

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







Tyler

Enterprise Support

Stakeholder Support



Jon Perlin

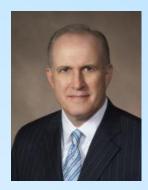


David

David Vulcano



Jane Englebright



Jon Foster



Chuck Hall

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

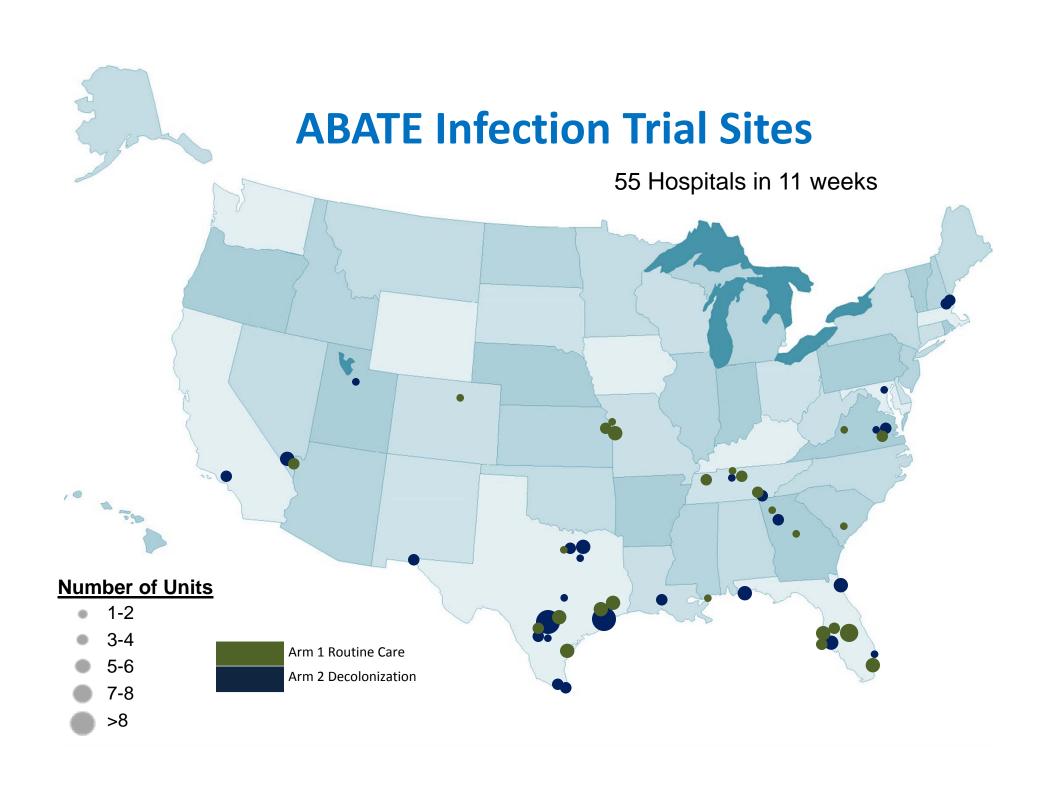
- Recruitment
- IRB Process
- Randomization
- Central Coordination
- On-Site Training
- CHG Compatibility
- Compliance
- Strain Collection
- Data Collection and Analysis of Outcomes
- Participant Commendations

Trial Timeline

Nov 2012 -Apr – Sept Apr – May Nov 2013 Mar 2014 Jun 2014 Feb 2016 Feb 2013 2013 2014 Recruitment • Randomi-• Phase-in • End of • IRB • Arm 2 Site • Interven-(Arm 2) Trial Ceding zation **Training** tion Start Eligibility Surveys



Recruitment November 2012 – February 2013





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

Arm	# Hospitals	# Units	# States Represented
1	26	88	11
2	27	103	11
Total	53	191	15

