



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

**Susan Huang, MD MPH**

**Ed Septimus, MD**

**Collaboratory Grand Rounds**

**October 24, 2014**

# Agenda

- Project Overview
- Participating Sites
- Training
- Product
- Compliance
- Competing Interventions
- Adverse Events
- Laboratory Strain Collection
- ABATE Ethical Supplement



# Project Overview

# ABATE Infection Project

## Active Bathing to Eliminate Infection

### **Trial Design**

- 2-arm cluster randomized trial to assess the value of chlorhexidine bathing and nasal decolonization in reducing hospital-associated infections in non-critical care units
- 50 HCA hospitals and their adult non critical care units
- Includes: adult medical, surgical, step down, oncology
- Excludes: pediatrics, 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 x 5 days for those MRSA+ by history or screen

# Outcomes

## Outcomes obtained from the HCA data warehouse

### Primary Outcome

- Unit-attributable clinical cultures with MRSA and VRE\*

### Secondary Outcomes

- Unit-attributable clinical cultures with GNR MDRO\*
- Bloodstream infections: all pathogens\*
- Bloodstream contaminants
- Urinary tract infections: all pathogens
- *Clostridium difficile* infections
- 30 day readmissions (total and infectious)
- Emergence of resistance (strain collection)



# Participating Sites

# Arm 1 Hospitals – Routine Care

Facility Name	State	# of Units
Coliseum Northside Hospital	Georgia	1
Colleton Medical Center	South Carolina	2
Conroe Regional Medical Center	Texas	6
Corpus Christi Medical Center	Texas	6
Garden Park Medical Center	Mississippi	1
Hendersonville Medical Center	Tennessee	2
Henrico Doctors' Hospital	Virginia	4
Kingwood Medical Center	Texas	6
Lee's Summit Medical Center	Missouri	1
LewisGale Hospital-Alleghany	Virginia	2
Methodist Stone Oak Hospital	Texas	3
Northeast Methodist Hospital	Texas	5
Northside Hospital	Florida	5
Osceola Regional Medical Center	Florida	7
Overland Park Regional Medical Center	Kansas	4
Palms West Hospital	Florida	5
Parkridge East Hospital	Tennessee	2
Plaza Medical Center of Fort Worth	Texas	1
Research Medical Center	Missouri	6
South Bay Hospital	Florida	4
St. Petersburg General Hospital	Florida	3
Summit Medical Center	Tennessee	4
Sunrise Hospital and Medical Center	Nevada	4
TriStar Horizon Medical Center	Tennessee	4

**24 Sites**  
**88 Units**

# Arm 2 Hospitals – Decolonization

Facility Name	State	# of Units
Blake Medical Center	Florida	6
Chippenham Johnston Willis Medical Center	Virginia	3
Clear Lake Regional Medical Center	Texas	7
Eastside Medical Center	Georgia	3
John Randolph Medical Center	Virginia	1
Las Colinas Medical Center	Texas	2
Las Palmas Medical Center	Texas	3
Medical Center of Plano	Texas	7
Methodist Hospital	Texas	11
Methodist Specialty and Transplant Hospital	Texas	4
Methodist Texsan Hospital	Texas	1
MountainView Hospital-Las Vegas	Nevada	7
North Hills Hospital	Texas	4
Orange Park Medical Center	Florida	6
Parkland Medical Center	New Hampshire	3
Parkridge Medical Center	Tennessee	3
Portsmouth Regional Hospital	New Hampshire	3
Regional Medical Center of Acadiana	Louisiana	3
Reston Hospital Center	Virginia	2
Rio Grande Regional Hospital	Texas	4
St. David's Medical Center	Texas	1
Timpanogos Regional Hospital	Utah	1
Valley Regional Medical Center	Texas	4
West Florida Hospital	Florida	6
West Hills Hospital & Medical Center	California	4
West Palm Hospital	Florida	2

