

LETTERS

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SMOKING CESSATION

Smoking prevalence in England <20% for first time in 80 years



NEWSCASTALANY

We would like to expand on the “who smokes” section of Zwar and Mendelsohn’s timely clinical review of smoking cessation by sharing the latest findings of a large national surveillance study, which has been tracking smoking prevalence in England since 2006.^{1,2} Each month a new sample of about 1800 people aged ≥16 years is selected by random location sampling to complete a computer assisted household survey with a trained interviewer. Prevalence data are weighted to match English census data on age, sex, and socioeconomic group. The resulting sample is nationally representative in its sociodemographic composition and proportion of smokers as compared with other large national surveys, such as Health Survey for England.² An advantage of this study is that the data are available within weeks of collection and published online (www.smokinginengland.info).

For the first time in probably 80 years, smoking prevalence in England has fallen below 20%. In 2013, 22 167 adults were surveyed. The prevalence of cigarette smoking was 19.3% (95% CI 18.8% to 19.8%). Smoking was rare at the start of the 20th century but increased relentlessly until the publication of “Smoking and Health” in 1962, by which time over 70% of men and 40% of women smoked.³

The decline in prevalence started in the 1970s and has since averaged 0.6% a year; in 2013 it was slightly higher, at 0.8% (www.smokinginengland.info). Much is still to be done, particularly on the social gradient in smoking, which contributes greatly to health inequalities.⁴ However, we hope that breaking the 20% barrier will motivate smoking cessation efforts across the country, including making more use of our stop smoking services.⁵

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Competing interests: See full response at: www.bmj.com/content/348/bmj.f7535/rr/683849.

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UNDER THE INFLUENCE

Alcohol industry’s response to *BMJ* investigation

We would like to respond to several points made in the *BMJ* investigation of the consultation on the minimum price for alcohol.¹

Firstly, the report argued that the number of meetings between government and the alcohol industry indicated unjustified access to government to lobby against minimum unit pricing. In reality, the government invited businesses to those meetings as part of the public health responsibility deal, and our representation indicated our commitment to that deal. Most meetings took place before the government announced its intention to consider minimum unit pricing.

Secondly, the article implied that these meetings were private lobbying events. But most were attended by non-governmental organisations (NGOs) and other stakeholders in the process, including the NGO co-chair Mark Bellis and his successor Nick Sheron, both of whom signed the *Daily Telegraph* letter that accompanied publication of your article.²

Thirdly, from the start, the secretary of state made it clear that alcohol pricing and taxation were not within the responsibility deal’s remit and that any discussions on those matters should take place elsewhere. Its focus was to deliver action on labelling, unit reduction, and measures to tackle underage drinking.

Finally, we reject the suggestion that the alcohol industry uniquely enjoys access to MPs through its involvement in all party groups. Public health NGOs have the same access through groups they are active in, such as the all party group on alcohol misuse, where Alcohol Concern provides the secretariat. Any sponsorship, funding, and administrative support provided to these groups is recorded transparently according to the rules, which apply to all industries or interest groups.

We entirely agree with the health minister’s remark that it is appropriate for government to seek views from stakeholders in matters that have a fundamental impact on them. As representatives of our members, we have the responsibility to highlight the impact of government policy decisions. We intend to continue doing just that.

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Competing interests: This letter is submitted by the WSTA, BBPA, NACM, and SWA which are referenced in the original article.

Full response at: www.bmj.com/content/348/bmj.g72/rr/684106.

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ACCESS TO CLINICAL TRIAL DATA

EMA’s window of opportunity more ajar than open?

Doshi and Groves recommend that readers get the data they might need from the European Medicines Agency (EMA) while they can, in light of potential changes to its policy on access to documents.¹ The agency’s transparency requirements are enshrined in the EU directive 200/83/EC, which regulates drug products, and in the European freedom of information regulation (1049/2001).

At *Prescrire*, an independent drug bulletin, we have conducted drug reviews on all new products and indications entering the EU and French market since 1981.² To do so, we often request various

types of unpublished document from the EMA. Over the past nine years our experience could best be described as a mixed bag.

Having widely reported on the shortcomings of the previous EMA access to documents policy from 2005 to 2009,³ we witnessed a change of heart from 2010 onwards, with more documents being promptly delivered and more questions being answered.

But some of this openness came to a halt in 2013, when we faced consecutive delays in response and data delivery, a shift in procedures, and a change of tone. Straightforward requests for periodic safety update reports were delayed or left unanswered. Generally, documents to which access had been previously granted were no longer available or supplied only after intense correspondence. Strangely, during 2013 the agency uploaded other process related documents to its website (agendas, meeting minutes, etc). So when it comes to transparency compliance at the EMA, is Peter being robbed to pay Paul?

