House of Commons Library

Debate Pack
20 December 2023
Number CDP 0235 (2023)

By Katherine Garratt,
Elizabeth Rough,
Siobhan Wilson

General debate: New Dementia Treatments

1 Background

1.1 What is dementia?

Dementia is not a single disease; it is a general term used to describe the deterioration of cognitive functioning.[1] Symptoms of dementias can vary in severity and progress through multiple stages. They include difficulties with thinking, problem-solving, remembering and making decisions, to the extent that daily activities can become challenging. Some people with dementia may also find it hard to control their emotions and aspects of their personality may change.

There are multiple types of dementia and symptoms may differ depending on the type. For further information see Alzheimer's Research UK, Types of dementia (not dated).

Alzheimer's disease

Alzheimer's disease is the most common type of dementia, accounting for between 60% and 70% of all dementia cases.[2] It is thought to be caused by the build-up of two types of proteins, tau and amyloid, in and around brain cells. Amyloid builds up into plaques (clusters/clumps of proteins) while tau forms what are termed "neurofibrillary tangles" in the brain.[3] Both damage neurons and disrupt their function. Neurons are specialised cells that transmit messages between different parts of the brain. The NHS notes that researchers "do not fully understand how amyloid and tau are involved in the loss of brain cells", but that research in this area "is continuing".[4]

1.2 Current treatments for dementia

Currently, there is no cure for dementia. There are medicines and treatments that can help manage, or temporarily reduce, some of the symptoms. These, however, do not treat the cause of the underlying disease. This means that they do not stop, or slow, its progression.

1 US NIH National Institute on Aging, What Is Dementia? Symptoms, Types, and Diagnosis, National Institute on Aging, December 2022

2 Alzheimer's Research UK, Subtypes of dementia - Dementia Statistics Hub, accessed 20 December 2023

3 US NIH National Institute on Aging, What Happens to the Brain in Alzheimer's Disease? | National Institute on Aging, May 2017

4 Causes of dementia – NHS, January 2021

More information on current treatments can be found on the NHS webpage: What are the treatments for dementia? - NHS (July 2023).

2 New 'disease-modifying' therapies

2.1 Immunotherapies

Drugs that slow, or stop, the progression of dementia (sometimes referred to as 'disease-modifying' treatments) have not, at the time of writing, been approved for use in the UK. There are, however, some new disease-modifying treatments in development that are aimed at those with mild cognitive impairment, or mild dementia, due to Alzheimer's disease. The drugs, known as immunotherapies, aim to slow the progression of the disease by helping the immune system to recognise and target the "amyloid plaques in the brains of people with Alzheimer's disease to try and help break them down".[5]

Immunotherapies are already used in other branches of medicine, such as cancer treatment, but are at various stages of development and regulatory approval for Alzheimer's disease. Further detail is provided below of two drugs, lecanemab and donanemab, that are scheduled to be appraised by the National Institute for Health and Care Excellence (NICE) in 2024.[6]

Lecanemab

Lecanemab, made by the pharmaceutical / biotechnology companies Eisai and Biogen, is a monoclonal antibody designed to reduce amyloid plaques in the brain among those with mild cognitive impairment due to Alzheimer's disease.[7] It is thus aimed at those at the very early stages of Alzheimer's disease, rather than those with moderate to late-stage dementia. It is given to patients via an intravenous drip every two weeks.

An 18-month Phase III trial, involving 1795 participants, compared lecanemab to a placebo (an inactive substance).[8] The results of the trial were published in the New England Journal of Medicine in January 2023. The researchers reported that lecanemab reduced levels of amyloid in the brain in early Alzheimer's disease and "resulted in moderately less decline on measures of

5 Three promising drugs for treating Alzheimer's disease bring fresh hope, Alzheimer's Society (alzheimers.org.uk), 19 July 2023

6 NICE gets ready to assess new dementia treatments. | News, NICE, 20 November 2023

7 Monoclonal antibodies are proteins manufactured in a laboratory. Monoclonal means that they are copies of one antibody. They are designed to act like human antibodies and therefore can enhance, modify or copy a patient's own immune system response to disease.

