

Drug Research and Development for Adults Across the Older Age Span

THE ERA OF COVID-19 AND BEYOND:

Older Adult Outreach & Networking Strategies

Jonathan N. Tobin, PhD, FAHA, FACE

President/CEO

Clinical Directors Network, Inc. (CDN)

New York NY

Senior Epidemiologist & Co-Director, Community Engaged Research

The Rockefeller University Hospital 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

Presented at:

National Academies of Sciences, Engineering & Medicine (NASEM) Virtual Workshop

August 6, 2020

1. Describe the Structure and Function of Networks
2. Discuss Barriers to including Older Adults into Research
 - a. Study Design
 - b. Study Access/Participation
3. Examine Three Case Studies of Network-conducted Research with Older Adults
4. Recommendations & Conclusions

Primary Care Practice-based Research Networks (PBRNs)

- Group of ambulatory care practices
- Network structure transcends a single research project
- Link practicing clinicians with experienced clinical investigators
- Enhance research skills of network clinician members
- Create a “Learning Healthcare System”

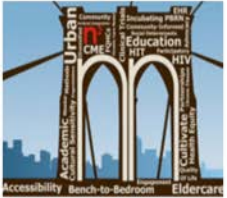
Mission:

- Service - primary care of patients
- Goal - improve quality of primary care
- Investigation - questions related to community-based practice



Translating Research into Practice

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](#)

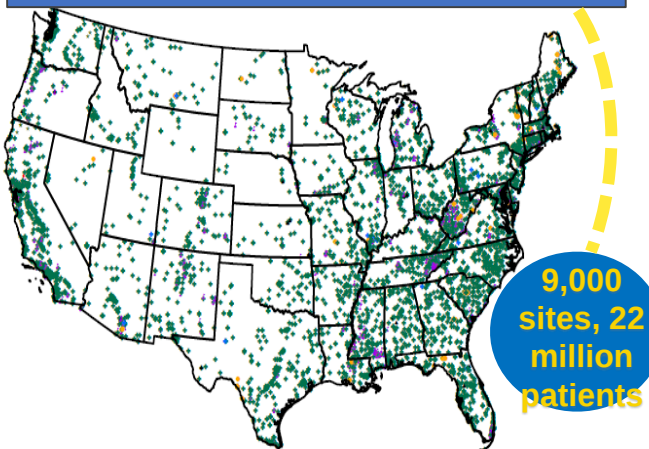


Urban
Academic
CME
Education
HIT
HIV
Research
Training
Accessibility
Bench-to-Bedroom
Eldercare

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

HRSA-funded Federally Qualified Health Center (FQHC) Patients by Age and Gender (2018)

	<u>National</u>		<u>New York</u>	
Total # Grantees	1,362		62	
Total # Delivery Sites	12,701		796	
<u>AGE</u>	<u>MALE</u>	<u>FEMALE</u>	<u>MALE</u>	<u>FEMALE</u>
<18	4,371,724	4,364,785	346,668	347,246
18-29	1,555,460	2,997,504	146,397	258,258
30-54	3,537,845	5,562,508	283,529	445,911
55-64	1,488,087	1,900,195	105,615	138,090
65-74	729,284	996,408	54,362	77,972
>75	335,925	539,955	26,648	46,559
>55	2,553,296 (21%)	3,436,558 (21%)	186,625 (19%)	262,621 (20%)
<u>TOTAL</u>	12,018,325	16,361,355	963,219	1,314,036

Major Barriers Need to be Overcome to Conduct Research that Engages Older Adults

We need to understand the challenges posed by these barriers, many of which are also the same barriers to implementing evidence-based interventions for older adults

