

**PRACTICE -  
BASED  
RESEARCH**



**CLINICIAN  
PATIENT  
COMMUNITY  
STAKEHOLDER  
ENGAGEMENT**

**PARTNERSHIP  
DEVELOPMENT**

**Community Engaged Research  
Jonathan N. Tobin, PhD**

**Presented at:  
The Rockefeller University  
Certificate Program in  
Clinical & Translational Research  
October 16, 2020**



**EDUCATION  
&  
TRAINING**



THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE



**DISSEMINATION  
&  
IMPLEMENTATION  
RESEARCH**



THE ROCKEFELLER UNIVERSITY HOSPITAL

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE



## PRESENTATION OVERVIEW

- Provide an overview of Clinical Directors Network (CDN), the practice-based research network (PBRN)
- Describe CDN's work with CTSA's, and with The Rockefeller University Center for Clinical and Translational Science (RU-CCTS)
- Describe the research and training partnerships – both academic and community
- Highlight selected examples of Community-Academic Collaborative Community Engaged Research (CEnR) studies

# ABOUT US

Clinical Directors Network, Inc. (CDN) is a not-for-profit clinician membership organization, practice-based research network (PBRN), and clinician training organization, founded to provide peer-initiated activities for clinicians practicing in low income, minority, and other underserved communities.

Translating research into practice for the enhancement of health equity and improvement of public health

## MISSION

We exist to advocate for meeting the health needs of underserved populations, while providing access to high quality health care, and greater social justice for all.



## VALUES

We believe that:

1. All people have the right to high quality, community-based health care
2. Practicing in a community-based health care center is a desirable, viable long-term career choice for clinicians
3. Practice-based research should be relevant, practical and timely
4. Research at the community-based health care center level supports the dissemination, adoption and implementation of new knowledge, resulting in sustained high quality of care, increasing health equity, and the improvement of public health

# CDN'S PRIMARY ACTIVITIES

## RESEARCH

We accelerate research translation. CDN has over 25 years of experience developing, conducting, implementing and evaluating practice-based research with Community Health Centers and other safety-net practices.

## EDUCATION

We provide peer support through training and education that integrates online and on-site didactic and experiential learning. Collaborate with us to meet your training needs.



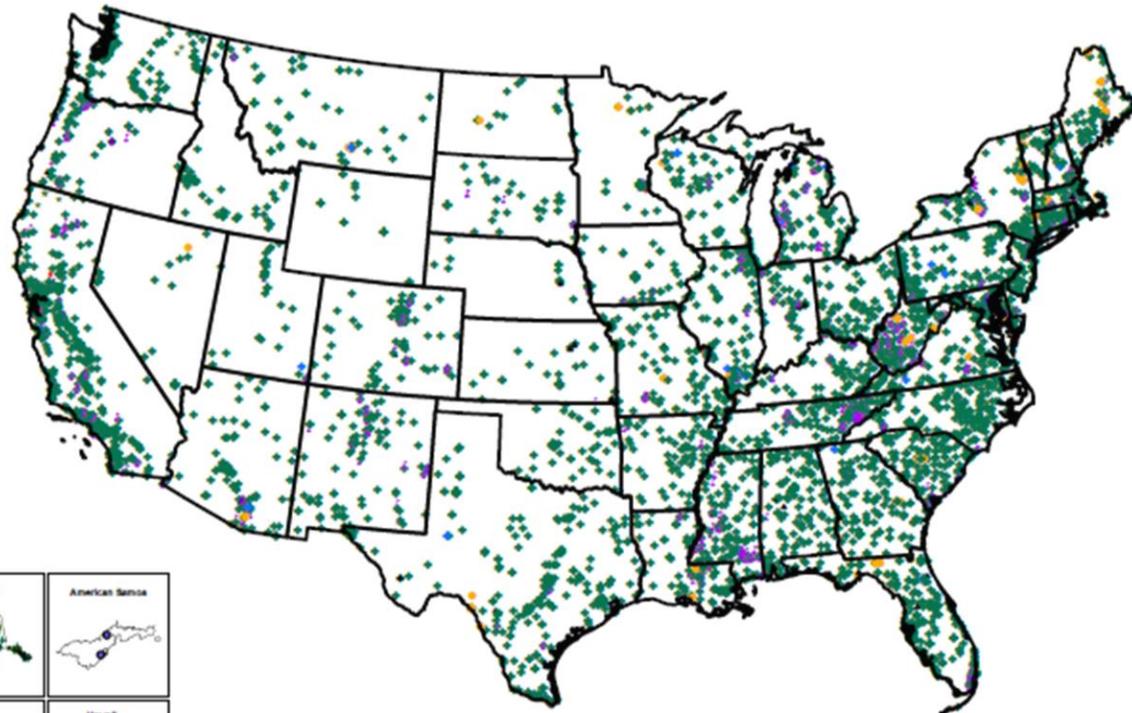
## PARTNERSHIP

We conduct research and educational activities in partnership with government, academic, not-for-profit, and for profit organizations. CDN has an extensive network of multidisciplinary researchers, clinicians, clinical leaders and policy-makers.

## DISSEMINATION

We provide dissemination services through webcasts for public health and clinical research projects. CDN has extensive experience disseminating research and training programs to our extensive network of multidisciplinary researchers, clinicians, clinical leaders and policy-makers.

# DHHS – HRSA: The Primary Health Care Safety-Net



**Health Centers - by Location Setting**

- Community Health Centers
- Correctional Facility
- Domestic Violence
- Hospital
- Nursing Home
- School
- Tribal
- All Other Types

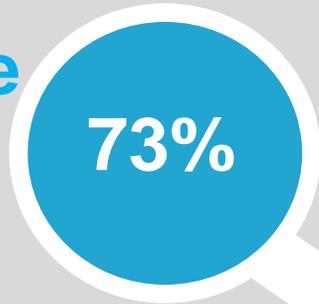
Prepared by: HRSA, Office of Information Technology  
 from the HRSA Data Warehouse,  
[datawarehouse.hrsa.gov](http://datawarehouse.hrsa.gov)

<u>FACILITIES, PATIENTS &amp; VISITS</u>	<u>National</u>	<u>New York</u>
<b>Total # Grantees</b>	1,367	65
<b>Total # Delivery Sites</b>	10,847	676
<b>Total # Medical Users</b>	21,880,295	1,698,867
<b>Total # Medical Encounters</b>	71,297,375	6,174,700
<b>Total # Dental Users</b>	5,656,190	466,656
<b>Total # Dental Encounters</b>	14,420,355	1,198,612
<b>Total # Medical/Dental Users</b>	25,860,296	2,038,538

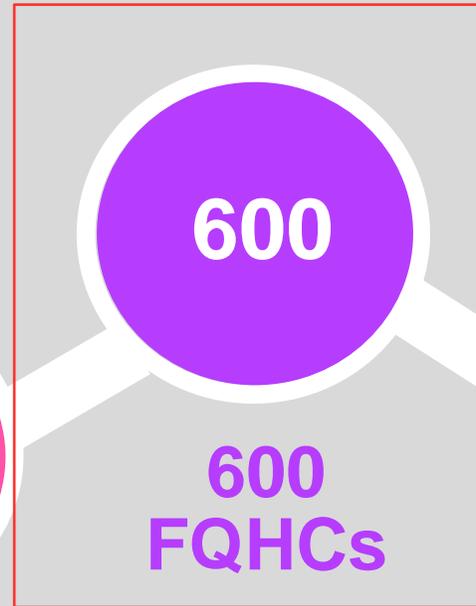
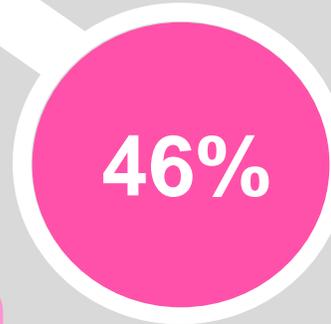
# CDN'S RECRUITMENT PORTFOLIO

1992-PRESENT

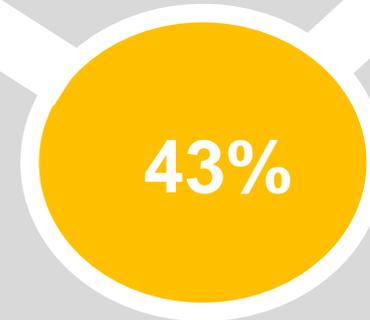
73%  
Female



46%  
African -  
American



360,000 +  
Patients  
Enrolled



43%  
Latino/a



**CDN has enrolled >13670,000 low income, minority, medically underserved patients into clinical trials and observational studies**



**A PRACTICE-BASED RESEARCH NETWORK (PBRN) THAT WORKS WITH FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs) AND OTHER PRIMARY HEALTH CARE SAFETY-NET PRACTICES**

CDN has built a **scalable research infrastructure** to serve the needs of the clinicians who practice in the **health care safety-net** by building on existing infrastructure, creating **new relationships**, providing **external practice facilitators (online, remote)**, and **dissemination channels**

DHHS – HRSA: The Primary Health Care Safety-Net



CDN N2-PBRN



## PBRN Partners

- Access Community Health Network (ACCESS)
- Alliance of Chicago (ALLIANCE)
- Association of Asian Pacific Community Health Organization (AAPCHO)
- Center for Community Health Education Research and Service (CCHERS)
- Clinical Directors Network (CDN) [LEAD PBRN]
- Community Health Applied Research Network (CHARN)
- Fenway Institute (FENWAY)
- New York City Research and Improvement Group (NYCRING)
- Oregon Community Health Information Network (OCHIN)
- South Texas Ambulatory Research Network (STARNet)
- Southeast Regional Clinicians Network (SERCN)
- Florida Clinical Research Consortium (One Florida)

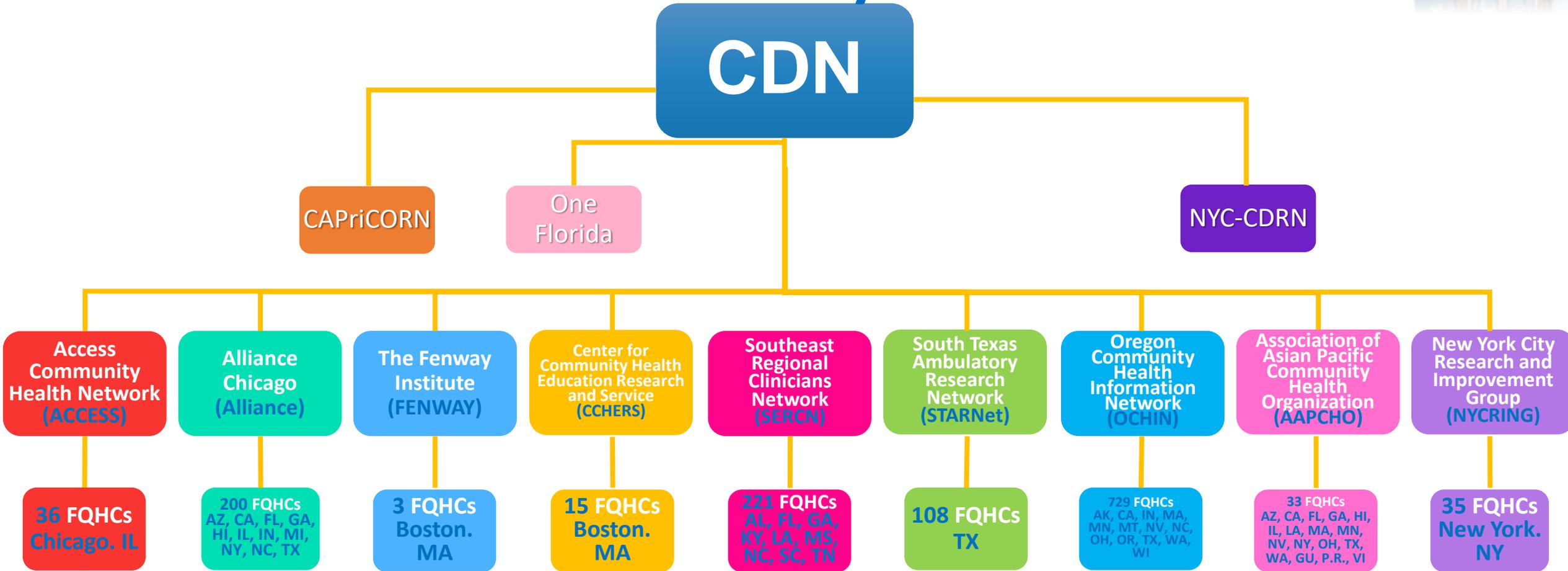
FACILITIES, PATIENTS & VISITS	National	New York
Total # Grantees	1,367	65
Total # Delivery Sites	10,847	676
Total # Medical Users	21,880,295	1,698,867
Total # Medical Encounters	71,297,375	6,174,700
Total # Dental Users	5,656,190	466,656
Total # Dental Encounters	14,420,355	1,198,612
Total # Medical/Dental Users	25,860,296	2,038,538

**AHRQ Center of Excellence for Practice-based Research and Learning**



# CDN N<sup>2</sup> PBRN

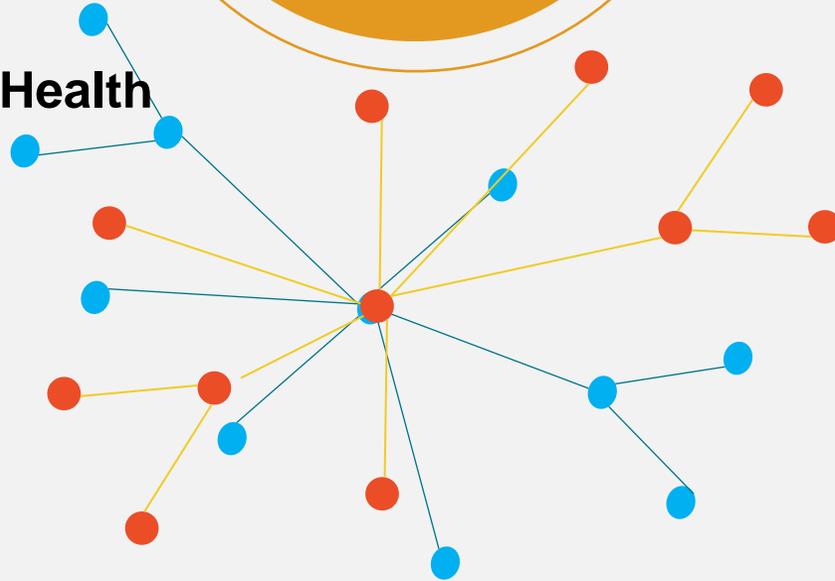
## Network of Safety-net PBRNs





**N<sup>2</sup> PBRN  
ACADEMIC  
PARTNERS &  
VIRTUAL  
FACULTY**

- **Albert Einstein College of Medicine/  
Montefiore Medical Center**
- **Boston University**
- **Columbia University**
- **Dartmouth Medical School**
- **Harvard University**
- **Kaiser Permanente Center for Health  
Policy Research**
- **New York University**
- **Northwestern University**
- **Oregon Health and Science  
University**
- **University of California/San  
Francisco (UCSF)**



- **University of California/Los  
Angeles (UCLA)**
- **RAND Corporation**
- **The Rockefeller University**
- **Tufts University**
- **University of Chicago**
- **University of Illinois at Chicago**
- **University of Miami**
- **University of Michigan**
- **University of Oregon**
- **University of Washington**
- **Weill Cornell**
- **Yale University**



# The Rockefeller University

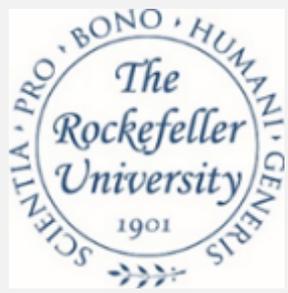


- Unique structure
  - 82 heads of labs
  - 26 Nobel prizes, 24 Lasker Awards, 20+ National Medals of Science
  - 100+ year tradition of translational research
  - 40 bed JCAHO-accredited research-only hospital
  - AAHRPP-accredited
- 250 protocols
  - 80% investigator - initiated
  - 20% phase I, II, III or device trials
- Center for Clinical Translational Science (2006 – Present)
  - Community Engaged Research Core:
    - **Addressing Basic Mechanistic Questions**
    - **Within Community-based Comparative Effectiveness Studies**

## CDN N<sup>2</sup>: Building a Network of Safety Net PBRNs AHRQ Center of Excellence for Practice-based Research and Learning

- ▶ **A Practice-based Research Network (PBRN)** that works with Federally Qualified Health Centers (FQHCs) and other Primary Health Care Safety-net Practices
- ▶ **Research Infrastructure to build a Learning Healthcare System**
- ▶ **A collaboration among:**
  - Access Community Health Network (ACCESS)
  - Alliance of Chicago (ALLIANCE)
  - Association of Asian Pacific Community Health Organization (AAPCHO)
  - Center for Community Health Education Research and Service (CCHERS)
  - **Clinical Directors Network (CDN) [LEAD PBRN]**
  - Community Health Applied Research Network (CHARN)
  - Fenway Institute (FENWAY)
  - New York City Research and Improvement Group (NYCRING)
  - Oregon Community Health Information Network (OCHIN)
  - South Texas Ambulatory Research Network (STARNet)
  - One Florida

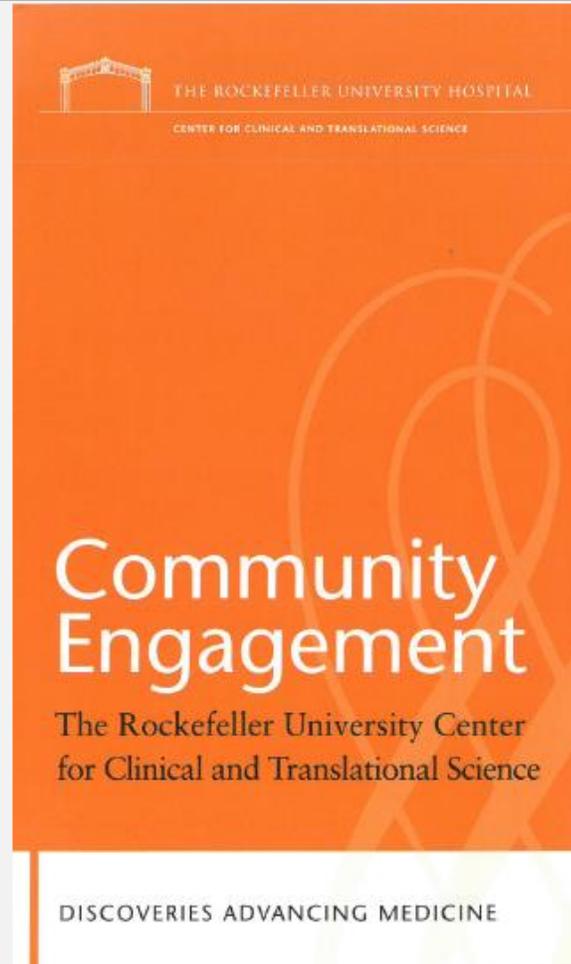




# THE ROCKEFELLER UNIVERSITY CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE *COMMUNITY-ENGAGED RESEARCH CORE*



**RHONDA G. KOST, M.D. & JONATHAN N. TOBIN, Ph.D.**  
**CO-DIRECTORS, COMMUNITY-ENGAGED RESEARCH CORE**



# BUILDING COMMUNITY-ACADEMIC TRANSLATIONAL RESEARCH PARTNERSHIPS

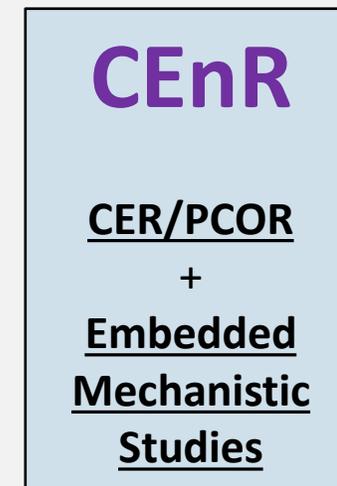
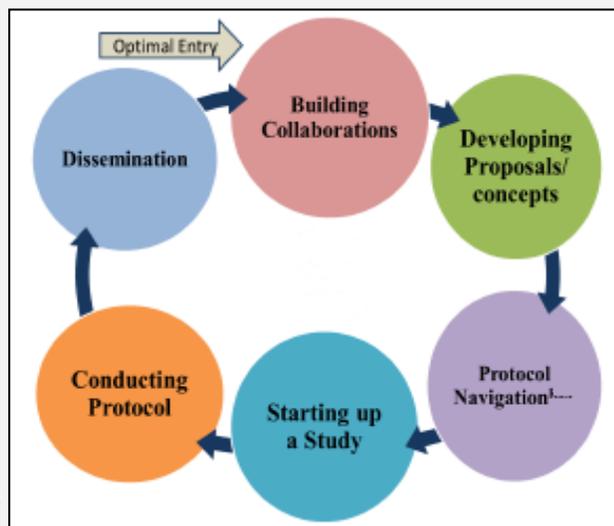
## CDN/N<sup>2</sup> = PBRN INFRASTRUCTURE<sup>1</sup>

- Quality Improvement
- Clinical Outcomes
- Comparative Effectiveness Research
- Patient Centered Outcomes Research (CER/PCOR)
- Training Clinician Investigators
- Implementation Science
- Disseminating Methods & Clinical Outcomes Results



## ROCKEFELLER = CTSA INFRASTRUCTURE<sup>2</sup>

- Laboratory Investigation
- Mechanistic Questions
- Protocol Navigation
- Clinical Scholars
- Bioinformatics/Phenotyping
- Disseminating Translational Research Methods



*CEnR-Navigation Process (CEnR-Nav)<sup>2</sup>  
[Investigators and partners  
may enter at any stage]*

<sup>1</sup> N<sup>2</sup>- Building a Network of Safety Net PBRNS, <https://www.pbrn.ahrq.gov/sites/default/files/docs/page/N2.pdf> ; <sup>2</sup> Kost, et al. Academic Medicine. 2017;92(3):374.

# KEY ATTRIBUTES OF THE RU-CDN TRANSLATIONAL RESEARCH MODEL

- Conducting rigorous practice-based comparative effectiveness/health outcomes research in collaboration with academic investigators, community-based clinicians and staff, patients, and other stakeholders
- Engaging FQHCs and Primary Care Clinicians as investigators
- Embedding basic science & mechanistic questions into clinical studies conducted in practice-based settings



LITTLE DATA

# CAMP1 & CAMP2 Stakeholders and Partners

## The Rockefeller University

Barry Collier, MD  
 Rhonda Kost, MD  
 Alexander Tomasz, PhD  
 Herminia de Lencastre, PhD  
 Maria Pardos de la Gandara, MD, PhD  
 Marilyn Chung, BA  
 Cameron Coffran, MS  
 Joel Correa da Rosa, PhD  
 Kimberly Vasquez, MPH  
 Teresa Evering, MD, MS  
 Mina Pastagia, MD, MS  
 Maija Neville-Williams, MPH

## CDN

Jonathan Tobin, PhD  
 Chamanara Khalida, MD, MPH  
 Brianna D'Orazio, BA  
 Tameir Holder, MPH  
 Musarrat Rahman, BS  
 Sisle Heyliger, BA  
 Anthony Rhabb  
 Cynthia Mofunanya  
 Jessica Ramachandran  
 Uma Siddiqui

## Metropolitan Hospital Center

Getaw Worku Hassen, MD, PhD  
 Jessica Ramachandran, MBBS  
 \*Van Johnson

## Coney Island Hospital

Regina Hammock, DO  
 Slava Gladstein, DO  
 Rosalee Nguyen, DO, MS  
 \*Ronnett Davis

## Community Healthcare Network

Satoko Kanahara, MD  
 Katrina Adams

## Academic Stakeholders

Christopher Frei, PharmD, MSc, FCCP, BCPS  
*South Texas Ambulatory Research Network/UTHSCSA*  
 Christopher Mason, PhD  
*Weill Cornell Medical College*  
 Eric Lofgren, PhD  
*Washington State University College of Veterinary Medicine*  
 Susan Huang, MD, MPH  
*University of California Irvine*

## NYU Lutheran Family Health Centers

William Pagano, MD, MPH  
 Paula Clemons, PA  
 Jason Hyde, MA  
 Jasbir Singh, MBBS  
 \*Keenan Millan

## Open Door Family Medical Center

Daren Wu, MD  
 Asaf Cohen, MD

## Urban Health Plan

Samuel DeLeon, MD  
 Franco Barsanti, PharmD  
 Shirish Balachandra, MD  
 Claude Parola, MD  
 Tracie Urban, RN  
 \*Brenda Gonzalez

## Hudson River Health Care

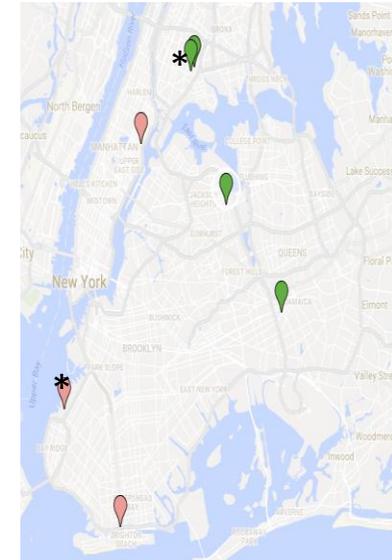
Carmen China, MD  
 Nancy Jenks, NP

## Manhattan Physician's Group

Ronda Burgess, RN

## PCORI Project Officers

Anne Trontell, MD, MPH  
 Jess Robb



- Community Health Centers
- Community Hospitals
- \* Participated in Previous MRSA Studies



Funded by:  
 Patient Centered Outcomes Research Institute (PCORI, CONTRACT # CER-1402-10800)  
 The Rockefeller University Center for Clinical and Translational Science (CCTS)  
 Pilot Grant and Administrative Supplement (NIH-NCATS Grant #8-UL1-TR000043)  
 AHRQ Grant # P30HS021667

# CAMP1 (Observational Cohort) & CAMP2 (CER/PCOR RCT)

## Stakeholders and Partners

### The Rockefeller University

Barry Collier, MD  
Rhonda G. Kost, MD  
Alexander Tomasz, PhD  
Herminia de Lencastre, PhD  
Maria Pardos de la Gandara, MD, PhD  
Marilyn Chung, BA  
Cameron Coffran, MS  
Joel Correa da Rosa, PhD  
Kimberly Vasquez, MPH  
Teresa Evering, MD, MS  
Mina Pastagia, MD, MS  
Maija Neville-Williams, MPH

### CDN

Jonathan N. Tobin, PhD  
Chamanara Khalida, MD, MPH  
Brianna D'Orazio, BA  
Tameir Holder, MPH  
Musarrat Rahman, BS  
Sisle Heyliger, BA  
Anthony Rhabb  
Cynthia Mofunanya, MD  
Jessica Ramachandran, MD  
Uma Siddiqui

