



Active **B**athing to **E**liminate Infection Project

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**for the ABATE Infection Trial Team**

# Disclosures

- Participating hospitals in this trial received contributed antiseptic product from Sage Products and Molnlycke
- Conducting other clinical studies in which participating hospitals and nursing homes receive contributed products from Sage Products, 3M, Xttrium, Clorox, and Medline
- Companies contributing product have no role in design, conduct, analysis, or publication

Funded by NIH

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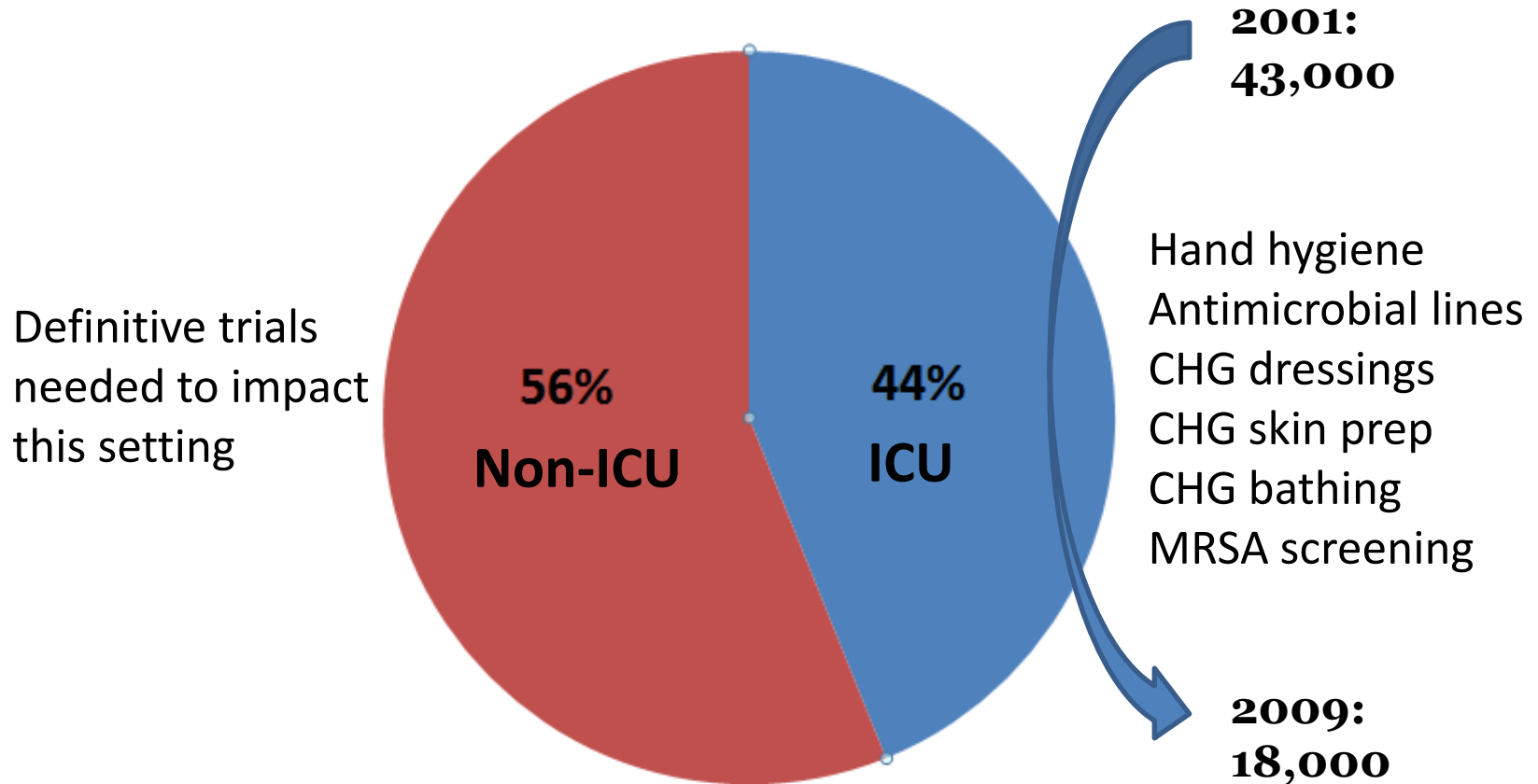
Funded by NIH

# Healthcare-Associated Infections (HAIs) in the United States, 2002

- 1.7 million hospital-associated infections
  - **1.3 million outside of ICUs**
  - 4.5 per 100 admissions
- 99,000 deaths associated with HAI infections
  - 36,000 pneumonias
  - 31,000 bloodstream infections

Klevens M, et al. Pub Health Rep 2007;122:160-6

# Central Line Associated Bloodstream Infections

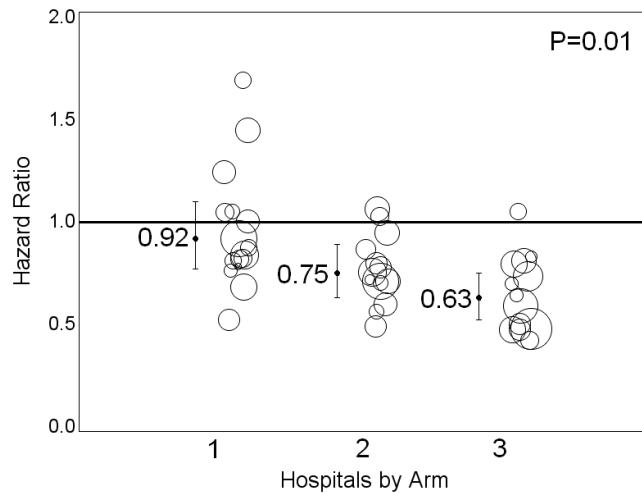


# ICU Decolonization Evidence Summary

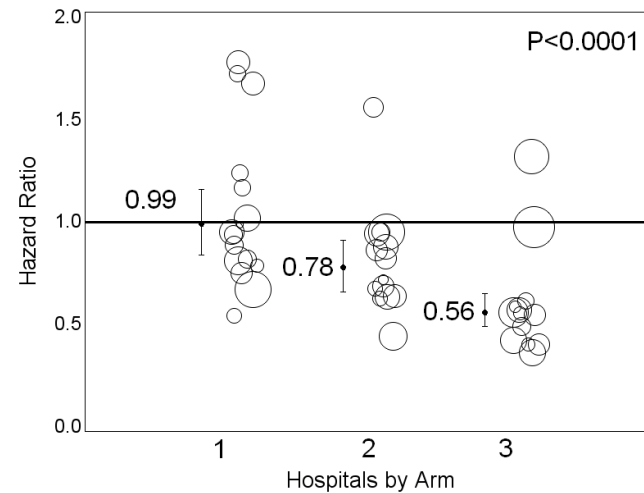
| Author    | Study Year  | Study Type  | Hospital | ICU | N       | Findings  | Publication                             |
|-----------|-------------|-------------|----------|-----|---------|---|---|
| Vernon    | 10/02-12/03 | Obs         | 1        | 1   | 1,787   | <b>65% less VRE acquisition<br/>40-70% less VRE on skin,<br/>HCW hands, environment</b> | Arch Int Med 2006;<br>166:306-312       |
| Climo     | 12/04-1/06  | Obs         | 4        | 6   | 5,293   | <b>66% less VRE BSI<br/>32% less MRSA acquisition<br/>50% less VRE acquisition</b>      | Crit Care Med 2009;<br>37:1858-1865     |
| Bleasdale | 12/05-6/06  | Obs         | 1        | 2   | 836     | <b>61% less primary BSI</b>   | Arch Int Med 2007;<br>167(19):2073-2079 |
| Popovich  | 9/04-10/06  | Obs         | 1        | 1   | 3,816   | <b>87% less CLABSI<br/>41% less blood contaminants</b>                                  | ICHE 2009;<br>30(10):959-63             |
| Climo     | 8/07-2/09   | Cluster RCT | 6        | 9   | 7,727   | <b>23% less MRSA/VRE acquisition</b>  | N Engl J Med 2013;<br>368:533-42        |
| Milestone | 2/08-9/10   | Cluster RCT | 5        | 10  | 4,947   | <b>36% less total BSI (as treated)</b>  | Lancet. 2013;<br>381(9872):1099-106     |
| Huang     | 1/09-9/11   | Cluster RCT | 43       | 74  | 122,646 | <b>37% less MRSA clinical cultures<br/>44% less all-cause BSI</b>                       | N Engl J Med 2013;<br>368:2255-2265     |

# Rationale for ABATE Infection Trial

- REDUCE MRSA Trial
  - 43-hospital cluster randomized trial of ICU decolonization
  - Daily chlorhexidine baths plus nasal mupirocin x 5 days
  - Reduced MRSA clinical cultures by 37%
  - Reduced ICU bloodstream infections by 44%



MRSA Clinical Cultures



All Bloodstream Infections

# Rationale for ABATE Infection Trial

- What about outside of ICUs?
  - 1.3 of 1.7 million HAIs
- Study at Rhode Island Hospital
  - 14,801 patients in 4 general medical units
  - Daily chlorhexidine (CHG) bathing
  - 64% reduction in MRSA, VRE infections
  - Evidence of decolonization impact outside of the ICU



# **ABATE Infection Project**

## **Active Bathing to Eliminate Infection**

### **Trial Design**

- Cluster randomized trial with Hospital Corporation of America
- 53 HCA hospitals, 194 adult non critical care units
- Includes: adult medical, surgical, step down, oncology
- Excludes: rehab, psych, peri-partum, BMT

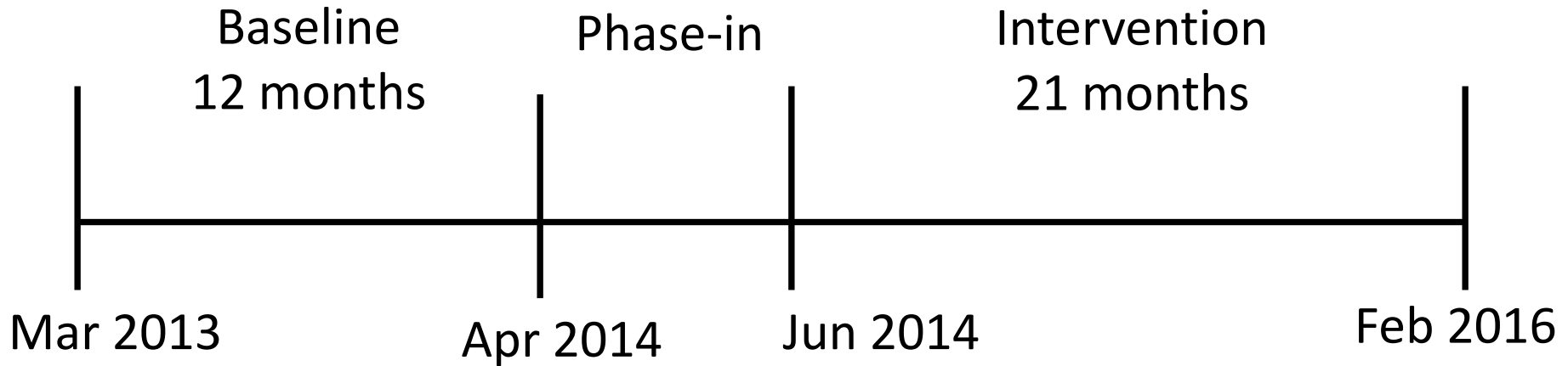
### **Arm 1: Routine Care**

- 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

# Baseline and Intervention Periods



# Outcomes

- **Primary Outcome**
  - Any MRSA or VRE isolate attributed to unit
- **Key Secondary Outcome**
  - Any bloodstream isolate attributed to unit

