

Pharmacists should support GPs, says new report

As a profession, pharmacists need to recognise the value of, and constructively support, general medical practice, according to a policy report from the School of Pharmacy, University of London, published this week.

“Even if [general practice’s] focus continues to shift more towards relatively intensive and complex care for the more seriously ill, this will not mean that community pharmacy could or should seek to replace the unique contributions of general medical practitioners,” says the report.

Defining the borderlines between community pharmacy care and general practice

provisions will be central to the success of the NHS, it adds.

The policy report, produced and published in partnership with Alliance Boots, offers recommendations as to what needs to be done to ensure that the vision for service improvement contained in the recent pharmacy White Paper (*PJ*, 12 April, p423) is translated into reality.

Its main finding is that remuneration and information systems need to be developed as rapidly as possible to encourage and facilitate joint working between GPs and community pharmacists, while also allowing for competition-led innovation where this will benefit

public health. Adapting the Quality and Outcomes Framework to provide shared payments or creating a separate pharmaceutical care QOF are suggested.

The report warns that establishing polyclinics, which it says restrict competition and choice as experienced by people using the NHS, is unlikely to deliver the public’s highest priority health needs.

“Commissioning for choice, quality and outcomes” is available on the School of Pharmacy website at www.pharmacy.ac.uk and via *PJ Online* (www.pjonline.com/pjlinks).

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Churchill tribute to pharmacist discovered

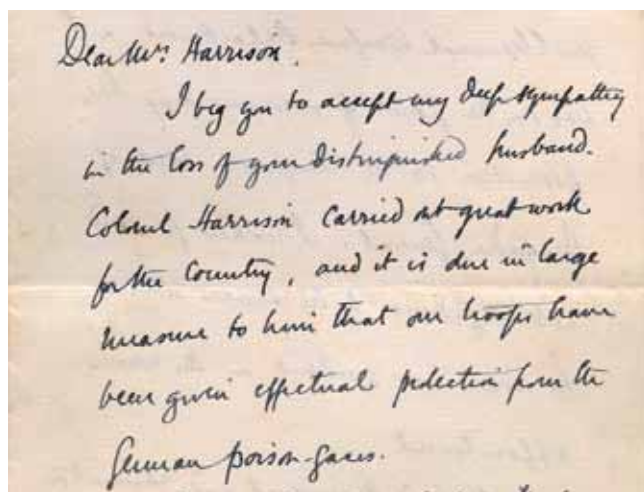
A letter from Winston Churchill paying tribute to the achievements of Edward Harrison, the pharmacist credited with inventing the gas mask that saved hundreds of thousands of soldiers’ lives in the 1914–18 war, has recently been discovered, it was disclosed this week.

The letter came to light during an archive search by the Royal Society of Chemistry’s media manager Brian Emsley. He was searching for material about Mr Harrison to include on a website to celebrate the forgotten heroes

of the war as part of the 90th anniversary events this November to mark its end.

Mr Emsley told *The Journal*: “I went to the Imperial War Museum and was given Harrison’s box from the archives, which was full of photos and letters of condolence, as well as medals and newspaper cuttings from *The Times* of 1918. Then I saw a hand-written letter with the name Winston Churchill at the bottom which I thought was of value. I asked the archivist if the museum was aware of the letter and he said ‘no’.”

The letter, signed by Churchill when he was minister of munitions, was written to Mr Harrison’s widow following her husband’s death, which occurred just a week before the end of the war. In it Churchill wrote: “It is due in large measure to him that our troops



The opening of Churchill’s letter to Mr Harrison’s widow

have been given effectual protection from the German poison gases.”

Mr Harrison had been working for the anti-gas department at the War Office and the letter said if he had not died he was going to be promoted to head of chemical warfare.

Mr Harrison died days before Armistice Day from influenza, although it is widely believed that his practice of testing the masks by wearing them in sealed gas-filled chambers contributed to his death.

A memorial plaque to Mr Harrison is on display outside the library at the Royal Pharmaceutical Society’s headquarters.

Every two years the Society awards the Harrison memorial medal to a pharmacist who has shown significant achievement in the science and practice of pharmacy.

Think tank criticises health minister’s polyclinics plan

Government plans for a network of polyclinics or super-surgeries in England — at the heart of the NHS review by health minister Lord Darzi — faced a setback last week following an analysis by the influential think tank the King’s Fund.

Its report urges the Government not to press ahead with one model of integrated care, and suggests that any future development of health services has to take into account the different needs and issues around access to services facing patients living in urban and rural communities.

It also highlights the workforce implications of moving clinics — and hospital consultants — out of secondary care and warns there may not be enough specialists to fulfil the plans.

The report, “Under one roof: Will polyclinics deliver integrated care?”, is based on an analysis of 93 GP premises built in England under the Government’s Local Improvement Finance Trust (LIFT) initiative, as well as looking at similar polyclinic models overseas.

Although the report says that any development of services should focus on new “care pathways” and more joint working across multi-professional teams, it fails to make any mention of the role community pharmacists could play in this new-look NHS.

