Active Bathing to Eliminate Infection Project

Backstage Tour
Coaching Call
April 19, 2016
Investigator Team

Susan Huang MD MPH, Ed Septimus MD, Julia Moody MS, Jason Hickok MBA RN, Ken Kleinman ScD, Robert A. Weinstein MD, Mary Hayden MD, John Jernigan MD MS
ABATE Infection Project
Active Bathing to Eliminate Infection

Trial Goal
Evaluate if antiseptic bathing for all non-critical hospitalized patients and nasal ointment for MRSA carriers can reduce the burden of multi-drug resistant organisms and hospital-associated infections

Trial Design
- 2-arm cluster randomized trial
- 53 HCA hospitals and their adult non critical care units

Arm 1: Routine Care
- Routine policy for showering/bathing

Arm 2: Decolonization
- Daily CHG shower or CHG cloth bathing routine for all patients
- Mupirocin x 5 days if MRSA+ by history, culture, or screen
ABATE Coordinating Team

**General Communications**
- Adrijana Gombosev
- Lauren Heim

**Rush University**
- Mary Hayden
- Karen Lolans
- Lena Portillo
- Jalpa Patel Sarup

**Laboratory Communication and Coordination**
- Julie Lankiewicz
- Katie Haffenreffer
- Lauren Shimelman
- Becky Kaganov
- Julia Moody
- Chris Bushe
Data Coordinating Team

**Harvard Team**
- Taliser Avery
- Michael Murphy
- Ken Kleinman, Statistician

**HCA Team**
- Caren Spencer-Smith
- Tyler Forehand
Enterprise Support

Stakeholder Support

Jon Perlin
David Vulcano
Jon Foster
Chuck Hall
Jane Englebright
HCA Sectors of Involvement

- HCA Corporate Leadership
- Clinical Services Group
- Compliance and Regulatory Affairs
- Infection Prevention
- Quality
- Unit Directors and Managers
- Supply Chain
- Pharmacy
- Laboratory and Microbiology
- IT
Agenda

• Recruitment
• IRB Process
• Randomization
• Central Coordination
• On-Site Training
• CHG Compatibility
• Compliance
• Strain Collection
• Data Collection and Analysis of Outcomes
• Participant Commendations
Trial Timeline

- Nov 2012 – Feb 2013
  - Recruitment
  - Eligibility Surveys

- Apr – Sept 2013
  - IRB Ceding

- Nov 2013
  - Randomization

- Mar 2014
  - Arm 2 Site Training

- Apr – May 2014
  - Phase-in (Arm 2)

- Jun 2014
  - Intervention Start

- Feb 2016
  - End of Trial
Recruitment

November 2012 – February 2013
ABATE Infection Trial Sites

55 Hospitals in 11 weeks
IRB Process

Julie Lankiewicz
Becky Kaganov
IRB Process

Centralized IRB Process

• 52 of 53 hospitals ceded to Harvard
  – One hospital provided their own oversight
  – Ceding process completed in 5 months (N=51, 98%)

• Authorized waiver of informed consent

• Prisoner representative – CJW Medical Center
Randomization
November 2013

Taliser Avery
Susan Huang
Ken Kleinman
Randomization Method

- Hospital Level: all participating units to same arm
- 53 hospitals participated in randomization
- Randomization accounted for baseline data
  - Hospital’s volume of patients in participating units
  - Hospital’s attributable patient days in participating units
  - Comorbidity index
  - % Surgery
  - % Cardiac/orthopedic patients
  - Prevalence of MRSA and VRE
  - Baseline MRSA and VRE clinical cultures
  - Baseline bloodstream infection rate
Randomization: Final List

<table>
<thead>
<tr>
<th>Arm</th>
<th># Hospitals</th>
<th># Units</th>
<th># States Represented</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>26</td>
<td>88</td>
<td>11</td>
</tr>
<tr>
<td>2</td>
<td>27</td>
<td>103</td>
<td>11</td>
</tr>
<tr>
<td>Total</td>
<td>53</td>
<td>191</td>
<td>15</td>
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</tbody>
</table>
53 hospitals participated in randomization
5 hospitals dropped out
  - 3 due to implementation of competing interventions
    - Arm 1
      - CHG pre-op bathing
      - CHG bathing in non-critical care units
    - Arm 2
      - Implementation of UV system
      - 1 due to single participating unit closing
      - 1 due to divestiture from HCA
Central Coordination

