PRACTICE, pp 45, 46

NEWS

1 Expanding psychological therapies will not cost NHS
Open access to research findings will deliver benefits but "will not be cost free"

2 Two men plead with senior judges to let doctors end their life legally
Achieving Nicholson challenge requires radical rethink on NHS
Full annual checks for diabetes are postcode lottery

3 MEP calls for law to stop drug trials that could be considered as marketing
Severely anorexic woman, aged 32, should be force fed, judge rules

4 PIP implants don't pose risk to health, experts conclude
London trusts warn practices over industrial action

5 Army doctor ignored our cries, says Iraqi detainee
Reduce use of antidepressants, Dutch doctors told

6 Geneticists condemn firm that tests for racial purity
US sees sharp rise in shop based medical clinics


Richard Layard calls for more mental health therapies, p 1

RESEARCH

RESEARCH HIGHLIGHTS

11 The pick of *BMJ* research papers this week

RESEARCH NEWS

12 All you need to read in the other general journals

RESEARCH PAPERS

14 Ursodeoxycholic acid versus placebo, and early term delivery versus expectant management, in women with intrahepatic cholestasis of pregnancy: semifactorial randomised clinical trial
Lucy C Chappell et al

15 The use of pioglitazone and the risk of bladder cancer in people with type 2 diabetes: nested case-control study
Laurent Azoulay et al
EDITORIAL, p 7

16 Assessment of female sex as a risk factor in atrial fibrillation in Sweden: nationwide retrospective cohort study
Leif Friberg et al
EDITORIAL, p 8

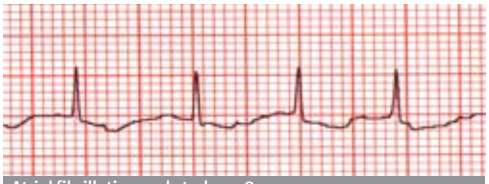
17 Prediction model to estimate presence of coronary artery disease: retrospective pooled analysis
Tessa S S Genders et al

18 The effectiveness and cost effectiveness of dark chocolate consumption as prevention therapy in people at high risk of cardiovascular disease: best case scenario analysis using a Markov model
Ella Zomer et al

COMMENT

EDITORIALS

7 Pioglitazone and the risk of bladder cancer
Dominique Hillaire-Buys and Jean-Luc Faillie


Atrial fibrillation and stroke, p 8

RESEARCH, p 15

8 Female sex as a risk factor for stroke in atrial fibrillation
Eva Prescott and Rikke Sørensen
RESEARCH, p 16

9 HER2 testing in patients with breast cancer
J Michael Dixon et al

10 Educating tomorrow's doctors
Neil Chanchlani and Fiona Godlee

FEATURES

19 London's Olympic public health legacy: Will it turn to dust?
London won the Olympic bid on the back of a promise to increase young people's participation in sport. Denis Campbell assesses the likelihood of success


Will the Olympics leave a public health legacy? p 19

23 A productivity challenge too far?
The NHS in England is already embroiled in a barely achievable productivity challenge. But if the government pushes this policy goal for a further four years beyond 2015, is the NHS setting itself up for failure? John Appleby looks at the figures

ANALYSIS

24 Post-marketing studies of new insulins: sales or science?
Edwin Gale's analysis of registered post-marketing studies of new treatments for diabetes showed that studies of insulin analogues have involved some 400 000 participants worldwide. Most studies were performed in middle or low income countries, had limited scientific value, and promoted wider use of more expensive insulins

28 Commentary: My experience in the drug industry
Anonymous

29 Commentary: "Catastrophic health expenditure"
John S Yudkin

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A note on how to cite each article appears at the end of each article, and this is the form the reference will take in PubMed and other indexes.

