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NEWS

NICE recommends minimum price for alcohol and advertising ban to curb high risk drinking

Zosia Kmietowicz LONDON

The government should consider increasing the price of alcohol, making it more difficult to buy, and banning advertising if it wants to create a sensible drinking culture, the National Institute for Health and Clinical Excellence (NICE) has said.

In its evidence based guidance on preventing harmful drinking, NICE recommends a minimum price per unit of alcohol, which, it says, should be regularly reviewed so that alcohol does not become more affordable over time. It also says limits should be put on how much alcohol people can import from abroad, the number of outlets selling alcohol in a given area, and the days and hours that alcohol can be purchased.

Health professionals are also being asked to question routinely their teenage and adult patients about how much they drink to identify those who are drinking too much.

Mike Kelly, director of public health at NICE said: “It is NICE’s job to improve the health of the population, and there is no doubt that if these measures are taken forward, they will significantly decrease alcohol consumption and thereby offset some of the serious social, economic, and physical health problems that arise as a consequence of drinking too much.”

Around one in four adults in England are currently drinking dangerous amounts of alcohol. Alcohol costs the NHS £2.7bn (£3.1bn; \$3.9bn) a year and causes 17 million days of sick leave



The number of shops selling alcohol in a given area should be restricted and limits put on imports

a year and half a million crimes. It was also responsible for nearly 15 000 deaths in 2005.

Anne Ludbrook, guidance developer and a health economist, said: “There is a strong body of evidence from around the world to show that making alcohol less affordable will reduce its consumption. This will in turn, improve the overall health of the population.”

“NICE’s recommendation to introduce a minimum price per alcohol unit is a very targeted measure as it is most likely to affect heavy drinkers who typically purchase

‘cheaper’ alcohol products,” she added.

In separate guidance NICE said that the NHS needed to improve its treatment of health problems caused by alcohol misuse.

Among the recommendations NICE advises that heavy drinkers at risk of seizures and delirium tremens should be admitted to hospital and assessed by an experienced health care professional.

The guidance is at www.nice.org.uk/PH24, and www.nice.org.uk/CG100.

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JEFF MORGAN/LAMY

NHS Confederation chief quits over concerns about financial stability

Mark Gould LONDON

Steve Barnett has resigned as chief executive of the NHS Confederation amid concerns about the financial stability and ambitions of the body and its subsidiary NHS Employers.

Mr Barnett was appointed to head up the NHS Confederation, the body that represents NHS organisations, in February after 10 months as acting chief executive.

The Department of Health—whose

contracts provide nearly all the income for NHS Employers, which represents trusts on workforce issues, and around half of the confederation’s income—has asked for reassurance about the organisation’s governance and financial stability.

Offering his resignation, Mr Barnett said that he could not and should not accept responsibility for the “actions or omissions of others,” but added, “I have never shied away from or

attempted to dispute the fact that accountability for oversight should properly rest with me.”

Mr Barnett was referring to the collapse of NHS Employers’ plan to offer human resources services to NHS trusts. The scheme, in which NHS Employers had invested some £3.4 million (£4 million; \$4.9 million), offered criminal record checks and 24 hour human resources support to trusts for £35 000 a year. Access to the

NHS Jobs website was to have been provided free of charge.

But this plan was dropped in March after it was revealed that just 17 trusts had signed up and that it was decided NHS Jobs should be put out to tender. The Department of Health was also concerned about a possible conflict of interest given NHS Employers’ national role in negotiating employment contracts with trade unions.

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IN BRIEF

Why US doctors don't perform abortions: A US study has found that doctors trained to provide abortions do not do so because of formal or informal policies of their private group practices, employers, and hospitals (www.guttmacher.org). Some restrictions had not been made clear when the doctors sought employment, and some of them found that their agreements with their practices prohibited them from providing abortions in other settings.

One in five Europeans have quit smoking: Almost a third (29%) of European citizens smoke; 49% have never smoked; and 22% have given up tobacco, says a new Eurobarometer survey for the European Commission. Across the 27 member EU, 38% of respondents allow smoking in the home and 16% in the family car. Around a quarter of citizens are exposed to tobacco smoke at work.

Dutch call for public debate on who should be able to help elderly die:

A campaign to change Dutch law to allow people other than doctors to help elderly people commit suicide has handed in a 116871 signature petition to parliament, almost three times the number needed to trigger a parliamentary debate under a "citizens' initiative" law. The action was timed to come just before the general election on 9 June (*BMJ* 2010;340:c1045).

