

Restrictions lifted on nicotine replacement therapy

Pharmacists have welcomed the announcement that children aged over 12 years and women who are pregnant or breast feeding can now use nicotine replacement therapy (NRT).

The Department of Health decision to lift the restrictions on NRT to these patient groups, as well as those who have heart, kidney or liver disease, diabetes mellitus or are taking concurrent medicines, follows a recommendation from the Committee on Safety of Medicines.

In a letter to health care professionals, Gordon Duff, chairman of the Commission on Human Medicines, advises that diabetic patients should monitor their blood glucose levels more closely than usual when starting NRT. In addition, he notes that NRT product information to date has detailed interactions that may occur as a result of stopping smoking, rather than starting NRT. He writes that the only significant interaction that may be directly attributable to NRT is with adenosine.

The CSM's recommendation, according to the DoH, was based on strong evidence that it



Pregnant women have traditionally been a hard-to-reach group

is "far more harmful" for these groups to continue smoking than to use NRT.

London pharmacist Andrew McCoig who has been offering smoking cessation services to patients for about five years said: "This de-

cision is long overdue. In the past I have really had to wrestle with young people to give up. Pregnant women have also been a hard-to-reach group with 25 per cent of them continuing to smoke when pregnant."

The announcement was also welcomed by the Royal Pharmaceutical Society President, Hemant Patel. He said: "This announcement means that pharmacists will be able to help more people give up. It also recognises that for the vast majority of people the well-established dangers of smoking far outweigh any risk from NRT.

"I hope that primary care organisations everywhere will support pharmacists to make a greater contribution to the smoking cessation work they are doing."

A leaflet explaining the new NRT product information will be made available to pharmacists, GPs and NHS smoking cessation clinics ahead of the details being updated in treatment packs. The information is also available from the Medicines and Healthcare products Regulatory Agency website (www.mhra.gov.uk).

NRT use in pregnancy increases risk of birth defects, study suggests

Using nicotine replacement therapy (NRT) in early pregnancy increases the risk of birth defects, according to data from a study published in the January issue of *Obstetrics and Gynecology* (2006;107:51).

Publication of the study follows the decision to make NRT available to pregnant women (see above).

The study involved over 76,000 pregnant women who were questioned about smoking

habits and the use of NRT in the first 12 weeks of pregnancy. It found that children exposed to prenatal tobacco smoking had no increase in the prevalence of congenital malformations compared with non-exposed children.

However, among mothers using NRT compared with the other non-smokers, there was a 60 per cent greater risk of birth defects (relative prevalence rate ratio 1.61 per cent,

95 per confidence interval 1.01–2.58). The authors say that their findings need to be replicated.

A spokeswoman for the Medicines and Healthcare products Regulatory Agency said: "The MHRA and the Commission on Human Medicines takes all studies relevant to medicines licensed in the UK very seriously. The MHRA and the CHM will review this particular study as soon as possible."

Pharmacists awarded MBEs in Honours list

Two pharmacists have been recognised in the New Year Honours list for 2006.

Mohammad Zafar Khan, FRPharmS, a community pharmacy proprietor in London, and a consultant to the pharmaceutical industry, has been appointed MBE for his services to health care. Since 1997, Mr Khan's pharmacy has offered the only 24-hour-a-day service in London. He is chairman of the Royal Pharmaceutical Society's West Metropolitan branch, regional communications officer for the Chiltern region and a member of the Kensington, Chelsea and Westminster Local Pharmaceutical Committee.

Chairman of the College of Pharmacy Practice, Charles Butler, FRPharmS, has also been awarded an MBE in recognition of his role in the college and for his service to the NHS. Mr Butler was a founder member of the college and was one of the first people to complete successfully the assessment for college fellowship. He has been a governor of the college for almost 10 years and its chairman since 2004. He is also chairman of the Chiltern region of the Society.

An MBE has been given to Keith Barnes, senior management technician in the department of pharmaceuticals at the School of Pharmacy, University of London, for his services to higher education. A CBE has been awarded to Vincent Lawton, president of the Association of the British Pharmaceutical Industry and managing director of Merck Sharp & Dohme, for services to the pharmaceutical industry.

