



DRP MARAZZI/SPL

► PRACTICE, p 42

NEWS

- 1 Device licensing bodies often put business before safety, finds investigation
One in four cases of bowel cancer are diagnosed as emergencies
- 2 Patients still not receiving drugs approved by NICE
Panel to review proposals for children's heart surgery
- 3 Researchers promise to be more open about use of animals in their work
Health minister agrees to meet academics to discuss access to clinical trial data
- 4 Revalidation will start in December
Head of ethics committee is not obliged to reveal source of complaint
NHS Gloucestershire keeps community services in public hands
- 5 Hepworth depicts surgical art
Virgin contract to run children's services is to go ahead despite non-compliance with law
- 6 Doctors call for use of secondhand devices to be legalised
New EU tobacco law delayed after health commissioner resigns
Girls do not see HPV vaccine as green light for sex, study says



Bowel cancer diagnosed late, 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 Benzodiazepine use and risk of dementia: prospective population based study
Sophie Billioti de Gage et al
- 15 Calcium intake and risk of primary hyperparathyroidism in women: prospective cohort study
Julie M Paik et al
► EDITORIAL, p 8
- 16 Intermediate acting non-depolarizing neuromuscular blocking agents and risk of postoperative respiratory complications: prospective propensity score matched cohort study
Martina Grosse-Sundrup et al
► EDITORIAL, p 9
- 17 Safe exclusion of pulmonary embolism using the Wells rule and qualitative D-dimer testing in primary care: prospective cohort study
Geert-Jan Geersing et al
- 18 Effect of intended intraoperative cholangiography and early detection of bile duct injury on survival after cholecystectomy: population based cohort study
Björn Törnqvist et al

Articles appearing in this print journal have already been published on bmj.com, and the version in print may have been shortened. bmj.com also contains material that is supplementary to articles: this will be indicated in the text (references are given as w1, w2, etc) and be labelled as extra on bmj.com.

Please cite all articles by year, volume, and elocator (rather than page number), eg *BMJ* 2012; 344:d286.

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.

COMMENT

EDITORIALS

- 7 Multimorbidity: when and how to take a palliative approach to care
Fred Burge et al
- 8 Calcium supplementation may reduce risk of primary hyperparathyroidism
James Norman
► RESEARCH, p 15
- 9 Antagonising neuromuscular block at the end of surgery
Jennifer M Hunter
► RESEARCH, p 16
- 10 The EU's system for regulating medical devices
Peter McCulloch
► FEATURE, p 19



Calcium and risk of hyperparathyroidism, p 8

FEATURES

- 19 How a fake hip showed up failings in European device regulation
Deborah Cohen investigates how EU authorities would be prepared to allow a fake hip prosthesis with dangerous design flaws onto the market
► EDITORIAL, p 10
- 22 BMA's Mark Porter: mastering the thorny issues
In a frank interview, the new BMA leader holds forth to Nigel Hawkes on pensions, regional pay, and privatisation of the NHS

ANALYSIS

- 24 The economic demands of ageing populations: lessons from Japan
What can a country do when an ageing population and prolonged recession put enormous strain on the national budget? Yohsuke Takasaki, Ichiro Kawachi, and Eric Brunner explain Japan's experience and what its government is doing to tackle the problems



Effects of the ageing population in Japan, p 24



Sid Watkins obituary, p 34

COMMENT

LETTERS

- 27 Perils of privatisation; Overtreatment; Prisons and health
- 28 Fitness to practise; Physical activity in children
- 29 Screening of older drivers
- 30 Assisted dying; Empowering patients; Ward rounds

