WORK-IN-PROGRESS AND LESSONS LEARNED

Stakeholder Engagement In A Comparative Effectiveness/Implementation Study To Prevent *S. Aureus* Infection Recurrence: Ca-Mrsa Project (Camp2)

Brianna D'Orazio, MPH[1*], Jessica Ramachandran, MD[1,2*] Chamanara Khalida, MD, MPH[1], Johana Gonzalez, MD [1], Rhonda G. Kost, MD[3], Kimberly S. Vasquez, MPH[3], Teresa H. Evering, MD MS[3], Getaw Worku Hassen, MD[2], Regina Hammock, DO[4], Rosalee Nguyen, DO[4], Ronette Davis[4+], Keenan Millan[5+], Claude Parola, MD[6], Barry S. Coller, MD[3], Jonathan N. Tobin, PhD[1,3]

[1]Clinical Directors Network (CDN) (New York, NY)

[2]Metropolitan Hospital/New York City Health + Hospitals (New York, NY)

[3]The Rockefeller University Center for Clinical and Translational Science (New York, NY)

[4]Coney Island Hospital/New York City Health + Hospitals (Brooklyn, NY)

[5]NYU Lutheran Family Health Center and Medical Center (NYU Langone at Brooklyn) (Brooklyn, NY)

[6]Urban Health Plan (Bronx, NY)

+ Patient stakeholders

*These authors contributed equally to this work.

Funding: PCORI #CER-1402-10800

ClinicalTrials.gov Identifier: NCT02566928

CORRESPONDING AUTHOR: Jonathan N. Tobin, Ph.D., Clinical Directors Network (CDN) and The Rockefeller University Center for Clinical and Translational Science. JNTobin@CDNetwork.org

Submitted 5 July 2020, revised 6 July 2021, accepted 29 August 2021

ABSTRACT

Background: Methicillin-Resistant (MRSA) or Methicillin-Sensitive (MSSA) *Staphylococcus aureus* skin and soft tissue infections (SSTIs) pose serious clinical and public health challenges. Few protocols exist for outpatient education, decolonization and decontamination.

Objectives: This trial implemented infection prevention protocols in homes via Community Health Workers/Promotoras.

Methods: We engaged clinicians, patient stakeholders, clinical and laboratory researchers, New-York-based Federally Qualified Health Centers and community hospital Emergency Departments. The Clinician and Patient Stakeholder Advisory Committee (CPSAC) convened in-person and remotely for shared decision-making and trial oversight.

Results: The intervention trial consentedparticipants with SSTIs from MRSA or MSSA, completed home visits, obtained surveillance cultures from index patients and household members and sampled household environmental surfaces at baseline and three months.

Lessons Learned: The retention of the CPSAC during the trial demonstrated high levels of engagement.

Conclusions: CPSAC was highly effective throughout design and execution by troubleshooting recruitment and home visit challenges.

KEYWORDS: Methicillin-Resistant *Staphylococcus aureus* (MRSA); Antibiotic-resistance; Skin and Soft Tissue Infection (SSTI); Colonization; Community Health Workers/Promotoras; Patient Stakeholder Advisory Committee; Community-based Participatory Research (CBPR); Randomized Clinical Trial (RCT)

BACKGROUND

Methicillin-Resistant *Staphylococcus aureus* (MRSA) is a multi-drug resistant infection that poses serious clinical and public health challenges. As one main cause of treatment-resistant skin and soft tissue infections (SSTIs),[1,2] MRSA and Methicillin-Sensitive *Staphylococcus aureus* (MSSA) carry significant morbidity and mortality, and impact patients, families, caregivers, and health-care institutions.[3,4] While effective protocols for hospital-acquired/healthcare-associated MRSA (HA-MRSA) exist[5], few have been adapted for use in community settings for community-associated MRSA (CA-MRSA) and CA-MSSA[6-11] which affect otherwise healthy, younger individuals without exposure to healthcare risk factors or contacts[12]. Little research has examined the feasibility and effectiveness of implementing evidence-based infection prevention interventions in primary care settings[13] and no studies have employed Community Health Workers (CHWs) or "Promotoras" to provide home-based education and training in decolonization and decontamination. The "CA-MRSA Project 2" (CAMP2) was designed to test the effectiveness and implementation of an evidence-based intervention tested and shown to be effective in the hospital intensive care unit (ICU) setting.[5]One of the most notable features of this patient-centered outcomes research study was the reliance on community-based participatory research (CBPR) to ensure the engagement of multiple academic and community-based stakeholders in critical phases of the trial. The stakeholder partnership was built upon a long-term, multi-year, highly-engaged community-academic research and learning collaborative that included practicing clinicians, patients, clinical researchers, laboratory researchers, several New-York-based Federally Qualified Health Centers (FQHCs), and several Community Hospital Emergency Departments (EDs).[14]

