

UK NEWS Many trusts fail to monitor impact of patients' complaints, p 739

WORLD NEWS Scientists welcome ruling on patent on breast cancer gene, p 740

bmj.com Mother asks surgeons to perform hysterectomy on daughter with cerebral palsy

Tooke inquiry calls for major overhaul of specialist training for medical graduates

Lynn Eaton LONDON

Doctors' postgraduate training needs to be completely reformed after the "sorry episode" of Modernising Medical Careers (MMC), John Tooke recommends in a highly critical report.

Professor Tooke's interim report, published on Monday, calls for the national computerised application system to be scrapped and for an end to the "run through" training introduced as part of MMC.

And he wants to see UK medical graduates automatically guaranteed a place on the first year of foundation training (F1). They would then, however, be expected to take a national examination at the end of the F1 year. This would give them a national rating that they would use to compete for training positions at a local level. Candidates from other European Union countries would also be able to apply for these posts, but not at the F1 stage.

However, the issue of medical graduates from outside the EU must also be dealt with, said Professor Tooke. "That's not to say that they have not made a fantastic contribution to the NHS in the past—and currently."

But when it costs £200 000 (€290 000; \$410 000) to £250 000 to train a UK medical graduate, said Professor Tooke, "some common sense has to prevail."

Professor Tooke, dean of the Peninsula Medical School, was asked in April by the then health secretary, Patricia Hewitt, to investigate the failed implementation of the government's Modernising Medical Careers programme. His interim report will be followed by six weeks' consultation, and then by a final report at the end of the year. His proposals, if accepted, could be fully implemented within two or three years, he believes.

Under his proposals, medical graduates who successfully complete their F1 year and gain entry to the medical register would then move into core specialty training, lasting three years. Trainee doctors would spend six sessions of six months each in one of a small number of defined core programmes (including medicine, surgery, and family medicine).

At the end of the core specialty training they would compete for the next round as

a specialist registrar. After this round they would emerge as either specialists or GPs. Appointment to a consultancy might entail a further examination. The report recommends that GP training should be extended from three to five years.

He was highly critical of the way the Department of Health had managed the whole Modernising Medical Careers project, which was managed by two separate people, the chief medical officer and the director of workforce.

To add to the problems, Professor Tooke said, neither the computerised medical training application service (MTAS) nor non-EU overseas medical graduates fell within the remit of either of the two senior managers.

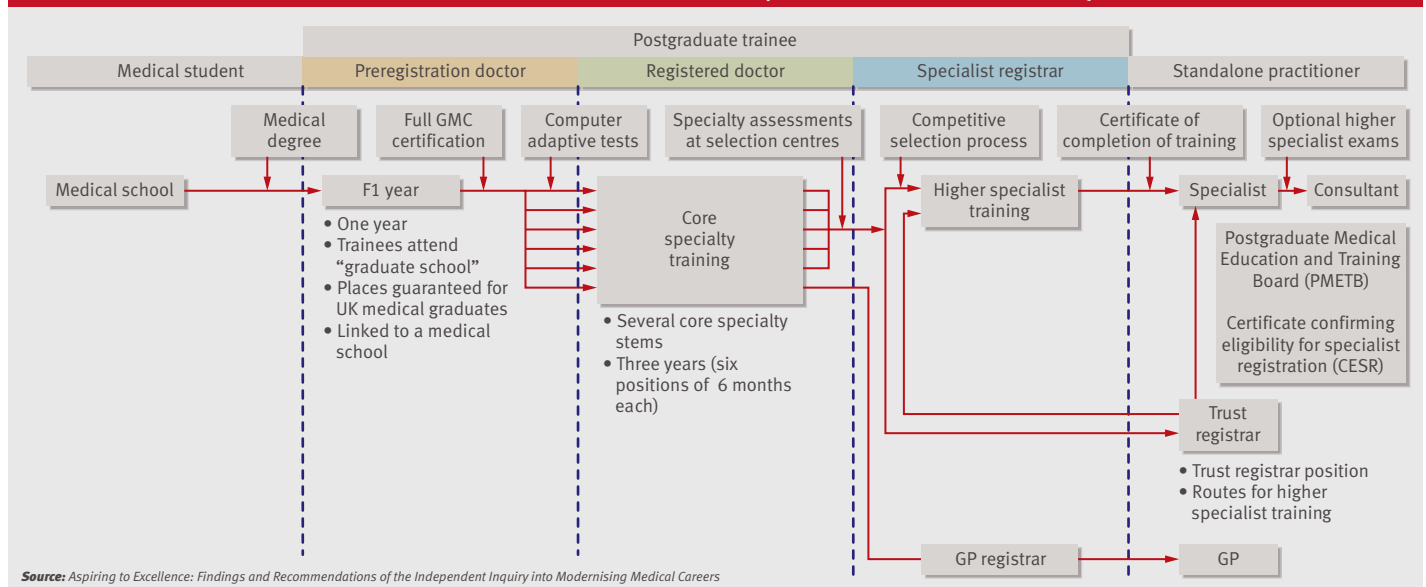
Commenting on the failings of MTAS Professor Tooke said, "Many of the problems were through the rushed implementation. Why, given the importance of this project, would you want to rush it? The process was not adequately managed."

