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LETTERS

BREAST CANCER SCREENING

Publicity of NHS breast cancer screening programme is unfair

More informative information for women on the benefits and harms of mammographic screening has been sought for a long time.[1 2] In December 2010 a revised leaflet finally appeared, but it is still misleading.[3]

The benefits cited are based on the programme's own review. On the basis of a 35% reduction in death rate among screened women, it estimates that 1347 deaths from breast cancer are prevented each year. But the recent US Preventive Services Task Force, based on all randomised trials, reports a 14% reduction in women aged 50-59 and 32% in those aged 60-70. Further, a Cochrane review argues that taking account of the likely biases in the trials, a 15% reduction overall is more plausible, leading to nearer 500 fewer deaths a year, not 1400. The estimate of the number of women who need to be screened over 10 years to prevent one death (400 in the leaflet) is also far too low; it is 1000 if the effect is 30% and 2000 if the effect is 15%.[4 5]

The leaflet also completely fails to pay enough attention to harm, although the chance of overdiagnosis may be higher than that of preventing death. General Medical Council guidelines say both should be communicated; women have a right to know, even if focus groups may advise against.

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Competing interests: None declared.

1 McPherson K. Should we screen for breast cancer? *BMJ* 2010;340:c3106.
2 Gøtzshe PC, Hartling OJ, Nielsen M, Brodersen J, Jørgensen KJ. Breast screening: the facts—or maybe not. *BMJ* 2009;338:446-8.
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Cite this as: *BMJ* 2011;342:d791

LAPAROSCOPY COMPLICATIONS

Understating under-reporting

Lamont and colleagues' article contains a masterful understatement: "Between April 2005 and April 2010, the NPSA [National Patient Safety Agency] received reports of 11 deaths and 37 serious incidents in patients who had deteriorated after laparoscopic surgery. These incidents are probably greatly under-reported."[1]

A survey of members of the Association of Laparoscopic Surgeons last year found 31 reports of deaths and 333 serious injuries.[2] Data from the NHS Litigation Authority showed 327 successful claims for such injuries over 15 years.[3] Although not wholly comparable, these figures are far greater than the NPSA's 2.2 deaths and 7.4 other serious incidents a year, and suggest that only 7-25% of cases were reported to them. Such under-reporting is probably no less common for other iatrogenic harms. From April 2010, hospitals have been under an enforceable duty to report all serious incidents to the NPSA. An audit of compliance is essential.

The coalition government made two potentially contradictory commitments: to abolish the NPSA, thereby causing re-disorganisation, and to "require hospitals to be open about mistakes and always tell patients if something has gone wrong."[4 5] The Department of Health is consulting about how and on whom this requirement should be enforced. The malpractice insurers, General Medical Council, and royal colleges oppose legal sanction, arguing (without evidence) that this already exists, or that it would encourage cover-ups. The NPSA and Litigation Authority have not commented.

Insurers fear rising costs, although there is evidence to the contrary. Doctors find it difficult to admit error and risk being caught between legal sanctions and bullying NHS managers prioritising reputational risks over patient safety. This reasonable concern should be alleviated by imposing the requirement on management.

As a doctor (who has inevitably made mistakes) and a patient (who nearly died of one), I know that most patients are forgiving of errors admitted, but outraged by dishonesty. Present systems virtually mandate cover-ups. The better alternative is to require managers to copy in patients on reports of serious incidents sent to the regulator, to protect patients and doctors and promote ethical practice.

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Competing interests: FWA suffered a laparoscopic perforation at an elective procedure. This was left untreated until seven days after surgery, which resulted in a subtotal excisional laparostomy, a cardiac arrest, and six months' convalescence. FWA is an unpaid member of the Department of Health working party cited above.

