We select the letters for these pages from the rapid responses posted on bmj.com favouring those received within five days of publication of the article to which they refer. Letters are thus an early selection of rapid responses on a particular topic. Readers should consult the website for the full list of responses and any authors' replies, which usually arrive after our selection.

## **LETTERS**



#### SURGICAL MORTALITY

#### Media attack

We are concerned that publishing non-risk stratified cardiac surgical mortality statistics may have adverse effects on surgical teams, bereaved parents, and people with children to be treated at targeted centres. We support data collection to maintain clinical standards, but hospital episode statistics are unreliable for measuring mortality and unsuitable for comparison between centres.

Half of units will be below the mean in rankings for surgical mortality. The lay press often interprets "below average" as inadequate or incompetent. Non-risk stratified death rates collected by the UK congenital cardiac audit database (CCAD) were recently published. These are difficult to understand for the lay reader. The Scottish press castigated the centre in Glasgow, whose overall survival rate was 95.9% (UK average 96.7%).² Comments included:

- •"Death rates for children's heart operations are significantly higher than the rest of the UK" (untrue)
- "This is totally unacceptable and I am very concerned . . . The hospital might be happy with its figures but I am not." (Quote from chairperson of Scottish Patients' Association.)

Local television covered the attack, and confidence in a thoroughly reputable unit was lost. The CCAD and Society for Cardiothoracic Surgery criticised the media's actions, but the damage was done. The press interpret data to present a sensational headline.

What was achieved by public reporting? Talented, hard working, and dedicated healthcare professionals were inappropriately forced to defend their practice. Prospective patients and relatives were filled with unnecessary anxiety. Cardiac surgery is the only specialty under

such intense public scrutiny in the UK, and the risk of unjust condemnation constitutes a third and unwelcome party in the consulting room.

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- Westaby S, Archer N, Manning N, Adwani S, Grebenik C, Ormerod O, et al. Comparison of hospital episode statistics and central cardiac audit database in public reporting of congenital heart surgery mortality. BMJ 2007:335-759 (13 October)
- 2 Foster K. Fears over child surgery deaths. Scotland on Sunday. 2007 June 10. http://scotlandonsunday. scotsman.com/index.cfm?id=906872007

## Hospital episode statistics *v* central cardiac audit database

We published the follow-up of the Bristol Royal Infirmary analysis to which Westaby et al refer<sup>1 2</sup> and have some comments on their paper.

The online version suggests that the clinical teams did not verify the data. We wrote to the clinical team at Oxford over a year before our paper was published. After some months and a reminder letter sent to them, we received a response from the medical director of the trust which did not dispute our figures. His letter also confirmed that the trust had become aware of a downturn in their results before 2000. This was noted in our paper.

We have previously made clear the limitations of using OPCS4 codes in defining open operations, in that there is no explicit code for open heart surgery. We used a definition arrived at by consultation for the Bristol inquiry.<sup>3</sup> Because this definition differs from that used within the central cardiac audit database (CCAD), they are not directly comparable. The Thames Valley Strategic Health Authority's report (on which Westaby et al say their report is based) came to the same conclusion.<sup>4</sup>

The mortality rates quoted in the Oxford paper differ importantly from the mortality figures quoted to us by the medical director of the trust. There are also differences in comparison with the official CCAD figures published on the congenital heart disease website (www.ccad.org.uk/congenital).

Paediatric cardiac surgery is a highly specialised, complex field. The Oxford paper's conclusions suggest that surgeons don't agree among themselves how best to monitor outcomes. We agree that the CCAD could potentially provide an alternative and improved data source for paediatric cardiac surgery outcomes. We also support the Thames Valley report's conclusions that hospital episode statistics and the CCAD both have an important role in measuring activity and outcomes in the clinical setting.4 Ideally, clinical and administrative datasets should function as one, but in any case, all clinicians should be prepared to take an active part in institutional data collection.<sup>5</sup>

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Competing interests: PA, AB, and BJ are employed by Imperial College and work within the Dr Foster Unit at Imperial. The Dr Foster Unit at Imperial is funded by a research grant from Dr Foster Intelligence (an independent health service research organisation).

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## Summary of other responses

Westaby et al make a good case for not publishing unreliable outcome data based on hospital episode statistics (HES),<sup>1</sup> but they miss what ought to be two critically important issues, says Stephen Black, a

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management consultant in London.

The first concerns how statistical information is presented. "Standard practice gives information to the public and to experts in a form almost guaranteed to mislead. This leads to the erroneous conclusion that members of the public can't be trusted to interpret complex statistics: but they can when they are framed and presented in the right way."