Outcomes defined by:

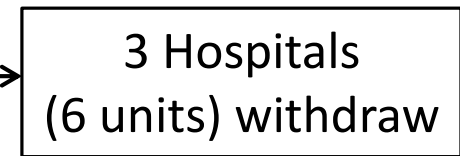
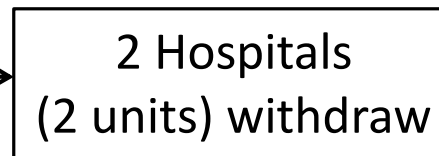
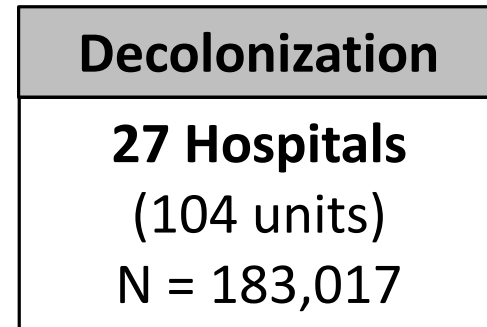
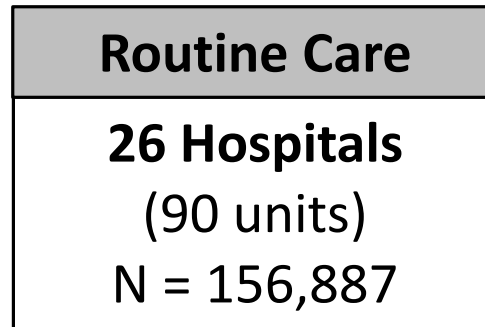
- Microbiology results alone
- > 2d after unit admit through 2d after unit discharge
- Skin commensals require 2 positive blood cultures

# HCA Hospitals and Units

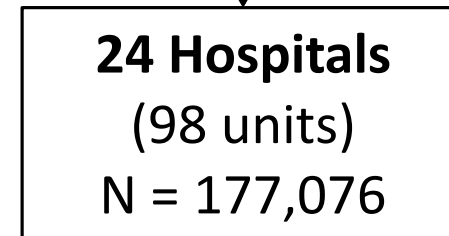
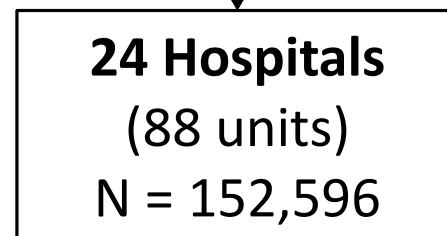
**Intervention:** 339,904 patients

1,294,153 attributable patient days

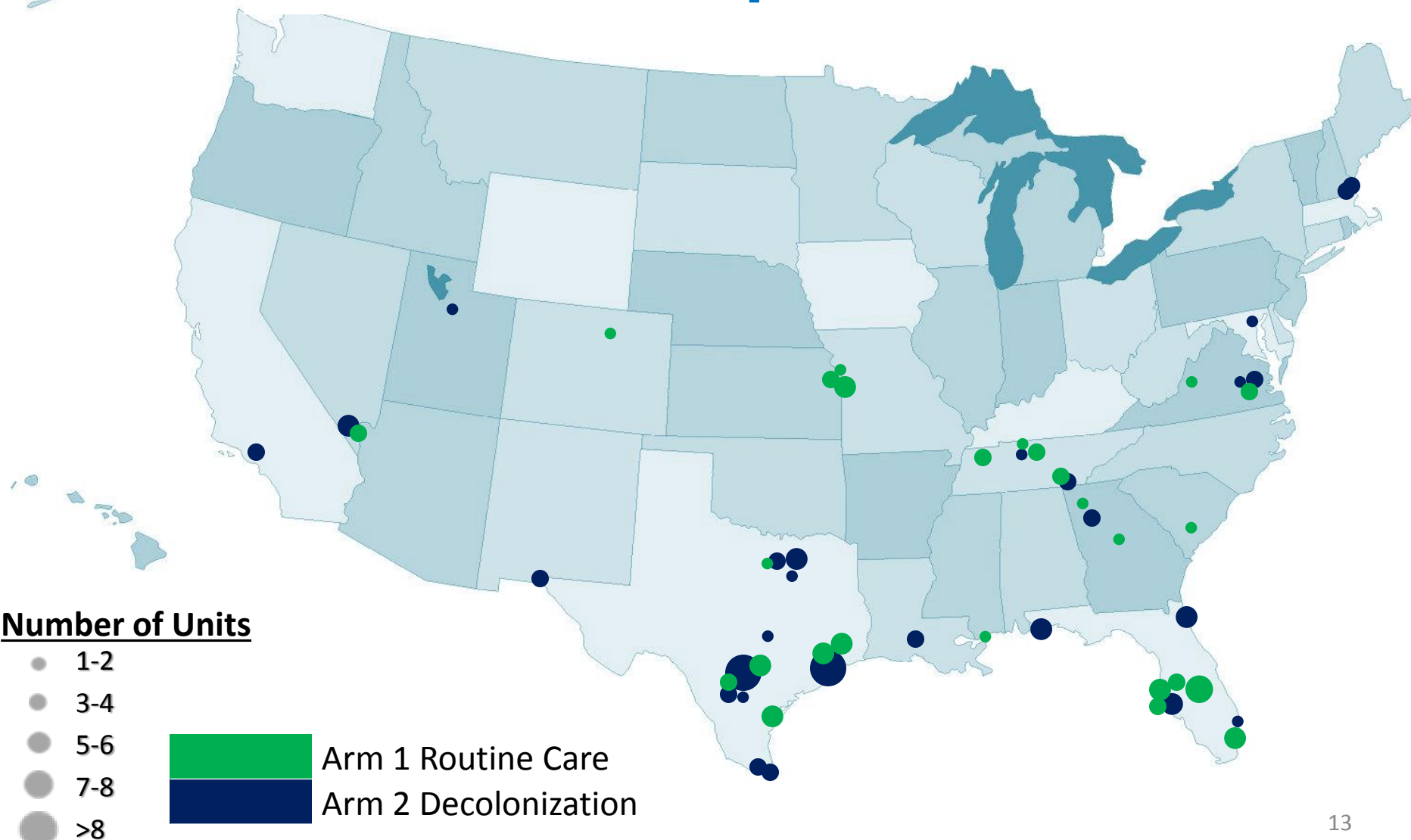
**As Randomized**



**As Treated**



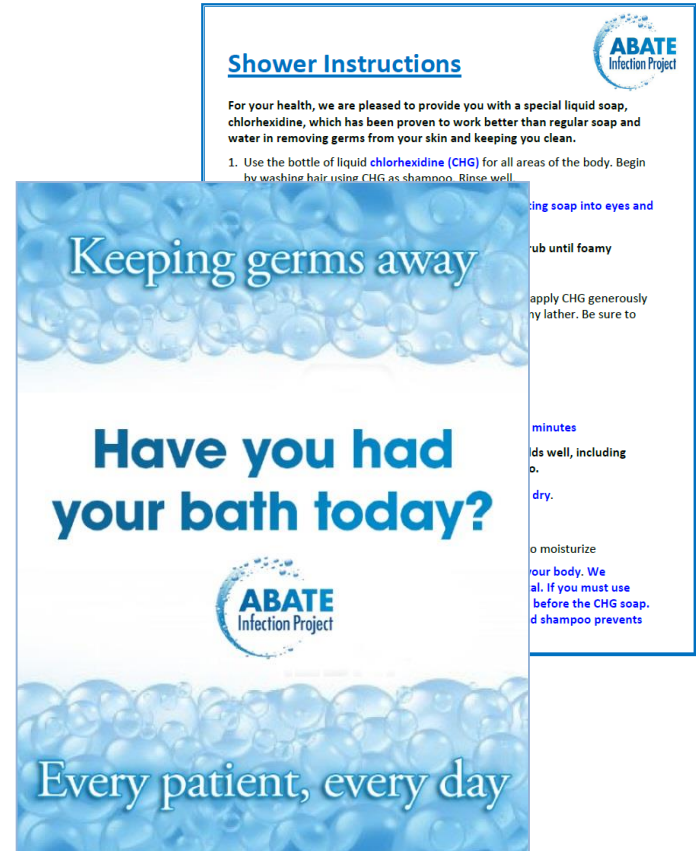
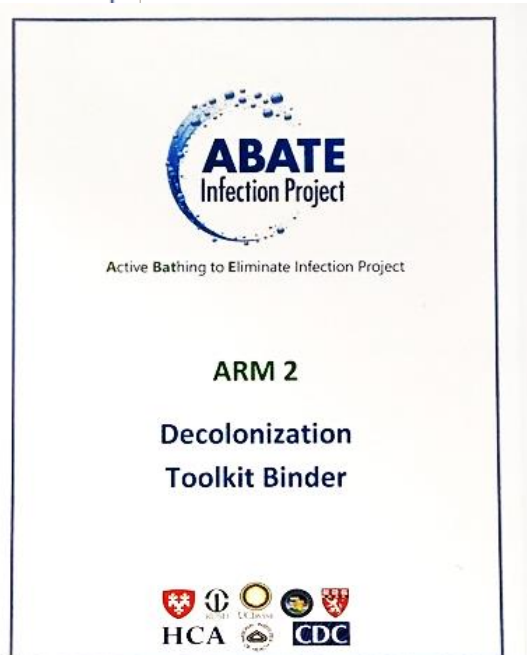
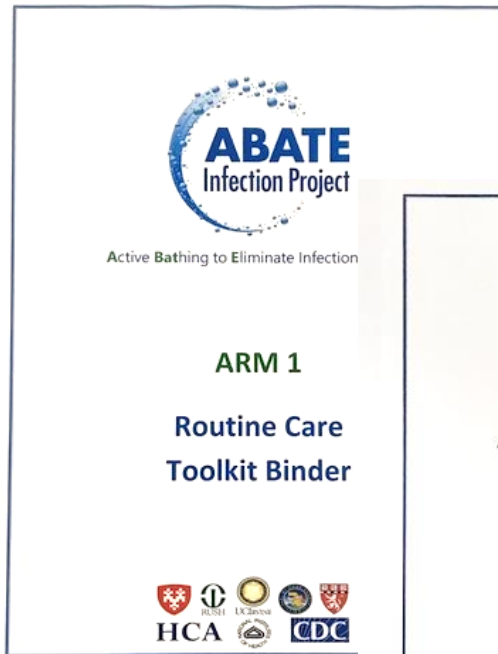
# ABATE Infection Trial HCA Hospital Sites



# Implementation

- Research to impact usual care
- Implemented by quality improvement personnel
- No on-site investigators
  - Coaching calls
  - Monthly compliance feedback
    - Based on daily nursing e-queries for CHG use
    - Mupirocin medication administration
    - Quarterly peer bathing observations
  - Site visits for bathing training, and as needed

