

MHRA begins to consider OTC availability of contraceptive pill

Potential benefits of reclassifying oral contraceptives from prescription-only to pharmacy medicines were discussed at a Medicines and Healthcare products Regulatory Agency conference in London this week.

Mary Armitage, chairman of the Commission on Human Medicines's expert advisory group on medicines for women's health, led the session "Contraception over the counter: moving from emergency contraception to oral contraception", during the MHRA's "Widening access to medicines — focus on women's health" seminar.

She said that the group was delighted to have this topic on the agenda. However, she added: "We are not aware of any applications pending, so this is about opening the dialogue." She emphasised that many parties would need to be committed to the process for a classification to work. Nonetheless, she said: "Opening up the debate is the first step."

Ailsa Gebbie, of Dean Terrace Family Planning Centre in Edinburgh, said the usual chain of events for obtaining oral contraception was mired by "time-consuming, expensive and unnecessary obstacles".

This chain could, she argued, be pruned to its bare essentials: "You'll attend a pharmacy and complete a checklist. You'll have your blood pressure checked and then you'll discuss the situation with the pharmacist. You will at that stage receive a first-class patient information leaflet and begin oral contraception," she suggested.

Pharmacists would be able to provide help and advice and could easily reassure women about some common concerns, such as gaining weight and "nuisance" side effects. In addition, she said, "it gives a powerful message to the public that oral contraception is not dangerous".

Connie Smith, of Westminster Primary Care Trust, looked at the obstacles to reclassifying oral contraceptives. She said that many questions needed to be answered before such a classification could go ahead. "Is it going to



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OTC availability could improve access

increase access? Is it going to decrease morbidity and unwanted pregnancy? Is it going to improve women's experience of using contraception," she asked. She also questioned how the cost of the medicines and for providing them would be allocated and how equity of provision could be guaranteed. "I think all these questions need to be answered," she said, "but I'm pleased that we have the opportunity to air the issues and I hope that this is not going to be the last of the discussions."

The opening of a debate about the reclassification of contraceptives has been welcomed by the National Pharmacy Association. Colette McCreedy, director of practice, commented: "The profession has a track record of dealing with sensitive issues such as the choice to use emergency hormonal oral contraception. This proposal can be seen as a natural progression towards pharmacists being able to look after the holistic needs of patients."

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First national board meeting

Peter Jones was elected chairman of the Welsh national board of the Royal Pharmaceutical Society at its inaugural meeting this week. The Welsh board is the first of the national boards to convene. After the meeting, Welsh Health and Social Services Minister Brian Gibbons opened the new Welsh office of the Society. Dr Gibbons said the Society's decision to invest in its new office at the Cardiff Gate Business Park was a vote of confidence in the direction in which health care in Wales was travelling.

Society p171

Lord Fraser of Carmyllie criminal charges dropped

Criminal charges levelled against the chairman of the Royal Pharmaceutical Society's Statutory Committee, Lord Fraser of Carmyllie, shortly before Christmas have been dropped.

Last week, the Crown Office confirmed that no proceedings are to be taken against Lord Fraser in connection with an alleged incident on a flight from London to Dundee (*PJ*, 6 January, p4) because there was insufficient evidence of an offence having taken place.

Tranexamic acid proposed as next POM-to-P switch

The first steps to making tranexamic acid available as a pharmacy medicine were taken this week with the launch of a consultation on its switch from POM to P status.

The Medicines and Healthcare products Regulatory Agency published details of the proposed reclassification, sought by Meda Pharmaceuticals for its product *Cyklo-f* 500mg tablets. The company wants tranexamic acid to be available over the counter in a pack of 18 tablets for the treatment of heavy menstrual bleeding. Consultation on the application closes on 19 March.

Coinciding with the consultation's launch, the pros and cons of pharmacy availability for treatments for heavy menstrual bleeding (HMB) were discussed at an MHRA conference in London entitled "Widening access to medicines — focus on women's health".

Mary Ann Lumsden, professor of medical education and gynaecology at the University of Glasgow, argued that there are two treatments that have considerable potential as candidates for POM-to-P switches — tranexamic acid and non-steroidal anti-inflammatory drugs (mefenamic acid and ibuprofen). In determining their suitability for pharmacy supply for this condition, Professor Lumsden said that one concern could be that gynaecological diseases such as endometrial cancer might be missed if a doctor is not consulted.

