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Trial results lead to calls for new national screening programme for colorectal cancer

Jacqui Wise LONDON

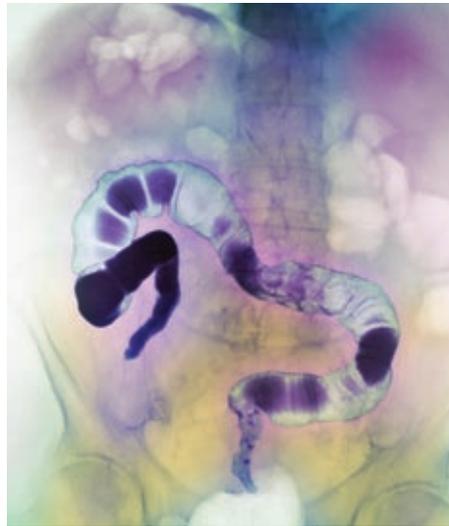
Experts on cancer have called for a new national screening programme for colorectal cancer, with all 55 year olds in the United Kingdom to undergo a one-off 5 minute sigmoidoscopy examination.

The call comes after the publication this week of a 16 year study showing that a single flexible sigmoidoscopy examination in men and women aged between 55 and 64 reduced the incidence of bowel cancer by a third (hazard ratio 0.67 (95% confidence interval 0.6 to 0.76)) and bowel cancer mortality by 43% (0.57 (0.45 to 0.72)), in comparison with a control group.

Harpal Kumar, chief executive of Cancer Research UK, called on the next government to add the test to the existing national bowel screening programme as one of its first priorities. "I think it is a no brainer," he said. "This is the most important development in cancer research for years. We very rarely see results as good as this."

Bowel cancer is the third most commonly diagnosed cancer in the UK and the second most common cancer killer, after lung cancer. One in 20 people in the UK will develop bowel cancer in their lifetime, half of whom will die from it.

The randomised trial followed more than



SPL

Removal of polyps at sigmoidoscopy led to a reduction in the incidence of bowel cancer

170 000 people over an average period of 11 years, of whom 40 674 underwent a sigmoidoscopy examination. The study, published online in the *Lancet*, took place at 14 UK centres (doi:10.1016/S0140-6736(10)60551-X).

Flexible sigmoidoscopy examines only the lower part of the bowel, where two thirds of colorectal cancers and adenomas occur. The examination can be carried out by doctors or by

specially trained nurses in outpatient clinics. Any small polyps found are removed straight away, as they can become cancerous if left untreated. In the study patients were referred for colonoscopy if any of the polyps were considered to be high risk—if they were over 1 cm in size, for example. Because colonoscopy is an examination of the whole bowel and is a longer procedure it would not be suitable for population screening.

During the follow-up period 2524 participants were given a diagnosis of colorectal cancer, 1818 in the control group and 706 in the screening group.

The study's leader, Wendy Atkin, professor of biosurgery and surgical technology at Imperial College London, said, "There has never before been trial evidence that shows that removing polyps reduces cancer incidence. This one-off 5 minute examination produces a big effect, reducing mortality by 43%."

Professor Atkin said that to prevent one cancer 191 patients must be screened and that for every 400 people screened one life would be saved. But she said she expected the benefits to prove even greater with even longer follow-up. The new test should dovetail with the existing screening programme, which uses faecal occult blood testing, she added.

Cite this as: *BMJ* 2010;340:c2344

US societies are urged to adopt code on relations with industry

Janice Hopkins Tanne NEW YORK

A US organisation is calling on all medical societies to sign up to a code of ethics that would set standards for their relations with drug companies and encourage them to be far more open about their funding.

The US Council of Medical Specialty Societies released the voluntary code on doctors' interactions with manufacturers of drugs and devices on 21 April. The council said that 13 of its 32 member societies had already adopted the code and that others

were planning to adopt it.

The council's member societies represent about 650 000 of the 920 000 or so doctors in the United States. Some societies have already adopted their own policies that are similar to the new code.

The council's code was developed by a 30 person task force drawn from its member societies.

