

# BMJ Open Quality Impact of the Norwegian National Patient Safety Program on implementation of the WHO Surgical Safety Checklist and on perioperative safety culture

Arvid Steinar Haugen <sup>1,2</sup>, Eirik Søfteland,<sup>1,3</sup> Nick Sevdalis,<sup>2</sup> Geir Egil Eide,<sup>4</sup> Monica Wammen Nortvedt,<sup>5</sup> Charles Vincent,<sup>6</sup> Stig Harthug<sup>7,8</sup>

**To cite:** Haugen AS, Søfteland E, Sevdalis N, *et al.* Impact of the Norwegian National Patient Safety Program on implementation of the WHO Surgical Safety Checklist and on perioperative safety culture. *BMJ Open Quality* 2020;**9**:e000966. doi:10.1136/bmjopen-2020-000966

► Additional material is published online only. To view please visit the journal online (<http://dx.doi.org/10.1136/bmjopen-2020-000966>).

Received 4 March 2020  
Revised 3 June 2020  
Accepted 24 June 2020



© Author(s) (or their employer(s)) 2020. Re-use permitted under CC BY-NC. No commercial re-use. See rights and permissions. Published by BMJ.

For numbered affiliations see end of article.

## Correspondence to

Dr Arvid Steinar Haugen;  
[arvid.haugen@helse-bergen.no](mailto:arvid.haugen@helse-bergen.no)

## ABSTRACT

**Objectives** Our primary objective was to study the impact of the Norwegian National Patient Safety Campaign and Program on Surgical Safety Checklist (SSC) implementation and on safety culture. Secondary objective was associations between SSC fidelity and safety culture. We hypothesised that the programme influenced on SSC use and operating theatre personnel's safety culture perceptions.

**Setting** A longitudinal cross-sectional study was conducted in a large Norwegian tertiary teaching hospital.

**Participants** We invited 1754 operating theatre personnel to participate in the study, of which 920 responded to the surveys at three time points in 2009, 2010 and 2017.

**Primary and secondary outcome measures** Primary outcome was the results of the patient safety culture measured by the culturally adapted Norwegian version of the Hospital Survey on Patient Safety Culture. Our previously published results from 2009/2010 were compared with new data collected in 2017. Secondary outcome was correlation between SSC fidelity and safety culture. Fidelity was electronically recorded.

**Results** Survey response rates were 61% (349/575), 51% (292/569) and 46% (279/610) in 2009, 2010 and 2017, respectively. Eight of the 12 safety culture dimensions significantly improved over time with the largest increase being 'Hospital managers' support to patient safety' from a mean score of 2.82 at baseline in 2009 to 3.15 in 2017 (mean change: 0.33, 95% CI 0.21 to 0.44). Fidelity in use of the SSC averaged 88% (26 741/30 426) in 2017. Perceptions of safety culture dimensions in 2009 and in 2017 correlated significantly though weakly with fidelity ( $r=0.07-0.21$ ).

**Conclusion** The National Patient Safety Program, fostering engagement from trust boards, hospital managers and frontline operating theatre personnel enabled effective implementation of the SSC. As part of a wider strategic safety initiative, implementation of SSC coincided with an improved safety culture.

## INTRODUCTION

Nearly two decades ago, the Institute of Medicine's report 'To Err Is Human' contributed to a major shift in healthcare's view on quality

and safety, with a call to improve hospitals' patient safety culture.<sup>1</sup> Studies indicate that safety culture is linked to clinical outcomes. In the UK, cultures of openness, transparency and accountability in 137 National Health Service hospitals were associated with lower mortality.<sup>2</sup> In the USA, a positive safety culture was associated with reduced surgical site infections in seven Minnesota community hospitals.<sup>3</sup> The increasing interest in safety culture has translated into several tools developed to monitor safety culture in hospitals such as the Hospital Survey on Patient Safety Culture (HSOPSC) questionnaire developed by the US Agency of Healthcare Research and Quality<sup>4</sup> or the Safety Attitudes Questionnaire (SAQ).<sup>5</sup> Such survey tools are widely used to capture 'snapshots' of an organisation's safety culture.<sup>6-8</sup>

Following on from the above developments in safety policy and evidence, large campaigns have been launched to reduce complications and preventable deaths in hospitals.<sup>9</sup> Surgical care has featured prominently among them—for instance, with the Safe Surgery Saves Lives campaign.<sup>10 11</sup> Surgery has also witnessed the development and application of one of the most prominent safety interventions globally in the past decade—the WHO Surgical Safety Checklist (SSC). The SSC offers a simple set of three checklists to be delivered before the patient is anaesthetised, immediately prior to incision and before the patient is transferred out of the operating theatre. Early evaluations of the SSC demonstrated reductions in complications and mortality.<sup>12-14</sup> Other studies however did not find similar results,<sup>15 16</sup> probably because of a failure to assess and achieve fidelity to the intervention delivery. Studies assessing SSC fidelity reported significant lower risk of postoperative complications

**Table 1** 'In Safe Hands 24/7'**Norwegian National Patient Safety Campaign (2011–2013) and Program (2014–2018)****Patient safety target areas**

- ▶ Safety culture.
- ▶ Surgical safety checklist.
- ▶ Medication conciliations.
- ▶ Prevention of falls.
- ▶ Prevention of decubitus.
- ▶ Prevention of malnutrition.
- ▶ Prevention of urinary tract infections.
- ▶ Prevention of blood stream infections.
- ▶ Prevention of suicides.
- ▶ Prevention of overdose mortality.
- ▶ National early warning score.\*
- ▶ Early detection of sepsis.\*
- ▶ Stroke treatment.
- ▶ Safe discharge.\*
- ▶ Management of patient safety.