See News p 738 and Editorial p 733

The report is at www.mmcinquiry.org.uk.

“Why, given the importance of this project [MTAS], would you want to rush it?”

STRUCTURE OF MEDICAL POSTGRADUATE TRAINING, AS RECOMMENDED BY TOOKE INQUIRY



Many trusts fail to monitor impact of patients' complaints

Zosia Kmiotowicz LONDON

NHS trusts in England are failing to act on and learn from the complaints they get, says the national healthcare watchdog.

Results from the Healthcare Commission's first ever audit of complaint handling in the NHS show that the way in which complaints are followed up varies greatly.

The commission identified the 10% of trusts that were most at risk of not meeting the core standard set down by the government on handling complaints. These 32 trusts, together with 10 others selected because they handled complaints well, were inspected by the commission in February and March this year.

The core standard requires trusts to make complaints procedures accessible, to act on concerns and make changes where appropriate, and to ensure that complainants are not discriminated against.

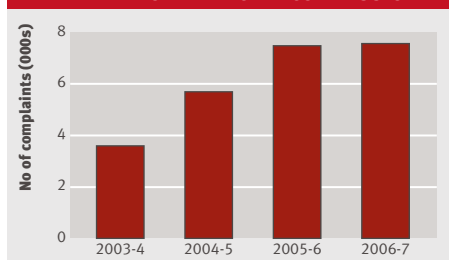
The inspectors found that only two of the 32 poorly performing trusts had adequate arrangements in place across all standards, 12 had areas for improvement, six were at risk of not complying with the core standard, and 12 had a significant lapse that could affect their rating in the commission's annual health checks.

The commission could have issued a total of 96 notifications to the 32 poor performing trusts: one for each of the three standards. However, overall the commission issued 25 notifications to 18 trusts. Most of these (14) related to discrimination against complainants.

The main concern was that no system was in place to monitor whether complaining had had a detrimental effect on patients' subsequent care.

Is Anyone Listening? A Report on Complaints Handling in the NHS is available at www.healthcarecommission.org.uk.

NUMBER OF NHS PATIENTS' COMPLAINTS REFERRED TO HEALTHCARE COMMISSION



Source: Healthcare Commission

Patients admitted as emergencies should

Zosia Kmiotowicz LONDON

Nearly four in 10 patients who are admitted to hospital as emergencies receive suboptimal care that in many cases is detrimental to their outcome, a UK study has found.

The latest report from the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) says that such patients should be seen by a senior doctor within 12 hours and that standardised forms should be introduced across the

NHS to make it clear that this has happened.

NCEPOD, an independent charity that aims to improve the delivery of health services, reviewed the care given in the first 24 hours and over the next seven days to more than 3000 adults admitted to 363 hospitals in England, Wales, Northern Ireland, and the Isle of Man on two predetermined dates in February 2005. It found that trainee doctors are failing to recognise the severity of very

sick patients when they are first seen in accident and emergency departments.

The report cites the example of a patient who was admitted to hospital from a nursing home and was assessed in the emergency department by a junior doctor but was given no treatment plan. When the patient was assessed by a consultant 17 hours after arriving in the emergency department the patient's condition had deteriorated.

Government scraps national training application system

Lynn Eaton LONDON

A national computerised system will not be used for matching junior doctors to specialist training posts next year, the Department of Health has confirmed.