The code includes seven core principles covering four areas: conflicts of interest, financial disclosures, independent

development of programmes, and independent leadership.

It calls for societies to separate their efforts to seek educational grants, sponsorships, charitable contributions, and research grants from their programming decisions. No leading society officials may have direct financial relations with the industry, and all relations with industry must be described in writing, including details of what the grants are for and the roles of the society and the company.

Societies must reveal to their members and the general public their policies on conflicts of interest; support from companies; and financial and uncompensated relations that key leaders of the society and members of its board of directors have with companies.

Societies will not accept charitable contributions or corporate sponsorships that don't align with the society's aim.

See www.cmss.org/.

Cite this as: *BMJ* 2010;340:c2246

IN BRIEF

Polio outbreak is reported in

Tajikistan: A team of experts has been sent to investigate an outbreak of polio in the southwest of Tajikistan, in the area bordering Afghanistan and Uzbekistan. The Global Polio Eradication Initiative and the World Health Organization will support the Tajik Ministry of Health in a mass immunisation campaign. As of 22 April, 128 cases of acute flaccid paralysis had been reported, and 10 infected children had died.

WHO reports major gains in malaria

control: From 2004 to 2009 aid for malaria in Africa rose 10-fold to nearly \$1.8bn (£1.2bn; €1.4bn), the number of insecticide treated bed nets in use rose from 30 million to 150 million, and the number of artemisinin based combination treatments procured rose from five million to 160 million, say the WHO and Unicef. Wider availability of inexpensive rapid diagnostic tests is also helping to make treatment more cost effective.

Obama grants hospital rights to

unmarried partners: Barack Obama has told his health secretary to issue new rules granting hospital visiting rights to same sex partners and to single people who rely on friends or clergy for comfort and help in making medical decisions. The rules will apply to US hospitals that treat patients under the federal Medicaid and Medicare programmes—essentially all US hospitals.

US paediatricians condemn ritual

female genital cutting: The American Academy of Paediatricians has opposed all forms of female genital cutting. It urges its members to refuse to perform such procedures, to “actively dissuade” parents from carrying out such procedures, and to tell parents about the lifelong physical and psychological suffering caused by the procedures.

Study will examine health impact

of mobile phones: A quarter of a million mobile phone users in the UK, the Netherlands, Sweden, Finland, and Denmark are to have their medical records tracked for more than 20 years to examine the effects on health of the devices. The cohort study on mobile communications (Cosmos) will look for increased rates of cancer, dementia, and other conditions, such as depression and sleep disorders. It is funded by the UK government's mobile telecommunications health research programme.

Cite this as:

BMJ 2010;340:c2290

Fewer, larger centres will improve children's heart surgery

Susan Mayor LONDON

A report on children's heart surgery in England is recommending fewer, larger centres, each with a minimum of four full time surgeons, as part of efforts to ensure that all children have equal access to the highest standards of care.

Four of the 11 heart surgery centres in England currently have two or fewer paediatric surgeons, says the report, produced by an expert group at the request of the NHS's National Specialised Commissioning Group. A public consultation this autumn will decide which centres should continue to provide surgery.

After reviewing the current service the expert group found that some centres cannot provide care round the clock and are not dealing with a wide enough range of heart surgery cases to provide the best quality of care. They found that hospitals with teams that regularly perform a larger range of complex heart operations tend to have the best results.

“The services were pioneered in a number of areas by talented and dedicated surgeons, but they were developed on an ad-hoc basis,” the group said, arguing that there is essentially a two tier system, with larger units having the staffing and volume of procedures to optimise outcomes while others are too small to meet the demands of increasingly complex heart operations.

“We need enough surgeons in each centre to meet the day-to-day demands of performing operations in theatre, being on call to respond to emergencies, doing ward rounds and holding



STEVE PARSONS/PA

Children's heart surgery at Oxford's John Radcliffe Hospital is threatened as it has only one surgeon

outpatients clinics,” their report recommends.

“Four is the magic number,” says the working group, advising that in the future each children's heart surgery centre should have a minimum of four full time surgeons.

