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LETTERS

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UNCOMPLEMENTARY DEBATE

What parliamentary witnesses also said about homoeopathy

Adrian O’Dowd’s two articles about the Science and Technology Committee’s evidence check on homoeopathy failed to mention several key responses made by witnesses at the parliamentary hearings¹⁻³—for example:

- There are 24 condition based systematic reviews of randomised controlled trials (RCTs) of homoeopathy, of which nine are positive, five negative, and 10 inconclusive (question 112 in transcript).
- Of 87 placebo controlled RCTs (efficacy trials) in peer reviewed literature, 37 provide positive evidence for homoeopathy; the remainder are mostly non-conclusive (Q145).
- Not all homoeopathic medicines are diluted beyond the point where no molecules of original substance are left in solution (Q123).
- The minister for health services, Mike O’Brien, considered homoeopathy worth further clinical research (Q199), and he stated that government should not stop NHS funding for homoeopathy (Q245-246).
- On medical practitioners of homoeopathy, Mr O’Brien stated, “There is a significant lobby of clinicians who are quite capable of looking at data and who take the view that [homoeopathy] works . . . There is an illiberality in saying that personal choice in an area of significant medical controversy should be completely denied” (Q248).
- And on patient choice he said, “We should not take the view that patients should not be able to have homoeopathic medicine when they want it” (Q248).

It is important to reflect on these facts when forming a balanced judgment of contributions made at the committee hearings.

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Competing interests: None declared.

- 1 O’Dowd A. Government says public backs homoeopathy despite lack of evidence. *BMJ* 2009;339:b5234. (2 December.)
- 2 O’Dowd A. Giving homoeopathy on the NHS is unethical and unreliable, MPs are told. *BMJ* 2009;339:b5080. (27 November.)
- 3 Science and Technology Committee. Evidence check 2: homoeopathy. 30 Nov 2009. www.parliament.uk/parliamentary_committees/science_technology/s_t_homoeopathy_inquiry.cfm.

Cite this as: *BMJ* 2010;340:c592

Editorial ignores evidence

The *BMJ*’s coverage of homoeopathy is biased and systematically ignores the evidence. We are astonished that the *BMJ* commissioned David Colquhoun’s polemical rant as an editorial.¹ He attacks the minister, the Department of Health’s chief scientist, the chief executive of the Medicines and Healthcare Products Regulatory Agency, and others who do not share his opinions, insulting them by describing their considered replies at the recent Commons Science and Technology Committee hearings on homoeopathy as “pure comedy gold.”

A recording of the entire proceedings is available online to those who prefer to make up their own minds, but we don’t recommend it for a laugh.² Colquhoun’s glossary is no doubt intended to be humorous, but the definitions he gives of acupuncture, herbal medicine, and homoeopathy bear no relation to the true definitions and belie any pretence that this is a serious contribution.

Despite the subtitle calling for a look at efficacy there is not a word about evidence. All attempts to inject evidence into this debate have come from those who believe homoeopathy deserves proper investigation (previous letter).

The only independent and contemporary citation Colquhoun offers in support of his views is from the *Sun*. It would be lamentable if the *BMJ*’s level of discourse emulated that publication.

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Competing interests: Most signatories of this letter are health professionals who incorporate homoeopathy and other forms of complementary medicine into their practice.

- 1 Colquhoun D. Secret remedies: 100 years on. *BMJ* 2009;339:b5432. (15 December.)
- 2 Science and Technology Subcommittee. Evidence check: homoeopathy. Witnesses. 30 Nov 2009. www.parliamentlive.tv/Main/Player.aspx?meetingId=5257.

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Herbal medicine and acupuncture: protecting patients

David Colquhoun’s editorial makes unfounded assertions about the Department of Health steering group and its recommendations.¹ Given that a public consultation has only recently closed, his views should not be seen as representative.

