Active Bathing to Eliminate Infection Project

NIH Collaboratory Meeting
UH3 Update
April 21, 2015
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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

Outcomes obtained from the HCA data warehouse

Primary Outcome

- Clinical cultures with MRSA and VRE

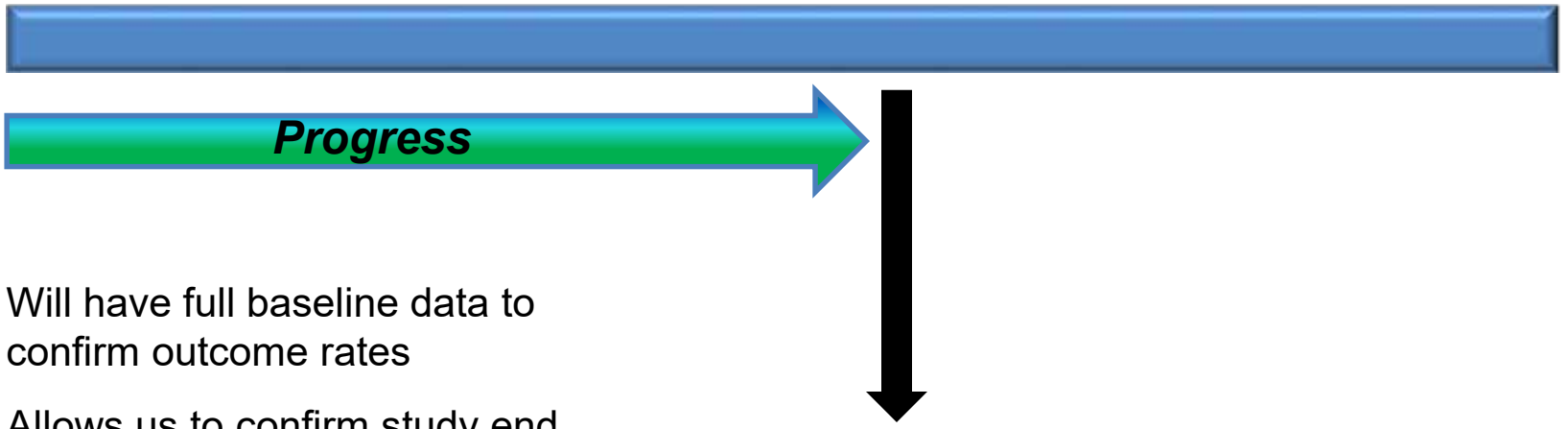
Secondary Outcomes

- 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



- 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

Patient Bathing Days	Total Reports Received	Definitely Related	Possibly Related	Unlikely Related	Study Drug Discontinued
612,000	24	9/24	9/24	6/24	13/24

- Anticipate under-reporting due to comfort with process

IRB- Adverse Event Form

STUDY-RELATED EVENT SUBMISSION FORM

Please use this form to report all study-related events.
For clinical decisions related to possible study-related events, please contact the treating physician.

Unit Director to fax completed study-related event forms to ABATE study staff on the 15th and 30th of each month.
Please complete all fields before faxing

****DO NOT INCLUDE ANY PATIENT IDENTIFIERS ON THIS FORM****
Fax completed form(s) to (617) 509-4280, ATTN: Rebecca Kaganov
Please DO NOT email this form – FAX ONLY
For questions, please contact ABATE Infection Study staff at (617) 509-4141

Facility name: _____ Facility COID: _____

Unit Name: _____

Please provide contact information below:

E-mail address of individual completing report: _____ Unit Phone: (___) ___-____

Unit Director Phone: (___) _____-_____

Section I: General Information

Date of First Symptom Onset: ___/___/_____ Date Symptom Resolved: ___/___/_____

Please fill out one form per study-related event.

Patient Gender: M F

Please choose the option that best describes the event:

☐ Skin/mucosa related, *continue to Section II: Skin Related Events*

☐ Non-skin related, *please provide a brief description of the event. You may be contacted for more information.*

_____

_____

Section II: Skin Related Events

Please indicate the study agent that you feel is related to the event:
☐ Chlorhexidine (CHG) ☐ Mupirocin

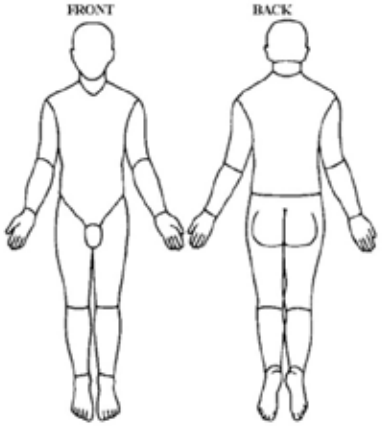
If you checked Chlorhexidine, please indicate the CHG product that was used:
☐ Liquid CHG ☒ CHG 2% Cloths

