PREVENT HAIs Healthcare-Associated Infections

Toolkit for Decolonization of Hospital Non-ICU Patients With Indwelling Devices

Based on the ABATE Infection Trial Protocol

Abbreviated Title:
Decolonization of
Non-ICU Patients With Devices

Introduction -- Toolkit Overview, Decision Making, and Recommended Prelaunch Activities

AHRQ Agency for Healthcare Research and Quality

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Section 1 – Introduction and Welcome

This toolkit will provide hospital infection prevention programs with instructions for implementing targeted decolonization in adult patients with medical devices in hospital units outside of intensive care (i.e., non-ICUs). The toolkit is based upon materials successfully used in the **A**ctive **Bat**hing to **E**liminate (ABATE) Infection Trial,[1] which was conducted in 53 community hospitals in HCA Healthcare (formerly Hospital Corporation of America). The ABATE Infection Trial found that decolonization with chlorhexidine gluconate antiseptic soap for bathing and nasal antibiotic ointment led to a 37 percent reduction in positive methicillin-resistant *Staphylococcus aureus* and vancomycin-resistant enterococcus clinical cultures and a 32 percent reduction in all-cause bloodstream infections among non-ICU patients with specific medical devices, namely central and midline catheters and lumbar drains.

This toolkit is organized into 14 sections as follows:

- **Sections 1–3: Introduction and Toolkit Overview**
- **Sections 4–7: Rationale, Decision-Making Process**
    - Provide decision-making tools and rationale to help hospital leadership understand the evidence for targeted decolonization of adults with medical devices outside of the ICU and to help determine whether this strategy represents the best course of action for your hospital.
- **Section 8: Preparation**
    - Lists suggested prelaunch activities and explains their importance.
- **Sections 9-11: Training**
    - Include evidence-based protocols and instructions, including videos, on how to perform targeted decolonization.
- **Sections 12–13: Assessment and Feedback**
    - Include assessment forms and sample feedback documents to assure the protocol is being followed correctly. Huddle documents are provided for nursing shifts.
- **Section 14: Frequently Asked Questions and Talking Points**
    - Covers commonly asked questions from providers, nursing staff, and patients and appropriate responses and talking points to help staff communicate with patients regarding decolonization.

In this toolkit, you will find:

- Introduction and toolkit overview
- Scientific rationale for implementing targeted decolonization
- Key considerations for decision making
- Implementation readiness
- Estimated cost implications of reducing bloodstream infections in patients with medical devices
- Action chart for implementing targeted decolonization
- Steps to prepare for launch
- Nursing protocols
- Training and educational materials
- Assessment and feedback materials
- Frequently asked questions and talking points

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1. Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multi drug-resistant organisms and all-cause bloodstream infection in general medical and surgical units: the ABATE Infection Cluster Randomized Trial. Lancet. 2019 Mar 23;393(10177):1205-15. PMID: 30850112.

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Trial funded by the National Institutes of Health (NIH)

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Section 3 – Toolkit Overview

What Is the Targeted Decolonization Toolkit and Who Should Use It?

This toolkit is for hospital infection prevention programs or performance improvement committees that wish to initiate targeted decolonization as a strategy to reduce hospital infections outside of intensive care units (i.e., in non-ICUs). This strategy is well suited for hospitals that have already successfully implemented universal decolonization in ICUs to reduce bloodstream infections (including central-line–associated bloodstream infections (CLABSI) and methicillin-resistant *Staphylococcus aureus* (MRSA). For implementing universal decolonization in ICUs, please see the Universal ICU Decolonization toolkit (https://www.ahrq.gov/hai/universal-icu-decolonization/index.html).

The Targeted Decolonization Toolkit provides a roadmap to implement topical decolonization for adult non-ICU patients who have selected medical devices. The regimen of topical decolonization includes the use of chlorhexidine as antiseptic soap for bathing and the application of mupirocin antibiotic ointment to the nares to reduce body bacterial bioburden and abate infection. It is based upon a large-scale pragmatic clinical trial (**A**ctive **Bath**ing to **E**liminate [ABATE] Infection Trial)[1] conducted in 53 community hospitals in HCA Healthcare that found a 37 percent reduction in multidrug-resistant organisms and a 32 percent reduction in all-cause bloodstream infections among patients with three specific devices: central lines, midlines, and lumbar drains. This toolkit focuses on the devices studied in the ABATE Infection trial (central lines, midline catheters, and lumbar drains). This does not preclude its use in patients with other devices (e.g., urinary catheters), but such use would be based on pragmatic needs or literature evidence other than from the ABATE Infection trial.[1,2]

Created for clinicians by clinicians, the targeted decolonization toolkit for non-ICU patients with devices is designed to serve as a roadmap for hospital champions of this intervention and frontline staff. This toolkit provides the necessary information and decision-making tools required to perform an evidence-based assessment of the need for this intervention and the hospital's readiness for adoption. Should the decision be made to implement targeted decolonization for patients with devices, this toolkit will provide frontline staff with training tools and resources to support change outside the ICU, presented through a step-by-step guide including the decolonization protocol, training modules, visual aids, skills assessment, and answers to frequently asked questions.

The toolkit assumes that there is existing infrastructure for quality improvement by which interventions and campaigns usually occur. The toolkit is well suited for hospital leaders in infection prevention or quality improvement seeking a practical, evidence-based strategy to improve care, lower infection rates for adult non-ICU patients with medical devices, and reduce the incidence of MRSA and multidrug-resistant (MDR) pathogens.

The Targeted Decolonization Toolkit WILL:

- Provide decision-making tools and the rationale to help hospital leadership understand the evidence for targeted decolonization of adults with medical devices outside the ICU and help determine if this strategy represents the best course of action for your hospital. The decision-making process is addressed in Section 5.
- Provide directions on how to garner institutional support from key stakeholders to support the adoption of a non-ICU targeted decolonization strategy within adult units.
- Provide evidence-based protocols and instructions, including videos, on how to perform targeted decolonization with chlorhexidine and mupirocin. This toolkit will describe the supplies needed and includes alternative methods or products that hospitals may choose.
- Describe the roles of clinical champions who will oversee the decolonization intervention and support protocol and educational training materials for frontline staff
- Provide tools to assess adherence to the decolonization protocol and reinforce training.

The Targeted Decolonization Toolkit WILL NOT:

- Provide instructions on how to build a comprehensive infection prevention or quality improvement program.
- Address how to construct the basic infrastructure that underlies general quality improvement campaigns.
- Change your usual processes for finding patients who are MRSA-positive. You should continue to use your hospital's current mechanisms for identifying these patients.
- Necessarily be appropriate for all hospitals. Hospital-based assessment and decision making are necessary parts of the implementation process.
- Necessarily be appropriate for children. The toolkit was not evaluated in pediatric populations in the ABATE Infection trial. Therefore, special considerations for pediatric units are not addressed.

Organization of Toolkit for Staff

Table 3-1 below can be used as a reference to direct staff to sections of this toolkit that are relevant to their job descriptions.

Table 3-1. Organization of Toolkit for Staff

Job Description	Sections
Administrators/Decision Makers/Champion	Section 1 – Introduction and Welcome Section 2 - ABATE Trial Investigators and Toolkit Project Team Section 3 – Overview Statement Section 4 – Scientific Rationale Section 5 – Decision Making and Readiness for Implementation Section 6 – Estimated Cost Implications of Reducing Bloodstream Infections in Patients With Medical Devices Section 7 – Action Chart Section 8 – Prelaunch Activities
Physicians	Section 1 – Introduction and Welcome Section 3 – Overview Statement Section 4 – Scientific Rationale Section 9 – Nursing Protocols (if standing order protocol for mupirocin is used)
Nurse Managers and Directors Only	Section 1 – Introduction and Welcome Section 8 – Prelaunch Activities
All Nurses, Including Managers and Directors	Section 9 – Nursing Protocols Section 10 – Instructional Handouts Section 11 – Protocol Training Section 12 – Adherence and Skills Assessments Section 13 – Huddle Documents Section 14 - FAQs and Talking Points

References

1. Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multi drug-resistant organisms and all-cause bloodstream infection in general medical and surgical units: the ABATE Infection Cluster Randomized Trial. Lancet. 2019 Mar 23;393(10177):1205-15. PMID: 30850112.
2. Huang SS, Septimus E, Hayden MK, et al. Effect of body surface decolonisation on bacteriuria and candiduria in intensive care units: an analysis of a cluster-randomised trial. Lancet Infect Dis. 2016;16(1):70-9. PMID: 26631833.

