Causal Analysis of World Health Organization’s Surgical Safety Checklist Implementation Quality and Impact on Care Processes and Patient Outcomes

Secondary Analysis From a Large Stepped Wedge Cluster Randomized Controlled Trial in Norway

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Objective: We hypothesize that high-quality implementation of the World Health Organization’s Surgical Safety Checklist (SSC) will lead to improved care processes and subsequently reduction of peri- and postoperative complications.

Background: Implementation of the SSC was associated with robust reduction in morbidity and length of in-hospital stay in a stepped wedge cluster randomized controlled trial conducted in 2 Norwegian hospitals. Further investigation of precisely how the SSC improves care processes and subsequently patient outcomes is needed to understand the causal mechanisms of improvement.

Methods: Care process metrics are reported from one of our earlier trials conducted in 2 Norwegian hospitals. Further investigation of precisely how the SSC improves care processes and subsequently patient outcomes is needed to understand the causal mechanisms of improvement.

Results: A total of 3702 procedures (1398 control vs. 2304 intervention procedures) were analyzed. High-quality SSC implementation (all 3 checklist parts) improved procedures and outcomes of care. Use of forced air warming blankets increased from 35.3% to 42.4% (P < 0.001). Antibiotic administration postincision decreased from 12.5% to 9.8%, antibiotic administration preincision increased from 54.5% to 63.1%, and nonadministration of antibiotics decreased from 33.0% to 27.1%. Surgical infections decreased from 7.4% (104/1398) to 3.6% (P < 0.001). Adjusted SSC effect on surgical infections resulted in an odds ratio (OR) of 0.52 (95% confidence interval [CI]: 0.38–0.72) for intervention procedures, 0.54 (95% CI: 0.37–0.79) for antibiotics provided before incision, and 0.24 (95% CI: 0.11–0.52) when using forced air warming blankets. Blood transfusion costs were reduced by 40% with the use of the SSC.

Conclusions: When implemented well, the SSC improved operating room care processes; subsequently, high-quality SSC implementation and improved care processes led to better patient outcomes.

Keywords: care process, checklist, complications, implementation fidelity, operating room, randomized controlled trial, surgery

The World Health Organization’s (WHO) Surgical Safety Check-list (SSC) has been reported to reduce both morbidity and mortality.1–2 The SSC was developed to improve teamwork, communication and consistency of care in operating rooms.3 Enhanced teamwork and communication is one of the mechanisms used to explain SSC effects on patient outcome.4–8 Facilitators of SSC use that strengthen implementation are reported to be education and training, audit and feedback interventions using local data on actual checklist usage, fostering local champions and leadership, and accountability for compliance.9–7 Perceived implementation barriers are design-related issues (including poor local tailoring of items, nonintegration into operating room workflow), lack of structured implementation approach, and resistance from senior clinicians.7,8

Precisely how the SSC, or indeed any other checklist that has been evaluated to date, achieves its effectiveness is far from clear. Mechanisms postulated to drive SSC positive effects have been associated with implementation strategies and actual utilization of the checklist.9,10 Moreover, in studies that find reduced morbidity and mortality,10–12 quality of SSC implementation is assumed to be
an important explanatory mechanism. A large scale study of the SSC effects in Canadian hospitals, including 215,711 procedures, did not find similar results. Nonetheless, the study raised concerns about quality of implementation strategies. In other studies high fidelity to the checklist intervention has proven important for improved patient outcomes. Taken together, the evidence-base to-date implies that explanatory mechanisms behind effectiveness (or lack thereof, as in the Canadian dataset) are yet to be fully understood.

Lack of understanding of what makes implementation of the SSC effective in some settings, but not in others severely hampers our ability to improve SSC implementation. We remain unaware of which implementation element matters the most and in which settings. In turn, this limits our ability to improve patient outcomes via better application of the SSC. In the WHO SSC implementation guide, hospital leadership, and monitoring of surgical results and complications are recommended to achieve successful implementation. Tracking of process and outcome measures have been encouraged, exemplified by percent of procedures having antibiotics provided at the correct time. Accordingly, the WHO SSC implementation guide rests on Donabedian’s approach to clinical quality improvement, in which improved structures enhance care processes; and both structures and care processes, in turn, improve patient outcomes.

This study investigates how exactly the SSC improves patient outcomes via analysis of clinical structures, processes, and outcomes related to SSC implementation in the operating room. The main hypotheses we are testing are:

$H_1$: High-quality implementation of the SSC improves care processes in the operating room;

$H_2$: Improved care processes lead to better patient outcomes;

$H_3$: Improved implementation (fidelity to SSC) leads to improved compliance with critical standards (improved care processes), and improved compliance leads to improved outcomes.

