Creating and Using a Safe Surgery Checklist

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Agenda

1. Welcome
2. Overview
3. Regulatory and Accreditation Requirements
4. Checklist Development
5. Checklist Implementation
6. Closing Thoughts
7. Questions

The Origins of the Checklist

- 1930's aviation—technology considered too complicated for the pilots
- Experience that showed the person with the most experience not always the one with the best results
- Checklists developed by pilots to ensure critical steps were not missed
- Focused on correcting mistakes or defects before they happened
- Drove improvement
- Spawned many federal agencies—FAA, NTSB

Thoughts from Atul Gawande—The Checklist Manifesto

- The professional Code of Conduct
  - Selflessness—place the needs of others above ours
  - Skill—aim for excellence in regards to knowledge and skill
  - Trustworthiness—responsible for personal behavior with others
- Aviators add another dimension
  - Discipline—following prudent procedure when working with others
- Medicine focuses on Autonomy
  - Direct opposition to discipline
- In the current medical environment of increasingly complicated technology, Autonomy does not seem to be what we should focus on

Why Use a Checklist?

- The more complex a procedure is, the more opportunities there may be to miss a critical step
- Checklists work because they point out missed steps or problems that may have been overlooked secondary to our own sense of familiarity with the procedure
- No matter how expert we are, a well designed checklist has been proven to improve outcomes
- Drives a culture of patient safety
- Doing the right thing at the right time may make all the difference

Medicare Reporting Requirements

Regulatory Requirements

- Initial reporting via Quality Net (www.qualitynet.org) summer of 2013
- May answer yes if used during any point in 2012
- Flexibility in design and use
- “No” answers do not incur financial penalties but may have public relations or local community implications
- No validation included in Medicare surveys
- Impacts payments in 2015

Medicare Detailed Requirements

- Must address effective communication and safe surgery practices in each of the three peri-operative periods
  - prior to administering anesthesia
  - prior to incision
  - prior to the patient leaving the operating room

Conditions for Coverage Requirements

Interpretive Guidelines for 42 CFR Section 416.42

Generally accepted procedures to avoid such surgical errors require:

- A pre-procedure verification process to make sure all relevant documents (including the patient's signed informed consent) and related information are available, correctly identified, match the patient, and are consistent with the procedure the patient and the ASC‟s clinical staff expect to be performed;
- Marking of the intended procedure site by the physician who will perform the procedure or another member of the surgical team so that it is unambiguously clear; and
- A "time out" before starting the procedure to confirm that the correct patient, site and procedure have been identified, and that all required documents and equipment are available and ready for use.

Accreditation Requirements—TJC

Universal Protocol

- UP.01.01.01: Conduct a pre-procedure verification process
- UP.01.02.01: Mark the procedure site
- UP.01.03.01: A time-out is performed immediately prior to starting procedures

