A national quality improvement programme to improve survival after emergency abdominal surgery: the EPOCH stepped-wedge cluster RCT

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Scientific summary

The EPOCH RCT

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Scientific summary

Background

Emergency abdominal surgery is associated with poor postoperative outcomes. Around 30,000 patients undergo this type of surgery each year in the UK NHS, with 30-day mortality rates in excess of 10% and wide variation in standards of care between hospitals. Several groups have studied the effect of quality improvement (QI) initiatives to implement individual interventions or 'care bundles' of several treatments, thereby improving care for these patients. Overall, the findings of these small studies suggest survival benefit, but most utilised uncontrolled cohort designs, which are associated with a high risk of bias. The feasibility and benefit of a national QI programme to implement a more extensive acute care pathway for this patient group remain uncertain. We studied the effectiveness of a national QI programme to implement a care pathway to improve survival for these patients.

Trial intervention

The Enhanced Peri-Operative Care for High-risk patients (EPOCH) trial care pathway was developed through an evidence-based Delphi consensus process, building on previously published guidelines, to produce a list of 37 component interventions considered best usual practice for this patient group. We used an evidence-based QI programme to implement this care pathway by changing the practice and culture of patient care. QI leads from surgery, anaesthesia and critical care were tasked with leading a hospital-wide improvement programme to implement the care pathway, with the support and guidance of the national EPOCH trial QI team. The key features of the QI methodology were (1) reframing the high mortality rates for these patients as a 'social problem', requiring reorganisation of existing care processes rather than technical innovation; (2) supporting QI leads to engage their front-line staff and executive leaders in the change process; (3) training local QI leads in basic improvement skills; and (4) supporting teams to analyse and feed back key process measure data to their colleagues to drive change. The EPOCH trial QI team provided a 1-day activation and education meeting for each geographical cluster shortly before or during the first week of activation, with further advice and support by telephone and e-mail. All QI resources, including data analysis tools, training materials and promotional documents, were available online through a virtual learning environment (VLE). Follow-up meetings were held 16 weeks after activation, so that QI leads and their teams could meet and share experiences. There were also two national meetings to facilitate shared learning during the trial period. QI leads were eligible to attend these only if their hospital had been activated to the trial intervention.

Methods

We studied the effect of the QI programme to implement the EPOCH trial care pathway in a stepped-wedge cluster randomised trial. This design allowed all participating hospitals to adopt the intervention at some point during the trial, while adjusting for the effect of temporal changes during the trial period. NHS hospitals delivering an emergency general surgical service were eligible for inclusion, provided they undertook a significant volume of emergency abdominal surgery cases. Hospitals were required to nominate specialty leads from surgery, anaesthesia and critical care, and to secure support from their NHS trust board or equivalent. Hospitals that were already implementing a care pathway to improve treatment for this patient group were excluded. Patients were eligible for inclusion in the data analysis if they were aged $\geq$ 40 years and undergoing emergency open abdominal surgery in a participating hospital during the 85-week trial period. Patients were excluded from the analysis if they were undergoing a simple appendicectomy, surgery related to organ transplant, gynaecological surgery, laparotomy for traumatic injury, treatment of complications of recent elective surgery or if they had previously been included in the EPOCH trial. Sample size calculations

were based on an analysis with fixed time effects and random cluster effects, modified to exclude data collected during the 5-week period in which the intervention commenced in individual clusters. Using Hospital Episode Statistics (HES) data, we estimated that 27,540 eligible patients would be registered across 90 NHS hospitals over 85 weeks, with a 90-day mortality rate of 25% in the usual care group and a between-hospital coefficient of variation of 0.15. Assuming independent hospital effects and a 5% significance level, the trial would have 92% power to detect a reduction in 90-day mortality from 25% to 22%. Hospitals were organised into 15 geographical clusters and commenced the QI programme in random order, based on a computer-generated random sequence, over an 85-week period. Trial data were collected through the National Emergency Laparotomy Audit database and linked using unique patient identifiers to HES and the Office for National Statistics in England and Wales and the Information Services Division of NHS Scotland. The trial was approved by the East Midlands (Nottingham 1) Research Ethics Committee.

The primary outcome measure was mortality within 90 days of surgery. Secondary outcomes were 180-day mortality, length of hospital stay and hospital readmission within 180 days. Analyses were performed on an intention-to-treat basis. The primary outcome was analysed using a mixed-effects parametric survival model, adjusting for time-related effects. In accordance with our analysis plan, we did not test patient-level process measures for statistical significance.

The trial included an ethnographic study of the adoption of the care pathway in six theoretically sampled sites in the UK and a mixed-method process evaluation of the QI programme and all trial sites. The ethnography combined observation of routine practice with interviews with team members in sampled sites to provide a rich qualitative understanding of the delivery of the QI training and the work of clinical leads in seeking to improve care in their hospitals. Data analysis for the ethnographic data were based on the constant comparative method and informed by sensitising concepts from the literature and discussions among the EPOCH trial team.

