

Second long term HRT trial stopped early

Caroline White *London*

A second trial looking into the long term effects of hormone replacement therapy (HRT) has been stopped early.

The UK Medical Research Council (MRC) announced last week that a decision had been taken to halt the women's international study of long duration oestrogen after menopause (WISDOM) for "scientific and practical reasons." The trial, which has cost £10m (\$15.5m; €15.9m), was due to be completed in 2016.

WISDOM was investigating the long term effects of oestrogen combined with progestogen and of oestrogen alone on the incidence of, among other diseases, cardiovascular disease, breast cancer, dementia, and osteoporosis.

In July one part of the US women's health initiative (WHI) study, a similar trial involving more than 16 000 women, was stopped early after a small increased risk of breast cancer, cardiovascular disease, blood clots, and stroke was found among the women taking the combined form of HRT.

The WHI's data and safety monitoring board concluded that these risks outweighed the decreased rates of osteoporotic fractures and bowel cancers. But the other part of the WHI study, comparing the effects of oestrogen alone with placebo in women who have had a hysterectomy, is still ongoing.

After publication of these initial results (*JAMA* 2002;288:321-33) the MRC set up an independent international committee to decide on WISDOM's future, although the trial's steering committee had wanted it to continue because important questions about the risk-benefit ratio of HRT remained unanswered.

The international committee's report to the MRC on 16 October agreed that some important questions about HRT are still unanswered. But it did not think that the WISDOM trial would substantially resolve them, especially as one of its chief concerns—a large reduction in the risk of coronary heart disease—was no longer likely.

WISDOM aimed to include 16 000 postmenopausal women from the United Kingdom plus 6000 from Australia and New Zealand, but it had recruited only 5700 women with the relevant criteria since 1999.

Ray Fitzpatrick, professor of public health and primary care and director of the Institute of Health Sciences at the University of Oxford, chaired the international committee.

In a statement issued by the MRC, he said: "The IIC [independent international committee] was concerned by the slow progress of WISDOM and considered that the results of the trial, which would not be available for another decade, would be unlikely to influence clinical practice."

Committee member, Philip Hannaford, professor of primary care at the University of Aberdeen, said that further trials looking at the timing and type of HRT would pose logistical difficulties because of the numbers of women required. □



Protestors lobby parliament over proposed change in mental health law

The voice of protestors against the planned reforms of the United Kingdom's Mental Health Act have reached the prime minister, who said last week that he "entirely understood" their concerns but added that public worries about people with severe mental disorders could not be ignored.

Speaking in the House of Commons, Tony Blair acknowledged the concerns of the Mental Health Alliance, a group of more than 50 organisations, including the Royal College of Psychiatrists and mental health charity MIND. He said the concerns would be carefully considered before the new legislation came before parliament.

"I entirely understand the concerns the Mental Health Alliance have. I think it is important that they realise there is pressure also from the public in a different direction, because the public worries that some people who, tragically, have a severe mental disorder can pose a danger and threat to the public. We need to balance these two things together," he said.

More than 1000 campaigners from the alliance lobbied parliament last week (pictured) to put pressure on MPs to oppose the draft bill. The group, which also includes Rethink (formerly the National Schizophrenia Fellowship) and the Law Society, has been actively campaigning against the new legislation since it was launched for consultation in June this year. It held a previous lobby of parliament the same month.

The alliance is now waiting to see whether the bill appears in its original form in the Queen's speech later this month.

Zosia Kmietowicz *London*

US mammography programme beset by flaws

Fred Charatan *Florida*

Concern is growing at the safety and effectiveness of the government approved mammography screening centres in the United States.

Every year more than 40% of the nation's 9500 mammography clinics have been cited for violating one or more federal rules governing their operation.

Last year the Food and Drug Administration sent out 357 warning letters to clinics with the most serious problems (including poor image quality) or which violated rules on training. But it has invoked its power to levy fines of up to \$10 000 (£6500; €10 300) only once in the past five years.

In 1992 the federal government set national standards for screening mammography. The Mammography Quality Standards Act required all mammography facilities in the United States be accredited by the American College of Radiology, be certified by the Food and Drug Administration, and receive an onsite inspection by a state agency acting on behalf of the US Department of Health and Human Services.

But in setting these standards, the federal government faced a dilemma. If the standards were too tough and

included skills tests and performance monitoring for mammogram readers, doctors resenting government intrusion into the practice of medicine would shun or leave the programme.

Many experts say that, as a result, the federal government's standards are too low, resulting in poor quality mammograms.

The federal rules require that doctors read at least 960 mammograms every two years, while many experts think that 5000, the number required in the United Kingdom and Canada, is necessary for proficiency. □