The clinical improvement framework and associated hypotheses we tested, based on Donabedian’s approach, are illustrated in Figure 1.

**METHODS**

**Study Design**

Our study was designed as a stepped wedge cluster randomized controlled (RCT) quality service improvement trial in 2009 to 2010. The stepped wedge cluster RCT design is increasingly used to evaluate patient safety interventions that inherently are expected to do more good than harm. The intervention is sequentially introduced to the clusters in a random way at different time points, which is particularly useful when the intervention cannot be delivered to all participants at the same time. Hence, the checklist intervention was provided to 1 cluster at the time. This study was conducted in 2 Norwegian hospitals, a community hospital and a tertiary teaching hospital, and included 5 surgical specialties (orthopedic, cardiothoracic, neurosurgery, urology, and general surgery). The dataset from the original study was further analyzed to search for the effects of process metrics on patient outcomes. Three of the study clusters had such process metrics registered, and were therefore included, hence all other clusters were excluded (SDC 1, http://links.lww.com/SLA/B343).

The 3 specialties (clusters of the RCT) were randomly allocated to receive the SSC intervention. Allocation sequences were generated by a draw of numbers into a rank order deciding the roll-out of the checklist intervention. The allocation assessor was blinded for clusters corresponding to the numbers. The SSC implementation started sequentially over 3 to 4 weeks after a 3-month baseline period. The intervention continued for 3 months after all clusters received the intervention. Details of the stepped wedge cluster (RCT) design and the SSC intervention have previously been described.

The SSC consists of 3 parts, the Sign in before anesthesia induction, the Time out before incision, and the Sign out at the end of the surgical procedure—before transfer to postoperative care unit. The SSC adapted for use in Norwegian operating rooms is presented in SDC 2, http://links.lww.com/SLA/B343. In the Norwegian check-list version, items to prevent hypothermia are listed both under the Sign in and under Time out parts.
Use of routinely collected anonymized data was regarded as clinical service improvement by the Regional Committee for Medical and Health Research Ethics (Unique identifier: 2009/561). Hence, approval of the study was given by the hospital privacy Ombudsmen (Ref: 2010/413) and hospital managers.

**Outcome Measures**
Measures relevant to operating room care processes and patient outcomes were the primary endpoints; quality of SSC implementation was a secondary endpoint.

To avoid possible study biases by introduction of new measurements on process metrics associated with items on the checklist, which could be regarded as competing interventions, we used process metrics that were already being registered as routine practice. Care process metrics were preoperative site marking; actions to sustain normothermia (prewarmed intravenous fluid, prewarmed blankets, forced air warming blankets); and timeliness of infection prophylactic provision of intravenous antibiotics. The latter was categorized into before and after incision, and no antibiotics.

Patient outcomes included surgical infection, surgical wound rupture, cardiac complication, respiratory complication, postoperative bleeding, and intraoperative blood transfusion. We classified the primary endpoints as 0 for no complication and 1 for verified complication. Secondary outcome was blood transfusion costs in USD.

Implementation quality was prospectively measured by the fidelity to actual use of the SSC, defined as compliance with all 3 parts of the checklist. To investigate SSC fidelity impact on patient outcomes as previously shown by Mayer et al,\(^\text{16}\) we categorized utilization of the Sign in, Time out and Sign out parts used as: no checklist; one of the checklist parts; combinations of 2 of parts; all 3 parts; and any parts.

**Data Collection**
Data from all age groups and elective or emergency surgery are included. Surgical procedures which the SSC was not adapted for were excluded (ie, donor surgery). Patient characteristics include age, sex, and comorbidity with the American Society of Anesthesiologists (ASA) classification. Further, data on elective or emergency surgery, type of anesthesia (general vs. regional), surgical procedures as orthopedic, cardiothoracic or neurosurgical, and duration of surgical procedures (knife time) were recorded in the hospital administrative data system as routine practice by clinical staff. Adherence to the SSC was prospectively recorded on a paper form by nurse anesthetists and operating room nurses. All items were marked for each patient, as the SSC parts were carried out. To decide whether it had been used or not, we determined a cut-off requiring more than 60% of items to be registered on the paper version. Additionally, the SSC parts were electronically recorded as used (all items required performed) or not, by the operating room nurse. If there were any discrepancies between paper and electronic recordings of SSC fidelity, the latter was preferred.

To ensure high fidelity to checklist performance, members of our multidisciplinary implementation team were present in the operating rooms. They provided advice through direct guidance and observations on site. Evaluation meetings on checklist fidelity were conducted with the operating teams in the operating theater 2 weeks and 2 months postimplementation of the SSC. Feedback on checklist compliance rates was posted on wall posters outside the operating rooms throughout the study.

