US clinical research under threat

Janice Hopkins Tanne, *New York*

Clinical research in the United States is facing a crisis largely due to the growth in managed care, the Institute of Medicine and the American Medical Association warned last week.

"The real problem is that American society is trying to control healthcare costs. Managed care organisations are the mechanism through which this is expressed," said Dr Kenneth Shine, president of the Institute of Medicine, part of the National Academy of Sciences. Academic medical centres, whose costs are 15-30% higher because of research and education, are forced to compete with community hospitals.

The Institute of Medicine organised a two day meeting in Washington, DC, to highlight these concerns; it coincided with a special issue of *JAMA*. The biggest single problem, Dr Shine said, is that clinical researchers are losing time to do research as their hospitals press them to see more patients. Basic science researchers usually hold a PhD qualification and so cannot be redirected to the care of patients.

Dr Ernest Moy, assistant vice president of the Association of American Medical Colleges, and colleagues found that since 1990 medical schools in markets with a high penetration of managed care showed a slower growth in the value of grants from the National Institutes of Health. The money was redirected to schools in low or medium managed care markets, whose awards increased (*JAMA* 1997;278:217-21).

Had the change not occurred, the schools in the high managed care markets would have received an additional $98m (£58m) in awards in 1995. Particularly vulnerable were traditional research project awards for proposals initiated by the investigator rather than awards in response to a call for proposals—some $56m of the "lost" $98 million was in these traditional research grants. In contrast, grants for basic science research continued to increase in all managed care markets.

"Because managed care penetration [of markets] isn't stopping, in five years it will be more intensive across the board. We're concerned that we will be doing less clinical research in general, developing fewer products to help patients," Dr Moy said.

Another study found that clinical researchers in high managed care markets publish fewer papers, have more responsibilities for the care of patients, and feel more stress than those in the least competitive markets (*JAMA* 1997;278:222-6). Health policy researcher Dr Eric Campbell, of Massachusetts General Hospital in Boston, and colleagues surveyed staff at the 50 universities that received the most funding from the National Institutes of Health in 1993. Clinical researchers in the least competitive markets published 17% more papers than those in the most competitive ones. Dr Campbell and colleagues concluded that researchers in competitive markets were "consistently more likely to perceive lower levels of departmental community and cooperation and greater levels of conflict."

V VAHRAMEER/SIS PARIS (DETAIL)

Fewer doctors are attracted to clinical research

Numbers decline

Dr Campbell warned that failing to protect clinical research may delay putting basic research findings into practice and also further discourage people from entering clinical research—their numbers have been declining for more than 15 years. Medical graduates often have debts of $100 000. Salaries for clinical researchers start at $40 000, whereas doctors in "procedure oriented" fields earn far more.

Patient oriented research also suffers through the National Institutes of Health's process of awarding grants, according to a study by Dr Gordon Williams of Harvard Medical School and colleagues of 12 000 proposals initiated by investigators (*JAMA* 1997;278:227-31). Applications for research involving patients had a lower success rate than those involving laboratory research. The success rate depended, however, on where the applications were reviewed. When clinical research applications were reviewed by study sections that primarily review clinical grants they did as well as applications for laboratory research. But when they were reviewed by sections that mainly review laboratory research applications, they did not.

Dr Williams and colleagues recommend changing where clinical research applications are reviewed, recruiting more clinical researchers to review the applications, and developing clearly defined criteria for evaluating clinical research applications.

Dr Herbert Pardes, dean of Columbia University's College of Physicians and Surgeons in New York, said that clinical medicine is jeopardised by "the constriction of virtually every revenue stream."

Dr James Thompson, dean of Bowman-Gray School of Medicine in North Carolina, said that something needed to be done to stop the decline in numbers of doctors working as medical researchers. He called on major groups in American medicine to set up a clinical research summit to set goals in research, seek increased flexibility in funding, restructure training for clinical research, and report annually on success in achieving these goals (*JAMA* 1997;278:241-5).

To preserve and strengthen clinical research, Dr Shine proposed a four year, 1% tax on health insurance premiums to replace the funding lost through cuts in Medicare and Medicaid and decreased faculty practice income. □

In brief

UK action on the Gulf war syndrome: The British government has promised Gulf war veterans a £6.5m ($11m) package of research and treatment. This will include testing the side effects of giving simultaneous pertussis and anthrax vaccines.