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Cite this as: *BMJ* 2011;342:d793

Apply safety rule of thumb

The National Patient Safety Agency (NPSA) team's article was extremely helpful in listing symptoms and signs that should alert health professionals to a possible laparoscopic related complication.[1] Patients should also be educated on these postoperative symptoms, with this information documented at perioperative consent and contained in patient information leaflets.

Delays in recognising and managing such complications compound morbidity. Major symptoms (abdominal distension, pyrexia, and shock) may predict laparoscopic related complications, but they tend to be late stage sequelae. Clinicians need to be aware of minor symptoms (mild abdominal pain, dyspepsia, nausea, constipation) that often do not greatly affect the patient's general health but represent early onset sequelae. Doctors should maintain a low threshold for further investigation of patients re-presenting shortly after laparoscopic surgery. As a rule of thumb assume that any patient who does not progressively improve after laparoscopic surgery has a laparoscopic related

complication until proved otherwise. Such a rule should encompass major and minor type presentation symptoms and would facilitate earlier senior clinician involvement, recognition, and intervention.

Abdominal laparoscopy is not performed solely by general surgeons. The NPSA may have missed a golden opportunity to involve other "stakeholders" (such as gynaecologists, urologists) when drafting this safety alert.[1] Most laparoscopic complications are not specific to a particular operation or specialty but relate to common mechanisms (such as injury at the time of laparoscopic entry[2] or delayed onset diathermy bowel injuries). Wider multispecialty consultation would have led to greater dissemination of this important safety message and improved patient safety awareness.

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Competing interests: None declared.

1 Lamont T, Watts F, Panesar S, Macfie J, Matthew D. Early detection of complications after laparoscopic surgery: summary of a safety report from the National Patient Safety Agency. *BMJ* 2011;342:c7221. (19 January.)
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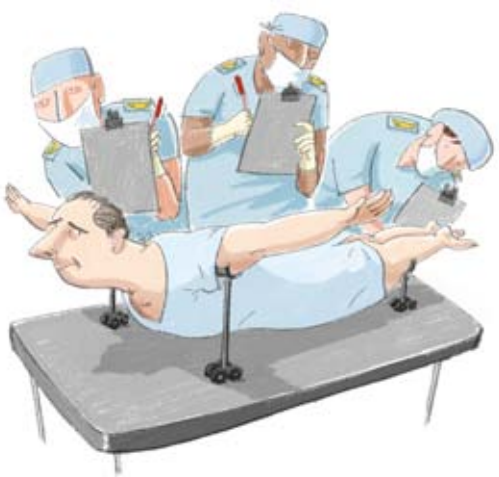
Cite this as: *BMJ* 2011;342:d799

AVIATION AND PATIENT SAFETY

Send in the marines?

To paraphrase James Carville, "It's the analogy, stupid." The problem is not how far we can go using the analogy of the aviation industry to improve patient safety,[1] but the analogy itself.

Groysberg and colleagues described the different operating styles within armed forces.[2] In the air force and navy, many day to day operations involve complex, closely coupled, and extended sequences that can be done safely only by following predetermined standard operating procedures, which are often rehearsed. An error in any one step has immediate repercussions along the tightly linked sequence. In such operations, flexibility is traded against safety. Groysberg and colleagues contrast this with the modular operating structure of the marines. They quote the military aphorism, "No plan survives first contact with the enemy" to illustrate the complexity and variability of marine ground operations. That complexity is what requires forces to be structured as interdependent but largely autonomous units within units that work in a coordinated but flexible manner to achieve the mission goals.[3]



WILLETT

In healthcare, tightly linked sequences that can be rehearsed and subjected to a checklist are relatively uncommon compared with care delivered by the complex interaction of more or less well coordinated modular groups of nurses within wards, doctors within teams, teams within units, units within institutions, and so on. As populations age and increasingly present with complex comorbid problems, the need for flexibility in healthcare delivery will increase. Is the next step in patient safety to send in the marines?

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Competing interests: None declared.

