

10 TIPS FOR

Controlling your prescribing spend

Dr John Hughes explains how practices can reduce the cost of medicines without any adverse impact on patient care

In these days of financial stringency, and with increasing pressure on practices from CCGs, one of the most important ways to stay within budget is to analyse practice prescribing. With care and attention, it is possible to make significant savings without adversely affecting patient care.

One benefit of reducing the volume of prescriptions is creating time for other, potentially more important, activities in the practice. Reducing prescribing costs does not necessarily have to excessively burden the GP partners – there are opportunities to work with community pharmacy colleagues and also for sessional GPs to do some of the audits and reviews.

Reducing the cost of prescriptions may also help keep within your CCG's budget and even achieve incentive payments where they have been agreed with the CCG. In some CCGs, including two in my area, GPs receive payments on the condition that money is reinvested in patient care and not used for practice profits. Check you agree with the ethics of local incentive schemes before signing up, and if in doubt consult your LMC.

Identify your own high-spend areas

1 First, establish where the high-spend areas are by looking at your ePACT data. This will identify your top 10 spends and also help clarify individual prescribing patterns (though this can be skewed by locum prescribing). A practice meeting – or even better a peer review meeting with neighbouring practices – can identify areas for attention.

Reduce waste

2 Medicines Use Reviews can be carried out either in the practice or by the community pharmacy. In the pharmacy, patients are sometimes more honest about which medicines they have stopped because of side-effects. Similarly the New Medicine Service component of the pharmacy contract can

identify problems with new medications prescribed by the GP or hospital which are not being tolerated and allow them to either be discontinued or changed.

Get CCG help for high-spend areas

3 Some high-cost areas cause problems because GPs lack knowledge of specific items and their indications. These might include catheters, stoma appliances, dressings and sip feeds and the issues can be addressed with the help of the CCG. In my area we have transferred most catheter prescribing to the community continence service and are in the process of doing the same with stoma supplies. These moves have both resulted in significant savings.

Cut back on diabetes test strips

4 First, look at those patients who are stable on treatment – they do not usually need to be testing their sugars several times a day. Second, liaise with your local diabetes specialist nurses or clinic to agree a small number of glucometer brands that should be used. Often drug company reps will provide clinics with free glucometers to hand out, but often these take very expensive test strips and lancet devices.

Target dispersible prescriptions

5 Substantial savings can be made by reviewing the prescribing of dispersible medications and restricting their use to patients who actually have a diagnosed swallowing difficulty. These products are often considerably more expensive than their regular equivalents.

Look for 'specials'

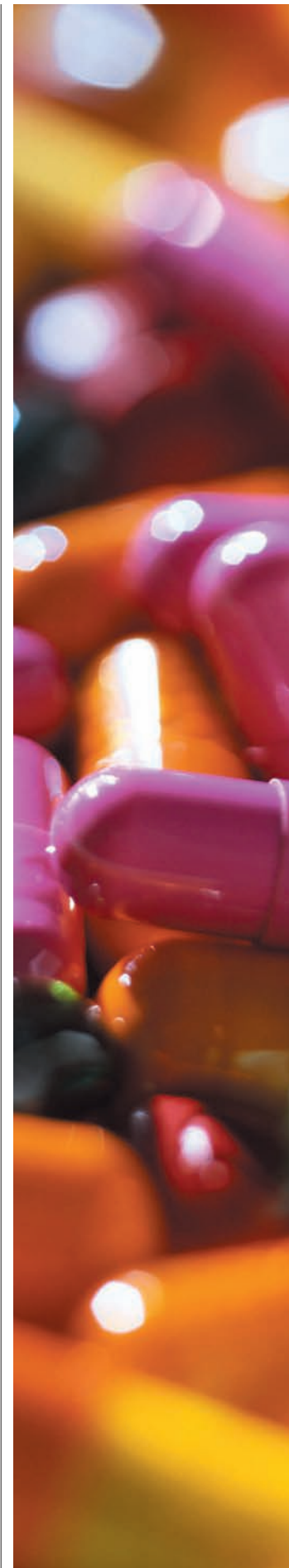
6 'Specials' – generally unlicensed liquid preparations of regular medications – show up on your prescribing screen as zero indicative cost. But nothing could be further from the truth, as 100ml can cost anything

