Thinking Differently

Preparing today to implement future dementia treatments

March 2018

Alzheimer’s Research UK
The Power to Defeat Dementia
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Foreword

Dementia is now the leading cause of death in the UK and people living with dementia, their families, and their carers desperately need new and effective treatments. Alzheimer’s Research UK’s mission is to bring about a life-changing treatment for dementia by 2025 and we are working every day to help make that a reality as soon as possible.

Every year, we are investing more and more in research, with over £21.4 million put towards research in 2016/17, including £7 million earmarked for our long-term commitment to the UK Dementia Research Institute. This landmark initiative is the UK’s single biggest endeavour in dementia research and aims to build a solid base of discovery science. Our research portfolio also includes pioneering strategic initiatives such as our network of Drug Discovery Institutes, dedicated to speeding up the development of promising new treatments.

But our job doesn’t end when those new treatments demonstrate success in clinical trials. When effective treatments are found, we need to ensure the people who need them will be able to access them.

There are no guarantees that when a new treatment is licensed it will be made available by the NHS. There are a number of factors that mean new dementia treatments face a very real challenge. Not only must the NHS be readied to deliver treatments, but the issue of the affordability of those treatments and their value to society must be reconciled in the face of increasingly tough financial pressures.

We can meet these challenges, but we must start preparing now.

By commissioning the London School of Economics and Political Science to model the potential impact of a new treatment for Alzheimer’s disease, Alzheimer’s Research UK is helping develop the evidence on which to base future discussions about how we prepare for new treatments.

This report shines a spotlight on the challenges ahead, so that we can work with partners across the NHS, government and the pharmaceutical industry to overcome them.

That’s why Alzheimer’s Research UK is launching the Dementia Access Taskforce to bring together all the necessary stakeholders to drive forward this critical discussion – if we are going to ensure people living with dementia will be able to access future treatments, we must collaborate, think differently and act now.

Hilary Evans
Chief Executive, Alzheimer’s Research UK
By 2025, there will be over 1 million people living with dementia in the UK. Currently, there are no treatments that can delay the onset or slow the progression of the diseases that cause dementia. But with promising treatments in late stages of clinical trials, we need to prepare now so people living with dementia will be able to benefit from future treatments once they are developed.

To provide evidence of the potential impact and to highlight the need to prepare now for future treatments, Alzheimer’s Research UK commissioned the London School of Economics and Political Science (LSE) Personal Social Services Research Unit (PSSRU) to model five hypothetical treatments for Alzheimer’s disease, the most common cause of dementia. These were developed with advice from a clinical advisory group and reflect a likely treatment that may become available in the next five years as well as more speculative treatment scenarios, which were selected based on the direction of research.

This modelling is the first of its kind and designed to provide a platform from which to start a conversation about preparing for future treatments and it highlights a number of areas that we need to consider. This work must begin now, both to make sure the changes that are currently being made in access to medicines policy will work for dementia, and to ensure that there are no delays to patient access when treatments show success in clinical trials.

We urgently need to come together and think differently to prepare the healthcare system for such treatments.

To address these challenges, Alzheimer’s Research UK is launching the Dementia Access Taskforce to bring together stakeholders from the NHS, NICE, government and industry to think differently about these challenges.

The healthcare system must begin to prepare for the scale and impact of future dementia treatments

Our analysis shows that a new treatment will have a large impact on the healthcare system, with between 310,000 and 750,000 people being eligible for treatment depending on the patient population in which each of our hypothetical treatments would be effective. This will require increased capacity in Memory Assessment Services, and a first-in-class treatment may also require reconfiguration of health services.

The cost of these treatments, and the long duration over which they would need to be taken, will also pose a challenge to the current system. For example, at a price point that would be considered cost-effective by NICE, the annual overall cost to the NHS of one of the treatment scenarios is estimated to be £420 million per year including £100 million for diagnosis.

Clearly, this poses serious questions about how a treatment will be funded and made available to those who would benefit. However the questions should not focus solely on overall cost; with an open-mind and willingness for innovation there are ways to address the challenges over longer time periods and to ensure savings made are recycled back into the system. We have a window of opportunity now to prepare for these treatments and ensure patient access.
Executive Summary

1. Recommendation
   There needs to be comprehensive horizon scanning in place to understand Alzheimer’s treatments in development and their likely impact on the health sector.

2. Recommendation
   The scale of the increased capacity and infrastructure changes required in the NHS needs to be scoped and considered now.

3. Recommendation
   Innovative funding models should be developed to respond to the challenge of delivering future Alzheimer’s treatments.

Early diagnosis will be vital for future treatments

Current scientific evidence suggests that disease-modifying treatments are likely to be most effective at the earlier stages of Alzheimer’s. Our modelling shows that by treating earlier, people will live with mild symptoms for longer before these symptoms worsen, and there will be fewer people living with dementia. Moving towards earlier diagnosis will require an increase in public and health professional understanding that Alzheimer’s starts long before symptoms are present. Therefore, it is necessary to scope the barriers and opportunities within the NHS to shifting towards earlier and biomarker-based diagnosis.

4. Recommendation
   NHS England and NHS Improvement should support awareness and education around the molecular-based diagnosis of Alzheimer’s and other dementias.

5. Recommendation
   The government needs to work with charities to increase public awareness of the value of earlier detection for dementia.
6 **Recommendation**

The NHS needs to prepare to diagnose the diseases that cause dementia more accurately and at a much earlier stage, shifting to detection around 15 to 20 years earlier.

7 **Recommendation**

As recommended by the Edinburgh Consensus, the NHS should pilot specialist Brain Health Clinics to test an infrastructure that could incorporate developments in diagnostics and prepare the NHS for earlier diagnosis.

