

Concerns over oxygen service continue to be raised

In response to the failures of the new home oxygen service, an action checklist has been drawn up by the Department of Health, the NHS and the new suppliers, but problems with the transfer of the service have continued to be raised.

The checklist states that GPs should continue to issue FP10s to patients requiring cylinder oxygen and that pharmacy contractors who supply against an FP10 prescription will be paid until the patient transfers to a new supplier. The guidance is available via *PJ Online* (www.pjonline.com/links/pj).

Difficulties with the introduction of the new service have continued to be highlighted this week, however. One pharmacist complained to *The Journal* that Allied Respiratory had told patients that it could not cope and that patients should dial 999 for help.

Steve Gullick, managing director of Allied Respiratory, told *The Journal*: "Last week we received in excess of 24,000 calls from existing cylinder patients but, due to the inaccurate information given to us by GPs, the contract was unserviceable. However, at no point did we suggest that patients call 999."

The chaotic start of the new contracts has also been described in several **Letters** to *The*

Journal (p204) and pharmacists have complained that they have been unable to contact Air Products via its helpline. A spokesman for Air Products told *The Journal*: "There were certainly difficulties last week and we apologise to those patients and pharmacists who could not get through. Along with the health authorities, we planned for around 3,000 calls a day to our helpline — more than 10 times the number you would expect during normal operations. In the first two days, 12,500 calls were made to our helpline. The company responded quickly to the volume of calls and put in place more than three times the levels of resource."

Another pharmacist writes that the wife of a patient receiving oxygen was told by BOC Vitalair that, in order to find information about the new service, she should visit her local library to use the internet. A spokesman for BOC told *The Journal*: "The Vitalair internet forms a part of BOC's communications to patients about the new home care oxygen arrangements. Over the last few months BOC has written to all patients, enclosing an explanatory letter from their local primary care trust and a BOC brochure about the new service. . . . In addition, patients receive a

comprehensive booklet from BOC when they are first supplied with oxygen by BOC." He also explained BOC's delivery policy following concerns that delivery days and times would be limited. "If a patient needs oxygen to be delivered every day then BOC will deliver every day," he said.

Disagreement has continued as to whether the present phased transition was intended. Before the transfer, Primary Care Contracting's communications team said: "After 1 February we expect pharmacists to withdraw progressively from the provision of cylinder services. . . . We expect all pharmacists to continue to provide a cylinder service within the validity of the prescription."

Air Products told *The Journal* this week: "A transition period to the new service was always planned where pharmacies could continue to supply oxygen to patients until they were transferred to the new service."

The Pharmaceutical Service Negotiating Committee said in a statement last week: "Although it was not the Department of Health's intention, where oxygen is required and the surgery cannot contact the new supplier, pharmacies will be reimbursed for dispensing prescriptions dated after 1 February."

Hewitt: 600,000 will quit after smoking ban

Health Secretary Patricia Hewitt predicted that over 600,000 people will give up smoking following Tuesday's Commons vote to ban it in all enclosed work places in England, including public houses and private clubs.

Next month she will issue advice to the NHS and pharmacies on the range of products on offer to help people kick the habit. A Department of Health spokesman said: "Pharmacies will continue to play a leading role in the anti-smoking strategy."

MPs voted 453 to 125 to ban smoking in pubs and nightclubs across England. They then voted 384 to 184 to extend the ban to members-only clubs. The Health Bill will now go to the House of Lords but, given the size of the Commons majority, it is unlikely to be watered down. The Bill is on course to become law in July and will take effect from October 2007, bringing England into line with Scotland, Wales and Northern Ireland.

Those caught lighting up in banned areas will suffer a fixed penalty of £50; proprietors who fail to display no smoking signs face fines of £200; and landlords who do not stop



Cigarette sales to under 18-year-olds can also be banned under the Bill

smoking on their premises will be fined up to £2,500. The Bill also allows ministers to raise the age for buying cigarettes from 16 to 18, and the department will launch a consultation exercise.

The Royal Pharmaceutical Society welcomed news of the ban. President Hemant Patel commented: "We have been lobbying for some time to seek support from MPs for the Society's position on a total ban in public places. . . . It will ultimately save lives."

NHS stop smoking success rates improve by 23 per cent

Between April and September 2005, 137,894 people using NHS stop smoking services said that they had successfully stopped smoking, compared with 112,250 in the same period in 2004, data issued by the Health and Social

Care Information Centre show. Quit dates were set by 264,508 people, 52 per cent of whom were successful. Of those who set a quit date, 82 per cent received nicotine replacement therapy.

7,100 now MUR-accredited

Almost 7,100 pharmacists have been accredited to provide medicines use reviews as part of the new community pharmacy contract, the Pharmaceutical Services Negotiating Committee has announced. The PSNC hopes the maximum number MURs will increase next year to reflect the uptake of the service.

