



# A retrospective analysis of the factors associated with surgical checklist compliance using data from a local health unit in Italy, 2018–2021

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## Abstract

**Rationale:** Since its publication, the World Health Organization Surgical Safety Checklist (SSC) has been progressively adopted by healthcare providers around the world to monitor and safeguard the delivery of surgeries. In one Italian region's health system, the SSC and other two surgery-specific checklists were supplemented by a document that records any non-conformity (NC) arising from the safety checks.

**Aims and Objectives:** In this study, we investigated the factors associated with NCs using data from a local health unit (LHU). The secondary aim of this study was to explore the potential impact of the coronavirus crisis on surgical checklist compliance.

**Methods:** We used data on surgical activity from the Modena LHU between 2018 and 2021 and the accompanying NC documents. The primary goal was to estimate the relative risk (RR) of NCs according to several factors, including checklist incompleteness and surgery class (elective, urgent or emergency), using Poisson regression. A similar analysis was performed separately for 2018–2019 and 2020–2021 to assess the COVID-19 potential impact.

**Results and Conclusions:** Checklist compliance in the LHU was 95%, with the presence of NCs in about 7% of surgeries. The factors that increased the RR were incompleteness of the checklist (adjusted RR = 3.12; 95% confidence interval [CI] = 2.86–3.40), urgent surgeries (adjusted RR [aRR] = 1.59; 95% CI = 1.47–1.72), emergencies (aRR = 2.09; 95% CI = 1.15–3.79), and surgeries with more than four procedures (aRR = 1.64; 95% CI = 1.41–1.92). Most notably, the RR for incomplete checklists showed a negative association with NCs before the COVID-19 outbreak but positive afterwards. Checklist compliance was overall satisfactory, though the observation of noncompliant checklists of about 1000 per year suggests there is still room for improvement. Moreover, attention to the checklist best practices and organization of outpatient workload may have been affected by the exceptional circumstances of the pandemic.

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**KEYWORDS**

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

## 1 | INTRODUCTION

Surgical procedures carry complication risks by their own nature, but these risks may increase with negligence and unsafe practices. In 2008, the World Health Organization (WHO) released the Surgical Safety Checklist (SSC), a 19-item list that guides the surgical team with the aim of a safer process.<sup>1</sup> The 19 items cover the three phases of surgery, namely the *sign-in* phase (before the administration of anaesthesia to the patient), the *time-out* phase (before the incision of the skin), and the *sign-out* phase (after the surgery is over and before the patient leaves the operating room).<sup>2</sup> Since the inception of the WHO SCC, numerous studies have reported significant reductions in surgical complications, including mortality, associated with the adoption of the checklist.<sup>3-19</sup>

The benefits of following the SSC during surgical procedures seem to be dampened by partial compliance, with limited evidence that the risk of complications is positively associated with checklist incompleteness and unidentified non-conformities (NCs).<sup>9,20</sup> However, studies that examine factors associated with the risk of NCs, when identified, are lacking. The objective of this study was to conduct such an investigation using data from a local health unit (LHU) in Italy that spans the 4-year period 2018–2021. Moreover, since the study period straddles the pre- and post-onset of the COVID-19 pandemic, a secondary analysis of this study was carried out to provide some insight into the impact of the coronavirus crisis on surgical checklist compliance.

## 2 | METHODS

### 2.1 | The checklists

Although the SSC is intended to be nearly universally applicable, the WHO encouraged healthcare providers<sup>2</sup> to adapt the checklist to their needs and specificities. The Emilia-Romagna region, where the LHU of Modena is located, developed its own SSC<sup>21</sup> and is comprised of two documents. The first document (which we will refer to as SSC) is the main checklist (23 items) with the same structure (sign-in, time-out and sign-out phases) and items as the WHO's SSC,<sup>22</sup> except for an additional item in the sign-out phase (this concerns the setup of a thromboembolism prophylaxis plan after surgery). The second document, which is used exclusively by the Emilia-Romagna healthcare providers, is called Deviation from Regional Standard Detection (DRSD) form. The purpose is to report, concurrently with the checklist, any non-compliance with each item of the SSC and to allow the operating room's staff to correct the deviation before proceeding to the next item.

The Modena LHU adopted three additional checklists for specific types of surgeries, namely the ambulatorial checklist (23 items) for all

outpatient surgeries that do not require general anaesthesia, except for cataracts; the cataract surgery checklist (17 items); and, starting in 2021, the Caesarean section (C-section) checklist (35 items), which overtook the SSC for safety checks concerning this particular surgical procedure. Each of these checklists has a matching NC document. The C-section checklist was not included in our main analyses as its adoption was recent, spanning only the last year of the study period.