However, she cited statistics used during the development of recent National Institute for Health and Clinical Excellence guidance, for which she acted as chairman of the guideline development group. "On average a GP will see a case of endometrial cancer in a woman under 45 years every 250 years and a death from the disease in this age group every 1,900 years. This communicates rarity," she stressed. "We don't need to get too hung up about this provided pharmacists ask the right questions," she said.

There are certain symptoms that might indicate significant disease, such as intermenstrual bleeding, postcoital bleeding, pelvic pain (between periods) and "pressure symptoms". However, she pointed out that GPs are advised only to question patients before starting treatment and that they are not likely to examine the patient if they have HMB alone. "Can pharmacists not do the same thing," she asked. "This is certainly an area where we can usefully move from POM to P quite soon," she concluded.

Section 60 Order approved

The Pharmacists and Pharmacy Technicians Order 2007, which modernises pharmacy regulation, was approved by the House of Commons on 5 February. Having been approved by both Houses of Parliament the Order was expected to be made by the Privy Council on 7 February after *The Journal* went to press.

Contract review starts to gather evidence

Pharmacy organisations have started to give evidence to the Department of Health's review of the pharmacy contract (*PJ*, 27 January, p99).

Anne Galbraith, who intends to complete the review by the end of March, took evidence from the Pharmaceutical Services Negotiating Committee, the National Pharmacy Association and the Company Chemists' Association last week.

The PSNC's evidence emphasised the strengths of the current contract in supporting high levels of access for patients, with that level of access being dependent on the confidence of businesses to invest in pharmacy premises and staff.

It was the PSNC's position that all communities, affluent and socially deprived alike, need prescribed medicines to be supplied promptly with advice, support for self care and over-the-counter medicines, along with support for healthy lifestyles.

A special meeting of the PSNC is now to consider questions posed by Mrs Galbraith. The committee will put forward proposals that:

- Offer value for money for the NHS and primary care trusts
- Reduce cost, complexity and administrative burdens on primary care trusts
- Support increased access where services are inadequate
- Develop the value of community pharmacy services for PCTs
- Support Government health priorities
- Support competition and choice, and
- Restore business confidence

The CCA told Mrs Galbraith that developing the contract through advanced services would be a powerful signal to the NHS that the Government was serious about community pharmacy as a provider of clinical services.

It expressed concern that the NHS did not understand the environment in which private



Anne Galbraith

sector businesses, such as pharmacies, invest, saying that pharmacies had invested in good faith on the back of the new contract and that the current direction of travel was right. It wanted to see more competition between different primary care service providers and over enhanced services in particular. The GP contract should include incentives that would encourage repeat dispensing and medicines use reviews, and GPs and pharmacists should be able to communicate electronically. Prevarication over role-based access to patient records for pharmacists should stop.

The NPA told Mrs Galbraith that PCTs needed to make better use of the enhanced services that community pharmacies could offer. The MUR service needed to be linked to the GPs' quality and outcomes framework, or to some other mechanism that would promote it. There should also be incentives to encourage teamworking with GPs.

It said that controls over the awarding of new pharmacy contracts were needed because without them PCTs would not have the sort of control they needed if they were to commission services effectively.

Fraud savings reach £800m

Savings for the NHS in England since it started to tackle losses due to fraud seven years ago have reached £811m. This is a 12:1 return on investment in counter-fraud work.

There have been 360 prosecutions (with a 96 per cent success rate) and 434 civil and disciplinary actions against members of the public and NHS staff who have committed fraud.

The latest figures were announced last month, together with the departure of the NHS's director of counter-fraud services Jim Gee. Mr Gee has moved to accountancy and consulting firm KPMG.

□ **Wales** Counter fraud work in Wales has recovered £1.766m since August 2001.

Drug trial processes improved

The Medicines and Healthcare products Regulatory Agency will seek advice from the Commission on Human Medicines and an Expert Advisory Group before approval of trials for high risk "first time in man" (FTIM) drugs, the MHRA has suggested this week.

For FTIM trials of such compounds — those acting (directly or indirectly) via the immune system, with a novel target or a novel mechanism of action, or having a secondary potential effect on the immune system via a mechanism of action which currently is not well characterised — trial sponsors will be requested to supply certain documents to the agency before making a clinical trial authorisation application.

