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The association between surgical complications and compliance to the World Health Organization Surgical Safety Checklist: A retrospective analysis of hospital records

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Abstract

Background: The World Health Organization Surgical Safety Checklist (SSC), now used by healthcare providers worldwide, has proved to be useful in the improvement of patients' health through the reduction of mortality and morbidity after surgery. In the Emilia-Romagna region in Italy the SSC is accompanied by a document that registers any non-conformity (NC) identified during SSC completion. This study aimed to investigate the association between surgical complications and checklist compliance, in terms of incompleteness and presence of NCs, using data from the Modena Local Health Unit (LHU).

Methods: We used data from surgeries performed in the Modena LHU between 2018 and 2022, with their SSC and related NC document. We estimated relative risks (RRs) of complications fitting three modified Poisson regression models. Model 1 included checklist incompleteness and NC presence, Model 2 adjusted Model 1 for patients' sex and age group, and Model 3 adjusted Model 2 for the other potential confounders. We also performed a sensitivity analysis estimating the same three models including death outcomes as complications.

Results: We found an increased risk of complications for both checklist incompleteness (unadjusted RR [uRR]= 2.04; 95% confidence interval [CI]: 1.17 to 3.54) and presence of NCs (uRR = 2.35; 95% CI: 1.71 to 3.22). Results were consistent after adjustment and in the sensitivity analysis.

Conclusions: Improving checklist compliance can reduce the risk of surgical complications. In particular, NCs are a risk factor that must be further investigated to better understand their relationship with complications. We believe that NCs data recording is helpful for both researchers in the scope of surgical complications, and healthcare professionals in the operating room.

KEYWORDS

health services research, operating room, patient safety, surgery complications

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1 | INTRODUCTION

Poor surgical treatment can have serious consequences. The strive for safety during surgery is strengthened by the World Health Organization's (WHO) Surgical Safety Checklist (SSC),[1] a 19-item list of safety checks that the surgical team follows through the *sign-in* phase (before anaesthesia), the *time-out* phase (before skin incision), and the *sign-out* phase (after surgery and before the patient leaves the operating room).[2] Several studies have shown a considerable reduction in surgical complications, including mortality, following the introduction of the SSC.[3–19] However, relatively fewer studies have analysed the relationship between checklist compliance and the risk of complications, especially in the presence of checklist incompleteness and non-conformities.[9,20]

In a randomized controlled study, Chaudhary et al. found not only a reduction in both complications and mortality related to the implementation of the SSC, but also an increased risk of complications in the presence of an incomplete checklist.[8] Similarly, Van Klei et al. found a decrease in in-hospital mortality following SSC implementation, as well as lower odds of death for surgeries with a complete checklist as compared to those with an incomplete one.[17]

In addition to the completeness of the checklist, lack of conformability is an aspect of compliance that may jeopardize the outcome of a surgery. We define the non-conformity (NC) of a completed checklist item as any deviation from what ideally the standard practice mandates via the checklist. Naturally, if the NC remains unidentified, it is not possible to rectify such a deviation.

Italy's national health service is administered on a regional basis through local health units (LHUs). The Emilia-Romagna Regional Health Service (RHS) consists of eight LHUs, each normally serving one or more region's province, and four University Hospitals. The Modena LHU, which provided the data for the present study, has a network of five medium-sized hospitals (Carpi, Mirandola, Pavullo nel Frignano, Vignola, and Castelfranco Emilia), that cover specialties like general surgery, endocrinology, nephrology, orthopaedics, obstetrics and gynaecology, otolaryngology, urology, and dental surgery.[21]

The Modena province includes two additional major University Hospitals (Modena teaching hospital and Baggiovara hospital) that, however, are not managed by the Modena LHU.[22]

The Emilia-Romagna RHS introduced the SSC in 2010, and requires that the surgical team members fill out, along the SSC, the so-called "Deviation from Regional Standard Detection" (DRSD) form[23,24] *during* the surgery. This means that NCs can potentially be identified thanks to the DRSD and, if detected, corrective actions must be initiated before proceeding to the subsequent surgical phase. Still, some deviations may increase the risk of complications even if identified and corrected.

Our study aimed to investigate the relationship between the risk of surgical complications and two factors related to checklist compliance, namely checklist incompleteness and presence of NCs during surgery. We analysed a large collection of linked hospital SSC and DRSD records from a Local Health Unit (LHU) in the Emilia-Romagna region.

