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BriefingMedia

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DH alarm over pharmacy drugs access scheme

Chief pharmacist intervenes over plans to allow pharmacists to dispense 16 POMs without GP prescriptions

EXCLUSIVE
 By Emma Wilkinson

The Department of Health has requested talks with pharmacy leaders after they gave the green light for the national roll-out of a scheme giving patients access to a wide range of medicines without a prescription.

The National Pharmacy Association (NPA) scheme will be offered to 12,500 pharmacies and would see patients given access to 16 medicines without a prescription, including salbutamol inhalers, trimethoprim and sildenafil.

The DH said it wanted pharmacists to consider if the inclusion of antibiotics was 'absolutely necessary' amid fears it could put strategies to combat increasing antimicrobial resistance 'at risk'.

The GPC also raised grave concerns about the scheme, which will allow pharmacists to dispense prescription-only medicines under a patient

EDITORIAL

Leave prescribing to the experts 17

group direction (PGD).

The NPA scheme has been piloted by the Day Lewis Pharmacy chain since October, but will be offered to all 12,500 NPA members from January.

Before signing up to the scheme, pharmacists have to obtain additional training online.

Patients will be able to obtain medicines after completing an online medical questionnaire and having a face-to-face consultation with the pharmacist or using a walk-in service.

The NPA says there have been



Salbutamol inhalers and some antibiotics are among the medicines to be included in the scheme

Drugs in the PGD

- Atovaquone/proguanil
- Azithromycin
- Calcipotriol
- Ciprofloxacin
- Doxycycline
- Hyoscine hydrobromide
- Mefloquine
- Salbutamol
- Sildenafil
- Trimethoprim

Source: National Pharmacy Association

no adverse events in the pilot so far and that all the official guidelines on non-NHS PGDs were followed in the development of the scheme, even though official guidance from the Medical and Healthcare Products Regulatory Agency urges 'particular caution' when issuing PGDs for antibiotics.

Deborah Evans, NPA director of pharmacy, said 'robust protocols' would be in place.

She said: 'The service is all about improving access to self-

care and increasing patient choice, without compromising quality.'

Kirit Patel, chief executive of Day Lewis Pharmacy, said: 'The service is convenient, and will make the most out of pharmacists' skills as experts in medicines while freeing up GPs' time.'

But after being alerted to the scheme, a DH spokesperson said the chief pharmaceutical officer, Dr Keith Ridge, was requesting a meeting with Day Lewis Phar-

macy and the NPA to discuss the plans.

'Decisions about treatment should be based on an assessment of a patient's needs and circumstances,' the DH said.

'It is important that if getting medicines from other sources, patient safety is not compromised.'

'Particular caution should be exercised in the use of antibiotics. Pharmacists should consider whether their inclusion in a PGD is absolutely necessary.'

'This will make sure strategies to combat increasing antibiotic resistance are not put at risk.'

Dr Bill Beby, chair of the GPC clinical and prescribing committee, said: 'PGDs of this nature are not allowed in practices - the asthma nurse cannot give out a salbutamol inhaler, despite her training. How can it be safe for pharmacies to sell them after an e-learning module?'

Dr Kevin Gruffydd-Jones, a GP in Box, Wiltshire, who has been involved in the development of several asthma guidelines, said he was 'very concerned' at salbutamol inhalers being made available without prescription and warned it was essential safeguards were in place to prevent patients 'going from pharmacist to pharmacist getting reliever medication alone'.

Earlier this year, the supermarket chain Asda announced it was to dispense salbutamol inhalers under a PGD without a doctor's prescription.

▶ @pulsetoday

MORE ONLINE
 Read the full list of medications included in the scheme
 pulsetoday.co.uk/clinical

News

- 2** Average MPIG practice gets £12k per year
- 4** CCGs to inherit large PCT debts
- 9** Price of anti-epilepsy drug soars
- 11** DH plans roll-out of e-consultations

Views

- 18** **Letters** It's time for GPs to dig their heels in over the contract crisis
- 23** **Peverley** The sad folly of the food diary
- 24** **Opinion** At a hefty £97m, revalidation is not worth the cost
- 26** **Clinical** Key questions Cervical cancer
- 27** **Ten top tips** Chronic pain
- 30** **The information** Pruritus in the elderly



- 32** **Urology** Common penile problems

Business & Commissioning

- 37** **Appointments** Five steps to 15-minute appointments
- 38** **CCGs** What you need to know about CCG constitutions

CPD in this issue: 3.5 hours
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The week in general practice

INSIDE

CCGs set to inherit multi-million-pound debts from PCTs
page 4

First-wave CCGs face serious authorisation conditions
page 6

Dr Charles Alessi



Price of anti-epilepsy drug rockets following sale of rights
page 9

GPC attacks NHS Mandate pledge to boost online records access
page 11

MORE ONLINE

A new vaccine against meningitis B has been approved by European drugs regulators
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PULSENEWS

Average MPIG practice gets £12k per year

DH figures reveal one practice receives £370k a year as planned funding shake-up splits profession

EXCLUSIVE

By Sofia Lind

Thousands of GP practices which are still dependant on MPIG receive an average of £12,000 a year in correction factor payments, according to Department of Health figures

which lay bare the likely impact of its planned changes to the GP contract.

Some 63% of practices in England currently receive some funding through the MPIG, and the DH has said that its plans to phase out the MPIG and move towards a more 'equitable' system of funding - to be implemented between 2014 and 2021 - will see 50% of practices lose funding and the other 50% gain.

But new DH figures obtained by Pulse this week reveal just how reliant many GPs are on correction factor payments, and will add fuel to GPC fears that the changes would be 'destabilising' for many practices.

The average £12,000 correction factor payment for prac-

tices still on the MPIG represents 4% of an average practice's global sum income, but that figure masks huge variation. The DH said one unnamed practice receives a correction factor payment worth more than nine times its global sum total - some £370,000 a year.

The DH figures follow predictions from one leading medical accountant that phasing out the MPIG could lead to a 'bloodbath' in practice funding, with those with a list size of fewer than 4,000 facing possible closure.

But while much of the profession has expressed alarm at ministers' plan to impose contractual changes, the phasing out of the MPIG has divided GPs.

Dr Om Aggarwal, a GPC member and GP in Cardiff, said: 'I am a partner at a small practice, and, oh yes, we will lose funding. Most practices in Wales stand to lose. It will be a question of survival.'

But Dr Brett La Hay, a GP in Tayside, whose practice gets zero MPIG weighting, said the correction payments had entrenched inequality.

He said: 'How can the BMA and the GPC continue to ignore that some practices are unfairly rewarded? For once I am entirely siding with the Government.'

'My practice has experienced seven years of this lower income and my patients have had lesser

MPIG in figures

£370k per year
Largest MPIG payment

£12k per year
Average payment to practices on MPIG

63%
Proportion of practices in England on MPIG

Source: Department of Health

Negotiators yet to

EXCLUSIVE

By Sofia Lind

GPC negotiators have so far refused to sign their CCG constitutions, as it emerged the BMA has consulted external lawyers to draw up new guidance for GPs on the legal documents.

Pulse can reveal that none of the four English negotiators has signed their local CCG's constitution.

The new BMA guidance, to be unveiled this week, will build on points made in the initial check list that the association published in June. However, it has been written by external lawyers and is 'much more thorough' than the previous guidance, a GPC spokesperson said.

The guidance is expected to extend advice to GPs on how to prevent the constitutions from imposing further contractual

responsibilities on practices, which the current legislation specifically prohibits. The GPC is negotiating with the Government to ensure this remains the case when secondary legislation is introduced. It comes after Pulse revealed last week that CCG constitutions will be legally

'Our CCG constitution has improved with LMC input'
Dr Chaand Nagpaul



binding on practices whether GPs sign them or not.

Dr Peter Holden, a GPC negotiator and a GP in Matlock, Derbyshire, said he was awaiting publication of the guidance before signing his constitution.

All the other negotiators confirmed that they had yet to sign

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Should MPIG go?



YES Some practices get significantly more pounds per patient, which means there are inequalities in funding. Seven years to address that is too long

Dr Tony Bentley, GP in Leicester

ANALYSIS

Only a part of the jigsaw

The predicted swings in funding with the removal of the MPIG are disturbing, but represent only one piece of the jigsaw in the DH revamp of practice funding. The move towards a 'single weighted capitation price' contains so many variables that it is impossible to accurately predict how practice funding may look from 2014 onwards. The wildcard is the DH's plan to revamp Carr-Hill to increase the weighting for deprivation and population age. How this works in practice will be crucial for smaller practices in more affluent areas which stand to lose most. These are the 'known unknowns', but the bigger elephant in the room is the political context. In shifting funding to more deprived areas, ministers will risk practices in leafy traditionally Tory areas going to the wall. Can they afford the wrath of the worried well once they find out their local practice is closing? The answer to this may determine the profession's future. Nigel Praetles is Pulse's deputy editor



Minister calls for more women on CCG boards

A health minister has admitted that women are underrepresented on CCG boards and said there is a problem with the career progression of female doctors. Earl Howe told a House of Lords debate this month that women were in a 'significant minority' in senior leadership roles, which was a 'loss all round'. Answering a question posed by BMA president Baroness Hollins about how to support women working in the NHS, Earl Howe said: 'I think this is less a problem with retention of female doctors, which is a serious and significant issue.'



NO It is bad for our practice to get rid of it. We have loads of worried well, who are very demanding and take ages, but we don't get much deprivation loading

Dr Fiona Cornish, GP in Cambridge

services because of it. "Destabilising" general practice just means some practices resent change. I resent the continuing disadvantage the MPIG gives to my patients.' GPC chair Dr Laurence Buckman said: 'The impact of losing MPIG ranges from none at all, to very little, to

potentially devastating.' 'The conference of LMCs has a policy that says the profession should move towards more equitable funding, but this needs to be done with consideration and involvement of practices.' @sofiaind_pulse ▶ Letters, page 18

Trajenta (linagliptin) advertisement featuring a yellow bird and the text 'Control and care matter'. Includes efficacy and safety information for type 2 diabetes patients.

sign constitutions

their constitutions. GPC chair Dr Laurence Buckman said he 'isn't signing' his constitution 'even though there is nothing wrong with it', but did not give his reasons why. He said: 'I am not going to sign it on principle, because I do not wish to sign it.' Dr Chand Nagpaul's practice in Stanmore, north London, has been involved in lengthy local debate over his local CCG's constitution. He said: 'Our CCG constitution has improved considerably with LMC input and many issues have been resolved with amendments and deletion of clauses. Our practice is considering signing but has not yet done so, pending clarifying a couple of points - so to be fair there have been positive changes using GPC guidance/LMC input. We now have a formal role for the LMC in the constitution, including observer

status at CCG board meetings.' Dr Richard Vautrety's practice in Leeds also has yet to sign a constitution but he said the CCG had closely involved the LMC and GP member practices in the process. Dr Vautrety said there would still be opportunities between now and April to make changes to constitutions. He said: 'We have been involved in setting it out and it has been a very positive process. I would have thought my practice will sign it when the meeting takes place. 'Even if you have signed, there will be opportunities to make changes.'

MORE ONLINE Read the GPC's checklist of what should be in your CCG constitution pulsetoday.co.uk/commissioning

Boehringer Ingelheim advertisement for Trajenta (linagliptin) with detailed medical information, efficacy data, and contact details.

CCGs to inherit debts from PCTs

Pulse investigation reveals some will be saddled with multi-million-pound deficits despite ministers' assurances

INVESTIGATION

By Jaimie Kaffash

CCG leaders are likely to be saddled with multi-million pound deficits from April next year, despite previous Government assurances they would not inherit legacy debts.

Managers in at least five areas across England are predicting they will begin the new financial year with a deficit.

It comes as the NHS Commissioning Board revealed it

is looking again at the issue of CCG debt. It is due to make an announcement in early December to clarify what will happen to any deficits or surpluses left over by PCTs.

Even earlier this year ministers were continuing to insist debts would not be passed on to CCGs - a key demand of Pulse's 'A Clean Slate' campaign.

Then-health secretary Andrew Lansley told CCG leaders at the Commissioning Show in July: 'We are still intending for CCGs to start in April

In the red

NHS North Yorkshire and York predicting £19 million deficit by the end of 2012/13

Croydon CCG worst-case scenario suggests a £12.6 million deficit

NHS Hillingdon CCG will pay back £15 million loan to Brent over three years

NHS Peterborough £6.4 million of historic debt will remain in 2013/14

NHS Enfield forecasting a £5.3 million deficit



2013 with no legacy debts.'

However, a Pulse investigation reveals that CCG leaders in many areas are likely to have large holes in their finances from April 2013.

A financial report from Croydon CCG forecasts a 'best case' scenario of a £5m deficit by the end of the financial year, and a 'worst case' of a £12.6m deficit if it does not get financial support.

NHS Hillingdon has had to borrow £15m from a neighbouring PCT to cover its deficit, which will have to be repaid by Hillingdon CCG over a three-year period.

Board papers show NHS Peterborough is predicting £6.4 million of the PCT's historic debt will remain in 2013/14 and NHS Enfield is forecasting a £5.3 million deficit.

And September board minutes for NHS North of England SHA cluster confirm that, as reported earlier this year, NHS North Yorkshire and York is anticipating a £19m deficit.

Meanwhile Stafford and Surrounds CCG said it is still forecasting a balanced position at the year end but it has overspent by £295k by the fifth month

and achieving a balanced position will depend on 'delivering a series of mitigating actions to offset the current known risks'.

Dr Michael Dixon, interim president of NHS Clinical Commissioners, said it was crucial CCGs were given a 'fighting chance' by being free from historic debt in April 2013.

He said: 'There is no reason



'There is no reason for CCGs to pay for the sins of their fathers.'

Dr Michael Dixon

for CCGs to pay for the sins of their fathers.'

Dr Huw Charles-Jones, chair of West Cheshire CCG, said CCGs with inherited debt would 'struggle', but added that the whole local health economy would have implications on CCGs' commissioning decisions.

He said: 'If your major provider has difficulties, it will make it harder.'

@pulsetoday

ANALYSIS

Every effort is being made to clear the debt

I think there is a heartfelt effort from the NHS Commissioning Board to ensure CCGs start with no inherited deficits.

Before 2012, in many instances the PCT dug themselves out of financial trouble. But sometimes they were bailed out by the SHAs, which held reserves built up by top-slicing PCT budgets.

The Operating Framework did say that any debts incurred after April 2012 would be taken on by the CCG and there will be PCTs still in deficit. However, the five that Pulse discovered is far fewer than was previously the case in the NHS.

As the NHS is reporting a surplus nationally, I hope any pre-existing debts are written off so that all CCGs start off with a clean slate. That would be the ideal scenario.

The reserves are more complicated. They should be held as a risk pool for distribution for CCGs, but with first call on those for the CCGs that generated them.

Dr David Jenner is a senior policy adviser at the NHS Alliance and a GP in Cullompton, Devon



GPC intervenes over PCT maternity data request

The GPC has intervened after PCTs demanded information from practices on the uptake of the pertussis vaccination that went beyond agreements made in the National Enhanced Service (NES).

DH guidance for PCTs released in October advised that practices should provide the PCT with the number of women with an estimated date of delivery that month, and how many had received a dose of pertussis vaccination Repevax.

But the GPC said this work went beyond agreements made in the NES for the Government's

£10 million temporary vaccination programme, and has written to NHS Employers asking for urgent clarification.

The NES only required practices to provide the PCT with the number of patients over 28 weeks pregnant and the number of women in that cohort who have received the vaccine. Any additional work should be arranged as a IES, the GPC said.

GPC deputy chair Dr Richard Vautrey said: 'PCTs underestimate how much work it will be for practices. Estimated delivery date is difficult to get. It's held in hand-held or maternity records.'



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References: 1. Thrane PS et al. Dental Health, 2003;48(3):8-12. 2. Thrane PS et al. Dental Health, 2010;48(1):6-10. 3. Young A et al. International Dental Journal, 2003;53:237-242. 4. Thrane PS et al. The Journal of Clinical Dentistry, 2007;18(2):62-66. 5. Saad S et al. Oral Diseases, 2011;17:180-181.



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References: 1. Ferguson SG and Shiffman S. The relevance and treatment of cue-induced cravings in tobacco dependence. *Journal of Substance Abuse Treatment* 2009; 36: 235-43. 2. Durcan MJ et al. Efficacy of the nicotine lozenge in relieving cue-provoked cravings. Presented at the 5th European SRNT, Padua, Italy, 2003.

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Date of Preparation: August 2012. CHGB/CHNIQ/0072/12

CCGs face authorisation conditions

NHS Commissioning Board makes recommendations on provisional conditions for 35 first-wave CCGs

EXCLUSIVE

By Jaimie Kaffash

First-wave CCGs have reported mixed outcomes from the NHS Commissioning Board's authorisation process, with some reporting high-level conditions may be placed on them, Pulse can reveal.

Some CCG leaders said they had been informed they may be authorised subject to condi-

Some people have said the process is bureaucratic, but it has to be

Dr Steve Kell

tions, including levels three to six, which indicate they could have some functions removed from their responsibility on authorisation.

Other first-wave CCGs are reporting that the whole process has been 'reasonable' and has helped them improve.

The NHS Commissioning Board's conditions panel met on 2 November and informed the 35



Dr Charles Alessi: NHS Commissioning Board must avoid trying to 'micromanage' CCGs

first-wave CCGs of provisional conditions to be placed on them.

They will have the opportunity to appeal any provisional conditions before they are officially authorised early next month.

There are six levels of conditions, which can be applied to CCGs against 119 criteria.

Pulse understands that some first-wave CCGs have had the

more serious conditions levels three to six placed on them. They have 10 days to respond to the conditions panel's findings; the final subcommittee will ratify their authorisation, with or without conditions, on 5 December.

One GP serving as a CCG board member, who asked not to be named, said: 'It has been

a challenging process and there have been teething problems. Some of the people in the assessing teams were as not as experienced as they should have been. There have also been variations in CCGs being given red and green flags.'

However, the officer said the process had been a good one on the whole and said the NHS

CCG condition levels

- 1 No action necessary
- 2 NHS board will make advice/expertise available if needed
- 3 NHS board sign-off needed for specific decisions made by the CCG
- 4 NHS board will place a specific team or individual on to the CCG board
- 5 CCG's accountable officer will not be ratified and an alternative will be appointed
- 6 Specific functions will be removed
- 7 All CCG functions will be removed

Source: NHS Commissioning Board

Commissioning Board should be applauded.

Another GP commissioning leader, also speaking on condition of anonymity, said her CCG was 'really pleased' to have received just a handful of red flags and one level-three condition.

Dr Steve Kell, chairman of Bassetlaw CCG, said: 'It has been a reasonable process. Some peo-

ple have said it is bureaucratic, but it has to be - CCGs are spending lots of public money. But our CCG has certainly been helped by the process.'

In a letter to the NHS Commissioning Board, interim NHS Clinical Commissioners chair Dr Charles Alessi warned that although authorisation was an important process, CCG leaders were concerned the board would attempt to 'micromanage' them.

He said: 'While we recognise that not all CCGs will be at the same level of development, we fully support the principle that it is for the CCG to propose the action to be taken to rectify the concern identified.'

'Given this, it is for the CCG to decide whether to make use of the support package proposed by the [NHS] Commissioning Board or to identify for themselves where to obtain the support needed to address the required development.'

A spokesperson for the NHS Commissioning Board insisted that all assessors carrying out 'desktop reviews' had been 'fully trained'. She added that more details about the authorisation process would be released in December.

CQC attacks 'scaremongering' PCTs

By Jaimie Kaffash

A LMC has been 'deluged' by complaints from GP practices after managers threatened them with breach of contract over their preparations for CQC registration.

NHS Manchester sent remedial letters to practices in the summer, with threats of breach of contract notices related to CQC standards.

But the CQC said the move was 'scaremongering' and advised PCTs to stop threatening practices over aspects of registration that had 'no basis in fact'.

The GPC also said it had 'repeatedly' heard reports of practices being set inappropriate standards related to premises and infection control and it has advised GPs to seek help from

their LMC if they are affected.

GP practices are now undergoing CQC registration, from September through to December this year, but the regulator has warned that it is still receiving reports that PCTs have been exaggerating the re-



quirements practices need to adhere to.

Dr John Hughes, chair of Manchester LMC, said he had recently had a 'deluge' of unhappy GPs contacting the LMC after remedial notices were issued

over their preparations for CQC registration.

He said: 'If there is breach of contract, it is up to the PCT to prove it and not for us to prove compliance.'

'We have asked them on numerous occasions to show us where in the regulations it shows the practice is in the breach of contract and they have not done that.'

'They simply refer to the Disability Discrimination Act and various other acts that are not part of the GP contract. It's not within their remit to decide what is part of CQC regulations.'

Dr Richard Vautrey, GPC deputy chair, said: 'The CQC is very clear what standards it will apply and they are far more reasonable and realistic than some of those being

pushed by PCTs in their dying days.'

A CQC spokesperson said: 'Any rumours that practices will have to rip up carpets in surgeries, have mounted paper dispensers removed, or have to change the height of reception desks for disability discrimination issues are nonsense and have no basis in fact.'

