

Clinical trial pharmacy services guidance launched

New practice guidance on clinical trial pharmacy services was launched this week. Advice on pharmacy staff and facilities, ethics committees and investigational medicinal product management is included in the guidance, which has been produced as a result of a collaboration between the Royal Pharmaceutical Society and the Institute of Clinical Research.

“Key recommendations are that designated pharmacy staff should look after all aspects of clinical trials in dedicated facilities and proper management structures including suitable archiving should be put in place,” said John Gilroy, chairman of the Institute of Clinical Research Pharmacy Subcommittee. He added that the guidance highlights the importance of pharmacy clinical trials personnel having good working relationships with other clinical trials staff working inside and outside NHS trusts.

The guidance has been developed as a result of significant additional regulation of

clinical trials and changes in practice in recent years. The EU clinical trials directive of 2001 resulted in changes to UK law that came into force in May 2004. Other changes include the Research Governance Framework for Health and Social Care, changes in the Central Office for Research Ethics Committees and developments in medicines management.

“A lot of trusts are likely to be already working to the standards suggested in the guidance,” said Mr Gilroy. He added: “For those that are not, they can identify the changes in practice that will be needed.” He recommended that all pharmacy staff, not just those involved in the clinical trials area, should become familiar with the guidance. He also suggested that external sponsors of trials (eg, drug companies) should read it, so that they know what standards NHS trusts will be working to.

The guidance was due to be formally launched during a meeting at the Society on



Geoff Tompkinson/SPL

All pharmacy staff should become familiar with the guidance

19 May. A full version is available from the practice section of the Society's website at www.rpsgb.org/practice. A slightly abridged version is available in this issue of *The Journal* (pp629–30).

Section 60 Order consultation delayed again

The timetable for the modernisation of the Royal Pharmaceutical Society's regulatory processes has been put back for a fourth time.

Consultation on an Order in Council under Section 60 of the Health Act 1999 will not now take place until August, with the Order itself being made in April 2006.

A Department of Health spokeswoman said that the delay is due to a reassessment of the volume of work involved. She added that the content of the Order would not be affected by the long-term review of non-medical regulation led by DoH workforce director Andrew Foster.

Nicholas Wood, President of the Royal Pharmaceutical Society said: “It is a matter of great concern to us that the Department of Health has announced yet further delays in

the pharmacy Order. These delays are entirely unacceptable.

“We have worked through a difficult process to develop our Charter in parallel with the Government's Order but now this timetable has slipped again. This delay, which is entirely outside of our control, will be deeply disappointing to the profession. This uncertainty about our future powers will be unsettling for the profession at this time. We also know that the Council for Healthcare Regulatory Excellence shares our concerns. “We gain some reassurance, however, that the content of the Order will not be affected by the review of non-medical regulation being led by Andrew Foster and that the Department of Health has made public its new revised timetable.”

AfC pay deadlines missed

Only 21 per cent of NHS organisations had hit the Agenda for Change target of transferring at least half their staff onto the appropriate AfC payband by the end of April, Andrew Foster, director of workforce at the Department of Health, said at the NHS annual human resources conference last week.

Commenting after the conference on this shortfall, he said: “I am disappointed by the latest overall position on assimilation, but this position masks some good performances by individual organisations”. He added: “I am satisfied that a solid start has been made and that the right processes have been put in place locally to ensure that good progress toward the target in September can be made.” Mr Foster said it was also encouraging to see that so far, across the NHS, 48 per cent of staff have been matched to their appropriate payband.

Vote on new EU directive

Last week, the European Parliament voted on a single directive to replace 15 directives that govern the recognition of professional qualifications across member states, including two that apply to pharmacy (85/432/EEC and 85/433/EEC). The aim of the new directive is to simplify the existing legislation and to improve the rules that govern the freedom of a professional in one member state to practise his or her profession in another member state. Charlie McCreevy, European Commissioner for Internal Market and Services, said: “With this directive, we will inaugurate a new era for professionals migrating within our internal market.” The directive must be transposed into national legislation before it becomes law in the UK.

New contract VAT concerns

VAT implications of the new contract arrangements were raised at the National Pharmaceutical Association's board of management's April meeting and at last week's Pharmaceutical Services Negotiating Committee meeting.

