SAINT FRANCIS **Hospital and Medical Center**

Background

Complications from unintended harm adversely affect patients and their families while increasing institutional health care costs. In June 2010, a White Paper released by the Society of Actuaries estimates that post-operative infections are one of the five most expensive complications related to medical error, averaging \$14,500 in excess costs per case.¹ Although the World Health Organization (WHO) checklist has been used globally to reduce postoperative morbidity and mortality, no formal study has used an evidence-based, standardized surgical outcomes database for validation. This checklist is a powerful and inexpensive tool that will facilitate effective communication and teamwork. Surgical team training has demonstrated the opportunity for stakeholders to professionally engage one another through leveling of the authority gradient to prevent patient harm.^{5,6,7,8}

The Association of peri-Operative Registered Nurses (AORN) Comprehensive Surgical Checklist released in April 2010 incorporates mandated clinical practice paradigms. This document compartmentalizes needed information to facilitate documentation throughout the perioperative process. Attentive compliance to the checklist improves patient 30-day morbidity by directing the surgical team to focus on the Surgical Care Improvement Project (SCIP) core measures, the Time Out, and the National Patient Safety Goals. As only one of six Connecticut hospitals using the NSQIP, we determined the positive impact of checklist use in 2010-2011 Saint Francis Hospital and Medical Center 30-day morbidity.

Methods

This is a prospective cohort design with historical controls. Prior to implementation of the standardized protocol using pre-operative briefing and post-operative debriefing checklists, surgical services staff participated in a team-based training program. The three 60-minute team training sessions were conducted by internal human resources and professional development staff based on the text Crucial Conversations: Tools for Talking When Stakes Are *High*. Participants were oriented to the use of the AORN Comprehensive Surgical Checklist and barriers to checklist use were discussed at the third team training session. Following the initial team training session, utilization of the AORN Comprehensive Surgical Checklist was introduced. Eligible cases included specific high risk procedures selected from those analyzed for NSQIP. Of this sample, electively scheduled cases were examined based on the availability of observers. Trained observers remained present for the full duration of study cases to assess the checklist completion and utilization. Observers also collected additional data regarding the number of circulating nurse exits during the case, the nature of peri-operative communication and any safety compromising events. Statistical analysis was completed via SPSS, version 18.0. Patient demographics, case characteristics, and morbidity were assessed using chi square tests. Operative time and circulating nurse exits were assessed with twotailed tests (bivariate comparisons).

WHO Comprehensive Surgical Checklist

Rue - World Health Organization		'E SURGICAL CHECKL on - Universal Protocol (JC) 2010 National Patie	
PREPROCEDURE	SIGN-IN	TIME-OUT	SIGN-OUT
CHECK-IN			
n Holding Area	Before Induction of Anesthesia	Before Skin Incision	Before the Patient Leaves the Operating Room
Patient/patient representative actively confirms with Registered Nurse (RN):	RN and anesthesia care provider confirm:	Initiated by designated team member All other activities to be suspended (unless a life- threatening emergency)	RN confirms:
Identity Yes Procedure and procedure site Yes Consent(s) Yes Site marked Yes RN confirms presence of: History and physical Yes Preanesthesia assessment Yes Diagnostic and radiologic test results Yes Diagnostic and radiologic test results Yes N/A Blood products Yes N/A Any special equipment, devices, mplants Yes N/A Include in Preprocedure check-in as per institutional custom:	Confirmation of: identity, procedure, procedure site and consent(s) Yes Site marked Yes N/A by person performing the procedure Patient allergies Yes N/A Difficult airway or aspiration risk? No Yes (preparation confirmed) Risk of blood loss (> 500 ml) Yes N/A # of units available Anesthesia safety check completed Yes Briefing: All members of the team have discussed care plan and addressed concerns Yes	Introduction of team members Yes All: Confirmation of the following: identity, procedure, incision site, consent(s) Yes Site is marked and visible Yes N/A Relevant images properly labeled and displayed Yes N/A Any equipment concerns? Anticipated Critical Events Surgeon: States the following: critical or nonroutine steps case duration anticipated blood loss Anesthesia Provider: Antibiotic prophylaxis within one hour before incision Yes N/A Scrub and circulating nurse:	Name of operative procedure Completion of sponge, sharp, and instrument counts Yes N/A Specimens identified and labeled Yes N/A Any equipment problems to be addressed? Yes N/A To all team members: What are the key concerns for recovery and management of this patient?

