

AHS Safe Surgery Checklist

User Manual

Version 2.0

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This manual was adapted from the **WHO Guideline for Safe Surgery** (2009 Edition) which can be viewed with the **Tools and Resources** section of the WHO website.

Link: <http://www.who.int/patientsafety/safesurgery/en>

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1. Introduction

According to a study by the World Health Organization (WHO) of 6,775 operations, the implementation of a simple checklist completed during surgical procedures reduced the overall incidents of complications and death significantly.

Haynes AB, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *N. Engl J Med*, 2009; 360; 491-9. (see Appendix IV)

Alberta Health Services (AHS) is committed to improving patient safety and the quality of care for all Albertans. Quality and safety have been identified within the AHS Strategic Direction (2009 – 2012) document as one of the 20 key strategic priorities for the organization.

The AHS Safe Surgery Checklist (see Appendix I) is being introduced as part of this commitment in Alberta to assist surgical teams in reducing the number of preventable surgical complications and further improve surgical results. The AHS Safe Surgery Checklist, while not limited to use in an operating room setting, should apply to every patient undergoing a surgical procedure as defined below. For the purpose of this manual the following definitions apply:

Surgical Procedure: Any procedure involving an incision, excision, manipulation or suturing of tissue. Any invasive or non-invasive procedure that requires regional, general or monitored anesthesia by an anesthesiologist or anesthetist, which may be performed in or outside of an operating room setting.

Surgical Team: Comprises the surgeons, anesthesiologists, nurses, technicians, and other personnel involved in the procedure. Alternatively, this can apply to any physician and support staff if the procedure occurs outside of an operating room setting (e.g. procedure rooms within the Emergency Department, Invasive Radiology, etc).

Patient: Refers to those people identified as “patient”, “client”, and / or “resident” who are receiving or registered to receive medical treatment which may involve surgical intervention.

Family: For the purpose of this manual, a family member may include a spouse, parent, sibling, child, guardian, or agent that have legal standing to provide consent on behalf of the patient for a medical procedure.

1.1 Ten Essential Objectives for Safe Surgery

To assist surgical teams in reducing the number of preventable surgical complications, the WHO as part of their 'Safe Surgery Saves Lives' campaign have identified **ten essential objectives** for safe surgery. These objectives were developed in consultation with surgeons, anesthesiologists, nurses, patient safety experts and patients from around the world.

WHO Ten Essential Objectives for Safe Surgery:

Reference: adapted from: *WHO Guidelines for Safe Surgery 2009*

1. The team will operate on the correct patient at the correct site on the patient's body.
2. The team will use methods known to prevent harm from administration of anesthesia while protecting the patient from pain.
3. The team will recognize and effectively prepare for life-threatening loss of airway or respiratory function.
4. The team will recognize and effectively prepare for risk of high blood loss.
5. The team will avoid inducing an allergic or adverse drug reaction for which the patient is known to be at significant risk.
6. The team will consistently use methods known to minimize the risk for surgical site infection.
7. The team will prevent inadvertent retention of instruments and sponges in surgical wounds.
8. The team will secure and accurately identify all surgical specimens.
9. The team will effectively communicate and exchange critical information for the safe conduct of the operation.
10. Hospitals and public health systems will establish routine surveillance of surgical capacity, volume and results

AHS has adopted these ten WHO objectives as part of the AHS Safe Surgery Checklist to be introduced to all AHS sites to help ensure the quality and safety provided to patients within surgical services. The implementation will also support AHS sites in compliance with the anticipated new Accreditation Canada Required Organizational Practices (ROP) Surgical Checklist standard (for introduction in 2011). The aim of the checklist is to reinforce accepted safety practices, and foster better communication and teamwork between clinical disciplines.

Every surgical team can improve the safety and quality of care delivered to their patients by the introduction of the AHS Safe Surgery Checklist. This manual has been created to assist sites:

1. In understanding how to use the AHS Safe Surgery Checklist;
2. With the implementation of the AHS Safe Surgery Checklist to all surgical services within a site;
3. Who wish to modify the AHS Safe Surgery Checklist to further improve surgical results and decrease associated complications, while still being compliant with AHS Safe Surgery Guidelines (see Section 2.0) and the ten essential safety objectives established by the WHO.

1.2 Key Messages

- The AHS Safe Surgery Checklist is meant as a communication tool to be used by AHS surgical teams to help ensure the safety of its patients; it is not meant to be used as a formal document.
- AHS surgical teams can use paper, electronic or poster versions of the AHS Safe Surgery Checklist.
- The AHS Safe Surgery Checklist does not replace any existing documentation or safety check procedures currently used at any AHS site.
- AHS sites must identify a surgical checklist, which must be used by surgical teams in compliance with Accreditation Canada ROP standard.
- AHS has developed an AHS Safe Surgery Checklist (see Appendix I) for general purpose use, which can be used by AHS sites.
- AHS sites can modify or develop their own surgical checklist(s) with the following provisions:
 1. Surgical checklists used by AHS sites must comply with the first eight objectives of the WHO Ten Essential Objectives for Safe Surgery.
 2. Surgical checklists used by AHS sites must encourage involvement by all members of the interdisciplinary surgical team in the communication of safety checks at three critical points:
 - Before the induction of anesthesia (Briefing)
 - Before skin incision (Time Out)
 - Before the patient leaves the OR (Debriefing)
 3. Modification or development of a surgical checklist(s) must involve surgeons, anesthesiologists, and nurses and must be trialed in simulated and real-life situations to ensure functionality.
 4. AHS sites may develop more than one surgical checklist to suit the specific safety issues related to an individual surgical procedure or set of procedures. Each individual checklist must comply with AHS (see Section 2.0) and WHO (see Section 1.1) guidelines.
 5. AHS sites that have modified the AHS Checklist or have developed their own checklist(s) are requested to supply a copy of the checklist(s) to the provincial zone leads (Operational and / or Clinical Quality Support Consultant) or chairs of the Implementation Working Group for review (see Appendix IV for list of Implementation Working Group members). The members of the Implementation Working Group are available to support AHS sites with suggestions on modification, implementation, communication and quality improvement. The exception are for sites that have only made minor modifications to the AHS Safe Surgery Checklist; specifically the addition or removal of non-bold bullet points that this manual has identified as 'optional' (See Section 3.1 Guidelines for Modification of AHS Checklist).

1.3 Frequently Asked Questions

Q. Where did the idea of a safe surgery checklist come from?

A. The original concept of the safe surgery checklist stems from the World Health Organization's (WHO) 2007/08 'Safe Surgery Saves Lives' campaign, which built on the experience of medical experts, healthcare professions, safety experts and patients from around the world. The Canadian Patient Safety Institute (CPSI) and the Royal College of Physicians and Surgeons of Canada (RCPSC), in collaboration with 15 in-country organizations, led the Canadian adaptation of the WHO campaign. A provincial AHS committee was established in early 2009, to develop and implement a provincial plan for adopting the checklist within all AHS facilities. Safety checks in operating room settings are not novel and the concept of the checklist was built on systems used internationally to help ensure safety of surgical patients.

Q. Why should we use a surgical checklist?

A. The surgical checklist has been shown to reduce the number of preventable complications associated with surgery by ensuring critical information is shared with all members of the surgical team, which is aligned to one of AHS key objectives for improving patient safety and quality of care. It also helps focus the entire team on patient safety at three critical stages during the surgical procedure (before induction, before incision and before closing). The checklist is simply a communication tool for members of a surgical team. It does not replace existing procedures or safety checks, but builds on them by ensuring the entire interdisciplinary team is involved in the safety communication at the same time.

Q. We are already very busy in the OR. Isn't this just one more task using up valuable time?

A. In actuality it may save time. Once the checklist becomes familiar to operating room teams, it requires very little extra time to perform. The AHS Safe Surgery Checklist is intended to only take no more than one (1) minute for each of the three stages to complete (unless issues arise), while adding no more than two (2) minutes in total to the surgical procedure time. The checklist can save time by identifying potential issues before they arise, ensuring better co-ordination between team members, and minimizing delays caused by retrieving additional equipment, etc.

Q. Is the surgical checklist another document and considered part of the patient record?

A. No, the surgical checklist is not meant to serve as a formal document and is not considered suitable for charting or recording. It is simply a communication tool to trigger members of the surgical team to ensure critical safety checks are completed at key stages in the procedure.

Q. Will all surgical facilities in the province be using the same checklist?

A. All AHS sites will be provided with the AHS Safe Surgery Checklist but sites should ensure the checklist is suitable for their particular environment to enable successful implementation. The checklist can be adjusted, based on predetermined modification criteria (see Section 3.1), to suit the needs of the sites to help ensure the safety of their patients, the flow of surgical procedures, and the commitment of the entire surgical team.

