Management of medications for Alzheimer's disease

DOCUMENT TO BE SCANNED INTO ELECTRONIC RECORDS / FILED IN NOTES

Patient Name: **Date of Birth:** **NHS No:**

Name of Referring Consultant: **Contact Number:**

INTRODUCTION

These guidelines have been produced to clarify the roles of primary and secondary care in the management of medications for Alzheimer's disease. They are based on the National Institute for Health and Care Excellence (NICE) Technology Appraisal 217 (March 2011) regarding donepezil, rivastigmine and galantamine (acetylcholinesterase inhibitors, or AChEIs) and memantine and the June 2018 NICE guideline on dementia, which also partially replaced the 2011 guidance document.

NICE GUIDELINE 2018 (NG97)

NICE guideline states the following:

1) The three acetylcholinesterase (AChE) inhibitors donepezil, galantamine and rivastigmine as monotherapies are recommended as options for managing mild to moderate Alzheimer's disease

2) Memantine monotherapy is recommended as an option for managing Alzheimer's disease for people with:

    - moderate Alzheimer's disease who are intolerant of or have a contraindication to AChE inhibitors or
    - severe Alzheimer's disease.

3)For people with an established diagnosis of Alzheimer's disease who are already taking an AChE inhibitor:

- consider memantine in addition to an AChE inhibitor if they have moderate disease
- offer memantine in addition to an AChE inhibitor if they have severe disease.

4) Treatment should be under the following conditions:

Initiation will take place by specialist from NELFT following clinical assessment and review. Where patient has been stabilised, patient will be discharged to the GP to continue treatment.

NICE guidelines do allow healthcare professionals such as GPs, nurse consultants and advanced nurse practioners to diagnose and treat Alzheimer's disease provided they have the specialist expertise and are competent to do so. Where primary care initiation takes place (e.g. GPwSI), the complete pathway from assessment to diagnosis, initiation, titration and follow-up would also remain within primary care, but this would not preclude subsequent referral to secondary care where there is a clinical need for specialist advice.

AChE inhibitors in people with Alzheimer's disease should not be stopped because of disease severity alone.

5) The 2018 NICE guideline emphasises that cognitive scores alone should not be the basis for assessing severity, pointing out that educational attainment, sensory problems and language barriers need to be taken into account. In the memory clinic, translated services are offered during MoCA cognitive assessment. Combination of an AChEI and memantine may occur where deemed clinically appropriate and switching between or combining the two is a clinical decision.

PATIENT PATHWAY

This pathway is for where patient has been initiated by specialist, NELFT and patient continued in primary care. Where GP, advanced nurse practitioners, nurse consultants (who have the expertise and competence) have initiated prescribing, they would be responsible for the whole pathway. Specialist advice is available where required.

Diagnosis	Prescribing Initiated By	Prescribing Continued By	Monitored By	Duration of Treatment
Alzheimer's disease, Dementia with Lewy bodies, mixed dementia and Parkinson's disease dementia.	Old Age or Learning Disability Psychiatrist, Neurologist or Geriatrician GP, ANP and Nurse consultant (who specializes in treating AD) on advice of above Specialist will initiate treatment following assessment and diagnosis, and titrate the medication. Once patient is stable, GP requested to continue to prescribe. Duration of treatment prescribed by specialist: 1-3 months, depending on medication & dose: Low dose: Donepezil 5mg or Rivastigmine up to 4.6mg/24 hrs: one month High dose: Donepezil 10mg or Rivastigmine up to 9.5mg/24 hrs: three months Memantine: titration pack 5mg/10mg/15mg/20mg : till titration completed to tolerated dose.	GP	Old Age Psychiatry Learning Disability Psychiatry Neurology Geriatric medicine == Annual review should include the following; - How is your memory? - Any improvement or decline? - Is there any evidence of behavioural problems, BPSD (behavioural and psychological symptoms related to dementia) - Is there any carer stress - Any side effects from the medication, dizziness, diarrhoea GP's can access specialist advice via "advice & guidance". Where indicated, specialist may advise referral to memory clinic.	Determined on a case by case basis as clinically appropriate/as per NICE guidelines.

Please note: during GP annual review, a steady decline in cognitive function year on year is to be expected so this on its own would not necessarily need a re-referral and review by the specialist memory clinic. However if GP, patient or carer has concerns, they can be referred for review. Patients suffering a significant deterioration, whose general

wellbeing is deteriorating, or who are showing signs of another mental health problem (e.g. depression, hallucinations or developing behavioural problems) should be referred back to the specialist memory clinic. This may be an urgent referral depending on the presentation and severity of symptoms.