The Society

Opioid prescribing

The Practice Committee is campaigning for sustained release morphine preparations and opioid patches to be prescribed by brand name (p215).

BPC student deal extended

Eligibility for £5 student day tickets for the British Pharmaceutical Conference has been extended to include third-year pharmacy students (p215).

Statutory Committee

Ethnicity data have been included for the first time in the latest annual report of the Statutory Committee (p216).

Pharmacists' rest breaks

A Law and Ethics Bulletin this week gives guidance on making adequate provision for pharmacists to have rest breaks (p216).

ABPI suspends Abbott over code of practice contraventions

Abbott Laboratories Ltd has been suspended from the Association of the British Pharmaceutical Industry for at least six months. Abbott will have to undergo an audit of its ABPI Code of Practice compliance procedures before readmission.

The suspension was imposed after the Prescription Medicines Code of Practice Authority heard anonymous complaints about inappropriate hospitality in 2004 involving two trips to greyhound racing events for 63 health professionals, a visit to a lap-dancing club for one doctor, invitations to senior hospital consultants to attend the Wimbledon Tennis Championships and a hospital department Christmas dinner.

In each case, Abbott told the PMCPA that the staff involved, including the general manager responsible for the Wimbledon invitations, had left the company. It claimed that their actions did not reflect any deficiency in the company's culture or processes.

After publication of the inquiries in the PMCPA's February 2006 code of practice review, Abbott said: "Abbott requires its employees to abide by the company's high standards outlined in its code of conduct. The company's office of ethics and compliance conducts a prompt and thorough investigation into all allegations of inappropriate activ-

ity or behaviour. The company has a zero tolerance policy for behaviours that breach the company's code of conduct. Sanctions are taken, including termination, if violations are found.

"The allegations made during this case relate to the individual actions of a small number of employees in 2004. Abbott conducted a thorough investigation and as a result, these employees either resigned or had their employment terminated."

Suspension of ABPI membership is a severe sanction and Abbott is only the fourth company ever to have faced it. Previous suspensions were of Bayer in 1986, and Duphar and Fisons in 1994.

No company has ever been expelled from the ABPI.

In another case, GlaxoSmithKline has been given a public reprimand for failing to comply with an undertaking it gave the PMCPA after being found guilty of making an unfair claim of superiority for Avandamet (rosiglitazone) compared with sulphonylureas in promotional material. The amended material had made an even more unfair claim. Issuing the reprimand, the ABPI management board said that compliance with undertakings was essential if self-regulation was to be effective.

Industry/ministerial group still trying to encourage pharmaceutical investment

Government ministers and pharmaceutical industry leaders are pressing on with an initiative to try to increase pharmaceutical investment in the UK (*PJ*, 14 April 2001, p498).

On the day of their latest meeting last week, Jane Kennedy, minister for health and co-chair of the Ministerial Industry Strategy Group said: "The Government wants the UK to maintain its position as a leading country for the pharmaceutical industry to develop medicines. We see from taskforce indicators that the UK attracts 9 per cent of world pharmaceutical industry research and development expenditure, while it has less than 4 per cent of the global market for medicines. We want to improve even further on this."

Ms Kennedy added that she wanted to see concrete proposals to maintain the UK's position as leader in developing new medicines when the group meets again in November.

The next stage of the group's work will look at improving the rate at which effective new treatments are made available to NHS patients, facilitating joint working between the NHS and the pharmaceutical industry and new ways of introducing new medicines

and ensuring the safety of medicines that are already licensed, while maintaining patient access to innovative medicines.

It will also develop proposals to help achieve the aims of the European Commission's Pharmaceutical Forum to make Europe a more attractive location for pharmaceutical company investment.

Last week, the Government also urged the pharmaceutical industry, the public sector and non-governmental organisations to develop new affordable treatments for children with HIV and AIDS. The Department for International Development said that although the price of antiretroviral drugs has been dramatically reduced in recent years, paediatric ARVs can cost more than six times as much as adult doses and are often harder to handle in terms of storage and distribution.

International development minister Gareth Thomas commented: "While pharmaceutical companies have done much to help improve access to treatment for HIV, more effort must be made to help provide effective and affordable treatment for children — especially for those in developing countries."

615 tonnes of medicines incinerated in 2004–05

Waste medicines accounted for 614.8 tonnes of the waste that was disposed of by incineration in England in 2004–05. This figure was released in Government statistics two weeks ago and before this week's launch of a Department for Environment, Food and Rural Affairs consultation on waste disposal.