Q. Who should be in charge of leading the surgical checklist in the OR/surgical suite?

A. AHS recommends that the sites or surgical groups determine who should be leading the surgical checklist prior to implementation. This decision should be based on the individual particulars of the site environment. Sites participating with the piloting of the checklist in Alberta had different successes with different approaches. Some groups felt the best success came with the surgeon leading the entire checklist. Other pilot groups assigned each section of the checklist to different groups, while others pre-identified specific portions of each section by function (i.e. the anesthesiologist lead all portions relating to anesthesia). The responsibility for the checklist lies with every member of the OR team, including surgeons, anesthesiologists, nurses, technicians and any other OR staff members.

Q. What procedures do you use the AHS Safe Surgery Checklist for?

A. AHS has defined surgery very broadly to include any procedure involving an incision, excision, manipulation or suturing of tissue requiring regional, general or monitored anesthesia by an anesthesiologist or anesthetist. The surgical checklist is not limited to only formal operating room settings and can be adapted to any procedure room at any AHS site to improve patient safety. It is up to the sites to evaluate which procedures the checklist is suitable for. The WHO recommends the surgical checklist be adapted in any environment and setting where 'surgical' procedures are being completed, including and not limited to emergency department procedure rooms, birth centers performing c-sections, radiology departments performing invasive radiology procedures, etc.

Q. What is the target date for implementation?

A. AHS is asking sites to introduce the AHS Safe Surgery Checklist to all surgical groups within existing functional operating room settings by April 2010. The use of a surgical checklist will become an Accreditation Canada requirement for all sites in Canada going through accreditation based on standards dated as of 2011.

Q. Is there support for surgical groups implementing the AHS Safe Surgery Checklist?

A. YES, AHS will be establishing a support system for individual sites during the implementation phase. There will be Quality and Operational staff that will be identified within zones (see Appendix III) to mentor groups, provide support to answer questions and communicate issues to the provincial steering committee for action.

Q. How will we know if implementing the AHS Safe Surgery Checklist has made a difference?

A. AHS is developing a measurement dashboard to support the implementation and sustainability of the surgical checklist which will measure usage of the checklist and the impact on outcome to patients. The measurement plan will be communicated to all AHS sites when it is completed. The plan will be relevant to sites using either paper OR charting or electronic patient management systems. Outcome measures are being developed with input by healthcare professionals from around the province to ensure appropriate metrics are in place so surgical teams understand the impact of the checklist on improving the safety of patients undergoing surgical procedures.

2.0 Guidelines for Use of the AHS Safe Surgery Checklist

The following are a set of guidelines developed to assist AHS sites in determining how to use the surgical checklist. For full discussion of the rationale and use of each item on the AHS Safe Surgery Checklist, please refer to Appendix II.

AHS sites are advised to review the WHO Safe Surgery website for additional support in understanding how to use the checklist. Alternatively, the Institute for Healthcare Improvement (IHI) and the Canadian Patient Safety Institute (CPSI) also have educational and supportive material (including demonstration videos) that may be beneficial to AHS sites (website addresses listed below).

<http://www.who.int/patientsafety/safesurgery/en/>

<http://www.ihl.org/IHI/Programs/ImprovementMap/WHOSurgicalSafetyChecklist.htm>

<http://www.patientsafetyinstitute.ca/English/toolsResources/sssl/Pages/default.aspx>

2.1 General Guidelines

1. The AHS Safe Surgery Checklist is intended as a communication tool that requires participation of ALL members of the surgical team.
2. AHS strongly urges ALL members of surgical team be present for all three (3) portions of the checklist (Briefing, Time Out and Debriefing). While it may not always be possible for all team members to be available to participate in the Briefing, all members of the surgical team **MUST** be present for the Time Out and Debriefing portions. Team members who are not able to attend the Briefing must pre-arrange to discuss the details of Briefing section with the other members of the surgical team prior to the case.
3. AHS urges AHS surgical teams to include (when appropriate) patients (or family members) for the Briefing portion of the checklist.
4. Surgical teams should pilot the checklist using established quality improvement approaches (e.g. PDSA) before full implementation to identify a process that ensures the smooth and efficient running of the checklist.
5. Surgical teams / sites should pre-assign the role of leading the safety checklist to (a) member(s) of the Surgical Team.
 - a. The WHO suggests that a single person be made responsible for performing the safety checklist.
 - b. Some AHS checklist pilot sites found it preferable to designate the lead of the checklist as follows:
 - Briefing – Anesthesia
 - Time Out – Surgeons
 - De-Briefing – Nursing

- c. Alternatively, other sites have designated the lead for the checklist according to subsections of checklist appropriate to their function (i.e. anesthesiologist will verbally review all portions of the checklist related to anesthesiology, etc).
6. The AHS Safe Surgery Checklist is designed to ensure the BOLD headings and bullet points are communicated verbally by the individual leading the checklist (or portion of) and verbally confirmed with the appropriate team member(s) to ensure that the key actions have been completed. The non-bold bullet points serve as triggers for discussion.
7. It is appropriate for the team member leading the checklist to skip a heading or bullet point on the checklist ONLY if it is NOT applicable to the patient or procedure.
8. Each individual section of the checklist should not take more than 1 minute to complete unless issues have been identified which require action. Ideally the checklist should add no more than 2 minutes of time in total to the surgical procedure.
9. Briefing Section should occur prior to induction of anesthesia (either in the holding area, operating theatre or procedure room).
10. Time Out Section should occur after induction and just prior to commencement of procedure (before skin incision).
11. Debriefing Section can occur simultaneously with wound closure, but must occur prior to the surgeon leaving the room.

2.2 Impact of the Safe Surgery Checklist for High Volume Cases

Some AHS sites that participated in the provincial pilot of the surgical checklist identified some issues with the flow of cases particularly when using the surgical checklist with high volume cases. Other sites did not experience any issues or negative impact on individual cases when implementing and integrating the checklist with any surgical procedure or group and found the checklist could be easily adapted to all groups.

AHS encourages sites to review the implementation strategy with the understanding that the surgical checklist should not negatively impact operational efficiency or impede the flow of surgical cases and procedures. AHS sites are encouraged to consult with the resources identified to support implementation if any site or surgical group finds the surgical checklist does not easily adapt to their situation. The Zone Operational leads and the Clinical Quality Support Consultants (see Appendix III) supporting this initiative through the Implementation Working Group are able to provide sites with insight and draw on the experiences of individuals from AHS that participated in the pilot phase.

3.0 Modifying the Checklist

AHS has approved a modified version of the WHO Surgical Safety Checklist for use across the province. The checklist, while intended to be universally applicable, may not be a perfect fit for all AHS sites. AHS sites or surgical groups may choose to use the AHS Safe Surgery Checklist or modify it to meet the needs of their unique procedures. Groups must ensure modifications are consistent with the AHS Guidelines (see Section 2.0) and the WHO 10 Essential Objectives for Safe Surgery (see Section 1.1).

3.1 Guidelines for Modification of AHS Safe Surgery Checklist

1. Modification must include three key stages for communication by the surgical team (i.e. briefing, time out and debriefing)
2. Sites may add additional items that are deemed essential; however, removal of any checklist item (heading or bullet point) is not an option with the following exceptions:
 - Optional **Briefing** Checklist Items:
 - a. “NPO status” bullet point
 - b. “Relevant and special equipment confirmed and in room” heading
 - c. “Relevant tests completed and checked” heading
 - d. Laboratory bullet point
 - e. Radiology bullet point
 - f. Pregnancy bullet point
 - g. Crossmatch (Type and Screen) bullet
(Note: Sites are NOT permitted to remove ‘Risk of Blood Loss’ bullet point in the Time Out section)
 - Optional **Time Out** Checklist Items:
 - h. “Procedure duration” bullet point
 - i. “Thromboprophylaxis (VTE) ordered” bullet point (**for pediatric procedures ONLY**)
 - j. “Anticoagulant” bullet point
 - k. “Mechanical” bullet point
3. Sites are free to modify the following aspects of the checklist:
 - a. Color
 - b. Formatting
 - c. Language / terminology
 - d. Move individual checklist items to another section of the checklist (i.e. move “Essential imaging displayed” to Briefing Section, etc) to correspond to current surgical routines
 - e. Duplicate essential items in multiple sections
 - f. Add designation of Surgical lead
 - g. Separate and color code the checklist according to Surgical lead
4. The process of modification at a site must involve members of the surgical team (surgeons, anesthesiologists, nurses and other members of the surgical team), and the resulting checklist trialed in simulated and real-life situations in order to ensure its functionality.

3.1.1 WHO Recommendation for Modifying the Surgical Checklist

The WHO has outlined the following guidelines to assist sites in evaluating and modifying the surgical checklist to ensure safety steps inspire effective change and comply with each element key surgical objective for safe surgery.

