



4th Liver Forum Meeting:

**Innovative Data Collection
Approaches to support RWE**

Our Leadership Team



Vicki Seyfert-Margolis, PhD
Founder, CEO

Senior Advisor, Regulatory Science and Innovation (US FDA)
Director, Office of Regulatory Science and Innovation (US FDA)
Previously: Immune Tolerance Network, National Institutes of Health

Ph.D. Immunology, University of Pennsylvania



Molly Varney-Muldoon
CAO

Previously: Onyx Pharmaceutical, FDA, AARP, HHS, White House

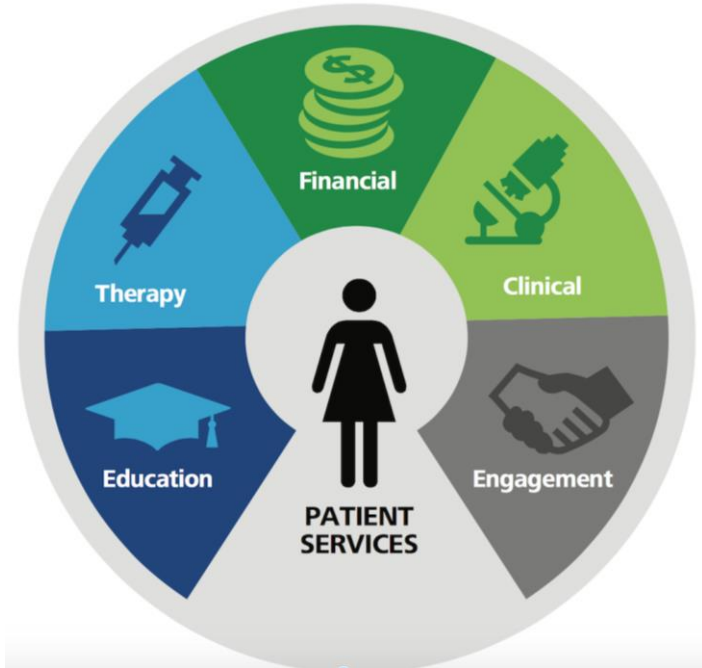


Trang Gisler
SVP, Client Services

Previously: FDA, HHS, DOD, UCSF/ITN, Ceva USA (Biomune)

