*** Warning ***

FDA Drug Safety Communication: Changes to the Heparin Sodium USP Monograph

Safety Announcement

[04-07-2010] Laboratory studies performed at the request of the U.S. Food and Drug Administration (FDA) have shown that Heparin Sodium, USP (heparin) made under the new United States Pharmacopeia (USP) Monograph ("new heparin") has approximately 10% less blood-thinning (anticoagulant) activity compared to heparin prepared using the previous ("old") USP Monograph. The studies were performed in order to better understand the clinical impact of the change in potency for heparin.

The FDA first alerted the public to changes in the potency of heparin in a Public Health Alert in October 2009.

The results of these studies reinforce FDA's previous recommendation for healthcare professionals to exercise clinical judgment in determining the dose of heparin for a patient and consider the clinical circumstances where the potency decrease may require dosage adjustments and more frequent monitoring.

Healthcare professionals should be aware that heparin products, i.e., those made using both the old and the new USP standards may be available for some time. Healthcare professionals may wish to consider not using the products interchangeably. Pharmacies and hospitals may wish to consider separating the supplies of old and new heparin and exhausting the supplies of "old" heparin before transitioning to the "new" product (see Table below, "How to Identify Heparin Products made to the New USP Standard").

Additional Information for Healthcare Professionals

FDA recommends that healthcare professionals:

- Be aware that there is an approximate 10% decrease in the anticoagulant activity (potency) of the "new heparin" compared with the "old heparin."
- Continue to exercise clinical judgment in determining the dose of heparin.
- Continue to individualize heparin dosing to the specific patient/patient-specific clinical situation.
- Understand that the labeling for heparin, including the recommended doses for heparin has not changed.
- Consider those clinical circumstances where the potency decrease may require dosage adjustments and more frequent monitoring, such as where aggressive anticoagulation is essential to the treatment of the patient, including:

- pediatric patients undergoing extracorporeal membrane oxygenation
- adults and children undergoing cardiopulmonary bypass
- the treatment or prevention of life-threatening thromboses

- Report any adverse events associated with the use of heparin

Data Summary

Studies to assess differences in heparin activity were performed in animals (*in-vivo*) and in human plasma (*in-vitro*). The results of the human plasma and animal studies were consistent in demonstrating an approximate 10% decrease in heparin activity of the "new" heparin products compared to "old" heparin products. The average activated partial thromboplastin time (aPTT) response to a dose of heparin changed in a dose-proportional manner.

The same studies also demonstrated that there were large individual variations in aPTT responses to a given dose of heparin. Therefore, in a clinical setting, a 10% decrease in heparin dose might not be reflected in the results of an aPTT or ACT (Activated Clotting Time) for an individual patient.

Given the inherent individual variability in response to a dose of heparin, a 10% decrease in heparin activity (potency) is not likely to have clinical significance. However, special clinical situations such as cardiac surgery and/or use in pediatric patients may require more intensive monitoring to achieve optimal therapeutic response. Since heparin therapy is routinely titrated to each patient (there are many patient-specific factors that can influence heparin dosing) the usual method of individualizing dosing will continue to ensure patient safety.

Table to Distinguish Between "New" and "Old" Heparin

Since new heparin will be available, starting October 2009 there will likely be supplies of both the old and new heparin stocked for use in hospitals and pharmacies for a period of about three years. Facilities that have stocks of old and new heparin may wish to consider segregating stores of the old heparin from the new and using the "old" heparin products first. The table below provides information on how to distinguish between the old and new product and company website for additional information.

How to Identify Heparin Products made using the New USP Standard

Manufacturer	(Date) Availability of Lots Made to the New USP Standard	How to Identify the New Product	Additional Information/Company Contact
APP	October 2009	"N" will appear after the Expiration Date	http://www.appdrugs.com
B. Braun	October 2009	"N" will appear after the Lot Number	http://www.bbraunusa.com
Hospira	October 2009	Lot Numbers will begin with the number "82" or higher	http://www.hospira.com/Files/HeparinUSP.pdf
Baxter	October 2009	"N" will appear before the Lot Number	http://www.baxter.com/index.html

Attention

Based on feedback from the recent field review, the Joint Commission revised the Universal Protocol as well as elements of the 2010 National Patient Safety Goals with some changes effective immediately and other changes effective January 1, 2010. The intent of the Universal Protocol revisions is to address patient safety issues while allowing organizations flexibility in applying the requirement within existing work processes, given the diversity of organizations that need to follow the Universal Protocol.

The Institute for Clinical Systems Improvement Perioperative Protocol was completed prior to The Joint Commission's September 2009 revisions. As the Perioperative Protocol includes content specific to The Joint Commission requirements, it is recommended that organizations refer to The Joint Commission directly for the most current information specific to Joint Commission requirements. Joint Commission requirements are available at http://www.jointcommission.org.

The Joint Commission changes will be reviewed and considered by the Perioperative Protocol work group as part of the 2010 ICSI Perioperative Protocol revision.

ICSI

INSTITUTE FOR CLINICAL SYSTEMS IMPROVEMENT

Health Care Protocol:
Perioperative Protocol

Second Edition
September 2009

The information contained in this ICSI Health Care Protocol is intended primarily for health professionals and the following expert audiences:

- physicians, nurses, and other health care professional and provider organizations;
- health plans, health systems, health care organizations, hospitals and integrated health care delivery systems;
- health care teaching institutions;
- health care information technology departments;
- medical specialty and professional societies;
- researchers;
- federal, state and local government health care policy makers and specialists; and
- employee benefit managers.

This ICSI Health Care Protocol should not be construed as medical advice or medical opinion related to any specific facts or circumstances. If you are not one of the expert audiences listed above you are urged to consult a health care professional regarding your own situation and any specific medical questions you may have. In addition, you should seek assistance from a health care professional in interpreting this ICSI Health Care Protocol and applying it in your individual case.

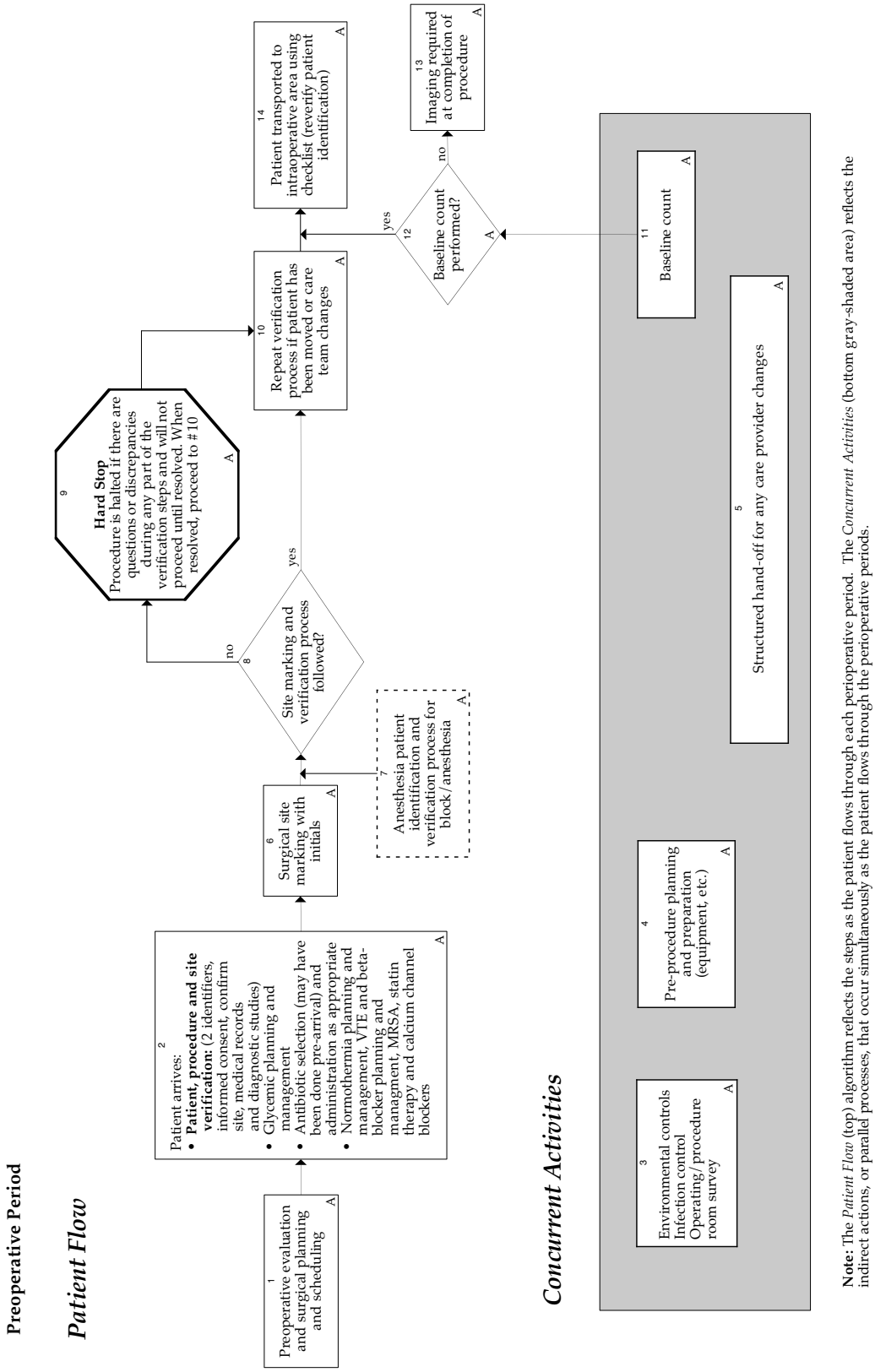
This ICSI Health Care Protocol is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients, and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. An ICSI Health Care Protocol rarely will establish the only approach to a problem.

Health Care Protocol:
Perioperative Protocol

Second Edition
September 2009

Preoperative Period Algorithm

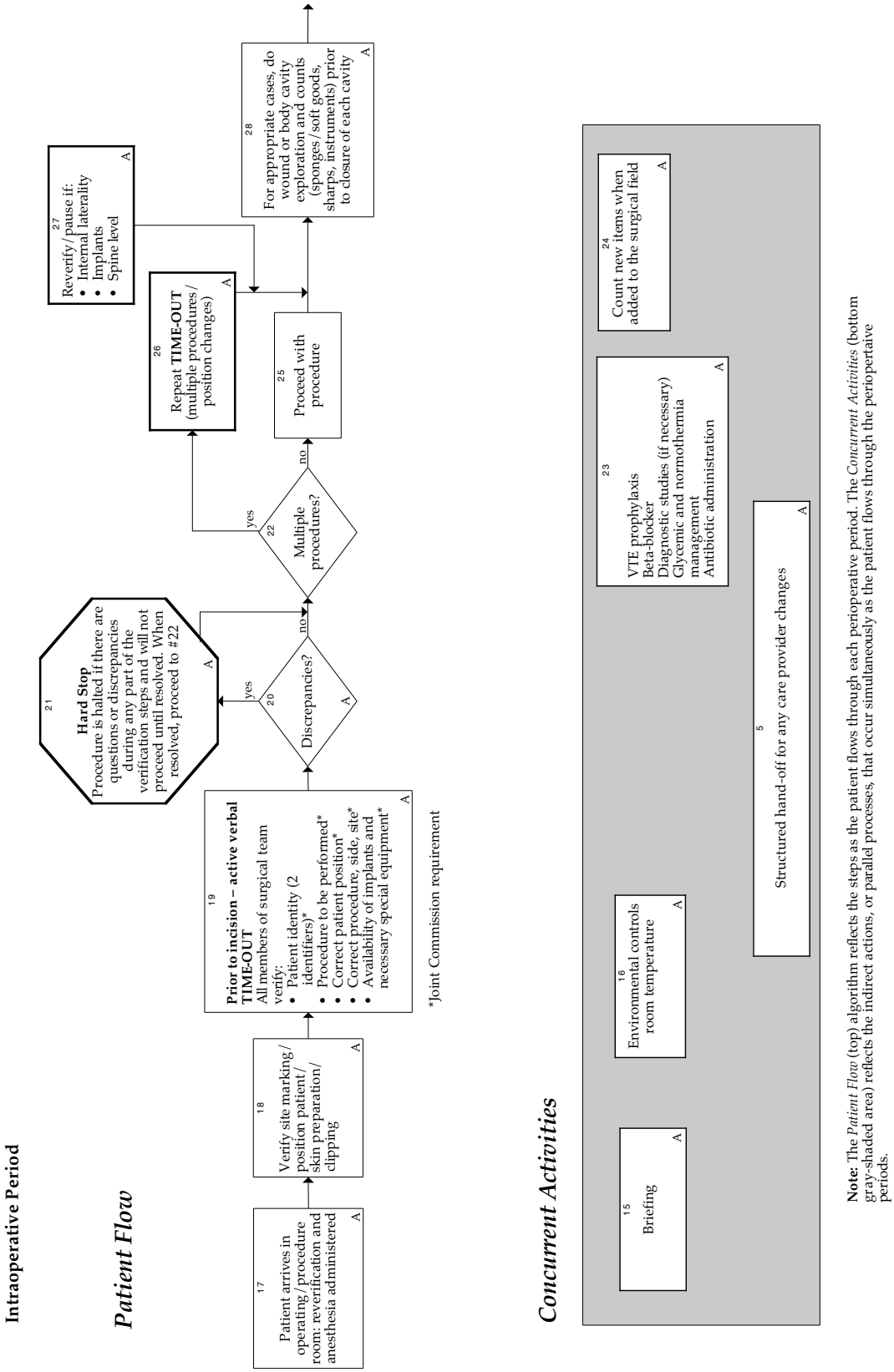
A = Annotation



Note: The *Patient Flow* (top) algorithm reflects the steps as the patient flows through each perioperative period. The *Concurrent Activities* (bottom gray-shaded area) reflects the indirect actions, or parallel processes, that occur simultaneously as the patient flows through the perioperative periods.

Intraoperative Period Algorithm

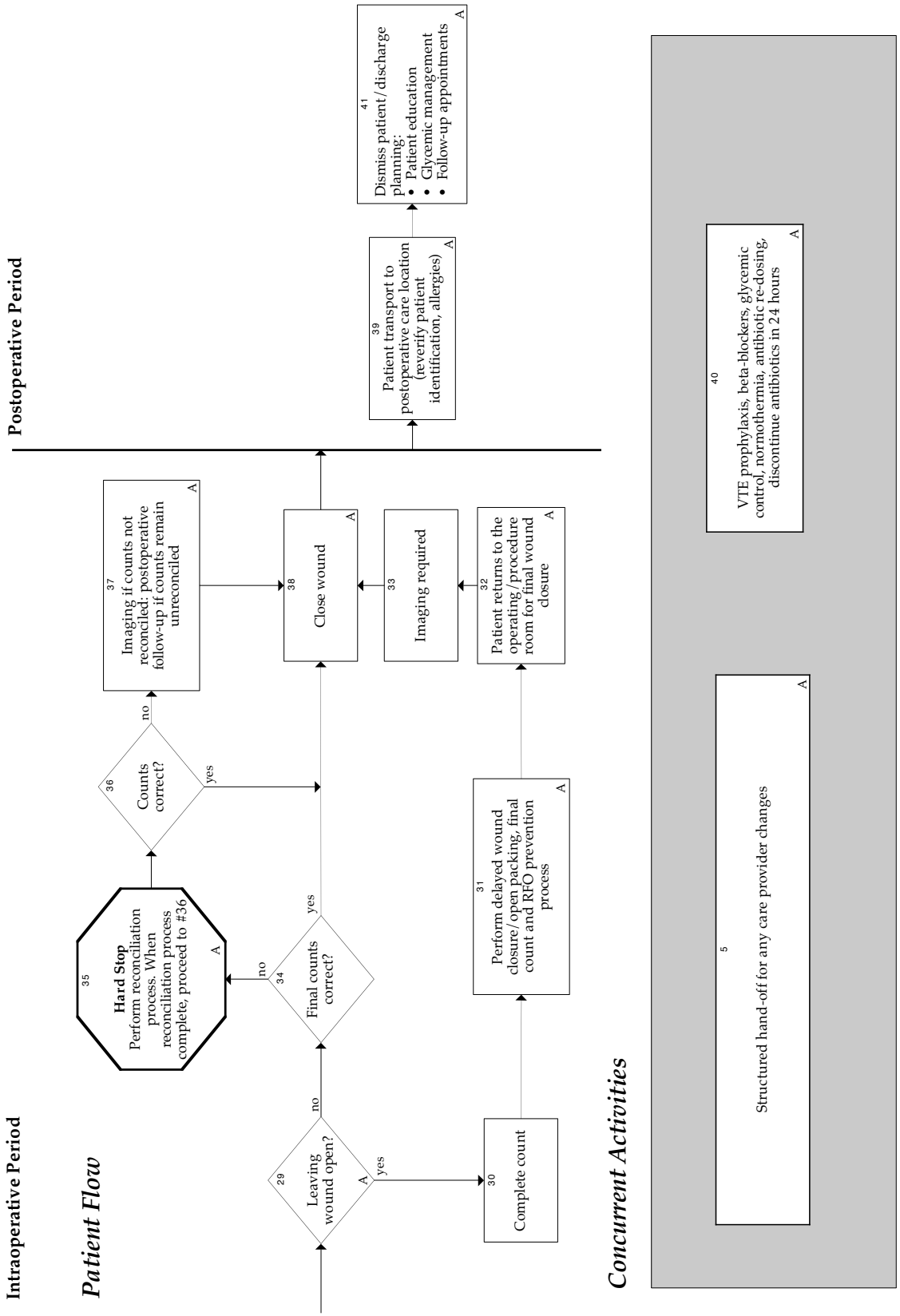
A = Annotation



Note: The *Patient Flow* (top) algorithm reflects the steps as the patient flows through each perioperative period. The *Concurrent Activities* (bottom gray-shaded area) reflects the indirect actions, or parallel processes, that occur simultaneously as the patient flows through the periopertaive periods.

Intraoperative and Postoperative Period Algorithms

A = Annotation



Note: The *Patient Flow* (top) algorithm reflects the steps as the patient flows through each perioperative period. The *Concurrent Activities* (bottom gray-shaded area) reflects the indirect actions, or parallel processes, that occur simultaneously as the patient flows through the periopertaive periods.

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Annotation Table by Topic

Numbers in table refer to specific annotations for ease in locating information by topic.
Also refer to alphabetized Index by Topic at the end of the document.

Focus Area	Preoperative	Intraoperative	Postoperative
Retained Foreign Objects	Baseline count[11, 12]	Counts throughout surgery[11]	
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		Imaging for unreconciled count[37]	
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	Environmental controls[3]	Normothermia management[23]	Glycemic control[40, 41]
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	Anesthesia site marking[7]	Repeat time out[26]	
	Anesthesia Time Out[7]	Reverification[17]	
	Hard stop[9]	Reverify/Pause[27]	
	Patient, procedure and site verification[2]	Time out[19]	
	Surgical scheduling[1]	Time out discrepancy[20]	
	Surgical site marking[6]	Verify site marking[18]	
Miscellaneous	Beta-blocker planning and management[2]	Beta-blocker management[23]	Beta-blocker management[40]
	Prep for colon surgery[1]	Briefing[15]	Follow-up appointments[41]
	Structured hand-off[5]	VTE prophylaxis[23]	Patient education[41]
	VTE prophylaxis[2]		VTE prophylaxis[40]

Foreword

The work group acknowledges that this is a lengthy and complex document. The algorithm and corresponding annotations provide recommended steps to be taken during the preoperative, intraoperative and postoperative periods of a surgical procedure. There are two process flow diagrams. The *Patient Flow* (top) algorithm demonstrates the steps as the patient flows through each perioperative period. The *Concurrent Activities* (bottom) algorithm demonstrates the indirect actions, or parallel processes, that occur simultaneously as the patient flows through the process. These steps are indicated in the gray-shaded area of the algorithm. It is important to note that many of the process steps and corresponding documentation are repeated throughout this document as they relate to each surgical process (e.g., site marking and verification process). Although the algorithm demonstrates the linear progression of the patient flow with corresponding parallel processes, this repetition allows for specific areas or aspects of the protocol to be implemented in a non-sequential manner.

Scope and Target Population

Patients of all ages having any type of surgical procedure performed in the operating/procedure room.

The protocol will describe the steps performed throughout the perioperative period (preoperative, intraoperative and postoperative) that are necessary to prevent wrong site, wrong patient or wrong procedure, as well as to prevent surgical site infection and prevent the unintentional retention of a foreign object.

Preventing wrong site, wrong patient or wrong procedure includes the processes involving patient consent and the verification and marking of the surgical site(s) including any procedure involving laterality, levels, multiple sites/digits or implants.

The prevention of surgical site infection covers adults or pediatric patients for abdominal; gynecologic; cardiac; orthopedic; ears, nose, throat; and neurologic surgical procedures, starting with the preoperative evaluation and surgical planning and proceeding through the perioperative period. The protocol includes antibiotic selection for prophylaxis, timing and discontinuation, surgical site preparation, glycemic control and normothermia.

The prevention of unintentionally retained foreign objects includes strict adherence to a counting process including obtaining radiographic imaging if the count process cannot be successfully reconciled.

Additionally, this protocol also includes management information specific to venous thromboembolism prophylaxis and beta-blocker therapy, recognizing the significance of these throughout the perioperative period.

Much of the evidence used to develop these recommendations is derived from populations of primarily adult patients. The work group has made the assumption that much of the benefit derived from these practices would be present in a similar population of pediatric patients.

Clinical Highlights and Recommendations

The following Clinical Highlights and Recommendations are summary statements only and are not intended to be the sole source of information for each point. It is important for you to read the annotation related to each item for a more detailed presentation of the material.

- Areas requiring focus throughout the perioperative period include venous thromboembolism prevention, beta-blocker therapy and methicillin-resistant staphylococcus aureus management. (*Annotations #2, 23, 40; Aim #3)*
- Preoperative verification process includes patient identification, procedure(s), site(s), laterality and level. This process is confirmed by source documents, consent form, medical record and discussion with the patient. Additional verification must occur at designated points in the perioperative period. *(Annotations #2, 7, 10, 14, 17, 18, 19, 26, 27, 39; Aim #1)*
- All procedure sites including level, position, laterality, multiple sites/digits in the same anatomic location, and bilateral procedures will be marked with the surgeons initials. The surgeon should follow the preoperative verification process prior to marking the sites. Surgeon initials must be visible at time of incision. Note: An anatomical diagram shall be used to identify surgical site(s) that are not visible through the surgical drape. *(Annotation #6; Aim #1)*
- Procedures involving level will have the preoperative imaging in the area where the procedure is being performed. High-quality intra-procedure imaging with opaque instruments marking specific bony landmarks will be taken and compared to the preoperative imaging to confirm the correct level/site prior to the procedure. *(Annotation #27; Aim #1)*
- A Time Out will be performed just prior to the start of the procedure (after the surgeon has gowned and scrubbed) with active verbal confirmation by all the professionals involved in the care of the patient. A repeat Time Out will be performed for multiple procedures or position changes. An intraoperative pause shall be performed for all procedures that involve level, implants and/or laterality after an orifice or midline entry. *(Annotations #19, 26, 27; Aim #1)*
- A pre-procedure briefing will be conducted. The purpose of the briefing is to present the plan for the procedure and confirm with the team members what will be needed during the procedure and when it will be needed. *(Annotation #15; Aims #1, 2, 3)*
- When a hand-off is required, a structured process should be followed. *(Annotation #5; Aims #1, 2, 3)*
- A Hard Stop will occur when either the verification process is incomplete and/or a discrepancy is identified. The procedure will not proceed until the discrepancy is resolved. *(Annotations #9, 21, 35; Aim # 1)*
- Efforts should be made to focus on the processes of care represented by the quality measures associated with the Surgical Care Improvement Project (SCIP). *(Annotations #1, 2, 18, 23, 40; Aim #3)*
- Baseline counts should be effectively and reliably performed for soft goods and sharps. *(Annotation #11; Aim #2)*
- Imaging is required if the final count is unable to be reconciled. *(Annotation #37; Aim #2)*

Priority Aims

Outcome Aims and Measures

1. Eliminate the wrong surgical procedure, or surgery performed on the wrong body part, or on the wrong patient.
2. Eliminate unintentionally retained foreign objects during a surgical procedure.
3. Decrease the rate of infections in surgical patients undergoing clean surgery.

Key Implementation Recommendations

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

System implementation:

- The facility is encouraged to customize the protocol with a key that identifies the individuals responsible for completing the algorithm tasks (e.g., green shapes for those individuals responsible for counts).
- Leadership support and a surgeon champion are absolutely essential for the successful implementation of this protocol.
- Develop a procedural checklist to document completion of each step and ensure that all elements of the protocol are completed.
- Direct observations, along with coaching and immediate feedback, are effective strategies in gaining staff adherence to the protocol following implementation. Additionally, the use of crucial conversation tactics can be effective for staff.
- As it relates to this protocol, create and implement a process that allows for the detection and management of disruptive and inappropriate behavior. This process should include education of all physicians and non-physicians regarding appropriate professional behavior and the development of policies and procedures. Refer to The Joint Commission's leadership standards.
- Red rules* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol)
  - *Red rules are the few, key rules created to prevent/address the specific actions that pose the highest level of consequence and risk to safety of patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure the safest environment and delivery of the care process.
  - Suggested red rules:
    - Never operate on a patient without verifying the correct patient identity, correct procedure and correct site.
    - Baseline counts are consistently performed before the patient arrives in the operating/procedure room unless parallel processing is used.
    - Unreconciled counts require imaging verification, and wound closure stops until count reconciliation is achieved.