The second concerns why the information is poor quality in the first place.

Ashok Handa, consultant vascular surgeon in Oxford, agrees: "All surgical units should prospectively collect activity and outcome data. Clinicians should insist on and hospital managers should provide adequate administrative support for this to be a matter of routine.

"The cardiac surgical community to their credit responded to Bristol with routine collection of clinically acquired data for national reporting. Vascular surgeons now also have a national vascular database organised by the Vascular Society. Unfortunately this is largely unfunded and unsupported by NHS managers."

Westaby et al's criticism of HES and those who use it to profile surgeon performance should not undermine confidence in what is the only mandatory database of NHS hospital activity in England, argues Muhammad Dawwas, specialist registrar in Cambridge. And the statistical evidence leading to the identification of Bristol's outlier status in the 1990s was largely based on HES-derived analyses.

Westaby et al did show that "coding is better in the registry data set than the routine data set and that with better coding you get better data capture," points out Stephen Duckett, a professor in Queensland. "This suggests adjusting the procedure code definitions in the routine data set rather than abandoning use of the data set altogether."

And why are registries separate from the routine data sets? Linking the multiple data holdings would enhance use of both data sources. "The registries would then be conceptualised not as special separate clinician data sets but rather as separate modules of the routine data set, giving more power and use to the routine data, leveraging the substantial investment that has been made in this data collection."

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Competing interests: None declared.

Westaby S, Archer N, Manning N, Adwani S, Grebenik C, Ormerod O, et al. Comparison of hospital episode statistics and the central cardiac audit database in the public reporting of congenital heart surgery mortality. BMJ 2007;335:759. (13 October.)

#### **FLUORIDATION**

### The Department of Health's view

Cheng et al's article on fluoridation of water supplies provides a welcome opportunity to restate our view that fluoridation has reduced the burden of dental disease and offers the potential to address persistent inequalities in oral health. As with other health measures, safety should continue to be monitored and the ethical dimension discussed.

We first address the doubts expressed about the Department of Health's objectivity. The Department of Health, in 1999, commissioned the University of York to undertake a systematic review of fluoridation.2 The York team considered 735 research studies that met their relevance criteria and found no conclusive evidence of a causal relation between fluoridation and systemic illness. Nevertheless, we accepted their primary recommendationthat the evidence base for fluoridation needed strengthening-and responded with a commitment to sponsor further research. In 2001, we asked the Medical Research Council (MRC) to identify and prioritise the research needed to inform public policy on fluoridation.3 In 2003, in accordance with MRC recommendations, we commissioned the University of Newcastle to investigate the bioavailability of fluoride from artificial and natural sources.4

Despite significant improvements in the past 30 years, many people still experience unnecessary pain and discomfort from dental disease, and inequalities still exist across the country. The probability of having decay in primary teeth is about 50% higher in the lowest social group than in the highest.<sup>5</sup> Fluoridation mitigates this association, as shown by York's finding that water fluoridation increases the number of children without tooth decay by 15%.<sup>2</sup> A meta-analysis found a 27% reduction in dental decay in adults living in fluoridated areas.<sup>6</sup>

Fluoride toothpaste alone will not reduce inequalities in oral health because its use depends on individual behaviour. Targeted fluoridation schemes offer greater potential because they are population based interventions.

We welcome new research, particularly into the safety of fluoridation. However, as the MRC pointed out,<sup>3</sup> research priorities should be determined by plausibility of effect. The study from Taiwan cited by Cheng et al does not fall into this category

because its authors say, "Our study found an excess rate of bladder cancer that was restricted to females. It seems biologically implausible for fluoride to affect cancer rates for one sex only."

The question of whether fluorides added to water should be licensed depends on whether they are categorised as medicines. The Medicines and Healthcare Products Regulatory Agency considers that, for regulatory purposes, drinking water (fluoridated or not) is a "food" and is not subject to the licensing requirements for medicines.

As the authors indicate, the ethical justification for fluoridation depends on the benefit to public health. We are satisfied that the persistence of inequalities in oral health provides this justification. Parliament accepted this argument as recently as 2005, when new requirements for consultations were approved by a large majority in both houses. Strategic health authorities may only make arrangements with a water provider to fluoridate an area if they have conducted open, wide ranging consultations.

The benefits, safety, and ethics have rightly been key issues in previous consultations on water fluoridation and continue to be at the heart of future consultations.

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Competing interests: None declared.