Patient complications were assigned *International Classification of Diseases—tenth version (ICD-10)* codes recorded by surgeons or ward physicians at patients’ discharge from hospital. All outcome data were extracted from hospital administrative databases and quality checked to verify incidence of any recorded complications.\(^\text{15}\)

**Data Handling**
The assessors handling and evaluating data validity were blinded to the randomization of patients and procedures into control and intervention cohorts. To protect the study from information bias, clinicians were not informed as to which study endpoints that were measured. All recovery and postoperative ward staff were not informed about the study, cohorts, or outcome of interest, and performed care as usual. Complications identified through *ICD-10* codes and care process data were verified against the patients’ medical records.\(^\text{12}\) This study followed the extended CONSORT statement for nonpharmacological randomized trials.\(^\text{21}\)

**Statistical Analysis**
The surgical clusters provided data in all the stepped wedges, being their own controls before and after the introduction of the SSC intervention. Hence, data across the cluster steps before (controls) were compared with the steps after SSC implementation (intervention).\(^\text{19}\) Fuller implementation of the SSC (ie, more parts completed) indicates higher fidelity to the intervention.\(^\text{22}\) To investigate effect of procedures 0 for highest SSC compliance we also compared controls to intervention procedures with full implementation of the SSC (n = 1743). Patient outcome, patient, and procedure characteristics for the control and intervention stages, and fidelity of checklist implementation (full vs. none) were analyzed using Pearson’s exact \(\chi^2\) test for categorical data, independent samples \(t\) test for continuous data, or nonparametric test (Mann–Whitney \(U\) test) as appropriate.

Based on our original sample size calculation, a minimum of 1100 patients were required in each one of the control and checklist groups for adequate study power.\(^\text{12}\) Intraclass correlation was not calculated as it is considered to have minimal impact on power due to the unidirectional stepped wedge implementation of the intervention.\(^\text{18}\) The primary endpoints were modeled with logistic regression. Model I: by SSC fidelity, and in Model II: controlling for patient and procedure characteristics, and process metrics. Analyses were carried out in SPSS version 23.0 (IBM Corp, Armonk, NY), and a 2-sided \(P\) value less than 0.05 was considered statistically significant.

**RESULTS**

**Patient Characteristics**
Overall, 3702 surgical procedures were included in this stepped wedge cluster RCT, with 1398 control procedures and 2304 intervention procedures. Distributions of patient and procedure characteristics across control and intervention arms are reported in Table 1. There were no differences between patients in age, sex, or comorbidity from control to intervention, though patients more often underwent orthopedic procedures, elective procedures, and regional anesthesia in the intervention arm.

**Implementation Outcomes (Fidelity of Checklist Usage)**
We measured the fidelity to the use of each SSC part. In the intervention group there was complete compliance with 1 part of the SSC only (mostly Sign in or Time out), in 4.7% (109/2304) of the surgical procedures. Combinations of 2 parts (Sign in and Time out, Time out and Sign out, or Sign in and Sign out) being fully utilized were found in 8.5% (196/2304) of the procedures. Full compliance, using all 3 parts (Sign in, Time out, and Sign out) of the SSC, was identified in 75.7% (1743/2304) of the procedures. A total of 38.9% (2048/2304) had used any parts of the checklist, including all cases of...
complete compliance with 1, 2, or 3 parts. Noncompliance with the checklists was 11.1% (256/2304) in intervention arm procedures.

Care Processes

The results of comparing all care process metrics from controls to intervention procedures and in procedures with high fidelity of SSC usage are reported in Table 2. Measures for preoperative site marking, normothermia protection (prewarmed intravenous fluids, prewarmed blankets, forced air warming blankets), and antibiotics before incision were all significantly more often used in the intervention procedures compared with the controls. When adjusting for elective and emergency procedures, surgical case-mix, and type of anesthesia, the use of normothermia protecting measures and infection prophylactic antibiotics remained better applied in the checklist arm of the trial (Table 3).

Patient Outcomes

Primary endpoints are reported in Table 4. Complications including respiratory, cardiac, surgical infections, wound rupture, bleeding, and blood transfusions were all significantly reduced in the intervention arm of the trial. In procedures with no use of the checklist (n = 256), there was a borderline significant reduction for infections and wound rupture, but not for the remaining outcomes. To statistically control for patient and procedure characteristics and process metric effects on complications, we used logistic regression analysis. Results are presented in Table 5. Use of forced air warming reduced odds ratio (OR) for cardiac complications and wound ruptures significantly. Further, infection prophylactic antibiotics provided before incision reduced OR for infections and wound rupture. In the intervention arm the SSC effects remained significant for all complications except respiratory complications.