**26 Sites**  
**101 Units**



# Hospital Recruitment

- **Initial recruitment**

- 53 hospitals randomized → 3 withdrew

- Two Arm 1 hospitals implemented CHG bathing

- One Arm 2 hospital implemented competing intervention

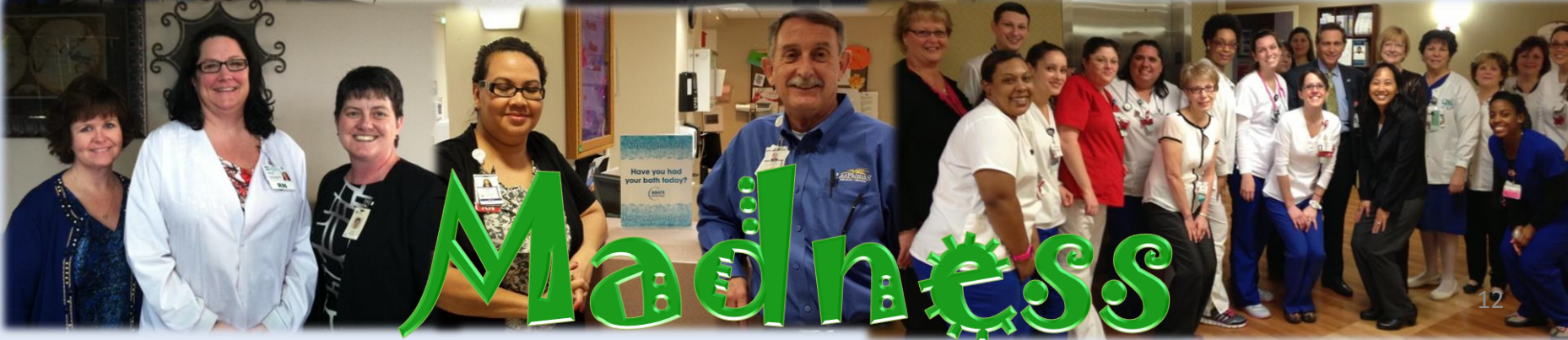


# Training

# Study Training

- **Arm-Specific Study Binders**
  - Sent to Study Champions, CMO, CNO, Quality Director, Infection Prevention, Nurse Educator, and Unit Director
- **Computer Based Training (CBT), Arm-Specific**
- **In-Person Training Site Visits (Arm 2)**
  - Study investigators and coordinators provided in-person training to 101 units over one-month period (March 2014)
  - Sage Clinical Science Liaison assisted with training of morning and night shifts (train-the-trainer sessions)
  - Bathing video recorded for training

# March



# Study Training – CBTs

- CBT assigned to nurses and CNAs working in participating units on an ongoing basis

Status	Arm 1	Arm 2
Unique Students	3,458	4,985
Not Yet Started	28	24
In Progress	54	62
Completed	3,407	4,928
Total Completed	97.65%	98.28%

# Arm-Specific Toolkit Binders



Active **B**athing to **E**liminate Infec

## ARM 2

### Universal Decolon Toolkit Binder



### Phone Matrix

Topic	What to do	Who to conta
General questions	Call or email	ABATE Infection Project Staff
Chlorhexidine bathing or mupirocin application	Call or email	Lauren Heim Adrijana Gombos
Study related event questions	Call or email	Rebecca Kaganc Julie Lankiewicz
Study related event reporting	Fax Study Related Event Form	ATTN: Rebecca Kaganc Katie Haffenreffi Lauren Shimelm
Lab strain collection	Call or email	Rebecca Kaganc Julie Lankiewicz
IRB questions	Call or email	Rebecca Kaganc Julie Lankiewicz
Lead Investigator questions	Call or email	Susan Huang, MD I

For questions related to HCA hospital policy, pro

Name	Phone Number	
Ed Septimus MD Medical Director, Infection Prevention and Epidemiology	(281) 714-5689	Edwar
Julia Moody MS SM (ASCP) Director, Infection Prevention	(615) 344-1692	Juli



