Decolonization to Prevent Infections and MDROs:

Clinical Trials Across the Continuum of Care

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Disclosures

- Conducting clinical studies in which participating nursing homes and hospital patients receive contributed antiseptic products from Xttrium
- Companies had no role in design, conduct, analysis, or publication

Healthcare-Associated Infection (HAI) Pathogens

Pathogens by HAI Type, 2015-17

Central Line-Associated Bloodstream Infection

Pathogen	Hospital Wards[c]		Hospital ICUs[a]	
	No. (%) Pathogens	Rank	No. (%) Pathogens	Rank
Staphylococcus aureus	5,386 (15.5)	1	2,497 (9.1)	3
Coagulase-negative staphylococci	3,792 (10.9)	2	3,789 (13.8)	1
Selected *Klebsiella* spp	3,344 (9.6)	3	1,708 (6.2)	8
Enterococcus faecalis[d]	2,636 (7.6)	4	2,117 (7.7)	5
Candida albicans[d]	2,469 (7.1)	5	2,844 (10.4)	2
Escherichia coli	2,279 (6.6)	6	1,129 (4.1)	9

Weiner-Lastinger LM et al. Infect Control Hosp Epidemiol. 2020;41(1):1-18.

Pathogens by HAI Type, 2015-17

Ventilator-Associated Pneumonia

Pathogen	Hospital ICUs[d]		Hospital Wards[a,c]	
	No. (%) Pathogens	Rank	No. (%) Pathogens	Rank
Staphylococcus aureus	2,673 (28.8)	1	58 (20.1)	2
Pseudomonas aeruginosa	1,192 (12.9)	2	63 (21.8)	1
Selected *Klebsiella* spp	936 (10.1)	3	38 (13.1)	3
Enterobacter spp	781 (8.4)	4	18 (6.2)	4
Haemophilus influenzae	550 (5.9)	5	10 (3.5)	8
All *Streptococcus* spp[e]	527 (5.7)	6	6 (2.1)	10

Weiner-Lastinger LM et al. Infect Control Hosp Epidemiol. 2020;41(1):1-18.

Pathogens by HAI Type, 2015-17

Surgical Site Infection

Pathogen	All Surgery Types[b] No. (%) Pathogens	Rank
Staphylococcus aureus	26,970 (17.5)	1
Escherichia coli	21,746 (14.1)	2
Enterococcus faecalis[g]	12,267 (8.0)	3
Coagulase-negative staphylococci	11,106 (7.2)	4
Pseudomonas aeruginosa	8,956 (5.8)	5
Selected *Klebsiella* spp	7,789 (5.1)	6

Weiner-Lastinger LM et al. Infect Control Hosp Epidemiol. 2020;41(1):1-18.

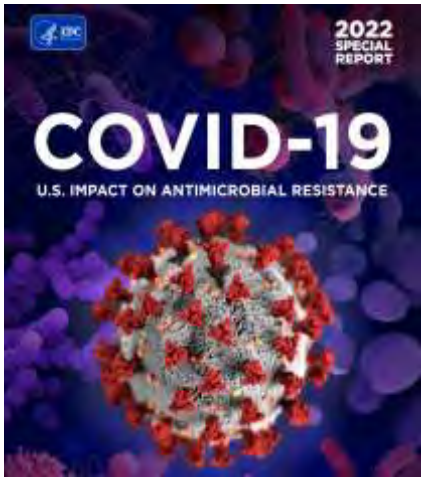
CDC Surveillance Network: U.S. COVID Impact

	2020 Q1	2020 Q2	2020 Q3	2020 Q4
CLABSI	↓ −11.8%	↑ 27.9%	↑ 46.4%	↑ 47.0%
CAUTI	↓ −21.3%	No Change[1]	↑ 12.7%	↑ 18.8%
VAE	↑ 11.3%	↑ 33.7%	↑ 29.0%	↑ 44.8%
SSI: Colon surgery	↓ −9.1%	No Change[1]	↓ −6.9%	↓ −8.3%
SSI: Abdominal hysterectomy	↓ −16.0%	No Change[1]	No Change[1]	↓ −13.1%
Laboratory-identified MRSA bacteremia	↓ −7.2%	↑ 12.2%	↑ 22.5%	↑ 33.8%
Laboratory-identified CDI	↓ −17.5%	↓ −10.3%	↓ −8.8%	↓ −5.5%

Weiner-Lastinger LM et al. ICHE. 2021;41(1):1-18

U.S. Antimicrobial Resistance Progress Erased by COVID

- 80% of COVID patients received antibiotics in 2020
- Hospital-onset MDROs between 2019 to 2020
  - CRAB increased 78%
  - *Candida auris* increased 60%
  - CRE increased 35%
  - ESBL increased 32%
  - MDR-Pseudomonas increased 32%
  - VRE increased 14%
  - MRSA increased 13%

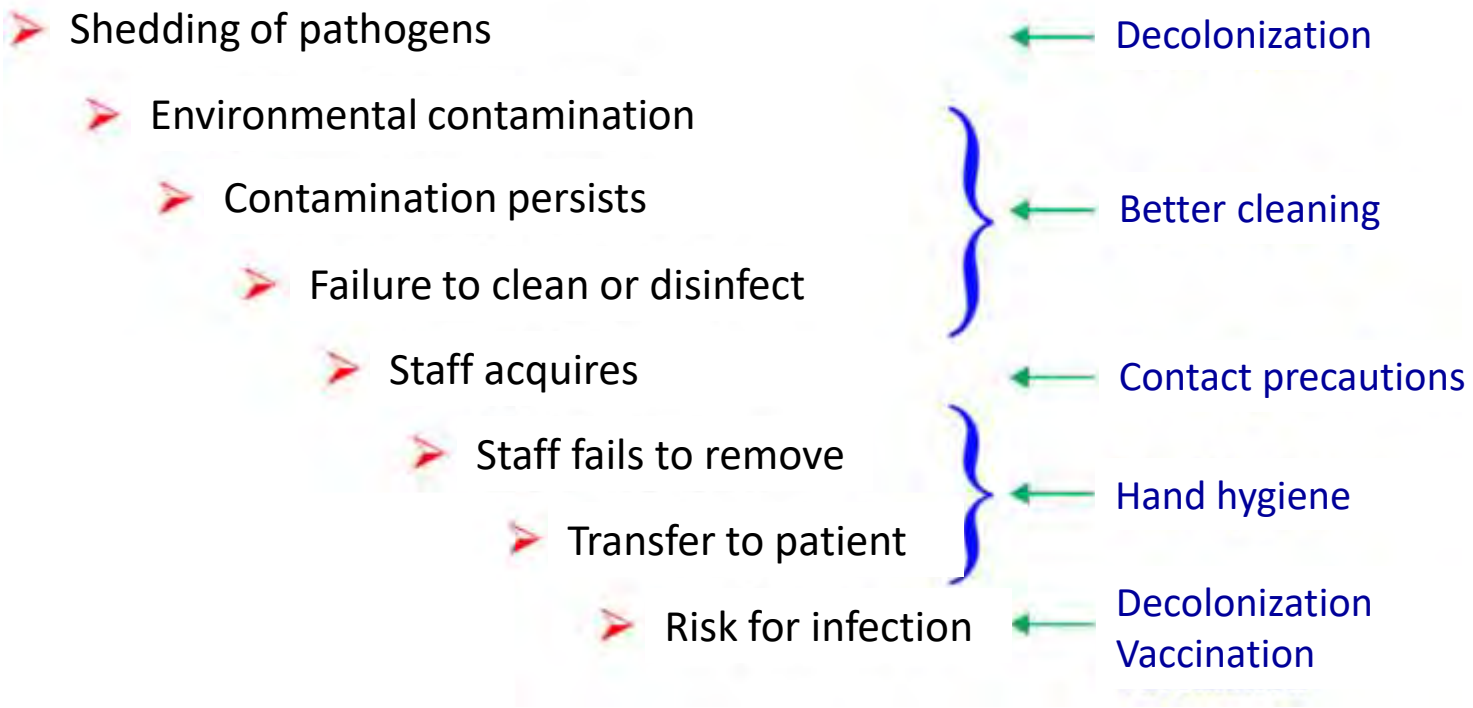


https://www.cdc.gov/drugresistance/pdf/covid19-impact-report-508.pdf

Human Pathogen Transmission: Cascade of Unfortunate Events

- Shedding of pathogens
  - Environmental contamination
    - Contamination persists
      - Failure to clean or disinfect
        - Staff acquires
          - Staff fails to remove
            - Transfer to patient
              - Risk for infection

Human Pathogen Transmission: Cascade of Unfortunate Events



Decolonization Prevents a Cascade of Unfortunate Events

- Shedding of pathogens ← **Prevents shedding**
  - Environmental contamination
    - Contamination persists
      - Failure to clean or disinfect
        - Staff acquires
          - Staff fails to remove
            - Transfer to patient
              - Risk for infection

Broad solution for all MDROs
Benefits carriers too

What is Topical Decolonization?

- Topical antiseptic or antibiotic agents to remove commensals or pathogens from the skin or nose
- Most studied products:
  - Skin: chlorhexidine
  - Nose: mupirocin, iodophor
- Strong safety record
- Targeted and universal uses

Use of Chlorhexidine

- Antiseptic uses in healthcare
  - Hand antisepsis at 2% and 4%
  - Dental hygiene
  - 1990s: Cleaning of skin prior to line insertion
  - 1990s: Pre-operative bathing
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  - 2019: CHG for non-ICU bathing
  - 2019: Post-discharge for MRSA carriers
  - 2023: Nursing homes

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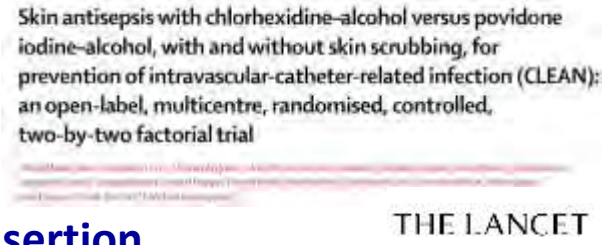
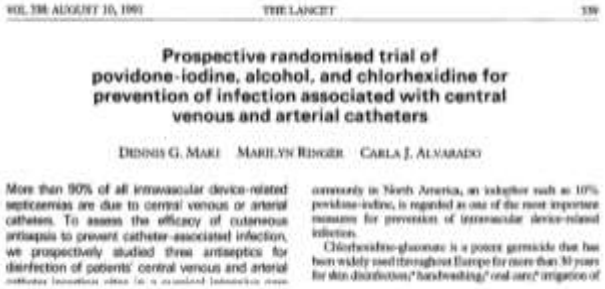


Skin antisepsis with chlorhexidine–alcohol versus povidone iodine–alcohol, with and without skin scrubbing, for prevention of intravascular-catheter-related infection (CLEAN): an open-label, multicentre, randomised, controlled, two-by-two factorial trial

THE LANCET



VOL. 338 AUGUST 10, 1991 THE LANCET 339

Prospective randomised trial of povidone-iodine, alcohol, and chlorhexidine for prevention of infection associated with central venous and arterial catheters

DENNIS G. MAKI MARILYN RINGER CARLA J. ALVARADO

More than 90% of all intravascular device-related septicaemias are due to central venous or arterial catheters. To assess the efficacy of cutaneous antisepsis to prevent catheter-associated infection, we prospectively studied three antiseptics for disinfection of patients' central venous and arterial

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ORIGINAL ARTICLE

Chlorhexidine–Alcohol versus Povidone–Iodine for Surgical-Site Antisepsis

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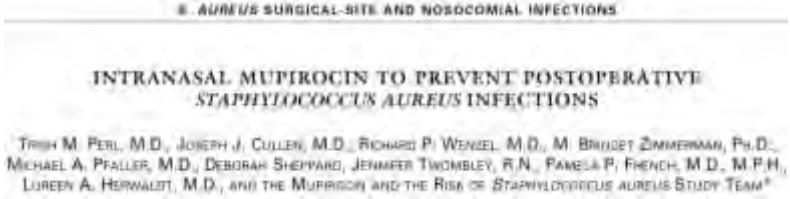
S. AUREUS SURGICAL-SITE AND NOSOCOMIAL INFECTIONS

INTRANASAL MUPIROCIN TO PREVENT POSTOPERATIVE *STAPHYLOCOCCUS AUREUS* INFECTIONS

TRISH M. PERL, M.D., JOSEPH J. CULLEN, M.D., RICHARD P. WENZEL, M.D., M. BRIDGET ZIMMERMAN, PH.D., MICHAEL A. PFALLER, M.D., DEBORAH SHEPPARD, JENNIFER TWOMBLEY, R.N., PAMELA P. FRENCH, M.D., M.P.H., LOREEN A. HERWALDT, M.D., AND THE MUPIROCIN AND THE RISK OF *STAPHYLOCOCCUS AUREUS* STUDY TEAM*


JAMA

Universal Screening for Methicillin-Resistant Staphylococcus aureus at Hospital Admission and Nosocomial Infection in Surgical Patients


The NEW ENGLAND JOURNAL of MEDICINE

Preventing Surgical-Site Infections in Nasal Carriers of *Staphylococcus aureus*

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ORIGINAL ARTICLE

Effect of Daily Chlorhexidine Bathing on Hospital-Acquired Infection

The NEW ENGLAND JOURNAL of MEDICINE

Targeted versus Universal Decolonization to Prevent ICU Infection

THE LANCET

Daily chlorhexidine bathing to reduce bacteraemia in critically ill children: a multicentre, cluster-randomised, crossover trial

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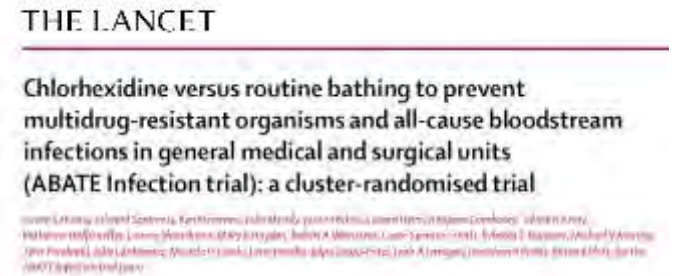
THE LANCET

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

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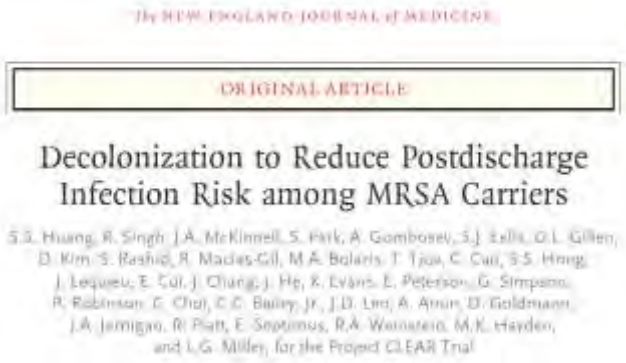
The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Decolonization to Reduce Postdischarge Infection Risk among MRSA Carriers

S.S. Huang, R. Singh, J.A. McKinnell, S. Park, A. Gombosev, S.J. Eells, O.L. Gillen, D. Kim, S. Rashid, R. Mades-Gil, M.A. Bolaris, T. Tjoa, C. Cui, S.S. Hong, J. Lequeu, E. Cui, J. Chung, J. He, K. Evans, E. Peterson, G. Simpson, R. Robinson, C. Choi, C.C. Bailey, Jr., J.D. Lee, A. Arun, D. Goldmann, J.A. Jernigan, R. Platt, E. Septimus, R.A. Weinstein, M.K. Hayden, and L.G. Miller, for the Project CLEAR Trial