Section 4 – Scientific Rationale

The Burden of Healthcare-Associated Infections

Healthcare-associated infections (HAIs) have been recognized as a major preventable cause of morbidity and mortality in the United States. In 1999, the Institute of Medicine (IOM) report "To Err Is Human: Building a Safer Health System" galvanized efforts to prevent healthcare-associated adverse events, including HAIs.[1] In 2002, it was estimated that over 1.7 million HAIs occurred annually in hospitals, resulting in 100,000 annual deaths at a cost of over $6.5 billion. The estimate is $40 billion for when out-of-hospital HAIs are included.[1] Since then, major efforts have been made at the national, State, and local level to reduce these preventable infections.[2]

In 2003, the IOM identified HAI prevention as a top 20 priority area for national action.[3] In 2008, the U.S. Government Accountability Office issued a report on HAIs in hospitals calling for national efforts by the Department of Health and Human Services (HHS) to prioritize prevention practices and standardize HAI surveillance.[4] In response, HHS spearheaded the development of the first National Action Plan to Prevent Healthcare-Associated Infections. In the meantime, The Joint Commission continued to increase its requirements for routine HAI surveillance for hospital accreditation,[5] and the Centers for Medicare & Medicaid Services (CMS) outlined and implemented a multiyear plan requiring hospitals to publicly report HAIs and perform well on HAI rankings or face reductions in reimbursement.[6]

Currently over 22,000 hospitals and other healthcare facilities report HAI events through the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) system. [2-7] In addition to providing gold-standard criteria for identifying HAIs, the NHSN has become the national repository for acute-care and long-term care facilities to report HAI surveillance data. Through use of NHSN data, CMS and State health departments are generating public reports of hospital-specific HAI performance. HAI performance has been adopted as a core safety measure by many state regulatory agencies, CMS, and private accrediting bodies such as The Joint Commission and Leapfrog.

Interest in Broad-Based HAI Reduction Strategies

The focus on HAIs produced important developments and raised important questions about prevention. It led to national programs and targeted strategies to reduce device and procedure-related HAIs, such as central-line–associated bloodstream infection (CLABSI), catheter-associated urinary tract infections (CAUTI), and surgical site infections (SSI), as well as targeted efforts to reduce multidrug-resistant organisms (MDROs) such as methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococcus (VRE). However, as pressure mounted to reduce all nationally monitored HAIs, interest increased in broad-based strategies that could be applied to a wide range of hospitalized patients to prevent multiple HAIs at the same time. The appeal in broad-based strategies was driven by the strong desire to protect patients from several types of HAIs, the limited capacity for multiple infection prevention campaigns by infection prevention programs, and the need for labor-efficient and cost-effective strategies.

Decolonization as a Broad-Based Strategy

Most HAIs are caused by bacteria that reside on the skin and in the nose and gain access to the bloodstream, lungs, and bladder by way of invasive devices and incisions that breach normal host defenses. These infecting bacteria may be the patient's normal flora, or they may be new, often antimicrobial-resistant organisms acquired during hospitalization. Reducing the bacterial burden through topical decolonization of the skin and nasal reservoirs has proven to be an effective broad-based strategy to reduce a wide range of HAIs.

Decolonization procedures have evolved and now most commonly involve the use of chlorhexidine gluconate (CHG) topical antiseptic for bathing or showering, with or without nasal decolonization using mupirocin antibiotic ointment or povidone iodine (iodophor). CHG has been used in healthcare for over 60 years and is FDA cleared for cleansing the skin and wounds. When applied well, particularly as a 2 percent no-rinse bathing solution, CHG is absorbed onto the skin surface and has up to 24 hours of persistent germicidal activity on the skin,[8] allowing continuous protection in the hospital with the use of daily bathing. Mupirocin nasal antibiotic ointment was FDA approved in 2002 and has been shown in clinical trials to reduce colonization and infection due to *S. aureus*, which resides most commonly in the nose. [9-12] Together, these topical products have proven effective for preventing HAIs when universally provided to high-risk groups, such as those undergoing surgical procedures, or those requiring ICU care.

The increased appreciation of HAI impact on morbidity and mortality stimulated the conduct of large-scale randomized clinical trials to evaluate decolonization and other infection prevention strategies. Large-scale pragmatic randomized trials involving CHG with and without nasal decolonization are reviewed and summarized in Table 4-1.[13]

Table 4-1. Large-Scale Randomized Clinical Trials Evaluating CHG Decolonization To Reduce HAIs

Location	Trial and Target Population	N	Intervention	Impact of Decolonization
Preoperative Use	***Bode et al.***[14]	918	Universal inpatient screening for *S. aureus* carriers randomized to CHG and mupirocin versus routine care	Among *S. aureus* carriers, 58% less inpatient *S. aureus* infection, including 79% less deep surgical site infection
	Harbarth et al.[15]	10,844	Universal inpatient screening for MRSA carriers randomized to CHG and mupirocin vs routine care	No difference in overall hospital-associated MRSA infection
Intensive Care Units (ICU)	***Climo et al.*** 6 academic medical centers[16]	7,727	Universal CHG bathing versus routine care (as-treated analysis)	23% less MRSA/VRE acquisition 28% less bloodstream infections 53% less CLABSI
	REDUCE MRSA Trial 43 community hospitals[12]	74,256	Group A: Targeted CHG and mupirocin for MRSA carriers Group B: Universal CHG and mupirocin Group C: Routine care	Group B: 37% less MRSA positive clinical cultures 44% less bloodstream infections
	Pediatric SCRUB Trial[17] 5 academic medical centers	4,947	Universal CHG bathing versus routine care (as treated analysis)	33% less bloodstream infections 30% less CLABSI
	Mupirocin Iodophor Swap Out 137 community hospitals[18]	~250,000	Group A: Universal CHG and mupirocin Group B: Universal CHG and iodophor	Group A: 18% less *S. aureus* positive clinical cultures 14% less MRSA positive clinical cultures Equivalent to Group B for bloodstream infections

Location	Trial and Target Population	N	Intervention	Impact of Decolonization
Non-ICUs	***ABATE Infection Trial*** 53 community hospitals[19]	339,902	Universal CHG bathing plus targeted mupirocin for MRSA carriers versus routine care	No difference in MRSA/VRE clinical cultures or bloodstream infection in overall non-ICU population, but in subset with medical devices: 37% less MRSA/VRE positive clinical cultures 32% less bloodstream infections (post-hoc analysis)
Postdischarge	***CLEAR Trial***[20]	2,121	Targeted education plus 5 days of CHG bathing, CHG mouthwash, and mupirocin repeated twice a month for 6 months versus education alone for MRSA carriers	In the year following discharge: 30% less MRSA infection 17% less all-cause infection Reduced readmissions
Nursing Homes	***Bellini et al.***[21]	4,750	Universal screening for MRSA followed by targeted CHG bathing, CHG mouthwash, nasal mupirocin, and room disinfection for MRSA carriers versus routine care	No difference in one-day MRSA point prevalence
	Protect Trial 28 nursing homes[22,23]	~18,000	Universal CHG bathing plus nasal iodophor versus routine care	18% fewer hospital transfers due to infection 23% fewer discharges to a hospital 29% reduction in MDRO carriage 24% reduction in MRSA carriage 61% reduction in VRE carriage 52% reduction in ESBL carriage

Huang SS. Chlorhexidine-based decolonization to reduce healthcare-associated infections and multidrug-resistant organisms (MDROs): who, what, where, when, and why? J Hosp Infect. 2019 Nov;103(3):235-43. Adapted with permission.

CHG = chlorhexidine gluconate; ESBL = extended spectrum beta-lactamase producers; MDRO = multidrug-resistant organism; MRSA = methicillin-resistant *Staphylococcus aureus*; VRE = vancomycin-resistant enterococcus

The results consistently show that decolonization in the ICU setting results in significant decrease in HAIs and colonization by MRSA and MDROs. In other care settings, the results are dependent on the specific care context. For example, in non-ICU patients, the **A**ctive **Bat**hing to **E**liminate Infection (ABATE Infection) Trial found that CHG decolonization had an impact primarily in the subset of patients with specific invasive devices: central lines, midlines, and lumbar drains.

HAIs Targeted by Decolonization

Decolonization has been broadly studied for its impact on MRSA infection, bloodstream infections including central line-associated bloodstream infections (CLABSI), and SSIs. We briefly review the importance of MRSA and CLABSI as a prelude to introducing this toolkit in the context of a prior AHRQ ICU decolonization toolkit.

Importance of MRSA in HAI Prevention

S. aureus is a major pathogen associated with HAIs, given its virulence, prevalence, diversity of disease spectrum, and propensity for widespread transmission. *S. aureus* caused 120,000 bloodstream infections and 20,000 deaths in the United States in 2017.[24] MRSA is a form of *S. aureus,* which is specifically resistant to oxacillin and similar antibiotics. MRSA is well known for producing HAIs, including skin and soft tissue infections, pneumonia, surgical site infections, blood and urine infections, and sepsis.[25-30] In 2000, MRSA was reported to cause or complicate 278,000 U.S. hospitalizations annually, resulting in 56,000 septic events and 19,000 deaths.[28] While prevention efforts have reduced MRSA HAIs, gains have plateaued in recent years and MRSA remains a major source of preventable morbidity and mortality associated with healthcare facilities.[24,25,31] This toolkit will describe a proven decolonization strategy to reduce MRSA and VRE in adult non-ICU patients with selected medical devices.

Importance of Bloodstream Infections in HAI Prevention, Including CLABSI Events

There has been a longstanding need to prevent device and procedure-associated infections. The breach of skin integrity by medical devices and surgeries compromises one of the most important human organs that protects against infection. While CLABSI rates have declined by over 50 percent in the past two decades, they remain a major source of serious bloodstream infections. Concurrently, the use of invasive devices has risen substantially, and now nearly 20 percent of hospitalized patients have a central line on any given day.[32] Despite gains in preventing CLABSI, there were an estimated 18,000 CLABSI cases in ICU patients and an additional 23,000 CLABSI cases in non-ICU patients in 2009.[33] Decolonization has been recommended in the Society for Healthcare Epidemiology of America (SHEA) Compendium as a 1A evidence-based strategy for CLABSI prevention in ICUs due to several clinical trials showing benefit to bloodstream infections and CLABSI, in particular[34] (Table 1). This toolkit will describe a proven decolonization strategy to reduce bloodstream infections in adult non-ICU patients with selected medical devices.

