

One month wait for full details of contract in England

Community pharmacists in England will have to wait another month to find out exactly how they will fare financially under the new contract.

Last week's announcement that a £1.766bn deal has been agreed to fund the new contract (*PJ*, 28 August, p277) will not mean much to pharmacists until it is determined how the sum will be distributed. This week, the Pharmaceutical Services Negotiating Committee confirmed that it is developing distribution models that will be discussed at the next PSNC meeting, to be held at the end of September. Provided that an agreement is reached, an announcement on future distribution of funding will follow this meeting.

The total sum is more than double the old global sum in England (about £800m). However, it is presumed that some of the new money will cover future losses in profits on drugs purchasing. This is discussed further in this week's **News feature** (see p308).

Meanwhile in Wales, pharmacists are expected to hear about funding for their new pharmacy contract within the next few weeks. The Welsh Assembly Government said last week that it was pleased to note that an agreement had been reached between the PSNC and the Department of Health on funding in England. A statement from the Assembly sent to Community Pharmacy Wales said: "As you are well aware, the negotiations have been conducted on an England and Wales basis, and we are now studying the details of the agreement and will be making a statement in due course." However, it also warned that from experience with other contract negotiations, a measured approach would be taken in Wales.

Peter Haydn Jones, chief executive of CPW, told *The Journal* that CPW is continuing to discuss the position with the Welsh Assembly Government. "We are expecting an announcement in two to three weeks," he commented.

In Scotland, an outline funding model was announced last month (*PJ*, 14 August, p211) although the precise level of financial support has yet to be agreed. However, it is expected that the new contract will be implemented on a transitional basis.

"While considerable work still needs to be done, it is hoped that over the next few months a clearer understanding of what the transitional arrangements might look like will be developed," said Frank Owens, chairman of the Scottish Pharmaceutical General Council.

"Successful delivery of the new contract services will require the provision of a number of pieces of supporting infrastructure. These take time to put in place, hence the need to consider transitional arrangements. We are already in the process of discussing these arrangements with the Scottish Executive, although we anticipate it will be some months yet before we are in a position to advise contractors further," he said.

NHS IT plans to be investigated by National Audit Office

The National Audit Office (NAO), is to investigate whether the English National Programme for IT (NPfIT) will be value for money for the NHS.

The NPfIT is to create an electronic infrastructure for the NHS that is intended to improve patient care by increasing the efficiency and effectiveness of clinicians and other NHS staff. Key elements are:

- Electronic transmission of prescriptions
- Shareable electronic patient records
- Online booking of hospital appointments
- Feedback on quality of care
- Storing and distributing digital diagnostic images

■ Ensuring that IT infrastructure meets current and future needs.

The Government has allocated £2.3bn to be spent over the three financial years up to 2005–06. The total value of contracts that have already been awarded (which cover a period of seven to 10 years) is £6.2bn.

Contracts for the major IT systems making up the national system were placed earlier this year. The NAO intends to examine the procurement processes used for placing the contracts, to decide whether the contracts are likely to deliver good value for money and to examine how the Department of Health is implementing the programme.

IT consultant and pharmacist Ian Shepherd said that the audit was to be welcomed. "I don't believe that that NPfIT has anything to fear from an audit," he said. "While there is not a lot of information available about how the contracts were procured, I am confident that everything has been done correctly and any potential conflicts of interest have been properly managed. If the national programme fails to deliver, it will not be down to the procurement process. But there will always be a risk that the technology will not deliver or that some professional group might boycott the system."

The audit report is expected to be published next summer.

Prime Minister visits pharmacy in Harlow, Essex, this week



Tony Blair during his visit to David Grainge Ltd in a campaign to tackle "yob" culture

The Society

Regulation of technicians

The Society's Council has agreed a fee structure for the registration of pharmacy technicians (p329); the Code of Ethics for Pharmacy Technicians has been published (p329); interim fitness-to-practise procedures for pharmacy technicians have been adopted (p330) and guidance has been prepared on acceptable work experience for those registering as pharmacy technicians (p330).