He states, as before,² that decisions are needed on whether disciplines being considered for statutory regulation are “nonsense” or sufficiently grounded in science and evidence based practice to justify regulation. If acupuncture and herbal medicine are nonsense, he thinks that regulation may officially endorse treatments with no proper evidence base. Colquhoun wrongly asserts that the steering group and the Department of Health lost this important point. The report states clearly that NHS funding should be available to complementary medicine only if there is evidence of efficacy, safety, and quality assurance,³ and it reviewed how best to implement meaningful research.

Statutory regulation and the quest for evidence should proceed together, and in the interests of patient safety, the second point should not be an absolute prerequisite for the first.⁴ Many conventional treatments prove ineffective as research proceeds, but to protect patients, practitioners are regulated while they practise according to current evidence. Lastly, as many as 10.6% of adults in England have accessed the more established therapies, so regulation to protect the public is a priority.

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Competing interests: RMP was chair of the Department of Health steering group on the statutory regulation of acupuncture, herbal medicine, traditional Chinese medicine, and other traditional medicine systems practised in the UK. He has also served as a trustee of the Prince’s Foundation for Integrated Health.

- 1 Colquhoun D. Secret remedies: 100 years on. *BMJ* 2009;339:b5432. (15 December 2009.)
- 2 Colquhoun D. Complementary medicine. A very bad report on regulating complementary medicine. *BMJ* 2008;337:a591.
- 3 Department of Health Steering Group on the Statutory Regulation of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK. Report to ministers. 2008. <http://hdl.handle.net/10059/176>.
- 4 Pittilo RM. Complementary medicine. Regulating herbal medicine and acupuncture: Author's reply. *BMJ* 2008;337:a590.

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Protecting patients?

In his letter (previous page) Pittilo states that in conventional medicine, many treatments prove ineffective as research proceeds. True! Sorting out the wheat from the chaff is precisely what evidence based medicine aims to achieve. All statutory regulations of UK healthcare professions include an obligation to practise evidence based medicine. But the proposed regulation of herbal, traditional Chinese medicine, and acupuncture practitioners does not include such an obligation. Why? Making sure that NHS funding is available to complementary medicine only where evidence exists is not the same as obliging practitioners to practise evidence based medicine. The omission of such an obligation is nothing short of establishing double standards in health care, and double standards do not protect patients.

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Competing interests: None declared.

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Regulation means patient safety

I am glad that David Colquhoun was entertained by my appearance before the Health Select Committee on Homoeopathy.¹ But he is mistaken when he says, "you cannot start to think about a sensible form of regulation unless you first decide whether or not the thing you are trying to regulate is nonsense."

Regulation is about patient safety. Acupuncture, herbal medicine, and traditional Chinese medicine involve piercing the skin or the ingestion of potentially harmful substances and present a possible risk to patients. The Pittilo Report recommends statutory regulation and we have recently held a public consultation on whether this is a sensible way forward.

Further research into the efficacy of treatments such as homoeopathy is unlikely to settle the debate, such is the controversy

surrounding the subject. That is why the Department of Health's policy towards complementary and alternative medicines is neutral.

Whether I personally think homoeopathy is nonsense or not is beside the point. As a minister, I do not decide the correct treatment for patients. Doctors do that. I do not propose on this occasion to interfere in the doctor-patient relationship.

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Competing interests: None declared.

1 Colquhoun D. Secret remedies: 100 years on. *BMJ* 2009;339:b5432. (15 December 2009.)

Cite this as: *BMJ* 2010;340:c617

Lead, follow, or get out of the way

In the previous letter Mike O'Brien, minister of state for health services, made a statement that cannot be allowed to stand without exposing its fallacies and cynicism:

Further research into the efficacy of therapies such as homoeopathy is unlikely to settle the debate, such is the controversy surrounding the subject. That is why the Department of Health's policy towards complementary and alternative medicines is neutral.

As a Queen's counsel, can Mr O'Brien imagine a judge telling a jury: "Don't bother to assess the truth, accuracy, and validity of the evidence and arguments submitted by the prosecution and defence; just decide not to make a decision"?

Does he imagine that it is neither possible nor desirable to decide how best to spend the taxpayer's money on NHS patients? Or, is he looking to some lobby?

