

## NPA calls on Society to halt plans for mandatory registration of technicians

THE National Pharmaceutical Association says that plans for the mandatory registration of pharmacy technicians should be put on hold until the effects of standard operating procedures (SOPs) in community pharmacies can be assessed.

The Royal Pharmaceutical Society has decided that SOPs should be in place in all pharmacies from 1 January 2005. The Society's Council agreed in December last year (*PJ*, 22/29 December 2001, p895) to move towards mandatory regulation of pharmacy support staff, without setting a specific date for when this should occur. A consultation paper on support staff was published in *The Journal* in June (*PJ*, 22 June, p888).

In a statement issued by the NPA on 8 August, the association says that its board has considered the question of regulation of support staff on a number of occasions over the past few months. It describes the consultation document as "complicated and framed in a manner which restricted expression of views". The NPA says that because of the fundamental importance of the issue to members of the Society it has decided to issue a position paper setting out the board's views.

The position paper says that the NPA accepts the regulation of support staff through the specification of educational standards, SOPs and the continuing professional accountability of the pharmacist. However, it believes that compulsory registration of pharmacy technicians is not necessary to deliver high quality services. It says that the drive for regulation is coming from hospital pharmacy, where technicians are taking on roles outside the core dispensing role. In community pharmacy, the NPA says, there are no specific roles in the dispensing process that are not covered by the professional responsibility of the pharmacist in charge, even when they have been delegated to suitably trained staff.

"The association is not aware of any sound evidence that community pharmacists are currently putting the public at risk by delegating tasks to members of staff who are not competent to undertake them. Nevertheless . . . we support the Council's decision on mandatory SOPs because this will, in practice, provide a transparent, formal risk management process. There is, however, no justification, in the public interest or otherwise, for the Council to impose mandatory registration of support staff, with all associated cost implications for community pharmacists, unless there is evidence that the SOP process has failed to achieve [better services for patients, protection of the public and a competent workforce]."

The NPA adds that registration only has any real meaning if a group of people who are registered are able to perform a task or carry out a responsibility which they cannot undertake if they are not registered. This is not the case for support staff in community pharmacies, it says.

In conclusion, the NPA's position paper recommends that no further mandatory registration should be considered until SOPs are in place and their effects have been properly studied.

The Royal Pharmaceutical Society said that responses to its consultation paper received so far had identified a number of concerns that would need to be addressed.



*The work of community pharmacy technicians is covered by pharmacists' professional responsibility and registration is unnecessary, the NPA says*

In particular, there was a need to engage with those individuals who were likely to fall within the scope of any new regulatory requirements.

The Society noted that the Association of Pharmacy Technicians believes that technicians should be regulated and that the Society is the most appropriate body to do this. In a recent survey conducted by the APT, 97 per cent of respondents supported registration with 63 per cent of respondents being APT non-members. The APT represents about 1,000 of the estimated 13,000 technicians working in hospital and community pharmacies.

## Supply of BCG vaccines halted following recall

ALL batches of BCG (tuberculosis) vaccine manufactured by Evans Vaccines, part of PowderJect Pharmaceuticals, have been recalled after a number of batches were found not to comply with the requirements of their registered specifications for potency throughout their shelf-lives (see p212). The recall also follows notification of suspension of the company's licence for BCG vaccine in Ireland.

A spokesperson for Evans Vaccines told *The Journal* that the vaccine is not expected to be made available again until April next year and that the company is assisting the Department of Health in finding an alternative source for obtaining supplies. However, the company adds that regulators are satisfied that there are no related safety implica-

tions and that "the vaccine should still be effective because the potential reduced efficacy is not of clinical relevance".

The Irish Medicines Board, which ordered the suspension of the company's contract to supply the BCG vaccine to the Irish Republic, says it is now reviewing the licences for all products the company supplies to the Irish market.

