### THE LANCET

### Supplementary appendix

This appendix formed part of the original submission and has been peer reviewed. We post it as supplied by the authors.

Supplement to: Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial. *Lancet* 2019; published online March 5. http://dx.doi.org/10.1016/S0140-6736(18)32593-5.



### ARM 2

# Decolonization Toolkit Binder



## Decolonization Arm 2

#### **Toolkit Binder**

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#### Welcome

Welcome to the Active Bathing To Eliminate Infection Trial. The ABATE Infection Trial is a 2-Arm cluster randomized trial of Hospital Corporation of America hospitals to assess the value of chlorhexidine (CHG) bathing for all patients and nasal decolonization for MRSA+ patients in reducing hospital-associated infections in non-critical care units. This trial is a joint collaboration between HCA, the University of California Irvine, Harvard Pilgrim Health Care Institute/Harvard Medical School, Rush University, Stroger Hospital of Cook County, and the Centers for Disease Control and Prevention (CDC). The trial is federally funded by the National Institutes of Health (NIH).

#### **Summary of Goals**

Healthcare-associated infections (HAIs) are a leading cause of preventable morbidity and mortality. Most infections result from common bacteria that normally live on the skin or in the nose and which overcome the body's normal defenses because of medical devices, surgical incisions, or medical illness associated with hospitalization. Studies in intensive care units (ICUs), including our previous highly successful REDUCE MRSA Trial, indicate that decolonization of patients' skin with CHG, and nares with mupirocin can prevent many HAIs. However, evidence is lacking about the effectiveness of decolonization in non-critical care settings, where the majority of HAIs occur. This trial will compare two quality improvement strategies to reduce HAIs and possibly reduce readmissions. The ABATE Infection Project will be a landmark study with a major public health impact. Participating HCA hospitals will be randomized into one of two groups (arms). The first arm, Routine Care, calls for no change in usual care. Arm two, Decolonization, requires non-critical care units to decolonize all patients with CHG and additionally decolonize MRSA-positive patients with mupirocin.

This trial will provide essential information about whether routine decolonization with CHG should become standard practice for 40 million patients hospitalized each year in the United States alone. Alternatively, it will suggest that tailored strategies distinct from those effective in ICU settings are needed for patients in non-critical care settings.





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#### **Phone Matrix**

Topic	What to do	Who to contact	Contact Information
General questions	Call or email	ABATE Infection Project Staff	
Chlorhexidine bathing or mupirocin application	Call or email	Lauren Heim Adrijana Gombosev	
Study related event questions	Call or email	Rebecca Kaganov Julie Lankiewicz	
Study related event reporting	Fax Study Related Event Form	ATTN: Rebecca Kaganov	
Lab strain collection	Call or email	Katie Haffenreffer Lauren Shimelman	
IRB questions	Call or email	Rebecca Kaganov Julie Lankiewicz	
Lead Investigator questions	Call or email	Susan Huang, MD MPH	

#### For questions related to HCA hospital policy, process, and products\*

HCA Investigator	Phone Number	Email
Ed Septimus MD		
Medical Director,		
Infection Prevention and Epidemiology		
Julia Moody MS SM (ASCP)		
Director, Infection Prevention		

<sup>\*</sup>Do not disclose protected health information (PHI) to ABATE Infection Project Staff. If you need to share PHI, we will direct you to HCA Study Investigators.





## Nursing Protocol: Chlorhexidine Bathing and Showering

- A. Target population: non-critical care patients in non critical care units participating in the ABATE Infection Project
- **B.** Excluded patients
  - a. Known allergy to chlorhexidine (CHG)
  - b. <12 y
- C. Nursing protocol

#### a. Protocol for Bed Bathing with Chlorhexidine Bathing Cloths

- Provide one-page instruction sheet for patients on CHG bathing to read prior to beginning bath ("Bathe daily with Chlorhexidine (CHG) cloths- Patients").
- Remove one set of warmed packets (3 packets in a set, 2 cloths per packet) of 2% CHG cloths from the Sage warmer (total 6 cloths). For obese or incontinent patients, additional cloths may be needed. Note: Cloths should not be removed from warmer until just before bath.
- Educate the patient that the CHG cloths work better than soap and water in removing bacteria from the skin and that the cloths serve as their routine bath.

- If the patient wishes to self bathe, provide verbal instructions, and assist with hard to reach areas. Refer to "Patient Talking Points" in your Toolkit binder for example verbal instructions for patients as well as how to encourage bathing.
- Use each of the 6 cloths for bathing the following body areas.
   Ensure that cloths are applied to skin by firm massage to ensure binding of CHG to skin proteins, which allows it to continue to kill germs for a minimum of 24 hours.
  - Cloth 1: Face, neck, and chest. Avoid eyes and ears.
  - Cloth 2: Both shoulders, arms, and hands
  - o Cloth 3: Abdomen and then groin/perineum
  - Cloth 4: Right leg and foot
  - Cloth 5: Left leg and foot
  - Cloth 6: Back of neck, back and then buttocks
- After application to body, use cloth to clean lines and tubing (e.g. central lines, urinary catheters, drains, G-tube/J-tubes, rectal tubes, chest tubes) within 6 inches of the patient. Wipe over non-permeable dressings. This will help remove bacteria close to where devices penetrate the skin. CHG is safe on devices and can be used over semi-occlusive dressings.
- For incontinence episodes use additional CHG cloths. The 3
  packets of 2-cloths each can be separated and each warmed in
  its own warmer slot. Use these additional packets as needed
  during the day.
- If soiling occurs, remove soiled incontinence pads or towels. Rinse
  the affected area with water and clean with liquid incontinence
  product. Then, clean skin with CHG cloths. Then, use CHG
  compatible barrier protection products for barrier protection
  (Refer to "CHG Compatibility Sheet" in your Toolkit binder).
- Allow to dry naturally do not wipe off

- CHG cloths have moisturizers. If additional moisturizer or lotion is needed, only use lotions that are known to be compatible with CHG (Refer to the "CHG Compatibility List" in your Toolkit binder)
- Do not place CHG cloths directly on bedding, as contact with bleach can create brown stain. Once CHG binds skin proteins, it will not rub off onto bedding.
- Dispose of CHG cloths in trash. Do not flush in commode.

NOTE: Use as many additional CHG bathing cloths as necessary to thoroughly cleanse body.

#### b. Protocol for Patients Showering with Liquid Chlorhexidine

- Provide one-page instruction sheet for patients on CHG showering to read prior to beginning shower ("Patient CHG Shower Instructions"). Patients will be more likely to read the instructions in their spare time.
- Provide patient with a single use 4-ounce 4% CHG bottle for each shower
- Provide patient with a mesh sponge to use and re-use during hospitalization. For extended stays, the mesh sponge may be replaced weekly, or upon patient request.
- Educate the patient that CHG works better than soap and water in removing bacteria from the skin and that additional non-CHG soap should not be used
- Provide the patient with the following verbal shower instructions:
  - o Use liquid CHG as shampoo in addition to body cleansing
  - Wet skin with water. Turn off water or stand out of water stream
  - Pour CHG onto wet mesh sponge and rub sponge until it is foamy
  - Firmly massage soapy sponge all over skin in the same order as indicated for the CHG cloth instructions. Reapply

**CHG** generously to keep sponge full of foamy lather. Be sure to clean from top down (cleanest to dirtiest areas).

- Leave CHG on body for 2 minutes before rinsing
- CHG should be encouraged for hair, face, and body use. However, if
  patients insist on using personal shampoo or face products, instruct
  them to use their personal products first with a separate wash cloth,
  rinse well, and keep personal bathing products off of the body
  because regular soaps and shampoos prevent CHG from working
  well.

### D. Additional Important Instructions for Both CHG Cloth Bathing and Showering

- **a.** Do not use regular soap with CHG. Many soaps inactivate chlorhexidine. CHG works better than soap and water in deeply cleansing the skin.
- **b.** Ensure thorough cleaning, with special attention to commonly soiled areas such as the neck, skin folds, and perineal areas. CHG is safe to use on perineal areas, including external mucosa.
- **c.** CHG is safe for superficial wounds, including stage 1 and 2 decubitus ulcers, superficial burns, as well as rashes and abrasions. Use of CHG on these areas kills germs and helps prevent infections. Do not use on large or deep wounds.
- **d.** Use CHG for all bathing purposes, including once-a-day full-body bathing, cleaning after soiling, or any other reasons for additional cleaning. This includes the face; however avoid contact with eyes and ears.
- e. If moisturizer is needed, provide patient with CHG-compatible lotion
- **f.** Allergic reactions are rare, but can occur. If your patient experiences a reaction possibly related to the study product, contact the patient's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Complete a "Study Related Event" form located in your Toolkit binder and submit to the unit nursing director who will report it to the ABATE study staff twice monthly.

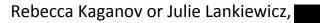
**g.** Adhere to facility policies for covering vascular access devices, dressings, etc. to prevent water penetration and introduction of water borne bacteria

#### **General questions:**

#### **Decolonization Protocol questions:**

Adrijana Gombosev or Lauren Heim,

Study Related Event questions:







## Nursing Protocol: Nasal Mupirocin Ointment

#### Who should receive mupirocin?

- Only use on patients who are known to be MRSA+ by history, screening test, or clinical culture
- Use twice daily for 5 days, or until unit discharge, whichever comes first
- Do not use if the patient has an allergy to mupirocin
- If patient is readmitted to the unit, protocol begins anew
- If a patient is transferred to your unit from the ICU and has already received a partial or complete cycle of 5-day mupirocin, new orders for mupirocin should be written for your unit and the previous ICU orders will be discontinued

#### **Excluded Patients**

- <12 y
- Known allergy to mupirocin

#### How to use mupirocin

- Place patient's bed at 30 degrees, if tolerated
- Apply blueberry sized amount of mupirocin tube into each nostril or use unit dosing from multi-dose tube per pharmacy medicine administration protocol

- Press nostrils together and massage gently for 60 seconds
- Do this twice a day for 5 days
- Avoid contact with eyes and other intranasal products (contact study staff if any questions)
  - o If nasal devices are in place (e.g. nasal intubation, NG tubes), place mupirocin around tubing and massage gently to distribute ointment
  - If nasal packing is in place (e.g. recent surgery/trauma), do not apply to that nostril

#### **Missed Doses**

If one dose is missed, have the patient restart mupirocin as soon as possible and go back to the regular schedule. Do *not* double up doses. Always restart with the single dose. If more than 1 days' worth of mupirocin is missed, the patient will need to restart completing the 5 days of therapy. In this case, the missed doses are rescheduled to the end of the original 5 day start.

#### **Adverse Events**

Allergic reactions are rare, but can occur. If the patient experiences a reaction possibly related to the study product, contact the patient's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Complete a "Study Related Event" form located in your Toolkit binder and submit it to the unit nursing director.

#### **General questions:**

#### **Decolonization Protocol questions:**

Adrijana Gombosev or Lauren Heim,

**Study Related Event questions:** 

Rebecca Kaganov or Julie Lankiewicz,





### **Frequently Asked Questions**

#### This section includes:

- ➤ General Study Questions for Arm 2
- ➤ Chlorhexidine Bathing Frequently Asked Questions (FAQs)
- ➤ Nasal Mupirocin Ointment FAQs
- ➤ Wound Care FAQs



# Frequently Asked Questions: General Study Questions Arm 2

#### What is the ABATE Infection Project?

A cluster randomized trial of adult non-critical care units comparing 2 quality improvement strategies to reduce multi-drug resistant pathogens and hospital-associated infections. Over 50 HCA hospitals are participating. Your hospital's adult non-critical care units have been randomized to Decolonization.

