Active Bathing to Eliminate Infection Project

Susan Huang, MD MPH
University of California, Irvine
Collaboratory Grand Rounds

ABATE Infection Trial - Structure
Active Bathing to Eliminate Infection

Principal Investigator:	Susan Huang, MD MPH
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Health System	Hospital Corporation of America Ed Septimus, MD **(HCA site lead)** Jason Hickok, MBA RN **(HCA administrative lead)** Julia Moody, MS SM Jonathan Perlin, MD PhD
Statistics	Ken Kleinman ScD, Dan Gillen PhD
Microbiology	Mary Hayden, MD
Project Coordination	Julie Lankiewicz MPH CCRC, Adrijana Gombosev BS

Hospital Corporation of America

Health System Partner:	Hospital Corporation of America Jonathan Perlin, MD PhD
Corporate Groups	3 regional groups, CFO/President
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

1 Klevens M et al. Pub Health Rep 2007;122:160-6
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 → hospital units same intervention
  - Uses QI implementation, training, adherence infrastructure

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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

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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

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?

At least 60 participating hospitals will be randomized to one of two arms

Arm 1: Routine Care
- Routine policy for showering/bathing

Arm 2: Decolonization
- Daily CHG cloth bathing (with or without shower) for all patients
- Mupirocin x 5 days for those MRSA+ by history or screen

Who can join?

Any HCA hospital with adult non-critical care units
- **Includes** adult medical, surgical, step down, oncology units
- **Excludes** ICUs, pediatrics, rehab, psych, peri-partum, BMT units

Hospitals ineligible for the concluded REDUCE MRSA Trial can be eligible for ABATE

Requirements for Participation
- Hospital leadership support
- Complete eligibility survey
- Document bathing in MEDITECH
- Laboratory support to collect strains and standardize reporting of micro data
- Willingness to be randomized
- IRB approval (or rely on Harvard IRB)
- Provide central line/foley device days

Important Points
- This trial uses a quality improvement design. Patient consent will not be required
- Sage Inc. will contribute a large amount of 2% CHG cloths to participants

Oct-Nov 2012	Nov- Dec 2012	Jan - Feb 2013	Fall 2013
- Commitments to participate	- Complete eligibility surveys - Lab processes confirmed - Bathing query setup completed - IRB approval/reliance begun	- Standardize micro lab data for 1y baseline reporting	- Randomization - Prepare for Spring intervention

QUESTIONS?
Toll free 855-33-ABATE (855-332-2283)
ABATEstudy@gmail.com

RUSH UCIrvine HCA CDC

FREQUENTLY ASKED QUESTIONS

ABATE Infection Project

Active Bathing to Eliminate Infection

What is the ABATE study?

The ABATE Infection Project (Active Bathing to Eliminate Infection Project) will evaluate the impact of decolonization on HAIs in the general patient population outside ICUs. Participating hospitals will have all adult non-critical care units randomized into one of two approaches.

Arm 1: Routine Care
- Routine bathing practice per established protocols

Arm 2: Decolonization
- Use of chlorhexidine for all showering/bathing
- Active encouragement of daily showering/bed bath
- Nasal mupirocin x 5 days for MRSA+ patients

What is the goal of the study?

While decolonization has been successful in short-stay high risk areas, such as ICUs, this trial provides the opportunity to address the larger number of HAIs that occur in non-critical care medical and surgical wards. The REDUCE MRSA trial was highly successful in showing that decolonization with mupirocin and chlorhexidine led to a 37% reduction in MRSA clinical cultures and a 44% reduction in bloodstream infections due to all pathogens in adult ICUs. Since most hospital associated infections now occur outside of ICUs, we want to test a similar strategy in general medical, cardiac, oncology, and surgical wards.

This cluster-randomized controlled trial will evaluate whether bathing non-critical care patients with antimicrobial soap prevents healthcare-associated infections and the readmissions they cause. Alternatively, it will suggest that tailored strategies distinct from those effective in ICU settings are needed for these patients outside ICUs.