**Campaign/programme impact on safety culture and implementation of the Surgical Safety Checklist**

- ▶ Measures of compliance, how to do data collection, to observe process metrics and how to report to the programme.
  - ▶ The checklist itself with available tools.
  - ▶ Evidence base for the checklist (review) with presentations and reports from the pilot available for use.
  - ▶ Additional material available for education of staff with videos and e-learning course to use for implementation.
  - ▶ Safety culture surveys.
  - ▶ Learn managers to handle patient safety.
- The WHO Surgical Safety Checklist was the first target area of the programme.

**Management of the programme**

Annual national patient safety meetings, regional meetings, national action plans, quality and improvement tools and seminars are readily available for use by managers and hospital staff and clinicians. Global trigger tool is used in all hospitals by trained staff to measure patient harm, and data are published on the safety programme's web site.†

**Local adaption of programme in surgical wards and operating theatres**

Patient safety units at hospital level handle the patient safety programme in collaboration with managers and clinicians. In meetings, the CEO feeds clinical directors and frontline managers with metrics on prevention of falls, decubitus and malnutrition for surgical wards and on the Surgical Safety Checklist for operating theatre managers. Then theatre managers provide feedback on compliance rates of the Surgical Safety Checklist to their clinical staff. Feedback also includes guidelines for checklist use and clinical audits that are used for monitoring quality of checklist performance and quality improvement. Local adaptations of the checklist are performed with multidisciplinary collaboration and stakeholders.

\*Target areas since 2017/2018.

†Sources: <https://www.pasientsikkerhetsprogrammet.no/>; <https://www.pasientsikkerhetsprogrammet.no/om-oss/om-pasientsikkerhetsprogrammet/pasientskader-i-norge>.

and mortality when all three parts of the checklist had been used.<sup>17–19</sup> The only globally available stepped wedge cluster randomised controlled trial (RCT), performed in two Norwegian hospitals by our group, found a reduction of complications from 19.9% to 11.5%, with an absolute risk reduction of 8.4% (95% CI 6.3 to 10.5), again when fidelity of SSC delivery was highest.<sup>20</sup> Reduction in length of stay at 0.8 days was also found in this study.

The SSC was introduced as a part of a regional hospital quality improvement project in the Western Norway Regional Health Authority in 2009–2010. Implementation and evaluation of the checklist intervention was designed as a cluster RCT, where the SSC was sequentially introduced to the clusters in stepped wedges in a randomised order.<sup>21</sup> The context of this RCT was as follows: the study was carried out in 2009–2010 preceding the Norwegian National Patient Safety Campaign (2011–2013). The SSC was the first national target area and became a proxy for implementation of a range of patient safety interventions, such as medication conciliations, stroke treatment, prevention of falls, malnutrition, decubitus, infections and suicides (table 1). Among all national target areas, implementation of the SSC became the first target area of the National Patient Safety Campaign (2011–2013) named 'In Safe Hands 24/7' and the following National

Patient Safety Program (2014–2018).<sup>22</sup> The programme consists of a bundle of patient safety target areas (table 1).

Implementation of the National Patient Safety Program in hospitals has been guided by national health policies and carried out by directors, patient safety units, managers, clinical staff, and through learning networks across hospitals, and ultimately fostering hospital safety culture. Hospitals' use of the SSC has been a quality indicator for the national programme, focusing on SSC compliance rates at hospital level, and for quality improvement. More specific, the programme trains managers in leadership of patient safety and quality improvement to influence and change safety culture. The checklist itself typically addresses operating theatre risk management items and teamwork and communication (ie, presentation of team members and enhance team members to speak up).<sup>12</sup> As a part of the hospital's wider focus on quality improvement in surgery, SSC implementation has been facilitated through the hospital managers' engagement, compliance feedback to clinical staff and managers being held accountable for checklist use and local tailoring of the SSC by multidisciplinary perioperative teams.<sup>23</sup>

The campaign evolved into the National Patient Safety Program (2014–2018), which drove the implementation of the SSC with the wider aims of improving hospitals

safety culture and reducing preventable complications by 25% in perioperative care in Norway by 2018.<sup>22</sup> At a national level, significant reduction of patient harm measured with Global Trigger Tool was achieved, from 13.7% in 2012 to 10.8% in 2018, and further a 44% reduction from 12.9% to 8.5%, respectively, was observed in our study hospital.<sup>24</sup> Likewise, during the 8-year period from 2010 to 2018, 30-day hospital survival rates significantly increased from 94.6% to 95.4% nationally and from 94.8% to 95.7% locally.<sup>25</sup>

A similar pattern in clinical improvements through scaled SSC implementation has been documented elsewhere too. Effective implementation of the SSC supported by a state-wide surgical safety programme showed significant reduction of 30-day mortality in US South Carolina hospitals.<sup>26</sup> The programme was enhanced by a state-level leadership team with clinical champions, administrators, researchers and insurance carriers representatives, with several activities to foster engagement, learning and to improve safety culture. This large-scale SSC implementation was also associated with improved safety culture dimensions as mutual respect, clinical leadership, assertiveness on safety, team coordination and communication.<sup>27</sup>

To date, the impact of the SSC in perioperative safety culture remains unclear: some studies have reported a positive impact of the SSC on culture,<sup>28–30</sup> whereas others have not.<sup>31</sup> Notably, we found no effect of the intervention on perioperative safety culture.<sup>32</sup> These conflicting results are rather puzzling—not least as the SSC is thought to bring about its beneficial effects on patient care through improved team working behaviours and attitudes throughout the perioperative team<sup>33</sup>—and one would thus expect a similar positive shift on the team's culture.

