**THE PRICE OF SILENCE**

18 Liverpool consultants reply

We have every confidence in the clinical safety of our services. There is no evidence in the trust’s adverse clinical event reporting system to support allegations made in the article by Gornall about poor clinical practices allegedly witnessed by Peter Bousfield. Mr Bousfield would have had a duty to report through this system in the course of his practice, had he harboured concerns of this kind, but no such reports exist. They would have then been dealt with as a matter of priority, depending on their nature, through the trust’s clinical governance processes, and the consultant body is confident that the organisation would have responded accordingly. In addition, we understand that the compromise agreement entered into by Mr Bousfield and the trust explicitly gave him the right to raise any issues about patient safety with the relevant regulatory bodies.

The consultant body is satisfied that individuals or clinical teams are able and encouraged to raise any issue of concern without the fear of reprisals or “gagging” by the executives or the board of directors. The trust has excellent relationships between consultants and managers.

The trust can demonstrate its compliance with the stringent standards set by our various regulators for all NHS organisations, which are accessible in the public domain. Liverpool Women’s Hospital has a strong track record in patient safety and clinical risk management. The trust is one of a small number of NHS organisations nationally to have achieved and sustained, since February 2005, the highest possible rating (CNST level 3) for general and maternity standards by the NHS Litigation Authority.

Finally, as a group of consultants, we find the editorial comment by Delamothe that accompanies this often factually inaccurate article, offensive, irresponsible, and completely unacceptable.

Elizabeth Adams consultant gynaecologist
Iwan Lewis-Jones consultant clinical andrologist

Author’s reply

The response from 18 consultants at Liverpool Women’s NHS Foundation Trust is understandable but beside the point: the article was not an attack on clinical standards but an account of the trust’s reaction to concerns raised by one of their former colleagues. Whatever the merits of those concerns, the real question is why the trust went to such remarkable lengths to silence a senior consultant.

Furthermore, it is disingenuous of the 18 to imply that, because there was “no evidence in the trust’s adverse clinical event reporting system” to support the allegations, Mr Bousfield’s concerns were non-existent. They were clearly documented in correspondence between him and senior management.

They also state that the trust and consultants have “excellent relationships,” but evidently this was not true in Mr Bousfield’s case. Are they suggesting his voice should be ignored simply because, like most whistleblowers, he was in a minority?

In his response to Delamothe’s editor’s choice, Dudley suggests that gagging clauses “do not fly in the face of Department of Health guidelines.” In fact, Alan Milburn’s letter of 1997, sent to coincide with the Public Information Disclosure Act, contained what remains the key text: “confidentiality (‘gagging’) clauses on NHS employment contracts contravene NHS Executive policy. I believe that such clauses discriminate against staff’s rights and responsibilities to bring unacceptable practices into the open and that there is no place for them in the NHS.”

A policy pack produced in July 2003 reiterated guidance in HSC 1999/198: trusts should have a gagging policy and “prohibit confidentiality ‘gagging’ clauses in contracts of employment, and compromise agreements which seek to prevent the disclosure of information in the public interest.”

If the NHS is serious about transparency, should it not be a matter of concern that while some trusts—Mid Cheshire, for example—have enshrined this commitment in their policies, others, including Liverpool Women’s, have not?

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Competing interests: None declared.

1 Dudley N. Rapid response. Gagging clauses do not fly in the face of Department of Health guidance. www.bmj.com/cgi/eletters/339/oct29_2/b4444#223975
2 Delamothe T. Gagging for it. BMJ 2009;339:b4444. (29 October.)
7 Liverpool Women’s NHS Foundation Trust. Raising concerns policy and procedure. [Emailed at author’s request by trust, 26 June 2009.]