Repeat dispensing uptake disappointing, say officials

Jeanette Howe and Keith Ridge, senior pharmacy officials at the Department of Health, have expressed some disappointment over progress on implementation of the new contract, particularly repeat dispensing. They were giving evidence at the All-Party Pharmacy Group's seventh session of its inquiry into the future of pharmacy.

In response, Howard Stoate, the group's chairman, said that the general medical services contract had worked for GPs because they had been incentivised to perform and completely change how they saw chronic disease management. "Wouldn't it be better to have a QOF [quality outcomes framework] in the pharmacy contract? I have got a vision of this," he said. QOFs had made a huge difference in a short time, he added.

Mrs Howe said that they had looked at a QOF during the negotiations. "We can look at it again and at the input that pharmacists can have, and identify what it is that pharmacists can contribute, distinct from others."

MPs to investigate medical records computerisation

A House of Commons inquiry has been launched into the planned electronic patient record and the use to which it will be put.

The inquiry, announced this week by the Health Committee, will focus on:

- Information to be held on local and national systems and whether patients can prevent the storage of personal data
- Who will have access to the data and under what circumstances
- Whether confidentiality will be adequately protected
- How any data can be used other than for care delivery, ie, for research
- Progress with the system

Written submissions, which must be received by 16 March, have been invited.

A **News feature** this week looks at web-based access to patient records (see p160).

NICE comes under scrutiny

The House of Commons Health Committee is to conduct an inquiry into the work of the National Institute for Health and Clinical Excellence. It will investigate why NICE decisions are increasingly being challenged, whether public confidence in NICE is waning and whether any particular group is disadvantaged by the evaluation process used by NICE. The committee will also examine implementation of NICE guidance. Written evidence is invited by e-mail (healthcommem@parliament.uk) until 23 March.

England's chief pharmacist calls for strong leaders

Chief pharmacists in NHS trusts need to become stronger leaders to ensure that clinical pharmacy continues to develop, Keith Ridge, chief pharmaceutical officer for England, told attendees at a conference in London last week.

Speaking at the *Hospital Pharmacist* medicines management conference, Dr Ridge used a football analogy to describe the current situation in the NHS. "Hospital chief pharmacists are currently playing in defence, having to balance service delivery with service development in an atmosphere of financial constraint," he said. "This 'defender mode' is understandable at present, but they need to move back up to midfield quickly, supporting their clinical strike force and dictating the pattern of play."

He added that it is not just local leadership that needs to be strengthened to support the enhanced clinical role of pharmacy, but leadership at a national level.

Dr Ridge called for a more collaborative approach between pharmacists working in



Damian Prestidge

Keith Ridge: collaboration needed

different sectors of the profession. "Irrespective of where you practise, there will

be a significant shift of services into the community," he said. Acute hospitals are going to become a lot more specialised and hospital and community pharmacists will need to work closer together, particularly with more community pharmacists specialising in clinical areas.

"It seems inevitable that there could be a net export of skilled pharmacy staff to primary care. This alone will need much closer working between the sectors," he said.

Turning to mental health services, Dr Ridge said that, despite concerns about the methodology used in the Healthcare Commission's report on medicines management in mental health (*PJ*, 20 January 2007, p65), mental health pharmacy is ahead of the game in many ways. However, it has been the "Cinderella service" for too long. "Within the Department of Health we are thinking about how best to help you and other professionals involved in medicines management in mental health tackle this problem," he said.

Primary care package should include pharmacy-led medication review

Pharmacist-led medication reviews should be included in a national primary care package designed to reduce emergency admissions, David Colin-Thomé, England's director for primary care, argues in a report published this week.

"Keeping it personal — clinical case for change" sets out changes to primary care designed to take the pressure off acute services, including having pharmacists working more closely with GPs in order to provide better services and better outcomes for patients.

"In future, comprehensive geriatric assessment, access to telephone advice, pharmacist-led medication reviews and nurse-led case

management will all be part of a primary care package which will also include social services. . . . This approach will reduce emergency admissions, readmission after treatment and allow for the early discharge of patients," Dr Colin-Thomé argues.

The Royal Pharmaceutical Society believes that such joint working needs to be based on closer links between the community pharmacy contract and the general medical services contract.

"It is clear that GPs are in an ideal position to take the pressure off acute services by providing more services within primary care," Hemant Patel, President of the Society, com-

mented in response to the report. "However, GPs need the support of the wider health care team, including pharmacists, in order to do this effectively. Pharmacy and general practice have much to gain from working together and this will benefit patients greatly."

