Susan Huang, MD MPH
University of California, Irvine
Collaboratory Grand Rounds
# ABATE Infection Trial - Structure

## Active Bathing to Eliminate Infection

<table>
<thead>
<tr>
<th>Principal Investigator:</th>
<th>Susan Huang, MD MPH</th>
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<tbody>
<tr>
<td><strong>Content Expertise</strong></td>
<td>Susan Huang MD MPH, Ed Septimus MD, Julia Moody RN MS, John Jernigan MD MS, Mary Hayden MD, Robert Weinstein MD</td>
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<tr>
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<td>Ed Septimus, MD (HCA site lead) Jason Hickok, MBA RN (HCA administrative lead) Julia Moody, MS SM Jonathan Perlin, MD PhD</td>
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<td><strong>Health System</strong></td>
<td>Hospital Corporation of America</td>
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<td><strong>Statistics</strong></td>
<td>Ken Kleinman ScD, Dan Gillen PhD</td>
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<td><strong>Microbiology</strong></td>
<td>Mary Hayden, MD</td>
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<td><strong>Project Coordination</strong></td>
<td>Julie Lankiewicz MPH CCRC, Adrijana Gombosev BS</td>
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| **Health System Partner:** | Hospital Corporation of America  
Jonathan Perlin, MD PhD |
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<tbody>
<tr>
<td><strong>Corporate Groups</strong></td>
<td>3 regional groups, CFO/President</td>
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</table>
| **Corporate Infection Prevention & Quality** | Ed Septimus MD  
Jason Hickok, MBA  
Julia Moody, MS |
| **Centralized IT/Data Warehouse** | Caren Spencer-Smith |
| **Regulatory/Compliance** | David Vulcano, MBA, VP Clinical Research |
| **Corporate Microbiology** | Chris Bushe, MHSA |
| **Corporate Nurse Education** | Debra Lily |
Agenda

- Project Overview
- Recruitment
- Surveys
- IRB
- Laboratory Strain Collection
- Baseline Data Streams
- Statistical Approach
- Next Steps
Project Overview
Preventing Healthcare-Associated Infections

- 1.7 million US hospital-associated infections/year \(^1\)
- Most outside of ICU
- Many infections from body’s own bacteria
  - Skin, gut, nose
  - Methicillin resistant *Staphylococcus aureus* (MRSA)
- Body decolonization reduces ICU infections \(^2\)
  - Disinfectant soap (chlorhexidine (CHG))
  - Nasal ointment (mupirocin)
- Strategies need for non-ICU settings

2 Huang SS et al. REDUCE MRSA Trial. IDWeek 2012
Comparative Effectiveness of Quality Improvement (QI) Interventions

- Hospitals make facility-wide changes for perceived improvement to patient safety, quality
  - products, processes, protocols, formularies
- Often QI precedes science
- Culture, peer support is a critical part of the success of QI
- Pragmatic trial
  - Comparative effectiveness of current QI processes
  - Whole hospitals randomized $\rightarrow$ hospital units same intervention
  - Uses QI implementation, training, adherence infrastructure
ABATE Infection Project
Active Bathing to Eliminate Infection

Purpose
Large scale pragmatic trial to assess the value of chlorhexidine bathing and nasal decolonization in reducing hospital-associated infections in non-critical care units

Planning Year Aims
• Recruit 50 hospitals for a 2-arm cluster randomized trial
• Obtain IRB approval /reliance at each site
• Standardize and collect baseline data
• Develop educational materials, electronic modules for the trial
ABATE Infection Project
Active Bathing to Eliminate Infection

Trial Design
- 2-arm cluster randomized trial
- 50+ 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 for those MRSA+ by history or screen
Hospital Units Eligibility

- Eligible units include:
  - Adult medical, cardiac/telemetry, mixed medical/surgical, surgical, orthopedic, step-down, oncology units

- Ineligible units include:
  - Dedicated units for bone marrow transplant, labor and delivery/post-partum care, psychiatry, acute rehabilitation
  - Pediatric units
Hospital Units Eligibility

• Additional Exclusion Criteria
  – Age < 12
  – Units already performing routine CHG bathing
  – Units with more than 30% of MRSA patients receiving decolonization regimen
Outcomes obtained from the HCA data warehouse