Between the two came a report from the British Society for Ecological Medicine that



Robert Brook/Science Photo Library

Incineration of waste is to increase

called for a freeze on the number of incinerators because of health risks. The report says that studies have shown higher rates of cancer and birth defects around municipal waste incinerators consistent with a causal relationship. It adds that epidemiological studies support this interpretation and suggest that the range of illnesses produced by incinerators may be much wider.

DEFRA's consultation favours an increase in incineration as one of two ways of producing energy from waste and dismisses the fears.

It states: "An independent health impacts review has concluded that on the evidence so far, the treatment of municipal solid waste has at most a minor effect on health."

News in brief

VAT and pharmacists

Treasury minister Dawn Primarolo has signalled that there will be no rethink of the VAT rules applying to pharmacists. In a Parliamentary written reply she said: "While different VAT reclaim rules apply for the different types of pharmacies, these reflect how successive governments have funded NHS VAT costs, and the fundamental difference for VAT purposes between NHS hospital pharmacies, which dispense drugs as a non-business activity, and community pharmacies, which make a 'business' supply when they dispense drugs."

Pharmacists have role in patient safety, says NPSA

How pharmacists can help to improve patient safety is addressed in consultation documents released last week by the National Patient Safety Agency (NPSA).

The consultations will form the basis for four patient safety alerts to be issued in the second quarter of the year, focusing on anticoagulant therapy, wrong route administration errors, preparation and administration of injectable medicines, and paediatric infusion safety.

The draft document on the safe use of anticoagulant therapy highlights that not all workers involved with the prescribing and monitoring of anticoagulants have received the necessary level of training. The proposal suggests the employment of pharmacists and nurses — with specialist training in a specified range of competencies — to prescribe and adjust anticoagulant regimens.

Another area of concern is the potential for errors when inadequate safety checks have been carried out during repeat prescribing and repeat dispensing of anticoagulants in the community. Pharmacists will have a role in formalising the required safety checks when anticoagulants are being dispensed for patients, for example, ensuring that the international normalised ratio (INR) is being



Claire Paxton and Jacqui Farrow/SPL

Intravenous drug infusions are high risk

monitored regularly and that the INR is within range at the prescribed dose.

Several recommendations have been made in the draft document on preventing wrong route errors. If implemented, the recommendations would require that only oral syringes be used for measuring and administering oral liquid medicines and enteral feeds and flushes. Trusts would also be required to use enteral feeding tubes with safe ports that cannot connect to intravenous syringes, and the removal of any adaptors that enable oral syringes to connect to parenteral lines would be mandatory.

The NPSA has made proposals intended to improve the safe preparation and adminis-

tration of injectable products in “near patient areas”. The recommendations include having a pharmacist and a senior practitioner undertake a standardised assessment of the risks involved in preparing and administering parenterals, as well as the risks presented by the individual injectable product. The NPSA plans to introduce a multiprofessional standard of practice for the preparation and administration of injectable medicines.

Paediatric infusion practices were also brought under scrutiny to produce the final draft patient safety alert. The NPSA calls for the introduction of clinical guidelines for the selection, management and monitoring of intravenous fluids in children and a review of training and supervision for all staff involved.

In terms of pharmacy involvement, the NPSA proposes that pharmacists oversee the removal of all hypotonic infusion fluids from general paediatric wards and restrict the use of these fluids to paediatric intensive care settings.

The NPSA welcomes comments and suggestions by 31 March. The consultation papers and feedback forms are available from the NPSA’s safer health care website (accessible via *PJ Online*: www.pjonline.com/links/pj) where a forum has been set up for stakeholders to discuss the initiatives.

SMC accepts six medicines for Scotland — four medicines rejected

Two antiretroviral medicines, emtricitabine (Emtriva) and emtricitabine/tenofovir (Truvada) have been approved by the Scottish Medicines Consortium (SMC) for use within NHS Scotland. The medicines have been accepted for use in HIV-1 infected individuals in combination with other antiretrovirals, prescribed only by HIV specialist doctors.

The SMC reviewed 10 medicines in total and offered advice to the NHS boards and area drug and therapeutics committees.

Long-acting beta-2 agonist formoterol has also been accepted in the form of Atimos Modulite 12µg metered dose inhaler, for the treatment of persistent moderate to severe asthma in patients requiring regular bronchodilator therapy in combination with long-term anti-inflammatory therapy.

Ibandronic acid (Bonviva), taken once a month, has been shown to reduce significantly the risk of vertebral fractures in postmenopausal women. The SMC has approved its use in the treatment of osteoporosis in this patient group.

Another medicine approved by the consortium is ibuprofen intravenous injection (Pedia) for the treatment of severe patent ductus arteriosus in preterm babies born at less than 34 weeks’ gestation. Ibuprofen — and similarly indometacin, used for many years for this indication — helps to close the ductus arteriosus through the inhibition of prostaglandin, which is responsible for keeping the duct open *in utero*.