Under Quality Outcome Framework, QOF 2021/22, practices are required to review care plan in a face-to-face review in the preceding 12 months - DEM004: (NICE 2015 menu ID: NM107).

ORAL DOSE AND ADMINISTRATION

This section contains detailed information for each medication. This may be relevant to the clinician who initiates medication. Prescribers should consult the latest edition of BNF and Summary Product Characteristics for further information.

Current medications for Alzheimer's disease can have modest but significant effects on cognition, psychiatric and behavioural symptoms and function in individuals. There is also evidence to support their use in mixed (Alzheimer's disease and vascular) dementia and Lewy body dementia.

The use of any pharmaceutical form other than solid oral tablets or capsules (including modified release forms), should be clinically justified by concordance issues or sensitivity to side effects. Alternative forms include oro-dispersible tablets, liquid preparations and transdermal patches but these may be considerably more expensive, and should only be used where it is clinically indicated (e.g. patients with established swallowing difficulties).

Donepezil

- Tablets/orodispersible tablets/oral solution
- Dose: 5 mg/day for 4 weeks then assess, maintenance 10 mg/day (normally night-time dosing)
- Common side effects include: diarrhoea, muscle cramps, fatigue, nausea, vomiting, headache and insomnia
- Caution in: supraventricular conduction abnormalities, particularly bradyarrythmias; gastric ulcers or people on non-steroidal anti-inflammatory drugs (NSAIDs); seizures; asthma or chronic obstructive pulmonary disease (COPD); patients on cholinergic agonists; patients on beta blockers

Galantamine

- Tablets/oral solution/modified release capsules
- Dose: 8 mg/day for 4 weeks then increased to 16 mg/day for 4 weeks, then if tolerated 24 mg/day (maintenance dose → 16-24mg per day)
- Tablets and oral solution need to be given in divided doses
- Side effects and cautions: nausea and vomiting, see under donepezil and consult Summary of Product Characteristics

Rivastigmine

- Capsules/oral solution – dose: 1.5 mg bd for 4 weeks, then 3 mg bd for 4 weeks, then 4.5 mg for 4 weeks and then if tolerated 6 mg bd (increased of steps of 1.5mg BD at intervals of at least 2 weeks)
- Patches – dose: 4.6 mg/24 hours for at least 4 weeks then 9.5 mg/24 hours. Dose can be increased to 13.3 mg/24 hours if required (patches to be used in caution in patients with weight of under 50kg)
- Side effects and cautions: nausea and vomiting, see under donepezil and consult Summary of Product Characteristics : Click here
- When switching from oral to transdermal rivastigmine:
  patients taking 3–6 mg by mouth daily should initially switch to 4.6 mg/24 hours patch, then titrate as above.

Patients taking 9 mg by mouth daily should switch to 9.5 mg/24 hours patch if oral dose stable and well tolerated
Patients taking 12 mg by mouth daily should switch to 9.5 mg/24 hours patch
if oral dose not stable or well tolerated. patients should switch to 4.6 mg/24 hours patch, then titrate as above..
The first patch should be applied on the day following the last oral dose.

Memantine

- Differs from the AChEIs in being an NMDA antagonist
- Tablets/oral drops/soluble tablet/orodispersible tablets/oral solution
- Dose: 5 mg/day for 1 week, then 10 mg/day for 1 week, then 15 mg/day for 1 week, then 20 mg/day (increased in

steps of 5mg every week)

- Renal impairment dose adjustment, as follows:

- mildly impaired renal function (creatinine clearance 50 – 80 ml/min): no dose adjustment is required.
- moderate renal impairment (creatinine clearance 30 – 49 ml/min) daily dose should be 10 mg.

If tolerated well after at least 7 days of treatment, the dose could be increased up to 20 mg/day according to standard titration scheme.

- In patients with severe renal impairment (creatinine clearance 5 – 29 ml/min) maximum daily dose should be 10 mg.