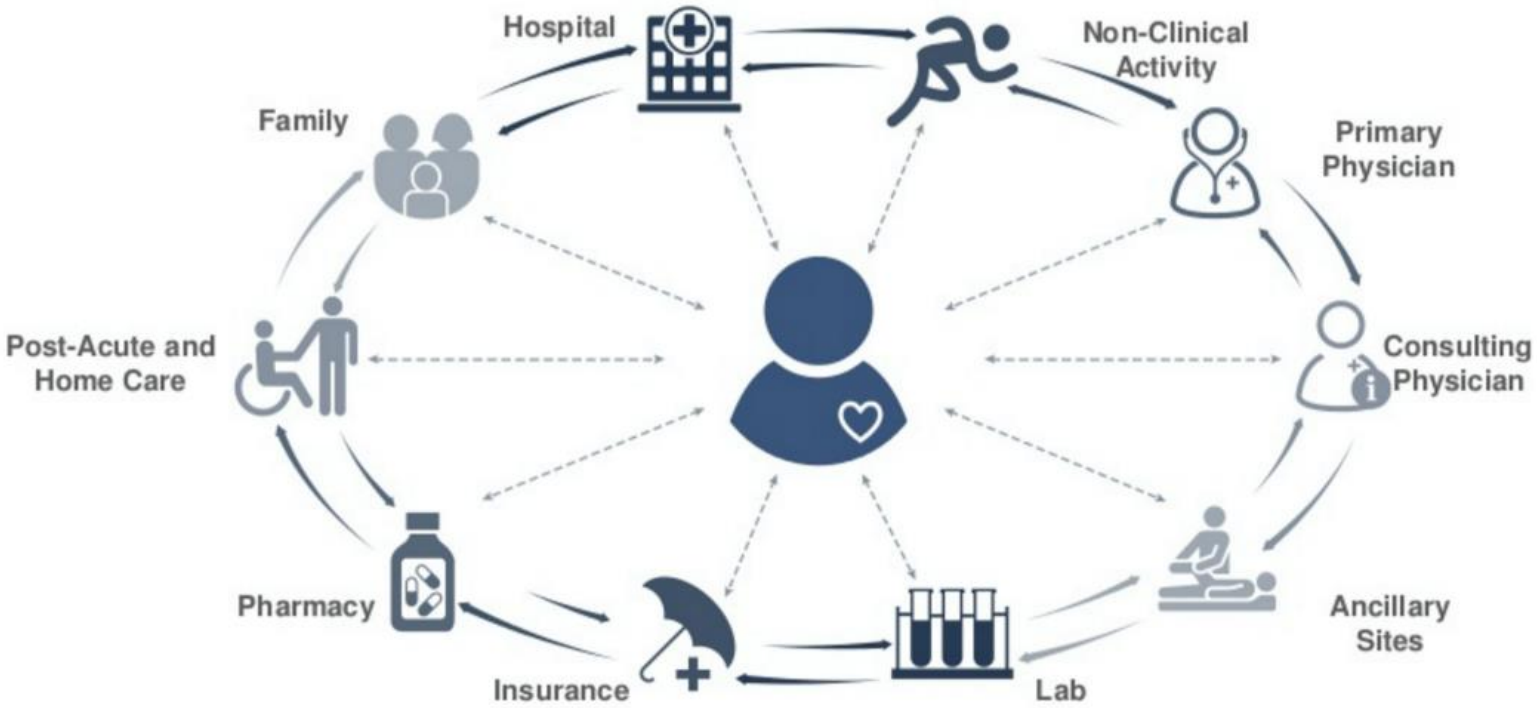


The Changing Landscape of Healthcare

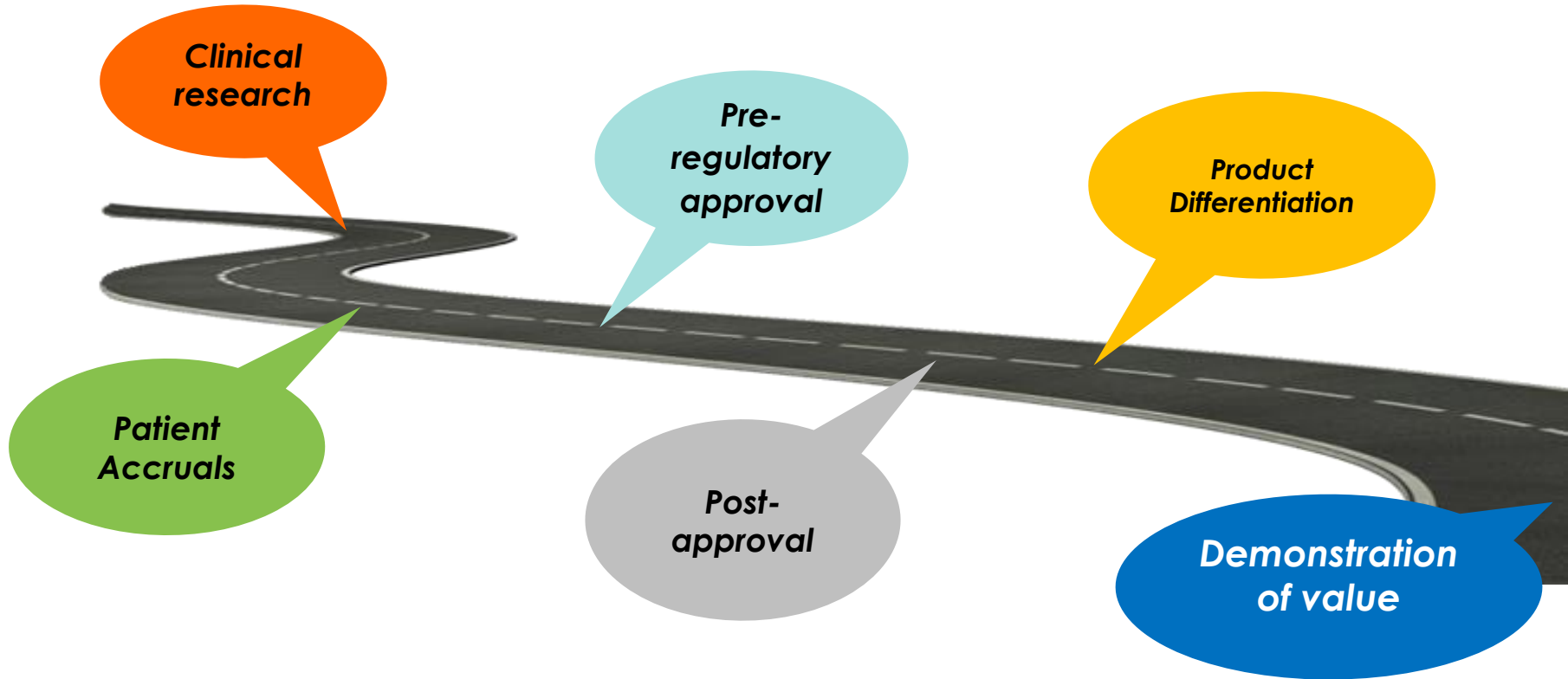


- Changes in the health care ecosystem are increasing the patient's role in decision making and reshaping expectations. Patients want solutions that are simple, coordinated, and accessible.
- Pay for performance, shift risk to providers and pharmaceutical companies to demonstrate effective outcomes.
- Real-world evidence (RWE) information from multiple sources that extend beyond clinical trials—implementation, use, preference
- RWE has influenced license (label), access, pricing, and use across countries and therapeutic areas.