He added: "The new pharmacy contract is a step in the right direction but we would like to see further alignment of the GP and community pharmacy contracts to better facilitate joint working between the two professions. It is important that GPs and community pharmacists dovetail their activities in order to be cost-effective and patient-friendly."

Inclusion of practice-based commissioning leads on PECs represents a conflict of interest

Automatic inclusion of practice-based commissioning (PBC) lead clinicians on primary care trust professional executive committees (PECs) has been challenged by national pharmacy bodies in their responses to "Fit to lead", the Department of Health's consultation on the future of PECs (*PJ*, 2 December 2006, p657 and p662).

A joint response from the Pharmaceutical Services Negotiating Committee, the Company Chemists' Association, the Royal Pharmaceutical Society, the Association of Independent Multiple Pharmacies and the National Pharmacy Association maintains that PBC clinicians having automatic PEC membership "would undermine the role of the PEC in scrutinising PBC in the way we envisage. In fact, we believe that guidance should go further and determine that no one professional group has a majority on the PEC."

Barbara Parsons, head of pharmacy practice, PSNC, said: "We have stressed the need for a wide range of professions . . . and for the selection process to be transparent and fair."

In their response, the pharmacy groups indicate that all professionals, including independent contractors, should have an equal opportunity to be appointed to PECs and "should be able to demonstrate their competence in their field along with evidence of frontline clinical experience with direct patient contact being essential".

The Primary Care Pharmacy Association raises similar concerns about commissioners being represented on PECs. Its separate response states: "This represents a potential conflict of interest since it might be the same individuals providing reassurance to the PCT that the PBC bids are appropriate. The representation of pharmacists and other profes-

sionals allied to medicine will help ensure that a broader view is taken."

The PCPA also recommends that primary care medicines management pharmacists should be eligible for new PEC roles. "We are confident that many possess the necessary leadership skills," the association responds.

Stephen Fishwick, head of NHS service development, NPA, told *The Journal*: "It would be bad news for pharmacy if the shake-out from the PEC review dislodges pharmacy representation at this critical time. Pharmacy needs leaders in key positions locally in order to restore momentum, towards an extended role, that has been lost over the period of NHS reconfiguration."

Ms Parsons added: "It is important that community pharmacy continues to have input and that the expertise gained from PEC pharmacists is not lost."

Guidance on H5N1 post-exposure prophylaxis issued

Guidance on post-exposure prophylaxis and treatment for farm workers and others involved in outbreaks of avian influenza due to H5N1 has been issued by the Health Protection Agency. It follows the discovery of the H5N1 strain of avian influenza on a poultry farm in North Suffolk last week.

The guidance, draft algorithms posted on the HPA website, indicates that people who have worked on, lived on or visited affected premises and who have been in close contact with poultry or poultry faecal dust from 48 hours before the onset of clinical symptoms in poultry should receive prophylaxis with oseltamivir (75mg daily for up to a maximum of 42 days). People involved in an outbreak

who develop febrile respiratory illness after exposure to diseased poultry should be admitted to hospital and cared for in strict respiratory isolation regardless of the severity of their symptoms and treated with oseltamivir (full treatment dose).

Maria Zambon, of the Health Protection Agency, said: "Despite this occurrence the current level of risk to humans from avian flu is extremely low. Most human H5N1 infections so far are thought to have occurred through close contact with live or dead infected poultry. In parts of the world where widespread infection in poultry has been reported, transmission of the virus to humans has occurred very infrequently. To date there

is no evidence that avian influenza H5N1 has adapted to spread easily between humans."

Sarah Cockbill, committee member of the Royal Pharmaceutical Society's Veterinary Pharmacists Group, said this week that there is no danger to humans at present. "Pharmacists should reassure members of the public who are concerned," she advised. "It is so small a risk as to be negligible." Dr Cockbill added that the bio-security at the farm involved in the H5N1 outbreak in Suffolk appeared to have been effective.

Updated information on avian influenza is available from the HPA and Department of Health websites (www.hpa.org.uk and www.dh.gov.uk).

Incentives offered for cost-effective flu vaccine purchasing by pharmacies in Scotland

Community pharmacists in Scotland are being offered a financial incentive to give the NHS value for money when purchasing influenza vaccines.