The three Modena LHU checklists (SSC, ambulatorial and cataract), along with their accompanying DRSD form, are provided in Supporting Information: Tables S4–S9.

### 2.2 | The data

Anonymized data on safety checklists for 48,850 surgeries conducted in five hospitals between January 2018 and December 2021 were provided by one LHU in Modena. Of these, 1531 observations were removed as they were checklists reported as not performed, while 15 were removed due to missing primary surgery ICD code. As per the analysis criteria, 102 C-sections were excluded. This resulted in 47,202 observations available for analysis. The hospitals comprised by the Modena LHU network are those in the towns of Carpi, Mirandola, Pavullo nel Frignano, Vignola and Castelfranco Emilia. The network, together with three other major hospitals that however belong to separate LHUs, covers a geographical area in the Emilia-Romagna region (northern Italy) of more than 2500 km<sup>2</sup> and a population of over 700,000.

For our analyses, we considered two outcomes: (i) the binary indicator of whether any NC was reported and (ii) the number of NCs reported. The factors that we determined as potentially affecting the likelihood of the outcomes were: an indicator for whether the checklist was incomplete, an indicator for whether time recording was incorrect, a categorical variable for surgery class (elective, urgent or emergency), a categorical variable for checklist type (SSC, ambulatorial or cataract), and a categorical variable for the number of procedures involved within the same surgery (less than 4, or 4 or more).

These factors were identified after examination of the literature and of the variables available in the data set, and after discussion with the healthcare data provider. A factor that may affect the likelihood of NCs is the nature of the surgery and whether the related checklist is compulsory. Based on Modena LHU's regulations, a checklist is compulsory for elective and urgent surgeries, which may imply higher attention of the medical staff in the operating room and more time for planning. On the other hand, emergencies, for which a checklist is not compulsory, require making decisions in stressful situations and prioritising actions on a narrow window of time, both of which may increase the likelihood of unintended or intended NCs. It should be noted that, although not compulsory, checklist completion during

emergencies is strongly recommended by the Modena LHU's regulations whenever the conditions of the patient allow it. Another potential source of NCs is the 'complexity' of the surgery, which we defined loosely by the number of procedures involved. It is worth stressing that this definition does not account for the 'intrinsic' difficulty of the surgery, regardless of how many procedures are involved, whose objective measurement however is beyond the available data and scope of the analysis. Another factor potentially related to NCs is the checklist itself. A longer, more detailed checklist could, on the one hand, increase the likelihood of NCs due to basic probability laws, but, on the other hand, it may reduce inaccuracies as it spurs more attention. NCs may arise also from negligence as reflected by an incomplete checklist or by an incorrect time stamping.

To address the main goal of this study, we fitted (modified) Poisson regression models with robust variance estimation<sup>23</sup> to estimate relative risks (RRs) for the presence of any NC in any checklist type, both univariable for unadjusted RRs (uRRs) and multivariable for adjusted RRs (aRRs). We repeated this analysis for each checklist separately to ascertain any source of heterogeneity among checklist types (Supporting Information: Table S1). We also fitted zero-inflated Poisson regression models (which corrects for zero-NC excess) to estimate aRRs for the expected number of NCs.

For the secondary goal of this study, we fitted the modified Poisson regression models mentioned above separately to the 2018–2019 and 2020–2021 time periods to investigate the potential impact of the coronavirus crisis on surgical checklist compliance (Supporting Information: Tables S2 and S3).

All regression results are reported as point estimates and 95% confidence intervals (CI).

### 3 | RESULTS

Out of 47,202 surgeries conducted in the 4-year study period, 10,759 (23%) were carried out in 2018, 12,214 (26%) in 2019, 10,298 (22%) in 2020 and 13,931 (29%) in 2021 (Table 1). The drop in 2020 and the sudden step increase in 2021 are likely accounted for by a postponement of surgeries due to the COVID-19 pandemic.

Many of these surgeries (33,399 out of 47,202 or 71%) fell within the scope of the SSC checklist. Ambulatorial and cataract surgeries represented, respectively, 17% and 12% of the surgeries. Elective surgeries were the majority (84%) and these comprised 25,839 SSC surgeries, in addition to all ambulatorial and cataract surgeries (which are, by definition, elective only).