Honour for Lord Newton

Lord Newton, the Society's former Parliamentary adviser, is to be awarded honorary fellowship of the Society (p331).

Resistance to influenza drug higher than expected

Resistance to the antiviral drug oseltamivir may be higher than expected, new research shows.

Japanese researchers have investigated resistance to oseltamivir, a neuraminidase inhibitor, in a group of children with influenza. In 50 children being treated with the drug, nine (18 per cent) were found to have neuraminidase mutations in positions known to confer resistance. Resistance was first detected four days after the start of treatment.

This level of resistance is higher than in previous reports. Kiso and colleagues, from the University of Tokyo, say that one explanation may be their rigorous detection techniques. They also note that lower paediatric oseltamivir doses may be used in Japan than in Europe or the US, which could be a contributory factor (*Lancet* 2004;364:759).

The researchers do not know whether the resistant viruses are less virulent or transmissible than normal.

Children, being more susceptible to influenza than adults, are seen as a useful group to study because they could provide a model

similar to that of a general population during an influenza pandemic.

In an accompanying leading article (p733), Anne Moscona, from the Mount Sinai School of Medicine, New York, describes the Japanese data as a timely wake up call. "The study challenges our complacency about neuraminidase-inhibitor resistance," she says.

Since stockpiles of antiviral drugs are a key part of contingency planning for an influenza pandemic, Dr Moscona says that it is vital to learn more about the incidence and mechanisms of resistance.

□ **Cost concern** Public health specialists are concerned about the cost of complying with National Institute for Clinical Excellence guidelines on use of oseltamivir to prevent influenza in nursing homes. NICE recommends that oseltamivir is given to all residents in nursing and residential homes each time a case of influenza-like illness is recognised in a resident or staff member and when flu is known to be circulating in the community.

The specialists, from the Royal Free hospital and the Health Protection Agency, have

The virulence of the resistant flu viruses is not known

assessed the implications of this advice. From a survey last winter, they calculate that two-fifths of nursing homes have a case of influenza-like illness every week in winter. "The use of a single case of influenza-like illness as the threshold for prophylaxis may be impractical and costly," they say, adding that further studies are needed to determine the best strategy for chemoprophylaxis. The study is published on *BMJ Online* this week.

New data from 4S trial show statins safe in long term

Reassuring data have been published on the long-term safety of statins. Post-trial follow-up of patients in the Scandinavian Simvastatin Survival Study (4S), one of the major secondary prevention statin trials, has shown no difference in cancer mortality between the simvastatin and placebo groups.

There has been some concern about a possible increased risk of cancer associated with pronounced cholesterol lowering. Although many trials have shown statins to have a good safety profile, the 4S researchers say that the average duration of such trials is fairly short in terms of studying cancer incidence. For this reason, they decided to extend post-trial follow-up of 4S participants.

National registers were used to assess cause-specific mortality and cancer incidence in the original treatment groups for a median

follow up of 10.4 years (5.4 years for the original trial, then a further 5 years).

The results of this five-year extension study are published in *The Lancet* (2004; 364:771). The data were analysed by intention to treat and there was no statistically significant difference between the two groups in cancer mortality or cancer incidence.

After the double-blind part of the trial, most patients in both groups took a statin but the survival benefit of patients allocated simvastatin in the initial trial period persisted, largely because of lower coronary mortality.

Tim O'Donoghue, a pharmacist at Greenlight Pharmacy, London, said the results are good news for those pharmacists who are actively taking up the challenge to prescribe OTC simvastatin. "No customer has specifically asked us about cancer," he added.

Reassurance over long-term safety of calcium antagonists

Long-acting nifedipine is safe for use by patients with stable angina. This is the main finding of the ACTION trial, published on *The Lancet* online (August 31).

The trial started in 1996 following concerns about the long-term safety of nifedipine, particularly short acting formulations. It included 7,665 patients randomised to receive nifedipine or placebo on top of their conventional therapy.