The Department of Health cannot take a neutral stance to funding complementary and alternative medicine. Either it funds it (ignoring the scientific evidence) or it takes account of critically appraised evidence.

Mr O'Brien's "neutral policy" amounts to a decision not to make a decision and to continue to waste taxpayers' money and patients' time and health. I would like to remind him of some remarks made by Thomas Paine:

It is error only, and not truth, that shrinks from inquiry.

Lead, follow, or get out of the way.

When men yield up the privilege of thinking, the last shadow of liberty quits the horizon.

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Competing interests: MP is a taxpayer and consumer of NHS services.

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Author's reply to the minister

I think the minister (fifth letter) is wrong in two ways, one relatively trivial but one very important. Firstly, he is wrong to refer to homoeopathy as controversial. It is not. It is quite the daftest of the common forms of magic medicine and essentially no informed person believes a word of it. Of course, as minister, he is free to ignore scientific advice. But he should admit that that is what he is doing, and not hide behind the (imagined) controversy.

Secondly, and far more importantly, he is wrong to say I was mistaken to claim that "you cannot start to think about a sensible form of regulation unless you first decide whether or not the thing you are trying to regulate is nonsense." If it were irrelevant that the subject you are trying to regulate was nonsense then why not have statutory regulation of voodoo and astrology? The Pittilo proposals would involve giving honours degrees in nonsense¹ if one took the minister's view that it doesn't matter whether the subjects are nonsense or not. Surely he isn't advocating that?

The minister is also wrong to suppose that regulation, in the form proposed by Pittilo, would do anything to help patient safety. Indeed, a good case can be made that it would endanger patients²: the main danger is patients being given "remedies" that don't work. The proposed regulatory body, the Health Professions Council (HPC), has already declared that it is not interested in whether the treatments work or not. That in itself endangers patients. In the case of traditional Chinese medicine, there is also a danger to patients from contaminated medicines. The HPC is not competent to deal with that either. It is the job of the Medicines and Healthcare products Regulatory Agency (MHRA) or the Trading Standards Institute, or both. There are much better methods of ensuring patient safety than those proposed by Pittilo.

To see the harm that can result from premature statutory regulation, it is necessary only to look at the General Chiropractic Council (GCC). Attention was focused on chiropractic when the British Chiropractic Association decided to sue Simon Singh for defamation. That led to close inspection of the strength of the evidence for its claims to benefit conditions such as infant colic and asthma. The evidence turned out to be pathetic.³ At the same time something like 600 complaints were made to the GCC (including two by me against practices run by the chair of the GCC himself, complaints which are being defended).

The processing of these complaints continues, but what is absolutely clear is that the statutory regulatory body, the GCC, fell foul of the

Advertising Standards Authority and the Trading Standards Institute for making false claims itself. There is no doubt that the HPC would be similarly engulfed in complaints if the Pittilo proposals went ahead.

It is one thing to say that the government chooses to pay for things like homoeopathy, despite it being known that they are only placebos, because some patients like them. It is quite another thing to endanger patient safety by advocating government endorsement, in the form of statutory regulation, of treatments that don't work.

I would be very happy to meet the minister to discuss the problems involved in ensuring patient safety. He has seen herbalists and others with vested interests. He has been lobbied by the Prince of Wales.⁴ Perhaps it is time he listened to the views of scientists too.

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Detailed critiques of the points made by Fisher and colleagues and Pittilo are available on www.bmj.com/cgi/eletters/339/dec15_1/b5432#228877.

Competing interests: None declared.

