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LETTERS

NHS REFORM

Study proposal

Because the proposed changes to the NHS have no overwhelming supporting evidence,[1] ethically the proposed changes can take place only in the form of a trial. I ask you to consider favourably the following study proposal that I submit without permission on behalf of the UK government.

Title: Reorganisation of the NHS in England.

Background: The NHS is in its 63rd year. It is suffering the same demographic and technological challenges as all high income countries, specifically ageing of the population and increasingly expensive new technologies. These are major problems that we seek to deal with. We also have concerns about outcomes in the NHS compared with other countries. France spends more on healthcare than the UK, has fewer deaths from heart attacks, but will shortly be overtaken by the UK in this mortality measure. We determine from this observation that the UK healthcare system is not delivering as much as it should and must change, but not to be like France in funding or structure, and hopefully not in the trend in heart attack deaths. We do not consider this to be an ecological fallacy, and we do not consider any other differences between the populations of France and England.[2]

Study design: Immediate full scale roll out without control or comparison group.

What this study adds to the current evidence: We offer no global, systematic appraisal of current evidence and take no account of quality of evidence. As lawmakers, evidence in the legal sense is our primary concern—oral and written statements from individuals and organisations—and we do not distinguish this from higher quality evidence.[3] We are confident that this study will accrue a substantial body of similar (grade 5) non-evidence with which to inform future reorganisations.

Study population: The entire population of England, of all ages, is served by the NHS, with the exception of the richest people, who will be exempt.

Interventions: (1) A market based healthcare system; open to all willing providers. (2) GP based commissioning and the closure of primary care trusts. (3) Transfer of public health to local authorities. (4) Providers that cannot generate enough profit will close, whereas those making the largest profits will succeed, irrespective of their clinical performance. Taxpayer funding will continue, allowing successful firms to become a conduit of money from the many to the few.

Comparison group: None.

Outcomes: No a priori health outcomes are specified, although multiple testing, case studies, and post hoc analyses are planned by all political parties for election purposes and generation of low grade evidence.

Ethical considerations: No ethical approval has been sought. We acknowledge the risk associated with changing the health service and are aware that small changes in important health outcomes can cause or prevent thousands of deaths.[3] Because we are certain that our approach is correct, we have no criteria for stopping the trial.

Consent: Population level consent sought and an election almost won on the basis of: "No top down reorganisation of the NHS." No consent sought on the specific interventions.

Study funding: Taxpayers are the sole funders of estimated costs of £1bn (€1.14bn; $1.63bn) to £3bn. Potential exists for future savings.

Potential conflicts of interest: None declared, although newspapers report the secretary of state for health has received £21 000 from the chairman of Care UK to fund his personal office.[4]

Thank you for considering our proposal.

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Competing interests: JJL is an NHS patient and an NHS employee.

1 Pollock A, Price D. How the secretary of state for health proposes to abolish the NHS in England. *BMJ* 2011;342:d1695. (22 March.)
2 Appleby J. Does poor health justify NHS reform? *BMJ* 2011;2011;342:d566.
3 Letter from health minister Paul Burstow MP. *Guardian* 2011 February 8. www.guardian.co.uk/society/2011/feb/08/deconstruction-of-the-nhs-bill?INTCMP=SRCH.
4 Watt H, Prince R. Andrew Lansley bankrolled by private healthcare provider. *Telegraph* 2010 January 14. www.telegraph.co.uk/news/newstopics/mps-expenses/6989408/Andrew-Lansley-bankrolled-by-private-healthcare-provider.html.

Cite this as: *BMJ* 2011;342:d2584

What about the politics of the reforms?

Walshe and Ham have taken the government's stated objectives at face value, with no attempt to acknowledge and put into context the political ideology underpinning these reforms.[1] The coalition government has a clear agenda to replace a large chunk of the public sector with the private and third sectors. "Rolling back the state" through privatisation, a reduction in the public sector workforce, and national pay bargaining and pension rights is one of the key supply side economic policies that this government thinks are necessary to tackle our dire economic situation. A low tax, low inflation, entrepreneurial environment is seen as vital to securing the confidence of international investors and the international bonds markets in the City of London.