'The commission is aware that some PCTs have been saying this to practices and would encourage anyone who has encountered this behaviour to pass that information on to the CQC who will advise the PCT that their advice is wrong and should stop scaremongering in this way,' he added.

NHS Manchester did not respond to requests for comment.

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Pathfinders to roll out telehealth to 100,000

GPs have been asked to make telehealth more readily available after the Government set a target for the scheme to be offered to 100,000 patients across seven regions in England next year.

Health secretary Jeremy Hunt told an Age UK conference that seven 'pathfinders', including CCGs and local authorities, were set to agree contracts with suppliers to offer telehealth.

This will help the Department of Health towards its target of offering the service to three million people by 2017.

The seven pathfinders cover Worcestershire, North York-

shire and York and Humber PCT cluster, NHS South Yorkshire and Bassetlaw, Kernow CCG and Cornwall and Isles of Scilly PCT, NHS Kent and Medway and Camden CCG.

Mr Hunt said: 'In a world where technology increasingly helps us manage our social and professional lives, it seems logical that it should also help people manage their health.'

The DH-funded Whole Systems Demonstrator pilot found that using telehealth can reduce mortality and help avoid emergency hospital care, but was unlikely to have a significant impact on costs.

NHS clarifies payments for oral typhoid vaccine

Practices will not be financially penalised for giving patients the oral typhoid vaccine, the NHS Prescription Service has said, following a shortage of injectable vaccine.

GPs will be reimbursed for prescribing Crucell's oral vaccine Vivitif if they submit it on the FP34 appendix, even though it is classed as a 'personally administered item' and taken in capsule form.

Last month, Sanofi Pasteur recalled 16 batches of its vaccine Typhim Vi after observing lower than expected antigen content in a number of batches.

It stressed there was no safe-

ty risk for people who were vaccinated from recalled batches, but the move has contributed to a shortage in supply of the injectable vaccine, with many GPs using the oral version instead.

A spokesperson from the NHS Prescription Service told Pulse: 'GPs can personally administer this item and will receive the relevant dispensing fee for doing so.'

'This follows normal procedure and does not represent a "concession" due to shortage of supply of equivalent items or any other reason.'

Claims on FP10s will not be accepted from January 2013.

Learn how to survive funding changes at Pulse Live

April 2013 - the go-live month for CCGs - is a buffer zone beyond which lies unnerving uncertainty for general practice.

Get a reality check on your future at Pulse Live, the new annual two-day conference for GPs and practice managers, in

PULSE 12 CPD hours

Attending this conference is worth 12 CPD credits towards the 50 annual credits you must build up for appraisal

Birmingham on 31 April and 1 May.

Come to this free* event to learn: how to cope with sweeping changes to GP funding; how to keep your QOF income up when lucrative organisational indicators are scrapped; and how to survive scrutiny post April 2013.

If the reforms promised you more control over your future, then Pulse Live Advisory Board member Dr Krishna Chaturvedi, a GP in Westcliff-on-Sea, Essex,

has warned it isn't playing out that way. 'It is looking like a mark two of PCTs,' he said, calling for grassroots GPs to rally at Pulse Live.

Book now at www.pulse-live.co.uk and decide which day(s) to attend when the detailed programme is out in the New Year.



Get involved
Contact Pulse Live producer Lisa Thomlinson at lisa.thomlinson@briefingmedia.com, or via Twitter @LisaThomlinson, and let us know what you would like to see on the Pulse Live programme.

Free to attend
*Pulse Live is free to attend for GPs and practice managers who are registered users of PulseToday/Pulse Learning and who book before 31 December.

NEW data demonstrates superiority of CHAMPIX over single and combination NRT for quit success at 1 year

The systematic review and multiple treatment comparison (MTC) meta-analysis reviewed 146 smoking cessation randomised controlled trials (RCTs), consisting of 53,412 patients, using direct and indirect comparisons of treatments.

CHAMPIX showed statistically significant improvements in smoking abstinence at 1 year vs.:

- Standard-dose NRT patch (≤ 22 mg)
- High-dose NRT patch (>22 mg)
- Combination NRT (NRT patch PLUS one additional NRT formulation*)

Statistical significance in smoking abstinence over time



Adapted from Mills EJ *et al.* *Ann Med* 2012. OR = Odds Ratio (OR >1 favours CHAMPIX)

CrI = 95% Credible Interval (Credible Intervals are the Bayesian equivalent of classic Confidence Intervals)

The meta-analysis only included open-label and blinded RCTs with at least 3 months follow-up post-target quit date together with biochemical confirmation of smoking abstinence.

Limitations with the MTC approach are that assumptions are made that the trials measure a similar outcome, study populations are appropriate to combine, and direct and indirect evidence is consistent.

Safety was not investigated in this meta-analysis. There are special warnings and precautions in relation to CHAMPIX regarding neuropsychiatric and cardiovascular risks – for further information please see the SmPC.

The results from this meta-analysis provide additional evidence to support the use of CHAMPIX as a first-line treatment option for smokers.

*The additional NRT formulation included gum, lozenge, inhalator and nasal spray.

CHAMPIX® Film-Coated Tablets (varenicline tartrate) ABBREVIATED PRESCRIBING INFORMATION – UK. (See Champix Summary of Product Characteristics for full Prescribing Information). Please refer to the SmPC before prescribing Champix 0.5 mg and 1 mg.

Presentation: White, capsular-shaped, biconvex tablets debossed with "Pfizer" on one side and "CHX 0.5" on the other side and light blue, capsular-shaped, biconvex tablets debossed with "Pfizer" on one side and "CHX 1.0" on the other side. **Indications:** Champix is indicated for smoking cessation in adults. **Dosage:** The recommended dose is 1 mg varenicline twice daily following a 1-week titration as follows: Days 1-3, 0.5 mg once daily, Days 4-7, 0.5 mg twice daily and Day 8-End of treatment, 1 mg twice daily. The patient should set a date to stop smoking. Dosing should usually start 1-2 weeks before this date. Patients who are not willing or able to set the target quit date within 1-2 weeks, could be offered to start treatment and then choose their own quit date within 5 weeks. Patients who cannot tolerate adverse effects may have the dose lowered temporarily or permanently to 0.5 mg twice daily. Patients should be treated with Champix for 12 weeks. For patients who have successfully stopped smoking at the end of 12 weeks, an additional course of 12 weeks treatment of 1 mg twice daily may be considered. Following the end of treatment, dose tapering may be considered in patients with a high risk of relapse. **Patients with renal insufficiency:** Mild to moderate renal impairment: No dosage adjustment is necessary. Patients with moderate renal impairment who experience intolerable adverse events. Dosing may be reduced to 1 mg once daily. Severe renal impairment: 1 mg once daily is recommended. Dosing should begin at 0.5 mg once daily for the first 3 days then increased to 1 mg once daily. Patients with end stage renal disease: Treatment is not recommended. **Patients with hepatic impairment and elderly patients:** No dosage adjustment is necessary. **Paediatric patients:** Not recommended in patients below the age of 18 years. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients. **Warnings and precautions:** Effect of smoking cessation: Stopping smoking may alter the pharmacokinetics or pharmacodynamics of some medicinal products, for which dosage adjustment may be necessary (examples include theophylline, warfarin and insulin). Changes in behaviour or thinking, anxiety, psychosis, mood swings, aggressive behaviour, depression, suicidal ideation and behaviour and suicide attempts have been reported in patients attempting to quit smoking with Champix in the post-marketing experience. Not all patients had stopped smoking at the time of onset of symptoms and not all patients had known pre-existing psychiatric illness. Champix should be discontinued immediately if agitation, depressed mood or changes in behaviour or thinking that are of concern for the doctor, the patient, family or caregivers are observed, or if the patient develops suicidal ideation or suicidal behaviour. In many post-marketing cases, resolution of symptoms after discontinuation of varenicline was reported, although in some cases the symptoms persisted; therefore, ongoing follow up should be provided until symptoms resolve. Depressed mood, rarely including suicidal ideation and suicide attempt, may be a symptom of nicotine withdrawal. In addition, smoking cessation, with or without pharmacotherapy, has been associated with the exacerbation of underlying psychiatric illness (e.g. depression). In a trial of patients with stable cardiovascular disease (CVD) certain cardiovascular events were reported more frequently in patients treated with CHAMPIX. Patients taking CHAMPIX should be instructed to notify their doctor of new or worsening cardiovascular symptoms and to seek immediate medical attention if they experience signs and symptoms of myocardial infarction. The safety and efficacy of Champix in patients with serious psychiatric illness has not been established. There is no clinical experience with Champix in patients with epilepsy. At the end of treatment, discontinuation of Champix was associated with an increase in irritability, urge to smoke, depression, and/or insomnia in up to 3% of patients, therefore dose tapering may be considered. There have been post-marketing reports of hypersensitivity reactions including angioedema and reports of rare but severe cutaneous reactions, including Stevens-Johnson Syndrome and Erythema Multiforme in patients using varenicline. Patients experiencing these symptoms should discontinue treatment with varenicline and contact a health care provider immediately. **Fertility, pregnancy and lactation:** Champix should not be used during pregnancy. It is unknown whether varenicline is excreted in human breast milk. Champix should only be prescribed to breast feeding mothers when the benefit outweighs the risk. There are no clinical data on the effects of varenicline on fertility. Non-clinical data revealed no hazard for humans based on standard male and female fertility studies in the rat. **Driving and operating machinery:** Champix may have minor or moderate influence on the ability to drive and use machines. Champix may cause dizziness and somnolence and therefore may influence the ability to drive and use machines. Patients are advised not to drive, operate complex machinery or engage in other potentially hazardous activities until it is known whether this medicinal product affects their ability to perform these activities. **Side effects:** Adverse reactions during clinical trials were usually mild to moderate. Most commonly reported side effects were abnormal dreams, insomnia, headache and nausea. Commonly reported side effects were increased appetite, somnolence, dizziness, dysgeusia, vomiting, constipation, diarrhoea, abdominal distension, stomach discomfort, dyspepsia, flatulence, dry mouth and fatigue. See SmPC for other less commonly reported side effects. **Overdose:** Standard supportive measures to be adopted as required. Varenicline has been shown to be dialyzed in patients with end stage renal disease, however, there is no experience in dialysis following overdose. **Legal category:** POM. **Basic NHS cost:** Pack of 25 11 x 0.5 mg and 14 x 1 mg tablets Card IEM/06/360/003: £27.30. Pack of 28 1 mg tablets Card IEM/06/360/004: £27.30. Pack of 56 0.5 mg tablets HDPE Bottle IEM/06/360/001: £54.60. Pack of 56 1 mg tablets HDPE Bottle IEM/06/360/002: £54.60. Pack of 56 1 mg tablets Card IEM/06/360/005: £54.60. Retail pack sizes may be marketed / marketed at launch. **Marketing Authorisation Holder:** Pfizer Limited, Sandwich, Kent, CT13 9NJ, United Kingdom. **Further information on request:** Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey KT20 7NS **Last revised:** 03/2012. Ref: 010_0

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 Pfizer Medical Information on 01304 616161.

For further information, please contact Pfizer Medical Information on 01304 616161 or email medinfo.uk@pfizer.com

Reference:
1. Mills EJ *et al.* Comparisons of high dose and combination nicotine replacement therapy, varenicline and bupropion for smoking cessation: a systematic review and multiple treatment meta-analysis. *Ann Med* August 2012



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 1[†]
- Improves patients' breathlessness and health status^{**} (vs. control)[†]
- 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: almirallprofessionalinformation.co.uk

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



Solutions with you in mind

CCGs alarmed by 24-fold increase in price of phenytoin following sale of rights to Flynn Pharma

PRESCRIBING

Price of anti-epilepsy drug rockets

By Mark Gould

Clinical commissioning groups have warned that a 24-fold rise in the cost of an anti-epilepsy drug could add £43m to commissioning costs across England.

Phenytoin has increased in price since September from 66p to £15.74 for 28 25mg tablets, and from £2.83 to £67.50 for 84 100mg tablets. This followed the acquisition of the rights by Flynn Pharma from Pfizer.

Sue Smith, head of prescribing and medicines management at Nene and Corby CCG and a pharmacist by training, said the 24-fold increase was 'difficult to comprehend'.

'In Northamptonshire, we are spending just over £5k per quarter on Epanutin at current prices, which will potentially increase to £120k per quarter,' she wrote in a letter to local MPs.

This equated to an estimated

£460k per year in additional costs for Northamptonshire CCG and £43 million per year for the NHS as a whole, she added.

The DH told Corby CCG in a letter that it was holding discussions with the company.

Flynn Pharma is a member of the 2009 Pharmaceutical Price Regulation Scheme, but phenytoin is not covered by the scheme, the DH added.

'Whilst any price increase is unwelcome, systems are in place to ensure, in the main, the NHS obtains the best value from medicines. For example, we were able to move quickly earlier this year to reduce the cost of atorvastatin to the NHS when it came off patent,' the DH letter added.

David Fakes from Flynn Pharma confirmed that discussions were taking place but refused to be drawn on specifics.

Dr Johnny Marshall, interim



Price of phenytoin has risen from 66p to £15.74 for 28 25mg tablets

Differing costs

Before	
25mg	66p/28 tablets
50mg	67p/28 tablets
100mg	£2.83/84 tablets
300mg	£2.83/28 tablets
After	
25mg	£15.74/28 tablets
50mg	£15.98/28 tablets
100mg	£67.50/84 tablets
300mg	£67.50/28 tablets

Source: BNF, NHS Prescription Services

director for partnership development at NHS Clinical Commissioners, said: 'We have written to [chief pharmaceutical officer] Dr Keith Ridge asking him why a 24-fold price rise has been agreed at no benefit to patients and to see if there are any steps that can be taken to mitigate the effect on CCG budgets.'

A DH spokesperson said: 'Our main concern is ensuring epilepsy patients continue to get phenytoin.'

@pulsetoday

CCGs

CCGs' promise 'unfulfilled'

CCGs are concerned that 'an official agenda' is preventing them from developing their own ways of working, a Department of Health-funded survey has found.

The survey of commissioning leaders found there was good support for local commissioning. However, many respondents felt this could have been achieved without the need for national reorganisation.

Researchers from the University of Manchester carried out in-depth interviews with 33 GPs and 47 managers at eight pathfinder CCGs, and conducted a web survey of all developing CCGs in December 2011 and April this year.

It found that CCGs were unclear on how to be accountable both upwards to the NHS Commissioning Board and

downwards to their members and to the public at large.

Particular issues included the difficulty of bringing in new GP leaders, and the requirements to appoint a nurse and a hospital consultant to CCG boards.

The report concluded: 'In general, the early promise that pathfinder CCGs would be able to influence the overall direction of policy was felt not to have been fulfilled. There was a perceived disconnect between early encouragement to develop their own ways of doing things and an emerging sense that there was an official agenda that must be adhered to.'

MORE ONLINE
Read the full report
[pulsetoday.co.uk/
commissioning](http://pulsetoday.co.uk/commissioning)

NHS BOARD

Clinical commissioners to appraise NHS Board

GP commissioners will appraise the NHS Commissioning Board annually to 'hold a mirror up to the new system'.

NHS Clinical Commissioners will lead the appraisals, which will discover how well the national board and local offices have been supporting CCGs.

Dr Michael Dixon, the interim president of NHS Clinical Commissioners, said: 'We believe the success of the NHS Commissioning Board in its duty to promote autonomy should be assessed through a CCG-led appraisal process.'

'It is essential that CCGs and the NHS Commissioning Board

support a co-productive relationship.

'Working with practices, patients and stakeholders from across health and social care, CCGs are well placed to gather the intelligence needed to hold a mirror up to the new system.'

Dr Dixon said CCGs should play a central role in assisting the NHS Commissioning Board to understand how it and its local offices were supporting the work of CCGs.

'It is also essential that feedback is provided to the board on its performance as commissioner of specialised services and primary care,' he said.

Some UK hospitals are using this probiotic yogurt drink in those at risk of antibiotic-associated diarrhoea and *C. diff*-associated diarrhoea...



...could it help your at risk antibiotic patients too?

Probiotics have been shown to help restore the balance of gut bacteria disturbed by antibiotic use.^{1,2} Actimel is a probiotic yogurt drink, containing *Lactobacillus casei* DN-114 001³, which has been shown to support the body's immune system in numerous clinical studies⁴. In one clinical study older hospitalised patients (over 50 years of age) drinking Actimel daily¹ during a course of antibiotics and for one week after showed significantly reduced incidence of antibiotic-associated diarrhoea and *C. difficile*-associated diarrhoea.² WGO Practice Guidelines report 'Recent research has indicated that *L. casei* DN-114 001⁵ is effective in hospitalised adult patients for preventing antibiotic-associated diarrhoea and *C. difficile* diarrhoea'.⁶ Some hospitals near your practice have already started integrating it into their *C. difficile* management plans.

Visit www.probioticsinpractice.co.uk to see the evidence for yourself and register for a new RPS accredited CPD e-learning module on probiotics, the immune system and gut microbiota.

Information for Healthcare Professionals

¹ *Lactobacillus casei* DN-114 001 (DNM-114) (*L. casei* Danone)
² Two bottles consumed daily

References: 1. De La Cucheta MF et al. *Microb Ecol* 2010;50:395-402. 2. O'Toole PW and Cooney JJ. *Heritosp Perspect Infect Dis* 2010; 170-180. 3. Danone Research. Clinical studies - Actimel publications. Available online at: www.danone.com (accessed August 2011). 4. Hickson ME et al. *BMJ* 2007;335:90. 5. World Gastroenterology Organisation Practice Guideline: Probiotics and Prebiotics. May 2010. Available online at: www.worldgastroenterology.org/probiotics-prebiotics.html (accessed August 2011).

AHC21 May 2012



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ABRIDGED PRESCRIBING INFORMATION

Inactivated Influenza Vaccine (Split Virion) BP

Refer to Summary of Product Characteristics for full product information. **Presentation:** Inactivated Influenza Vaccine (Split Virion) BP contains 15 micrograms of antigen (per 0.5 millilitre) from each of the three virus strains recommended by the World Health Organization for the present influenza season. It is supplied as single dose pre-filled syringes each containing 0.5 millilitre of suspension for injection. The vaccine may contain traces of eggs, such as ovalbumin, neomycin, formaldehyde and octadecyl 9 which are used during the manufacturing process. **Indications:** Prophylaxis of influenza especially in those who run an increased risk of associated complications. Inactivated Influenza Vaccine

(Split Virion) BP is indicated in adults and children from 6 months of age. **Dosage and administration:** Adults and children from 36 months should receive one 0.5 millilitre dose. In children aged 6 months to 35 months clinical data are limited and dosages of 0.25 or 0.5 millilitre have been used. Children who have not been previously vaccinated should receive a second dose of vaccine after an interval of at least 4 weeks. Doses should be administered intramuscularly or deep subcutaneously. **Contraindications:** Hypersensitivity to the active substances, to any of the excipients, to eggs, chicken protein, neomycin, formaldehyde, and octadecyl 9. Immunisation should be postponed in patients with febrile illness or acute infection. **Warnings and precautions:** Do not administer intravascularly. Medical treatment should be

available in the event of rare anaphylactic reactions following administration of the vaccine. Immunosuppressed subjects may not produce adequate antibodies. Other vaccines may be given at the same time at different sites, however adverse reactions may be intensified. **Pregnancy and lactation:** Inactivated influenza vaccines can be used in all stages of pregnancy. May be administered during lactation. **Undesirable effects:** Common side effects include: injection site reactions (redness, swelling, pain, erythema, induration) and systemic reactions (fever, malaise, shivering, fatigue, headache, sweating, myalgia, arthralgia). These usually disappear within 1 to 2 days. Other serious side effects have been reported and include: allergic reactions (in rare cases leading to shock, angioedema), convulsions, transient

thrombocytopenia, vasculitis with transient renal involvement and neurological disorders such as encephalomyelitis, neuritis and Guillain-Baré syndrome.

For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **Package quantities and basic NHS cost:** Single dose pre-filled syringes in single packs, basic NHS cost £6.59; packs of 10 single dose pre-filled syringes, basic NHS cost £65.90. **Marketing authorisation holder:** Sanofi Pasteur MSD Limited, Wellesbourne Road, Bridge Avenue, Maidenhead, Berkshire, SL6 1QP. **Marketing authorisation number:** PL 6745/0095

Legal category: POM. Date of last review: April 2012

Reference: 1. Sanofi Pasteur MSD. Data on file 2012 UK15877

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 Sanofi Pasteur MSD, telephone number 01628 785291.

NHS MANDATE

DH plans e-consultations roll-out

GPC warns of confidentiality risk as NHS Commissioning Board mandate prioritises online access to GPs

By Sofia Lind

The Government has set out the final mandate to the NHS Commissioning Board, including a commitment for all patients to be able to email their GP practice by 2015 and plans to expand e-consultations by GPs.

It set out broad areas for the NHS Commissioning Board to work to from April 2013 to March 2015, but the targets were substantially watered down from a draft version published earlier in the year.

As well as targets on improving clinical outcomes and patient experience, it signalled a major move towards modernising primary care and implementing the Government's 10-year Information Strategy published earlier this year.