Donaldson joins patient safety agency: Professor Liam Donaldson, who stepped down as chief medical officer for England at the end of May, has been appointed chairman of National Patient Safety Agency. "Quality and safety of health care has been a passion of mine for over 25 years," he said.

Men's skin cancer deaths have doubled in 30 years: Figures from Cancer Research UK show that rates of death from malignant melanoma in men have doubled over the past 30 years. More than 1100 (3.1/100000) men died from the disease in 2008 compared with fewer than 400 (1.5/100000) in 1979, says the charity. Death rates in men over 65 have more than trebled during this time.

Mexico overturns rape abortion ban: Mexico's Supreme Court has ruled that rape victims can get emergency contraception and abortions, overturning laws banning abortion in any circumstances. The decision "affirms women's rights to health and life by enabling rape victims to avoid forced pregnancies," says Human Rights Watch.

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Judge rules that cancer patient should have lifesaving surgery

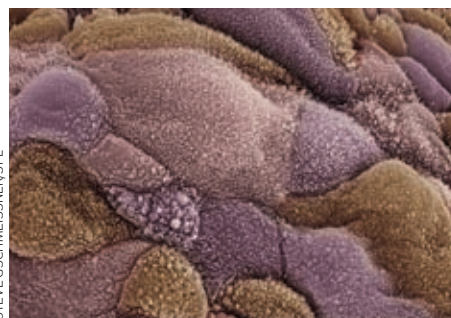
Anne Gulland LONDON

Doctors will be allowed to carry out cancer surgery on a woman with learning disabilities against her wishes, a judge has ruled.

The treatment was ordered by Nicholas Wall, president of the Family Division in the Court of Protection, after surgeons at the hospital where the woman was being treated applied for permission to force her to have surgery. They said that without a hysterectomy and removal of her ovaries and fallopian tubes the patient's cancer of the uterus would eventually kill her.

The woman, known as PS, has a phobia of hospitals and needles and has repeatedly cancelled hospital appointments. Under the terms of the Mental Capacity Act 2005 she does not have the ability to make decisions about her health care and treatment.

The hospital has tried to explain the need for surgery, and she has previously agreed to undergo an operation. She failed, however, to turn up to hospital for treatment.



Doctors considered options other than surgery to treat the uterine cancer as impractical

The hospital has come up with a plan of action. A consultant anaesthetist will travel with an ambulance crew to the patient's home and if she refuses treatment she will be given a dose of sedative mixed with a soft drink. A learning disability nurse at PS's local mental health trust who has built up a relationship with the patient said she will make "every effort" to avoid the use of a sedative.

After surgery PS will be sedated and the hospital will bandage a cannula so she cannot pull it out.

Doctors considered treating the patient with chemotherapy and radiotherapy, but given her history of refusing to attend hospital believe these would be impractical.

Sir Nicholas made the judgment public to "assist others who may be faced with a similar dilemma."

He concluded, "I am entirely satisfied that it was right to make the declarations sought by the trust, and although the application is unusual and may involve the use of force, I am nonetheless impressed by the care and thought which have gone into ensuring that PS receives the treatment which she plainly needs, and which it is plainly in her interests to have."

Doctors and campaigners for the rights of people with learning disabilities have welcomed Sir Nicholas's decision. A BMA spokesperson said, "When it is absolutely clear that an individual lacks sufficient capacity to make a decision it only right that the courts allow health professionals to go ahead and treat the patient."

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Spanish doctors set to carry out first double leg transplant in the world later this year

María de Lago MADRID

The Spanish National Transplant Organization has given the go ahead to La Fe Hospital in Valencia, Spain, to carry out the world's first double leg transplant.

The procedure will be carried out by Pedro Cavadas and a team of around 35 health professionals on a young man who lost both his legs in a car crash.

Dr Cavadas performed Spain's first face transplant last August and the country's first hand transplant in 2006. The intention is to perform the leg transplant later this year, he said, but the date will depend on how long it takes to find

the right donor, who, among other things, will need to be of similar height to the patient.

The transplant is the only option for the patient to regain mobility, explained Rafael Matesanz, director of the National Transplant Organization. Prosthetic limbs have been ruled out because the young man has only 15 cm of flesh remaining below his hips. "Authorisation would not have been granted if the patient had had a unilateral or bilateral amputation that had left more flesh in place."

The patient is otherwise in good health and the procedure complies with all the ethical and legal requirements, he said, adding that



The number of new HIV/AIDS patients in the Congo able to start treatment has been cut sixfold

Donor fatigue is slashing access to AIDS care in Africa, warns charity

Peter Moszynski LONDON

Growing donor fatigue towards funding HIV/AIDS risks undermining years of positive achievements and will cause many more unnecessary deaths, says a report by the charity Médecins Sans Frontières.

