Dramatic drop in HIV infections halts circumcision trials

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Notes
Doctor helps Italian patient die

Fabio Turone MILAN

Piergiorgio Welby, the terminally ill Italian man with muscular dystrophy who in an open letter to the Italian president pleaded for his right to die, has died.

Just before Christmas, after a long battle against the illness, he was sedated by an anaesthetist, who unplugged the mechanical ventilator that had kept him alive against his will.

“My dream, my desire, my request—which I want to put to any authority, from political to judicial ones—is today in my mind more clear and precise than ever: being able to obtain euthanasia,” Mr Welby had written from the bed in which he spent his last months, unable to eat, speak, or breathe by himself.

His open letter to President Giorgio Napolitano put the personal battle at the centre of a heated political debate about advance directives, assisted suicide, and euthanasia (BMJ 2006;333:719). Mr Welby’s lawyers asked a court in Rome to allow his ventilator to be turned off, but in mid-December the answer revealed a legal loophole: although Italian patients have the constitutional right to refuse treatment, no doctor is obliged to respect such refusal, and assisted suicide and euthanasia are punishable by prison terms of up to 15 years.

After this legal attempt failed, Mario Riccio, an anaesthetist working in a hospital in Cremona, in northern Italy, volunteered to carry out Mr Welby’s wish.

“I got to know Piergiorgio Welby,” he said. “We had a long talk in which he confirmed fully his will that the therapy be interrupted.”

In Mr Welby’s apartment in Rome, in the presence of dozens of Mr Welby’s relatives and friends—among them law makers from the centre left majority parties—Dr Riccio sedated him intravenously for about 40 minutes as the respirator that had kept him alive since 1997 was disconnected.

Dr Riccio told reporters that he did not fear legal consequences. He said, “In Italian hospitals therapies are suspended all the time, and this does not lead to any intervention from magistrates or to problems of conscience.”

He was briefly questioned by the police, but his lawyers said that he was not accused of anything. The medical board is also evaluating the case.

Mr Welby’s wife and sister, both practising Roman Catholics like him, asked for a religious funeral in their parish in the Cinecittà quarter of Rome, but Vatican authorities, who have always opposed euthanasia and insist that any life must be safeguarded until its “natural” end, said that his funeral could not be celebrated in a Catholic church.

“The debate will continue,” said the prime minister, Romano Prodi, a Catholic who heads a centre left coalition, “and it is clear that a country, a government, cannot help taking into account the great value of human life and therefore must reflect deeply on this case.”

GPs to carry out routine follow-up of patients after surgery

Zosia Kmietowicz LONDON

Responsibility for carrying out routine check-ups of patients six weeks after surgery is to shift from consultants to GPs. The Department of Health estimates that the move will save the NHS in England £1.9bn (€2.8bn; $3.7bn) a year.

Dr Colin-Thomé told the BMJ that patients who develop complications such as pain or infections normally do so within six weeks and would see their GP rather than waiting to see a consultant at their routine six week follow-up appointment.

He said, “Many places around the world offer patients advice about when they should see their GP, and when they are given this many require no follow-up at all. In many parts of the country GPs are already making arrangements with surgeons locally about which patients should be followed up. But we are saying that this should become a general principle.”

Mayur Lakhani, chairman of the Royal College of General Practitioners, said that if the changes can be set up properly they should benefit doctors as well as patients.

“We should not see this as a tussle between GPs and surgeons but [as] the best outcome for patients and the best use of GPs’ and consultants’ time,” he said. “We can’t get away from the statistics which show that many follow-up appointments are unnecessary. Practice based commissioning could drive this change. But I don’t think this should be done in an unmanaged and unsupported way. One way forward would be for surgeons and GPs to agree locally which procedures would be followed up in primary care and for which follow-up is clinically important.”

The NHS in England provides 31.5 million check-up appointments in hospitals every year at a cost of £90 each.
Hepatitis C morbidity to double in next decade

Andrew Cole LONDON

The number of people facing death or serious liver disease from the bloodborne hepatitis C virus will double over the next decade, the UK Health Protection Agency has warned.

In its latest report on what it calls a “silent killer,” the health watchdog estimates that 230,000 adults in England and Wales are currently infected. Most of them still do not know they have the condition, which can cause cirrhosis and cancer of the liver if left untreated.

Helen Harris, an expert on hepatitis C at the agency, said the disease remained underdiagnosed simply because people were unaware they were carrying it. “By increasing awareness of the infection, more people will be tested, will receive earlier and more effective treatment, and they can avoid passing it on to others.”

The latest figures show the number of new diagnoses of the disease rose from 2,116 in 1996 to 7,580 in 2005. Hospital admissions, transplants, and deaths related to hepatitis C all increased steeply, and deaths from end stage liver disease rose from 76 in 1997-8 to 216 in 2004-5.

The agency predicts the number of people who go on to develop cirrhosis or serious liver failure will double in the next 10 years, rising from 4,855 in 2005 to more than 10,000 in 2015, of whom 2,540 will die without a transplant. The 2005 figure is itself a threefold increase compared with a decade earlier.