The primary end-point was a combination of death, acute myocardial infarction, refractory angina, new heart failure, debilitating stroke and peripheral revascularisation.

With mean follow-up of 4.9 years, there

was no difference between the two groups. Study chairman Philip Poole-Wilson, from Imperial College London, emphasises that although the primary end point for efficacy did not differ between treatment groups, "ACTION did not accord with past claims that nifedipine induces myocardial infarction or heart failure".

Martin Cowie, professor of cardiology at the Royal Brompton Hospital, London, commented to *The Journal* that ACTION would not change practice but it offered reassurance about safety. "It confirms in a large prospective study that calcium antagonists are safe for patients with cardiovascular disease," he said.

News in brief

Gel helps stress incontinence

A gel that is injected into the urethra reduces leakage in women suffering from stress urinary incontinence, a study presented at last week's International Continence Society congress in Paris shows. It found that Zuidex, which is an injectable gel consisting of hyaluronic acid and dextranomer, reduced leakage in 77 per cent of women after 12 months.

Wear elastic stockings after DVT

Patients with deep venous thrombosis can reduce their risk of post-thrombotic syndrome by wearing compression stockings, research shows. In a trial of patients with a first episode of symptomatic proximal DVT, 44 out of 90 not wearing stockings developed post-thrombotic problems compared with 23 out of 90 wearing stockings (*Annals of Internal Medicine* 2004;141:249).

Risks of sugary drinks clarified

Strategies to prevent obesity should focus on reducing consumption of sugary drinks. Researchers found that women who consume one or more of these drinks each day had a relative risk of type 2 diabetes of 1.83 compared with those who consumed less than one per month. They also gained more weight (*JAMA* 2004;292,927).

Nine risk factors that will predict most heart attacks

Nine easily measured risk factors can predict more than 90 per cent of heart attacks, according to a major global study.

The INTERHEART study, reported at the European Society of Cardiology in Munich this week, matched 15,152 people suffering a first myocardial infarction (MI) with healthy controls for age and sex. Researchers systematically assessed the relationship between a wide range of factors and the risk of MI and found nine significant factors.

The leading risk factor was raised lipids — measured as the ratio of apolipoprotein B to apolipoprotein A-1. People in the highest quintile had nearly four times the risk of MI as those in the bottom quintile. Smoking was the second most important risk factor, with current smokers at nearly three times the risk of MI as non-smokers. Diabetes imposed a

similar tripling of MI risk, while hypertension increased risk by 2.5 times. Abdominal obesity and psychosocial stress doubled MI risk. Low daily consumption of vegetables and fruit, taking little regular exercise, and excessive (or no) alcohol intake are the other factors.

The risk factors were multiplicative, so that a person with all of them was at more than 100 times the risk of an MI (odds ratio 129.2) as someone without any risk factors.

The study leader, Salim Yusuf, professor of medicine, McMaster University, Hamilton, Ontario, said: "The vast majority of heart attacks can be predicted by nine easily measurable factors. It has previously been thought that only half of the risk of MI could be foreseen, but the findings mean that the overwhelming majority of heart attack risk can be predicted."

Low consumption of fruit and vegetables is a risk factor

Can early, aggressive statin use cut cardiovascular events?

It remains unclear whether aggressive use of statins to lower cholesterol after an acute coronary syndrome (ACS) event may prevent death and major cardiovascular events, following inconclusive results from a new trial.

The study, the second part of the "A to Z" (Aggrastat to Zocor) trial, compared an early, aggressive approach to statin treatment with delayed, lower dose treatment.

In the trial, 2,265 patients who had had an ACS event received aggressive statin therapy (40mg simvastatin for 30 days followed by 80mg per day), and 2,232 patients were randomised to less aggressive therapy (placebo for 30 days followed by 20mg simvastatin per day). Patients were followed up for six to 24 months.