New class of antibiotics created: United States scientists report that they have produced new antibacterials with a broad potency similar to erythromycin when tested in culture (*Science* 1997;277:367-9).

Warning over diet drugs: Doctors from the Mayo Clinic in Rochester, Minnesota, said that 24 women taking fenfluramine and phentermine have developed symptoms of heart valve disease and five have needed open heart surgery. The Food and Drug Administration has warned doctors about the possible link, but there are no plans to withdraw the drugs.

Holland to raise legal drinking age: The Dutch government is proposing to raise the legal age at which alcohol can be bought from 16 to 18. The plan will be scrutinised by the government's advisory body before being debated in parliament. Research last month showed that alcohol use by 12 to 18 year olds had increased from 42% to 53% between 1992 and 1996.

Respiratory infection linked to heart problems: British researchers have found that patients with the highest blood levels of antibodies to *Chlamydia pneumoniae* had a four times higher risk of subsequent heart disease than patients with no such detectable antibodies (*Circulation* 1997; 96:404-7). A single, three day course of antibiotics eliminated the increased risk, they report.

Plan for paediatric intensive care: £5m ($8.4m) is being made available to fund specialist centres for paediatric intensive care throughout England. Health authorities will no longer have to provide such care. Instead, resources will be concentrated in regional lead centres.

Smoking crackdown by UK government

John Warden,
parliamentary correspondent, BMJ

The British government is to implement a wide range of interlocking measures to reduce tobacco consumption, public health minister Tessa Jowell told an antismoking conference in London this week.

In addition to its commitment to ban tobacco advertising, the government is to consider making it illegal to sell tobacco to young people under 18. Other suggestions are for a health levy on tobacco profits, controlling the nicotine content of cigarettes, no smoking in public places, and legal action against manufacturers—although Ms Jowell said that health authorities cannot lawfully seek to recover costs from them.

She was addressing a "tobacco summit" of doctors, academics, and business people to discuss proposals for a white paper by the end of the year. The government has yet to take a view on which ideas would be desirable or possible. But Ms Jowell emphasised that the government plans a range of complementary measures that will reinforce each other.

"Today's young people will fill tomorrow's cancer wards unless effective action is taken to reduce smoking," she said. She added that there was no defence for a product which first causes people to become addicted and then "kills them off at a rate of 120 000 a year in the UK alone."

New figures show that among 15 year olds, 28% of boys and 33% of girls are regular smokers. Of secondary school children under 15 in England, 13% smoke at least one cigarette a week compared to 14% in Scotland because of a sharp rise in the number of boys who smoke. Among adult smokers, 69% said that they would like to stop smoking, with 83% of them giving health as a reason. Almost half (46%) of current smokers had received advice about giving up smoking by medical professionals.

Ms Jowell ruled out approaches from the tobacco industry for another "voluntary agreement" on their terms, although she predicted a transitional period for ending tobacco sponsorship in sport. □

Half the deaths of young infants may be avoidable

Benjamin Hope, *Clegg scholar, BMJ*

More than half the stillbirths and deaths before the age of 1 month in Britain could have been prevented, a report released last week has found. Figures obtained by the confidential inquiry into stillbirths and deaths in infancy have led the report's authors to recommend an urgent review of current procedures relating to labour and delivery.

