The OR is no place for compromise:

A comprehensive approach to address HAIs, HOB, and surgical complications

Alyssa Clore, PA-C, MSPH
Medical Science Liaison
Becton, Dickinson and Company (BD)

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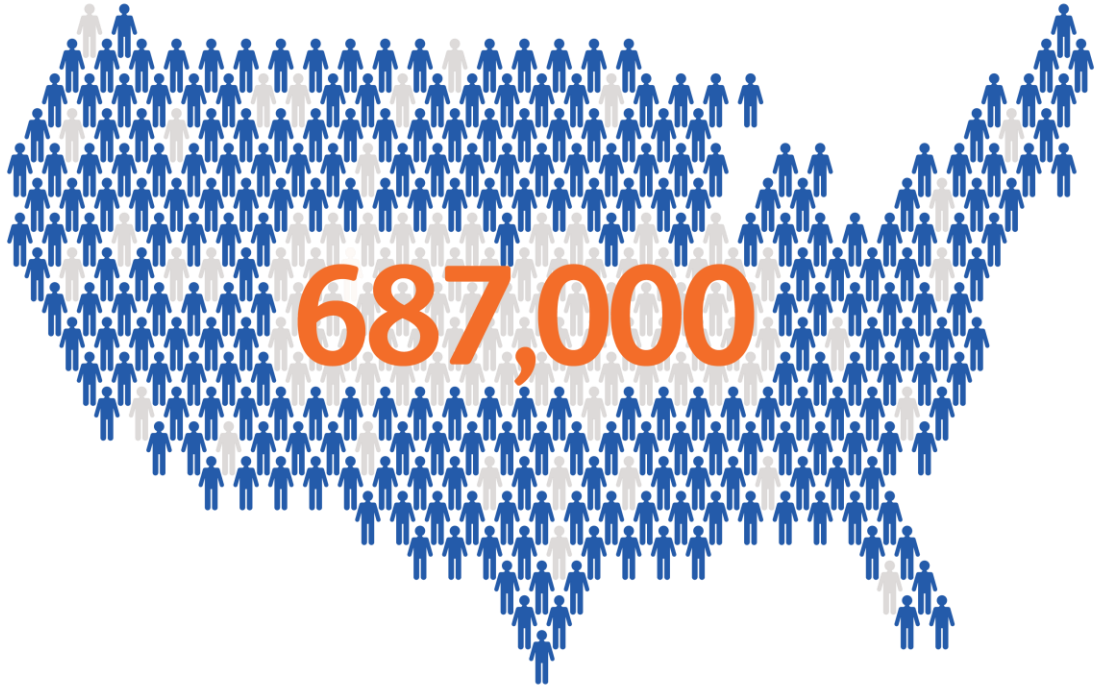
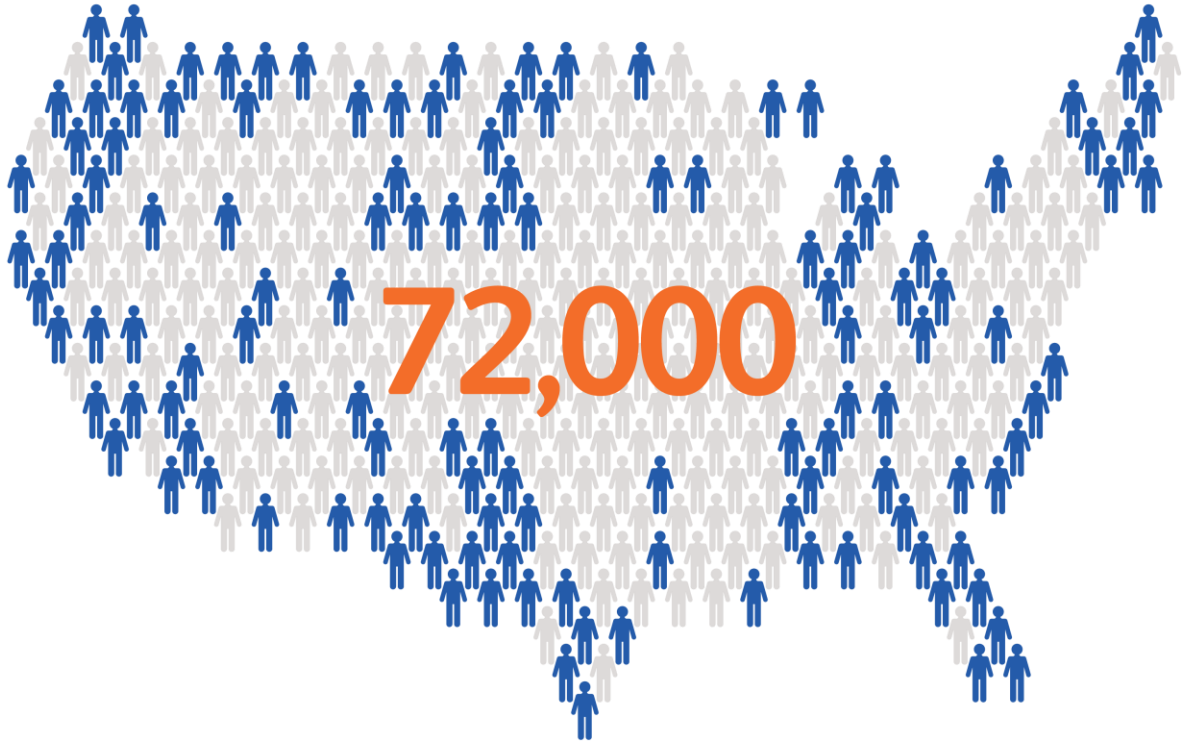
HAIs – a growing issue impacting quality, costs and outcomes

HAIs kill more people annually than breast cancer[1,2]
7.4% of patients who experience an adverse event will die[3]



687,000 patients develop HAIs in the US[1]



72,000 patients die in the US every year[1]

HAI: Healthcare-associated infection

1. Centers for Disease Control and Prevention. Healthcare-associated infections. CDC website. https://www.cdc.gov/hai/data/portal/index.html. Accessed May 20, 2019.
2. Breast Cancer Facts and Statistics. Breastcancer.org. Available at: https://www.breastcancer.org/facts-statistics. Accessed March 3, 2023
3. **3.** De Vries EN, Ramrattan MA, Smorenburg SM, Gouma DJ, Boermeester MA. The incidence and nature of in-hospital adverse events: a systematic review. Qual Saf Health care. 2008;17(3):216–223.

The OR is a major source of HAIs with surgical site infections (SSI)

SSIs place your patients and hospital at risk.

Account for **1 of 5 HAIs** globally[1]

Can increase patient mortality by **up to 11x**[3]

Cost U.S. hospitals **$11,874–$34,670** per patient on average[2]

Increase a patient's post-operative hospital stay by **7–11 days**[3]

- **1.** Ban KA et al. *J Am Coll Surg.* 2017;224(1):59-74. **2.** Scott RD. 2009. Accessed January 2023 at https://www.cdc.gov/hai/pdfs/hai/scott_costpaper.pdf. **3.** Anderson DJ et al. *Infect Control Hosp Epidemiol.* 2014;35(6):605-627.

HOB is a proposed metric to track quality in hospitals

Hospital-onset bacteremia & fungemia or HOB is a hospital-onset bloodstream infection (BSI) diagnosed on or after the 4th day of hospital admission.

