

UH3

Data Sets and Data Sharing



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

Data Access

- Investigators have established an Memorandum of Understanding and Data Use Agreements with Hospital Corporation of America to allow protected access to data of the following types behind their corporation firewall. The HCA IT department does the data extraction for specified variables for dates of service and places it on a secured server.
 - 1) Administrative (census) data
 - 2) Microbiology data
 - 3) Supply chain
 - 4) Limited pharmacy data
 - 4) Sharing of statistical programs and software

Data Retention

- Investigators never take possession of the data (all analyzed behind HCA's firewall on their servers).
- Thus, we have no line item data retained at any time.
- Only summary-level models and descriptive characteristics across the arms of the trials are received.
- Data are considered proprietary to HCA.

Data Sharing

- We have no line item data that can be shared since we do not take possession of it at any time.
- Shared resources thus consist of the following important contributions, which fall under the ABATE resource sharing plan:
 - Educational materials and toolkits
 - Instructional video
 - Roadmap for implementation
 - Statistical/randomization software
 - Presentation and publication

Resource / Software Product Overview

Resource/Software Products	Description	UH3			
		Y1	Y2	Y3	Y4
Resources					
1. Decolonization Toolkit	Trial related materials to implement decolonization in hospitals			X	
2. Computer Training Modules	Computer-based training module for decolonization	X			
3. Product Compatibility Charts	Chlorhexidine compatibility charts for skin care products	X			
4. Podcasts and Webinar Content	Podcasts and PowerPoint presentations for decolonization	X			
5. Publications	Publication of all trial, resistance, and cost outcomes		X	X	X
Programs and Software					
1. Stratification Assessment Software	SAS/R software for stratified cluster randomization	X			
2. Power Assessment Software	SAS/R software for stratified cluster randomization		X		
3. Analytic Programs	SAS programs for analysis of cluster randomized trials				X

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Resource and Software Sharing Plan



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

Overview

- An extensive resource sharing plan has been developed as part of the ABATE Infection Study, related to:
 - 1) Trial design and execution concepts,
 - 2) Dissemination of trial results,
 - 3) Sharing of trial materials and tools, and
 - 4) Sharing of statistical programs and software

Trial Design and Execution Concepts

Trial Design and Execution Concepts

- Roadmaps and lessons-learned from our large scale cluster randomized trials in community hospitals, including:
 - Health system partnership
 - Guidance on rapid recruitment
 - Efficient IRB clearance and ceding
 - Methods for optimizing randomization
 - Guidance documents for trial conduct
- Implementation document highlights processes and procedures essential to the ABATE Infection Trial that will not have sufficient attention in a scientific publication

Dissemination of Trial Results

Dissemination of Trial Results

- Presentations at national meetings, and publication in peer-reviewed journals and press releases
- Participation on national advisory committees and professional societies
- Grand rounds presentations
- Contacts through state departments of public health, state hospital associations

Sharing of Trial Materials and Tools

Sharing of Trial Materials and Tools

- Utilize the Collaboratory's dissemination mechanism to make publicly available:
 - Decolonization toolkit
 - Computer based training modules
 - Patient flyers and handouts
 - Product compatibility
 - Bathing instruction materials
 - Audio podcasts & special coaching calls

Sharing of Statistical Programs and Software

Statistical Programs and Software

- ABATE will produce statistical programs/software applications
- Programs will be shared openly and made freely available to biomedical researchers, health care delivery systems, research institutions and government health care systems and researchers.

Statistical Programs and Software

- We will provide the following statistical resources to improve analysis and balance in cluster randomized trials
 1. Published roadmaps
 2. SAS stratification assessment software
 3. SAS bootstrap power assessment software
 4. R (open source) stratification assessment software
 5. R (open source) power assessment software

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