Effectiveness of Decolonization With Chlorhexidine and Mupirocin

The use of decolonization to prevent HAI has biological plausibility. CHG and similar compounds reduce bacteria on the skin to prevent infection. This reduction in bioburden reduces the likelihood of infection from a patient's own flora, and it also reduces the spread of pathogens from one patient to another. Large-scale randomized clinical trials have now informed best practice guidance on patient populations that may benefit from decolonization.

CHG has been safely used for bathing, showering, and dental hygiene for over 60 years. It is used for showering as a 4 percent rinse-off solution or for bathing as a 2 percent no-rinse solution that is directly applied to skin as an antiseptic skin cleanser. Numerous studies have shown marked reductions in skin bacteria following serial CHG bathing or showering,[35-41] and it is widely used as a preoperative showering agent.[42,43] CHG is absorbed onto the skin surface for up to 24 hours after application and retains its antibacterial activity.

Evidence supports repeated application for sufficient and persistent skin decontamination. [38-41,44] In addition, CHG bathing as a universal strategy has gained favor since evidence is mounting that CHG can reduce colonization and infection from a variety of HAI pathogens[45-47] with a 44–87 percent reduction in bloodstream infection in ICU patients.[46,47,48,49,51] There is also evidence that CHG skin bathing reduces MRSA acquisition and infection by 40–50 percent in high-risk settings such as ICUs.[12,46,49-51]

Mupirocin is a prescription topical drug that is FDA approved for eradicating nasal carriage of *S. aureus*, including MRSA. Nasal mupirocin is highly effective in eradicating *S. aureus* in the short term. Several studies have shown 90 percent efficacy within two weeks of a 5-day regimen.[52-56] The impact of nasal decolonization is substantial, as it also significantly reduces short-term hospital-associated MRSA transmission and infections by over 50 percent in observational and crossover intervention studies.[49,52,57,58,59] However, long-term clearance after a single treatment regimen is only 60 percent after 6–8 weeks, largely due to recolonization with a person's original strain. [11,49,53-56,60-62] Therefore, repeated courses may be necessary.

Used together, CHG and mupirocin provide effective decolonization support for a range of important HAI pathogens. In the following section, we review evidence for their joint use in ICUs as a prelude to discussing the value of their use in adult non-ICU patients who have medical devices.

Precedent in ICU Patients: The ICU Decolonization Toolkit From The REDUCE MRSA Trial

This non-ICU decolonization toolkit has precedent in a previously released ICU toolkit for universal decolonization (https://www.ahrq.gov/hai/universal-icu-decolonization/index.html). In 2013, three large cluster-randomized clinical trials were published, which evaluated universal ICU decolonization with and without nasal decolonization (Table 1).[12,16,17] The AHRQ-funded **R**andomized **E**valuation of **D**ecolonization versus **U**niversal **C**learance to **E**liminate MRSA (REDUCE MRSA) Trial was the largest of the three trials and involved nearly 75,000 adult ICU patients in 43 community hospitals (across 16 States) affiliated with HCA Healthcare (formerly Hospital Corporation of America).[14] The hospitals were randomized to one of three study groups:

Group 1, Routine Screening and Isolation: Continued bilateral nares screening on ICU admission, with routine use of contact precautions for patients known to be MRSA carriers by history, screening test, or clinical cultures.

Group 2, Targeted Decolonization: MRSA screening and routine contact precautions similar to Group 1. In addition, ICU patients known to be MRSA carriers received 5 days of twice daily mupirocin and 5 daily baths with no-rinse 2 percent CHG cloths.

Group 3, Universal Decolonization: MRSA screening was discontinued. Routine contact precautions continued to occur for known MRSA carriers by history or clinical cultures. In addition, all ICU patients received 5 days of twice daily mupirocin and daily bathing with no-rinse 2 percent CHG cloths for the duration of the ICU stay.

The REDUCE MRSA Trial found that Universal Decolonization was most successful in reducing the trial outcomes of MRSA-positive clinical cultures and bloodstream infections attributable to the ICU. Compared with the control arm (Group 1), Universal Decolonization Group patients experienced a statistically significant 37 percent reduction in MRSA-positive clinical cultures and a statistically significant 44 percent reduction in all-cause bloodstream infections, including CLABSIs.[12]

The success of the REDUCE MRSA Trial led to the creation of the AHRQ Universal Decolonization Toolkit (https://www.ahrq.gov/hai/universal-icu-decolonization/index.html), which provided a roadmap for hospital infection prevention or quality improvement programs to evaluate their need and readiness to implement universal decolonization in their ICUs. The toolkit provided the protocols and training materials to implement the universal decolonization intervention of the REDUCE MRSA Trial.

This current toolkit extends the application of CHG and mupirocin to hospitalized patients with selected medical devices outside of the ICU based upon the ABATE Infection Trial (see below).[2] Elements of the Targeted Decolonization toolkit will be familiar to hospitals that have already implemented universal ICU decolonization with CHG and mupirocin. If an ICU universal decolonization strategy has not yet been implemented, we recommend considering concurrent or sequential implementation of decolonization in that population (described at: https://www.ahrq.gov/hai/universal-icu-decolonization/index.html) because the rates of hospital-associated bloodstream infections and MRSA clinical cultures are known to be higher in ICU patients. Thus, such benefits may be greater for the ICU subpopulation. Additional reasons relate to logistics. Universal strategies are generally easier to implement than targeted strategies that require methods for identifying qualifying patients and ensuring a different process of care for those patients. Developing experience with whole-unit practices for ensuring adequate supplies and staff training can help with the transition to a practice that involves targeted criteria for only some patients in a unit. Finally, non-ICU bathing strategies require additional training for addressing questions from patients who are alert or desire self-bathing or showering instructions.

Rationale for Evaluating Decolonization To Reduce HAI Beyond Intensive Care Units

For over 30 years, the major focus of HAI prevention has been on ICUs because of the combination of high complexity medical care, high prevalence of invasive interventions, and severity of illness result in ICU patients having the highest risks for HAIs.[45,46,49,63-68] Numerous studies have described the morbidity and mortality attributable to this setting and demonstrated gains in reducing catheter-related bloodstream infections,[45,46, 65,69] catheter-related urinary tract infections, and pneumonia [70-73] in ICU settings.

Although ICUs have the highest *incidence* rate of HAIs, the vast majority of HAIs, in absolute numbers, actually occur in non-ICU settings (i.e., non-ICU settings have a higher attributable fraction of HAIs). This has prompted attention on HAIs occurring outside of ICUs. Non-ICU settings most commonly consist of step-down units, which represent an intermediate level of care between the ICU and a routine non-ICU area, as well as medical, surgical, mixed medical/surgical, and oncology units. It is estimated that 75 percent of HAIs occur outside of ICU settings.[26]

The ABATE Infection Trial was the first large-scale cluster-randomized trial of decolonization in the non-ICU setting. This trial was important because a decolonization strategy that works in ICUs may not be effective in non-ICU settings. There are several reasons for this. First, HAI rates in non-ICUs are generally lower than rates found in ICUs. Use of invasive devices is less frequent in non-ICU settings, and reducing bacterial reservoirs on the skin and in the nose may convey a smaller benefit. Nevertheless, the relatively larger numbers of non-ICU patients can mean that the total number of HAIs may be similar or greater in non-ICU settings.

Second, a non-ICU decolonization regimen cannot be delivered in an identical fashion to the ICU setting. Patients in non-ICU settings are typically more awake, are more ambulatory, and some may refuse a daily bath or choose to perform their own bed bath. Others may choose to shower, where rinsing off CHG leaves less residual effect on the skin compared with a no-rinse bed bath. Thus, decolonization will be generally more difficult to standardize and apply uniformly and effectively outside of the ICU. Nevertheless, this is an important aspect of real-life circumstances in non-ICU settings.

Third, the level and intensity of contact between patients and nursing staff differs between ICU and non-ICU settings. It also differs between patients themselves, especially those sharing a room in general hospital units. Since these interactions are important determinants of transmission of pathogens to patients, the results of an ICU intervention are not necessarily applicable to the non-ICU setting. Thus, it was important to test the effectiveness of a decolonization regimen under conditions of actual use and assess both its impact on infections and the frequency of adverse effects on patients. This was done through the ABATE Infection Trial.

The ABATE Infection Trial

The ABATE Infection Trial was a large-scale cluster randomized trial of 53 community hospitals located in 14 states affiliated with HCA Healthcare that evaluated the impact of universal CHG bathing for adult non-ICU patients and additional nasal decolonization for MRSA carriers on the

outcomes of MRSA-positive and VRE-positive clinical cultures and all-cause bloodstream infections. We define MRSA carriers as patients known to the hospital to be MRSA carriers (by reported history, prior culture result, or information from transferring facilities).

Participating hospitals were randomized to one of two arms of the ABATE Infection Trial:

> **1. Routine Bathing:** Continued use of routine nonantiseptic disposable cloths for bed bathing, and liquid soap for showering at usual frequency
>
> **2. Decolonization:** Universal daily bathing with 2 percent leave-on CHG-impregnated cloths for baths **or** 4 percent rinse-off CHG for showering for the duration of the non-ICU stay plus targeted nasal mupirocin for MRSA carriers for 5 days. The bathing protocol involved cleaning the 6 inches of all devices closest to the patient.