Those centres that are approved will be designated specialist surgical centres and will continue to provide surgery or interventional procedures for children. Assessment of them will use a new indicator: the number of complications experienced by children after surgery. These figures will be shared with children's parents and with the public.

“Having larger centres will mean that we can more easily understand what the morbidity data is telling us, and we will have a much better understanding of the overall quality of care in each centre,” the working group says.

Those centres not designated to provide surgery and interventional procedures on children will become “children's cardiology centres.” *Children's Heart Surgery: The Need for Change* is at www.specialisedservices.nhs.uk/?dI_id=363.

Cite this as: *BMJ* 2010;340:c2341

Doctor is awarded £0.5m after her employer refused to take account of her back pain

Clare Dyer *BMJ*

A former consultant in geriatrics and general medicine has won a near record £0.5m (€0.6m; \$0.8m) for disability discrimination after she felt forced to leave her job four years before retirement when her employers cut her pay and refused to make reasonable adjustments for her back problems.

London North Employment Tribunal ruled last year that claims by Gwen Sayers, who worked at Northwick Park Hospital in north London, for constructive unfair dismissal, direct disability discrimination, failure to make reasonable adjustments, and unauthorised deduction from wages were all “well founded.” The tribunal awarded her £550 000, one of the

highest awards ever made under the Disability Discrimination Act.

Her employers, Harrow Primary Care Trust, and her line manager, David Cohen, appealed but in a compromise agreement have now agreed to drop the appeal and pay her £500 000. Dr Sayers told the *BMJ* that she refused to sign the confidentiality clause they requested because she wanted to publicise her case to try to make sure that no other doctors suffered a similar experience.

“I hope that my case sends a clear message to NHS managers that they cannot act in a way that is unlawful,” she said.

Dr Sayers, 64, was described by the tribunal as well regarded in her profession, particularly



HIV testing in UK hospitals is a “lottery,” show latest findings

Susan Mayor LONDON

Large numbers of cases of HIV infection remain undiagnosed because healthcare professionals working in UK hospitals are failing to offer testing routinely to people at high risk of infection, warn three studies.

The studies were reported at the second joint conference of the British Association for Sexual Health and HIV and the British HIV Association, held in Manchester on 20 to 23 April.

“These research studies clearly demonstrate that HIV testing in high prevalence areas remains a ‘lottery,’ despite national guidelines

which recommend routinely offering an HIV test to adults in high prevalence areas,” said Keith Radcliffe, a consultant in genitourinary medicine at the Heart of Birmingham Teaching Primary Care Trust and president of the British Association for Sexual Health and HIV. More than a third of people with HIV get a late diagnosis, causing avoidable morbidity, mortality, and onward transmission, he argued.

The first study, by P J Read and colleagues, looked at patterns of HIV testing in a large inner city trust in London—Guy’s and St Thomas’s NHS Foundation Trust—which has a high local

prevalence. All HIV tests performed in 2008 were analysed and stratified on the basis of location of request. Where test results were positive, a case note study review established the circumstances surrounding the test and identified previous presentation, HIV indicator diseases, and any missed opportunities for HIV testing. A total of 41 095 tests were performed for 36 392 people, of whom 363 (1%) were given a positive diagnosis.

Analysis of the results showed that 41% of HIV positive patients had been in contact with a health professional for an HIV related reason in the previous two years but had failed to be offered a test. The authors considered that local implementation of HIV testing guidelines would have detected more than one third of late presenters at an earlier stage and prevented subsequent admissions to hospital.

The second study, by N Perry and colleagues, looked at a six month pilot of routine HIV testing of all adult (aged 16-79) acute general medical admissions to Brighton and Sussex University Hospitals. It found that only one third of previously undiagnosed HIV positive patients were correctly targeted, according to risk factors, for testing.

A third study, by M Rayment and colleagues, investigated the feasibility and acceptability of routinely offering HIV tests in the emergency department of a London hospital. The study showed that fears that health professionals may feel uncomfortable offering tests routinely may be misplaced. It offered all patients a saliva HIV test; 61% accepted the offer. The test acceptance rate did not differ by ethnicity or sexual orientation, showing that people at higher risk are happy with test offers in such settings.