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ORIGINAL ARTICLE

Decolonization in Nursing Homes to Prevent Infection and Hospitalization


JAMA | Original Investigation

Reducing Hospitalizations and Multidrug-Resistant Organisms via Regional Decolonization in Hospitals and Nursing Homes

Decolonization in ICUs

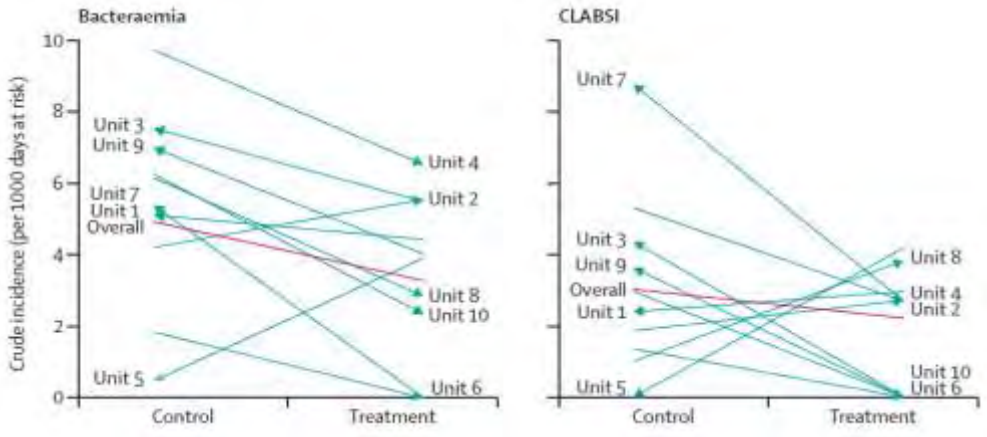
Universal CHG Decolonization in Academic ICUs

- 12 Adult ICU cluster randomized cross-over trial
- 1 hospital dropped out → 9 ICUs, 7,727 patients in 6 hospitals
  - ICUs: daily CHG baths & routine soap for 6 months each
  - As-treated analysis
    - ✓ **Reduced MRSA and VRE acquisition by 23%**
    - ✓ **Reduced bacteremia by 28%**
    - ✓ **Reduced CLABSI by 53%**
- No evidence of CHG resistance

Climo et al. NEJM 2013;368:533-42

Pediatric SCRUB Trial
Universal CHG in 10 Academic PICUs

- Randomized cross-over trial of universal CHG bathing, N=1,547
- Two-thirds of parents consented
- As-treated analysis, 36% reduction in bloodstream infections



Milstone AM et al. Lancet 2013:381(9872):1099-106

Reducing MRSA and Bloodstream Infections in Community ICUs

REDUCE MRSA Cluster Randomized Trial of Hospitals

Randomized **E**valuation of **D**ecolonization vs. **U**niversal **C**learance to **E**liminate MRSA

- **Arm 1: Routine Care**
  - Screened all patients; isolated known MRSA+
- **Arm 2: Targeted Decolonization**
  - Screened all patients; isolated known MRSA+
  - Decolonized if MRSA+ (5 days mupirocin, 5 days CHG)
- **Arm 3: Universal Decolonization**
  - No screening; isolated known MRSA+
  - Decolonized all (5 days mupirocin, daily CHG)

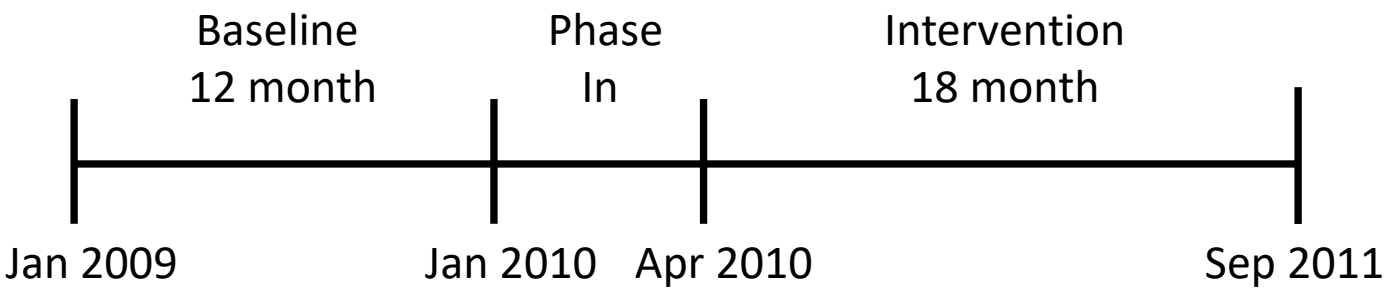
Huang SS et al. NEJM 2013:368:2255-2265

Baseline and Intervention Periods

43 HCA Healthcare hospitals (formerly Hospital Corporation of America)

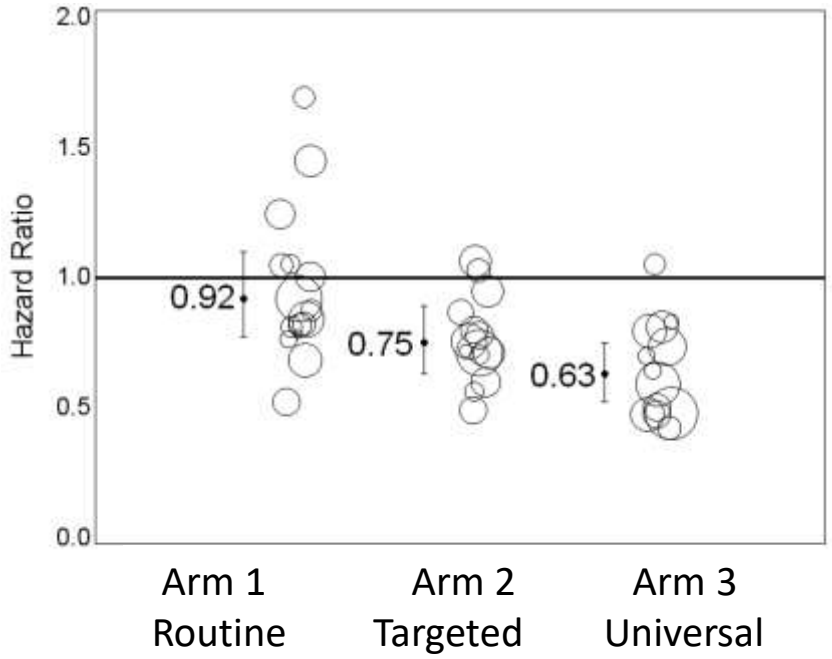
74 adult ICUs

74,256 patients and 282,803 ICU patient days



Huang SS et al. NEJM 2013:368:2255-2265

MRSA Clinical Cultures



Primary outcome

Overall P=0.01

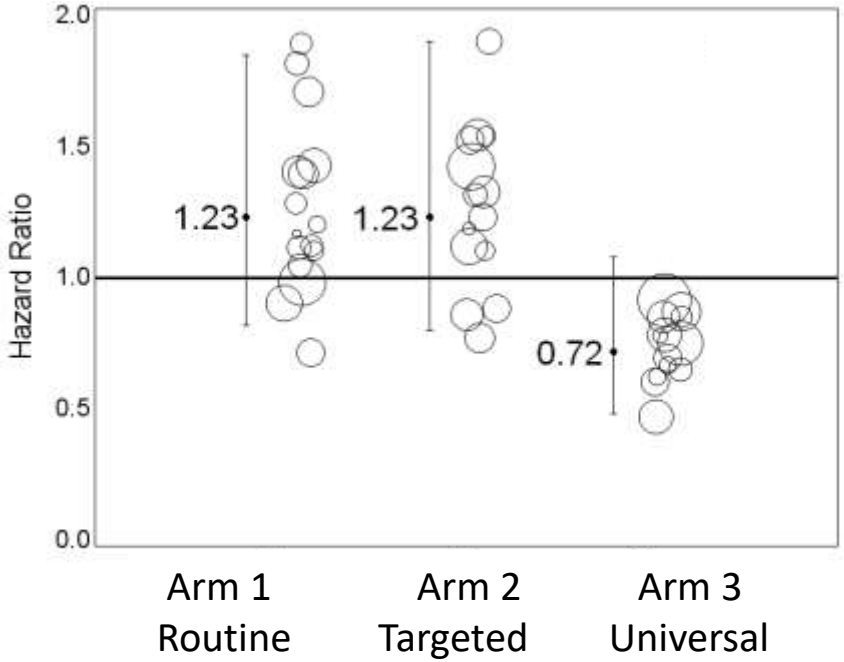
Arm 2 vs 1 P=0.09

Arm 3 vs 1 P<0.003

Arm 3 vs 2 P=0.16

Huang SS et al. NEJM 2013:368:2255-2265

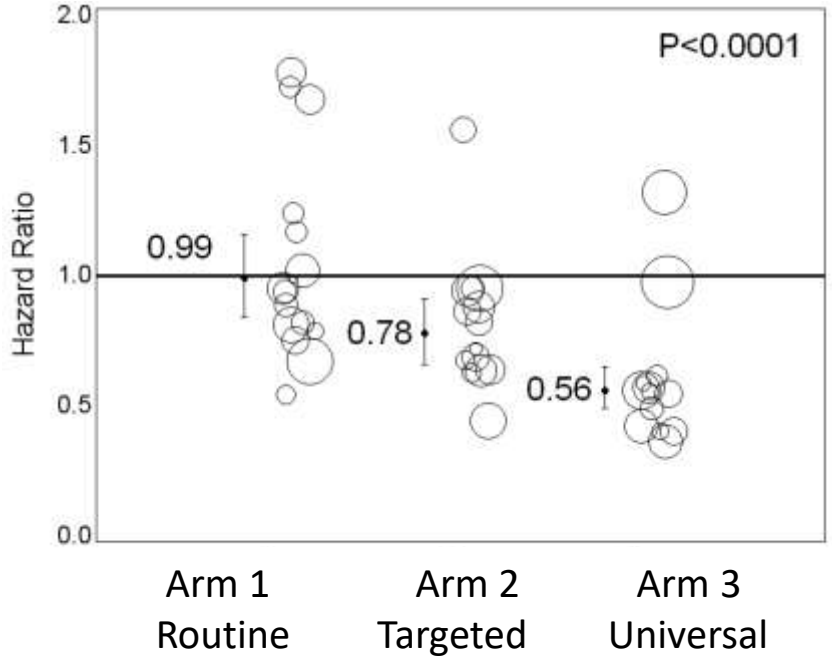
MRSA Bloodstream Infection



Overall P=0.11

Huang SS et al. NEJM 2013:368:2255-2265

All Pathogen Bloodstream Infection



Overall P<0.0001

Arm 2 vs 1 P=0.04
Arm 3 vs 1 P<0.0001
Arm 3 vs 2 P=0.003

Huang SS et al. NEJM 2013:368:2255-2265

Additional Decolonization Impact

- Universal decolonization with mupirocin and CHG
  - Highly cost-effective and prevents need to screen [1]
  - Reduces blood culture contamination [2]
  - Reduces bacteriuria and candiduria in men [3]
  - No emergence of CHG or mupirocin resistance in trial [4]
  - CLABSI benefit seen with rapid adoption in 95 hospitals [5]
- By 2021, 63% of US hospitals adopted universal ICU decolonization[6]

[1] Huang SS et al. ICHE 2014; 35 S3:S23-S31
[2] Septimus EJ et al. ICHE 2014; 35 S3:S17-S22.
[3] Huang SS et al. Lancet ID 2016;16(1):70-9
[4] Hayden M et al. JCM 2016; 54(11):2735-42
[5] Septimus ES et al. CID 2016;63(2):172-7
[6] NHSN survey, 2021

Decolonization Outside of ICUs

ABATE Infection Project
Active Bathing to Eliminate Infection

Trial Design

- Cluster randomized trial with HCA Healthcare
- 53 hospitals, 194 adult non-critical care units
- Includes: adult medical, surgical, step down, oncology

Arm 1: Routine Care

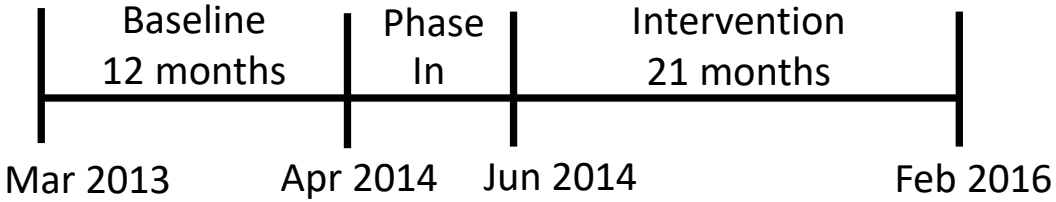
- Routine policy for showering/bathing

Arm 2: Decolonization

- Daily 4% rinse off CHG shower or 2% leave-on CHG bed bath
- Mupirocin x 5 days if MRSA+ by history, culture, or screen

Outcomes and Study Period

- **Primary Outcome**
  - Any MRSA or VRE isolate attributed to unit
- **Key Secondary Outcome**
  - Any bloodstream isolate attributed to unit (2 positives for skin commensals)
- **339,904 patients, 1,294,153 patient days (intervention)**



Huang SS Lancet 2019;393(10177):1205-1215

Results: Decolonization Outside of ICUs

- No overall population benefit, unlike ICU trials
  - Lower risk and smaller effect size
  - 8.7% non-significant reduction for MDROs
  - 6.2% non-significant reduction in bloodstream infection

- Benefit seen in **higher risk patients with lines and devices**
  - 37% reduction in MRSA and VRE clinical cultures
  - 32% reduction in all pathogen bloodstream infection

Huang SS Lancet 2019;393(10177):1205-1215

Medical Devices: Attributable Impact

- Benefit seen in **higher risk patients with lines and devices**
  - 10% of population, but a third of MRSA+VRE cultures
  - 10% of population, but 60% of bloodstream infections

Huang SS Lancet 2019;393(10177):1205-1215

Importance of Nasal Decolonization

S. aureus and MRSA Infections in ICUs

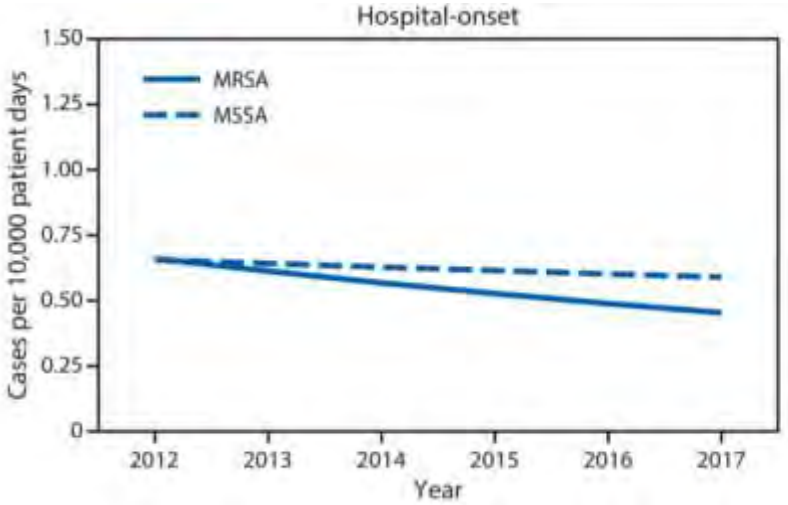
- Adult ICU infections assessed in single-day multi-center chart review
- 1150 centers in 88 countries

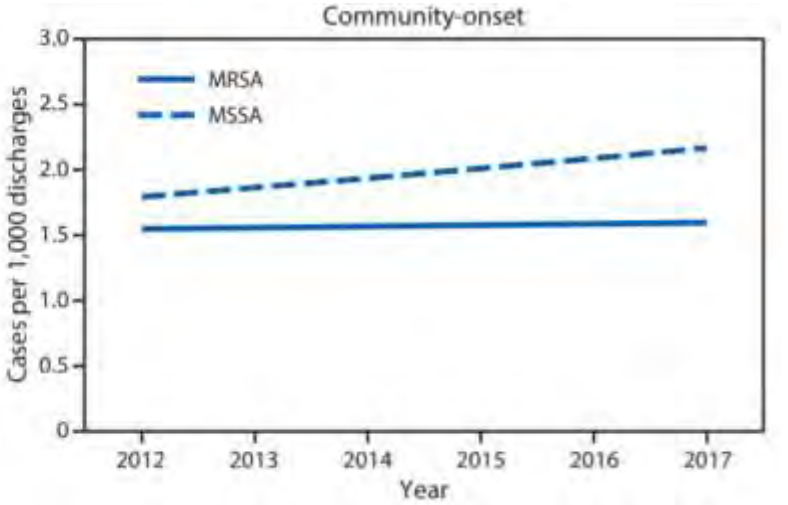
Causal Agent	Africa	America (North)	America (Central/South)	Asia/ Middle East	Australasia	Europe (Eastern)	Europe (Western)
S. aureus	8%	23%	17%	10%	17%	16%	15%
MRSA	5%	10%	7%	5%	4%	6%	2%

Vincent JL, et al. JAMA. 2020;323(15):1478-1487

S. aureus Invasive Disease in U.S.

- 120,000 *S. aureus* bloodstream infections / year
- 20,000 associated deaths / year





Kourtis AP et al. MMWR. 2019;68(9):214-219.

