

Clinical evidence summaries

# 3M™ Skin and Nasal Antiseptic

(Povidone-Iodine Solution 5% w/w [0.5% available iodine] USP)

## Patient preoperative skin preparation

### Summary 1

## Compared to mupirocin, Skin and Nasal Antiseptic provides more value, defined as quality of outcomes divided by cost

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.

### Objective

The purpose of this study is to compare the efficacy of Skin and Nasal Antiseptic to Bactroban® nasal ointment. Decolonization with mupirocin presented barriers including poor patient compliance and concerns about antibiotic resistance that led to a search for an alternative.

### Design

Investigator initiated, prospective, randomized, controlled, open-label trial comparing deep surgical site infection (SSI) within 90 days after surgery.

### Surgeries

Arthroplasty or spine fusion.

### Methods

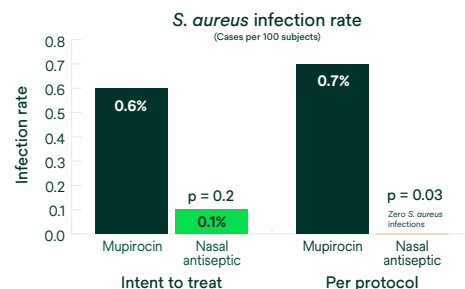
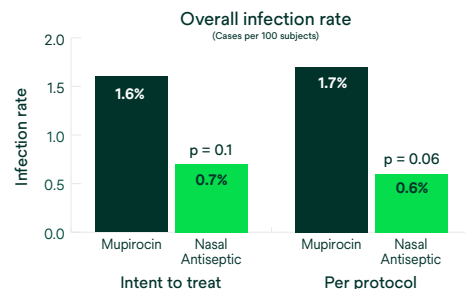
All patients were provided 2% CHG cloths for use the evening prior to and the morning of surgery.

Randomized to either:

- Skin and Nasal Antiseptic (PI group), 1 dose given in the pre-operative hold area within 2 hours of incision.
- Bactroban® nasal ointment (antibiotic group), twice daily for the 5 days prior to surgery.

### Results

1,697 patients were included in the intent-to-treat analysis and 1,539 in the per-protocol. Efficacy results in the intent to treat and per protocol groups are provided in the graphs below. Patients in the Skin and Nasal Antiseptic group reported significantly fewer treatment-related adverse events (1.8% vs 8.9%,  $p < 0.05$ ) than the mupirocin group.



## Summary 2

# Supplementing decolonization protocol with Skin and Nasal Antiseptic significantly lowered SSI rates in urgent lower extremity fracture repairs

Urias DS, Varghese M, Simunich T, Morrissey S, Dumire R. Preoperative decolonization to reduce infections in urgent lower extremity repairs. *European Journal of Trauma and Emergency Surgery*. 2018:1–7. doi:10.1007/s00068-017-0896-1.

## Objective

The purpose of this study was to measure the effectiveness in reducing SSIs in patients undergoing repair of urgent lower extremity fractures.

## Design

Investigator initiated, retrospective review comparing SSI rates after surgery.

Prior to January 2013, patients were followed for 1 year. Post January 2013, patients were followed for 30 days (superficial SSI) and 90 days (deep incisional or organ/space).

## Surgeries

Trauma patients undergoing urgent lower extremity fracture (hip/femur, knee, tibia/fibula, and ankle) repair with hardware.