The ABATE Infection Trial involved nearly 340,000 patients in 194 adult non-ICUs. It found that universal CHG bathing for all patients outside the ICU plus mupirocin for MRSA carriers did not significantly reduce clinical cultures with multidrug-resistant organisms or all-cause bloodstream infections compared with routine care. However, **a significant benefit was found in the subgroup of patients with any of the three medical devices that were electronically trackable (i.e., central lines (including dialysis catheters and port-a-caths), midline catheters, and lumbar drains). In these patients, decolonization with CHG decreased all-cause bacteremia by 32 percent and MRSA-positive and VRE-positive clinical cultures by 37 percent.** This reduction is even more meaningful considering patients with medical devices represented only 10 percent of the total study population but were responsible for 37 percent of MRSA-positive and VRE-positive cultures and 56 percent of all-cause bloodstream infections.

The materials provided in this toolkit reflect the protocols and training materials from the ABATE Infection Trial and focus on the devices studied in the ABATE Infection trial, specifically central lines, midline catheters, and lumbar drains. Data were available to trial investigators for only these three devices. Thus, the impact of non-ICU decolonization on other medical devices in the ABATE Infection Trial is unknown. Among the three devices, the estimated benefit of decolonization on each specific device was the same. In this toolkit, we refer to these devices as "selected medical devices," in reference to devices that were studied within the ABATE Infection Trial.

This toolkit does not preclude the use of its decolonization protocol in patients with other devices (e.g., urinary catheters), but such use would be based upon pragmatic needs or literature evidence other than from the ABATE Infection trial.[74] For example, secondary analysis of the REDUCE MRSA Trial, showed a reduction in bacteriuria and candiduria in male ICU patients who received decolonization.[74]

Safety of Mupirocin and Chlorhexidine

Both mupirocin and CHG have excellent safety profiles. Systemic absorption of both drugs is minimal.[75-79] Of the minimal amount of mupirocin that is absorbed, nearly all is rapidly converted to monic acid, an inactive metabolite.[75,76] Furthermore, systemic absorption remains negligible following single or repeated intranasal applications over consecutive days in adults.[47] Multiple observational studies and randomized controlled trials have also shown no systemic

absorption of mupirocin following intranasal application.[78-82] Safety data for mupirocin from the manufacturer states that fewer than 1 percent of patients in clinical trials withdrew due to adverse events. The most frequently reported adverse events were as follows: rhinitis (1.0%), taste perversion (0.8%), and pharyngitis (0.5%). Postmarketing surveillance has not identified any additional concerns.

As an over-the-counter skin cleanser used in healthcare for over 60 years, CHG has an even more extensive safety record.[46,50,58,59,83-89] Several groups have confirmed the absence of systemic absorption following topical use or oral rinsing with CHG.[90-93] Moreover, even if ingested, CHG is known to have negligible absorption with undetectable blood levels.[94-96] Side effects are largely limited to skin irritation, which is uncommon, and anaphylaxis, which is extremely rare. In fact, anaphylaxis has only been reported in case reports.[97,98] Estimates for these effects are expected to be very small given the large numbers of people using an unregulated over-the-counter product. No deleterious effects have been reported with daily use in either long-term ICU patients or with repeated use in the post-discharge setting.[20,48,49] The major manufacturer of over-the-counter CHG states that CHG "can be used many times a day without causing irritation, dryness, or discomfort."[98] It is also safe to use on superficial wounds. CHG is currently cleared by the U.S. Food and Drug Administration (FDA) for use in patients at least 2 months of age. Notably, in 2012, the FDA changed the recommendation for CHG use in neonates less than 2 months of age from "contraindicated" to "use with care." This toolkit is specifically designed for adults in noncritical care units who have selected medical devices.

Nasal Iodophor as an Alternative to Mupirocin

Due to U.S. regional differences in mupirocin resistance[99] and facility preferences for mupirocin versus nasal iodophor for nasal decolonization protocols (e.g., pre-operative decolonization), this toolkit will provide pragmatic directions for the use of nasal iodophor as an alternative to mupirocin.[100] Hospital choices may be further informed by the Mupirocin-Iodophor ICU Decolonization Swap Out Trial, a large-scale non-inferiority pragmatic cluster-randomized trial comparing decolonization with mupirocin/CHG to iodophor/CHG in ICU patients.[18]

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Section 5 – Decision Making and Readiness for Implementation

Assessing the Quality of the Evidence

There are several factors for hospitals to consider when assessing whether to adopt a new intervention. Often, new literature or growing literature around a strategy with a strong rationale for positive impact can propel hospitals to adopt that strategy, especially in the setting of a perceived need. The balance between early adoption before definitive clinical trials and adoption after definitive trials must be determined based upon local needs and culture.

The results of the **A**ctive **Bat**hing to **E**liminate (ABATE) Infection Trial provide strong evidence for targeted decolonization in non-intensive care unit (ICU) patients with devices in order to reduce methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococcus (VRE), and all-cause bloodstream infection. In assessing the quality of evidence of a new strategy, well-conducted randomized controlled trials provide the highest level of certainty about the effect of an intervention. The ABATE Infection Trial has the following high-quality features:

- **Randomized controlled trial.**
- **Large-scale trial** with 53 hospitals, 194 non-ICUs, and nearly 340,000 patients.
- **Pragmatic implementation.** The decolonization strategy was implemented by the same hospital staff and processes usually responsible for quality improvement campaigns. This means that it was rolled out in a manner that reflects how most hospitals would implement this strategy.
- **Generalizable.** Unlike many studies of hospital-based interventions conducted in major academic centers, the ABATE Infection Trial was conducted in nearly all community hospitals. Since these hospitals provide the majority of care in the United States, the results of this trial are likely to be widely applicable.
- **Comparison with current best practice.** Sometimes trials compare an intervention with older practices that are no longer considered best practice. The ABATE Infection Trial compared a decolonization strategy with current standards of care and showed a significant benefit in a subgroup of the study population, patients with specific medical devices.

It is often important to consider additional supporting evidence in the literature. This evidence usually consists of previous single-center studies that laid the foundation for a major trial. Three such studies preceded the ABATE Infection Trial.[1-3]

Assessing the Need for Targeted Decolonization in Non-ICUs

Once the evidence of the need for this targeted decolonization in your hospital is well understood, it is important to assess the likely gains that the hospital will attain if the targeted decolonization strategy is adopted. Since the ABATE Infection Trial found that decolonization impacted bloodstream infection rates, as well as MRSA-positive and VRE-positive clinical cultures attributable to non-ICUs, those outcomes should be of interest to hospitals considering adoption. In addition, because the benefit was limited to adult non-ICU patients with specific medical devices, it will be important to assess these outcomes in patient populations with devices of interest in your hospital.

- **Determining hospital-associated bloodstream infection rates for non-ICU patients with medical devices.** The ABATE Infection Trial showed a **32 percent reduction** in all-cause bacteremia in patients in community hospitals who had specific medical devices. We recommend identifying the following to help estimate the expected impact should universal decolonization be adopted in the hospital. Inpatient census data and data from the clinical microbiology laboratory are needed for this estimate. For ease of calculation, you can use one bacteremia per patient.
    - **Simplified Estimate: Bacteremia Counts (one per patient)**
      A simple estimate begins with counts of bloodstream infections. Choose a 1-year period and count the number of unique patients who have a positive blood culture from any pathogen occurring at least 2 days after admission while in a non-critical-care unit location (or having been in a non-critical-care location 2 days prior to the culture date, if that information can be obtained). Exclude any patient younger than 18 years old (or, if easier, exclude pediatric or neonatal units in addition to ICUs). Two positive blood cultures with the same skin commensal organism should be required for counting this event as a bloodstream infection. This requirement is consistent with Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network definitions and should be familiar to infection prevention programs.
    - Next, the count of non-ICU bloodstream infections needs to be limited to those who have the selected medical devices studied in the ABATE Infection Trial, namely central lines, midlines, or lumbar drains. This count can be estimated in two ways:
        - In the ABATE Trial, 56 percent of all non-ICU bloodstream infections were in patients with those specific medical devices. It could be reasonably assumed that approximately half of all non-ICU bloodstream infections in your hospital would be in patients with those devices.

        - Alternatively, reported CLABSI events occurring in non-ICUs could be used as an underestimate of the bloodstream events that would occur due to devices.
    - **Comprehensive Estimate: Bacteremia Rates (one per patient)**
      The best estimate to use is the one calculated to match the targeted population with specified devices. This would be the rate of non-ICU bacteremia cases per 1,000 non-ICU days among patients with the specified medical devices. To obtain this rate, divide the count of bacteremia cases identified in the simplified estimate by the number of non-ICU days among those with those medical devices. The non-ICU days should be counted from the third day of a non-ICU stay until transfer to an ICU or until hospital discharge.
        - To change the calculated rate into a rate per 1,000 ICU patient days, multiply the rate (number of events divided by the denominator of non-ICU days among patients with the specified devices) by 1,000 = total events per 1,000 ICU patient days.
    - **Estimated Reduction Due to Targeted Decolonization**
      The ABATE Infection Trial showed a **32 percent reduction** in this bacteremia rate.
- **Determining MRSA-positive and VRE-positive clinical cultures for non-ICU patients with medical devices.** Decolonization in the ABATE Infection Trial also reduced MRSA-positive and VRE-positive clinical cultures attributable to non-ICUs **by 37 percent** in patients with the above-mentioned medical devices**.** Thus, it would be of additional value to estimate this outcome in hospitals considering adoption of targeted decolonization. This can be similarly estimated in one of two ways:
    - **Use Usual Processes for Determining MRSA Status**
      Remember, we are not asking you to change your testing/screening processes for MRSA. Use your current processes for identifying MRSA carriers using reported history, prior culture result, or information from transferring facilities to target those with devices.