8 Clinical trials are typically divided into three stages, known as 'phases'. Phase III trials are later stage trials that focus comparing new treatments with the currently best available treatment. They generally involve a larger number of participants than Phase I and Phase II trials

cognition and function than [the] placebo at 18 months".[9] More specifically, lecanemab slowed the rate of cognitive decline by 27%, while the incidence of adverse events (such as infusion-related reactions) was 21.3% for those who received lecanemab and 9.3% for those who received a placebo.[10]

Lecanemab initially received an "accelerated approval", from the US Food and Drug Administration (FDA), as a treatment for early Alzheimer's disease in patients in the US. This was converted by the FDA to a 'full' approval in July 2023.[11]

Donanemab

Donanemab is manufactured by the pharmaceutical company Eli Lilly and also works by helping the immune system to recognise, target and break down amyloid plaques in the brain. Alzheimer's Research UK explains some of the differences between lecanemab and donanemab:

> Although both drugs target amyloid protein, they target it at different stages in how it builds up in the brain.
>
> Lecanemab targets amyloid as it begins to form fibres, whereas donanemab binds to amyloid once these fibres have clumped together to become a larger build-up or plaque in the brain.[12]

An 18-month Phase III trial, involving 1736 participants with early symptomatic Alzheimer disease and evidence of amyloid and tau pathology, compared donanemab to a placebo. Partcipants were located in eight countries and received either donanemab or the placebo intravenously, every 4 weeks, for 72 weeks.[13] The results were published in JAMA (the Journal of the American Medical Association) in July 2023.

The researchers found that, in those with early-stage Alzheimer's Disease, donanemab was able to slow the progression of the disease (calculated by measuring the memory and thinking skills of participants) by 35% when compared to the placebo group. At 76 weeks, donanemab had cleared amyloid plaques in 76% of participants receiving the treatment.

---

9 Christopher H. van Dyck and others, Lecanemab in Early Alzheimer's Disease, N Engl J Med 2023; 388:9-21

10 US National Institute of Aging statement on report of lecanemab reducing cognitive decline in Alzheimer's clinical trial | National Institute on Aging (nih.gov), July 2023

11 FDA Converts Novel Alzheimer's Disease Treatment to Traditional Approval | FDA, July 2023. After the accelerated approval was granted by the FDA, the drug manufacturer was required (as part of the approvals process) to conduct a further clinical trial to verify the anticipated clinical benefit of lecanemab. Had these 'postapproval' conditions not been met, the FDA could have withdrawn its approval.

12 What is donanemab? | Alzheimer's Society (alzheimers.org.uk), July 2023

13 The countries were the United States, Australia, Canada, Czech Republic, Great Britain, Japan, the Netherlands, and Poland.

The drug also caused side effects; 24% of participants reported experiencing side effects, such as headaches, falls, and infusion-related reactions. The incidence of serious adverse events, such as swelling of the brain, was 17.4% in the donanemab group and 15.8% in the placebo group. Four participants died during the trial; 3 who received donanemab and 1 in the placebo group. The researchers reported that their deaths were "considered related to the treatment".[14]

The Guardian newspaper stated in July 2023 that Eli Lilly had applied for regulatory "approval for donanemab in the US and will do so in the UK in the coming weeks".[15]

2.2 When might new treatments be available on the NHS?

Licencing new treatments

Before a medicine can be sold in a country, and administered in people, it must receive a 'marketing authorisation' (sometimes referred to as a 'licence'). In the UK, marketing authorisations are issued by the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA's role to ensure a medicine is safe, that it works as it is intended and that it can be manufactured to a consistently high-quality standard.

The developers of the drug need to gather sufficient safety and drug effectiveness data during clinical trials to demonstrate that the benefits of the new drug outweigh the risks. This data is then used in their application for a marketing authorisation from the MHRA.

To date, only the manufacturers of lecanemab have submitted a marketing authorisation to the MHRA for their drug as treatment for early Alzheimer's disease.[16] Lecanemab has been designated by the MHRA for the Innovative Licensing and Access Pathway (ILAP). Established in 2021, ILAP aims to speed up and streamline the regulatory approval process for drugs that target "life-threatening or seriously debilitating" conditions and where there is a "significant patient or public health need".

