

Further DoH guidance provides clarification on PBC

Further guidance on the implementation of practice-based commissioning (PBC) is published by the Department of Health this week. The guidance supersedes "Practice-based commissioning: achieving universal coverage", published in January.

The new guidance provides clarification and strengthening of governance and accountability arrangements to avoid potential conflicts of interest between the commissioner and provider roles in PBC. It also clarifies the procurement rules for services commissioned through PBC and sets out an alternative to the tendering process.

The guidance says that tendering is not required for providers looking to provide a routine elective service. The opportunity for any provider who can demonstrate that they meet national minimum quality criteria to supply services should not be constrained by commissioners, however, there are no guarantees of volume or payment in any given contract.

Commenting on the guidance, Graham Phillips, a community pharmacist and member of the Royal Pharmaceutical Society's Council, said: "In other words, the primary care trust will give you the contract but cannot guarantee you the business. This is good for pharmacy — it is what pharmacists spend their lives doing."

The guidance says that the same approach of fostering, not limiting, choice should be extended to the development of enhanced



Call for pharmacists to be guaranteed a seat at the commissioning table

primary care services through PBC. "PCTs should seek to establish a range of providers (such as GP limited companies, third sector organisations that are values-driven, community pharmacies and private companies) from which patients can choose, driving up quality through contestability," it says. The tendering process should only be necessary when the intention is to create a monopoly by awarding a contract to a single provider, it adds.

Mr Phillips believes that the guidance does not go far enough. "If pharmacy does not get a guaranteed seat at the commissioning table,

how can it ever progress to provide enhanced services and make use of independent prescribers and pharmacists with special interests," he said.

At the NHS Alliance annual conference held in Bournemouth last week, Mr Phillips asked Duncan Selbie, commissioning director at the Department of Health, whether he would make some commitment to guarantee that pharmacists have at least a reasonable seat at the commissioning table which, he said, they currently lack. Mr Selbie replied that he had met the representative bodies of community pharmacy that week and that they contributed to the DoH's new guidance on PBC. "Community pharmacists are a big part of the solution. Some pharmacy providers are as trusted as the NHS in the public's mind to give advice and to assist, so it is all to play for," Mr Selbie said.

Mr Phillips later said that he had further discussed this with Mr Selbie. He pointed out that there is already guidance for PCTs on engaging pharmacists in PBC produced by Primary Care Contracting (*PJ*, 8 July, p37). All that is necessary is to turn the advisory guidance into obligatory guidelines, which strategic health authorities should monitor. "Until this is done, GPs will continue to hijack PBC with impunity while community pharmacists are sidelined along with other potential providers," he told *The Journal*.

Evidence of benefits needed if pharmacists want to succeed in PBC

Good evidence of the benefits of pharmacy-based services will be essential if pharmacists are to wrest control of practice-based commissioning from GPs, the All-Party Pharmacy Group's inquiry into the future of pharmacy heard this week.

Sandra Gidley (Lib Dem, Romsey) asked witnesses from primary care organisations what they thought needed to be done to counter GPs' concerns over pharmacists encroaching on their territory. Good evidence

of pharmacists providing improved services is the key, said Donal Markey, community pharmacy development manager at Richmond and Twickenham Primary Care Trust.

"If you are trying to be innovative, it is difficult to find evidence, certainly UK-based evidence, of a pharmacist intervention service improvement — that is what I have found from a primary care trust level."

Without appropriate evidence, pharmacists are reliant on the goodwill of GPs to

move forward on practice-based commissioning, he said. He added that pharmacists' decisions over which areas they should tackle were also important, particularly in terms of choosing a quality and outcomes framework area to target. "You've got to be clever about what you are going to go for," he said. "The LPCs all come along with the same ideas, but they have got to start being more innovative in what they want to do and encourage pharmacists on the ground to go along with that."

Extending CD prescribing poses no risk

There are no safety concerns with allowing pharmacist and nurse independent prescribers to prescribe Controlled Drugs, the Commission on Human Medicines has decided.

At a meeting on 12 October, the CHM decided that so far as pharmacist and nurse independent prescribing are concerned, CDs should not be considered differently from any other medicines. Commissioners agreed that the legal classification of CDs related to their potential for diversion from the legitimate supply chain and misuse. They were unanimously of the view that there was no evidence that expanding CD prescribing to the new independent prescribers would lead to increased abuse.

Consequently, the CHM is to advise the Home Office's Advisory Council on the Misuse of Drugs that independent prescribers should be allowed to prescribe any Schedule 2, 3, 4 or 5 CD according to their professional competence.