Details of the new payment, negotiated between the Scottish Pharmaceutical General Council and Scottish Executive Health Department, were published in an NHS circular this week. It says the "effective purchasing payment" is designed to return to contractors a share of the benefits they achieve through effective purchasing. The

payment will be calculated on an individual contractor basis and depends on the number of vaccines purchased.

The circular explains the arrangements for influenza vaccine supply for the 2007-08 season. GPs should advise community pharmacists of their vaccine requirements by 23 February, and pharmacists should place orders by 9 March. Each vaccine will attract a handling fee of 55p and a risk minimisation fee of 55p (providing certain criteria are met, including dividing the order between at least

three manufacturers). Future changes to the vaccine purchasing arrangements look likely.

The circular states: "A review of flu vaccine purchasing arrangements is under way. It has however been decided that any substantial change in supply arrangements will not take effect until purchasing for the 2008-09 season."

A second NHS circular details the arrangements for pneumococcal vaccine supply. Again, GPs should advise community pharmacists of their requirements by 23 February.

Motion on Pfizer put to Scottish Parliament

A motion about Pfizer's planned change to its distribution arrangements has been lodged this week in the Scottish Parliament.

The motion, by Bruce Crawford MSP (Scottish National Party, Mid Scotland and Fife), expresses concern that the changes will have cost implications for the NHS, will be detrimental to patient care and, if other pharmaceutical manufacturers follow suit, will adversely affect the ability of community pharmacists to deliver pharmaceutical care to the people of Scotland.

Contract updates circulated in Scotland

Community pharmacists in Scotland will this week receive two updates on their new contract: one from the Scottish Pharmaceutical General Council and the other an NHS circular.

In its newsletter, the SPGC states that the minor ailment service is going well, with 0.6 million patients registered at the end of 2006. During October, the top items prescribed were paracetamol, ibuprofen and simple linctus. It adds that revised patient leaflets and posters about MAS will be distributed to pharmacies shortly. On the public health service, the SPGC says it has taken longer than expected to implement the second tier of the service but that it is hopeful a company has now been found to provide the display materials.

The NHS circular states that current remuneration arrangements will continue during 2007-08 and that the details of this should be finalised with the SPGC before the end of March. In addition, contractors are expected to receive new funding to prepare for the acute medication service and chronic medication service.

Late March or early April will see two NHS workshops: one on the pharmaceutical care services planning tool (replacing control of entry) and the other for pharmacy champions.

Numark launches new concept pharmacy



Numark has launched a new concept pharmacy (pictured). Its main feature is counter pods either side of a glass wall showcasing pharmacy medicines that act as prescription reception and prescription collection areas. The Numark design includes "goalposts" that define categories around the perimeter wall bays, overhead gondola signage that signposts categories, seating areas in the middle of the pharmacy to encourage customers into the sales area, and consultation rooms with a sink, seating, signage, PC connectivity and a telephone line.

Steve Voyse, Numark retail services manager, said: "With the new design we have created more useable space and a more professional, clinical looking area. We have also introduced a pull-out counter section for easier use by disabled customers."

NPA claims to represent all

The National Pharmacy Association believes that all community pharmacies in the UK are members, now that Whitworths Chemists Ltd has joined the organisation. Until recently, Whitworths had obtained insurance and legal advice from other organisations.

Writing SOPs for CDs

Guidance on how to produce standard operating procedures for handling Controlled Drugs has been published by the Department of Health. It says that SOPs should cover every aspect of CD use from procurement to destruction and that most will require multidisciplinary collaboration.

Stoma consultations extended

The deadlines for Department of Health consultations on reimbursement and remuneration arrangements for stoma and incontinence appliances have been extended to 2 April so they can be considered in parallel with a terms of service review.

PCT considers major outsourcing

Hillingdon Primary Care Trust is considering outsourcing all its operations except those involving interactions with the public and patients because it has lost control of its spending. The commissioning of pharmacy services is included in the proposal.

This means that three of the four primary roles of the PCT — assessment and planning, contracting and procurement, and performance management, settlement and review — could be contracted out to a private sector organisation.

A report written by the PCT's deputy chief executive, Yi-Mien Koh, and considered by the PCT board late in January said: "Hillingdon PCT has failed as an organisation and significant changes are required to turn it around."

The report set out four options — do nothing, build internal capacity, share services with other organisations or outsource. The board asked staff to work up a detailed assessment of all four options, including details of the financial and workforce implications, for consideration at its next meeting on 27 April.

Professor Koh said: "This paper has no direct impact on patient services."