OBSERVATIONS

GOING PUBLIC

- 31 Finding the smoking gun
Annabel Ferriman

VIEWS AND REVIEWS

PERSONAL VIEW

- 32 We should contest political decisions that cause harm
Sean E Roche

BETWEEN THE LINES

- 33 Much about madness
Theodore Dalrymple

MEDICAL CLASSICS

- 33 Forty Years of Murder An autobiography
by Keith Simpson
Harry Haynes

Medicine in *Twelfth Night*, p 33

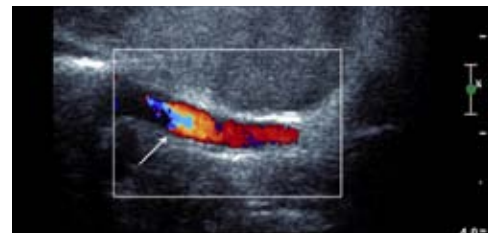
OBITUARIES

- 34 Sid Watkins
The Formula One doctor who made racing safer
- 35 Antony John Essex-Cater; Edward Daniel Fox; Patricia Mathews; David McGill; Philippa Anne Mitchelson; Issy Pilowsky

LAST WORDS

- 49 A licence to bill Des Spence
- All together now James Owen Drife

EDUCATION



Investigating and managing salivary gland swellings, p 36

CLINICAL REVIEW

- 36 Salivary gland swellings
Hisham Mehanna et al

PRACTICE

GUIDELINES

- 42 Assessment and management of psoriasis: summary of NICE guidance
Eleanor Samarasekera et al

UNCERTAINTIES PAGE

- 45 Should selective digestive decontamination be used in critically ill patients?
Andrew P Walden et al

ENDGAMES

- 48 Quiz page for doctors in training

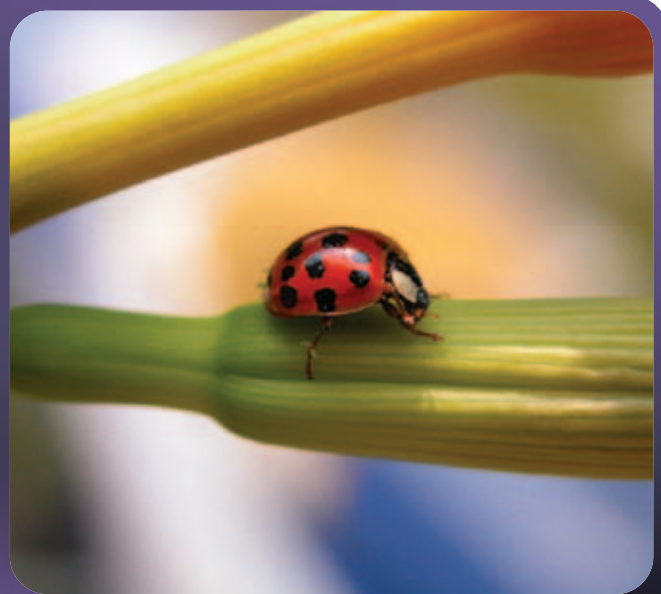
MINERVA

- 50 Rotator cuff repair failure rates, and other stories

Join your colleagues.

BMJ Masterclasses

masterclasses.bmj.com



The Editor, *BMJ*
 BMA House, Tavistock Square,
 London WC1H 9JR
 Email: editor@bmj.com
 Tel: +44 (0)20 7387 4410
 Fax: +44 (0)20 7383 6418
BMA MEMBERS' INQUIRIES
 Email: membership@bma.org.uk
 Tel: +44 (0)20 7383 6642
BMJ CAREERS ADVERTISING
 Email: sales@bmjcareers.com
 Tel: +44 (0)20 7383 6531
DISPLAY ADVERTISING
 Email: sales@bmjgroup.com
 Tel: +44 (0)20 7383 6386
REPRINTS
 UK/Rest of world
 Email: ngurneyrandall@bmjgroup.com
 Tel: +44 (0)20 8445 5825
 USA
 Email: mfogler@medicalreprints.com
 Tel: +1 (856) 489 4446
SUBSCRIPTIONS
 BMA Members
 Email: membership@bma.org.uk
 Tel: +44 (0)20 7383 6642
 Non-BMA Members
 Email: support@bmjgroup.com
 Tel: +44 (0)20 7383 6270
OTHER RESOURCES
 For all other contacts:
resources.bmj.com/bmj/contact-us
 For advice to authors:
resources.bmj.com/bmj/authors
 To submit an article:
submit.bmj.com

The BMJ is published by BMJ Publishing Group Ltd, a wholly owned subsidiary of the British Medical Association.