Pharmacists recruited to fight terrorism

Pharmacies, and other high street retailers, have been asked to be alert to the possibility that some products they sell could be used by terrorists.

They have been sent leaflets produced by the National Counter Terrorism Security Office asking staff to be on the lookout for unusual purchases of products that have ingredients that could be used in home-made explosives, such as hydrogen peroxide or acetone.

An NCTSO spokeswoman said that the sale of a large amount of hydrogen peroxide in March 2005 had raised suspicions in a seller's mind. But at that time there had been no one to whom the suspicion could be reported. Hydrogen peroxide was one of the components of the four bombs that exploded on underground trains and a bus in London on 7 July 2005. The leaflets ask retailers to note as much detail as possible — descriptions of individuals or motor vehicles — to keep any CCTV recordings and to report any suspicious purchases or inquiries to the anti-terrorist hotline on 0800 789321.

Views sought on code for promoting NHS services

Whether pharmacists should be included under a new "Code of practice for promotion of NHS services" is one of the points raised in a consultation document on the proposed code, published by the Department of Health this week.

The document describes a self-regulatory approach to promotion of NHS services under a code of practice.

The DoH says that the plans should provide safeguards to ensure that:

- Information patients receive is not misleading, inaccurate, unfair or offensive
- The brand and reputation of the NHS is protected
- Expenditure of public money on promotional activity is not excessive

Lynsey Balmer, head of professional ethics at the Royal Pharmaceutical Society, commented: "It is important that safeguards are in place to ensure that information about health services is not inaccurate or misleading. The Society's Code of Ethics and Standards currently details professional requirements for the publicity and promotion of information. The [Society's] code requires that any information material about pharmacy services must be accurate and honest and should be presented so as to allow the recipient to decide independently whether to use a service."

Ms Balmer said that the Society would be considering the detail of the DoH consultation document and the implications for pharmacy.

Alastair Buxton, head of NHS services, Pharmaceutical Services Negotiating Committee, said that the appropriate advertising of professional services to patients is important to ensure the public is aware of and can make the most of the wide range of NHS services available from community pharmacies. "The contract requires pharmacies to notify their patients of the NHS services they provide, including via the production of a practice leaflet," he said.

Mr Buxton added: "PSNC will need to carefully consider its response to this DoH consultation document. The added value of the proposed self-regulatory framework will need to be assessed against the current Society guidance on the promotion of professional services."

Pharmacy patient satisfaction surveys soon

Patients may soon be asked how well they think community pharmacies are delivering NHS pharmaceutical services.

Responding to a Department of Health announcement that a patient satisfaction survey would determine whether GPs get £8,000 of their NHS pay, the Pharmaceutical Services Negotiating Committee's head of NHS services, Alastair Buxton, said that he hoped that an announcement would be made soon about surveys that pharmacies will have to carry out.

Mr Buxton said that there was no expectation that elements of pharmacy remuneration would become dependent on measured levels of patient satisfaction, but added:

"Anything is possible at the end of the day."

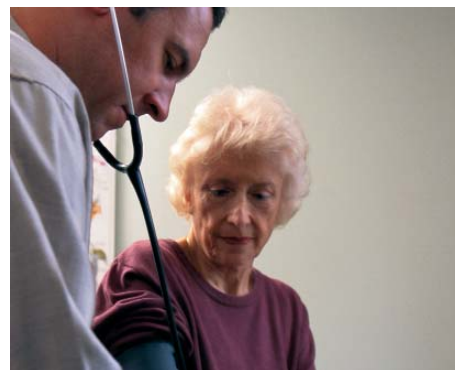
The idea that patients' views of the quality of pharmacy services should be sought was introduced as part of the new pharmacy contract for England and Wales. One of the requirements of clinical governance — an essential service that is mandatory for all contractors — is that pharmacies must carry out annual patient satisfaction surveys based on national templates and consider changes to improve service provision.

Contractors will be required to tell their primary care trust or local health board what they intend to do about the area identified as offering the greatest potential for improvement.

PSNC suggests pharmacies should consider chaperones

Community pharmacies offering services that involve physical contact with patients, or consultations in private consultation areas, should consider having a chaperone policy in place, according to the Pharmaceutical Services Negotiating Committee.

In guidance issued last week, the PSNC says that, although having a chaperone policy cannot be considered mandatory for pharma-



Patients could be asked if they want a chaperone

cies, pharmacists should keep their practices under review and carry out periodic risk assessments to establish whether to implement or revise chaperone policies.