Cite this as: *BMJ* 2010;340:c2255



Nearly two thirds of patients in the emergency department of a London hospital accepted a saliva HIV test

for her work on ethics. She chaired both the clinical ethics and research ethics committees at Northwick Park and had worked there for nine years.

She has chronic back pain with occasional acute episodes, affecting her ability to lift and move objects and to spend prolonged periods on her feet examining patients. Her problems began when, despite earlier spinal surgery, she experienced major back pain during lengthy ward rounds involving newly admitted patients.

This was not a large part of her work, and the trust’s occupational health consultant suggested that she stop it as a reasonable adjustment to her disability. But Dr Cohen, a consultant physician and the lead clinician, insisted that all consultants must work under the same conditions and that he could not treat her differently from the others.

The tribunal found that this “demonstrated a particular attitude of mind in relation to addressing someone suffering with a disability.”

The tribunal said that Dr Cohen had effectively “washed his hands” of her requests for adjustments to weekend rotas. It described as “quite remarkable” his admission that he did not even speak to the two other doctors that she told him had agreed to cover the few weekend days a year she would have been required to work.

Dr Sayers was put on a new “physician of the week” rota, which would have required her to do five consecutive eight hour days of acute clinical work, including weekends, four times a year, against the advice of occupational health professionals. She was taken off the rota only when the trust’s own spinal surgeon said she



Dr Gwen Sayers refused to sign a confidentiality agreement

was unfit to do the work.

But although she had offered to do part of the work, give up days of annual leave, or perform other work in lieu, the trust docked her pay by £589 a month. The move was branded a “punishment” by the tribunal.

The “last straw” was when her office was moved without notice to a different floor from her secretary, on whom she relied to bring her patients’ files and books. When she complained she was sent what the tri-

ibunal described as a “belittling and dismissive” email from a senior manager pointing out that she could use the lift. She resigned in February 2007, a month short of her 61st birthday, saying that she believed the treatment she had experienced amounted to constructive dismissal.

Cite this as: *BMJ* 2010;340:c2263

FDA is told to act to wean US citizens off high salt diet

Bob Roehr WASHINGTON, DC

The US Food and Drug Administration has been called on to regulate the amount of sodium added to foods after a report found that several decades of voluntarily efforts to reduce the unacceptably high levels of sodium that US citizens consume have failed.

The report by the Institute of Medicine found that the average US citizen consumes 3400 mg of sodium a day, more than double the 1500 mg believed to be an adequate intake for a person under the age of 50 (older people need less). More than three quarters of sodium comes from processed and restaurant foods. The report recommends reducing consumption to 2300 mg, about 1 teaspoon a day, over some years.

Jane Henney, professor of medicine at the University of Cincinnati and chair of the committee that wrote the report, said, "The strategies identified in this report have the potential to greatly impact the lives of Americans.

"It has been estimated that reducing sodium intake could prevent more than 100 000 deaths annually and save billions in medical costs."

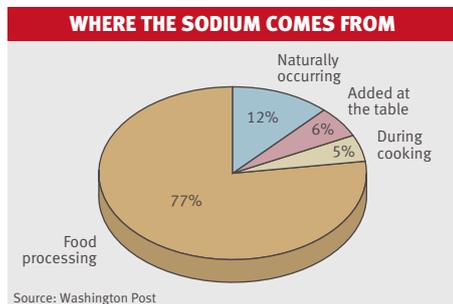
The report says the FDA already has the authority to regulate sodium that is added to food and it should use it.

However, sodium plays so ubiquitous a role in "improving food taste and flavor, maintaining food safety and shelf life, and impacting the texture of food" that people will have to be weaned off their high salt diets over a period of years and give their taste time to adjust. Industry will have to be given time to adjust their recipes and processes, said Dr Henney.

Strategies supporting regulation should include national education efforts on the benefits of lower salt diets.

Strategies to reduce sodium intake in the United States is available at www.iom.edu/Reports/2010/Strategies-to-Reduce-Sodium-Intake-in-the-United-States.aspx.

