NICE faces legal challenge over restriction on dementia drugs

Clare Dyer *legal correspondent, BMJ*

The National Institute for Health and Clinical Excellence (NICE), the body that decides what treatments are supplied on the NHS in England and Wales, is facing a High Court challenge to its decision to restrict the use of drugs for Alzheimer's disease.

NICE rejected an appeal by drug companies in October over its guidance stating that patients with early or late stage Alzheimer's disease should not have access to donepezil (Aricept), galantamine (Reminyl), or rivastigmine (Exelon) (*BMJ* 2006;333:165).

The US drug company Pfizer and a Japanese biotechnology company, Eisai, announced last week that they would seek a judicial review of the process NICE followed in making its decision. The British company Shire later said it would join the legal challenge as an interested party.

Eisai, the licence holder of donepezil, and Pfizer, its co-promotion partner, said a letter had gone to NICE saying that the companies planned to apply for a judicial review. NICE, which has never before faced such a challenge, has 14 days to respond, after which the companies will have to get the court's permission to launch the proceedings.

Assuming they get the go ahead, which is likely, the companies' lawyers expect the case to reach court by late January or early February 2007.

The companies said they believed the decision making process was "unfair" because NICE had repeatedly refused to disclose "a fully working version of the cost effectiveness model used to determine the value of treatment in patients with mild Alzheimer's disease."

Also, they argue, many of the conclusions in NICE's final guidance "cannot be supported legally, or are irrational."

Olivier Brandicourt, managing director of Pfizer UK, said: "By denying consultees the opportunity to check the accuracy of their economic analyses, NICE has left no option but to proceed in this way to ensure that patients with Alzheimer's disease are protected from failures in process."

News of the legal challenge was welcomed by the Alzheimer's Society, which organised more than 30 protests against NICE's decision across England and Wales last week.

NICE's chief executive, Andrew Dillon, said: "We will respond to Eisai's letter and act appropriately in any court proceedings which may follow." □

NICE emphasises social care for people with dementia

Michael Day *London*

Joint health and social care guidelines have been published aimed at integrating the care of the 700 000 people in England and Wales with dementia and their carers.

The guidance by the National Institute for Health and Clinical Excellence (NICE) and its social services equivalent, the Social Care Institute for Excellence (SCIE), aims to boost services that are currently dogged by lack of coordination between hospitals and community care.

Andrew Dillon, the chief executive of NICE, said the guidelines, which were the first his organisation had produced with the social care group, "demonstrated the real importance of health and social care professionals working closely together."

The guidance, which covers the full range of medical, psychological, and social treatment, recommends that memory assessment services should be the single point of reference for all people with a possible diagnosis of dementia. It also says that people with dementia must not be excluded from any recommended services because of age or learning disability. In addition, £20m (€30m; $40m) should be set aside for the psychological support of carers.

Tim Kendall, a consultant psychiatrist and the joint director of the National Collaborating Centre for Mental Health, said: "I think this guideline … will lead to huge improvements in dementia care throughout England and Wales."

However, the guidelines also include NICE's controversial ruling that excludes more than 50 000 patients with Alzheimer's disease from NHS treatment with cholinesterase inhibitors.

Patients' groups and professional associations reacted with fury last month when NICE announced that it would not relax its ruling on the drugs for people with mild or advanced disease (*BMJ* 2006;333:774).

As a result, from this week patients with a new diagnosis of Alzheimer's disease will be able to get the drugs through the NHS only if they have moderate disease.

Mr Dillon denied that the timing of the new joint guidelines for patients with all types of dementia was designed to deflect attention away from the ban. □

MARK THOMAS

Andrew Dillon, chief executive of NICE (right), and Tim Kendall (left), joint director of the National Collaborating Centre for Mental Health, present the guidelines to the press

Dementia: Supporting People with Dementia and their Carers in Health and Social Care is at www.nice.org.uk/cG042.