Adapted from: WHO Guidelines for Safe Surgery 2009.

Focused

- The Checklist should strive to be concise, addressing the most critical issues not adequately checked by other safety mechanisms.
- Five to nine items in each section of Checklist is ideal.

Brief

- The Checklist should take no more than a minute for each section to complete.
- A more exhaustive Checklist will impact the flow of care.

Actionable

- Every item on the Checklist must be linked to a specific, unambiguous action.

Verbal

- The function of the Checklist is to promote and guide a verbal interaction among team members which is critical to its success.

Collaborative

- Any effort to modify the Checklist should be in collaboration with representatives from groups who might be involved in using it.
- Actively seeking input from nurses, anesthesiologists, surgeons and others is important in creating the feeling of “ownership” which is central to adoption and permanent practice change.

Tested

- Prior to any rollout of a modified Checklist, it should be tested in a limited setting.
- The real-time feedback of clinicians is essential to the successful development and implementation.
- Important to test using “simulation” with may involve simply running through the Checklist with team members sitting around a table.
- Suggest using the Checklist for a single day by a single operating team and collecting feedback to ensure an easy fit in the flow for the operating room.
- Plan the wider implementation to all groups.

Integrated

- Many of the processes that are part of the WHO Checklist are part of the current processes for ensuring safe surgical outcomes.
- The major additions to existing routines involve the integration of team communication, briefings, and debriefings which are of critical importance and should not be removed from the Checklist.
- Teams may consider adding other safety checks for specific procedures, particularly if they are part of a routine process established in the facility
 - availability of essential implants (such as mesh or a prosthetic),
 - specific equipment needs
 - critical preoperative biopsy results

4.0 Implementation of the AHS Safe Surgery Checklist

The following section provides suggestions and recommendations for implementing the checklist with different surgical groups at AHS sites, understanding that different practice settings will adapt the use and performance of the surgical checklist to their own circumstance.

AHS recommends that each surgical team practice with the checklist to ensure the integration can easily be adapted into everyday practice. The ultimate goal of the AHS Safe Surgery Checklist is to help ensure that teams consistently follow a few critical safety steps and thereby minimize the most common and avoidable risks that endanger the lives and well-being of surgical patients.

4.1 Recommended Process for Implementing the AHS Safe Surgery Checklist

1. **Identify Champions**

- Identify a surgical, anesthesia, and nursing lead at each site to develop a strategic planned approach for implementing the surgical checklist.

2. **Meet with Hospital/Site Leaders**

- Ensure support for implementation and discuss how the hospital/site leadership can assist in promoting the checklist.

3. **Start to Communicate the Message**

- Develop a communication strategy.
- Start the communication by introducing the surgical checklist to all members of the surgical team (surgeons, anesthesiologist, nursing, and other OR staff members).
 - Recommend presentation of the surgical checklist by the surgical lead at site / regional surgical meetings.

4. **Identify a Surgical Group**

- Identify and approach a surgical group most likely to be supportive of the surgical checklist and would be willing to be the first to use the checklist.

5. **Involve Site Clinical Quality Support Consultants**

- Clinical Quality Support staff can provide surgical groups with guidance in strategic approaches for implementation, measurement of quality improvement, piloting strategies, etc.

6. **Build a Team**

- Establish a site (or service) project team with representation of all clinical team members involved in surgical procedures.
- Identify a core group of people who are enthusiastic about the checklist while trying to involve at least one member from each of the clinical disciplines.
- At the early stages of planning and implementation, work with those who are interested and willing to participate, rather than trying to change the most resistant people.
- Set up regular meeting schedule for the team.

7. **Review Support Material**

- Video links and support material to understand how to use the checklist appropriately are available at the following websites:
 - <http://www.who.int/patientsafety/safesurgery/en/>
 - <http://www.ihl.org/IHI/Programs/ImprovementMap/WHOSurgicalSafetyChecklist.htm>
 - <http://www.patientsafetyinstitute.ca/English/toolsResources/sssl/Pages/default.aspx>

8. Adopt a Quality Improvement Strategy That Will Work for the Site / Service

i. Start Small, Then Expand

- Start with a single operating room, department and / or surgeon.
 - It was noted by sites participating in the WHO study that sites that tried to implement the checklist in multiple operating rooms simultaneously faced the most resistance and had the most trouble convincing staff to use the checklist effectively.
 - Consider using an approach, such as PDSA cycles, that will allow the team to test the suggested changes and the impact on current processes, before fully implementing the checklist.

ii. “Test Drive” the Checklist

- Trial the checklist in one operating room with one team, then move forward after problems have been addressed.
 - Some provincial sites involved in the original pilot phase found it useful to:
 - Set a targeted “go-live” date.
 - Roll out / introduce the checklist to different surgical groups for a week of “practice runs”
 - Practice with a new surgical group each week.
 - Address comments or concerns at the project team level.
 - As you spread the implementation of the checklist, use the learning from previous teams to assist new teams with implementation.

iii. Implement After a Practice Run

9. Monitor Implementation Progress

- The Implementation Working Group will support sites / surgical groups in monitoring the progress of the implementation.

10. Measure Usage and Impact on Outcome

- Measurement of the usage and outcome of implementation will be developed by the AHS Safe Surgery Checklist Steering Committee and will be communicated to sites when available.

11. Communicate the Progress of the Implementation to All Surgical Members

12. Celebrate and Reward Successes

4.2 Support for Implementing the AHS Safe Surgery Checklist

AHS will be supporting AHS sites with implementation of the AHS Safe Surgery Checklist. An Implementation Working Group has been established to provide direct support for sites in each of the five (5) provincial zones (see Appendix III). Each Zone will have an operational representative and a Clinical Quality Support (CQS) Consultant representative. These individuals will provide direct support and guidance for sites. The Zone operational and CQS representatives are members of the provincial Working Group, which act as the communication link for sites to the Provincial Steering Committee and report on the progress of the implementation. The working group will have available to them the knowledge that was developed at AHS during the pilot phase and involve individuals that have supported and assisted in the development of the AHS Safe Surgery Checklist and this manual.

CPSI and Safer Healthcare Now (SHN) have announced ‘*Checklist Action Series*’ and workshops to support Canadian sites with the implementation of the surgical checklist. AHS supports and

recommends sites take advantage of the opportunity to participate (link for information and registration details can be found on the CPSI website).

<http://www.patientsafetyinstitute.ca/English/toolsResources/sssl/Pages/default.aspx>

AHS sites are advised to review the WHO Safe Surgery, the Institute for Healthcare Improvement (IHI), and the Canadian Patient Safety Institutes (CPSI) website for support in understanding how to implement the checklist as part of their routine. Each of the websites listed below have educational and supportive material (including demonstration videos) that can assist sites in understanding how to adopt and use the checklist appropriately.

<http://www.who.int/patientsafety/safesurgery/en/>

<http://www.ihl.org/IHI/Programs/ImprovementMap/WHOSurgicalSafetyChecklist.htm>

<http://www.patientsafetyinstitute.ca/English/toolsResources/sssl/Pages/default.aspx>

4.3 Quality Improvement Strategies for Implementation

AHS surgical teams / sites should use a quality improvement approach to pilot the checklist and test the impact on current operational processes before full implementation. The use of quality improvement techniques such as PDSA cycles to test suggested changes to existing OR processes are very useful before surgical groups fully implementing the checklist. They enable teams to determine the impact the change has on efficiency and flow of procedures, and ensure the quality of care and patient safety is maintained. Clinical Quality Support staff are available to provide support to any site or surgical group regarding methods for piloting improvement initiatives such as the surgical checklist.

4.4 Communication Strategies

The development of a communication strategy by sites is critical to the success of any implementation and change management process. Sites must develop methods to effectively promote the surgical checklist to all the key stakeholders (patients, surgeons, anesthesiologist, OR staff, hospital staff, hospital leadership, etc). The Implementation Working Group (see Appendix III) has tools and support that can be made available to sites upon request that may assist in effectively communication and message to all. The communication strategy should be included as part of the implementation plan for each site.

- Templates for posters that can be used by sites to promote the use of the surgical checklist can be obtained from the Operational Working Group (see Appendix III) and an example will be included as part Implementation Package.
- Communication strategies and material can be found at websites listed below:
 - <http://www.who.int/patientsafety/safesurgery/en/>
 - <http://www.ihl.org/IHI/Programs/ImprovementMap/WHOSurgicalSafetyChecklist.htm>
 - <http://www.patientsafetyinstitute.ca/English/toolsResources/sssl/Pages/default.aspx>

Additional support will be provided to sites through the Implementation Working Group (see Appendix III) which can share communication tools and power point presentations that were used by other sites around the province to promote the surgical checklist.

