

Prison pharmacy services in England need to be brought up to NHS standard

PHARMACY services within prisons in England need to be brought up to standards equivalent to those within the National Health Service over the next three years, according to a new report. During this period, primary care trusts (PCTs) with prisons in their areas will take responsibility for commissioning health care for prisoners.

Funding for health services within English prisons was transferred from the Home Office to the Department of Health in April this year. There are 137 prisons, and pharmacy services are provided in a number of ways. In-house pharmacy departments serving major prisons and smaller units that are part of "cluster groups" make up three-quarters of the service. The rest are contracted out to local hospitals, community pharmacies or pharmacy companies.

The report, "A pharmacy service for prisoners", was drawn up by a joint Department of Health and HM Prison Service team. It says that at present pharmacists and their staff within prisons "tend to be isolated, both from the health care staff within the establishments they serve and other prison pharmacy service providers". As a consequence, services are "fragmented and have largely pursued an individual, independent and largely uncoordinated course". There are pockets of excellence but the services they provide fail to spread to other prisons. To overcome this, the DoH is to fund regional pharmacy development leads who will have responsibility for putting many of the report's recommendations into practice.

Joe Asghar, regional pharmaceutical adviser for the NHS Executive's Northern

Yorkshire office, was one of those consulted by the team drawing up the report. He said that the report gives those involved a chance to take stock of what is happening and what needs to change. Development of the prison pharmacy service is part of a wider development of the health service within prisons as a whole.

"Prisoners have the same rights to self-care and health as the general public, taking custodial issues into account," Dr Asghar said. He believes that there is unlikely to be any one-size-fits-all model for reformed services because different prisons have different needs. "PCTs will have to understand how the prison health service operates and how it can be brought into alignment with the NHS. It will be a challenge for all concerned."

Sharon Kebell, pharmaceutical adviser to Durham and Chester-le-Street PCT, said that the PCT had set up a working group which includes pharmacists from HMP Durham. "The PCT recognises its role in prison health but work is at an early stage."

The report says that the aim is to move to a patient-focused service where pharmacists and their staff provide a greater level of clinical advice to prisoners. In general, prisoners should be able to take responsibility for their own medication (if appropriate) and to have access to pharmacy services similar to those provided in primary care, both in terms of dispensed medicines and access to medicines for self-care.

To support better prescribing within prisons, pharmacy information technology needs to be upgraded and repeat prescribing

and dispensing systems established in parallel with those in the NHS. The courses of medicines for prisoners to have in their own possession should be standardised through a move to patient packs, the report advocates.

In total, the report makes 29 recommendations. These are concerned with bringing the prison pharmacy service up to NHS standards and with ensuring that pharmacy staff have the support, standards and personal and career development they need.

The report is available via *Pj Online* (www.pjonline.com/links/pj).

No need to remove supplements from sale yet, Society advises

COMMUNITY pharmacies do not need to withdraw any vitamin or mineral supplement products from sale at present, the Royal Pharmaceutical Society is advising. Regulations currently being discussed in Parliament will not take effect until 1 August 2005.

Two pieces of European legislation, when transposed into British law, will impinge on the sale of complementary medicines. European Directive 2002/46/EC on food supplements will be put into effect in England in 2005 through the Food Supplements (England) Regulations 2003. The European Commission is also discussing a proposed directive on regulating traditional herbal medicines.

Two major concerns have been expressed about the food supplement regulations. The first is that some ingredients of food supplements sold in the United Kingdom are omitted from the approved list of vitamins and minerals in the directive.

These include boron, cobalt, nickel, silicon, tin and vanadium.

The second is that the permitted levels allowed in the directive are based on nutritional need and not (as in the UK) on safety considerations. Both issues are being addressed by the Food Standards Agency which regulates food supplements not sold as medicines. The herbal medicinal products directive would require products not currently sold as medicines to be licensed by the Medicines and Healthcare products Regulatory Agency and manufactured to good manufacturing practice standards. Products would not have to demonstrate efficacy. Instead, the products would need to have a documented record of traditional use over 30 years.

