American Journal of Infection Control 45 (2017) 1074-80

Contents lists available at ScienceDirect

American Journal of Infection Control

journal homepage: www.ajicjournal.org

Major Article

Methodologic considerations of household-level methicillin-resistant *Staphylococcus aureus* decolonization among persons living with HIV

Jason E. Farley PhD, MPH, ANP-BC, FAAN [a,*], Laura E. Starbird MS, RN, APHN-BC [a], Jill Anderson BA [a], Nancy A. Perrin PhD [b], Kelly Lowensen MSN, RN, ACRN [a], Tracy Ross BS, MT(ASCP) [c], Karen C. Carroll MD [c]

[a] *Department of Community and Public Health, Johns Hopkins University School of Nursing, Baltimore, MD*
[b] *Johns Hopkins Center for Global Health, Johns Hopkins University School of Nursing, Baltimore, MD*
[c] *Division of Medical Microbiology, Department of Pathology, Johns Hopkins University School of Medicine, Baltimore, MD*

Key Words:
Social network
Clinical trial
Pilot

Background: People living with HIV (PLWH) have a higher prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization and likelihood of recurrent infection than the general population. Simultaneously treating MRSA-colonized household members may improve success with MRSA decolonization strategies. This article describes a pilot trial testing household-level MRSA decolonization and documents methodologic and pragmatic challenges of this approach.

Methods: We conducted a randomized controlled trial of individual versus individual-plus-household MRSA decolonization to reduce recurrent MRSA. PLWH with a history of MRSA who are patients of an urban HIV clinic received a standard MRSA decolonization regimen. MRSA colonization at 6 months was the primary outcome.

Results: One hundred sixty-six patients were referred for MRSA screening; 77 (46%) enrolled. Of those, 28 (36%) were colonized with MRSA and identified risk factors consistent with the published literature. Eighteen were randomized and 13 households completed the study.

Conclusions: This is the first study to report on a household-level MRSA decolonization among PLWH. Challenges included provider referral, HIV stigma, confidentiality concerns over enrolling households, and dynamic living situations. Although simultaneous household MRSA decolonization may reduce recolonization, recruitment and retention challenges specific to PLWH limit the ability to conduct household-level research. Efforts to minimize these barriers are needed to inform evidence-based practice.

Methicillin resistant *Staphylococcus aureus* (MRSA) has emerged as a significant public health concern in community settings. MRSA can cause abscesses, boils, and systemic infections in persons colonized with the bacteria.[1] Community-associated MRSA disproportionately affects persons living with HIV (PLWH).[2] PLWH have a higher prevalence of MRSA colonization (8%-20% compared with 1.5%),[2-5] higher rates of MRSA-associated skin and soft tissue infections (SSTIs),[6-8] and an increased likelihood of recurrent infection than the general population.[9,10] Colonization with MRSA is associated with an increased risk of subsequent MRSA infection.[11,12] Decolonization with a standard regimen is effective at preventing further infection in approximately 65% of patients[13-15]; however, the lasting effects of MRSA decolonization in the general population are minimal, with as many as 75% of patients treated showing evidence of recurrent MRSA colonization in long-term follow-up.[13]

Recurrence of MRSA colonization among individuals is associated with colonization of household members.[16] A whole-genome sequence comparison of 146 MRSA isolates in Chicago and Los Angeles found that households present an ongoing opportunity for transmission among people with SSTIs and family members may serve as a lasting reservoir of specific MRSA strains.[17] In the setting of HIV, preliminary studies found a shared MRSA strain type within 11.8% of couples served by an academic medical center HIV service.[18] Not only is concurrent colonization of household members associated with higher treatment failure rates,[19] but sexual partners may also play a role in transmission.[20,21] Skin-to-skin contact is a major source

* Address correspondence to Jason E. Farley, PhD, MPH, ANP-BC, FAAN, 1909 McElderry St, SON House #204, Baltimore, MD 21205.
E-mail address: jfarley1@jhu.edu (J.E. Farley).
Conflicts of interest: None to report.

0196-6553/
http://dx.doi.org/10.1016/j.ajic.2017.05.010

of transmission of community-associated MRSA.[22] A randomized trial evaluating MRSA decolonization in individuals found that a 1-week decolonization protocol had no effect on MRSA colonization after 6 months compared with a placebo.[15] Therefore, simultaneous treatment of MRSA-colonized household members and sexual partners may reduce long-term treatment failure.[17,20,23] Studies of the microbiome of cohabitating adults have demonstrated a shared microbial ecology.[24] As both a colonizing organism and one that survives for long periods of time on environmental surfaces, the household microbiome may clearly play a role in repeated colonization and/or infection with MRSA.

Multiple studies in the past decade call for a household-level MRSA decolonization trial.[14,16,17,22,25-27] With increasing prevalence and burden of MRSA among PLWH, lasting decolonization in this population is all the more pressing.[28] This article describes the first pilot trial addressing the need for household-level MRSA decolonization and documents the methodologic and pragmatic challenges of this approach.