Communication strategies used by AHS pilot sites included:

- Posters in the operating rooms.
- Presentation by surgical / anesthesiology site leads at medical rounds.
- Presentation at site based quality and safety committees.
- Presentations at OR staff meetings.
- Email reminders to members of the surgical team before the start of the trial / pilot.
- Posting and sharing the New England Journal of Medicine article (see Appendix I).
- Memos from hospital and medical leaders supporting and endorsing the surgical checklist.

4.5 Key Communication Messages to Assist with Implementation and Engagement

1. Each individual portion of the AHS Safe Surgery Checklist has been included based on clinical evidence or expert opinion gathered from around the province. The inclusions of specific portions of the checklist have been incorporated to reduce the likelihood of serious, avoidable surgical harm.
2. The AHS Safe Surgery Checklist was designed for simplicity and brevity. Many of these steps are already accepted as routine practice in facilities around the world but the checklist brings all of them together in a forum of open communication.
3. Successful implementation requires adapting the checklist to local routines and expectations.
4. The AHS Safe Surgery Checklist is meant to be used as a communication tool to provide teams with a simple efficient set of high priority checks for improving communication which will help to ensure that the safety of the patient is a top priority in every single operation that is done.

4.6 Physician Engagement Strategies

Physician engagement is a critical aspect and key success factor in the implementing of any improvement initiative in healthcare. The surgical checklist must be viewed by physicians as adding value to patient care and improving the outcome for their surgical patients. The key to the success of the implementation lies with ensuring that physicians at each site take ownership, are consulted and are involved with all aspects of the review and implementation process. Their involvement and participation on site based implementation teams is essential. Some physicians may view the checklist as a nursing tool and project team should ensure surgeons and anesthesiologists understand that it is a surgical safety tool that requires the involvement and active participation of all members of the surgical team.

Names of physician that are willing to act as mentors to other physicians are available through the Implementation Working Group (see Appendix III). These are surgeons and anesthesiologists that were involved in the piloting of the checklist and the design of AHS Safe Surgery Checklist that are willing to discuss the checklist and their experience using the checklist with other physicians.

4.7 Measurement

AHS has established a Measurement Working Group to develop a provincial measurement plan which will provide long term review and reporting in compliance with the new Accreditation Canada Surgical Checklist ROP standard. The AHS Safe Surgery Checklist provincial steering committee will ensure the measurement plan is relevant to sites using either paper OR charting or electronic patient management systems. The plan will include identification of appropriate metrics for both usage and outcome, and ensure reporting to key local, zone and provincial stakeholders.

There are two separate stages to implementation; the first stage is the actual introduction and implementation of the checklist at the sites. There are plans for a measurement piece that will provide sites and the Steering Committee with feedback on the progress of the implementation. The second phase of implementation is the long term provincial Safe Surgery Checklist measurement plan which the Steering Committee will implement after development and careful review with surgeons, anesthesiologist and nurses from around the province. This measurement plan will be communicated to all sites prior to the rollout.

APPENDIX I AHS Safe Surgery Checklist



AHS Safe Surgery Checklist

Before Induction of Anesthesia	Before Skin Incision	Before Patient Leaves Operating Room
<i>Briefing</i>	<i>Time Out</i>	<i>Debriefing</i>
Patient (family member) and / or surgical team members have verbally confirmed: <ul style="list-style-type: none"> • Patient identity • Procedure • Site, side or level • Consent(s) • Known allergies and reactions • NPO status 	All team members have introduced themselves by name and role Surgeon, Anesthesiologist, and Nurse have verbally confirmed: <ul style="list-style-type: none"> • Patient • Procedure • Site 	Surgical team have verbally confirmed: <ul style="list-style-type: none"> • Name of the procedure • Applicable sponge and instrument counts • Specimen labeling and handling • Equipment problems addressed
Special precautions <ul style="list-style-type: none"> • Malignant hyperthermia • Latex • Isolation • Other 	Anticipated critical events: <ul style="list-style-type: none"> • Surgeon review: <ul style="list-style-type: none"> • Critical or unexpected steps • Procedure duration • Risk of >500mL (7mL/Kg in Children) blood loss • Anesthesiologist review: <ul style="list-style-type: none"> • Patient-specific concerns • Adequate intravenous access and fluid planned • Nursing review: <ul style="list-style-type: none"> • Sterility issues • Equipment issues 	Surgical team have reviewed recovery plan: <ul style="list-style-type: none"> • Patient disposition • Analgesia • O₂ needs for transfer • Specific concerns
Weight (Kg) recorded on chart	Applicable medication concerns: <ul style="list-style-type: none"> • Antibiotic prophylaxis given within last 60 minutes • Thromboprophylaxis (VTE) ordered: <ul style="list-style-type: none"> • Anticoagulant • Mechanical • Other specific medication concerns 	
Anesthesia safety and equipment check completed	Essential imaging displayed	
Difficult airway/aspiration risk <ul style="list-style-type: none"> • Applicable equipment / assistance available 	Any other questions or concerns before proceeding?	
Patient positioning and support confirmed		
Relevant and special equipment confirmed and in room: <ul style="list-style-type: none"> • Prosthesis • Warming devices • Loaner instrument 		
Relevant tests completed and checked: <ul style="list-style-type: none"> • Laboratory <ul style="list-style-type: none"> • Pregnancy • Crossmatch (Type and Screen) • Radiology 		

This checklist was adapted from the World Health Organization (WHO) Surgical Safety Checklist (URL: <http://www.who.int/patientsafety/safesurgery/en>; © World Health Organization 2008, All Rights Reserved). Version 8 (Jan 21, 2009)

APPENDIX II

Guidelines for Use of the AHS Safe Surgery Checklist (detailed)

I. Before Induction of Anesthesia- BRIEFING

These safety checks are to be completed *before induction of anesthesia* in order to confirm that key safety procedures have been completed and reviewed before proceeding. AHS strongly urges that all members of the surgical team make every effort to attend and participate at each of the three portions of the surgical checklist. The individual leading the checklist may complete this section all at once or sequentially, depending on the flow of preparation for anesthesia. The details for each of the safety steps are as follows:

1. Patient (family member) and / or Surgical Team Members have Verbally Confirmed

The individual leading the checklist for this section verbally confirms:

- patient's identity,
- procedure,
- site, side or level,
- consent for surgery has been given.

While it may seem repetitive, this step is essential for ensuring that the team does not operate on the wrong patient, wrong site or perform the wrong procedure on the patient. When confirmation by the patient is impossible, such as in the case of children or incapacitated patients, a guardian or family member can assume this role. If a guardian or family member is not available, the surgical team can confirm that they are all in agreement to the items covered prior to proceeding.

It is also important at this time to verbally confirm if the patient has any known allergies and what the typical reaction to the allergen is for the patient.

NPO Status has been placed on the checklist in this section – It is the only optional item in this section and can be removed during modification of the checklist if it is deemed non-essential information to your local process.

2. Special Precautions

The individual leading the checklist also completes this next step in the presence of the patient or family member by asking if the patient has any special cautions that may impact the outcome of the procedure. For example, does the patient know of issues with malignant hyperthermia, latex allergies, requires isolation precautions, etc.

3. Weight (Kg) Recorded on Chart

Many dosages are based on weight for pediatric and adult procedures and it is essential that confirmation of the weight has been recorded on the chart.

4. Anesthesia Safety and Equipment Check Completed

The individual leading the checklist completes this next step by asking the anesthesiologist to verify completion of the anesthesia safety check which may involve formal inspection of all anesthetic equipment, breathing circuit, medications and review of the patient's anesthetic risk. The anesthesia team should complete the **ABCDE's** (**A**irway equipment, **B**reathing system - including oxygen and inhalational agents, **s**uction, **d**rugs and **d**evelopments and **e**mergency medications, **e**quipment).

5. Difficult Airway/Aspiration Risk

The individual leading the checklist should verbally confirm that the anesthesia team has objectively assessed whether the patient has a difficult airway. Death from airway loss during anesthesia is still a common disaster globally but is preventable with appropriate planning. If the airway evaluation indicates a high risk for a difficult airway, the anesthesia team must prepare against any potential issues including (but not limited to): adjusting the approach to anesthesia (for example, using a regional anesthetic, if possible); and having emergency equipment accessible. A capable assistant—whether a second anesthesiologist, the surgeon, or a nursing team member—should be physically present to help with induction of anesthesia. The risk of aspiration should also be evaluated as part of the airway assessment. If the patient has symptomatic active reflux or a full stomach, the anesthesiologist must prepare for the possibility of aspiration. The risk can be reduced by modifying the anesthesia plan, for example using rapid induction techniques and enlisting the help of an assistant to provide pressure during induction. For a patient recognized as having a difficult airway or being at risk for aspiration, induction of anesthesia should begin only when the anesthesiologist confirms that he or she has adequate equipment and assistance present at the bedside.

