For Use Only in the United Kingdom

What the Experts Say Chlorhexidine Gluconate (CHG)

Guidelines and Recommendations epic 3: IVAD 21

"Consider the use of daily cleansing with chlorhexidine in adult patients with a central venous catheter as a strategy to reduce catheter-related bloodstream infection" CLASS B recommendation

Loveday, H.P, et al., epic 3: National Evidence-Based Guidelines for Preventing Healthcare-Associated Infections in NHS Hospitals in England. Journal of Hospital Infection. 2014; 86S1:S9.

Joint Commission International – Preventing Central Line-Associated Bloodstream Infections; Chapter 3: CLABSI Prevention Strategies, Techniques, and Technologies

"The US CDC and SHEA/IDSA recommendations suggest that daily bathing of ICU patients older than 2 months of age with a 2% chlorhexidine-impregnated washcloth may be a useful strategy to decrease CLABSI rates "

Preventing Central Line-Associated Bloodstream Infections: A Global Challenge, A Global Perspective. Joint Commission, 2013:55.

SHEA Strategies to Prevent Healthcare-Associated Infection in Acute Care Hospitals: 2014 Update

"To gain the maximum antiseptic effect of chlorhexidine, adequate levels of CHG must be achieved and maintained on the skin. Typically, adequate levels are achieved by allowing CHG to dry completely. "

Infection Control and Hospital Epidemiology, June 2014, Vol 35, No.6.

Importance of a Medicine License

Granted only when:

- High standards of safety and quality are met during the whole development and manufacture of a medicine
- Clinical outcomes, including multiphase studies about the medicine must be completed:
 - o Phase 3 information gathered from a large

number of people (often several thousand) to see how well it works and how safe the medicine (formula) is.

o Phase 4 - happens after a license has been granted and it involves studies to monitor the medicine on an ongoing basis to see if there are any unexpected side effects or if the medicine causes problems in certain categories of people

Medicines information - licensing. NHS Choices, Oct 2012.

RAPID REVIEW PANEL (RRP):

"The panel assesses product for use in healthcare settings and makes recommendations. It does this on the basis of robust scientific evidence and seeks improvements over existing product in effectiveness, innovation and quality."

Rapid Review Panel. gov.uk, July 2014.

"SAGE Products – Antiseptic Body Cleansing Washcloths: This product is a rinse and alcohol free antiseptic body cleaning washcloths with 2% Chlorhexidine gluconate indicated for skin antisepsis as part of a advanced pre-operative cleansing regimen and general skin antisepsis. Based upon the evidence supplied concerning intensive care patients this product has demonstrated a reduction in skin colonization with nosocomial pathogens leading to a reduction in surgical site infection and infection transmissions."

Sage Products - Antiseptic Body Cleansing Washcloths. Designated as a Level I Reccomendation by the Department of Health, April 2008.

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Clinical Outcomes

No-Rinse application of SAGE 2% CHG Cloths deposited more residual CHG on the skin and did not have gaps in CHG application to the skin.

Edmiston CE, et al., Preoperative Shower Revisited: Can High Topical Antiseptic Levels Be Achieved on the Skin Surface Before Surigal Admission? American College of Surgeons. 2008; 207:233-239.

When a standard bathing procedure using 2% CHG Cloths on all ICU patients was implemented, VRE contamination of patient's skin, the environment and health care workers hands was reduced and patient acquisition of VRE decreased.

Vernon, MO, et al., Chlorhexidine Gluconate to Cleanse Patients in a Medical Intensive Care Unit: The Effectiveness of Source Control to Reduce Bioburden of Vancomycin-Resistant Enterococci. Archives of Internal Medicine. 2006:306-312.

Universal patient bathing with SAGE 2% CHG Cloths in an ICU reduced BSI by 60 percent.

Bleasdale S, et al., Effectiveness of Chlorhexidine Bathing to Reduce Catheter-Associated Bloodstream Infections in Medical Intensive Care Unit Patients. Archives of Internal Medicine. 2007:2073-2079.

Universal patient bathing with SAGE 2% CHG Cloths in a large multisite randomized controlled trial found that Central Line associated BSI was reduced by 53% when compared to a no-rinse a pre-packaged bath. All cause bacteraemias (BSI) showed a reduction of 31%. (6 Hospitals, 9 ICUs; 7,727 Patients)

Climo MW, et al., Effect of Daily Chlorhexidine Bathing on Hospital-Acquired Infection. The New England Journal of Medicine. Feb 2013;368(6):533-542.

A universal approach to patient bathing with SAGE 2% CHG Cloth with a topical nasal antibiotic was twice as effective (44% BSI reduction) as a Targeted approach (22% BSI reduction) by treating only those patients that were positive for antibiotic resistant organisms. (43 Hospitals, 74 ICUs, 74,256 Patients)

Huang S, Septimus E, et al., Targeted versus Universal Decolonization to Prevent ICU Infection. The New England Journal of Medicine. May 2013: 1-11.

Universal approach to patient bathing with SAGE 2% CHG Cloth was effective in a 36% Reduction in Bactaraemia (BSI). Furthermore, the treatment was well tolerated by the patient population. The study was conducted in ICU children over 2 months of age in 5 hospitals, 10 ICUs, 4,072 per protocol patients

Milstone AM, et al., Daily chlorhexidine bathing to reduce bacteraemia in critically ill children: a multicentre, cluster-randomised, crossover trial. The Lancet. Jan 2013: 1-8.

Basic research and development, validation and recent in use evaluations have shown benefits that should be available to NHS bodies to include as appropriate in their cleaning, hygiene or infection control protocols: The SAGE 2% CHG Cloths showed a reduction in C-Section surgical site infections by 27%.

The Result: Using technology to help fight infection. HCAI Technology Innovation Program Showcase Hospitals report number 9 Sage 2% Chlorhexidine Gluconate Cloth. NHS Department of Health.

Implementation of the SAGE 2% CHG Cloths reduced MRSA transmissions by 74% over a 3 year period. Bacteraemias were reduced by 89% since the SAGE 2% CHG Cloth introduction in 2007.

Wyncoll D, et al., Daily Bathing with 2% CHG Washcloths Leads to Almost Total Elimination of MRSA Bacteraemia. Poster Presented at Society of Critical Care Medicine 2011.

Marketing authorisation holder: Sage Products Coöperatief U.A. Herikerbergweb 238, Luna Arena, 1101 CM, Amsterdam, Netherlands Name of Product: Chlorhexidine Gluconate 2% w/v Impregnated Pad.

Name of Product Control Pada Dosage Form: Impregnated Pad. Cost: E 299 per case of 40 packages. Indications: Skin antisepsis as part of an advanced preoperative cleansubg regimen and general skin antisepsis. PL 43018/0001. Warnings and Contra-Indications: For external use only. Keep out of reach and sight of children. Do not use on premature or low birth weight infants or infants less than 2 months of age or receiving phototherapy. Do not use on patients with known allergies to chlorhexidine gluconate or any other ingredients in this product. Do not use immediately prior to any invasive techniques, such as venepuncture, jumbar puncture or surgery. Do not use on possible or broken skin. 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 water right away. Do not use if irritation, sensitization or allergic reaction occurs. Do not store above 25°C. Do not refrigerate or freeze Store flat. Dispose of as a solid waste. Do not flush pads in toilet. For posology, method of administration and side effects refer to SPC. Supply classification: (GSL).