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## CORRESPONDENCE

## Re: The use and impact of national confidential enquiries in high-income countries

*BMJ Qual Saf* 2011;20:38–45

Angelow and Black<sup>1</sup> mount a series of scathing criticisms of the national confidential enquiries (NCEs). They suggest 'nesting' NCEs within prospective National Clinical Audits. The competing interest declared by one of the authors is that he chairs the National Clinical Audit Advisory Group. He was also a member of the group convened by the National Patient Safety Agency (NPSA) that advised on the future of the NCEs.

The criticisms are without merit, and I deal with them in turn.

First, it is alleged that the research evidence of the impact of the recommendations is poor, with no time series analysis or experimental studies and is restricted to considering their impact on the structure and process rather than the outcome of care.

The role of the NCE is to enable the profession to describe the gap between what is happening to selected groups of patients and what it believes should happen, to suggest improvements and to propagate those suggestions. The undoubted value of audit does not denigrate the value of detailed observational studies. Neither time series analyses nor experimental studies are relevant to assess the impact of what is best seen as a means by which the profession is able to learn from its own experience.

The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) does not depend upon demonstration of cause and effect, and therefore the argument that we are vulnerable to compounding factors and the dangers of hindsight is also irrelevant. When we looked at a sample of those who died within 30 days of starting systemic anticancer therapy, what mattered was not the discovery that the experts thought that death was attributable to the therapy rather than the disease in a large minority of cases; what mattered far more was that only 35% of patients received care that the advisors would accept from their own teams or their own institutions.<sup>2</sup> These are the views of mainstream professionals rather than hot-headed enthusiasts. They identified specific improvements which were immediately welcomed by the cancer tsar and the rest of the profession. The National Chemotherapy Advisory Group set out a series of recommendations to address these concerns, which were said by the DH in their Outcomes Strategy for Cancer in January 2011 to remain highly relevant and suitable for use in developing quality standards.

Similar impact could be demonstrated in respect of recent studies into parenteral

nutrition, acute kidney injury, sickle-cell disease and now surgery in older people. The authors make no reference to the citation indices of the NCEPOD reports, the clinical impact they have in the guidelines changed or the extent to which the studies have been replicated by the application of our toolkits which, like our reports, are all available free of charge from the NCEPOD website.

Second, they question the validity of recommendations in the reports. The principal example cited arises from

another before and after study conducted in a single hospital which looked at the impact of a NCEPOD recommendation that patients with a fractured femur should undergo pre-operative echocardiography claimed that this harmed patient care by increasing the incidence of operative delays of 3–10 days from 14% to 21% (though not statistically significant given the small study size).

In 2001, NCEPOD authors extrapolated that more than 200 patients a year were dying of undiagnosed aortic stenosis or other cardiac disease in the course of non-cardiac surgery. They suggested that an asymptomatic cardiac murmur should be investigated preoperatively by echocardiography. There was no proposal to subject all fractured femurs to echo. The report recognised that echo services were under pressure and called for proper resourcing.

The article referenced by the authors found that at Haywards Heath, in four cases, it took 4–10 days to organise an echo and suggested that clinicians should exercise their own judgement where it would involve a preoperative delay of >48 h. NCEPOD would hardly have disagreed since one of its principal recommendations then, as repeated in the recent study into surgery in older people, was that treatment of fractured neck of femur should not be delayed.

Over the following years, the profession agreed that surgical teams should investigate incidental signs of cardiac abnormality more actively, and in most places echo services improved to support them. The picture varies because there are still no nationally accepted indications for echo—in most places, recommendations regarding the advice about which murmurs should undergo evaluation have been refined. Far from indicating that NCEPOD's recommendations were invalid, this episode shows how two suggestions have changed practice. In the recent study *An Age Old Problem*, cases studied in 2008 described no deaths from undiagnosed aortic stenosis.<sup>3</sup>

Third, the most worrying criticism was the

concern about the lack of information on the cost benefit of NCEs was recognised by the major funder of NCEs in England and Wales in 2007.

The reference given is the minutes of a board meeting of the NPSA in March

2007. That board meeting received the NPSA's own detailed review of NCEPOD's work, which included among numerous other favourable comments:

At approximately £0.5m per study, the panel considered that NCEPOD provided remarkably good value for money but question whether this could be sustained.