On the basis of detailed analyses made in eight sub-Saharan countries, the report illustrates how major international funding institutions such as the US president's emergency plan for AIDS relief, the World Bank, UNITAID, and donors to the global fund have decided to cap, reduce, or withdraw their spending on HIV treatment and antiretroviral drugs over the past 18 months.

The charity says the findings "confirm our concerns in terms of donor backtracking on

commitments to scale up the fight against the HIV/AIDS epidemic. Today, this disengagement is starting to become visible in the field and the level of HIV care is beginning to deteriorate."

The report says effective HIV/AIDS interventions "have numerous cross benefits and spin offs on the broader health sector" and that achieving the Millennium Development Goals cannot be tackled without addressing HIV/AIDS. Yet a lack of sustained donor commitment "is jeopardising worldwide efforts to fight this deadly disease."

Overall funding cuts "have translated into a reduction in the number of people able to start their ARV [antiretroviral] treatment." In Congo the number of new patients able to start treatment has been cut sixfold.

Mit Philips, the charity's health policy analyst, told the *BMJ* that donors are shifting attention from AIDS funding towards health system strengthening but "this policy is not coherent" as already fragile health systems "will become increasingly strained by an increasing patient load requiring more intensive care."

The report says that drug stock outs and disruptions in drug supply "are already a reality, and will become more frequent if sufficient funding is not made available."

It points out that antiretroviral treatment is "lifesaving but also lifelong." This means that the number of patients under treatment increases cumulatively each year, thus requiring incrementally growing and sustainable funding.

Reduced funding not only hampers HIV treatment scale-up but also "threatens to undermine" all the positive effects that high coverage of antiretroviral treatment brings in terms of "community-wide reduction of mortality, morbidity and transmission."

Any retreat from the current efforts towards antiretroviral treatment scale-up "will have far reaching and very real negative consequences" for HIV patients and front line workers.

Dr Philips says that donors are being "penny wise and pound foolish" because delays in starting antiretroviral treatment in line with the World Health Organization's guidelines will eventually result in increased long term health costs.

She warned that this "head in the sand response" means that the AIDS crisis will return with a vengeance, adding "How can we give up the fight halfway and pretend that the crisis is over?"

The report, *No time to quit: HIV/AIDS treatment gap widening in Africa*, is available at www.msf.org.uk.

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the patient understood he might need to take immunosuppressant drugs for life.

The surgery is likely to be less complicated than arm transplants, which Dr Cavadas has performed several times since 2008, he continued. But rehabilitation could take up to a year because the patient's nerves will have to grow to the end of the new legs. The nerves are expected grow at a rate of 1 mm a day, he said.

The transplant authority has made it clear that this case does not signal blanket permission for leg transplants and that future cases will need to be considered on an individual basis. The reason why similar transplants have not been given the green light before now has more to do with a lack of demand than a lack of technical expertise, suggested Dr Matesanz.

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BMA calls for regulator to scrap latest "disproportionate" plans for revalidation

Rebecca Wilkins LONDON

Doctors' leaders have called for the latest plans for revalidation drawn up by the General Medical Council to be scrapped saying they seem both "threatening and disproportionate."

The BMA says the GMC should "go back to the drawing board" to deal with fundamental problems in its consultation document *Revalidation: the way ahead*, which was launched in March.

Feedback from BMA committees led the BMA to conclude that its "confidence in the process [of revalidation] is seriously undermined."

The BMA said that the current proposals for revalidation "appear designed to describe excel-

lence as a doctor rather than what is needed to maintain registration." The response draws particular attention to the specialist standards that have been developed by some of the royal colleges and advises that these need to be realistic and "simplified as a matter of urgency."

BMA chairman Hamish Meldrum has requested detailed responses to a number of issues, in particular about how the revalidation programme will be funded and an assurance that certain tools currently being piloted will only be used if trials show they work.

The BMA's response can be seen at www.bma.org.uk.

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CHRIS HARRIS/PA

The Queen's speech signals changes to the way in which drug prices will be set

Pharmaceutical industry braced for “value based” drug pricing

Nigel Hawkes LONDON

Government plans to alter the way in which the prices of drugs are set could leave patients waiting longer, analysts have warned.

In place of the existing system, in which companies can set their own prices at launch, subject only to a limit on the overall profits they can make, drugs will be subject to value based pricing, the new government has indicated. Health secretary Andrew Lansley says it would be “a much more rational system.”