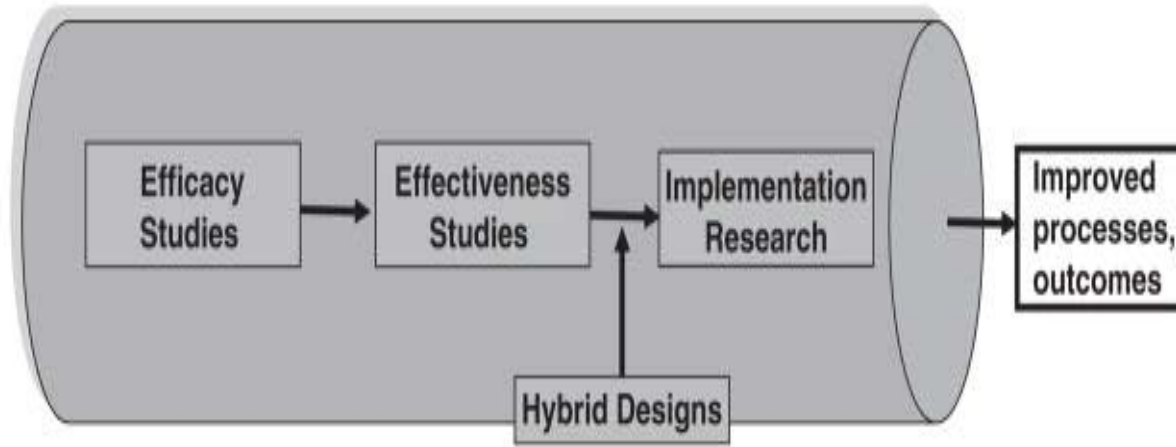
They involve:

a. Study Design Considerations (inclusion, exclusion criteria, trial settings, design, conduct)

b. Access Barriers (transportation, language, literacy, comfort/convenience, trust)

Studies Need to be Pragmatic, Hybrid Effectiveness/Implementation Studies

1. What works (Effectiveness) - pharmacotherapeutics
2. How to deliver the intervention (Implementation) – designed for delivery



Curran, G. M., Bauer, M., Mittman, B., Pyne, J. M., & Stetler, C. (2012). Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical care*, 50(3), 217–226.

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3731143/>
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3731143/>

An Overview of Hybrid Effectiveness-Implementation Designs – CDN Webcast

<https://www.CDNetwork.org/library/an-overview-of-hybrid-effectiveness-implementation-designs>



Journal of Clinical Epidemiology 62 (2009) 464–475

Journal of
Clinical
Epidemiology

ORIGINAL ARTICLE

A pragmatic—explanatory continuum indicator summary (PRECIS):
a tool to help trial designers

Kevin E. Thorpe^{a,*}, Merrick Zwarenstein^b, Andrew D. Oxman^c, Shaun Treweek^d,
Curt D. Furberg^e, Douglas G. Altman^f, Sean Tunis^g, Eduardo Berge^h, Ian Harveyⁱ,
David J. Magid^j, Kalipso Chalkidou^k

^aDalla Lana School of Public Health, University of Toronto, Toronto, Ontario, Canada M5T 3M7

^bCentre for Health Services Sciences, Sunnybrook Research Institute, Sunnybrook Health Sciences Centre; Institute for Clinical Evaluative Sciences; Department of Health Policy, Management and Evaluation, University of Toronto, Toronto, Ontario, Canada

^cPreventive and International Health Care Unit, Norwegian Knowledge Centre for the Health Services, Oslo, Norway

^dDivision of Clinical & Population Sciences and Education, University of Dundee, Dundee, UK; Norwegian Knowledge Centre for the Health Services, Oslo, Norway

^eDivision of Public Health Sciences, Wake Forest University School of Medicine, Winston-Salem, NC, USA

^fCentre for Statistics in Medicine, University of Oxford, Oxford, UK

^gCenter for Medical Technology Policy, Baltimore, MD, USA

^hUNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland

ⁱFaculty of Health, University of East Anglia, Norwich, UK

^jInstitute for Health Research, Kaiser Permanente Colorado; Departments of Preventive Medicine and Biometrics and Emergency Medicine, University of Colorado Health Sciences Center, Denver, CO, USA

^kNational Institute for Health and Clinical Excellence, London, UK

Accepted 13 December 2008

Abstract

Objective: Pragmatic trials seek the question, “C but no tool course of two in methodology, an **Results:** We how pragmatic c **Conclusion:** consistent with t