The aim of the present study is to address this conundrum in the SSC evidence base, using the globally unique 'natural experiment', that implementation of the SSC in Norway as part of the national safety campaign affords us. We hypothesise that scaled patient safety national campaigns and programmes require a broader strategy and engagement by trust boards and hospital managers, which in turn makes SSC implementation stronger and enables the SSC implementation an opportunity of changing safety culture perceptions in clinical staff. These aforementioned developments at a national and local level, and across an entire decade, allowed us to test this hypothesis. Our primary objective was to study the longitudinal impact of the Norwegian national patient safety programme on SSC implementation and, through it, perioperative personnel's safety culture perceptions in a tertiary teaching hospital. As a secondary objective, we further investigate associations between fidelity of delivery of the SSC and safety culture.

## METHODS

### Design

We performed a longitudinal follow-up of the safety culture in operating theatre teams. Safety culture was

first investigated in a controlled intervention study before (2009) and after (2010) our stepped wedge cluster randomised controlled SSC trial,<sup>20</sup> using a validated survey instrument, the HSOPSC.<sup>32</sup> After the initial trial, the SSC was further implemented locally until all surgical departments had received the checklist intervention. Safety culture was assessed again for a third time in January 2017. Throughout, fidelity of SSC implementation (ie, use of the entire checklist or parts of it) was electronically recorded in real time by operating theatre nurses and nurse anaesthetists in the operating theatres.

### Population

The study was performed in a large tertiary teaching hospital offering all types of surgery except transplantations: cardiothoracic; neuro; ear–nose–throat and maxillofacial; orthopaedic; upper and lower gastrointestinal; urology; vascular; breast and endocrinology; gynaecology and obstetrics; ophthalmic; and plastic and burn surgery. Surgical volume amounts to over 30 000 surgical procedures annually with the operating teams consisting of surgeons, anaesthesiologists, nurse anaesthetists and operating theatre nurses. All eligible team members were included in the survey together with perioperative ancillary staff.

### Outcome measures

Primary outcome was the results of the patient safety culture measured by the culturally adapted Norwegian version of the HSOPSC. Our previously published results were compared with new data collected in 2017.<sup>32 34</sup> The HSOPSC was originally developed by the US Agency of Healthcare Research and Quality.<sup>4</sup> The 12 safety culture dimensions consist of 42 single items distributed as three or four items per dimension. The dimensions cover aspects of hospitals safety culture as: 'Overall patient safety', 'Frequency of events', 'Unit managers support to patient safety', 'Organisational learning – continuous improvement', 'Teamwork in unit', 'Communication openness', 'Error feedback', 'Non-punitive', 'Adequate staffing', 'Hospital managers support to patient safety', 'Teamwork across units', and 'Hand-offs and transitions'. Items are scored on 1–5 Likert scales (anchored at 1='strongly disagree' to 5='strongly agree', or 1='never' to 5='always'). Psychometric properties of the questionnaire items and safety culture dimensions have been reported to be sound at the individual, unit and hospital levels of analysis and can be used to assess hospitals' patient safety culture.<sup>35 36</sup> Secondary outcome was correlation between SSC fidelity and safety culture.

### Data collection

The HSOPSC questionnaires were distributed pre-SSC and post-SSC implementation in 2009 and 2010<sup>32 34</sup> and were compared against data collected in 2017. The questionnaires were forwarded to operating theatre personnel through a paper version and an online electronic version over 3–4 weeks. Throughout, fidelity data on the WHO SSC were registered in an electronic operating planning

system (ORBIT) by nurse anaesthetists or operating theatre nurses. The checklist consist of three parts (online supplementary file 1). All items on the sign in, time out and the sign out were to be completed.

### Statistical analysis

Statistical analysis was performed using SPSS V.24. Descriptive statistics were used to report respondents' characteristics, mean scores and SDs of the 12 safety culture dimensions. Internal reliability of the HSOPSC was assessed with Cronbach's  $\alpha$  coefficient. Missing values were replaced by the mean scores of the items.<sup>32</sup> To take into account responses on the entire HSOPSC scale (all 12 dimensions), we used multivariate analysis with General Linear Model (multivariate regression analysis with Wilks' lambda exact test) to assess possible changes from 2009 to 2010 and 2017. Correlations between safety culture dimensions and SSC compliance were measured with Pearson's *r*. Two-tailed *p* values  $\leq 0.05$  were considered statistically significant.

### RESULTS

For the 2009, 2010 and 2017 questionnaire administrations, the response rates were 61% (349/575), 51% (292/569) and 46% (279/610), respectively, and the global response rate reached 52% (920/1754). Sample characteristics of the responders are reported in [table 2](#).

Internal reliability of the HSOPSC was assessed with Cronbach's  $\alpha$  separately for each questionnaire administration at three time points (2009, 2010 and 2017). The global mean  $\alpha$  value for all 12 dimensions was 0.73 (SD: 0.07). Individual safety culture dimensions'  $\alpha$  values ranged from 0.63 to 0.84. These findings show that internal reliability of the HSOPSC was satisfactory and allowed further analyses ([table 3](#)).

