

## SOP

### PILOT EVALUATION SOP: CSF ASSAY FOR ALZHEIMER'S DISEASE BIOMARKERS

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## Introduction

The Alzheimer's Society estimates there are 982,000 people living in the UK with dementia. This number is expected to rise to over 1.4 million by 2040 (Alzheimer's Society, 2024). In Gloucestershire, there are 6,591 people aged 65 and above who have been diagnosed with dementia (as of April 2025) and an estimated 3,500 more people living with undiagnosed dementia.

The One Gloucestershire [Dementia Strategy \(2023-28\)](#) outlines a system-wide approach to improving dementia care across the county. Drawing on the NHS England Well Pathway for Dementia, the strategy is mapped around five key priorities:

1. Preventing Well – Risk of people developing dementia is minimised
2. Diagnosing Well – Timely, accurate diagnosis, care plan, and review within first year
3. Supporting Well – Access to safe high-quality health and social care for people with dementia and carers
4. Living Well – People with dementia can live normally in safe and accepting communities
5. Dying Well – People living with dementia die with dignity in the place of their choosing

## Background

To make a diagnosis of Alzheimer's disease, one requires a comprehensive patient history, collateral history, examination, blood tests (to rule out reversible causes of memory symptoms), neuroimaging and cognitive testing. Often, by the time the person has presented to their GP with memory symptoms, they have already progressed beyond mild stages of the disease. This represents a lost opportunity for people to make lifestyle changes to reduce their risk of developing Alzheimer's Disease earlier in life and perhaps represents a potential lost opportunity to be prescribed newer disease modifying drugs aimed at people in the early stages of disease. Some of these medications (Lecanemab and Donanemab), have been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) and are available privately. However, they have not been approved for NHS use by the National Institute for Health and Care Excellence (NICE), which has cited limited clinical benefit and high costs. Encouragingly, there are many other disease-modifying treatments in development, and it is anticipated that some will receive a positive Technology Appraisal (TA) in the future. Once NICE issue a TA, the NHS will be required to implement a new diagnostic and treatment pathway within 90 days. It is for this reason a concerted effort has been made to find a way to make faster, more accurate diagnoses at earlier stages of the disease.

Biomarkers, pathognomonic of Alzheimer's Disease, have been discovered. These are proteins which can be detected in the cerebrospinal fluid (CSF) of patients, in some cases 20 years before any clinical manifestation of memory symptoms. Being able to identify a patient at risk of developing Alzheimer's 20 years before the onset of symptoms would be game changing for the population and clinicians alike and is a particularly important as we await NICE's ongoing review of disease modifying drugs for Alzheimer's disease.

At the moment, analysis of these biomarkers is not freely available in the NHS. We can only request them in rare cases of diagnostic uncertainty and Trusts are restricted to couriering CSF samples to laboratories in London. We are suggesting it is going to be increasingly important for Gloucestershire to be able to provide their own CSF biomarker analysis and it supports the second priority listed in the One Gloucestershire [Dementia Strategy \(2023-28\)](#), of "Diagnosing Well". Not

only would timely and accurate diagnosis benefit our local population, but we could expand the service to include other counties in the South West of England and South Wales to become a regional leader in the field.

A coalition has been formed between Psychiatry in Gloucestershire Health and Care NHS Foundation Trust and Neurology and Pathology in Gloucestershire Hospitals NHS Foundation Trust, to try to make this a reality. We are working with Roche Diagnostics who have kindly agreed to provide the CSF assay analysis for free during the pilot period. We aim to pilot the CSF Biomarker service by taking referrals from private patients and will use the analysis to form the basis of the business case to expand this to benefit NHS patients.

## Protocol

1. A referral letter will be written by private memory clinic consultants to Dr Stokin (Consultant Neurologist) and emailed to the neurology secretaries at [ghn-tr.neurology.secretaries1@nhs.net](mailto:ghn-tr.neurology.secretaries1@nhs.net). The patient will need MRI before referral.
2. The referral will be screened by Dr Stokin.
3. If appropriate, neurology secretaries will create a Trust patient record and send out appointment letter for lumbar puncture. Included with this letter will be a patient information leaflet (Appendix 1).
4. Neurology medic (or other trained technician) to perform lumbar puncture in neurology outpatient clinic and document procedure using consent form (Appendix 2) and diagnostic lumbar puncture procedure checklists (Appendix 3).
5. CSF samples will be harvested using the aliquot and polypropylene tubes recommended by Roche. **4 samples** to be collected in total.
6. All samples to be sent to GRH biochemistry lab via porters
7. First sample to be discarded if contaminated with blood. Lab to analyse 1x 2.5ml polypropylene tube on Roche Elecsys platform. Second 2.5ml polypropylene tube to be sent to Manchester (on dry ice or biofreeze) for cross titration and referencing. Fourth sample to be analysed as per standard CSF samples (protein, oligoclonal bands etc).
8. CSF results to be checked by Dr Stokin (for pilot only) and results fed back to referring clinician.
9. Referring clinician to inform patients of their results and use them as part of the formulation for dementia diagnosis. If dementia is present, patient will be referred to usual post-diagnostic follow-up pathway. If dementia is not present or not likely, they can be reassured and discharged.
10. Feedback collected from patient and referring consultant using QR codes (Appendix 4).

