Appendix 2a: Studies related to bathing with an antiseptic soap vs. plain soap

Author, year, reference	Design, scope, setting, popu-lation	Objective	SSI definition	Type of surgery	Study methods	Intervention	Results	Limitations
Ayliffe, 1983 [24]	Cross-over study (60 weeks) 2 large district hospitals and 1 orthopaedic hospital United Kingdom 5536 patients Exclusion: trauma surgery	To compare wound infection rates in patients bathing pre-operatively with either CHG detergent or non-medicated soap.	Mild: a wound with a small or superficial area of inflammation and with minimal discharge. Moderate: superficial inflammation of the whole wound with a serous or small amount of purulent discharge or a deeper wound infection involving a small area usually with purulent discharge.	General, gynaeco-logical, orthopaedic and urological procedures	Surgical wards were divided into groups to either use CHG 4% detergent (Hibiscrub®, Mölnlyke Health Care, Gothenburg, Sweden) or non-medicated bar soap for all preoperative bathing. Wards using CHG scrub were supplied with instruction cards and patients either bathed themselves or were bathed by nursing staff. After a 30-week period, wards	Group 1: CHG 4% Group 2: non-medicated bar soap	Group 1: wound infections 147/2703 Group 2: wound infections 140/2833 *P*=0.440	No instructions given to patients using non-medicated bar soap; unblended due to nature of cleansers; impossible to confirm appropriate use of CHG detergent.

			Severe: deep purulent infection with or without sinuses or fistulae, widespread cellulitis or wound breakdown with an obvious inflammatory reaction and pus.		switched to the opposite cleansing agent. No other skin preparation procedure was changed during the trial.			

Byrne, 1992 [17]	Prospective, randomized, controlled, double-blind trial (regular soap) 3733 patients United Kingdom	To study the importance of definition and post-discharge wound surveillance on reported wound infection rates.	Primary outcome: wound infection (defined as discharge of pus from a wound for inpatients or outpatients or an ASEPSIS score of >9). Secondary outcomes: death, allergic reactions, cost Follow-up: 6 weeks	Elective or potentially contaminated surgery.	Randomization was performed in blocks of 6 using computer-generated random numbers and allocated in a sealed envelope. All personnel and patients were blinded. All patients showered 3 times preoperatively using 50 mL of the allocated agent at admission, the night before surgery, and the morning of surgery. Written instructions were provided to each patient.	Group 1: CHG 4% Group 2: detergent without CHG	Group 1 SSI: 256/1754 (14.6%); Group 2 SSI: 272/1735 (15.7%) *P*=NS	

Earnshaw, 1989 [18]	Prospective RCT 66 patients United Kingdom	To determine whether two CHG baths could reduce the incidence of post-operative sepsis.	Primary outcome: wound infection was defined as discharge of pus from a wound; one patient with severe cellulitis was also included. Secondary outcome: death	Vascular re-construction	Randomization methods not specified. All patients had two baths: Group 1: entire body painted with undiluted CHG 4% followed by rinsing in the bath. Precise instructions given. Group 2: non-medicated soap used. No specific instructions provided.	Group 1: CHG 4% Group 2: non-medicated soap	Group 1 SSI: 8/31 Group 2 SSI: 4/35 *P*=1.20	No written instruction were given to the control group, potentially resulting in less thorough washing than the intervention group, which received precise instructions.

Hayek, 1988 [19]	Cluster RCT 1 hospital (4 wards) and 1 hospital (2 wards) over 2 years United Kingdom 2015 patients Exclusion: patients receiving antibiotics or with existing infection.	To study the reduction of postoperative wound infection after 2 pre-operative baths or showers with CHG scrub, regular soap or non-medicated soap.	Primary outcome: wound infection was defined as either discharge of pus from a wound, or erythema, or swelling considered to be greater than expected.	Routine general surgery	Randomization not specified. All patients had either a shower or bath on the day before and morning of their operation. Primary outcome was wound infection.	Group 1: CHG 4%. Instruction card for washing provided. Group 2: detergent without CHG. Instruction card for washing provided (5 months into the study, the regular soap was found to have antimicrobial properties and was changed). Group 3: bar soap. No washing instructions provided.	Group 1 SSI: 62/689 (9.0%); Group 2 SSI: 83/700 (11.7%); Group 3 SSI: 80/626 (12.8%) $P<0.05$	Liquid agents were given with instructions. No written instruction were given to the control group, potentially resulting in less thorough washing than the intervention group, which received precise instructions.