[Table 4](#) summarises the main findings on the safety culture dimension' scores. Safety culture dimensions that related directly to the patient safety programme, as well as the SSC implementation were: hospital managers' (top and frontline) dedication to patient safety, handling of errors

**Table 2** Characteristics of operating theatre (OT) staff responses (n=920) in a longitudinal follow-up study on hospital safety culture before (2009) and after (2010 and 2017) the implementation of the WHO's Surgical Safety Checklists in a stepped wedge cluster-randomised controlled trial at Haukeland University Hospital, Bergen, Norway

Survey years	2009		2010		2017	
	n=349	%	n=292	%	n=279	%
<b>Characteristics</b>						
<b>Profession</b>						
Surgeon	125	35.8	94	32.2	50	17.9
OT nurse	78	22.3	70	24.0	74	26.5
Anaesthesiologist	44	12.6	41	14.0	42	15.1
Nurse anaesthetist	77	22.1	71	24.0	75	26.9
Ancillary personnel	25	7.2	17	5.8	16	5.7
Missing	–	–	–	–	22	7.9
<b>Years in profession</b>						
<1	10	2.9	14	4.8	14	5.0
1–5	97	27.8	78	26.7	64	22.9
6–10	103	29.5	73	25.0	50	18.3
11–15	40	11.5	42	14.4	43	15.8
16–20	25	7.2	38	13.0	48	17.2
>21	65	18.6	41	14.0	54	19.4
Missing	9	2.6	6	2.1	6	2.2
<b>Weekly working hours</b>						
<20	16	4.6	7	2.4	7	2.5
20–37	140	40.4	114	39.0	126	45.2
>37	189	54.2	168	57.5	141	50.5
Missing	3	0.9	3	1.0	5	1.8
<b>Handling patients</b>						
Yes	322	92.3	269	92.1	225	80.6
No	21	6.0	17	5.8	13	4.7
Missing	6	1.7	6	2.1	41	14.7

**Table 3** Internal reliability of the HSOPSC's safety culture factors in 920 responses to a longitudinal follow-up study of operating theatre staff perceptions on hospital safety culture after a stepped wedge cluster randomised controlled trial implementation of the WHO's Surgical Safety Checklists at Haukeland University Hospital, Bergen, Norway, 2009–2017

Safety culture dimensions*	Items	Survey years			
		2009	2010	2017	All
Overall PS in hospital	4	0.78	0.71	0.76	0.76
Frequency of events	3	0.82	0.82	0.75	0.81
Unit managers support PS	4	0.85	0.84	0.80	0.84
Continuous improvement	3	0.64	0.67	0.63	0.65
Teamwork in unit	4	0.76	0.73	0.70	0.74
Open communication	3	0.67	0.72	0.67	0.69
Error feedback	3	0.72	0.77	0.78	0.76
Non-punitive	3	0.67	0.60	0.72	0.67
Adequate staffing	4	0.59	0.67	0.63	0.63
Hospital manager support PS	3	0.80	0.76	0.81	0.79
Teamwork across units	4	0.68	0.69	0.60	0.67
Handoffs and transitions	4	0.74	0.76	0.76	0.75

\*All dimensions gave average scores on the included items on a scale from 1 to 5.

$\alpha$ , Cronbach's alpha; HSOPSC, Hospital Survey on Patient Safety Culture; PS, patient safety.

(feedback and non-punitive), continuous improvement work, communication and teamwork. From 2009 to 2017, we observed significant improvement for the dimensions: 'Unit managers' support to patient safety', 'Continuous improvement', 'Teamwork in unit', 'Error feedback', 'Non-punitive', 'Hospital managers support to patient safety', 'Teamwork across units' and 'Information handoffs and

transitions'. The largest positive changes were found for 'Hospital managers' support to patient safety', from 2.83 at baseline in 2009 to mean score 3.15 in 2017 (mean change: 0.33, 95% CI 0.21 to 0.44). For 'Unit managers support to patient safety', we observed a positive change from 3.66 at baseline and 3.86 to mean score 3.86 in 2017 (mean change: 0.21, 95% CI 0.09 to 0.33) (tables 4 and 5).

**Table 4** Descriptive statistics for all HSOPSC factors in the longitudinal follow-up study of operating theatre staff perceptions' on hospital safety culture in the stepped wedge cluster RCT implementation of the WHO's Surgical Safety Checklists in Haukeland University Hospital, Bergen, Norway

Use of surgical safety checklists	2009	2010		2017
	No	No	Yes	Yes
	(n=349)	(n=135)	(n=141)	(n=279)
<b>Safety culture factors (HSOPSC)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>	<b>Mean (SD)</b>
Overall patient safety	3.49 (0.70)	3.53 (0.66)	3.63 (0.59)*	3.58 (0.70)
Frequency of events	2.80 (0.79)	2.81 (0.84)	2.78 (0.70)	2.89 (0.70)
Unit managers support patient safety	3.66 (0.79)	3.55 (0.86)	3.70 (0.69)	3.86 (0.65)***
Continuous improvement	3.33 (0.66)	3.36 (0.71)	3.51 (0.55)**	3.52 (0.58)***
Team work in unit	3.61 (0.62)	3.55 (0.62)	3.73 (0.54)*	3.80 (0.57)***
Open communication	3.60 (0.65)	3.61 (0.67)	3.63 (0.65)	3.68 (0.61)
Error feedback	3.18 (0.72)	*3.00 (0.77)	3.22 (0.72)	3.35 (0.73)**
Non-punitive	3.82 (0.64)	3.82 (0.61)	3.91 (0.62)	3.97 (0.62)**
Adequate staffing	3.41 (0.64)	3.45 (0.64)	3.60 (0.60)**	3.50 (0.65)
Hospital managers support patient safety	2.82 (0.75)	2.95 (0.73)	2.92 (0.73)	3.15 (0.75)***
Team work across units	3.07 (0.53)	3.14 (0.51)	3.04 (0.50)	3.20 (0.49)**
Handoffs and transitions	3.04 (0.61)	*3.11 (0.59)	3.07 (0.60)	3.21 (0.62)***

\* $P \leq 0.05$ ; \*\* $p \leq 0.01$ ; \*\*\* $p \leq 0.001$ ; from multivariate regression analysis as detailed in table 5.

