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# LETTERS

## AFTER FUKUSHIMA

### Ethics should trump science



SANKEI VIA GETTY IMAGES

In response to the suggestion that radiation dose should be estimated for every exposed person in Fukushima,<sup>1,2</sup> the National Cancer Centre of Japan will conduct a huge cohort study on the exposed population to investigate the risk of low dose radiation.<sup>3</sup> It will provide Fukushima residents with dosimeters so that cumulative exposure can be measured.<sup>3</sup> In addition, the Radiation Effects Research Foundation is planning to follow-up 150 000 people for more than three decades.

Currently, although an evacuation area has been set, radiation hot spots with cesium-134/137 of more than 600 GBq/km<sup>2</sup>—comparable to the “permanent control zone” in Chernobyl—are not uncommon outside the evacuation zone.<sup>4</sup> Disturbingly, the legal limit of radiation exposure has recently been raised from 1 mSv/year to 20 mSv/year for the general public, so people may now be expected to live in affected regions. The legal limit for nuclear workers in Japan has also recently been raised from 100 mSv/year to 250 mSv/year.

In Fukushima, where the crisis is ongoing, scientific opportunity should remain secondary to the humanitarian spirit of medicine—to save lives and maintain health. However, the Japanese government has still given no indication of any concrete medical and social welfare plans for affected residents. The lack of adequate governmental support contrasts greatly with the ambitious plans for the cohort study. Meanwhile, a government adviser for the nuclear crisis has resigned, citing doubts about the government’s will to protect the people.<sup>5</sup>

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## REGULATION OF MEDICAL DEVICES

### Initiative in anaesthesia

Wilmshurst’s article implies that the problems created by the EU Medical Devices Directive necessitate legal sanctions because “clinicians cannot be trusted to police themselves.”<sup>1</sup> But sanctions take time to enact.

In anaesthesia we have long faced problems with clinically untested airway management devices introduced to market.<sup>2-4</sup> Trusts are attracted by low prices, and when evidence is lacking it is difficult to support alternatives to the cheapest.

The Difficult Airway Society (DAS; a specialty organisation in anaesthesia with about 3000 members) has now issued formal guidance that members (who sit on trust procurement committees) should recommend purchase of only those products supported by at least a minimum level of evidence (a published case controlled clinical trial).<sup>5</sup> This strategy exploits the limitation that the directive can dictate what can be sold but not what must be purchased. Purchasers are entitled to make decisions on any criteria they like; DAS has resolved to make decisions based on evidence.

Although our minimum level of evidence falls considerably short of the ideal, it immediately excludes many devices that lack any clinical evidence. This step itself will place considerable pressure on industry to support and publish results from high quality clinical trials before marketing. Furthermore, the society’s evolving research network offers industry an independent platform to conduct the needed trials.<sup>5</sup>

Unlike sanctions, this strategy requires no legislation so might lead to early positive results.

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Competing interests: JJP is scientific officer of the Difficult Airway Society.

- 1 Wilmshurst P. The regulation of medical devices: unsatisfactory, unscientific, and in need of major overhaul. *BMJ* 2011;342:d2822. (13 May.)
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## MADNESS OF CHILD PROTECTION

### Has child protection become a form of madness? Yes and No

Has child protection become a form of madness, as the *BMJ* recently debated?<sup>1,2</sup> In response to the authors’ points, the answer is both “yes” and “no.” Yes, we need to focus on the underlying causes that disadvantage children and that in the process may place children at the risk of abuse; but no, in that abuse of children is a widespread phenomenon to which society and professionals have become increasingly aware, so we should continue to make every effort to identify and protect such children.

The concept of “safeguarding” neatly embraces both the need to protect those who need protection and to intervene early in the lives of many children who are vulnerable for some reason. Children who are subject to child protection plans are not a discrete and remote group but are an integral part of the child population as whole; more than five times as many children have child in need plans than are subject to child protection plans, and one in three of all children are considered “vulnerable.” Approaches to deal with this problem need to consider how to respond to the needs of all of these children.

Both sets of authors are right to an extent, therefore. Protecting children remains an important and worthwhile activity, but so does the need to deal with the underlying factors

that make our children some of the most disadvantaged in the developed world.

The two issues are part of the same problem, with similar solutions. As I say at every training session I deliver, “The better we safeguard the many, the better we protect the few.”

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- 1 Gregoire A, Hornby SA. Has child protection become a form of madness? Yes. *BMJ* 2011;342:d3040. (18 May)
- 2 Spinelli M, Howard LM. Has child protection become a form of madness? No. *BMJ* 2011;342:d3063. (18 May.)