The full version of this article is available at bmj.com.

In brief

Three quarters of AIDs deaths occur in sub-Saharan Africa: Sub-Saharan Africa still bears the brunt of the HIV and AIDS pandemic, says a report from the joint United Nations agency for HIV and AIDS. UNAIDs says that almost two thirds of new infections in 2006 occurred there, but the areas with the most striking recent increases were East Asia, Central Asia, and Eastern Europe. About 40 million people worldwide are now HIV positive. See www.unaids.org.

Gynaecologist faces bill for unplanned child: Germany's Federal Court has decided that a gynaecologist must for 18 years pay monthly compensation of €600 (£410; $770) to an unmarried woman who conceived a child because of the faulty implantation of a contraceptive device.

UK regulator cracks down on junk food advertising: Television advertisements for food containing high proportions of fat, salt, and sugar will be banned completely on children's channels and during children's programmes under rules put forward by the regulator, Ofcom. The ban will also apply to adult programmes watched by large numbers of children.

US appoints antiabortionist to top family planning post: Dr Eric Keroack, who advocates abstinence until marriage and heads five centres in Massachusetts that use ultrasound images to dissuade women from abortion, has been appointed US deputy assistant secretary for health and human services. He will supervise programmes on teenage pregnancy and family planning.

GPs may boycott NHS database: Half of all GPs in England will consider refusing to put patients' records automatically on a new national database, because of fears over the security of the system, a poll of 1026 GPs and hospital doctors has found. The electronic database, known as the spine, is part of the £12bn (€18bn; $23bn) upgrade of the NHS computer system (*Guardian* 21 Nov, p 1).

NHS employs too many hospital doctors, health secretary says

Lynn Eaton *London*

The NHS is employing far more hospital doctors than it should be, the health secretary for England, Patricia Hewitt, has told the parliamentary select committee on health.

Staffing levels were above what had been proposed in the NHS workforce plans, she said at a hearing this week on deficits in the NHS.

The Department of Health had estimated that the number of hospital doctors employed by 2007 in England should be 74 590.

"Already the NHS has employed more hospital doctors than it was intended to by 2007," she said.

"In fact, by 2004 the NHS employed 78 000 hospital doctors, and by 2005 [the number] had risen to 82 000."

The NHS had spent more of its money for growth on extra staffing than had been planned and had taken on "significantly more" hospital doctors and nurses and "somewhat more" GPs than had been intended. This was happening even in trusts that were heading for deficit, she said.

"That's why [trusts] are having to make very difficult decisions in some cases to get to a position where they employ the right number of staff that they can afford. That's clearly a reason why some organisations are in real financial problems."

Ms Hewitt said some NHS trusts were failing to adopt new approaches to delivering care—such as using day surgery—that would enable them to treat more patients with fewer doctors than traditionally needed.

She referred to the deficit at the Royal Cornwall Hospital, which despite its financial crisis took on an extra 250 staff last year. She said, "They could not afford them, and now they are in a position of having to consider redundancies." The amount of day case surgery there was below the average for England, although using it would enable the hospital to use fewer staff, she said.

The Labour MP Sandra Gidley said it seemed that NHS staff were being hit because the focus of reform had moved away from reducing waiting lists and was now on finance.

And members of the Health Select Committee found it hard to understand how the situation could have got so out of control. Ms Hewitt said the health department did not run the NHS "Soviet style," with central control. "The recruitment is down to individual hospital trusts and PCTs [primary care trusts]." □

The full version of this article is available at bmj.com.

More than one antiviral should be stockpiled to fight pandemic

Oona Mashta *London*

CHRIS RADBURN/PA-EMPICS

Experts recommend the government stockpiles zanamivir (Relenza) as well as oseltamivir (Tamiflu)

The UK government is ill prepared to cope with a flu pandemic, warns a report from the Royal Society and the Academy of Medical Sciences. It says this is because of its lack of consultation with independent experts in the field.

