**THIS WEEK**

Articles in this print journal have already been published on thebmj.com and may have been shortened. Full versions with references and competing interests are on thebmj.com

---

**NEWS & VIEWS**

1. News and research news
2. BMJ Confidential: Jane Dacre

**FEATURES**

14. No correction, no retraction, no apology, no comment: paroxetine trial reanalysis raises questions about institutional responsibility
   - Peter Doshi
   - EDITORIAL, p 10
   - RESEARCH, p 11

**ANALYSIS**

17. Evidence about electronic cigarettes: a foundation built on rock or sand?
   - Martin McKee and Simon Capewell

**RESEARCH**

11. Restoring Study 329: efficacy and harms of paroxetine and imipramine in treatment of major depression in adolescence
   - Joanna Le Noury et al
   - EDITORIAL, p 10
   - FEATURE, p 14

12. Potential of trans fats policies to reduce socioeconomic inequalities in mortality from coronary heart disease in England: cost effectiveness modelling study
   - Kirk Allen et al
   - EDITORIAL, p 8

**EDITORIALS**

7. Time to question the NHS diabetes prevention programme
   - Public Health England’s focus on individual behaviour change is unlikely to stem the epidemic of type 2 diabetes
   - Eleanor Barry et al

8. Dietary fats, health, and inequalities
   - There’s nothing good about trans fats; a total ban would be best for public health
   - J Lennert Veerman
   - RESEARCH, p 12

9. Deficiencies in services for acute upper GI bleeding
   - Patients need rapid access to specialist care round the clock
   - Alan Lobo et al

10. Liberating the data from clinical trials
    - Liberated trial data have enduring potential to benefit patients, prevent harm, and correct misleading research
    - David Henry and Tiffany Fitzpatrick

**PRACTICE**

32. Assessment and management of facial nerve palsy
   - Liam Masterson et al
   - CPD/CME hour

**EDUCATION**

27. Dengue fever
   - Senanayake A M Kularatne
   - CPD/CME hour

**PRACTICE POINTER**

36. Minerva

**BMJ CAREERS**

News: Consultants must not become scapegoats
- Doctors need support, not resilience training
- Why bother with a substantive post?
- Followed by jobs and courses
PICTURE OF THE WEEK

Pictograms and Arabic writing on a makeshift sign show the way to a rest area and medical treatment in an emergency shelter for refugees on 14 September 2015 at the railway station in Salzburg, Austria. German authorities announced that they were temporarily reinstating controls along Germany’s border with Austria in order to stem the recent influx of migrants.

THEBMJ.COM POLLS

Last week’s poll asked:

Do we need more men in medicine

YES: 351 (51%)  NO: 341 (49%)

Total votes: 692

http://www.bmj.com/content/351/bmj.h4646/rr-1

This week’s poll:

Was Public Health England right to endorse electronic cigarettes as a smoking cessation aid?

http://www.bmj.com/content/351/bmj.h4863
RESPONSE OF THE WEEK

E-cigarettes may be free from the toxins and carcinogens that cause lung cancer and other lung diseases but still contain nicotine and are harmful. Nicotine is not only addictive but also associated with peptic ulceration, coronary thrombosis, stroke, and peripheral vascular disease. From my 16 years of working as a surgeon in India I have memories of doing many lumbar sympathectomies and leg amputations for ischaemia in patients with Buerger’s disease as a result of nicotine from the smoking of beedis. Surely these dangers make a case for total quitting and certainly not for the increasing availability of e-cigarettes.

Frank I Tovey, retired consultant surgeon, Lymington, UK, in response to, “Fuming about e-cigarettes and harm”

BMJ 2015;351:h4634

OVERHEARD ON TWITTER

@DrEdFitzgerald

#LookLikeASurgeon made it into The BMJ this week. Read our @bmj_latest blog on how it started http://bmj.co/ILookLikeASurgeon

@ThomIPhillips

Seen @bmj_latest? Data show that CVD and oncology patients are LESS likely to hospital admission: a case for expanded seven day services? BMJ 2015;351:h4596

@Trisha_the_doc

So many of my heroes featuring in this week’s @bmj_latest, not least the obituary for Oliver Sacks.

POPULAR ONLINE

Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies

BMJ 2015;351:h3978

Mental illness, challenging behaviour, and psychotropic drug prescribing in people with intellectual disability: UK population based cohort study

BMJ 2015;351:h4326

Increased mortality associated with weekend hospital admission: a case for expanded seven day services?

BMJ 2015;351:h4596

LATEST BLOGS

Delivering women centred care in maternity services

Do maternity services put women at the centre of care? Are medical professionals providing women with the necessary resources, choices, and information to have a positive birthing experience? Florence Smith, an NHS maternity support worker, reports on a recent conference that looked at how women centred care should be the practice and the norm.

http://bmj.co/NHSmaternity

Global health and altruism

The past 10 years have not been easy for refugees hoping for sanctuary in Canada, writes Chris Simms, who says this is part of a wider government strategy, which has also seen Canada’s social safety net significantly weakened. He cites research that shows rich countries that are less charitable to vulnerable populations at home also give less aid to poorer countries, and hopes for the sake of those at home and abroad that governments can show more generosity.

http://bmj.co/global_health_altruism

Why is it hard to do the right thing?