The Society's complementary and alternative medicines working group is continuing to monitor the situation and will provide further information as it arises.

Article, p55

Law change will enable supply of drug paraphernalia

THE law is being changed to allow pharmacists to supply drug paraphernalia to illicit drug users.

From 1 August, it will no longer be an offence for pharmacists, doctors and drug treatment workers to supply equipment to help prevent disease and infection.

Supply of five types of items will be allowed. They are ampoules of water for injections, swabs, utensils for the preparation of a Controlled Drug (spoons, bowls, cups and dishes), citric acid and filters.

Home Office Minister Caroline Flint commented: "Our top priority is to get users off drugs. But we need to be realistic that, for some drug users, that will not happen overnight and we need to help them reduce the amount of harm they do to themselves and others."

The Royal Pharmaceutical Society welcomed the news, and said it would allow pharmacists to provide better help for drug users.

Passive smoking issue raised by CMO

THE health risk associated with passive smoking is one of five key public health issues highlighted by the Chief Medical Officer for England in his annual report.

Published last week, the report covers passive smoking, the safe administration of intrathecal chemotherapy, West Nile fever, obesity and poor clinical performance by NHS doctors. "The issues may sound familiar but I have chosen them either because they herald potentially serious problems in the future or because action so far has failed to make the inroads that are necessary," said Sir Liam Donaldson.

Passive smoking The CMO calls for all employers to introduce smoke-free workplaces and for "very serious consideration" to be given to introducing a ban on smoking in public places. He wants both health professionals' and the public's knowledge of the health risks from passive smoking to be improved.

In England, 27 per cent of adults smoke. "The majority of people in England are non-smokers and object to others smoking near them," the CMO says. "Moves to make public places and workplaces smoke-free

would create a climate in which 'no smoking' is the social norm, it would help smokers to give up and it would remove the risks of passive smoking for millions of people."

The report's recommendations on passive smoking are strongly supported by PharmacyHealthLink. "We are calling for the Government to make the introduction of primary legislation to protect staff and the public from the harm caused by passive smoking a priority," said Dr Geof Rayner, director of PharmacyHealthLink. In May, the charity wrote to the then Health Secretary Alan Milburn to urge him to make all NHS premises "smoke-free".

Intrathecal chemotherapy Safe administration of intrathecal chemotherapy is highlighted in the report. National guidance on eliminating errors associated with intrathecal chemotherapy has been produced. However, the CMO says that some local NHS organisations have been slow in complying with this guidance. In addition, the Department of Health is working with manufacturers of intrathecal chemotherapy to identify a design solution to make it physically impossible to make an error.

West Nile fever Although the risk of West Nile fever coming to the United Kingdom is low, the CMO says that a contingency plan against the possibility of the disease emerging and becoming established is needed.

Three factors — increases in the mosquito population, infection of domestic bird populations and climate changes — could result in the emergence of West Nile fever, as it has in the United States.

Obesity The CMO expresses concerns over rising levels of obesity, particularly among children. He suggests that health professionals and primary care trusts should take action to prevent and tackle obesity. Pharmaceutical companies producing drug treatments for obesity should help to provide training for primary care professionals on ways to tackle obesity and implement national guidance.

ROYAL PHARMACEUTICAL SOCIETY NEWS

Council acts on members' concerns

The Council has agreed to develop its future organisational model to reflect its commitment to an integrated role as a professional and regulatory body. It made its decision at an all-day meeting on 2 July, at which it discussed the issues that had led to the special general meeting on 1 June (p65).

Buscopan move to GSL sought

THE manufacturer of Buscopan (hyoscine butylbromide) is seeking reclassification of the drug to a general sale list medicine.

