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LETTERS

UK CANCER SURVIVAL STATISTICS

Rebuttal to editorial saying cancer survival statistics are misleading

Beral and Peto's 2010 editorial on cancer survival statistics is unfounded, untenable, and inconsistent.[1] Godlee reported in September 2010 that they were then too busy to defend it.[2] The editorial is indefensible. It should be withdrawn.

The editorial is unfounded. The provocative subtitle, "UK cancer survival statistics are misleading and make survival look worse than it is," is pure conjecture. Conjecture becomes assertion, then conclusion, with no intervening evidence:

> *If* the first months or years of the illness are never traced, the earliest event registered *may be* some aspect of cancer recurrence. The date of this recurrence *would* then be taken as the date from which 'survival rates' are calculated. This *makes* short term survival look misleadingly worse in the UK than in countries such as Sweden .... [our italics][1]

The editorial is untenable. It posits two errors that supposedly make UK cancer survival misleading. Full scale simulation with the national cancer registry shows that even implausibly extreme levels of the alleged errors could not account for the UK-Sweden survival deficit.[3] Evidence refutes conjecture.

The editorial is inconsistent: one of the authors published survival estimates for England in 1998-9 using the same cancer registry data criticised in the editorial without mentioning these criticisms. Survival trends were interpreted (quite reasonably) as reflecting improved treatment.[4] Data quality has improved substantially since the 1990s.[5] If clinical interpretation of survival estimates derived from the national cancer registry was acceptable in 1999, why not now?

A misleading *BMJ* editorial by such eminent authors is not trivial. It is inappropriately cited in support of a criticism that health policy aimed at improving cancer survival "fails to acknowledge *substantial methodological problems* with studies reporting these [survival] rates" [our italics].[6] The editorial undermines research to explain the UK cancer survival deficit, as well as policy designed to reduce the deficit. That is a disservice to patients with cancer in the UK.

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Competing interests: None declared.

1 Beral V, Peto R. UK cancer survival statistics. *BMJ* 2010;341:c4112.
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Cite this as: *BMJ* 2011;343:d4214

Authors' reply

Our original editorial remains an appropriate comment on underemphasised problems in interpreting the currently available evidence on UK cancer survival rates. The figure shows the recent declines in breast cancer mortality in selected European populations at ages 45-54. By this important measure, the UK is doing comparatively well.

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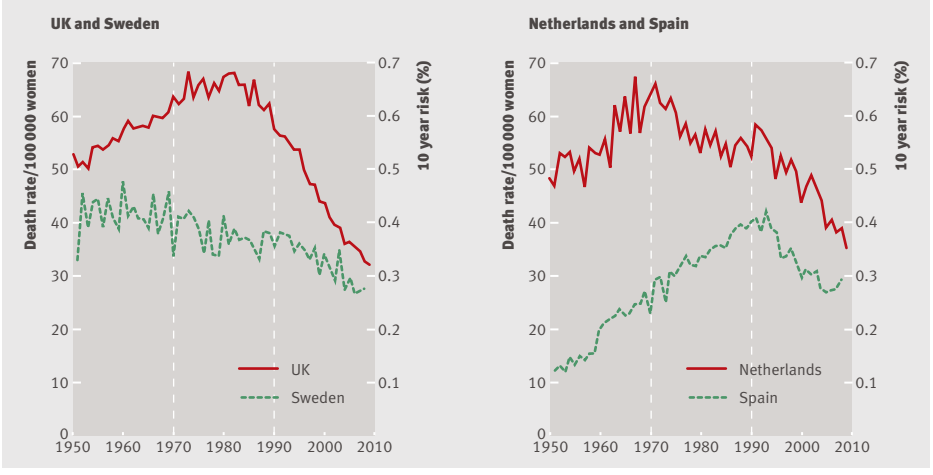
Competing interests: None declared.

Cite this as: *BMJ* 2011;343:d4217



Trends in breast cancer death rates at ages 45-54 in selected European populations. Values are means of death certification rates at 45-49 and 50-54. Source: WHO mortality and UN population estimates. UK trends at these ages are little affected by screening, as the mean age of the first UK screening invitation is 51.0 years

DRUG REGULATION DATA

UK drug regulator destroys all evidence after 15 years

Jørgensen and I recently gained access to clinical study reports and trial protocols of placebo controlled trials at the European Medicines Agency (EMA).[1] Some drugs, however, have not been approved centrally, and in such cases the EMA advises contacting the relevant national drug agencies.