The suspension of the contract for the vaccine in Ireland follows a recall of one batch of the BCG vaccine in Ireland last month. Tests revealed it had a lower potency than usual, and was therefore less effective. That prompted an inspection of the company's manufacturing facility at Speke, Liverpool by the Irish Medicines Board. Dr Joan Gilvarry, medical director, Irish Medi-

cines Board, commented: "The board was dissatisfied with the procedures adopted in producing the vaccine". The inspection revealed "inconsistencies" in the potency of the vaccines and that some batches were less effective than others. While there was no public safety threat, a decision to suspend the contract was taken as a precautionary measure. An alternative supplier has been found in Denmark.

The Irish Medicines Board says that it has expressed concern to the Medicines Control Agency over the inconsistency in the quality of the vaccine supplied by Evans Vaccines and has asked for its co-operation in investigating the plant. A further, more detailed, inspection of the Speke facility is planned.

## Inappropriate drugs prescribed for many elderly patients living at home

MANY elderly patients living at home are taking medicines that are inappropriate for them, according to new research (*Archives of Internal Medicine* 2002;162:1707).

Finnish researchers found that about a third of elderly patients taking beta-blockers had conditions, in addition to concomitant heart disease, where use of these drugs is considered inappropriate. They found that 37.9 per cent of those with peripheral vascular disease were taking beta-blockers, which can increase leg pain in this instance.

Meanwhile, 32.5 per cent of those with diabetes taking oral hypoglycaemics or insulin and 27.2 per cent of patients with chronic obstructive pulmonary disease (COPD) were also taking beta-blockers, which can mask symptoms of low blood sugar and affect breathing. In addition, the researchers found 19.3 per cent of COPD patients were using sedatives, which can suppress breathing.

The researchers surveyed over 3,000 urban residents in Helsinki, Finland, aged 75–95 years, to determine the prevalence of drug use considered inappropriate for 15 common medical conditions according to recommendations made by an American

expert group in 1997. They also assessed the general prevalence of drug use considered to be inappropriate in the elderly, but found this was low compared with that found in previous studies. Of those responding to the survey, 12.5, 1.3 and 0.2 per cent were regularly taking one, two or three inappropriate drugs, respectively. The antiplatelet drug dipyridamole was the most prevalent inappropriate drug, occurring in 3.6 per cent of cases, followed by long-acting benzodiazepines, in 2.6 per cent of cases.

In an accompanying editorial, Dr Jerry Gurwitz from Massachusetts University Medical School suggests that the apparently low level of inappropriate drug use found in this study may be due to the fact that many of the drugs included in the American expert group's 1997 list are no longer used or no longer available in Finland. He suggests the prevalence of inappropriate medication among the elderly could be higher than that found by this study and that enhanced collaboration between those who prescribe drugs and those who know medications best — clinical pharmacists — would improve the quality of medicine use in these patients.

**n Medication review in the UK** A news feature in *The Journal* this week explores what is currently being done in the United Kingdom to improve medication use among the elderly, through regular medication reviews (p209).

## DTB questions whether Yasmin contraceptive is truly different

THE claim that Yasmin, a new combined oral contraceptive, is "truly different" is not justified and should be withdrawn, according to the latest *Drug and Therapeutics Bulletin*.

The *DTB* concludes that there is no compelling evidence to suggest that Yasmin, which contains the new progestogen drospirenone (a derivative of spironolactone), offers any advantages over other, longer-established, combined oral contraceptives with regard to weight gain, skin condition or premenstrual symptoms.

The *DTB* reports that a claim made by Schering Health Care, manufacturer of Yasmin, that the product is a "pill for well-being" is based on a survey in which the authors state that there was no significant change in overall well-being. Professor Joe Collier, editor, *DTB*, said: "Overall, as there is no compelling evidence that Yasmin is any better than other combined oral contraceptives, we cannot recommend it."

In response to the *DTB* review, Schering Health Care said that the company wholly disagrees with the conclusions made. It describes the review as misleading and a flawed assessment of Yasmin. "We believe that this critique is unbalanced and inadequately supported by the discussion and analysis of the published work reviewed."