HSOPSC, Hospital Survey on Patient Safety Culture; RCT, randomised controlled trial.;



**Table 5** Results from multivariate regression analysis of the 12 safety culture dimensions of the Hospital Survey On Patient Safety Culture in 920\* responses to a longitudinal follow-up study after a stepped wedge cluster RCT on surgical safety checklists, in Haukeland university Hospital, Bergen, Norway, 2009–2017

HSOPSC safety culture dimensions	2009 (n=330)		2010 versus 2009 (n=139 and 137 vs 330)		2017 versus 2009 (n=265 vs 330)		2017 versus 2010 (n=265 vs 137)					
	SSC	b <sub>0</sub>	b <sub>1</sub>	95% CI	P value†	b <sub>2</sub>	95% CI	P value†	b <sub>2</sub>	95% CI	P value†	
Overall patient safety	No	3.49	(3.42 to 3.57)	0.05	(-0.09 to 0.18)	0.470	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.13	(-0.01 to 0.26)	0.067	0.09	(-0.02 to 0.20)	0.123	-0.04	(-0.18 to 0.10)	0.574
Frequency of events	No	2.80	(2.72 to 2.88)	0.01	(-0.14 to 0.16)	0.948	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	-0.02	(-0.17 to 0.13)	0.819	0.09	(-0.03 to 0.22)	0.134	0.12	(-0.04 to 0.28)	0.129
Unit managers support	No	3.66	(3.58 to 3.74)	-0.11	(-0.26 to 0.04)	0.153	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.05	(-0.10 to 0.20)	0.538	0.21	(0.09 to 0.33)	0.001	0.15	(-0.00 to 0.31)	0.053
Continuous improvement	No	3.33	(3.26 to 3.40)	0.03	(-0.10 to 0.15)	0.657	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.19	(0.06 to 0.31)	0.003	0.19	(0.09 to 0.30)	<0.001	0.03	(-0.10 to 0.16)	0.671
Team work in unit	No	3.61	(3.54 to 3.67)	0.05	(-0.16 to 0.07)	0.440	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.12	(-0.00 to 0.24)	0.052	0.19	(0.10 to 0.29)	<0.001	0.08	(-0.05 to 0.20)	0.227
Open communication	No	3.60	(3.53 to 3.67)	0.02	(-0.11 to 0.15)	0.764	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.02	(-0.11 to 0.15)	0.745	0.09	(-0.02 to 0.19)	0.099	0.07	(-0.07 to 0.20)	0.327
Error feedback	No	3.18	(3.10 to 3.26)	-0.17	(-0.31 to 0.02)	0.025	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.05	(-0.10 to 0.20)	0.515	0.17	(0.05 to 0.29)	0.004	0.15	(-0.01 to 0.30)	0.058
Non-punitive	No	3.82	(3.75 to 3.88)	-0.09	(-0.21 to 0.03)	0.156	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.09	(-0.04 to 0.21)	0.165	0.15	(0.05 to 0.25)	0.004	0.08	(-0.05 to 0.20)	0.243
Adequate staffing	No	3.41	(3.34 to 3.48)	-0.09	(-0.22 to 0.04)	0.180	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.18	(0.05 to 0.31)	0.006	0.09	(-0.01 to 0.20)	0.084	-0.09	(-0.22 to 0.05)	0.210
Hospital managers support	No	2.82	(2.74 to 2.91)	0.16	(0.01 to 0.30)	0.039	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.09	(-0.06 to 0.24)	0.237	0.33	(0.21 to 0.45)	<0.001	0.23	(0.08 to 0.39)	0.003
Teamwork across units	No	3.07	(3.01 to 3.12)	0.07	(-0.03 to 0.18)	0.151	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	-0.03	(-0.13 to 0.07)	0.552	0.13	(0.05 to 0.22)	0.002	0.16	(0.06 to 0.27)	0.002
Handoffs and transitions	No	3.04	(2.97 to 3.10)	0.13	(0.01 to 0.25)	0.035	n.a.	-	n.a.	-	-	-
	Yes	n.a.	-	0.03	(-0.10 to 0.15)	0.674	0.17	(0.08 to 0.27)	0.001	0.15	(-0.04 to 0.24)	0.170

\*The analysis is based on 871 cases with complete data for all dimensions and surveys.

†P values—from t-tests in the multivariate linear regression model. Multivariate test for all dimensions: F=3.45, df1=36, df2=2527, p<0.001 (Wilk's lambda, exact test).

‡Estimates from model with 2010 SSC as reference category.

b<sub>0</sub>, intercept, represents the estimated mean value of the dimension in 2009 (reference category); b<sub>1</sub> and b<sub>2</sub>, estimated regression coefficients, represent average changes in dimension scores from 2009 to 2010 and 2017, respectively; HSOPSC, Hospital Survey on Patient Safety Culture; n.a., not applicable; RCT, randomised controlled trial; SSC, Surgical Safety Checklist.

Changes in perioperative staff's safety culture perceptions based on multivariate linear regression analysis are detailed in [table 5](#). In total, 8 of 12 safety culture dimensions significantly improved over the study period and the remaining four dimensions followed the same trend, though they did not reach significance. Multivariate regression analysis with Wilks' lambda exact test for all safety culture dimensions was significant at  $p < 0.001$ .

Lastly, we analysed relations between operating theatre staff's perceptions of safety culture and the SSC compliance rates. Compliance was 75% (1767/2367) in orthopaedic, thoracic and neuro surgery from 2009 to 2010.<sup>32</sup> In 2017, overall and for all types of surgery the SSC compliance averaged 88% (26 741/30 426) of the operations. We further investigated the associations between safety culture and use of the checklist in 2009 and in 2017, and we found that correlations between use of the SSC and improved safety culture dimensions were significant though weak ( $r = 0.09 - 0.21$ ).

