating illness can be. They are a legitimate object for intervention to decrease distress and harm and to increase quality of life. However, the management of such symptoms of dementia can be difficult. Our current systems have grown by chance rather than by active planning or commissioning. They deliver a largely drug-based response that is likely to do considerable harm as well as failing to address many of the behavioural problems in dementia. There are excellent services providing high quality care to people with dementia up and down the country, but these are seldom sufficiently resourced to meet the needs of all with dementia in their population.

There are no easy answers to this difficult issue. There are some simple actions which need to be avoided, such as prohibition or wholesale cessation of these medications. Such actions may themselves compromise patient safety, causing considerable harm and leading to a paradoxical increase in distress for people with dementia and their carers. Carrying on as we are also cannot be the answer. A measured, planned approach is needed. The next part of this review sets out a broad plan of action that can address these problems and has the potential to do so quickly and safely, with modest increased investment coupled with the re-design of existing structures to ensure that specialist input is available into key decisions in care planning.

Part 3: Recommendations for action

Chapter 5: Making a reduction in the use of antipsychotics for people with dementia a clinical governance priority for primary and secondary care

5.1 Quality, clinical governance and antipsychotic use for people with dementia

Quality has increasingly been identified as the overarching principle for the NHS, with “quality at the heart of everything we do”;³⁴ the three key factors in achieving this are patient safety, clinical effectiveness and patient experience. The NHS has stressed the importance of patient safety. *High Quality Care for All*³⁵ states that “...safety must be paramount for the NHS. Public trust in the NHS is conditional on our ability to keep patients safe when they are in our care.” The data gathered in completing this review suggest that the current level of use of antipsychotics for people with dementia represents a significant issue in terms of quality of care, with negative impacts in terms of patient safety, clinical effectiveness and patient experience.

Clinical governance is the system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care, by creating an environment in which good quality clinical practice can occur. All clinical NHS providers have in place systems for maintaining good clinical governance and addressing potentially problematic performance.

34 DH. *High Quality Care for All: Our Journey So Far*. London: TSO, 2009.

35 Darzi A. *High Quality Care for All*. London: TSO, 2008.

It is clear from this review and others that there is overprescribing of antipsychotic medication for behavioural problems in dementia, and that this prescribing is associated with significant harm in terms of increased mortality and incidence of cerebrovascular events, including serious ones such as stroke. Balancing this in clinical governance terms is the potential good that these drugs may be doing for individuals with dementia in terms of the control of distressing symptoms, the supporting of carers, and the prevention of unnecessary transitions into care homes. The size of this positive effect appears relatively modest and, given the risks, best practice suggests that prescription should be reserved for those with the most severe, complex and critical problems, often when non-pharmacological approaches have not been successful. It is clear that non-pharmacological approaches are seldom deployed.

Primary care – The data are not good, but the large majority of antipsychotic prescriptions in care homes and in the community appear to be initiated and maintained by GPs in primary care. Clinical experience suggests that the standard of record keeping with respect to indication, alternatives considered and plans for reduction and cessation of the medication is often low, making it difficult to be sure that best practice has been followed.

Specialist mental health services – A further, smaller, group of people with dementia will have been started on antipsychotic medications following referral to specialist dementia services, most commonly older people's community mental health teams but also services in in-patient units. Here the rationale for initiation is often better made, but there seems to be a similar lack of deployment of alternatives in the community and a lack of plans for reduction and cessation of medication. Again, direct evidence that best practice has been followed is often not available.

General hospital services – A final group may have been started on these medications by non-specialist secondary care services, for example during an episode of in-patient care in an acute hospital or in an outpatient setting. Here there is often little detail on indications and no plan given for reducing and stopping the drugs. Instead, people are discharged from hospital still taking these drugs and then stay on them. In general hospitals, the National Dementia Strategy calls for the appointment of a clinical lead for dementia. This individual should consider the place to be taken in the hospital's care pathway development by the use of antipsychotics in hospital and after discharge for those with dementia. The commissioning of specialist older people's mental health liaison services for general hospitals is also advocated by the National Dementia Strategy, and such services could be of value in supporting good practice in the initiation and maintenance of antipsychotic medication for people with dementia in general hospitals.

Given the evidence of risk, and on the basis of patient safety, the use of antipsychotic medications for people with dementia should therefore be a clinical governance issue for:

- primary care services;
- older people's mental health services; and
- general hospitals.

It is therefore a recommendation of this review that the need to reduce the use of antipsychotic drugs for people with dementia be made a clinical governance priority for all those who run services in and for the NHS that include contact with people with dementia. This will include all PCTs, all mental health trusts and all acute trusts running general hospital services or services for older people. Using their existing clinical governance structures, Medical Directors (or their equivalent) should review their level of risk in this area and ensure that systems and services are put in place to ensure well recorded, transparent and good practice in the initiation, maintenance and cessation of antipsychotic drugs for people with dementia. Details of such systems and services are provided in the present chapter and in the National Dementia Strategy. It is important to note that the recommendations that follow in the next chapters are presented in the order they appear in the Strategy text. The order does not indicate priority, they should all be considered to have equally priority, neither does it indicate a proposed sequence for their implementation.

Recommendation 1: Reducing the use of antipsychotic drugs for people with dementia and assuring good practice when they are needed should be made a clinical governance priority across the NHS. Using their existing clinical governance structures, Medical Directors (or their equivalent) in all primary care trusts, all mental health trusts and all acute trusts should review their level of risk in this area and ensure that systems and services are put in place to ensure good practice in the initiation, maintenance and cessation of these drugs for people with dementia.

Good clinical governance requires that any harm or disruption to patients is minimised. It is therefore important that seemingly simple responses to this issue, that may have unintended negative consequences, are not adopted. Clinical governance committees may therefore need to co-opt individuals with specialist skill to inform their decision-making.

In developing this review two fears were expressed concerning potential responses that might have the potential to do considerable harm to the finely balanced and sometimes precarious patterns of care that have developed. The first involve the effect of a blanket

ban on the use of antipsychotic medication, for example a ban introduced by a PCT for its GPs or a mental health trust for its old age psychiatrists. There was widespread concern that it would be unwise and unsafe simply to stop the medication for those who had been prescribed it without the provision of care and support and a management plan to address contingencies. In some patients there could be significant withdrawal reactions that might further jeopardise their safety. There was also fear that difficult behaviours might reoccur, and that in such a climate primary care services might refuse to help carers on the basis that they were not allowed to prescribe the medication. It is also clear that there are circumstances where such medication is needed on the grounds of risk, so denying such medication in all situations is of itself poor clinical practice and governance.