### Universal Decolonization – Arm 2

#### DO

- Use either 2% chlorhexidine (CHG) cloth for daily bed bathing or 4% liquid CHG for daily showers. Use CHG for all shower/bathing needs.
- Apply to all patients, every day, for entire unit stay
- Massage CHG onto skin for best effect
- Use CHG on lines, tubes, drains, and over non-gauze dressings. Use on superficial wounds and rashes to remove germs
- For MRSA+ patients, use nasal mupirocin twice a day for 5 days of unit stay
- Restart for patients who are readmitted or transferred from another ward
- Report mupirocin/CHG related events to treating physician and unit nursing director

#### DON'T

- Do NOT get CHG into eyes or ears
- Do NOT wipe off after applying CHG cloths. Let air dry
- Do NOT flush CHG cloths
- Do NOT continue protocol after unit discharge
- Do NOT include patients who are:
  - < 12 years old
  - Allergic to mupirocin and/or CHG

REFER TO NURSING PROTOCOL FOR STEP-BY-STEP INSTRUCTIONS

General Questions  
(855) 332-2283  
ABATEStudy@gmail.com

Study Related Events  
(617) 509-4141 phone  
(617) 509-4260 fax

# Study Clings

## 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.**

Placed in shower



Placed in patient room

# Patient and Staff Handouts

Prevent infections during the hospital stay

## BATHE daily with Chlorhexidine (CHG) soap

### STAFF

While in the hospital, bathe patients *every day* with a special antiseptic soap (CHG) to help remove germs and prevent infection.

**6 cloths should be applied as below:**

**Encourage CHG shower or bath**

Reminders

- Your enthusiasm is the greatest predictor of patients wanting to use CHG
- Encourage bathing every day. Starting on

**Protect your patients every day**

SHOWERING with CHG soap

- Rinse body with warm water
- Wash hair and face with CHG
- Turn off the water and lather washcloth

Prevent infections during your hospital stay

## BATHE daily with Chlorhexidine (CHG) cloths

### PATIENT

During your stay, we will bathe you *every day* with a special antiseptic (CHG) which removes germs and prevents infection better than soap and water.

**Each packet has 6 cloths to be used on all skin areas as shown below:**

**Take a CHG Bed Bath**

BATHING with CHG cloths

- Use CHG every day. Starting on the admission day works best to remove germs before IVs, lines, urinary

**Protect yourself every day**

Important Points and Reminders

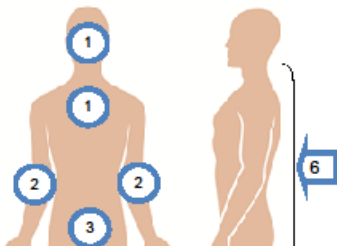
- CHG is proven to work better than soap and water to get rid of germs
- CHG cloths have aloe and are good for

Prevent infections during your hospital stay

## SHOWER daily with Chlorhexidine (CHG) soap

### PATIENT

During your stay, shower *every day* with a special antiseptic soap (CHG) which removes germs and prevents infection better than soap and water



**Take a CHG Shower**

SHOWERING with CHG soap

- You will be given a 4 oz CHG bottle to wash your hair, face, and body each day
- Begin with hair and face, rinse
- Apply generous amount of CHG to mesh sponge and rub until foamy
- Use the mesh sponge. It helps CHG lather well

**Protect Yourself Every Day**

Reminders

- CHG is proven to work better than regular soap to get rid of germs
- Once massaged onto skin, CHG works to kill germs for 24 hours
- Use CHG every day. Starting on the admission day works best to remove germs before IVs, lines, urinary catheters, and procedures or surgery



# CHG Bathing Video

ABATE\_03\_19\_14 FINAL - April 2014





# Product

# Study Materials Sent

- Sage Warmers
- 2% CHG Cloths
- 4% Liquid CHG
- Mesh Sponges



Coordinated through  
HCA corporate and  
local supply chain

- Binders
- Shower Clings
- Wall Clings
- Handouts (electronic file)