#### What is Decolonization?

Decolonization refers to use of chlorhexidine (CHG) for routine daily bathing of **ALL patients** for their **entire unit stay**. This includes daily clean-up for incontinence or to "freshen up." In addition, patients who are known to be MRSA+ will receive nasal mupirocin **twice daily for 5 days**, or until unit discharge, whichever comes first. If a patient is readmitted to the unit, the decolonization protocol will begin anew regardless of prior receipt of CHG or mupirocin in other units or in the previous unit stay. For example, if a patient who is an MRSA carrier just received 5 days of mupirocin and daily CHG bathing in an ICU and then comes to your unit, they will continue to receive daily CHG baths and they will begin a 5-day course of mupirocin on your unit.

#### Who should be decolonized with nasal mupirocin ointment?

Your unit will be decolonizing all patients ≥12 years old known to be MRSA+ by history, screening tests, or clinical culture. These patients will receive both the daily CHG bath or shower PLUS nasal mupirocin twice daily for 5 days or until discharge, whichever comes first.

#### How should mupirocin and CHG be applied?

Please refer to the Nursing Protocol in your Toolkit binder. For any questions, contact the ABATE Infection Project Helpline at or

#### How do I report a possible study related event?

Please contact the patient's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Please report the possible event to the Nurse Manager or Director of your unit who will provide bimonthly reports to the ABATE Infection Project for tracking purposes. Nurse Manager or Director: On the 15<sup>th</sup> and 30<sup>th</sup> of each month, fax the completed Study Related Event form to Rebecca Kaganov at if you have any events to report.

### Who do I contact with questions? General questions:

**Decolonization Protocol questions:** 

Adrijana Gombosev or Lauren Heim,

**Study Related Event questions:** 

Rebecca Kaganov or Julie Lankiewicz,

**Study Link:** 





## Frequently Asked Questions: Chlorhexidine Bathing

#### What is chlorhexidine (CHG) and how safe is it?

CHG is an antiseptic agent that helps to reduce the amount of germs on your skin, including antibiotic-resistant germs such as MRSA. CHG is FDA approved for this purpose and its safety profile is excellent.

#### Why does my patient need to be bathed daily with CHG?

CHG binds to skin proteins to provide protection for 24 hours. Therefore, bathing **everyday** is important to protect the patient for their entire unit stay. Also, with daily bathing, patients are more likely feel cleaner and refreshed. Daily bathing will improve their overall hospital experience.

#### What if my patient refuses a bath?

Similar to any medical care or routine practice, patients can refuse any therapy. However, as you know, it is not routine practice to ask patients whether they want to refuse each component of usual standard of care (e.g. admission orders, type of bathing or shampoo product...). If, in the course of usual explanation of the bathing process, the patient does not wish to have this done, it is their right to refuse. Remember that hospitalization is a vulnerable time for patients, and devices and procedures increase their risk for infection. The success of this protocol is highly dependent on the enthusiasm of nursing staff in encouraging

patients to bathe each day and to start bathing on admission to protect the patient as soon as possible.

Encourage the patient several times before accepting a decline. If they are tired, check back later (give them a time point, half hour, etc.). Remind the patient that the bath is short and only takes 5-10 minutes and the bath will protect them from germs. Providing the one-page instructional handout can help the patient understand the value of the bath and save nursing time.

# Does the CHG bath or shower have to be taken at the same time each day in order for bathing documentation to be captured appropriately in the bathing query?

No, bathing does not have to occur at the same time each day. **However**, a bath or shower must be taken once per calendar day to be captured in the bathing documentation and have maximum benefit. If a bath or shower is not taken once per calendar day it will appear as noncompliant when data is pulled from central warehouse and this will affect the compliance metrics for your unit and the trial. The most important thing is that the documentation is based on a calendar day.

### Some of the patients can perform their own bath or shower. What should be used, and can the patients bathe themselves?

If the patient wishes to self bathe, provide the patients with the 1-page "Shower daily with CHG Soap" or "Bathe daily with CHG Cloths" patient handouts found in your Toolkit binder. Having the patient read the instructions will save you time later because the patient will become familiar with the bathing process. Then, prior to bathing, verbally repeat the cloth bathing or showering instructions to ensure proper application. Remind the patient that if the bathing is not performed correctly, they may not receive the protective benefits.

If the patient wishes to perform a bed bath, remember to show the patient how to open the packages since they are difficult to open from the ends. Remind them to massage the CHG onto their skin and over non-absorbent dressings. Help them to clean hard to reach areas and to clean the 6 inches of any tube, drain, or line closest to the body. If the patient is able to step into the shower, 4% CHG liquid soap along with a mesh sponge for application should be provided. Again, help them clean hard to reach areas and parts of tubes, drains, and lines nearest the body.

### What if my patient would like to use their own shampoo, conditioner, or face wash?

Remind the patient that regular soap and shampoo can inactivate CHG and prevent it from working. If your patient insists on using their own shampoo or face wash, instruct them to use these first and try to keep the shampoo and face wash off the body so CHG will work as body soap.

#### Is it okay for my patients to shave and use deodorant?

Even though shaving cream and deodorant may inactive CHG, we understand that patients will want to shave and use deodorant. If shaving is performed, ensure that shaving cream does not reach parts of the body other than the area being shaved.

### What if my patient has an incontinence episode or needs freshening up throughout the day?

CHG cloths should be used for all bathing purposes, including once-a-day full-body bathing, cleaning after soiling, or any other reasons for additional cleaning such as freshening up. Do not use soap to cleanse incontinent patients because soap can inactivate CHG. First remove urine/stool with usual incontinence wipes or cloths and water. Next, clean with CHG and allow to air dry. Finally, apply CHG compatible barrier protection over the area. Repeat as often as needed throughout the day.

#### My patient reports that their skin feels sticky after the bath.

The sticky feeling is due to the moisturizing ingredients in the CHG cloths and it will go away as it dries. The cloths contain aloe vera.

#### Is it safe to use on the perineum?

Yes, CHG is safe to use on the perineum and external mucosa.

#### Is CHG safe to use on lines, tubes, and drains?

Yes, it is very important to clean lines, tubes, and drains in addition to the skin surrounding these devices in order to prevent infection. The 6 inches of any tube, drain, or line nearest the body should be cleaned. Non-absorbable (non-gauze) dressings should also be wiped over with the CHG cloth after the skin is cleaned.

### I am having trouble with applying bandages after bathing my patients with CHG. Does CHG weaken bandage adhesive?

If you are having trouble reapplying a bandage after bathing a patient with CHG, it's usually because not enough time has elapsed to allow for drying. After bathing a patient, please allow the CHG to dry for about 5 minutes. This should provide ample time for the CHG to absorb and not affect the bandage adhesive. If you cannot wait the full 5 minutes and if the patient's skin still feels tacky, it will prevent the bandage from sticking properly.

#### Are there special instructions for large or obese patients?

In order to be effective in removing germs, is important that CHG cloths are applied with a firm massage on all skin areas (gently massaged onto wounds). This is particularly important in skin folds of large or obese patients since dirt, sweat, and germs can accumulate there. Make sure that after the CHG cloth is applied, the skin fold areas are allowed to fully dry. Lift skin folds to clean by firmly massaging the entire skin with the CHG cloth. Sometimes placing rolled towels to prop open skin folds may help with the application or drying process. Use as many CHG cloths as necessary.

### What are the most commonly missed bathing practices that we can enforce with our staff?

- **1.** Cleaning lines, drains, and tubes closest to the body as well as cleaning over non-absorbable dressings
- 2. Ensure cloths are applied to skin with firm massage
- **3.** Using the CHG wipes on superficial wounds/stage 1 & 2 decubitus ulcers

#### Should gloves be worn or changed during bathing with CHG cloths?

Yes. Although it is safe to handle the CHG cloths with bare skin, gloves should be worn for bathing patients. If gloves become soiled, they should be changed.

#### How should we dispose of the CHG cloths?

Used CHG cloths should be disposed of in the trash. The CHG cloths will clog the pipes. Do not flush. Instruct patients not to place the wipes in the commode or toilet.

### If my patient was already bathed prior to their arrival in my unit, do they need to bathe again?

Yes. Regardless if your patient has bathed with CHG in another unit or at home for pre-operative bathing, your patient will start bathing with CHG upon arrival in your unit, and will do so every day for their entire unit stay.

# For documentation, if a transferring patient recently bathed with CHG prior to transfer do I answer "Yes" to the nursing prompt about CHG bathing and does it count toward the unit CHG bathing that day?

No. Regardless of what a patient recently experienced (for example, even if they report having a CHG pre-operative bath or shower at home or on the transferring ward), please answer the nursing prompt based upon whether the CHG bath was provided in the unit itself. Only CHG baths received in the unit will count toward CHG bathing.

### Should the study protocol continue to be applied to unit patients who are temporarily transferred out for radiologic or surgical procedures?

Yes. The study protocol should continue for patients being transferred for procedures or surgery. A daily CHG bath can be applied during the time when the patient is physically in the unit. In the event the patient is incontinent, the standard clean up available will be used in off-unit locations. Upon returning to the unit, use the study protocol for incontinence cleanup, which includes reapplication of CHG.

#### Will long-term use of CHG cloths cause bacteria to become resistant?

This is always a possibility and the reason why we are collecting bacterial isolates from your microbiology laboratory to assess resistance to CHG over the course of the trial. Thus far, despite wide use, CHG resistance has rarely been reported in the U.S.

### I think my patient may be having a reaction to the CHG cloths or CHG liquid soap. What should I do?

Please contact the patient's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Please report the possible event to your Nurse Manager or Director who will provide bimonthly reports to the ABATE Infection Project for tracking purposes.

Nurse Manager or Director: On the 15<sup>th</sup> and 30<sup>th</sup> of each month, fax the completed Study Related Event form to Rebecca Kaganov at have any events to report. Do not send patient identifiers.





## Frequently Asked Questions: Nasal Mupirocin Ointment

#### Who should be decolonized with nasal mupirocin ointment?

Your unit will be decolonizing all patients ≥12 years old known to be MRSA+ by history, screening tests, or clinical culture. These patients will receive nasal mupirocin twice daily for 5 days or until transfer or discharge, whichever comes first. These patients will also receive a CHG bath or shower everyday while hospitalized in participating units.

#### What will be the order process for mupirocin?

Your facility will incorporate the "ABATE Study Protocol" order set in the pharmacy ordering system (Refer to the order set template in the "Technical Documents" section of your Toolkit binder). The nurse or physician should order the protocol when the MRSA MEDITECH NPR report or HCA MDRO Tracker indicate a positive screening test, or clinical culture, or within the last 365 days. In addition, order the protocol if the facility has other knowledge of prior history of MRSA based upon a positive screening test, or clinical culture, or within the last 365 days. You must also place mupirocin orders for patients who tell you they have a history of MRSA or are on contact precautions for MRSA once admitted to the floor.

#### Which form of mupirocin is acceptable for decolonization?

Our trial protocol specifies the use of generic mupirocin. However, the trial is approved for use of either generic mupirocin or Bactroban Nasal<sup>®</sup>. Thus, if Bactroban Nasal<sup>®</sup> is inadvertently used, that is still acceptable to the trial although generic is preferred.

# If an MRSA-positive patient is transferred or discharged from the unit and returns, does the mupirocin 5-day regimen pick up where they left off or start over at day 1?

The protocol begins anew for each readmission, regardless of the time since transfer or discharge or regardless of prior receipt of CHG or mupirocin. This also applies if the patient goes to the ICU and returns to a participating unit.

### If a patient is transferred from an adult ICU performing decolonization and has fully or partially completed mupirocin, does the mupirocin start again?