Report co-author Candace Imison said: “There is a strong case for challenging the way we organise healthcare in England. For some health communities the development of polyclinic-type facilities could offer great opportunities to establish more integrated care that delivers real benefit to patients. But these benefits will only be realised if the focus is on changing the way we deliver care, not just changing where care is delivered.”

The King’s Fund report comes as the British Medical Association continues its campaign against polyclinics on the grounds that they will fragment general practice. Lord Darzi’s next report as part of his Next Stage review is due to be published at the end of June or beginning of July.

New system will measure PCT commissioning performance

The Government’s vision of world class commissioning in England came closer last week with the launch of an assurance system that will measure primary care trust commissioning performance in the key areas of health outcomes, competencies and governance.

It will also include an assessment of PCTs’ potential for improvement. It is a national system but is managed locally by strategic health authorities. There is an assurance toolkit to help implementation. The toolkit and a handbook are available at www.dh.gov.uk.

Pharmacists found to make poor ethical decisions

Community pharmacists have been found wanting when it comes to making ethical decisions at work, according to research published last week in the *Journal of Medical Ethics* (2008;34:441).

Some of the 23 pharmacists involved in the study revealed they relied on their religious beliefs, experience and common sense when faced with ethical issues and they nearly all admitted that their professional code of ethics and their training had little influence on the decisions they reached.

Their top priority when faced with an ethical dilemma in the pharmacy was whether or not it meant they were at risk of being disciplined or prosecuted — the interests of patients were not always important to them, the study found.

The pharmacists were ethically “inactive” even in cases where action by another health professional — such as a GP prescribing for a patient a medicine that could cause a dangerous interaction — and a case of a nurse known to have an alcohol problem went unreported, the researchers discovered.

The researchers say: “Pharmacists admitted that they should have done something but did nothing and, furthermore, often recognised that their inaction might have perpetrated the problem and even could have resulted in harm.” This “ethical passivity” meant there was a real need for the ethical education and training of pharmacists to be reviewed.

They add: “The emergence of ethical passivity presents a formidable challenge for pharmacists and the pharmacy profession, raising questions about how ethics and values can be effectively taught, communicated and applied in pharmacy practice.”

The study, carried out by the universities of Sheffield and Nottingham, was based on interviews with a sample of community pharmacists working in two counties in northern

England. Their responses were measured against a four-stage decision making model which considered ethical attention, reasoning, intention and action.

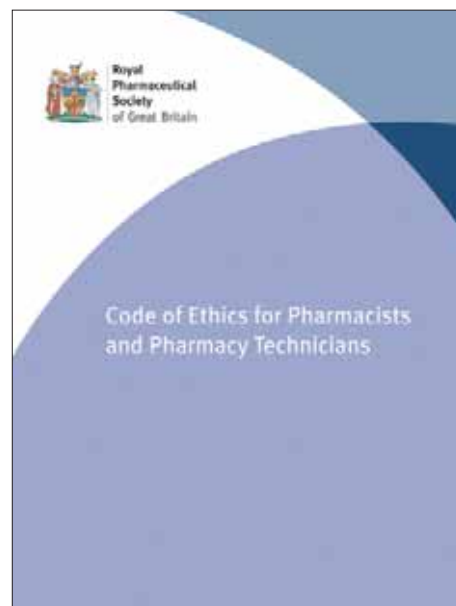
Commenting on the research findings, professor of pharmacy law and ethics at the University of Nottingham and a co-author of the study Joy Wingfield said: “I think it’s true that most practising pharmacists actually do think of the law first . . . which is self-protection I suppose.

“Pharmacists do tend to be cautious and rule-bound rather than supportive of patients and a lot of them rely on common sense.”

But if you question them closely about how they reach their decision they are often unable to justify it, she said.

The findings of the research confirmed her view that the profession is inadequately trained in the complexities of ethics and the law, which will become increasingly more important as pharmacists’ clinical responsibilities increase.

“As a profession we tend to focus on the criminal law and the Medicines Act,” she said.



Code of Ethics and training have little effect on pharmacists’ ethical decisions, study suggests

Study raises more questions than it answers, says the Society

David Pruce, the Royal Pharmaceutical Society’s director of practice and quality improvement, said: “This is an interesting study which raises more questions than it answers. It is not surprising that pharmacists tend to base their decisions on their professional experience and ‘common sense’ rather than consulting the Code of Ethics and this is probably true of all healthcare professionals.”

He explained that the code was revised in 2007 and changed from what he described as “rule book” to a more principle-based code. Its effect will increase when it becomes more established in undergraduate and preregistration training and education, he believes. He added: “The study suggests that pharmacists look to the legal framework as one of their key reference points. Pharmacists are by nature conscientious and medicines are highly regulated, so it is not surprising that one of their main concerns is not to do something wrong.

“As pharmacists develop a greater clinical role, the number of ‘grey areas’ not covered by the legal framework naturally increases. It will be important that pharmacists develop a greater understanding of the principles underlying ethical decision making as they develop their clinical role.”