Key Outcomes
- Proportion of patients harboring multi-drug resistant organisms (MDROs) and *C difficile*
- All pathogen bloodstream infections

Additional Evaluations
- All pathogen urinary infections, by gender
- 30-day readmission rates (all cause and infection-related)
- Blood culture contamination
- Development of antibiotic resistance to mupirocin or chlorhexidine

October 2012	November - December 2012	January - February 2013	2013-2014
- Recruitment	- Complete eligibility surveys - IRB approval/Harvard reliance - Lab processes confirmed - Bathing query setup	- Standardize micro lab data and begin 1 year baseline data/strain collection	- Randomized fall 2013 - Intervention phase-in (Spring 2014) - 18 month intervention

Are hospitals that were ineligible for the REDUCE MRSA trial allowed to participate?

Yes. The REDUCE MRSA trial was an ICU trial. This is a trial in non-critical care areas and all HCA hospitals are encouraged to participate and fill out the participation survey, which will determine eligibility.

Are hospitals that are in the STOP SSI trial allowed to participate?

Yes. The STOP SSI trial does not in itself produce a conflict. All HCA hospitals are encouraged to fill out the participation survey, which will determine eligibility.

If we are interested in participating, what do we need to do?

You need to let us know! You can call us at 855-332-2283 or email us at ABATEstudy@gmail.com. We will put your hospital name on a list of interested parties and send you surveys to complete for eligibility.

Requirements of participation include:
1) Support by hospital leadership
2) Have eligible non-critical care adult units
3) Have a supporting microbiology laboratory
4) Complete the eligibility survey which has 3 parts
   a. Facility survey (filled out by hospital leadership, e.g. CNO)
   b. Unit based survey (filled out by each potential adult unit)
   c. Laboratory survey (filled out by microbiology laboratory)
5) Participate in a webinar/Q&A for interested hospitals

As soon as the survey is completed, we will be able to determine eligibility. If eligible, a letter of commitment will be needed from hospital leadership. We will provide the draft letter.