It is hard to pinpoint the reasons for such shifts, but during 2013 the agency faced legal action by two drug companies, underwent a major reorganisation, and appointed a new head of legal services with a long career in the drug industry. Regardless of any underlying cause, the EMA is falling short and not fully meeting its transparency obligations established in EU legislation. So, as far as we see it, this window is ajar, not fully open.

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Full response at: www.bmj.com/content/348/bmj.g63/rr/684047.

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Cite this as: *BMJ* 2014;348:g1411

NHS REGULATOR

Root and branch reform required

The role of the Care Quality Commission (CQC) is to check whether healthcare providers are meeting national standards, so it's good that MPs now consider it fit for purpose.¹ Why its new chairman David Prior is loudly proclaiming the non-evidence based ideology that the panacea for NHS woes is more competition to drive up standards is anyone's guess, and surely this is not his role.

In fact, I wonder how much he actually knows about the NHS and its services. Educated at Charterhouse and Cambridge, he has worked at Lehman Brothers and Lazard Freres and was arrested as part of an investigation into financial

irregularities at the private sector Cawston Park Hospital in Norfolk in 2007.² Although exonerated, he admits the pain of seeing his reputation traduced in the local and national media without an opportunity to rebut the false allegations.² This at least should make him empathise with the NHS, suffering a similar treatment at present.

Those like Prior who venture into health policy might care to reflect on the experience of competition in social care in England.³ This tells a tale of adverse effects on quality of care, deregulation and casualisation of the work force, and market failure, with serious consequences for patients, care users, and families. MPs may be happy, but I sense further reorganisation and considerable culture change in the CQC may still be required, perhaps with some changes at the very top.

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Competing interests: I support a comprehensive public service NHS financed out of general taxation.

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NEW ORAL ANTICOAGULANTS

The lack of antidotes for new oral anticoagulants

Warfarin is a bit like great aunt Mabel's old car—slow, uneconomical, temperamental, and often in need of repair—but still reasonably reliable. A classic motor that starts, stops, and shakes.

Perhaps great aunt Mabel might be better with a new car from the nice garage down the road: the “NOAC (new oral anticoagulant) roadster” is more comfortable, more economical, and has much longer service intervals. Available today, with no deposit and no repayments.

So why are anaesthetists and surgeons anxious about the prospect of seeing large numbers of NOAC roadsters? The answer is that in an emergency it is not possible to do an emergency stop. Whereas the effect of warfarin can be reversed, or dramatically reduced, within a few hours with vitamin K and fresh frozen plasma, no antidotes are currently available for new anticoagulants. The only strategy is to wait for the drug to wear off, and this can take many hours or even days.¹ For patients with major bleeding, an inability to rapidly reverse the anticoagulant effect may seriously compromise the clinical outcome and even render the situation unsalvageable.

National Institute for Health and Care

Excellence (NICE) draft guidelines try to mitigate this risk by using the HAS-BLED score to identify people at higher risk of bleeding,^{2 3} but haemorrhage can affect anyone.¹ NICE emphasises the importance of involving patients in discussions about the decision to use new anticoagulants. Given that “the dealership” knows about this problem with “the brakes” and that customers might reasonably assume the brakes on a new car to be better than those on an old one, shouldn't we mention this problem during “consent” discussions?

Many patients will still drive off in a new NOAC roadster; but great aunt Mabel might be happier (for the moment) with her shakes and brakes.

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Competing interests: None declared.

Full response at: www.bmj.com/content/348/bmj.g313/rr/684835.

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Cite this as: *BMJ* 2014;348:g1438

NICE ON HEAD INJURY

CT after head injury for patients taking any anticoagulant?

In its guideline on the early management of head injury, the National Institute for Health and Care Excellence has included warfarin treatment as an indication for computed tomography in adult patients.¹ I am worried, however, that no mention is made of other anticoagulants, including long term low molecular weight heparins and the new oral agents, such as apixaban. These drugs are increasingly being used for thromboprophylaxis after elective orthopaedic surgery or as an alternative to warfarin in atrial fibrillation.

My fear is that the use of the term “patients on warfarin” in the published guideline rather than “patients on anticoagulants” may prevent many patients on anticoagulants from receiving computed tomography imaging at an appropriate time.

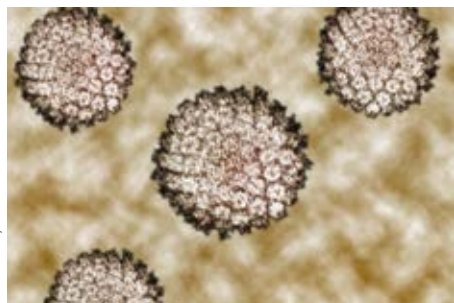
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Competing interests: None declared.