## Methods

### Pre-intervention group:

October 1, 2012 – September 30, 2014

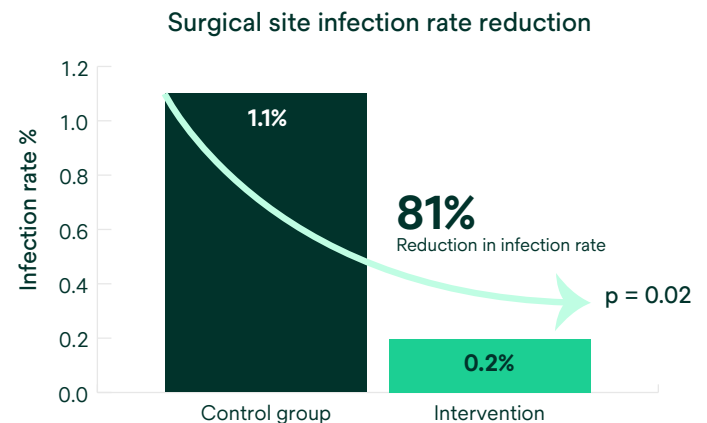
Patients either bathed with 2% chlorhexidine gluconate (CHG) cloths or showered with 4% CHG solution. One bath/shower the night before surgery, if possible, and always the morning of surgery.

### Intervention group:

October 1, 2014 – September 30, 2016

Patients followed pre-intervention CHG bath/shower protocol. And also received povidone-iodine skin and nasal antiseptic (PI-SNA) preoperatively within 1 hour of incision.

## Results



1,746 unique patients underwent 1,892 surgeries; 862 patients in the pre-intervention group and 884 patients in the intervention group.

The change in SSI rate from 1.1% (10/930, pre-intervention) to 0.2% (2/962, intervention) was statistically significant (p value = 0.020).

Both cancer and decolonization were shown to be statistically significant independent risk factors for developing a post-operative SSI defined by the CDC criteria.

## Summary 3

# Using Skin and Nasal Antiseptic as part of the patient preparation protocol does not rely on patient compliance and eliminates the risk of mupirocin resistance which resulted in an average cost savings of \$93.95 per patient

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.

## Objective

The purpose of this study was to compare the efficacy and cost of Skin and Nasal Antiseptic to MRSA screening and treatment with mupirocin.

## Design

Investigator initiated, retrospective, before-and-after intervention study comparing surgical site infection rates within 90 days of surgery and cost-effectiveness of each protocol.

## Surgeries

Primary or revision total knee arthroplasty (TKA) or total hip arthroplasty (THA).

## Methods

### Control:

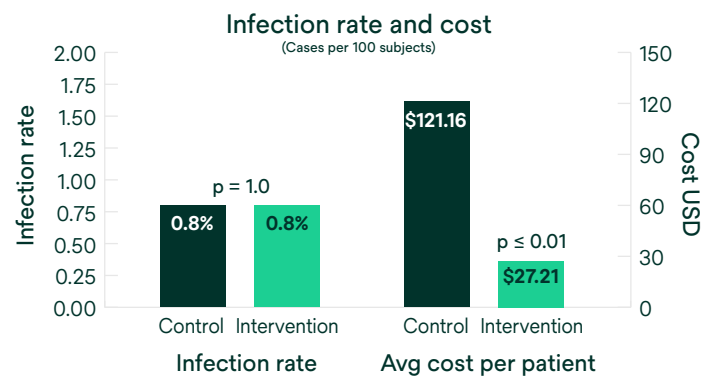
All patients undergoing primary or revision TKA or THA surgery from November 2011 – April 2013 were screened for MRSA. Those who were culture positive were treated preoperatively with mupirocin twice daily for 5 days.

### Intervention:

May 2013 – October 2014 – All patients received Skin and Nasal Antiseptic preoperatively.

All patients from both groups were also instructed to bathe with chlorhexidine gluconate (CHG) for 5 days before surgery and the operative leg was cleansed with a CHG wipe in preop on the day of surgery.

## Results



1,853 patients were included; 849 in the control group, 1,004 in the intervention group.

There was no difference in the SSI rate between groups (0.8% in both groups); ( $p = 1.0$ ).

There was a significant difference in the mean cost per case between the MRSA screening group (\$121.16) and the Skin and Nasal Antiseptic group (\$27.21); ( $p \leq 0.01$ ).

## Summary 4

# Universal decontamination protocol which includes a 5% povidone iodine solution intranasally may be considered an additional prevention strategy for SSIs in patients undergoing orthopedic surgery with implants

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.

## Objective

The purpose of this study was to examine the effect a preoperative decontamination protocol had on SSI rates.

