

# Creating and Using a Safe Surgery Checklist

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# Discussion Outline

- 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

- 1930s 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

- The more complex a procedure is, the more opportunities there are 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
- It is the right thing to do for our patients

- Usage
  - Successfully adapted in a wide variety of settings and countries
  - Third phase most frequently incomplete
  - Steps related to time out components missed
  - High compliance with items already in established policy; lower compliance with new items
  - Adoption rates stronger with nurses and anesthesiologists vs. surgeons
  - Customization and training critical to adoption rates
- Patient outcomes and communication
  - “Promising intervention” for decreasing patient morbidity and mortality
  - Increased detection of potential safety hazards
  - Decreased surgical complications
  - Improved communication among OR staff
  - Other factors may contribute to improvements
- Impact hinges on implementation process—understanding why and how

- Initial reporting via Quality Net ([www.qualitynet.org](http://www.qualitynet.org)) summer of 2013
  - Attestation of use during any point in 2012
  - Flexibility allowed in design and use of checklist
  - “No” answers do not incur financial penalties but may have public relations or local community implications
  - No validation included in Medicare surveys
- CMS proposed regulations
  - For CY 2016, proposed to alter the data collection and submission time periods for the Safe Surgery Checklist Use and ASC Facility Volume
  - Data collection would be the calendar year occurring 2 years prior to the payment determination year
  - Data submission period would be expanded from July 1 - August 15 to January 1 - August 15 in the year prior to the payment determination
  - If implemented for the CY 2016 payment determination:
    - Data collection period would be DOS January 1, 2014 - December 31, 2014
    - Data submission period would be January 1, 2015 - August 15, 2015

## 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
  - 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



Must address effective communication and safe surgery practices in each of the three perioperative periods

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- Prior to administering anesthesia
- Prior to incision
- Prior to the patient leaving the operating room

## 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

## 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, 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



## COMPREHENSIVE SURGICAL CHECKLIST

Blue = World Health Organization (WHO)    Green = The Joint Commission - Universal Protocol (JC) 2013 National Patient Safety Goals    Orange = JC and WHO

PREPROCEDURE CHECK-IN	SIGN-IN	TIME-OUT	SIGN-OUT
<b>In Holding Area</b>	<b>Before Induction of Anesthesia</b>	<b>Before Skin Incision</b>	<b>Before the Patient Leaves the Operating Room</b>
<b>Patient/patient representative actively confirms with Registered Nurse (RN):</b>	<b>RN and anesthesia care provider confirm:</b>	<b>Initiated by designated team member</b> <span style="color: green;">All other activities to be suspended (unless a life-threatening emergency)</span>	<b>RN confirms:</b>
<p style="font-size: x-small;">Identity <input type="checkbox"/> Yes                      Procedure and procedure site <input type="checkbox"/> Yes                      Consent(s) <input type="checkbox"/> Yes                      Site marked <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                      by person performing the procedure</p> <p><b>RN confirms presence of:</b></p> <p style="font-size: x-small;">History and physical <input type="checkbox"/> Yes</p> <p style="font-size: x-small;">Preanesthesia assessment <input type="checkbox"/> Yes</p> <p style="font-size: x-small;">Diagnostic and radiologic test results <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p style="font-size: x-small;">Blood products <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p style="font-size: x-small;">Any special equipment, devices, implants <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <div style="border: 1px solid black; padding: 5px; font-size: x-small;"> <p>Include in Preprocedure check-in as per institutional custom:                          Beta blocker medication given (SCIP) <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                          Venous thromboembolism prophylaxis ordered (SCIP)  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                          Normothermia measures (SCIP)  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> </div>	<p style="font-size: x-small;"><span style="color: red;">Confirmation of: identity, procedure, procedure site and consent(s) <input type="checkbox"/> Yes</span>  <span style="color: red;">Site marked <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</span>                      by person performing the procedure</p> <p style="font-size: x-small;">Patient allergies <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p style="font-size: x-small;">Difficult airway or aspiration risk?  <input type="checkbox"/> No  <input type="checkbox"/> Yes (preparation confirmed)</p> <p style="font-size: x-small;">Risk of blood loss (&gt; 500 ml)  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                      # of units available _____</p> <p style="font-size: x-small;">Anesthesia safety check completed  <input type="checkbox"/> Yes</p> <p><b>Briefing:</b>                      All members of the team have discussed care plan and addressed concerns  <input type="checkbox"/> Yes</p>	<p style="font-size: x-small;">Introduction of team members <input type="checkbox"/> Yes</p> <p><b>All:</b>                      Confirmation of the following: identity, procedure, incision site, consent(s)  <input type="checkbox"/> Yes                      Site is marked and visible <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p style="font-size: x-small;">Relevant images properly labeled and displayed  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p style="color: red; font-size: x-small;"><b>Any equipment concerns?</b></p> <p><b>Anticipated Critical Events</b>  <b>Surgeon:</b>                      States the following:  <input type="checkbox"/> critical or nonroutine steps  <input type="checkbox"/> case duration  <input type="checkbox"/> anticipated blood loss</p> <p><b>Anesthesia Provider:</b>  <input type="checkbox"/> Antibiotic prophylaxis within one hour before incision <input type="checkbox"/> Yes    <input type="checkbox"/> N/A  <input type="checkbox"/> Additional concerns?</p> <p><b>Scrub and circulating nurse:</b>  <input type="checkbox"/> Sterilization indicators have been confirmed  <input type="checkbox"/> Additional concerns?</p>	<p style="font-size: x-small;">Name of operative procedure                      Completion of sponge, sharp, and instrument counts <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                      Specimens identified and labeled  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A                      Any equipment problems to be addressed?  <input type="checkbox"/> Yes    <input type="checkbox"/> N/A</p> <p><b>To all team members:</b>                      What are the key concerns for recovery and management of this patient?                      _____                      _____                      _____                      _____                      _____</p> <p style="font-size: x-small;">June 2013</p> <div style="text-align: right; margin-top: 20px;"> </div>