14 John R. Sims and others, Donanemab in Early Symptomatic Alzheimer Disease. The TRAILBLAZER-ALZ 2 Randomized Clinical Trial. JAMA 2023;330(6):512-527; NIHR, Drug donanemab hailed as breakthrough in treat Alzheimer's disease following trial, accessed 8 January 2024

15 Andrew Gregory, Experts urge health regulators to approve 'turning point' dementia drugs | Alzheimer's, The Guardian, 17 July 2023

16 EISAI Submits Marketing Authorization Application for Lecanemab as Treatment for Early Alzheimer's Disease In Great Britain | Biogen, 21 May 2023

NICE technology appraisal

If a drug receives a marketing authorisation from the MHRA it would also need to be recommended for use by the National Institute for Health and Care Excellence (NICE) before it could become available to patients via the NHS.

In England, NICE is responsible, through its technology appraisal process, for making recommendations on the use of new and existing medicines and treatments within the NHS in England. NICE's technology appraisals are a type of cost/benefit analysis that is based on a review of clinical and economic evidence:

- Clinical evidence shows how well the medicine or treatment works.
- Economic evidence shows how well the medicine or treatment works in relation to how much it costs the NHS: does it represent 'value for money'?

Typically, NICE determines the cost effectiveness of a treatment through looking at 'quality-adjusted life years' (QALYs); how many QALYs may a patient, on average, gain from taking the drug being appraised compared with existing therapies that are already available? This is then considered in the context of the price of the new drug and how much each QALY costs, again in comparison to existing treatments (if there are, in fact, existing treatments).

The different stages in the technology appraisal process are set out by NICE on its website: Single technology appraisal (STA) timeline.

NICE has stated that it has "already begun work in readiness for [...] companies submitting their evidence" for what it terms "disease-modifying dementia treatments (DMDTs)". This work includes:

> [...] work done by NICE's Health Technology Assessment Innovation Laboratory (HTA Lab) to identify the key issues that might arise during planned and future evaluations, based on current knowledge, publicly available evidence and in-depth discussions with researchers, patient groups and NHS colleagues.[17]

As noted above, NICE has stated that it is scheduled to appraise both lecanemab and donanemab in 2024.[18] The outcome of its appraisal of "Lecanemab for treating mild cognitive impairment or mild dementia caused by Alzheimer's disease" is expected to be published on 17 July 2024. A timeline for the appraisal of donanemab has not yet been published by NICE.

[17] NICE gets ready to assess new dementia treatments. | News | News | NICE, November 2023
[18] NICE gets ready to assess new dementia treatments. | News, NICE, 20 November 2023

3 Preparing for new treatments

3.1 Diagnosing dementia

NHS England publishes monthly data on dementia diagnosis rates in England. The rate is calculated by comparing the number of people aged 65 and over who are diagnosed with dementia to the estimated number of people aged 65 or over thought to have dementia. The 'national ambition' for the dementia diagnosis rate is for at least two-thirds of people with dementia to have a formal diagnosis (see section 4 below for more information).[19] In November 2023, the diagnosis rate was 64.7%.[20] This means around one in three people with dementia do not have a diagnosis.

There are currently no national standards for waiting times for dementia assessments. In response to a parliamentary question about introducing national standards the Government referred to guidance on the dementia care pathway commissioned by NHS England, which sets an aspiration to increase the number of people receiving a diagnosis and starting treatment within six weeks of referral.[21]

The Government has said it allocated £17 million to NHS England in 2021/22 to address waiting lists and increase dementia diagnosis rates. NHS England is expected to report on progress and examples of good practice by March 2024.[22]

Alzheimer's disease

There are many diseases that can cause dementia and often individuals receive a general diagnosis of dementia. The new treatments are designed to treat Alzheimer's disease specifically. This means that patients with dementia would need further testing to find out if Alzheimer's is their 'subtype' of dementia to be suitable for the treatment. Evidence from trials using donanemab to treat Alzheimer's disease also suggests the earlier it is given,

19 Department of Health and Social Care press release, Dementia diagnosis to be overhauled, 15 May 2013

20 NHS Digital, Primary Care Dementia Data, November 2023, 14 December 2023

21 PQ 4160 [on Memory clinics: Standards], 28 November 2023; National Collaborating Centre for Mental Health, The Dementia Care Pathway: Full implementation guidance, 2018

22 PQ 5270 [on Dementia: Diagnosis], 5 December 2023

the greater the benefit. The medications lecanemab and remternetug[23] are designed to treat people with early-stage Alzheimer's disease.[24]