New MRSA strain is not at epidemic level

Owen Dyer LONDON

Despite two recent hospital outbreaks of bacteria that produce the Panton-Valentine leucocidin (PVL) toxin, Britain is not facing an epidemic of dangerous strains of *Staphylococcus aureus*, says the Health Protection Agency’s expert on methicillin resistant *S aureus* (MRSA).

Angela Kearns said that although incidence “waxes and wanes” over time, recent cases in England implicate at least three different strains. “While we are seeing an overarching PVL related pattern of disease here, we’re definitely not seeing an epidemic of a single strain.”

The latest outbreak, reported three days before Christmas, involved a neonatal unit at Norfolk and Norwich University Hospital. Six premature babies were affected by methicillin sensitive, PVL positive *S aureus*. One developed an active infection and has died; the hospital’s chief executive, Paul Forden, said that the bacterium “may have played a part in the death.”

The other five babies did not develop active infection and are now in isolation, undergoing treatment with antibiotics. A consultant microbiologist, Judith Richards, said they were doing well.

Until now only one death is believed to have been caused by an infection transmitted in hospital. That case involved a patient who died in March at the University Hospital of North Staffordshire in Stoke-on-Trent, from PVL positive MRSA. A nurse who died in September at the same hospital, Maribel Espada, is now known to have contracted the infection elsewhere, said Dr Kearns. She said, “Fourteen cases have been identified by the hospital this year, including two retrospectively identified just before Christmas.”

A previous outbreak of PVL positive *S aureus* affected 10 mothers and babies in the maternity unit of Derriford Hospital, Plymouth, in 2003. Those cases involved methicillin sensitive bacteria, though not the same strain as in the Norwich outbreak. At least 14 strains of PVL positive *S aureus* are known.

Less than 2% of *S aureus* bacteria produce the PVL toxin, which was first identified in the United Kingdom in the 1930s. Subsequent “look-back” research indicated that such bacteria date back to at least the beginning of the 20th century and are not a result of antibiotics used in humans. In the 1990s methicillin resistant strains began to emerge.

“It’s only recently that we’ve had tests with good sensitivity and specificity,” said Dr Kearns.
Outrage over death sentences in Libyan AIDS trial

Peter Moszynski LONDON

Last month’s reimposition of death sentences on six foreign medical workers for supposedly infecting hundreds of Libyan children with HIV has caused international condemnation and demands for their conviction to be overturned on appeal.

A Palestinian doctor and five Bulgarian nurses have been in detention since 1999. They were first sentenced to death in May 2004 after being convicted of deliberately infecting 426 children with HIV in Al Fateh Children’s Hospital, Benghazi.

On 25 December 2005 Libya’s Supreme Court ordered a retrial after noting “irregularities” in their interrogations, but the healthcare workers were again found guilty on 19 December 2006 and condemned to death, although their lawyers have filed a further appeal. Capital convictions are automatically referred to the Supreme Court for review, which could take at least a year. Death sentences can also be commuted in exchange for “blood money” paid to the victim’s relatives. There are currently diplomatic negotiations as to the level of compensation required.

The World Medical Association and International Council of Nurses condemned the convictions, blaming the outbreak on poor hospital hygiene. Their statement said, “The decision turns a blind eye to the science and evidence which points clearly to the fact that these children were infected well before the medical workers arrived at the hospital.

How many children will go on dying in Libyan hospitals while the government ignores the root of the problem?”

Amnesty International announced, “We deplore these sentences and urge the Libyan authorities to declare immediately that they will never be carried out. In this trial, as in their earlier one, confessions which they have repeatedly alleged were extracted from them under torture were used as evidence against them, while defence lawyers were not allowed to bring in international expertise and the evidence produced by Libyan medical experts was questioned by international medical experts.”

Tulio de Oliveira, lead author of a study published in Nature last month that used the genetic sequences of HIV and hepatitis C viruses to reconstruct the transmission history of the strains involved, told The BMJ that his team had been able to provide “direct molecular evidence that the outbreaks were under way before the accused medical staff began working in Libya,” but this and other relevant evidence had not been heard at the trial.

Dr de Oliveira cautioned, “The implications of this verdict extend far beyond the infected and accused in Libya. There are currently more than 24 million people infected with HIV/AIDS in Africa alone. Africa needs international medics to combat the HIV/AIDS epidemic. The scientific evidence needs to be heard in the case of these medics.”

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Dramatic drop in HIV infections halts circumcision trials

Bob Roehr WASHINGTON, DC

Men who are circumcised have about half the risk of acquiring HIV infection through vaginal intercourse as do men who are uncircumcised. Two randomised controlled trials in Uganda and Kenya, conducted with the support of the US National Institutes of Health (NIH), reached that conclusion during interim analysis by a data safety monitoring committee. The trials were stopped early, and the announcement came on 13 December.