Leigh, 1983 [25]	Prospective cohort study 1 hospital; over 4 months The Netherlands 224 patients (127 male) undergoing a procedure involving a skin incision. Exclusion: not stated.	To investigate if the use of preoperative whole-body bathing with CHG-detergent solution was more effective than non-medicated soap in reducing the bacterial flora of certain specified areas of the body and to determine the influence of this procedure in the development of postoperative wound infection.	Wound infection was "assessed by the infection control nursing officer by frequent visits to the wards and a final examination of inpatient notes".	Mixed surgical procedures, consisting of 72% clean procedures.	Patients were usually admitted the day before or morning of surgery; bathing was carried out a few hours before operations. The 2 treatments were alternated between the male and female wards for 4 months, beginning with the male ward using non-medicated soap first. Primary outcomes included bacterial flora and post-operative wound infection.	Group 1: CHG 4%. Group 2: non-medicated soap Instructions were posted in each bathroom and the procedure of total body bathing explained to each patient. Hair washing was not compulsory.	Wound infection (clinical) Group 1:12/109 Group 2: 13/115	Hair washing was not compulsory; depending on the procedure, deferringhair washing may contribute to an increased number of microorganisms.

Lynch, 1992 [20]	Double-blind RCT April 1987 – December 1989 United Kingdom 3482 general surgery patients. Exclusion: not stated.	To measure the efficacy of whole-body disinfection with a CHG 4% detergent solution in reducing the postoperative wound infection rate in patients undergoing clean or potentially contaminated surgery.	Wound infection was defined as: 1. discharge of pus from the wound in hospital = inpatient clinical; 2. no discharge of pus, but ASEPSIS >10 = inpatient ASEPSIS; 3. discharge of pus from the wound after leaving hospital = outpatient clinical. Secondary outcomes: colony-forming units, cost.	Elective clean or potentially contaminated surgery	Follow-up period All patients had 3 showers with liquid soap provided (either CHG or regular soap). First shower upon admission before putting on clean clothes, second before going to bed, and the third on the morning of the operation before changing into clean cloths. After third shower, agar skin contact plates were taken from the axillae and groin areas and incubated for 24 hours (colony-forming units measured). Wounds were assessed postoperatively	Group 1: CHG 4% solution Group 2: detergent without CHG	SSI Group 1 SSI: 250/1744 Group 2 SSI: 263/1738 *P*=NS	

					using the ASEPSIS scoring system, as well as by clinical observation of the wound.			
Randall, 1985 [21]	RCT; 3-arm United Kingdom 94 patients	To assess the true wound infection rate for vasectomy at the hospital and its subsequent morbidity and to elucidate any factors that may be responsible for infection.	Primary outcome Wound infection was defined as discharging either purulent or serous fluid.	Vasectomy	Follow-up period: one week after discharge	Group 1: 1 preoperative shower with CHG 4%, Group 2: 1 shower with normal soap. Group 3: no shower.	Group 1 SSI: 12/32 (37.5%); Group 2 SSI: 10/30 (33.3%); Group 3 SSI: 9/32 (28.1%). *P*<0.05	Unclear if group 3 was specifically instructed not to shower or if other hygienic cleansing may have occurred.

Rotter, 1988 [22]	Cluster RCT Austria 2953 patients Exclusion criteria: temperature >37.5°C, antibiotics given within 7 days of surgery, incarcerated inguinal hernia, radical mastectomy.	To compare the effect of pre-operative whole-body bathing on 2 occasions with a detergent containing CHG on the incidence of wound infection in elective clean surgery with two bathings with a detergent without CHG.	Wound infection was defined in the report as "inflammation of the surgical wound with discharge of pus, spontaneous and/or after surgical intervention that occurs during hospitalization or during routine follow-up".	Elective clean surgery	All patients had 2 showers; one on the day before surgery and one on the day of surgery. Group 1: used 50 mL of CHG 4% for each shower. Group 2: regular soap. Special application instructions were provided to all participants.	Group 1: CHG 4% Group 2 detergent without CHG	SSI: Group 1: 37/1413 (2.6%); Group 2: 33/1400 (2.4%). *P*=NS	

Veiga, 2008 [23]	RCT university-affiliated hospital Brazil 150 adult patients Exclusion: hypersensitivity to CHG, skin lesions, diabetes heavy smoking, immune-suppression.	To assess the effect of pre-operative CHG showers on skin colonization and post-operative infection rates associated with plastic surgery procedures involving the trunk.	SSI (CDC criteria) Secondary outcome: adverse reactions	Plastic surgery	Group 1: shower with liquid-based detergent containing CHG 4%. Group 2: shower with the same liquid-based detergent, without CHG. Group 3: no preoperative showering instructions were given. Follow-up: 30 days	Group 1: liquid based CHG 4%. Group 2: detergent without CHG. Group 3: no wash. All patients were prepped with an alcohol-based solution of CHG 0.5% paint following sample collection.	Group 1 SSI: 1/50 (2%) Group 2 SSI: 1/50 (2%) Group 3 SSI: 0/50 (0%) No adverse reactions reported. *P*=0.6	Group 3 (control) was not given instructions and therefore preoperative bathing may have occurred with normal soap or other personal hygiene practices.

SSI: surgical site infection; RCT: randomized controlled trial; CHG: chlorhexidine gluconate; ASEPSIS (scoring system): **A**dditional treatment, **S**erous discharge, **E**rythema, **P**urulent exudate, **S**eparation of deep tissues, **I**solation of bacteria and **S**tay as inpatient prolonged over 14 days CDC: Centers for Disease Control and Prevention; NS: not significant.