Rationale for Mupirocin-Iodophor Swap Out Trial

- Adoption of nasal mupirocin for universal ICU decolonization is variable despite burden of *S. aureus* ICU infections
- Some are concerned universal ICU mupirocin will elicit resistance
- Iodophor and other antiseptics are less likely to lead to resistance
- Swap Out Trial: **non-inferiority cluster randomized trial** to assess if iodophor is as effective as mupirocin in preventing *S aureus* cultures when combined with CHG baths for ICU universal decolonization

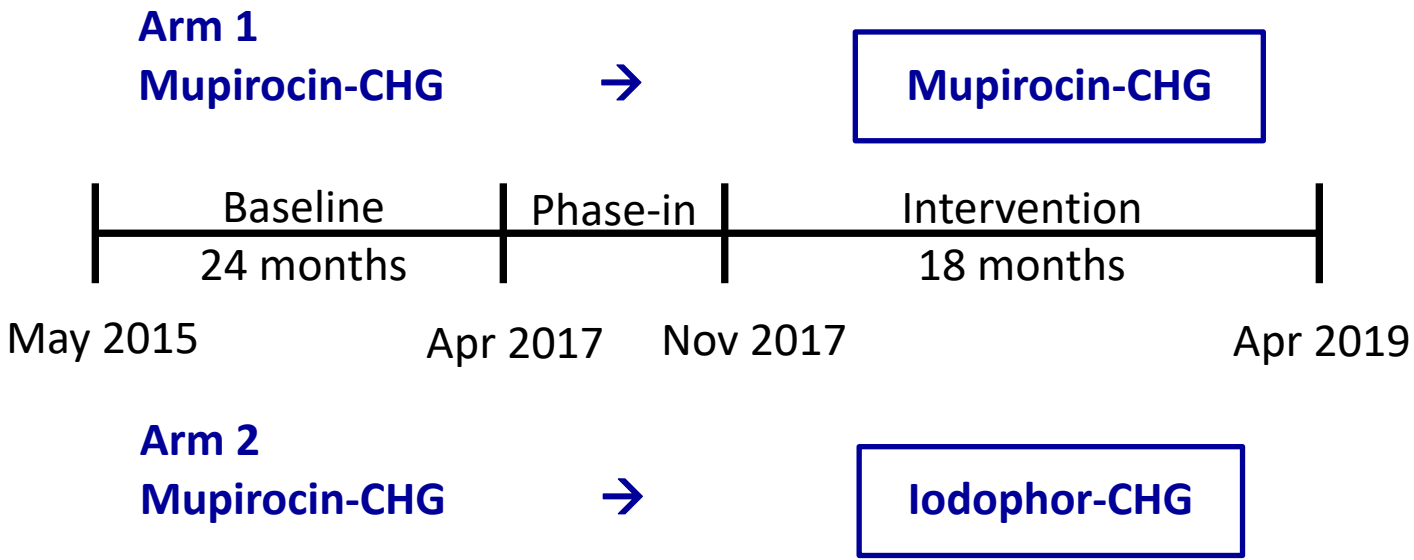
Huang SS et al. JAMA 2023; 330 (14):1337-47

Mupirocin-Iodophor Swap Out Trial

- 18 Month cluster-randomized ICU non-inferiority study
- 137 HCA hospitals, 233 adult ICUs
  - **Mupirocin Arm**: Daily CHG & 5 days twice daily 2% mupirocin
  - **Iodophor Arm:** Daily CHG & 5 days twice daily 10% iodophor
- Outcomes
  - *S. aureus* (MRSA & MSSA) ICU clinical cultures **(primary)**
  - MRSA clinical cultures
  - All-cause bacteremia
  - Emergence of resistance to mupirocin, iodophor

Huang SS et al. JAMA 2023; 330 (14):1337-47

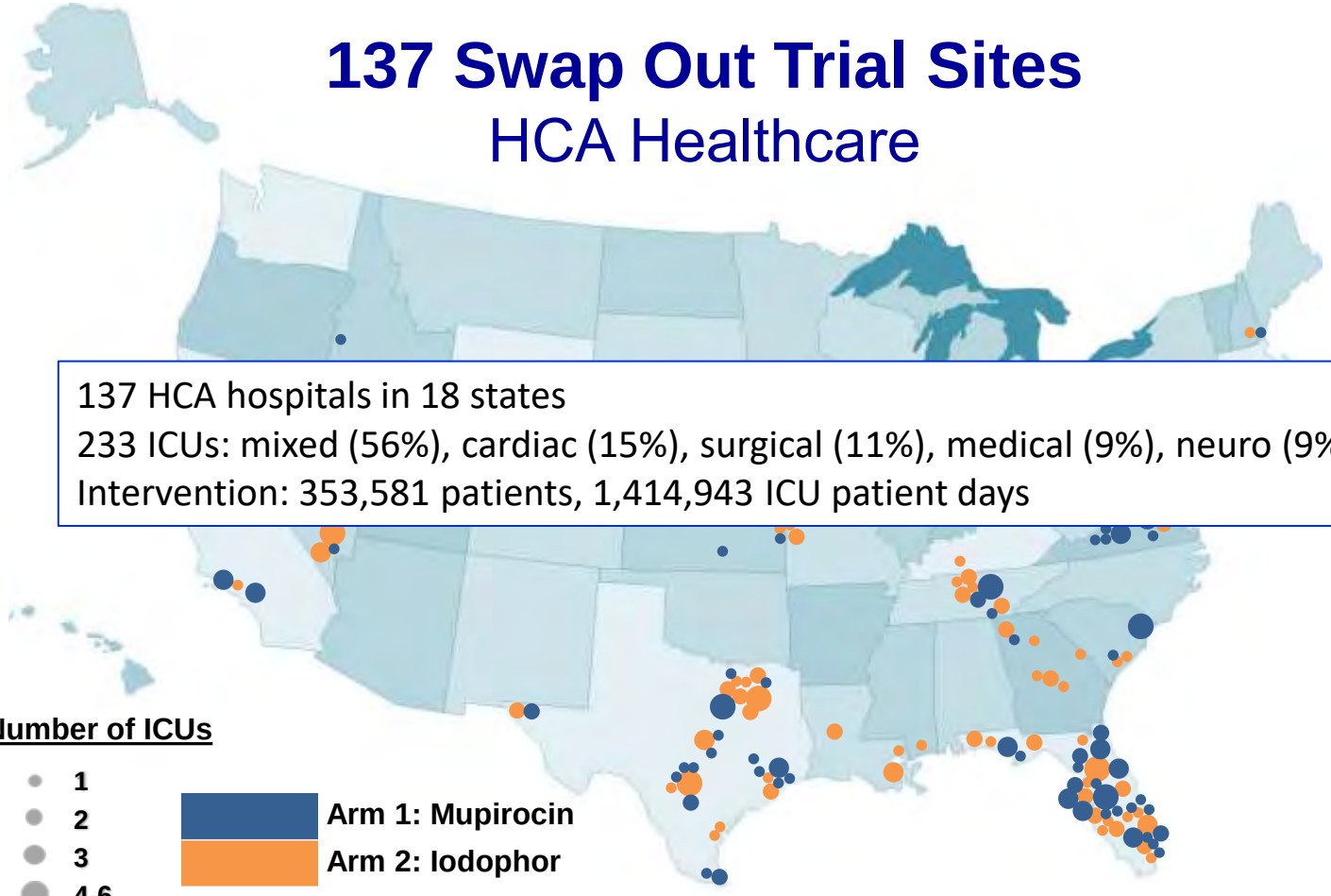
Baseline and Intervention Periods



Huang SS et al. JAMA 2023; 330 (14):1337-47

137 Swap Out Trial Sites

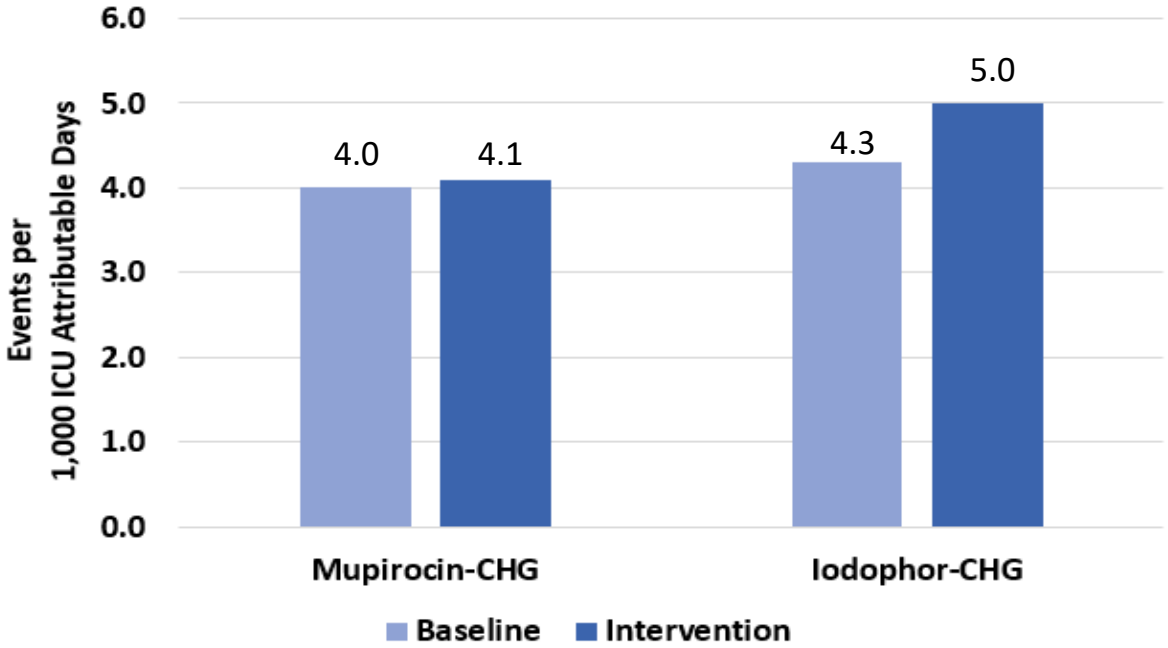
HCA Healthcare



137 HCA hospitals in 18 states
233 ICUs: mixed (56%), cardiac (15%), surgical (11%), medical (9%), neuro (9%)
Intervention: 353,581 patients, 1,414,943 ICU patient days

Huang SS et al. JAMA 2023; 330 (14):1337-47

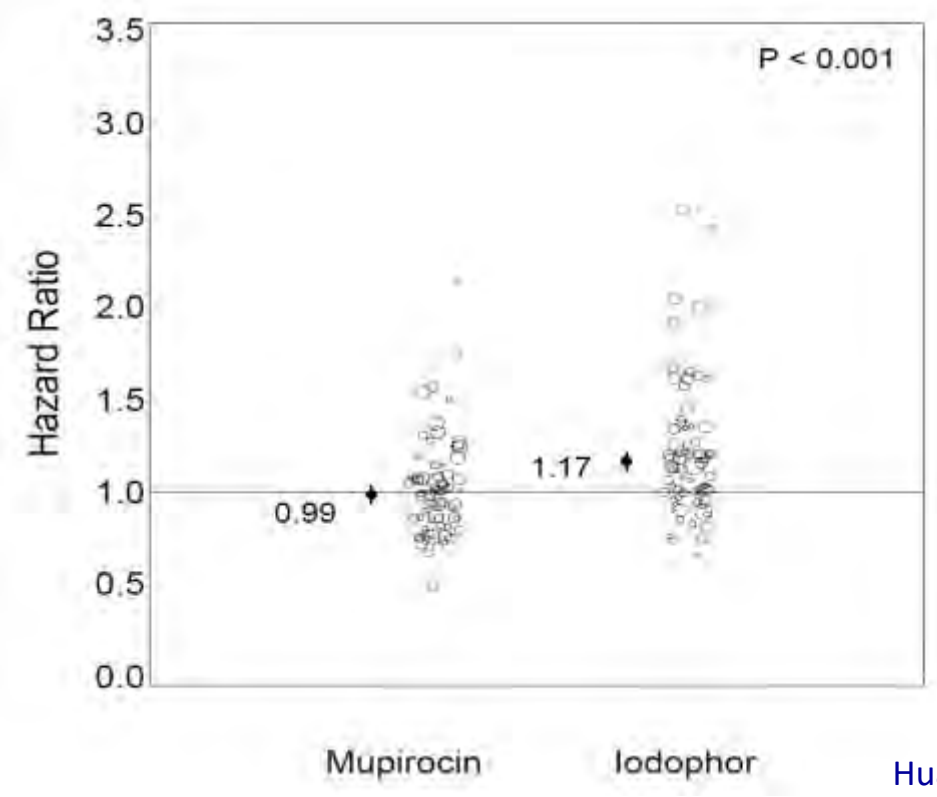
ICU-Attributable *S. aureus* Clinical Cultures As Randomized: Crude Event Rates



Provided rates are crude rates summed across all participating hospitals. Patient-days after each event were excluded

Huang SS et al. JAMA 2023; 330 (14):1337-47

ICU-Attributable *S. aureus* Clinical Cultures As Randomized Clustered Analysis



As Randomized Conclusion:

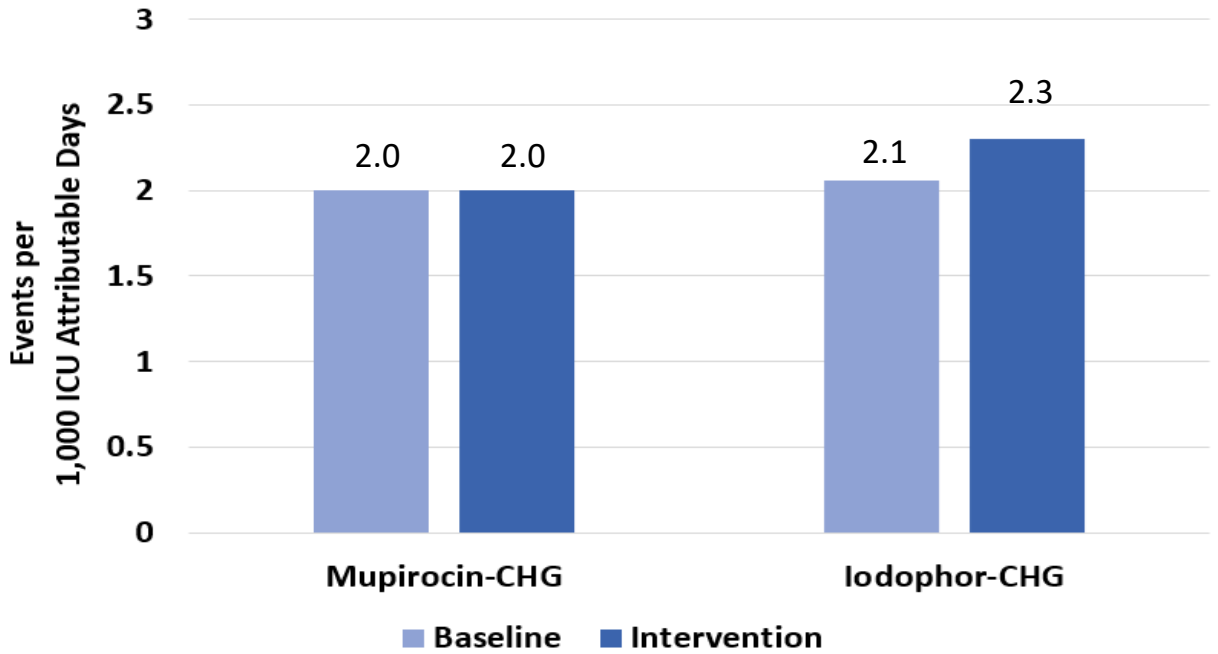
Mupirocin superior to iodophor

18% fewer *S. aureus* cultures

P<0.001

Huang SS et al. JAMA 2023; 330 (14):1337-47

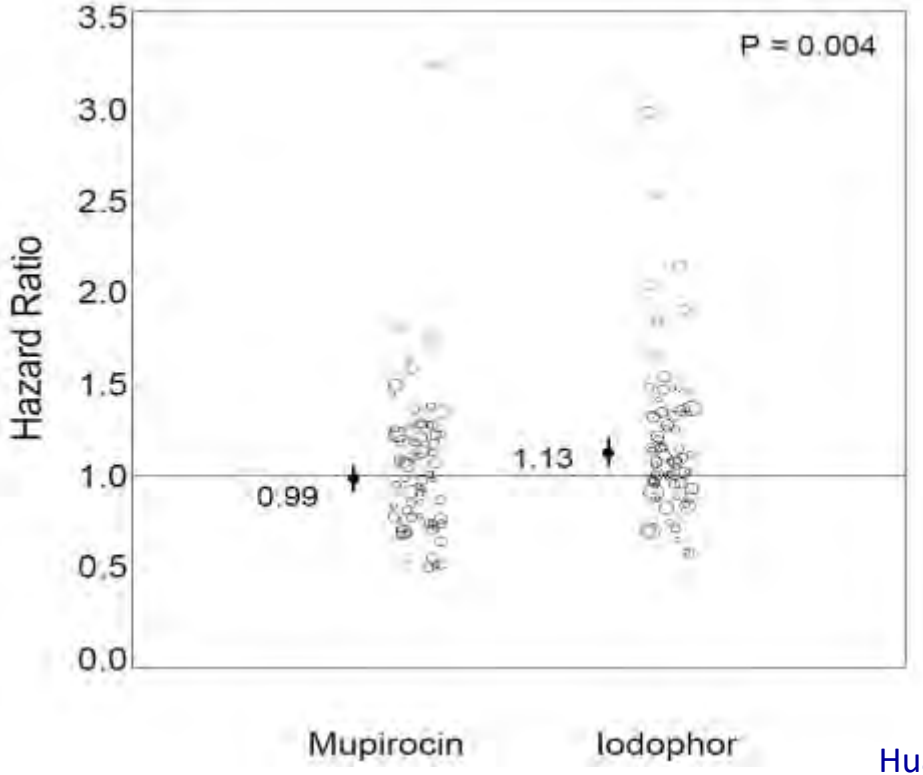
ICU-Attributable MRSA Clinical Cultures As Randomized Crude Event Rates



Provided rates are crude rates summed across all participating hospitals. Patient-days after each event were excluded

Huang SS et al. JAMA 2023; 330 (14):1337-47

ICU-Attributable MRSA Clinical Cultures As Randomized Clustered Analysis



As Randomized Conclusion:

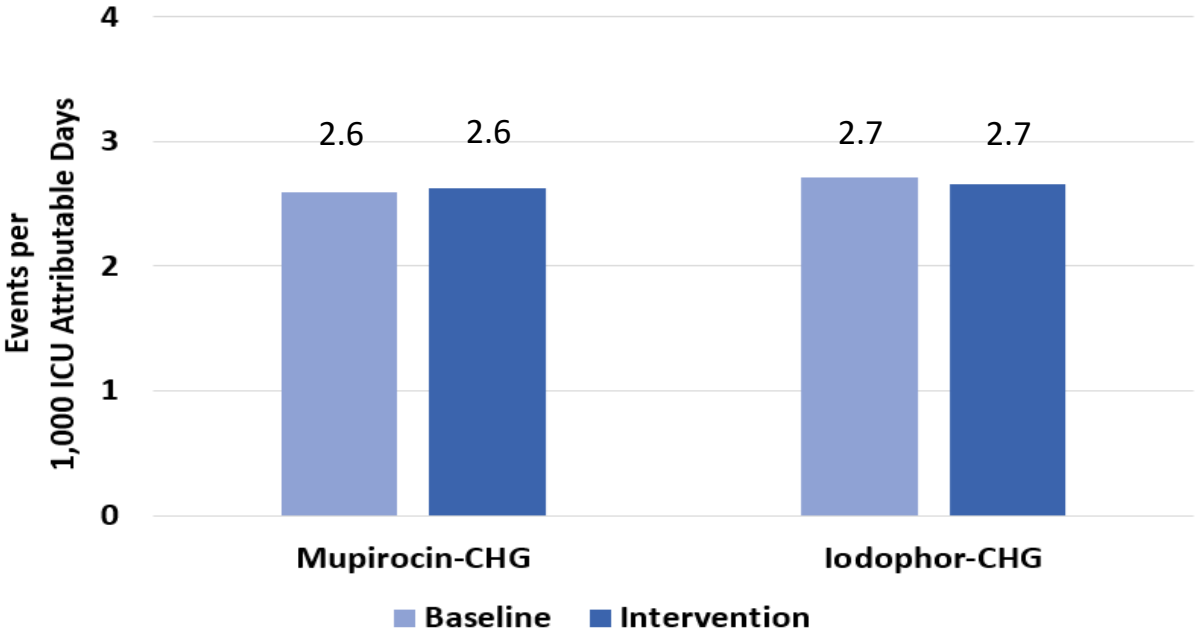
Mupirocin superior to iodophor

14% fewer MRSA cultures

P<0.004

Huang SS et al. JAMA 2023; 330 (14):1337-47

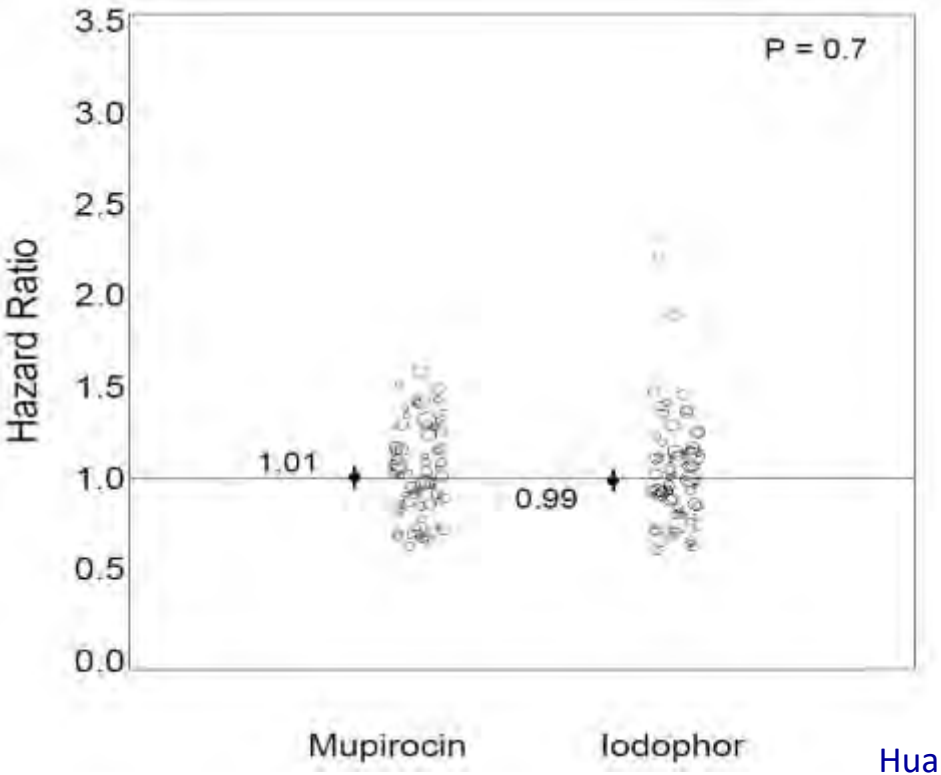
ICU-Attributable Bloodstream Infections As Randomized Crude Event Rates



Provided rates are crude rates summed across all participating hospitals. Patient-days after each event were excluded

Huang SS et al. JAMA 2023; 330 (14):1337-47

ICU-Attributable Bloodstream Infections As Randomized Clustered Analysis



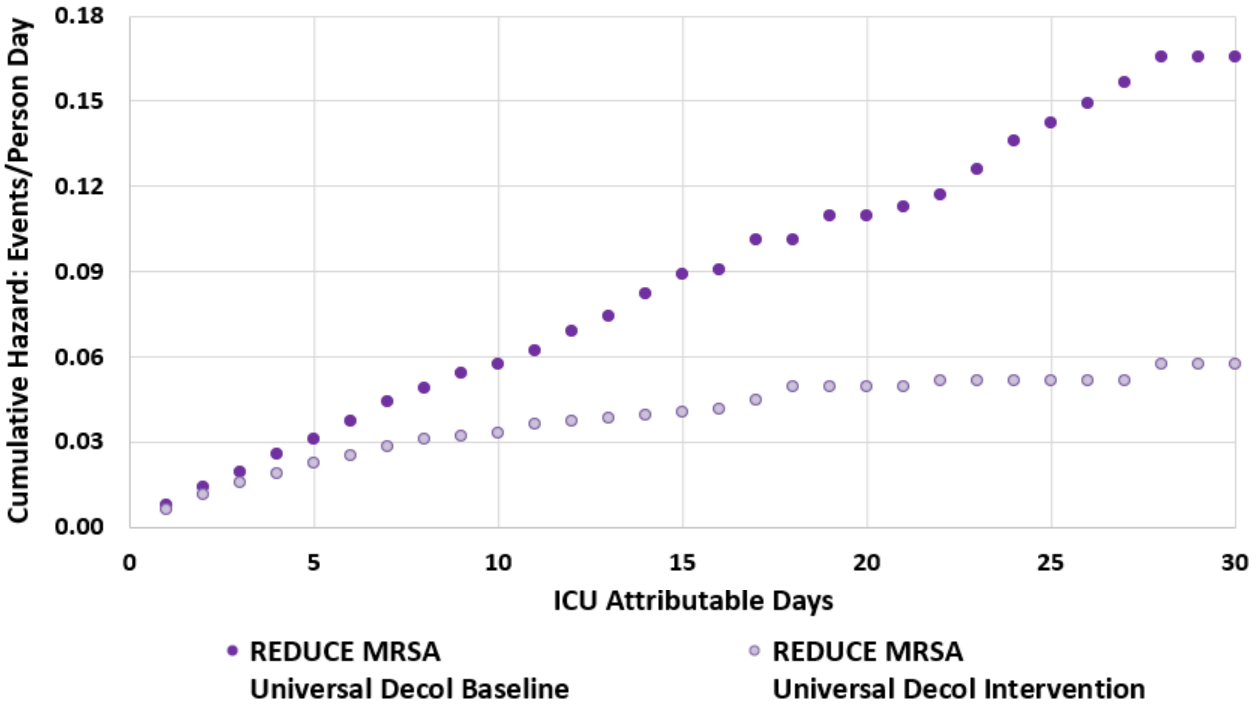
As Randomized Conclusion:

Iodophor non-inferior to mupirocin

P=0.7

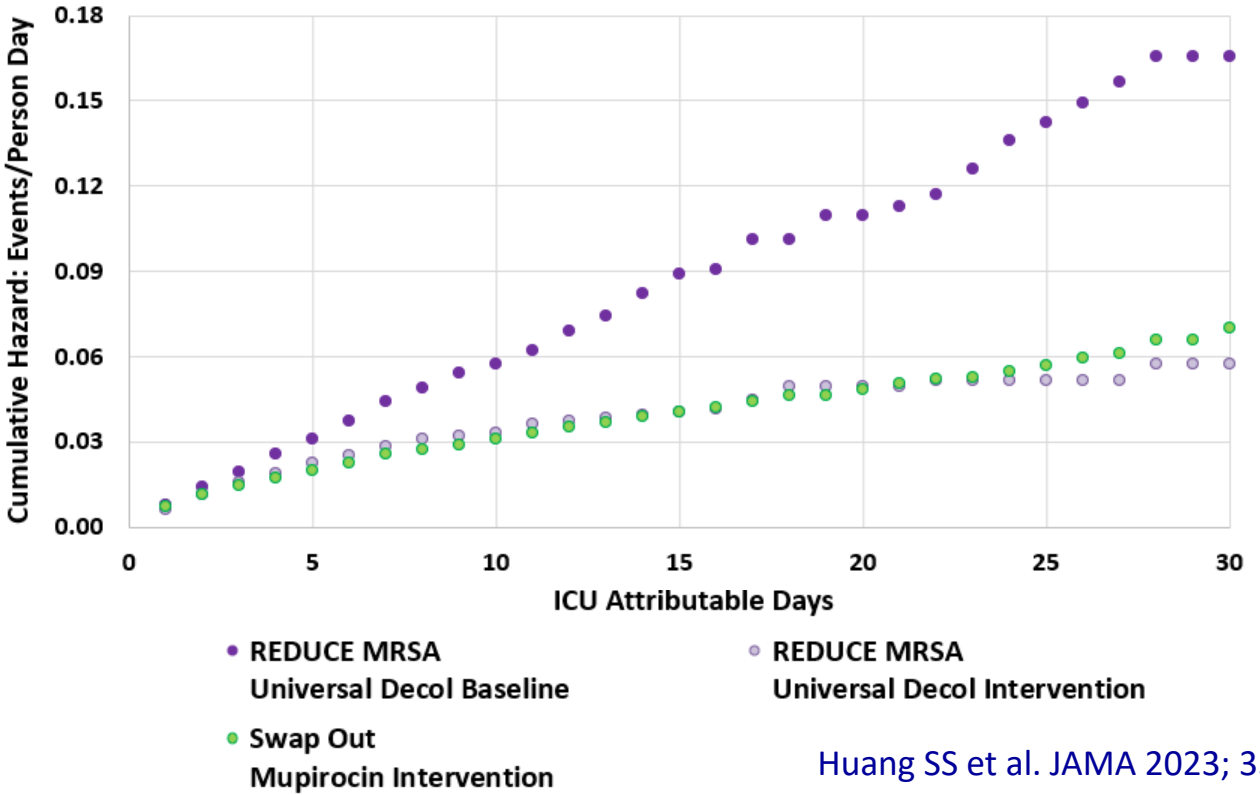
Huang SS et al. JAMA 2023; 330 (14):1337-47