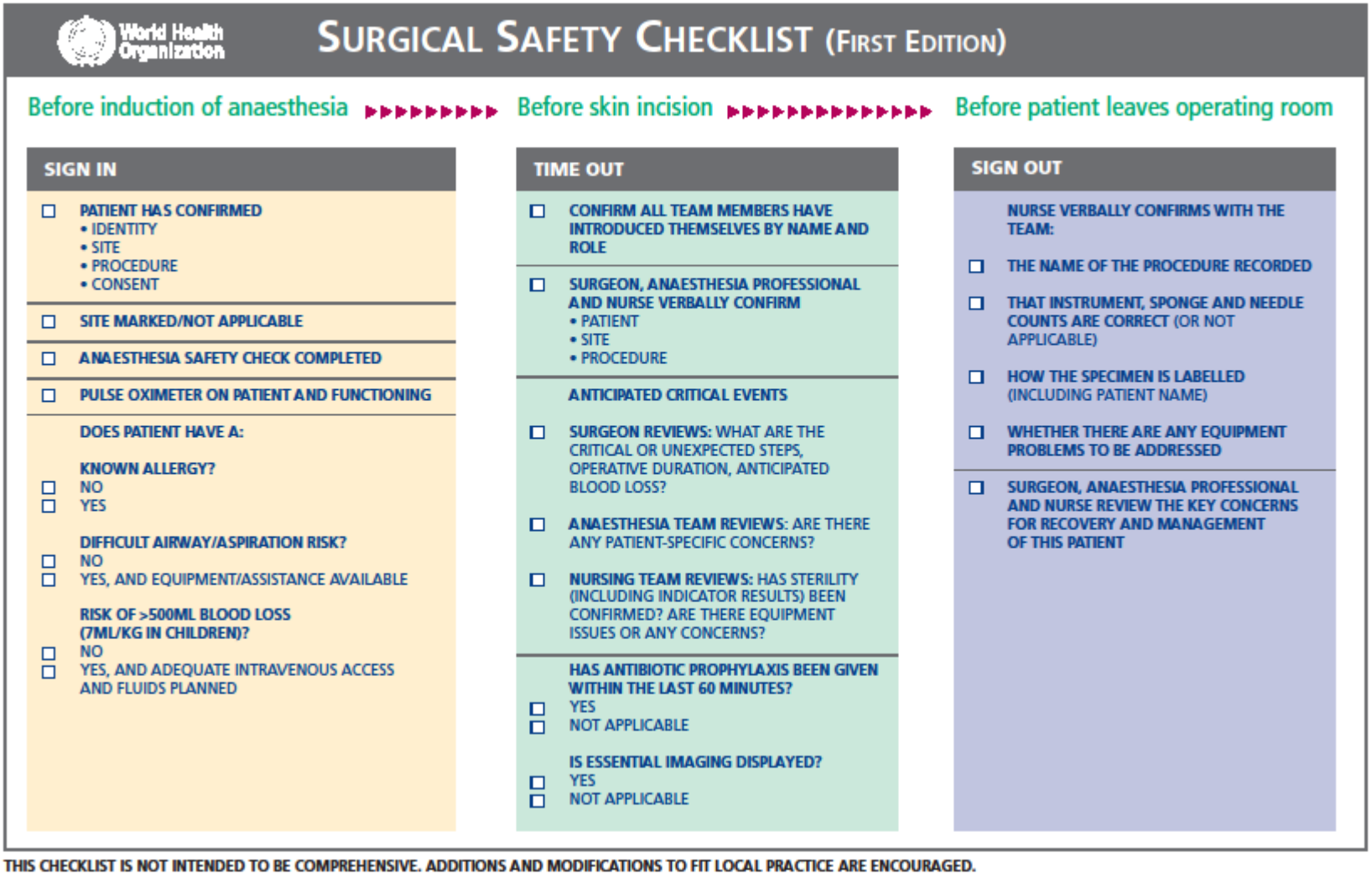
Accreditation Requirements—AAAHC

Chapter 10. U and Chapter 10. V

- The organization utilizes a process to identify and/or designate the surgical procedure to be performed and the surgical site, and involves the patient in that process. The person performing the procedure marks the site. For dental procedures, the operative tooth may be marked on a radiograph or a dental diagram. Chapter 10. U

- Immediately prior to beginning a procedure, the operating team verifies the patient's identification, intended procedure, and correct surgical site, and that all equipment routinely necessary for performing the scheduled procedure along with any implantable devices to be used, are immediately available in the operating room. The provider performing the procedure is personally responsible for ensuring that all aspects of this verification have been satisfactorily completed prior to beginning the procedure. Chapter 10. V

Sample Checklists—World Health Organization



World Health Organization

SURGICAL SAFETY CHECKLIST (FIRST EDITION)

Before induction of anaesthesia ▸▸▸▸▸▸▸▸▸ Before skin incision ▸▸▸▸▸▸▸▸▸▸▸▸▸ Before patient leaves operating room

SIGN IN

- ☐ PATIENT HAS CONFIRMED
  - IDENTITY
  - SITE
  - PROCEDURE
  - CONSENT
- ☐ SITE MARKED/NOT APPLICABLE
- ☐ ANAESTHESIA SAFETY CHECK COMPLETED
- ☐ PULSE OXIMETER ON PATIENT AND FUNCTIONING
- DOES PATIENT HAVE A:

