

# Consider supplying EHC in advance, says Society

Pharmacists can supply emergency hormonal contraception in advance but they must consider the clinical appropriateness of a supply when faced with a request, says the Royal Pharmaceutical Society.

The Society released its updated advice this week following recent news reports that BPAS (formerly the British Pregnancy Advisory Service) and Marie Stopes International support the advance supply of EHC.

The Society is not against the advance supply of EHC in principle, it says. However, it recommends that pharmacists should decline repeated requests for advance supply and advise customers to use more reliable methods of contraception.

If selling EHC in advance, pharmacists should provide reminders to ensure that any prospective use of EHC is safe, effective and appropriate. For example, the customer should be advised to read the information leaflet before taking the product to ensure that it is still suitable for them.

Women should also be reminded that the efficacy of EHC decreases over time and that it is only effective if taken within 72 hours of intercourse, that intra-uterine devices can be fitted up to 120 hours after unprotected sex or within five days of expected ovulation, and that EHC cannot be used if they are already pregnant.

Last week BPAS urged women to keep EHC at home in case they risk pregnancy. It said that the price of EHC from pharmacies can be prohibitive for poorer women and announced that women can obtain advance EHC from 17 BPAS clinics around England, without an appointment, for £10.



Pharmacists should consider clinical appropriateness of advance supplies of emergency contraception

The advance prescribing of EHC is supported by the Faculty of Family Planning and Reproductive Health Care and the Royal College of Obstetricians and Gynaecologists.

## S60 Order published; expected to come into force early in 2007

The long-awaited Pharmacists and Pharmacy Technicians Order 2007 has been published as a draft Statutory Instrument.

Debates on the Order in the House of Commons and in the House of Lords are expected to take place in January 2007. Following approval by both Houses, it is expected that the Order will be made at a Privy Council meeting on 7 February.

After the draft Order was published at the end of last week, a Royal Pharmaceutical Society spokeswoman said: "The Society is delighted to see that the draft section 60 Order has been published as this signals that the Order is well advanced in its progression through the various stages of Governmental approval."

However, not all parts of the Order will come into effect at once since the process of bringing the various sections into effect will be linked to the making of rules for various functions by the Royal Pharmaceutical Society's Council. This rule-making process will be divided into various stages. Fitness-to-practise and registration rules will be made soon after the Order itself.

The Order, made under Section 60 of the Health Act 1999, repeals the Pharmacy Act 1954 and brings in a new regulatory regime for pharmacists. It also makes the occupation of pharmacy technician a regulated profession in England and Wales, but not Scotland.

The final draft includes some of the alterations requested by the Society's Council earlier this year (*PJ*, 17 June, p707). One such change is to the definition of pharmacy or pharmacy technician practice, which will now include working in or giving any advice in relation to the practice of pharmacy. Another is that GB registered pharmacists who work overseas will be able to be on the non-practising part of the Society's Register.

The Council has been partially successful in its request that the chairman of the new Disciplinary Committee continue to be appointed by the Privy Council, as has been the case for the Statutory Committee. The final draft provides for the appointment to be made by the Privy Council, but allows the Privy Council to seek assistance from the Government's Appointments Commission.

## Electronic care records to go ahead with mixed consent model

From spring 2007, the electronic summary care record will be implemented in early adopter sites in England but patients will be able to amend records and choose to opt out if they wish, health minister Lord Warner said this week.

The announcement follows the recommendations of the NHS Summary Care Record Taskforce, which was established earlier this year (*PJ*, 5 August, p152). Harry Cayton, chairman of the taskforce, said: "Members of the taskforce agreed that the creation of the summary care record is a tremendous opportunity for patient safety, quality and efficiency of care for all patients but that it must be implemented with public support and clinical confidence."

The taskforce envisages that the process for creating summary care records will allow patients a period of time to review their records, either via the internet-based HealthSpace or by asking to see a printed copy provided by their GP. Patients will be asked to correct or amend them and to consent for them to be shared or to opt out of sharing. After this time, it will be assumed that any patient who has not viewed his or her record has given implied consent.