1 CPD HOUR

Go online to complete this article as a CPD module for a suggested 1 credit. This module will be available free to all members of Pulse Learning until 1 February pulse-learning.co.uk



Prescribing CPD
 ● How we reduced prescribing errors
1 CPD HOUR
 ● How we reduced vitamin D spend
1 CPD HOUR
pulse-learning.co.uk





from £300 upwards. There are obviously patients such as infants with heart failure where such preparations are the only option. But often patients have been prescribed them unnecessarily by hospitals when an alternative such as oro-dispersible or crushed medication is more appropriate.

Commit to a formulary

7 Development of a local or practice formulary to reduce use of expensive medications when cheaper alternatives are available can result in substantial cost reductions, though this requires the co-operation of all parties involved. Beware the rogue prescriber in your midst.

Help develop a policy for hospital prescriptions

8 Develop a policy across the CCG or even larger areas to classify medications recommended by secondary care into:

- 'green' – can be prescribed without restriction by GPs
- 'amber' – may be prescribed by GPs under shared care protocols and may require a LES (for instance, drugs such as goserelin or depot antipsychotics)
- 'red' – must be prescribed and provided by secondary care – (drugs such as HIV antiretrovirals and epoetin).

Such a scheme reduces the flow of expensive preparations onto the GP prescribing budget. Again the support of CCG medicines management staff is vital to ensure a robust policy is developed and to deal with the constant attempts by secondary care to slip expensive medications under the radar and onto the GP's prescribing budget.

Beware expensive generics

9 Use of generics has been a prescribing target in many areas for several years now. Generic prescribing can result in significant cost reductions, but must be carefully monitored, as some generics are now more expensive than their branded alternatives. Your clinical system drug database should indicate this.

Tighten local policy on over-the-counter medicines

10 Cutting costs by avoiding prescribing medications that are available OTC is controversial.

It may be unsuccessful in low-income areas, where patients will simply not buy the required medication if they cannot get it free on prescription. However, it is worth examining use of prescriptions for Calpol, painkillers and emollients to see if a tighter policy can be developed. This may be tied in to the minor ailments scheme in areas where this is available, reducing prescribing costs and consultation overload.

Dr John Hughes is the secretary of Manchester LMC and is a GP in the city

FINANCE DIARY: JANUARY

Get ahead now for next year's tax return



Many GPs prefer not to think about their tax bill, but putting it off can increase costs. **Bob Senior** offers tips on how to lessen the pain

Few GPs welcome paying their January tax, but wise GPs send their information to their accountants months before the deadline. They know how much they owe and have set aside enough money.

Sadly not all GPs do this. An accountant might advise: 'Given your income you need to save x% of everything you receive for tax'. This instruction might be misinterpreted. The GP might save x% of monthly drawings, but not of their QOF or end-of-year payments. A year on, their tax funds will be lacking.

Some GPs give their accountants all they need as soon as they can after the end of the tax year. Others leave it as late as they possibly can and are left scrabbling around at this time of year to provide the relevant information.

Peculiarly enough, these GPs often say afterwards: 'It really doesn't take very long once you get started.' While a GP who is slow to provide information may put their accountant under pressure to meet the 31 January tax return deadline,

in reality the main person affected will be the GP. It is they who will face an unwelcome tax bill without much notice.

However, there are also ramifications for the whole partnership if one partner is late sending expenses information. This holds up completion of the partnership tax return, which can delay the finalisation of all the partners' tax returns. Those well-organised partners who got their information in on time are likely to be justifiably irritated.

So how can a practice encourage a partner to sort out their affairs in a timely manner? Here are two examples of methods I have seen work.