The mandate included a commitment for all patients to have online access to their patient record, the ability to book GP appointments and order repeat

prescriptions online, and the facility to have secure electronic communication with their GP practice by 2015.

But the GPC said the plans would increase GP workload and risked information falling into the hands of 'abusers'.

It also says that e-consultations should become 'much more widely' available by 2015.

The NHS Commissioning Board has yet to set out an implementation plan for how the new technology needed will be installed and paid for.

A spokesperson said the board was awaiting the conclusions of an RCGP report being prepared on behalf of the Government before the end of the year.

The new DES proposed by the Department of Health for expanding access to online services for 2013/14 - paid for by retiring organisational QOF indicators - will also be used towards this aim.

Health secretary Jeremy



The Government has set a target for more e-consultations by 2015

Key targets for the NHS

- Ensure patients have access to NICE treatments and drugs
- Involve patients in their care
- Better use of technology
- Reducing health inequalities
- Rollout of personal health budgets
- Improve access to GP care, including out-of-hours

Source: NHS Mandate

Hunt said: 'None of these ambitions can be realised without the wholehearted support of GPs. They are an incredibly important part of this process because they are now running CCGs.'

GPC chair Dr Laurence Buckman said the plans for online records and e-consultations would not risk patient confidentiality.

'We could see it ending up in the hands of abusive people or third parties,' he said.

@pulsetoday

ANALYSIS

Protection of patient confidentiality is crucial

GP practices that offer patients access to their health records via the practice website must ensure the system is robust enough to protect confidential information and that regular checks are carried out to monitor data security.

Similarly, any online system for booking appointments or requesting repeat prescriptions must also be secure. A named practice staff member should monitor such online requests to ensure that none are missed. Before setting up such systems, it is advisable to seek expert IT advice.

Any practices looking to communicate with patients via email/text message must get the patient's express consent to do so and it should be sent via

the secure practice system.

Patients should be informed that emails and texts should not be used for serious or emergency situations and should include the minimum necessary information.

Where patients agree to consult via online video links, patients should be given clear information on how this process works. Doctors must recognise when this mode of consultation is not sufficient to properly assess the patient and to arrange a face-to-face consultation.

Dr Barry Parker is a medical adviser at MDDUS



FUNDING

RCGP criticised for 'foisting' work on GPs

A senior member of the GPC has attacked the RCGP for providing political cover for some of the Government's proposed GP contract changes.

Last month, the Department of Health said it wanted to retire the organisational domain of the QOF and shift those funds towards expanding online access to GP services. The RCGP is now preparing a report on this subject for the DH.

The GPC member - who did not wish to be named - told Pulse: 'They've cosied up to the Government and agreed to foist a load of new work on GPs, without

bothering to check who is going to do it, and who is going to pay.'

But Dr John Rawlinson, a GP in Ascot, a member of the GPC and chair of Berkshire LMC, said: 'We all want what is best for patients, but what seems a good idea in theory is not always a good idea in practice.'

An RCGP spokesperson said: 'It is important that this work is led from general practice. The college can provide the professional leadership and support that GP practices will need to deliver patient online access in a way that is appropriate, workable and realistic for all parties.'



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✓ Fast acting relief from **15 MINUTES**¹

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Contains Flurbiprofen (SP 8.75mg per lozenge). Indication: Symptomatic relief of sore throat. Dosage and administration: Adults and children over the age of 12 years: One lozenge sucked/dissolved slowly in the mouth every 3-6 hours as required. Maximum 5 lozenges in a 24 hour period. The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. The patient should consult a doctor if symptoms persist or worsen, or if the product is required for more than 3 days. It is recommended that this product should be used for a maximum of three days. Children: Not indicated for children under 12 years. Elderly: No dose modification is required. As with all lozenges, Strefen Honey and Lemon should be moved around the mouth without sucking. Contraindications: Hypersensitivity to flurbiprofen or any of the excipients in the product. Patients who have previously shown hypersensitivity reactions (e.g. asthma, rhinitis, angioedema, or urticaria) in response to aspirin or other non-steroidal anti-inflammatory drugs. Active or history of recurrent peptic ulcer/haemorrhage (low or more distal episodes of proven ulceration or bleeding). History of gastrointestinal bleeding or perforation related to previous NSAIDs therapy. Severe heart failure, renal failure or hepatic failure. Last trimester of pregnancy. Special warnings and precautions for use: Pregnancy and lactation: Risk to foetus: effects have been demonstrated in animal experiments; the use of Strefen Honey and Lemon should, if possible, be avoided during the first 6 months of pregnancy. During the 3rd trimester flurbiprofen is contraindicated as there is a risk of premature closure of the ductus arteriosus with possible persistent pulmonary hypertension. The onset of labour may be delayed and the duration increased with an increased bleeding tendency in both mother and child. Flurbiprofen appears in the breast milk in very low concentration and is unlikely to affect the breast-fed infant adversely. Undesirable effects: Strefen Honey and Lemon have the potential for inducing local irritation of the buccal mucosa. The most frequently reported adverse event in clinical trials was taste perversion. Other sensitivity reactions have been reported and these may consist of: non-specific allergic reactions and (eosinophilic) respiratory tract reactions (e.g. asthma, aggravated asthma, bronchospasm, dyspnoea) various skin reactions (e.g. pruritus, urticaria, erythema) and more rarely exfoliative and bullous dermatoses (including epidermal necrolysis and erythema multiforme). The list of the following adverse effects relates to those experienced with NSAIDs at doses available over the counter for short-term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur: hypersensitivity reactions: Uncommon: Hypersensitivity reactions with urticaria and pruritus. Very rare: severe hypersensitivity reactions. Symptoms could be facial, tongue and laryngeal swelling, dyspnoea, tachycardia, hypotension, angioedema (angioedema severe shock), bronchospasm of varying severity and bronchospasm. Gastrointestinal: The most commonly observed adverse events are gastrointestinal in nature. Uncommon: abdominal pain, nausea, dyspepsia. Rare: diarrhoea, flatulence, constipation and vomiting. Very rare: peptic ulcer, perforation or gastrointestinal haemorrhage, melena, haematemesis, sometimes fatal, particularly in the elderly. Usual side effects: dizziness, headache, dizziness, dizziness, dizziness. (Section 4.4). Nervous System: Uncommon: Headache. Very rare: Asthenia, dizziness. Single cases have been reported: very rarely: Paresthesia. Acute renal failure, papillary necrosis, especially in long-term use, associated with non-steroidal anti-inflammatory drugs. Very rare: liver disorders. Haematological: Very rare: Haematopoietic disorders (anaemia, leucopenia, thrombocytopenia, pancytopenia, agranulocytosis). First signs are fever, sore throat, superficial mouth ulcers, flu-like symptoms, severe exhaustion, unexplained bleeding and bruising. Dermatological: Uncommon: Various skin rashes. Very rare: Severe forms of skin reactions and cutaneous reactions including: Stevens-Johnson syndrome, erythema multiforme and toxic epidermal necrolysis can occur. Immune System: In patients with existing autoimmune diseases (such as systemic lupus erythematosus, mixed connective tissue disease) during treatment with flurbiprofen, single cases of symptoms of severe meningitis, such as stiff neck, headache, nausea, vomiting, fever or disorientation have been observed (see section 4.4). Cardiovascular and Central Nervous System: hypotension and cardiac failure. Have been reported in association with NSAID treatment. Clinical trial and epidemiological data suggest that the use of NSAIDs (particularly at high doses 2400 mg daily) and long-term treatment may be associated with a small increased risk of arterial thrombotic events (for example myocardial infarction or stroke). WFR®: £3.99 for 16 lozenges (Drug Tariff Price: £2.55). Product licence number: 030270135. Product Name: Strefen. Coleson Healthcare Ltd, Nottingham N102 3PA. Legal category: P. Date of preparation: 03/06/2012

All 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 Reckitt Benckiser Healthcare UK Ltd on 0500 455 456

UK/STF/0912/0007

1. Benimaj SJ et al. Clin Drug Invest 2001; 21:183-93



"Sometimes it seems to take over your life"

"Don't feel normal" "Cannot sleep"

"Part of your mind is on your **pain**, and another part of your brain is taken up with **constipation**"

"I know I have to take my pain meds but it's *awful* to always feel constipated"

"Makes one feel isolated"

"It is a constant discomfort and makes me unhappy"

"It dominates **everything** I can do"

"Constantly worrying or upset"

Real patient quotes taken from a survey commissioned by Napp Pharmaceuticals of 2,000 UK opioid treated patients.

When was the last time you asked them about it?

59% of patients taking opioids suffer from constipation.¹
They might not tell you unless you ask.

1. Napp Pharmaceuticals Limited. Constipation survey of 2,000 UK adults taking opioids. July 2012. Data on file.



BMA to study complaints effects

As complaints rise, BMA will investigate their impact on GP welfare and whether they lead to defensive care

By Sofia Lind

The BMA is to investigate the psychological effect on doctors of rising patient complaints to assess the personal and professional repercussions of the trend.

Starting next week, the BMA will survey almost all of its members by email for the first time regarding their experience of complaints made to the GMC, managers or other sources.

It will also assess the impact of rising complaints on how GPs practise, asking whether fear of complaints - even among those who have not had a negative experience themselves - is making GPs practise defensively.

The study, led by the BMA Doctors for Doctors Unit, King's College London and Imperial College Healthcare NHS Trust, will survey 119,000 doctors, with a target response rate of 50%.

The BMA said the work did not aim to 'silence patients', but was designed to look at whether

the impact on doctors was proportionate to the seriousness of a complaint. The union said if the study unveiled problems with the complaints-handling process, it would lobby for change.

The BMA said that while the increased complaints had not led to more doctors being struck off, the professional and personal repercussions for doctors were unknown.

Dr Michael Peters, head of the BMA Doctors for Doctors Unit, said: 'If a doctor has a complaint made against them, it goes into their psyche. It is not like being an accountant who slips up; it can mean the destruction of a whole person.'

A BMA statement said: 'The impact on a doctor against whom even a minor complaint is made can be huge and is not well understood. Doctors will be asked about any complaints from whatever source, their views on the fairness of the process they went through as a result, and



Dr Laurence Buckman: 'GPs are usually very badly affected'

Rising GP complaints

Data on complaints from 2011/12 compared with previous year

8.2%
rise in NHS complaints

23%
rise in complaints to the GMC

16%
rise in complaints about list removal to health ombudsman

Source: NHS Information Centre, GMC; health ombudsman

the impact of the experience.'

The move comes after both the GMC and the health ombudsman reported rising complaints against GPs. Recent statistics suggested GPs are increasingly likely to face complaints to the GMC, with the number reported in 2011 up 23% on 2010, from 7,153 to 8,781.

GPC chair Dr Laurence Buckman said: 'GPs are usually very badly affected by complaints.'

Professor Tom Bourne, visiting professor in surgery at Imperial College London, who will help lead the study, said: 'The system is supposed to protect patients. If it is resulting in defensive medicine, the impact may be counterproductive and lead to a deterioration in quality of care.'

GPs urged to cut obesity in staff

GPs would be required to reduce obesity in their staff, under proposals from a peer that have been backed by ministers.

Baroness Finlay of Llandaff, former president of the Royal Society of Medicine, suggested all employers in the NHS should ensure their staff were good role models for patients.

During the debate in the House of Lords, health minister Earl Howe said Baroness Finlay had raised an important point and he wanted employers to tackle the issue.

Cross-bencher Baroness Finlay said: 'Are the Government considering including in commissioning from health service employers a requirement to address obesity in their staff at all levels, given that the staff are

often quite severely obese and act as a very poor role model for those patients whose obesity should be addressed?'

Earl Howe replied: 'Dame Carol Black and I chair a network within the Department of Health which draws together employers from a range of sectors to address health in the workplace.'

'It is a tremendously important opportunity if we can engage good employers to realise that it is in their direct interest to ensure their employees enjoy good health and lead healthy lifestyles.'

Dr George Rae, chief executive of North Tyneside LMC, said the comments were 'absolutely insulting' and should not be taken seriously.

For moderately active ulcerative colitis (UC): Rx Asacol 800mg MR tablets - 4.8g/day (2.4g BD)

Help your newly diagnosed patients and those that flare get back to normal everyday life

Asacol 800mg MR tablets at 4.8g/day were studied in three clinical trials (ASCEND I, II & III) with primary efficacy endpoints at 6 weeks and post-hoc analysis (ASCEND I & II) including efficacy evaluation at 2 weeks¹⁻⁴

Fast symptom improvement (decrease in symptom score from baseline of ≥1 point) in **73%** of patients at just 2 weeks⁴

Mucosal healing (endoscopy subscore of 0 or 1) in **80%** of patients, regardless of disease extent at 6 weeks - on oral therapy alone³



Good to be back! Getting back to normal life with Asacol 800mg MR tablets. Asacol 800mg MR tablets are a long-acting mesalazine formulation that helps to control the inflammation in the gut. It is a 5-aminosalicylic acid (5-ASA) derivative. Asacol 800mg MR tablets are available in 800mg and 400mg tablets. The 800mg tablets are taken twice daily with food. The 400mg tablets are taken four times daily with food. Asacol 800mg MR tablets are a long-acting mesalazine formulation that helps to control the inflammation in the gut. It is a 5-aminosalicylic acid (5-ASA) derivative. Asacol 800mg MR tablets are available in 800mg and 400mg tablets. The 800mg tablets are taken twice daily with food. The 400mg tablets are taken four times daily with food. Asacol 800mg MR tablets are a long-acting mesalazine formulation that helps to control the inflammation in the gut. It is a 5-aminosalicylic acid (5-ASA) derivative. Asacol 800mg MR tablets are available in 800mg and 400mg tablets. The 800mg tablets are taken twice daily with food. The 400mg tablets are taken four times daily with food.

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IN BRIEF

Award for Peverley

Pulse's star columnist Dr Phil Peverley has won the columnist of the year title at the prestigious British Society for Magazine Editor awards.

RCGP priorities

The RCGP has announced its clinical priorities for 2013/16, including chronic kidney disease, youth mental health and epilepsy.

Outcomes targets final

The final set of outcomes targets the NHS will be held to has been published by the Department of Health.



'Offer every partner £160k to join an ICO'

Leading think tank calls for goodwill pay-off for partners to go salaried

By Emma Wilkinson

GP partners should be offered a one-off goodwill payment of £160,000 each to relinquish their independent contractor status and join an integrated care organisation, a leading think tank is proposing.

A report from the Policy Exchange - often dubbed 'David Cameron's favourite think tank' - says NHS care would be less fragmented if all GPs were salaried employees of ICOs.

The think tank looked at ideas to encourage 'competitive integration' in the NHS.

The Department of Health currently runs integrated health pilots at 16 sites across England, but this report encourages it to go further, bringing together primary, community and acute

NHS services with a single budget for purchase and provision.

It recommended a pilot programme of 10 full-scale ICOs covering a population of around 250,000 each, but warned that bringing GPs into ICOs was a major financial and legal hurdle, given that 'they are essentially private contractors to the NHS'.

It concluded: 'We believe that many GPs currently practising under a partnership model might be encouraged to work on a salaried basis for the integrated care organisation. The "price" for relinquishing their independent partnership status could be the value tied up in the goodwill of their practice lists.'

It goes on to state that it would 'cost the Government nothing' to get GPs to trade the goodwill of their surgeries - something that would currently be against the law.

And salaried GPs might be attracted to work for an ICO by salaries in line with their partnered colleagues.

Henry Featherstone, former head of health and social care at the Policy Exchange and report author, said the NHS was fragmented and full of perverse incentives. He said: 'We need to take the opportunity to reorganise care and one of the ways you could do that is to allow GPs to sell the goodwill of their practice into the ICO.'

Former Conservative Party deputy chair David Prior wrote the report's foreword.

But GPC deputy chair Dr Richard Vautrey said the GPC would oppose any such change because, while it could benefit current partners, 'it would mark an end to general practice as we now know it'.

He added: 'We would vigorously oppose all GPs being forced into a salaried model.'

'This would be the ultimate privatisation of primary care and would see the end of GPs being independent advocates for their patients.'

Dr Johnny Marshall, interim partnership development director for NHS Clinical Commissioners, said he backed the calls for ICO pilots so that models of care could be properly assessed.

But on the issue of GPs giving up their partnered status to join an ICO, he stressed that was just one possible option.

He added: 'We do need a debate about the potential models and how GPs feel about them.'

MORE ONLINE
Join the debate at
pulsetoday.co.uk/forum



Dr Johnny Marshall: 'We do need a debate about the potential models'

Integrated care proposals

- Pilot programme of 10 full-scale ICOs, each covering population of 250,000, equating to 5% of NHS capacity
- Overhaul of QOF and Clinical Excellence Awards to incentivise joint working, e.g. reducing admissions
- Work to calculate the current healthcare-related costs of the most common long-term conditions and adding services such as diagnostics and treatment to NHS tariffs
- A framework to enable financial pooling arrangements between purchasers and providers to work in a virtual model of integrated care

Source: *All Together Now*, Policy Exchange 2012. Full report at pulsetoday.co.uk/practice

Norovirus and rotavirus make early appearance

The annual rise in norovirus cases has struck early this year, according to experts at the Health Protection Agency.

Laboratory reports on the 'winter vomiting' bug so far this season were up by 27% by the end of October, compared with the same period last year, data shows. The norovirus season starts in late July for reporting purposes.

And nationally the number of calls to NHS Direct for vomiting are above expected for this time of year, suggesting higher levels of the bug circulating in the community, the HPA said.

Figures collected through Qsurveillance also show that GP consultations for vomiting

and diarrhoea are above those normally seen at this time, with the latest showing consultation rates of 20.1 and 32.9 per 100,000 practice population, respectively.

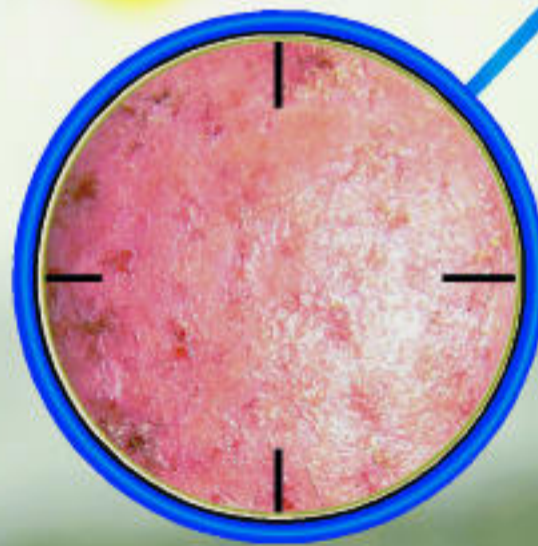
Rotavirus has also put in an early appearance, with a 41% rise in laboratory-confirmed cases in weeks 35-44 of the year, compared with the average over the past decade. But rates have now fallen back to what would be expected in November, the HPA weekly report said.

John Harris, an HPA epidemiologist specialising in the surveillance of norovirus, said: 'Since the beginning of October, we have seen a rise in the number of laboratory reports.'

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Field-directed treatment

PRESCRIBING INFORMATION (Please consult the Summary of Product Characteristics (SPC) before prescribing). **Solaraze™ 3% Gel 30 mg diclofenac sodium**. Active ingredient: Each gram contains 30 mg diclofenac sodium 0.3% w/w. For excipients, see section 6.1. **Indications:** For the treatment of actinic keratosis. **Dosage and Administration:** Solaraze is applied locally to the skin twice daily. Consult SPC and package leaflet for method of administration. **Contraindications, Special warnings etc:** Contraindications: Hypersensitivity to diclofenac sodium or to any of the excipients. Patients with a history of hypersensitivity reactions such as symptoms of asthma, allergic rhinitis, arthritis, angioedema and/or other non-infectious allergic reactions. Solaraze is contraindicated in the presence of pregnancy. **Special warnings, etc:** The possibility of systemic adverse events from application of topical diclofenac cannot be excluded. If the preparation is used on large areas of skin and over a prolonged period, please consult the Summary of Product Characteristics. This product should be used with caution in patients with a history of and/or acute gastrointestinal ulceration or bleeding, or reduced heart, liver or renal function. Caution should be used in patients with intracranial haemorrhage and bleeding disorders. Other cautions, including children, should be viewed during treatment. Solaraze should not be applied to the hands, or lesions or viral virus dermatitis. It should not be allowed to come into contact with the eyes or mucous membranes and

should not be ingested. Discontinue the treatment if sensitivity reactions or a generalised skin rash develop after applying the product. Should not be used with an astringent cosmetic dressing. **Interactions:** Since systemic absorption of diclofenac from a topical application is very low, such interactions are very unlikely. **Pregnancy and lactation:** Not recommended in pregnancy or lactation unless clearly necessary. Consult SPC. If diclofenac is used by a woman attempting to conceive, or during the first and second trimester of pregnancy, the dose should be kept as low as 30% of the body surface and duration of treatment as short as possible (not longer than 3 weeks). Contraindicated during the third trimester of pregnancy and not to be applied to breasts of nursing mothers. **Ability to drive and use machines:** Cautionary application of topical diclofenac has no influence on the ability to drive and use machines. **Adverse Effects:** Common: Conjunctivitis, application site reactions (itching, inflammation, irritation, pain and tingling or burning at the treatment site), hyperkeratosis, hyperkeratosis, localized paronychia, dermatitis (including contact dermatitis), eczema, dry skin, erythema, oedema, pruritus, rash, scale, scaly skin, skin hyperpigmentation, skin irritation, urticaria, rash. **Caution:** Solaraze is related to other NSAIDs. **Legal Category:** POM. **Product Authorisation Number(s):** PL 16973/012. **NHS cost (excluding VAT):** £38.30 - 50 (tube); £76.60 - 100 (tube). **Marketing Authorisation Holder:** Almirall S.A., Avenida General Ballester, 151, 08001 Barcelona Spain. **Further information is available from:** Almirall Limited, 1 The Square, Stockley Park, Uxbridge, Middlesex, UB11 1TB, UK. Tel: +44 (0) 207 866 2500. Fax: +44 (0) 208 7583 988.