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## WE NEED TO TALK ABOUT NURSING

### Impact of contracting out care

Stories about bad nursing are regularly reported in the media,<sup>1</sup> and I am in no doubt that care in these cases is appalling. However, what is really happening?

Over the past 10-15 years the NHS seems to have been changing, with a drive to save money by cutting the number of “qualified nurses” and employing bank (temporary staff) or expensive agency nurses. The ability to maintain contracted nurses has become increasingly difficult as the workplace becomes more demanding, impersonal, and demoralising.

In any clinical area, a qualified nurse may be supported by one other trained, possibly junior, colleague, sharing duties of monitoring, drug rounds, record keeping, and general management. The basic essential care is left to limited numbers of untrained staff, referred to as nurses by patients and relatives.

This may be where the problems originate. The new NHS needs to address the devastating effects of contracting out its nursing staff. It needs to learn to respect its staff and allow them to do the job they have been trained and employed to do. A hospital is a business operation, and in many cases operates like one. However, filling the gaps in nursing teams with staff with no caring skills is pulling the NHS and its good nurses down.

There are bad eggs in any business organisation, and bad behaviour is usually not tolerated—yet it appears to be ignored and brushed under the carpet in an environment where caring is of the utmost importance and the failure to provide it can have devastating effects on many lives. Many good nurses are holding what’s left of the NHS together—let’s not forget them.

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- 1 Delamothe T. We need to talk about nursing. *BMJ* 2011;342:d3416. (2 June.)

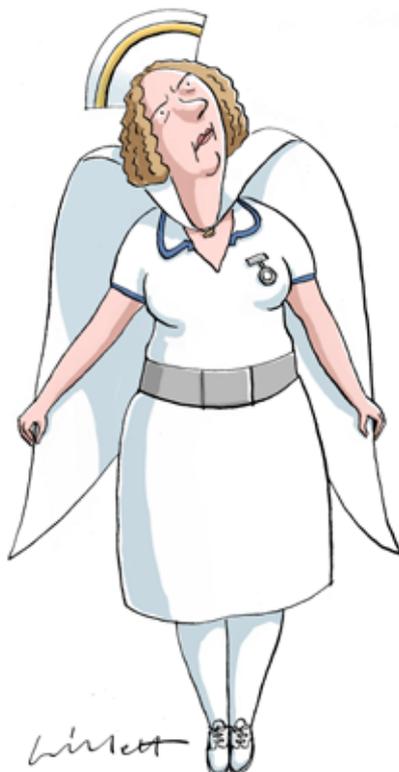
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### Let’s look at system failure

Nothing can excuse the reprehensible nursing care described by Delamothe.<sup>1</sup> Nurses providing deplorable care are not worthy of their title, but the issues are wider. Why has this type of behaviour gone unchallenged by senior health professionals and managers, and what is wrong with a system that perpetuates this degree of inhumanity? The “sorry state” of nursing in some hospitals referred to by Delamothe is symptomatic of system failure.

Evidence shows that the quality of the practice environment has an impact on patient care. Today’s nurses need to be highly educated so that they are skilled to care for people with a myriad of chronic health and social care needs. To provide safe, high quality care also requires sufficient numbers of staff and an appropriate skill mix. Over-extended nurses, burdened by increasing patient to nurse ratios, have higher rates of “burnout,” which is directly related to increases in co-morbidity and mortality for patients.<sup>2</sup>

Better patient outcomes are associated with positive teamwork and good nurse-doctor relationships. Challenging poor care requires leadership and support from nurses, doctors, and all members of the multidisciplinary team.<sup>3</sup> Nurses must accept responsibility for the part they can play in leading the way. Nevertheless, leadership is key at all levels in the healthcare system, including doctors and managers, to enable care to be delivered with humanity and compassion.



No one yet knows how the proposed NHS reforms in England will affect nursing standards or patient care, but the need for reform should not be justified as an inevitable outcome of universal poor quality care. Rarely reported are the good stories of nursing that are part of everyday care. We should use these examples to inform the sort of NHS that is worth saving.

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- 1 Delamothe T. We need to talk about nursing. *BMJ* 2011;342:d3416. (2 June.)
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### Let’s think operationally

Reports of appalling nursing care cause shame, bewilderment, and anger. Failure to care is an act of betrayal. Delamothe’s editor’s choice prompted much discussion among nurses completing their MScHC at the University of Glasgow.<sup>1</sup> These nurses hold nursing to be a caring profession with clinical expertise, good communication, and compassion as the cornerstones of practice.