KNOWN ALLERGY?
- ☐ NO
- ☐ YES

DIFFICULT AIRWAY/ASPIRATION RISK?
- ☐ NO
- ☐ YES, AND EQUIPMENT/ASSISTANCE AVAILABLE

RISK OF >500ML BLOOD LOSS (7ML/KG IN CHILDREN)?
- ☐ NO
- ☐ YES, AND ADEQUATE INTRAVENOUS ACCESS AND FLUIDS PLANNED

TIME OUT

- ☐ CONFIRM ALL TEAM MEMBERS HAVE INTRODUCED THEMSELVES BY NAME AND ROLE
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE VERBALLY CONFIRM
  - PATIENT
  - SITE
  - PROCEDURE

ANTICIPATED CRITICAL EVENTS

- ☐ SURGEON REVIEWS: WHAT ARE THE CRITICAL OR UNEXPECTED STEPS, OPERATIVE DURATION, ANTICIPATED BLOOD LOSS?
- ☐ ANAESTHESIA TEAM REVIEWS: ARE THERE ANY PATIENT-SPECIFIC CONCERNS?
- ☐ NURSING TEAM REVIEWS: HAS STERILITY (INCLUDING INDICATOR RESULTS) BEEN CONFIRMED? ARE THERE EQUIPMENT ISSUES OR ANY CONCERNS?

HAS ANTIBIOTIC PROPHYLAXIS BEEN GIVEN WITHIN THE LAST 60 MINUTES?
- ☐ YES
- ☐ NOT APPLICABLE

IS ESSENTIAL IMAGING DISPLAYED?
- ☐ YES
- ☐ NOT APPLICABLE

SIGN OUT

NURSE VERBALLY CONFIRMS WITH THE TEAM:

- ☐ THE NAME OF THE PROCEDURE RECORDED
- ☐ THAT INSTRUMENT, SPONGE AND NEEDLE COUNTS ARE CORRECT (OR NOT APPLICABLE)
- ☐ HOW THE SPECIMEN IS LABELLED (INCLUDING PATIENT NAME)
- ☐ WHETHER THERE ARE ANY EQUIPMENT PROBLEMS TO BE ADDRESSED
- ☐ SURGEON, ANAESTHESIA PROFESSIONAL AND NURSE REVIEW THE KEY CONCERNS FOR RECOVERY AND MANAGEMENT OF THIS PATIENT

THIS CHECKLIST IS NOT INTENDED TO BE COMPREHENSIVE. ADDITIONS AND MODIFICATIONS TO FIT LOCAL PRACTICE ARE ENCOURAGED.

Sample Checklist—AORN

COMPREHENSIVE SURGICAL CHECKLIST

Blue = World Health Organization (WHO) Green = The Joint Commission - Universal Protocol (JC) 2010 National Patient Safety Goals Orange = JC and WHO

PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
In 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 ▫ N/A by person performing the procedure **RN confirms presence of:** History and physical ▫ Yes Preanesthesia assessment ▫ Yes Diagnostic and radiologic test results ▫ Yes ▫ N/A Blood products ▫ Yes ▫ N/A Any special equipment, devices, implants ▫ Yes ▫ N/A **Include in Preprocedure check-in as per institutional custom:** **Beta blocker medication given (SCIP)** ▫ Yes ▫ N/A **Venous thromboembolism prophylaxis ordered (SCIP)** ▫ Yes ▫ N/A **Normothermia measures (SCIP)** ▫ Yes ▫ N/A	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 ▫ Additional concerns? **Scrub and circulating nurse:** ▫ Sterilization indicators have been confirmed ▫ Additional concerns?	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? _____ _____ _____ _____ _____ _____ _____ _____ **April 2010** AORN

The JC does not stipulate which team member initiates any section of the checklist except for site marking.
The Joint Commission also does not stipulate where these activities occur. See the Universal Protocol for details on the Joint Commission requirements.