6. Patient Positioning and Support Confirmed

To prevent delays, the surgeon must review their plan for patient positioning and support requirements for the team. If the surgeon is unable to attend the Briefing portion of the checklist, they must ensure that a review occurs with the attending anesthesiologist prior to the team briefing.

7. Relevant Special Equipment Confirmed and In Room

The individual leading the checklist should verbally review the need for any relevant and special equipment not normally found in the theatre. This may include but is not limited to confirmation that prosthesis, warming devices or loaner instruments are checked and confirmed. This box is optional on the checklist and may be removed if not applicable to local procedures.

8. Relevant Tests completed and checked

The individual leading the checklist should verbally confirm that someone has reviewed and confirmed the completion and availability of all relevant laboratory and radiology procedures. This may include confirmation of pregnancy test for female patients, completion of a type and screen and/or crossmatch to ensure that blood products can be made available if required. Confirmation of requested radiology should also ensure availability of all essential imaging during the procedure. This box is optional and may be removed during modification if not applicable to local practice.

A decision was made to move the discussion of blood loss to the time out section to avoid increasing the stress to the patient and/or family members present. It was decided however, that it was important to have the confirmation of the crossmatch in the briefing section to save time if it had indeed been missed.

II. Before skin incision- TIME OUT

Before making the first surgical incision, a momentary pause should be taken by the team in order to confirm that several essential safety checks are undertaken. These checks must involve **all** team members.

9. All Team Members Have Introduced Themselves by Name and Role

Operating room team members may change frequently. Effective management of high risk situations requires that all team members understand who each member is and their roles and capabilities. A simple introduction can achieve this. The individual leading the checklist should ask each person in the room to introduce him or herself by name and role.

Teams already familiar with each other can confirm that everyone has been introduced. If additional staff have rotated into the operating room since the last operation, they should introduce themselves. This introduction should include students or other personnel.

10. Surgeon, Anesthesiologist, and Nurse Have Verbally Confirmed: Patient, Procedure, Site

The individual leading the checklist will request all team members to stop and verbally reconfirm:

- name of the patient,
- procedure to be performed,
- site of surgery

For example, the circulating nurse might announce, “Before we make the skin incision does everyone agree that this is patient X, undergoing a right inguinal hernia repair?” The anesthesiologist, surgeon and circulating nurse should explicitly and individually confirm agreement.

11. Anticipated Critical Events

To ensure communication of critical patient issues, the individual leading the checklist leads a swift discussion among the surgeon, anesthesia and nursing staff of critical dangers and operative plans. The order of discussion does not matter, but each clinical discipline should provide information and communicate concerns.

a. Surgeon Review

The surgeon’s review should involve the following:

- A **review of the critical steps** associated with the procedure that may result in injury or risk of morbidity. This is also a chance to review steps that might require special equipment, implants or preparations.
- **Duration of procedure** is to ensure that all team members understand the expected length of the procedure which may be longer (or shorter) than expected due to issues unique to the procedure or patient.
- A review of the **Risk of >500 mL blood loss (7 mL/Kg in children)** is one of the WHO 10 essential objectives for safe surgery and is a requirement for all surgical checklist.

Large volume blood loss is among the most common and important dangers for surgical patients, with risk of hypovolemic shock escalating when blood loss exceeds 500 mL (7 mL/Kg in children). Adequate preparation and resuscitation may mitigate consequences considerably. Surgeons may not consistently communicate the risk of blood loss to anesthesia and nursing staff. Therefore, if

the specific risk of major blood loss associated with the patient or the procedure is unknown or unclear, the surgeon can discuss the situation with the team prior to commencement.

b. Anesthesiologist Review

The anesthesiologist's review should involve the following:

- Are there any patient-specific concerns?
- Is there adequate intravenous access and fluid planned?

If there is a significant risk of a greater than 500 mL blood loss, it is highly recommended that at least two large bore intravenous lines or a central venous catheter be placed prior to skin incision. In addition, the team should confirm the availability of fluids or blood.

c. Nursing Review

The nurse's review should involve the following:

- Are there any issues relating to sterility
- Are there any issues relating to equipment

The scrub nurse or technologist who sets out the equipment for the case should verbally confirm that sterilization was performed and that, for heat-sterilized instruments, a sterility indicator has verified successful sterilization. Any discrepancy between the expected and the actual sterility indicator results should be reported to all team members and addressed before incision. This is also an opportunity to discuss any problems with equipment and other preparations for surgery.

During routine procedures or those with which the entire team is familiar, the surgeon can simply state, "This is a routine case of X duration" and then ask the anesthesiologist and nurse if they have any special concerns. For many procedures that do not generally entail particularly critical risks or concerns anesthesiologist and nurse can also simply say, "I have no special concern regarding this case."

12. Applicable Medication Concerns**• Antibiotic Prophylaxis Given Within Last 60 Minutes**

This is another of the 10 WHO essential objectives for safe surgery. Despite strong evidence and wide consensus that antibiotic prophylaxis against wound infections is most effective if serum and/or tissue levels of antibiotic are achieved, surgical teams are inconsistent about administering antibiotics within one hour prior to incision.

To reduce surgical infection risk, the individual leading the checklist will ask out loud whether prophylactic antibiotics were given during the previous 60 minutes. The team member responsible for administering antibiotics (typically the anesthesiologist) should verbally confirm if prophylactic antibiotics have been administered and if not it should be administered prior to incision. If prophylactic antibiotics have been administered longer than 60 minutes prior, the team should consider re-dosing the patient.

A simple verbal "not applicable" announcement will suffice if prophylactic antibiotics are not considered appropriate.

- **Thromboprophylaxis (VTE) Ordered**

VTE is one of the most common and preventable complications of hospitalization. If VTE thromboprophylaxis is not instituted, then 10 to 40% of general surgery patients and 40 to 60% of hip surgery patients will develop VTE. This is not one of the WHO 10 essential objectives for safe surgery, but is listed as a recommended addition that a number of countries have included in their checklist. The medical members of the Surgical Checklist Steering Committee felt strongly that this must be part of the AHS Safe Surgery Checklist is not optional.

How-to Guide: Prevention of Venous Thromboembolism. *Safer Healthcare Now!* Campaign May 2008.

<http://www.saferhealthcarenow.ca/EN/Interventions/vte/Documents/VTE%20Getting%20Started%20Kit.pdf>

- **Other Specific Medication Concerns**

This provides the team to highlight any additional medication related concerns.

13. Essential Imaging Displayed

Imaging is critical to ensure proper planning and conduct of many operations and is one reason for delays. Before skin incision, the individual leading the checklist should ask the surgeon if imaging is needed for the case and confirmation that essential imaging is available and prominently displayed. If imaging is needed but not available, it should be obtained and the surgeon can decide whether to proceed without the imaging.

14. Any Other Questions or Concerns Before Proceeding

This provides all members of the team the opportunity to voice any concerns prior to commencement.

III. Before Patient Leaves Operating Room- DEBRIEFING

These safety checks should be completed before removing the patient from the operating room. The aim is to facilitate the transfer of important information to the care teams responsible for the patient after surgery. The checks can be initiated by the circulating nurse, surgeon or anesthesiologist and should be accomplished before the surgeon has left the room. It can coincide with wound closure.

15. Surgical Team Have Verbally Confirmed

- **The Name of the Procedure**

Since the procedure may have changed or expanded during the course of an operation, the individual leading the checklist should confirm with the surgeon and the team exactly what procedure was done. This can be done as a question, “What procedure was performed?” or as a confirmation, “We performed X procedure, correct?”

- **Applicable Sponge and Instrument Counts**

Retained instruments, sponges and needles are uncommon but persistent and potential errors that may result in serious harm to the patient. The scrub or circulating nurse should therefore verbally confirm the completeness of final sponge and needle counts. In cases with an open cavity, instrument counts should also be confirmed to be complete. If counts are not appropriately reconciled, the team should be alerted so that appropriate steps can be taken (such as examining the drapes, garbage and wound or, if need be, obtaining radiographic images).

- **Specimen Labeling and Handling**

Incorrect labeling of pathological specimens is potentially disastrous for a patient and has been shown to be a frequent source of errors. The scrub or circulating nurse should confirm the correct labeling of any pathological specimen obtained during the procedure by reading out loud the patient’s name, the specimen description and any orienting marks.

- **Whether There Are Any Equipment Problems to be Addressed**

Equipment problems are universal in operating rooms. Identifying the sources of instruments or equipment failure is important in preventing devices from being recycled back into the room. The individual leading the checklist should ensure that equipment problems arising during a case are identified by the team.