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SCREENING FOR HPV

We shouldn't yet burden women with their HPV status



SCIENCE VU/SPL

Elfström and colleagues do not discuss the ethics of human papillomavirus (HPV) testing, which will become a more contentious problem as more women are screened for HPV.¹

We encourage patients diagnosed with sexually transmitted infections to tell their sexual partners. It is mandatory for patients to inform their partners of potentially life threatening infections like HIV: if the patient refuses to do so, the doctor may break confidentiality to inform the at-risk partner.² Knowingly exposing someone to HIV infection is a crime in the UK.³

HPV infection is common—most sexually active adults will be infected with at least one strain at some point: 39% of 20-24 year old women in the UK have potentially oncogenic HPV types 16 or 18.⁴

Except for strains that cause genital warts, most HPV infections are initially asymptomatic: currently most HPV infected women are blissfully ignorant of their status. If widespread HPV testing is rolled out, how will we advise women to talk to their sexual partners about their HPV status? Sexually transmitted infections are still a difficult topic to discuss: especially if the infection is untreatable.

Will we ask women to tell partners that they are infected with an untreatable infection? Or say that they need to tell their partners only about oncogenic strains and strains that cause warts? There might be legal ramifications for a woman who knowingly transmits HPV to a male partner, who subsequently infects another female, who develops cervical cancer.

We need to arm patients with the facts, so that they can have a meaningful conversation about HPV with their partners. If we are going to tell women their HPV status, we should support their ability to cope with that information.

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Competing interests: None declared.

Full response at: www.bmj.com/content/348/bmj.g130/r/684409.

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Cite this as: *BMJ* 2014;348:g1443

STOP SITTING ON THE FENCE

Joy of shared decision making

Sarela's central assertion that doctors should provide a clear recommendation to guide decision making is correct.¹ However, he asserts that medical decisions are often so complex that informed decision making by patients is "almost always impossible," and he uses the case of multidisciplinary teams discussing cases at length without unanimity as support for this.

These statements show a lack of understanding of the role that patients should have in a shared decision. Shared decision making does not expect patients to navigate the complex waters of modern medicine. Instead, it asks them to share their aims and values for treatment, and a different kind of question is needed to elicit this information.² Is their aim cure at all costs? What sort of effect will this complication have on their life? Are the complications of this treatment too much of a trade off for them? This involves information sharing—not to delegate the decision but to elicit values. This is why many multidisciplinary teams debate cases at length—the team may not acknowledge that the decision about which treatment is "best" is a value judgment as well as a clinical one. The value that matters in this judgment is that of the patient.

Finally, although the recommendation is central to the interaction between doctor and patient, clinicians should pay close attention to the way in which it is delivered. It should take place after the options have been discussed and be followed by a description of why this particular treatment is being recommended.³

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Competing interests: None declared.

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Cite this as: *BMJ* 2014;348:g1435

CLINICAL AUDIT

Central clinical audit database?

In their call to action about access to clinical trial results, Goldacre and Heneghan alluded to "the most basic research tool in medicine—audit."¹ Every year, thousands of audits are done across the NHS by clinicians of all levels, and they often provide valuable insight into clinical practice and how it can be improved. Yet despite their usefulness, audit results are generally confined to the department they are performed in or to the archives of specialist journals.

In the interests of transparency and spreading these useful findings, it seems logical that alongside a clinical trials results database, there should be a national clinical audit results database.

NHS England would seem the ideal organisation to take the lead on this.

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Competing interests: None declared.

- 1 Goldacre B, Heneghan C. Improving, and auditing, access to clinical trial results. *BMJ* 2014;348:g213. (15 January)

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How to improve clinical audit

There are two ways that we might improve clinical audit's contribution to improving quality of care.¹ One is to re-establish a central repository of information on the 50-60 national clinical audits in England. A previous attempt (Directory of Clinical Databases) provided not only information on the data available but also an independent assessment of the quality of the data in the national clinical audit.² Unfortunately, after a few successful years the NHS Information Centre decided not to maintain this database, although it is still archived on the web (<http://docdat.ic.nhs.uk/>). There is a current initiative, funded by NHS England and led by the Healthcare Quality Improvement Partnership, to create a new resource during 2014.³

The second approach is along the lines suggested by Smith.⁴ I agree that there are many imaginative and enterprising local quality improvement initiatives. A website that highlighted the best and most successful ones would help their dissemination and wider uptake. However, it would be essential that such a resource was kept up to date—often a challenge after initial enthusiasm starts to wane.

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Competing interests: I chair the National Advisory Group for Clinical Audit and Enquiries that advises NHS England.

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