Yes. If the patient has already received a partial or complete 5-day course of mupirocin in the ICU, they will still receive a new order for a 5-day course when the patient arrives on your floor. The ABATE protocol is unit-specific and we do not expect you to keep track of what was previously received in another unit or during a prior hospitalization.

# What if the patient transfers from one non-ICU ward to another ward and both wards are participating in ABATE. Does mupirocin continue or start over for 5 days?

Yes. If the patient has already received a partial or complete 5-day course of mupirocin in the ICU, they will still receive a new order for a 5-day course when the patient arrives on your floor. All protocols are unit specific. We do not expect you to keep track of what was previously received in another unit or during a prior hospitalization.

#### What if the patient misses any doses of mupirocin?

If the patient misses one dose of mupirocin and it is **greater than 6 hours** until the next dose, give the missed dose and restart mupirocin on same schedule until all 10 doses are administered. If the patient misses one dose and it is **less than 6 hours** until the next dose, then skip the dose and re-start mupirocin on same schedule until all 10 doses are administered. Doses that are taken before the missed dose will count toward the total of 10 doses to be received. Do not double up doses. Always restart with single dose. If more than 2 doses of mupirocin are missed, the patient will need to restart the 5 days of therapy. A new order will need to be sent to pharmacy.

#### What if the patient has been prescribed other nasal medications?

Some nasal products may inactivate mupirocin and prevent it from working against MRSA. If the patient's doctor has prescribed or recommended other nasal medicines, the patient should continue to use them as prescribed. If possible, separate those medications from nasal mupirocin by several hours.

#### Does mupirocin ointment have any side effects?

The most common complaint is that the mupirocin ointment feels thick or goopy once applied inside the nose. This can be alleviated by having the patient blow their nose, if possible, prior to application. It can also be alleviated by gently massaging the nostrils for approximately 60 seconds to distribute the ointment. Other side effects that may involve burning, stinging, pain or itching are rare.

## How important it is to massage the patient's nose for 60 seconds after applying the nasal mupirocin ointment?

Massaging the patient's nose will ensure that the nasal mupirocin ointment is spread throughout the nostrils to get rid of bacteria. Massaging can also make the patient feel more comfortable because the ointment is thick. Sixty seconds may feel like a long time, so you also encourage the patient to perform the massaging themselves if they are able.

### Are participating units supposed to continue MRSA screening upon admission?

This trial does not affect your hospital's current screening protocol. Continue to conduct MRSA screening for high risk patients.

### How does the ABATE Infection Project affect the contact precaution policy for MRSA+ patients?

The trial does not affect application of contact precautions. If a patient is known to be MRSA+ or has another indication for contact precautions, then those precautions should be applied.

### I think my patient may be having a reaction to the nasal mupirocin ointment. What should I do?

Please contact the patient's treating physician for all clinical decisions on whether to stop the product or provide any medication to address a possible reaction. Please report the possible event to your Nurse Manager or Director who will provide bimonthly reports to the ABATE Infection Project for tracking purposes.

Nurse Manager or Director: On the 15<sup>th</sup> and 30<sup>th</sup> of each month, fax the completed Study Related Event form to Rebecca Kaganov at if you have any events to report. Do not include any patient identifiers on the form.





### Frequently Asked Questions: Wound Care

# The majority of our nurses feel comfortable using chlorhexidine (CHG) cloths on superficial wounds, but some do not. How would you suggest easing their concerns?

CHG cloths are safe to use on superficial wounds and stage 1 & 2 decubitus ulcers. There are several ways in which concerns may be alleviated: 1) Use the buddy system; 2) Contact your local wound care advisor. If your wound care nurse or nurse educator does not feel comfortable educating on CHG, ask the ABATE study staff to provide contacts for wound care educators or corporate care educators who can help. 3) Request a dedicated conference call, webinar, or site visit from the study team. We can arrange for HCA wound care nurses to be on the call to provide instruction and reassurance. These three suggestions will provide additional information and a hands-on approach to bathing with CHG cloths.

#### Should I be concerned about CHG having a stinging effect on wounds?

Antiseptic over-the-counter products often contain alcohol and will sting when applied to wounds. In contrast, CHG cloths do not contain alcohol and should not sting. In fact, CHG cloths contain dimethicone and aloe vera which are moisturizers and actually have a soothing effect on the superficial wound area.

#### Will CHG be absorbed if I put it on a wound?

There is minimal to no systemic absorption when using CHG on a superficial wound. In addition, the CHG may be particularly important to get rid of bacteria in an open wound and prevent infection.

#### For what types of wounds is CHG safe?

CHG can be gently applied to any superficial wound, including stage 1 and 2 decubitus ulcers, friable skin/rash, and superficial burns. We recommend not using CHG on large or deep open wounds.

#### Can I use CHG cloths over a closed surgical incision?

Yes. CHG is beneficial and should be applied over a closed surgical incision to remove bacteria and reduce the risk of infection.

#### What if my patient has a wound vac?

CHG should be applied over any semi-permeable or occlusive dressing. This includes wound dressings that meet that criteria, as well as wound vacs. CHG can also be applied over sutured or stapled wounds. If the dressing is permeable (for example, gauze), then use CHG up to the dressing.

#### How firmly should I apply CHG cloths to a wound?

It depends on whether the wound is over a bony prominence or not. If the wound is well healed and is not over a bony prominence, then CHG should be applied with a firm massage to ensure adequate contact and anti-bacterial activity. However, if the wound is in the location of a bony prominence, a *gentle massaging motion* should be used to avoid causing additional soft tissue damage or extension of the wound due to pressure against the bone. Similarly, if the wound is tender, a *gentle massaging motion* is recommended.

### I am having trouble with applying bandages after bathing my patients with CHG. Does CHG weaken bandage adhesive?

If you are having trouble applying a bandage after bathing a patient with CHG, it's usually because not enough time has elapsed to allow for complete drying. After bathing a patient, allow the CHG to completely dry for about 5 minutes. This should provide ample time for the CHG to absorb and not affect the bandage adhesive. If you cannot wait the full 5 minutes and if the patient's skin still feels tacky, it may prevent the bandage from sticking properly.







#### **Decolonization – Arm 2**

#### DO

- Use chlorhexidine (CHG) daily for all bathing/showers needs for all patients,
   for entire unit stay
- Use 2% (CHG) cloth for daily bed bathing or 4% liquid CHG for daily showers
- Massage CHG onto skin for best effect
- Use CHG on lines, tubes, drains, and over non-gauze dressings. Use on superficial wounds and rashes to remove germs
- For MRSA+ patients, use nasal mupirocin twice a day for 5 days of unit stay
- Restart for patients who are readmitted or transferred into your unit
- Report mupirocin/CHG related events to treating physician and unit nursing director

#### **DON'T**

- Do NOT get CHG into eyes or ears
- Do NOT wipe off after applying CHG cloths. Let air dry
- Do NOT flush CHG cloths in the commode
- Do NOT continue protocol after unit discharge
- Do NOT use protocol on patients <12 years old
- Do NOT use mupirocin and/or CHG on patient if patient is allergic

REFER TO NURSING PROTOCOL FOR STEP-BY-STEP INSTRUCTIONS

**General Questions** 

**Study Related Events** 



## Patient Talking Points: Chlorhexidine (CHG) Bathing

Patients may have questions regarding CHG bathing and nasal mupirocin. Below are some suggested responses to common patient questions. REMEMBER: Your **enthusiasm** and **encouragement** will be the greatest predictor of a patient's acceptance and their support for the protocol.

#### What is the purpose of this bath?

"This is your protective bath while you are staying in this unit. All patients on our unit are receiving this bath. This type of bathing is deeply cleaning and works better than soap and water to remove germs and protect you from infection. It has been used on hundreds of thousands of patients in many hospitals across the country to clean the skin and protect patients from germs."

### I don't feel as clean after bathing with the cloths and my skin feels sticky.

"This bath works better than soap and water to remove germs from the skin. It is deeply cleansing and will protect you more than soap and water. The sticky feeling is due to the aloe moisturizing ingredient in the cloths and will go away once dry."

#### Can I use my own soap and/or lotions along with this bath?

"No, other soaps and lotions may prevent this bath from working and may not protect you because they interfere with the germ fighting ingredient in the soap. This bath works better than soap and water to protect you, so it is important that you only use the soap we give you during your stay."

#### I would prefer to use my own shampoo and face soap. Is this okay?

"Other soaps and shampoos may interfere with the CHG soap which works the best to remove germs from your body. We strongly encourage you to use the CHG while you are here. However, if you must use you your own shampoo or face soap, please use them first and try to keep the shampoo and face wash off of the body so CHG will work as body soap.

#### I am too tired and I don't feel like bathing.

"I understand you must be tired, but this bath is important to protect you from bacteria and germs. It will only take 5 to 10 minutes and will make you feel refreshed. I will help you. If you are too tired right now, I can come back later and check in with you."

#### I don't think I can bathe because I have an IV.

"Don't worry, we do this all the time. In fact, because you have lines, it's even more important to keep germs off the skin and prevent infection. We actually clean the lines after we clean your skin. I will help you with areas around the lines and any other hard to reach areas."

#### I would prefer to perform my own bed bath.

"If you wish to bathe yourself, let me give you important instructions and a handout ("CHG Bathing for Patients"). Remember to read the instructions carefully, as the bath may not protect you if it is not done correctly. The CHG cloths have a special no-rinse soap that works better than soap and water to remove germs that can cause infection. Massage the skin well with the cloths to remove skin germs. Don't rinse since the CHG continues to work for 24 hours to keep germs away. Don't forget to clean all skin areas, including the neck and skin folds. Most patients need some help. I can help you with any hard to reach areas as well as help you clean on and around your lines or drains."

#### Can I wait to bathe tomorrow? I just arrived on the floor today.

"Your first day in the unit may be the most important day to take a bath and protect you from germs before any surgeries, procedures, or lines placed while in the hospital. Bathing takes only 5-10 minutes and will make you feel refreshed and clean."

#### Can I use the soap on wounds or skin rashes?

"Yes. In fact, cleaning skin wounds and rashes is particularly important since germs can get under the skin when there is a skin break. You should also use the cloth over plastic dressings and clean 6 inches of any line, tube, or drain closest to your body. I will help with that part of your bath."

### I already received a 5 day course of nasal mupirocin ointment in another unit. Why do I have to start the course again?

"Our unit practice is that we will restart the nasal ointment to protect you for your entire hospital stay."





## Patient Talking Points: Nasal Mupirocin

Patients may have questions regarding CHG bathing and nasal mupirocin. Below are some suggested responses to common patient questions. REMEMBER: Your **enthusiasm** and **encouragement** will be the greatest predictor of a patient's acceptance and their support for the protocol.

#### What is the purpose of the nose ointment?

"Germs in the nose often get onto the skin and other body areas and can produce infection. This nose ointment will remove germs from your nose to protect you during your hospital stay."

### I already received a 5 day course of nasal mupirocin ointment in another unit. Why do I have to start the course again?

"Our unit practice is that we will restart the nasal ointment to protect you for your entire hospital stay. Germs in the nose can often come back and we want to ensure that you are protected from infection while you are here in this unit."

#### The ointment feels really goopy in my nose.

"I know the ointment can feel a little uncomfortable, but it's really important to clear the germs from your nose. If you continue to massage your nostrils as I have just done, this will help spread the nasal ointment around so it doesn't feel so goopy. For your next dose, it often helps to blow your nose before the ointment is given to you. Let's try that next time. It should help."



