NHS
West Kent

# RESPONSE TO NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE REVIEW OF TA 111: THE EFFECTIVENESS AND COST-EFFECTIVENSS OF DONEPEZIL, GALANTAMINE, RIVASTIGMINE AND MEMANTINE FOR THE TREATMENT OF ALZHEIMER'S DISEASE

NHS West Kent and NHS Islington welcome the opportunity to participate in this consultation of the review of the effectiveness and cost effectiveness of Donepezil, Galantamine, Rivastigmine and Memantine for the treatment of Alzheimer's Disease.

We recognise the importance of treatment strategies for this condition, particularly when viewed against the background of an increasingly elderly population.

As a Primary Care Trust, our responsibility is to commission high quality services for the population we serve. To do this, we need to balance the total health needs of the whole population and manage competing priorities.

In terms of a strategy for the development of comprehensive health and social care services, it is important to note that drug treatments are just one element within the overarching strategy for dementia care. Other approaches include support for carers (e.g. Admiral Nurses), cognitive stimulation therapy and psychological methods to help with behavioural problems and occupational activities.

NHS West Kent and NHS Islington recognise the devastating impact that a diagnosis of Alzheimer's disease has on those affected, their family and carers. As such, the development of dementia services is a commissioning priority. In responding to this consultation, we recognised the need to reflect the views of the wider NHS. In achieving this, we have endeavoured to consult as widely as possible, with commissioning organisations across England. A short questionnaire was sent out nationally, in order to obtain baseline and background information and to gain a wider view of dementia services across England. Response to this was limited, however we have endeavoured to include the views of those who contributed. In addition, we are aware that the Department of Health is undertaking a national audit of

dementia services, although this is not due to be published until later this year.

We summarise the key responses to the PenTAG review:

We believe this is a well constructed review, which addresses some of the limitations of the previous review. We believe the methodology to be sound; and has included all relevant studies including UK studies where available, and has appropriately excluded studies outside the scope.

It is extremely disappointing to note the lack of additional evidence in this field, given the long term nature of the disease, since the publication of the previous review.

Our expertise in cost effectiveness modelling is limited; however it is striking to note that Table 118 on page 324 which highlights the cost utility analysis results assuming a treatment effect on survival and identifies that all treatments delay death by between 22 – 26 days. We would question whether this is a clinically meaningful outcome, particularly when taking in to account the significantly reduced quality of life at this end stage of disease.
In addition, Table 121 (page 334) highlights the degree of uncertainty in the modelling assumption and the impact that this has on the cost-effectiveness of AChEIs. This table highlights that this limited assumption of treatment effect on survival is not supported by any published RCT or epidemiological evidence, and this has a high impact on both the uncertainty of the data and also the cost effectiveness. When this assumption is used in the incremental benefit figures, it forms typically the single largest component in the benefit of the drug versus best supportive care. We would be keen to see the impact of removing this component and replacing with an alternative outcome measure such as for example, improved symptom control, for which there is published (albeit of poor quality and duration) evidence.

We do not believe further debate around costing is relevant (e.g. drug price drops following patent expiry), given the poor quality of the available clinical evidence.

We recognise the impact that AD has on the family and carers, who place great emphasis on the management of behavioural and psychological symptoms. Indeed De Vugt et al (2005) found that it was the carer's response to these symptoms that predicted entry to institutional settings, rather than the symptoms themselves. Many of the studies make reference to best supportive care as a comparator, however this is not defined and following our consultation with other England PCTs it is clear that there is huge variability in what constitutes best supportive care, and to the extent to which it is provided and accessed. With such limited and poor quality evidence of efficacy of the drugs, we would be keen to explore the impact of alternative non-pharmaceutical strategies, which could provide better outcomes for both patients, and importantly for carers and families. We recognise that there is huge support for these drugs from carers and their support groups; however,

we would argue more benefit may be derived from prioritising other interventions such as the provision of respite care / peer support before extending access to pharmaceutical interventions based on limited and poor quality evidence.

**The Impact of Implementing Guidance – From an NHS Perspective**

As previously identified, service provision nationally is highly variable, and therefore the impact of extending access to these drugs will be equally variable. However we have attempted to quantify what this may mean locally.

Estimations from NHS Islington suggest increased costs could be in the region of £500,000 per year, based on a population of just under 200,000. Unfortunately due to the complexity of service delivery within NHS West Kent, actual figures to assess current baseline prescribing are not available.

Additionally, estimation of impact is difficult as adherence to current guidance is not known. Information provided by the Information Centre on the use of NICE appraised medicines in the NHS in England showed that prescribing was significantly higher than expected rates in all SHAs (the ratio of expected prescribing to observed prescribing ranged from 1.5 – 2.4)[1].

We would also like to highlight practical issues around implementation of guidance which assumes application to a specific patient population based upon diagnosis. It is well documented in evidence and in the PenTAG review that the diagnosis of AD and the stratification of severity can be highly subjective. This will have huge implications to the practising clinician and to the ability to estimate the impact, and therefore to effectively and equitably commission services.

Furthermore, should the cohort of patients for which this treatment is available increase, there would be some significant challenges to develop both secondary and primary care services to ensure adequate capacity for accurate diagnosis, prescribing and monitoring. We recognise that given the predicted rise within this group, capacity will need to be developed regardless of whether the intervention is pharmacological or non-pharmacological.

A significant influencing factor on costs relates to the length of treatment and the extent to which treatment is successfully ceased at an appropriate juncture. We recognise that this is can be a difficult action for clinicians to take, particularly when faced with highly emotional carers and family members. We would like to see the supportive material provided for both within the implementation guidance of this review strengthened.

[1] **Use of NICE appraised medicines in the NHS in England – Experimental Statistics;** NHS The Information Centre, September 2009.

We also recognise the desire amongst clinicians to provide effective interventions as early as possible following diagnosis. However as custodians of public money, it is essential that we spend it wisely on evidence based treatments.

To conclude, it is the view of NHS West Kent and NHS Islington that committing public funds to extend the use of these drugs on the basis of such poor quality evidence would be inappropriate.