Hospital-onset bacteremia (HOB) and fungemia has been suggested as a **more comprehensive quality metric** for HAIs. It passed the National Quality Forum (NQF) Patient Safety Committee review as a **recommended metric** to the Centers for Medicare & Medicaid Services.[1,2]

The HOB metric will potentially expand hospital surveillance of bloodstream infections (BSIs) beyond current state and provide an **opportunity** to **re-evaluate infection prevention strategies**.[3]

- **1.** Yu KC, Ye G, Edwards JR, et al. Hospital-onset bacteremia and fungemia: an evaluation of predictors and feasibility of benchmarking comparing two risk-adjusted models among 267 hospitals. *Infect Control Hosp Epidemiol.* 2022;43(10):1317-1325. doi:10.1017/ ice.2022. **2.** Centers for Medicare & Medicaid Services. FY 2023 hospital inpatient prospective payment system (IPPS) and long-term care hospitals (LTCH PPS) proposed rule—CMS 1771-0. April 18, 2022. Accessed Feb 22, 2023. https://www.cms.gov/newsroom/fact-sheets/fy-2023-hospital-inpatient-prospective-payment-system-ipps-and-long-term-care-hospitals-ltch-pp **3.** Schrank G, Snyder G, Leekha S. Hospital-onset bacteremia and fungemia: examining healthcare-associated infections prevention through a wider lens. *Antimicrob Steward Healthc Epidemiol.* 2023;3(1):e198.

Sources of Hospital Onset Bacteremia & Fungemia (HOB)?

What are some sources of HOB?[1]

CLABSI
Central Line Bloodstream Infection

CRBSI
PIVC, midlines

UTI
Urine source: UTI, CAUTI

SSI
Surgical site/ post-procedure infection

VAP
Pneumonia source

WOUND
Skin and soft tissue infections

- **1.** American Hospital Association (AHA). Hospital Onset Bacteremia, Hospital leaders' attitudes on HOB sources, prevention and treatment. AHA/BD 2023.

Why should hospitals care about HOB*?[1]

+13–16 days increased LOS

$35–49k added cost

Mortality rates significantly higher with HOB (3x)

30-day readmission rates significantly higher

*statistics for CLABSI HOB

- **1.** Yu KC, Jung M, Ai C. Characteristics, costs, and outcomes associated with central-line–associated bloodstream infection and hospital-onset bacteremia and fungemia in US hospitals. Infection Control & Hospital Epidemiology. 2023;44(12):1920-1926. doi:10.1017/ice.2023.132

SSI and HOB co-occurrence: Clinical and economic outcomes[1]

Sample size
- 38 acute care hospitals
- 242 NHSN-reported SSI cases, 30 (12.4%) HOB co-occurrence

LOS (days) – added LOS per event
- SSI vs control: 11.6 days
- SSI + HOB vs SSI control: 6.3 days

Hospital costs ($) – incremental cost per event
- SSI vs control: $30,689
- SSI + HOB vs SSI control: $24,586

Relative mortality risk
- SSI vs control: 3.4 RR
- SSI + HOB vs SSI control: 3.4 RR

30-day readmission rates
- SSI vs control: 1.5 RR
- SSI + HOB vs SSI control: 2.7 RR

Patients with SSI had 6-fold higher risk of HOB

HOB + SSI co-occurrence = Increased clinical and economic burden

- **1.** Ai, C, Jung, M, Bastow, S, Adjaoute, G, Bostick, D, Yu, K. Clinical Outcomes and Hospital-Reported Cost Associated with Surgical Site Infections and the Co-occurrence of Hospital Onset Bacteremia and Fungemia Across US Hospitals. Infect Control Hosp Epidemiol. 2025 Feb19;46(4):1-7.

HOB tracking will lead to many questions for key hospital stakeholders

Staff nurse

Will this change **my current practices?**

How will I **learn these new techniques consistently?**

ICU clinician

Which of my patients **are at greater risk?**

How often should we be **testing for bloodstream infections?**

Infection preventionist

Will we have the resources to **track infections, enforce protocols, and investigate more incidences?**

What are the primary causes of **HOB** for us to focus on?

CNO

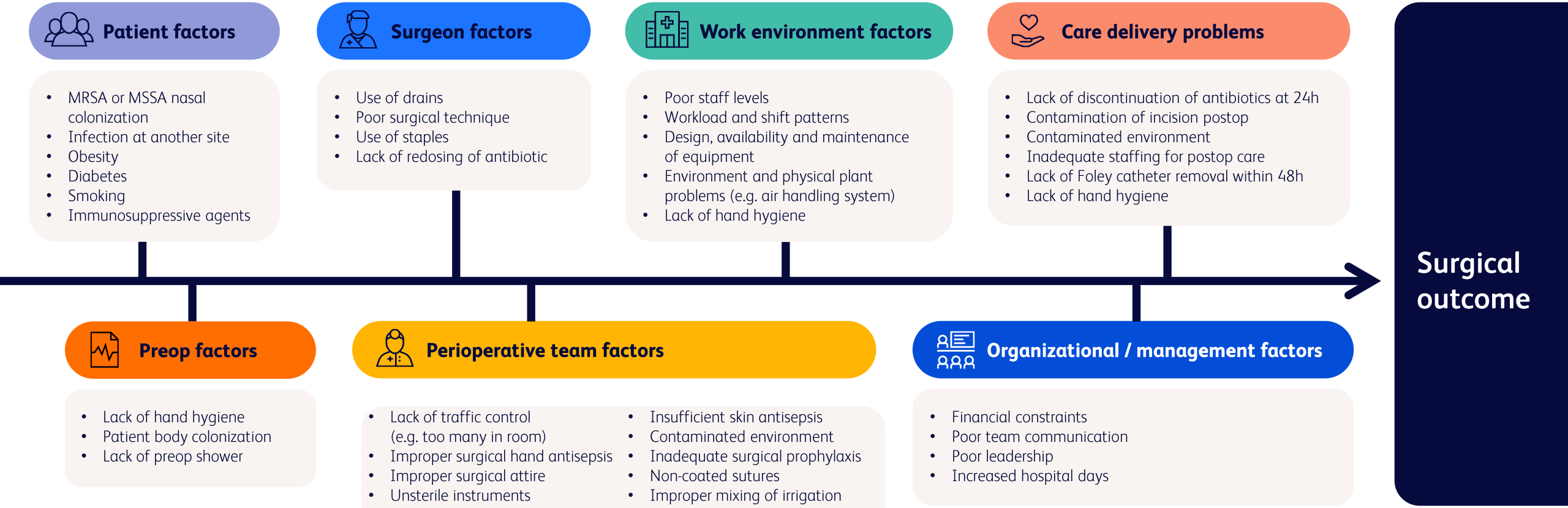
How will this **impact our reimbursement and hospital evaluation?**

How will **our staff be able to meet** these tracking needs?

"We have not taken concrete steps, but infection control is already working on changes to the EMR dashboard and trying to figure out how to handle reporting peripheral line infections." – CNO

"I think it will be very disruptive given how common peripheral IVs are and how little attention they have been given until now. Nurses are not systematic in changing dressings and following sterile protocols, so it will definitely require training." – Vascular Access Team Specialist

The clinical challenge in the OR: multiple factors contribute to SSI/HOB risk[1]



One factor could lead to failure

- There are many different strategies that are required to **reduce SSI risk to the lowest extent possible**
- The **most successful method of implementation** to prevent SSIs is the use of **bundles**, i.e, addressing multiple risk factors simultaneously

Perioperative

- The time period of a patient's procedure, from pre-op to post-op

1. Adapted from Spencer M. Working Toward Zero Healthcare Associated Infections. http://www.workingtowardzero.com/uploads/4/6/4/2/ 4642325/aorn1929_going_forward_-_preventing_ssis__dec_2014.pdf.

Addressing the clinical challenge requires a holistic approach[1-3]

1. Berríos-Torres SI et al. *JAMA Surg.* 2017;152(8):784-791. **2.** World Health Organization. Accessed in September 2022 at https://apps.who.int/iris/handle/10665/277399. **3.** Calderwood MS et al. *Infect Control Hosp Epidemiol.* 2023;44(5):695-720.