The VAT implications of new contract services have yet to be resolved with HM Customs and Excise and the NPA board believes this will cause worry and uncertainty for contractors. The NPA board is concerned that, since pharmacists' remuneration will no longer be centred almost exclusively around dispensing, it may no longer be zero-rated for VAT purposes. Whatever scheme is devised, it should be cost neutral for contractors, the board believes.

PSNC contract roadshows

Roadshows are to be organised later in the year by the Pharmaceutical Services Negotiating Committee to provide information and support to help contractors in England fully comply with the new community pharmacy contract services, the PSNC's chief executive Sue Sharpe said at a press briefing following last week's committee meeting. The PSNC also announced that details of the implementation of electronic transmission of prescriptions will be available in the next few weeks and that pharmacies included in the Essential Small Pharmacies Scheme would not be excluded from exit payments. Any ESPS contractors wishing to relinquish their contracts need to give primary care trusts three months' notice.

NHS stop-smoking services success rate increased

The number of people who have quit smoking with the help of NHS stop-smoking services has increased by almost 50 per cent in one year, according to provisional Government figures.

From April to December 2004, 170,600 people who had set a date to stop smoking using NHS services were still not smoking at a four-week follow-up, which is a 47 per cent increase on the same period in 2003, the figures show.

Nicotine replacement therapy alone was used by 79 per cent of people using the

service, 7 per cent used only bupropion (Zyban) and 1 per cent used both NRT and bupropion. The total cost of these items prescribed in GP practices and dispensed in the community during this period was over £30m.

The figures also show that success with quitting smoking increases with age. Miriam Armstrong, chief executive of Pharmacy-HealthLink, said that pharmacists are clearly playing a significant role in achieving this success rate. She commented: "What was a surprise was the high proportion of people

aged 60 years and over who successfully quit at four weeks. Since this group are both high users of pharmacies and are the most reliable group to follow up at four weeks, it would make sense for pharmacists who are providing specialist NHS stop-smoking support to target them in their promotional activities and thus further increase the likelihood of achieving primary care trust targets."

The figures show that the cost of the stop-smoking services during this period, excluding the cost of NRT or bupropion on prescription, was £32.3m.

Health responsibilities reconfigured as new minister given pharmacy

Jane Kennedy, the newly appointed Minister of State for quality and patient safety has been given the pharmacy portfolio previously assigned to Rosie Winterton.

Ms Kennedy's other responsibilities include standards, inspection and performance, patient safety including the National Patient Safety Agency, clinical governance and quality issues, clinical negligence, methicillin-resistant *Staphylococcus aureus*, reducing bureaucracy, the National Institute for Health and Clinical Excellence, genetics, the Medicines and Healthcare products Regulatory Agency and medicines, the pharmaceutical industry, research and development, counter fraud and departmental management.

Although Ms Kennedy is responsible for pharmacy, other ministers' responsibilities will overlap to some extent. For example, Ms Winterton's new portfolio as Minister of State for health services includes prison health care, which has become an NHS function in which primary care trusts have a role. Her other responsibilities are for interna-



Jane Kennedy takes over from Rosie Winterton

tional and EU business, emergency preparedness, cancer services, cardiac services, diabetes services, mental health, dentistry, patient and

public involvement, renal services and equality and diversity issues.

The Royal Pharmaceutical Society's President has written to the Secretary of State and to the new pharmacy minister to introduce the Society and to outline the profession's key concerns for the immediate future.

Director of public affairs and communications Beverley Parkin said: "The Society established an excellent working relationship with its ministers in the last Government. We shall be working hard to ensure that the profession continues to have the ear of the new Government as we go forward."

Sue Sharpe, Pharmaceutical Services Negotiating Committee chief executive, commented: "We had an immensely good relationship with Rosie Winterton. She really did see the potential of community pharmacy and worked with us and she was a tremendous supporter of community pharmacy. At the moment we don't know Jane Kennedy. We've written to her to welcome her to her new post and we'll seek an early meeting with her."

Easier access to negligence compensation announced

Victims of clinical negligence in the NHS are to get access to a new scheme for redress.

Announced in the Queen's Speech this week, the NHS Redress Bill will provide for a quick response to low value clinical negligence claims. The NHS Litigation Authority will oversee the scheme and cases will need to meet a number of criteria, including falling below an agreed financial threshold and being brought within a specified time.