Diagnosing subtypes of dementia requires more advanced and invasive procedures, which stakeholders say are not widely available in the NHS. They say diagnostic capacity in the NHS will need to increase significantly to support the use of new treatments.[25]

Diagnostic testing for Alzheimer's disease can require procedures such as lumbar punctures or PET (positron emission tomography) scans.[26] Alzheimer's Research UK estimates that 2% of people can currently access these tests. [27] The charity says there would need to be an increase in lumbar punctures from 2,000 to 20,000 per year to support new treatments. [28] It also says the Government needs to invest in new diagnosis methods, such as blood tests that pick up biomarkers for dementia.[29]

The Government has said NHS England has established a national programme team that is working with stakeholders to prepare for the potential roll out of new treatments for Alzheimer's disease. The plans assume the need for "significant diagnostic capacity, including amyloid PET-CT, lumbar puncture and MRI" to identify patients who could benefit from the treatments and provide safety monitoring. It also said research into other modes of diagnosis, including blood-based biomarker and digital tests, is ongoing.[30]

A £5 million project led by Alzheimer's Research UK, the Alzheimer's Society and the National Institute of Health and Care Research hopes to make blood tests for Alzheimer's disease available on the NHS in the next five years.[31]

---

23 Remternetug is another immunotherapy drug in development, also made by Eli Lilly. Like Donanemab, it targets and reduces amyloid plaques (in those with early-stage Alzheimer's disease) once they have clumped together in the brain. Remternetug, however, holds the possibility of being given to patients via an injection under the skin, rather than an intravenous drip.

24 Alzheimer's Society, Three promising drugs for treating Alzheimer's disease bring fresh hope (Accessed 28 December 2023)

25 Alzheimer's Society, Alzheimer's Society briefing – Westminster Hall Debate on New Treatments for Dementia (PDF), January 2024; Alzheimer's Research UK, Tipping Point: The Future of Dementia, September 2023

26 National Institute of Health and Care Excellence, Dementia: assessment, management and support for people living with dementia and their carers, section 1.2, 20 June 2018

27 Alzheimer's Research UK, Tipping Point: The Future of Dementia, September 2023, p27

28 As above, p28

29 As above, p28

30 PQ HL320 [on Dementia: Diagnosis], 14 November 2023

31 Alzheimer's Research UK, A five-year project to bring Alzheimer's blood tests to the NHS (Accessed 27 December 2023)

3.2 Delivering new treatments

Donanemab and lecanemab are delivered by intravenous drip. This means a liquid medicine is delivered via a cannula into the blood. [32] In delivering new treatments, services would need to consider where, and by which team, treatment is administered and how patients would be monitored for side effects.

A joint project by the Royal College of Psychiatrists and Alzheimer's Research UK, 'Are we ready to deliver disease modifying treatments?', found that around one third of psychiatrists thought their services could deliver new, disease modifying treatments within a year of their approval. Alongside diagnostic capacity, psychiatrists were concerned about having sufficient staffing, skills and resources to deliver and monitor new treatments.[33]

Alzheimer's Research UK has called for the rollout of a UK-wide network of 'brain health clinics'. The clinics would work alongside existing dementia services to deliver early intervention to help lower people's risk of dementia, early diagnosis and new treatments, and opportunities to participate in clinical trials. The charity has also called for a 'cross-speciality Alzheimer's Disease Clinical Pathway Council' to develop a new pathway for diagnosing and treating dementia.[34]

The Government has said NHS England is aware of the brain health clinic model and it could be considered by NHS England and Integrated Care Boards if disease modifying treatments for Alzheimer's disease are recommended for use in the NHS.[35]

NHS England has said it recognises additional staffing capacity and further training will be needed to deliver new treatments. It said Integrated Care Boards will be the primary commissioners for most of the new referral and treatment pathway, supported by NHS England.[36]

In June 2023, NHS England published the NHS Long Term Workforce Plan. The plan uses modelling to assess demand on the NHS workforce and how it can be met. From 2025/26 onwards, the modelling takes into account the

32 Alzheimer's Society, Three promising drugs for treating Alzheimer's disease bring fresh hope (Accessed 3 January 2024)

33 Royal College of Psychiatrists and Alzheimer's Research UK, Are we ready to deliver disease modifying treatments?, May 2021