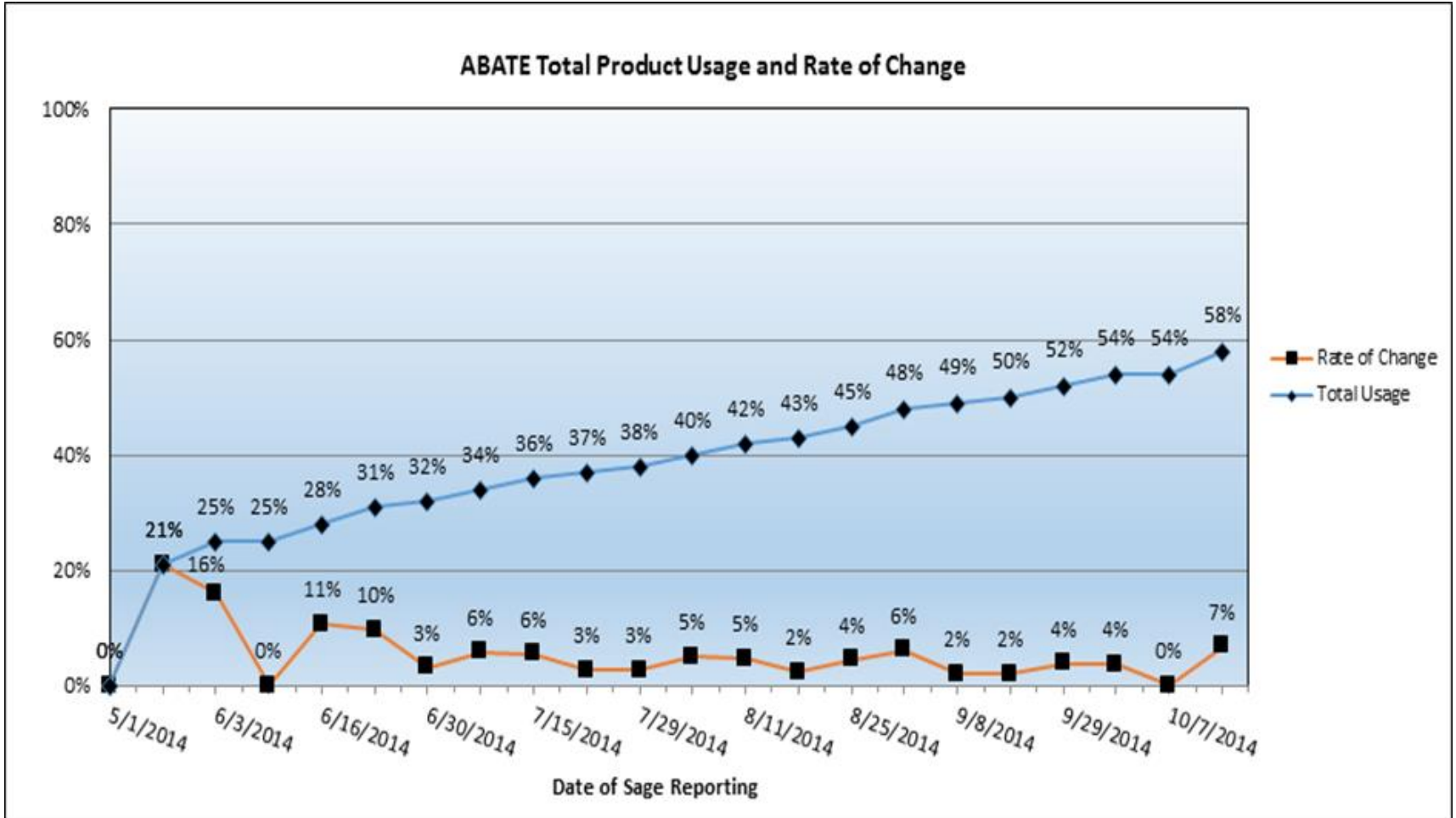


Coordinated through  
ABATE study staff

# Study Product


- Comprehensive tracking system
  - Tracking manufacturer → divisional warehouse → local warehouse → hospital → participating unit
- Contributed product marked for study use with specific code
  - Ensures study product usage is tracked and used by participating units only