2 | METHODS

Data were collated from the five hospitals of the Modena Local Health Unit network (Carpi, Mirandola, Pavullo nel Frignano, Vignola, and Castelfranco Emilia), between 1st January 2018 and 31st December 2022. The LHU registered an average of 24,798 hospitalizations per year in the study period, with about 47% of these being surgical hospitalizations (Table S1). The yearly average of surgical hospitalizations for the entire Emilia-Romagna region was 375,881, of which 2.5% were covered by the Modena LHU.

The data set consisted of 40,058 surgeries (Figure 1), 39,488 primary (index) surgeries for 34,232 inpatients. These were surgeries that required sedation and the presence of an anaesthetist, and are documented by their SSC and related DRSD form.

For patients who had multiple surgeries recorded in the data set, we indexed the first occurring surgery as the primary surgery. Any surgical emergency or urgent surgery occurring after the date of the primary surgery, but within the same hospital stay, was classified as a surgical complication of the primary surgery (none of the surgeries performed in the LHU requires a priori any planned follow-up surgery). The 4,256 surgeries for the same patients that occurred after the primary surgery, but outside the hospital stay of the primary surgery, were treated as new independent surgeries. The main outcome in our analysis is the binary indicator for the presence of at least one surgical complication. The goal of this study is to investigate the association between surgery complications risk, checklist incompleteness and NC presence. We considered several potential confounders of the main association, starting from patient's sex and age, and a categorical variable indicating whether the primary surgery was elective, urgent, or an emergency. In addition, we included an indicator for *monitored* surgeries. Monitored surgeries are more complex surgeries that have an increased risk of surgical site infections[25] and thus require stricter surveillance.

We estimated the unadjusted and adjusted relative risk (RR) of surgery complications in relation to checklist incompleteness and NC presence using (modified) Poisson regression with robust variance.[26] The competing regression models were: Model 1, a crude model with checklist incompleteness and NC presence, the two exposures; Model 2, same as Model 1 but adjusted for patients' age and sex; and Model 3, same as Model 2 but additionally adjusted for all the other potential confounders. Results were reported as point estimates and 95% confidence intervals (CI).

In-hospital deaths of patients who did not experience surgical complications represented a source of ambiguity. For this reason, we conducted a sensitivity analysis where deaths were treated as complications, by assuming that those patients would have likely undergone an emergency procedure had they survived. We did not perform a regression analysis of surgery-related mortality as a separate outcome since this study was not designed for this purpose.

All analyses were performed in the statistical language R version 4.2.3.[27]