The adoption of CBPR in clinical research settings has transformed the landscape of community engagement, by enhancing the capacity to achieve shared research goals through the development of multidisciplinary partnerships and collaborations.[15,16] Grounded in the notion of promoting social change,[17] CBPR has been utilized to implement and evaluate evidence-based interventions that promote disease prevention and management among target populations.[15,16,18,19] Under-resourced communities often benefit from CBPR initiatives as they experience extensive health disparities due to long-standing social determinants of health, including barriers that impede access to care and multiple comorbidy that often result in high disability and mortality rates.[16,19-21] Given these disparities, and in the effort to promote health equity, research personnel are encouraged to exercise active learning around the contextual and cultural factors that characterize the community with whom we have been engaged in collaborative research.[15,16,19,22] This builds a sense of inclusion during projects, which can cultivate effective communication, create shared experience and build trust among project collaborators. As such, engaging a variety of community members as stakeholders and team partners enriches the research development process, as it: 1) strengthens relationships between academic personnel and local community partners; 2) fosters a sense of ownership and agency among local community partners; 3) integrates a variety of skill-based abilities, and 4) provides opportunities for knowledge exchange, which facilitates shared decision-making and enhances the sustainability of the research collaboration.[15,16,20,22,23] While the benefits of this engagement are evident, lack of sufficient trust of the research process among community members often serves as a barrier that research teams strive to overcome.[15,16,22,24]

The integration of community feedback into research protocols by using CBPR is a *pragmatic* strategy. CBPR can thus reinforce and strengthen the operations of Practice-Based

Research Networks (PBRNs) which are enduring structures that uphold the mission of examining clinical effectiveness and implementation of innovations within primary care settings.[25-27] PBRNs likewise serve as a resource by evaluating scalability of CBPR interventions and by facilitating dissemination of relevant information to key audiences. Ultimately, PBRNs are dedicated to enhancing both clinical services and research quality through collaboration among constituents such as community health centers, academic institutions and hospital systems.[27,28]

In this article, we describe some of the logistical and procedural aspects of the community-based participatory research (CBPR) approaches and practice-based research network (PBRN) methodologies that were used in the design and conduct of this trial and further highlight the ways in which stakeholders contributed to the CAMP2 trial.

METHODS

The CAMP2 study was conceptualized by the research team during a prior observational epidemiologic study, the CA-MRSA Project 1 (CAMP1), which examined the correlates, treatments, and outcomes for patients with SSTIs presenting for treatment with microbiologically confirmed *S. aureus* infections, either due to MRSA or MSSA since they are often clinically indistinguishable.

CAMP2 [29] was the next logical step in this CBPR-PBRN community-academic partnership, where we endeavored to intervene upon patient-centered features that we observed in the CAMP1 study.[30,31] The CAMP2 trial tested a community-based intervention to enhance outpatient treatment for CA-MRSA. This comparative effectiveness/patient centered outcomes research trial recruited study participants at three FQHCs and three EDs in New-York City. Eligible study participants were between 7-70 years, fluent in English or Spanish, presented with

the signs and symptoms of an SSTI, had a laboratory-confirmed baseline wound culture positive for MRSA or MSSA, and were willing to participate in two home visits (baseline and three month follow-up).

Recruitment, informed consent, and baseline clinical assessment were conducted by trained CHW/Promotoras, who worked in collaboration with FQHC/ED clinicians and office staff. Research protocols were reviewed and approved by the Institutional Review Boards at both the Clinical Directors Network (CDN) and The Rockefeller University. All study participants received clinician-directed standard-of-care treatment, including incision and drainage (I&D) and/or oral antibiotics. Study participants were assessed at baseline and then randomized to experimental or control condition. Two interventions were compared using a two-arm 1:1 randomized controlled trial: (1) CDC-Guidelines directed care (i.e., incision and drainage (I&D) and antibiogram-selected oral antibiotics[32,33] and an educational pamphlet; (Usual Care) versus (2) CDC Guidelines-directed care combined with universal household decolonization and environmental decontamination interventions based on the REDUCE MRSA Trial,[5,32,33] provided in the home by CHW/Promotoras (Experimental Group).

With the multiplicity of stakeholders' perspectives in mind,[34] and having observed significant levels of infection recurrence and discussed anecdotes of household transmission during CAMP1,[30] we arrived at the shared research priorities of preventing infection recurrence and household transmission. The experimental intervention was designed to enhance study participants' knowledge and encourage self-efficacy, active self-management and preventive health behaviors. [35]). Study participants had baseline home visits following laboratory confirmation of their SSTIs, follow-up home visits at three months and their EHRs were reviewed for SSTI recurrence over six months following the index SSTI treatment.

PBRNs and CBPR Approach

Practice-based Research Networks (PBRNs) are groups of primary care clinicians and practices working together to answer community-based health care questions and to translate research findings into practice (https://pbrn.ahrq.gov). PBRNs develop an infrastructure that endures beyond a single study, and have a commitment to the ongoing education, training and professional development of clinicians and staff who participate in research, and conduct research that matters to clinicians and the patients and communities that they serve. PBRNs engage clinicians in research and quality improvement activities by drawing on the experience and insight of practicing clinicians to identify and frame research questions whose answers can improve primary care practice. PBRNs often create partnerships between practicing clinicians, academic researchers and community stakeholders to generate questions and use rigorous research methods in routine care settings. PBRNs can be top-down (researcher-focused, funder-focused) or bottom-up (clinician-focused and/or patient-centered) drawing upon CBPR methods, or a mixture of both models. A key strength of PBRNs is that they can serve both as the laboratory to produce new research findings as well as the channel to disseminate research results that are immediately relevant to the clinician and, in theory, more easily implemented into everyday clinical practice. An important advantage of research conducted by PBRNs is that these studies are more generalizable to broader populations of practices, clinicians and patients than research conducted only in academic settings. In this way, PBRN studies are more often related to questions of effectiveness (rather than efficacy) and implementation, and studies are more often pragmatic in their design.