One client requires partners to get professional expenses information to me by 30 June. In July, all the partners go out for dinner. If everyone has sent in their information, the bill is paid by the practice (disallowed for tax purposes, of course). If a partner has not sent in their information, the bill is passed to them.

The other method was more drastic.



Finance diary
Read Bob's columns on enhanced service funding, tax liability and private pensions
pulsetoday.co.uk/financediary

A GP client who normally has a blind spot about expenses excelled one year and got his information in on time. He had broken his leg and was on sick leave. Looking for diversion, he sorted out his paperwork. Predictably, he returned to his bad habits the following year.

Accountants take pride in filing tax returns on time and will pull out all the stops to make the deadline, even if the information does not come in until the last week in January. But their nerves will be worn to a frazzle; they will probably be paying overtime. The extra costs and aggravation will undoubtedly be reflected in their bills.

As the drive for cost efficiencies continues in 2013, GPs can avoid unnecessary charges by organising their tax paperwork in plenty of time.

Bob Senior is chair of the Association of Independent Specialist Medical Accountants and the head of medical services at RSM Tenon



Editor's choice
From the latest practice business and working life articles online



Practice accounts

A simple summary of how to make sense of your surgery's finances
pulsetoday.co.uk/read-accounts



Safer data

Lawyers Chris Alderson and Edwina Farrell provide a five-step guide
pulsetoday.co.uk/safer-data



CCG constitutions

1 CPD HOUR Dr Chaand Nagpaul answers your latest questions on practice-CCG agreements
pulsetoday.co.uk/CCG-FAQ



Last-minute QOF

Dr Simon Clay provides ten tips ahead of the March deadline
pulsetoday.co.uk/lastminute-QOF



Assessing profits

Accountant Michael Ogilvie offers a quick guide
pulsetoday.co.uk/check-profits



Expedition GP

Dr Jenny Corser explains how she came to work in expedition medicine
pulsetoday.co.uk/expedition-GP

ALAMY X3, ANDY LANE, JULIAN CLAXTON

Prescribing Information

Macrobid® (Nitrofurantoin MR Capsules)

MacroDantin® (Nitrofurantoin Capsules)