The report recommends that the Department of Health urgently reconsider its decision to stockpile only one antiviral drug, oseltamivir (Tamiflu), in light of emerging scientific evidence that the H5N1 strain of the avian influenza virus can develop resistance to this drug. It says that stockpiling the alternative antiviral zanamivir (Relenza), alongside oseltamivir, could provide an important second line of defence in the event of a pandemic.

John Skehel, chairman of the report's working group, said: "We are concerned that decisions are being made—as the UK prepares for a possible pandemic—that fail to take account of expert advice. For example, the decision to continue to stockpile just one antiviral drug is a major concern. This needs to be reconsidered. New evidence that H5N1 can develop resistance to Tamiflu indicates that a combination of antivirals should be stockpiled by the UK for the most effective management of a pandemic."

The government's most recent flu pandemic contingency plan was published in October 2005 and is currently under revision. It is expected to be republished in 2007.

The report also calls for a leading independent flu specialist to be appointed as an adviser to the government to help plan for a pandemic.

And it calls on the government to work more with industry on vaccine production. The report says that it would not be possible to make enough supplies of flu vaccine globally in a pandemic. But limited vaccine supplies can be combined with compounds known as adjuvants to increase their effectiveness. □

Pandemic Influenza: Science to Policy is accessible at www.royalsoc.ac.uk.

The full version of this article is available at bmj.com.

Experts defend NICE against attack by US politician

Zosia Kmietowicz *London*

Commentators have defended the work of the National Institute for Health and Clinical Excellence (NICE) after a newspaper claimed that the White House was backing large drug companies in their efforts to have unrestricted access to the NHS as part of a free market.

The US deputy secretary for health, Alex Azar, who met officials in London last week, said that mechanisms such those of NICE for rationing drugs to keep costs down stifle innovation, the article in the *Guardian* reported (14 Nov, p 1). Allowing all new drugs to be used in the NHS would result in drug companies "fighting it out" on price, he said, which would cut drug costs.

The drug companies have themselves repeatedly lobbied ministers for NICE to be reformed and to allow their drugs to be made available on the NHS more quickly.

In his interview with the *Guardian* Mr Azar said he recognised that healthcare costs in rich nations were rising while budgets were shrinking as the population aged. "On the other side we have to focus on long-term innovation," he said.

"How are we making sure that we don't take steps on cost containment that are short-sighted and prevent the investment in long-term biomedical research and development and innovation?"

Charles Medawar, director of Social Audit, an independent health consumer lobby group, described the attack on NICE as "absolutely typical behaviour for the United States."

"It is extremely disruptive," he said. "The whole emphasis behind this initiative [NICE] is that new drugs are in themselves welcome, but there needs to be an effort to distinguish between them on grounds of effectiveness."

Chris Ham, professor of heath policy and management at the University of Birmingham, said he was not surprised by pressure from the US. "It is entirely to be expected. A lot of pharmaceutical companies have been frustrated at what they see as delays and barriers to getting their drugs approved for use on the NHS," he said. "One hopes that the UK government will be robust in its response."

Ike Iheanacho, editor of the *Drug and Therapeutics Bulletin*, said that Mr Azar's suggestion that NICE stifles innovation in the pharmaceutical industry is "at best questionable and at worst laughable."

ROGELIO SOLIS/EMPICS

Alex Azar, US deputy secretary for health, said all new drugs should be allowed in the NHS

He said, "A lot of the arguments are that if drug companies were to get unfettered access to the NHS and to patients that would drive down the drugs bill. If it was so simple, why has this not happened before? NICE has only been in existence for six years, and before then we had spiralling drug costs."

Dr Iheanacho also challenged the use of the word "innovation" in relation to the development of new pharmaceutical compounds. Many new drugs are just that, he said: new but not necessarily innovative.

"The kind of activity that consumes a lot of drug companies' time and effort is making minor modifications to drugs that are coming off patent, and it is questionable whether these new products really offer any compelling advantages to patients," he said.