Email: [almirall@professionalphaceuticals.co.uk](mailto:almirall@professionalpharmaceuticals.co.uk). Date of Revision: 09/07/12. **Non-UK:** UK031201. Solaraze is a trademark.

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

PRESCRIBING INFORMATION (Please consult the Summary of Product Characteristics (SPC) before prescribing). **ActiKerall 5 mg/g + 100 mg/g Citric Acid Solution**. Active ingredient: 5 mg of diclofenac sodium and 100 mg of citric acid. **Indications:** For the topical treatment of slightly subacute and/or moderately thick hyperkeratotic actinic keratosis (AK) on the sun-exposed skin of the face. **Dosage and Administration:** Citric acid solution. Apply to actinic keratosis once daily. Multiple actinic keratosis can be treated simultaneously. There is experience in treating up to ten lesions at the same time. The total area of skin being treated at any one time should not exceed 15 cm² (5 cm x 3 cm). ActiKerall should only come into contact with the actinic lesions and a size of max. 0.5 cm of the healthy skin surrounding the lesion. The treated area should not be covered after application and the solution should be left to dry to form a film over the applied area. Each time ActiKerall is supplied the existing film

Almirall

Solutions with you in mind

Call for local pay deals for GPs

By Julia Gregory

GP contracts should be negotiated locally to break the 'monopoly' in primary care and allow private firms to manage more practices, says a prominent think tank.

The centre-right think tank Reform said primary care remains a 'cottage industry' with too many small and inefficient practices.

It recommended the national GP contract be broken up to ensure greater co-ordination of NHS services, but the BMA rejected the proposals and said local contracts would undermine the values of the NHS.

In a report into reforming the NHS workforce, Reform concluded: 'To improve the quality and productivity of primary care, and ensure that out-of-hospital care is more coordinated, it is essential to break the GP monopoly.'

'This, in turn, will mean moving from national GP contract negotiations to local contracting arrangements.'

It also called for CCGs to have the power to manage the performance of GPs locally and remove them, if necessary. It said local contracts could free CCGs to bring in private firms and 'more cost-effective providers'.

Reform said: 'Future mod-

els of primary care, such as retail clinics, walk-in centres and large practice groups, as well as community and social care services delivered by a diverse

'It would end up with local pay cartels.'

Dr George Rae



range of public, private and charitable providers also need to be encouraged.'

The report, *Doctors and Nurses*, also launched an attack on the

royal colleges, claiming that professional leadership can 'block more innovative use of health-care professionals'.

It said: 'The royal colleges have focused on protecting the standing of the profession, such as maintaining boundaries between clinicians, but they should lead reform of the profession to raise standards and back employers who seek to innovate.'

But BMA chair Dr Mark Porter refuted the proposals on local contracts. He said: 'Nationally agreed contracts are fundamental to a national health service. Regionally negotiated pay would undermine the national ethos of the NHS, waste resources, and

lead to recruitment problems for some areas.'

Dr George Rae, chief executive of the North Tyneside LMC and a member of BMA council, said local pay contracts were a 'total anathema' to him and would create an 'absolute minefield'.

He said: 'It would end up with local pay cartels. I think a national approach to contracts is what GPs want. We all have shared values. I foresee recruitment and retention problems.'

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and how GPs feel about them'



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...ing should be removed before use by simply peeling it off. Response can be seen as early as six weeks. Response increases over time and data are available for treatment up to 12 weeks. Complete healing of the lesion or optimal therapeutic effect may not be evident for up to eight weeks after treatment cessation. Consult SmPC and package leaflet for method of administration. **Contraindications, Warnings, etc:** Contraindications: Hypersensitivity to the active ingredients or to any other ingredients. Contraindicated in the lactating period, or during pregnancy or by women for whom pregnancy cannot be excluded with certainty. Not to be used in breast patients with usual insufficiency. In conjunction with bromine, camphor and analgesic. Additional must not be allowed to come into contact with the eye or mucous membranes. **Precautions:** Actikerall contains the cytotoxic agent 5-Fluorouracil. Inhibitors, deficiency or increased activity of dihydropyrimidine dehydrogenase (DPD) can result in accumulation of fluorouracil. If applicable, the determination of DPD enzyme activity is indicated before starting treatment with fluorouracil or other fluoropyrimidines. Patients who take phenytoin concomitantly with fluorouracil should be regularly tested for elevated plasma levels of phenytoin. In patients with severe diabetes (e.g. those with diabetic ketoacidosis) close medical monitoring of the treatment area is required. There is currently no data available on the local treatment of other body areas apart from the face, forehead and hair scalp. If areas of skin with a thin epidermis are treated, the solution should be

applied less frequently and the course of the therapy monitored more often. This medicinal product contains dimethyl sulfoxide. May be irritant to the skin. The bottle should be closed tightly after use or the solution will dry up quickly and can no longer be used correctly. The solution should not be used if crystals occur. Should not come into contact with lenses or contact lenses (e.g. acrylic contact lenses) as the solution may cause permanent stain. Contact lenses should be kept away from face or clothes. **Interactions:** The enzyme dihydropyrimidine dehydrogenase (DPD) plays an important role in the breakdown of fluorouracil. Metabolic analogues such as thymidine and uracil may lead to a direct increase in plasma concentrations of fluorouracil or other fluoropyrimidines with associated increase in toxicity. For this reason, an interval of at least 4 weeks between the use of fluorouracil and thymidine, uracil and analogues should be observed. In case of accidental administration of radiolabelled analogues such as thymidine and uracil to patients who are being treated with fluorouracil, effective measures for reducing fluorouracil toxicity should be taken. Admission to a hospital may be indicated. All necessary measures for protection from systemic infections and dehydrations should be introduced. Elevated plasma levels of phenytoin leading to symptoms of toxicity (ataxia, nystagmus, low level) reported with the concomitant administration of phenytoin and fluorouracil. There is no evidence for increased systemic absorption of salicylic acid, however

described salicylic acid may interact with metformin and sulphonylureas. **Pregnancy and lactation:** Actikerall is contraindicated in pregnancy and lactation. **Ability to drive and use machines:** Actikerall has no influence on the ability to drive and use machines. **Adverse Effects:** Very common: erythema, inflammation, irritations (including burning), pain, pruritus. Common: bleeding, erosion, oedema, dryness, irritation, fissures. Consult SmPC in relation to other side-effects. **Legal Category:** POM. **Marketing Authorisation Number(s):** PL 331900055 - 100ml bottle containing 25 ml of solution with brush applicator for patch in a carton. **NHS Cost:** £28.20 (including VAT). **Marketing Authorisation Holder:** Almirall - Hermal GmbH/Schollhausstr. 3, 21405 Hamburg, Germany. **Further information is available from:** Almirall Limited, 1 The Square, Twickenham Park, Twickenham, Middlesex, TW20 1TR, UK. Tel: 020 760 160 2500. Fax: 020 760 7543. Site: Email: clinical.inquiries@almirall.com. **Date of Review:** 19/02/2012. **Item code:** UKATC139.

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

GPs need mental health training

GPs need more training to help them understand mental illness, concludes a report into the state of care for patients with schizophrenia and psychosis.

The Schizophrenia Commission's report said some patients with schizophrenia were being offered 'unacceptable' care by a 'broken and demoralised system' which failed to deliver the quality of treatment they needed to recover.

The report - co-authored by RCGP chair Dr Clare Gerada - said Health Education England and the GMC should urgently review ways for medical students to spend more continuous time in their psychiatric placements.

It argued that greater emphasis should be placed on mental health, rather than the day a week 'which is all too common'. It also said GPs needed more training.

In its report, *The Abandoned*

Service, it said: 'There is a particular need to address gaps in GP and other primary care professionals' skills in working with people with schizophrenia.'

It strongly supported the RCGP's campaign to secure

We need a shared approach to service delivery between GPs and psychiatrists

Dr Clare Gerada

agreement for an extra year of GP training, with a key focus on severe mental illness.

Dr Gerada said: 'We need a shared approach to service delivery between general practitioners, psychiatrists and other mental health professionals working together.'

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Fasting makes very little difference to the results of patients' cholesterol tests, a study has found

CVD

Fasting lipid tests 'unnecessary'

By Pat Anderson

GPs do not need to ask patients to fast before taking a cholesterol test as it makes very little difference to the results, a large-scale study has suggested.

Canadian researchers found that mean levels of total cholesterol and HDL-cholesterol varied by less than 2% among individuals with fasting times of between one and 16 hours.

The researchers concluded fasting for routine lipid levels was 'largely unnecessary', contradicting best practice as recommended by NICE and the Joint British Societies.

Their study looked at the laboratory results of blood samples from 111,048 women and 98,132 men in the community and cross-referenced this with the duration they had fasted before the sample was taken.

The data was from a six-month period in 2011 and researchers controlled for the differing age of patients. They then estimated the mean levels of cholesterol subclasses recorded at different fasting times.



Fasting before routine lipid level tests 'largely unnecessary'

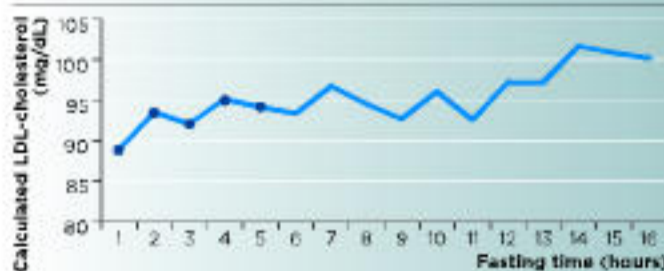
The mean levels of total cholesterol and HDL-cholesterol differed little among individuals with various fasting times, with variations of less than 2%.

Fasting times of up to five hours did show statistically significant differences among calculated LDL-cholesterol levels and triglycerides compared with either a nine-to-12-hour fasting time or a greater-than-eight-hour fasting time. LDL-cholesterol values were also statistically different after over 13 hours of fasting, compared with a nine-to-12-hour fasting time.

But the variations in the calculated LDL-cholesterol levels were low overall, with a variation of less than 10% among patients with different fasting intervals. Mean triglyceride levels showed variations of up to 20%.

NICE recommends 'at least one' fasting blood test to measure total cholesterol, LDL cholesterol, HDL cholesterol and triglycerides. The JBS2 guidelines also recommend a fasting sample 'to measure a full lipoprotein profile' in patients at high cardiovascular risk.

Association between LDL-cholesterol and fasting time in men



Source: Arch Intern Med 2012, online 12 November

● Statistically significant from a greater-than-eight-hour fasting time

The authors concluded: 'We found that fasting time showed little association with lipid subclass levels in a large, community-based cohort. This finding suggests that fasting for routine

lipid level determinations is largely unnecessary.'

Dr Mike Knapp, associate medical director of the British Heart Foundation and a part-time GP in Cambridge, said the findings would reduce the 'hassle' of cholesterol testing.

He said: 'Cardiovascular algorithms are usually based on either total cholesterol or total cholesterol-to-HDL ratio. So I would continue to do cholesterol levels on non-fasting blood, and just select the smaller number of patients for whom I want fasting glucose or fasting lipids.'

Online CPD

Case-based learning: hyperlipidaemia



pulse-learning.co.uk

IBS

Little evidence for IBS acupuncture on NHS

There is little evidence to support the widespread use of acupuncture for irritable bowel syndrome on the NHS, although it may be cost effective for patients with severe IBS, say UK researchers.

Their probability analysis found that, at a value of £30,000 per QALY gained, acupuncture had a 40% chance of being cost-effective for patients with IBS.

The study looked at 233 patients recruited from GP practices in England. Over 110 were randomised to receive acupuncture alongside usual GP care, while 117 received usual GP care alone. All patients were followed

for one year post-randomisation. Acupuncture resulted in a £52,429 per QALY gained using information on both IBS and non-IBS costs to the NHS.

The equivalent figures for subgroups was a cost-effectiveness ratio of £6,377 per QALY gained in patients with severe IBS. The probability that acupuncture is cost effective in this group was 60%, based on a threshold of £30,000 per QALY.

The University of York researchers said: 'This trial does not support the use of acupuncture for IBS patients as an appropriate use of NHS resources.' *Gastroenterology* 2012, available online 24 Oct

PNEUMOCOCCAL INFECTION

Pneumo jabs only cost effective for liver disease

Immunising at-risk groups for pneumococcal infection is unlikely to be cost effective for most patients, conclude Dutch researchers.

Their economic evaluation found that, of all the high-risk groups included in a pneumococcal vaccination programme, just one cost less than the threshold of £30,000 per QALY gained.

The study included people aged two years and older who were at an increased risk of invasive pneumococcal disease due to falling into one of eight at-risk groups: chronic kidney disease, splenic dysfunction, HIV, a compromised immune system,

chronic heart disease, chronic liver disease, a chronic respiratory illness or diabetes.

Only vaccination of patients with chronic liver disease was deemed cost effective, costing £20,324 per QALY gained. HIV was the next most cost effective, at £61,200 per QALY gained, but was under the cost-effectiveness threshold.

The researchers concluded: 'We found that the cost effectiveness of the 13-valent pneumococcal conjugate vaccine programme based on risk group will mainly depend on the time of using the vaccine and its effectiveness.'

BMJ 2012, available online 26 October

CANCER

Bone drug cancer risk for women

Bisphosphonate use is associated with an increased risk of cancer, particularly in women, according to new research on a UK cohort.

Researchers from London found a 13% increased risk for upper gastrointestinal cancer in those who had taken bisphosphonates compared with patients who had not.

The study included 8,636 men and women who had a recorded incident of upper gastrointestinal cancer, matched to 34,544 controls with no record of upper gastrointestinal cancer. Bisphosphonate use was defined as any patient having been prescribed one during the 13-year period.

Women taking bisphosphonates had a 34% increased risk of cancer, adjusted for smoking status, compared with controls, whereas men experienced a 19% decrease in risk.

When they restricted analysis to look at oesophageal cancer alone, they found a 43% increase in risk for women who had taken bisphosphonates, compared with controls. For men, there was a 13% decrease compared with controls.

The researchers concluded: 'It would be sensible to exercise caution in prescribing bisphosphonates to patients with pre-existing risk factors for upper gastrointestinal cancer.'

PLOS One 2012, online 24 October

GUIDELINE ROUND-UP

Omalizumab loses NICE backing

NICE has withdrawn its recommendation that omalizumab should be used as an add-on therapy for severe persistent allergic asthma in adults and children over 12 years. The new appraisal has suggested the evidence relating to long-term efficacy of the drug in adult populations is very limited, and that there is a lack of evidence on improvement in children.

NICE TA133, 7 November

Scots accept new bronchodilator

The Scottish Medicines Consortium has accepted acclidinium bromide as a maintenance bronchodilator in adult patients with COPD. The recommendation is based on two studies that showed the antimuscarinic acclidinium bromide was better than placebo at improving FEV1. *SMC*, November 2012

Steroids useful for Bell's palsy

Oral steroids are likely to be the most effective treatment for recovering full-strength facial muscles in people with first-time symptoms of Bell's palsy, says a new guideline from the American Academy of Neurology. The guideline states that short-term use of steroids was safe and tolerable.

Neurology 2012, online 7 November

CVD

BMI rivals cholesterol as indicator of CVD risk

BMI should replace cholesterol in CVD risk tools, as its predictive power is almost equivalent, suggests a new analysis.

An analysis in 18,000 patients older than 16 years has found BMI is better at discriminating between people at high and low CVD risk than total cholesterol.

Framingham does not currently include any measure of BMI when estimating the cardiovascular risk of patients, but the researchers found BMI was

significantly associated with mortality and had a better predictive ability compared with cholesterol.

The difference in Brier scores between BMI and the cholesterol prediction models was small, but higher for the BMI model, with scores of 17.46 and 17.48 respectively.

The researchers concluded: 'Our results suggest that BMI may be a valuable alternative to cholesterol in CVD risk prediction models.'

Arch Intern Med 2012, online 12 November

CPD TIP OF THE WEEK

No evidence for amitriptyline in headache

A course of up to 10 sessions of acupuncture over five to eight weeks is the recommended prophylactic treatment for chronic tension-type headache, according to a case-based learning module.

Although amitriptyline has been recommended in previous guidelines, NICE now says there is no strong evidence to recommend use of pharmacological prophylaxis for patients with chronic tension-type headache.

Only one study comparing the use of amitriptyline with placebo featured in the guidelines, but this was deemed to be of low quality and not enough to warrant recommendation of the drug for prophylaxis.



ONLINE CPD

See guideline rebrief: headache at pulse-learning.co.uk

Leave prescribing to the experts

A GMC review published in May this year received a lot of attention for its finding that as many as one in 20 GP prescriptions contains an error.

What received less attention was the study's conclusion that serious errors are rare and the majority of GP prescribing is safe, proportionate and responsible. But despite this, there has been a steady erosion in recent years of the role of the GP as gatekeeper of the FP10.

First there were patient group directions, then supplementary prescribers and independent prescribers, and the dangerous rise in the availability of mail-order prescription-only medicines via the internet.

But most divisive of all has been the drive to make more medicines available without a prescription in pharmacies.

This move - first mooted in Labour's NHS Plan in 2000 - was designed to increase the availability of prescription-only medicines and enable patients to self-care. A laudable aim, but clumsy in its execution.

The Medicines and Healthcare Products Regulatory Agency (MHRA) made it a high priority, leading to a number of drugs being declassified from prescription only to the pharmacy sales list, including simvastatin, sumatriptan and chloramphenicol.

This was a massive boon to the pharmaceutical industry and the status of pharmacists as a profession - but GP leaders questioned whether adequate safeguards had been put in place and if the commercial imperative in pharmacies could interfere with good medical care.

Then the MHRA approved a trial of making the antibiotics azithromycin and trimethoprim available without a prescription in 2008. This move led to uproar from microbiologists, who argued it would



Nigel Praities
Deputy editor

undermine the campaign to minimise antimicrobial resistance.

In 2010, the Government's own advisers asked the DH to exclude antibiotics from the POM-to-P reclassification drive. It was a welcome injection of common sense into what was becoming a free-for-all.

But as we learn this week, the National Pharmacy Association has continued quietly making prescription-only medicines - including several antibiotics and salbutamol inhalers - available under patient group directions.

The list of 16 medicines it is planning to make available in all 12,500 pharmacies from January has incensed GP leaders and led to urgent talks with the DH after being alerted to the scheme.

Pharmacist leaders claim the service is more convenient for patients and will free up GP time, but that completely misses the point. A prescription may only be a flimsy

bit of green paper, but it represents a whole process of medical training, checks and lines of responsibility to ensure that patients are kept safe.

The MHRA guidance is clear that patient group directions must only be used when there is an 'advantage for patient care without compromising patient safety'.

There were no adverse events in the pilot of the NPA's scheme but, particularly in the case of antibiotics and asthma medicines, prescriptions should be part of a wider care plan for patients and an appreciation of the wider health of the population.

The DH must call a moratorium on this and all other such schemes, at the very least until appropriate approval procedures are put in place to consider their wider impact.



Do you agree? Let us know by emailing Nigel at nigel.praities@pulsetoday.co.uk

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Time to dig our heels in over the latest contract crisis

From Dr Kaiser Chaudhri
Preston

Despite grassroots GPs warning of the dangers of some aspects of the 2003 contract, the GPC did not take notice. As a result we are now at breaking point, with the Department of Health regularly threatening to change the GMS contract and shuffling around QOF points at every opportunity.

It is difficult to say what the GPC should do now to try and wrest back some control over GP workload and pay. Half-baked strikes are a waste of time. Perhaps the GPC needs to start talking openly about the likely 'consequences' of the planned imposition rather than industrial sanctions that might require a ballot ('BMA refuses to rule out ballot on strike over GP contract deal', pulsetoday.co.uk/news).

For example, tightening QOF indicators will lead to a vast increase in referral to secondary care. Similarly, if GPs are tied up with lots of new work they will have less time to deal with emergencies and are likely to direct ill patients to A&E.

There is only so much time in the day available for GPs to fit in their work. If many new duties are added, the result will be to divert a lot of existing work to secondary care, which will lead to a massive increase in costs. This isn't industrial action on our part, but a predictable consequence of the Government's ill-thought plans.

● From Dr Mike Ashcroft
Wigan

Haven't we heard all this debate over the contract before? We had exactly the same headlines in 2004, and those of us with longer memories will recall 1990 as no different.