Instead deaneries will organise their own recruitment process for posts in England in 2008, and junior doctors' start dates will be staggered, the health minister Ben Bradshaw has said. He has also announced plans to re-examine the current policy allowing medical graduates from outside Europe to apply for jobs in the United Kingdom.

Abandoning a national computerised system will leave deaneries responsible for advertising their own vacancies and issuing their own application forms (which will ask for CV type information). A maximum of three recruitment processes will take place each year, although the main intake will continue to be in August, particularly for the first year of specialty training.

"We have learned important lessons from the difficulties with this year's recruitment process and have apologised

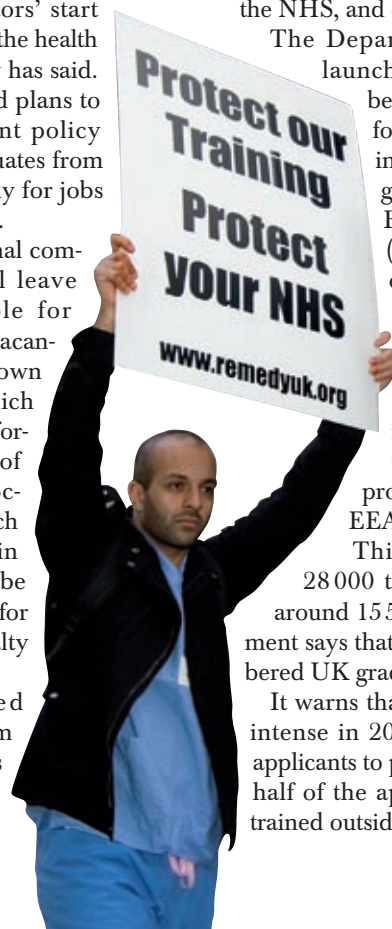
to junior doctors for any distress caused to them and their families," said Mr Bradshaw. "We said we would listen to doctors and their representatives, and today's announcement reflects this."

He added that any future system would be "rigorously tested and agreed with doctors, the NHS, and others involved."

The Department of Health has also launched a consultation on how best to manage applications for foundation and specialty training programmes from medical graduates from outside the European Economic Area (EEA). The consultation ends on 22 October. One suggestion is that jobs should be filled by non-EEA applicants—including applicants with limited leave to remain in the UK, such as those on the highly skilled migrant programme—only if no suitable EEA applicant was available.

This year in England nearly 28 000 trainee doctors applied for around 15 500 posts. The health department says that overseas graduates outnumbered UK graduates applying for posts.

It warns that competition will be more intense in 2008 and forecasts a ratio of applicants to posts closer to 3:1. More than half of the applicants are likely to have trained outside Europe.



see consultant in 12 hours

Despite aggressive treatment the patient died 24 hours later.

Overall the review found that 40% of patients were not seen by a consultant within 12 hours of admission. In half the cases poor documentation made it impossible to determine when a consultant saw the patient.

The authors judged that in 16% of cases the time to the first review by a consultant was unacceptably long, which may have worsened the outcome.

Part of the problem may be the fact

that consultants caring for 69% of the patients had other duties to perform while on call, and 21% were doing more than three duties at the same time. In addition, 15% of units did not have 24 hour access to computed tomography and 7% did not have access to conventional radiography.

The report calls for all patients admitted as emergencies to be seen by a consultant within 12 hours and for consultants on call to be available to deal with emergency admissions.

The report is available at www.ncepod.org.uk.



Trainee doctors are failing to recognise the severity of very sick patients

“Increased investment in medical training since 1997 means that the NHS no longer relies so heavily upon doctors from outside Europe,” said Mr Bradshaw. “We now have four new medical schools, and medical school places in England have increased from 3749 in 1997 to 6451 in 2007.

“It is also important to recognise that most international medical graduates who come to work or train in the NHS don’t stay very long: 80% leave within four years of joining the NHS. Ultimately the NHS loses the trained GPs and consultants it needs when international medical graduates leave.

“The choice facing us and the medical profession is whether we accept that international medical graduates will displace UK medical graduates, or we decide to maximise the opportunities for UK medical graduates and the taxpayers’ investment in them. Most other countries give a priority to their own medical school graduates when appointing to specialist training posts.”