Nurses do not exist in isolation: they work in a system with other healthcare professionals. Nurses’ omnipresence 24/7, their being the largest group in the healthcare workforce, and their ubiquity across healthcare delivery mean that they are often the public face of the organisation.

These eight operational points may therefore be worth considering:

- (1) The redeployment of “problem” employees, which moves the person from place to place over time
- (2) The process of identifying problem employees in which they are counselled, advised, educated, and offered further opportunity to perform competently. Some go off sick with stress, return to work, and restart the process
- (3) The inability to remove indifferent, demonstrably uncaring people from practice efficiently and with union and management agreed on the way forward
- (4) The role of management in recognising and addressing system failures
- (5) The lack of resources that has an impact on response times and causes anxiety, frustration, and mistakes on a daily basis, with

- nurses finding themselves unable to deliver the kind of care they want to
- (6) The extent to which poor nursing care represents organisational malaise
  - (7) That the term nurse is not protected in legislation and therefore may be used for a range of staff delivering front line care
  - (8) The length of time that the Nursing and Midwifery Council takes to hear disciplinary cases.

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1 Delamothe T. We need to talk about nursing. *BMJ* 2011;342:d3416. (2 June.)

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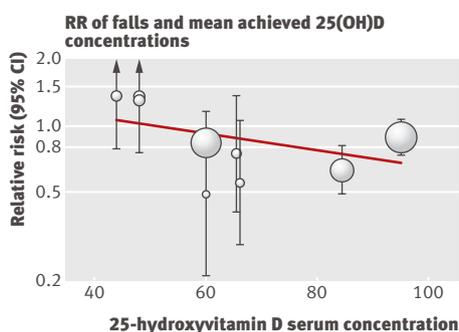
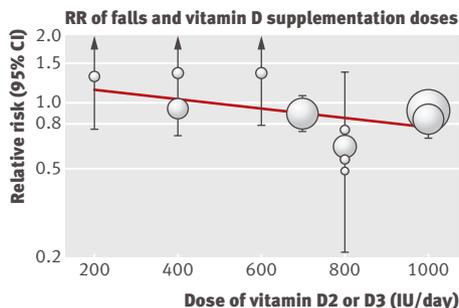
## FALL PREVENTION WITH VITAMIN D

### Institute of Medicine responds

The Institute of Medicine (IOM) criticised inconsistencies and misrepresentations of data in the meta-analysis of vitamin D and fall prevention by Bischoff-Ferrari and colleagues.<sup>1 2</sup> The authors replied to the IOM,<sup>3</sup> and we respond to them as members of the IOM committee.

In assessing the dose-response relation between vitamin D dose, serum 25-hydroxyvitamin D concentration, and risk of a fall the authors opted to compare subgroups of studies above or below a cut off point of vitamin D dose and serum 25 hydroxyvitamin D concentration selected by “visual inspection”—that is, in an entirely data driven way. They found significant differences in two subgroups (in a meta-regression framework) and interpreted them as evidence for an inverse relation. However, analyses using nearby cut off points are not significant. The IOM’s reanalysis of the authors’ data using vitamin D dose as a continuous variable showed no significant relation. Furthermore, trying to establish a “threshold” between falls and serum 25 hydroxyvitamin D concentration is too simplistic when non-comparable assays are performed over 12 years.

Bischoff-Ferrari and colleagues acknowledge that they included a trial conducted by Broe et al in violation of their stated eligibility criteria.<sup>3 4</sup> They maintain that it was appropriate to do so because it had a high quality fall assessment. However, the study by Graafmans et al also violated the inclusion criteria since “falls” was only added as an end point in a cohort study two years after randomisation to a fracture study.<sup>5</sup> Four of the five negative results relating to a threshold on “low dose” vitamin D and falls were by Broe et al and Graafmans et al.



**Meta-regression plot. Relative risk is 0.95 (95% confidence interval 0.89 to 1.02; P=0.13) per 100 IU/day increase in dose and 0.92 (0.80 to 1.05; P=0.17) per 10 nmol/L increase in mean achieved 25-hydroxyvitamin D concentration. Reproduced with permission from reference 1 by the National Academy of Sciences**

Figure 3 in Bischoff-Ferrari and colleagues’ meta-analysis is misleading<sup>2</sup>: it was not simply misinterpreted by the Institute of Medicine. The figure uses the layout of a typical meta-regression plot and shows a “trend line” that resembles a meta-regression summary line. Using the same data, the IOM found that the meta regression analysis on falls was not significant (figure).<sup>1</sup>

The internal inconsistencies of the paper and the selectivity of the dose-response analyses justified the IOM’s reanalysis. Properly powered double blind studies of vitamin D on falls are needed but no more meta-analyses.

