LETTERS

Letters are selected from rapid responses posted on bmj.com. After editing, all letters are published online (www.bmj.com/archive/sevendays) and about half are published in print
To submit a rapid response go to any article on bmj.com and click "respond to this article"

TELEHEALTH AND TELECARE

Over-claiming the evidence for telehealth and telecare?

It would seem that the emperor has few clothes.[1] Telehealth and telecare have been relentlessly plugged in the *Health Service Journal* for the past year or so in a succession of features, some accompanied by the sector manufacturing the technology. At no point did the journal have an open, balanced *BMJ* style head to head debate so that the sceptics could have their say and restore balance to the narrative.

Despite the Department of Health being the sponsor of the Whole Systems Demonstrator (WSD) trial, the government selectively revealed the more positive pieces of data from this work before it had been published in a peer reviewed journal, accompanied by exhortations "now we know that it works" to adopt at pace and scale. This showed little respect for the integrity of the research process. There has been an unseemly rush to push us towards a "3 million lives" uptake of the technology (why 3 million?), perhaps driven by a too cosy relationship with the limited companies that manufacture it. Meanwhile "technologies" that do have a substantial, mature body of peer reviewed evidence base behind them, such as comprehensive geriatric assessment for frail older people,[2] are not promoted with the same, concerted vigour, perhaps because there is no margin to be made from them for the "medical industrial complex."

I note that the WSD researchers pointedly distanced themselves from some of the early spinning of the findings[3] and that respected commentators have expressed similar concerns.[4 5] And of course, they knew what subsequent WSD results would go on to show. I do not claim that these technologies could not provide a range of benefits. But to promote a policy, commission research to support it, and then prematurely over-claim the benefits is an abuse of research process. Better to say "we are innovating because we think it's a good idea." Even then, in a time of austerity in health and social care, there is surely an onus to commission services that are known to work before innovating for its own sake.

David Oliver visiting professor of medicine for older people, City University, London, UK
david.oliver.1@city.ac.uk

Competing interests: None declared.

1 Henderson C, Knapp M, Fernández J-L, Beecham J, Hirani SP, Cartwright M, et al; for the Whole System Demonstrator evaluation team. Cost effectiveness of telehealth for patients with long term conditions (Whole Systems Demonstrator telehealth questionnaire study): nested economic evaluation in a pragmatic, cluster randomised controlled trial. *BMJ* 2013;346:f1035. (22 March.)
2 Ellis G, Whitehead MA, Robinson D, O'Neill D, Langhorne P. Comprehensive geriatric assessment for older adults admitted to hospital: meta-analysis of randomised controlled trials. *BMJ* 2011;343:d6553.
3 Steventon A. Rapid responses. Re: Effect of telehealth on use of secondary care and mortality: findings from the Whole System Demonstrator cluster randomised trial. bmj.com 2012. 2 August. www.bmj.com/content/344/bmj.e3874?tab=responses.
4 Greenhalgh T. Whole System Demonstrator trial: policy, politics, and publication ethics. *BMJ* 2012;345:e5280.
5 McCartney M. Show us the evidence for telehealth. *BMJ* 2012;344:e469.

Cite this as: *BMJ* 2013;346:f3377

DRUG COMBINATION FOR OBESITY

First do no harm with anti-obesity and other drugs

We welcome the decision by the European Medicines Agency to refuse marketing authorisation for the fixed dose combination of topiramate (an antiepileptic) and phentermine (an appetite suppressant amphetamine).[1]

The loss of a few kilograms cannot justify exposing patients to the known adverse effects of the two drugs combined, such as psychiatric disorders, cardiac arrhythmias, and metabolic acidosis.[2] Yet, given the attractiveness of the antiobesity market, submissions for marketing approval are expected for other similarly dangerous appetite suppressants, such as lorcaserin, lisdexamfetamine, liraglutide, and combined bupropion-naltrexone.[3]

The EMA has clearly prioritised patient safety and public health by saying no to this hazardous combination and issuing a diametrically opposed recommendation to that of the US Food and Drug Administration.

But plenty of other risky drugs are under review by the EMA, including the respiratory stimulant almitrine, the anti-inflammatory diclofenac, the antiemetic domperidone, the anti-anaemia iron dextran, the benzodiazepine tetrazepam, plus third and fourth generation combined oral contraceptives.[4 5]

All eyes are on the EMA—will the precautionary principle prevail and the lessons learnt from past public health disasters be taken on board? Will the agency follow suit, stick to its guns, and "first, do no harm?"[3]

Bruno Toussaint editorial director, *Prescrire*, Paris, Cedex 11, France contact@prescrire.org

Competing interests: None declared.