Adrijana Gombosev
Lauren Heim
Central Coordination Responsibilities

- Study calls
- Gmail and 800 number response
- Maintain contact information
- Study documents
- Protocol education
- Compliance reports
- Maintain log of key issues that arise
- Coordinate and training and site visits
- Tracking competing interventions
Many conference calls are held throughout the week to ensure trial runs smoothly

- Steering Committee
- Analytics
- IT/data pulls
- Coordination

Field Calls

- Coaching calls
- Special Coaching calls
- Site specific compliance calls
Coaching Calls

- **Number of Arm 1 calls**: 22
- **Number of Arm 2 calls**: 40
- **Number of Lab calls**: 11
- **Special Coaching Calls**: 7

<table>
<thead>
<tr>
<th>Title</th>
<th>Presented by</th>
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<tbody>
<tr>
<td>Compendium of Strategies to Prevent HAIs</td>
<td>Deborah Yokoe, MD, MPH – Brigham &amp; Women’s Hospital and Dana-Farber Cancer Institute</td>
</tr>
<tr>
<td>The Road to ABATE: The HCA Journey</td>
<td>Ed Septimus, MD – HCA</td>
</tr>
<tr>
<td>ABATE Baseline Strain Collection Results</td>
<td>Mary Hayden, MD – Rush University</td>
</tr>
<tr>
<td>Secondary Analyses: REDUCE MRSA Trial</td>
<td>Susan Huang, MD MPH – U of California, Irvine</td>
</tr>
<tr>
<td>Nasal Decolonization of <em>S aureus</em>: Present and Future Prospects</td>
<td>Ed Septimus, MD – HCA</td>
</tr>
<tr>
<td>Major Infection Control Publications</td>
<td>Robert A. Weinstein, MD – Rush University</td>
</tr>
<tr>
<td>Considerations in QI Research</td>
<td>Susan Huang, MD MPH – U of California Irvine</td>
</tr>
</tbody>
</table>
Central Coordination

- # of Gmail Inquires Addressed: 11,183

ABATEStudy@gmail.com

(855) 33-ABATE
(855) 332-2283
Educational Materials

# of Binders Shipped: 239

# of Wall Flyers Shipped (Arm 2):
2,330 room flyers; 1,149 shower flyers
Educational Materials

Arm 2 Instructional Handouts Provided in English and Spanish

Arm 2 Huddle Documents Covering 14 Topics
Computer Based Training

• Web based training module with audio for each study arm
  – *Arm 1 module*: 11 slides + 6 question post-test
  – *Arm 2 module*: 30 slides + 8 question post-test
• Launched on Healthstream in January 2014
• Required for all nursing staff on participating units
• Continued use for protocol reinforcement and training new staff
• Annual CBTs completed

<table>
<thead>
<tr>
<th></th>
<th>2014</th>
<th>2015</th>
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<tbody>
<tr>
<td>Arm 1</td>
<td>3,407</td>
<td>2,022</td>
</tr>
<tr>
<td>Arm 2</td>
<td>4,928</td>
<td>3,721</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>8,335</strong></td>
<td><strong>5,743</strong></td>
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Arm 2 – Training Video

• 10 minute CHG bathing demonstration video scripted by ABATE investigators
• Accessible to nursing staff throughout trial via Atlas
  – Use for refresher, float, and new staff training
• Special thanks to Sage Products for producing and filming!
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
On Site Training

Jason Hickok
Ed Septimus
Julia Moody
Chris Bushe
Susan Huang
Arm 2 On-Site Training

- Visits conducted during March-early April 2014 by Sage Medical Liaisons and ABATE Study Staff
  - 26 baseline training visits completed
- 10 additional refresher training visits completed
Arm 2 On-Site Training

Instructional Presentation and Product Demonstration

Visiting Participating Units

Product Compatibility Checks
CHG Compatibility

Lauren Shimelman

Laurie Brewer
Ensuring CHG Compatibility

• Several lotions, ointments, incontinence cleanup and barrier products, soap and bathing products inactivate CHG