"Whether one agrees or disagrees with individual decisions that NICE makes, most commentators agree that a system is needed to decide which drugs should be available on the NHS, and to get rid of it would be a retrograde step."

The *Guardian* article quoted Mr Azar as saying that he had "some great discussions" with Patricia Hewitt, the health secretary for England, when she visited the US two weeks ago. He also said he supported direct advertising of drugs to patients, something permitted in the US but banned throughout Europe.

A spokesman for the US Department of Health and Human Services said the purpose of Mr Azar's trip was to share experiences of the US health service and not to try to influence politicians to change national policies. □

The full version of this article is available at bmj.com.

Germany's drug regulatory body is attacked

Annette Tuffs *Heidelberg*

The independent institute that assesses new drugs in Germany is facing criticisms similar to those aimed at its equivalent body in the United Kingdom, the National Institute for Health and Clinical Excellence.

Last week in Cologne a member of an association for people with diabetes and representatives of the drug industry walked out of a hearing of the Institute for Quality and Economic Efficiency in Health Care in Cologne because they were not allowed to record the hearing, which was on the use of short acting insulin analogues.

The institute has provoked anger among patients' groups and the drug industry by saying that no evidence has been shown that short acting insulin analogues had any advantage over human insulin (*BMJ* 2006;332:874).

After the walk-out drug firms accused the institute, which was founded in 2004, of insufficient transparency. The institute's director, Peter Sawicki, said that its rules did not allow participants to record hearings and that this had always been the case.

Tension between the drug industry and the institute has grown since the German government proposed expanding the institute's role, so that it will no longer consider only the clinical effectiveness of new drugs but also their cost effectiveness. The proposal is part of the government's package of reforms currently before parliament (*BMJ* 2006;333:720, 7 Oct).

The institute's evidence based evaluations will become the basis for decisions by the federal joint committee of doctors, health insurance companies, and patients' representatives that decides which treatments will be reimbursed by the state health insurance companies. Under the new reforms this committee will include independent members as well as representatives of doctors and health insurance companies chosen by the health ministry.

"For the analysis of the cost effectiveness of treatments we will use internationally accepted methods, just as we do for looking at the scientific evidence," said Professor Sawicki.

Before his institute can carry out any analysis, however, the government will have to decide what costs are to be taken into account when weighing up a drug's cost effectiveness—whether it is the costs to the health insurance companies, the health system, or the social security systems.

Dr Sawicki said that a public debate is needed involving the federal ethics committee and other institutions to consider the use of monetary equivalents of measures of clinical effectiveness such as survival and number of quality adjusted life years.

The institute's work is also under pressure because of difficulties in recruiting experts. Each project is advertised on the institute's homepage (www.iqwig.de), and renowned experts are also directly asked to apply. "However, experts have to be familiar with the methods of evidence based medicine, and this is not so common in Germany," said Professor Sawicki. □

The full version of this article is available at bmj.com.

bmj.com news roundup

Full versions of these stories are available at: **bmj.com/content/vol333/issue7578/#NEWS_ROUNDUP**

Guide tells editors how to root out plagiarism and fraud

Editors from some of the leading international biomedical and scientific journals—including the editor of the *BMJ*—have joined forces to produce a guide to rooting out poor and unethical practice in science publishing.

The Committee on Publication Ethics has published a practical, step by step guide for journal editors, with 14 flow charts that give straightforward advice on what to do when facing certain publishing dilemmas.

The flow charts include advice on what editors should do if they suspect plagiarism, fabricated information, or redundant or previously published data. They also cover how to deal with requests for changes in authorship, suspected undisclosed interests, and ethical issues.

"There is nothing else like these flow charts," said Elizabeth Wager, author of the flow charts and a publications consultant. "Current ethical guidelines for scientific and biomedical editors tend to be expressed in abstract terms. We have translated the theory into something really practical."

