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#### QUALITY AND SAFETY

# The surgical safety checklist and patient outcomes after surgery: a prospective observational cohort study, systematic review and meta-analysis

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#### **Abstract**

**Background:** The surgical safety checklist is widely used to improve the quality of perioperative care. However, clinicians continue to debate the clinical effectiveness of this tool.

Methods: Prospective analysis of data from the International Surgical Outcomes Study (ISOS), an international observational study of elective in-patient surgery, accompanied by a systematic review and meta-analysis of published literature. The exposure was surgical safety checklist use. The primary outcome was in-hospital mortality and the secondary outcome was postoperative complications. In the ISOS cohort, a multivariable multi-level generalized linear model was used to test associations. To further contextualise these findings, we included the results from the ISOS cohort in a meta-analysis. Results are reported as odds ratios (OR) with 95% confidence intervals.

Results: We included 44 814 patients from 497 hospitals in 27 countries in the ISOS analysis. There were 40 245 (89.8%) patients exposed to the checklist, whilst 7508 (16.8%) sustained  $\geq$ 1 postoperative complications and 207 (0.5%) died before hospital discharge. Checklist exposure was associated with reduced mortality [odds ratio (OR) 0.49 (0.32–0.77); P<0.01], but no difference in complication rates [OR 1.02 (0.88–1.19); P=0.75]. In a systematic review, we screened 3732 records and identified 11 eligible studies of 453 292 patients including the ISOS cohort. Checklist exposure was associated with both reduced postoperative mortality [OR 0.75 (0.62–0.92); P<0.01;  $I^2$ =87%] and reduced complication rates [OR 0.73 (0.61–0.88); P<0.01;  $I^2$ =89%).

Conclusions: Patients exposed to a surgical safety checklist experience better postoperative outcomes, but this could simply reflect wider quality of care in hospitals where checklist use is routine.

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Key words: cohort studies; operative/mortality; postoperative care/methods; postoperative care/statistics and numerical data; surgery; surgical procedures

#### Editor's key points

- The surgical safety checklist is being promoted as an effective tool to enhance patient safety
- This study provides outcome data from a large and diverse collection of hospitals from around the world
- Surgical safety checklist use was associated with a lower incidence of postoperative mortality, but not of postoperative complications
- A pooled analysis of previous studies found that checklist use was associated with a lower incidence of both postoperative complications and death

More than 310 million surgical procedures are carried out worldwide every year. Estimates of morbidity and mortality vary.<sup>2–4</sup> However, recent data suggest that approximately 75 million patients will experience a postoperative complication, leading to two million deaths each year.  $^{5,6}\,\mathrm{An}$  important cause of avoidable harm is healthcare acquired illness or injury. In the UK, perioperative adverse events account for one in six patient safety incidents, and as many as half are potentially avoidable.8 Preventable adverse events are costly in both human and financial terms. The UK Department of Health estimates that iatrogenic harm costs the National Health Service more than £1 billion each year, 9 and other developed countries are likely to be exposed to similar costs.

Checklists are a simple and reproducible way to standardize selected aspects of patient care. The World Health Organisation (WHO) surgical safety checklist is the most widely used surgical checklist, comprising 19 items in three domains: before induction of anaesthesia, before surgical incision, and before the patient leaves the operating theatre. Actions include checks for a variety of items including patient identity, introducing all team members, and antibiotic prophylaxis. 10 Since its inception, the checklist has been adopted in >4000 hospitals worldwide, 11 and is now considered a surrogate marker for quality of patient care. 12 However, there is only limited evidence of any effect of checklist use on health outcomes. 12 A previous meta-analysis reported insufficient high-quality evidence to draw robust conclusions, but there have been further studies since this publication. 12,13 Meanwhile, the clinical effectiveness of the surgical safety checklist remains unclear and some clinicians object to its use. 14,15

In the recent International Surgical Outcomes Study (ISOS) we collected prospective data describing surgical safety checklist use, along with patient outcomes following elective in-patient surgery in 27 countries.<sup>6</sup> Given the apparent widespread and growing use of the surgical safety checklist and the need for further evidence, we performed a prospective analysis of the effects of checklist exposure on postoperative patient outcomes. To contextualise the results of this analysis and to describe the current evidence for this intervention, we included these findings in a systematic review and metaanalysis of the published literature.

#### **Methods**

This was a pre-planned secondary analysis of prospectively collected data as part of ISOS. To complement this, we conducted a systematic review of the existing literature and a meta-analysis, in which we included the results of ISOS analysis.

#### ISOS analysis: design, setting, and participants

ISOS was a 7-day international cohort study, the main results of which have been reported previously. 6 In the UK, the study was approved by the Yorkshire and Humber Research Ethics Committee (Reference: 13/YH/0371). In other countries, regulatory requirements varied with some requiring research ethics approval and some requiring only data governance approval. The inclusion criteria were all adult patients (age ≥18 years) undergoing elective surgery with a planned overnight stay in hospital. Each participating country selected a single data collection week between April 2014 and August 2014. Patients undergoing emergency surgery, day-case surgery, or radiological procedures were excluded. During the 1week study period, data were collected for consecutive patients until hospital discharge, using standardized paper case record forms. Data included baseline demographic information, details of the surgical procedure, postoperative care, and in-hospital postoperative clinical outcomes. The use of the surgical safety checklist was collected by study investigators at each site as part of the core dataset. Data were censored at 30 days following surgery for patients who remained in hospital. Data were anonymized and entered onto a purpose-built secure internet database, which included automated checks for plausibility, consistency, and completeness.

#### ISOS analysis: outcome measures

The primary outcome measure for the analysis of the ISOS cohort was in-hospital mortality. The secondary outcome measure was the presence of any postoperative in-hospital complication assessed according to predefined criteria. 6,16 A patient with any of the following complications was deemed to have met the secondary outcome: surgical site infection, body cavity infection, pneumonia, urinary tract infection, bloodstream infection, myocardial infarction, arrhythmia, pulmonary oedema, pulmonary embolism, stroke, cardiac arrest, gastro-intestinal bleed, acute kidney injury, postoperative bleed, acute respiratory distress syndrome, anastomotic leak, or other un-categorized complications. The severity of complications was graded as mild, moderate, or severe. 16

#### ISOS analysis: statistical methods

Data were included for hospitals returning valid data for ≥20 participants, and countries with at least 10 participating hospitals. We dichotomized the sample according to the presence

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