In the less aggressively treated group, 16.7 per cent of patients experienced a heart attack, stroke or cardiovascular death or were readmitted to hospital, compared with 14.4 per cent of those treated early and aggressively ($P=0.14$). The results are not statistically significant, but the authors point out that, in the aggressively treated group, cardiovascular death occurred in 4.1 per cent of patients and congestive heart failure occurred in 3.7 per cent, compared with 5.4 per cent and 5 per cent, respectively, in the less aggressively treated group (P values 0.05 and 0.04). The aggressively treated group also experienced a 0.4 per cent increase in myopathies compared with the less aggressively treated group.

An accompanying commentary points out: "It is important to reassure practising physicians and patients that the unfavourable risk-benefit relationship observed in the A to Z trial does not in any way diminish the value of intensive statin treatment in secondary prevention."

The study was presented at the European Society of Cardiology this week and is also published in an express article in *JAMA* (2004;292:1307).

Kidney protection in diabetes comparable for angiotensin receptor blocker and ACE inhibitor

Telmisartan, the angiotensin receptor blocker (ARB), is comparable to the angiotensin converting enzyme (ACE) inhibitor enalapril in protecting against deterioration in kidney function in patients with type 2 diabetes, according to results from the first long-term study to compare the two drug classes.

The study randomised 250 patients with type 2 diabetes, hypertension and early nephropathy to telmisartan (80mg once daily) or enalapril (20mg daily) for five years. All had previously been on an ACE inhibitor for at least three months.

Results, reported this week at the European Society of Cardiology in Munich, showed similar protection against further loss of kidney

function. Over the five years, the mean fall in glomerular filtration rate (GFR) was 17.9ml/min/1.73m² with telmisartan and 14.8ml/min/1.73m² with enalapril. Tony Barnett, professor of medicine, University of Birmingham, pointed out that diabetes patients with proteinuria not treated with renoprotective agents show a GFR reduction of about 50–60ml/min/1.73m² over five years.

The mortality rate in the study was 5 per cent over five years, which was half that expected. "The results showed comparable efficacy of telmisartan and enalapril, making the ARB a valid choice for first-line treatment of hypertensive type 2 diabetes patients with early nephropathy," Professor Barnett concluded.

New cannabinoid receptor blocker found effective in obesity

Treating obesity with the selective cannabinoid-1 receptor blocker rimonabant is significantly more effective than reducing calorie intake alone, reveals a new study presented at the European Society of Cardiology conference in Munich this week.

The study, RIO-EUROPE (Rimonabant in Obesity Europe), compared rimonabant with placebo in 1,507 obese or overweight people. All were advised to follow a mildly hypocaloric diet and to be physically active.

Results after one year showed that patients taking rimonabant (20mg/day) lost an average of 8.6kg compared with 3.6kg for those taking placebo ($P<0.001$). Those randomised to rimonabant 5mg lost 4.8kg.

More than one-third (39 per cent) of patients on the higher dose of rimonabant lost more than 10 per cent of their initial body weight, compared with 12.4 per cent of the placebo group ($P<0.001$).

Reporting the results, Luc Van Gaal, professor of diabetology, University Hospital Antwerp, Belgium, noted that a 10 per cent loss of body weight was generally deemed necessary to reduce significantly the cardiovascular risk associated with obesity.

Metabolic risk factors also improved. The number of patients with metabolic syndrome (a cluster of cardiovascular risk factors including dyslipidaemia and hypertension) halved from 42.2 per cent at baseline to 19.6 per cent in the rimonabant 20mg group ($P<0.001$). HDL-cholesterol increased by 27 per cent, compared with 17.3 per cent in the placebo group. Triglyceride levels also improved. Weight loss accounted for only half of the improvement seen in triglycerides, indicating a direct effect of rimonabant on lipid metabolism, independent of weight loss.

Side effects with rimonabant were mainly mild and transient.

NICE changes tune on eczema drugs

Topical tacrolimus and pimecrolimus have both been approved by the National Institute for Clinical Excellence for use in atopic eczema.

NICE has changed its decision on pimecrolimus, although it still puts restrictions on use of the drug: its preliminary recommendation was that the drug should not be used at all.