Patient Will be at the Center of the Future Healthcare System



The Real World Evidence Product Pathway



How RWE Impacts Product Lifecycle



Unmet needs

- Clinical presentation of disease
- **Patient-reported treatment shortfalls**

Disease root cause and subtype

- Role of genomics
- **Patient behavior**

Manage R&D

- Asset prioritization
- **Innovative R & D with providers**

Cohort Selection

- **Recruitment**
 - More diverse patients**
 - Primary care settings**
 - Community practice patients**

Trial Management

- Bring trial to patient – home
- Retention through engagement
- **New trial designs – adaptive/pragmatic**
- **Real time data and analysis**
- **Give data back**

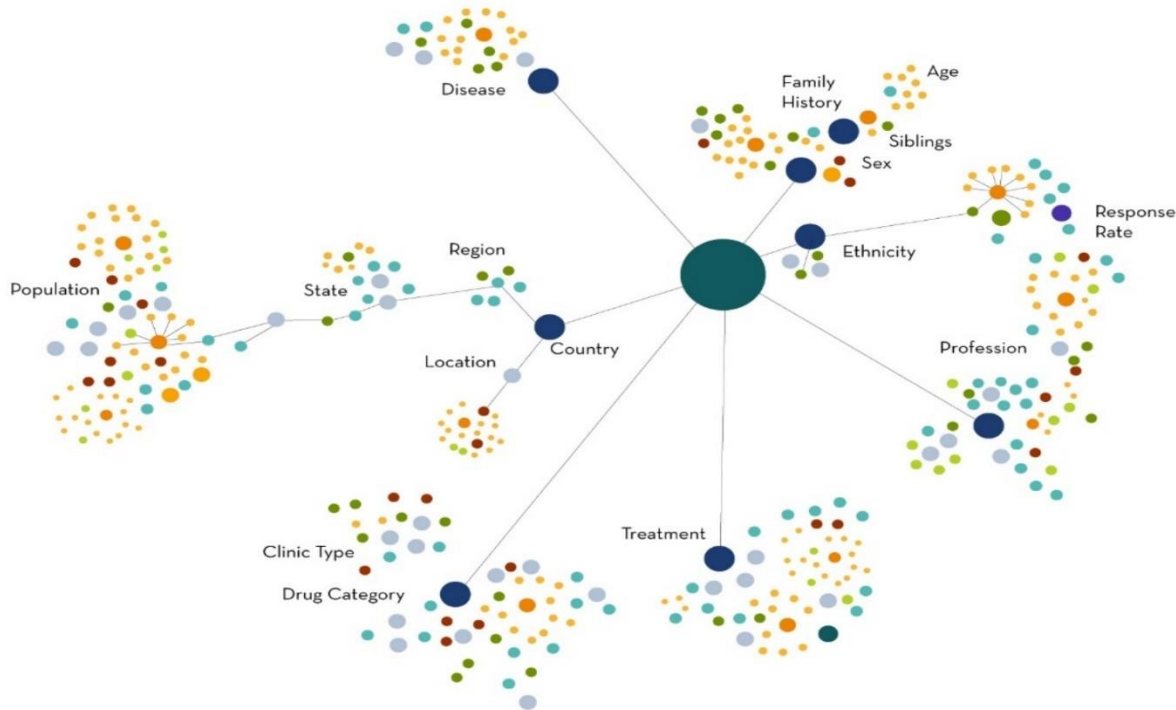
Economic Value

- Positioning Product
- Tracking economic value
- **Adverse event monitoring**

Precision Targeting

- Market sizing
- **Target cohort definition**
- **Market access**
- **Design combined offerings (e.g., Rx + device)**
- **Design integrated offering (e.g. Rx + device + pathway changes)**

RWE- Networks of Multi-Dimensional Information



Multiple stakeholders generate evidence and insert their own recommendations of adoption, coverage, reimbursement and end use of products

mHealth is Growing to Support Patients



AND HEALTHCARE IS NEXT



7 in 10 U.S. adults track at least one health indicator

And the means of tracking are remarkably primitive



mHealth apps are set to become a regular part of care

86%

of clinicians believe mHealth apps will be important for patient health management over next 5 years

Use mobile devices to engage patients

90%



Using Technology for Connectivity



1. Provide patient and family caregiver with the right tools-shared interface



2. Connect them to their Healthcare Providers/Study to study/ improve outcomes



3. Engage them with their Community



4. Turn Data into Action

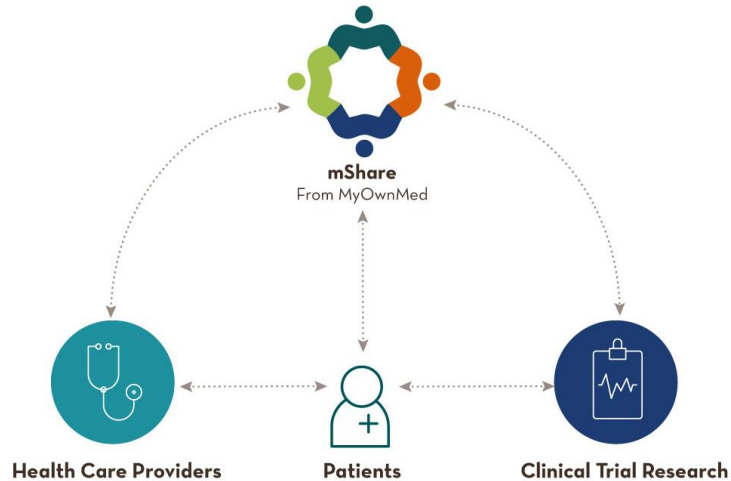




Real World Evidence for Real World Solutions to enable better Health Outcomes

That is MyOwnMed, Inc.

