### LETTERS

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#### **QUALITY OF CARE IN ISTCs**

### Independent sector treatment centres are a busted flush

We always suspected that independent sector treatment centres (ISTCs) would show better surgical outcomes than traditional NHS surgical providers because ISTCs treat just a small repertoire of cases. <sup>1</sup> In ISTCs surgeons and anaesthetists easily find their patients preoperatively, rather than having to search the hospital as happens in the traditional NHS. In ISTCs surgeons and anaesthetists are not distracted by the needs of patients who are not on their operating list, in stark contrast to the traditional NHS model. Surgeons in ISTCs are unlikely to find their operating list disrupted by emergency cases. They are also not distracted by having to teach medical students and mentor junior medical staff. And on the wards of ISTCs nursing staff are focused on the needs of patients having specific surgery and not the needs of those with complex medical and social conditions.

Despite these tremendous advantages, ISTCs show no significant outcome benefit over the traditional NHS model. <sup>12</sup> Separating emergency treatment from elective work has not shown the expected benefit, and we believe that ISTCs have shown themselves to be a busted flush—with no reason to justify why they are allowed to cherry pick easy cases from traditional NHS surgical providers.

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 Bardsley M, Dixon J. Quality of care in independent sector treatment centres. BMJ 2011;343:d6936. (4 November.)

2 Chard J, Kuczawski M, Black N, van der Meulen J. Outcomes of elective surgery undertaken in independent sector treatment centres and NHS providers in England: audit of patient outcomes in surgery. BMJ 2011;343:d6404. (19 October).

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### Research on outcomes is essential

Research on outcomes in independent sector treatment centres (ISTCs) is welcome, indeed essential. Chard and colleagues' paper shows that some routine elective operations performed by cherry picked surgeons on selected low risk patients do not have significantly better outcomes than those in standard NHS care. <sup>1</sup> <sup>2</sup> Why then was this system introduced?

Data on cost comparison and long term outcome data are missing. There is likely to be residual confounding by case mix.

It will not be cost effective for ISTCs to acquire medical equipment, facilities, and expertise for emergency complications in their elective patients. Emergency transfer is unlikely to outperform integrated care in an NHS hospital.

Generalising the limited findings of this study to state that ISTCs provide "Quality of care... that seems to be as good as the NHS" is an over-representation of the facts. "ISTCs seem to be no better than NHS care, and questions regarding safety and cost remain unanswered" might be a more accurate rendering of this evidence.

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- 1 Chard J, Kuczawski M, Black N, van der Meulen J. Outcomes of elective surgery undertaken in independent sector treatment centres and NHS providers in England: audit of patient outcomes in surgery. BMJ 2011;343:d6404. (19 October)
- 2 Bardsley M, Dixon J. Quality of care in independent sector treatment centres. BMJ 2011;343:d6936. (4 November.)

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# What is cost effective is always effective

Investment decisions in independent sector treatment centres (ISTCs) must be informed by evidence of cost effectiveness. Chard and colleagues offer some good effectiveness data.<sup>1</sup> They found that some initial ISTC contracts were paid at payment by results tariff plus 15%. Why is this not discussed to illuminate cost effectiveness?

It is time for the *BMJ* to stop publishing incomplete evaluations of policies such as ISTCs, competition, and patient safety. Remember always that what is effective may not be cost effective and what is cost effective is always effective.

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- Bardsley M, Dixon J. Quality of care in independent sector treatment centres. BMJ 2011;343:d6936. (4 November.)
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#### **COMPETITION BETWEEN HOSPITALS**

# If we want kindness we need cooperation, not competition

Bertrand Russell said "The only thing that will redeem mankind is cooperation." I believe that the same can be said about the NHS. Bevan and Skellern show a lack of clear evidence of any benefit from interhospital competition.1 However, I think that competition (or targets and performance regulation) has a deeper insidious effect on the core aspect of healthcarekindness. If senior managers exist in a world of targets, competition, and performance regulation, such ideas will permeate the organisation and become the pervading culture. Front line healthcare professionals will have to devote much of their physical and mental energy to this culture, thereby reducing the amount of compassion and kindness they can show to patients.

Let us not forget Mid Staffordshire NHS
Trust—to quote the eponymous report, "Its strategic focus was on financial and business matters at a time when the quality of care of its patients was well below acceptable standards."<sup>2</sup> The drive to become a foundation trust had taken compassion away from front line staff, as Ballatt and Campling highlight.<sup>3</sup>
The NHS constitution states that care and compassion matter most.<sup>4</sup> If we want that to be a reality we must make the world that senior management operates in a cooperative exercise and not a competition.