A spokesman confirmed that staff involved with commissioning pharmacy services are included in the review.

The PCT has accumulated a deficit of £54m over the past few years and expects it to rise by a further £11m by the end of this financial year. Most of that increase — £9.8m — will be because of overspending on acute services.

PCT chief executive Anthony Sumara, brought in late last year to solve the crisis, told the *Health Service Journal* last week: "I want to get rid of everything, outsource it — and we are distancing the PCT from its provider functions."

Michael Levitan, secretary of the Middlesex group of local pharmaceutical committees, hopes that any outsourcing of PCT commissioning services will not have a major effect on community pharmacy. He told *The Journal* this week: "Community pharmacy is not seen as a major drain on PCTs. They're not paying for a huge structure that has to be paid for whether it delivers or not."

Community pharmacies in Hillingdon are currently paid to provide a minor ailments service, a smoking cessation service, a national pathfinder service to educate and monitor diabetes patients, a care homes service and out-of-hours and palliative care service, as well as normal essential services under the pharmacy contract.

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Clomifene better than metformin for PCOS infertility

Clomifene is more useful than metformin for helping women with polycystic ovary syndrome (PCOS) achieve pregnancy, report US researchers (*New England Journal of Medicine* 2007;356:551).

They explain that women with PCOS frequently experience insulin resistance and that previous studies have shown that insulin sensitizers such as metformin can increase ovulation. Several smaller studies have also suggested that metformin, either taken alone or with clomifene, can result in greater fertility rates for PCOS patients than clomifene taken alone.

The researchers randomly assigned 626 infertile women with PCOS to one of three treatments: clomifene plus placebo, metformin plus placebo, or metformin plus

clomifene. After six months follow up, fewer women in the metformin-only group had given birth compared with either of the clomifene groups (7.2 per cent compared with 22.5 per cent for clomifene only and 26.8 per cent for the group taking both metformin and clomifene).

Compared with other women, obese women were less likely to conceive during the course of the study and were less likely to ovulate in response to metformin. The researchers note that women in the combination therapy group ovulated more frequently than women in either the clomifene-alone or the metformin-alone groups. However, the tendency to ovulate more frequently did not translate into a significantly greater number of pregnancies for the combination group.

“Our results show that you can’t use ovulation as a surrogate for pregnancy,” lead investigator Richard Legro, Pennsylvania State University College of Medicine, said. “An ovulation on clomifene treatment is twice as likely to result in pregnancy as an ovulation on metformin.”

The researchers also report that women who became pregnant in the clomifene groups had more occurrences of multiple pregnancy: 6.0 per cent for the clomifene-only group, 3.1 per cent for the combination group and 0 per cent for the metformin group.

They also note that although metformin alone did not improve the chances for pregnancy, it was useful for lowering the high blood testosterone levels that occur with PCOS.

Aprotinin during coronary artery bypass graft surgery has long-term mortality risks

Patients given aprotinin, a serine protease inhibitor, to reduce blood loss during coronary artery bypass graft (CABG) surgery are at an increased risk of death after five years’ follow-up, a study published this week in *JAMA* suggests (2007; 297:471).

The study involved 4,374 patients who received aprotinin, tranexamic acid, aminocaproic acid (not available in the UK) or no anti-bleeding agent during CABG surgery — the main outcome measure was all-cause mortality over five years. Aprotinin treatment was associated with increased mortality compared with the control group (five-year mortality, 20.8 per cent versus 12.7 per cent; covariate

adjusted hazard ratio 1.48, 95 per cent confidence interval 1.19–1.85; $P < 0.001$). Conversely, neither tranexamic acid nor aminocaproic acid were associated with significantly increased mortality over the five-year follow-up compared with control.

The authors say: “Importantly, aprotinin’s association with death sustained comprehensive covariate challenges, remaining significant when assessed among multiple subgroups with differing risk profiles and among patients surviving the [surgical admission].” They suggest that serious safety concerns extend beyond the perioperative period and that safer alternatives such as tranexamic acid should be used.

Intensive statin therapy reduces mortality in ACS but not CHD US study gives clues to views on advance supply of EHC

Intensive statin therapy reduces the risk of mortality more than moderate statin therapy in patients with acute coronary syndrome (ACS), a recent meta-analysis suggests (*Heart Online First*, 3 February, <http://heart.bmj.com>).