The BMA says that overseas medical students currently at UK medical schools should be allowed to complete their full postgraduate training in the UK. The BMA’s chairman, Hamish Meldrum, said, “The immigration status of overseas doctors during the recruitment process this year was extremely vague, creating the possibility of discrimination.

“Overseas medical students have come to the UK on the understanding that they’d be able to train and work in the NHS. They’ve often made personal and financial sacrifices to come here. It would be hugely unfair to deny them opportunities to work in the NHS.”

The consultation paper on international medical graduates is available at www.mmc.nhs.uk.

Darzi promises easier access to GPs and 150 new health centres

Zosia Kmietowicz LONDON

The health minister Ara Darzi was criticised last week for not having consulted widely enough before publishing his review of the NHS. But his report was welcomed by many commentators for the extra funding that it promised for new technologies.

In his interim report, which was launched earlier than expected, Lord Darzi has promised better access to GPs, a new health innovation council to develop and deploy high technology health care, infection screening for all patients admitted to hospital, and annual infection control inspections in acute trusts.

Lord Darzi insisted that his vision for a world class NHS throughout England would be achieved by giving greater power to local NHS staff and others with an interest in developing health services. He said, “This is not about imposing more changes from the centre. Effective change needs to be led locally, driven by clinicians and others working in partnership across the service.”

To improve access to GPs Lord Darzi said that 100 new practices would open in areas with the worst provision and that new money would be made available to create 150 new GP run health centres that would be open seven days a week from 8 am to 8 pm. Another plan in the report is for at least half of all new and existing general practices to open their doors on Saturday mornings or one or more evenings

each week, the Department of Health announced.

The health innovation council will be chaired by Lord Darzi and will be jointly funded by the health department and the Wellcome Trust to the tune of £100m (€145; \$204m) over the next five years.

Although some of the report’s proposals will not be developed until the full report is launched next year, to coincide with the 60th anniversary of the NHS, others—such as access to GP services—will be acted on immediately, said the secretary of state for health, Alan Johnson.

The package of changes to improve access to GPs is “a massive investment in primary care provision and will benefit millions of patients across the country,” Mr Johnson said.

However, Iona Heath, a GP in north London and chairwoman of the Royal College of General Practitioners’ international committee, said that the proposals were a mismatch between what GPs had negotiated with the government in their contract and what was being planned. “The contract excludes GPs from working outside the hours of 8 30 am to 6 30 pm so I don’t see quite how it [the proposed increased access] is supposed to work,” she said.

If the thinking behind longer opening hours was to introduce shifts for GPs then this would destroy the balance between access and continuity, where patients could see the same doctor, said Dr Heath.

Richard Vautrey, deputy chairman of the BMA’s General Practitioners Committee, called for doctors’ leaders to be included in talks about key issues such as access to GPs and infection control.

The interim report is at www.nhs.uk/ournhs.

“A massive investment in primary care ... will benefit millions of people”

Nobel prize is awarded for work leading to “knockout mouse”

Geoff Watts LONDON

The award of the 2007 Nobel prize in physiology or medicine to three gene technologists has been widely applauded by biologists. They believe that the three scientists' achievements will play a major part in revealing the extent of genetic influences in human disease.

Rather less enthusiastic is the animal rights lobby. The work for which Mario Capecchi, Martin Evans, and Oliver Smithies were awarded the prize led to the development of the quaintly but aptly named “knockout mouse.” Now an essential tool of laboratory research into the role of genes, its creation reversed a fall in the number of experiments carried out each year on animals.

The Nobel citation talks of the trio's discovery of “principles for introducing specific gene modifications in mice by the use of

embryonic stem cells.” Working independently, Professor Capecchi, of the University of Utah, and UK born Professor Smithies, of the University of North Carolina, showed how such modifications could be brought about by using homologous recombination, the natural process by which our maternally and paternally derived chromosomes are able to swap sections of their genetic material.

The outcome of these exchanges is an increase in the genetic variation in a population, fostering the emergence of new characteristics through which natural selection brings about evolutionary change.

Professors Capecchi and Smithies showed that this recombination mechanism could be exploited to incorporate completely new DNA—new genes, in other words—into a

genome. It was work by the third of the trio, Professor Evans, of the University of Cardiff, that allowed this principle to be exploited in the production of genetically modified animals.