The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements. Figure 1: AORN WHO Comprehensive Surgical Checklist (see handout below)

Results

Overall completion of the WHO checklist columns was 97.26% with completion of individual checklist items varying from 24.7% to 100.00%. Further, circulating nurse exits for observed cases varied from 0 to 25 per case.

Frequency of Checklist Component Completion

Preprocedure Check-in Completed?	100.0 %	Time-out Completed?
Identity documented?	98.6 %	Introduction of team members documented?
Procedure and procedure site documented?	95.9 %	Confirmation of the following: identity, procedure, incision site, consent(s)
Consent(s) documented?	93.2 %	documented?
Site marked documented?	98.6 %	Site is marked and visible documented?
History and physical documented?	97.3 %	Relevant images properly labeled and displayed documented?
Preanesthesia assessment documented?	93.2 %	Any equipment concerns documented?
Diagnostic and radiologic test results documented?	91.8 %	Antibiotic prophylaxis within one hour before incision documented?
Blood products documented?	95.9 %	Sterilization indicators have been confirmed documented?
Any special equipment, devices, implants documented?	93.2 %	Sign-out Completed?
Beta blocker medication given (SCIP) documented?	24.7 %	Name of operative procedure, completion of sponge, sharp, and instrument
Venous thromboembolism prophylaxis ordered (SCIP) documented?	34.2 %	counts documented?
Normothermia measures (SCIP) documented?	34.2 %	Specimens identified and labeled documented?
Sign-in Completed?	97.3 %	Any equipment problems to be addressed documented?
Confirmation of: identity, procedure, procedure site and consent(s) documented?	26.0 %	
Site marked documented?	91.8 %	
Patient allergies documented?	98.6 %	
Difficult airway or aspiration risk documented?	93.2 %	
Risk of blood loss (> 500 ml) documented?	79.5 %	
Anesthesia safety check completed documented?	76.7 %	
Briefing documented?	56.2 %	

Figure 2: Percentage of checklist documentation by section and individual component

ACS NSQIP 30-day Outcomes Supports Implementation of a Surgical Safety Checklist: Changing Culture

