

Self care guide for long-term conditions published

Pharmacists' role in helping patients take control of their long-term conditions has been outlined in a guide to self care published by the Department of Health last week.

"Supporting people with long term conditions to self care — a guide to developing local strategies and good practice" outlines ways to develop self care programmes and describes examples of present good practice, including three pharmacy projects.

Community pharmacies can be a valuable source of information for people suffering from long-term conditions, the guide says, and it recommends that those developing a self care support strategy work with their local pharmaceutical committee to ensure that community pharmacists support self care and medicines management.

"If you are a pharmacist, ensure you maximise your expertise in the effective and safe

use of medicines and the promotion of healthy lifestyles, particularly for people with long-term conditions," it adds.

Following publication of the guide, the Royal Pharmaceutical Society said it would be launching its own self care strategy document for pharmacists in England that supports the message in the guide. "Our document will seek to create a call for action to engage pharmacists in increasing self care support. Similar documents will also be published for Scotland and Wales to reflect the differences in health policies within the home countries," Hemant Patel, President of the Society, added.

"Supporting people with long-term conditions to self care" is available on the DoH website (www.dh.gov.uk/longtermconditions) and via *PJ Online* (www.pjonline.com/links/pj).

News feature p260



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Self care programmes and examples of best practice are outlined in the guide

Self-regulation under threat, says President

The Royal Pharmaceutical Society's unique position as both professional body and regulator is under threat for political reasons, according to Hemant Patel, President of the Society.

Speaking at a Young Pharmacists' Group conference held in Birmingham last weekend, Mr Patel said that there was speculation about how the Government planned to respond to the Foster review of health regulators. He said: "We fear that the review may have adopted a position based on the political imperative of being seen to change things rather than delivering genuine improvement to health regulators."

Also speaking at the conference, Sue Sharpe, chief executive of the Pharmaceutical Services Negotiating Committee and former director of professional standards at the Society, suggested the Society was unlikely to continue in its current form. She said she was doubtful about the sustainability of pharmacy's regulatory position. "Yes, it has worked brilliantly, but it is anomalous . . . I do query

whether we are going to see the end of self-regulation, in terms of discipline, for all the health care professions."

The YPG conference, entitled "Twenty twenty vision" took the opportunity to celebrate the group's founding some 20 years ago, and focused on the past and future of the profession. In her speech, Mrs Sharpe gave examples of political and environmental challenges for the profession over the past 20 years, as a background for discussing three key elements: service development, competition and regulation.

In response to the challenges around regulation, Mrs Sharpe said: "I suspect that what we might be moving towards is actually a splitting of regulatory functions, and the professions will take care of the entry qualifications, the training, the continuous professional development. But the disciplinary function I personally doubt is going to stay with each individual profession for very much longer."

DoH meets Society and PSNC for home oxygen service talks

Problems with the new home oxygen services have been discussed in Department of Health meetings with both the Royal Pharmaceutical Society and the Pharmaceutical Services Negotiating Committee this week.

"The department accepts that there has been failure by the NHS to implement the changeover in an organised way and we have expressed our Council's deep concerns very clearly," Hemant Patel, President of the Society, said.

The meeting helped the Society understand how the situation will be managed in future, he said, with more NHS central man-

agement support to improve communication at local level. "The role of pharmacists in helping ameliorate the effect on patients has been highly praised by ministers and officials alike, and I have been assured that no pharmacist re-engaging with the service to help out patients in the transition will suffer financially as a result," he added.

"We shall keep a watching brief on the situation, we shall do all we can to help patients through it and we shall help the department identify lessons to learn for future change management planning, involving the profession," he said.

Embrace EPS changes

Pharmacists setting up the systems that will enable them to provide an electronic prescription service should "embrace the changes", according to Andrew Murphy, of Co-operative pharmacy in Keighley, West Yorkshire, who has been involved in early implementation of the service.

In an interview published on the NHS Connecting for Health website, he said: "The introduction of the electronic prescription service caused minimal disruption to my working life. Some computer upgrades were required, and then some minimal training into the background of the electronic prescription service, and then we went live.

"The advice that I would give to anyone embarking on the electronic prescription service is to embrace the changes. You'll soon see the benefits, and you won't want to return."