The proton pump inhibitor rabeprazole (Pariet) has been approved by the SMC for use in patients with Zollinger-Ellison syndrome, a condition in which over-production of the hormone gastrin results in excessive gastric acidity.

The other four medicines under consideration were rejected by the consortium.

The BuTrans buprenorphine patch was rejected for lack of evidence of comparative efficacy with a relevant treatment for chronic pain already available in the UK [amended text].

A clarithromycin oral suspension granules product (ClaroSip), which uses sip

technology — where granules are contained inside a drinking straw — was rejected because of its higher cost compared with conventional clarithromycin products, without evidence of improved compliance.

A combination product containing paracetamol and tramadol (Tramacet) was shown to have similar efficacy to other combination analgesics. But because the amount of paracetamol in each tablet (325mg) is lower than the 500mg strength considered appropriate in the UK, and due to the significantly higher cost of the combination product compared with the individual ingredients alone, the SMC has not recommended its use within NHS Scotland.

Modified release nicotinic acid (Niaspan) was rejected because of a lack of evidence for its use in dyslipidaemia. The SMC issued advice on Niaspan in 2004, stating that the product could not be endorsed for the treatment of hypercholesterolaemia and mixed dyslipidaemia within NHS Scotland (*PJ*, 24 April 2004, p500).

National Service Framework for Older People to be given facelift with release of DoH report

A report called “Improving standards of care for older people — next steps” will be published by the Department of Health in April.

The report aims to refresh the National Service Framework for Older People, published in March 2001, at the midway point of its 10-year implementation plan, providing a renewed focus and setting

priorities for the next five years. The document will be based around the central themes of dignity in care, responsive services and active ageing.

These themes will address culture, system reform and aspirations for improving older people’s health and well-being.

Frequent-flyer report points to role for pharmacists

Pharmacists could help patients who are admitted to hospitals as emergencies more than three times a year — termed high-impact users or frequent-flyers by health staff — and who cost the NHS £2.3bn in 2003–04.

This is a key finding of a report produced by Dr Foster Intelligence, which says: “Many of these emergency admissions could be avoided and people supported to manage their conditions outside hospital through the right combination of health and social care, as long as care is provided at the right time.”

Pharmacy organisations have pointed out that pharmacists are part of the solution to achieving this. National Pharmacy Association chief executive John D’Arcy said that the report underscores the need to en-

sure the best use of resources in managing long-term conditions and the role of pharmacists in doing that. This could be both by providing care services in the community and by helping to educate patients about managing their own conditions.

David Pruce, director of practice and quality improvement at the Royal Pharmaceutical Society, said: “The report underlines the core theme of last week’s Government [health] White Paper in highlighting the important role that primary care has to play in reducing hospital admissions. Community pharmacists are ideally placed to help patients manage their conditions at home and the challenge for Government will be to ensure that sufficient resources are available to support the

new range of primary care services that will be required.”

One case study outlined in the report is of a 60-year-old man who, in 12 months, had 11 emergency admissions associated with chronic obstructive pulmonary disease. These admissions, taken with others in the preceding two years meant he had spent 231 days in hospital at an estimated cost of £25,680. Possible recommended solutions included regular medication reviews.

The report, prepared from an analysis of Department of Health admissions data, says that the most common cause of emergency admission is COPD, followed by angina, ear nose and throat infections, asthma and convulsions and epilepsy.

Irish “risk Shipman-type pharmacy scandal”, warns Society

The Irish Republic has been warned that it risks a Shipman-type scandal in the pharmacy sector because of the lack of legislative controls to remove rogue operators.

The warning was delivered by Mandie Lavin, director of fitness to practise and legal affairs at the Royal Pharmaceutical Society, who pointed out that, unlike the UK, the Republic has no robust fitness-to-practise system for pharmacists. “If I had a serious criminal conviction, I could own and oper-

ate a pharmacy,” she declared. Speaking at a conference in Dublin earlier this month hosted by the Irish Pharmaceutical Union, she said that the way in which Shipman perpetrated the killings had important lessons for Irish legislators. In Britain, the Royal Pharmaceutical Society could remove from the register a pharmacist found to have acted in an unprofessional manner. In Ireland, however, which had no such controls, “there is a real fear that a person like Shipman

could obtain large amounts of potent drugs”.

The current rules for regulating the Irish pharmacy sector, she pointed out, date back to 1875 and do not contain provisions for rogue pharmacists to be struck off. In response to the criticism, a spokesperson for Irish health minister Mary Harney said legislation was being prepared that would introduce fitness-to-practise regulations and empower the IPU to enforce them.