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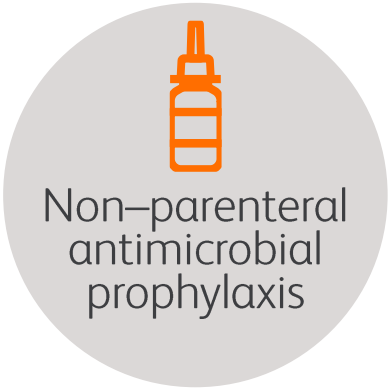
Parenteral and non-parenteral antimicrobial prophylaxis is essential

- Administer according to evidence-based standards and guidelines[1,3]
- Administer within 1 hour of incision[3]
- Re-dose for lengthy procedures and in cases with excessive blood loss[3]
- Discontinue antimicrobial agents after incisional closure in the OR[1,3]



- Uncertain trade-offs between benefits and harm of intraoperative antimicrobial (e.g. antibiotic) irrigation[1,3]
- Do not apply antimicrobial agents (i.e. ointments, solutions, or powders) to the surgical incision[1]
- Use combination of parenteral and oral antimicrobials for elective colorectal surgery[2,3]

1. Berríos-Torres SI et al. *JAMA Surg.* 2017;152(8):784-791. **2.** World Health Organization. Accessed in September 2022 at https://apps.who.int/iris/handle/10665/277399. **3.** Calderwood MS et al. *Infect Control Hosp Epidemiol.* 2023;44(5):695-720.

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Maintaining patient temperature control and glucose is recommended in all care bundles

Glycemic control

- Use protocols to maintain perioperative glycemic control for both diabetic and non-diabetic adult patients undergoing surgical procedures[1-3]
  - Perioperative Target < 200 mg/dL[1-2]
  - Maintain postoperative level between 110-150 mg/dL[3]
- Ideal method for controlling glucose unknown[3]
  - Continuous infusion insulin
  - Sliding scale (subcutaneous) insulin

Normothermia

- Maintain perioperative normothermia[1-3]
  - Temperature >35.5°C
- No specific optimal strategy on how to maintain normothermia[1,2]
  - Fluid warmers
  - Warm blankets
- No standardized duration of warming[2,3]
  - 30 min – 2 hours

1. Berríos-Torres SI et al. *JAMA Surg.* 2017;152(8):784-791. **2.** World Health Organization. Accessed in September 2022 at https://apps.who.int/iris/handle/10665/277399. **3.** Calderwood MS et al. *Infect Control Hosp Epidemiol.* 2023;44(5):695-720.

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Several strategies utilizing antiseptic prophylaxis are addressed in bundled approaches

Preoperative Bathing

- Plain or antimicrobial soap for preoperative bath or shower at least night before the operative day[1-2]
- Data are mixed on at-home preoperative bathing with CHG-containing products alone[1-3]

Nasal Decolonization

- Decolonize in nasal carriers of *Staphylococcus aureus*[2,3]
  - Intranasal mupirocin and CHG bathing
  - Up to 5 days prior to surgery
- Preliminary data on povidone-iodine intranasal immediately prior to surgery[3]

Screening for MRSA

- Routine use of mupirocin alone without screening may lead to resistance[3]
- Routine decolonization with antiseptics without screening can be done with antiseptics such as povidone iodine[3]

1. Berríos-Torres SI et al. *JAMA Surg.* 2017;152(8):784-791. **2.** World Health Organization. Accessed in September 2022 at https://apps.who.int/iris/handle/10665/277399.
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Surgical hair clipping waste: more than a mess, an infection risk

Identifying the challenge

- Use of razors may compromise the skin and increase the risk of contamination[1]
  - Clippers support patient preoperative hair removal in a single pass and minimize the risk of compromising the skin
- Loose hair can increase the risk of contamination for your patients[2]
- Adhesive tapes, commonly used for hair cleanup, are not sterilized or kept under controlled conditions, and may become colonized with organisms and contribute to HAIs[3]
  - Frequently used on multiple patients
  - Often contain hair from previous patients

Addressing the challenge

A study compared hair removal using standard surgical clippers with surgical tape vs. clippers fitted with a vacuum-assisted hair collection device and found it resulted in[2]:

- Reduced contamination
  - Significantly reduced microbial contamination by 85% compared to clipping and tape cleanup*
- Faster clipping and cleanup time
  - An average of 40% faster compared to clipping and tape cleanup
- Less residual loose hair†

* Results were measured by $\log_{10}$ colony forming units (CFU) as recovered from comparative chest and groin sites following clipping.

† The mean weight of recovered hair from beneath the test site for the combination of clipping and tape was 0.212 g, while the mean weight of hair recovered from beneath the vacuum-assisted hair collection device was 0.003 g.

1. Mangram AJ, Horan TC, Pearson ML, Silver LC, Jarvis WR, the Hospital Infection Control Practices Advisory Committee. Guideline for the prevention of surgical site infection, 1999. *Infect Control Hosp Epidemiol* 1999;20:247-280. Updated in *JAMA Surg.* 2017;152(8):784-791 **2.** Edmiston CE Jr, Griggs RK, Tanner J, Spencer M, Seabrook GR, Leaper D. Perioperative hair removal in the 21st century: utilizing an innovative vacuum-assisted technology to safely expedite hair removal before surgery. *Am J Infect Control.* 2016;44(12):1639-1644. **3.** Redelmeier, DA, Livesley NJ. Adhesive tape and intravascular-catheter-associated infections. *J Gen Intern Med.* 1999;14(6):373-375

Vacuum-assisted devices help support patient preoperative hair removal needs by minimizing contamination risk in the OR, and reducing the risk of compromising the skin.

- Quick, clean and comprehensive solution for pre-op hair removal
- Up to 40% faster clipping and clean up time compared to clippers and adhesive tape[1]
- A vacuum-assisted device can capture an average 98.5% of hair and airborne contaminants at the source, eliminating the need for extra clean up with tape or mitts[1]

- **1.** Edmiston CE Jr, Griggs RK, Tanner J, Spencer M, Seabrook GR, Leaper D. Perioperative hair removal in the 21st century: utilizing an innovative vacuum-assisted technology to safely expedite hair removal before surgery. Am J Infect Control . 2016;44(12):1639–1644.