- 1 Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and other Traditional Medicine Systems Practised in the UK. 2009. www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_086358.pdf.
- 2 McLachlan JC. Response to the Consultation on the Report to Ministers from the DH Steering Group on the Statutory Regulation of Practitioners of Acupuncture, Herbal Medicine, Traditional Chinese Medicine and Other Traditional Medicine Systems Practised in the UK. Available at: www.dcsience.net/Pittilo-consultation-JMc.pdf.
- 3 Ernst E. Chiropractic for paediatric conditions: substantial evidence? *BMJ* 2009;339:b2766. (9 July.)
- 4 Walker T. Prince Charles lobbies Andy Burnham on complementary medicine for NHS. *Telegraph* 31 Oct 2009. www.telegraph.co.uk/news/newstoppers/mandrake/6474595/Prince-Charles-lobbies-Andy-Burnham-on-complementary-medicine-for-NHS.html

Cite this as: *BMJ* 2010;340:c640

ENGLISH MORTALITY FROM A/H1N1

Comparisons with recent flu mortality

How do the number of deaths from pandemic A/H1N1 compare with influenza related mortality in recent years?^{1,2}

The official estimate of influenza mortality is produced by the Health Protection Agency (HPA). It is derived from excess (above "expected" level) all cause death registrations in the winter. The estimates for the past five years in England and Wales are: 1965 (2004-5 winter season), 0 (2005-6), 0 (2006-7), 426 (2007-8), and 10 351 (2008-9). The highest estimate in recent years (21 497) was for the 1999-2000 flu season. This method has its limitations. It does not examine causation directly, so excess deaths may have causes

other than flu. If the number of deaths is small, the estimate may be zero.

The HPA is currently reporting excess deaths weekly. At 17 December 2009, no excess deaths had been seen since February 2009. Had we relied solely on this measure, we would not have been aware of any deaths due to A/H1N1 influenza so far. Our study has value in filling this gap.

A second estimate of flu deaths is found in the annual mortality statistics produced by the Office for National Statistics. These statistics record the underlying cause of death. The number of deaths for England and Wales with an underlying cause of influenza for the four recent calendar years are: 39 (2008), 31 (2007), 17 (2006), and 44 (2005). Many more deaths are attributed to pneumonia, some of which will be secondary to influenza.

Our study includes any death with pandemic flu (or synonym) mentioned anywhere on the death certificate and any death with a laboratory positive swab for pandemic flu, irrespective of the reported cause of death. Our method has also rapidly captured information on underlying illness patterns. While absolute numbers of deaths may not be out of the ordinary, a relatively large number have occurred in children and young adults.

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Competing interests: Full details are available in the original article.² www.bmj.com/cgi/content/full/339/dec10_1/b5213.

- 1 Delamothe T. Deaths attributed to influenza in previous years. [electronic response to Donaldson LJ, et al. Mortality from pandemic A/H1N1 2009 influenza in England: public health surveillance study]. *BMJ* 2009. www.bmj.com/cgi/eletters/339/dec10_1/b5213#227728.
- 2 Donaldson LJ, Rutter PD, Ellis BM, Greaves FEC, Mytton OT, Pebody RG, et al. Mortality from pandemic A/H1N1 2009 influenza in England: public health surveillance study. *BMJ* 2009;339:b5213. (10 December.)

Cite this as: *BMJ* 2010;340:c612

Discrepancies in published data

A BBC report with which Sir Liam Donaldson¹ was associated in September 2007 stated: "According to Department of Health figures, flu contributes to over 25 000 excess winter deaths every year and thousands of people are hospitalised due to serious complications."²

In 2006 I downloaded from the Department of Health website other statements about flu mortality that were not only mutually contradictory but also out of line with the present disclosure¹ or, indeed, the BBC report.³ Another of Sir Donaldson's publications stated, "Ordinary

flu occurs every year during the winter months in the UK. It affects 10-15% of the UK population, causing around 12 000 deaths every year."⁴ An information page reported, "Even during a winter where the incidence of flu is low, 3000-4000 deaths may be attributed to flu; this can rise much higher in epidemic years, for example there were an estimated 13 000 deaths in 1993 which were attributable to flu and 29 000 in 1989/90."⁴

How can Donaldson et al explain the apparent distortion of policy based on claims of thousands of deaths from flu every year when their records show an average of no more than 33 deaths a year for the past four years?

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Competing interests: None declared.