The value of dementia treatments to individuals and society may not be fully recognised in the current system

Alzheimer’s has a huge impact on individuals, families and society. As well as its devastating personal impact, Alzheimer’s disease alone accounts for £18 billion of the £26 billion total cost of dementia to the UK economy each year. An effective treatment would bring great value to people affected by this disease as well as wider society. The majority of this £18 billion is in social and informal care costs, yet savings that would be made in these sectors as a result of new treatments will not be completely captured in the current system of evaluating cost-effectiveness. It is vital that we understand the full value of a treatment and ensure that this is recognised as part of the assessment process.

8 **Recommendation**

The domains that reflect the true value of Alzheimer’s treatments for individuals and society need to be identified, including where there are gaps in the data.
Dementia is the greatest healthcare challenge of our time. There are an estimated 850,000 people living with Alzheimer’s and other forms of dementia in the UK at an annual cost of over £26 billion to society\(^1\), and both prevalence and cost are expected to more than double by 2050. Around the world, there are an estimated 50 million people living with dementia, a number predicted to triple by 2050\(^2\). For the first time ever, the condition will cost $1 trillion globally this year\(^3\).

Current treatments can only temporarily alleviate symptoms and there are no treatments to slow, stop or prevent the diseases that cause dementia. Alzheimer’s and other dementias have now overtaken heart disease as the leading cause of death in the UK\(^4\).

Alzheimer’s Research UK’s mission is to bring about the first life-changing treatment for dementia by 2025. To better understand the impact of such a treatment for Alzheimer’s, we commissioned the LSE to model five possible treatments.

The purpose of this modelling is to demonstrate the potential impact of a new treatment both for people with the disease, and for our healthcare system, in order to drive conversation and actions that will ready us for the future. If we are going to ensure people will be able to access new treatments for dementia, we need to collaborate, prepare early and think differently.
Introduction

Towards a new treatment

The last several years have been a time of unprecedented progress and attention on dementia, both nationally and internationally. In the UK, the £250 million UK Dementia Research Institute was founded in 2017 with funding from the Medical Research Council, Alzheimer’s Society and Alzheimer’s Research UK. Last year also saw the endorsement of the Global Action Plan for Dementia by the World Health Organisation (WHO).

The progress in research over recent years means we are closer to the goal of a disease-modifying treatment than ever before. As our mission to bring about the first life-changing treatment by 2025 comes closer, Alzheimer’s Research UK is continuing to look forward to the impact a treatment may have and to ensuring breakthroughs in research reach the people who need them.

In 2016, we published ‘Treatments of Tomorrow: preparing for breakthroughs in dementia’, exploring the factors that could impact timely access to future dementia treatments.

In this report, we build on those themes using new analysis from the LSE to stimulate important discussions about how future dementia treatments can reach people. Our aim is, firstly, to highlight the access challenges that a new Alzheimer’s disease treatment faces and, secondly, to identify solutions prior to the launch of any new treatment so the health system can be well prepared.

There are a number of factors that make this the time to start considering access to new treatments:

1. There are 12 phase three trials of disease-modifying treatments for Alzheimer’s due to be completed by 2021, meaning a treatment for the disease could be as little as three years away.

2. The formation of Sustainability and Transformation Partnerships (STPs) and devolved healthcare regions are creating new health and social care models. These changes present an opportunity to integrate considerations for dementia into the development of new services.

3. The current medicines policy landscape is evolving with commitments in the Life Sciences Industrial Strategy, the implementation of an Accelerated Access Pathway (AAP) and the introduction of an affordability test within NHS England’s Budget Impact Test (BIT). We need to make sure policy developed now is sensitive to the challenges of new dementia treatments.

4. With Brexit negotiations ongoing, there is current uncertainty over future regulatory alignment with the EU and the small market share of the UK health sector compared with Europe, which could delay the introduction of new treatments for patients in the UK. While the NHS provides advantages in terms of data collection at a national scale, if the environment is not conducive to patient access for new treatments these advantages may be lost.
In England there is now an affordability test called the Budget Impact Test (BIT). Under this test, if a new treatment is projected to cost more than £20 million in any of its first three years, then commercial negotiations between NHS England and the company are triggered. If an agreement cannot be reached, then NHS England can apply for additional time to introduce the treatment in a phased approach.

According to our economic model, a new treatment for Alzheimer’s disease will trigger this test. Now is the time to consider a sustainable solution for how these types of treatments will be funded in the future to ensure they are not delayed in reaching patients.
Introduction

Treating hepatitis C – lessons for Alzheimer’s

The novel hepatitis C drug Sofosbuvir is an example of a high cost, first-in-class cure that led to limited access for patients because of the affordability challenge it presented to the NHS. The drug was considered cost-effective by NICE, but the high cost and large patient population (an estimated 160,000 people in England) meant the NHS was unable to meet demand. This caused controversy and the NHS was accused of breaking its charter by rationing the treatment and denying people access.

We are still several years away from new treatments for Alzheimer’s, so the time to think differently and prepare the system is now. We must ensure the people who so desperately need new treatments will be able to access them as quickly as possible.

Driving the conversation – the Dementia Access Taskforce

Using the evidence from the LSE’s model, Alzheimer’s Research UK aims to further drive a conversation about how we can better prepare for new dementia treatments.

To achieve this, Alzheimer’s Research UK is launching the Dementia Access Taskforce to bring together a broad range of stakeholders to collaboratively refine and act on recommendations in this report to ensure people who need these treatments can access them. We are calling on industry, government, NHSE and NICE to join us in developing these solutions.

