



Tackling the brain drain, p 579



Scrapping prescription charges in Wales, p 579



Drug company marketing tactics, p 589



Preventing alcohol misuse, p 573

## EDITORIALS

- 567 Incentives to quit smoking in primary care**  
Spirometry with pictorial feedback on lung age, not just raw data, improves quit rates, say Raphaël Bize and Jacques Cornuz » [Research p 598](#)
- 568 Giving antioxidants to infants with Down's syndrome**  
Does not improve psychomotor development, says Tim Reynolds » [Research p 594](#)
- 569 Evaluating laboratory diagnostic tests**  
International collaboration to set standards and methods is urgently needed, says Tom Walley » [News p 575, Analysis p 590](#)
- 570 Illness in people with intellectual disabilities**  
Is common, underdiagnosed, and poorly managed, say Afia Ali and Angela Hassiotis
- 571 Government's response to the Tooke inquiry into Modernising Medical Careers**  
Lacks a sense of urgency and an explicit timetable, says Tony Delamothe

## LETTERS

- 573 Tackling alcohol misuse; Diabetes education**
- 574 Joining the DOTS; Private companies and GPs**

## NEWS

- 575 Pfizer asks journal for comments made by peer reviewers**  
UK experts call for system to evaluate diagnostic tests
- 576 Company managed to block development of generic drug**  
UK government will tighten law on trial results
- 577 Demand for prescription drugs in rich areas rises after abolition of charges in Wales**  
GPs reluctantly accept government's offer on extended hours as lesser of two evils
- 578 China wants to make health care more affordable to poor**  
Public health doctors press hospitals to evict fast food outlets  
Venezuelan doctors resent their government's importation of Cuban doctors
- 579 Rich states "snatch" trained doctors from poor countries**
- 580 94% of patients suing Merck over rofecoxib agree to terms of company's offer**  
Drugs for rheumatoid arthritis may have heart benefits  
Hospitals in Gaza have power cuts for 8-12 hours a day
- 581 Scientists consider meat pie mammography and self heating bathtubs**

## SHORT CUTS

- 582 What's new in the other general journals**

## FEATURE

- 584 Cabin fever**  
Health emergencies on aeroplanes often make the headlines, but how common are they and what would you be expected to do if you were on the flight? Alison Tonks investigates

## 586 The gene detective

Howard Cedar got sucked into genetics research when it was still in its infancy. He talks to Rebecca Coombes about breathtaking progress in oncology and barriers to further advances

## OBSERVATIONS

### BODY POLITIC

- 588 There's no biological alternative, says Parliament**  
Nigel Hawkes

### MEDICINE AND THE MEDIA

- 589 The return of the spoof**  
Bob Burton

## ANALYSIS

- 590 Genetic tests for common diseases: new insights, old concerns?**  
The clinical utility of newly identified genetic variants associated with common diseases needs evaluation say David Melzer and colleagues » [Editorial p 569](#)

## RESEARCH, CLINICAL REVIEW, AND PRACTICE

See next page

## VIEWS AND REVIEWS

### PERSONAL VIEW

- 616 A wing and a prayer: the tale of an in-flight emergency**  
Osman A Dar

### REVIEW OF THE WEEK

- 617 The Fake Trade**  
Ike Iheanacho

### COLUMNISTS

- 618 Supermarket sweep**  
Des Spence

**Having a nose for it**  
Wendy Moore

- 619 There will be blood**  
Theodore Dalrymple

### MEDICAL CLASSICS

- 619 The Unmasking of Medicine**  
James Curran

## OBITUARIES

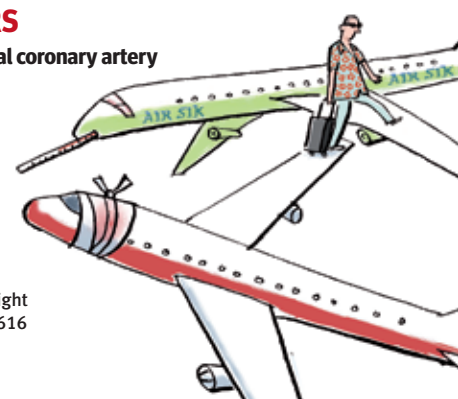
- 621 Eduard Aleksandrovich Stepanov; John Short Happel; Ruth D'Arcy Hart; Thomas Dunn Herriott; John Derrick Morris; Robert Nash; Susan Elizabeth Openshaw**