Mr Murphy went on to highlight some of these benefits. "I've seen a reduction in dispensing incidents," he said. He attributed this to the fact that data are no longer copied from the prescription by the dispensing assistant. "I am running a smoother, safer pharmacy. The advantages to us once it's fully rolled out are that we should be able to plan our working life better."

He added that he was looking forward to the time when patients would be able to nominate a pharmacy that they want to use.

N3 connection A list of providers of N3 network connection has been published on the NHS Connecting for Health website (www.connectingforhealth.nhs.uk). The list indicates whether the type of network connection provided is approved by NHS CfH and whether a gateway (hardware that allows secure connection between the provider and the N3 network) has been ordered and implemented.

Fear stops pharmacists reporting dispensing errors

Community pharmacists and their support staff are unlikely to report adverse incidents occurring on pharmacy premises, according to research carried out at the University of Manchester and published in *Quality and Safety in Health Care* this week (2006;15:48).

The researchers conclude that community pharmacists and their staff are not convinced that the advantages to them and to patients of reporting patient safety incidents outweigh possible consequences and blame.

However, the finding has been questioned by the National Patient Safety Agency. Wendy Harris, NPSA head of safety solutions and a pharmacist, said that incident reports from community pharmacies are running at 400 to 1,000 a month and are growing exponentially.

Half of the reports were of dispensing errors and 1 per cent resulted in serious harm.

This harm ratio was comparable to reports from all other professional sources.

"This really shows pharmacists' willingness to share with us in an anonymous and confidential way," Ms Harris said. "Our experience is that, compared with other professions and NHS organisations, pharmacy's reporting rate is very, very good."

However, she warned: "There is still a blame culture in the profession. This is something that our professional body needs to think about long and hard. Pharmacists do not set out to do harm."

The University of Manchester researchers set out nine hypothetical scenarios involving different types of error and differing severity of outcome for patients. They found that support staff were generally less likely than pharmacists to report incidents and that both were less likely to report incidents to the National

Patient Safety Agency than to report them internally. In almost all cases, the likelihood of reporting an incident increased with severity of outcome.

The researchers attribute their findings to a disparity between the prevailing culture in community pharmacy and national policy that mistakes should be reported so that lessons can be learnt across the NHS.

"Adverse incidents in community pharmacies are associated with less than satisfactory performance and reporting incidents is associated with the attribution of blame," they say. "The key to success will be to develop a reporting culture in which staff feel able to report incidents without fear of retribution." They point out that this will be difficult so long as dispensing errors remain a potential criminal offence under the Medicines Act 1968.

Childhood obesity a target for the profession

The Government's ability to fulfil its public service agreement (PSA) "to halt the increase in obesity among children under the age of 11 by 2010" has been called into question in a joint report published this week by the Audit Commission, the Healthcare Commission and the National Audit Office.

The report warns that the organisations involved in delivering the child obesity PSA target (first set in July 2004) have been unclear about their roles because the Government has delayed publishing the key ingredients of its delivery plan — now not expected until May.

Gul Root, principal pharmaceutical officer at the Department of Health, highlighted the opportunities raised by PSA targets at a Young Pharmacists Group conference held in Birmingham last weekend. She said that the targets are challenging but non-negotiable commitments that the Government needs to carry out.

Mrs Root spoke of "pharmacy premises becoming a venue for public health", and said that pharmacists have a real opportunity to contribute to public health through PSA targets such as those for smoking, under-18 conception rates and obesity among children.

Scottish intrathecal injection guidance published

Guidance on the safe handling of intrathecal and intraventricular injections in Scotland has been produced by the Scottish Executive Health Department. It complements earlier guidance on the safe handling of intrathecal and intraventricular cytotoxics.

In essence, the guidance says that intrathecal and intraventricular injections must only be prepared and administered by named individuals who have been suitably trained and authorised. Pharmacists can be included on the list of persons authorised to prepare the injections.

In order to prevent errors, intrathecal or intraventricular injections have to be prepared separately, and at different times, from injections for administration by any other route. In addition, they should always be prepared and administered by the same person or prepared by one person and delivered direct to the individual who is to give the injection. Where this is not possible, injections must be placed in a locked cupboard and signed for when removed for use. Again, only authorised people should be involved in the supply chain.

Drop-in centre helps smokers with their cessation attempts



David Carter (right) gives smoking cessation advice to a member of the public

Pharmacists are providing smoking cessation advice to smokers in South Shields as part of a community initiative called "Drop in 2 quit".

