

## How did UK cigarette makers reduce tar to 10 mg or less?

EDITOR—To try to reduce the harm caused by cigarette smoking, the European Commission established maximal values for tar (10 mg), nicotine (1 mg), and carbon monoxide (CO; 10 mg) per cigarette, as measured by the International Organization for Standardization (ISO) method, from 1 January 2004.<sup>1</sup> The easiest way to reduce yields is by increasing filter ventilation,<sup>2</sup> but this allows smokers easily to control the dose of smoke they can obtain, usually to facilitate increased intake from lower yield cigarettes.<sup>2,3</sup> We compared yields and design features of 10 cigarette brands sold in the United Kingdom before and after the EC standard was implemented.

Researchers at Roswell Park Cancer Institute performed analyses in September–October 2005. The 1999 brand versions had been stored unopened at room temperature since purchase; current versions were purchased in September 2005.

Full details of methods and data are available on the web ([www.roswellttrc.org/research3\\_3.htm](http://www.roswellttrc.org/research3_3.htm)). Filter ventilation was assessed using a KC-3 digital apparatus (Borgwaldt-KC, Richmond, VA, USA) following a published protocol.<sup>4</sup> ISO tar, nicotine, and CO yields were obtained from packs (1999 CO values are from LGC<sup>5</sup>). Wilcoxon tests assessed average changes across brands.

The table shows yields and filter ventilation for each brand. Originally rated at 11–13 mg tar (median 12 mg), all brands dropped to 10 mg tar (17% drop,  $P < 0.002$ ), while reducing nicotine from a median of 1.0 mg to 0.9 mg ( $P < 0.008$ ). The ratio of tar to nicotine did not change ( $P > 0.45$ ).

Carbon monoxide yields also dropped significantly, from a median of 13 mg to 10 mg ( $P < 0.01$ ). Median ventilation increased by 479% ( $P < 0.006$ ) from 1999 to 2005. None of the other design features measured showed consistent changes.

Our findings indicate that manufacturers complied with the EC's recent mandated yield reduction primarily by increasing filter ventilation rates on cigarettes—a design feature that promotes compensatory smoking.<sup>2</sup> The current “10-1-10” standard is therefore unlikely to reduce smoke exposure for smokers.<sup>3</sup> The EC, while recognising the compensation problem, has said that it will not revise the standard until solid evidence shows that better methods exist.<sup>1</sup>

Our data suggest that removing erroneous yields from packs and adopting alternative approaches to reducing the harmfulness of cigarettes, such as banning filter vents, seems warranted. However well intentioned the EC's effort to make cigarettes less harmful, focusing solely on the use of maximum yields has served to promote increased levels of filter ventilation, which is both ineffective and misleading.

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Competing interests: KMC and LTK have provided expert testimony in court cases against the tobacco industry. KMC received travel expenses for speaking at a tobacco litigation seminar. RJO, AM, and GAG have no competing interests to declare.

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## People seem confused about sensible drinking messages

EDITOR—Eleven years after publication of guidelines on sensible drinking,<sup>1</sup> the social repercussions from the abuse of alcohol remain worrying in the UK. Unit labelling of alcohol drink containers was introduced in 1998 on a voluntary basis. In 2004 the government encouraged manufacturers to add messages on sensible drinking.<sup>2</sup>

We investigated two interrelated aspects of public health education—recall of sensible drinking messages and awareness of drink labelling—among Scottish supermarket shoppers. The supermarket visited has pre-empted UK drink labelling innovations—since 2003 wine sourced from its own supplier has displayed a comprehensive label showing the percentage of alcohol, the units of alcohol in the particular bottle, and daily guidelines of sensible drinking for both sexes.

Shoppers at three city supermarkets were approached on three consecutive weekdays (July 2005). Of 263 drinkers surveyed, 174 (66%) were women and 248 (94%) purchased alcoholic drinks from supermarkets.