Exactly how people will be able to opt out of their records being shared or uploaded onto the national database will be decided by an advisory group, which will oversee the development of the summary care record and

advise on its use. The group will be chaired by Martin Marshall, deputy chief medical officer, and will include representatives from the Royal College of General Practitioners, the British Medical Association, the Royal College of Nursing and patient organisations.

In its report, the taskforce says that over time the content of the record will increase, subject to consent, to include a more complete data set from GPs and also information from detailed records held by providers of care, for example hospital and community services. It is expected that independent sector organisations delivering care or services on behalf of the NHS will also supply information to the summary care record.

## How to obtain oxygen away from home

Arrangements for supplying oxygen to patients from Scotland during visits to England and Wales, and vice versa, are outlined in an NHS circular published by the Scottish Executive this week. Patients need to be aware of the different routes of supply (ie, regional oxygen suppliers in England and Wales, and pharmacies in Scotland).

All patients should be advised to get a home oxygen order form from their prescriber at least four weeks before travelling. For patients who live in Scotland, this form should be sent to Scottish Healthcare Supplies which will arrange oxygen delivery with a regional supplier in England or Wales. For patients who live in England or Wales, the form should be sent to their oxygen supplier which will contact Scottish Healthcare Suppliers. It will then tell the patient which pharmacy will supply the oxygen.

The home oxygen order form is recognised in Scotland as an NHS prescription. Further details can be found in the NHS circular, which can be accessed via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Welsh school will jointly host burns research centre

The UK's first major centre for burns research is to be hosted by the Welsh School of Pharmacy, in partnership with the schools of medicine and dentistry at Cardiff University and Morriston Hospital Swansea.

The centre will focus on research aimed at improving the treatment and long-term support for survivors of burns, and addressing issues such as infection control and immunology, inflammation following major burns and improved understanding of scar formation. The pharmacy school will contribute expertise in biomaterial design and infection control.

Steven Denyer, head of the Welsh School of Pharmacy, commented: "This prestigious award is recognition of the strong interdisciplinary relationships which have become established in South Wales."

The centre — the Healing Foundation UK Centre for Burns Research — will be based within Cardiff University's school of medicine and at the Welsh Centre for Burns and Plastic Surgery at Morriston Hospital Swansea.

### In brief

#### Scottish Drug Tariff changes

Changes to the Scottish Drug Tariff have been set out in two NHS circulars published this week. One comprises a revised "zero discount" list and the other revised tariff prices for dressings and chemical reagents. The changes will apply to dispensings made from 1 November.

## Adjustments to reimbursement/remuneration switch still needed

Contractors in Scotland have been told that the transfer of money from reimbursement to remuneration, scheduled to take place in this financial year, might not be completed. Instead, further adjustments could be needed early in the next financial year.

The original intention was to transfer £30m from reimbursement to remuneration, with that money funding the new minor ailment service, public health service and infrastructure support. Payments for these services began as planned but, according to an NHS circular, the amount transferred out of reimbursement (as a result of price changes in the April and July Drug Tariffs) fell short of the target figure.

Prices set for October's Drug Tariff mean that more money will be taken out of reimbursement and could mean that the £30m is saved by the end of the year.

Elspeth Weir, head of community pharmacy policy development, Scottish Pharmaceutical General Council, told *The Journal* that the balancing effect of October prices was a reason to be optimistic. However, she added: "Once figures for October dispensing volumes are available and the January Drug Tariff prices have been set, we will be reviewing the figures to see if any adjustment to clawback is needed." An announcement is expected in March.



Money transfer from reimbursement to remuneration might be delayed

The NHS circular states: "The full £30m transfer from reimbursement to remuneration may not be completed during 2006–07." It tells NHS boards that there may be a requirement to carry forward a deficit or credit into 2007–08, and that any savings arising from October prices should not be deployed until a final review has been made.

The circular reiterates that from next year, the £30m will be permanently moved into remuneration and included within the global sum.