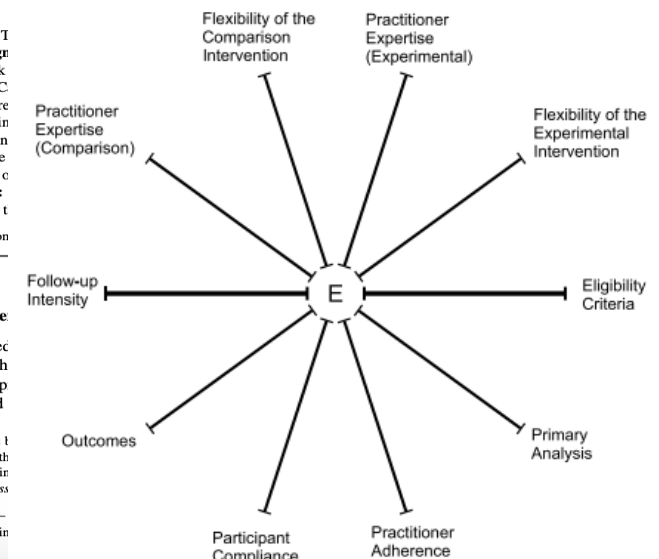
Keywords: Random

1. The problem

Randomized controlled trials are categorized as either explanatory or pragmatic. Although we p Schwartz and

This article is in the Journal of Clinical Epidemiology and the * Corresponding author. E-mail address

0895-4356/09/\$ — doi: 10.1016/j.jclinepi



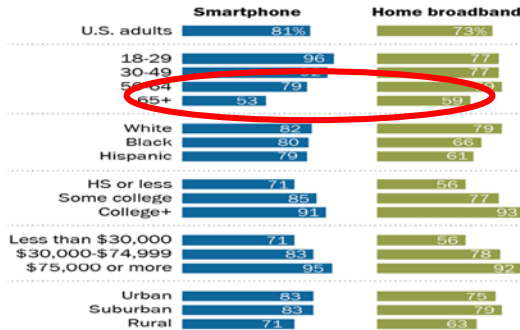
pose. attitude. Pragmatic trials are focused on the explanatory, il. During the planning, trial decisions are

d the terms choose be- scribe trials given inter- ic trials are an interven- be applied, ed to deter- nider ideal

A pragmatic—explanatory continuum indicator summary (PRECIS): a tool to help trial designers Thorpe, Kevin E. et al. Journal of Clinical Epidemiology, Volume 62, Issue 5, 464 – 475
www.PRECIS-2.org

Majorities of Americans have a smartphone, subscribe to broadband, but this varies by education, income

% of U.S. adults who say they have or own the following



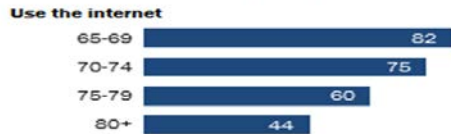
Note: Respondents who did not give an answer are not shown. Whites and blacks include only non-Hispanics. Hispanics are of any race.

Source: Survey of U.S. adults conducted Jan. 8-Feb. 7, 2019. "Mobile Technology and Home Broadband 2019"

PEW RESEARCH CENTER

Tech use is especially limited among those ages 75 and up

% of U.S. adults in each age group who say they ...



Subscribe to home broadband services



Own a smartphone



Source: Survey conducted Sept. 29-Nov. 6, 2016. "Tech Adoption Climbs Among Older Adults"

PEW RESEARCH CENTER

Access Barriers:

Use mHealth, eHealth & Telehealth Technologies BUT Need to Overcome Barriers to their Use

- Older adults face unique barriers to technology adoption
 - physical challenges
 - lack of comfort and familiarity with technology
- o Just 26% of internet users ages 65 and over say they feel very confident when using computers, smartphones or other electronic devices to do the things they need to do online
- o Roughly one-third describe themselves as only a little (23%) or not at all (11%) confident in their ability to use electronic devices to do necessary online activities
- o **Most seniors say they need help using new electronic devices**
- o Only around a third of disabled seniors say they have home broadband

<https://www.pewresearch.org/internet/2017/05/17/barriers-to-adoption-and-attitudes-towards-technology/>

<https://www.pewresearch.org/internet/2017/05/17/tech-adoption-climbs-among-older-adults/>

<https://pewresearch-org-preprod.go-vip.co/internet/2019/06/13/mobile-technology-and-home-broadband-2019/>



