

Inquiry ordered after organ donor found to have CJD

Bryan Christie, *Edinburgh*

An inquiry has been ordered into the screening system for organ donors in Britain after a woman who donated eye tissue to three patients was found to have been infected with Creutzfeldt-Jakob disease (CJD).

The case has highlighted a weakness in the current system, which can result in tissue infected with CJD being used in transplants before a donor's infected status becomes apparent. However, both CJD specialists and the government say that any such circumstances are likely to be extremely rare and the overall risks of the fatal brain disease being transmitted in this way are low. Mrs Marion Hamilton, 53, from Stirlingshire, died in February of inoperable lung cancer but she also had neurological problems that led to a postmortem

examination at Stirling Royal Infirmary. Brain tissue was sent to the National CJD Surveillance Unit in Edinburgh because doctors suspected that she may have had the classic form of CJD.

Despite these fears, which were confirmed last week when the final results were produced, no action was taken to prevent Mrs Hamilton's corneas and sclera being used in transplants. The three patients who received this tissue have now been informed.

The government's inquiry is expected to focus on the decision to allow Mrs Hamilton's eyes to be used for corneal transplants when there were concerns that she may have CJD. Scotland's health minister, Sam Galbraith, said: "We need to know whether indications about the

donor's condition at the time of her death should have led to more questions about the use of her eyes for transplantation."

Sandra Galloway of the CJD Support Network, a group established to help families who have experienced CJD, raised wider fears that CJD infected organs are being transplanted without anyone knowing about it. "Everyone involved with CJD feared this would happen. It would be so easy for someone carrying a donor card to be incubating the disease without knowing it."

Checks are carried out on organs and other tissues donated for use in transplant procedures in Britain to ensure that they are not infected with viruses such as HIV and hepatitis. But Dr James Ironside of the National CJD Surveillance Unit said that in the

absence of an effective screening test for CJD, it was difficult to see how a system could be created to eliminate completely the risk of infection. "We cannot screen for CJD the way we can for HIV, and as a result we cannot tell if someone is incubating the disease. However, if someone dies with clinical features of the disease, then obviously these patients should not be admitted into the organ donation programme."

Mr Galbraith has called on doctors who are assessing the suitability of patients as organ donors to be aware of the possible risk of transmitting infectious diseases. "In the light of this case, the government are exploring urgently what steps can be taken to reduce even further the risk of something like this happening," he said. □

El Niño causes diarrhoea outbreaks

Adam Easton, *Manila*

El Niño may have begun to affect people's health on both sides of the Pacific Ocean, with an increase in outbreaks of diarrhoea and dehydration.

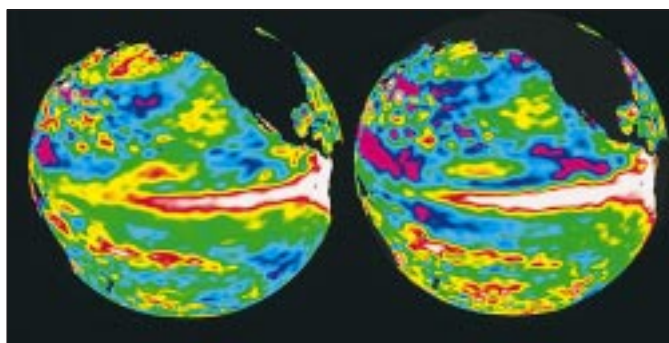
Higher seasonal temperatures in South America and droughts in South East Asia brought on by El Niño may have led to higher incidences of the disease. Manila in the Philippines and Lima in Peru have experienced marked increases in the number of cases of diarrhoea, mainly among infants and young children.

In the last two weeks of November Manila experienced 160 cases of diarrhoea, with 138 clustered in the area of San

Andres. On average the city has 80 cases a month. The increase came as the city began water rationing due to the light monsoon rains thought to be caused by El Niño. The Filipino meteorological bureau reported a 40% drop in rainfall. Manila has been declared a "calamity" area, and police have been ordered to arrest people wasting water.

Many of those affected had got their drinking water from a rubber hose connected to a booster pump tapping the main water line. It was noted that infants who got sick were not breast fed. Dr Concepcion Roces of the Department of Health's field epidemiology training programme said: "It is likely the outbreak was caused by a contaminated water supply after the rationing was introduced."

On the other side of the Pacific the rehydration unit at the Cayetano Heredia Hospital in Lima, experienced a 35%



El Niño is moving eastwards across the Pacific Ocean

increase in the number of cases of diarrhoea in April to June 1997 compared with figures from January to March (*Lancet* 1997;350:1597-8). This compares with a 16% average decrease in the number of cases in April to June 1993-6. In Lima, hospital admissions for diarrhoea normally peak during the summer months, between December and May. However, during 1997, the temperature

remained above 20°C until the end of September, possibly due to El Niño.

