Reducing Surgical Mortality in Scotland: The WHO Safe Surgery Checklist as part of a National Patient Safety Initiative

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Transparency declaration: the lead author affirms that the manuscript is an honest, accurate, and transparent account of the study being reported. No important aspects of the study have been omitted. Any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Ethical approval: This project was reviewed by proportionate Research Ethical Review using the Integrated Research Application System (IRAS) and was approved (IRAS Ref 196391).

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Abstract

Introduction

The World Health Organisation (WHO) Surgical Safety Checklist has been widely implemented since its launch in 2008. It was introduced in Scotland as part of the Scottish Patient Safety Programme (SPSP) between 2008-2010 and is now integral to surgical practice. However, its influence on outcomes, when analysed at a population level, remains unclear.

Methods

This is a population cohort study. All admissions to any acute hospital in Scotland between 2000-2014 were included. Standardized differences were used to estimate balance of demographics over time after which interrupted time series (segmented regression) analyses were performed. Data were obtained from the Information Services Division, Scotland.

Results

There were 12,667,926 admissions, of which 6,839,736 were operative. Amongst the operative cohort, inpatient mortality rate in 2000 was 0.76% (95% CI: 0.6772, 0.8376) and 0.46% (95% CI: 0.4184, 0.4970) in 2014. Accordingly, the intervention was associated with a 36.57% (95% CI: -55.2073, -17.9416) relative reduction in mortality (p=0.0009). Mortality rate before the implementation were -0.0026% per year (95% CI: -0.0172, 0.0121), A decrease of 0.0693% per year (95%CI: -0.0922, -0.0463) was seen during, and 0.0185% per year (95%CI: -0.0378, 0.0008) after implementation. No such improvement trends were seen in the non-operative cohort over this timeframe.

Conclusions

Since the implementation of the checklist as part of an overall national safety strategy, there has been a reduction in peri-operative mortality. Whilst the cause of this reduction may be multi factorial, the specific intervention in surgical practice during this period was that of the surgical checklist.

Introduction

Surgery continues to be an important treatment for a wide variety of conditions with an estimated 312.9 million operations performed per year across the globe[1,2]. Every surgical procedure performed has an associated risk of morbidity and mortality[3]. Multiple complex factors influence surgical outcomes; with both technical and non-technical components being key factors. Consequently, surgical outcomes are influenced by multiple team members, and the systems of care in which they work[4,5]. The rates of adverse events vary across hospitals, regions and countries, with up to half due to provider or system-wide shortcomings[6,7-9]. As a result, various measures to improve surgical team performance and thus mitigate against surgical complications or adverse events have been advocated[10].

The World Health Organisation (WHO) Surgical Safety Checklist is one such measure which has been implemented internationally[3]. This checklist was launched in 2008 and has since become an integral part of the surgical process across the globe[11-13]. It aims to ensure safer surgical procedures by ensuring adherence to established safety practices as well as creating a culture of communication and teamwork that supports patient safety. The checklist is used by the entire operative team at three key pause points during any intervention in which harm could potentially ensue[3,14]. The overarching aim of this implementation is to improve safety of surgical procedures[3], thereby improving patient outcomes[15] and mortality rates[16]. However, its impact on mortality improvements in mandatory, nationwide implementation has been questioned[14,17-19].

The initial pilot study analysing the impact of checklist implementation in eight hospitals in eight separate countries[20] noted a significant reduction in peri-operative mortality rates and inpatient complications. However, these were prospectively collated data undertaken in a trial format. Whether this reduction is replicated in the real-world scenario outside the context of a trial has yet to be definitively proven. Studies performed in different healthcare facilities and regions have had mixed results on the checklist influencing outcome[11,12,17,21-24]. Implementing the checklist by mandate in Ontario with limited training and support demonstrated no significant reduction in death three months after hospitals certified compliance[17]. However, in a voluntary South Carolina programme, hospitals completing a collaborative, unit-based implementation protocol supported by educational programmes achieved a 22% reduction in mortality[25]. We seek to understand if similar improvements have been seen in hospitals across a country where implementation of the checklist was mandated through a national collaborative program to improve safety of hospital healthcare services.