Schering Health Care also refutes the *DTB* claim that Yasmin's effects on cardiovascular risk have not been quantified. "This

has been repeatedly quantified in periodic safety reports submitted to the various European regulatory authorities, and remains currently well within the expectation for a combined oral contraceptive product."

It adds that some aspects of the analysis of the published literature on Yasmin are unduly sceptical, with no support provided for the position taken by the *DTB*.

The *DTB* concludes that Yasmin cannot be recommended because it has no proven superiority over other combined oral contraceptives and costs more — 12 cycles of Yasmin cost the National Health Service approximately £59 compared with £7 to £38 for other products (2002;40:57).

**n Oral antihistamines** There is little to choose between oral antihistamines in terms of clinical effectiveness, the same issue of the *DTB* concludes (ibid, p59). However, it recognises that desloratadine (Neoclarityn) and fexofenadine (Telfast) may relieve nasal congestion, a symptom that tends not to respond to antihistamine treatment.

The *DTB* suggests that cetirizine (Zirtek) and fexofenadine are the oral antihistamines of choice among second generation drugs, since terfenadine and mizolastine (Mistamine and Mizollen) can cause unwanted cardiac effects, acrivastine (Semprex) requires frequent dosing, and experience with desloratadine and levocetirizine (Xyzal) is limited.

## NICE set to endorse imatinib use for all stages of chronic myeloid leukaemia

NATIONAL Institute for Clinical Excellence guidance on the use of imatinib (Glivec) is likely to recommend that the drug be made available to chronic myeloid leukaemia patients in all three stages of the disease — chronic, accelerated and blast.

Provisional guidance issued in May (*Pj*, 18 May, p675) recommended that the drug should only be available to patients in the accelerated phase. However, following consultation and after further clinical trial evidence was submitted to NICE, the appraisal committee has changed its recommendations.

The final appraisal indicates that imatinib will be recommended as a treatment option for adults with chronic-phase CML who are Philadelphia-chromosome positive and who are intolerant of interferon-alpha or in whom interferon-alpha treatment has failed. The guidance is also likely to recommend use of imatinib for the treatment of adults with Philadelphia-chromosome positive CML in the accelerated phase or blast crisis provided they have not received imatinib previously.

The final appraisal, which is available in full on the NICE website ([www.nice.org.uk](http://www.nice.org.uk)), has been sent to consultees who have until 27 August to appeal against it.

# UniChem investors unveil pharmacies

THE first community pharmacies owned by participants in UniChem's enterprise investment scheme were publicly unveiled last week.

UniChem established its investment scheme in 2000. The scheme consists of a number of parallel companies, each of which is set up to attract tax-efficient investment from community pharmacists and others wishing to put money into pharmacy. The companies use invested funds to buy and operate community pharmacies. UniChem itself has a 27 per cent stake in each company and the pharmacies use UniChem as their principal wholesaler.

The first company, Pharmacy Initiative 1 Plc (PI 1), currently has around 15 to 20 investors and owns a pharmacy at Woodstock, Oxfordshire. A second company, Pharmacy Initiative 2 Plc (PI 2) owns pharmacies at Perivale, Middlesex, and Goring, West Sussex.

John Jaquiss, controller of commercial support at UniChem, explained that typical investors were pharmacists with capital to invest or those looking to retire from business ownership while remaining active in pharmacy. Investors can get income and capital gains tax relief if they comply with the terms of the scheme.

Woodstock Pharmacy was acquired by PI 1 last year and has undergone a full refurbishment, including the fitting of a consultation area with a computer to enable access



*Chris Eberington, managing director of UniChem, (left) shows Woodstock Pharmacy's patient consultation area to the Duke of Marlborough*

to patients' medication records and electronic information sources such as the BNF and Martindale. The pharmacy has two pharmacists, one of whom is focused on clinical pharmacy and medicines management. Stock has been merchandised to

reflect the upmarket, rural location and an older population. The pharmacy was officially opened by the Duke of Marlborough, owner of Blenheim Palace, on 9 August.