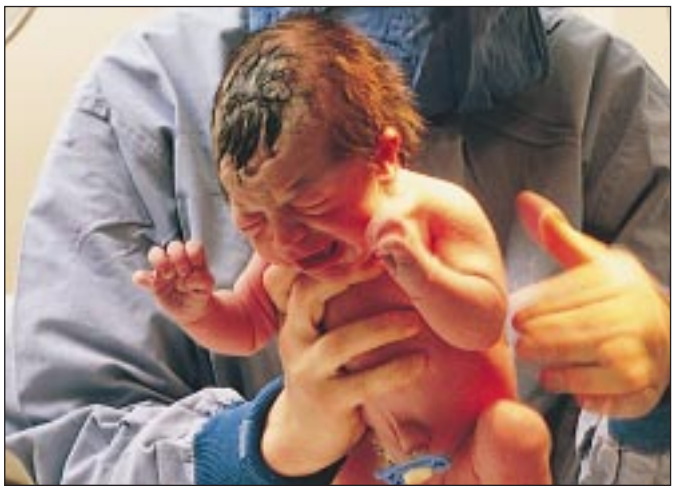
The inquiry investigated 1266 deaths in 1994 and 1995 that occurred after the onset of labour and before the age of 1 month in babies weighing at least 1500g with no congenital abnormalities. Multidisciplinary panels made up of obstetricians, pathologists, paediatricians, and midwives judged 873 of these deaths to be the result of asphyxia or trauma during labour or delivery. In 52% of the cases, the panels found that different care "would reasonably have been expected to have made a difference"; in a further 25% different care "might have made a difference."

Obstetricians were responsible for suboptimal care in 60% of the cases, with hospital midwives implicated in 46%. Only 20% of cases involved consultants and higher grade midwives. The report notes that the lower mortality associated with consultant involvement suggests that improved supervision of less experienced staff should be considered. Failure to act on potentially avoidable problems was identified as a more common shortcoming than failure to identify a problem. Staffing issues and equipment failure were rarely implicated.

However, Professor Ralph Settatree, clinical director of the confidential inquiry into stillbirths and deaths in infancy, emphasised the high standards set by the panels. "We must call these deaths avoidable even though most clinicians would have had difficulty in doing a better job," he said.

To improve care the consortium is calling for a nationally approved standard of assessment and accreditation of skills of relevant professionals, and development of standardised, multidisciplinary guidelines for particular clinical issues, such as fetal heart monitoring, that arise during labour.

"There will probably always be an underlying death rate for this group of births," said Professor Settatree. "What we cannot tolerate is the same mistakes recurring. In some places perinatal care is exemplary. We have to ensure that these models are followed universally." □



GAILLARD, JERRICAN/SPL

A review of labour and delivery procedures is called for

Shake up of emergency surgery needed

Jacqui Wise, *BMJ*

The Royal College of Surgeons of England has called for a major reorganisation of emergency surgical services which would lead to the merging of many smaller units.

It says that the ideal emergency service would serve a population of around 500 000, with consultants in the main surgical specialties freed from other commitments while on emergency duty; services would also have 24 hour dedicated operating and imaging facilities.

The president of the college, Sir Rodney Sweetnam, said: "Competing emergency services can no longer be provided by every district general hospital." He added: "Trusts with only 200 000 patients which are competing against one another should pass into history, as frankly there aren't the resources."

Sir Rodney said that such reorganisation would not mean that hospitals would have to close, but hospitals would need to cooperate with each other. One hospital, for example, could provide the emergency services while its neighbour could concentrate on day case surgery, outpatient appointments, and specialist clinics.

The college's report, *The Provision of Emergency Surgical Services: an Organisational Framework*, says that a major expansion in the number of consultants is needed for the changes to occur.

JOHN GREIM/SPL

Emergency surgical services are under strain

But perhaps more importantly the public and politicians would need to recognise that it is not possible for each small hospital to provide a satisfactory service for surgical emergencies and that patients may need to travel to get such a service. Sir Rodney said that the service has become increasingly strained due to patients' rising expectations, the new specialist training arrangements for doctors, and the reduction in junior doctors' hours. □

Goodbye to the "hello nurse" in casualty departments

Jacqui Wise, *BMJ*

The publication of figures showing how soon patients are assessed after arrival in accident and emergency units is to be abandoned as part of an overhaul of the NHS performance tables. Health ministers said that this would mean the end of the "hello nurse" employed in casualty departments by some trusts to ensure a good rating regardless of how long patients had to wait for treatment.

The health secretary, Frank Dobson, announced that from 1 October there would be a new standard for assessment in casualty departments to ensure that patients are properly assessed and treated according to clinical priority. This was the first step towards developing a linked standard on total waiting time in accident and emergency units.

The BMA said that it welcomed the move: "The five minute assessment standard can be meaningless and has undermined good triage procedures in accident and emergency departments."