Hospital Recruitment

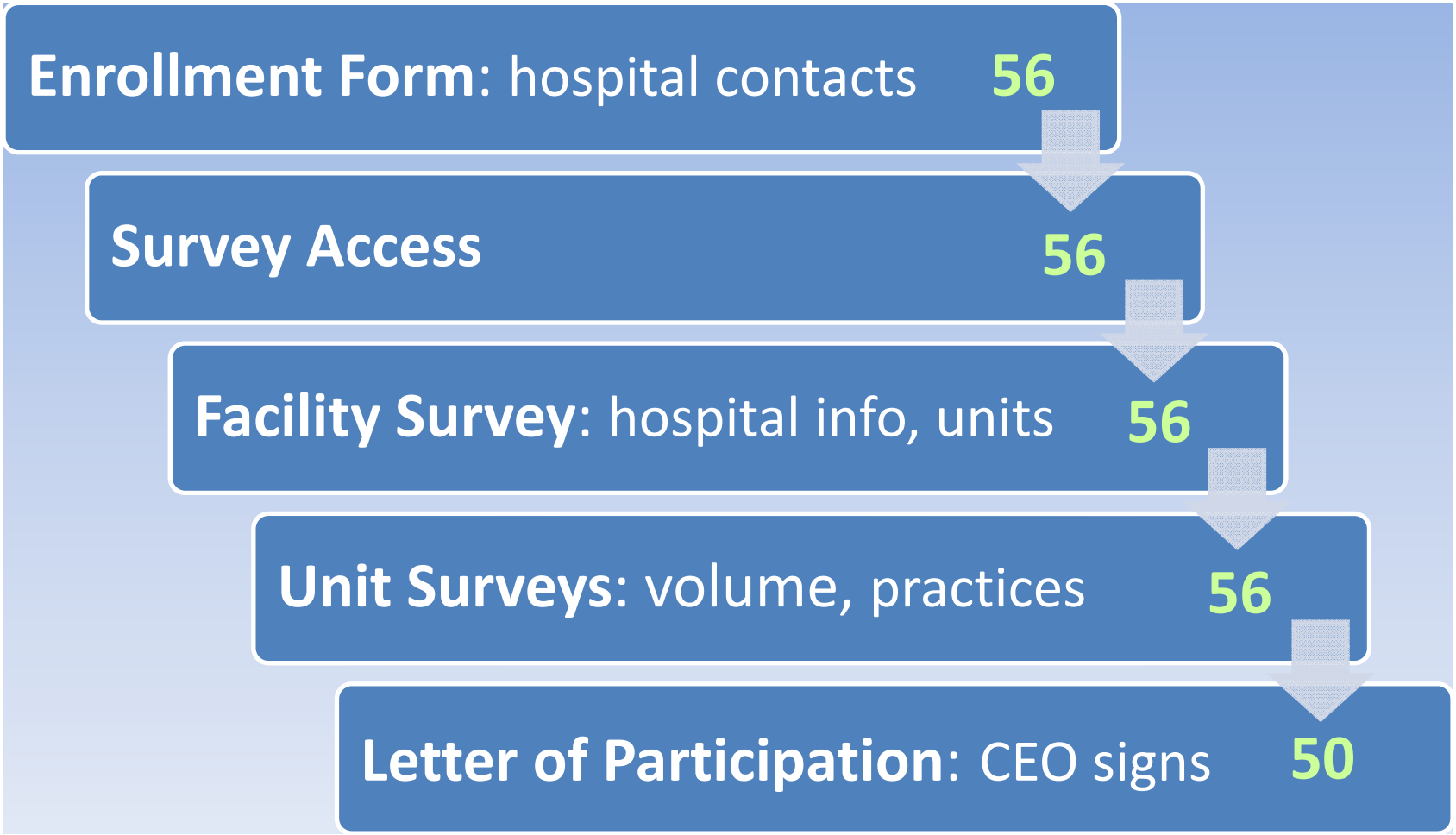
Response

- Time to completed enrollment form

# Hospitals	% Total Recruitment	Duration
14	25%	4 business days
29	50%	7 business days
43	75%	9 business days
56	100%	11 weeks

- 218 Non-Critical Care Adult Units

Determining Eligibility



HCA clinical services group

ABATE Facility Enrollment Form
Facility Contacts List
October 2012

Please complete the following information and return on or before November 1, 2012 to Jason.Hickok@HCAhealthcare.com or Julia.Moody@HCAhealthcare.com.

Facility Name:	
Facility COID:	
Division/Market:	
CNO Name:	
CNO Email:	
	Complete for each adult noncritical care unit at the facility • Includes*: adult medical, surgical, step down, oncology • Excludes: pediatrics, rehab, behavioral health, peri-partum, bone marrow transplant
Unit Name:	
Unit Description*:	
Unit Director Name:	
Unit Director Email:	
Unit Name:	
Unit Description*:	
Unit Director Name:	
Unit Director Email:	
Unit Name:	
Unit Description*:	
Unit Director Name:	
Unit Director Email:	
Unit Name:	
Unit Description*:	
Unit Director Name:	
Unit Director Email:	
Microbiologist Name:	
Microbiologist Email:	
Lab Director Name:	
Lab Director Email:	
Infection Preventionist Name:	
Infection Preventionist Ema	

ABATE Enrollment

Facility Name Pg 2:	
Pharmacy Director Name:	
Pharmacy Director Email:	
Quality Director Name:	
Quality Director Email:	
Facility CMO Name:	
Facility CMO Email:	
IT&S Director Name:	
IT&S Director Email:	

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Facility Survey

PRIMARY Contact

ABATE Study Team

ABATEstudy@gmail.com
Toll Free Study Help Line: 855-33-ABATE (855-332-2283)

SECONDARY Contacts

Julia Moody, MS, SM(ASCP)
Clinical Director
Infection Prevention and Epidemiology
Hospital Corporation of America
Julia.Moody@HCAhealthcare.com
(615) 344-1692

Ed Septimus, MD, FACP, FIDSA, FSHEA
Medical Director
Infection Prevention and Epidemiology
Hospital Corporation of America
Edward.Septimus@HCAhealthcare.com
(281) 714-5689

Summary of Goals

Healthcare-associated infections are one of the 10 most frequent causes of death in the United States and incur over $6.5 billion dollars of healthcare costs each year. Although most

I. FACILITY QUESTIONS

1. Is the facility leadership (CEO, CNO, CFO, COO) aware of and committed to this project?
   ☐ Yes
   ☐ No
2. Please complete the below table with your contact information.

Person Completing Survey	Position/Title	Phone/Email

3. Please complete the below table with facility and contact information.
4. Number of annual admissions to this facility in 2011 _____
5. Number of *non-critical* care adult units in this facility (use 2011 data) _____
6. Do your adult non-critical care units currently and consistently use the Medi Tech nursing queries related to daily bathing?
   ☐ Yes
   ☐ No
7. Please list below all *non-critical* care units in your facility by type that meet *inclusion* criteria (e.g., medical, cardiac/telemetry, mixed medical/surgical, surgical, orthopedic step-down, oncology, etc). Please use 2011 data.