For the process evaluation, we collected a range of QI programme activity data (including data on participation in programme activities, such as meetings, and use of the trial VLE) and sent an exit questionnaire to all QI leads. The 37-item, online questionnaire, administered at the end of the trial, was designed to allow description of activities undertaken, as well as their overall experience of leading the improvement projects. Only one response was required per hospital, but QI leads were asked to complete the questionnaire with colleagues. The programme activity and questionnaire data were analysed and reported using descriptive statistics. Free-text data in the exit questionnaire were coded by two investigators, using both inductive and deductive content analysis techniques.

For the health economic analysis, data describing survival and inpatient stay after surgery, and data on resource use and health-related quality of life (measured using the EuroQol-5 Dimensions, three-level version), collected in a sample of eight trial hospitals, were employed to estimate costs and quality-adjusted life-years (QALYs) of patients receiving the QI intervention and those receiving usual care in the subsample. Within-trial analyses were conducted first and then the cost-effectiveness over the lifetime was assessed by employing assumptions of long-term effects. Using regression models developed based on the subsample, costs and effects were estimated for the full trial population and the cost-effectiveness was assessed within the trial period and over the lifetime horizon.

Findings

In total, 15,873 eligible patients underwent surgery in 93 NHS hospitals between 3 March 2014 and 19 October 2015. Primary outcome data were analysed for 8482 patients in the usual care group and 7374 patients in the QI group. There were only modest improvements among the 10 measures selected to reflect key processes of care within the pathway. In some cases, the baseline rate of adherence to process measures was higher than anticipated. The primary outcome occurred in 1393 patients in the usual care group (16%) compared with 1210 patients in the QI group (16%) [QI vs. usual care hazard ratio (HR) 1.11,

95% confidence interval (CI) 0.96 to 1.28]. We found no differences in 180-day mortality or hospital readmission, and a small increase in hospital stay in the QI group (HR for discharge 0.90, 95% CI 0.83 to 0.97). There were only modest overall improvements in processes of patient care following QI implementation.

The process evaluation data confirmed that the QI programme was delivered as intended, with further activities and resources added in response to the needs of teams in individual sites. Attendance at the initial cluster educational meeting was very good, as was use of the online resources, but attendance at the cluster follow-up meetings was lower. The evaluation identified considerable variation in the use of the of the hospital-level interventions, including differences in which components of the pathway teams attempted to improve and the QI approaches they chose to do this. Reflections from QI leads, captured by the exit questionnaire, suggest that the social aspects of improving care are very important but time-consuming, as are activities related to measurement and data feedback to colleagues.

The ethnographic study revealed near-universal receptivity to the concept of a pathway as a means of improving perioperative processes and outcomes, but concern about the impact on appropriate professional judgement. Teams in the hospitals studied took different approaches to QI, particularly in the extent to which they made use of data and how they used the plan–do–study–act methodology. Some sites were troubled by wider organisational turbulence, which made achieving change through the EPOCH trial challenging; leads in other found it difficult to create a 'burning platform' that would prompt behavioural change among their colleagues. In all sites, the EPOCH trial was but one change among many, but there were signs that it could play a significant role in longer-term improvement trajectories.

In the base-case analysis on the subsample of patients in the health economics analysis, the QI intervention was associated with higher costs (mean difference £458) but fewer QALYs gained over the trial period (mean difference –0.002) than usual care; thus, the QI intervention was dominated. However, over the lifetime horizon, the QI intervention was associated with higher costs (mean difference £1508) and more QALYs gained (mean difference 0.131), resulting in an incremental cost-effectiveness ratio (ICER) of £11,511 per QALY, lower than the recommended threshold. The probabilities of being cost-effective at cost-effectiveness thresholds of £13,000, £20,000 and £30,000 per QALY were 51.8%, 56.3% and 58.7%, respectively, indicating considerable uncertainty. For the whole EPOCH trial population, the QI intervention was associated with higher costs and fewer QALYs over the trial period (i.e. it was dominated). However, over the longer time horizon, QI was associated with higher costs and more lifetime QALYs, generating an ICER of £31,632, higher than the highest cost-effectiveness threshold value of £30,000 per QALY. For patients at a higher risk of mortality and morbidity before surgery, this intervention was associated with more QALYs and increased costs within the trial period and over the lifetime horizon. The corresponding ICERs were £119,400 per QALY and £3839 per QALY, respectively.

Conclusions

Despite the success of some smaller projects, there was no survival benefit from a national QI programme to implement a care pathway for patients undergoing emergency abdominal surgery. Through a mixed-methods approach, we were able to identify the reasons for the difficulties in changing patient care in individual hospitals. To succeed, large, national QI programmes need to allow for differences between hospitals and ensure that teams have both the time and the resources needed to improve patient care. The intervention was not cost-effective within the trial period. However, the intervention may be cost-effective for the lifetime horizon, particularly for patients at greatest risk of death.

Trial registration

This trial is registered as ISRCTN80682973 and *The Lancet* protocol 13PRT/7655.

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