# **Chlorhexidine (CHG) Bathing and Showering Instruction Handouts for Nursing Staff and Patients**

#### This section includes:

- Staff CHG Bathing Instructions Handout
  - English
  - Spanish
- ➤ Patient CHG Bathing Instructions Handout
  - English
  - Spanish
- ➤ Patient CHG Showering Instructions Handout
  - English
  - Spanish
- Sample CHG Shower Cling



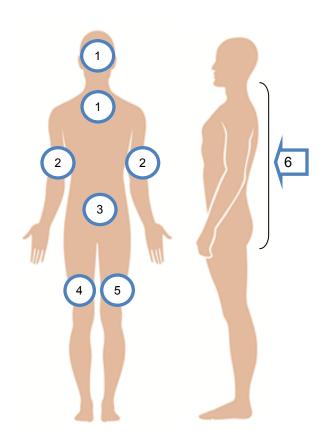
### Prevent infections during the hospital stay

### **BATHE** daily with Chlorhexidine (CHG) soap



While in the hospital, bathe patients every day with a special antiseptic soap (CHG) to help remove germs and prevent infection.

6 cloths should be applied as below:



**Caution: Avoid eyes and ear canals.** 

#### **Encourage CHG shower or bath**

#### **Reminders**

- Your enthusiasm is the greatest predictor of patients wanting to use CHG
- Encourage bathing every day. Starting on admission is ideal, before IVs, lines, urinary catheters, and procedures/surgery.
- Patients need direction on how to apply correctly and thoroughly
- Help clean 6 inches of lines, drains, tubes
- CHG is better than soap and water in removing germs and works for 24 hours
- CHG is safe to use on surface wounds, rashes and burns and removes germs
- Allow to air dry for best effect

#### Clean all skin areas with special attention to:

- Neck
- All skin folds
- Skin around all devices (line/tube/drain)
- Wounds unless deep or large
- Armpit, groin, between fingers/toes

#### Protect your patients every day

#### **SHOWERING with CHG soap**

- 1. Rinse body with warm water
- 2. Wash hair and face with CHG
- 3. Turn off the water and lather washcloth with plenty of CHG soap
- 4. Lather and massage soap in all 6 areas
- 5. Leave soap for 2 minutes before rinsing

#### **BATHING with CHG cloths**

- 1. Patients need instruction that these cloths are their protective bath
- 2. Use all 6 cloths. More, if needed.
- 3. **Firmly massage** to clean skin. CHG will kill germs for 24 hours if applied well.
- 4. Clean over semi-permeable dressings
- 5. Clean 6 inches of lines, tubes and drains
- 6. Use only compatible lotions.
- 7. Dispose of CHG cloths in a regular trash bin. Do not flush in commode.





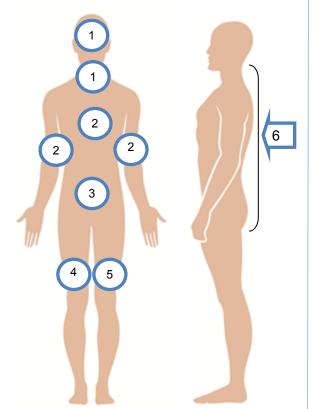
#### Prevent infections during your hospital stay

### **BATHE** daily with Chlorhexidine (CHG) cloths



During your stay, we will bathe you every day with a special antiseptic (CHG) which removes germs and prevents infection better than soap and water.

Each packet has 6 cloths to be used on all skin areas as shown below:



Avoid eyes and ear canals

#### Take a CHG Bed Bath

#### **BATHING with CHG cloths**

- Use CHG every day. Starting on the admission day works best to remove germs before IVs, lines, urinary catheters, and procedures/surgery
- These no-rinse cloths are your protective bath. The CHG continues to get rid of germs for 24 hours
- 3. Use all 6 cloths. More, if needed
- 4. **Firmly massage** on all skin areas to ensure deep cleaning of skin
- 5. Clean over non-gauze dressings
- 6. Your nurse will clean parts of lines, tubes and drains nearest the body
- 7. Throw away in trash. **Do not flush.**





#### Protect yourself every day

#### **Important Points and Reminders**

- CHG is proven to work better than soap and water to get rid of germs
- CHG cloths have aloe and are good for your skin. CHG is less drying than soap.
- Do not rinse. Once massaged onto skin,
   CHG works to kill germs for 24 hours
- Be thorough. Ask for help for hard to reach areas, backside, around devices.
- CHG is safe on rashes and wounds that are not very large or deep
- Clean lines, drains, tubes 6 inches from the body. Ask for help, if needed.

#### Clean all skin areas with attention to:

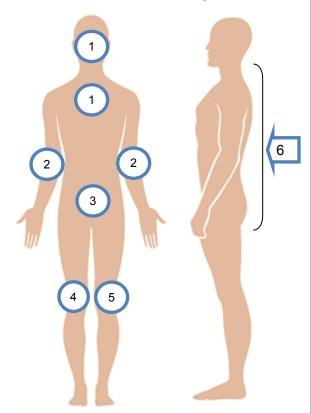
- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds and open skin
- Armpits, groin, between fingers/toes

### Prevent infections during your hospital stay

### **SHOWER** daily with Chlorhexidine (CHG) soap



During your stay, shower every day with a special antiseptic soap (CHG) which removes germs and prevents infection better than soap and water



### Avoid eyes and ear canals

\* Regular soap and shampoo prevent CHG from working well. If you must use your own shampoo or face wash, use them first and try to keep the shampoo and face wash off the body so CHG will work as body soap.

#### Take a CHG Shower

### **SHOWERING with CHG soap**

- You will be given a 4 oz CHG bottle to wash your hair, face, and body each day
- 2. Begin with hair and face, rinse
- 3. Apply generous amount of CHG to mesh sponge and rub until foamy
- 4. Use the mesh sponge. It helps CHG lather well
- Apply CHG with water off or stand out of water stream
- Firmly massage onto skin. Clean from top down (cleanest to dirtiest areas). Reapply CHG to keep sponge foamy
- 7. Ask for help for hard-to-reach areas
- For best effect, leave soapy lather on skin for 2 minutes. Rinse body well.
   Rinse mesh sponge and hang to dry.
- 9. If needed, ask your nurse for CHG-compatible lotions to moisturize

### **Protect Yourself Every Day**

### **Reminders**

- CHG is proven to work better than regular soap to get rid of germs
- Once massaged onto skin, CHG works to kill germs for 24 hours
- Use CHG every day. Starting on the admission day works best to remove germs before IVs, lines, urinary catheters, and procedures or surgery
- Be thorough. Ask for help to reach hard
   -to-reach areas, including backside,
   around devices, on wounds
- CHG is safe on rashes, burns, and wounds that are not large or deep

### Clean all skin areas with attention to:

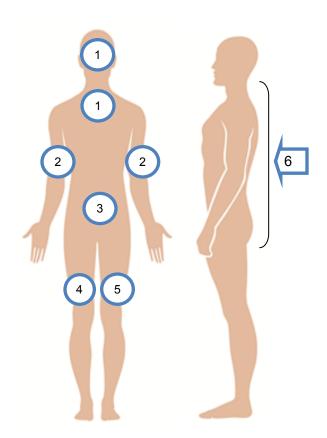
- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds and open skin
- Armpit, groin, between fingers/toes

## Evite las infecciones durante la hospitalización Bañar diariamente con el jabón CHG

### El Personal

Durante la hospitalización, bañe a los pacientes diariamente con el jabón antiséptico especial (CHG) para ayudar a eliminar los microbios y prevenir la infección.

Use 6 panós en las áreas indicadas.



Precaución: Evite ojos y canales auditivos.

#### Animar el baño o ducha con CHG

#### Recuerde

- Su entusiasmo resultara en un mejor uso de CHG en los pacientes
- Anímelos que se bañen diariamente. Es ideal usarlo al ser ingresados, antes de introducir línea intravenoso, sondas, catéteres urinarios y antes de las cirugías o procedimientos.
- Los pacientes necesitan instrucciones sobre como aplicar correctamente y a fondo.
- Ayúdeles limpiar hasta 6 pulgadas de líneas, tubos y drenajes que están cerca del cuerpo.
- El CHG es más efectivo que el agua y jabón para eliminar microbios y protege por 24 horas.
- El CHG es seguro para uso en heridas superficiales, erupciones y quemaduras y elimina los microbios.
- Para un mejor efecto, deje secar al air.

### Limpie toda la piel del cuerpo, especialmente:

- El cuello
- Todos los pliegues cutáneos
- La piel alrededor de los aparatos (líneas/ tubos/drenajes)
- Las heridas, amenos que sean grandes o profundas
- Las axilas, la ingle y entre todos los dedos

### Proteja a sus pacientes diariamente

### **BAÑO EN REGADERA con el jabón CHG**

- 1. Enjuague el cuerpo con agua tibia
- 2. Lave el pelo con champú o CHG
- 3. Cierre el agua y empape el paño con CHG
- 4. Enjabone y masajee en todas las 6 áreas
- 5. Deje que el jabón permanezca por 2 minutes antes de enjuagar

### **BAÑO** con los paños CHG

- Los pacientes necesitan saber que estos paños son su baño protector.
- 2. Use los 6 paños, más si es necesario.
- 3. **Masajee con firmeza** para limpiar la piel. Si se aplica bien, el CHG eliminará los microbios por 24 horas.
- 4. Limpie sobre los vendajes semipermeables.
- 5. Limpie 6 pulgadas de líneas, tubos y drenajes.
- 6. Sólo use la crema compatible.
- 7. Tire los paños CHG en un bote de basura y no en el inodoro.

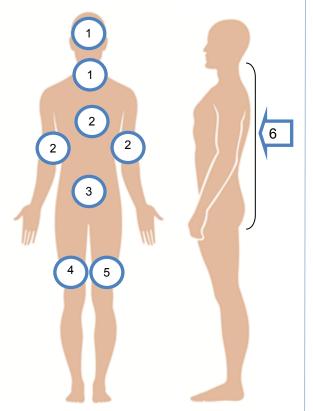




### **EI PACIENTE**

Durante su estancia, le vamos a bañar todos los días con un antiséptico especial (CHG), que elimina microbios y previene la infección mejor que el agua y jabón.

Cada paquete tiene 6 panós para ser usados en todas las aéreas de la piel como se indica a continuación:



Evitar en los ojos y los canales auditivos

### Tomar un baño de CHG

### El BAÑO con paños CHG:

- Use CHG diariamente, empezándolo el día de su ingreso. Funcionara mejor para eliminar microbios antes de las cirugías/ procedimientos, intravenosos, líneas, y catéteres urinarios.
- Estos paños de no enjuague son su baño protector. CHG continúa eliminando microbios por 24 horas.
- 3. Use todos los 6 paños. Más si lo necesita.
- Masajee firmemente sobre todas las áreas para asegurar que la piel este bien limpia.
- 5. Limpie sobre los vendajes sin gasa.
- Su enfermera limpiara las partes de las líneas, tubos y drenajes más cercano al cuerpo.
- 7. Tirelos en un bote de la basura. **No** echarlos en el inodoro.





### Protéjase diariamente

### Puntos importantes y avisos

- CHG está demostrado funcionar mejor que el jabón para deshacerse de microbios.
- Los paños CHG tienen sábila y son buenos para su piel. CHG reseca la piel menos que el jabón.
- No lo enjuague. Ya que sea masajeado sobre la piel, CHG trabaja para eliminar microbios por 24 horas.
- Sea cuidadoso. Pida ayuda para llegar a las zonas de difícil alcance la parte trasera y alrededor de los aparatos.
- CHG es seguro de usar en las ronchas y heridas que no son muy grandes o profundas .
- Limpie las líneas, drenajes, y tubos que están
   6 pulgadas cerca del cuerpo. Pida ayuda si lo necesita.