More information needed

The account of Mr Bousfield’s departure from Liverpool Women’s NHS Foundation Trust raises matters of the utmost seriousness. The reply by consultants from the trust disputes certain elements of the story but, crucially,
Response to the Liverpool trust

I thank Jonathan Gornall for his sensitive and accurate article,1 much of which was based on correspondence between senior staff at the Liverpool Women’s Hospital NHS Foundation Trust and me. This had become available after a public Bar Standards Board hearing relating to my son, Andrew Bousfield. Most of my concerns and the correspondence related to practices at the Aintree Unit, which was managed by the Liverpool Women’s Hospital Trust. I note with interest that at the relevant time most of the signatories of the response from the trust (first letter) would have had no significant knowledge of the day to day running of the unit at Aintree. In my opinion, the issues were too acute and important to be consigned to the comparative obscurity of an effete internal body concerned with clinical incident investigation. I doubt if the 11 other doctors gagged and discarded by this trust would wish to share the attempted portrayal of a unified happy unit.

I also thank Professor McKee for succinctly identifying the crux of this issue (previous letter). The correspondence, including the letter threatening an injunction, is available to legitimate parties from my son at andrew@tcij.org.

Peter Bousfield

Competing interests: None declared.


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Clarification on gagging clauses

Cassidy’s feature article is very concerning.2 I want to make clear that any doctor who wants to report genuine concerns will have nothing to fear from the General Medical Council. The GMC emphasises the responsibility of doctors to report their concerns, and this is echoed throughout our guidance. In particular Good Medical Practice (2006) states both that doctors should raise concerns about inadequate resources and that they must protect patients from risk of harm posed by a colleague’s conduct, performance, or health. Raising Concerns (2006) makes clear that provided that doctors have been honest, raising a concern is justified even if it turns out to be groundless.

The feature article alleges that some trusts are using gagging clauses to prevent doctors from speaking out.1 The Public Interest Disclosure Act 1998 prohibits the NHS from inserting “gagging” clauses into employment contracts for doctors. Doctors should not enter into agreements or sign contracts which prevent them from fulfilling their professional obligations or complying with our guidance. Any manager who is registered with us and who is complicit in implementing a gagging clause could be subject to our fitness to practise procedures and would therefore be placing his or her registration at risk.

The GMC’s guidance Management for Doctors (2006) makes clear that doctors in a management role must make sure that adequate systems are in place for complaints to be thoroughly investigated and that those who raise concerns are protected from unwarranted criticism or actions. Agreements or contracts that impede doctors raising genuine concerns with us about the conduct or competence of another doctor represent a significant risk to patient safety and would be of obvious concern to the GMC.

Peter Rubin chair, General Medical Council, London NW1 3NJ press@gmc-uk.org

Competing interests: None declared.

1 Cassidy J. Falling foul of gagging clauses. BMJ 2009;339:b4203. (27 October.)

Cite this as: BMJ 2009;339:b4991

Clarification of a clarification

The General Medical Council has no power tovary employment contracts. Employers are not registered with the GMC unlike the other party to the contract, the lucky doctors, so it is unclear how the GMC would control the issue, or in which forum or court. I cannot see what the cause of action would be.

I am even unsure that a termination agreement is an employment contract, as no employment results from it. The GMC is a “disapproval organisation.” You can read into the chair’s letter (above) how he itches to get hold of any doctors involved in gagging clauses and say, “Oh very bad doctors, strike them all off!” whereas the employers get off scot free to do it all over again with another willing party.

This episode serves much better to show that there is an inbuilt conflict between employers and the GMC, which may have different aims and world views. And it will get worse when the great money waster Revalidation takes hold as it is the GMC who directs and the employers who will pay for the Great Paper Run Around.

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Competing interests: GS is not registered with or licensed by the GMC or in any way get-at-able, so is able to speak out on this issue.

