

In brief

NICE issues draft guidance on IVF: Couples should be able to have three cycles of in vitro fertilisation treatment on the NHS, and no more than two embryos should be transferred during any one cycle, suggest the latest draft guidelines on fertility treatments from the National Institute for Clinical Excellence (see www.nice.org.uk).

Hungarian doctors ousted after strike threat: Dr Péter Kupcsulik has been ousted as president of the Hungarian Medical Chamber, along with several other leading members of the organisation, because of their reluctance to push for amendments to a hospital privatisation bill enacted in June. Chamber members said they were prepared to strike if certain revisions to the bill were not made.

Production of antiepilepsy drug extended: The British Epilepsy Association has welcomed AstraZeneca's decision to extend production of primidone (Mysoline) until August 2004. It was due to be discontinued by January 2004 owing to low demand. The association feared that the estimated 10 000 UK patients taking primidone had not been given enough time to withdraw from the drug safely.

Women delay seeking help for breast cancer: One in three women are likely to delay seeking medical help for breast cancer for as long as three months, says a study based on 500 women carried out at Guy's, King's, and St Thomas's medical school. See *British Journal of Health Psychology* (2003;8; part 3).

Florida's malaria identified: Health officials have said that three cases of malaria in Palm Beach county are due to *Plasmodium vivax*. While searching for the index case, officials have started a telephone campaign to nearly half a million households, with a recorded 15 second warning to remind people to protect themselves against mosquito-borne diseases.

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US pacemaker manufacturer faces British lawsuit

Owen Dyer *London*

St Jude Medical, a major manufacturer of heart valves and pacemakers, is to face a lawsuit in Britain over its Silzone heart valves, which were discontinued after a recall in January 2000.

The Minnesota based company, which is already the target of class action lawsuits over Silzone in the United States and Canada, is to be sued in London's High Court by Billy McCombe of Northern Ireland. Mr McCombe's wife, Myrtle, died in July 1998, aged 44, 10 weeks after receiving a Silzone mitral valve implant.

The Silzone valve is a variant of the standard St Jude valve, with a silver coating on the sewing cuff used for attachment. The silver was meant to discourage bacterial infection and reduce the rate of endocarditis, one of the most common and dangerous complications of artificial valve implantation. Silzone valves were approved in the

United Kingdom in 1997.

About 37 000 Silzone valves were implanted worldwide, including about 1300 in the United Kingdom, 10 000 in the United States, and 2300 in Canada. Most of the rest were implanted in Europe.

Leigh, Day & Co, solicitors for Mr McCombe, say the device was not adequately studied before marketing. They also cite a confidential document, written by a member of St Jude's marketing advisory panel, that describes Europe as "the guinea pig continent."

Richard Meeran, a partner at Leigh, Day & Co, said: "It is hard to see how St Jude can defend this case. The Consumer Protection Act imposes strict liability on manufacturers. Many people in this country may potentially have been seriously harmed by this product."

Peter Gove, vice president of St Jude Medical, told the *BMJ* that he believed that the British claim had less merit than lawsuits under way in the United States and Canada, where six provincial health ministries are among the plaintiffs. "Mrs McCombe had a thrombus, which is a risk associated with all heart implants and all heart surgery. The Canadian and

American suits concern paravalvular leak, which was the problem identified in the AVERT study we commissioned to monitor this device in the patient population."

In the AVERT study, eight patients in the Silzone treatment arm had to have their implant removed because of paravalvular leak, compared with one patient in the group using standard St Jude valves. In January 2000, the study's independent board suspended further enrolment. The company issued a recall of valves that had not yet been implanted. Patients with implanted valves have been advised to keep them.

Other problems have been reported. In Britain, the Medical Devices Agency issued an advisory warning in November 1999 about a "high rate of early thromboembolic complications," including stroke.

Peter Gove says media reports that his company is resigned to paying out over Silzone are wrong: "We regard the issue as unresolved." He said that product testing complied with international testing standards and the Food and Drug Administration's guidance on heart valves. "To this day, no one really knows what was wrong with the valve." □

WHO relaunches polio campaign

Fiona Fleck *Geneva*

The World Health Organization has relaunched a 15 year old campaign to eradicate poliomyelitis after missing its original goal of 2000 because of armed conflicts, insufficient funding, and lack of government commitment in some regions.

The Geneva based agency said that if donors provide \$210m (£133m; €192m) in addition to some \$3bn already invested in the programme, polio, which mainly affects the under 5s, could be stamped out globally by 2005.

The plan would be to vaccinate up to 175 million children by the end of the year in the seven countries where the virus is still widely present—Egypt, Nigeria, Pakistan, India, Afghanistan, Somalia, and Niger.

Mass immunisations would also be conducted in neighbouring regions and in countries with poor vaccination coverage that are vulnerable to future outbreaks. According to WHO, in the past 12 months polio viruses have spread from Nigeria to Ghana and Burkino Faso, which had until then been free of polio.

Dr Jong-Wook Lee, WHO's new director general, has made reviving the Global Polio Eradication Initiative a priority and has appointed the infectious diseases specialist David Heymann as his representative on polio eradication after Dr Heymann's success heading a team that helped to stop the spread of the severe acute respiratory syndrome (SARS) earlier this year.

See the profile of Dr Lee (p 468). □



POLIO ERADICATION/WHO