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

## DEVELOPMENT

**Do you have clear, concise objectives for your checklist?**

- 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?

## DRAFTING

**Does the checklist consider the following?**

- 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?

## VALIDATION

**Before you implement the checklist have you done the following?**

- Tried 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?

- Does your surgical checklist have 3 phases—before induction of anesthesia, before skin incision, and before the patient leaves the room?
- Are the items on the checklist meant to be read aloud, without reliance on memory, so all team members can hear them?
- Does every person in the room have the opportunity to say something before skin incision at a minimum to introduce themselves with their role or state they are ready to proceed?
- Will the surgeon share an operative plan and discuss: anticipated blood loss, expected duration of the procedure, possible difficulties, and implant or special equipment with the entire team before skin incision?
- Will the nurses and surgical techs discuss the entire team and their concerns about the patient?
- Will the anesthesia provider discuss the anesthetic and airway plan with the entire team?
- Will the surgeon ask the entire team to speak up if they have any concerns during the case?
- Before the patient leaves the OR will all the team discuss what could have been done better?

*Recommendations from Safe Surgery 2015: South Carolina*

Items that belong on the checklist are ones that have serious consequences if they are missed

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- Is this a safety step that you might not notice if it is not done?
- Is this item discussed at a time when all relevant team members are present?
- Is this adequately checked by another mechanism?
- Is the checklist the best way to take care of it?
- Can something be done about it?
- If the item will not help you, will this item help anyone here?



- World Health Organization (WHO)
  - [http://www.who.int/patientsafety/safesurgery/ss\\_checklist/en/index.html](http://www.who.int/patientsafety/safesurgery/ss_checklist/en/index.html)
- 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
  - <http://www.ascaconnect.org/CONNECT/Home/>
- The Joint Commission
  - [http://www.jointcommission.org/standards\\_information/up.aspx](http://www.jointcommission.org/standards_information/up.aspx)
- Gawande, A. (2009). The Checklist Manifesto. New York, NY: Picador Books
- Safe Surgery 2015: South Carolina
  - [www.safesurgery2015.org](http://www.safesurgery2015.org)

# Implementing a Safe Surgery Checklist

- Engage actively with key stakeholders
- Develop clear tools and processes to support implementation
- Set clear expectations for individual accountability
- Make it part of your culture

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

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- 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

- 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
  - Toolkits
  - Videos
  - Flow diagrams

- Set Expectations
  - Clear definition of top level performance
    - Deliver results/demonstrate technical competency and live the values
    - What does it look like?
    - Pay for performance
  - Include clear expectations on checklist use
    - As a team member, 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

- 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
  - Not point out an error is as serious as making an error
- Celebrate success
  - Stories
  - Turnarounds
  - Consistency

- The more complex a procedure is, the more opportunities there are 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
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# Questions



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