Checklist completeness was high (95%), particularly for cataracts (almost 100%). However, incomplete checklists were disproportionately higher among emergencies (9% vs. 5% and 3% for elective and urgent, respectively) since completion of the checklist is not mandatory for this category. Similarly, start time recording was correct in a large proportion of checklists (94%), though in a lower proportion for ambulatorial checklists (88%). The rate of incorrect time recording was disproportionately higher among emergencies (15% vs. 6% and 4% for elective and urgent, respectively).

The majority of the surgeries (96%) had less than four procedures. Complex surgeries (four or more procedures) were disproportionately higher (12%) among cataracts.

Overall, there were 4280 NCs reported across checklists, affecting about 7% of them, and these NCs occurred mostly as single NCs (2890). A small number of checklists had two or more NCs (with a maximum of nine). Cataract checklists were those less affected with only 1% of them presenting only one NC, while the rest were NC-free. Finally, we note that NCs were not uniformly distributed across the three phases of the surgery, with 60%, 32% and 8% of the 4280 NCs reported in the sign-in, time-out and sign-out phases, respectively.

Estimated RRs of checklists reporting at least one NC are given in Table 2. Incomplete checklists had a higher estimated probability of incurring at least one NC as compared to complete checklists. The uRR was 3.27 (95% CI = 3.00–3.56) and remained similar after adjustment.

Incorrect start time recording was negatively associated with the risk of NCs. The uRR was 0.86 (95% CI = 0.74–1.00), while it slightly decreased to 0.74 (95% CI = 0.64–0.86) after adjustment.

Before adjustment, the NC risk for urgent surgeries and emergencies was, respectively, 1.64 (95% CI = 1.53–1.77) and 2.27 (95% CI = 1.28–4.02) times the NC risk for elective surgeries. After adjustment, these estimates did not change sensibly.

Compared to the SSC, the ambulatorial checklist had similar NC risk (uRR = 1.03; 95% CI = 0.95–1.12), while the cataract checklist had a substantially lower risk with a uRR equal to 0.16 (95% CI = 0.12–0.20). However, after adjustment, the aRR for the ambulatorial checklist was 1.20 (95% CI = 1.11–1.31).

Compared to surgeries with less than four procedures, more complex surgeries had an estimated uRR equal to 1.17 (95% CI = 1.00–1.36). However, after adjustment, the aRR was sensibly higher at 1.64 (95% CI = 1.41–1.92).

Supplementary results (Supporting Information: Table S1) show aRRs of checklists reporting at least one NC separately for each checklist type. Remarkably, incomplete ambulatorial and cataract checklists had aRRs equal to 23.24 (95% CI = 20.68–26.13) and 17.15 (95% CI = 6.10–48.30), respectively, thus much higher than the estimate for the combined data set. In contrast, the aRR for SSCs was below unity (0.68; 95% CI = 0.56–0.83). The aRR for incorrect start time recording was consistently below unity across checklist types, with a particularly low estimate for cataracts due to zero observed NCs among incomplete checklists. The aRRs for surgery class were, of course, driven by SSCs. Finally, the increased risk of NCs due to higher complexity of the surgery was confirmed for SSCs (aRR = 1.56; 95% CI = 1.34–1.81), but not for ambulatorial and cataract checklists.

Results from the zero-inflated regression on the expected number of NCs are shown in Table 3. There was a clear zero-NC excess (odds = 2.73; 95% CI = 2.50–2.98). The estimated aRRs were consistent with those from the modified Poisson, except for ambulatorial checklists. The latter showed a lower expected number of NCs compared to SSCs (aRR = 0.80; 95% CI = 0.73–0.89).

Finally, the results of the secondary analysis on the potential impact of the coronavirus crisis on surgical checklist compliance are

**TABLE 1** Number of surgeries (%) overall and by variables categories, for all checklists combined and for each checklist type, for surgeries performed between 2018 and 2021 within the Modena local health unit.

