Beyond SCIP: Leading the Way to SSI Reduction

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Disclosure

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- Registered nurse participants can receive 1.0 contact hours upon course completion

Presented by:

- Ellen Anderson Manz, MSN, RN, 3M Infection Prevention Division
Learning Objectives

1. Describe how CMS measures have evolved into Value Based Purchasing

2. Describe patient protocols that will help reduce the risk of SSI

3. Identify relevant clinical studies and guidelines supporting each protocol
Fig. 1. Measures enacted by commercial payers and governmental insurance agencies in the United States to enhance the value of patient care.
## CMS Hospital Value Based Purchasing

<table>
<thead>
<tr>
<th>Domain</th>
<th>FY 2013 Weight</th>
<th>FY 2014 Weight</th>
<th>FY 2015 Weight</th>
<th>FY 2016 Weight</th>
<th>FY 2017 Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Process of Care</td>
<td>70%</td>
<td>45%</td>
<td>20%</td>
<td>10%</td>
<td>5%</td>
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<tr>
<td>Patient Experience of Care (HCAHPS)</td>
<td>30%</td>
<td>30%</td>
<td>30%</td>
<td>25%</td>
<td>TBD</td>
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<tr>
<td>Outcome*</td>
<td>NA</td>
<td>NA</td>
<td>20%</td>
<td>40%</td>
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<tr>
<td>Efficiency**</td>
<td>NA</td>
<td>NA</td>
<td>20%</td>
<td>25%</td>
<td>TBD</td>
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</table>

*Hospital mortality measures for acute MI, heart failure, and pneumonia; CLABSI measure; CAUTI measure; SSI strata, and AHRQ PSI 90 composite - includes HACs

**Medicare spending per beneficiary measure

CMS.gov
## Clinical Process of Care Domain

<table>
<thead>
<tr>
<th>Measure ID*</th>
<th>Measure Description</th>
<th>FY 2013</th>
<th>FY 2014</th>
<th>FY 2015</th>
<th>FY 2016</th>
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</thead>
<tbody>
<tr>
<td>AMI-7a</td>
<td>Fibrinolytic Therapy Received Within 30 Minutes of Hospital Arrival</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>AMI-8a</td>
<td>Primary PCI Received Within 90 Minutes of Hospital Arrival</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>HF-1</td>
<td>Discharge Instructions</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
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<tr>
<td>IMM-2</td>
<td>Influenza Immunization</td>
<td>No</td>
<td>No</td>
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<tr>
<td>PN-3b</td>
<td>Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>PN-6</td>
<td>Initial Antibiotic Selection for CAP in Immunocompetent Patient</td>
<td>Yes</td>
<td>Yes</td>
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<td>SCIP-Card-2</td>
<td>Surgery Patients on a Beta Blocker Prior to Arrival That Received a Beta Blocker During the Perioperative Period</td>
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<td>SCIP-Inf-1</td>
<td>Prophylactic Antibiotic Received Within One Hour Prior to Surgical Incision</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>SCIP-Inf-2</td>
<td>Prophylactic Antibiotic Selection for Surgical Patients</td>
<td>Yes</td>
<td>Yes</td>
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<tr>
<td>SCIP-Inf-3</td>
<td>Prophylactic Antibiotics Discontinued Within 24 Hours After Surgery End Time</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
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<td>SCIP-Inf-4</td>
<td>Cardiac Surgery Patients with Controlled 6AM Postoperative Serum Glucose</td>
<td>Yes</td>
<td>Yes</td>
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<td>No</td>
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<td>SCIP-Inf-9</td>
<td>Postoperative Urinary Catheter Removal on Post Operative Day 1 or 2</td>
<td>No</td>
<td>Yes</td>
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<td>Yes</td>
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<tr>
<td>SCIP-VTE-1</td>
<td>Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered</td>
<td>Yes</td>
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<td>No</td>
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<td>SCIP-VTE-2</td>
<td>Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

**FY 2017**

Six clinical process of care measures to be removed as they have “topped out”

Addition of one new clinical process of care measure: *early elective deliveries* – may also be included as one of two new safety measures as well

https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772237361
**FY 2017**

Two new outcome measures:

1. Hospital onset MRSA bacteremia
2. Hospital onset C. diff infection

<table>
<thead>
<tr>
<th>Measure ID**</th>
<th>Measure Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>MORT-30-AMI</td>
<td>Acute Myocardial Infarction (AMI) 30-Day Mortality Rate</td>
</tr>
<tr>
<td>MORT-30-HF</td>
<td>Heart Failure (HF) 30-Day Mortality Rate</td>
</tr>
<tr>
<td>MORT-30 PN</td>
<td>Pneumonia (PN) 30-Day Mortality Rate</td>
</tr>
<tr>
<td>AHRQ Composite (PSI-90)</td>
<td>Complication/Patient safety for selected indicators (Composite)</td>
</tr>
<tr>
<td>CAUTI</td>
<td>Catheter-Associated Urinary Tract Infection</td>
</tr>
<tr>
<td>CLABSI</td>
<td>Central Line-Associated Blood Stream Infection</td>
</tr>
</tbody>
</table>
| SSI          | SSI - Colon Surgery  
               | SSI - Abdominal Hysterectomy |

[https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772237361](https://www.qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772237361)
CMS Hospital readmission reduction

- Conditions monitored for readmission within 30 days of discharge
  - Acute myocardial infarction
  - Pneumonia, including aspiration pneumonia and sepsis with pneumonia on admission
  - Heart failure
- 2015 added
  - COPD exacerbation
  - Total hip arthroplasty
  - Total knee arthroplasty
- 2017 will add CABG
Perioperative Surgical Home Value Equation

\[
\text{VALUE} = \frac{\text{QUALITY} + \text{SAFETY} + \text{SATISFACTION}}{\text{$\$ \text{TOTAL COSTS OF CARE}$}}
\]

Fig. 2. Health care value equation for the Perioperative Surgical Home model.

Anesthesiology Clin 33 (2015) 771–784
SSI Epidemiology


> SSI are common complications

- SSI occur in 2-5% of patients undergoing inpatient surgery
- Approximately 160,000-300,000 SSI occur each year in the US
- SSI represent 20% of all HAI in hospitalized patients
- SSI is now the most common and costly HAI
Outcomes associated with SSI

- Up to 60% of SSI may be preventable by use of evidence-based guidelines
  - Each SSI increases LOS by approximately 7-11 days
  - SSI is associated with 2-11 times higher risk of mortality compared with operative patients without SSI
- 77% of mortality in patients with SSI is directly attributable to that SSI
  - Attributable costs of SSI depend on the type of operative procedure and the infecting pathogen
- Believed to account for $3.5-10 billion annually in health care expenditures
Process Variability

\[
\left( \frac{\text{Dose of Bacteria}}{\text{(Contamination)}} \right) \times \left( \frac{\text{Virulence}}{\text{(Resistance)}} \right)
\]

\[\text{Risk}\]

Resistance of the Host
(Patient)

Patient Variability

Patient Variability: Resistance of the host (patient)

- Age
- Compromised Immune System
- Diabetes
- Remote Site Infection (Not Treated Prior To Surgery)
- Nutritional Status
- Nicotine Use
- Prolonged Preoperative Stay
- Obesity
- Steroid Use
- Duration of Surgery

Risk = (Dose of Bacteria \times Virulence) \\
(Resistance)
Process Variability

- Hand hygiene
- Appropriate antimicrobial prophylaxis
- **Preoperative bathing**
- Nasal decontamination
- Oral decontamination
- **Hair removal**
- **Skin preparation**
- Surgical hand antisepsis
- Appropriate surgical attire and drapes

- Operating room characteristics
  - Ventilation, traffic, environmental surfaces
  - Sterilization

- Patient management
  - **Normothermia**
  - Glucose control
  - Oxygenation

- Surgical technique
  - Hemostasis
  - Failure to obliterate dead space
  - Tissue trauma
Pre-Operative
Bathing/Showers/Wipes
Decreasing Microbial Counts on the Skin

- Preoperative showers / baths / wipes
  - Cleanse the skin by removing dirt and debris
  - Products that include an antimicrobial agent will also decrease microbial counts
Preoperative Bathing Recommended Practice

CDC – Guideline for Prevention of Surgical Site Infections, 1999

“Require patients to shower or bathe with an antiseptic agent at least the night before the operative day” (Category IB)

“Chlorhexidine gluconate-containing products require several applications to attain maximum antimicrobial benefit, so repeated antiseptic showers are usually indicated. Even though preoperative showers reduce the skin’s microbial colony counts, they have not definitively been shown to reduce SSI rates.”
“Preoperative bathing with chlorhexidine-containing products”
(Unresolved issue)