Key Outcomes
• Clinical cultures with multi-drug resistant organisms

Additional Outcomes
• Bloodstream infections: all pathogens
• Urinary tract infections: all pathogens
• Infectious readmissions
• Emergence of resistance (strain collection)
Recruitment
Hospital Recruitment

Hospital Corporation of America (HCA)
165 US Hospitals, 15 Divisions, 3 Groups

Recruitment Efforts

- Endorsed by corporate HCA
- 2 recruitment webinars (200+ hospitals each)
- Divisional meetings
- Corporate CMO/CNO webinars
- Direct contact with infection prevention programs
- Direct contact with participants of previous ICU trial
- Large internal effort by HCA Co-Investigators
CALL FOR PARTICIPATION:
ABATE INFECTION TRIAL
Active Bathing to Eliminate Infection

Can chlorhexidine (CHG) bathing and MRSA decolonization reduce infection and readmissions in non-critical care units?

All eligible hospitals will be randomized to one of two arms:

Arm 1: Routine Care
- Routine policy for CHG bathing

Arm 2: Decolonization
- Daily CHG bath for patients
- More aggressive contact precautions

Who can join?
- Any HCA hospital with adult non-critical care units
- Participating hospital must have at least 200 patients admitted per week

Requirements for Participation:
- Hospital leadership support
- Complete eligibility survey
- Commitment to improve patient safety
- Documenting in MEDITECH
- Participating ICUs

Key Outcomes:
- Proportion of patients requiring multidrug-resistant organisms (MDRPs)
- All patients without infections

Additional Considerations:
- All patients with bloodstream infections
- All patients with MRSA

[Diagram with timelines and additional information]

FREQUENTLY ASKED QUESTIONS

ABATE Infection Project
Active Bathing to Eliminate Infection

What is the ABATE study?
The ABATE Infection Project is a clinical trial designed to evaluate the impact of CHG bathing on MRSA infections in non-critical care units. Participating hospitals will have all adult non-critical care units randomized into one of two arms.

Arm 1: Routine Care
- Routine bathing practices per established protocol

Arm 2: Decolonization
- Use of CHG for all patients
- Encourage prophylactic use
- Initiate education
- CHG bathing every 5 days for MRSA patients

What is the goal of the study?
The goal of the study is to evaluate whether CHG bathing can reduce MRSA infections in non-critical care units. The project will involve a randomized controlled trial in which eligible hospitals will be randomized to either the CHG bathing arm or the control arm. The primary outcome measure will be the proportion of patients who acquire MRSA infections during the study period.

Imported Points:
- This trial uses a quality improvement design. Patient consent is not required.
- Each hospital will contribute data on a large number of patients.

[Diagram with timelines and additional information]
Hospital Recruitment

Response

• Time to completed enrollment form

<table>
<thead>
<tr>
<th># Hospitals</th>
<th>% Total Recruitment</th>
<th>Duration</th>
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<tbody>
<tr>
<td>14</td>
<td>25%</td>
<td>4 business days</td>
</tr>
<tr>
<td>29</td>
<td>50%</td>
<td>7 business days</td>
</tr>
<tr>
<td>43</td>
<td>75%</td>
<td>9 business days</td>
</tr>
<tr>
<td>56</td>
<td>100%</td>
<td>11 weeks</td>
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• 218 Non-Critical Care Adult Units
Determining Eligibility

Enrollment Form: hospital contacts

Survey Access

Facility Survey: hospital info, units

Unit Surveys: volume, practices

Letter of Participation: CEO signs
56 Hospitals – all eligible
15 states, average annual admissions 11,833
218 adult non-ICUs
47% medical, 36% surgical, 17% medical/surgical

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<thead>
<tr>
<th>Quartile</th>
<th># Beds</th>
<th>LOS</th>
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<tbody>
<tr>
<td>25%</td>
<td>20</td>
<td>3.9</td>
</tr>
<tr>
<td>50%</td>
<td>30</td>
<td>4.6</td>
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<tr>
<td>75%</td>
<td>36</td>
<td>5.4</td>
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Institutional Agreements

3-Way Memorandum of Understanding
- Hospital Corporation of America
- University of California Irvine
- Harvard Pilgrim Health Care

Data Use Agreement
- Data from centralized HCA Corporate Data Warehouse
- Data accessed and analyzed behind HCA secure firewall
- Summary level results transferred to analytic center
Centralized IRB

Harvard Pilgrim Health Care = central IRB

- Sept 2012 approved for UH2 year, baseline data
- Feb 2013 approved for full trial