Dementia Access Taskforce

Alzheimer’s Research UK is calling on the government to join us in a taskforce to address access challenges for new dementia treatments. This taskforce will be led by Alzheimer’s Research UK and will seek to:

1. Develop ideas to update understanding of Alzheimer’s disease among health professionals and the public, particularly that Alzheimer’s has a long pre-symptomatic stage before the onset of symptoms.
2. Engage with the NHS and practising clinicians with experience of dementia to help develop a framework for new services, to highlight bottlenecks of capacity that need to be addressed, and to recommend timescales for implementation.
3. Scope the barriers and opportunities to establish earlier diagnosis and shift towards molecular-based diagnosis and risk profiling. Develop an action plan for the implementation of such an approach within the NHS.
4. Recommend how the UK health system could accommodate the specialist investigations required to select patients and prescribe future dementia treatments.
5. Ensure the assessment of value of new disease-modifying treatments for dementia captures their full value, including their impact on carers and both the health and social care systems. This will include technical understanding of which elements have the biggest impact on calculations of value and/or cost-effectiveness.
6. Develop innovative access and funding models to share cost and risk across industry and the NHS in order to ensure the introduction of innovative medicines and diagnostics into the UK for people with dementia.
2. Methodology – economic analysis

To understand the effect a new treatment for Alzheimer’s could have, we commissioned the LSE to produce an economic model evaluating the cost of five hypothetical new disease-modifying treatments for Alzheimer’s. The model is designed to produce a maximum cost of treatment that would be deemed cost-effective by NICE using the standard £20,000 per QALY threshold (discussed below). We worked with an expert clinical advisory group to ensure the treatment scenarios developed are as clinically relevant as possible.

In order to develop the model, we needed to make a number of assumptions and decisions:

- We focused on Alzheimer’s rather than other forms of dementia as it is the most common cause of the condition, therefore treatments for the disease are likely to have the biggest impact our healthcare system. It is also the most heavily researched form of dementia, meaning the first life-changing dementia treatment is likely to be for Alzheimer’s.
- The LSE model uses a range of data sources on rates of transitions between severity states and on mortality, costs and quality of life in different stages. In view of data limitations, the findings of the modelling should be treated with a degree of caution and further detail can be found in the LSE’s report.
- In Treatments 1 to 4, we have not specified the disease process that the treatment will target. Treatment 5 targets the hallmark Alzheimer’s protein, β-amyloid, as it is one of the first pathologies to appear in the disease and Treatment 5 is the earliest treatment scenario.
- We also considered at what point treatments may no longer be effective and therefore when to stop treatment. In Treatments 1 and 3, we model treatments that would be effective up until the severe stages of dementia. Treatments 2, 4 and 5 are given before the onset of dementia and are effective in the pre-symptomatic stages only, meaning the treatment would be halted in the mild stage of dementia.
- We have assumed 100% uptake so that each person eligible for a treatment receives it. The model also assumes that every person who receives a treatment complies fully with the treatment regimen by taking every dose. Due to lack of data on compliance or uptake, we made these assumptions, which we recognise are likely to be overestimates.
- We have assumed the diagnostic tests correctly identify each individual with no false positives or false negatives.
- The model does not take into account the cost of introducing a new treatment, such as training additional staff, purchasing new equipment or increasing the capacity of services. We assume that all necessary infrastructure is in place.

Stages of Alzheimer’s disease

In the model, we describe five hypothetical treatments for Alzheimer’s, each delivered at a different stage of the disease. The normal course of Alzheimer’s can be loosely divided into five increasingly severe stages:

- Pre-symptomatic Alzheimer’s: people with biological markers of disease (β-amyloid positive) but no cognitive symptoms.
- Prodromal Alzheimer’s: people with biological markers of disease (β-amyloid positive) and mild cognitive impairment (MCI) – a decline in cognition not yet severe enough to be classed as dementia.
- Mild Alzheimer’s dementia.
- Moderate Alzheimer’s dementia.
- Severe Alzheimer’s dementia.

Current scientific evidence suggests that disease-modifying treatments for Alzheimer’s will be most effective when started in the earlier stages of the disease, ideally before symptoms start. That’s why we have modelled treatment scenarios that start from pre-symptomatic Alzheimer’s to the mild stages of Alzheimer’s dementia. In this report, we have focused on Treatments 1, 2, and 3, which
target patients who have symptoms, as they most closely reflect treatments currently in clinical trials.

Each of the treatments reduces the rate of progression to the next stage of the disease. By slowing the progress of the disease, the time taken to move into the more severe stages is increased and it is this delay that creates cost savings and, more importantly, maintains a higher quality of life for people living with Alzheimer's.

### Overview of the different treatments modelled

The following is a summary of the treatment scenarios that were modelled showing the stages of the disease and treatment duration. In this report, we have focused the discussion on the mid-treatment effects for each Treatment scenario. For more information about the slowing effects modelled across the treatments, please see the LSE report\(^9\).

<table>
<thead>
<tr>
<th>Treatment scenarios</th>
<th>Patient characteristics</th>
<th>Diagnostic test</th>
<th>Treatment effect</th>
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| **Treatment 1**     | Mild Alzheimer's dementia  
                      | All ages  
                      | β-amyloid positive | Patients have a diagnosis of mild dementia  
                      | Test using CSF or PET for β-amyloid | Slow progression of disease by 5%, 10%, 25% and 50%  
                      | Treatment frequency: unspecified  
                      | Treatment halt: at the onset of severe dementia |
| **Treatment 2**     | Prodromal Alzheimer's  
                      | All ages  
                      | β-amyloid positive | Patients have an MCI diagnosis  
                      | Test using CSF or PET for β-amyloid | Slow progression of disease by 10%, 30% and 50%  
                      | Treatment frequency: unspecified  
                      | Treatment halt: at the onset of mild dementia |
| **Treatment 3**     | Pre-symptomatic Alzheimer’s  
                      | Age 70  
                      | β-amyloid positive | Patients have no cognitive symptoms  
                      | Test using CSF or PET for β-amyloid | Slow progression of disease by 5%, 10%, 25% and 50%  
                      | Treatment frequency: unspecified  
                      | Treatment halt: at the onset of severe dementia |
| **Treatment 4**     | No Alzheimer's disease  
                      | Age 50  
                      | No β-amyloid | Patients have no cognitive symptoms  
                      | No diagnostic test | Delay onset of β-amyloid pathology by 1, 3, or 5 years  
                      | Treatment frequency: every 2 years or every 5 years  
                      | Treatment halt: at the onset of mild dementia |

Table 1. Summary of the Treatment scenarios modelled

*In this report, we have focused the discussion on the mid-treatment effects for each Treatment scenario.*
Methodology

2.1 What the model tells us

In this report we highlight a number of findings from key aspects of the modelling from the LSE, to illustrate the impact a new treatment could have on both individuals and the health and social care sectors. The detailed data that informs this report can be found in the LSE report\(^\text{10}\). In this report we use the middle estimates of either 25% (Treatment 1 and 4) or 30% (Treatment 2 and 3) slowing of progression (for more detail see Table 1).