### Funded by:

*Patient Centered Outcomes Research Institute (PCORI, CONTRACT # CER-1402-10800)*

*The Rockefeller University Center for Clinical and Translational Science (CCTS)  
Pilot Grant and Administrative Supplement (NIH-NCATS Grant # 8-UL1-TR000043)*

*AHRQ Grant # P30 HS 021667*

### Metropolitan Hospital Center

Getaw Worku Hassen, MD, PhD  
Jessica Ramachandran, MBBS  
\*Van Johnson

### Coney Island Hospital

Regina Hammock, DO  
Slava Gladstein, DO  
Rosalee Nguyen, DO, MS  
\*Ronnett Davis

### Community Healthcare Network

Satoko Kanahara, MD  
Katrina Adams

### Academic Stakeholders

Christopher Frei, PharmD, MSc, FCCP, BCPS  
*South Texas Ambulatory Research Network/UTHSCSA*  
Christopher Mason, PhD  
*Weill Cornell Medical College*  
Eric Lofgren, PhD  
*Washington State University College of Veterinary Medicine*  
Susan Huang, MD, MPH  
*University of California Irvine*

\*Patient/Community Stakeholders

### NYU Lutheran Family Health Centers

William Pagano, MD, MPH  
Paula Clemons, PA  
Jason Hyde, MA  
Jasbir Singh, MBBS  
\*Keenan Millan

### Open Door Family Medical Center

Daren Wu, MD  
Asaf Cohen, MD

### Urban Health Plan

Samuel DeLeon, MD  
Franco Barsanti, PharmD  
Shirish Balachandra, MD  
Claude Parola, MD  
Tracie Urban, RN  
\*Brenda Gonzalez

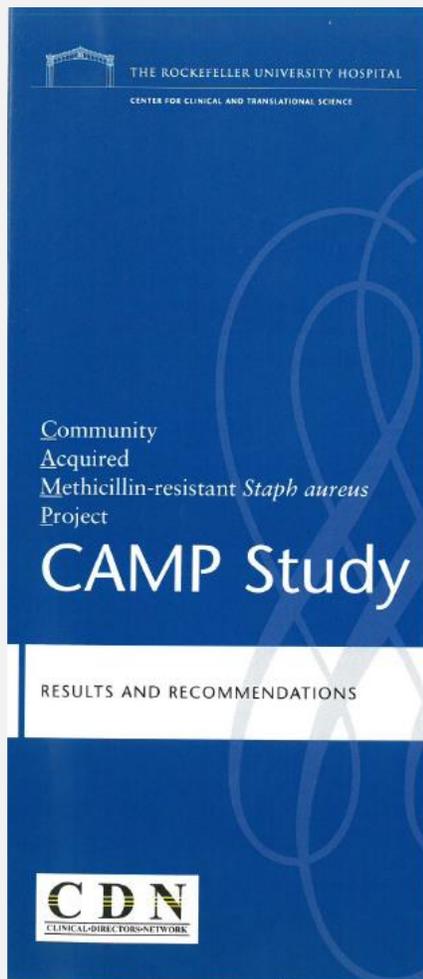
### Denny Moe's Superstar Barbershop

\*Dennis "Denny Moe" Mitchell

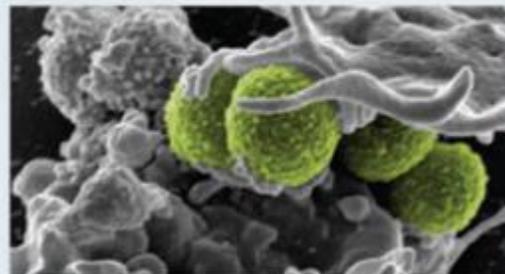
### PCORI Project Officers

Anne Trontell, MD, MPH  
Jess Robb





## Using Community Engagement to Tackle a Hard-to-Treat Bacterial Infection



Interaction of MRSA (green bacterial) with a human white cell. The bacteria shown is strain MRSA252, a leading cause of hospital-associated infections in the United States (National Institute of Biomedical Imaging and Bioengineering Photo).

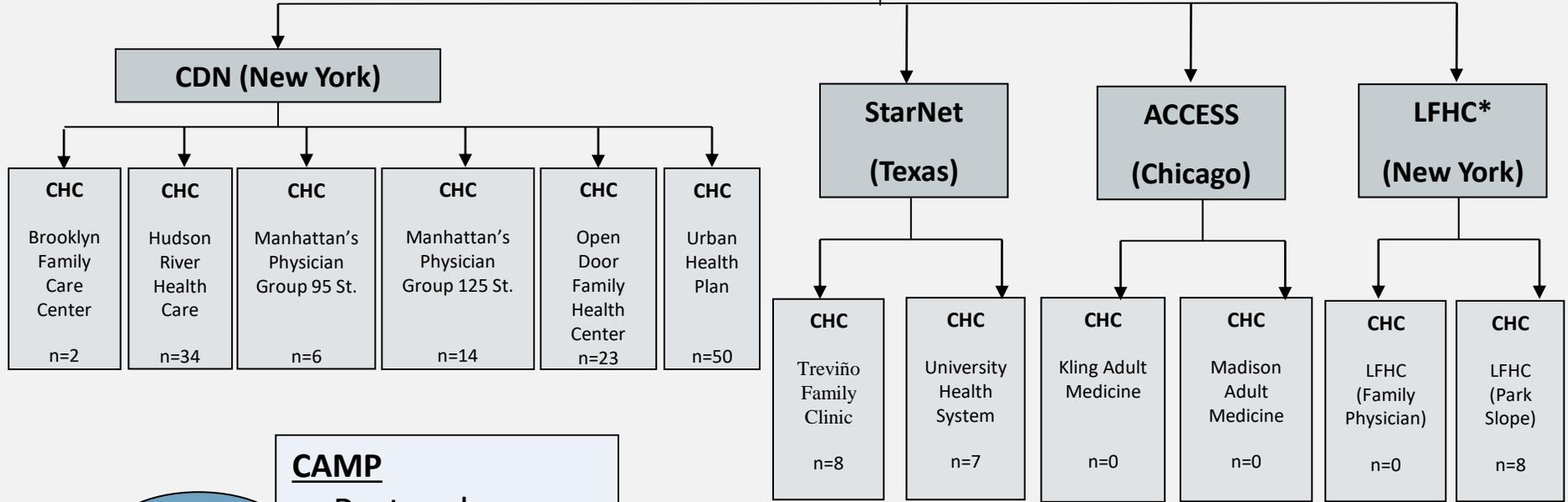
MRSA bacteria are resistant to many commonly used antibiotics and cause several hard-to-treat infections in humans. Although MRSA traditionally infects hospital patients, CA-MRSA also can infect healthy people who have not been hospitalized. Community clinicians identified CA-MRSA skin infection as an emerging problem in the FQHCs' patient population. The Rockefeller CE group provided training to community clinicians on best practices for treating CA-MRSA. Following the training, clinicians helped the project's MRSA scientific expert to design research questions related to the molecular biology of MRSA. In addition, the team developed a protocol for carrying out best practices and met regularly to advance the project at continuing medical education workshops.

Community and patient engagement are priorities for the CTSA program. The Rockefeller University CTSA's Community Engagement (CE) Core teamed with the Clinical Directors Network, a primary care practice-based research network that works with Federally Qualified Health Centers (FQHCs), to conduct a study on the significance of community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) infection in the health care setting. For the initiative, called the Community Acquired MRSA Project (CAMP), clinicians were engaged around the unmet clinical need related to MRSA, and basic scientists were involved to gain a better understanding of the molecular basis of MRSA bacteria. Using a team science-based approach and combining expertise in basic science with patient and community-driven research can simultaneously advance discovery that translates into improved patient care.

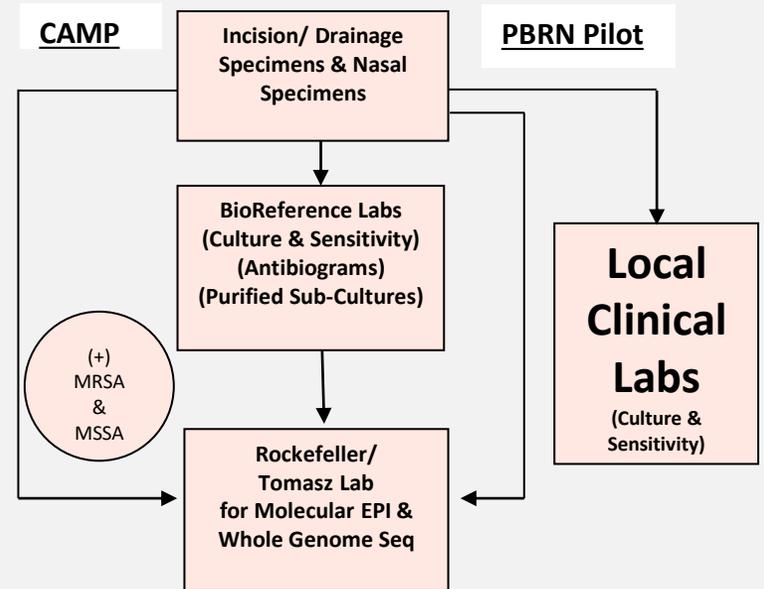
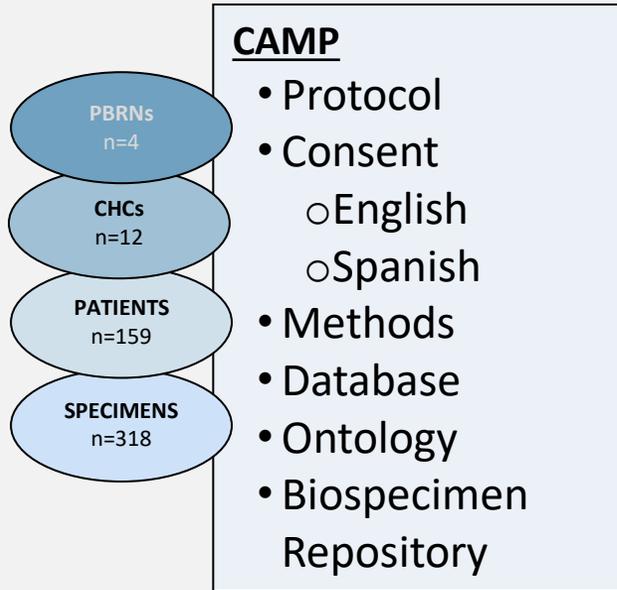
The clinicians engaged MRSA patients at Community Health Center town hall meetings, focus groups and information sessions to learn about their MRSA experiences and identify patients' priorities. Patients were most concerned about increasing their knowledge of MRSA infection. As a result, the interdisciplinary CE team developed a MRSA education and outreach project with local barbershops, an initiative that significantly increased community awareness and knowledge about MRSA infection and its prevention. The outcomes of this effort resulted in a second grant that began in November 2014. In the second phase of the project, patients, clinicians, scientists and local community health workers will be engaged to conduct household visits to test the effectiveness of strategies for preventing MRSA recurrence and reducing household transmission.

**CCTS Pilot → CTSA Administrative Supplement → PCORI CER R01**

# CDN PBRN<sup>2</sup>

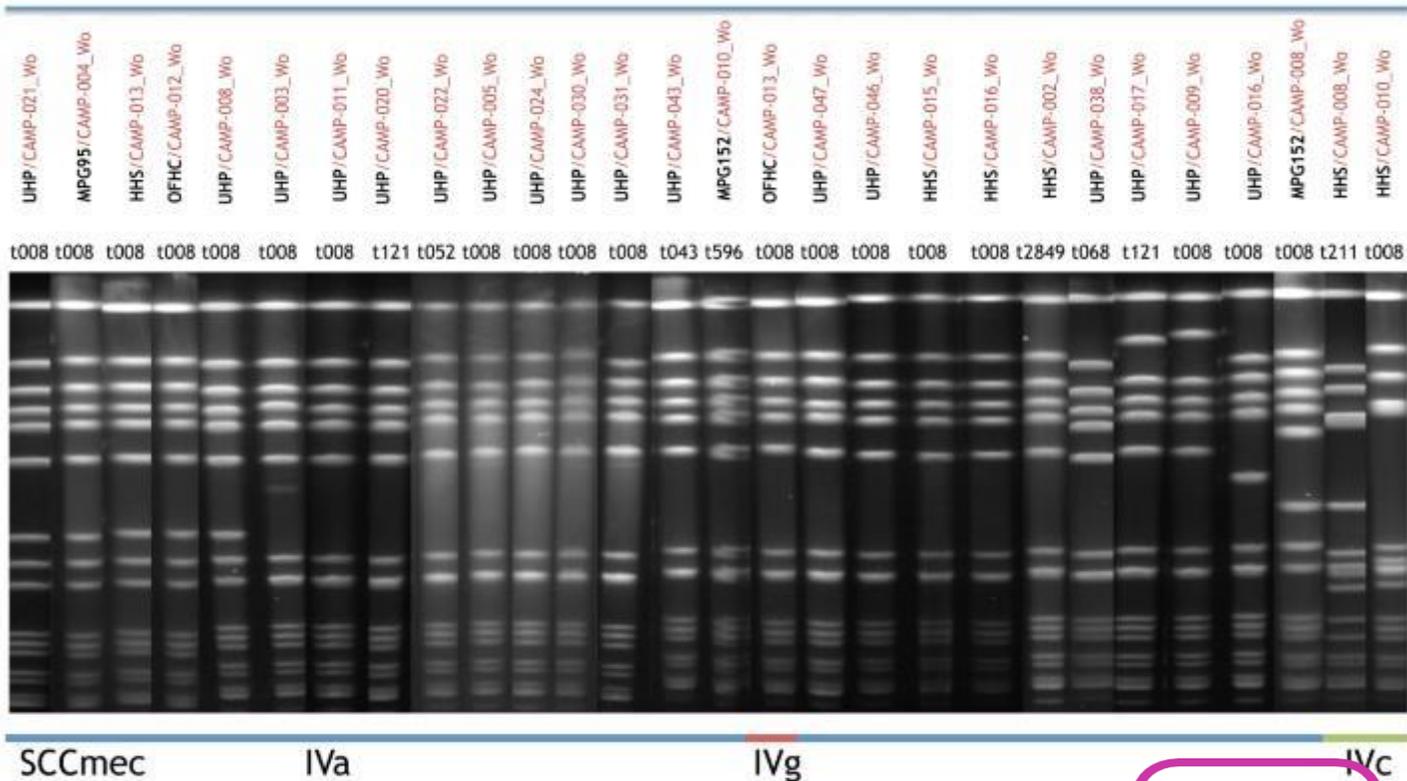


\*Incubator PBRN



# CA-MRSA Molecular Epidemiology: (T1 Laboratory Investigator Expertise/Interest)

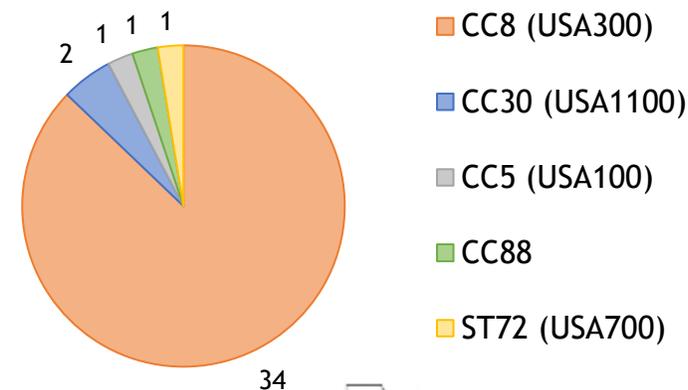
## Molecular profile of USA 300 MRSA wound isolates



All MRSA wound isolates belonging to the USA 300 clone (ST 8) were:

- *pvl* +
- ACME type I

## Clonal distribution of MRSA wounds

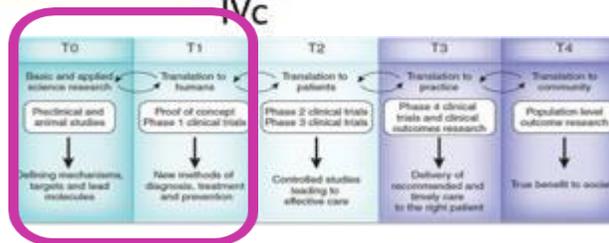


Molecular Types of Methicillin-Resistant *Staphylococcus aureus* and Methicillin-Sensitive *S. aureus* Strains Causing Skin and Soft Tissue Infections and Nasal Colonization, Identified in Community Health Centers in New York City

Maria Paredes de la Cruz<sup>1</sup>, Juan Antonio Regalado Garcia<sup>2</sup>, Mahesh Menegh<sup>3</sup>, Jonathan M. Tobin<sup>4</sup>, Andrew Tang<sup>1</sup>, Charissa Kalkbrenner<sup>5</sup>, Brian O'Connell<sup>6</sup>, Richard G. Boock<sup>7</sup>, Andreia Leal-Ferreira<sup>8</sup>, Gilberta Oliveira<sup>9</sup>, Teresa M. Fleming<sup>4</sup>, Barry S. Collier<sup>4</sup>, Shripal Bhattacharya<sup>4</sup>, Tracy Urban<sup>4</sup>, Charles Pinsky<sup>4</sup>, Scott Salzman<sup>4</sup>, Nancy Anon<sup>4</sup>, Dana Wu<sup>4</sup>, Ricardo Regalado<sup>4</sup>, Marilyn Chung<sup>4</sup>, Benjamin de Lencastre<sup>10</sup>, & Alexander Tomasz<sup>11</sup>

<sup>1</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>2</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>3</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>4</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>5</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>6</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>7</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>8</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>9</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>10</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA; <sup>11</sup>Division of Microbiology and Infectious Diseases, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA

In November 2011, The Rockefeller University Center for Clinical and Translational Science (CCTS), the Laboratory of Microbiology and Infectious Diseases, and Clinical Infection Network (CIN) launched a research and learning collaborative project with six community health centers in the New York City metropolitan area to determine the extent, clonal type, and community spread of methicillin-resistant *Staphylococcus aureus* strains causing skin and soft tissue infections (STIs). Between November 2011 and March 2013, wound and nasal samples from 129 patients with acute STIs (50 samples for *S. aureus* were collected and characterized by molecular typing techniques. In 65 of 129 patients, the skin wounds were infected by *S. aureus* methicillin-resistant *S. aureus* (MRSA) was recovered from 78 wounds and methicillin-sensitive *S. aureus* (MSSA) was recovered from 16. Most—46 of the 65 wound isolates belonged to the CC8 lineage. Validation studies also positive (PVL+) group of *S. aureus* clone USA300. 31 of these studies were MRSA and 12 were MSSA. Of the 65 patients with *S. aureus* infections, 30 were also colonized by *S. aureus* in the same site of colonization; 16 were MRSA and 14 were MSSA, and the majority of the colonizing isolates belonged to the USA300 clonal group. In most cases (79%), the colonizing isolates belonged to the same clonal type as the strains isolated with the infection. In three of the patients, the identity of the colonizing MRSA isolates was further corroborated by whole-genome sequencing.



# Patient-Centered CER Study of Home-based Interventions to Prevent CA-MRSA Infection Recurrence: CA-MRSA Project 2 (CAMP2)

Patient Centered Outcomes Research Institute (PCORI), Grant # CER-1402-10800

The Rockefeller University Clinical and Translational Science Award Program (CTSA) and an  
Administrative Supplement and Pilot Project Awards (NIH-NCATS Grant #UL1-TR-000043)

N<sup>2</sup>-PBRN: Building a Network of Safety Net PBRNs (AHRQ Grant #1 P30-HS-021667)



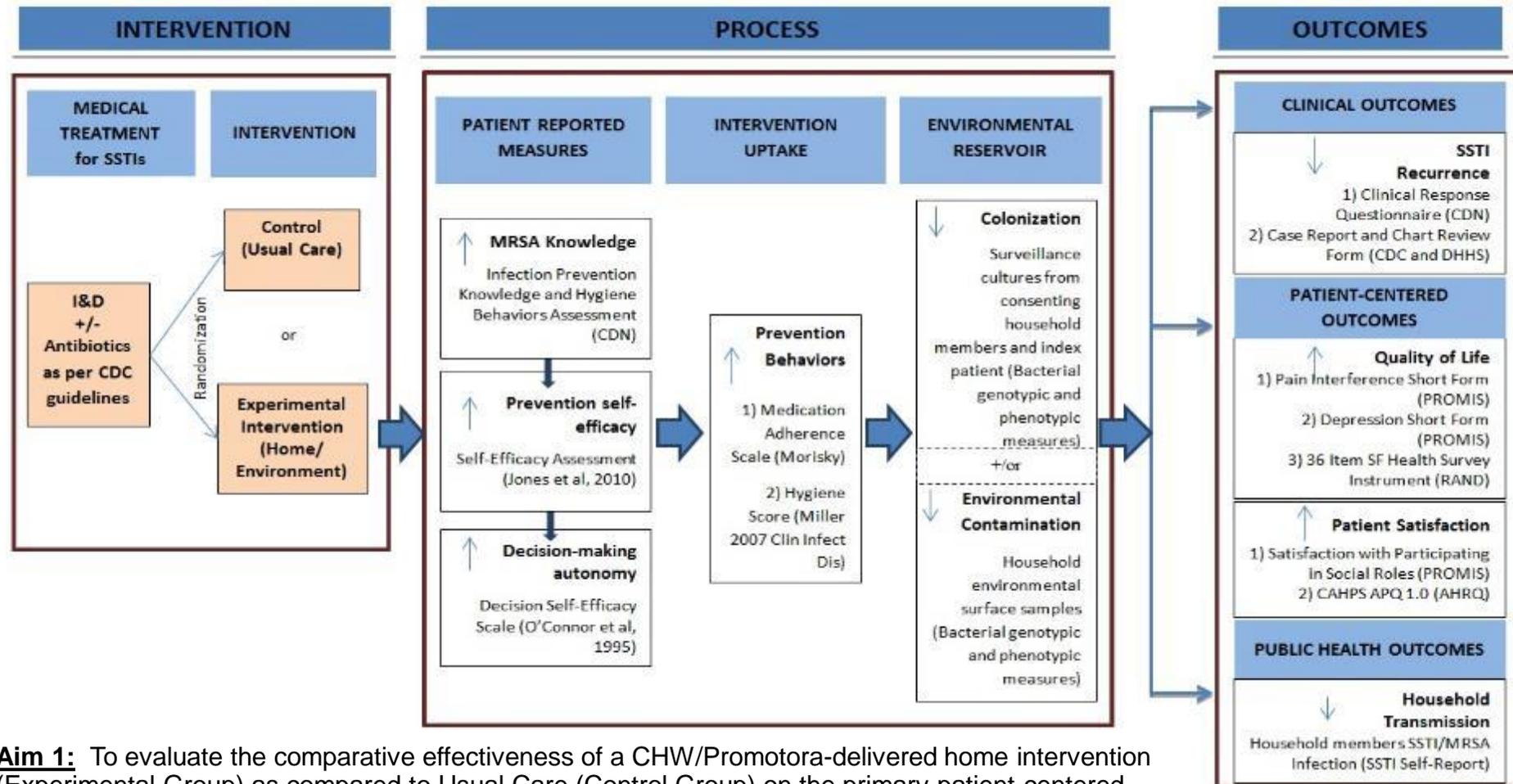
# OBJECTIVES

To evaluate the comparative effectiveness of a CHW/Promotora-delivered home intervention (Experimental Group) as compared to Usual Care (Control Group) on the primary patient-centered and clinical outcome (SSTI recurrence rates) and secondary patient-centered outcomes (pain, depression, quality of life, care satisfaction) and public health outcomes (household transmission) using a two-arm randomized controlled trial (RCT).



# CAMP2 Specific Aims

- **Aim 1:** To evaluate the **comparative effectiveness of a CHW/Promotora-delivered home intervention** (Experimental Group) as compared to Usual Care (Control Group) on the primary patient-centered and clinical outcome (SSTI recurrence rates) and secondary patient-centered and clinical outcomes (pain, depression, quality of life, care satisfaction) **using a two-arm randomized controlled trial (RCT)**
- **Aim 2:** To understand the **patient-level factors** (CA-MRSA infection prevention knowledge, self-efficacy, decision-making autonomy, prevention behaviors/adherence) and environmental-level factors (household surface contamination, household member colonization, transmission to household members) that are associated with differences in SSTI recurrence rates
- **Aim 3:** To understand **interactions of the intervention with bacterial genotypic and phenotypic** variables on decontamination, decolonization, SSTI recurrence, and household transmission
- **Aim 4 [Exploratory]:** To explore the **evolution of stakeholder engagement and interactions** among patients and other community stakeholders with practicing community-based clinicians and academic laboratory and clinical investigators over the duration of the study period



**Aim 1:** To evaluate the comparative effectiveness of a CHW/Promotora-delivered home intervention (Experimental Group) as compared to Usual Care (Control Group) on the primary patient-centered and clinical outcome (SSTI recurrence rates) and secondary patient-centered and clinical outcomes (pain, depression, quality of life, care satisfaction) using a two-arm randomized controlled trial (RCT).

**Aim 2:** To understand the patient-level factors (CA-MRSA infection prevention knowledge, self-efficacy, decision-making autonomy, prevention behaviors/adherence) and environmental-level factors (household surface contamination, household member colonization, transmission to household members) that are associated with differences in SSTI recurrence rates.

**Aim 3:** To understand interactions of the intervention with bacterial genotypic and phenotypic variables on decontamination, decolonization, SSTI recurrence, and household transmission.

**Aim 4 [Exploratory]:** To explore the evolution of stakeholder engagement and interactions among patients and other community stakeholders with practicing community-based clinicians and academic laboratory and clinical investigators over the duration of the study period.