## Appendices

Appendix 1. Diagnostic Lumbar Puncture: Patient information leaflet.

[https://www.canva.com/design/DAGmxJdn-Dg/WL\\_z6D04bmzdIV7vRQNjeA/view?utm\\_content=DAGmxJdn-Dg&utm\\_campaign=designshare&utm\\_medium=link2&utm\\_source=uniquelinks&utlId=h7d7220a208](https://www.canva.com/design/DAGmxJdn-Dg/WL_z6D04bmzdIV7vRQNjeA/view?utm_content=DAGmxJdn-Dg&utm_campaign=designshare&utm_medium=link2&utm_source=uniquelinks&utlId=h7d7220a208)

Appendix 2. Diagnostic Lumbar Puncture: Consent Form.

[https://www.canva.com/design/DAGpYepQ3qo/QG\\_pOG6oE\\_xU-mKYSUCbGA/edit?utm\\_content=DAGpYepQ3qo&utm\\_campaign=designshare&utm\\_medium=link2&utm\\_source=sharebutton](https://www.canva.com/design/DAGpYepQ3qo/QG_pOG6oE_xU-mKYSUCbGA/edit?utm_content=DAGpYepQ3qo&utm_campaign=designshare&utm_medium=link2&utm_source=sharebutton)

Appendix 3. Diagnostic Lumbar Puncture Checklist

[https://gloscare-my.sharepoint.com/:w/g/personal/alex\\_thatcher\\_ghc\\_nhs\\_uk/EaiVLU7ESXZAqXe\\_8jboGn4BmroGS0FE9iQ6OznLZRZMkQ?e=Fb1XsC](https://gloscare-my.sharepoint.com/:w/g/personal/alex_thatcher_ghc_nhs_uk/EaiVLU7ESXZAqXe_8jboGn4BmroGS0FE9iQ6OznLZRZMkQ?e=Fb1XsC)

Appendix 4. Feedback Form QR Code for Patients and Clinicians

[https://www.canva.com/design/DAGhb8PDqbY/kGIZDWBhU8TO5clTw-JYWw/view?utm\\_content=DAGhb8PDqbY&utm\\_campaign=designshare&utm\\_medium=link2&utm\\_source=uniquelinks&utlId=hca8e89221e](https://www.canva.com/design/DAGhb8PDqbY/kGIZDWBhU8TO5clTw-JYWw/view?utm_content=DAGhb8PDqbY&utm_campaign=designshare&utm_medium=link2&utm_source=uniquelinks&utlId=hca8e89221e)

## References

Alzheimer's Society (2024). *How many people have dementia in the UK?* [online] [www.alzheimers.org.uk](https://www.alzheimers.org.uk/blog/how-many-people-have-dementia-uk). Available at: <https://www.alzheimers.org.uk/blog/how-many-people-have-dementia-uk>.

Dementia Strategy Improving the lives of people affected by Dementia in Gloucestershire. (2023). Available at: [https://www.nhsglos.nhs.uk/wp-content/uploads/2024/04/Dementia-Strategy\\_FINAL-April24.pdf](https://www.nhsglos.nhs.uk/wp-content/uploads/2024/04/Dementia-Strategy_FINAL-April24.pdf).

## Version Control

Version Number	Date	Summary of Amendment	By	Organisation
0.1	April 2025	Draft	Dr Alex Thatcher (ST5, Resident Dr in Psychiatry)	GHC
0.2	May 2025	Review and amendments	Dr Gorazd Stokin (Consultant Neurologist)	GHT
0.3	May 2025	Review, no amendments	Professor Tarun Kuruvilla (Consultant Psychiatrist) Emma Jelfs (Deputy General Manager, Care of the Elderly, Neurology and Stroke)	GHC GHT
0.4	June 2025	Review and amendments	Mel Meller (Clinical Commissioning Manager – Dementia) Steve Shelley-King (Clinical Lead for Dementia)	ICB ICB/GHC
0.5	June 2025	Review, no amendments	Jane Haros (Deputy Director of Nursing) Dr Hein le Roux (GP/Deputy CMO)	ICB ICB/GP
0.6	June 2025	Review, amendments made and finalised.	Dr Alex Thatcher (ST5, Resident Dr in Psychiatry) Professor Tarun Kuruvilla (Consultant Psychiatrist) Dr Gorazd Stokin (Consultant Neurologist)	GHC GHC GHT



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