The drop-in clinics are being held on eight consecutive weekends and are staffed by pharmacists and pharmacy staff qualified as smoking cessation advisers. The first week's session, held on 18 February, attracted over

200 smokers, of whom 172 were issued with nicotine replacement therapy products via a local "care in the chemist" prescription form.

David Carter, chairman of Gateshead and South Tyneside Local Pharmaceutical Committee and a smoking cessation adviser, explained that smokers who register with the service are expected to return each week for further advice and supplies.

News in brief

No Smoking Day continues to reach smokers successfully

No Smoking day encourages and helps individuals to stop smoking, according to a recent study (*Tobacco Control* 2006;15:19). The study looks at annual tracking, three-month follow-ups, media evaluation, web tracking and helpline calls over a number of years. The authors suggest that media campaigns supported by local activity can be effective in helping smokers to quit.

New guidelines to help control MRSA drawn up

Updated guidelines for the control of methicillin-resistant *Staphylococcus aureus* (MRSA) have been drawn up by a joint working party of the British Society for Antimicrobial Chemotherapy, the Hospital Infection Society and Infection Control Nurses Association.

The guidelines now include recommendations on a number of antibiotics launched since the previous set of guidelines were published in 1998, including teicoplanin (Targocid), quinupristin/dalfopristin (Synercid) and linezolid (Zyvox). They recommend that, in skin and soft tissue infections, the use of glycopeptides or linezolid should be considered where the risk of bacteraemia is high and that intravenous glycopeptides or linezolid be used in severe intravenous site infection. The guidelines also recommend the use of either glycopeptides or linezolid for pneumonic infections where MRSA is the causative agent.

The working party's previous guidelines focused on prevention and control of MRSA infections. The new guidelines also look at prophylaxis and treatment of MRSA infections. Laboratory diagnosis and susceptibility testing are also covered.

For surgical site prophylaxis, the guidelines recommend that patients who require surgery (and have a history of MRSA colonisation or infection without documented eradication) should receive glycopeptide prophylaxis alone, or in combination with other antibiotics, and that the use of aminoglycosides should be reassessed in patients not expected to have MRSA colonisation.

Hayley Wickens, senior microbiology pharmacist at St Mary's Hospital, London, commented: "This is an extensive and welcome review of the evidence for effective prophylaxis and treatment of MRSA infection. The guidelines highlight the need for further research in areas such as decolonisation regimens and use of older oral agents in combination treatment of MRSA infections. Hospital pharmacists will want to discuss the document with their microbiology and infection control



Glycopeptides or linezolid are recommended for MRSA skin and soft tissue infections with high bacteraemia risk

Mike Wyndham Medical Library

colleagues, particularly as it will have an impact on prescribing guidelines within their trusts."

The guidelines, which have been produced at the request of the Department of Health's Special Advisory Committee on Antimicrobial Resistance, are due to be published in the April issue of the *Journal of Antimicrobial Chemotherapy* and are available via *PJ Online* (www.pjonline.com/links/pj).

Health to be excluded from European services directive

European politicians have now agreed that health services will not be included in plans to allow services to be provided across EU member states' borders.

The European Parliament voted on 16 February to exclude both public and private health services from the draft services directive, as suggested by its Internal Market Committee (*PJ*, 10 December 2005, p713).

The amended draft directive will now go to the European Council of Ministers for consideration.

Article p268

Health Bill will lead to NHS contracts being awarded wrongly, argues pharmacist MP

Provisions in the Health Bill to allow NHS contracts in England to be awarded according to commercial considerations are unworkable, Sandra Gidley (Lib Dem, Romsey) argued during the Health Bill debate last month.

She said that, as drafted, amendments to Clause 32, which deals with applications for pharmaceutical services contracts, would mean that contracts could be awarded according to promises made in relation to the commercial part of pharmacy businesses. "That is wrong and unenforceable," she argued.

She asked how primary care trusts would be able to monitor contractors' price promises on a regular basis or how PCTs could

deal with pharmacies being sold to contractors with different marketing or pricing policies. She also said it would be difficult to see how a PCT could balance different offers — such as for over-the-counter medicines or for enhanced services — in different applications. "In short, the clause is unworkable as it stands, being difficult both to monitor and sustain," she added.