### TABLE 2. WHO SSC Impact on Care Process Metrics in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010)

| Characteristic Category | Control (n = 1398) | Intervention (n = 2304) | P Value |
|-------------------------|-------------------|-------------------------|---------|
| Age in years, mean (SD) | 53.5 (23.4)       | 53.9 (23.4)             | 0.621   |
| Male sex, n (%)         | 759 (54.3)        | 1247 (54.1)            | 0.919   |
| Morbidity by ASA, n (%) |                   |                        |         |
| ASA I                   | 238 (17.0)        | 464 (20.1)             | 0.107   |
| ASA II                  | 568 (40.6)        | 964 (41.9)             |         |
| ASA III                 | 474 (33.9)        | 700 (30.4)             |         |
| ASA IV                  | 57 (4.1)          | 86 (3.7)               |         |
| ASA V                   | 2 (0.1)           | 2 (0.1)                |         |
| No ASA score            | 59 (4.2)          | 87 (3.8)               |         |
| Surgical procedure, n (%) |                |                        |         |
| Orthopedic              | 721 (51.6)       | 1557 (67.6)            | <0.001  |
| Thoracic                | 293 (21.0)       | 392 (17.0)             |         |
| Neuro                   | 384 (27.5)       | 355 (15.4)             |         |
| Surgery, n (%)          |                   |                        |         |
| Elective                | 693 (49.6)        | 1274 (55.3)            | 0.001   |
| Emergency               | 705 (50.4)        | 1030 (44.7)            |         |
| Anesthesia, n (%)       |                   |                        |         |
| Regional                | 446 (32.9)        | 1013 (45.5)            | <0.001  |
| General                 | 909 (67.1)        | 1213 (54.5)            |         |

| Care Process Metrics Category | Control (n = 1398) | Intervention (n = 2304) | P Value |
|------------------------------|--------------------|-------------------------|---------|
| Site marking                 | 971 (69.4)         | 1689 (73.3)             | 0.012   |
| Prewarmed intravenous fluid  | 766 (54.8)         | 1477 (64.1)             | <0.001  |
| Prewarmed regular blankets   | 1049 (75.0)        | 1856 (80.6)             | <0.001  |
| Forced air warming blankets  | 494 (35.3)         | 977 (42.4)              | <0.001  |
| Antibiotics                  | 408 (29.1)         | 734 (32.3)              | <0.001  |

| Antibiotics before incision  | 762 (54.5)         | 1454 (63.1)             | 118 (46.1) |
| Antibiotics after incision   | 174 (12.5)         | 228 (9.8)               | 85 (33.2)  |
| No antibiotics               | 462 (33.0)         | 624 (27.1)              | 53 (20.7)  |

| Care Process Metrics Category | No Checklist Parts Used vs. Control (n = 256) | P Value |
|------------------------------|-----------------------------------------------|---------|
| Site marking                 | 140 (54.7)                                   | <0.001  |
| Prewarmed intravenous fluid  | 136 (53.1)                                   | 0.633   |
| Prewarmed regular blankets   | 183 (71.5)                                   | 0.242   |
| Forced air warming blankets  | 58 (22.7)                                    | <0.001  |
| Antibiotics before incision  | 118 (46.1)                                   |         |
| Antibiotics after incision   | 85 (33.2)                                    |         |
| No antibiotics               | 53 (20.7)                                    |         |

| Care Process Metrics Category | All SSC Parts Used vs. Control (n = 1743) | P Value |
|------------------------------|--------------------------------------------|---------|
| Site marking                 | 1336 (76.6)                                | <0.001  |
| Prewarmed intravenous fluid  | 1152 (66.1)                                | <0.001  |
| Prewarmed regular blankets   | 1439 (82.6)                                | <0.001  |
| Forced air warming blankets  | 815 (46.8)                                 | <0.001  |
| Antibiotics before incision  | 1194 (68.5)                                |         |
| Antibiotics after incision   | 143 (8.2)                                  |         |
| No antibiotics               | 406 (23.3)                                 |         |

1Procedures that include full use of WHO SSC, partial use of WHO SSC, or noncompliance.
2From Pearson's exact $x^2$ test, except $t$ test for age.
3ASA indicates American Society of Anaesthesiologists' risk score; RCT, randomized controlled trial; SD, standard deviation.
when adjusted for time effects (variation in process metrics and patient outcomes over time, i.e., per study month).