“Preoperative showering with agents such as chlorhexidine has been shown to reduce bacterial colonization of the skin. Several studies have examined the utility of preoperative showers, but none has definitively proven that they decrease SSI risk. A recent Cochrane review evaluated the evidence for preoperative bathing or showering with antiseptics for SSI prevention. Six randomized, controlled trials evaluating the use of 4% chlorhexidine gluconate were included in the analysis, with no clear evidence of benefit noted. To gain the maximum antiseptic effect of chlorhexidine, adequate levels must be achieved and maintained on the skin. Typically, adequate levels are achieved by allowing CHG to dry completely.”

Preoperative Bathing Recommended Practice

AORN – Perioperative Standards and Recommended Practices, 2015

➢ “The collective evidence supports that preoperative patient bathing may reduce the microbial flora on the patient’s skin before surgery.”

➢ “The patient should be instructed to bathe or shower before surgery with either soap or a skin antiseptic on at least the night before or the day of surgery.”

➢ Although many studies support the use of 2% CHG cloths for preoperative bathing, additional research is needed before a practice recommendation can be made.”

AORN. Guidelines for Perioperative Practice, Denver, Colorado: AORN, Inc.: 2015
CHG bathing

- The patient’s endogenous flora is the leading cause of SSI and antiseptics decrease bacteria present on the skin\(^1\)
- Preoperative bathing with CHG is effective in reducing skin flora, the same effect is not achieved with the use of soap alone\(^2-4\)
- Review by Webster\(^5\) did not show a statistically significant reduction in SSI, the studies included were limited to use of 4% CHG
- Use of a non-rinseable form of CHG (2% impregnated cloths) results in a significantly increased reduction in skin flora compared to 4% CHG showers. This reduction was greater with repeated application\(^6\)

5. Webster J, Osborne S. Preoperative bathing or showering with skin antiseptics to prevent surgical site infection (Review). The Cochrane Library 2012; 9.
CHG bathing

• Meta-analysis by Chlebicki, et al\(^1\) did not find a significant reduction is SSI rates
  • varying protocols and CHG concentrations

• Additional studies specifically examining the effect of 2% CHG cloths demonstrate an appreciable impact on SSI\(^2\)-\(^6\)

• Recent systematic review that included studies with consistent bathing protocols of two preoperative baths, found that the use of 2% CHG cloths significantly reduced SSI risk\(^7\)

• Low risk and low cost intervention that has proven effective in reducing bacteria on the skin, a risk factor for SSI

5. Graling PR, Vasaly FW. Effectiveness of 2% CHG cloth bathing for reducing Surgical Site Infections. AORN 2013; 97(5): 547-51.
Preoperative bathing and SSI

Kapadia BH, et al. Pre-admission Cutaneous Chlorhexidine Preparation Reduces Surgical Site Infections In Total Hip Arthroplasty

- \textit{J Arthroplasty} 2013;28:490-493
- Compare SSI incidence in THA pts using 2% CHG protocol the night before and morning of procedure (n=557), to pts undergoing only in-hospital skin prep (n=1901)
- Infections in CHG protocol group = 0.5% vs 1.7% in group not using protocol (p=0.0428)
- The benefits of an effective chlorhexidine cloth protocol have the potential to decrease periprosthetic infections
Summary
Preoperative Wipes or Showers

- Reduces the bacterial burden on the patient’s skin prior to surgical incision

- **Practical problems:** patient compliance, patient’s ability to bath/shower, and consistency in method of preparation

- 2% CHG impregnated cloth proven more effective than 4% CHG liquid detergent in multiple studies

- Patient information regarding CHG
  - Inactivated by soaps and shampoos
  - Keep out of eyes and ears
  - Do not use lotions, powders, or creams after application
Reducing Bacteria in the Nares
Process Variability

- Hand hygiene
- Appropriate antimicrobial prophylaxis
- Preoperative bathing
- Nasal decontamination
- Oral decontamination
- Hair removal
- Skin preparation
- Surgical hand antisepsis
- Appropriate surgical attire and drapes

Operating room characteristics
- Ventilation, traffic, environmental surfaces
- Sterilization

Patient management
- Normothermia
- Glucose control
- Oxygenation

Surgical technique
- Hemostasis
- Failure to obliterate dead space
- Tissue trauma
Why Implement an Intervention to Reduce Bacteria in the Nares?