The second concern was that primary care services might change their referral behaviour, sending all patients with a behavioural problem of any sort as a result of dementia to the local community mental health team for older people. Such teams are available across the country, but are often small and relatively undeveloped. They are currently set up to deal with only the most severe and complex problems, and do so following referrals from primary care. If the referral threshold were substantially reduced, as could be imagined, then these specialist services would be swamped and would be unable to work through the cases referred to them.

It is therefore important that decisions are not made that simply shift responsibility to another service. It is clearly not a sustainable response, or one promoting good clinical governance, for referrals to be made to a service that cannot provide the service requested by reason of its low capacity. Extra investment will be needed to allow sharing of skills and risk. In the sections below dealing with care homes and the community, methods of service change to deliver joint supported working and decision-making are presented that would obviate the need for unilateral changes in practice.

5.2 Information on and audit of use of antipsychotics for people with dementia

Good quality relevant information on the use of antipsychotic medications is needed if local systems of clinical governance are to work to reduce the use of these medications, and to ensure that, when they are used, they are used according to good practice guidelines. Local audits led by Medical Directors, Clinical Directors and pharmacy in each PCT and mental health trust need to be established to:

- estimate the prevalence of use of antipsychotic medications in dementia;
- understand patterns of prescribing, identifying high and low users;
- measure use against quality standards;

- feed back data to prescribers;
- generate a plan for reduction of use;
- implement the plan; and
- re-measure prevalence and patterns of use against quality standards.

The prime use of such an audit would be to help local services manage antipsychotic prescribing as a local problem. However, there would be major value in the same data gathering techniques being usable across England to enable the easy collation of the data generated, allowing comparison by PCT and region and therefore the monitoring of progress at national and regional levels as well as at the local level. This objective could be pursued through and with the support of the National Clinical Audit Programme.

There is a need for co-ordination and leadership for such a programme. As discussed earlier, this is a particular, specific issue among the general set of issues relating to quality of care and services for people with dementia. This means that the structures put in place for the implementation of the National Dementia Strategy can be of help. There should however be specific national leadership, but with no delay imposed in generation of the audit. It is therefore a recommendation of this review that the National Clinical Director for Dementia should be charged with this leadership role, reporting on progress to the Minister of State for Care Services on a six-monthly basis. In terms of an indicative timetable, he or she could work with national and local clinical audit structures to generate and publish the framework for such an audit by the end of March 2010. This would seem to be a reasonable target, given the work done to date by NICE in this area among others. The use of prescribing committees (district or area prescribing committees may be best placed for this) to support local implementation of the good prescribing practice generated is likely to be beneficial. The first wave of this audit could then be completed between April and July 2010, generating baseline data across England. It could be repeated yearly for the next three years to gauge progress against the specific local and national goals that are set.

Recommendation 2: National leadership for reducing the level of prescription of antipsychotic medication for people with dementia should be provided by the National Clinical Director for Dementia, working with local and national services. He or she should report on a six-monthly basis to the Minister of State for Care Services on progress against the recommendations in this review.

Recommendation 3: The National Clinical Director for Dementia should develop, with national and local clinical audit structures and leads, an audit to generate data on the use of antipsychotic medication for people with dementia in each primary care trust in England. This audit should be completed as soon as possible following the publication of this report, generating baseline data across England. It should be repeated one, two and three years later to gauge progress.

5.3 Goals for a reduction in the use of antipsychotic medication

It is a conclusion of this review that people with dementia should be treated with antipsychotic medication only when they really need it and then according to good practice. During consultation to prepare this report two messages on this topic emerged. First, there was a desire for simple, realistic but ambitious goals to be set for the reduction of the use of these medications in dementia. The actions described in this report, taken as a whole, are designed to result in such a reduction. Second, there was a message that goals need to be set that are meaningful in their local context and that are owned by the local clinicians involved in the hard work needed to achieve them and by the local commissioners who are responsible for prioritisation and ensuring that sufficient resources are available to clinicians to enable the work to be done.

Throughout this report an attempt has been made to be clear where there are gaps in the data and to generate best estimates where data are patchy or lacking, in order to form a coherent plan. There is a school of thought which states that all data should be perfect before taking any action; however, this would not be appropriate in the present case, as this issue is too important to put off action in this way. Clearly, there is uncertainty at present about the number of people with dementia who are on antipsychotic medication at any time, and also about the proportion of these for whom such medication is necessary. The estimate made here is that there are likely to be 180,000 people with dementia so treated in any year. The completion of the audit set out in Recommendation 3 (above) will give detailed information on the exact numbers and distribution of this prescribing by practice, PCT and region. These data will then enable local clinicians and commissioners to set local goals and to monitor progress using their quality improvement, patient safety and clinical governance structures.

The burden that will fall on individual GPs and secondary care services will need to be taken into account as local goals are set. The goals will vary according to the numbers of people with dementia under their care and their clinical practice with respect to the use of antipsychotics in dementia. For example, those looking after care homes will be likely to have more cases under their responsibility. However, in broad brush-terms the numbers equate to an estimated 1,200 people with dementia on antipsychotics per year per PCT. What is the likely burden on an individual GP? In 2005 there were just over 29,000 GPs in

England (whole time equivalent), so on average the number of cases that might require review would be 6.2 per GP. If the sampling frame is taken as all people over 65 on antipsychotics, then this would rise, but only by a third at the most, to around 9 per GP. Even if these estimates are out by 100%, which is quite unlikely, then this would mean 18 cases per GP needing review. This does not seem an impossible task, especially if it were spread over two years. The likely clinical activity for those identified by the audit as on antipsychotic medication would be for the cases to be identified, and then for the primary care team to work steadily through those cases over a given period of time. At the end of this time all those on such medications would have been reviewed and those who do not need them would have had them stopped, be they at home or in care homes. Each decision needs to be a clinical decision made by the patient's doctor, with support from secondary care if needed. Some patients would stay on medication, but the rationale for this would be clearly stated and understood by all and so would be defensible as good quality care. The data from the annual repeats of the audit would provide information on the progress of GPs, practices and PCTs in this.

Lasting reduction in the use of antipsychotic medications requires a decrease in the numbers already on the medications and a decrease in initiation and maintenance of treatment. As discussed above, realistic local goals can only be set following the baseline audit. National goals would need to follow the aggregation of such data. However, in consultation, there was strong encouragement to provide some general estimate of what an ambitious but feasible pace might be, given the need for commissioning of services and the conduct of the audits. Weighing the data available, the following would seem to be realistic aims given the changes proposed. The goal would be to decrease by one-third the level of use of antipsychotics at the end of the first year of the implementation following the baseline audit (ie following review of half of all existing cases). At the end of the second year of the implementation (ie following review of all existing cases and having in place input into care homes) use should then be decreased by a further half, ie to 33% of baseline. These aims are only provided as an indication of the pace of travel and ambition possible. Locally agreed aims in terms of proportion of reductions and pace of implementation should be generated and reviewed in the light of the baseline audit and the yearly reviews at national, regional and local levels, with information published yearly on progress towards them at each level.