How to Leverage PBRNs to Engage Clinicians, Staff, Participants and Obtain Data



Three Case Studies of research conducted by **Clinical Directors Network (CDN)**

- Primary Care Practice-based Research Network (PBRN)
 - Clinician Training/CME Organization
 - Network of Networks (N²-PBRN) (Center of Excellence funded by AHRQ)
1. mHealth & eHealth studies of improving hypertension control (Cluster RCTs Funded by NHLBI) and diabetes control (RCT funded by NIDDK)
 2. Tipping Points Study (Cluster RCT) of Adding Health Coaches for Patients with Multiple Chronic Conditions in FQHCs (Funded by PCORI)
 3. DASH Diet Implementation Study: A Before-After Cluster Trial of Implementing the DASH Diet in Congregate Meal Settings in CBOs (Funded by DHHS/ACL and NIH-NCATS CTSA)

Case Study #1a/b: Using mHealth & eHealth Frameworks

- 1) Coaching Sessions
 - Calculating patient's ASCVD risk score
 - Goal setting and empowerment
 - Behavioral change techniques

- 2) Phone Check-Ins with HIV+ peer educators

- 3) Texting to facilitate ABCS goal setting and self-management

Mosio Texting Platform – GREAT2 Study

- Mobile platform designed for clinical research
- HIPAA compliant
- 2-way communication (fosters patient engagement and activation)
 - Text message alerts regarding ADCS goal choice and SMS (short message service) surveys
 - Text messages that call for simple numeric responses (ie. 1, 2, 3, 4)
 - Incentives for active engagement
 - Opt-out feature available



T2 Coach
Elliot 1-0001 Sign Out

Glucose Level (mg/dL) *

124

Reading Time *

2019-11-05 11:33

Insulin Taken (Units)

e.g. 2

Cancel Create

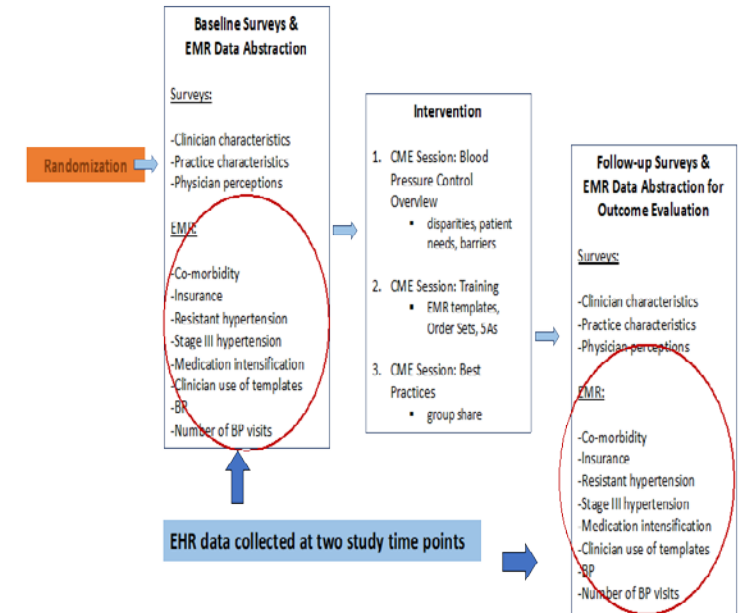
I noticed that your blood sugar is usually higher after dinner. 70% of your meals in the last two weeks had more than 3 portions of carbs (more than 45g).

Here is a suggestion:
Decrease your carbs at dinner. Try to eat no more than 3 portions of carbs at dinner.

Would you like to follow this goal?

Y. Yes
N. No, show me other goal options

ELECTRONIC HEALTH RECORD DATA



NHLBI Grant #1 U01 HL142107-01
with University of Rochester & Parkland Health
MPIs: Kevin Fiscella MD, MPH
Jonathan N. Tobin, PhD

NIDDK Grant #1 R01 DK113189-01A1
with Columbia University
PI: Lena Mamykina, PhD PI
Co-PI: Jonathan N. Tobin, PhD

NHLBI Grant #1-R18-HL-117801
with University of Rochester
MPIs: Kevin Fiscella, MD MPH
Jonathan N. Tobin, PhD

Case Study #2: Preventing Tipping Points in High Comorbidity Patients

What Is the Effect of Adding a Health Coach to Patient-Centered Medical Homes for Managing Multiple Chronic Conditions?