Reliance Agreements

- 41 of 56 hospitals have agreed to cede to Harvard
  - Requires site champion, human subjects training, FWA
  - 8 completed all documentation
- 15 of 56 hospitals pending decision to cede
- 2 hospitals pursuing own IRB
Prisoners may be admitted to trial hospitals

Prisoner Representative

- Harvard IRB does not have a prisoner representative
- One HCA hospital will provide this service
- Harvard will rely on that hospital for this requirement (as permitted under 45 CFR 46.304(b))
Informed Consent

Waiver of Documentation of Informed Consent

• Granted by Harvard IRB
  - Minimal risk
  - Evaluation of quality improvement programs
  - Population impact due to contagion

• Requirement of informative sign in each patient room
FOR YOUR INFORMATION

Our hospital is dedicated to improving medical care for its patients. We are currently participating with 57 other US hospitals in an evaluation of 2 different approaches to protect patients from highly antibiotic-resistant bacteria. Both approaches are already being used in US hospitals, but it is not known whether one method is better than another. Units in this hospital are providing screening and infection control precautions for patients who harbor certain antibiotic-resistant bacteria to reduce the risk of infection in the rest of the patient population. This practice has been in place in this hospital for several years, and we are now conducting a formal evaluation of this approach. Data from this unit population as a group will be used in this assessment. No individual patients will be identified.

This research is funded by the National Institutes of Health. If you have a question or want additional information, please talk to your nurse.

ABATE Infection Project

Laboratory
Baseline Strain Collection
Concern for Resistance

Universal decolonization in non-ICU settings
  • Concern for emergence of resistance
  • Pre and post strain collection

Resistance
  • 4-7% to mupirocin among MRSA strains, variable
  • Negligible for CHG → case reports in select bacteria
ABATE Infection Project

Active Bathing to Eliminate Infection Project

Microbiology Laboratory Survey

ABATE Infection Project - Lab Survey

SUMMARY OF GOALS

The purpose of this Microbiology Laboratory Survey is to assess variation in microbiology procedures, processes, and reporting of results across laboratories of potential interest to hospital participants. This survey will allow us to ensure that all laboratory data is in the HCA central data warehouse for the next study of study data. We anticipate this study will also help inform ongoing HCA-wide efforts to standardize results and reporting.

1. MICROBIOLOGY LABORATORY CHARACTERISTICS

   1. Microbiology Laboratory Name:

   2. HCA Facility (CIS #):

   3. Facility Name:

   4. Person Completing Survey:

   5. Position/Titles:

   6. Please provide your contact information for each of the below and indicate which is the best way to contact you:

   Office Title:________
   General Lab Title:________
   Email:________

   7. Is this microbiology laboratory located on-site or at an offsite hospital campus?

   Yes

   No

   8. How many cultures did this microbiology laboratory process in 2011 from each of the HCA facilities listed above? Please include any significant cultures.

   Facility Name
   # of Bacteria Cultures Processed in 2011
   # of Viruses Cultures Processed in 2011

   □ Other

   9. Internally reported MDR/AMR screening tests done at the microbiology laboratory in 2011 (Optional)

   Name:________
   % Not Screening Culture Positive:________
   % Non-colonial:________
   Other:________

   ABATE Infection Project - Lab Survey
ABATE Microbiology Lab Launch Timeline

Dec-Jan 2012

Complete lab survey

Jan-Feb 2013

Check micro data streams in HCA data warehouse

Feb-Mar 2013

Supplies & toolkits shipped to labs

Begin shipping baseline strains to central lab at Rush University
ABATE Lab Strain Collection Timeline

- **Feb 2013**: Lab Coaching Call
- **Mar 2013**: 12-month BASELINE COLLECTION
- **Mar 2014 - Oct 2014**: 8-month Collection “Break”
- **Oct 2014**: Refresher Coaching Call
- **Nov 2014**: 12-month INTERVENTION COLLECTION
ABATE Lab Strain Collection Toolkit Binder

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Active Bathing to Eliminate Infection Project
ABATE Strain Collection
Microbiology Lab Toolkit Binder

ABATE Lab Coordination Team Contact Information:
Email: ABATEstudy@gmail.com Phone: (617) 509-4141

ABATE Strain Collection
STEP-BY-STEP INSTRUCTIONS

Step 1: Collect & record field data
- Please fill in the demographic information on the back of the sheet.
- Record all observations and incidents.