Clinician and Patient Stakeholder Advisory Committee (CPSAC) Composition and Procedures

The Clinician and Patient Stakeholder Advisory Committee (CPSAC) brought together patient stakeholders (i.e., members of the community who were not enrolled in this trial), clinical staff (physicians, nurses, nurse practitioners, physician assistants) from six New York City area FQHCs and EDs, professional research staff from Clinical Directors Network (CDN, www.CDNetwork.org), a primary care practice-based research network (PBRN) and AHRQ-designated Center of Excellence for Practice-based Research and Learning (#1 P30-HS-021667), as well as academic investigators and physician-scientists from the NIH/NCATS-funded Clinical and Translational Science Award (CTSA) (#8 UL-1 TR-000043) at the Center for Clinical and Translational Science at The Rockefeller University, and scientists from the Laboratory of Microbiology and Infectious Diseases at The Rockefeller University (see Table 2). Patient stakeholders were recruited from among CAMP1 participants, which included participants in the observational study, focus groups and Research Town Hall meetings. Patient stakeholders were not study participants in the current trial. In addition, the CPSAC included a designated patient stakeholder representative from an FQHC, and one patient stakeholder representative from each ED (n=3). CDN recruited one additional community representative to serve on the CPSAC, a local businessman and barbershop owner from previously conducted CTSA-funded pilot study on MRSA and Hepatitis C[36]. All prospective CPSAC members were nominated by their respective organizations, and invited to join the committee and attend regular meetings.

The CPSAC met in person or via web/teleconference, as determined by the members, with logistical and financial support provided by CDN. Meetings were held every 1-2 months, either in-person at The Rockefeller University (2-3 hours) or by web/teleconference (1-1.5 hours). A total of 25 CPSAC meetings were held throughout the course of the project. CPSAC members' study roles and contributions to the project are summarized in Table 3. During the

CPSAC meetings, the team discussed study conduct and progress, identified barriers and opportunities, recommended strategies to increase recruitment, engagement, and retention of study participants, identified audiences and opportunities for dissemination, and reviewed and edited presentation content.

To engage stakeholders outside CPSAC meetings, we also initiated regular communiques and encouraged stakeholders to provide ongoing input through emails and phone calls.. This active engagement of stakeholders fostered equitable collaboration by focusing on ongoing and multi-level communications and ensured transparency shared decision-making at each step. Through all stages of the project, our stakeholders shared their perspectives, preferences, and priorities.

CPSAC members participated in robust discussions as to whether to conduct routine *S. aureus* surveillance on the study team's CHWs, since they were conducting home visits with study participants who were actively undergoing treatment for *S. aureus* SSTIs. In settings with higher rates of MRSA/MSSA exposure such as the hospital ICU, colonization in health care workers is low,[37-39] persistent carriage is rare[40,41] and screening of healthcare workers is not routine. After extensive discussions with infectious disease and infection control experts and a review of the occupational safety literature, the decision was made not to conduct routine surveillance on the CHW/Promotoras. CHW training included guidelines for enhancing occupational safety and infection prevention, similar to precautions taken by healthcare workers in settings with higher infection exposure and transmission risk.As seen in Table 1, the team incorporated feedback into the study design at the outset and continuously throughout the project.**LESSONS LEARNED**

Value Added by Patient Stakeholders and Community Partners

The CPSAC, including CHWs/promotoras, routinely met to provide input and guidance on all aspects of the project. Working together, academic, clinician, CHW, and patient stakeholder members made recommendations for various aspects of the trial, including but not limited to: (a) designing the home intervention, (b) selecting the primary outcomes and their measurement, (c) ensuring that patient-centered outcomes were meaningful, without being burdensome to study participants, (d) improving patient identification/recruitment, (e) obtaining informed consent, (f) intervention delivery (g) methods to improve the scheduling and completion of home visits, (h) retention goals, (i) planning dissemination activities, (j) the protocol's burden on study participants, and (k) feedback on protocol changes.

In the predecessor CAMP1 observational cohort study, study participants, the research team, and clinicians identified important topics that we chose to further explore in the CAMP2[14] intervention study. For example, stakeholders stressed the importance of patient education and support designed to inform study participants of how the index patient and their household members could work together to implement low-cost behavioral, hygienic and environmental steps to reduce the index patient's risk of recurrent infections and prevent transmission to household members.

During the design phase of CAMP2, the research team voiced strong concerns that while patients with MRSA received excellent decolonization and decontamination practices in-hospital, their needs were largely unaddressed once they left the hospital setting. At a series of community engagement meetings held at participating FQHCs, attendees articulated their perspectives on developing a project to address CA-MRSA in the household environment, in response to a clinical case presentation by an FQHC clinician of a CAMP1 participant with multiple SSTI recurrence.[30]

CPSAC members also discussed issues related to the conduct of home visits during early CAMP2 meetings. Meeting attendees voiced concerns that study participants might hesitate to invite strangers into their homes, or might cite "lack of trust" as a reason for failing to enroll or withdrawing from the trial. Another issue included study participants' fears of potential shaming and stigmatization about their home being "dirty" or "contaminated". These concerns were addressed through the utilization of CHWs/Promotoras who underwent careful training to implement the home visits, and we also engaged the Community Health Worker Network of New York City to help train study CHWs (See Supplemental Table 1 – CHW/Promotora Training Agenda).