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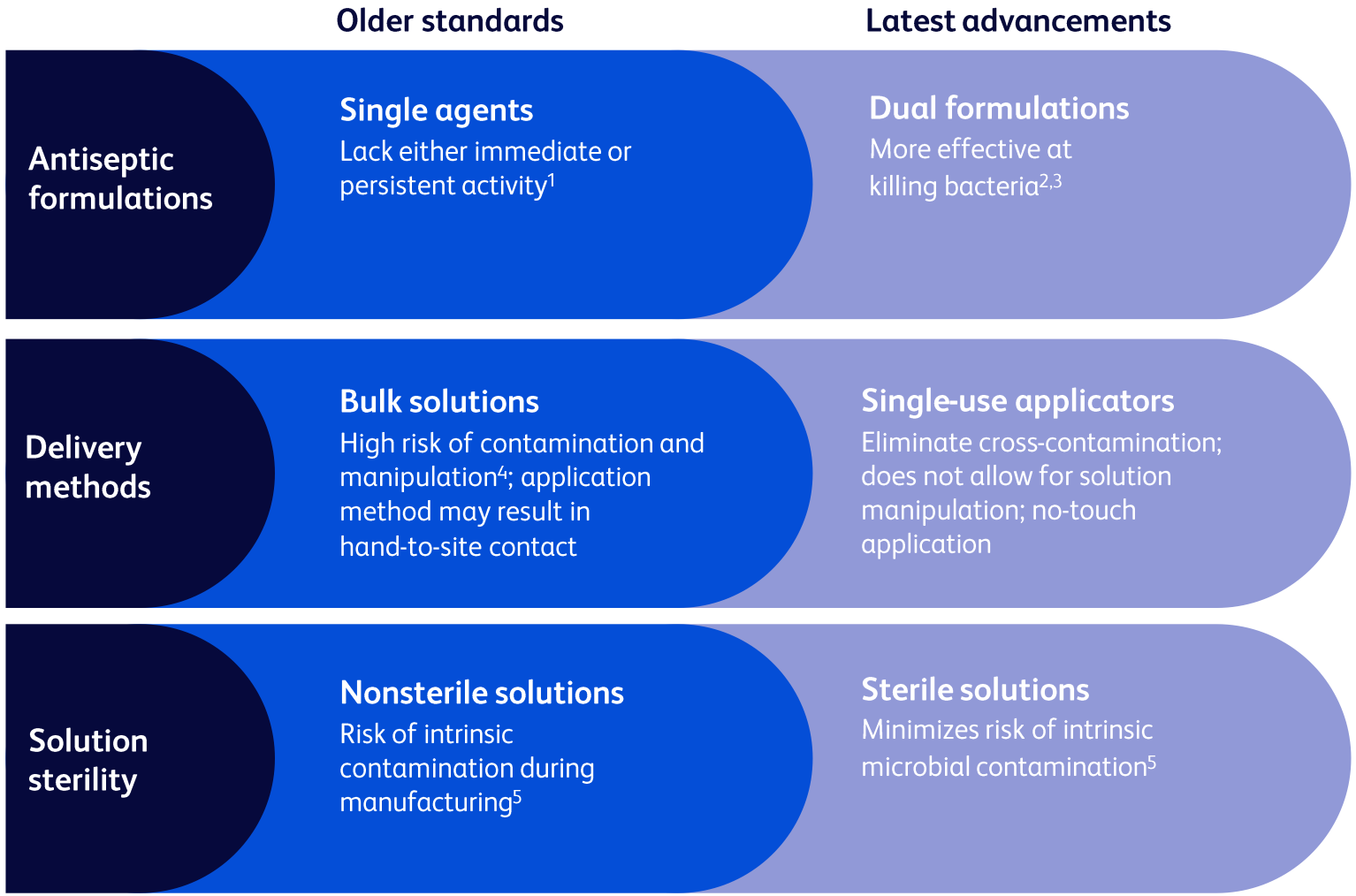
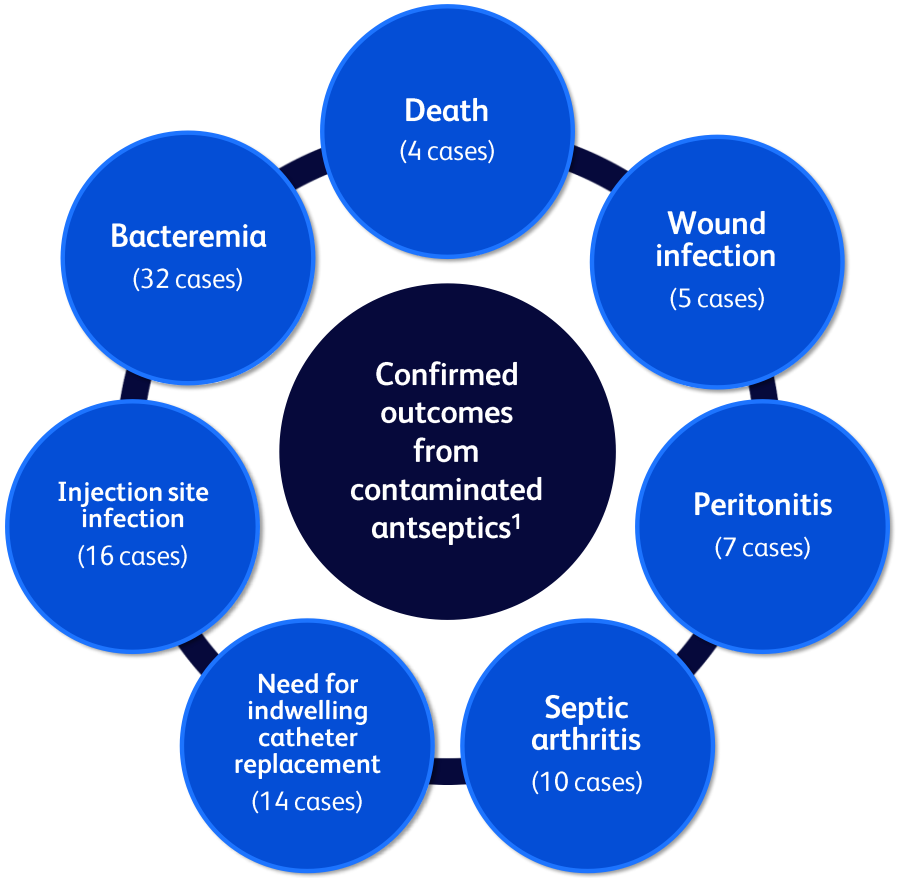
Important advances continue to be made



Recent evolution of patient preoperative skin preparation

1. Hemani ML, et al. Rev Urol. 2009;11(4):190-195. doi: 10.3909/riu0467. **2.** Ostrander RV, et al. J Bone Joint Surg Am. 2005;87(5): 980-985. **3.** Saltzman MD, et al. J Bone Joint Surg Am. 2009;91(8):1949-1953. **4.** Association of periOperative Registered Nurses. In: Guidelines for Perioperative Practice. Denver, CO: AORN, Inc; 2016. **5.** Food and Drug Administration. www.fda.gov/drugs/drugsafety/ucm374711.htm. Accessed March 19, 2019

Contaminated antiseptics are a documented cause of HAIs



Outcomes may be underreported for a range of reasons, including[2]

- Disposal of contaminated product before infection is discovered
- Inconsistent contamination within the same lot

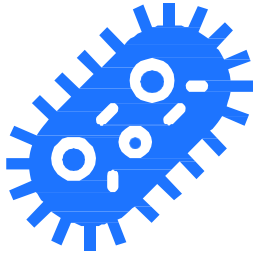
1 Food and Drug Administration. https://www.fda.gov/drugs/drugsafety/ucm374711.htm. Accessed March 19, 2019. 2 Chang CY, et al. N Engl J Med. 2012;367(23):2170-2173.

Antiseptic sterilization minimizes the risk of intrinsic bacterial threats

Maintains the efficacy and purity

of the antiseptic solution[1]

Less than a 1 in a million chance



Chance that a viable microorganism can exist[1]

Sterility assurance level of 10^{-6}

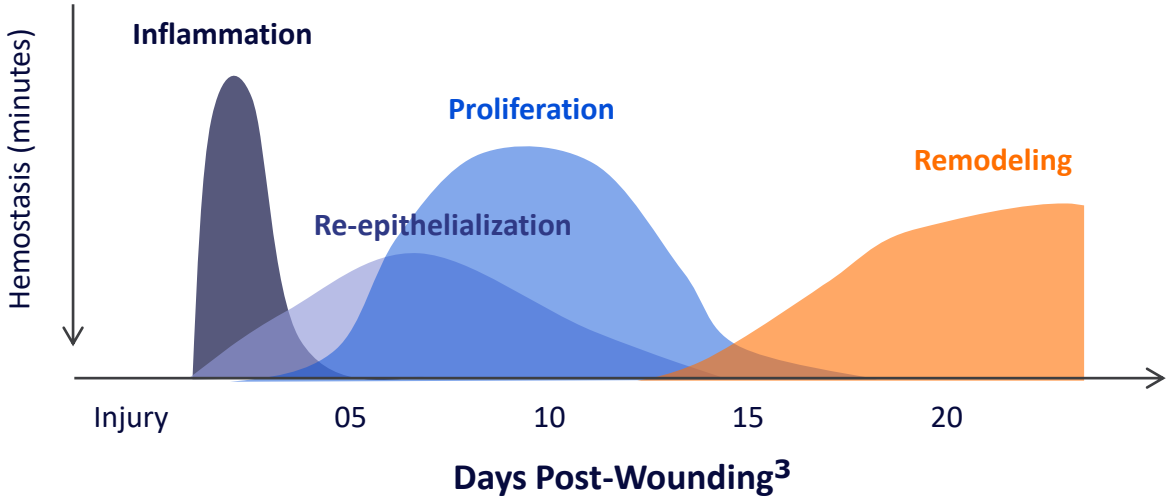
—the same level required for injectable products[1]

1 Degala, et al. United States Patent 9,078,934. July 14, 2015.

Persistence is another important consideration of antiseptic skin preparations

Definition of Persistence

Antimicrobial persistence defined as post-treatment microbial counts less than or equal to pre-treatment counts.[1,2]



Why is persistence important?