School of Pharmacy and FIP join in global project to develop pharmacy

A school of pharmacy is hoping to become a global leader in the development of pharmacy and its influence on public health in a unique partnership with the International Pharmaceutical Federation (FIP).

The School of Pharmacy, University of London, and FIP have established the FIP Collaborating Centre for Pharmacy and Health (FIPCC) with the aim of building links with international health organisations such as the World Health Organization and UNESCO.

The FIPCC will support research into pharmacy and public health as well as provide policy analysis and encourage international collaboration and innovation in pharmacy so that it will become known as an international centre for pharmacy excellence and expertise.

The centre is jointly chaired by David Taylor, professor of pharmaceutical and public health policy at the school, and Ian Bates, head of education development at the school.

FIP is a federation of international pharmaceutical associations and represents the interests of more than one million pharmacists and scientists worldwide.

Unison and RCN vote to accept three-year pay deal for NHS staff

Health union Unison and the Royal College of Nursing have both voted to accept a three-year pay deal from the Department of Health with an overall increase of almost 8 per cent (*PJ*, 12 April, p424) for NHS workers. Unison is the largest health union, representing around 470,000 staff, whereas the RCN represents around 400,000 nurses.

Health union Unite, whose members include NHS-employed pharmacists who are members of the Guild of Healthcare Pharmacists, represents approximately 77,000 healthcare workers. Unite has balloted its members with advice to reject the pay deal. The results of the ballot were due shortly after *The Journal* went to press. Several other health unions (eg, those representing physiotherapists, hospital engineers and construction workers, and ambulance drivers) have already rejected the deal.

The NHS Staff Council will consider the opinions of all health unions before making its final decision on whether to implement the pay deal. Their decision is expected to be announced after the council meets on 1 July.

MTX melanoma risk

Patients with rheumatoid arthritis (RA) who are treated with methotrexate are at increased risk of melanoma and other malignancies, a new review of data suggests.

Researchers in Australia identified 87 malignancies among 459 RA patients who had been treated with methotrexate.

Compared with their healthy peers, the patients were found to have an estimated 50 per cent excess risk of developing cancer in any form. The risk of non-Hodgkin's lymphoma was more than five times higher in the RA patients than in the general population. RA patients also had a three-fold increased risk of melanoma and almost a three-fold increased risk of lung cancer (*Arthritis Care & Research* 2008;59:794).

The researchers point out that the increased risk levels for non-Hodgkin's lymphoma and lung cancer are in line with findings from related studies in Europe and the US but add: "This study is, to our knowledge, the first to report an increased risk of melanoma in patients with RA treated with methotrexate compared with the general population."

The researchers observed a 2.5-fold increased cancer risk for methotrexate-treated RA patients exposed to cyclophosphamide, but no increased risk with exposure to azathioprine.

They suggest that further investigation is needed to determine whether the risk is unique to Australia and what role methotrexate, immunosuppression and environmental factors, such as exposure to UV radiation, play in its development.

Avoid contaminated Clexane for pregnant women, says MHRA

Batches of Clexane (enoxaparin sodium; Sanofi-Aventis) contaminated with small amounts of over-sulphated chondroitin sulphate (OSCS) should not be used for pregnant women, the Medicines and Healthcare products Regulatory Agency advised last week.

The MHRA says that, although there is no evidence of any specific risks to women who are pregnant, or to the developing fetus, use of affected Clexane should be avoided on a purely precautionary basis.

Sanofi-Aventis has announced that uncontaminated 40mg syringes are now available — the strength most commonly prescribed for use during pregnancy. Clexane 40mg syringes

with the batch numbers 04329, 04351, 04352 and 14326 are free of the contaminant. The company is asking pharmacists to check that Clexane dispensed to pregnant patients is not contaminated.

Pharmacists unable to obtain stock from these batches from their usual supplier are advised to contact Sanofi-Aventis (tel 0800 854430), which will arrange a direct delivery for individual patient use.

□ **EMA review** The European Medicines Agency (EMA), as part of its review of the risks associated with OSCS contamination of heparin products, has looked at what long-term approaches could be adopted to minimise the possibility of future contamination. The EMA's Committee for Medicinal Products for Human Use (CHMP) has recommended that European Pharmacopoeia monographs for heparins be updated to include tests for detecting OSCS.

The EMA also stated last week: "The CHMP was of the opinion that it is necessary to operate in a co-ordinated way within the EU to address all issues relating to the contamination. This includes any investigation into the origin of the contamination and any inspection of factories where heparins are made."

The CHMP believes that an international dialogue should be started with China to strengthen supervision of manufacture.

Notice-board p713

Background

At the end of April, the MHRA issued a warning that certain batches of Clexane syringes contained low levels of the contaminant OSCS (*PJ*, 3 May, p529).

The MHRA recommended that, since the risk associated with the contamination was minimal, the affected batches should continue to be supplied to avoid a shortage of low molecular weight heparins. The MHRA subsequently advised against the use of parallel-imported packs of Clexane because some batches supplied to overseas markets were contaminated with higher levels of OSCS (*PJ*, 17 May, p588).