- *S. aureus* is the leading cause of SSI\(^2\)
- Approximately 30% of the population are colonized with *S. aureus* in the nares.\(^2\)
- 80% of the *S. aureus* infections are caused by the patient’s own nasal flora.\(^3\)

» In a study published in the New England Journal of Medicine in which nasal screening was done, for the patients from which samples were available from both the nares and the surgical site (known as paired isolates), over 84% of the *S. aureus* strains isolated from the nares were identical to those isolated from the surgical site.


Nasal Carriage of *S. aureus* is a Major Risk Factor for SSI


- Meta-analysis of five clinical studies
- On average, nasal carriage of *S. aureus* increases the risk of SSI by nearly 6-fold
  - OR = 5.92, 95% CI [1.15-30.39]; p = 0.033

- Retrospective cohort study
- 9863 procedures with nasal MRSA PCR screening
- Surgery type
  - Abdominal 29.8%, ortho 21.8%, neuro 19.7%, cardiothoracic and vascular 16.7%
  - 4.3% with at least 1 positive MRSA PCR day of or within 30 days of procedure
- 1.86% PCR positive developed SSI compared to 0.2% PCR negative (p< 0.0001)
- **Multivariate analysis:** positive MRSA PCR was an independent risk factor for SSI
  - OR, 9.20; 95%CI, 3.81-20.47, p< 0.0001
Guidelines and Recommendations

2014 SHEA/IDSA Practice Recommendation

- If unacceptably high SSI rates exist for surgical populations despite implementation of the basic SSI prevention strategies then applying standard infection control methods for outbreak investigation and management are recommended, including:
  - Screen surgical patients for *S. aureus* and decolonize preoperatively for high risk procedures including some orthopedic and cardiac procedures
  - Routine preoperative decolonization with mupirocin without screening and targeted use is not currently recommended due to concerns about evolving resistance

Reducing *S. aureus* in the Nares Prior to Surgery

**Intranasal mupirocin calcium ointment, 2%**
- Indicated for institutional outbreaks of MRSA*
- Greater than 90% of subjects/patients in clinical trials had eradication of nasal colonization 2 to 4 days after therapy was completed*

**Mupirocin challenges**
- Full 5-day treatment does not fit into pre-surgical logistics
- Poor patient compliance
- Antibiotic resistance

Antiseptic Prep – 5% Povidone Iodine

- Applied 1 hour before incision
- Provides a 99.5% reduction of *S. aureus* in the nares at 1 hour
- Maintains this log reduction for at least 12 hours
- Patented formula designed specifically for the nose—presents unique challenges compared to prepping skin

**Example for 12-hour Time Point**
Baseline: 4.72 logs or 52,000 *S. aureus* – 2.37 logs killed = 220 bacteria remaining at 12 hours
Antiseptic Prep – 5% Povidone Iodine

Advantages

• Resistance has not been shown,\(^1\) supports antibiotic stewardship
• Broad spectrum
• Easy to implement in pre-op
• No need to change current protocols
  • i.e., screening
• Directly observed application ensures compliance\(^2\)
• Demonstrated efficacy in reducing SSI risk

Disadvantages

• A small number of patients may be sensitive to povidone iodine-containing products
• Reduces bacteria, does not eradicate

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1. 3M Study 05-011322
Clinical Evidence-Implementation
Clinical Trial Designs – Hierarchy of Evidence

- **Experimental Studies**
  - Randomization
  - Control over use of intervention
- **Observational Studies**
  - No control over allocation of intervention
  - No randomization
- **Descriptive Studies**
  - No comparative group
  - Description of exposed subjects

- Systematic Reviews
- Meta-analyses
- Randomized Controlled
- Quasi-experimental
- Cohort Studies
- Case Control Studies
- Case Series
- Case Reports

Quality of evidence

- No comparative group
- Description of exposed subjects
- No randomization
- No control over allocation of intervention
- Randomization
- Control over use of intervention
Clinical Trial Designs – Hierarchy of Evidence for Nasal Antisepsis

- Systematic Reviews
- Meta-analyses
- Randomized Controlled
- Quasi-experimental
- Cohort Studies
- Case Control Studies
- Case Series
- Case Reports