Interventions/
Comparators

- PCMH
- PCMH with health coach

Outcomes

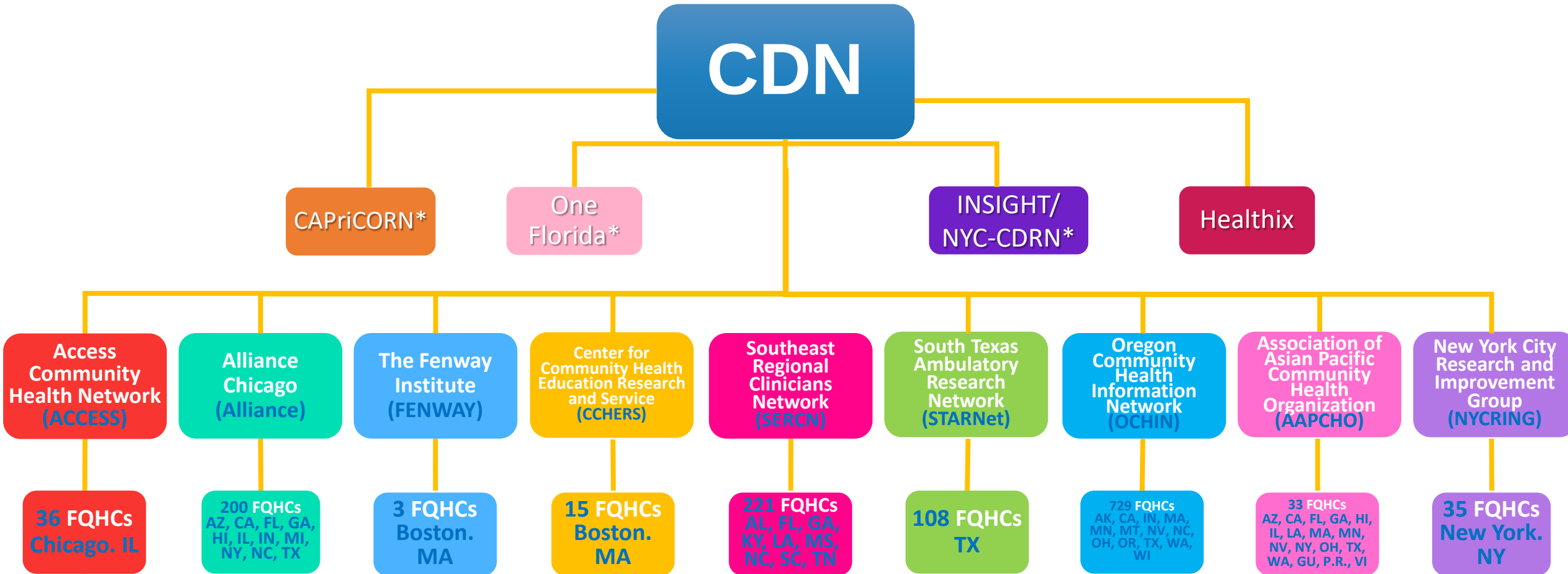
Primary: unplanned hospitalizations, disability

Secondary: ER visits, patient activation, patient education and self-management

- Cluster Randomized Clinical Trial
- Engage 4 Health Systems with 4 of their FQHC sites with at least **500 patients** who have high comorbidity (**total=16 FQHCs in NYC & Chicago**)
- Predominantly low-income, black and Latino/a adult patients with multiple chronic diseases (**Charlson Comorbidity Index ≥ 4**)
- Conduct recruitment (**N=1920**), assessment and intervention through trained Health Coaches (now via telephone)

Funding: PCORI/IHS-2017C3-8923

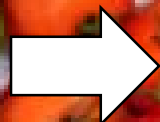
CDN N²-PBRN NETWORK OF NETWORKS[&]



DASH Diet Implementation Study at Carter Burden Network Senior Centers in NYC

www.CDNetwork.org/CBN-DASH

**Dietary Approaches to Stop
Hypertension (DASH) Diet
Intervention Project-
Administration for
Community Living (ACL)**

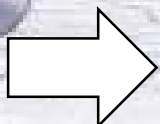


Primary Aim: To determine whether implementation of the DASH diet delivered through the congregate meal programs (with educational and behavioral support) can lower blood pressure in seniors receiving the program.