34 Alzheimer's Research UK, Tipping Point: The Future of Dementia, September 2023, p29

35 PQ 202685 [on Dementia: Clinics], 23 October 2023

36 NHS England blog, Preparing for a new chapter: disease modifying treatments for early Alzheimer's disease, 27 December 2023

increased complexity of some treatments, such as for dementia, when determining workforce projections.[37]

3.3 Approval and funding

As noted in section 2.2, for use in the NHS, new treatments need to be approved by NICE (the National Institute for Health and Care Excellence) based on clinical and cost-effectiveness. Alzheimer's Research UK says it is concerned the treatments might not be determined to be affordable for the NHS compared to the current spend on dementia. It wants NICE to consider the wider context of the cost of informal care for dementia when they review the economic evidence for its approval:

> As the bulk of the cost of dementia falls on social and informal care (£22.7bn per year) rather than the NHS (£1.7bn per year), any new dementia treatment is unlikely to pass the NHS value threshold and will not be approved. A dementia treatment would have far-ranging benefits for society and the economy, beyond the clear benefits for the patient, and it is essential NICE and equivalent bodies in other parts of the UK consider these throughout their assessments.[38]

The charity is also concerned that it will take time to build up evidence of the long-term clinical benefits of the treatments.[39]

New treatments can also require the NHS to invest in diagnostic and treatment capacity. For example, Alzheimer's Research UK estimates that increasing the number of lumbar punctures to 20,000 per year would require a £16 million investment in infrastructure, equipment and staffing.[40]

The charity also wants the NHS and drug companies to consider conditional access arrangements, whereby there is managed access to a treatment whilst further data is collected.[41] This evidence is then used to assess whether the treatment should be made routinely available on the NHS. These arrangements aim to give patients quicker access to promising new treatments whilst addressing any concerns about clinical or cost effectiveness. There are two dedicated NHS England funding sources for treatments in managed access, each with an annual budget of £340: the Cancer Drugs Fund and the Innovative Medicines Fund.[42]

---

37 NHS England, NHS Long Term Workforce Plan, Annex B: Modelling approach and assessment, June 2023, p119

38 Alzheimer's Research UK, Tipping Point: The Future of Dementia, September 2023, p33

39 As above, p33

40 As above, p29

41 As above, p29

42 NICE, Managed access (Accessed 3 January 2024)

4 Dementia policy and funding commitments

4.1 Forthcoming Major Conditions Strategy

In January 2023, the Government announced it will publish a Major Conditions Strategy that will cover six conditions including dementia.[43] The strategy will be published instead of a separate strategy for dementia, which had been expected in 2022.[44] The Government has said all previous research will be used to inform the plan and it remains committed to accelerating diagnosis and developing the latest treatments.[45]

In August 2023, the Department of Health and Social Care published the Major conditions strategy: case for change and our strategic framework. The framework commits to recovering the 'national ambition' for dementia. The ambition, first announced in 2013, is for at least two-thirds of people with dementia to have a formal diagnosis. [46] NHS England publishes monthly data on dementia diagnosis rates in England.

The framework says the national ambition was not achieved for the first time in four years in March 2020 and there is significant variation across England. The commitment to recovering the diagnosis rate is included in the NHS 2023/24 priorities and operational planning guidance. The framework also notes the Office for Health Improvement and Disparities will support the investigation of the variation in rates across the country.

The framework recommits to doubling funding for dementia research by 2024/25, as initially pledged in the 2019 Conservative Manifesto.[47] In December 2023, the Government said it remains committed to increasing funding for dementia research to £160 million per year by 2024/25 and has spent over £413 million on dementia research from 2017/18 to 2021/22.[48]

The Major Conditions Strategy strategic framework also says NHS England will map medicines for Alzheimer's disease and explore the establishment of a steering group to ensure the system is ready for new treatments. [49] A national

---

43 HCWS514 [on Government Action on Major Conditions and Diseases], 24 January 2023

44 Department of Health and Social Care, press release, Health Secretary announces 10-year plan for dementia, 17 May 2022