If you checked CHG 2% Cloths, please indicate whether the patient has a known aloe sensitivity or allergy:
☒ Yes, the patient has a known aloe sensitivity or allergy
☐ No, the patient does not have a known aloe sensitivity or allergy
☐ Unknown

Corrective Action Taken (Check all that apply):
☐ Study Drug Discontinued ☐ Topical cream/lotion applied ☐ Other *(please specify below)*
☐ Oral/IV Benadryl given ☐ Oral/IV steroids given ☐ Non

STUDY-RELATED EVENT SUBMISSION FORM

Please shade the parts of the body, to scale.
ONLY INDICATE RASHES BELIEVED TO BE RELATED TO A STUDY DRUG EFFECT:



Erythema (Redness)
☐ None
☐ Mild (spotty or diffuse)
☐ Moderate, uniform redness
☐ Intense redness

Scaling
☐ None
☐ Mild, "dry skin" scale
☐ Moderate scaling
☐ Desquamation/sloughing

Blistering
☐ None
☐ Papules only
☐ Localized blisters
☐ Extensive blisters or bullae

Is the face involved? ☐ Yes ☐ No

In your opinion, how certain are you that this event is related to the trial agent (study drug) above?
☐ Definitely related
☐ Possibly related
☐ Unlikely to be related

Is it possible that another medication/product could have produced this reaction?
☐ Yes ☐ No

Have any other drug(s) been discontinued?
☐ Yes ☐ No
If yes, please specify: _____

Please fax completed form to ABATE Study Staff at (617) 509-4260, ATTN: Rebecca Kaganov
Remember: DO NOT include any patient identifiers on this 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

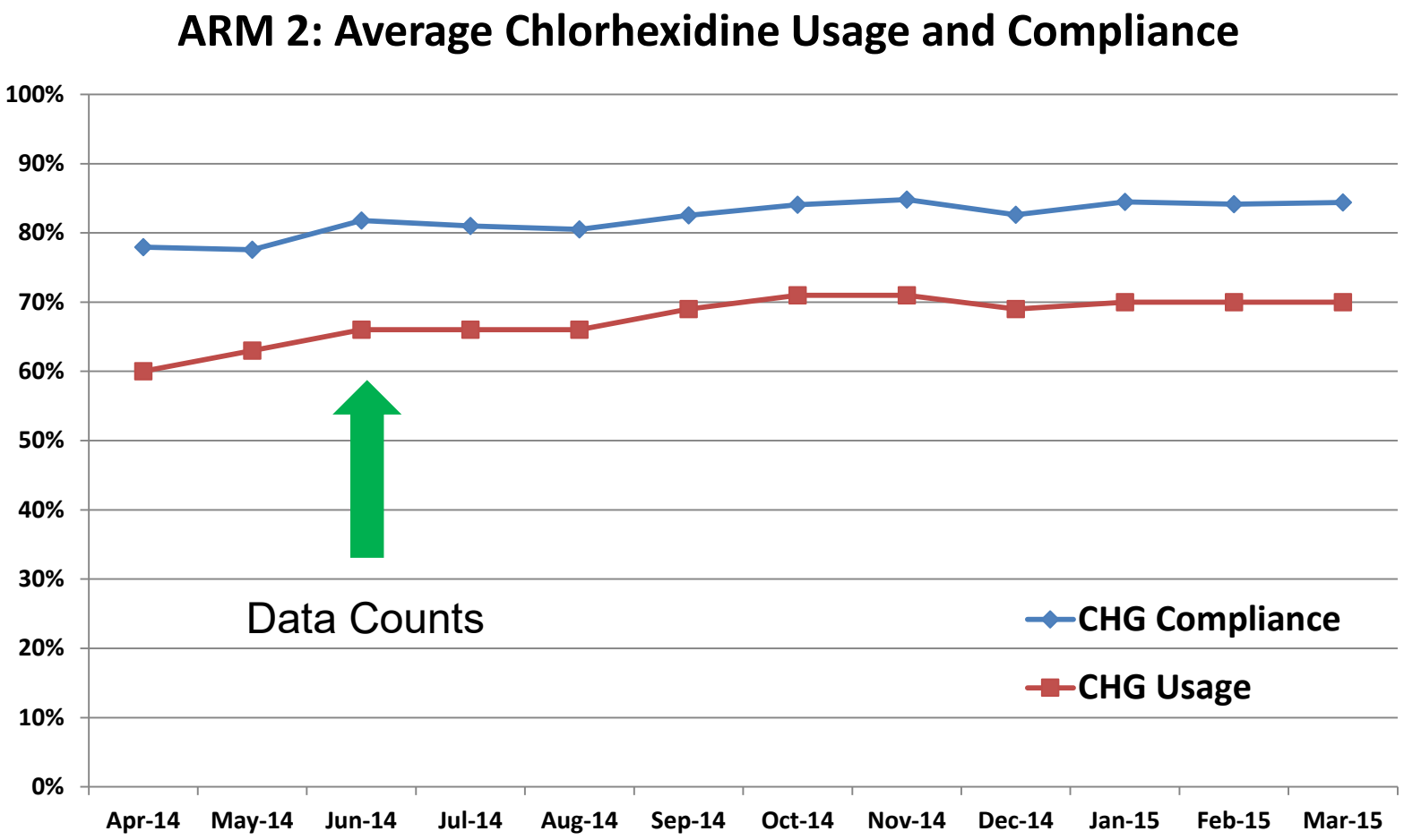
Total Reported	Allowed	Not Allowed
156	107	49