GI ulceration with nicorandil highlighted in latest *Drug Safety Update*

Risk of gastrointestinal ulceration with nicorandil (Ikorel) is highlighted in this month's issue of *Drug Safety Update*, published by the Medicines and Healthcare products Regulatory Agency.

Healthcare professionals should consider nicorandil treatment as a possible cause in patients who present with symptoms of gastrointestinal ulceration, including perianal ulceration, it advises.

Although mouth ulceration has long been recognised as a side effect of nicorandil, ulceration in any region of the gastrointestinal tract has more recently been associated with its use, it says.

The bulletin highlights that ulceration is often severe and refractory to treatment; withdrawing nicorandil is the only way to resolve the problem. However, withdrawal should take place only under the supervision of a cardiologist, it adds.

The bulletin also draws attention to the need to monitor for progressive multifocal leukoencephalopathy (PML) and impaired liver function in patients taking natalizumab



Gastrointestinal ulceration is a risk with nicorandil therapy

(Tysabri) for multiple sclerosis. It advises that if patients develop PML or severe liver injury, natalizumab should be permanently discontinued. Patients treated with natalizumab should be given an alert card, which provides information about the symptoms of PML.

The bulletin also advises that immunocompromised patients, those receiving beta-interferon or glatiramer, and those with known active malignant disease (except cuta-

neous basal-cell carcinoma) should not be prescribed natalizumab. If patients experience hypersensitivity reactions, treatment with natalizumab should not be resumed if there are still antibodies present after six weeks.

It is estimated that at least 1,000 patients in the UK are currently taking natalizumab. There have been 18 reports of adverse drug reactions received by the MHRA since its launch in July 2006, one of which was fatal.

NHS Scotland has access to seven more medicines

Dabigatran etexilate (Pradaxa) has been accepted for use within NHS Scotland for the primary prevention of venous thromboembolic events. The latest round of appraisals by the Scottish Medicines Consortium sees it accept seven medicines and reject eight (see Panel).

Dabigatran can be used in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

The SMC also accepted perindopril arginine (Coversyl Arginine) 2.5mg, 5mg and 10mg tablets for the treatment of essential hypertension. In addition, the 2.5mg and 5mg tablets are accepted for the treatment of symptomatic heart failure. Perindopril arginine/indapamide tablets (Coversyl Arginine Plus) are accepted for the treatment of essential hypertension in patients whose blood pressure is not adequately controlled on perindopril alone.

Adults with chronic plaque psoriasis who have failed to respond to, have a contraindication to or are intolerant to, other systemic therapy, can now be treated with adalimumab

(Humira) within NHS Scotland after it was approved.

Another drug accepted by the SMC was nilotinib (Tasigna) for restricted use for the treatment of chronic phase Philadelphia chromosome positive chronic myelogenous leukaemia. The drug should be restricted to patients resistant to or intolerant of at least one prior therapy, including imatinib.

Epoetin zeta (Retacrit) was accepted for treatment of anaemia associated with chronic

renal failure in adult and paediatric patients on haemodialysis and adult patients on peritoneal dialysis, and for the treatment of severe anaemia of renal origin accompanied by clinical symptoms in adult patients with renal insufficiency not yet undergoing dialysis.

Finally, *Clostridium botulinum* neurotoxin type A (Xeomin) was accepted for the symptomatic management of blepharospasm and cervical dystonia of a predominantly rotational form (spasmodic torticollis) in adults.

Eight medicines have been rejected by the SMC

Three medicines were rejected by the SMC because the manufacturers did not present a sufficiently robust economic analysis: anidulafungin (Ecalta) was rejected for the treatment of invasive candidiasis in adult non-neutropenic patients; bevacizumab (Avastin) was rejected in combination with fluoropyrimidine-based chemotherapy for treatment of patients with metastatic carcinoma of the colon or rectum; and glucosamine (Alateris) for relief of symptoms in mild to moderate osteoarthritis of the knee.

A further five medicines were rejected because the manufacturers did not make a submission to the SMC: lidocaine 70mg/tetracaine 70mg (Rapydan 70mg/70mg medicated plaster); loteprednol etabonate 5mg/ml (Lotemax 0.5 per cent eye drops, suspension); bosentan 62.5mg, 125mg film-coated tablets (Tracleer); panitumumab 20mg/ml concentrate for solution for infusion (Vectibix); and teriparatide 20µg/80µl solution for injection, in prefilled pen (Forsteo). Details of the specific indications for which these drugs were rejected are available on the SMC website (www.scottishmedicines.org.uk).

Scottish contract announcement expected

Community pharmacists in Scotland can expect to hear the details of this year's remuneration package, including an announcement on new services, at the end of June.

Alex MacKinnon, head of corporate affairs, CPS, told *The Journal* this week that CPS hopes the Scottish Government will make an announcement on pharmacy services in the very near future.

"We hope to be in a position to provide details of the remuneration settlement for 2008–09 soon," he said.