Working with stem cells from early mouse embryos, Professor Evans first showed how to grow them in culture. He went on to inject stem cells of one mouse strain into the embryo of a different strain, then implanted the embryo into a surrogate mother. The mice born from this procedure turned out to be a mosaic of cells: some of one strain, some of the other.

He then used a retrovirus able to integrate its own genes into mouse DNA to genetically modify mouse embryonic stem cells. This time the resulting mice were a mosaic of normal cells and of others carrying the viral DNA. Further breeding allowed him to produce mice in which the germ line had been altered, so ensuring that all cells in all their offspring carried the alien genetic material.

In the 1980s the technologies devised by the three researchers were brought together to create animals with specific genetic abnormalities.

The great strength of the new technique lies in the possibility it offers for gene targeting. In essence this involves using a length of DNA to inactivate a particular gene: to “knock it out.” This allows researchers to investigate the effects of single genes.

Commenting on Professor Evans's contribution, Martin Rees, president of the Royal Society, described the award as fitting recognition for groundbreaking research. “He is a world leader in mammalian genetics, and his research has undoubtedly increased our understanding of human diseases,” said Lord Rees. “Stem cell research has immense potential. It is a field where UK scientists . . . have made pioneering contributions and maintain a powerful presence.”



Professor Martin Evans helped propel research into genetic diseases

NICK TREHARNE/CARDIFF UNIVERSITY

Scientists welcome ruling on patent on breast cancer gene

Rory Watson BRUSSELS

The European Patent Office has rejected an appeal by the US drug company Myriad Genetics and the University of Utah against an earlier decision revoking the patent concerning the BRCA1 gene and its applications.

The ruling has been welcomed by European researchers working on

tests for a predisposition to breast and ovarian cancer. Dominique Stoppa-Lyonnet, head of the genetics department at the Institut Curie in Paris, said: “This is an important decision, since it means we can continue our work without fear of being attacked for infringing a patent.”

The decision is the latest stage in a long running battle between

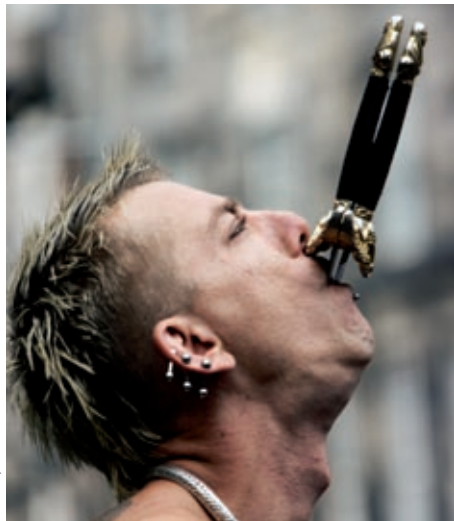
European public health practitioners and the US company. Myriad Genetics was granted the patent in November 2001 and handed over its rights to the University of Utah Research Foundation three years later, while keeping an exclusive licensing agreement.

The patent relates to the BRCA1 gene isolated from the human

genome, to mutant forms of that gene, and to its use in diagnosing predisposition to breast and ovarian cancer. Among other things the patent describes diagnostic methods designed to identify mutant forms of the gene and to facilitate early detection of enhanced susceptibility to these forms of cancer.

Soon after the patent was awarded,

Inventors of “gay bomb” and *BMJ* authors win Ig Nobel prizes



THE NEWS/ALAMY

Study into perils of sword swallowing reaps award

Jeanne Lenzer BOSTON

A novel weapon under investigation by the US Air Force has won this year's Ig Nobel peace prize. The Ig Nobel awards, given for science that “first makes you laugh, then makes you think,” were given to recipients from five continents by six winners of the actual Nobel prize last week at Harvard University.

The unusual weapon, confirmed by Pentagon sources, is a “gay bomb” (<http://blog.washingtonpost.com/offbeat>, 12 Jun, “Sunshine project uncovers US military ‘gay bomb’”). The project, which officials say has now been scrapped, was to come up with a device to release unspecified hormones that could be absorbed through the skin or lungs, thereby incapacitating soldiers who—according to the plan—would be too busy swooning over each other in homosexual ecstasy to waste any time dashing about planting roadside bombs.