Impact on quality of life for someone with dementia

To measure the impact of a treatment on quality of life, we use a measurement called a quality adjusted life year (QALY), which is the standard measure used by NICE. QALYs include both the quality and the quantity of life lived and are calculated by weighting each year of life with a quality-of-life score on a scale from zero to one, with death being zero and full health being one. This number is then multiplied by each year of life following a treatment\(^\text{11}\).
Methodology

Savings due to treatment

The costs of Alzheimer’s can be broadly split into healthcare, social care and informal care costs. In a NICE assessment, only healthcare and limited social care costs are considered however, in this model we have included all health, social and informal care costs of people living with Alzheimer’s to provide a full picture of the impact of the disease. Our reasons for doing this and the questions this poses for the assessment of future treatments are discussed in greater detail in Section 5: Assessing value.

A new treatment could deliver improvements in two ways: by reducing the prevalence (overall number of people affected) and by reducing the severity of Alzheimer’s. Reducing the prevalence means fewer people needing care and fewer people living with symptoms of dementia. Reducing the severity means people need less care and have a higher quality of life compared with the normal course of the disease.

Cost of diagnosis

The cost to the NHS includes the cost of the treatment and the cost of diagnosis. Diagnostic testing, including cost and method, is described in Section 4: Diagnosis.

Maximum cost based on NICE threshold

We estimate each treatment’s maximum annual cost per person in order for it to be compatible with a cost-effectiveness threshold of £20,000 per QALY. This means that if the treatment cost is under this threshold, it will be recommended by NICE. We include healthcare, social care and informal costs in our model, although not all of these costs are currently considered by NICE. We believe the inclusion of these costs is important to understand the full value of new dementia treatments.

The maximum cost calculated in this analysis includes price of the treatment, delivery of the treatment (for example, tablet or infusion), and cost of monitoring, as these are included in the costs to the health sector of the treatment and would therefore be included in a NICE assessment. We are not forecasting the outcome of negotiations between manufacturers and the NHS on the prices of the new treatments.
3. Infrastructure
The healthcare system must begin to prepare for the scale and impact of future dementia treatments

The impact of a new treatment

The large and increasing number of people affected by Alzheimer’s will mean that a new treatment is likely to have a large impact on the health system in the UK.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Number of People</th>
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<tr>
<td>Treatment 1</td>
<td>480,000</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>310,000</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>750,000</td>
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Based on the treatments modelled, the patient population that would benefit from treatments could range from 480,000 in Treatment 1 to 310,000 in Treatment 2 and 750,000 in Treatment 3, equal to the entire populations of Edinburgh, Swansea or Leeds respectively (see Figure 2). The increased number of people seeking a diagnosis and treatment will require a significant increase in resource and capacity.

The increase in the number of people accessing the health service for these treatments will require greater numbers of experienced healthcare professionals who have knowledge and experience of people living with dementia to deliver these services. As well as an increase in capacity, the introduction of first-in-class treatments may require the current structure of clinical services to be re-evaluated. This may involve a need for more multi-disciplinary working across specialities, to ensure that people affected by dementia can get timely access to experienced healthcare professionals with relevant skills for molecular-based diagnosis and to deliver and monitor treatments.

Memory Assessment Services (MASs), or memory clinics, where people with suspected Alzheimer’s are referred, have already seen large rises in numbers of patients without an increase in the numbers of clinics, creating concerns about current capacity. To manage the likely increase in the number of people coming forward for diagnosis and treatment, there may need to be a step change in the design and availability of these services in terms of scale, skills and coverage.

Figure 2. The number of people being treated at any one time
The structure of services will also have to be re-evaluated. Currently, the primary specialism involved in care for people living with dementia is old age psychiatry. However, the introduction of a new treatment is likely to require greater involvement of other specialities, such as neurology and nuclear medicine expertise for the interpretation of data. Though not included in the modelling, we recognise there may be side-effects, the assessment of which will require specialist knowledge and experience. Assessment of eligibility for treatment and safety monitoring is likely to involve the use of specialist imaging (MRI and nuclear medicine) and access to radiolabelled tracers. Safely treating and managing patients with a new treatment will require a diverse care team that needs to be designed, resourced and evaluated prior to widespread dementia service change.

Alongside access to healthcare professionals, how a treatment is taken (such as by infusion, injection or in tablet form) will have implications for the healthcare system. For example, if an infusion is required, this will necessitate an increased capacity of infusion services for which there is currently limited spare capacity to cope with such increased demand\textsuperscript{14}.

**Recommendation**

The scale of the increased capacity and infrastructure changes required in the NHS needs to be scoped and considered now.

**Annual cost of a new treatment**

- **£318 million**
  - Treatment 1
- **£2.0 billion**
  - Treatment 2
- **£2.7 billion**
  - Treatment 3

*Figure 3. Annual cost of Treatments*
A treatment that will benefit a large patient population combined with a long treatment time – ranging from three to nine years - will be expensive (see Figure 3). For Treatment 1, if we assume the actual price set for the treatment by industry will reflect the maximum annual treatment cost considered cost-effective by NICE, the overall cost would be £318 million per year and the cost of diagnosis would be £100 million. This is over a third of the total cardiovascular medicines bill\(^\text{15}\). These costs are based on a steady-state situation, after a treatment has been fully integrated into the system. They do not include the costs needed to expand the testing and treatment infrastructure.