# Implementation Toolkits



# of Binders Shipped: 239

# of Clings Shipped (Arm 2):  
2,330 room clings; 1,149 shower clings

# Instructional Handouts

Evite las infecciones durante su hospitalización  
**DUCHAR** diariamente con el jabón Chlorhexidine (CHG) **EI PACIENTE**

Prevent infections during your hospital stay  
**SHOWER** daily with Chlorhexidine (CHG) soap **PATIENT**

Evite las infecciones durante la hospitalización  
**Bañar** diariamente con el jabón CHG **EI Personal**

Prevent infections during the hospital stay  
**BATHE** daily with Chlorhexidine (CHG) soap **STAFF**

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


SHOWERING with CHG soap

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

BATHING with CHG cloths


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



Active Bathing to Eliminate Infection Project

Daily Staff Huddle Reminders for CHG Bathing:  
Patient Talking Points



Active Bathing to Eliminate Infection Project

Daily Staff Huddle Reminders for CHG Bathing:  
Cleaning Wounds and Devices

- Do not forget wounds and devices! Cleaning them prevents surface bacteria from diving into the body and causing infection
- Clean **ALL devices** on the body- lines, tubes, drains
- Clean **ALL wounds** unless packed
- Patients don't feel comfortable cleaning their wounds and devices, staff **HAVE TO HELP** clean them
- For showering patients, staff should take a single 2-pack of CHG and clean their wounds and devices for them after the shower

encourage patients

**at time** would be a

ing is one of the most  
of germs being  
protect the patient

Arm 2 Instructional Handouts  
Provided in English and Spanish

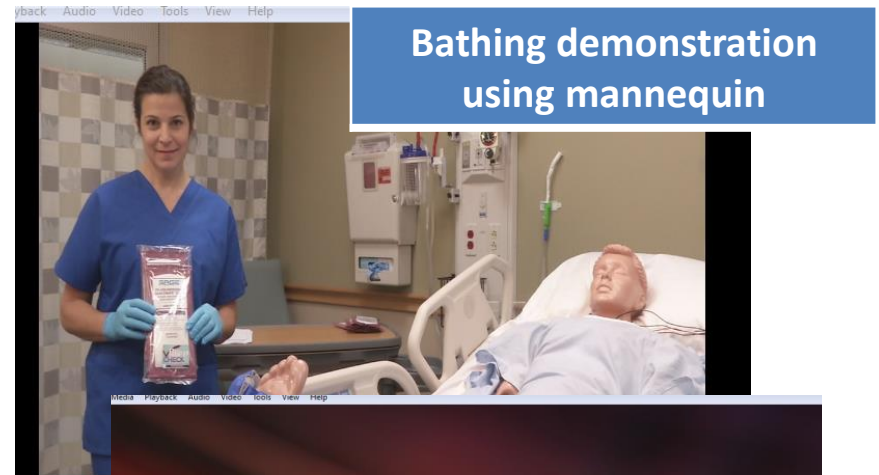
Arm 2 Huddle Documents  
Covering 14 Topics



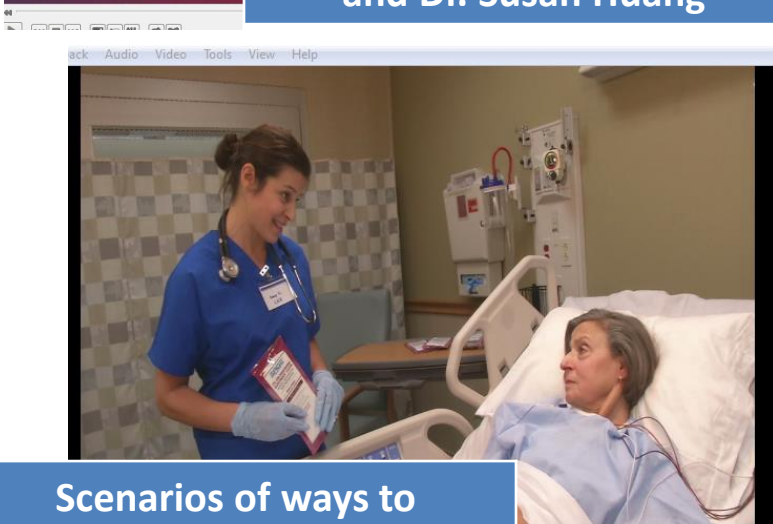
# Arm 2 – Training Video



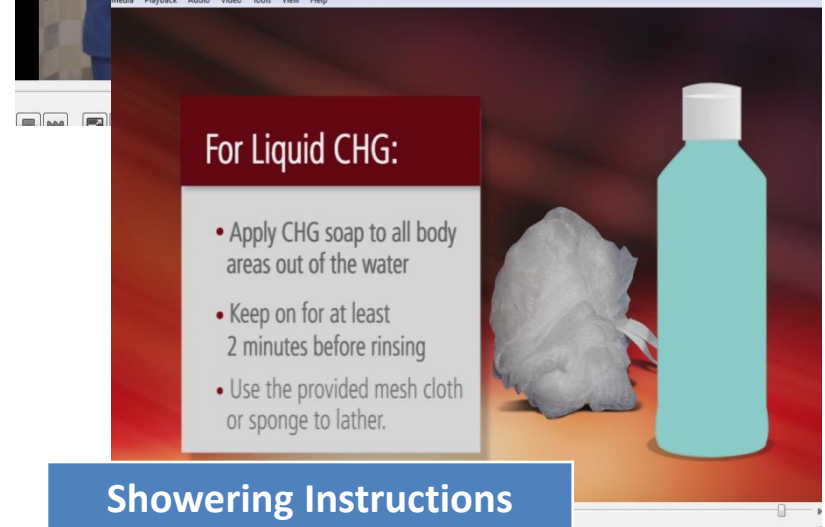
Special introduction and overview by Dr. Ed Septimus and Dr. Susan Huang



Bathing demonstration using mannequin



Scenarios of ways to encourage patients to bathe



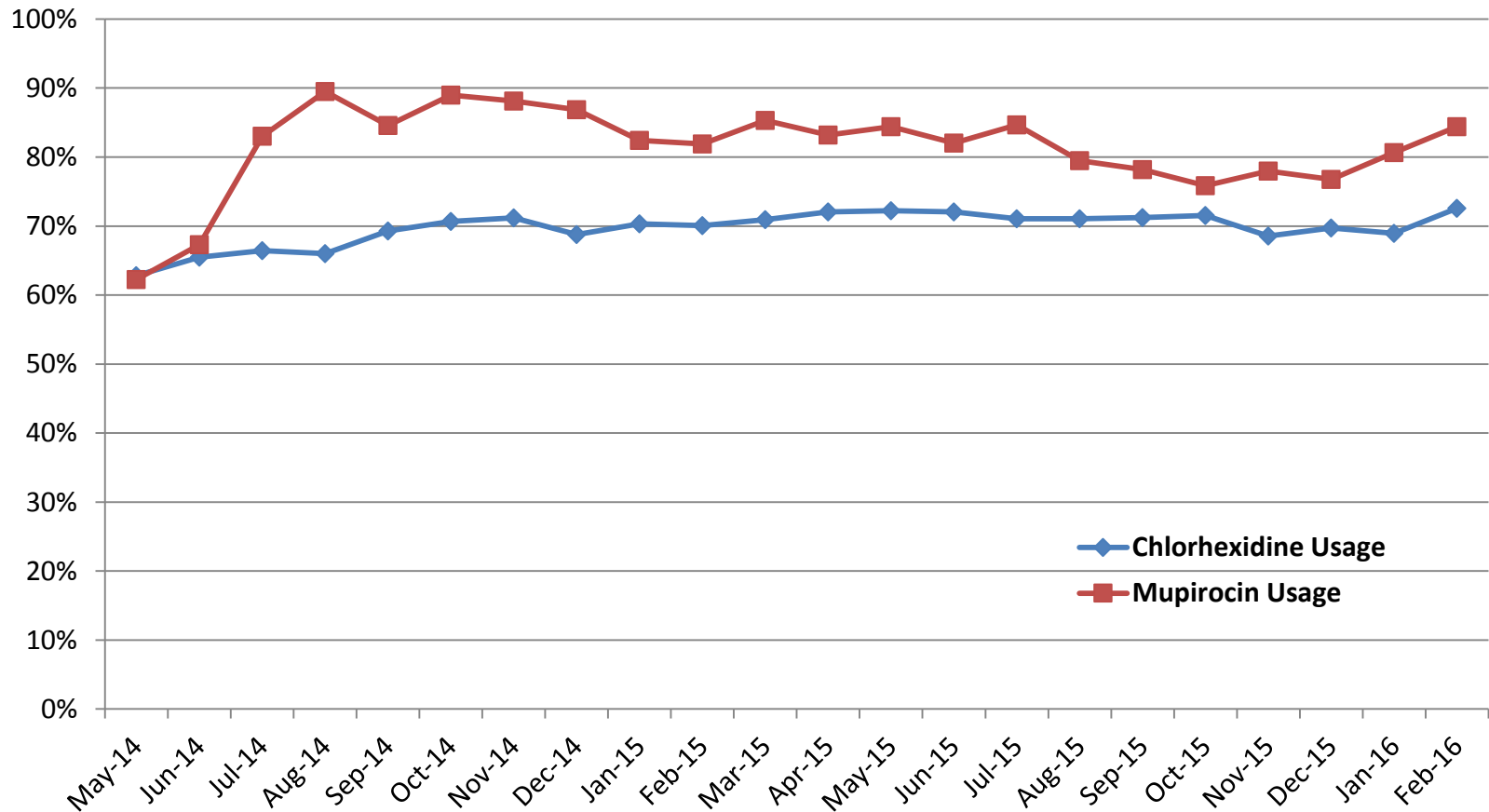
## For Liquid CHG:

- Apply CHG soap to all body areas out of the water
- Keep on for at least 2 minutes before rinsing
- Use the provided mesh cloth or sponge to lather.