1 Gaba DM. Have we gone too far in translating ideas from aviation to patient safety? No. *BMJ* 2011;342:c7310. (14 January.)
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Cite this as: *BMJ* 2011;342:d801

We cannot go too far in the pursuit of patient safety

It strikes me that two prime differences exist between pilots and doctors. Firstly, pilots kill their passengers in large very visible batches while doctors kill their patients one at a time; secondly, whereas pilots often perish in the incident that kills their passengers, doctors are rarely personally at risk as the threat to a patient's survival unfolds.

Both of these factors, it could be argued, add motivation to pilots to ensure that processes of safety and quality are in place and followed, over and above that of doctors.

Have we gone too far in translating ideas from aviation to patient safety?[1] Difficult to answer this specifically; what I do think is that we cannot go too far in the pursuit of patient safety; eating a little humble pie in learning from other safety dependent industries is a small discomfort to tolerate for that end.

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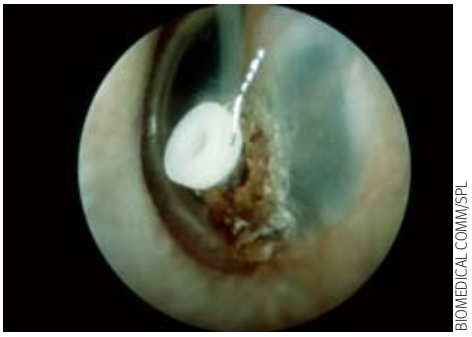
Competing interests: MC is a general practitioner, appraiser, and national director of the NHS Revalidation Support Team.

1 Rogers J. Have we gone too far in translating ideas from aviation to patient safety? Yes. *BMJ* 2011;342:c7309. (14 January.)

Cite this as: *BMJ* 2011;342:d802

PAEDIATRIC ENT SURGERY

Grommets and rates of cholesteatoma



BIOMEDICAL COMM/SPL

Spence is entitled to his views on grommets, but, on the important question of cholesteatoma after grommet insertion, he is not entitled to statistical errors or selective use of literature.[1]

The paper by Golz et al is retrospective and uncontrolled.[2] Their diagnosis of grommet induced cholesteatoma was observational and based on two possibly flawed premises—namely, that after grommet surgery cholesteatoma arising behind an intact drum or in a perforation of the pars tensa resulted from grommet insertion.

Even if they are correct, their 1.1% incidence of cholesteatoma after grommets was an overall observation from a study period of 20 years, not an annual incidence, whereas the figure Spence uses as a control (from Kemppainen et al[3]) is an annual incidence. Golz et al give only a range (1-20 years) for follow-up of their cases. If the average is assumed to be some 10 years, annual incidence would be 0.11% compared with an annual incidence of cholesteatoma from Kemppainen et al of 0.009%. This would be a cholesteatoma rate some 10 times, not 100 times, higher than the general population (assuming comparable populations).

A prospective study using tympanostomy in one ear with the other as control has been done, but the numbers were small.[4] At 15 years there were three cholesteatomas in the operated ears and none in the unoperated ears (not significant). The site of each cholesteatoma was stated, and none would have fitted Golz et al's criteria for grommet induced disease.

Other studies show no increase in the rate of operation for cholesteatoma in the UK, despite a dramatic increase in use of tympanostomy tubes.[5 6] I remain unconvinced of the association.

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Competing interests: None declared.

Editor's note: A correction has been published to the author's reply by Spence with regard to the rate of cholesteatomas associated with grommet surgery.

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Cite this as: *BMJ* 2011;342:d647

MMR SCARE

The *BMJ*'s measly editorial policies

The *BMJ* is right to pursue the autism/MMR/Wakefield issue,[1] and to highlight the need for wider vaccination against measles. But problems remain. How is "good" investigative journalism to be reliably distinguished from the "bad" of certain newspapers and magazines? By detail alone? I am not convinced that if the *Daily Mail*'s Melanie Phillips, say, had spent the same amount of time on the story, she would necessarily have ended up believing Andrew Wakefield to have been fraudulent, or even deliberately dishonest.