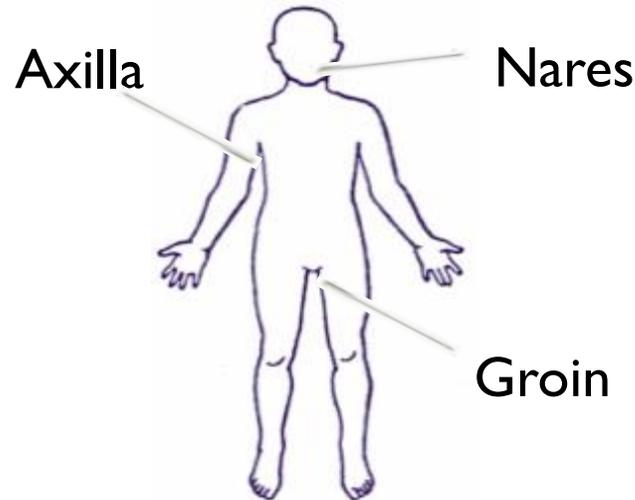
# CAMP2 Home Visit Assessment: Household Surface Sampling

Collected at Baseline and 3 Months Post Intervention from:

- Index patients (n=186)
- Consenting household members
- Home Environment Surfaces

**Environment**  
(n=13 surfaces per household)

**Index Patients and  
Household Members**  
(n=3 per participant)  
Baseline and 3-Months



## Surface to Swab

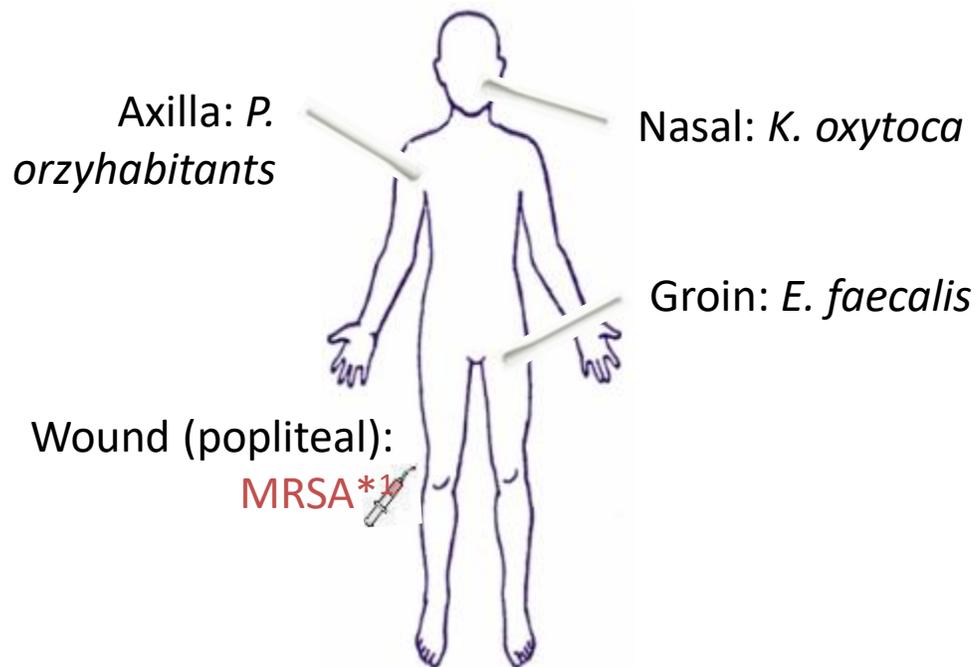
Front doorknob	Kitchen floor
TV remote	Bathroom sink handle
Telephone	Hair brush
Kitchen light switch	Toilet seat
Kitchen countertop	Bedroom floor
Refrigerator door handle	Favorite child's toy (non-plush)
Kitchen sink handle	

# CA-MRSA Molecular Epidemiology:

(T1 Laboratory Investigator Expertise/Interest)

## CAMP2 Case #32: Clinical samples

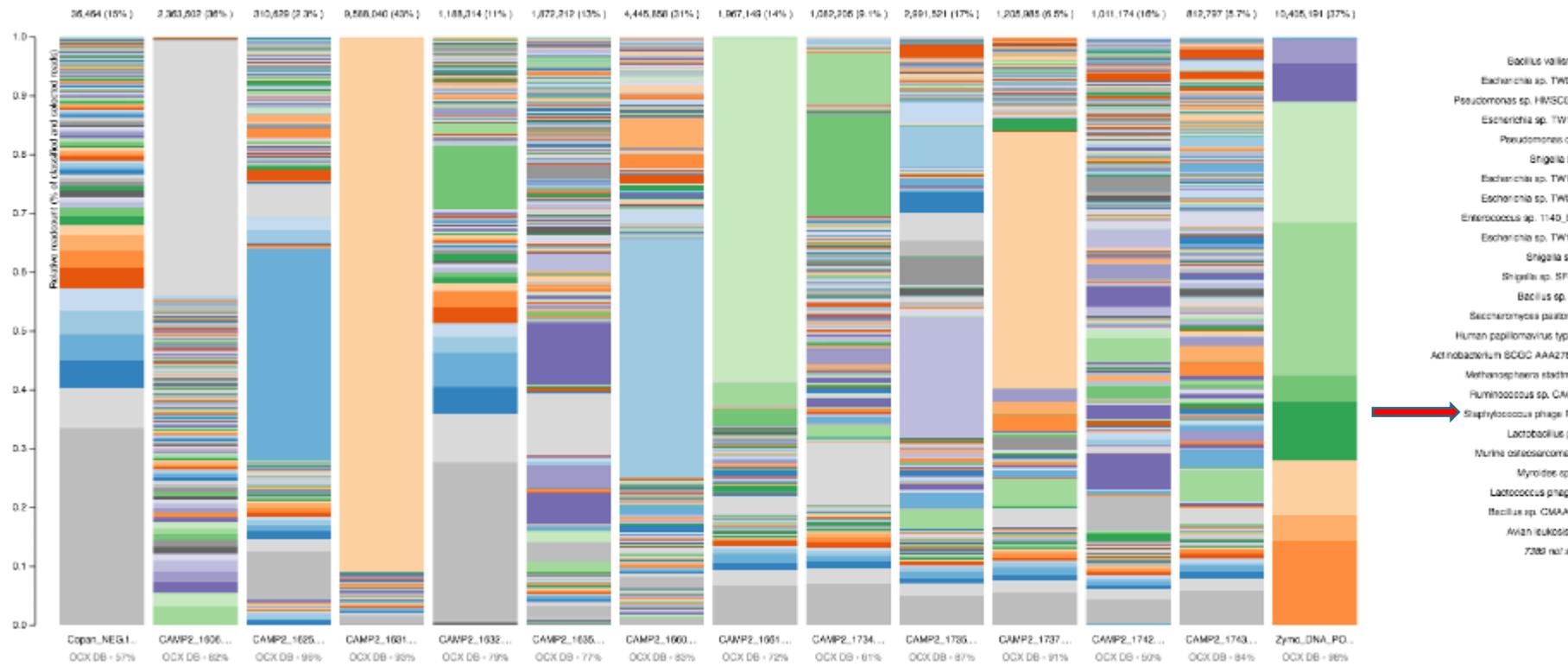
## Household #32, T1 Results



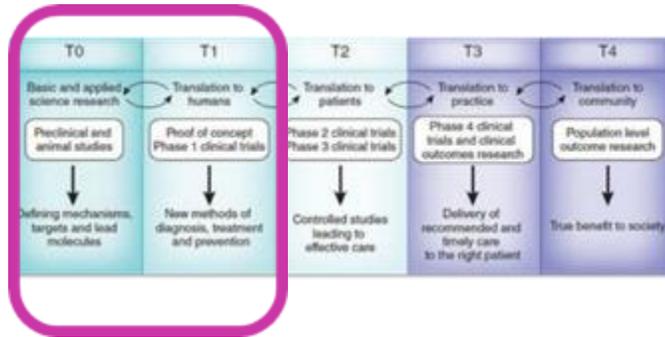
Location	<i>spa</i>	MLST	<i>mecA</i>	PVL	ACME	ATB
Wound	t318	ST30	—	+	—	OXA, ERY
Nasal	ND	ND	ND	ND	ND	ND
Axilla	ND	ND	ND	ND	ND	ND
Groin	ND	ND	ND	ND	ND	ND

Location	Material	<i>spa</i>	MLST	<i>mecA</i>	PVL	ACME
Index Patient	nasal	t318	ST30	—	+	—
Index Patient	axilla	—	ND	ND	ND	ND
Index Patient	groin	ND	ND	ND	ND	ND
H.H. Member #1	nasal	t1451	ST398	—	—	—
H.H. Member #1	axilla	ND	ND	ND	ND	ND
H.H. Member #1	groin	t1451	ST398	—	—	—
H.H. Member #2	nasal	ND	ND	ND	ND	ND
H.H. Member #2	axilla	ND	ND	ND	ND	ND
H.H. Member #2	groin	ND	ND	ND	ND	ND
H.H. Member #3	nasal	ND	ND	ND	ND	ND
H.H. Member #3	axilla	ND	ND	ND	ND	ND
H.H. Member #3	groin	ND	ND	ND	ND	ND
H.H. Member #4	nasal	t318	ST30	—	+	—
H.H. Member #4	axilla	t16335	ST508	—	—	—
H.H. Member #4	groin	—	ND	ND	ND	ND
H.H. Member #5	nasal	ND	ND	ND	ND	ND
H.H. Member #5	axilla	ND	ND	ND	ND	ND
H.H. Member #5	groin	ND	ND	ND	ND	ND
Front Door Knob	Metal	ND	ND	ND	ND	ND
Living TV Remote	Plastic	t318	ST30	—	+	—
Living Cell Phone	Glass	t318	ST30	—	+	—
Kitchen Light Switch	Plastic	ND	ND	ND	ND	ND
Kitchen Countertop	Formica	ND	ND	ND	ND	ND
Kitchen Refrigerator Handle	Plastic	ND	ND	ND	ND	ND
Kitchen Floor	Vinyl	—	ND	ND	ND	ND
Kitchen Sink Handle	Metal	ND	ND	ND	ND	ND
Bathroom Sink Handle	Metal	t318	ST30	—	+	—
Bathroom Hairbrush	N/A	ND	ND	ND	ND	ND
Bathroom Toilet Seat	Plastic	—	ND	ND	ND	ND
Bedroom Floor	Vinyl	t318	ST30	—	+	—
Bedroom Child's Toy	Plastic	ND	ND	ND	ND	ND

# Environmental Samples vs. Isolates:



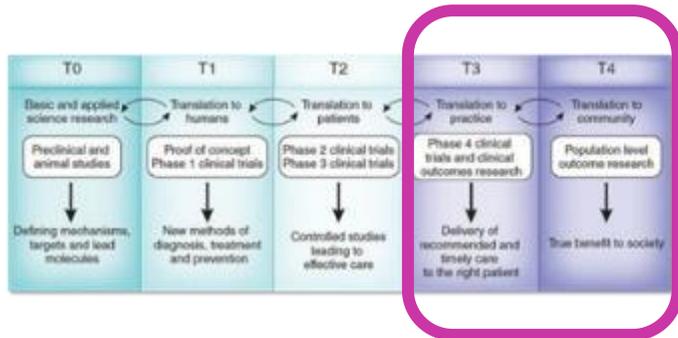
One Codex: A Sensitive and Accurate Data Platform for Genomic Microbial Identification, Samuel S Minot, Niklas Krumm, Nicholas B Greenfield  
 bioRxiv 027607; doi: <https://doi.org/10.1101/027607>



(T3/T4 Clinician & Public Health Investigators Expertise/Interest)

# CAMP2 Baseline Results (4/17/17)

Surveillance Site	Patient Colonization (n=135)	Household Member Colonization (n=40)	Household Surface Site	Household Surface Contamination (n=52)
			Nares	51.9%
Axilla	17.8%	17.5%	<b>Toilet seat</b>	<b>23.1%</b>
Groin	34.1%	25.0%	<b>Bedroom floor</b>	<b>21.2%</b>
0 Colonized sites	33.3%	67.5%	Refrigerator handle	13.5%
1 Colonized site	35.6% ]	15.0% ]	TV remote	11.5%
2+ Colonized sites	29.7% ] <b>65%</b>	17.5% ] <b>33%</b>	Telephone	11.5%
			Bathroom sink handle	11.5%
			Kitchen countertop	9.6%
			Kitchen light switch	5.8%
			Front doorknob	5.8%
			Child's toy	3.8%
			Hairbrush	3.8%
			Kitchen sink handle	1.9%
			No Contamination (0 surfaces)	40.4%
			Moderate Contamination (1-3)	48.1% ]
			High Contamination (> 4)	11.5% ] <b>60%</b>

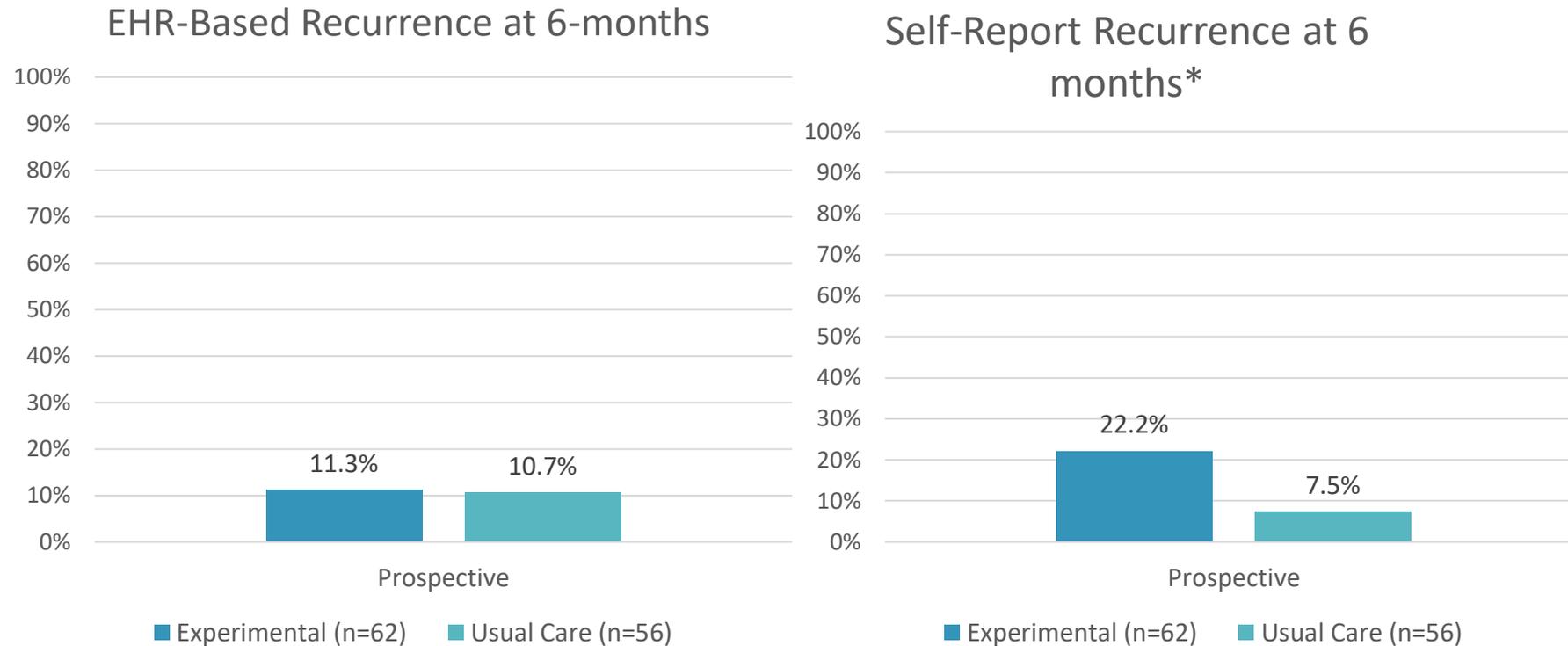


# Clinical & Secondary Outcomes

# Aim 1

- To evaluate the comparative effectiveness of a CHW/Promotora-delivered home intervention (Experimental group) as compared to usual care (Control group) on the primary patient-centered and clinical outcome (SSTI recurrence rates)
- Secondary outcomes included patient-centered and clinical outcomes (pain, depression, quality of life, care satisfaction)

# SSTI Recurrence at Six-Month Follow-Up<sup>1,2</sup>



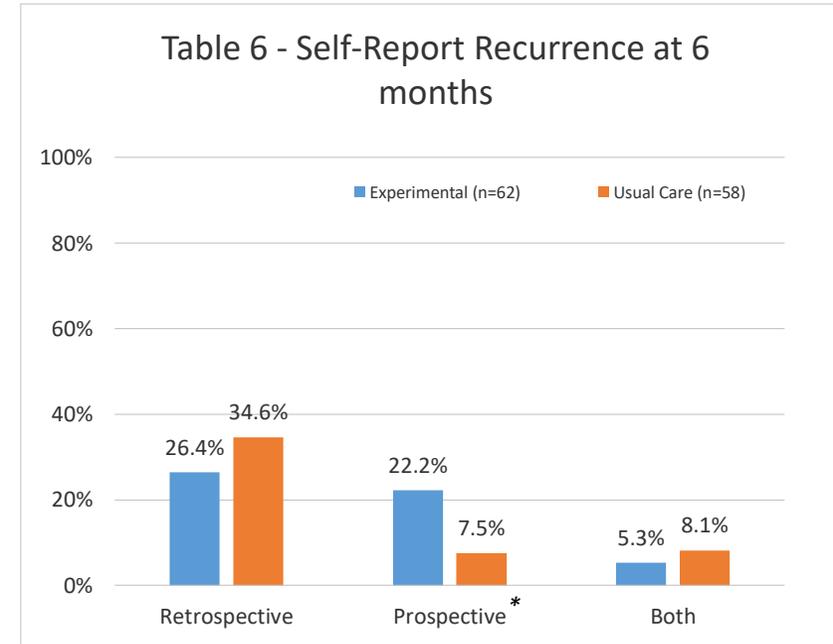
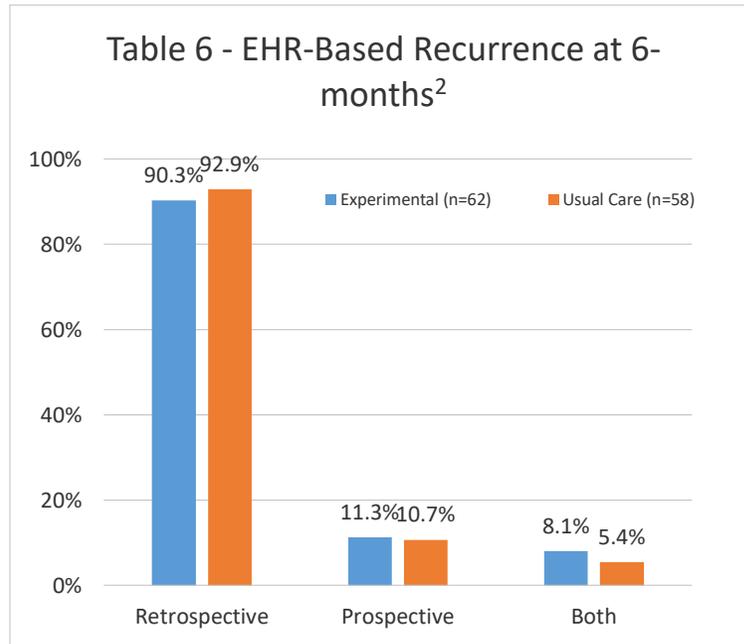
\* $p=0.07$

Notes:

<sup>1</sup>Prospective recurrence is defined as report of a new SSTI in the 6-month period following the initial (baseline) infection for which the participant was recruited. EHR-based outcomes were assessed at 6-months post-baseline and include the time period 12 months prior and 6 months after the baseline infection. Self-report prospective recurrence was assessed at the 6-month telephone assessment (T4).

<sup>2</sup>The observed prospective recurrence rate at 6 month EHR review for the Observation Only Group (n=66, 10.5%) was not different from either the Experimental (11.3%) or Usual Care (11.0%) or Total (10.8%).

# SSTI Recurrence at Six-Month Follow-Up<sup>1</sup>



\*p=0.07

Notes:

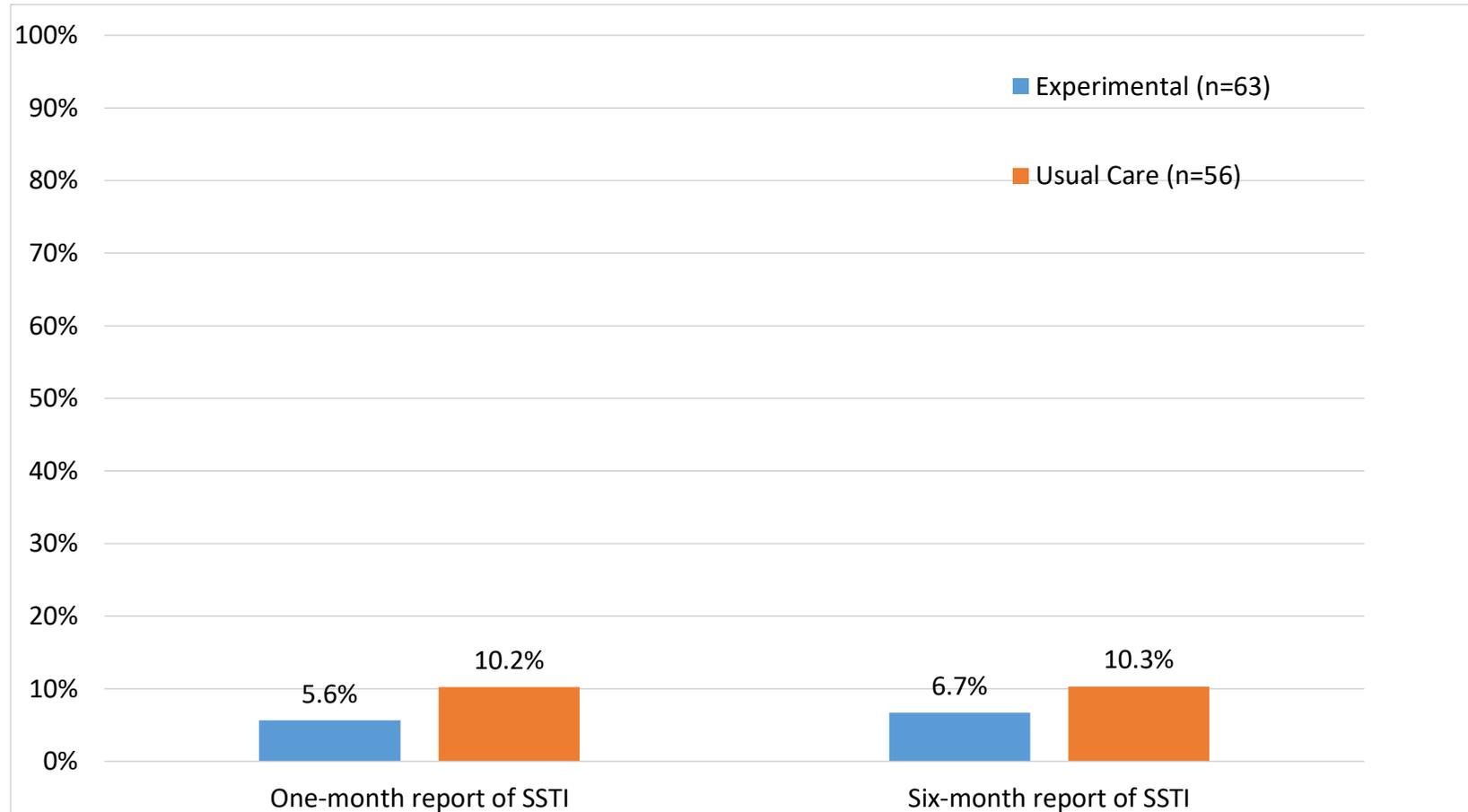
<sup>1</sup>Prospective recurrence is defined as report of a new SSTI in the 6-month period following the initial (baseline) infection for which the participant was recruited. Retrospective recurrence is defined as a report of SSTI prior to the initial (baseline) infection for which the participant was recruited. EHR-based outcomes were assessed at 6-months post-baseline and include the time period 12 months prior and 6 months after the baseline infection. Self-report retrospective recurrence was assessed at the baseline telephone assessment (T0), and prospective recurrence was assessed at the 6-month telephone assessment (T4).

<sup>2</sup>The observed prospective recurrence rate at 6 month EHR review for the Observation Only Group (n=66, 10.5%) was not different from either the Experimental (11.3%) or Usual Care (11.0%) or Total (10.8%).