Cite this as: *BMJ* 2010;340:c2219



Spanish doctors carry out world's first transplantation of a full face

Lynn Eaton LONDON

Surgeons at a Spanish hospital are claiming the first successful transplantation of a complete face after a 24 hour operation on a young man with severe facial injuries.

The operation was carried out in late March at Vall d'Hebron University Hospital in Barcelona, and the patient is "progressing favourably," said the lead surgeon, Joan Pere Barret.

"He is growing a beard at the moment," said Dr Barret, who said he was "amazed" at the results. "We knew it was going to be good, but we didn't know it would be that good," he said.

Now Dr Barret, who has specialised in treating burns victims in the past and who has worked at the St Andrews Centre for Plastic Surgery and Burns in Chelmsford, Essex, believes that where someone has severe facial injuries it maybe better to perform a full face transplantation than to try to patch them up with skin grafts.

The patient had lost the centre of his face—his nose, his mouth, the mandibles of the jaw, both cheekbones, his eyelids, and part of his soft tissue—in a "severe, high energy" accident.

"He had sustained the injury in 2005 and had

already had nine operations in another hospital in an attempt to restore his oral competence," he said.

The previous operations involved skin grafts from the man's upper chest, leaving an uneven surface on his face. In 2007 the team at the Barcelona hospital was alerted to the patient's plight and began to see whether the man, whose age is given as between 25 and 35, would be a suitable recipient of a face transplant. After psychological investigations doctors decided that he was a good candidate. Approval from the Madrid based National Organ Transplant Body was finally given in August 2009.

The first facial transplantation, of a partial face, was carried out in France in 2005 by Jean-Michel Dubernard (*BMJ* 2005;331:1359). In that case the patient had been mauled by a dog. In all there have been 10 partial face transplantations worldwide to date, a hospital spokeswoman in Barcelona said. Two of these took place in Spain. Others were in China and America.

Finding a suitable donor for his patient was not easy, said Dr Barret. "It's not just about the face looking like that of the patient but about

India-EU trade deal "threatens access to cheap, generic drugs"

Peter Moszynski LONDON

A free trade agreement being negotiated between India and the European Union could radically restrict access to cheap generic drugs across the developing world, says the charity Médecins Sans Frontières.

The charity held a press conference in Brussels this week to warn of the dangers presented to the supply of generic drugs by provisions on intellectual property rights being discussed at a closed meeting at the European Union.

MSF points out that India is the source of 80% of the antiretrovirals it uses in its projects and maintains that "without quality affordable

medicines from Indian sources, it would have been impossible to scale up treatment to the levels seen today, and millions of lives would not have been saved."

It says that the draft agreement contains "several alarming provisions on intellectual property and enforcement, much stricter than anything required under the international trade rules," and that these provisions threaten the supply of essential drugs from India.

One of the provisions under discussion is "data exclusivity," which MSF claims "creates a new patent-like barrier to access to medicines and vaccines," even when these products are



Computer generated images showing the transplantation on a man who lost the centre of his face in 2005

ensuring that the bone structure, eye position, skin tone, and weight are similar," he said.

"The age should also be similar," he said. "The tissues need to match up, and they need to last for a long time."

The donor's family may also find the idea of burying a loved one whose face has been removed unacceptable, he said.

Dr Barret led a 30 strong clinical team with eight consultants, who worked in shifts, two hours at a time. Before removing the donor's face they created a silicone mask from it, so that the donor's body could still appear to have a face. They then removed the face from the hairline to the mid-neck and from ear to ear. They removed all the facial bones, including the teeth and jaw. It took almost five hours to harvest the donor's face, which included severing the jugular veins and external carotid arteries.

Halfway through this process the patient was prepared to receive the face. Doctors began inducing immunosuppressants. Dr Barret said, "That was dangerous, as in some transplantations patients can get allergic reactions," said Dr Barret. But the Barcelona team were lucky. They initially connected the donor's face to the femoral artery at the patient's groin, to ensure that the tissues had good vascular contact. That took about 45 minutes and was successful.

