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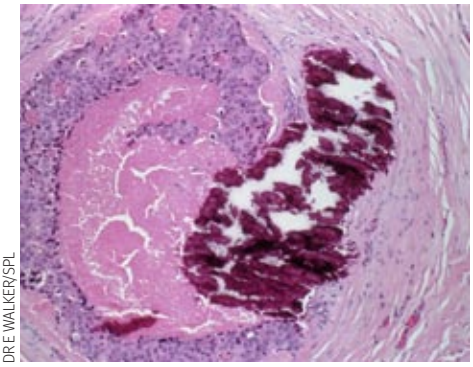
LETTERS



DR E WALKER/SPL

SCREENING AT BREAST REDUCTION

More than a little extra work

We were surprised that no histopathology opinion was sought in discussing the implications of histopathological examination of breast tissue excised during breast reduction surgery.[1]

Mammographic screening entails radiological examination of the entire breast. "Tissue screening" exclusion of malignancy would entail examining all the tissue histologically since most ductal carcinoma in situ is not visible on gross examination. However, given the available resources, it would be impractical to submit all tissue from breast reduction specimens for histological examination as this would entail many tens of tissue blocks from each case. Even if the entire specimen were submitted, only about 0.15% (a 4 µm section from each 3-4 mm tissue block) would be examined under the microscope.

The commentaries suggested that the specimen should be oriented as this "would seem to need little extra work." However, reduction specimens are often received in multiple pieces, each of which would need to be oriented. Retaining this orientation by painting each piece with multiple colours would significantly increase the workload of the pathologist. Even if it is meticulously done, assessment of margins would remain imprecise unless each piece is submitted separately with information describing its precise spatial relation to all the pieces recorded by the surgeon and retained during pathological blocking and examination.

To achieve screening the test has to be fit for purpose. Preoperative mammography (or postoperative specimen radiography) are more practical and cost effective ways of excluding occult malignancy in patients undergoing reduction mammoplasty. The Royal College of Pathologists has identified this type of specimen as being of "limited clinical value" and suggested that it not be submitted for pathological examination unless there is a specific radiological or clinical indication for doing so.[2]

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Competing interests: None declared.

1 Keshtgar M, Hamidian Jahromi A, Davidson T, Escobar P, Mallucci P, Mosahebi A, et al. Tissue screening after breast reduction. *BMJ* 2009;338:b630. (10 March.)
2 Royal College of Pathologists. *Histopathology of limited or no clinical value*. 2nd ed. London: Royal College of Pathologists, 2005.

Cite this as: *BMJ* 2009;338:b2342

SAFEGUARDING NHS STANDARDS

Bring back the SAC

Klein is vague about how professionals can speak out to protect standards in the NHS.[1] Before the reforms of modernising medical careers the specialty advisory committee (SAC) system of the royal colleges and specialty associations was such a conduit.

Visiting teams, comprising experienced clinicians in the specialty, carried out regular and triggered visits and became expert at "turning over stones" and looking carefully underneath for poor practice and standards. Their main focus was on training issues, but poor practice inevitably impinged on training. Their reports could make uncomfortable reading but were usually effective in producing change.

Chief executives understandably objected to the number of visits but only when the government started to ramp up inspections by other quangos. Probably in the interests of economy, these depended much more on submitted data than on in depth site visits and interviews. How sad that the royal colleges allowed this major plank in the supporting structure of standards to be removed in favour of the much diluted approach imposed when the Postgraduate Medical Education and Training Board was introduced.

If the colleges are serious about their role as guardians of the standards of care, then they should reintroduce independent site visits and inspections by their emissaries. I am sure that many would consider taking this on as a professional duty and in their own time if the NHS would not offer support. Endorsement of standards by a royal college is still the best kite mark of quality and provides the professional voice espoused by Klein.

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Competing interests: None declared.

1 Klein R. Safeguarding NHS standards. *BMJ* 2009;338:b1958. (13 May.)

Cite this as: *BMJ* 2009;338:b2328

Medical responsibility is key

Is the answer to safeguarding standards really to introduce another layer of bureaucracy—"quality accounts"—that need to be signed off?[1]

The strong pressure for doctors to behave as corporate beings can conflict with doing what is in the patient's best interest. If doctors—not just those in managerial positions—are aware of major shortcomings in a service, then it is surely their duty to report them, if necessary outside the established "line" and "risk management" mechanisms.