Postoperative bleeding identified through ICD-10 codes decreased from 2.6% (36/1398) to 1.0% (24/2304) in the intervention arm (P < 0.001). In support to this finding, adjusted for patient and procedure characteristics the risk of postoperative bleeding was reduced in the intervention steps (Table 5). Further, evaluating intraoperative blood loss percentiles, there was significant reduction of 750 mL to 1000 mL blood loss (6.0% vs. 4.5%), and increase for intraoperative blood loss percentiles, there was significant reduction of 750 mL to 1000 mL blood loss (6.0% vs. 4.5%), and increase for

| TABLE 3. WHO SSC Impact on Care Process Metrics in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010) |
| Care Process Metrics | Intervention Procedures vs. Control | Use of All 3 WHO SSC Parts vs. Control |
|-----------------------|--------------------------------------|----------------------------------------|
|                       | OR 95% CI P Value                     | OR 95% CI P Value                      |
| Intravenous fluid (room tempered* vs. prewarmed) | 1.46 (1.23, 1.73) <0.001 | 1.53 (1.27, 1.85) <0.001 |
| Blankets (room tempered* vs. prewarmed)       | 1.31 (1.10, 1.56) <0.001 | 1.44 (1.19, 1.75) <0.001 |
| Forced air warming (regular* vs. forced)       | 1.25 (1.07, 1.45) <0.001 | 1.43 (1.22, 1.68) <0.001 |
| Antibiotics (no* vs. preoperatively provided)  | 1.25 (1.07, 1.48) <0.001 | 1.51 (1.27, 1.79) <0.001 |
| Site marking (no marking* vs. marking)          | 1.01 (0.82, 1.24) 0.966 | 1.23 (0.97, 1.55) 0.084 |

*Reference value.

OR indicates odds ratio; P value – from likelihood ratio test in logistic regression adjusted for emergency vs. elective surgery, surgical case-mix, and anesthesia provided.

| TABLE 4. WHO SSC Impact on Patient Outcome in the Stepped Wedge Cluster RCT (n = 3702) in a Norwegian University Hospital (2009–2010) |
|---|---|---|---|---|---|
| Main Complications | Control (n = 1398) | Intervention (n = 2304) | No Checklist Parts Used vs. Control (n = 256) | Used All Parts of the WHO SSC vs. Control (n = 1743) |
|                     | Cases (%) | Cases (%) | P Value | Cases (%) | P Value | Cases (%) | P Value |
| Cardiac             | 112 (8.0) | 116 (5.0) | <0.001 | 15 (5.9) | 0.253 | 81 (4.6) | <0.001 |
| Respiratory         | 116 (8.3) | 93 (4.0)  | <0.001 | 20 (7.8) | 0.807 | 60 (3.4) | <0.001 |
| Infection           | 104 (7.4) | 82 (3.6)  | <0.001 | 10 (3.9) | 0.043 | 57 (3.3) | <0.001 |
| Wound rupture       | 25 (1.8)  | 5 (0.2)   | <0.001 | 0 (0.0)  | 0.044 | 5 (0.3)  | <0.001 |
| Bleeding            | 36 (2.6)  | 24 (1.0)  | <0.001 | 3 (1.2)  | 0.190 | 17 (1.0) | <0.001 |
| Blood transfusions  | 95 (6.8)  | 123 (5.3) | 0.072  | 19 (7.4) | 0.788 | 78 (4.5) | 0.005  |

1Intervention (include full use of WHO SSC, partial use of WHO SSC, and noncompliance).

Blood transfusions: are transfusions provided intraoperatively during surgical procedures; P value indicates analysis using Pearson’s exact χ² test.
telets in the SSC intervention
WHO SSC Impact on Intraoperative Blood Trans-

tions—in the Stepped Wedge Cluster RCT, Haukeland Uni-

versity Hospital (2009–2010). All blood transfusions = 1 or
more transfusions per surgical procedure.

increasing ASA classification; 1.01 (95% CI, 1.01–1.02) by increasing
knife time (minutes); 2.68 (95% CI, 1.26–5.69) in orthopedic pro-
dure(s); and 0.40 (95% CI, 0.20–0.81) for neurological procedures.

Forced air warming blankets were more frequently used in procedures
requiring blood transfusions OR 2.68 (95% CI, 1.26 to 5.69).

Costs for blood transfusion units in USD were overall
recorded per procedure for all transfusion units of plasma, eryth-
ocytes, or platelets administered to patients. Mean blood transfusion
costs in control procedures were USD 46.42 vs. USD 36.39 in the
intervention procedures (P = 0.092). The cost was USD 28.03 in
intervention procedures utilizing the SSC with high fidelity (all 3
parts, P = 0.007), representing a 40% cost reduction of blood
transfusions.