Decolonization Compliance

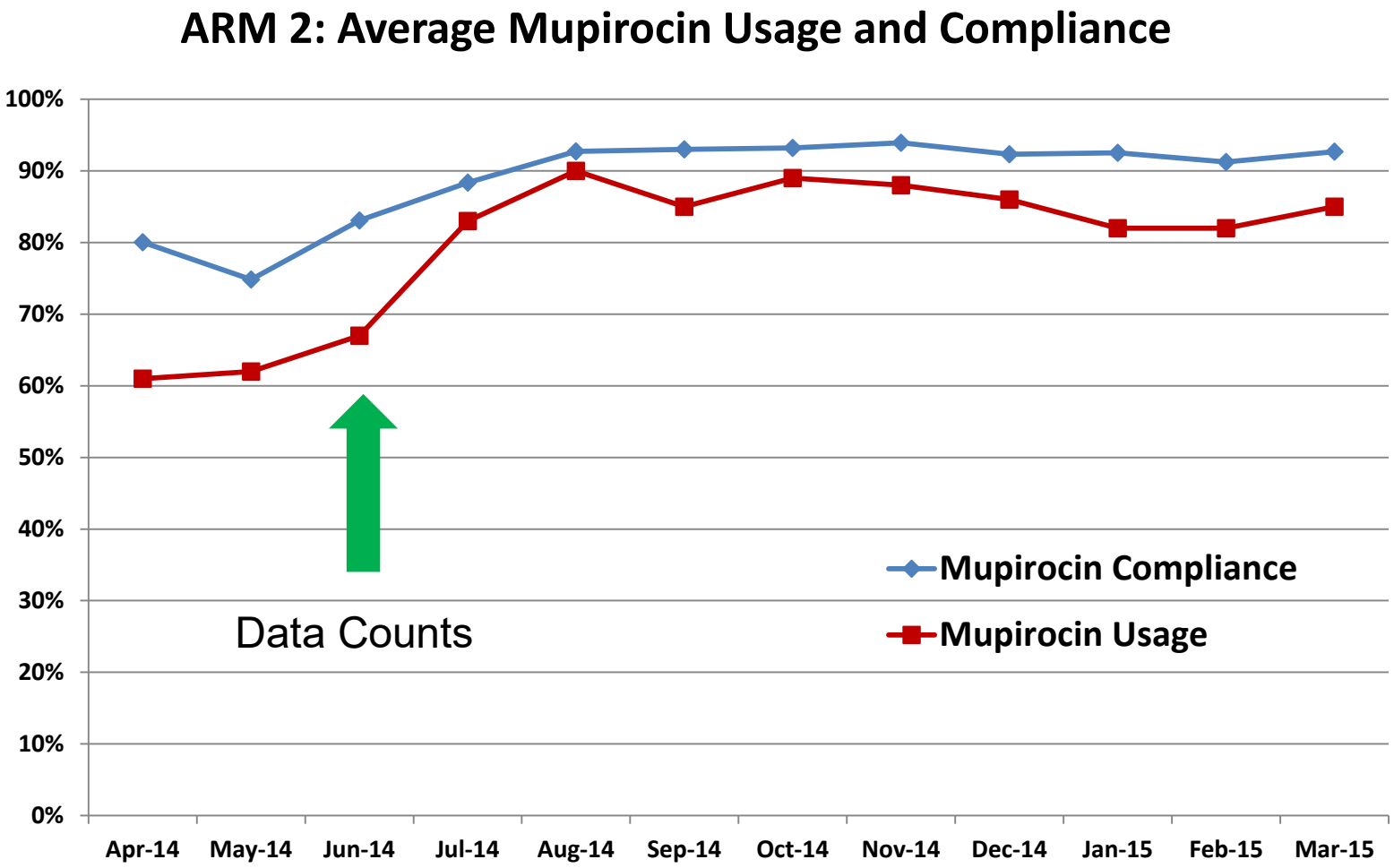
- Units large and diverse
- Patients alert
- Bathing time not uniform
- Higher training and re-training investment
- Patient to staff ratios high
- Staff turnover, float pool
- Short stay patients
- Issues with under and overuse
- Lower CHG bathing adherence in non-ICUs than ICUs*