In response, health minister Jane Kennedy said: "The important point is that although the price of over-the-counter medicines must obviously be a factor, the clause is not simply about price; to a large degree, it is about support and advice to the patient in the management of such medicines."

Pharmaceutical R&D investment falls for second year

Investment in pharmaceutical research and development in the UK has declined for the second year in succession.

Figures released by the Association of the British Pharmaceutical Industry show that total expenditure on R&D of new medicines by UK-based pharmaceutical companies slid by 2 per cent in real terms to £3,244m in 2004. R&D capital expenditure declined from £490m in 2003 to £424m in 2004. Expenditure in this area has been declining since a peak of £532m in 2000.

ABPI director general Richard Barker said: "This country must not follow the paths of so many other European nations in creating barriers to innovation, whether through over-regulation or through concentration on the price of medicines rather than their value."

Dr Barker called for new rules of engagement for the industry, the NHS and the Government. Productivity and outcomes were more important than numbers treated, he said.

Pharmacy 20:20

Echoing "Pharmacy in a New Age", a new project is to be undertaken to develop a socially responsible vision of where pharmacy will be by the year 2020 (p277).

Cross-sector experience

The Council has decided not to make cross-sector experience a mandatory part of preregistration training (p277).

New presentation on careers

The Society has developed a new presentation for use in careers talks arranged by its branches (p278).

Celecoxib doubles risk of MI

Treatment with celecoxib (Celebrex) doubles the risk of myocardial infarction compared with placebo, the authors of a meta-analysis suggest this week (*Journal of the Royal Society of Medicine* 2006;99:132).

The researchers conducted a systematic review and meta-analysis of randomised double-blind clinical trials of at least six weeks' treatment with celecoxib and which presented data on serious cardiovascular thromboembolic events. Data from four trials involving 4,422 patients were examined.

The researchers calculated that the odds ratio of myocardial infarction in patients taking celecoxib, compared with those taking placebo, was 2.26 (95 per cent confidence interval 1.0–5.1).

"This meta-analysis provides evidence that the use of celecoxib, the most commonly prescribed cyclo-oxygenase-2 specific inhibitor, is associated with an increased risk of myocardial infarction. While this finding is limited by the small number of clinical trials of celecoxib that reported outcomes, it is consistent with a class effect of COX-2 specific inhibitors increasing the risk of myocardial infarction," the authors say.

However, a spokesman for Pfizer, manufacturer of Celebrex, said that the authors' conclusions were not applicable to the drug as used within its licensed indications. Celebrex is licensed for a maximum dose of 200mg for osteoarthritis or 400mg for rheumatoid arthritis, but the trials included patients on 800mg doses, he explained. The

number of patients involved in the meta-analysis was relatively small, he added, and larger numbers of patients would need to be pooled to form reliable conclusions.

In addition, a study of the efficacy and gastro-intestinal safety of celecoxib, published last month, included a post-hoc analysis of cardiovascular event rates and found no statistical difference between the number of cardiovascular events reported for celecoxib and the comparator groups (*American Journal of Medicine* 2006;119:255). However, the authors acknowledge that the numbers of events were low and the study was not powered to detect such differences.

In response to the latest research, the Medicines and Healthcare products Regulatory Agency said: "This new study is based on data already assessed by regulatory agencies within Europe. The finding of the authors is entirely consistent with the conclusions of the former Committee on Safety of Medicines and the European Medicines Agency, who reviewed the cardiovascular safety of the selective COX-2 inhibitors in 2005." Following the review, the CSM and EMEA issued updated advice on the use of selective COX-2 inhibitors.

They recommended that patients treated with COX-2 inhibitors who have established ischaemic heart disease or cerebrovascular disease should be switched to non-coxib treatment and that, for all other patients, treatment should be individually assessed for risks and benefits (*PJ*, 26 February 2005, p228).

News in brief

Heart attacks go unrecognised

A third of men and over half of women who suffer a heart attack do not know they have had one, say researchers who examined data from over 4,000 men and women aged 55 years and older for a median follow-up of 6.4 years (published online in the *European Heart Journal*).

GTN metabolism examined

Some Chinese individuals do not respond well to glyceryl trinitrate (GTN) because of a gene mutation present in 30 to 50 per cent of this population. The affected gene gives rise to a faulty version of the enzyme mitochondrial aldehyde dehydrogenase-2, which is responsible for converting GTN to its active form, nitric oxide (*Journal of Clinical Investigation* 2006;116:506).