Sample →

Type	Floor Code	# Licensed Beds	Average Daily Census	Average LOS	GL Code
Cardiac	7S Tower	20	14	7	651
Surgical	9C	16	11	5	663

I

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Unit Survey

HCA clinical services group
Hospital Corporation of America

PRIMARY Contact

ABATE Study Team

ABATEstudy@gmail.com
Toll Free Study Help Line: 855-33-ABATE (855-332-2283)

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(281) 714-5689

Summary of Goals

Healthcare-associated infections are one of the 10 most frequent causes of death in the United States and incur over $6.5 billion dollars of healthcare costs each year. Although most prevention trials have focused on intensive care unit (ICUs), where the daily risk for infection is the highest, the majority of healthcare-associated infections occur outside of ICUs. This cluster-randomized controlled trial will evaluate whether bathing non-ICU patients with antimicrobial soap prevents healthcare-associated infections and the readmissions they cause.

Hospital Corporation of America (HCA) has partnered with academic investigators funded by National Institutes of Health to conduct a cluster-randomized trial of HCA hospitals to assess the clinical effectiveness of decolonization in non-ICU settings, where the majority of healthcare-associated infections (HAIs) now occur. This trial will provide a critically needed evaluation of decolonization to reduce hospital infection risk and infectious readmissions in nearly all hospitalized patients. It will provide essential information to determine whether routine decolonization through daily bathing with chlorhexidine should become standard practice.

This survey will provide important information about participating hospitals and units in the ABATE Infection Project.

Please fill out one *Unit Survey* for each adult non-ICU unit listed in # 8 of the *Facility Survey* that is eligible to participate. We recommend that the nurse director/manager be selected as the respondent.

I. ADULT UNIT CHARACTERISTICS

1. Facility Name _____
2. Facility COID ___ ___ ___ ___ ___
3. Unit Name _____
4. Unit Department Number _____
5. GL Code _____
6. Adult Unit Type: (Please select one)
   ☐ Medical
   ☐ Cardiac/Telemetry
   ☐ Mixed Medical/Surgical
   ☐ Surgical
   ☐ Orthopedic
   ☐ Step Down
   ☐ Oncology
   ☐ Other _____
7.

Person Completing Survey	Position/Title	Phone/Email

8. Number of admissions to this unit in 2011 (entire year) _____
9. Average daily census in 2011 _____
10. Average length of stay in this unit in 2011 (days) _____
11. Number of patients <18yo admitted to this unit in the last quarter _____

Hospital Recruitment

56 Hospitals – all eligible

15 states, average annual admissions 11,833

218 adult non-ICUs

47% medical, 36% surgical, 17% medical/surgical

Quartile	# Beds	LOS
25%	20	3.9
50%	30	4.6
75%	36	5.4

IRB

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

IRB Efficiencies

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

Version 11.26.2012

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 routinely providing patients with anti-bacterial baths and nasal ointment to remove these bacteria and reduce the risk of infection in our patients.

All patients will receive daily bathing with anti-bacterial soap or cloths. Patients who harbor certain antibiotic-resistant bacteria will also receive twice-a-day treatment in the nose with a topical antibiotic ointment. The cloths contain an antiseptic agent that has been used for skin cleansing in hospitals for many years and is available over the counter at your local drugstore. Both products are approved by the FDA and are extremely safe. If you have a history of sensitivity or allergy to either product, they will not be used. 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

Version 11.26.2012

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

Active Bathing to Eliminate Infection Project

Microbiology Laboratory Survey

HCA clinical services group

Hospital Corporation of America

PRIMARY Contact – ABATE Study Team

ABATEstudy@gmail.com

Study Help Line: (617) 509-4141 – for Laboratory Survey related questions

SECONDARY Contacts – Hospital Corporation of America

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Julia.Moody@HCAhealthcare.com
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Medical Director
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(615) 344-1727

Summary of Goals

Hospital Corporation of America (HCA) has partnered with academic investigators funded by National Institutes of Health to conduct a cluster-randomized trial of HCA hospitals to assess the clinical effectiveness of decolonization in non-ICU settings, where the majority of healthcare-associated infections (HAIs) now occur. This trial will provide a critically needed evaluation of decolonization to reduce hospital infection risk and infectious readmissions in nearly all hospitalized patients. It will provide essential information to determine whether routine decolonization through daily bathing with chlorhexidine should become standard practice.

