ABATE Infection Trial
*Barriers and Lessons Learned*

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Disclosures

Conducting clinical studies in which participating hospitals and nursing homes are receiving contributed antiseptic product from Sage Products, Molnlycke, 3M, Clorox, and Xttrium.

Sage Products and Molnlycke contributed products to the participants of the ABATE Infection Trial.

Contributing companies have no role in the design, conduct, analysis or publication of these studies.
ABATE Infection Trial
Active Bathing to Eliminate Infection

Trial Design
• 2-arm cluster randomized trial
• 53 HCA hospitals and 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 CHG shower or CHG cloth bathing routine for all patients
• Mupirocin x5 days if MRSA+ by history, culture, or screen
Outcomes

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

Additional Outcomes
• Bloodstream infections: all pathogens
• Bloodstream contaminants
• Unit-attributable clinical cultures with GNR MDRO
• Unit-attributable clinical cultures with *C. difficile*
• Urinary tract infections: all pathogens
• 30 day readmissions (total and infectious)
• Emergence of resistance (strain collection)
• Cost effectiveness
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
# Barriers Scorecard: ABATE

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td>X</td>
</tr>
<tr>
<td>Engagement of clinicians and Health Systems</td>
<td>X</td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td></td>
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<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
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<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
<td>X</td>
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</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty
Top 3 Lessons Learned
Operational Expertise is Essential

Intervention insights
• Processes for approvals
• Expected time to change
• Expected variation
• Expected training lapses

Tracking and Data
• Supply chain
  • Compatibility
  • Tracking
• Legacy systems
Culture Change is Hard

Logo Helps

Active Bathing to Eliminate Infection Project
Culture Change is Hard

Color Helps
Culture Change is Hard

FAQs and Talking Points

Project FAQs: Universal Decolonization - Arm 2

1) What is the ABATE Infection Project?
A cluster randomized trial of adult non-critical care units comparing 2 top strategies to reduce multi-drug resistant pathogens and hospital-associated infection. Over 50 HCA hospitals are participating. Your hospital’s adult non-ICUs have been randomized to Universal Decolonization.

2) What is Universal Decolonization?
Decolonization refers to use of chlorhexidine (CHG) for routine daily bathing of ALL patients for their entire unit stay. This includes daily clean-up for incontinence or to “freshen up.” In addition, patients who are known to be MRSA+ will receive nasal mupirocin twice daily for 5 days, or until unit discharge, whichever comes first.

If a patient is readmitted to the unit, the decolonization protocol will begin anew regardless of prior receipt of chlorhexidine or mupirocin in other units or in the previous unit stay. For example, if a patient who is an MRSA carrier just received 5 days of mupirocin and daily chlorhexidine bathing in an ICU and then comes to your unit, they will continue to receive daily chlorhexidine baths and they will begin a 5-day course of mupirocin on your unit.

3) Who should be decolonized with nasal mupirocin ointment?
Your unit will be decolonizing all patients known to be MRSA+ by clinical history, screening test, or clinical culture. These patients will receive both the daily CHG bath or shower PLUS nasal

Avoid eyes and ear canals

Take a CHG Bed Bath

BATHING with CHG cloths

1. Use CHG every day. Starting on the admission day works best to remove germs before IVs, lines, urinary catheters, and procedures/surgery.
2. These no-rinse cloths are your protective bath. The CHG continues to get rid of germs for 24 hours.
3. Use all 6 cloths. More, if needed.
4. Firmly massage on all skin areas to ensure deep cleaning of skin.
5. Clean over non-gauze dressings.
6. Your nurse will clean parts of lines, tubes and drains nearest the body.
7. Throw away in trash. Do not flush.

Protect yourself every day

Important Points and Reminders
- CHG is proven to work better than soap and water to get rid of germs.
- CHG cloths have aloe and are good for your skin. CHG is less drying than soap.
- Do not rinse. Once massaged onto skin, CHG works to kill germs for 24 hours.
- Be thorough. Ask for help if hard to reach areas, backside, around devices.
- CHG is safe on rashes and wounds that are not very large or deep.
- Clean lines, drains, tubes 6 inches from the body. Ask for help if needed.

Clean all skin areas with attention to:
- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds and open skin
- Armpits, groin, between fingers/toes

11
### Public Accountability

#### Culture Change is Hard

### Hospital % CHG % Compliance % CHG % Compliance % CHG % Compliance

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<th>March 8-14</th>
<th>March 15-21</th>
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<td>82%</td>
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1 unit missing
2 or more units missing
<85% compliance
>85% compliance
Data Solutions are Key

Compliance reports
  • Manual → Electronic

Strain Collection Report
  • Manual → Electronic

REDUCE MRSA Trial

<table>
<thead>
<tr>
<th>Total Eligible MRSA during study period (n=7405)</th>
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<tr>
<td>Number of isolates sent to central laboratory (n=4566)</td>
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Data Solutions are Key

Compliance reports
  • Manual $\rightarrow$ Electronic

Strain Collection Report
  • Manual $\rightarrow$ Electronic

<table>
<thead>
<tr>
<th></th>
<th>Baseline Isolates Confirmed</th>
<th>Intervention Isolates Confirmed</th>
<th>Total Isolates Confirmed</th>
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<tbody>
<tr>
<td>ABATE Infection Trial</td>
<td>4263</td>
<td>2884</td>
<td>7147</td>
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Capture by laboratories > 90%
Focused entirely on attributable isolates
Top Lessons Learned

• Operational expertise is essential
• Culture change is hard
• Data solutions are key

Questions?