Steven Kayne appointed to herbal advisory committee

Steven Kayne, an independent pharmacy consultant, has been appointed a professional member of the new Herbal Medicines Advisory Committee, it was announced this week.

The HMAAC gives ministers and the Medicines and Healthcare products Regulatory Agency independent expert advice on the recently introduced registration scheme for traditional herbal medicines and on unlicensed herbal remedies supplied under Section 12 of the Medicines Act 1968.

Dr Kayne told *The Journal* that he hopes his position will enable him to promote the role pharmacists can play in ensuring patients self-treat appropriately.

Pharmacist is made head of strategic development for health at Abertay university

David McNaughton, a pharmacist and former director of the Abertay Pain Management Research Centre, has been appointed head of strategic development (health) at the University of Abertay, Dundee.

Professor McNaughton will oversee the development of degree programmes and short courses for health professionals, including pharmacists. The university already has a strong base in sociology, biomedical sciences and health, and runs short courses in pain management for health care professionals.

Professor McNaughton told *The Journal* that he has been asked by the university to look at the possibility of developing both MPharm and DPharm courses. He envisages that the courses will be based on the changing role of pharmacists and will have an evidence-based focus.

He is also looking at developing post-graduate and MSc courses for pharmacists. “We will be developing new kinds of degrees, delivered in new ways, including distance-learning and work-based learning. We will also offer modules from these degrees and specially tailored short courses that can



Professor McNaughton plans to develop courses for pharmacists

be studied at a pace to suit individuals’ career development plans,” Professor McNaughton explained.

He is also considering developing a physician assistant degree, which, he believes, may be of interest to some pharmacists.

In brief

Advertising appeals

John Ferguson, formerly Secretary and Registrar of the Royal Pharmaceutical Society, has been reappointed to the Medicines and Healthcare products Regulatory Agency’s Independent Review Panel for Advertising. Sheila Stevens, a former head of the Society’s Scottish Department, has also been reappointed.

SSRIs still prescribed for children despite warnings

In 2004, 85,251 child prescriptions were issued for selective serotonin reuptake inhibitors that the Medicines and Healthcare products Regulatory Agency ruled the year before should not be given to children.

The total amounted to one in three of all antidepressants issued to juveniles, Paul Burstow (Lib Dem, Sutton and Cheam) was told in a Parliamentary written reply made by the Department of Health.

More than 6,000 of the prescriptions were for paroxetine, a drug which the MHRA had judged to be safe only for adults and should

not be given to under-18s. But such rulings are not binding on GPs, who are free to use their own discretion when prescribing.

Over 27,000 prescriptions for SSRIs, including paroxetine, were written for children under 18. The MHRA in 2004 issued revised guidelines saying that only fluoxetine was safe for juveniles and even that should only be prescribed as a last resort.

Mr Burstow said: "There has been long-standing under-investment in child and adolescent mental health and the admitted levels of prescribing SSRIs to youngsters is a direct

consequence of that. There should be more emphasis on therapy and less on prescribing drugs which can increase the risk of emotional distress, self-harm and even suicidal tendencies."

He pointed to recent research that suggested that eight out of 10 GPs themselves believe that too many SSRI prescriptions are issued to both children and adults.

A DoH spokesman said: "Not all SSRIs issued to under-18s are for the treatment of depression. A proportion are for phobic states, bed-wetting and other disorders."

Health of a generation to be investigated

Generation Scotland, a large study to investigate the influence of genetics and lifestyle on disease and response to treatment, started last week.

Researchers are planning to recruit 50,000 Scottish volunteers to the study. The aim is to help identify groups of people at high risk of developing heart disease, osteoporosis and mental illness. "We can also discover which groups of the population respond best to which medicines, enabling us to target those resources more effectively, making sure that the right patients get the right treatment," said health minister Andy Kerr.

The Generation Scotland study will be initially recruiting patients aged 35–55 years, along with their families, through GPs. Participants will be asked to provide blood and urine samples, along with details of their lifestyle and medical history. The health of the family will be traced over 10 to 30 years.



Genetic influences on disease and response to treatment will be studied

The study is being run by the universities of Aberdeen, Dundee, Edinburgh and Glasgow, and NHS Scotland. It is being funded by a £4.4m grant from the Scottish Executive.

Potential cost-effectiveness of polypill estimated

The costs of prescribing the "polypill" to all adults over the age of 50 years for the primary prevention of cardiovascular disease could preclude its use, according to researchers (*Journal of Epidemiology and Community Health* 2006;60:213).

