



3MSM Health Care Academy

Nasal Colonization and Surgical Site Infection (SSI) Risk

Learning Objectives

1. Describe how nasal carriage of *S. aureus* relates to SSI
2. Identify relevant clinical studies related to preoperatively reducing bacteria in the nose
3. Describe guidelines and recommended practices that support nasal intervention

Surgical Site Infections

- ▶ Surgical procedures are becoming increasingly more complicated
- ▶ Population of surgical patients has more underlying conditions
- ▶ These factors increase the risk for developing surgical site infection (SSI)



SSI Epidemiology

ICHE 2014 35 (6): Strategies to prevent SSI in Acute Care Hospitals: 2014 Update

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

Reducing Bacteria in the Nares

S. aureus is the leading
cause of surgical site
infections

Sievert DM, et al. Antimicrobial-Resistant Pathogens Associated with Health care-Associated Infections: Summary of Data Reported to the National Health care Safety Network at the Centers for Disease Control and Prevention, 2009–2010. *Infect Control Hosp Epidemiol* 2013; 34(1):1-14.

Distribution of Top Ranking Pathogens – 2009-2010

Pathogens	SSI
<i>Staphylococcus aureus</i>	30.4%
<i>Coagulase Negative Staph (CNS)</i>	11.7%
<i>Escherichia coli</i>	9.4%
<i>Enterococcus faecalis</i>	5.9%
<i>Pseudomonas aeruginosa</i>	5.5%
<i>Enterobacter spp.</i>	4%
<i>Klebsiella pneumoniae</i>	4%
<i>Enterococcus spp.</i>	3.2%
<i>Proteus spp.</i>	3.2%

Approximately 30% of the population are colonized with *S. aureus* in the nares and 1% carry MRSA

80% of the *S. aureus* infections are caused by the patient's own (clonal) nasal flora

Perl TM, Cullen JJ, Wenzel RP, et al. Intranasal mupirocin to prevent postoperative *Staphylococcus aureus* infections. *N Engl J Med* 2002;346(24):1871-1877.

Kalmeijer MD, van Nieuwland-Bollen E, Bogaers-Hofman D, et al. Nasal carriage of *Staphylococcus aureus* is a major risk factor for surgical site infections in orthopedic surgery. *Infect Control Hosp Epidemiol* 2000;21:319-323.

Kluytmans JAJW, Mouton JW, Ijzerman EPF, et al. Nasal carriage of *Staphylococcus aureus* as a major risk factor for wound infections after cardiac surgery. *J Infect Dis* 1995;171:216-219.

Nasal carriage of *S. aureus* is a major risk factor for SSI following cardiac open heart surgery.

Nasal carriage of *S. aureus* is a major risk factor for SSI following orthopedic prosthetic joint surgery.

