ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Now Available: Final Rule for FDAAA 801 and NIH Policy on Clinical Trial Reporting

Trial record **1 of 31** for: REDUCE MRSA

Previous Study | Return to List | Next Study

Cluster Randomized Trial of Hospitals to Assess Impact of Targeted Versus Universal Strategies to Reduce Methicillin-resistant Staphylococcus Aureus (MRSA) in Intensive Care Units (ICUs) (REDUCE-MRSA)

This study has been completed.

Sponsor:
Harvard Pilgrim Health Care

Collaborators:
Agency for Healthcare Research and Quality (AHRQ)
Centers for Disease Control and Prevention
Hospital Corporation of America
University of California, Irvine
Department of Population Medicine, Harvard Medical School / Harvard Pilgrim Healthcare Institute

Information provided by (Responsible Party):
Richard Platt, Harvard Pilgrim Health Care

ClinicalTrials.gov Identifier:
NCT00980980

First received: September 19, 2009
Last updated: August 22, 2016
Last verified: August 2016
History of Changes

Full Text View | Tabular View | **Study Results** | Disclaimer | How to Read a Study Record

Results First Received: May 14, 2014

Study Type:	Interventional

Study Design:	Allocation: Randomized; Primary Purpose: Prevention
Condition:	**Methicillin-resistant Staphylococcus Aureus**
Intervention:	Drug: Chlorhexidine bath and nasal mupirocin

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
45 out of 165 Hospital Corporation of America (HCA) hospitals were recruited for this trial of adult ICUs. There was a 12-month baseline period from January 1 through December 31, 2009; a phase-in period from January 1 through April 7, 2010; and an 18-month intervention period from April 8, 2010 through September 30, 2011.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
74,256 patients were involved in the intervention period among adult ICUs from the 43 participating hospitals. Routinely collected information for about 48,390 individuals cared for during the baseline period was used for comparison to the experience of the patients in all three arms of the Intervention period.

Reporting Groups

	Description
Arm 1: Usual Care-Active Surveillance	Active Surveillance in All Adult ICUs, Contact Precautions for MRSA+
Arm 2: Targeted Decolonization	Continue Active Surveillance (AS), MRSA decolonization based on AS, Continue Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US – a combination of baths with 2% chlorhexidine cloths plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)

Arm 3: Universal Decolonization	Chlorhexidine bath and nasal mupirocin for all, Discontinuation of Active Surveillance , Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US – a combination of daily baths with 2% chlorhexidine cloths plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)

Participant Flow: Overall Study

	Arm 1: Usual Care-Active Surveillance	Arm 2: Targeted Decolonization	Arm 3: Universal Decolonization
STARTED	**16**	**14**	**13**
COMPLETED	**16**	**13**	**13**
NOT COMPLETED	**0**	**1**	**0**
Withdrawal by Hospital	**0**	**1**	**0**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
'Number of Participant' totals reflect total Baseline and Intervention participants combined. 45 hospitals were randomized to a study group, 2 dropped due to exclusion criteria, 43 began the assigned intervention. 1 hospital withdrew during the intervention and was included in as-assigned analyses.

Reporting Groups

	Description
Arm 1: Usual Care-Active Surveillance	Active Surveillance in All Adult ICUs, Contact Precautions for MRSA+

Arm 2: Targeted Decolonization	Continue Active Surveillance (AS), MRSA decolonization based on AS, Continue Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US – a combination of daily baths with 2% chlorhexidine cloths plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)
Arm 3: Universal Decolonization	Chlorhexidine bath and nasal mupirocin for all, Discontinuation of Active Surveillance, Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US – a combination of daily baths with 2% chlorhexidine cloths plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)
Total	Total of all reporting groups

Baseline Measures

	Arm 1: Usual Care-Active Surveillance	Arm 2: Targeted Decolonization	Arm 3: Universal Decolonization	Total
Overall Participants [units: participants]	**39296**	**39970**	**43380**	**122646**
Age [units: Years] Median (Inter-Quartile Range)				
Baseline Age	**65** **(52 to 77)**	**66** **(53 to 77)**	**65** **(51 to 77)**	**65** **(52 to 77)**
Intervention Age	**65** **(52 to 77)**	**66** **(53 to 77)**	**65** **(52 to 77)**	**65** **(52 to 77)**
Gender, Customized [1] [units: participants]				
Females - Baseline	**7465**	**7183**	**8314**	**22962**
Males - Baseline	**8351**	**8035**	**9042**	**25428**

Females - Intervention	**11176**	**11683**	**12361**	**35220**
Males - Intervention	**12304**	**13069**	**13663**	**39036**
[1] Proportion of female study participants, during baseline and intervention study phases.				
Overall Number of Participants, by Phase [1] [units: Admissions]				
Baseline Participants	**15816**	**15218**	**17356**	**48390**
Intervention Participants	**23480**	**24752**	**26024**	**74256**
[1] This table reflects number of admissions with an ICU stay during the Baseline and Intervention periods, separately. Please note that the table above, "Overall Number of Baseline Participants" reflects the total number of participants for which baseline characteristics were measured, across Baseline and Intervention phases combined.				