Atul Gawande's Guidance on Checklist Development

DEVELOPMENT Do you have clear, concise objectives for your Checklist?	DRAFTING Does the Checklist consider the following?	VALIDATION Before you implement the Checklist have you done the following?
• Does it include the critical safety steps that are highly likely to be missed? • Are the items not adequately checked by other mechanisms? • Are the items actionable, with a specific response ? • Can the items be affected by the use of the checklist? • Is the checklist designed to be read out loud? • Have all team members been included in the checklist development?	• Utilize breaks in workflow? • Use simple language? • Have a title that reflects its objectives? • Have a simple, logical, uncluttered format? • Fit on one page? • Minimize the use of color? • Is the font sans serif, upper and lower case, large enough to read? • Is the text dark on a light background? • Are there fewer than 10 pause points per item?	• Trialed the checklist with front line users? • Modified the checklist in response to repeated trials • Ensured that the checklist fits the flow of work? • Ensured that errors are detected at a time when they can still be corrected? • Determined that the checklist can be completed in a reasonably brief period of time? • Put in place a review and revision timeline?

Safe Surgery Checklist Study Findings

Prevention vs. Correction: Observational studies say the Safe Surgery Checklist improves surgical outcomes; mandated adoption itself doesn't seem to have increased safety

Complications and Morbidity Results

- New England Journal of Medicine (March 2014)
  - Ontario, Canada w/ 101 hospitals
  - Focus on complications and morbidity
  - "Overall results showed that the Safe Surgery Checklist is less effective in practice than suggested by existing literature"
- Annuls of Surgery (2014)
  - 5295 procedures, non-randomized study
  - Risk adjusted
  - "overall results showed slight decrease in mortality rate and no change in complication rate with use of the Safe Surgery Checklist"

Observational Results

- AHRQ/HRET Cohorts
  - Pre- and post-study culture survey
    - Enhanced communication
    - Improvements in teamwork
  - Promotion of a culture in which safety is a high priority
- Atul Gawande, MD
  - Must be supplemented with specialty training
  - "The Surgical Checklist is a powerful tool for reducing complications and deaths, but it only works if you use it right."
  - 2014 Tweet: "Some still oppose WHO Safe Surgery Checklist because no RCT was done. Well, new RCT finds it cut complications 42%"

HRET Safe Surgery 2015 Checklist Template

Checklist Development

Safe Surgery 2015 Checklist Template

Before Induction of Anesthesia

Nurse and Anesthesia Provider Verify:

- ❑ Patient identification (name and DOB)
- ❑ Surgical site
- ❑ Surgical Procedure to be performed matches the consent
- ❑ Site marked
- ❑ Known allergies
- ❑ Patient Positioning
- ❑ The anesthesia safety check has been completed

Anesthesia Provider Shares Patient Specific Information with the Team:

- ❑ Anticipated airway or aspiration risk
- ❑ Risk of significant blood loss
  - Two IVs/central access and fluids planned
  - Type and crossmatch/screen
  - Blood availability
- ❑ Risk of hypothermia - operation >1h
  - Warmer in place
- ❑ Risk of venous thromboembolism
  - Boots and/or anticoagulants in place

Before Skin Incision

Entire Surgical Team:

- ❑ Is everyone ready to perform the time out?
- ❑ Please state your name and role

- ❑ Patient's name
- ❑ Surgical procedure to be performed
- ❑ Surgical site
- ❑ Essential imaging available

- ❑ Has antibiotic prophylaxis been given within the last 60 minutes?
  - Plan for redosing discussed

Briefing

Surgeon Shares:

- ❑ Operative Plan
- ❑ Possible difficulties
- ❑ Expected duration
- ❑ Anticipated blood loss
- ❑ Implants or special equipment needed

Anesthesia Provider Shares:

- ❑ Anesthetic plan
- ❑ Airway concerns
- ❑ Other concerns

Circulating Nurse and Scrub Tech Share:

- ❑ Sterility, including indicator results
- ❑ Equipment issues
- ❑ Other concerns

Surgeon says:
"Does anybody have any concerns? If you see something that concerns you during this case, please speak up."