Changes in ISO yields and ventilation for selected “full flavour” brands, United Kingdom, 1999–2005

Brand	Tar (mg)		Nicotine (mg)		CO (mg)		Ventilation (%)	
	1999	2005	1999	2005	1999	2005	1999	2005
Benson and Hedges Special Filter	11	10	0.9	0.9	13	10	26.8	29.7
Berkeley Superkings	11	10	0.9	0.9	16	10	3.9	33.5
Club King Size	12	10	1.0	0.8	15	10	3.2	22.6
Lambert and Butler King Size	12	10	1.0	0.9	13	10	4.1	12.0
Marlboro “Red” King Size	12	10	0.9	0.8	12	10	20.7	25.9
Peter Stuyvesant Luxury Length or 100s	13	10	1.2	0.8	13	10	3.6	37.1
Regal King Size	12	10	1.0	0.9	15	10	3.8	16.3
Richmond King Size	12	10	1.0	0.9	NA	10	4.2	11.8
Rothman's Royals King Size	11	10	1.0	0.8	11	10	27.0	22.7
SuperKings	12	10	1.0	0.9	NA	10	5.0	30.9
Median	12	10	1	0.9	13	10	4.2	24.3

ISO=International Organization for Standardization.  
CO=carbon monoxide.

NA=CO yields were not available in LGC report.<sup>5</sup>

## Summary of questionnaire responses

Response	No (%) of respondents
All participants (n=263):	
Recall of daily sensible drinking guidelines for women (2-3 units)	21 (8)
Recall of daily guidelines for men (3-4 units)	12 (5)
Women (n=174):	
Use of unit system to monitor personal drinking	43 (25)
Men (n=89):	
Use of unit system to monitor personal drinking	17 (19)
Respondents "ever drinking wine" (n=225):	
Awareness of enhanced wine label	97 (43)

Definition of a UK unit of alcohol was good; only 24 women (14%) and 14 men (16%) could not respond. However, accurate knowledge of UK daily guidelines was poor (table). Many respondents simply divided the older, weekly guidelines by seven.<sup>3</sup> Around a third failed to answer.

Few participants used the alcohol unit system to monitor their consumption (table). Some linked use to judging fitness to drive. Of 121 participants (46%) who preferred wine, 27 (22%) offered no estimate of the unit content of an average bottle of wine (75 cl; around 9 units) and 43 (36%) suggested 7 or fewer units.

Under half of those "ever drinking wine" were aware of the enhanced wine label (table). Only 19 (20%) of those claimed that it influenced their buying. Awareness was roughly equal between the sexes. Price offers influenced buying more than label information. Altogether 195 participants (75%) favoured drink labelling.

This pilot study highlights considerable confusion about sensible drinking messages in the UK. Few respondents used the unit system to monitor their drinking. Their preference for the superseded weekly guidelines,<sup>3</sup> questions whether the aim of the 1995 revision, "to help people avoid drunkenness,"<sup>1</sup> has been tested adequately.

Respondents' enthusiasm for labelling is countered by other countries finding no correspondence between labelling and positive behavioural change.<sup>4,5</sup> However, should the substance of a message be reviewed before the means by which it is disseminated? Current alcohol education initiatives in the UK may fail adults wishing to drink sensibly.

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## Cannabis and psychosis

## Let's start from the null hypothesis

EDITOR—Fergusson et al say that it is better to reach interim conclusions about the relation between cannabis and psychosis despite the uncertain evidence.<sup>1</sup> This is contrary to the scientific principle of starting from the null hypothesis. The null hypothesis should be overturned only if there is sufficient evidence.

Moreover, the argument they use to tip the balance in favour of a causal association depends on biased evidence about the neurobiological basis of psychotic disorders, such as schizophrenia. The authors say that the dopamine system is known to have a key role in the development of psychotic symptoms. However, unequivocal evidence of a hyperactivity of dopaminergic neurotransmission in schizophrenia has not been found.<sup>2</sup> It is pure speculation for Fergusson et al to suggest that repeated exposure to  $\Delta^9$ -tetrahydrocannabinol may lead to permanent changes in transmitter function. Let's wait to see if the Val/Val variant of the COMT gene really increases the strength of association of cannabis and psychosis.<sup>3</sup> Many behavioural genetic studies have not been replicated,<sup>4</sup> and this finding needs to be confirmed. The effects of cannabis on dopamine processing in the brain do not necessarily cause psychosis, as dopamine activity may be normal in psychosis.