Community Pharmacy Scotland has been lobbying for extensions to the public health service, in particular calling for national smoking cessation and emergency hormonal contraception services (*PJ*, 24 May, p613).

CPS supports drugs strategy

Community Pharmacy Scotland pledged this week to help develop pharmacy services that will support the Scottish Government's new national drugs strategy that focuses on recovery from addiction (*PJ*, 7 June, p683).

CPS head of corporate affairs, Alex MacKinnon, said: "While there is a significant emphasis currently on substitute prescribing and the ethos of harm reduction, [there has been] a lack of key services to allow a problem drug user to recover and move towards a drug-free life."

Mr MacKinnon said CPS will work with the Scottish Government to explore pharmacists' roles in future services for drug users. "Moving from an approach that has been biased towards harm reduction to a focus that is firmly based on recovery could mean considerable changes to the pattern of services and in Government's expectation of what service providers will be expected to deliver," he said.

Dispensing consultation end

Pharmacists wishing to comment on whether professional guidelines should be changed to allow removal of medicines from blister or foil packs ahead of dispensing and the dispensing of out-of-date or returned medicines in the case of an influenza pandemic should make their views known by 20 June.

Details of the consultations are available on the world of pharmacy section of the Royal Pharmaceutical Society's website (www.rpsgb.org/worldofpharmacy) by clicking on "Consultations."

Pfizer Award for 2008



This year's Pfizer Award, recognising achievement among preregistration trainee pharmacists in Scotland, was won by David Chartres, preregistration trainee at Ninewells Hospital in Dundee. Mr Chartres audited the treatment of community-acquired pneumonia. He received his award certificate from John Cromarty, chairman of the NHS Scotland Directors of Pharmacy, and Paul Stein of Pfizer UK.

Access to *PJ Online* is free to all

Agenda

This series, which started in 2002, is intended to make the profession think about its future. Recent articles consider achieving integrated care by 2020 and providing medicines information to the public.
www.pjonline.com/agenda

Hospital Pharmacist

The June issue of *Hospital Pharmacist* is now online. The Life-long Learning questions concern psoriatic arthritis and a specialist pharmacist in rheumatology talks about his role. There is a report from the Guild of Healthcare Pharmacists/UK Clinical Pharmacy Association meeting and an article on developing accredited checking technicians in technical services. The June issue of *Guild Matters* is also available.
www.pjonline.com/hp

Debate rumbles on over intensive glycaemic control

No definitive answer to the therapeutic problem of glycaemic control in patients with type 2 diabetes at high risk of cardiovascular events has been provided by the results of two recently completed multicentre clinical trials, according to the author of an editorial published this week in *The New England Journal of Medicine* (2008;358:2633).

The ACCORD and ADVANCE trials, published in the same issue (*ibid*, p2545 and p2560, respectively), both show that intensively targeting blood glucose levels to near-normal in adults with type 2 diabetes at high cardiovascular risk has no effect on reducing the risk of major cardiovascular events. Furthermore, the ACCORD trial identified an association between intensive glucose lowering in such patients and increased mortality, compared with standard treatment — a trend previously unrecognised and not observed in the ADVANCE study. In February this year, the National Heart, Lung, and Blood Institute of the National Institutes of Health in the US



Sergey Lavrentev/Dreamstime.com

Intensive targeting of blood glucose levels did not lower cardiovascular risk

stopped the intensive glucose lowering treatment arm of the ACCORD study early due to safety concerns (*PJ*, 23 February, p208).

In the editorial, William Cefalu, of the Pennington Biomedical Research Centre, Louisiana State University System, Baton Rouge, suggests that a target HbA_{1c} level of

approximately 7 per cent may be appropriate in this high-risk population, especially when the use of aggressive pharmacological therapy is under consideration.

The authors of a second editorial (*ibid*, p2630), Robert Dluhy and Graham McMahon, *NEJM* editors, add that neither trial should be interpreted as diminishing the importance of glycaemic control and that the lower than expected rate of cardiovascular events seen in the intensive and standard treatment groups in these studies is an affirmation of the success of modern therapeutics. They add that if hypoglycaemia was a contributing cause of death in the ACCORD trial, future studies of cardiovascular risk reduction should focus on targeting near-normal glycaemic levels with the use of strategies and therapies associated with a lower risk of hypoglycaemia.

Dr Dluhy and Dr McMahon also say that clinicians should continue to emphasise the benefits of lifestyle and dietary modification.

ACCORD design and outcomes

In the ACCORD trial, 10,251 patients (mean age 62.2 years) from 77 clinical centres across the US and Canada were randomly assigned to receive either comprehensive intensive therapy, targeting a HbA_{1c} level of less than 6 per cent, or standard therapy, targeting a level of 7 to 7.9 per cent. Stable median glycated haemoglobin levels of 6.4 per cent and 7.5 per cent were achieved at one year in the two groups, respectively. After a mean of 3.5 years, 257 people in the intensive strategy group had died, compared with 203 participants in the standard strategy group — a 22 per cent increase in mortality. The intensive group had 41 more cardiovascular deaths than the standard group — a 35 per cent higher cardiovascular death rate. There was no significant reduction in major cardiovascular events.