Presentation: Macrobid capsules are supplied as modified release hard gelatin capsules containing 100mg nitrofurantoin in macrocrystalline and monohydrate forms. MacroDantin capsules are supplied as hard gelatin capsules containing 50mg or 100mg nitrofurantoin in macrocrystalline form. **Indications:** Treatment and prophylaxis against acute or recurrent, uncomplicated lower urinary tract infections (UTI) or pyelitis either spontaneous or following surgical procedures. Nitrofurantoin is specifically indicated for the treatment of infections due to susceptible strains of *Escherichia coli*, *Enterococcus sp.*, *Staphylococcus sp.*, *Citrobacter sp.*, *Klebsiella sp.*, and *Enterobacter sp.* Macrobid is not indicated for treatment of associated renal cortical or peri-nephric abscesses. **Dosage and Administration:** For oral administration taken with food or milk. **Macrobid capsules. Adults and children over 12 years of age:** Acute or recurrent uncomplicated UTI and pyelitis – 100mg twice daily for 7 days. Surgical prophylaxis – 100mg twice daily on the day of the procedure and 3 days thereafter. **Elderly:** unless significant renal impairment exists, dosage as for adults (See *Warnings and Precautions*). **Children under 12 years:** Macrobid is not suitable for children under 12 years of age. **MacroDantin capsules. Adults:** Acute uncomplicated UTI: 50mg four times daily for 7 days. Prophylaxis: 50mg four times daily for the duration of the procedure, and for 3 days after. In addition MacroDantin can also be used for severe chronic recurrence (UTIs): 100mg four times daily for seven days and long term suppression: 50-100mg once a day. **Elderly:** unless significant renal impairment exists, dosage as for adults (See *Warnings and Precautions*). **Children and infants over 3 months of age:** Acute urinary tract infections: 3mg/kg/day in four divided doses for seven days. Suppressive – 1mg/kg, once a day. For children less than 25kg body weight consideration should be given to the use of the suspension. **Contraindications:** Known hypersensitivity to Nitrofurantoin or other nitrofurans, or ingredients of Macrobid/MacroDantin capsules. Patients with renal dysfunction, G6PD deficiency, acute porphyria, pregnancy at term (including labour and delivery) and in infants under 3 months of age. **Warnings and Special Precautions:** Use with caution in patients with pulmonary (lung) disease, hepatic (liver) dysfunction, neurological disorders, peripheral neuropathy, anaemia, diabetes mellitus, those with vitamin B or folate deficiency, electrolyte imbalance and allergic diathesis. May cause haemolysis in patients with deficiency of glucose-6-phosphate dehydrogenase. Patients on long term treatment should be monitored for appearance of hepatic or pulmonary symptoms and other evidence of toxicity. Taking the drug with food or milk or adjustment of dosage minimises GI reactions. Urine may be coloured yellow or brown, may cause false positive for urinary glucose. Discontinue treatment if otherwise unexplained pulmonary, hepatotoxic, haematological or neurological syndromes occur. Contains lactose. **Pregnancy and Lactation:** Contraindicated in pregnancy at term (including labour and delivery). Nitrofurantoin is detected in trace amounts in breast milk. Should be avoided if breast feeding infants suspected to have G6PD deficiency. **Interactions:** Concurrent use with quinolones, magnesium trisilicate, uricosuric drugs such as probenecid and sulphapyrazone, carbonic anhydrase inhibitors, urine alkalinising agents, oestrogen, oestrogen containing contraceptives and oral typhoid vaccine is not recommended. Increased absorption with food or agents delaying gastric emptying. **Adverse Effects:** Nausea, anorexia, emesis, abdominal pain and diarrhoea have been reported. Less common and rare are those events that affect the respiratory system. Acute pulmonary reactions occur in first week of treatment and are reversible with cessation of therapy. Sub-acute and chronic reactions (collapse, cyanosis, fever, chills, cough and dyspnoea) can occur with continuous treatment for six months or more. Hepatic (reactions including cholestatic jaundice, and chronic active hepatitis which may lead to hepatic necrosis occur rarely). Fatalities have been reported. Neurological (peripheral neuropathy and optic neuritis infrequently), Haematological (anaemia's, G6PD deficiency and other rarely reported events such as leucopenia, agranulocytosis, granulocytopenia and thrombocytopenia resolve with cessation of therapy). Allergic reactions including rashes eczematous eruptions and pruritus. Angioneurotic oedema, anaphylaxis, Lupus-like syndrome, sialadenitis, pancreatitis. Transient alopecia and benign intracranial hypertension have been reported. Superinfections by fungi or pseudomonas may occur. Please refer to Summary of Product Characteristics for detailed information. **Legal Category:** POM. **Basic NHS Price:** Macrobid: £4.89 per pack of 14 capsules. MacroDantin: £2.49 per 30-capsules pack of 50mg, £4.81 per 30-capsules pack of 100mg. **Marketing Authorisation Number:** Macrobid 100mg PL 12762/0052. MacroDantin 50mg PL 12762/0048, MacroDantin 100mg PL 12762/0049. **Marketing Authorisation Holder:** Mercury Pharma Group, NLA Tower, 12-16 Addiscombe Road, Croydon, Surrey, CR0 0XT, UK. **Date of Revision:** April 2012.

References:

1. Bean DC *et al.* Antimicrobial resistance in community and nosocomial *Escherichia coli* urinary tract isolates London 2005-2006. *Annals of Clinical Microbiology* 2008;7:13.
2. Brumfitt W and Hamilton-Miller JMT. Efficacy and safety profile of long term Nitrofurantoin in urinary infections: 18 years experience. *Journal of Antimicrobial Chemotherapy* 1998;42:363-371.