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#### WORDS ARE ALL WE HAVE

### Changes make it harder to respond to patients' needs

Heath alerts us to the degradation or subversion of the meaning of care, quality, and profession and to the slow disappearance of attentiveness, wonder, courage, trust, commitment, concern, conscience, touch, and tenderness.<sup>1</sup>

The space for these "softer" but important values is being swallowed up by the Quality and Outcomes Framework and revalidation, which force GPs to spend every spare moment ticking boxes, doing audits, reviewing referrals, arranging multi-source feedback, and so on. Although some of these activities may be of value, the sheer quantity is overwhelming and demoralising, especially when the essential work we do—listening to patients, showing empathy, helping patients negotiate the complex hospital interface, and providing continuity of care—seems to be unrecognised and unrewarded.

Part of the cause may lie in the disastrous trap of measuring and valuing only those things that can be measured easily and, as McGilchrist argues, the dominance of left brain over right brain function in our modern world.<sup>2</sup>

Those of us who trained in the 1970s and 1980s still try to provide a genuinely patient centred service, but the current generation of GPs, brought up in this new mechanistic environment, may find it harder to provide primary care that serves patients' needs and best interests, rather than those of governments and "experts."

In the age of evidence based medicine, where are the research studies showing that these changes imposed on GPs (I wish we had never signed up for the new GP contract in 2004) make us better at responding to patients' needs?

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#### ANAL NEOPLASIA AND CANCER

## Early treatment of anal intraepithelial neoplasia

Simpson and Scholefield did not mention anal cytology and high resolution anoscopy in their review of the diagnosis and management of anal intraepithelial neoplasia and anal cancer.<sup>1</sup>

High resolution anoscopy detects anal intraepithelial neoplasia (AIN), analogous to cervical intraepithelial neoplasia (CIN), and uses the same colposcopic equipment. It has been used most in HIV positive people, particularly HIV positive men who have sex with men, who are at high risk of anal neoplasia. Services caring for HIV positive people in the UK, as elsewhere, have been developing pathways to screen and treat patients with anal intraepithelial neoplasia using a combination of anal cytology and biopsy directed by high resolution anoscopy. The accuracy of routine mapping biopsies can be improved with such anoscopy.

Anal intraepithelial neoplasia is important because the incidence of anal cancer is increased in HIV positive people, particularly now that long term survival is achievable, and outcomes are poorer than in HIV negative people if anal cancer develops. <sup>3</sup> <sup>4</sup> Although the natural history is not as well defined, treatment strategies should mirror those of cervical intraepithelial neoplasia (CIN 2 and 3). <sup>5</sup> Options include application of trichloroacetic acid or 5% imiquimod, as well as ablative treatments such as laser ablation and infrared coagulation. These methods can be used for both internal AIN 2 and 3 disease and external or perianal disease.

These approaches can improve outcomes for both HIV positive and negative people but they require close collaboration between services offering high resolution anoscopy and services in comprehensive cancer networks.

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#### NICE ON COLORECTAL CANCER

### Barium enema and diagnosis of colorectal cancer



Surprisingly, the National Institute for Health and Clinical Excellence (NICE) recommends barium enema as the preferred radiological method for diagnosing colorectal cancer in patients with significant comorbidities.<sup>1</sup>

New data from the Special Interest Group in Gastrointestinal and Abdominal Radiology (SIGGAR) show that computed tomographic colonography detects significantly more cancers than barium enema. Moreover, it is better tolerated than barium enema. In many hospitals it has superseded barium enema, and newly qualified radiologists are more likely to be skilled in it than in performing and interpreting barium enemas.

Barium enema requires similar bowel preparation and degrees of mobility to colonoscopy; if patients are fit for barium enema they are also arguably fit for colonoscopy (especially as colonoscopy is currently often performed without sedation). Furthermore, these guidelines give no advice about patients who may not be able to tolerate full bowel preparation. Minimal preparation computed tomography with oral contrast (faecal tagging) is a suitable option for them and has a reported negative predictive value for colorectal cancer of more than 90%. 4

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#### SIR KARL POPPER, SWANS, AND GPs

### Think that you may be mistaken

Few experiences are worse than a missed cancer diagnosis, but being missed by doctors who persistently refused to consider it possible is one. Doctors do not diagnose what they have not thought of. Berghmans' cancer was diagnosed by "a thoughtful neurosurgery assistant... willing to look beyond the lower back."

Patients may forgive errors, but not when the doctor-patient relationship is poor. A doctor who is not listening, uncaring, or dismissive is liable to be sued.