16. Surgical Team Has Reviewed the Recovery Plan

The surgeon, anesthesiologist and nurse should review the post-operative recovery and management plan, focusing in particular on intraoperative or anesthetic issues that might affect the patient. Events that present a specific risk to the patient during recovery may not always be evident to all members of the surgical and recovery team. The aim of this step is the efficient and appropriate transfer of critical information to the entire team so the following issues should be reviewed:

- **Patient Disposition**
- **Analgesia**
- **O2 Needs for Transfer**
- **Specific Concerns**

With this final step, the AHS Checklist is completed.

APPENDIX III
AHS Implementation Working Group Membership List

Implementation Working Group Membership List

Member	Location	Contact Information
Co-Chairs		
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APPENDIX IV Reference Article I

Haynes AB, et al. A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population. *N. Engl J Med*, 2009; 360; 491-9.

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SPECIAL ARTICLE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

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ABSTRACT

BACKGROUND

Surgery has become an integral part of global health care, with an estimated 234 million operations performed yearly. Surgical complications are common and often preventable. We hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce complications and deaths associated with surgery.

METHODS

Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients participated in the World Health Organization's Safe Surgery Saves Lives program. We prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing noncardiac surgery. We subsequently collected data on 3955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. The primary end point was the rate of complications, including death, during hospitalization within the first 30 days after the operation.

RESULTS

The rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward ($P=0.003$). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist ($P<0.001$).

CONCLUSIONS

Implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing noncardiac surgery in a diverse group of hospitals.

From the Harvard School of Public Health (A.B.H., T.G.W., W.R.B., A.A.G.), Massachusetts General Hospital (A.B.H.), and Brigham and Women's Hospital (S.R.L., A.A.G.) — all in Boston; University of California–Davis, Sacramento (T.G.W.); Prince Hamzah Hospital, Ministry of Health, Amman, Jordan (A.-H.S.B.); University of Washington, Seattle (E.P.D.); College of Medicine, University of the Philippines, Manila (T.H.); St. Stephen's Hospital, New Delhi, India (S.J.); St. Francis Designated District Hospital, Ifakara, Tanzania (P.L.K.); National Institute of Health–University of the Philippines, Manila (M.C.M.L.); University of Auckland and Auckland City Hospital, Auckland, New Zealand (A.F.M.); Imperial College Healthcare National Health Service Trust, London (K.M.); and University Health Network, University of Toronto, Toronto (R.K.R., B.T.). Address reprint requests to Dr. Gawande at the Department of Surgery, Brigham and Women's Hospital, 75 Francis St., Boston, MA 02115, or at safesurgery@hsph.harvard.edu.

*Members of the Safe Surgery Saves Lives Study Group are listed in the Appendix.

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SURGICAL CARE IS AN INTEGRAL PART OF health care throughout the world, with an estimated 234 million operations performed annually.¹ This yearly volume now exceeds that of childbirth.² Surgery is performed in every community: wealthy and poor, rural and urban, and in all regions. The World Bank reported that in 2002, an estimated 164 million disability-adjusted life-years, representing 11% of the entire disease burden, were attributable to surgically treatable conditions.³ Although surgical care can prevent loss of life or limb, it is also associated with a considerable risk of complications and death. The risk of complications is poorly characterized in many parts of the world, but studies in industrialized countries have shown a perioperative rate of death from inpatient surgery of 0.4 to 0.8% and a rate of major complications of 3 to 17%.^{4,5} These

rates are likely to be much higher in developing countries.⁶⁻⁹ Thus, surgical care and its attendant complications represent a substantial burden of disease worthy of attention from the public health community worldwide.

Data suggest that at least half of all surgical complications are avoidable.^{4,5} Previous efforts to implement practices designed to reduce surgical-site infections or anesthesia-related mishaps have been shown to reduce complications significantly.¹⁰⁻¹² A growing body of evidence also links teamwork in surgery to improved outcomes, with high-functioning teams achieving significantly reduced rates of adverse events.^{13,14}

In 2008, the World Health Organization (WHO) published guidelines identifying multiple recommended practices to ensure the safety of surgical patients worldwide.¹⁵ On the basis of

Table 1. Elements of the Surgical Safety Checklist.*

Sign in
Before induction of anesthesia, members of the team (at least the nurse and an anesthesia professional) orally confirm that:
The patient has verified his or her identity, the surgical site and procedure, and consent
The surgical site is marked or site marking is not applicable
The pulse oximeter is on the patient and functioning
All members of the team are aware of whether the patient has a known allergy
The patient's airway and risk of aspiration have been evaluated and appropriate equipment and assistance are available
If there is a risk of blood loss of at least 500 ml (or 7 ml/kg of body weight, in children), appropriate access and fluids are available
Time out
Before skin incision, the entire team (nurses, surgeons, anesthesia professionals, and any others participating in the care of the patient) orally:
Confirms that all team members have been introduced by name and role
Confirms the patient's identity, surgical site, and procedure
Reviews the anticipated critical events
Surgeon reviews critical and unexpected steps, operative duration, and anticipated blood loss
Anesthesia staff review concerns specific to the patient
Nursing staff review confirmation of sterility, equipment availability, and other concerns
Confirms that prophylactic antibiotics have been administered ≥ 60 min before incision is made or that antibiotics are not indicated
Confirms that all essential imaging results for the correct patient are displayed in the operating room
Sign out
Before the patient leaves the operating room:
Nurse reviews items aloud with the team
Name of the procedure as recorded
That the needle, sponge, and instrument counts are complete (or not applicable)
That the specimen (if any) is correctly labeled, including with the patient's name
Whether there are any issues with equipment to be addressed
The surgeon, nurse, and anesthesia professional review aloud the key concerns for the recovery and care of the patient

* The checklist is based on the first edition of the WHO Guidelines for Safe Surgery.¹⁵ For the complete checklist, see the Supplementary Appendix.

A SURGICAL SAFETY CHECKLIST

these guidelines, we designed a 19-item checklist intended to be globally applicable and to reduce the rate of major surgical complications (Table 1). (For the formatted checklist, see the Supplementary Appendix, available with the full text of this article at NEJM.org.) We hypothesized that implementation of this checklist and the associated culture changes it signified would reduce the rates of death and major complications after surgery in diverse settings.

METHODS
STUDY DESIGN

We conducted a prospective study of preintervention and postintervention periods at the eight hospitals participating as pilot sites in the Safe Surgery Saves Lives program (Table 2). These institutions were selected on the basis of their geographic distribution within WHO regions, with the goal of representing a diverse set of socioeconomic environments in which surgery is performed. Table 3 lists surgical safety policies in place at each institution before the study. We required that a coinvestigator at each site lead the project locally and that the hospital administration support the intervention. A local data collector was chosen at each site and trained by the four primary investigators in the identification and reporting of process measures and complications. This person worked on the study full-time and did not have clinical responsibilities at the study site. Each hospital identified between one and four operating rooms to serve as study rooms. Patients who were 16 years of age or older and were undergoing non-

cardiac surgery in those rooms were consecutively enrolled in the study. The human subjects committees of the Harvard School of Public Health, the WHO, and each participating hospital approved the study and waived the requirement for written informed consent from patients.

INTERVENTION

The intervention involved a two-step checklist-implementation program. After collecting baseline data, each local investigator was given information about areas of identified deficiencies and was then asked to implement the 19-item WHO safe-surgery checklist (Table 1) to improve practices within the institution. The checklist consists of an oral confirmation by surgical teams of the completion of the basic steps for ensuring safe delivery of anesthesia, prophylaxis against infection, effective teamwork, and other essential practices in surgery. It is used at three critical junctures in care: before anesthesia is administered, immediately before incision, and before the patient is taken out of the operating room. The checklist was translated into local language when appropriate and was adjusted to fit into the flow of care at each institution. The local study team introduced the checklist to operating-room staff, using lectures, written materials, or direct guidance. The primary investigators also participated in the training by distributing a recorded video to the study sites, participating in a teleconference with each local study team, and making a visit to each site. The checklist was introduced to the study rooms over a period of 1 week to 1 month. Data collection resumed during the first week of checklist use.

Table 2. Characteristics of Participating Hospitals.

Site	Location	No. of Beds	No. of Operating Rooms	Type
Prince Hamzah Hospital	Amman, Jordan	500	13	Public, urban
St. Stephen's Hospital	New Delhi, India	733	15	Charity, urban
University of Washington Medical Center	Seattle, Washington	410	24	Public, urban
St. Francis Designated District Hospital	Ifakara, Tanzania	371	3	District, rural
Philippine General Hospital	Manila, Philippines	1800	39	Public, urban
Toronto General Hospital	Toronto, Canada	744	19	Public, urban
St. Mary's Hospital*	London, England	541	16	Public, urban
Auckland City Hospital	Auckland, New Zealand	710	31	Public, urban

* St. Mary's Hospital has since been renamed St. Mary's Hospital-Imperial College National Health Service Trust.