# Product Usage



# Product Compatibility

- Comprehensive list of CHG compatible products provided

		Commonly Used HCA Approved Chlorhexidine (CHG) Compatible Products	
<b>LOTIONS</b>			
<b>Compatible</b>			
✓	ConvaTec Aloe Vesta 2-Moisturizing Skin Conditioner	✓	Medline Remedy Basics Moisturizing Body Lotion
✓	ConvaTec Sensi-Care 2 – Moisturizing Body Cream	✓	Medline Remedy Olivamine Skin Repair Cream
<b>NOT Compatible</b>			
✗	Johnson & Johnson Baby Lotion*	✗	Medline MedSpa Hand & Body Lotion*
✗	Medline MedSpa Baby Lotion*	✗	Steris Kindest Kare Skin Cream*
<b>INCONTINENCE BARRIER PRODUCTS</b>			
<b>Compatible</b>			
	<u>BARRIER CREAM</u>		<u>BARRIER CREAM CLOTH / WIPE</u>
✓	ConvaTec Aloe Vesta 3 – Protective Barrier Spray	✓	Sage Comfort Shield Barrier Cream Cloths



# Compliance

# Compliance

- Daily CHG bathing and mupirocin tracking
- High stable compliance ( $\geq 85\%$ ) enables facilities reduction to weekly assessment
  - Requires documentation for compliance with assigned protocol, including acceptable reasons for deviation (e.g. patient allergic, late arrival to floor)
- Certificate to units and commendation letters for individual staff to be sent for their work on obtaining high compliance