For the antidepressant drug fluoxetine, the United Kingdom acts as Reference Member State according to the Mutual Recognition Procedure in the European Union. The UK Medicines and Healthcare Products Regulatory Agency (MHRA) has, however, informed us that it no longer holds the requested reports:

> Under MHRA record management policy, all application files and data for licences are held for 15 years. After this period, files are destroyed unless there is a legal, regulatory, or business need to keep them, or unless they are considered to be of lasting historic interest.

Legal or historic interest? How ironic. Court cases have shown serious scientific misconduct in placebo controlled industry sponsored trials of antidepressant drugs including fluoxetine—for example, recoding suicidal events as "emotional lability," "hospital admission," "lack of effect," or "drop-out" while patients were taking the drugs and adding suicides to the placebo group that had not occurred while the patients were taking placebo.[2 3]

Despite these manipulations, selective serotonin reuptake inhibitors as a drug class increase the risk of suicide in children and adolescents.[2 3] But the action of the MHRA may mean that it is impossible for independent researchers to correct the seriously flawed publication record on fluoxetine, which, ironically, is the only drug approved for use in childhood depression.

I have asked the UK Department of Health and the EMA how we can obtain the data the MHRA has destroyed, and I suggest legislation be introduced to prevent the MHRA from destroying the evidence in future. Lack of space is no excuse because the documents can be scanned.

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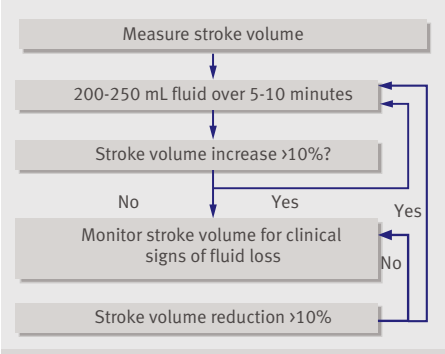
Competing interests: None declared.

1 Gøtzsche PC, Jørgensen AW. Opening up data at the European Medicines Agency. *BMJ* 2011;342:d2686. 10 May 2011
2 Healy D. Did regulators fail over selective serotonin reuptake inhibitors? *BMJ* 2006;333:92-5.
3 Healy D. *Let them eat Prozac*. New York University Press, 2004.

Cite this as: *BMJ* 2011;343:d4203

INTRAOPERATIVE FLUID MANAGEMENT

What did Doppler monitoring study show?



I have long championed so called haemodynamic optimisation in high risk surgery, having published a randomised controlled trial in the *BMJ* in 1999.[1] I have used oesophageal Doppler monitoring many hundreds of times, and still do occasionally.

I was therefore interested in the article by Kuper and colleagues, but I don't know what to believe from this piece of work, which seems to be a form of audit, yet with selective results presented in a research style and served up to the audience as quality improvement.[2] Many questions remain unanswered, and the obvious potential for bias in the structure of the evaluation is large.

Why was a consecutive intervention cohort not compared with a consecutive historical cohort? The authors chose matched controls instead, which is not comparing like with like. How were these controls chosen? Was there any blinding? Is this not beginning to sound like it should have been a formal case-controlled study with ethics approval?

Why were no data presented on the incidence of complications and death?

The lengths of stay before the intervention (in the selected controls) seemed to be particularly lengthy, and one centre did not show an improvement. In our hospital the median length of stay in a published study of selected high risk major surgery was 8.5 days.[3]

The manufacturer proclaims on its home page (www.deltexmedical.com): "NICE [the National Institute for Health and Clinical Excellence] have stated that the CardioQ-ODM should be adopted for use in patients undergoing major or high risk surgery." This is not quite the same as NICE's recommendation that "the CardioQ-ODM should be considered for use in patients undergoing major or high risk surgery."[4]

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Competing interests: RJTW has received honorariums for lecturing from Deltex (manufacturers of the oesophageal Doppler device), LiDCO (manufacturers of competing technology), and Fresenius-Kabi (manufacturers of intravenous fluid).