- 1 Donaldson LJ, Rutter PD, Ellis BM, Greaves FEC, Mytton OT, Pebody RG, et al. Comparisons with recent flu mortality. *BMJ* 2010;340:c612. (1 February.)
- 2 BBC News. At risk urged to get flu shot. 2007 September 27. <http://news.bbc.co.uk/1/hi/health/7016172.stm>.
- 3 Stone J. Some published UK data [electronic response to Jefferson T. Influenza vaccination: policy versus evidence]. *BMJ* 2007. www.bmj.com/cgi/eletters/333/7574/912#146323.
- 4 Department of Health. Explaining pandemic flu: a guide from the chief medical officer. 2005. www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4121751.

Cite this as: *BMJ* 2010;340:c613

WHO SURGICAL CHECKLIST

Customise by specialty

The widespread use of the WHO surgical checklist will undoubtedly bring about improved safety, making existing safety systems increasingly redundant and building a team approach with shared responsibility in operating theatres.¹ The universal use of the WHO checklist, however, risks endangering patients if the checklist items are not relevant to the surgical specialty.

Many months ago we trialled the NHS version of the WHO checklist in cardiac surgical practice in our institution. We found immediately that the checklist omitted many important safety checks crucial to the safe conduct of cardiac operations, such as checks on perfusion equipment and preparations for postoperative intensive care. The Society for Cardiothoracic Surgery in the United Kingdom and Ireland subsequently developed a specific checklist for cardiac surgery,



which has now been approved by the National Patient Safety Agency for use in all cardiac operations in the UK and will be available on the Society for Cardiothoracic Surgery's web site (www.scts.org).

Surgical specialties should adapt the checklist to maximise safety in their patient population. Only when checklists are specific to the environment and developed by the surgeons who will use them will safety be fully improved.

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Competing interests: None declared.

- 1 Vats A, Vincent CA, Nagpal K, Davies RW, Darzi A, Moorthy K. Practical challenges of introducing WHO surgical checklist: UK pilot experience. *BMJ* 2010;340:b5433. (13 January.)

Cite this as: *BMJ* 2010;340:c589

GAGGING AND DUTY

What of outsourced settings?

Tony Delamothe's editor's choice highlighted articles by Jonathan Gornall and Jane Cassidy that show the dangers of employers gagging doctors from raising serious concerns about patient safety.¹⁻³ He observed that "George Orwell would have savoured the designation of these [employing authorities] as 'trusts'."

The two articles show trusts behaving as "big brothers," by silencing those who would speak the truth to protect senior managers' reputations, bonuses, and jobs.^{2,3} Within the NHS, doctors can rely on the flimsy protection of ministerial statements that confidentiality clauses on NHS employment contracts contravene NHS executive policy and staff's rights to bring unacceptable practices into the open.⁴ In outsourced health care the situation is worse. Here, incentives to abuse legal muzzles are fortified by "shareholder value," and rights of commercial confidentiality may be so sanctified in law as to be virtually unchallengeable.

Outsourcing is occurring in community care (out of hours work, walk-in clinics, commercial practices), secondary care (independent surgical treatment centres), and custodial settings (privatised prisons and immigration detention centres). Does ministerial prohibition of gags in NHS bodies apply to these commercial entities? Or will they be allowed to apply clinical equivalents of super-injunctions?⁵ Concerned clinicians may be able to rely on the General Medical Council's Duties of a Doctor for support if they speak out in such a situation. Or they may not.

We urgently need enforceable legal protection for employees of commercial organisations contracted to provide state responsibilities for health care where their ethical duties require them to speak out.

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Competing interests: FA was reported to the General Medical Council by the management of a privately run immigration detention centre after giving potentially life saving medical advice to three detainees. He experienced considerable anxiety during the months it took for the GMC to decide that there was no evidence to support the allegations made against him and that he had done nothing that violated his duties as a doctor.