Outcome Measures

Show All Outcome Measures

1. Primary: Main Outcome: Patients With Nosocomial **MRSA** Clinical Cultures [Time Frame: The 30-month time frame represents 12-month baseline and 18-month intervention periods. During these time periods, outcomes are defined as events occurring during attributed ICU time: from day 3 of the ICU stay until 2 days after ICU discharge.]

Show Outcome Measure 1

2. Secondary: **MRSA** Bloodstream Infection [Time Frame: The 30-month time frame represents 12-month baseline and 18-month intervention periods. During these time periods, outcomes are defined as events occurring during attributed ICU time: from day 3 of the ICU stay until 2 days after ICU discharge.]

Show Outcome Measure 2

3. Secondary: ICU-attributable All-pathogen Bloodstream Infection [Time Frame: The 30-month time frame represents 12-month baseline and 18-month intervention periods. During these time periods, outcomes are defined as events occurring during attributed ICU time: from day 3 of the ICU stay until 2 days after ICU discharge.]

Show Outcome Measure 3

4. Secondary: Intervention Impact on Healthcare Costs [Time Frame: 12-month period]

Hide Outcome Measure 4

Measure Type	Secondary
Measure Title	Intervention Impact on Healthcare Costs
Measure Description	Costs (in dollars) per 1000 ICU-admissions associated with 3 ICU strategies to reduce ICU Bloodstream infection (BSI), (Arms 1-3).
Time Frame	12-month period
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Annual adult ICU admissions per hospital, over the course of 1 year.

Reporting Groups

	Description
Arm 1: Usual Care-Active Surveillance	Active Surveillance in All Adult ICUs, Contact Precautions for MRSA+
Arm 2: Targeted Decolonization	Continue Active Surveillance (AS), MRSA decolonization based on AS, Continue Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US - a combination of daily baths with 2% chlorhexidine cloths , plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)
Arm 3: Universal Decolonization	Chlorhexidine bath and nasal mupirocin for all, Discontinuation of Active Surveillance, Continuation of Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the

	most commonly used topical regimen in the US - a combination of daily baths with 2% chlorhexidine cloths , plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)

Measured Values

	Arm 1: Usual Care-Active Surveillance	Arm 2: Targeted Decolonization	Arm 3: Universal Decolonization
Overall Participants [units: participants]	**1000**	**1000**	**1000**
Intervention Impact on Healthcare Costs [units: Dollars per 1000 ICU-admissions]			
Cost of MRSA screening tests	**9,120**	**9,120**	**0**
Cost of contact precautions	**69,010**	**68,830**	**24,890**
Cost of decolonization	**0**	**4,679**	**36,500**
ICU costs (not including intervention costs)	**19,320,000**	**19,250,000**	**19,170,000**

No statistical analysis provided for Intervention Impact on Healthcare Costs

5. Secondary: Blood Culture Contamination Rates [Time Frame: 24-month time frame for this analysis represents a 6-month baseline and 18-month intervention period.]

Show Outcome Measure 5

6. Secondary: Intervention Impact on Bacteriuria and Candiduria [Time Frame: 30-month time frame represents 12-month baseline and 18-month intervention periods.]

Hide Outcome Measure 6

Measure Type	Secondary
Measure Title	Intervention Impact on Bacteriuria and Candiduria

Measure Description	Proportional hazard ratio for as-randomized, unadjusted, ICU-attributable bacteriuria, comparing Baseline to Intervention period across Arms, accounting for clustering by hospital. High-level bacteriuria is defined as ≥50,000 CFU/mL, high-level candiduria is defined as ≥50,000 CFU/mL.
Time Frame	30-month time frame represents 12-month baseline and 18-month intervention periods.
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The number of participants analyzed reflects the combined total of baseline and intervention admissions with an ICU stay, for each arm.

