



Manchester Mental Health
and Social Care Trust



Medical Directorate

SHARED CARE GUIDELINES For TREATMENT of ALZHEIMER'S DISEASE

Dementia Governance Group: March 2011
Medicines management committee October 2011
Review October 2013

Rationale

The National Institute for Health and Clinical Excellence (NICE) reviewed the guidance for the use of the Cholinesterase Inhibitors in 2011 and also published advice within the broader guidelines for the care and treatment of people with dementia (NICE 2006).

The Trust has considerable experience and expertise in the use of these treatments and a recent supra district audit (Purandare et al 2006) highlighted our compliance with the original 2001 NICE guidelines. We welcome the stated opinion of NICE that these drugs are clinically effective and we aim to work towards their cost effective use. With this in mind these local guidelines describe the format used across the MMHSC Trust to treat patients with Alzheimer's disease.

As an organization we have developed a process whereby initiation of Cholinesterase Inhibitors and memantine for Alzheimer's disease is made only by consultant psychiatrists in Later Life under the auspices of the three Memory Treatment Clinics. An emphasis has been placed upon suitability assessment prior to the initiation of treatment, whilst regular monitoring of efficacy has ensured a fairly steady state in terms of numbers on treatment.

Protocols for the monitoring of side effects and efficacy of the drugs are appended (see Appendix 1). It is expected that GPs will share the care, prescribing and share clinical responsibility for the drug after 3 months if the patient is tolerating the drug.

These revised local guidelines will follow the NICE guidance but will also allow for the consultants clinical discretion in individual cases based upon individual needs.

Scope of Guideline

This guideline covers the use of the Cholinesterase Inhibitors Donepezil, Rivastigmine and Galantamine for mild to moderate Alzheimer's disease. It also considers the use of memantine for moderate to severe Alzheimer's disease or as an option for the treatment of those who are intolerant of or may have a contraindication for a cholinesterase inhibitor. It describes how the treatments should be initiated, monitored and how care should be shared between primary and secondary care. Discontinuation of treatments following deterioration is also included.

The guidelines are aimed at all staff in primary and secondary care either involved in prescribing, monitoring or dispensing the treatments. This guideline does not cover the use of these drugs in disorders other than Alzheimer's disease although co-morbidity is not exclusion to their use. It does not discuss non-drug methods of managing dementia.

- 1 All patients will have to meet the criteria for Alzheimer's disease. Diagnostic investigations should include a brain scan and in accordance with NICE 2006 guidelines on dementia this should ideally be an MR scan but CT is acceptable in most cases.
- 2 There will be no age discrimination in the use of these drugs.
- 3 The initial trial data also excluded patients who were living in residential homes or nursing homes. No such exclusion will be made in selection of patients under the care of a consultant within Manchester.
- 4 Patients should, as far as possible, have an awareness of their diagnosis within the limits of their cognitive impairment and be fully compliant with the investigation and treatment of their dementia. This will include a willingness not only to take the medication but also to cooperate as much as their illness allows with investigations, both biological (e.g. blood tests) and psychological (e.g. tests of cognitive function), over a prolonged period of time. It is not appropriate for this drug to be prescribed to patients at the request of relatives without the consent of the patient and such requests will be refused – the exception to this will be when that patient lacks the capacity to make such a decision and it is decided that treatment is in the best interests of the patient.
- 5 Patients with concomitant medical problems and taking other medications will be discussed on a case-by-case basis taking into account relevant information obtained from studies and the clinical experience with the drug.
- 6 Decisions as to the choice of cholinesterase inhibitor will be made taking into account adverse event profile, medical co-morbidity, possibility of drug interaction, need for slow titration, importance of once daily dosage to ensure compliance, previous exposure to the drugs and cost. All treatments currently licensed will be available for prescribing across the city. Where all else is equal choice of treatment will reflect the product (from each class of drug) with the lowest unit cost.
- 7 An ECG must be performed when considering the use of a cholinesterase inhibitor and safety of prescribing must be assured by a medical practitioner reviewing the ECG.
- 8 Assessments of the clinical effectiveness of the drug and a decision as to whether or not to continue the drug will be on-going (see Appendix 1). The data from the drug trials suggest that a minority of patients gained no benefit from the drug. Continuing treatment with the drug needs to be targeted to those patients with demonstrable benefit at the same time avoiding withdrawal effects on cognitive function (as described with

Tacrine). In a progressive disorder benefit should include lack of deterioration and needs to be assessed in the four domains of cognition; activities of daily living; non-cognitive symptoms (behavioural and psychological symptoms in dementia, BPSD) and clinical global impression of change.

