

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

Outcomes

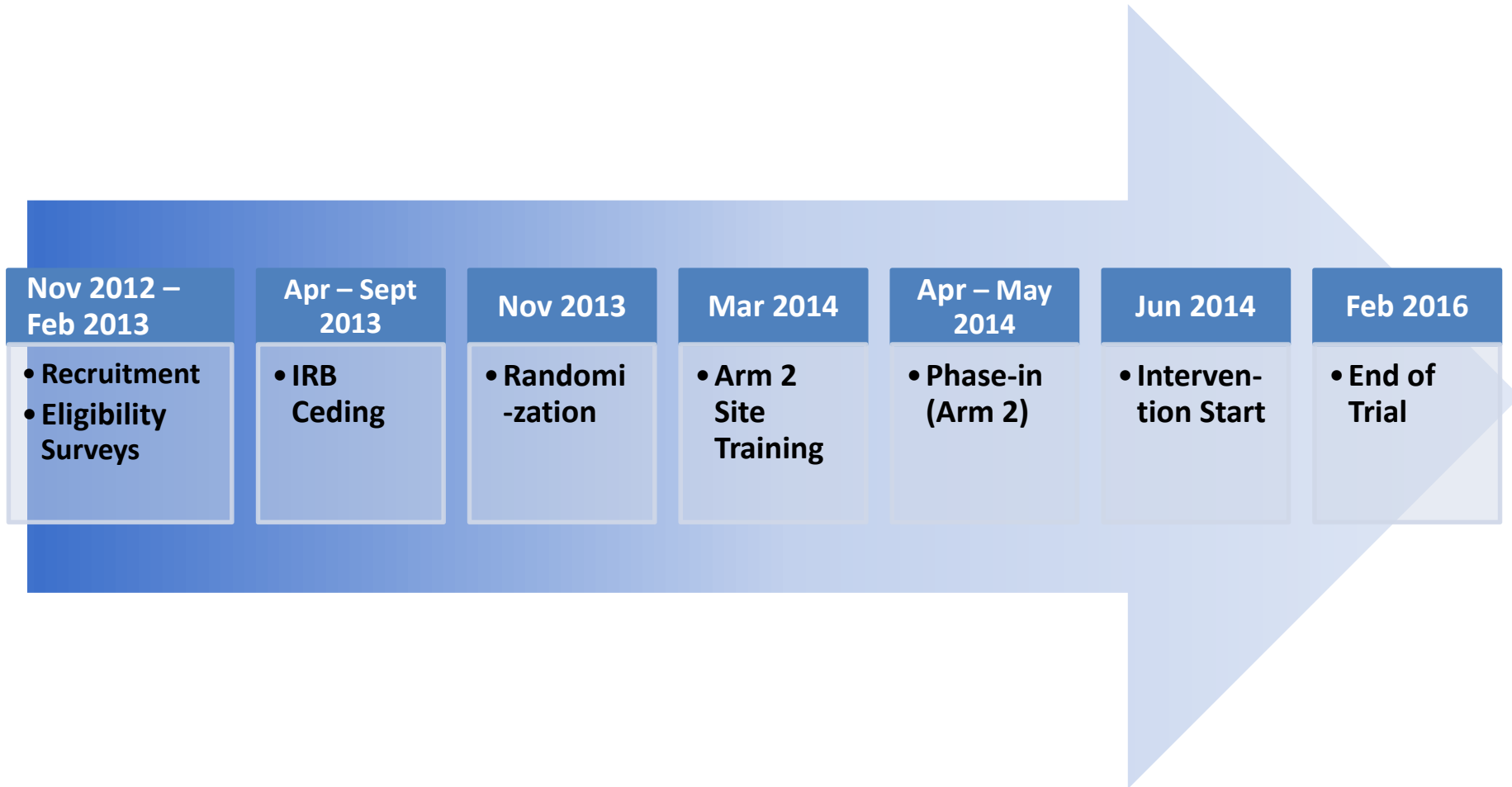
Primary Outcomes

- 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



Barriers Scorecard: ABATE

Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects	X				
Engagement of clinicians and Health Systems	X				
Data collection and merging datasets			X		
Regulatory issues (IRBs and consent)	X				
Stability of control intervention	X				
Implementing/Delivering Intervention Across Healthcare Organizations	X				