Having recently completed several online 360 degree appraisals, I was struck by the lack of explicit questions on personal integrity or willingness to stand up for what is right despite the possible consequences for career betterment. We should consider adding these two simple mandatory questions in all appraisals:

1 How likely is this doctor to act at all times in his or her patient's best interest?
2 How likely is this doctor to challenge authority, even when this might affect personal ambition, when patient care is being compromised?

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Competing interests: None declared.

1 Klein R. Safeguarding NHS standards. *BMJ* 2009;338:b1958. (13 May.)

Cite this as: *BMJ* 2009;338:b2329

Staff satisfaction surveys

The anonymised annual staff satisfaction survey that each trust carries out is the means of safeguarding NHS standards.[1]

Firstly, well trained frontline staff know whether the standard of patient care in their trust is good.

Secondly, the general dissatisfaction of NHS

staff is because they are not able to do their job as well as they know they ought to. This feeling should be revealed by the answers to three questions in the survey:

1 I am able to do my job to a standard I am personally pleased with
2 Care of patients is my trust's top priority
3 I am able to deliver the patient care I aspire to.

The data required to support or refute the usefulness of these questions in assessing standards in each trust are available to the Department of Health by relating them to each trust's outcomes. For too long insufficient notice has been taken of the people looking after patients.

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1 Klein R. Safeguarding NHS standards. *BMJ* 2009;338:b1958. (13 May.)

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NICE ON OSTEOPOROSIS

Women over 75 with fragility fractures should have DEXA

The recent NICE guidance on osteoporosis has generated much controversy and the publication of "alternative" guidelines.[1] An aspect which has escaped attention is the advice that bone density scanning by dual energy x ray absorptiometry (DEXA) may not be required in women aged ≥75 who have had a fragility fracture. This has been incorporated into the osteoporosis direct enhanced service agreement for general practitioners, which advises that these patients should be offered preventive treatment with bone sparing drugs without further investigation.

This advice is presumably based on the assumption that most women aged ≥75 with fragility fractures have osteoporosis. We reviewed the results of DEXA in women aged ≥75 with fragility fractures who were evaluated by the Lothian and Glasgow fracture liaison services in 2007. The table shows that only half of them had osteoporosis.

To suggest that all women aged ≥75 with fragility fractures should be given drug treatment is not supported by our evidence. Osteoporosis treatments in common use have all been evaluated in patients in whom the diagnosis was established by DEXA, and the most commonly used treatment—alendronate—does not prevent fractures in patients with osteopenia.[2]

Prevalence of osteoporosis, osteopenia, and normal bone mineral density by service. Values are numbers (percentages)

Service	Osteoporosis*	Osteopenia†	Normal‡
Lothian (n=367)	145 (39.5)	138 (37.6)	84 (22.8)
Glasgow (n=677)	376 (55.5)	252 (37.2)	49 (7.2)
Total (n=1044)	525 (49.9)	390 (37.3)	133 (12.7)

*T score <−2.5 at either spine or hip. †T score between −1.0 and −2.5. ‡T score >−1.0.

A basic principle of good medical care is to give treatment only when the benefit outweighs the risk. If general practitioners adhere to the direct enhanced service agreement, around half of elderly women will be prescribed drugs which in many cases will cause harm[3 4] and for which evidence of efficacy against fracture is lacking. DEXA should be performed in these patients to identify who will benefit from treatment.

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Competing interests: SHR acts as a consultant for Proctor and Gamble, Merck, and Novartis; SJG has received lecture fees for Eli Lilly; ARMcL has received lecture fees for Proctor and Gamble.

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Cite this as: *BMJ* 2009;338:b2340

HOMOEOPATHIC PRODUCT LICENCE

Back to square one

It is tragic that we now have a respected body, the Medicines and Healthcare products Regulatory Agency (MHRA), granting a licence for a product for which there is not only no evidence of efficacy but good evidence against any efficacy.[1] I have some sympathy with the MHRA in the face of a European Directive which has to be obeyed but which is almost totally irrational. However, I think that because "efficacy" appears in the directive and there is evidence against efficacy, it could have resisted granting a licence.