The Scottish Patient Safety Programme (SPSP) is a national initiative which aims to improve in-hospital mortality in Scotland[26]. The SPSP programme was established in 2008 and had peri-operative management, including implementation of the WHO surgical checklist, as one of its four key initial frontline work-streams. This programme offered a systematic approach to improve patient safety across all hospitals in the country[26]. It utilised a multidisciplinary team approach to implement key drivers for change. By implementing the surgical checklist through the peri-operative arm of SPSP, Scotland co-ordinated its introduction nationally, with regional and local support. In this study, we aim to address whether implementation of the surgical checklist through a national level improvement strategy combined with a unit-based partnership, had an impact on population outcomes following surgery in Scotland.

Methods:

Data retrieval and case selection

This is a population cohort study. The Information Services Division (ISD) of the National Health Service Scotland prospectively collects data on all components of health service provision in the country. It utilises a unique identifier which can track individual patient outcomes through time[27]. All admissions to an acute hospital in Scotland between 2000-2014 (inclusive) were included. Patients who were admitted to a psychiatric department, rehabilitation facility or long term care hospital were excluded from the study.

Data are based on a continuous episode of treatment in hospital. Data were summarised and anonymised at source in ISD. Data on age, gender, deprivation, specialty, rates of return to theatre, operative urgency, cause of death and number of in hospital deaths were obtained.

Cohort definition and end points

Inclusion criteria were any admission to an acute care hospital in Scotland. The operative cohort was defined as any inpatient admission in which an operation (by OPCS4 code association with the admission) was performed between January 1, 2000 and December 31, 2014. The non-operative cohort were all patients admitted to the same hospital settings in which no operation was undertaken. Primary end point was in-hospital mortality. Secondary end point in the operative cohort was return to theatre of those cases undertaken in an elective manner.

SPSP implementation of surgical checklist

The SPSP is a Scottish government led initiative launched in 2008. The initial delivery of SPSP has been described previously[26]. In brief, the development was based on the Institute for Healthcare Improvement (IHI) collaborative model[28]. All local health boards were recruited to encourage clinicians, in a multidisciplinary team approach, to change the ethos around patient safety. This was supported by regional leadership groups and SPSP managers within each health boards who provided oversight of its activities and output. The perioperative checklist implementation was encompassed within the SPSP and was led locally by nurses or clinicians. Although nationally driven, SPSP implementations have minor local variations to adapt to relevant specialities, context and regions.

The SPSP perioperative management arm aimed to 1. provide appropriate, reliable and timely care to patients in order to reduce rates of surgical site infections and deep vein thrombosis; and 2. to create a team culture and approach to detect and rectify potential peri-operative issues and errors. Both drivers were included within the perioperative checklist implementation.

Implementation was introduced using the Plan Do Study Act improvement cycle. Staff education or training to support the theatre leadership to implement change was provided and biannual nationwide meetings were held to share effective approaches of checklist implementation. These were supported by continual data collection on adherence[26]. As an example, data were obtained on the frequency of checklist utilisation in each theatre. Run charts displaying these data were published in all theatre suites displaying concordance with the process and differences between theatres were highlighted. Regular reports were collated and shared within health boards and nationally[26].

Time frame

The checklist was established in Scotland between 2008-2010. By the end of 2010, its use was nearly uniform across the county[29,30]. Given the time taken for adopting the checklist appeared to take three years (2008-2010), we defined years until 2007 as the pre-checklist period; 2008-2010 as the Implementation period; and 2011 onwards as the post-checklist period.

Statistical analysis

Patient demographics in the three time periods were described using proportions. To estimate if these demographics were balanced over time (and thus unlikely to be confounders), we used standardized differences. Standardized differences of less than 10% have been found to reflect well-balanced demographics over time[31]. Interrupted time series (segmented regression) analyses were performed to determine if there were changes in the level and slope of the rates during the three periods and not a constant downward secular trend that continued over time[32]. The levels and slopes of the rates in the three time periods were estimated using optimal weighted least squares[33,34], with a robust standard error to account for possible over dispersion due to clustering of outcomes within hospitals (even though we do not have hospital-level data, this robust standard error can account for over dispersion)[35]. All analyses were performed in SAS 9.4.