Adverse events should be reported to the local regulatory authority. Reporting forms and information can be found at <http://yellowcard.mhra.gov.uk>. Adverse events should also be reported to Mercury Pharma Medical Information at 08700 70 30 33 or via e-mail to medicalinformation@mercurypharma.com

Visit www.managinguti.com for more information.



MercuryPharma

You know when you've made the right choice for your patient

You've chosen a treatment that is minimally compromised by resistance¹ and with a macrocrystalline formulation that's better tolerated than generic Nitrofurantoin²

TWICE DAILY
MacroBID®
Nitrofurantoin Modified Release

MacroDantin®
Nitrofurantoin Capsules

DERMAL
50
1963-2013

Like Jack, Dermol can also do two things at once!

Dermol knocks out *Staph*
and soothes itchy eczema



Dermol® A family of antimicrobial emollients

WASH SHOWER LOTION CREAM BATH

The Dermol family of antimicrobial emollients - for patients of all ages who suffer from dry and itchy skin conditions such as atopic eczema/dermatitis.

- Specially formulated to be effective and acceptable on sensitive eczema skin
- Significant antimicrobial activity against MRSA and FRSA (fusidic acid-resistant *Staphylococcus aureus*)¹
- Over 15 million packs used by patients²

www.dermal.co.uk

Dermol® Wash, Dermol® 200 Shower Emollient and Dermol® 500 Lotion Benzalkonium chloride 0.1%, chlorhexidine dihydrochloride 0.1%, liquid paraffin 2.5%, isopropyl myristate 2.5%.

Dermol® Cream Benzalkonium chloride 0.1%, chlorhexidine dihydrochloride 0.1%, liquid paraffin 10%, isopropyl myristate 10%.

Uses: Antimicrobial emollients for the management of dry and pruritic skin conditions, especially eczema and dermatitis, and for use as soap substitutes. **Directions:** Adults, children and the elderly: Apply direct to the skin or use as soap substitutes.

Dermol® 600 Bath Emollient Benzalkonium chloride 0.5%, liquid paraffin 25%, isopropyl myristate 25%.

Uses: Antimicrobial bath emollient for the management of dry, scaly and/or pruritic skin conditions, especially eczema and dermatitis. **Directions:** Adults, children and the elderly: Add to a bath of warm water. Soak and pat dry.

Contra-indications, warnings, side-effects etc: Please refer to SPC for full details before prescribing. Do not use if sensitive to any of the ingredients. In the unlikely event of a reaction stop treatment. Keep away from the eyes. Take care not to slip in the bath or shower. **Package quantities, NHS prices and MA numbers:** Dermol Wash: 200ml pump dispenser £3.55, PL00173/0407. Dermol 200 Shower Emollient: 200ml shower pack £3.55, PL00173/0156. Dermol 500 Lotion: 500ml pump dispenser £6.04, PL00173/0051. Dermol Cream: 100g tube £2.86, 500g pump dispenser £6.63, PL00173/0171. Dermol 600 Bath Emollient: 600ml bottle £7.55, PL00173/0155.

Legal category: [P] **MA holder:** Dermal Laboratories, Tatmore Place, Gosmore, Hitchin, Herts, SG4 7QR. **Date of preparation:**

February 2012. 'Dermol' is a registered trademark.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Dermal.

References:

1. Gallagher J. *et al*. Poster presented at EADV Congress 2009.
2. Dermol Range – Total Unit Sales since launch. Dermal Laboratories Ltd. Data on file.

 **DERMAL™**
TOPICAL INNOVATION

DILEMMA

Family conflict over end-of-life care

Three experts advise a GP caught between family members with opposing wishes

An elderly patient who has had a severe stroke is bedbound and unable to communicate. He is being looked after by both his son and daughter, but there is a lot of conflict between them. The patient has now developed severe anaemia and weight loss.

You discuss with the family members whether the patient should be subjected to investigations for these problems. But the son and daughter have diametrically opposed views. He wants 'everything possible done' while she insists that her father should be left alone and kept comfortable.