Bayesian thinking is more appropriate than Popper's falsifiability paradigm. Common things commonly occur; unlikely events need

extraordinary evidence. The bird outside your window is a sparrow not a canary. How do we recognise the canary?

Osler exhorted "Listen to the patient, she is telling you the diagnosis" with the sixth sense tuned to the unspoken. Feelings matter to the skill of diagnosis, and need education. The busier you are the more important it is to take a good history. Berghmans' case should not encourage more "inappropriate"

referrals. Serious rare possibilities should be "ruled out" by sensitive tests or "ruled in" by specific tests. Careful re-taking of the history (plus blood tests and scans if red flags are present or the patient doesn't improve) is most likely to spot rarer causes.

RARE DISEASES

for primary care

The challenge

This salutary story should inspire us to improve consulting diagnostic skills, particularly our feelings, attitudes, and expectations. I recommend reading *How Doctors Think*<sup>2</sup> and wonder if the *BMJ* sequel might be *How Patients Feel*.

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- 1 Berghmans R, Schouten HC. Sir Karl Popper, swans, and the general practitioner. *BMJ* 2011;343:d5469 (3 October.)
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### Cognitive biases affect clinical judgment

Berghmans and Schouten highlight the role of cognitive errors in causing delayed diagnoses. 

The problem seemed to be localising the site of a pathological process rather than diagnosing a rare disease. With hindsight, severe back pain, difficulty in walking, and leg spasms should have prompted early magnetic resonance imaging or a specialist referral. However, retrospection (hindsight bias) makes things look less complex than when the events unfolded.

The authors attributed the delayed diagnosis to confirmation bias, which unreasonably sustains a wrong diagnosis when subsequent evidence raises doubts about its validity. This bias may act in concert with illusory superiority—the tendency to overestimate qualities like knowledge and skills—and our tendency to jump to unshakeable conclusions on the basis of very little evidence—the "blink" bias. Furthermore, sunk costs and

loss aversion biases could prevent reversal of wrong diagnoses because of the risk of embarrassment and loss of status.

The range of cognitive errors that could influence medical judgment is not widely appreciated and the literature is limited. A recent paper explored how various cognitive biases (including framing, anchoring, availability, representativeness, and blind obedience) resulted in neurological diagnostic error. These biases are among

several others that influence how we think.

As one solution to cognitive errors, the authors advocated paying more attention to the philosophy of science in medical schools. They referred to Karl Popper's paradigm that hypotheses should be tested by falsification. This suggestion is timely, but the focus should not be restricted to philosophical principles alone but include the whole spectrum of cognitive and logical processes.

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## Doctors must bear in mind the fallibility of their assumptions

Berghmans and Schouten set their arguments within a philosophical framework, but I am not sure if "confirmation bias" is as important as they suggest. I think it is more likely to be consideration of disease prevalence: common things commonly occur; benign low back pain is common in 50 year old men with a history of benign back pain.

In *Pluto's Republic*, Medawar discusses medical diagnosis and says that even though we have a naive belief that induction is the thought process in medical diagnosis, in reality a hypothetico-deductive method is used. <sup>2</sup> As doctors we set up hypotheses and try to refute or gather support for them. Why is this process any different for GPs than for other doctors? It gets easier for specialists—you don't have to be a particularly thoughtful (neurosurgery) assistant to order an extensive scan when you are at least the third opinion.

The discussion about diagnosis applies across the medical profession. All doctors must bear in mind the fallibility of their assumptions and search for alternative explanations for their patients' symptoms.

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Competing interests: None declared.

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#### **RECURRENT ANGIO-OEDEMA**

## Don't forget angio-oedema associated with ACE inhibition

Fitzharris and Jordan report that angiooedema occurs in 0.1-0.7% of all patients taking angiotensin converting enzyme (ACE) inhibitors. In 2002 my coworkers and I evaluated the prevalence of angio-oedema in patients in our allergy clinic and the use of ACE inhibitors by those with angio-oedema. The prevalence of angio-oedema was higher (2.2%) than that reported by Fitzharris and Jordan and the use of ACE inhibitors was 7.9%, which is much lower than that reported by Banerji et al in 2008. Theirs was a multicentre study of the prevalence of angio-oedema induced by ACE inhibitors in all patients presenting with angio-oedema to five emergency departments during 2003-5. The frequency was 28%, 31%, and 31%, respectively.

The difference between our data and theirs is probably due to the different clinical settings. However, from around 8% to almost a third of all patients with angio-oedema are taking ACE inhibitors. Thus doctors should bear this association in mind when treating them.