“Before and After” Bundle

Skin and Nasal Antiseptic

Phillips, et al.
Rezapoor, et al.
Bebko, et al.
Hogenmiller, et al.
Waibel, et al.
Osborn & Reynolds
Torres, et al.
Flynn & Carr
Brown, et al.
Protocol to reduce the risk of SSI consisted of:
- CHG bathing the night before and the morning of surgery
- Intranasal mupirocin ointment twice daily for 5 days preoperatively

Barriers to protocol:
- 86% compliance to mupirocin regimen
- 8% of patients reported difficulty obtaining mupirocin due to cost
- Concerns regarding reports of mupirocin resistance

These barriers led to search for an alternative.
Clinical Studies
Randomized trial comparing SSI after arthroplasty or spine fusion surgery. Patients receiving two applications of 2% CHG cloths were randomized to:

» one time treatment of 5% Skin and Nasal Antiseptic or
» five days of intranasal mupirocin ointment prior to surgery

The primary end point was deep SSI within 3 months of surgery

Results: Intent to treat (n=1,697); Per protocol (n=1,539)

Conclusion:

- 5% nasal PI may be considered as an alternative to mupirocin in a multifaceted approach to reduce SSI.

Other observations:

- Compared to mupirocin in terms of cost and efficacy, 5% nasal PI provides more value, defined as quality of outcomes divided by cost.

- Application of 5% nasal PI by the patient care team just prior to surgery may ensure greater compliance.
Clinical Studies

Prospective study comparing SSI in elective orthopedic surgery with hardware before and after implementation of a preoperative decontamination protocol:

» 2% CHG cloths and 0.12% CHG oral rinse night before and morning of surgery

AND

» 5% Skin and Nasal Antiseptic morning of surgery

The primary end point was 30 day SSI rates

Results:

- 100% compliance to protocol
- Multivariate logistic regression: Decontamination protocol = Significant independent protective factor against SSI

(OR 0.24 [95% CI, 0.08-0.770]; p = 0.02)
Conclusion

“Universal decontamination using this low-cost protocol may be considered as an additional prevention strategy for SSIs”...

Other observations:

– Wider implementation without the need of SA carrier screen and treat may allow for cost savings.
– Advantages to the protocol include shorter duration, cost effectiveness (compared to PCR based protocols), and potentially fewer concerns about antibiotic resistance.
Clinical Studies
Randomized controlled trial comparing S. aureus cultures at baseline and after application of nasal treatment in patients undergoing total joint arthroplasty

<table>
<thead>
<tr>
<th>Treatment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized to either:</td>
</tr>
<tr>
<td>• Off the shelf 10% povidone iodine (10% PI)</td>
</tr>
<tr>
<td>• 5% Skin and Nasal Antiseptic (5% PI) formulated with a polymer</td>
</tr>
<tr>
<td>• Saline (control)</td>
</tr>
</tbody>
</table>

Nasal swabs were taken preoperatively prior to nasal treatment (baseline), and again at 4 hours and 24 hours after treatment.

429 patients were randomized, of which 95/429 (22.1%) were positive at baseline for *S. aureus* and 13.6% of these were MRSA.

5% PI formulation demonstrated significantly more effective intranasal decolonization of *S. aureus* over the 4 hour time interval (p=0.003).

10% PI no different than saline (control)
Conclusion

The specially formulated 5% PI solution, which contains a specific adherent polymer, remains in the nares for a longer period, which may explain its better efficacy.
Additional References


• Waibel ML. Revisiting Process Improvement for Total Joint Arthroplasty SSI. Presented at the APIC National Conference, Fort Lauderdale, FL, June 2013.


• Osborn N, Reynolds L. Embedding an Infection Preventionist (IP) in the OR. Presented at the AORN Surgical Conference and Expo, Denver, CO, March 2015.
Summary

- Nasal carriage of *S. aureus* increases risk of SSI, and is of increased focus for high risk surgical procedures.

- If *S. aureus* SSI is higher than benchmark despite effective basic SSI risk reduction strategies then implementation of *S. aureus* decolonization program is recommended.

- Intranasal mupirocin has been used historically to decolonize the nares and is associated with compliance burdens.