*Rupp et al. ICHE 2012; 33(11): 1094-1110

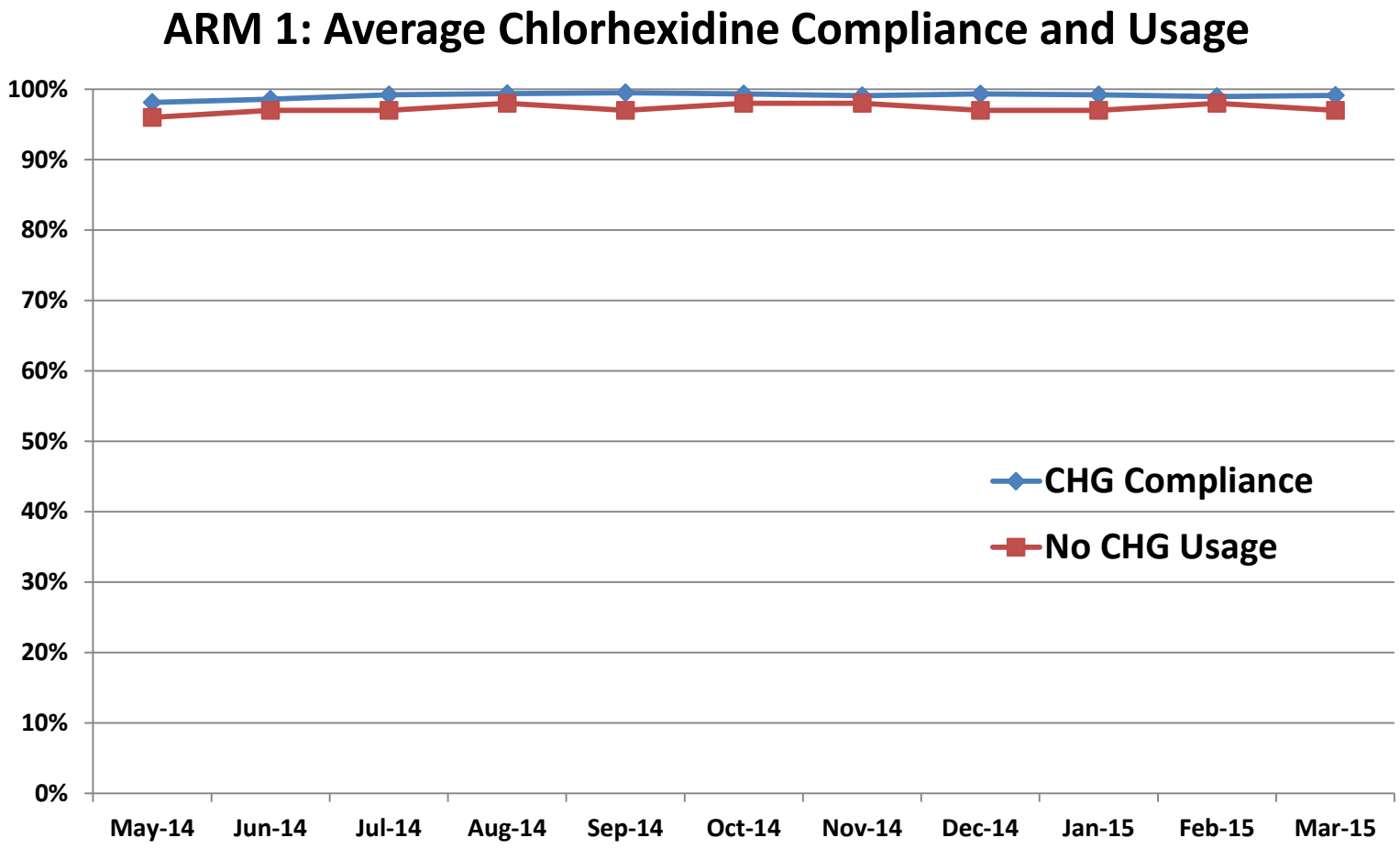
Compliance and Usage of CHG



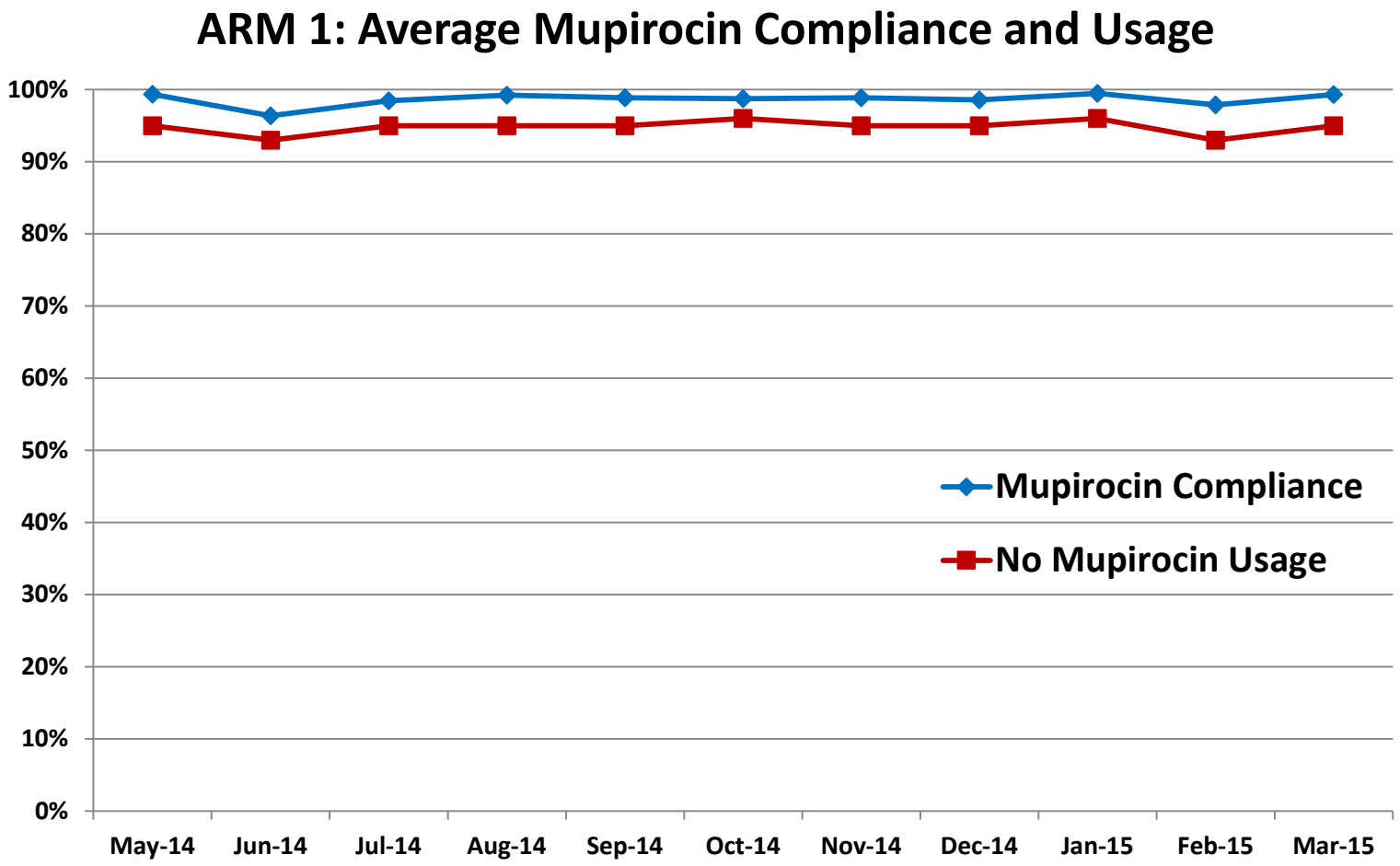
Compliance and Usage of Mupirocin



Control Arm: Compliance & Non-Usage of CHG



Control Arm:
Compliance & Non-Usage of Mupirocin



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

Barrier	Level of Difficulty				
	1	2	3	4	5
Enrollment and engagement of patients/subjects					
Engagement of clinicians and Health Systems					
Data collection and merging datasets					
Regulatory issues (IRBs and consent)					
Stability of control intervention					

1 = little difficulty
5 = extreme difficulty

NIH Collaboratory Rethinking Clinical Trials®
Health Care Systems Research Collaboratory