The BMA grants editorial freedom to the Editor of the *BMJ*. The views expressed in the journal are those of the authors and may not necessarily comply with BMA policy. The *BMJ* follows guidelines on editorial independence produced by the World Association of Medical Editors (www.wame.org/wamestmt.htm#independence) and the code on good publication practice produced by the Committee on Publication Ethics (www.publicationethics.org.uk/guidelines/).

The *BMJ* is intended for medical professionals and is provided without warranty, express or implied. Statements in the journal are the responsibility of their authors and advertisers and not authors' institutions, the BMJ Publishing Group, or the BMA unless otherwise specified or determined by law. Acceptance of advertising does not imply endorsement.

To the fullest extent permitted by law, the BMJ Publishing Group shall not be liable for any loss, injury, or damage resulting from the use of the *BMJ* or any information in it whether based on contract, tort, or otherwise. Readers are advised to verify any information they choose to rely on.

©BMJ Publishing Group Ltd 2012
 All Rights Reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any other means, electronic, mechanical, photocopying, recording, or otherwise, without prior permission, in writing, of the *BMJ*.

Published weekly. US periodicals class postage paid at Rahway, NJ. Postmaster: send address changes to *BMJ*, c/o Mercury Airfreight International Ltd Inc, 365 Blair Road, Avenel, NJ 07001, USA. \$796. Weekly

Printed by Polestar Limited



PICTURE OF THE WEEK

This brochure was designed to promote a fictitious hip implant invented by the *BMJ* and the *Daily Telegraph*. The *BMJ* and *Telegraph* modelled their hip on an implant described as one of the biggest disasters in orthopaedic history, yet European device regulators said that they were prepared to take forward an application to license the fictitious device. Full report starts on p 19. See also news, p 1, and editorial, p 10.

MOST COMMENTED ON BMJ.COM

Bad medicine: clinical breast examination

Cardiovascular disease risk in healthy children and its association with body mass index: systematic review and meta-analysis

Clinicians' gut feeling about serious infections in children: observational study

Assisted dying: "all good doctors do it anyway"

Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial

MOST READ ON BMJ.COM

Plantar fasciitis

Benzodiazepine use and risk of dementia: prospective population based study

Is there equal pay in healthcare? Not if you are a doctor

Diagnosis and management of headaches in young people and adults: summary of NICE guidance

Cardiopulmonary resuscitation

BMJ.COM POLL

Our last poll asked: "Will calorie counts on vending machines reduce consumption of unhealthy food?"

50.2% voted yes (total 1099 votes cast)

► News (*BMJ* 2012;345:e6884)

This week's poll asks:

"Who is mainly at fault for denying access to negative clinical trial results?"

Legislators; Pharma; Regulators; Universities; Ethics committees

► Vote now on bmj.com

RESPONSE OF THE WEEK

I am aware of several doctors and other clinicians who decided to flee the [United Arab Emirates] in the night in fear of being persecuted after a patient under their care had died. The extreme blame culture forced you to practice medicine extremely defensively and you did all you could to prevent the "flat line" while on your shift...