- Cheng KK, Chalmers I, Sheldon TA. Adding fluoride to water supplies. BMJ 2007;335:699-702. (6 October.)
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## Interpreting the Newcastle fluoride bioavailability study

We are surprised that the chief dental officer and chief medical officer for England in their full response to Cheng et al consider that the Newcastle study on bioavailability "contributed to a better understanding of the health effects of water fluoridation." <sup>1</sup> <sup>2</sup> The researchers themselves urged caution when

interpreting the results.<sup>3</sup> It is disappointing that such senior public health officials make the error of assuming that "no statistically significant differences in bioavailability between artificially and naturally fluoridated water" has any meaning when the study was too small to find scientifically important differences.

Interestingly, despite the small size, the Newcastle study did report a significant difference in the relative bioavailability of fluoride in drinking water (plasma Fp%) at three hours (27%) and eight hours (36%) follow-up (mean difference in Fp\% (0-8)=35, 95% confidence interval 5.9 to 64.5).3 However, the authors removed one of the 20 data points, which they determined was an outlier because one subject had much larger values than others. This manoeuvre reduced the statistical significance below the critical value. The trend of increased bioavailability in artificially fluoridated water, however, remained in all plasma comparisons (tables 5-7).3 Discarding an outlier (removing 5% of the data) to eliminate an "inconvenient" significant result is not best practice and raises doubts about the validity of the inferences.

Given the weaknesses in the study design and analysis it is surprising that these senior health officials should state that "as a result, we may continue to have confidence in the safety of fluoridation."

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Competing interests: None declared.

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## Addressing the arguments

Cheng et al<sup>1</sup> are well placed to sound cautionary notes about fluoridation as two of the authors were involved in the only scientifically defensible assessment of the evidence so far.<sup>2</sup> I also served on the advisory panel to the York review, after two years of parliamentary questioning of the rationale for fluoridation.

It is depressing then to see restatements of old positions, instead of engagement with their arguments. After 60 years we are still



not clear about fluoridation's benefits, even less clear about harms, and least clear about reductions in dental health inequalities. York and the Medical Research Council<sup>3</sup> are not the only bodies to outline areas of needed research. Yet while government accepts this, fluoridation continues, new schemes are encouraged, and in the seven years since York one small and inconclusive study has been funded.4 This looks more like lip service than commitment to good science. Can promoters of fluoridation not see the possible risks to 5 million people taking a lifetime's uncontrolled dose of fluoride? And how do they interpret Cheng's graph showing that several European countries do well without it?

Medical ethics are crucial. Cheng at al pointed to the need for patient consent before treatment. In their response the chief officers conflate scientific and ethical arguments as though benefit could override patients' lack of consent; they cite Cheng at al for an argument they did not use and claim parliamentary support for an ethical standpoint that was not voted on.5 Meanwhile the Medicines and Healthcare Products Regulatory Agency may be challenged in court for its failure to adhere to the European directive on medicinal products; the fact that a substance is governed by another law, such as the water act, is no defence.

To avoid a continuing dialogue of the deaf, defenders of fluoridation should address Cheng et al's points. And, in the interests of good science, the government—which deserves praise for setting up the York review—should provide for the review's updating and incorporation into the Cochrane Library.

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#### PREVENTING CHILDHOOD OBESITY

### Too early to ditch the campaign

We believe that James et al's conclusion that an intervention to reduce children's consumption of carbonated drinks and prevalence of overweight was not effective two years after completion<sup>1</sup> is not warranted for two reasons.

Firstly, they base their conclusions on the proportion of overweight children, which was significantly different between the two groups at 12 months, but not at three years. However, average values of body mass index (BMI), Z score, and waist circumference would be better outcome measures.  $^2$   $^3$ 

Changes in BMI, Z score, and waist circumference moved towards significance. Thus, the intervention did not have a significant effect on overweight after 12 months, but it was moving in the right direction.

If the children continued to consume fewer carbonated drinks as a result of the intervention, they would put on less weight each year. James et al should measure the children's BMIs in a few years—they may find the desired significant results.

Secondly, the trial characteristics were flawed. The trial was powered to detect differences in consumption of carbonated drinks, not proportion of overweight. Power was further reduced by loss to follow-up at three years. Large (though not significant) differences occurred at baseline—average BMI, Z score, and waist circumference were lower in the intervention group than in controls.

Childhood obesity and how to tackle it is a huge problem, with few solutions. James et al dismiss what could be a promising result, on the basis of an inappropriate outcome measure from an insufficiently powered and poorly randomised trial.

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Competing interests: None declared.

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Or maybe, judging from the July/August edition of *GMCtoday*, it helps cover the cost of playing around with actors from the National Theatre for the day."