	All checklists	SSC	Ambulatorial	Cataract
Total surgeries	47,202	33,399	8147	5656
Year				
2018	10,759 (22.8)	9804 (29.4)	752 (9.2)	203 (3.6)
2019	12,214 (25.9)	9519 (28.5)	1718 (21.1)	977 (17.3)
2020	10,298 (21.8)	6505 (19.5)	1822 (22.4)	1971 (34.8)
2021	13,931 (29.5)	7571 (22.7)	3855 (47.3)	2505 (44.3)
Checklist completeness				
Complete	44,942 (95.2)	31,603 (94.6)	7697 (94.5)	5642 (99.8)
Incomplete	2260 (4.8)	1796 (5.4)	450 (5.5)	14 (0.2)
Start time correctness				
Correct	44,618 (94.5)	32,070 (96.0)	7211 (88.5)	5337 (94.4)
Incorrect	2584 (5.5)	1329 (4.0)	936 (11.5)	319 (5.6)
Surgery class				
Elective	39,642 (84)	25,839 (77.4)	8147 (100.0)	5656 (100.0)
Urgent	7494 (15.9)	7494 (22.4)	0 (0.0)	0 (0.0)
Emergency	66 (0.1)	66 (0.2)	0 (0.0)	0 (0.0)
Number of procedures				
<4	45,406 (96.2)	32,333 (96.8)	8113 (99.6)	4960 (87.7)
4+	1796 (3.8)	1066 (3.2)	34 (0.4)	696 (12.3)
Non-conformities				
0	43,720 (92.6)	30,675 (91.8)	7461 (91.6)	5584 (98.7)
1	2890 (6.1)	2181 (6.5)	637 (7.8)	72 (1.3)
2	442 (0.9)	403 (1.2)	39 (0.5)	0 (0.0)
3	115 (0.2)	106 (0.3)	9 (0.1)	0 (0.0)
4+	35 (0.1)	34 (0.1)	1 (0.0)	0 (0.0)

Abbreviation: SSC, Surgical Safety Checklist.

shown in Supporting Information: Tables S2 and S3. Notably, the association between incomplete checklist and NC risk reversed from negative (aRR = 0.73; 95% CI = 0.54–1.00) to positive (aRR = 5.21; 95% CI = 4.75–5.72) before and after the onset of the COVID-19 pandemic, respectively. Similarly, before the pandemic, ambulatorial checklists were associated with lower NC risk compared to SSCs (aRR = 0.49; 95% CI = 0.40–0.60) but, after the pandemic, with higher risk (aRR = 2.03; 95% CI = 1.83–2.25).

## 4 | DISCUSSION

In this analysis of a large data set on surgery checklists recorded in an LHU in Italy between 2018 and 2021, we examined factors associated with NC risk. The SSC represented the largest checklist category since not only its scope is clearly broader than that of the

more specific cataract checklist, but also because in this LHU inpatients largely outweigh ambulatorial patients. Overall, there was a low occurrence of NCs affecting about 7% of the surgeries. However, the risk of NC and the number of NCs were found to be associated with factors that may inform corrective actions.

First, we found that the highest proportion of NCs was reported for items of the sign-in phase, which includes the preliminary checks on the patient before surgery. These tasks are primarily conducted in the ward by personnel other than the surgical team (e.g., identification bracelet check and surgical site marking). While further information on the practices adopted in the ward is needed to make further assessments, communication between the surgical ward and the operating room may be a key factor. There are very few studies that examined NCs during the different surgery phases. However, it is important to stress that while our study is based on unique NC data obtained via the DRSD form during surgery, other studies carried out

**TABLE 2** Estimated risk and relative risk (RR), along with 95% confidence intervals, of observing at least one checklist non-conformity for surgeries performed between 2018 and 2021 within the Modena local health unit.

	RR (baseline risk)	Lower	Upper
<b>Unadjusted</b>			
Complete checklist (ref)	(0.067)	0.064	0.069
Incomplete checklist	3.272	3.004	3.564
Correct start time (ref)	(0.074)	0.072	0.077
Incorrect start time	0.864	0.743	1.005
Elective surgery (ref)	(0.067)	0.064	0.069
Urgent	1.643	1.526	1.770
Emergency	2.267	1.280	4.018
SSC checklist (ref)	(0.082)	0.079	0.085
Ambulatorial	1.032	0.953	1.119
Cataract	0.156	0.124	0.197
<4 procedures (ref)	(0.073)	0.071	0.076
4+ procedures	1.170	1.002	1.365
<b>Adjusted</b>			
Baseline category <sup>a</sup>	(0.064)	0.061	0.068
Incomplete checklist	3.121	2.865	3.399
Incorrect start time	0.745	0.643	0.862
Surgery class (ref: elective)			
Urgent	1.595	1.473	1.726
Emergency	2.086	1.148	3.792
Checklist type (ref: SSC)			
Ambulatorial	1.205	1.113	1.306
Cataract	0.185	0.146	0.234
4+ procedures	1.645	1.409	1.921

Note: Unadjusted and adjusted estimates were obtained from, respectively, univariable and multivariable modified Poisson regression models.