What should you do?

Professor Mayur Lakhani
Communicate directly with the family and explore the conflict



The scenario indicates a gentleman who is at the end of life from a probable gastrointestinal malignancy. That being the case, the best strategy is palliative care to allow a dignified death at home.

The scenario implies a lack of mental capacity. However this should be formally confirmed. If capacity is present the patient's wishes are paramount. If not, the GP should determine if there is a lasting power of attorney. The GP is the key decision-maker in clinical matters.

The GP should communicate empathetically but directly with the family and avoid euphemisms. For example: 'I am sorry your father is very ill. It is possible that he could die. We need to consider what to do next.' Explain clearly the futility of further investigation and treatment.

Explore the conflict by asking the son directly: 'It helps us to understand why you want these tests and treatment, can you tell us your reasons?' Often a plea for active treatment is a sign of distress in coping with the situation or an unrealistic expectation of medical intervention.

Confident leadership from the GP is essential here. Good GPs provide care even without a definite diagnosis, and can exercise best-interests care for the patient even if family conflict persists.

A discussion with a consultant may back up your strategy.

Professor Mayur Lakhani is chair of the National Council for Palliative Care and a GP in Loughborough, Leicestershire

Dr Peter Nightingale

This patient needs a best-interests decision made for him

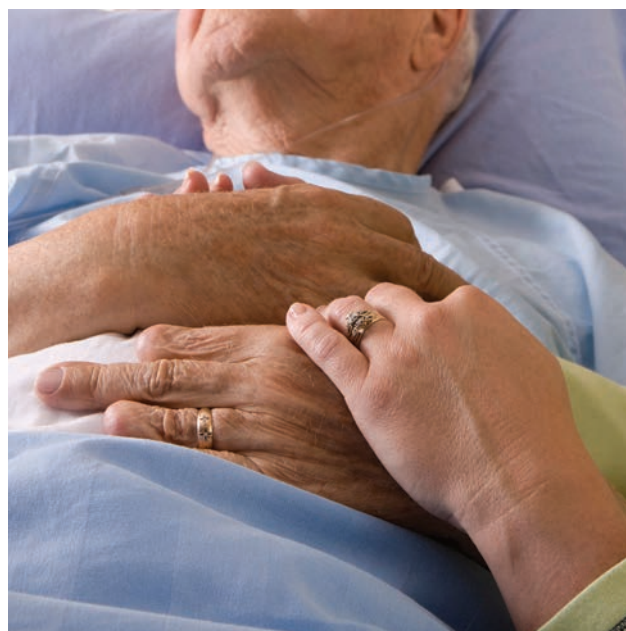


This situation highlights the benefits of advance care planning, because if the wishes of the elderly patient were known at a time when he had capacity, this difficult situation could be solved more easily.

In the ideal situation, he would have appointed a lasting power of attorney with responsibility for health and welfare. Failing that, an advance decision to refuse treatment, properly presented, would guide decision-making. Least powerful, but still useful, would be a preferred priorities of care document.

As this patient cannot communicate, he needs the best-interests decisions to be made for him.

The Mental Capacity Act requires you to consider the person's expressed wishes



GPs have no obligation to offer futile tests or treatments



New this month: Dilemmas

- Should we switch to 15-minute appointments?
- Is renting a room to a complementary practitioner a good move?

pulsetoday.co.uk/dilemmas

and feelings, beliefs and values, and to take into account the views of others who have an interest in the person's welfare – their carers and those appointed to act on their behalf.

Hopefully by discussing the situation with all involved, an agreed decision can be made in the patient's best interests. Doctors have no obligation to offer futile treatments or investigations, but if there is still conflict I would also contact the Office of the Public Guardian. It is always wise to seek another opinion from an experienced medical colleague. *Dr Peter Nightingale is a GP in Lancaster with a special interest in palliative care*

Andrew Alonzi

If the patient lacks capacity to consent, the GP can make the decision about investigations



You need to determine whether the patient has the capacity to consent. This is essential where any kind of physical intervention is

being proposed and is done via the two-stage test for assessing capacity under the Mental Capacity Act 2005 (England and Wales). The patient lacks capacity to consent to the investigation if he is 'suffering from an impairment of, or disturbance in, the functioning of the mind or brain' which causes him to be unable to:

- understand information relevant to the particular decision being made
- retain that information
- use it to make the decision, or
- communicate that decision by any means (the functional test).

