Authors' reply

DOI:

[10.1136/bmj.c2992](https://doi.org/10.1136/bmj.c2992)

[Link to publication record in Manchester Research Explorer](#)

Citation for published version (APA):

Wearden, A. J., Dowrick, C., Chew-Graham, C., Bentall, R. P., Morriss, R. K., Peters, S., Riste, L., Richardson, G., Lovell, K., & Dunn, G. (2010). Authors' reply. *Bmj*, 340(7759), 1262. [c2992]. <https://doi.org/10.1136/bmj.c2992>

Published in:

Bmj

Citing this paper

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LETTERS

LASER EYE INJURIES

Maculopathy from handheld green diode laser pointer

Macular laser treatment with a thermal laser can result in permanent scotoma at the laser burn site.¹ We report on a teenager who presented with central scotomas from a high powered handheld laser pointer. He had bought a green diode laser pointer over the internet and shone the laser beam into his eyes while playing with it.

Visual acuity was 6/12 for both eyes at presentation. He had no previous ophthalmic or medical problems. Dilated funduscopy showed bilateral foveal granularity (figure (a)). Fundus fluorescein angiography and optical coherence tomography confirmed disturbance of retinal pigment epithelium (figure (b), (c)). Electrodiagnostic results were normal. Two months later visual acuity improved to 6/6 for both eyes. Funduscopy results were unchanged.

Retinal injuries from lasers can result from ablative, thermal, or photochemical mechanisms depending on power, wavelength, exposure time, and size of pupil. Although they may cause only a transient afterimage, they may disturb the retina and choroid and induce "idiopathic" choroidal neovascularisation with visual loss in later years.²

The UK Health Protection Agency has received no previous reports of such injury from laser pointers.³ It advises that laser products sold to the general public for use as laser pointers should be restricted to class 1 or 2 devices (laser power less than 1 mW) in accordance with the British Standard, and be accompanied by sufficient information on their safe operation.

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Competing interests: None declared.

Patient consent obtained.

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Cite this as: *BMJ* 2010;340:c2982

(a) Fundus photographs showing small areas of foveal burns with hyperpigmented border (arrows); (b) late phase fluorescein angiograms showing window defects consistent with retinal pigment epithelial defects and narrow areas of adjacent masking consistent with hyperpigmentation (arrowheads); (c) optical coherence tomograms showing subfoveal disturbances in retinal pigment epithelium (arrows)

SLEEP APNOEA

Multidisciplinary community based approach needed

Gøtzsche and Berg describe the challenges faced by patients undergoing continuous positive airway pressure (CPAP) treatment for sleep apnoea.¹ Patients have to accept not only that they have a chronic disease but that treatment is, in most cases, lifelong. They need considerable support in the early stages to overcome difficulties with the mask and machine.² Simply sending a patient home with a CPAP machine without detailed training increases the likelihood of treatment failure as patterns of adherence are established in the first week of treatment and predict long term use.³

Modern CPAP machines monitor patient use, and as a result more is known about adherence to CPAP treatment than adherence to pharmaceutical interventions. Given that self reported adherence to cardiovascular drug treatment in patients who have coronary artery disease is <40%, rates of objective CPAP adherence (>4 hours a night) of 17-71% are not surprising.²

Approaches to exploring sleep apnoea and initiating treatment vary widely internationally. In France sleep physicians work as part of a multidisciplinary team with community based technicians who visit the patient at home to install the machine and then visit regularly to support the

patient, modify the interface, and monitor use. This approach optimises machine use and increases patient satisfaction.⁴

Gøtzsche's negative view of treatment is not universal. Patients whose symptoms are relieved are more likely to adhere to treatment, many becoming enthusiastic proponents of CPAP. For those who cannot tolerate CPAP treatment despite the best efforts of the multidisciplinary team, recent mandibular advancement devices offer a second line of treatment and can reduce apnoea events and alleviate symptoms.⁵

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Cite this as: *BMJ* 2010;340:c2989

ANTIPHOSPHOLIPID SYNDROME

What benefit has the label?

"Doctors believe to greatly benefit a patient by giving his illness a name" (Immanuel Kant). The benefit of the label "antiphospholipid syndrome"¹ is unclear—how treatment should differ for patients with the syndrome (disease and positive antiphospholipid antibody tests) from those without (disease and negative tests) is uncertain.

Syndrome defining criteria,² both clinical and laboratory, are complex but leave room for variable interpretation and dissension. Criteria are based on limited consensus, reflecting contradictory evidence from many studies, done in variably selected patients, with variable tests that correlate poorly and that lack an established comparator, and with variably defined outcomes. Basic mechanisms and paradoxes remain unexplained.