Data from 28,350 patients were reviewed. The authors showed that patients with recent ACS had a reduction in all-cause mortality over a mean follow-up of two years (4.6 per cent to 3.5 per cent, odds ratio 0.75, 95 per cent confidence interval 0.61–0.93).

Intensive statin therapy was also associated with fewer major adverse cardiovascular events (0.84, CI 0.77–0.91) and fewer admissions to hospital for heart failure (0.72, CI 0.62–0.83). However, for patients with stable coronary heart disease (CHD) intensive statin therapy was no better than moderate statin therapy for reducing all-cause mortality over a mean of 4.7 years.

The authors say: “These findings suggest that intensive statin therapy should be the standard of care in patients with recent ACS.”

□ HDL cholesterol Researchers have quantified what changes in high-density lipoprotein (HDL) cholesterol are seen in patients who experience reduction in low-density lipoprotein (LDL) cholesterol and regression of atherosclerosis in response to statin therapy (*JAMA* 2007;297:499). In an analysis of four randomised trials — involving



Patients with recent ACS should receive intensive statin therapy

a total of 1,455 patients who underwent serial intravascular ultrasonography while receiving a statin — reductions in atheroma volume of 5 per cent or greater were observed in patients with LDL cholesterol levels below 2.3mmol/L during treatment and with percentage increases of HDL cholesterol of more than 7.5 per cent ($P < 0.001$).

However, the authors say that it is unknown whether the associations seen translate into improved clinical outcomes.

Women with an advance supply of emergency hormonal contraception (EHC) are more likely to use it promptly (odds ratio 2.43, 95 per cent confidence interval 1.24–4.80) and report high convenience (4.25, CI 2.32–7.76) than those provided EHC through a clinic, according to a US study (*American Journal of Obstetrics & Gynecology* 2007;196:29.e1).

However, women with direct pharmacy access were no more likely to use the drug within 24 hours or to report it as being highly convenient, the researchers found.

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Medicines uptake increases but geographical variation still exists

Uptake of medicines has increased across England but the rate of increase varies substantially, according to a report commissioned by the Ministerial Industry Strategy Group, an advisory body with members from the Department of Health and the pharmaceutical industry.

“Medicines uptake in England: a quantitative analysis of variation” looked at medicines across a range of therapeutic areas — for the 28 strategic health authorities and 303 primary care trusts in place before the 2006 restructuring — analysing trends over time, variation between geographical areas and changes in such variations over time.

“There is considerably more variation between geographic areas when looking at drugs mainly used in hospitals, than those prescribed in primary care. In part, the lower variation in primary care is due to well-established therapies for diseases and conditions with relatively high prevalence,” the report says. It adds that variations are more likely for newer medicines in primary care, a trend which decreases over time. There is a tendency for hospital medicines to be newer and more specialised, and for

the use of such therapies to be more concentrated within London.

There appears to be considerable variation in the uptake of therapies that have been appraised by the National Institute for Health and Clinical Excellence, in relation to the timing of NICE appraisal. “Some have already been widely used prior to the NICE guidance, some appear to increase in uptake in anticipation of the assessment by NICE and in others there appears to be delay in increased uptake,” the report claims.

The report on uptake of medicines supports a wider document published this week by the MISG detailing the group’s “Long-term leadership strategy” for better Government and industry co-operation.

The strategy involves three working groups which aim to improve the relationship between the NHS and industry to support the better use of cost-effective medicines, to support the European Commission’s plans to improve the competitiveness of the European pharmaceutical industry and to consider what is needed to improve the effectiveness of medicines regulation.

IT delays medicines licensing

Computer problems at the Medicines and Healthcare products Regulatory Agency have been blamed for a growing backlog of applications for marketing authorisations.

Health minister Caroline Flint admitted to the House of Commons last month that “operational difficulties” with a new electronic data and document management system had caused the time taken to issue product licences and licence variations to grow longer. This meant that applications had to be prioritised according to the need for the medicine. The delays have had a particular impact on the market for parallel imports.

e-Prescribing specification

Nine months of work with health professionals, professional bodies and NHS trusts culminated last week in publication of the base-line version of the functional specification for e-prescribing in NHS hospitals in England.

Ann Slee, clinical lead for the e-prescribing programme, said: “The document will be used to guide software development by NHS Connecting for Health’s local service providers (LSPs).”

A draft version of the specification was published for consultation late last summer (*PJ*, 2 September 2006, p269).

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