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DATA COLLECTION

We obtained data on each operation from standardized data sheets completed by the local data collectors or the clinical teams involved in surgical care. The data collectors received training and supervision from the primary investigators in the identification and classification of complications and process measures. Perioperative data included the demographic characteristics of patients, procedural data, type of anesthetic used, and safety data. Data collectors followed patients prospectively until discharge or for 30 days, whichever came first, for death and complications. Outcomes were identified through chart monitoring and communication with clinical staff. Completed data forms were stripped of direct identifiers of patients and transmitted to the primary investigators. We aimed to collect data on 500 consecutively enrolled patients at each site within a period of less than 3 months for each of the two phases of the study. At the three sites at which this goal could not be achieved, the period of data collection was extended for up to 3 additional months to allow for accrual of a sufficient number of patients. The sample size was calculated to detect a 20% reduction in complications after the checklist was implemented, with a statistical power of 80% and an alpha value of 0.05.

OUTCOMES

The primary end point was the occurrence of any major complication, including death, during the period of postoperative hospitalization, up to 30 days. Complications were defined as they are in

the American College of Surgeons' National Surgical Quality Improvement Program¹⁷: acute renal failure, bleeding requiring the transfusion of 4 or more units of red cells within the first 72 hours after surgery, cardiac arrest requiring cardiopulmonary resuscitation, coma of 24 hours' duration or more, deep-vein thrombosis, myocardial infarction, unplanned intubation, ventilator use for 48 hours or more, pneumonia, pulmonary embolism, stroke, major disruption of wound, infection of surgical site, sepsis, septic shock, the systemic inflammatory response syndrome, unplanned return to the operating room, vascular graft failure, and death. Urinary tract infection was not considered a major complication. A group of physician reviewers determined, by consensus, whether postoperative events reported as "other complications" qualified as major complications, using the Clavien classification for guidance.¹⁸

We assessed adherence to a subgroup of six safety measures as an indicator of process adherence. The six measures were the objective evaluation and documentation of the status of the patient's airway before administration of the anesthetic; the use of pulse oximetry at the time of initiation of anesthesia; the presence of at least two peripheral intravenous catheters or a central venous catheter before incision in cases involving an estimated blood loss of 500 ml or more; the administration of prophylactic antibiotics within 60 minutes before incision except in the case of preexisting infection, a procedure not involving incision, or a contaminated operative field; oral confirmation, immediately before incision, of the

Table 3. Surgical Safety Policies in Place at Participating Hospitals before the Study.

Site No.*	Routine Intraoperative Monitoring with Pulse Oximetry	Oral Confirmation of Patient's Identity and Surgical Site in Operating Room	Routine Administration of Prophylactic Antibiotics in Operating Room	Standard Plan for Intravenous Access for Cases of High Blood Loss	Formal Team Briefing	
					Preoperative	Postoperative
1	Yes	Yes	Yes	No	No	No
2	Yes	No	Yes	No	No	No
3	Yes	No	Yes	No	No	No
4	Yes	Yes	Yes	No	No	No
5	No	No	No	No	No	No
6	No	No	Yes	No	No	No
7	Yes	No	No	No	No	No
8	Yes	No	No	No	No	No

* Sites 1 through 4 are located in high-income countries; sites 5 through 8 are located in low- or middle-income countries.¹⁶

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identity of the patient, the operative site, and the procedure to be performed; and completion of a sponge count at the end of the procedure, if an incision was made. We recorded whether all six of these safety measures were taken for each patient.

STATISTICAL ANALYSIS

Statistical analyses were performed with the use of the SAS statistical software package, version 9.1 (SAS Institute). To minimize the effect of differences in the numbers of patients at each site, we standardized the rates of various end points to reflect the proportion of patients from each site. These standardized rates were used to compute the frequencies of performance of specified safety measures, major complications, and death at each site before and after implementation of the checklist.⁴⁹ We used logistic-regression analysis to calculate two-sided P values for each comparison, with site as a fixed effect. We used generalized-estimating-equation methods to test for any effect of clustering according to site.

We performed additional analyses to test the robustness of our findings, including logistic-regression analyses in which the presence or absence of a data collector in the operating room and the case mix were added as variables. We classified cases as orthopedic, thoracic, nonobstetric abdominopelvic, obstetric, vascular, endoscop-

ic, or other. To determine whether the effect of the checklist at any one site dominated the results, we performed cross-validation by sequentially removing each site from the analysis. Finally, we disaggregated the sites on the basis of whether they were located in high-income or low- or middle-income countries and repeated our analysis of primary end points. All reported P values are two-sided, and no adjustments were made for multiple comparisons.

RESULTS

We enrolled 3733 patients during the baseline period and 3955 patients after implementation of the checklist. Table 4 lists characteristics of the patients and their distribution among the sites; there were no significant differences between the patients in the two phases of the study.

The rate of any complication at all sites dropped from 11.0% at baseline to 7.0% after introduction of the checklist ($P<0.001$); the total in-hospital rate of death dropped from 1.5% to 0.8% ($P=0.003$) (Table 5). The overall rates of surgical-site infection and unplanned reoperation also declined significantly ($P<0.001$ and $P=0.047$, respectively). Operative data were collected by the local data collector through direct observation for 37.5% of patients and by unobserved clinical teams for the remainder. Neither the presence nor

Table 4. Characteristics of the Patients and Procedures before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Age		Female Sex		Urgent Case		Outpatient Procedure		General Anesthetic	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
			years				percent					
1	524	598	51.9±15.3	51.4±14.7	58.2	62.7	7.4	8.0	31.7	31.8	95.0	95.2
2	357	351	53.5±18.4	54.0±18.3	54.1	56.7	18.8	14.5	23.5	20.5	92.7	93.5
3	497	486	51.9±21.5	53.0±20.3	44.3	49.8	17.9	22.4	6.4	9.3	91.2	94.0
4	520	545	57.0±14.9	56.1±15.0	48.1	49.6	6.9	1.8	14.4	11.0	96.9	97.8
5	370	330	34.3±15.0	31.5±14.2	78.3	78.4	46.1	65.4	0.0	0.0	17.0	10.0
6	496	476	44.6±15.9	46.0±15.5	45.0	46.6	28.4	22.5	1.4	1.1	61.7	59.9
7	525	585	37.4±14.0	39.6±14.9	69.1	68.6	45.7	41.0	0.0	0.0	49.1	55.9
8	444	584	41.9±15.8	39.7±16.2	57.0	52.7	13.5	21.9	0.9	0.2	97.5	94.7
Total	3733	3955	46.8±18.1	46.7±17.9	56.2	57.6	22.3	23.3	9.9	9.4	77.0	77.3
P value			0.63		0.21		0.26		0.40		0.68	

* Plus-minus values are means ±SD. Urgent cases were those in which surgery within 24 hours was deemed necessary by the clinical team. Outpatient procedures were those for which discharge from the hospital occurred on the same day as the operation. P values are shown for the comparison of the total value after checklist implementation with the total value before implementation.

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Table 5. Outcomes before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Surgical-Site Infection		Unplanned Return to the Operating Room		Pneumonia		Death		Any Complication	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
	<i>percent</i>											
1	524	598	4.0	2.0	4.6	1.8	0.8	1.2	1.0	0.0	11.6	7.0
2	357	351	2.0	1.7	0.6	1.1	3.6	3.7	1.1	0.3	7.8	6.3
3	497	486	5.8	4.3	4.6	2.7	1.6	1.7	0.8	1.4	13.5	9.7
4	520	545	3.1	2.6	2.5	2.2	0.6	0.9	1.0	0.6	7.5	5.5
5	370	330	20.5	3.6	1.4	1.8	0.3	0.0	1.4	0.0	21.4	5.5
6	496	476	4.0	4.0	3.0	3.2	2.0	1.9	3.6	1.7	10.1	9.7
7	525	585	9.5	5.8	1.3	0.2	1.0	1.7	2.1	1.7	12.4	8.0
8	444	584	4.1	2.4	0.5	1.2	0.0	0.0	1.4	0.3	6.1	3.6
Total	3733	3955	6.2	3.4	2.4	1.8	1.1	1.3	1.5	0.8	11.0	7.0
P value			<0.001		0.047		0.46		0.003		<0.001	

* The most common complications occurring during the first 30 days of hospitalization after the operation are listed. Bold type indicates values that were significantly different (at $P < 0.05$) before and after checklist implementation, on the basis of P values calculated by means of the chi-square test or Fisher's exact test. P values are shown for the comparison of the total value after checklist implementation as compared with the total value before implementation.

absence of a direct observer nor changes in case mix affected the significance of the changes in the rate of complications ($P < 0.001$ for both alternative models) or the rate of death ($P = 0.003$ with the presence or absence of direct observation included and $P = 0.002$ with case-mix variables included). Rates of complication fell from 10.3% before the introduction of the checklist to 7.1% after its introduction among high-income sites ($P < 0.001$) and from 11.7% to 6.8% among lower-income sites ($P < 0.001$). The rate of death was reduced from 0.9% before checklist introduction to 0.6% afterward at high-income sites ($P = 0.18$) and from 2.1% to 1.0% at lower-income sites ($P = 0.006$), although only the latter difference was significant. In the cross-validation analysis, the effect of the checklist intervention on the rate of death or complications remained significant after the removal of any site from the model ($P < 0.05$). We also found no change in the significance of the effect on the basis of clustering ($P = 0.003$ for the rate of death and $P = 0.001$ for the rate of complications).