Statement on contract monitoring issued

In monitoring the new contract, representatives of primary care trusts can enter pharmacy premises and request documents necessary for audit and monitoring purposes. However, contractors are not obliged to send copies of these documents to PCTs, according to the Pharmaceutical Services Negotiating Committee and the Primary Care Contracting team.

In a joint statement issued in December, the PSNC and PCC say that in some areas PCTs have developed their own monitoring toolkits rather than using the pharmacy assurance framework published on the PCC website. This has led to questions from contractors about whether they have to comply with requests that differ from those specified in the national toolkit.

An area of particular concern is standard operating procedures (SOPs). The PSNC and PCC make it clear that monitoring compliance only requires PCTs to determine whether a pharmacy has a suitable SOP, not to make a detailed assessment of the contents of the SOP. The most appropriate way to do this is to check that the SOP exists during a monitoring visit, then ask appropriate members of staff questions about procedures to ensure that it is being complied with, they say.

"It would be unwise for a PCT to carry out any detailed examination, because it will be unable to determine what is appropriate for the individual pharmacy concerned," the statement says.

Drug donations cause health and economic problems

In an emergency situation, drug donations are useless — they cause additional public health problems for the affected population and economic problems for the country, a report by the humanitarian organisation *Pharmaciens Sans Frontières* (PSF) concludes.

Shortly after the tsunami in South-East Asia, PSF reported that tonnes of inappropriate medicines were arriving in the region (*PJ*, 5 February 2005, p139). Between 20 May and 20 July 2005, it carried out a survey, funded by the World Health Organization, to assess the usefulness of drug donations for the population living in the tsunami-affected districts of Aceh Province, Indonesia. The survey targeted health centres, hospitals, pharmaceutical warehouses, ports and airports, and national and international non-governmental organisations.

Although no drug requests had been made, the survey revealed that 4,000 tonnes of drugs were received for a population of two million. Drugs were donated from 53 Indonesian organisations, 48 international organisations and 39 foreign governments. Of the drugs donated, 60 per cent were not on the national list of essential drugs, 70 per cent were labelled in a foreign language, and 25 per cent had an inadequate expiry date.



Inappropriate donations hinder the work of health staff

Excessive quantities of appropriate drugs, such as oral rehydration salts, dextromethorphan and tetracycline, also arrived and, based on the current rate of consumption, will not be used before their expiry dates.

Storage capacity in the province was greatly reduced by the tsunami and nearly half of health personnel died. The survey found that this has led to drugs being stored in offices, corridors, patients' rooms and outside in courtyards and sheds. "Such condi-

tions of storage cannot guarantee the quality of drugs. In addition, overcrowding greatly hinders the work and movements of health staff and patients in hospitals and health centres," says a report of the survey results.

Waste disposal is a further issue. The survey revealed that about 600 tonnes of donations need to be destroyed due to inadequate expiry dates. The PSF estimate that the cost of disposal will be about €2.4m.

The PSF acknowledges that many organisations are trained and prepared for immediate action after a disaster, but says that in the post-emergency phase technical support should be provided by pharmaceutical experts to the health authorities of the recipient countries. "The objective is to assess what the actual needs for drugs are, as well as drug storage needs, drug distribution needs, and training needs for local health professionals," it says. The PSF recommends that good drug donation practices should be mandatory for all donor organisations. The "Guidelines for drug donations", published 10 years ago by the WHO, should be included in the national drug policy of countries and should be internationally regulated as a public health protection measure, says the report.

Clot risk the same for all modes of transport

Travelling for more than four hours in any form of transport increases the risk of venous thromboembolism (VTE), a series of studies funded by the Department of Health, the Department of Transport and the European Commission has shown.

One of the studies collected data from patients presenting to anticoagulation clinics in the Netherlands with a first VTE. The patients' partners were used as matched controls. Of 1,851 patients studied, 235 had travelled for more than four hours in the

eight weeks preceding the VTE. The risk of VTE from flying was similar to that from travelling by car, train or bus.