Retained foreign object implementation:

- The work group recommends that a preformatted white board be used as the primary record of the count. Documenting counts on a white board allows all surgical staff, and in particular the scrub tech, to independently view the count record. A public display of the count record in an area where the entire surgical team can view it is likely to reinforce the importance of the count process.
- The work group also recommends that a count worksheet be used as a memory aid when the white board is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. A piece of scratch paper should not be used. In contrast, if the white board is located very close to the area when the count occurs, and if the circulating nurse can easily write the counts on the white board without leaving the count area, there will be no need to use the count worksheet.
- Distractions and interruptions should be kept to a minimum during the count process. If a count is interrupted, then the category of items (e.g., laps) being counted will need to be recounted.

Surgical infection implementation:

- Using preprinted or computerized order sets can help in reminding and remembering specific antibiotics, timing, dose and discontinuation.
- Review patient education material to verify the message around no self-shaving before surgery. Distribute standardized patient education messages to surrounding outpatient clincs, as well.
- Remove all razors from the perioperative area.
- Use warming blankets, hats and booties routinely for patients.
- Establish an effective surveillance process that includes postdischarge or outpatient surveillance. Use inpatient case-finding for postdischarge or outpatient. It is important to include the following:
  - Use standardized definitions for surveillance of infections. These definitions also need to take into account the setting in which the surgical procedure was performed (acute care, ambulatory surgical center, etc.).
  - Establish a risk stratification for estimating surgical infection that adjusts for risk factors associated with infection for different care settings and procedures.
  - Work with surrounding outpatient clinics to develop communication strategy for tracking surgical infections and reporting back to the hospital.

Safe site implementation:

- To facilitate implementation of the Hard Stop concept, have your Chief Executive Officer communicate to all staff and physicians their support for the institution of the Hard Stop.
- The Time Out is best followed when a particular person/role has responsibility to call the Time Out. The surgeon should then be the one to take the lead on running the Time Out and have the circulator begin the review of information.
- Establish pre-procedure and post-procedure communication standards in the form of structured hand-offs.
- Develop a verification process at the point of scheduling. The work group recommends that this process include:

- Corroboration between the surgical consent, the order to schedule a procedure and an independent source document dictation (such as a radiology report or pathology report).
- Review of documents by a clinical professional, with attention directed specifically to the organ to be operated upon and laterality as appropriate before proceeding to the scheduling process.
- The independently verified documentation provided on paper, fax or electronic format, not by telephone or verbal communication. The only exception to this is during emergency situations.

Related ICSI Scientific Documents

Guidelines

- Antithrombotic Therapy Supplement
- Preoperative Evaluation
- Venous Thromboembolism Prophylaxis

Order Sets

- Subcutaneous Insulin Management
- Surgical Site Infection Prevention for Adults
- Surgical Site Infection Prevention for Children

Protocols

- Prevention of Unintentionally Retained Foreign Objects During Vaginal Delivery
- Skin Safety Protocol: Risk and Assessment of Pressure Ulcer
- Treatment of Pressure Ulcer
- Safe Site Invasive Procedure Non-Operating Room

Disclosure of Potential Conflict of Interest

ICSI has adopted a policy of transparency, disclosing potential conflict and competing interests of all individuals who participate in the development, revision and approval of ICSI documents (protocols, order sets and protocols). This applies to all work groups (protocols, order sets and protocols) and committees (Committee on Evidence-Based Practice, Cardiovascular Steering Committee, Women's Health Steering Committee, Preventive & Health Maintenance Steering Committee and Respiratory Steering Committee).

Participants must disclose any potential conflict and competing interests they or their dependents (spouse, dependent children, or others claimed as dependents) may have with any organization with commercial, proprietary, or political interests relevant to the topics covered by ICSI documents. Such disclosures will be shared with all individuals who prepare, review and approve ICSI documents.

Carol Hamlin, RN, MS has a family member employed by Arizant; company product includes Bair Hugger.

Dana Langness, RN, BSN, MA will be speaking for Optima Health in which she will receive an honorarium.

Peter Argenta, MD has received a travel honorarium as a consultant for Ipsen, a French pharmaceutical company.

Greg Bielman, MD serves as an Advisory Board Committee Member for Hutchinson Technology, Inc. and has participated in the evaluation of The Inspectra product and has received associated reimbursement.

Greg Beilman, MD has received compensation from Lilly for participating as a speaker, an Advisory Board Committee Member, and has been a participant in studies.

Marc Swiontkowski, MD was a priniciple investigator for a randomized control trial on hip fracture management associated with NIAMS/NIH. No associated compensation was disclosed.

No other work group members have potential conflicts of interest to disclose.

Introduction to ICSI Document Development

This document was developed and/or revised by a multidisciplinary work group utilizing a defined process for literature search and review, document development and revision, as well as obtaining input from and responding to ICSI members.

For a description of ICSI's development and revision process, please see the Development and Revision Process for Protocols, Order Sets and Protocols at http://www.icsi.org.

Evidence Grading System

A. Primary Reports of New Data Collection:

Class A:	Randomized, controlled trial
Class B:	Cohort study
Class C:	Non-randomized trial with concurrent or historical controls Case-control study Study of sensitivity and specificity of a diagnostic test Population-based descriptive study
Class D:	Cross-sectional study Case series Case report

B. Reports that Synthesize or Reflect Upon Collections of Primary Reports:

Class M:	Meta-analysis Systematic review Decision analysis Cost-effectiveness analysis
Class R:	Consensus statement Consensus report Narrative review
Class X:	Medical opinion

Citations are listed in the protocol utilizing the format of *(Author, YYYY [report class])*. A full explanation of ICSI's Evidence Grading System can be found at http://www.icsi.org.

Introduction

An ongoing challenge faced by the work group is the limited number of peer-reviewed research studies to guide the development of the overall protocol recommendations.

Commercial aviation safety experts faced the same lack of evidence when they developed their, now generally accepted, standard operating procedures aimed at eliminating airplane accidents. Aviation has shown that broadly and systematically employing processes that include standardized procedures to minimize variation, implementing communication techniques such as crew resource management, and minimizing distractions during critical steps lead to improved safety and reliability *(Helmreich, 2000 [R])*.

Anesthesiology has led the health care industry in safety. One of the key safety strategies deployed by this group was the adoption of standardized processes for how anesthesiologists monitor and respond to intra-operative changes in the patient's condition. Incorporating these standards – developed by using human factors principles and communication strategies – into their workflow has helped anesthesia become the only health care discipline that has approached the Six Sigma level of performance *(Gaba, 2000 [R])*. See Appendix A, "Incorporating Human Factors Systems Design into Work Process Design," for an expanded discussion on human factors systems design principles.

The work group incorporated these principles, successfully employed by aviation and anesthesiology, into the development of this protocol. To aid in its future development it will be important to gather outcomes and costs associated with the implementation of the protocol.

Retained foreign objects

For as long as the medical community has been performing surgery or invasive procedures, there has been the risk and misfortune of unintentionally leaving items behind. Many measures have been instituted to mitigate the likelihood of an unintentionally retained item, but unfortunately they continue to occur. Exactly how often it happens is unknown; however, it has been estimated that on a national basis, approximately 1,500 patients per year will have a foreign body unintentionally retained following surgery *(Gawande, 2003 [C])*.

Professional organizations such as the American College of Surgeons *(American College of Surgeons, 2005 [R])*, Surgical Clinics of North America *(Gibbs, 2005 [R])*, the Association of PeriOperative Registered Nurses *(AORN, 2006 [R])*, Department of Veterans Affairs Veterans Health Administration *(Eldridge, 2006 [NA]); VHA Directive, 2006 [NA])*, the Council on Surgical and Perioperative Safety *(Council on Surgical and Perioperative Safety, 2005 [R])*, American College of Obstetricians and Gynecologists *(ACOG, 2006 [R])* and The Joint Commission *(Joint Commission International Center for Patient Safety, 2006 [R])* have all developed guidelines for the prevention of retained items. In an article published in February 2006, the Association of PeriOperative Registered Nurses *(AORN, 2006 [R])* established a set of six practices that if implemented, are expected to significantly reduce the risk of an unintentionally retained item.

The Joint Commission categorizes the unintended retention of a foreign body after surgery or other procedure as a sentinel event. Health care organizations are required to conduct a root cause analysis and to develop a corrective action plan designed to reduce the probability of a repeat occurrence.

As part of the Minnesota Adverse Health Event law, these events are reported directly to the state and are publicly disclosed. In the Minnesota Department of Health's Fifth Annual Public Report, covering periods October 7, 2007-October 6, 2008, 312 total adverse events were reported with 37 reported, as unintentionally retained objects *(Adverse Health Event in Minnesota. Fifth Annual Public Report, 2008 [NA])*.

Surgical infection

Surgical site infections are linked to a major cause of patient injury and death, and they consume substantial health care resources. A large percentage of the number of surgical site infections (40%-60%) is thought to be preventable and as such, characterized as a "never event" medical error. Surgical site infection rates have been cited in the literature as occurring in 2%-5% percent of patients after clean extra-abdominal surgeries and up to 20% of patients undergoing intra-abdominal procedures. It is difficult to identify nosocominal infections in patients who have been discharged. Some studies following patients in the post-discharge period have reported even higher rates.

The majority of surgical site infections have been linked to the failure to administer prophylactic antibiotics or the inappropriate timing of antibiotic prophylaxis. Baseline data from the National Surgical Infection Prevention Project indicate a surgical site infection rate of 2% of approximately 30 million surgeries per year.

While that rate may not seem large, patients who develop a surgical site infection are two to three times more likely to die compared to patients who do not develop a surgical infection. Data from the National Surgical Infection Prevention Project show that only 55.7% of patients received appropriate timing of antibiotic prophylaxis during the 60 minutes prior to incision of the selected procedures *(Bratzler, 2005b [R])*.

By focusing on adherence to recognized techniques and protocols, the National Surgical Infection Prevention Collaborative was able to reduce surgical site infections by 27% by focusing on timing of antibiotic prophylaxis, use of appropriate antibiotics, and the discontinuation of antibiotics within 24 hours in patients undergoing a variety of major procedures.

Safe site

This protocol is consistent with and based heavily on The Joint Commission's Board of Commissioners' approved Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery. The Universal Protocol was created to address the continuing occurrence of these medical errors. The Universal Protocol became effective July 1, 2004 for all accredited hospitals, ambulatory care and office-based surgery facilities and drew upon, expanded and integrated a series of requirements under The Joint Commission's National Patient Safety Goals. It is applicable to all operative and other invasive procedures.

The Universal Protocol is endorsed by nearly 50 professional health care associations and organizations including the American Medical Association, American Hospital Association, American College of Physicians, American College of Surgeons, American Dental Association, and the American Academy of Orthopedic Surgeons.

The work of implementing this protocol requires coordination between the physician/clinician, the patient/legal guardian, operating/procedure room staff, preoperative holding room staff, the patient's bedside nurse, procedural and clinic teams, radiology personnel, and anesthesia practitioners. All individuals involved in the process must take an active role in complying with this protocol, including patients as they are able.

Why is the focus for improvement important? Why is a zero error rate for wrong site events the goal? If we compare ourselves to the equally high-risk airline industry, which employs processes no different from procedural and surgical verification in its step-by-step approach, and if they set their goal at a 99.9% error-free rate, nationally there would be two major airline crashes per week. A 99.9% error-free rate for the health care industry equates to 500 wrong surgical site surgeries nationally every week. In Minnesota, there are still patients affected by a wrong surgical or procedure event that directly applies to areas in this protocol. As part of the Minnesota Adverse Health Event law, these errors are also reported directly to the state and are publicly disclosed.

Each year as the protocol is reviewed, updated and redistributed to hospitals, many organizations make a concerted effort to review and educate all staff and physicians on the new changes to the existing protocol.

Definitions and Specifications

Body cavity: an anatomic cavity, orifice or a small cavity created as a result of the procedure being performed. This does not include the initial surgical incision.

Colonization versus infection: with colonization, a microorganism can inhabit a specific site on or in the body (e.g., the nares of the nasal passages) but not cause signs or symptoms of infection; however, the pathogen does have the capacity to cause an infection. Any colony can cause subsequent infection in the same patient or another person when it is transferred between sites or persons.

Colonization differs from infection in that an infection is caused by a pathogen that causes signs and/or symptoms of infection in a patient. Signs and symptoms may include redness, fever, pus, etc. *(Mangram, 1999b [R])*. In most cases, an infection is invasive, whereas with colonization, colonies of organisms may live on surface structures and not be actively fought by the body defense system.

Count stages:

Baseline count: conducted prior to the patient's arrival in the operating/procedure room (unless parallel processing is used) to establish the initial record of countable items that might be used during the procedure.

Closing a cavity within a cavity count: conducted before surgeon closes a cavity within a cavity. This count is performed to ensure that the count is reconciled prior to moving to the next level of wound closure.

Closing count: performed before wound closure begins.

Final count: performed at skin closure.

Count during hand-off that occurs with temporary relief of staff: a count that occurs during the hand-off each time there is temporary relief of staff.

Count during hand-off that occurs with permanent relief of staff (e.g., at shift change): a count that occurs during the hand-off each time there is permanent relief of staff.

Countable items: any item that could be unintentionally left behind during a surgical procedure *(AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]; Joint Commission International Center for Patient Safety, 2006 [R]; VHA Directive, 2006 [NA])*. This includes:

- **Instruments:** tools or devices designed to perform a specific function, such as cutting, dissecting, grasping, holding, retracting or suturing.
- **Miscellaneous items:** includes vessel clips, vessel loops, suture reels, peripheral intravenous catheters and introducers, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes and other small items.
- **Sharps:** items with edges or points capable of cutting or puncturing through other items. In the context of surgery, sharps include, but are not limited to, suture needles, scalpel blades, hypodermic needles, electrosurgical needles and blades and safety pins.
- **Sponges:** includes any soft goods such as gauze pads, cottonoids, peanuts, dissectors, tonsil sponges, laparotomy sponges, and towels used to absorb fluids, protect tissues or apply pressure or traction.
- **Tucked sponge:** refers to any soft good used to stop bleeding or absorb liquid, or used in conjunction with an instrument or the surgeon's hand to obtain traction, and that is left in location for the duration of the procedure.

Count documentation: a standardized format to document the number of sponges/soft goods, sharps and instruments.

This may be in paper and/or electronic format. Organizations may or may not choose to store specific count information for future retrieval.

- **White board:** A preformatted dry erase board or computer screen, directly viewable by the entire surgical team, should be used to document sponges/soft goods, sharps, miscellaneous item counts, and when possible, instrument counts. The ability of the entire team to view the count information and assist in the correct identification of tucked and unaccounted for items enhances safety and reduces the risk of errors *(France, 2005 [D])*.
  - The white board should have preformatted names of categories of countable items with standard columns and rows to record counts. In addition to the count, the white board should include the patient's name and other pertinent or patient unique information.
  - It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.
- **Paper:** a paper count sheet may be used in organizations where the use of a white board is not possible due to space limitations.
  - A standardized, formatted paper count sheet may be used instead of the white board or as a supplement for procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures). Refer to Resource Table Tool Kit for sample count sheet.
  - The paper form should be a standardized, preformatted form and when possible, specific to the procedure specialty/service.

Hard stop is performed when either the safe site surgical verification process has not been followed completely and a discrepancy is identified or when a count discrepency is identified. The procedure is halted and will not proceed until the appropriate verification/reconciliation steps have been performed and/or the discrepancy is resolved.

High-risk procedure is any procedure that is known to expose a patient to the risk of permanent loss of function or injury *(Joint Commission, 2004 [NA])*. Generally, this includes procedures requiring consent by the patient.

Hospital-acquired surgical infection: defined as an infection of the surgical site within 30 days after the operation. For procedures involving an implant, a hospital-acquired infection is defined as an infection occurring within six months for bone grafts and one year for other implants *(Mangram, 1999b [R])*.

- Excluded infections that are not reported as hospital-acquired surgical infections are stitch abscess infections; they are outside the scope of this protocol.
- Infection of an episiotomy or newborn circumcision site or infected burn wounds are reported using other specific criteria and are outside the scope of this protocol.

Criteria for defining surgical infection: in addition to the definition above, surgical site infections are classified as either incisional or organ/space infections. Incisional infections are subdivided for those involving only the skin and subcutaneous tissue and for those involving deeper soft tissue. Surveillance can include reviewing patients receiving antibiotic therapy for any reason within the defined period of time after a surgical procedure.

Superficial incisional infections: infection involving only the skin or subcutaneous tissue of the incision and one or more of the following:

- Purulent drainage from the superficial incision with or without laboratory confirmation
- Organisms confirmed by culture from either an aseptically obtained fluid or tissue from the superficial incision
- One or more signs of infection (pain/tenderness, localized swelling, redness or heat) AND the superficial incision is deliberately opened by the surgeon unless the incision is culture-negative
- A surgeon or attending physician diagnoses a superficial incision surgical site infection

Deep incisional infections: infection involving deep soft tissue of the incision such as facial and muscle layers and one or more of the following:

- Purulent drainage from the deep incision but not from the organ or space component of the surgical site
- The deep incision spontaneously separates or is deliberately opened by a surgeon when the patient has one or more of the signs of infection (fever over 38ºC, localized pain or tenderness) unless the site is culture-negative
- A surgeon or attending physician diagnoses a deep incision surgical site infection

Organ/space infections: infection involving any part of the body, for example, organs or spaces, other than the incision, that was opened or manipulated during the procedure and one or more of the following:

- Purulent drainage from a drain that is placed through a stab wound into the organ/space
- Organisms confirmed by culture from either an aseptically obtained fluid or tissue from the organ/space
- Presence of an abscess or other evidence of infection involving the organ/space that is found on direct examination, during re-operation, or by histopathologic or radiologic examination
- A surgeon or attending physician diagnoses an organ/space surgical site infection

Hypothermia: defined as body temperature below 36ºC (96ºF) *(Mangram, 1999b [R])*.

Intraoperative image: a radiographic image obtained within the operating/procedure room, usually with portable radiographic equipment.

Intra-procedure pause: a pause during the procedure(s) when the clinician will indicate verbally:

- Level(s)
- Internal laterality after a midline or orifice entry
- Implant information

An intra-procedure pause should not to be confused with the Time Out.

Invasive procedure: any procedure that exposes the patient to more than minimal risk. This includes, but is not limited to, any entry, puncture or insertion of an instrument or foreign material into tissues, cavities or organs. This applies to any procedure performed in settings such as special procedure units, rooms or clinics, or at the patient's bedside. These procedures may involve moderate or deep sedation. Generally, this includes

procedures requiring consent by the patient. This excludes venipuncture, intravenous therapy, nasogastric tube insertion, Foley catheters, flexible sigmoidoscopy, and vaginal exams (Pap smears) *(Joint Commission, 2004 [NA])*. See Appendix B, "List of Invasive, High-Risk or Surgical Procedures," for examples.

Laterality: refers to any anatomical structure that occurs on both sides of the body, both internally and externally (i.e., right, left or bilateral). Reference to laterality is always with respect to the patient (i.e., the patient's right or left, not the clinician's) *(Joint Commission, 2004 [NA])*.

Level: refers to any anatomical structures that include multiples occurring linearly (e.g., spinal vertebrae, ribs).

Major surgical procedure: a procedure performed in an operating/procedure room and involving general or regional anesthesia, monitored anesthesia care or conscious sedation.

Micro needle: a surgical needle that, for adults, is less than 13 mm in size. When using portable radiographic equipment, needles smaller than 13 mm in length are very difficult to detect in the adult torso *(Macilquham, 2003 [D])*; however, they may be visible in adult extremities or in children. Each organization will need to establish a policy for the use of intraoperative imaging when attempting to locate an unaccounted for micro needle. Unintentionally retained micro needles are not reportable as retained foreign objects.

Normothermia: defined as the core temperature 36º-38ºC (96.8º-100.4ºF) *(Mangram, 1999b [R])*.

Notification: if an unintentionally retained foreign object is found during a patient examination in a clinic or emergency department, or during a subsequent hospitalization, the facility that performed the original procedure should be notified.

Parallel process: two separate activities performed simultaneously in the same area with two entirely separate groups of staff. Parallel processing is not multitasking. When parallel processing is used in relation to this protocol, two circulators will be needed: one dedicated to patient care and one dedicated to the baseline count process, for example.

Perioperative period: the perioperative period is considered to be from the night before the surgical procedure until 48 hours postoperatively.

Physician/clinician designee/dentist: a member of the team performing the procedure who is a credentialed and privileged provider as defined by the institution's medical staff by-laws or who is a physician in residency training.

Position: refers to the placement or angle of the patient for the procedure (e.g., supine, prone). Reference to position is important when determining laterality *(Joint Commission, 2004 [NA])*.

Possibles: refers to possible sites and/or procedures listed on the patient consent; the decision whether to perform the additional procedure is based on the findings of the initial procedure. These should follow the same process for site marking and verification listed for multiple sites.

Radiology room image: a radiographic image obtained in a radiographic room with a fixed tube and moving grid.

Safety stop: refers to taking a break from the procedure any time a team member perceives a threat to patient safety. Examples include a perceived threat to patient safety stemming from how the Time Out or a count was conducted.

Selected surgical patient: any adult or pediatric patient having had a surgical procedure, with an incision, performed in an operating/procedure room. Specific procedures include cardiac; orthopedic; abdominal; gynecologic; ear, nose, throat; and neurological surgeries, but the term applies to any surgical patient.

Site: the specific anatomic location of the procedure site (incision, insertion, or injection) as indicated by a description of the body part(s), levels (e.g., spine level or ribs) and digits (for hands, use thumb, index, long, ring, small; for toes, use great toe, 2nd, 3rd, etc.) to be subjected to intervention. Midline not associated with laterality or level need not be marked; however, if the internal target site involves laterality, site marking is required to indicate the intended side and/or level. This mark is at or near the incision/instrumentation site to indicate correct side or level of proposed procedure. For spinal procedures, the incisional site, anterior or posterior, and general level (cervical, thoracic or lumbar) are marked *(Joint Commission, 2004 [NA])*.

Source document: refers to an original radiology or pathology report that identifies laterality and/or specifies anticipated procedural location.

Structured hand-off: standardized method of communication to improve exchange of information during patient care transition.

Surgeon: a physician who treats disease, injury or deformity by operative methods. For the purposes of this document, surgeon refers to the individual(s) who are primarily responsible for the actual procedure; this may include individuals currently in a fellowship or residency program. Those individuals authorized to complete surgeon responsibilities should be determined by individual organizational policy.

Surgical retained foreign object: an object that is unintentionally retained after final closure of the wound, excluding micro needles.

Surgical procedure: a procedure performed in an operating/procedure room that involves an incision and general, regional, local or monitored anesthesia, or conscious sedation.

Surgical wound classification: the following are the four definitions for types of surgical wounds.

Class I/clean – an uninfected surgical wound in which no inflammation is observed and the respiratory, alimentary, genital or uninfected urinary tract is not entered.

Class II/clean-contaminated – a surgical wound in which the respiratory, alimentary, genital or urinary tracts are entered as part of the planned surgical procedure and without unusual contamination.

Class III/contaminated – open, fresh accidental wounds or procedures with major breaks in sterile technique or gross gastrointestinal spillage. Also includes surgical wounds when acute, non-purulent inflammation is observed.

Class IV/dirty-infected – old wounds from trauma with retained devitalized tissue or surgical wounds with existing infection or perforated viscera.

Time Out: the full verification that is performed just prior to the start of the procedure, when the entire care team will actively and verbally confirm *(Joint Commission, 2004 [NA])*:

- Patient's identity (two identifiers)
- Procedure to be performed
- Correct patient position
- Correct procedure side/site and/or level including visualization of surgeon's initials if applicable; and
- As appropriate, imaging, equipment, implants or special requirements (e.g., pre-procedure antibiotic administration

Vendor: A non-hospital individual who provides support to the surgeon and surgical services personnel.

Verification: refers to checking for consistency between the:

- informed consent documentation,
- physician's order,
- diagnostic studies, and
- response of the patient/legal guardian.

Special Circumstances

Anatomical variation: when a patient is known to have anatomical variation involving the procedure site, this information should be shared with the care team and additional steps taken to confirm the correct procedure site. This may include additional imaging or a second physician confirming the procedure site.

Communication of unresolved counts in operating/procedure room: in the event that a countable item is lost and cannot be accounted for, surgical teams that may be performing subsequent procedures in the same room prior to its terminal cleaning should be alerted. The circulator should record the date, time, type and number of the missing item on the room's white board, if present, or other salient documentation devices so that the next surgical team is aware of the unresolved discrepancy. Word of mouth is an insufficient means for communicating this information.

Equipment: it is important that operating/procedure room staff be familiar with all equipment used during a specific procedure. To reduce the risk of any retained items, specific attention should be directed towards equipment that has removable parts and/or parts that have the potential to break off during a procedure.

Outside events: events within a department, between departments or outside of an organization where the procedure is taking place that can contribute to the occurrence of an error. Strict labeling of specimens with a verification process is encouraged to reduce the potential of an error in a report, medical record documentation or diagnostic study that could lead to a wrong site, wrong patient or wrong procedure.

Patient management considerations

- **Heart valve condition** – in addition to the recommendations established in this protocol, patients with a heart valve condition should be managed according to guidelines regarding the selection of antibiotic, use of oral antibiotics before the day of surgery and length of course of antibiotic prophylaxis.
- **Existing infection** – recommendations for patients with an existing infection either elsewhere on the body or at the surgical site are outside the scope of protocol.
- **Management of comorbidities** – management of patient comorbidities beyond what is outlined for glycemic control for the prevention of surgical site infection, venous thromboembolism prophylaxis beta-blocker therapy and statin therapy are outside the scope of this protocol.