The Pentagon did not respond to inquiries

from the *BMJ* about possible future plans for its “make love not war” initiative.

Brian Witcombe, a consultant radiologist from Gloucester, won this year's Ig Nobel medicine prize for his article in the *BMJ*, “Sword swallowing and its side effects” (*BMJ* 2006;333:1285-7). Dr Witcombe said: “I was interested in swallowing disorders.”

He accepted the prize jointly with his coauthor, Dan Meyer, a sword swallower from Antioch, Tennessee, who swallowed a 60 cm sword before an awestruck audience at the ceremony. Dr Witcombe said he was surprised that sword swallowers use real, not trick, swords.

The biology prize went to Johanna van Bronswijk, of the Eindhoven University of Technology, the Netherlands, for doing a census of “all the mites, insects, spiders, pseudoscorpions, crustaceans, bacteria, algae, ferns, and fungi with whom we share our beds each night.”

The erectile dysfunction drug sildenafil (Viagra) made its first showing at this year's Ig Nobel ceremony. Patricia Agostino and her colleagues at the Department of Science and Technology at the Universidad Nacional de Quilmes, Argentina, found that sildenafil can alleviate symptoms related to jet lag—in hamsters. In an interview with the *BMJ* Dr Agostino's colleague, Diego Golombek responded to concerns that the erectile side effects of the drug might lead pilots to reach for the wrong joy stick. Dr Golombek said that although his team had yet to conduct clinical trials in humans, he believed that sildenafil might enhance safety in the air, not detract from it, as the drug “speeds up production of cyclic GMP [guanosine monophosphate], allowing faster re-entrainment of circadian rhythms,” so pilots would not be jet lagged.

Government backs down on merger of regulatory bodies

Adrian O'Dowd LONDON

The government has decided not to merge the United Kingdom's two regulatory bodies in the field of human reproduction and embryo research. But it gave approval for the creation of human-animal embryos (“inter-species embryos”) for the purposes of research into disease, with the agreement of the regulator.

The Department of Health's previous proposal to merge the Human Fertilisation and Embryology Authority (HFEA) and the Human Tissue Authority (HTA) has been formally dropped.

The decision was announced as part of the government's formal response last week to a report published in August by a committee (representing both houses of Parliament) that scrutinised the draft bill on human tissues and embryos (*BMJ* 2007;335:224-5, 4 Aug).

The public health minister, Dawn Primarolo, said there was now a clear way forward for the draft bill, which represented a major overhaul of the law on assisted human reproduction and embryo research. The bill is likely to be included in the Queen's Speech next month.

Ms Primarolo said the idea to merge the HFEA and the HTA to become a new Regulatory Authority for Tissue and Embryos had been dropped after consultation with stakeholders.

“This bill will allow legitimate medical and scientific use of human reproductive technologies for research to flourish in this country, while giving the public confidence that they are being used and developed sensibly with appropriate controls in place,” she said. The government's response is available at the publications and statistics section of www.dh.gov.uk.

opposition to the decision began to emerge among public health researchers in Europe. Beginning with the Institut Curie, Paris Public Hospitals, and the Institut Gustave-Roussy, near Paris, it soon included genetics societies, Greenpeace, and the Dutch and Austrian health ministries.

Critics feared that the patent's wide ranging nature would give Myriad Genetics a monopoly in a key area of research and would force European

laboratories to send DNA samples from patients who are considered to be at risk of the cancers to the company's testing facilities in Salt Lake City.

Not only would European researchers be open to legal attack if they failed to comply, but the arrangements, argues the Institut Curie, would have enabled the company to build up the world's sole genetic data bank.

For more see www.epo.org.



Scientists at the Institut Curie in Paris test for the BRCA1 gene

IN BRIEF

Bush vetoes children's health bill:

George Bush has vetoed a bill that would have expanded US health insurance coverage to four million uninsured children for five years, at a cost of \$35bn (£17bn; €25bn). Democrats and some Republicans in Congress hope to over-ride the veto on 18 October. See p 749.

Chinese doctors agree not to use prisoners' organs:

The Chinese Medical Association has issued a statement agreeing that the use of organs of executed prisoners for transplantation, except for members of their immediate family, should be forbidden. The promise to change current practice comes after years of international condemnation.