Necessary to limit bacteria on the skin and help minimize its entry into an incision or device-insertion site after application.

SURGICAL

Healing takes time.
Re-epithelialization can take up to 2 weeks[3]

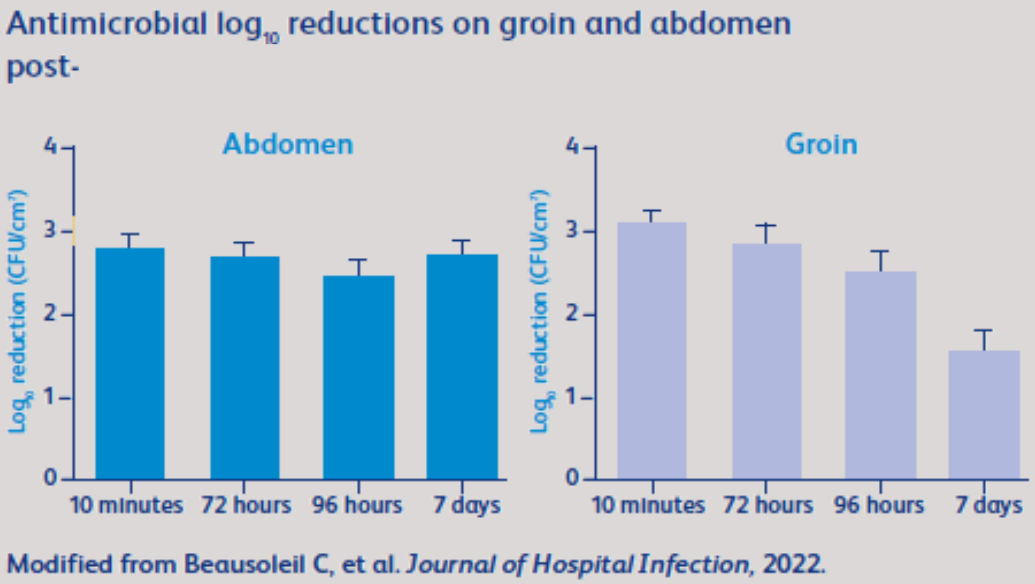
VASCULAR

Dressing
Changes can occur between 2-7 days

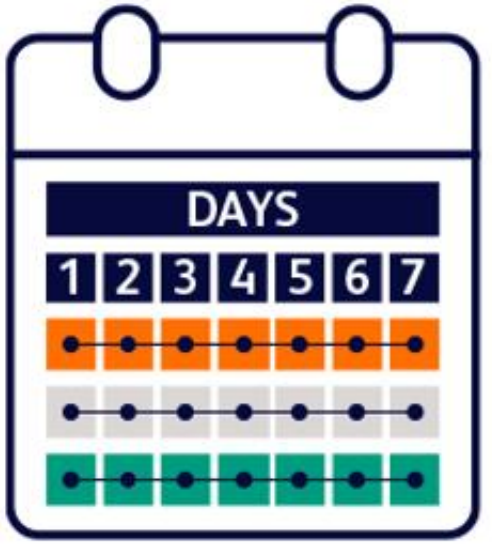
1. Beausoleil C, Comstock SL, Werner D, Li L, Eby JM, Zook EC. Antimicrobial persistence of two alcoholic preoperative skin preparation solutions. *J Hosp Infect.* 2022 Nov;129:8-16
2. FDA 12/20/2017 - Final Rule: Finalizes rulemaking for healthcare antiseptics **3.** desJardins-Park HE, Mascharak S, Chinta MS, Wan DC, Longaker MT. The Spectrum of Scarring in Craniofacial Wound Repair. Front Physiol. 2019 Mar 29;10:322

A recent study shows at least 7 days persistence for 2% chlorhexidine and 70% isopropyl alcohol[1]

A clinical study to evaluate the persistent antimicrobial properties of 2% chlorhexidine and 70% isopropyl alcohol.



Modified from Beausoleil C, et al. *Journal of Hospital Infection*, 2022.



AT LEAST
7 DAYS
PERSISTENCE

Design

Randomized, single-center, partially blinded, clinical study 101 healthy volunteers between the ages of 18 and 69. Evaluated the antimicrobial persistence of prep stick out to 7 days.

1. Beausoleil C, Comstock SL, Werner D, et al. Antimicrobial persistence of two alcoholic preoperative skin preparation solutions. *J Hosp Infect.* 2022;129:8-16

Evidence-based, recommended properties of patient preoperative skin antiseptics enable clinicians to reduce microorganisms on patients' skin that may cause infections.

- Choose a dual formulation
- Broad-spectrum, rapid-acting patient preoperative skin preparation with persistent antimicrobial activity for at least 4 days (PVP-I+IPA) and 7 days (CHG+IPA).[1]
- When possible, choose a terminally sterile product. A sterility assurance level (SAL) of 10^{-6}, is the same level of sterilization required for injectable products - there is less than 1-in-a-million chance that microorganisms can exist. The sterilization process does not adversely affect the strength, quality, safety, efficacy or purity of the solution.

CHG: chlorhexidine gluconate
PVP-I: povidone-iodine

1. Beausoleil C, Comstock SL, Werner D, et al. Antimicrobial persistence of two alcoholic preoperative skin preparation solutions. *J Hosp Infect.* 2022;129:8-16

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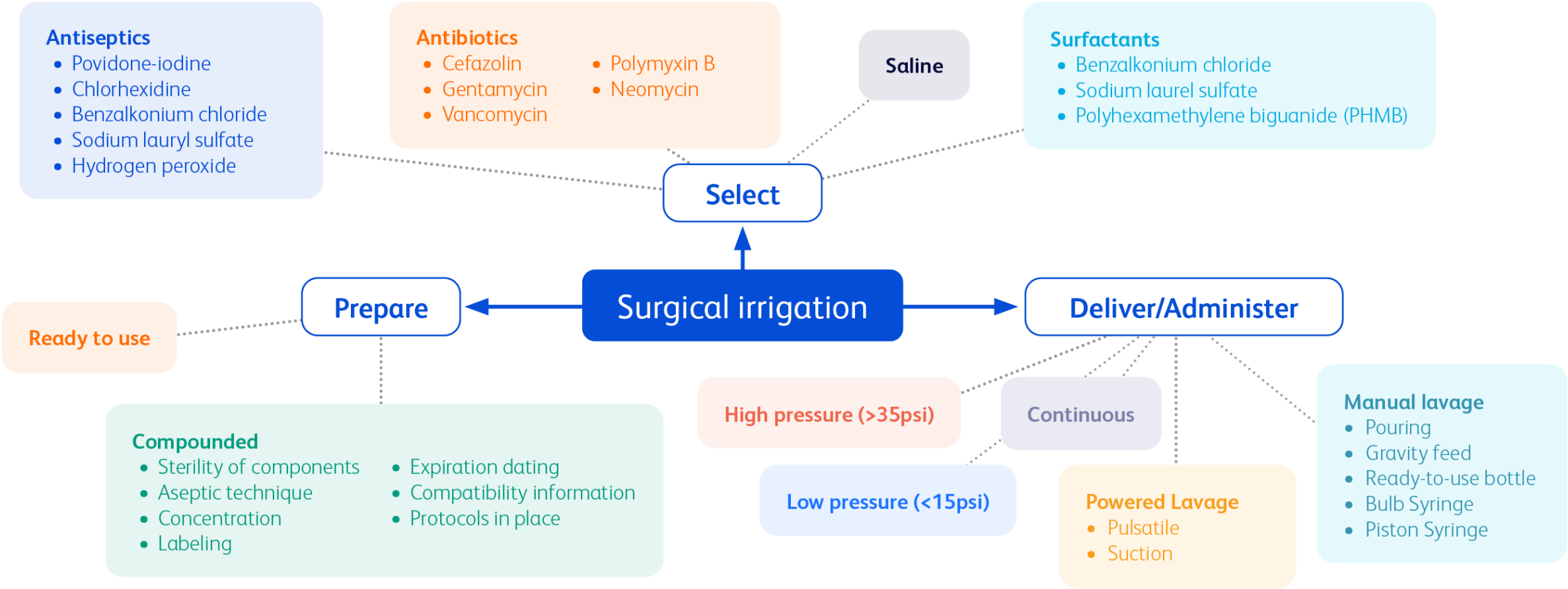
Surgical irrigation is a process that is often overlooked in bundled approaches and in the literature