MyOwnMed Overview – What we do

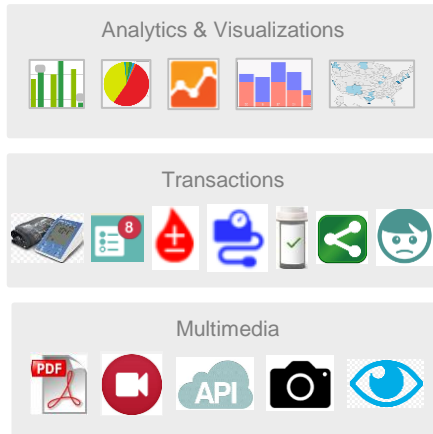


- **Generate real world evidence** for healthcare providers and pharma that support market access and Product differentiation, post-market activities, and manage costs.
- **Aggregate multiple points of data information** based on health reported outcomes.
- **Provide real time analytics and insights** to drive smart population management strategies.

Adaptive Platform Design

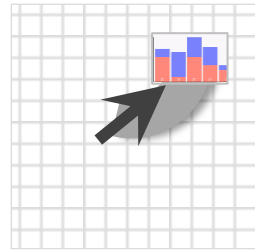


Pre-Built Modules

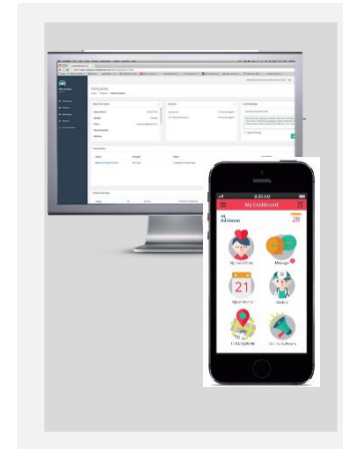


Drag and Drop

1. Insert a module
2. Set location
3. Save . . .Done



Configurable Platform with Workflows



The MyOwnMed Platform contains an extensive library of web and mobile-optimized and touch-enabled modules covering transactions, data visualizations, and other building blocks.

Platform Flexibility to Address Diverse Needs



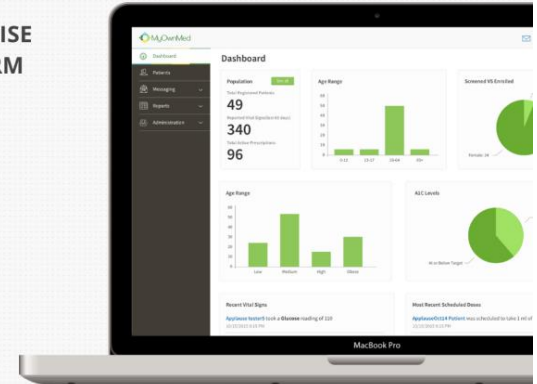
Multicultural
Geography
Demography
Socioeconomic
Communities- family, friends, healthcare, disease, cultural, racial/ethnic

1 PRE-BUILT MODULES



2 DRAG & DROP

3 INTUITIVE ENTERPRISE "CUSTOM" PLATFORM WITH WORKFLOWS



The MyOwnMed Platform contains an extensive library of web and mobile-optimized and touch-enabled modules covering transactions, data visualizations, and other building blocks.

Toolkit for PRO/Outcomes Clinical Research: Patient Screening & Management



Customize the rules that determine which patients qualify for enrollment, bring study to patients where they are (home, community, primary care), and track their study compliance

UTHealth

Participant Population

Home / Participant Population

+ Add a new participant

Drag a column header and drop it here to group by that column

Participant ID	Participant Name	Location	First Encounter Date	Screening Status	Reason for
18018	Dana Tester	BRL	09/01/2015	Eligible	
18018	Dana Tester	BRL	09/01/2015	Eligible	
			09/01/2015	Eligible	
			09/01/2015	Eligible	
			09/01/2015	Eligible	
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			09/01/2015	Eligible	
			09/01/2015	Eligible	

Eligibility Screener

Are you eligible?

Please answer "yes" or "no" to the questions below. There are eight questions in total. You will only receive your eligibility status after completing the entire screener. The box directly below will show you the status of your screening and will be filled once completed.

Are you between the ages of 65 and 85 years old?

Yes

No

Need to start over?
To reset the screener and start over, please [click here](#).