Thus, the political and economic reality is that public services need to be privatised and marketised, and the Health and Social Care Bill has been designed to do exactly that to the NHS. The key market levers contained within the bill that will drive this process are the mutually reinforcing policies of patient and consumer choice, competition between a plurality of any willing providers, payment by results, the purchaser-provider split, increased freedom for foundation trusts, the pro-competition nature of Monitor and the NHS Commissioning Board, and an information revolution. Lansley sees competition as the key and stated this in a speech to the NHS Confederation: "So the first guiding principle is this: maximise competition . . . which is the primary objective." He also alluded to the importance of not only increasing the number of providers to stimulate competition, but also the number of consumers. He stated that: "The statutory formula should make clear that choice should be exercised by patients, or as close to the patient as possible, thereby maximising the number of purchasers and enhancing the prospects of competition, innovation, and responsiveness to patients."[2]

Putting budgets into the hands of GPs is problematic because most GPs and patients want to be referred to a good local hospital, and this is fundamentally anti-market. Thus the bill will use Monitor, the NHS Commissioning Board, and EU competition law to prevent GP consortiums from favouring incumbent providers. In addition, the private takeover of commissioning through FESC (Framework for Procuring External Support for Commissioners) will further stimulate this process.

Because these mutually reinforcing polices are so crucial to the political and economic objectives of this government, any attempts to seriously water them down will be met with considerable opposition, despite the difficult and politically unpopular situation the government is in. Thus any government concessions that result in amendments to these policies must be forensically examined for loopholes. There is already concern that the widely publicised U turn on price competition has not gone far enough, for example.[3]

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Competing interests: CP is co-chair, NHS Consultants' Association, and a member of the BMA Council and BMA Political Board.

1 Walshe K, Ham C. Can the government's proposals for NHS reform be made to work? *BMJ* 2011;342:d2038. (31 March.)
2 Lansley A. Extract from "The future of health and public service regulation" speech. 2005 July 9. www.andrewlansley.co.uk/newsevent.php?newseventid=21.
3 Dowler C. Government has not done enough to prevent price competition. 2011 March 21. www.hsj.co.uk/news/policy/government-has-not-done-enough-to-prevent-price-competition-confed/5027839.article.

Cite this as: *BMJ* 2011;342:d2587

Bill is not fit to be amended

The King's Fund should be bold and declare that the proposed NHS reforms will worsen the existing problems of poor communication and collaboration in the NHS.[1] They will not address poor standards of care and will widen inequalities.

The potentially beneficial parts of the bill, such as greater clinician participation in decision making, are too tightly hitched to the most damaging parts, such as the purchaser-provider split and the external market. The damaging parts of the bill are so dangerous that no amount of amending can make it safe.

The NHS is in need of reform. Six problems urgently need to be fixed.

(1) Improve collaboration. Community, primary care, and hospital specialists need to work together. Currently, shared care is poor or non-existent with a few exceptions.

(2) Share responsibility. All providers need to share responsibility for the health of a population. We must abandon the purchaser-provider split. GPs are providers of healthcare. If GPs are purchasers a conflict of interest cannot be avoided. The purchaser-provider split damages relationships between GPs and specialists and hinders rather than facilitates joint responsibility for patient care because GPs are trying to reduce medical interventions to save money while hospitals and others are trying to increase interventions to earn money.

(3) Continue to invest in the National Institute for Health and Clinical Excellence and improve the dissemination of guidelines and the monitoring of their use. Much is to be gained from better adherence to clinical evidence. Guidelines are too often not followed because of lack of familiarity rather than clinical reasoning.

(4) Measure outcome data more effectively. The outcome of healthcare is health gain. Health gain is difficult to measure because of the many variables, the social determinants of health, the subjective nature of health, and the variable time lags between interventions and outcomes. To become more efficient, we need also to agree on how to measure efficiency.