- 5% PI formulated specifically for intranasal application is an option that provides directly observed, just in time application with demonstrated efficacy in reducing the risk of SSI.
Pre-Operative Hair Removal
Process Variability

- Hand hygiene
- Appropriate antimicrobial prophylaxis
- Preoperative bathing
- Nasal decontamination
- Oral decontamination
- **Hair removal**
- Skin preparation
- Surgical hand antisepsis
- Appropriate surgical attire and drapes

Operating room characteristics
- Ventilation, traffic, environmental surfaces
  - Sterilization

Patient management
- Normothermia
- Glucose control
- Oxygenation

Surgical technique
- Hemostasis
- Failure to obliterate dead space
- Tissue trauma
Hair Removal Methods

- Clipping
- Chemical Depilatory
- Shaving (Razor)
Pre-Operative Hair Removal

Shaving causes:
- Nicks
- Cuts
- Microscopic epidermal injuries

Which can lead to Surgical Site Infection (SSI)

Pre-Operative Hair Removal

<table>
<thead>
<tr>
<th>Hair-Removal Method</th>
<th>Discharge</th>
<th>30-Day Follow-up</th>
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<tbody>
<tr>
<td>PM Razor</td>
<td>14/271</td>
<td>23/260</td>
</tr>
<tr>
<td>AM Razor</td>
<td>17/266</td>
<td>26/260</td>
</tr>
<tr>
<td>PM Clipper</td>
<td>10/250</td>
<td>18/241</td>
</tr>
<tr>
<td>AM Clipper</td>
<td>4/226</td>
<td>7/216</td>
</tr>
<tr>
<td>Total</td>
<td>45/1,013</td>
<td>74/977</td>
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</table>

SSI Rates

PM Razor: 14/271 (5.2%) 23/260 (8.8%)
AM Razor: 17/266 (6.4%) 26/260 (10.0%)
PM Clipper: 10/250 (4.0%) 18/241 (7.5%)
AM Clipper: 4/226 (1.8%) 7/216 (3.2%)
Total: 45/1,013 (4.4%) 74/977 (7.6%)

2015 AORN Guideline

- Hair removal at the surgical site should be performed only in select clinical situations

- Patients should be instructed not to shave at home

- When necessary, hair at the surgical site should be removed by clipping or depilatory methods in a manner that minimizes injury to the skin

- Hair should be removed in a location outside the operating room or procedure room
Prewarming to Maintain Normothermia
Normothermia

- Perioperative hypothermia is defined as any core temperature less than 36.0°C (96.8°F)¹,²

- The induction of anesthesia is the most significant contributor to unintended perioperative hypothermia in surgical patients¹,²

- Reducing the impact of redistribution temperature drop through prewarming is an effective way to help maintain patient normothermia¹,²

Effects of Anesthesia

- Anesthesia causes vasodilation, or an opening of arterial shunts, allowing the warm blood from the core to flow freely and mix with the colder periphery.

- As the blood circulates, it cools until returning back to the heart, where it causes a drop in core temperature.

- This is known as **heat redistribution**, commonly referred to as **RTD (redistribution temperature drop)**.
Adverse Effects of Unintended Perioperative Hypothermia

There are many documented adverse effects of unintended perioperative hypothermia including:

• Wound infection
• Myocardial ischemia and cardiac disturbances
• Coagulopathy

• Prolonged and altered drug effect
• Increased mortality
• Shivering and thermal discomfort
• Delayed emergence from anesthesia

Benefits of Normothermia

Maintaining normothermia may yield positive results such as:

- Reduction in the use of blood products
- Shortened length of hospital stay
- Decreased ICU time
- Reduced rate of wound infection
- Decreased likelihood of myocardial infarction
- Lower mortality rates

The Science Behind Prewarming
What Is Prewarming?

Prewarming: the application of heat *prior to anesthesia* for the purpose of increasing total body temperature

- Prewarming = “banking heat”
- Total body temperature = the average combined temperature of the periphery and core
Why Is Prewarming Important?

- It is difficult to **treat** RTD but it can be **prevented** by prewarming.
- Prewarming increases the temperature of the periphery, which limits the amount of heat lost from the core through redistribution.