Older Dutch people seek help for alcohol problems:

Demand for alcohol related outpatient care among Dutch people aged 55 or over has risen by 80% since 1996. In younger groups the rise is 35%. People aged over 55 now account for one in five patients seeking such treatment, data from the National Alcohol and Drugs Information System show. See www.sivz.nl.



Polish doctors strike over low pay: The crisis in Poland's health system escalated after 2000 doctors resigned this week in protest against low pay and poor working conditions, and a further 1000 doctors staged strikes, ahead of parliamentary elections in three weeks' time.

Ombudsman upholds complaint by woman who was denied a scan:

A woman who was refused funding to undergo a scan of her lungs has had her complaint against Health Commission Wales upheld by the Public Services Ombudsman for Wales. The woman needed positron emission tomography or a thoracotomy to determine whether a mass near her lungs was malignant. The ombudsman said the decision was "perverse and absurd." See www.ombudsman-wales.org.uk.

More US pregnant women are using antidepressants:

The proportion of pregnant women in the United States who use antidepressants is now nearly 8%. The percentage grew from 2% in 1996 to 7.6% in 2004 and 2005. A study of 118935 deliveries between 2001 and 2005 shows that 6.6% of women were prescribed an antidepressant during pregnancy (*American Journal of Obstetrics and Gynecology* doi: 10.1016/j.ajog.2007.07.036).

UK is failing heavily addicted smokers, college report says

Susan Mayor LONDON

Heavily addicted smokers do not get enough support to help them quit, warns a UK report published last week. It calls for better access to nicotine replacement treatment as part of a harm reduction strategy.

It proposes that a new nicotine regulatory authority be established to oversee all aspects of regulation of nicotine products and to coordinate efforts to end the advantage that cigarettes currently have in the marketplace over alternative products such as gums and patches.

The report, published by the Royal College of Physicians, argues that smokers smoke mainly for the effects of nicotine, that nicotine itself is not especially hazardous, and that providing nicotine in an acceptable and effective form such as cigarette substitutes could save millions of lives. It recommends changing the regulations governing nicotine products so that substitutes are as easy to buy as cigarettes and so that they can provide a higher level of nicotine than is provided by the substitutes currently available.

Current regulatory systems governing nicotine products in most countries, including the United Kingdom, actively discourage the development, marketing, and promotion of substitute products to smokers, the

“Smokers smoke because they are addicted to nicotine”



AP PHOTO/SPL

Stronger tobacco substitutes should be allowed

report says. In contrast, cigarettes are relatively unregulated, giving them an unfair advantage in the marketplace.

John Britton, professor of epidemiology at Nottingham University and chairman of the royal college's tobacco advisory group, said, “Smokers smoke because they are addicted to nicotine, but it isn't nicotine in cigarette smoke

that kills: it's the hundreds of other toxic chemicals that come with it.”

Harm Reduction in Nicotine Addiction: Helping People Who Can't Quit is at www.rcplondon.ac.uk/pubs/brochure.aspx?e=234.

Bristol-Myers Squibb made to pay \$515m

Janice Hopkins Tanne NEW YORK

Bristol-Myers Squibb and its subsidiary Apothecon have agreed to pay more than \$515m (£255m; €365m) in a settlement with the US Department of Justice and the Office of the United States Attorney for Massachusetts to resolve allegations involving their drug marketing and pricing practices.

The Department of Justice said in a press release that the “settlement covers a wide assortment of illegal marketing and pricing practices.”

The department said that from about 2000 to mid-2003 Bristol-Myers Squibb made illegal payments to doctors and other healthcare providers to induce them to purchase the company's drugs. The payments were made in the form of consulting fees and expenses to participate in consulting programmes, advisory boards, and preceptorships. Some of the

programmes involved trips to luxury resorts.

From 1994 to 2001 Apothecon paid illegal remuneration to retail pharmacies and wholesalers to buy its drugs. The government alleged that in paying this illegal remuneration the company and its subsidiary submitted false and fraudulent claims to the US government healthcare programmes.

The government also said that from 2002 to 2005 Bristol-Myers Squibb promoted its atypical antipsychotic drug aripiprazole (sold as Abilify) for use in children and for treating dementia related psychoses. The drug is approved only for use in adult patients with schizophrenia or bipolar disorder. The company's sales representatives urged doctors and healthcare providers to prescribe the drug for off-label use in children and in adults with dementia related psychoses in nursing homes.