Boehringer Ingelheim says that reclassification is appropriate because the product has been available for over 45 years, including more than 10 years as a pharmacy medicine. For GSL sale, the product would be restricted to 10mg tablets in 24-tablet packs and renamed Busco-calm. Warnings advising patients to consult a doctor before first-time use or if symptoms worsen or do not improve over two weeks would be put on the packs.

The Medicines and Healthcare products Regulatory Agency is seeking comments on the consultation. These should be sent to Amanda Lawrence, Room 14-152, MHRA, Market Towers, 1 Nine Elms Lane, London SW8 5NQ (e-mail amanda.lawrence@mhra.gsi.gov.uk) by 13 August.

Afternoon and evening hardest time for smokers to abstain

SMOKERS who use 16-hour nicotine patches to help them quit are more likely to experience their first lapse in the afternoon or evening rather than in the morning, say researchers from St George's Hospital Medical School, London.

This may be because plasma nicotine levels are reducing, but could also be attributed to fewer smoking restrictions in the evenings or a reduction in cortisol levels at this time, they add.

In a study of 200 smokers, supported by Cancer Research UK, 7 per cent of relapses occurred during the 12-hour period between midnight and noon, while 93 per cent occurred during the afternoon and evening. "Despite nicotine patches providing limited nicotine replacement for the first few hours after waking, there is no evidence that this undermines quit attempts by failing to prevent lapses during that time," the researchers say. They point out that the first lapse has been shown reliably to predict complete relapse to smoking and suggest that coping strategies should be focused on the time of day smokers feel most tempted to smoke, ie, afternoons and evenings.

Relapse rates Nearly half of smokers who manage to abstain from cigarettes for at least a year will begin to smoke again within

eight years, according to a report in the *BMJ*. An eight-year follow up of smokers who participated in a randomised controlled trial of the nicotine patch has shown that of the 153 participants who had stopped smoking for a year in the original trial, 83 were still not smoking, but just under half had relapsed (2003;327:28).

BRIEFLY

CD handwriting exemption checks

The Home Office has changed the telephone numbers that pharmacists should use when seeking confirmation that a prescriber has been granted a handwriting exemption for Controlled Drug prescriptions. The new numbers are 020 7217 8230, 8434 and 8713.

The Royal Pharmaceutical Society asks pharmacists to amend the telephone numbers given on p25 of the new edition of 'Medicines, ethics and practice: a guide for pharmacists' (*PJ*, 5 July, p30), which went to press before the change was announced.

New stroke warning for OTC products

OVER-THE-COUNTER cough and cold products containing sympathomimetics can increase risk of stroke, researchers say.

They identified 22 patients with strokes associated with cough and cold products containing sympathomimetics from a register at a neurological centre in Mexico. Sixteen had received phenylpropanolamine, four pseudoephedrine, and two nasal decongestants. Doses varied between patients with some taking recommended doses and others excessive doses. For phenylpropanolamine, doses went from 50mg to 675mg and for pseudoephedrine from 60mg to 300mg.

Previous research suggested that stroke is associated with use of higher doses of

sympathomimetics, particularly those used as appetite suppressants by women in America. This study suggests that an association exists between stroke and sympathomimetics in cough and cold preparations too.

The earlier data led to a reduction in the number of marketed products containing phenylpropanolamine in several countries. But the authors of the new research warn that an association also exists for other decongestants: "Although most [strokes] were related to phenylpropanolamine, stroke can also occur with the use of other sympathomimetics, particularly pseudoephedrine," they comment. "The relationship between stroke and pseudo-

ephedrine was evident in four patients in our series including two cases by the ingestion of recommended doses."

Their research showed that stroke occurred after a single dose in 17 patients and after longer use in the others. Onset of stroke symptoms occurred between 30 minutes and 24 hours after exposure to sympathomimetics. High blood pressure was present in 90 per cent of patients on admission to hospital. Persistent or uncontrolled hypertension was present in eight cases, including three patients who had taken a single dose of sympathomimetic.