Mr Jaquiss said that Woodstock pharmacy represented the kind of pharmacy the investment companies were looking at — independent businesses providing services to local communities but which are underdeveloped or in need of refurbishment and investment. Each pharmacy is expected to retain its own local name and character.

Watmans Pharmacy, Perivale, was sold to PI 2 by its owner who has been kept on as pharmacy manager. The pharmacy underwent a minor relocation to larger premises and now has a glass-fronted consultation room, used for smoking cessation counselling and similar professional services. Stock is merchandised to reflect a suburban location with many young mothers.

Four further investment companies have been set up by UniChem but they are currently inactive. Mr Jaquiss said that there would be a rolling programme with companies being open for investment for 12 months, then closed for five years before action is taken to allow investors to realise any capital gains made. This could include stock market flotations, trade sales or mergers. Further details and prospectuses can be obtained from Mr Jaquiss at UniChem on 020 8391 2323 (e-mail john\_jaquiss@unicem.co.uk).

## Antibody link between MMR and autism suggested

AN INAPPROPRIATE immune response to the measles component of the MMR vaccine could be related to the pathogenesis of autism, researchers have suggested (*Journal of Biomedical Science* 2002;9:359).

Dr Vijendra Singh and colleagues at Utah State University, United States, found "an unusual MMR antibody" in the blood of 75 out of 125 autistic children (60 per cent) they tested. However, they did not find this antibody in any of the 92 vaccinated non-autistic children. Further analysis revealed that the antibody in question was specific for measles haemagglutinin protein, but not

measles nucleoprotein, rubella or mumps viral proteins. The researchers also found that over 90 per cent of blood samples containing this antibody also tested positive for myelin basic protein autoantibodies. Dr Singh and colleagues say that autoimmunity to the central nervous system, and to myelin basic protein in particular, may play a causal role in autism and that their results suggest a strong association between MMR and CNS autoimmunity in autism.

However, the United Kingdom Public Health Laboratory Service told *The Journal* the authors had not used any of the cur-

rently available tests that could measure specific antibodies to measles, mumps and rubella and that there was insufficient viral protein in MMR vaccine to show up positive in test used in the study. Head of the immunisation division at the PHLS, Dr Liz Miller, said: "There are no data in this paper that implicates MMR vaccine as a cause of autism or that challenges the robust body of evidence on the safety of the vaccine."

## US pharmacists convicted of fraud

TWO American pharmacists, along with two doctors and four pharmacy and medical equipment company owners, have been convicted of defrauding the American Medicare scheme of millions of dollars between 1993 and 1997. Eighteen other defendants pleaded guilty before the five-and-a-half month trial.

The conspiracy centred on four pharmacies in Miami which manufactured solutions for nebulisation containing albuterol (salbutamol), metaproterenol (orciprenaline), isoetharine or acetylcysteine. Patients were paid \$50 for the use of their Medicare cards

in the fraud, then the doctors ordered unnecessary tests, medical equipment and aerosol medications for \$100 per patient. The pharmacies concerned prepared the solutions in unsanitary conditions without weighing the active ingredients and the equipment companies billed Medicare.

"The abuse of trust shown by the licensed pharmacists and doctors who perverted the practice of pharmacy and medicine for personal gain is both disheartening and needlessly harmful to those professions that strive to help those truly in need," said Assistant US Attorney Paul Pelletier.

### BRIEFLY

#### Shop front damage

Over half the pharmacies contacted in a survey for Eagle Star's small business insurance division had had their glass shop fronts damaged or smashed in the past three years. Vandalism was to blame for around half the incidents, robbery for just over one-third and accidents for just one in 10.

#### Lloydspharmacy advertising

Lloydspharmacy has started running the second of its national television advertisements, part of a £2.5m campaign, focusing on the relationship between its pharmacists and their customers.