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out checklist utilization a	and 75 Cases Tollow	wing team train	ing with che	klist 25% 23.6%
	Procedure Type Cases without Ca		l Control	20%
			ses p value	15.9%
Laparoscopic Cholecystectomy Open Cholecystectomy	F	8% (21) 14.1% 8% (5) 2.3%	r	
Herniorrhaphy	F	1% (22) 30.5%	F	
Peritoneal or Omental Procedure		3% (9) 26.8%	r	5%
Lower Extremity Amputation Esophageal Procedure	F	4% (1) 1.9% 7% (2) 2.5%	F	
Small Bowel Procedure		5% (4) 14.1%		Any Adverse Event (p=0.000) Major Event (p=0.205) Minor Event (p=0.620)
Large Bowel Procedure	F	0% (8) 15.4%	(320) 0.58	
Any Bowel Procedure Appendectomy	F	5% (23) 43.0% 8% (5) 10.8%	r	
Rectal Procedure	r	7% (2) 1.9%	F	
Hepatic Procedure		7% (2) 1.0%	r	
Gastric or Bariatric Procedure Figure 3: Procedure ty	, ;	3% (9) 11.4% ween cases with		12%
cases with checklist and	historical control cas	ses		10%
	Operative Case Inform			8.9%
Time in Operating Room (min)		es with Historica 75±80.30 153.26		8%
Operative Priority	24.59/ (52)	0/ (4) 20.20/	.006	6.1%
Emergency Elective		% (4) 20.3% % (69) 79.7%		6% 5.0% 4.9%
Wound Class		0((05) 04 50(.387	
I - Clean II - Clean/Contaminated		% (25)34.5%% (39)45.2%		4%
III - Contaminated	13.4% (33) 11.09	% (8) 12.3%	(256)	2%
IV - Dirty/Infected ASA Class	6.5% (16) 1.49	% (1) 8.0%	.680	1.2%
1		% (5) 8.5% % (47) 52.6%		0.4% 0.0% 0.0%
3		% (47) 52.6% % (20) 32.6%		All Urinary Events (p=0.680)All Cardiac Events (p=0.124)All Nervous System Events (p=0.587)All Pulmonary Events (p=0.087)All Infectious Events (p=0.087)All Original (p=0.087)
4 5		% (1) 5.6% % (0) .4%		■ Historical Control Cases ■ Cases Without Checklist ■ Cases With Checklist
Figure 4: Comparison	of case character	、 <i>·</i>	<u> </u>	Figure 7: Comparison of rates of 30-day morbidity between historical contro
checklist, cases with che				without checklist use and cases with checklist use
Patient Dem	ographics and Pre-ope Cases without Ca			30-Day Morbidity
Sex	Checklist C	Checklist Control C	Cases p value	7%
Male		42.9% (30) 39.9%	(827)	6.1% 6%
Female Age (years)		57.1%(40)60.1%4.83±15.7254.61±1		5.3% 5.5% 5%
Race			.531	5%
White Black		30.3%(57)76.6%4.1%(10)16.9%		4% 3.0% 3.0%
Native Hawaiian or	.4% (1)	.0% (0) 2.4%	(49)	3% 2.7% 2.8% 2.8% 2.7% 2.4% 2.6% 2.6%
Pacific Islander Asian	.4% (1)	1.4% (1) .7%	(15)	2%
Unknown	3.3% (8)	4.2% (3) 3.5%	<u> </u>	1%
Diabetes None		37.7% (64) 86.0%	0.898 (1788)	0%
Non-insulin Dependent		8.2%(6)8.7%4.1%(3)5.3%		Bleeding Requiring Ventilator >48hrs (p=0.311) Pneumonia (p=0.362) UTI (p=0.972) All SSIs (p=0.845) Transfusion (p=0.392)
Smoker			0.199	■ Historical Control Cases ■ Cases Without Checklist ■ Cases With Checklist
Yes No		2.3%(9)18.4%37.7%(64)81.6%		Figure 8: Comparison of rates of 30-day morbidity between historical controls, cases with
Functional Status		2.20((74) 00.00(0.075	and cases with checklist use
Independent Partial Dependent		97.3%(71)90.8%2.7%(2)5.1%		Checklist Component Completion and 30-day Morbidity Rates
Totally Dependent	2.4% (6)	.0% (0) 4.1%	(85) 0.021	
COPD	6.5% (16)	1.4% (1) 3.3%		Documented Not Documented
No Pneumonia	93.5% (230) 9	98.6% (72) 96.7%	(2011) 0.432	1.9%
Yes	1.2% (3)		(13)	Introduction of team members documented? 1.970 All Infectious Events (p=0.015) 21.1%
No Congestive Heart Failure	98.8% (243) 10	00.0% (73) 99.4%	(2066) 0.366	
Yes	2.8% (7)	.0% (0) 2.5%	(53)	Introduction of team members documented?
No Renal Failure	97.2% (239) 10	00.0% (73) 97.5%	(2026) 0.432	Major Event (p=0.004) 21.1%
Yes	1.2% (3) 98.8% (243) 10	.0% (0) .6%	(13)	0.0%
No Dialysis	98.8% (243) 10	00.0% (73) 99.4%	0.3	Procedure and procedure site documented? 0.0% Deep Surgical Site Infections (p=0.041) 33.3%
Yes No	.4% (1) 99.6% (245) 10	.0% (0) 1.3% 00.0% (73) 98.7%	(27)	33.370
Cancer		30.1%	0.382	Identity documented?
Yes No	· · ·	1.4%(1)2.4%98.6%(72)97.6%	(49) (2030)	Deep Surgical Site Infections (p=0.014)
Open Wound			0.719	0% 10% 20% 30% 40% 50% 60% 70% 80% 90%
Yes No		2.7%(2)4.8%97.3%(71)95.2%		
Steroids			0.616	
Yes No		1.4%(1)3.4%98.6%(72)96.6%		Figure 9: Relationships between documentation of individual checklist components and morbidity rates achieving statistical significance
Bleeding			0.424	
Yes No		4.1%(3)6.6%95.9%(70)93.4%		Time in Operating Room and Morbidity
Transfusion Yes	3.3% (8)	.0% (0) .9%	0.003	Time in Operating Room (min
No			(19) (2060)	Present Absent p
Sepsis	3.7% (9)	.0% (0) 2.1%	(42)	Any Morbidity 259.16±165.29 134.51±60.56
Sepsis None		.0% (0) 2.1% 98.6% (72) 90.0%		Major Morbidity 318.25±172.34 134.70±60.36
Septic Shock SIRS	2.0% (5) 4.5% (11)	.0% (0) 1.4% 1.4% (1) 6.5%	· · ·	Minor Morbidity 270.33±230.20 139.37±66.91 Infactious Event 274.40±180.03 135.22±60.30
Myocardial Ischemia			0.396	Infectious Event 274.40±180.03 135.22±60.39 Surgical Site Infection 294.50±201.30 136.07±60.36
Yes No	.0% (0) 100.0% (246) 10	.0% (0) .6% 00.0% (73) 99.4%	(12) (2067)	Surgical Site Infection 294.30±201.30 130.07±00.30 Urinary Tract Infection 361.50±236.88 138.65±66.71
Peripheral Vascular Disease			0.822	Sepsis 459.00±98.99 135.90±59.92
Yes No		1.4%(1)1.7%98.6%(72)98.3%	· · ·	Superficial Surgical Site Infection 88.00 145.54±80.57
		, , , , , , , , , , , , , , , , , , , ,	0.315	Deep Surgical Site Infection 172.00 144.38±80.79
Prior Operation	3.3% (8)	.0% (0) 2.9%		