The guidance offers advice about the role of chaperones, training for chaperones and issues related to consent, children and lone working. It also makes recommendations about communication and record keeping and suggests that details of any examination performed in the presence or absence of a chaperone should be documented in the patient medication record.

The PSNC guidance, available from its website (www.psnc.org.uk), is a summary of guidance produced by the NHS Clinical Governance Support Team in June 2005.

Health and social care regulation to merge

Plans to merge the Healthcare Commission and the Commission for Social Care Inspection have been put out for public consultation by the Department of Health. The new inspectorate will also take over the role of the Mental Health Act Commission.

The new commission will be responsible for ensuring the safety and quality of all publicly and privately funded health care and adult social care and for assessing performance. It will share responsibility for promoting choice and competition with the Office of Fair Trading and will help strategic health authorities monitor primary care trusts.

Sir Ian Kennedy, chairman of the Healthcare Commission, said that the proposals will ensure that regulation works in tandem with other changes in health and social care to promote better outcomes.

The new care regulator will be expected to register all public and private providers of health and adult social care and to measure them against a single set of national standards.

Sir Ian said that this will give patients a single assurance on safety and quality regardless of where they go for treatment. He added: "Where there are serious doubts about the safety of patients, the move would give the regulator powers to withdraw a provider's right to provide NHS services."

The consultation closes on 28 February 2007.

□ **Stronger regulation** A better regulatory system is needed for the emerging NHS market, according to the King's Fund. On the day that consultation started on plans to merge health and social care regulation, a King's Fund report called for stronger regulation to monitor and enforce the right competitive relationship between health care providers and to ensure an effective way of dealing with hospital failures. King's Fund chief executive Niall Dickson added: "We need to balance the danger of over-regulation, which will stifle innovation, and an unbridled market, which could deliver chaos and inequity."

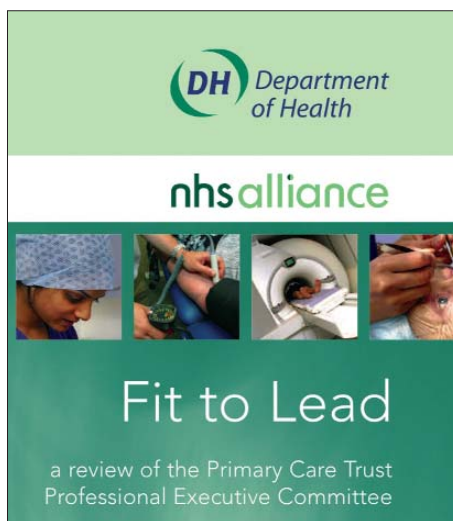
Consultation begins on the future structure of PECs

Consultation on a review of primary care trust (PCT) professional executive committees (PECs) in England began last week when the NHS Alliance, on behalf of the Department of Health, published "Fit to lead", a review of PECs informed by the opinions and experiences of key stakeholders, including pharmacists.

Reconfiguration of PCTs, the move to practice-based commissioning and the success of some PECs, but not others, are reasons cited by the DoH for its review (*PJ*, 16 September, p325). Indeed, there is consensus among contributors to the review that PECs need to change to reflect the changing roles of PCTs.

There is also agreement that a flexible approach is needed. "PCTs vary hugely in their population size, geography and health needs. Prescriptive advice from the DoH should be kept to a minimum, although guiding principles and facilitation are essential," says the consultation paper.

The paper was launched at the NHS Alliance conference held in Bournemouth last week. During a session entitled "Engaging clinicians in the newly reconfigured PCTs", Gary Belfield, head of primary care at the Department of Health and lead for the review, reassured participants that the DoH does not yet have a view on the future structure and functions of PECs. "The only view we have is that PECs are needed — it is a blank sheet of paper," he said.



The consultation was launched last week

Several PEC chairmen at the conference expressed concern that the committees would end up being constituted of mainly GPs with little input from other professionals. However, Mr Belfield confirmed that the DoH recognises the importance of multiprofessional involvement in PECs. "We need to think about how to get a broad church of people involved — the DoH is interested in that," he said.

Mark Bulmore, a pharmacist and chairman of the professional executive committee at South East Essex PCT, believes that the re-

view offers an opportunity to ensure that community pharmacists, as clinical leaders in primary care, continue to be involved in these committees. "The DoH has not yet made up its mind about the future structure of PECs. It is therefore important that pharmacists respond to the consultation in order to ensure that they continue to play an important role in future PECs," he told *The Journal*.

