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Letter to the Editor

Reply letter to: "A commentary on "cost-effectiveness of a national quality improvement programme to improve survival after emergency abdominal surgery, health economic evaluation" (int J Surg 2019; epub ahead of print)"

The quality improvement (QI) programme in the Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial aimed to improve survival for patients undergoing emergency abdominal surgery. Analyses of the trial results showed no survival benefit from this QI programme within 90 or 180 days of surgery [1]. In the cost-effectiveness analysis (CEA) [2], we assessed the outcomes of the QI programme within the 180-day trial period and over a lifetime, by taking both life expectancy and quality of life into consideration.

As highlighted by the commentator, the effectiveness of a QI intervention may be expected to improve with more successful implementation or fidelity. However, we aimed to evaluate the benefits of the QI programme as it was implemented in the EPOCH trial cohort, rather than how it would be expected to perform with optimal implementation. Problems in the implementation of the QI programme as part of the EPOCH study have been reported [3]. Our results reflect the cost-effectiveness of the QI programme as implemented. If the QI programme had been implemented more successfully, the cost-effectiveness results may be different, but this was beyond the scope of our analysis, with uncertain impacts on costs and effects. Nevertheless, the lessons learned from this trial could help to improve the design of future similar QI programmes. Further research may be worthwhile to investigate the cost-effectiveness of a fully implemented QI programme for these patients.

The commentator suggested the comparison should only be made under the same premise of background level of patient care. However, one aim of the EPOCH trial was to explore the feasibility of implementing the QI programme on a national scale [1]. Therefore, we evaluated its cost-effectiveness at the national level rather than by hospital. Additionally, the QI programme in the EPOCH trial required an extensive care pathway with 37 components to be implemented, rather than components related to nursing only [1]. In light of these, this study demonstrated the cost-effectiveness of the EPOCH QI programme and the results should not be interpreted as reflecting other QI programmes that include different components.

The quality-adjusted life year (QALY) is a generic measure of health which combines the impacts the intervention has on a patient's life expectancy and quality of life into a single outcome measure to quantify the potential health benefits [4]. QALYs are widely used internationally for assessing healthcare interventions and are the recommended measure for the National Institute for Health and Care Excellence (NICE) in the UK [5]. They are an important tool that enables comparisons of interventions across different diseases. Although use of the QALY faces criticisms [6,7], they remain the recommended metric for the measurement in a UK setting and the measure most relevant to inform the allocation of scarce resources in the UK NHS.

The EPOCH was a stepped-wedge randomised cluster trial and the implementation of the QI programme was at cluster level (about 6 hospitals each cluster). Patients undergoing the surgery before the implementation of the QI programme were in the usual care group and those undergoing the surgery after the programme implementation were in the QI group. This stepped-wedged cluster design may result in patients in the two arms (usual care and QI) being unbalanced (e.g. as a result of a temporal trend) although it was considered the best study design for evaluating the QI programme. The EPOCH subsample was patients undergoing surgery in eight hospitals which were amongst those which commenced the QI programme midway through the trial period, so the issue of unbalanced samples may also exist, although may be further mitigated by choosing hospitals who switched midway. Before analysing the data, we compared the baseline characteristics of patients in the two arms of the EPOCH subsample and they were broadly comparable with the exception of baseline HRQoL scores and proportion of patients with multiple surgical indications. These differences have been adjusted for in data analysis and we have noted this as a potential limitation.

The main conclusions about the cost-effectiveness of the QI programme were made based on the analyses for the EPOCH subsample. We conducted multiple regression models and the best-performing model indicated by the goodness-of-fit measures such as Akaike Information Criteria (AIC) was used to predict outcomes for the rest of the EPOCH population. This was a secondary analysis to explore whether the conclusions were consistent, which they were. The approach of using the models based on the subsample to predict HRQoL and costs of the whole EPOCH population may be a concern, however, this did not affect the conclusion that the QI programme appears not cost-effective.

In summary, this CEA showed that the EPOCH QI programme is unlikely to be cost-effectiveness for patients undergoing emergency abdominal surgery in the UK. The results were supported by the secondary analysis for the whole EPOCH population. QALY is the recommended metric of health benefits to inform the allocation of scarce resources in the UK NHS. The stepped-wedge cluster design of the EPOCH trial might lead to unbalanced patients in the two arms, but patients' baseline characteristics were broadly comparable and the differences in HRQoL and proportion of patients with multiple surgical indications have been adjusted for in data analysis.

We would like to thank the commentator for the comments on this manuscript and welcome discussion of this work.

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Ethical approval

The trial was approved by the East Midlands (Nottingham 1) Research Ethics Committee Research Ethics Committee (13/EM/0415).

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Author contribution

Fan Yang conducted data analysis and was primarily responsible for drafting the manuscript, Simon Walker and Gerry Richardson contributed to study design, data analysis and interpretation of the results. Tim Stephens, Mandeep Phull, Ann Thompson, and Rupert M. Pearse contributed to interpretation of the results. All authors reviewed the manuscript, commented on the manuscript and approved the final version.

Trial registry number

1. Name of the registry: ISRCTN registry
2. Unique Identifying number or registration ID: ISRCTN80682973
3. Hyperlink to the registration (must be publicly accessible): Lancet protocol 13PRT/7655 http://www.epochtrial.org/epoch.php?page=docs

Guarantor

Fan Yang.

Provenance and peer review

Not Commissioned, internally reviewed.

Data statement

Due to information governance restrictions imposed by organisations governing data access, we are unable to share the trial data unless applicants secure the relevant permissions. All trial materials are freely available on the trial website (www.epochtrial.org).

Declaration of competing interest

None.

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