The syndrome's umbrella covers extraordinary heterogeneity of antibody target(s), epitope(s), and pathomechanism(s); of test principles, performance, and interpretation; and of associated disease(s). Such heterogeneity defies the scientific

principles of reproducibility and falsifiability; a hypothesis that cannot be falsified is “not even wrong.”

It requires considerable efforts to keep up to date, and considerable time to counsel confused patients and colleagues. Studies of higher quality³⁻⁵ generally report much less, or no, significance of “antiphospholipid” antibodies than studies with less stringent methods. While stronger evidence is lacking, the main themes of counselling should be that the importance of “antiphospholipid” tests is at best uncertain, and that a treatment plan should be based more on clinical than on laboratory factors.

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Cite this as: *BMJ* 2010;340:c2983

CHILD INFLUENZA VACCINATION

Ramifications of adverse events in children in Australia

Many serious adverse reactions to this year's seasonal influenza vaccine have occurred across Australia, and its use remains suspended in children aged 5 years and under.¹⁻³ Data released on 1 June 2010 show that 1 in every 110 young children vaccinated with the CSL vaccine had a febrile seizure.³

A previous H1N1 vaccine study published earlier this year showed that a large proportion of children developed fevers after vaccination: between three and six in every 10 children under 3 years, depending on dose.⁴ The study was, however, underpowered to detect febrile convulsions at the current rates in Australia because it included only 162 children under 3 years.

Fever is the most important risk factor for febrile convulsions. The vaccine manufacturer CSL, which sponsored the trial, and Australia's regulatory body, the Therapeutic Goods Administration,

which used these data in approving the vaccine for children, were presumably aware of these important findings.⁴ But the authors did not discuss the high incidence of fever associated with vaccination,⁴ and most data were reported without comment in the online only supplementary tables.⁴

The many children with adverse effects and the subsequent suspension of the vaccine challenge the assumption that regulators are ensuring the safety and efficacy of all marketed therapeutics. Influenza vaccine is said to have “an established record of safety in all age groups.”² However, published data on the effects of vaccinating young children against influenza are comparatively few.⁵ Some manufacturers have even withheld data from public scrutiny amid general indifference.^{2,5}

Last winter the likelihood that a child without risk factors would die from swine flu was less than one in a million.² When such a high proportion of children develop moderate to severe febrile reactions to the influenza vaccine, more harm than good seems likely from vaccinating them.

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Cite this as: *BMJ* 2010;340:c2994

See **FEATURE**, p 1274

TACKLING ANTIBIOTIC RESISTANCE

International action required

So and colleagues suggest that we need concerted action to conserve (the function of) existing antimicrobial drugs but could have spelt out what actions are needed.¹

Antibiotic resistance shares many features with global warming. It is largely invisible, what we do today has implications for the health and wellbeing of future generations, and many uncertainties exist, including how much technological developments will rescue us.

The outpatient use of antibiotics varies widely

MALCOLM WILLET

in Europe,² yet life expectancy is similar across most countries in western Europe. Italy and France use more outpatient antibiotics per capita than Germany, the United Kingdom, or the Netherlands. So France and Italy may be using an unjust share of this limited resource.

If one country uses antibiotics only when there will be a substantial benefit but another uses them for the most trivial reasons, in excessive amounts, for unnecessary durations, or to support cruel farming methods,³ then we might judge the second country less well than the first.

To make comparisons we need to compare like with like using agreed standards for antimicrobial usage. Minimum standards for human use of antibiotics might include a doctor's prescription and minimum requirements for evidence of benefit, and recommended doses and durations for more common conditions.

Reliance on local policy and practice may be insufficient to deal with the problem of antibiotic resistance. International agreements do not yet exist, but perhaps, as with carbon dioxide, the control of antibiotic resistance requires such agreements.

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Competing interests: None declared.

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Cite this as: *BMJ* 2010;340:c2978

FINE TRIAL FOR CFS

Both significant and small?

Does pragmatic rehabilitation reduce the “fatigue” experienced by people diagnosed with CFS/ME according to the Oxford criteria?¹ Wearden and colleagues report in the abstract of their paper that after 20 weeks of treatment participants had “significantly improved fatigue,”² and, in their linked editorial, Moss-Morris and Hamilton state that participants receiving this treatment were “significantly less fatigued.”³ However, in the body of the text, Wearden and colleagues describe the improvement as “small”

and “clinically modest.” Thus, the effect of pragmatic rehabilitation on fatigue seems to be simultaneously significant and small.