ADVANCE design and outcomes

The ADVANCE trial involved 11,140 patients (from 215 collaborating centres in 20 countries from Asia, Australasia, Europe and North America) randomly assigned to a treatment strategy of intensive glucose control (modified release gliclazide and other drugs, as required, that lowered the HbA_{1c} value to 6.5 per cent) or standard glucose control.

It showed that those who underwent intensive glucose control yielded a 10 per cent relative reduction in the combined outcome of major macrovascular and microvascular events, primarily as a consequence of a 21 per cent relative reduction in nephropathy.

The researchers say that there was no evidence that this strategy increased mortality.

Glitazone may delay retinopathy

Rosiglitazone may delay the onset of proliferative diabetic retinopathy, say researchers (*Archives of Ophthalmology* 2008;126:793). It may also be associated with less loss of visual acuity. Lucy Shen, of the Jules Stein Eye Institute, University of California, Los Angeles, and colleagues reviewed the medical records of 124 patients with non-proliferative diabetic retinopathy treated with rosiglitazone and compared them with those for 158 matched controls who were not taking rosiglitazone or another glitazone drug.

At the start of the study, severe non-proliferative diabetic retinopathy was affecting 14 eyes in the rosiglitazone group and 24 eyes in the control group. After three years, 19.2 per cent in the rosiglitazone group and 47.4 per cent in the control group had progressed from non-proliferative to proliferative diabetic retinopathy — a 59.5 per cent relative risk reduction for those treated with rosiglitazone. In addition, fewer eyes in the rosiglitazone group experienced a visual acuity loss of three or more lines.

The researchers say that rosiglitazone may delay the progression of retinopathy and preserve vision by reducing the formation of new blood vessels. However, they conclude that because their study “does not rigorously prove that rosiglitazone either reduces the incidence of proliferative diabetic retinopathy or prevents loss of visual acuity, and because there may be adverse effects from therapy, rosiglitazone treatment of patients with diabetes specifically to reduce these ophthalmic complications is not advocated at this time”.

Sirolimus linked to diabetes risk

Sirolimus is associated with an increased risk of new-onset diabetes in kidney transplant patients, researchers report. Using data from the US renal data system, researchers evaluated the association between sirolimus use at the time of transplantation and new-onset diabetes among 20,124 adult recipients of a first kidney transplant. They found that, compared with patients treated with ciclosporin and either mycophenolate mofetil or azathioprine, sirolimus-treated patients were at increased risk for new-onset diabetes, whether it was used in combination with ciclosporin, tacrolimus, mycophenolate mofetil or azathioprine.

Similar results were obtained in a multivariate subgroup analysis of 16,861 patients known to be treated with the same immunosuppressive regimen throughout the first post-transplantation year and this, the researchers say, confirmed that sirolimus was independently associated with new-onset diabetes. They comment that new-onset diabetes is an increasingly common post-transplantation complication and is associated with transplant failure. Possible mechanisms for this, they suggest, include impaired insulin-mediated suppression of hepatic glucose production, insulin resistance from ectopic triglyceride deposition or direct beta cell toxicity. They add: “Given the importance of new-onset diabetes as a determinant of post-transplantation outcomes and the current use of sirolimus in both pancreas and islet cell transplantation, the findings of our study should be confirmed in further studies.”

The study is due to be published in the July issue of the *Journal of the American Society of Nephrology*.

Tailor care plan according to disease's impact on patients' day-to-day lives, says COPD expert

Community pharmacists should place greater emphasis on the impact of chronic obstructive pulmonary disease (COPD) on patients' every-day lives when tailoring care, according to an expert in the condition.

Anna Murphy, chairman of the United Kingdom Clinical Pharmacy Association respiratory group and consultant respiratory pharmacist at University of Leicester Hospitals NHS Trust, said: "It is important for community pharmacists to appreciate and take charge of the influence they have with COPD patients. Medicines use reviews for people with COPD offer the ideal opportunity for the pharmacist to have the conversation about the impact of their disease on everyday activities; a jointly agreed action could be another way of ensuring this is considered by [the patient's] GP or nurse."

Ms Murphy's comments follow publication of an AstraZeneca-sponsored report "Unleash the life within: a patient's perspective of living with chronic obstructive pulmonary disease", which highlights results from a survey of 326 people with COPD conducted in April 2008. Questionnaires were handed out by community pharmacists to patients collecting medicines for treating COPD.

The survey reveals that respondents used a wide range of medicines to relieve their symptoms and control their disease. However, 24 per cent thought their symptoms were getting worse, and 21 per cent reported that their COPD was not well controlled.

Most patients were regularly reviewed (85 per cent had their COPD reviewed by a doctor or nurse during the previous 12 months) but while most healthcare professionals asked about clinical symptoms, only 32 per cent of people were asked about the effect of their COPD on their day-to-day lives.