DISCUSSION

We studied in detail how the quality of the SSC implementa-
tion impacts its clinical effectiveness. Our results indicate that better
use of the checklist (ie, high-fidelity application) is needed for
clinical effectiveness to materialize. Both process metrics and patient
outcomes improved when all parts of the checklist were utilized. In
line with the UK study on the SSC,10 our results show that high-
fidelity use of the checklist, including all 3 parts of the checklist,
provides the lowest rates of odds ratio (Table 5).

Good-quality implementation of the SSC improved both care
processes and outcome for patients. The findings correspond well to
the clinical improvement model that we hypothesized in Figure 1.
The outcome improves as a function of better care processes being in
place and due to good actual use of the SSC.

Our results replicate early findings by Haynes et al—the SSC
improved safety and process measures (airway evaluation, pulse
oximeter use, intravenous catheter, antibiotics, patient identity and
site marking, and sponge count), though their process measures were
not compared directly to patient outcomes.11 The WHO recommends
monitoring safety and care processes associated with the SSC
implementation.16 This is in accordance with Donabedian’s frame-
work for improvement that outlines care structures, processes, and
outcomes.1723 The strength of this perspective lies within this
interrelationship where structure (the SSC in this case) improves
the process, and both structure and process then improve out-
comes.1617 This was especially evident in the use of hypothermia
preventing care processes (forced air warming) and timeliness of
infection prophylactic antibiotic provided in the operating room.

Even mild hypothermia (34°C to 36°C) is known to increase
the incidence of surgical wound infections,24 blood transfusions,25
prolonged hospitalization,2425 and prolonged recovery from drugs.26 Hence, to obtain patients’ normothermia is of vital impor-
tance to prevent intra- and postoperative complications. Ensuring
normothermia may be associated with increased use of prewarmed
blankets and forced warming air blankets after the SSC implemen-
tation (Table 2). Both the use of the SSC and active warming
blankets with forced air were significantly related to lower risk
of surgical wound rupture and cardiac complications. These results
correspond to previous research that indicated a 55% reduction in
risk of morbid cardiac events when normothermia was main-
tained.27 Hypothermia is well known to increase risk of cardiac
complications due to elevations in blood pressure, heart rate, plasma
concentrations of catecholamine, and thus myocardial ischemia by
turning myocardial oxygen balance into a net deficit.28 With an
increased use of prewarmed intravenous fluid, prewarmed blankets,
and forced warming air that correspond to items on the SSC, we find
it reasonable to attribute the effect on surgical wound ruptures and
cardiac complication to the checklist intervention and improved
hypothermia preventing care processes.

Another major finding is the improved timeliness of prophyl-
lactic antibiotics provided in operating rooms through good use of
the SSC. Antibiotics were administered to patients significantly
more frequent before incision and fewer times after incision in the
intervention procedures. Our results underline the recommenda-
tions on preoperative measures for surgical site infections recently
released by the WHO Guideline Development Group. Surgical
antibiotic prophylaxis is to be administered within 120 minutes
before incision customized to the half-life time of the antibiotics.29

Optimal timing of antibiotics has been estimated to potential reduce
infections in cardiac surgery by 9% to 31%.30 We identified a
significant reduced odds ratio for having a surgical infection,
0.54 (95% CI, 0.37–0.79), when antibiotics were provided before
incision rather than no antibiotics given or antibiotics provided after
incision. The use of checklists seems to influence on better timing of
antibiotics and reduction of surgical infections. The efficacy of
antibiotic prophylaxis in preventing surgical site infections has been
clearly established,31 hence antibiotic items on the checklist may
optimize and ensure adequate tissue levels of the antibiotic micro-
hial prophylaxis according to the half-life time of the drug at the
initial incision.

In a recent randomized controlled trial of a modified surgical
safety checklist, surgical wound, abdominal and bleeding-related
complications were significantly lowered in the checklist arm of
the study.32 Similarly, we observed a significant reduction in
postoperative bleeding from 2.6% to 1.0% and significant improve-
ment of intraoperative bleeding in the SSC intervention procedures.
Adding to this, we found a significant reduction in transfusions
of plasma, erythrocytes, and platelets in the SSC intervention
procedures. The clinical relations between the checklist, intraop-
erative bleeding, and need of blood transfusion are multifactorial;
however, we find the 2 hypothermia preventing items on the
checklist to be important. These relations are supported by the
improvement seen in use of forced air warming (Tables 2 and 3)
and subsequent reductions in bleedings and blood transfusions.
A plausible explanation is prevention of hypothermia induced by the
checklist intervention.25

Implementation of the SSC in US hospitals was estimated to
generate cost savings once it prevents at least 5 major complications
in hospitals with a 3% baseline rate on major postoperative
complications.33 We observed an approximate 40% cost reduction
associated with blood transfusions after implementation of the SSC in
our Norwegian hospitals. This result suggests a potential economic
benefit of the SSC intervention with improved care processes and
patient outcomes.
Strengths and Limitations