According to the Department of Health, the Bill will introduce a real alternative to litigation and avoid its associated delays and costs. It will drive consistency in the way claims are dealt with across the NHS and emphasise providing patients with an explanation, apology and reassurance as a matter of course.

There will also be a Hospital Hygiene Bill, which will introduce a hygiene code of prac-

tice for all NHS bodies, independent health care providers and care homes to try to reduce the incidence of methicillin-resistant *Staphylococcus aureus*. Inspections will be carried out by the Healthcare Commission and the Commission for Social Care Inspection, which will be able to issue improvement orders. There will be consultation on the planned code and any enforcement sanctions.

Measures to restrict smoking in enclosed public places and workplaces over a three-year period were also announced.

Beverley Parkin, director of public affairs and communications for the Royal Pharmaceutical Society, said: "There are seven Bills and measures of direct interest to the profession and we will track them as they roll out. There is going to be a packed few months ahead of us."

£140,000 made available for research on the new contract

The Pharmacy Practice Research Trust, which is supported by the Royal Pharmaceutical Society, is offering up to £140,000 to fund a research project exploring the implementation of the new contractual frameworks for community pharmacy.

The trust is keen to identify factors that help or hinder progress with the new contract. It wants to focus on what pharmacists are doing differently under the new arrangements and how to manage and support the changes.

As a result of the project, the trust intends to work with the NHS to produce briefing materials for primary care trusts.

The deadline for applications is 2pm on 25 July.

See also p627

PCTs see pharmacies as businesses, NAO concludes

Primary care trusts prefer to view community pharmacies as businesses, rather than primary care providers, when considering NHS local improvement finance trust (LIFT) schemes. LIFT schemes entail joint funding by the NHS centrally, local health stakeholders and private enterprise for the redevelopment of primary care premises. These are then rented to providers at reduced rates and to third-party organisations at commercial rates.

The National Audit Office reported this week that community pharmacies are likely to be the most significant source of third party income for LIFT projects.

It said that, unlike other primary care providers, such as GPs and dentists, who receive some automatic reimbursement for the rent paid to practise from primary care premises, it is up to PCTs to decide whether to treat pharmacies as primary care providers.

“More often, pharmacy is treated as a business, which as such will pay full rent to occupy space in a LIFT building,” the report states.

It draws no conclusion on whether or not this approach is appropriate.

Overall, the NAO concludes that the LIFT initiative, launched in 2001, is an effective

means of improving primary health and social care. The model was seen to have a number of strengths, including taking a long-term strategic approach to local health care provision and combining the benefits of national support and local control.

Shiv Bagga, a Royal Pharmaceutical Society Council member involved with a LIFT scheme in east London where he has to pay the full commercial rent, said: “Pharmacies should not be used as cash cows and should be integrated into NHS services. We have made them understand that locally and they have been reasonably sympathetic.”

Weight gain counters benefits of quitting smoking on lung function

Preventing weight gain after smoking cessation could maximise the beneficial effects of quitting on lung function, according to a study published this month (*Lancet* 2005;365:1629).

Susan Chinn, department of public health sciences, King's College London, and colleagues investigated the net effect of smoking cessation and the independent effects of smoking and weight change on lung func-

tion. The study involved 6,654 participants who each completed a questionnaire on smoking habits and had their lung function and weight measured in 1991–93, and again in 1998–2002.

The net effect of quitting smoking on decline in lung function — the difference between quitters and smokers — was similar for men and women; however, the effect of

weight gain on lung function was greater in men. The researchers calculated that the benefit of quitting on lung function is diminished by 38 per cent in men and 17 per cent in women when either gains 1kg per year.

“Our results strongly support inclusion of a weight reduction intervention as part of randomised controlled trials of smoking cessation,” the researchers conclude.

News in brief

New SPGC website

The Scottish Pharmaceutical General Council has relaunched its website at www.spgc.org.uk. Contractors need to register to access all the available information, and registration to the old SPGC website will not be automatically transferred to the new website. Some parts of the new site are still under construction.

Prescription charge refunds

The Scottish Pharmaceutical General Council wrote to community pharmacists this week to clarify that pharmacies in Scotland do not have to give prescription charge refunds. Pharmacies in Scotland are only required to provide patients with claim forms and envelopes.