## Low potassium levels may increase stroke risk for elderly taking diuretics

LOW serum potassium levels in patients taking diuretics, and low potassium intake in those not taking diuretics, is associated with an increased incidence of stroke in the elderly, say American researchers.

Dr Deborah Green, of the Neuroscience Institute at the Queen's Medical Centre in Honolulu, Hawaii, and colleagues conducted an observational study involving 5,600 men and women over 65 years of age. The participants, who had not had a stroke when they started the study, were followed for four to eight years and the number and type of strokes that occurred were recorded.

The researchers found that serum potassium levels less than or equal to 4.0mEq/L were associated with an increased relative risk for stroke, but only for people receiving diuretics. Among users of hydrochlorothiazide diuretics, those with the lowest level of potassium in their blood were 3.1 times more likely to have a stroke than those with the highest level (95 per cent confidence interval 1.7–5.8,  $P<0.0005$ ). For loop diuretics and potassium-sparing diuretics the relative risks were 2.4 (1.2–4.7,  $P<0.001$ ) and 2.0 (1.1–3.7,  $P<0.05$ ), respectively.

However, the researchers stress that the results do not imply that diuretics create an excessive risk of stroke. "It is important to note that we are neither implying, nor does our data support, any excess risk for stroke associated with the use of diuretics. The question can be raised, however, as to whether diuretics would be even more effective if potassium levels were maintained at normal levels," they say. Furthermore,

they found that stroke risk was associated with lower dietary intake of potassium only in people not taking diuretics. In this group, people with the lowest amount of potassium in their diet were 1.76 times (1.21–2.57,  $P<0.025$ ) more likely to have a stroke than those with the highest amount of potassium in their diet.

The researchers also examined the small number of diuretic users who also had atrial fibrillation. They found that those with atrial fibrillation and low serum potassium were nearly 10 times more likely to develop a stroke than diuretic users with regular heart rhythms and higher blood potassium levels. They say that, although the numbers were small, this finding is intriguing enough to warrant further study (*Neurology* 2002;59:314).

In an accompanying editorial, Dr Steven Levine, of the Mount Sinai School of Medicine in New York, and Dr Bruce Coull, of the University of Arizona Health Science Centre, comment that the study suggests diuretics may modulate the risk of stroke associated with potassium levels or intake. "Even a slightly increased risk of low potassium added to established stroke risk factors, such as hypertension, diabetes mellitus, atrial fibrillation and cigarette smoking, could have a large effect, given the extensive use of diuretic drugs and the presumed ease of dietary manipulation of potassium," they say (*ibid*, p302).

## Botulinum toxin reduces spasticity after stroke

INJECTIONS of botulinum toxin A (Botox) can reduce spasticity of muscles and associated disability in stroke patients, a double-blind randomised controlled trial has shown (*New England Journal of Medicine* 2002;347:395).

American researchers compared the safety and efficacy of a one-off injection of botulinum toxin A (200–240 units) with placebo in 126 people who had increased flexor tone in their wrist and fingers following a stroke. Almost two-thirds of patients (62 per cent) injected with botulinum toxin A reported improvements of at least one point on the Disability Assessment Scale after six weeks, compared with only 27 per cent of the placebo group.

Self-reported disability related to hygiene, dressing, pain and limb position, and patients selected one area where they experienced moderate to severe disability as the principal treatment target. The botulinum toxin A group reported greater improvements in principal target areas than the placebo group over the duration of the 12-week study.

Furthermore, patients injected with the toxin suffered no major adverse effects, and prevalence of minor adverse events such as headache was similar in both groups.

The researchers conclude that a one-off botulinum toxin A injection into the spastic muscles could improve flexor tone, functional disability and quality of life in patients suffering post-stroke spasticity of the fingers and wrist.

## Linoleic acid may protect against ischaemic stroke

LINOLEIC acid may protect against ischaemic stroke, a Japanese study has suggested (*Stroke* 2002;33:2086).