- **Simplified Estimate: MRSA/VRE Counts (one per patient)**
  A simple estimate begins with identifying a year's worth of counts of new MRSA-positive or VRE-positive clinical cultures among unique patients occurring at least 2 days after admission while in a non-critical-care unit location (or having been in a non-critical-care location two days prior to the culture date, if that information can be obtained). Exclude any patient less than 18 years old (or, if easier, exclude pediatric or neonatal units in addition to ICUs).

  Next, the count of new positive MRSA/VRE clinical cultures needs to be limited to those who have medical devices (specifically central lines, midlines, or lumbar drains). This count can be estimated as follows:
  - In the ABATE Trial, 37 percent of all non-ICU new positive MRSA/VRE clinical cultures were in those with the above-mentioned medical devices. Multiplying the total non-ICU count by 0.37 would yield a reasonable estimate.
- **Comprehensive Estimate: MRSA/VRE Rates (one per patient)**
  Divide the positive MRSA/VRE clinical culture counts identified in the simplified estimate by the number of non-ICU days among those with the above-mentioned medical devices. The non-ICU days should be counted from the third day of a non-ICU stay until ICU transfer or hospital discharge.
  - To change the calculated rate into a rate per 1,000 ICU patient days, simply multiply the rate (number of events divided by the denominator of non-ICU days among patients with devices) by 1,000 = total events per 1,000 ICU patient days.
- **Estimated Reduction Due to Targeted Decolonization**
- The ABATE Infection Trial showed a **37 percent reduction** in this MRSA/VRE rate.

Decision To Implement

Once the evidence has been reviewed and baseline data on non-ICU bloodstream infections and MRSA-positive and VRE-positive clinical cultures among patients with medical devices have been collected, this information should be used to determine the need for targeted decolonization. Early involvement of potential stakeholders and decision makers as is described later in this section is important. Criteria for deciding about implementation include the following:

- **The strength of the evidence that this intervention will impact care in the hospital.** This includes the magnitude of impact found in published studies and similarities of the hospital to the patient populations studied. The latter includes case mix, hospital type, and whether the comparator groups in the studies reflect current infection prevention standards at the hospital.

- **The numbers and/or rates of non-ICU bloodstream infections and MRSA-positive and VRE-positive clinical cultures found in adult non-ICUs, and the hospital leadership's desire to target these outcomes for improvement.** Importantly, these data can also be used for internal benchmarking to assess the impact of the intervention once a decision to implement has been made.
- **Alignment with existing guidance and position statements from national committees and societies, survey requirements for accreditation, and State laws.** As evidence increases on prevention of healthcare-associated infections, legislative and regulatory requirements may change. It is important to know State legislative mandates, accreditation requirements, and guidance provided by the CDC and other national societies related to healthcare-associated infections. The following sites may be helpful for reviewing national guidance on decolonization strategies:
    - The ABATE Infection Trial Targeted Decolonization Strategy is supported by the CDC as an effective strategy to reduce MRSA bloodstream infections in patients with devices outside of ICUs https://www.cdc.gov/hai/prevent/staph-prevention-strategies.html
    - Healthcare Infection Control Practices Advisory Committee (HICPAC), Publications https://www.cdc.gov/infectioncontrol/guidelines/index.html
    - Guidelines and Resources, Society for Healthcare Epidemiology of America (SHEA) https://www.shea-online.org/index.php/practice-resources
    - SHEA Healthcare Associated Infections Compendium https://www.shea-online.org/index.php/practice-resources/priority-topics/compendium-of-strategies-to-prevent-hais

Assessing the Intervention Scope

Experience with successful implementation of prior strategies can help guide the type of rollout. Hospitals with robust experience in rolling out ICU universal decolonization strategies may be better suited to engage in rollout of targeted decolonization for medical device patients in non-ICUs. In addition, hospitals may be aided by prior experience with preoperative chlorhexidine gluconate (CHG) bathing.

- Initial decisions related to the scope of the intervention include:
    - Determining the need for a pilot launch in a single unit
    - Determining the ultimate scope of units to be included in the final launch
- Reasons to pursue a pilot launch:
    - Targeted interventions can be complicated due to the need to identify specific subgroups of patients. A pilot launch can help determine the best method to use

for your hospital. If relying on a manual approach, it may be especially wise to pilot the forms and processes on a single unit.

  - In addition to identifying selected patients with devices, targeted decolonization requires the stocking of CHG product for both bed bathing and showering and ensuring a process for providing and documenting CHG bathing. A pilot launch can help work out the logistics for both product stocking, provision, documentation, and staff training. Remember, this toolkit provides several protocols that allow you to choose which formulation of CHG or nasal product might be the most appropriate for your institution. For example, you can use the products exactly as in the ABATE Infection Trial, which included impregnated 2% CHG cloths for bed baths and 4% rinse of CHG for the shower plus nasal mupirocin. As an alternative to using impregnated cloths, we also provide a substitute protocol for bedside basin bathing, using diluted 4% liquid CHG. Similarly, we provide a protocol for nasal iodophor, that can be used as an alternative to nasal mupirocin.
  - If you have a strong champion in one non-ICU but uncertain support in other non-ICUs, you may want to pilot in the one that is most likely to demonstrate success so that that unit can serve as a beacon for others who may doubt the feasibility of high-fidelity adoption. Success in one unit can help drive additional support and adoption.
  - Hospital leadership may like to see implementation success on a single unit before expanding to others.
- Full implementation scope
  - The strength of the trial should support eventual rollout to all adult non-ICUs targeting patients with medical devices, but hospitals will differ on whether they wish to adopt an intervention based upon published trial results or await guidance from the CDC or national societies. Higher rates of non-ICU bloodstream infection and MRSA-positive and VRE-positive clinical cultures among patients with medical devices may help drive decision making. Currently, CDC supports the use of targeted decolonization as a method for *S. aureus* prevention in patients with devices: https://www.cdc.gov/hai/prevent/staph-prevention-strategies.html.

Assessing the Timing of the Decolonization Intervention

Once the evidence base is understood and baseline rates have been defined, it is important to assess whether the timing is right for a new intervention. Considerations for timing include:

- Urgency related to high bloodstream infection or MRSA/VRE rates among non-ICU patients with medical devices.
- National guidance or regulatory standards.

- Other recent campaigns or new educational training for staff. Does this intervention fit with an ongoing non-ICU campaign? If not, is there a better time in the near future to adopt this when non-ICU staff and educators have the time and availability for another campaign? Is there a scheduled training update for clinical staff to which this could be easily added?
- It may be best to avoid launching new campaigns during or immediately prior to the end-of-the-year holiday season unless all collective stakeholders determine that it is the most appropriate time.

Garnering Institutional Support From Key Stakeholders

Once the rationale, baseline data, and timing support the implementation of targeted non-ICU decolonization in patients with medical devices, it is important to ensure institutional support. Key elements of ensuring institutional support include the following:

- Develop an analysis of cost implications, such as the one included in Section 7 of the toolkit. Select pieces of the above rationale, your hospital rates for outcomes, and comments on recommended timing for a pilot study or full launch.
- Develop a **business case** for hospital leadership
    - Basic steps needed to develop a business case for infection prevention strategies are well described by Perencevich et al[9]:
    - For targeted non-ICU decolonization in patients with medical devices, the business case will require the following cost saving estimates from outcome reduction:
        - Number of prevented hospital-specific non-ICU bloodstream infections among patients with medical devices (see above). As a reminder, the ABATE Infection Trial showed a 32 percent reduction in bloodstream infections among patients with medical devices.
        - Number of prevented hospital-specific non-ICU MRSA-positive and VRE-positive clinical cultures among patients with medical devices (see above). As a reminder, the ABATE Infection Trial showed a 37 percent reduction in MRSA-positive and VRE-positive clinical cultures.
        - Estimated excess cost of a non-ICU-attributable bloodstream infection in medical device patients is $32,000.
        - Estimated excess cost of an infection due to an antibiotic-resistant bacteria (versus antibiotic-sensitive bacteria) is $18,500 to $29,000.
        - Refer commonly cited references for further guidance[4-10]
    - The business case will also require cost estimates for product use:
        - Number of patients with medical devices in adult non-ICUs and their mean non-ICU duration of stay to estimate the number of CHG baths to be given

        - Hospital-specific excess cost of CHG bathing product (bath and shower) over routine bed bath or shower soap product times number of patient days of required bathing per year.
    - Number of patients with medical devices in adult non-ICUs who are known to harbor MRSA:
        - Hospital-specific cost of a 5-day course of mupirocin (or the average length of non-ICU stay if shorter than 5 days) times number of patients per year. Most hospitals are using a single patient multidose tube of generic mupirocin.

