Active Bathing to Eliminate Infection Project

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Ed Septimus, MD
Hospital Corporation of America

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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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

Central Line Associated Bloodstream Infections

Definitive trials needed to impact this setting

2001: 43,000
2009: 18,000

Hand hygiene
Antimicrobial lines
CHG dressings
CHG skin prep
CHG bathing
MRSA screening

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm
# ICU Decolonization Evidence Summary

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

NEJM Jun 2013:368:2255-2265
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

Kassakian et al. ICHE 2011;32(3):238-43
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

- Baseline: 12 months (Mar 2013 to Apr 2014)
- Phase-in: (Apr 2014 to Jun 2014)
- Intervention: 21 months (Jun 2014 to Feb 2016)
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

Clinicaltrials.gov: NCT02063867
HCA Hospitals and Units

**Intervention:** 339,904 patients
1,294,153 attributable patient days

### As Randomized

<table>
<thead>
<tr>
<th>Routine Care</th>
<th>Decolonization</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>26 Hospitals</strong>&lt;br&gt;(90 units)&lt;br&gt;N = 156,887</td>
<td><strong>27 Hospitals</strong>&lt;br&gt;(104 units)&lt;br&gt;N = 183,017</td>
</tr>
<tr>
<td>2 Hospitals&lt;br&gt;(2 units) withdraw</td>
<td>3 Hospitals&lt;br&gt;(6 units) withdraw</td>
</tr>
</tbody>
</table>

### As Treated

| 24 Hospitals<br>(88 units)<br>N = 152,596 | 24 Hospitals<br>(98 units)<br>N = 177,076 |
ABATE Infection Trial
HCA Hospital Sites

Number of Units
- 1-2
- 3-4
- 5-6
- 7-8
- >8

Arm 1 Routine Care
Arm 2 Decolonization
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
Arm 2 Instructional Handouts
Provided in English and Spanish

Instructional Handouts

Arm 2 Huddle Documents
Covering 14 Topics
Arm 2 – Training Video

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

Scenarios of ways to encourage patients to bathe

Bathing demonstration using mannequin

Showering Instructions Overview
Arm 2: Overall CHG and Mupirocin Usage

Arm 2: CHG and Mupirocin Usage Average

- **Chlorhexidine Usage**
- **Mupirocin Usage**

![Graph showing CHG and Mupirocin usage over time]
Arm 2 – Quarterly Staff and Patient Compliance Assessments

# completed: 1,469

# 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

<table>
<thead>
<tr>
<th>Variable</th>
<th>Routine Care</th>
<th>Decolonization</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (mean years)</td>
<td>62.3</td>
<td>62.6</td>
</tr>
<tr>
<td>Female</td>
<td>53.9%</td>
<td>54.8%</td>
</tr>
<tr>
<td>Comorbidity Score (Elixhauser)</td>
<td>2.8</td>
<td>2.9</td>
</tr>
<tr>
<td>Surgery (CDC)</td>
<td>20.9%</td>
<td>22.4%</td>
</tr>
<tr>
<td>Non-ICU Length-of-Stay (days)</td>
<td>5.7</td>
<td>5.7</td>
</tr>
<tr>
<td>Central Lines</td>
<td>9.1%</td>
<td>10.7%</td>
</tr>
<tr>
<td>MRSA History</td>
<td>1.4%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>
MRSA & VRE Clinical Cultures

P = 0.16
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

<table>
<thead>
<tr>
<th>Population</th>
<th>Base Event Rate</th>
<th>Arm 2 vs 1 Effect</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Cohort</td>
<td>2.4</td>
<td>-8.7%</td>
<td>0.16</td>
</tr>
<tr>
<td>High Rate Hospitals</td>
<td>3.7</td>
<td>2.1%</td>
<td>0.86</td>
</tr>
<tr>
<td>Patients with Devices</td>
<td>3.5</td>
<td>-32.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients without Devices</td>
<td>2.1</td>
<td>2.9%</td>
<td>0.72</td>
</tr>
</tbody>
</table>

Patients with Devices: 12% of study population, 35% of all events
### MRSA and VRE Clinical Cultures

- Event rate per 1,000 patient days

<table>
<thead>
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<td>0.16</td>
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<tr>
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<td>3.7</td>
<td>2.1%</td>
<td>0.86</td>
</tr>
<tr>
<td>Patients with CVCs</td>
<td>3.5</td>
<td>-32.0%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Patients without CVCs</td>
<td>2.1</td>
<td>4.2%</td>
<td>0.60</td>
</tr>
</tbody>
</table>

Patients with CVCs: 11% of study population, 34% of all events
MRSA & VRE Clinical Cultures: Patients with Central Lines and Devices

Arm 1                       Arm 2
Routine Care               Decolonization

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

<table>
<thead>
<tr>
<th>Arm 1</th>
<th>Arm 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine Care</td>
<td>Decolonization</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Population</th>
<th>Base Event Rate</th>
<th>Arm 2 vs 1 Effect</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full Cohort</td>
<td>1.3</td>
<td>- 6.2%</td>
<td>0.44</td>
</tr>
<tr>
<td>High Rate Hospitals</td>
<td>1.8</td>
<td>6.8%</td>
<td>0.62</td>
</tr>
<tr>
<td>Patients with Devices</td>
<td>3.3</td>
<td>- 27.8%</td>
<td>0.004</td>
</tr>
<tr>
<td>Patients without Devices</td>
<td>0.8</td>
<td>14.9%</td>
<td>0.29</td>
</tr>
</tbody>
</table>