Recommendation 4: People with dementia should receive antipsychotic medication only when they really need it. To achieve this, there is a need for clear, realistic but ambitious goals to be agreed for the reduction of the use of antipsychotics for people with dementia. Explicit goals for the size and speed of this reduction, and improvement in the use of such drugs where needed, should be agreed and published locally following the completion of the baseline audit. These goals should be reviewed yearly at primary care trust, regional and national levels, with information published yearly on progress towards them at each level.

5.4 Need for further research

There are clear gaps in the evidence base with respect to the clinical and cost effectiveness of non-pharmacological approaches to the management of BPSD. There are similar questions concerning the potential efficacy of non-antipsychotic pharmacological treatments. Trials are generally small, with multiple and poorly defined outcomes. There is need for further research across the whole scope of this report.

Recommendation 5: There is a need for further research to be completed, including work assessing the clinical and cost effectiveness of non-pharmacological methods of treating behavioural problems in dementia and of other pharmacological approaches as an alternative to antipsychotic medication. The National Institute for Health Research and the Medical Research Council should work to develop programmes of work in this area.

Chapter 6: Improving the management of dementia in care homes

6.1 People with dementia in care homes

There are approximately 19,000 care homes in England, with a total capacity of 441,000 places.³⁶ Data from the Health Survey for England indicate that 4% of individuals over the age of 65 are resident in care homes, but that this proportion increases progressively with age to 30% of those aged 90 and over.³⁷ According to the latest data from the NHS Information Centre, 266,000 out of the 326,000 local authority placements in care homes (82%; the remainder are privately placed) are aged 65 or more (a crude but effective proxy for the population at risk of dementia).³⁸ This equates to around 15,600 homes in which people with dementia might reside in England or 100 per average PCT. The total number of older people living in care homes can be expected to rise as the UK population ages.

Over the past three decades care homes have undergone profound change. They have moved from being largely run by local authority social services departments to being largely run by the private sector. The severity of physical illness in those admitted has increased, as has the proportion of beds occupied by people with dementia and the complexity of the cases admitted. This change in the state of affairs with respect to the prevalence, the severity and the complexity of dementia in general has occurred not only in specialist care homes but in the whole stock of care home beds (residential as well as nursing, specialist as well as non-specialist). A major source of the problems now in care homes – with the use of antipsychotic drugs for dementia specifically, and the quality of dementia in general care in general – is that these changes have not been planned for, either through commissioning services or through workforce development.

In the course of the review strong points were made consistently about general issues concerning the care home sector. These included the need for stability in the workforce

36 Szczepura A, Nelson S, Wild D. In-reach specialist nursing teams for residential care homes: uptake of services, impact of care provision and cost-effectiveness. *BMC Health Services Research*, 2008, 8, 1–15.

37 Bajekal, M. *Health Survey for England 2000: Characteristics of Care Homes and Their Residents*. London: TSO, 2002.

38 NHS Information Centre. *Community Care Statistics 2007-08: Referrals, Assessments and Packages of Care for Adults, England*. London: TSO, 2008

and the role that pay and career structure might play in achieving this. Variation in the services received by homes from primary care, and the terms and costs of such input, were also cited. These general issues are important contextual factors in the use of antipsychotic medication in care homes, but are beyond the scope of this review. The analysis and solutions presented here are designed to improve quality of care and decrease the use of antipsychotics, even within the current system. Nonetheless, it certainly is the case that anything done to stabilise and improve the workforce as a whole and improve the general standard of healthcare in homes is likely to be of use to the people with dementia being cared for in them.

There is no doubt that residential care may be the most appropriate and effective way of meeting the needs of someone with dementia, and a service of choice. There are care homes that provide excellent care for people with dementia. The characteristics of such homes have become increasingly clear. They generally pay close attention to leadership and staff management, staff training and development, and person-centred care planning. They also provide a physical environment that enables people with dementia to move around the home freely but safely. They provide purposeful activities that relate to individual preferences as well as general entertainment, and actively involve relatives and friends in the care of residents. They include a therapeutic approach in their nursing model and promote social interaction with staff at times other than when personal care is being delivered. They develop strong links with, and involvement in, their local communities and effective links with local healthcare services, including with specialist old age psychiatric services. They have a strong view of the resident as an individual with a set of past experiences which can form the basis for communication and the development of relationships. Equally, such homes seek out and enable the provision, within the home, of therapeutic activities such as art therapy, music therapy or dramatherapy, which may enhance the social environment and the possibility for self-expression.

However, the reality of living in a care home is far from this for the large majority of the 215,000 people with dementia who live in such homes. Evidence from the Alzheimer's Society *Home from Home* report on the current state of care indicated the following:³⁹

- 54% of carers reported that their relative did not have enough to do in a care home.
- The typical person in a care home spent just two minutes interacting with staff or other residents over a six-hour period of observation (excluding time spent on care tasks).
- The availability of activities and opportunities for occupation is a major determinant of quality of life, affecting mortality, depression, physical function and behavioural symptoms, but these activities are seldom available.

39 Alzheimer's Society. *Home from Home*. London: Alzheimer's Society, 2007.

- Staff enjoy providing opportunities for activity and occupation and would like to be able to do more of this within their work, but do not feel they have the time.

6.2 Change in need but no change in service

So, the mental health needs of people living in care homes now are extensive and generally not well met. Up to 75% of residents in non-specialist care homes for older people have dementia, and the prevalence rises to between 90% and 100% in homes with a dementia speciality. In addition, an estimated 50% of all care home residents have depressive disorders that would warrant intervention. Behavioural disturbance in dementia in these settings is both very common and a cause of stress to residents and staff. It is striking that there is often very little in the way of active non-pharmacological management of these problems in these settings, despite accumulating evidence of the effectiveness of such intervention. Current input from older people's mental health services is generally on an ad-hoc basis or reactive, with referrals at times of crisis.⁴⁰

The use of antipsychotic medication in care homes for the management of BPSD has been identified as a major problem. Those who have criticised current practice include the Public Accounts Committee, the Alzheimer's Society and the All-Party Parliamentary Group on Dementia. It appears that antipsychotics are initiated too freely, that they are not reviewed appropriately following initiation, and that they are not reduced or withdrawn as quickly as they could be. Balancing the risks is the incontrovertible fact that behavioural problems in people with dementia can be distressing and dangerous; so, in some cases, antipsychotic medication may be the best option.