REDUCE MRSA & Swap Out Trials
Cumulative Hazard of *S. aureus* Clinical Cultures



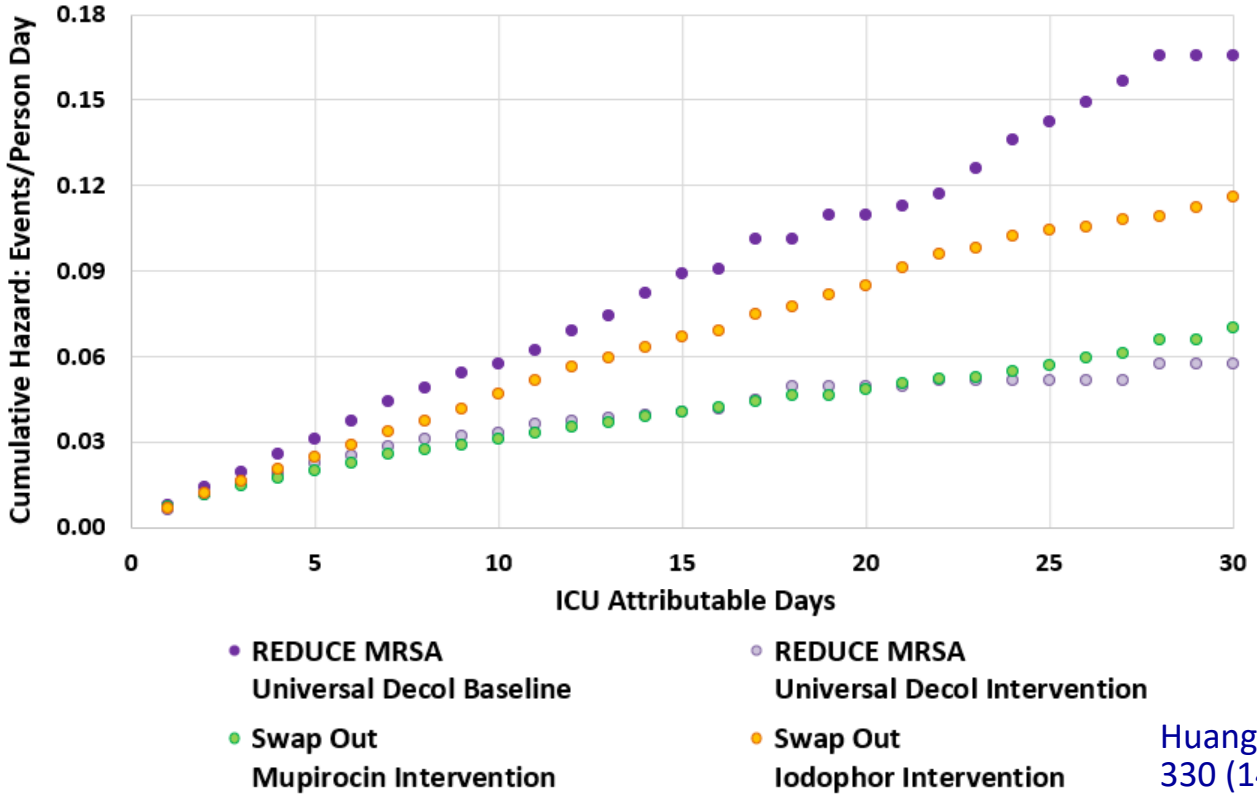
Huang SS et al. JAMA 2023; 330 (14):1337-47

REDUCE MRSA & Swap Out Trials
Cumulative Hazard of *S. aureus* Clinical Cultures



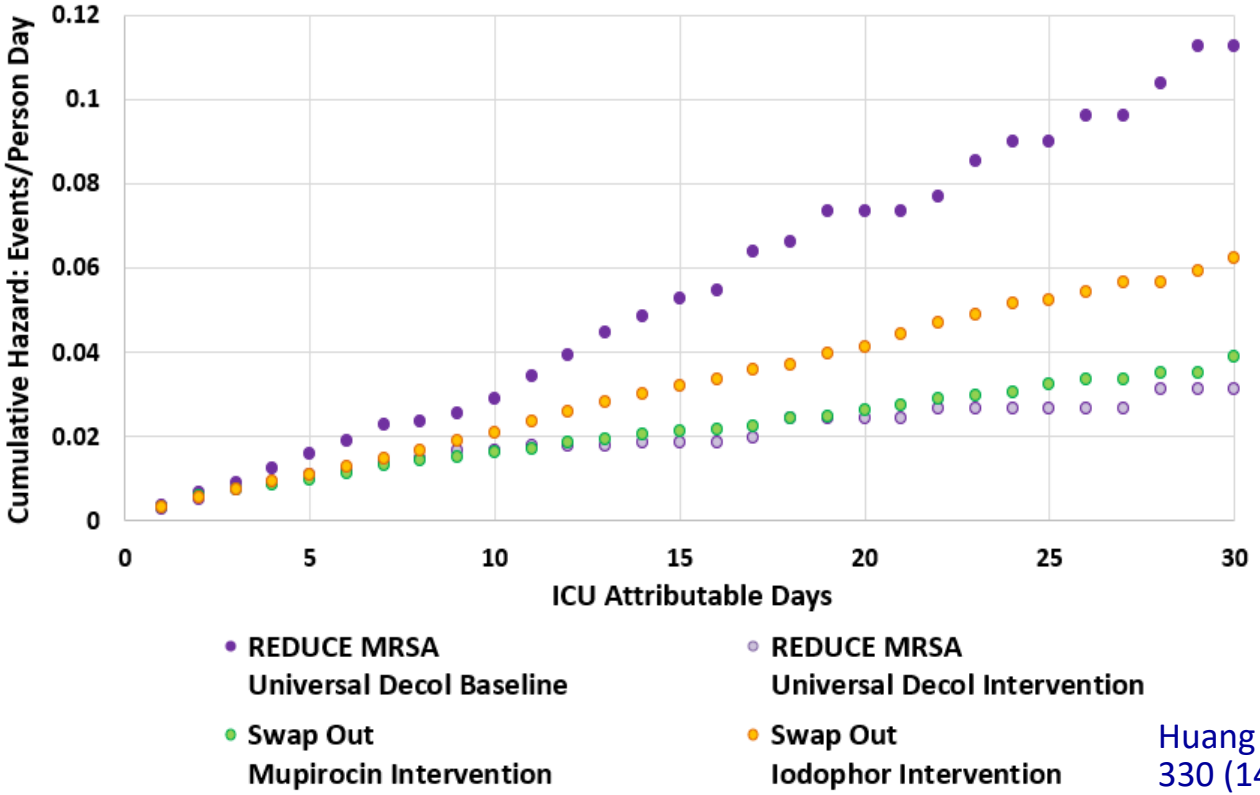
Huang SS et al. JAMA 2023; 330 (14):1337-47

REDUCE MRSA & Swap Out Trials
Cumulative Hazard of *S. aureus* Clinical Cultures



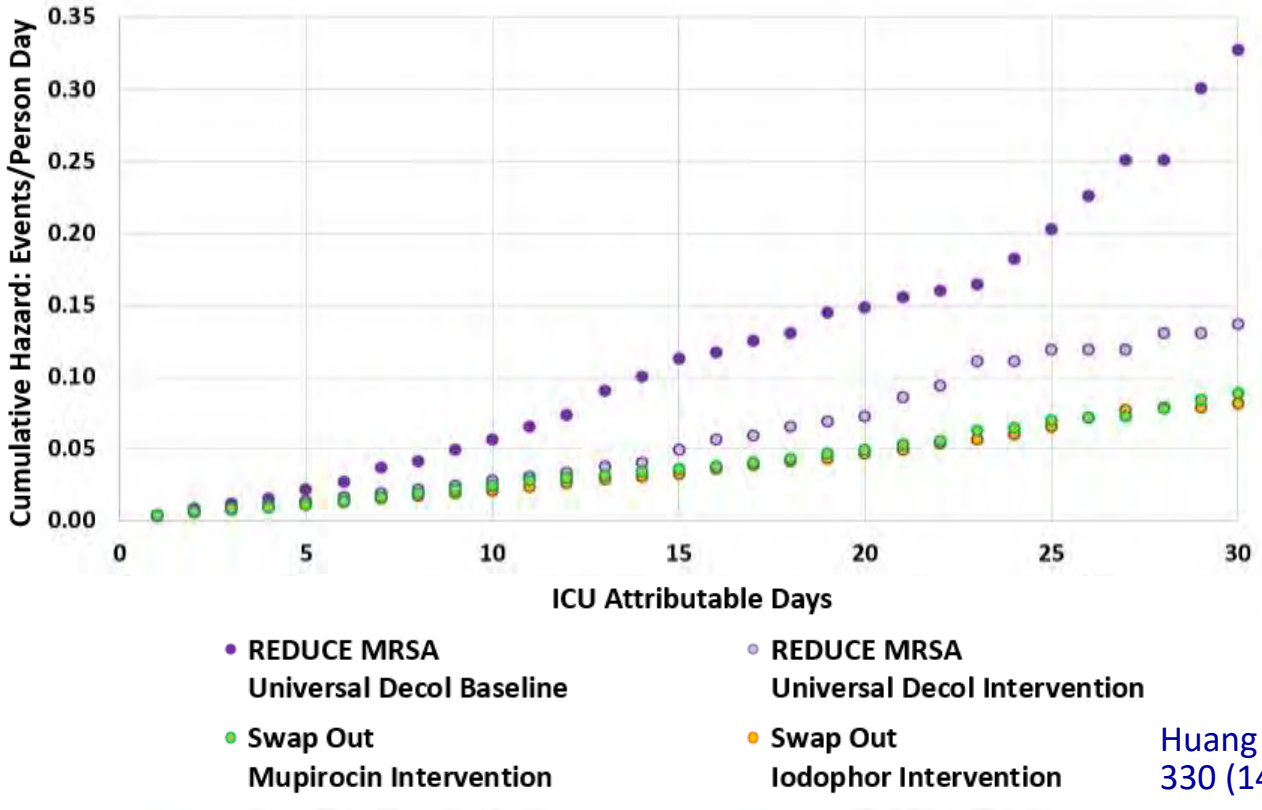
Huang SS et al. JAMA 2023
330 (14):1337-47

REDUCE MRSA & Swap Out Trials
Cumulative Hazard of MRSA Clinical Cultures



Huang SS et al. JAMA 2023
330 (14):1337-47

REDUCE MRSA & Swap Out Trials
Cumulative Hazard of Bloodstream Infection



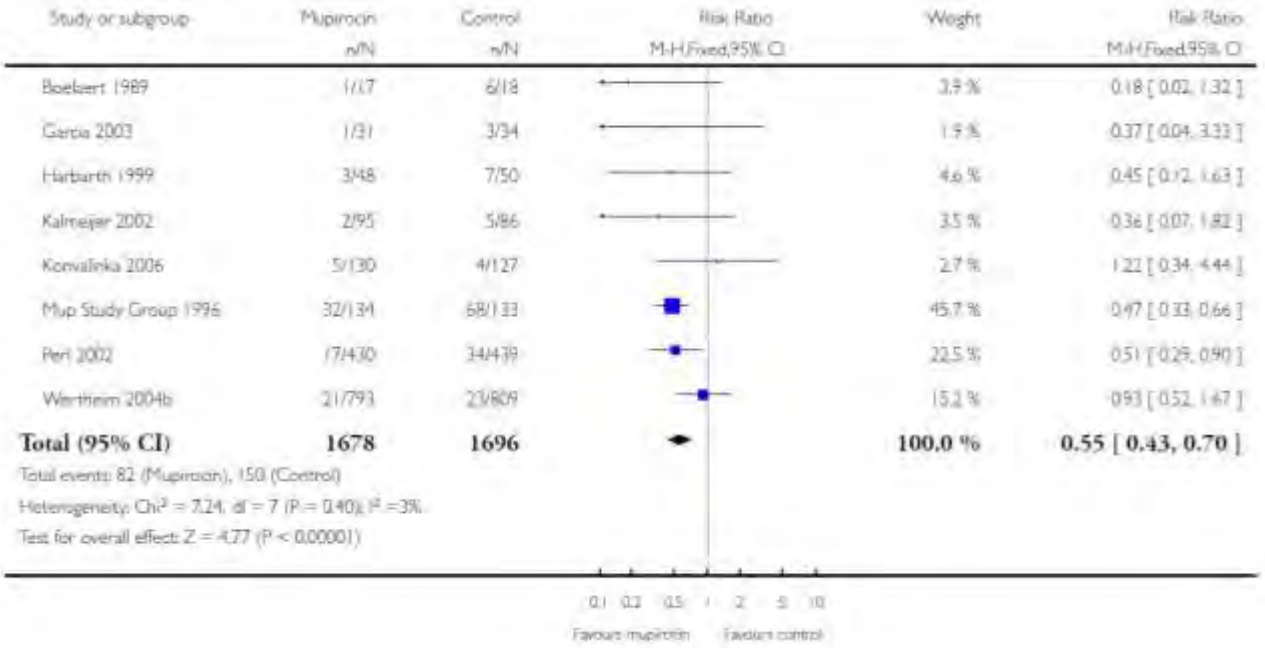
Huang SS et al. JAMA 2023
330 (14):1337-47

Importance of ICU Nasal Decolonization for MRSA

- *S. aureus* remains a formidable pathogen in ICUs
- Superiority of mupirocin over iodophor supports value of nasal decolonization
- Iodophor is superior to no nasal decolonization. May be preferred if mupirocin resistance is high or prescription logistics are problematic
- Mupirocin-CHG effect in reducing *S. aureus,* MRSA, and bloodstream infections persisted over 10 years, suggesting minimal emergence of resistance

Mupirocin Alone Works

45% ⬇ nosocomial MRSA infection among treated carriers



van Rijen M et al. Cochrane DSR. 2008;(4):CD006216

Role of CHG for MRSA and Disease Prevention

- As solo agent, CHG
  - Does not sufficiently clear MRSA for individual carriers [1-2]
  - Does reduce skin burden and transmission to others
  - Is active against other MDROs and pathogens

[1] Harbarth et al. AACT 1999:43(6):1412-16
[2] Fritz et al. ICHE 2011:32(9):872-80

Decolonization Beyond the Hospital

- Individual randomized clinical trial
- MRSA+ patients on hospital discharge
- Education vs decolonization
- Follow up for 1 year for infection

Huang SS NEJM 2019; 380(7):638-650

Post-Discharge MRSA Infection Risk

Figure 1. Distribution of Weeks Between Previous Hospitalization and Current Admission Date, Stratified by Long-term Care Facility Residence