Lynn Eaton *London*

The flow charts are available at www.publicationethics.org.uk/media.

European nations draw up strategy to fight obesity

European governments have identified obesity as one of today's most serious public health challenges. The need to tackle the epidemic has been recognised by the 48 members of the World Health Organization's European region.

At a WHO ministerial conference in Istanbul last week they all signed a special charter acknowledging the scale of the problem and presenting a strategy to tackle it.

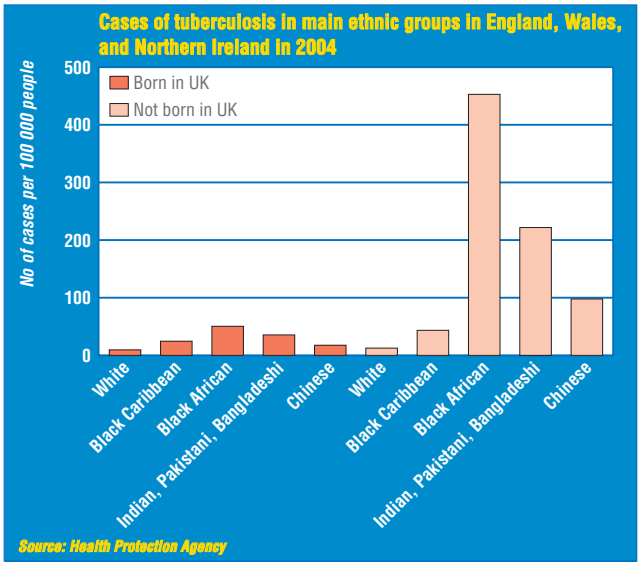
The prevalence of obesity in Europe has tripled in the past two decades. Half of all adults and one in five children in the WHO's European region are overweight. Of these a third are obese.

It is estimated that excess body weight is responsible for more than a million deaths a year in the region and that by 2010 one in 10 of its children will be obese.

The five page charter sets a target of making visible progress towards reducing the prevalence of obesity among children and adolescents over the next four to five years and reversing the trend by 2015 at the latest.

(See editorial, p 1081.)

Rory Watson *Brussels*



Report on health of migrants to UK shows high risk of TB and HIV

Nearly three quarters of cases of tuberculosis and HIV reported in England, Wales, and Northern Ireland in 2004 were in people born outside the United Kingdom. This is the finding of a report on infectious diseases among migrants published by the UK Health Protection Agency.

Most of the newly recorded cases of chronic hepatitis B in England and Wales were also in people not born in the UK.

Jane Jones, a consultant epidemiologist and head of the travel and migrant health section of the Health Protection Agency's Centre for Infections and one of the report's authors, said: "Migrants clearly have a disproportionate burden of infectious diseases."

However, she added, "This must be seen in context: most migrants do not have these diseases. Most are healthy young adults who have come to the UK mainly to work or study."

Susan Mayor *London*

Migrant Health: Infectious Diseases in Non-UK Born Populations in England, Wales and Northern Ireland. A Baseline Report—2006 is accessible at www.hpa.org.uk.

WHO report highlights Africa's health challenges

Africa will never climb out of poverty unless its devastating health challenges are tackled, says the World Health Organization's first African regional health report.

The continent faces a "silent epidemic" of maternal and child mortality, it says. Of the 20 countries with the highest maternal mortality ratios in the world 19 are in Africa. Africa also has the highest neonatal death rate in the world.

AIDS continues to decimate the population of Africa, which has 11% of the global population but 60% of the world's people infected with HIV. More than 90% of the 300-500 million cases of malaria in the world each year are in Africa, mainly in children aged under 5 years.

One key reason for Africa's health problems is that basic sanitation needs remain largely unmet, says the report: "Only 58% of people living in sub-Saharan Africa have access to safe water supplies."

Peter Moszynski *London*

The Health of the People: The African Regional Health Report is available at www.who.int.