In order to build a sustainable and effective response to reduce the use of antipsychotics for people with dementia in care homes, it is important that action addresses the root causes. Again, the fundamental issue here is a general failure in terms of development and provision of healthcare for people with dementia, leading to the specific problem of the overprescribing of antipsychotic drugs for people with dementia.

6.3 Commissioning a service that can address the overprescribing of antipsychotics in care homes

It is clear that there is overuse of antipsychotic medication in care homes and there is an unacceptable level of risk and harm associated with that overuse. In the course of this review and alongside the development of the National Dementia Strategy, it has emerged that there is, in care homes, a fundamental lack of the skills needed to diagnose and manage dementia. There is a need for change and a need for that change to have its effect quickly. How might this be achieved?

40 Alzheimer's Society. *Home from Home*. London: Alzheimer's Society, 2007.

There is a range of options that have been suggested and considered, and that are not mutually exclusive. Broadly, these include:

- prohibition;
- restricting initiation of antipsychotics by complication;
- building skills in primary care;
- building skills in care home staff; and
- commissioning specialist support into care homes.

Prohibition seems attractive at first sight. Here there would be a blanket ban on the use of antipsychotics for people with dementia. However, we heard clearly that there are occasions when these drugs can be vital to maintaining people safely with good quality of life in care homes and in the community. There is a need for clinical discretion to be preserved in order to deliver good quality care. The decision whether or not to prescribe depends on the outcome of a risk/benefit analysis following consultation with interested parties, including carers and the person affected. There were strong fears expressed that simple prohibition would lead to a jump to different classes of ineffective medication being used, without improving the quality of non-drug-based care or increasing the consideration given to the alternatives to medication. Wholesale withdrawal of these medications from all prescribed them, without offering support for care homes and alternatives, would also be likely to cause major problems for people with dementia, including withdrawal reactions and resurgence of BPSD. Prohibition would also potentially take a long time to implement if legislative change were needed. What we need to do is to promote good practice in the management of BPSD and the use of these medications; and to prohibit bad practice, not the use of these medications altogether.

Restricting initiation of antipsychotics by complication is an alternative, less absolute option. In this, prescribing of these medications would be prevented by making it bureaucratically complicated to initiate or maintain them, in the hope that this would make prescribers think carefully about their use and account for it. An example of this is the way in which controlled drugs, such as diamorphine, are treated. Questions were raised about the practicalities of this and about the impact on those who need to have these medications prescribed for other illnesses such as schizophrenia and bipolar disorder. There are concerns that this action would 'demonise' these medications and so make people worried about taking them in a way that was not helpful. It was felt that an unintended effect of such action would be to increase the stigma attaching to people with mental disorders and their treatment, which is already considerable. It might also increase the perceived stigma and 'otherness' of dementia and its treatment in the primary care

setting and so paradoxically lead to a decrease in ownership and in the quality of care provided for people with dementia and their carers. Some questioned the proportionality of this response: it is certain that there are much more toxic medications prescribed in general medicine and continued in general practice than the antipsychotics, and yet these medications are free of prescribing constraint. Again, a wholesale cessation of these medications to those prescribed them without the offer of support for care homes and alternative treatments would also be likely to cause major problems for people with dementia. On the positive side, there can be no doubt that this would inhibit GP prescribing and would lead to a decrease in the use of antipsychotics.

Building skills in primary care (GPs and the wider primary care team) is vital if we are to improve the quality of care provided to people with dementia and their carers. In the Netherlands, doctors who look after nursing homes can complete specific training to become a nursing home physician, which includes elements of geriatrics and old age psychiatry, including the essentials of dementia care.⁴¹ There is no such mandatory training for GPs in England, and there are relatively few GPs with a special interest in geriatrics, old age psychiatry or dementia and relatively few opportunities to develop such skills. There are deficiencies in undergraduate and postgraduate medical curricula with respect to the development of knowledge and skills in dementia assessment and care. In terms of continuing professional development the need to improve skills in dementia is seldom identified by doctors. Changing all this will take commitment and time; it is a core aim of the National Dementia Strategy but will not deliver GPs able to manage complex or resistant BPSD in the short term. Equally, clinical behaviour change here is not a matter of a simple clinical algorithm that can be learnt in a few sessions and implemented across the board. There are important potential roles for nurses in primary care; so there is a need to build skills in primary care, but this will not be a quick or easy business. There is a need for primary care services to be supported by those with a current specialist skill set in the assessment and care of people with dementia. This can help to build knowledge and skills in situ.

Recommendation 6: The Royal Colleges of General Practitioners, Psychiatrists, Nursing and Physicians should develop a curriculum for the development of appropriate skills for GPs and others working in care homes, to equip them for their role in the management of the complexity, co-morbidity and severity of mental and physical disorder in those now residing in care homes. This should be available as part of continuing professional development.

Building skills in care home staff (nurses and care staff) is also vital if we are to improve the quality of care provided for people with dementia and their carers in care homes. The

41 Schols JM, Crebolder HF, van Weel C. Nursing home and nursing home physician: the Dutch experience. *Journal of the American Medical Directors Association*, 2004, 5(3), 207–12.

issues here are analogous to those for primary care. The increase in severity and complexity of the case load in care homes and the concentration within them of cases of dementia has not been matched by the development of an appropriate set of knowledge, attitudes and skills. There are deficiencies with respect to the development of knowledge and skills in dementia assessment and care in undergraduate and postgraduate nursing curricula and in vocational training. There are excellent detailed recommendations in this area set out in the Alzheimer's Society's *Home from Home* report⁴² and the All-Party Parliamentary Group on Dementia's report *Prepared to Care*.⁴³

Again, changing this will take time, though it is a core aim of the National Dementia Strategy to achieve such change. The recommendation of this review is that DH should work with Skills for Care and Skills for Health to ensure the development of a National Vocational Qualification (NVQ) in dementia care for those working with people with dementia.

The content of such training should include the basics of person-centred care in dementia that takes account of an individual's history, hobbies, interests and preferences, generating an individually tailored care plan and a stimulating social environment. This approach has been reported to reduce antipsychotic drug use by up to a half.⁴⁴ There are data emerging on the potential value of specific psychosocial interventions, and other non-pharmacological therapies in care homes. Unfortunately the evidence base is very small and limited by the small size and poor quality of most of the trials. Options explored include multi-sensory stimulation (Snoezelen), bright light therapy, aromatherapy, and massage. Each of these has been the subject of a Cochrane systematic review whose results have been generally negative due to the state of the evidence base. The current evidence does not conclusively support the use of bright light therapy⁴⁵ or Snoezelen⁴⁶ but these are interesting avenues for further work. One small RCT of aromatherapy, involving the simple application of *Melissa* (lemon balm) to the head and forearm, suggested benefit across a range of behavioural outcomes⁴⁷. Another small but well conducted trial suggests that hand massage may be effective in reducing agitation at least for one hour

42 Alzheimer's Society. *Home from Home*. London: Alzheimer's Society, 2007.

43 All-Party Parliamentary Group on Dementia. *Prepared to Care*. London: APPGD, 2009.

44 Fossey J, Ballard C, Juszczak E, James I, Alder N, Jacoby R, Howard R. Effect of enhanced psychosocial care on people with severe dementia: cluster randomised trial of antipsychotic use in nursing home residents. *British Medical Journal*, 2006, 332, 756–761.