## MINERVA

- 622 Heparin and elective hip replacement, and other stories**

## FILLERS

- 605 Congenital coronary artery disease**



Tale of an in-flight emergency, p 616



LAUREN SHEAR/SPL

Antioxidant and folic acid supplements for children with Down's syndrome, p 594



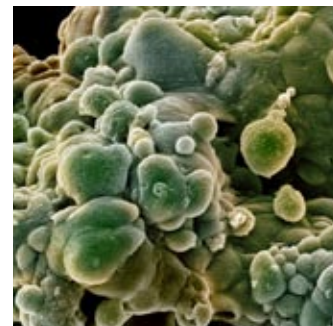
JAMES STEVENSON/SPL

Does telling patients the age of their lungs affect the smoking quit rate? p 598



P. MARAZZI/SPL

Prescribing for older people, p 606



DAVID MCCARTHY/SPL

Guidelines: prostate cancer, p 610

## RESEARCH

### 594 **Supplementation with antioxidants and folic acid for children with Down's syndrome: randomised controlled trial**

Daily oral supplementation with antioxidants or folic acid, or both, or placebo made no difference to infants' biochemical or developmental outcomes up to 18 months later  
Jill M Ellis, Hooi Kuan Tan, Ruth E Gilbert, David P R Muller, William Henley, Robert Moy, Rachel Pumphrey, Cornelius Ani, Sarah Davies, Vanessa Edwards, Heather Green, Alison Salt, Stuart Logan  
» Editorial p 568

### 598 **Effect on smoking quit rate of telling patients their lung age: the Step2quit randomised controlled trial**

Quit rates in the next year doubled after smokers were told their lung age, with a number needed to treat of 14  
Gary Parkes, Trisha Greenhalgh, Mark Griffin, Richard Dent  
» Editorial p 567

### 601 **Empirical evidence of bias in treatment effect estimates in controlled trials with different interventions and outcomes: meta-epidemiological study**

In this meta-review of more than 1000 trials those with objectively assessed outcomes had the least biased estimates of treatment effect  
Lesley Wood, Matthias Egger, Lise Lotte Gluud, Kenneth F Schulz, Peter Jüni, Douglas G Altman, Christian Gluud, Richard M Martin, Anthony J G Wood, Jonathan A C Sterne

## CLINICAL REVIEW

### 606 **Prescribing for older people**

James C Milton, Ian Hill-Smith, Stephen H D Jackson

## PRACTICE

### 610 **Guidelines: Diagnosis and treatment of prostate cancer—summary of NICE guidance**

This is one of a series of *BMJ* summaries of new guidelines, which are based on the best available evidence; they will highlight important recommendations for clinical practice, especially where uncertainty or controversy exists  
John Graham, Mark Baker, Fergus Macbeth, Victoria Titshall, on behalf of the Guideline Development Group

### 612 **Commentary: Controversies in NICE guidance on prostate cancer** Timothy J Wilt

### 614 **Change Page: Don't add aspirin for associated stable vascular disease in a patient with atrial fibrillation receiving anticoagulation** Change Page aims to alert clinicians to the immediate need for a change in practice to make it consistent with current evidence Gregory Y H Lip

## RESEARCH PUBLISHED AHEAD OF PRINT

### **Effectiveness of single dose rifampicin in preventing leprosy in close contacts of patients with newly diagnosed leprosy: cluster randomised controlled trial**

*BMJ*, doi:10.1136/bmj.39500.885752.BE

F Johannes Moet, David Pahan, Linda Oskam, Jan H Richardus, for the COLEP Study Group

## HOLD THE BACK PAGE!

As you may have noticed, we recently combined the *BMJ* and *BMJ Careers* within one set of covers. This has presented some practical problems, one being the splitting up of the obituary pages. We intend to move the obituaries further forward so the short and long obituaries are together again and, by doing this, we will gain a page for editorial content at the back of *Minerva*.

We have now finalised the format for this page, which we have called *Endgames*. There will be a regular statistics question, case report, clinical and picture quiz, along with a question of the week from *OnExamination* to test your knowledge. If you would like to submit questions for this page please refer to our advice for authors on [bmj.com](http://resources.bmj.com/bmj/authors/types-of-article) (<http://resources.bmj.com/bmj/authors/types-of-article>) or contact Amy Davis ([adavis@bmj.com](mailto:adavis@bmj.com)).