"As previously suspected, it is clear from the epidemiological studies that seated immobility is a risk factor for VTE," the authors conclude. "These studies confirm that the longer the period of travel, the greater the risk. Multiple flights in a short period probably reflect the same phenomenon," they add. A report of the studies is available via a link on *PJ Online* (www.pjonline.com/links/pj).

Letrozole reduces breast cancer recurrence rates

Compared with tamoxifen, letrozole (Femara; Novartis) significantly reduces the risk of recurrence of hormone-receptor-positive breast cancer in post-menopausal women, new data have shown (*New England Journal of Medicine* 2005;26:2747).

The study of 8,010 women compared four treatment groups: five years of treatment with letrozole; five years of tamoxifen; two years of letrozole followed by three years of tamoxifen; and two years of tamoxifen followed by three years of letrozole.

At 25.8 months of follow-up, women given letrozole monotherapy or initial letrozole treatment showed increased disease-free survival (hazard ratio for recurrence, contralateral cancer or death 0.81, 95 per cent confidence interval 0.70–0.93; $P=0.003$) and reduced recurrence at distant sites (hazard ratio 0.73, 0.60–0.88).

Although fractures were more frequent with letrozole monotherapy or initial treatment (5.7 per cent vs 4.0 per cent, $P<0.001$), these regimens were associated with fewer thromboembolic events (1.5 per cent vs 3.5 per cent), a lower rate of vaginal bleeding (3.3 per cent vs 6.6 per cent) and fewer endometrial biopsies (2.3 per cent vs 9.1 per cent, all $P<0.001$). In order to determine whether letrozole will continue to reduce the risk of relapse for several years after the cessation of treatment, longer follow-up studies will be needed, the authors state.

CHD risk associated with diabetes higher in women

Research has revealed that women with diabetes are at higher risk of dying from coronary heart disease than men with diabetes.

Researchers examined 39 studies, involving over 447,000 patients. The overall relative risk for fatal CHD associated with diabetes was 3.50 in women, compared with 2.06 in men (95 per cent confidence interval 2.70–4.53 and 1.81–2.34, $P<0.0001$). Diabetes may induce a more adverse cardiovascular profile in women, the authors suggest, and this may combine with a reduced likelihood of women attaining recommended levels of other risk factors.

The study was published on *BMJ Online First* (www.bmj.com) on 21 December 2005.

Intensive treatment reduces cardiovascular disease risk in type 1 diabetes

Intensive diabetes treatment reduces the long-term risk of cardiovascular disease in patients with type 1 diabetes, new data have confirmed (*New England Journal of Medicine* 2005;353:2643).

Over a mean of 17 years of following patients in the Diabetes Control and Complications Trial, researchers found that intensive treatment reduced the risk of any cardiovascular disease event by 42 per cent (95 per cent confidence interval, 9–63 per cent; $P=0.02$) and the risk of non-fatal myocardial infarction, stroke or death from cardiovascular disease by 57 per cent (12–79; $P=0.02$).

First guidance for pharmacists published by CfH

Guidance on what pharmacy contractors in England need to do in order to implement release 1 of the electronic prescription service (EPS) has been published by NHS Connecting for Health (CfH).

The guidance tells contractors that they will need to order an upgrade to their pharmacy system so that it is EPS compliant, install hardware and software, arrange suitable network connectivity, obtain smartcards for their pharmacists and ensure their staff are trained in the operation of the new system.

When choosing a compliant system, NHS CfH advises contractors to speak to their current pharmacy system supplier to see what solution they can offer. Future developments for release 2 of EPS implementation should be taken into account, it says. There are currently eight EPS-accredited systems that are commercially available. A list of suppliers, and whether their systems have been granted authority to be rolled out nationally, is available via the NHS CfH website (www.connectingforhealth.nhs.uk). System suppliers will supply a smartcard reader and barcode scanner, as well as software for operating the EPS.