Pediatric populations

Much of the evidence used to derive these recommendations is derived from populations of primarily adult patients. The work group has made the assumption that much of the benefit derived from these practices would be present in a similar population of pediatric patients.

Surgical considerations and implants

- Donor and tissue testing for transmittable diseases or infection – the testing and/or confirming that donor tissue and other implants are free of infectious agents is outside the scope of this protocol.
- Dropped organs or other items – recommendations for reducing the possibility of infection due to dropped organs or other implants is outside the scope of this protocol.

Algorithm Annotations

Preoperative Period Algorithm Annotations

1. Preoperative Evaluation and Surgical Planning and Scheduling

The verification process will be carried throughout the organization's entire pre-procedure processes from scheduling through the verification of the patient/procedure/side/site at the time of presentation of the patient for surgery. Documentation of the verification process will be performed in the appropriate medical record.

Scheduling

A verification process must exist at the point of scheduling. To eliminate mistakes, such as left/right translation errors, made in the documentation of a surgical visit for evaluation and planning of a procedure, the work group recommends that the surgical scheduling process require corroboration between the surgical consent, the order to schedule a procedure and an independent source document dictation (such as a radiology report or pathology report). Attention by a clinical professional must be directed specifically to the organ to be operated upon and laterality as appropriate before proceeding to the scheduling process. Independently verified documentation should be provided on paper, facsimile or electronic format, not by telephone or verbal communication. The only exception to this is during emergency situations. Ideally, the patient should also be provided the same information in hard copy form.

Verification of consistency between the planned procedure, the consent and the "source document" should occur when the patient arrives at the surgical facility, along with the rest of the preoperative verification process (refer to Annotation #2, "Patient Arrives [Patient, Procedure and Site Verification]"). A hard stop will occur during the verification process if a discrepancy is noted. The patient will not proceed through the perioperative process until the discrepancy has been resolved. The clinical professional will contact the attending surgeon for resolution of any discrepancies between the scheduled procedure, consent, radiographic/pathology report (other "source document") or the final imaging review. The discrepancy must be reconciled at any point when such discrepancies are discovered.

Preoperative Waiting Area

Verification of the correct person, surgical procedure, side and site will occur in the preoperative waiting area. The clinical professional verbally and visually verifies the patient's name and date of birth, surgical procedure/site/side, and the attending surgeon with the patient, family member, legal representative or hospital care provider/interpreter. In addition, they will verify that the patient information is consistent with identification wristband, scheduled procedure, consent, radiographic/pathology report (other "source document") or the final imaging review. The clinical professional will contact the attending surgeon for resolution of any discrepancies. There will be a hard stop. The patient will not proceed through the perioperative process until the verification process is complete and any discrepancies have been resolved.

Operating/Procedure Room

The verification process will occur upon patient entry into the operating/procedure room. The registered nurse verbally re-verifies the patient's name and date of birth, surgical procedure/site/side, and the primary surgeon with the patient, family member, legal representative or hospital care provider/interpreter. The registered nurse will verify that the patient's information is consistent with identification wristband, scheduled procedure, consent, radiographic/pathology report (other "source document") or the final imaging review. If there are any clarifications necessary, the appropriate care provider will be contacted. When all the members of the surgical/procedural team are not in agreement, the discrepancy needs to be resolved before proceeding with incision/procedural start.

In addition to the initial review of imaging at the surgical planning visit, the relevant imaging should also be reviewed by the attending surgeon immediately prior to the procedure, and viewed specifically in conjunction with the radiologist's/pathologist's report for congruency. If for some reason the independently documented imaging/pathology report is not available at the time of surgery, the surgeon must indicate which report in the medical record is relevant in order for it to be retrieved prior to the preparation of the patient for surgery.

Preoperative Evaluation

Prevention of surgical site infection begins with the preoperative evaluation.

Preoperative evaluation includes:

- Medical history, including past surgical infections
- Physical examination
- Preoperative diagnostic testing based on patient and surgical risk indications
- Patient education
  - Procedure-specific
  - General orientation
  - Preoperative surgical site infection prevention

Refer to the ICSI Preoperative Evaluation guideline for more information.

Medical history and physical examination

In addition to obtaining a thorough medical history and performing a routine physical examination, a nutritional assessment of the patient is important in the evaluation of the risk for a surgical site infection.

Risk Factors for Development of Surgical Site Infection *(Mangram, 1999a [R])*

Patient Factors	Local Factors	Microbial Factors
• Age • Unintentional weight loss of 30 pounds or more in the last three months • Immunosuppression • Obesity • Diabetes mellitus • Chronic inflammatory process • Malnutrition • Peripheral vascular disease • Anemia • Radiation • Chronic skin disease • Carrier state (e.g., chronic staphylococcus carriage) • Recent operation • Smoking status (especially for head and neck surgeries) (*Kuri, 2005[B]*)	• Poor skin preparation • Contamination of instruments • Inadequate antibiotic prophylaxis • Prolonged procedure • Local tissue necrosis • Hypoxia, hypothermia	• Prolonged hospitalization (leading to nosocomial organisms) • Toxin secretion • Resistance to clearance (e.g., capsule formation)

Many of the same factors that increase a patient's risk of surgical site infection also put the patient at increased risk for development of a pressure ulcer. As part of the physical examination, a risk assessment for the patient's risk of pressure ulcer and prevention planning are also important.

See the ICSI Skin Safety Protocol: Risk and Assessment of Pressure Ulcer for more information.

Penicillin allergy management

Given that many of the recommendations for surgical prophylaxis are cephalosporins, there is often a concern about giving cephalosporins to patients with known penicillin allergy. When penicillin allergy is identified, often these patients receive agents that should be preserved for treatment of resistant organisms, which contributes to antibiotic resistance.

Current evidence-based practice guidelines for pediatrics endorse the use of certain cephalosporins in patients with reported allergies to penicillins, provided that the reactions are not severe or life threatening. This practice provoked a meta-analysis of data assessing the safe use of cephalosporins in penicillin allergic patients *(Pichichero, 2007 [M])*.

Previously, the cited rate of cross-reactivity was approximately 10%. This data has now been found to be an over-estimate for a number of reasons. The data was collected in the 1960s and 1970s and was based on results from in-vitro testing not supported by clinical skin testing in penicillin allergic patients. At that time, researchers were not taking into account the three-fold increased risk of adverse reaction to any unrelated drugs in patients with a penicillin allergy. The term allergy was also loosely defined and included unspecified rash. In addition, before 1980, first generation cephalosporins were produced by a mold later found to contain trace amounts of penicillin *(Pichichero, 2007 [M])*.

IgE mediated reactions (type I hypersensitivity reactions), such as angioedema, laryngeal edema, urticaria, and anaphylaxis, are the only true allergic reactions, and are the only reactions that should be considered when making choices regarding cephalosporin alternatives.

Idopathic drug reactions such as maculopapular or morbilliform rashes can occur in 1%-4% of patients receiving penicillins and cephalosporins *(Pichichero, 2005 [R]; Pichichero, 2006 [M]; Romano, 2004 [D])*. This incidence is reported at a higher rate in children (3%-7%) *(Pichichero, 2005 [R])*. These rashes are most likely not IgE medicated, although they may be if they occur late in the antibiotic coarse and are pruritic *(Pichichero, 2005 [R]; Pichichero, 2006 [M])*.

Some viral infections can alter the immune response to antibiotics. A prime example of this is the rash that develops when amoxicillin is given in patients with acute Epstein-Barr virus infection. These rashes are typically maculopapular and pruritic, but are unlikely to reoccur with later penicillin class challenge *(Pichichero, 2005 [R]; Pichichero, 2006 [M])*.

While penicillins and cephalosporins do share similarities in their chemical structures, they contain important differences in ring structures, substitution sites, and degradation patterns. Based on these differences, there should be minimal immunologic cross-reactivity between these compounds *(Pichichero, 2007 [M])*.

The incidence of cross-reactivity with cephalosporins in penicillin allergic patients does vary, and depends on similarity in side-chain structure. First-generation cephalosporins do have a potential for cross-reactivity, but at a risk closer to 0.5% (versus the previously quoted 10%). It is now commonly accepted that most second or third generation cephalosporins are actually unlikely to be associated with any cross-reactivity based on differences in their chemical structures *(Pichichero, 2007 [M])*.

Current data suggests that patients with a true, documented IgE mediated allergic reaction to penicillins should not be given cephalosporins with similar side chains, but those with different side chains can be administered safely *(Pichichero, 2007 [M])*.

Skin testing

The ability of penicillin skin testing to predict cephalosporin allergy is controversial. In order for penicillin skin testing to reliably predict corresponding cephalosporin allergy, the side chains must be similar. Skin testing does not necessarily predict a clinical reaction, as approximately 90% of patients who possess IgE antibodies to penicillin or amoxicillin do tolerate cephalosporins that contain similar or even identical side chains *(Pichichero, 2007 [M])*.

Consult Appendix C, "Cephalosporin Side-Chain Similarity Determinations Table" in order to understand how the penicillins and cephalosporin classes are related, and to assist with antibiotic decision-making.

Vancomycin allergy management

Vancomycin allergy is rare. Red-man syndrome, a pruritic, truncal redness, is caused by histamine release with rapid infusion rate. This reaction may be mislabeled as an allergy. Infusion times of 90-120 minutes at usual doses should prevent this reaction.

Perioperative management of multidrug-resistant organisms (methicillin-resistant Staphylococcus aureus)

In order to control or eradicate multidrug-resistant organisms, a number of interventions need to be utilized. Administration must be able to ensure prompt and effective communication of patients known to be colonized or infected with multidrug-resistant organisms, maintain appropriate staffing levels, and enforce adherence to infection control practices (hand hygiene, standard and contact precautions). Patients with known colonization or infection should be assigned priority for a single room (isolation). If this is not possible, cohorting patients with shared multidrug-resistant organisms is an option. Dedication of non-critical medical equipment should be implemented to avoid contamination. While decolonization regimens have not been routinely used to eradicate multidrug-resistant organisms, this option is being studied and reported in the literature. Antimicrobial agents should be used judiciously by increasing use of narrow spectrum agents, treating infections versus contaminants, restricting use of broad-spectrum agents, and avoiding excessive duration of therapy. The use of active surveillance cultures to identify patients colonized with multidrug-resistant organisms (cultures of the nares for methicillin-resistant staphylococcus aureus screening) has been reported as beneficial by some studies, but more research is needed in this area *(Siegel, 2007 [R])*.

Glycemic control

Determination of a patient's glycemic control status is an important factor in preventing surgical site infection. In diabetics, outcomes are improved in patients with preoperative Hgb A1C less than 7; however, there is no data on interventions that establish tight control *(Dronge, 2006 [B])*.

The evidence that strict glycemic control is necessary in patients without diabetes is controversial *(Dellinger, 2001 [X]; Latham, 2001 [C]; Van den Berge, 2001 [A])*.

Recommendations:

- A standardized protocol for preoperative, intraoperative and postoperative glucose monitoring should be implemented.
    - All patients with known diabetes should have baseline blood sugar tested prior to surgery.
    - Selection of patients to monitor intraoperatively (typically hourly) should be made by clinical judgment regarding patient illness, type and length of surgery.
    - An insulin nomogram should be available for treatment of insulin-dependent diabetics and patients undergoing inpatient surgery. A hospitalwide policy for care of these patients should be instituted, including monitoring for resulting hypoglycemia.

- Tight glycemic control (blood sugar < 110 except parturients, blood sugar < 100), while possibly ideal, adds risks of hypoglycemia to selected patients (increased severity of illness, renal failure, sepsis). In addition, the stress response to surgery and nutritional needs should be considered. Clinical judgment on a case-by-case basis is best. Some clinicians consider blood sugars in the range of 140-180 to be adequate.

- Outpatients who are found to be severely hyperglycemic (> 200) and are insulin-naïve should be referred to their primary care physician. If insulin is required to be started intraoperatively, overnight stay, observation for hypoglycemia, and plans made for optimizing blood sugar control may be indicated *(American College of Endocrinology, 2004 [R]; Classen, 2004 [NA]; Krinsley, 2007 [C]; Nunally, 2005 [X])*.

Oral hypoglycemic therapy

According to the American College of Endocrinology, oral hypoglycemic medications such as sulfonylureas and thiazolidinediones do not contribute to tight glycemic control and should be avoided in hospitalized patients unless they are eating a regular diet. Many of these medications do not directly affect serum glucose; instead, they increase insulin sensitivity. Metformin, specifically, is used with caution perioperatively due to the potential risk for development of postoperative lactic acidosis *(Martinez, 2007 [X])*.

Preoperative preparation for colon surgery

As a result of pivotal trials performed in the 1970s by Condon, Gorbach and Nichols, surgeons of the last generation have incorporated routine mechanical and oral antibiotic bowel preparations into the practice of surgery on the colon. However, a number of recent trials in the modern era suggest that these two mainstays of preparation may not be necessary.

Mechanical bowel prep: At least 10 randomized control trials have demonstrated no difference in surgical site infection rates for patients receiving mechanical bowel preparation *(Fa-Si-Oen, 2005 [A]; Wille-Jorgensen, 2005 [M])*. Mechanical bowel preparation for patients undergoing colorectal surgery is controversial and at the discretion of the surgeon. The classic dogma requiring a mechanical bowel preparation has been challenged recently, with a number of studies failing to identify a decrease in contamination of the wound after mechanical bowel preparation.

Antibiotic bowel prep: in the era of availability of modern single- and double-agent prophylactic therapy at the time of surgery, an oral antibiotic for bowel preparation the day prior to surgery is controversial and at the discretion of the surgeon *(Jimenez, 2003 [R]; Nichols, 2005 [R]; Zmora, 2001 [M])*.

All patients should receive a dose of intravenous antibiotics at the time of surgery with efficacy against colonic and skin flora.

Patient education

Patient education on the specifics of the procedure, as well as a general orientation, is part of the preoperative evaluation. This includes where possible, written instruction on which medications they should continue to take, how their medications and conditions will be managed during their surgical procedures (anticoagulation bridging, insulin management, etc.), and how long before the surgery to have nothing by mouth.

Patients should be given specific instructions on how to decrease their risk of surgical site infection. These include:

- instructions not to shave or remove any hair at or near the surgical site area,
- cleansing the skin the night before or morning of surgery, and
- for patients with diabetes, instructions on the additional benefit of good glucose control for the prevention of surgical site infections.

There is no evidence stating a specific time frame to tell patients when they should refrain from hair removal at or near the surgical site. Shaving at or near the surgical site more than 24 hours prior to the procedure is documented to increase infection risk *(Mangram, 1999b [R])*.

Patients should cleanse the skin the night before or the morning of surgery to reduce the bacteria load at the surgical site. There is insufficient evidence to support that having patients use an antiseptic agent reduces the risk of infection; their doing so is at the discretion of the surgeon *(Edwards, 2006 [M])*.

2. Patient Arrives (Patient, Procedure and Site Verification)

The American Society of PeriAnesthesia Nurses, the professional organization for the specialty of perianesthesia nursing, is responsible for defining and establishing the scope of practice for perianesthesia nursing. The Standards of Perianesthesia Nursing Practice define the scope of practice as including care in the following areas *(American Society of PeriAnesthesia Nurses, 2004 [R])*:

- Care prior to admission
- Care the day of surgery prior to the moving the patient into the operating/procedure room

Patient, Procedure and Site Verification

With the patient awake and aware if possible, the clinicians involved in the care of the patient will confirm the patient's identity, procedure and site by comparing the following:

- Patient's identity, using two identifiers
- Procedure name and site in informed consent documentation
- Information in the medical record
- Diagnostic studies
- Discussion with the patient/legal guardian

The ultimate responsibility for procedure, site and side verification lies with the surgeon/clinician performing the procedure.

- This verification process should be done every time a new team member has interaction with the patient.
- A minimum of two should verify; each facility should define roles.
- Use a verification checklist.

Glycemic Planning and Management

Refer to recommendations in Annotation #1, "Preoperative Evaluation and Surgical Planning and Scheduling."

Antibiotic Selection (may have been done pre-arrival) and Administration as Appropriate

Antibiotic choice is based on the activity against the normal flora associated with the surgical site and addressing specific patient factors such as methicillin-resistant staphylococcus aureus status *(Bratzler, 2005a [R]; Medical Letter, Treatment Guidelines, 2006 [R]; Prokuski, 2005 [R])*.

Procedure Type/Surgical Site	Common Pathogens	Antibiotic Choice[1]	Alternative to First Choice When IgE Allergy Present
Cardiovascular	S.epidermidis S.aureus	Cefazolin or cefuroxime (intranasal mupirocin the night before, day of surgery and BID x 5 days if nares positive for MRSA)	Vancomycin or clindamycin
Gastroduodenal High risk only[2]	Enteric gram-negative bacilli, gram positive cocci	Cefazolin or cefotetan or cefoxitin or ceftizoxime or cefuroxime	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam)
Biliary tract High risk only[3]	Enteric gram-negative bacilli, enterococci, clostridia	Cefazolin or ceftizoxime	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam)
Endoscopic retrograde chlangiopancreatography (ERCP) (no antibiotic needed without obstruction)	Enteric gram-negative bacilli, enterococci, clostridia	If obstruction or possible incomplete drainage: ciprofloxacin or ceftizoxime or piperacillin/tazobactam	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam)
Colorectal, includes appendectomy[4]	Enteric gram-negative bacilli, anaerobes, enterococci	Cefazolin + metronidazole cefoxitin or cefotetan or ampicillin-sulbactam or ertapenem[5]	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin or aztreonam) or metronidazole + aztreonam + (ciprofloxacin, levofloxacin or gentamicin)
Head and neck (antibiotics appear efficacious only for procedures involving oral/pharyngeal mucosa. Uncontaminated head and neck surgery does not require prophylaxis.)	Anaerobes, enteric gram-negative bacilli, S.aureus	Clindamycin or cefazolin + metronidazole	Gentamicin + clindamycin
Neurosurgical	S.aureus, S.epidermidis	Cefazolin	Vancomycin or clindamycin
Orthopedic[6]	S.aureus, S.epidermidis	Cefazolin or cefuroxime or ceftriaxone	Clindamycin or vancomycin
Urologic (anibiotics needed only if preoperative bacteriura [positive culture or unavailable] or preop catheter)	Enteric gram-negative bacilli, enterococci	Cystoscopy alone or with manipulation or upper tract instrumentation: ciprofloxacin, trimethoprim/sulfamethoxazole	
		Open or laparoscopic surgery: cefazolin	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin, or aztreonam)
Obstetric/gynecologic	Enteric gram-negative bacilli, anaerobes, Gp B strep, enterococci	Laproscopic, vaginal or abdominal hysterectomy: cefazolin or cefoxitin or cefotetan or cefuroxime or ampicillin-sulbactam Caesarean: cefazolin	Clindamycin + (ciprofloxacin, levofloxacin, gentamicin, or aztreonam)
Thoracic (non-cardiac)	S.aureus, S.epidermidis, streptococci, enteric gram-negative bacilli	Cefazolin or cefuroxime	Vancomycin
Vascular	S.aureus, S.epidermidis, enteric gram-negative bacilli, clostridia	Cefazolin	Vancomycin

The information in this table was compiled from The Sanford Guide to Antimicrobial Therapy 2009, and Treatment Guidelines from the Medical Letter, Antimicrobial Prophylaxis for Surgery 2009 and is current as of June 22, 2009. For the most up-to-date medication and prescribing information, consult with your pharmacist or consider the following sources: www.micromedex.com, www.uptodate.com and The Sanford Guide to Antimicrobial Therapy.

1. New guidelines are recommending only a **single dose** of antibiotics for procedures lasting **less than four hours**. In procedures lasting more than four hours or those with major blood loss, intra-operative re-dosing should occur every one to two half-lives of the antibiotic in patients with normal renal function *(Fonseca, 2006 [B]; Med Letter Treatment Guidelines 2009 [R])*.
2. High-risk patients for infection include esophageal obstruction, morbid obesity, reductions in gastric acidity or gastric motility (due to obstruction, hemorrhage, gastric ulcer, malignancy, or proton pump inhibitor therapy). Not indicated for routine gastroesophageal endoscopy.
3. High-risk patients include greater than 70 years, acute cholecystitis, a non-functioning gallbladder, obstructive jaundice, common bile duct stones with cholangitis, treat as infection, not prophylaxis.
4. In the era of availability of modern single- and double-agent prophylactic therapy at the time of surgery, an oral antibiotic for bowel preparation the day prior to surgery is at the discretion of the surgeon *(Jimenez, 2003 [R]; Nichols, 2005 [R]; Zmora, 2001 [M])*.
5. The 2009 Medical Letter guidelines advise against the routine administration of carbapenems for surgical prophylaxis because widespread use of these drugs may result in increased rates of resistance.
6. If a tourniquet is used in procedure, the entire dose of antibiotic must be infused prior to its inflation.

Antibiotic Administration within 60 Minutes Prior to Incision

Antibiotics should be administered so that the bactericidal concentration is present in the tissues at the time of incision. Vancomycin and fluoroquinolones should be given 120 minutes prior to incision due to long infusion time.

Normothermia Planning and Management

The American Society of Anesthesiologists' Practice Management Guidelines for perioperative normothermia document consequences of "even mild hypothermia (one to two degrees C below normal)" as:

- prolonged drug action and delayed recovery and hospital discharge *(Heier, 1991 [C]; Lenhardt, 1997 [A]; Leslie, 1995 [D]),*
- post-anesthetic shivering and thermal discomfort *(Kurz, 1995 [A]; Sessler, 1991 [D]),*
- increased susceptibility to infection *(Bremmelgaard, 1989 [C]; Kurz, 1996 [A]; Melling, 2001 [A]),*
- impaired coagulation and increased transfusion requirements *(Schmied, 1996 [A]; Winkler, 2000 [A])*, and
- cardiovascular stress and cardiac complications *(Frank, 1997 [A]; Frank, 1995a [D]; Frank, 1995b [A]; Persson, 2001 [A])*.

The causes of perioperative hypothermia include:

- anesthetic-induced impairment of thermoregulatory control,
- body cavities and organs exposed to cool operating/procedure room environment *(Roe, 1971 [D])*, and
- core-to-peripheral redistribution of body heat *(Matsukawa, 1995 [D])*.

Recommendations:

Temperature should be monitored in all patients receiving anesthesia when significant changes in body temperature are intended, anticipated or suspected *(ASA Standards, Guidelines, and Statements, 2007 [R])*. Many means to monitor temperature exist with varying levels of accuracy and ease of use. These include oral, tympanic membrane, esophageal, axillary, skin, bladder, rectal, trachea, nasopharynx, and pulmonary artery catheters. The choice of the site depends on access, type of surgery and accuracy.

- There are a variety of methods to maintain body temperature, including control of ambient temperature, administration of warmed intravenous fluids, and surface warming with forced hot air or circulating water. The choice of modalities is a medical judgment made by the anesthesiologist considering the patient and procedural issues in an individual case.
- Achievement of an immediate postoperative temperature greater than 36ºC is an important, beneficial, and realistic goal for patients undergoing general anesthesia lasting more than 60 minutes.

Methicillin-Resistant Staphylococcus Aureus Planning and Management

Refer to Annotation #1, "Preoperative Evaluation and Surgical Planning and Scheduling."

Venous Thromboembolism Proplylaxis Planning and Management

The American College of Chest Physicians recommends that every hospital develop strategies to address the prevention of venous thromboembolism *(Geerts, 2008 [R])*. All patients undergoing surgery should be assessed for risk factors using an appropriate grading/scoring system. Determination of mechanism for prevention of venous thromboembolism (mechanical versus pharmacologic) should be made based on patient risk level *(AORN Journal, 2007 [R])*.

The most current American College of Chest Physicians Guidelines recommend *(Geerts, 2008 [R])*:

- Aspirin alone should not be used as thromboprohylaxis for any patient group.
- Mechanical methods of thromboprophylaxis should be used in patients with high bleeding risk or possibly as an adjunct to anticoagulant thromboprophylaxis.

A multidisciplinary approach, requiring discussion among the surgeon, anesthesiologist and cardiologist/internist regarding continuation/discontinuation or addition of pharmacologic thromboprophylaxis, is necessary. Of particular concern:

- The cessation of antiplatelet therapy in patients with drug-eluting stents. There is a high incidence of perioperative stent thrombosis (29%) with accompanying mortality rate of 20%-45% *(Grines, 2007 [R])*.
- A risk of spinal hematoma following central neuraxial anesthesia or analgesia *(Horlocker, 2003 [R])*.
- It is recommended that each institution define its protocols for emergency access of interventional cardiology for coronary revascularization if needed for stent thrombosis, and its neurological monitoring protocols for patients post-spinal or epidural anesthesia. Physician-to-physician communication is vital.

For recommended prophylaxis based on surgery type, refer to the ICSI Venous Thromboembolism Prophylaxis guideline.

Special considerations based on patient type are as follows:

- All major trauma/spinal cord injury patients should receive thromboprophylaxis.
- All patients admitted to intensive care unit should be assessed for risk of venous thromboembolism and most should receive thromboprophylaxis.

Current American College of Chest Physicians guidelines for perioperative management of antithrombotic therapy during temporary interruption of vitamin K antagonist therapy *(Douketis, 2008 [R])*:

Patients with mechanical heart valve/atrial fibrillation/venous thromboembolism:

- High risk for thromboembolism: recommend bridging with therapeutic-dose subcutaneous low-molecular-weight heparin or intravenous unfractionated heparin over no bridging.
- Moderate risk for thromboembolism: recommend bridging with therapeutic dose subcutaneous low-molecular-weight heparin, therapeutic-dose intravenous unfractionated heparin, or low-dose subcutaneous low-molecular-weight over no bridging.
- Low risk for thromboembolism: recommend low-dose subcutaneous low-molecular-weight heparin or no bridging over bridging with therapeutic-dose subcutaneous low-molecular-weight heparin or intravenous unfractinated heparin.