## NPC launches campaign to improve statin prescribing

Resources to support high quality, cost effective prescribing and medicines management of statins are available through an online campaign, launched last week by the National Prescribing Centre.

The campaign website ([www.npc.co.uk/statin.htm](http://www.npc.co.uk/statin.htm) or [www.npc.nhs.uk/statin.htm](http://www.npc.nhs.uk/statin.htm)) provides various new materials, such as audio workshops, recent work on the evidence base for statin prescribing and patient consultation aids.

Richard Seal, director of medicines management at the NPC, said: "This is the first time the NPC has pooled a range of resources and practical tools to help improve health care professionals' knowledge base and to share good practice."

The statin prescribing campaign materials are presented in the following categories:

- Policy and guidance
- Therapeutics
- Implementation resources
- Monitoring tools

"Many of the materials are templates that can be downloaded and customised for local use, others, such as those providing evidence base, cannot be changed," said Mr Seal.

In October, the NHS Institute for Innovation and Improvement published "Better value, better care indicators"; one of the indicators was increasing low-cost statin prescribing. Mr Seal said that the campaign was partly in response to the request for support when changing statin prescribing in favour of low-cost products. Future campaigns are still to be agreed but may include other CV diseases and long-term conditions, Mr Seal told *The Journal*.

## Company law to change with approval of Companies Bill

The Companies Bill received Royal Assent last month and introduces changes to simplify and improve UK company law.

Provisions to allow businesses to use electronic communications to shareholders rather

than paper will be introduced in January 2007.

Benefits for private companies include no need to have a company secretary or to hold an annual general meeting.

# NPSA to change its focus as part of new patient safety strategy

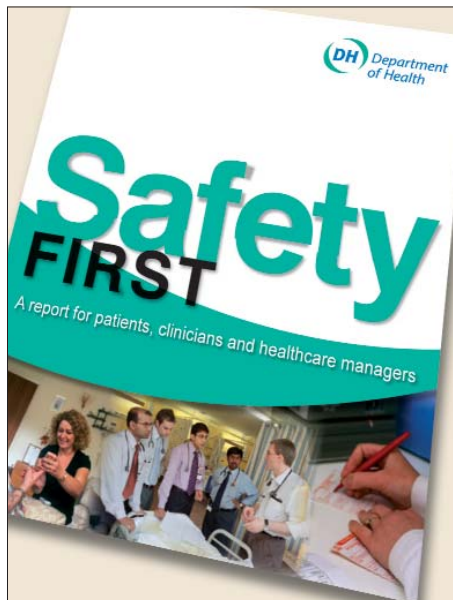
Procedures designed to improve patient safety are to be overhauled next year, including a re-design of the National Patient Safety Agency's National Reporting and Learning System and of the NPSA itself. The recommendations come in "Safety first: a report for patients, clinicians and health care managers", published by the Department of Health last week as part of a renewed national strategy for patient safety.

The report is the result of a review commissioned by the Chief Medical Officer for England to address issues raised in the National Audit Office report "A safer place for patients: learning to improve patient safety" (*PJ*, 12 November 2005, p597) as well as to look at the NHS approach to patient safety more widely.

The review found little evidence, despite the large volume of reports, that the NPLS is delivering high-quality, routinely available information on patterns, trends and underlying causes of harm to patients. It says that the system must be re-engineered to make it more effective. Near misses and a new category of "adverse events that could happen" should be reported and reports should be simplified. To promote rapid and effective learning, reports should be confidential but not anonymous. The new system will be relaunched in 2007.

The report also recommends that the role of the NPSA should be refocused on its core objective of collecting and analysing patient safety data to inform rapid patient safety learning, priority setting and co-ordinated activity across the NHS.

It advises that the NPSA should work in partnership with agencies that gather data,



The DoH's report

such as complaints, claims and coroners' reports, to ensure that all deaths and serious harm associated with adverse events are identified.