Indemnity policy for technicians

Professional indemnity insurance is being offered to pharmacy technicians and accuracy checking dispensary assistants by NPA subsidiary Pharmacists Professional Indemnity Ltd. The policy provides up to £4m professional indemnity cover for technicians and £50,000 for accuracy checkers plus up to £250,000 for legal expenses. Annual premiums range from £41 to £105.

UniChem launches guide to advanced services

UniChem is launching its second “Solutions” guide, to help pharmacy contractors meet the requirements of advanced services under the new community pharmacy contract. Its first guide, to essential services, was launched in January (*PJ*, 29 January, p101).

The guide offers a step-by-step approach to help contractors understand the service specifications, competencies and accreditation necessary to provide advanced services. It includes case studies, action points and a list of useful sources of information and advice. It will be available to UniChem customers via their account managers from next week.

UniChem is also offering its customers a new consultation area, alone or as part of a premises upgrade, to meet the accreditation requirements of advanced services. The consultation area is a stand alone, modular room that can be tailored to each customer. The room



Consultation area is a stand alone room

plus equipment costs £5,000. UniChem says that the room will also be suitable for providing enhanced services in the future.

Locums can earn loyalty points with agency

A loyalty points system for locums has been launched by Healthcare Locums.

Points can be spent on registration fees for the Royal Pharmaceutical Society (equivalent to 1,500 hours' work), luxury leisure packages, professional training or items of medical clothing.

So far, 1,500 locums working for Healthcare Locums' subsidiary companies,

Thames Medics, Eurosite Medical and Medical Technical, have set up accounts with Healthcare Locums VIPpoints loyalty programme. The programme credits staff with VIPpoints based on the hours they have worked for the agency and the number of colleagues they have referred to the agency. Locums can access their accounts through the companies' websites.

Contraceptive advice may confuse

New guidance on the advice that health professionals should give to women who have missed some of their oral contraceptive pills may be confusing, claim the authors of a comment published in *The Lancet* this week.

The new guidance, issued by the UK Faculty of Family Planning and Reproductive Health Care last month, recommends additional methods of contraception if a woman misses three or more pills containing 30–35µg ethinylestradiol or two or more pills containing 20µg or less. It says that emergency contraception may be required if these pills are missed in the first week of the pack, effectively extending the pill-free interval.

Some health professionals have expressed concern about these new recommendations, say the authors, and point out that women may be unsure if their pills contain oestrogen or how much ethinylestradiol they contain.

They also say that the guidelines do not define how many hours late a pill must be to be classed as “missed”. They suggest that one rule for all doses of pill would be less confusing, with more information provided to women about the risk of extending the pill-free interval.

Toni Belfield, director of information at the Family Planning Association, said: “Our helpline work shows that most women do know what kind of pill they are on, but they may not know the name correctly as often it is not easy to say. Clearly, where information is now relating to women using 20µg ethinylestradiol pills versus 30µg ethinylestradiol pills this demands better communication and information from professionals providing any contraception service.”

The new guidance can be accessed via *PJ Online* (www.pjonline.com/links/pj).

CSM warning on atypical antipsychotics not heeded

Risperidone (Risperdal) and olanzapine (Zyprexa) are still being prescribed to a large proportion of people with dementia, according to the Alzheimer’s Society, despite Committee on Safety of Medicines advice that they should not be used for this indication.

In September 2003 the CSM advised that these atypical antipsychotic drugs should not be used for treating behavioural symptoms of dementia because they are associated with an increased risk of stroke in elderly patients.

However, the Alzheimer’s Society has published a preliminary report from a larger study, showing that 81 per cent of patients who were prescribed the drugs before the CSM warning were still being prescribed them a year later. The research involved 166 people with dementia across 12 UK nursing homes.

Jim Kennedy, prescribing spokesman for the Royal College of General Practitioners, commented: “It is not clear from the report whether dosages have been decreased, prescribed less frequently or that patients are being offered less powerful drugs. However, we would have expected to see more of a shift towards reducing the role of neuroleptic drug treatment altogether.” He added that drugs have a small short-term role in the treatment of dementia and stressed the importance of good nursing care.

Is EHC reaching those women most at risk?

More research is needed into whether new routes of supply of emergency hormonal contraception are appropriate for younger women and those from lower socio-economic groups, researchers say (*BMJ* 2005;365:1668).