## DISCUSSION

To our knowledge, this is the first longitudinal assessment of perioperative safety culture, spanning 8 years, following introduction of the SSC. We identified significant improvements in a majority of safety culture dimensions from 2009 to 2017. The changes were especially evident for 'hospital managers' support to patient safety' in 2010 and even more in 2017. Improvements in how hospital leaders, from chief executive officer (CEO) to clinical directors and frontline managers, are perceived to support and promote patient safety in the hospital may have been influenced by the managers' organisational focus on quality improvement, as a result of the national patient safety campaign and programme;<sup>23</sup> though direct assessment of managerial focus is complex and hard to measure directly, our results indicate that this safety culture dimension has improved over time.

Overall, introduction of the SSC in itself was not enough to drive an overall change in the safety culture from 2009 to 2010<sup>32</sup>; however, the SSC has subsequently become an important part of the patient safety programme. National regulatory bodies enact governance of quality in hospital services through making trust boards accountable of quality improvement with use of systematic methods and tools to improve outcome for patients, of which measuring compliance rates and quality of SSC use in Norwegian hospitals is part of.<sup>22</sup> Measuring SSC compliance rates (ie, fidelity of use) with feedback to trust boards, from CEO to clinical managers and clinicians combined with multidisciplinary team engagement to local adaptation of the SSC,<sup>23</sup> appears to have positively influenced SSC use over time. Emerging evidence on the benefits of using the SSC in Norwegian hospitals has been used by boards and managers as motivation for monitoring compliance rates and to stimulate use of the SSC (a typical 'audit-and-feedback' implementation strategy).<sup>20</sup> Boards with higher levels of maturity regarding quality improvement

government have been characterised to explicitly prioritise quality improvement, balancing short and long-term investment in quality improvement, using data for quality improvement, engaging staff and patients in quality improvement and encouraging a culture of continuous improvement.<sup>37</sup> The hospital managers' strategic and systematic organisational focus on monitoring compliance and support to clinical staff in using the WHO SSC may then seem to have influenced or at least coincided with improvement in the safety culture dimensions of top and frontline managers' support to patient safety.

An overall aim for the WHO SSC is to improve teamwork, communication and consistency of care.<sup>38</sup> In this longitudinal study of the SSC impact on teamwork as part of the safety culture, we observed significant improvement in teamwork within units and across units. In a study from Scotland, the SSC was found to improve teamwork and communication via stimulating sharing of information about the anaesthetic plan within the anaesthesia team. Haynes and colleagues reported significantly better overall safety attitude scores in the postintervention group of SSC implementation, in a global WHO study of the SSC effectiveness.<sup>28</sup> In a Japanese study of the SSC impact on safety culture measured with the SAQ,<sup>5</sup> similar positive changes were found on teamwork and communication.<sup>29</sup> Safety culture was improved in five of six safety culture domains (including teamwork) of the SAQ – Operating Room version 1 year after introduction of Patient Safety Firsts' 5 Steps for Safer Surgery, including the WHO SSC and preoperative and postoperative briefings, in a UK tertiary care hospital.<sup>30</sup> Across three US states, the programme of team strategies and tools to enhance performance and patient safety, labelled as TeamSTEPS, was introduced in 37 hospitals including team training to improve safety culture and team behaviour in a longitudinal study. They reported that transformational change in safety culture team training by using team training is possible when work environment supports transfer of learning.<sup>39</sup> Our findings on longitudinal improved teamwork and communication (handover and transfer of information) may also well be associated with the managers and wider organisational persistence over time focusing on effective use of the SSC.

Furthermore, we observed improvements for 'Organisational learning – continuous improvement', feedback on error and non-punitive culture. Learning from errors is a key goal typically met via using critical incident reporting.<sup>40</sup> Error reporting systems enables clinical managers to build in error reduction strategies through systematic analysis of errors using frameworks as suggested by Vincent and colleagues.<sup>41</sup> 'Continuous improvement' could be associated to persistent focus on the SSC in the hospital; however, the checklist relationship with error reporting and a non-punitive culture is probably more complex. Stronger focus on error identification and reduction as part of the wider patient safety national campaign and programme in Norway may have enhanced focus on learning from error in our surveys.

It could also have contributed to improve to perceived feedback and continuous learning at the individual level. Furthermore, a high level of non-punitive scores may reflect that the hospital organisation has a 'flaws in system' approach to errors rather than 'blame and shame' when errors occur.<sup>1</sup>

### Limitations and strengths

A possible limitation to the study findings is that structural and organisational changes that we were unable to assess may have impacted on parts of the safety culture as well as the SSC implementation. Introduction of the SSC does not 'automatically' improve communication and team interactions,<sup>42</sup> even though some checklist items are designed for enhancing team members to speak up (as introduction of names and roles in the time out) and sharing of critical information.<sup>12</sup> Still, alongside our study, we have observed that a persistent organisational focus on the SSC over 8 years contributed to a better perception on the majority of the safety culture dimensions studied. The managerial focus on quality improvement could also have been influenced by hospital economy. Importantly, during the period of the patient safety programme, the funding bodies rewarded hospitals with higher score on a few selected quality improvement indicators financially. Another limitation of the study could be that we in our analyses treated all survey responses as independent respondents. It was not possible to link these individual responses for anonymity reasons, and we consider that a long time between the surveys would mitigate implications on survey outcomes. Generalisability may be limited to large size hospitals.