Abbreviation: SSC, Surgical Safety Checklist.

<sup>a</sup>The baseline category is represented by complete SSC checklists with correct start time for elective surgeries with less than four procedures.

ex-post investigations, thus making a direct comparison very difficult if not inappropriate. In a 2011 retrospective analysis based on a random sample of 671 surgeries performed in an American tertiary hospital, Sparks et al.<sup>23</sup> analysed both completion (i.e., nonuse) and accuracy (i.e., misuse) of the SSC shortly after its implementation over a 1-year period by means of a composite score measuring compliance. They found that the sign-out phase had the lowest composite score compared to the other phases. However, their results do not allow separating completion from accuracy, the latter being the closest to our definition of NC. The observational study by Gillespie et al.<sup>24</sup> carried out structured observations to assess surgical

**TABLE 3** Estimated relative risk (RR), along with 95% confidence intervals (CIs), of the number of non-conformities (NCs) and estimated odds, along with 95% CIs, of zero NCs excess for surgeries performed between 2018 and 2021 within the Modena local health unit.

	RR (baseline rate)	Lower	Upper
Baseline category <sup>a</sup>	(0.321)	0.296	0.348
Incomplete checklist	2.520	2.239	2.835
Incorrect start time	0.834	0.711	0.978
Surgery class (ref: elective)			
Urgent	1.653	1.520	1.797
Emergency	1.972	1.002	3.879
Checklist type (ref: SSC)			
Ambulatorial	0.803	0.727	0.886
Cataract	0.137	0.108	0.174
4+ procedures	1.679	1.419	1.986
	<b>Odds zero excess</b>	<b>Lower</b>	<b>Upper</b>
	2.733	2.503	2.983

Note: Adjusted estimates were obtained from multivariable zero-inflated Poisson regression models.

Abbreviation: SSC, Surgical Safety Checklist.

<sup>a</sup>The baseline category is represented by complete SSC checklists with correct start time for elective surgeries with less than four procedures.

teams' checklist use before and after the implementation of a patient safety programme as well as a retrospective audit of clinical incidence (i.e., NC) data before and after the programme. However, they did not report information on NCs by phase.

We found that compliance with the SSC system is an important factor. Addressing checklist incompleteness may have important implications on surgery outcomes. van Klei et al.<sup>17</sup> compared in-hospital 30-day mortality by checklist completion status and found that, relative to non-completed checklists, the odds ratio for full and partial completed checklists were 0.34 (95% CI = 0.22–0.51) and 0.90 (95% CI = 0.69–1.17). Our regression analyses showed that incomplete checklists had higher risk of NCs as compared to complete checklists, especially after the start of the coronavirus crisis. The dramatic RR increase during 2020–2021 may be explained by the pressure hospitals were under in that early phase of the pandemic. Attention to the checklist best practices may have lessened to accommodate more stringent precautions to prevent viral infections. Partial support to this explanation comes from the substantial increase in the number of incomplete checklists which went from 565 (out of 22,973 or 2%) during 2018–2019 to 1695 (out of 24,229 or 7%) during 2020–2021. While compliance was, in general, satisfactory, the total number of incomplete checklists (2260), together with those not carried out at all (1531), amounted to a non-negligible number of non-compliant checklists of about 1000 per year, which leaves room for improvement. This may take the form of targeted training to promote full compliance with the surgical checklist.<sup>25</sup>



Unexpectedly, incomplete SSC checklists were inversely related to NC risk. This apparent inconsistency may be explained by the fact that partial completion of the checklist could be a reflection of the same underlying negligent behaviour that leads to NCs: poor adherence to checklist guidelines in general and higher propensity to miss or not to report NCs (underreporting). On the other hand, Sparks et al.<sup>23</sup> found that along with a high checklist completion score, there was a comparatively lower average accuracy score, thus suggesting an opposite correlation as compared to what we found. Still, we need to remember that their definition of accuracy may not side with our measure of NC.