Health minister Baroness Jay said that the government had decided to publish the performance tables for 1996-7 (despite opposing the scheme before taking office) because they do contain some useful information. For the first time, for example, the tables contain information on the numbers of patients who fail to keep hospital appointments. Baroness Jay said that she was shocked at the high numbers and estimated that missed appointments cost the health service more than £500m ($840m).

The tables show that last year the number of patients on the NHS waiting list increased by 10% compared with the year before to a record 1 158 000, with a sevenfold increase, to 31 200, in the numbers waiting for more than a year. Baroness Jay said that the figures confirmed the legacy Labour had inherited from the Conservative party.

She said that the government was committed to improving the information collected: "We shouldn't just count things that are easily counted but provide meaningful data about the quality and effectiveness of treatment in the NHS."

To this end the Department of Health, together with the Joint Consultants Committee, has developed 15 clinical indicators (see box). This month trusts will receive data showing how their hospitals compare with the national average for each of the indicators.

League tables containing the data will not be published at this stage. Once the indicators have been assessed, however, the Department of Health hopes to make the information public. Sir Norman Browse, chairman of the Joint Consultants Committee said that the committee will be making its own independent assessment of the scientific validity of the indicators during the next three months.

Baroness Jay said that the 15 indicators were just a starting point and in particular she would like to see more that were directly related to nursing care.

Both the BMA and the NHS Confederation welcomed the move towards developing more meaningful information for the public but warned about the problems of comparing like with like.

Baroness Jay acknowledged this could be a problem but said one possibility was to cluster together specialist centres that receive more complicated cases. (See p 142.) □

Proposed clinical indicators for hospitals' performance

- Deaths in hospital within 30 days of surgery
- Emergency readmissions within 28 days of discharge
- Wound infection in hospital after surgery
- Discharge home within 56 days of emergency admission from home with a stroke
- Surgery for recurrence of hernia after previous surgery
- Deaths in hospital within 30 days of emergency admission with a heart attack
- Damage to organs in hospital after surgery
- Pulmonary emboli in hospital after surgery
- Heart complications in hospital after surgery
- Complications in the central nervous system after surgery
- Adverse events related to the use of drugs in hospital
- Repeat operation after previous surgery on the prostate
- Discharge home within 56 days of a fractured neck of femur
- Deaths in hospital within 30 days of a fractured neck of femur
- Frequency of dilatation and curettage among women under 40 years of age

"Smart" rationing is possible

Sandra Goldbeck-Wood, *BMJ*

The barriers to fair rationing are fewer than we think, according to Dr David Eddy, senior adviser for health policy and management at Kaiser Permanente, a large managed care organisation in the United States.

Addressing a conference in London, *Rationing in the NHS: Time to Get Real*, Dr Eddy said that rationing has always taken place in all healthcare systems, but what we currently have in the NHS is "dumb rationing."

The conference, which was attended by 250 delegates, was organised by the BMA, the King's Fund, the College of Health, and the *BMJ*. Dr Eddy said that the current system is "arbitrary, inconsistent, unsuccessful, and harmful." An example, he said, is "rationing by postcode," in which a drug such as interferon beta is available to patients on one side of a geographical boundary but not on the other. Instead we need "smart" rationing, which takes into account evidence on efficacy as well as nationally agreed priorities to allow equitable distribution of scarce resources.

"Rationing is not simply a matter of administrative efficiencies or control of price of drugs, supplies, and salaries," said Dr Eddy. "It means the withholding of a beneficial treatment because of its cost. This phrase captures more honestly the painful reality we face. Wherever there's a boundary [for instance, in the age cut off for breast screening], there's someone who could benefit on the other side." But smart rationing is not about targeting expensive treatments or about selecting out whole categories of treatment or patients but about transferring resources from low to high value activities, he said.

The obstacles to smart rationing are fewer than we may think, according to Dr Eddy. "We do not need to wait for economists to agree on the percentage of gross domestic product to be allocated to health care or for the methodologists to reach agreement on ideal measures of quality. We do not need to have perfect information either on health or economic outcomes, nor to get bogged down in debates about statistical significance, P values, or experimental biases. We don't need sophisticated clinical or financial accounting systems, nor do we need to tackle every problem at once," said Dr Eddy, who believes that there are plenty of examples of where poor value for money is clearly evident.