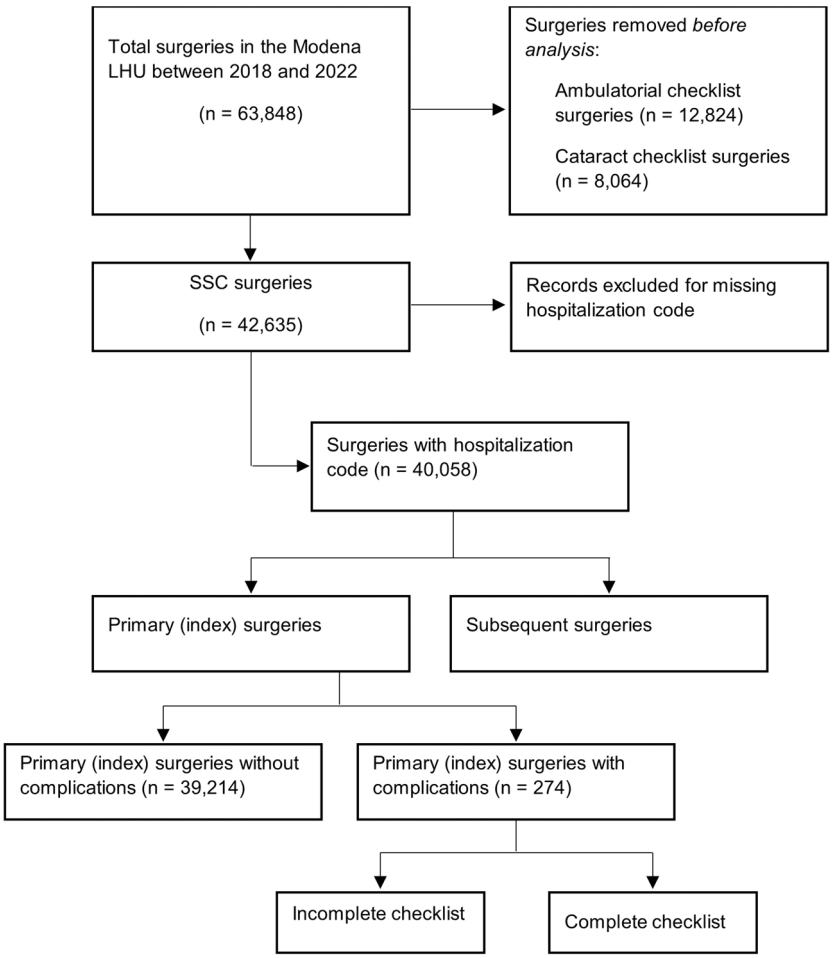

FIGURE 1 Data-flow diagram of the selection of surgeries performed in the Modena Local Health Unit, 2018–2020.

3 | RESULTS

Of the 39,488 primary surgeries performed in the Modena LHU between 2018 and 2022, 274 (0.7%) were identified as surgeries followed by at least one surgical complication, while in 140 cases (0.4%) the patient died before their hospital discharge (Table 1).

A total of 1,015 surgeries (2.5% of all primary surgeries) were documented by incomplete checklists, of which 13 (1.3%) were for surgeries followed by a surgical complication. The complication rate for surgeries with incomplete SSC (1.3%) was higher than the rate for those with complete checklists (0.7%), with a RR equal to 1.89 (95% CI: 1.08 to 3.28) (Table S2). Incompleteness was also associated with a higher complication-free mortality rate (RR: 3.52; 95% CI: 1.95 to 6.35).

Non-conformities were present in 3,113 primary surgeries (Table 1) and were associated with an increased complication rate (RR: 2.29; 95% CI: 1.67 to 3.15) (Table S2) as well as with a greater complication-free mortality rate (RR: 2.2; 95% CI: 1.4 to 3.4) (results not shown).

Higher complication rates were observed in males, older patients (particularly in the 80+ years group), and among patients who received urgent or emergency primary surgeries (Table 1). For higher-risk surgeries that belonged to the monitored category, the RR of complications was 2.4 (95% CI: 1.9 to 3.1) (Table S2) while the complication-free mortality RR was 3.6 (95% CI: 2.5 to 5.4) (results not shown).

The Poisson regression analysis (Table 2 and Tables S3-S5) confirmed the results above, as it gave higher RRs associated with SSC incompleteness and presence of NCs when both were included in the same model (Model 1): the RRs of surgical complications were 2.04 (95% CI: 1.17 to 3.54) and 2.35 (95% CI: 1.71 to 3.22), respectively.

Similar RRs were observed after adjusting for sex and age of the patients (Model 2). On the other hand, the magnitude of the associations between complications and the main exposures was attenuated after adjusting for primary surgery class and monitored surgery status in addition to sex and age (Model 3), with a RR equal to 1.36 (95% CI: 0.69 to 2.68) for incomplete checklists and 1.97 (95% CI: 1.43 to 2.71) for NC presence.

In the sensitivity analysis, where complication-free surgeries followed by in-hospital death were added to surgery with complications (Tables S6–S8), the magnitude of the RRs was larger for incomplete checklists (e.g., Model 3 RR: 1.68; 95% CI: 1.08 to 2.62) but remained approximately the same for NC presence when compared to the main results in Table 2.

TABLE 1 Number (%) of primary surgeries classified into (a) complication-free surgeries (either not-followed or followed by in-hospital death) and (b) surgeries followed by complications by main exposures and confounders performed in the Modena Local Health Unit, 2018–2022.