### <u>Limpie toda la piel del cuerpo, especialmente:</u>

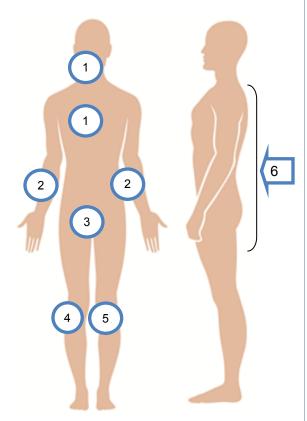
- El Cuello
- Todos los pliegues cutáneos
- La piel alrededor de los aparatos (tubos/ drenajes)
- Las heridas y la piel rota.
- Las axilas, la ingle y entre todos los dedos

### Evite las infecciones durante su hospitalización

### **DUCHAR** diariamente con el jabón Chlorhexidine (CHG)



Durante su estancia, ducharse todos los días con un jabón antiséptico especial (CHG), que elimina microbios y previene la infección mejor que el agua y jabón.



### Evitar en los ojos y canales auditivos

\*El uso de jabón y champú previene que el CHG funcione bien. Si tiene que usar su propio champú o lavado de cara, úselos primero y trate que no toquen el cuerpo para que el CHG funcione como el jabón para cuerpo.

#### Tomar una ducha con CHG

#### **DUCHARSE** con jabón CHG

- 1. Se le dará una botella de 4 oz de CHG para lavarse el pelo, la cara y el cuerpo cada día.
- 2. Empiece con el pelo y la cara, luego enjuáguelos.
- Aplique generosa cantidad de CHG a la esponja de malla y frote hasta que de espuma.
- 4. Use la esponja de malla, le ayudara al CHG formar bien espuma.
- 5. Aplique el CHG con el agua apagado o permanezca fuera de la corriente de agua.
- 6. Masajee firmemente sobre la piel. Limpie de arriba hacia abajo, (de aéreas más limpias a más sucias). Vuelva a aplicar CHG para mantener la esponja espumosa.
- 7. Pida ayuda para las aéreas fuera de su alcance.
- 8. Para un mejor efecto, deje espuma jabonosa en la piel durante 2 minutos. Enjuague la esponja de malla y colgar para secar.
- 9. Si es necesario para hidratar su piel, pida a su enfermera loción compatible con CHG.

### Protéjase diariamente

#### **Avisos**

- CHG está demostrado funcionar mejor que el jabón para deshacerse de microbios .
- Ya que sea masajeado sobre la piel, CHG trabaja para matar microbios por 24 horas.
- Para trabajar mejor, use CHG diario a partir del día de ser ingresado para quitar microbios antes de que le pongan intravenoso, líneas, catéteres urinarios, y antes de procedimientos o cirugías.
- Sea cuidadoso. Pida ayuda para llegar a las zonas de difícil alcance, incluyendo la parte trasera, alrededor de los aparatos, y en las heridas.
- CHG es seguro en las erupciones, quemaduras y heridas que no son grandes o profundas.

### Limpie toda la piel del cuerpo especialmente:

- El Cuello
- Todos los pliegues cutáneos
- La piel alrededor de los aparatos (tubos/ drenajes)
- Las Heridas y la piel rota
- Las axilas, la ingle y entre todos los dedos

### **Shower Instructions**



For your health, we are pleased to provide you with a special liquid soap, chlorhexidine, which has been proven to work better than regular soap and water in removing germs from your skin and keeping you clean.

- 1. Use the bottle of liquid **chlorhexidine (CHG)** for all areas of the body. Begin by washing hair using CHG as shampoo. Rinse well.
- 2. Next, clean face with CHG, but take care to avoid getting soap into eyes and ears. Rinse.
- 3. Apply generous amount of CHG to mesh sponge and rub until foamy
  - Wet skin with water
  - Turn water off or stand out of water stream
  - **FIRMLY MASSAGE** soapy sponge onto all skin. Reapply CHG generously to the sponge to keep sponge with plenty of foamy lather. Be sure to clean from top down (cleanest to dirtiest areas).
    - ✓ Neck and chest
    - ✓ Both shoulders, arms and hands
    - ✓ Abdomen, hip and groin
    - ✓ Both legs and feet
    - ✓ Back of neck, genitals and buttocks last
  - For best results, leave soapy lather on skin for 2 minutes
- 4. Don't forget to clean your neck, armpits, and skin folds well, including under the breast. Clean between fingers and toes too.
- 5. Rinse body well. Also rinse mesh sponge and hang to dry.
- 6. Dry with clean towel
- 7. If needed, ask your nurse for CHG-compatible lotion to moisturize

CHG continues to work for 24 hours to keep germs off your body. We recommend you use it to wash daily while in the hospital. If you must use your own shampoo and face products, please use them before the CHG soap. Please try to keep them off the body as regular soap and shampoo prevents CHG from working as well.



### **Active Bathing to Eliminate Infection Project**

# Nursing Protocol Training Decolonization ARM 2



## **ABATE Infection Project: Introduction**

Your hospital has agreed to participate in the ABATE Infection Project, which is a federally funded collaboration between HCA, the University of California Irvine, Harvard Pilgrim Health Care/Harvard Medical School, Rush University, Stroger Hospital of Cook County, and the Centers for Disease Control and Prevention (CDC).

- From this training you will learn:
  - Which study arm your unit belongs to
  - How to implement decolonization with chlorhexidine (CHG)
  - ✓ How to selectively implement mupirocin for MRSA carriers
  - How to address special circumstances related to decolonization
  - How to contact study staff for additional information
- This training module will take approximately 20 minutes to complete.
- We highly recommend the audio accompaniment.

## What is the ABATE Infection Project?

This trial compares 2 strategies (arms) to see if one is better able to prevent multi-drug resistant organisms and hospital-associated infections in non-ICU units. This trial will last approximately 21 months:

### Arm 1: Routine Care

On unit admission, all patients will receive routine bathing per current established protocols

### Arm 2: Decolonization

On unit admission, all patients will be bathed daily with chlorhexidine during their entire unit stay. Patients known to have MRSA will also receive mupirocin nasal ointment.

53 HCA hospitals (194 units) are participating in this trial.

Your facility has been randomized to Arm 2: **Decolonization** 

## **Is Patient Consent Required?**

### No. Patient consent is not required.

This protocol has been IRB (Institutional Review Board) approved by your institution and HCA corporate, in compliance with the Code of Federal Regulations (45 CFR part 46), to be implemented as a cluster randomized study of **two routine Quality Improvement strategies that are already in use in the US today.** This improvement strategy has met all criteria for waiver of patient consent.

Similar to other Quality Improvement projects, the entire unit will adopt the assigned strategy as usual care for all patients in the unit. All patients will receive the strategy unless they explicitly refuse.

## How do I Perform Decolonization?

- Use Chlorhexidine (CHG) for all daily bathing or shower needs for ALL patients, every day, for entire unit stay.
- For MRSA+ patients, use nasal mupirocin ointment twice a day for 5 days of unit stay.
- For patients <12 years old, the decolonization protocol does not apply.</li>

Decolonization stops when discharged or transferred out of the unit. If readmitted or transferred to the unit, protocol begins anew regardless of prior receipt of CHG or mupirocin.

### **Chlorhexidine for Bath or Shower**

Patients may be cleansed with chlorhexidine (CHG) in one of two ways

- Bed bath with 2% no-rinse CHG disposable cloths
- Shower with 4% CHG liquid soap with mesh sponge applicator

CHG is the primary bathing/cleansing agent. It should **NOT** be used as a supplemental topical agent after other types of bathing.

CHG replaces usual soap and water. **Soap will inactivate CHG**, so only CHG should be used.

If applied correctly, CHG works better than soap and water to remove bacteria. In order for CHG to protect your patient, it should be firmly massaged into the skin. Once applied, it will continue to work to keep germs off the skin for 24 hours.

For maximum protection, **begin bathing on admission**, and if possible, before lines/catheters, procedures and other medical care activities

## **CHG Talking Points**

- Patients need <u>encouragement</u> for their daily bath
- Your <u>enthusiasm is critical</u> to protect patients by bathing
- Talking points:
  - > CHG reduces germs on your skin better than soap and water
  - > CHG serves as your protective bath to prevent infection
  - > The bath will only take about 10 minutes
  - If you wish to bathe yourself, let me give you directions on how to use the soap in the right way to get rid of bacteria and protect you from infection. Let me help with hard-to-reach areas.
- If your patient declines a bath, try again later in the day

## CHG Cloth Bathing Instructions

- Replace regular bed bath routine with CHG cloths
- Use CHG cloths for all daily bathing needs
- Bathe with CHG cloths for entire unit stay, no matter how long
- CHG cloths come in a 3-pack (2 cloths per packet) = 6 cloths
- Obtain cloths from warmer (takes 2 hours to warm).
- Cloths are hard to open from the ends. Open pack at notch located on the back.









## CHG Bathing Cloth Warming Instructions

- 1. Warming is for comfort only. CHG is already active regardless of temperature.
- 2. Place unopened CHG packages in warmer
- Warmer lights change: "not ready" to "ready"
- 4. Cloths require 2 hours to warm
- 5. If warmer lights show "dispose" (after 84h), remove product and discard
- 6. After removing, replace with a new package





Caution: check temperature of cloth prior to use. Gloves diminish sense of heat.

# Warming Extra CHG Bathing Cloths

- Sometimes extra CHG bathing cloths are needed
- Common reasons include reapplication of CHG after incontinence clean up, freshening up, and large body size
- CHG baths come in a 3-pack (2 cloths per packet)
- These packs can be separated and each packet placed into an individual slot
- Same warming instructions apply for separated packets
- Packets in a single slot should be used together to ensure that the timer for warming and discarding remains correct for all packets in a slot

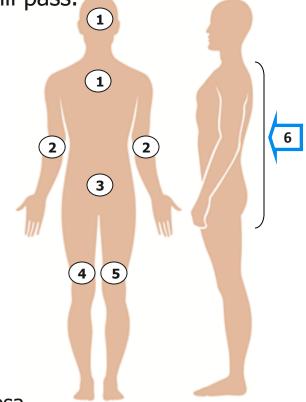
## **Bathing Procedure**

Using CHG bathing cloths, **firmly massage** the body to remove bacteria.

Skin may feel sticky for a few minutes, but this will pass.

Use the **6 CHG cloths** in the following order:

- 1. Face, neck & chest. **Avoid eyes and ears.**
- 2. Both shoulders, arms and hands
- 3. Abdomen & *then* groin/perineum
- 4. Right leg & foot
- 5. Left leg & foot
- 6. Back of neck, back & **then** buttocks
- For each cloth, clean 6 inches of all tubes, drains, lines closest to the body.
- If you need more than 6 CHG cloths,
   use as many cloths as needed
- CHG is safe to use on perineum and external mucosa
- If breastfeeding wipe CHG off nipple area with water before feeding



## Can a Patient Self-Bathe with CHG cloths?

- Self-bathing patients still need instructions and encouragement
- To save time, give handout to patients an hour or two before bathing
- At the time of the bath, go over the 1-page CHG cloth bathing handout

### Be sure to mention:

- ✓ How to open the cloths using the tear notch on the back
- ✓ The cloths serve as their protective bath
- ✓ CHG is safe, over-the-counter, and better than soap
- ✓ The bath is no-rinse, allowing CHG to kill germs for 24 hours.
- ✓ Massage (rather than wipe) into all areas of skin for effect.
- ✓ You will help them with hard to reach areas
- ✓ Pay special attention to the neck, skin folds
- Clean all lines, tubes, drains within 6 inches of the body
- ✓ Ok to clean on semi-permeable or occlusive dressings
- ✓ Safe on rashes, burns, wounds that are not deep or large

## **Bathing Clean Up**

Dispose of each washcloth in the trash

Do **NOT** flush washcloths in the toilet





## CHG Bathing Cloths Critical Points to Remember

### DO

- Use CHG cloths for daily bathing
- Firmly massage skin to cleanse
- Pay special attention to neck and tubes, drains, lines
- Safe on rashes, cuts, scrapes
- Safe on burns, superficial wounds
- If readmitted, protocol starts anew
- Only use CHG compatible lotions\*:

### **DON'T**

- Do NOT wipe off. Let air dry
- Do NOT save open packs for later use
- Do NOT flush
- Do NOT use on deep/large wounds
- Do NOT use on patients <12 years</p>
- Do NOT use on patient if allergic

<sup>\*</sup> Study staff will contact your unit to confirm product compatibility

## **CHG Showering Instructions**

- Patients who wish to shower should receive:
  - 1-page CHG showering instruction sheet to read 1-2 hours prior to showering
  - Verbal review of written patient instructions for CHG showering
  - 4 oz CHG liquid bottle
  - Mesh sponge to lather CHG onto body
  - Shower Cling will be posted in shower



### **Shower Instructions**



For your health, we are pleased to provide you with a special liquid soap, chlorhexidine, which has been proven to work better than regular soap and water in removing germs from your skin and keeping you clean.