Then came the point of no going back, said Dr Barret. The team removed all the soft tissue and remains of the patient's cheekbones and mandibles. "We ended up with the same big hole that we had had on the donor. All that was left of the recipient's face was the frontal bone and two eyeballs. From that moment there was no way it was reversible," he said.

It took his team 30 minutes to connect the main arteries and veins. They then sculpted the bones to fit the new face and used titanium miniplates and screws to create the cheekbones. The team then recreated the jaw to ensure that the patient would be able to chew properly. Finally came the nerves: five main nerve branches and numerous smaller ones needed to be connected.

"That was quite tricky," Dr Barret admitted. The intraorbital optic nerve and the dental nerve were hardest of all. "With the dental nerve, from where it exits the skull and before it enters the mandibles there is probably only 2 cm to work on. But if we hadn't done this, all he would have had would have been an insensitive face mask."

The patient should be able to smile and chew once the nerves have rebuilt after four to six months.

Cite this as: *BMJ* 2010;340:c2303

European court rules that NHS prescribing schemes are legal

Clare Dyer *BMJ*

NHS schemes that offer doctors financial incentives to prescribe cheaper drugs do not contravene European law, the European Court of Justice has ruled in a judgment that should save many millions of pounds.

Five judges in the Luxembourg court went against the recommendation of the court's advocate general that they should rule that prescribing incentive schemes for GPs in England and Wales breach a European directive on the promotion of medicinal products (*BMJ* 2010;340:c1945).

On the contrary, they ruled, the NHS schemes are compatible with the European directive and do not prejudice the objectivity of prescribing doctors because doctors are obliged by their code of conduct to prescribe in the patients' best interests.

But the health authorities must provide the drug industry with information showing that the schemes are based on objective criteria and do not discriminate between products from UK manufacturers and those from other European Union countries, the judges said.

And the authorities must make the schemes public and give the industry and healthcare professionals the evaluations showing the therapeutic equivalence between the cheaper products and the more expensive.

The Department of Health welcomed the ruling and is considering its implications.

Cite this as: *BMJ* 2010;340:c2232

not protected by a patent. India's current liberal laws prevent patents being granted for certain improvements of existing drugs and their use in new combinations or in paediatric forms, which has allowed the development of new fixed dose, combination antiretrovirals, such as atazanavir with ritonavir.

The charity says that if India introduces data exclusivity, manufacturers of generic drugs wishing to register a product will be obliged to repeat clinical studies instead of relying on bioequivalence and stability tests to prove that the drug works in the same way as the original.

This will not only create "huge financial barriers," MSF says, but will also be "in violation of medical ethics, as people are subjected to the risks of clinical studies for something that is already known."

See www.msf.org.uk/FTA_update_20100421.news.

Cite this as: *BMJ* 2010;340:c2309



MSF says that India is the source of 80% of the antiretroviral drugs it uses in its projects

NICO HEIJENBURG/MSF

Health spokesmen disagree on managing hospital closures

Zosia Kmiotowicz LONDON

The health spokesmen for the three main political parties clashed over the best way to manage changes in health services when they took part in a debate on 22 April.

Health secretary Andy Burnham defended decisions made by Labour in recent years to close some hospital maternity, children's, and emergency departments to allow the same departments in hospitals nearby to specialise.

When the shadow health secretary, Andrew Lansley, promised to put a stop to further changes should the Conservatives win power in May, Mr Burnham accused him of insincerity.

Mr Lansley explained that he was not against change but that any hospital closures should be based on evidence and consider the wellbeing of patients.

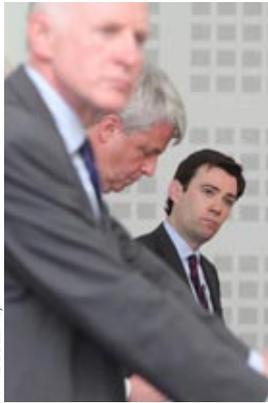
But Mr Burnham replied that

he was saying what people wanted to hear, and when Mr Lansley tried to explain Mr Burnham said he had dug "himself into a large hole."

