Active Bathing to Eliminate 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
  o Dictionary
  o Assumptions
  o 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
  o Health system
  o 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
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