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SEASONAL VACCINE AND H1N1

Selection bias explains seasonal vaccine’s protection

Vaccine efficacy is estimated to be around 80% for trivalent inactivated flu vaccine during seasons when the components closely match circulating strains.1 The surface HA/NA proteins included in the 2008-9 vaccine are antigenically very distant from those of the 2009 pandemic A/H1N1 (pH1N1) virus. Few adults given the 2008-9 vaccine developed neutralising antibody against pH1N1,2 but Garcia-Garcia and colleagues report 73% (95% confidence interval 34% to 89%) cross-protection against pH1N1 with it.3 This finding probably stems from a selection bias associated with their second paradoxical finding: participants with chronic conditions were at 80% (55% to 91%) reduced risk of hospitalisation for pH1N1, a result that contradicts known risk factors for severe flu outcomes generally and for pH1N1 specifically.4 In their study, cases and controls emerged from different source populations. Cases more often presented directly requiring hospitalisation (98% v 34%). Controls were more often seen after specialty referral. Hospitalised cases reflect immunisation rates in the community whereas controls reflect referrals with greater healthcare contact and immunisation opportunities—an indication of selection bias. The authors report significantly more controls (65%) than cases (25%) with comorbidity. The proportion of young adult controls with chronic conditions (57%) was 10-fold higher than population estimates of around 5% for Mexico City.5 People with...
comorbidity are a priori more likely to receive seasonal vaccine under the high risk immunisation programme administered in Mexico. Therefore, with a higher rate of chronic conditions, the proportion of controls who were immunised (29%) was also high—about twice that based on seasonal vaccine doses distributed per capita in Mexico (9%).

Selection bias driving higher rates of chronic conditions among controls explains why both underlying comorbidity and previous immunisation with seasonal vaccine were associated with paradoxical protection against pH1N1. Cases more often than controls were artificially ventilated (43% v 2%) and died (30% v 1%). Thus ascertainment of immunisation status for cases compared with controls probably relied more on proxies with imperfect recall of vaccine status, leading to further exaggeration of vaccine benefit.

Finally, the risk of pH1N1 varies by age, an important confounder. The authors matched frequency for broad age categories but used conditional logistic regression—the wrong analytical approach for a frequency (v paired) matching design. Ultimately, however, no analytical technique can overcome selection bias. From the clear evidence in the data presented, we conclude that this study’s findings are best explained by selection bias exacerbated by a combination of recall bias and inadequate adjustment for confounding.

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Authors’ reply

Skowronski and colleagues question the effectiveness of seasonal vaccine against pandemic A/H1N1 flu observed in our study. The confidence intervals are wide and similar to those described when seasonal flu vaccine strains are not antigenically well matched to circulating endemic strains (27% to 65%).

Evidence of the effectiveness of seasonal vaccines against pandemic strains indicates some degree of protection against antigenically differing flu strains. Therefore the effectiveness we observed in our study is likely to be real.

We do not agree that cases and controls emerged from different source populations. Both cases and controls came from the population that is served by the study hospital and resides in the geographical area that had most of the flu cases during the study. Although the hospital is a specialist hospital, a considerable proportion of its patient population (both cases and controls) is not referred as the referral system is poor. Differences between cases and controls in underlying chronic diseases are explained by the characteristics of the patient population requesting care at the study hospital that includes both patients with acute (many of which occur among previously healthy individuals) and chronic respiratory diseases.

Data on vaccine coverage are limited nationwide. National estimates are available only for some age groups. Therefore we do not agree with comparing our observed prevalence of seasonal vaccination among flu cases in a specialty hospital in Mexico City with Skowronski and colleagues’ estimation of national coverage.

We agree that one of the limitations of the study was investigating seasonal vaccination by face to face or telephone interview of patients or close relatives. Trained staff used a standardised format to reduce the bias associated with vaccine status. We differentiated whether the interviewed person was informed or not about vaccine status.

We reanalysed our results by unconditional logistic regression including the matching variables in the model. Adjusted odds ratio and estimation of effectiveness did not differ from those published.

Although our study provides preliminary evidence of a protective effect of seasonal vaccination against the A/H1N1 flu virus, it is limited because of its small sample size and retrospective design. Therefore, similar studies in other settings are needed to confirm or refute our results.

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Competing interests: LV-G is employed by Laboratorios de Biológicos y Reactivos de México (BIRMEX).


We are concerned that this review may be used as evidence that emergency doctors who have completed a sedation course (unspecified) may safely use ketamine (or propofol or midazolam with intravenous narcotics) on unfasted children to manipulate fractures or suture facial lacerations. Recognising sick children and potentially difficult airways requires experience. Paediatric exposure is usually limited even for emergency doctors who have received anaesthetic training, and maintenance of practical skills such as airway manipulation is an accepted problem. Ketamine and propofol have no specific antidotes, unlike benzodiazepines and narcotics.