Commenting on a study in which EHC access was made available from pharmacies without a prescription, or as an advance supply, they point out that increasing ease of access to EHC has not been shown to deter regular contraceptive use or to increase risky sexual behaviour. However, they say that there is a chance that such routes of supply may not be appropriate for those most at risk of unwanted pregnancy. For example, the advance supply of EHC involves an initial consultation

with a health professional to obtain stocks of the product. The researchers question whether this may deter younger women and those from lower socio-economic groups.

They also note that their previous research has shown that the main users of free supply of EHC from community pharmacies was women aged over 20 years, and that pharmacists’ perception was that these women mainly came from higher socio-economic groups.

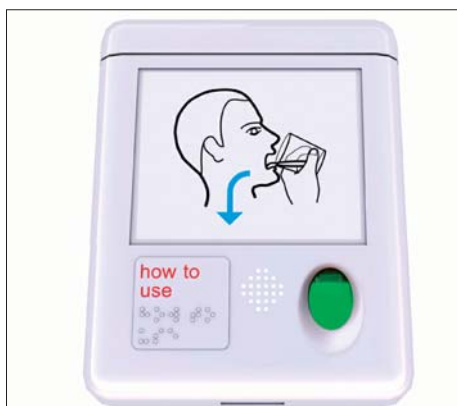
The researchers say that studies are needed to examine how younger women and those from lower socio-economic groups perceive EHC and what are the best ways of targeting those women most at risk of unwanted pregnancy.

Bleeding risk offsets aspirin benefit in healthy over-70s

Benefits of low-dose aspirin on the risk of cardiovascular disease in patients aged 70 years or over who do not have overt cardiovascular disease are offset by increases in bleeding, a study published online has shown (*BMJ Online First* www.bmj.com).

Epidemiological modelling in a hypothetical population of 20,000 Australian men and women showed that the benefits of routine use of low-dose aspirin in terms of reductions in incidence of myocardial infarction and ischaemic stroke were outweighed by increases in the incidence of gastrointestinal and intracranial bleeding.

LCD drug pack wins award



A tablet or capsule pack with an LCD screen, showing patients how to take their medicine, has won James Barber, University of Leeds, a design award sponsored by Almus. The pack uses icons to help non-English speakers and people who cannot read, and features Braille for visually impaired users.

UK mumps epidemic threat

Cases of mumps in England and Wales increased dramatically last year, and the Health Protection Agency has announced. In 2004 8,104 cases of mumps were confirmed, compared with a total of 3,907 cases in the previous five years.

Most cases occurred in young adults born before 1988, who would not have been routinely scheduled for the measles, mumps and rubella vaccination. Only 2.4 per cent of confirmed cases in 2004 occurred in children who would have routinely been offered two doses of the vaccine. The scientists suggest that school leavers should have their vaccinations reviewed to ensure that they have received two MMR doses (*BMJ* 2005;330:1119). A second paper reveals that there were almost 5,000 notifications of mumps in January alone, mainly among 19–23 year olds, and that there is now a threat of outbreaks among under-immunised children, since uptake of the MMR vaccine fell (*ibid*, p1132).

Vitamin E may protect against Parkinson’s disease

Dietary vitamin E may protect against the development of Parkinson’s disease, a meta-analysis of eight studies of dietary vitamin intake has shown (*Lancet Neurology* 2005;4:362). The effect was significant for medium, but not high intake. No protective effect of either vitamin C or beta carotene was found.

Letrozole improves survival

Letrozole (Femara) offers a survival benefit over tamoxifen in hormone-sensitive early breast cancer. A phase III trial involving 8,028 women showed that at a median of 26 months those taking letrozole had a 19 per cent reduced risk of post-surgery recurrence compared with those taking tamoxifen ($P=0.003$).

Rituximab maintenance therapy

Maintenance therapy with rituximab (MabThera) in patients with follicular non-Hodgkin's and mantle cell lymphoma who were initially treated with rituximab and chemotherapy almost doubled time to relapse, new data suggest. Patients in the rituximab maintenance group were in remission for more than three years compared with 19 months for those in the observation group ($P=0.0171$).

Chemotherapy improves survival in operable GI cancer

Giving chemotherapy before and after surgery improves survival in patients with operable gastric and lower oesophageal cancers, according to a Medical Research Council study presented at the American Society of Clinical Oncology annual meeting this week.