	(a) Complication-free surgeries			
	Not followed by in-hospital death	Followed by in-hospital death	(b) Surgeries followed by complications	Total (a+b)
Total	39,074 (99.0)	140 (0.4)	274 (0.7)	39,488
Checklist completeness				
Incomplete	990 (97.5)	12 (1.2)	13 (1.3)	1,015
Complete	38,084 (99.0)	128 (0.3)	261 (0.7)	38,473
Checklist non-conformities				
Present	3,046 (97.8)	22 (0.7)	45 (1.4)	3,113
Absent	36,028 (99.0)	118 (0.3)	229 (0.6)	36,375
Sex				
Male	17,804 (98.8)	74 (0.4)	147 (0.8)	18,025
Female	21,270 (99.1)	66 (0.3)	127 (0.6)	21,463
Age groups (years)				
1–19	2,009 (99.9)	-	2 (0.1)	2,011
20–39	6,102 (99.6)	1 (<0.1)	24 (0.4)	6,127
40–59	12,415 (99.4)	8 (0.1)	62 (0.5)	12,485
60–79	13,873 (98.8)	48 (0.3)	121 (0.9)	14,042
80+	4,675 (96.9)	83 (1.7)	65 (1.3)	4,823
Surgery class				
Elective	30,340 (99.6)	12 (< 0.1)	109 (0.4)	30,461
Urgent	8,537 (96.8)	122 (1.4)	158 (1.8)	8,817
Emergency	197 (93.8)	6 (2.9)	7 (3.3)	210
Monitored surgery				
Yes	18,247 (98.4)	107 (0.6)	187 (1.0)	18,541
No	20,827 (99.4)	33 (0.2)	87 (0.4)	20,947

TABLE 2 Point estimates and 95% confidence intervals of baseline risk (in brackets) and adjusted relative risk (aRR) of surgical complications in relation to checklist incompleteness status and presence of non-conformities (NCs) for surgeries performed in the Modena Local Health Unit, 2018–2022.

	Model 1			Model 2[a]			Model 3[b]		
	RR	Lower	Upper	RR	Lower	Upper	RR	Lower	Upper
Reference*	(0.006)	0.005	0.007	(0.005)	0.004	0.007	(0.003)	0.002	0.004
Incomplete checklist	2.035	1.169	3.542	2.000	1.154	3.468	1.356	0.687	2.677
NCs present	2.345	1.706	3.222	2.273	1.654	3.123	1.971	1.434	2.710

*The reference category is represented by surgeries with complete checklists and no NCs.

[a]adjusted for sex and age of the patients.

[b]adjusted for sex and age of the patients, primary surgery class, and monitored surgery status.

4 | DISCUSSION

In our study, we found increased surgical complications risks for two factors related to checklist compliance, namely checklist incompleteness and presence of non-conformities (NCs) during surgery. In our main analysis we did not include in-hospital death as a complication, but similar results (indeed, slightly stronger) were obtained when accounting for mortality as an adverse outcome possibly linked to the primary surgery.

Given the protective nature of the SSC against mortality and morbidity, we expected to find a positive association between incomplete checklists and the risk of surgical complications. All items of the SSC have been designed to increase, each in its own way and extent, the safety of patients before, during, and after the surgery. Neglecting one or more items may pose a risk for the health of patients, and potentially lead to surgical complications. Bentivegna et al. reported the results of direct observation of SSC compliance in the operating room (OR) of Emilia-Romagna hospitals, revealing that checklists are not always properly completed, especially in the *sign-in* and *sign-out* phases.[28]

Schwendimann et al. identified factors that interfered with the correct completion of the SSC, such as the absence of key OR team members when these were busy with other tasks and lack of teamwork.[29] In a study with OR personnel regarding their attitudes towards a checklist, O'Connor et al. found that nurses are more sensitive to the issue of checklist completion than surgeons and anaesthetists.[30] The latter category was found to be particularly averse to the SSC, as it is generally completed during critical phases of their duties in surgery. Investigating personnel's attitude towards the SSC and identifying the potential obstacles to its correct use could lead to an adaptation of the document and its timing to the OR team needs, boosting compliance and reducing risks for patients. Biffl and colleagues also found variability in compliance with individual SSC items across surgical specialties.[31] Although the Emilia-Romagna SSC and DRSD data provide scope for investigating individual surgical specialties, we defer such an analysis to a separate study.

Overall, the *sign-out* phase appeared to be the most neglected (226 checklists were incomplete in the *sign-out* phase). Some of the items in this phase contain information on instruments counts and the critical aspects of the patient's care after surgery, both fundamental for the patient's recovery and possible complications. Although incompleteness on paper does not necessarily imply neglect in practice, it is imperative that this phase of the checklist is completed with particular attention, possibly even in case of emergencies.