The problem of interpretation arises because of the hypothesis of brain abnormality as the primary cause of mental disorder.<sup>5</sup> I am not saying that cannabis does not cause emotional problems; nor that people do not use it to deal with their emotional problems. Cannabis use is likely to be a proxy measure for poor premorbid adjustment associated with psychosis. Focusing on cannabis as a potential aetiological factor should not, but may, avoid understanding of the psychosocial origins of psychosis.

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## Does cannabis really cause psychosis?

EDITOR—Does cannabis really cause psychosis?<sup>1</sup> Recent studies and clinical experience have shown that at least half of all UK teenagers use some cannabis. Colleagues from countries which abjure alcohol report high levels of recreational cannabis use. Certain Caribbean countries use cannabis regularly. How come the incidence of psychosis is the same for all these populations?

Many, but not all, in our secure unit use cannabis, but so do many more outside it. Cannabis seems to worsen psychosis in mentally ill people but not in their mentally stable peers.

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## Barriers to using warfarin in non-valvular atrial fibrillation

EDITOR—Anticoagulation is underused in the treatment of non-valvular atrial fibrillation. Choudhry et al show that adverse outcomes from anticoagulation have greater influence on its management than occurrences of avoidable ischaemic stroke.<sup>1</sup> They speculate that this result arises from undue fear or concern about adverse consequences of anticoagulation.

We are conducting a representative national survey of 1000 Australian general practitioners, addressing how fear of anticoagulation affects management of non-valvular atrial fibrillation. Our preliminary findings indicate that aversion to the risk of intracranial haemorrhage is substantial. Doctors are overly cautious in prescribing anticoagulation where there is a perceived risk of major and even minor bleeding even when the benefits of anticoagulation outweigh the risks.

In 207 early responses, 95 doctors reported the experience of an ischaemic stroke in their patients with non-valvular atrial fibrillation without anticoagulation. Only 27 reported experiencing an intracranial haemorrhage in such patients receiving anticoagulants. Over half of general practitioners (112) expected to feel equal responsibility for either an intracranial haemorrhage in a patient taking anticoagulants or a fatal or disabling ischaemic stroke without anticoagulation. Nearly a fifth (40) would feel more responsible for an intracranial haemorrhage.

When asked to select treatment for a hypothetical patient with non-valvular atrial fibrillation at "high" risk of stroke,<sup>2</sup> nearly three quarters of doctors (150) would appropriately select warfarin. A perceived risk of bleeding markedly reduced selection of warfarin even when the risk of bleeding was acceptable, according to best available evidence.<sup>3,4</sup> In the presence of a risk of minor falls that would not contraindicate anticoagu-

lation,<sup>5</sup> fewer than half of doctors (96) selected warfarin. Only just over a quarter (58) would give anticoagulants to a patient at high risk of stroke with a history of recurrent nosebleeds. Only a fifth of doctors (42) would give anticoagulants to such a patient with a previously treated, bleeding peptic ulcer.

Implementing evidence based management of non-valvular atrial fibrillation is proving difficult, and the potential to reduce the risk of stroke is yet to be fully realised.<sup>5</sup> Our preliminary findings support the assertion by Choudhry et al, that the under-prescribing of anticoagulants for atrial fibrillation has a profound psychological dimension. Any strategy to improve the evidence based management of non-valvular atrial fibrillation will need to tackle the excessive concerns that clinicians have about anticoagulation. We need to reduce anxiety about "acts of commission" in the management of non-valvular atrial fibrillation.

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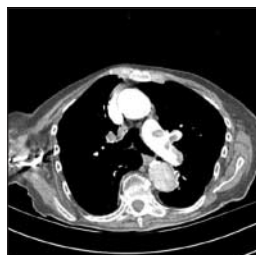
Competing interests: None declared.