The national pharmacy bodies produced a joint response to inform the review, which highlighted the inherent conflict of interest in many practices taking on both a commissioning and a provider role under practice-based commissioning. They argue that, since PCTs remain accountable financially for the decisions of their constituent commissioning groups, the new PECs could play a key role in scrutinising decisions made within these groups. This, they say, would give PCTs confidence that commissioning plans take into account the full range of delivery options and ensure value for money. To be effective in this new role, they say, the PEC should be a cross professional and sectoral forum involving providers and frontline clinicians rather than PCT employees. No one profession should be in the majority.

The full consultation document can be accessed at the DoH website (www.dh.gov.uk) and via *PJ Online* (www.pjonline.com/links/pj). Responses to the key questions must be received by 7 February 2007.

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Government consults on stoma appliances

Proposals to change the reimbursement prices for stoma and incontinence appliances and the terms of service under which they are supplied have been set out in two consultations published by the Department of Health this week.

"Arrangements for the remuneration of services relating to appliances within Part IX of the Drug Tariff" describes a number of changes to pharmacy contractors' current terms of service. It says that patients should be offered an appropriate supply of complimentary wipes and disposal bags when a stoma item is dispensed, and appropriate advice should be provided by suitably trained and experienced personnel.

"Arrangements for the reimbursement pricing of stoma and incontinence appliances under Part IX of the Drug Tariff" sets out the DoH's suggested classification structure for stoma and incontinence appliances and its method for setting the reimbursement prices for these products.

The consultations on these proposals close on 5 March 2007. Details of how to respond are available from the Department of Health website (www.dh.gov.uk).

CPP proposes a royal college for professional leadership

The College of Pharmacy Practice has proposed the creation of a royal college of pharmacy to absorb the professional leadership functions of the Royal Pharmaceutical Society.

In its response to the Foster review of professional regulation (*PJ*, 22 July, p97), the CPP tells the DoH that one way of clarifying the separation of the professional leadership and regulatory functions of the Royal Pharmaceutical Society would be to combine the

Society's professional leadership role with the current functions of the CPP in a new royal college of pharmacy.

The CPP also points out that the Society's regulatory role is exercised by the independent Statutory Committee and not by the Council. It adds that if the Society were to retain its leadership role it would not be acceptable for the Council's elected professional members to be replaced by appointed members nor for the Council to have a lay majority.

Foster review ignores non-NHS professionals, says IPMI

Recent regulatory proposals from the Department of Health seem to apply only to health professionals who work in the NHS, the Institute of Pharmacy Management International has said. The consequences for professionals who do not work with patients have not been considered.

The IPMI's response to the Foster review of non-medical regulation (*PJ*, 22 July, p97) also criticises the report for focusing on England without making adequate consideration of organisations and structures in Scotland. However, the IPMI agrees with many of the proposals.

It also supports proposals for broad standards frameworks for professional practice, but warns that they could impede developments.

"Government must remember that progress is made by challenging or changing practice, and innovation must not be stopped for fears of regulatory action for straying outside existing practice standards in patients' interests," the IPMI says.

It adds: "Professional regulation must relate to all roles the profession fulfils, not just the majority role. Quite how to regulate and revalidate managerial roles or industrial or academic pharmacists is not considered."

Vigorous education vs training debate expected

Robust discussion of the relationship between education and training has been forecast by the heads of schools of pharmacy.

Responding to a Royal Pharmaceutical Society consultation paper setting out draft principles for pharmacy education and training (*PJ*, 27 May, p639), the Council of University Heads of Pharmacy Schools says: "Some of our hospital colleagues believe that the pharmacy degree should be about training, rather than education."

Overall, the response sees no major problems with the Society's draft principles, although it warns that proposals about equal opportunities and widening access to phar-

macy training might come into conflict with ensuring the academic ability of course applicants and their suitability for entering the profession.

However, warning that principles for choosing only the best and most suitable students for training might become irrelevant, one CUHOPS member comments: "With the large growth in pharmacy undergraduate numbers of the last years, it is possible that in future recruitment onto MPharm programmes, rather than selection, will be the norm."

The response calls on the Society to issue guidance on circumstances or conditions that

could be a barrier to professional registration, such as criminal convictions or medical conditions. CUHOPS says that this would be unnecessary if student registration was introduced, but the council only wants to see this happen as part of an integrated package of developments.

The Society has received a total of 82 written submissions in response to the consultation. After analysis by an external consultant a series of discussion workshops will be held early in 2007 to consider the results and next steps with stakeholders. The final version of the draft principles will be considered by the Society's Council in April 2007.