(5) Federate GPs in a geographical area so that they can work collaboratively to share resources and take responsibility for peer performance. That primary care trusts and the GP profession have failed to manage underperforming GPs is inexcusable. The Royal College of General Practitioners has proposed this idea previously. It will need firm leadership, expert management, and a range of incentives if it is to succeed.

(6) Reduce health inequalities. Proposed funding allocations will widen inequalities and threaten the financial viability of general practice in areas with the greatest health needs. Efficient care depends on efficient patients, and the impact of markets on inefficient patients will result in the inverse care law. Strong public health leadership and close collaboration is essential.

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Competing interests: None declared.

1 Walshe K, Ham C. Can the government's proposals for NHS reform be made to work? *BMJ* 2011;342:d2038. (31 March.)

Cite this as: *BMJ* 2011;342:d2591

The horse has already bolted

I thank Pollock and Price for their analysis, which explains my Kafkaesque correspondence with the Department of Health since 13 December 2010.[1]

I forwarded to the department a low priority procedure list that had been circulating in the primary care trust since August 2010. It set out which services would no longer be available, and I asked whether it was right that certain treatments were excluded locally, contrary to the pledge in the NHS constitution that "The NHS provides a comprehensive service, available to all."[2]

I will not bore readers with the tedious exchange culminating in: "However, I should assure you that there is a statutory obligation on the NHS to provide funding for treatments and drugs recommended by the National Institute for Health and Clinical Excellence (NICE) within three months of the final NICE technology appraisal guidance being published."

The low priority procedure list includes bariatric surgery and chronic fatigue, both of which have been assessed by NICE, so my logical next question was how would the department enforce the breach of the local primary care trust's statutory obligation? The answer:

"We have replied to you on this matter previously, and in setting out the government's position on this issue, we have answered your questions fully. Therefore, we will note any further correspondence from you on this matter, but we may not reply unless the government's position changes or any new information becomes available."

My protestations that the question has not been addressed have gone unanswered. We seem therefore to have already reached the point where local health authorities can with impunity randomly decide which treatments are excluded from the "comprehensive" package; this is not a future issue to worry about, as Pollock and Price suggest.

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Competing interests: None declared.

1 Pollock A, Price D. How the secretary of state for health proposes to abolish the NHS in England. *BMJ* 2011;342:d1695. (22 March.)
2 NHS constitution. Department of Health. 2010. www.nhs.uk/choiceintheNHS/Rightsandpledges/NHSConstitution/Documents/nhs-constitution-interactive-version-march-2010.pdf.

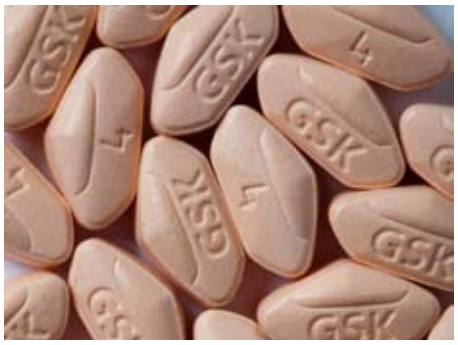
Cite this as: *BMJ* 2011;342:d2597

ROSIGLITAZONE SAGA

Should we throw the baby out with the bathwater?

The authors disapprove of doctors who prescribe thiazolidinediones but still advocate for "tight" glycaemic control.[1]

"Tight" control (7% glycated haemoglobin (HbA_{1c})) did not lead to increased mortality in the UKPDS.[2] "Very tight" glycaemic control in ACCORD was associated with a small increase in mortality, for reasons unknown,[3] but the



MARK THOMAS

results cannot be generalised to patients with newer onset diabetes. Some guidelines now recommend an HbA_{1c} of 7%, with more relaxed targets in at risk groups (such as elderly patients, those with cardiovascular disease).[4] The expressed contempt for "guidelines" therefore seems misleading. The authors point out important differences between rosiglitazone and pioglitazone; we still await an analysis from ACCORD that examines the effects of rosiglitazone, widely used in the intensive group.[3]