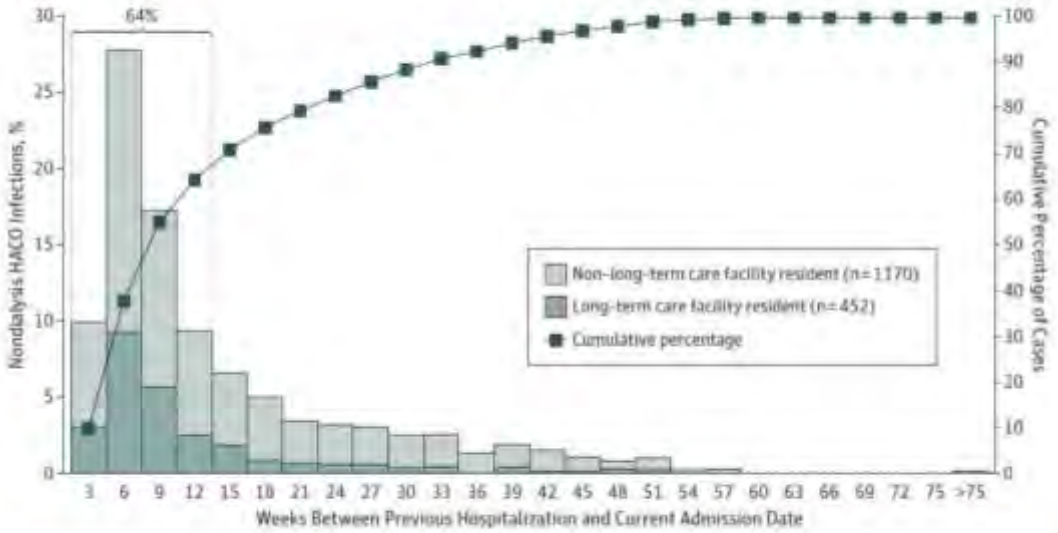


Table 3. National Estimated Incidence and Mortality of Invasive MRSA Infections,[a] United States, 2005 and 2011

Dantes et al. JAMA Int Med 2013;173(21):1970-8

Project CLEAR Trial

- **2,121 inpatients, ~535,000 days of follow up**
- **Two Arms**
  - Arm 1: Hygienic Education
  - Arm 2: Hygienic Education + Repeated Decolonization
- **Inclusion Criteria**
  - ≥18 years old
  - Hospitalized within the past 30 days
  - MRSA+ culture within 30 days of hospitalization

Huang SS NEJM 2019; 380(7):638-650

Serial Decolonization

- 5-day regimen twice monthly for 6 months
  - Twice daily 2% nasal mupirocin
  - Twice daily 0.12% chlorhexidine oral rinse
  - Daily 4% rinse-off chlorhexidine bath/shower
- 1 Year follow up
  - Body swabs and surveys
  - Months 1, 3, 6, 9 post-recruitment
  - Phone exit survey at month 12

Huang SS NEJM 2019; 380(7):638-650

Project CLEAR Outcomes

- **Primary Outcome**
  - Time until MRSA infection (CDC criteria)
- **Secondary Outcomes**
  - Time to any infection (CDC criteria)
  - Time to MRSA infection (ID clinical judgment)
  - Time to any infection (ID clinical judgment)

- Blinded assessment of 8,000+ redacted records
- Each chart reviewed by two ID physicians

Huang SS NEJM 2019; 380(7):638-650

Types of Infection
CDC-Defined MRSA Infection

	Education N (%)	Decolonization N (%)
N (first per person)	98	67
Skin and Soft Tissue	34 (35%)	32 (48%)
Pneumonia	18 (18%)	9 (13%)
Primary Blood/Vascular	13 (13%)	10 (15%)
Bone and Joint Infection	13 (13%)	9 (13%)
Surgical Site Infection	13 (13%)	2 (3%)
Other	7 (7%)	5 (7%)
Involving Bacteremia	28 (29%)	19 (28%)
Requiring Hospitalization	83 (85%)	57 (85%)
Time to Infection, Mean (SD)	110.6 (91.1)	117.3 (93.4)

Huang SS NEJM 2019; 380(7):638-650

Types of Infection
CDC-Defined All-Cause Infection

	Education N (%)	Decolonization N (%)
N (first per person)	252	207
Skin and Soft Tissue	80 (32%)	59 (29%)
UTI	38 (15%)	46 (22%)
Pneumonia	39 (15%)	25 (12%)
Primary Blood/Vascular	20 (8%)	14 (7%)
Bone and Joint Infection	20 (8%)	14 (7%)
Surgical Site Infection	20 (8%)	8 (4%)
GI Infection	20 (8%)	21 (10%)
Involving Bacteremia	46 (18%)	37 (18%)
Requiring Hospitalization	225 (89%)	169 (82%)
Time to Infection (Mean)	103.3 (87.3)	109.6 (90.5)

Time to Infection Outcomes, Unadjusted

	Hazard Ratio (95% CI) Decolonization vs Education	P-value
CDC NHSN Criteria		
MRSA Infection*	0.70 (0.52-0.96)	0.026
Any Infection	0.84 (0.70-1.01)	0.061
Clinical Criteria**		
MRSA Infection	0.71 (0.52-0.97)	0.031
Any Infection	0.83 (0.70-0.99)	0.035

* Primary Outcome, main unadjusted analysis
Proportional hazards model assumption met

** Blinded assessment by 2 ID physicians, redacted records

Huang SS NEJM 2019; 380(7):638-650

Primary Outcome, by Adherence
Time to CDC-Defined Infection

- Adherence measured at each visit, time-varying covariate
- Cox proportional hazards model

Adherence Relative to Education	*MRSA Infection*		*All-Cause Infection*	
	Est. HR (95% CI)	*P-value*	*Est. HR (95% CI)*	*P-value*
- Education	1.0		1.0	
- None	1.31 (0.72,2.38)	0.383	1.68 (1.19,2.36)	0.003
- Partial	0.64 (0.40,1.00)	0.050	0.86 (0.67,1.11)	0.241
- Full	0.56 (0.36,0.86)	0.009	0.60 (0.46,0.78)	<.001

- Non-adherent subjects fared worse than the average control
- Fully adherent subjects had 44% reduction in MRSA infection and 40% reduction in all-cause infections

Huang SS NEJM 2019; 380(7):638-650

Number Needed to Treat

	Overall	Full Adherence
MRSA Infection	30	26
MRSA Hospitalization	34	27
Any Infection	26	11
Hospitalization due to Infection	28	12

Huang SS NEJM 2019; 380(7):638-650

Decolonization in Long-Term Care

The Rise of MultiDrug-Resistant Organisms (MDROs)

- Methicillin Resistant *Staphylococcus aureus* (MRSA)
- Vancomycin Resistant Enterococcus (VRE)
- MultiDrug-Resistant Pseudomonas
- Extended Spectrum Beta Lactamase Producers (ESBLs)
- Carbapenem Resistant Enterobacterales (CRE)
- Carbapenem Resistant *Acinetobacter baumanii* (CRAB)
- *Candida auris*

10-15% of hospital patients harbor at least one of the above

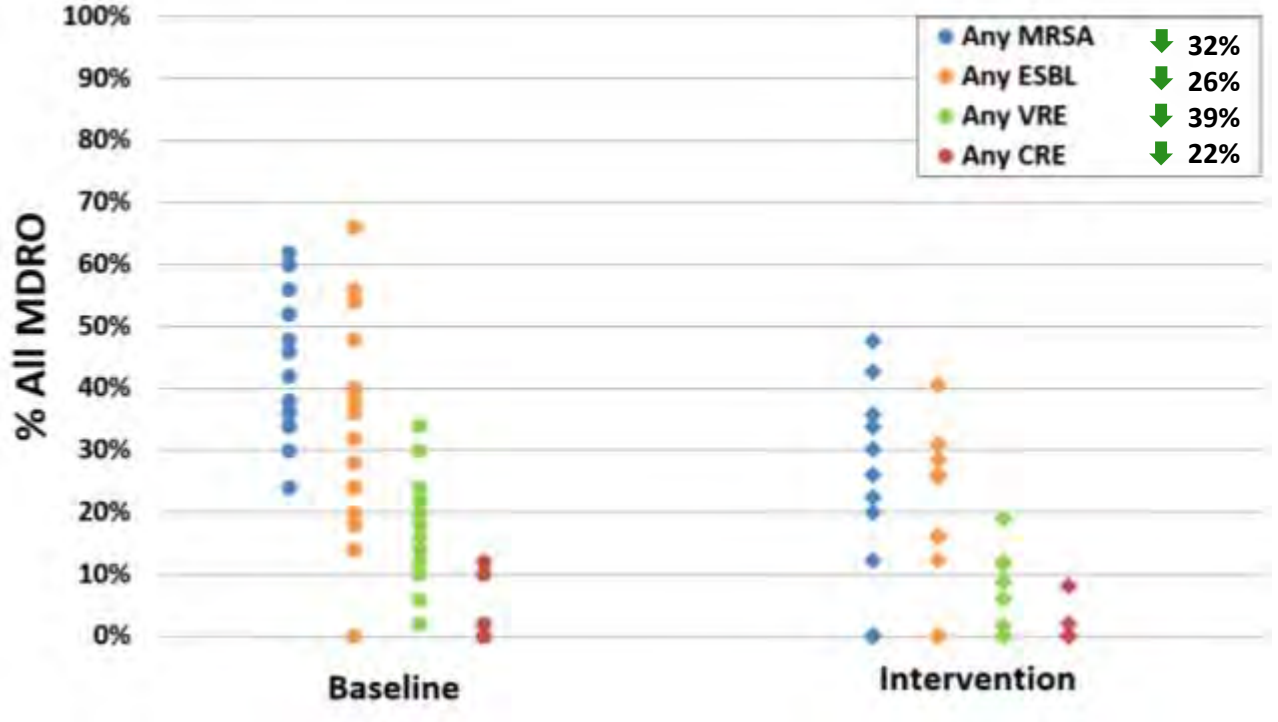
64% of nursing home residents harbor at least one of the above

SHIELD OC: 35 Facility Regional Decolonization

- **28-month regional intervention:** April 2017-July 2019
- **Participants:** 16 nursing homes (NHs), 3 long-term acute care hospitals (LTACHs), 16 hospitals with high patient sharing in Orange County, CA
- **NHs and LTACHs:** universal decolonization
  - ✓ Chlorhexidine (CHG) antiseptic soap for routine bathing/showering
  - ✓ Nasal iodophor for 5d on admission and every other week
- **Hospitals:** decolonize patients on contact precautions
  - ✓ Daily CHG bathing/showering
  - ✓ Nasal iodophor decolonization for 5 days
  - ✓ Support ongoing ICU CHG daily bathing

Gussin G et al. JAMA Online ahead of print. April 1, 2024

Nursing Home Impact: 23% MDRO Reduction



Gussin G et al. JAMA Online ahead of print. April 1, 2024

Figure 1. MDRO Point Prevalence (Screening) Among Facilities Participating in the Regional Decolonization Collaborative, Baseline and End of Intervention

Colonization	Baseline		Intervention		OR (95% CI)	P value
	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %		
Nursing homes						
Any MDRO	511	63.9 (12.2)	709	49.9 (11.3)	0.77 (0.69-0.86)	<.001
Nares	236	29.5 (7.3)	360	25.1 (8.6)	0.84 (0.71-0.99)	.04
Axilla or groin	370	46.3 (13.7)	337	24.7 (8.0)	0.51 (0.44-0.60)	<.001
Perirectal	412	51.5 (13.5)	473	34.1 (11.1)	0.65 (0.57-0.74)	<.001
Any MRSA	343	42.9 (11.2)	422	29.8 (9.3)	0.68 (0.59-0.79)	<.001
Nares	236	29.5 (7.3)	360	25.1 (8.6)	0.84 (0.71-0.99)	.04
Axilla or groin	247	30.9 (10.5)	176	13.1 (6.5)	0.40 (0.33-0.49)	<.001
Perirectal	207	25.9 (9.2)	142	10.8 (5.5)	0.39 (0.31-0.48)	<.001
Any VRE	125	15.6 (7.6)	134	9.4 (6.7)	0.61 (0.48-0.78)	.001
Axilla or groin	68	8.5 (5.4)	37	2.7 (3.3)	0.32 (0.21-0.48)	<.001
Perirectal	114	14.3 (7.8)	120	8.4 (5.8)	0.60 (0.47-0.78)	.002
Any ESBL	269	33.6 (17.2)	356	25.5 (10.5)	0.74 (0.63-0.87)	.003
Axilla or groin	167	20.9 (12.0)	163	12.1 (6.1)	0.55 (0.44-0.68)	<.001
Perirectal	248	31.0 (16.5)	310	22.3 (9.5)	0.70 (0.59-0.83)	<.001
Any CRE	17	2.1 (4.3)	22	1.6 (2.8)	0.78 (0.41-1.47)	.44
Axilla or groin	12	1.5 (3.5)	16	1.1 (2.0)	0.79 (0.37-1.68)	.54
Perirectal	8	1.0 (2.1)	11	0.9 (1.5)	0.83 (0.33-2.09)	.70

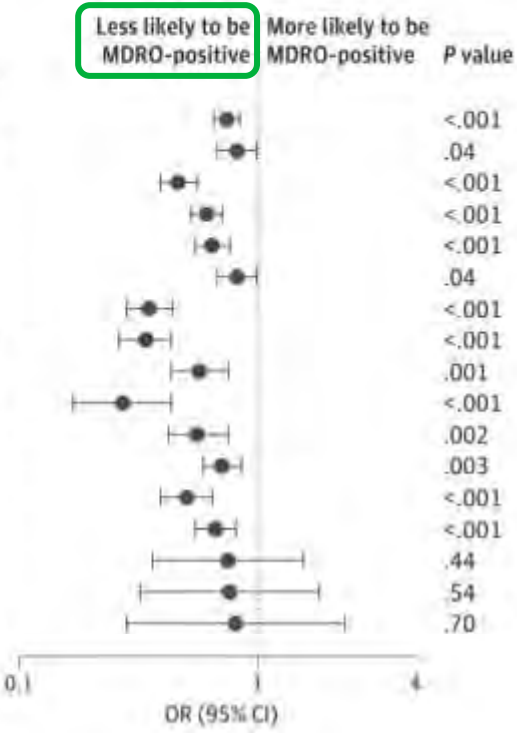


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Figure 1. MDRO Point Prevalence (Screening) Among Facilities Participating in the Regional Decolonization Collaborative, Baseline and End of Intervention

Colonization	Baseline		Intervention		OR (95% CI)	P value
	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %		
Long-term acute care facilities						
Any MDRO	120	80.0 (7.2)	80	53.3 (13.3)	0.67 (0.50-0.89)	.01
Nares	35	23.3 (9.5)	25	16.7 (8.3)	0.71 (0.43-1.20)	.20
Axilla or groin	91	60.7 (9.0)	36	24.0 (6.0)	0.40 (0.27-0.58)	<.001
Perirectal	109	72.7 (9.5)	68	45.3 (12.9)	0.62 (0.46-0.85)	.003
Any MRSA	49	32.7 (8.3)	30	20.0 (10.6)	0.61 (0.39-0.97)	.04
Nares	35	23.3 (9.5)	25	16.7 (8.3)	0.71 (0.43-1.20)	.20
Axilla or groin	25	16.7 (3.1)	12	8.0 (2.0)	0.48 (0.24-0.96)	.04
Perirectal	28	18.7 (11.0)	11	7.3 (7.6)	0.39 (0.20-0.79)	.01
Any VRE	83	55.3 (5.0)	38	25.3 (10.1)	0.46 (0.31-0.67)	<.001
Axilla or groin	55	36.7 (6.4)	13	8.7 (3.1)	0.24 (0.13-0.43)	<.001
Perirectal	78	52.0 (5.3)	38	25.3 (10.1)	0.49 (0.33-0.72)	<.001
Any ESBL	58	38.7 (9.0)	39	26.0 (10.4)	0.67 (0.45-1.01)	.06
Axilla or groin	40	26.7 (5.8)	18	12.0 (3.5)	0.45 (0.26-0.79)	.01
Perirectal	52	34.7 (8.1)	34	22.7 (11.7)	0.65 (0.42-1.01)	.06
Any CRE	13	8.7 (1.2)	10	6.7 (3.1)	0.77 (0.34-1.76)	.53
Axilla or groin	11	7.3 (1.2)	5	3.3 (3.1)	0.45 (0.16-1.31)	.14
Perirectal	11	7.3 (1.2)	10	6.7 (3.1)	0.91 (0.38-2.15)	.83