The politicians will set their battle lines, with minuscule carrots and threats about what will happen if we don't comply. They will prime the *Daily Mail*, eager for 'shock horror' stories about greedy GPs. The GPC will huff and puff and hope to eke some morsel from the carnage, and present it to the profession as 'the best deal under the circumstances'. Then we'll get on with work as we always do, with less remuneration for more effort. Then the politicians will renege on the parts of the contract they don't like because the 'contract' will have a clause in it that says they can basically do what they want, when they want. And then in a few years we'll have a set of different politicians imposing yet another contract, and so on. It is as it has always been.

I have little confidence in our ability as a profession to change anything. The 'day of action' this year in support of GP pensions was a damp squib because most practices did not take part. Mine did, and had

LETTER
OF THE
WEEK



The Government's new contract for GPs could cost more money

superb support from patients. What a wasted opportunity to be united and strong. Politicians know we are politically weak and take advantage of that. Unfortunately we get what we deserve.

Can I make a plea to all GPs to think hard about any contract they sign? Let's not repeat the mistakes of 2004, when we were led like lambs to the slaughter. Politicians have tuition in how to be evasive and deceitful when answering questions. They have no interest in patient care unless it affects their electoral chances. If they thought euthanasia was popular it would be part of QOF. Whatever they come up with is unlikely to be in the interests of patients or GPs, so why sign it? Because the GPC says we should? Or because everyone else is signing it? Not good enough. Think about it. If we all dig our heels in, are they going to sack us all? I think not.

MPIG is a fudge that has to go

From Dr Brett La Hay
Dundee

I am a partner in a practice that receives zero MPIG weighting. When the new contract was brought in more than seven

years ago there were promises of payment for quality practice and equality of funding for patients. Instead the GPC negotiators delivered a fudge called the MPIG that has entrenched inequality.

How can it be right to pay some practices far less per patient than others? The excuse the GPC is using now is that the extra money is for work done. Please can someone tell me when this assessment of the work each practice does was carried out? This is a lame excuse for inequality in funding.

I am disappointed to see our so-called professional leaders using exaggeration and hyperbole in their negotiations with the government. The 'bloodbath' you refer to in the story, ('Bloodbath' predicted for GP practices due to MPIG phase-out', pulsetoday.co.uk/news) actually means some GPs will have their income reduced and won't like it.

My practice has experienced seven years of this lower income and my patients have had fewer services because of it. 'Destabilising' general practice just means some practices resent change. I resent the continuing disadvantage MPIG gives to my patients and me.

How can the GPC continue to ignore the fact that some practices are unfairly rewarded compared with those on low

or zero MPIG? When are our political leaders going to do something about that?

For once I side entirely with the Government and would ask the profession to think about the whole picture and not just self-interest.

Changing the formula is not the answer

From Dr Brian McGregor
York

via pulsetoday.co.uk

In his article, 'Scrapping Carr-Hill is long overdue' (pulsetoday.co.uk/comment), Dr John Ashcroft writes that 'it has long been accepted that the most effective way to reduce health inequalities is to invest in primary care'. I disagree - don't housing, social care, and nutrition all have greater effect?

Politicians tried to manipulate the Carr-Hill formula for deprivation using the MPIG, which threatened to destabilise hundreds of practices. Considering they also want to influence the new formula for deprivation, it seems politicians and the DH have short memories.

Best action is to boycott CCG work

From Dr Malcolm Freeth
Retired GP, Bournemouth

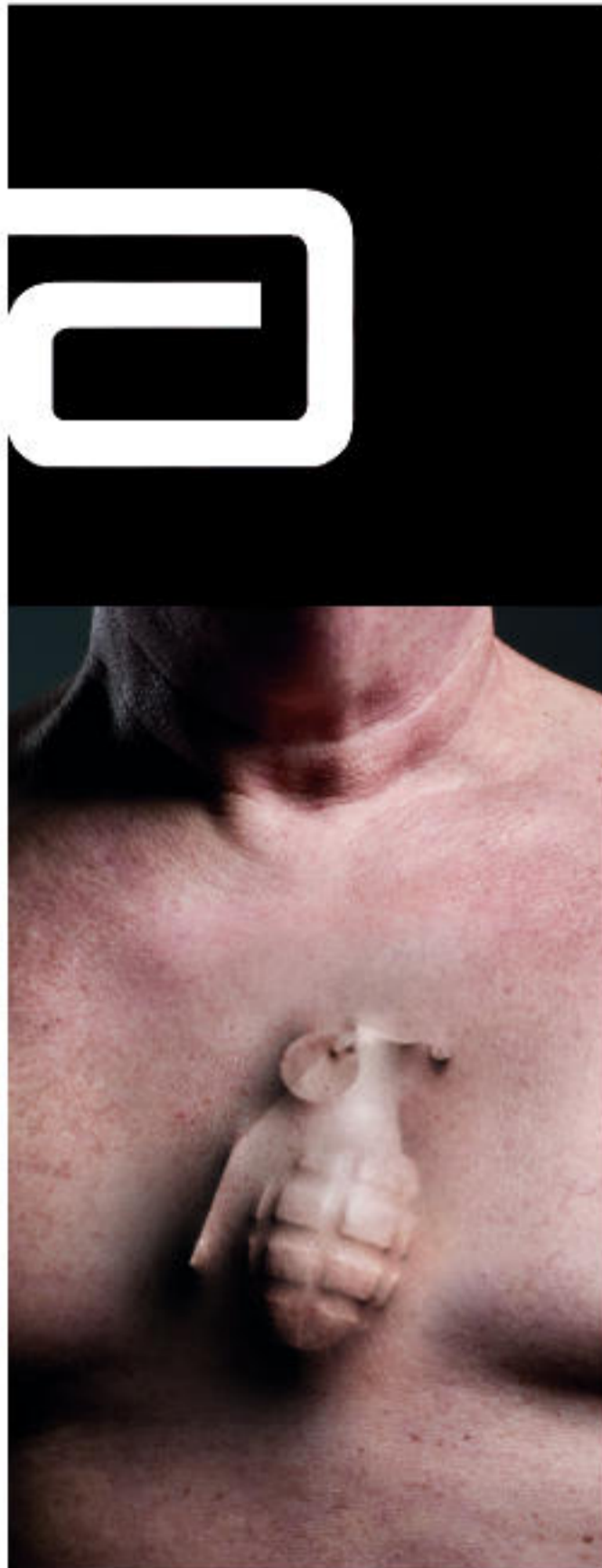
via pulsetoday.co.uk

The last BMA ballot on industrial action resulted in a poor result for the profession ('BMA refuses to rule out ballot on strike over GP contract deal', pulsetoday.co.uk/news). The Government now believes there is no will in the profession for action. In truth, there is little action that would not result in some difficulty for patients - and few GPs will want this. The obvious action to take, which would need almost all GPs to act in concert, would be to withdraw from CCGs and cease other committee work with PCTs. But does the profession have the will to take this action?

● From Dr Alyson Jones
Edmonton, north London

via pulsetoday.co.uk

When we signed the new contract we were promised that the clause allowing the Government to unilaterally alter the contract would only be invoked in times of national emergency (such as a natural disaster or pandemic). We couldn't believe them then, and we can't believe them now, so it seems that withdrawing from CCGs is the only action to take.



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Date of preparation: April 2012

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Constitution rules are a nonsense

From Dr Andrew Milmagh
Chair of Sefton LMC and GP,
Sefton

Via pulsetoday.co.uk

I read your story, 'CCG constitutions legally binding whether signed or not' (pulsetoday.co.uk/news) with interest. I have just completed drafting a contract with Her Majesty's Government entering into a partnership with myself, which claims 50% equity of the gross national product of the United Kingdom of Great Britain and Northern Ireland. Unfortunately a party to the contract has not signed it but, as with the CCG constitution, I believe it is binding. On a more serious note, anyone who seriously believes that several hundred years of contract law can be dispensed with in the manner the government suggests should dream on.

'Certificate culture' holds jabs back

From Dr Tom Inskip
Bedford

Via pulsetoday.co.uk

I think that a major part of this problem ('Midwives duck out of whooping cough campaign', pulsetoday.co.uk/news) is the farce of the ever-escalating retraining that

professionals need to do. It is the fear of a job being given without the back-up of a certificate, that means managers prevent their staff giving either flu or pertussis vaccination.

Harmoni sale is business logic

From Dr Jane Lockhart
Retired GP, Ashton under Lyne
via pulsetoday.co.uk

I was interested to read your story, 'Care UK buys largest GP out-of-hours provider' (pulsetoday.co.uk/news). Up until fundholding was first introduced, the NHS didn't really have a business model. Nothing was costed, there was little consistency of practice and money was wasted by the bucketload. But what we are now witnessing is the tail end of the process, started by fundholding, of trying to impose some business sense on the NHS.

I do not question that this is a necessary process, however it has been hampered at every stage by party politics of all colours.

Sexual health must be GPs' responsibility

From Dr Aqeela Ansari
Manchester

Via pulsetoday.co.uk

Sexual health must be the responsibility of GPs and they must be funded appropriately

('We can't let sexual health services go without a fight', pulsetoday.co.uk/comment). GPs are the first point of access for most women, especially for those over 20, so fragmentation of sexual services will have damaging effects on women's health. Current provision of sexual health services and the resulting good outcomes have only been achieved after long years of hard work.

Ombudsman is making a leap too far

From Dr Arturo Lupoli
Solihull

Via pulsetoday.co.uk

The ombudsman recognises in her annual report that there have been a total of 16,337 complaints, of which 399 were investigated by her team ('Rise in patient complaints after being removed from GP lists', pulsetoday.co.uk/letters). Out of that 399, 10 were about GPs removing patients from their lists. On the back of this, Dame Julie and her team are able to link this with the ability of GPs to engage with commissioning. What nonsense!

This smacks of political interference

From Dr Mark McCartney
Cornwall

Via pulsetoday.co.uk

After reading the story on

complaints, I didn't understand how the ombudsman can link this issue to commissioning. This smacks of political interference - they should just stick to what they are asked to do.

I would have expected better

From Dr David North-Coombes
Chertsey, Surrey

Via pulsetoday.co.uk

If this is the sort of comment the health ombudsman makes I would seriously question whether she is the proper person for the job. It is rather inane and immature, and it comes from someone who should be more responsible and know better.

Evidence of faith's health benefits

From Dr Richard Scott,
Margate, Kent

I am grateful to Dr Andrew Clarke in last week's Pulse for requesting the source of evidence on the influence of faith on patients' health ('Where is the evidence on religion?' pulsetoday.co.uk/news).

Three American professors, under the leadership of Professor Harold Koenig, found many conditions studied were seen to improve with the influence of faith. Most of the rest of the conditions he studied showed no association, with only a small proportion showing negative results.

Since then, Koenig et al have discovered an exponential increase in papers and reviews (now 4,000) on the subject. A second edition of *The Handbook of Religion and Health* by Koenig, King and Carson (ISBN: 978-0-19-533595-8) has been published this year.

For the record

Pulse's priority is accuracy. However, in the busy process of preparing a weekly publication, mistakes can occur. To draw our attention to an error, email letters@pulsetoday.co.uk



The sale of out-of-hours provider Harmoni shows the NHS has warmed to business sense



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the vaccine virus has not been reported. However, post-marketing experience with varicella vaccines suggest that transmission of vaccine virus may occur rarely between vaccinees who develop a varicella-like rash and susceptible contacts (for example, VZV-susceptible infant grandchild). Transmission of vaccine virus from varicella vaccine recipients without a varicellozoster virus (VZV)-like rash has been reported but has not been confirmed. This is a theoretical risk for vaccination with Zostavax. The risk of transmitting the attenuated vaccine virus from a vaccinee to a susceptible contact should be weighed against the risk of developing natural zoster and potentially transmitting wild-type VZV to a susceptible contact. As with any vaccine, vaccination with Zostavax may not result in protection in all vaccine recipients. **Pregnancy and lactation:** Zostavax is not intended to be administered to pregnant women. Pregnancy should be avoided for three months following vaccination. Caution should be exercised if ZOSTAVAX is administered to a breast-feeding woman. **Undesirable effects:** Very common side effects include: pain/tenderness, erythema, swelling and pruritus at the injection site. Common side effects include: warmth, haematoma and induration at the injection site, pain in extremity, and headache. Post marketing use has shown hypersensitivity reactions including anaphylactic reactions, joint and muscle pain,

fever, swollen glands, rash, also hives and rash at the injection site. For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **Package quantities and basic cost:** Vial and pre-filled syringe with two separate needles. The cost of this vaccine is £99.96. **Marketing authorisation holder:** Sanofi Pasteur MSD SNC, 8 Rue Jonas Salk, F-69007 Lyon, France **Marketing authorisation number:** EU/1/06/341/011 **Legal category:** PCM * **Registered trademark:** **Date of last review:** June 2012

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References: 1. Miller E, Marshall R, Wudien J. Epidemiology, outcome and control of varicella-zoster infection. *Rev Med Microbiol* 1993; 4: 222-30. 2. Bowsher D. The lifetime occurrence of Herpes zoster and prevalence of post-herpetic neuralgia: A retrospective survey in an elderly population. *Eur J Pain* 1999; 3: 335-42. 3. ZOSTAVAX[®] SmPC.
* The need for a second dose is currently unknown



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Workforce crisis needs race response

From Dr Shaba Nabi
Training programme director,
Bristol GPST (part of the
Severn Deanery) and GP,
Bristol

via pulsetoday.co.uk

I am very concerned about the disparity in CSA pass rates between local graduates and international medical graduates (IMGs) ('RCGP faces legal threat over international GP trainee failure rates', pulsetoday.co.uk/news). I completely dismiss the accusations of institutional racism; it is not as simple as that. The bigger issue is the prioritisation of core values and competencies within the RCGP.

Interpersonal skills, while crucial, should not trump all other skills such as effective decision making, management and emotional resilience. Most of the MRCGP is weighted towards white, middle-class females – as shown in the reflective e-portfolio logs and the CSA. I totally agree with the frustrations of international medical graduates who have undergone rigorous selection procedures, successfully completed consultation observation tools and case-based discussions, only to be told they are not up to scratch. The college and the GPC need to wake up to the fact that we do not have enough GP recruits to fill future capacity and those who are qualifying are likely to pursue a part-time career in a salaried post.

From Dr Stuart Buchanan
GP trainee, Lurgan,
Northern Ireland
via pulsetoday.co.uk

Part of general practice training is the management of divergent views, and cultural awareness features prominently in the curriculum – hence I would have hoped for an air of co-operation when looking at the reasons for the disparity in pass rates between different candidate groups.

Constructive analysis is what is needed here, not threats of legal action.

From what I gather, the British Association of Physicians of Indian Origin, an organisation that represents the interests of one nationality, is implying that the examiners of the RCGP, which I understand to be a multicultural organisation, discriminate against non-UK graduates, hence by definition, are racist, even if they have not actually used the word itself.

Such language is likely to be inflammatory and damaging to the profession, creating rifts within our ranks at a time when unity is needed more than ever. I am sure the DH can't wait to use this as ammunition to further undermine the profession – I will keep an eye on the news stand for the next headlines... 'Racist College of General Practitioners in exam scam'.

I hope that common sense prevails and that the GMC acts

swiftly to deal with anyone making unprofessional or unfounded allegations in what is a very sensitive area, so that this situation does not spiral out of control.

From Dr Prasad Thakur
Leicester

via pulsetoday.co.uk

Many of the comments here reflect the head-in-the-sand attitude adopted by the RCGP, when confronted with cold, hard facts.

Explanation should be sought for the steep drop in percentage of IMGs passing the CSA from September 2010 onwards. If these IMGs were so pathetic, how did they manage to clear their workplace-based assessments and their annual review of competence progression? Does this mean an abysmal incompetency on the part of their trainers and other assessors, who have failed to spot these extreme deficiencies in the initial vocational training years? Changes to the CSA were randomly imposed without proper consultation with the trainers or the trainees. Most trainers did not have a clue about the new system, even when their trainees were just days away from the exam.

The RCGP lacks insight into its actions. An impartial consideration of the facts by the judiciary is the need of the hour.

From Dr Imran Malik
Norwich

via pulsetoday.co.uk

If an exam system is subject to this sort of criticism after two years, then there must be some reason for it. Clearly this exam cannot be classed as a 'standard' and fair exam if it is seen to favour one side of the spectrum. If we make the necessary changes to the system to make it more fair then we learn from these experiences.

From Dr Martin Shutkover
Featherstone

via pulsetoday.co.uk

The CSA is, to a considerable extent, a test of communication and language skills. If I wanted to practise as a GP speaking a language other than English I would expect to find it difficult and would not be surprised to find other first-language English speakers similarly disadvantaged with a tendency to have a higher failure rate for a CSA-type exam than doctors who were native language speakers. So this is nothing to do with racism.

What would be of concern to me would be if candidates from a visible racial minority, but who were raised as native speakers of English and trained in the UK, were failing more often.

CQC doesn't want reams of paperwork

From Professor David Haslam
National Professional Adviser,
CQC

While I have always found Dr



The percentage of international medical graduates passing the CSA has fallen sharply since 2010

I really do think it's important to point out to Pulse readers that CQC absolutely does not want, or require, box files full of 'protocols' cluttering up shelves in surgeries ('One more policy and I'll scream', pulsetoday.co.uk/copperfield).

Providers will not have to submit reams of evidence with their application and we wouldn't expect providers to have to collect much information that they don't already have. The majority of providers who have already

made their application will confirm this to be the case along with those involved in the inspection pilot. To support those who have yet to make an application and to all providers who will be inspected from next year, we will repeat our

position over and over again: while they will need to be able to demonstrate compliance if asked, I am fully confident that a well-run surgery will be able to do this without any problem.

We will be publishing the findings of our inspection pilot soon, which will include some first-hand experience of the inspection process from the practices involved, and their apparent surprise at discovering we really weren't obsessed with protocols and paper. I hope this will help prove that a good practice has nothing to fear from CQC registration and on-going monitoring of compliance.

From Dr Joe McEvoy
Derry

via pulsetoday.co.uk

Dr Copperfield's blog has crystallised my feelings exactly – the politicians are transforming a challenging – but rewarding – job into an unpleasant and impossible one. Now are we going to do anything about it?

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References:

1. Grew SJ, Skjott GA. Foam Preparations for the Treatment of Ulcerative Colitis. *Gastroenterology*. 2011 Jun 14.
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suppression and acute adrenal crisis, particularly in adolescents and children, or potentially as a result of trauma, surgery, infection or rapid dose reduction. Patients should be advised that flutiform contains a small amount of ethanol; however this negligible amount does not pose a risk to patients. flutiform is not recommended in children under 12 years of age. Interactions: Caution is advised in long-term co-administration with strong CYP3A4 inhibitors (e.g. ritonavir, atazanavir, clarithromycin, indinavir, itraconazole, nelfinavir, saquinavir, zalcitabine and zalcitabine); co-administration should be avoided if possible. flutiform in particular should be avoided, unless the benefits outweigh the risks of systemic side-effects. Caution is advised with use of non-potassium sparing diuretics (e.g. loop or thiazide), vanilign derivatives, glucocorticosteroids, L-Dopa, L-tyrosine, cyclosporin, alcohol or other adrenergic drugs. There is an increased risk of arrhythmias in patients receiving concomitant anaesthesia with halogenated hydrocarbons. Hypokalaemia may increase the risk of arrhythmias in patients being treated with digitalis glycosides. Concomitant use of β-adrenergic drugs can have a potentially additive effect. Extreme caution should be taken when using formoterol fumarate with drugs known to prolong the QTc interval, such as tricyclic antidepressants or MAOIs (and for two weeks following their discontinuation), as well as antipsychotics (including phenothiazines), quinolones, disopyramide, procainamide and antiarrhythmics. Concomitant use of an MAOI or a similar agent, such as fenoldopam or procainamide, may precipitate hypertensive reactions. β-blockers and formoterol fumarate may inhibit the effect of each other. β-blockers may produce severe bronchospasm in asthma patients, and they should not normally be treated with β-blockers including those that are used as eye drops to treat glaucoma. Under certain circumstances, e.g. as prophylaxis after myocardial infarction, cardioselective β-blockers could be considered with caution. Pregnancy and lactation: flutiform is not recommended during pregnancy. It should only be considered if benefits to the mother outweigh risks to the foetus. It is not known whether fluticasone propionate or formoterol are excreted in breast milk; a risk to the breast feeding infant cannot be excluded. A decision should be made on whether to discontinue breastfeeding or discontinue/abstain from flutiform. Side-effects: Potentially serious side-effects: hyperglycaemia; depression; aggression; behavioural changes (predominantly in children); paradoxical bronchospasm; agitation; vertigo; palpitations; ventricular extrasystoles; angina pectoris; tachycardia; hypertension; dyspnoea; peripheral oedema; Cushing's Syndrome; adrenal suppression; growth retardation; cataract and

glaucoma; hypersensitivity reactions and QTc interval prolongation. Please consult the SPC for details of non-serious side-effects and those reported for the individual molecules. Legal category: POM Package quantities and price: One inhaler containing 120 actuations 50 µg/5 µg - £18.00, 125 µg/5 µg - £29.25, 250 µg/10 µg - £45.55 Marketing Authorisation numbers: PL 16950/0167 PL 16950/0168 PL 16950/0169 Marketing Authorisation holder: Napp Pharmaceuticals Limited, Cambridge Science Park, Milton Road, Cambridge CB4 0DN UK. Tel: 01223 424444. Member of the Napp Pharmaceutical Group. For medical information enquiries, please contact medinfo@napp.co.uk

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UK/FLUT-11019
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*The 'lung' device (logo) is a registered trade mark of Mundipharma AG.
Date of preparation: October 2012.
EU/RES-11058p
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RESPIRATORY

The sad folly of the food diary



Instead of ripped abs, **Phil's** foray into personal training has merely given him insight into the fibs patients tell

There is a new tyrant in my life. His name is Adam and he is my personal trainer. He's a whipcord-straight lycra-clad *Sturmabannführer*. Strutting about and barking orders at me at random, he appears to be wearing an invisible sergeant major's uniform. He makes my life a total misery.