Showering Instructions Overview

# Arm 2: Overall CHG and Mupirocin Usage

Arm 2: CHG and Mupirocin Usage Average



# Arm 2 – Quarterly Staff and Patient Compliance Assessments

Hospital Name: \_\_\_\_\_ Unit Name: \_\_\_\_\_

**HCA** Skills Assessment:  
Hospital Corporation of America™ **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  
 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 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**

- How many cloths were used (1 cloth set = 6 cloths, 1 cloth set plus 1 single pack = 8 cloths)  
\_\_\_\_\_
- If more than 1 cloth set (6 cloths) was used, provide reason.  
\_\_\_\_\_
- Do you reapply CHG after an episode of incontinence has been cleaned up?  
\_\_\_\_\_
- Are you comfortable applying CHG to superficial wounds, including surgical wounds?  
\_\_\_\_\_
- Are you comfortable applying CHG to lines, tubes, drains and non-gauze dressings?  
\_\_\_\_\_
- Do you ever wipe off the CHG after bathing?  
\_\_\_\_\_

Email to [ABATEStudy@gmail.com](mailto:ABATEStudy@gmail.com) or fax to (949) 824-3985

# completed: 1,469


Hospital Name: \_\_\_\_\_ Unit Name: \_\_\_\_\_

**HCA** Skills Assessment:  
Hospital Corporation of America™ **CHG Cloth – Patient Self-Bathing**

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

**CHG Showering – Patient Self-Bathing**  
Please record patient responses after the patient showered with CHG liquid.

**Questions**

- Were you provided a handout with instructions on how to apply the CHG liquid in the shower?  
 Y     N
- Were you told that CHG kills germs better than regular soap and water?  
 Y     N
- Did you use the mesh sponge to apply the CHG?   Y     N
- Did you soap up twice with CHG before rinsing?  
 Y     N
- Did you leave the CHG on your skin for 2 minutes before rinsing off?  
 Y     N
- Were you told NOT to use other bathing soaps or lotions while in this unit?  
 Y     N
- Were you told to bathe or shower daily with CHG while in this unit?  
 Y     N
- Did you or an assistant clean your lines, tubes, and/or drains with a CHG cloth after showering?  
 Y     N     N/A
- Did you or an assistant clean your wounds with a CHG cloth after showering?  
 Y     N

# completed: 1,251

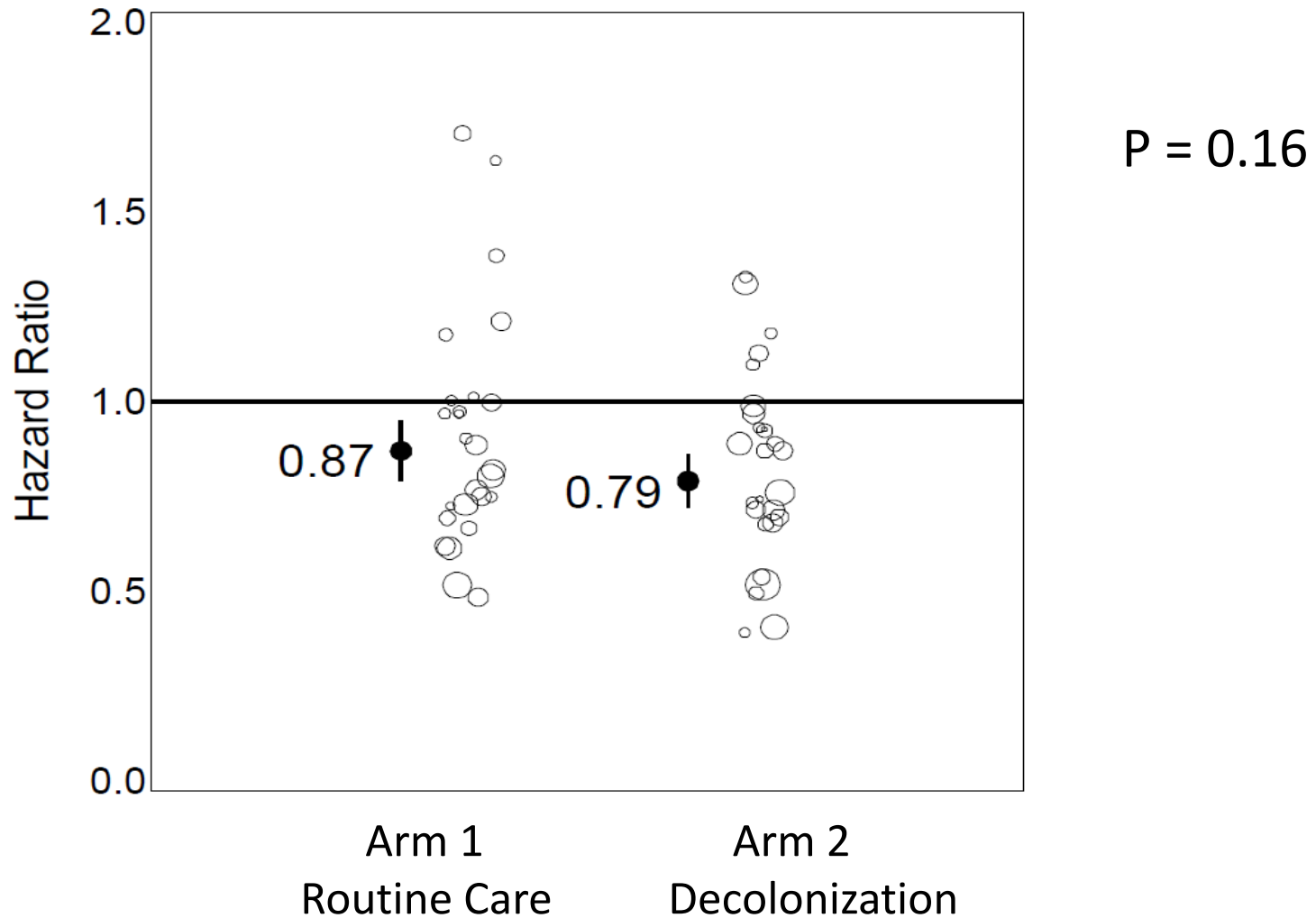
# Analysis

- Main results are as-randomized, unadjusted
- Compared baseline to intervention rates across arms
  - Proportional hazards models with shared frailties to account for clustering within hospital
  - Success: significant difference across arms in change in baseline and intervention hazards
- Sensitivity Analyses
  - As treated
  - Adjusted (MRSA importation, LOS, comorbidities)

# Select Population Characteristics

| Variable                       | Routine Care | Decolonization |
|--------------------------------|--------------|----------------|
| Age (mean years)               | 62.3         | 62.6           |
| Female                         | 53.9%        | 54.8%          |
| Comorbidity Score (Elixhauser) | 2.8          | 2.9            |
| Surgery (CDC)                  | 20.9%        | 22.4%          |
| Non-ICU Length-of-Stay (days)  | 5.7          | 5.7            |
| Central Lines                  | 9.1%         | 10.7%          |
| MRSA History                   | 1.4%         | 1.3%           |