Regarding network connectivity, the guidance says that a number of options are available depending on individual pharmacy requirements. Indirect connections to N3 (national network for the NHS) can be purchased as part of a system supplier package or via a commercial network provider, a list of which will be available on the NHS CfH website shortly.



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Pharmacists need smartcards to use the electronic prescription service

Direct connections may be an appropriate option for large pharmacy chains with corporate networks. The guidance says that companies wishing to follow this route will need to be sponsored, in most cases by their PCT, in order to purchase a connection.

Smartcards are necessary to enable dispensing staff to access the EPS and will be issued to all community pharmacists, including locum pharmacists. Smartcards will be issued by PCTs and can be used in any community pharmacy in England. Pharmacists should contact their PCT registration authority to arrange registration and issue of smartcards, the guidance states. To obtain a smartcard, a face-to-face meeting, proof of identity and a completed registration form are necessary.

Staff training on the use of new pharmacy systems will also be available from the system suppliers. In addition, an NHS CfH leaflet "The electronic prescription service — a guide for healthcare professionals" can be used to brief staff. The leaflet should be available via the NHS CfH website shortly.

There is no need for pharmacists to co-ordinate "going live" with local GP practices. Traditional FP10s will still be able to be processed in the usual way, but barcoded prescriptions can be scanned allowing prescription details to be retrieved electronically.

The guidance is available on the NHS CfH website. Implementation guidance on release 2 of EPS will be distributed before national deployment.

News in brief

Patients get to choose

NHS patients in England are now able to choose any one of four places they are offered when referred by GPs for specialist treatment. The NHS improvement plan sets a target of 2008 for patients to be able to choose from any provider that meets NHS standards at NHS costs (*PJ*, 3 July 2004, p5).

Ketamine controls

Ketamine became a Schedule 4 Part 1 Controlled Drug on 1 January. This means that pharmacies must keep records of amounts acquired and supplied and may only destroy stocks in accordance with the Misuse of Drugs Regulations 2001.

Hangover cures

No compelling evidence exists to suggest that available interventions are effective at preventing or treating alcohol-induced hangovers, a study has shown (*BMJ* 2005; 331:1515).

Over 6,000 chlamydia test kits issued in Boots pilot

More than 6,000 test kits for the sexually transmitted infection chlamydia have been issued by Boots pharmacists in the first month of a pilot scheme in London.

The two-year pilot, in which pharmacists at 200 Boots branches in the capital offer a free and confidential screening service, was

launched in November in an attempt to increase access to chlamydia testing for 16- to 24-year-olds (*PJ*, 12 November 2005, p596).

Free kits have been requested by both young men and young women aged between 23 and 24 years, the Department of Health and Boots confirmed.

Draft CD management guidance to be altered

Draft guidance on the safer management of Controlled Drugs is to be revised in the light of responses to last year's consultation on the subject.

The revised guidance, which is to be published early this year by the Department of Health, will reflect the Royal Pharmaceutical Society's concern that the draft form could have resulted in clinical needs being neglected by health professionals concentrating on avoiding risk, rather than maintaining benefit for patients (*PJ*, 16 July 2005, p71).

The majority of respondents to the consultation believed that the draft guidance achieved the right balance between strength-

ening controls and maintaining patient access to necessary CDs, but there was general concern that prescribers should not be deterred from using CDs.

Respondents' views on whether the planned new arrangements make best use of existing controls were split evenly between those who thought that they did and those who thought that they did not or who had no strong view. Nevertheless, the revision will provide more clarity on how strengthened controls fit within existing systems.

The revised guidance will also make it clear that it applies to all CDs, regardless of their schedule status.

Vitamin D could reduce cancer risk

Supplementation with 1,000IU of vitamin D₃ daily could reduce the incidence of colon, breast, prostate and ovarian cancer, at low cost and with few adverse effects, according to researchers at the Moores Cancer Centre, University of California, San Diego.

They conducted a systematic review of 63 observational studies of vitamin D status in relation to cancer risk. The review included 30 studies of colon cancer, 13 of breast, 26 of prostate and seven of ovarian cancer. The researchers found that most studies showed a protective relationship between adequate vitamin D levels and risk of cancer.