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

- ▶ **Bactroban Nasal[®] (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*

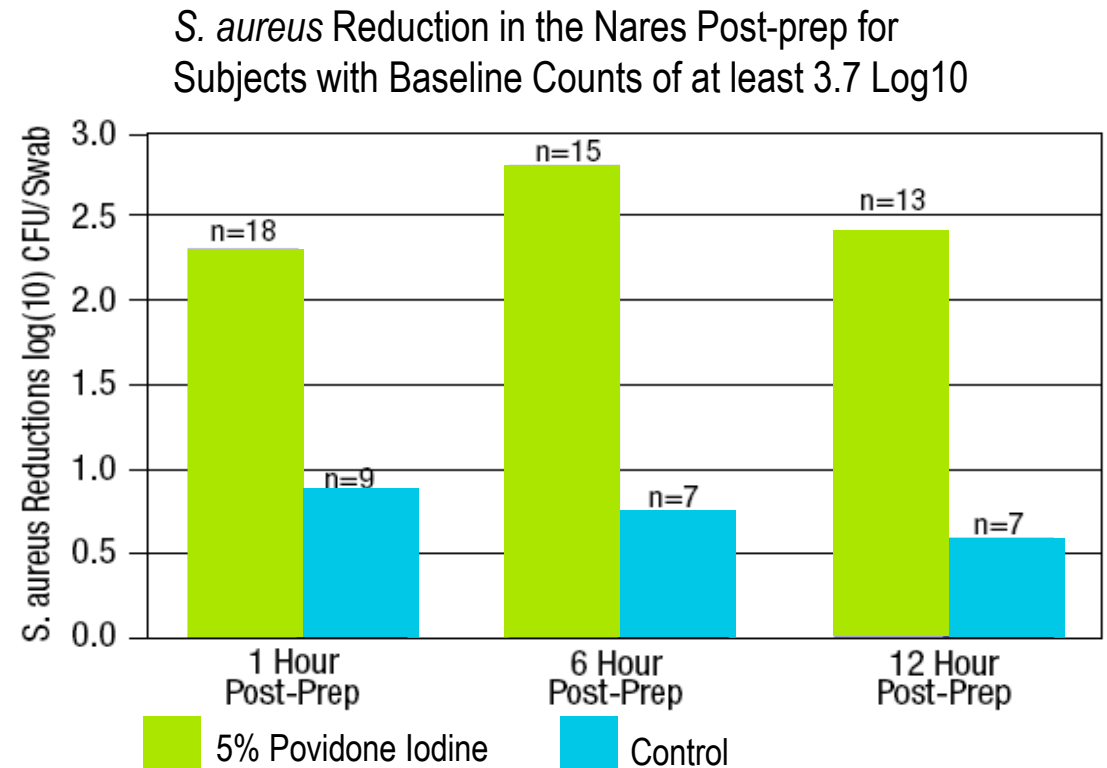
- ▶ **mupirocin challenges**
 - Full 5-day treatment does not fit into pre-surgical logistics
 - Poor patient compliance
 - Antibiotic resistance

* http://us.gsk.com/products/assets/us_bactroban_nasal.pdf

Antiseptic Prep – 5% Povidone Iodine

- ▶ One-time application 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

3M Study-05-011100



Example for 12-hour Time Point

Baseline: 4.72logs or 52,000 *S. aureus* –
2.37logs 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 compliance²
- Demonstrated efficacy in helping reduce SSI risk

► Limitations

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

1. 3M Study 05-011322

2. Phillips M, Rosenberg A, Shopsin B, et al. Preventing surgical site infections: A randomized, open-label trial of nasal mupirocin ointment and nasal povidone-iodine solution. *Infect Control Hosp Epidemiol* 2014;35(7):826-832.

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 helping to reduce the risk of SSI



Clinical Studies- Phillips M et al., ICHE 2014

Clinical Study Rationale

Preventing Surgical Site Infections: A Randomized, Open-Label Trial of Nasal Mupirocin Ointment and Nasal Povidone-Iodine Solution

- ▶ Protocol to reduce the risk of SSI consisted of:
 - CHG bathing the night before and the morning of surgery nasal
 - Nasal 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

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



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.



Conclusion

There were significant cost savings with no difference in infection rates; therefore, the 5% povidone-iodine nasal antiseptic is financially and clinically successful.

Evidence-Does Formulation Matter?

Results

MRSA Log₁₀ Reduction (mean reduction across all isolates)

	Timepoint		
Treatment	1 hour	6 hours	24 hours
3M Skin and Nasal Antiseptic	5.8 ± 0.26*	6.6 ± 0.47*	6.9 ± 0.41*
Clorox Healthcare Nasal Antiseptic	4.1 ± 0.42	3.5 ± 0.4	2.4 ± 0.51
Betadine Solution	4.8 ± 0.41	4.1 ± 0.60	1.9 ± 0.37

* denotes significant difference from other treatments (**p≤0.05**)

3M Skin and Nasal Antiseptic was significantly more effective than Clorox and Betadine at reducing MRSA at 1, 6 and 24 hours.