Project Locations:

Luncheon Club- CBN's first senior center
Leonard Covello Senior Program-NYC Dept. for the Aging innovative senior center (open 7 days per week) in East Harlem

**DASH Diet Intervention
Project at CBN
Senior Centers**



Primary Outcomes:

- a) Change in mean systolic BP at 1 month after the full after implementation of the DASH-aligned congregate meals, compared to baseline
- b) Increase in the proportion of individuals whose blood pressure is controlled according to JNC-8 guidelines, for age > 60 years, SBP/DBP < 150/90

*This work is funded by grant # HHS-2018-ACL-AOA-INNU00300 DHHS/Administration on Aging Innovations in Nutrition Programs and Services Administration for Community Living (ACL) with additional support from the NIH-NCATS/CCTS grant UL1 TR001866 to The Rockefeller University
PIs: Dozene Guishard, EdD (CBN), Rhonda Kost, MD (Rockefeller), Jonathan N. Tobin, PhD (CDN/Rockefeller)*

NYC Department for the Aging (DFTA) Meals Served (2019)

The NYC Department for the Aging served 229,875* older New Yorkers through its in-house and contracted programs

Population of Older New Yorkers*

Age Group	Population
60-64	453,546
65-74	600,110
75-84	316,300
85+	139,844
Total	1,509,800

Client Data		Service Data	
DFTA Clients	229,875	Congregate Meals <i>(breakfast, lunch, dinner and weekend meals)</i>	7,175,639
Senior Center Participants	167,607	Average Daily Congregate Meals	28,684
Average Daily Senior Center Participants	29,727	Home Delivered Meals	4,554,828
Home Delivered Meal Clients	27,065		

- **Served 229,874 older adults**
 - 11.7 million meals were served
 - 7.18 million congregate meals at senior centers
 - 4.55 million meals delivered to seniors in their homes

* <https://www1.nyc.gov/assets/dfta/downloads/pdf/reports/ProfileOfOlderNewYorkers2019.pdf>



Case Study #3: DASH Diet Implementation Study: A before-after Cluster RCT of Implementing the DASH Diet in Senior Centers



- a. Combining a PBRN (CDN), NIH CTSA CEnR Core (RU-CCTS) and a network of senior services providers (CBN) funded by NYC-DFTA & philanthropic sources
- b. Illustrates a different network of services providers including an academic research center (RU-CCTS), a practice-based research network (CDN), a network of community-based meals and educational providers (CBN)
- c. CBN provides daily congregate meals, take home food, and continuing adult educational and social services referrals for community-residing low income, food-insecure older adults in East Harlem and other parts of NYC
- d. Similar principles operate to enhance research participant and public health reach & impact
 - i. * Warm handoff (Introductions of clients by social service providers to PBRN Staff)
 - ii. * Trust by Proxy (trust between social service providers and PBRNs, between social services providers and their clients)
 - iii. * Integration of multiple providers and data sources

www.CDNetwork.org/CBN-DASH

Mitigate Access Barriers

Increase the use of:

- Telehealth, mHealth, eHealth, Apps
- Home visits for assessments, delivery of therapies, treatments, and other interventions
- Navigators by telephone
- Peer outreach
- Flyers/outreach letter mail-outs printed on institutional letterhead and signed primary care clinician
 - Including recruiter's/evaluator's phone #
 - Using a trusted organization as a "middle-man"
 - Print materials: low literacy, high-quality large print, culturally appropriate, FAQs



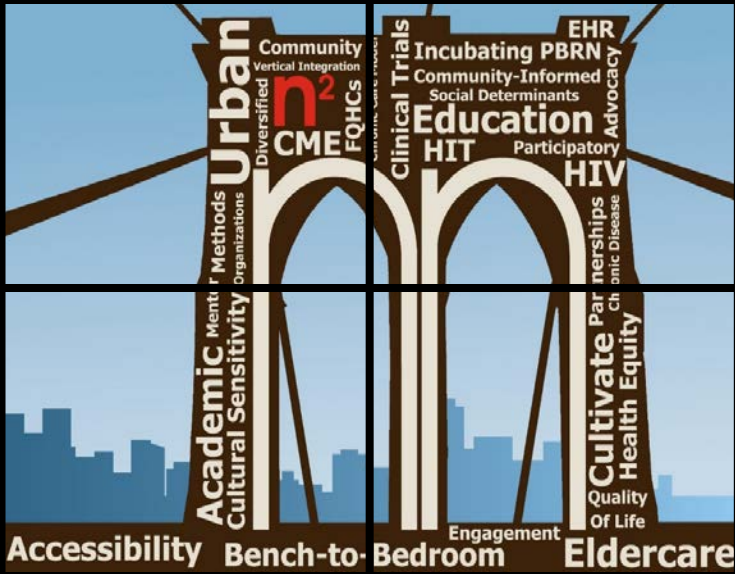
- Leverage community-based partnerships with organizations that serve older adults
- Identify from the EHR and approach patients when they come in for an appointment
- Caller ID from known clinical site
- Target patients attending educational classes/session at sites
- Engage family members and caregivers
- Recruiter/research staff use active listening and motivational interviewing strategies