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#### **BEVACIZUMAB OFF-LABEL**

### Blanket disapproval of all unlicensed indications is wrong

"Off-label" covers a variety of situations.

Applications for marketing authorisations—
licences that lead to a "label"—are made by
companies for almost entirely commercial
reasons. The company that makes bevacizumab
does not apply for an authorisation for use in
macular degeneration because it also makes the
more expensive licensed product.

This is a failing of the licensing system, in that it relies on companies to do things in the best interests of patients because these usually coincide with their commercial interests. In this situation, they do not.

The General Medical Council and Kyle mistakenly disapprove of all unlicensed indications. If it were open (practically and legally) to the NHS to apply for a marketing authorisation, bevacizumab would probably become licensed for this indication, but with pressure from companies and their allies to prevent this, the opportunity to benefit more patients will be lost.

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Competing interests: None declared

SJE is a member of the pharmacovigilance working party at the European Medicines Agency but this is strictly a personal view.

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#### **RESPONSE**

### The Australian responds to Ray Moynihan and Melissa Sweet

In his recent critique of the Health of the Nation series published by Australia's national daily newspaper, *The Australian*, Ray Moynihan concludes with a plea that health reporting be done "fairly and accurately." We agree and wish that he and fellow critic Melissa Sweet had held themselves to the same standards.<sup>2</sup>

Ms Sweet quoted Gary Schwitzer as claiming that the series—which was sponsored by the Australian pharmaceutical industry's umbrella body, Medicines Australia—amounted to the "drug industry influencing public discussions in one more infectious way." Mr Moynihan claimed that one of the deal's "most insidious effects will be self-censorship—invisible, immeasurable, but chilling in its effect on the free flow of public debate." No evidence was offered to support such assertions, which is not surprising because they are not true.

Two issues need to be considered. The first is whether the series pandered to drug industry interests, the second, whether such deals necessarily impair a newspaper's ability to scrutinise the drug industry in future.

Any objective look at the first issue would be expected to start with an account of what was printed as part of the series. Yet neither Ms Sweet nor Mr Moynihan attempted this. Indeed, how much of it they or those they interviewed had read remains unclear: Ms Sweet wrongly states that the series appeared on 15 October, by which date nearly 25 000 words had already been published in 23 articles.

For the record, the series comprised 12 pages published in the Inquirer section of The Weekend Australian between 30 July and 15 October. The sponsorship was disclosed on each occasion. (Selected elements of this coverage were later reprinted in a one-off magazine, which appeared on 22 October.) One page of all this (published on 27 August) addressed medicines policy. It described the affordability challenges created by expensive new drugs of limited efficacy, and was accompanied by an independent comment which argued that taxpayer subsidies for generic drugs were far too high—a notion that is anathema to Medicines Australia, the series sponsor.

That was pretty much it so far as drugs are concerned. Elsewhere in the series we reported on the growing problem of out of pocket costs, particularly for poor people, highlighting the case of one patient with cancer who had to pay \$A17000 (£10650; €12380; \$16540) towards her surgical and other care, despite

having top level private insurance. Other issues addressed included the rise of chronic disease; disciplines such as mental and dental care that are currently not well provided for; and the problems dogging the introduction of electronic health records. None of this is a free kick for the drug industry, yet by omitting these details Ms Sweet and Mr Moynihan suggest the reverse.

As for the second issue, both authors implied the arrangement will see *The Australian* cowed into taking a more industry friendly line. Not only is this demonstrably wrong, it betrays a fundamental misunderstanding of the ethical framework in which newsrooms operate.

Ms Sweet quotes Schwitzer as claiming that journalists should not be "party" to such deals, but these arrangements are strictly between advertisers and advertising departments: journalists are never "party" to them. This is not hair splitting, but a crucial distinction on which all journalists at commercial organisations rely. Every day advertisements appear in major newspapers for supermarkets, banks, department stores, airlines, and other clients as part of deals worth far more than the Health of the Nation sponsorship. The idea that these companies are then spared legitimate scrutiny is absurd. The Health of the Nation deal is no different

Conflicts of interest are ubiquitous and are not limited to pharma deals. We argue most such conflicts can be managed ethically and successfully. For reassurance that that is the case, we need look no further than the *BMJ*, which runs an annual awards scheme itself partly funded by pharma sponsorship.

Many researchers, academics, clinicians, and others find that commercial realities require them to seek industry funding. Some grow tired of the implication that such links are "tantamount to malpractice." It is time to ask if a more nuanced—and evidence based—debate over conflicts of interest is now overdue.

Clive Mathieson editor

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