Alliance Boots takes action against GIRP

The wholesale and commercial affairs division of Alliance Boots plc has begun legal proceedings in Belgium to review the actions of the European Association of Pharmaceutical Full-line Wholesalers (GIRP) in relation to Pfizer and UniChem's "Direct to pharmacy" (DTP) distribution agreement in the UK.

The move coincides with Alliance Boots executive deputy chairman Stefano Pessina's resignation from the GIRP steering committee over GIRP's response to the distribution model.

The Times reported last week that "the action is designed to overturn efforts by the wholesalers group to block [the Pfizer/UniChem] deal".

However, a spokeswoman for Alliance Boots wholesale and commercial affairs told *The Journal* that the legal action is designed to

prevent the company's competitors from influencing GIRP to try to block the deal, and not as reported in *The Times*.

"Alliance Boots WSCA believes that GIRP is not acting in the interest of all its members and is being used to voice criticism of the DTP model by full-line wholesalers who were not appointed by Pfizer in its recent tender process in the UK," the company said in a statement.

□ **Welsh view** Community Pharmacy Wales discussed Pfizer's distribution plan at a meeting held in Cardiff last week. The CPW committee released the following statement: "CPW is gravely concerned about the Pfizer proposals and the resultant reliability of the supply chain to contractors and the impact on both the community pharmacy business model, pharmacy workload and provision of dispensed medication to patients."

ABPI sees clinical trial opportunity in CfH records

Electronic patient records could be used to help recruit clinical trial volunteers, according to Richard Barker, director general of the Association of the British Pharmaceutical Industry.

At a briefing last month, Dr Barker said: "If you could wire together 48 million people's medical records on an anonymised basis and select people [to invite to participate in] clinical trials automatically and survey their use of medicines automatically, we would be the clinical research Mecca of the world."

Dr Barker also spoke of the need to increase preclinical research and development skills in the UK.

"While the number of people we are training in different medical specialties is going up . . . the one discipline that's gone down is clinical pharmacology," he said.

Do not send originals of CD prescriptions to NHS pricing offices yet, PSNC warns

Pharmacy contractors should continue to send copies of private prescriptions for Schedule 2 and 3 Controlled Drugs to the NHS Business Services Authority and keep the original forms for their own records, despite information to the contrary in Part XX of the Drug Tariff, the Pharmaceutical Services Negotiating Committee said last week.

In a statement published on its website, the PSNC points out that although the Misuse of Drugs Regulations were amended on 1 September to allow the original form FP10PCD for Schedule 2 and 3 CDs to be sent to the NHSBSA, a change in the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980 is also required. These regulations are expected to be updated shortly.

Audit committee scrutinises NHS Wales's finances

Consideration of changes to the monitoring of the financial performance of local health boards has been recommended by the Welsh national assembly's audit committee.

A report by the committee says that a number of LHBs are unlikely to be able to meet their statutory duty to achieve financial balance in every year. The committee recommends that the Welsh Assembly Government should consider whether annual monitoring of financial performance is still appropriate.

In addition, the audit committee expresses concern that some deficits in the Welsh health service are held by single LHBs, while some are shared with other LHBs.

Because of this, it suggests that LHB strategic change and efficiency plans should be subject to rigorous approval processes to make sure that it is clear who is responsible for meeting them and that their financial impact is properly allocated.

Access to *PJ Online* is free to all

2007 health events

Health events for 2007 have been added to the diary section.
www.pjonline.com/diary

Assisted suicide

A two part series on pharmacists' involvement in assisted suicide or euthanasia where the practice is legal.
www.pjonline.com/series

Christmas

This year's Christmas page will contain details of company closures over Christmas/New Year and charitable schemes over the Christmas period.
www.pjonline.com/xmas

Separate or together

Discussion of the pros and cons of the Society's dual role
www.pjonline.com/dualrole

HAART adherence barriers similar across settings and countries

Barriers to adherence to highly active antiretroviral therapy (HAART) are largely consistent across multiple settings and countries, a recent study suggests (*PLoS Medicine* 2006;3[11]:e438).

The study — a systematic review of 37 qualitative studies and 47 surveys (with a quantitative methodology), of which 12 were conducted in developing nations — found that the following important barriers to adherence were reported across the board: fear of disclosure of HIV status; concomitant substance misuse; forgetfulness; suspicions of treatment; too complicated regimens; number of pills required; decreased quality of life; work and family responsibilities; sleeping at the time a dose is required; and access to medicines.