All anaesthetists know that the international guidelines for fasting (six hours for food, four hours for breast milk, and two hours for clear fluids) may not guarantee an empty stomach, especially in children with trauma who have delayed gastric emptying. However, the suggestion that fasting is unnecessary on the basis of a 10 year old study of 257 procedures during which no child suffered aspiration pneumonia is brave.

Despite the frustration of requiring a six hour fast (and possibly breaching four hour stays in the emergency department), general anaesthesia with a protected airway given by a specialist remains the safest option for many children.

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Competing interests: None declared.

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Utility of intranasal midazolam

In their clinical review of pain management and sedation for children in the emergency department, Atkinson and colleagues do not mention intranasal midazolam. It is associated with adequate analgesia in emergency settings, and given through a mucosal atomisation device provides faster sedation than the buccal route, which also has the risk of the drug being swallowed or spat out.

Also, in emergency settings the standard dose of midazolam is usually higher than 0.2 mg/kg—for example, 0.4-0.8 mg/kg for intranasal administration. We also disagree with the maximum dose of 5 mg up to 10 years of age reported in table 2. A 10 year old child can weigh more than 30 kg, so a dose tailored to weight seems to be more appropriate.

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We could do better

Atkinson and colleagues correctly state that paracetamol 30 mg/kg is a safe and effective initial dose, but paediatricians and pharmacists consider a loading dose of 20 mg/kg to be excessive and criticise emergency medicine specialists for using the higher dose. Our pharmacy, for example, is currently trying to ban the 20 mg/kg dose used in nurse triage. These misconceptions add to the reprehensible oligoanalgesia rife in acute pain in emergency settings.

The authors do not specify that morphine 100 µg/kg is a target for intravenous titration and not a fixed dose every three or four hours. A fixed dose of intravenous morphine would cause either inadequate analgesia or oversedation. The dose titrated to response may be above or below this target.

They do not mention that intramuscular ketamine 4 mg/kg is a good alternative to intravenous ketamine for procedural sedation. At that dose, sedation is consistent and lasts long enough for most procedures but may cause more vomiting. The College of Emergency Medicine’s recent guideline on paediatric sedation recommends an intramuscular dose of 2 mg/kg, which is likely to provide inconsistent sedation and require a top-up second dose.

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Competing interests: None declared.

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Call to action: catch The Wave

International environmental health activists have called for public health to take a central role in the UN climate change talks. However, despite increasingly dire warnings of the economic and health catastrophes that unabated climate change will cause, most health professionals and lay people have not been stirred into the necessary collective action. Giddens suggests that environmental doomsday messages leave us feeling powerless and overwhelmed. Yet health professionals must highlight the health benefits of tackling climate change:

• Reducing car use will reduce carbon dioxide emissions and road traffic accidents, as well as respiratory and cardiovascular disease through reduced air pollution and increased exercise

• Reducing meat over-consumption will reduce energy use from food production and probably the risk of cardiovascular disease and certain cancers.

As health professionals we must quickly come to terms with the urgency of the situation. We need an active, multidisciplinary health movement advocating the reduction of carbon dioxide emissions using positive, “win-win” messages that strike a chord with policy makers and the public.

To this end, we urge all health professionals to come to The Wave: a civil society demonstration in support of action on climate change in London on 5 December 2009. A coalition of health organisations will meet in central London before joining the main march to parliament to demand a healthier, low carbon society for ourselves and future generations. We must act now: our health depends on it.

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Tony Waterston, Medact
Frances Mortimer. Campaign for Greener Healthcare
Robin Stott. Climate and Health Council
Jonny Currie. Medsin-UK

Competing interests: The authors are members of the organisations taking part in The Wave.
1 Jara M. Activists call for public health to take central role in UN climate change talks. BMJ 2009;339:b4611. (9 November.)
5 Campaign for Greener Healthcare. Health professionals catch The Wave. www.greenerhealthcare.org/health-wave

Cite this as: BMJ 2009;339:b4962