

- O NEWS, p 2 **○** EDITORIAL, p 7
- **○** FEATURE, p 26 OBSERVATIONS, p 35

NEWS

- MPs demand tighter regulation of medical devices across Europe
 - Breast screening is beneficial, but women need more information
- Doctors plea for politicians to tackle problem of missing data
 - Abused patients from closed care home may be at risk in new placements
 - FDA raises concerns about ultra-long acting insulin
- 3 NHS in England paid out £3.1bn for claims linked to maternity care in past decade
- Government "makes up hospital bailout policies on the hoof"
- London trust should be broken up, says administrator St John's wort causes most drug interactions, finds 5
 - review of 85 studies GPs end partnerships with Virgin Care over conflicts of interest
- Doctor's failings as an expert witness were dangerous. court finds US firm accused

of manipulating iournal articles and paving millions to authors of sponsored studies



RESEARCH

RESEARCH HIGHLIGHTS

- The pick of BMJ research papers this week
 - **RESEARCH NEWS**
- All you need to read in the other general journals 12 **RESEARCH PAPERS**
- Association between fish consumption, long chain omega 3 fatty acids, and risk of cerebrovascular disease: systematic review and meta-analysis Raiiv Chowdhurv et al
 - **○** EDITORIAL, p 9
- Identifying the lowest effective dose of acetazolamide for the prophylaxis of acute mountain sickness: systematic review and meta-analysis Emma V Low et al
 - © EDITORIAL, p 8
- Effect of hormone replacement therapy on cardiovascular events in recently postmenopausal women: randomised trial Louise Lind Schierbeck et al
- Neglected tropical diseases: survey and geometry of randomised evidence
 - Shanthi Kappagoda and John P A Ioannidis
- Use of 3×2 tables with an intention to diagnose approach to assess clinical performance of diagnostic tests: meta-analytical evaluation of coronary CT angiography studies Georg M Schuetz et al

RESEARCH

RESEARCH METHODS AND REPORTING

19 Consort 2010 statement: extension to cluster randomised trials Marion K Campbell et al

COMMENT

EDITORIALS

- Clinical trial data for all drugs in current use Fiona Godlee
 - O NEWS, p 2; FEATURE, p 26; OBSERVATIONS, p 35
- Acetazolamide for the prophylaxis of acute mountain sickness Chris Imrav
 - ORESEARCH, p 15



- The role of fish oils in the prevention of stroke Janette de Goede and Johanna M Geleijnse
 - ORESEARCH, p 14
- Changes to the GP contract threaten general practice in the UK

Laurence Buckman

FEATURES

Tamiflu: the battle for secret drug data

The influenza drug oseltamivir has made billions of pounds for Roche, but why won't the company give patients and doctors access to the full clinical data? As part of the BMJ's open data campaign, this week we launch a new site dedicated to the cause. David Payne reports

Bright lights and big city health problems Nigel Hawkes reports on the magnified problems that modern cities present and how public health is responding to the challenges

ANALYSIS

23 Future of WHO hangs in the balance

WHO is in crisis. Unless member states can be persuaded to "untie" their donations and give the organisation leeway to control its budget and set priorities, WHO will slide further into irrelevance, with disastrous consequences for global health, warns David Legge



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



Griffith Edwards obituary, p 38

COMMENT

LETTERS

- 30 Hip arthroplasty endpoints
- 32 Fluid resuscitation in severe trauma
- 33 Plantar fasciitis; monitoring aminoglycoside levels

OBSERVATIONS

REALITY CHECK

34 Too much medicine, not enough mirth Ray Moynihan

BMJ OPEN DATA CAMPAIGN

35 Open letter to Roche about oseltamivir trial data Fiona Godlee

VIEWS AND REVIEWS

PERSONAL VIEW

36 It is too difficult for ill people to claim benefits Anne E Dyson

BETWEEN THE LINES

- **37 Not just bluff and bluster** Theodore Dalrymple MEDICAL CLASSICS
- 37 Rachel's Holiday A novel by Marian Keyes Naomi Devaney



OBITUARIES

88 Griffith Edwards

Key contributor to the study and science of addiction

39 Elizabeth Akwaeze; Colin Broadbent; Callum Roy Weir Bain; James Macrae Cuthill; Walter Elliott; John Stanley Howell; Simon Dafydd Glyn Stephens

LAST WORDS

51 How end of life care has been transformed Des Spence

Botany and birth control Wendy Moore

EDUCATION

CLINICAL REVIEW

40 Management of chronic rhinosinusitis
Kim Lawrence Ah-See

Kim Lawrence Ah-See et al



PRACTICE GUIDELINES

45 Diagnosis of active and latent tuberculosis: summary of NICE guidance

Ibrahim Abubakar et al

A PATIENT'S JOURNEY

47 Tuberculosis

Mel Burden and Hugh Bakere

ENDGAMES

50 Quiz page for doctors in training

MINERVA

52 Dairy products and blood pressure, and other stories

Finding it hard to keep up to date?

BM Masterclasses

masterclasses.bmj.com



BMJ

3 November 2012 Vol 345

The Editor, BMJ BMA House, Tavistock Square, London WC1H 9JR Email: editor@bmi.com Tel: +44 (0)20 7387 4410 Fax: +44 (0)20 7383 6418 BMA MEMBERS' INCILIRIES Email: membership@bma.org.uk Tel: +44 (0)20 7383 6642 **BMJ CAREERS ADVERTISING** Email: sales@bmjcareers.co 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 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.bmi.com

BM Group

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.thm#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

A Hyper Realistic Marshmallow Hand from *Eat Your Heart Out*, a medically inspired cake shop, which was set at St Bart's Pathology Museum this Halloween. Among the numerous cakes that graphically illustrate medical conditions and symptoms of disease were chocolate ganache filled vertebrae, each showing various stages of osteoarthritis; cupcakes demonstrating maggot therapy on a diabetic ulcer; prostate cancer truffles; and many more stomach churning treats.