This fiasco takes us back to the days before drug regulation was introduced, partly to prevent the hazards of snake oil-type remedies. While this product may have no benefit, it probably has no direct harm either. But it may have major indirect harms—not only in individual patients who may not benefit from other effective remedies but also in a general sense by undermining the rational basis for medicine.

NATIONAL LIBRARY OF MEDICINE/SPL

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Competing interests: SJE is a former employee of the UK Medicines Control Agency (now MHRA) and a member of the Pharmacovigilance Working Party of the CHMP at the European Medicines Agency.

1 Cohen D. Drugs agency grants its first licence to homoeopathic product. *BMJ* 2009;338:b2055. (20 May.)

Cite this as: *BMJ* 2009;338:b2332

MHRA label seems to be illegal

The strap line for the Medicines and Healthcare products Regulatory Agency (MHRA) is "We enhance and safeguard the health of the public by ensuring that medicines and medical devices work and are acceptably safe."

Yet the MHRA has made mockery of its own aims by ignoring the bit about "ensuring that medicines work" and allowing Arnica 30C pills to be labelled: "a homoeopathic medicinal product used within the homoeopathic tradition for the symptomatic relief of sprains, muscular aches, and bruising or swelling after contusions."[1]

This label should be illegal anyway because the pills contain no trace of the ingredient on the label, but this deceit has been allowed through a legal loophole for a long time now. If you sold strawberry jam that contained not a trace of strawberry you'd be in trouble.

But I can see no legal loophole that allows the manufacturers of Arnica 30C to evade the provisions of the Consumer Protection from Unfair Trading Regulations 2008. One of the 31 commercial practices which are in all circumstances considered unfair is "falsely claiming that a product is able to cure illnesses, dysfunction, or malformations."

The consumer protection laws apply to the way that "the average consumer" will interpret the label. The average consumer is unlikely to know that "used within the homoeopathic tradition" is a form of weasel words that

actually means "there isn't a jot of evidence that the medicine works."

Since there is not the slightest evidence that Arnica 30C pills provide symptomatic relief of sprains, etc, the labelling that the MHRA has approved seems to be illegal. The MHRA is not selling anything itself, so I presume that it won't find itself in court, but anyone who follows its advice could well do so.

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Competing interests: None declared.

1 Cohen D. Drugs agency grants its first licence to homoeopathic product. *BMJ* 2009;338:b2055. (20 May.)

Cite this as: *BMJ* 2009;338:b2333

Being useless may be useful

Giving homoeopathy credit for any kind of demonstrable efficacy is ludicrous, and we all know it.[1]

However, a good placebo is an incredibly useful (and powerful) therapeutic tool, which should only be used with caution.[2] In this context, and when there is a need to give something more to a patient than just good words, a truly inactive placebo, with little risk of harm, might actually be useful, if only to avoid giving more dangerous but still useless drugs.

The first indication the NHS should consider for homoeopathy is the common cold followed by acute sinusitis (if it doesn't get better within a week, then use antibiotics), insomnia (as effective as benzodiazepines after two weeks, and much less addictive), and any number of uselessly overtreated illnesses. It should be offered in a choice of colours appropriate to the indication,[3] the content being irrelevant, with clear indications that this will not alter the course of the disease. But the patient will feel better, which is one of the aims of medicine's art, if not its science.

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Competing interests: NM is a trained pharmacologist, and rejects vehemently the use of homoeopathy and pharmacology in the same sentence.

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Cite this as: *BMJ* 2009;338:b2334

SCREENING AT YOUR PARISH CHURCH

Is "efficient" and "painless" screening worth the candle?

My elderly relative recently received an invitation on a letterhead entitled "Life Line Screening: the Power of Prevention" for the same package of tests referred to by Warlow.[1] She had been made extremely anxious by the letter and thought she would go along "just to be on the safe side." The letter had a postscript: "Your friends and family are welcome to have these tests even if they haven't received a letter. Please tell a friend or a loved one—you may just save a life."

Eighteen months ago a patient of mine was invited for "thermographic breast screening" at her private gym. Having recently lost a relative to breast cancer, she turned up and paid £75. She had a heat sensitive probe passed across her torso and received a report two weeks later, reassuring her that all was normal but advising her to re-attend annually for the same test. She told me: "I think I've been had," and gave me consent to use her anonymised details to pursue the perpetrators of the scam.