- **Stakeholder support:** Present overview statement and protocol to key stakeholders, such as the chief medical officer, chief nursing officer, and medical and administrative directors of infection control and prevention. In addition, non-ICU nurse managers and inpatient nursing directors will be critical stakeholders for buy-in and protocol implementation. The order of approaching these key stakeholders will depend on the culture, standard processes, and existing relationships at the hospital, but they should all be included in the decision-making process. Inclusion of patient advocates can also be extremely helpful.
    - **Infection prevention program:** The hospital infection prevention and control program may be one of several groups to initiate this campaign. If so, it will be important that the initiator ensures that the entire infection prevention program (e.g., administrative director, medical director and chair of the infection prevention committee, and infection preventionist[s] providing support to adult non-ICUs) is fully supportive, understands the above rationale, and can speak to this endeavor.
    - **Non-ICU directors (nurse, physician):** The hospital inpatient leadership team may be another group to initiate this campaign and is essential for support. Nursing directors (and medical directors, if available) can inform the logistics of identifying qualifying patients and targeting CHG bathing/showering protocols and mupirocin orders for patients who are MRSA carriers.
    - **Purchasing and pharmacy:** The purchasing department can provide not only the current hospital-specific costs of CHG cloths and/or liquid for showering but may be able to engage in price negotiations due to anticipated increases in the amount of products purchased. In addition, the pharmacy department should be engaged to account for anticipated increases in mupirocin orders.
    - **Hospital administration and leadership:** Joint support is required from the Chief medical officer and Chief nursing officer to have a successful campaign. Advance preparation of the business case (including anticipated product costs and cost-savings due to prevention of bloodstream infections), description of supporting stakeholders within the hospital, and implementation strategy are important.

Common stakeholder questions regarding universal decolonization should be anticipated. These include the following:

- **What is the evidence for decolonization in non-ICU patients with medical devices?**
  See the above section on the Quality of the Evidence.
- **What is the hospital's need for this intervention?**
  See above section on assessing the Need for the Intervention. The response to this question should include consideration of hospital rates of non-ICU bloodstream infection and positive MRSA/VRE clinical cultures in adults with medical devices, as well as national guidelines, regulation, and any relevant State legislation.
- **What is the cost of this intervention and how is it justified?**
  See the above section on Developing a Business Case.
- **Who is supportive of this intervention?**
  Be prepared to demonstrate support from key stakeholders described above.
- **What is the added benefit of mupirocin over the daily CHG baths?**
  - Previous studies have demonstrated the benefit of targeted decolonization as the combination of CHG plus mupirocin in adult ICUs.[11-12]
  - *S. aureus* is one of the most common causes of healthcare-associated infections in the United States, including CLABSI.
  - The nose is the major reservoir of *S. aureus.* Evidence strongly supports the use of mupirocin as an essential component of eradication and prevention of *S. aureus* infections. Nasal decolonization has been shown to be critical to eradication of MRSA and MSSA compared with CHG alone.[13-17]
  - Even among hospitals where screening for MRSA is currently occurring or mandated by State law, it is important to recognize that MSSA is a major pathogen. Nationally, MSSA constitutes half of *S. aureus* healthcare-associated infections.

- **Are there specific formulations of CHG that should be used?**
  The benefits seen in large randomized controlled trials in ICU settings, including the **R**andomized **E**valuation of **D**ecolonization versus **U**niversal **C**learance to **E**liminate MRSA (REDUCE MRSA) Trial and now the **A**ctive **Bat**hing to **E**liminate (ABATE) Infection Trial in non-ICUs, were based upon the use of no-rinse 2% CHG-impregnated cloths. Theoretically, methods that deliver an equivalent amount of active decolonizing agent to the skin should be effective. However, the method of application may have appreciable effects on achieving appropriate residual concentrations of CHG on the skin. Specifically, no-rinse applications of CHG using a 2% cloth achieve significantly higher residual concentrations of CHG on the skin than applications of 4% with rinsing.[18] In addition, attention to skin coverage in applying CHG is critical.[19,20] Shower-based liquid applications have been shown to result in gaps in skin antisepsis compared with cloth-based applications.[21] Nevertheless, 4% rinse-off CHG solution has been associated with sizeable reductions in MRSA infections in MRSA carriers in a large randomized post-discharge trial.[22]
- **Will we need to modify our MRSA testing/screening processes to implement decolonization?**
  - No. Maintain your current processes for identifying patients with MRSA-positive clinical cultures, screening cultures, and history of MRSA to target those with devices.
- **Should we be concerned about producing antibiotic resistance?**
  The benefits and potential risks should be weighed with any strategy. As with all antibiotics, we will need to be vigilant about antibiotic resistance. We provide some discussion points below.
  - It is important to ensure that CHG and mupirocin are applied properly. Inadequate application can lead to low concentrations of the products that may increase the likelihood of selecting for resistant strains.
  - Because CHG and mupirocin are used for decolonization and are not used to treat active infection, resistance to these agents will not result in the loss of therapeutic antibiotics.
  - Many of the large randomized controlled trials listed in Section 4, Table 1 have not detected emergence of resistance to CHG or mupirocin during the trials across thousands of MRSA isolates.[23-25] Emergence of CHG resistance at this time is largely considered to be a theoretical rather than practical concern.
  - Evidence for emergence of antibiotic resistance during the use of mupirocin is mixed. The literature has reported evidence of increased mupirocin resistance with broad use of mupirocin, increased resistance to mupirocin in the absence of broad use of mupirocin, and no increase in resistance with broad use. Thus,

surveillance by researchers and national surveillance systems will be important in monitoring resistance. Alternative agents for mupirocin are also actively being studied. Since mupirocin use in this context is very targeted, we do not anticipate that resistance emergence will be a problem.

  - Since mupirocin resistance is not routinely tested by microbiology laboratories, most hospitals will not have local data to inform their decision. If the hospital does have these data, they can be used to inform the use of this agent.

- **What if our clinicians prefer to use nasal iodophor instead of mupirocin?**
  Due to U.S. regional differences in mupirocin resistance and facility preferences for mupirocin versus nasal iodophor for nasal decolonization protocols (e.g. preoperative decolonization), this toolkit will provide pragmatic directions for the use of nasal iodophor as an alternative to mupirocin.[26] Hospital choices may be further informed by the Mupirocin-Iodophor ICU Decolonization Swap Out Trial, a large-scale noninferiority pragmatic cluster-randomized trial comparing decolonization with mupirocin/CHG to iodophor/CHG in ICU patients.[27]
- **Aren't some bacteria good for us? Will this strategy remove good bacteria?**
  Even the "normal" (i.e., commensal) bacteria on the skin can become harmful during hospitalization. The use of lines and devices, as well as surgical wounds and other breaks in the skin result in a higher chance that our normal body bacteria can enter sterile places and produce infection during high-risk periods. Targeted decolonization is being advocated during high-risk hospitalizations involving medical devices that compromise skin integrity and increase risk for infection. The ABATE Infection Trial demonstrates that this use of decolonization removes highly antibiotic resistant bacteria that are unwanted on the skin and reduces the real risk of life-threatening bloodstream infection.

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Section 6 – Estimated Cost Implications of Reducing Bloodstream Infections in Patients With Medical Devices

What Is the Cost and Cost Savings Associated With Decolonization?

Determining the cost of the decolonization intervention and the expected cost savings associated with preventing infection can be key to the decision-making process. The following tables can help you estimate the cost and cost savings associated with implementing decolonization at your hospital.

First, it is important to estimate the expected reduction in infections if decolonization is adopted. The ABATE Infection Trial[1] showed that the use of decolonization in patients with select devices (central lines, midline catheters, and lumbar drains), led to the following:

- 32 percent reduction in all-cause bloodstream infections
- 37 percent reduction in positive MRSA and vancomycin-resistant enterococcus (VRE) clinical cultures

Table 6-1 shows the calculations necessary to estimate the reduction in infections at your hospital if decolonization is implemented. First, identify all annual bloodstream infections in non-ICU patients with central lines, midline catheters, and lumbar drains at your hospital. This includes all bloodstream infections regardless of whether they were related to the device. This number should be entered in place of variable AA below. A reduction of 32 percent is expected. If this number is not readily available, the annual number of central line-associated bloodstream infections (CLABSIs) in could be used as a surrogate. Be aware that the use of CLABSI will underestimate the expected benefit.

Second, identify all annual MRSA and VRE clinical cultures in non-ICU patients with central lines, midline catheters, and lumbar drains at your hospital. Enter that number into the table in place of variable BB. A 37 percent reduction in MRSA and VRE clinical cultures is expected if decolonization is implemented.

Table 6-1. Estimated Benefit From Targeted Decolonization in non-ICU Patients With Selected Devices

Metric	Current Annual #	After Adoption of Universal Decolonization
Annual non-ICU bloodstream infections among unique patients with selected devices	AA	[AA * (1-0.32)]
Annual non-ICU positive MRSA and VRE clinical cultures among unique patients with selected devices	BB	[BB * (1-0.37)]

Table 6-2 lists additional data elements needed to complete the cost analysis.

Table 6-2. Input Variables

Variable	Definition
Bathing costs	Incremental cost of chlorhexidine bathing per patient day = daily chlorhexidine cost minus daily routine soap cost
Patient days	Patient days generated by non-ICU patients with selected devices
Admissions	Number of admissions to non-ICU locations involving patients with selected devices

After obtaining the above data, enter the numbers into Table 6-3. This table helps calculate the cost savings from prevented bloodstream infections after subtracting the added costs of chlorhexidine over regular soap. The cost savings from prevented MRSA and VRE clinical cultures are not estimated here since the costs saved depend on the type of infection which may vary across hospitals. Thus, the overall cost savings from Table 6-3 are an underestimate.