CPSAC members also defined the optimal process by which the project team could reach community audiences, providing input on discussions of cultural sensitivity, patient autonomy, shaming and stigmatization related to potential home contamination, and community health priorities. To address these concerns, attendees suggested having two CHWs/promotoras attend each home visit, instituting a warm hand off between clinicians and study staff, employing CHWs/promotoras who were trusted members of the community, and by explicitly addressing prevention of shaming and stigmatization in CHW/Promotora training sessions. The CPSAC also suggested additional content for training CHWs/promotoras, outlining the manner by which CHWs/promotoras should rehearse and demonstrate their competence. CPSAC members participated in discussions about improving patient identification and consent, methods to improve the scheduling and completion of home visits, and ways to improve the consent rate of household members.

Where approporiate, CPSAC workgroups were asked to provide input on issues germane to their expertise. CHWs tested the data collection web-based application and refined informed

consent language and assessment procedures to address language, literacy and cultural sensitivity. Community clinician members participated in refining and finalizing the study protocol, adapting and expanding the clinical workflow, and identifying patient and clinician engagement strategies. Academic members shaped discussions about participant consent and human subjects protection, the quality and acceptability of educational materials, the laboratory measures, and the patient-centered and self-reported outcomes assessment battery. They also provided input based on recently published literature on CA-MRSA and the home environment/microbiome, and guided the discussion of methods to measure intervention fidelity. Academic investigators also conducted ongoing discussions on building capacity for patient stakeholders to have an influence on the health of their communities. Both clinician and academic members were engaged in the development of the study-specific CHW training protocol (see See Supplemental Table 1 – CHW/Promotora Training Agenda), which was implemented by an established, well-recognized CHW training organization, Community Health Worker Network of New York City (www.CHWNetwork.org). They were also involved in planning dissemination activities. Patient stakeholder members were engaged in discussions about increasing the scope of dissemination venues in the community. They provided feedback regarding protocol changes (e.g., decision to not use oropharyngealswabs), as well as the acceptability of dissemination of information only (but not intervention kits), to usual care participants at the end of the study (See Table 3).

This active engagement of CPSAC members fostered equitable collaboration through shared decision-making by focusing on ongoing and multi-level communications and ensuring transparency at each step. CPSAC members shared their perspectives, preferences and priorities at all stages of the project. For example, in problem-solving recruitment/retention challenges,

they suggested a more personalized exchange among the site clinicians, study recruitment staff and CHW/Promotoras. As such, we instituted a "warm handoff", whereby the site clinician directly introduced the prospective study participants to the recruiter and CHW/promotora and invited them to participate in the study[42]. In theory, when a patient has an established relationship with the clinician, a warm hand off by the clinician is thought to increase the likelihood that the patient will agree to participate in the study ("trust-by-proxy"). This procedure includes the study participant as an active team member and engages the patient in the shared decision-making process.

In addition, we were particularly eager to understand why one-third of the participants who consented to home visits withdrew from the study before they were informed about their randomized treatment assignment, and therefore never received the intervention. Home visit implementation presented a major challenge due to participants either being unreachable following their baseline visit to the FQHC or ED for treatment of their SSTIs, or they were unwilling or unable to participate due to subsequent lack of agreement by other members in the household. The perceived and actual intrusiveness of home visits proved difficult to overcome, and the study was conducted during a time when anti-immigrant and deportation policies may have contributed to fear of immigration status disclosure during household visits. When we shared this difficulty of retention of study participants who were recruited in clinical settings but refused to participate once the project team contacted them at home, the CPSAC was instrumental in performing a "leaky pipe analysis" (see Table 4). This analysis examined the flow of prospective participants over the study's lifecycle, from presenting for care to informed consent to baseline home visit completion, and explored the points at which participants withdrew from the study. We undertook this analysis to improve our retention rates and to guide

other community-based research projects with similar research designs. Based on CPSAC guidance we changed several procedures of the study. For example, we began making appointments at the FQHC or ED with each study participant upon provision of informed consent (prior to laboratory confirmation), and subsequently cancelled appointments if the microbiological assessment showed that the infection was not due to *S. aureus*. This analysis also provided quantitative data about our recruitment and retention strategies and allowed us to improve our performance over the course of the trial. [29]

Continued Engagement of Patient and Community Partners

CPSAC members were highly engaged as evidenced by their enthusiasm and follow-through over the study period. We observed that the retention during the project of the CPSAC community and patient members was excellent, indicating an extremely high level of engagement. Among the community partners, although fewer in number as compared to the professionals, 100% remained with the project throughout the entire study and continue to collaborate as advisors in new patient-centered outcomes research studies (See Table 5). The involvement, input and continued engagement of community partners represents an important and integral feature of the design, conduct, and dissemination of CAMP2 and its legacy.

CONCLUSIONS

CAMP2 aimed to intervene at multiple levels in the patient's ecosystem, including the systems, patient, pathogen, and environmental factors associated with MRSA/MSSA SSTI recurrence and household transmission. CAMP2 was designed based on the input of a diverse stakeholder group of practicing clinicians, patients, clinical researchers, laboratory researchers, and CHWs/promotoras. Convening the CPSAC for regular meetings gained input and guidance

across all aspects of the project and encouraged sustained involvement of the CPSAC in decision-making processes.