As second-line treatments, tacrolimus is recommended as an option for moderate to severe eczema in adults and children aged two years and older and pimecrolimus for moderate eczema on the face and neck in children aged two to 16. For both immunomodulators, NICE recommends use only if the disease is not controlled by topical steroids and where there is a serious risk of side effects, particularly skin atrophy, from further use of steroids.

Tacrolimus and pimecrolimus have similar mechanisms of action but different licensed indications. NICE's recommendation for tacrolimus is similar to its licensed indications. For pimecrolimus, the recommendation is more restricted because this drug is licensed for mild to moderate eczema in both adults and children, and not only for facial use. However, the recommendation for use of the drug in children has been welcomed by Novartis, manufacturer of Elidel (pimecrolimus).

Pimecrolimus is now recommended for facial eczema in children over two years old

In Scotland, the Scottish Medicines Consortium has recently announced that pimecrolimus cream is not recommended for NHS use. It says there is no evidence of clinical advantage over alternative treatments, such as mild-to-moderately potent steroids, and that the economic case for using pimecrolimus is unproven. Novartis comments that this decision denies access to a treatment that has been licensed in over 80 countries and recommended by NICE. The SMC recommends restricted use of tacrolimus.

The NICE guidance is available via links on *PJ Online* (www.pjonline.com/pj/links).

Use topical steroids only once or twice a day

Topical steroids should be used only once or twice a day in the treatment of atopic eczema, says the National Institute for Clinical Excellence. It also recommends that where more than one steroid within a potency class is clinically appropriate, the drug with the lowest cost should be prescribed.

In new guidance on frequency of application, NICE says that there is no compelling evidence of a clinically significant difference between once-daily application and more frequent application in terms of effectiveness, patient satisfaction or adverse effects.

The British National Formulary already notes that it is not necessary to apply topical steroids more than once or twice a day. Some products are licensed for more frequent use and two of the newer products — fluticasone propionate cream and mometasone furoate cream and ointment — are licensed for use only once a day. NICE comments that use of these “once daily only” products costs more than twice-daily use of one of the older steroids of equivalent potency.

The guidance is available via *PJ Online* (www.pjonline.com/links/pj).

Asthma prevalence is stable

The rate of increase of the prevalence of asthma in children appears to have slowed, according to UK data published last week.

In a survey in Aberdeen, parents of 3,537 primary school children (aged nine to 12 years) completed a questionnaire on respiratory symptoms and diagnoses of asthma, eczema and hay fever. Similar surveys over the past 35 years have shown a marked increase in asthma prevalence. The new data, for 1999, show little change in prevalence of asthma or wheeze since 1994. Even so, around one-quarter of children have been diagnosed as having asthma at some time in their lives.

Hay fever and eczema were, however, more likely in 1999 than 1994, suggesting that the tendency for children to develop allergies is still increasing (*British Medical Journal* 2004;329:489).

News in brief

New vaccines information

Leaflets explaining changes to the childhood immunisation programme in Scotland will be sent to pharmacies this week. NHS Health Scotland has also launched a new website containing publications and information for parents about the new programme. It is available at www.healthscotland.com/immunisation.

NPSA hand cleaning alert

All hospital patients are to have an alcohol-based hand rub placed by their bedsides to encourage health care staff to clean their hands. It is estimated that complying with this latest safety alert from the National Patient Safety Agency will save 450 lives and £140m a year. Details at www.npsa.nhs.uk/cleanyourhands.

Pharmacists can accelerate hospital discharge

Hospital pharmacy staff can contribute to the timely discharge of patients from hospital by making sure that discharge medicines are ready on time. This is clear from guidance issued by the Department of Health last week.

At least 80 per cent hospital discharges are simple discharges: patients are discharged to their own home, with simple ongoing health care needs which can be met without complex planning. Streamlining this process — to bring discharges forward by just a few hours — can have a dramatic impact on the availability of hospital beds and significantly reduce admission delays.