Charity highlights decline in health in Gaza

A survey of patients in hospitals and clinics throughout the Gaza strip has indicated that public health is suffering as a result of the combined effects of military incursions and the embargo on international aid.

Conditions in Gaza, one of the world's most densely populated areas, have deteriorated sharply since April, when the electoral victory of Hamas led foreign governments to suspend aid to the Palestinian Authority.

A survey conducted by the aid charity Médecins du Monde in June highlighted widespread poverty, growing mental health problems, and a rising prevalence of diarrhoea among children.

The charity called on Israeli authorities to open the border crossings at Karni and Erez, on the border with Israel, and Rafah, on the border with Egypt, to allow passage of food and medical supplies.

A spokesman for Israel's foreign ministry said: "I have figures showing that between 1 November and 11 November, 1480 lorries crossed at Karni, including 12 carrying medical supplies, while 1647 crossed at Sufa, including two with medical supplies."

Owen Dyer *London*

The survey can be seen at www.medecinsdumonde.org.

US television science news can be public relations in disguise

The science news that is broadcast by US television stations is sometimes not genuine reporting by a science journalist who works for the television station or the network. Instead it is prepared by a public relations firm for corporate or government clients, says a report from the non-profit making Center for Media and Democracy.

Video news releases are designed to look like news reports, but they present the point of view of the sponsor.

This month's report is a follow-up to a document that the centre issued in April, entitled *Fake News* (www.prwatch.org/fakenews/execsummary), which says that US television stations often do not divulge the source of prepackaged video information and broadcast it as news (*BMJ* 2006;332:919).

The report in April named 77 US television stations that had used at least one of 36 video news reports that the centre had tracked over a 10 month period.

The video news reports were prepared for corporate clients such as Pfizer, Exxon Mobil, General Motors, Intel, Siemens, General Mills, and Capital One, and also for the American College of Physicians and the American Dental Association.

Janice Hopkins Tanne *New York*

Rate of syphilis in UK rises as HIV holds steady

The number of new diagnoses of HIV in the United Kingdom last year was close to the 2004 figure, says a report from the Health Protection Agency, but the number of new cases of syphilis rose by 23% (from 2282 to 2816). The number of new cases of HIV was 7450 in 2005 and 7492 in 2004.

In 2005 an estimated 63 500 adults in the UK were HIV positive, and altogether almost 800 000 diagnoses of acute sexually transmitted infections were made.

The report found that rates of infection of genital chlamydia, genital herpes, and genital warts (caused by the human papillomavirus) were still high. Gonorrhoea was the only disease that showed improvement: the number of new diagnoses fell by 13% from 2004 to 2005, continuing a trend first seen in 2002.

Almost two thirds of all new cases of HIV in 2005 were diagnosed in people from ethnic minorities; and the number of new diagnoses reported among men who have sex with men was higher than ever before.

Claire Frauenfelder *BMJ*

A Complex Picture is available at www.hpa.org.uk.

Judge over-rules family's wish that patient should be allowed to die

England's senior family judge has ruled that a woman in a persistent vegetative state (PVS) should be given a sleeping pill that has been reported to temporarily wake up PVS patients, despite the wishes of her family that she should be allowed to die with dignity.

Mark Potter, president of the High Court's family division, backed the official solicitor, acting for the 53 year old woman, who argued that the drug zolpidem should be given a brief trial before a final decision was made to discontinue artificial nutrition and hydration.

The woman, who cannot be named, is in a PVS after she had had a brain haemorrhage in August 2003 while on holiday with her family.

The official solicitor took expert advice after reading reports of cases where patients in a PVS temporarily woke up and in some cases spoke after being given zolpidem.

The woman's family were against the move because they thought it would be in her best interests to be allowed to die rather than to live with severe disabilities and to be aware of her condition.