Brian Deer himself seems to recognise the limits of his three *BMJ* pieces. In a *Press Gazette* interview last year he indicated that there is no real distinction between scientific journals and newspapers.[2] Why, then, bother having his first piece "peer reviewed" by the usual anonymous process? Perhaps declining such a doubtful endorsement would have been more consistent.

The Deer/*BMJ*'s overall account ignores the context in which the worldwide anti-vaccination movement has grown. The *BMJ* itself, even at the height of the MMR scare in the UK, promoted scepticism about the "inappropriate domination of the Western view of mental health," a process in which "doctors and the pharmaceutical industry" irresponsibly push both "Western cultural ideas" and "a rapid growth in the numbers of children diagnosed with conditions such as attention deficit hyperactivity disorder and autism."[3]

Many opinion pieces by the *BMJ*'s columnist Des Spence have gone further: "big pharma use[s] political lobbying to pervert the course of medical justice,"[4] and "A medicated childhood is blunt, defies reason, and is just bad medicine."[5]

When some read such views, given the indifference by the "medical establishment" to neurodevelopmental disorders, it is not very surprising that they prefer a different version of events: Andrew Wakefield's continued fight against Western medicine's vaccine industry.

No doubt the financial transaction between the *BMJ* and Deer was modest; it remains open whether the new policy of commercially encouraging "good" investigative journalism, at the expense of "bad," will have the desired results.

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Competing interests: NMacF has consulted to the Priory Group within the past three years.

1 Deer B. The Lancet's two days to bury bad news. *BMJ* 2011;342:c7001. (18 January.)
2 Amos O. Interview. One in the arm for MMR. March 2009. http://briandeer.com/solved/gazette-large.htm.
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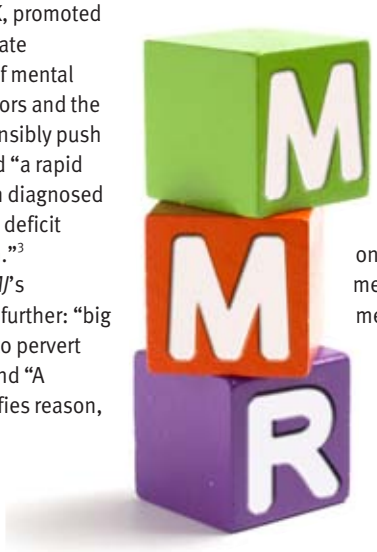
Cite this as: *BMJ* 2011;342:d809

Are the GMC, news media, and *BMJ* the right tribunals?

In three instalments chronicling his investigation of Andrew Wakefield, Brian Deer is the investigator, research-analyst, solver of the crime, and storyteller.[1-3] That one person has performed this Herculean task demands debate on who should be performing these distinct roles, and, given the destruction of reputations involved, whether a single journalist should be granted the power to exact such a heavy price from the subjects of his story.

Who checked the *Lancet* paper's contents? Its 13 co-authors covering different medical areas of expertise did and corrected it for publication. Deer checks and finds the paper wanting.

Deer offers his findings to the *Lancet*'s editor, and he checks them with the authors. The editor has some misgivings, but the paper stands to Deer's dissatisfaction.



After seven years the GMC panel decides against the two doctors, having heard testimony from expert witnesses on both sides. But were the members qualified in the medical expertise and ethics to make sense of the expert testimony heard in a case without precedent in the GMC's history?

Deer is vindicated by the GMC. Whether the truth has now been established and public interest restored are questions that remain. However, the over-riding question is whether the GMC, news media, and *BMJ* (whatever roles they are entitled to have) are the right tribunals for settling scientific and ethical disputes, including serious allegations of rigging results, where the accused are denied judgment by their academic peers but must face the ultimate price of their lifetime reputations destroyed.