Dana tester BRL-18018

Home / Participant Population / Dana tester

Eligible for follow-up

Participant Info | Communication Log | Vital History | Events | First Encounter

Vitals Overview

Blood Pressure **140/80** | BMI **21** | Height **5'4** | Weight **125** | Flu Vaccine **Yes**

Health Conditions

Last Attended: 9/1/2015, City of San Benito Health Fair

First Encounter **Completed - Declined** (10/5/2015)

Follow - Up 1 **Incompleted - Eligible** (Due Completed 10/5/2015, 10/12/2015)

Follow - Up 2 **Pending**

Follow - Up 3 **Pending**

Follow - Up 4 **Pending**

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Collaborations



UMC Utrecht



SCHOOL OF MEDICINE
INDIANA UNIVERSITY



University of Texas Health Center

Community health workers and MyOwnMed support T2DM outcomes management and research



PROBLEM: Brownsville, TX - 180,000 residents

- mostly Spanish speaking
- 48% children live in poverty
- 80% overweight/obese
- 30% have diabetes and don't know it
- 67% have no health insurance
- 48% have hypercholesterolemia
- Most have multiple chronic diseases

T2DM Management Data:

- Recruited **+12,000** users (and growing)
- **+16,500** vital signs entered
- **+1500** questionnaires / surveys completed
- **+3000** in-home visits
- **+800** educational classes with **+14,000** attendees



TESTIMONIAL: "My Own Med moves our data entry and participant tracking closer to the point of interaction, and our providers can access participant information to make informed decisions - in the field."
E Ray Gard, UTHealth.

Implemented diabetes treatment and control services



- ▶ Evidence based Wagner CCM model
 - ▶ Helpful discussions with Steve Conti, Sefon Healthcare Family
- ▶ Regional partnerships for implementation
- ▶ Diabetes management program funded by 1115 waiver
- ▶ Served over 1800 clients
- ▶ Free DSME education
- ▶ CHW home visits
- ▶ Case management review
- ▶ Re-engagement with medical home
- ▶ Referrals and services for behavioral health
- ▶ Results show average A1c decreasing

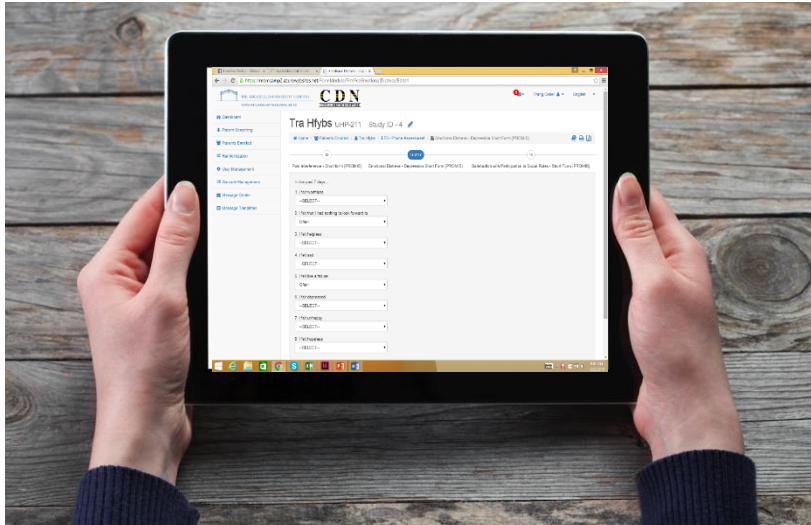
Reimbursement for Prevention Programs



March 23, 2016 – HHS Secretary announce expansion of Reimbursement for CDC-Recognized Diabetes Prevention Programs(DPP)



Collaboration Bringing the Clinical Trials to Patients



Patient recruitment can contribute to over 25 % of clinical trial costs

Enrollment and keeping patients enrolled throughout the trial accounts for significant delays in timelines between 1/3 and 1/2 of the total study duration

In a global world achieving economies of scale is essential a unified platform is critical to manage costs

Cervical Cancer Screening Program



Funded by GE Foundation

To help improve the prevention of cervical cancer in women living in medically underserved areas

Using Community Health Workers from each community, they will recruit 750 women who have not been screened for HPV and/or cervical cancer within the last the years. We are partnering with Health Choice Network of Florida, Inc., that has Federally-Qualified Health Centers in these communities.

Haitian community of South Florida have an unusually high incidence of cervical cancer

Clinical trials meet patients where they are



PROBLEM: Methicillin-resistant *Staphylococcus aureus* (MRSA) – 2 in 100 people carry MRSA. In an urban metropolis the size of New York City, hunting this microbe is a challenge that can only be tackled by a collaborative, multidisciplinary research team

DIGITAL ENGAGEMENT: Using My Own Med platform, the research team with clinical nurses and community health workers to use technology to support study home visit, patient engagement, education training, and management of sample biorepository.



CAMP -The Community Acquired MRSA Project (CAMP) Collaboration Community members have an active role in defining the research agenda while academic scientists are able to dive deep into intriguing questions to uncover pathways to new treatments.