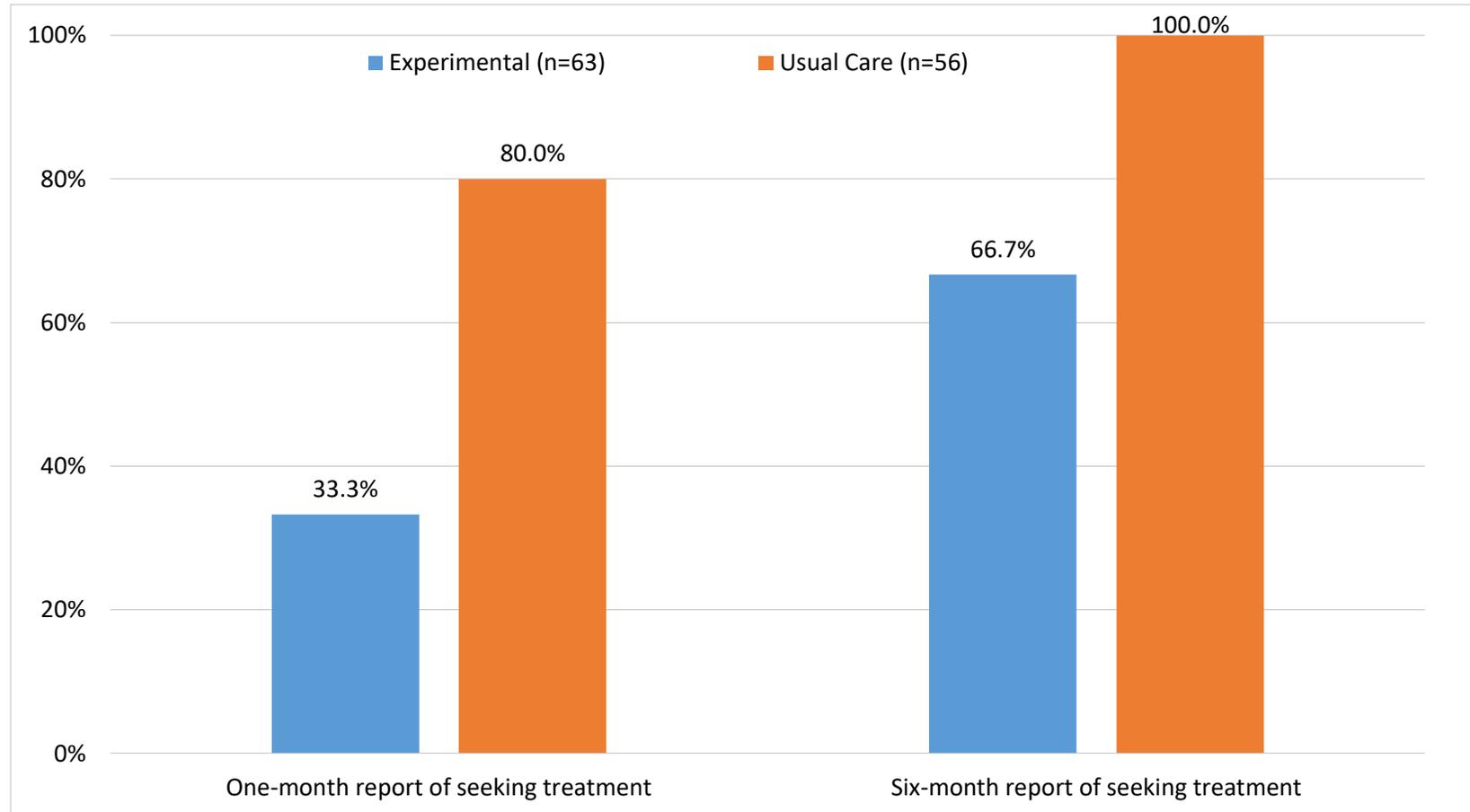
# Summary of Logistic Regression Analyses of SSTI Recurrence Within Six-Months By Key Subgroups (Heterogeneity of Treatment Effects)

Model	Outcome: SSTI Recurrence within 6 months by EHR (1=Experimental, 0=Usual Care)	Odds Ratio	95%CI Lower	95%CI Upper	p-value
	<u>Planned Subgroup Analyses</u>				
1	Overall	1.14	0.36	3.65	0.82
2	By Culture Type (MRSA vs MSSA)	1.03	0.22	4.7	0.96
3	Non-USA Born	2.36	0.35	15.87	0.38
	USA Born	1.12	0.23	5.46	0.89
4	High Household Contamination Level	1.385	0.213	9.009	0.73
	Low Household Contamination Level	1.042	0.234	4.651	0.96
5	Household Members Colonization Present	UE*	UE	UE	0.95
	Household Members Colonization Absent	0.83	0.24	2.95	0.78
	<u>Unplanned Subgroup Analyses</u>				
7	Emergency Department (ED)	1.44	0.42	4.88	0.56
	Federally Qualified Health Center (FQHC)	UE*	UE	UE	0.96
8	I&D Treatment	0.80	0.17	3.90	0.78
	No I&D Treatment	1.58	0.25	9.80	0.62
	*Unestimatable due to sparse data				

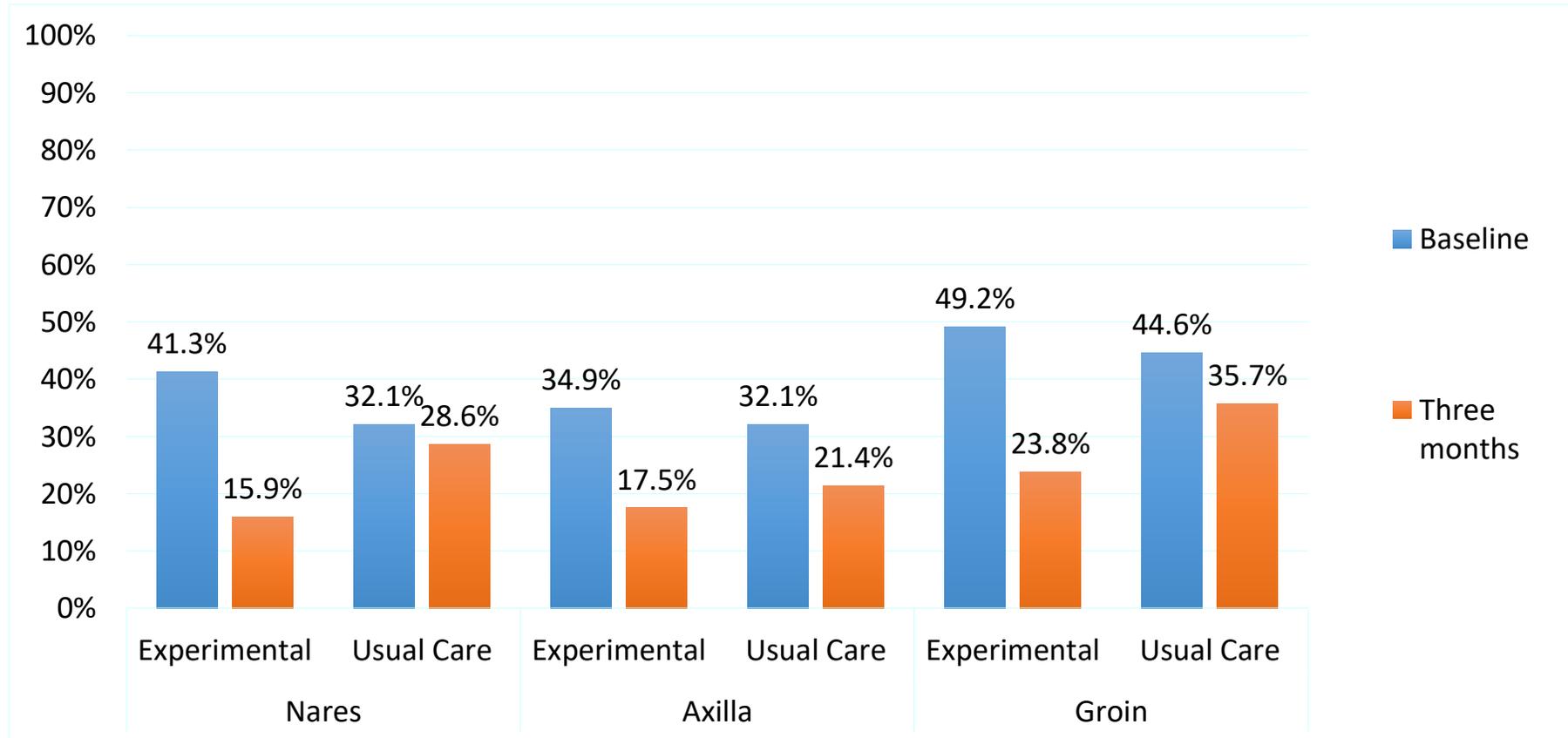
# Self-Report From Index Patient of Household Member SSTI



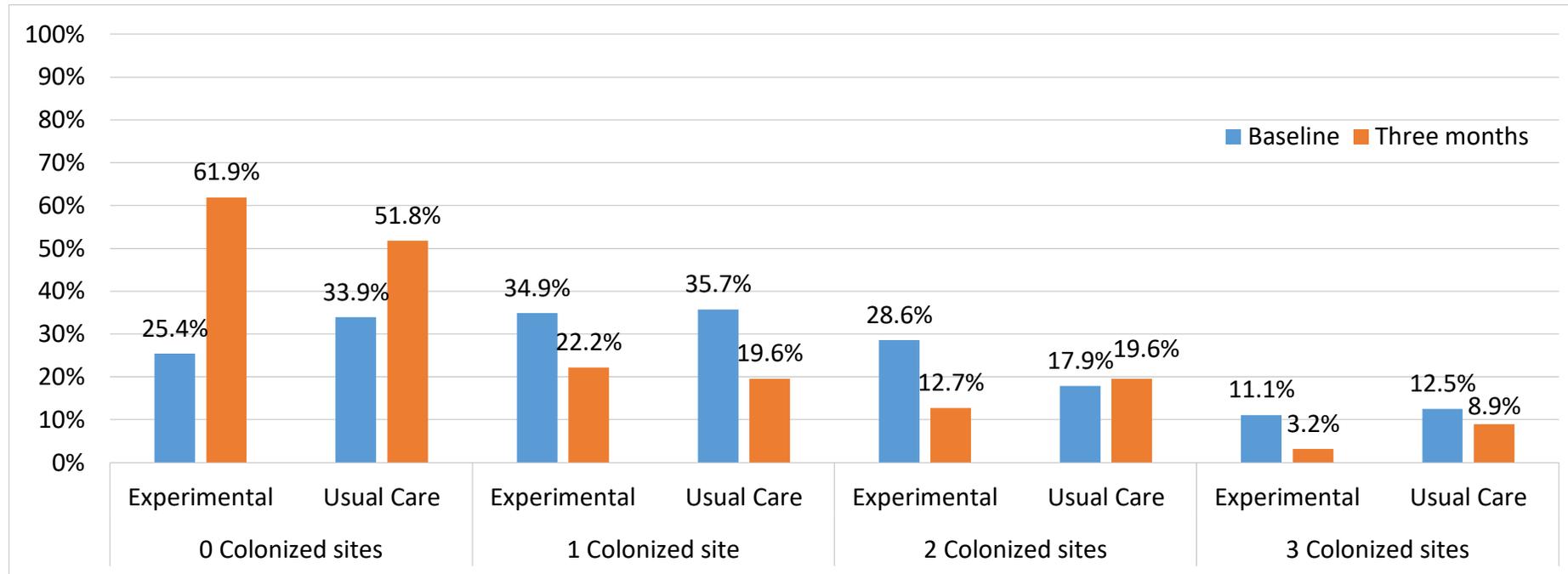
# Self-Report From Index Patient of Household Member Seeking Treatment for SSTI



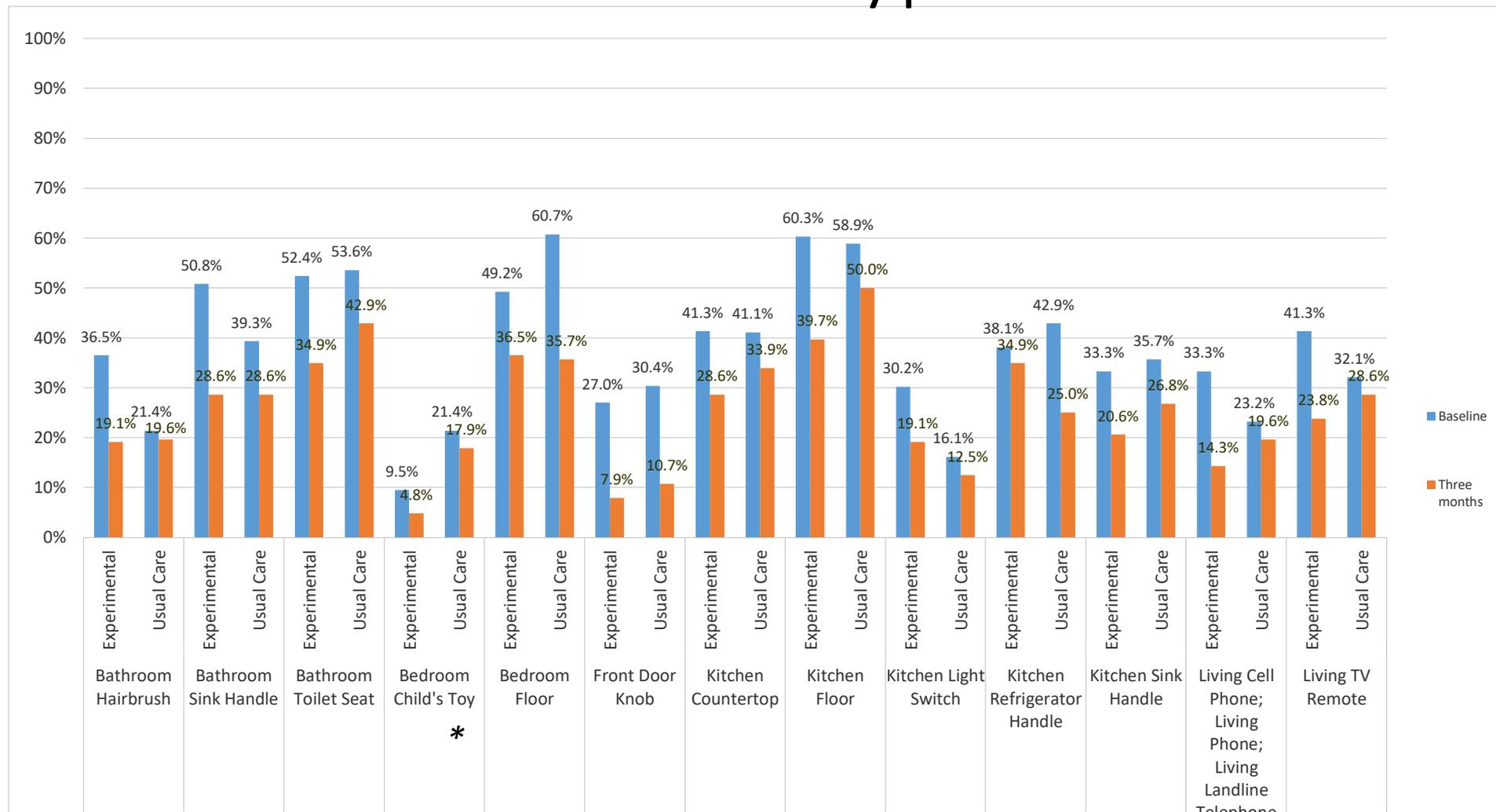
# Proportion of Index Patient Colonization at Household Visits by Site



# Proportion of Index Patient Colonization at Household Visits by Number of Sites

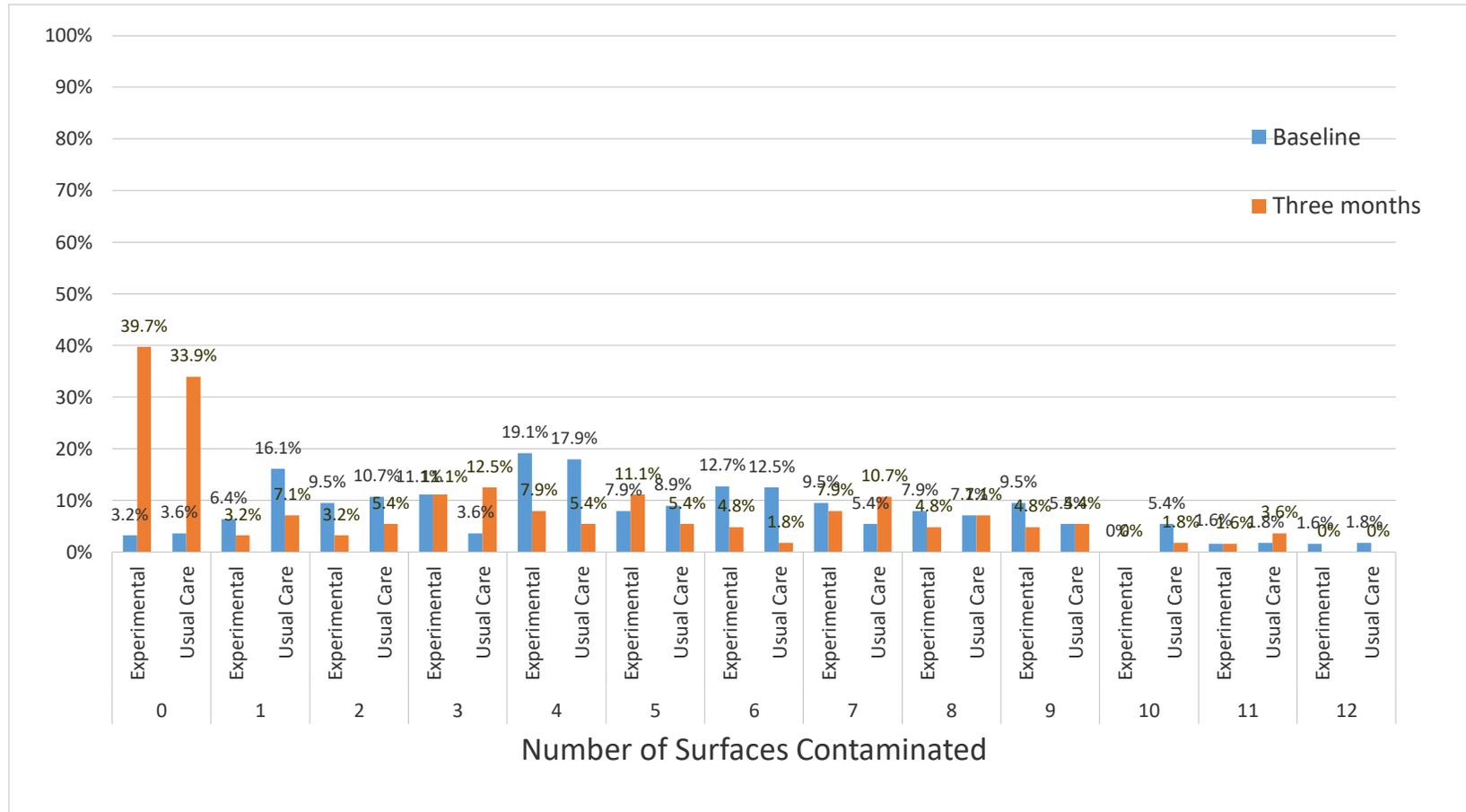


# Household Contamination by Surface Type



\* $p=0.0614$

# Household Contamination by Surface Amount





# Conducting Community-Engaged Team Science Across the Translational Research Spectrum



**T<sub>1</sub>**

**JCM**  
Journal of Community Medicine

### Molecular Types of Methicillin-Resistant *Staphylococcus aureus* and Methicillin-Sensitive *S. aureus* Strains Causing Skin and Soft Tissue Infections and Nasal Colonization, Identified in Community Health Centers in New York City

Maria Pardos de la Gandara,<sup>a</sup> Juan Antonio Raygoza Garay,<sup>b</sup> Michael Mwang,<sup>c</sup> Jonathan N. Tobin,<sup>c,d</sup> Amanda Tsang,<sup>e</sup> Chamanara Khaldia,<sup>f</sup> Brianna D'Orazio,<sup>g</sup> Rhonda G. Kost,<sup>h</sup> Andria Leibinger-Jahari,<sup>i</sup> Cameron Coffran,<sup>j</sup> Teresa H. Evering,<sup>k</sup> Barry S. Collier,<sup>l</sup> Shriish Balachandra,<sup>m</sup> Tracie Urban,<sup>n</sup> Claude Parola,<sup>o</sup> Scott Salvato,<sup>p</sup> Nancy Jenks,<sup>q</sup> Diane Wu,<sup>r</sup> Rhonda Burgess,<sup>s</sup> Marilyn Chung,<sup>t</sup> Hermilia de Lencastre,<sup>u</sup> Alexander Tomasz<sup>v</sup>

Laboratory of Microbiology and Infectious Diseases, The Rockefeller University, New York, New York, USA<sup>a</sup>; Department of Biochemistry and Molecular Biology, Penn State University, University Park, Pennsylvania, USA<sup>b</sup>; Clinical Directors Network (CDN), New York, New York, USA<sup>c</sup>; The Rockefeller University Center for Clinical and Translational Science, New York, New York, USA<sup>d</sup>; Urban Health Center, Bronx, New York, USA<sup>e</sup>; Hudson River Health Care, Poughkeepsie, New York, USA<sup>f</sup>; Open Door Family Medical Center, Channing, New York, USA<sup>g</sup>; Manhattan Physician Group—125th Street Clinic, New York, New York, USA<sup>h</sup>; Laboratory of Molecular Genetics, Instituto de Tecnologia Química e Biológica (ITQBAMB), Oeiras, Portugal<sup>i</sup>

In November 2011, The Rockefeller University Center for Clinical and Translational Science (CCTS), the Laboratory of Microbiology and Infectious Diseases, and Clinical Directors Network (CDN) launched a research and learning collaborative project with six community health centers in the New York City metropolitan area to determine the nature (clonal type) of community-acquired *Staphylococcus aureus* strains causing skin and soft tissue infections (SSTIs). Between November 2011 and March 2013, wound and nasal samples from 129 patients with active SSTIs suspicious for *S. aureus* were collected and characterized by molecular typing techniques. In 63 of 129 patients, the skin wounds were infected by *S. aureus* methicillin-resistant *S. aureus* (MRSA) was recovered from 39 wounds and methicillin-sensitive *S. aureus* (MSSA) was recovered from 24. Most—86 of the 63—wound isolates belonged to the CC9/Panton-Valentine leukocidin-positive (PVL+) group of *S. aureus* clone USA300; 34 of these strains were MRSA and 12 were MSSA. Of the 63 patients with *S. aureus* infections, 39 were also colonized by *S. aureus* in the nares: 16 of the colonizing isolates were MRSA, and 14 were MSSA, and the majority of the colonizing isolates belonged to the USA300 clonal group. In most cases (70%), the colonizing isolate belonged to the same clonal type as the strain isolated with the infection. In those of the patients, the identity of the wound and colonizing MRSA isolates was further down

**T<sub>2</sub>**

### Recurrent Furunculosis Caused by a Community-Acquired *Staphylococcus aureus* Strain Belonging to the USA300 Clone

Shriish Balachandra,<sup>1</sup> Maria Pardos de la Gandara,<sup>2</sup> Scott Salvato,<sup>1</sup> Tracie Urban,<sup>1</sup> Claude Parola,<sup>1</sup> Chamanara Khaldia,<sup>1</sup> Rhonda G. Kost,<sup>1</sup> Teresa H. Evering,<sup>1</sup> Mira Pastagia,<sup>1</sup> Brianna M. D'Orazio,<sup>1</sup> Alexander Tomasz,<sup>2</sup> Hermilia de Lencastre,<sup>3</sup> and Jonathan N. Tobin<sup>1,4</sup>

**Background:** A 24-year-old female with recurrent skin and soft tissue infections (SSTI) was enrolled as part of a center observational cohort study conducted by a practice-based research network (PBRN) on community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA). **Methods:** Strains were characterized by pulsed-field gel electrophoresis (PFGE), spa typing, and multilocus sequence typing. MRSA strains analyzed for SCOne type and the presence of the Panton-Valentine leukocidin (PVL) and arginine slic mobile element (ACME) using PCR. **Results:** In the first episode, *S. aureus* was recovered from the d and inguinal folds; in the second, *S. aureus* was recovered from a lower abdomen furuncle, inguinal and parietal fold. Molecular typing identified CA-MRSA clone USA300 in all samples as spa-type 008, SCCmecIVa, and a typical PFGE pattern. The strain carried virulence genes *pv1* and ACME type 1. Five episodes were documented despite successful resolution by antibiotic treatment, with and without incision drainage. **Conclusions:** The source of the USA300 strain remains unknown. The isolate may represent a tent strain capable of surviving extensive antibiotic pressure or a persistent environmental reservoir may be source, possibly in the patient's household, from which bacteria were repeatedly introduced into the skin with subsequent infections.

**T<sub>3</sub>**

**WORK-IN-PROGRESS & LESSONS LEARNED**

### From the Bench to the Barbershop: Community Engagement to Raise Awareness About Community-Acquired Methicillin-Resistant *Staphylococcus aureus* and Hepatitis C Virus Infection

Andria Leibinger-Jahari, MPH,<sup>1</sup> Rhonda G. Kost, MD,<sup>2</sup> Brianna D'Orazio, MS,<sup>3</sup> Rhonda Burgess, RN,<sup>4</sup> Chamanara Khaldia, MD, MPH,<sup>5</sup> Amanda Tsang, MPH,<sup>6</sup> Dennis Mitchell,<sup>7</sup> Alexander Tomasz, PhD,<sup>8</sup> Hermilia de Lencastre, PhD,<sup>9</sup> Maria Pardos de la Gandara, MD, PhD,<sup>10</sup> Teresa H. Evering, MD, MPH,<sup>11</sup> Tameri Holder, MPH,<sup>12</sup> Barry S. Collier, MD,<sup>13</sup> Jonathan N. Tobin, PhD<sup>14</sup>

**Background:** Infectious diseases, such as hepatitis C and community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA), are emerging health issues. **Objectives:** The CA-MRSA Project (CAMPI) extended its learning collaborative to the barbershop/retail salon setting to increase awareness and prevention of CA-MRSA and hepatitis C infections. **Methods:** Education sessions on CA-MRSA and hepatitis C were conducted with 43 aestheticians at nine barbershop/retail salons in New York City. All completed pre- and post-intervention knowledge tests. Low cost primary care referral cards were also distributed in the CA-MRSA education project. **Results:** Knowledge about CA-MRSA risks ( $p < .0001$ ) and infection prevention measures ( $p < .0001$ ), as well as hepatitis C knowledge and prevention (both  $p < .0001$ ) increased. Nine shops received referral cards ( $n = 300$ ) and 4% of the cards ( $n = 10$ ) were distributed to clients. No self-referrals were reported. **Conclusions:** CAMPI successfully recruited and trained a cadre of aestheticians on CA-MRSA and hepatitis C prevention, increasing their health knowledge, dispersing our engagement with the community. **Keywords:** Community health partnerships, community health research, health disparities, health promotion, bacterial infections, skin disease.

**T<sub>4</sub>**

### Molecular profile of USA 300 MRSA wound isolates

SCCmec: IVa, IVg, IVc

All MRSA wound isolates belonging to the USA 300 clone (ST 8) were:
 

- gel +
- ACME type 1

**T<sub>4</sub>**

**T<sub>4</sub>**

**Table 3. Intervention Outcomes: CA-MRSA**

Module	Performance, Mean (SD)			Pre-Post Test Comparison, t Value (p)		
	Baseline <sup>a</sup>	Follow-up (T1) <sup>b</sup>	Follow-up (T2) <sup>c</sup>	Baseline to T1	T1 to T2	Baseline to T2
MRSA infection prevention (IP) <sup>d</sup>						
Raw score	7.5 (1.7)	8.6 (1.1)	8.8 (1.0)	4.0 (0.0003)	0.4 (0.681)	4.4 (0.0001)
Percent correct	75.2 (17.9)	86.0 (11.5)	87.2 (10.2)			
MRSA knowledge <sup>e</sup>						
Raw score	4.6 (2.1)	6.7 (1.7)	7.3 (1.5)	6.6 (< 0.0001)	0.9 (0.3625)	5.2 (< 0.0001)
Percent correct	51.2 (23.4)	74.9 (18.7)	81.0 (16.3)			

CA-MRSA, community-acquired methicillin-resistant *Staphylococcus aureus*; IP, infection prevention; T1, follow-up 1 month post-intervention; T2, follow-up 3 months post-intervention. <sup>a</sup> Total amount of items = 34. <sup>b</sup> Total amount of items = 45. <sup>c</sup> Total amount of items = 45. <sup>d</sup> Conducted 1 month post-intervention, n = 34. <sup>e</sup> Conducted 3 months post-intervention, n = 34.