When he’s faced with a patient who complains of being tired, GP Samir Dawlatly finds himself at one of those crossroads that occur regularly in primary care: the choice to investigate what may be medicalised symptoms or do nothing. He describes how making this decision is made all the more difficult by all the other barriers to good care that practising GPs have to overcome.

http://bmj.co/right_thing_hard

THIS WEEK IN 1915

Dr Kenneth Campbell, surgeon to the Western Ophthalmic Hospital, writes about a case of hysterical amblyopia. The patient was a 21 year old woman whose visual acuity varied within wide limits—sometimes as low as 1/60, sometimes as high as 6/6. There was no element of malingering, no signs of disease, her blood pressure was not raised, and her urine was free from albumin. She did, however, exhibit classical symptoms of hysteria—she was emotional, self conscious, had poor will power, spoke in a whisper, and her life had no satisfying aims. Applying Freud’s method of tracing every symptom to “some antecedent experience in the life history of the individual,” it was found that the patient’s father’s eyesight had recently begun to fail, and this preyed considerably on her mind. Once the patient acknowledged the source of her condition, and brought the “entire circumstances of it under the criticism of the mind,” a cure was effected within nine months.

Cite this as BMJ 1915;2:434

THIS WEEK IN 1915

Dr Kenneth Campbell, surgeon to the Western Ophthalmic Hospital, writes about a case of hysterical amblyopia. The patient was a 21 year old woman whose visual acuity varied within wide limits—sometimes as low as 1/60, sometimes as high as 6/6. There was no element of malingering, no signs of disease, her blood pressure was not raised, and her urine was free from albumin. She did, however, exhibit classical symptoms of hysteria—she was emotional, self conscious, had poor will power, spoke in a whisper, and her life had no satisfying aims. Applying Freud’s method of tracing every symptom to “some antecedent experience in the life history of the individual,” it was found that the patient’s father’s eyesight had recently begun to fail, and this preyed considerably on her mind. Once the patient acknowledged the source of her condition, and brought the “entire circumstances of it under the criticism of the mind,” a cure was effected within nine months.

Cite this as BMJ 1915;2:434

http://bmj.co/NHSmaternity

http://bmj.co/co-production

http://bmj.co/right_thing_hard
This week we release our first “RIAT” reanalysis of a previously published randomised trial (p 11). Avid readers will remember that RIAT stands for “restoring invisible and abandoned trials.” As described by its originators in 2013 (doi: 10.1136/bmj.f2865), it provides a mechanism for researchers unaffiliated with the original trial to publish unpublished (or to republish misreported) clinical trials when sponsors and original investigators fail to do so.

Last year Tom Treasure and colleagues reported a trial whose data had remained unpublished for 20 years (doi: 10.1136/bmjopen-2013-004385). In a narrative article in *The BMJ* the restorative authors said that the data cast doubt on the now common practice of carcinoembryonic antigen testing and metastasectomy in people with colorectal cancer (doi: 10.1136/bmj.g2085).

We expect many other trials to fall within RIAT’s purview. However, when RIAT was first conceptualised, I and others had one specific trial in mind. Study 329 was a placebo controlled randomised trial of paroxetine and imipramine in adolescents with major depression. As originally reported in 2001, it concluded that paroxetine was “generally well tolerated and effective.”

Paroxetine has never been approved for use in children, but as Peter Doshi reports (p 14), millions of off-label prescriptions later, Study 329 has become infamous. Funded by the manufacturer of paroxetine, SmithKline Beecham, now GSK, it was quickly dubbed by the US Food and Drug Administration a “failed trial,” as neither treatment was found to be better than placebo. We learnt that the paper was drafted not by any of the 22 listed authors but by a writer paid by the manufacturer. But most alarmingly, reports emerged of serious adverse effects of paroxetine in adolescents, including self harm and suicidal ideation. In 2012 the US Department of Justice, investigating a failure to report safety data and other misconduct by GSK, settled criminal and civil proceedings with a record $3bn fine. Efforts to get the authors, the journal that published the trial, the professional society that publishes the journal, and the authors’ institutions to act or even respond to criticism have failed.

Given this history, there was little doubt that the study needed restoration. That the original authors chose not to do this came as little surprise. The restorative authors set to work accessing and analysing the clinical study report and patient level data. From this immense task they concluded that there is no advantage of paroxetine or imipramine over placebo. They also uncovered “serious, severe, and suicide related adverse events” that had been overlooked or hidden.

The RIAT re-analysis marks a new chapter in the story of Study 329, showing the remarkable power of open data. But it also shows how much our current systems are failing patients and the public. It should not have taken 14 years to get to this point. It shows that we need regulation, and perhaps legislation, to ensure that the results of all clinical trials are made publicly available and that individual patient data are available for legitimate independent third party scrutiny.

Fiona Godlee, editor in chief, *The BMJ* fgodlee@bmj.com
Cite this as: *BMJ* 2015;351:h4973

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