The review also highlighted that African-Americans, who have higher rates of mortality for colon, breast, prostate and ovarian cancer, have approximately half the plasma level of vitamin D as white people because increased skin pigmentation reduces their ability to synthesise vitamin D.

The researchers say that a dose of 1,000IU of vitamin D₃ (25µg) daily should maintain serum levels of vitamin D at or above 30ng/ml in most people. Throughout the US, exposure to sunlight for 15 minutes per day between 11am and 2pm, in the summer, under clear skies, should maintain a similar level. However, the researchers warn that if sunlight is used as a source of vitamin D, exposure should be scrupulously monitored so that no reddening of the skin occurs. "Oral vitamin D₃ supplementation,



Steve Horvath/SPL

Vitamin D: safe in doses up to 2,000IU daily

rather than solar exposure, should be used by fair skinned or sun-sensitive persons, or by individuals taking medicines causing photosensitivity." They add that according to the National Academy of Sciences, no known health risks are associated with doses of vitamin D up to 2,000IU daily.

"Strong evidence indicates that intake or synthesis of vitamin D is associated with reduced incidence and death rates of colon, breast, prostate and ovarian cancers," they say. However, despite these reassuring studies, the public health and medical communities have failed to adopt its use for cancer prevention, they point out. "Leadership from the public health community will provide the best hope for action," they conclude (*American Journal of Public Health* 2006;96:9).

Broad spectrum p10

Statins have neutral effect on cancer incidence

Statins have a neutral effect on the risk of developing or dying from cancer, conclude the authors of a paper published in *JAMA* this week (2006;295:74).

They conducted a meta-analysis of 26 randomised controlled trials involving 86,936 participants to investigate the effect of statin therapy on cancer incidence and cancer death. The researchers also looked at the effect of statins on specific cancers and at whether hydrophilic, lipophilic, naturally derived or synthetically derived statins affected incidence of cancer. Trial sizes ranged between 151 and 20,536 participants, mean age was between 50 and 76 years, and most participants

were male. Duration of follow-up was between 1.9 and 10.4 years. The studies evaluated atorvastatin, cerivastatin, fluvastatin, lovastatin, pravastatin or simvastatin versus placebo or standard care.

The researchers did not observe any significant differences in incidence of cancer or cancer death between patients receiving statins and controls for any of the prespecified cancer subtypes (breast, prostate, respiratory, gastrointestinal, colon and skin). "When we limited the analysis to individual statins, statins with high or low lipophilicity, or natural or synthetic statins, no significant differences were observed versus control," they add.

LDL cholesterol lowered by new food product

A new cholesterol lowering ingredient, Reducol, is expected to be sold in food products this month. It is a mixture of phytosterols derived from coniferous trees and can be mixed with spreads, yoghurts and other food and drinks.

Peter Jones of the school of dietetics and human nutrition at McGill University, Montreal, and colleagues conducted a double blind randomised controlled trial of 32 men with total cholesterol levels of between 6.5 and 10mmol/L. Subjects were given a healthy North American diet of prepared foods alone or the same diet but with phytosterols suspended in the margarine component (22mg/kg) for 30 days. The researchers found that, on day 30, low-density lipoprotein levels had decreased by 8.9

per cent in the control group and 24.4 per cent in the group receiving a phytosterol-enriched diet ($P<0.01$). High-density lipoprotein cholesterol and triglyceride concentrations did not change significantly in the two groups, say the researchers. No difference in the rate of synthesis of endogenous cholesterol was observed between the groups (*American Journal of Clinical Nutrition* 1999;69:1144).

Typical reductions in LDL cholesterol seen with other cholesterol-lowering margarines are about 10 per cent (*PJ*, 26 February 2000, p323). Forbes Medi-Tech, manufacturer of Reducol, says it is different from other cholesterol lowering foods containing plant sterols because it does not contain sterol esters — which add calories to a diet.

Correction

Ketamine, a Schedule 4 Part 1 Controlled Drug is not subject to record keeping requirements and pharmacists are free to destroy surplus stocks, and not as stated (p5).