Ethical review

ISD follows the principles of the Data Protection Act 1998 (DPA), UK[36]. This project was reviewed by a proportionate Research Ethical Review using the Integrated Research Application System (IRAS) and was approved (IRAS Ref 196391).

Results:

Demographic Information

In Scottish hospitals between 2000-2014, there were 12,667,926 admissions, of which 6,839,736 had operations. Table 1 summarizes the demographic information pertinent to these operative admissions. Over the pre-implementation period (2000/2001-2007/2008), during- implementation period (2008/2009-2010/2011), and the post-implementation period (2011/2012-2014/2015), the following covariates were found to be well-balanced with average absolute standardized differences <10%: gender (female: 0.79), older age (>80+ years: 3.21), SIMD (SIMD1: 3.00), and surgical specialty (Trauma and Orthopaedic Surgery: 4.27). Admission type was found to have an average standardized difference >10% across the three periods (non-elective admission: 10.25), indicating that this covariate could be a potential confounder.

Overall Mortality Trends- Operative cohort

Among hospital admissions with an operation performed, inpatient mortality rate in 2000 was 0.76% (95% CI: 0.6772, 0.8376) and 0.46% (95% CI: 0.4184, 0.4970) in 2014. Figure 1 shows the results of our time-series analysis for overall mortality across the three periods. In the pre-implementation period, the mortality rate had an absolute decrease of 0.0026% per year (95%CI: -0.0172, 0.0121); in the during-implementation period, the mortality rate decreased 0.0693% per year (95%CI: -0.0922, -0.0463); and in the post-implementation period, it decreased 0.0185% per year (95%CI: -0.0378, 0.0008). The downward trend in mortality seen in this model in the during-implementation period was found to be significantly different from the trend in the pre-intervention period (p-value: 0.0006). Although the mortality trend in the post-implementation period was not found to be significantly different than the pre-implementation period (p-value = 0.1532), the estimates for overall mortality in the pre-implementation period as compared to the post-implementation period were significant (p-value <0.0001). In this model, the inpatient mortality rate in 2000 was 0.76% (95% CI: 0.68, 0.84) and the 2014 inpatient mortality rate was 0.46% (95% CI: 0.42, 0.5); if the trend in the before-implementation period had persisted, the 2014 mortality rate would have been

0.72% (95% CI: 0.59, 0.85). Thus, the intervention was associated with reduced mortality, demonstrating a 36.57% (95% CI: -55.21, -17.94) relative reduction in mortality over the time studied (p-value: 0.0009).

A time-series analysis was also performed adjusting for admission type, which was found on exploration of our demographic information to be a potential confounder. The results of our adjusted model can be seen in Figure 2.
Trends across the three time periods were found to be similar in this model, which also demonstrated that the intervention was associated with reduced mortality.

Return to Theatre

Figure 3 shows the time-series analysis for return to theatre for elective admissions across the three time periods. In the pre-implementation period, the return to theatre rate increased 0.0016% per year (95%CI: 0.0010, 0.0022); in the during-implementation period, the return to theatre rate decreased 0.0033% per year (95%CI: -0.0046, -0.0019); and in the post-implementation period, it decreased 0.0018% per year (95%CI: -0.0024, -0.0012). The comparison of the during-implementation trend to the pre-implementation trend was found to be statistically significant (p-value <0.0001). The comparison of the pre-implementation trend to the post-implementation trend was also statistically significant (p-value: <0.0001). The estimates for return to theatre in the pre-implementation period as compared to the post-implementation period were significant (p-value: 0.0007).

Overall Mortality Trends- Non-operative cohort

We then performed the time series analysis for the 5,828,190 individuals in the non-operative cohort. Using the same time frames for pre implementation, during implementation and post implementation, no improvement in mortality was observed (p=0.4176).

Discussion:

In this nationwide population based cohort study, we observe a substantial reduction of mortality in patients undergoing surgical intervention in Scotland following the introduction and implementation of the WHO Surgical checklist as part of a nationwide patient safety initiative. This reduction persists when the data is controlled for urgency of admission, the only baseline demographic that altered during the timeframe. No such trend in improvement is observed in the non-operative cohort. From these data, we can infer that the improvement seen in the operative group was temporally associated with the SPSP implementation of the surgical checklist.