Before Patient Leaves Room

Nurse reviews with Team:

- ❑ Instrument, sponge and needle counts are correct
- ❑ Name of the procedure performed
- ❑ Specimen labeling
  - Read back specimen labeling including patient's name

Debriefing

Entire Surgical Team Discusses:

- ❑ Equipment problems that need to be addressed.
- ❑ Key concerns for patient recovery and management
- ❑ What could have been done to make this case safer or more efficient

HRET
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Version -3-30-12

This checklist is not intended to be comprehensive. Additions and modifications to fit local practice are encouraged. Based on the WHO Surgical Safety Checklist, URL http://www.who.int/patientsafety/safesurgery/en, © World Health Organization 2008 All rights reserved.

SCA

Safe Surgery Checklist Resources

- World Health Organization (WHO)
  - http://www.who.int/patientsafety/safesurgery/ss_checklist/en/
- SafeSurg.org:
  - For a modifiable template: http://www.safesurg.org/template-checklist.html
  - For examples, including for endoscopy centers: http://www.safesurg.org/modified-checklists.html
- AORN (combines WHO checklist and JC universal protocol)
  - http://www.aorn.org/PracticeResources/ToolKits/CorrectSiteSurgeryToolKit/Comprehensivechecklist/
- ASCA Connect
- Gawande, A. (2009). *The Checklist Manifesto*. New York, NY: Picador Books
- Agency for Healthcare Research and Quality
  - http://ascsafetyprogram.org/cohort-pages
- Health Research & Educational Trust
  - http://www.safesurgery2015.org/aha-hret.html

Implementing a Safe Surgery Checklist

- Engage actively with key stakeholders
- Develop clear tools and processes to support implementation
- Set clear expectations for individual accountability
- Train to ensure robust use and interactive caregiver communications
- Make it part of your culture

Engagement with Key Stakeholders

Lack of engagement in the development and revision of the Checklist is the number one reason for poor Checklist pull through

- Include all members of the team in the development and implementation of the Checklist
- Identify key physicians who will champion the process
- Focus on the WHY
  - Evidenced based studies showing that checklist improvement improves results
  - Gawande's thoughts on autonomy
- Agree on usage commitments
  - Ask your MD champion to talk about the Checklist with colleagues and ask for support with the process
  - Track usage and report on success at MEC/Governing Board/Medical Staff meetings and teammate meetings

Tools and Processes

- Trial the Checklist
  - Try out the suggested checklist a few times—either simulated or live
  - Make changes if needed and re-trial
- Model the usage of the Checklist in detailed way
  - Tool Kits
  - Videos
  - Flow Diagrams
- Conduct observational rounds
  - Use an observation tool
  - Watch teams use the checklist—coach on what they do well and ways to improve
  - Collect and share the stories from when the checklist catches errors

Personal Accountability

- Set Expectations
  - Clear definition of top level performance
    - Deliver results/demonstrate technical competency + live the values
    - What does it look like?
    - Pay for performance
  - Include clear expectations on checklist use
    - As a teammate, you cannot be a top performer if you do not continually work to improve results
    - As a leader, you cannot be a top performer if you do not deliver clinical results
- Set the pace
  - Observe Time Outs
  - Verify Checklist pull through
  - Talk about clinical quality at the start of every call and meeting
  - Use the WHY to drive pull through

Culture of Patient Safety

- Paint the picture
  - Talk in terms of Healthcare Harm
  - Good is not enough
  - Widely disseminate the metrics/results
- Set standard for transparency
  - Have the tough conversations/openly discuss errors
  - Agree to call each other out on mistakes, omissions, behavior not consistent with values
  - To not point out an error can be as serious as making an error
- Celebrate success
  - Stories
  - Turnarounds
  - Consistency

Closing Thoughts

- The more complex a procedure is, the more opportunities there may be to miss a critical step
- Checklists work because they point out missed steps or problems that may have been overlooked secondary to our own sense of familiarity with the procedure
- No matter how expert we are, a well designed checklist has been proven to improve outcomes
- Checklists are more effective when they are used to promote a robust conversation between members of the team
- Doing the right thing at the right time may make all the difference

Questions

Contact Information

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