• Assessed skin products in clean supply areas for Arm 2 units
  – ~ 200 products reviewed
  – Removed incompatible bathing products
  – Alternative options provided for incompatible products and/or products with unknown compatibility
CHG Compatibility

- Product Compatibility Handout included in toolkit binders, emailed and uploaded to ATLAS

<table>
<thead>
<tr>
<th>SOLUTIONS</th>
<th>Compatible Products</th>
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<tbody>
<tr>
<td>Handout</td>
<td>Toolkit binders, emailed and uploaded to ATLAS</td>
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<table>
<thead>
<tr>
<th>RECENTENNE SURGICAL PRODUCTS</th>
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<tbody>
<tr>
<td>Compatible Products</td>
</tr>
<tr>
<td>- CHG All-Star Pads 1-Protective Barrier Cream</td>
</tr>
<tr>
<td>- CHG All-Star Pads 2 - Protective Barrier Cream</td>
</tr>
<tr>
<td>- CHG All-Star Pads 3 - Protective Barrier Cream</td>
</tr>
<tr>
<td>- Medical Grade Ointment Ointment Paste</td>
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<tr>
<td>- Medical Grade Ointment Ointment Paste</td>
</tr>
<tr>
<td>- Medical Grade Ointment Ointment Paste</td>
</tr>
<tr>
<td>NOT Compatible Products</td>
</tr>
<tr>
<td>- Medical Grade Ointment Ointment Paste</td>
</tr>
</tbody>
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<thead>
<tr>
<th>BECOMENNE CLEAN UP, PULMONAL CLEANERS, BABY WINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Compatible Products</td>
</tr>
<tr>
<td>- Personal Cleaners</td>
</tr>
<tr>
<td>- CHG All-Star Pads 1-Protective Barrier Cream</td>
</tr>
<tr>
<td>NOT Compatible Products</td>
</tr>
<tr>
<td>- Personal Cleaners</td>
</tr>
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**GENERAL GUIDELINES**
- DO NOT USE ANY BATHING, SOAP OR SHAMPOO PRODUCTS. CHG getting used on CHG liquid soap results in zero and not yet.
- SHAMPOO: Leave-in Shampoo Cream may be used with care. Minerals for body skin, suggested products include CHG compatible with tested and found safe.
- **DO NOT USE ANY BATHING, SOAP OR SHAMPOO PRODUCTS.** CHG getting used on CHG liquid soap results in zero and not yet.
- **NOT Compatible:** Products intended to treat active skin infections or for medical management of infections can be used as needed, including and targeted cream, topical cream, ointment, and no cable products.

*Product compatibility is unknown, or has not been tested by manufacturer for compatibility
**Product is not compatible with chlorhexidine, as confirmed by manufacturer
Compliance

Lauren Heim
Compliance Tracking

• Daily checks for all units until ≥85% compliance or greater met consistently for all measures, then moved to monthly (once/week) checks
  ➢ CHG bathing
  ➢ Mupirocin administration
  ➢ Documentation (Arm 2)

• Number of unit compliance reports submitted: **7,933**
ABATE Nursing Query

- Bath in 24 hours
  1. No bath
  2. Bath/Shower with CHG
  3. Bath/Shower without CHG

Hygiene Care

Bath/Shower in past 24 hours:

Reason for no bath:
Tableau Reports

- Corporate IT&S developed user friendly reports to capture bathing and mupirocin administration
- Eased process for completing compliance spreadsheets

Special Thanks to Tyler Forehand and the Corporate IT&S Team!
Arm 1: Protocol Compliance

Arm 1: Per-protocol non-use of CHG and mupirocin
Arm 1:
Overall CHG and Mupirocin Non-Usage

Arm 1: Reflects usage even with acceptable exceptions per protocol
Arm 2: Protocol Compliance

Arm 2: CHG and Mupirocin Compliance Average

- Chlorhexidine Compliance
- Mupirocin Compliance
Arm 2:
Overall CHG and Mupirocin Usage

Arm 2: CHG and Mupirocin Usage Average

- Chlorhexidine Usage
- Mupirocin Usage
Arm 2 – Quarterly Staff and Patient Compliance Assessments