Evidence from Published Clinical Studies
1. Prewarming Study

*Effects of Prewarming Patients in the Outpatient Surgery Setting*

**Study Design**
Randomized Control Trial (RCT). Patients (N=100) randomized to:
- Forced-air warming (FAW – Treatment, N=50)
- Cotton blankets (Control, N=50)

**Objective**
Effect of prewarming on the patient temperature at arrival to PACU
Results

FAW is more effective than warmed cotton blankets in:
  - achieving higher temperature post-op (p=0.000)
  - more patients self reported thermal comfort (p=0.000)
### Study Design

RCT – Patients (N=94) Randomized to:

- **Standard warming** – FAW blankets from induction through the end of surgery (N=48)
- **Prewarming** – FAW gown for preoperative, intraoperative, and PACU through discharge (N=46)

### Outcomes Measured

- Rates of hypothermia (<36ºC)
- Patient wellbeing (perception of temperature always controlled, request for extra blankets, and anxiety)
- Costs of warming

---

Results:

• **Standard Warming**
  • Significant higher drop in core temperature (RTD) following baseline preop to intraop (p<0.01).

• **Prewarming**
  • *Rate of hypothermia* was reduced by 48% although it was not statistically significant (p=0.12)
  • Significantly increased the patients’ report of temperature control (p=0.04)
  • Significantly decreased patient requests for additional blankets (p=0.006)
  • Significantly decreased anxiety levels (p=0.001).

• **Prewarming** with the FAW Gown system resulted in a cost savings of $84 per patient versus standard warming processes in this study.
3. Prewarming Study

Effect of Prewarming on Post-Induction Core Temperature and the Incidence of Inadvertent Perioperative Hypothermia in Patients Undergoing General Anesthesia

Study Design

- Elective spinal surgery patients (N=68) randomized to one of two groups:
  - **Prewarmed** (n=31)
    - 38°C for 60 min preoperatively and warmed intraoperatively with FAW Gowns
  - **Intraop warming only** (n=37)

Objective

- Efficacy of prewarming in preventing inadvertent perioperative hypothermia

Study Findings

- **Prewarming** for 60 min with a forced-air warming gown resulted in:
  - Temperature maintained >36°C in 21 (68%) patients in the prewarmed group, compared with 16 (43%) patients in the control group (p=<0.05)
  - Significantly smaller decrease in mean core temp at 40, 60 and 80 min (p<0.05)
Summary of Clinical Evidence

- Prewarming can decrease the incidence of perioperative hypothermia

- Prewarming is associated with reduced rates of SSIs

- Prewarming patients has been associated with decreased anxiety and increased satisfaction and comfort rates

- Prewarming can result in cost savings

Normothermia: An Important Topic

Institute for Health Care Improvement (IHI)

APIC
AST

AORN

Canadian Patient Safety Institute

The Joint Commission (TJC)

AANA

Canadian Patient Safety Institute

ASA

National Institute for Health and Clinical Excellence (NICE)

UK Department of Health – National Health Service (NHS)

ASPA

Scottish Patient Safety Alliance

SHEA

Australian Commission for Safety and Quality in Health Care

Swedish Association of Local Authorities and Region

CMS
AORN’s *Recommended Practices for Unplanned Perioperative Hypothermia*

- Create a plan to reduce the risk of unintended perioperative hypothermia
- Monitor core temperatures starting in pre-op and continuing throughout the perioperative process
- 15 minutes of prewarming prior to the start of anesthesia
- Maintenance of normothermia during surgery

- Utilize a warming modality such as:
  - Forced-air warming – Safe, proven, effective and commonly used
  - Circulating-water garments – Effective in adult and pediatric patients
  - Energy transfer pads – Effective in reducing hypothermia during off-pump cardiac surgery

Prewarming and Patient Satisfaction

- Prewarming can provide both clinical and comfort benefits
- Recent studies have examined the effects of prewarming on patient comfort and satisfaction
- Prewarming with a forced-air warming gown vs. warmed cotton blankets can positively affect patient comfort, satisfaction and anxiety levels

Warmth can play a role for a positive patient experience

Reducing Bacteria on the Skin
Intraoperative
# Surgical Site Skin Antisepsis

<table>
<thead>
<tr>
<th>SHEA IDSA&lt;sup&gt;1&lt;/sup&gt;</th>
<th>“Wash and clean skin around incision site; Use a dual agent skin preparation containing alcohol, unless contraindication exists“</th>
</tr>
</thead>
</table>
| CDC<sup>2</sup> Guideline for the Prevention of Surgical Site Infection<sup>2</sup> | “Use an appropriate antiseptic agent for skin preparation (Table 6).“  
**Category IB**  
“Apply preoperative antiseptic skin preparation in concentric circles moving toward the periphery. The prepared area must be large enough to extend the incision or create new incisions or drain sites, if necessary.”  
**Category II** |
| AORN<sup>3</sup> | Recommendation III  
“The collective evidence indicates that there is no one antiseptic that is more effective than another for preventing SSI.” |