Table 6-3. Estimated Cost Reduction From Universal Decolonization

Metric	Calculation
$ Potentially saved from averted bloodstream infections (C)	[AA * (0.32)] * $32,000[2] = C
$ Saved from MRSA/VRE clinical cultures averted	Not calculated[a]
Product cost (D)	[(Bathing Cost * Patient Days) + (Mupirocin Cost[b] * Admissions)] * .79 = D[c]
Intervention savings (IS)	Difference (i.e., C-D=IS)

[a]Since the cost of MRSA and VRE clinical cultures is dependent on the type of infection plus any later sequelae due to MRSA/VRE acquisition, this amount is not easy to estimate without additional chart review at the hospital. Thus, we conservatively calculate cost savings without this outcome. Cost savings are therefore likely to be underestimated.

[b]Assumes a generic 22g multidose single patient tube of mupirocin will be dispensed to each qualifying patient to cover a 5-day course; this results in a single tube cost regardless of how many days the patient remains in the hospital.

[c]Represents the 79 percent adherence in the ABATE Infection Trial that yielded the 32 percent reduction in bloodstream infections.

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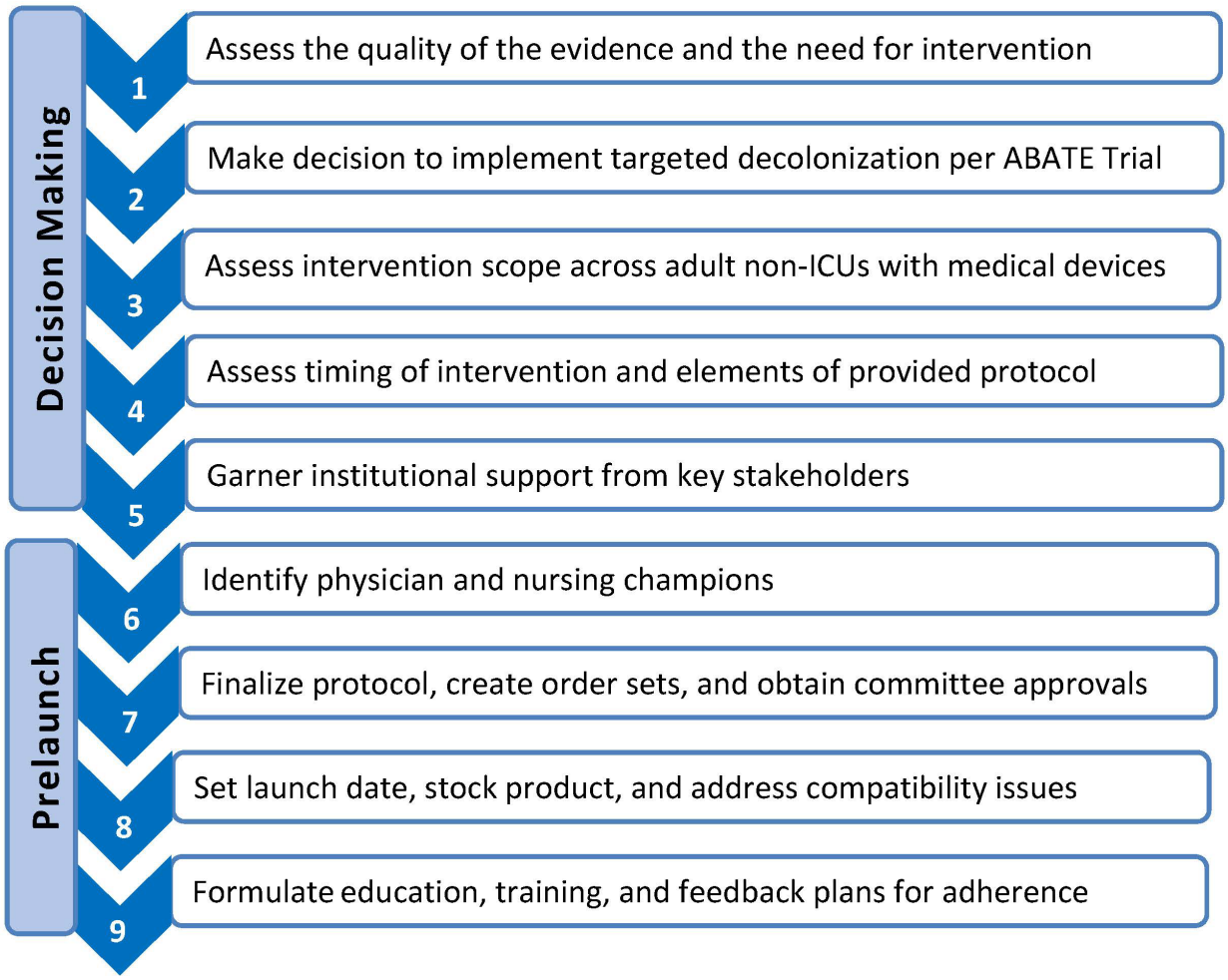
2. Stevens V, Geiger K, Concannon C, et al. Brown J, Dumyati G. Inpatient costs, mortality and 30-day re-admission in patients with central-line-associated bloodstream infections. Clin Microbiol Infect. 2014 May;20(5):O318-24. PMID: 24112305.

Section 7 – Action Chart for Implementing Targeted Decolonization



Organization of Toolkit for Staff

As you begin to review the prelaunch activities, Table 7-1 can be used as a reference to direct staff to sections of this toolkit that are relevant to their job descriptions.

Table 7-1. Organization of Toolkit for Staff

Job Description	Sections
Administrators/Decision Makers/Champion	Section 1 – Introduction and Welcome Section 2 - ABATE Trial Investigators and Toolkit Project Team Section 3 – Overview Statement Section 4 – Scientific Rationale Section 5 – Decision Making and Readiness for Implementation Section 6 – Estimated Cost Implications of Reducing Bloodstream Infections in Patients With Medical Devices Section 7 – Action Chart Section 8 – Prelaunch Activities
Physicians	Section 1 – Introduction and Welcome Section 3 – Overview Statement Section 4 – Scientific Rationale Section 9 – Nursing Protocols (if standing order protocol for mupirocin is used)
Nurse Managers and Directors Only	Section 1 – Introduction and Welcome Section 8 – Prelaunch Activities
All Nurses, Including Managers and Directors	Section 9 – Nursing Protocols Section 10 – Instructional Handouts Section 11 – Protocol Training Section 12 – Adherence and Skills Assessments Section 13 – Huddle Documents Section 14 - FAQs and Talking Points

Section 8 – Toolkit Prelaunch Activities

We recommend that you follow the prelaunch checklist below (Table 8-1) for successful implementation. As is the case with many infection prevention programs, it will take time to achieve culture change. Expect that it will take 3–6 months to achieve solid adoption after training, feedback, and encouragement. Some sites may find it helpful to review the toolkit and make a comparison table between their current practices and toolkit recommendations that need to be changed. Such a comparison table can be used to make the prelaunch checklist specific to your institution.

Table 8-1. Prelaunch Checklist

Status	Item
☐	Identify physician and nursing champions
☐	Set launch date
☐	Obtain required committee approvals
☐	Identify and implement process for targeting patients with devices
☐	Work with supply chain and pharmacy to purchase and stock decolonization products
☐	Ensure chlorhexidine gluconate (CHG) compatibility with routine skin products
☐	Provide staff education and training
☐	Print staff and patient handouts and skills assessment forms
☐	Develop a feedback plan to assure adherence and reinforce training

✓ Identifying Physician and Nursing Champions

For each non-critical-care unit that will adopt this strategy, it is important to identify a nursing champion who is well respected by their peers and can speak in strong support of the intervention. Nursing champions differ from key stakeholders in that they are personnel that routinely provide oversight within the non-intensive care units (ICUs) such as the nurse manager/director. Nursing champions should be able to:

- Promote the intervention and serve as a peer leader for this intervention
- Speak to the rationale of targeted decolonization for patients with medical devices in non-ICUs during rounds and nursing huddles
- Support collection of baseline and followup data on methicillin-resistant *Staphylococcus aureus* (MRSA) and vancomycin-resistant enterococcus (VRE) burden and bloodstream infections among patients with medical devices in that unit
- Provide adherence data on use of decolonizing products and bathing checks
- Encourage high compliance among unit staff

A physician champion can help support the targeted decolonization protocol by galvanizing other physicians and garnering physician support for the protocol. This support is particularly important if you use a mupirocin-based regimen that requires a physician order.

✓ Set Launch Date

A launch date should be set that accounts for the following:

- Timing of committee approvals
- Timing required for product stocking and compatibility assessment (see" Stock Product and Address Compatibility Issues" below)
- Timeline required for educational training, including possible computer-based training modules, presentations to nurse manager forums, nursing skills day or quality fairs, nursing staff meetings, medical staff meetings, and medicine grand rounds or other non-ICU physician forums
- Sequence of timing for expansion if sequential rollout to multiple non-ICUs is planned
- Other competing campaigns and holidays

✓ Obtain Required Committee Approvals

Most hospitals will implement targeted decolonization as a standardized nursing protocol, often coupled with the use of order sets within the electronic medical record.

These processes will need to undergo usual hospital approval by relevant committees, which may include infection prevention, nursing governance, pharmacy & therapeutics, and the medical executive committees. Determination of committees from which to seek approval is the responsibility of each hospital. Scheduling time on the agenda for these committees will be essential to the planning and launch of this prevention strategy.