But in countries that already negotiate drug prices there is often a delay as the terms of

reimbursement are worked out. In the United Kingdom a drug can be marketed as soon as it has a licence, and at a price the company chooses. This has made the UK an attractive market in which to launch drugs, especially as the NHS price can then be used as a guide to pricing in other markets. Adrian Towse, director of the Office of Health Economics, says he fears that the change will lead to “administered prices and substantial delays.”

The UK market already has a measure of value: the assessments made by the National Institute for Health and Clinical Excellence

(NICE), which rejects new drugs if they are not cost effective. But although NICE can at present only say yes or no, under value based pricing it would have a third option: “Yes, but only if it costs less than £X per treatment.” Value based pricing could make NICE even more powerful.

Critics of the present system, the Pharmaceutical Price Regulation Scheme, include the Office of Fair Trading, which concluded in a report in 2007 that the NHS could save £500m (€574m; \$721m) a year by moving to value based pricing. The government believes lower prices will enable life prolonging drugs to be provided to cancer patients at the end of life, because companies would have to price the drugs appropriate to their benefit. To free market economists the Pharmaceutical Price Regulation Scheme is a stitch up between producers and purchasers that keeps drug prices higher in the UK than elsewhere, though the figures show that has not been true for several years. But even its critics have to acknowledge that the system, through its capacity to allow companies to offset research costs, has kept the drug industry healthy. Value based pricing will have to include similar incentives.

A recent report by 2020health, a centre right think tank for health and technology, warned that abandoning the current pricing scheme altogether “could have an adverse impact on pharmaceutical and biomedical R&D [research and development] investment and is in itself unlikely to have a sizeable effect on the level of NHS spending on medicines.” Off patent medicines already represent 80% in volume terms of the drugs prescribed by GPs.

Richard Barker, director general of the Association of the British Pharmaceutical Industry acknowledges that resistance would be in vain. “Personally I don’t think it’s worthwhile

German experts call for controls on new cancer drugs

Annette Tuffs HEIDELBERG

German healthcare experts have called for an independent committee to control the introduction of new cancer drugs to the market reported an article in *Der Spiegel* on 17 May 2010.

A leaked confidential report submitted to the German health ministry by five healthcare experts, spearheaded by health economist Gerd Glaeske from Bremen University, indicates that the price of new cancer drugs should be linked to proof that they work in normal clinical settings rather than in clinical trials of selected patient groups—as now.

The German equivalent of the UK National Institute for Health and Clinical Excellence, the Institute for Quality and Efficiency in Health Care (IQWiG), has never been asked to evaluate the efficacy of cancer drugs.

“Cancer therapy in Germany is a holy cow,” commented head of IQWiG, Peter Sawicki, in *Der Spiegel*. “The health insurance companies have no idea what to do if the efficacy of a number of drugs is called into question.”

But the German health ministry is unlikely to take up the report’s recommendation as it had already taken steps to curb rising drug costs earlier this year. In March 2010, the Liberal Democrat health minister Philipp Rösler announced plans to force the drug industry to discount its entire range of new drugs, in the hope of saving more than €1bn (£0.87bn; \$1.26bn).

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NHS London chief resigns in protest at axed plans



Richard Sykes said the government’s and NHS London’s plans for the capital differed too much

to oppose VBP [value based pricing]; we're past that point," he told a conference last year. "Now it should be about discussing how VBP could work, recognising practical barriers, like limited cost effectiveness data. Industry needs to think about how a value system could look."

Two possible models for value based pricing exist: ex-post, in which companies set initial prices that are reviewed as evidence of effectiveness emerges; or ex-ante, in which prices are controlled from the start, but may be changed later. The industry would prefer the first model: the NHS the second.

Value based pricing would apply only to drugs that cost more than those already on the market for the same indication. Whichever model was chosen would depend on NICE, or a similar body, to measure value. But ex-ante pricing would need NICE to carry out the assessment while the medicine was in phase III trials to avoid delays. A risk sharing mechanism might be negotiated between the Department of Health and drug companies while data on value were being collected.

Prices would be determined by negotiation between the Department of Health and the companies on the basis of the NICE data. Technically it would be possible for prices to start low and be raised later if a drug is more effective than expected. But the industry is sceptical that the NHS would ever allow price increases.

Problems surround what constitutes value. NICE uses quality adjusted life years (QALYs) to assess value, but takes no account of the value of a medicine to carers, or to patient preferences. QALYs are a blunt instrument in dealing with the end of life where a drug may provide only a month or two of extra life, but denying it to patients causes a public furore.