Sonali Sonecha, lead pharmacist HIV services, North Middlesex Hospital, speaking on behalf of the HIV Pharmacy Association, said that the study offers a good starting point for considering what the true barriers to treatment adherence might be, enabling pharmacists to develop strategies to overcome such barriers. Ms Sonecha said that, although more antiretroviral drugs have become available over the past three to four years, treatment has become simpler to take (eg, fewer pills, fewer food restrictions). “HIV is now viewed as a chronic illness and patients can



Sleeping when a dose is required can be a barrier to HAART adherence

expect to be on regular drug treatment for many years,” she pointed out.

“Whereas before,” she said, “the focus would have been on giving practical advice on managing complex regimens, now pharmacists are involved in supporting patients in maintaining good adherence over a long period of time.”

According to the study, patients in developed nations identified important facilitators to adherence as: having a sense of self-worth; seeing positive effects of antiretrovirals; accepting their HIV seropositivity; understanding the need for strict adherence; making use of reminder tools; and having a simple regimen.

Clear evidence against episodic HIV treatment

HIV-infected patients are at increased risk of opportunistic disease or death if they are treated using a strategy of episodic antiretroviral therapy guided by their CD4+ count, rather than given continuous antiretroviral therapy, say researchers in *The New England Journal of Medicine* (2006;355:2283).

The latest evidence against such a treatment strategy, which the researchers describe as “clear and compelling”, is from the so-called SMART (strategies for management of antiretroviral therapy) study. The study was halted early in January when an analysis of interim data revealed that subjects on episodic treatment (see Panel) had more than twice the risk of disease progression than those taking continuous antiretroviral therapy (*PJ*, 28 January, p98).

The full report of the trial, which involved 5,472 patients followed for an average of 16 months, shows that the hazard ratio for opportunistic disease or death from any cause among patients treated episodically was 2.6 per cent (95 per cent confidence interval 1.9–3.7; $P < 0.001$).

The researchers explain that interruption of antiretroviral therapy has been advocated as

a treatment strategy to enhance quality of life, limit adverse events and allow for the emergence of wild-type virus in patients infected with multidrug-resistant HIV.

A recent study showed that the strategy could result in significant cost savings with no evidence of treatment resistance (*PJ*, 12 August, p182).

However, the researchers conclude that the episodic treatment strategy used in the SMART study is deleterious, and did not reduce the risk of death from causes other than opportunistic disease as they had expected.

SMART treatment groups

Patients with CD4+ counts of more than 350 cells per cubic millimetre were randomised to episodic or continuous antiretroviral therapy. Patients in the episodic treatment group had antiretroviral therapy deferred until their CD4+ count decreased to less than 250 cells per cubic millimetre. Treatment was then continued until their count rose to more than 350 cells per cubic millimetre.

63,500 HIV cases in UK

An estimated 63,500 adults are living with HIV in the UK, according to the Health Protection Agency. The figure includes individuals who have received a diagnosis and just over 20,000 who the HPA estimates to be unaware of their condition.

In a report entitled “A complex picture” published to coincide with World AIDS Day on 1 December, the HPA concludes that initiatives in the UK have been successful in maintaining high numbers of HIV-infected individuals on antiretroviral therapy and reducing the proportion of children exposed to maternal HIV infection. The report makes a number of recommendations, including improved access to sexual health services, earlier HIV testing, more focused prevention programmes and a substantial increase in the volume of chlamydia screening.

□ **HIV resurgence** There is evidence that some countries are seeing a resurgence in HIV infection rates that were previously stable or declining, according to the World Health Organization. The WHO estimates that there are 39.5 million people infected with HIV worldwide, with 4.3 million new infections in 2006.

Varenicline launch next week

Smokers may be able to kick the habit with the help of a new medicine, available in the UK next week from Pfizer.

Launched as Champix, varenicline binds with high affinity and selectivity to the $\alpha 4\beta 2$ nicotinic acetylcholine receptor, acting as a partial agonist that has lower intrinsic efficacy than nicotine and has antagonist activity in the presence of nicotine.

Varenicline therapy is started one to two weeks before the date of smoking cessation. Following a one-week titration period (with a dedicated treatment initiation pack), varenicline is taken at a dose of 1mg twice a day.

Notice-board p663

New CML treatment available

A new treatment for chronic myeloid leukaemia (CML) has been launched by Bristol-Myers Squibb.