45 Forbes D, Morgan DG, Bangma J, Peacock S, Pelletier N, Adamson J. Light therapy for managing sleep, behaviour, and mood disturbances in dementia. *Cochrane Database Systematic Reviews*, 2004(2).

46 Chung JC, Lai CK, Chung PM, French HP. Snoezelen for dementia. *Cochrane Database Systematic Reviews*, 2002(4).

47 Ballard CG, O'Brien JT, Reichelt K, Perry EK. Aromatherapy as a safe and effective treatment for the management of agitation in severe dementia: the results of a double-blind, placebo-controlled trial with *Melissa*. *Journal of Clinical Psychiatry*, 2002, 63(7), 553–8.

after application.^{48,49} More evidence is required to confirm the suggestion of efficacy (especially because non-randomised interventions have in each case suggested at least the theoretical possibility of harm⁵⁰) and to define the optimal content and mode of administration, given that 'massage' and 'aromatherapy' may describe a variety of quite different interventions.

Recommendation 7: There is a need to develop a curriculum for the development of appropriate skills for care home staff in the non-pharmacological treatment of behavioural disorder in dementia, including the deployment of specific therapies with positive impact. Senior staff in care homes should have these skills and the ability to transfer them to other staff members in care homes. A national vocational qualification in dementia care should be developed for those working with people with dementia.

But the effect of this will take time, and the issues raised by the prescription of antipsychotic medication are too pressing to wait for this development to work itself through. It will also be insufficient in itself: we need not only to improve the quality of social care and to change GP skills, but also to enable consistent, coherent support from specialist services.

Commissioning specialist support into care homes offers the possibility of a response that can be deployed quickly, that can build skills in primary care and in care home staff and that has a high likelihood of success in terms of decreasing the use of antipsychotic drugs for people with dementia in care homes and increasing the quality of care provided to them. Specialist community mental health teams for older adults have the skills needed to assess and manage people with dementia in the community, even those with the most complex of BPSD. However, there is an uneven playing field with respect to their work within care homes.

In preparing this report we heard of assertive care homes that required (through GPs) that all new admissions with the possibility of dementia were referred to, and seen by, specialist services as a matter of course. This was often resented or resisted by these specialist services, who stated that they were being asked to provide a higher level of service to these homes compared with the less assertive majority. They expressed concern that this was a disproportionate use of the limited resource commissioned by their PCT and that it created an unfair two-tier system, with those people lucky enough to be in the high-service homes getting better dementia care. Equally, there were cases

48 Viggo HN, Jorgensen T, Ortenblad L. Massage and touch for dementia. *Cochrane Database of Systematic Reviews*, 2006(4).

49 Remington R. Calming music and hand massage with agitated elderly. *Nursing Research*, 2002, 51(5), 317–23.

50 Thorgrimsen L, Spector A, Wiles A, Orrell M. Aroma therapy for dementia. *Cochrane Database of Systematic Reviews*, 2003(3).

where services had instituted regular input and reviews in certain homes in order to deal with the high level of referrals or disturbance among their clients. Again, concerns were expressed about the creation of a two-tier service in terms of accessibility of secondary care. However the reports also included positive evidence of the value that could accrue from such programmed contact with care homes. There are limits to the literature, but it suggests that such a service can reduce antipsychotic use by up to 40% without an increase in BPSD and also decrease hospital admissions and use of GP time.⁵¹

The recommendation here is that PCTs should commission specifically an extension of the work of existing community mental health teams for older people. The volume of work will depend on the numbers of care home beds in each PCT, but this is additional activity and should be commissioned as such by the purchasing of additional capacity within these teams. In completing this review it was made clear that it would be useful to include some specifics of a potential service specification for this and so these are given below.

If we accept the figures at the beginning of the chapter there are, on average, 100 care homes in the average PCT where people with dementia might reside, with 2,400 residents, up to 80% of whom may have dementia. Clearly some homes are very small and some very large; the amount of visiting which will need to be commissioned will depend on the number of residents and turnover. Modelling this, in order to provide a service to a typical PCT with a typical population of 50,000 over-65s and an average number of care home places, an additional six whole time equivalent multidisciplinary community team members would be needed. If each care home interaction is for a 2-hour session and there are two such sessions (plus travel and administration) per working day, with one day a week for team meetings and supervision and 40 working weeks in the year, then six whole-time equivalent team members will deliver 1,920 sessions per year. If a third of sessions are used for regular reviews and work in that time and a third are used for specific extra intervention and follow-up, then this would enable 12 monthly visits per care home per year and one session dispersed over a three-month period for other non-regular activities. In local reality this provides a stock of person time, and some homes would need weekly visiting or more while others would need none (if they had no people with dementia and no older people admitted). Averaged out, however, this approach would provide the kind of resource needed to have a meaningful input into care homes of the sort proposed in this report. The precise size and activity needed will clearly depend on analysis of local need and care home distribution and size: in some areas where there are above average numbers of care home beds then a larger resource may be needed and vice versa. This is for local determination.

51 Ballard C, Powell I, James I., et al. Can Psychiatric Liaison reduce neuroleptic use and reduce health service utilization for dementia patients residing in care facilities? *International Journal of Geriatric Psychiatry* 2002, 17, 140–5.

In terms of service model the two possibilities are for a separate stand alone care home team or for them to work not as a separate team, but instead be distributed in existing community mental health teams (CMHTs) for older people to enhance the capacity of existing teams to achieve these new tasks. Again, local decision-making is key here, but during the preparation of this report there was a clear preference for the latter approach, ie placing this new resource into existing multidisciplinary teams. This was on the basis that they should already have the required support systems, including access to the medical and psychological expertise that will be needed in complex cases. They would also have a capacity to respond to crises and have ready pathways through to other care that might be needed, including in-patient care. The effect would be to make such liaison a core team function, so that all staff members engage in contact with care homes, not just appointees to the new posts. This would generate a robust and sustainable response. In doing so, GPs and care homes could change their expectations of the help that they received from community mental health teams for older people.