The Scottish Patient Safety Programme (SPSP) is a unique national programme which aims to change the healthcare culture to one which has patient safety at its forefront, whenever care is delivered[26]. A key element of the SPSP has been the testing and application of evidence-based interventions and quality improvement methodology to improve the reliability and safety of routine healthcare systems and processes. These implementations have been supported locally through co-production, educational programmes and prospective data on adherence. Since its launch, the programme has contributed to a significant reduction in harm through relevant quality improvement strategies[26,37]. Following testing, review and feedback from health boards across Scotland, the surgical checklist was included as one of the ten Patient Safety Essentials to be implemented across all health boards in Scotland[37]. The surgical checklist was not a stand-alone intervention. However, it was the only Patient Safety Essential which specifically targeted surgical patients during the period studied[37]. Thus, the addition of the checklist to the other parameters within the SPSP may have contributed to the improvement in results observed in this study.

The implementation of each of the SPSP interventions, was mandated but with emphasis placed on collaborative working with front line clinicians and teams together with local clinical leadership. The SPSP ensures that healthcare improvement implementations are adopted in a nationally co-ordinated approach and, as such, allows for patient safety initiatives to be developed and rolled out regardless of hospital location, clinician experience or underlying knowledge. We have not assessed checklist fidelity[38] or the effectiveness of the educational programmes in this study[39]. Furthermore, the surgical checklist in Scotland has predominantly involved the clinical team only; with variation noted regarding patient involvement; another potential area in which checklist quality can further be improved[40].

By utilising an observational approach at the population level, the risks of observation bias are greatly reduced. Therefore, these data highlight "real world" improvements out-with the contexts of clinical trials or research centres. However, there are limitations to both our data and its analysis. One of the key markers would have been to assess the rates of specific events such as wrong site surgery. We do not have these data in this study and the rates of these events are so low that identifying significant trends is very challenging. Specific details on how each unit conducted training sessions or developed frameworks during the implementation stage were not available during this analysis. However, we noted all regions supported checklist implementation with additional structures and training of clinical staff in all theatre settings which were tailored to suit each hospital and speciality.

We acknowledge that attributing causal links to our findings in population wide dataset analysis is not possible. The data was obtained in a summarized manner and individualised patient level data was not available, precluding multivariate analysis. Thus, standardized differences, previously reported in observational research[31], were used to analyse changes in demographic characteristics over time and incorporated into bivariate analysis for effect of urgent admission, the sole factor with average standardized difference greater than 10% .

Our findings of improved outcome are in agreement with several studies looking specifically at the implementation of a surgical safety checklist[20,21,23,24] but are nevertheless at odds with another analysing population based outcomes in the early period after checklist initiation[17]. In our study, we have utilised a more longitudinal approach, thereby allowing for a “bedding down” period where the checklist has been established as part of the workload culture of surgical theatre life in Scotland. The results in this study provide further evidence that success of the checklist implementation has been more pronounced when its implementation is supported by a cohesive and wider approach to of patient safety.. Additionally, the emphasis on collaborative implementation is an important feature of the Scottish experience and this may contribute to stronger implementation.

Conclusion

In the biggest review of its type, both in terms of number of patients and timeframe, we have observed a marked and sustained reduction in operative mortality after the implementation of the surgical checklist in Scotland as part of the SPSP.

A cohesive nationwide implementation of the checklist through a structured national patient safety program, with clinical collaboration and local ownership, occurred contemporaneously with improvements in outcome. Whilst there will continue to be improvements made to the application of the checklist, the process is embedded within the surgical culture in Scotland and may have achieved its aim in contributing to this marked improvement in surgical outcome and patient safety in Scotland.