Table 6 shows the changes in six measured processes at each site after introduction of the checklist. During the baseline period, all six measured safety indicators were performed for 34.2% of the patients, with an increase to 56.7% of patients after implementation of the checklist

($P < 0.001$). At each site, implementation of the checklist also required routine performance of team introductions, briefings, and debriefings, but adherence rates could not be measured.

DISCUSSION

Introduction of the WHO Surgical Safety Checklist into operating rooms in eight diverse hospitals was associated with marked improvements in surgical outcomes. Postoperative complication rates fell by 36% on average, and death rates fell by a similar amount. All sites had a reduction in the rate of major postoperative complications, with a significant reduction at three sites, one in a high-income location and two in lower-income locations. The reduction in complications was maintained when the analysis was adjusted for case-mix variables. In addition, although the effect of the intervention was stronger at some sites than at others, no single site was responsible for the overall effect, nor was the effect confined to high-income or low-income sites exclusively. The reduction in the rates of death and complications suggests that the checklist program can improve the safety of surgical patients in diverse clinical and economic environments.

Whereas the evidence of improvement in surgical outcomes is substantial and robust, the ex-

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act mechanism of improvement is less clear and most likely multifactorial. Use of the checklist involved both changes in systems and changes in the behavior of individual surgical teams. To implement the checklist, all sites had to introduce a formal pause in care during surgery for preoperative team introductions and briefings and postoperative debriefings, team practices that have previously been shown to be associated with improved safety processes and attitudes^{14,20,21} and with a rate of complications and death reduced by as much as 80%.¹³ The philosophy of ensuring the correct identity of the patient and site through preoperative site marking, oral confirmation in the operating room, and other measures proved to be new to most of the study hospitals.

In addition, institution of the checklist required changes in systems at three institutions, in order to change the location of administration of antibiotics. Checklist implementation encouraged the administration of antibiotics in the operating room rather than in the preoperative wards, where delays are frequent. The checklist provided additional oral confirmation of appropriate antibiotic use, increasing the adherence rate from 56 to 83%; this intervention alone has been shown to reduce the rate of surgical-site infection by 33 to 88%.²²⁻²⁸ Other potentially lifesaving measures were also more likely to be instituted, including an objective airway evaluation and use of pulse oximetry, though the change in these measures was less dramatic.¹⁵ Although the omission of individual steps was still frequent, overall adherence to the subgroup of six safety indicators increased by two thirds. The sum of these individual systemic and behavioral changes could account for the improvements observed.

Another mechanism, however, could be the Hawthorne effect, an improvement in performance due to subjects' knowledge of being observed.²⁹ The contribution of the Hawthorne effect is difficult to disentangle in this study. The checklist is orally performed by peers and is intentionally designed to create a collective awareness among surgical teams about whether safety processes are being completed. However, our analysis does show that the presence of study personnel in the operating room was not responsible for the change in the rate of complications.

This study has several limitations. The design, involving a comparison of preintervention data

Table 6. Selected Process Measures before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Objective Airway Evaluation Performed (N = 7688)		Pulse Oximeter Used (N = 7688)		Two Peripheral or One Central IV Catheter Present at Incision When EBL \leq 500 ml (N = 953)		Prophylactic Antibiotics Given Appropriately (N = 6802)		Oral Confirmation of Patient's Identity and Operative Site (N = 7688)		Sponge Count Completed (N = 7572)		All Six Safety Indicators Performed (N = 7688)	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
1	524	598	97.0	98.5	100.0	100.0	95.7	83.6	98.1	96.9	100.0	100.0	98.9	100.0	94.1	94.2
2	357	351	72.0	75.8	97.5	98.6	78.8	61.3	56.9	76.9	9.5	97.2	100.0	100.0	3.6	55.3
3	497	486	74.7	66.3	98.6	100.0	83.8	82.5	83.8	87.7	47.1	90.1	97.8	96.8	30.8	51.0
4	520	545	94.6	95.8	100.0	100.0	66.7	48.6	80.0	81.8	98.9	97.6	97.3	99.1	67.1	63.7
5	370	330	6.2	0.0	68.9	91.2	7.6	2.7	29.8	96.2	0.0	86.1	0.0	92.4	0.0	0.0
6	496	476	46.2	56.3	76.4	83.0	49.2	57.9	25.4	50.6	21.8	64.9	99.4	99.4	1.4	18.1
7	525	585	97.5	99.7	99.4	100.0	32.0	100.0	42.5	91.7	98.9	100.0	100.0	100.0	46.7	92.1
8	444	584	0.5	94.0	99.3	99.5	68.8	57.1	18.2	77.6	16.4	98.8	61.3	70.0	0.0	51.7
Total	3733	3955	64.0	77.2	93.6	96.8	58.1	63.2	56.1	82.6	54.4	92.3	84.6	94.6	34.2	56.7
P value			<0.001		<0.001		0.32		<0.001		<0.001		<0.001		<0.001	

* Prophylactic antibiotics were considered to be indicated for all cases in which an incision was made through an uncontaminated field and appropriately administered when given within 60 minutes before an incision was made. Sponge counts were considered to be indicated in all cases in which an incision was made. P values are shown for the comparison of the total values before and after checklist implementation, calculated by means of the chi-square test. EBL denotes estimated blood loss, and IV intravenous.

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with postintervention data and the consecutive recruitment of the two groups of patients from the same operating rooms at the same hospitals, was chosen because it was not possible to randomly assign the use of the checklist to specific operating rooms without significant cross-contamination. One danger of this design is confounding by secular trends. We therefore confined the duration of the study to less than 1 year, since a change in outcomes of the observed magnitude is unlikely to occur in such a short period as a result of secular trends alone. In addition, an evaluation of the American College of Surgeons' National Surgical Quality Improvement Program cohort in the United States during 2007 did not reveal a substantial change in the rate of death and complications (Ashley S. personal communication, <http://acsnsqip.org>). We also found no change in our study groups with regard to the rates of urgent cases, outpatient surgery, or use of general anesthetic, and we found that changes in the case mix had no effect on the significance of the outcomes. Other temporal effects, such as seasonal variation and the timing of surgical training periods, were mitigated, since the study sites are geographically mixed and have different cycles of surgical training. Therefore, it is unlikely that a temporal trend was responsible for the difference we observed between the two groups in this study.

Another limitation of the study is that data collection was restricted to inpatient complications. The effect of the intervention on outpatient complications is not known. This limitation is particularly relevant to patients undergoing outpatient procedures, for whom the collection of outcome data ceased on their discharge from the hospital on the day of the procedure, resulting in an underestimation of the rates of complica-

tions. In addition, data collectors were trained in the identification of complications and collection of complications data at the beginning of the study. There may have been a learning curve in the process of collecting the data. However, if this were the case, it is likely that increasing numbers of complications would be identified as the study progressed, which would bias the results in the direction of an underestimation of the effect.

One additional concern is how feasible the checklist intervention might be for other hospitals. Implementation proved neither costly nor lengthy. All sites were able to introduce the checklist over a period of 1 week to 1 month. Only two of the safety measures in the checklist entail the commitment of significant resources: use of pulse oximetry and use of prophylactic antibiotics. Both were available at all the sites, including the low-income sites, before the intervention, although their use was inconsistent.

Surgical complications are a considerable cause of death and disability around the world.³ They are devastating to patients, costly to health care systems, and often preventable, though their prevention typically requires a change in systems and individual behavior. In this study, a checklist-based program was associated with a significant decline in the rate of complications and death from surgery in a diverse group of institutions around the world. Applied on a global basis, this checklist program has the potential to prevent large numbers of deaths and disabling complications, although further study is needed to determine the precise mechanism and durability of the effect in specific settings.

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APPENDIX

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