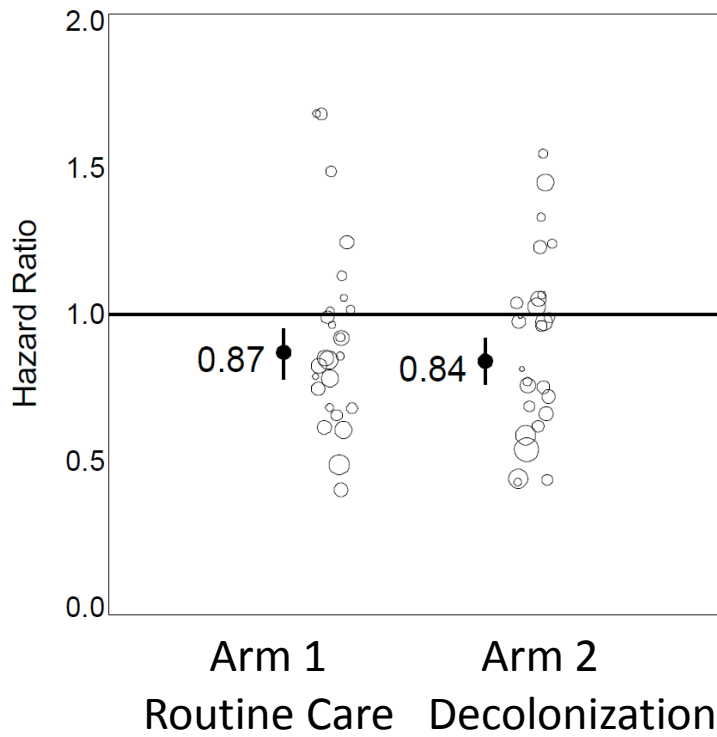
# MRSA & VRE Clinical Cultures



# MRSA & VRE Cultures Stratified

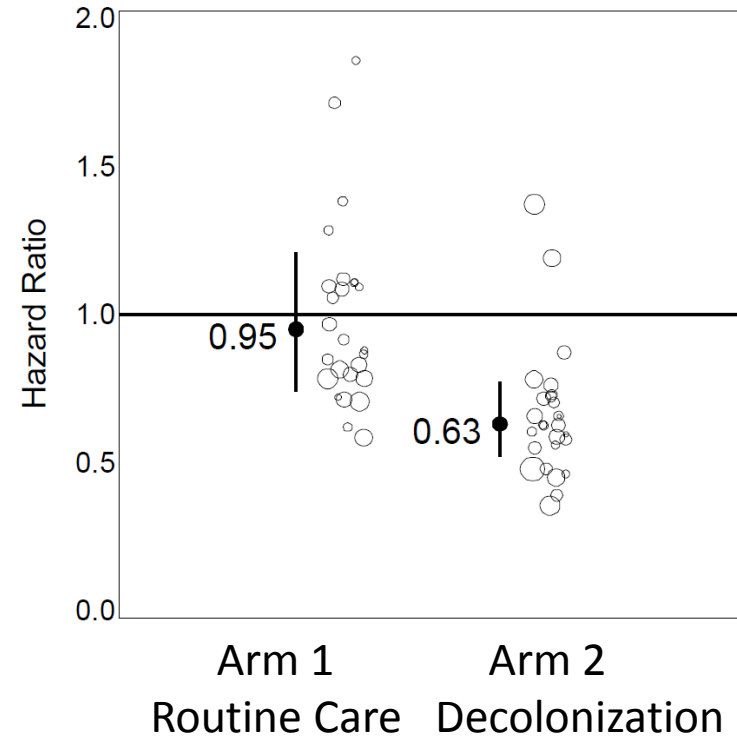
MRSA Clinical Cultures

P=0.63

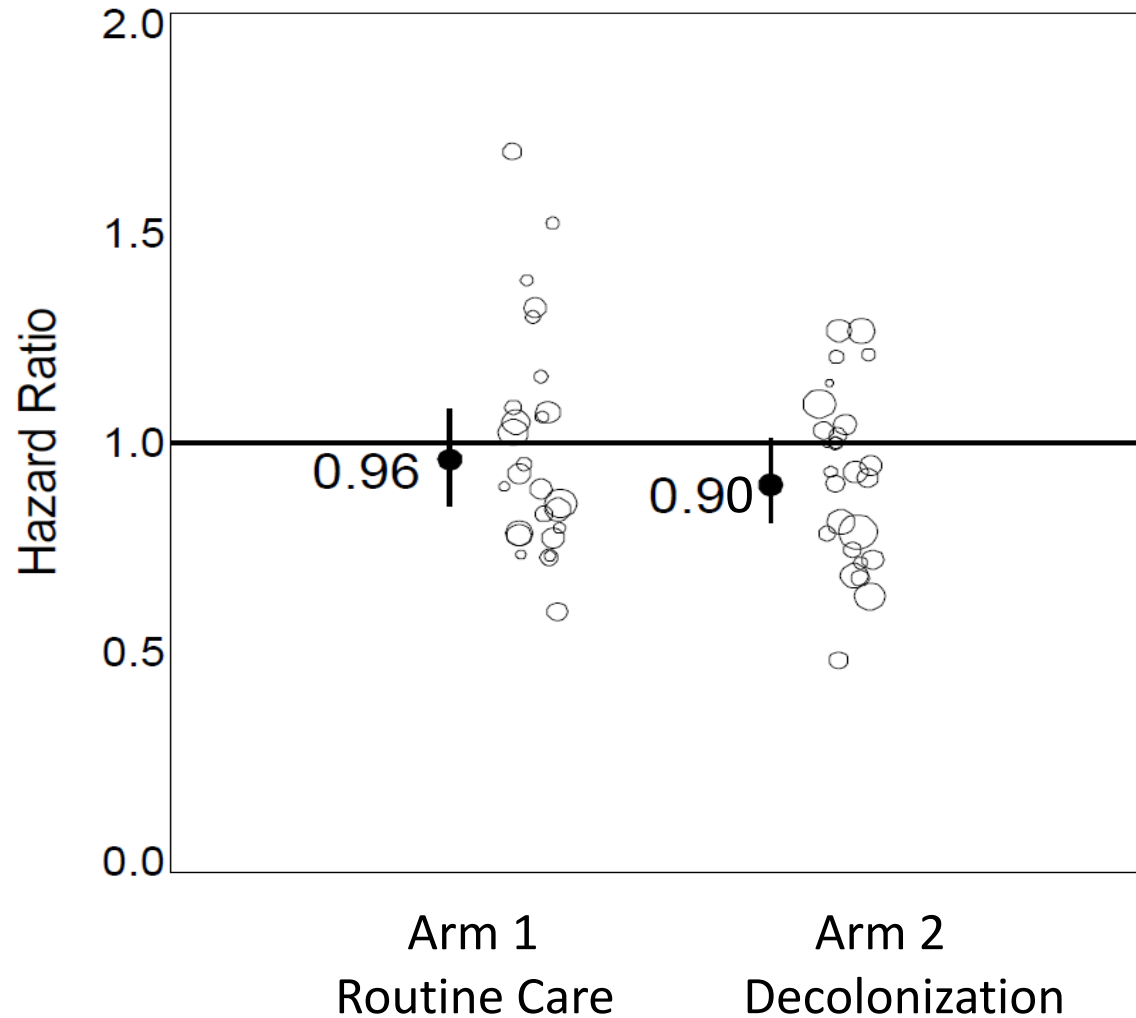


VRE Clinical Cultures

P=0.01



# All Pathogen Bloodstream Infection



P = 0.44



# Subpopulation Analysis

- Post-hoc evaluation
- Are there subsets that may benefit due to higher risk?
  - High rate hospitals (top quartile)
  - Patients with Central Lines (CVC) and Other Devices
  - Oncology patients
  - Surgical patients

# MRSA and VRE Clinical Cultures

- Event rate per 1,000 patient days

| Population               | Base Event Rate | Arm 2 vs 1 Effect | P-value |
|--------------------------|-----------------|-------------------|---------|
| Full Cohort              | 2.4             | - 8.7%            | 0.16    |
| High Rate Hospitals      | 3.7             | 2.1%              | 0.86    |
| Patients with Devices    | 3.5             | -32.1%↓           | <0.001  |
| Patients without Devices | 2.1             | 2.9%              | 0.72    |

Patients with Devices: 12% of study population, 35% of all events

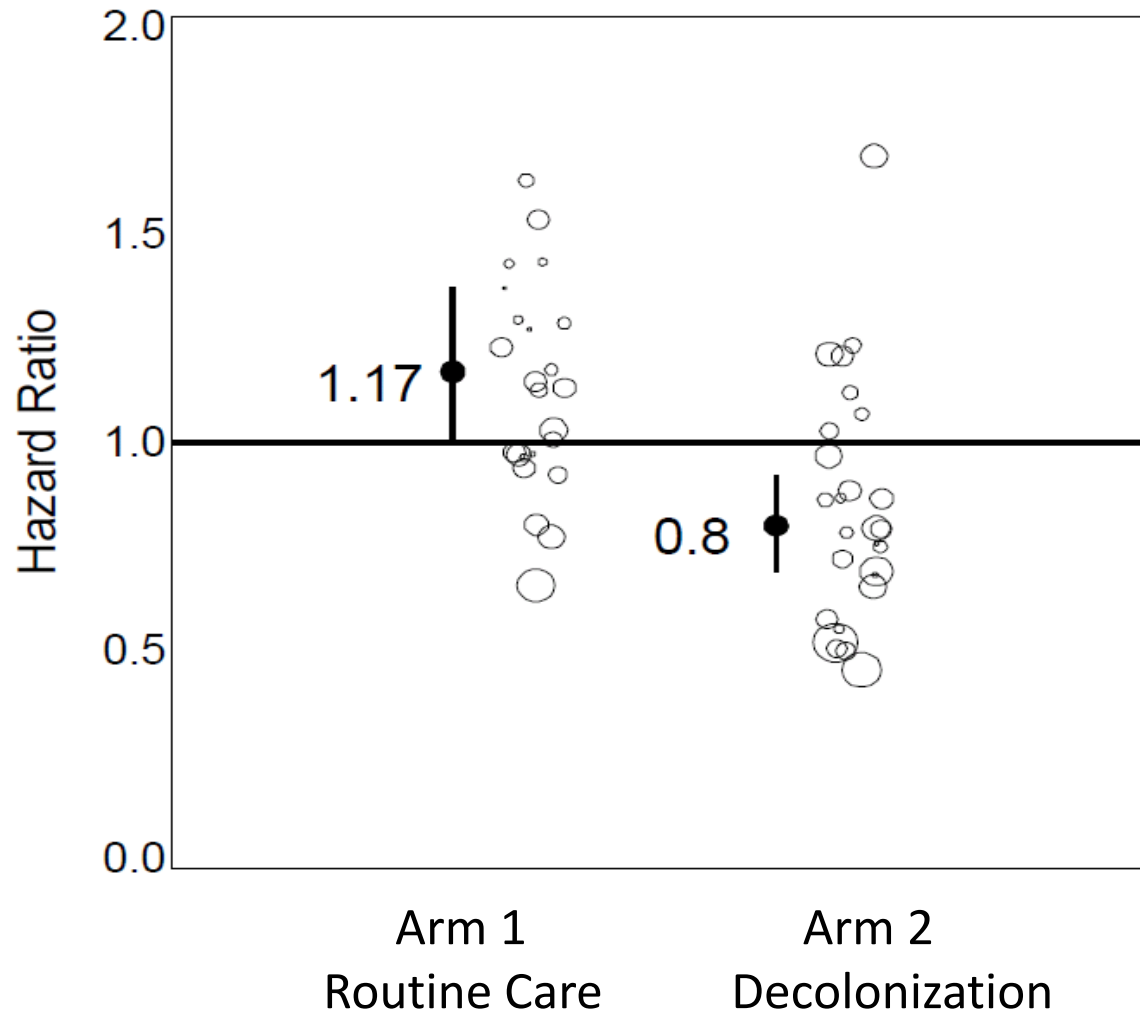
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| Full Cohort           | 2.4             | - 8.7%            | 0.16    |
| High Rate Hospitals   | 3.7             | 2.1%              | 0.86    |
| Patients with CVCs    | 3.5             | - 32.0%↓          | <0.001  |
| Patients without CVCs | 2.1             | 4.2%              | 0.60    |