Dasatinib, marketed as Sprycel, is indicated for the treatment of adults with chronic, accelerated or blast phase CML, with resistance or intolerance to prior therapy. It also has an indication for the treatment of adults with Philadelphia chromosome positive acute lymphoblastic leukaemia and lymphoid blast CML with resistance or intolerance to prior therapy.

Dasatinib is a protein kinase inhibitor that binds to the inactive and active conformations of the BCR-ABL kinase. It inhibits the activity of the BCR-ABL kinase and the activity of the SRC family kinases and a number of other oncogenic kinases.

Notice-board p663

Antibiotics more beneficial in bilateral otitis media

Antibiotics are beneficial for relieving pain and fever in children aged under two years with acute otitis media in both ears or for children of any age with acute otitis media and otorrhoea (discharge from the ear), the authors of a study published in *The Lancet* conclude (2006;368:1429). For most other children with mild disease a watch and wait policy seems justified, they say.

The meta-analysis combined data from six trials involving 1,643 children aged six months to 12 years. The primary outcome was persistence of otitis media with pain or fever, or both, at three to seven days.

In children under two years old with bilateral otitis media, four would need to be treated to prevent an extended course of the disease in one child. In children older than two years with bilateral infection the number needed to treat would be nine. In children with unilateral infection the numbers needed to treat would be 20 and 15, respectively. The researchers also found that children with otorrhoea were more likely to benefit from antibiotics.

The researchers postulate that in children younger than two years with bilateral otitis media and in those with otorrhoea, the infection is more often bacterial than viral.

Antihistamines and decongestants

Antihistamines and decongestants should not be used either alone or in combination to treat acute otitis media with discharge in children, according to a recent Cochrane review (www.thecochranelibrary.com). The reviewers analysed 15 trials involving 1,516 children and found no statistical or clinical benefit for any of the interventions or outcomes studied. In addition, in the six studies that examined side effects, treated subjects experienced 11 per cent more side effects than untreated subjects. This means that for every nine children treated, one will be harmed and none will benefit.

Full correction of anaemia in CRF poses risks

Correction of haemoglobin levels to within the normal range (13–15g/dL; known as full correction) with epoetin does not improve cardiovascular outcomes for patients with chronic renal failure, two studies published in *The New England Journal of Medicine* have shown.

The first study (2006;355:2071) randomised 603 patients with chronic kidney failure to receive epoetin beta to achieve either full correction of haemoglobin or partial correction (haemoglobin 10.5–11.5g/dL). The investigators found no difference in the risk of cardiovascular events between the two groups.

Furthermore, in the second study (*ibid*, p2085) of 1,432 patients treated with epoetin alfa, researchers found that aiming for a haemoglobin level of 13.5g/dL — compared with a lower level of 11.3g/dL — elicits a higher risk of adverse events (composite of death, myocardial infarction, admission to hos-



Josh Slier/Science Photo Library

Epoetin injections are given for anaemia associated with chronic renal failure

pital for heart failure and stroke, 125 events versus 97 events, hazard ratio 1.34, 95 per cent confidence interval 1.03–1.74; $P=0.03$) without superior improvement in quality of life.

News in brief

Chloramphenicol eye ointment

Three companies (Aventis Pharma Ltd, Optrex Ltd and Galpharm International Ltd) have applied to the Medicines and Healthcare products Regulatory Agency for their chloramphenicol 1 per cent eye ointment products to be classified as pharmacy medicines. Consultation on the applications closes on 4 January 2007.

GSL application for cetirizine

Galpharm Healthcare Ltd has applied to the Medicines and Healthcare products Regulatory Agency for Galpharm Hayfever and Allergy Relief (cetirizine 10mg tablets) to be added to the general sales list. Consultation on the application closes on 12 December.

Heart failure project likely to be recognised as enhanced service

An award winning community pharmacy heart failure medicines service in Scotland is on track to receive funding to continue as a locally enhanced service.

The Glasgow community pharmacy heart failure team won the National Pharmacy Association, Guild of Healthcare Pharmacists, NHS Alliance, Merck Sharp & Dohme joint pharmacy award for 2005–06 (*PJ*, 19 November 2005, p625), which allowed them to evaluate pharmacists' and patients' views of the adherence support service.

"As a result of the case made by evaluation of the service (including the qualitative research) it is on the cards that the service will receive ongoing funding as a locally enhanced service," said Richard Lowrie, lead clinical pharmacist at NHS Greater Glasgow and team leader. Mr Lowrie presented some of the results of the evaluation at the NHS Alliance annual conference held in Bournemouth last week.