The use of a stepped wedge cluster randomized controlled methodology has been described as a robust study design for quality improvement clinical trials. It prevents extraneous influences as it has controls and intervention steps across the same time periods, and offers the possibility for modeling the effects of time on the effectiveness of the SSC intervention. However, our study has some limitations. Routinely collected data may be hampered by random errors or inaccuracy regarding data quality. In our study, data on SSC compliance were prospectively recorded on paper forms. These data were validated against concurrent electronic registrations of checklist utilization. Use of routine data may also have been of some benefit, as it made it possible to leave the healthcare personnel unaware of the specific data of interest to the study. This also applied to process data, as well as outcome measures. In our study we did not have access to care process metrics associated with every single item of the SSC, which is a limitation of our study. Items that did not have corresponding metrics could also have improved the care processes and may have contributed further to improvement of the outcomes. There were no changes in how routine data were recorded in the study period. Random errors would most likely be equally present both before and after the intervention steps.

Intraoperative bleeding was significantly lower in procedures where the SSC had been utilized. The size of this reduction does perhaps not seem clinically relevant when presented as average group values, and might need further exploration. However, the finding was strengthened by a significant reduction of blood transfusions in the SSC procedures. Another possible limitation was that the process metric “forced air warming” increased the odds ratio for having a blood transfusion. Initially, this might seem contradictory, but preventing hypothermia to prevent further blood loss, might render forced air warming more frequently used in patients with large bleedings. Thus, this offer a clinical explanatory mechanism to the seemingly increased likelihood of bleeding by “forced air warming.”

Another limitation was lack of patients’ core temperature as a parameter. However, due to incomplete data as temperature measures for all surgical procedures at the time of the study, and to avoid introducing competing interventions, we omitted use of patients’ core temperature as process metric. Further, for other important items like the team briefing and different risk assessments there were no available metrics. This might represent a limitation for our study as these items also may have contributed to the improved outcomes, however difficult to measure.

Between control and intervention steps there were no differences in patient characteristics. However, we acquired a larger proportion of orthopedic procedures and regional anesthesia in the intervention part of the study, due to the stepped wedge design, as following random allocation the intervention started in orthopedic surgery (with largest number of procedures). Variation in elective and emergency procedures may have been influenced by the intervention itself, as we previously reported a drop in unplanned returns to the operating room from 1.7% to 0.6%, \( P < 0.001 \). To control for these indifferences from control to intervention procedures we used logistic regression analysis to adjust for case mix and possible confounding effects. In surgical quality service improvement trials it is difficult to control for complexity and all possible factors that may influence or explain outcome.

Future Research

Our study sheds some light in what may be defined as clinical “micro-processes” within the operating room. The need remains to better understand how the complexity in hospital organization, safety culture, team cohesion, and communication impact on how well surgical improvement interventions are introduced and implemented, and how in turn care processes and patient outcomes improve as a result. Further studies are necessary to establish quantitative relationships between specific checklist items and related care processes and complications.

CONCLUSION

This study successfully applied Donabedian’s improvement framework of clinical structures, processes, and outcomes as a clinical causal model for the SSC intervention. Use of SSC improved operating room care processes; subsequently, high-quality SSC implementation and improved care processes led to better patient outcomes.