Patients with CVCs: 11% of study population, 34% of all events

# MRSA & VRE Clinical Cultures: Patients with Central Lines and Devices

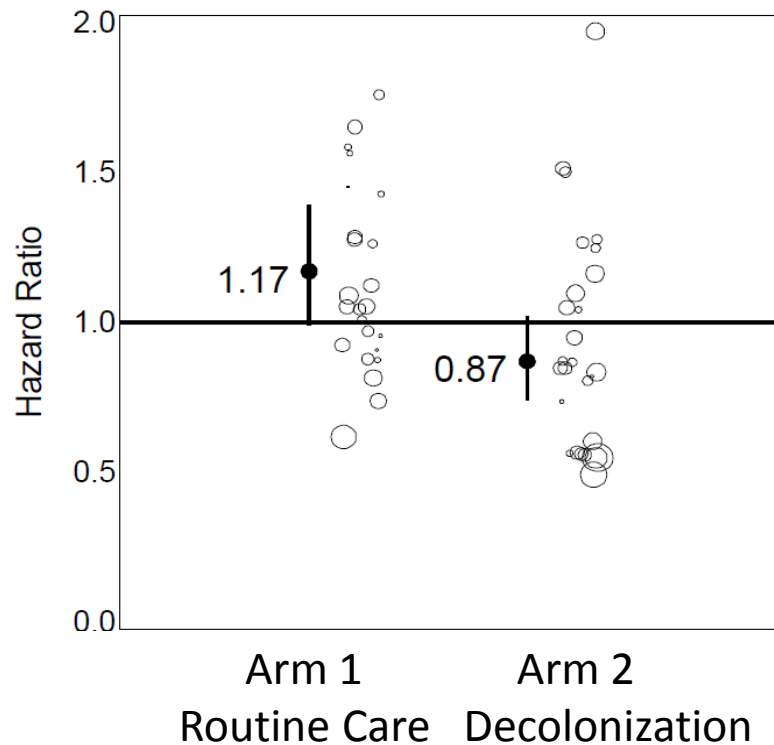


**P < 0.001**

# MRSA & VRE Cultures Stratified Patients with Central Lines and Devices

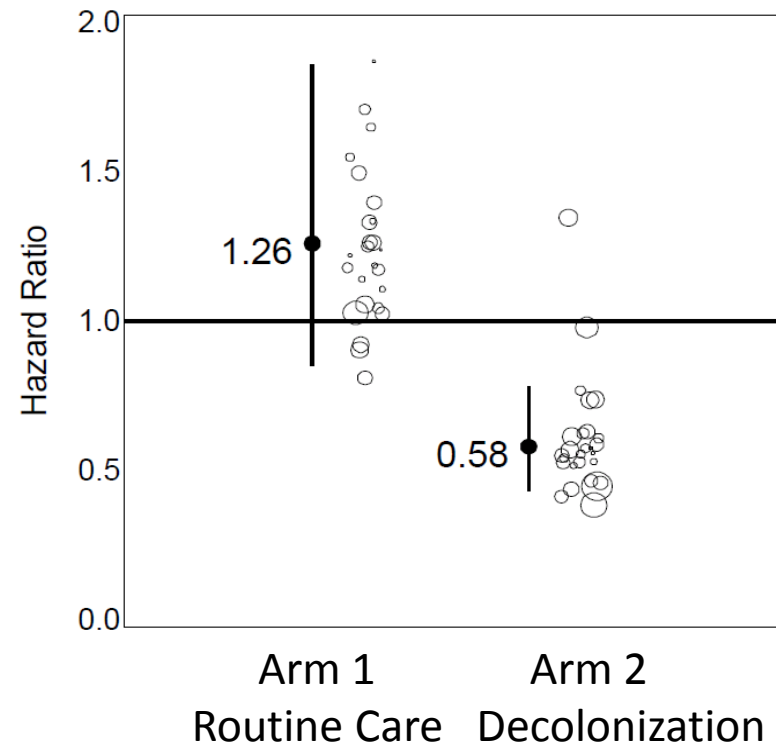
MRSA Clinical Cultures

**P=0.01**

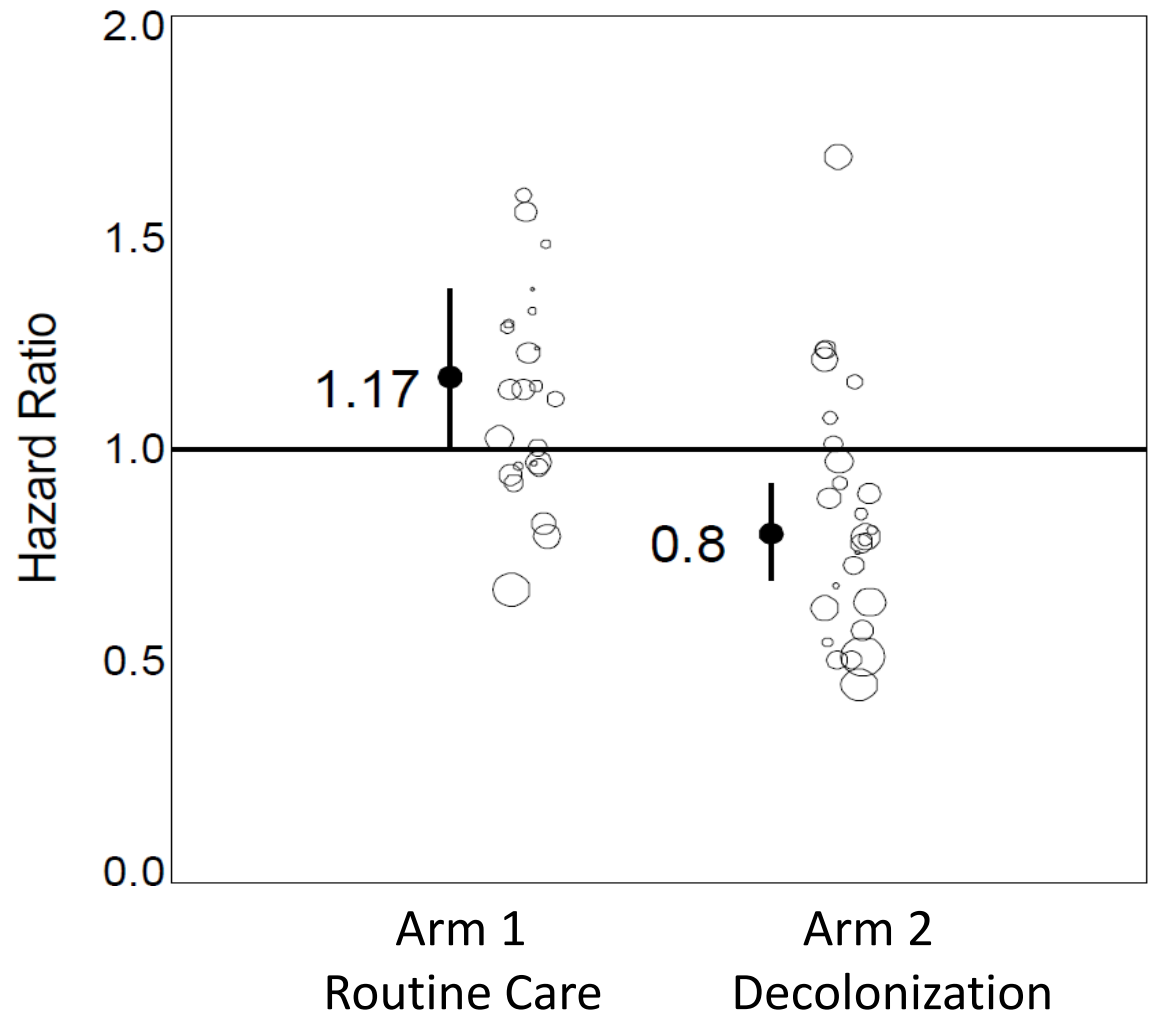


VRE Clinical Cultures

**P=0.002**



# MRSA & VRE Clinical Cultures: Patients with Central Lines

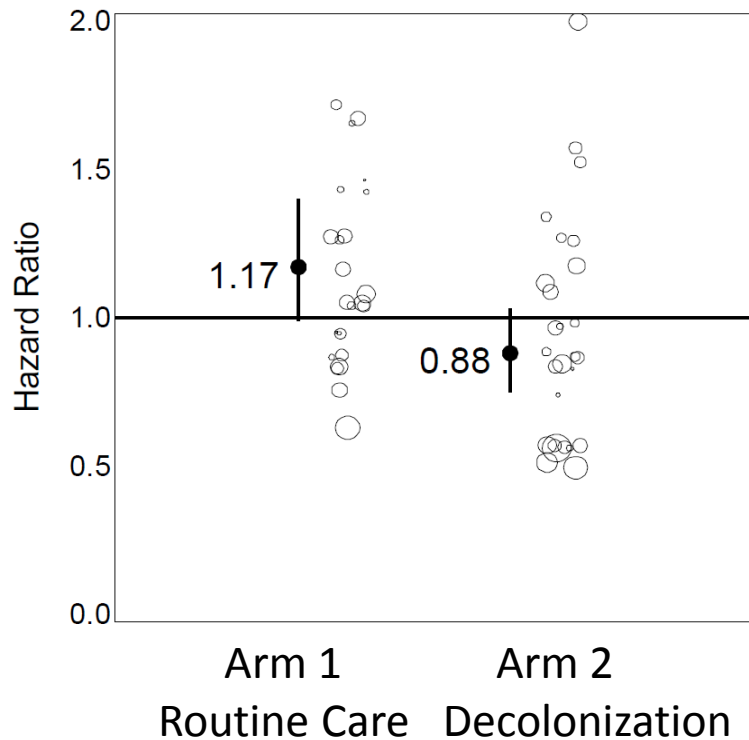


**P < 0.001**

# MRSA & VRE Cultures Stratified Patients with Central Lines

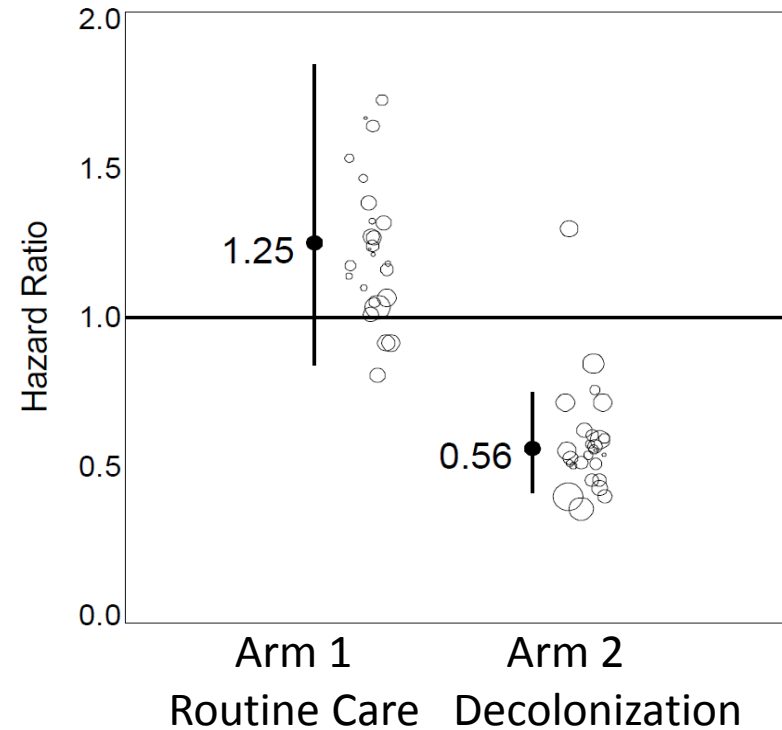
MRSA Clinical Cultures

**P=0.02**




VRE Clinical Cultures

**P=0.001**



# All Pathogen Bloodstream Infection

- Event rate per 1,000 patient days


| Population               | Base Event Rate | Arm 2 vs 1 Effect   | P-value |
|--------------------------|-----------------|---|---------|
| Full Cohort              | 1.3             | - 6.2%  | 0.44    |
| High Rate Hospitals      | 1.8             | 6.8%  | 0.62    |
| Patients with Devices    | 3.3             | - 27.8%  | 0.004   |
| Patients without Devices | 0.8             | 14.9%   | 0.29    |

Patients with Devices: 12% of study population, 59% of all events



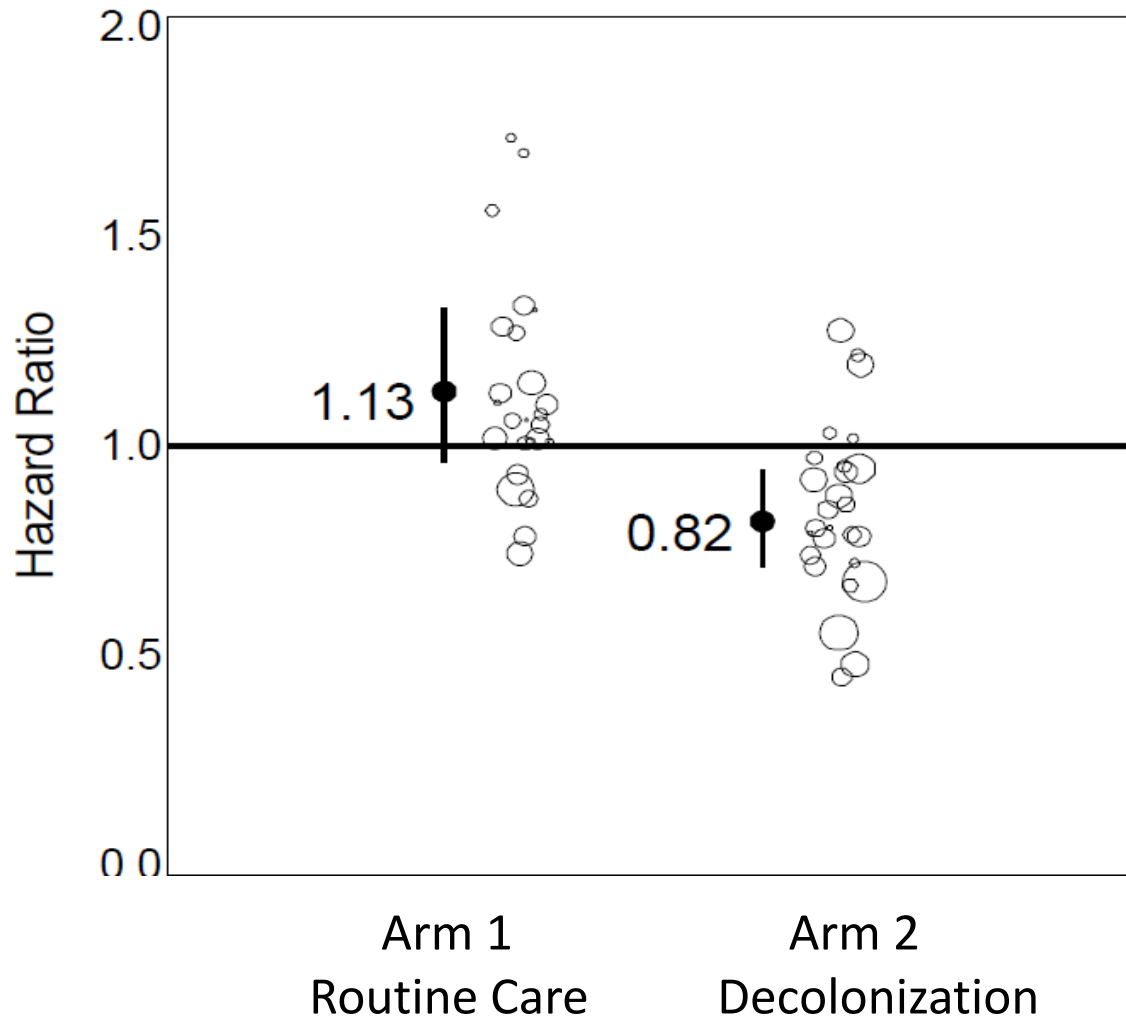
# All Pathogen Bloodstream Infection

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| Population            | Base Event Rate | Arm 2 vs 1 Effect   | P-value |
|-----------------------|-----------------|---|---------|
| Full Cohort           | 1.3             | - 6.2%  | 0.44    |
| High Rate Hospitals   | 1.8             | 6.8%  | 0.62    |
| Patients with CVCs    | 3.3             | - 26.9%  | 0.005   |
| Patients without CVCs | 0.8             | 17.0%   | 0.22    |

