in 86% of the patients because of disease progression, toxicity, or death. Most clinicians will, we suspect, find this convincing evidence, but it is not perfect. We don't know whether the patients enrolled into these studies (all people who had asked for Di Bella's treatment) were representative, and we don't know whether controls would have done better or worse. The researchers should have conducted randomised controlled trials.

Why were these trials not randomised? Even though some experts claim that phase II clinical trials are usually non-comparative,[3] and the authors argued that they were using these studies to assess whether randomised studies were warranted,[2] the best way of avoiding bias is through randomising patients to intervention and control groups.[4] The usual reasons for not randomising are difficulties with randomisation and recruitment, cost, ethical considerations, and time.[5]

Difficulties with randomisation or recruitment seem to be weak reasons. Most would agree that simultaneously performing 11 multicentre studies within 10 months is no mean feat. So why not take it a bit further? The authors claim that patients would probably not have agreed to be randomly allocated to different treatments (or, in this case, placebo). But is that really so? Given that "several thousand patients requested treatment with Di Bella's multitherapy," several hundred might well have agreed to participate in a randomised controlled trial. Costs may have played a part. Arguably it would have been better to assess Di Bella's therapy in fewer types of cancer, but there was obviously a need to test the treatment in a broad range of cancers. The authors also say that they could not have done randomised trials for ethical reasons—but these are not clear. Indeed, some would claim that the inferior design of these studies was unethical. Time was probably the most influential factor, as there was increasing public pressure on the Italian health minister to clarify this issue.[6]

The design of these studies is flawed; the results are already known; and Di Bella and his followers probably would not accept the findings, even if the studies had been randomised, double blind, and placebo controlled. So, why are we publishing this paper in the *BMJ*? Firstly, even though the results have appeared in the media, these studies and their design have not been formally published. Secondly, we should acknowledge this swift concerted action against a bogus therapy of nationwide importance. Thirdly, treating this topic seriously may prevent future cases—both of the implementation of treatments with unknown efficacy and side effects and of studies of weak design to answer important questions.

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The NHS: possibilities for the endgame

Think more about reducing expectations

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Uwe Reinhardt, the American health economist, thinks that all health systems may eventually converge to a three tier system that offers high quality, fee for service care to the very rich; insurance based managed care to the expanding middle class; and rough and ready care for the poor. The United States and much of South American already have such a system. Could it happen in Britain? The current media frenzy over the latest NHS crisis prompts speculation on how the NHS might end.

Most institutions on the scale of the NHS end not with a bang but with a whimper, and the current "crisis" will probably pass like so many before it as the media move on to other stories. The NHS will not simply collapse. Nor is any government in the foreseeable future likely to seek a radical solution and privatise the service. But one possible endgame is that the middle classes lose confidence in the service and begin to make other arrangements. If comfortable Britain begins to seek health insurance and private care on a large scale resources will shift from the NHS and so, crucially, will political attention. Preserving the NHS at all costs will not be the political imperative that it is now. It could become a rump service. We would then arrive at Reinhardt's prediction.

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And why would the middle classes lose confidence? Most probably because of problems with access and quality. People are unlikely to migrate in large numbers because they have to wait to have their hernias repaired, but they will worry about finding it difficult to see their general practitioner and if they think that casualty may not be able to cope when they have their heart attack, that they (or, worse, their children) won't have access to an intensive care bed when needed, or that they are being fobbed off with a generalist when they should see a specialist. If the middle classes decide that they want immediate access to paediatricians or gynaecologists then the NHS will struggle to cope. The middle classes are also becoming much more concerned about the quality of care. Increasingly they do not believe that one surgeon is as good as another: they want the best. There is also increasing concern about the quality of communication and the non-clinical side of care.

The government recognises the demand for quality and is giving priority to attempts to raise quality. Unfortunately it may be underestimating the difficulty.

Ministers are trying to reverse the fragmentation of the health service by introducing more central control and direction, but, as those knowledgeable about quality improvement remind us, telling people to do better will not improve quality. Nor will keeping scorecards improve quality. The NHS is a huge organisation, and nobody knows how to encourage the spread of best practice. The monolithic nature of the NHS may yet be part of its failure.