On the other hand, the single most neglected item (in 849 checklists) was found in the *time-out* phase. This item assesses whether or not the anaesthetist informed the surgical team on the patient's characteristics, anaesthesiologic risk and other potential issues.

Boosting SSC compliance could be supported by providing specific training to healthcare professionals on checklist best practices. Stressing the importance of specific items is fundamental to raise their awareness of possible risks and encourage the completion of critical items even for emergency surgeries, for which checklists are not compulsory. It would also be useful to question the operating room team on their perception of the checklist completion process to identify possible flaws, thus improving guidelines to facilitate their job. As checklist compliance is not exempt from cultural attitude, safety walkarounds could induce the operating room personnel to better adhere to checklist completion practices.[32]

The presence of NCs identified during surgery and the increased risk of subsequent complications is a novel and important finding given the uniqueness of our data. The information about NCs that is systematically collected by the Emilia-Romagna LHU through the DRSD form does not seem to have equals in other healthcare systems, either national or international. If, on the one hand, we cannot refer to other studies that can either confirm or contradict our results, on the other we are able to raise attention to a clinically significant factor that can potentially double (RR: 1.97; CI: 1.43 to 2.71) the risk of complications. The presence of an NC is indeed an indication that something went amiss, and this may carry potential repercussions on the likelihood of complications, notwithstanding the fact that corrective actions were implemented upon identification of the NC. The increased risk of complications would be, even more so, explained by deviations that, even if identified, require corrective actions that might affect health risks for the patient. Possible examples may be the need to reopen the surgical site as a result of the wrong surgical instruments counts in the *sign-out* phase (extending the time of surgery), the wrong timing of the antibiotic prophylaxis in the *time-out* phase, or the missed haemorrhagic risk assessment in the *sign-in* phase associated with the need of blood components that are not available in the OR (causing a delay for the surgery and for the daily workflow). This suggests that a classification of NCs and their impact that may depend on the particular checklist item and the phase of the surgery they refer to, as well as on surgery characteristics. Such a study represents a high-dimensional classification problem that we are currently tackling via machine learning algorithms.

One limitation to the interpretation of the results discussed above and to the correct quantification of the risks associated with checklist compliance is represented by the relationship between checklist incompleteness and NC presence. In our previous study using data up to 2021,[33] we found that incomplete SSCs were associated with a lower risk of NCs, which we attributed to a possible consequence of potential underreporting. If an item of the checklist is missing (not complete), there is a non-zero probability that such an item could hide a NC, which, may or may not have increased the risk of complications depending on its severity. However, by hypothetically completing a checklist and, thus, identifying all the unidentified NCs, the overall change in complications risk cannot be but a decrease: a decrease due to checklist completeness and a decrease due to the benefits of corrective actions for those NCs that are responsive to such actions. Checklist completeness, therefore, remains fundamental and to be encouraged regardless. On the other hand, further investigation of the specific NCs that might be related to an increased risk of complications would offer valuable information to develop solutions for reducing the likelihood of occurrence of checklist deviations, with particular attention to those that are less sensitive to corrective actions.

Our findings rely on about 40,000 SSC surgeries collected in one particular LHU (out of eight) of the Emili-Romagna region, the only region in Italy that has adopted the DRSD form. We did exclude two important hospitals in the province as their data are managed separately from those of the other five hospitals. These two hospitals offer surgeries in specialties that tend to have higher risks of complications, therefore raising a potential issue of bias in the association between checklist incompleteness and complications risk as estimated from our data. We believe that such a bias would be downwards since, even assuming the true complications rate is higher as that compared to what our data suggest, there is no reason to expect a different checklist completion rate and pattern for those two hospitals given the same checklist training of its medical personnel (who often work across all hospitals of the same LHU).

Finally, since checklist practices have been standardised throughout the Emilia-Romagna region since 2010, we do not have reasons to expect different findings should the data be coming from different LHUs.

Our study suggests that the risk of surgery complications can be reduced by improving checklist compliance. The latter is defined in terms of completeness of the checklist and conformity to the standard practice mandated by the checklist. Specifically, we identified non-conformity as a clinically important risk factor, independent from checklist completeness, that warrants further investigation. Our study also underscores the value of collecting data on checklist non-conformity alongside the SSC itself. Such an exercise, we believe, not only helps researchers and healthcare managers attain a better understanding of surgery complications risks, but it also contributes to raise staff awareness in the operating room.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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