



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

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Collaboratory Grand Rounds

Agenda

- Project Overview
- Recruitment
- IRB
- Laboratory Strain Collection
- Baseline Data Streams
- Statistical Approach
- Timeline



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

ABATE Infection Project

Active Bathing to Eliminate Infection

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

Condition*period design

- Baseline period: data collection only
- Intervention period: intervention, in intervention arm; monitoring to ensure no competing intervention in routine care arm

Outcomes

Outcomes obtained from the HCA data warehouse

Primary Outcome

- Clinical cultures with MRSA and VRE

Secondary Outcomes

- Clinical cultures with Gram Negative MDROs
- Bloodstream infections: all pathogens
- Urinary tract infections: all pathogens
- Blood culture contamination
- Infectious readmissions
- Emergence of resistance (strain collection)



Recruitment

Hospital Recruitment

Response

# Hospitals	% Total Recruitment	Duration
14	25%	4 business days
29	50%	7 business days
43	75%	9 business days
55	100%	11 weeks

- 15 states
- 55 CEO participation letters in hand

55 Hospitals

Average annual admissions	11,833
Mean LOS (median)	4.7 (4.6) days
Non-Critical Care Adult Units	197
Mixed Medical/Surgical	35%
Cardiac/Telemetry	16%
Surgical	13%
Medical	10%
Step-down	10%
Oncology	4%
Other	12%

Hospital Unit Exclusions

- **Exclusion Criteria**
 - Pediatric, BMT, peri-partum, psychiatry, rehab units
 - Units already performing routine CHG bathing
 - Units with >30% cardiac or hip/knee orthopedic surgeries
 - LOS < 2 days
- **Unit Engagement Survey / Data streams**
 - 9-10% exclusion



IRB

Centralized IRB

Central IRB approved Feb 2013 (Harvard Pilgrim)

Reliance Agreements

- 54 of 55 hospitals have agreed to cede to Harvard

# Hospitals	%	Time to Approval (Months)
7	13%	1
24	44%	2
38	69%	3
46	84%	4
51	93%	5
54	98%	6

- 1 hospital providing prisoner oversight

Informed Consent

Will waive informed consent

Will not post informative signs

OHRP waiver conditions met

- Minimal risk criteria
- Evaluation of quality improvement programs
- Population impact due to contagion