- Renal function to be checked prior to commencement of memantine
- The BNF and SPC does not state how often renal function should be monitored. At discharge, GP should use clinical judgement on when to monitor renal function. Seek specialist advice if require dose adjustments.
- To be used in caution in patients with: Epilepsy; history of convulsions; risk factors for epilepsy
- Side effects: dizziness, headache, constipation, somnolence, hypertension

Drug Product	**Cheapest Price in Primary Care (June 2023 Drug Tariff)***
Donepezil tablets	5 mg x28 – £1.22 10 mg x28 – £1.42
Donepezil orodispersible tablets sugar free	5 mg x28 – £33.58 10 mg x28 – £87.61
Donepezil oral solution	1mg/ml 150ml £97.00
Galantamine tablets (special-order)	Prices vary- community pharmacy to get quote from manufacturer prior to ordering
Galantamine oral solution	20 mg/5mL x100 mL – £120.00
Galantamine MR capsules	8 mg x28 – £51.88 16 mg x28 – £64.90 24 mg x 28 – £79.80
Memantine tablets	10 mg x28 – £1.25 20 mg x28 – £1.60
Memantine oral solution	5 mg/actuation (10 mg/mL) x50 mL – £7.46
Memantine orodispersible tablet sugar free	10mg x 28 - £24.99 20mg x 28 - £49.98
Rivastigmine capsules	1.5 mg x28 – £3.66 3 mg x28 – £4.21 4.5 mg x28 – £23.53 6 mg x28 – £27.19
Rivastigmine oral solution	2 mg/mL x120mL – £96.82
Rivastigmine patches	4.6 mg/24 hours x30 – £ 77.97 9.5 mg/24 hours x30 – £19.97 13.3 mg/24 hours x30 – £77.97

*Please refer to current edition of Drug Tariff for the current prices,

MONITORING

1. Pulse check is required before treatment and after each dose increase with AChEIs and a pre-treatment electrocardiogram (ECG) (usually carried out in secondary care) is advised in some cases to look for atrioventricular conduction abnormalities and bradyarrythmias. (need to consider Blood pressure). If there has been a recent ECG (within the past 3 months) this can also be considered. Specialist would look at recent ECG or make arrangement for baseline ECG. For galantamine and rivastigmine- LFTs, renal function need to be considered.
2. Monitoring of cognitive function, global functional abilities and behavioural problems (taking into account views of carers). These domains are assessed clinically. Frequency not specified in NICE guideline. Good practice suggests this should be at least yearly for stable patients. This monitoring can be carried out in primary care or in secondary care for those who need on-going specialist follow up. (more frequent monitoring following initiation of medication as per specialist). Patients suffering a significant deterioration, whose general wellbeing is deteriorating, or who are showing signs of another Mental Health problem e.g. depression, hallucinations or developing behavioural problems should be referred back to the specialist memory clinic. This may be urgent depending on the severity of presentation and symptoms.
3. No requirement for regular blood tests in relation to the prescription of medication for Alzheimer's disease (unless part of routine blood monitoring for co-morbidities).

The table below only lists the key important adverse drug reaction – for comprehensive information on cautions, contra-indications and interactions. Please refer to the current British National Formulary and Summary of Product Characteristics.

Adverse Effects	**Symptoms/Signs**	**Actions**
For donepezil, galantamine and rivastigmine: Common side effects include: diarrhoea, muscle cramps, fatigue, nausea, vomiting, headache and insomnia. Caution in: supraventricular conduction abnormalities, particularly bradyarrythymias; gastric ulcers or people on NSAIDs; seizures; asthma or COPD; people on cholinergic agonists; people on beta blockers. Caution in: patients with epilepsy, history of convulsions; risk factors for epilepsy	Severe and/or persistent common side effects that outweigh benefits of treatment should prompt consideration regarding discontinuation. New or worsening cardiovascular symptoms (if they occur are usually secondary to bradycardia), e.g. dizziness, syncope. Exacerbation of COPD/asthma/epilepsy/peptic ulcer disease associated with starting these drugs should prompt review.	Discontinue if side effects severe, otherwise discuss with Old Age Psychiatry, Learning Disability Psychiatry or Neurology regarding appropriate action. For symptoms suggestive of cardiovascular side effects examine cardiovascular system and consider ECG.
For memantine: Side effects: dizziness, headache, constipation, somnolence, hypertension.	Severe and/or persistent common side effects that outweigh benefits of treatment should prompt consideration regarding discontinuation.	Discontinue if side effects severe, otherwise discuss with Old Age Psychiatry, Learning Disability Psychiatry or Neurology regarding appropriate action.

