NICE hears appeals over dementia drugs

Zosia Kmietowicz *London*

The National Institute for Health and Clinical Excellence (NICE) last week heard five appeals over two days against its decision to restrict the use of drug treatments for Alzheimer's disease to patients with moderate stages of the condition.

In its original guidance, issued in January 2001, NICE recommended that the drugs donepezil, rivastigmine, and galantamine could be prescribed for people with mild and moderate stages of the disease, defined as having a score of 12 or more on the mini-mental state examination, where a higher score indicates a milder disease (*BMJ* 2001;322:190).

But in revised guidance proposed in May this year, NICE recommended that the drugs should be used only in people with moderate disease. This was defined as those with a score of between 10 and 20, thus setting an upper limit and excluding people with

the mildest form of the disease. Another drug, memantine, is not recommended for use outside clinical trials.

The Alzheimer's Society, which launched a joint appeal with Age Concern, Counsel and Care, the Dementia Care Trust, and the Royal College of Nursing, claims the advice is discriminatory because it is based on the mini-mental state examination score, which varies depending on education and race. It also says that restricting the drugs will lead to increased prescribing of unlicensed sedatives to treat people with dementia.

The society has charged NICE with overestimating the cost of prescribing the drugs because it has assumed that doctors will continue to prescribe them even if patients are not responding to them. "This is simply not what happens in reality," it says in a statement. NICE had also ignored the savings that the drugs can bring in reduced caring time.

Leading the appeal, Clive Ballard, the director of research at the Alzheimer's Society, said last week, "The NHS has long been the envy of the world, but today the world is watching to see if it will return to the

The Alzheimer's Society organised a demonstration in June against NICE's revised guidance on dementia drugs

dark ages of dementia care."

Other appellants included drug manufacturers Eisai, Lundbeck, and Shire Pharmaceuticals, while the Royal College of Psychiatrists and the British Geriatrics Society launched a joint appeal.

In a separate action, Eisai, the manufacturer of the Alzheimer's disease treatment donepezil (Aricept), has referred the information commissioner to the parliamentary ombudsman for failing to tackle the refusal by

NICE to disclose the calculations behind its decision on the anti-dementia drugs.

According to the company, NICE has repeatedly refused to make available the new mathematical model it used to reach the conclusion that antedementia medicines are no longer a cost effective treatment in the early stages of Alzheimer's disease.

NICE's guidance is available at www.nice.org.uk.

Israel looks into claims of "illegal medical experiment"

Judy Siegel-Itzkovich *Jerusalem*

Diabetic Medicine, a monthly journal published by Blackwell Publishing, has retracted an article it published in 2004 from the Meir Medical Center, Tel Aviv, after being informed by the centre's chief executive of concerns over the ethical conduct of the researchers and the reliability of their findings (2006;23:818).

The original article reported on a study of about 60 middle aged and elderly women with type 2 diabetes, many of whom were Arab, carried out in 2001-3, in which two conventional drugs were compared with each other and with a combination of the two (*Diabetic Medicine* 2004;21:471-5).

Now Israel's Ministry of Health has asked the medical centre to hand over its internal review of the experiment and is deciding what action to take.

The journal's retraction says, "*Diabetic Medicine* has been advised by the Chief Executive Officer of the Mair [sic] Medical Center that the... study, done in collaboration with the Sackler University of Tel Aviv, has raised concerns over ethical conduct and security of findings.

"Specifically, a local investigatory committee found that ethical permission was only given approximately 3 months after *Diabetic Medicine* accepted the paper for publication. In addition, whilst the investigatory committee believed that the research had been undertaken, they were unable to access research records and thus confirm the results, even though the study was conducted as recently as 2001.

"In these circumstances, *Diabetic Medicine* regrets publication

of the article, and suggests that its readers treat its findings with caution. The senior author has been advised of our wish to have the article retracted and has made a statement of confidence in the findings."

Details of the controversy were recently reported in the Israeli newspaper *Haaretz* (www.haaretz.com, "Widespread illegal experiment conducted at Meir Hospital," 5 Jul), which referred to the study as an "illegal medical experiment."

The research study was conducted by Mordechai Ravid, a specialist in internal medicine, who left the hospital in 2004 to become director general of a medical centre in another city.

Ehud Davidson, director of the Sapir Medical Centre, which is better known as Meir Hospital, said, "It was I, in fact, who initiated the investigation, as my suspicions were raised two years ago when I learned from a staff member who was asked to read a medical student's paper on a supposedly new experiment that he had remembered reading

about in *Diabetic Medicine*."

Dr Davidson informed the Clalit Health Services, the hospital's owner, of the incident but not the health ministry, which he said by law "did not have to be told" about it, and Clalit kept the information to itself. Only after reading about the matter in *Haaretz* did the ministry learn of the matter.

Dr Davidson asserted that no ethnic or religious prejudice was involved and that in towns and settlements near the Meir centre type 2 diabetes was more common in Arab than in Jewish women; thus they served as a suitable population for the study.

Professor Ravid, who was previously director of one of Meir Hospital's internal medicine departments, told *Haaretz* that the whole incident was just "an administrative and technical screw up and not a moral failing, with no malice or intent to deceive." He added that the affair is "a tempest in a teacup" and insisted that "there were no forged research or forged records here."