FDA

- Confirmed no oversight



Laboratory Baseline Strain Collection

Strain Collection Protocol

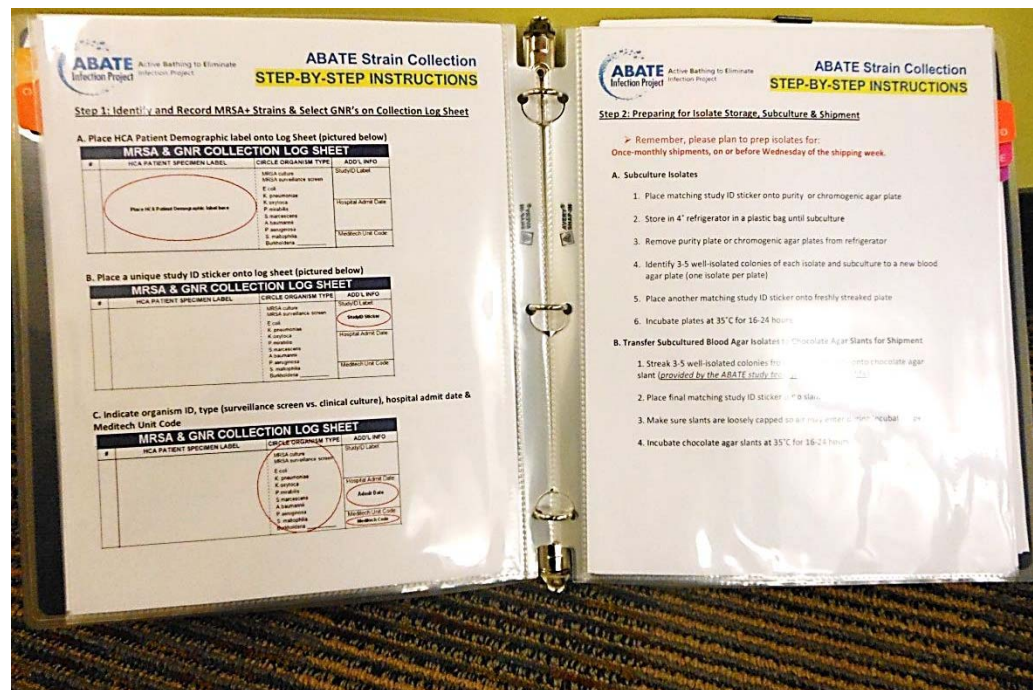
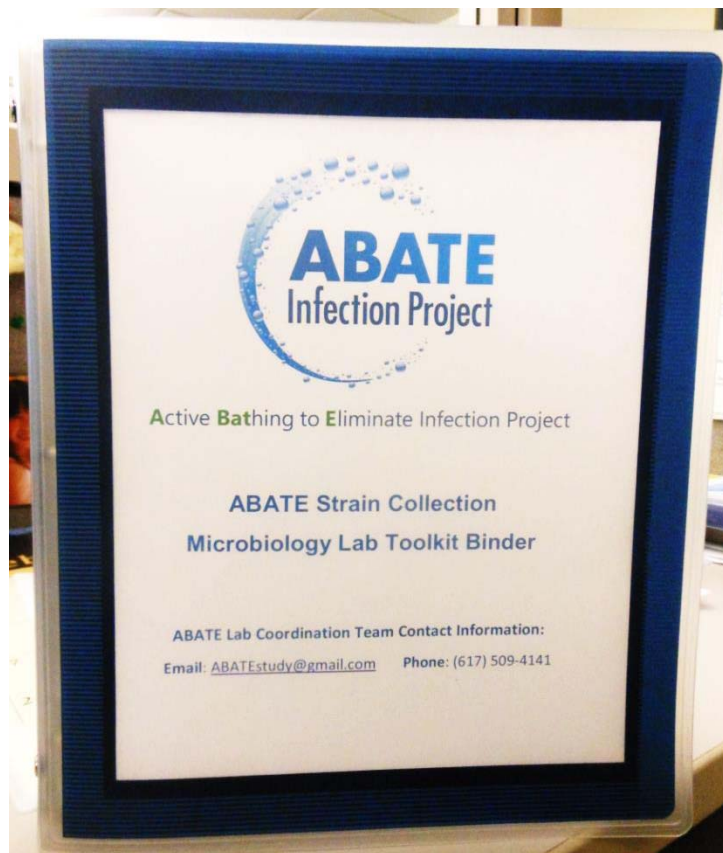
Assess resistance to decolonization agents

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

2 phases of strain collection

- Baseline Collection
- Intervention Collection

Strain Collection Toolkit Binder



As received



Assembled



- 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

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

Strain Collection Protocol

Overall Collection Goals

	Baseline	Intervention
MRSA	1200	1200
GNR	1400	1400
Total	2600	2600

Monthly Lab Collection Goals

MRSA	up to 10 MRSA+ isolates
GNR	up to 10 select GNR isolates
Total	max of 20 total isolates/month