While these represent high costs to the healthcare sector, they improve quality of life for people living with dementia and provide some savings in care. Taking all the benefits and savings into consideration, they would be considered cost-effective by NICE. We have included a broader range of cost savings because we think they are most appropriate for dementia and believe these savings should be considered in NICE’s cost-effectiveness assessments for future dementia treatments. For example in Treatment 1, there are savings in the health and social care sectors of almost £500m a year due to a reduction in the length of the severe stages of Alzheimer’s dementia, where care needs and therefore cost are highest.

The high cost and long treatment times will make funding a challenge in the current system. By preparing now through comprehensive horizon scanning of dementia treatments in development, the potential impact on the NHS can be forecasted and action can be taken to remove barriers to access. Initiatives such as the Accelerated Access Collaborative (AAC) are designed to begin this process and it is imperative that dementia is incorporated as a high priority condition.

If preparation begins now, the healthcare sector has time to adapt to new treatments in a manner that is sustainable and responsible, creating a system of proactive healthcare that benefits all patients and provides access to life-changing treatments.

**Recommendation**

1. **Recommendation**
   
   There needs to be comprehensive horizon scanning in place to understand Alzheimer’s treatments in development and their likely impact on the health sector.

2. **Recommendation**

   Innovative funding models should be developed to respond to the challenge of delivering future Alzheimer’s treatments.
Learning from changes in urgent stroke care

The challenge of large infrastructure changes needed to deliver an effective treatment is not an unknown dilemma for the NHS. One example is urgent stroke care and the use of thrombolysis.

Thrombolysis is a treatment for stroke that involves giving intravenous therapy immediately after a stroke to break down blood clots that can cause irreparable damage. To achieve the best results in the use of thrombolysis, treatment has to be initiated less than three hours after the stroke, with better outcomes from giving the drug as soon as possible.

To achieve this rapid treatment, stroke care was transformed by centralising services into highly-specialised acute units with the full range of necessary equipment and specialist clinicians from a range of fields. There was initial resistance to the change, as some general hospitals lost their stroke services and related highly trained staff, compounding the difficulties inherent in altering care pathways and embedding new practices. The complexity of these changes led to delays in introducing the new system compared to other nations that more quickly adopted the treatment and delivered improved care.

These acute units now show far higher rates of acute treatment and improved outcomes for stroke care and are internationally competitive. The example of stroke shows that the NHS can be a pioneer in healthcare, but that structural change is challenging, setting a benchmark for success that we aim to exceed.
“It is very hard to have a discussion with my patients in which the central theme is that our treatment options are limited. I can only imagine what it be must be like for them after the appointment when they think, ‘Well, what now?’

“The holy grail would be some sort of treatment that improves function, doing things like driving and managing bank accounts. These are drugs that are not likely to be simple, like taking a tablet at night. That means we’re going to have to think hard about how these treatments will be delivered. We’re going to have to think about the facilities that we have - hospital settings, day care units, and upskilling GP surgeries.

“Logistically this is a very considerable challenge, but that’s okay because it’s a challenge we should accept if we have a drug that works.”

Dr Dennis Chan
Academic Neurologist
4. Diagnosis

Earlier diagnosis is vital to ensure future treatments can be effectively delivered to the right people at the right time.

Impact of treating earlier in the disease

Current scientific evidence suggests that disease-modifying treatments for Alzheimer’s will be most effective when started in the earlier stages of the disease, ideally before symptoms start (see Figure 1).

This is because earlier slowing of the disease will keep people in the earlier, milder stages of disease for longer and consequently there will be fewer people living with Alzheimer’s dementia (see Figure 4). There will also be a greater reduction in the severity of the disease. For example in Treatment 1, there would be a 26% decrease in the amount of time spent in the severe stage of disease compared to a 41% reduction in Treatment 3 (see Figure 5). Intervening before symptoms start would also create larger savings in social and informal care, because people would require less intensive levels of care. However, to treat before the onset of Alzheimer’s dementia will require the ability to diagnose before this stage is reached, which would be a step change from current practice.

Figure 4. Impact of each treatment on prevalence of Alzheimer’s dementia

* The first three treatment scenarios, represent the treatments most likely to be available in the next 5-10 years.
In order to move towards earlier diagnosis, it will be important to improve the public’s and health professionals’ understanding of Alzheimer’s as a disease that starts long before symptoms are present (see Figure 1), and to challenge the misconception that dementia is a condition of old age. Currently, only 23% of people recognise dementia as being caused by brain diseases\textsuperscript{16}.

A recent poll showed that over half (54%) of people who knew someone with dementia felt there was a delay between experiencing symptoms and receiving a diagnosis, mainly because the early symptoms were too gradual to notice (50% agreed) or because the person experiencing symptoms was reluctant to go to the doctor (45% agreed)\textsuperscript{17}.

\textbf{Diagnosis}

\begin{figure}
\centering
\includegraphics[width=\textwidth]{diagram.png}
\caption{A disease-modifying treatment would reduce the time spent in the severe stages of the disease}
\end{figure}

\textbf{Improving understanding of Alzheimer’s disease}

In order to move towards earlier diagnosis, it will be important to improve the public’s and health professionals’ understanding of Alzheimer’s as a disease that starts long before symptoms are present (see Figure 1), and to challenge the misconception that dementia is a condition of old age. Currently, only 23% of people recognise dementia as being caused by brain diseases\textsuperscript{16}.

A recent poll showed that over half (54%) of people who knew someone with dementia felt there was a delay between experiencing symptoms and receiving a diagnosis, mainly because the early symptoms were too gradual to notice (50% agreed) or because the person experiencing symptoms was reluctant to go to the doctor (45% agreed)\textsuperscript{17}.  