Although the CPSAC for the CAMP2 program was highly satisfying for the members of the CPSAC, there were challenges that presented themselves. One challenge was ensuring that all types of stakeholders felt comfortable speaking up during our meetings (particularly the patient stakeholders). We addressed this through relationship management strategies by making sure patients felt welcome and prioritizing time for them to respond on each agenda item. Engaging clinical providers was a challenge due to their time constraints; we held in-person meetings at hospitals whenever possible so they were able to attend. Given that this was the era before the covid pandemic, engaging people virtually between meetings proved to be a challenge (e.g., busy providers aren't able to answer emails quickly). To address this challenge we relied on the CHWs/recruitment staff to help facilitate communication in those circumstances (i.e., CHWs were a helpful touchpoint at our sites). Logistical challenges mostly revolved around ensuring patient stakeholders had transportation to in-person meetings, for which we provided a travel stipend.

One limitation of was the higher proportion of professional representation on the CPSAC as compared to patients; this resulted, in part, from the high turn-over among the medical/clinical site and clinical research members. Additionally, the process evaluation of the CPSAC lacked measurement via a standardized tool to measure engagement and satisfaction (CPSAC members were reluctant to complete an extensive survey tool provided by the funder). A brief engagement survey, delivered at regular intervals, could have helped to quantify CPSAC member satisfaction. Future analyses will examine the growth over time using social network analysis (SNA) and sociometric methods.[43]

CAMP2 benefited from the input of: 1) clinicians and staff affiliated with participating FQHCs and EDs, 2) patient stakeholders associated with affiliated practices, and 3) a community partner/local barbershop owner, positioned to identify SSTIs among barbershop clients. Also vital to this conversation were CHWs/promotoras who maintained a working knowledge of the neighborhoods where participants resided. The CPSAC was formed to create bidirectional communications, incorporate insights from each of these partners, and address aspects of study design, implementation and dissemination.

In conclusion, the members of the CPSAC were instrumental at all stages of the study, from design through implementation and dissemination of this comparative effectiveness/patient-centered outcomes research study. They contributed to hypothesis development and study design, selection of outcome measures, key covariates and intervention components, and they identified areas of concern during the conduct of the study. The composition of the CPSAC represented the patient and community-based clinician points of view, and identified remedies for various study challenges (e.g., recruitment and retention), and CPSAC members remained highly engaged throughout the project. Accomplishing longevity within community-based research endeavors requires both coordinated efforts among participating stakeholders and knowledge of the target population. CAMP2 utilized both CBPR and PBRN approaches. Having a PBRN that can support community-academic research collaborations is vital to project sustainability and also encourages the development of future partnerships. This report provides some reflections and detailed descriptions of an example of CBPR conducted with the infrastructure support of a primary care PBRN in collaboration with the community-engaged research core of a CTSA and provides models of collaboration that can be applied to new

community-academic research partnerships, in particular, those who engage basic scientists, practicing clinicians, clinical researchers and patient stakeholders.[14]

ACKNOWLEDGEMENTS

Clinical Directors Network, Inc. (CDN) Research Team

Andrea Cassells, MPH; TJ Lin, MPH; Dena Moftah, BA; Anthony Rhabb, MA, Branny F. Tavarez, MD, Cynthia Mofunanya, MD, Jasbir Singh, MBBS, MPH, Musarrat Rahman, MPH, Raul Silverio, MD, Sisle Heyliger, BA, Tameir Holder, MPH, Umamah Siddiqui, BS, Viktorya Snkhchyan MD, and Lois Lynn, MS.

The Rockefeller University Research Team

Andrea Leinberger-Jabari, MPH, Cameron Coffran, MS, Helen Marie Curry, Maija Neville Williams, MPH, Marilyn Chung, Mina Pastagia, MD, MS, Teresa L. Solomon, JD, Alexander Tomasz, PhD, Hermínia de Lencastre, PhD, and Maria Pardos de la Gandara, MD, PhD.

Federally Qualified Health Centers (FQHCs) and Hospital Emergency Departments (EDs) Community Health Network: Site Investigator: Satoko Kanahara MD, FAAP and Tyler Evans, MD.

Family Health Centers at NYU Langone: Site Investigator: William Pagano, MD, MPH, Barry Kohn MD, PhD, Isaac Dapkins, MD; Site Staff: Paula Clemons, PA; Viral Patel, MD and Jason Hyde, LMSW, MEd. Patient Stakeholder: Maria Ferrer.

Open Door Family Health Center: Site Investigator: Daren Wu, MD, Site staff: Asaf Cohen, MD.

Urban Health Plan: Site Investigator: Claude Parola, MD, Tracie Urban, RN, Franco A. Barsanti, PharmD; Site Staff: Ali Saleh, PA, Scott Salvato, PA, Jennifer Concepcion.

NYC Health + Hospitals

Coney Island Hospital ED: Site staff: Candace Gopaul.

Metropolitan Hospital ED: Patient Stakeholder: Van Johnson.

Community Stakeholders:

Rosa Perez, RPh (Cordette Pharmacy)

Dennis Mitchell (Denny Moe Barber Shop)

Data and Safety Monitoring Board (DSMB):

Katherine Freeman, DrPH (DSMB Chair, Extrapolate Statistic LLC, Florida Atlantic University)

Marilyn Gaston, MD (DSMB Member, Assistant Surgeon General & HRSA Associate Administrator for Primary Health Care (ret.))