1 Wilson J, Woods I, Fawcett J, Whall R, Dibb W, Morris C. Reducing the risk of major elective surgery: randomised controlled trial of preoperative optimisation of oxygen delivery. *BMJ* 1999;318:1099-103.
2 Kuper M, Gold SJ, Callow C, Quraishi T, King S, Mulreany A, et al. Intraoperative fluid management guided by oesophageal Doppler monitoring. *BMJ* 2011;342:d3016 (24 May.)
3 Davies S, Yates D, Wilson RJT. Dopexamine has no additional benefit in high-risk patients receiving goal-directed fluid therapy undergoing major abdominal surgery. *Anesth Analg* 2011;112:130-8.
4 National Institute for Health and Clinical Excellence. CardioQ-ODM (oesophageal Doppler monitor). NICE medical technologies guidance, March 2011. www.nice.org.uk/MTG3.

Cite this as: *BMJ* 2011;343:d3973

Outcomes not justified by data

Kuper and colleagues' non-randomised before and after project merely tries to reproduce the outcomes of previous randomised trials.[1] To create a study that does not advance knowledge of goal directed fluid treatment in major surgery seems to be nonsensical.

Although this study is billed as a quality improvement report, there is no mention of advice, if not approval, having been sought from a research ethics committee. The assumption is that this study is a service evaluation.

Were the patient groups comparable on the basis of a single physiological scoring system? The intervention group seemingly contains many more young patients with less morbidity. Perhaps the group demographics should be given?

The choice of colloid solution was inconsistent across sites. Can cardiac output measurements be comparable when the two have dissimilar pharmacokinetics?

We read the guide produced by the NHS Technology Adoption Centre with the help of the authors. Some of its statements are bold, given that the re-admission and re-operation data are not significant.

We are curious about how much this guide cost to produce when something similar could have been produced using the increasingly popular NHS Networks—a free platform specifically developed to promote the sharing of ideas and pooling of experience among NHS employees.

In conclusion, much effort and resource has been expended on this implementation project, which cites the evidence base of no less than eight randomised controlled trials and yet produces outcomes that are not justified by the data presented.

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1 Kuper M, Gold SJ, Callow C, Quraishi T, King S, Mulreany A, et al. Intraoperative fluid management guided by oesophageal Doppler monitoring. *BMJ* 2011;342:d3016 (24 May.)

Cite this as: *BMJ* 2011;343:d3974

Authors' reply

In reply to Wilson, randomised controlled trials of oesophageal Doppler are many. Our study aimed at exploring barriers to purchase and implementation and seeing whether the benefits predicted by research could be obtained in practice. The sites, not all large centres, were chosen to represent the diversity of NHS providers, and one site had no previous intraoperative experience of Doppler. In this quality improvement project, we compared a consecutive cohort following implementation with a historical cohort. There was no blinding or randomisation. The project was approved by each trust's clinical audit process and endorsed by executive teams.

Important barriers to purchase and implementation were overcome, and Doppler use increased from 12% to 63% of eligible operations with an associated reduction in median length of stay across all sites from 12 to 10 days. Table 5 shows complications and inhospital mortality, with non-significant reductions.

The study design cannot exclude confounding by other factors changing over time and potential for bias, as we discussed. Quality improvement reports cannot and should not replace randomised controlled trials, but we believe that our implementation study will help and encourage clinicians to translate research into real benefit for patients.

In reply to Miura and colleagues, we implemented into routine practice a recommended intervention with a strong evidence base.[1] We acknowledged differences in the group matching. POSSUM is the best validated scoring system for evaluating perioperative risk and is used in many relevant randomised controlled trials.[2] The use of different colloids at different hospitals reflects variation in fluid prescription across the UK and increases the generalisability of the results. The comments about colloid pharmacology and volume expansion are not supported by current research.[3]

The NHS Technology Adoption Centre's "how to why to" guides support technology implementation for patient benefit. We trust that perioperative NHS Networks share these aims and will promote widespread implementation of Doppler, in keeping with guidance from the National Institute for Health and Clinical Excellence,[4] to improve outcomes for patients undergoing major surgery.

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Competing interests: DHC received expenses to travel to a meeting from Deltex Medical after acceptance of the quality improvement report in March 2011.

1 Powell-Tuck J, Gosling P, Lobo DN, Allison SP, Carlson GL, Gore M, et al. British consensus guidelines on intravenous fluid therapy for adult surgical patients (GIFTASUP). 2008. http://journal.ics.ac.uk/pdf/1001013.pdf.
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4 National Institute for Health and Clinical Excellence. CardioQ-ODM (oesophageal Doppler monitor). NICE medical technologies guidance, March 2011. www.nice.org.uk/MTG3.