Lack of consent is sufficiently proved if the patient is assessed as being unable to do any one of these four things.

Assuming the patient lacks capacity to consent, and there is no limitation to the GP's ability to make a best interests decision on the patient's behalf (such as lasting power of attorney for health and welfare in favour of the patient's son or daughter), the GP as decision-maker will work out whether or not an investigation is in his best interests.

Andrew Alonzi is a Mental Capacity Act training consultant

HOW DO THEY DO IT?



JON ENOCH

Professor Clare Gerada

The RCGP chair explains how she juggles her college role with clinical work, in the first in Pulse's new series on GPs' working lives

As chair of council of the RCGP, I haven't got a typical working day, though I do try and divide up the week, with Tuesdays, Wednesdays, Thursdays and evenings spent on college business.

On Tuesday, for example, I had a meeting at the King's Fund, then a session filming with the BBC's *Panorama* for a programme about abortion. Then I had to give a keynote speech to the GP Foundation (part of the RCGP) and attend a lunch at the House of Commons promoting better continence care. The afternoon included a meeting with health minister Dan Poulter. In the evening I went to dinner with the Faculty of Medical Leadership and Management.

Clinical work as a GP

I top and tail the week with clinical work for the Hurley Group – the group of practices in south London of which I am a partner – on Mondays, Fridays and Saturdays. I try not to interrupt that. It's incredibly difficult but I have become very disciplined about it. In some clinical sessions I see patients who attend the surgery at short notice (many of whom do not have English as a first language). I also see patients with substance misuse problems and sick doctors, for whom I provide continuity of care via the Practitioner Health Programme. I have been seeing some of them for 20 years. I am also chairing an integrated care pilot.

Tips for success

- Get the basics right – home, relationships and family. I am married with two sons, both of whom are now

grown-ups, and I feel it is really important to have support in moments when it's really tough. Don't beat yourself up about family. Invest in as much good childcare as you can. As long as you provide the right kind of home, the fact you're not always there will matter more for you than for them.

- Be organised – I have fantastic secretarial support. People don't believe me when I say that sometimes I have no time to send a text, but it is true. I get 1,000 emails a day so I can't personally read them all. I try to have half a day off at the weekend but it is an honour to be chair of council and I owe it to the members to be available. I don't have a cut-off time for stopping work in the evening, but I do now switch my phone to silent during the night.

- Set the rules – the sick doctors and drug misusers I see through the Practitioner Health Programme can contact me directly by text because that is much easier, but I set the rules, and they do not abuse this way of contacting me.

What keeps me going

I have never had an entirely normal working life because I have always done several roles at once – for example, I used to run a clinic for homeless drug users when I was a GP registrar.

The RCGP is inclusive, and has had inspiring leaders. Leadership is frightening. Every morning when I listen to the news I think 'Is this something that's going to affect GPs, and am I going to need to respond?' But my role is immensely enjoyable.



I get 1,000 emails a day – I have fantastic secretarial support

CV: Professor Clare Gerada

- Qualified in medicine at University College London, in 1982.
- Trained in psychiatry and worked at the Maudsley Hospital, south London, specialising in substance misuse.
- Qualified as a GP in 1992. Became a partner at the Hurley Clinic, a practice on the ground floor of a 19-storey housing estate in Lambeth in south London.

- Awarded an MBE for services to medicine and substance misuse in June 2000.
- Established the RCGP's Certificate in the Management of Drug Misuse in 2001. Sat as chair of the RCGP ethics committee and council vice chair before being voted in as chair in November 2010. She is the college's first female chair for 50 years.