Maria Ferrer (Patient Representative)

Scientific Consultants/Advisors

Susan Huang, MD, MPH (University of California at Irvine)

Christopher R. Frei, PharmD, MSc (STARNet/University of Texas Health Science Center at San Antonio)

Eric Lofgren, PhD (Washington State University)

Christopher Mason, PhD, Ebhrahim Afshinekoo, BS, Chou Chou, MD (Weill Cornell Medicine)

Shirshendu Chatterjee, PhD, (The City University of New York (CUNY) School of Public Health)

Sarah Johnson, MD (NYC Department of Health and Mental Hygiene, Public Health and Preventive Medicine Residency Program & CUNY School of Public Health)

Bárbara Milioto, E Denise Digirolomo, Edward Clayton (Genpath/Bioreference Labs)

Vicky Seyfert-Margolies, PhD, Dana Wershiner, Trang Gisler, MS (MyOwnMed, Inc.)

Suzanne Lechner, PhD, Sara Vargas, PhD, Suzanne Hower, PhD (Consulting Associates, Inc.)

Funding Agency

Patient Centered Outcomes Research Institute (PCORI): Anne Trontell, MD, MPH, Donna Gentry, MA and Jess Robb, MPH.

REFERENCES

1. Moran GJ, Krishnadasan A, Gorwitz RJ, et al. Methicillin-resistant *S. aureus* infections among patients in the emergency department. *N Engl J Med.* 2006;355(7):666-674.
2. Farr AM, Aden B, Weiss D, Nash D, Marx MA. Trends in hospitalization for community-associated methicillin-resistant *Staphylococcus aureus* in New York City, 1997-2006: data from New York State's Statewide Planning and Research Cooperative System. *Infect Control Hosp Epidemiol.* 2012;33(7):725-731.
3. Klevens RM, Morrison MA, Nadle J, et al. Invasive methicillin-resistant *Staphylococcus aureus* infections in the United States. *JAMA.* 2007;298(15):1763-1771.
4. Centers for Disease Control and Prevention. Methicillin-resistant *Staphylococcus aureus* (MRSA) infection in healthcare settings. http://www.cdc.gov/HAI/organisms/mrsa-infection.html. Published 2012. Accessed February 2, 2019.
5. Huang SS, Septimus E, Kleinman K, et al. Targeted versus universal decolonization to prevent ICU infection. *N Engl J Med.* 2013;368(24):2255-2265.
6. Tenover FC, Goering RV. Methicillin-resistant *Staphylococcus aureus* strain USA300: origin and epidemiology. *J Antimicrob Chemother.* 2009;64(3):441-446.
7. Cluzet VC, Gerber JS, Metlay JP, et al. The effect of total household decolonization on clearance of colonization with methicillin-resistant *Staphylococcus aureus*. *Infect Control Hosp Epidemiol.* 2016;37(10):1226-1233.
8. Huang SS, Septimus E, Kleinman K, et al. Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial. *Lancet.* 2019;393(10177):1205-1215.
9. Papastefan ST, Buonpane C, Ares G, Benyamen B, Helenowski I, Hunter CJ. Impact of decolonization protocols and recurrence in pediatric MRSA skin and soft-tissue infections. *J Surg Res.* 2019;242:70-77.
10. Fritz SA, Hogan PG, Hayek G, et al. Household versus individual approaches to eradication of community-associated *Staphylococcus aureus* in children: a randomized trial. *Clin Infect Dis.* 2012;54(6):743-751.
11. Ellis MW, Griffith ME, Dooley DP, et al. Targeted intranasal mupirocin to prevent colonization and infection by community-associated methicillin-resistant *Staphylococcus aureus* strains in soldiers: a cluster randomized controlled trial. *Antimicrob Agents Chemother.* 2007;51(10):3591-3598.
12. DeLeo FR, Otto M, Kreiswirth BN, Chambers HF. Community-associated meticillin-resistant *Staphylococcus aureus*. *Lancet.* 2010;375(9725):1557-1568.
13. Fritz SA, Camins BC, Eisenstein KA, et al. Effectiveness of measures to eradicate *Staphylococcus aureus* carriage in patients with community-associated skin and soft-tissue infections: a randomized trial. *Infect Control Hosp Epidemiol.* 2011;32(9):872-880.
14. Kost RG, Leinberger-Jabari A, Evering TH, et al. Helping basic scientists engage with community partners to enrich and accelerate translational research. *Acad Med.* 2017;92(3):374-379.
15. Springer MV, Skolarus LE. Community-based participatory research. *Stroke.* 2019;50(3):e48-e50.
16. Teufel-Shone NI, Schwartz AL, Hardy LJ, et al. Supporting new community-based participatory research partnerships. *Int J Environ Res Public Health.* 2018;16(1).