Refer to ICSI Antithrombotic Therapy Supplement Guideline for specific recommendations regarding bridging regimens.

Patients with bare metal coronary stent requiring surgery within six months of stent placement: recommend continuing aspirin and clopidogrel in perioperative period.

Patients with drug-eluting coronary stent requiring surgery within 12 months of stent placement: recommend continuing aspiring and clopidogrel in perioperative period.

Refer to ICSI Preoperative Evaluation Guideline for further information on management of specific comorbidities.

Beta-Blocker Planning and Management

Beta adrenoreceptor antagonists (beta-blockers) have been studied for their role in prevention of cardiac complications surrounding surgical procedures. These medications reduce heart rate and contractility, therefore increasing perfusion and decreasing oxygen demand. These effects may play a role in stabilizing vulnerable coronary plaques and reducing inflammation via decreased sympathetic tone *(Mason, 2006 [R])*.

Current literature suggests that perioperative ischemia, risk of myocardial infarction, and death may be reduced by beta-blocker use in high-risk patients. There is evidence to strongly suggest starting beta-blockers days to weeks before elective surgery, although this has not been proven true. Goal heart rate should be titrated to a resting heart rate of 60 beats per minute *(Fleisher, 2007 [R])*. The Poise Trial has indicated that benefits may not outweigh risks of beta-blocker regimes in non-selected patient populations *(POISE Study Group, 2008 [A])*.

American College of Cardiology/American Heart Association 2007 Guidelines on Perioperative Cardiovascular Evaluation and Care for Non-Cardiac Surgery *(Fleisher, 2007 [R])*:

Beta-blockers should be given to the following patients:

- Patients currently receiving beta-blockers to treat ACC/AHA class I guideline indications (angina, symptomatic arrhythmia, hypertension, etc.)
- Patients undergoing vascular surgery who are found to have ischemia on preoperative testing (high cardiac risk)

Beta-blockers are probably recommended for the following patients:

- Patients undergoing intermediate risk or vascular surgery who have been identified as having coronary heart disease or are classified as high cardiac risk (presence of more than one clinical risk factor)

Beta-blocker use is uncertain in the following patients:

- Patients identified as having a single clinical risk factor undergoing intermediate risk or vascular surgery
- Patients undergoing vascular surgery with no clinical risk factors who are not currently taking beta-blockers

Beta-blockers should not be used in the following patients:

- Patients undergoing surgery who have absolute contraindications to beta-blockers

Recommendations:

1) Each patient should be evaluated for his/her Revised Cardiac Risk Index *(Lee, 1999 [B])*.

   a) High-risk surgery (orthopedic, intraperitoneal, vascular, intrathoracic)? Yes____No___

   b) Ischemic heart disease? Yes____No___

   c) Cerebral vascular disease? Yes____No___

   d) Renal insufficiency (Creatinine > 2.0)? Yes____No___

   e) Diabetes (insulin dependent diabetes mellitus or non-insulin dependent diabetes mellitus? Yes____No___

2) If patient scores more than two "yes" answers, start one of following protocols:

   a) Atenolol 25-50 mg oral daily x three weeks; start one week preoperative. Clinician's judgment regarding size and age of patient.

   b) Metoprolol 25 mg oral twice daily x three weeks, start one week preoperative (note slight reduction in risk with atenolol versus metoprolol *(Redelmeier, 2005 [B])*

   c) Patient already on beta-blockers; continue.

   d) Unable to use beta-blockers, consider clonidine (0.2 mg oral night before surgery and morning of surgery, or clonidine TTS #2 Patch (0.2 mg/24 hrs) applied night before surgery).

   e) Metoprolol 5 mg intravenous as needed perioperatively. Continue on metoprolol 25 mg twice daily for 10-14 days postoperatively.

   f) Risks/benefits information to patient as well as contact person for problems (primary care physician).

3) Goal is heart rate control around 60 beats per minute.

(Beattie, 2008 [M]; Fleisher, 2007 [R]; Redelmeier, 2005 [B]; Wallace, 2008 [X])

The work group acknowledges that studies have proven beta-blocker use beneficial in high-risk patients. Studies are needed, however, in the areas of target population, duration of preoperative titration, and route of administration. Research also needs to be done to explore the negative outcomes associated with perioperative beta-blocker use in low-risk patients *(Fleisher, 2007 [R])*.

Perioperative Statin Therapy

Current ACC/AHA guidelines provide recommendations regarding perioperative statin use. Observational studies have shown statins to be potentially cardio-protective surrounding non-cardiac surgery. The work group acknowledges that perioperative statin use may benefit select patients, but more research needs to be done in order to identify target patients, optimal statin doses, and optimal target lipoprotein levels. The perioperative period is an opportunity for health care providers to impact long-term health, and assessing the need for statin therapy may be one avenue by which to do so. Specific ACC/AHA recommendations:

Class I:

For patients currently taking statins and scheduled for non-cardiac surgery, statins should be continued.

Class IIa:

For patients undergoing vascular surgery with or without clinical risk factors, statin use is reasonable.

Class IIb:

For patients with at least one clinical risk factor who are undergoing intermediate-risk procedures, statins may be considered *(Fleisher, 2007 [R])*.

Perioperative calcium channel blockers

Current ACC/AHA guidelines refer to 2003 meta-analysis that showed calcium channel blockers to be associated with trends toward reduced death and myocardial infarction, and reductions in ischemia and supraventricular tachycardia. This meta-analysis concluded that larger scale trials are necessary in order to define the value of calcium channel blockers perioperatively *(Fleisher, 2007 [R])*.

3. Environmental Controls/Infection Control/Operating/Procedure Room Survey

The following recommendations for surgical staff are based on experimental, clinical or epidemiological studies, or theoretical rationale and are supported by consensus statements of several professional organizations *(Association of Operating Room Nurses, 2006 [R]; Boyce, 2002 [R]; Mangram, 1999a [R])* or federally regulated *(Centers for Disease Control, 1991 [R]; Centers for Disease Control, 2001 [R]; U.S. Department of Labor, 2006 [R])*.

Recommendations for Surgical Staff

Hand hygiene

- Skin is a major potential source of microbial contamination.
- Hand hygiene is a critical step in prevention and spread of infection. It is the single most important step in the prevention of infection. General hand hygiene should be performed before and after each patient contact, after glove removal, following any contact with blood or other infectious materials, before and after eating, and after using the restroom. Wash with soap and water with mechanical friction for 15 seconds. If hands are not soiled, a waterless alcohol preparation may be used. Waterless alcohol preparations reduce more organisms on the hands than soap and water alone *(Boyce, 2002 [R])*.
- Fingernails should be short, clean and healthy. Nail polish should not be chipped. Association of Peri-Operative Registered Nurses recommends that artificial nails not be worn. Artificial nails can make it more difficult to eliminate bacteria from under the nails. Strict adherence to appropriate hand washing and the use of alcohol-based cleansers is critical to reducing the risk of surgical site infection from organisms transferred by health care worker hands, either with or without artificial nails *(McNeil, 2001 [C])*.
- Cuticles, hands and forearms should be free of open lesions and breaks. This presents a risk for exposure to blood-borne pathogens for both patients and personnel.
- All jewelry must be removed.
- Surgical hand antisepsis (surgical scrub) is performed to significantly reduce the number of microorganisms on the hands and forearms of scrubbed members of the surgical team.
- Antiseptic agents should be limited to those that are Federal Drug Administration compliant, have a documented ability to kill organisms upon application, provide persistence to reduce regrowth and have a cumulative effect over time. (Alcoholic chlorhexidine has been shown to have the greatest residual effect.) Studies have measured bacterial colony counts; no trials have evaluated the impact of scrub agent choice on surgicalsite infection. Alcohol is the European gold standard; 7.5% povidone-iodine and 4% CHG are the United States agents of choice.

Management of surgical personnel

- Educate and encourage staff to report promptly to their supervisor if they have signs and symptoms of a transmissible infectious illness.
- Develop policies on reporting illness, work restrictions and work clearance following an illness.
- Culture and exclude from direct patient care surgical personnel who have exudative skin lesions or weeping dermatitis until infection has been ruled out or therapy resolves it.
- All personnel who might be exposed to blood-borne pathogens should receive the hepatitis B vaccine unless medically contraindicated *(Centers for Disease Control, 1991 [R]; Centers for Disease Control, 2001 [R]; U.S. Department of Labor, 2006 [R])*.
- Personnel participating in exposure-prone procedures or postoperative cleaning and processing of exposure-prone equipment (as identified by the institution) should know their human immunodeviciency virus status. Those who do not have serologic evidence of immunity to HBV should know their HbsAg status, and if positive, should know their HbeAg status *(Centers for Disease Control, 1991 [R])*.
- Personnel who are infected with human immunodeficiency virus or HBV (and HbeAg positive) should not perform exposure prone procedures or postoperative cleaning and processing of exposure-prone equipment (as identified by the institution) unless they have been advised they may continue to perform these procedures as determined by an expert review panel *(Centers for Disease Control, 1991 [R])*.
- Mandatory testing of personnel for human immunodeficiency virus or HBV is not recommended *(Centers for Disease Control, 1991 [R])*.
- It is not necessary to exclude personnel who are colonized with organisms such as staphylococcus aureus or group A Streptococcus unless they are linked to an outbreak.

Recommendations for operating/procedure room environmental controls

Operating/procedure room environmental controls are mandated and regulated by each state's department of health. For specific recommendations from the Minnesota Department of Health, see:

http://www.health.state.mn

Management of operating/procedure room surfaces

- Operating/procedure room surfaces (tables, floors, walls, etc.) have rarely been shown to be the source of surgical infection for patients.
- Routine cleaning practices are important to return the operating/procedure room to a clean state after each procedure.
- Operating/procedure room surfaces that are visibly soiled or contaminated with potentially infectious material should be cleaned with an EPA-approved hospital disinfectant before the next procedure.
- Cleaning of all operating/procedure room surfaces with an EPA-approved hospital disinfectant is routinely performed after the last procedure.
- Routine microbial sampling of operating/procedure room surfaces is not recommended. Microbial sampling should be reserved for epidemiologic investigations.

Sterilization of operating/procedure room devices

- Inadequate sterilization of surgical instruments has resulted in surgical infections, and routine monitoring of the quality of the sterilization process is recommended.

- Surgical devices may be sterilized by:
  - **Steam under pressure**

    Microbial monitoring of steam autoclave performance is necessary and organizations should follow the manufacturer's recommendations and regulations established by their state's department of health.
  - **Peractic acid**
  - **Plasma hydrogen perioxide**
  - **Cold sterilants**
  - **Dry heat**
  - **Ethylene oxide**
  - **Flash sterilization**

Use of flash sterilization should be kept to a minimum. Flash sterilization should be used only in selected clinical situations and in a controlled manner.

Flash sterilization may be associated with increased risk of infection to patients because of pressure on personnel to eliminate one or more steps in the cleaning and sterilization process. Proper decontamination is essential in removing bioburden and preparing an item for sterilization by any method. Failures in instrument cleaning have resulted in transmission of infectious agents.

Flash sterilization should be used only when there is insufficient time to process by the preferred wrapped or container method. Flash sterilization should not be used as a substitute for sufficient instrument inventory.

System Approaches to the Identification and Surveillance of Surgical Site Infections

Surveillance of surgical site infection with appropriate data to surgeons is an important step to decreasing surgical site infections. Between 12% and 84% of surgical site infections are detected after patients are discharged *(Mangram, 1999a [R])*. The difficulty is not only the identification of surgical site infections in patients who have been discharged or received care outside of the care system, but having the staff and resources for effective surveillance processes.

Surveillance systems need to be simple, with reliable data. The following areas are crucial for an effective surveillance system:

- Use standardized definitions for surveillance of infections. These definitions also need to take into account the setting in which the surgical procedure was performed (acute care, ambulatory surgical center, etc.).
- Establish an effective surveillance process that includes postdischarge or outpatient surveillance. A strong postdischarge surveillance process is becoming more important as hospital stays shorten and more surgical procedures are performed in other care settings.
  - Use inpatient case-finding for postdischarge or outpatient.
  - Surveillance will result in underestimations of many surgical infections rates.

Important surveillance can consist of direct and indirect observation. Direct methods include observation of the surgical site by the surgeon, trained nurse surveyor, or infection control practitioner for the identification of surgical site infection. Indirect methods consist of review of lab reports, patient records and interactions with caregivers.

Postdischarge surveillance can include direct examination of the patient's wound during follow-up physician visits, review of medical records of surgery clinic patients, patient surveys by mail or telephone, or surgeon surveys. At present, there is no standard method for performing surgical site infection surveillance outside the hospital *(Janelle, 2004 [R])*. Some studies show that utilizing automated claims data and pharmacy data improves the possible detection of surgical site infections and is less resource intensive over more traditional surveillance systems *(Platt, 2002 [B]; Yokoe, 2004 [B])*. The use of pharmacy data for antibiotic exposure in the absence of standard definitions and criteria for determining possible surgical site infections is insufficient for surveillance systems.

Operating/Procedure Room Survey Performed by Circulator Prior to Baseline Count

The operating/procedure room survey is a safety check done to ensure that all items associated with a previous patient and procedure are removed from the operating suite or room. This is done after the patient has left the operating/procedure room.

The circulating nurse will be the designated person in charge of the survey. Other surgical team members including scrub personnel, anesthesia personnel, surgical assistants and housekeeping will be expected to assist in this process. The circulating nurse will be the final designee expected to do the final survey of the room prior to preparation for the next patient and procedure including the first procedure of the day.

The room survey includes, but is not limited to, the following considerations:

- Remove all items related to the previous patient.
- Remove any paper or electronic medical records, labels or imaging films.
- Verify that the white board and other record keeping documents are clean and do not contain information from the previous procedure. The exception is the documentation required from a previous case when there was a missing item that was never recovered.
- Observe for any personal items of the patient. Examples include hearing aids, eyeglasses, dentures, clothes or any medical devices such as braces or assistive devices. These items may have been left with family members or may have been brought to the operating/procedure room with the patient.
- Limit the number of receptacles for discarded items, particularly for sponges.
- Check all receptacles, particularly those used for sponges. Ensure they are empty and that depending on the method of disposal, all items or bags from the previous procedure are removed from the room.
- Remove any equipment or supplies from the previous procedure that will not be needed for the next procedure.

Does Circulator Perform Room Survey Prior to Baseline Count?

If the circulator does not perform the room survey prior to the baseline count, then there is the potential for the baseline count to be compromised. In the event that the circulator does not perform the room survey prior to the baseline count, then all counts may be considered compromised and an image may be obtained at the close of the case.

4. Pre-Procedure Planning and Preparation (Equipment, etc.)

Pre-procedure planning and preparation includes those activities done at various times prior to the procedure to ensure preparedness for the patient and procedure. This includes:

- The circulating and scrub review the surgeon orders, equipment requests, preference cards and any other information that will contribute to the specific preparation required for the patient and procedure.
- Preparation is carried out for special patient needs including positioning requirements, allergies, height, weight, etc.
- Prepare the room, ensuring all is in working order including such items as operating/procedure room table, lights, tourniquet and microscope.
- Confirm that all needed instruments and implants are available and ready.
- Confirm that all staff needed for the procedure are available and ready. This may include residents, hemodynamic staff or company representatives.

Refer to Annotation #15, "Briefing," for related discussion.

5. Structured Hand-Off for Any Care Provider Changes

During the perioperative period, care is serially assumed by various individuals. It remains extremely important to fully communicate patient data and pertinent problems each step of the way. A transfer of care occurs when one health care provider transfers responsibility for the patient's care to another health care provider. This occurs from pre-anesthesia to hospital discharge. Each care team is obligated to remain in close proximity to the patient as long as medically necessary and until the receiving health care provider has all the information needed to assume care.

To increase efficiency and consistency in the exchange of information, it is recommended that a standard format be developed for giving "report" from one health care provider to another. This includes, but is not limited to, patient name, procedure, medications given and to be given, pertinent problems, allergies, fluid status, cardiorespiratory status and laboratory values received or pending. An opportunity for the receiving health care provider to have any questions answered must be provided. It is STRONGLY recommended that this information be given person to person, e.g., for transfer of the patient from the operating/procedure room or post-anesthesia care unit to the intensive care unit, physician-to-physician personal communication is optimal rather than information given through one or more intermediaries *(Guidelines for Patient Care in Anesthesia, 2007 [R])*.

Structured Hand-off Process

A structured hand-off is a standardized method of communication to ensure a complete exchange of information occurs when the patient is transitioned from health care provider to health care provider; whether or not that transition includes a geographic change.

The kind of information that should be provided during the transition includes the following:

- Patient name
- Type of procedure to be performed, being performed, or performed
- Critical test results
- Patient status
- Recent/anticipated changes in patient condition

- Plan of care/goals
- What to watch for in next interval of care

Preoperative Care Areas: utilize the hand-off process when transferring the care of a patient to the preoperative holding area and for shift changes or break relief.

Examples: In-patient registered nurse to preoperative holding registered nurse
Preoperative registered nurse to preoperative registered nurse

Intraoperative Care Area: utilize the hand-off process with intraoperative personnel during shift changes, break relief, or when there is an addition or change to the surgical team.

Examples: Anesthesia provider to anesthesia provider
Circulator to circulator
Scrub to scrub
Resident surgeon to attending surgeon and vice versa
Attending surgeon to attending surgeon
Resident surgeon to resident surgeon

Postoperative Care Area: utilize the hand-off process when transferring the care of a patient and for shift changes or break relief.

Examples: Anesthesia provider to same day surgery/post-anesthesia care unit personnel
Anesthesia provider to in-patient unit nurse
Post-anesthesia care unit registered nurse to post-anesthesia care unit registered nurse
Post-anesthesia care unit registered nurse to in-patient unit nurse
Physician to physician

See Resources Available for Surgical Care Tool Kit for Hand-off Tools.

6. Surgical Site Marking with Initials

All personnel (e.g, preoperative nurse, circulating nurse, surgeon, and/or clinician designees, and anesthesia practitioner) involved in the surgical procedure must take an active role in this process. If at any time a particular section of the protocol is not required (e.g, site marking), the other verifications and consent steps still apply.

Documentation of each step of the verification process is required. A single, consistent form/checklist or process within the electronic medical record system is recommended. Refer to Resources Available for Surgical Care Tool Kit for example.

Site Marking by Surgeon

The surgeon will verify the patient's identity, the correct site and side of the surgical procedure and will mark the surgical site with his/her ***initials***. Prior to marking, the surgical site location will be confirmed through a review of:

- procedure and site identification information in the informed consent documentation,
- information in the medical record,
- diagnostic studies, and
- discussion with the patient/legal guardian.

The initials indicating the surgical site will be written using a surgical marker and will be **visible when the patient is positioned and draped**.

The work group recommends the use of an anatomical diagram when the surgeon's initials are not visible because of drapes.

Sensitive site marking – when there is a site sensitive area, mark the site on the correct operative side, directly above the site. Ensure that this marking is visible through drapes or use an anatomical diagram if it will not be visible.

For multiple sites/digits on the same anatomical site – the procedures should be numbered on the informed consent documentation and the sites marked with the appropriate corresponding number.

For procedures involving laterality – the informed consent documentation will indicate the laterality and the site marked accordingly.

Laterality also applies to procedures that have a midline or orifice entry but the internal target location involves laterality. The laterality for procedures entered via midline or orifice entry will be indicated on the informed consent documentation. See the definition for Site for more information.

Bilateral procedures will have both sites marked.

For procedures involving level (spine or ribs) – the informed consent documentation will indicate the laterality and level, and the site will be marked in a way to indicate anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number).

Exceptions to skin site marking

The procedure must have the exception to site marking documented in the patient record and "Not Applicable" or "NA" should be written for any site not requiring a mark. The other verifications and consent steps still apply.

- Single organ cases (e.g., Caesarean section, cardiac procedures)
- Teeth – Mark the operative tooth (teeth) on the dental radiographs or dental diagram.
- Premature infants for whom the mark may cause a permanent tattoo. All infants under the corrected gestational age of 38 weeks should not be marked. It is recommended that the surgical site be marked on an anatomical diagram.
- Interventional procedures where the insertion site is not predetermined (e.g., cardiac catheterization, peripherally inserted central catheter lines, central lines, arteriogram).
- Situations where marking the site would cause the patient harm (e.g., emergency procedures and unstable back fractures); the site should not be marked and the rationale documented in the patient record.
- Procedures that enter through an orifice where the target organ is not associated with laterality (e.g., endoscopies, cystoscopy, bronchoscopy, laryngoscopy).
- Site-sensitive areas that may be marked above or lateral to the procedure site (e.g., scrotal sites will be marked on the groin area on the appropriate side of the body; breast sites will be marked on the breast or above the breast on the upper chest area).
- Patient refusals – a defined procedure should be in place for documentation of a patient refusal of site marking.
- Site marking is not required when the credentialed privileged clinician performing the procedure is in continuous physical presence with the patient from arrival for the procedure to conclusion of the

procedure. All the essential patient identifiers, consents, medical records, x-rays, and the necessary equipment must be present in the room and consulted; the clinician will not leave the room for any reason.

Site marking in multiple procedure cases involving multiple surgeons who cannot all mark their respective site(s) before patient is transported to operating/procedure room

For some cases, multiple surgeons are scheduled to perform independent procedures on the same patient. Sometimes they are not all able to visit the patient to mark their respective site(s) before the patient is transported to the operating/procedure room. In lieu of marking the physical site, these surgeons will mark the surgical site on an anatomical diagram. (They will follow the site marking protocol before marking the diagram: The patient's chart and affirmation of informed consent will be checked, the relevant image[s] will be consulted where appropriate, and the patient and/or patient's representative[s] will be consulted, if available, before marking the anatomical diagram. A discrepancy between these information sources will be resolved before marking the site on the anatomical diagram.) Each diagram featuring the relevant site marking will be included in the patient's chart and will be referenced in the operating/procedure room during the Time Out for that particular procedure. A Time Out must be performed just prior to the onset of each procedure.

Individual facililities are encouraged to consider and interpret the 2009 National Patient Safety Goal recommendations (effective January 2009) that state:

Elements of Performance for UP.01.02.01

1. *For all procedures involving incision or percutaneous puncture or insertion, the intended procedure site is marked. The marking takes into consideration laterality, the surface (flexor, extensor), the level (spine), or specific digit or lesion to be treated.*

   Note: For procedures that involve laterality of organs, but the incision(s) or approaches may be from the midline or from a natural orifice, the site is still marked and the laterality noted.

2. *The procedure site is initially marked before the patient is moved to the location where the procedure will be performed and takes place with the patient involved, awake and aware, if possible.*

3. *The procedure site is marked by a licensed independent practitioner or other provider who is privileged or permitted by the hospital to perform the intended surgical or non-surgical invasive procedure. This individual will be involved directly in the procedure and will be present at the time the procedure is performed.*

   Note: Final confirmation and verification of the site mark takes place during the Time Out.

4. *The method of marking the site and the type of mark is unambiguous and is used consistently throughout the hospital.*

5. *The site marking has the following characteristics:*

   - *It is made at or near the procedure site or the incision site. Other non-procedure site(s) are not marked unless necessary for some other aspect of care.*
   - *It includes, preferably, the surgeon's or proceduralist's initials, with or without a line representing the proposed incision.*
   - *It is made using a marker that is sufficiently permanent to remain visible after completion of the skin prep and sterile draping. Adhesive site markers are not to be used as the sole means of marking the site.*
   - *It is positioned to be visible after the patient has his or her skin prepped, is in his or her final position, and sterile draping is completed.*

6. *For spinal procedures, in addition to preoperative skin marking of the general spinal region, special intraoperative radiographic techniques are used for marking the exact vertebral level.*

7. *A defined, alternative process is in place for patients who refuse site marking or who cannot easily be marked under the following conditions:*

   - *For cases in which it is technically or anatomically impossible or impractical to mark the site (mucosal surfaces, perineum, premature infants), an alternative method for visually identifying the correct side and site is used. For example, the hospital may place a temporary, unique wrist band on the side of the procedure containing the patient's name, and use a second identifier for the intended procedure and site.*
   - *For minimal access procedures that intend to treat a lateralized internal organ, whether percutaneous or through a natural orifice, the intended side is indicated by a mark at or near the insertion site, and remains visible after completion of the skin prep and sterile draping.*
   - *For interventional procedure cases for which the catheter/instrument insertion site is not predetermined (for example, cardiac catheterization, pacemaker insertion).*
   - *For teeth, the operative tooth name(s) and number are indicated on documentation or the operative tooth (teeth) is marked on the dental radiographs or dental diagram. The documentation, images, and/or diagrams are available in the procedure room before the start of the procedure.*
   - *For premature infants, for whom the mark may cause a permanent tattoo (Joint Commission, 2008 [NA]).*

7. Anesthesia Patient Identification and Verification Process for Block/Anesthesia

Ideally the surgeon will mark the surgical site prior to the administration of any sedation or regional anesthesia.

Inherent in the risks of surgery are the separate risks of anesthesia. The importance of patient verification, informed anesthesia consent, laterality, marking and anesthesia Time Out prior to the onset of anesthesia or regional block for postoperative pain has been recognized in the rare but not unheard-of incidents of wrong patient, wrong type of anesthetic, wrong side regional block, and the need for disclosure of risks inherent to the anesthesia alone. While not currently mandated by current regulatory agencies *(Center for Medicaid and State Operations/Survey and Certification Group, Hospital Interpretive Guidelines for Informed Decision Making and Informed Consent, 2007 [NA])*, most hospitals and surgicenters have implemented procedures for prevention of problems specifically related to correct patient, site and type of anesthetic.