Martin C Scholtz, consultant psychiatrist, Devon, UK, in response to "The imprisonment of Cyril Karabus is deplorable" *BMJ* 2012;345:e6815

EDITOR'S CHOICE

The scandal of medical device regulation

Legislation is what is now urgently needed to protect patients

Try describing Europe's system for regulating medical devices and, as Peter McCulloch says in his editorial this week, the response from your audience will be incredulous (p 10). Read his description and see if you too find yourself asking, "How could this have come about?" It's a question that now demands urgent remedy. If this was not already clear from recent *BMJ* investigations (*BMJ* 2011;342:d2748, *BMJ* 2012;344:e1410), a new investigation makes it uncontroversially so. Working with undercover reporters from the *Telegraph* newspaper, the *BMJ*'s Deborah Cohen has exposed a fragmented, poorly regulated, market driven system, with financial incentives to prioritise manufacturers' interests over those of patients, and with no requirement for clinical evaluation of a device's safety or effectiveness (p 19).

Armed with a fictitious hip implant modelled on one that was recalled on safety grounds in 2010, the reporters approached 14 of the 78 "notified bodies" to which the European Union delegates the job of certifying medical devices. The one to which they eventually submitted their glossy dossier was happy with the design and confirmed that it would approve the device subject to manufacturing documents and a factory visit.

Why did we decide to work with the *Telegraph* on this "secret shopping" exercise? Firstly, there was a clear and pressing public interest. Secondly, we took the view that the information could not have been obtained by other means. Thirdly, we were reassured by the fact that the *BMJ* has successfully used fake information to test various systems in the past. As part of a randomised

trial published in 1998 (*JAMA* 1998;280:237-40), we sent out for peer review hundreds of copies of a research paper into which we had inserted errors. The reviewers were not told that the paper was a fake. For this study, as with the fictitious hip implant, we obtained approval for our plans from the *BMJ*'s ethics committee.

More famously, in 1868, the *BMJ*'s then editor Ernest Hart placed a newspaper advertisement in which he posed as a father seeking a foster mother for his illegitimate child. His aim was to expose the notorious Victorian practice of baby farming, in which unwanted infants were taken in to be nursed in exchange for payment, but were instead neglected and often killed. The advertisement received 333 replies and sparked a series of articles calling for reform (*BMJ* 28 March 1868, 301-2). According to the historian Peter Bartrip, the journal's influence was crucial in achieving legislation.

If the latest undercover operation has similar effect, we will consider the means worthy of the end. Because legislation is what is now urgently needed to protect patients. McCulloch says this must go beyond the tinkering reforms proposed by the EU. Instead, he calls for a system of provisional licensing in which devices could only be marketed if they were being used within clinical studies of their safety and effectiveness. Whatever new system is proposed, he is right to say that it must have patient safety, not trade, at its heart.

Fiona Godlee, editor, *BMJ* fgodlee@bmj.com

Cite this as: *BMJ* 2012;345:e7180

► To receive Editor's Choice by email each week, visit www.bmj.com/newaccount

Twitter

► Follow the editor, Fiona Godlee, at twitter.com/fgodlee, and the *BMJ* at twitter.com/bmj_latest



Sign up today using your smartphone

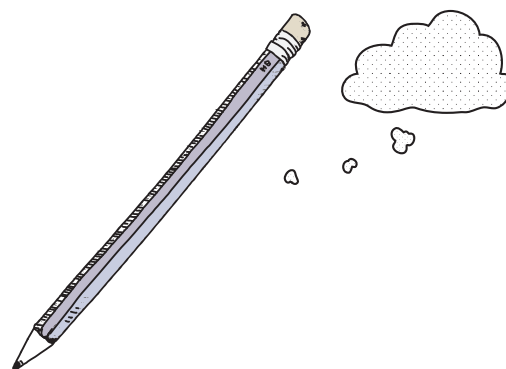
—follow these steps:

- Download a free QR reader from your handset's app store
- Hold your smartphone over the QR code
- You will then be forwarded to the email sign up page

Author submissions

Get published

Have you ever thought about submitting your work to one of the most respected general medical journals in the world? Think no longer—here's your chance. Find out how you can get your research published in the *BMJ* today.



Visit
bmj.com/authors

BMJ