The study is published in *Stroke* (2003;34:1667).

Thrombosis seen less frequently in cancer patients on dalteparin

THE low-molecular-weight heparin, dalteparin (Fragmin), is more effective than warfarin for preventing recurrent venous thromboembolism in patients with cancer, say researchers.

In a study of 672 cancer patients who had been diagnosed with a thrombotic event (deep vein thrombosis or pulmonary embolism), subsequent prophylaxis with dalteparin reduced the incidence of further thromboembolism by a half (27 of 336 patients treated with dalteparin, versus 53 of 336 patients treated with an oral anticoagulant). The reduced incidence of thromboembolism was achieved without an increased frequency of bleeding (*New England Journal of Medicine* 2003;349:146).

In an accompanying editorial, Dr Rodger Bick of the University of Texas Southwestern medical school, Dallas, says: "[The trial] provides clear evidence that low-molecular weight heparin should become the therapeutic and prophylactic agent of choice in cancer-associated thromboembolic disease." He adds that the cost of such therapy has been previously overestimated, pointing out that it is generally unnecessary to monitor its anticoagulant

effect. The reduced frequency of thrombosis also lowers the overall cost of medical care, he says (*ibid*, p109).

Study dispels fears over contraceptive pill use and stroke

NEW research has found no evidence to support an association between low-dose oral contraceptive use and ischaemic stroke.

Researchers from the National Stroke Research Institute of Australia identified 234 women with ischaemic stroke and compared their use of the oral contraceptive pill (OCP) with 234 controls. Current users of OCP at doses of 50µg of oestrogen or less were not at increased risk of stroke (odds ratio 1.76, 95 per cent confidence interval, 0.86 to 3.61, $P=0.124$).

Factors associated with an increased risk were hypertension, transient ischaemic attacks, previous myocardial infarctions, diabetes, a family history of stroke and smoking more than 20 cigarettes a day.

The researchers say they decided to re-examine the link between OCP and stroke because of changes in the formulation of oral contraceptives and to guidelines on their use. They point out that these products contain lower doses of oestrogen and progestogen than previously and that current recommendations restrict their use to women with no other risk factors for cardiovascular disease (*Stroke* 2003;34:1575).

Clue to how beta-blockers can work in heart failure

CARVEDILOL (Eucardic) seems to improve ventricular function in patients with heart failure, but only for those with ischaemia or whose heart muscle fails to contract despite being viable. Indeed, a positive response to carvedilol could be used as a test of myocardial ischaemic risk obviating the need for coronary revascularisation.

Professor John Cleland, Castle Hill Hospital, Hull, and colleagues compared the effects of carvedilol with those of placebo in patients with stable chronic heart failure due to ischaemic left-ventricular systolic dysfunction. They found that the improvement in myocardial function

induced by carvedilol was dependent on the volume of myocardium affected by ischaemia or hibernation. (Hibernation describes the state of heart muscle that is still viable but which fails to contract.) Little or no increase in ventricular function was recorded for patients who had no myocardial hibernation or ischaemia, whereas substantial increases were seen in patients affected by these syndromes.

The researchers suggest several ways in which carvedilol could improve function in hibernating myocardium. Slowing the heart rate might improve the efficiency of heart cells and enhance diastolic blood flow. This

could redistribute blood flow to areas of contractile dysfunction, they say (*Lancet* 2003;362:14).

In an accompanying commentary, Dr Henry Dargie, department of cardiology, Western Infirmary, Glasgow, says the implications of the trial are potentially significant because British patients are not routinely investigated for hibernation status (*ibid*, p2).

The trial, which has the acronym CHRISTMAS, was published alongside the COMET trial (*ibid*, p7), the main results of which were reported at the European Society of Cardiology heart failure meeting in Strasbourg last month (*P7*, 28 June, p882).

Which? questions NHS Direct advice

ADVICE from NHS Direct is inconsistent and sometimes dangerous, according to the consumer magazine *Which?* (July 2003, p10).