Cite this as: *BMJ* 2011;343:d4021

BENZODIAZEPINE MISUSE

Phenazepam is currently being misused in the UK

Phenazepam is a benzodiazepine not currently controlled in the United Kingdom, mainland Europe, or the United States. Developed in the 1970s for the treatment of epilepsy, alcohol withdrawal syndrome, insomnia, and anxiety,[1 2] it is currently prescribed only in the former Soviet Bloc.

However, recent reports from Sweden, Finland, and the US describe its illicit use.[3] In the UK concern over the safety of phenazepam was raised in 2010, when three people in the East Midlands and six people in Scotland were admitted to hospital after phenazepam overdoses.[4 5] These cases and increased seizures of the drug by police led the Scottish Government to issue warnings about phenazepam. Having been alerted about its presence, we began screening necropsy blood samples for phenazepam in our forensic toxicology laboratory in Dundee from the end of January 2011.

To date, we have identified nine cases in which postmortem blood samples contained phenazepam. There was a history of drug misuse in all cases, and they occurred in men and women aged 31 to 45. Death was from the adverse effects of opiates in seven cases and from non-drug related causes in two.

This many cases suggests that the use of phenazepam by drug misusers in the UK is on the rise. Phenazepam can be obtained legally on the internet so it could become more widely used as substitute for controlled benzodiazepines or designer drugs such as mephedrone. Doctors should be aware of both the availability and illicit use of phenazepam in the UK.

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Competing interests: None declared.

1 Zacusov VV. A new psychotropic: phenazepam. Preparation. *Pharm Chem J* 1979;13:1094-7.
2 Buckley NA, Dawson AH, Whyte IM, O'Connell DL. Relative toxicity of benzodiazepines in overdose. *BMJ* 1995;310:219-21.
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5 Williams M. Warning over online "Valium." *Herald Scotland* 2010 Aug 24. www.heraldscotland.com/news/health/warning-over-online-valium-1.1050122.

Cite this as: *BMJ* 2011;343:d4207

LAWYERS' FEES AND NHS SAVINGS

Savings? What savings?

You don't have to be Ben Goldacre to realise that there is something fishy about the values quoted by Dyer for NHS payments of damages and legal costs in clinical negligence cases.[1] The justice secretary, Kenneth Clarke, used these values when he told listeners of BBC Radio 4's *Today* programme on 29 March 2011: "I mean in 2008-9 the NHS did pay out £312m (€350m; $500m) in damages; it paid far more out to lawyers in fees, £456m. So it is the wrong way round, and it is not where the NHS should be spending money."

According to data published by the National Health Service Litigation Authority, total payments for clinical negligence claims in 2008-9 were £769m, In evidence to Lord Justice Jackson, the authority stated that legal costs paid to claimants and defendants' lawyers in 2008-9 totalled £143m. In 2009-10 payments totalled £787m, with legal costs of just under £164m.

The proposed changes are bad for patients and bad for patient safety. The total amount saved is unlikely to exceed £30m and will easily be wiped out by the additional defence costs incurred as a result of the reforms.

The pity is that the reforms do not tackle the real issue: the current adversarial system is ridiculously expensive and unfair because patients are forced to initiate, investigate, and prove a claim. Behaviour drives costs. Defendants can avoid the bulk of their costs bill if they are prepared at the outset to strive to narrow issues and settle meritorious cases.

Everyone interested in patient safety and justice should be collaborating to devise a new model combining a full, open, and independent investigation of an adverse outcome conducted in a blame-free atmosphere. Proper compensation should be paid in avoidable medical accidents and steps taken to prevent mistakes being repeated.

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Competing interests: As a lawyer RL has an interest in lawyers' fees.

1 Dyer C. Changes to lawyers' fees in personal injury cases are set to save the NHS millions. *BMJ* 2011;342:d2112. (1 April.)

Cite this as: *BMJ* 2011;343:d4035

Author's reply

The values I quoted came from the justice secretary, Kenneth Clarke, who gave them during a radio interview.[1] They were widely quoted, but he had mixed them up. In fact, £456m is the cost for damages (£312m) plus defence legal costs (£40m) plus claimant legal costs (£104m).

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Competing interests: None declared.