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Treatment 1</th>
<th>Treatment 2</th>
<th>Treatment 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prodromal stage</td>
<td>Mild</td>
<td>Moderate</td>
<td>Severe</td>
</tr>
<tr>
<td>Treatment duration</td>
<td>6.1 years</td>
<td>3.6 years</td>
<td>8.6 years</td>
</tr>
</tbody>
</table>
Diagnosis

Alzheimer’s is largely diagnosed based on the assessment of symptoms and patient history. In order to treat earlier, we need to diagnose earlier, which means improvements must be made in diagnostic testing and the NHS must be ready to adopt new processes.

This is widely recognised in the literature with new diagnostic criteria increasingly including more advanced diagnostics, such as biomarkers, and there are a number of collaborative initiatives focused on improving and standardising the use of these biomarkers. Progress has already begun in clinical trials where improvements in the quality of diagnostic tools have supported more precise diagnosis, with the vast majority of trials now using biomarker tests to confirm the presence of underlying disease mechanisms and proteins called β-amyloid and tau, two hallmarks of Alzheimer’s disease.

Using the advice of the clinical group, a combination of cerebrospinal fluid (CSF) tests and positron emission tomography (PET) scans for β-amyloid were used in the modelling, with 90% of people receiving a CSF test and 10% receiving a PET scan. A greater proportion of CSF testing is used as it is easier to expand at the necessary scale, significantly less expensive and included in the new draft NICE guidance.

There are, however, some drawbacks to using a CSF test. For instance, to take a sample of CSF requires a lumbar puncture that not all people can receive, such as those with scoliosis or using blood-thinners, which means some availability of PET will be needed. There is also a low rate of lumbar puncture acceptance in the UK compared to other countries, and while it is likely that this will increase over time thanks to education and greater familiarity with the procedure, it is another factor that may delay patient access to treatments.

The potential total annual cost of diagnostics is substantial; for example, it is estimated to be £100 million in Treatment 1. The cost of diagnosis will need to be taken into account when considering the overall cost of new treatments. However, these costs could be phased in prior to the first new treatment, as this would facilitate more tailored and targeted care and support of patients, including helping to build resilience (remaining as cognitively and physically healthy as possible despite the diagnosis by building coping structures and making positive lifestyle changes).

To achieve this, the NHS must scope the barriers and opportunities to establishing diagnosis earlier, shifting towards molecular-based diagnosis, such as blood-based, CSF or imaging tests, and risk profiling. The NHS must also develop an action plan for implementation.

### Method of diagnosis

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### Recommendation

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NHS England and NHS Improvement should support awareness and education around the molecular-based diagnosis of Alzheimer’s and other dementias.

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The government needs to work with charities to increase public awareness of the value of earlier detection for dementia.
to address this. One way this could be achieved is by piloting new approaches, such as Brain Health Clinics in a number of specialist centres across the country. These would focus on molecular-based diagnostics, maintaining brain health using risk reduction, resilience building, and delivering complex pharmaceutical interventions\(^{19} \). A Brain Health Clinic could be developed in one locale to begin with while best practice, cost and value are evaluated.

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**Recommendation**

6

The NHS needs to prepare to diagnose the diseases that cause dementia more accurately and at a much earlier stage, shifting to detection around 15 to 20 years earlier.

**Recommendation**

7

As recommended by the Edinburgh Consensus, the NHS should pilot specialist Brain Health Clinics to test an infrastructure that could incorporate developments in diagnostics and prepare the NHS for earlier diagnosis.

---

“The availability of CSF and PET biomarkers, that can demonstrate the presence of Alzheimer pathologies in living people, allows us to diagnose the condition based not just on the pattern of a person’s impairment, but on a molecular basis.

“This not only increases diagnostic accuracy, which will be crucial if we are to offer targeted treatments, but also allows for much earlier diagnosis. However, current use and capacity for CSF or PET in diagnosis is limited.

“In due course it may be that blood-based biomarkers, perhaps combined with genetic risk profiling, could be used to identify individuals for treatments. However, for now we should start to expand the use of tools that are available, like CSF and PET.”

Prof Jonathan Schott
“When I was first diagnosed with dementia in November 2016, I was shocked, in denial, and felt that my life was as good as over. Thankfully, I was wrong. I have been lucky to have exceptional care, both from my wife and from the Memory Assessment Service.

“One of the key reasons I believe I have received such good support is because I was diagnosed early. This enabled me to better understand my condition and the resources available to me. I was immediately put on medication to help with the symptoms of dementia, an intervention that might not have been an option if I was diagnosed later.

“Our experience with Alzheimer’s is that there is a wealth of support out there for anyone who seeks it, and the chance to make new friendships, both with the staff and others in the same situation as ourselves.

“Getting diagnosed was an important step for me, and I would encourage others who know someone with memory problems to persuade them to seek a doctor’s advice. It might take one or two nudges in the right direction, but you might have done that person a great favour.

“While there is currently no treatment that will slow the progression of the disease, one day that could be an option for people and early diagnosis will be important.”

John
82-year-old with Alzheimer’s disease
5. Assessing value
The value of dementia treatments to society may not be fully recognised in the current assessment process

The impact of Alzheimer’s on individuals, families and to society represents a unique situation for healthcare. A new treatment could have great value to people affected by dementia and to society as a whole, but these might not be fully recognised in the current system and a specialist route may be needed for access and uptake.

From our modelling, for Treatment 1 to be considered cost-effective the maximum overall annual cost to healthcare would be £310 million, which takes into account the cost of the treatment minus the savings to the healthcare sector. This would represent a significant cost to the healthcare system, but a new treatment will also change the pattern of the cost of Alzheimer’s. When we consider the wider costs across social and informal care sectors the picture radically changes. As shown in Figure 6, the full value is only demonstrated when a broader perspective of the savings across sectors is considered.

Currently, the majority of the £18 billion annual cost of Alzheimer’s is paid for by the informal and social care sectors. In Treatments 4 and 5, there is an overall cost saving, with the savings largely made in the informal and social care sectors – yet the treatment is paid for by the healthcare sector. This poses interesting questions about how cost savings are shared across the health and care sector, where one part of the system is paying for the intervention, but another part of the system gets most of the benefit (cost saving). This wider question is currently being considered across health and social care and the prospect of a future dementia treatment only adds to the argument for better integration.