**HCA Skills Assessment: CHG Cloth Observation Checklist**

*Please complete for THREE different staff per unit*

**Individual Grooming CHG Bath**
- 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 guidance
- [Y] N: Patient told that both his/ her clothes that provide protection from gown
- [Y] N: Provided rationale to the patient for not using soap at any time while in unit
- [Y] N: Massaged skin/joints with CHG cloth to ensure adequate cleansing
- [Y] N: Cleaned face and neck well
- [Y] N: Cleaned between fingernail
- [Y] N: Cleaned between all folds
- [Y] N: N/A: Cleaned exclusive and semi-permeable dressings with CHG cloth
- [Y] N: N/A: Cleaned 6 inches of all tubers, central lines, and drains closed to body
- [Y] N: N/A: Used CHG on superficial wounds, rash, and stages 1 & 2 decubitus ulcers
- [Y] N: N/A: Used CHG on surgical wounds (defects, primary dressing, or packed)
- [Y] N: Allowed CHG to air dry / does not wipe off CHG
- [Y] N: Dried with soft cloth in tissue / does not flush

**HCA Skills Assessment: CHG Cloth – Patient Self-Bathing**

*Please complete for THREE different patients per unit*

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

# completed: 1,469

# completed: 1,251
Top CHG Patient Bathing Issues

- Patient was NOT:
  - Provided instructional handout on how to apply CHG cloths
  - Told to NOT use other bathing soaps or lotions while on unit
  - Told that the temporary stickiness was due to aloe and would go away when dried

- Patient or bathing assistant did NOT:
  - Clean wounds
  - Clean lines, tubes, and/or drains
  - Use all six cloths
Top CHG Patient Showering Issues

- Patient was **NOT:**
  - Told to soap up twice with CHG before rinsing
  - Provided instructional handout on how to apply liquid CHG

- Patient or bathing assistant did **NOT:**
  - Clean lines, tubes, and/or drains with a CHG cloth after showering
  - Clean superficial wounds with a CHG cloth after showering
  - Leave CHG on skin for 2 minutes before rinsing off
  - Use the mesh sponge for application
## Intervention Tracking

- New/proposed interventions evaluated by Steering Committee to check for conflict with trial outcomes

<table>
<thead>
<tr>
<th>Arm</th>
<th>Proposed Interventions</th>
<th>Allowed</th>
<th>Not Allowed (Conflicting)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>83</td>
<td>47 (57%)</td>
<td>36 (43%)</td>
</tr>
<tr>
<td>2</td>
<td>102</td>
<td>73 (72%)</td>
<td>29 (26%)</td>
</tr>
<tr>
<td>Division</td>
<td>9</td>
<td>7 (78%)</td>
<td>2 (22%)</td>
</tr>
<tr>
<td>Corporate</td>
<td>2</td>
<td>2 (100%)</td>
<td>0 (0%)</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>196</strong></td>
<td><strong>129 (66%)</strong></td>
<td><strong>67 (34%)</strong></td>
</tr>
</tbody>
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*Additional 8 (4%) intervention reported, but withdrawn*
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<thead>
<tr>
<th>Commonly Reported Interventions</th>
</tr>
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**Interventions deemed **in conflict** with the study:**

- New use of UV cleaning systems or UV/ATP monitoring
- New practice audits that provide feedback for improvement (e.g. direct environmental cleaning audits)
- New use of alcohol caps for central lines

**Interventions deemed **not in conflict** with the study:**

- Vendor swap out (highly similar product)
- Re-inservicing on current gold standard practice
Strain Collection

Lauren Shimelman

Katie Haffenreffer
Strain Collection Overview

• Goal: Assess emergence of mupirocin and CHG resistance
• MRSA and select GNR collection throughout trial, VRE collection for part of Intervention
• One isolate per species from a single patient admission
• 38 laboratories shipped isolates to Rush University
• Eligible Isolate Report (EIR) developed and implemented
• ~2,000 phone calls to laboratories throughout trial
Strain Collection Overview

Isolate Documentation and Shipping Materials

800 isolate shipping kits sent to participating laboratories
Strain Collection Totals