Cite this as: *BMJ* 2011;343:d4036

ASSISTED DYING DEBATE

Call for an evidence based debate on assisted dying

As members of the steering committee of Healthcare Professionals for Assisted Dying, founded by Ann McPherson,[1] we welcome both O'Neill's and Terry Pratchett's contributions to the assisted dying debate.[2] We believe that an honest and open exploration of the issues surrounding assisted dying is crucial.

We were therefore dismayed by the motion proposed by Yorkshire Regional Council at the BMA annual representatives meeting that criticised the current editorial position of the *BMJ* on assisted dying. We also noted the inherent contradiction in the motion, which attacked the Commission on Assisted Dying, chaired by Lord Falconer, calling on the meeting to "support the BMA's stance in not giving evidence" to the commission while at the same time calling on the BMA Ethics Committee to make the association's opposition clear to the commission.

The media, including the *BMJ*, should question the proposals of those who seek change. But surely the validity of the arguments of those who seek to defend the status quo should also be questioned? As advocates of change, we accept with good grace the editorial hostility of some sections of the media, but we welcome the fact that publications such as the *BMJ* and organisations such as the BBC are able to present both sides of the argument.

Assisted dying is a serious issue, on which people hold strong opinions. But can we not strive to have a respectful debate in which we accept that views are divided within the healthcare professions? We therefore repeat our call for the professional bodies to remain neutral on the issue of assisted dying and for an evidence based debate in which both sides are held to account.

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On behalf of the steering committee of Healthcare Professionals for Assisted Dying: Iain Chalmers, Harriet Copperman, Terence English, David Goldberg, Isky Gordon, Philip Graham, Evan Harris, Karen Sanders, Ray Tallis, Peter Townsend, Charles Warlow, Graham Winyard

Competing interests: As members of Healthcare Professionals for Assisted Dying we are supportive of a change in the law on assisted dying for terminally ill, mentally competent adults, within up-front safeguards.

1 Warlow C. Ann McPherson. *BMJ* 2011;342:d3424. (2 June.)
2 O'Neill D. Assisted dying: we are not alone. *BMJ* 2011;342:d3772. (15 June.)

Cite this as: *BMJ* 2011;343:d4222

Editor's note: The motion was passed in all its parts (Hawkes N. Doctors back BMA's refusal to join debate on assisted dying. *BMJ* 2011;343:d4188).

Missed opportunity to advance debate on assisted dying

In his review of Terry Pratchett's documentary on assisted dying O'Neill focused on caregivers' feelings.[1] From experience, I can confirm that caregivers and loved ones often try to dissuade patients from euthanasia. However, I submit that caregivers' feelings are a secondary concern because patients' feelings should count for more than caregivers'. As for families, evidence from the Netherlands is reassuring: on average, bereavements are more serene after euthanasia than after other deaths.[2]

Andrew died sadly on the cold sofa of Dignitas in Zurich. Had this occurred in Belgium, the Netherlands, or Luxembourg, he would likely have died at home, warmly and less prematurely. Recently I assisted in the euthanasia of a patient with advanced cancer who was in palliative care in Belgium. My patient hugged and kissed her

loved ones and died smiling, her son holding her arm, his head on her shoulder, her mother embracing her. Her other relatives and friends stood in a semi-circle holding hands.

The ensuing BBC2 debate concentrated on whether assisted dying (*a*) endangers vulnerable people and (*b*) impedes palliative care. The debaters ignored abundant empirical evidence on these two points—for example:

(*a*) Where assisted dying is allowed by law vulnerable people are under-represented among those who choose this option.[3 4] In Belgium legalisation shifted assisted dying not at patients' request to assisted dying at patients' request and increased carefulness about end of life decisions.[4] Over this time Belgians' confidence in their healthcare system has risen—from 87% in 1999 to 92% in 2008.

(*b*) In the three Benelux countries, palliative care greatly expanded after assisted dying was legalised. In Belgium about half the cases of euthanasia occur at the end of a multidisciplinary palliative care pathway.[5] Palliative care and assisted dying are not necessarily incompatible; they can mutually reinforce each other.[6]

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Competing interests: None declared.

JLB cofounded the first palliative care service in Belgium in 1979.

1 O'Neill D. Assisted dying: we are not alone. *BMJ* 2011;342:d3772. (15 June.)
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Cite this as: *BMJ* 2011;343:d4221