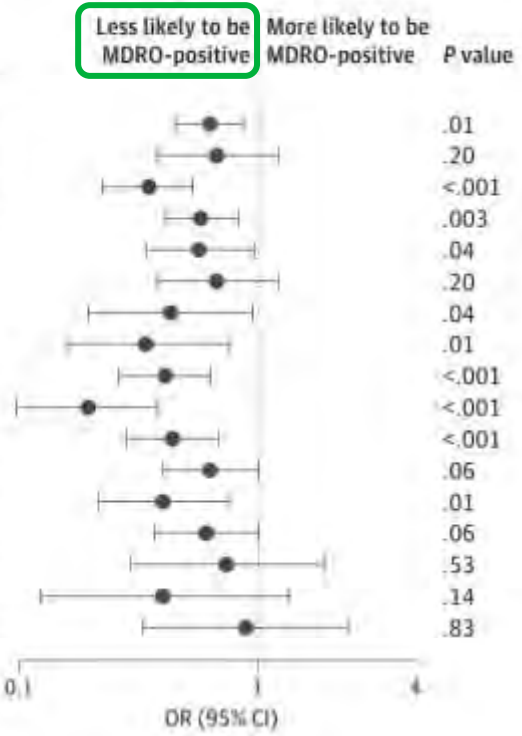

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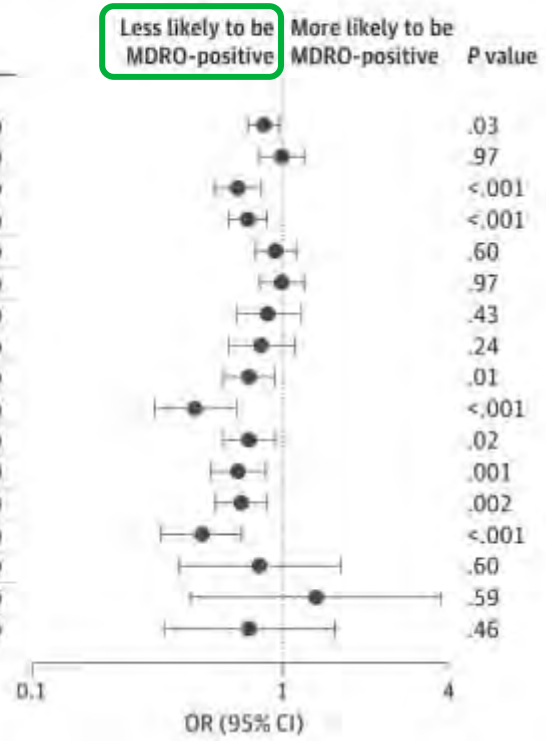
Figure 1. MDRO Point Prevalence (Screening) Among Facilities Participating in the Regional Decolonization Collaborative, Baseline and End of Intervention

Colonization	Baseline		Intervention		OR (95% CI)	P value
	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %	No. of MDRO-positive persons	Mean (SD) prevalence across facilities, %		
Hospitals with patients in contact precautions						
Any MDRO	474	64.1 (8.5)	409	55.4 (13.8)	0.86 (0.75-0.98)	.03
Nares	221	29.9 (6.5)	220	29.7 (10.9)	1.00 (0.83-1.21)	.97
Axilla or groin	242	32.9 (10.8)	167	22.5 (14.1)	0.69 (0.57-0.84)	<.001
Perirectal	363	49.2 (9.0)	273	37.2 (13.2)	0.75 (0.64-0.88)	<.001
Any MRSA	265	35.9 (7.6)	252	34.2 (13.3)	0.95 (0.80-1.13)	.60
Nares	221	29.9 (6.5)	220	29.7 (10.9)	1.00 (0.83-1.21)	.97
Axilla or groin	104	14.1 (7.5)	93	12.8 (11.0)	0.89 (0.68-1.18)	.43
Perirectal	105	14.3 (6.7)	88	12.1 (9.2)	0.84 (0.64-1.12)	.24
Any VRE	185	25.1 (7.1)	141	19.3 (11.9)	0.76 (0.61-0.94)	.01
Axilla or groin	101	13.8 (6.6)	49	6.7 (5.9)	0.48 (0.34-0.68)	<.001
Perirectal	175	23.8 (6.7)	134	18.4 (11.6)	0.76 (0.61-0.95)	.02
Any ESBL	202	27.3 (6.8)	143	19.3 (6.0)	0.69 (0.55-0.87)	.001
Axilla or groin	97	13.1 (5.9)	49	6.7 (3.4)	0.71 (0.57-0.88)	.002
Perirectal	181	24.5 (5.5)	125	16.9 (6.6)	0.51 (0.36-0.71)	<.001
Any CRE	18	2.4 (2.3)	15	2.1 (3.0)	0.83 (0.42-1.65)	.60
Axilla or groin	6	0.8 (1.3)	8	1.1 (1.6)	1.34 (0.46-3.86)	.59
Perirectal	17	2.3 (2.0)	13	1.8 (2.5)	0.76 (0.37-1.57)	.46



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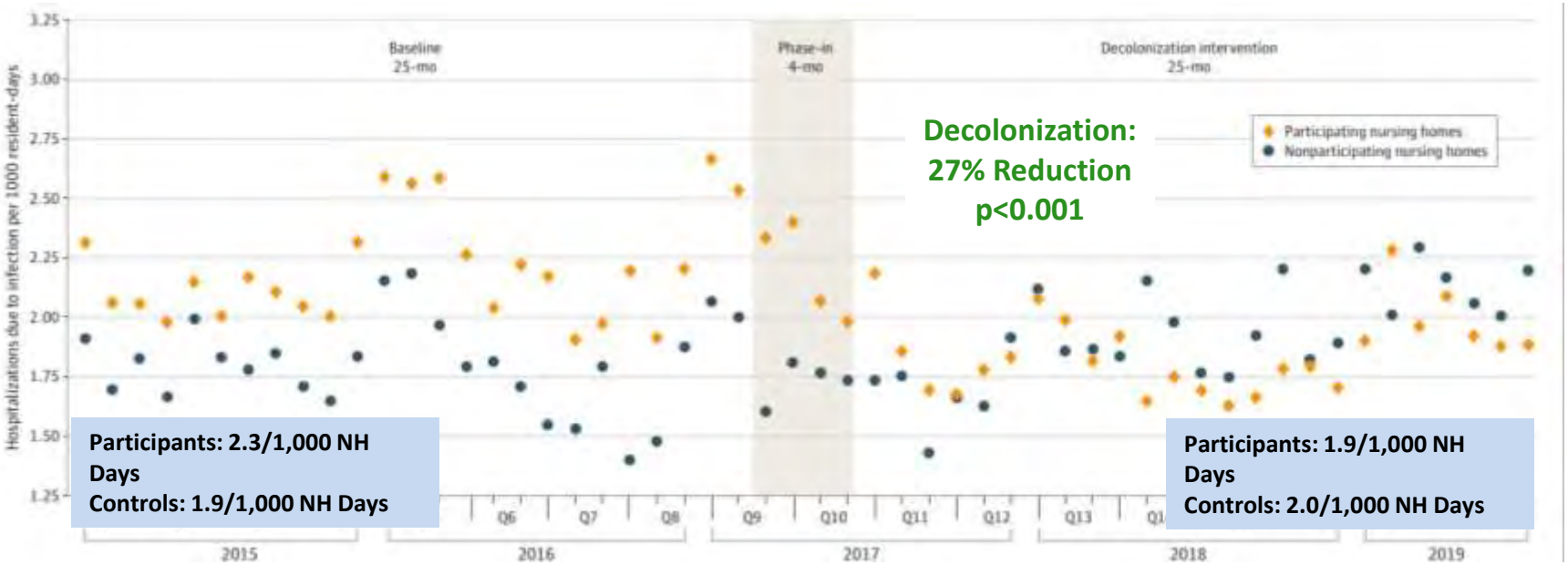
Impact: NH Hospitalizations Due to Infection

Figure 5. Monthly Infection-Related Hospitalization Rates Among Nursing Homes Residents in Participating (Decolonization) vs Nonparticipating Nursing Homes



Decolonization:
27% Reduction
p<0.001

Participants: 2.3/1,000 NH Days
Controls: 1.9/1,000 NH Days

Participants: 1.9/1,000 NH Days
Controls: 2.0/1,000 NH Days

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NH Hospitalization-Related Costs & Deaths

Costs Associated with Infection-Related Hospitalization					
Decolonization Group	Costs per 1,000 Resident Days		Adjusted Analysis [b]		
			Clustered Cost Ratio	Group-By-Period Interaction Effect	
	Baseline	Intervention		% Reduction (95% CI)	P-value
Participant	$64,651	$55,149	0.96	-26.8% (-26.7, -26.9)	<0.001
Non-Participant	$55,151	$59,327	1.31		

Deaths Associated with Infection-Related Hospitalization					
Decolonization Group	Events per 1,000 Resident Days		Adjusted Analysis [b]		
			Clustered Hazard Ratio	Group-By-Period Interaction Effect	
	Baseline	Intervention		% Reduction (95% CI)	P-value
Participant	0.29	0.25	0.62	-23.7% (-4.5, -43.0)	0.006
Non-Participant	0.23	0.24	0.81		

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The Protect Trial

Pragmatic Trial

- 28 nursing homes
- Involved nearly 14,000 residents
- All activities performed by usual nursing home staff

Group 1: Routine Care

- Usual soap for showering/bathing

Group 2: Decolonization

- CHG for all bathing/showering
- Nasal iodophor for all residents, M-F twice daily, every other week

Miller LG et al. NEJM 2023 (Nov 9); 389:1766-1777

CHG for All Routine Bathing and Showering

- Liquid CHG for showering
  - 4% rinse off CHG
- CHG cloths for bed bathing
  - 2% leave on CHG

4% rinse off for shower

2% cloths for bath

Iodophor for Nasal Decolonization

- 10% povidone-iodine swabs (iodophor) to each nostril
- Facility-wide universal strategy
- Twice daily for 5 days
- On admission and M-F every other week

MDRO Carriage Reduction (Skin/Nares)

Table 3. Prevalence of MDRO Carriage during the Baseline Period and near the End of the Intervention Period.*

MDRO or sample	Prevalence in the Routine-Care Group		Prevalence in the Decolonization Group		Risk Ratio (95% CI)†
	Baseline (N=700)	Intervention (N=650)	Baseline (N=700)	Intervention (N=550)	
	percent (number of positive samples)				
Any MDRO	48.3 (338)	47.2 (307)	48.9 (342)	32.0 (176)	0.70 (0.58–0.84)
Any MRSA	37.6 (263)	36.9 (240)	36.4 (255)	25.1 (138)	0.73 (0.59–0.92)
Nostril swab sample	29.1 (203)	27.1 (176)	29.9 (209)	22.0 (121)	0.81 (0.62–1.05)
Skin swab sample	26.1 (183)	25.4 (165)	22.6 (158)	11.6 (64)	0.58 (0.42–0.79)
VRE	5.9 (41)	5.1 (33)	8.3 (58)	2.2 (12)	0.29 (0.14–0.62)
ESBL producer	15.9 (111)	17.9 (116)	16.7 (117)	9.2 (51)	0.50 (0.34–0.75)
CRE	1.4 (10)	0.6 (4)	0.4 (3)	0.4 (3)	3.53 (0.44–28.52)

Miller LG et al. NEJM 2023 (Nov 9); 389:1766-1777

Trial Outcomes

Outcome	Infection-Related Hospitalization	Any Hospitalization
Reason among hospitalizations Reason among discharges	**17% reduction** in infection–related hospitalizations, among hospitalized	**15% reduction** in hospitalizations, among discharged
Per 1,000 Resident Days	**31% reduction** in infection–related hospitalizations per 1,000 resident days	**18% reduction** in hospitalizations per 1,000 resident days
Number Needed to Treat (NNT)	**9.7 residents**	**8.9 residents**

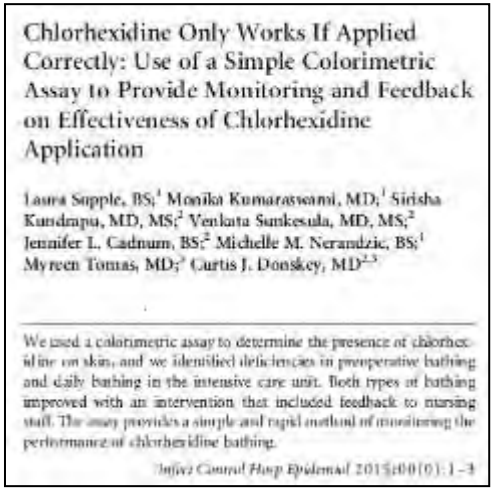
1.9 infection-related hospitalizations averted per month per 100-bed nursing home

Miller LG et al. NEJM 2023 (Nov 9); 389:1766-1777

Training Guides & Ready-to-Use Tools

Decolonization Success Depends on Application

- Lack of training shown to yield no benefit
- Training pearls for CHG
  - Massage firmly
  - Avoid cotton cloths
  - Clean wounds, devices, breaks in skin
  - Check lotion, skin product compatibility
  - 4% rinse-off CHG, 2% leave-on (air dry)



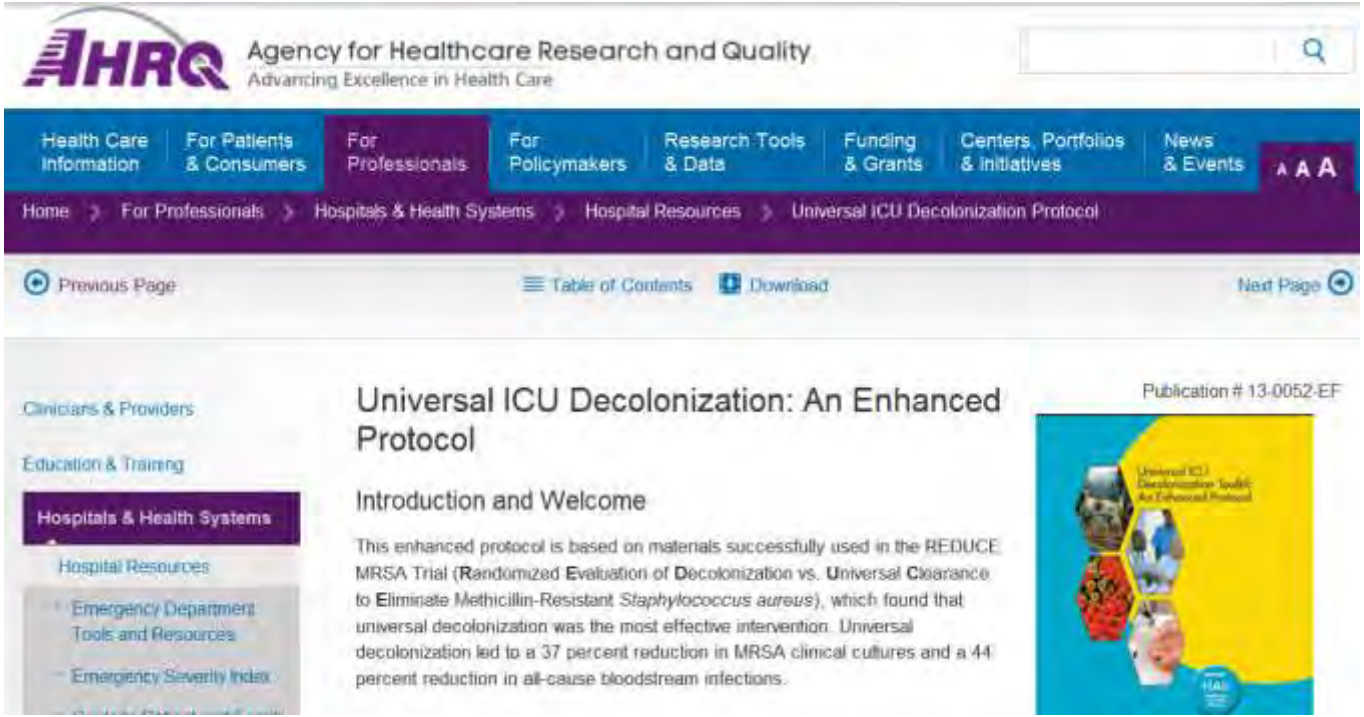
Chlorhexidine Only Works If Applied Correctly: Use of a Simple Colorimetric Assay to Provide Monitoring and Feedback on Effectiveness of Chlorhexidine Application

Laura Supple, BS;[1] Monika Kumaraswami, MD;[1] Sirisha Kundrapu, MD, MS;[2] Venkata Sunkesula, MD, MS;[2] Jennifer L. Cadnum, BS;[2] Michelle M. Nerandzic, BS;[1] Myreen Tomas, MD;[3] Curtis J. Donskey, MD[2,3]

We used a colorimetric assay to determine the presence of chlorhexidine on skin, and we identified deficiencies in preoperative bathing and daily bathing in the intensive care unit. Both types of bathing improved with an intervention that included feedback to nursing staff. The assay provides a simple and rapid method of monitoring the performance of chlorhexidine bathing.