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## Pulmonary embolism in hospital practice

### Certain crucial procedures were omitted

EDITOR—Robinson says that diagnosis of pulmonary embolism can be difficult but does not mention the available scoring systems that are useful in defining the likelihood of pulmonary thromboembolism.<sup>1,2</sup> Most importantly, she makes no mention of biomarkers and does not emphasise the critical importance of echocardiography or computed tomography scanning to identify right ventricular strain.



Patients with a raised troponin concentration (I or T) and echo or computed tomographic evidence of right ventricular overload have 10 times the risk of death or major adverse event than individuals with a normal troponin value and normal right ventricular function.<sup>3,4</sup>

Importantly, the recommendation of low molecular weight heparin as initial treatment for all applies only to stable patients. Patients with shock should receive intravenous heparin, since cutaneous perfusion is compromised, and low molecular weight heparin may not be absorbed.

Finally, Robinson makes no mention of life saving surgical embolectomy or percutaneous fragmentation procedures, which have a key role in a gravely ill patients with massive pulmonary embolism.<sup>2,5</sup>

Modern management of patients with pulmonary embolism demands three investigations: an immediate troponin measurement, computed tomographic pulmonary angiography, and definition of involvement of the right ventricle by computed tomography or echocardiography. Without these we will remain stuck in 1990s medicine.

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### View from primary care is chest pain and breathlessness, but not together

EDITOR—Robinson describes pulmonary embolism in hospital practice.<sup>1</sup> Pleuritic chest pain in primary care is common, usually with no other signs. What tests, if any, need to be done in patients not "ill," to rule out small pulmonary emboli?

Silent breathlessness is also common. What is the best investigation, again from primary care, to exclude a silent pulmonary embolism if a V/Q scan is now obsolete and trying to get any activity related to computed tomography in a reasonable time scale not possible?

I write as a general practitioner who has seen four or five silent pulmonary embolisms over the years (suggested by outpatient V/Q scans) and two deaths from missed emboli that

recurred or extended. If it is a D-dimer test, what can be taken as a value below which the risks are minimal?

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## Severe hepatic injury and adulterated Chinese medicines

EDITOR—The incidence of obesity in the United Kingdom is increasing in parallel with an increase in the use of slimming aids, including traditional Chinese medicines. The safety and quality of herbal medicines have been weakly regulated because of an exemption in the Medicines Act 1968 that allowed them to be marketed without going through stringent criteria required for licensing of normal medicine.<sup>1</sup>

Between November 2003 and June 2004 we treated four patients who developed severe acute liver injury within two months of starting to take such a slimming aid (Shubao), widely available in the West Midlands. Three patients fully recovered on discontinuing the agent; one patient progressed to fulminant hepatic failure, requiring liver transplantation. Samples of Shubao were forwarded to the Medicines and Healthcare products Regulatory Agency (MHRA), and laboratory analysis showed adulteration with N-nitrosufenfluramine, a recognised hepatotoxin. This derivative of fenfluramine is an appetite suppressant that was withdrawn by the MHRA in 1997 after reports of cardiac valvular dysfunction.<sup>2</sup> The N-nitroso derivative may have enhanced hepatotoxicity and has been linked with hepatic carcinogenesis.<sup>3</sup>

These patients highlight deficiencies in the previous regulation of the safety and quality of traditional Chinese medicines in the UK. The European Traditional Herbal Medicinal Products Directive, effective in the UK since October 2005, demands compulsory registration of all manufactured, pre-packaged unlicensed herbal products, and represents progress in the regulation of manufactured herbal medicines.<sup>4</sup> All new manufactured herbal medicines must meet specific standards of safety and quality, show either efficacy or longstanding traditional use, and be accompanied by the necessary information for the product to be used safely. All existing products must be compliant with the scheme by April 2011. This should ensure that all herbal medicines are of an acceptable standard and misleading claims are not made about efficacy.