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Competing interests: MH is father of an autistic son.

1 Deer B. How the case against the MMR vaccine was fixed. *BMJ* 2011;342:c5347. (5 January.)
2 Deer B. How the vaccine crisis was meant to make money. *BMJ* 2011;342:c5258. (11 January.)
3 Deer B. The Lancet's two days to bury bad news. *BMJ* 2011;342:c7001. (18 January.)

Cite this as: *BMJ* 2011;342:d812

Response from the UK Research Integrity Office

The UK Research Integrity Office (UKRIO) welcomes your recent series on research misconduct. It is incorrect, however, to suggest that UKRIO is ceasing its operations.[1] We continue to fulfil our remit: provision of independent and expert support on issues of research conduct to all involved in research.

The number of cases that UKRIO deals with—more than 60 in 2010 alone—shows the real need for our services. Whistleblowers and organisations that might be expected to hesitate about sharing problems with a non-regulatory body are, in fact, willing to seek our guidance and they value our confidential support. Our published standards are used by many institutions and have been recommended by professional bodies and research funders.[2 3] The costs of providing this service are minimal compared with the consequences of research misconduct.

We have therefore established UKRIO as a company limited by guarantee and are seeking additional funds to continue this vital work. Although securing funding in the current economic climate may be challenging, UKRIO has shown that its services are needed and valued, and that it fills a gap that is not currently provided by any other UK institution.

It is correct that UKRIO has no mandatory powers.[4] This, unsurprisingly, is because parliament has chosen not to act in this area. UKRIO has stepped in to fill the breach, providing support to the research community and the public where there was none. A large proportion of UKRIO's staff are experts who give their time to the project pro bono. Individuals and organisations with experience in dealing with research misconduct are welcome to collaborate with UKRIO.

Ian Kennedy chair, UK Research Integrity Office, Sussex Innovation Centre, University of Sussex, Brighton BN1 9SB, UK **info@ukrio.org**

Competing interests: IK is chair of the UK Research Integrity Office (UKRIO).

1 Godlee F. Institutional and editorial misconduct in the MMR scare [editor's choice]. *BMJ* 2011;342:d378. (19 January.)
2 UK Research Integrity Office. Procedure for the investigation of misconduct in research. 2008. www.ukrio.org/resources/UKRIO%20Procedure%20for%20the%20Investigation%20of%20Misconduct%20in%20Research.pdf.
3 UK Research Integrity Office. Code of practice for research: promoting good practice and preventing misconduct. 2009. www.ukrio.org/resources/UKRIO%20Code%20of%20Practice%20for%20Research.pdf.
4 Marcovitch H. Is research safe in their hands? *BMJ* 2011;342:d284. (19 January.)

Cite this as: *BMJ* 2011;342:d807

Robust procedures for research conduct are needed

I congratulate Brian Deer for exposing the MMR (mumps. measles, and rubella) story—it makes depressing reading.[1]

It would be comforting to think that researchers who manipulate results are "bad apples" that occur from time to time, and that we should learn to guard against them. Sadly this is optimistic. Research misconduct is widespread, varying from the minor ("omit this patient") to substantial ("invent the results").

The UK does not have a good record of investigating research misconduct.[2] Institutions and journals may judge that the consequences of brushing tiresome misconduct under the carpet are less damaging than instituting a potentially adverse investigation. The battles against research misconduct by such (very few) champions as Peter Wilmshurst have been conducted at great personal cost, with little recognition.[3]

Research misconduct can have serious clinical consequences. The MMR publicity led to a reduction in public confidence in vaccination and a fall in MMR uptake, with a resurgence of measles. The media gives scant attention to corrections and retractions, so false information has a stronger life than truth.

There is a wider dimension. Public trust in science is diminishing, at a time when science is central to maintaining our civilised life (*Horizon* BBC2 25 Jan 2011). We need science to deliver solutions, and to do this it has to have public trust. Nothing undermines this trust so rapidly as research misconduct.