**T<sub>4</sub>**

Travel Medicine and Infectious Disease (2016) 14, 551–560

Available online at [www.sciencedirect.com](http://www.sciencedirect.com)

ScienceDirect

Journal homepage: [www.elsevier.com/locate/jtm](http://www.elsevier.com/locate/jtm)

**Differences in prevalence of community-associated MRSA and MSSA among U.S. and non-U.S. born populations in six New York Community Health Centers**

N. Piper Jenks<sup>a,b,1</sup>, M. Pardos de la Gandara<sup>c,1</sup>, B.M. D'Orazio<sup>d</sup>, J. Correa da Rosa<sup>e</sup>, R.G. Kost<sup>f</sup>, C. Khaldia<sup>g</sup>, K.S. Vasquez<sup>h</sup>, C. Coffran<sup>i</sup>, M. Pastagia<sup>j</sup>, T.H. Evering<sup>k</sup>, C. Parola<sup>l</sup>, T. Urban<sup>m</sup>, S. Salvato<sup>n</sup>, F. Barsanti<sup>o</sup>, B.S. Collier<sup>o</sup>, J.N. Tobin<sup>a,4,\*</sup>

<sup>a</sup> Clinical Directors Network, Inc. (CDN), 5 West 37th Street, 10th Floor, New York, NY 10018, USA  
<sup>b</sup> Hudson River HealthCare, 1027 Main Street, Poughkeepsie, NY 12566, USA  
<sup>c</sup> Laboratory of Microbiology & Infectious Diseases, The Rockefeller University, 1230 York Avenue, New York, NY 10021, USA  
<sup>d</sup> Center for Clinical and Translational Science (CCTS), The Rockefeller University, 1230 York Avenue, New York, NY 10021, USA  
<sup>e</sup> Urban Health Clinic, 1065 Southern Boulevard, Bronx, NY 10459, USA

**Differences in prevalence of community-associated MRSA and MSSA**

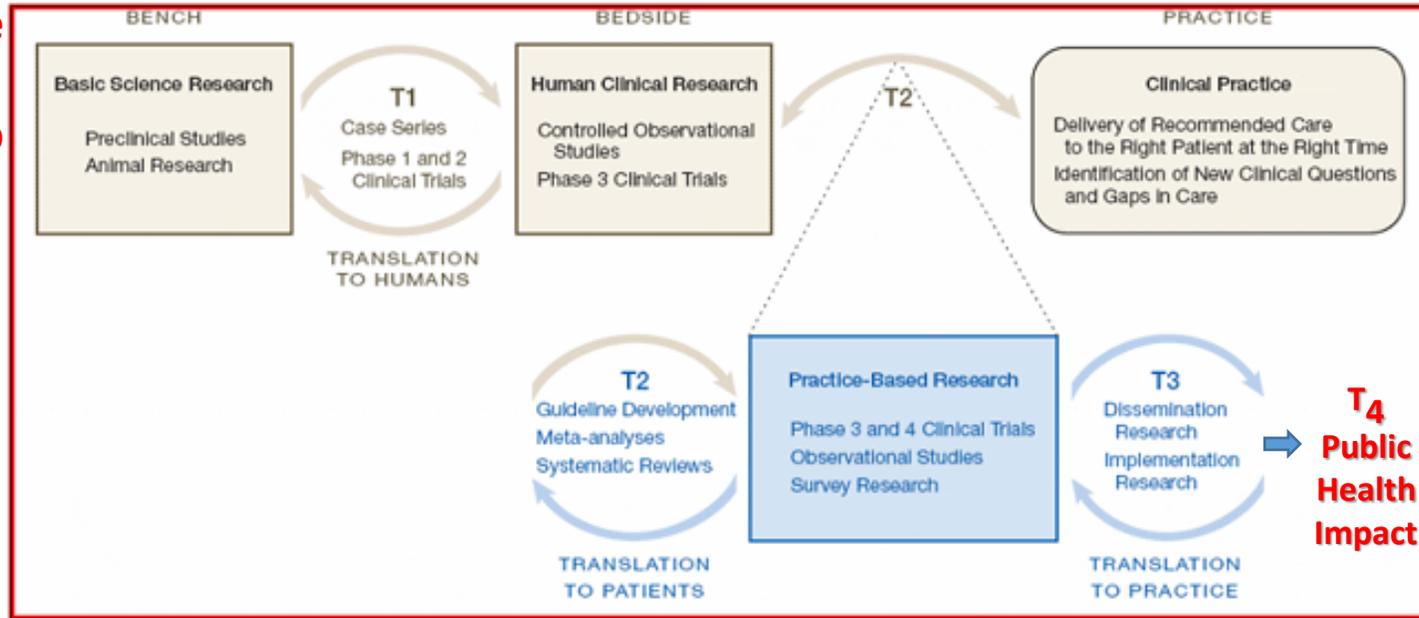
FIG. 2. This map shows the geographic location of the countries of origin of foreign born patients to the study. Different colors mark different countries and both the size of dots and the number inside the dots correlate with the number of patients from each country. Mexico, Central and South America, and the Caribbean were categorized as Latin America.

# Translational Research & NIH “Blue Highways”

SOURCE: Westfall, et al., “Practice-Based Research—“Blue Highways” on the NIH Roadmap” *JAMA* 2007; 297: 403-406

What made the partnership work:

T<sub>0</sub> Basic Science →



▪**Aim 3:** To understand interactions of the intervention with bacterial genotypic and phenotypic variables on decontamination, decolonization, SSTI recurrence, and household transmission

▪**Aim 2:** To understand patient-level factors (CA-MRSA infection prevention knowledge, self-efficacy, decision-making autonomy, prevention behaviors/adherence) and environmental-level factors (household surface contamination, household member colonization, transmission to household members) associated w/ diffs in SSTI recurrence rates

▪**Aim 1:** To evaluate the comparative effectiveness of a CHW/Promotora-delivered home intervention (Experimental Group) as compared to Usual Care (Control Group) on the primary patient-centered and clinical outcome (SSTI recurrence rates) and secondary patient-centered and clinical outcomes (pain, depression, quality of life, care satisfaction) using a two-arm randomized controlled trial (RCT)

▪**Aim 4:** To explore the evolution of stakeholder engagement and interactions among patients and other community stakeholders with practicing community-based clinicians and academic laboratory and clinical investigators over the duration of the study period

# Big Data



# Obesity, Cardiometabolic Risk and Adolescent Pregnancy:

## Building a De-Identified EHR Research Database to Examine the Biological and Social Determinants of Nutritional Status, Pregnancy and Birth Outcomes

### FUNDED BY:

The Sackler Center for Biomedicine and Nutrition (SCBN) Research at The Rockefeller University; The Sackler Institute for Nutrition Science at The New York Academy of Sciences; (3) N<sup>2</sup>: Building a Network of Safety-Net PBRNs (AHRQ 1-P30-HS-021667); (4) The National Center for Advancing Translational Sciences/The Rockefeller University Center for Clinical and Translational Science (NIH-NCATS Grant #UL1-TR-000043)

# TYPES OF STAKEHOLDERS

- ▶ Physicians
  - ▶ Pediatrics
  - ▶ OBGYN
  - ▶ Family Medicine
  - ▶ Bariatric Surgery
- ▶ Midwives
- ▶ Nurses
- ▶ Nutritionists
- ▶ Researchers
- ▶ IT Analysts
- ▶ Biostatisticians
- ▶ Bioinformaticians
- ▶ Basic Scientists
- ▶ Funders
- ▶ Scientific Publishers





**OBESITY, CARDIOMETABOLIC RISK  
AND ADOLESCENT PREGNANCY:  
BUILDING A DE-IDENTIFIED EHR RESEARCH  
DATABASE TO EXAMINE THE BIOLOGICAL AND  
SOCIAL DETERMINANTS OF NUTRITIONAL STATUS,  
PREGNANCY AND  
BIRTH OUTCOMES**

**The Rockefeller University\*\*\***

- **Jan L. Breslow, MD\***
- Peter R. Holt, MD
- Caroline S. Jiang, MS
- Bruce S. McEwen, PhD
- Rhonda G. Kost, MD
- Kimberly S. Vasquez, MPH
- Joel Correa da Rosa, PhD
- Cameron Coffran, MS
- Donna Brassil, MA, RN, CCRC

**The Sackler Institute for Nutrition  
Science/The New York Academy of  
Sciences**

- **Megan Bourassa, PhD\***
- Mireille McLean, MPH
- Julie Shlisky, PhD
- Gilles Bergeron, PhD

**Clinical Directors Network, Inc. (CDN)**

- **Jonathan N. Tobin, PhD\*\***
- Amanda Cheng, MPH
- Dena Moftah, BA
- Julie Wilcox, MFA

**Albert Einstein College of Medicine/  
Montefiore Medical Center\*\*\***

- Peter S. Bernstein, MD, MPH
- Rebecca Mahn, MD/MS candidate
- Siobhan Dolan, MD
- Stephanie Morgan, MS
- Daryl Wieland, MD, MSMI

**Clinician Advisory Committee**

- Tyler Evans, MD
- Elizabeth Dubois, MSN, FNP-BC, AAHIVS
- Mayer Sagy, MD
- Abbe Kirsch, CNM, MSN, MPH

**NYU-Langone / Lutheran Medical Center\*\*\***

- William Pagano, MD, MPH
- Barry Kohn, MD, PhD
- Isaac Dapkins, MD, FAAP
- Rabih Nemr, MD

**\*Project Officers**

**\*\*Principal Investigator**

**\*\*\*CTSA hubs**

**FUNDED BY:**

The Sackler Center for Biomedicine and Nutrition (SCBN) Research at The Rockefeller University; The Sackler Institute for Nutrition Science at The New York Academy of Sciences; (3) N<sup>2</sup>: Building a Network of Safety-Net PBRNs (AHRQ 1-P30-HS-021667); (4) The National Center for Advancing Translational Sciences/ The Rockefeller University Center for Clinical and Translational Science (NIH-NCATS Grant #UL1-TR-000043, -001866)

**CROSS-CTSA COLLABORATION**

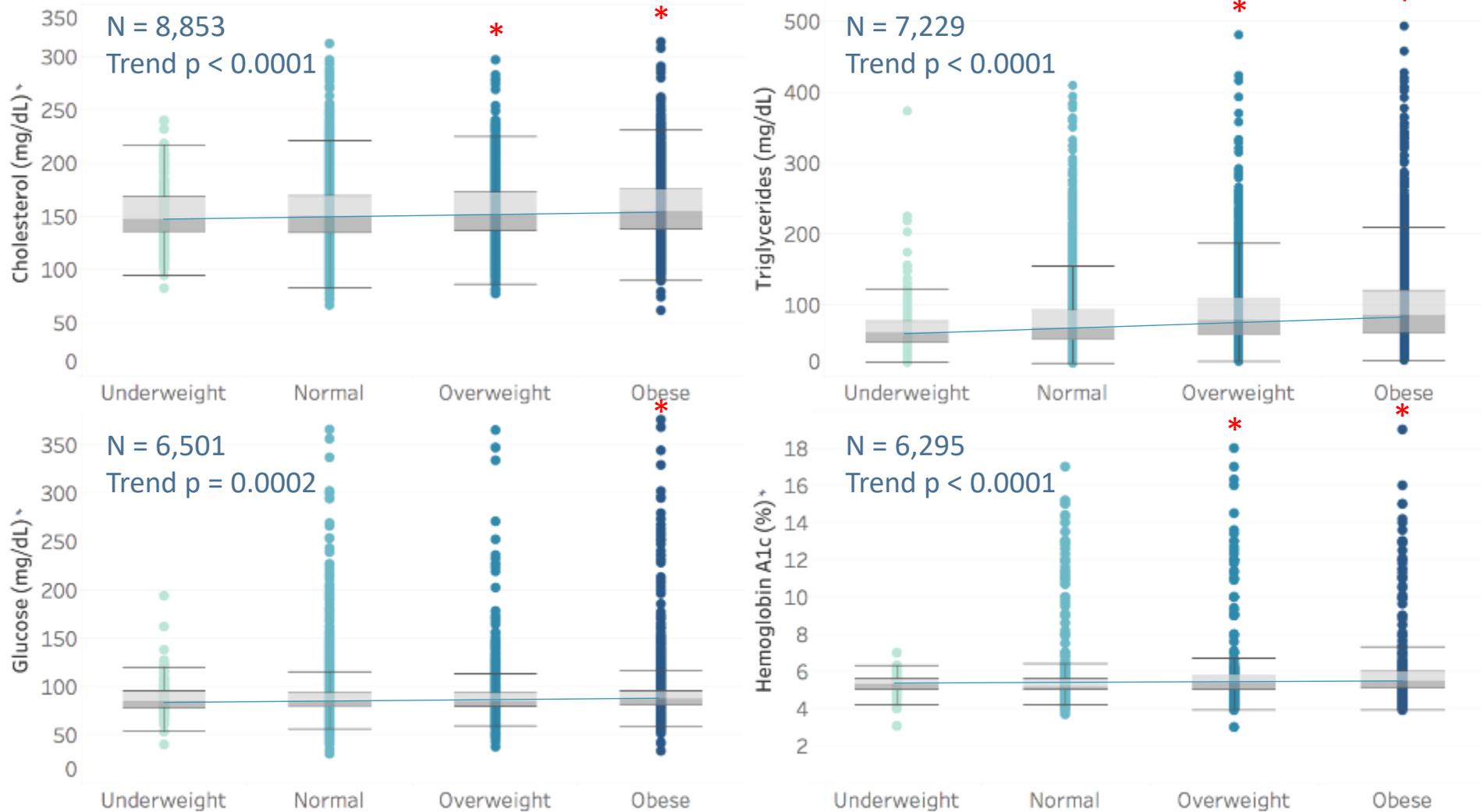


## OBJECTIVES

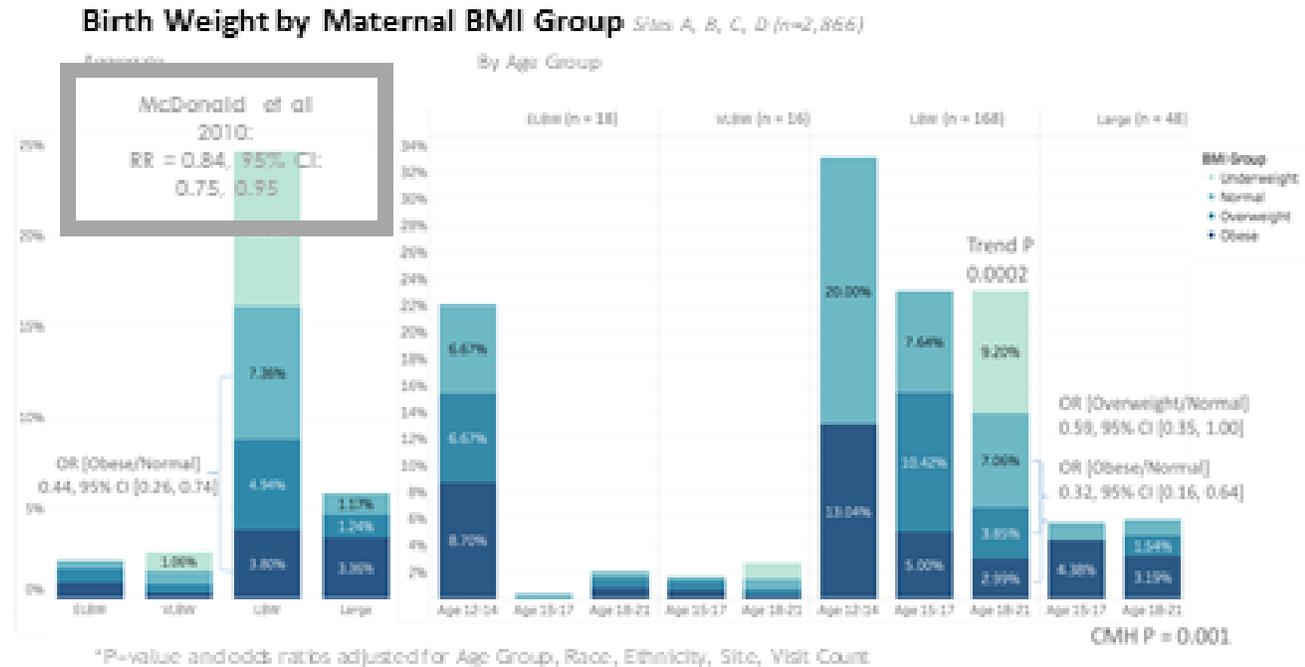
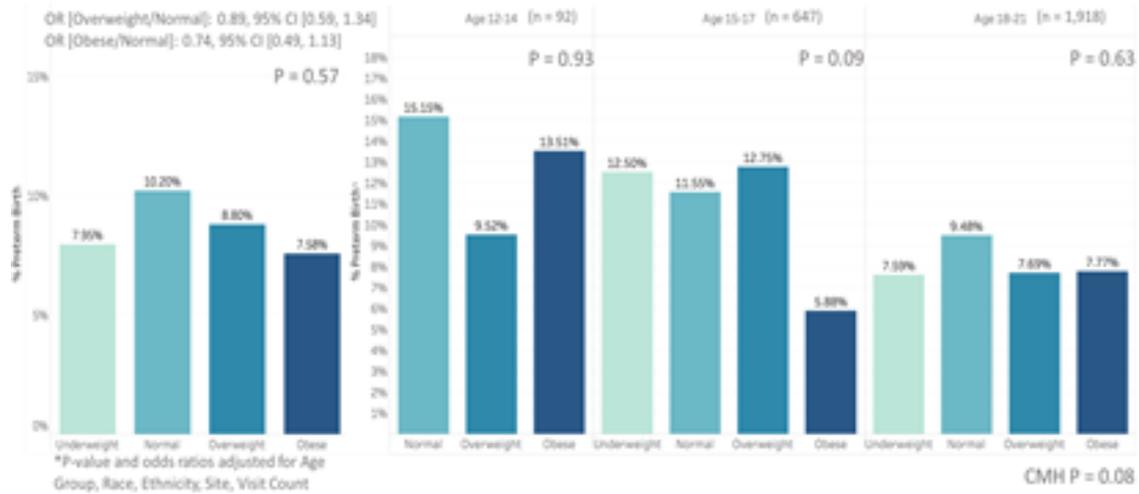
This community-academic partnership involves the creation of a **multisite de-identified Electronic Health Records (EHR) database** that will demonstrate the feasibility of using available measures conducted as part of routine clinical care to explore associations and identify targets for future interventions that address adolescent nutritional and pregnancy outcomes.

This “Big Data” EHR-based study addresses the disproportionate health burdens experienced by overweight and obese adolescents and their infants up to the age of 24 months.

## All Females Cardiometabolic Measures (Sites A, B, C, D; n=6,295-8,853)



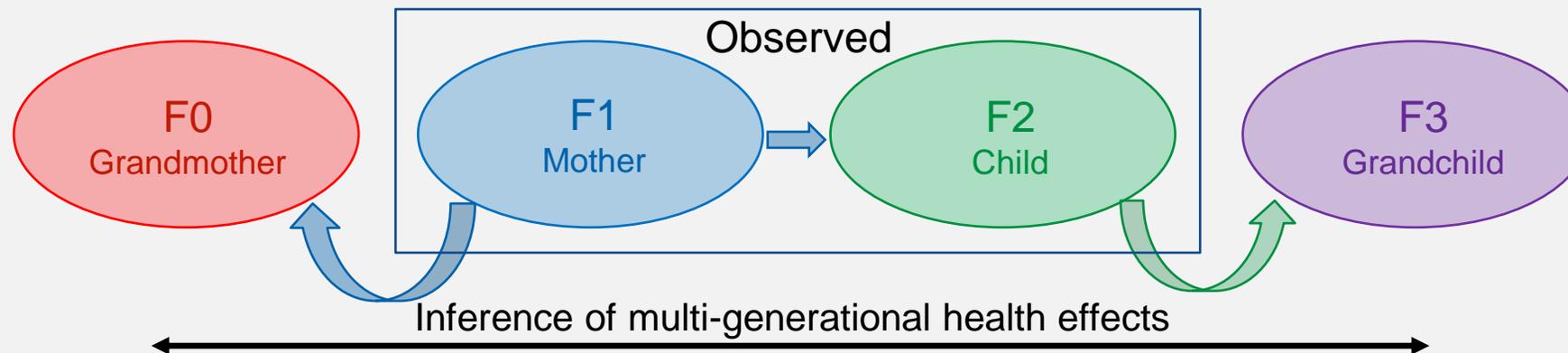
# Linking Maternal & Neonatal EHR Data: Maternal Weight Influences Birthweight



## Baby Birth Weight by Maternal BMI Group for Pregnant Adolescents (Sites A, B, C, D: n=2,866)

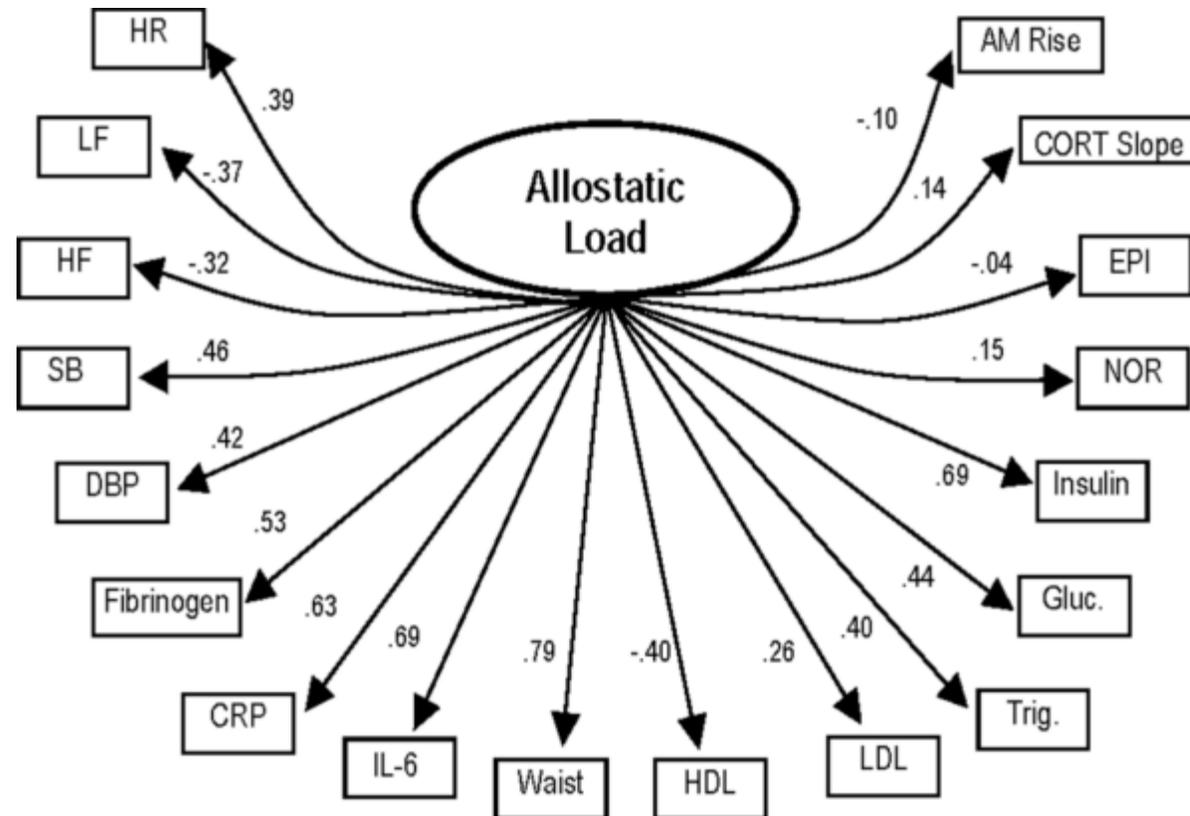
Birth Weight Group	Underweight (n=94) (3%)	Normal (n=1,278) (45%)	Overweight (n=809) (29%)	Obese (n=685) (23%)	Total (n=2,866) (100%)	P-value
Extremely LBW	<b>0%</b>	<b>0.5%</b>	0.7%	0.9%	0.6%	0.001*
Very LBW	<b>1.06%</b>	<b>0.7%</b>	0.5%	0.3%	0.6%	
LBW	<b>8.5%</b>	<b>7.4%</b>	4.9%	3.8%	5.9%	
Normal	90.4%	90.3%	92.6%	91.7%	91.3%	
Large	0%	1.2%	<b>1.2%</b>	<b>3.4%</b>	1.7%	

\*P-value from logistic regression after combining [ELBW, VLBW, LBW] and [Normal, Large] with BMI group as a continuous variable for trend testing and site as a fixed effect.



# Allostatic Load

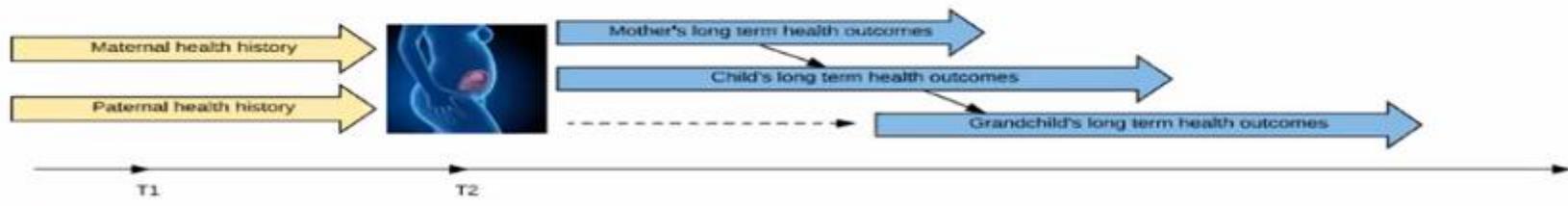
- The wear and tear on the body over time
- Reflects impact of life experiences, genetic load, lifestyle habits, developmental experiences, patterns of behavior and physiological reactivity



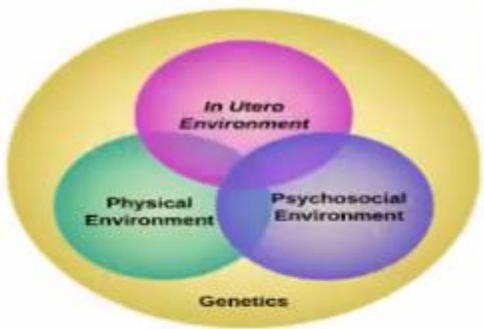
McEwen BS. Protective and damaging effects of stress mediators: central role of the brain. *Dialogues in clinical neuroscience*. 2006 Dec;8(4):367.  
 Seeman T, Gruenewald T, Karlamangla A, Sidney S, Liu K, McEwen B, PhD, Schwartz J, "Modeling multi-system biological risk in young adults: the Coronary Artery Risk Development in Young Adults Study (CARDIA)" *Am J Hum Biol*. 2010 Jul-Aug; 22(4): 463–472.

# ELE Conceptual Model

A transgenerational approach to clinical care: Early life exposures and later life health



Measurable Early Life Exposures (Defined as perinatal to age 20)



- Genetic and Epigenetic Mechanisms**  
Genetic and epigenetic predispositions to disease and rates of aging and their interaction with the environment.
- In Utero Environment**  
Unique period of exposure during a critical period of development. Maternal health and birth complications may have lasting effects on child health. The intersection between the maternal physical and psychosocial environment also has potential for long term effects.
- Physical Environment**  
Exposure to pollutants - Infectious disease, air pollution, soil contamination, radiation, lead, etc.  
Neighborhood environment - Access to care, activity environment, food accessibility.
- Psychosocial Environment**  
Family, friends, socioeconomic status, education, social networks, racism, segregation, income inequality, access to care, childhood health screening practices, neighborhood discrimination, resilience, and psychological stress.  
Adverse childhood experiences, child maltreatment (physical abuse, psychological abuse), exposure to 2nd hand smoke.  
Health behaviors - Smoking, illicit drug use, diet, exercise.