Thermography is an unreliable screening test for breast cancer because of the high proportion of false negative results. My patient had been "screened" by a registered general nurse who had promised her that her thermographic scans would be reported by "qualified doctors." The doctors in question were based in the United States. I telephoned the Healthcare Commission and was told that because the doctors were not UK based, it had no powers of governance over the organisation.

It advised me to report the nurse (who was also the company's managing director) to the Nursing and Midwifery Council, which I did. By the time my complaint was heard she had already been struck off the nursing register for an unrelated offence (theft of prescription drugs).

Like the thermographic screening test, the Life Line stroke screening package is presented as "fast," "painless," and "non-invasive." The results of the tests, the letter promises, will be assessed by a "fully accredited consultant." However, the only medically qualified person mentioned on the organisation's website is based in the US. When I phoned the Life Line help line I was assured that my results would be looked at by British consultants but the adviser was unable to tell me who they were.

Life Line Screening's website also contains a number of testimonials thanking the company for detecting conditions that are now being followed up by the person's general practitioner. One who tested negative added: "I should also like to say that the whole screening process was a very pleasant experience, carried out quietly and efficiently and with understanding and with no extra waiting about. I think the whole thing is an excellent idea and would like to thank all concerned."

What the testimonials miss, and what the propaganda fails to acknowledge, is that screening tests worth having are often slow, undignified, painful, messy, and inconvenient. Conversely, a package that avoids intimate orifices, body fluids, exposure to radiation, and other hassles may be little better at confirming or excluding life threatening conditions than spitting in the wind.

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Competing interests: None declared.

1 Warlow C. The new religion: screening at your parish church. *BMJ* 2009;338:b1940. (20 May.)

Cite this as: *BMJ* 2009;338:b2336

HOSPICES AND CPR GUIDELINES

Sudden and unexpected death in a palliative care unit

The mode of death in specialist palliative care units or hospices could inform discussions on cardiopulmonary resuscitation (CPR).[1 2] We recently analysed 100 consecutive deaths in our 20 bed unit.

All patients had cancer, and the deaths represented half of the 197 admissions over 24 weeks. Mode of death was categorised pragmatically at weekly multidisciplinary team meetings as gradual and expected (an expected death preceded by a gradual (several days-weeks) terminal decline); sudden but expected (an expected death preceded by a rapid (1-2 days) decline); or sudden and unexpected (an unexpected death with little or no warning).

Sudden and unexpected deaths were considered most likely to require an instant decision on whether to start or withhold CPR. The use of the care of the dying pathway was noted as an additional indicator of an expected death.

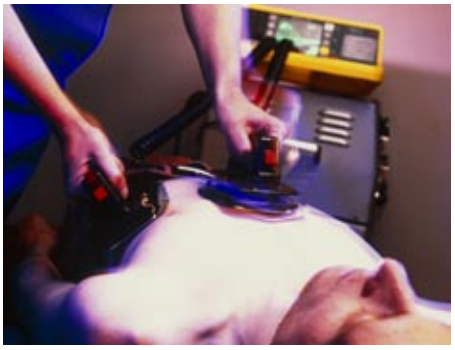
In all, 84 deaths were gradual and expected with all but one patient on the care of the dying pathway; 11 deaths were sudden but expected with none of the patients on the pathway; and five deaths were sudden and unexpected, with none on the pathway.

The sudden and unexpected death in case 1 (table) was immediately preceded by chest pain and shortness of breath, raising the possibility of a pulmonary embolism or cardiac event; the remainder were found dead in bed. None had any history of heart disease. All had a documented decision not to attempt CPR as it was unlikely to be successful on the basis

Details of the five sudden and unexpected deaths

Case No	Performance status		Length of stay (days)
	ECOG	Karnofsky (%)	
1	2	70	19
2	3	60	3
3	3	50	22
4	3	30	2
5	3	30	13

ECOG=Eastern Cooperative Oncology Group.



MICHAEL DONNE/SPL

of individual assessments of the presence of advanced incurable cancer with or without poor performance status (table).

Sudden and unexpected death was not uncommon. Our data suggest that even in palliative care a definite decision could save instant decisions having to be made, reduce the risk of inappropriate attempts at CPR, and ensure CPR is not withheld when it is appropriate.

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Competing interests: None declared.