Doctors from the unit said in the *Lancet*: "In Peru and neighbouring countries affected by El Niño—Chile, Ecuador, and Colombia—we anticipate an outbreak of diarrhoea and dehydration in the coming summer months when the high seasonal temperatures will be exacerbated by the presence of El Niño." □

HIV epidemic is far worse than thought

Jacqui Wise, *BMJ*

HIV infection is far more common than previously thought, according to a report from the joint United Nations programme on HIV/AIDS (UNAIDS) and the World Health Organisation. The new figures show that about one third more people are living with HIV worldwide than was estimated in December 1996.

Dr Peter Piot, executive director of UNAIDS, said: "We are now realising that rates of HIV transmission have been grossly underestimated—particularly in sub-Saharan Africa, where the bulk of infections has been concentrated to date."

Over 30 million adults and children are now believed to be living with HIV infection—one in every 100 sexually active adults worldwide. And if current transmission rates hold steady, by the year 2000 the number of people living with HIV or AIDS will reach 40 million.

The pattern of infection had been assumed to be similar in different countries in the same region, but as more data became available it became apparent that there were huge differences in the way the epidemic was devel-



Estimates of the number of people infected with HIV are a third higher than previously thought

oping in different countries. In sub-Saharan Africa, for example, very few countries had reliable data on HIV infection and some, notably Nigeria and South Africa, had virtually none. The country with the best surveillance rates was Uganda, and that showed that infection rates were beginning to level off, with new infections dropping in younger age groups. The situation in Uganda was wrongly taken to be typical of the whole region.

Over 90% of people with HIV live in the developing world, where few facilities exist for voluntary testing and counselling and where, according to UNAIDS, 9 out of 10 HIV positive people will have no idea they

are infected. The organisation warns that the full impact in terms of mortality from AIDS is only just beginning. It is estimated that 2.3 million people died of AIDS in 1997—a 50% increase on 1996. Nearly half of those deaths were in women, and 460 000 were in children under 15.

The report states that in very badly affected countries the development gains achieved over the past few decades are being wiped out by the epidemic. In Botswana, for example, life expectancy, which rose from under 43 years in 1955 to 61 years in 1990, has now fallen to levels found in the late 1960s. On current trends, Zimbabwe's infant mortality can be expected

to rise by 138% by the year 2010 because of AIDS.

Clare Short, Britain's international development secretary, said that although recent scientific advances were very encouraging, people in developing countries were unlikely to see the benefit: "The new advances in drug therapies are prohibitively expensive in societies where expenditure on all health needs is often only £3 a day. It is just not feasible for such therapies to be a solution for the vast majority of people affected by HIV today. The search must continue for affordable means of slowing down the progression of HIV to AIDS and to increase protection, especially for young people." □

Researchers' offices raided over banned AIDS drug

Pat Sidley, *Johannesburg*

South Africa's drug regulatory authority, the Medicines Control Council, has raided the offices and home of two researchers who developed a controversial drug, Virodene, to treat AIDS. They were looking for evidence of the sale and manufacture of Virodene, which has been banned.

Although nothing was found, the council has asked the police to investigate the possibility of laying charges against the developers. Virodene hit the headlines earlier this year as a cheap possible cure to AIDS (8 February, p 450). Its active ingredient is an industrial solvent known as

P058. Its developers, however, had followed no protocols in its development, either at the university at which they worked at the time or through the Medicines Control Council.

The researchers had then approached the minister of health, Dr Nkosazana Dlamini-Zuma, directly and through her had presented their "cure" to the Cabinet. With a huge and growing AIDS problem, and no scientific expertise, the Cabinet had greeted the development of the drug enthusiastically. The resulting media publicity caused a huge outcry, and two official inquiries stopped the development of the

drug (15 March, p 771). The developers were accused of having misunderstood the literature on the solvent and of not having followed correct procedures for trials on humans.

With the latest figures of HIV infection in South Africa estimated at 2.6 million and climbing faster than predicted, the demand for Virodene has continued. Proponents argued that the drug, which costs just 200 rands (£25) a month, would be better than no treatment at all. Dr Zuma has berated the Medicines Control Council for its stance over the drug. She said that it should be the right of people with AIDS to take any drug they like.

The raid by the Medicines Control Council followed a complaint from a patient who had received treatment with Virodene illegally. Not knowing this, and not knowing why he had

become ill, he had sought treatment at a state hospital. The hospital determined that his illness was caused by the solvent, which was effectively poisoning him. In an effort to deal with his problem he went for help to the Centre for Applied Legal Studies at the University of the Witwatersrand.