Statin prescribing up

Prescribing of statins has been rising, from a low base, by an average of 30 per cent a year since publication of the National Service Framework for Coronary Heart Disease in 2000, health minister Rosie Winterton has revealed. In a Parliamentary written reply she said that in the last financial year the NHS spent around £750m on statins.

Contracts worth £33m for H5N1 vaccine awarded

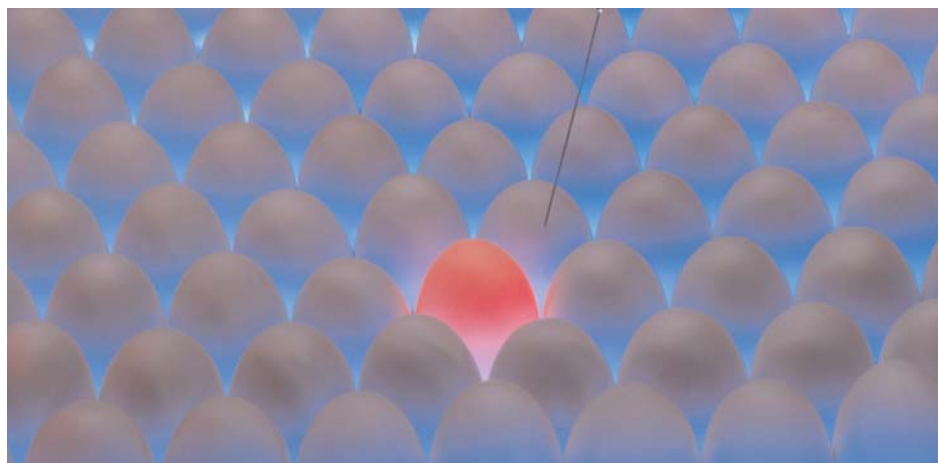
Contracts worth £33m to make 3.5 million doses of H5N1 influenza vaccine have been awarded by the Department of Health to Baxter and Chiron. Baxter is to prepare two million doses.

The vaccine, scheduled for delivery in two instalments in May and October this year, is to be used for research and to vaccinate front-line health care workers if pandemic flu based on the H5N1 avian influenza virus breaks out. It is hoped that this will provide a buffer while a specific vaccine is produced.

Baxter and Chiron were selected out of the five companies that tendered for the contract.

The contract is additional to the sleeping contracts that have already been placed for 120 million doses of specific pandemic flu vaccine once the strain is identified.

Health minister Rosie Winterton said: "We take the potential threat posed by pandemic flu very seriously and, as the World Health Organization and a recent Lords Science and Technology Committee have



R. Maisonneuve, Publibphoto Diffusion/Science Photo Library

Traditional vaccine production uses one hen's egg per dose

recognised, the UK is among the best prepared countries in the world."

Baxter is also working with the US National Institutes of Health on the development of cell culture-based H5N1 candidate

pandemic flu vaccine. This would make vaccine production independent of the availability of hen's eggs. Traditional production methods require one hen's egg for each dose prepared.

Warning over vaccine-related events during pandemic preparations

A cautionary tale from the Centres for Disease Control, Atlanta, Georgia, on mass vaccination could lead governments and national media to temper their enthusiasm for vaccination as the major way that any influenza pandemic is ultimately controlled.

John Iskander, project officer for CDC's vaccine adverse events reporting system, was involved in the 1976 US swine flu vaccine programme that prepared for "a pandemic that wasn't" and instead — as an unintended consequence — produced a vaccine-related

increase in Guillain-Barré syndrome. Dr Iskander told the Bird Flu Summit held in Washington, DC, earlier this week that the 1976 increase in Guillain-Barré syndrome (GBS) was a "classic rare but extremely serious event". The vaccines were associated with a GBS increase of one case per 100,000 vaccinated.

The disease requires admission to hospital, intensive care and ventilator use, all resources that would be in short supply during an influenza pandemic, Dr Iskander noted.

Current studies are looking at the 1976 vaccines to see if they can determine what caused the increase in GBS. He added that the incidence of GBS has been declining and has not been associated with other vaccines.

Dr Iskander also commented that existing vaccine tracking programmes may have to be enhanced during an influenza pandemic to include more data to pick up possible adverse events more effectively. One option being considered is bar-coding vaccines and linking them to patient records.