Reduction in the incidence of partial compliance may be achieved by intervening upon the cultural attitude towards checklist completion starting from, for example, patient safety walkarounds.<sup>26</sup> In their systematic review, Wangoo et al.<sup>27</sup> reported a general lack of rigour in checklist completion across studies and found evidence that targeted training often improves staff sensibility towards the issue and therefore compliance. The study by Gillespie et al.<sup>24</sup> observed the efficacy of the patient safety programme (designed to facilitate behaviour change) on compliance, with particular reference to the sign-out phase. Wangoo et al.<sup>27</sup> also highlighted how in many studies, the sign-out phase is the most neglected. The observational study by Pickering et al.<sup>28</sup> reports that, while time-out was attempted in 87.4% of the 294 procedures, the sign-out phase was initiated in less than 9% of the cases. Similarly, Cullati et al.<sup>29</sup> found that time-out was correctly completed 13% of the time, while sign-out was only 3%. Information on the sign-in phase is missing from the literature.

Wrong time recording was associated with a lower NC risk. This result, too, was unexpected as logically one would assume that such a mistake is an indication of inattention and thus conducive of NCs. An explanation may come from the same logic suggested above, that is an underlying negligent behaviour that leads to both incorrect time recording and NC underreporting. On the other hand, it may also be a reflection of data miscommunication between information systems. Interestingly, Sparks et al.<sup>23</sup> included consistency between the recorded and actual time of the surgery in the calculation of their accuracy score. Although they did not provide detailed outcomes related to individual components of the score, their study supports our intuition that time recording does have a predictive value.

Emergencies had the highest risk of at least one NC as well as the highest expected number of NCs, while electives had the lowest, with urgent surgeries in between. This result may be explained by the fact that unexpected surgeries create some degree of commotion from which NCs arise. Since many NCs arise in the sign-in phase and are more likely to be generated in the surgical ward before the patient reaches the operating room, it could be expected that the surgical ward personnel are more prone to miscommunication when facing an unexpected patient rather than one for whom surgery was planned. Moreover, given the need for rapid decisions in such life-threatening conditions, the medical personnel may forgo less relevant checks at their discretion. Coherently, it could be beneficial to identify the most essential items and update checklist completion guidelines encouraging their completion in emergencies.

The ambulatorial checklist had the highest risk of containing at least one NC, even after adjustment. Our secondary analysis showed that this result was mainly driven by surgeries performed during 2020–2021, after the onset of the coronavirus pandemic. While the absolute NC risk for SSCs decreased from 9% to 6% between those two time periods (Supporting Information: Table S2), the risk for ambulatorial checklists increased from 4% to 10%. Upon closer inspection, we found that out of the 686 ambulatorial checklists affected by at least one NC, about 62% had an NC for one specific checklist item (positioning of the peripheral venous access). Moreover, out of the 424 NCs for this item across the network, 368 (87%) were reported by a single operating unit in one of the five hospitals, all in 2021. Rather than negligence, the cause of this NC was due to an internal decision not to conform to this item. In a sensitivity analysis (not shown) where these 368 observations were removed, the adjusted NC risk for the ambulatorial checklist relative to the SSC's was 0.58 (95% CI=0.52–0.66) down from 1.20 (95% CI= 1.11–1.31; Table 2), thus putting SSC at the top of the NC risk ranking. This raises the question of “cultural” differences across surgical wards that causes heterogeneity and bias in the assessment of risks related to checklist non-compliance. Further research that looks into individual item NCs is currently under way.

The regression model for NC counts showed that SSC checklists had the highest expected number of NCs (which is consistent with the SSC being at the highest risk of at least one NC based on the revised analysis mentioned above). This may be because SSC surgeries are more invasive and elaborate in nature. As the length of a checklist increases so does the severity of the surgery performed and the risk of incurring in NCs. Moreover, a larger number of items to check may generate more deviations from the standard practice, all else being equal. This is consistent with a much lower expected number of NCs estimated for the shorter cataract checklist relative to the longer SSC and ambulatorial checklist. With technological and scientific advancements in the medical field, some of the surgeries now performed under inpatient care may in the future become outpatient care procedures, carrying checklist simplifications along with it.