The developers have since denied making the drug but say that they have given the formulation to several people who have asked. They have also said that they have distributed the formulation to several African countries, where patients are receiving it. Mark Heywood of the Centre for Applied Legal Studies said that several people with whom the centre is in contact are receiving the drug. They are experiencing severe side effects, but most are not prepared to risk stopping treatment as they are all very ill with AIDS. □

UK needs an extra 1000 doctors

Linda Beecham, *BMJ*

British medical schools should increase their intake by 1000 each year to meet the future demands for health care, according to a government committee.

The Medical Workforce Standing Advisory Committee concluded that a range of measures were needed to deal with the current imbalance between the demand for doctors and the domestic supply. Although the committee looked at ways to improve the retention of doctors, it said that these could only alleviate the problem. It has therefore recommended that the annual intake of medical students should be increased by about 1000 as soon as possible.

The committee was appointed in 1991 by the secretary of state for health. In its third

report the committee suggests the following options for increasing medical student numbers: expanding existing medical schools; widening the geographical spread of clinical teaching facilities; increasing existing post-graduate facilities to cover undergraduate education; or opening one or more new undergraduate medical schools. The committee also suggests that scope exists for introducing shorter medical education courses for graduates in other disciplines to broaden the field from which doctors are recruited.

Sir Colin Campbell, vice chancellor of Nottingham University, who chaired the committee, wants the NHS to pay more attention to improving recruitment and retention by, for exam-

ple, improvements in training, career planning, and counselling and by increased use of flexible working patterns. The NHS, together with the General Medical Council and the royal colleges, should try to attract a more of high quality overseas doctors by offering training of the same high standard as is offered to home doctors. The report suggests more research into wastage, particularly from medical school, skill mix, and flexible working, and it wants more consideration given to the likely effects on the demand for doctors of policy changes, demography, working patterns, and economic factors.

Health minister Mr Alan Milburn said that several of the recommendations chimed with the government's own thinking and should be welcomed. "But the recommendation on increased medical school intake has very significant implications and will need careful examination." □

EU approves rights to genetic material

Rory Watson, *Brussels*

After 10 years of agonised debate the European Union is poised to introduce harmonised rules in all 15 member states on the application of patent protection to biotechnological inventions.

The proposal to allow companies exclusive rights to genetic research material was approved by EU governments last week and now requires the final endorsement of the European parliament before coming into force. Two years ago members of the European parliament unexpectedly killed an earlier version of the legislation, as they feared insufficient ethical safeguards had been built into the text. Such a revolt is unlikely this time round as many of the improvements suggested by MEPs to the proposal have now been taken on board by EU governments.

Supporters of the legislation say that it will provide a framework for protecting biotechnology inventions in the union and will encourage long term investment in biotechnology, putting European industries on the same footing as their American and Japanese competitors.

The new legislation would provide legally binding ethical standards in all member states and would not allow the patenting of procedures involving cloning for purposes of human reproduction, procedures involving modification of the germ line genetic identity of the human being, or particular uses of human embryos.

The prospect of EU legislation on biotechnological inventions has been condemned by the environmental organisation Greenpeace, which accused the union of opening the door to "a new form of genetic imperialism" which would "encourage big business of the North to exploit the biodiversity rich South."

Seven developing countries had appealed to EU governments not to approve the legislation. But only the Netherlands opposed the proposal, with Belgium and Italy abstaining. □

Mothers should breast feed for at least a year

Charles-Gene McDaniel, *Chicago*

Mothers should breast feed for at least the first year of an infant's life because of the health benefits for both baby and mother, says the American Academy of Pediatrics.

In a new policy statement, published in the December issue of the journal *Pediatrics*, the academy said that studies conducted in industrialised countries have shown that breast feeding can decrease the incidence or severity of conditions such as diarrhoea, ear infections, and bacterial meningitis. The research has also shown that breast feeding may offer protection against the sudden infant death syndrome, insulin dependent diabetes, and allergic diseases, among others.

Breast feeding reduces the mother's risk of ovarian and premenopausal breast cancer. It can also save a family more than \$400 (£250) on the cost of infant formula during the first year of life and reduce parental absence from work due to child illness. However, only 21% of women in the United States breast feed at six months. □



Breast feeding benefits both mother and child

Recommendations on breast feeding from the American Academy of Pediatrics

- Mothers should breast feed as soon as possible after giving birth, preferably within the first hour of life
- The newborn baby should stay with the mother during the postnatal period to facilitate breast feeding
- Instead of using crying as an indicator of infant hunger, mothers should breast feed on demand, in response to signs of hunger—such as increased alertness or activity, mouthing, or rooting
- Mothers should not give supplements, such as formula or water, to breast feeding newborns unless such supplements are medically indicated
- When direct breast feeding is not possible, a mother may "express" milk for consumption by her infant
- Mothers should breast feed exclusively for about the first six months, then add iron enriched solid foods to complement the breast milk diet

NHS aims to improve care for colorectal cancer

Zosia Kmietowicz, *London*

The Department of Health has launched an initiative to improve NHS services for people with colorectal cancer—the second most common cause of death from cancer in the United Kingdom and which claims the lives of 17 000 people every year.