## Design

Investigator initiated, prospective, before-and-after intervention, cohort study comparing surgical site infection rates within 30 days of surgery.

## Surgeries

Elective orthopedic surgery with hardware implantation.

## Methods

Control and intervention groups received standard perioperative prevention measures.

## Intervention

### Control:

October 1, 2012 – April 30, 2013

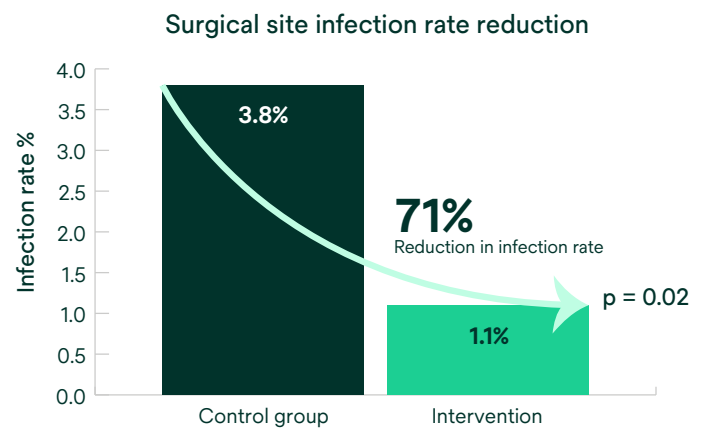
Standard perioperative preventative measures.

### Preoperative decontamination protocol:

May 1, 2013 – December 31, 2013

2% chlorhexidine gluconate cloths and 0.12% chlorhexidine oral rinse the night before and morning of surgery AND Skin and Nasal Antiseptic the morning of surgery.

## Results



A total of 709 patients were included, 344 patients in control group, 365 patients in intervention group.

Multivariate logistic regression identified the decontamination protocol as a significant independent protective factor against SSI (OR 0.24 [95% CI, 0.08–0.77]; p = 0.02).

100% compliance to decontamination protocol in intervention group.

## Summary 5

# Skin and Nasal is a contributing factor in demonstrating an improvement with *S. aureus* transmission and reducing the risk of SSI

Loftus RW, Dexter F, Goodheart MJ, et al. The Effect of Improving Basic Preventive Measures in the Perioperative Arena on *Staphylococcus aureus* Transmission and Surgical Site Infections: A Randomized Clinical Trial. *JAMA Netw Open.* 2020;3(3): e201934. doi:10.1001/jamanetworkopen.2020.1934.

## Objective

The purpose of the study was to assess whether improved basic preventive measures can reduce perioperative *Staphylococcus aureus* transmission and surgical site infections.

- Targeted UV-C light therapy to OR environments exposed to *S. aureus* transmission within the prior 2 weeks. Surveillance was used for the detection process.

## Design

Investigator-initiated randomized, prospective clinical trial.

## Surgeries

Plastic, Orthopedics, General Abdominal.

## Methods

Surgeons and their associated patients were randomized 1:1 via a random number generator to treatment group (Infection Prevention (IP) Bundle) or to usual care group.

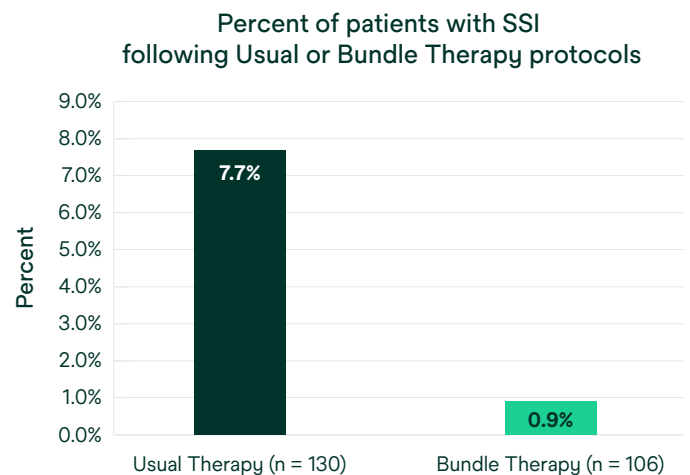
### Usual Care Group consisted of:

- Hand hygiene
- Isopropyl alcohol (IPA) pads used to disinfect IV ports, top-down cleaning of anesthesia machine and equipment
- Patient decolonization which included 1 of 3 procedures, as follows:
  - Nasal mupirocin ointment and chlorhexidine wipes for 5 days, including the morning of surgery.
  - No decolonization protocol.
  - Chlorhexidine wipes the day before and morning of surgery.