\*Note: Click boxes above for more detail

Measurable Outcomes throughout the Life Course



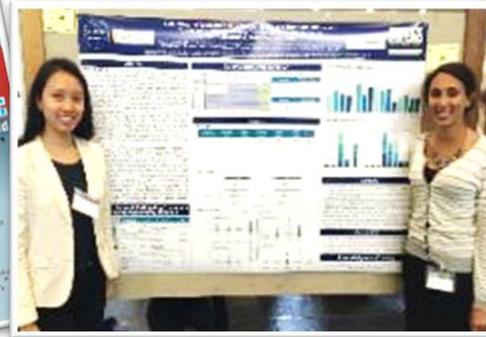
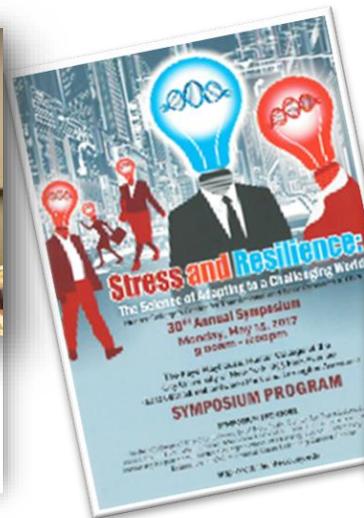
- Overall Health and Well-Being
- Physical
- Psychosocial

\*Note: Click boxes above for more detail

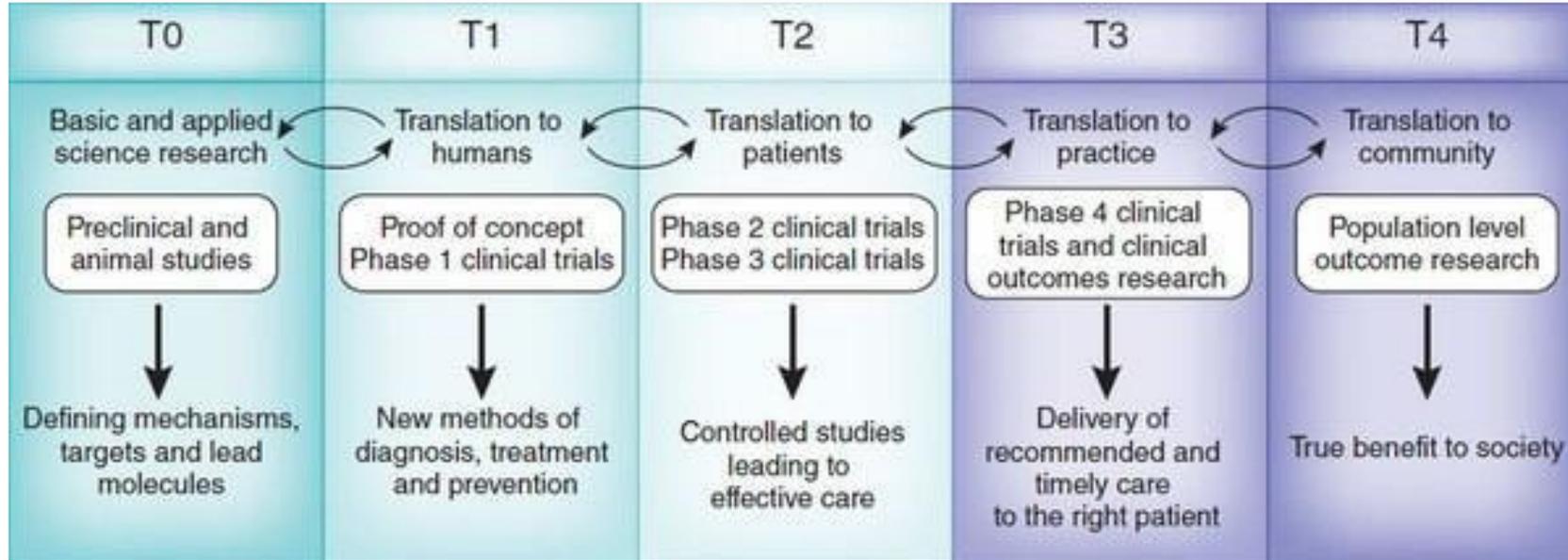


# SACKLER DISSEMINATION

1. NIH-NIMHHD/Weill Cornell-Hunter CTSA Conference: “Stress & Resilience: The Science of Adapting to a Challenging World Symposium – 30th Annual Symposium of the Center for Translational and Basic Research Conference” (NYC May 15, 2017) - Received Best Poster Award: 1st Place (out of 81 posters).
2. NIH-NCATS article entitled “NCATS Enables Scientists, Community Clinicians to Collaborate on Health Initiatives” (Posted August 2017 at <https://ncats.nih.gov/pubs/features/rockefeller> )



# SPECTRUM OF TRANSLATIONAL RESEARCH



	T0	T1	T2	T3	T4
<b>CAMP2</b>	Metagenomics	Molecular Epidemiology/ Genotyping	Incision & Drainage Antibiogram	CDC Guidelines Dissemination and Implementation	Prevention of Recurrence and Transmission
<b>Sackler</b>	Micronutrient & Macronutrient	Allostatic Load Index	<u>Efficacy and Effectiveness Studies of Health Care:</u> Preconception Prenatal Postnatal Pediatric	<u>Implementation and Dissemination Studies of Health Care:</u> Preconception Prenatal Postnatal Pediatric	Validation with NCHS Surveys and Meta-Analysis



## CONDUCTING FULL-SPECTRUM TRANSLATIONAL RESEARCH: BIG DATA MEETS EMBEDDED MECHANISTIC STUDIES

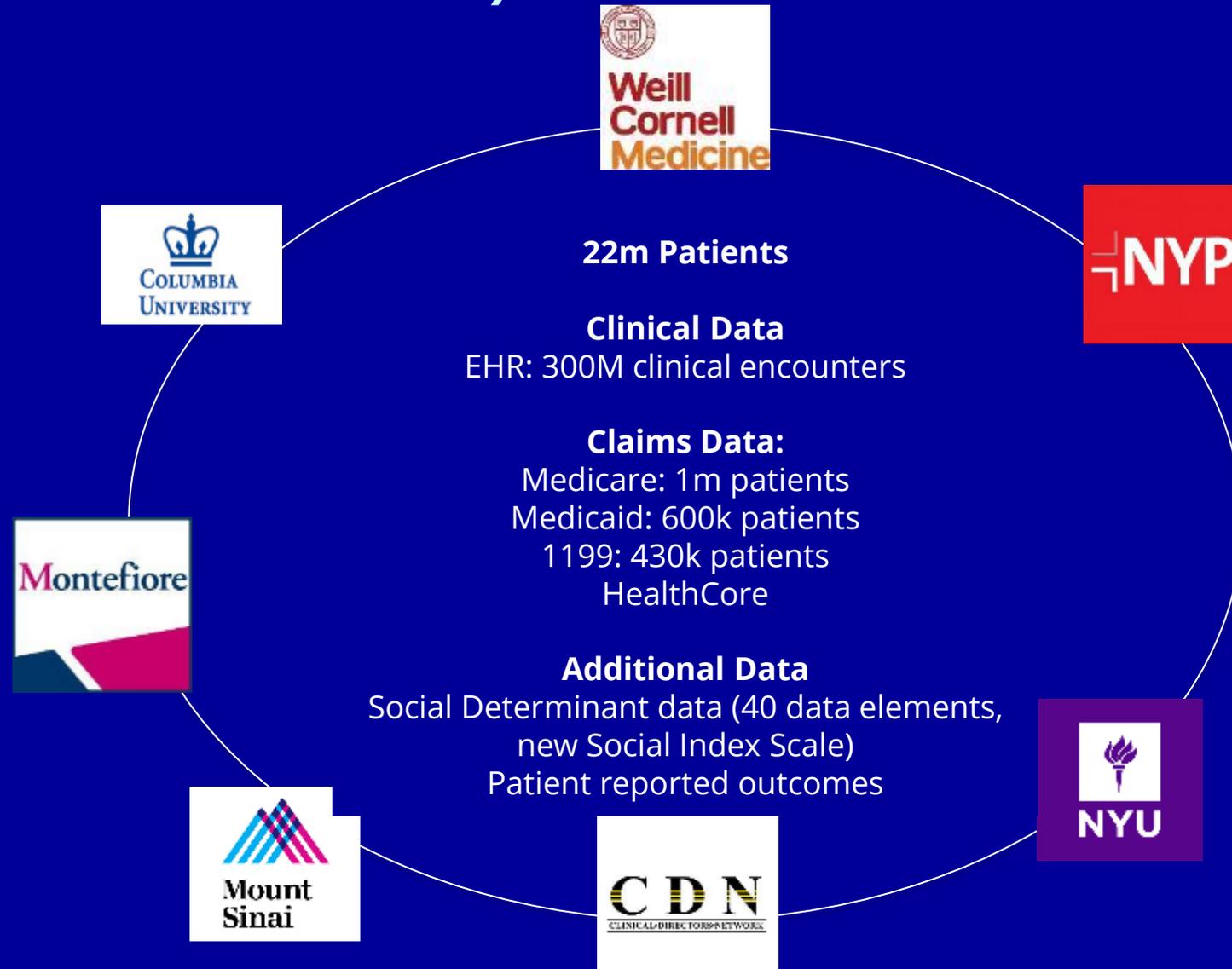
**Ana Emiliano, MD MSc**  
Assistant Professor  
of Medicine  
Columbia University  
Medical Center  
Rockefeller University  
Clinical Scholar Alumna

**Rabih A. Nemr, MD FACS**  
General Surgery, Bariatric Surgery  
Assistant Professor of Surgery  
NYU Langone Brooklyn  
(Lutheran) Medical Center

**Rhonda G. Kost, MD**  
Director, Clinical Research Support  
Office  
Co-Director, Community Engaged  
Research Associate Professor of  
Clinical Investigation  
The Rockefeller University  
Center for Clinical and Translational Science

**Jonathan N. Tobin, PhD**  
President/CEO  
Clinical Directors Network, Inc.  
Co-Director, Community Engaged Research  
The Rockefeller University  
Center for Clinical and Translational Science  
Professor, Department of Epidemiology  
& Population Health  
Albert Einstein College of  
Medicine/Montefiore Medical Center

# NYC Clinical Data Research Network (NYC-CDRN) INSIGHT Network



**PCORnet represents: ~110 million patients who have had a medical encounter in the past 5 years**

# Bariatric Metabolic Outcomes Project (BMOP)

## Ana Emiliano MD MSc (2014-2015)

### Retrospective Study

Using Electronic Health Records (EHR) data to Examine Measures of change in cardiometabolic parameters (BMI; BP; A1c; FBG; LDL, HDL, TG) and medications before and after bariatric surgery overall and by clinical subgroups (*Diabetes; Obstructive Sleep Apnea; Rheumatoid Arthritis; Depression*)

### Prospective Study

Consecutively enrolled bariatric surgery patients will be invited to undergo a brief series of

Questionnaires (completed by a telephone online interview with NYC-CDRN Funding)

- Quality of life – SF12; NYC-CDRN Obesity Measures
- Depression – PHQ9;
- OSA – Eppworth and Stopbang;
- RA – Rapid3

### Biological Specimens:

- Blood – CRP, ESR, IL-6, leptin, ghrelin, adiponectin
- Rectal swab – to characterize the microbiome





# Baseline patient characteristics in predicting metabolic responses to bariatric surgery: a community health center study.

Ana Emiliano, MD, Rabih Nemr, MD, Joel Correa da Rosa, PhD, William Pagano, MD, Jonathan Tobin, PhD.  
The Rockefeller University, New York, NY; the Lutheran Medical Center, NY and Clinical Directors Network, NY.

### ABSTRACT:

**Introduction:** Bariatric surgery has become a popular treatment for obesity and associated metabolic disorders. However, the extent of weight loss and metabolic improvement varies significantly among patients. We sought to identify baseline characteristics that predict the extent of weight loss and metabolic improvement in a community health center population.

**Methods:** We reviewed the medical records of 1,000 patients who underwent bariatric surgery at the Lutheran Medical Center, a community health center in Brooklyn, New York City.

**Results:** We analyzed baseline characteristics and 12-month post-operative weight loss, glycemic control, and blood pressure. We found that baseline characteristics such as age, sex, and BMI were significantly associated with weight loss and metabolic improvement.

**Conclusion:** A baseline BMI of 40 or greater was associated with a greater degree of weight loss and metabolic improvement. Other baseline characteristics such as age, sex, and comorbidities were also associated with weight loss and metabolic improvement.

### INTRODUCTION:

Obesity has become a global public health problem, with prevalence rates increasing in all major regions of the world. Obesity is associated with a higher risk of cardiovascular disease, type 2 diabetes, and certain cancers. Bariatric surgery has emerged as a treatment option for obesity and associated metabolic disorders. However, the extent of weight loss and metabolic improvement varies significantly among patients. We sought to identify baseline characteristics that predict the extent of weight loss and metabolic improvement in a community health center population.

### METHODS:

We reviewed the medical records of 1,000 patients who underwent bariatric surgery at the Lutheran Medical Center, a community health center in Brooklyn, New York City. We analyzed baseline characteristics and 12-month post-operative weight loss, glycemic control, and blood pressure. We found that baseline characteristics such as age, sex, and BMI were significantly associated with weight loss and metabolic improvement.

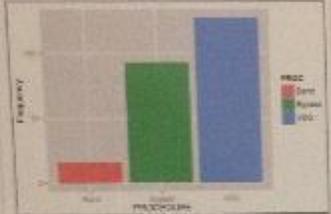


Figure 2. Frequency of bariatric procedures among BMI categories at the Lutheran Medical Center (n=1,000).

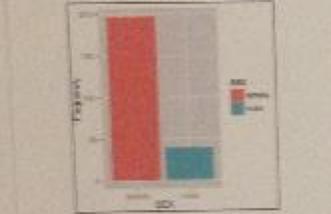


Figure 3. Frequency of bariatric procedures among BMI categories at the Lutheran Medical Center (n=1,000).

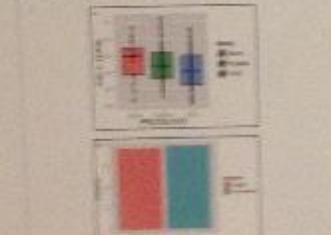


Figure 4. Frequency of bariatric procedures among BMI categories at the Lutheran Medical Center (n=1,000).

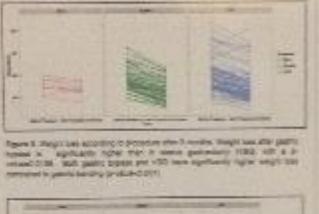


Figure 5. Weight loss at 12 months post-operative for patients with baseline BMI categories (n=1,000).

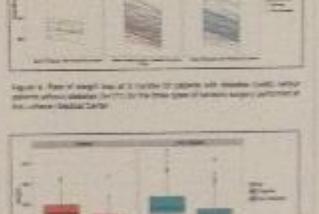


Figure 6. Weight loss at 12 months post-operative for patients with baseline BMI categories (n=1,000).

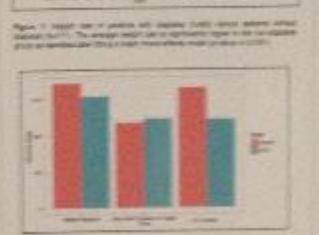


Figure 7. Weight loss at 12 months post-operative for patients with baseline BMI categories (n=1,000).

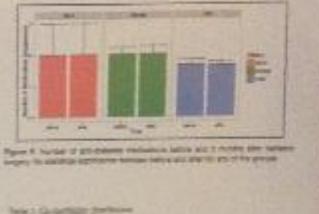


Figure 8. Frequency of bariatric procedures among BMI categories at the Lutheran Medical Center (n=1,000).

Characteristic	RYGB	Sleeve	BPD/DS	Total
Age (mean)	44	44	44	44
Sex (male)	110	110	110	330
Female	110	110	110	330
Comorbidities	110	110	110	330
Baseline BMI (mean)	44	44	44	44

Table 1. Characteristics of patients (n=1,000).

### RESULTS:

We found that baseline characteristics such as age, sex, and BMI were significantly associated with weight loss and metabolic improvement. The extent of weight loss and metabolic improvement was significantly greater in patients with a baseline BMI of 40 or greater.

### CONCLUSIONS:

1. A baseline BMI of 40 or greater was associated with a greater degree of weight loss and metabolic improvement.
2. Other baseline characteristics such as age, sex, and comorbidities were also associated with weight loss and metabolic improvement.

### REFERENCES:

1. [Reference 1]
2. [Reference 2]



"Comparative Effectiveness of Bariatric Procedures for Weight Loss and Safety: A PCORnet Cohort Study"

Annals of Internal Medicine – In Press, 2018

M17-2786

# Baseline Patient Characteristics in Predicting Metabolic Response to Bariatric Surgery: A Community Health Center Study

Ana Emiliano, MD, Rabih Nemr, MD, Joel Correa da Rosa, PhD, William Pagano, MD, MPH Jonathan N. Tobin, PhD.

The Rockefeller University, New York, NY; the NYU Lutheran Medical Center, Brooklyn, NY and Clinical Directors Network, Inc. (CDN), New York NY

## ABSTRACT:

**Introduction:** Bariatric surgery has become a popular treatment for obesity and diabetes mellitus associated with obesity. However, there is limited data on outcomes in community health centers as opposed to academic centers. In addition, no stringent criteria for patient selection has been developed that would predict who would most benefit from bariatric surgery in terms of metabolic outcomes.

**Method:** We obtained de-identified electronic health data from 236 patients who underwent bariatric surgery in the NYU Lutheran Medical Center, a community health center in Brooklyn, New York City.

**Result:** We are reporting data from before and up to 6 months after laparoscopic gastric banding, gastric bypass and sleeve gastrectomy. Our analysis focused on identifying predictors of better metabolic outcomes in the baseline clinical and demographic characteristics.

**Conclusion:** A diagnosis of diabetes mellitus is associated with a lower degree of weight loss compared to what is experienced by patients without diabetes mellitus.

## INTRODUCTION:

Bariatric surgery has grown in popularity as a treatment option for obese individuals, especially if also suffering from type 2 diabetes mellitus. In general, bariatric surgery has proven superior to diet and exercise in producing sustained weight loss and improvement in glucose homeostasis. However, it is not known whether there are patient populations who benefit more from bariatric surgery versus medical weight loss alone and in whom the metabolic improvements will be sustained. We hypothesized that patient baseline clinical and laboratory characteristics may accurately inform who will respond to bariatric surgery with significant and sustained metabolic improvement.

## METHODS:

We extracted de-identified data from electronic health records from approximately 200 patients from a community health center (Lutheran Family Health Center Practices), who underwent bariatric surgery. We analyzed their baseline characteristics (demographics, ethnicity, clinical and laboratory data) as well as response to bariatric surgery measured in clinical and laboratory parameters, such as blood glucose, hemoglobin A1C, weight, weight loss, number and types of medications before the surgery and up to 6 months of follow-up. Mixed model for repeated measures with random effects for the intercept and time was used to examine changes over time by group. The association of diabetes duration and weight loss among patients with diabetes was examined using Spearman correlation.

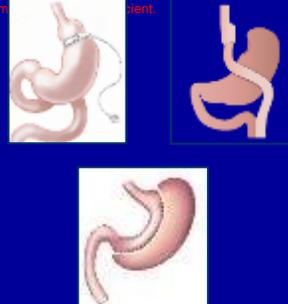


Figure 1. Types of bariatric surgery performed at the Lutheran Medical Center: laparoscopic gastric banding, roux-en-Y gastric bypass and vertical sleeve gastrectomy.

Table 1. Baseline demographic and clinical characteristics

Characteristic	Bypass (n=93)	VSG (n=122)	P-value
Age (years)	42.2 ± 10.5	38.9 ± 11.4	0.03
Female (%)	89.2%	81.1%	0.10
Hispanic ethnicity	53.8%	46.7%	0.30
BMI	47.8 ± 6.6	48.5 ± 9.4	0.54
Weight (lbs)	283.3 ± 54.1	295.1 ± 74.4	0.20
Systolic BP (mm Hg)	124.2 ± 15.5	124.5 ± 16.9	0.87
Diastolic BP (mm Hg)	77.4 ± 8.4	77.5 ± 9.7	0.92
Hemoglobin A1c (%)	7.5 ± 1.7	6.5 ± 0.9	0.02
Glucose	134.0 ± 33.5	154.3 ± 30.9	0.25

\* Data are presented as mean ± SD.

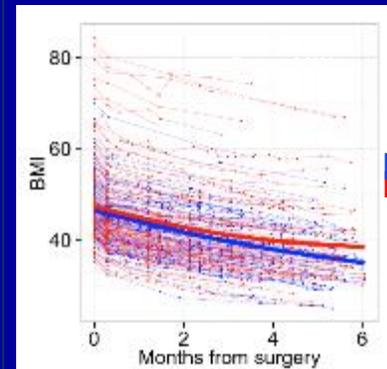


Figure 2. Both gastric bypass and VSG groups showed decreasing BMI post-surgery with a steeper decrease in the bypass group.

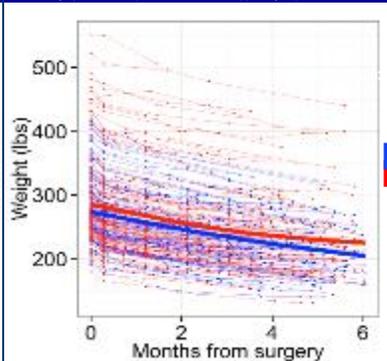


Figure 3. Both gastric bypass and VSG groups lost weight over time with more weight loss in the bypass group.

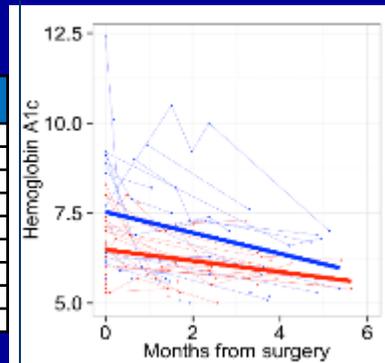


Figure 4. VSG patients had lower HbA1c on average and both groups

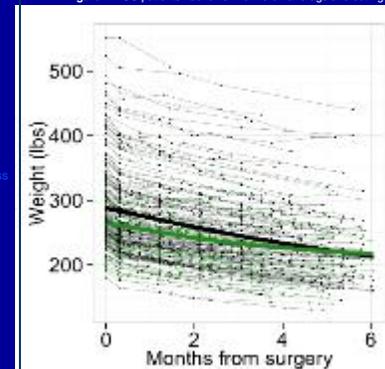


Figure 5. Patients with diabetes lost less weight compared non-diabetes patients after bariatric surgery.

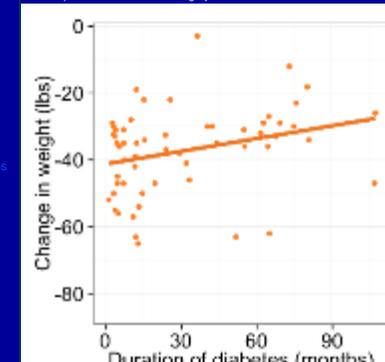


Figure 6. Longer duration of diabetes was associated with less weight loss from bariatric surgery in the subset of 57 subjects with diabetes.

Replace with something else? We don't know the time of "after" surgery. NYU Lutheran just provided meds before and after surgery without dates.

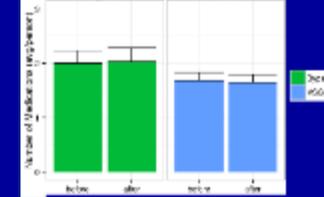


Figure 7. Number of anti-diabetes medications before and after bariatric surgery. No statistical significance between before and after for either group.

Table 2. Comorbid conditions

Comorbidity	Bypass (n=93)	VSG (n=122)	P-value
Depression	18.3%	18.0%	0.96
Diabetes	36.6%	23.8%	0.04
Hyperlipidemia	31.2%	23.0%	0.18
Hypertension	49.5%	43.4%	0.38
Hypertriglyceridemia	3.2%	2.5%	1.00
Sleep apnea	54.8%	59.8%	0.46

## RESULTS:

We found that sleeve gastrectomy is the most frequent procedure (55%), followed by roux-en-y gastric bypass (35%) and gastric banding (10%). Females represent the vast majority of patients undergoing bariatric surgery at the Lutheran Center (90%). In terms of co-morbidity, approximately 30% of patients in this cohort had type 2 diabetes mellitus, 40% had hypertension, 27% had hyperlipidemia, 17% had depression and 54% had sleep apnea. In terms of co-morbidity, approximately 30% of patients in this cohort had type 2 diabetes mellitus, 40% had hypertension, 27% had hyperlipidemia, 17% had depression and 54% had sleep apnea. Gastric bypass leads to the greatest degree of weight loss at 3 months, as previously shown. Moreover, a diagnosis of diabetes is associated with a lower rate of weight loss.

## CONCLUSIONS:

- In a Community Health Center, vertical sleeve gastrectomy is the most common type of bariatric surgery, possibly reflecting surgeon preference.
- Women were the majority of patients undergoing bariatric surgery.
- As shown in previous studies, gastric bypass leads to the greatest degree of weight loss.
- A diagnosis of diabetes prior to the surgery is associated with a lower rate of weight loss compared to patients with obesity without diabetes mellitus.
- In our cohort, at 3 months there was not a

## REFERENCES:

1. Schauer PR, Kribzynski SR, Wittnik K, Brethauer SA, Khran JP, Pories CE, Thomas S, Aboud D, Nissen SL, Bant DL. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. The New England Journal of Medicine. 2012; 366(17):1567-76. 16.  
 2. Schauer PR, Kribzynski SR, Wittnik K, Brethauer SA, Khran JP, Pories CE, Thomas S, Aboud D, Nissen SL, Bant DL. Bariatric surgery versus intensive medical therapy for obesity: a clinical outcomes trial. JAMA. 2014; 311(2):901-909.