The adjuvant gastric infusional chemotherapy trial randomised 503 patients with gastric, oesophagogastric junction and lower oesophageal cancers to be treated with pre- and post-operative chemotherapy or surgery alone. The 250 patients in the chemotherapy arm received three preoperative and three postoperative cycles (at three-week intervals) of 50mg/m² daily of intravenous bolus epirubicin, 60mg/m² daily of cisplatin infusion, and 200mg/m² daily of continuous fluorouracil infusion.

Chemotherapy increased survival by 25 per cent (hazard ratio 0.75; 95 per cent confidence interval 0.60–0.93; $P=0.009$), with a five-year survival rate of 36 per cent compared with 23 per cent for patients who had surgery alone ($P=0.009$). Progression-free survival with chemotherapy was also prolonged by 34 per cent ($P=0.0001$), with a median survival of 24 months compared with 20 months in the control group.

David Cunningham, professor of oncology, Royal Marsden Hospital, Surrey, said that use of perioperative chemotherapy should become standard for these cancer patients. Tim Root, chairman of the British Oncology Pharmacy Association, commented that this was another example of how indications for chemotherapy continue to expand, explaining the increase in the number of chemotherapy doses given in the past few years.

Trastuzumab halves the risk of recurrence in early breast cancer

The HER2-receptor blocker trastuzumab (Herceptin) reduces the risk of recurrence by 46 per cent in women with early-stage breast cancer expressing HER2, according to results from the international HERA (Herceptin adjuvant) study, which specialists agreed would change practice.

The study was presented at the American Society of Clinical Oncology annual meeting in Orlando, Florida, this week and included nearly 5,100 women from 39 countries. The women were randomised to treatment with trastuzumab or placebo every three weeks for 12 or 24 months, following surgery to remove their tumours and chemotherapy, in addition to radiotherapy in some cases. Trastuzumab also increased disease-free survival. Results were announced for 12 months' treatment since the 24-month arm of the study is ongoing.

Martine Piccart, Jules Bordet Institute, Brussels, and lead researcher of the study, said: "These results now add to the growing body

of evidence that Herceptin should be considered in the care of HER2-positive breast cancer patients, regardless of the stage of their disease." She added: "It is now crucial that testing for HER2 status becomes standard for all women at primary diagnosis of breast cancer."

Combined results reported at the meeting from two further North American trials including 3,300 women with early HER2-positive breast cancer showed similar results with trastuzumab, with a 52 per cent reduction in risk of cancer recurrence and 33 per cent reduction in risk of death. The size of the reduction was similar to that with tamoxifen in cancers expressing oestrogen receptors.

Tim Root, chairman of the British Oncology Pharmacy Association, said: "We have to resource our pharmacy chemotherapy services to cope with the addition of new types of drugs — such as Herceptin — to chemotherapy regimens."

Angiogenesis inhibitor extends survival in lung cancer and advanced breast cancer

The angiogenesis inhibitor bevacizumab (rhuMab-VEGF; Avastin) extends survival in patients with non-small cell lung cancer (NSCLC) and in women with advanced breast cancer, according to studies reported this week at the American Society of Clinical Oncology annual meeting.

A US study randomised 878 patients with previously untreated advanced non-squamous NSCLC to standard platinum-based chemotherapy (paclitaxel and carboplatin) plus bevacizumab (15mg/kg) or placebo, given every three weeks for up to six courses. Results showed that bevacizumab increased overall survival by 30 per cent. The median survival was 12.5 months in patients treated with bevacizumab compared with 10.2 months in the placebo plus chemotherapy group ($P=0.0075$).

Results demonstrated a 61 per cent improvement in progression-free survival, with median progression-free survival of 6.4 months with bevacizumab compared with 4.5 months for chemotherapy alone

($P<0.0001$). There was also an increase in response rates in the active treatment group (27 per cent vs 10 per cent; $P<0.0001$).

The lead author of the study, Alan Sandler, associate professor of medicine at Vanderbilt University Medical Centre, Nashville, Tennessee, said: "This is the first study in years to show an increase in survival for the first-line treatment of patients with advanced NSCLC."