- a. Broader eligibility criteria (+multiple comorbidity +polypharmacy)
- b. Investigator team to include not only researchers, but also clinicians, other services providers
- c. Engaging clinicians, social services staff, as well as patients and their caregivers
- d. Focus on pragmatic designs
 - o Conducted in real world settings, using workflow & existing data streams
 - o Principles of “Participatory Design” for intervention and evaluation
- e. Incorporate key types of study designs
 - o Pragmatic study designs
 - o Hybrid Effectiveness/Implementation Studies
 - o Cluster Randomized Trials - **testing both intervention and setting effects**

Conclusions

CDN N²-PBRN is an example of how networks can play a significant role in reducing barriers to engaging older adults in research – by demonstrating how networks:

- a. increase access in real world settings
- b. increase heterogeneity of both patient-level and organization-level variables
- c. provide adequately powered sample sizes for subgroup analyses
- d. allow greater statistical power to examine heterogeneity of treatment effects
- e. enhance participation through trust (staff, participants, researchers)
- f. capture more comprehensive, integrated longitudinal data about experiences, services and outcomes across a broader set of community-based providers
- g. be deployed both to generate new evidence and to disseminate and implement new evidence into practice which will enhance public health for these underserved populations
- h. These networks provide an existing and well-tested infrastructure that is effective at engaging a broad range of underserved populations, including older adults



RESEARCH



CLINICAL • DIRECTORS • NETWORK

PARTNERSHIP



CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE



N² PBRN

Jonathan N. Tobin, PhD, FAHA, FACE
President/CEO
Clinical Directors Network, Inc. (CDN)

Senior Epidemiologist & Co-Director, Community Engaged Research
The Rockefeller University Hospital
Center for Clinical and Translational Science

Professor, Department of Epidemiology & Population Health
Albert Einstein College of Medicine/Montefiore Medical Center

JNTobin@CDNetwork.org

www.CDNetwork.org

EDUCATION

DISSEMINATION

ENGAGEMENT

NT

I will focus on several Key Barriers Limiting Research Participation for Older Adults

- a. Multiple chronic diseases (MCDs)
- b. Polypharmacy
- c. Older adults are often excluded from participating in clinical research because their Inclusion introduces
 - i. significant heterogeneity
 - ii. potential for confounding
 - iii. limiting generalizability from results of studies including only younger, healthier adults
- d. The inclusion of older adults will
 - i. Enhance generalizability
 - ii. Require larger numbers of clinical subgroups, adequately powered for subgroup analysis/heterogeneity of treatment effects



Case Study #1: Tipping Points (PCORI): A Cluster RCT for Implementing Health Coaches in FQHCs for Patients with Multiple Chronic Diseases



- a. Network of Networks includes 2 PBRNs and 4 of their member HRSA-funded Health Systems with 16 of their FQHCs, as well as 2 PCORI-funded CDRNs, a NYS DoH-funded Health Information Exchange and 2 proprietary patient data providers in NYC and Chicago
- b. CDN and our Academic Partner, WCM integrate electronic health data from MCD patients
- c. Data are captured routinely in the Patient-Centered Medical Home (PCMH) settings where they receive their comprehensive primary care
 - i. Patients have a trusted, ongoing relationship with their PCMH and PCPs
 - ii. FQHC Clinicians, Staff, Board & Community have a trusted and ongoing relationship with the PBRNs
 - iii. Using “Warm Handoffs” the FQHC clinicians and staff make introductions of potentially eligible patients to the PBRN staff who are integrated into the practices
 - iv. Using “Trust by Proxy” overcomes many of the patients’ concerns about their safety, privacy & wellbeing
- d. Ongoing clinical care relationship and well-designed, patient-friendly trials enhance retention
- e. N2-PBRN integrates comprehensive longitudinal data (EHR-based combined with patient-reported assessments) across multiple service providers, conducted and captured in real-world settings, generating relevant real-world evidence on both effectiveness and implementation
- f. By conducting research in settings where people receive their ongoing care across multiple health systems and care delivery settings, thereby generating real world data in broader, less highly selected populations
- g. The same types of settings where the research is conducted will be the vehicle for disseminating and scaling up the implementation of the results
- h. PBRN generates new evidence and disseminates and implements new evidence more broadly