Engaging Scientists, Clinicians, Community Health Workers and Patients to Conduct a Comparative Effectiveness Study of Home-Based Interventions to Reduce CA-MRSA Recurrence and Household Transmission

Bianna M. D'Orazio¹, Rhonda G. Kost¹, Chamana Khalid¹, Andrea Leinberger-Jabari¹, Mina Pastagia¹, Teresa H. Evering¹, Maria Pardo de la Gandara^{2,3}, Dana Wershiner⁴, Sergio Matos⁴, Trang Gislert⁴, Cameron Coffran², Joel Correa de Rosa², Treacle Urban², Franco Barantse², Hermine de Lencastre^{2,3}, Alexander Tomasz^{2,3}, Berry S. Collier², Jonathan N. Tobin^{1,2}

¹Clinical Directors Network (CDN) (New York, NY), ²The Rockefeller University Center for Clinical and Translational Science and Laboratory of Microbiology and Infectious Diseases, The Rockefeller University (New York, NY) (NHLN/CATSUSL1-TR-00043), ³My Own Med (Bethesda, MD), ⁴The Community Health Worker Network of NYC and Health Innovation Associates (New York, NY), ⁵Urban Health Plan (Bronx, NY)



ABSTRACT

OBJECTIVE/SPECIFIC AIMS: Community-Associated Methicillin-Resistant *Staphylococcus aureus* (CA-MRSA) skin and soft tissue infections (SSTIs) recurrence ranges from 14% to 41% and presents significant challenges to clinicians, patients, and families. This comparative effectiveness research study aims to develop and evaluate a home-based intervention implemented by Community Health Workers (CHWs) or "promoters" to prevent recurrence of CA-MRSA in patients presenting to primary care with SSTIs and transmission within their households.

METHODS/STUDY POPULATION: In partnership with three Community Health Centers and four community hospitals in NYC, this study will recruit patients (n=278) with confirmed MRSA SSTIs and their household members. Participants will be randomized to receive either a CHW/Promoter-delivered decolonization-decontamination intervention or Usual Care. The highly engaged stakeholder team finalized the intervention protocol, developed and implemented CHW and clinician training, and developed an online health portal application for data management and exchange ("OneMed").

RESULTS/ANTICIPATED RESULTS: Eight CHWs completed a 49-hour training consisting of Epidemiology and MRSA (16), Research Ethics and Human Subjects Protocols, Survey Techniques, Health Portal Training, Quality Control, Treatment, Adherence, Promotion, and CHW-specific skills. Clinicians (n=33) were trained to identify, screen and enroll patients, conduct specimen collection and transport, and use the health portal.

DISCUSSION/SIGNIFICANCE OF IMPACT: This study aims to understand the patient- and environmental-level factors associated with SSTI recurrence and household transmission, and to examine the interactions between bacterial genomics and clinical/phenotypic factors on decolonization, decontamination, SSTI recurrence and household transmission.

INTRODUCTION

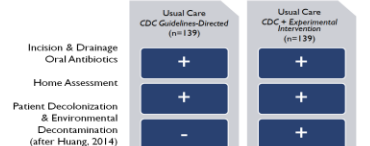
Previous studies built a community-engaged research and learning collaborative among Community Health Centers (CHCs), Community Hospitals, The Rockefeller University Center for Clinical and Translational Science, Clinical Directors Network (CDN), a practice-based research network (PBRN), and PBRN partners. We developed infrastructure to conduct comparative effectiveness research (CER) and patient-centered outcomes research (PCOR) with embedded mechanistic studies of treatment, prevention, and molecular epidemiology. Our current focus is whether interventions routinely applied in the hospital intensive care unit (ICU) setting to prevent the transmission of MRSA can be successfully applied in the home environment, and whether molecular analyses can predict recurrence and strategies to prevent recurrence. This study will also explore the profile and impact of the microbiome of index patients, household members, and home environment on the treatment, transmission and recurrence of CA-MRSA skin and soft tissue infections.



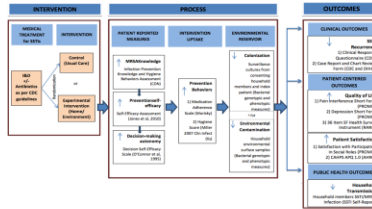
Figure 1. Map and corresponding list of the geographical locations of the participating Community Health Centers and Hospitals

METHODS

Research Design



Logic Model: Study Process and Outcomes Measures



In collaboration with the Laboratory of Microbiology and Infectious Diseases (Alexander Tomasz, PhD) at The Rockefeller University and the Christopher Mason Institute for Computational Biomedicine/PathoMap of Weill Cornell Medical College (Christopher Mason, PhD), we will collect and analyze samples at two timepoints (pre- and post-intervention) from (1) patients with wounds testing positive for MRSA/MSSA, (2) consenting household contacts, and (3) household environmental surfaces.

