Chlorhexidine Gluconate Bathing
Disclosure

The Food and Drug Administration has approved a New Drug Application submitted by Sage Products, Inc. for use of the 2% Chlorhexidine Gluconate (CHG) Cloth (*equivalent to 500mg chlorhexidine per cloth) for the indication, “Patient Preoperative Skin Preparation.”

This document refers to a use outside the approved FDA Indication and is to be used at the discretion of your hospital based on the clinical evidence. This document is not to be considered a Sage Product recommendation, but simply an example, based on published literature.

Any questions regarding use of the 2% CHG Cloths for off-label purposes described in this document must be addressed by a Sage Products Medical/Clinical Science Liaison only.
The following is a training presentation for the application of daily bathing with Sage 2% CHG cloths and is an off-label use of this product. The content is provided to educate clinicians on this off-label application and is based on protocols consistent with the approach used in various clinical studies.
Factors Driving Practice

• Evidence Based Practice:
  – CHG daily bathing reduces CLBSI and patient acquisition of VRE, MRSA and Acinetobacter1, 2, 3, 4

• CDC Guideline Recommendation:
  – CLBSI Reduction Guideline 2011: “Use a 2% CHG wash for daily skin cleansing to reduce CLABSI”5

• Reimbursement Pressure:
  – CMS declaring select hospital acquired infections as ‘Never Events’ and no longer reimbursing hospital for associated costs
How CHG Works?

- CHG binds to bacterial surface, disrupts integrity of cell membrane and leads to cell death

- Effective against:
  - *Gram-negative bacteria (E.Coli)*
  - *Gram-positive (MRSA)*

- Effective in reducing bacterial load while on patient skin
Additional Uses of CHG

– General skin cleansing by reducing microorganisms on patient skin
– Pre-op Bathing (night before, morning of surgery)
– Vascular catheter site preparation
– Impregnated catheter site dressings
– Impregnated catheters
– Oral decontamination (0.12% CHG)
2% CHG Cloths Facts

- Contain Surfactants to lift dirt & debris
- Contain Emollients (Aloe Vera & Dimethicone) to moisturize skin
- Alcohol Free
- pH Mimics Skin pH (2% CHG clothes = 4-5, normal skin = 4.5 – 5.5)
- Cloth delivery = does not rinse off with water
- Each cloth contains 500mg of 2% CHG
The 2% CHG Bath

• CHG cloths warmed for patient comfort
  – May be used at room temperature (i.e. febrile patient)

• Use special warmer only
  – Do not put cloths in microwave

• Do not flush used cloths!!!

• CHG can stain linens – throw in trash

• Documentation CHG bath should be completed in the patient chart under: __________________________
The 2% CHG Bath (conti.)

- Wipe the skin for ~20 seconds per cloth
- Focus on neck area where bacteria colonize (especially with patients with a central line)
- Skin may feel tacky for a minute or two
  - Patient will be feeling the emollients and aloe
  - Tacky feeling will go away
- **Do Not Rinse!**
- **Do Not Towel Dry!**
CHG Daily Bathing Plan

• Use CHG cloths for daily bath (unless known CHG allergy) on all ICU patients
• Will be used in place of a “soap/water” bath unless the skin is visibly dirty
• Exception = do not use on face
• One package containing 6 cloths to be used for each bath (obese patient may require additional cloths)
• Instruction sheet (next 2 slides) will be posted in units for reference
Reduce Hospital Acquired Infections

BATHING PROTOCOL

- Chlorhexidine (CHG) replaces routine bathing for entire unit stay.
- DO NOT use soap below the jawline. Soap may inactivate CHG.
- DISPOSE of all cloths in the trash. Do NOT flush.
- Use only CHG compatible lotion

APPLY CHLORHEXIDINE WITH FIRM MASSAGE TO REMOVE BACTERIA

INCONTINENCE:
- Clean bulk in normal fashion
- Do NOT use soap
- If skin is raw also apply Barrier Cream
- Apply CHG to involved area
- Dispose in the trash. Do NOT flush.

LINES AND TUBES:
- Apply CHG right up to dressing
- Per your unit protocol
- Dispose in the trash. Do NOT flush.

ONLY USE CHG CLOTHS BELOW THE JAWLINE
ONLY USE CHG CLOTHS BELOW THE JAWLINE

1. Neck, shoulders & chest
2. Armpits, arms & hands
3. Abdomen, groin & perineum
4. Right leg & foot
5. Left leg & foot
6. Back & buttocks

Skin may feel sticky for a few minutes after CHG application. Do NOT wipe off. Allow to air dry.
Incontinence Episodes

• After an incontinence episode, CHG should be reapplied to the involved area to ensure constant antimicrobial activity on whole body.

  – Pg. 307, “stool from incontinent patients was removed with terrycloth towels, (soap), and water; then, the involved skin was cleansed using that period’s method”

• Skin should be dry prior to reapplying CHG

• Use compatible lotion if necessary
CHG Compatibility

• Effect of CHG can be counteracted by certain lotions and creams
• Use only hospital approved products as needed for skin protection compatible with the CHG molecule and do not neutralize the antiseptic effect.
• Additional skin products used in conjunction with CHG should be minimized or avoided when possible
• Regardless of compatibility issues, patient’s skin has priority. Address skin issues as indicated by wound care or medical team.
Antimicrobial Resistance Concerns?