The effect cannot be both large and small, so which interpretation best matches the data? Fatigue was measured using the 11 item Chalder fatigue scale “scored dichotomously on a four point scale (0, 0, 1, or 1).” This scale has been criticised because it “has a low ceiling, so patients with maximal scores at baseline will not be able to record an exacerbation after treatment.”⁴ The maximum score is 11, and participants receiving pragmatic rehabilitation in this trial had a mean baseline score of 10.49. It can be calculated that 47-88 of the 95 participants started treatment with the maximum score. Thus, at least half of the participants could not report that treatment had worsened their fatigue, if it did. The inability of the Chalder fatigue scale to measure deterioration in this patient cohort therefore biases the trial in favour of finding “improvements” in fatigue and favours pragmatic rehabilitation because exercise induced relapses cannot be recorded.

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Competing interests: None declared.

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Cite this as: *BMJ* 2010;340:c2988

Missing data

Wearden and colleagues published the protocol for this study in 2006,¹ so it is strange that they do not mention many of the measures in the current paper.² The most important omission is one of the outcome measures—the step test: time to take 20 steps (or number of steps taken if this is not achieved) and maximum heart rate reached on the test.¹

Another omission is the number of patients who satisfy the Centres for Disease Control chronic fatigue syndrome (CFS) criteria,³ the most widely used research criteria. Even though we were told how many people satisfied the London ME criteria, we were given no information on how they fared after the interventions. Just because the trial was largely unsuccessful does not mean such data are not of interest. For example, the patients in the pragmatic rehabilitation arm of the trial could have done worse at 20 weeks—there is certainly a large increase in the standard deviation of the Chalder fatigue scale scores at that stage.

It is unclear whether data from some of the

other measures—“CALPAS measure of therapeutic alliance” (measured at three time points), “Visual analogue scale: treatment expectation,” “Symptom interpretation questionnaire,” “Brief social support measure,”⁴ “Brief supportive listening process measure,” and “Brief belief measure”—will be published in the future. Given the cost of this trial to the taxpayer (an estimated £1.3m (€1.6m; \$1.9m)), it would be useful if all the data were made available.

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Cite this as: *BMJ* 2010;340:c2990

Authors' reply

We agree with Carter and other correspondents that the fatigue scale is limited by a ceiling effect, but this is more of a problem at baseline (before treatment starts) than at follow-up assessments.^{1,2} With the fatigue scale re-scored to 0, 1, 2, 3, we can demonstrate a clinically modest, but statistically significant, effect of pragmatic rehabilitation compared with general practitioner treatment as usual at both outcome points. Given the chronicity of chronic fatigue syndrome in our sample, we believe that this on average small improvement in fatigue is important to these individuals.

Kindlon points out that we have not analysed all the outcomes that we measured.³ We reported our primary outcomes and the related secondary clinical outcome data that we thought would be of interest in judging the clinical effectiveness of our intervention. We did not report the step test as an outcome because of a large amount of missing data. Further papers will examine exercise capacity and illness beliefs as potential mediators of the effects of pragmatic rehabilitation. We will also be reporting on predictors or moderators of treatment response; among the variables we will examine will be criteria fulfilled (Centres for Disease Control, London ME), ambulatory status, and comorbidities. Other papers will examine economic outcomes and barriers to delivering these treatments. All papers will use the acronym

FINE and have the same ISRCT number, so can be linked to the *BMJ* paper.

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Competing interests: None declared.

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Cite this as: *BMJ* 2010;340:c2992

DON'T TAKE ME TO YOUR LEADER

“Great men” need not apply

Delamothe's observations on leadership assume agreement on what we are talking about.¹ Leadership is not an option in any organisation: it has to happen. The question is, how should it operate?

Nearly 70 years ago army psychiatrists and psychologists, later associated with the Tavistock Clinic and Institute, introduced the “leaderless group” method of selecting officers for the next phase of the second world war. They found that the most effective leaders were those who could take initiatives attuned to the needs of the group rather than those who were necessarily the most educated or athletic.²

The chief innovator in the War Office Selection Boards (WOSB) was Dr Wilfred Bion (1897-1979), who had been awarded the DSO for his bravery as a tank commander in the first world war.^{3,4} He was supported by Dr John Rickman (1891-1951), a Quaker who as a conscientious objector had worked as a doctor and educator in pre-revolutionary Russia. Their colleague Dr John Bowlby (1907-1990), the originator of attachment theory, followed up No 2 WOSB and found that the rate of loss of officers fell from 45% to 15%.⁵

Group assessments of leadership were taken

up after the war by the civil service, fire and police services, and some major businesses. They are still in use today in both private and public sector organisations as a more discriminating identifier of leadership than interview alone.