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- 1 Institute of Medicine. Dietary reference ranges for calcium and vitamin D. 2010. [www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D](http://www.iom.edu/Reports/2010/Dietary-Reference-Intakes-for-Calcium-and-Vitamin-D).
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## DIGITAL RECTAL EXAMINATION

### Good medical practice

Spence may be being deliberately provocative in arguing that digital rectal examination is bad medicine,<sup>1</sup> but in geriatric and general medicine rectal examination is important other than for detecting rectal tumours or assessing the prostate.

As has been emphasised in the National Audit of Continence Care for Older People,<sup>2</sup> faecal impaction is a cause of urinary incontinence and its treatment may result in symptomatic cure. Rectal examination is imperative when assessing faecal incontinence to determine impaction or diarrhoea as a cause of the incontinence, thereby determining appropriate management.

In addition, knowing whether the rectum contains melaena or fresh blood is helpful in patients who present with possible gastrointestinal bleeding. Assessment of anal tone and sensation is critical in possible spinal cord damage or disease, and such close examination is an opportunity to inspect pressure areas.

Furthermore, older people do not find digital rectal examination too unpleasant: indeed they expect it and believe that the examination has been thorough when it is included.<sup>3</sup> To get trainee doctors to carry out this crucial part of the examination is hard enough without their being given excuses not to by weekend columnists.

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- 1 Spence D. Bad medicine: digital rectal examination. *BMJ* 2011;342:d3421. (1 June.)
- 2 Royal College of Physicians. *National Audit of Continence Care report*. RCP, 2010.
- 3 Morgan R, Spencer B, King D. Rectal examination in elderly subjects: attitudes in patients and doctors. *Age Ageing* 1998;27:353-6.

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### Beyond the valley of the dolls?

As a hospital clinician, I see a great reluctance among some doctors to do anything that might be regarded by patients as undignified. Yet a stay in hospital requires that patients undergo or perform far less dignified processes than digital rectal examination many times over.<sup>1</sup>

I don’t think that we as doctors are necessarily lazy: I think that from medical school onwards we are indoctrinated to show such deference to patients’ feelings that if we are not careful we can come to view certain bits of their anatomy as entirely out of bounds. So nothing vaguely “offensive” can be done, such as breast examinations or genital inspection or even palpation of the groins and lower abdomen, at the risk of upsetting a patient’s sensitivities. Even with cardiac auscultation, a perfunctory listen at the

aortic area now seems to suffice in female patients for fear of delving further towards the mitral area or exposing any flesh below the neckline.

I sometimes think that we are heading back to the days of the ancient Chinese with their ivory medicine dolls.

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1 Spence D. Bad medicine: digital rectal examination. *BMJ* 2011;342:d3421. (1 June.)

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## What would the number needed to examine be?

There is only one conflict about digital rectal examination: its use in routine general practice for screening and its use in selected secondary care settings. Spence seems to have argued against its use in routine general practice for screening and has been taken to task inappropriately by rapid responders for supposedly arguing against its use in selected secondary care settings.<sup>1 2</sup>

Spence's list of indications for digital rectal examination is undoubtedly woefully inadequate. Secondary care practitioners abandoning this examination do so at their peril. But I doubt that Spence would ever see spinal cord compression in his surgery without other symptoms that would prompt referral to secondary care. Neither would

finding a retrocaecal appendix in a patient with vague, as yet unexplained, abdominal pain be a concern when the advice of the local surgeon would be sought anyway.

So let's all agree that the routine use of digital rectal examination in primary care has little value (God only knows what the number needed to examine would be), while the performance of the examination in secondary care is mandatory.

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1 Spence D. Bad medicine: digital rectal examination. *BMJ* 2011;342:d3421. (1 June.)

2 Rapid responses. Bad medicine: digital rectal examination. *bmj.com* 2011. www.bmj.com/content/342/bmj.d3421.full#responses.