  “Chlorhexidine has a long-standing track record of being a safe and effective product with broad antiseptic activity and little evidence of emerging resistance” Page 278

  – “For the 3 periods, the median chlorhexidine minimum inhibitory concentrations (MIC) for strains of VRE . . . were similar” Page 310
Additional Clinical Points

• Patients with heavy body odor may have a “soap & water” bath. CHG can be applied after bath once skin pores have returned to baseline (~1 hour after bath or shower). This helps prevent deeper penetration of CHG into skin layers which may cause skin irritation.

• Wipe Foley from meatus, outward six inches (or follow your hospital's protocol).

• OK for use on minor skin tears, over approximated or sutured incisions
CHG Bath Warmer

- Place packs in special Sage warmer
- Warmers will indicate when cloths are ready for use
- Cloths need 2 hours to warm
- Expire in 84 hours
  - light will indicate
- Don’t overstock warmer
  - only put packs in warmer that are needed
Warmer Lights

NOT READY (approximately 0-2 hours)
Indicates the package in this slot has not been in the warmer long enough to reach target temperature.

READY (approximately 2-84 hours)
Indicates the package in this slot has been in the warmer long enough to reach target temperature and is ready for use.

DISPOSE (over 84 hours)
Flashes when the package in this slot has been in the warmer for greater than 84 hours and should be discarded.
Final Remarks...

• Communicate the rationale of CHG Bathing to patients and their families

  “CHG (or medicate antiseptic) cloths are used for patient bathing in the hospital to help reduce the risk of infection.”

• Our target date for implementation is:________________
References


Drug Facts (continued)

- use first cloth to prepare the skin area indicated for a moist or dry site, making certain to keep the second cloth where it will not be contaminated. Use second cloth to prepare larger areas.
- dry surgical sites (such as abdomen or arm): use one cloth to cleanse each 161 cm² area (approximately 5 x 6 inches) of skin to be prepared.
- vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.
- moist surgical sites (such as inguinal fold): use one cloth to cleanse each 66 cm² area (approximately 2 x 5 inches) of skin to be prepared. Vigorously scrub skin back and forth for 3 minutes, completely wetting treatment area, then discard. Allow area to air dry for one (1) minute. Do not rinse.

Other information
- store product flat
- keep container tightly closed
- avoid excessive heat above 40°C (104°F)
- area to air dry for one (1) minute. Do not rinse.
- discard each cloth after a single use
- after package has been opened discard any used cloth

Inactive ingredients
- aloe vera, dimethicone, fragrance, glucuronidase, lactates, phenoxyethanol, polysorbate 20, propylene glycol, USP purified water
- cloth: polymer

Questions or comments?
- call toll-free 800-323-2220
- Monday to Friday 8 AM-5 PM CST
- www.sageproducts.com

Reorder # 9707

NDC 053462-705-22

2% CHLORHEXIDINE GLUCONATE* CLOTH
PATIENT PREOPERATIVE SKIN PREPARATION
* equivalent to 500 mg chlorhexidine gluconate per cloth
NON-STERILE
Provides rapid bactericidal action against a broad spectrum of microorganisms
Significantly reduces the number of microorganisms on intact skin
Demonstrates continued antimicrobial activity for up to 6 hours after application

Active ingredient
- Chlorhexidine gluconate 2% solution, Antiseptic

Uses
- helps reduce bacteria that can potentially cause skin infection for preparation of skin prior to surgery

Warnings
- For external use only

Do not use
- in premature or low birthweight infants, infants recovering from surgery or therapy or children less than 2 months of age on patients with known allergies to chlorhexidine gluconate or any other ingredients in this product
- for tympanic punctures or in contact with the meninges
- on open skin wounds or as a general skin cleanser

When using this product
- keep out of eyes, ears and mouth. May cause serious or permanent injury if chlorhexidine is permitted to enter and remain. If contact occurs, rinse with cold water right away and contact a doctor.
- Stop use and ask a doctor if irritation, sensitization or allergic reaction occurs. These may be signs of a serious condition.
- Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
- do not microwave
- product and packaging are not sterile, follow your hospital policy for skin preparation with non-sterile products
- To open package
- hold top of package in one hand and lift flap on backside of package with other hand
- grasp flap at top and pull down to tear flap away and expose foam
- hold outside of package to prevent foam and cloths to prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination
- or using sterile scissors, cut off end seal of package
- transfer contents onto prep table, avoiding contact between cloths and outside of package to reduce risk of cloth contamination

2 DISPOSABLE CLOTHS
7.5 in x 7.5 in (19.1 cm x 19.1 cm)
DO NOT MICROWAVE

Alcohol free — Rinse free
For external use only — Single use

DO NOT FLUSH CLOTHS INTO TOILET
LATEX FREE