During the pre-anesthetic visit, anesthesiologists disclose common risks of general and regional anesthesia (sore throat, nausea, vomiting, drowsiness, urinary retention, pain management problems, headache, bleeding, infection, failure to provide anesthesia/analgesia, and backup methodologies). More severe and potentially devastating risks, such as postoperative vision loss, aspiration, malignant hyperthermia, permanent nerve damage, seizures, coma and death, need to be mentioned, but it is suboptimal for patients to be first hearing about these in the preoperative holding area. A dialogue about an uncommon but higher-incidence complication in relation to a specific procedure should be commenced in the surgeon's office ahead of time (e.g., risk of postoperative vision loss associated with major reconstructive spine surgery) *(O'Leary, 2008 [X])*.

General Recommendations

Overall, each institution should define in writing its own practice parameters with regards to patient identification, verification of procedure, cross-referencing surgical consent, anesthesia consent, anesthesia marking and Time Out.

Specific Recommendations

- **Patient identification/verification.** Asking the patient to verbalize name, date of birth and understanding of the proposed procedure prevents mistakes from patients with dementia, hearing loss, severe stress or mental illness, who may simply nod in response to query. In addition, checking the patient's nameband and cross-referencing the surgical consent are common practices.

- **Anesthesia informed consent.** Informed consent for anesthesia separate from surgery is done for anesthesia procedures *without* surgery, such as pain procedures, sedation for magnetic resonance imaging, placement of central catheters, etc. Whether a department of anesthesiology chooses to formulate its own separate anesthesia consent or not for surgical anesthesia, discussion of complications from anesthesia should be documented in the patient's medical record *(American Society of Anesthesiologists Newsletter, 2006 [X]; American Society of Anesthesiologists Newsletter, 2000 [X]; American Society of Anesthesiologists Newsletter, 2007 [X])*.

Each organization should consider utilization of a standardized, institutional anesthesia consent that details common risks of all techniques, and patient-specific risks can be added.

The elements of informed consent are *(American Medical Association Professional Resources [legal issues] informed consent, 2008 [X])*:

- The patient understands the diagnosis (if known), nature of the procedure and the indications for the proposed procedure.
- The patient understands potential short- and long-term risks and benefits of the proposed procedure.
- Reasonable alternatives have been discussed (regardless of their cost or the extent to which the treatment options are covered by health insurance).
- The risks and benefits of alternative treatment, including the option of no treatment, and consequences of refusing treatment are understood.

- **Anesthesia marking**

  Site marking of the surgical site (see Annotation #6, "Surgical Site Marking with Initials") is ideally marked by the surgeon prior to onset of anesthesia or regional blockade for postoperative pain. However, when the anesthesiologist sees the patient, it is recommended that prior to the surgeon, the anesthesiologist and the patient collaborate to mark an "A" with a circle around it (suggested) on the intended site so that the block can be performed prior to surgical marking. It is specifically noted that the anesthesiologist *should not use his/her initials*, as this is reserved for the surgeon. Heightened awareness and rigid adherence to established procedures for identification and marking will decrease the likelihood of wrong site anesthesia *(American Society of Anesthesiologists Newsletter, 1996 [X])*.

- **Anesthesia Time Out**

  Prior to commencement of regional blockade a "procedural Time Out" should be performed among the anesthesia professional, the patient and the assistant.

9. Hard Stop

If any part of the verification process was not followed and/or a discrepancy is discovered, the procedure is halted and will not continue until the missing steps of the verification process are completed and the discrepancies resolved.

Resolution of discrepancies will include:

- reverification of patient identification,
- review of the information in informed consent documentation,
- review of the medical record,

- review of diagnostic studies, and
- discussion with the patient/legal guardian (if appropriate).

Conversations related to resolution of discrepancies should be held in a quiet location, away from activity/distractions.

To consider a discrepancy resolved, confirmation of the correct procedure or surgical site and side must include all forms of documentation, as well as a discussion with the patient/legal guardian. After the discrepancy has been resolved, the procedure and site verification will be repeated.

If the steps of the verification process cannot be completed or are not completed and/or any discrepancies cannot be resolved, the procedure is canceled and rescheduled.

10. Repeat Verification Process If Patient Has Been Moved or Care Team Changes

Refer to Annotation #5, "Structured Hand-Off for Any Care Provider Changes."

11. Baseline Count

Perform Baseline Count Before Patient Arrives in the Operating/Procedure Room Suite

The counting recommendations outlined in this protocol are based on consensus statements and guidelines of American College of Obstetricians and Gynecologists and the American Academy of Pediatrics *(AORN, 2006 [R]; ACOG Committee on Quality Improvement and Patient Safety, 2006 [R]; American College of Surgeons, 2005 [R]; Brennan, 2004 [C]; Council on Surgical and Perioperative Safety, 2005 [R]; CRICO/RMF, 2006 [R]; Eldridge, 2006 [NA]; Gibbs, 2005 [R]; Joint Commission International Center for Patient Safety, 2006 [R]; Harder, 2006 [D]; Leape, 1991 [C]; Thomas, 2000 [C]; Vincent, 2004 [R])*.

In addition, articles on communication, teamwork, multitasking and interruptions and their relationship to unanticipated events were consulted *(ECRI, 2005 [R]; Haig, 2006 [D]; Leonard, 2004 [D]; Lingard, 2004 [D])*.

Accurately accounting for all items that could potentially become unintentionally retained is a priority of the entire surgical team, though the primary responsibility for performing the count process belongs to the circulator and scrub. The circulator must be a registered nurse *(AORN, 2006 [R]; American College of Surgeons, 2005 [R])*.

Radiographic imaging is not a substitute for performing accurate count procedures. Count procedures may be omitted or modified in an extreme patient emergency. This exception will be documented in the patient's medical record and when the patient's condition allows, radiographic imaging should be obtained to rule out the possibility of an unintentionally retained foreign object.

What Items Will Be Included in the Count Process

Best practice is the use of radiopaque items in the surgical wound (*AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]; VHA Directive, 2006 [NA])*. The work group recognizes that not every item that may be used during a surgical procedure is radiopaque.

It is the recommendation of the work group that radiopaque items should be used if that product is manufactured in a radiopaque form and all non-radiopaque items should be counted, regardless of whether that item is a required, countable item.

Sponges/soft goods – sponges/soft goods will be counted for all procedures when they are used. Only radiopaque sponges/soft goods will be present within the surgical field *(AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R]; VHA Directive, 2006 [NA])*.

Laparotomy sponges or 4x8 sponges will not be cut into pieces or otherwise used for dressing *(AORN, 2006 [R]; Council on Surgical and Peroperative Safety, 2005 [R]; VHA Directive, 2006 [NA])*.

Non-radiopaque gauze used for dressing will be held in a separate area until the wound is closed *(AORN, 2006 [R]; American College of Surgeons, 2005 [R])*.

Sharps – Sharps will be counted for all procedures when they are used *(AORN, 2006 [R]; American College of Surgeons, 2005 [R])*.

An unintentionally retained micro needle is not reportable as a retained foreign object. Organizations will need to define a micro needle depending on their patient population (e.g., infants).

Miscellaneous items – miscellaneous items will be counted for all procedures *(AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council on Surgical and Perioperative Safety, 2005 [R])*.

Examples of a miscellaneous item include vessel clips, vessel loops, vascular inserts, cautery scratch pads, trocar sealing caps, catheter sheaths, non-radiopaque items such as hernia tapes and other small items.

Instruments – instruments will be counted for all procedures when the possibility exists that an instrument could be unintentionally left behind *(AORN, 2006 [R])*.

Organizations will need to define instruments that are at risk for being unintentionally retained. The work group has listed the following guiding principles to assist organizations in defining instruments to be counted:

- Size of the wound relative to the instruments being used
- Instruments that leave the hand of the operator after being placed in the operative field
- Instruments that are obscured within the wound and not clearly visible throughout the procedure (clips, guide wires, small clamps, etc.)

It is the recommendation of the work group that instruments that are to be counted should be identified by specialty/service and specific to the procedure and surgical technique employed.

Examples of surgical procedures where instruments may be identified as a required countable item include chest, open abdominal, and pelvic procedures. Refer to Resources Available for Surgical Care Tool Kit for examples of a standardized instrument count sheet.

When the Count Process Will Be Performed *(AORN, 2006 [R]; VHA Directive, 2006 [NA])*

- The baseline count will occur before the patient is brought to the operating/procedure room unless parallel processing is used. When parallel processing is used, two different circulators will be needed: one dedicated to the count process and one dedicated to patient care.
- At the time of closure of a cavity within a cavity
- Before wound closure (e.g., fascia)
- At the end of the procedure/final closure (e.g., skin) – sponges/soft goods used for wound debridement procedures for burn patients are exempt from the final count process. A final count, as outlined in the protocol, must be performed for all other items (sharps, miscellaneous items, instruments) used in wound debridement procedures for burn patients.

- Any time a member of the surgical team has concerns about the accuracy of the counts, even when the counts appear correct
- Whenever there is a permanent staff change of the circulator:
  - All visible items will be counted and all items in use in the surgical field will be accounted for.
  - If there is a permanent change in a member of the surgical team other than the circulator, a report is required but a count is not.
  - When the circulator is changed for a short duration (e.g., lunch break), a structured hand-off is required but a count is not.
- At final closure of a wound that was intentionally delayed (damage control), temporary implants are used, or a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponge)

How the Count Process Will Be Performed

- The circulator and scrub (the circulator must be a registered nurse) will directly view the items being counted and will count out loud and concurrently (*AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R])*.
- There is evidence that distractions, multitasking and conflicting priorities, especially during critical cognitive steps such as counting, will, with high predictability, lead to an error *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [R])*. Therefore, distractions and interruptions should be minimized during the count process *(ACOG Committee on Quality Improvement and Patient Safety, 2006 [R]; American College of Surgeons, 2005 [R])*. If the count process is interrupted, the circulator and scrub will restart the count of the count category that was interrupted.
- The circulator will document the number and type of sponges/soft goods, sharps, miscellaneous items, and instruments on a preformatted white board or other standardized, preformatted documentation record. The scrub verbally confirms the number.
  - It is best practice for the circulator to document the number of each item immediately after counting them. This diminishes the likelihood that the number will be recalled incorrectly or the circulator will forget to document the number on the white board.
  - Best practice is to use a preformatted white board, directly viewable by the entire surgical team *(France, 2005 [R])*.
  - For procedures where there is a large number and/or specificity of certain items (e.g., cardiac procedures), a standardized, preformatted paper record may be used. See Resources Available for Surgical Care Tool Kit for sample document.
  - It is the recommendation of the work group that, whenever possible, only one source of count information be used during the procedure.
- All sponges/soft goods, sharps, miscellaneous items, and instruments will be counted in the same order each time *(AORN, 2006 [R])*.
  - It is the recommendation of the work group that items be counted in the order they are listed on the preformatted white board.

- Sponges/soft goods will be separated and counted individually *(AORN, 2006 [R])*.
  - Some organizations allow 4x8 sponges to be held by the bottom third and counted by individually separating the top two-thirds of each sponge. It is the work group's recommendation that best practice is to separate all sponges and count them individually.
- Every sponge/soft good will be visually inspected to ensure that the radiographic-detectible indicator is present *(AORN, 2006 [R]; American College of Surgeons, 2005 [R]; Council of Surgical and Perioperative Safety, 2005 [R])*.
  - If the indicator is not present, the entire package of sponges/soft goods will be removed from the suite and given to the designated person for follow-up with the manufacturer *(AORN, 2006 [R])*.
- Instruments should be counted in sets.
  - It is the work group's recommendation that best practice is for all instruments, regardless of whether they are required countable items or not, be added to the surgical field in pairs and retrieved in pairs.
- Packages where the labeling on the package does not match the number of items in the package will be removed from the suite and given to the designated person for follow-up with the manufacturer *(AORN, 2006 [R])*.
- Counts will begin at the surgical field and move away from the patient.
- Gauze and other soft goods used by anesthesia will not enter the surgical field or be mixed in with sponges/soft goods used and counted for the surgical procedure.
- Sponges/soft goods, sharps, miscellaneous items, and instruments added during a procedure will be counted prior to entering the surgical field *(AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R])* and documented as soon as possible.
- Used sponges/soft goods will be unballed, separated and pulled apart for counting.
- All sharps, miscellaneous items, and instruments will be inspected for broken or missing pieces when counted *(AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R])*.
- Any sponge/soft good, sharp, miscellaneous item, or instrument dropped during the procedure will be retrieved, shown to the person responsible for counting, and isolated from the surgical field to be included in the final count.
- Gauze and other soft goods used for wound dressing will not be present in the surgical field until the wound is closed.
- Any item intentionally left behind in a patient because it would do more harm to retrieve will be documented in the patient's medical record.

12. Baseline Count Performed?

If the baseline count cannot be performed prior to the patient being brought to the operating/procedure room (unless parallel processing is used – see below), the counts should be considered compromised and inaccurate. Continue to follow the Perioperative Protocol and obtain portable, intraoperative radiographic imaging for a potentially retained foreign object.

Some organizations are utilizing parallel processing methods to improve operating/procedure room turnover times. Parallel processing is when two separate activities with two entirely separate groups of staff are performed simultaneously. Parallel processing is **not** multitasking. For the count process, two different circulators will be needed: one dedicated to the count process and one dedicated to patient care.

If separate staff is not available, the baseline count **must** occur **before** the patient arrives in the operating/procedure room.

13. Imaging Required at Completion of Procedure

Refer to Annotation #37, "Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled."

14. Patient Transported to Intraoperative Area Using Checklist (Reverify Patient Identification)

The transition of the patient from one location to another, whether or not the care providers change, creates the opportunity for errors to occur. Prior to moving the patient from the preoperative area to the operating/procedure room, the anesthesia care provider is responsible for final verification, including:

- Verifying consent is complete;
- Verifying the patient's identification;
- Verifying preoperative checklist has been completed by all required staff. Refer to Resource Table Tool Kit for additional information on pre-procedure verification checklist;
- Verifying operative site has been marked if appropriate; and
- Notifying preoperative staff, verbally and/or electronically, that the patient is being moved to the operating/procedure room.

Whenever possible, the patient should be an active participant in the verification process.

Upon arrival in the operating/procedure room, the anesthesia care provider and circulating nurse will verify the patient's identification, surgeon and procedure to be performed before moving the patient to the operating/procedure room table. If possible, the patient should participate in the verification process. If the circulating nurse is in the process of performing the baseline count with the scrub when the patient arrives, the verification process cannot be performed until the counting is complete. Refer to parallel processing definition.

Intraoperative Period Algorithm Annotations

15. Briefing

It is expected that the initial plan for the surgical procedure will have been disseminated prior to the day of surgery, preferably at the time of scheduling. The briefing is intended as a time to confirm the plan for a particular procedure. Ideally, the briefing should be conducted in the operating/procedure room after anesthesia induction and before patient positioning. It is recommended that members of the operating/procedure room team (surgeon, circulating nurse, anesthesia care provider, scrub) who will be present during the procedure will participate in the briefing. The purpose of the briefing is to confirm the plan for the surgical procedure and to confirm with team members what will be needed during the procedure and when it will be needed. During the briefing, the team members should be informed about particular patient needs and about the equipment and supplies that will be needed – particularly if there are any requirements for a particular case that are not typically needed for that type of procedure. With advance planning the circulating nurse and/or other team members will be able to ensure that the equipment and supplies needed for the procedure will be available at the time they are needed – this will minimize the delays caused by the circulating nurse leaving the operating/procedure room to retrieve an item. Further, an effective briefing to confirm particular patient needs will help to ensure that all team members are prepared for potential problems or issues that might arise.

Appropriate elements for the briefing include:

- Introduction of individual team members
- Any special patient needs or potential issues including safety precautions based on patient history or medication use
- Anticipated problems
- Patient positioning
- Status of the patient consent
- Patient allergies
- Medications (e.g., antibiotics)
- Anticipated blood components
- Specimens, if applicable, and how they should be handled
- Discussion about radiological images, if applicable including whether they are properly labeled and appropriately displayed
- Discussion of implants, if applicable
- Details regarding special equipment
- Discussion of any special intraoperative requests (e.g., surgeon informs circulating nurse and scrub about times during the procedure when he or she would prefer that they avoid taking a break).
- Team members are asked whether or not they have any other concerns or issues related to the patient or the procedure

If these elements are covered thoroughly in the briefing, then team members will know what is expected of them, delays while waiting for required equipment and supplies should be minimized, and the procedure should run more smoothly and efficiently.

For organizations that have not implemented the briefing, these elements would be required during the Time Out.

16. Environmental Controls/Room Temperature

Surgical staff and operating/procedure room environmental controls

The following recommendations for surgical staff are based on experimental, clinical or epidemiological studies, or theoretical rationale and are supported by consensus statements of several professional organizations *(Association of Operating Room Nurses, 2006 [R]; Boyce, 2002 [R]; Mangram, 1999a [R])* or federally regulated *(Centers for Disease Control, 1991 [R]; Centers for Disease Control, 2001 [R]; U.S. Department of Labor, 2006 [R])*.

Preoperative scrub

- Wash hands and forearms with plain or antimicrobial soap.
- Clean the subungual areas of both hands; use nail cleaner (first scrub of day).
- Rinse hands under running water.
- Dispense scrub agent; apply to wet hands and forearms with sterile soft sponge. Brushes are not recommended.

- Hold hands higher than elbows and away from the body.
- In the operating/procedure room, dry hands and arms with a sterile towel.
- It may be preferable to perform steps one through three, then dry hands and forearms thoroughly with a paper towel. Apply a Federal Drug Administration-approved alcohol-based solution, preferably containing CHG, to hands and forearms, rubbing until dry. Depending on manufacturer, it may be necessary to repeat application process.
- Put on sterile gown and gloves.
- Double gloving has been shown to decrease hand contamination with blood-borne pathogens through perforations in the gloves *(Berridge, 1998 [A]; Lin, 2005 [R])*. Surgical staff, particularly those who are involved with exposure-prone procedures or who handle exposure-prone instruments, should consider double gloving as a precaution against the exposure to blood-borne pathogens.
- Alcohol-based hand rubs may be used for routine decontamination of hands. Using an alcohol-based hand rub for hands that are visibly dirty or contaminated is not recommended. Soap and water should be used and may then be followed by an alcohol-based solution.

Surgical asepsis

The following are guidelines by which contamination with microorganisms may be prevented. There are not studies to support whether these methods are effective; however, having similar recommendations among organizations does help staff that work across multiple organizations.

- Individuals who enter the semirestricted and restricted areas of the operating/procedure room should wear freshly laundered surgical attire donned at the facility.
- Surgical attire should be changed daily or whenever it becomes visibly soiled, contaminated or wet.
- Surgical attire should not be home laundered. Laundered attire should be protected from contamination during transfer and storage.
- Personnel should wear long-sleeved jackets that are closed during use when there is the possibility of contact with blood-borne pathogens.
- Personnel should cover head and facial hair, including side burns, when in restricted or semirestricted areas.
- Masks should be worn in the restricted area when open sterile supplies and equipment are present.
- Protective barriers (gloves, eyewear) must be available to reduce the risk of exposure. Gowns and shoe covers should be worn when exposure to blood or infectious materials is anticipated.
- Scrubbed persons should function within a sterile field. Following hand antisepsis, they should don sterile gown and gloves. The gown is sterile from the chest to the level of the sterile field. The sleeves from two inches above the elbow to the cuff, the cuff should remain covered by the sterile glove and should remain at or below the natural wrist.
- Sterile drapes should be used to establish a sterile field and provide an aseptic barrier to minimize microorganisms between non-sterile and sterile areas. These should be placed on the patient, furniture and equipment to be included in the sterile field.
- Drapes should be handled as little as possible, held in a compact manner, and gloved hands should be protected by cuffing the drape. Drapes must not be moved after they are positioned.

- Items used within the sterile field must be sterile. Sterility should be event related. All items should be opened, dispensed and transferred by methods that maintain sterility and integrity.
- It is standard practice when performing surgical procedures that involve two surgical sites, one clean and one clean-contaminated, to always move from the clean to the clean-contaminated site. When this is not possible, use separate instruments and other materials for the two surgical sites.
- Sharps, heavy objects and peel-packed items should be presented to scrubbed staff, to prevent tearing of the drapes. Rigid containers should be opened on a separate surface.
- Unscrubbed personnel should never reach over the sterile field to introduce sterile items. Liquids should not be allowed to splash. Medications should be delivered aseptically, stoppers should not be removed; rather, sterile transfer devices should be used.
- Sterile field should be monitored at all times and prepared as close as possible to the time of use (there is no designated amount of time supplies can be opened, event related); supplies should be opened for only one case at a time.
- Sterile fields should not be covered.
- Equipment should be secured to the sterile field with non-perforating devices.
- Unscrubbed staff should face sterile fields on approach, not pass between two sterile fields, and should keep their distance.
- Traffic in and out of the room should be kept to a minimum.

Recommendations for Operating/Procedure Room Environmental Controls

Operating/procedure room environmental controls are mandated and regulated by each state's department of health. For specific recommendations from the Minnesota Department of Health, see:

http://www.health.state.mn

Temperature Control

Development of hypothermia in the patient has been shown to be associated with increased risk of infection. Prevention of hypothermia begins prior to patient arrival in the room. The room temperature should be such that a minimally clothed patient is comfortable. It is appropriate to adjust room temperature to a level comfortable for the operating/procedure room personnel once the patient has received active or passive measures to prevent heat loss. (See Annotation #2, "Patient Arrives [Patient, Procedure and Site Verification]," for information on normothermia planning and management.)

Noise Control to Minimize Distraction and Patient Stimuli

Adjust music volume to level that is appropriate to work being performed. The music should not interfere with communication among members of the operating/procedure room team.

Recommendations for Operating/Procedure Room Vendor Access

The surgical environment can be enhanced by establishing guidelines for effective control of operating/procedure room access to external constituencies. Vendors can be granted access to the operating/procedure room when services are pertinent to patient care. It is recommended that a specific policy be established for the purposes of defining vendor access. Examples of vendor procedure statements may include the following:

- All vendors must initially contact hospital administration through the proper institutionally designated process.

- **Vendors will be admitted to the operating/procedure room only after the patient has been draped for the purpose of providing a resource to the surgeon or staff in the use of instrumentation, equipment or patient care items.**
- One vendor per operating/procedure room per surgeon unless there are clinical reasons.
- Appointments will be pre-arranged and scheduled by one of the following: surgeon, nurse manager/supervisor or charge nurse.
- The nurse manager/supervisor and/or surgeon's secretary will contact the surgical administration office to confirm prior vendor approval.
- Vendors who have received access to the operating/procedure room will register at the surgical administration office and be provided an identification tag to be worn during their operating/procedure room visit.
- Vendors will not set up displays in or around the operating/procedure room unless a surgical services educator or designee has requested an educational display be provided for staff.
- The vendor is accountable to the surgeon and surgical personnel while in the operating/procedure room.
- Surgery administration reserves the right to govern and restrict vendor access visits to the operating/procedure room.
- **Vendors do not provide patient care. Vendors must not open any surgical supplies, implantables or surgical instrumentation. The purpose of a site visit to the operating/procedure room is to answer questions about the operation of their equipment or to trouble-shoot any problems occurring with the use of the equipment.**
- Demonstration of new equipment to be used for new procedures will be done in an appropriate setting outside of the operating/procedure room.
- Vendors will restrict their visit to the designated area. Expanded visits require pre-arrangement with the nurse manager/supervisor or designee of other specialty areas.
- No cell phones or personal digital assistants are allowed in the operating/procedure room.
- Must have closed-toe, non-fabric shoes that are clean and professional in appearance.
- Pagers will be set on silent.

Example of Vendors Check-In Process

- Fill out visitor card yearly (kept for one calendar year), filed by vendor name.
- Provide business card (dated by office staff and filed in card file).
- Visitor name badge is required.
- Receive locker assignment.
- Change into surgical scrubs.
- Return to the surgical administration office.
- Lock all cell phones, cameras, personal digital assistants and other personal items in the locker.
- Escort to appropriate operating/procedure room.

17. Patient Arrives in Operating/Procedure Room: Reverification and Anesthesia Administered

Complete reverification. Refer to Annotations # 2, "Patient Arrives (Patient, Procedure and Site Verification)," Annotation #7, "Anesthesia Patient Identification and Verification Process for Block/Anesthesia," and Annotation #14, "Patient Transported to Intraoperative Area Using Checklist (Reverify Patient Identification)," for specifics.

18. Verify Site Marking/Position Patient/Skin Preparation/Clipping

Verify Site Marking

Refer to Annotation #6, "Surgical Site Marking with Initials," for site-marking specifics.

Skin Preparation and Hair Removal

Most surgical site infections are from skin normal flora (coagulase-negative staphylococcus non-aureus).

- The surgical site should be assessed before skin preparation. Skin should be assessed for the presence of moles, warts, rashes or other skin conditions. Inadvertent removal of lesions may provide an opportunity for wound colonization.
- The surgical site and surrounding areas should be clean.
- Antiseptics are shown to reduce bacteria on the skin, but a corresponding decrease in surgical site infection rates has not been demonstrated. The Centers for Disease Control's 1999 guidelines do recommend the use of antiseptics *(Ellenhorn, 2005 [A]; Hibbard, 2002 [A]; Jacobson, 2005 [A]; Ostrander, 2005 [A]; Sowapat, 2005 [C])*. There is insufficient evidence from randomized trials to support the use of antiseptic preparation of the skin, or of one antiseptic over another *(Edwards, 2006 [M])*. Several antiseptic agents are available for preoperative preparation of skin at the incision site. Careful consideration should be given to the patient's condition. Some antiseptic agents may burn mucous membranes, and others are highly flammable. The prepared area must be large enough to extend the incisions or create drain sites. Some guidelines recommend applying the antiseptic with sterile supplies, but again there is no literature to support this.
- Personnel should be knowledgeable in skin preparation techniques, including maintaining skin integrity and preventing injury to the skin *(Association of Operating Room Nurses Recommended Practices Committee, 2002 [R]; Mangram,1999a [R])*. Special considerations should include:
  - preparing areas with high microbial counts last;
  - isolating colostomy sites, covering with an antiseptic-soaked sponge, and preparing them last;
  - using normal saline to prepare burned, denuded or traumatized skin;
  - avoiding the use of chorhexidine gluconate and/or alcohol based products on mucous membranes;
  - allowing sufficient contact time for antiseptics before applying sterile drapes;
  - allowing sufficient time for complete evaporation of flammable agents; and
  - preventing antiseptics from pooling beneath patients or equipment.
- Patient skin preparation should be documented in the patient record.
- Policies and procedures on skin prep should be reviewed regularly to assess new evidence.