Furthermore, the level of service seems to be declining, with the advice being more likely to put patients at risk than when similar research was conducted by *Health Which?* in 2000. "It's clear the phonenumber isn't functioning as it should," says Nikki Ratcliff, author of the report.

However, the methods used by *Which?* have been described as flawed by the Department of Health. The DoH has also criticised *Which?* for not sharing details of the research to allow NHS Direct to learn from it.

"NHS Direct takes the quality of its service very seriously and is constantly seeking to improve its performance in all areas. However, as yet *Which?* have not shared their research with us," a DoH spokesman said.

The *Which?* researchers posed as patients with one of three health problems and made 33 calls to 11 NHS Direct regional call centres. The calls were recorded by *Which?* and the advice received was evaluated by a panel of three health professionals — a general practitioner and two nurses.

The panel identified several areas of concern — long waits, potential emergen-

cies being missed and a failure by NHS Direct staff to tailor questions appropriately.

On two occasions the researchers had to wait almost an hour for a nurse to call them back. More worryingly, on three occasions, the researchers did not receive a call-back at all.

One of the scenarios tested whether NHS Direct advisers could identify the risk of ectopic pregnancy. All but one adviser failed to stress this as a possible outcome. Many also missed the clues that suggested another researcher had unstable angina.

The researchers also found that advice given by NHS Direct Online and by the NHS Direct self-help guide was inconsistent. In addition, although easy to use, neither service allowed the researchers to explain their symptoms in full.

The DoH spokesman said the results needed to be interpreted with caution. "This small study of 33 calls to 11 NHS



Advice given by NHS Direct Online and by the NHS Direct self-help guide was inconsistent, says *Which?*

Direct centres cannot be relied upon to give a true picture of the advice given by NHS Direct," he said.

"We know through continual evaluation that NHS Direct has safely delivered health care advice and information to more than 18 million callers and on many occasions acted as a lifesaver. The service's excellent safety record has been highlighted many times through independent research, including evaluation by the National Audit Office," he added.

Call for NHS charges to be reviewed

A COALITION of medical and consumer organisations is calling for the system of charges made under the National Health Service, including prescription charges, to be reviewed.

Writing in *The Independent* on 8 July, the signatories to a letter say that the system has become incoherent, with creeping charges emerging. They note that while prescription charges have increased, the list of medical exemptions has not been updated since

1968. Systems designed to help those on low incomes are not working effectively either, they add. They call for a fundamental review of the system designed to answer the question: "What is the purpose of charges in a tax-funded NHS that is based on clinical need rather than the ability to pay?"

The 14 signatories to the letter include representatives of the British Medical Association, Help the Aged, the National Consumer Council and the Social Market Foundation.

PJ Online

PJ Online contains the editorial contents of *PJ* publications.

"Ask about medicines" week

A campaign to promote concordance.
www.pjonline.com/topics

Advice to patients

This series on commonly used drugs is intended as a reminder of points to be made by pharmacists as they hand out dispensed medicines.
www.pjonline.com/noticeboard/tips

Legal status of medicines

Up-to-date guidance on the legal status of thousands of human medicines is now available from a live searchable database on the Royal Pharmaceutical Society's website.
www.pjonline.com/mep

What's new

PJ Online is continually being updated. Details of recent changes can be found on the "What's new" page or via the "New on this site" link on the homepage.
www.pjonline.com/whatsnew

Communication

A two part series, giving an overview of how barriers can get in the way of good communication skills with patients, and how to improve them.
www.pjonline.com/noticeboard/series

Photocopies/reprints

The Society's library offers a photocopy service, for which there is a charge. Colour reprints are available from the *PJ* advertising department.
www.pjonline.com/about

BRIEFLY

Children's NSF consultation

The consultation period for "Emerging findings", a document setting out how the Children's National Service Framework will be developed, has been extended to 10 August. The report can be accessed via *PJ Online* (www.pjonline.com/links/pj).