Top 3 Lessons Learned

#1: Data Cleaning & Validation Takes Time

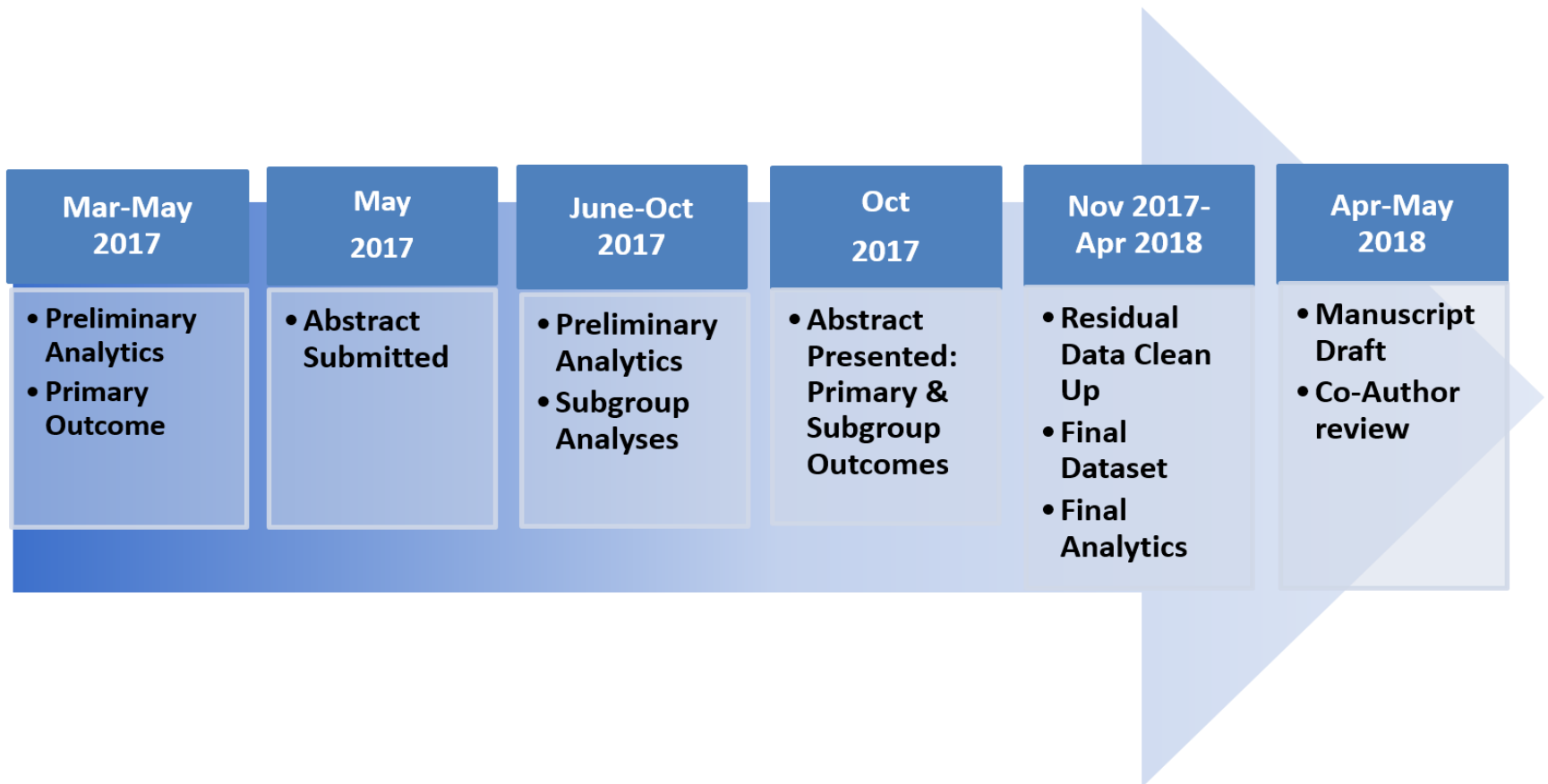
Pragmatic Trials

- 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



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 $\geq 85\%$ 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

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 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 N/A

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 (cleanest 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 the body as regular soap and shampoo prevents CHG from working as well.



Keeping germs away

Have you had your bath today?



Every patient, every day

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?

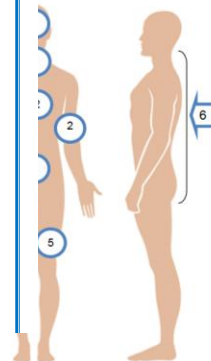
Your unit will be decolonizing all patients known to be MRSA+ by **clinical history, screening test, or clinical culture**. These patients will receive both the daily CHG bath or shower **PLUS** nasal

ent infections during your hospital stay
THE daily with Chlorhexidine (CHG) cloths

PATIENT

ur stay, we will bathe you with a special antiseptic ch removes germs and nfection better than soap

st has 6 cloths to be used areas as shown below:



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 for 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

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?



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