**QUALITY AND PATIENT SAFETY** 

# Impact of the World Health Organization's Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study

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## **Editor's key points**

- The World Health Organization's Surgical Safety Checklist was introduced to improve perioperative morbidity, mortality, and adherence to clinical protocols.
- The role of changes in safety culture in the positive effects of this checklist was assessed in a prospective controlled intervention survey in operating theatre personnel.
- Successful checklist implementation had limited impact on patient safety culture in this single-site study, for unclear reasons that require further study.

**Background.** Positive changes in safety culture have been hypothesized to be one of the mechanisms behind the reduction in mortality and morbidity after the introduction of the World Health Organization's Surgical Safety Checklist (SSC). We aimed to study the checklist effects on safety culture perceptions in operating theatre personnel using a prospective controlled intervention design at a single Norwegian university hospital.

**Methods.** We conducted a study with pre- and post-intervention surveys using the intervention and control groups. The primary outcome was the effects of the Norwegian version of the SSC on safety culture perceptions. Safety culture was measured using the validated Norwegian version of the Hospital Survey on Patient Safety Culture. Descriptive characteristics of operating theatre personnel and checklist compliance data were also recorded. A mixed linear regression model was used to assess changes in safety culture.

**Results.** The response rate was 61% (349/575) at baseline and 51% (292/569) postintervention. Checklist compliance ranged from 77% to 85%. We found significant positive changes in the checklist intervention group for the culture factors 'frequency of events reported' and 'adequate staffing' with regression coefficients at -0.25 [95% confidence interval (CI), -0.47 to -0.07] and 0.21 (95% CI, 0.07-0.35), respectively. Overall, the intervention group reported significantly more positive culture scores including at baseline.

**Conclusions.** Implementation of the SSC had rather limited impact on the safety culture within this hospital.

Keywords: checklist; safety; safety climate; safety culture; surgery

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An estimated 234 million major surgical operations are performed annually worldwide.<sup>1</sup> As volume and importance of surgery in global healthcare increase, patient safety and quality in surgical care gain more attention.<sup>2 3</sup> Nearly one in 10 in-hospital patients experience iatrogenic events and more than half of them occur within perioperative care.<sup>4</sup>

In 2008, the World Health Organization (WHO) launched the Safe Surgery Saves Lives campaign and produced the 'Surgical Safety Checklist' (SSC) designed to reduce complications and deaths associated with surgery.<sup>5</sup> In an international pilot study, the SSC intervention resulted in a decrease in mortality (1.5–0.8%) and morbidity (1.7–1.1%).<sup>6</sup> Similar effects were found after implementing the more comprehensive Surgical Patient Safety System (SURPASS) checklist on patient outcomes in the Netherlands.<sup>7</sup> An important purpose of introducing the WHO SSC was to improve basic clinical processes as shown by the increase in appropriate antibiotic use from 56% to 83%, correct site marking from

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54% to 92%, and overall clinical safety processes from 34% to 57%, suggesting improved reliability in clinical care.<sup>6</sup>

Within the healthcare and other industries, checklists are more than a simple intervention. At a basic level, they function as reminders, which ensure basic care processes are adhered to (assuming whichever checklist is in place is used correctly). At a broader level, checklists and their usage have implications for team working, team cohesion, and safety culture. Checklists require people to change their work routines-for example, the Time Out phase of the WHO SSC requires the entire operating theatre team to gather and pause for a few seconds before proceeding with a procedure. Given that the healthcare industry was rarely using such interventions until recently, it has been argued that checklists are not a panacea that will fix every safety problem—rather they are likely to interact with the team and safety culture of the local team and wider organization.<sup>8</sup> If significant wider problems exist within an organization, the likely outcome is that a checklist will not have a positive benefit, and indeed, it may be reduced to a tick box exercise.<sup>9</sup>