Delamothe cites Atul Gawande and the possibilities of teams. Good leaders exploit teams, not by telling people what to do but by getting the best out of them. To some extent, the NHS has been bullied by successive governments, a process that tends to pass anxiety down the line. Effective health service managers do not transmit anxiety: they contain it, acknowledging its inescapable presence at the heart of healing. That is leadership. No “great men” are required.

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Cite this as: *BMJ* 2010;340:c3009

Aspirational idiocy at large

A wise old leader told me recently that motivated, high achieving professionals need less leadership and more savvy management.

Delamothe's observation of the ridiculous overuse of the word leadership in the medical world demonstrates perfectly that the term is not understood and is used as a generic cover for a plethora of issues.¹ Where does the NHS want to be led to? Out of its current problems into a happy Utopian future where the fourth largest employer in the world functions as a small cottage business with shiny happy innovative leaders safely steering the ship? Yes, aspirational idiocy is alive and well in the health service.

Good leaders of any shape or size are apparent regardless of their background. They are able to adapt to their environment, understand the people whom they are working with and for, and make decisions that allow change to be implemented in an organisation by ensuring that all staff own it and are accountable for it. Frankly, I don't care what background NHS leaders have, but I would like to see people appointed who have a bit of savvy: the need to lead being secondary to the ability to manage current circumstance.

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Cite this as: *BMJ* 2010;340:c3007

SCIMAY/SPL

RESPONSE

Barry Miller replies to Des Spence

I suspect that I am not alone in being concerned about the opinions of Dr Des Spence in his recent article revisiting pain and its treatment.^{1,2}

I take issue with six of his most recent assertions.¹

(1) 20% of the population experiences chronic pain, but this defies common sense

This figure is well recognised—for example, a recent report claimed 19% on the basis of interviews with 46 000 people across Europe.³

The standard definition is a pain occurring more than twice a week for more than 6 months and of a severity of more than 5/10. It is a point prevalence, and will include people whose duration of pain is limited, but it clearly describes an important problem.

(2) This evidence is based on the unscientific definition that “pain is whatever the patient says it is,” an assertion so simplistic that it cannot be true

Pain has a commonly agreed definition from the International Association for the Study of Pain: “An unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in such terms.”

The importance of symptoms, with or without signs, is one of the most important advances in medicine. It allows for the management of almost all of the conditions that cause suffering. For example, nausea, anxiety, depression, hallucinations, indigestion (with negative endoscopic results) are common and managed successfully, often by treatments aimed at the symptoms alone because the diseases are complex and either poorly understood or not understood at all.

(3) Many problems are explained away by “pseudoaddiction,” another nebulous term

The term addiction is a dubious medical entity. It is a much abused word, aimed entirely at de-legitimising users of substances with psychotropic effects. A more accurate description is the desire for a drug,

caused by its use and then absence, and causing psychological and or physiological dysfunction—most commonly seen in smokers and coffee drinkers.

In medicine we wouldn't describe a diabetic patient's reliance on insulin as an addiction, or the hypothyroid patient's on thyroxine. Inadequate doses of these medicines cause problems eased by appropriate doses—that is, pseudoaddiction. Dr Spence implies that the nervous system is immune from a dysfunction causing suffering, so use of strong analgesia is a problem.

(4) Reducing pain to a collection of numbers... is reductionist nonsense

Medicine is the art of pattern recognition, the reduction of symptoms and signs into groups previously recognised, and the application of comparatively circumscribed approaches is the way to heal. The imperfect nature of the tool (in this case, validated questionnaires) doesn't make it useless.

Blood pressure has a crude association with cardiac and cerebrovascular disease. Many with “high” values will never have had problems, but we treat because of the numbers, and aim to save lives and reduce suffering.

(5) I wish I could show the evidence for harm of opioid use in the United Kingdom, but I can't
 Let's first look for evidence of risk and benefit. The Oxford based critical review on the effects of opioids in chronic pain is a good place to start.^{4,5} The evidence base may be flawed but to simply suggest that a flaw is a binary arbiter of good or bad medicine is bizarre. By that definition every side effect associated with every treatment would have led to its abandonment, and we would still be relying wholly on leeches, maggots, and vinegar purges.

(6) We have an evidence based disaster in the making

Here we agree, although the nature of the disaster is the absolute breach of our oath to help relieve suffering, and not to allow millions to suffer long and die hard because of prejudice towards the sufferers and the treatment.

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Competing interests: None declared.

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Cite this as: *BMJ* 2010;340:c3011