Post Randomization Drop Out

- 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

Schedule of Calls

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

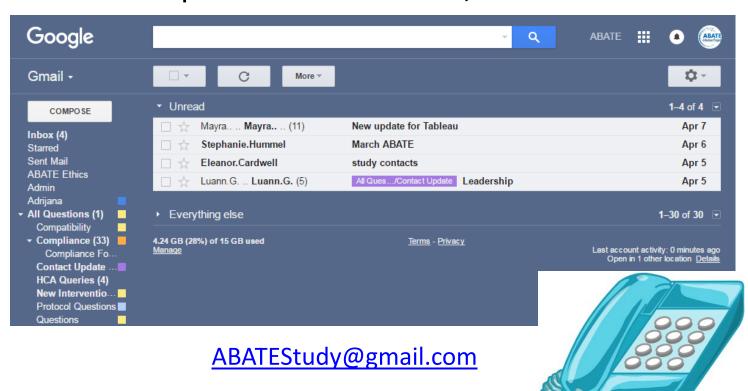
• Number of Lab calls: 11

• Special Coaching Calls: 7

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

Central Coordination

of Gmail Inquires Addressed: 11,183



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

Educational Materials

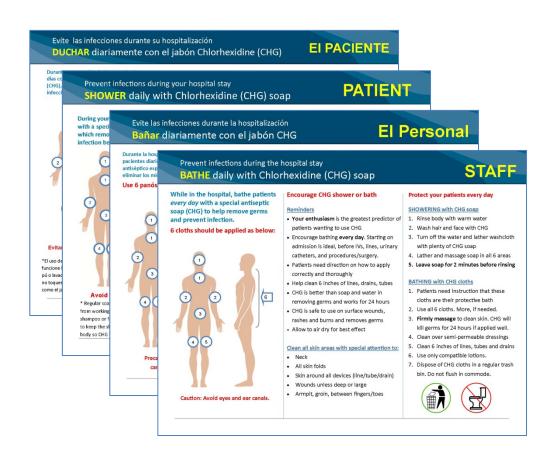




of Binders Shipped: 239

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

Educational Materials





Daily Staff Huddle Reminders for CHG Bathing:
Patient Talking Points



Daily Staff Huddle Reminders for CHG Bathing:
Cleaning Wounds and Devices

➤ Do not forget wounds and devices! Cleaning them prevents surface bacteria from diving into the body and causing infection

> Clean ALL devices on the body- lines, tubes, drains

> Clean ALL wounds unless packed

➤ Patients don't feel comfortable cleaning their wounds and devices, staff HAVE TO HELP clean them

➤ For showering patients, staff should take a single 2pack of CHG and clean their wounds and devices for them after the shower encourage patients