Twice a week we meet for my ritual humiliation (for which I pay thirty quid an hour). During this time, he makes me squat and crouch in inelegant positions, sometimes carrying a heavy rubber tube on the back of my neck.

He tells me this will improve the strength in my thighs, but to be honest I suspect that he is subjecting a 'rather stout gennelman of eight-and-forty' (as Dickens might describe me) to some embarrassing procedures that involve me inelegantly sticking my arse out, for the edification and entertainment of the excessively toned lycra-clad gym bunnies elsewhere in the establishment.

"Tuck those buttocks in!" he bellows at

me. This puzzles me. How am I supposed to do that, exactly? Does he think that I have retractable ones?

I don't agree with much of what he says. Why am I supposed to drink four litres of bottled water every day? My cardiologist seems to think it's important that I take a diuretic, so who's right? I don't question Adam however, because I can imagine what he would say, which would be 'Drop and give me 50!' And that would be just the start of it.

I'm slightly sorry that he hasn't asked me for a note from my GP (which is still me; I know, I know) saying it is 'safe' for me to do cripplingly arduous exercise. I would have handed him a scribbled note saying 'I'll take the risk, signed, Me.' But he doesn't appear to be worried that I'll drop dead, even though it often feels like I might.

Adam has invaded other aspects of my life. I have to give him a food diary, and this is where it gets relevant for GPs. Heisenberg's uncertainty principle applies mainly to quantum physics, but there is another version known as the observer principle that applies to all other aspects of life, and it is this; it is

I'll carry the pasty over, in case I don't have time for lunch

impossible to measure or record anything without altering it.

I find it is simply impossible to record an accurate food diary. No one reading it would believe it, and no one recording it would do so accurately. Let's have a look at mine, today.

Breakfast; nothing. OK, fair enough. Lunch; couldn't decide between a corned beef sandwich and a corned beef pasty from the shop, so bought both. Can't write both of those down, or Adam might karate-chop me to the back of the neck, so I'll carry the pasty over until tomorrow in case I don't have time for lunch. Could happen, I suppose. Dinner tonight; corned beef hash.

Snacks; half a jar of Branston pickle with a teaspoon. Can't write that down, because it's ridiculous, despite the fact that we've all done it. Second snack; cold baked beans drunk out of the tin in front of the telly. This is similar to drinking any liquid, except it takes a lot longer. Again, ludicrous, so I can't write that down either. So I put 'a dry Ryvita, spread with absolutely nowt'. Maybe Adam will believe it, and not bury me up to my neck in sand.

The point being, ladies and gentlemen, don't bother asking any of your patients to record any sort of diary, whether it's diet, periods, headaches, fits, or anything else. They'll lie to you. I'm my own GP, and I even lie to myself.

Dr Phil Peverley is a GP in Sunderland

Margaret McCartney

Picking up the pieces



Why does the NHS always seem to bear the costs of ill-conceived private contracts, asks **Margaret**

There can hardly be a GP in the land who has not noticed the mess that we are being invited to mop up over the Government's work capability assessments.

The programme to reassess whether people on benefits are fit for work - as contracted out to the French technology company Atos at a cost of £100m a year¹ - is creating distress in patients and additional workload for practices as many people are told to ask their GP for a letter to try and support their claim.

We are asked to fill in cursory forms that give space only for confirmation of the diagnosis; barely any space to describe the impact of illness on a patient. A doctor recently wrote in the *BMJ* about how difficult she found the process; how much worse is it for patients who are unused to form filling and bureaucracy?²

The fall-out for ordinary people is immense. Many people who have worked all their lives and who feel guilt and shame

at being 'burdens' on the state find the process of claiming benefits humiliating and degrading.

There are multiple harms created for citizens that are going unmeasured - the ongoing stress of the uncertainty of the process has profound impacts on many people's health.

The costs of this are not being borne by the company running the scheme; the NHS is bearing the brunt of them.

Earlier this year, the LMCs conference called for the process to be scrapped, saying it should be replaced with 'a rigorous and safe system that does not cause avoidable harm to some of the weakest and most vulnerable in society'.³

It is not a fair system (and there is copious evidence of its unfairness) and its failings will be borne by the most vulnerable. The stress caused by its inadequacies will be pushed on to the NHS.

People who have worked all their lives feel shame at claiming benefits

Of the many people who appeal, some 38% win.⁴ People who have the help of agencies such as Citizens' Advice are more likely to be successful at appeal - suggesting that the process does not favour people unfamiliar with the system.²

In October, Margaret Hodge MP, chair of the Public Accounts Committee, described the Government's contract with Atos as 'unacceptably loose and (permitting) loopholes that can all too easily be exploited by contractors'.⁴

Let's hope the £400m contract Atos won in August to reassess people for the new Personal Independence Payment, which will replace the Disability Living Allowance, is not also full of similar 'loopholes'.

I believe this will be a recurring problem as large Government contracts with the private sector become more involved in healthcare. Why on earth are we franchising out the care of our most ill to a profit-making system? We need to pull the plug on these contracts.

Dr Margaret McCartney is a GP in Glasgow

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- 1 National Audit Office 2012, Contract management of medical services HC527 Published Oct
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- 3 *BMJ* 2012, UK Government's contract with Atos is 'unacceptably loose', MPs say. Published 22 Oct
- 4 Public Service 2012, Hodge: DWP management contract is 'easily exploited'. Published 22 Oct

Revalidation is not worth its cost

The £97 million bill would be better spent on patient care, writes
Dr Peter Swinyard

Does revalidation offer value for money in times of severe financial stringency? The days of above-inflation increases in NHS resources are now long gone and the ever increasing costs of health care, forced up by an ageing demographic, increasing needs for dementia care (both real need and political imperative) and increasing costs of new treatments are conspiring to add pressure to budgets across the health service.

Pulse reported last week that the scheme will cost doctors over £450 in 'opportunity costs' per revalidation cycle and will only prevent 0.75% of cases of death, severe harm and moderate harm per year ('Revealed: Revalidation will cost £97m a year', pulsetoday.co.uk/news).

I am aware of the need not to be too cynical about improving standards in general practice. For instance, I find appraisal helpful - if only because some poor colleague of mine has to listen to me talking about myself for two hours - and I do find that doing them directs my learning to some extent. It's a

shame that 27% of doctors do not seem to participate in appraisal, either for lack of opportunity or other reason.

But does revalidation - as distinct from appraisal - add value? I know it is rather like questioning whether we should prescribe β -blockers for patients with heart failure - but, as doctors, we should be questioning received wisdom.

We now hear that revalidation is going to have annual costs of £97 million. Reading the Department of Health paper on the subject, 'Medical Revalidation - Costs and Benefits' (yes, I have read the whole paper), the costings are based on conjecture as much as on evidence.

Zero benefits

Part of the analysis was something called a 'BC2 survey', in which doctors were asked to speculate as to whether revalidation might reduce rates of suspension, sickness absences among doctors, the number of avoidable deaths and incidents of severe harm to patients, and litigation claims.

But doctors' responses to these questions made clear that some of the presumed benefits of revalidation would not bear out - for example, the estimated benefits of avoiding sickness absences in the BC2 survey quoted in the paper are 0%. Yes, zero.

We are told that revalidation will prevent 0.75% of cases of avoidable death, severe or moderate harm per year (again this is a speculative figure). As the National Patient Safety Agency figures quoted in the government paper say that 44,274 cases fell into this category in 2011/12, 0.75% of this would mean the prevention of 332 cases for that year.

The DH confirmed that revalidation would prevent an estimated 97 cases of death or serious harm.

We can believe that if we will. The National Patient Safety Agency of course, no longer exists and its functions are now with the NHS Commissioning Board.

We are told that revalidation will prevent 3% of litigation costs - which is borne by the taxpayer for hospital-employed

doctors, but by insurance or mutual societies for GPs. However, I do not anticipate a 3% reduction in my medicolegal fees next year.

We are told by politicians that revalidation will improve the public's confidence in their doctors. But with respect, according to Poll Watch, David Cameron's approval rating last week stood at minus 16 points and Nick Clegg's at minus 55 while GPs consistently achieve top scores in measures such as Ipsos Mori's veracity index. Who really needs the ratings boost?

The proposed benefits for revalidation - the Government is predicting a £50-£100m saving from 2017 onwards - are worryingly specious. They talk about an improvement in quality-adjusted life years (QALY) yet they wrap this up in such jargon that even the CEO of the Family Doctor Association, who studied health econometrics as part of her first degree at St Andrews, could not interpret this in real English. They offer a QALY gain of 0.001 years to 100 patients from 20% of 73% of appraised doctors. Eh?

Going into tabloid media mode for a while, there are other ways to describe the cost of revalidation in terms of clinical care. For example, this revalidation exercise is costing the equivalent of 12,933 total hip replacements in a year.

It costs £50,000 per QALY for the most expensive drug in renal cancer - spending revalidation cash here would allow an extra

1,940 years of good quality life for renal cancer patients each year. Not a bad result. NICE's usual threshold for recommendation of a new treatment is £30,000 per QALY. These treatments relieve pain and suffering and improve the quality of life of our patients. Does revalidation do the same?

Dr Peter Swinyard is the chair of the Family Doctor Association and a GP in Swindon



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for previous HPV exposure and potential benefit from vaccination. As with all vaccines, appropriate medical treatment should always be available in case of rare anaphylactic reactions. The vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder because bleeding may occur following an intramuscular administration in these individuals. Syncope, sometimes associated with falling, has occurred after vaccination with Gardasil; vaccines should be carefully observed for approximately 15 minutes after vaccination. There is insufficient data to recommend use of Gardasil during pregnancy therefore the vaccination should be postponed until after completion of the pregnancy. The vaccine can be given to breastfeeding women. Gardasil will only protect against diseases that are caused by HPV types 6, 11, 16 and 18 and to some limited extent against diseases caused by certain related HPV types. Vaccination is not a substitute for routine cervical screening. Individuals with impaired immune responsiveness, due to either the use of potent immunosuppressive therapy, a genetic defect, or other causes, may not respond to the vaccine. As with any vaccine, vaccination with Gardasil may not result in protection in all vaccine recipients. There are no safety, immunogenicity or efficacy data to support interchangeability of Gardasil with other HPV vaccines. **Undesirable effects:** Very common side effects include: headache and at the injection site, erythema, pain and swelling. Common side effects include bruising and pruritus at the injection site, pyrexia, nausea, and pain in the extremity. Rarely urticaria and very rarely bronchospasm has been reported. Idiopathic thrombocytopenic purpura, Guillain-Barré Syndrome and hypersensitivity reactions including, anaphylactic/anaphylactoid reactions have also been reported. For a complete list of undesirable effects please refer to the Summary of Product Characteristics. **Package quantities and basic NHS cost:** Single pack containing

one 0.5 millilitre dose pre-filled syringe with two separate needles. **NHS cost:** £86.50 per dose. **Marketing authorisation holder:** Sanofi Pasteur MSD SNC, 8 rue Jonas Salk, F-69007, Lyon, France **Marketing authorisation number:** EU/1/06/357/007 (pre-filled syringe with two separate needles) **Legal category:** POM © Registered trademark **Date of last review:** May 2012

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In this issue

Key questions 1.5 CPD hours

Cervical cancer
page 26

Ten Top Tips

Chronic pain
page 29

The Information

Pruritus in the elderly
page 30



Primary care urology 1 CPD hour

Penile conditions
page 32

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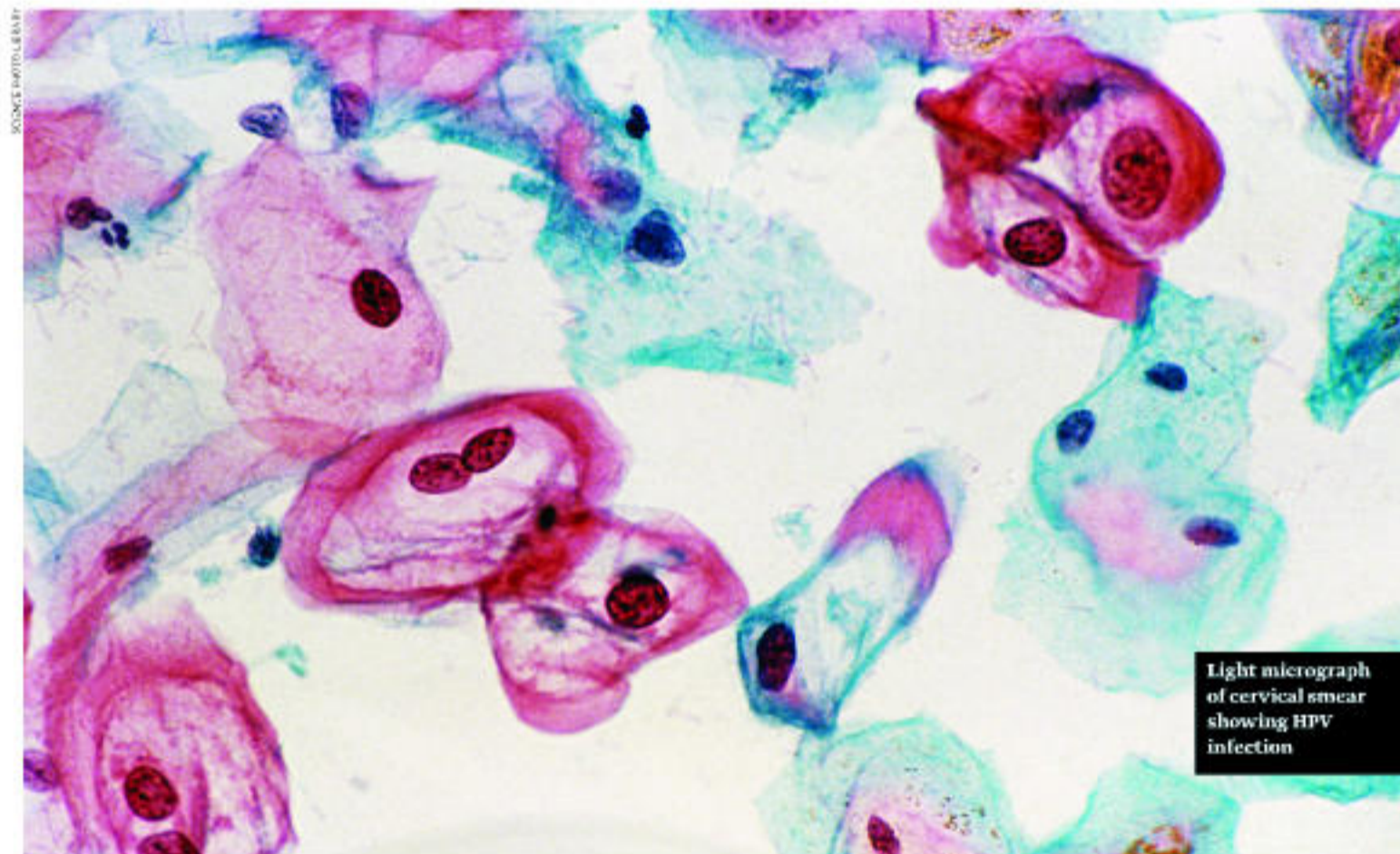


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Light micrograph of cervical smear showing HPV infection

KEY QUESTIONS

Cervical cancer

Gynaecological surgeon

Professor Martin Widschwendter

and colleagues

answer GP **Dr Sara Ritchie's** questions

on risk factors, HPV vaccination and cervical screening

1 The main risk factors for cervical cancer are the high-risk HPV serotypes and smoking, but how important is family history, or use of the combined pill?

Family history does not play any role in cervical cancer. In a study published in the *New England Journal of Medicine*, 44,788 pairs of twins listed in the Swedish, Danish, and Finnish twin registries were assessed for the risks of cancer at 28 anatomical sites.⁴ This study shows an inherited risk for some specific cancers, but it confirmed inherited factors do not play any role in the development of cervical cancer.

Studies demonstrate an association - whether causal or promoting - between

long-term use of the oral contraceptive pill (longer than five years) and cervical cancer. The association decreases after cessation of pill use and is very weak 10 years after last use. Improved screening programmes and initiation of vaccination against HPV infection have established a new paradigm in cervical cancer control, so fear of the disease should not be a reason to avoid using the oral contraceptive pill.⁴

2 What key symptoms should alert GPs to the possibility of cervical cancer?

Abnormal vaginal bleeding - post-coital bleeding, inter-menstrual bleeding or post-menopausal bleeding - is the first noticeable

symptom of cervical cancer. Other non-specific symptoms are pain in and around the vagina, foul-smelling discharge or pain when passing urine. Constipation and bowel habit changes, swelling of legs, haematuria, back-pain, weight loss and tiredness are non-specific symptoms which indicate advanced-stage cervical cancer.

3 Some GPs take early - unscheduled - smears if the patient has symptoms, such as post-coital bleeding. Is this logical, or is it more appropriate to refer for colposcopy?

There is no indication to perform a smear test when symptoms of abnormal bleeding are present. Smears should only be used as a screening test in asymptomatic women.

Women with post-coital bleeding, inter-menstrual bleeding or persistent vaginal discharge should undergo a vaginal examination and be referred for colposcopy if cancer is suspected.

In young women with post-coital bleeding, take swabs to exclude chlamydia and then make an urgent referral to colposcopy if these swabs are negative.

4 How should we respond to requests for smears from women who are too young to be included in NHS screening?

It is important to reassure women under the age of 25 that their risk of developing cervical cancer is extremely low and so screening does not benefit them. Explain that cervical screening is not a test for cancer but a test for cervical abnormalities that could develop into cancer in future. These abnormalities are common in women under the age of 25, but cervical cancer in this age group is very rare. One in three women screened under the age of 25 would have an abnormal result compared with one in 14 for all women screened (25 to 64 years old).

Most abnormalities in younger women will clear up on their own so are not a good indication of future cervical cancer. Screening younger women may lead to unnecessary investigations and possibly treatment which could damage the cervix and cause pregnancy complications later.

You can reassure patients that there has been no increase in mortality in women aged 20 to 25 since the screening age was raised to 25.

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*Tested on dental pain over 12 hours with one Nuromol tablet versus co-codamol (paracetamol 1000mg + codeine 30mg). The maximum allowed OTC in the UK is 1000mg paracetamol plus 25.6mg codeine.

26 If a woman under 25 has symptoms of cervical cancer – post-coital or inter-menstrual bleeding, or an offensive discharge – take swabs to exclude chlamydia and examine her cervix. If examination is abnormal, make an urgent gynaecological referral. Cervical screening is not indicated in symptomatic women.

5 In HIV-positive women, HPV can be more aggressive than usual – is it true that in immunosuppressed patients the wart-causing strains of HPV can also cause cancer? And do lesbian women need routine screening?

NHS Evidence advises that women who are HIV positive should be offered cervical cytology and ideally colposcopy at diagnosis, and annual cervical screening subsequently. The link between HPV and HIV in the origin of cervical cancer is well recognised – cervical cancer is an AIDS-defining diagnosis among HIV positive women.

HIV positive women have a higher prevalence of squamous intraepithelial lesions (20–40%) than women who are HIV negative (3%). This may be related to a higher incidence of persistent high-risk HPV infection as a consequence of immunosuppression. HIV-induced immunosuppression can also lead to genital infections such as warts that are particularly severe and difficult to treat. But there is no evidence that HPV 6 and 11 – which are responsible for most genital warts – show oncogenic potential in HIV positive women.

The HPV which causes cervical cancer can be transmitted between women. And there is a risk of HPV transmission in women who have never had sex with men, although lower than in women who have. So it is still advisable to offer screening to lesbian women.

6 Women with previously normal smears are often reluctant to come for smears in their sixties. How rigorously should we encourage them to continue screening until 65?

NHS Cervical Screening Programme statistics show that in 2009–10 screening coverage for women over 50 dropped below 80% for the first time in 10 years, and in 2010–11 the figure fell again – from 78.9% to 78%.

A survey in January 2012 showed that about 30% of women aged between 50 and 70 didn't realise cervical screening was a necessary health test for all women. Yet screening is important in this age group – even if the patient has never had abnormal smears.