To allow this to happen, the report recommends that a number of the NPSA's current functions should be commissioned from other expert agencies. These functions include patient involvement, awareness raising, technical solution development and education. A pilot should be established to examine whether the National Institute for Health and Clinical Excellence could develop technical patient safety solutions.

## Reporting systems miss many patient safety incidents

Routine incident reporting systems considerably under-report the scale and severity of patient safety incidents, according to research published online in *BMJ First* last week (15 December, www.bmj.com).

Incidents identified through a two-stage retrospective review of patients' case notes (carried out by trained nurses and doctors) were compared with data submitted to the routine incident reporting system for a large NHS trust in England. Data collected covered 1,006 admissions under eight specialties.

Between January and May 2004, 324 patient safety incidents were identified in 230 of the 1,006 admissions (22.9 per cent). Case note review identified 303 of the incidents (94 per cent) and the reporting system identified 54 incidents (17 per cent).

Of the 1,006 admissions, 110 (10.9 per cent) had at least one patient safety incident resulting in harm. All of these incidents were detected by case note review but only six were detected by the reporting system. All 21 of the patient safety incidents missed by case review were minor, whereas 130 incidents missed by the reporting system resulted in patient harm. There were 71 drug problems missed by the incident reporting system.

"If the NHS is to gather accurate information on serious injuries and deaths resulting from patient safety incidents . . . then relying on voluntary reporting may not be sufficient," say the researchers. They suggest that early themes emerging from National Reporting and Learning System data may be useful but estimates of the type and severity of the incidents may be biased. "Health care organisations should consider routinely using structured case note review on samples of medical records as part of quality improvement," they say.

## Guidance published on primary medical services

A guide to primary medical services for potential contractors — including pharmacists — has been published by NHS Primary Care Contracting.

It offers an introduction to primary medical services contracting — including general medical services, personal medical services and alternative provider medical services — and the surrounding regulatory framework.

Primary medical services are offered to registered patients alongside traditional general practice and can be provided by anyone capable of securing the delivery of such services. Specialist personal medical services arrangements, it says, may be of particular interest to non-GP providers, such as pharmacists, since essential general practice services need not be provided. The guide is available at www.primarycarecontracting.nhs.uk.

### Other recommendations

- All incident reports should be considered locally within 24 hours and the NPSA should be notified of any incidents involving serious patient harm or death within 36 hours
- Patient safety action teams, accountable to strategic health authorities, should work to support local NHS organisations and would decide which incidents should be investigated and at what level
- The NHS Institute for Innovation and Improvement should work with the medical Royal colleges to develop a patient safety curriculum, which should be widely implemented in undergraduate, postgraduate and continuing education
- A National Patient Safety Forum should be established to bring together key stakeholders and influence the development of the patient safety agenda
- The NHS should take steps to ensure that patient safety is embedded as a core principle that underpins the next round of national priorities, which will be established from 2008

## Delay to conclusions on reimbursement of branded generics

The Department of Health is deferring its conclusions on the reimbursement of branded generic drugs, following its consultation on the subject, until after it has received the Office of Fair Trading report on the Pharmaceutical Price Regulation Scheme,

expected early in 2007. In a recent Parliamentary written answer health minister Andy Burnham told Laura Moffatt (Lab, Crawley): "Responses to the proposals in this consultation raised a number of complex issues which could not be easily resolved."

# Long-term HIV study confirms lack of advantage of three-class strategy for initial antiretroviral therapy

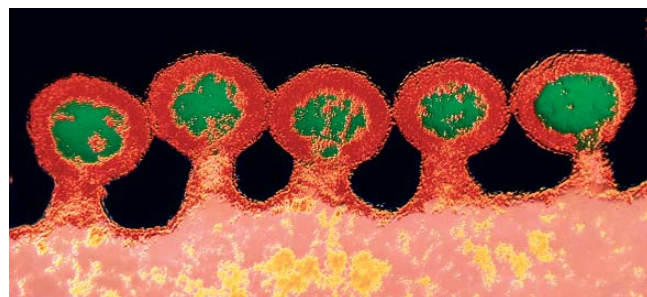
For HIV-infected patients, a treatment regimen containing three classes of antiretroviral drugs offers no advantages over a two-class strategy for immunological and clinical outcomes, and is associated with increased toxic effects, data from a long-term trial reveal (*Lancet* 2006;368:2125).