Researchers conducting a prospective case-control study identified 197 Japanese people aged 40–85 years who had suffered haemorrhagic or ischaemic stroke (75 and 122 individuals, respectively), and matched three controls with each case. Analysis of blood samples from these individuals revealed that those who had suffered a stroke had lower serum concentrations of linoleic and arachidonic acids, compared with controls. In addition, they had higher concentrations of saturated and mono-saturated fatty acids in their serum than those in the control group.

After adjusting for hypertension, diabetes, serum total cholesterol and other cardiovascular risk factors, the researchers calculated that a five per cent increase in serum linoleic acid concentration could decrease an individual's risk of ischaemic stroke by a third (34 per cent) and haemorrhagic stroke by a fifth (19 per cent). Conversely, they found that a 4 per cent increase in serum saturated fatty acid concentration increased an individual's risk of stroke by about the same amount — 35 per cent for ischaemic stroke and 21 per cent for haemorrhagic stroke.

They conclude that a higher intake of linoleic acid may protect against ischaemic stroke in particular, possibly by decreasing blood pressure and platelet aggregation, and by enhancing deformability of erythrocytes.

## Even light smoking increases risk of MI

SMOKING as few as three cigarettes a day increases the risk of myocardial infarction (MI), Danish researchers have found. Furthermore, women are more susceptible than men to the effects of tobacco on vascular morbidity, even if they do not inhale.

The researchers, from the Institute of Preventive Medicine, Copenhagen, used data from the Copenhagen city heart study — a 22-year follow-up of 12,149 men and women — to determine the risk of MI and all cause mortality associated with light smoking and inhalation habits.

From the start of the study in 1976 until 1998, 872 men and 476 women suffered an MI, of which 40 per cent of cases were fatal. During the same period, a total of 2,883 men and 2,305 women died from all causes.

The researchers found that, compared with non-smokers, men who inhaled the smoke of 6–9g of tobacco (equivalent to six to nine cigarettes) a day doubled their risk of MI (relative risk 2.10, 95 per cent confidence interval 1.40–3.14).

Among women, inhaling the smoke of just 3–5g of tobacco a day doubled the risk for MI or death from all causes (relative risk

2.14, 1.11–4.13 and 1.86, 1.37–2.51, respectively). Smoking 6–9g a day, but not inhaling, increased a woman's risk of MI by almost 60 per cent (relative risk 1.58, 1.03–2.43).

The differences in smoking-related vascular morbidity seen between men and women may be explained biologically by the anti-oestrogenic effect of smoking, the researchers say.

They add that in current inhaling smokers they saw a clear dose-response relationship between amount smoked and risk of MI and all-cause mortality.

“Although, from a toxicology point of view, it is not surprising that the dose-response relation between smoking and morbidity does not have a lower threshold limit, from a public health point of view it is important to recognise the increased risk associated with even a low consumption of tobacco,” they conclude (*Journal of Epidemiology and Community Health* 2002;56:702).

## Half who try to quit smoking on the NHS are successful

HALF of all smokers in England who seek help from the National Health Service and set a date to give up smoking are successful four weeks later, according to new Department of Health statistics. Success is defined as not having smoked at all since two weeks after the quit date.

From April 2001 to March 2002, 227,308 people tried to give up smoking with help from the NHS and 119,813 were successful. The Government's target was for 50,000 people to give up the habit. Women form a small majority among people setting dates to give up smoking, by men are marginally more successful at actually doing so.

The Government claims that seven out of 10 people who smoke want to stop. To help them it spent over £53m on smoking cessation services up to March 2002. A further £20m is to be spent in the current year, plus the cost of prescribed cessation aids, including medicines.

Most people who try to give up smoking with help from the NHS do so using nicotine replacement therapy or bupropion. Around 63 per cent of people receive NRT only, 19 per cent are treated with bupropion and 2 per cent try both.

The Department's figures are based on people's unverified claims to have successfully stopped smoking. Most of those who claimed to have stopped smoking (89,748) agreed to a carbon monoxide breath test to verify their claim. Although the tests confirmed that most had given up, they showed that 9,980 people had not, in fact, done so.