Surveillance Swabs

Collected from index patients (n=278), consenting household members, and home environment
Environment (n=13 per household, at Baseline and at 3-Months)
Swab Category (n=3 per participant, at Baseline and at 3-Months)



Intervention: Decolonization and Decontamination

- Decolonization:**
- Mupirocin ointment, Nasal application, twice per day
 - Chlorhexidine wash, Shower application, daily
- Household Environmental Decontamination:**
- Participant education (hand-washing techniques, sharing of personal items)
 - Laundry sheets and towels once per week
 - Household surface disinfection (Clorox wipes provided)



TRAINING ACTIVITIES

Community Health Worker (CHW) Training

- CHW Training Curriculum**
- Part 1 (Stakeholder Team)**
- Epidemiology (101)
 - Study Aims, Steps, and Timeline
 - Workflow and Health Portal Training
 - Recruitment and Survey Techniques
 - Quality Control SOPs and Reporting Adverse Events
 - Home Visit Protocol
 - Ethics and Human Subjects Protection
 - Household Member Consent
 - Home Assessments (Intervention, Surveys and Specimen Sampling)
 - MRSA + "101"
 - Treatment Adherence Promotion
- Part 2 (CHW Network of New York City and Health Innovation Associates)**
- Health, Public Health, and Healthcare
 - CHW History
 - CHW Roles, Skills, and Tasks
 - Teaching and Communication Skills
 - Health Promotion Training
 - Clinical Skills and Home-Based Training

We recruited 10 CHWs, 9 underwent training, and 8 successfully completed training (80%). The curriculum consisted of a seven-day, 49-hour training which was conducted in two parts. Part One was conducted by members of the stakeholder team from CDN, The Rockefeller University, participating CHCs, The Mason Lab at Weill Cornell, and My Own Med. Part Two was conducted by the Community Health Worker Network of New York City and Health Innovation Associates.

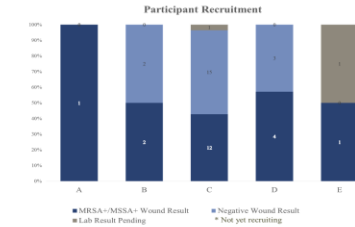


Clinician Training



RESULTS

Participant Recruitment and Eligibility (n=15)



Of the n=42 patients who have been recruited to date (lab results pending for n=1 patient), we have enrolled n=20 (7.2% of goal) patients with MRSA+ or MSSA+ wound results. The *S. aureus* positivity rate is 48.8% (n=20 of 41)

NEXT STEPS

To date we have recruited six sites, of which two are Community Health Centers and four are Community Hospitals, finalized the protocol, obtained IRB approvals, hired and trained Community Health Workers to conduct the home visits, trained clinicians at participating sites, created a web-based health portal for data collection, and refined the sampling methodology. The household has been established as an important persistent community reservoir for *S. aureus*.¹⁴ Family members of index cases may be asymptomatic carriers with identical or closely related strains¹⁴, and MRSA colonization in the outpatient setting may recur due to the presence of concurrently colonized household members.⁷ Studies conducted in hospital ICU settings have identified effective strategies for decolonization/decontamination that reduce recurrence,⁸⁻¹⁰ but have not been tested in primary care settings such as FQHCs.^{14,15} This study aims to test the effectiveness of employing these techniques in the primary care setting.

This study aims to test whether a CHW-delivered home-based intervention for decolonization and environmental decontamination is more successful at preventing CA-MRSA infection recurrence than CDC-guidelines based care (incision and drainage and antibiotics). It will contribute providing a more complete picture of the CA-MRSA home environment with the larger goal of evaluating its role in disease treatment, recurrence, and transmission.

References:

1. Pastagia M, Tomasz A, Hernandez A, Davis B. Transmission of methicillin-resistant *Staphylococcus aureus* in a household. *Emerging Infectious Diseases*. 2010;16(10):1594-1596.
2. CDC. MRSA: antibiotic resistance in staphylococcus aureus. <http://www.cdc.gov/mrsa/>
3. CDC. MRSA: antibiotic resistance in staphylococcus aureus. <http://www.cdc.gov/mrsa/>
4. CDC. MRSA: antibiotic resistance in staphylococcus aureus. <http://www.cdc.gov/mrsa/>
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14. CDC. MRSA: antibiotic resistance in staphylococcus aureus. <http://www.cdc.gov/mrsa/>
15. CDC. MRSA: antibiotic resistance in staphylococcus aureus. <http://www.cdc.gov/mrsa/>

FUNDING:

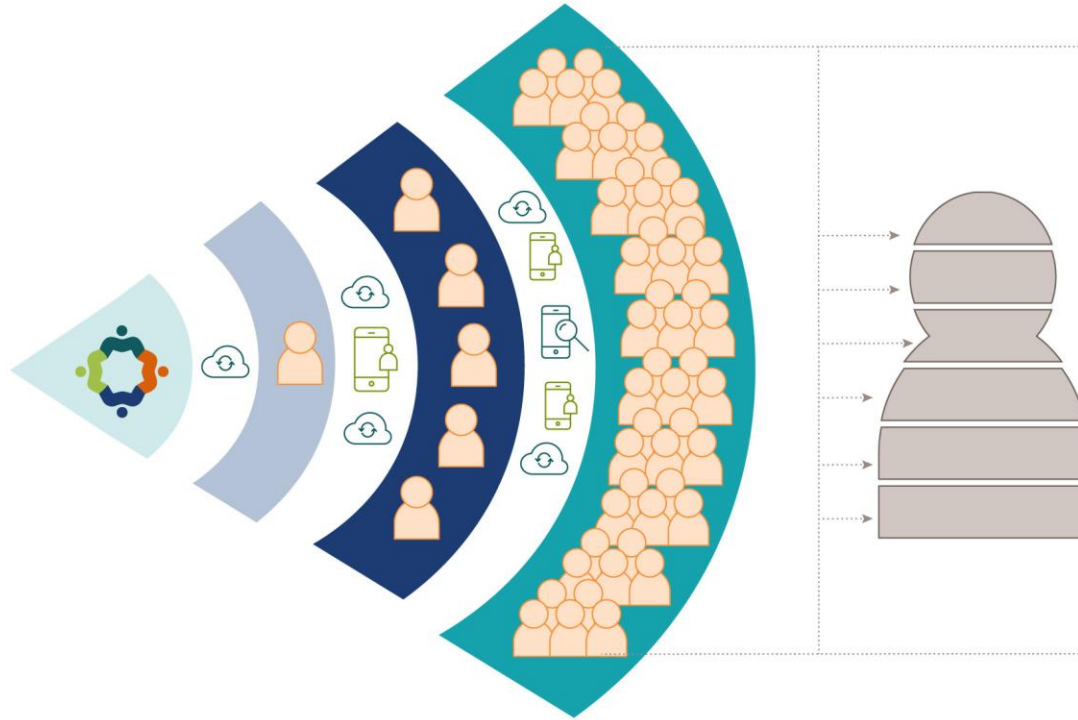
1. Patient-Centered Outcomes Research Institute (PCORI), Grant # CEIR-1402-18000
2. The Rockefeller University, Clinical and Translational Science Center (CTSC) and an Administrative Supplement and Pilot Project Research (PBRN-NCATSUSL1-TR-00043)
3. NY-PBRN Building a Network of Safety Net PBRNs (APRQ Grant #1-F30-HS-021667)

In the Field- Bringing HCP to Patients

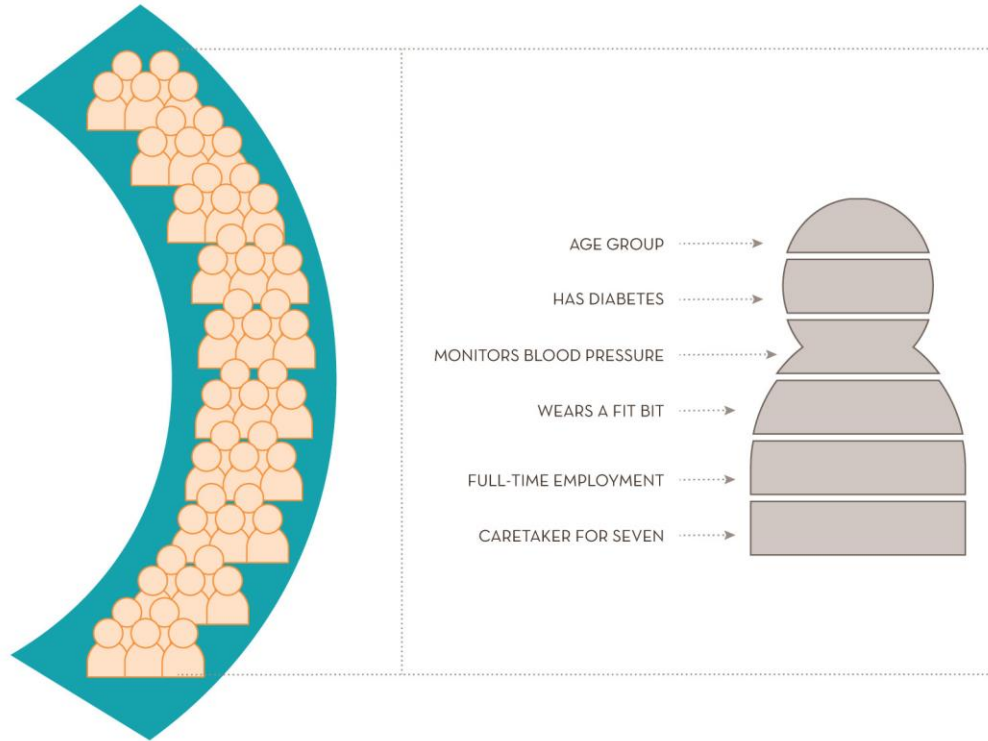


- **Health Professionals – Appointments at Classes or GPS**
 - Med Tech - Medical Technician
 - PCT- Patient Care Technician
 - HHA Home Health Aide
 - CNA Certified Nurses Assistant
 - GNA - Geriatric Nurses Assistance
 - GCM - Geriatric Care Manager
 - CMA - Certified Medical Assistant
 - LPN - Licensed Practical Nurse
 - RN - Registered Nurse
- **Services Performed:**
 - Phlebotomy
 - Infusions / Injections
 - EKG
 - First Aid
 - CPR
- **Recruiting** – 200 people a month
 - Vitals, observations, interviews, errands, med management- \$20- \$25 hr.
 - Infusions, blood draws \$30-\$35 hr.

Building Connected Networks for Research



Networks for Retrospective and Prospective Research



Thank you!

Trang Gisler, SVP, Operations

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