Reporting Groups

	Description
Arm 1: Usual Care-Active Surveillance	Active Surveillance in All Adult ICUs, Contact Precautions for MRSA+
Arm 2: Targeted Decolonization	Continue Active Surveillance (AS), MRSA decolonization based on AS, Continue Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US - a combination of daily baths with 2% chlorhexidine cloths , plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)
Arm 3: Universal Decolonization	Chlorhexidine bath and nasal mupirocin for all, Discontinuation of Active Surveillance, Continuation of Contact Precautions for MRSA+ Chlorhexidine bath and nasal mupirocin: The intervention / decolonization regimen will consist of the most commonly used topical regimen in the US - a combination of daily baths with 2% chlorhexidine cloths , plus 5 days of topical intranasal mupirocin ointment (bilateral nares, twice daily)

Measured Values

	Arm 1: Usual Care-Active	**Arm 2: Targeted**	**Arm 3: Universal**

	Surveillance	Decolonization	Decolonization
Overall Participants [units: participants]	**39296**	**39970**	**43380**
Intervention Impact on Bacteriuria and Candiduria [units: Hazard Ratio] Number (95% Confidence Interval)			
High-level bacteriuria (all patients)	**1.02 (0.88 to 1.18)**	**0.88 (0.76 to 1.02)**	**0.87 (0.77 to 1.00)**
High-level bacteriuria (women)	**0.97 (0.80 to 1.17)**	**0.83 (0.70 to 1.00)**	**0.93 (0.79 to 1.09)**
High-level bacteriuria (men)	**1.09 (0.85 to 1.40)**	**1.01 (0.79 to 1.29)**	**.78 (.63 to .98)**
High-level candiduria (all patients)	**1.14 (.95 to 1.37)**	**.99 (.83 to 1.18)**	**.83 (.70 to .99)**
High-level candiduria (women)	**1.09 (.88 to 1.36)**	**1.00 (.81 to 1.24)**	**.94 (.76 to 1.16)**
High-level candiduria (men)	**1.21 (.88 to 1.68)**	**1.01 (.73 to 1.39)**	**.63 (.45 to .89)**
Any bacteriuria (all patients)	**.95 (.84 to 1.09)**	**.92 (.8 to 1.04)**	**.86 (.77 to .97)**
Any bacteriuria (women)	**.91 (.77 to 1.08)**	**.86 (.73 to 1.01)**	**.95 (.82 to 1.10)**
Any bacteriuria (men)	**1.01 (.81 to 1.25)**	**1.04 (.83 to 1.3)**	**.74 (0.61 to .9)**

No statistical analysis provided for Intervention Impact on Bacteriuria and Candiduria

7. Secondary: Intervention Impact on Chlorhexidine and Mupirocin Susceptibility of **MRSA** Isolates [Time Frame: TBD]

Results not yet reported. Anticipated Reporting Date: 10/2016 **Safety Issue:** No

Serious Adverse Events

Show Serious Adverse Events

Other Adverse Events

Show Other Adverse Events

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.

There is **NOT** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Dr. Susan Huang
Organization: University of California, Irvine
phone: 949-824-5073
e-mail: sshuang@uci.edu

Publications of Results:

Huang SS, Septimus E, Kleinman K, Moody J, Hickok J, Avery TR, Lankiewicz J, Gombosev A, Terpstra L, Hartford F, Hayden MK, Jernigan JA, Weinstein RA, Fraser VJ, Haffenreffer K, Cui E, Kaganov RE, Lolans K, Perlin JB, Platt R; CDC Prevention Epicenters Program.; AHRQ DECIDE Network and Healthcare-Associated Infections Program.. Targeted versus universal decolonization to prevent ICU infection. N Engl J Med. 2013 Jun 13;368(24):2255-65. doi: 10.1056/NEJMoa1207290. Erratum in: N Engl J Med. 2013 Aug 8;369(6):587. N Engl J Med. 2014 Feb 27;370(9):886.

Other Publications:

Platt R, Takvorian SU, Septimus E, Hickok J, Moody J, Perlin J, Jernigan JA, Kleinman K, Huang SS. Cluster randomized trials in comparative effectiveness research: randomizing hospitals to test methods for prevention of healthcare-associated infections. Med Care. 2010 Jun;48(6 Suppl):S52-7. doi: 10.1097/MLR.0b013e3181dbebcf.

Huang SS, Septimus E, Platt R. Targeted decolonization to prevent ICU infections. N Engl J Med. 2013 Oct 10;369(15):1470-1. doi: 10.1056/NEJMc1309704.

Responsible Party:	Richard Platt, Harvard Pilgrim Health Care
ClinicalTrials.gov Identifier:	NCT00980980 History of Changes
Other Study ID Numbers:	PH000223K HHSA2902005003I TO #11
Study First Received:	September 19, 2009
Results First Received:	May 14, 2014
Last Updated:	August 22, 2016
Health Authority:	United States: Institutional Review Board