In this trial, the microbiology laboratory of participating hospitals will need to be engaged to collect and send microbiology samples to a central laboratory to assess for emerging resistance. Additionally, the microbiology laboratory will provide standardized reporting to a centralized HCA data warehouse. This protocol is similar to that of the REDUCE MRSA Trial, which concluded successfully in September 2011.

This survey will provide important information about participating microbiology laboratories in the ABATE Infection Trial.

The purpose of this Microbiology Laboratory Survey is to assess variation in *microbiology procedures and reporting of results* across laboratories of potential trial hospital participants. This upfront effort will allow us to ensure standardized reporting of microbiology data to the HCA central data warehouse for electronic retrieval of study data. We anticipate this will also help inform ongoing HCA-wide efforts to standardize results and reporting.

I. MICROBIOLOGY LABORATORY CHARACTERISTICS

1. Microbiology Laboratory Name _____
2. HCA Facility(s) Served _____
3. Facility COID(s) _____
4.

Person Completing Survey	Position/Title

5. Please provide your contact information for each of the below and indicate which is the best way to contact by checking the corresponding box.

	Contact Phone Number/Email	Best Way to Contact
Office Line	( ) -	☐
General Lab Line	( ) -	☐
Email		☐

6. Is this microbiology laboratory located off-site (not on hospital grounds)?
   ☐ Yes
   ☐ No
7. How many cultures did this microbiology laboratory process in 2011 from each of the HCA facilities listed above? Please include only **inpatient** cultures.

Facility Name	# of Blood Cultures Processed In 2011	# of Urine Cultures Processed In 2011