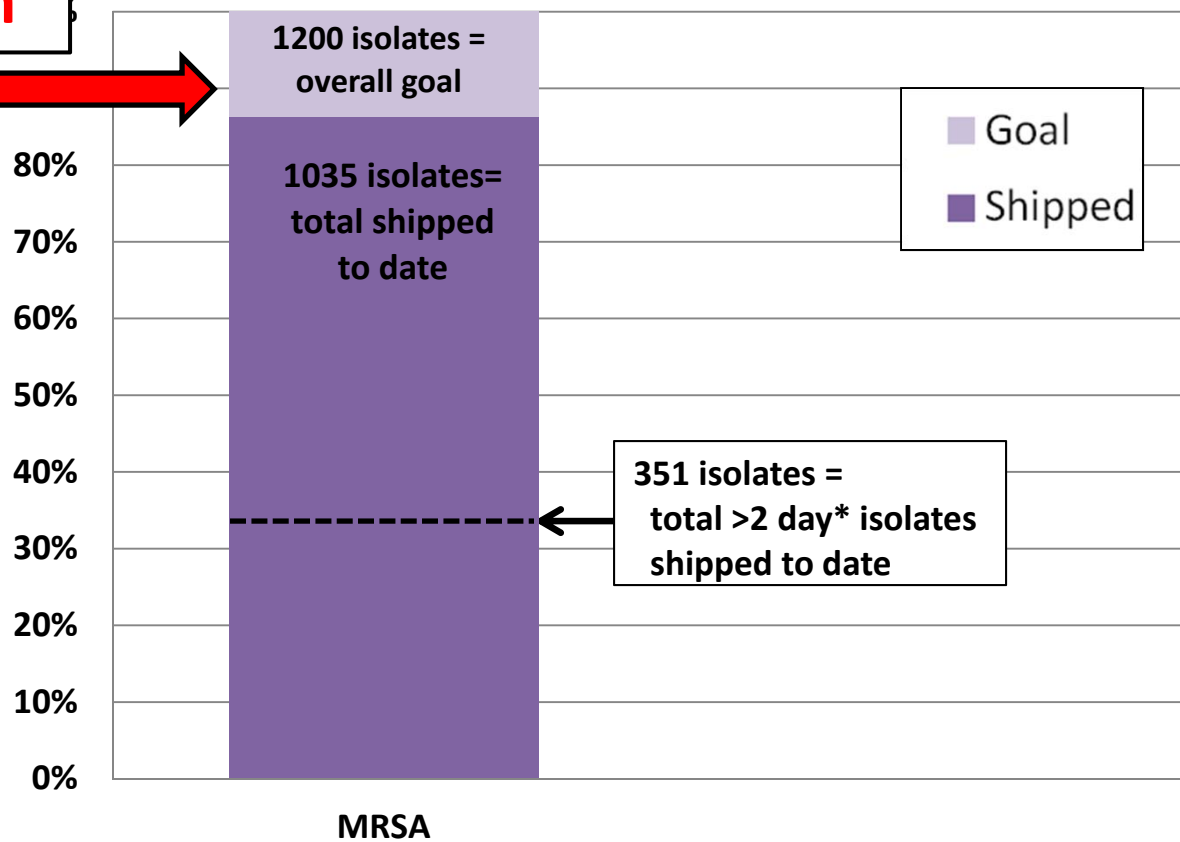
MRSA Collection Estimates

MRSA Collection Totals & Rates	
# Facilities Eligible to Ship	54
# Facilities that Have Shipped	48
Total Number of Isolates Shipped	1035
Total Number of Isolates Confirmed	899
Monthly Shipping Average per Lab	3.9/lab

MRSA Collection Estimates

Ongoing collection

Baseline Completion – MRSA Collection



*Day 1 = day of hospital admission

GNR Collection Estimates

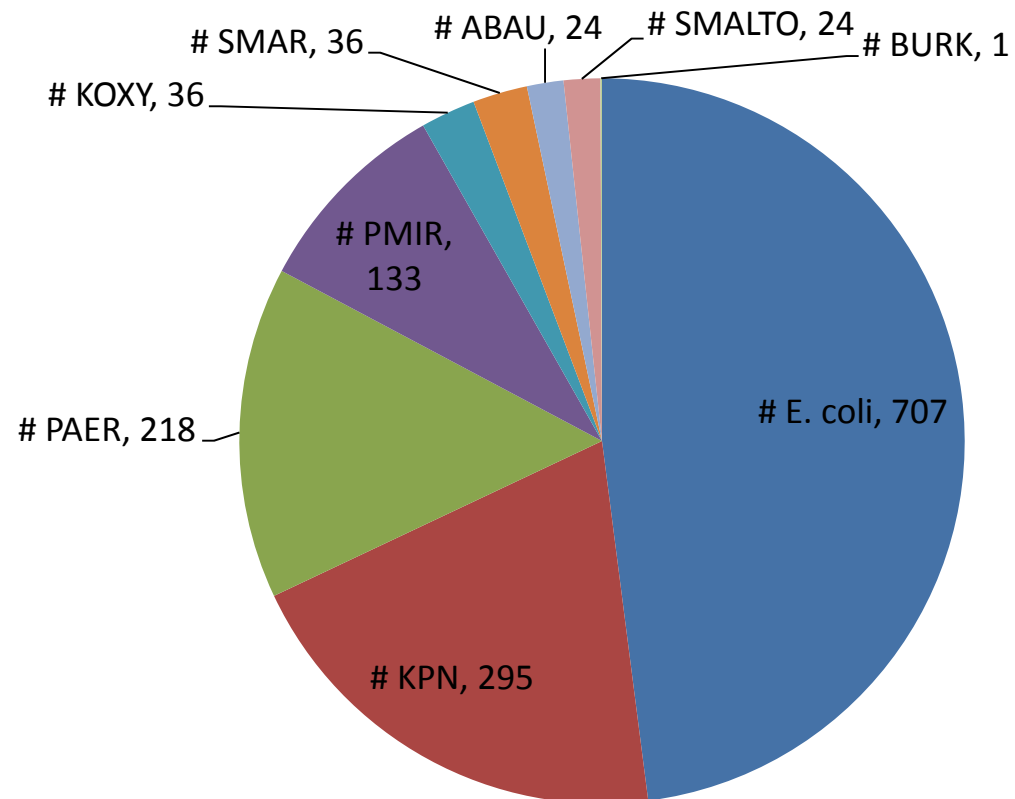
GNR Collection Totals & Rates	
# Facilities Eligible to Ship	54
# Facilities that Have Shipped	48
Total Number of Isolates Shipped	1652
Total Number of Isolates Confirmed	1474
Monthly Shipping Average per Lab	6.3/lab