MATERIAL AND METHODS

Study design and sample

The Stop Community MRSA Colonization among Patients (SUSTAIN) study (ClinicalTrials.gov identifier: NCT02029872) was a prospective randomized controlled trial to test whether a MRSA decolonization intervention has greater influence if applied to all members of a patient's household and/or sexual partner network compared with the individual patient alone. This study was conducted within The Johns Hopkins University AIDS Service (JHUAS) Moore Clinic, a hospital-based outpatient practice that provides specialty care in Baltimore, Maryland. More than 50% of Moore Clinic patients reside in East Baltimore. At the time the study was conducted, the demographic characteristics of the patient population at this clinic paralleled the HIV epidemic in Maryland: 37% women; 81% African American; mean age of 39 years; and composed of the following self-reported HIV exposure categories: 33% heterosexual transmission, 18% men who have sex with men, 38% injection drug user, 4% both men who have sex with men and injection drug user, and 7% other/unknown. A previous study conducted in this setting found a MRSA colonization prevalence of 15.2% among 500 patients.[18]

Participants were recruited January 2014-March 2015, with follow-up visits completed during November 2015 and microbiologic outcomes completed during June 2016. Eligible index subjects were aged at least 21 years, receiving HIV care within the JHUAS Moore Clinic, had a history of MRSA colonization or SSTI, and had at least 1 household member or sexual partner willing to participate. Household members were defined as anyone physically living in the same home regardless of HIV status, age, or relationship. Sexual partner was defined as an individual in a self-defined sexual relationship for at least 6 months. Individuals were excluded if they had an allergy to any component of the decolonization protocol, were pregnant or breastfeeding, or were unable to provide written informed consent. Patients who were homeless or lived in group transitional and rehabilitative housing were also excluded due to inability to define the household members and challenges maintaining confidentiality.

Potential participants were recruited from the following sources: participants in a previous study by the principal investigator evaluating the prevalence of MRSA colonization who agreed to be contacted for future studies, flyers in the HIV outpatient clinic, targeted provider referral, and self-referral by interested patients. Recruitment of the household members and/or primary sexual partner occurred by referral from the enrolled index participant. If interested, household members were given the option to meet with the study team at their home or in the clinic to review the study information and informed consent. Index participants were offered a $25 gift card at the completion of the MRSA decolonization regimen and also at the completion of the 6-month follow-up visit. Each household randomized to the intervention arm was offered a $50 gift card at the completion of the MRSA decolonization regimen and the 6-month follow-up visit. The SUSTAIN study was approved by The Johns Hopkins Medicine Institutional Review Board.

Risk factor evaluation

A baseline 48-item questionnaire that was used by the principal investigator in prior studies to assess a participant's risk for acquisition of MRSA was administered at enrollment.[18,29,30] An abbreviated 39-item version of the questionnaire was completed at 3 months and 6 months after study enrollment. The interviewers were study team members who were trained in administration of the questionnaire and participated in pilot testing the instrument. Interviews were conducted face-to-face in a private setting. The clinic population is routinely screened for substance use, sexual history, and sexually transmitted infections at each clinic visit and study participants were informed about the confidentiality of their responses. The time frame for any sexual activity or drug use was the 12 months before the interview. Medical records were reviewed by the study team for HIV-related lab results, medications, and comorbidities. Information from medical records was used if discrepancies occurred with self-reported information.

Precautions, including a separate consent form and questionnaire for household members, were used to ensure no disclosure of HIV status among household members. Household members could select enrollment through a one-on-one session or as a household group. Once enrolled all questionnaires were completed in a private location of the participant's choosing, either in their home or at the clinic. For children younger than age 13 years, a parent completed the risk factor questionnaire with the child.

Intervention

A total of 4 swabs for men and 5 for women were collected, plus an additional swab for anyone with a wound. Anterior nares, throat, perineum, rectal, and vaginal swabs were obtained using BactiSwab II (Becton, Dickinson and Company, Franklin Lakes, NJ) dual-headed culturettes and evaluated using standard culture methods. For children younger than age 18 years, only the nares, throat, and rectum were screened. All screening of children younger than age 13 years were conducted with a parent present. Household screenings were completed at the home if requested and swabs were collected privately in the bathroom. The intervention did not include environmental testing nor any study-recommended cleaning procedures for the household environment.

Participants who screened positive for MRSA in any site were randomized to either individual or individual-plus-household MRSA decolonization and followed for 6 months to determine whether there was a difference in treatment success between the individual and individual-plus-household arms. According to the Infectious Diseases Society of America clinical practice guideline,[23] the standardized decolonization regimen for the nose and groin included a 7-day course of nasal mupirocin calcium 2% ointment applied inside the nose twice daily, plus a 4% chlorhexidine gluconate soap used in the shower/bath every day for 7 days. For individuals colonized in the throat we added chlorhexidine gluconate oral rinse 0.12% used in a gargle and spit fashion twice daily for 7 days.[19,25] A standardized educational session on use, accompanying the Centers for Disease Control and Prevention frequently asked questions handout, and an instructional medication sheet were also provided. Participants were contacted daily during the treatment period to record data on self-reported treatment adherence and side effects. Upon completion of the decolonization regimen, individuals were