Infect Control Hosp Epidemiol 2015;00(0):1–3

Popovich KJ Int Care Med 2010;36(5):854-8
Supple L ICHE 2015;36(9):1095-7



https://www.ahrq.gov/hai/universal-icu-decolonization/index.html

https://www.ahrq.gov/hai/tools/abate/index.html

SHIELD MDRO Acute & Long-Term Care Toolkits

Is SHIELD Right for You?

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs

The SHIELD intervention is right for you if:

- Your facility is experiencing cultures or infections due to MDROs
- Your facility is worried about MDROs in general
- Your facility is willing to do a campaign to reduce MDROs
- Your facility is interested in the benefits of "decolonization" but needs "how to" help

The SHIELD program is effective against the following organisms:

- CRE: carbapenem-resistant Enterobacteriaceae
- MRSA: methicillin resistant *Staphylococcus aureus*
- VRE: vancomycin-resistant Enterococcus
- ESBL: extended spectrum beta-lactamase producers

Hospital Toolkit | Nursing Home Toolkit | LTACH Toolkit

www.ucihealth.org/shield

Nursing Home Decolonization Toolkit

ucihealth.org/shield

Step 1: Adopt SHIELD program as Quality Assurance Performance Improvement (QAPI)

1. QAPI Project Documentation Form (PDF) (DOC)
2. Universal Plan of Care (PDF) (DOC)
3. Resident Plan of Care (PDF) (DOC)
4. Pre-Launch Checklist for the Infection Preventionist (PDF) (DOC)

Step 2: What to Expect? (PDF) (DOC)

Step 3: Communication to Residents

1. Admission Packet Letter (PDF) (DOC)
2. Resident/Ombudsman Information Sheet (PDF) (DOC

Step 4: Products & Protocols

1. Products (PDF) (DOC)
2. CHG Compatibility (PDF) (DOC)
3. Protocol: Bed Bath With CHG Cloths (PDF) (DOC)
4. Protocol: Bed Bath With CHG Liquid (PDF) (DOC)
5. Protocol: Showering With CHG (PDF) (DOC)
6. Protocol: Nasal Iodophor (PDF) (DOC)
7. Order Set Examples (PDF)
8. Admission – SHIELD Checklist (PDF) (DOC)

Step 5: Staff Education & Training

1. Paper or Computer Based Training (PDF) (PPT)
2. Staff Post-Training Test and Answer Key: Basin Bed Bathing
3. Staff Post-Training Test and Answer Key: CHG Cloths (PDF)
4. Physician and Staff Notification Flyer (PDF) (DOC)
5. Staff Handouts for CHG Bathing/Showering (PDF) (PUB)
6. Staff Handout for Basin Bed Bathing With CHG (PDF) (PUB)
7. Staff Handout for Nasal Iodophor (PDF) (PUB)
8. Staff Huddle Reminder Documents (PDF) (DOC)
9. FAQ: General (PDF) (DOC)
10. FAQ: Nasal Iodophor (PDF) (DOC)
11. FAQ: CHG for Bathing (PDF) (DOC)
12. FAQ: Wound Care (PDF) (DOC)
13. FAQ: Do and Don't (PDF) (DOC)

Step 6: Resident Education & Training

1. Resident Handout for CHG Bed Bath (PDF) (PUB)
2. Resident Handout for CHG Shower (PDF) (PUB)
3. Resident Handout for Nasal Iodophor (PDF) (PUB)
4. Waterproof Shower Poster for Residents (PDF) (DOC)
5. Resident Talking Points: CHG (PDF) (DOC)
6. Resident Talking Points: Iodophor (PDF) (DOC)

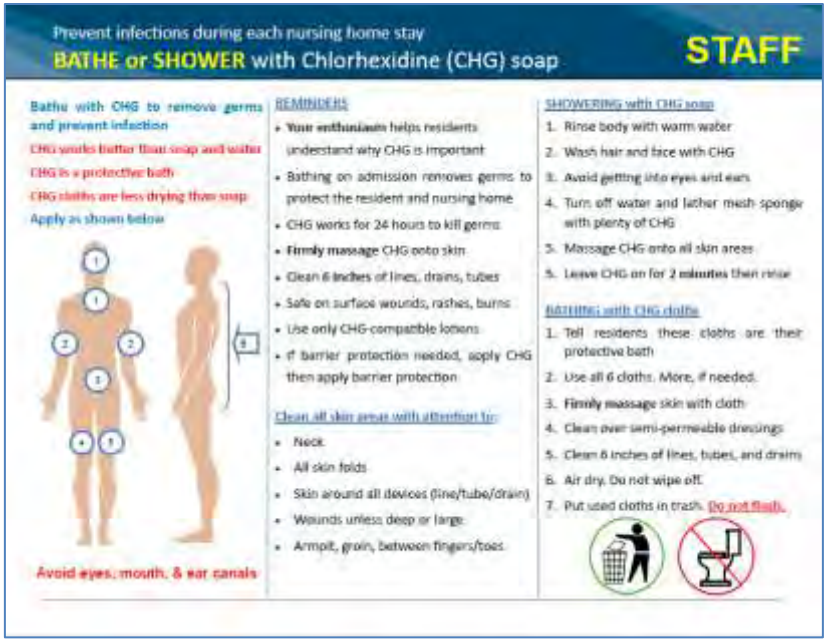
Step 7: Skills Assessments and Compliance Checks

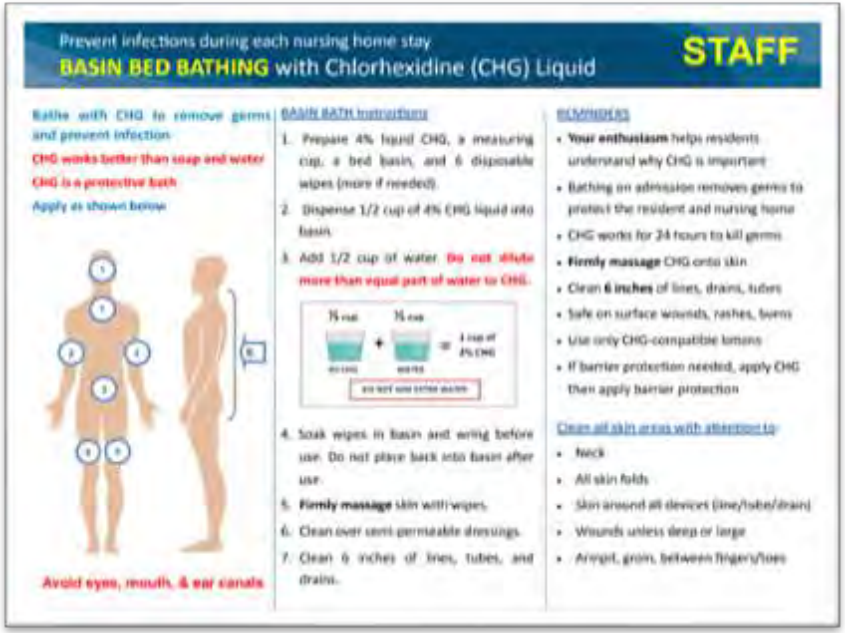
1. CHG Cloth Skills Assessment Checklist (PDF) (DOC)
2. CHG Liquid Bed Bath Skills Assessment Checklist (PDF) (DOC)
3. Resident Self-Showering Assessment (PDF) (DOC)
4. Resident Self-Bed Bath Assessment (PDF) (DOC)

Step 8: Safety and Side Effects

1. Safety and Side Effects (PDF) (DOC)
2. Side Effect Tracking Form (PDF) (DOC)

Staff Decolonization Training

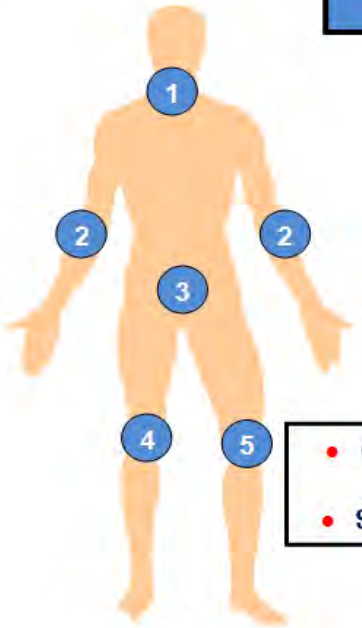




ucihealth.org/shield

Apply Chlorhexidine WITH FIRM MASSAGE to remove bacteria

USE ALL 6 CHG CLOTHS
Avoid EYES & EAR CANAL



FRONT

1. FACE, NECK SHOULDERS & CHEST
2. BOTH ARMS & HANDS
3. ABDOMEN, GROIN & PERINEUM
4. RIGHT LEG & FOOT
5. LEFT LEG & FOOT
6. BACK, THEN BUTTOCKS

BACK

- Clean 6 inches of all tubes, lines, and drains closest to patient with CHG
- Safe on superficial wounds, rash, burns

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

THIS IS a PROTECTIVE BATH
Do not use soap which can inactivate CHG

Decolonization FAQs

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs

Frequently Asked Questions
Chlorhexidine for Bathing

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

What if my resident refuses a bath?

Is it okay for my residents to shave and use deodorant?

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

My resident reports that their skin feels sticky after the bath.

Is it safe to use on the perineum?

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

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

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs

Frequently Asked Questions
Wound Care

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

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

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

For what types of wounds is CHG safe?

Shared
Healthcare
Intervention to
Eliminate
Life-threatening
Dissemination of MDROs

Frequently Asked Questions
Nasal Iodophor

What is the purpose of putting it in the nose?

CHG Cloth Observation Checklist

Please complete for **THREE** different staff **per unit**

Individual Giving CHG Bath

Please indicate who performed the CHG bath.

☐ Nursing Assistant (CNA) ☐ Nurse ☐ Other: _____

Observed CHG Bathing Practices

Please check the appropriate response for each observation.

☐ Y ☐ N Patient received CHG cloth bathing handout
☐ Y ☐ N Patient told that bath is a no rinse cloth that provides protection from germs
☐ Y ☐ N Provided rationale to the patient for not using soap at any time while in unit
☐ Y ☐ N Massaged skin *firmly* with CHG cloth to ensure adequate cleansing
☐ Y ☐ N Cleaned face and neck well
☐ Y ☐ N Cleaned between fingers and toes
☐ Y ☐ N Cleaned between all folds in perineal and gluteal area
☐ Y ☐ N ☐ N/A Cleaned occlusive and semi-permeable dressings with CHG cloth
☐ Y ☐ N ☐ N/A Cleaned 6 inches of all tubes, central lines, and drains closest to body
☐ Y ☐ N ☐ N/A Used CHG on superficial wounds, rash, and stage 1 & 2 decubitus ulcers
☐ Y ☐ N ☐ N/A Used CHG on surgical wounds (unless primary dressing or packed)
☐ Y ☐ N Used all 6 cloths (more if needed)
☐ Y ☐ N Allowed CHG to air-dry / does not wipe off CHG
☐ Y ☐ N Disposed of used cloths in trash /does not flush

Query to Bathing Assistant/Nurse

1. Do you ever use soap in conjunction with a CHG bathing cloth? If so, when?

_____

2. Do you reapply CHG after an episode of incontinence has been cleaned up?

_____

3. Are you comfortable applying CHG to superficial wounds, including surgical wounds?

_____

4. Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?

_____

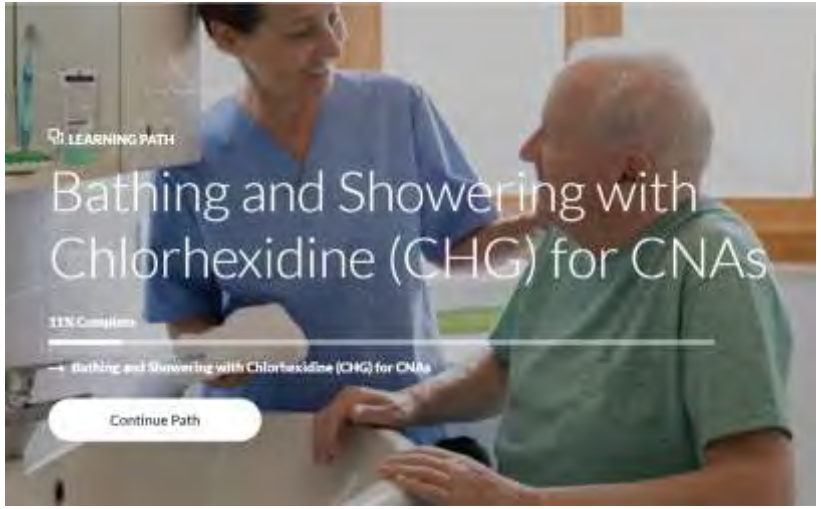
5. Do you ever wipe off the CHG after bathing?

_____

NACCHO
National Association of County & City Health Officials

UNIVERSITY

an online education and training resource to develop knowledge and competencies for local public health



https://www.pathlms.com/naccho/courses/

Training Video for CHG Bathing

- CHG bathing and showering instructions
- Scenarios for how to encourage patients to accept bath
- Commonly missed and important protocol details
  (i.e., cleaning lines, tubes, drains, superficial wounds)
- Instructions for patients wishing to self-bathe

https://www.ahrq.gov/hai/tools/abate/index.html

Summary of Decolonization Trials

- Topical decolonization of skin and nose repeatedly shows benefit:
  - ✓ reduces MDROs, Gram+ and Gram-
  - ✓ reduces bloodstream infections
  - ✓ reduces hospitalizations
  - ✓ highly cost effective
- Universal application most effective in high-risk populations
- Nasal decolonization, ideally with mupirocin, is essential to reduce MRSA
- No emergence of resistance attributed to trial decolonization groups
- High value while we monitor for resistance and seek more options