# Collaboration with PCORnet Bariatric Study



Annals of Internal Medicine ORIGINAL RESEARCH

## Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss

### A PCORnet Cohort Study

David Arterburn, MD, MPH; Robert Wellman, MS; Ana Emiliano, MD; Steven R. Smith, MD; Andrew O. Odegaard, PhD, MPH; Sameer Murali, MD; Neely Williams, MDiv; Karen J. Coleman, PhD; Anita Courcoulas, MD, MPH; R. Yates Coley, PhD; Jane Anau, BS; Roy Pardee, JD, MA; Casie Horgan, MPH; and Kathleen

**Background:** There has been a dramatic increase in bariatric procedures, but little is known about their comparative effectiveness.

**Objective:** To compare weight loss and safety of bariatric procedures.

**Design:** Retrospective observational study from 2008 to September 2015. (ClinicalTrials.gov identifier: NCT01171599)

**Setting:** 41 health systems in the National Patient-Centered Clinical Research Network.

**Participants:** 65 093 patients aged 18 to 75 years with a body mass index (BMI) of 35 kg/m<sup>2</sup> or greater who underwent bariatric procedures.

**Intervention:** 32 208 Roux-en-Y gastric bypass (RYGB), 3192 sleeve gastrectomy (SG), and 3192 adjustable gastric banding (AGB) procedures.

**Measurements:** Estimated percent weight loss at 1, 3, and 5 years; 30-day rates of major complications.

**Results:** Total numbers of eligible patients at 1, 3, and 5 years were 44 971 (69%), 31 715 (49%), and 21 715 (33%), respectively. Thirty-day rates of major complications were 5.0% for RYGB, 2.6% for SG, and 2.2% for AGB. One-year mean TWLs were 31.2% (95% CI, 30.5% to 31.9%) for RYGB, 25.2% (CI, 25.1% to 25.4%) for SG, and 25.1% (CI, 25.0% to 25.2%) for AGB.



Surgery for Obesity and Related Diseases 14 (2018) 1374–1388

Original article

## Comparative effectiveness of bariatric procedures among adolescents: the PCORnet bariatric study\*

Thomas H. Inge<sup>a,b,\*</sup>, R. Yates Coley<sup>c</sup>, Lydia A. Bazzano<sup>d</sup>, Sengwee Toh<sup>e</sup>, Kathleen McTigue<sup>f</sup>, David Arterburn<sup>g</sup>, Neely Williams<sup>g</sup>, Rob Wellman<sup>g</sup>, Anita Courcoulas<sup>h</sup>, Nirav K. Desai<sup>i</sup>, Jane Anau<sup>c</sup>, Roy Pardee<sup>c</sup>, Senjaya S. Prasad<sup>j</sup>, Andrea Cook<sup>c</sup>, Jessica Sturtevant<sup>k</sup>, Casie Horgan<sup>k</sup>, Ava J. Zebrić<sup>l</sup>, and the PCORnet Bariatric Study Collaborative

<sup>a</sup>Department of Surgery, University of Colorado, Denver, Aurora, Colorado; <sup>b</sup>Children's Hospital of Colorado, Aurora, Colorado

<sup>c</sup>Kaiser Permanente Washington Health Research Institute, Seattle, Washington

<sup>d</sup>Department of Epidemiology, Tulane University School of Public Health, New Orleans, Louisiana

<sup>e</sup>Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio

<sup>f</sup>Departments of Medicine and Epidemiology, University of Pittsburgh, Pittsburgh, Pennsylvania

<sup>g</sup>Community Partners' Network, Nashville, Tennessee

<sup>h</sup>Department of Research and Evaluation, Kaiser Permanente Southern California, Pasadena, California

<sup>i</sup>Department of Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania

<sup>j</sup>Division of Pediatric Gastroenterology, Hepatology, and Nutrition, Boston Children's Hospital, Boston, Massachusetts

<sup>k</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA

<sup>l</sup>Duke Clinical & Translational Science Institute, Durham, North Carolina

<sup>m</sup>REACHnet (a PCORnet CDRN), New Orleans, Louisiana

<sup>n</sup>Department of Pediatric Surgery, Nationwide Children's Hospital, Columbus, Ohio

Received 8 January 2018; received in revised form 28 March 2018; accepted 10 April 2018

Observational Comparative Effectiveness

-- Outcomes Study

SURGERY FOR OBESITY AND RELATED DISEASES -- Outcomes Study

--Methodological Study

## Combining distributed regression and propensity scores: a doubly privacy-protecting analytic method for multicenter research

This article was published in the following Dove Press journal: Clinical Epidemiology

Sengwee Toh<sup>1</sup>, Robert Wellman<sup>2</sup>, R. Yates Coley<sup>3</sup>, Casie Horgan<sup>4</sup>, Jessica Sturtevant<sup>5</sup>, Erick Moynour<sup>6</sup>, Cheri Janning<sup>6</sup>, Roy Pardee<sup>7</sup>, Karen J. Coleman<sup>8</sup>, David Arterburn<sup>9</sup>, Kathleen McTigue<sup>10</sup>, Jane Anau<sup>11</sup>, Andrea J. Cook<sup>12</sup>

On behalf of the PCORnet Bariatric Study Collaborative

<sup>1</sup>Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, MA, USA; <sup>2</sup>Kaiser Permanente Washington Health Research Institute, Seattle, WA, USA; <sup>3</sup>StatLog Economics, Inc., Montreal, QC, Canada; <sup>4</sup>Duke Clinical and Translational Science Institute, Durham, NC, USA; <sup>5</sup>Kaiser Permanente Southern California, Pasadena, CA, USA; <sup>6</sup>Department of Medicine, University of Pittsburgh, Pittsburgh, PA, USA

**Purpose:** Sharing of detailed individual-level data continues to pose challenges in multicenter studies. This issue can be addressed in part by using analytic methods that require only summary-level information to perform the desired multivariable-adjusted analysis. We examined the feasibility and empirical validity of 1) conducting multivariable-adjusted distributed linear regression and 2) combining distributed linear regression with propensity scores, in a large distributed data network.

**Patients and methods:** We compared percent total weight loss 1-year postsurgery between Roux-en-Y gastric bypass and sleeve gastrectomy procedure among 43,110 patients from 36 health systems in the National Patient-Centered Clinical Research Network. We adjusted for baseline demographic and clinical variables as individual covariates, deciles of propensity scores, or both, in three separate outcome regression models. We used distributed linear regression, a method that requires only summary-level information (specifically, sums of squares and cross products matrix) from sites, to fit the three ordinary least squares linear regression models. A comparison set of analyses that used pooled deidentified individual-level data from sites served as the reference.

**Results:** Distributed linear regression produced results identical to those from the corresponding pooled individual-level data analysis for all variables in all three models. The maximum numerical difference in the parameter estimate or standard error for all the variables was  $3 \times 10^{-11}$  across three models.

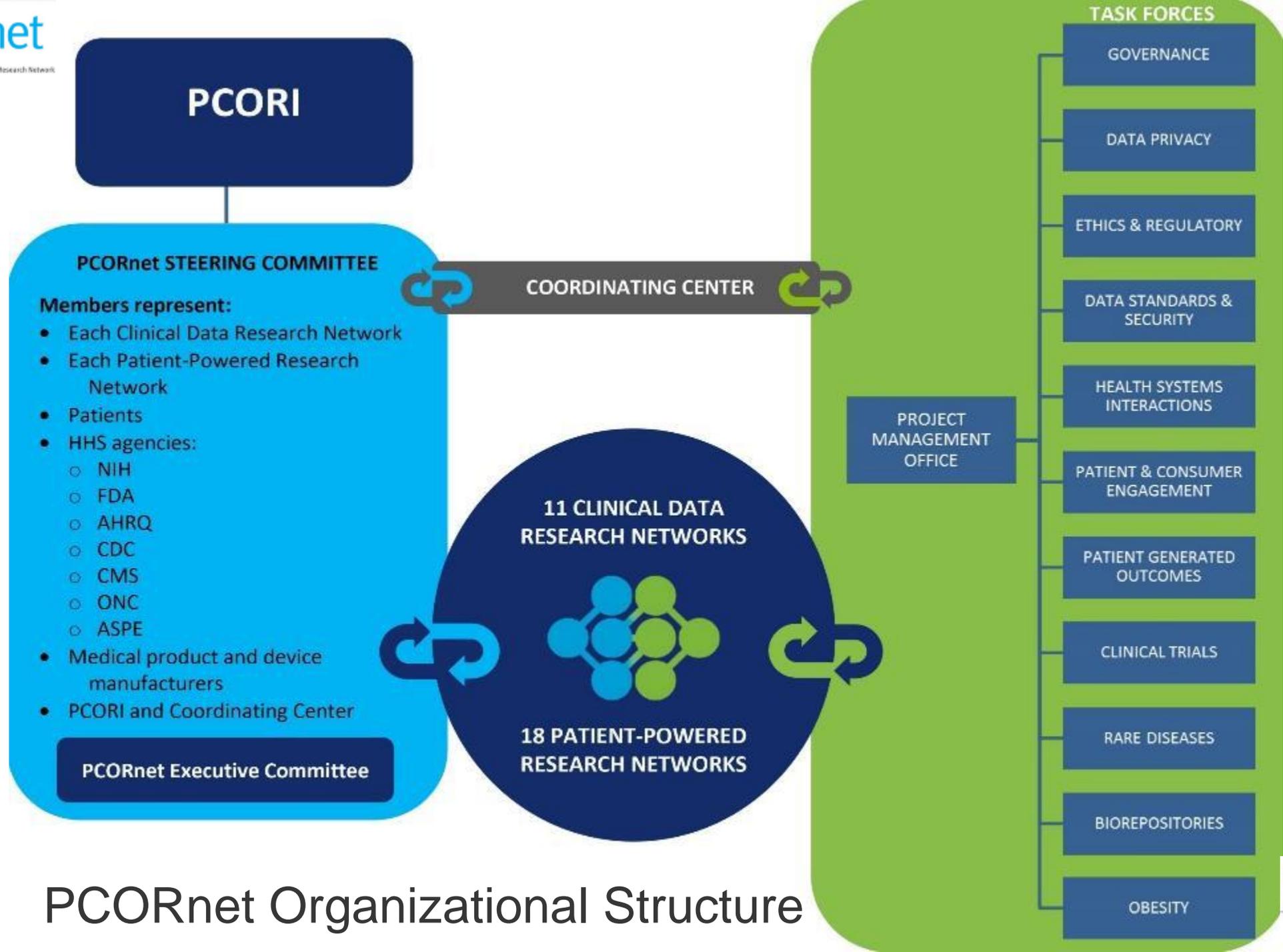
**Conclusion:** Distributed linear regression analysis is a feasible and valid analytic method in multicenter studies for one-time continuous outcomes. Combining distributed regression with propensity scores via modeling offers more privacy protection and analytic flexibility.

**Keywords:** distributed regression, propensity score, distributed data networks, privacy-protecting methods

Arterburn, D., Wellman, R., Emiliano, A., et al. "Comparative Effectiveness and Safety of Bariatric Procedures for Weight Loss." *Annals of Internal Medicine*. 2018, 169 (11): 741-750. PMID: 30383139

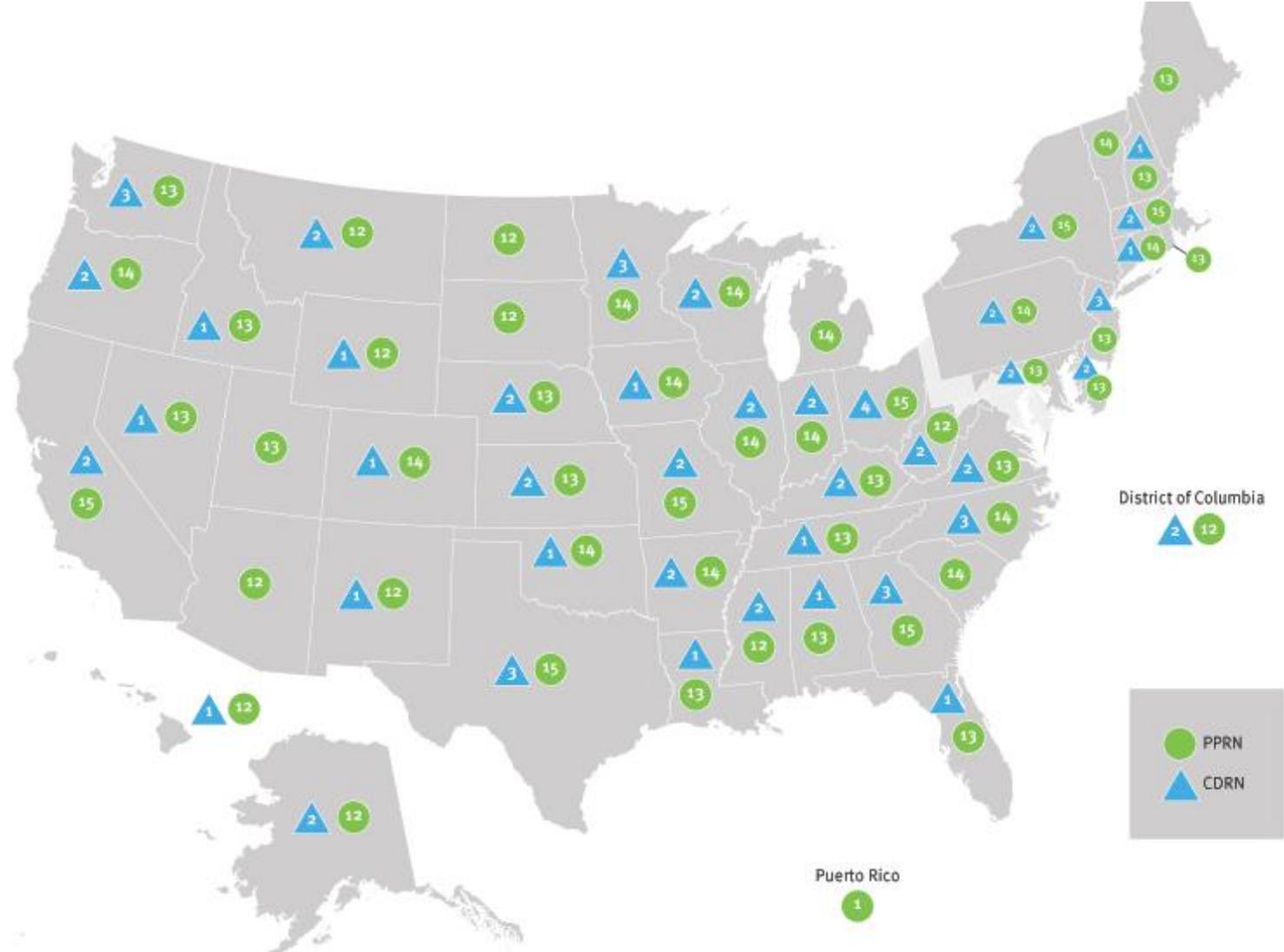
Thomas H. Inge et al. "Comparative effectiveness of bariatric procedures among adolescents: the PCORnet bariatric study" *Surgery for Obesity and Related Diseases* 2018;14:1374-1388

Toh, S., Wellman, R., Coley, R.Y., et al. "Combining Distributed Regression and Propensity Scores: a Doubly Privacy-Protecting Analytic Method for Multicenter Research." *Clinical Epidemiology*, 2018, 10:1773-1786. PMID: 30568510



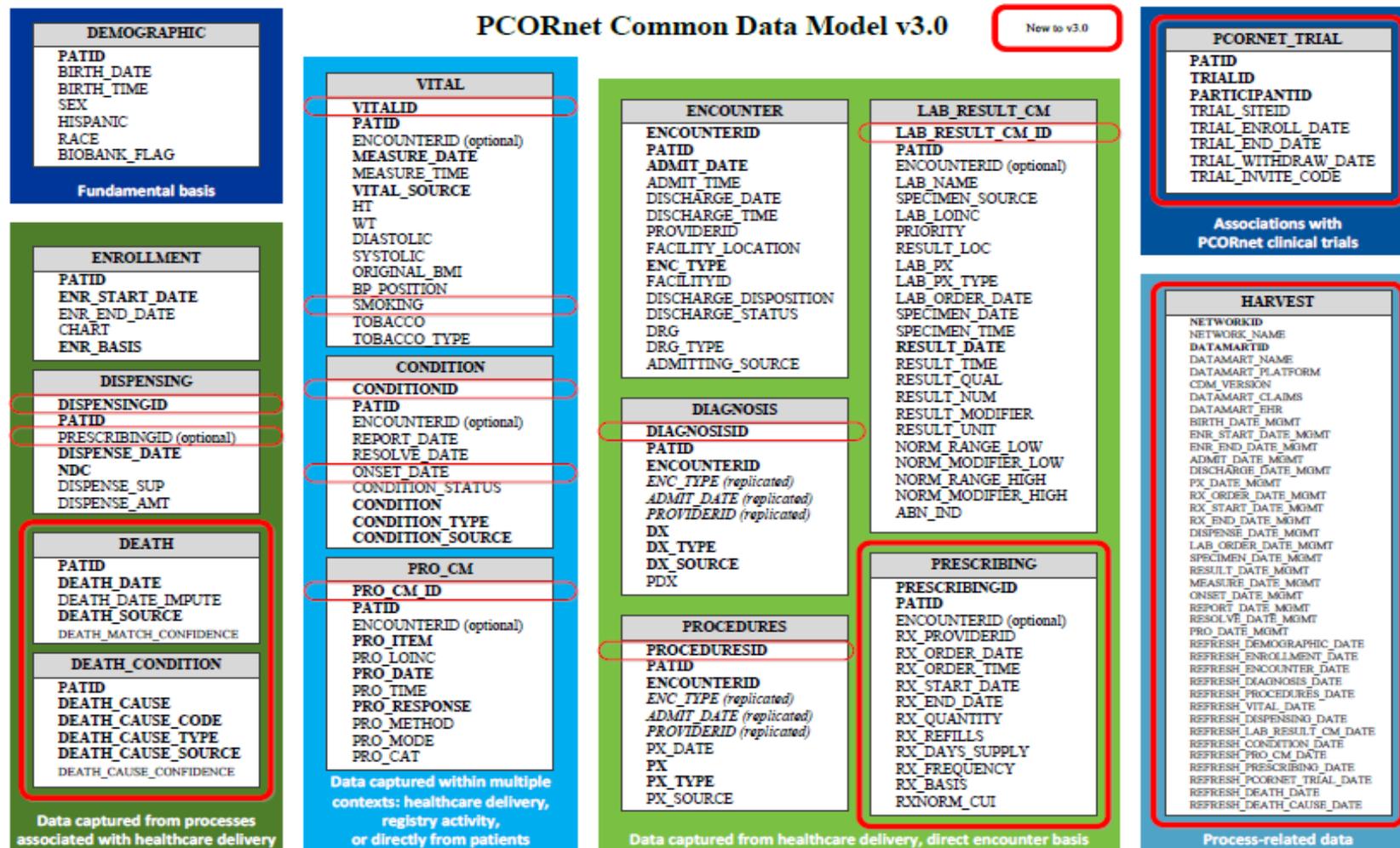
PCORnet Organizational Structure

- **Large diverse population**
- **Geographic co-location in a fragmented healthcare market**
- **Centralized structure**
- **Largest concentration of AMCs**



# COMMON DATA MODEL

## 2.4. Overview Diagram



Bold font indicates fields that cannot be null due to primary key definitions or record-level constraints.

# CLINICAL DATA RESEARCH NETWORKS (CDRNs)

## CLINICAL DATA RESEARCH NETWORKS (CDRNS)

System-based networks that originate in healthcare systems, such as hospitals, health plans, or practice-based networks, and securely collect health information during the routine course of patient care



CDN PCORnet  
PBRN Partners



**NYC-CDRN**  
New York City Clinical  
Data Research Network



**CAPriCORN**



**OneFlorida**  
Clinical Research Consortium



OPEN ACCESS

## Changing the research landscape: the New York City Clinical Data Research Network

Rainu Kaushal,<sup>1,2</sup> George Hripcsak,<sup>3</sup> Deborah D Ascheim,<sup>4</sup> Toby Bloom,<sup>5</sup> Thomas R Campion Jr,<sup>1</sup> Arthur L Caplan,<sup>6</sup> Brian P Currie,<sup>7</sup> Thomas Check,<sup>12</sup> Emme Levin Deland,<sup>2</sup> Marc N Gourevitch,<sup>6</sup> Raffaella Hart,<sup>8</sup> Carol R Horowitz,<sup>4</sup> Isaac Kastenbaum,<sup>2</sup> Arthur Aaron Levin,<sup>9</sup> Alexander F H Low,<sup>1</sup> Paul Meissner,<sup>7</sup> Parsa Mirhaji,<sup>7</sup> Harold A Pincus,<sup>2,3</sup> Charles Scaglione,<sup>13</sup> Donna Shelley,<sup>6</sup> Jonathan N Tobin,<sup>10,11</sup> on behalf of the NYC-CDRN

### ABSTRACT

The New York City Clinical Data Research Network (NYC-CDRN), funded by the Patient-Centered Outcomes Research Institute (PCORI), brings together 22 organizations including seven independent health systems to enable patient-centered clinical research, support a national network, and facilitate learning healthcare systems. The NYC-CDRN includes a robust, collaborative governance and organizational infrastructure, which takes advantage of its participants' experience, expertise, and history of collaboration. The technical design will employ an information model to document and manage the collection and transformation of clinical data, local institutional staging areas to transform and validate data, a centralized data processing facility to aggregate and share data, and use of common standards and tools. We strive to ensure that our project is patient-centered; nurtures collaboration among all stakeholders; develops scalable solutions facilitating growth and connections; chooses simple, elegant solutions wherever possible; and explores ways to streamline the administrative and regulatory approval process across sites.

health management, patient-centered clinical trials, observational studies, and precision medicine. Specific goals include aggregating data on a minimum of 1 million patients, engaging patients and front-line clinicians in all phases of the project, embedding research activity into the delivery of healthcare, aligning regulatory oversight across multiple health systems, and disseminating study results across healthcare systems.

This paper describes the project's goals, governance and organizational structure, and technical approach.

### ORGANIZATIONAL AND SCIENTIFIC APPROACH

The NYC-CDRN includes a robust and collaborative governance and organizational infrastructure, which takes advantage of its participants' experience, expertise, and history of collaboration.

### Participating institutions

The NYC-CDRN's participating institutions (table 1) have several notable features that provide an important foundation for the consortium. The NYC-CDRN includes six Clinical and Translational Science Award (CTSA) centers<sup>2</sup> which already collaborate on



OPEN ACCESS

## CAPriCORN: Chicago Area Patient-Centered Outcomes Research Network

Abel N Kho,<sup>1</sup> Denise M Hynes,<sup>2,3</sup> Satyender Goel,<sup>1</sup> Anthony E Solomonides,<sup>4</sup> Ron Price,<sup>5</sup> Bala Hota,<sup>6</sup> Shannon A Sims,<sup>6</sup> Neil Bahroos,<sup>7</sup> Francisco Angulo,<sup>8</sup> William E Trick,<sup>8</sup> Elizabeth Tarlov,<sup>9</sup> Fred D Rachman,<sup>10</sup> Andrew Hamilton,<sup>10</sup> Erin O Kaleba,<sup>10</sup> Sameer Badlani,<sup>11</sup> Samuel L Volchenboum,<sup>12</sup> Jonathan C Silverstein,<sup>4</sup> Jonathan N Tobin,<sup>13</sup> Michael A Schwartz,<sup>3</sup> David Levine,<sup>14</sup> John B Wong,<sup>15</sup> Richard H Kennedy,<sup>5</sup> Jerry A Krishnan,<sup>2,7</sup> David O Meltzer,<sup>11</sup> John M Collins,<sup>16</sup> Terry Mazany,<sup>17</sup> for the CAPriCORN Team

### ABSTRACT

The Chicago Area Patient-Centered Outcomes Research Network (CAPriCORN) represents an unprecedented collaboration across diverse healthcare institutions including private, county, and state hospitals and health systems, a consortium of Federally Qualified Health Centers, and two Department of Veterans Affairs hospitals. CAPriCORN builds on the strengths of our institutions to develop a cross-cutting infrastructure for sustainable and patient-centered comparative effectiveness research in Chicago. Unique aspects include collaboration with the University HealthSystem Consortium to aggregate data across sites, a centralized communication center to integrate patient recruitment with the data infrastructure, and a centralized institutional review board to ensure a strong and efficient human subject protection program. With coordination by the Chicago Community Trust and the Illinois Medical District Commission, CAPriCORN will model how healthcare institutions can overcome barriers of data integration, marketplace competition, and care fragmentation to develop, test, and implement strategies to improve care for diverse populations and reduce health disparities.

### PARTICIPATING HEALTH SYSTEMS

CAPriCORN brings together an unprecedented Chicago-wide collaboration between 11 diverse healthcare institutions and multiple partner institutions (table 1). Healthcare institutions include: academic medical centers (Loyola University Health System (LUHS), Northwestern Medicine (NM), NorthShore University HealthSystem (NS), Rush University Medical Center (RU), University of Chicago (UC), and the University of Illinois Hospital and Health Sciences System (UI)); Cook County Health and Hospital System (CCHHS); the Alliance of Chicago's FQHCs (Alliance); two local Department of Veteran's Affairs Hospitals and clinics (HinesVAH and Jesse Brown VA (JBVAMC)); and leading pediatric hospitals (Lurie Children's Hospital, Children's Hospital of University of Illinois, and University of Chicago Medicine Comer Children's Hospital). Together, CAPriCORN healthcare institutions provide primary healthcare to over one million patients who mirror the great socioeconomic and racial diversity of our region. Insurance coverage varies from over 70% uninsured to 100% insured.

For numbered affiliations see end of article.

### Correspondence to

Rainu Kaushal, 425 East 61st Street, Suite 301, New York, NY 10065, USA; [rak2007@med.cornell.edu](mailto:rak2007@med.cornell.edu)

Received 28 February 2014  
Revised 15 March 2014  
Accepted 25 March 2014

For numbered affiliations see end of article.