hat time would be a

ng is one of the most d of germs being rotect the patient

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

	2014	2015
Arm 1	3,407	2,022
Arm 2	4,928	3,721
Total	8,335	5,743

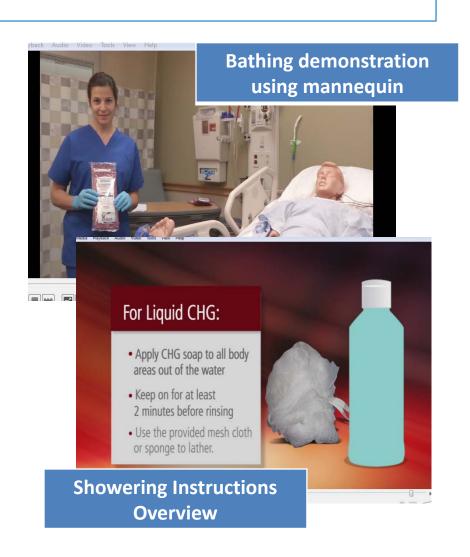
Arm 2 – Training Video

- 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









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

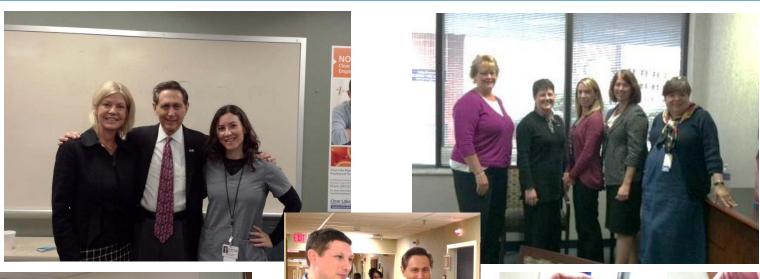








Arm 2 On-Site Training





Instructional Presentation and Product Demonstration



Visiting Participating Units



Product Compatibility Checks



CHG Compatibility



Lauren Shimelman



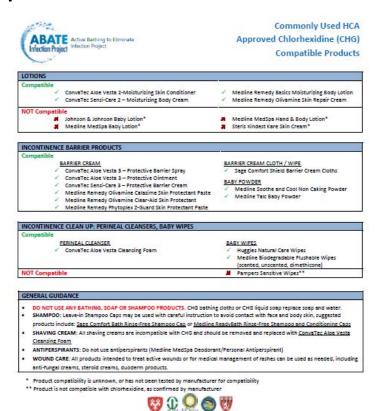
Laurie Brewer

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





Compliance



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

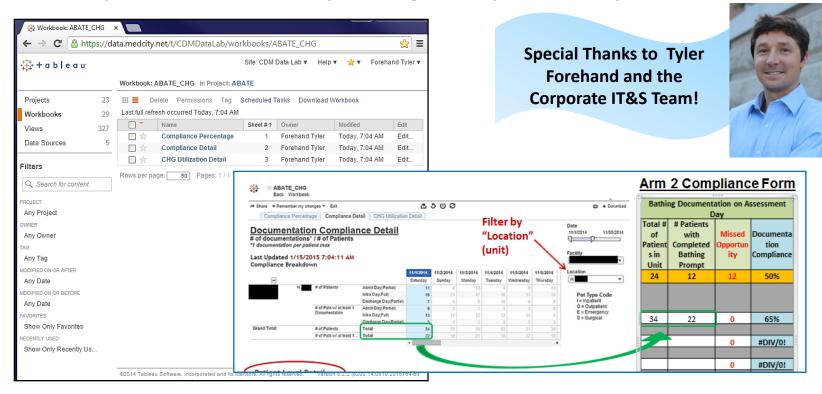
ABATE Nursing Query



Tableau Reports

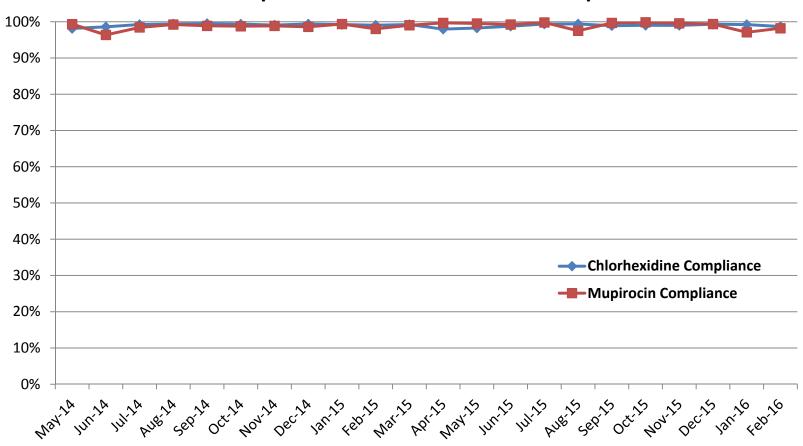
 Corporate IT&S developed user friendly reports to capture bathing and mupirocin administration