Align your choice of surgical irrigation with the latest **best practice guidelines**

Use PVP-I solution and *not* antibiotics for wound irrigation[1,2,3,4]

Do not use antibiotic incisional wound irrigation
– WHO[1]

Aqueous iodophor solution
– WHO[1], CDC[2], AAOS[3], SHEA[4]

Dilute povidone-iodine lavage, making sure sterility is maintained
– SHEA[4]

Label container to avoid errors and ensure patient safety[5,6]

Label solutions in various procedural settings both on and off the sterile field
– USP[5], The Joint Commission[6]

Apply adequate pressure when irrigating[7]

Recommended range 4 to 15 PSI
– AHCPR[7]

PVP-I: Povidone Iodine; **WHO:** World Health Organization; **CDC:** Centers for Disease Control and Prevention; **AAOS:** American Academy of Orthopaedic Surgeons; **SHEA:** Society for Healthcare Epidemiology of America; **USP:** United States Pharmacopoeia; **AHCPR:** Agency for Health Care Policy and Research.

1. World Health Organization. Accessed in September 2022 at https://apps.who.int/iris/handle/10665/277399 **2.** Berríos-Torres SI et al. *JAMA Surg.* 2017;152(8):784-791. **3.** American Academy of Orthopaedic Surgeons (AAOS). Intraoperative Risk Factors. In Surgical Risk Reduction Toolkit. Accessed on September 6, 2022, at https://www.aaos.org/quality/quality-programs/quality-toolkits/intraoperative-irrigation/. **4.** Calderwood MS et al. *Infect Control Hosp Epidemiol.* 2023;44(5):695-720. **5.** USP. Pharmaceutical compounding – sterile preparations <797>. Rockville, MD: USP; November 1, 2023. **6.** National Patient Safety Goals® Effective January 2025 for the Hospital Program. The Joint Commission website. https://www.jointcommission.org/-/media/tjc/documents/standards/national-patient-safety-goals/2025/hap-npsg-simplified-2025-accessible.pdf. Published January 2023. Accessed May 28, 2025. **7.** Mak SS, Lee MY, Cheung JS, et al. Pressurised irrigation versus swabbing method in cleansing wounds healed by secondary intention: a randomised controlled trial with cost-effectiveness analysis. *Int J Nurs Stud.* 2015;52(1):88-101.

Including the many operational challenges with surgical irrigation

Identifying the challenge

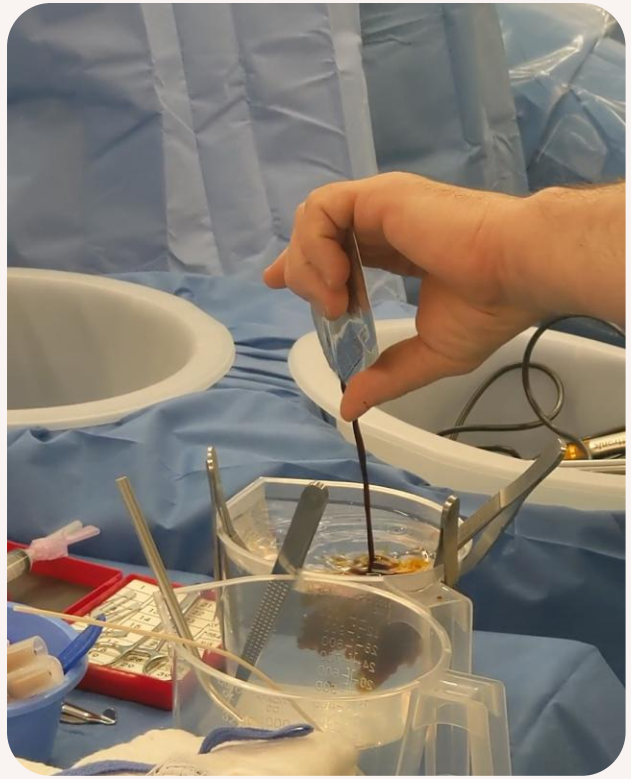
A recent study of over 400 scrub nurses and techs identified opportunities to address challenges with homebrew irrigation:

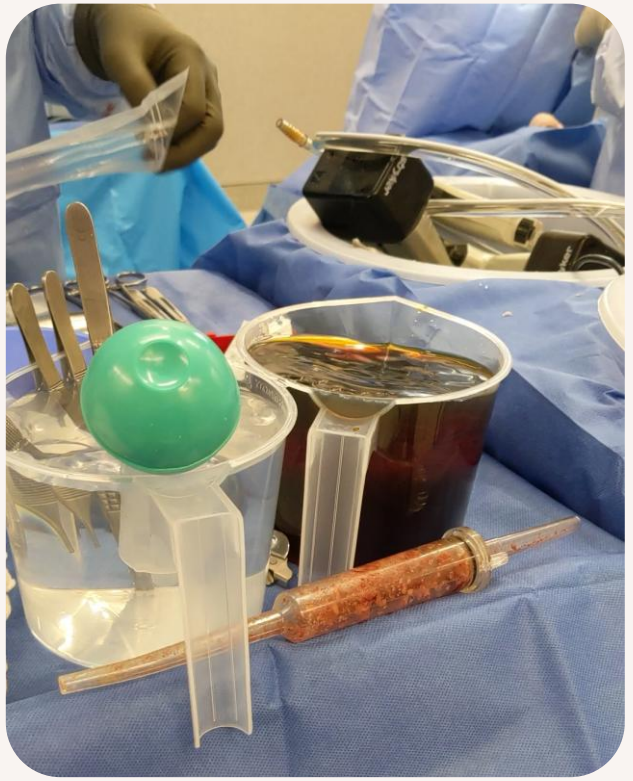
50% made the wrong mixture[1]

1 in 12 cases, respondents needed to leave the OR[1]

90% reported using non-sterile PVP-I, violating regulatory standards[1]

45% wore non-sterile or no gloves at all[1]