Peramivir tests revived

Safety and efficacy trials for the neuraminidase inhibitor peramivir are starting this spring, BioCryst Pharmaceuticals director of peramivir development Shane Arnold, told the Bird Flu Summit held in Washington, DC, this week.

The antiviral has been shown to be effective in animals in inhibiting both influenza A and B neuraminidases. Dr Arnold said the drug is easier and quicker to manufacture than oseltamivir (Tamiflu), is potent against resistant strains and has been shown to have effects even if administered as much as 72 hours after infection.

Although developed in the late 1990s, progress on peramivir was halted based on lacklustre sales of other flu-related drugs. The spectre of a flu pandemic has revived the company's interest in the antiviral. Tests are being conducted using peramivir in injectable and intravenous form since it did not perform as well in tests when administered orally.

Human trials for promising influenza vaccine planned

Genetically engineered adenoviral-based influenza vaccine being developed at the University of Pittsburgh School of Medicine was successful in fending off fatal avian influenza infections in both mice and chickens, researcher Andrea Gambotto, told the Bird Flu Summit in Washington, DC, earlier this week. Dr Gambotto is planning human trials to assess the vaccine's safety.

The vaccine is manufactured using cell-based technology and so can be produced quickly. It also creates a broad immune response that could work even with antigen drift. Animal tests showed that immunised mice lost weight when infected with bird flu but still survived the potentially fatal disease.

Possible safety concerns in humans include problems treating individuals with pre-existing immunity and for those with immunosuppression, Dr Gambotto said.

News in brief

Consumption of poultry safe

When poultry products are safely handled and properly cooked, humans are not at risk of acquiring H5N1 infection through food, according to the World Health Organization. Since December 2003, this virus is known to have infected 173 people and none of the infections has been linked to the consumption of properly cooked poultry or poultry products, it said.

Cytotoxics for avian influenza

Cytotoxic therapy could be considered for patients with severe avian influenza, a *Lancet* article published online this week suggests. Haemophagocytosis has been found in avian influenza patients and so treatments for it may help reduce mortality associated with avian influenza (www.thelancet.com).

Weight concerns can reduce adherence in diabetes

Type 2 diabetes patients' concerns over weight gain are associated with reduced adherence to medication, a study of patients' beliefs has shown (*Diabetic Medicine* 2006;23:265).

An analysis of 121 questionnaires completed by type 2 diabetes patients aged 40 years or over aimed to assess patients' beliefs about taking medicines and any correlation with their intention to take their medicine and self-reported adherence.

In the survey, nearly one third of patients agreed or strongly agreed with a statement that taking diabetes medicines regularly would cause unpleasant side effects, but this did not correlate with the subjects' intention

to take their medicines, or their self-reported adherence.

Another patient belief — “changes to my daily routine would make it more difficult to take my diabetes medicines regularly” — was associated with reduced adherence. On the other hand, beliefs about benefit were strongly associated with the intention to take medicines regularly, but were not associated with an increase in adherence.

Lead researcher Andrew Farmer, from the department of primary health care at the University of Oxford, said that exploring these identified beliefs can usefully form part of the process of developing treatment plans. “Further work to develop interven-

tions to help people who have difficulty in taking their medication, based on this study, is currently being undertaken, funded by the Medical Research Council,” Dr Farmer added.

□ **Knowledge gap** Only 20 per cent of individuals at a high risk of developing diabetes consider themselves to be at risk, according to the results of a survey commissioned by Diabetes UK. The survey also showed that many patients with diabetes are not aware of the serious health complications of having the disease — half of those surveyed were not aware of the increased risk of stroke, and a third did not know that diabetes can lead to heart disease.

Obesity may affect response to asthma treatments

Obesity can affect patients' response to different asthma treatments, data from a recent *European Respiratory Journal* study indicate (2006;27:495).

The retrospective analysis was performed on data pooled from four studies randomising 3,073 adults with asthma to receive montelukast, beclometasone or placebo.

Researchers observed a reduced response to beclometasone and placebo with increasing body mass index (BMI). At normal BMI beclometasone was superior to montelukast. However, montelukast response remained largely unaffected by BMI increases. The authors conclude that “differences in responsiveness to montelukast and beclometasone by body mass index may be important in considering treatment choices in individual adult asthmatics”.