The UK Research Integrity Office was set up to enhance research conduct but suffers from a lack of funds and has no regulatory powers.[4] It needs to be put on a secure base. Having robust procedures for the conduct of research and the investigation of suspected misconduct should be a high priority for every research active institution, and for the country.

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Competing interests: MG was director of research and development at the NHS in 1999. He was head of several academic institutions.

1 Godlee F. Institutional and editorial misconduct in the MMR scare [editor's choice]. *BMJ* 2011;342:d378. (19 January.)
2 Marcovitch H. Is research safe in their hands? *BMJ* 2011;342;d284. (19 January.)
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Cite this as: *BMJ* 2011;342:d805

In the wake of Wakefield

Marcovitch describes the failure of an independent body to investigate research fraud because of lack of mandatory powers and long term funding,[1] and, although Kennedy reassures us that the UK Research Integrity Office is still active,[2] perhaps the research community should now consider taking responsibility.

If it were to fund such a body it could persuade journal editors to require that the authors of all submitted articles should agree to a site visit and inspection of the data in the event of a challenge. The requirement of a random audit was suggested in the wake of the Darsee affair,[3] and more recently was considered by one journal but ruled out on the grounds of cost and potential litigation. However, the cost of the present mismanagement by the parties that should have acted is incalculable. Lesser forms of research misconduct are probably more common than we would like to admit, but the prospect of an independent audit would deter potential transgressors and hopefully lead to a change in culture.

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Competing interests: None declared.

1 Marcovitch H. Is research safe in their hands? *BMJ* 2011;342:d284. (19 January.)
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Cite this as: *BMJ* 2011;342:d806

RESEARCH APPROVAL

NHS research: a world of frosted glass

The report from Sir Michael Rawlins and the Academy of Medical Sciences on the bureaucratic stifling of science is opportune and overdue,[1] but I fear that the system it criticises will be true to form and delay any attempt at reform. I write this after a meeting with the finance manager of an NHS trust where we hope to do a second project—our first project (a complex randomised controlled trial) was very successful and recruited more patients there than at any other site. Yet the manager was reluctant to sign up because he had found no evidence of financial benefit to the trust. As the project was funded by the National Institute of Health Research and supported by the Mental Health Research Network, organisations that aim to "embed research within the NHS," I was sure that this must be untrue and promised to investigate.

When I discussed this with the research network I was admonished for suggesting that money would "flow back to the trust from recruitment" (despite official tariffs that give precise figures) and told that "activity based funding" using a complex formula determined the trust funding for our research. This was combined with all research as an "infrastructure grant," but it was impossible to break this down by individual projects. I persisted in asking for some hard figures that I could pass back to the trust but was rebuffed at every turn. Small wonder that in this opaque world of NHS poker so few seem to know what is going on at the places where the research money flows and obstacles are placed at every turn. Transparency must be a key element in its reform.

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Competing interests: None declared.

1 Dillner L. UK needs new health research agency to speed up approval process. *BMJ* 2011;342:d185. (11 January.)

Cite this as: *BMJ* 2011;342:d803

INCOME TO SURVIVE

Clarification from the BMA, please

Fielden states: "A small number of people working within the BMA, such as catering staff, are employed and paid by external contractors. As such, we do not know their individual rates of pay."[1] Such people tend to be paid at or just above the minimum wage. In effect, the BMA seems to be saying that it has subcontracted the employment of workers who are most likely to receive the minimum wage to external companies and has no idea (and perhaps doesn't care?) what they are paid. This hardly seems a responsible action from an organisation that constantly rails against poverty and inequality in society.

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Competing interests: AM is a member of the BMA.

1 Fielden C. BMA pays well over minimum wage. *BMJ* 2010;341:c7305. (30 December.)

Cite this as: *BMJ* 2011;342:d446