As we expected, surgery complexity, as determined by the number of procedures involved, was positively associated with NC risk. In fact, more complex surgeries, with several procedures performed in the same sitting, may require substantial organisational, logistical and technical effort. Our finding that cataract surgeries have a disproportionately higher number of procedures may, in fact, be explained at least in part by double coding for bilateral surgeries. In any case, the association between number of procedures and higher NC risk was present when either adjusting or stratifying for checklist type. As mentioned in the Introduction, our definition of complexity does not capture the intrinsic difficulty of the surgery or its potential adverse impact on the patient's health. In an exploratory study based on a small sample of surgeries, Cullati et al.<sup>29</sup> looked at SSC completion in relation to surgery severity provided as a score by an anesthesiologist via a four-level scale routinely used in Geneva University Hospitals for administrative and safety purposes. They

found that completion was higher in more severe surgeries compared to lower-risk surgeries. Sparks et al.<sup>23</sup> defined case complexity as preparation time and operative time, and found no association with SSC compliance. Clearly, the differences between surgery complexity (or severity) measures across studies limits the conclusions we can draw about our finding. On the other hand, this encourages us to exploit our large and unique data by using a more refined measure of complexity that builds on the surgeries' ICD codes.

The Modena LHU surgical performance between 2018 and 2021 was overall satisfactory in terms of safety compliance. However, there is still room for improvement in terms of execution of safety checklists and data collection. Making sure the medical staff is constantly informed and trained on safety measures, as well as monitoring the compliance with said measures is key in guaranteeing the quality of services offered to patients. In particular, the LHU should focus on reducing NCs, especially in the sign-in phase, by improving inter-ward communication. Decreasing NCs may also improve surgical productivity, due to a cut in the time spent detecting and fixing deviation from the standard practice during surgeries. It is therefore in the best interest of the LHU to act on the factors that mine safety as well as productivity.

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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.

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## REFERENCES

- World Health Organization. Safe Surgery. n.d. World Health Organization. Accessed March 24, 2023. <https://www.who.int/teams/integrated-health-services/patient-safety/research/safe-surgery>
- World Health Organization. WHO Guidelines for Safe Surgery 2009: Safe Surgery Saves Lives. 2009.
- Almeida RE, Rodrigues MCS. Execução da lista de verificação de segurança cirúrgica em operações pediátricas: avaliação da conformidade. *Rev Gaucha Enferm*. 2019;40:e20180270. doi:10.1590/1983-1447.2019.20180270
- Askarian M, Kouchak F, Palenik CJ. Effect of surgical safety checklists on postoperative morbidity and mortality rates, Shiraz, Faghihy Hospital, a 1-year study. *Qual Manag Health Care*. 2011; 20(4):293-297. doi:10.1097/QMH.0b013e318231357c
- 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(3):150-158. doi:10.1002/bjs.9381
- Berrisford RG, Wilson IH, Davidge M, Sanders D. Surgical time out checklist with debriefing and multidisciplinary feedback improves venous thromboembolism prophylaxis in thoracic surgery: a prospective audit. *Eur J Cardiothorac Surg*. 2012;41(6):1326-1329. doi:10.1093/ejcts/ezr179
- Böhmer AB, Wappler F, Tinschmann T, et al. The implementation of a perioperative checklist increases patients' perioperative safety and staff satisfaction: patients' perioperative safety and staff satisfaction. *Acta Anaesthesiol Scand*. 2012;56(3):332-338. doi:10.1111/j.1399-6576.2011.02590.x
- Chaudhary N, Varma V, Kapoor S, Mehta N, Kumaran V, Nundy S. Implementation of a surgical safety checklist and postoperative outcomes: a prospective randomized controlled study. *J Gastrointest Surg*. 2015;19(5):935-942. doi:10.1007/s11605-015-2772-9
- de Vries EN, Prins HA, Crolla RMPH, et al. Effect of a comprehensive surgical safety system on patient outcomes. *N Engl J Med*. 2010;363(20):1928-1937. doi:10.1056/NEJMsa0911535
- Haugen AS, Sjøteland E, Almeland SK, et al. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg*. 2015;261(5): 821-828. doi:10.1097/SLA.0000000000000716
- 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(5):491-499. doi:10.1056/NEJMsa0810119
- Kwok AC, Funk LM, Baltaga R, et al. Implementation of the World Health Organization surgical safety checklist, including introduction of pulse oximetry, in a resource-limited setting. *Ann Surg*. 2013;257(4):633-639. doi:10.1097/SLA.0b013e3182777fa4
- Lacassie HJ, Ferdinand C, Guzmán S, Camus L, Echevarria GC. World Health Organization (WHO) surgical safety checklist implementation and its impact on perioperative morbidity and mortality in an academic medical center in Chile. *Medicine*. 2016;95(23):e3844. doi:10.1097/MD.0000000000003844
- Lynch N, Kerin M. Effect of the World Health Organization checklist on patient outcomes: a stepped wedge cluster randomized controlled trial. *Ann Surg*. 2016;263(2):e24. doi:10.1097/SLA.0000000000001012
- Takala RSK, Pauniah SL, Kotkansalo A, et al. A pilot study of the implementation of WHO surgical checklist in Finland: improvements in activities and communication. *Acta Anaesthesiol Scand*. 2011;55(10):1206-1214. doi:10.1111/j.1399-6576.2011.02525.x
- Truran P, Critchley RJ, Gilliam A. Does using the WHO surgical checklist improve compliance to venous thromboembolism prophylaxis guidelines? *Surgeon*. 2011;9(6):309-311. doi:10.1016/j.surge.2010.11.024
- van Klei WA, Hoff RG, van Aarnhem EEHL, et al. Effects of the introduction of the WHO "Surgical Safety Checklist" on in-hospital mortality: a cohort study. *Ann Surg*. 2012;255(1):44-49. doi:10.1097/SLA.0b013e31823779ae
- Weiser TG, Haynes AB, Dziekan G, Berry WR, Lipsitz SR, Gawande AA. Effect of a 19-item surgical safety checklist during urgent operations in a global patient population. *Ann Surg*. 2010;251(5):976-980. doi:10.1097/SLA.0b013e3181d970e3
- Yuan CT, Walsh D, Tomarken JL, Alpern R, Shakph J, Bradley EH. Incorporating the World Health Organization surgical safety checklist into practice at two hospitals in Liberia. *Jt Comm J Qual Patient Saf*. 2012;38(6):254-260. doi:10.1016/s1553-7250(12)38032-x
- Bajracharya J, Shrestha R, Karki D, Shrestha A. Compliance of WHO surgical safety checklist at a pediatric surgical unit in a tertiary level hospital: a descriptive cross-sectional study. *J Nepal Med Assoc*. 2021;59(244):1256-1261. doi:10.31729/jnma.7045