Along these lines, checklist-driven improvements have been hypothesized to impact positively on team and safety culture and, in turn, to drive decreases in patient mortality and morbidity.<sup>6</sup> Safety culture relates to personnel's attitudes, common thoughts, and behaviours within an organization.<sup>10</sup> Although not easy to measure, a number of surveys that assess safety culture have been published<sup>11</sup> alongside studies that investigate culture via ethnographic approaches and observation.<sup>12 13</sup> Survey instruments typically investigate a range of facets of culture, including team working,<sup>14 15</sup> communication,<sup>16 17</sup> and attitudes to safety.<sup>18</sup> Studies to date have linked occurrence of patient safety incidents with safety culture and hence tools to monitor culture within hospitals have been implemented.<sup>11 19</sup>

To date, the effects of the WHO SSC have been evaluated regarding compliance,<sup>20</sup> communication,<sup>21 22</sup> staff attitudes, and partly safety culture.<sup>18 22 23</sup> Published studies are typically pre-/post-implementation designs without control groups. The primary aim of this study was to measure the effects of the WHO SSC on operating theatre personnel perceptions of safety culture using a controlled study design. We hypothesize that implementation of the SSC is associated with positive changes in safety culture.

### Methods

The study was reviewed by the Regional Committee for Medical and Health Research Ethics (Ref: 2009/561) and the hospital privacy Ombudsman, who approved it (Ref: 2010/ 413). Written informed patient consent was waived. Operating theatre personnel gave consent by responding to the surveys.

#### Study design

This was a prospective controlled intervention study using pre- and post-intervention surveys with the intervention and control groups. The primary outcome was the changes of safety culture perceptions in operating theatre personnel after implementation of the Norwegian version of the WHO Surgical Safety Checklist, introduced after WHO guidelines.<sup>5</sup> A randomized stepped wedge design<sup>24</sup> was utilized to determine the order of intervention introduction across three surgical specialities (orthopaedic, thoracic, and neurosurgery—see the following section for details) in the intervention site of the hospital. Compliance with checklist usage was the secondary outcome.

#### Study population

The study took place in Haukeland University Hospital, a 1100-bed tertiary university hospital in the western part of Norway. The perioperative setting comprised 10 surgical departments and the accompanying departments of anaesthesia and intensive care administering anaesthesia and perioperative care. The target population of perioperative personnel included all eligible surgeons, anaesthetists, operating theatre nurses, nurse anaesthetists, and ancillary personnel (unit assistants, clerks, and cleaning assistants) located at two separate sites. The intervention group comprised personnel from orthopaedic surgery, thoracic surgery, and neurosurgery placed at the central hospital site. The control group comprised personnel from ear, nose, and throat; maxillofacial; plastic; endocrine; urology; gastrointestinal; obstetric; and gynaecological surgery specialities located at the peripheral hospital site. Within the hospital, operating theatre clinical and other personnel work in the separate sites without rotation, except for a few anaesthetists. Inclusion was based on work list information. A census approach was taken for recruitment-with the entire target population (as described above) invited to take part in the study. A total of 349 participants responded at baseline and 292 responded at post-intervention.

#### Study procedure

The study was carried out over 9 months from October 2009 to July 2010. Baseline and post-Checklist intervention survey data were collected during two 4 week periods in October 2009 and June 2010 (Fig. 1). The surveys were forwarded to the operating theatre personnel using both hospital electronic mail and the internal mail system (i.e. hardcopies). Identification numbers were assigned to or printed on each questionnaire to match individuals for the pre- and postintervention surveys. Compliance with the Checklist was prospectively recorded (i.e. Checklist 'used' or 'not used') via the computer-based operating planning system within the operating theatres of the hospital. Nurse anaesthetists and theatre nurses also checked manually whether the paper versions of the Checklist had been completed for every case.

#### **Checklist intervention**

The Norwegian version of the SSC was introduced using a randomized sequential roll-out of the intervention.<sup>24</sup> In a joint venture between the Norwegian National Unit for Patient Safety, the Health Trust of Førde, and the Surgical

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