Phoenix extends loans

Phoenix Medical Supplies is now offering a loan guarantee scheme nationally. Loans can be used to establish a pharmacy or to purchase, relocate or refurbish an existing business. A specialist finance business manager will prepare proposals for ratification by Phoenix and the customer's choice of bank.

New website for CPA

The Commonwealth Pharmaceutical Association has a new website at www.commonwealthpharmacy.org. The site includes general information about the CPA, details of CPA projects, current news, an announcement of its August conference in Jamaica (*PJ*, 21 June, p866) and a report of a recent meeting in Malta. There are also links to useful resources, including the *PJ Online* continuing professional development pages (www.pjonline.com/CPD).

The new site replaces the CPA webpages formerly hosted on the Royal Pharmaceutical Society's website (www.rpsgb.org.uk).

ETP decision is expected imminently

A DECISION on the way forward for electronic transmission of prescriptions (ETP) is expected within a few weeks.

The three ETP pilots ended on 30 June, a spokesman for the Department of Health told *The Journal*. The pilots were originally scheduled to finish at the end of 2002 but in January this year the DoH announced that they could continue for another six months. However, one pilot, run by the Flexiscript consortia, stopped in April (P7, 19 April, p535).

The DoH spokesman confirmed that a report evaluating the pilots is expected to be published within the next few weeks. He added: "The vision on ETP is still the same."

The evaluation is being carried out by the Sowerby Centre for Health Informatics at Newcastle and eHealth Horizons in collaboration with the Industrial Statistics Research Unit at the University of Newcastle, the University of Manchester School of Pharmacy and Pharmaceutical Sciences and QinetiQ.

The group submitted a report to the Department of Health in April this year. The full contents are not publicly available



Pharmacists should find ETP acceptable

but the report is known to confirm that ETP is technically viable and that key stakeholders (patients, pharmacists and general practitioners) are likely to find it acceptable.

However, Dr Julian Harrison, of the Pharmacy 2U consortium, said that he had serious concerns over the accuracy of the

report. Data had only been collected for a short space of time at the end of last year, but much of the prescription volume had occurred this year. Even the report itself had acknowledged this lack of data was a limitation, he added. "The report contains a lot of opinions and not much fact," he said.

Ewan Davis, chairman of Pharmed, part of the TransScript consortium, expressed similar concerns about the evaluation. However, he pointed out that health minister Rosie Winterton had recently written to the pilot consortia stating that the Government remained committed to the ETP targets. These are that ETP is 50 per cent implemented by the end of 2005 and fully implemented by the end of 2007. "Whatever the evaluation report says, we must be encouraged by this reiteration of the targets," said Mr Davis.

But he stressed: "We need a signed-off specification." Although Mr Davis believes the Government targets are ambitious, he says they can be met so long as the final specification is announced soon. "It's unhelpful to leave us in limbo."

Most endorsements do not change payments made

MOST endorsements made by pharmacists make no difference to the reimbursement they receive for a prescription. This is the conclusion of a new study from the Prescription Pricing Authority.

Researchers at the PPA analysed a sample of 1,031 items on 506 randomly selected prescription forms. For each, they examined what was written on the form by the prescriber and what was added by the dispensing contractor. They then assessed the extent that the added information was used in calculating payments.

A significant level of over-endorsing by contractors was found. A total of 2,440 pieces of information were added against the 1,031 items but only 14 per cent were used in reimbursement and remuneration calculations. "These findings suggest that in 86 per cent of cases recording and processing the additional information adds no value to the process," the PPA concludes.

The PPA report breaks down endorsements by category. It found that two-thirds of endorsements about pack size were unnecessary. Pack size was added in 74 per cent of cases but only 26 per cent of the items had more than one pack size available.