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Competing interests: None declared.

1 Eaton L. Tooke inquiry calls for major overhaul of specialist training. BMJ 2007;335:737. (13 October.)

#### **AMBLYOPIA**

### Occlusion studies are ambiguous

The editorial<sup>1</sup> and report<sup>2</sup> about occlusion treatment for amblyopia include ambiguities. Loudon and Simonz did not consider anatomic defects as the aetiology for severe visual impairments, attributing poor outcomes solely to compliance failure.<sup>1</sup>

Amblyopia is a diagnosis of exclusion applied after eliminating organic causes of impaired vision. Optic nerve hypoplasia, for example, is an important cause of childhood visual disability<sup>3</sup> and perhaps the most common optic disc anomaly seen in clinical practice.<sup>4</sup> Accurate diagnosis of this condition requires imaging and measurements that were apparently not used in this study.<sup>2</sup>

A study of the literature found no studies of natural history of amblyopia, no firm evidence on its impact on quality of life, no randomised controlled trials of treatment versus no treatment, and only one prospective controlled trial of screening.5 The report by Stewart et al<sup>2</sup> failed to include controls. The mean age of the subjects in the study was 5.6. Improved responses to eye charts would be expected as a result of children learning to read, regardless of treatment protocols. Their findings that "the final level of attainment for all ages between 3 and 8 years is the same" and the similarity of responses to different amounts of occlusion reinforce the likelihood that patching has little to do with final results.2 The lack of an untreated cohort makes the attribution of improvement solely to occlusion treatment doubtful.

The gold standard for clinical trials includes placebo groups. Until amblyopia treatment studies include untreated subjects for comparison and incorporate objective diagnostic methods they will continue to produce uncertain results.

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#### **GMC AND THE MMC COLLAPSE**

## Summary of responses

The Tooke inquiry suggests that the General Medical Council should regulate postgraduate as well as undergraduate medical education.<sup>1</sup>

"Surely you are joking," writes A Lim, a junior doctor in London. "The GMC has yet to explain its substantial role in the collapse of MMC Modernising Medical Careers and MTAS Medical Training and Applications Service. The Tooke inquiry correctly identified that many overseas doctors had competed and gained training posts on merit-and this has stirred unease, particularly when it has been perceived to be at the expense of locally trained individuals. The solution seems to be moving towards implementing discriminatory measures against non-EU doctors (as nothing can be done about EU applicants). But if there are too many non-EU doctors in the UK, why does the GMC continue to conduct overseas recruitment drives?"

K Sundar, a specialist registrar in London, agrees: "In the next six months alone, there are five examination dates for part I in 14 countries and five part II sittings. At £575 a pot for both parts, the GMC is raking it in."

"And why isn't the GMC clearly outlining the employment situation in the UK on its website?" asks G Balasingham, unemployed in Manchester. "Why is there no restriction on the number of people being able to gain entry into the UK with 'certification' but no jobs after having spent thousands of pounds? I suggest that IMGs (international medical graduates) would have a case at an employment tribunal."

William Holmes, a foundation year 2 doctor in East Kilbride, thinks he can explain the economics: "Perhaps it is the cost of conducting overseas excursions to find more recruits that forces the GMC to charge a yearly subscription of  $\pounds 290$ .

#### **ACADEMIC BOYCOTTS**

# Royal Society of Medicine under attack by pro-Israel doctors

In relation to the debate about academic boycott and freedom, <sup>1 2</sup> it seems relevant to record another way in which the refusal to address the voluminous and independent evidence of medical ethical violations in Israel is being maintained.

The Royal Society of Medicine (RSM) has lately been under attack. Months ago, I was invited to speak at an RSM conference on religion, spirituality and mental health, to contribute to a session on the role of health professionals in conflict situations. As a reflection of my research interests and publications on medical ethics since 1992, my main case study was on Israel and Palestine. Once the conference was publicised, the RSM became subject to pressure from pro-Israel doctors to remove me from the conference programme. They went so far as to threaten a challenge to the RSM constitution as a charity if a "political" (and biased) person were permitted to speak.

After weeks of this, to save the conference the RSM asked me to withdraw. But, in the end the RSM steeled itself and decided to go ahead, and the conference was held on 9 October.

The editors of UK medical journals publishing human rights material on the Occupied Palestinian Territories have been subject to comparable pressures; in the US pro-Israel groups are hounding (and effectively) individual academics, conferences, publishers, and universities. These ominous developments recall the era of McCarthyism.

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Competing interests: None declared.

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