See Appendix D, "Overview of Topical Antiseptics Used for Preoperative Skin Preparation."

Hair removal

- The operating/procedure room should be assessed for amount and degree of hair removal.
- Refrain from hair removal unless the hair at or around the incision may interfere with the procedure *(Winston, 1992 [D])*. Hair removal should be the exception, not the rule.
- Hair removal, when necessary, should occur as close as possible to the time of a surgical procedure and should be performed with clippers *(Mangram, 1999a [R])*. There is no evidence stating a specific time when to refrain from hair removal at or near the surgical site. Shaving more than 24 hours prior to the procedure is documented to increase infection risk *(Mangram, 1999b [R])*.

Definitions for hair removal should be clarified

- The shaving method uses a sharp blade over the patient's skin to cut hair close to its surface. The razor is typically disposable. Shaving with a razor may result in cuts and abrasions to the skin and therefore should not be used.
- The clipping method uses clippers with fine teeth to cut hair close to the patient's skin. It leaves a short stubble of hair typically one millimeter in length. A clipper typically has a disposable head or is disinfected between patients. Staff should follow manufacturer's instructions provided with the hair clippers. Clippers do not come in contact with the patient's skin, thus decreasing cuts and abrasions.
- The use of depilatory creams is a method in which chemicals dissolve the hair. This is a slower process lasting anywhere from 5 to 20 minutes. Chemical depilatories may irritate the skin or result in an allergic reaction. A patch test is recommended 24 hours prior to cream applications.
- Consideration should be given to where hair removal occurs. Hair removal at the sterile field could potentially contaminate the surgical site and/or sterile fields due to loose hairs.
- For some surgical procedures, hair removal may not be necessary. Patients requiring emergent procedures may not have time for hair removal.
- Staff performing patient hair removal should be instructed to use the proper technique.
- Policies and procedures should indicate when and how to remove hair at the incision site. Hair removal should occur under physician orders and/or following protocol for particular surgical procedures.
- If hair removal occurs, it should be documented. Documentation should include condition of the skin at the surgical site, who has done the removal, the method of hair removal, area of hair removal and when it was done.

19. Prior to Incision – Active Verbal Time Out

The Time Out is to be performed after the surgeon has scrubbed and gowned and just prior to beginning the procedure. It is the final safety stop before the surgical procedure is begun. The purpose of the Time Out is to ensure that the correct patient, procedure to be performed, site of the procedure and patient positioning are all correctly verified.

All the elements to be included in The Joint Commission (2009 National Patient Safety Goals) required Time Out are consistent with the elements included in the briefing **and** Time Out within this protocol.

The recommendation from this work group is to cover all those required elements, but to cover them in two distinct temporal steps. Also see Annotation #15, "Briefing," for the specific elements covered in the briefing.

During the Time Out, each person in the operating/procedure room must cease his/her activity and actively participate in the process. The team includes the surgeon, resident(s), student(s), anesthesia care provider, scrub and circulator. No individual (e.g., student[s], vendor[s]) is exempt from stopping his/her activity during the Time Out. If a member of the team refuses to actively participate in the Time Out, the scalpel or cutting/incising device is not handed to the surgeon until that individual is replaced and the Time Out completed.

The Time Out is to be initiated by the surgeon. The scalpel or other cutting/incising device is not to be handed to the surgeon until the Time Out has been completed.

It is recommended that a visual memory aid be used to remind the surgeon to initiate the Time Out. For example, a Time Out sign or towel can be used to cover the scalpel or cutting/incising device. When one of these aids is used, it is important to hand it off the surgical field at the conclusion of the Time Out so it is not retained in the patient.

Each Time Out must include the following standard elements:

- Patient identity, using a minimum of two identifiers (e.g., patient name and medical record number)
- Procedure to be performed
- Site of procedure (and level, if applicable) including **visualization of the surgeon's initials** (either on the patient's body or on an anatomical diagram), if applicable
- Patient position

The initiation of the Time Out is the responsibility of the surgeon (e.g., "Let's do the Time Out"). The circulator reads the patient's affirmation of informed consent for the Time Out elements. However, prior to its use the consent must have been validated against other documents, such as history and physical, radiology or pathology reports, progress notes, etc. While the circulator reads the elements of the Time Out, the anesthesia care provider verifies that his/her information matches what the circulating nurse reads. After the circulator reads the patient, procedure, site and patient position information from the patient's affirmation of informed consent, the following team verification is recommended:

(a) Anesthesia Provider:

  (i) Reads patient's name, medical record number, and procedure – circulating nurse verifies that information on affirmation of informed consent matches what anesthesia care provider reads.

  (ii) States antibiotic name and dose (optional).

(b) Scrub:

  (i) States procedure he/she has set up for.

  (ii) Announces that he/she sees the site marking.

(c) Surgeon – says patient's name, complete procedure, and site.

Environmental distractions are to be eliminated as much as possible during the Time Out. For example, music is turned off, pagers are set on vibrate, talking other than participation in Time Out ceases and no staff are permitted to enter or exit the room. If during the Time Out an interruption or distraction occurs (pager goes off or an individual enters the room), the Time Out must be restarted.

The attending surgeon may designate a surgical resident or fellow to initiate the Time Out in the attending surgeon's absence. When the attending surgeon joins the case in the operating/procedure room, the surgical resident or fellow will communicate the patient's name and procedure to the attending surgeon.

A Time Out is to be performed prior to the onset of each procedure when multiple procedures are performed on the same patient during the same surgical period whether or not the procedures involve a new surgical team. The process and elements of the Time Out as described above must occur prior to the start of each procedure.

If the patient needs to be repositioned during the procedure and this repositioning affects the patient's presentation (i.e., the patient is turned prone), an abbreviated Time Out including the site (including level, if applicable) and visualization of the surgeon's initials will be conducted. The Time Out process will be conducted in the same manner as described above.

Individual facilities are encouraged to consider and interpret the 2009 National Patient Safety Goal recommendations (effective January, 2009) that state:

Rationale for UP.01.03.01

The purpose of the Time Out immediately before starting the procedure is to conduct a final assessment that the correct (patient), site, positioning, and procedure are identified and that, as applicable, all relevant documents, related information, and necessary equipment are available.

The Time Out is consistently initiated by a designated member of the team and includes active communication among all relevant members of the procedure team. It is conducted in a standardized fail-safe mode (that is, the procedure is not started until all questions or concerns are resolved).

Elements of Performance for UP.01.03.01

1. *The Time Out is conducted prior to starting the procedure and, ideally, prior to the introduction of the anesthesia process (including general/regional anesthesia, local anesthesia, and spinal anesthesia), unless contraindicated.*
2. *The Time Out has the following characteristics:*
   - *It is standardized (as defined by the hospital).*
   - *It is initiated by a designated member of the team.*
   - *It involves the immediate members of the procedure team including the proceduralist(s), the anesthesia providers, the circulating nurse, the operating room technician, and other active participants as appropriate for the procedure, who will be participating in the procedure at its inception.*
   - *It involves interactive verbal communication between all team members, and any team member is able to express concerns about the procedure verification.*
   - *It includes a defined process for reconciling differences in responses.*
3. *During the Time Out, other activities are suspended, to the extent possible without compromising patient safety, so that all relevant members of the team are focused on the active confirmation of the correct patient, procedure, site, and other critical elements.*
4. *When two or more procedures are being performed on the same patient, a Time Out is performed to confirm each subsequent procedure before it is initiated.*
5. *The Time Out addresses the following:*
   - *Correct patient identity*
   - *Confirmation that the correct side and site are marked*
   - *An accurate procedure consent form*
   - *Agreement on the procedure to be done*
   - *Correct patient position*
   - *Relevant images and results are properly labeled and appropriately displayed*
   - *The need to administer antibiotics or fluids for irrigation purposes (See also NPSG.07.05.01, EP 7)*

- *Safety precautions based on patient history or medication use*

6. *The completed components of the Universal Protocol and Time Out are clearly documented (Joint Commission, 2008 [NA]).*

20. Discrepancies?

If during the Time Out discrepancies among the consent, team members, imaging and/or equipment are discovered, the scalpel or cutting/incising device will not be handed to the surgeon until the discrepancy is resolved. It is important that the organization and surgical services leadership team set the expectation that staff may, at any time, raise concerns or objections related to elements of the Time Out if they believe discrepancies do or may exist. Demeaning, derogatory or retaliatory statements and/or actions taken against one or more individuals as a result of a concern raised during the Time Out or any other part of the procedure are not to be tolerated. Each organization must have a process for immediate management when such behavior exists (The Joint Commission 2009 requirement).

21. Hard Stop

If any part of the verification process was not followed and/or a discrepancy is discovered, the procedure is halted and will not continue until the missing steps of the verification process are completed and the discrepancies resolved.

Resolution of discrepancies will include:

- reverification of patient identification,
- review of the information in informed consent documentation,
- review of the medical record,
- review of diagnostic studies, and
- discussion with the patient/legal guardian (if appropriate).

Conversations related to resolution of discrepancies will be held in a quiet location, away from activity/distractions. To consider a discrepancy resolved, confirmation of the correct procedure or surgical site and side must include all forms of documentation, as well as a discussion with the patient/legal guardian. After the discrepancy has been resolved, the procedure and site verification will be repeated.

If the steps of the verification process cannot be completed or are not completed and/or any discrepancies cannot be resolved, the procedure is canceled and rescheduled.

23. Venous Thromboembolism Prophylaxis, Beta-Blocker, Diagnostic Studies (If Necessary), Glycemic and Normothermia Management, Antibiotic Administration

Readministration of antibiotics for surgical site infection prophylaxis is based on the antibiotic selected and the length of the surgical procedure. Newer guidelines are recommending only a single dose of intravenous antibiotics for procedures lasting less than four hours. In procedures lasting more than four hours or when major blood loss occurs, re-dosing should occur every one to two half-lives of the antibiotic (in patients with normal renal function) so that the bactericidal concentrations are maintained in the tissues while the incision remains open *(Bratzler, 2005a [R]; Zanetti, 2001 [B])*.

Institutions may consider adding a reminder system or note on anesthesiology flow sheets close to the four-hour point of a surgery to prompt the question of whether to re-dose the antibiotic. This system may help

ensure that patients in longer surgeries receive sufficient concentration of antibiotic, while still decreasing the risk of antimicrobial resistance.

(Medical Letter, Treatment Guidelines, 2009 [R])

For most antibiotics, the concentration is reached 30 minutes after infusion.

Modifying the Safe Site Protocol to include antibiotic prophylaxis has been shown to increase timely antibiotic administration *(Peterson, 2006 [D])*.

(Medical Letter, Treatment Guidelines, 2006 [R])

Glycemic Control

Glycemic control planning and management

In patients undergoing heart surgery, increased intraoperative blood sugars were associated with increased complications *(Gandhi, 2005 [D])*. Intraoperative infusions of glucose, insulin and potassium in heart surgery have not demonstrated convincing benefits in multiple randomized trials *(Pittas, 2004 [M])*.

Lead Author	Timing	Population	Study Design	n	Results
Pittas	SICU	Diabetics, glucose control	Meta-analysis of 35 RCTs	na	Mortality decreased in all subgroups (O.R. less than 1.0)

Tight blood glucose control (80-110 mg/dL) using insulin infusion results in decreased mortality in surgical patients admitted to the intensive care unit.

- Insulin infusion is associated with decreased mortality and sternal wound infection in diabetic patients undergoing coronary artery bypass grafting.
- Obtain tight glucose control using insulin infusion in all surgical patients with diabetes until baseline oral intake and insulin dosing are restored.
- Consider closer monitoring and treatment of non-diabetic patients with hyperglycemia.

Lead Author	Timing	Population	Study Design	n	Results
Furnary	Postop	Diabetics with cardiac surgery	Prospective observational (two time periods subQ vs. drip insulin)	3,554	Mortality (subQ insulin vs. drip) 5.3% vs. 2.5%
Furnary	Postop	Diabetics with cardiac surgery	Prospective, observational (as above)	2,467	Sternal wound infection (subQ insulin vs. drip) 2.0% vs. 0.8%
Van den Berghe	Postop	Surgical ICU patients	Prospective, randomized: tight (80-110) vs. standard Rx	1,548	Mortality ("tight" vs. "standard") 7.2% vs. 10.9%

(Furnary, 1999 [C]; Furnary, 2003 [C]; Van Den Berghe, 2001 [A])

The work group acknowledges that while benefits of tight glucose control have been proven in critically ill patients, some diabetic patients, and postoperative cardiac surgery patients, there is controversy over which other patient populations may benefit from this type of glycemic control. Studies are ongoing, and further study regarding target glucose concentration, glucose variability, and consequences of hypoglycemia is warranted before tight glycemic control is implemented for every surgical patient *(Blondet, 2007 [R])*.

See the ICSI Subcutaneous Insulin Management order set for more information.

Normothermia Management

Refer Annotation #2, "Patient Arrives (Patient, Procedure and Site Verification)."

Beta-Blocker

Due to demonstrated efficacy, a beta-blocker regimen should be utilized to achieve and maintain a heart rate of 60-65 beats per minute during the intraoperative and postoperative period *(Fleisher, 2007 [R])*.

During surgery, the patient's blood pressure should be maintained within 20% of the baseline value *(Feneck, 2007 [M])*.

Venous Thromboembolism Prophylaxis

- When performing preoperative assessment, confirm that anti-embolism stockings/intermittent pneumatic compression devices are placed properly, and thromboprophylactic medications are given as ordered.
- Intermittent pneumatic compression devices should be turned on before the beginning of induction of general anesthesia or before regional anesthesia has been administered.
- Avoid extreme degrees of flexion/internal rotation of hip/knee in order to prevent endothelial damage due to abnormal leg positioning.
- Unnecessarily high tourniquet pressures and prolonged periods of inflation of tourniquets should be avoided if possible.
- Avoid reverse Trendelenburg position whenever possible.
- Check anti-embolism stockings for correct positioning during/after movement to operating/procedure room bed or during positioning.
- Ensure that intermittent pneumatic compression devices are working properly throughout the procedure.

24. Count New Items When Added to the Surgical Field

Refer to Annotation #11, "Baseline Count."

26. Repeat Time Out (Multiple Procedures/Position Changes)

Refer to Annotation #19, "Prior to Incision – Active Verbal Time Out."

27. Reverify/Pause If Internal Laterality/Implants/Spine Level)

If the procedure performed involves internal laterality, spine levels or the insertion of one or more implants, an intraoperative pause will be conducted. The pause will include the following elements (as appropriate):

- Side or site involved (e.g., left ovary, right kidney)

- Level to be entered (e.g., T4 left side) using images to validate location. Procedures involving level (spine or ribs) will have pre- and intraoperative imaging present in the operating/procedure room. Using high-quality imaging and best available technology, the level will be indicated using opaque markers with specific bony landmarks for the intraoperative imaging. The surgeon will stop after the initial incision and confirm the target level of the procedure by comparing the pre- and intraoperative imaging.
- Implant to be inserted, specifically the:
  - Implant specification/type/expiration date
  - Size
  - Side or laterality

The pause should include the surgeon, circulating nurse and scrub.

28. For Appropriate Cases, Do Wound or Body Cavity Exploration and Counts (Sponges/Soft Goods, Sharps, Instruments) Prior to Closure of Each Cavity

Body Cavity Entered/Created

Entering an existing body cavity or creating an artificial cavity during a surgical procedure, whether it is an open surgical wound or through a laparoscopic or hand-assisted procedure, increases the risk for an unintentionally retained foreign object. For the purposes of this protocol, an existing or artificially created body cavity are treated the same.

A methodical wound exploration will be performed prior to the closure of the wound and/or any body cavity. It is possible that the surgeon may perform multiple wound/body cavity explorations during the procedure (e.g., the stomach and abdominal cavities *(AORN, 2006 [R]; Eldridge, 2006 [NA]; American College of Surgeons, 2005 [R]; VHA Directive, 2006 [NA])*.

Whenever possible, the surgeon will use both visualization and touch during the cavity exploration. Generally, the type of surgical procedure performed guides the wound exploration technique employed. It is recommended that the wound exploration be methodical and performed by each physician the same way each time (e.g., top to bottom, quadrant to quadrant). For an example of a detailed methodical wound exploration process for open abdominal, pelvic or thoracic surgery, refer to Appendix E, "Veterans Administration Methodical Wound Exploration Process" *(American College of Surgeons, 2005 [R]; Council of Surgical and Perioperative Safety, 2005 [R]; Edlridge, 2006 [NA]; Gibbs, 2005 [R])*.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes clinically unstable. The method used to perform the wound exploration will be documented by the surgeon as part of the operative note.

The cavity exploration may be performed simultaneously with the counting by the scrub and circulator. The cavity will not be closed until counts have been reconciled. If the counts cannot be reconciled even after a thorough exploration of the cavity and the cavity is expected to be closed at the end of the procedure, an intraoperative film must be obtained prior to the cavity closure.

Intraoperative and Postoperative Period Algorithm Annotations

29. Leaving Wound Open?

Certain circumstances require that a wound be left open following a surgical procedure with the intent that the wound be left open or the patient return to the operating/procedure room at a later time for final wound closure. Examples of these cases include grossly contaminated wounds (Class III and IV wounds), and situations in which patient is unstable or has potential to develop instability (e.g., damage control procedure).

31. Perform Delayed Wound Closure/Open Packing, Final Count and Retained Foreign Object Prevention Process

When the closure of a wound is intentionally delayed (damage control) or when implants are used as part of the treatment (e.g., antibiotic beads, wound-vacuum sponges), the following will be performed:

- Radiopaque items will be used if that product is manufactured in a radiopaque form *(AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R])*.
- Count the items and document the item categories and numbers in the procedure record.
- Any sponges/soft goods packed in the operating/procedure room and removed must be counted and documented in the patient's medical record.
- Any sponge/soft goods added to the wound must be counted and documented in the patient's medical record.

32. Patient Returns to the Operating/Procedure Room for Final Wound Closure

- Count the sponges/soft goods, sharps and instruments that will be used in the final wound closure procedure and document them on a preformatted white board (or on a preformatted count worksheet if that is what your organization uses).
- When the patient returns to the operating/procedure room for final wound closure, sponges/soft goods used for the original packing should be isolated from sponges/soft goods used in the final wound closure procedure.
- Count items from the original packing as they are removed from the wound and reconcile the count with what was previously documented in the procedure record.
- When there is a discrepancy between what was removed and what was previously documented in the procedure record, an attempt to reconcile the discrepancy is performed as described in Annotation #35, "Hard Stop – Perform Reconciliation Process."
- Count the sponges/soft goods, sharps and instruments that were used in the final wound closure procedure and reconcile the count with what is documented on the preformatted white board (or on a preformatted count worksheet if that is what your organization uses).
- A thorough wound exploration is performed prior to closing the wound.
- When there is a discrepancy between the count and the count record, an attempt to reconcile the discrepancy is performed as described in Annotation #35, "Hard Stop – Perform Reconciliation Process."
- If radiopaque items were used, an intraoperative radiographic image should be obtained prior to final wound closure to ensure all items have been removed.

35. Hard Stop – Perform Reconciliation Process

Process for Managing Count Discrepancies

When a discrepancy in countable items is identified, the missing item and number are reported to the surgical team by the circulator. A discussion (involving the surgeon, circulator nurse and scrub) will occur during which the circulator will communicate to the surgeon the type(s) and number(s) of missing foreign objects. If the patient's condition permits, wound closure should be suspended during the discussion regarding the missing foreign object. If wound closure has begun it will not continue until the discussion occurs. This is a hard stop.

The work group recommends that the circulating nurse organize used countable items in such a way that counts (e.g., closing a cavity within a cavity, initial closing count, final count) performed after the baseline count can be performed effectively and efficiently. Sponge count bags and numbered needle boards are tools that will help to organize items for counting.

If a closing count is incorrect, the following steps will be taken to reconcile the count if the patient's condition permits *(AORN, 2006 [R]; VHA Directive, 2006 [NA])*:

(1) The surgeon *must* be notified immediately. A discussion will occur, during which the circulator will communicate to the surgeon the type(s) and number(s) of missing items. This is a hard stop.

(2) The circulating nurse will summon additional personnel to the operating/procedure room to assist with resolving the count.

(3) The surgeon will re-explore the wound paying special attention to the location where that particular item may be retained (e.g., sponges tucked behind organs).

(4) The count is repeated and verified. A discrepancy with the count will never be resolved by using the number listed on opened packages.

(5) Surgical closure may continue at the surgeon's discretion, but final skin closure cannot occur until all x-ray results are reviewed and communicated back to the surgeon by the radiologist.

(6) If the item is still missing after the recount and wound exploration, the scrub team must search the drapes, field, Mayo stand, and back table. At the same time, the circulating nurse must search the sponge count bag, trash, linen, floor, kick bucket(s) and all items that have been counted off the field. Sponges/soft goods will be unballed and separated for counting.

(7) If the item is located in this search, a complete recount *must* be conducted and the correct count documented.

(8) If counts cannot be reconciled by team members, and the missing item is radiopaque, notify the attending surgeon and obtain an x-ray order to "rule out retained foreign object."

(i) These images will be marked "STAT" and will be prioritized before other radiology requests.

(ii) Portable intraoperative imaging should be obtained and reviewed by the surgeon and radiologist before wound closure. See Annotation #37, "Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled."

(iii) The intraoperative film order will indicate a phone number for the appropriate operating/procedure room for proper follow-up to occur.

(iv) In response to a film ordered to "rule out retained foreign object," the interpreting radiologist will discuss the findings with the surgeon. The two individuals will view the images simultaneously to identify all findings. The name of the surgeon and time the call was made will be

recorded in the radiology report. Additional films with various angles may also be requested in order to view the possible retained foreign object.

If the counts cannot be reconciled, all the measures taken and the outcomes of those steps should be documented per the organization's policy. A radiographic image obtained in a radiology room with fixed equipment and moving grid should be obtained.

Note: The Minnesota Adverse Event Reporting law requires the reporting of a retained foreign object if an object is detected after skin closure. The above reconciliation steps give consideration to the current definition of a reportable event and are intended to avoid such an adverse event. The work group will continue to review for evidence supporting best practice.

Policy exception:

An exception may occur when the attending surgeon decides that any delay required for an intraoperative x-ray or removal of the foreign object(s) will cause harm to the patient due to their emergent medical condition.

37. Imaging If Counts Not Reconciled: Postoperative Follow-Up If Counts Remain Unreconciled

Radiographic imaging, whether a portable radiographic image obtained in the operating/procedure room or a postoperative image obtained in a radiographic room, is not a substitute for performing an accurate count process and methodical wound exploration.

An intraoperative radiographic image can be used to exclude the possibility of a retained foreign object. Portable radiographic imaging has limitations that should be considered, especially for visualizing micro needles. In addition, the type of imaging equipment (e.g., C-arm) used and cassette orientation relative to the surgical site should be considered.

The highest quality radiographic imaging is obtained in a radiographic room with fixed radiographic equipment and moving grid. If there are still unreconciled counts, it is recommended that the surgeon have a discussion with the patient and make a follow-up plan. The plan could include additional imaging (x-ray, computed tomography, magnetic resonance imaging).

Portable imaging considerations and limitations:

- patient condition
- size and type of retained item (non-radiopaque items, micro needles)
- limited placement options of the radiographic film cassettes under operating/procedure room tables limiting anatomy included on the images
- lower tube power
- instruments obscuring the image area
- availability of portable radiographic equipment and staff

Portable intraoperative imaging should be obtained when:

- counts are off and cannot be reconciled,
- the patient's condition did not allow for the count process to be followed (rushed counts, incomplete counts),
- any individual has a concern about the accuracy of the counts, or
- before final closure when the wound was previously intentionally left open/packed.

Imaging requests to rule out a possible retained foreign object need to include the following information:

- Callback number and surgeon's name
- Location and status of patient (e.g., in operating/procedure room with wound closure suspended, in post-anesthesia care unit)
- Type of surgery
- Type of item missing
- Details of the surgery as appropriate

The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. If the surgeon is unable to verify adequate anatomic coverage on the portable intraoperative images, postoperative radiographic imaging with fixed radiographic equipment should be obtained.

The work group recommends that the radiologist and surgeon simultaneously review the radiographic images both verbally and visually to correlate the anatomical coverage of the images with the surgical procedure, as well as a description of the potentially retained foreign object.

If a radiologist is not immediately available, the preliminary interpretation of the radiographic images to exclude a potentially retained foreign object is the responsibility of the surgeon.

Postoperative radiographic imaging in a radiographic room with fixed radiographic equipment and moving grid should be obtained as soon as possible when there is a discrepancy in the counts and:

- the patient's condition did not allow for intraoperative imaging to be obtained,
- the entire anatomic area was not included in the portable intraoperative imaging, or
- the intraoperative imaging failed to locate the retained foreign object and the counts could not be reconciled.