These new staff members could be drawn from any of a number of professional backgrounds (medical, nursing, clinical psychology, occupational therapy). They would work as part of existing community teams, with all team members taking on a liaison role with specific care homes in their area. This would enable relationships to be built over time between the homes, the primary care input into them, and specific team members; but would also provide a system robust enough to deal with periods of sickness, leave and other absences, with members of the team substituting for absent colleagues. Equally, it would mean that specific expertise could be drawn from the team into specific homes if needed. This approach would involve a relatively small number of staff on a trust by trust basis, who could be recruited from wards and other teams with those places being backfilled by more junior staff, so enabling a quick start.

This care home liaison function would enable a system of regular specialist older people's mental health assessment for all following admission to a care home, and make available regular in-home specialist review for this vulnerable population. This would enhance the quality of care and skills available by providing a regular forum for discussion between nursing staff, GPs and mental health teams to identify and manage the mental health problems of care home residents. It would give the support needed for staff in homes to attempt non-pharmacological management of BPSD and to reduce or stop medication, in the knowledge that there was specialist advice that they could call upon. Such a service would also be of benefit to older people with anxiety, depression and other mental disorder in the care homes. Any intervention would be made in an agreed partnership with the GPs responsible for care within care homes. In this system the quality of mental health care for residents in care homes could be improved by:

- Specialist assessment of mental health needs, including diagnosis or exclusion of dementia following all admissions.

- Regular six-monthly mental health reviews of residents in conjunction with the GP and nursing home staff.
- Building of skills in primary care and in care homes by joint working and skills development.
- Provision of access to specialist advice for problems arising between reviews.
- Prevention of escalation of problem behaviours by means of early intervention.
- Formulation and deployment of non-pharmacological management strategies for behavioural disorder in dementia, so avoiding the initiation of antipsychotic medication.
- Specialist input into decision-making concerning the initiation, review and cessation of antipsychotic medication for people with dementia.
- Rapid specialist review of all those with dementia initiated on anti-psychotic medication in order to minimise and stop that medication as soon as possible, deploying alternative strategies as needed.
- Rapid specialist response to problems within homes, as they occur, from a specialist team member familiar to the home.
- A source of expertise to draw on in order to build and maintain a social and therapeutic environment within the care home that is positive for people with dementia and tailored to their needs.

All the above would act to minimise the use of antipsychotics. Clearly there would be a cost associated with such a service, in that it would require extra funding for specialist older people's mental health teams. However, there are also likely to be savings for the health and social care economy as a whole, not least in the minimisation of the use of expensive atypical antipsychotic medications and the prevention of emergency admissions to general hospitals and to mental health units. In terms of drug costs alone, the Alzheimer's Society estimates that £80 million a year is currently spent on antipsychotic drugs for people with dementia. If this were reduced by two-thirds, then nearly £55 million per year would be released. A common source of admissions to hospitals is the deterioration of the physical health of people with dementia in care homes, resulting in emergency admission to general hospital, and deterioration in their mental state resulting in admission to acute mental health wards. Early identification of what is, and what is not, a symptom of dementia should improve the physical and mental health of this group and lead to fewer unplanned admissions. Such disruption may mean

that there is a need to move home, which is a source of expense to social care services or to families themselves. Movement of people with dementia between homes is not positive and is associated with increased mortality in itself. Again, this new service would enable people to stay in their care home, or for moves to be planned rather than a consequence of emergency. This is a core recommendation of this review, and it requires the case for new funds from PCTs to be made rapidly so that they can commission new capacity to start working during 2010/2011, in order that the other recommendations can be met.

Taken as a whole the quality improvements accruing from this proposal would be high for people with dementia, their carers, primary care staff, care home staff and specialist mental health services. The costs incurred would be modest (around £450,000 per year in an average PCT; £68 million per year overall for England). A formal impact assessment and analysis of clinical and cost effectiveness is beyond the scope of this review, and the case is made on the basis of clinical need, good clinical governance and fundamental issues of patient safety, as well as cost. However, when balanced against potential savings from the costs of antipsychotics (£55 million overall for a 66% decrease in use) the figures seem to add up, and the costs of this recommendation are likely to be offset to a large extent by savings in admissions to general hospitals and transfers, as well as reduced drug costs and improvement in the quality of life of people with dementia. It is for local determination to decide what other routine inputs into care homes might be of value, with pharmacy having a potential role to play that is complementary to the services discussed above.

Recommendation 8: Each primary care trust should commission from local specialist older people's mental health services an in-reach service that supports primary care in its work in care homes. This extension of service needs the capacity to work routinely in all care homes where there may be people with dementia. This is a core recommendation of this report and it requires new capacity to be commissioned by primary care trusts in order that the other recommendations can be met. They may be aided by regular pharmacist input into homes.

Recommendation 9: The Care Quality Commission should consider using rates of prescription of antipsychotic medication for people with dementia, adherence to good practice guidelines, the availability of skills in non-pharmacological management of behavioural and psychological symptoms in dementia and the establishment of care home in-reach from specialist mental health services as markers of the quality of care provided by care homes. These data should be available by analysis of local audit data and commissioning decisions.

Chapter 7: Improving the management of dementia in people's own households in the community

7.1 People with dementia in their own households in the community

Two-thirds of people with dementia live in their own households in the community, either alone or with family carers, often their frail older spouses. We have less information on the extent of use of antipsychotic medication in this group than we do on people in care homes. However, from extrapolation of the IMS data and other evidence received it seems likely that there are substantial numbers of people with dementia who are initiated on antipsychotic medication in the community. Some of these will have been initiated and maintained on such medication by specialist old age psychiatric services, but it seems likely that it is more common than not for these decisions to be made by primary care services without reference to specialist services. We heard that in some cases these medications may be particularly valued by family carers, enabling people to continue living in their own homes, rather than needing admission to care homes, and thus maintaining their quality of life.

7.2 The possibility of prevention

Early diagnosis of dementia for all is the central tenet of the National Dementia Strategy. The Strategy advocates as an early action the establishment of a new network of memory services serving the whole country, making it the rule rather than the exception that people are diagnosed early and well and that they are provided with the information, treatment and support that they need thereafter. This stance makes diagnosis and initial management clearly an issue for specialist services, providing that diagnostic service for GPs so that they do not have to carry out this complex task. In the medium and longer term the potential use of antipsychotic medications can be minimised if people with dementia and their carers become aware that they have dementia early in their illness, so that crises can be avoided.

This approach can enable discussions to take place between the person with dementia, carers and clinicians in order to establish what the person with dementia themselves would want if they were in the position of potentially needing these drugs. In early

dementia most will have the capacity to engage in such discussion if given the opportunity by services; memory services could build this into their work. Then people with dementia could decide themselves what risk they would wish to bear in order (for example), to delay transition to a care home, or to enable their spouse to continue caring for them.