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## Author's reply

I have never suggested that rectal examination has no value but merely that clinicians must know its limitations. In primary care the prevalence of rectal and lower urinary tract symptoms is high, but the prevalence of sinister disease low, especially in young people. Consequently, even in those with symptoms, digital rectal examination is of unknown sensitivity and specificity with an unknown potential for both false reassurance and false positive outcomes. For example, around 70% of abnormal results on prostate examination

were normal a year later.<sup>1</sup> Around a quarter of rectal tumours are missed on rectal examination in primary care, and 70% of those diagnosed with a "palpable rectal tumour" on such examination do not have cancer.<sup>2</sup>

Doctors should have absolute clarity of indication and always question whether rectal examination will change clinical management. Digital rectal examination is indicated for tenesmus and possible faecal impaction and to assess anal tone and prostatitis. But these are rare indications in primary care, and I stand by my conclusion that digital rectal examination has very occasional and limited indication. Routine rectal examination such as in everyone admitted to a care of the elderly or surgical ward is simply not justifiable, despite the protests and anecdotes offered.<sup>3 4</sup> Digital rectal examination is what it is: an unpleasant invasive procedure and of questionable benefit. The point of my article was to raise this debate.

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1 Ankerst DP, Miyamoto R, Nair PV, Pollock BH, Thompson IM, Parekh DJ, et al. Yearly prostate specific antigen and digital rectal examination fluctuations in a screened population. *J Urol* 2009;181:2071-6.

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3 Taylor KG. Kenneth Taylor responds to Des Spence. *BMJ* 2011;342:d3957.

4 Snape J, Elliott B. Good medical practice. *BMJ* 2011;342:d3949.

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## RESPONSE

### Kenneth Taylor responds to Des Spence

The time and place for digital rectal examination in the full assessment of a patient are all important.<sup>1</sup>

I recall the case of a middle aged person who collapsed in the street. There was no significant history, and the main finding on examination was a significant postural drop in blood pressure. Rectal examination showed melaena, and, after resuscitation, the patient was found to have a bleeding duodenal ulcer. Not a useless examination in this case.

What about a patient with an acute abdomen with suspected acute appendicitis in whom acute tenderness is shown on rectal examination owing to a pelvic appendix? Is it a useless test then?

What about a patient with Crohn's disease and tender, thickened loops of bowel in the pouch of Douglas?

What about patients presenting with rectal bleeding attributed to haemorrhoids by some primary care physicians? Such patients may turn out to have an underlying cancer of the rectum. Large bowel cancer is one of the commonest cancers in both sexes in the UK. Such tumours

are most likely to occur in the rectum, a large proportion within reach of a finger during rectal examination. Every patient who notices a significant change in bowel habit that does not resolve fairly quickly or who has rectal bleeding warrants digital rectal examination. Early diagnosis may lead to curative treatment. If too many doctors adopt Spence's attitude<sup>1</sup> the UK may come even worse in the European cancer league tables than it does already.

A man presents with dysuria. A rectal examination may help to distinguish benign prostatic hypertrophy from cancer of the prostate, a hard woody prostate being classically malignant.

Snape and Elliott emphasise the importance of diagnosing faecal impaction by rectal examination in older people.<sup>2</sup> Quite often this condition can present with spurious diarrhoea or urinary incontinence. I have seen the spurious diarrhoea treated with a constipating agent—namely, codeine phosphate—with unfortunate consequences simply because rectal examination was omitted.

And let us not forget neurology. Lesions of the lower sacral cord can result in normal power in the legs and preserved stretch reflexes, but the perianal and genital regions must be examined for loss of sensation, together with anal and bulbocavernosus reflexes. The tone of the anal sphincter usually

increases when a finger is inserted into the rectum, but it is lost with lower sacral cord lesions and is an important physical sign.

Thus digital rectal examination is indicated in many important clinical situations. The more often it is performed the more skill is gained and experience accumulated. It is not pleasant for patients, and is a bit embarrassing for them, but a patient's health and survival come before a little transient embarrassment. With every new patient a doctor has to ask whether a rectal examination is indicated.

Spence's article is really bad medicine. That he has been peddling bad medicine to medical students is profoundly worrying. Some of them may have read his article,<sup>1</sup> but I doubt that few will read the responses.<sup>3</sup> His word will be taken as gospel in some quarters because he has received editorial approval from the *BMJ*.

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**Competing interests:** None declared.

1 Spence D. Bad medicine: digital rectal examination. *BMJ* 2011;342:d3421. (1 June.)

2 Snape J, Elliott B. Good medical practice. *BMJ* 2011;342:d3949.

3 Rapid responses. Bad medicine: digital rectal examination. *bmj.com* 2011. www.bmj.com/content/342/bmj.d3421.full#responses.

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