GNR Collection Estimates

Select GNRs

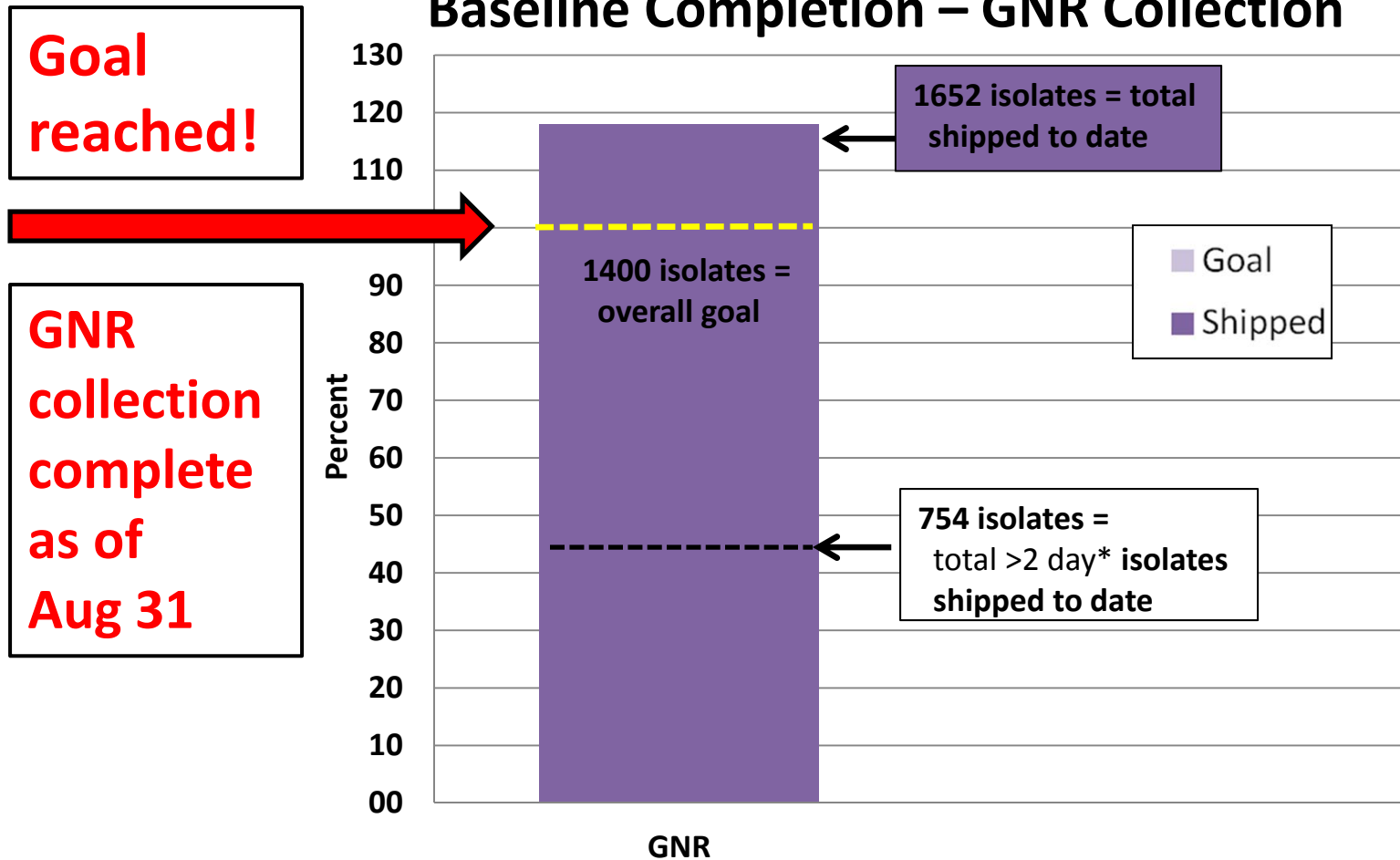
- *E. Coli*
- *K. pneumoniae*
- *P. aeruginosa*
- *P. mirabilis*
- *K. oxytoca*
- *S. marcescens*
- *A. baumannii*
- *S. maltophilia*
- *Burkholderia sp*