SHARED CARE

This shared care guideline provides information allowing patients to be managed safely by primary care , secondary care and across the interface. It assumes a partnership and an agreement between a hospital specialist, GP and the patient and sets out responsibilities for each party. The intention to shared care should be explained to the patient and accepted by them. Patients are under regular follow-up and this provides an opportunity to discuss drug therapy**. The doctor who prescribes the medicine has the clinical responsibility for the drug.** For initiation within primary care, clinicians with the expertise and competence to assess, diagnose, initiate and monitor treatment would be responsible for the complete pathway, with advice available from specialists where required..

CONSULTANT

1. Ensure that the patient/carer is an informed recipient in therapy. For patients who lack capacity to consent to treatment a decision should be made in their best interests in line with Mental Capacity Act guidance.
2. Take account of the patient's medical history / comorbid conditions that may impact on prescribing Acetylcholinesterase inhibitors or Memantine.
3. With regard to Acetylcholinesterase inhibitors, aim to prescribe the drug with the lowest acquisition cost unless there is a clinical reason to prescribe an alternative drug / formulation.
4. Ensure that patients understand their treatment regimen and any monitoring or follow up that is required (using advocacy if appropriate).
5. Ensure baseline investigations are normal before commencing treatment. Initiate treatment or advise the GP on the initiation of treatment, as appropriate.
6. Send letter/results notification to the GP after each clinic attendance, ensuring current dose stated.
7. Evaluation of any reported adverse effects by GP or patient.
8. Advise GP on review, duration or discontinuation of treatment where necessary.
9. Inform GP of patients who do not attend clinic appointments. Another appointment may be offered, particularly if patient had forgotten.
10. Document assessment, management plan and treatment in the patient notes and inform the GP.
11. Ensure that all patients on combination treatment (Memantine and AcetylCholinesterase inhibitor) are reviewed within three months.

GENERAL PRACTITIONER

1. Reinforce the patient's understanding of the nature, effect and potential side effects of the drug before prescribing it as part of the shared care programme and contact the specialist for clarification where appropriate.
2. Report any adverse events to the consultant, where appropriate.
3. Report any adverse events to the Committee on Safety of Medicines via the Yellow Card system, where appropriate.
4. Help in monitoring the progression of disease. GP can contact specialist for advice where required, via "advice and guidance".
5. Prescribe the drug treatment as described (either as shared care, with initiation by NELFT specialist or by primary care clinician who has expertise and competence to take responsibility for assessment, diagnosis, titration, monitoring and review)
6. Carry out annual reviews for those patients no longer under specialist care

INTEGRATED COMMISSIONING BOARD

1. To provide feedback to Trusts via Trust Medicines Committees.
2. To facilitate resolution of issues or problems reported by clinicians with respect to pathway by liaising with relevant stakeholders.
3. To support Trusts in resolving issues that may arise as a result of shared care.

PATIENT/CARER

1. Report any adverse effects to their GP and/or specialist.
2. Ensure they have a clear understanding of their treatment.
3. Report any changes in disease symptoms to GP and/or specialist.
4. Alert GP and/or specialist of any changes of circumstance which could affect management of disease.
5. Take/administer the medication as prescribed.

6. Undertake any monitoring as requested by the GP and/or specialist.
7. Attend appointments for review.

CONTACT DETAILS

BHRUT switchboard (request the initiating consultant or a member of the clinical team caring for the patient)	01708 435 000
NELFT switchboard (requesting the initiating consultant)	03005551200
Barking, Havering and Redbridge University Hospitals NHS Trust	0330 400 4333 Dr Bayo Adewole Dr Khalid Haque Dr Stephen O'Connor
Memory Services	
Redbridge	0300 555 1179 Dr Samina Karamat
Havering	0300 555 1135 x66700 Dr Janet Carter Dr Kehkashan Khan
Barking and Dagenham	0300 555 1016 Dr Hilary Kinsler Dr Mike Devine Dr Amber Selwood
Waltham Forest	03005551279 Dr. Samir Shah
Learning Disabilities	
Redbridge	020 8708 7018 Dr Rehana Akhter
Havering	01708 433446 Dr Bini Thomas
Barking and Dagenham	020 8227 5434 Dr Ehab Khattab
Waltham Forest	Dr Afia Ali and Dr Boni Iparragirre 020 8521 0337

REFERENCES

- NICE Technology Appraisal 217 (March 2011)- last updated 20 June 2018
- NICE Dementia Guideline 2018
- : https://bnf.nice.org.uk/
- Refer to the NHS Barking, Havering and Redbridge CCG website to obtain the latest version of this guideline
- Choi, Seong Hye, Kyung Won Park, Duk L Na, Hyun Jeong Han, Eun-Joo Kim, Yong S Shim, Jae-Hong Lee, and Expect Study Group. "Tolerability and Efficacy of Memantine Add-on Therapy to Rivastigmine Transdermal Patches in Mild to Moderate Alzheimer's Disease: A Multicenter, Randomized, Open-label, Parallel-group Study." Current medical research and opinion 27, no. 7 (2011): doi:10.1185/03007995.2011.582484.