RESPONSE OF THE WEEK

Thames Water tell me that my Hampstead water has 273 mg/l of calcium. With 2 litres of tea, soup, and tap water I will ingest the 500 mg that the author recommends.

Crawford and Crawford demonstrated increased coronary calcification in cadaver hearts of Londoners (hard water) compared to Glaswegians (soft water) over 40 years ago. The dangers of excess calcium seem to be very real in South East England where our drinking water comes from the limestone and chalk hills all around.

Perhaps the recommendation for calcium supplements should only apply to soft water areas.

Michael D Beary, consultant psychiatrist, Priory Hospital North London, London, UK, in response to "Increased calcium intake may reduce risk of primary hyperparathyroidism" (*BM*J 2012;345:e6646)

BMI.COM POLL

Our last poll asked: "Who is mainly at fault for denying access to negative clinical trial results?"

69% voted Pharma (total 569 votes cast)

This week's poll asks: "Is it unethical to donate used cardioverter defibrillators to patients in India?"

- News, Doctors call for use of secondhand devices to be legalised (*BMJ* 2012;345:e7053)
- ▶ Vote now on bmj.com

MOST READ

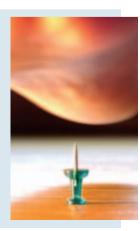
Plantar fasciitis

Benzodiazepine use and risk of dementia:

prospective population based study

Cardiopulmonary resuscitation

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



EDITOR'S CHOICE

Open data: seize the moment

Can the momentum of the UK campaign help push for change in Europe and beyond?

● 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 OR code
- You will then be forwarded to the email sign up page

One of the most popular videos on TED.com is a minilecture by the writer, doctor, and academic Ben Goldacre, called "What doctors don't know about the drugs they prescribe" (http://tinyurl.com/9y8chac). In the video, Goldacre (whose latest book, *Bad Pharma*, does much to expose the damage caused by withheld and misreported data from clinical trials) says that in trials funded by drug companies "positive findings are around twice as likely to be published as negative findings." Since it was posted two months ago, the video has attracted over 387 000 views. Does this suggest that the public is waking up to one of the biggest scandals in clinical research: that big pharma does not make all the clinical trial data for all drugs in current use available for independent scrutiny?

Certainly *BMJ* editor Fiona Godlee, who has led an ongoing campaign for open data, hopes that we are on the brink of a "sea change in the public mood." In an editorial this week (p 7) she asks, "How have commercial companies been allowed to evaluate their own products and then to keep large and unknown amounts of the data secret even from the regulators?"

The past fortnight has seen several initiatives that might help to make this moment a tipping point in the United Kingdom. The first came from general practitioner and Conservative MP Sarah Wollaston, who last week raised in the House of Commons the issue of missing data affecting the medical evidence base (p 2). In response, Norman Lamb, the minister for care services, agreed that access to all data from clinical trials was a "really important issue." He committed the government to a meeting with campaigners.

The second initiative was a letter to the *Times* this

week, signed by 28 campaigners—including Fiona Godlee and Ben Goldacre. The letter called on the government to act to end "ongoing secrecy" surrounding the reporting of clinical trials (p 2). "Vitally important information about drug trials continues to be withheld from doctors and the public, meaning that patients are harmed, and money is wasted," the campaigners wrote.

The third initiative is part of the BMJ's own open data campaign. As David Payne, editor of bmj.com, reports (p 26), the BMJ has this week launched a dedicated website aimed at persuading Roche, the manufacturers of oseltamivir (Tamiflu), to give doctors and patients access to the full data on the influenza drug. The site (www. bmj.com/tamiflu) displays emails and letters dating back to 2009, when Cochrane researcher Tom Jefferson asked Roche for the unpublished dataset used in a 2003 analysis of oseltamivir. The site's aim is to persuade Roche to fulfil a public promise it made in 2009 to release full clinical trial reports, in response to an investigation by the BMJ, Tom Jefferson, and his Cochrane colleague Peter Doshi. The latest addition to the site is a letter from Fiona Godlee to John Bell, regius professor of medicine at Oxford University and a Roche board member, urging the company to disclose the full data (p 35). Jefferson and Doshi explain more about the open data campaign in this week's BMJ podcast (www.bmj.com/podcasts).

Can the momentum of the UK campaign help push for change in Europe and beyond? As Fiona Godlee's editorial says, "We should seize this moment with both hands."

Trevor Jackson, deputy editor, BMJ tjackson@bmj.com

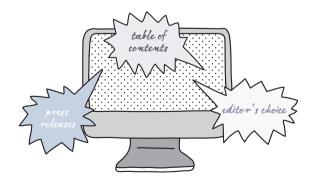
Cite this as: *BMJ* 2012;345:e7332

Email alerts

Busy? Little time to source information of direct relevance to you? Explore the range of email alerts from the *BMJ*'s table of contents, editor's choice, press releases, and others related to your medical specialty. You choose and get the alert delivered straight to your inbox.



bmj.com/email-alerts



BMJ