8. How many **inpatient** MRSA screening tests did this microbiology laboratory process in 2011 (January-December)?

Source	# of Screening Cultures Processed
Nares	
Rectal/Perirectal	
Other	

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

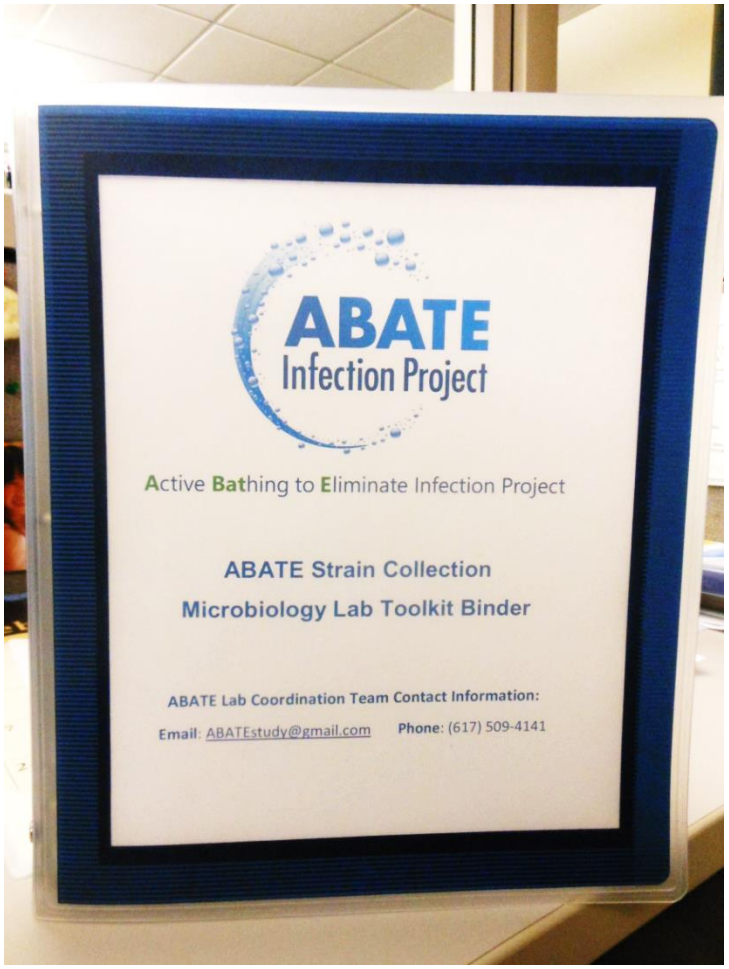
Supplies & toolkits shipped to labs

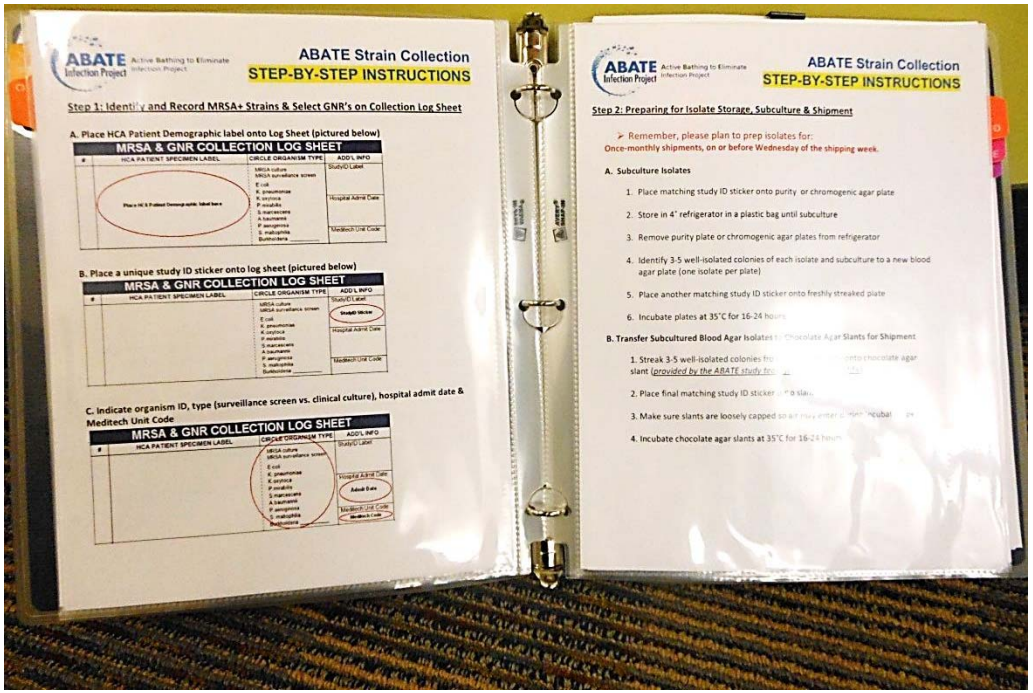
Begin shipping baseline strains to central lab at Rush University

ABATE Lab Strain Collection Timeline

Feb 2013	Mar 2013	Mar 2014 - Oct 2014	Oct 2014	Nov 2014
Lab Coaching Call	12-month BASELINE COLLECTION	8-month Collection “Break"	Refresher Coaching Call	12- month INTERVENTION COLLECTION

ABATE Lab Strain Collection Toolkit Binder

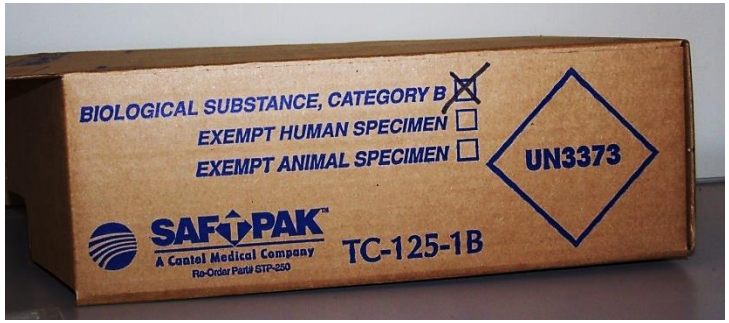




As received

1) clear plastic Biohazard Bag,
2) white Secondary Biohazard envelope
3) Saf-T-Pak shipping box
4) bubble wrap for slants
5) absorbent sheet
6) Pre-paid & pre-addressed FedEx slip

Assembled



Please make sure 'BIOLOGICAL SUBSTANCE, CATEGORY B' is checked

ABATE Infection Project

Active Bathing to Eliminate Infection Project

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

Bathing Query

Health System Partnership

- Little known about patient bathing in non-ICUs
- Preliminary data suggests 15-20%/day