1 European Medicines Agency. Refusal for the marketing authorisation for Qsiva (phentermine/topiramate). Questions and Answers. 2013. www.ema.europa.eu/docs/en_GB/document_library/Summary_of_opinion_-_Initial_authorisation/human/002350/WC500139215.pdf.
2 Prescrire Editorial Staff. Topiramate+phentermine, an excessively dangerous appetite-supressant combination. *Prescrire Int* 2013;22:64-7.
3 Prescrire. Medicinal products used in weight control: first, do no harm! 2012. http://english.prescrire.org/en/79/207/46302/2374/1884/SubReportDetails.aspx.
4 SCRIP. Fragrance or folly: 15 drug events will resolve before April. *Informa News* 22 February 2013.
5 European Medicines Agency. PRAC: Agendas, minutes and highlights webpage. www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000353.jsp&mid=WC0b01ac05805a21cf.

Cite this as: *BMJ* 2013;346:f3026

CALCIUM AND CARDIOVASCULAR RISK

What is the appropriate MHRA regulatory response?

Concern has been expressed repeatedly in recent years about inadequate oversight by regulatory authorities of drugs and medical devices. Recently, the Medicines and Healthcare Products Regulatory Agency (MHRA) recommended restricting the prescription of strontium ranelate for osteoporosis.[1] This was because strontium increased the risk of myocardial infarction (relative risk 1.6, 95% CI 1.07 to 2.38), although it did not increase mortality, in a pooled analysis of about 7500 participants in randomised controlled trials.

Strontium is a divalent cation that mimics many chemical and biological properties of calcium and binds to the calcium receptor. Its effects on fracture are similar to those of calcium. Strontium decreases the risk of non-vertebral fractures by 14% but does not prevent hip fractures.[2] Similarly, calcium decreases the risk of total fractures by 12% but does not prevent hip fractures.[3] Calcium, with or without vitamin D, also increased the risk of myocardial infarction (1.25, 1.08 to 1.45) in pooled analyses of 13 trials (n=29 277).[4]

The MHRA's response to the finding of increased cardiovascular risk with calcium was strikingly different from its response to that for

strontium.[5] For calcium, the MHRA recommended that no changes to prescribing practice were needed. It concluded that calcium should be prescribed to postmenopausal women who receive treatment for osteoporosis unless the prescriber was confident that the patient had an adequate calcium intake[5]—in effect, a recommendation to continue the widespread prescribing of calcium supplements.

We disagree with the MHRA's interpretation of our analyses. We are particularly worried that, by dismissing safety concerns about calcium supplements that it acknowledges are legitimate, the MHRA is endorsing clinical practice that causes net harm. The MHRA should be consistent in its handling of these matters and show the same concern for the welfare of potential calcium users as it does for those taking strontium.

Mark J Bolland senior research fellow, Department of Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand
m.bolland@auckland.ac.nz
Alison Avenell clinical research fellow, Health Services Research Unit, University of Aberdeen, Aberdeen AB25 2ZD, UK
Andrew Grey associate professor
Ian R Reid distinguished professor, Department of Medicine, University of Auckland, Private Bag 92 019, Auckland 1142, New Zealand

Competing interests: None declared.
Full response with link to correspondence with the MHRA at www.bmj.com/content/342/bmj.d2040/rr/644631.

1 Medicines and Healthcare Products Regulatory Agency. Strontium ranelate (Protelos): risk of serious cardiac disorders—restricted indications, new contraindications, and warnings. *Drug Safety Update* 2013;6:S1.
2 O'Donnell S, Cranney A, Wells GA, Adachi JD, Reginster JY. Strontium ranelate for preventing and treating postmenopausal osteoporosis. *Cochrane Database Syst Rev* 2006;3:CD005326.
3 Reid IR, Bolland MJ, Grey A. Effect of calcium supplementation on hip fractures. *Osteoporos Int* 2008;19:1119-23.
4 Bolland MJ, Grey A, Avenell A, Gamble GD, Reid IR. Calcium supplements with or without vitamin D and risk of cardiovascular events: reanalysis of the Women's Health Initiative limited access dataset and meta-analysis. *BMJ* 2011;342:d2040.
5 Medicines and Healthcare Products Regulatory Agency. Calcium and vitamin D: studies of cardiovascular risk do not support prescribing changes. *Drug Safety Update* 2011;5:H1.

Cite this as: *BMJ* 2013;346:f3413

SHARING DATA FROM CLINICAL TRIALS

Should we always share data?

