Evaluation results from the Portsmouth and Wirral pilots found that testing was a success with both patients and health care professionals and reached a high proportion of the target group. A total of 75% of those offered screening accepted and approximately 1 in 10 were found to be infected; 95% of those diagnosed with chlamydia returned for treatment. The two centres are currently investigating reinfection rates for chlamydia, in order to ascertain the frequency required for an effective national programme.

Public Health Minister, Hazel Blears said: 'We are committed to tackling the rising rates of all sexually transmitted infections and today's announcement is an important step in the right direction. As we continue to implement the first ever National Strategy for Sexual Health and HIV we will deliver a range of measures to increase public awareness, improve access to GUM services and offer better treatment and care to those who need it.'

The first ten sites will primarily target women aged 16–24 years who access sexual health services. Young women, particularly those under 21 years, are at greatest risk of infection and the long-term complications of untreated chlamydia are more serious for women. However testing will be offered to both men and women presenting with symptoms, and greater uptake of testing among men will be promoted. Efforts will also be made to trace partners or ex-partners of those found to be infected to offer treatment.

The increase in diagnosis of chlamydia over recent years is, in some part, due to improved awareness of the infection amongst both public and professionals and increased testing. However, continued efforts to increase awareness are needed – ongoing work will be supported by the Department of Health's public information campaign to be launched in Autumn 2002. It will highlight the risk of contracting all STIs, including human immunodeficiency virus (HIV), and the importance of practising safe sex.

Source: Department of Health

JAMA 2002; 288(3): 321-333

fractures.

JOURNAL CLUB

Risks and benefits of estrogen plus progestin

in healthy postmenopausal women. Principal

results from the Women's Health Initiative

Randomized Controlled Trial. Writing Group

for the Women's Health Initiative Investigators.

The results of this large study shows that for

every 10 000 women using combined continuous

hormone replacement therapy (HRT) compared

to those women not using HRT there would be an additional eight cases of invasive breast cancer,

seven myocardial infarctions (MI), eight

cerebrovascular accidents (CVA) and eight

pulmonary emboli (PE). However, there would

be six fewer bowel cancers and five fewer hip

part to study the possible long-term health

benefits of HRT. A total of 161 809 women were

recruited into a set of clinical trials that included calcium and vitamin D supplementation, a low-

fat diet, in addition to two HRT trials. The

primary outcome of the HRT arm was coronary

heart disease (CHD) and it was widely

anticipated at that time that HRT would

demonstrate a beneficial effect in keeping with

The Women's Health Initiative (WHI) clinical trials were designed in 1991–1992 in

## Legal action against the manufacturers of third-generation pills fails in the UK

An action against the manufacturers of combined oral contraceptives (COCs) containing third-generation progestogens began in 1997 and was heard in court between March and July 2002. The lawyers representing the former users of these contraceptive pills had to show beyond reasonable doubt that the third-generation pills were defective (i.e. not as safe as the women were entitled to expect) and that they caused the injuries sustained by the women. On 29 July 2002, the judge gave his judgement that he accepted the defence case that the evidence did not establish reliably that there was an excess risk from third-generation pills compared to second-generation pills. The judge also concluded that none of the claimants were able to demonstrate that their venous thromboembolism (VTE) was 'more likely than not to have been caused by the third-generation contraceptive pill' The claimants had to show that the thirdgeneration pills were twice as likely to have caused the VTE than a second-generation pill containing levonorgestrel and this they had failed to do

Although the judge expressed the view that this trial was 'the most exhaustive examination this question has ever received', this can only be said to be true in the legal sense.

Most readers of this journal will remember the intense and sometimes acrimonious public and private discussions following the publication of the four epidemiological studies in 1995 and 1996 showing a difference in the incidence of venous thrombosis between second- and thirdgeneration pills. Numerically the number of events was small compared to the number of users. However, the conclusion from these studies that third-generation pills carried twice the risk of the second-generation pills led to the Committee for Safety of Medicines (CSM) in the UK issuing a warning to prescribers. The advice was to only use third-generation pills if the user

the available observational and experimental data. Additional clinical secondary outcomes to be studied were incidence of osteoporotic fracture, invasive breast cancer, endometrial cancer, colorectal cancer and other cardiovascular disease. More than 16 000 women with an intact uterus aged 50–79 years were recruited into a randomised primary prevention trial comparing estrogen plus progestin (Premarin 0.625 mg plus Provera 2.5 mg both daily) versus placebo.

In May 2002, the US Data and Safety Monitoring Board recommended the termination of the oestrogen plus progestin component of the WHI study on the basis that the 'stopping boundary' for invasive breast cancer had been exceeded and the global index statistics supported risks exceeding benefits. The data was released to the public in July 2002 and the world media became whipped up into a frenzy over the results. Most UK daily newspapers carried variations on the 'killer HRT' headline predicting massive discontinuation of HRT.

The risk-benefit profile of HRT was not found to be consistent with primary prevention of chronic disease. The effects of HRT on venous thromboembolism (two-fold increase) and breast cancer (26% increase) were entirely in keeping with earlier data. The fracture data for HRT was surprisingly robust with a 33% reduction in hip fractures and 24% reduction in total fractures. HRT was also found to decrease colorectal cancer by 37%. However, it was the finding that women on HRT had 29% more CHD events and was intolerant of second-generation pills. Following reanalysis of the original data obtained in the epidemiological studies, the estimates of harm were revised downwards, while controversy continued about bias and statistical manipulation.

By 2001, the regulatory authorities in the UK and in Europe had concluded that degree of difference in risk between second- and third-generation pills was of the order of 1.5 to 2. The information that is given to patients quantifies the risk of VTE as:

- about five cases per 100 000 women per year when not taking any hormonal contraception
- about 15 cases per 100 000 women per year when taking second-generation COCs
- about 25 cases per 100 000 women per year taking third-generation COCs.

The legal decision does not affect this advice which should be put into proportion by considering the risk of VTE in pregnancy (about 60 per 100 000 women per year).

While welcoming the news that the class action against the manufacturers of the thirdgeneration COCs has failed, the legal decision does little to help practising clinicians in their everyday work with patients. Scientific evidence, argued over by many experts in journals, seems a better guide than a decision based on a single legal judgement. For the majority of patients with no added personal risk factors, the differences between the small risks of VTE associated with the use of a second- or third-generation progestogen will matter less than the acceptability of their chosen pill. Discussion of the risks and benefits with patients, in language that they can understand, will be the best protection against further legal actions.

Source: Report and comment by Dr Gill Wakley, Writer and Lecturer, General Practitioner Nonprincipal, Abergavenny, UK

41% more strokes over 5 years that caused particular concern. The investigators emphasised that the overall absolute risks were small and all-cause mortality was not increased with HRT.

It is very difficult to predict the impact of this study on prescribing patterns and how women will view HRT in the future. The data are likely to have serious repercussions for the pharmaceutical industry for which long-term HRT prescribing for women worldwide was a major goal. The majority of HRT users in the UK who take HRT in the short term primarily for beneficial effects on menopausal symptoms are unlikely to be perturbed by the results of this study. It is simply not known whether these results relate particularly to the combination of Premarin and Provera or whether it can be assumed that all HRT would exhibit similar effects. Women in the parallel arm of the WHI study taking oestrogen alone have not been found to have increased breast cancer risk and this arm will continue as planned until 2005. However, the clear message from this study is that combined HRT should not be initiated or continued for the indication of primary prevention of CHD at the present time. The medical establishment should welcome highquality data on this subject even though it may not be the answer we anticipated or wanted to hear.

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