Prior to the radiographic images being interpreted by radiology, the surgeon will review the radiographic images for adequate anatomic coverage related to the procedure and operative site. The radiology technologist will review the radiographic images for quality and repeat the imaging as necessary *(AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R]; VHA Directive, 2006 [NA])*.

38. Close Wound

Close Wound and Finish Procedure

A radiographic image prior to closure of the wound does not need to be obtained when count processes are rigorously followed and all counts can be reconciled.

Post-procedure tasks

- Any countable item that accompanies the patient out of the operating/procedure room will be communicated to the circulator and documented *(AORN, 2006 [R]; Council on Surgical and Perioperative Safety, 2005 [R])*.
- After the counts have been reconciled, all items will be removed from the operating/procedure room. No items will be removed from the operating/procedure room until all counts have been reconciled and inspections completed.

- The white board will be cleaned at the end of the procedure and before setup begins for the next procedure.
    - Note: The date, time, type and number of any unaccounted for item will be recorded on the white board and communicated to each subsequent surgical team until the operating/procedure room is terminally cleaned.

Postoperative Period Algorithm Annotations

39. Patient Transport to Postoperative Care Location (Reverify Patient Identification, Allergies)

Receiving staff completes verification process and reviews for other pertinent patient-care related elements such as allergies, procedure completed, clinical information, etc., while establishing postoperative plan of care.

40. Venous Thromboembolism Prophylaxis, Beta-Blockers, Glycemic Control, Normothermia, Antiobiotic Re-dosing, Discontinue Antibiotics in 24 hours

It is recommended that each organization assign who is responsible for oversight and management of the following.

Postanesthesia Care (typically under the direction of the anesthesiologist) in Postanesthesia Care Unit: nursing care provided in the immediate post-anesthesia period following a surgical procedure.

Infection Prevention

- **Antibiotic Re-dosing**

  The bactericidal concentration of antibiotics should be present in the tissues a few hours, at most, after the incision has been closed *(Mangram, 1999b [R])*. Antibiotic prophylaxis within the first 24 hours in the absence of infection is left to the discretion of the surgeon. Refer to Annotation #23, "Venous Thromboembolism Prophylaxis/Beta-Blocker/Diagnostic Studies (if Necessary)/Glycemic and Normothermia Management/Antibiotic Administration."

- **Inspired FIO2**

  The effects of the level of inhaled oxygen on surgical site infection rates have been studied. Although an initial study provided evidence that patients who received high levels of inhaled oxygen during colorectal surgery developed fewer surgical site infections *(Greif, 2000 [A])*, data to the contrary recently have been reported *(Pryor, 2004 [A])*. Unfortunately, several of the aforementioned studies report surgical site infection rates among study patients that are higher than those reported and expected among similar groups of patients, making comparison difficult. Of note, stratification using the NNIS classification methodology was not employed. Further evaluation via multicenter studies is needed prior to implementation of these modalities as standard therapies.

Normothermia Management

Upon arrival to post-anesthesia care units, initial patient assessment should include signs of hypothermia. Postoperative shivering, while an effective thermoregulatory mechanism, results in increased cardiac stress and

should therefore be treated using active warming devices *(Brauer, 2004 [A]; Kurz, 1996 [A]; Melling, 2001 [A]; Nesher, 2005 [A])*. Isolated shivering in a normothermic patient can be treated with meperidine.

Patients undergoing procedures employing cardiopulmonary bypass should be rewarmed using an active warming device. The use of any device is more important than the specific type of device.

Postoperative Management (typically under the direction of the surgeon, intensivist and anesthesiologist)

Infection Prevention

- **Antibiotic discontinuation**

  There is evidence that extending antibiotic prophylaxis past 24 hours does not decrease the risk of surgical site infection and does increase the potential for patient intolerance and complications *(Bratzler, 2005b [B]; Mangram, 1999a [R]; Mui, 2005 [A]; Prokuski, 2006 [R])*.

- **Hand hygiene**

  - Skin is a major potential source of microbial contamination.
  - Hand hygiene is a critical step in prevention and spread of infection. It is the single most important step in the prevention of infection.
  - Hand washing by nursing staff and physicians managing wound dressings should take place before and after every contact. Hand gels appear to be as effective as washing with soap.

  (Mangram, 1999a [R])

Normothermia Management

Body temperature should be maintained as close to normal as possible, using any of a variety of safe, non-invasive means.

Glucose Control

Refer to Annotation #1, Preoperative Evaluation and Surgical Planning and Scheduling."

Beta-Blockers

Studies have shown that beta-blockers should be continued through hospitalization, if not longer. Beta-blockers should be tapered, instead of abruptly discontinued, to avoid hyperadrenergic withdrawal responses. One study observed an increased risk for postoperative myocardial infarction in patients who had beta-blockers discontinued immediately after surgery. Other studies indicated that therapy could be discontinued after the first postoperative week in low- to moderate-risk patients, and should be continued at least 14 to 30 days postoperatively in patients undergoing vascular procedures. Patients who had been receiving long-term therapy may be maintained on a regimen for continuity of therapy *(Mason, 2006 [R])*.

Venous Thromboembolism Prophylaxis

- Continue established protocol orders for deep vein thrombosis/pulmonary embolism prevention (mechanical and/or pharmacologic prophylaxis). Refer to ICSI Venous Thromboembolism Prophylaxis guideline.
- Ensure intermittent pneumatic compression devices, if used, do not hinder ambulation and are not removed for long periods of time.

- Ensure that intermittent pneumatic compression devices, if used, are turned on and are working properly; confirm with nurse assuming care.
- Instruct patient in importance of moving and ambulation per the surgeon's postoperative orders.

(AORN Guideline for Prevention of Venous Stasis, 2007 [R])

Incision Management and Wound Care

- Protect the incision with sterile dressing for 24-48 hours.
- Minor surgical wounds can be allowed to get wet in the first 48 hours without increasing risk of infection *(Heal, 2006 [A])*.
- Extremity wounds may be covered with a clear film dressing, which reduces the rate of blistering and exudates *(Cosker, 2005 [A])*.
- Surgical wounds in children may be left without dressings without additional risk of infection *(Merei, 2004 [A])*.
- Limb amputation wounds are best treated with rigid postoperative dressings to reduce the rate of infection.
- There are no unique advantages to any type of dressing/packing following septoplasty.

41. Dismiss Patient/Discharge Planning: Patient Education/Glycemic Management/Follow-Up Appointments

Hospital stay should be as short as possible. Current literature supports the subrecommendations listed below.

Patient Education

- Patients and families should be educated on how to manage their postoperative pain, incision and wound care including the signs and symptoms of potential infection, frequency of dressing changes and wound cleaning, and how to manage other risk factors such as diabetes, incontinence, impaired immune status/response, and other factors.
- Patients and families should be educated on eating and drinking guidelines, alcohol consumption, and personal hygiene (e.g., shower/bathing) medication reconciliation and My Medicine List. This education should be provided and led by the nurse.
- All patients should be informed not to go to work or drive a vehicle until completely recovered. They should also avoid alcohol and delay making important decisions for at least 48 hours *(Knottenbelt, 2007 [X])*.
- All patients should be educated on the signs and symptoms of surgical site infection including *(Mangram, 1999a [R])*:
  - purulent discharge;
  - pain or tenderness, localized swelling, redness or heat around the incision area;
  - fever over 38°C; and
  - spontaneous separation of the incision.
- Patients and families should be provided emergency contact numbers and instructions on whom to call.

- Nurse must confirm that discharge instructions have been explained and patients and family confirm they understand by a verbalized response. Patients often forget verbal instructions or ignore them; therefore, written instructions should be provided *(Schlossberg, 1992 [X])*.
- Nurse should verify relevant care assistance for at least 24 hours.
- Patient and families should be educated on the importance of good hand hygiene in the prevention of infection. Patients and families managing wound dressings should wash their hands (either soap and water or waterless hand gels) before and after every contact. Hand gels appear to be as effective as washing with soap *(Mangram, 1999a [R])*.
- Patients and families should be instructed on proper incision and wound care recommendations:
  - Protect the incision with sterile dressing for 24-48 hours.
  - Minor surgical wounds can be allowed to get wet in the first 48 hours without increasing risk of infection *(Heal, 2006 [A])*.
  - Extremity wounds may be covered with a clear film dressing, which reduces the rate of blistering and exudates *(Cosker, 2005 [A])*.
  - Surgical wounds in children may be left without dressings without additional risk of infection *(Merei, 2004 [A])*.

Glycemic Control

Patients with diabetes should receive instructions on the additional benefit of good glucose control for the prevention of surgical site infections. In patients with diabetes, outcomes are improved in those with preoperative Hgb A1C less than 7; however, there is not any data on interventions to allow tight control *(Dronge, 2006 [B])*.

Beta-Blockers

Refer to Annotation #40, "Venous Thromboembolism Prophylaxis, Beta-Blockers, Glycemic Control, Normothermia, Antiobiotic Re-dosing, Discontinue Antibiotics in 24 Hours."

Follow-Up Appointments

Patients should be encouraged to schedule and keep all follow-up appointments with their surgeon and primary provider. Follow-up appointments provide the opportunity for the surgeon and primary provider to assess the patient for signs and symptoms of infection related to the surgical procedure and intervene or modify the care plan as appropriate *(Mangram, 1999a [R])*.

Appendix A – Incorporating Human Factors Systems Design into Work Process Design

Two large population-based studies of medical injury published in 1991 and 2000 led to the initiation of many efforts to reduce medical error. The first of the studies, the Harvard Medical Practice Study (HMPS), examined the outcomes of 30,121 randomly chosen patient cases from 51 hospitals in New York State in 1984 *(Brennan, 1991 [C]; Leape, 1991 [C])*. In the second, the Utah and Colorado Medical Practice Study (UCMPS), the records of 14,052 randomly selected hospitalizations from 28 hospitals in Utah and Colorado in 1992 were reviewed *(Thomas, 2000 [C])*. Similar results were found in both studies, and extrapolation from the results of the most recent of the studies, the UCMPS, indicates that approximately 44,000 deaths recorded in 1997 in the United States of America could have occurred as a result of preventable adverse events. Many efforts to reduce medical error that were initiated as a result of these studies have included Human Factors methodology to investigate and improve health care systems.

Human Factors emphasizes designing systems and producing work processes that enhance human performance. Human Factors Systems Design considers weaknesses and strengths in the entire medical delivery process from diagnosis through the prescription and delivery of treatment, and includes examining the work processes of, for example, surgeons, anesthesiologists, nurses, scrub technicians, phlebotomists, pharmacists, and health unit coordinators.

Human Factors Systems Design focuses on how the work process and performance of health care providers are affected by issues such as work space design; the functionality and ease of using electronic medical records systems; distractions and interruptions; workload; the complexity, length and urgency of procedures, fatigue and personal stress; intra- and interdepartmental communication issues; staffing requirements; the use of float staff; shift changes; staff competencies; and training.

Human Factors Systems Design seeks to identify the probable and potential causes of errors and to identify factors contributing to safety gaps in medical processes. Then design improvements, based on Human Factors principles, are developed so that the errors and safety gaps are addressed without introducing problems elsewhere in the system. The goal is to foster better work environments, minimize potential errors, improve patient care, and enhance patient safety.

Communication Factors and Events

In root cause analysis findings submitted to The Joint Commission in the 10 years from 1995 to 2005, the number one reason identified as causal in all sentinel events was communication *(Joint Commission of Accreditation Organization, 2006 [NA])*. In 2006, in an attempt to address these findings, The Joint Commission required accredited organizations to implement a national patient safety goal (NPSG) related to communication. While organizations have been given flexibility in determining how to meet the expectations of this goal, many have adopted SBAR (situation, background, assessment and recommendation) as one way of improving communication. While SBAR has its origins in the nuclear power and commercial aviation industries, it has been successfully adapted to the medical community *(Haig, 2006 [D])*.

One of the benefits of this communication model is that it addresses the different ways in which physicians are trained to communicate versus other health care professionals, especially nurses *(Leonard, 2004 [D])*.

One mechanism to decrease events, including retained items, is the use of preprocedural briefings. The purpose of a briefing is to ensure that all the members of the team are working toward a common goal and are aware of any concerns the physician/nurse midwife may have related to the procedure. The briefing also provides a platform for any member of the team to raise a misgiving *(ECRI, 2005 [R])*. At the conclusion of the procedure, team members can debrief the process to identify what went well, what could have been done differently, and what can be done the next time *(ECRI, 2005 [R])*.

Both communication methodologies promote the use of "stop the line." Again, developed outside the health care industry, this concept allows any member of the team to speak up about a patient safety concern at any time during the procedure. Implementing a "stop the line" process requires a culture that promotes and rewards behaviors consistent with patient safety efforts. No matter the outcome, the willingness of the individual to raise a concern is directly related to the organization's administrative support of the action.

(Lingard, 2004 [D]; Harder, 2006 [D])

Distractions, Environmental Factors and Events

When an event occurs, one of the contributing factors that are explored is the environment. Noise in the procedure room, including music, can interfere with the team's ability to communicate, increase stress levels and adversely affect motor skills *(Vincent, 2004 [R])*. Distractions (e.g., pagers in the Labor and Delivery room) and interruptions by individuals not directly involved should be kept to a minimum, especially during critical stages of a procedure *(ACOG, 2006 [R])*. Other factors that should be taken into consideration when evaluating the environment are adequate lighting in the room for team members to see clearly and read labels, unpleasant odors that may be a direct result of the procedure being performed, or the room temperature. While the latter two factors may be outside the direct control of the team members, nonetheless they should be taken into consideration and recognized as risk factors for an event.

Appendix B – List of Invasive, High-Risk or Surgical Procedures*

- Any procedures involving skin incision
- Any procedures involving general or regional anesthesia, monitored anesthesia care, or conscious sedation
- Injections of any substance into a joint space or body cavity
- Percutaneous aspiration of body fluids or air through the skin (e.g., arthrocentesis, bone marrow aspiration, lumbar puncture, paracentesis, thoracentesis, suprapubic catheterization, chest tube)
- Biopsy (e.g., bone marrow, breast, liver, muscle, kidney, genitourinary, prostate, bladder, skin)
- Cardiac procedures (e.g., cardiac catheterization, cardiac pacemaker implantation, angioplasty, stent implantation, intra-aortic balloon catheter insertion, elective cardioversion)
- Endoscopy (e.g., colonoscopy, bronchoscopy, esophagogastric endoscopy, cystoscopy, percutaneous endoscopic gastrostomy, J-tube placements, nephrostomy tube placements)
- Laparoscopic procedures (e.g., laparoscopic cholecystectomy, laparoscopic nephrectomy)
- Invasive radiological procedures (e.g., angiography, angioplasty, percutaneous biopsy)
- Dermatology procedures (biopsy, excision and deep cryotherapy for malignant lesions – excluding cryotherapy for benign lesions)
- Invasive ophthalmic procedures, including miscellaneous procedures involving implants
- Oral procedures including tooth extraction and gingival biopsy
- Podiatric invasive procedures (removal of ingrown toenail, etc.)
- Skin or wound debridement performed in an operating/procedure room
- Electroconvulsive treatment
- Radiation oncology procedures
- Central line placement
- Kidney stone lithotripsy; and
- Colposcopy, and/or endometrial biopsy

Procedures **NOT** considered surgical, high-risk or invasive include:

- Electrocautery of lesion
- Venipuncture
- Manipulation and reductions
- Chemotherapy/oncology procedure
- Intravenous therapy
- Nasogastric tube insertion
- Foley catheter insertion
- Flexible sigmoidoscopy
- Vaginal exams (Pap smear)

This list is not meant to be comprehensive and was drawn from United States Department of Veterans Affairs. The PDF version of VHA Directive 2004-028 was last accessed on June 16, 2009, at http://www1.va.gov/vhapublications/ViewPublication.asp?pub ID=1106.

Appendix C – Cephalosporin Side-Chain Similarity Determinations Table

Side-chain similarity determines cross-reactivity among cephalosporins and between penicillins and cephalosporins.

To use this table clinically, check the antibiotic your patient is allergic to for possible cross-reactivity with other antibiotics based on both the 7-position and 3-position side-chains. Avoid drugs that share structural similarity of either side-chain position. Antibiotics that do not share similarity of either side-chain are unlikely to exhibit cross-reactivity and can be recommended.

7-POSITION SIDE-CHAIN				
SIMILAR SIDE-CHAIN CROSS-REACTIVITY POSSIBLE WITHIN THESE 3 GROUPS*			**COMPLETELY DISSIMILAR SIDE-CHAINS MAKE CROSS-REACTIVITY UNLIKELY FOR THESE DRUGS†**	
Cefoxitin (2)	Cefaclor (2)	Cefepime (4)	Cefoperazone (3)	Cefixime (3)
Cephalothin (1)	Cephradine (1)	Ceftizoxime (3)	Cefotetan (2)	Cefprozil (2)
Penicillin G	Cephalexin (1)	Cefpirome (4)	Cefazolin (1)	Cefmetazole (2)
	Cefadroxil (1)	Cefotaxime (3)	Cefuroxime (3)	Ceftibuten (3)
	Amoxicillin	Cefpodoxime (3)	Cefdinir (3)	Ceftazidime (3)
	Ampicillin	Ceftriaxone (3)	Cefditoren (3)	

3-POSITION SIDE-CHAIN						
SIMILAR SIDE-CHAIN CROSS-REACTIVITY POSSIBLE WITHIN THESE SIX GROUPS‡						**DISSIMILAR SIDE-CHAINS MAKE CROSS-REACTIVITY UNLIKELY FOR THESE DRUGS§**
Cefadroxil (1)	Cefmetazole (2)	Cefotaxime (3)	Ceftibuten (3)	Cefuroxime (2)	Cefdinir (3)	Cefpodoxime (3)
Cephalexin (1)	Cefoperazone (3)	Cephalothin (3)	Ceftizoxime (3)	Cefoxitin (2)	Cefixime (3)	Cefprozil (2)
	Cefotetan (2)					Ceftibuten (3)
						Ceftriaxone (3)
						Cefepime (4)
						Cefpirome (4)
						Cefazolin (1)
						Cefaclor (2)
						Ceftazidime (3)

* Based on the 7-position side-chain structure similarity, allergic cross-reactivity might occur among cefoxitin (second-generation cephalosporin), cephalothin (first-generation cephalosporin) and penicillin. The same interpretation applies to the next two columns.

† Based on the 7-position side-chain structure uniqueness, allergic cross-reactivity would be highly unlikely for all of these cephalosporins with each other and with all other cephalosporins, as well as with penicillins.

‡ Based on the 3-position side-chain structure similarity, allergic cross-reactivity might occur between cefadroxil (first-generation cephalosporin) and cephalexin (first-generation cephalosporin). The same interpretation applies to the next five columns.

§ Based on the 3-position side-chain structure uniqueness, allergic cross-reactivity would be highly unlikely for all these cephalosporins with each other and with all other cephalosporins, as well as with penicillins.

Reprinted with permission from Cephalosporins Can Be Prescribed Safely for Penicillin-Allergic Patients. *J Family Prac*, 2006;55:106-12.

Appendix D – Overview of Topical Antiseptics Used for Preoperative Skin Preparation

The properties listed in the left-hand column are those that are desirable in a skin preparation product. No one product has all desirable traits and is also without potential risk. No studies have adequately assessed the comparative effects of these preoperative skin antiseptics on surgical site infection risk in well-controlled, operation-specific studies.

Properties	Chlorhexadine (CHG)	Povodine-iodine (PVP-I)	Alcohol	CHG + Alcohol	PVP-I + Alcohol	PCMX
Examples of trade names	Hibiclens	Betadine	Alcohol	Chloraprep	Duraprep	Technicare*
Killing gram pos. bacteria	Excellent	Excellent	Excellent	Excellent	Excellent	Good
Killing gram neg. bacteria	Good	Good	Excellent	Excellent	Excellent	Fair (*Good against Pseudomonas*)
Rapidity of action	Intermediate	Intermediate	Most Rapid	Rapid	Rapid	Intermediate
Persistence	Excellent	Minimal but will maintain as long as present on skin	None	Excellent	Minimal but will maintain as long as present on skin	Good
Maintains activity in presence of organic material	Yes	No	No	Yes	No	Yes
Minimal systemic absorption	Yes	No	Yes	Yes	No	Yes
Toxicity	Ototoxicity Corneal injury Avoid contact with meninges Keep away from eyes, ears and mouth	Absorption from skin with possible thyroid toxicity – especially in low-birth-weight infants	Drying to skin Should not be used near eyes	Ototoxicity Corneal injury Avoid contact with meninges Keep away from eyes, ears and mouth	Drying to the skin Absorption from skin with possible thyroid toxicity – especially in very-low-birth-weight infants	Non-toxic in the Technicare formulation
Comments	Incidence of skin irritation minimal. When used for cleansing superficial wounds, will not cause additional tissue injury or delay healing. May be more effective and safer than iodophors	Significant transcutaneous absorption may occur after the topical application in infants and can cause alterations in thyroid function – especially in very-low-birth-weight infants.	Flammable – care must be taken to remove excess liquid and allow to completely dry prior to using cautery	See comments on CHG and alcohol	See comments on PVP-I and alcohol. Duraprep adds benefit of "shellac" type activity that adheres to the skin and *may* inhibit organisms from releasing into the wound.	Can be used for treatment of chronic wounds. Is not harmful to eyes or ears

References:
MicroMedex Online
CDC Guidelines for Prevention of Surgical Site Infection – 1999
CareTech Laboratories information on Technicare online: http://www.caretechlabs.com/DesktopDefault.aspx?tabid=18
*** Reflects published data – however, formulation enhances the performance of PCMX. See Caretechlab.com.**
Prepared by Sue Gustafson, Infection Control Department, Fairview Health Services, 2/16/2005

Appendix E – Veterans Administration Methodical Wound Exploration Process

A methodical wound exploration will be performed prior to the closure of that cavity. Surgeons will use both touch and sight during the exploration whenever possible and should not rely on just one sensory perception.

A methodical wound exploration may be omitted or abbreviated in an extreme patient emergency or if the patient becomes critically unstable. This exception will be documented in the surgical record and if appropriate, a radiograph should be performed as soon as is reasonable, based on the patient's condition.

Abdominal and Pelvic Process

Unless contraindicated for a specific patient, these steps should be performed prior to the removal of stationary or table-mounted retractors. The methodical wound exploration process includes the exploration of all four quadrants of the abdomen.

- Lift and examine around the transverse colon.
- Examine above and around the liver.
- Examine around the spleen.
- Examine within and between the loops of bowel.
- For the pelvis:
  - Examine behind the bladder.
  - Examine behind the uterus (if present).
  - Examine around the upper rectum.
- Examine the area inside of the vagina if it was entered as part of the procedure.
- Examine in and around any place a retractor or retractor blades were placed.

Mediastinum or Thorax Process

Unless contraindicated for a specific patient, these steps should be performed for all procedures involving the mediastinum or thorax.

- For cardiac procedures:
  - Examine the heart by elevating the apex of the heart and examine the retrocardiac space.
  - Examine the transverse sinus to the right and left of the aorta and pulmonary vein.
  - For procedures involving the mediastinum, if the mediastinal pleura was opened, examine the ipsilateral pleural cavity.
  - For thoracic procedures:
    - Examine the thoracic cavity, paying particular attention to the thoracic apex and base of the lungs, paravertebral sulcus and inferior recesses. Examination includes placing a hand or finger behind the lung and palpating from apex to base.

Appendix F – Protocol

The Perioperative Protocol is for patients of all ages having any type of surgical procedure procedure performed in the operating/procedure room.

Preoperative Evaluation and Surgical Planning and Scheduling

- Scheduling
  - Corroboration among scheduled procedure, surgical consent, source document and physician order
- Evaluation
  - Preoperative evaluation, testing, surgical planning
  - Nutritional assessment
    - Risk factors for surgical site infection
  - Penicillin allergy management
    - Use of certain cephalosporins for penicillin-allergic patients
  - Methicillin-resistant staphylococcus auerus identification
  - Glycemic control for diabetic patients
  - Patient education
    - Skin preparation night before and morning of surgery

Patient Arrives

- Patient, procedure and site verification
- Items included in the pre-procedure verification include the following:
  - Patient's identity, using two identifiers
  - Procedure name and site in the informed consent documentation
  - Information in the medical record
  - Diagnostic studies
  - Discussion with the patient/legal guardian
- Glycemic planning and management
- Antibiotic selection and administration
- Normothermia management
- Venous thromboembolism management
- Beta-blocker planning and management
- Methicillin-resistant staphylococcus auerus planning and management
- Perioperative statin therapy

Environmental Controls/Infection Control/Operating/Procedure Room Survey

- Hand hygiene
- Operating/procedure room surfaces
- Sterilization of devices
- Surveillance of surgical site infections
- Operating/procedure room survey
  - Remove all items related to previous patient, including records, label, films
  - Limit and check receptacles in room
  - Verify white board and record keep documents are cleaned from previous procedure

Pre-Procedure Planning and Preparation

- Review of surgeons orders, equipment, preference cards
- Special needs considered: patient height, weight, positioning, allergies
- Operating/procedure room equipment in working order
- Ensure all needed instruments and implants if applicable are available.
- Ensure that all staff are available: residents, hemodynamic staff, company representatives, etc.

Site Marked with Surgeon Initials

- Prior to marking the site, the provider will complete a procedure verification.
- The site will be marked using a surgical marker that will be visible when the patient is positioned.
- For multiple sites/digits on the same anatomic site, they will be marked appropriately following the informed consent documentation.
- For procedures involving midline or orifice entry, the laterality will be indicated on the informed consent documentation.
- For procedures involving level (spine or ribs), the informed consent will indicate the laterality and level and the site will be marked to indicate anterior or posterior, and general level (cervical, thoracic, lumbar, or rib number).
- Site sensitive areas may be marked above or lateral to the procedure site.