GNR Breakdown by Organism



GNR Collection Estimates

Baseline Completion – GNR Collection



*Day 1 = day of hospital admission

Strain Collection Timeline





Educational & Training Materials

Arm-Specific Toolkit Binders



Active Bathing to Eliminate Infection

ARM 2

Universal Decolonization Toolkit Binder



Phone Matrix

Topic	What to do	Who to contact
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

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	Julie



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

Arm-Specific CBT Training



Nursing Protocol Training Universal Decolonization

ARM 2

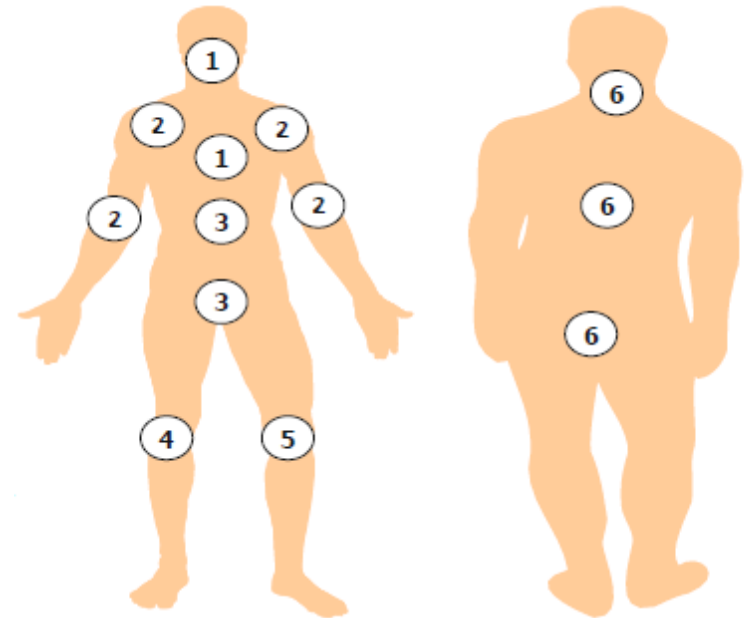


Bathing Clean Up

Dispose of each
washcloth in the trash



Do **NOT** flush
washcloths in the toilet



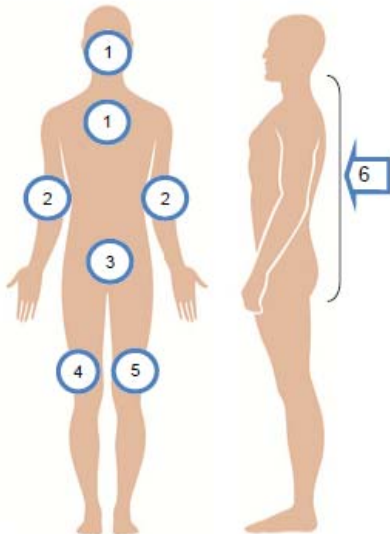
Patient and Staff Flyers

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:

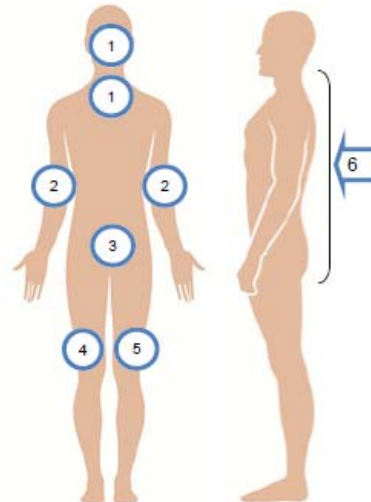


Prevent infections during your hospital stay
 Bathe daily with Chlorhexidine (CHG) soap

PATIENT

While in the hospital, bathe *every day* with a special antiseptic soap (CHG) shown to remove germs and prevent infection better than soap and water

6 cloths should be applied as below:



Take a CHG shower or bed bath

Reminders

- CHG is proven to work better than soap and water in removing germs
- Once massaged onto skin, it works to kill germs for 24 hours
- Use CHG every day. Starting on admission is best, before IVs, lines, urinary catheters, and procedures/surgery
- Be thorough. Ask for help to cover all skin
- CHG is safe on rashes, burns, and wounds that are not large or deep to remove germs and prevent infection
- Clean lines, drains, tubes attached to body
- Allow to air dry for best effect

Clean all skin areas with special attention to:

- Neck
- All skin folds
- Skin around all devices (tubes/drains)
- Wounds unless deep or large
- Armpit, groin, between fingers/toes

Protect yourself every day

SHOWERING with CHG soap

1. Rinse body with warm water.
2. Wash hair with CHG or regular shampoo
3. Turn off the water and lather washcloth with plenty of CHG soap
4. Lather and massage soap in all six areas
5. Leave soap for 2 minutes before rinsing

BATHING with CHG cloths

1. These cloths are your protective bath
2. Use all 6 cloths. More, if needed
3. Firmly massage to clean skin. CHG will kill germs for 24 hours if applied well
4. Clean over non-absorbable dressings
5. Clean 6 inches of lines, tubes and drains nearest the body
6. Dispose of CHG cloths in a regular trash bin. Do not flush

Caution: Avoid eyes and ear canals

Arm-Specific Protocols

How to use Nasal Mupirocin Ointment

For MRSA+ patients:

- Place patient's bed at **30 degrees**, if tolerated
- Apply 1 inch of ointment from tube directly into **each nostril**
- Press nostrils together and massage gently for **60 seconds**
- Do this **twice a day for 5 days**
- Avoid contact with eyes and other intranasal products
(contact study team if any questions)

Compatibility Guidance



Active Bathing to Eliminate Infection Project

Commonly Used HCA Approved Compatible Products

Lotions, Creams, & Ointments

- **Compatible**
 - ConvaTec Aloe Vesta 2 – Moisturizing Skin Conditioner*
 - Baby Magic Baby Lotion
- **NOT Compatible**
 - Medline Hand & Body Lotion
 - Johnson's Baby Lotion
 - Keesler Cream

Barrier Products

- **Compatible**
 - ConvaTec Aloe Vesta 3 – Protective Ointment*
 - ConvaTec Aloe Vesta 3 – Protective Barrier Sprav*

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 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.*



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

Baseline Characteristics

	4 month Baseline Data
Admissions with non-ICU stay (N)	73,648
Non-ICU Patient Days	394,011
Hospital Stay in Days (Mean (SD))	6.6 (5.1)
Non-ICU stay in Days (Mean (SD))	5.3 (3.8)
Age in Years (Mean (SD))	63.8 (17.9)
Female	55%
Race (%)	
White	68%
Black	12%
Other	20%
Comorbidities (%)	
COPD	27%
Diabetes	32%
Congestive heart failure	17%
Renal failure	19%
Myocardial infarction	7%
Cerebrovascular disease	8%
Cancer	9%
Surgery During Admission (%)	29%

Baseline Outcomes

	Rate (Event/1,000 patient days) ^a	Event/Attributable Patient Days ^b
Primary Outcome		
MRSA and VRE Clinical Cultures	2.2	547/253,329
Select Secondary Outcomes ^c		
GNR Multi-Drug Resistant Org.	0.6	163/255,436
All-Cause Bloodstream Infection	1.1	272/254,318

Based Upon March-June, 2013 Data ^a

^a Events occurring >2 days into unit admission through 2 days following unit discharge)

^b Denominators differ due to censoring of patient days following an identified event

^c Select key outcomes provided



STATISTICAL DESIGN

Plans for Randomization

Lack of balance on key covariates can open the door to confounding: a threat to cluster-randomized trials

Our approach: stratified randomization

Key covariates

- Volume
- Baseline outcome rates
- Case mix
- Product use
- Type of unit (medical/surgical)

Plans for Randomization

How to balance all of these at once?