### Infection Prevention (IP) Bundle Group consisted of:

- Sustained improvements in perioperative hand hygiene, vascular care, environmental cleaning, and patient decolonization efforts with the addition of:
  - Organization of the anesthesia work area – separated clean items from contaminated items.
  - Frequency and quality of environmental cleaning improvements.
  - Intravascular catheter and syringe tip disinfection.
  - Patient decolonization with nasal povidone iodine – 5% nasal povidone iodine used as directed on the morning of surgery in same-day holding before OR entry. It was also used after induction of anesthesia and patient stabilization in the OR.

## Result



Significantly less SSIs occurred in the infection prevention bundle group (P = 0.04). The results from 236 patients (106 treatment – IP bundle, and 130 control – usual care) that participated in the study concluded that: IP bundle group had a statistically significant reduced mean number of transmitted perioperative *S. aureus* isolates compared to the usual care group (based on serial cultures taken from patient, environment, caregivers throughout the perioperative period); IP bundle group also had a statistically significant lower incidence of *S. aureus* transmission; Overall, 10 patients experienced a surgical site infection in the usual care group whereas 1 patient had a surgical site infection in the IP bundle group.

## Conclusion

Improved basic preventive measures (which includes patient decolonization with 5% nasal povidone iodine) in the perioperative arena can reduce *S. aureus* transmission and surgical site infections.

## Summary 6

# Off the shelf povidone iodine is not as effective as Skin and Nasal Antiseptic for intranasal *S. aureus* decolonization

Rezapoor M, Nicholson T, Tabatabaee RM, Chen AF, Maltenfort MG, Parvizi J. Povidone-Iodine–Based solutions for decolonization of nasal *Staphylococcus aureus*: A randomized, prospective, placebo-controlled study. *The Journal of Arthroplasty*. 2017;32(9):2815–2819.

## Objective

The purpose of this study was to compare the efficacy of off the shelf 10% povidone iodine to Skin and Nasal Antiseptic (5% povidone iodine).

## Design

Investigator initiated, prospective, randomized, controlled trial comparing nasal *S. aureus* cultures at baseline, 4 hours and 24 hours after treatment.

## Surgeries

Primary or revision total joint arthroplasty, femoracetabular osteoplasty, pelvic osteotomy, or total shoulder arthroplasty.

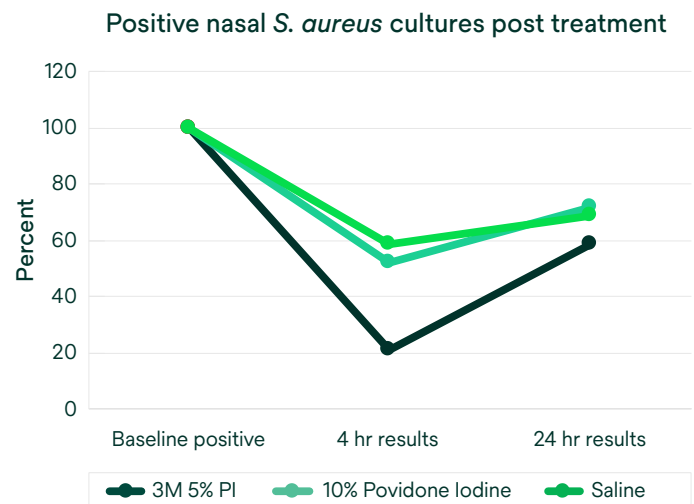
## Methods

Patients were randomized to preoperatively receive one of three nasal treatments:

- Off the shelf 10% povidone iodine (10% PI)
- Skin and Nasal Antiseptic (3M 5% PI)
- Saline (control)

All treatments were applied according to the Skin and Nasal Antiseptic instructions for use. Nasal swabs were taken for cultures preoperatively prior to nasal treatment (baseline), and at 4 hours and 24 hours after treatment.