Site Marking Not Required

- Site marking is not required when the provider performing the procedure is in continuous physical presence with the patient from arrival for the procedure to its conclusion.
- Patient refusals
- Site marking where the marking would cause harm

Anesthesia Patient Identification and Verification Process for Block/Anesthesia

- Patient identification and procedure verification
- Anesthesia marking (should NOT be initials)

Hard Stop

- The procedure will be halted if any questions or discrepancies during any part of the verification steps and will not resume until the discrepancy is resolved.

Repeat Verification Process If Patient Has Been Moved or Care Team Changes

- Repeat patient identification and procedure verification

Baseline Count

- Items included in the count process include:
  - Sponges/soft goods – only radiopaque sponges will be present in the surgical field
  - Sharps
  - Miscellaneous items
  - Instruments, for procedures where the possibility exists that a particular instrument could be unintentionally left behind
  - In addition to the items listed above, all non-radiopaque items will be counted.
- The count process will be performed at the following times:
  - A baseline count will occur before the patient is brought to the surgical suite unless parallel processing is used. For the count process using parallel processing, two separate circulators will be needed: one dedicated to the count process and one dedicated to the patient care and setup.
  - Closure of a cavity within a cavity
  - Before wound closure
  - At the end of the procedure
  - Any time a member of the surgical team has concerns about the accuracy of the count process
  - Whenever there is a permanent staff change of the circulator
  - When closure of the wound in intentionally delayed (damage control), temporary implants are used, or a wound is temporarily closed with a non-radiopaque item (e.g., wound vacuum sponge)

- The count process will be performed in the following manner:
  - The circulator and scrub person (one of whom must be a registered nurse) will directly view the items being counted and will count out loud concurrently.
  - The circulator will document the number and type of sponges/soft goods, sharps, miscellaneous items, and instruments on a preformatted white board or other standardized, preformatted documentation record. The scrub person verbally confirms the number.
  - All items will be counted in the same order for each count, usually in the order listed on the white board.
  - Soft goods will be separated and counted individually
  - Sponges/soft goods will have visual verification that the radiographic-detectible indicator is present.
  - Instruments will be counted in sets.
  - Counts will begin at the surgical field and move away from the patient.
  - Items added during the procedure will be counted prior to entering the surgical field and documented on the white board as soon as possible.
  - Used sponges/soft goods will be unballed and pulled apart for the count process.
  - Instruments and sharps will be inspected for broken or missing pieces for the count process.

Briefing

- Ideally the briefing should be conducted in the operating/procedure room after anesthesia induction and before patient positioning and should at a minimum include the following:
  - Introduction of individual team members
  - Any special patient needs or potential issues
  - Anticipated problems
  - Patient positioning
  - Status of the patient consent
  - Patient allergies
  - Medications (e.g., antibiotics) given or to be given
  - Anticipated blood components
  - Specimens, if applicable, and how they should be handled
  - Pathology
  - Discussion about radiological images, if applicable
  - Discussion of implants, if applicable
  - Details regarding special equipment
  - Discussion of any special intraoperative requests (e.g., surgeon informs circulating nurse and scrub about times during the procedure when he or she would prefer that they avoid taking a break)
  - Team members are asked whether or not they have any other concerns or issues related to the patient or the procedure.

Patient Transported to Operating/Procedure Room

- Anesthesia care provider completes final verification of the following:
  - Consent is complete
  - Verification of patient's identification
  - Universal protocol checklist completed by all required staff
  - Operative site marked as appropriate
  - Notification to preoperative staff that patient is being moved to the operating/procedure room Upon arrival to the operating/procedure room, anesthesia care provider and circulating nurse verify patient identification, surgeon and procedure before moving patient to the operating/procedure table.

Environmental Controls

- Preoperative scrub
- Surgical asepsis
- Temperature controls
- Vendor access
- Noise

Anesthesia Administration

- Prior to regional block, a "procedural Time Out" is performed between the anesthesia professional, the patient and staff
- Prior to anesthesia of any type and for all cases, a verification Time Out is completed

Position Patient/Verify Site Marking/Hair Removal

- Prior to incision:
  - Hair removal (if hair removal is necessary, use clippers)
  - Skin preparation
  - Complete antibiotic administration (within 60 minutes of incision)

Time Out

- Performed immediately prior to start of the procedure and initiated by surgeon
- Elements included:
  - Patient identity, using minimum of two identifiers
  - Procedure(s) to be performed
  - Patient positioning if not already verified
  - Procedure side, site and/or level including visualization of surgeon's initials
  - As appropriate imaging, equipment, implants or special requirements (e.g., pre-procedure antibiotics)
- Recommended order of verification:
  1. Circulator
  2. Anesthesia care provider
  3. Scrub
  4. Surgeon
- Additional Time Outs are performed when two or more different procedures are performed during the same procedure time.
- If repositioning is required, an abbreviated Time Out is conducted.
- If the procedure involves a single provider, an abbreviated Time Out is still required.

Hard Stop

- The procedure will be halted if any questions or discrepancies during any part of the verification steps and will not resume until the discrepancy is resolved.

Count New Items Added to Surgical Field

- Follow count process outlined for baseline count.

Intra-Procedure Management

- Antibiotic re-dosing as required based upon length of surgery
- Glycemic control
- Normothermia management (monitor continuously or every 30 minutes and warm patient as indicated)
- Beta-blocker therapy
- Venous thromboembolism
  - Intermittent pneumatic compression devices turned on before anesthesia administration
  - Avoid Trendelenburg position when possible
  - Check for correct positioning of anti-embolism stockings

Intra-Procedure Pause

- The provider will conduct an Intra-Procedure Pause to confirm internal laterality/level/implant prior to proceeding in the following situations:
  - Procedures that have midline or orifice entry
  - Procedures involving level (spine or ribs)
  - Implants (specifications/type/expiration date, size, laterality)

Wound or Body Cavity Exploration and Count Prior to Closure of Each Cavity

- A methodical wound exploration will be performed prior to the closure of the wound and/or any cavity.
- The type of surgical procedure will guide the wound exploration technique employed.

Close Wound and Finish Procedure

- Radiographic imaging prior to wound closure does not need to be obtained when count processes are rigorously followed and all counts can be reconciled.

Wound Closure Delayed/Open Wound Packing

- The number and type of items used in the wound packing will be documented in the procedure record.
- Any items removed or added to the wound must be counted and documented in the patient's medical record.
- When the patient returns to the operating/procedure room for final wound closure, items used in the original packing will be isolated and counted separately from the items used in the final wound closure procedure. Both counts should be reconciled prior to wound closure.
- If a discrepancy is noted, an attempt should be made to reconcile the discrepancy.
- A thorough wound exploration will be performed.
- If radiopaque items were used, portable intraoperative imaging should be taken prior to final wound closure.

Hard Stop – Perform Reconciliation Process for Count Discrepancies

- When a discrepancy is identified, the number and type of item missing are reported to the surgical team by the circulator.
- A decision is held within between surgical team, if patient's condition permits, wound closure should be suspended during discussion.
- A manual inspection of the operating/procedure room is conducted, including a visual inspection of the area surrounding the surgical field, the floor, kick buckets, linens, and trash receptacle.
- The count is repeated and verified.
- The wound is reexplored.
- Portable intraoperative imaging is obtained if the counts cannot be reconciled.

Patient Transported to Postoperative Care Location

- Receiving staff completed verification process and reviews for pertinent patient-care related elements such as allergies, procedure completed, clinical information, etc.

Postoperative Management

- The following items should be addressed in the immediate postoperative period:
  - Antibiotic discontinuation
  - Normothermia management (monitoring for hypothermia and warm patient as indicated)
  - Glucose control
  - Incision management (sterile dressing over incision for 24-48 hours)
  - Beta-blocker continuation
  - Venous thromboembolism prophylaxis

Dismiss Patient/Discharge Planning

- Patient education to include
  - Signs and symptoms of surgical site infection
  - Incision and wound care recommendations
  - Hand hygiene
  - Postoperative pain control
  - Follow-up appointments

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Brief Description of Evidence Grading

Individual research reports are assigned a letter indicating the class of report based on design type: A, B, C, D, M, R, X.

A full explanation of these designators is found in the Foreword of the protocol.

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This section provides resources, strategies and measurement specifications for use in closing the gap between current clinical practice and the recommendations set forth in the protocol.

The subdivisions of this section are:

- Priority Aims and Suggested Measures
  - Measurement Specifications
- Key Implementation Recommendations
- Knowledge Resources
- Resources Available

Priority Aims and Suggested Measures

Outcome Aims and Measures

1. Eliminate the wrong surgical procedure or surgery performed on the wrong body part, or on the wrong patient. *(Annotations #15, 19)*

   Possible measures for accomplishing this aim:

   Outcome Measures:

   a. Wrong surgery events per month.

   b. Rate of wrong surgery events per month.

   c. Near misses reported per month.

2. Eliminate unintentionally retained foreign objects during a surgical procedure. *(Annotations #11, 24, 37)*

   Possible measures for accomplishing this aim:

   Outcome Measure:

   a. Number of unintentionally retained foreign objects in surgery.

   b. Rate of unintentionally retained foreign objects in surgery.

3. Decrease the rate of infections in surgical patients undergoing clean surgery. *(Annotations #2, 3)*

   Possible measure for accomplishing this aim:

   Outcome Measures:

   a. Rate or percentage of postoperative wound infection in patients undergoing clean surgery. (IHI, 5M Lives Campaign)

Process Aim and Measures

4. Improve the adherence of the key components of the Perioperative Protocol. *(Annotations #1, 2, 3, 5, 9, 11, 14, 15, 19)*

   Possible measures for accomplishing this aim:

   Process Measures:

   a. Percentage of surgical patients with documentation of preoperative verification of correct patient, procedure, and site/side/level.

   b. Percentage of appropriate surgical patients who had their site marked by the surgeon in preoperative with his/her initials.

   c. Percentage of surgical cases in which a verbal, active Time Out has been conducted by all appropriate members of the surgical team prior to incision.

   d. Percentage of surgical cases where the baseline count was conducted prior to the patient arriving in the operating/procedure room.

   e. Percentage of surgical cases where counts were not reconciled and imaging was performed.

   f. Percentage of surgical patients with prophylactic antibiotic received within 60 minutes prior to surgical incision. (SCIP-Inf-1*)

g. Percentage of surgical patients receiving prophylactic antibiotic selection consistent with guidelines for specific surgical type. (SCIP-Inf-2*)

h. Percentage of surgical patients whose prophylactic antibiotic is discontinued within 24 hours after surgery end time. (SCIP-Inf-3*)

i. Percentage of cardiac surgery patients with controlled 6 a.m. blood glucose (greater than or equal to 200 mg/dL) on postoperative day one and postoperative day two. (SCIP-Inf-4*)

j. Percentage of selected surgical patients with appropriate surgical site hair removal. (SCIP-Inf-6*)

k. Percentage of patients with urinary catheter removed on postoperative day one or postoperative day two with day of surgery being zero. (SCIP-Inf-9*)

l. Percentage of selected surgical patients with immediate postoperative normothermia (greater than or equal to 96.8ºF) within 15 minutes after leaving the operating/procedure room. (SCIP-Inf-10*)

m. Percentage of surgical patients on beta-blocker therapy prior to admission who received beta-blocker during the perioperative period. (SCIP-Card-2*)

n. Percentage of surgery patients with recommended venous thromboembolism prophylaxis orders within 24 hours prior to surgical incision time to 24 hours after surgery end time. (SCIP-VTE-1*)

o. Percentage of surgery patients who received appropriate venous thromboembolism prophylaxis within 24 hours prior to surgical incision time to 24 hours after surgery end time. (SCIP-VTE-2*)

p. Percentage of surgical patients who have had all required components of the perioperative protocol applied.

* For current and comprehensive information on SCIP measures, refer to the Specifications Manual for National Hospital Inpatient Quality Measures.

Measurement Specifications

Possible Success Measurement #1a

1a. Number of wrong surgery events per month

or

1b. Rate of wrong surgery events per N surgical procedures.

Population Definition

Patient of all ages who have a surgical procedure performed.

Data of Interest

1a. # of wrong surgery events per month, see definition below

1b. Rate of wrong surgery events per N surgical procedures

$$\frac{\text{\# of wrong surgery events}}{\text{Total \# of surgical cases per month}} \times N$$

N is determined based on the size of the denominator

If denominator is less than 100, use a rate of per 100

If denominator is greater than 100 – less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 – less than 10,000, use a rate of per 100,000

If denominator is greater than 10,000 – less than 100,000, use a rate of per million

Numerator and Denominator Definitions

Numerator: Wrong surgery event is defined as a wrong surgical procedure, a surgical procedure performed on the wrong patient, or a surgical procedure performed on the wrong side, site or level.

Denominator: Surgery is defined as an invasive procedure that takes place in an operating/procedure room by surgeon.

Method/Source of Data Collection

Event data should be reported through an incident or sentinel event report or follow the hospital's policy for reporting.

Total surgical cases can be collected through the surgical schedule, log, or hospital billing.

Data Collection Time Frame

The suggested time period is a calendar month, but three months could be consolidated into quarterly data points, as well, if case load and/or event numbers are small.

Possible Success Measurement #2

2a. Number of unintentionally retained foreign objects in surgery

or

2b. Rate of unintentionally retained foreign objects in surgery

Population Definition

Patients of all ages who have a surgical procedure performed.

Data of Interest

2a. # of unintentionally retained foreign objects (reported as a raw number)

2b. Rate of unintentionally retained foreign objects

$$\frac{\text{\# of unintentionally retained foreign objects}}{\text{Total \# of surgical cases per month}} \times N$$

N is determined based on the size of the denominator

If denominator is less that 100, use a rate of per 100

If denominator is greater than 100 but less than 1,000, use rate of per 1,000

If denominator is greater than 1,000 but less than 10,000, use a rate of per 10,000

If denominator is greater than 10,000 but less than 100,000, use a rate of per 100,000

Numerator/Denominator Definitions

Numerator: Unintentionally retained foreign object is any object unintentionally retained after a surgical procedure.

Denominator: Surgery is defined as an invasive procedure that takes place in an operating/procedure room by a surgeon.

Method/Source of Data Collection

Event data should be reported through an incident report or sentinel event report.

Total surgical cases can be collected through the surgical schedule, log, or hospital billing.

Time Frame Pertaining to Data Collection

The suggested time period is a calendar month but three months could be consolidated into quarterly data points, as well, if caseload and/or event numbers are small.

Possible Success Measurement #3

Rate or percentage of infection in patients undergoing clean surgery.

Numerator/Denominator Definitions

Numerator: Number of clean surgery patients having a postoperative wound infection

Denominator: Number of clean surgery patients

- If reporting as a rate, you would take the numerator divided by the denominator and multiple by 1,000)

Denominator exclusions:

- Patients who had a principal or admission diagnosis suggestive of preoperative infectious diseases
- Patients with documentation by physician of infection prior to surgical procedure

Method/Source of Data Collection

Sample size: Suggestion to begin by looking for total surgical site infections. If less than or equal to 25 cases occur per month, analyze total number. If greater than 25, you may choose to review all or take a random sample of 25.

Time Frame Pertaining to Data Collection

Monthly

Possible Success Measurement #4

Improve the adherence of the key components of the safe site protocol in surgical cases.

Measurement Specification

4a. Percentage of surgical patients with documentation of verification of correct patient, site/side and procedure.

4b. Percentage of appropriate surgical patients who have their site marked by the surgeon in preop with his/her initials.

4c. Percentage of surgical cases in which a verbal, active Time Out is conducted by all appropriate members of the surgical team prior to incision.

4d. Percentage of surgical cases where the baseline counts was conducted prior to the patient arriving in the operating/procedure room.

4e. Percentage of surgical patients with antibiotic administration within 60 minutes prior to surgical incision.

Population Definition

Patients of all ages who have a surgical procedure performed.

Data of Interest

4a. $\frac{\text{\# of charts/flowsheets/electronic medical record with documentation of verification of correct patient, correct site/side and correct procedure}}{\text{Total \# of surgical patients reviewed}}$

4b. $\frac{\text{\# of surgical patients with sites marked with surgeon's initials}}{\text{Total \# of patients appropriate for site marking}}$

4c. $\frac{\text{\# of surgical cases observed to have active, verbal participation in the Time Out prior to incision/insertion by all appropriate team members}}{\text{Total \# of surgical cases observed}}$

4d. $\frac{\text{\# of patients having a baseline count conducted and documented on the white board prior to surgical Time Out}}{\text{Total \# of surgical cases}}$

4e. $\frac{\text{\# of selected surgical patients whose prophylactic antibiotics were initiated within 60 minutes prior to surgical incision}}{\text{Selected surgical patients (exclusions listed below)}}$

Denominator exclusions:

- Patients who had a principal or admission diagnosis suggestive of preoperative infectious diseases
- Patients who were receiving antibiotics within 24 hours prior to arrival
- Patients who were receiving antibiotics more than 24 hours prior to surgery

- Patients with documentation by physician of infection prior to surgical procedure
- Patients who had other procedures that required general or spinal anesthesia that occurred within 24 hours prior to this procedure during this hospital stay

Method/Source of Data Collection

Retrospective collection of any measures associated with documentation can be done by randomly sampling charts of patient cases.

Concurrently, collection will need to be done through direct observation either by a quality/safety advocate or "secret shopper," someone who has a dual function on the team but whose observation and measurement function is not known.

Data Collection Time Frame

Suggested sample size and time frame for any of these measures would be minimum of 10 per month. A larger hospital with a large caseload for surgery and adequate resources could have a larger sample size.

Key Implementation Recommendations

The following system changes were identified by the protocol work group as key strategies for health care systems to incorporate in support of the implementation of this protocol.

System implementation:

- The facility is encouraged to customize the protocol with a key that identifies the individuals responsible for completing the algorithm tasks (e.g., green shapes for those individuals responsible for counts).
- Leadership support and a surgeon champion is absolutely essential for the successful implementation of this protocol.
- Develop a procedural checklist to document completion of each step and ensure that all elements of the protocol are completed.
- Direct observations, along with coaching and immediate feedback, are effective strategies in gaining staff adherence to the protocol following implementation.
- As it relates to this protocol, create and implement a process that allows for the detection and management of disruptive and inappropriate behavior. This process should include education to all physicians and non-physicians regarding appropriate professional behavior; the development of policies and procedures. Refer to The Joint Commission's leadership standards.
- Red rules* should be established, followed by staff and physicians and supported by leadership (see below for specific red rules suggested for this protocol).
    - *Red rules are the few, key rules created to prevent/address the specific actions that pose the highest level of consequence and risk to safety of patients or staff. The intention is to develop solid habits around these rules so that they are followed consistently and accurately each time. Individual responsibility to adhere to each red rule is imperative to ensure the safest environment and delivery of the care process.
    - Suggested red rules:
        - Never operate on a patient without verifying the correct patient identity, correct procedure and correct site.
        - Baseline counts are consistently performed before the patient arrives in the operating/procedure room unless parallel processing is used.
        - Unreconciled counts require imaging verification, and wound closure stops until count reconciliation is achieved.

Retained foreign object implementation:

- The work group recommends that a preformatted white board be used as the primary record of the count. Documenting counts on a white board allows all surgical staff, and in particular the scrub tech, to independently view the count record. A public display of the count record in an area where the entire surgical team can view it is likely to reinforce the importance of the count process.
- The work group also recommends that a count worksheet be used as a memory aid when the white board is not easily accessible in a timely manner. The count worksheet should be used only as a memory aid for the baseline count and, if needed, for subsequent counts. It should be used rather than a piece of scratch paper. In contrast, if the white board is located very close to the area when

the count occurs, and if the circulating nurse can easily write the counts on the white board without leaving the count area, there will be no need to use the count worksheet.

- Distractions and interruptions should be kept to a minimum during the count process. If a count is interrupted, then the category of items (e.g., laps) being counted will need to be recounted.

Surgical infection implementation:

- Using preprinted or computerized order sets can help in reminding and remembering specific antibiotics, timing, dose and discontinuation.
- Review patient education material to verify the message around no self-shaving before surgery. Distribute standardized patient education messages to surrounding outpatient clincs, as well.
- Remove all razors from the perioperative area.
- Use warming blankets, hats and booties routinely for patients.
- Establish an effective surveillance process that includes postdischarge or outpatient surveillance. Use inpatient case-finding for postdischarge or outpatient. It is important to include the following:
  - Use standardized definitions for surveillance of infections. These definitions also need to take into account the setting in which the surgical procedure was performed (acute care, ambulatory surgical center, etc.).
  - Establish a risk stratification for estimating surgical infection that adjusts for risk factors associated with infection for different care settings and procedures.
  - Work with surrounding outpatient clinics to develop communication strategy for tracking surgical infections and reporting back to the hospital.

Safe site implementation:

- To facilitate implementation of the Hard Stop concept, have your chief executive officer communicate to all staff and physicians their support for the institution of the Hard Stop.
- The Time Out is best followed when a particular person/role has responsibility to call the Time Out. The surgeon should then be the one to take the lead on running the Time Out and have the circulator begin the review of information.
- Establish pre-procedure and post-procedure communication standards in the form of structured hand-offs.
- Develop a verification process at the point of scheduling. The work group recommends that this process include:
  - Corroboration between the surgical consent, the order to schedule a procedure and an independent source document dictation (such as a radiology report or pathology report).
  - Review of documents by a licensed independent practitioner or an RN, with attention directed specifically to the organ to be operated upon and laterality as appropriate before proceeding to the scheduling process.
  - The independently verified documentation provided on paper, fax or electronic format, not by telephone or verbal communication. The only exception to this is during emergency situations.

Knowledge Resources

Criteria for Selecting Resources

The following resources were selected by the Perioperative Protocol work group as additional resources for providers and/or patients. The following criteria were considered in selecting these resources.

- The site contains information specific to the topic of the protocol.
- The content is supported by evidence-based research.
- The content includes the source/author and contact information.
- The content clearly states revision dates or the date the information was published.
- The content is clear about potential biases, noting conflict of interest and/or disclaimers as appropriate.

Resources Available to ICSI Members Only

ICSI has a wide variety of knowledge resources that are ***only*** available to ICSI members (these are indicated with an asterisk in far left-hand column of the Resources Available table). In addition to the resources listed in the table, ICSI members have access to a broad range of materials including tool kits on CQI processes and Rapid Cycling that can be helpful. To obtain copies of these or other Knowledge Resources, go to http://www.icsi.org/improvement_resources. To access these materials on the Web site, you must be logged in as an ICSI member.

The resources in the table on the next page that are not reserved for ICSI members are available to the public free-of-charge.

Resources Available

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
	American College of Surgeons	The American College of Surgeons is a scientific and educational association of surgeons that work to improve the quality of care for the surgical patient. The Web site provides information for patients, the public, and surgeons.	Health Care Professionals; Patients and Families	http://www.facs.org
	American Hospital Association	Tips for Safer Surgery A tip sheet for patients and their families with questions to ask before surgery.	Patients and Families	http://www.aha.org
	American Society of Anesthesiology	The American Society of Anesthesiology is an educational, research and scientific association of physicians organized to raise and maintain the standards of the medical practice of anesthesiology and improve the care of the patient.	Health Care Professionals	http://www.asahq.org
	American Society of PeriAnesthesia Nurses (ASPAN)	The American Society of PeriAnesthesia Nurses is the professional specialty nursing organization representing the interests of nurses practicing in all phases of preanesthesia and postanesthesia care, ambulatory surgery, and pain management.	Health Care Professionals	http://www.aspan.org
	Association of Peri-Operative Registered Nurses (AORN)	The Association of periOperative Registered Nurses (AORN) is a professional association that "empowers the operating/procedure room nurse with education, standards of practice, and peer networking."	Health Care Professionals	http://www.aorn.org
	Department of Veterans Affairs Veterans Health Administration, Washington, DC 20420	VA National Center for Patient Safety (NCPS) The Web site's provides information for health care professionals and health care administrators. However, veterans and the general public are encouraged to explore the site. The Patient Safety for patients sections provides information, tips and tools, and resources for patients and families.	Health Care Professionals; Patients and Families	http://www.va.gov/ncps/

* Available to ICSI members only.

*	Author/Organization	Title/Description	Audience	Web Sites/Order Information
*	Institute for Clinical Systems Improvement, the ICSI Perioperative work group, and ICSI member groups	Surgical Care Tool Kit – • Surgical Procedural Checklist • Sample Count Sheet • Sample Cardiovascular Blade and Needle Count Sheet • Hand-off Communication Scrub to Scrub • Hand-off Communication Surgical Services • WHO surgical safety checklist • Briefings Handout • Briefings "How To" • Pre-procedure Verification Checklist	Health Care Professionals	http://www.icsi.org/tools
	Institute for Healthcare Improvement	Independent not-for-profit organization helping to lead the improvement of health care throughout the world. Web site provides various tools supporting patient safety.	Health Care Professionals	http://www.ihi.org
	The Joint Commission	Joint Commission Web site for regulatory standards and patient safety goals.	Health Care Professionals	http://www.jointcommission.org
	Minnesota Department of Health	Minnesota Department of Health The site provides patient safety information that includes adverse event reporting and information for consumers and patients.	Health Care Professionals; Patients and Families	http://www.health.state.mn.us/patientsafety/index.html
	Minnesota Hospital Association	The Minnesota Hospital Association Safe Site Call to Action Web site includes tools that address procedures outside the operating room.	Health Care Professionals	http://www.mnhospitals.org
	National Initiative for Children's Healthcare Quality Pediatric Affinity Group	Reducing Surgical Complications/ Surgical Site Infections: Pediatric Supplement A how-to guide for surgical site infection in the pediatric population.	Health Care Professionals	http://www.nichq.org/NICHQ/

* Available to ICSI members only.

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