Eased process for completing compliance spreadsheets



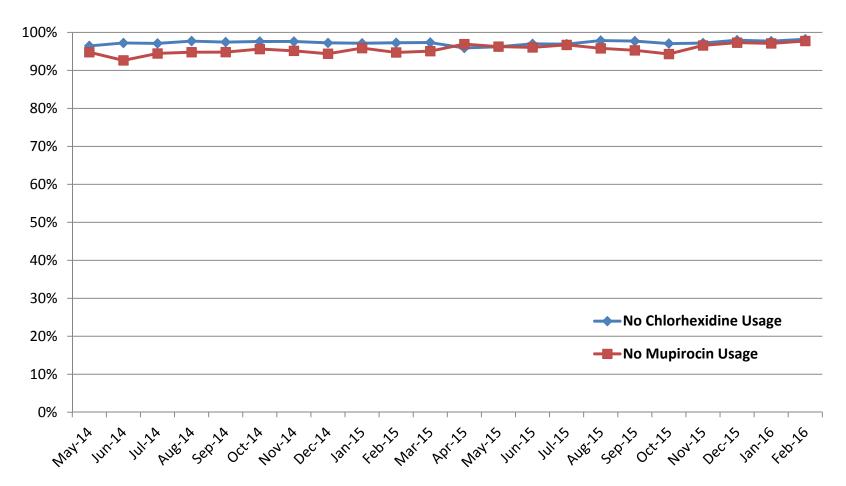
Arm 1: Protocol Compliance

Arm 1:Per-protocol non-use of CHG and mupirocin



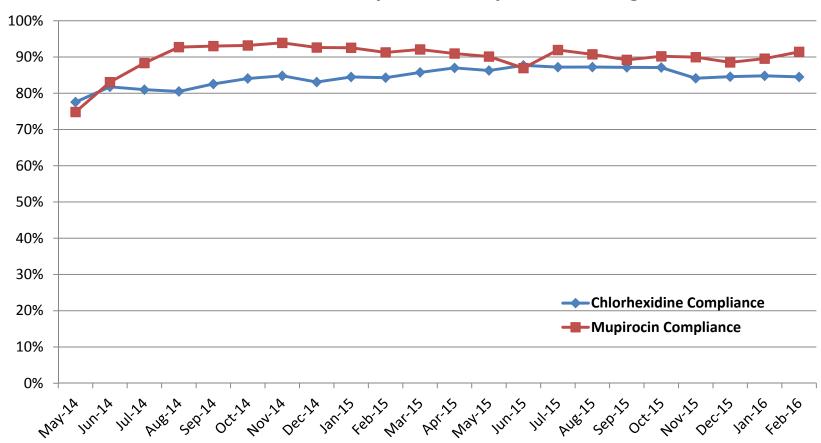
Arm 1: Overall CHG and Mupirocin Non-Usage