Doping in sport, p 30

COMMENT

LETTERS

30 Banning drugs in sport; Human rights abuses; Health worker flu vaccination

31 Mandatory child vaccination; Five years after baby Peter; 15 minute consultations

32 NHS data in the time of reform

33 Drugs for opioid dependence; Personalised medicine; Emergency four hour targets

OBSERVATIONS

REALITY CHECK

34 Has novelty in healthcare gone a little stale? Ray Moynihan

MEDICINE AND THE MEDIA

35 Are schoolchildren really unhealthily underhydrated? Margaret McCartney

VIEWS AND REVIEWS

PERSONAL VIEW

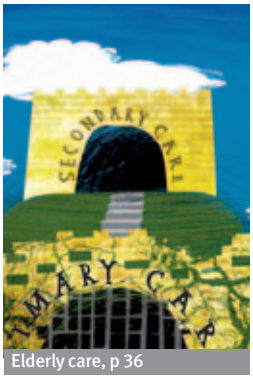
36 The primary-secondary care divide fails older patients John Hughes

BETWEEN THE LINES

37 An end to institutions? Theodore Dalrymple

MEDICAL CLASSICS

37 The Extraction of the Stone of Madness by Heironymous Bosch Desmond O'Neill



Elderly care, p 36

OBITUARIES

38 Lester Breslow
Proved that seven habits make for a healthier life

39 Marshall Barr; John Robert Billinghurst; Michael Harry Dalton; John Gask; Ernest Munro Jack; Raymond Henry Jones; Margaret Marshall

LAST WORDS

49 Does early diagnosis really save lives? Des Spence

Summertime Robin Ferner

EDUCATION

CLINICAL REVIEW

40 Communicating risk
Haroon Ahmed et al

PRACTICE

10-MINUTE CONSULTATION

45 Tick bite and early Lyme borreliosis
Christopher J A Duncan et al

A PATIENT'S JOURNEY

46 Lyme neuroborreliosis
Joyce Hobson and Mark W Weatherall

Explaining risk to patients, p 40

ENDGAMES

48 Quiz page for doctors in training

MINERVA

50 Tolerance of extreme cold, and other stories

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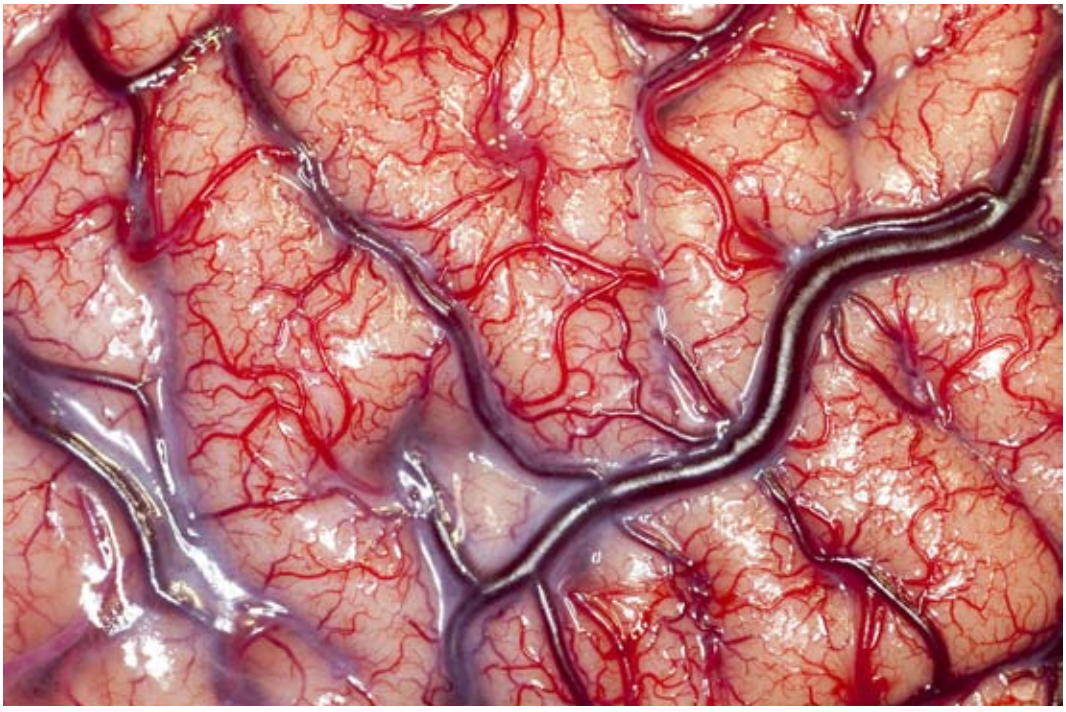

ROBERT LUDLOW, UCL INSTITUTE OF NEUROLOGY, LONDON

PICTURE OF THE WEEK

This picture taken by Robert Ludlow, a medical photographer at University College London's Institute of Neurology, is the overall winner of this year's Wellcome Image Awards. It shows the cortex of an epileptic patient and was taken before a procedure which allowed the identification of the specific areas of the brain that needed to be removed. The winning images are on display at the Wellcome Collection in London until 31 December 2012.