The document, *Improving Outcomes in Colorectal Cancer*, is designed to help health authorities, GPs, hospitals, and community health practitioners to plan and provide the most effective services for colorectal cancer. Evidence exists that Britain lags behind other countries in terms of outcomes for colorectal cancer and that performance varies significantly across the country and between surgeons.

Professor Bob Steele, professor of surgery at Ninewells Hospital in Dundee, said: “The most important concept of the publication is that patients with colorectal cancer should be looked after by groups of people with a special interest in the disease and that the care is multidisciplinary—people should work together. As

far as improving outcomes is concerned, the most important thing that can be done is diagnose the disease earlier.”

One of the problems with colorectal cancer is that public awareness of the symptoms is low, so many patients present late, added Professor Steele. Screening could lead to earlier diagnosis and reduce mortality, he said. And although the present document does not address screening, the matter is being discussed.



Public awareness of the symptoms of colorectal cancer is low

The new guidance has been produced by the Department of Health's cancer guidance subgroup, part of the Clinical Outcomes Group, after examining the evidence available. The work is published as three linked documents: a practical manual, the research evidence, and a summary report. □

The manual and research documents may be obtained free of charge by calling the NHS Response Line on 0541 555 455.

US state rules that a viable fetus is a person

Norra Macready, *San Francisco*

A viable fetus is a person and covered by state child abuse laws, the Supreme Court of South Carolina has stated, in a ruling that differs from that of every other US state that has addressed the issue.

Cornelia Whitner, now 33, pleaded guilty in 1992 to criminal child neglect because she gave birth to a son with traces of cocaine in his system. She was sentenced to eight years in prison but was released in 1994 after serving 16 months. She then filed a request to have her conviction overturned, saying that she had received inadequate legal counsel and was not advised that her fetus might not legally be considered a person.

The state's Supreme Court noted that it had in earlier cases concluded that “a fetus, having reached that period of prenatal maturity where it is capable of independent life apart from its mother, is a person” and that “a viable fetus, while still in the womb, need not be born alive for another to maintain an action for wrongful death of the fetus.” In this case, the court stated: “The consequences of abuse or neglect which takes place after birth often pale in comparison to those resulting from abuse suffered by the viable fetus before birth.”

Nelson Weston, a paediatrician and president of the South Carolina Medical Association, said: “I think this is an unfortunate decision. It makes a viable fetus the same as a person, so the laws that apply to people now apply to fetuses.”

Ms Whitner's attorney, C Rauch Williams, said: “This decision is fraught with government interference in the doctor-patient relationship.” He notes that, because of the state's child abuse laws, the ruling implies that any doctor who treats an addicted woman in the third trimester must report her to the authorities or go to jail himself. It also effectively bans third trimester abortion, since the doctor could be prosecuted for murder. Ms Whitner is appealing to the US Supreme Court. □

Antiretroviral combinations do not eliminate HIV entirely

Deborah Josefson, *San Francisco*

Researchers in the United States have confirmed that, although combinations of potent antiretroviral drugs are effective in arresting replication of HIV, they fail to eliminate the virus entirely.

The drug combinations—typically a mixture of reverse transcriptase and protease inhibitors—act synergistically to disable the reproductive capacity of the virus and have helped to prolong the life of patients with AIDS. With HIV infection suppressed, patients' immune systems can combat opportunistic infections. The new studies show that even patients whose viral titres are suppressed to serologically undetectable levels harbour copies of HIV in quiescent immune cells.

Three teams, working independently but using similar research methods, reached the same conclusion—that CD4 memory cells can harbour latent but viable HIV and that these cells, when activated, can be induced to produce competent and infective viral copies (*Science* 1997;278;1291-4, 1295-300; *Proceedings of the National Academy of Sciences* 1997;94;13193-7). The study populations ranged from 6 to 22 patients.

Blood was harvested from patients who had been taking antiretroviral “triple” treatment for 30 months and whose viral loads were serologically undetectable. When this blood was mixed with undetected blood in culture and a T cell stimulant

added, CD4 memory cells harbouring latent HIV could activate the virus, which then entered HIV naive cells, propagating the infection.

Since the latent HIV is in a non-replicative state, it is not susceptible to antiretrovirals and cannot develop resistance to them. Dr David Ho of the Aaron Diamond Research Center in New York said: “This shows that the drugs are really quite good and are doing what they are supposed to do. It should be a motivation for patients to carry on and adhere closely to their regimen.”

However, although drug resistance in the study groups was negligible, such resistance may not be reflected in the general population: compliance may be a problem as the drugs must be taken regularly, according to a strict regimen, and many have unpleasant side effects. Moreover, the drugs are expensive—\$15 000 (£9400) a year. □