The proposed polypill — consisting of three blood pressure lowering drugs, a statin, folic acid and aspirin — was first mooted in 2003 (*PJ*, 28 June 2003, p881). Three years later, researchers have calculated the potential costs of widespread treatment with the pill using data collected from the Framingham Heart Study and the Framingham Offspring Study. To be cost-effective among populations at a 20 per cent 10-year risk of coronary heart disease, the annual cost of the polypill should be no more than €302 for men aged 50 years and €410 for men aged 60 years, they say.

"Even if the polypill would be offered for free no cost savings would be achieved if the intervention were implemented in populations at moderate levels of risk or if it would be given to the total population irrespective of risk levels," said the researchers.

They conclude that the largest benefits would be obtained if the polypill were to be given to everyone from aged 60 years or to those over 60 years with a high risk of CVD. "However, this implies the medicalisation of a large section of the population and the exposure of healthy subjects to adverse effects."

MPs slam NICE Alzheimer's recommendation

Over 20 MPs have backed an all-party motion describing as "unethical" the recent recommendation by the National Institute for Health and Clinical Excellence to allow access to Alzheimer's disease drugs only to patients in the moderate stage of the illness (*PJ*, 28 January, p98).

The motion, by Howard Stoaite (Labour, Dartford), said: "The decision is illogical as it excludes both mild and severe patients from effective treatment, removing the choice of clinicians

to diagnose and treat patients early and effectively, and removing the choice of clinicians to prescribe more than one class of drug. It is unethical to expect clinicians to wait for patients to deteriorate before offering well-proven and efficacious treatments and the decision will place clinicians in the difficult position of having to withdraw treatments from severe stage patients at a point when behavioural issues are more prevalent and problematical and carers more stressed."

Range of antivirals may be stockpiled by DoH

Antivirals may be stockpiled in readiness for an influenza pandemic, the Department of Health has suggested.

Health minister Rosie Winterton said: "Officials are actively reviewing the antiviral strategy in the context of emerging data and we are looking carefully at other antivirals as a possible back-up to oseltamivir."

She said that the DoH has been approached by GlaxoSmithKline, the manufacturer of zanamivir (Relenza), in relation to supply for pandemic preparedness, but that there are practical issues concerning the use of Relenza during a pandemic, since it is not licensed for prevention of influenza, or for use in children, and has to be administered via inhalation.

PJ Online

Access to *PJ Online* is free to all

Tomorrow's Pharmacist

This year's edition of *Tomorrow's Pharmacist*, a guide for students and preregistration trainees, is now online. www.pjonline.com/tp

POEMs

POEMs (Patient Oriented Evidence that Matters) is a regular series in *The Journal*. www.pjonline.com/poems

Vitamin D supplements fail to reduce hip fractures

Supplementation with calcium and vitamin D increases hip bone density, but does not reduce hip fracture or colorectal cancer, data from the Women's Health Initiative trial published this week have shown.

Hip bone density was 1.06 per cent higher in women taking 100mg calcium carbonate and 400IU vitamin D₃ daily than in those taking placebo ($P < 0.01$). Differences in fracture rates between the two groups (the primary effect being measured) were not significant, the researchers found (*New England Journal of Medicine* 2006;354:669).

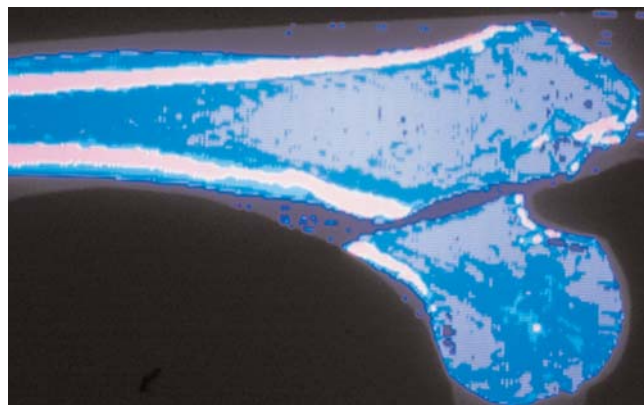
But the trial, involving 36,282 post-menopausal women did find that calcium and vitamin D supplements increase the risk of developing kidney stones (hazard ratio 1.17; 95 per cent confidence interval, 1.02–1.34).

"The statistically null primary effect argues against recommending universal calcium

with vitamin D supplementation for already calcium-replete women," the authors conclude.

The analysis of the effect of calcium and vitamin D supplementation on colorectal cancer, published separately (ibid p684), found that seven years of supplementation had no effect on the incidence of colorectal cancer.

"The long latency associated with the development of colorectal cancer, along with the seven-year duration of the trial, may have contributed to this null finding. However, these results do not provide support for the



GiLP/Science Photo Library

Supplements do not increase bone density enough to reduce hip fractures

general use of calcium plus vitamin D supplementation to prevent colorectal cancer," the researchers say.