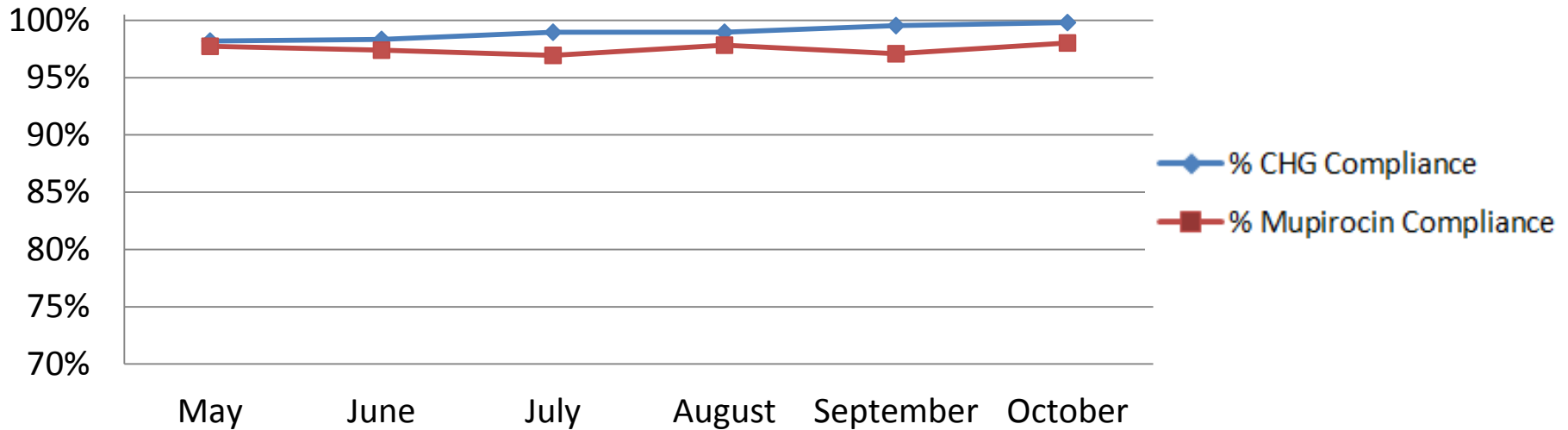


# Methods to Increase Compliance

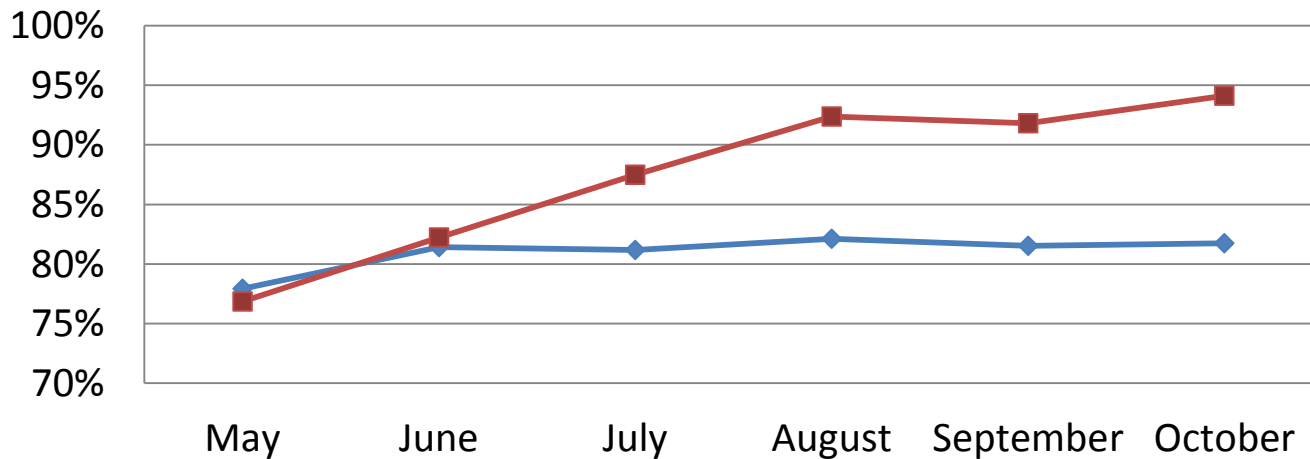
- For mupirocin: units partner with pharmacy and/or create local reports
- For CHG: add IT prompts to nursing status board
- HCA is building an additional custom report to assist with compliance reporting
- Follow up site visits are being scheduled for additional training and/or support

# Compliance Tracking

## Arm 1 Compliance



## Arm 2 Compliance



# QI Skills Assessment

Hospital Name: \_\_\_\_\_ Unit Name: \_\_\_\_\_

**HCA**

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## Skills Assessment: 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 Used all 6 cloths (more if needed)
- 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

- Do you ever use soap in conjunction with a CHG bathing cloth? *If so, when?*  
\_\_\_\_\_
- 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](mailto:ABATEStudy@gmail.com) or fax to (949) 824-3985

Hospital Name: \_\_\_\_\_ Unit Name: \_\_\_\_\_

**HCA**

Hospital Corporation of America™

## Skills Assessment: CHG Cloth – Patient Self-Bathing

Please complete for **THREE** different patients **per unit**

Please record patient responses after the patient bathed him/herself with the CHG cloths.

### Questions

- Were you provided a handout with instructions on how to apply the CHG bathing cloths?  
 Y  N
- Were you told that the CHG bathing cloths kill germs better than regular soap and water?  
 Y  N
- Were you told that the temporary stickiness was due to aloe and would go away when dried?  
 Y  N
- Were you told that the CHG bathing cloths should not be rinsed off?  
 Y  N
- Were you told to NOT use other bathing soaps while in this unit?  
 Y  N
- Were you told to bathe daily with the cloths while in this unit?  
 Y  N
- Did you use all six cloths?  
 Y  N
- Did you or a bathing assistant clean your lines, tubes, and/or drains?  
 Y  N  N/A
- Did you or a bathing assistant clean your wounds?  
 Y  N  N/A
- Did you throw the used cloths in the trash (did not flush them)?  
 Y  N

Email to [ABATEStudy@gmail.com](mailto:ABATEStudy@gmail.com) or fax to (949) 824-3985



