



Date: Sat, 27 Nov 1999 19:00:10 +0000
Reply-To: "R.N.Curnow" [REDACTED]
Sender: allstat
From: "R.N.Curnow" [REDACTED]
Subject: Re:Open letter to public inquiry on Bristol Royal Infirmary
Content-type: text/plain; charset="us-ascii"

Statistical analysis at BRI Inquiry

As members of the Expert Group advising the Bristol Royal Infirmary Inquiry, we have advised on the initial data processing and analysis and heard presentations of the thorough and impressive work of the statisticians contracted by the Inquiry. We have seen their reports submitted to the Inquiry. We are in full agreement with their response on Allstat dated November 26 to the earlier criticisms by Dr Poloniecki.

Mike Campbell, Robert Curnow, Stephen Gallivan, Alison Macfarlane, Klim McPherson

 Robert Curnow


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Date: Fri, 26 Nov 1999 14:27:37 GMT
Reply-To: [REDACTED]
Sender: allstat
From: [REDACTED]
Subject: Re: Open letter to public inquiry on Bristol Royal Infirmary

 Statistical analysis at BRI Inquiry

Dear Dr Poloniecki,

As those who worked on data analysis for the BRI Public Inquiry we would like to comment on your open letter to the Inquiry team (attached below). We are sorry for the delay in replying but some coordination was necessary.

We should first point out that for the Inquiry there was a team who worked together on the joint analyses and agreed the detailed approach to be taken, after discussion with a wider group of statisticians who acted as expert advisors. This letter comes from the analysts, who take full responsibility for the content of the published reports.

We emphasise that we are not replying on behalf of the Inquiry, and so cannot comment on either its brief or its possible future recommendations. It is also important to note that the purposes of the Inquiry were very different to those of the GMC consideration of serious professional misconduct, and the Inquiry is not seeking to decide "on a case to be accepted or rejected". The consequences are that the statistical approach should match the objectives of the Inquiry. The analysis of the GMC data needs to be considered entirely separately - one of us (DJS) was responsible for this analysis.

Your main concerns appear to be the many sources of multiplicity, and the resulting potential for finding false-positive conclusions. There are three sources of multiplicity: 1) multiple centres, 2) multiple operations, and 3) possible multiple looks at accumulating data. We share these concerns: there could be dangers in a prospective system for monitoring performance that repeatedly examined accumulating data, and then identified a centre or surgeon on the basis of apparently above-average mortality on a single class of operations.

However, we believe that examination of the statistical evidence to the BRI Inquiry will show that these valid concerns were, where appropriate, fully taken into account. Examining each source of multiplicity in turn:

1. Multiplicity of centres: The basis of our analysis was to examine if the performance of Bristol or any other centre was compatible with 'standard' between-centre variation. All interval estimates of 'excess mortality' (essentially leave-one-out residuals), and all assessed 'probabilities that excess mortality is greater than zero', were based on a random effects model that explicitly allowed for inevitable between-centre variability. You are right to say that such variability must be taken into account: we did so. Furthermore, the entire analysis was repeated for each centre symmetrically and the results reported. The conclusions are therefore not based on any selection procedure.

2. Multiplicity of operations: The analyses considered all operations, both individually and in combination. Emphasis was placed on the consistency of results across operation types, and with the 'significance' of overall totals.

3. Multiplicity of looks at the data: We were carrying out a

retrospective analysis of the data, and not making any statement concerning what might have been monitored at the time. We were not concerned with a trial-like decision, nor were we dealing with what might be done in the future. All this is made clear in the reports.

We also made it very clear that our analyses did not provide reasons for the differences which we found, and the evidence from the clinical case note review suggests that performance of individual surgeons was only one factor, and possibly not the most important one, which might explain the findings.

We again emphasise that we agree with your concerns about how to fairly identify and act on apparently 'divergent' performance in the future. This is a complex issue, even without considering the vital problems of case-mix and those of ascertaining non lethal but negative outcomes through routine data collection systems. For example, if the Inquiry is going to make recommendations for future monitoring procedures then there will be a need for careful consideration of repeated significance testing. Also, it is right that 'acceptable' performance is a clinical judgement and this might also be addressed by the Inquiry.

In conclusion, even casual scrutiny of the reports should show that the results concerning Bristol's divergent performance are robust enough to withstand a wide range of analyses and assumptions. We believe the analysis was carried out in a fair, open and reasonable way. All our reports are available from <http://www.bristol-inquiry.org.uk/brisDSAnalysis.htm> .

Finally, summaries of our reports are being submitted to medical and statistical journals, which will provide a forum for further discussion. We therefore regret that we will not contribute to allstat further correspondence on this issue.

Yours sincerely

Paul Aylin
Nicky Best
Stephen Evans
Gordon Murray
David Spiegelhalter

(Authors of statistical reports for the BRI Inquiry).

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Date: Wed, 10 Nov 1999 13:05:07 +0000 (GMT)

From: Jan Poloniecki [REDACTED]

To: skingswo@bri-inq.org.uk

Cc: Maria Shortis - Constructive Dialogue for Clinical Accountability
[REDACTED]

Subject: Open letter to public inquiry on Bristol Royal Infirmary

Ms Sue Kingswood
The Bristol Royal Infirmary Inquiry
2-10 Temple Way
Bristol BS2 0BY

Dear Sue,

Thank you for your letter of 8th October regarding my comments on Phase Two of the Inquiry. I would be happy for our correspondence including this letter to be put on the Inquiry's website on the understanding that it

represents my personal views and not that of any institution.

The statistical conclusions that have been drawn first by the GMC and now at the BRI Inquiry are fatally flawed by reason of inadequate allowance for repeated significance testing, and not taking into account the method by which Bristol was selected for scrutiny [See Reference for more detail regarding these flaws].

If the Inquiry is to be constructive, it must examine the control processes, and specifically the GMC. It must consider the process by which the case was referred to the GMC, and distinguish this from a random sampling procedure. It must consider the implications of the precedent set by the GMC's findings that Mr. Wisheart should have stopped operating after the 12th case. In doing so, it must be considered that no numerical argument for this conclusion was presented during the trial or in the judgement.

It must explicitly consider the frequency of testing to be allowed for in relation to multiple significance testing.

It must explicitly acknowledge that real differences in death rates exist between operators and between institutions. It must acknowledge that such differences cannot be removed from the NHS.

It should consider whether the question of what is an acceptable difference in death rates is capable of a single answer, and that some differences might be acceptable to some surgeons and some patients but not necessarily to all patients or all purchasers.

It should consider what is a suitable forum for discussion of this topic, and who is a competent authority to specify the size of difference that makes it an offence for a surgeon to continue operating.

Yours sincerely,

Jan

Reference: Half of all doctors are below average. BMJ 1998;316(Jun6):1734-6.
<http://www.bmj.com/cgi/content/full/316/7146/1734>



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