Table 1. PCORI Patient-Centered Questions Addressed by CAMP2 Trial

PCORI Patient-Centered Questions examined during CAMP1[17]	**CAMP1 Stakeholder Feedback Addressed in CAMP2: Patient-Centered Features Incorporated into the CAMP2 Design**
1) *"Given my personal characteristics, conditions, and preferences, what should I expect will happen to me?"*	78% of CAMP1 patients rated reducing the spread of MRSA in their household as "very important" to them. Moreover, 84% rated preventing their MRSA infection from coming back as "very important". One of the goals of this project was to **reduce future recurrence** and uncertainty. Patient education and self-efficacy were crucial to the implementation of this intervention. CHW/Promotoras collaborated in developing the home visit scripts and protocol to address the cultural, socioeconomic, and medical needs of patients.
2) *"What are my options and what are the potential benefits and harms of those options?"*	The CAMP2 study **compared the effectiveness of two interventions to prevent MRSA recurrence**. If effective when implemented in the community-based settings, the intervention could help reduce the spread of MRSA infection and reduce future morbidity and suffering. Given the patients who received care in the health systems settings that provide care to an urban, multi-ethnic low income population, many of whom have been disenfranchised by the health care system, all protocols were highly sensitive to participants' autonomy and their role as the ultimate decision-maker.
3) *"What can I do to improve the outcomes that are most important to me?"*	Qualitative results demonstrated that patients were most concerned about **recurrence, pain, and ability to perform functions**. CAMP2 intervention aims to empower patients to play a more active role in reducing the burden of recurrent MRSA infections through tools and methods to decolonize themselves and household members and to disinfect their households[18].
4) *"How can clinicians and the care delivery systems they work in help me make the best decisions about my health and healthcare?"*	Through close relationships with the communities they serve, clinicians in FQHCs and community hospital emergency departments, worked with study-supported staff, including onsite study recruiters. To minimize impact on practice workflow, research staff were present and obtained informed consent in a **collaborative style, to ensure that each participant understood that the project** was designed to help them make the best decisions for themselves, and to take active steps to reduce the possibility of infection recurrence and household transmission.

Table 2. Clinician and CHW/Promotora Role and Interactions with Study Participants During the Intervention Trial by Type of Recruitment Site

Stakeholder Type	**Role and Interactions with Study Participants During the Intervention Trial**	**# FQHCs**	**# EDs**	**TOTAL**
Clinicians	· Conducted patient screening and recruitment · Obtained informed consent · Assessed dermatological symptoms, collected specimen, treated wounds, among other activities during Baseline Study Visit · Assisted with follow-up of "warm handoff" protocol	4	5	**9**
CHW/ Promotoras	· Conducted patient screening and recruitment · Obtained informed consent · Participated in "warm handoff" protocol · Conducted home visits · Conducted telephone assessments	2	4	**6**
Patient Stakeholders/ Community Members	- No interactive role with study participants	1	4	**5**
TOTAL		**7**	**13**	**20**

Table 3. Community and Patient Stakeholder Advisory Committee Strategic and Logistical Project Contributions

Stakeholder Type	**Description of Project Contributions**
Academic/Laboratory Investigators	-Reviewed Protocol/Proposal and Project/Protocol Conduct -Evaluated the quality and acceptability of educational materials, the laboratory measures, and the patient-centered and self-reported outcomes assessment battery -Led discussions on building capacity for patient stakeholders to have an influence on the health of their communities; discussions about patient consent and human subjects protection -Planned dissemination activities with community clinicians and collaborators
Community-Based Primary Care Clinicians	-Reviewed Protocol/Proposal and Project/Protocol Conduct -Participated in refining and finalizing the study protocol -Adapted and expanded the clinical workflow -Identified patient and clinician engagement strategies -Planned dissemination activities with academic collaborators
Patient Stakeholders/ Community Members	-Reviewed Protocol/Proposal and Project/Protocol -Helped in reviewing the home intervention, developing and selecting the primary outcomes and their measurement -Ensured patient outcomes were meaningful without being burdensome -Led discussion on intervention delivery methods to improve the scheduling and completion of home visits -Reflected on the protocol's burden on participants, and provided feedback on protocol changes -Provided input on discussions of cultural sensitivity, patient autonomy, shaming and stigmatization related to potential home contamination, and community health priorities -Evaluated acceptability of dissemination of information to usual care participants
CHW/Promotoras	-Reviewed Protocol/Proposal and Project/Protocol -Determined acceptability of education materials and home visit protocol elements prior to study initiation -Provided input on discussions of cultural sensitivity, patient autonomy, shaming and stigmatization related to potential home contamination, and community health priorities -Tested the data collection application and refined informed consent language -Reflected on the protocol's burden on participants, and provided feedback on protocol changes -Led discussion on intervention delivery methods to improve the scheduling and completion of home visits -Helped with assessment procedures to address language, literacy and cultural sensitivity

Table 4. “Leaky Pipe” Model for Evaluating Recruitment and Home Visits Completion

CAMP2 "Leaky Pipe" Model for Evaluating Recruitment and Home Visits

			A		B			C		D
Sites	# Screened	# Recruited	% Recruited of Patients Screened	# Enrolled (MRSA+/ MSSA+)	% S. aureus positive	Baseline Home Visits Scheduled for All Recruited Patients^	Baseline Home Visits Scheduled for Confirmed Eligible Patients	% Scheduled of Positive Patients	Baseline Home Visits Completed	% Home Visits Completed of # Scheduled
FQHC A	89	33	37%	17	52%	11	11	65%	10	91%
FQHC B	4	2	50%	2	100%	2	2	100%	2	100%
FQHC C	22	18	82%	7	39%	4	4	57%	4	100%
ED A	238	210	88%	93	44%	57	53	57%	52	98%
ED B	194	124	64%	54	44%	49	47	87%	44	94%
ED C	55	34	62%	13	38%	8	8	62%	8	100%
TOTAL	**602**	**421**	**70%**	**186**	**44%**	**131**	**125**	**67%**	**120***	**96%**
GOAL				**278**					**278**	
%MRSA+/MSSA+				**44.1%**		**% of original goal (n=278) who completed baseline home visits (n=120)***			**43.2%**	