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Table 1: Demographic information

	Pre-Intervention*	During Intervention*	Post-Intervention*	Standardized Difference^: Pre-During	Standardized Difference^: Pre-Post	Standardized Difference^: During-Post
Female	1962618 (54.07%)	755201 (54.55%)	985197 (53.96%)	-0.96	0.22	1.18
Age						
0-19	413402 (11.39%)	137549 (9.94%)	167837 (9.19%)	4.71	7.23	2.52
20-49	1250792 (34.46%)	442432 (31.96%)	543558 (29.77%)	5.32	10.05	4.73
50-79	1645698 (45.34%)	669554 (48.36%)	927711 (50.81%)	-6.06	-10.97	-4.90
80+	319710 (8.81%)	134890 (9.74%)	186602 (10.22%)	-3.22	-4.82	-1.59
Specialty						
Gen Surg	1246081 (34.33%)	439280 (31.73%)	596410 (32.67%)	5.53	3.53	-2.01
Ortho+	553391 (15.25%)	242323 (17.50%)	321701 (17.62%)	-6.10	-6.41	-0.31
Other	1830130 (50.42%)	702822 (50.77%)	907598 (49.71%)	-0.69	1.42	2.11
SIMD 1	882743 (24.47%)	316824 (23.00%)	409965 (22.56%)	3.45	4.50	1.05
SIMD 2	805597 (22.33%)	299106 (21.71%)	387959 (21.35%)	1.48	2.37	0.89
SIMD 3	713275 (19.77%)	281949 (20.47%)	370022 (20.36%)	-1.74	-1.48	0.26
SIMD 4	632085 (17.52%)	253796 (18.42%)	342368 (18.84%)	-2.36	-3.42	-1.07
SIMD 5	574266 (15.92%)	225861 (16.40%)	306996 (16.89%)	-1.30	-2.64	-1.33
Non-elective admission	856453 (23.60%)	259751 (18.76%)	317758 (17.40%)	11.85	15.38	3.53

*Pre-Intervention: 2000/2001 – 2007/2008; During: 2008/2009 – 2010/2011; Post: 2011/2012-2014/2015

^ Past literature suggests that standardized differences with absolute values <10% reflect well-balanced covariates.[31]

Figure 1: Time-series analysis for overall mortality across pre-implementation, implementation, and post-implementation periods