Instead what we must do is analyse practice at the level of specific indications, change from qualitative to quantitative reasoning, and focus on populations not on individuals. We must also ensure the measures used to judge quality support this strategy. "We have to help patients to understand the consequences of a limited resource pool and the need to be fair, and this means joint leadership from the professions and the government. It's too threatening an issue for any one group alone," he said. □

Ruling on interferon beta will hit all health authorities

Clare Dyer, *legal correspondent, BMJ*

North Derbyshire Health Authority acted unlawfully in denying a patient with multiple sclerosis treatment with interferon beta, a High Court judge ruled last week. The landmark judgment has ramifications for cash-strapped health authorities throughout Britain and will boost the case for a separate NHS fund to pay for expensive new drugs coming on the market as a result of biotechnological advances.

Mr Justice Dyson said that the health authority had knowingly imposed what was in effect a blanket ban on the use of the drug, despite guidance in an NHS circular on making it available through hospitals. "A blanket ban was the very antithesis of national policy, whose aim was to target the drug at patients who could most benefit from the treatment," said the judge. Kenneth Fisher, aged 33, from Dronfield, near Sheffield, had been prescribed the drug by two consultant neurologists at Sheffield's Royal Hallamshire Hospital. But the drug was banned in the hospital pharmacy for patients from North Derbyshire because the authority refused to pay the cost of £10 000 a year. Mr Fisher has the relapsing/remitting form of multiple sclerosis, which the treatment has been shown to benefit. But it helps only those who are still ambulant, and the court was told that Mr Fisher's condition had deteriorated in the 18 months since he was refused the drug.

His QC, John Grace, said: "That is a matter for the consciences of the individuals who took the decision in question." The judge imposed a 14 day deadline for the authority to reassess Mr Fisher to see whether he still qualifies for the treatment and ordered the health authority to pay Mr Fisher's costs. The total bill for both sides' costs is likely to be at least £50 000, enough to treat five patients for a year. The case focused attention on the issue of covert rationing in the NHS.

The authority adopted a policy that the drug would not be made available outside a clinical trial and continued to refuse to pay for it even when told that a proposed national trial had been postponed indefinitely. An internal note spoke of "creative constraints" on the use of the drug. "Creative" was a euphemism for "disingenuous," said the judge. David Body, Mr Fisher's solicitor, said: "This judgment is putting treatment choices for patients back in the hands of clinicians. All of us assume when we go into hospital that the person at the bedhead is the person who is making the choice for us."

JAMES KING-HOLMES/SPL

Interferon beta can cost £10 000 a year for one patient

North Derbyshire authority said that evidence of the benefits of interferon beta was "limited," and it gave priority to the use of proved treatments which cured or eased the conditions of large numbers of people. But it would immediately review the position with interferon beta and "identify possible sources of increased funding."

Stephen Thornton, chief executive of Cambridge and Huntingdon Health Authority and director of the NHS Confederation's health authority council, said: "Those health authorities in a similar position to North Derbyshire will now need to review their policies. If additional money is to be spent on interferon beta, it will mean taking cash from some other sources." □

Dear Mr Dobson . . .

Delegates attending a conference in London last week entitled *Rationing in the NHS: Time to Get Real* called on the British government to face up to its responsibilities. In an open debate the multidisciplinary assembly of 250 doctors, patients, and healthcare managers voted overwhelmingly in favour of the motion "the government has an obligation take a lead in rationing." The conference then sent this open letter to the secretary of state for health

Dear Mr Dobson,

At a conference in London last week about 250 people from all parts of the National Health Service agreed that not all health services can be provided to everybody who might benefit from them. This will remain true even with more generous funding, greater efficiency, and lower management costs.

Rationing has always existed in all health services and always will. Many health interventions produce in some patients small benefit at enormous cost—for example, treating high cholesterol in a young woman with no other risk factors for heart disease or offering magnetic resonance imaging to a young person with uncomplicated migraine. These are not ineffective interventions but they don't offer much value for money.

Although rationing of healthcare is inevitable, the problem has become more severe because there seems to be an increasing gap in all health services between what could be offered and what can be afforded. For example, we have a steady stream of new treatments that offer what is often small benefit at very high cost. This is the case with new treatments for patients with motor neurone disease, Alzheimer's disease, and multiple sclerosis.