Equally, early diagnosis allows the carer to be given information and training. This can enable carers to become aware of early signs of deterioration in behaviour, so that help can be sought early, and crises that may lead to the use of antipsychotics can be avoided. Again, the support of carers, in this way and the provision of good quality information on when to seek help is a core part of the National Dementia Strategy and will enable such early intervention by arming carers with good quality information, including the number of their local dementia care adviser. Once these posts are commissioned and in place, then family carers can contact their local dementia care adviser, who will signpost them to the care that they need, be that from specialist community mental health teams for older people or from others.

The actions set out in this review are complementary to those in the National Dementia Strategy. We cannot, however, wait the five years of the strategy to deal with the problems that we have, and a preventative approach may not reach those already established on antipsychotic medications at home or in care homes. So action is needed to address the current state of care.

7.3 Options for intervention

The options for intervention to support primary care teams in their work with people with dementia who have BPSD in their own homes are similar to those discussed above for care homes. These include:

- Prohibition.
- Restricting initiation of antipsychotics by complication.
- Building skills in primary care.
- Building skills in family carers.
- Commissioning further specialist support for primary care teams.

The same arguments apply with respect to prohibition and restriction of prescription. It is also the case that the need for building skills in primary care is clear and is addressed in the National Dementia Strategy and above. It should be aided by generalisation of the skills developed in the course of the care home-based liaison detailed above. Building

skills in family carers is also a goal of the National Dementia Strategy and, as services for early diagnosis and treatment for dementia are introduced, then carer and peer support can be provided. The provision of good-quality information for carers on how best to care and deal with BPSD is needed and should be developed and disseminated as part of the implementation of the National Dementia Strategy.

There is now a large amount of literature attesting to the wide-ranging potential benefits of carer interventions in dementia.⁵² Carer interventions include:

- Psychoeducational interventions, many of which include an element of carer training.
- Psychological therapies, eg cognitive behavioural therapy (CBT), and counselling.
- Carer support.
- Respite care.

Interventions may include several of these elements in combination. This literature has been the subject of several systematic reviews and meta-analyses^{53,54,55,56,57} the limitation being that many of the trials included were non-randomised. Outcomes studied include carer strain, psychological morbidity or depression and subjective well-being; behaviour disturbance and mood in the care recipient; and institutionalisation.

Interventions seem to reduce carer strain and carer depression and anxiety, with the largest impact on the latter from CBT. Carer support interventions seem to be efficacious in increasing carers' subjective well-being. For respite care, if data from quasi-experimental and other non-randomised interventions is considered, then there are significant reductions in carer strain and psychological morbidity. Because of the high cost of institutionalisation and the generally lower life quality in care homes, prevention or

- 52 Sorensen S, Duberstein P, Gill D, Pinquart M. Dementia care: mental health effects, intervention strategies, and clinical implications. *Lancet Neurology* 2006, 5(11), 961–73.
- 53 Pinquart M, Sorensen S. Helping caregivers of persons with dementia: which interventions work and how large are their effects? *International Psychogeriatrics*, 2006, 18(4), 577–95.
- 54 Smits CH de LJ, Droes RM, Meiland F et al. Effects of combined intervention programmes for people with dementia living at home and their caregivers: a systematic review. *Int J Geriatric Psychiatry*, 2007, 22(12), 1181–93
- 55 Brodaty H, Green A, Koschera A. Meta-analysis of psychosocial interventions for caregivers of people with dementia. *Journal of the American Geriatrics Society*, 2003, 51(5), 657–64.
- 56 Lee H, Cameron M. Respite care for people with dementia and their carers. *Cochrane Database of Systematic Reviews*, 2004(2).
- 57 Spijker A, Vernooij-Dassen M, Vasse E, et al. Effectiveness of nonpharmacological interventions in delaying the institutionalization of patients with dementia: a meta-analysis. *Journal of the American Geriatrics Society*, 2008, 56(6), 1116–28.

delay would confer a substantial societal benefit; a systematic review identified 13 trials of the effects of carer interventions on this outcome. Meta-analysis indicated a large, statistically significant reduction in the pooled odds of institutionalisation (OR=0.60, 95% CI=0.43–0.85). The effective interventions were all structured, intensive and multicomponent, offering a choice of services and supports to carers.

This makes clear the potential value of psychotherapeutic input for carers including CBT. There has been major government investment to increase the capacity of the health service to deliver psychological therapies via the Improving Access to Psychological Therapies programme. The ready availability of such psychotherapeutic approaches would be likely to decrease the use of antipsychotic medication by providing alternatives to their initiation. The review heard that, while there was a strand of this initiative that focused on older people, it was very much focused on adults of working age, so very few older people with dementia or their carers would be likely to benefit from the investment, the production of a practice guide for older people notwithstanding. There was a strong belief expressed that few older people and fewer people with dementia and their carers were benefiting or would benefit from the programme as currently designed and delivered. This is of concern, since any rational and non-ageist analysis of cost-effectiveness would demonstrate the potential monetary value of therapy to prevent the institutionalisation associated with BPSD and carer strain as well as the improvements in life quality by the prevention of the use of antipsychotic medication.

Recommendation 10: The Improving Access to Psychological Therapies programme should ensure that resources are made available for the delivery of therapies to people with dementia and their carers. Information and support should be available to carers to give them the skills needed to spot behavioural problems quickly, to seek help early, and to deploy elements of non-pharmacological care themselves in the home.

7.4 Need for further information to plan for service change

We heard clear and compelling testimony that there was a need not only to improve liaison between primary care and specialist services for dementia in care homes but also in the community. Positive messages were heard concerning systems where there was regular programmed monthly contact between the primary care team and a specific member of the old age psychiatric community team, where cases could be discussed and advice given, including on initiation, maintenance, dose minimisation and the cessation of antipsychotic medication for people with dementia as well as the consideration of alternatives to their use.

Such practice-based liaison would clearly be of benefit if there were the capacity to provide such contact on the part of the primary care team as well as on the part of the

specialist mental health team. It is difficult to make definitive recommendations about the level of service change needed to meet the challenge of the prescription of antipsychotic drugs for people with dementia in the community in the absence of information on its extent.

We therefore need to generate information on the scale of prescription in order to plan what is needed. Data to do this should be available from the audits specified above. When these data are available, specialist older people's mental health services and GPs should meet in order to plan how to address the issue of people with dementia in their own homes on antipsychotic medication. Using practice and patient-level data from completed audits, they should agree how best to review and manage existing cases and how to ensure that the future use of antipsychotic medication follows best practice in terms of initiation, dose minimisation and cessation. Consideration should be given at this time to the establishment of a routine meeting where existing cases can be worked through and where new cases can be discussed. If this cannot be achieved within the existing resource base (including the extra team members provided for care home liaison), then an evidence-based case could be made to the PCT using these data.