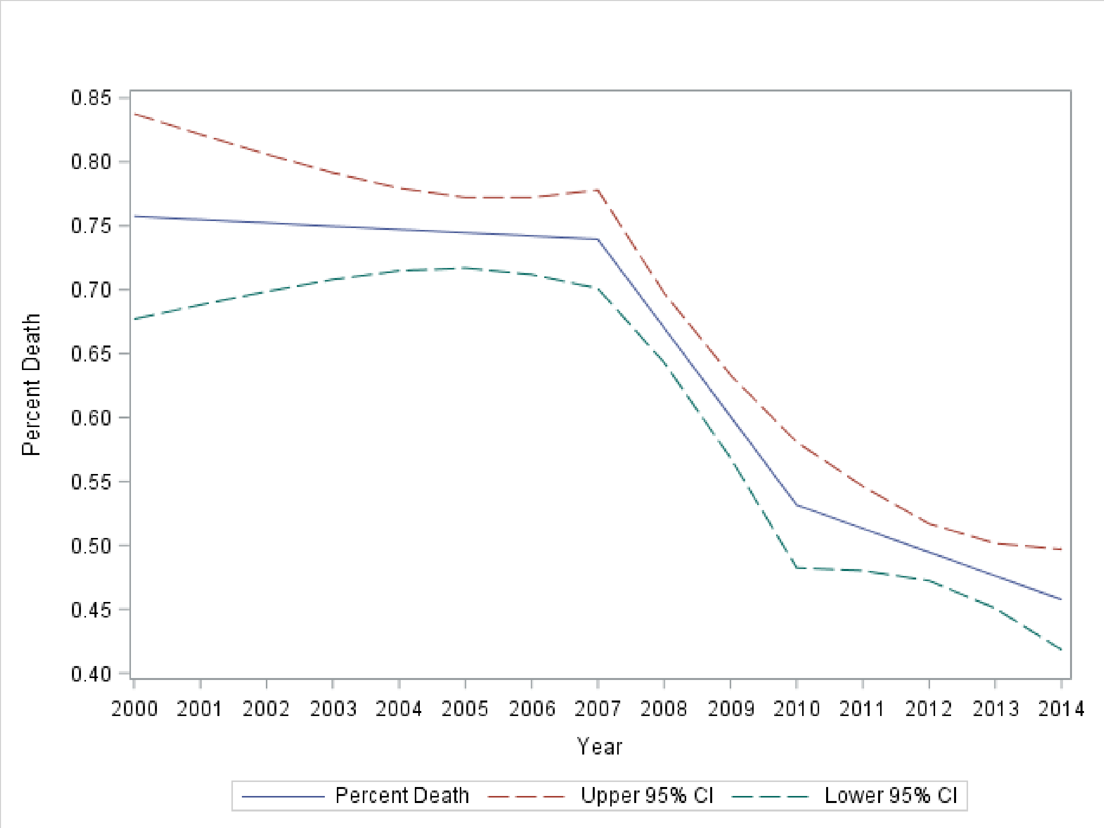

Figure 2: Time-series analysis for overall mortality across pre-implementation, implementation, and post-implementation periods adjusted for admission type

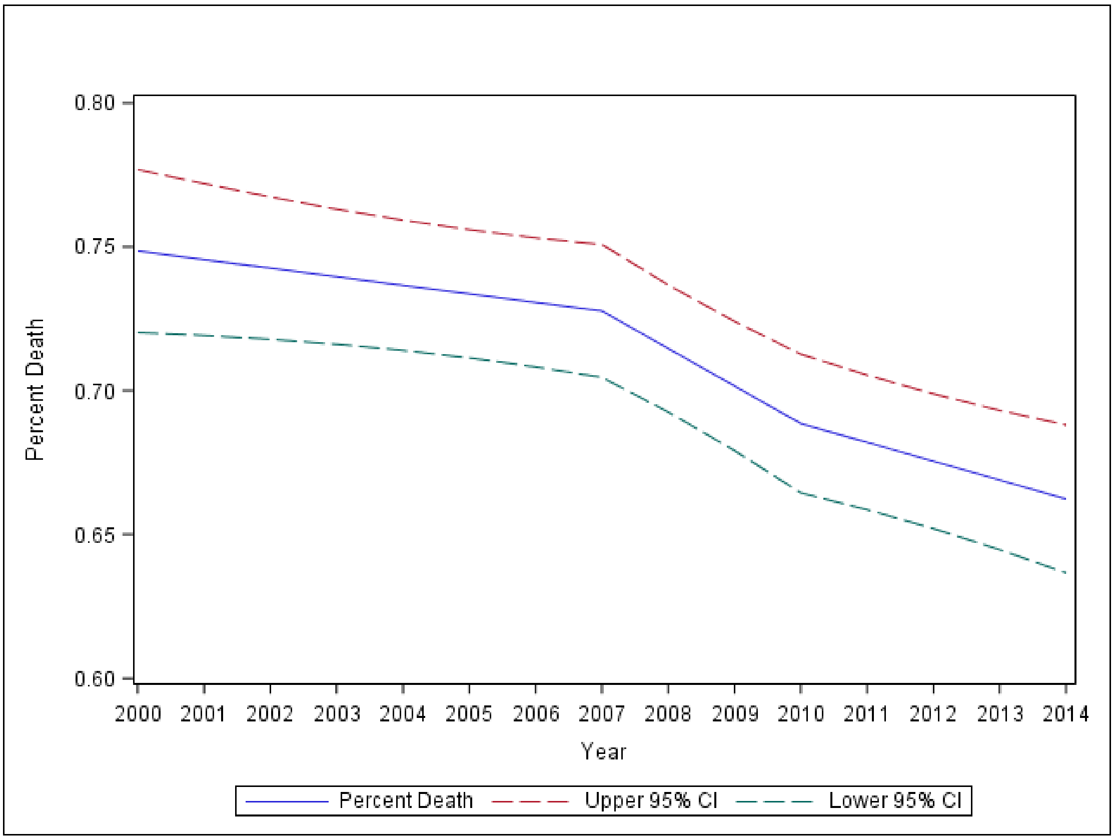

Figure 3: Time-series analysis for return to theatre for elective admissions across pre-implementation, implementation, and post-implementation periods