At present all health services have what David Eddy, a leading United States health policy expert, called "dumb rationing." What we want is "smart rationing." Rationing in Britain is currently inefficient, inequitable, undemocratic, and opaque. Many patients feel as if the availability of services is determined by a lottery with unknown rules. Many of these failures can be laid at the door of the previous government's reforms, but that is not the whole explanation.

Other countries—particularly Norway, Sweden, the Netherlands, and New Zealand—have begun to tackle healthcare rationing, and we believe that Britain should join them. Tackling this issue is in many ways a test of the political maturity of a country. The prime minister said this weekend that we cannot shy away from the difficult questions, and health care rationing is one of the most difficult. We seem to have in Britain at the moment a chance to regain the national sense of community and cohesion that led to the creation of the NHS. We believe that by facing the question of healthcare rationing together we can strengthen the NHS and rebuild the confidence of both patients and staff in this most important of British institutions.

There must be much more openness in healthcare rationing, and equity should be one of the main criteria we use to decide who gets what. We heard at the conference how patients are very confused and disturbed by somebody on one side of a street being able to get a service that is denied to those with the same problem living on the other side. George Levvy, the chief executive of the Motor Neurone Disease Association, told us that his members would not expect that every patient could get every new drug, but they wanted to know the criteria that were being used and see that they were applied fairly.

Decisions about rationing must be taken responsibly at every level of the health service, including nationally. The government should be providing leadership and guidance to health workers and decision makers, and the general public. One method might be through appointing a national commission that might well include a majority of non-health professionals. Almost everybody at the conference supported such a development as one element of the arrangements that are needed.

"Smart rationing" means thinking about the value of health services not just their cost. There is scope in all health services—for switching from low value (but not ineffective) treatments to high value ones. The way that this is done must be transparent, and decisions made by government, health authorities, and doctors should be based on well known and widely agreed criteria. They should be developed through the participation of an informed public. Citizens—whose taxes fund the NHS—should be given information about the issues we all face and the opportunity to take part in debates about setting priorities for the health service. Citizens' juries and deliberative polls are two innovative ways of involving people in making decisions about resource allocation, both locally and nationally. Experience with citizens' juries show that people understand the need to ration and can play a useful part in the process.

We would like to help you to develop a framework within which difficult but essential decisions about the future of the health service can be made. We hope that the new Labour government will be willing and able to tackle this difficult problem and bring about a more equitable and responsive NHS. The NHS will never be stable until this problem is faced. Rationing is a positive opportunity, not a threat, for the future of the health service.

Ian Kennedy, *head and dean of the school of law, King's College*
George Levvy, *chief executive, Motor Neurone Disease Association*
Sandy Macara, *chairman, BMA Council*
Robert Maxwell, *chief executive, King's Fund*
Alan Maynard, *department of health sciences and clinical evaluation, University of York*
Richard Smith, *editor, BMJ*
Ron Zimmern, *director of public health, Cambridge and Huntingdon Health Authority*

Cerebral palsy linked to maternal fever

Alison Boulton, *London*

Babies of normal birth weight who are exposed to infection and maternal fever while in the uterus seem to have a ninefold increased risk of developing cerebral palsy.

Maternal or placental infection had been associated with an increased risk of cerebral palsy in low birthweight babies. In a recent study American researchers studied the records of babies born in hospital in California between 1983 and 1985, all of whom weighed at least 2500 g at birth. In all, 46 children with disabling spastic cerebral palsy and 378 randomly selected control children were included in the study.

The researchers found that two factors—a maternal fever exceeding 38°C in labour and a clinical diagnosis of chorioamnionitis—were associated with a ninefold increase in the risk of unexplained spastic cerebral palsy (*JAMA* 1997;278:207-11).

Dr Judith Grether of the California birth defects monitoring programme in Emeryville and Dr Karin Nelson of the National Institute of Neurological Disorders and Stroke in Bethesda, Maryland, found that maternal infection was also linked to a low Apgar score (assessment of a newborn's condition within 60 seconds of birth) and neonatal seizures—signs commonly attributed to asphyxia at birth.