None of these state that one antiseptic agent is preferred over another

DOI: 10.1086/676022  
2. Centers for Disease Control and Prevention, “Guideline for Prevention of Surgical Site Infections,” Infection Control and Hospital Epidemiology, Vol 20, No 4, April 1999  
Preoperative Skin Antisepsis

- The skin cannot be sterilized
- Always some level of bacteria present and repopulating the skin surface
- Average bacteria counts on the skin: up to 1,000,000 colonies/cm²
- After patient preoperative skin prepping: up to 4,000 colonies/cm²

2. 3M data on file (LIMS 8918).
Why follow the Manufacturer’s Directions for Use?

- **Efficacy of Prep is based on following Directions for Use**
  - Paint vs. Scrub Application

- **Warnings: Flammability of Alcohol Preps**
  - Allow to dry completely before draping
  - Remove solution soaked materials
  - Wick any pooled solution
  - Include in time-out (prep is dry)

- **Warnings: Do not Use Statements**
  - All preps have warnings and contraindications
  - Patients can have allergies or irritation
  - Preps cannot be used universally on all areas of the body
Creating a Sterile Surface

- Skin bacteria are the leading cause of SSI
- Preps only disinfect the skin
- Still bacteria left on the skin after the prep
- Incise drapes provide a sterile surface to the wound edge and immobilize bacteria not killed by skin prep

- Most of the incise drapes are breathable and allow for moisture-vapor transmission thru the film
- Iodophor impregnated adhesive incise drapes kill bacteria that contact the adhesive
Creating a Sterile Surface

- Adhesion most effective when skin is prepped with a film forming prep and allowed to dry completely

- One study showed a six-fold increase in infection when the incise drape lifted at the edge of skin compared to operations with no lifting of incise drape

- ECRI Institute in their 2009 Clinical Guide to Surgical Fire Prevention:
  - Recommends the use of incise drapes, if possible, to help isolate the head, face, neck and upper-chest incisions from the oxygen-enriched atmosphere and from flammable vapors beneath the drapes.
  - The incise drape can help prevent gas communication channels between the under-drape space and the surgical site.

Comparison of Efficacy and Cost of Iodine Impregnated Drape vs. Standard Drape in Cardiac Surgery: Study in 5,100 Patients

Bejko et al. Journal of Cardiovascular Translational Research Sep 2015

OBJECTIVES:
1. Incidence of superficial and deep SSIs post 90 days of discharge
2. Cost analysis

DESIGN: Retrospective study on prospectively collected data from 5,100 consecutive cardiac surgeries

Methods: Subject treatment groups via a matched analysis (N=808 per group):
1. Non-antimicrobial incise drape manufactured in Germany
2. Iodine antimicrobial incise drape

<table>
<thead>
<tr>
<th></th>
<th>Non Antimicrobial Drape</th>
<th>Iodine Antimicrobial Incise Drape</th>
<th>Cost Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSI¹</td>
<td>6.5%</td>
<td>1.9%</td>
<td></td>
</tr>
<tr>
<td>Complete Adhesion¹,²</td>
<td>57.9%</td>
<td>95.0%</td>
<td></td>
</tr>
<tr>
<td>Cost</td>
<td>12.5MM €</td>
<td>11,7 MM €</td>
<td>773K € ($828K)</td>
</tr>
</tbody>
</table>

¹ p-value = 0.001,
² Was not a study objective, but was measured in each patient at the end of the procedure

*Iodine antimicrobial incise drape ensured a significantly lower incidence of SSI and proved to be cost effective in cardiac surgery*
Process Variability

\[
\frac{\text{(Dose of Bacteria)} \times \text{(Virulence)} \times \text{(Resistance of the Host)}}{\text{(Patient)}} = \text{Risk}
\]

Patient Variability

CDC Guideline For Prevention Of Surgical Site Infection, 1999
http://www.cdc.gov/ncidod/dhqp/gl_surgicalsite.html
Questions?

Thank you!