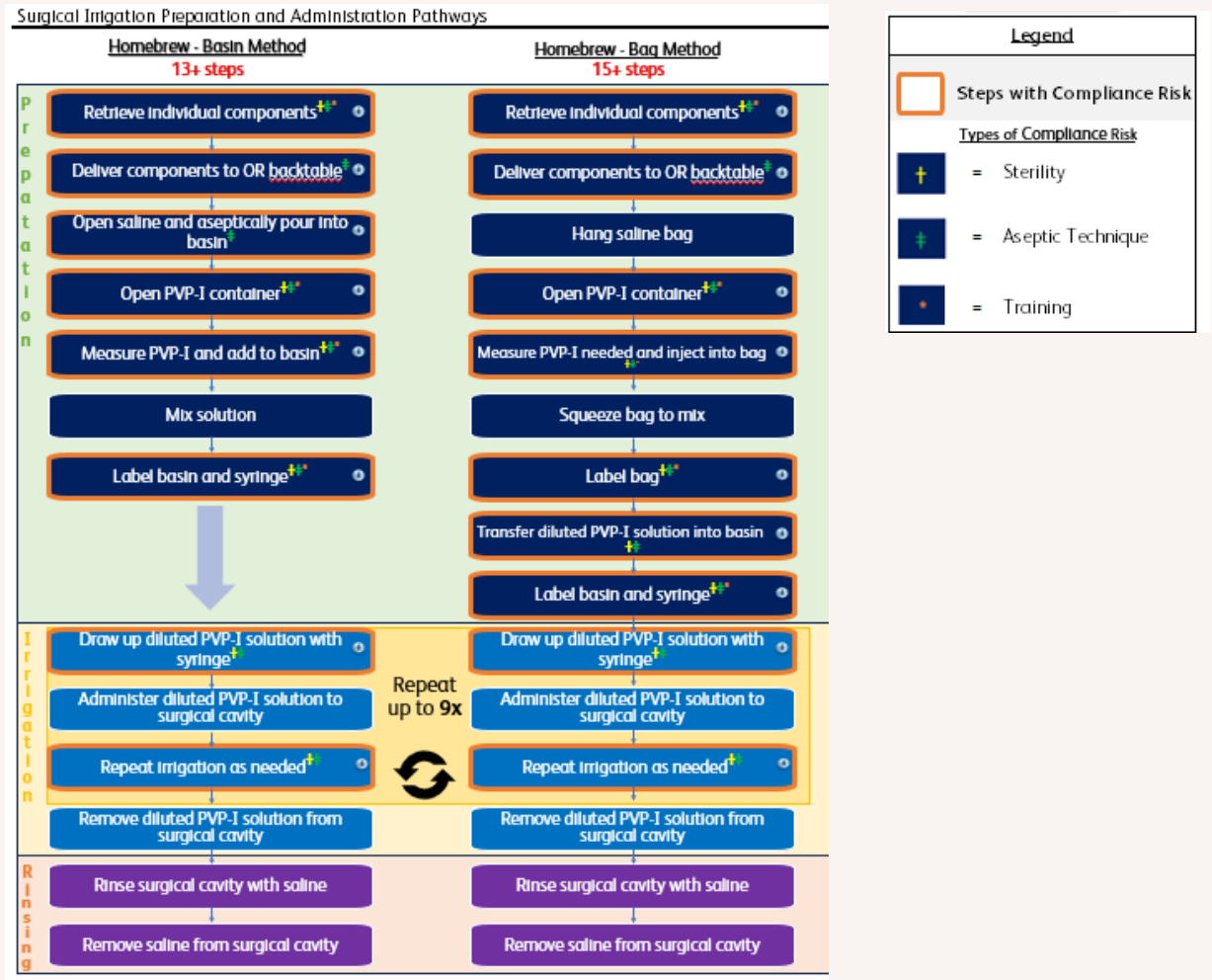
1. BD Data on file for reference.
Videos provided by Dr. Javad Parvizi

And numerous steps and risks along the way

Every step and variation in homebrew irrigation preparation can increase risk.[1,2]

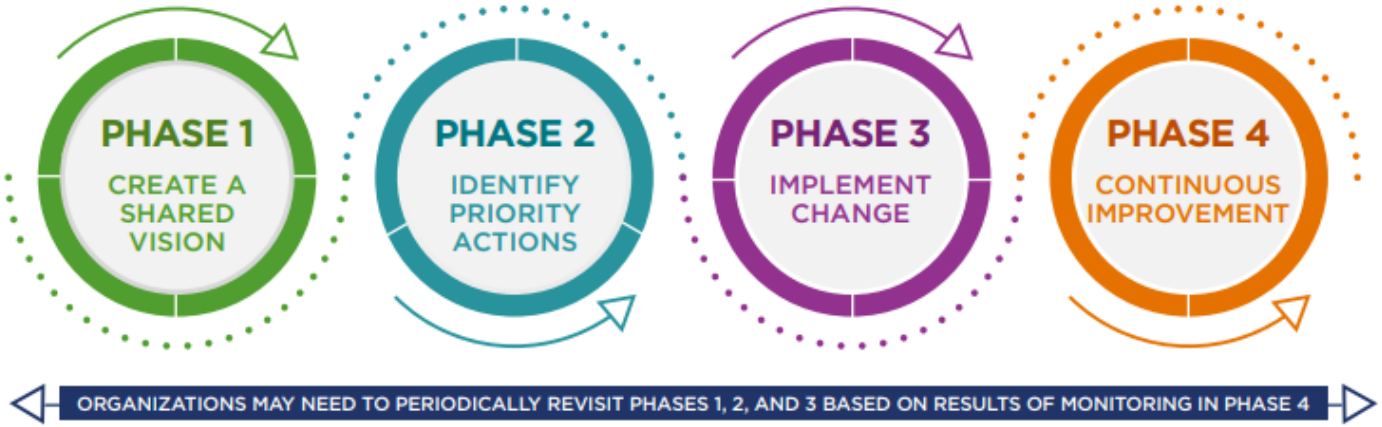
- Non-sterile formulations
- Non-standard irrigation concentrations
- Bacterial contamination
- Inconsistent aseptic technique
- Medical errors

Example steps and associated compliance risk for compounding povidone-iodine surgical irrigation solutions in the OR



1. Barnes S, Spencer M, Graham D, Johnson HB. Surgical wound irrigation: a call for evidence-based standardization of practice. Am J Infect Control. 2014;42(5):525-529. **2.** USP. Pharmaceutical compounding—sterile preparations <797>. Rockville, MD: USP; November 1, 2023

Build on your existing HAI program to address HOB[1]



ACTION AREA 1: Develop Buy-In and Ownership

ACTION AREA 2: Review Data Infrastructure

ACTION AREA 3: Assess Organizational Culture

ACTION AREA 4: Build Awareness

ACTION AREA 5: Define the Current State

ACTION AREA 6: Identify Opportunities for Improvement

ACTION AREA 7: Set Organizational Goals

ACTION AREA 8: Engage Patients and Families in HOB Management

ACTION AREA 9: Prevent HOB—Recognize and Mitigate Risk

ACTION AREA 10: Identify HOB—Assess and Recognize Symptoms

ACTION AREA 11: Treat HOB—Guide Timely and Accurate Care

ACTION AREA 12: Monitor Progress

ACTION AREA 13: Promote Sustainability

This playbook was sponsored by BD, a leader in advancing healthcare quality & patient safety.

1. National Quality Forum (NQF). Hospital Onset-Bacteremia and Fungemia Playbook. Washington, DC: NQF, 2024.

Want to learn more?

- Catheter-associated urinary tract infections (CAUTIs) and non-CAUTI hospital-onset urinary tract infections: Relative burden, cost, outcomes and related hospital-onset bacteremia and fungemia infections
- Characteristics, costs, and outcomes associated with central-line–associated bloodstream infection and hospital-onset bacteremia and fungemia in US hospitals
- Implementation of a multi-modal intervention adopting new technologies, clinical services, and feedback improves catheter-associated urinary tract infections
- Prevalence of Hospital-Onset Bacteremia Pre-and Post-Implementation of a Needleless Blood Sampling Device From Existing Peripheral Catheters
- Clinical outcomes and hospital-reported cost associated with surgical site infections and the co-occurrence of hospital-onset bacteremia and fungemia across US hospitals

Every choice in the perioperative suite matters.

The BD skin antiseptics portfolio of products have been in clinical use for over 21 years.

Now, we continue to advance perioperative care with a **fully sterile, ready-to-use skin preparation and surgical irrigation portfolio**—designed to support your efforts to improve:

Standardization | **Clinical outcomes** | **Operational efficiency**

Thank you

Disclaimer

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

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BD® Surgiphor™ Antimicrobial Irrigation System

Description: An antimicrobial irrigation system containing 0.5% povidone (PVP-I) in phosphate-buffered saline, potassium iodide and Vitamin E TPGS. PVP-I acts as a preservative to help inhibit microbial growth in the irrigation solution.