The committee determined that the reduction in risk of acquiring HIV was 48% in Uganda and 33% in Kenya. The trials validate what was seen in a similar trial conducted in South Africa that was likewise stopped early when interim analysis in 2005 found that circumcision reduced female to male transmission of HIV by at least 60%.

All three trials enrolled adult volunteers who wanted to be circumcised and randomised them to undergo the procedure immediately or after two years. All participants were educated in safer sex practices and the use of condoms.

“These results indicate that adult male circumcision could be an important addition to an HIV prevention strategy for men,” said Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases at NIH.

“However, it is not completely protective and must be seen as a powerful addition to, not a replacement for, other HIV prevention methods.”

Circumcision removes the foreskin, which is rich in Langerhans cells, a type of cell that is particularly vulnerable to HIV infection, Dr Fauci explained. The procedure also changes the head of the penis from a mucosal surface, which the virus can easily enter, to a keratinised surface that offers a tougher barrier to infection.

The World Health Organization began to develop activities concerning male circumcision after results of the South African trial became known last year, said Kevin De Cock, director of WHO’s department of HIV and AIDS. WHO will offer guidance and training to countries that choose to make circumcision more widely available.
Holland bans private stem cell therapy

Tony Sheldon

The Dutch government has banned the “clinical application” of controversial stem cell therapy being offered by private clinics in the Netherlands for conditions such as amyotrophic lateral sclerosis and multiple sclerosis.

The ban has been imposed as part of a new regulation on the transplantation of stem cells governing the way in which they are used to regenerate different tissue and organs—for example, in the heart, liver, or kidneys.

The ministry of health describes such therapy as “promising,” with “possible applications” in the future for Parkinson’s disease, epilepsy, and amyotrophic lateral sclerosis. But it is concerned that “centres in the Netherlands are offering this form of treatment as if it is common practice” while it is in the early stages of development.

The ban, which came into force on 1 January, was imposed because of the therapy’s associated health risks and the lack of proved effectiveness. It affects two private clinics in particular—the Preventive Medical Clinic in Rotterdam and Cells4Health, registered near Zutphen.

Many British patients have been treated at the Preventive Medical Clinic in the past two years.

The clinic was temporarily ordered to stop stem cell therapy in October by the Dutch Healthcare Inspectorate after a British patient became seriously ill after treatment (BMJ 2006;333:770).

The Dutch health minister, Hans Hoogervorst, wrote to MPs, saying that present commercial stem cell therapy can endanger patients’ health and that he shares the opinion of senior clinicians that it amounts to “dangerous quackery.”

The new regulation cites a report published in May by Rotterdam University’s Erasmus Medical Centre and the Institute for Medical Technology Assessment, which concluded that most stem cell therapy research was still in a preclinical stage.

An appendix to the regulation emphasises that the differentiation of stem cells demands special expertise to prevent spontaneous growth or unstable or incorrect differentiation.

In future, therefore, a licence will be required for stem cell transplantation.

Simplify patient incident reporting, says CMO

Zosia Kmietowicz

Liam Donaldson, the chief medical officer for England, has ordered a shake-up of the services responsible for patient safety, demanding that “more needs to be done to accelerate the pace of change in this area.”

A national forum will be at the heart of the new plans, which are detailed in a report commissioned by Professor Donaldson and published in December. The forum is designed to bring together key agencies responsible for patient safety to facilitate learning, share best practice, and coordinate delivery. It will be chaired by Professor Donaldson and David Nicholson, the NHS’s chief executive, and will convene for the first time early in January.

“Although the vast majority of NHS patients receive safe and effective care, we have to recognise that in our modern, increasingly complex health service that treats one million patients every 36 hours, mistakes can and will inevitably happen. Often it is systems that have failed, rather than any individual being at fault,” Professor Donaldson said.

The report, Safety First: a Report for Patients, Clinicians, and Healthcare Managers, looked at organisational arrangements that support patient safety in the NHS. It points out that, from 2008, all levels of the NHS need to consider patient safety as a priority and ensure that national priorities take explicit account of patient safety. Systems for reporting incidents also need to be made easier and quicker for staff to use, it adds.

The report recommends that the National Patient Safety Agency refocusses its objectives and concentrates on collecting and analysing patient safety information through its national reporting and learning system. The system needs to be simplified, says the report, so that incidents involving serious harm to patients are reported within 36 hours, as well as “near misses.”

The agency was criticised in July by the public spending watchdog, the Public Accounts Committee, for not knowing how many patients die each year from medical errors (BMJ 2006;333:59). Shortly afterwards, the joint chief executives of the agency, Sue Osborne and Susan Williams, were sent on extended leave pending an inquiry into their managerial record (BMJ 2006;333:318). They remain on extended leave.

Among the report’s other recommendations were a national campaign to engage clinical staff in tackling patient safety; the establishment of patient safety action teams at local level to provide support to frontline staff; more involvement of patients and their families in promoting patient safety; and greater support to patients when things go wrong.

Andy Burnham, a health minister, said, “Making changes to how the current reporting system works will make it easier for staff to report serious incidents quickly.” The report is at www.dh.gov.uk.