Incidentally, the authors failed to reference similarly favourable external reviews of NCEPOD's standing and impact carried out by the National Institute for Clinical Excellence in 2004 and a reputation audit by Opinion Leader Research in 2006. The latter praised our methodology and reported that recommendations often led to action by NHS trust boards because we are seen as independent.

NCEPOD's grant has been reduced so that we will now have £250 000 per study in future. It would be unfortunate if in fact this reduction was triggered by incorrect advice to the DH about cost–benefit.

Bertie Leigh

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## Authors' response

As with all approaches to assessing and improving the quality of healthcare, it is important that we establish, as rigorously as possible, their impact and cost-effectiveness. Just as we rightly expect healthcare practice and policy to be informed by research evidence, we should expect the same for quality assessment and improvement activities that consume resources that could otherwise be spent on care. Without rigorous evaluation, we cannot know how best to improve the quality of healthcare.

With this goal in mind, we undertook a long overdue review of the research evidence of the impact of national confidential enquiries (NCEs), an approach to assessing the safety of care that has changed little since its inception about 50 years ago. We concluded by pointing out the need for more rigorous evaluation of NCEs and suggested that the value of NCEs might be enhanced by conceiving them as complementary to prospective national clinical audits.<sup>1</sup> Mr Leigh seems to have viewed these recommendations as threats rather than as ways of strengthening the value of NCEs.<sup>2</sup>

Mr Leigh argues that rigorous evaluative methods are not needed or appropriate when considering the impact of NCEs. He writes that the National Confidential Enquiry into Patient Outcome and Death (NCEPOD) 'does not depend upon demonstration of cause and effect' so that neither 'time-series analyses nor experimental studies are relevant to assess the impact of what is best seen as a means by which the profession is able to learn from its own experience.' While clinicians' beliefs and opinions were seen as sufficient evidence of the benefits of healthcare activities in the past, this is no longer deemed adequate by the public, policy-makers, managers and most clinicians. Thus, his claim that NCEPOD is not 'vulnerable to compounding [sic] factors and the dangers of hindsight' is a bold assertion that needs to be demonstrated before it could be accepted. It is highly unlikely that the apparent impact of an NCE is not vulnerable to confounding or reporting bias.

Mr Leigh was also concerned that we questioned the validity of recommendations based on the findings of NCEs. The basis of our view is that as an NCE is a case series, it cannot establish causality, and therefore great care should be exercised in drawing conclusions as to how policy or practice should change. The value of a case series

lies in generating hypotheses that then need to be tested using analytical methods (case-control, cohort—including time-series—or experimental designs) to establish both causality and the strength of any observed relationships. Only then can recommendations for practice and policy be made with any confidence.

The lack of any published studies of the impact of NCE recommendations on the outcome of care means that there is no rigorous evidence as to the validity of such recommendations. The nearest to such an example is the study we cited by Guryel *et al.*<sup>3</sup> In that study, the authors suggest that a recommendation from NCEPOD to perform echocardiography before surgery, in patients suspected of having aortic stenosis, was associated with an increase in the proportion of patients experiencing an operative delay (of 3–10 days) from 14% to 26%. Although this was a small study in one hospital, it illustrates that unintended consequences may occur and underlines the urgent need for definitive evaluations of the impact of recommendations derived from NCEs.

Finally, Mr Leigh criticises our questioning of the cost–benefit of NCEs as unwarranted and states that this has not been a concern of the National Patient Safety Agency (NPSA) in England. To support our claim, we cited the minutes of the NPSA Board for January 2007 when the conclusions of a review of the Confidential Enquiry into Maternal & Child Health (CEMACH) were accepted. That review noted that 'without any cost v benefit analysis [the NPSA] were less able to assess its value in terms of cost' and concluded that 'there is a need to provide cost benefit analysis both in terms of implementation and non-implementation for the NHS in terms of clinical outcomes and patient safety. CEMACH must prove value for money...'. We agree with NPSA and feel this is consistent with the research evidence.

We were aware of external reviews such as those carried out by NICE and Opinion Leader Research that offered supportive opinions of NCEs, but, as we made clear, we confined our review to scientific evaluations in peer-reviewed journals.

Given the range of approaches available for assessing and improving the quality of healthcare, it's essential that opportunity costs are considered and that the limited resources available support the most cost-effective activities. This can only be achieved if everyone committed to enhancing quality accepts the need for rigorous evaluation to inform the best ways of organising and managing quality assessment and improvement.

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## Authors' response

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