Arm 1: Reflects usage even with acceptable exceptions per protocol



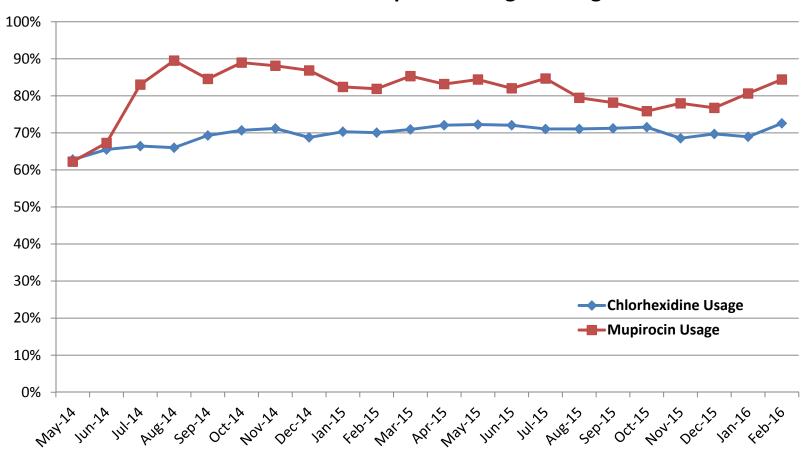
Arm 2: Protocol Compliance

Arm 2: CHG and Mupirocin Compliance Average



Arm 2: Overall CHG and Mupirocin Usage

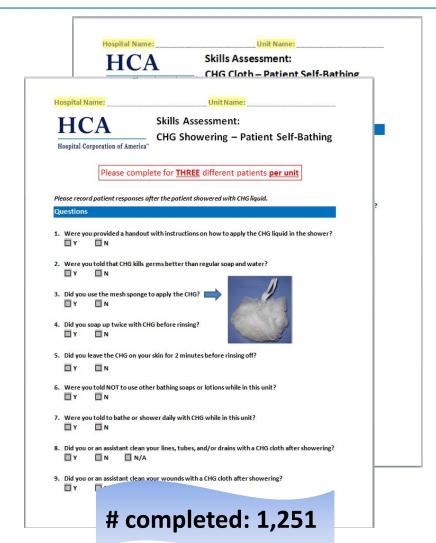
Arm 2: CHG and Mupirocin Usage Average



Arm 2 – Quarterly Staff and Patient Compliance Assessments

		Unit Name:
HCA	Skills Asse	
		Observation Checklist
Hospital Corporation		
Ple	ase complete for THREE	different staff per unit
Individual Giving C	HG Bath	
Please indicate who p	erformed the CHG bath.	
Nursing Assistant	(CNA) Nurse	Other:
Observed CHG Bat	hing Practices	
	opriate response for each observ	ation.
Y N Patient	received CHG cloth bathing han	dout
		that provides protection from germs
	ed rationale to the patient for no ed skin <i>firmly</i> with CHG cloth to	t using soap at any time while in unit
	d face and neck well	ensure adequate creatising
Y N Cleane	d between fingers and toes	
	d between all folds	
		rmeable dressings with CHG cloth entral lines, and drains closest to body
		ds, rash, and stage 1 & 2 decubitus ulcers
		(unless primary dressing or packed)
	d CHG to air-dry / does not wipe	
Y N Dispose	ed of used cloths in trash /does r	not flush
Query to Bathing A	Assistant/Nurse	
1. How many cloths w	vere used (1 cloth set = 6 cloths,	1 cloth set plus 1 single pack = 8 cloths)
2. If more than 1 clot	h set (6 cloths) was used, provide	reason.
3. Do you reapply CHO	G after an episode of incontinen	ce has been cleaned up?
	·	ce has been cleaned up?
4. Are you comfortabl	·	ounds, including surgical wounds?
4. Are you comfortabl	le applying CHG to superficial wo	ounds, including surgical wounds?
4. Are you comfortabl	le applying CHG to superficial wo	ounds, including surgical wounds? Irains and non-gauze dressings?

completed: 1,469



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

Arm	Proposed Interventions	Allowed	Not Allowed (Conflicting)
1	83	47 (57%)	36 (43%)
2	102	73 (72%)	29 (26%)
Division	9	7 (78%)	2 (22%)
Corporate	2	2 (100%)	0 (0%)
Total	196	129 (66%)	67 (34%)

^{*}Additional 8 (4%) intervention reported, but withdrawn

Commonly Reported Interventions

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 <u>not in conflict</u> 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 \rightarrow 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



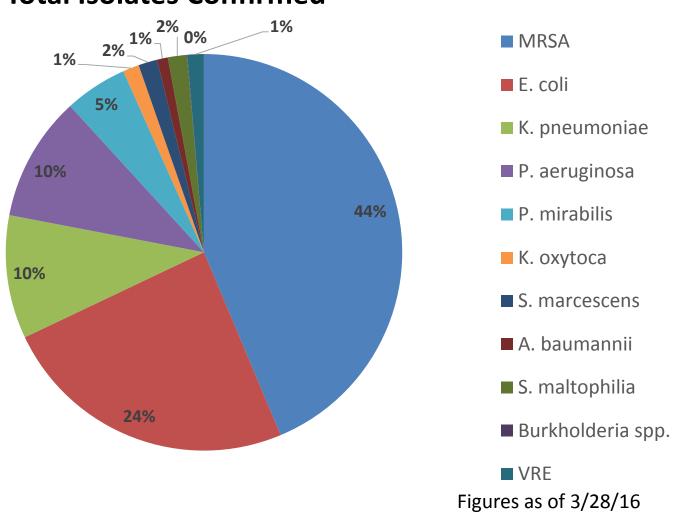


Fa La Pi	Active Bathing to Eliminate Infection Project In	ABATE Strain Collection COLLECTION LOG SHEET Fax completed Collection Log to: Fax: 866-947-4620 Attn: Julia Moody	
Sr	nipment Date: MRSA & GNR COLLECT	DOWN MORN LANDS AN INCOME.	
#	HCA PATIENT SPECIMEN LABEL	CIRCLE ORGANISM TYPE	
	PLACE 1st SMALL LABEL ABOVE DOTTED LINE IF AVAILABLE, PRINT AND PLACE 2nd SMALL LABEL THAT INCLUDES THE DATA ELEMENTS LISTED BELOW, OR HAND WRITE THE INFORMATION INTO THE SPACES PROVIDED Age and/or Date of Birth:// Sex: M	MRSA culture E coli K. pneumoniae K. oxytoca P. mirabilis S.marcescens A.baumannii P.aeruginosa S. maltophilia Burkholderia	StudyID Label: Hospital Admit Date: Day of Lab Collection Unit of Lab Collection Qualifying ABATE Location Day of Transfer to ABATE Location