- Use the bottle of liquid chlorhexidine (CHG) for all areas of the body. Begin by washing hair using CHG as shampoo. Rinse well.
- Next, clean face with CHG, but take care to avoid getting soap into eyes and ears. Rinse.
- 3. Apply generous amount of CHG to mesh sponge and rub until foamy
  - Wet skin with water

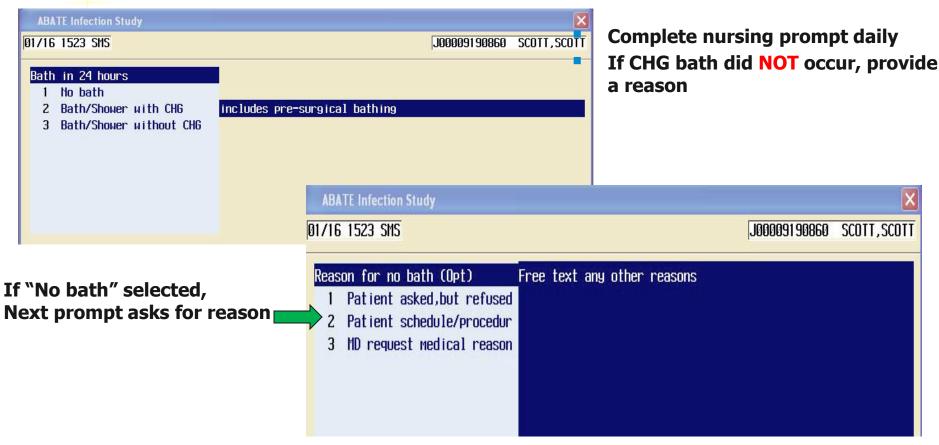
## **CHG Showering Instructions**

### Be sure to mention:

- CHG works better than soap and water to kill germs and keep them off the body for 24 hours if applied correctly
- Safe for shampoo and face/body wash. Avoid eyes/ears.
- Use the provided mesh sponge. CHG foams well with it, but not without.
- Apply to skin with water off or out of water stream
- For best results, keep body soapy for 2 minutes before rinsing
- Massage all over skin. Pay attention to neck and skin folds
- If patients insist on using personal shampoo or face wash, but are willing to use CHG for body wash, instruct them to avoid contact with other skin as much as possible since soaps and shampoos can inactivate CHG and prevent it from working. Try to encourage only use of CHG if at all possible.

## Daily Nurse Prompt for CHG Bathing Confirmation

### **Nursing Prompt #1**



**Nursing Prompt #2** 

## Nasal Mupirocin Ointment: For MRSA+ Patients Only

- Mupirocin is an antibiotic ointment which is active against MRSA
- It is topical and used in the front of the nose (nostrils).
- Your unit will be using mupirocin for:
  - ✓ Patients at least 12 years old
  - ✓ Patients who have a positive MRSA screening test
  - ✓ Patients with a MRSA+ clinical culture
  - ✓ Patients who tell you they have a history of MRSA
- Mupirocin is applied twice a day for 5 days while in the unit
- Protocol stops upon unit discharge
- If patients are readmitted to the unit, mupirocin protocol starts anew regardless of prior receipt of mupirocin
- If patients are transferred from the ICU and have received a partial or complete cycle of 5-day mupirocin, new **non-ICU** orders will be written and the previous ICU orders will be discontinued

# How to use Nasal Mupirocin Ointment

### For MRSA+ patients:

- Place patient's bed at 30 degrees, if tolerated
- Apply a blueberry-sized amount, or amount indicated per pharmacy, of ointment from tube directly into each nostril
- Press nostrils together and massage gently for 60 seconds
- Do this twice a day for 5 days
- Avoid contact with eyes and other intranasal products (contact study team if any questions)
- Patients may say that mupirocin feels goopy in the nose. If this happens, gently massage the nostrils for 60 seconds to distribute ointment. This can be prevented by having patients blow their nose before applying mupirocin.

## **Special Circumstances**

- Devices
- Incontinence
- Wounds
- Obese Patients

### **CHG Cloths and Devices**

- Remember to clean not only the skin surrounding the device, but the device itself to prevent infection. CHG is safe on devices
- In the example of central lines:
  - Ensure careful cleansing of skin around lines to remove bacteria
  - ✓ After cleaning skin, clean 6 inches of line closest to the body
  - ✓ OK to use over semi-permeable dressing
- The same instructions also apply to all other devices, such as drains, G-tubes, rectal tubes, chest tubes, EKG leads, urinary catheters:
  - ✓ If dressing removed for changing, clean the entire area well with CHG and allow to **fully dry** before replacing dressing. Avoid deep surgical wounds.
  - ✓ If dressing is in place, clean skin and over dressing. **After** skin is cleaned, use cloth to clean at least 6 inches of tubing closest to patient.

### **CHG Cloths and Incontinence**

Do NOT use soap to cleanse incontinent patients. Soap can inactivate CHG. If needed, use barrier products which are compatible with CHG\*

- Remove urine/stool with usual incontinence wipes/cloths and water. Do NOT use soap.
- Cleanse with CHG and allow to air dry (about a minute)
- Use as many CHG cloths as necessary
- Apply CHG compatible barrier protection over affected area, as needed
- If additional barrier protection is needed during day, OK to use additional CHG compatible barrier protection products
- If additional bathing is required throughout the day, clean with CHG cloths, then reapply CHG compatible barrier protection products, as needed

<sup>\*</sup>See CHG Compatibility Sheet in Unit Study Binder provided to nurse manager/director for list of CHG compatible products.

### **CHG and Wounds**

Use of CHG on wounds helps remove bacteria and prevent infection. CHG cloths or liquid CHG for showering can be used on all superficial wounds. These include:

- Superficial Decubitus Ulcers (Stage 1 & 2)
- Friable Skin/Rash
- Superficial Burns

Clean the wound carefully with CHG

CHG can be used over semi-permeable/occlusive dressings, including wound vacs.

CHG can be applied over sutured or stapled wounds.

CHG will not sting on wounds.

Do **NOT** use on large or deep wounds.

## **CHG Bathing of Obese Patients**

### **Obese Patients:**

- Nurses should use as many CHG cloths as necessary and throughout the day if additional bathing is required (incontinence, sweating, or other reasons)
- For patients who shower, nurses should provide additional 4 oz liquid CHG bottles upon patient request or as needed
- Remind patient to ensure neck and all skin folds are well-cleaned

## **ABATE Infection Project Exclusions**

- Patients <12 years old should be excluded from the decolonization protocol</li>
- If a patient is allergic or develops an allergy to either mupirocin or CHG, they can still participate in the project. Simply discontinue the agent in question.
- As with any medical care, the patient can refuse the protocol, but your enthusiasm can often help them understand the value of removing germs on their body to protect them from infection

## **Long Term Use of CHG**

CHG has been used to safely bathe hundreds of thousands of patients, including patients in ICUs and burn units, as well as before and after surgery.

Long term use of CHG does not cause deterioration of skin or other problematic skin conditions. It is safe to use for daily bathing in patients who require prolonged care and has been shown to be **better for the skin** than regular soap and water.

It is safe to use repeatedly in patients with multiple incontinent episodes in a day.

# Mupirocin Nasal Ointment and Nasal Devices

- Removable Nasal Devices:
   Briefly remove nasal prongs before applying mupirocin
- Nasal endotracheal tube/Nasogastric tubes:
   Apply mupirocin around tube
- Nasal Trauma:Do NOT use mupirocin if nostril(s) are packed

Remember, gently massage nostrils together for 60 seconds.

# Reporting Suspected CHG/Mupirocin Study Related Events

Mupirocin and CHG have minimal side effects.

For mupirocin, side effects may include brief itching and burning in the nose.

For CHG, side effects may include dry skin, rash in <1%.

As with any drug, both mild and severe allergies (rare) can occur.

### **Report suspected Mupirocin/CHG-related events**

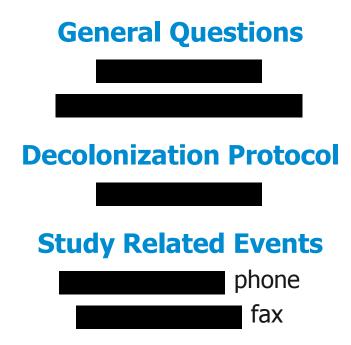
- If you suspect a reaction is due to a study product, contact the patient's treating physician for all medical assessment and treatment decisions
- Complete Study Related Event Submission Form found in the Toolkit Binder and submit to your Unit Nursing Director
- Nursing Director- Fax all completed forms to \_\_\_\_\_\_ on the 15<sup>th</sup> and 30<sup>th</sup> of each month. This is a secure fax.
- Once reported, the patient's nurse may receive a follow-up phone call by an ABATE study team member

## **Key Points**

### **Decolonization Protocol involves all unit patients:**

- Use CHG daily for entire unit stay for ALL patients
- Use nasal mupirocin ointment on MRSA+ patients ONLY
- Be encouraging and supportive. Patients will be more inclined to bathe with your enthusiasm.
- To save time, give your patient the 1 page bathing/showering handout a few hours before the bath/shower.
- Patients who self bathe still need verbal directions for CHG to be effective
- If readmitted to the unit, protocol begins again regardless of prior receipt of CHG or mupirocin
- The decolonization protocol ends when the patient leaves the unit

## **Questions?**



This is a landmark trial to identify the best strategies for reducing hospital-associated infections and multi-drug resistant organisms.

Thank you for your participation.