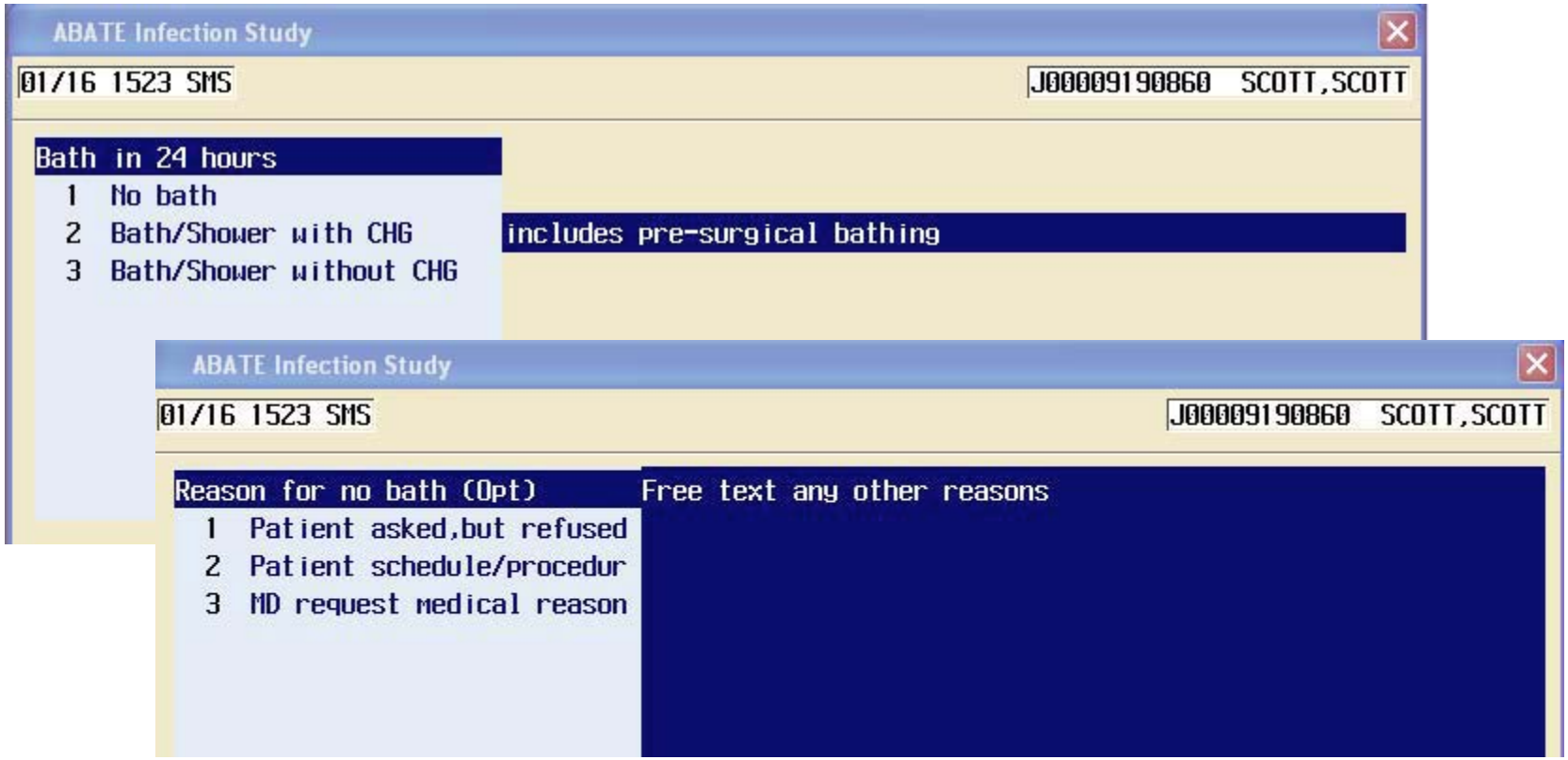
Building a Bathing Query

- HCA IT resources
- Corporate-wide daily nursing query
- Tailored for ABATE Infection Project participants

HCA Nursing Bathing Query

Daily screens → monthly reports, more detailed inquires

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

	Preferred Resulting Method by Hospitals							
	Complete Use		Partial Use		No Use		Total	
	#	%	#	%	#	%	#	%
Prior	23	41%	28	50%	5	9%	56	100%
Current	42	75%	10	18%	4	7%	56	100%

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

Summary & Next Steps

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

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