Total Isolates Confirmed

- MRSA: 44%
- E. coli: 24%
- K. pneumoniae: 10%
- P. aeruginosa: 10%
- P. mirabilis: 5%
- K. oxytoca: 1%
- S. marcescens: 1%
- A. baumannii: 2%
- S. maltophilia: 2%
- Burkholderia spp.: 0%
- VRE: 1%

Figures as of 3/28/16
Rush University
Antibiotic/Antiseptic Resistance Testing

Rush University

Mary Hayden
Karen Lolans
Lena Portillo
Jalpa Patel Sarup
Mupirocin Susceptibility Testing (MRSA)

- **Susceptible**
  - MIC < 8 µg/ml

- **Low-level Resistance**
  - MIC 8-64 µg/ml

- **High-level Resistance**
  - MIC > 256 µg/ml
CHG Susceptibility Testing (All Isolates)

- Microtiter method using 20% aqueous chlorhexidine digluconate diluted in cation-adjusted Mueller Hinton broth

Minimum Inhibitory Concentration (MIC) – μg/ml

| Growth control | 32 | 16 | 8 | 4 | 2 | 1 | 0.5 | 0.25 | 0.125 | 0.06 | 0.03 |

Denotes MIC of test isolate
Data Collection and Analysis of Outcomes

Taliser Avery
Susan Huang
Ken Kleinman
Caren Spencer-Smith
Types of Data

Admission
- Encrypted Patient ID
- Admission Dates
- Sex
- Ethnicity
- Insurance
- 21 Diagnoses codes
- 21 POA indicators
- 15 Procedure codes
- Final disposition

Nursing Query
- Encrypted Patient ID
- Specimen ID
- Nursing Date
- Unit / Charge Type
- Chlorhexidine bath

Supply Chain
- Gloves, gowns,
- Alcohol rub

Charge
- Charge Date
- Unit / Charge Type
- Unit name
- Mupirocin use
- Chlorhexidine use

Lab
- Encrypted Patient ID
- Specimen ID
- Collection Date
- Screen vs. Culture
- Pathogen
- Antibiotic
- Result
Analysis Plan: Population

- All patients who entered a participating ABATE unit at 53 hospitals, 191 units

- Timeframe

<table>
<thead>
<tr>
<th>Baseline</th>
<th>April 2013-March 2014</th>
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<tbody>
<tr>
<td>Phase-In (2 months)</td>
<td>April-May 2014</td>
</tr>
<tr>
<td>Intervention (21 months)</td>
<td>June 2014-Feb 2016</td>
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</tbody>
</table>
Outcomes obtained from the HCA data warehouse

**Primary Outcomes**
- Unit-attributable clinical cultures with MRSA and VRE

**Additional Outcomes**
- Unit-attributable clinical cultures with GNR MDRO
- Unit-attributable clinical cultures with *C. difficile*
- Bloodstream infections: all pathogens
- Bloodstream contaminants
- Urinary tract infections: all pathogens
- 30 day readmissions (total and infectious)
- Emergence of resistance (strain collection)
- Cost effectiveness
Outcomes obtained from the HCA data warehouse

Primary Outcomes

• Unit-attributable clinical cultures with MRSA and VRE

Additional Outcomes

• Unit-attributable clinical cultures with GNR MDRO
• Bloodstream infections: all pathogens
Analysis Plan: Primary Manuscript

- HCA has 45-60 day window to finalize data (June 2016)
- Conservative Estimates – hope to accelerate
  - Data cleaning: 6-8 months
  - Analysis: 1-2 months
  - Submit abstract to ID week: May 2017
  - Present to HCA participants: October 2017
  - Present at ID week: October 2017
Participant Commendation
Participant Certificates - Hospital

Certificate of Appreciation

Presented on March 1, 2016 to

“Hospital Name”

In recognition for your outstanding participation in the ABATE Infection Project. Your dedication to this trial was instrumental to its success.
Participant Certificates - Lab

Certificate of Appreciation

Presented on March 1, 2016 to

"[Lab Name]"

In recognition for your microbiology laboratory’s outstanding participation in the ABATE Infection Project. Your dedication to this trial was instrumental to its success.
Thanks to Our Participating Hospitals, Investigative Team, & Supporters

Active Bathing to Eliminate Infection Project