### **Arm 2: Just in Time Training**

The ABATE Infection Project compares 2 strategies to prevent hospital associated infections. This hospital is participating in **Arm 2**: **Decolonization for ALL unit patients.** 

### Nursing Intervention in MEDITECH

- 1. For all unit admissions, create a nursing intervention
  - In the NUR intervention dictionary, attach screen hcaABATE
  - Next, locate the Standards of Care diagnosis/problem and attach the intervention
  - Complete the daily nursing prompt via MEDITECH for whether a CHG bath was given
- 2. If caring for a patient already admitted, complete the daily prompt on CHG bathing

### **Decolonization Protocol**

#### 1. Chlorhexidine

- Use 2% chlorhexidine (CHG) cloths for daily bed bathing or 4% liquid CHG for daily showers. Use CHG for all shower/bathing needs every day for the ENTIRE unit stay
- Decolonization stops when discharged or transferred out of the unit
- If readmitted or transferred from a non-participating unit, protocol begins anew

#### 2. Mupirocin Nasal Ointment

• For MRSA+ patients **ONLY**, use nasal mupirocin twice a day for 5 days of unit stay

### 3. How to Bathe

- Work with your RN "buddy" trained on bathing protocols to oversee this process
- Decolonization Static Cling is posted in each unit room (see provided image)
- Review attached 1-page staff education
- To save time, provide 1-page bathing/showering instructions handout a few hours before bath
- Use CHG Cloths on ALL skin areas.
- Avoid eyes and ears.
- Let air dry.
- Do NOT flush cloths.
- Do NOT use soap (can inactivate CHG)
- For incontinence, clean with incontinence wipes (water if needed), cleanse with CHG cloth, then use CHG-compatible barrier product



Signature	Flease return complete	lease return completed form to the ome charge warse	
Print Last Name	Print First Name	Date	

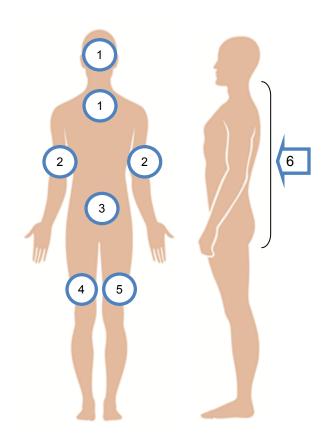
#### Prevent infections during the hospital stay

#### **BATHE** daily with Chlorhexidine (CHG) soap



While in the hospital, bathe patients every day with a special antiseptic soap (CHG) to help remove germs and prevent infection.

6 cloths should be applied as below:



**Caution: Avoid eyes and ear canals.** 

#### **Encourage CHG shower or bath**

#### **Reminders**

- Your enthusiasm is the greatest predictor of patients wanting to use CHG
- Encourage bathing every day. Starting on admission is ideal, before IVs, lines, urinary catheters, and procedures/surgery.
- Patients need direction on how to apply correctly and thoroughly
- Help clean 6 inches of lines, drains, tubes
- CHG is better than soap and water in removing germs and works for 24 hours
- CHG is safe to use on surface wounds, rashes and burns and removes germs
- Allow to air dry for best effect

#### Clean all skin areas with special attention to:

- Neck
- All skin folds
- Skin around all devices (line/tube/drain)
- Wounds unless deep or large
- Armpit, groin, between fingers/toes

#### Protect your patients every day

#### **SHOWERING with CHG soap**

- 1. Rinse body with warm water
- 2. Wash hair and face with CHG
- 3. Turn off the water and lather washcloth with plenty of CHG soap
- 4. Lather and massage soap in all 6 areas
- 5. Leave soap for 2 minutes before rinsing

#### **BATHING with CHG cloths**

- 1. Patients need instruction that these cloths are their protective bath
- 2. Use all 6 cloths. More, if needed.
- 3. **Firmly massage** to clean skin. CHG will kill germs for 24 hours if applied well.
- 4. Clean over semi-permeable dressings
- 5. Clean 6 inches of lines, tubes and drains
- 6. Use only compatible lotions.
- 7. Dispose of CHG cloths in a regular trash bin. Do not flush in commode.



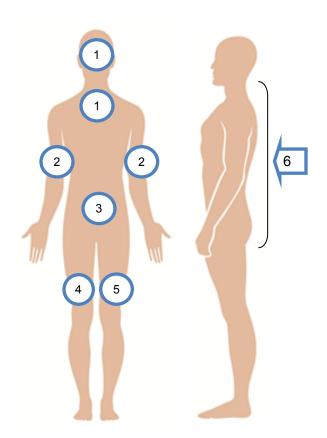


# Evite las infecciones durante la hospitalización Bañar diariamente con el jabón CHG

### El Personal

Durante la hospitalización, bañe a los pacientes diariamente con el jabón antiséptico especial (CHG) para ayudar a eliminar los microbios y prevenir la infección.

Use 6 panós en las áreas indicadas.



Precaución: Evite ojos y canales auditivos.

#### Animar el baño o ducha con CHG

#### Recuerde

- Su entusiasmo resultara en un mejor uso de CHG en los pacientes
- Anímelos que se bañen diariamente. Es ideal usarlo al ser ingresados, antes de introducir línea intravenoso, sondas, catéteres urinarios y antes de las cirugías o procedimientos.
- Los pacientes necesitan instrucciones sobre como aplicar correctamente y a fondo.
- Ayúdeles limpiar hasta 6 pulgadas de líneas, tubos y drenajes que están cerca del cuerpo.
- El CHG es más efectivo que el agua y jabón para eliminar microbios y protege por 24 horas.
- El CHG es seguro para uso en heridas superficiales, erupciones y quemaduras y elimina los microbios.
- Para un mejor efecto, deje secar al air.

#### Limpie toda la piel del cuerpo, especialmente:

- El cuello
- Todos los pliegues cutáneos
- La piel alrededor de los aparatos (líneas/ tubos/drenajes)
- Las heridas, amenos que sean grandes o profundas
- Las axilas, la ingle y entre todos los dedos

#### Proteja a sus pacientes diariamente

#### **BAÑO EN REGADERA con el jabón CHG**

- 1. Enjuague el cuerpo con agua tibia
- 2. Lave el pelo con champú o CHG
- 3. Cierre el agua y empape el paño con CHG
- 4. Enjabone y masajee en todas las 6 áreas
- Deje que el jabón permanezca por 2 minutes antes de enjuagar

#### **BAÑO** con los paños CHG

- 1. Los pacientes necesitan saber que estos paños son su baño protector.
- 2. Use los 6 paños, más si es necesario.
- Masajee con firmeza para limpiar la piel. Si se aplica bien, el CHG eliminará los microbios por 24 horas.
- 4. Limpie sobre los vendajes semipermeables.
- Limpie 6 pulgadas de líneas, tubos y drenajes.
- 6. Sólo use la crema compatible.
- 7. Tire los paños CHG en un bote de basura y no en el inodoro.







# Commonly Used HCA Approved Chlorhexidine (CHG) Compatible Products

#### **LOTIONS**

#### Compatible

- ConvaTec Aloe Vesta 2-Moisturizing Skin Conditioner
- ✓ ConvaTec Sensi-Care 2 Moisturizing Body Cream
- ✓ Medline Remedy Basics Moisturizing Body Lotion
- ✓ Medline Remedy Olivamine Skin Repair Cream

#### **NOT Compatible**

- Johnson & Johnson Baby Lotion\*
- Medline MedSpa Baby Lotion\*

- ✗ Medline MedSpa Hand & Body Lotion\*
- Steris Kindest Kare Skin Cream\*

#### **INCONTINENCE BARRIER PRODUCTS**

#### Compatible

#### BARRIER CREAM

- ✓ ConvaTec Aloe Vesta 3 Protective Barrier Spray
- ✓ ConvaTec Aloe Vesta 3 Protective Ointment
- ✓ ConvaTec Sensi-Care 3 Protective Barrier Cream
- ✓ Medline Remedy Olivamine Calazime Skin Protectant Paste
- ✓ Medline Remedy Olivamine Clear-Aid Skin Protectant
- ✓ Medline Remedy Phytoplex Z-Guard Skin Protectant Paste

#### BARRIER CREAM CLOTH / WIPE

Sage Comfort Shield Barrier Cream Cloths

#### **BABY POWDER**

- Medline Soothe and Cool Non Caking Powder
- Medline Talc Baby Powder

#### **INCONTINENCE CLEAN UP: PERINEAL CLEANSERS, BABY WIPES**

#### **Compatible**

#### PERINEAL CLEANSER

✓ ConvaTec Aloe Vesta Cleansing Foam

#### BABY WIPES

- ✓ Huggies Natural Care Wipes
- Medline Biodegradable Flushable Wipes (scented, unscented, dimethicone)
- NOT Compatible 

  ➤ Pampers Sensitive Wipes\*\*

#### **GENERAL GUIDANCE**

- DO NOT USE ANY BATHING, SOAP OR SHAMPOO PRODUCTS. CHG bathing cloths or CHG liquid soap replace soap and water.
- **SHAMPOO:** Leave-in Shampoo Caps may be used with careful instruction to avoid contact with face and body skin, suggested products include: <u>Sage Comfort Bath Rinse-Free Shampoo Cap</u> or <u>Medline ReadyBath Rinse-Free Shampoo and Conditioning Caps</u>
- **SHAVING CREAM**: All shaving creams are incompatible with CHG and should be removed and replaced with <u>ConvaTec Aloe Vesta Cleansing Foam</u>
- ANTIPERSPIRANTS: Do not use antiperspirants (Medline MedSpa Deodorant/Personal Antiperspirant)
- **WOUND CARE**: All products intended to treat active wounds or for medical management of rashes can be used as needed, including anti-fungal creams, steroid creams, duoderm products.
  - \* Product compatibility is unknown, or has not been tested by manufacturer for compatibility
  - \*\* Product is not compatible with chlorhexidine, as confirmed by manufacturer





#### STUDY-RELATED EVENT SUBMISSION FORM

Please use this form to report all study-related events.
For clinical decisions related to possible study-related events, please contact the treating physician.

Unit Director to fax completed study-related event forms to ABATE study staff on the 15<sup>th</sup> and 30<sup>th</sup> of each month.

Please complete all fields before faxing

#### \*\*\*\*DO NOT INCLUDE ANY PATIENT IDENTIFIERS ON THIS FORM\*\*\*\*

Fax completed form(s) to

ATTN: Rebecca Kaganov

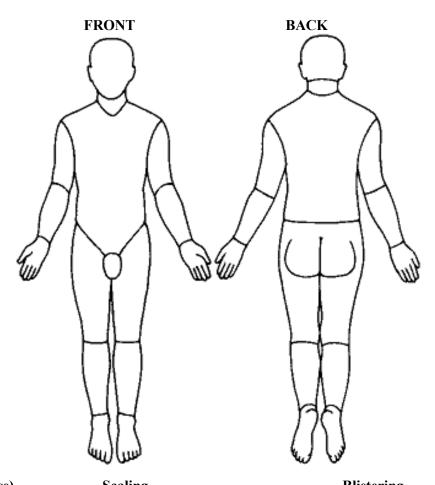
Please DO NOT email this form - FAX ONLY

For questions, please contact ABATE Infection Study staff at

Facility name:	Facility COID:
Unit Name:	
Please provide contact information below:	
E-mail address of individual completing report:	Unit Phone: ()
Unit Director Phone: ()	
Section I:	General Information
Date of First Symptom Onset://	Date Symptom Resolved:/
Please fill out one form per study-related event.	
Patient Gender: M F	
Please choose the option that best describes the event:	
Skin/mucosa related, continue to Section II: S	kin Related Events
☐ Non-skin related, please provide a brief descri	iption of the event. You may be contacted for more information.
Section  Please indicate the study agent that you feel is related	II: Skin Related Events to the event:
	Aupirocin
If you checked Chlorhexidine, please indicate the CH Liquid CHG CHG 2%	
If you checked CHG 2% Cloths, please indicate wheth Yes, the patient has a known aloe sensitive No, the patient does not have a known alo Unknown	ity or allergy
	cream/lotion applied



#### Please shade the parts of the body, to scale. ONLY INDICATE RASHES BELIEVED TO BE RELATED TO A STUDY DRUG EFFECT:



Erythema (Redness)  None Mild (spotty or diffuse) Moderate, uniform redness Intense redness	Scaling None Mild, "dry skin" scale Moderate scaling Desquamation/sloughing	Blistering None Papules only Localized blisters Extensive blisters or bullae
Is the face involved?		
In your opinion, how certain are you that Definitely related Possibly related Unlikely to be related	at this event is related to the trial agent (st	tudy drug) above?
Is it possible that another medication/pro	oduct could have produced this reaction?	
Have any other drug(s) been discontinued.  Yes No If yes, please specify:	ed?	