![Figure 6. Changes in annual cost of Alzheimer's under the different Treatment scenarios](image-url)
Assessing value

Standard assessments by NICE consider healthcare costs and benefits, and some social care costs but not informal care. By not including all social care and informal care costs, the total impact of a treatment is not evaluated and for Alzheimer’s and other forms of dementia, the majority of the value will not be recognised. In our modelling, we can see that excluding some sectors changes the perceived impact of the treatment significantly. To give a fair assessment of the value of these treatments to the individual and to society, these broader impacts must be accounted for.

In previous NICE assessments of symptomatic treatments for Alzheimer’s, NICE included carer quality of life for the first time. Given the impact that Alzheimer’s has beyond the person with the disease, and especially on carers, we anticipate that this would also be included in future assessments to accurately reflect the value of treatments. In addition, as Alzheimer’s is a complex and multifaceted disease, we may need to think differently about how we assess and encapsulate the broader domains of value beyond just cognition and function, which are the primary domains currently measured.

It is clear from this modelling that the first disease-modifying treatments will not lead to efficiency gains (or cost savings) for the healthcare system. Furthermore, treatment times will be long, between three and nine years, due to the need to diagnose and start treatment as early as possible. In the current system, this could create additional challenges in demonstrating the value of a treatment today for someone who would not see the benefit of delayed progression for several years. This is also true for the health and social care sectors, which would have to introduce and fund treatments for some years before recouping any savings.

Adding to this challenge, NHS England and NICE recently brought in changes to manage the introduction of new treatments where major investment would be needed. The modelling shows that in all five Treatments, if the drug developer set the maximum price to meet NICE criteria, the Budget Impact Test threshold of £20 million would be exceeded. For example, if just 10% of eligible patients received a treatment or diagnosis in Treatment 1, the annual cost would be around £42 million.

We must use the time that we have now before a treatment becomes available to prepare and bring stakeholders together to consider these challenges and develop innovative approaches that work for people with dementia, the NHS and industry. The broad consultation we have carried out in relation to this project has shown there is already enthusiasm across stakeholders to work together to find solutions to these complex challenges and enable future treatments to reach the people who need them.

Recommendation

The domains that reflect the true value of Alzheimer’s treatments for individuals and society need to be identified, including where there are gaps in the data.
6. Conclusion
The high unmet need for people living with dementia means the UK should be set up for early adoption.

The LSE’s modelling of the potential impact of a new treatment for Alzheimer’s has developed a much-needed evidence base to better inform how we prepare for future treatments and, for the first time, shines a spotlight on the scale of the challenge ahead.

This is a complex challenge with many facets, but it is a challenge that we can meet. In the years leading up to the first disease-modifying treatment for Alzheimer’s, we have an opportunity to prepare for such a treatment and find the necessary solutions, ensuring people living with dementia will not lose out by being unable to access them. Achieving this will mean ensuring the true value of future treatments is assessed, the right infrastructure is in place to deliver them, and people are diagnosed at the right time to be able to benefit from them.

Alzheimer’s Research UK’s Dementia Access Taskforce will drive forward the recommendations in this report, bringing together all the relevant stakeholders who need to play their part. If we are going to ensure people living with dementia will be able to access future treatments, we must collaborate, think differently and act now.

“My mother, before she was diagnosed with Alzheimer’s, was a lovely, bubbly, vivacious person. As her condition gradually deteriorated she became bedridden and couldn’t talk. She didn’t recognise me. She couldn’t say my name. And that to me is probably one of the cruellest parts of Alzheimer’s.

I’m hoping in the future there will be a cure for Alzheimer’s so other people wouldn’t have to see their loved ones go through what my mother did. We’ve got a long way to go to find this cure for Alzheimer’s. Although I know it will take time, I truly believe we will get there in the end.”

Viv,
Mother had Alzheimer’s disease
### Conclusion

**Dementia Access Taskforce and report recommendations**

The Dementia Access Taskforce will address the recommendations of this report through its following objectives.

<table>
<thead>
<tr>
<th>Objective 1</th>
<th>Develop ideas to update understanding of Alzheimer’s disease among health professionals and the public, particularly that Alzheimer’s has a long pre-symptomatic stage before the onset of symptoms.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 4</td>
<td>NHS England and NHS Improvement should support awareness and education around the molecular-based diagnosis of Alzheimer’s and other dementias.</td>
</tr>
<tr>
<td>Recommendation 5</td>
<td>The government needs to work with charities to increase public awareness of the value of earlier detection for dementia.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective 2</th>
<th>Engage with the NHS and practising clinicians with experience of dementia to help develop a framework for new services, to highlight bottlenecks of capacity that need to be addressed, and to recommend timescales for implementation.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 2</td>
<td>The scale of the increased capacity and infrastructure changes required in the NHS needs to be scoped and considered now.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective 3</th>
<th>Scope the barriers and opportunities to establishing earlier diagnosis and shift towards molecular-based diagnosis and risk profiling. Develop an action plan for the implementation of such an approach within the NHS.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 6</td>
<td>The NHS needs to prepare to diagnose the diseases that cause dementia more accurately and at a much earlier stage, shifting to detection around 15 to 20 years earlier.</td>
</tr>
<tr>
<td>Recommendation 7</td>
<td>As recommended by the Edinburgh Consensus the NHS should pilot specialist Brain Health Clinics to test an infrastructure that could incorporate developments in diagnostics and prepare the NHS for earlier diagnosis.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective 4</th>
<th>Recommend how the UK health system could accommodate the specialist investigations required to select patients and prescribe future dementia treatments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 1</td>
<td>There needs to be comprehensive horizon scanning in place to understand Alzheimer’s treatments in development and their likely impact on the health sector.</td>
</tr>
<tr>
<td>Recommendation 7</td>
<td>As recommended by the Edinburgh Consensus, the NHS should pilot specialist Brain Health Clinics to test an infrastructure that could incorporate developments in diagnostics and prepare the NHS for earlier diagnosis.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective 5</th>
<th>Ensure the assessment of value of new disease-modifying treatments for dementia captures their full value, including their impact on carers and both the health and social care systems. This will include technical understanding of which elements have the biggest impact on calculations of value and/or cost-effectiveness.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 8</td>
<td>The domains that reflect the true value of Alzheimer’s treatments for individuals and society need to be identified, including where there are gaps in the data.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Objective 6</th>
<th>Develop innovative access and funding models to share risk across industry and the NHS and ensure the introduction of innovative medicines and diagnostics into the UK for people with dementia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommendation 3</td>
<td>Innovative funding models should be developed to respond to the challenge of delivering future Alzheimer’s treatments.</td>
</tr>
</tbody>
</table>
7. Acknowledgements