- 9 Patients who have failed to tolerate, failed to benefit or lost benefit from a cholinesterase inhibitor may be switched to another drug of the same class if they remain within the criteria for prescription of a cholinesterase inhibitor. For all drugs used, the definition of benefit will include stability or improvement. Measures to assess clinical effectiveness will include global assessments and measures of functioning and carer stress (see Appendix 2).
10. The use of memantine will be an alternative for patients with moderate to moderately severe dementia or for whom a cholinesterase inhibitor may present safety issues. Clinical judgment may also result in the use of memantine as a second line treatment for those who have failed to respond to an initial trial of a cholinesterase inhibitor. In addition, in light of the CSM warnings about the use of atypical antipsychotics in dementia, the use of memantine as an option for management of behavioral disturbances in dementia can be considered.
- 11 Before treatment commences patients and their carers need to be advised of the uncertainties of clinical effectiveness in these drugs and that treatment will be stopped if objectively there is no evidence of benefit. Clinical assessments will determine whether stopping the drug has resulted in an abrupt deterioration. The risks and benefits of use outside of the license will be discussed with the patient and carer.
- 12 As with any drug given to people in whom compliance is potentially impaired, reasonable steps will be taken to ensure compliance by recruiting help from relatives, carers and other professionals e.g.: district nurses. If compliance cannot be assured and is shown to be low, the drug will be stopped.
- 12 All patients commenced on one of the treatments will be given a patient information leaflet produced by the MMHSC Trust. Patients must be made aware of the potential risks and benefits of treatment and given an opportunity to reflect before making an informed decision regarding such treatment. Additional information such as that provided by the Alzheimer's society should be offered to the patient.
- 13 Patients/carers and GPs will be advised that should they be concerned at any point about the actions, side effects or interactions with any of the drugs, they should call the Dementia Treatment Clinic. The telephone number will be available for all clients, carers and GPs.

- 14 Patients/carers and GPs should also note that should a patient become unwell either as a result of the treatment or due to concurrent conditions, treatment can be withheld until the Dementia Treatment Clinic can be contacted.
- 15 If a GP becomes concerned about an individual's mental state between appointments, the clinic will provide an extra assessment at the request of the GP.
- 16 We would expect to continue to audit the use of both classes of drugs across the city and develop the protocols advised by our findings as to their benefit in clinical practice.

References:

National Institute for Health and Clinical Excellence, 2011 Final appraisal determination Donepezil, galantamine, rivastigmine and memantine for the treatment of Alzheimer's disease (review of NICE technology appraisal 111)

National Institute for Health and Clinical Excellence & Social Care Institute for Excellence 2006. Dementia: the treatment and care of people with dementia in health and social care

Purandare N, Swarbrick C, Fischer A, Burns A. 2006
Cholinesterase inhibitors for Alzheimer's disease: variations in clinical practice in the north-west of England. *Int J Geriatr Psychiatry*. 21(10):961-4.

Appendix 1

Staged Process

Baseline

- 1 Check patients meet Trust criteria for treatment with Cholinesterase Inhibitors as outlined above.

- 2 Administer assessments of:
 - Cognitive function: primarily the MMSE

 - Non-cognitive features of AD: measurement scales could include Mini-MOUSEPAD/Neuropsychiatric Inventory/BEHAVE-AD

 - Functional abilities: IDDD or other suitable and recognised ADL scale. If uncertainties arise advice from an occupational therapist should be sought.

- 3 Advice given re: side effects and expected efficacy of the drug and prescription given either donepezil 5 mg od or rivastigmine 1.5 mg bd or galantamine XL 8 mg od or memantine at the selected initiation dose – usually 10mg..

Consultant or registered nurse prescriber working within a clinical management plan will take clinical responsibility for initiation and monitoring of the treatment. GP, patient and carer take responsibility for informing the treating clinic of any potential adverse effects noted during this time.

Baseline - 3months

- 1 Patients and carers will be advised to contact nursing staff in the Memory Treatment Clinics if there are concerns about patient's compliance or if patients are experiencing adverse effects.

For patients where concordance has been identified as a potential problem, mechanisms will be put in place using support workers from the Trust, social service care staff or District Nurses to attempt to improve compliance.

Mechanisms need to be in place to inform the Clinic if patients do not tolerate the drugs either initially or if the dose is increased. Normally this will be by carers or patients telephoning the Clinic if there are

difficulties although individual arrangements for closer monitoring may be necessary for patients with no carers.

- 2 Patient or carer supplied with a further 2 months' supply either of donepezil 5 mg, rivastigmine 3 mg bd or galantamine XL16mg od or memantine at the selected dose usually 20mg daily in a single or divided dose.

Baseline + 3 months

- 1 If patients have achieved concordance and are tolerating the medication their GP will be advised of this by the clinic and shared care arrangements will commence.

Baseline + 6 months (& 6-monthly thereafter)

- 1 Patients will now have been on the therapeutic dose of the drug for 4 - 6 months which will allow assessments of clinical effectiveness to be made. The assessments will normally be done in the 4 domains of cognition, psychopathology, functioning and a clinical global impression of change.
- 2 GPs will be advised of the results of the assessment and of further management eg: discontinuation or change in drug or dose.

The treating team led by the consultant will retain responsibility for these assessments to ensure the patient continues to derive benefit from this treatment.

Patients will remain under the care of their sector consultant and may be reviewed outside of the dementia treatment clinic depending on individual needs and changing circumstances.

Appendix 2

Common Adverse Effects and Interactions

Effect	Action Required
Nausea and vomiting	Encourage patient to continue. Usually self-limiting
Prolonged/projectile vomiting	Withhold treatment and contact clinic
Headache/nightmares/insomnia	Treat symptoms symptomatically

Common Drug Interactions

Possible complications during surgical procedures using para -
sympathomimetic agents.

Secondary Care Contact Details

North

Lead Consultant: Dr Bamrah/Dr Alkamil
Specialist Nurse: Andrea Skelly, Julie Raghib
Clinic number: 0161 720 2737/2852

Central

Lead Consultant: Dr H Allen
Specialist Nurse: Sandra Phillips,
Clinic number: 0161-273-3049

South

Lead Consultants: Dr Suzanne Jeffries
Specialist Nurses: Sean Page, Susan Butler
Clinic number: 0161-291-6942