People's expectations may rise much faster than the ability of the NHS to deliver, particularly when expectations are stoked not only by the media and access to the internet but also by politicians themselves. Ian Morrison, the Scottish Californian futurologist, has a joke that in Glasgow death is viewed as imminent, in Canada as inevitable, and in California as optional. If a large number of Britons grow to have the expectations of Californians then a service that pretends to be comprehensive, free at the point of access, and high quality runs into serious problems. The Californians may ultimately be discouraged by the bills they have to pay, but the aspiring Briton encounters no such deterrent—and certainly won't elect a government that proposes to raise taxes. The demise of the NHS may lie in this mismatch between expectation and provision. And now the law is increasing the tension by insisting that the NHS must provide long term care and that blanket bans on particular treatments are illegal.

One group that suffers from the mismatch between expectation and provision is NHS staff. They are caught like hamsters in a wheel that must go faster and faster. Instead of being compensated for pay that is generally poorer than in the private sector by the feeling that they are doing an important job well, they are now conscious of increased pressure and of failing to deliver an optimum service. They have low pay and disappointment. So nurses and managers migrate to other sectors, and doctors begin to think about providing services outside the NHS. Wholesale demoralisation of the staff may be an important component of the endgame.

Can I end this editorial optimistically? I think so. A mismatch between expectation and provision can be approached in two ways. Clearly it's necessary to improve the provision, and politicians always promise such improvements. But it would also seem sensible for everyone—politicians, reseachers, clinicians—to work on the expectations: death is inevitable; most major diseases cannot be cured; antibiotics are no use for flu; artificial hips wear out; hospitals are dangerous places; drugs all have side effects; most medical treatments achieve only marginal benefit and many don't work at all; screening tests produce false negative results; and there are better ways to spend money than on more healthcare technology. "The best healthcare system in the world," which politicians in every country promise, will not be one that provides everything for everybody but rather one that determines what that society wants to spend on health care and then provides explicitly limited, evidence based services in a humane and open way without asking the impossible of its staff.

Richard Smith *Editor, BMJ*

The firing of Brother George

The AMA has damaged itself by sacking JAMA's editor

The American Medical Association damaged itself and medical journals when last week it sacked George Lundberg, the editor of its journal *JAMA*. Lundberg, who had edited *JAMA* for 17 years, was sacked for fast tracking publication of a study showing that many American college students do not think of oral sex as "having sex." The study, in the issue of 20 January, was fast tracked because of its relevance to President Bill Clinton's impeachment trial. According to the *New York Times*, Dr E Ratcliffe Anderson, the AMA's executive vice president, said that he didn't object to the content of the paper but to its acceleration. "I happen to believe that Dr Lundberg was focused on sensationalism here, not science."[1]

In sacking its editor the association is reverting to type. Editors used to be regularly browbeaten, sacked, or edged out for upsetting the deeply conservative membership of the association, and as a result the journal had little international respect. Lundberg turned a journal that was an embarrassment into a respected major journal. Yet while *JAMA* has flourished the AMA has withered. Its membership has fallen steadily to 38% of American doctors, and it is perceived as a reactionary organisation concerned only with self interest. (The BMA, in contrast, has over 80% of British doctors in membership and is seen as more than a doctors' trade union.) The already poor image of the AMA was then tarnished further by the "Sunbeam affair," which led to several senior executives leaving the association over a sponsorship deal that went wrong.[2] Anderson has been brought in to "clean up" the organisation, but firing Lundberg is a poor start.

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Editors do upset their associations, as the leaders of the BMA and the Massachusetts Medical Society (owners of the *New England Journal of Medicine*) will testify. Unsettling the establishment, one of my predecessors argued, is an editor's duty.[3] The challenge to the association leadership is to put the long term development of the journal, which can come only with editorial independence,[4] before short term political irritation. The AMA leadership has failed that challenge.

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