## Results



429 patients were randomized, of which 95/429 (22.1%) were positive at baseline for *S. aureus* and 13 (3%) of these were MRSA. Skin and Nasal Antiseptic demonstrated significantly more effective intranasal decolonization of *S. aureus* over the 4 hour time interval ( $p = 0.003$ ).

Summary 7

# Intranasal povidone-iodine antiseptic is cost effective and has the potential to reduce costs, increase patient satisfaction, and eliminate the risk of mupirocin resistance

Rieser GR, Moskal JT. Cost efficacy of methicillin-resistant *Staphylococcus aureus* decolonization with intranasal povidone-iodine. *The Journal of Arthroplasty*. 2018;33:1652–1655.

## Objective

The purpose of this study was to investigate the cost-effectiveness of universal intranasal povidone iodine treatment vs screening and treating of MRSA positive patients with mupirocin.

## Design

Investigator initiated, retrospective study.

## Surgeries

Primary total knee arthroplasty (TKA) and total hip arthroplasty (THA).

## Methods

The incidence of MRSA colonization in the preoperative THA and TKA population was calculated. Patients undergoing THA and TKA from February 1, 2012 – November 16, 2016 were screened preoperatively by PCR for nasal MRSA colonization. If the culture was positive, the patient would use mupirocin twice daily for five days. Rescreening would take place, and if the patient remained positive, the patient received vancomycin perioperatively in addition to the standard antibiotic order. Patients also bathed with chlorohexidine gluconate five days prior to surgery.

Postoperative infection rates including patient never colonized, decolonized and/or failed decolonization were calculated using data from November 1, 2013 – November 16, 2016.

Costs for each of the components in universal povidone iodine protocol and screen/treat mupirocin decolonization protocol were itemized.

An equation was developed to calculate the cost associated with each MRSA decolonization protocol.

The number of THA and TKA procedures performed at the facility were identified from the fiscal year 2016.

## Results

**Incidence of MRSA nasal colonization:** 5,584 cases THA and TKA revealed a 3.5% incidence of MRSA positive patients.

**Infection rate:** The review of 3,864 cases identified 21 patients (0.54%) with a surgical site infection within 90 days. These 21 patients all tested negative for MRSA during the initial nasal screening and therefore did not receive mupirocin treatment.

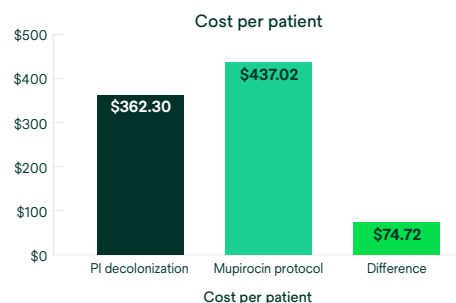
### Protocol component costs to hospital

- PCR MRSA Screening Test = \$83.86
- Mupirocin tube, 5 d BID = \$5.13
- 2 g IV vancomycin x 2 = \$19.98
- Povidone-iodine swabs = \$12.50

**Number of procedures in fiscal year 2016:** 1360 TKA/THA procedures (809 primary TKAs and 551 THAs)

Using 2016 data and assuming equivalent infection rates for both decolonization protocols as demonstrated in Torres, et al. (see Summary 3) the costs for each protocol per year were calculated.

The equations and spreadsheet used in the calculation are available in the appendix to the original article (<https://doi.org/10.106/j.arth.2018.01.033>) and allows other institutions to input data to estimate cost to convert to a protocol using povidone-iodine.



	PI Decolonization	Mupirocin Protocol	Difference
<b>Cost per 1,360 patients</b>	\$492,729.08	\$594,351.16	\$101,622.08
<b>Cost per patient</b>	\$362.30	\$437.02	\$74.72



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