In 2007 there were 537 cases of cervical cancer in women aged 50–64 years – 18% of all cases of cervical cancer that year. The NHS Cervical Screening Programme's *Audit of Invasive Cervical Cancer National Report 2007–11* found that 56% of women between 50 and 64 years old who had cervical cancer had not had a screen for seven years. The equivalent figure for women who did not have cervical cancer was 16%. This report can be downloaded from pulsetoday.co.uk/tools-and-resources.

The risk of HPV-related cervical cancer remains even if a woman has not been sexually active for several years. So GPs should make every effort to encourage screening uptake in this age group.

7 Is preterm labour more common after a large-loop excision of the transformation zone (LLETZ) or cone biopsy? When might routine cervical length screening or cervical cerclage be offered? Is there any advice we can offer women in whom this is not indicated?

Many studies have shown an association between treatments for cervical intraepithelial neoplasia (CIN) and adverse obstetric outcomes, with a preterm delivery risk in these women of up to four times that of low-risk pregnancies.

In England, 6.7% of all singleton births are preterm. But the figure is 8.8% in women who have had colposcopy. Yet after adjusting for various confounding factors an increased risk in women attending colposcopy has not been demonstrated.

It may be that the amount of tissue removed, rather than the method used for excision, is the most important factor in determining prematurity at birth. An

excision depth of more than 10–12mm appears to be linked to increased risk of prematurity, so large or repeat excisions are likely to carry the greatest risk.

The exact cause of premature delivery after cervical treatment is uncertain but cervical length may predict risk. Cerclage has not been shown to prevent preterm birth, even in women with a shortened cervix.

Most women who have been treated once with a LLETZ or cone biopsy can be reassured that their risk of preterm delivery is relatively low, and this must be weighed against the importance of treatment to prevent future cancer.

Women should be reminded to disclose a history of cervical treatment during antenatal booking. Where a woman has had repeated or very large excisional treatments, monitoring of cervical length may inform further interventions during pregnancy and allow appropriate discussions to take place between the patient and her obstetrician about use of cerclage, progesterone, anti-inflammatories and antibiotics.¹

8 When might hysterectomy be considered for stage 1 cervical cancer? After hysterectomy, should vault smears be continued by the GP at the usual recall intervals?

Early cervical cancer, particularly in the presence of favourable pathologic risk factors (for example, low grade, no lymph-vascular space invasion) is associated with a very low incidence of parametrial involvement and lymph node metastasis, and less radical surgery may be safe in these patients.

Beside a trachelectomy in young women who want to preserve their fertility, a simple total hysterectomy for early-stage cervical cancers may be an option for women who have finished their family. After a hysterectomy for cervical cancer there is no need for GPs to continue routine smears because the patient will be followed up by the oncologist.

9 What guides the choice of LLETZ or cone biopsy for treatment in high-grade abnormalities of CIN II or III?

The choice of treatment depends on the degree of abnormality, the size of the lesion and the position of the squamocolumnar junction. Where complete excision of a high-grade pre-malignant lesion can be performed in an outpatient setting, a LLETZ is usually the preferred procedure as it can be done under local anaesthetic and is inexpensive.

More Q&As online

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The online version of this article has three more Q&As:

- Can the HPV vaccine be given to older women and gay men?
- How reliable is three-yearly screening?
- Is HPV test of cure used in all cases?

A knife cone biopsy is performed under general anaesthetic and has traditionally been used where the squamocolumnar junction is within the cervical canal, where a lesion extends into the canal and for treatment of glandular lesions.

It is also used where invasive cancer cannot be excluded or when an apparently early tumour has been found on a previous LLETZ and requires confirmation of complete excision.

As a knife cone biopsy can be easily tailored to the size and shape of the lesion, it is often used where the lesion is very large. The margins of a knife cone specimen are not obscured by diathermy artefact, making diagnosis of completeness of excision easier for the pathologists.

Professor Martin Widschwendter is head of the department of women's cancer at University College London and a gynaecological oncology consultant surgeon at UCLH

Dr Sara Ritchie is a GP in Stoke Newington, north London

This article was co-authored with Dr Nicola MacDonald, consultant gynaecological oncologist and centre lead, Miss Adeola Olaitan, consultant gynaecological oncologist and Mr Tim Meuld, consultant gynaecological oncologist, all at UCLH.

A key component in the successful development of the UCL department of women's cancer has been their relationship with The Eve Appeal. The charity has grown and developed in parallel with the department and has played a crucial role in providing seed funding, core infrastructure funding and project funding. Much research remains to be done for women-specific cancers and the kind of support provided by The Eve Appeal is vital. For further information or to order patient information leaflets go to eveappeal.org.uk or call 020 7605 0100.

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STÉRIMAR

Natural Sea Water Nasal Spray

Dr Tim Williams, a GP and community pain specialist, offers his top tips on this tricky primary care problem

1 View pain as a chronic disease. Chronic pain is now seen by many as a chronic disease in its own right. An acceptance of this premise helps both patient and practitioner take a more long-term view of management, as we do with chronic lung or heart disease. This changes the aim of treatment to helping the patient regain control rather than seeking out nonexistent cures.

2 Avoid prescribing more painkillers initially. It is important for the patient and practitioner to take time to consider the most appropriate course of action (which is rarely to arrange further investigations). Also, possibly the most unhelpful thing to do on first contact is to prescribe yet another painkiller.

3 Split your assessment into two appointments. Splitting the assessment into two appointments stops you being overwhelmed by what may be a complex situation. The first appointment can seek to answer the question: 'How did the patient get to this point?' Ask when the pain started, how it has progressed and how it is now. Also ask about previous investigations and management, including helpful - or otherwise - medications and interventions. The second appointment can then ask: 'Where is the patient going?' A realistic plan can help to avoid frustration for both the patient and the GP.

4 Explain pacing techniques to patients. It is useful for you to be able to explain some concepts and management techniques to patients - for example pacing, where patients gradually increase their level of activity. Discussing pacing is a particularly good rapport-building tool, as most patients can relate this to their own experiences. I've found this discussion can be done in a couple of minutes of the precious 10-minute consultation and is time well spent. These and other concepts can be found at www.paincommunitycentre.org.

5 Ask specifically about neuropathic pain. It's worth asking specifically about neuropathic pain symptoms, such as constant burning pain, intermittent shooting pain that is like an electric shock, dysaesthesia, paraesthesia, hyperalgesia and allodynia. Neuropathic pain will often coexist with chronic pain and responds poorly, in many cases, to standard analgesics. I would suggest familiarising yourself with a few medications that may be helpful for these patients. NICE offers some useful guidance on neuropathic pain management.²

6 Use STEPS to manage medications. I find that a useful approach to medicines management in chronic pain is to follow these STEPS:

- Safety - is it safe for the patient to continue on this medication in the long term?
- Tolerability - can the patient tolerate this medication and its side effects?
- Effect - is the medication effective?
- Price - are patients taking the best-priced treatment? Expensive medications are fine as long as they work.



TEN TOP TIPS

Chronic pain

7 Use strong opiates with care. The patient needs to be clear about what you're trying to achieve by prescribing strong opiates. Used correctly, strong opiates can be very effective in chronic pain management for some patients, but should be prescribed by practitioners who are confident in their use. Opiates used in this context are distinct from palliative care, where the emphasis is primarily on symptom alleviation using a combination of short- and long-acting preparations. In contrast, chronic pain management is more about function, in my opinion, and short-acting strong opiates have a very limited - if any - contribution to make. In particular, short-acting strong opiates can quickly lead to a patient and practitioner feeling out of control on ever-escalating doses. The British Pain Society has produced useful guidance on this issue.³

8 Encourage self-management. Successful pain management depends more on the patient than the GP. Pain management is the patient's responsibility and the skilled practitioner is able to help the patient find their ability to respond to their chronic pain and its consequences. This may involve simply directing patients to self-management resources such as the pain tool kit, which can be downloaded from pulsetoday.co.uk/tools-and-resources, or self-help groups, such as the Expert Patient Program.

9 Remove the focus from the pain. Patients with chronic pain can have their life dominated by it. In a patient who is managing their pain well, the focus starts to shift away from pain as they begin doing more and 'getting their life back'.

10 Aim for continuity. Take an active interest in your patients' onward management - enjoy the benefits of a patient-practitioner partnership centred on self-management. Do your best to prevent other practitioners getting involved, because this can lead to the patient receiving inconsistent advice, unhelpful medication changes or referrals for often fruitless further investigations.

11 Simplicity - is the analgesic regime as simple as possible? Would a long-acting preparation be preferable to frequent doses of short-acting analgesics? Also consider non-drug treatments such as warmth, ice, transcutaneous electrical nerve stimulation and acupuncture, which are helpful for some patients, and relaxation techniques, which are useful for most.

Sometimes the pain may actually stay the same and it's the other aspects of life that improve, including sleep, exercise tolerance, mood and general well-being - which are all very worthy end points. Some time spent addressing poor sleep and depression, although not necessarily directly affecting the pain, can make living with chronic pain more manageable.

Dr Tim Williams is a GP partner and community pain specialist in Sheffield. Dr Williams has received payment for pain-related presentations from pharmaceutical companies including Pfizer, Grünenthal and Napp. He also deliberated as part of an expert panel, funded by Astellas Pharma, that recommended Qutenza as an appropriate topical treatment for some patients with neuropathic pain. For the past 12 months Dr Williams has led a Health Trainer Community Pain Management Pilot in Sheffield.

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THE INFORMATION

Pruritus in the elderly

Dermatologists **Dr Paul Yesudian** and **Dr Kun Sen Chen** offer their guidance on how to manage this presentation using PUNs and DENs



xerosis in the elderly. Common underlying systemic causes are listed in the table, right.⁴

Drugs – commonly aspirin, opioids, ACE inhibitors and statins – may also be a systemic cause of pruritus in the elderly.

If, after a thorough history and examination, the underlying systemic cause is not obvious, request:

- FBC
- Blood film
- U&Es
- LFT
- TFT
- Ferritin
- Fasting blood glucose
- ESR or CRP

Depending on the history and examination, other investigations such as chest radiography and urinalysis may be requested.

If no primary skin disorders or systemic causes are found, consider idiopathic itch.

THE PATIENT'S UNMET NEEDS (PUNs)

A 78-year-old man attends complaining of very itchy skin for a couple of months. He has no dermatological history, is fit and well and takes no medication. Examination reveals no obvious skin pathology other than widespread reddened areas which the patient attributes to scratching. He's agitated and explains that it is getting him down – he's keen for you to prescribe something to ease the symptom.

THE DOCTOR'S EDUCATIONAL NEEDS (DENs)

It can be difficult to determine whether skin lesions are the cause or the result of itching. Which primary skin disorders should we suspect?

When assessing a patient with widespread pruritus, the first aim is to determine if it is due to an underlying skin disorder or a generalised pruritus without skin lesions. Common pruritic primary skin disorders in the elderly are listed in the box below. Xerosis (dry skin) is the most common cause.

Generalised pruritus without skin lesions is a diagnosis of exclusion. It presents with widespread excoriations and erythema on a background of normal skin, without any features of primary skin disorders.

Where there is no specific skin disease, how likely is a systemic cause? What investigations should we perform?

When a diagnosis of generalised pruritus without skin lesions is established, the next aim is to look for an underlying systemic cause, which is present in 13–50% of patients.¹ The itch threshold can be lowered by systemic diseases and can be further exacerbated by

Common pruritic primary skin disorders

- Xerosis/asteatotic dermatitis
- Scabies
- Contact dermatitis
- Atopic dermatitis
- Psoriasis
- Lichen planus
- Urticaria
- Nodular prurigo
- Bullous pemphigoid
- Dermatitis herpetiformis

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Date of preparation: May 2012. MUC12001a

¹Chronic obstructive pulmonary disease

ARE YOUR PATIENTS DROWNING FROM CO

Although xerosis is probably the most common factor, many elderly patients do not have xerotic skin. Other factors like age-related changes in nerve fibres, central disinhibition of itch, decreased skin surface lipids, and reduced sweat and sebum production may be associated.

If no systemic or skin disease is apparent, what topical treatments should be offered? Do any specific emollients have particular advantages?

It is essential to recognise that cognitive and physical impairments in older people could affect compliance with topical treatments. The help of family members and carers may be required.

Before using topical treatments, offer general tips to ensure optimal skin hydration and prevent the itch-scratch cycle:

- Maintain a humidified environment.
- Wear light and loose clothing.

- Don't dwell too long in baths and showers, and use cool or lukewarm water. Apply emollients immediately afterwards.

- Use soap substitutes and avoid alkaline or alcohol-containing cleansers.

- Keep fingernails short.

Emollients are the mainstay of treatment, especially in patients with xerosis, and should be applied at least twice daily. They improve the skin barrier function, preventing water loss and entry of irritants. Ointments are more effective than creams or lotions but are less well tolerated. Emollients containing urea improve skin hydration but may cause irritation. Preparations like menthol in aqueous cream distract from the itch with cold sensation. Emollients containing lauromacrogols are reputed to relieve pruritus via their mild anaesthetic effect, but no studies of this are available.

Topical cromolone is helpful for localised pruritus and may be trialled for widespread

Common systemic causes of pruritus

- Chronic kidney disease
- Cholestasis
- Thyroid disease
- Diabetes mellitus
- Polycythaemia vera
- Iron deficiency
- Malignancy

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pruritus if emollients are unsatisfactory. Other treatments like doxepin and capsaicin creams, and topical antihistamines and anaesthetics are also helpful for localised pruritus but are not recommended for generalised pruritus because of side effects and impracticality in widespread use. Only use topical corticosteroids and calcineurin inhibitors if an inflammatory dermatosis is present.

Elderly patients with pruritus are commonly stressed or depressed.

Is pruritus often a manifestation of underlying anxiety or depression, or are psychological symptoms usually secondary to the pruritus? Is a trial of an antidepressant worthwhile?

Chronic pruritus can affect patients' quality of life comparably to chronic pain. Low self-esteem, distress and sleep impairment in particular, result in fatigue that influences work and family relationships. This can lead to anxiety and depression which is present in 32% of patients with generalised pruritus. On the other hand, pruritus is a presenting symptom of depression in 4% of patients.⁴ So anxiety and depression are most likely to be secondary to pruritus.

Tricyclic antidepressants (doxepin) and SSRIs (paroxetine) are reported to be effective in psychogenic pruritus. Mirtazapine has a sedative effect so is useful for nocturnal itch. Resolution of depression-associated pruritus has been seen when depression is treated with antidepressants. Whether this is because of improvement of the depression or the anti-pruritic effect of antidepressants is unknown. So a trial of antidepressants is worthwhile in anxious or depressed patients with pruritus. Start at low doses and taper up cautiously to avoid side effects.

Antihistamines are often prescribed in patients with pruritus. Is there any evidence behind their use? Is it best to prescribe a sedating antihistamine if one is used at all?

Histamine is one of several neurotransmitters that stimulate pruritus by binding with histamine 4 receptors and to a lesser degree with histamine 1 receptors (H1R). H1R antagonists are the only antihistamines currently available to treat pruritus. Sedating H1R antagonists, such as hydroxyzine and chlorphenamine, tend to be more effective than non-sedating H1R antagonists, such as cetirizine and loratadine. Histamine 2 receptor antagonists are ineffective.

Antihistamines are effective for pruritus in histamine-mediated diseases like urticaria, but are of limited efficacy in standard doses for pruritus of other causes, where high doses (four times the licensed dose) or a combination of different antihistamines are required.⁴ But high-dose antihistamines - particularly when taken over the counter - should be used with caution in the elderly due to their sedative and anticholinergic side effects, and interactions with other drugs.

If an antihistamine is used, sedating H1R antagonists are recommended for nocturnal pruritus and non-sedating H1R antagonists for daytime use. Sedating H1R antagonists in lower doses divided throughout the day are an alternative option.

Dr Paul Yesudian is a consultant dermatologist and **Dr Kun Sen Chen** is an ST4 dermatology specialty trainee at Betsi Cadwaladr University Health Board, North Wales

Competing interests None to declare

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Go to pulsetoday.co.uk/clinical to view other articles in this series on urticaria, acne and hyperhidrosis

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The British Geriatrics Society (BGS) is a membership association for healthcare professionals with a special interest in the medical care of older people and in promoting better health in old age. It runs two large multidisciplinary conferences each year, alongside several smaller meetings around more focussed topics. Go to bgsociety.org for more information, and to keep up to date with BGS news follow @gerisoc on Twitter.

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PRIMARY CARE UROLOGY

Penile conditions

Urologists Mr Ian Eardley and Mr Vishwanath Hanchanale discuss common penile problems and their management

Penile disorders are commonly seen in day-to-day practice and these can be difficult to diagnose and treat effectively, especially in children, where addressing parents concerns can add to the difficulty. This article looks at the diagnosis and management of some of the most common penile conditions presenting in primary care.

Phimosis

Patients with phimosis are unable to retract or have difficulty retracting the foreskin. Physiological phimosis, caused by adhesions between the prepuce and glans, is managed conservatively but pathological phimosis, caused by scarring or balanitis xerotica obliterans for example, requires surgical intervention. At birth, the foreskin adheres



to the glans penis and these adhesions may persist for six to eight years, giving the false impression of non-retractable foreskin. This physiological phimosis should not be confused with true phimosis due to scarring of the foreskin - and careful examination of the foreskin is required to differentiate the two. Many phimosis referrals seen in paediatric urology clinics are normal physiologically phimotic foreskins - this can cause unnecessary anxiety for parents and children about the need for surgery. Most boys will have retractable skin by 10 years of age, and 95% will have by 16-17 years.

Adult phimosis is usually caused by scarring of the foreskin secondary to recurrent balanitis (inflammation of the glans penis), posthitis (inflammation of the foreskin), forcible retraction of the foreskin or BXO. These patients can find it difficult to keep the penis clean which might result in recurrent balanitis and, in later life, an increased susceptibility to carcinoma. Symptomatically, the usual complaint is of pain during sexual intercourse and - in severe cases - problems with micturition.

Treatment

In young children with physiological adhesions, you should advise parents on normal washing, using soap and water,

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and gentle retraction during urination and bathing since most foreskins will become retractable over time. Forcible retraction of the foreskin is not helpful and may actually cause preputial scarring.

Minimal scarring of the foreskin may be treated by preputioplasty - where the tight ring of the foreskin is divided longitudinally and sewn transversely. Pathological phimosis, especially secondary to BXO, will require circumcision.

Clinical indications for circumcision include true phimosis, BXO and recurrent balanoposthitis.

After a circumcision the wound must be kept clean and dry. The dressing can be removed within 48 hours and normally the scab separates in five to seven days time. The sutures dissolve in two to four weeks. If there are signs of infection then antibiotic therapy may be necessary.

Topical steroid treatment can be helpful for phimosis related to BXO - its main use is for treatment of BXO affecting the glans following circumcision. Topical steroids are not effective in non-BXO related phimosis.

Paraphimosis

Paraphimosis is an inability to protract a tight foreskin that is stuck behind the corona. It usually occurs following retraction of a tight foreskin (phimosis). Because of the venous and lymphatic blockage, the glans and distal foreskin swell and cause further pressure within the obstructing ring of foreskin. The condition is extremely painful and may cause urinary retention.

Treatment

Urgent replacement of the foreskin to its normal position by medical means - icebags, gentle manual compression and injection of a solution of hyaluronidase in normal saline can be effective. If this fails then surgical treatment with dorsal slit or circumcision is necessary.

After resolution of the acute episode a circumcision is usually necessary anyway.

Balanitis xerotica obliterans

BXO is an idiopathic, chronic, progressive, sclerosing inflammatory dermatosis of the genitals in men. There is thickening and depigmentation of the foreskin, which is often adherent to the glans penis. BXO primarily affects the foreskin, but it can affect the glans penis and rarely the anterior

BXO may present with a history of persistent 'thrush'

urethra. It occurs most frequently in middle age but may appear in children.

Early in its course, BXO may be relatively asymptomatic, or may present with history of persistent 'thrush'. Most patients present with itching and phimosis. A sclerotic white ring at the tip of the foreskin is diagnostic and may progress to phimosis. Narrowing of the urethral meatus might lead to spraying of the urinary stream and rarely to urinary retention. Diagnosis is made on the basis of these clinical features.

Treatment

Topical steroid cream is effective in the early stages of mild BXO where there is minimal scarring of the foreskin.

Circumcision is almost always indicated in patients who also have phimosis. Surgery is not always straightforward because of adhesions between the glans penis

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and foreskin which can occur. If there is significant meatal stenosis or urethral stricturing then surgical reconstruction of the meatus or urethra is necessary.

Peyronie's Disease

Peyronie's disease is an uncommon condition characterised by penile deformity and palpable penile plaques within the

corpora cavernosa. Peyronie's disease is most commonly seen in men aged between 40 and 60 years. Its aetiology is uncertain, but minor injury of the erect penis causing microhaemorrhage under the tunica albuginea and secondary fibrosis is a possible cause. These plaques slowly progress over 12 to 18 months, before stabilising, causing bending of the erect penis.

Patients usually present with penile deformity, pain on erection or a lump in the penis - in fact, Peyronie's disease is almost the only cause for a lump in the penis.

The most common direction of deformity is dorsal deformity - towards the abdomen. This may be mild, or, in some cases there may be a bend of 90° or more. Spontaneous improvement occurs in around 15% of patients, while 40-50% will get worse and the rest will remain stable. This deformity can cause painful erections or - in 40-50% - erectile dysfunction. Peyronie's disease is more commonly seen in men with Dupuytren's contracture.