Clare Dyer *legal correspondent, BMJ*

WHO is to change its polio eradication programme in India

Claire Frauenfelder *BMJ*

The World Health Organization is to change its polio eradication programme in India, adding a monovalent oral vaccine to the existing regimen, says a study published in *Science* last week. It is hoped that this addition will finally rid the country of the disease.

The study's key finding was that poor sanitation and overcrowding produce an ideal environment for the virus in some regions in India (*Science* 2006;310:625-6). The poor health of impoverished children also limits the effectiveness of the trivalent vaccine that has been the mainstay of WHO's eradication programme in India, said Bruce Aylward, director of WHO's global polio eradication initiative.

Data analysed in the report showed that the northeastern Indian states of Uttar Pradesh and Bihar are the problematic areas. The authors pointed out that these same areas were the last in Asia to see smallpox in the final stages of its eradication programme.

The conditions described in the report produce "disease reservoirs where transmission persists throughout all seasons," said Christophe Fraser, one of the report's authors. In these reservoirs the otherwise successful trivalent vaccine has had "very, very poor efficacy."

Dr Aylward said that the monovalent vaccine for type 1 poliovirus works twice as fast as the trivalent vaccine to build immunity and is effective in more children. The trivalent vaccine targets all three serotypes of polio but is slower to become effective.

The type 1 virus is responsible for most of the disease in India, the report says. Consequently "the government is able to respond with monovalent vaccine to directly target the type 1 viral strain," explained another of the report's coauthors, Nicholas Grassly. He said that type 2 was successfully eradicated in India and hasn't been seen there since 1997, while type 3 accounts for few cases of polio in India.

The authors commended WHO and the government of India for "opening the programme up to outside scrutiny" and taking into account the results of the report.

The programme came very close to completely eradicating polio in 2002, but Dr Aylward said that "cutbacks of vaccination in disease-free areas due to funding difficulty led to the increase in cases," highlighting the importance of maintaining immunity in all areas, not just the worst affected regions.

Describing eradication strategies as "the venture capital of public health," Dr Aylward said that current funding levels were high but could not be sustained for much longer.

Margaret Chan's support of the programme, outlined in her first speech as WHO's director general, is a positive sign that "finishing off polio" is high on WHO's agenda, said Dr Aylward. The push to finally eradicate the disease in India will be the focus of the programme in the first half of 2007, he said.

Children in high risk areas in India will continue to receive the trivalent vaccine and will be given an additional dose of oral monovalent vaccine for type 1 virus, Dr Aylward said. The vaccination will be repeated every eight weeks, up to eight times. He also explained that very young children will receive extra vaccinations between these doses. □

The full version of this article is available at bmj.com.

P.VIROT/WHO

Third time lucky?

The government is planning its third attempt to change mental health law in England and Wales, but the concerns of professional and legal groups about civil liberties and the rights of mentally ill people remain

The government is steeling itself for a struggle to push through controversial reforms to mental health legislation in England and Wales. The plans, unveiled last week in the Queen's speech, are strongly opposed by mental health and legal organisations, opposition parties, and many of the government's own backbench MPs.

The Mental Health Bill, which will allow preventive detention of people with dangerous and severe personality disorders and compulsory treatment in the community, is the government's third attempt to get such legislation passed. Two previous tries to replace the existing Mental Health Act 1983 with a new act were dropped in the face of opposition.

Andy Bell, chairman of the Mental Health Alliance, which embraces 78 organisations and charities, declared the bill "flawed" and said that campaigners would be "profoundly disappointed."

He said, "The legislation falls far short of what is needed and does not truly reflect the needs of those who have to live and work with it. It introduces new powers for services without the necessary safeguards for patients."

Reform of the law concerning treatment of patients who are a danger to themselves or others has been under consideration since 1998. Concern was triggered by the case of Michael Stone, who was convicted that year for the murder of Lin Russell and her daughter Megan. He was considered to have a dangerous and severe personality disorder and to be untreatable under the 1983 act's criteria for detention, although a later inquiry showed that psychiatrists were divided about his diagnosis.

