ABATE Infection Project
Active Bathing to Eliminate Infection

Trial Design
- 2-arm cluster randomized trial
- 53 HCA hospitals and their adult non critical care units
- Includes: adult medical, surgical, step down, oncology
- Excludes: rehab, psych, peri-partum, BMT

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 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)
**ABATE Current Status**

**Study Start:**
June 2014

**Study End:**
November 2015

**Progress**

- Will have full baseline data to confirm outcome rates
- Allows us to confirm study end in November or determine if one more quarter is needed

**May 2015:**
Revaluation of Power
Lessons Learned
Progress, Barriers and Successes
Centralized IRB

- IRB process streamlined
- Minimal adverse events reported
- Process for reporting
  - 2x/month reminders on coaching calls to report
  - Ease of reporting to IRB for reported cases

<table>
<thead>
<tr>
<th>Patient Bathing Days</th>
<th>Total Reports Received</th>
<th>Definitely Related</th>
<th>Possibly Related</th>
<th>Unlikely Related</th>
<th>Study Drug Discontinued</th>
</tr>
</thead>
<tbody>
<tr>
<td>612,000</td>
<td>24</td>
<td>9/24</td>
<td>9/24</td>
<td>6/24</td>
<td>13/24</td>
</tr>
</tbody>
</table>

- Anticipate under-reporting due to comfort with process
IRB- Adverse Event Form
Communication

Standing weekly investigative meetings

- Steering Committee
- Project Coordination (2)
- IT Data Requests
- Data Cleaning/Analytics

Standing coaching calls with participants

- Track attendance
- Follow up with polling questions
- Engage control arm
Compatibility

- Systematic process for assessing CHG compatibility
- Substantially aided by HCA’s standardization of products
- Highly coordinated system - HCA corporate supply chain
- Constant monitoring of new products
Competing Interventions

- Constant communication with participating hospitals to capture potential conflicting strategies or interventions
- Successful prevention of competing interventions
- Majority of reported interventions deemed not in conflict

<table>
<thead>
<tr>
<th>Total Reported</th>
<th>Allowed</th>
<th>Not Allowed</th>
</tr>
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<tbody>
<tr>
<td>156</td>
<td>107</td>
<td>49</td>
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</table>
Decolonization Compliance

- Units large and diverse
- Patients alert
- Bathing time not uniform
- Higher training and re-training investment
- Patient to staff ratios high
- Staff turnover, float pool
- Short stay patients
- Issues with under and overuse
- Lower CHG bathing adherence in non-ICUs than ICUs*

*Rupp et al. ICHE 2012; 33(11): 1094-1110
Compliance and Usage of CHG

ARM 2: Average Chlorhexidine Usage and Compliance
Compliance and Usage of Mupirocin

ARM 2: Average Mupirocin Usage and Compliance

Data Counts

- Mupirocin Compliance
- Mupirocin Usage
Control Arm: Compliance & Non-Usage of CHG

ARM 1: Average Chlorhexidine Compliance and Usage

- **CHG Compliance**
- **No CHG Usage**

Data points for May-14 to Mar-15.
Control Arm: Compliance & Non-Usage of Mupirocin

ARM 1: Average Mupirocin Compliance and Usage

- Mupirocin Compliance
- No Mupirocin Usage
Laboratory Isolate Collection

- Select bacteria sent to central lab
  - Bacteria collected >48 hours from hospital admit
  - Patient in an ABATE unit prior to collection
- Labor intensive → built automated query
- Run daily, identifies isolates for shipping
- Keep up with mnemonic changes by lab
Data Pulls and Cleaning

- Large number of facilities
- Scheduled time to pull data and assess QC
- Changes in unit ward names/locations
- Often multiple data streams to obtain complete data
- Process checking groups of variables
## Barriers Scorecard

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Level of Difficulty</th>
</tr>
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<tbody>
<tr>
<td>Enrollment and engagement of patients/subjects</td>
<td></td>
</tr>
<tr>
<td>Engagement of clinicians and Health Systems</td>
<td></td>
</tr>
<tr>
<td>Data collection and merging datasets</td>
<td></td>
</tr>
<tr>
<td>Regulatory issues (IRBs and consent)</td>
<td></td>
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<tr>
<td>Stability of control intervention</td>
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</tbody>
</table>

1 = little difficulty  
5 = extreme difficulty