Addition of name, manufacturer and supplier is not necessary for generic items in part VIII of the Drug Tariff or for proprietary items. However, they were added in 46 and 43 per cent of items, respectively.

Endorsing product presentation, strength and quantity is only needed when they have not been specified by the prescriber. Only one or two items required this information to be added but it had been endorsed in roughly a third of cases.

The PPA researchers also conducted a second piece of research involving a much larger sample of prescriptions. They assessed the impact of additional information on calculating payments in 54,000

items that were either in part VIII of the Drug Tariff or were proprietary products. The difference in the total payments for these prescriptions when additional information was included or not was £977, which was just 0.17 per cent of the total cost.

The PPA concludes: "For the majority of prescriptions where proprietary items or generic items falling within Part VIII of the Drug Tariff are prescribed, dispensing endorsements do not significantly affect the reimbursement or remuneration price paid to the dispensing contractor."

However, the Pharmaceutical Services Negotiating Committee advised pharmacists not to stop endorsing but to ensure that prescriptions are only endorsed with necessary information. The PSNC and PPA will be preparing guidance for contractors on endorsing within the next few weeks.

The research is available at the PPA website (www.ppa.org.uk).

Rowlands joins CCA

ROWLANDS Pharmacy has become the latest multiple pharmacy group to join the Company Chemists' Association.

Rowlands is the fourth largest chain in the United Kingdom with over 300 pharmacies located predominantly in the north west of England. It is owned by Phoenix, the third largest national wholesaling group.

It joins existing CCA members: Asda, Boots The Chemists, Lloydspharmacy, Moss Pharmacy, Safeway, Superdrug, Sainsbury's and Tesco.

Little growth in OTC market in 2002

THERE was little overall growth in the non-prescription medicines market last year, according to figures from the Proprietary Association of Great Britain. However, in categories where medicines have been reclassified to general sales list status, sales did grow.

The PAGB says that in value terms the over-the-counter medicines market grew by 1 per cent to £1.76bn in 2002, compared with 2.4 per cent growth the year before. In

volume terms, growth was also low at 1.4 per cent, essentially the same rate as 2001.

Mike Owen, commercial director at the PAGB, said that the disappointingly low overall growth disguised a few important trends. Higher rates of growth had been seen in categories where products had been switched to GSL status — 5.8 per cent for hay fever remedies, 11.5 per cent for smoking cessation products and 20 per cent for medicated mouthwashes and sprays.

“Artificial intelligence” picks best AIDS therapy

“ARTIFICIAL intelligence” could be used to find effective treatments for HIV-infected patients whose drug therapy is failing, say researchers.

Dr Brendan Larder, RDI Ltd, described the system at a workshop on HIV drug resistance in Mexico recently. RDI Ltd is a not-for-profit company that is building databases of clinical data relating to HIV drug resistance in practice.

RDI has developed a “neural network” using data from 350 heavily treated patients to predict how well patients will respond to different combinations of drugs. The neural network “learns” as it analyses the relationships between HIV genotype, viral load and the patient’s previous response to drugs.

RDI chief executive Andrew Revell told *The Journal* that data from around 10 per cent of patients were available to test the neural network. In these patients, the model predicted viral load change with 79 per cent accuracy. “These are spectacular results,” he said. The model was then used to predict how patients would respond to different combinations of drugs when fed information from 139 failing patients. In every case, it identified an alternative drug combination that it predicted would be effective. On average, the alternatives were predicted to reduce the amount of virus in the patient’s

bloodstream by over 99 per cent. Based on its accuracy, had the system been used to select treatment, 110 out of 139 patients might have responded to treatment instead of failing. The company is now following up these patients to see what happens in practice.

Mr Revell commented that the tool was not yet developed fully enough to allow it to be in general clinical use. But he hoped that 20,000 patients would eventually be included in the database and that the neural network would be available free to predict the results of alternative HIV drug combinations in failing patients.

New cancer drug for relapsed myeloma

A NEW class of anticancer drugs has been shown to be active in patients with relapsed multiple myeloma refractory to conventional therapy.