The trial, known as the FIRST (flexible initial retrovirus suppressive therapies) study, involved 1,397 treatment-naïve patients and set out to answer two questions: Is it better to begin initial antiretroviral therapy with a three-class strategy than with a two-class

strategy? And, which of the two-class strategies (protease inhibitor-based or non-nucleoside reverse transcriptase inhibitor-based) is better as initial therapy?

Researchers randomly allocated patients to one of three starting treatment strategies (see Panel) and followed them for an average of 60 months. They found that the three-class strategy did not result in a greater increase in CD4 cell count than the two-class strategies, and had the disadvantage of increased toxic effects.

In a comparison of the two two-class strategies, the researchers found that patients assigned to the non-nucleoside reverse transcriptase inhibitor (NNRTI) regimen had better virological outcomes than patients allocated to the protease inhibitor (PI) strategy. However, the researchers point out that even consistent differences over time in viral sup-



**HIV: even consistent differences in viral suppression did not translate to differences in clinical outcomes**

pression did not result in differences in the study's composite endpoint of an AIDS-defining event or death, or in mean change in CD4 cell count.

The researchers write: "It seems reasonable to conclude that starting treatment with either an NNRTI-based regimen or a PI-based regimen, but not both together, are good strategies for long-term antiretroviral management in treatment-naïve patients with HIV with a wide range of baseline CD4 cell counts and diverse demographics."

## Treatment strategies used in the FIRST study

- PI strategy (PI, mainly nelfinavir, plus two nucleoside reverse transcriptase inhibitors [NRTIs], mainly zidovudine and lamivudine)
- NNRTI strategy (NNRTI, mainly efavirenz plus two NRTIs)
- Three-class strategy (PI plus NNRTI plus one or two NRTIs)

# Bevacizumab plus chemotherapy improves survival in lung cancer

Addition of bevacizumab to a standard platinum-based, two-agent chemotherapy regimen in the treatment of selected patients with non-small-cell lung cancer improves survival but is associated with an increased risk of treatment-related deaths, according to research published in *The New England Journal of Medicine* last week (2006;355:2542).

Researchers randomised 878 patients with recurrent or advanced non-small-cell lung cancer to receive chemotherapy with paclitaxel and carboplatin or paclitaxel and carboplatin plus bevacizumab. The chemotherapy was administered every three weeks for six cycles. Bevacizumab was administered every three weeks until disease progression or until toxic effects were intolerable. Patients with squamous-cell tumours, brain metastases,

clinically significant haemoptysis or inadequate organ function were excluded.

The median survival was 12.3 months in the bevacizumab group compared with 10.3 months in the chemotherapy-alone group (hazard ratio 0.79, 95 per cent confidence interval 0.67–0.92;  $P=0.003$ ).

Median progression-free survival was also improved in the bevacizumab group compared with the chemotherapy-alone group (6.2 months vs 4.5 months, HR 0.66, CI 0.57–0.77;  $P<0.001$ ). Response rates were 35 per cent and 15 per cent, respectively ( $P<0.001$ ).

Rates of adverse events, including hypertension, proteinuria, bleeding, neutropenia, febrile neutropenia, thrombocytopenia, hyponatraemia, rash and headache were higher

in the bevacizumab group ( $P<0.05$ ). The difference between the two groups appeared during the third cycle. In addition, there were 15 deaths related to toxic effects of treatment in the bevacizumab group and two in the chemotherapy-alone group ( $P=0.001$ ). Most of the deaths occurred during the first two cycles of therapy.

The researchers explain that bevacizumab works well in combination with chemotherapy because, in addition to cutting off the tumour's blood supply, it makes the remaining blood vessels healthier and enables them to diffuse the chemotherapy drugs into the tumour better.