Recommendation 11: Specialist older people's mental health services and GPs should meet in order to plan how to address the issue of people with dementia in their own homes who are on antipsychotic medication. Using practice and patient-level data from the completed audits on the use of these medications, they should agree how best to review and manage existing cases and how to ensure that future use follows best practice in terms of initiation, dose minimisation and cessation.

Chapter 8: Concluding remarks

In completing this report, I have worked to retain a balanced view and to refrain from polemical language. However, considered as a whole, there can be no equipoise with respect to the current use of antipsychotic drugs in people with dementia. The use of these drugs in those with dementia has substantial clinical risk attached, including a conservative estimate of 1,800 extra deaths and 820 extra serious adverse events such as stroke per year.

The problems identified must not be allowed to continue and action is needed quickly. This review sets out a simple, affordable, coherent plan to deal with this. As I was completing this work I started to meet with an element of concern on the part of practitioners and commissioners. They were dubious that things would change, either because money would not be available because of the problems with international finance, or because there were other priorities such as pandemic flu; or because the system would quickly forget about people with dementia, as it had before.

The positive act in commissioning the review needs to be followed up by effective action. The NHS and social services can always respond to new priorities as they emerge and also deal with multiple simultaneous challenges. This review identifies clear problems and solutions in terms of quality of care, patient safety, clinical effectiveness and patient experience. Addressing these now needs to be an NHS priority.

Annex: Acknowledgements

Many individuals and organisations have assisted in undertaking this review. I am deeply grateful to the following organisations and individuals, who generously supplied information, met with me, and kindly arranged visits or meetings with members of the public, patients, carers, health professionals, NHS managers, academics, experts from other countries and representatives of the pharmaceutical and care home industries.

- Alzheimer Europe
- Alzheimer's Disease International
- Alzheimer's Society
- Association of Directors of Adult Social Services
- Barchester Healthcare
- British Geriatrics Society
- British Medical Association
- British Pharmacological Society
- Bupa
- English Community Care Association
- For Dementia
- IMS (Intercontinental Marketing Services) Health
- Jeremy Wright MP
- Lundbeck UK
- NHS Confederation Mental Health Network

- Oxleas NHS Foundation Trust
- Paul Burstow MP
- Royal College of General Practitioners
- Royal College of Psychiatrists (Faculty of Old Age Psychiatry)

Innumerable others contributed vital data and insights throughout the consultation process for the National Dementia Strategy. I have benefited from the wise counsel and specific expertise of a number of individuals who have acted to inform the report and to test ideas.

The report and any mistakes and misunderstandings are mine, but the following deserve thanks for their help and forbearance:

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An independent report commissioned and funded by
the Department of Health

GOVERNMENT RESPONSE TO PROFESSOR SUBE BANERJEE'S REPORT ON THE PRESCRIBING OF ANTI-PSYCHOTIC DRUGS TO PEOPLE WITH DEMENTIA: 12 NOVEMBER 2009

1. The Government welcomes the independent clinical report prepared by Professor Sube Banerjee on the prescribing of anti-psychotic drugs to people with dementia, and accepts the conclusions and recommendations he has reached. The report was commissioned by the Government in recognition of widespread concern about the over-prescription of these drugs, and as part of the priority being given to improving care for people with dementia.
2. There have been a number of previous reports addressing this difficult issue. However, Professor Banerjee's report brings together for the first time all the clinical evidence available in a comprehensive way, with clear recommendations on how to take matters forward. We need to ensure that anti-psychotic drugs are only prescribed to people with dementia when necessary, and are not used when non-pharmacological approaches can be equally effective.
3. The figures contained in the report on people with dementia dying as a result of being prescribed anti-psychotic drugs are totally unacceptable. There is inevitably an element of risk with the prescribing of any medication. However, there is clear evidence that anti-psychotic drugs are currently being over prescribed, when alternative non-pharmacological approaches to dealing with anxiety and behavioural problems are available and should be used.
4. A number of the report's recommendations are addressed to bodies outside the Department of Health. The report will therefore be widely disseminated by the Department to those with an interest, and we expect the findings and recommendations to be taken into account by all relevant organisations. The Government supports the best practice guidance identified in the report, with quality and safety being the overriding principles. There will be a need for PCTs, local authorities and other bodies to work together to take forward the report's recommendations, particularly taking into account the interface between health and social care services.
5. All clinical decisions to prescribe anti-psychotic drugs to people with dementia should be taken on the best evidence available, with proper regard to the existing NICE guidance. This guidance makes clear that people with dementia should only be offered anti-psychotics if they are severely distressed or there is an immediate risk of harm to the person or others. The NHS locally should be following NICE guidance and PCTs have a responsibility to ensure that this happens.
6. The Government accepts the conclusion reached by Professor Banerjee that there should not be a ban on the prescribing of anti-psychotic medication to people with dementia, as there will

undoubtedly be occasions when the use of drugs will be necessary and in the best interests of the person involved. As the report points out, behavioural problems in people with dementia can be distressing and dangerous, so in some cases antipsychotic medication may be the best option.

7. The position of a new National Clinical Director for Dementia was advertised yesterday on 11 November, with an expectation that the position will be filled in January 2010. One of the most important tasks of the new Director will be to provide leadership in taking forward the recommendations contained in Professor Banerjee's report. Notably he or she will be charged with:
 - reporting on a six monthly basis to the Minister for Care Services on progress against the recommendations of the report; and
 - leading a national audit to generate data on the prescribing of anti-psychotic drugs to people with dementia in each PCT in England. The first audit should be completed within six months of the National Clinical Director coming into post, and repeated on an annual basis for at least the next three years to measure progress.
8. National and local progress on addressing the conclusions of the report will also be monitored by the National Dementia Strategy Implementation Board responsible for delivery and implementation of the National Dementia Strategy. Progress on auditing the prescription of anti-psychotic drugs to people with dementia, and reducing current levels of prescription, will from now on form part of the programme for implementing the Strategy. Progress on further research on the clinical and cost effectiveness of non-pharmacological methods of treating behavioural problems in dementia will also be assessed by the Ministerial Group on Dementia Research. The establishment of the Ministerial Group was announced on 5 November, to take forward the conclusions of the Dementia Research Summit held in July 2009. The membership and terms of reference for the Group will be announced in the near future.
9. The Government welcomes the fact that the Alzheimer's Society has given its support to the contents of the report, and that they are represented at the launch by the Society's Chief Executive, Neil Hunt. The Department of Health will be working closely with the Society to produce advice for people whose family members with dementia are currently being prescribed anti-psychotic drugs and who may have concerns at their possible effects.