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## NHS Direct did not emerge from an evidence free void

EDITOR—The claim by McDonnell et al, that the implementation of NHS Direct ran ahead of the evidence has little basis.<sup>1</sup>

Preceding the observational study cited by McDonnell et al, a wide range of evidence existed about the successful operation of similar services both in the United Kingdom and internationally.<sup>2,3</sup> There was also survey evidence of strong public demand for such services, plus additional design and evaluative work.<sup>4</sup>

The observational study provided valuable information about the limited initial impact of NHS Direct on immediate care but was not focused on measuring wider impacts such as general practitioners' routine consultations. Useful evidence on these was, however, provided by survey and monitoring work. These indicated that a sizeable proportion of callers appeared to be contacting NHS Direct instead of their general practitioner.

McDonnell et al say that one finding of the National Audit Office study of NHS Direct, that not all of the helpline spend is offset by encouraging more appropriate use of NHS services, raises questions about the remaining £45mn (\$80m; €65m).<sup>1</sup> The National Audit Office, however, raised no such concerns, presumably because £1 net per head per year was recognised as good value for a highly popular 24/7 information and advice service. The overall conclusion was that the implementation of NHS Direct so far has been a success.

McDonnell et al note that NHS Direct is associated with high consumer satisfaction, but so are most health services.<sup>1</sup> The caller satisfaction ratings for NHS Direct have been consistently around the 95% mark, extraordinarily high even for a health service. (User satisfaction levels on general practitioners' services and inpatient services tend to run at around 85% and 70%.)

It is instructive to compare the position on speed of implementation and availability of evidence for the NHS Direct helpline with that for NHS Direct Interactive, the recently launched digital TV service. Here the starting position was quite different. No experience of such services existed in the UK or internationally, so there was no prior evidence. In this case therefore the Depart-

ment of health established an extensive pilot programme that was thoroughly evaluated before any implementation decisions were made.<sup>5</sup>

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## JAMA's policy does not go far enough

EDITOR—The main objection I have to the *JAMA* policy is not that it requires independent validation of analysis but that it seems to require it only for studies sponsored by the pharmaceutical industry.<sup>1</sup> There have been a whole host of examples, ranging from McBride's "studies" of Debendox to the recent case of stem cell research in South Korea, where "academic" researchers seem to have falsified data. Academics (and I am one) are subject to many pressures, ranging from desire for fame to need to get tenure to ambition for promotion. These "interests" are extremely important but go largely unrecognised. Hardly any contributors to medical journals ever declare them.

As a statistician and a sceptic, I am not against distrust, but I am against selective distrust. If distrust is our currency we need to make it universal and apply it to academics and journal editors as well. To make an apposite analogy, the "constant gardener syndrome," from which our society suffers, is to take it as axiomatic that the pharmaceutical industry is uniquely corruptible by motive while forgetting that authors of thrillers as well as film producers, directors, and actors also make a living.

After the stem cell meltdown, what justification does *JAMA* have for giving academics a free ride?

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## One step forward in engaging clinicians in IT

EDITOR—We read with sympathy the experience of setting up and maintaining a database.<sup>1</sup> As rheumatologists in a district general hospital, we went through a similar process, but with a more positive outcome.

We initially explored standalone databases, which were costly, not guaranteed to link with our hospital systems, and requiring the expense of annual back up. One of us (MEL) sat on the hospital information technology (IT) committee (which, unsurprisingly, had plenty of vacancies for clinicians). We worked with our hospital IT department to set up a system based on the hospital patient administration system, a surprisingly powerful data storage tool. It took several months to complete but resulted in a robust and well supported system that has survived to the dawn of the national programme for IT in the NHS (NpIT).<sup>2</sup> We have been lucky to have adaptable and dedicated secretaries. Although the system is more cumbersome to type in, time is saved by pulling all demographic data automatically via hospital number. It worked so well that the diabetes clinic also adapted it.

We learnt some lessons:

- You can't underestimate the lack of knowledge IT departments have about clinical practice and process
- IT departments can't underestimate the lack of knowledge that consultant rheumatologists have about computing
- If your hospital IT department didn't install your system don't expect them to be able to back it up when it goes wrong (and it will go wrong)
- If there's a hospital committee that has a major impact on your work try to get a seat on it.

The electronic patient record will make our database, and others like it, obsolete. However, the effort was worth it. Our department and IT understand each other a bit better, and we have a more realistic view of what can and can't be achieved. We're still talking to each other, and to the IT department.

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