



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

NIH Collaboratory Meeting
Data Sharing Plan
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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

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
- *C difficile* infection
- Blood culture contamination
- Infectious readmissions
- Emergence of resistance (strain collection)

Data Sharing Plan

Methods of Data Sharing

Current Proposed Strategies

- Publications and presentations
- Shared toolkit – protocols and educational materials
- Shared instructional video
- Microbiologic samples
- Analytic programs
- Supervised data enclave

Issue #1: Ownership

Ownership

- ✓ All data used for trial analysis were collected for usual operational health system purposes

Issue #2: Privacy

Protections

- ✓ Individuals
- ✓ Hospitals
- ✓ Health system

Issue #3: Responsibility

Accuracy of data inquiry

- ✓ Data complexity
 - Dictionary
 - Assumptions
 - Limitations
- ✓ Data intent
- ✓ Data analytic plan
- ✓ Data conclusions

Issue #4: Duration of Provisions

Permanent – no requirement of ongoing resources

- ✓ Publications and presentations
- ✓ Shared toolkit – protocols and educational materials
- ✓ Shared instructional video
- ✓ Analytic programs

Temporary – requires ongoing resources

- ✓ Supervised data enclave
- ✓ Microbiologic samples
- ✓ Responsibility for assuring resources for promised time
- ✓ Turnover of staff, programmers, statistician

Supervised Data Enclave

Brokered access

- ✓ Request form
- ✓ Confirmation of scope, planned use of data
 - Health system
 - Investigative team
- ✓ Review of/creation of proposed analytic programs
- ✓ Payment fee to cover expenses

Duration

- ✓ Requires knowledge of dataset for access
- ✓ Requires programmer analysts, statistical expertise
- ✓ 3 years from primary publication

Microbiology Specimens

Access to Bacterial Specimens

- ✓ Request form
- ✓ Confirmation of planned use of specimens
- ✓ Payment fee to cover expenses

Duration

- ✓ Requires knowledge of inventory
- ✓ Maintenance of specimen stocks
- ✓ 3 years from primary publication

Data Sharing Questions

Have your research partners expressed concerns?

- Yes, significant
 - Health system: leadership, compliance, legal
 - Investigators: data use, data integrity, analytic integrity
 - Expenses

How will individual health systems be identified

- ✓ Supervised data enclave – no direct release of data
- ✓ Summary reports only

Can the analysis be replicated?

- ✓ Submission of alternative analyses
- ✓ Supervised access to full data