ABATE Infection Trial

Barriers and Lessons Learned

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Disclosures

Conducting clinical studies in which participating hospitals and nursing homes receive contributed antiseptic product from Sage (Stryker), Molnlycke, 3M, Clorox, Medline, 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
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
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>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td>X</td>
</tr>
<tr>
<td>Stability of control intervention</td>
<td>X</td>
</tr>
<tr>
<td>Implementing/Delivering Intervention Across Healthcare Organizations</td>
<td>X</td>
</tr>
</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty
Top 3 Lessons Learned
#1: Data Cleaning & Validation Takes Time

Pragmatic Trials

- Very large datasets
- Complex data
- Assessments for variation
- Resolution of hospital changes (unit names, unit opening/closing, patient population changes)

General Underestimation

- Grant review committees
- Clinicaltrials.gov
- Investigative team
Post-Trial Timeline

- **Mar-May 2017**
  - Preliminary Analytics
  - Primary Outcome

- **May 2017**
  - Abstract Submitted

- **June-Oct 2017**
  - Preliminary Analytics
  - Subgroup Analyses

- **Oct 2017**
  - Abstract Presented: Primary & Subgroup Outcomes

- **Nov 2017-Apr 2018**
  - Residual Data Clean Up
  - Final Dataset
  - Final Analytics

- **Apr-May 2018**
  - Manuscript Draft
  - Co-Author review
Data Cleaning & Validation Scope

ABATE Infection Pragmatic Trial

- 53 hospitals, 194 units
- 12-month baseline, 21 month intervention

Scope

- ~530,000 patients
- ~1.3 million attributable days
- Raw dataset: 20 million records, 483 million data elements
- Cleaned to analytic dataset: 50 million elements
#2 Manual Compliance Tracking Can Work

- While functional electronic solutions are better, manual processes can be invaluable
  - Electronic solutions take time
  - Electronic solutions may not be successful
- Instituted manual process for compliance checking with standardized form
  - Daily checks till ≥85% compliance then once/week check
  - Greater action/engagement than back end pull
  - Need feedback
- Number of unit compliance reports submitted: 7,933
Quarterly Staff and Patient Compliance Assessments

# Completed: 1,469

# Completed: 1,251
#3 Pragmatic Trials Create Ready Implementation Tools

- Dissemination tools ready for launch (edit away logo)
  - Computer based training for HCA system
  - Flyers and training documents
  - FAQs
  - Video
Posted Flyers

Shower Instructions
For your health, we are pleased to provide you with a special liquid soap, chlorhexidine, which has been proven to work better than regular soap and water in removing germs from your skin and keeping you clean.

1. Use the bottle of liquid chlorhexidine (CHG) for all areas of the body. Begin by washing hair using CHG as shampoo. Rinse well.
2. Next, clean face with CHG, but take care to avoid getting soap into eyes and ears. Rinse.
3. Apply generous amount of CHG to mesh sponge and rub until foamy
   - Wet skin with water
   - Turn water off or stand out of water stream
   - FIRMLY MASSAGE soapy sponge onto all skin. Reapply CHG generously to the sponge to keep sponge with plenty of foamy lather. Be sure to clean from top down (clearest to dirtiest areas).
   - Neck and chest
   - Both shoulders, arms and hands
   - Abdomen, hip and groin
   - Both legs and feet
   - Back of neck, genitals and buttocks last
   - For best results, leave soapy lather on skin for 2 minutes
4. Don’t forget to clean your neck, armpits, and skin folds well, including under the breast. Clean between fingers and toes too.
5. Rinse body well. Also rinse mesh sponge and hang to dry.
6. Dry with clean towel
7. If needed, ask your nurse for CHG compatible lotion to moisturize

CHG continues to work for 24 hours to keep germs off your body. We recommend you use it to wash daily while in the hospital. If you must use your own shampoo and face products, please use them before the CHG soap. Please try to keep them off of the body as regular soap and shampoo prevents CHG from working as well.
Ready Hand Outs

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
Top Lessons Learned

- Plan extensive time for data cleaning and validation
- Manual compliance reviews are possible and can be helpful
- Pragmatic trials yield implementation tools for dissemination

Questions?