See http://images.wellcome.ac.uk/ for more information.

RESPONSE OF THE WEEK

"Keeping a cool head and displaying an outward calm are desirable for sure, but let's not for a moment think that they are incompatible with empathy. Truly empathic doctors will often realise that upset patients need just these behaviours. But my bet is that such patients value no less the ability described by Colin Murray Parkes of empathy, 'to sense accurately and appreciate another person's reality and to convey that understanding sensitively'.

As to whether it can be taught, I find it revealing how often students find the first part easy—sensing accurately and appreciating another person's reality—and yet need to be encouraged to try doing the second, taking a small chance and conveying that understanding. No tears or other 'outward effusions of emotion' needed but certainly far more than mere politeness."

James Gilbert, doctor, Royal Devon and Exeter Hospital, Exeter, UK, in response to "How to be a cool headed clinician" (*BMJ* 2012;344:e3980)

BMJ.COM POLL

This week's poll asks:
"Should doctors' organisations be neutral on assisted dying?"

Editorial: *BMJ* 2012;344:e4075
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EDITOR'S CHOICE

More marketing than science

A common hallmark of post-marketing studies is that they are "extravagantly powered"

The lessons from this week's Patient Journey are a bit old fashioned, says Mark Weatherall, the neurologist who managed Joyce Dobson's care when she developed facial palsy, double vision, and unsteadiness in her late 70s. "Cast your differential diagnosis wide," he writes, "don't dismiss results that don't fit your diagnosis; many brains are better than one (even a neurologist); and the answer, more often than not, lies in the history." The answer in this case was Lyme neuroborreliosis, contracted while the patient was on holiday in southern France (p 46).

Despite alarming symptoms and some continuing troubling sequelae, the outcome for this patient was largely good. And so it is for most people who develop symptoms after tick bites, according to Christopher Duncan and colleagues (p 45). They advise against testing or giving prophylaxis to asymptomatic patients, and the figures they quote should help to reassure those who do develop erythema migrans. Neurological involvement is rare, especially if the disease is contracted from tick bites in the UK.

Explaining the risks relating to symptoms, tests, and treatments is perhaps one of the most difficult parts of being a doctor, especially where the data are uncertain, says this week's clinical review (p 40). One uncertainty at least seems now to be resolved—the link between bladder cancer and pioglitazone. The study by Laurent Azoulay and colleagues clearly confirms an increased risk (p 15), which the linked editorial says could have been predicted earlier (p 7). Post-marketing studies found a link, but other clues were not picked up or acted on.

Post-marketing studies are crucial to our understanding of the safety and effectiveness of new drugs in the real world. But as currently done they are a cause for serious concern. As Edwin Gale observes, they are often of low scientific value, with no control group and no clear question, and they are poorly regulated especially outside the United States (p 24). The overall impression is that they are more marketing than science.

A common hallmark is that they are "extravagantly powered." In the case of studies of new insulins, Gale reports that large numbers of patients were switched to the new treatment, well beyond the numbers required to detect common adverse events. The benefits to the manufacturer are clear: doctors' prescribing habits have been changed, new patients are started on the new drug, and the costs of the trial and the ongoing treatment are borne by the patient or the health system. The benefits to patients are harder to detect, not least because most results remain unpublished. And since, as John Yudkin reports (p 29), most such studies are now happening in low income countries, the effect can be "catastrophic health expenditure."

Gale calls for much tighter regulation to ensure a proper balance between the commercial and clinical functions of such studies. Perhaps most crucially, a company should be bound by the regulatory and legal framework of the country in which it is based, rather than by the far less well regulated, low resource environment in which such studies often take place.

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