He explained that patients are referred to a community pharmacy of their choice (90 per cent of pharmacies in Glasgow offer the service) by prescribing support pharmacists, hospital pharmacists or heart failure liaison nurses. Community pharmacists follow up any specified issues, carry out an initial assessment of symptoms and monitor progress against this baseline every month (*PJ*, 5 March 2005, p258).

In telephone interviews with 65 patients who had used the service, 67 per cent said their knowledge of heart failure had improved, 72 per cent said their knowledge of their medicines had improved, 59 per cent



Patient progress is monitored monthly

said that their knowledge of their symptoms had improved and 9 per cent said their routine for taking their heart failure medicines had changed. "We were not too disappointed with that last result since we did not select patients on the basis that they were poor compliers," said Mr Lowrie. Part of the evaluation has come as a result of joint work between NHS Glasgow Community Pharmacy Development Team and the University of Strathclyde department of pharmaceutical sciences.

The award for 2006–07 is currently under review with a view to broadening it to include primary care pharmacists and other health care professionals who work alongside pharmacists. Further information will be announced next year.

Statins used for CV primary prevention reduce morbidity

Use of statins for people without cardiovascular disease (primary prevention) offers a reduction in major coronary and cerebrovascular events, researchers have found. But their meta-analysis failed to reveal a reduction in mortality.

In their analysis published this week (*Archives of Internal Medicine* 2006;166:2307) researchers looked at seven trials involving 42,848 patients (of whom 90 per cent had no history of cardiovascular disease) and found that statin therapy decreased the relative risk of major coronary events by 29.2 per cent (95 per cent confidence interval 16.7–39.8; $P<0.001$), of major cerebrovascular events by 14.4 per cent (2.8–24.6; $P=0.02$) and of revascularisation procedures by 33.8 per cent (19.6–45.5; $P<0.001$) over a mean follow-up of 4.3 years.

The relative risk of both overall death and death due to coronary heart disease was not significantly reduced. The authors say that a reduction in mortality with statin therapy was not observed "because of the relatively low risk of mortality in this patient population and insufficient length of follow-up".

DTB moves to BMJ Group

The *Drug and Therapeutics Bulletin* has been acquired by the BMJ Group. The move follows the Department of Health's decision not to renew its bulk subscription to *DTB* for doctors, pharmacists and other health care professionals in England (*PJ*, 6 May, p524).

Fresh start for Healthy Start

Healthy Start, launched in Devon and Cornwall last year (*PJ*, 5 February 2005, p138), went UK-wide last weekend. The programme replaces the Welfare Food Scheme and provides vouchers to pregnant women and low-income families with children to redeem for fruit, vegetables, milk and infant formula from participating stores and pharmacies.

Welsh smoking ban progress

Final draft Regulations to enable enforcement of the smoking ban in enclosed public spaces in Wales were published last week and will now be scrutinised by the Welsh Assembly Government's Health and Social Services Committee. A consultation report is available (www.smokingbanwales.co.uk). The ban is expected to be introduced in Wales on 2 April 2007.

Bivalirudin reduces bleeding risk compared with standard therapy in coronary syndromes

Use of bivalirudin to treat acute coronary syndromes is as effective as standard drugs but reduces the risk of major bleeding, a study published last week suggests (*New England Journal of Medicine* 2006;355:2203).

In the acute catheterisation and urgent intervention triage strategy (ACUITY) trial, 13,819 patients were enrolled into one of three treatment groups: unfractionated heparin or enoxaparin, combined with a glycoprotein IIb/IIIa inhibitor, bivalirudin and a glycoprotein IIb/IIIa inhibitor or bivalirudin alone. Almost all patients received aspirin and most received clopidogrel before angiography.

The trial investigators did not identify a significant reduction in ischaemic events with bivalirudin, but they did show that the drug is as good as heparin for this endpoint. And al-

though bivalirudin alone had similar rates of ischaemic complications, revascularisations or death as the other groups, it had lower rates of major bleeding complications (3.0 per cent versus 5.7 per cent; $P<0.001$, relative risk 0.53, 95 per cent confidence interval 0.43–0.65).

The study was supported by Nycomed, the manufacturer of bivalirudin.

The author of an accompanying editorial (*ibid*, p2249) points out that patients assigned to bivalirudin monotherapy who were not pretreated with clopidogrel had a significant increase in ischaemic events compared with those treated with a glycoprotein IIb/IIIa inhibitor. "This finding suggests, but does not prove conclusively, that patients treated with bivalirudin monotherapy should be pretreated with clopidogrel."

News in brief