Meanwhile the Liberal Democrats' health spokesman, Norman Lamb, argued that he favoured empowering locally elected health boards to make decisions about which services best suited the population. This would make services more accountable, but the decisions needed to be evidence based so that if a service was moving into the community it had to be shown to be better than one provided by hospitals, said Mr Lamb.

The debate was organised jointly by the BMA, the King's Fund, the NHS Confederation, and the Royal College of Nursing.

On the subject of minimum pricing of alcohol Mr Lansley said, "I agree with Andy," after Mr Burnham described Labour's intention to focus primarily on



KATE COLLINS/PA

Norman Lamb, Andrew Lansley, and Andy Burnham debate health policies

tackling large discounts on alcohol. It was these which meant teenagers "could afford to drink every night of the week," said Mr Burnham, although he did not rule out legislation on a minimum price per unit of alcohol at a later date.

Only the Liberal Democrats favour a swift move to introduce a minimum price of alcohol. Mr Lamb contradicted Mr Lansley's assertion that minimum pricing would have a significant impact on low income families and said that "big business was having an impact on policy."

Mr Lamb promised that the Liberal Democrats would deliver proposals on social care within a year if they win the election, saying they favoured a compulsory contribution similar to that put forward by Labour. However, the Conservatives said they preferred a voluntary scheme—an idea dismissed by both Mr Burnham and Mr Lamb, who said a voluntary policy would have only a 20% uptake, which would benefit only 10% of those who need help.

The three men had different ideas on the role of private providers in the NHS. While Mr Burnham repeated his mantra of "NHS first" in the provision of services, Mr Lamb said there should be a level playing field for all providers, while Mr Lansley said that "patients deserve to have the best possible care from whoever can provide it."

Cite this as: *BMJ* 2010;340:c2238

The political power of cancer

David Cameron thinks that promising cancer patients unfettered access to cancer drugs is an election winner. **Nigel Hawkes** explores the background to the issue

Nigel Hawkes LONDON

To rally the faithful it's never a bad idea for a Tory leader to champion an idea nurtured by the *Daily Mail*—but without necessarily admitting it. David Cameron's promise to fund cancer treatments given at the end of life without regard to measures of cost effectiveness tapped into that newspaper's hatred of the UK National Institute for Health and Clinical Excellence (NICE) and its readiness to spring to the aid of patients who find themselves on the wrong side of a NICE judgment.

But why cancer and not Alzheimer's disease or mental illness? Dan Wellings, head of public health and social marketing at the survey research company Ipsos-

MORI, said, "When we ask questions about the biggest health problems facing people today, cancer tops the list," he says. "It's above obesity, it's above diabetes, and it's above mental health by a long, long way. That's what politicians recognise."

The Conservative party's position on anticancer drugs is that too few patients in the UK are getting them in comparison with those in similar countries and that reforms of the system intended to make more end of life drugs accessible to more patients have failed. The party believes that, in the long run, value based pricing of drugs will solve the problem: if the drugs are ineffective, the companies making them will not get paid. But bringing in value based

pricing will take several years.

Until then the Tories' policy is that if a clinician believes that a particular drug will benefit a patient at the end of life then that patient will get it. The plan bypasses NICE, though the Tories say that they have no argument with NICE, only with the framework within which it works.

For end of life treatments this framework came into effect in January 2009. The normal rules on the cost per quality adjusted life year (QALY) of a drug can be modified if four conditions are met: patients have a life expectancy of 24 months or less; the treatment offers an extension to life of at least three months; no alternative drug with similar benefits is available; and the patient



David Cameron talks to Gurpreet Bharya in the teenage cancer unit at University College Hospital, London

population is small. A greater cost per QALY than the normal threshold of £30 000 (€35 000; \$45 000) can then be considered.

The new rules were meant to end the stories about patients mortgaging their houses to pay for a few more months of life but have not done so. Since the rules came in, NICE says it has completed seven assessments: five that recommended the drugs considered and two that rejected them. But

Rural Scotland needs innovative solutions for out of hours care

Bryan Christie EDINBURGH

Serious shortcomings have been identified in out of hours services to rural and remote parts of Scotland since family doctors were allowed, in 2004, to opt out of providing 24 hour care.