The guidance — described by the DoH as a toolkit — includes a number of case studies that show how simple changes can make a difference.

One, describing procedural changes made at Chesterfield and North Derbyshire Royal Hospital, shows the benefits of changing ward rounds so that patients who are likely to be

discharged are seen first. Prescriptions for discharge medicines were written during these rounds. A further change was the opening of a discharge lounge where patients could wait, rather than continue to occupy a bed. Discharge prescriptions were checked and dispensed in the lounge by pharmacy technicians.

The toolkit implies that simple changes such as these can prevent the experience of one patient, set out as an example of what should not happen. The patient said: "When I was due for discharge, the ambulance arrived but medicines were not ready. Then, by the time the medicines were ready there were no ambulances."

Effective medicines management is also seen as a component of the solution to delayed discharge.

One of nine factsheets appended to the guidance summarises the hospital medicines management collaborative (HMMC) pro-



Patients need discharge medicines on time

gramme to optimise medicines management systems in hospitals in England.

A key factor in the HMMC programme is the development of partnerships between primary and secondary care, including joint admission and discharge planning.

News in brief

Drug-related deaths down

The number of deaths resulting from misuse of drugs has fallen in Scotland, according to data released this week. There were 317 drug-related deaths in 2003, 17 per cent less than in 2002. Heroin/morphine was involved in 175 deaths, diazepam in 153, methadone in 87, temazepam in 35, cocaine in 29 and ecstasy in 14 (some deaths involved more than one drug).

Diabetes educational resource

A guide to planning education about diabetes for staff working in the health service was launched this week by NHS Education for Scotland. It is aimed at people who have a responsibility for planning educational programmes.

Probiotics not effective in vaginal thrush

Lactobacillus is not effective in preventing vulvovaginal candidiasis after antibiotic treatment, a new Australian study has shown.

A randomised controlled trial assessed the efficacy of this commonly used probiotic treatment. General practices and community pharmacies recruited non-pregnant women, aged 18 to 50 years, with non-gynaecological infections who were starting a short course of antibiotics.

The treatments tested were lactobacillus oral powder or lactobacillus vaginal pessary, with matched placebos. The main constituent was *Lactobacillus rhamnosus*. Women were randomised to four groups: oral and vaginal lactobacillus, oral lactobacillus and vaginal placebo, oral placebo and vaginal lactobacillus, and oral and vaginal placebo. Treatment was taken during the antibiotic course and for four days after. The women recorded any symptoms of candidiasis and provided vaginal

swabs for analysis (at baseline and after 14 days).

Overall, 55 of 235 women (23 per cent) developed post-antibiotic candidiasis. There was no evidence of any beneficial effect from the "active" treatment.

The authors comment that use of lactobacillus in post-antibiotic vulvovaginitis is widespread, despite lack of a biologically plausible basis or evidence of effectiveness. They have previously found that 40 per cent of women with a history of vulvovaginitis had used yoghurt or lactobacillus to prevent antibiotic-associated candidiasis. "Our results should prompt health professionals to inform women that lactobacillus is unlikely to prevent post-antibiotic vulvovaginitis and that they should consider using proved antifungal treatment if symptoms develop," they say.

The study is published on *BMJ online* (August 27).

NHS overseas recruitment to be tightened up

Proposals to tighten up the National Health Service code of practice on recruitment of staff from overseas have been announced. A revised code will be published later this year. The aim of the code is to stop the NHS recruiting professional staff from developing countries to the detriment of health care there.

The main proposals for strengthening the existing code of practice are:

- Giving private sector employers that adopt the code access to NHS recruitment programmes

- Extending the code to the recruitment of locum and temporary staff

- Extending the code to domestic recruitment agencies.

Health Minister John Hutton said: "These proposals strengthen the code even further, bring the private sector into line with the NHS and will ensure that NHS contracts go to those signed up to the code. We're also proposing to close the loophole that allows NHS trusts to recruit temporary staff from developing countries and extending the code to cover even more recruitment agencies."



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