NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory

Active Bathing to Eliminate Infection (ABATE)

Susan Huang, MD, MPH

Meeting Participants (June 17, 2013):

☒	Jeremy Sugarman (Johns Hopkins)	☒	Laurie Kunches (Harvard Pilgrim)	☒	Clayton Huntley (NIH)	☒	Tammy Reece (Coord Center)
☒	Rob Califf (Duke)	☒	Julie Kaneshiro (OHRP)	☒	Catherine Meyers (NIH)	☐	
☒	Susan Huang (UC Irvine)	☒	Jerry Menikoff (OHRP)	☒	Wendy Weber (NIH)	☐	
☒	Sheila Fireman (Harvard, IRB)	☒	Irene Stith-Coleman (OHRP)	☒	Sarah Carr (NIH)	☐	
☒	Julie Lankiewicz (Harvard)	☒	Ivor Pritchard (OHRP)	☒	Carla James (NIH)	☐	
☒	Paula Tebeau (Harvard)	☒	Dave Wendler (NIH)	☒	Josephine Briggs (NIH)	☐	

The minutes from the June 17, 2013 meeting were circulated to all participants on the call for two rounds of review and they reflect all corrections that were received.

AGENDA ITEMS	DISCUSSION June 17, 2013	PROPOSED ACTION June 17, 2013	CURRENT STATUS as of June 1, 2015
Review of Demonstration Project	• Dr. Huang gave an overview of the ABATE (**A**ddressing **B**ioburden while **A**dmitted **T**o **E**liminate) Infection Trial. ABATE will efficiently evaluate the impact of decolonization on multi-drug resistant organisms and hospital-associated infections (HAIs) in the general patient population outside ICUs. This cluster-randomized trial will randomize ~50 hospitals treating nearly 400,000 patients to evaluate 1) universal daily chlorhexidine bathing, combined with 2) nasal decolonization with mupirocin for known carriers of methicillin-resistant		No changes have been made to the ABATE study design or implementation as a result of this discussion/teleconference.

	Staphylococcus aureus (MRSA), one of the most common causes of HAIs. While decolonization has been successful in short-stay high risk areas, such as ICUs, this trial will address the much larger problem of HAIs in non-ICU medical and surgical wards. • Lead centers involved include: UC Irvine, Harvard Pilgrim Health Care Institute (Lead IRB), Rush University, Stroger Hospital of Cook County, CDC, and Hospital Corporation of America • **Trial Design:** 2-arm cluster randomized trial, ~50 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 product and policy for showering/bathing. • **Arm 2: Decolonization.** Daily shower/bathing with chlorhexidine routine for all patients, mupirocin nasal ointment x 5 days if known to be MRSA+ (carriers). • Primary outcome: Clinical cultures with multi-drug resistant organisms. Secondary outcomes: 1) bloodstream infections: all pathogens, 2) urinary tract infections: all pathogens, 3) infectious readmissions: all pathogens, 4) emergence of resistance among key pathogens. • No questions of protocol design voiced.		
Minimal Risk	• Sheila Fireman from the Harvard IRB reviewed the minimal risk documentation that was provided to the group (appended). They reviewed the proposed use of the products and considered that the probability of harm was low		

	and that there were no known risks of using these products beyond usual care. They felt that this was consistent with quality improvement measures, since they are using FDA approved products in accordance with current product labeling. They concluded that the intervention and the data/evaluation met the criteria for minimal risk. • Special conditions that have been addressed or under review: 1) Children over 12 yrs. old - minimal risk as the products are labeled for use over age 12, 2) Pregnant Women – Under review but believed to be minimal risk, 3) Prisoners – no more than minimal risk. Mupirocin is FDA regulated product, but still minimal risk. • There was consensus that the study met criteria for a "minimal risk" determination.		
Consent (Patient and Physician)	• IRB is requiring subjects be provided with written information about the research in admission materials and on posted flyer in room. Nurses are trained to discuss the intervention within the context of a hospital wide initiative. • Clarified that the plan is to have a waiver of consent in that notices about the project will be posted but there will be no need for an affirmative agreement participate. That is, no verbal individual consent will be obtained. • Written consent it not usually required for hospital bathing or choice of soap/antibacterial. The choice of the product is at the hospital-level for both arms. Patients can ask for a bath at any time and they can refuse a bath as well. Close monitoring routinely in place with hospital	• NIH will follow up with staff at FDA to verify that studies of regulated products that are used in accordance with labeling	NIH discussed with FDA and received confirmation that the use of these products in this study was not subject to FDA jurisdiction. The IRB waived informed consent. Consistent with the evaluation of a quality improvement strategy, no notices about the study are being posted. Nurses and nursing assistants are trained to discuss the intervention

	infection control staff to monitor changes in outbreaks or hospital-associated infections. • Posting of the flyers will occur in both Arms of the project. • The group considered whether the study was exempt from FDA/IND regulations, as such regulations may impact on the informed consent process. As published FDA guidances relate that studies of regulated products that use products in accordance with product labeling are exempt from IND regulations, the consensus was that FDA would therefore not have jurisdiction for this trial. As there have been similar discussions about other projects within the Collaboratory, NIH staff indicated that further discussion with FDA staff about this issue would be worthwhile.		(use of antiseptic soap for bathing and nasal ointment for clearing MRSA) when bathing is offered in the course of usual care. As with all medical care, patients have the right to refuse.
HIPAA	• The consensus of the group was that the criteria for U.S. Health and Human Services Regulation 45 CFR 164.512 were satisfied and waiver of HIPAA was acceptable and no concerns mentioned. • Patient identifiers will remain at the individual hospitals and not disclosed externally. Coded data will be shared for research and the code key will be accessible only to Infection Control and Prevention staff at HCA.		No changes, but providing clarification of the original minutes that identified data are accessible to individual hospitals and corporate HCA (as is the case routinely), but not to external investigators.
Monitoring and oversight	• The study will require a Data and Safety Monitoring Plan, which will be approved by NIAID, the primary NIH IC, prior to study initiation. • Currently there is no plan to formally appoint an external DSMB for study oversight. NIAID has reviewed the project and in accordance with		Plan approved. Study-related event forms distributed to all participating sites.

	their policies, does not require that a DSMB be constituted for this project.		Consistent with quality improvement strategies, patients' physicians address any product-related events. Regular reminders provided to unit directors to report events and their resolution retrospectively to study team.
Issues beyond the ABATE Trial	• None voiced.		
Conclusion of meeting	• Follow-up needed as noted in action items.	• Case study will be written up to provide guidance for others planning similar trials to facilitate navigation of the ethics and regulatory issues.	
Additional regulatory or ethics issue(s) that arose after the meeting			
Additional follow-up information			