They say that the increased risk of toxic effects must be considered within the context of the survival benefit conferred.

## Ertapenem as prophylaxis

Ertapenem, a long-acting carbapenem, is more effective than the cephalosporin cefotetan in preventing surgical site infections in patients undergoing elective colorectal surgery, researchers report. However, they warn that ertapenem may be associated with more *Clostridium difficile* infections (*New England Journal of Medicine* 2006;355:2640).

## Regulators' review of substance misuse services published

Improvements can be made across all areas of community prescribing services for substance misusers, according to a review by the Healthcare Commission and the National Treatment Agency for Substance Misuse.

*The Journal* reported some of the review's preliminary findings earlier this year (*PJ*, 16 September, p327) — methadone prescribing was highlighted as an area where improvements are needed.

The full report, published this week, says: "Pharmacists, particularly those undertaking daily dispensing, are often among those professionals most frequently in contact with service users. They therefore offer a potential source of information to service providers, including how to ensure services can be most effective."

The report can be accessed via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

# Modest intake of cranberry juice OK with warfarin

The significance of an interaction between cranberry juice and warfarin has been called into question by the authors of a recent study (*Journal of the American Dietetic Association* 2006;106:2057).

Researchers randomised seven men stabilised on warfarin to receive one week of cranberry juice (250ml per day) followed, after one week's washout, by a week of placebo drink, or vice versa. They found no significant changes in international normalised ratio (INR) for either group for all test points in the study.

The authors say that, despite the small sample size, it is clear that a cranberry juice interaction is not a general effect in every patient taking anticoagulants.

However, the authors say: "The study does not eliminate the possibility of idiosyncratic

susceptibility to the effects of cranberry juice on warfarin metabolism in individuals with genetic polymorphisms of the cytochrome P450 system."

They suggest that modest consumption of cranberry products and routine INR monitoring be emphasised to patients.

The Medicines and Healthcare products Regulatory Agency's most recent advice (October 2004) states: "It is not possible to define a safe quantity or brand of cranberry juice and therefore patients taking warfarin should avoid this drink unless the health benefits are considered to outweigh any risks." The MHRA says that it is not known whether other cranberry products, such as capsules or concentrates, might interact with warfarin and recommends similar caution with these products.



**Patients on warfarin advised to drink cranberry juice in moderation**

Dreamstime.com

## Call for folic acid fortification of flour to be mandatory

Mandatory fortification of flour with folic acid in the UK is one of the recommendations made by the Scientific Advisory Committee on Nutrition in its final report on folic acid and disease prevention.

Coinciding with the report, the Food Standards Agency launched a consultation setting out options for improving intake of folic acid by young women. Besides mandatory fortification, the FSA suggests that the food industry could be encouraged to fortify more foods with folic acid on a voluntary basis.

The consultation is available online at [www.food.gov.uk/folicacid](http://www.food.gov.uk/folicacid) and via *PJ Online* ([www.pjonline.com/links/pj](http://www.pjonline.com/links/pj)).

## Low daily alcohol intake may prevent rheumatoid arthritis

Mice ingesting low levels of alcohol on a daily basis have a reduced risk of developing rheumatoid arthritis, researchers report.

They injected mice with collagen to induce arthritis then fed them with water or water containing 10 per cent ethanol. After several weeks, mice ingesting alcohol had slower onset of the arthritis and displayed less destructive symptoms as it progressed. The researchers say that the mice experienced no liver toxicity or other health problems, suggesting that safe levels of alcohol consumption may alleviate arthritis in humans (published online in *Proceedings of the National Academy of Sciences* [www.pnas.org](http://www.pnas.org), 18 December).

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#### Treasures of the Royal Pharmaceutical Society

A series that aims to raise awareness of key historical pharmacy-related material maintained by the Society. [www.pjonline.com/series](http://www.pjonline.com/series)

#### Christmas page

Closures and past Christmas articles. [www.pjonline.com/xmas](http://www.pjonline.com/xmas)