ecklist use



ific 30-day

The utilization of a comprehensive surgical safety checklist and the implementation of a structured team training curriculum produced a measurable and statistically significant decrease in 30-day morbidity. Furthermore, utilization of specific checklist items can be correlated with decreased morbidity rates. The team training introduced the concept of a safety checklist. Despite limited instruction, compliance with the checklist was 97.26% with most individual component completion rates greater than 90%. This suggests that adoption of a comprehensive checklist is feasible with minimal intervention and can produce measurable improvements in patient outcomes. When compared with historical controls, cases with checklist utilization showed a small reduction of time in the OR. Lower frequencies of circulating nurse exits from the OR during cases are correlated with decreased rates of morbidity that achieve statistical significance.

Several study limitations temper the strength of these findings. Although utilization of the NSQIP database provided a robust historical control population of 2079 cases, the small number of cases with checklist utilization and observation hindered identification of trends in morbidity rates and reduced the likelihood of establishing statistically significant relationships. The presence of trained observers during cases with checklists may have influenced the actions of peri-operative staff and contributed to some of the improvements reflected in 30-day morbidity reduction. Team training sessions did not capture all members of the peri-operative team. This may have undermined the new communication dynamics other staff tried to establish utilizing the team training curriculum.

Based on the results of this initial study, future research efforts will focus on assessment of qualitative measures of patient safety across the peri-operative spectrum and changes in morbidity rates with more frequent checklist use. Next steps involve analysis of qualitative data as well as correlating observed behaviors with measurable outcomes. Further investigations may include an ethnographic assessment of OR safety attitudes and communication based on focused groups and semi-structured interviews. The pilot data presented in this study will be used to support the universal adoption of a surgical safety checklist. Following adoption of a peri-operative checklist, NSQIP data will be revisited to determine if other statistically significant relationships are identified with a larger sample size. Ongoing interventions associated with this research include development of a follow-up team training curriculum. Reinforcement of communication strategies will be achieved via adherence to the medical staff professional code of conduct. Finally, changes in safety attitudes and perception of the institutional culture of safety will be assessed. This multidimensional strategy of intervention and reflective analysis of both patient outcomes and team member perception will lead to an improvement in our institution's culture of safety.

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Circulating Nurse Exits and Morbidity

	Circulating Nurse Exits					
	Present	Absent	p value			
Any Morbidity	10.7±8.4	4.7±4.0	0.002			
Major Morbidity	14.3±8.1	4.7±3.9	0.000			
Minor Morbidity	7.7±7.2	5.1±4.6	0.354			
Infectious Event	11.4±9.2	4.7±3.9	0.002			
Surgical Site Infection	13.5±9.1	4.71±3.9	0.000			
Urinary Tract Infection	9.5±9.2	5.1±4.6	0.190			
Sepsis	12.5±5.0	5.0±4.6	0.024			
Superficial Surgical Site Infection	4.00	5.2±4.7	0.800			
Deep Surgical Site Infection	25.00	4.9±4.1	0.000			
Bleeding Requiring Blood Transfusion	11.5±6.4	5.0±4.6	0.053			
Figure 11: Comparison between circulating nurse exits when 30-day						

morbidity present and absent Conclusions

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