Patients with Devices: 12% of study population, 59% of all events
### All Pathogen Bloodstream Infection

- Event rate per 1,000 patient days

<table>
<thead>
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<th>P-value</th>
</tr>
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<tr>
<td>Full Cohort</td>
<td>1.3</td>
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<td>0.44</td>
</tr>
<tr>
<td>High Rate Hospitals</td>
<td>1.8</td>
<td>6.8%</td>
<td>0.62</td>
</tr>
<tr>
<td>Patients with CVCs</td>
<td>3.3</td>
<td>-26.9%</td>
<td>0.005</td>
</tr>
<tr>
<td>Patients without CVCs</td>
<td>0.8</td>
<td>17.0%</td>
<td>0.22</td>
</tr>
</tbody>
</table>

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

Arm 1: Routine Care

Arm 2: Decolonization

Hazard Ratio

1.15

0.84

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
### Hospital Participants

<table>
<thead>
<tr>
<th>Arm 1 Facilities</th>
<th>Arm 2 Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cartersville Medical Center</td>
<td>Blake Medical Center</td>
</tr>
<tr>
<td>Coliseum Northside Hospital</td>
<td>Methodist Specialty &amp; Transplant Hospital</td>
</tr>
<tr>
<td>Colleton Medical Center</td>
<td>Methodist Texan Hospital</td>
</tr>
<tr>
<td>Conroe Regional Medical Center</td>
<td>Clear Lake Regional Medical Center</td>
</tr>
<tr>
<td>Corpus Christi Medical Center</td>
<td>Eastside Medical Center</td>
</tr>
<tr>
<td>Garden Park Medical Center</td>
<td>John Randolph Medical Center</td>
</tr>
<tr>
<td>Hendersonville Medical Center</td>
<td>Las Colinas Medical Center</td>
</tr>
<tr>
<td>Henrico Doctors' Hospital</td>
<td>Las Palmas Medical Center</td>
</tr>
<tr>
<td>Kingwood Medical Center</td>
<td>Medical Center of Plano</td>
</tr>
<tr>
<td></td>
<td>Methodist Hospital</td>
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<tr>
<td>Lee’s Summit Medical Center</td>
<td>Regional Medical Center of Acadiana</td>
</tr>
<tr>
<td>LewisGale Hospital-Alleghany</td>
<td>Research Medical Center</td>
</tr>
<tr>
<td>Methodist Stone Oak Hospital</td>
<td>South Bay Hospital</td>
</tr>
<tr>
<td>North Suburban Medical Center</td>
<td>St. Petersburg General Hospital</td>
</tr>
<tr>
<td>Northeast Methodist Hospital</td>
<td>Summit Medical Center</td>
</tr>
<tr>
<td>Northside Hospital</td>
<td>Sunrise Hospital and Medical Center</td>
</tr>
<tr>
<td>Osceola Regional Medical Center</td>
<td>TriStar Horizon Medical Center</td>
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<tr>
<td>Overland Park Regional Medical Center</td>
<td>TriStar Horizon Medical Center</td>
</tr>
<tr>
<td>Palms West Hospital</td>
<td>TriStar Horizon Medical Center</td>
</tr>
<tr>
<td>Parkridge East Hospital</td>
<td>Reston Hospital Center</td>
</tr>
<tr>
<td>Plaza Medical Center of Fort Worth</td>
<td>Rio Grande Regional Hospital</td>
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<tr>
<td>Research Medical Center</td>
<td>St. David's Medical Center</td>
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<tr>
<td>South Bay Hospital</td>
<td>Timpanogos Regional Hospital</td>
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<tr>
<td>St. Petersburg General Hospital</td>
<td>TriStar Southern Hills Medical Center</td>
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<tr>
<td>Summit Medical Center</td>
<td>Valley Regional Medical Center</td>
</tr>
<tr>
<td>Sunrise Hospital and Medical Center</td>
<td>West Florida Hospital</td>
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<tr>
<td>TriStar Horizon Medical Center</td>
<td>West Hills Hospital &amp; Medical Center</td>
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<tr>
<td>TriStar Horizon Medical Center</td>
<td>West Palm Hospital</td>
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</table>
Special Thanks

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Jalpa Patel Sarup, MT(ASCP)

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Julie Lankiewicz, MPH

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Tyler Forehand, BS

RUSH
Robert Weinstein, MD

CDC
John Jernigan, MD MS
Next Steps for HCA Implementation
Generating and adapting to new evidence of effective care is the hallmark of learning health care systems.
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.¹
- Improving population health outcomes relies on implementation of findings from clinical and health services research.²

It takes an average of 17 years for research to reach clinical practice³

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³ Balas EA, Yearbook of Medical Informatics 2000;65-70.
Time Line: Rapid Adoption REDUCE Infection Trial

Baseline (Pre)  
Jan 2011

Ramp-up
Jan 2013

Full Implementation (Post)  
Jul 2013

Presented ID Week

Published *N Engl J Med*

Feb 2014

137 ICUs from 96 hospitals
## Coaching Calls

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

Abbreviations: CHG, chlorhexidine; CLABSI, central line–associated bloodstream infection.
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 = 0.004, 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