Bortezomib is a boronic acid dipeptide. It acts as a selective and reversible inhibitor of proteasome, a multi-enzyme complex present in cells. Proteasome degrades proteins that regulate cell cycle progression.

A phase II, open label trial enrolled 202 patients with relapsed myeloma refractory to the therapy they had received most recently. Bortezomib was given as an intravenous bolus twice weekly for two weeks followed by one week without treatment for up to eight cycles (24 weeks). In patients with a sub-optimal response oral dexamethasone was added to the regimen.

Out of 193 patients who could be evaluated, there was a 35 per cent response rate to bortezomib. This included 19 patients in whom myeloma protein became undetectable or only minimally detectable.

The median overall survival was 16 months, with a median duration of response of 12 months. Adverse events included thrombocytopenia (in 28 per cent of patients), fatigue, peripheral neuropathy and neutropenia (*New England Journal of Medicine* 2003;348:2609).

An international, randomised, multi-centre phase III trial comparing the drug with high dose dexamethasone is ongoing.

Drugs for arthritic disease continue to show promise

A NOVEL cyclo-oxygenase-2 inhibitor and a human anti-TNF antibody could help improve arthritic disease, according to data presented at the annual meeting of the European League Against Rheumatism held in Lisbon last month.

Novartis reported data on lumiracoxib (Prexige), confirming its efficacy in osteoarthritis. Results from a 13-week study in patients with osteoarthritis of the knee showed that lumiracoxib was more effective in reducing pain intensity and improving functional status compared with placebo. It also showed the drug to be as effective as celecoxib after 13 weeks of treatment.

The conference also heard results of new research on adalimumab, a fully human

anti-TNF monoclonal antibody for the treatment of rheumatoid arthritis. Adalimumab has received regulatory approval in the United States. A European licence is expected in September 2003.

Manufacturer Abbott says the new data show that patients taking adalimumab (40mg every other week) in conjunction with methotrexate “can expect to enjoy one additional day of ‘perfect health’ for every 10 days of treatment compared to patients being treated with methotrexate alone”. This is equivalent to an additional 36 days a year. “Perfect health” was measured by a questionnaire reviewing a patient’s dexterity, emotional well-being, level of pain, speech, hearing and vision.

Earlier data from the studies, originally reported in 2001 (*Pf*, 30 June 2001, p873), showed sustained efficacy and reduction of disability for 24 months in over 70 per cent of patients with adalimumab and methotrexate.

Professor Paul Emery, department of rheumatology, Leeds University, said: “Traditional rheumatoid arthritis treatments may become less effective over time and patients may also experience problems with tolerability and side effects. Approximately 40 per cent of people stop work within five years of being diagnosed with RA, so the radiographic data presented for adalimumab are encouraging in terms of their implications [for improving] disability.”

BRIEFLY

Cocaine dependence vaccine

Xenova has reported results from phase II studies showing its vaccine, TA-CD, for cocaine dependence is safe and well tolerated with a dose-related immune response. Of 16 patients who used cocaine after vaccination, 14 reported a reduction of the usual euphoric effect associated with cocaine use.

Nanoparticles deliver hepatic drugs

JAPANESE researchers believe they have found a new way of delivering drugs to the liver. They used a protein — envelope “L” particle — from the hepatitis B virus. When this protein is produced in large quantities it produces nanoparticles. Genes or proteins can be put inside these particles using pulses of electric current.

The researchers transferred the gene encoding human clotting factor IX into the nanoparticles and injected the product into

mice transplanted with human liver tumours. The nanoparticles travelled to the human liver cells where the genes were released and expressed.

Shun-ichi Kuroda and colleagues from the research group say that the yeast-derived L particle is free of viral genomes, highly specific to human liver cells and able to accommodate drugs as well as genes. The study is published as an advance online publication in *Nature Biotechnology*.