Please fax completed form to ABATE Study Staff at Remarks ATTN: Rebecca Kaganov Remember: DO NOT include any patient identifiers on this form!



# Have you had your bath today?



Every patient, every day



Active Bathing to Eliminate Infection Project

### ARM 1

# Routine Care Toolkit Binder





# Routine Care Arm 1

#### **Toolkit Binder**

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Frequently Asked Questions		2
Computer Based Training		3





#### Welcome

Welcome to the Active Bathing To Eliminate Infection Trial. The ABATE Infection Trial is a 2-Arm cluster randomized trial of Hospital Corporation of America hospitals to assess the value of chlorhexidine (CHG) bathing for all patients and nasal decolonization for MRSA+ patients in reducing hospital-associated infections in non-critical care units. This trial is a joint collaboration between HCA, the University of California Irvine, Harvard Pilgrim Health Care Institute/Harvard Medical School, Rush University, Stroger Hospital of Cook County, and the Centers for Disease Control and Prevention (CDC). The trial is federally funded by the National Institutes of Health (NIH).

#### **Summary of Goals**

Healthcare-associated infections (HAIs) are a leading cause of preventable morbidity and mortality. Most infections result from common bacteria that normally live on the skin or in the nose and which overcome the body's normal defenses because of medical devices, surgical incisions, or medical illness associated with hospitalization. Studies in intensive care units (ICUs), including our previous highly successful REDUCE MRSA Trial, indicate that decolonization of patients' skin with CHG, and nares with mupirocin can prevent many HAIs. However, evidence is lacking about the effectiveness of decolonization in non-critical care settings, where the majority of HAIs occur. This trial will compare two quality improvement strategies to reduce HAIs and possibly reduce readmissions. The ABATE Infection Project will be a landmark study with a major public health impact. Participating HCA hospitals will be randomized into one of two groups (arms). The first arm, Routine Care, calls for no change in usual care. Arm two, Decolonization, requires non-critical care units to decolonize all patients with CHG and additionally decolonize MRSA-positive patients with mupirocin.

This trial will provide essential information about whether routine decolonization with CHG should become standard practice for 40 million patients hospitalized each year in the United States alone. Alternatively, it will suggest that tailored strategies distinct from those effective in ICU settings are needed for patients in non-critical care settings.





#### Active Bathing to Eliminate Infection Project

#### **University of California Irvine**

Susan Huang, MD MPH, Lead Investigator

#### **Harvard Pilgrim Health Care Inst./Harvard Medical School**

Ken Kleinman, ScD

#### **Rush University**

Mary Hayden, MD

#### **Stroger Hospital of Cook County**

Robert Weinstein, MD

#### **Centers for Disease Control and Prevention**

John Jernigan, MD MS

#### **Hospital Corporation of America**

Ed Septimus MD, Medical Director, Infection Prevention and Epidemiology Julia Moody MS SM (ASCP), Clinical Director, Infection Prevention Jason Hickok MBA RN AVP, Critical Care and Infection Prevention and Lab Chris Bushe MSHA, MT (ASCP), Director, Laboratory Services Jane Englebright PhD RN, Chief Nursing Officer Jonathan Perlin MD PhD, Chief Medical Officer





#### **Phone Matrix**

Topic	Who to contact	Contact Information
General questions	ABATE Infection	
	Project Staff	
New intervention/campaign	ABATE Infection	
reporting	Project Staff	
Lab strain collection	Katie Haffenreffer	
	Lauren Shimelman	
IRB questions	Rebecca Kaganov	
	Julie Lankiewicz	
Lead Investigator questions	Susan Huang, MD MPH	

#### For questions related to HCA hospital policy and process\*

HCA Investigator	Phone Number	Email
Ed Septimus MD		
Medical Director,		
Infection Prevention and Epidemiology		
Julia Moody MS SM (ASCP)		
Director, Infection Prevention		

<sup>\*</sup>Do not disclose Protected Health Information (PHI) to ABATE Infection Project Staff. If you need to share PHI, we will direct you to HCA Study Investigators.





Active Bathing to Eliminate Infection Project

# Frequently Asked Questions: General Study Questions Arm 1

#### What is the ABATE Infection Project?

A cluster randomized trial of adult non-critical care units comparing 2 quality improvement strategies to reduce multi-drug resistant pathogens and hospital-associated infections. Over 50 HCA hospitals are participating. Your hospital's participating adult non-critical care units have been randomized to Routine Care.

#### What is Routine Care?

Your facility is randomized to Routine Care. This means that all participating adult non-critical care units will continue routine bathing and showering of patients with your usual products as you are already doing. There will be no change to your current practice. Please do NOT implement new campaigns or quality improvement initiatives that may change current bathing practice or compliance. If you currently screen high risk patients for MRSA per HCA guidance, you will continue this practice. Your hospital will not implement routine chlorhexidine (CHG) or mupirocin decolonization. Participation in this arm includes an agreement to NOT implement new quality improvement initiatives that involve CHG or mupirocin.

### What should I do if my facility currently uses CHG bathing for preoperative patients?

This is fine if it is already being done. Please do **NOT** implement new campaigns or quality improvement initiatives that may change compliance. Continue to follow your current routine preoperative bathing policy. For any questions, contact the ABATE Infection Project Helpline at

### What should I do if my facility does **NOT** use CHG bathing for preoperative patients?

Continue to follow your current preoperative bathing policy, and do **NOT** begin CHG bathing. For any questions, contact the ABATE Infection Project Helpline at

### What should I do if a physician requests an MRSA+ patient to be decolonized?

Always follow the physician orders. However, please remind them that your facility is randomized to Arm 1 of the ABATE Infection Project, which asks you to continue your usual care procedures without decolonization.

#### Who do I contact with questions?

<b>General questions:</b>	
Study Link:	





#### **Active Bathing to Eliminate Infection Project**

# Nursing Protocol Training Routine Care ARM 1



# **ABATE Infection Project: Introduction**

Your hospital has agreed to participate in the ABATE Infection Project, which is a federally funded collaboration between HCA, the University of California Irvine, Harvard Pilgrim Health Care/Harvard Medical School, Rush University, Stroger Hospital of Cook County, and the Centers for Disease Control and Prevention (CDC).

- From this training you will learn:
  - Which study arm your unit belongs to
  - ✓ The importance of competing interventions and how to avoid them
  - ✓ How to contact study staff for additional information
- This training module will take approximately 10 minutes to complete.
- We highly recommend the audio accompaniment.

# What is the ABATE Infection Project?

This trial compares 2 strategies (arms) to see if one is better able to prevent multi-drug resistant organisms and hospital-associated infections in non-ICU units. This trial will last approximately 21 months:

#### Arm 1: Routine Care

On unit admission, all patients will receive routine bathing per current established protocols

#### Arm 2: Decolonization

On unit admission, all patients will be bathed daily with chlorhexidine (CHG) during their entire unit stay. Patients known to have MRSA will also receive mupirocin nasal ointment.

Your facility has been randomized to Arm 1: Routine Care

# **Arm 1: Routine Care** *Screening & Isolation*

- Upon unit admission, continue to screen high risk patients for MRSA using bilateral nares cultures
- Continue to use contact precautions on patients who:
  - Have a prior history of MRSA or other MDRO
  - Are newly found to be positive for MRSA or other MDRO by admission screen or other culture
- Routine use of CHG that is already in place in your unit may continue
  - Skin prep for central lines
  - Pre-operative bathing policies if already well-established
  - CHG in dressing change kits
  - CHG dressing on central lines

### **Competing Interventions**

#### **IMPORTANT**

Participation in this arm includes an agreement **NOT** to implement NEW Quality Improvement initiatives that involve mupirocin or CHG bathing or impact infection.

Your **key role** is to *maintain* current processes consistent with what you have done for the HCA Aim for Zero Campaign. Do *not* change current **basic** practices. Do *not* start or introduce new QI projects or new interventions that impact transmission or infection in your unit. Continue to emphasize basic practices.

- Maintain usual skills training and highly compliant evidence based care practices
- Maintain high rates of MRSA nares screening for high risk populations per ABCs of MRSA protocol
- Maintain high rates of universal decolonization in adult ICUs.

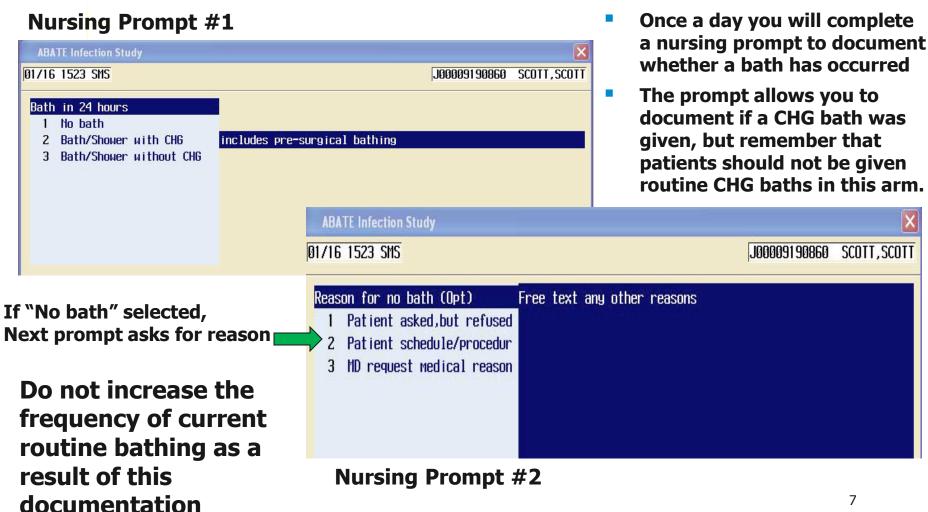
### Why Avoid Competing Interventions?

Here are 2 scenarios on the importance of avoiding competing interventions:

- Let's assume decolonization has no true effect. Arm 2 hospitals add in some additional interventions that improve infection rates while Arm 1 hospitals do not. The trial suggests that decolonization is beneficial and many hospitals adopt decolonization and incur cost.
- Let's assume decolonization has a real effect. Arm 1 hospitals add in some additional interventions that improve infection rates while Arm 2 hospitals do not. The trial shows no difference between Arm 1 and 2 hospitals and decolonization is deemed to be not-effective. No hospitals adopt decolonization and an important and effective solution is lost.

By working together, all hospitals in the ABATE Infection Trial will collectively learn the effect of the decolonization strategy.

# **Daily Bathing Nursing Prompt**



# **Special Circumstances**

### **Preoperative Bathing**

- If your preoperative patients currently bathe or shower with chlorhexidine (CHG), you may continue this practice
- If your preoperative patients do NOT bathe or shower with chlorhexidine (CHG), do NOT start this practice
- If chlorhexidine (CHG) is given pre-operatively for only select surgeries, continue CHG bathing for only patients undergoing those surgeries
- Do NOT implement new policies that require routine use of chlorhexidine (CHG)

# Physician Request for MRSA Decolonization

If a physician places an order to decolonize an MRSA-positive patient with mupirocin, chlorhexidine, or both, you should:

- 1. Follow the physician orders
- 2. Remind the physician that this unit is part of the ABATE Infection Project. This unit has been randomized to the routine care arm which does not involve decolonization of MRSA-positive patients.

## Thank you

This is a landmark trial to identify the best strategies for reducing hospital associated infections and multi-drug resistant organisms.

Your role in the Routine Care arm of this trial is critical to understand whether decolonization is or is not beneficial over current best practice.