Evidence that very tight control reduces cardiovascular outcomes is sparse but the reduced risk of microvascular complications cannot be discounted. Blindness and renal failure are important to patients, as is hypoglycaemia. Patients' values should be incorporated into clinical practice guidelines, not just "evidence" from observational studies or poorly conducted meta-analyses.[5] Insulin is generally safe and effective but requires injections and frequent monitoring; it also causes weight gain and hypoglycaemia. Many patients are reluctant or unable to take insulin. It is complex for patients to manage and requires education. Most patients would probably choose a pill over an injection.

Many patients will need multiple treatments, including insulin, to control glycaemia,[3] even with lower targets,[2] making the development of safe and effective oral drugs an important goal. Clinically important outcomes including safety should be studied in long term trials before their use becomes widespread.

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Competing interests: CM participates in clinical trials of new drugs in type 2 diabetes that are sometimes funded by drug companies. She was a site investigator for the ACCORD trial and a member of the expert committee for the 2008 Canadian Diabetes Association clinical practice guidelines for the management of diabetes in Canada.

1 Montori VM, Shah ND. What have we learnt from the rosiglitazone saga? *BMJ* 2011;342:d1354. (17 March.)
2 UK Prospective Diabetes Study Group. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *Lancet* 1998;352:837-53.
3 Action to Control Cardiovascular Risk in Diabetes Study Group. Effects of intensive glucose lowering in type 2 diabetes. *N Engl J Med* 2008;358:2545-59.
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5 Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes [published correction in: *N Engl J Med* 2007;357:100]. *N Engl J Med* 2007;356:2457-71.

Cite this as: *BMJ* 2011;342:d2566

Authors' reply

We agree that achieving glycaemic control is a tough task for clinicians and patients, and that high quality evidence and a strong regulatory framework are needed to guide care.[1 2]

Regarding the safety of rosiglitazone, the Nissen meta-analysis—despite its methodological shortcomings—yielded results that other more rigorous meta-analyses have reproduced and that new evidence has not contradicted.[3] We do not expect the subanalyses of ACCORD to contribute much more.

McDonald makes a strong case for the central role of patient preferences and values in choosing antihyperglycaemic drugs. Our group is conducting research and implementing shared decision making for diabetes drugs. This research will help achieve the model that McDonald and we prefer to guide the choice of drugs for diabetes. Tools to promote shared decision making in diabetes are freely available (http://kercards.e-bm.info), and we expect to make these available in other formats soon.

Finally, taking all the evidence into account (rather than selecting studies by their results), we believe that the evidence supporting tight glycaemic goal (aiming at glycated haemoglobin <7-7.5%) is weak so this policy should not be dogmatically promoted or rejected. The associated burdens and costs, potential harms, and low likelihood of benefit from pursuing such control with currently available drugs makes it an unattractive proposition for most informed patients. Perhaps we are too conservative, but that is one lesson we learnt from the rosiglitazone saga.

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Competing interests: None declared.

1 McDonald C. Should we throw the baby out with the bathwater? *BMJ* 2011;342:d2566.
2 Montori VM, Shah ND. What have we learnt from the rosiglitazone saga? *BMJ* 2011;342:d1354. (17 March.)
3 Nissen SE, Wolski K. Effect of rosiglitazone on the risk of myocardial infarction and death from cardiovascular causes [published correction in: *N Engl J Med* 2007;357:100]. *N Engl J Med* 2007;356:2457-71.