In addition, the government said that the

Systematic review shows no evidence that individualised herbal treatments are effective

Susan Mayor LONDON

No good evidence exists that individually tailored prescriptions of a mixture of herbs are effective, concludes a systematic review published last week.

The study reviewed all available studies of individualised herbal medicine for any indication (*Postgraduate Medical Journal* 2007;83:633-7). The researchers, from the Universities of Exeter and Plymouth, found only three randomised controlled trials out of 1300 studies they identified that they considered were of sufficient quality to draw meaningful conclusions. These three trials showed no convincing evidence of benefit.

One trial, involving patients with osteoarthritis of the knee, showed a non-significant trend favouring active treatment over placebo. However, the researchers said that this trend probably resulted from large differences at baseline and regression to the mean.

In a trial of patients with irritable bowel syndrome, individualised herbal treatment was better than placebo in four of the five outcomes tested but was inferior to a standardised herbal treatment (a mixture of herbs not tailored to the individual) in all outcomes.

In the third trial they looked at, individualised herbal treatment was no better than placebo in preventing chemotherapy induced toxicity.

The researchers warned: "Individualised herbal medicine, as practised in European medical herbalism, Chinese herbal medicine, and Ayurvedic herbal medicine, has an extremely sparse evidence base and there is no evidence supporting its use in any indication.

"The paucity of data supporting the effectiveness of individualised herbal medicine, and the important safety concerns associated with this particular form of phytomedicine, should

be taken into account by policymakers."

In an accompanying editorial Edzard Ernst, professor of complementary medicine at the Peninsula Medical School at the University of Exeter, considered that the public was in danger of confusing different types of herbal medicine.

He explained that phytotherapy (plant therapy practised by a health practitioner), which includes use of

with traditional herbal medicine, in which practitioners prescribe individual mixtures of herbs and over the counter remedies that are based on plants and sold as dietary supplements.

Professor Ernst argued that properly conducted clinical trials should be carried out as part of improving the regulation of herbal medicines.



specific herbs, such as St John's wort, that contain a range of pharmacologically active ingredients and for which data on effectiveness are "reasonable," is often confused

"Individualised herbal medicine has an extremely sparse evidence base"

to settle US lawsuits

company and its subsidiary set fraudulent and inflated prices for a number of cancer and generic drugs, knowing that government health programmes set reimbursement rates that were based on those prices.

Finally, the government said that Bristol-Myers Squibb misrepresented its best price for the antidepressant nefazodone (Serzone). The company was supposed to report to Medicaid, the government health insurance programme for poor people, the best price it charged its commercial customers. The result was that Medicaid did not get the best price.

Bristol-Myers Squibb said it "is pleased to have resolved these matters from the past and is proud of its commitment to conduct business with the highest standards of integrity in its mission to extend and enhance human life."

German pharmacists are investigated for using unregistered drugs in chemotherapy

Annette Tuffs HEIDELBERG

More than 100 pharmacies in Germany are being investigated for importing drugs not registered in Germany for use in the preparation of intravenous chemotherapy. Two companies in Denmark and the Isle of Man that import and export drugs are also being investigated.

The district attorney in Mannheim said in a press release that the main charge being considered was one of fraud, because the chemotherapy drugs were bought at low prices abroad but had been illegally sold at the high price of registered drugs in Germany.

The chief financial victims of the alleged fraud seem to be the insurance companies, because they were charged inflated prices. The problem came to light when a health insurance company noticed irregularities in

the billing for courses of chemotherapy.

It is not yet known whether patients were harmed. The district attorney said it was possible that fake drugs were used, as well as drugs that were ineffective or did not contain enough of the active ingredient.

Insurance companies have probably lost several million euros, because one course of chemotherapy costs between €15000 (£10000; \$21000) and €25000. The German Society of Haematology and Oncology says that about €900m is spent every year on intravenous chemotherapy in Germany. The profit margin for the individual pharmacy preparing the infusion is normally between 10% and 50%.

Of the 21000 independent pharmacies in Germany, only 300 have a licence to prepare intravenous chemotherapy.