- 1 Delamothe T. Gagging for it. *BMJ* 2009;339:b4444. (29 October.)
- 2 Gornall J. Whistleblowing: the price of silence. *BMJ* 2009;339:b3202. (27 October.)
- 3 Cassidy J. Falling foul of gagging clauses. *BMJ* 2009;339:b4203. (27 October.)
- 4 Secretary of State for Health. MISC (97)65: Freedom of speech in the NHS. 1997. www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Miscellaneousletters/DH_4018033.
- 5 Rusbridger A. Trafigura: anatomy of a super-injunction. *Guardian* 2009 October 20. www.guardian.co.uk/media/2009/oct/20/trafigura-anatomy-super-injunction.

Cite this as: *BMJ* 2010;340:c601

Administrative accountability

Paul Galea's letter eloquently makes the case for a mechanism within the NHS for employees to complain about administrative incompetence or misconduct.¹

General practitioners within the NHS, while not strictly speaking employees, labour under the same deficiency. Sadly, the Department of Health does not recognise this as a problem. We recently wrote to the secretary of state for health on this matter, having exhausted every avenue within the NHS.

The initial response was that the appropriate authority was our local strategic health authority (NHS London). Once we had confirmed it was outside their remit, the department replied that "the only recourse is to settle the dispute with legal action" and that this "reflects [their] policy regarding such matters."

This could better be described as the absence of a policy, and the department is not persuaded that there is a problem that needs solving. In the meantime, precious NHS resources are wasted by primary care trusts defending themselves in court, with the blessing of the Department of Health.

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Competing interests: None declared.

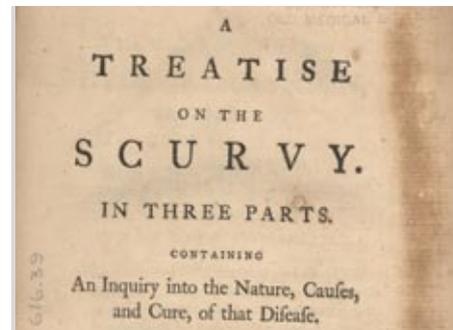
- 1 Galea P. Gagging and duties. *BMJ* 2010;340:c148. (13 January.)

Cite this as: *BMJ* 2010;340:c602

UNRECOGNISED SCURVY

Vitamin C requirements

In their article on unrecognised scurvy, Choh and colleagues¹ do not refer to the important human experiment on the effects of vitamin C deprivation on conscientious objectors in Sheffield in 1942.² This study demonstrated the earliest signs of scurvy and showed that young



men could remain healthy on as little as 10 mg ascorbic acid a day for at least a year.

Of the 20 young male volunteers, three were given a diet containing 70 mg ascorbic acid a day, seven a diet containing 10 mg a day, and 10 a diet providing no food containing vitamin C. All 10 of those in the last group developed clinical scurvy after four to seven months. None of those in the two other groups developed any signs of scurvy or any illness which could be attributed to scurvy.

Choh and colleagues mention the occurrence of follicular hyperkeratosis as an early sign of scurvy. In our 10 deprived subjects thousands of very small (1-2 mm) haemorrhages around the bases of the hair follicles were the first most obvious clinical sign.² This sign and a careful dietary history should make it possible to diagnose scurvy before serious haemorrhages as described occur.

The authors state that adults require 40 mg of vitamin C daily. We found that seven young men remained healthy for at least a year on only 10 mg daily, but we suggested 30 mg daily to provide a margin of safety.

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Competing interests: None declared.

- 1 Choh CTP, Rai S, Abdelhamid M, Lester W, Vohra RK. Unrecognised scurvy. *BMJ* 2009;339:b3580. (17 September.)
- 2 Medical Research Council. *Vitamin C requirement of human adults*. 1953. (Special Report Series No 280.)

Cite this as: *BMJ* 2010;340:c590

RISK MONEY FOR TRIAL VOLUNTEERS

Not payment, but compensation

We should not treat participation in medical trials as if it were a gladiatorial performance, with participants paid for their bravery.¹

However, all participants in trials should be provided with adequate insurance policies against the risk of adverse reactions.

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Competing interests: None declared.

- 1 Saunders J. Should healthy volunteers in clinical trials be paid according to risk? No. *BMJ* 2009;339:b4145. (22 October.)

Cite this as: *BMJ* 2010;340:c587