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- Tariot, Pierre N, Martin R Farlow, George T Grossberg, Stephen M Graham, Scott McDonald, Ivan Gergel, and Memantine Study Group. "Memantine Treatment in Patients with Moderate to Severe Alzheimer Disease Already Receiving Donepezil: A Randomized Controlled Trial." JAMA 291, no. 3 (2004): doi:10.1001/jama.291.3.317.

- North East London Foundation NHS Trust policies and guidance on ECG:

ECG Competency MDSO (1).pptx

ECG IN ADULTS FACT SHEET2.pdf

Guidelines: Management of Medications for Alzheimer's Disease		
Version number: 1.1	**Replaces (if applicable):**	
Author(s)/Originator(s):		
Name	**Position**	**Organisation**
Wajid Qureshi	Lead Directorate Pharmacist for Barking & Dagenham, Havering, and Redbridge	NELFT
Dr Kehkashan Khan	Consultant Psychiatrist Havering Memory Service	NELFT

Approved by:

Shared care guideline, Version 1.0 was reviewed and updated with minor amendments. The guideline has been given an extension for 18 months.

Name of Committee	**Date of Approval**
Medicines Optimisation Group, NELFT	22nd June 2023

Review by:

January 2025 (unless need to review sooner due to change in clinical evidence and guidance).

North East London NHS
NHS Foundation Trust

NELFT MEMORY SERVICES
ECG PROTOCOL

1. Purpose

1.1 There is variation in practice across the four NELFT Memory Clinics with regard to pre-treatment ECGs prior to cholinesterase inhibitor (ChEI) prescribing. Some boroughs perform a pre-treatment ECG on all patients whilst others request an ECG only in specific circumstances. The aim of this document is to provide a minimum set of standards consistent with safe prescribing practice.

2. Context

2.1 In patients presenting with cognitive impairment, systemic physiological causes of acute or chronic confusion should be excluded, or identified and managed, prior to referral to secondary care Memory Services. In general, the patient's GP is best placed to carry out this initial physical health screening, which should include blood investigations as a minimum. In certain instances, such as when symptoms suggestive of ischaemic heart disease are present, it will be necessary for an ECG to be included as part of the initial physical health assessment in Primary Care.

2.2 There are variations in practice between the four boroughs covered by NELFT MHS Memory Services with regard to physical health assessment, the chief variable being the relative extent to which physical health investigations are carried out in primary care prior to referral or completed in Memory Services as part of the secondary care assessment following receipt of referral. Reasons for this variation include differences in Memory Service resource between boroughs and in access to advice from secondary care Geriatricians. ECG screening of all patients referred to Memory Services may help identify cardiac conduction abnormalities but, like any screening programme, carries its own implications in terms of resources, the further management of identified abnormalities, potential 'false positive' findings and appropriate counselling of patients and carers.

2.3 NICE guidance[1] suggests that a basic dementia screen be conducted at the time of presentation, usually in primary care, and that the need for an ECG be "determined by clinical presentation". Clinical situations in which an ECG is required include the investigation of new symptoms, such as chest pain and syncope, of possible cardiac origin and the investigation of abnormal heart rates and rhythms, particularly when prescription of medication with the potential for affecting cardiac conduction is being considered. ChEIs prescribed in Memory Services are one such group of drugs.