"The results of this survey come at a crucial time," Ms Murphy continued. "COPD is moving up the health agenda and with the National Service Framework for COPD [due to be published by 2009] we will see a new future in the management of COPD.

"By drawing attention to the shortfalls of current care — as well as its strengths — we hope that this report will focus attention on the goals of treatment which matter most to people with COPD, so that the most effective strategies can be devised for achieving them," she added.

Plans to tackle inequalities should maximise pharmacy contribution

Plans to tackle health inequalities should maximise the contribution that pharmacists and their teams can make, the Royal Pharmaceutical Society has said in response to Government proposals on the issue.

"The location of community pharmacies provides extended opportunities for community involvement and leadership via school and workplace initiatives," said David Pruce,

the Society's director of practice and quality improvement.

The Society intends to consider carefully the detail of the report, "Health inequalities: progress and next steps", which sets out the Government's approach to tackling health inequalities.

In the report, the Government calls on primary care trusts to commission services

based on need, not historical patterns of spend, and to work with pharmacists as well as GPs, dentists and optometrists to ensure that primary care services reflect the needs of people in relatively disadvantaged groups. It also wants more providers to implement the principles set out in "You're Welcome quality criteria: Making health services young people friendly", published in March 2007.

Swiss move for Alliance Boots

Alliance Boots has moved the headquarters of the group holding company from Gibraltar to Switzerland. The company says that the move will "enhance the position of Alliance Boots as a leading international pharmacy-led health and beauty group alongside a number of the world's leading pharmaceutical manufacturers".

The news comes in the same week that the company published its 2007-08 annual review and consolidated financial statements, which can be accessed at www.allianceboots.com. The results included information about pharmacy services and indicate that the number of medicines use reviews carried out by Alliance Boots pharmacists has more than doubled, and that the company's like-for-like dispensing volume is up 3.9 per cent.

Duke visits London pharmacy



The Duke of Edinburgh visited Boss Pharmacy in Clapham, London, earlier this month where he heard about the delivery of community pharmacy services, including those commissioned by the local primary care trust.

Dilip Joshi, a prescribing pharmacist and former chairman of the National Pharmacy Association, demonstrated the IT link between the pharmacy and local doctors and explained his role in the management of asthma patients.

The picture shows Mr Joshi (right) introducing the duke to the pharmacy staff.

New stoma appliance provision proposals

Revised proposals on the arrangements for provision of stoma and urology appliances — and related services — in primary care, under Part IX of the Drug Tariff, have been published by the Department of Health.

The latest proposals form part of the department's ongoing review of the arrangements. The Department last consulted on proposals in September 2007.

The consultation document can be accessed online via the DoH website (www.dh.gov.uk) and PJ Online (www.pjonline.com/pjlinks). The deadline for responses is 8 September.

Advertising breach

A pharmacy group in the Midlands has been judged to be in breach of advertising regulations following a complaint that its website was advertising an unlicensed homoeopathic injection as an anticancer treatment. Murrays Healthcare has agreed to remove all references to Abnobaviscum from its website.

Funding for champions

Funding for community pharmacy practitioner champions in Scotland will continue during 2008–09, the Scottish Government has announced. The pharmacy champion's role, which remains unchanged with the new funding, is to support pharmacists to implement the new community pharmacy contract.

Oxygen supplies

The current shortage of DD oxygen cylinders (integral head portable cylinders) is expected to start improving in June. Interim arrangements are described in an NHS Scotland circular published this week.

Antispasmodic launched for overactive bladder syndrome

Patients with overactive bladder syndrome could benefit from a new urinary antispasmodic — fesoterodine fumarate — now available from Pfizer.

Marketed as Toviaz, the medicine is indicated for the treatment of symptoms that can occur in patients with overactive bladder syndrome (ie, increased urinary frequency, urgency or urgency incontinence). The recommended starting dose is 4mg once a day, increased to 8mg once a day based on individual response.

Part of fesoterodine's metabolism occurs via cytochrome P450 isoenzymes CYP2D6 and CYP3A4. Pfizer advises caution when prescribing fesoterodine with inhibitors of these enzymes and recommends that inducers

of CYP3A4 should not be co-administered. Patients with renal impairment or hepatic impairment are at a higher risk of toxicity when taking fesoterodine, particularly when treatment is combined with a CYP3A4 inhibitor.

The summary of product characteristics for Toviaz sets out when the fesoterodine dose should be modified and when the medicine is contraindicated, depending on the degree of a patient's kidney or liver dysfunction or the kind of CYP3A4 inhibitor co-administered.

In line with its antimuscarinic action, the most common side effect of fesoterodine is dry mouth (occurring in 28.8 per cent of patients in clinical studies).

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Incontinence product first for Boots Centre for Innovation

A device designed to control urinary stress incontinence has been launched by the Boots Centre for Innovation.

IncoStress, the first product to be launched by the centre, controls incontinence by pro-

viding support to the bladder and applying gentle pressure to the urethra.

Since it opened last year, the Swansea-based centre has received over 400 product ideas from inventors.