Lastly, as with any survey study, response rates averaged 52%; overall, this is a limitation of all such studies. We previously investigated whether non-responders differed from responders on gender, experience and profession. Inclusion and adjusting of covariates did not influence conclusions.<sup>32</sup>

### Implications for clinical practice and further research

Change of safety culture perceptions is possible, but it may take a long time and require long-term involvement from hospital managers, leading clinicians and frontline staff. Effective implementation of surgical safety checklists, as shown in this study, depends on having a carefully planned and broad strategy for the intervention. Surgical teams are multidisciplinary, and keeping everyone on the same page is important. Hence, implementation should include all professions involved, stakeholders/influencers and especially when tailoring the checklist to fit clinical practice. Monitoring use of the checklist with care, use of clinical audits and feedback to managers and clinicians are helpful tools for an effective implementation. Further investigation of associations between patient outcomes and patient safety culture dimensions will increase knowledge on precisely how patient safety culture impacts on clinical quality improvement and outcomes of care.

## CONCLUSION

The Norwegian patient safety national programme, fostering engagement from trust boards, hospital managers and frontline perioperative staff, enhanced SSC fidelity. Implementation of SSC as part of a wider strategic safety initiative coincided with an improved perioperative safety culture.

### Author affiliations

<sup>1</sup>Department of Anaesthesia and Intensive Care, Haukeland University Hospital, Bergen, Norway

<sup>2</sup>Center for Implementation Science, Health Service, and Population Research Department, King's College London, London, United Kingdom

<sup>3</sup>Department of Clinical Medicine, Faculty of Medicine, University of Bergen, Bergen, Norway

<sup>4</sup>Centre for Clinical Research, Haukeland University Hospital, Bergen, Norway

<sup>5</sup>Centre for Evidence Based Practice, Western Norway University of Applied Sciences, Bergen, Vestland, Norway

<sup>6</sup>Department of Experimental Psychology, University of Oxford, London, UK

<sup>7</sup>Department of Research and Development, Haukeland University Hospital, Bergen, Norway

<sup>8</sup>Department of Clinical Science, University of Bergen, Bergen, Norway

**Twitter** Arvid Steinar Haugen @HaugenArvid

**Acknowledgements** We would like to thank the study participants for their contributions.

**Contributors** ASH, ES, NS and SH conceived the study. ASH collected data and performed all analysis with GEE (professor in biostatistics). MWN and CV contributed to interpretation of data. ASH drafted the manuscript and ES, NS, GEE, MWN, CV and SH revised it critically for intellectual content. All authors approved the final version to be published and agree to be accountable for all aspects of the work.

**Funding** This study received departmental support. ASH received postdoctoral grant from the Western Norwegian Regional Health Authority with grant number: HV1172. Parts of the work were carried out during a research stay at the Centre of Implementation Science, IoPPN, King's College London, UK. NS's research is funded by the National Institute for Health Research (NIHR) via the 'Collaboration for Leadership in Applied Health Research and Care South London' at King's College Hospital NHS Foundation Trust, London, UK. NS is also a member of King's Improvement Science, which is part of the NIHR CLAHRC South London and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity, the Maudsley Charity and the Health Foundation.

**Disclaimer** The views expressed are those of the authors and not necessarily those of the International Federation of Nurse Anaesthetists (IFNA), European Society of Anaesthesiologists' (ESA) Patient Safety and Quality Committee, NHS, the NIHR or the Department of Health and Social Care. The funders had no role in the design, conduct or analysis of this study. The Norwegian Directorate of Health had no role in planning the design, conduct or analysis of this study.

**Competing interests** ASH represent the IFNA in the ESA Patient Safety and Quality Committee. NS is the Director of London Safety and Training Solutions Ltd, which provides quality and safety training and advisory services on a consultancy basis to healthcare organisation globally. The other authors report no conflicts of interest. SH had a role as lead of the Scientific Advisory Board appointed by the Norwegian Directorate of Health 2011–2013. IFNA, ESA, London Safety and Training Solutions Ltd.

**Patient and public involvement** Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

**Patient consent for publication** Not required.

**Ethics approval** The Regional Committee for Medical and Health Research Ethics in Western Norway reviewed our study before data collection. The study was considered as quality service improvement (Ref: 2009/561) and approved by hospital managers and the privacy Ombudsman (Ref: 2010/413).

**Provenance and peer review** Not commissioned; externally peer reviewed.

**Data availability statement** The raw datasets generated and/or analysed during the current study are not publicly available due data privacy rules, though anonymous data are available from the corresponding author on reasonable request.

**Open access** This is an open access article distributed in accordance with the Creative Commons Attribution Non Commercial (CC BY-NC 4.0) license, which permits others to distribute, remix, adapt, build upon this work non-commercially, and license their derivative works on different terms, provided the original work is properly cited, appropriate credit is given, any changes made indicated, and the use is non-commercial. See: <http://creativecommons.org/licenses/by-nc/4.0/>.