^Total, including those scheduled using protocol to schedule at time of consent prior to lab result

*One patient was determined subsequently to have HA-MRSA and was excluded from the main effects analysis (n=119)

Table 5. Retention/Turnover CAMP2 Research Team

TYPE OF STAKEHOLDER	# Beginning of study	# End of study	% Retention
FQHC/HOSP ED*	23	13	57%
ACADEMIC/MEDICAL CENTER	24	19	79%
PBRN	17	9	53%
PATIENT/COMMUNITY PARTNER	5	5	100%
PRIVATE/CORPORATE PARTNER	4	2	50%
FUNDER	3	3	100%
TOTAL	**76**	**51**	**67%**

*FQHC/HOSP ED=Federally Qualified Health Center/Hospital Emergency Department

Supplemental Table 1. CHW/Promotora Training Materials

Training Agenda

CAMP-2 Community Health Worker Training: Days 1-3

Date	Time		Duration (hrs)	Module	Training Facilitator
	Start	Finish			Name
Tues 6/2/15	9:00 AM	5:00 PM	7.0	Introduction, Research Skills, and Protocol Training, Day 1	
	9:00 AM	9:30 AM	0.50	I. Welcome & Introduction	Jonathan N. Tobin, PhD
	9:30 AM	10:30 AM	1.00	II. Introduction to CAMP-2 A. Study Aims B. Study Steps C. Timeline	Jonathan N. Tobin, PhD Chamanara Khalida, MD, MPH
	10:30 AM	11:00 AM	0.50	III. Project Specific Training Part 1 D. Study Workflow	Trang Gisler, Dana Wershiner Chamanara Khalida, MD, MPH
	11:00 AM	11:30 AM	0.50	E. Recruitment and survey techniques	Brianna D'Orazio Andrea Leinberger-Jabari, MPH; Chamanara Khalida, MD, MPH
	11:30 AM	12:00 PM	0.50	F. Quality Control SOPs and Reporting/Documenting Adverse Events	Chamanara Khalida, MD, MPH
	12:00 PM	1:00 PM	1.00	BREAK	
	1:00 PM	4:00 PM	3.00	IV. Project Specific Training Part 2 G. Home Visits G-1. Preparation and Documentation	Trang Gisler, Dana Wershiner Chamanara Khalida, MD, MPH
				G-2. Index Patient and Household Member Surveys	Chamanara Khalida, MD, MPH

	4:00 PM	5:00 PM	1.00	H. Health Portal Practice	Trang Gisler, Dana Wershiner, Brianna D'Orazio
Wed 6/3/15	**9:00 AM**	**5:00 PM**	**7.00**	**Protocol Training, Day 2**	
				V. Research Skills Training	Rhonda Kost, MD Andrea Leinberger-Jabari, MPH
	9:00 AM	12:00 PM	3.00	Research Ethics and Human Subject Protection Household Member Consent	
	12:00 PM	1:00 PM	1.00	BREAK	
	1:00 PM	2:30 PM	1.50	VI. Project Specific Training Part 3 I. Home Assessment- Surveillance Sampling	
				I-1. Patient and Household Member Self-sampling	Maria Pardos, MD, PhD; Tracie Urban, RN
				I-2. Environmental Sampling and Data Collection	Ebrahim Afshinnekoo
				I-3. Sampling Etiquette	Maria Pardos, MD, PhD; Tracie Urban, RN
	2:30 PM	3:30 PM	1.00	I-4. Sampling pets I-4a. Safety plan for Handling Pets I-4b. Equipment Requirements for swabbing pets	Vladimir Bonhomme
	3:30 PM	4:15 PM	0.75	I-5. Sample identification and annotation	Chamanara Khalida, MD, MPH
	4:15 PM	5:00 PM	0.75	I-6. Sample packaging and transportation	Chamanara Khalida, MD, MPH Maria Pardos, MD, PhD Ebrahim Afshinnekoo
Thurs 6/4/15	**9:00 AM**	**5:00 PM**	**7.00**	**Protocol Training Part 3**	
				VII. Project Specific Training Part 4 Intervention Package	Mina Pastagia, MD, MS

9:00 AM	10:30 AM	1.50	J. Decolonization J-1. Mupirocin Ointment Application, Side Effects, and Safety J-2. Chlorhexidine Wash Application, Side Effects, and Safety	
10:30 AM	12:00 PM	1.50	K. Decontamination K-1. Handwashing techniques K-2. Laundering K-3. Discarding or disinfecting potentially contaminated hygiene articles K-4. Disinfecting household surfaces K-5. Storage and Safety Protocol	
12:00 PM	1:00 PM	1.00	**BREAK**	
1:00 PM	**2:00 PM**	**1.00**	**VIII. Disease Specific Training** L. MRSA-101: a. Background, Impact, Pathogenesis and Epidemiology b. Risk Factors c. Treatment d. Prevention	**Teresa Evering, MD, MS**
2:00 PM	2:30 PM	0.50	M. Treatment adherence promotion	Teresa Evering, MD, MS
2:30 PM	5:00 PM	2.50	N. Home Visit Run-Through	CHWs and Study Team
		21.00	**TOTAL, Days 1-3**	

Sample Handout of Study Flow Chart