### Correspondence to

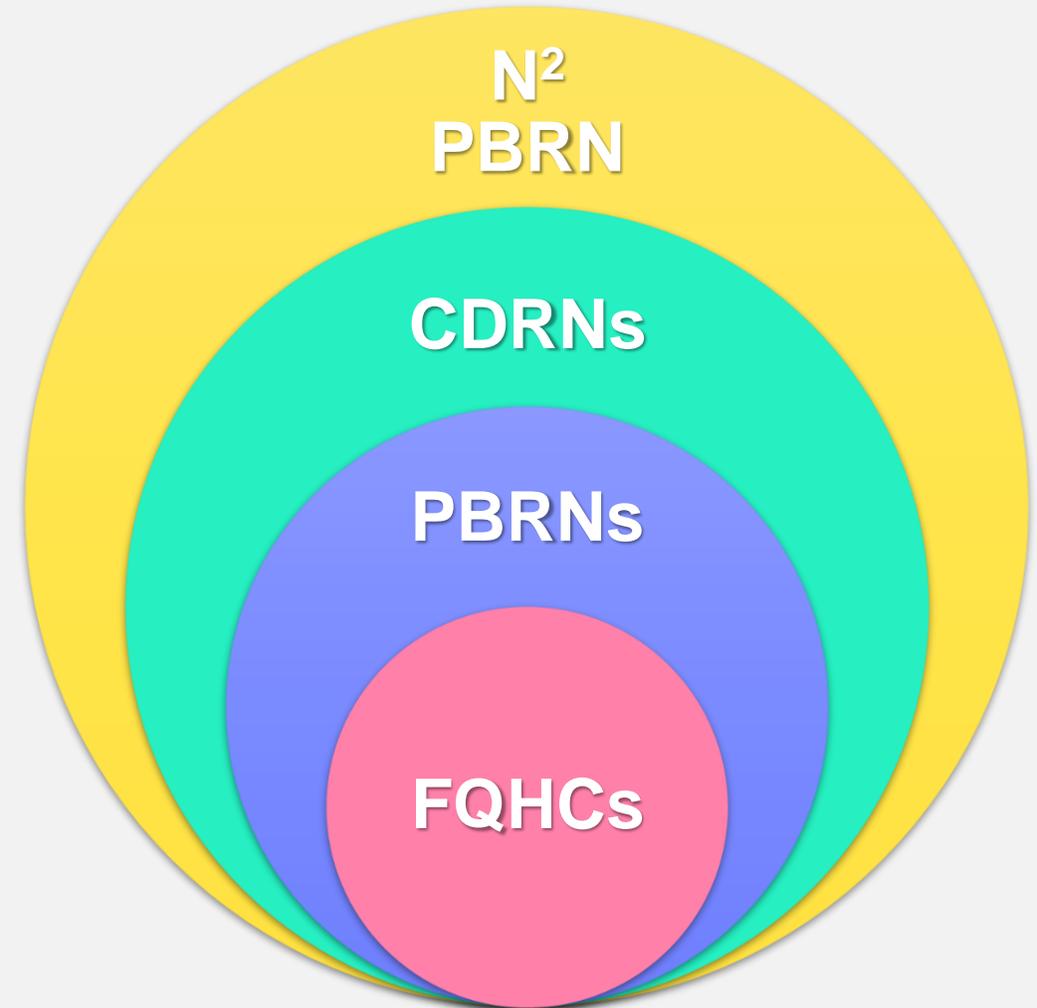
Dr Abel N Kho, Division of General Internal Medicine, Northwestern University, 750 N Lake Shore Drive, 10th Floor, Chicago, IL 60611, USA; [Abel.kho@nmff.org](mailto:Abel.kho@nmff.org)

Received 25 March 2014  
Revised 4 April 2014  
Accepted 8 April 2014

# A N<sup>2</sup> PBRN SCALE-UP MODEL



CDN N<sup>2</sup>-PBRN HAS BUILT A  
**SCALABLE RESEARCH**  
INFRASTRUCTURE TO SERVE THE  
NEEDS  
OF THE CLINICIANS WHO  
PRACTICE IN THE HEALTH CARE  
**SAFETY-NET**  
BY BUILDING ON EXISTING  
INFRASTRUCTURE, CREATING NEW  
**RELATIONSHIPS PROVIDING**  
EXTERNAL PRACTICE FACILITATORS  
(ONLINE, REMOTE), AND  
**DISSEMINATION CHANNELS**



# **EXERCISE #2**

**Translational Research Spectrum**  
**CE Research Partnership Continuum**

# Exercise #2: Moving Towards More Engaged Translational Research: An Exercise

1. Form 2-4 academic and community groups
2. Select a health need
3. Write your research question
4. Brainstorm study aims (minimum 1 community and 1 academic) Hint: Try to span the Translational Research spectrum!
5. Indicate with a “X” where your aims and partnership fall on the *Translational Research vs CE Partnership* plot
6. Indicate on the CE Partnership Continuum how you could make your project more engaged

The Rockefeller University  
Clinical Directors Network  
Introductory Clinical and Translational Science Course 2020-2021  
Lecture Four: Full Spectrum Community Engaged Research  
Exercise 2

Name:

Date:

1. **Role** (Community or Academic): \_\_\_\_\_

2. **Health Need** (e.g. Zika, HIV/AIDS, Cardiovascular Disease, Asthma)

3. **Research Question**

4. **Study Aims:** (*Minimum one each*)

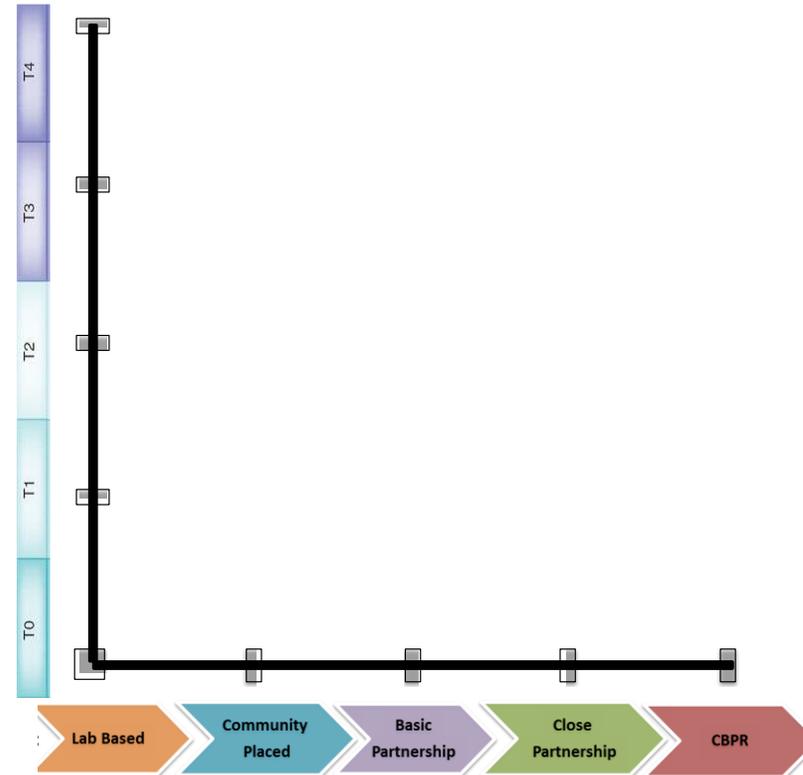
**Scientific Aim** (e.g. reliable diagnosis, HIV vaccine, new statin, development of oral treatment)

**Community/Patient-Centered Aim** (e.g. avoid mosquito bites, prevent transmission and recurrence)

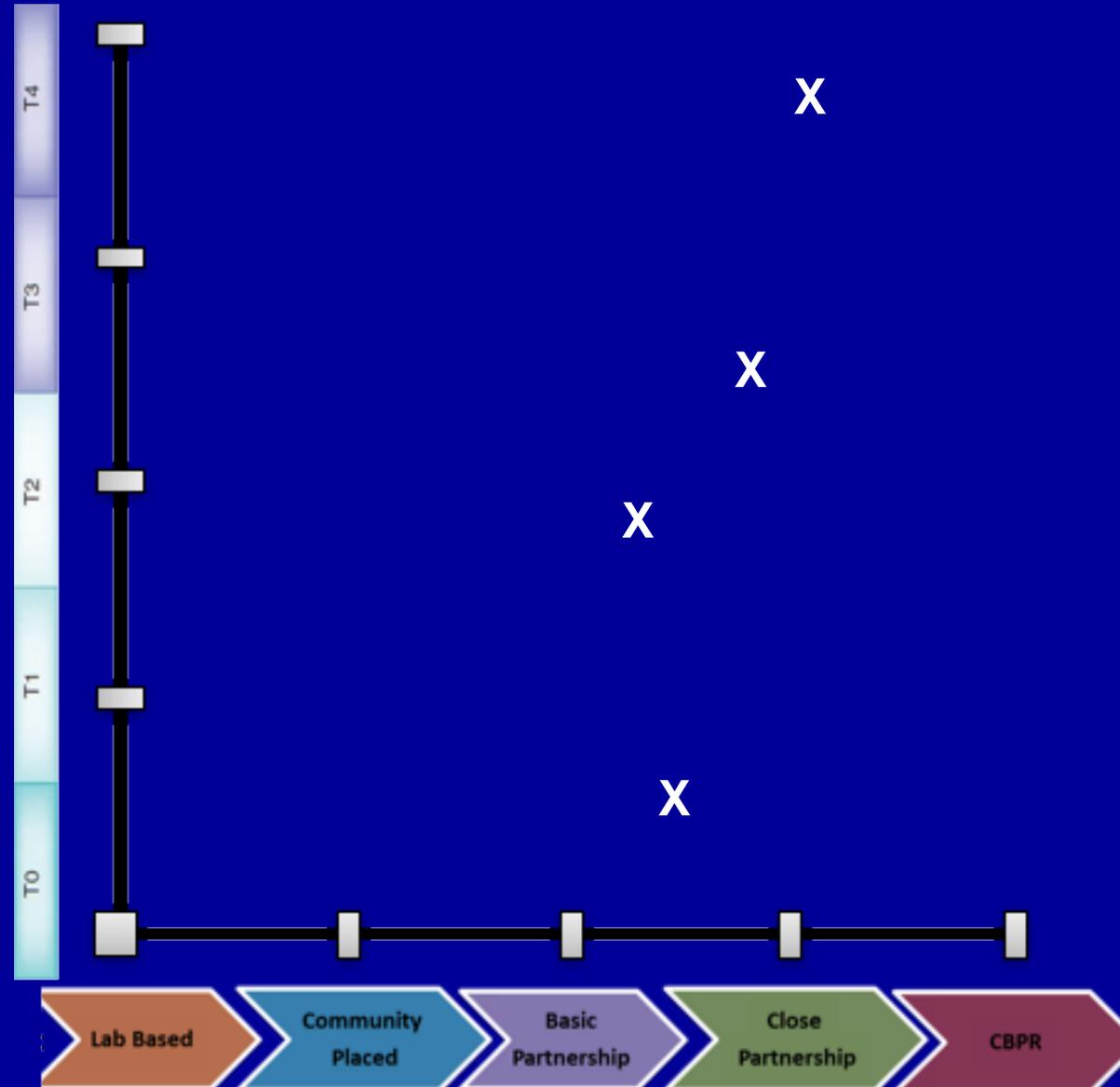


The Rockefeller University  
Clinical Directors Network  
Introductory Clinical and Translational Science Course 2020-2021  
Lecture Four: Full Spectrum Community Engaged Research

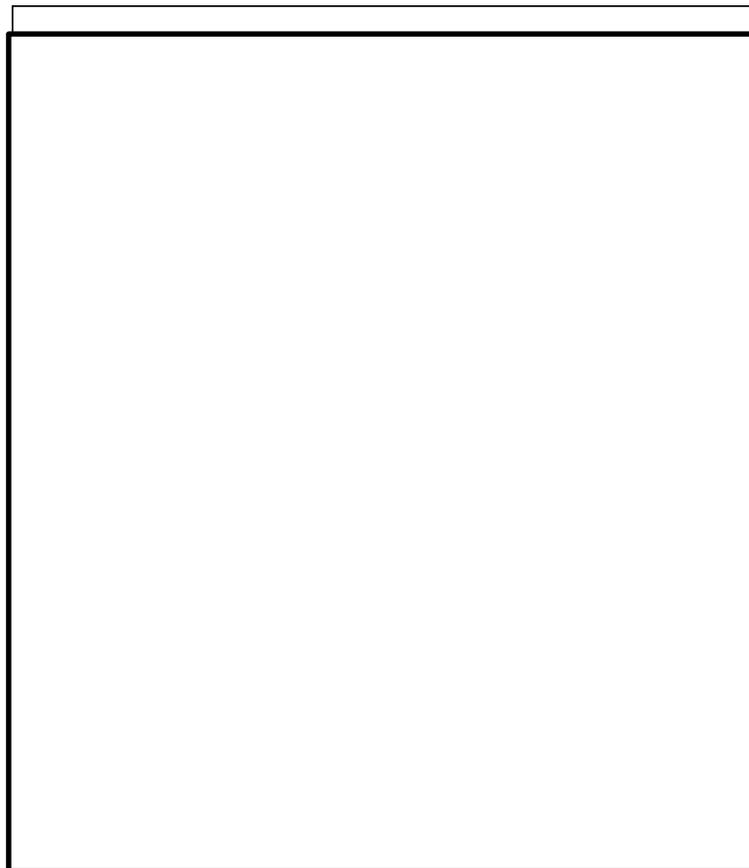
5. Indicate with a "X" where your aims and partnership fall on the *Translational Research vs. Community Engagement/Partnership* Plot.



# Translational Research vs. CE Partnership



6. How can you make the project more engaged (minimum 3 ideas)? Hint: What activities would allow you to shift your position (e.g. upward, right)



**EDUCATION**

CDN is an AHRQ designated Center of Excellence for Primary Care Practice-Based Research and Learning (2012).

[LEARN MORE](#)



Clinical Directors Network, Inc. (CDN) is a not-for-profit clinician membership organization, practice-based research network (PBRN), and clinician training organization, founded to provide peer-initiated activities for clinicians practicing in low income, minority, and other underserved communities. CDN's overall goal is to translate clinical research into clinical practice for the enhancement of health equity and improvement of public health. [MORE](#)



### Research

CDN was designated a "Best Practice" Clinical Research Network by the NIH (2006).

**We accelerate research translation.** CDN has over 25 years of experience developing, conducting, implementing and evaluating practice-based research with Community Health Centers and other safety-net practices. [MORE](#)



### Education

CDN is an AHRQ designated Center of Excellence for Primary Care Practice-Based Research and Learning (2012).

**We provide peer support through training and education** that integrates online and on-site didactic and experiential learning. Collaborate with us to meet your training needs. [MORE](#)



### Partnership

CDN has an extensive network of multidisciplinary researchers, clinicians, clinical leaders and policy-makers.

**We conduct research and educational activities** in partnership with government, academic, not-for-profit, and for profit organizations. Our national network represents an enormous resource for change. [MORE](#)



### Dissemination

CDN has extensive experience disseminating research and training programs to our extensive network of multidisciplinary researchers, clinicians, clinical leaders and policy-makers.

**We provide dissemination services through webcasts** for public health and clinical research projects. [MORE](#)



# CTSA Dissemination & Implementation Research Work Group Webcast: Dissemination and Implementation Science: What is it and Why is it Critical to Translational Science?



ABOUT US | RESEARCH | EDUCATION | DISSEMINATION | LIBRARY | PARTNERSHIPS | CONTACT US

Home » Library

## Dissemination and Implementation Science: What is it and Why is it Critical to Translational Science?

Complete the form below to view this video.

### Speakers:

#### Enola Proctor, PhD, MSW

Director, Center for Dissemination and Implementation at the Institute for Public Health; Director, Center for Mental Health Services Research and Shanti K. Khindka Distinguished Professor at the Brown School

#### Stephen Bartels, MD, MS

Professor of Geriatrics, and Professor of Psychiatry, Community & Family Medicine, and of Health Policy at The Dartmouth Institute

#### Laura-Mae Baldwin, MD, MPH (Moderator)

Professor, Department of Family Medicine, Director, Community Engagement, Institute of Translational Health Sciences, University of Washington

[www.CDNetwork.org/library](http://www.CDNetwork.org/library)

[www.CDNetwork.org/library/Dissemination-Implementation-Science-Critical-translational-science](http://www.CDNetwork.org/library/Dissemination-Implementation-Science-Critical-translational-science)

### Recent Webcasts

From Molecular Epidemiology to Medical Anthropology: Trust in the Time of MRSA-BKV  
October 16, 2019



Innovative Strategies to Eliminate HCV  
June 7, 2019



Medicaid Delivery and Payment Reform: Experience of MA and NY Community Health Centers  
April 25, 2019



# Dissemination of the Rockefeller-CDN Translational Research Model

Innovation Report

OPEN BLOG

## Helping Basic Scientists Engage With Community Partners to Enrich and Accelerate Translational Research

Rhonda G. Kost, MD, Andrea Leinberger-Jabari, MPH, Teresa H. Evering, MD, MS,  
Peter R. Holt, MD, Maija Neville-Williams, MPH, Kimberly S. Vasquez, MPH,  
Barry S. Collier, MD, and Jonathan N. Tobin, PhD

### Abstract

#### Problem

Engaging basic scientists in community-based translational research is challenging but has great potential for improving health.

#### Approach

In 2009, The Rockefeller University Center for Clinical and Translational Science partnered with Clinical Directors Network, a practice-based research network (PBRN), to create a community-engaged research navigation (CEnR-Nav) program to foster research pairing basic science and community-driven scientific aims. The program is led by an academic navigator and a PBRN navigator. Through meetings and joint activities, the program

facilitates basic science–community partnerships and the development and conduct of joint research protocols.

#### Outcomes

From 2009–2014, 39 investigators pursued 44 preliminary projects through the CEnR-Nav program; 25 of those became 23 approved protocols and 2 substudies. They involved clinical scholar trainees, early-career physician–scientists, faculty, students, postdoctoral fellows, and others. Nineteen (of 25; 76%) identified community partners, of which 9 (47%) named them as coinvestigators. Nine (of 25; 36%) included T3–T4 translational aims. Seven (of 25; 28%) secured external funding, 11 (of 25; 44%) disseminated

results through presentations or publications, and 5 (71%) of 7 projects publishing results included a community partner as a coauthor. Of projects with long-term navigator participation, 9 (of 19; 47%) incorporated T3–T4 aims and 7 (of 19; 37%) secured external funding.

#### Next Steps

The CEnR-Nav program provides a model for successfully engaging basic scientists with communities to advance and accelerate translational science. This model's durability and generalizability have not been determined, but it achieves valuable short-term goals and facilitates scientifically meaningful community–academic partnerships.



#### When

Wednesday, June 19, 2018 from 12:00 PM to 1:00 PM  
PT

[Add to Calendar](#)

#### Contact

Clinical Directors Network, Inc. (CDN)  
12-882-0699 ext 248  
[learning2@CDNetwork.org](mailto:learning2@CDNetwork.org)

Connect with us on social media!



[www.CDNetwork.org](http://www.CDNetwork.org)

## Dissemination and Implementation Science: What is it and Why is it Critical to Translational Science?

### SPEAKERS:



#### Enola Proctor, PhD, MSW

Director, Center for Dissemination and Implementation at the Institute for Public Health; Director, Center for Mental Health Services Research and Shanti K. Khindka Distinguished Professor at the Brown School



#### Stephen Bartels, MD, MS

Professor of Geriatrics, and professor of Psychiatry, Community & Family Medicine, and of Health Policy at The Dartmouth Institute



#### Laura-Mae Baldwin, MD, MPH

Professor, Department of Family Medicine, Director, Community Engagement, Institute of Translational Health Sciences, University of Washington

Acad Med. 2017;92:374–379.

# THE N<sup>2</sup> PBRN ONLINE RESEARCH TRAINING CERTIFICATE PROGRAM CURRICULUM (CPBRN)

## TRACKS

- PBRN Research Management Innovations (for PBRN Senior Staff)

1

- PBRN Methods (for PBRN Senior Staff & Academic Collaborators)

2

- Introduction to Research (for CHC Nodes Staff & New PBRN Staff)

3

- PBRN Study Results (for CHC Nodes, CHC Partners, PBRN Senior Leadership & Staff, Academic Partners)

4

Aims to enhance the skills of current PBRN researchers and practicing clinicians who are interested in participating in clinical research

## CONTENT

- Evidence-based practices and **best practices** demonstrated to be effective at transforming clinical research into a more clinician-engaged, accelerated research and translation model, with significant clinical and public health impact
- A “Virtual Faculty” of N<sup>2</sup> PBRN Directors and their PBRN-related research
- N<sup>2</sup> PBRN Academic Partners “Virtual Faculty” and their PBRN-related research
- Training in **research methodology** for practicing clinicians who wish to become more active and engaged in practice-based research
- New content added on **Pragmatic Clinical Trials, CER & PCOR Research methods**



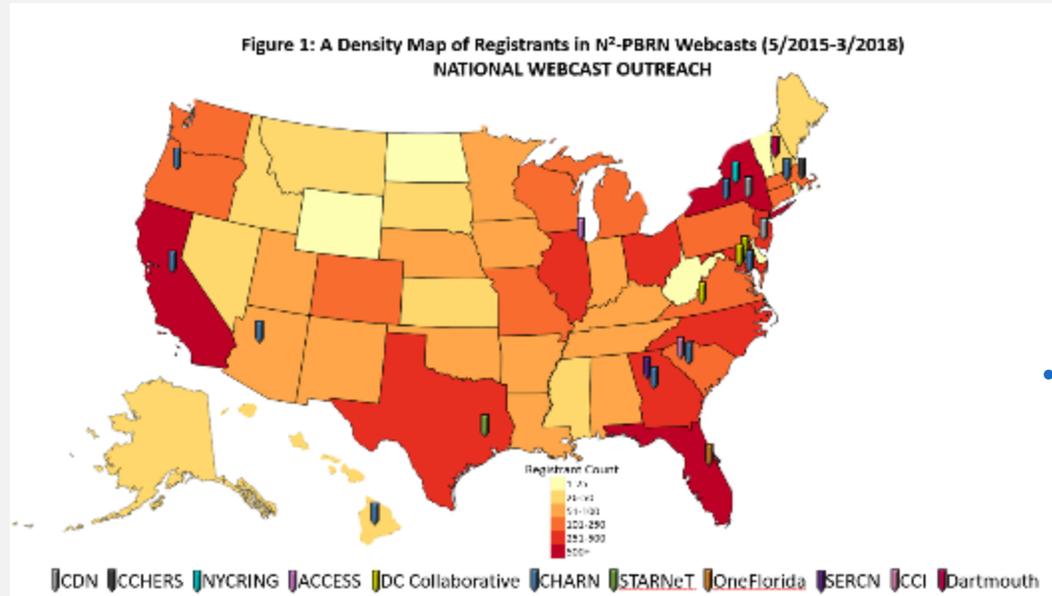
A collaboration between CDN, Case Western Reserve University, Collaborative Ohio Inquiry Network (COIN) and the eight AHRQ-funded N<sup>2</sup>-PBRN Centers of Excellence in Practice-Based Research and Learning

This fellowship program seeks to develop a new generation of independent investigators within the practice-based research network (PBRN) community, and was launched in September 2015. It provided training in concepts, skills, and methods for conducting practice based research and building PBRNs. The program is designed for individuals who aspire to become independent PBRN research investigators and for experienced investigators who want to develop expertise in PBRNs. Fellows devote approximately 4-6 hours/month to learning activities during the ten-month program. Each fellow will have a local mentor who devotes 1-2 hours/month. .

# ROCKEFELLER - CDN DISSEMINATION & REACH:



- As part of N<sup>2</sup>-PBRN, a total of **93** N<sup>2</sup>-PBRN webcasts have been conducted and disseminated to clinicians and researchers across the CTSA, N2-PBRNs, FQHCS (9/2012-3/2018) <http://www.CDNNetwork.org/Rockefeller>



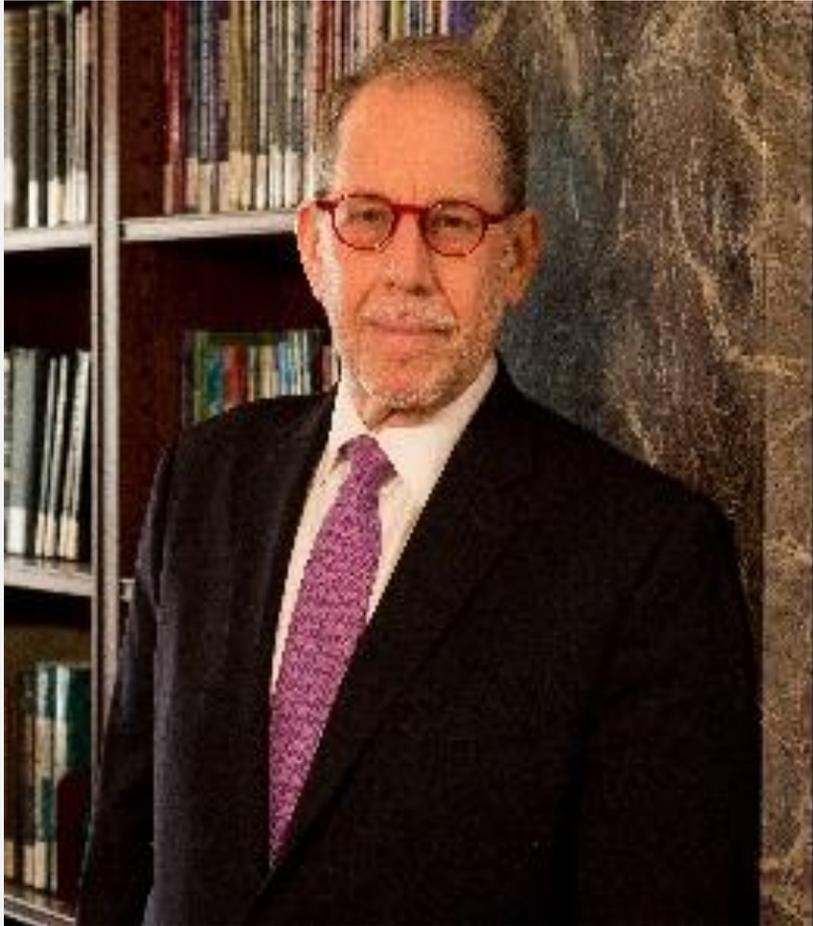
- 82 CME credits** awarded to participants from 50 US states and territories, including Puerto Rico and the US Virgin Islands

CDN N<sup>2</sup>-PBRN – Center of Excellence for Primary Care Practice-based Research and Learning funded by AHRQ Grant: P30HS021667

[www.CDNNetwork.org](http://www.CDNNetwork.org)

	Live Viewers	Enduring Viewers	Total Viewers	Credit(s)	% Rated Good to Excellent
<b>Total</b>	10,998	2,860	<b>13,858</b>	89	98 sessions
<b>Average</b>	113	30	143	1.11	<b>95%</b>

# Jonathan N. Tobin, PhD, FAHA, FACE



President/CEO  
**Clinical Directors Network, Inc. (CDN)**  
**New York NY**

Co-Director, Community Engaged Research  
Senior Epidemiologist & Adjunct Professor  
**The Rockefeller University**  
**Center for Clinical and Translational Science**  
**New York NY**

Professor, Department of Epidemiology &  
Population Health  
**Albert Einstein College of Medicine**  
**Montefiore Medical Center**  
**Bronx NY**

**(212) 382-0699 ext. 234**

**JNTobin@CDNetwork.org**

**jtobin@Rockefeller.edu**

[www.CDNetwork.org/](http://www.CDNetwork.org/)