We can't, but we can try different stratification/pairing schemes assess their impact on the balance.

Schemes:

- 1. Choose pairs that minimize the total Mahalanobis distance between pairs. (1a: weight variables)**
- 2. Rank by volume, then within classes of similar volume, rank by baseline rates, etc.**
- 3. ...**

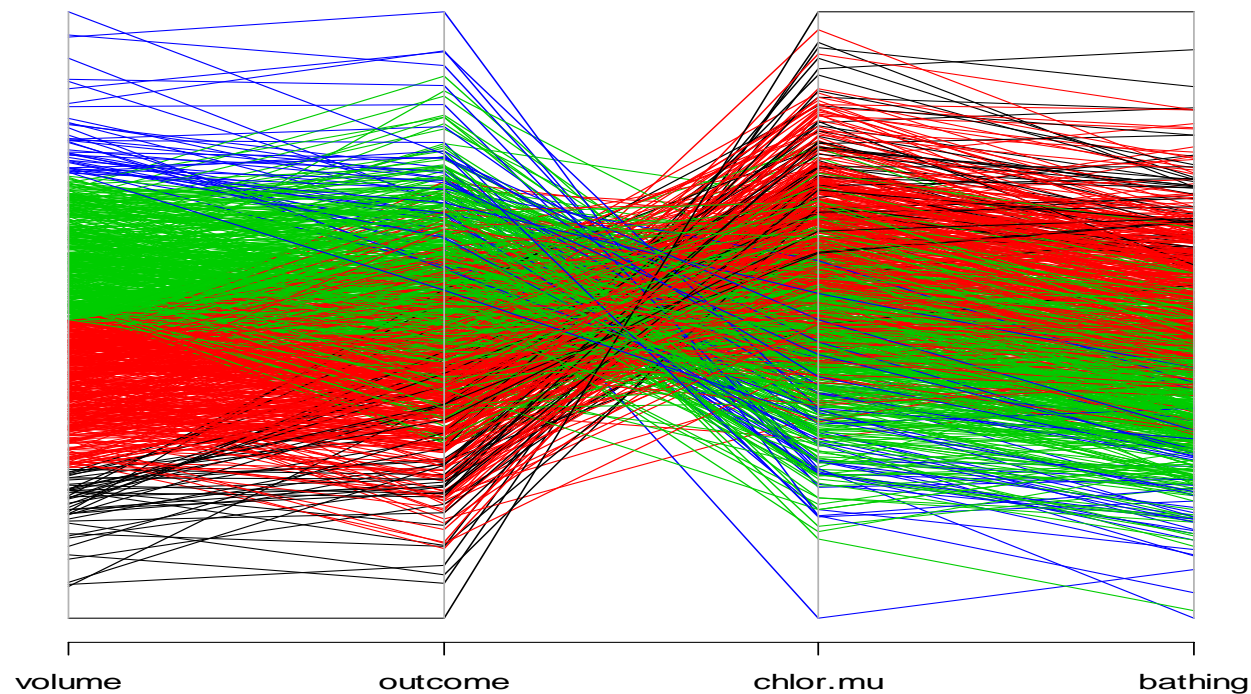
Plans for Randomization

There can be no one “correct” stratification scheme. If we had no preliminary or baseline data, we’d have to just take a shot in the dark. But we have a lot of baseline data.

Approach:

- 1) Implement each stratification scheme many times;**
- 2) Assess the resulting balance**
- 3) Choose the scheme with the results we like best**

Mock-up of assessment



Blue scheme matches poorly on volume and outcome but well on baseline chlorhexidine use and bathing. Black scheme is reversed, while green and red are approximately balanced.

Planned data analysis

The primary outcome: clinical culture with MRSA or VRE.