Indication for use: Surgiphor™ Antimicrobial Irrigation System is intended to mechanically loosen and remove debris, and foreign materials, including microorganisms, from wounds.

Contraindications: Surgiphor™ Antimicrobial Irrigation System should not be used in patients with known allergic reaction to any of the ingredients in the solutions. Surgiphor™ Antimicrobial Irrigation System should also not be combined with other irrigation or antiseptic solutions due to potential reactions and reduction in the effectiveness of the system. Not for use in neonates.

Warnings: Do not use or mix with other cleansers, soaps, lotions, or ointments. Do not use for injection or infusion. Do not swallow. Do not use in eyes or ear canals. Discontinue use immediately if irritation or an allergic reaction occurs. Do not use if packaging is damaged or if seal integrity is compromised. Do not reuse Surgiphor™ solution after 24 hours.

Precautions: Surgiphor™ solution may cause a temporary irritation and/or burning sensation on exposed skin in very rare cases. Surgiphor™ solution may cause allergic reactions such as rash or skin irritation in patients with iodine allergy. Anaphylaxis with the use of Surgiphor™ solution may occur in patients with severe iodine allergy. Federal law restricts this device to sale by or on the order of a licensed physician. Single patient use only. Not for at-home use. Please consult product insert for complete indications, contraindications, warnings, precautions, safety information and instructions for use.

BD ChloraPrep™ Patient Preoperative Skin Preparation with Sterile Solution

BD PurPrep™ Patient Preoperative Skin Preparation with Sterile Solution

Prior to use, refer to the product Instructions for Use (IFU) for indications for use, precautions, warnings and contraindications. Use in accordance with the policies and procedures of your facility. For more information, visit bd.com.

BD Surgical Clippers Fair and Balance

Surgical Clipper and Charging Adapter Stand Instructions For Use

Intended use: The BD Surgical Clipper REF 5513E is a rechargeable clipper used with charging adapter (REF 5514 series) and BD disposable blades only (REF 4406, 4403A or 4412A). It is intended to remove head and body hair prior to any medical procedure requiring hair removal. The hair is removed by each blade oscillated by an electric motor. The BD 5513E Clipper will easily and effectively remove body hair and even the thickest hair from the chest with BD disposable blade REF 4406, scalp and other thick coarse hair with BD disposable blade REF 4412A, and other difficult-to-clip areas of the body with BD disposable blade REF 4403A. The Clipper effectively removes wet or dry hair.

Instructions for use: Only trained healthcare personnel should use the Surgical Clipper. Healthcare personnel should wear gloves when performing hair removal. Clipper should be disinfected prior to initial use. Patient's skin should be clean. Healthcare professional should instruct patient to avoid sudden movement during clipping process.

Disinfection: Clipper should be disinfected after each use.

Warning: BD blades (REF 4406, 4403A, and 4412A) are single use only and specifically designed for use with the BD 5513E. The user assumes responsibility for appropriate use of this Clipper. Using blades not manufactured or approved by BD will void any warranty and patient results cannot be predicted. Re-use of blades may result in a nonfunctional product and could contribute to cross contamination; potentially putting patient safety at risk.

BD Surgical Clippers Fair and Balance (cont.)

Prior to use: The clipper REF 5513E must be used with REF 5514 series charger. Disposable single use blades (REF 4406, 4403A and 4412A) are designed for optimal use with 5513E only. Keep charging adapter cord away from heated surfaces. Do not position charging adapter where it is difficult to unplug. Do not place the Clipper on the charging adapter until charging adapter is seated on a flat surface or securely mounted to a wall. Prior to charging Clipper ensure charging adapter is free of metallic debris. Do not expose to hot water, salt water, organic solvents or bleach solutions. Do not use with damaged blade, handle, or both. Do not take the housing apart as this can affect the watertight construction. Inspect treatment site for selection of appropriate blade. If skin irregularities are present, proceed with caution.

During use: Do not apply Clipper blade to injured skin area. Operating Clipper without blade could lead to injury. Do not use near flammable anesthetic, aerosol spray or oxygen — administering equipment other than nasal or mask types. Do not leave Clipper running without applying to skin for more than 1 minute as blade temperature may exceed 60 °C and potentially leading to thermal injury. Do not keep the Clipper blade applied to the same position of the patient's skin for longer than 1 minute (these operations may result in blade surface becoming hot). In cases of minor injury, seek medical treatment if necessary.

After use: Do not use hydrocarbon or phenol-based cleaners or cleaners containing acetone or ketones. Do not submerse Clipper in water or other solution deeper than 3.3 feet (1m) for longer than 30 minutes. Do not plug in with wet hands. Do not connect to charging adapter if Clipper is wet. Do not replace supply cord. If supply cord is damaged return to manufacturer or service agent for replacement to avoid hazard. Do not sterilize.

BD ClipVac™ Fair & Balance Statement

Intended Use: The intended use of the BD ClipVac™ System is to vacuum clipped hair and airborne contaminants generated from the clipping process. It should be used with the BD Surgical Clipper (REF 5513E). Only trained healthcare personnel should use BD ClipVac™ System and the BD Surgical Clippers. If the BD Surgical Clippers and BD ClipVac™ System are being used for the first time, see the training materials provided by BD.

Operating Instructions: The bottom side of the clipper blade should remain flat and gently rest on the surface of the skin while clipping. To ensure hair is properly collected by the vacuum, never tilt the blade edge into the skin. For optimal performance, use on dry hair.

Disinfection Instructions: The BD ClipVac™ Vacuum Unit should be disinfected after each use, using one of the recommended disinfectant solutions listed below:

- Isopropyl Alcohol/Quaternary Ammonia solution
- Chlorinated bleach solution

Inspection/Maintenance: The BD ClipVac™ Vacuum Unit requires no routine maintenance aside from cleaning system after each patient use. If a replacement is needed, contact your local BD representative or customer service. Service or attempted repair performed by unqualified personnel may result in a risk of injury, electric shock, fire, or permanent damage to the equipment and will void any warranty.

BD ClipVac™ Fair & Balance Statement (cont.)

Cautions:

- Use the BD ClipVac™ system as described in the Operating Instruction. Avoid direct patient contact with the nozzle. Direct patient contact should be with the bottom side of the clipper blade.
- Never use BD ClipVac™ Vacuum Unit, battery or charging adapter that appears to be defective, damaged, or not working properly.
- Do not cover vacuum unit to prevent obstructing air flow as this made cause overheating of the vacuum unit.
- Do not re-use disposable filter assembly, it is intended to be single use only.
- Clean the vacuum unit after each patient use, refer to cleaning and disinfecting instructions.
- Do not submerse or spray the vacuum unit, battery, or charging adapter with any liquid.
- Do not sterilize the vacuum unit, battery, or charging adapter.
- Do not short the battery terminals.
- Avoid excessive physical shock or vibration to the battery.
- Do not place the battery and charging adapter in a location where it is subjected to direct sunlight and keep away from other external heat sources.
- Do not dispose the battery with general waste. Never incinerate the lithium-ion battery.
- Do not replace charging adapter cord. Use only the battery and charging adapter supplied by BD.
- Do not attempt to modify or repair the vacuum unit, battery, or charging adapter as this can result in damage of the BD ClipVac™ system and will void the warranty.

BD ClipVac™ Fair & Balance Statement (cont.)

EMC Information of REF 5500: The BD ClipVac™ System is intended for use in the electromagnetic environment specified in the Instructions For Use (IFU) provided with the BD ClipVac™ System.

Warning: REF 5500E should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, REF 5500E should be observed to verify normal operation in the configuration in which it will be used.

REF 5500E has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference. This equipment generates, uses, and can radiate radio frequency energy and, if not installed or used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to the other devices which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures;

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service for help.