#### ORCID iD

Arvid Steinar Haugen <http://orcid.org/0000-0002-1899-9858>

## REFERENCES

- Kohn LT, Corrigan JM, Donaldson MS. *To err is human: building a safer health system*. Washington, DC: National Academy Press, 1999.
- Toffolutti V, Stuckler D. A culture of openness is associated with lower mortality rates among 137 English National health service acute trusts. *Health Aff* 2019;38:844–50.
- Fan CJ, Pawlik TM, Daniels T, et al. Association of safety culture with surgical site infection outcomes. *J Am Coll Surg* 2016;222:122–8.
- Nieva VF, Sorra J. Safety culture assessment: a tool for improving patient safety in healthcare organizations. *Qual Saf Health Care* 2003;12 Suppl 2:17ii–23.
- Makary MA, Sexton JB, Freischlag JA, et al. Patient safety in surgery. *Ann Surg* 2006;243:628–35.
- Farzi S, Taheri S, Ehsani M, et al. Perspective of nurses toward the patient safety culture in neonatal intensive care units. *Iranian Journal of Neonatology* 2017;8:89–94.
- Magill ST, Wang DD, Rutledge WC, et al. Changing operating room culture: implementation of a postoperative Debrief and improved safety culture. *World Neurosurg* 2017;107:597–603.
- Zingiryan A, Paruch JL, Osler TM, et al. Implementation of the surgical safety checklist at a tertiary academic center: impact on safety culture and patient outcomes. *Am J Surg* 2017;214:193–7.
- Wachter RM, Pronovost PJ. The 100,000 lives campaign – a scientific and policy review. *Jt Comm J Qual Patient Saf* 2006;32:621–7.
- WHO. WHO Guidelines for Safe Surgery 2009. In: *Guideline, review, Committee*. Geneva: WHO, 2009.
- Weiser TG, Makary MA, Haynes AB, et al. Standardised metrics for global surgical surveillance. *Lancet* 2009;374:1113–7.
- 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;360:491–9.
- Borchard A, Schwappach DLB, Barbir A, et al. A systematic review of the effectiveness, compliance, and critical factors for implementation of safety checklists in surgery. *Ann Surg* 2012;256:925–33.
- 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;101:150–8.
- Urbach DR, Govindarajan A, Saskin R, et al. Introduction of surgical safety checklists in Ontario, Canada. *N Engl J Med* 2014;370:1029–38.
- Vargas M, Servillo G. The world health organisation surgical safety checklist does not reduce mortality in general surgery. *Br J Anaesth* 2018;120:1135–7.
- 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.
- 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;255:44–9.
- Haugen AS, Wæhle HV, Almeland SK, et al. 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. *Ann Surg* 2019;269:283–90.
- 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;261:821–8.
- Hemming K, Haines TP, Chilton PJ, et al. The stepped wedge cluster randomised trial: rationale, design, analysis, and reporting. *BMJ* 2015;350:h391.
- Government. In safe hands 24/7, 2015. Available: <http://www.pasi.entsikkerhetsprogrammet.no/> [Accessed 4 Mar 2020].
- Haugen AS, Bakke A, Løvøy T, et al. Preventing complications: the Preflight checklist. *Eur Urol Focus* 2016;2:60–2.
- Government. Patient harms in Norway 2018 [In Norwegian: Pasientskader i Norge 2018]. Available: <https://www.helsedirektoratet.no/rapporter/pasientskader-i-norge/resultater> [Accessed 4 Mar 2020].
- Government. Quality indicator 30 day survival. [In Norwegian: Overlevelse 30 dager etter innleggelse på sykehus], 2018. Available: <https://www.helsedirektoratet.no/english> [Accessed 4 Mar 2020].
- Haynes AB, Edmondson L, Lipsitz SR, et al. Mortality trends after a voluntary Checklist-based surgical safety collaborative. *Ann Surg* 2017;266:923–9.
- Molina G, Jiang W, Edmondson L, et al. Implementation of the surgical safety checklist in South Carolina hospitals is associated with improvement in perceived perioperative safety. *J Am Coll Surg* 2016;222:725–36.
- Haynes AB, Weiser TG, Berry WR, et al. Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. *BMJ Qual Saf* 2011;20:102–7.
- Kawano T, Taniwaki M, Ogata K, et al. Improvement of teamwork and safety climate following implementation of the who surgical safety checklist at a university hospital in Japan. *J Anesth* 2014;28:467–70.
- Hill MR, Roberts MJ, Alderson ML, et al. Safety culture and the 5 steps to safer surgery: an intervention study. *Br J Anaesth* 2015;114:958–62.
- Erestam S, Haglind E, Bock D, et al. Changes in safety climate and teamwork in the operating room after implementation of a revised who checklist: a prospective interventional study. *Patient Saf Surg* 2017;11:4.
- Haugen AS, Sjøteland 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;110:807–15.
- Russ S, Rout S, Sevdalis N, et al. Do safety checklists improve teamwork and communication in the operating room? A systematic review. *Ann Surg* 2013;258:856–71.
- Haugen AS, Sjøteland E, Eide GE, et al. Patient safety in surgical environments: cross-countries comparison of psychometric properties and results of the Norwegian version of the hospital survey on patient safety. *BMC Health Serv Res* 2010;10:279.
- Sorra JS, Dyer N. Multilevel psychometric properties of the AHRQ Hospital survey on patient safety culture. *BMC Health Serv Res* 2010;10:199.
- Olsen E. Reliability and validity of the Hospital Survey on Patient Safety Culture at a Norwegian hospital. In: Øvretveit J, Sousa PJ, eds. *Quality and safety improvement research: methods and research practice from the International quality improvement research network (QIRN)*, 2008: 173–86.
- Jones L, Pomeroy L, Robert G, et al. How do hospital boards govern for quality improvement? a mixed methods study of 15 organisations in England. *BMJ Qual Saf* 2017;26:978–86.
- 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 Overseas Ed* 2009;360:491–9.
- Jones KJ, Skinner AM, High R, et al. A theory-driven, longitudinal evaluation of the impact of team training on safety culture in 24 hospitals. *BMJ Qual Saf* 2013;22:394–404.
- Mahajan RP. Critical incident reporting and learning. *Br J Anaesth* 2010;105:69–75.
- Vincent C, Taylor-Adams S, Stanhope N. Framework for analysing risk and safety in clinical medicine. *BMJ* 1998;316:1154–7.
- Aveling E-L, McCulloch P, Dixon-Woods M. A qualitative study comparing experiences of the surgical safety checklist in hospitals in high-income and low-income countries. *BMJ Open* 2013;3:e003039.