45 Department of Health and Social Care blog post, Major Conditions Strategy: What you need to know, 17 May 2023

46 Department of Health and Social Care press release, Dementia diagnosis to be overhauled, 15 May 2013

47 Conservative Party, Conservative Party Manifesto 2019, November 2019

48 PQ 4416 [on Dementia: Research], 21 December 2023

49 Department of Health and Social Care, Major conditions strategy: case for change and our strategic framework, 21 August 2023

programme team for early Alzheimer's treatments was established in summer 2023.[50]

Autumn Statement 2023

In the 2023 Autumn Statement, the Chancellor announced that up to £20 million of £121 million in funding for improving clinical research in the UK (first announced in May 2023) would be used to launch the first Clinical Trial Delivery Accelerator focused on Dementia.[51]

Dame Barbara Windsor Dementia Mission 2022

In August 2022, then Prime Minister Boris Johnson launched a national mission to tackle dementia, named in memory of Dame Barbara Windsor who died with dementia. This included £95 million of ringfenced funding and a new taskforce for speeding up dementia research.[52]

Life Sciences Vision 2021

In July 2021, the Government and the life sciences sector published Life Sciences Vision, setting out a ten-year strategy to stimulate the sector and address significant healthcare challenges. This included a 'mission' to improve translational capabilities in neurodegeneration and dementia. This means working to translate new research findings into novel treatments for dementia. Alongside the Life Sciences Vision, the Government announced a £200 million Life Sciences Investment programme.[53]

NHS Long Term Plan 2019

The NHS Long Term Plan noted that over the preceding decade the dementia diagnosis rate had doubled and the prescription of antipsychotic drugs halved. Antipsychotic medicines are used as a last resort in dementia care to treat severe agitation or distress and can cause serious side effects.[54] The Long Term Plan also said research investment for dementia would double between 2015 and 2020.[55]

---

50 NHS England blog, Preparing for a new chapter: disease modifying treatments for early Alzheimer's disease, 27 December 2023

51 HM Treasury, Autumn Statement 2023, 22 November 2023, para 4.83

52 Gov.uk press release, Prime Minister launches 'Dame Barbara Windsor Dementia Mission', 14 August 2022

53 Gov.uk press release, Bold new life sciences vision sets path for UK to build on pandemic response and deliver life-changing innovations to patients, 6 July 2021

54 Alzheimer's Society, Antipsychotics and other drug approaches in dementia care (Accessed 5 January 2024)

55 NHS England, NHS Long Term Plan, 7 January 2019, para 1.20

Prime Minister's Challenge on Dementia 2012 and 2015

In March 2012, then Prime Minister, David Cameron, launched Dementia 2012: A national challenge. The challenge aimed to deliver major improvements in dementia care and research by 2015, focusing on creating dementia friendly communities, improving awareness and driving improvements in health, care and research.[56]

In February 2015, the Government published the successor to the 2012 challenge on dementia, the Challenge on Dementia 2020. It set several objectives. This included achieving, by 2020, a national average of six weeks for an initial dementia assessment following referral by a GP and cures or disease modifying therapies on track to exist by 2025.[57]

[56] Department of Health, Prime Minister's challenge on dementia, 26 March 2012

[57] Department of Health, Prime Minister's challenge on dementia 2020, 21 February 2015

5 Parliamentary material

5.1 Parliamentary questions

Dementia: Research
21 December 2023 | UIN 4416

Asked by: Chi Onwurah

To ask the Secretary of State for Health and Social Care, with reference to her Department's press release entitled Prime Minister launches Dame Barbara Windsor Dementia Mission, published 14 August 2022, what progress her Department has made on its commitment to reach dementia research funding of £160 million a year by 2024; and if she will make an assessment of the potential impact of the Autumn Statement on that commitment.

Answering member: Helen Whately | Department: Department of Health and Social Care

The Government is committed to supporting research into dementia and has committed to double funding for dementia research. We will double funding for dementia research to £160 million per year by 2024/25. The Government spent over £413 million on dementia research from 2017/18 to 2021/22.

In August 2022, the former Prime Minister launched the Dame Barbara Windsor Dementia Mission, along with £95 million of Government funding. The Mission is part of the commitment to double dementia research funding and aims to speed up the development of new treatments. In the Autumn Statement the Chancellor announced up to £20 million funding to launch a Clinical Trial Delivery Accelerator, focused on dementia. This investment also contributes to meeting the commitment to double dementia research funding and will scope out innovative new tools and approaches to clinical research in the National Health Service. It will leverage the United Kingdom’s world-class strengths in data, digital sciences and genomics capabilities to increase the speed and quality of clinical trials, while driving down the cost of large-scale trials.