Another phase III trial demonstrated benefits for the first time with anti-angiogenic therapy in breast cancer, randomising 722 women with previously untreated metastatic breast cancer to paclitaxel with or without bevacizumab. Adding bevacizumab increased median progression-free survival to 11 months, compared with six months for patients treated with standard chemotherapy. Results from this interim analysis showed a 49 per cent improvement in overall survival and a response rate of 28 per cent in the women treated with bevacizumab compared with 14 per cent in those treated with chemotherapy alone.

Doxorubicin-docetaxel toxicity stops breast cancer trial early

Combination therapy with doxorubicin and docetaxel for breast cancer was associated with a high risk of life-threatening complications and led to premature termination of a trial involving 627 women.

There were two deaths related to drug toxicity and one to perforative peritonitis

among patients with febrile neutropenia in the doxorubicin-docetaxel group. The incidence of febrile neutropenia was higher in the doxorubicin-docetaxel group (40.8 per cent) than the doxorubicin-cyclophosphamide group (7.1 per cent) (*JAMA* 2005;293:2367).

Statins cost-effective for wider range of people

Statin therapy may be cost-effective in a wider range of people than was previously thought, new data suggest.

Researchers analysed data from the Heart Protection Study in which 20,536 adults with vascular disease or diabetes were randomly allocated 40mg simvastatin daily or placebo for an average of five years. They compared the costs of statin treatment with the costs of hospital stays and estimated the cost-effectiveness of the drugs for different subgroups of people.

They found that statin therapy was associated with a 22 per cent relative reduction in the costs of hospital admissions for all vascu-

lar events (95 per cent confidence interval 16–27; $P < 0.0001$).

The researchers say that statin therapy is currently recommended when a patient's estimated 10-year risk of a non-fatal heart attack or coronary death is at least 15–20 per cent. They point out that previous data from the HPS study demonstrated that statin therapy also reduces the risk of stroke and revascularisation procedures, and that guidelines should be based on the risks of all major vascular events, and not just coronary events.

Furthermore, they note that the price of generic simvastatin has fallen to about 15 per

cent of its 2001 proprietary price since it reached the end of its patent. They say that, at this price, the cost savings from reduced hospital stays would outweigh the cost of 40mg simvastatin daily for people whose risk of having a major vascular event within five years is as low as 12 per cent. This is approximately equivalent to a major coronary event risk of at least 4 per cent, much lower than the currently recommended threshold for statin treatment. They conclude that the estimated risk level at which statin therapy is recommended should be reduced (*Lancet* 2005;365:1779).

Isotretinoin does not increase depression

Treating adolescents who have moderate to severe acne with isotretinoin (Roaccutane) does not increase symptoms of depression, a new study suggests.

The researchers used a standardised scale to assess baseline depression symptoms of 132 adolescents with moderate to severe acne. For three to four months 59 of the subjects were treated with isotretinoin 1mg/kg daily and 73 were treated with maximal conservative therapy, consisting of a topical antibiotic, topical retinoid and twice daily administration of an oral antibiotic. The adolescents' depression symptoms were then reassessed.

At baseline, 14.3 per cent of subjects in the isotretinoin group had scores indicating depression, compared with 19.2 per cent in the conservative treatment group. Of the 101 subjects available for follow-up after three to

four months, the proportion of subjects classified as being depressed had decreased to 8.2 per cent in the isotretinoin group and 15.4 per cent in the conservative treatment group.

The researchers point out that isotretinoin has been associated with depression and suicide but a causal link has not been established. Conversely, previous research has found that treatment of acne with the drug improves symptoms of depression, although in this study the researchers found no statistical difference in the reduction of depression between the two treatment groups.

The researchers acknowledge the limitations of their study, such as the small sample size, and say that further studies of patients who experience depression induced by isotretinoin are warranted (*Archives of Dermatology* 2005;141:557).

News in brief

Paediatric trials network

A network that supports research into children's medicines has been launched. The UK Medicines for Children Research Network aims to develop safe, effective drugs with involvement of professionals, the pharmaceutical industry, children and their families. The co-ordinating centre will be at the University of Liverpool's Institute of Child Health.

Split paracetamol suppositories

Researchers show that paracetamol is uniformly distributed in suppositories. However, when anaesthetists split them (to achieve doses for children) a wide range of doses were recorded (*Anesthesia and Analgesia* 2005;100:1303).