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REFERENCES

1. Borchard A, Schwappach DIL, Barbir A, et al. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. Ann Surg. 2012;256:925–933.
2. Bergs J, Hellings J, Cleemput I, et al. Systematic review and meta-analysis of the effect of the World Health Organization surgical safety checklist on postoperative complications. Br J Surg. 2014;101:150–158.
3. Weiser TG, Haynes AB, Lashoher A, et al. Perspectives in quality: designing the WHO Surgical Safety Checklist. Int J Qual Health Care. 2010;22:365–370.
4. Roux S, Rout S, Sevdalis N, et al. Do safety checklists improve teamwork and communication in the operating room? A systematic review. Ann Surg. 2013;258:856–871.
5. Thomassen Ø, Storesund A, Søfteland E, et al. The effects of safety checklists in medicine: a systematic review. Acta Anaesthesiol Scand. 2014;58:5–18.
6. Haynes AB, Edmondson L, Lipsitz SR, et al. Mortality trends after a voluntary checklist-based surgical safety collaborative. Ann Surg. 2017 [Epub ahead of print].
7. Russ SJ, Sevdalis N, Moorthy K, et al. A qualitative evaluation of the barriers and facilitators toward implementation of the WHO surgical safety checklist across hospitals in England: lessons from the “surgical checklist implementation project”. Ann Surg. 2015;261:81–91.
8. Haugen AS, Bakke A, Løvøy T, et al. Preventing complications: the preflight checklist. Eur Urol Focus. 2016;2:60–62.
9. Haynes AB, Berry WR, Gawande AA. What do we know about the safe surgery checklist now? Ann Surg. 2015;261:829–830.
10. Mayer EK, Sevdalis N, Rout S, et al. Surgical checklist implementation project: the impact of variable WHO checklist compliance on risk-adjusted clinical outcomes after national implementation: a longitudinal study. Ann Surg. 2016;263:58–63.
11. Haynes AB, Weiser TG, Berry WR, et al. A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med. 2009;360:491–499.
12. Haugen AS, Søfteland E, Almeland SK, et al. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster random controlled trial. Ann Surg. 2014;261:821–828.
13. Urbach DR, Govindarajan A, Sasmik R, et al. Introduction of surgical safety checklists in Ontario, Canada. N Engl J Med. 2014;370:1029–1038.
14. Leape LL. The checklist conundrum. N Engl J Med. 2014;370:1063–1064.
15. van Klei WA, Hof F, van Aarhem EEHL, et al. Effects of the introduction of the WHO “Surgical Safety Checklist” on in-hospital mortality: a cohort study. Ann Surg. 2012;255:44–49.
16. WHO Safe Surgery Saves Lives 2009. Available at: http://www.who.int/patientsafety/safesurgery/en/. Accessed May 22, 2017.
17. Donabedian A. The quality of care. How can it be assessed? JAMA. 1988;260:1743–1748.

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18. Brown C, Lilford R. The stepped wedge trial design: a systematic review. *BMC Med Res Methodol*. 2006;6:54.

19. Brown C, Hofer T, Johal A, et al. An epistemology of patient safety research: a framework for study design and interpretation. Part 2. Study design. *BMJ Qual Saf*. 2008;17:163–169.

20. Haugen AS, Søfteland E, Eide GE, et al. Impact of the World Health Organization’s Surgical Safety Checklist on safety culture in the operating theatre: a controlled intervention study. *Br J Anaesth*. 2013;110:807–815.

21. Boutron I, Moher D, Altman DG, et al. Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Ann Intern Med*. 2008;148:295–309.

22. Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. *Implement Sci*. 2007;2:40.

23. Donabedian A. *An Introduction to Quality Assurance in Health Care*. In: Bashshur R, ed. New York: Oxford University Press; 2003.

24. Kurz A, Sessler DI, Lenhardt R. Perioperative Normothermia to Reduce the Incidence of Surgical-Wound Infection and Shorten Hospitalization. *N Engl J Med*. 1996;334:1209–1216.

25. Sun Z, Honar H, Sessler DI, et al. Intraoperative core temperature patterns, transfusion requirement, and hospital duration in patients warmed with forced air. *Anesthesiology*. 2015;122:276–285.

26. Leslie K, Sessler DI, Bjørksten AR, et al. Mild hypothermia alters propofol pharmacokinetics and increases the duration of action of atracurium. *Anesth Analg*. 1995;80:1007–1014.

27. Frank SM, Fleisher LA, Breslow MJ, et al. Perioperative maintenance of normothermia reduces the incidence of morbid cardiac events: a randomized clinical trial. *JAMA*. 1997;277:1127–1134.

28. Frank SM, Higgins MS, Breslow MJ, et al. The catecholamine, cortisol, and hemodynamic responses to mild perioperative hypothermia. A randomized clinical trial. *Anesthesiology*. 1995;82:83–93.

29. Allegranzi B, Bischoff P, de Jonge S, et al. New WHO recommendations on preoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet Infect Dis*. 2016;16:e276–e287.

30. Koch CG, Nowicki ER, Rajeswaran J, et al. When the timing is right: antibiotic timing and infection after cardiac surgery. *J Thorac Cardiovasc Surg*. 2012;144:931–937.e4.

31. Classen DC, Evans RS, Pestotnik SL, et al. The timing of prophylactic administration of antibiotics and the risk of surgical-wound infection. *N Engl J Med*. 1992;326:281–286.

32. Chandhary N, Varma V, Kapoor S, et al. Implementation of a surgical safety checklist and postoperative outcomes: a prospective randomized controlled study. *J Gastrointest Surg*. 2015;19:935–942.

33. Semel ME, Resch S, Haynes AB, et al. Adopting a surgical safety checklist could save money and improve the quality of care in U.S. hospitals. *Health Aff*. 2010;29:1593–1599.

34. Hull L, Athanasiou T, Russ S. Implementation Science: a neglected opportunity to accelerate improvements in the safety and quality of surgical care. *Ann Surg*. 2017;265:1104–1112.
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