## Bicalutamide shows promise as early treatment in prostate cancer

IMMEDIATE treatment with bicalutamide (Casodex) reduces the risk of tumour progression in patients with localised or locally advanced prostate cancer, an ongoing study suggests (*Journal of Urology* 2002;168:429). The results, presented earlier this year at a European Association of Urology meeting, show that the drug also reduces the risk of bone metastases by a third.

Dr William See and colleagues from the Casodex early prostate cancer trialist group analysed data from three ongoing, double-blind trials in which 8,113 patients were randomised to receive either bicalutamide 150mg daily or placebo, in addition to standard care (radical prostatectomy, radiotherapy or watchful waiting).

Results from the three trials show that 363 patients (9.0 per cent) in the bicalutamide group showed evidence of clinical progression compared with 559 patients (13.8 per cent) in the standard care alone group (hazard ratio 0.58, 95 per cent confidence interval 0.51–0.66,  $P < 0.0001$ ). The researchers comment that reductions in disease progression were seen across the entire patient population, irrespective of primary treatment or disease stage. However, they say that benefits of reduced disease progression must be balanced with morbidity associated with long-term hormonal therapy.

The researchers found that the incidence of bone metastases was reduced by 33 per cent in patients treated with bicalutamide (214 events compared with 321 events in the standard care alone group). No difference between the two groups was

observed in terms of survival. The researchers comment that it is important to demonstrate a direct survival benefit of early treatment because differences in time to progression do not necessarily translate into improved survival. However, they say that the lack of improvement was probably due to the fact that relatively few deaths (6 per cent) had occurred and that only some had been related to prostate cancer (<2 per cent).

The most frequently reported adverse events in the bicalutamide group were gynaecomastia plus breast pain (53.1 per cent), breast pain alone (19.7 per cent) and gynaecomastia alone (13.1 per cent). Each was reported by less than 5 per cent of standard care patients. The incidence of hot flushes, decreased libido and impotence was relatively low, say the researchers.

### BRIEFLY

Allergies and exposure to bacteria  
A new study supports the theory that the children of farmers have fewer allergies because they are exposed to more microbes. Such children express genes encoding for the receptor proteins CD14 and TLR2 more than other children, say researchers. Increased expression of these genes occurs after exposure to certain bacterial components and can modulate the innate immune system (*Lancet* 2002;360:465).

## Patient self-testing of blood glucose levels lacks evidence, says NPC

THERE is little evidence to support self-monitoring of blood glucose levels in all people with diabetes, according to the National Prescribing Centre's *MeReC Bulletin*.

The bulletin recommends that for self-monitoring to be useful, it should form part of a wider management programme, and that patients should be adequately trained in self-monitoring techniques. In addition, the bulletin suggests that health care professionals should be clear about what they hope to achieve through self-monitoring by patients.

"Although self-monitoring is common practice and a consensus view encourages it, evidence for its effect on control of blood glucose is unclear, particularly in patients with type 2 diabetes. In addition, the effects of self-monitoring of blood glucose on patient outcomes have not been adequately documented," the bulletin states.

It adds that there is no evidence that blood testing is more effective than urine testing at improving blood glucose control in

people with type 2 diabetes. Because of this and because of the higher cost of blood testing, the bulletin suggests urine testing could be considered for some patients, including those that find blood testing difficult. The *MeReC Bulletin* concludes that patients using insulin for either type 1 or type 2 diabetes who adjust their dose according to the results of the tests are most likely to benefit from self-monitoring. However, it points out that measuring glycosylated haemoglobin (HbA<sub>1c</sub>) levels is likely to provide more helpful information about glycaemic control than day-to-day monitoring of blood glucose.

The value of self-monitoring blood glucose was also investigated in an article, published in *The Journal* recently (*PJ*, 15 June, p847). It concludes there is confusion around whether patients should self-monitor and suggests national guidance would help clarify matters.