A report from the Scottish parliament's health committee says that trust and confidence in current services "has clearly been lost" and urges NHS boards to work with local communities to develop solutions.

The report was prompted by complaints from several remote communities across Scotland that they have been left with little or no medical cover at night and at weekends. In one of these, Kinloch Rannoch in Perthshire, the nearest doctor is 30 km away along single track roads. Out of hours care is currently being provided by first responders trained in first aid.

It has been calculated that it would cost a minimum of £150 000 (€175 000; \$230 000) a year to provide round the clock medical cover for Kinloch Rannoch, which works out at around £400 a patient. This compares with £8 a patient in Glasgow and £43 in rural Argyll.



Round the clock care in some areas in Scotland costs £400 a patient, compared with £8 in Glasgow

However, the health committee says that innovative solutions to these problems have already been found in some parts of Scotland and should be examined by other areas to see whether similar approaches can be effective. These include the use of teams of advanced nurse practitioners in Grampian and salaried GPs in the Borders who also work in hospital accident and emergency departments to make the work more varied and attractive.

The report, the culmination of a six month inquiry, says, "NHS Boards should be given

responsibility for devising—and should be enabled to deliver—specific, sustainable and often innovative arrangements to meet the needs of individual communities. This should be delivered in consultation with these communities."

The committee also found that rural communities had little confidence in the medical helpline NHS 24 and that patients were confused about whom they should contact for help.

Report on Out-of-Hours Healthcare Provision in Rural Areas is available at www.scottish.parliament.uk.

Cite this as: [BMJ 2010;340:c2291](#)



RICHARD POHLE/THE TIMES/PA

For six further treatments for which guidance is not yet final, NICE is minded to reject five: three because the criteria are not fulfilled; two because the appraisal found against them. These five would affect another 4260 patients a year.

These statistics can be used two ways: by NICE to argue that of the drugs that met the end of life criteria most were approved, and by critics to argue that of the drugs submitted to NICE under these rules most were rejected. The Rarer Cancers Forum, a charity supported by a number of drug companies, published a report in March calling for an urgent independent review of the way NICE is interpreting the end of life criteria.

The forum's chief executive, Andrew Wilson, said, "It is unacceptable that many thousands of patients are still missing out on the treatments they need and which their doctors want to give them because NICE has decided their treatment does not meet some arbitrary criteria."

The Association of the British Pharmaceutical Industry agrees that the end of life criteria are not delivering the result that was envisaged when the need for them was agreed. In many cases, it says, drug companies have offered access schemes—essentially, cutting prices—but have still had their products turned down. The Rarer Cancers Forum lists 15 such schemes, of which six resulted in a positive recommendation and nine in a rejection.

David Cameron's plan did not, therefore, come out of the blue but has support from the industry and from patients. Its estimated cost, £200m a year, is almost exactly what the NHS will save by not having to pay higher employers' National Insurance contributions if the Tories, who will axe the proposed increase, are elected. But is this not, as John Appleby of the healthcare think

tank the King's Fund said, a false claim, as the increase in National Insurance has not occurred, and you cannot claim to save what you are not already spending? Andrew Lansley, the Tories' shadow health secretary, responded by saying that the increase in National Insurance is expected and is therefore in the forward spending plans of the NHS. So it is a saving, at least one that cash prudent finance directors would have already budgeted to spend.

These arcane considerations may not matter to most voters, anyway. When Ipsos-Mori has polled people in the past about NHS spending, a third say that the NHS should provide

all drugs and treatments, no matter what the cost is. "The public thinks you can find the money somewhere," Mr Wellings says. And if the political heat is great enough, the NHS generally can.

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this list excludes two appraisals in which the end of life criteria were not satisfied and that therefore also ended in rejection.

As a result of these appraisals 8450 patients a year gained access to drugs they would not otherwise have had. But 16 000 patients were denied access: half because the drug was deemed not to meet the end of life criteria; half because the criteria were met but the drug still failed the cost effectiveness test.