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Developing countries call on WHO to focus on public health not drug patents

John Zarocostas GENEVA

Developing countries in Africa, Asia, and Latin America—spearheaded by India and Brazil—have secured passage of a resolution that calls for a major review of the World Health Organization's role in combating counterfeit and sub-standard drugs.

The demands seek to curtail the role of WHO in intellectual property enforcement issues and to prioritise public health concerns.

The resolution calls for Margaret Chan, head of WHO, to establish a working group to examine from a "public health perspective, excluding intellectual property considerations," the agency's role "in measures to ensure the availability of quality, safe, efficacious and affordable medicinal products."

It also calls for an examination of WHO's relationship with the International Medical Products Anti-counterfeiting Taskforce, which includes the International Federation of Pharmaceutical Manufacturers & Associations, and international agencies such as the World Customs Organization, Interpol, the World Trade Organization, the OECD, among others.

Maria Nazareth Farani Azevedo, Brazil's ambassador to the UN in Geneva, told the *BMJ*, "What we have today in WHO is a blurred process in which governments, private sector, and bureaucrats participate in deciding policies where there is a risk for potential conflict of interest because of the number of patents expiring in the near future."

"[The resolution is] a very important victory, not only for developing countries, but for WHO itself. In WHO, it should be governments in the forefront of decisions taken here, and not other stakeholders. This is just the beginning of a process where governments will set the mandate of WHO [in] the fight against falsified medicines."

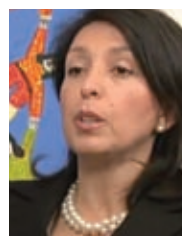
Similarly, James Love, director of Knowledge Ecology International, a Washington based advocacy group for social justice, told the *BMJ*, "Today the WHA [World Health Assembly] took [the] first steps to addressing a failure at the WHO—the privatisation of policy making on drug quality and patient safety. The large pharmaceutical companies that have funded WHO work in this area have made a number of mistakes. We hope this resolution will lead to change."

But senior western diplomats told the *BMJ* the resolution does not prejudice any outcome, and added that for the present the work WHO is doing with its Impact team will continue.

WHO Impact, which was created in 2006, is made up of governments, agencies, and drug industry representatives aimed at sharing expertise and seeking solutions to the problem of counterfeit medicines.

Dr Chan told members of WHO's governing board that the agency will continue with its public health work until it has final guidance from the expert working group, which is expected to report to next year's World Health Assembly.

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Maria Nazareth Farani Azevedo, Brazil's ambassador to the UN

Jacqui Wise LONDON

Richard Sykes, the chairman of NHS London, has resigned in protest at the government's decision to halt the reorganisation of health care in the capital.

Last week, the new health secretary Andrew Lansley announced he would halt the Healthcare for London changes devised by former health minister Ara Darzi. The plans included a reorganisation of hospital services, with centralised major trauma; heart attack, stroke, and vascular surgery networks; and the building of GP led polyclinics. Mr Lansley had made an election pledge to put an immediate moratorium on any proposals to downgrade emergency department

services and close maternity units in the capital as a result of the plans.

In his resignation letter to Mr Lansley, Sir Richard wrote, "Our visions of healthcare delivery bear so little in common that it would make no sense to continue in this role."

Sir Richard, who has been chairman of NHS London since 2008, said other members of the board of NHS London are also considering their positions. He says he had been appointed to deliver the programme of change outlined by Lord Darzi in Healthcare for London and "relished" that task.

Writing in response Mr Lansley said, "Many of the things achieved through the Healthcare for London

programme are entirely consistent with my vision for improved health care in the capital and indeed the country at large."

But he added that a range of innovative and challenging solutions for how to improve health care in London should be set out. "Neither the government nor NHS London should dictate the decisions made. The decisions that patients make through choice, and which GPs make through commissioning should not be pre-empted from on high," he wrote.

NHS London is the biggest authority in the health service, employing 200 000 people. In its strategic plan for 2010-15 published this January it said that by 2016-17 the NHS in

London will face a funding shortfall of between £3.8bn (€4.4bn; \$5.5bn) and £5.1bn per year on a recurrent basis.

NHS London confirmed that Gerry Archer, a non-executive director of the health authority, has also resigned. But it would not confirm newspaper reports that five of the six other non-executive directors are also likely to resign in protest at the move.

Lord Darzi commented: "This is sad day for the NHS in London." But he added: "I have been reassured by the Secretary of State for Health that the London Framework for Action will remain the driving vision of reform in the capital."

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