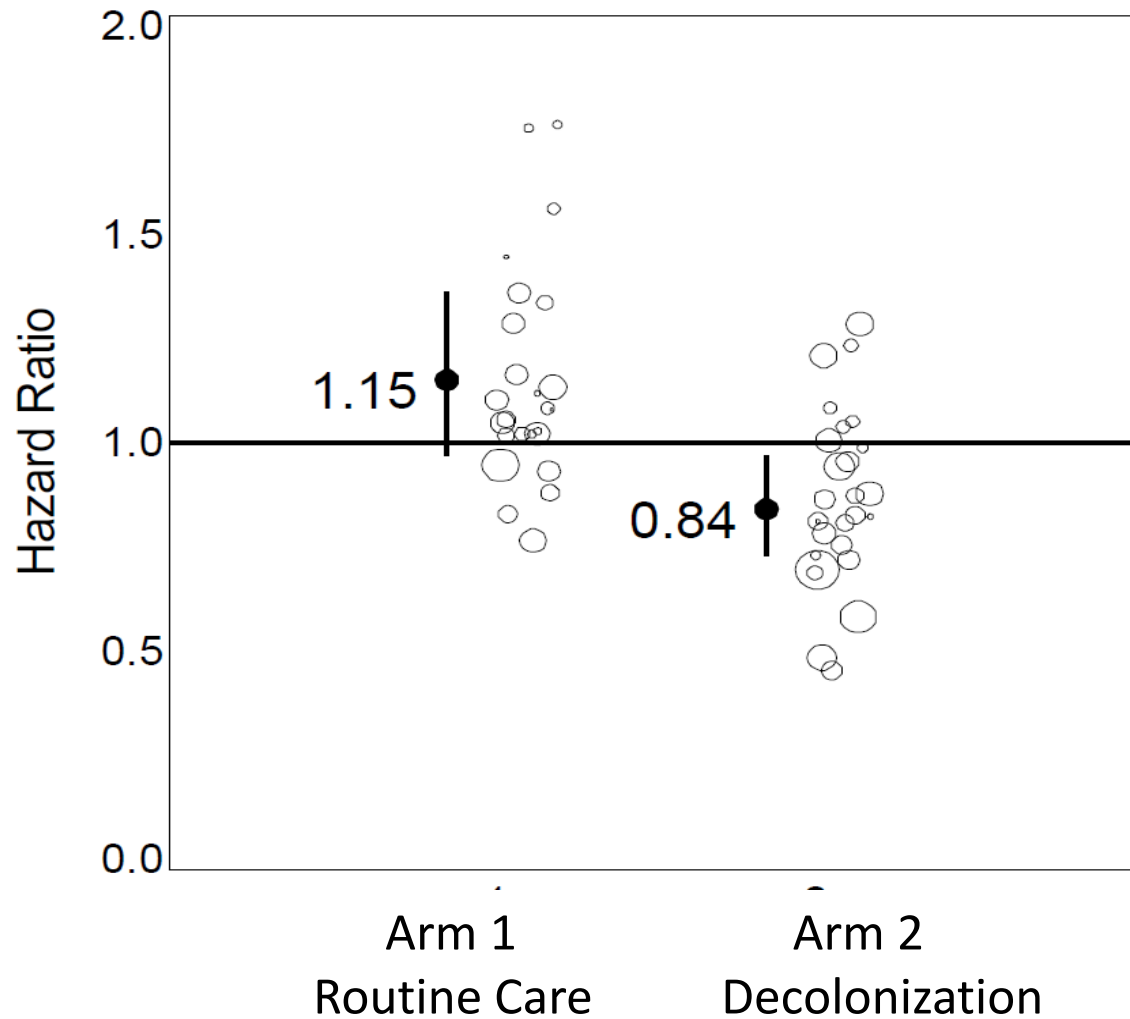
Patients with Devices: 11% of study population, 58% of all events

# All Pathogen Bloodstream Infection: Patients with Lines and Devices



**P = 0.004**

# All Pathogen Bloodstream Infection: Patients with CVC



**P = 0.005**

# Decolonization in General Wards

- Did not see overall impact, unlike ICU trials
- Why?
  - Lower risk and smaller effect size
  - 8.7% for MDROs, 6.2% bloodstream infection (P=NS)
- Benefit seen in **higher risk patients with lines and devices**
  - 32% reduction in MRSA and VRE clinical cultures
  - 28% reduction in all pathogen bloodstream infection
  - ~10% of population, but a third of MRSA+VRE cultures
  - ~10% of population, but 60% of bloodstream infections

# Limitations

- Community-based hospital trial
- May not translate to high risk centers
- Subset analyses are post hoc
- Cost-effectiveness analysis needed for device effect
- Assessment of resistance underway

# Conclusions

- Universal CHG bathing in general medical and surgical units with targeted mupirocin for MRSA carriers:
  - Did not reduce overall MDRO or BSI
  - Reduced MRSA and VRE by 32% and all-cause bloodstream infections by 28% in patients with central lines and devices
- **Recommendation**
  - Use CHG daily bathing for all inpatients with devices and central lines and provide additional nasal decolonization if they are MRSA carriers
  - Continue to use decolonization in ICU patients

# Hospital Corporation of America

# HCA

## Hospital Participants

### Arm 1 Facilities

|                                |                                       |                                     |
|--------------------------------|---------------------------------------|-------------------------------------|
| Cartersville Medical Center    | Lee's Summit Medical Center           | Parkridge East Hospital             |
| Coliseum Northside Hospital    | LewisGale Hospital-Alleghany          | Plaza Medical Center of Fort Worth  |
| Colleton Medical Center        | Methodist Stone Oak Hospital          | Research Medical Center             |
| Conroe Regional Medical Center | North Suburban Medical Center         | South Bay Hospital                  |
| Corpus Christi Medical Center  | Northeast Methodist Hospital          | St. Petersburg General Hospital     |
| Garden Park Medical Center     | Northside Hospital                    | Summit Medical Center               |
| Hendersonville Medical Center  | Osceola Regional Medical Center       | Sunrise Hospital and Medical Center |
| Henrico Doctors' Hospital      | Overland Park Regional Medical Center | TriStar Horizon Medical Center      |
| Kingwood Medical Center        | Palms West Hospital                   | TriStar Horizon Medical Center      |

### Arm 2 Facilities

|  |   |                                       |
|--|---|---------------------------------------|
| Blake Medical Center                   | Methodist Specialty & Transplant Hospital | Reston Hospital Center                |
| Chippenham Johnston Willis Medical Ctr | Methodist Texsan Hospital                 | Rio Grande Regional Hospital          |
| Clear Lake Regional Medical Center     | MountainView Hospital-Las Vegas           | St. David's Medical Center            |
| Eastside Medical Center                | North Hills Hospital                      | Timpanogos Regional Hospital          |
| John Randolph Medical Center           | Orange Park Medical Center                | TriStar Southern Hills Medical Center |
| Las Colinas Medical Center             | Parkland Medical Center                   | Valley Regional Medical Center        |
| Las Palmas Medical Center              | Parkridge Medical Center                  | West Florida Hospital                 |
| Medical Center of Plano                | Portsmouth Regional Hospital              | West Hills Hospital & Medical Center  |
| Methodist Hospital                     | Regional Medical Center of Acadiana       | West Palm Hospital                    |

# Special Thanks



Susan Huang, MD MPH  
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Taliser Avery, MS  
Katie Haffenreffer, BS  
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# **Next Steps for HCA Implementation**

*Clinical Infectious Diseases*

MAJOR ARTICLE



# Closing the Translation Gap: Toolkit-based Implementation of Universal Decolonization in Adult Intensive Care Units Reduces Central Line-associated Bloodstream Infections in 95 Community Hospitals

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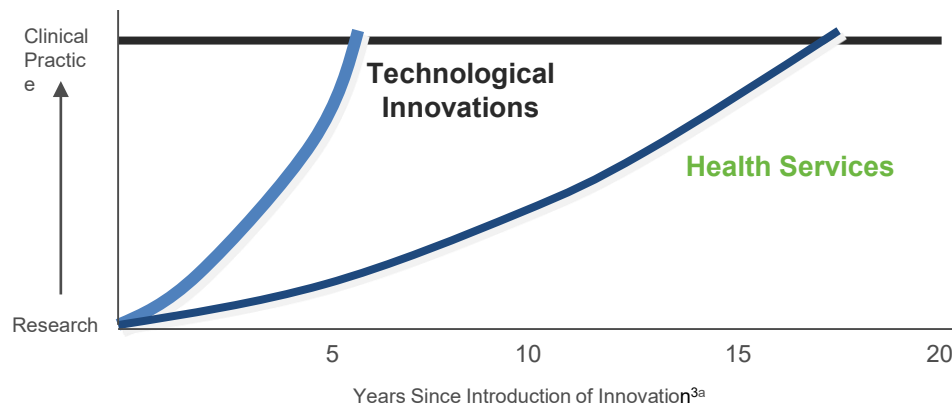
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Generating and adapting to new evidence of effective care is the hallmark of learning health care systems

*Clin Infect Dis* 2016;63(2):172–7

# A Gap Between Evidence and Practice

- One of the most consistent findings from clinical and health services research is the failure to translate research into practice and policy.<sup>1</sup>
- Improving population health outcomes relies on implementation of findings from clinical and health services research.<sup>2</sup>

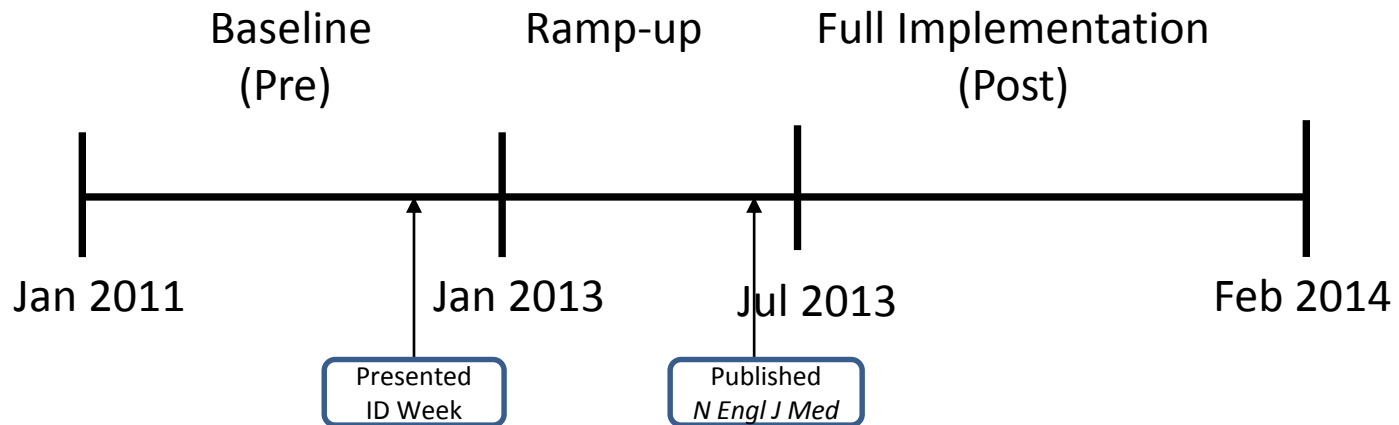


<sup>a</sup>For illustrative purposes only based on data from Balas EA.