Evaluation includes taking a sexual history and examining genitals to assess the location, size and tenderness of plaques. Deformity can be assessed by getting the patient to bring

in a digital photograph of the erect penis or by inducing an erection. Very rarely Doppler ultrasound and MRI can be used to assess complex or extensive cavernosal masses.

All men should be assessed for other causes of erectile dysfunction - do fasting and blood sugar, serum lipid and morning testosterone assay.

Treatment

Medical treatments, although often used, are rarely effective and not licensed for this indication. Drugs that have been used include vitamin E and tamoxifen.

During the active phase of the condition the primary objective is symptomatic treatment so, if there is significant pain, analgesics are useful while in those men with erectile dysfunction an oral PDE5 inhibitor is helpful. No oral or injectable therapy has been shown to make any significant difference to the penile deformity or to the plaque size, although preliminary studies in the United States using injectable collagenase are promising. Regulatory studies with this agent are ongoing.

Surgery must be avoided during the active phase of the disease.



For those patients with dry skin conditions such as eczema, The British Association of Dermatologists guidelines advise that the use of soap or detergent based products can exacerbate their symptoms. They recommend the use of soap substitutes.

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



The glans and distal foreskin may swell in paraphimosis

After the disease has stabilised, if the patient has significant deformity, then corrective surgery is indicated. This may be with Nesbit's procedure which involves plication of the corpora cavernosa, or a Lue procedure which involves plaque incision and grafting. Common consequences of surgery are loss of length and erectile dysfunction, so it is only indicated where deformity interferes with sexual activity.

Carcinoma of the penis

Penile cancer is rare in the UK but common risk factors include HPV infection, BXO and smoking. Definite pre-carcinomatous states are leucoplakia of the glans and carcinoma

in situ of the penis - and contributory factors are phimosis and chronic balanoposthitis. Circumcision soon after birth confers immunity against carcinoma of the penis.

Carcinoma in situ of the penis typically presents as a red patch on the glans (erythroplasia of Queyrat) or shaft of the penis (Bowen's disease). These red patches on the glans require careful observation and suspicious lesions need urgent biopsy - any red lesion that persists for more than four weeks must be considered suspicious. Carcinoma in situ can be treated by topical 5-fluorouracil cream, CO₂ laser ablation or surgical excision.

Carcinoma of the penis is most typically

a SCC arising from the glans or the foreskin. Most cases start as leucoplakia or as papilloma which grows over months or years to become a flat and infiltrating or warty lesion. Distant metastasis is rarely observed. Many patients present late, with a large tumour, either because of embarrassment or misdiagnosis. Around half present with palpable inguinal lymph nodes, often due to infection. Rarely, a patient presents with a fungating offensive mass of the glans or the inguinal nodes. Erosion of the femoral or external iliac vessels by these fungating inguinal glands - and sudden death - has been reported.

Treatment

Management depends on the stage and grade of disease, which is divided into treatment of the primary tumour and treatment of the inguinal nodes. Surgical excision is the mainstay of treatment for the primary tumour, for example glansectomy, partial penectomy, total penectomy with perineal urethrostomy.

In some cases, inguinal lymph node enlargement is secondary to infection, so treatment of the inguinal lymph nodes should be delayed until at least four weeks after local treatment of the primary lesion. Again, surgical excision is required for malignant inguinal nodes.

Five-year survival rates for tumours confined to penis are over 80% and for those with nodal involvement are 40%.

Mr Ian Eardley is a consultant urologist and **Mr Vishwanath Hanchanale** is an SpR in urology at St James's University Hospital, Leeds

The Urology Foundation is the only charity in the UK and Ireland that covers all urological conditions and cancers. It is focussed on improving the knowledge and skills of urologists and funding research visits to improve patient outcomes. It receives no Government funding and relies wholly on donations. The foundation's website offers clear, basic information for patients, including signs and symptoms, diagnoses and treatment options. Information about programmes and grants is also available for urology professionals. Visit: theurologyfoundation.org

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- a GP in Banff, Scotland
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favourite recent modules

Guideline debrief: headache **2 CPD hours**

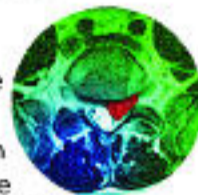
If you wish to increase your confidence in diagnosis and management of headache, I highly recommend this module.

It's a great update of the recent NICE guidance and introduces the new triptan/NSAID recommendation for acute onset of migraine. Topiramate for migraine prophylaxis was new to me - this, and propranolol, are now recommended as first-line drugs.



Hot topics in back pain **2 CPD hours**

This is a really useful module that will make assessment of the patient with back pain less daunting for those who have completed it. It introduces the STarT Back screening tool which triages patients with back pain into low, moderate and high risk in terms of likelihood of chronicity, and covers ankylosing spondylitis - a condition often subject to diagnostic delay.



Neuropathic pain **2 CPD hours**

My day-to-day management of this patient group has changed thanks to this module. It discusses the use of duloxetine first line and combination therapy with pregabalin for diabetic neuropathy. If you want to be up to date on the current pharmacological management of this and other causes of neuropathic pain then this module will provide you with the knowledge necessary to give your patients the best evidence-based treatment.



Attention deficit hyperactivity disorder **2 CPD hours**

We have all been there - a parent comes in saying that Johnny's behaviour is an absolute nightmare and asks the question - could it be ADHD? Your heart sinks and you ask yourself 'where do I start?' Not any more. The module covers the core diagnostic symptoms of inattention, hyperactivity and impulsiveness. I am now more confident in dealing with such enquiries from parents and more alert to the possibility of this diagnosis.



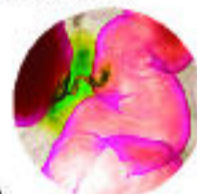
Hot topics in gout **1.5 CPD hours**

I had a patient with severe renal impairment and almost weekly episodes of gout. Many of the traditional drugs for gout were contraindicated because of her renal function. I did not know where to go next until I took this module. She is now gout free as a direct consequence of this module - it will change your management of this common condition.



Irritable bowel syndrome **2 CPD hours**

This module will revolutionise your approach to IBS. We deal with this condition all the time in general practice so we should be good at managing it but many patients remain symptomatic despite our best efforts. This module uses the ABC approach to diagnosis of this condition, a new approach to me. It seems that we have been mismanaging this condition for decades.



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1 CPD hour

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page 36

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Five steps to 15-minute appointments

Dr Sarah Bruml provides a guide to an appointments system that has reduced GP stress and proved popular with patients

Our 15-minute appointments system had humble beginnings. The idea came up at our surgery, a PMS practice, eight years ago.

We were frequently running an hour late and we didn't have the time to finish complex consultations. My colleagues and I admitted 'praying for DNAs' so that we could catch up and it was clear that our system wasn't working.

In a poster published earlier this year, we showed that offering 15-minute appointments at our surgery was not associated with an increase in the time GPs spent consulting with each patient per year. We also improved well above the national average on accessibility indicators and overall experience in the National Patient Survey.

At our practice, GPs spent an average of 31 minutes per patient per year in 2006, which corresponded with the national average, but we found that if we had been consulting at the rate of the national average, we would have expected GPs to spend 37 minutes on each patient, five minutes above the national average and nine minutes above our actual rate. For more detail, see the resource at pulsetoday.co.uk/business.

The following is a retrospective guide to the way we introduced 15-minute appointments and have since honed the system.

1 Research and discuss potential benefits

While short consultations might seem more productive or efficient in terms of fitting more appointments into a session, we also knew that longer

25%
are happy to wait a day for an appointment after talking to a GP



consultations improved uptake of screening, increased patients' understanding of their health and improved satisfaction with our service.

We hypothesised, as many GPs do, that longer appointments might mean that patients would consult less frequently. We also guessed that waiting times would come down and the waiting room would be less crowded if we offered longer appointments.

My partners agreed to trial 15-minute appointments for one surgery a week, initially on a Friday morning.

We previously ran 15 appointments of 10 minutes between 9am and 11.30am, with one catch-up appointment per session.

During the trial, we ran nine appointments of 15 minutes between 9am and 11.15, followed by four appointments of 10 minutes between 11.15am and 12.05pm.

We didn't make any cost predictions at the time, though most practices would wish to model this now. We knew we were working inefficiently. As already mentioned, we ran over time every day, so we reckoned our finish time would not change much.

Initially, doctors suggested that patients with complex needs book on a Friday, usually when arranging a follow-up. Patients weren't informed that they had more time with the doctor; they were simply invited to book Friday mornings.

2 Trial the system

The trial went surprisingly smoothly. Doctors felt less stressed on Friday morning, and we found we had enough appointments to manage demand. The longer appointments were useful for dealing with patients who had medically unexplained symptoms or were frequent attenders. We found that patient-doctor communication improved generally. We managed to do more medicines-use reviews during the sessions and uncover issues that had not previously been discussed.

After six months, we agreed to roll the scheme out throughout the week (afternoons first, then mornings), with a few adaptations.

For instance, some doctors were using double 10-minute appointments for work such as smears, baby checks and six-week check-ups for mothers; we agreed that these types of appointments should be offered in 15 minutes. Same-day appointments would be offered end-of-surgery 10-minute slots.

3 Roll it out and keep adapting
We have now offered 15-minute appointments for over eight years, and there have been some tweaks to the system.

The main change is that we try to combine all our work in one appointment rather than asking the patient to go out from the GP appointment to see a nurse. Nurse appointments are also 15 minutes, so breaking up the work between two clinicians is usually inefficient if one or the other could manage to do everything in the time allowed.

Travel advice and immunisations are only offered by our nurses. Baby and childhood immunisations are booked into routine nurse surgeries or baby clinic. Until recently, baby clinics were first come, first served for immunisations, but parents prefer to book the appointment either in the baby clinic or at a time that suits. A few appointments are kept free for the less organised.

Routine appointments now encompass opportunistic work where appropriate, including smear tests, flu vaccinations, smoking cessation, advice on alcohol consumption, diabetes reviews and asthma and COPD reviews.

We also offer six-week mother-and-baby checks in a 30-minute appointment.

The access system has been adapted to offer phone triage over a 90-minute period in the mornings for patients who request a same-day appointment - this reduces demand for face-to-face appointments by at least 30%.

A further 25% are happy to wait a day for an appointment after talking to a GP about the problem and, as mentioned earlier, our

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same-day appointments are the shorter ones. In cases where the patient still wants a same-day appointment, we make sure the patient either sees the doctor they spoke to on the phone so that the pair of them have already started to deal with the health issue, or their usual doctor if available.

We book appointments at least three months ahead, so we always have something available for a patient seeking a follow-up. This reduces the number of patients who ring up at the last moment for follow-up and the DNA rate for these appointments booked well in advance is no higher than same-day appointments.

We use a text reminder system for early-morning commuter clinic appointments, patients who request it and serial DNA offenders.

4 Look for opportunities to improve practice income

We use an IT system called Front Desk, which prompts us to collect QOF data for patients. It's always live onscreen and, since we switched to 15-minute appointments, we have had the time to do valuable QOF work. Smoking cessation, medicines-use reviews, hypertension, asthma and COPD reviews are squeezed in after patients' presented concerns. We have time to discuss patients' health concerns as well as educate them and encourage self-help.

Another IT improvement we made was to start using double screens on the GPs' desktop computers. During appointments this means I can see the patient's record and the appointment diary at the same time. I can see who's coming up, whether I'm running to time and whether I can help colleagues running behind schedule by picking up one of their patients.

Our list size has increased with an above-average rate of growth, which has undoubtedly increased the demand for appointments. But part of our growth we believe is down to positive feedback from patients about access.

Positive comments left on NHS Choices this year include:

- 'They have always been available in a very short time via email or telephone in times of crisis and I never feel rushed during appointments.'
- 'They always take time to listen, are compassionate and I have never felt rushed.'
- 'Doctors are informative and take as much time as they can give.'

We still overrun, but we've managed to cut

it down to 20-30 minutes rather than an hour. Increasing appointment times has in fact reduced the number of appointments each patient asks for, and given us greater capacity for list growth.

5 Forget the 'one problem, one consultation' rule

The biggest difficulty has been persuading GPs new to the practice to do all this work in one consultation. The mentality of 'one problem, one consultation' seems to run deep in the profession.

Some GPs worry that running 15-minute appointments as standard will result in 'wasted' time, such as patients who only need five minutes for a sick note, pill prescription or blood pressure check. Firstly, we've trained our receptionists to take blood pressure and handle repeat prescription requests. But I'm sure colleagues know what I mean when I say there's never a quiet moment.

We take violent patients at our practice to get income from the DES, so it has been important to make sure doctors aren't stressed and waiting times aren't too long. We think that improving our follow-up appointments booking system has also made the practice calmer.

Most doctors worry that there just won't be sufficient appointments to offer, but look at the scheduled finish time and then the actual finish time, and reconsider whether 15-minute slots would actually work better. You may find, as we have, that demand falls as patient satisfaction increases.

Dr Sarah Bruml is a GP partner in Herne Hill, south London

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CCG constitutions: what you need to know

With confusion over practices' obligation to sign constitutions, **Dr Sarah Pinto-Duschinsky** introduces the NHS Commissioning Board's advice, while **Dr Chaand Nagpaul** outlines 'known unknowns'

THE HEALTH AND SOCIAL CARE ACT (2012) requires each CCG to have a constitution that sets out how it will discharge its responsibilities, writes Dr Pinto-Duschinsky. This is one of the key pieces of evidence the NHS Commissioning Board uses when assessing a CCG's application for authorisation. CCGs also need to provide evidence of good engagement with member practices as part of the authorisation process. It is up to each CCG and its member practices to decide how they prepare their constitution and agree on the sign-off arrangements. Conditions might be put on authorisation of CCGs if improvements are needed in the engagement and support of GP practices.

The following advice from the board aims to answer a partner's questions about whether to sign their local CCG's constitution.

Is it possible to remain a member practice of the CCG without signing the constitution?

Ultimately, it is going to be a legal requirement for all GP practices in England to be a member of a CCG. It is up to each CCG to choose how best it wishes to demonstrate member practices' 'sign-off' of the constitution. The board will look in the round at any evidence relating to the strength of the relationship between a CCG and its member practices. It will want to assess all the evidence relating to the strength of the relationship between a CCG and its member practices.



Dr Chaand Nagpaul (CN) writes: This is the first time an NHS statutory body will operate as a 'membership organisation', and with members signing a 'constitution'. This is a new organisational proposal without precedent, and in itself it raises some vexing questions.

Ordinarily an individual or organisation can choose to be a 'member' of another organisation, and in doing so would sign a document agreeing to the terms of the membership. There is also the provision to cease membership for any reason. Membership of the BMA, RCGP, and NHS confederation are typical examples.

As stated in the board's response, statutorily practices will be forced to be members of CCGs whether they actually wish to be so or not, and even where they actively disagree with the terms of a CCG's membership. This does not accord with the ordinary meaning of 'membership' of an organisation. Such issues did not apply with PCTs where a practice's relationship with its PCT was via its contract and not as a 'membership organisation'.

There is still a lack of clarity of how the board will assess 'evidence' of member practice 'sign-off'.

Presumably there will be several CCG authorisation applications where one or several practices have either not demonstrated any written support, or have



actively disagreed with the constitution.

Is it the board's view that it is acceptable for some practices not to support a CCG constitution? Is the proposal for a 'majority' of practices to demonstrate support, or a 'significant majority' and if so is there a percentage of practices that need to demonstrate support? It would be helpful to have information on any objective measures of assessment of 'sign-off'.

What happens to practices that do not agree with the constitution? Are their CCGs authorised while they are left out?

This proposal is without precedent and it raises some vexing questions

The board is responsible for authorising CCGs and will work closely with each CCG to ensure their plans and structures have the support of their members. The board will want to look at all the evidence relating to the strength of the relationship between a CCG and its member practices. Where conditions are given, relevant support packages would be offered in agreement with the board's local area teams and regional directors.

CN As with the previous question, is it the intention that all practices should end up supporting the CCG's plans and structures? Is this achievable given the disparity of GP practices' views in general?

There is mention of 'evidence' of support and engagement - it would be helpful to know what criteria will be used to assess such support, and as mentioned in the previous question, a signature does not in itself equate to active informed support.

There is mention of 'conditions' and 'relevant support packages' and it would be helpful to have an idea of what these would be. Is it the intention to establish the reasons why some practices have not 'signed off' and facilitate the CCG to achieve such support?

Must CCGs show evidence that all member practices have agreed with the constitution in order to be authorised?

The board advises that it is up to each CCG to choose how best it wishes to demonstrate member practice 'sign-off' of the constitution. The board will look in the round at any evidence relating to the strength of the relationship between a CCG and its member practices.

CN The GPC has had feedback from many practices that felt rushed and under pressure to sign a constitution due to the tight timescales for authorisation, and being warned that failure to sign it may jeopardise authorisation.

We have reports of practices having signed constitutions without reading them and being fully aware of its contents due to timescale pressures. Hence 'signing' a constitution does not necessarily constitute informed 'support'.

Will the board attempt to assess member support beyond signatures by assessing the views of grassroots GPs and member practices?

Must the CCG have the accord of all partners at a practice, or just the representative partner? What process should a partnership and CCG follow where one partner is not happy for the practice to sign up to the CCG, although the rest of the practice is?

The member practice must decide for itself who will represent it within the CCG. If there is a difference of opinion within a practice, it is up to the partners to manage this internal disagreement, as it would in the day-to-day running of the practice.

CN I would agree with this response. Practices will always face ongoing issues of making choices in which all partners may not agree. Practices have developed their own methods of reaching decisions, from voting to consensual agreement.

What defines a constitution document exactly? For example, is this a contract, an agreement, what are the technical differences, and what is its legal status?

Every CCG must have a constitution. This will be a key document for each CCG that sets out various matters including:

- the arrangements it has made to discharge its functions and those of its governing body
- its key processes for decision-making - including arrangements for ensuring openness and transparency in the decision-making of the CCG and its governing body
- arrangements for managing conflicts of interest.

The board must be satisfied that the constitution complies with the requirements of the NHS Act (2006) as amended by the Health and Social Care Act (2012) and subsequent regulations and is otherwise appropriate.

CN As previously stated, there is no precedent in the NHS for the CCG model as a 'membership organisation' bound by a 'constitution'.

The constitution will nevertheless define the governance and operating arrangements of the CCG and will directly impact on GP practices as members. It is therefore vital that practice members are involved in its development, and consent to the content of a constitution.

Dr Sarah Pinto-Duschinsky is the head of authorisation at the NHS Commissioning Board

Dr Chaand Nagpaul is the GPC's lead negotiator on commissioning and a GP in Stanmore, Middlesex

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EDITOR'S CHOICE

Educating patients on antibiotics

GPs cannot combat increasing antimicrobial resistance on their own, writes Dr Naomi Stanton

During a recent meeting to discuss antimicrobial resistance, a GP asked why those responsible for the problem - the vets, the dentists and secondary care - were not being tackled for their irresponsible prescribing.

There seems to be a blame culture, rather than one where we take collective responsibility. There is good evidence that in primary care there is

wide variation in antibiotic prescribing and antimicrobial resistance rates. There is no evidence that case-mix is responsible for these differences or that there is any rise in complication rates in those areas that prescribe less. The evidence suggests our choice of antibiotic is improving but we are still prescribing more antibiotics overall.

Both the World Health Organisation and the RCGP have flagged increasing antimicrobial resistance as a major global threat. With few new antibiotics in the



Dr Naomi Stanton

development pipeline we will soon see the impact of increasing resistance in the community; it will no longer be a hospital phenomenon.

So, GPs are up against it. We have to decide whether a patient in front of us needs an antibiotic, often without evidence of benefit.

Some strategies seem to help doctors to reduce prescribing: interactive booklets, communication skills training, delayed antibiotic prescribing and point-of-care tests. But we can't change prescribing habits on our own.

We need to engage with patients and empower them. We need to win the argument that if antibiotics are to work in the future, we cannot prescribe them as readily as previously...

Dr Naomi Stanton is the GP representative on the Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection and a GP in Gilfach Goch in Wales

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Read the full article pulsetoday.co.uk/opinion

OPINION



Lewisham GP Dr Louise Irvine explains why she has helped set up National Health Action, a new single-issue political party that is encouraging NHS professionals to stand for Parliament.

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... on one peer's call for GPs to tackle obesity in their own practice staff



BIG INTERVIEW

Dying matters

The Big Interview this week is with Professor Mayur Lakhani, former RCGP chair and now chair of the Dying Matters Coalition. He explains how GPs can talk to patients about dying and end-of-life care and discusses the recent controversy over the Liverpool Care Pathway.

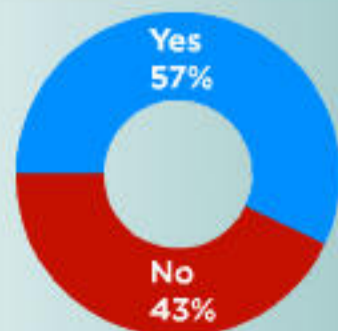
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THIS WEEK'S POLL

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[page 23](#)