A copy of the *MeReC Bulletin*, "When and how should patients with diabetes mellitus test blood glucose?" (2002;13 No. 1), is included with this week's issue of *The Jour-*

*nal* sent to community and hospital pharmacists in England and Wales.

The publication is also available on the National Prescribing Centre websites ([www.npc.co.uk](http://www.npc.co.uk) and [www.npc.ppa.nhs.uk](http://www.npc.ppa.nhs.uk)).

## Trial supports first-line carboplatin monotherapy for ovarian cancer

SINGLE-AGENT carboplatin could be considered a first-line treatment option for ovarian cancer, a new study suggests. Researchers from the International Collaborative Ovarian Neoplasm Group found that regimens of carboplatin alone or cyclophosphamide, doxorubicin plus cisplatin (CAP) were as effective as paclitaxel plus carboplatin as first-line treatments.

They randomly assigned 2,074 patients from 130 centres in eight countries, including the United Kingdom, to receive either paclitaxel plus carboplatin, or a control regimen — carboplatin alone or CAP. More than 80 per cent of patients in all groups received six cycles of chemotherapy. The researchers found that after a median follow-up of 51 months, 1,256 patients had died, with no evidence of a difference in overall survival between the three groups. Median overall survival was 36.1 months for those in the paclitaxel plus carboplatin group and 35.4 months for the controls (difference 0.7 months, 95 per cent confidence interval -3.6-4.7). Median progression-free survival was 17.3 months for the paclitaxel plus carboplatin group and 16.1 per cent for the controls (difference 1.2 months, -0.5-2.8).

The researchers suggest single-agent carboplatin, CAP and paclitaxel plus carboplatin are all safe and show similar effectiveness as first-line treatments for women requiring chemotherapy for ovarian cancer. "Of these three treatments, carboplatin might be regarded as the preferred treatment because of its better toxicity profile,"

they say. The study confirmed that paclitaxel plus carboplatin was more toxic than carboplatin alone, in particular causing more alopecia, fever and sensory neuropathy.

The researchers add that the study does not imply that paclitaxel has no role in the treatment of women with advanced ovarian cancer but that specifying the best way to use this drug may be needed. They say about a third of patients on carboplatin alone went on to receive a taxane at some stage and conclude: "The optimum way of using paclitaxel might be to use it after single-agent carboplatin either before or after progressive disease has been identified."

In guidance issued in May 2000, the National Institute for Clinical Excellence recommended that paclitaxel in combination with a platinum therapy (cisplatin or carboplatin) should be the standard initial therapy for women with ovarian cancer following surgery (*PJ*, 13 May 2000, p716).

## All haj pilgrims need meningitis vaccine

OF those pilgrims returning from the annual Islamic pilgrimage to Mecca and Medina (haj), almost a fifth (17 per cent) are carrying meningococcal bacteria, a study in this week's *BMJ* shows (2002;325:365).

As such, vaccination should become mandatory for all haj pilgrims, and should also be considered for their families, say the researchers. They point out that many countries currently give meningococcal

## Long-acting atypical antipsychotic drug launched

A LONG-ACTING injectable formulation of risperidone, Risperdal Consta, has been launched this week by Janssen-Cilag (see p212).

The formulation consists of risperidone encapsulated in microspheres. When these are injected into the gluteal muscle, the drug is released gradually and provides continuous and consistent levels of drug in the bloodstream.

The injection, which is given every two weeks, initially releases less than 1 per cent of the administered dose and the main phase of risperidone release starts after three weeks. Therefore, the company recommends antipsychotic supplementation is given during the first three weeks of treatment with Risperdal Consta. Therapeutic plasma concentrations of risperidone remain until four to six weeks after the last Risperdal Consta injection.

vaccine (covering A and C strains) to haj pilgrims but suggest that vaccination with the quadrivalent meningococcal vaccine (also covering the W135 strain) should become mandatory.

"Transmission of this clone from vaccinated haj returnees to their unvaccinated household contacts was substantial, putting contacts at particular risk of developing invasive disease," they add.