Cite this as: *BMJ* 2011;342:d2567

Demonisation of rosiglitazone

Loke and colleagues consider the idea that pioglitazone yields cardiovascular benefits, but readily dismiss it.[1] This is an equally plausible explanation of the analysis, however, given that it compares pioglitazone and rosiglitazone rather than placebo or control treatment. There is moderate evidence that the composite end point of death, myocardial infarction, and stroke is reduced by pioglitazone in high risk vascular patients (PROactive study hazard ratio 0.84, 95% confidence interval 0.72 to 0.98)[2] and lower risk patients (0.75, 0.55 to 1.02), which, when combined (n=16 390 patients), results in an 18% reduction (0.82, 0.72 to 0.94; P=0.005).[3] Furthermore, the reduced rate of progression of coronary atherosclerosis associated with pioglitazone, compared with glimepiride, in the PERISCOPE study, is also compelling evidence for its beneficial cardiovascular effects.[4]

Rosiglitazone's harmful vascular effect is similar in size to pioglitazone's beneficial effect compared with control therapy (14-22%).[1 2] It seems unreasonable to interpret the findings negatively towards rosiglitazone when they could be interpreted positively for pioglitazone, avoiding further demonisation of rosiglitazone. It is nevertheless appreciated that adverse effects of the peroxisome proliferator activated receptor γ agonists, such as non-fatal congestive heart failure, apply generally to all agents in this class of drugs.

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Competing interests: None declared.

1 Loke YK, Kwok CS, Singh S. Comparative cardiovascular effects of thiazolidinediones: systematic review and meta-analysis of observational studies. *BMJ* 2011;342:d1309. (17 March.)
2 Dormandy JA, Charbonnel B, Eckland DJA, Erdmann E, Massi-Benedetti M, Moules IK, et al. Secondary prevention of macrovascular events in patients with type 2 diabetes in the PROactive Study (PROspective pioglitAzone Clinical Trial in macroVascular Events): a randomised controlled trial. *Lancet* 2005;366:1279-89.
3 Lincoff AM, Wolski K, Nicholls SJ, Nissen SE. Pioglitazone and risk of cardiovascular events in patients with type 2 diabetes mellitus: a meta-analysis of randomized trials. *JAMA* 2007;298:1180-8.
4 Nissen SE, Nicholls SJ, Wolski K, Nesto R, Kupfer S, Perez A, et al. Comparison of pioglitazone vs glimepiride on progression of coronary atherosclerosis in patients with type 2 diabetes: the PERISCOPE randomized controlled trial. *JAMA* 2008;299:1561-73.

Cite this as: *BMJ* 2011;342:d2571

Authors' reply

Heazlewood describes the modest evidence for pioglitazone's beneficial effect on a composite cardiovascular end point but fails to mention the inconclusive data on individual end points,

such as myocardial infarction (relative risk 0.81, 95% confidence interval 0.64 to 1.02; P=0.08) or death (0.92, 0.76 to 1.11; P=0.38) compared with non-thiazolidinedione drugs or placebo.[1 2] In our study, the comparatively unfavourable findings for rosiglitazone could stem from pioglitazone having relatively less harmful or neutral effects, or from some yet unproved benefit for pioglitazone (compared with non-thiazolidinediones) in reducing myocardial infarction or death.[3] Given the absence of compelling data for such benefit, speculative conclusions on the virtues of pioglitazone should be avoided. Interpretation of the pioglitazone meta-analysis is hampered by the drug company making trial data available to only one group of investigators[1] and some of the data still not being in the public domain, thus precluding any replication of the findings. The arguments for the efficacy of pioglitazone are driven mainly by the findings of a trial (ProActive) where a new composite outcome was introduced during the study period.[4] Finally, the evidence of impact on the surrogate outcome of coronary atheroma volume should not be construed as compelling evidence of benefit relating to patient centred outcomes.[5]

Given these uncertainties, we are not persuaded that pioglitazone is superior to other drugs for type 2 diabetes, although we do agree that it is probably less harmful than rosiglitazone.

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Competing interests: None declared.