Quality of life increased by both pseudoephedrine and montelukast treatment

Pseudoephedrine is as effective in improving quality of life and nasal airflow as montelukast in individuals suffering from allergic rhinitis, an *Archives of Otolaryngology — Head and Neck Surgery* study reveals (2006;132:164).

A total of 58 adults with seasonal allergic rhinitis were randomised to receive either pseudoephedrine hydrochloride 240mg sustained release (unavailable in UK) or montelukast 10mg for a period of two weeks. Both medicines resulted in improvements in all allergic rhinitis symptoms and in quality of life.

Nasal congestion was the only symptom where changes from baseline were significantly different between the two treatment groups — pseudoephedrine was more effective than montelukast in controlling this symptom ($P=0.01$).

Acupuncture as effective as drug treatments for prevention of recurrent migraine

Patients who suffer from recurrent migraines experience similar relief whether they are treated with sham acupuncture, traditional Chinese acupuncture or prophylactic drug treatment (beta blockers, flunarizine or valproate), a German study has revealed.

The prospective, randomised controlled trial of 794 patients showed a mean reduction in days with migraine of 2.3 for the Chinese acupuncture group (95 per cent confidence interval 1.9–2.7), 1.5 (CI 1.1–2.0) for the sham acupuncture group and 2.1 (CI 1.5–2.7) for the drug treatment group. The reductions were significant for all three groups ($P<0.001$) but no significant difference was detected between them ($P=0.09$).

“Ultimately, one could argue that the efficacy of a treatment, especially a treatment with almost no adverse events or contraindications, is more important than the knowledge of the mechanism of action of this



Andrew McClellan/Science Photo Library

Acupuncture was compared with beta blockers, flunarizine and valproate

particular therapy,” the researchers say (*Lancet Neurology* published online on 2 March <http://neurology.thelancet.com>).

Childhood UTI antibiotics may have unacceptable side effects

Long-term antibiotic use for the prevention of urinary tract infections (UTIs) in children may cause unacceptable side effects.

A Cochrane Database Review considered three trials involving a total of 151 patients, comparing antibiotic use with placebo or no treatment. The duration of antibiotic prophylaxis treatment varied from 10 weeks to 12 months.

The overall rate of recurrent UTI in the placebo/no treatment group was 63 per cent. Compared with placebo/no treatment, antibiotics reduced the risk of recurrent UTI (relative risk 0.36, 95 per cent confidence interval 0.16–0.77). No side effects were described in any of these three trials.

One double-blind trial ($n=120$) reported that nitrofurantoin was more effective than trimethoprim in recurrent UTI prevention

over a six-month period (relative risk 0.48, 95 per cent CI 0.25–0.92).

However, patients receiving nitrofurantoin were more likely to discontinue the antibiotic due to side effects (mainly gastrointestinal) than patients receiving trimethoprim (relative risk 3.17, 95 per cent CI 1.36–7.37). By the age of seven years, 8.4 per cent of girls and 1.7 per cent of boys will have suffered at least one UTI episode.

The authors conclude that most published studies to date have been poorly designed, and were likely to overestimate the true treatment effect.

The review found evidence to indicate that some antibiotics were effective, but that the side effects (including vomiting) associated with many others were too frequent to justify their use in this setting.

Trastuzumab regimen preserves cardiac function

Adjuvant treatment with docetaxel (Taxotere), compared with vinorelbine (Navelbine), improves recurrence-free survival in women with early breast cancer, say researchers (*New England Journal of Medicine* 2006;354:809). In addition, a short course of trastuzumab (Herceptin), administered concomitantly, is beneficial in women with HER2-positive breast cancer and appears to have minimal cardiac side effects.

The researchers randomised 1,010 women with breast cancer to receive three cycles of docetaxel or vinorelbine followed by three cycles of fluorouracil, epirubicin and cyclophosphamide (FEC). Women with HER2-positive breast cancer were further randomised to receive or not to receive nine weekly infusions of trastuzumab.

Trastuzumab was administered before other cardiotoxic therapies and concomitantly with potentially synergistic chemotherapy — but for only nine weeks — to test the hypothesis that such a schedule would limit cardiotoxicity and maintain efficacy, say the researchers.