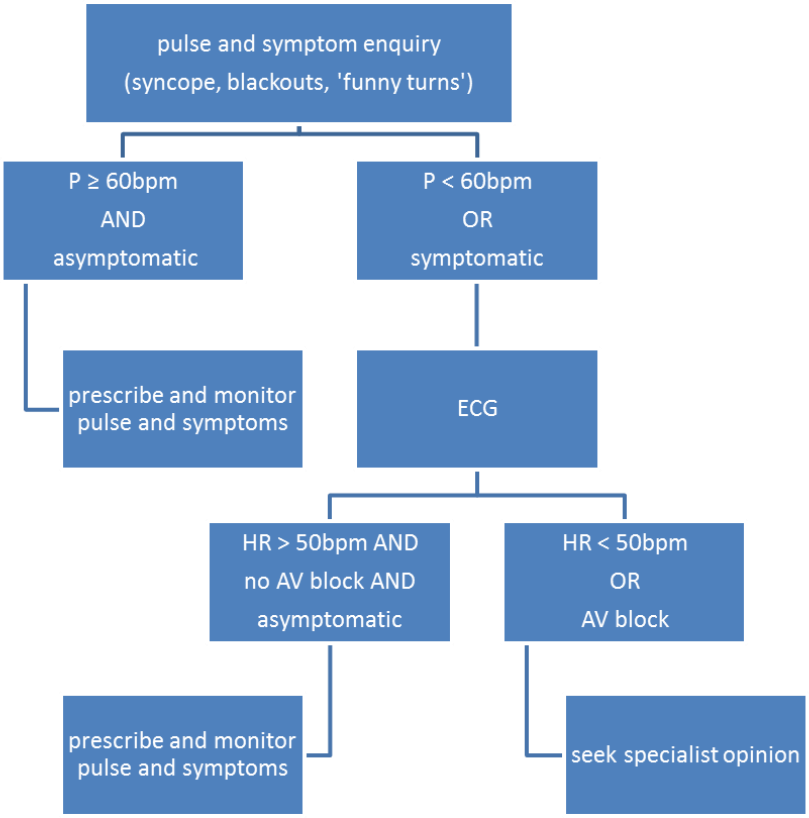
2.4 NELFT guidelines for carrying out physical health investigations, including ECGs, across all its secondary care mental health services are currently awaited. In the meantime, ECG machines have been provided to the four Memory Service sites within the Trust and staff are being trained to use these. There is a need, therefore, for a Trustwide protocol consisting of a set of minimum standards which Memory Services must meet in carrying out ECGs.

3. Cardiovascular monitoring with cholinesterase inhibitor medications

3.1 Cholinesterase inhibitors (ChEIs) are well tolerated and serious adverse events are rare. However, they are associated with rare incidences of atrioventricular heart block and sinus bradycardia, with potentially serious consequences. This tends to manifest clinically as a slow heart rate, frequently, but not always, associated with syncope. Neither the NICE 2006 Dementia Guideline (CG42) nor the more recent NICE 2011 Technology Appraisal of antidementia medications (TA217) included any comment on ECG monitoring in relation to ChEIs. A 2007 review[2] of

this topic suggested a clinical protocol and it was recommended[3] that this "should be the adopted standard for both procedure and audit for all memory clinics". There has been no more recent comprehensive review of this area. The protocol balances the need for appropriate clinical vigilance against the need for pragmatism and appropriate use of resources, and is summarised in the flow chart below (original figure appended).

4. Suggested protocol for ECG and cardiac monitoring in relation to ChEI prescribing (adapted from Rowland et al 2007)



4.1 The key components are a baseline pulse check on all patients being considered for ChEI prescribing, together with an enquiry as to the presence of episodes of syncope. The protocol can be simplified and summarized as follows: for patients with syncopal symptoms or pulse rate <60bpm, ChEIs should be withheld, an ECG carried out and specialist advice sought on further management where necessary. It would be appropriate to carry out these ECGs within the Memory Service, seeking further advice from Primary Care and/or specialist cardiology services where the ECG confirms abnormalities. For asymptomatic patients with pulse rate >60bpm, prescribing should go ahead with routine monitoring of pulse rate and enquiry for syncopal symptoms at follow-up.

4.2 The four NELFT Memory Services should adopt this protocol as the accepted minimum standard with regard to all patients being considered for ChEI medication.

References

1. NICE Dementia Care Guideline CG42 (2006, updated March 2011). Dementia: Supporting people with dementia and their carers in health and social care. NHS - National Institute for Health and Clinical Excellence.

2. Rowland et al (2007). Cardiovascular monitoring with acetylcholinesterase inhibitors: a clinical protocol. *Advances in Psychiatric Treatment* **13**, 178–184 doi: 10.1192/apt.bp.106.002725

3. Bullock (2007). A breath of pragmatism. Invited commentary on … Cardiovascular monitoring with acetylcholinesterase inhibitors. *Advances in Psychiatric Treatment* **13**, 185–186 doi: 10.1192/apt.bp.107.003574

Mike Devine June 2013