They conclude that their observations "arouse hope that therapeutic efforts targeting maternal infection or the inflammatory response to infection can lower the risk of cerebral palsy in term infants." But in an accompanying editorial Dr David Eschenbach of the University of Washington, Seattle, warned that antibiotic resistance could become a problem if antibiotics were used increasingly in labour wards in an attempt to reduce the incidence of cerebral palsy.

WILLIAM AND DENI MCINTYRE/SPL

Maternal infection could explain some cases of cerebral palsy

Peter Soothill, professor of maternal and fetal medicine at the University of Bristol, said that the results were interesting but there should be no immediate change in clinical practice. "The current study cannot exclude all possible compounding variables. Some women may be at an increased risk of infection and having a child with cerebral palsy, but that doesn't necessarily prove that infection causes a rise in cerebral palsy," he said.

Mr John Spencer, consultant obstetrician and gynaecologist at Northwick Park and St Mark's NHS Trust in Harrow, Middlesex, said: "Given the absence of evidence of neonatal infection in this study, the rise in maternal temperature may be the key component to the current observations, acting as a surrogate marker for a long and difficult labour." □

US doctors lie to help patients

Norra Macready, *California*

Over half of doctors would deceive insurance companies to obtain coverage for their patients, according to a survey presented at the annual meeting of the Society of General Internal Medicine in Washington, DC, last week.

Many doctors are finding that their role as a patient advocate often conflicts with their financial and contractual obligations to third party payers, said Dr Victor Freeman from the clinical economics research unit of Georgetown University Medical Center in Washington, DC. Occasionally, there is a true ethical conflict—for example, when a third party payer's rules preclude coverage for a medically indicated referral.

Doctors in this dilemma have an ethical obligation both to their patient and to following the rules. To determine doctors' decisions in this situation, Dr Freeman posed six clinical scenarios of varying severity to 167 consultant physicians in six major cities around the United States.

The doctors' willingness to deceive depended on the severity of the patient's condition. For example, one theoretical patient had chronic, non-healing leg ulcers caused by atherosclerosis. The patient, who had never smoked, experienced pain while at rest. The insurance company denied coverage on the grounds that this was a pre-existing condition. In another example a patient sought coverage for rhinoplasty because she felt "sad and unattractive" and was teased over her nose. This was denied because she experienced no breathing problems. While 57% of the doctors sanctioned deception to help the first patient, only 3% did so for the second. In all, 75% of the doctors described themselves as patient advocates but tried to follow the rules whenever they could. However, 57% admitted to lying sometimes.

"What is most concerning is, what would these doctors do in real life?" asked Dr Freeman. "If only 57% of the doctors are willing to deceive when confronted with the most severe dilemma, what happens to the patients of the doctors who play by the rules?" □

Canada cuts drug evaluation procedures

David Spurgeon, *Quebec*

The Canadian federal government has abolished 191 jobs of people who deal with food and drug safety to save a total of $C8m-9m a year. Critics fear that lives will be endangered by the move.

A petition signed by more than 70 scientists in the food directorate asks the health minister to reconsider the cuts, which they believe will "seriously affect the future health of Canadian infants, children, and adults."

Assessment of new drug safety and efficacy, formerly done by the drug research bureau, now will be carried out by the pharmaceutical companies that submit the drugs for approval, by university researchers—many of whom are funded by drug companies—and by the regulatory agencies of other countries such as the United States and Britain.

Art Beaubien, a retired pharmacologist formerly with the drug research bureau, said: "This will mean that we will no longer have an unbiased viewpoint when it comes to the marketing of drug products." Scientists in the health department agree, saying that the potential for conflicts of interest among academic and industry researchers will increase.

In an internal document some health department scientists said: "The opportunity for conflicts of interest to arise from external research already being funded or in contractual relationship to drug manufacturers whose product is to be subjected to examination is very real and a major concern."

But Dan Michaels, director general of the drug directorate, said that the Canadian government cannot afford to spend the hundreds of millions of dollars it would take to replicate industry research to prove drugs are safe.

He added that regulatory agencies in many countries also research the same product. "Why do all these regulatory agencies have to have the same research capacity?" □