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**PICTURE OF THE WEEK**

Motivational deficiency disorder, the spoof illness which started life on the internet two years ago as a satirical dig at drug industry marketing strategies, is now the subject of a fake television “story” designed as an educational aid for the public and health professionals. The new video clips, available online, are part of Consumers International Marketing Overdose campaign, and show a stricken woman unable to get off the sofa without the aid of miracle drug Strivor. See Observations p 589.

**THE WEEK IN NUMBERS**

**57** Number of countries with a shortage of healthcare workers, of which 36 are in Africa (News p 579)

**14** Number needed to treat for one person to quit smoking at one year after telling patients their lung age (Research p 598)

**20%** Proportion of people over 70 who take five or more drugs (Clinical Review p 606)

**9000** Number of men who die from prostate cancer in England and Wales each year (Guidelines p 610)

**40%** Estimated proportion of counterfeit drugs in Lagos, Nigeria, at the end of the 20th century (Review of the Week p 617)

**THE WEEK IN QUOTES**

“At a conference last year, the UK Medical Protection Society said it had no record of anyone being sued for helping during an in-flight medical emergency” (Features p 584)

“In an age of evidence based medicine, the marketing of genetic tests with little evaluation is an unwelcome anomaly” (Analysis p 590)

“Systematic reviewers should routinely assess the risk of bias in the results of trials” (Research p 601)

“Will the traditional, small, local family practice be subsumed into McDonald’s-style medical franchises?” (From the Frontline p 618)

## EDITOR'S CHOICE

## A legal framework for drug safety



Cover illustration: Malcolm Willett

Feature, p 584

Personal View, p 616

It's welcome news that the UK government will close the legal loophole that allowed GlaxoSmithKline to escape prosecution last week for not disclosing evidence of increased suicide risk in children taking seroxat (News p 576). But this piece of legislation alone is not enough. It should be seen as just one further step on the legislative road to full mandatory disclosure of data from clinical trials.

There's no mistaking the UK regulator's frustration at having to drop its attempts to prosecute GSK. Staff at the Medicines and Healthcare products Regulatory Agency reviewed thousands of documents dragged out of GSK over four years. But in the end the existing EU legislation let them down: at the time it didn't require companies to disclose adverse events from trials in groups of patients for whom the medicine was not licensed. On the basis of the same data but in a different legal framework, New York state successfully prosecuted GSK in 2004 for persistent fraud (*BMJ* 2004;329:590).

In his letter to GSK, Kent Woods, the MHRA's chief executive, said it should be self evident that information on adverse effects should be made available promptly in order to protect the public's health: "That moral responsibility now needs to be insisted upon by the unambiguous force of the law." (<http://tinyurl.com/38sggg>)

This raises the question of whether there is a stronger moral responsibility on the drug industry to ensure safety than on, say, the catering or transport industries. Whether there is or not, this case has shown that moral responsibility alone cannot be relied on. Commenting on last week's

other drug industry story—the successful efforts by the makers of Gaviscon to delay the development of a generic alternative (News p 576)—Joe Collier says that whatever efforts are made to tighten the law or industry codes of conduct, companies will find a way to push their boundaries to the limit: "Doctors, government, and regulators of medicines have got to recognise that the industry may not have the best interests of patients or the NHS at heart."

The new UK legislation will remove any remaining doubt about a company's responsibility to declare all evidence on adverse effects, whether before or after marketing, on or off label, within or outside the EU. In addition, the health secretary should undertake a thorough review of the current legal framework for ensuring the safety of prescribed drugs. Legislation similar to the new FDA Amendment Act in the United States, which mandates timely disclosure of trial results for all drugs and devices (*BMJ* 2008;336:170), should be enacted across Europe, with additional measures to ensure that the disclosed data are comprehensive and meaningful and include the trial protocol.

The drug industry has made progress towards greater transparency, both voluntarily and under pressure from journals and regulators. But there are limits to the force of moral responsibility. So for everyone's sake let's rely on the law and make sure it is strong, clear, enforceable, and enforced.

**Fiona Godlee, editor, *BMJ*** [fgodlee@bmj.com](mailto:fgodlee@bmj.com)

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## PLUS

Career Focus, jobs, and courses appear after p 620.

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