The bill will apply to anyone with "any disorder or disability of the mind" who needs to be detained for his or her own health or safety or the protection of others and will abolish the "treatability" test for detention: that the treatment given under detention should be "likely to alleviate or prevent a deterioration" in the patient's condition. Instead the bill simply requires that "appropriate medical treatment" be available for the patient. This includes "nursing, psychological intervention, and specialist mental health habilitation, rehabilitation and care."

Explanatory notes to the bill say that this could include counselling and services designed to improve patients' social functioning.

Another controversial provision creates a new regimen of supervised community treatment to alleviate the problem of "revolving door" patients—those released from hospital who fail to take their drugs, relapse, and have to be sectioned again to be readmitted. The new provision would apply to patients released from detention in hospital whose mental health problem makes them a risk to themselves or others. An appropriate package of support and treatment would have to be put in place before the patient was released.

Patients undergoing supervised community treatment who fail to comply with the conditions of release will not be forced to take treatment in the community without their consent but could be recalled to hospital for treatment without being sectioned again. Doctors would not have to wait until they relapsed but could readmit them much earlier, if they stopped taking their drugs or flouted other conditions.

The bill also closes the "Bournewood gap": the lack of protection for patients who lack capacity to consent but are admitted to hospitals or care homes in their own best interests.

The move follows a 2004 ruling from the European Court of Human Rights in Strasbourg that an autistic man's right to liberty was breached when doctors invoked the common law doctrine of necessity to admit him to Bournewood Hospital in Chertsey, Surrey, against the wishes of his carers, and to keep him there for four months.

A new provision amending the Mental Capacity Act—a law that is not due to come into force until April 2007—introduces safeguards for these patients, most of whom have dementia or serious learning disabilities.

The Mental Health Bill requires admission to be authorised by a supervisory body—in England the local authority (for care homes) or the primary care trust (for hospitals) and in Wales the Welsh Assembly—and allows for the decision to be challenged in the Court of Protection.

The bill was published a day after a report found that the murder of a man in Richmond Park in London by a paranoid schizophrenic man with a known history of violence could have been avoided. The inquiry into John Barrett's care and treatment found that serious failures by a mental health trust had allowed him to walk out of a secure unit.

However, the report said that the remedy "lies not in new laws or policy changes" but in "sound clinical practice and organisational management." Mental health groups said that the report could not therefore be considered as ammunition in the government's struggle to change the law.

Supporting the proposed changes, Louis Appleby, England's national director for mental health, said of the new treatability test: "It's still essential that care has a therapeutic purpose, but you don't have to say that recovery is expected."

But Sheila Hollins, president of the Royal College of Psychiatrists, said the college was "particularly concerned that any compulsory treatment should have a clear clinical purpose and be of benefit to the patient."

The Mental Health Alliance vowed to continue campaigning for legislation that ensured that:

- All treatment under compulsion benefited the health of the patient
- Community treatment orders were limited to a small number of people who really needed them and did not impose unnecessary conditions
- Everyone sectioned under the act was given the right to an advocate, and
- Patients and carers were given the right to an assessment when they asked for it, before a crisis point was reached.

The Law Society said its main concern was that "the legislation fails to uphold the human rights of patients and provide access for care for people with mental illness, with compulsory treatment used only as a last resort."

Tony Calland, chairman of the BMA's medical ethics committee, said: "It is essential that anyone with a mental health disorder can only be compulsorily treated if there is some clear health benefit linked to this action. Mental health legislation cannot be used to detain people whom the authorities simply want locked away. If people are deemed a danger to others then criminal proceedings need to be implemented, if appropriate." □

Clare Dyer *legal correspondent, BMJ*

METROPOLITAN POLICE/PAEMPICS

The government's Mental Health Bill is designed to protect the public from murders like that committed by John Barrett, seen here being arrested in Richmond Park, who killed after walking out of a secure unit