# Competing Interventions

# Competing Interventions

- All sites report any possible new interventions
- Polled on coaching calls – 1x/mo for Arm 1, 2x/mo for Arm 2

Arm	Interventions Proposed	Allowed	Disapproved (Conflicting)
Arm 1	39	25	14
Arm 2	64	47	17
<b>Total</b>	<b>103</b>	<b>72</b>	<b>31</b>



# Adverse Events

# Adverse Event Reporting



## STUDY-RELATED EVENT SUBMISSION FORM

Please use this form to report all study-related events to your Unit Nursing Director.  
For clinical decisions related to possible study-related events, please contact the treating physician.  
*Unit Director to fax completed study-related event forms to ABATE study staff on biweekly basis.*  
\*\*\*\*\*

Fax completed form to (617) 509-4260, ATTN: Rebecca Kaganov  
For questions, please contact ABATE Infection Study staff at [ABATEstudy@gmail.com](mailto:ABATEstudy@gmail.com) or (617) 509-4141

Name of individual filing report: \_\_\_\_\_ 34 ID Number: \_\_\_\_\_

Title/Position of individual filing report: \_\_\_\_\_

Facility Name: \_\_\_\_\_ Facility COID: \_\_\_\_\_

Please provide all forms of contact information below:

E-mail address: \_\_\_\_\_ Unit General Phone: ( ) \_\_\_\_\_ - \_\_\_\_\_

Unit Manager Name: \_\_\_\_\_ Unit Manager Phone: ( ) \_\_\_\_\_ - \_\_\_\_\_

### Section I: General Information

Today's Date: \_\_\_\_/\_\_\_\_/\_\_\_\_ Date of First Symptom Onset: \_\_\_\_/\_\_\_\_/\_\_\_\_

*Please fill out one form per adverse event.*

Patient Name: \_\_\_\_\_ Medical Record Number (MRN): \_\_\_\_\_

Unit Name: \_\_\_\_\_ Patient Age: \_\_\_\_\_ Patient Gender: M F

Please choose the option that best describes the event:

- Skin/mucosa related, *continue to Section II: Skin Related Events*
- Non-skin related, *please provide a brief description of the event. We will contact you for more information.*

# Adverse Events – Report Update

- As of October 16, 2014 → 19 AEs reported
- All mild and related to CHG
  - Possibly/definitely related
    - 15/301,000 patient bathing days
    - 10 discontinued study product
  - Unrelated
    - 4/301,000 patient days





# Laboratory Strain Collection

# Strain Collection Protocol

## **Assess resistance to decolonization agents**

- Baseline level of CHG and mupirocin resistance
- Will more resistance emerge in one arm vs. the other?