The National Institute for Health and Care Research launched a number of new initiatives to support dementia research, such as investing nearly £11 million to develop new digital approaches for the early detection and diagnosis of dementia.

Dementia: Drugs
19 December 2023 | HL1158

Asked by: Lord McCrea of Magherafelt and Cookstown

To ask His Majesty's Government, further to the call from Alzheimer's UK for any drugs “deemed safe and effective” to treat dementia to be made available on the NHS as soon as possible, what plans they have to do so.

Answering member: Lord Markham | Department: Department of Health and Social Care

To be made routinely available to National Health Service patients in England, new medicines must receive a marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) and a positive recommendation from the National Institute for Health and Care Excellence (NICE) to demonstrate clinical and cost effectiveness.

Several potential new disease modifying treatments for Alzheimer’s disease are in development and MHRA, NICE, NHS England and the Department are working closely to ensure that arrangements are in place to support the adoption of any new licensed and NICE recommended treatment for Alzheimer’s disease as soon as possible.

Dementia: Medical Treatments
12 December 2023 | HL646

Asked by: Lord Browne of Belmont

To ask His Majesty's Government what steps they are taking to ensure that patients diagnosed with dementia are able to access breakthrough treatments as soon as possible.

Answering member: Lord Markham | Department: Department of Health and Social Care

Several potential new disease modifying treatments for dementia caused by Alzheimer’s disease are in development. The Medicines and Healthcare products Regulatory Agency, the National Institute for Health and Care Excellence (NICE), NHS England and the Department are working closely to ensure that arrangements are in place to support the adoption of any new licensed and NICE recommended treatment for dementia as soon as possible.

NICE’s evaluations of two new potential treatments, lecanemab and donanemab, are now underway. NICE has begun work in readiness for the companies submitting their evidence. This includes work done by NICE’s Health Technology Assessment Innovation Laboratory (HTA Lab) to identify the key issues that might arise during planned and future evaluations, based on current knowledge, publicly available evidence and in-depth discussions with researchers, patient groups and National Health Service colleagues. The NICE HTA Lab report found that NICE’s methods and processes for evaluating new treatments for use in the NHS are appropriate for the new class of Alzheimer’s drugs and identified key issues that need to be considered during evaluation.

Dementia: Research

05 December 2023 | UIN 4714

Asked by: Rachael Maskell

To ask the Secretary of State for Health and Social Care, what steps her Department is taking to increase research on the (a) prevention and (b) treatment of dementia.

Answering member: Andrew Stephenson | Department: Department of Health and Social Care

The Government is strongly committed to supporting research into dementia. In 2019, we committed to double funding for dementia research to £160 million per year by 2024/25. This will span all areas of research, including prevention and treatment of dementia. The Department funds dementia research via the National Institute for Health and Care Research (NIHR).

The Department, via the NIHR, is taking several steps to increase research on the prevention and treatment of dementia, such as commissioning a Dementia and Neurodegeneration Policy Research Unit (PRU) worth £6 million to further boost evidence for policymaking. The PRU's remit will cover research into policy interventions intended to reduce or prevent dementia and other neurodegenerative conditions. Alongside the Dame Barbara Windsor Dementia Mission, which is backed by £95 million worth of funding, NIHR is investing in the Dementia Translational Research Collaboration which seeks to significantly expand the UK's early phase clinical trial capabilities in dementia. This seeks to support the Dementia Mission's aim to speed up the development of new treatments for dementia.

Dementia: Medical Treatments and Research

28 November 2023 | UIN 3144

Asked by: Andrew Rosindell

To ask the Secretary of State for Health and Social Care, what steps she has taken to (a) fund and (b) support new dementia (i) treatment and (ii) research in (A) Romford and (B) England.

Answering member: Helen Whately | Department: Department of Health and Social Care

We want a society where every person with dementia, their families and carers, receive high quality, compassionate care, from diagnosis through to end of life.