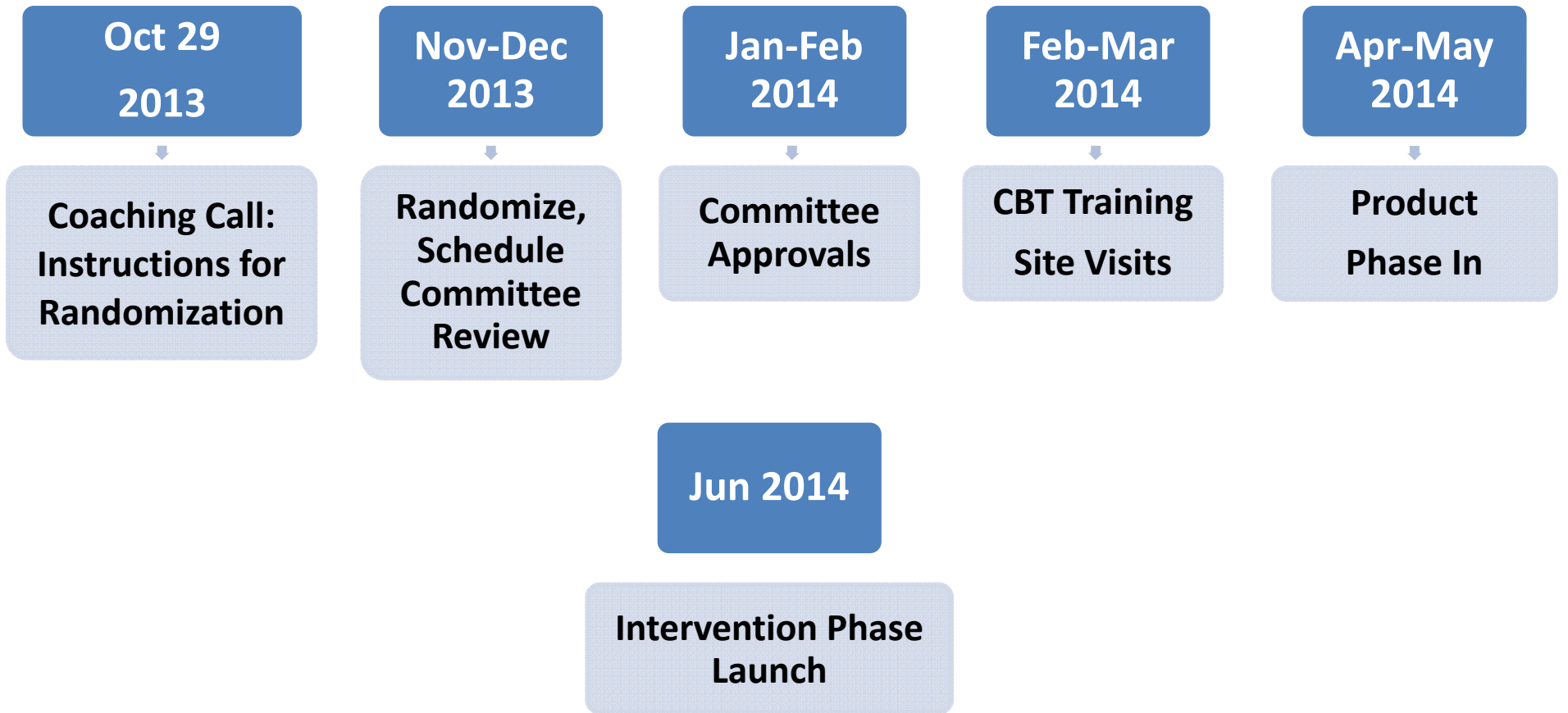
Length of stay differs between individuals, probability of positive culture may vary over time of stay:

→ Survival analysis via proportional hazards, a.k.a Cox, regression

Randomization by hospital, not by patient:

→ Frailty model, random effects for proportional hazards

ABATE Study Timeline



ABATE Infection Trial

Active Bathing to Eliminate Infection

Principal Investigator:	Susan Huang, MD MPH
Content Expertise Infectious Diseases & Hospital Epidemiology	Susan Huang MD MPH, Ed Septimus MD, Julia Moody RN MS, John Jernigan MD MS, Mary Hayden MD, Robert Weinstein MD
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, Chris Bushe, MHSA
Project Coordination	Adrijana Gombosev BS, Lauren Heim BS, Julie Lankiewicz MPH CCRC, Katie Haffenreffer BS
IRB	David Vulcano, MBA, VP Clinical Research Sheila Fireman JD, Rebecca Kagenov, BS



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