NIH PRAGMATIC TRIALS COLLABORATORY

Rethinking Clinical Trials®

ABATE Infection Project

Active Bathing to Eliminate (ABATE) Infection

Principal Investigator
Susan Huang, MD, MPH

ClinicalTrials.gov Identifier
NCT02063867

Sponsoring Institution
University of California, Irvine

Collaborators
- HCA Healthcare
- Harvard Medical School/Harvard Pilgrim Health Care
- University of California, Irvine School of Medicine
- Rush University
- John H. Stroger Hospital
- Centers for Disease Control and Prevention

NIH Institute Providing Oversight
National Institute of Allergy and Infectious Diseases (NIAID)

DATA AND RESOURCE SHARING

- **Data sharing checklist**
- **Data request**
- **Primary study results:** Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial. *Lancet*. 2019;393(10177):1205-1215. PMID: 30850112.

STUDY AT A GLANCE

STUDY QUESTION AND SIGNIFICANCE

Universal antiseptic bathing and nasal decolonization are known to reduce bloodstream infections and multidrug-resistant organisms in intensive care unit (ICU) settings. However, the effects of this type of decolonization outside the ICU are unknown. The objective of the study was to evaluate the use of universal chlorhexidine bathing plus targeted nasal decolonization for methicillin-resistant *Staphylococcus aureus* (MRSA) carriers in hospitalized patients outside the ICU.

DESIGN AND SETTING

Cluster randomized trial in 53 hospitals with 194 non–critical care units, of which 26 hospitals (with 90 non–critical care units) were randomly assigned to routine care and 27 hospitals (with 104 non–critical care units) were randomly assigned to the intervention.

INTERVENTION AND METHODS

The intervention included daily chlorhexidine bathing for all patients in the unit plus nasal mupirocin for known MRSA carriers. The primary outcome was MRSA or vancomycin-resistant enterococcus (VRE) clinical cultures attributed to participating units. The primary analysis was an unadjusted intention-to-treat analysis using proportional hazards models that accounted for clustering within hospitals. The analysis assessed whether the hazard ratio between the intervention and baseline periods differed significantly between study groups. Clinical cultures of multidrug-resistant, gram-negative bacteria and all-cause bloodstream infection were evaluated as secondary outcomes.

FINDINGS

Universal decolonization did not reduce multidrug-resistant bacteria or bloodstream infection in the overall non-ICU population. In a post hoc analysis of patients with medical devices, decolonization was associated with a significant 32% reduction in all-cause bloodstream infections and a significant 37% reduction in MRSA or VRE clinical cultures attributable to participating units. Targeting patients with devices may be particularly valuable because they represented 10% of the non-ICU population but were responsible for 37% of all MRSA and VRE clinical cultures and 56% of all bloodstream infections in non-ICU patients.

CONCLUSIONS AND RELEVANCE

Universal decolonization and targeted nasal decolonization did not significantly reduce the risk of multidrug-resistant infections in the overall non–critically ill patient population, but large reductions were seen in the subset of patients with medical devices.

GENERALIZABLE LESSONS

Challenge	Solution
Hospital quality improvement initiatives that could compete with the trial intervention and influence trial outcomes	Monthly tracking of quality improvement initiatives in both study arms and review with Steering Committee; and encouragement of hospitals considering competing interventions to delay implementation, narrow implementation to non-trial units, or withdraw from the trial
Changes in hospital leadership and changes in nomenclature of units in electronic health system, which is needed to identify participating locations	Requests during monthly coaching calls for study champions to disclose changes in leadership or contact information and changes in unit names or patient composition
Greater need for data cleaning and standardization in trials with very large datasets, and idiosyncratic differences between sites not amenable to economy of scale for data cleaning	Budgeting of increased programming effort for data cleaning, standardization, and analysis
Requirement to have dedicated ethical oversight for any prisoner admitted to non-ICU area during the course of the trial, despite meeting minimal risk criteria	Identification of participating site with prisoner representative on IRB to provide oversight

"Quality improvement initiatives are integral and common to healthcare. Tracking, discussing, and delaying competing interventions is critical to assuring participants, investigators, and stakeholders that the trial question can be answered." — Susan Huang

"While every trial has different data issues, it was incredibly helpful within the Collaboratory to discuss data cleaning and standardization issues as a common and integral part of any trial. It is worthwhile for the Collaboratory to continue to right-size expectations for data cleaning and analysis for large pragmatic trials." — Susan Huang

"We did not encounter a major barrier to finding an oversight committee with a prisoner representative, but this experience raised the question of how to enable minimum-risk quality improvement research for all vulnerable groups without requiring dedicated oversight."

— Susan Huang

ADDITIONAL RESOURCES

- Article: Calculating Power by Bootstrap, With an Application to Cluster-Randomized Trials
- Video interview: Dr. Huang Discusses the ABATE Infection Project
- NIH Pragmatic Trials Collaboratory Grand Rounds: ABATE Infection Trial: Backstage Tour
- NIH Pragmatic Trials Collaboratory Steering Committee Meeting Presentation: ABATE Infection Trial: Barriers and Lessons Learned

Access the complete set of ABATE Infection resources.