Diet may not reduce cancer and CV risk

Dietary changes might not reduce the risk of some cancers and cardiovascular disease, according to a recent study.

The Women's Health Initiative involving 48,835 post-menopausal women has examined the risks of breast cancer (*JAMA* 2006;295:629), colorectal cancer (ibid, p643) and cardiovascular disease (ibid, p655) through a "dietary modification intervention" programme, over an 8.1-year average follow-up period.

The programme aimed to motivate participants — through strategies such as group sessions and self-monitoring techniques — to reduce dietary fat intake and increase consumption of fruit, vegetables and grains. The comparison group received diet-related education material but were asked not to make diet changes actively.

In the intervention group, 0.42 per cent of women developed invasive breast cancer, compared with 0.45 per cent of controls, representing no significant reduction in risk (hazard ratio 0.91; 95 per cent confi-

dence interval 0.83–1.01). The authors observed nonsignificant trends that, they say, suggest a reduced breast cancer risk with a low-fat dietary pattern, and might be shown to be significant over a greater number of years.

Investigators also found that, compared with controls, the intervention group did not have a significantly reduced risk of colorectal cancer (HR 1.08; 95 per cent CI 0.90–1.29), or cardiovascular disease (HR 0.98; 95 per cent CI 0.92–1.05).

Five a day okay Eating more than five servings of fruit and vegetables per day can protect people from stroke, a meta-analysis concludes (*The Lancet* 2006;367:320).

The authors found that, compared with individuals who consumed fewer than three fruit and vegetable servings per day, those who ate more than five servings were at significantly less likelihood of both ischaemic and haemorrhagic stroke (pooled relative risk 0.74; 95 per cent confidence interval 0.69–0.79).

NEC a risk with H₂ blockers

Premature babies given H₂ antagonist drugs are slightly more likely to develop necrotising enterocolitis (NEC) — serious ulceration of the ileum and colon — according to a recent study (*Pediatrics* 2006;117:137).

The authors suggest that increased gastric pH, caused by H₂ antagonist treatment, may be a factor in pathogenesis of NEC. But they did not rule out the possibility that the need for such drugs could be an indication of a neonate's fragile condition rather than a cause of disease.

Call for post-market studies

Prospective observational studies should be carried out for every medicine when it is first marketed, says Portsmouth University's Drug Safety Research Unit.

After reviewing drug withdrawals in the UK and US markets from 1999 to 2001 the DSRU concluded that only two products were withdrawn because of evidence for a patient-relevant outcome from comparative studies.

Hope for narcoleptics to regain muscle tone

Narcoleptics can now be treated to reduce the loss of muscle tone that narcolepsy induces.

The new treatment (Xyrem) has as its active substance the sodium salt of gamma hydroxybutyrate (sodium oxybate). Gamma hydroxybutyrate is a CNS depressant with well known abuse potential, so the summary of product characteristics advises evaluating patients for a history of drug abuse and following them closely. The recommended starting dose is 2.25g (4.5ml) twice a day.

The dose should be adjusted up or down in increments of 0.75g per dose up to a maximum of 4.5g twice a day to achieve best effect and tolerability. A minimum of two weeks is recommended between dosage increments.

Xyrem should be taken orally upon getting into bed and again between 2.5 and 4 hours later — the SPC recommends that both doses of Xyrem be made up at the same time (on retiring to bed).

Notice-board p200

Women lack information on contraceptive choices

Women do not have enough information about long-acting reversible contraception.

Only 32 per cent of oral contraceptive users calling the fpa helpline had discussed alternatives with a doctor or nurse. Most (76 per cent) had not heard of levonorgestrel-releasing intrauterine devices, 34 per cent were unaware of other IUDs, 24 per cent did not know about implants and 12 per cent had not heard of contraceptive injections.

Genetically engineered bird flu vaccines tested

Genetically engineered avian influenza vaccines have been successfully tested in mice and poultry by two teams of scientists in the US. The results were published online on 2 February in *The Lancet* (www.thelancet.com) and in the February issue of the *Journal of Virology* (2006;80:1959).

Current H5N1 vaccines depend on a supply of embryonated eggs to produce inactivated sub-virion vaccines. Since availability of eggs during a pandemic would be limited and, according to the researchers, approximately four billion embryonated eggs would be needed to produce vaccine for the estimated 1.2 billion people that could be affected by the virus, researchers are developing egg-independent strategies to combat bird flu.

Mary Hoelscher of the Centres for Disease Control and Prevention, Atlanta, Georgia, and colleagues genetically engineered a human adenovirus to produce a protein called haemagglutinin subtype 5 — a component of the H5N1 virus isolated from humans in Hong Kong. One group of mice was injected with the vaccine and the other was injected with saline. The researchers found that immunised mice were protected from death, weight



Eggs for vaccine production may be in short supply during a pandemic

loss and primary viral replication when infected with H5N1. They explain that the adenovirus-vector-based vaccine generated specific T-cells as well as antibodies, whereas current vaccines work by activating cellular immunity alone.

