



## EU legislation threatens clinical trials

Rory Watson

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**In brief****“Door to needle” time for thrombolytic treatment speeds up:**

An audit by the Royal College of Physicians shows that the proportion of heart attack patients receiving thrombolytic treatment within 30 minutes of arriving in hospital has risen from less than 50% at the beginning of 2001 to 76% in the first three months of 2003. The second report of the myocardial infarction national audit project is accessible at [www.rcplondon.ac.uk](http://www.rcplondon.ac.uk)

**Rare death from avian flu:**

The “extremely rare” death of a 57 year old Dutch veterinary surgeon from avian flu was the result of the “unique and especially unfortunate convergence of factors,” an independent investigation has concluded. Jan Bosch died from pneumonia 15 days after taking blood samples from an infected chicken (*BMJ* 2003;326:952, News Extra 3 May).

**Non-smokers use nicotine**

**patches:** Five per cent of US high school students said they have used nicotine patches or gum—including some who misuse the products, a US survey reports. The survey found that, overall, 18% of all nicotine replacement users, including adults, were not smokers (*Archives of Pediatrics and Adolescent Medicine* 2003;157:517-22).

**Iron tablets can kill young**

**children:** Records in Ontario, Canada, show that almost half of all hospital admissions for iron poisoning in young children could be prevented if iron supplements were kept out of reach of children in the year before and after the birth of a sibling. The researchers say that as few as 10 ferrous sulphate tablets, totalling 600 mg of elemental iron, can kill a small child (*CMAJ* 2003;168:1539-47).

**CHCs granted a reprieve:**

Community health councils (CHCs), which were due to be abolished by the end of August, have been granted a temporary reprieve until the end of December. Guidance on the new patients' forums, due to take over from the councils in September, is still out for consultation (see [www.doh.gov.uk/involvingpatients](http://www.doh.gov.uk/involvingpatients)).

**EU legislation threatens clinical trials**

Rory Watson *Brussels*

European Union legislation due to take effect next year could seriously reduce the scope for non-commercial clinical trials, says Cancer Research UK.

The new rules are designed to simplify and harmonise the many different national provisions now in force relating to good practice in the conduct of clinical trials of medicinal products. Their aim is to ensure good care of patients and to make it easier to conduct pan-European research.

But, as governments now prepare the enabling legislation to implement the EU rules in domestic law, fears are emerging that the outcome could be the opposite of what is intended.

A conference in Brussels organised by the European Forum for Good Clinical Practice and the European Cancer

Research Managers Forum and supported by the European Commission and the European Organisation for Research and Treatment of Cancer heard that the result could be fewer trials.

Critics fear that differences in national implementation will not result in the simplification and harmonisation of existing procedures and that as a result it will be increasingly difficult to conduct publicly funded pan-European trials.

The legislation's definition of “sponsor” is causing special concern. It is defined as “an individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial.” Critics consider that the definition is too rigid and does not take account of the partnership structure that non-commercial trials tend to use.

Richard Sullivan, the head of clinical programmes at Cancer Research UK, points out that the partnership system involving academics and various parties in trials does not seem to be recognised in the EU directive.

“It is unlikely that any body involved in publicly funding cancer trials, be it Cancer Research UK or others, will be able to take on this role, and without a sponsor publicly funded cancer trials in the United Kingdom will stop,” he warned.

He added that, even if a sponsor could be found, trials are under threat from the increased administration that could result from the legislation. Mr Sullivan estimates that the overall cost of setting up, running, and closing down trials will increase some fourfold because of the extra demands, without increasing the protection of patients.

“There will be fewer trials to offer patients, and answers to important clinical questions will be significantly delayed or remain unanswered in adult and childhood cancers,” he predicted.

The various organisations at the conference decided to establish a platform of partnerships that will try to alert governments and the medical profession to apply the legislation with a degree of flexibility. □

**Statins cut cardiovascular events by a quarter in people with diabetes**

Susan Mayor *London*

Statin treatment reduces major coronary events, revascularisations, and stroke by nearly a quarter in people with diabetes regardless of whether they have occlusive arterial disease or raised cholesterol. This was the finding from a major study published last week.

The Medical Research Council/British Heart Foundation heart protection study randomly allocated 5973 UK adults (aged 40-80 years) with a history of diabetes—90% with type 2 diabetes and 10% with type 1—to 40 mg simvastatin daily or a matching placebo for five years. Results showed that the combined end point of first major coronary event, stroke, and revascularisation was reduced by 22% (95% confidence interval 13% to 30%) in patients treated with simvastatin compared with those given placebo.

A total of 601 (20.2%) first events occurred in the simvastatin group, 748 (25.1%) in the



Professor Rory Collins

placebo group ( $P < 0.0001$ ). The researchers, the Heart Protection Study Collaborative Group, argued that as compliance was not 100% in the trial, full compliance with the daily statin regimen would probably reduce major vascular events by even more than seen in the study—by about a third, they estimated (*Lancet* 2003;361:2005-16).

Reductions in cardiovascular events with simvastatin were

similar regardless of whether patients had raised cholesterol levels at baseline. Nearly half (2426 patients) of the study group had pretreatment LDL (low density lipoprotein) cholesterol levels below 3.0 mmol/l. Statin treatment reduced events in this group by 27% (13% to 40%;  $P = 0.0007$ ). The 2912 patients without diagnosed occlusive arterial disease also shared similar risk reduction, of 33% (17% to 45%;  $P = 0.0003$ ).

Lead researcher Rory Collins, professor of medicine and epidemiology at the clinical trials service unit and epidemiological studies unit at the Radcliffe Infirmary, Oxford, said: “The results provide direct evidence that cholesterol lowering therapy is beneficial for people with diabetes even if they do not already have manifest coronary disease or high cholesterol concentrations.”

He argued that his team supported renewed emphasis on the control of macrovascular complications of diabetes other than hyperglycaemia: “The study showed that the benefits of cholesterol lowering therapy were additional to those of other cardioprotective treatments.” □