21. Servizio Assistenza Ospedaliera Regione Emilia-Romagna. Linee Guida Flusso SSCL Surgical Safety Checklist. 2016. <https://salute.regione.emilia-romagna.it/siseps/sanita/sicurezza-chirurgia/documentazione/normativa>. Accessed on 3/24/2023 Retrieved from.
22. Agenzia sanitaria e sociale regionale – Regione Emilia-Romagna. Raccomandazioni per la sicurezza in sala operatoria. 2010. Accessed March 24, 2023. <https://assr.regione.emilia-romagna.it/publicazioni/rapporti-documenti/raccomandazioni-per-la-sicurezza-in-sala-operatoria>
23. Sparks EA, Wehbe-Janek H, Johnson RL, Smythe RW, Papaconstantinou HT. Surgical Safety Checklist compliance: a job done poorly. *J Am Coll Surg*. 2013;217(5):867-873. doi:10.1016/j.jamcollsurg.2013.07.393
24. Gillespie BM, Harbeck EL, Lavin J, et al. Evaluation of a patient safety programme on Surgical Safety Checklist Compliance: a prospective longitudinal study. *BMJ Open Qual*. 2018;7(3):e000362. doi:10.1136/bmjopen-2018-000362
25. Ferorelli D, Benevento M, Vimercati L, et al. Improving healthcare workers' adherence to surgical safety checklist: the impact of a short training. *Front Public Health*. 2022;9:732707. doi:10.3389/fpubh.2021.732707
26. Graham S, Brookey J, Steadman C. Patient safety executive walkarounds. In: Henriksen K, Battles JB, Marks ES, Lewin DI, eds. *Advances in Patient Safety: From Research to Implementation (Volume 4: Programs, Tools, and Products)*. Agency for Healthcare Research and Quality; 2005.
27. Wangoo L, Ray RA, Ho Y-H. Compliance and surgical team perceptions of WHO surgical safety checklist; systematic review. *Int Surg*. 2016;101(1-2):35-49. doi:10.9738/INTSURG-D-15-00105.1
28. Pickering SP, Robertson ER, Griffin D, et al. Compliance and use of the World Health Organization checklist in U.K. operating theatres. *Br J Surg*. 2013;100(12):1664-1670. doi:10.1002/bjs.9305
29. Cullati S, Le Du S, Raë AC, et al. Is the Surgical Safety Checklist successfully conducted? An observational study of social interactions in the operating rooms of a tertiary hospital. *BMJ Qual Saf*. 2013;22(8):639-646. doi:10.1136/bmjqs-2012-001634

## SUPPORTING INFORMATION

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

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