1 Lincoff AM, Wolski K, Nicholls SJ, Nissen SE. Pioglitazone and risk of cardiovascular events in patients with type 2 diabetes mellitus: a meta-analysis of randomized trials. *JAMA* 2007;298:1180-8.
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Cite this as: *BMJ* 2011;342:d2573

AUDIT OF MATERNAL-CHILD DEATHS

Child Head Injury Enquiry has also been suspended

As a lay trustee of the Centre for Maternal and Child Enquiries (CMACE), I share the alarm of clinicians and epidemiologists over the decision to suspend the National Confidential Enquiries into Maternal and Perinatal Deaths to "review" them.[1] This does a grave disservice to all pregnant women and their babies. Why the break in continuity, when CMACE could have continued work in the meantime, mitigating the haemorrhage of expertise and valuable information?

The axing of the CMACE child head injury project, two thirds of the way through the study, is also extremely worrying. CMACE offered to complete this work (excluded from the tender process) at no cost to the National Patient Safety Agency (NPSA), but has instead had to hand over the data. Investment of about £600 000 (€684 745; £978 355) of public money, with contributions from charities including the NSPCC, will be wasted. According to the NPSA, the study findings may be superseded by the Safe and Sustainable review of neurosurgery. But according to the clinicians involved in this review, the evidence obtained from this study will be highly relevant to their recommendations to improve quality of care.

These perverse decisions must be reversed. Otherwise, we can only conclude that the coalition government fears robust independent audit of the quality of health service provision. The losers will be patients and their families.

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Competing interests: None declared.

1 Mayor S. Funding of audit of maternal and perinatal deaths has been suspended, UK agency reports. *BMJ* 2011;342:d2158. (4 April.)

Cite this as: *BMJ* 2011;342:d2574

RISK ILLITERACY

The real problem is the biomedical ignorance of statisticians

Heath's review supports a book that gives a "devastating dissection of the statistical illiteracy of doctors,"[1] when the real problem is the devastating biomedical ignorance of statisticians.

Why should a doctor need to know how to calculate the chance of breast cancer in a patient with a positive screening mammogram, given "a prevalence of 1%, a sensitivity of 90%, and a false positive rate of 9%"? What the doctor needs is a test that gives a straight yes or no answer, or something close to it. A positive test that reveals only a 1/10 chance is, at best, just a screen for more investigation; it is not a test on which an answer can, or should, be given to the patient. It is a bad "test," and no amount of statistical juggling will improve it. The clinician needs better tests not better statistics—the better the test the less statistics is needed for its understanding; the usefulness of a test is inversely related to the statistics required for its interpretation.

The misguided reliance on statistics in contemporary health studies strangles their meaning. The problem is not that clinicians need more statistical nous to deconstruct them, but that clinical studies need to be more quantitative, methodologically rigorous, and above all imaginative, so that their science is understood and their conclusion obvious without having to peel away obtrusive, oversupportive, statistical packaging.

Statistics has wormed its way to the core of clinical research; it should return to being the simple ancillary aid that it once was.

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Competing interests: None declared.

1 Heath I. Dare to know: risk illiteracy and shared decision making. *BMJ* 2011;342:d2075. (6 April.)

Cite this as: *BMJ* 2011;342:d2579

Rather difficult calculations

The screening calculation that Heath describes is rather difficult.[1] I have a PhD in screening but it took me a few minutes of writing algebra on a scrap of paper to reach the answer (I think that the positive predictive value of screening is roughly 0.09, assuming the "false positive rate" cited is 1 – specificity). So I'm not surprised that the average gynaecologist might get it wrong 60% of the time when eyeballing the figures in a consultation, if they were all that was available.

If there is a failing there, it's that they don't simply know that the positive predictive value of that screening test is around that figure. To be fair, we all have a lot of clinical numbers to carry around in our heads, and I'm sure we often get them wrong when citing them to patients, friends, or colleagues. But we need to keep learning, relearning, and updating those figures and guiding our practice with them. That's what evidence based medicine means, in practice.

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Competing interests: None declared.

1 Heath I. Dare to know: risk illiteracy and shared decision making. *BMJ* 2011;342:d2075. (6 April.)

Cite this as: *BMJ* 2011;342:d2577