Recurrence-free survival at three years was higher in the docetaxel than in the vi-



Dr P. Marazzi/Science Photo Library

Trastuzumab regimen has unexpected cardiac benefit

noelbine group (91 per cent versus 86 per cent; hazard ratio 0.58; 95 per cent confidence interval 0.40–0.85; $P=0.005$). Development of distant metastases was also less common in the docetaxel group ($P=0.008$), however, overall survival was not significantly different between the two groups. Docetaxel was associated with more adverse effects than was vinorelbine — 36.9 per cent in the docetaxel group developed neutropenic fever which necessitated a reduction in its starting dose during the study (from 100mg/m² to 80mg/m²).

Among the women with HER2-positive breast cancer, those who received trastuzumab had better three-year recurrence-free survival than those who did not (89 per cent versus 78 per cent; hazard ratio 0.42; 95 per cent confidence interval 0.21–0.83; $P=0.01$). They also had fewer distant recurrences of cancer ($P=0.002$) and overall survival tended to be better ($P=0.07$). None of the trastuzumab-treated women had cardiac failure, said the researchers. They added that, unexpectedly, these women had slightly better maintenance of left ventricular ejection fraction than those who did not receive trastuzumab. They suggested that administration of trastuzumab before FEC and radiotherapy as well as the small cumulative dose of epirubicin may have contributed to the preservation of cardiac function.

The author of an accompanying editorial (*ibid*, p789), commented: “The study by Joensuu *et al* demonstrates that trastuzumab can be given in therapeutically active doses with negligible cardiac side effects, but whether a similar result might hold in larger numbers of patients or in women with preexisting heart disease is now a pressing question.”

Problems with ICU corticosteroids identified

Corticosteroid use in intensive care is associated with increased rates of pneumonia and septicemia, according to the authors of a case-control study (*Archives of Surgery* 2006;141:145).

Researchers looked at data for 100 patients who received corticosteroids during intensive care unit (ICU) stays and 100 matched ICU controls. Steroids are used in ICU for many indications, including spinal cord injury, septic shock, optic neuritis and airway oedema. Current ICU practice, the

authors say, leans towards their use for patients with sepsis and relative adrenal insufficiency.

They found that corticosteroid use in ICU patients was associated with an increased rate of pneumonia (odds ratio 2.64, 95 per cent confidence interval 1.21–5.76; $P<0.05$) and septicemia (OR 3.25, 95 per cent CI 1.26–8.38; $P<0.05$). Corticosteroid-treated patients spent five days longer on ventilators ($P<0.01$) and seven days longer in ICU ($P<0.01$). Trends towards urinary tract infection and increased mortality were observed.

Sirolimus reduces cancer risk in kidney transplant

Early replacement of ciclosporin with the mTOR (molecular target of rapamycin) inhibitor sirolimus more than halves the risk of cancer in kidney transplant recipients, a study published in the *Journal of the American Society of Nephrology* has revealed (2006;17:581).

Three months after renal transplantation, the 430 study patients were randomly assigned to remain on an immunosuppressant regimen of ciclosporin, sirolimus and steroids or have ciclosporin withdrawn and receive high-dose sirolimus and steroids.

At five years, the median time to first skin carcinoma was delayed in the sirolimus group (1,126 days versus 491 days in the ciclosporin group; $P=0.007$), and the incidence of non-skin cancer was reduced (4.0 per cent versus 9.6 per cent in the ciclosporin group; $P=0.03$).

Commenting, Alan Jardine, consultant nephrologist, Western Infirmary, Glasgow, said: “Although immunosuppressive agents have undoubtedly improved the quality of life for many organ recipients, it is widely accepted that they can also increase malignancy risk. Cancer is now the second most common cause of premature death in kidney recipients (behind cardiovascular disease), with estimates showing that the post-transplant rates of some cancers are 20 times higher than those seen in the general population.”

He added that the use of mTOR inhibitors meant that limiting cancer development was becoming more feasible.

Anticholinergic drugs impair cognition in older people

Older patients taking anticholinergic drugs are at risk of mild cognitive impairment, according to research published in the *BMJ* (2006;332:455).

Researchers performed cognitive assessment on 372 individuals over 60 years of age without a previous diagnosis of dementia, of whom 9.2 per cent had continuously used anticholinergic drugs in the year before assessment. Mild cognitive impairment was identified in 80 per cent of continuous anticholinergic drug users and in 35 per cent of those not using anticholinergic drugs (odds ratio 5.12; $P=0.001$). No association between anticholinergic use and the development of dementia was observed after an eight-year follow-up.



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