Avoid antioxidant supplements during chemo- and radiotherapy

Use of supplemental antioxidants during chemotherapy and radiotherapy should be avoided until they are shown to be safe, according to the authors of a commentary published in the *Journal of the National Cancer Institute* (2008;100:773). The combined treatment approach should be discouraged because of the possibility of tumour protection and reduced survival, they say.

The authors, from the US, reviewed data from published randomised clinical studies addressing the putative benefits and potential risks of antioxidant supplementation concurrent with cytotoxic therapy. They say that, despite two decades of research on the matter, data remain insufficient to provide a clear guide for clinical practice.

Several randomised clinical trials have shown that concurrent administration of antioxidants reduces treatment-related side effects. However, some data indicate that antioxidants may protect tumour cells as well as healthy cells from the oxidative damage generated by radiation therapy and some chemotherapeutic agents, the authors say.

Limited data regarding the mechanisms of action of dietary antioxidants suggest that, at high doses, some of these compounds may enhance the effects of some cytotoxic regimens or decrease their toxicity, or both, without reducing oncological efficacy.

However, the authors also found that data from a limited number of randomised controlled trials of antioxidants and radiation therapy show that high-dose antioxidant sup-



Antioxidant supplements may not be safe during cancer treatment

plementation during radiotherapy decreases local tumour control and shortens the survival of cancer patients. They say that although the potential for harm during radiotherapy may be limited to a few antioxidants, uncertainty about what doses and which compounds are clearly safe suggests that high doses of any antioxidant should be avoided unless clear evidence is available that the benefits outweigh the potential risk.

The authors comment that they have serious concerns about the potential for harm with adjunctive antioxidant treatments in cancer patients and that continuing research is warranted.

Mobile telephones help cancer patients manage side effects

Teenagers with cancer are using mobile telephones to monitor the side effects of their chemotherapy treatment at home in an initiative that may be rolled out across the UK.

The young people, aged 13 to 18 years, can send details of any side effects via the phone to a central server at their hospital that is managed by specialist cancer nurses who can interpret the information.

The nurses can text the young person back with advice if necessary and, if the symptoms become severe, the technology allows a nurse to be paged to contact the young person at home.

The specially adapted phones, used by 40 young patients from the Royal Marsden and University College hospitals in London, also contain patient information about common side effects that the teenagers can access.

So far, the phones have been made available to teenagers with lymphoma, soft tissue sarcoma and bone tumours. Researchers hope they could, at a later date, be offered to young people with leukaemia as well.

Details of the project were given this week at the fifth international conference on teenage and young adult cancer medicine in London organised by the Teenage Cancer Trust charity. The charity, which has funded the initiative with support from another charity CLIC Sargent, announced that the phones are now being used by another 150 young people at centres across the UK with the hope that the project will be rolled out across the UK in future.

Cyclophosphamide could have role in multiple sclerosis therapy

Treatment with cyclophosphamide, without bone marrow transplantation, appears to reduce disease activity and disability in patients with aggressive relapsing-remitting multiple sclerosis.

In an open-label trial, nine patients received cyclophosphamide intravenously (50mg/kg/day) for four consecutive days, followed by granulocyte colony-stimulating factor filgrastim (5µg/kg/day) six days after completion of treatment with cyclophosphamide until their absolute neutrophil count exceeded 1.0×10^9 cells/L for two consecutive days. They were followed up for a mean period of 23 months.

The researchers found that the patients experienced an average 39.4 per cent reduction in disability and an 87 per cent improvement in scores on a composite test measuring physical and mental function. A decrease in the average number of MS-related brain lesions from 6.5 to 1.2 lesions was seen. They say that treatment with high-dose cyclophosphamide was safe and well tolerated and did not lead to excess morbidity or accelerated brain atrophy.

The researchers conclude: "This immunosuppressive regimen of cyclophosphamide for patients with aggressive MS is worthy of further study and may be an alternative to bone marrow transplantation."

The study is published online in *Archives of Neurology* (9 June 2008, <http://archneur.ama-assn.org>).

MHRA publishes its plans to tighten rules on reporting safety data from clinical trials

Proposals to amend UK legislation to state explicitly that marketing authorisation holders should report safety information from clinical trials outside the licensed indication and information arising from third countries, and to provide a timescale for reporting such information, have been put forward by the Medicines and Healthcare products Regulatory Agency.

The proposals follow an MHRA investigation into GlaxoSmithKline and Seroxat (*PJ*, 15 March, p302). The consultation closes on 15 August.

Aliskiren provides renoprotective effect

Aliskiren appears to have a renoprotective effect independent of its blood pressure lowering effect in patients with type 2 diabetes and nephropathy who are receiving losartan (at the maximum recommended renoprotective dose) and optimal antihypertensive therapy (*New England Journal of Medicine* 2008;358:2433). In a study of 599 people, treatment with aliskiren, 150mg daily for three months then 300mg daily for three months, reduced albuminuria compared with placebo ($P < 0.001$). A 50 per cent reduction in albuminuria was seen twice as often in the aliskiren as in the placebo group ($P < 0.001$).