**It takes an average of 17 years for research to reach clinical practice<sup>3</sup>**

1. Grimshaw et al. *Implementation Science*. 2011;7:50. 2. Evans et al. *Implementation Science*. 2013;8:17. 3. Balas EA, *Yearbook of Medical Informatics* 2000;65-70.

# Time Line: Rapid Adoption REDUCE Infection Trial



137 ICUs from 96 hospitals

# Coaching Calls

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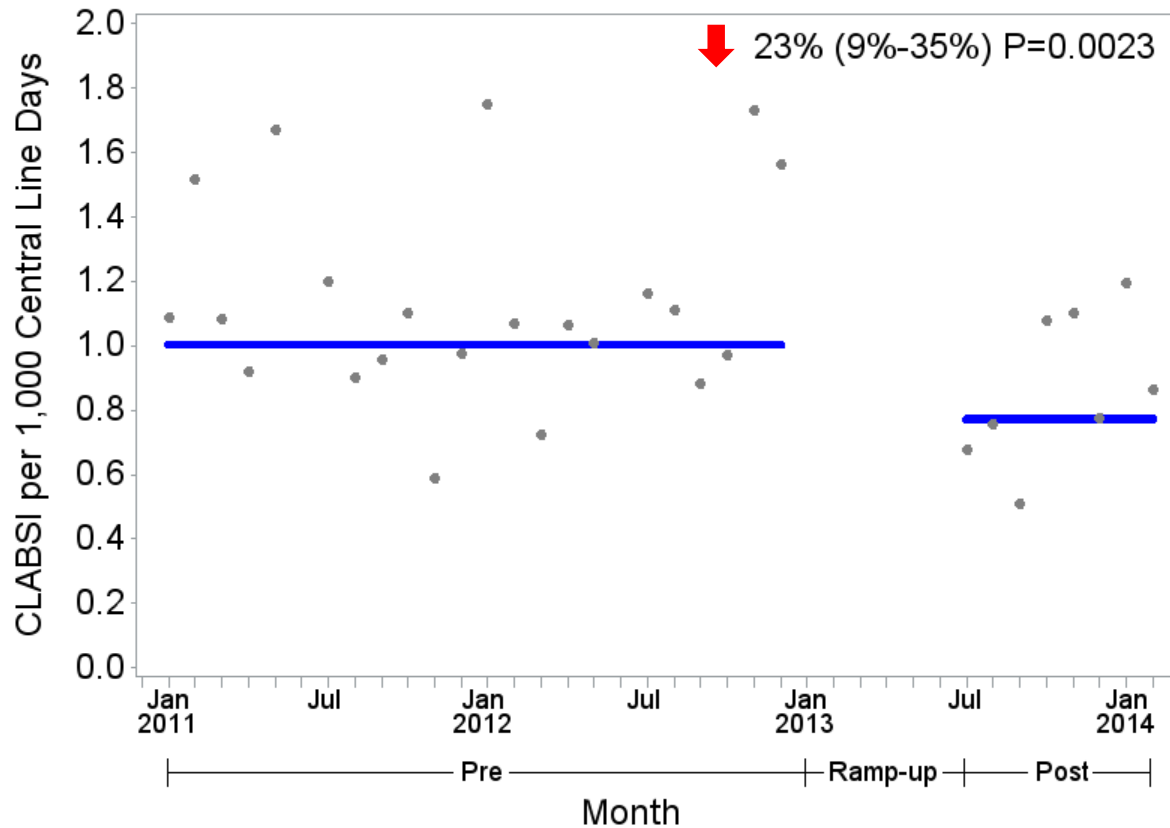
| Call Number     | Goals   |
|-----------------|---|
| Coaching call 1 | Communicate goal/create the vision<br>Define each member's roles and responsibilities                         |
| Coaching call 2 | Hospital protocol<br>Electronic order set   |
| Coaching call 3 | Go Live<br>Supply chain requests<br>Nursing education (CHG bathing, mupirocin, documentation)                 |
| Coaching call 4 | Define process and outcome metrics (compliance, CLABSI)   |
| Coaching call 5 | Identify opportunities and refine the process<br>Monitor process and metrics daily, then weekly, then monthly |

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Abbreviations: CHG, chlorhexidine; CLABSI, central line-associated bloodstream infection.

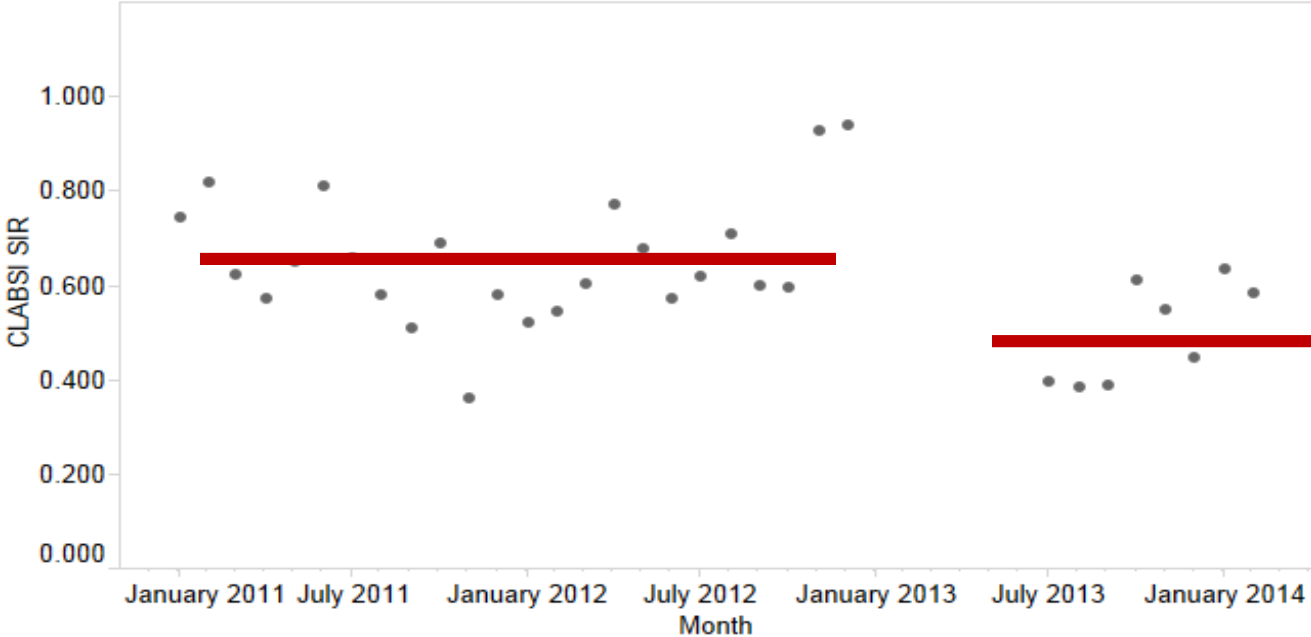
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# Significant Reduction of CLABSI in HCA Adult ICUs



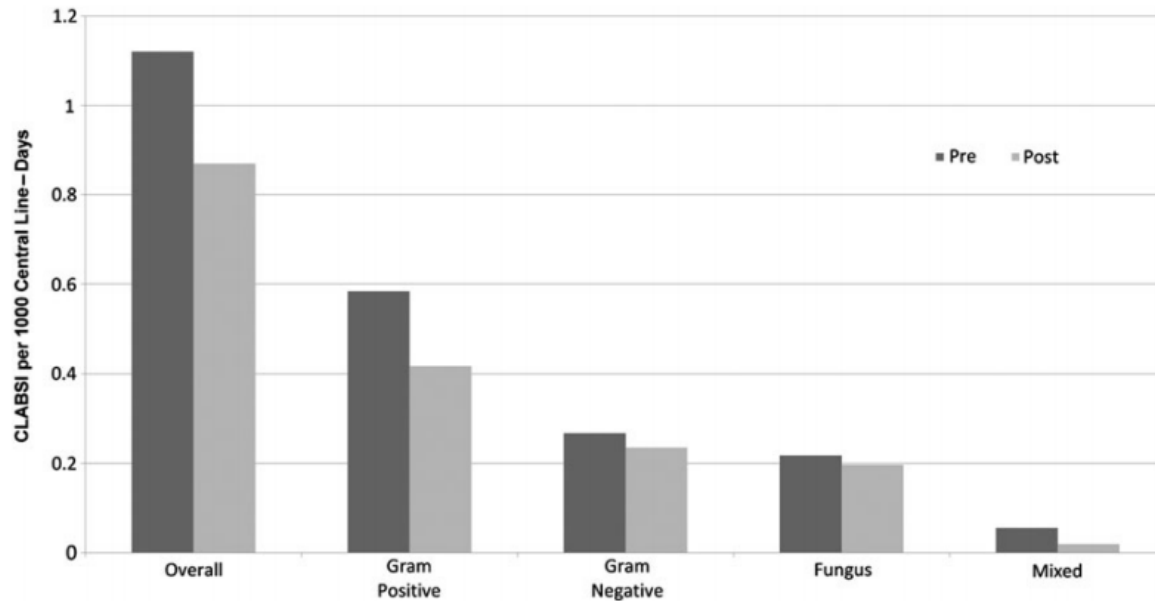
Source: National Healthcare Safety Network (NHSN)

**CLABSI Standardized Infection Ratios (SIR) by Month in HCA Adult ICUs**



**(SIR) decreased 21.5% (p =.004, 95% CI [7.5%, 33.5%])**

# Rate of central line-associated bloodstream infections (CLABSIs) per 1000 central line-days pre- and post implementation, stratified by pathogen type.





# ABATE Implementation

- October to December 2017:
  - Planning and implementation will be coordinated by corporate infection prevention(IP) team
  - Create toolkit with implementation guidance and materials including detailed decolonization protocols and training including a skills assessment guide and computer based training
  - Develop sample policies, order sets, and procedures for all noncritical care patients with devices and central lines
  - Begin work with IT to help identify patients with central lines
  - Create Nursing data portal, Tableau and NPR reports for CHG and mupirocin compliance
  - Work with supply chain to begin process of ordering supplies (mupirocin, warmers, CHG cloths and CHG liquid with mesh sponges)

# ABATE Implementation

- January 2018 First coaching call #1
  - Discuss rationale and science around decolonization for patients with central lines and devices
  - Develop a team locally with a physician champion(s), nurse champion(s), representative from, senior leadership, IP, supply chain-define roles and responsibilities
  - Introduce toolkit, computer based training, and video
  - Nursing education to include CHG bathing and mupirocin application
- February 2018 Coaching call #2
  - How to implement hospital protocol and order sets
  - Physician education
  - Define process and outcome measures (e.g. compliance and CLABSIs)
  - Remove products that are not CHG compatible
- March 2018 Coaching call #3
  - Ramp up to go live (will take 3-4 months)
  - Identity implementation opportunities and feedback using Tableaux and NPR reports