Mcal & Qtr Collection Log Sheet

Step 2: Prepare for lab process
- Ensure all necessary equipment is ready.
- Sterilize all materials.

Mcal & Qtr Collection Log Sheet

Step 3: Process samples
- Follow the correct protocol for each sample type.
- Store samples at the appropriate temperature.

Mcal & Qtr Collection Log Sheet

Additional Instructions:
- Always follow safety guidelines when handling samples.
- Maintain a proper chain of custody for all collected samples.

Mcal & Qtr Collection Log Sheet
As received

1) clear plastic Biohazard Bag,
2) white Secondary Biohazard envelope
3) Saf-T-Pak shipping box
4) bubble wrap for slants
5) absorbent sheet

Assembled

6) Pre-paid & pre-addressed FedEx slip

Please make sure ‘BIOLOGICAL SUBSTANCE, CATEGORY B’ is checked
Monthly Strain Collection and Shipping Overview

**STEP 1: IDENTIFY & RECORD STRAINS**
- (A) Collect up to 20 /month 10 MRSA+ & 10 select GNR
- (B) Fill out Strain Collection Log Sheet

**STEP 2: SUBCULTURE & STORE**
- (A) Assign study ID & subculture isolates
- (B) Subculture and transfer to chocolate agar slants

**STEP 3: SHIP TO RUSH UNIVERSITY**
- (A) Prepare Saf-T-Pak:
  1. Slants
  2. De-identified log sheet
  3. Shipment packing list
- (B) FedEx Saf-T-Pak to Rush University
- (C) Fax the fully-identified Strain Collection Log Sheet to HCA

**FAX: 1-866-947-4620**
Attn: Julia Moody, MS SM (ASCP) Clinical Director, Infection Prevention Clinical Services Group, HCA
Baseline Data Streams
Data Streams

Data Sources
- HCA Data Warehouse
- Meditech

Baseline Data Streams
- Nursing Queries
- Admission Discharge Transfer (census by unit)
- Administrative
- Pharmacy
- Central supply
- Financial
- Microbiology
Data Streams

Data Sources
• HCA Data Warehouse
• Meditech

Baseline Data Streams
• Nursing Queries
• Admission Discharge Transfer (census by unit)
• Administrative
• Pharmacy
• Central Supply
• Financial
• Microbiology
Health System Partnership
  • Little known about patient bathing in non-ICUs
  • Preliminary data suggests 15-20%/day

Building a Bathing Query
  • HCA IT resources
  • Corporate-wide daily nursing query
  • Tailored for ABATE Infection Project participants
HCA Nursing Bathing Query

Daily screens → monthly reports, more detailed inquiries

Launched mid-February
Microbiology Standardization

Current Standard

• Microbiology labs wide range of acceptable resulting
• 4 acceptable resulting methods in Meditech
• 1 provides easiest data capture

Complexities

• Micro data has multiple data streams
  • One culture → multiple organisms
  • Each organism → susceptibility profile
• Urine culture outcomes require bacterial colony count
## Microbiology Standardization

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<thead>
<tr>
<th></th>
<th>Preferred Resulting Method by Hospitals</th>
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<tbody>
<tr>
<td></td>
<td>Complete Use</td>
</tr>
<tr>
<td></td>
<td>#</td>
</tr>
<tr>
<td><strong>Prior</strong></td>
<td>23</td>
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<tr>
<td><strong>Current</strong></td>
<td>42</td>
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**Corporate Deadline for Standardization:** March 1, 2013
Data Plans for Randomization

Stratified randomization options
• Volume
• Baseline outcome rates
• Baseline allowable product usage
• Case mix

Achieving balance and mitigating imbalance
• Critical importance of baseline period
• Simulating scatter of potential draws by randomization
UH2 Aim 1: Recruitment
  • 50 hospital target met → 56 hospitals enrolled

UH2 Aim 2: IRB
  • Centralized IRB approval received for full trial
  • Individual hospitals → 14% approved, >90% ceding

UH2 Aim 3: Baseline Data & Strain Collection
  • Launched on target, on time (March 1)
  • Data accessed, initial checks complete, ongoing checks

UH2 Aim 4: Trial Educational Materials
  • In progress, foundation from prior trial
ABATE Infection Project

Active Bathing to Eliminate Infection Project