## **2 phases of strain collection**

- Baseline Collection – completed
- Intervention Collection – in progress

# Strain Collection Toolkit Binder & Packaging Materials



# Baseline Strain Collection Summary

## Baseline Collection: Shipped vs. Nosocomial<sup>†</sup> Isolates

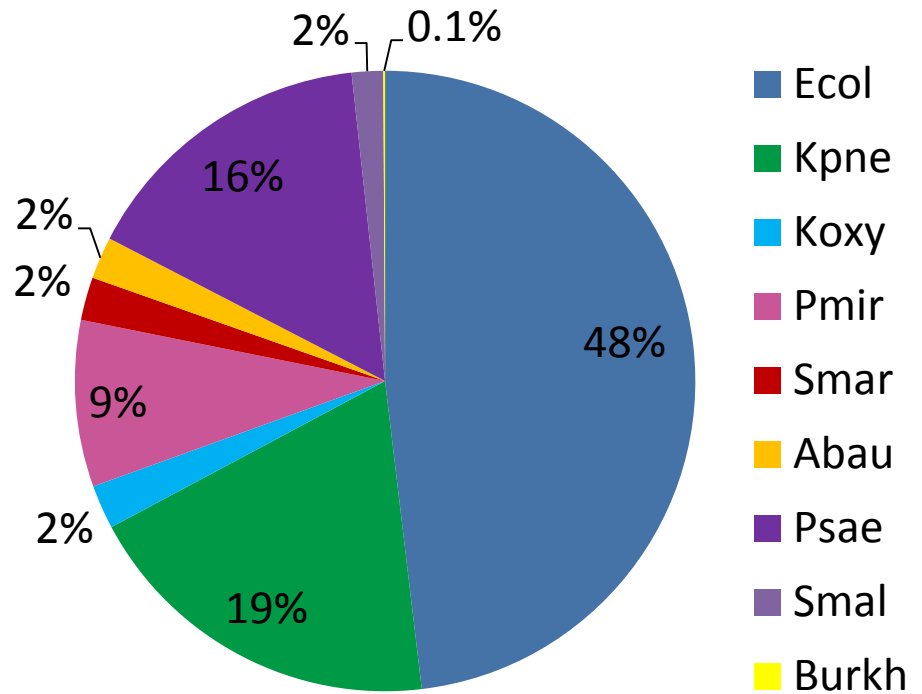
	Total Shipped	Total Nosocomial*	% Nosocomial
MRSA	2,169	491	23%
GNR	2,182	745	34%
<b>TOTAL</b>	<b>4,351</b>	<b>1,236</b>	<b>28%</b>

<sup>†</sup> Nosocomial isolates are those collected >2 calendar days post hospital admit date

\*Based on preliminary Lab Strain Data linkage to HCA EDW data

# Distribution of GNR Species

Selected GNR	# of Isolates
<i>E. coli</i>	1031
<i>K. pneumoniae</i>	409
<i>P. aeruginosa</i>	336
<i>P. mirabilis</i>	186
<i>K. oxytoca</i>	49
<i>S. marcescens</i>	48
<i>A. baumannii</i>	47
<i>S. maltophilia</i>	35
<i>Burkholderia spp.</i>	2





# ABATE Ethics Supplement

# Project Overview & Aims

Address the ethical gray space related to the interface of minimal risk research and quality improvement projects as they would be applied to Learning Health Systems

- **Three inter-related surveys**
  - Hospitalized Patients
  - Directors of QI Programs
  - IRB Chairs and Directors

# Progress

- **Survey of Hospitalized Patients**
  - ✓ Survey IRB approved
  - ✓ Administered at UC Irvine Health, Brigham and Women's Hospital
- **Survey of Directors of QI Programs**
  - ✓ Survey IRB approved
  - ✓ Applied for national society to send to members (SHEA)
  - Request to HCA, Collaboratory, CTSA, PCORnet for support
- **Survey of IRB Chairs and Directors**
  - ✓ Survey being drafted
  - ✓ Applied to send to PRIM&R listserv
  - Request to HCA, Collaboratory, CTSA, PCORnet for support



# ABATE Infection Trial

## Active Bathing to Eliminate Infection

<b>Principal Investigator</b>	Susan Huang, MD MPH
<b>Content Expertise Infectious Diseases &amp; Hospital Epidemiology</b>	Susan Huang MD MPH, Ed Septimus MD, Julia Moody RN MS, John Jernigan MD MS, Mary Hayden MD, Robert Weinstein MD
<b>Health System</b>	Hospital Corporation of America Ed Septimus, MD ( <b>HCA site lead</b> ) Jason Hickok, MBA RN ( <b>HCA administrative lead</b> ) Julia Moody, MS SM Chris Walker, MHCI Candidate Jonathan Perlin, MD PhD
<b>Statistics</b>	Ken Kleinman ScD, Dan Gillen PhD
<b>Microbiology</b>	Mary Hayden MD, Chris Bushe MHSA
<b>Project Coordination</b>	Adrijana Gombosev MS, Lauren Heim MPH, Katie Haffenreffer BS, Lauren Shimelman BS
<b>IRB</b>	David Vulcano MBA, VP Clinical Research Sheila Fireman JD, Rebecca Kaganov BS



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

**Thank you!**