We would like to acknowledge the support and advice from our clinical advisory group in developing the treatment scenarios for this work:
Prof Iracema Leroi, University of Manchester
Prof John O’Brien, University of Cambridge
Dr Richard Perry, Imperial College London
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Prof Gordon Wilcock, University of Oxford

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London School of Economics and Political Science, Personal Social Services Research Unit
Prof Martin Knapp, Director of PSSRU and Director of NIHR SSCR
Raphael Wittenberg, Associate Professorial Research Fellow
Robert Anderson, Visiting Fellow

Dr Ron Handels, Maastricht University
8. Glossary

- **Biomarker**: A biological molecule found in blood, other body fluids, or tissues that is a sign of a normal or abnormal process, or of a condition or disease. A biomarker may be used to see how well the body responds to a treatment for a disease or condition.

- **Cerebrospinal fluid (CSF)**: Spinal fluid that bathes our brain and spinal cord to act as a shock absorber, circulates nutrients filtered from the blood and removes waste products from the brain.

- **Dementia**: An umbrella term used to describe a set of symptoms that occur as a result of neurodegenerative diseases, of which Alzheimer’s is the most common.

- **Disease-modifying**: Treatments that act on an underlying disease process (as opposed to treating only symptoms) to slow or stop the progression of the disease.

- **Lumbar puncture**: Where a thin needle is inserted between the bones in your lower spine and can be used to take a sample of fluid from your spinal cord (cerebrospinal fluid) to help diagnose a condition. Also known as a spinal tap.

- **Mild cognitive impairment (MCI)**: A term used to describe early memory and thinking problems in older people. It is not a disease in itself.

- **Magnetic resonance imaging (MRI)**: A scan which gives a picture of the brain and can be used to help diagnose dementia.

- **National Institute of Health and Care Excellence (NICE)**: Provides national guidance and advice to improve health and social care.

- **Nuclear medicine**: A branch of medicine that usually involves a small amount of radioactive material, known as a tracer, followed by a series of images taken using a special scanner. It is used to diagnose and treat a number of diseases.

- **Positron emission tomography (PET)**: A type of brain scan that can be used to assess the deposition of Alzheimer’s related proteins, such as β-amyloid.

- **Steady state**: A simplifying assumption which states that the features of the population remain the same as the current population, in terms of prevalence, incidence and mortality. When looking at the aggregate assumptions the steady state is used again by modelling the total effect of a treatment as if the current population had already been treated. Steady state, that is, annual expenditure not in the early years after the intervention has been adopted but after it has been in use for enough years for all those who received it in the early years to have died. – from LSE report.
## 9. Appendix

<table>
<thead>
<tr>
<th>Mid-range scenario; Aggregate costs</th>
<th>Treated population (n)</th>
<th>Diagnostic testing population (n)</th>
<th>Change in prevalence of Alzheimer’s (n)</th>
<th>Diagnostic cost (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment 1</td>
<td>480,000</td>
<td>204,000</td>
<td>+32,000</td>
<td>102</td>
</tr>
<tr>
<td>Treatment 2</td>
<td>310,000</td>
<td>220,000</td>
<td>-59,600</td>
<td>110</td>
</tr>
<tr>
<td>Treatment 3</td>
<td>750,000</td>
<td>220,000</td>
<td>-32,300</td>
<td>110</td>
</tr>
<tr>
<td>Treatment 4</td>
<td>2,610,000</td>
<td>614,000</td>
<td>-76,600</td>
<td>307</td>
</tr>
<tr>
<td>Treatment 5 (3-year delay; 2-year booster)</td>
<td>29,500,000</td>
<td>0</td>
<td>-394,000</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 2. Aggregate outputs
## Appendix

<table>
<thead>
<tr>
<th>Total annual treatment cost (£m)</th>
<th>Cost saving due to treatment</th>
<th>Net annual expenditure change (including diagnostics) (£m)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healthcare (£m)</td>
<td>Social care (£m)</td>
</tr>
<tr>
<td>318</td>
<td>110</td>
<td>370</td>
</tr>
<tr>
<td>2,025</td>
<td>340</td>
<td>790</td>
</tr>
<tr>
<td>2,725</td>
<td>470</td>
<td>1,210</td>
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<tr>
<td>1,400</td>
<td>460</td>
<td>1,070</td>
</tr>
<tr>
<td>9,400</td>
<td>2,140</td>
<td>5,000</td>
</tr>
</tbody>
</table>
10. References


17. AXA Health Tech and You State of the National survey 2017. Survey by YouGov. All figures, unless otherwise stated, are from YouGov Plc. Total sample size was 2,057 adults. Fieldwork was undertaken between 20–21 November 2017. The survey was carried out online. The figures have been weighted and are representative of all GB adults (aged 18+).


If you are interested in discussing Thinking Differently in more detail, please contact Dr Matt Norton, Director of Policy and Strategy on 01223 824575.