The researchers said that the vaccine also has the advantage of conferring cross-

protection against continuously evolving H5N1 viruses without the need for an adjuvant. The vaccine can be grown to high titres and would therefore be suitable for stockpiling, they said. "This approach is a feasible vaccine strategy against existing and newly emerging viruses of highly pathogenic avian influenza to prepare against a potential pandemic," they concluded.

The paper published in the *Journal of Virology* details research undertaken by Andrea Gambotto, University of Pittsburgh School of Medicine, Pennsylvania, and colleagues who developed a similar vaccine against haemagglutinin protein isolated during the outbreak of avian influenza in Vietnam. The researchers tested their vaccine in mice and then in chickens (subcutaneously and intranasally). The vaccine administered subcutaneously completely protected chickens from the virus, which was lethal to unvaccinated chickens within two days.

The researchers say that they achieved vaccine production within 36 days of acquiring the virus sequence, which would be useful if the virus were to begin to mutate rapidly. The group is planning a small trial in humans in the near future.

New drug could reduce disability following stroke, researchers say

Free-radical-trapping agent NXY-059 has shown benefits in reducing disability in stroke patients.

Kennedy Lees, of the acute stroke unit and cerebrovascular clinic, Western Infirmary, Glasgow, and colleagues conducted a randomised, double blind, placebo-controlled trial involving 1,722 patients with acute ischaemic stroke. Patients received a 72-hour intravenous infusion of NXY-059 or placebo within six hours of the onset of stroke. Alteplase treatment was given to 28.7 per cent of patients. The primary outcome measure was level of disability at 90 days as measured by the modified Rankin scale (0 = no residual symptoms; 5 = bedbound).

NXY-059 (Cerovive), under development by AstraZeneca, reduces the size of the infarct and preserves brain functioning in animal models of acute ischaemic stroke.

Patients in the NXY-059 group showed a reduction in disability at 90 days compared with those in the placebo group ($P=0.038$). Researchers calculated that the odds for avoiding disability were about 20 per cent better in the NXY-059 group than in the placebo group. "This benefit was seen at both ends of the scale: 4.4 per cent more patients who received the study drug became asymptomatic and 3.7 per cent more were able to walk without help, as compared with those in the placebo group," say the researchers.

Survival and the incidence of adverse events were similar in the two groups. The researchers found no significant interaction between NXY-059 and stroke severity, treatment with alteplase, or time from onset of stroke to treatment "indicating that the treatment benefit is present irrespective of these factors". A post-hoc analysis revealed that in those who also received alteplase, NXY-059 was associated with a lower incidence of haemorrhagic transformation and symptomatic intracranial haemorrhage.

Secondary outcomes of neurological functioning were not significantly improved with NXY-059 and the researchers say that a considerably larger, confirmatory study is required to determine whether it has a benefit in stroke.

Long-acting opioid antagonist may benefit pathological gamblers, study data suggest

Pathological addiction to gambling may respond to low doses of the long-acting opioid antagonist, nalmefene, according to a new study (*American Journal of Psychiatry* 2006;163:303).

Researchers in the US monitored a total of 207 outpatients over a period of 12 months and found that urges/thoughts and behaviours towards gambling were significantly reduced when treated with nalmefene 25mg daily.

The authors report that a similar drug, naltrexone, has shown some efficacy in treating

patients with alcohol and drug abuse — but that its use is limited due to dose-dependent hepatotoxicity.

Patients with documented symptoms of pathological gambling (according to DSM-IV criteria) were randomised to nalmefene (25mg/day, 50mg/day and 100mg/day) or placebo during this 16-week, double blind, placebo-controlled dose-ranging trial.

In terms of the primary outcome measure (total score on the Yale-Brown Obsessive Compulsive Scale Modified for Pathological Gambling, a 10-item clinician-administered

scale used to rate gambling symptoms within the previous seven days), there was a significant reduction difference favouring nalmefene 25mg/day (from 14.01 at baseline to 6.99 at week 16; $P=0.007$ versus placebo).

The authors concluded: "Subjects who received nalmefene had a statistically significant reduction in the severity of pathological gambling. Low-dose nalmefene (25mg/day) appeared efficacious and was associated with few adverse effects. Higher doses (50mg/day and 100 mg/day) resulted in intolerable side effects".

Correction

Legislation to introduce fitness-to-practise regulations in the Irish Republic will empower the Pharmaceutical Society of Ireland to enforce the regulations, not the Irish Pharmaceutical Union as stated (p194).