New this month
Go online to see new Working Life articles on:
● Working with the homeless
● Cruise ship medicine
● Medicolegal advice
pulsetoday.co.uk/working-life

Around-the-clock COPD symptom control, making a real difference to patients' lives^{1,2}



- Comparable efficacy to traditional LAMA treatment with twice daily dosing^{3-5†}
- Sustained bronchodilation from day 1¹
- Improves patients' breathlessness and health status^{**}(vs. control)¹
- Simple and easy-to-use device^{3,5-7}
- 15% annual cost saving vs. tiotropium^{7††}

* Based on the cost of 1 Spiriva[®] HandiHaler[®] vs. Eklira[®] Genuair[®] initiation at month 1

† Network meta-analysis and phase III study evaluation of acclidinium vs. tiotropium

** Measured by St George's Respiratory Questionnaire

†† Assumes use of 1 Spiriva[®] HandiHaler[®] and 11 refills in 1 year or 12 EKLIRA GENUAIR packs in 1 year

Eklira[®] Genuair[®] ▼
322 micrograms inhalation powder acclidinium bromide

Active Ingredient: Each delivered dose contains 375 µg acclidinium bromide equivalent to 322 µg of acclidinium. Each metered dose contains 12.6 mg lactose monohydrate. **Indication:** As a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and Administration:** The recommended dose is one inhalation of 322 µg acclidinium twice daily. Consult SmPC and package leaflet for method of administration. **Contraindications, Warnings, etc:** Contraindications: Hypersensitivity to acclidinium bromide, atropine or its derivatives, including ipratropium, oxitropium or tiotropium, or to the excipient lactose monohydrate. **Precautions:** Should not be used to treat asthma or for relief of acute episodes of bronchospasm, i.e. rescue therapy. May cause paradoxical bronchospasm. Re-evaluation of the treatment regimen should be conducted if there is a change in COPD intensity. Use with caution in patients with a myocardial infarction during the previous 6 months, unstable angina, newly diagnosed arrhythmia within the previous 3

months, or hospitalisation within the previous 12 months for heart failure functional classes III and IV as per the "New York Heart Association". Consistent with its anticholinergic activity, dry mouth has been observed and may in the long term be associated with dental caries. Also, use with caution in patients with symptomatic prostatic hyperplasia or bladder-neck obstruction or with narrow-angle glaucoma. Patients with rare hereditary problems of galactose intolerance, Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine. **Interactions:** Although co-administration with other anticholinergic-containing medicinal products is not recommended and has not been studied; no clinical evidence of interactions when taking the therapeutic dose has been observed. **Pregnancy and lactation:** Acclidinium bromide should only be used during pregnancy if the expected benefits outweigh the potential risks. It is unknown whether acclidinium bromide and/or its metabolites are excreted in human milk. The benefit for the breast-feeding child and long-term

benefit of therapy for the mother should be considered when making a decision whether to discontinue therapy. **Ability to drive and use machines:** The effects on the ability to drive and use machines are negligible. The occurrence of headache or blurred vision may influence the ability to drive or use machinery. **Adverse Effects: Common:** sinusitis, nasopharyngitis, headache, cough, diarrhoea. **Consult SmPC in relation to other side-effects.** **Legal Category:** POM **Marketing Authorisation Number(s):** EU/1/12/778/002 – Carton containing 1 inhaler with 60 unit doses. **NHS Cost:** £28.60 (excluding VAT) **Marketing Authorisation Holder:** Almirall S.A. General Mitre, 151 08022 Barcelona Spain. **Further information is available from:** Almirall Limited, 1 The Square, Stockley Park, Uxbridge, Middlesex UB11 1TD, UK. Tel: (0) 207 160 2500. Fax: (0) 208 7563 888. Email: almirall@professionalinformation.co.uk

Date of Revision: 09/2012 **Item code:** UKACL1352 Eklira and Genuair are both registered trademarks.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall Ltd.