Not many clinicians or scientists would argue with the campaign by "AllTrials" to register and report the full methods and results of clinical trials.[1] But is it sensible to go so far as to "encourage authors of all *BMJ* papers to share their datasets publicly," so that all may see?[2]

We routinely reassure participants in clinical trials that their data will be held securely and confidentially. Research ethics committees rightly insist on locked filing cabinets and ensuring that only the researchers have access to digital data. Is this reassurance consistent with public release of patients' confidential data without their consent? Although only "anonymised" data are proposed for public release, are data truly anonymous when details of age, sex, and perhaps locality are linked to past and current medical details?

And what will potential trial participants of the future think of the reassurance of confidentiality when they know that their "anonymised" data will be publicly available for anyone to access? Will this encourage more patients to take part in trials or will it have the opposite effect?

I prefer the Medical Research Council's current policy on access to research data. The council considers release only to bona fide researchers, who work for bona fide research organisations, and who sign up to the same standards of respecting the confidentiality of the data as did the original researchers.[3]

Peter D White professor of psychological medicine, Queen Mary University London, St Bartholomew's Hospital, London EC1A 7BE, UK p.d.white@qmul.ac.uk

Competing interests: PDW has received several Freedom of Information requests from members of the public for all the data from a recent trial of non-pharmacological treatments of chronic fatigue syndrome.

1 Groves T, Godlee F. The European Medicines Agency's plans for sharing data from clinical trials. *BMJ* 2013;346:f2961. (8 May.)
2 AllTrials. All trials registered. All results reported. www.alltrials.net.
3 Medical Research Council. Data sharing requirements for population and patient studies. www.mrc.ac.uk/Ourresearch/Ethicsresearchguidance/Datasharing/policy/PHSpolicy/requirements/index.htm.

Cite this as: *BMJ* 2013;346:f3379

MONITORING THE SAFETY OF DEVICES

Tracking devices with bar codes is a start

The important matter of obtaining high quality routine data to monitor the safety of devices and procedures is worthy of urgent action and debate.[1]

Device tracking is certainly a start. All devices should be bar coded. For inpatients, the bar code should be scanned and added to the procedure (or a new) field in the computerised data. This has several benefits:

- It facilitates recall: centrally held computer records are easy to scan if and when required
- The cost of additional data collection is minimised. No new registry needs to be established and the only additional cost is that of setting up scanning facilities at relevant locations. These facilities should ideally be where the devices are inserted, but they could be located centrally in patient records departments
- Any researcher who wants to track particular types of devices as a special research project, on a regular basis, or as part of other research could gain access to the data
- Keeping a record of which specific devices have been inserted also improves costing of procedures.

Stephen Duckett director, health programme, Grattan Institute, Melbourne, Vic, Australia
stephen.duckett@grattan.edu.au

Competing interests: None declared.

1 Campbell B, Stainthorpe AC, Longson CM. How can we get high quality routine data to monitor the safety of devices and procedures? *BMJ* 2013;346:f2782. (7 May.)

Cite this as: *BMJ* 2013;346:f3380

ADULTERATION OF THE FOOD CHAIN

Fake meat scandals add to Chinese food fears


CHINAFOTOPRESS/GETTYIMAGES

First there were 20 000 dead pigs floating down the Huangpu river,[1] a main source of water for Shanghai city. That was followed by thousands of dead ducks in the Nanhe river in the southwest province of Sichuan. Dead pigs and ducks had been used in the production of fake meat. Farmers in Fujian province who were contracted to destroy diseased pigs have been detained for allegedly selling the carcasses collected from farms and roadsides to restaurants in neighbouring provinces.

Now the Ministry of Public Safety says that it has apprehended meat traders in eastern China who were passing rat off as lamb. The police arrested 63 suspects accused of selling rat labelled as lamb for more than $1.6m (£1.1m; €1.2m). As well as the scandals involving pigs, ducks, and lamb, the Public Security Ministry says there have been at least another 10 meat scandals recently involving cattle and chickens. If this state of affairs does not change, the consequences of similar cases could be extremely serious.

Meat smuggling and food adulteration are rampant in China. In these cases, the suspects are accused of using gelatin, red pigment, and nitrates to alter the dead pigs, ducks, and rats. Chinese food production is now on a larger scale and more technological, and sophisticated technology is being used to beat regulators and cheat customers. Tainted meats are an ongoing problem. China's government says it is making food safety a top priority in the first year of president Xi Jinping's leadership.

Cong Dai ward doctor congdai2006@sohu.com
Min Jiang professor, department of gastroenterology, First Affiliated Hospital, China Medical University, Heping District, Shenyang City, Liaoning Province, People's Republic of China

Competing interests: None declared.

1 Liu CY, Hua J. Dead pigs scandal questions China's public health policy. *Lancet* 2013;381:1539.

Cite this as: *BMJ* 2013;346:f3385