Conclusion

3M Skin and Nasal Antiseptic was persistent and superior to Clorox Healthcare Nasal Antiseptic and Betadine Solution for reducing MRSA (including MRSA high-level mupirocin-resistant isolates) burden over 24 hours.

Clinical Studies

Randomized controlled trial comparing *S. aureus* cultures at baseline and after application of nasal treatment in patients undergoing total joint arthroplasty

Treatment		
Randomized to either:		
• Off the shelf 10% povidone iodine (10%PI)	• 3M™ Skin and Nasal Antiseptic (5% PI)	• Saline (control)

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

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.

Not all formulations are created equal

	Polymeric solution with swabs for nasal use	Povidone iodine saturated swabs
Active Ingredient	5% PI	10% PI
Formulation	Patented formula designed specifically for the nose	?
Proven efficacy in the nose	Yes	No
Clinical studies with SSI outcome	9	0

Summary of Clinical Evidence

- ▶ One time application of 5% PI Nasal Antiseptic helps reduce the risk of SSI when part of a comprehensive preoperative protocol¹⁻⁹
- ▶ It is cost effective¹⁻³
- ▶ It has better antimicrobial efficacy in the nose than 10% PVP-I¹⁰

1. Phillips M., et al. Preventing Surgical Site Infections: A randomized, open-label trial of nasal mupirocin ointment and nasal povidone-iodine solution. *Infect Control Hosp Epidemiol* 2014; 35(7): 826-832
2. Bebko SP, Green DM, Awad SS. Effect of a Preoperative Decontamination Protocol on Surgical Site Infections in Patients Undergoing Elective Orthopedic Surgery With Hardware Implantation. *JAMA Surg*. Published online March 04, 2015. doi:10.1001/jamasurg.2014.3480.
3. Torres EG, Lindmair-Snell JM, Langan JW, Burnikel BG. Is preoperative nasal povidone-iodine as efficient and cost-effective as standard methicillin-resistant *Staphylococcus aureus* screening protocol in total joint arthroplasty? *J Arthroplasty*. 2016; 31: 215-218.
4. Flynn N, Carr M. Skin and Nasal Antiseptic use in the prevention of post-operative infections. Presented at the SHEA Conference, Orlando, FL, May 2015.
5. Rivera K, Smith RL, Rose L, Hardenstine H, Snedeker L, Wolfgang J. Implementation of a Total Joint Replacement Pre-Operative Sin and Nasal Decolonization Process for the Reduction of *Staphylococcus aureus* (SA) and Methicillin Resistant *Staphylococcus aureus* (MRSA) Infection. Presented at the APIC National Conference, Charlotte, NC, June 2016.
6. Brown L, Shelly M, Greene L., et al. The Effect of Universal Intranasal Povidone Iodine Antisepsis on Total Joint Replacement Surgical Site Infections. Presented at the APIC National Conference, Anaheim, CA, June 2014.
7. Waibel ML. Revisiting Process Improvement for Total Joint Arthroplasty SSI. Presented at the APIC National Conference, Fort Lauderdale, FL, June 2013.
8. Hogenmiller J, Hamilton J, Clayman T., et al. Preventing Orthopedic Total Joint Replacement SSIs through a Comprehensive Best Practice Bundle/Checklist. Presented at the APIC National Conference, Baltimore, MD, June 2011.
9. Osborn N, Reynolds L. Embedding an Infection Preventionist (IP) in the OR. Presented at the AORN Surgical Conference and Expo, Denver, CO, March 2015.
10. Rezapoor M, Nicholson T, Patel R, Mostafavi R, Chen AF, Parvizi J. Do iodine-based solutions differ in their effectiveness for decolonizing intranasal *Staphylococcus aureus*? Presented at the MSIS Annual Meeting, Cleveland, OH, August 2015



THANK YOU FROM MY POSSE 😊

Questions?