800 isolate shipping kits sent to participating laboratories

Strain Collection Totals

Total Isolates Confirmed



ABATE Infection Project

Rush University Antibiotic/Antiseptic Resistance Testing

Rush University



Mary Hayden



Karen Lolans

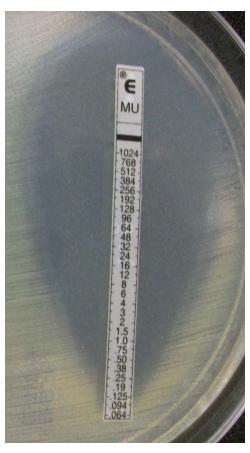


Lena Portillo

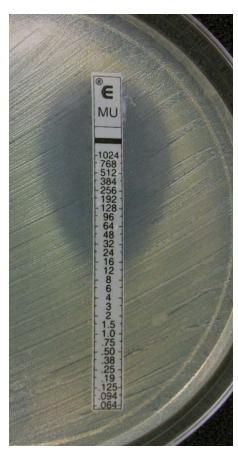


Jalpa Patel Sarup

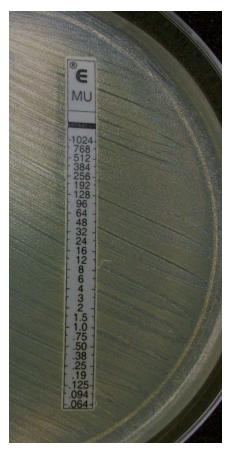
Mupirocin Susceptibility Testing (MRSA)



Susceptible MIC <8 µg/ml



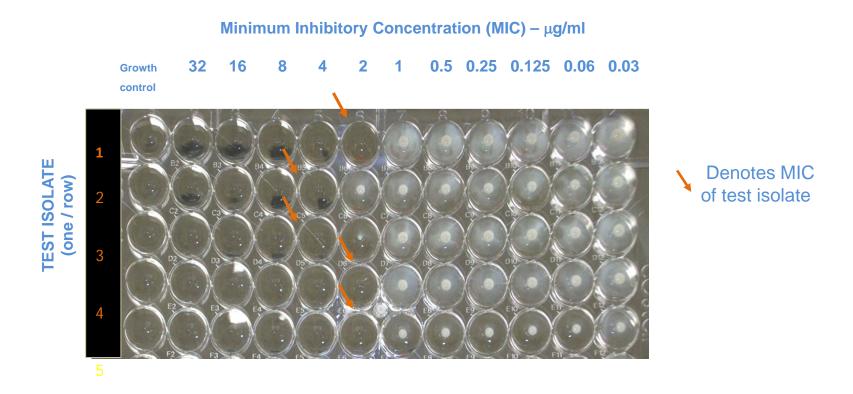
Low-level Resistance MIC 8-64 μg/ml



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





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

Baseline	April 2013-March 2014
Phase-In (2 months)	April-May 2014
Intervention (21 months)	June 2014-Feb 2016

Outcomes

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

Primary Manuscript

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



Active Bathing to Eliminate Infection Project

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.

Jonathan B. Perlin, MD, PhD, MSHA, MACP, FACMI President, Clinical Services and Chief Medical Officer - HCA







Ed Septimus, MD, FIDSA, FACP, FSHEA Medical Director, Clinical Services Group Infection Prevention and Epidemiology - HCA

Participant Certificates - Lab



Active Bathing to Eliminate Infection Project

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.

Jonathan B. Perlin, MD, PhD,MSHA, MACP, FACMI President, Clinical Services and Chief Medical Officer- HCA







Chris Bushe, MSHA, MT (ASCP) Director, Laboratory/Services Clinical/Services Group - HCA

Thanks to Our Participating Hospitals, Investigative Team, & Supporters



Active Bathing to Eliminate Infection Project