1 Regnard C, Randall F. Should hospices be exempt from following national cardiopulmonary resuscitation guidelines? No. *BMJ* 2009;338:b986. (26 March.)
2 Watson M, McPherson A, Murray SA. Should hospices be exempt from following national cardiopulmonary resuscitation guidelines? Yes. *BMJ* 2009;338:b965. (26 March.)

Cite this as: *BMJ* 2009;338:b2343

One successful resuscitation every 4400 years

National guidelines already contain sensible advice on decision making about cardiopulmonary resuscitation (CPR) in very ill patients.[1] Currently, a fifth of this hospice's inpatients are potentially for CPR. This, I hope, is a valid surrogate marker of non-discriminatory attitudes in our organisation. However, after 5800 patients and 18 years of care, we are yet to encounter our first patient requiring CPR.

Less than one out of hospital cardiac arrest is likely every two years in a setting where 250 adults over the age of 50 spend 16 hours a day.[2] Increasing this statistic fivefold and applying it to our day hospice, which offers 48 six hour places a week, we might expect one cardiac arrest every 22 years. An optimistic immediate success rate of CPR of 5%, of whom 10% survive to return home, gives us one long term survivor per 200 CPR attempts. We might witness such success once every 4400 years if legitimate "not for resuscitation" decisions did not add thousands more years to that figure.

Such calculations do not weaken patient rights, but they do help to put the debate into perspective.

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Competing interests: None declared.

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Cite this as: *BMJ* 2009;338:b2344

ASSESSING CARDIOVASCULAR RISK

Correction and transparency of BNF risk charts

The Joint British Societies' (JBS) charts use a "traffic lights" system to emphasise different categories of cardiovascular risk.[1] They were published in 2005 in conjunction with the societies' guidelines[2] and are reproduced biannually in the *BNF*.

We recently observed that the green (<10% risk) area was missing from the charts for non-diabetic male non-smokers aged 50-59, and to a minor degree in the charts for similarly aged non-diabetic male smokers, and older non-diabetic male non-smokers. The charts were inaccurately reproduced in this form for over three years. We estimate that 16% of the 2.5 million non-smoking men aged 50-59 in the UK would be wrongly categorised into the higher (10-20%) risk category.[3] Patients may have been caused unnecessary concern, and lifestyle advice may have differed for low and moderate risk patients. Also, lower (10%) drug treatment thresholds are a future possibility, given the increasing evidence for treating lower risk populations.

The *BNF* published revised charts in March 2009. Although this change was mentioned briefly on the British Hypertension Society website, it should have been publicised more widely, given the charts' extensive use. That this error persisted for so long probably reflects the lack of transparency surrounding the methods used to calculate risk in the original publication.[2] The lack of a widely available risk calculator also hampers cross checking of the calculation. A computer calculator can be individualised for patients while still providing a useful graphical representation of risk.[4]

The JBS charts remain a valuable tool, but we hope that the publication of the further revisions currently being proposed by the BHS will be more open.

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Competing interests: RAP is author of a website which produces patient specific risk calculations including charts similar to those of the Joint British Societies.

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Cite this as: *BMJ* 2009;338:b2330

SAMPLE SIZE CALCULATIONS

Must do better

As a reviewer in several study sections at the US National Institutes of Health, I have noted that it is impossible to replicate sample size and power calculations in the overwhelming number of otherwise excellent research proposals.[1] I then noted that replication is very difficult in journal articles.

The sources of sample size calculations, with reference to a specific program or algorithm or to equations and method of calculation, are almost absent from the literature. Rather, the norm can be summarised: "The study has 80% power to detect a 10% difference with an alpha of 0.05." Rarely do authors or proposal applicants specify "using the method of Smith and Jones" or "using the sample size calculator available at . . ." and then cite a URL or statistical package. Thus, reviewers cannot ascertain the method used, and the sample size specifications remain only assertions.

Researchers must refer to a specific method, statistical module, or equation. Otherwise, readers are essentially being asked to "suspend disbelief" and assume that the authors have done the calculations correctly, and in the only way feasible. The assumption can be dangerous, and while suspension of disbelief is a wonderful tool for reading novels, it is completely inappropriate in science. We need to do better.

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Competing interests: None declared.

1 Charles P, Giraudeau B, Dechartres A, Baron G, Ravaud P. Reporting of sample size calculation in randomised controlled trials: review. *BMJ* 2009;338:b1732. (12 May.)

Cite this as: *BMJ* 2009;338:b2323