Several potential new disease modifying treatments for Alzheimer's disease are in development. The Medicines and Healthcare products Regulatory Agency, National Institute for Health and Care Clinical Excellence (NICE), NHS England and the Department are working closely to ensure that arrangements are in place to support the adoption of any new licensed and NICE recommended treatment for Alzheimer's disease in England as soon as

possible. NICE's appraisals of lecanemab and donanemab for treating early Alzheimer's disease is currently underway and, subject to licensing, NICE expects to publish final guidance in summer 2024 as close to licence as possible.

The Government is strongly committed to supporting research into dementia. The Department delivers research via the National Institute for Health and Care Research (NIHR).

The NIHR has launched several exciting new initiatives to support new dementia research. This includes: investing nearly £11 million to develop new digital approaches for the early detection and diagnosis of dementia; investing £9 million to continue funding the Three Schools Dementia Programme, which links public health, primary care and social care via our NIHR research schools; and commissioning a Dementia and Neurodegeneration Policy Research Unit worth £6 million to further boost evidence for policymaking. This work will support research across the country.

The usual practice of NIHR is not to ring-fence funds for expenditure on particular topics or regions. Research proposals in all areas compete for the funding available and funding applications are judged in open competition, with awards being made based on the importance of the topic to patients and health and care services, value for money and scientific quality.

5.2 Debates

Dementia Research in the UK
10 February 2022 | House of Commons | 708 cc1153-1185

Dementia: Fuelling the Moonshot
16 November 2021 | House of Lords | 816 cc225-235

Dementia Action Week
27 May 2021 | House of Commons | 696 cc646-604

6 Press material

The following is a selection of news and media articles relevant to this debate.

Please note: the Library is not responsible for either the views or the accuracy of external content

Putting your voice at the heart of complex decisions on new dementia drugs
Alzheimers Research UK
21 December 2023

New Alzheimer's drugs bring hope of slowing disease for UK patients
The Guardian
17 December 2023

NICE gets ready to assess new dementia treatments
National Institute for Health and Care Clinical Excellence (NICE)
20 November 2023

How far away is a dementia 'cure'?
Which? News
9 November 2023

Surgery-free brain stimulation could provide new treatment for dementia
Imperial College London
19 October 2023

The evolving story of Alzheimer's disease [subscription needed]
New Scientist
27 July 2023

More than 250,000 dementia patients in England could miss new treatments
The Guardian
20 July 2023

New dementia drugs: patients to pay privately or face NHS postcode lottery
The Guardian
16 July 2023

'This looks like the real deal': are we inching closer to a treatment for Alzheimer's?
The Guardian
22 November 2022

7 Further reading

Potential issues and challenges in evaluation of disease-modifying treatments (PDF)
National Institute for Health and Care Clinical Excellence (NICE)
November 2023

Tipping Point: The Future of Dementia
Alzheimers UK
September 2023

Fuelling the Moonshot: Unleashing the UK's potential through dementia research (PDF)
Alzheimers UK
September 2021

All Party Parliamentary Group on Dementia
Lords Library briefing paper
12 November 2021

Dementia: policy, services and statistics overview
Commons Library briefing paper CBP07007
21 June 2019

Disclaimer

The Commons Library does not intend the information in our research publications and briefings to address the specific circumstances of any particular individual. We have published it to support the work of MPs. You should not rely upon it as legal or professional advice, or as a substitute for it. We do not accept any liability whatsoever for any errors, omissions or misstatements contained herein. You should consult a suitably qualified professional if you require specific advice or information. Read our briefing 'Legal help: where to go and how to pay' for further information about sources of legal advice and help. This information is provided subject to the conditions of the Open Parliament Licence.

Sources and subscriptions for MPs and staff

We try to use sources in our research that everyone can access, but sometimes only information that exists behind a paywall or via a subscription is available. We provide access to many online subscriptions to MPs and parliamentary staff, please contact hoclibraryonline@parliament.uk or visit commonslibrary.parliament.uk/resources for more information.

Feedback

Every effort is made to ensure that the information contained in these publicly available briefings is correct at the time of publication. Readers should be aware however that briefings are not necessarily updated to reflect subsequent changes.

If you have any comments on our briefings please email papers@parliament.uk. Please note that authors are not always able to engage in discussions with members of the public who express opinions about the content of our research, although we will carefully consider and correct any factual errors.

You can read our feedback and complaints policy and our editorial policy at commonslibrary.parliament.uk. If you have general questions about the work of the House of Commons email hcenquiries@parliament.uk.