✓ Identify and Implement Process for Targeting Patients With Devices

Discuss with nursing and medical leadership, information technology leaders, pharmacy, and supply chain how best to implement targeted decolonization for non-ICU adult patients with new or existing medical devices (e.g., central lines, midlines, or lumbar drains).

Select the best process for your hospital. Options may include:

- **Manual process** – Round on non-critical care units daily to identify adult patients with new or existing medical devices (e.g., central lines, midlines, and lumbar drains). Nurse activates standardized nursing protocol to give these patients 2% no-rinse CHG bed baths or 4% rinse-off showers on a daily basis and contacts treating physician to order nasal decolonization if patient is considered to harbor MRSA based on the criteria below.
- **Electronic process** – Adult patients with the medical devices of interest are automatically identified based on nursing device documentation in the electronic medical record

(EMR), and CHG decolonization is initiated using an order set (Table 8-2) that activates the standardized nursing protocol for CHG bathing. In addition, the EMR identifies an additional subset of patients with targeted medical devices who are also known to be MRSA carriers and activates a nasal decolonization order set for those patients.

Mixed electronic/manual process – Adult patients with medical devices of interest are automatically identified based on nursing documentation in the EMR, and a report is generated. The report may also identify the subset of patients with those medical devices who are known to be MRSA carriers. A nurse champion uses the report on a daily basis to activate a standardized nursing protocol to bathe these patients with CHG and contacts the treating physician to order nasal decolonization if the patient is known to harbor MRSA.

- **Options for identifying MRSA carriers include:**
  - Past history of MRSA flagged in EMR system
  - MRSA-positive culture or history documented on transfer
  - MRSA-positive screening test (if performed) or clinical culture positive
  - Patient gives verbal history of being MRSA positive
  - Remember, we are not asking you to change your testing/screening processes for MRSA. Use your current processes for identifying MRSA-positive clinical cultures, screening cultures, and history of MRSA to target those with devices. Recognize that there may be patients with a history of MRSA, but with recent negative surveillance cultures who should be included.

Table 8-2. Example of Standing Order Set

Order Set Name	Device Decolonization
Protocol Details	Daily CHG bath with 2% no-rinse impregnated CHG cloths for bed bathing or 4% liquid rinse-off CHG for showering for non-ICU adult patients with new or existing medical devices
Medication	Mupirocin 2% nasal ointment • Activate order for patients with medical devices who are also known to be MRSA+ (MRSA+ flag present, MRSA+ screening test or clinical culture, documented MRSA+ history on transfer, patient gives history of being MRSA+) • Mupirocin 2% nasal ointment, 0.5 gram applied to each nostril 2 times per day for 5 days, for a total of 10 doses. Follow targeted decolonization protocol for missed doses.

Note: MRSA+ = MRSA positive

✓ Work With Supply Chain and Pharmacy To Purchase and Stock Decolonization Products

Work with your supply chain and usual vendors to purchase and stock decolonization products ahead of the targeted decolonization launch date (Tables 8-3 and 8-4). CHG bathing and showering formulations do not need a prescription. Mupirocin requires an M.D. order/prescription and will need to be adequately stocked through pharmacy based upon anticipated usage.

Table 8-3. Decolonization Products

CHG Cloths for Bed Bathing	• 2% CHG impregnated cloths for no-rinse bed bathing
CHG for Showering	• 4% CHG liquid (4 oz bottle) with mesh sponge for single patient use for showering
Mupirocin	• 2% nasal mupirocin ointment, twice daily for 5 days • Dosing options may include: Option 1: Single-patient multidose 22 g tube Option 2: Pharmacy dispensed unit dose bubble pack

Table 8-4. Alternative Products

CHG Liquid for Bed Bathing	• 4% CHG liquid (4 oz bottles) diluted once with 4 oz of water to create 2% CHG leave-on liquid for bed bathing with disposable cloths • Use non-cotton disposable cloths for application
Iodophor Nasal Decolonization	• 10% povidone-iodine (iodophor) swabsticks • One per nostril twice daily for 5 days

✓ Ensure CHG Compatibility for Routine Skin Products

Many topical skin products (e.g., lotions, barrier creams/wipes, perineal cleansers, baby wipes, shaving creams, deodorants) can inactivate CHG and prevent it from killing germs. Prior to launching targeted decolonization, ensure that all stocked prophylactic topical skin products are CHG compatible. Topical prescription products prescribed for treatment do not need to be checked as they are required for patient care. Since 80–90 percent of U.S. hospitals have implemented decolonization in the ICU setting, in general, most hospitals have a limited set of CHG-compatible prophylactic topical skin products stocked. Check with your supply chain and ICUs first. However, if you are not certain, check both ICU and non-ICU products.

To check CHG compatibility for prophylactic skin products, contact the manufacturers of lotions and skin products that are stocked in the hospital. The most reliable source of confirmation will be the manufacturer. We recommend that you ask the following questions and request written documentation of compatibility:

1. Has the product been tested for CHG compatibility?
2. Can you provide the data confirming CHG compatibility?

If the product has not been tested for CHG compatibility or data are not available to confirm compatibility, look for an alternative product that is confirmed by the manufacturer to be CHG compatible. Most healthcare skin products have been tested by the manufacturer due to the commonplace use of CHG leading to large numbers of healthcare providers seeking confirmation of compatibility.

- **Medicated or wound care skin products**
  If your patient is prescribed a treatment regimen for the skin, used as medically directed and continue to apply CHG for routine bathing. We do not recommend that CHG compatibility be checked for prescribed medications because they are needed for medical care. Such products can include steroid creams, antifungal creams, and burn or wound creams for treatment.

- **Products known to be CHG incompatible**
  The following products commonly contain ingredients that are known to be CHG incompatible and should be used sparingly:
  - Soaps – **DO NOT USE**. CHG bathing cloths or CHG liquid soap replace soap and water.
  - Deodorant
  - Shaving cream
  - Shampoos – use no-rinse shampoo caps to avoid contact with face and body skin. All shampoos contain ingredients that will inactivate CHG.
  - In the shower, we recommend CHG be used for shampooing. If alternative shampoo is used in the shower, keep off as much of the body as possible when rinsing.

✓ Provide Staff Education and Training

Prior to launch of targeted decolonization, train frontline staff (nurses, certified nursing assistants, etc.) using the educational materials provided in this toolkit.

Computer-based training module – This PowerPoint presentation can be incorporated into your computer-based training system for assignment to designated frontline staff. It can also be used for dedicated training during nursing skills' days or other educational forums. A brief post training test is included.

Videos

- CHG bathing videos – includes a demonstration of how to perform a CHG bath, with staff-patient interaction scenarios describing how to explain to patients what the CHG bath is and how to encourage patients to accept the bath.
- Device-cleaning videos – separate videos include detailed demonstrations of how to use CHG to clean central/midline catheters and lumbar drains and their dressings.
- Videos can be incorporated into your hospital's computer-based training system for assigned viewing by designated staff. Alternatively, videos can be presented during staff huddles.

Just-in-time training – this document can be used for new, registry, or float staff in conjunction with staff one-page instructional handouts. It is recommended copies be placed at nursing stations to be available for frontline staff that require day-of training.

Huddle documents – brief key reminders to be shared with frontline staff during huddles covering various protocol topics. Examples include:

- Why Is Nasal Decolonization Important?
- How to Address Bathing/Showering Refusals
- CHG and Device Care
- CHG and Wound Care

Options for frequency of huddle document messaging include:

- Covering one key topic for an entire week (best option for critical reminders to reach all staff in all shifts)
- Tailoring the huddle topic to the issues present on that shift (best option when issues differ between shifts and shift champions can tailor huddle messages to address existing issues)

✓ Print Staff and Patient Handouts and Skills Assessment Forms

Staff instructional handouts – one-page handouts with instructions for performing a CHG bed bath, providing shower instructions, and applying nasal decolonization. Copies should be placed at nursing stations to be available for all frontline staff.

Patient instructional handouts – one-page handouts with instructions on why and how CHG is used for bed bathing, and on how to apply CHG in the shower, are provided. Copies should be placed at nursing stations to be available for all frontline staff to give to patients. These handouts will save nursing time by answering many questions that patients may have about decolonization.

Skills assessment forms – one-page handouts for staff to perform peer-to-peer assessment or for nursing leaders to assess competency of nursing staff in CHG bed

bathing. Also includes one-page handouts for patients to complete a small set of questions about their knowledge and experience with CHG bathing or showering.

✓ Develop a Feedback Plan to Assure Adherence and Reinforce Training

As with any campaign, it is important to provide regular assessments of adherence to intervention protocols. In this toolkit, we provide the "Bathing Skills Assessment" tool for observing bathing practice and asking key questions to ensure understanding of the protocol. For example, a small number of baths per unit should be observed on a weekly basis post-implementation, with reduction over time to monthly maintenance assessments as adherence is assured. This could be done by a non-ICU nurse manager, a facility nurse educator, or a designee. The frequency of sample observations (e.g., weekly, monthly) should be tailored to the results of these assessments (e.g., more frequent observations if protocols are not fully adhered to or if understanding appears limited; less frequent observations where protocol compliance is higher).

Nurse training can be reinforced with the following, which are provided in this toolkit:

- Instructional Handouts
- Huddle Documents
- Do and Don't Fact Sheet
- Protocol Training
- Adherence and Skills Assessments
- Frequently Asked Questions

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