How to Minimize/Mitigate Barriers to Participation By Increasing the Use of:



- a. Telehealth and mHealth app services
- b. Home visits for assessments, delivery of therapies, treatments, and other interventions
- c. Navigators by telephone
- d. Peer outreach
- e. Flyers/outreach letter mail-outs on institution letterhead and signed by primary care clinician
- f. Including recruiter's/evaluator's phone # (leave voicemail)
- g. Telephone calls need to be placed from familiar telephone numbers – eg FQHC
- h. Using a trusted organization as a "middle-man"
- i. Print materials: low literacy, high-quality large print, culturally appropriate, FAQs
- j. Leverage community-based partnerships with organizations that serve older adults
- k. Identify from EHR, approach patients when they come in for an appointment
- l. Target patients attending educational classes/session at FQHCs, CBOs
- m. Engage family members and caregivers
- n. Recruiter/research staff use active listening and motivational interviewing

Building Community-Academic Translational Research Partnerships

ROCKEFELLER = CTSA INFRASTRUCTURE

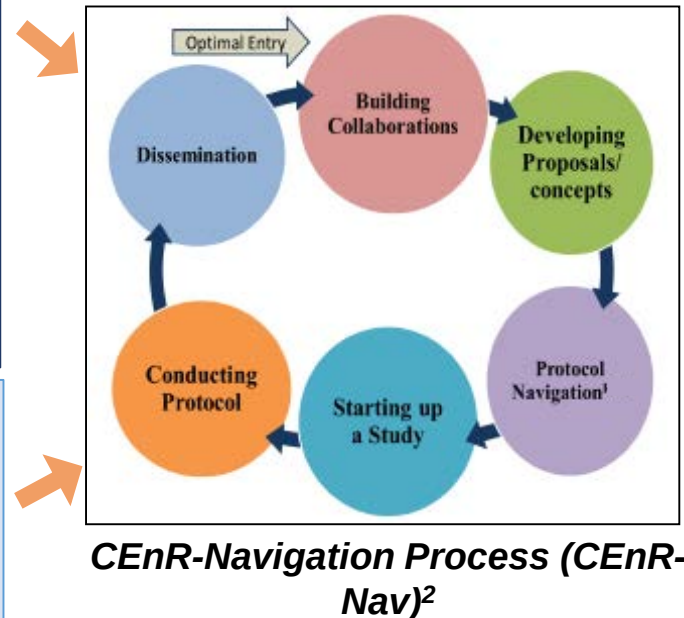
Focus on:

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

CDN/N² = PBRN INFRASTRUCTURE¹

Focus on:

- Quality Improvement
- Clinical Outcomes
- Comparative Effectiveness Research (CER)
- Implementation Science



**CE
CEnR**

CER/PCOR

+
Embedded
Mechanistic
Studies

¹Kost, R.G., Leinberger-Jabari, A., Evering, T.H., Holt, P.R., Neville-Williams, M., Vasquez, K.S., Coller, B.S., Tobin, J.N., "Helping Basic Scientists Engage with Community Partners to Enrich and Accelerate Translational Research." Academic Medicine. 2017;92(3):374.

²N²- Building a Network of Safety Net PBRNS, <https://www.pbrn.ahrq.gov/sites/default/files/docs/page/N2.pdf>

Journal of Clinical and Translational Science

Journal of Clinical and
Translational Science

www.cambridge.org/cts

Editorial

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Address for correspondence:

K. R. Stevens, RN, EdD, ANEF, FAAN, JCTS Senior
Editor, Castella Endowed Distinguished
Professor, University of Texas Health San
Antonio MSC 7949, 7703 Floyd Curl Drive, San
Antonio, TX 78229-3900, USA.
Email: stevensk@uthscsa.edu

*The article by Ramsey et al., “Designing for
Accelerated Translation (DART) of emerging
innovations in health,” is part of the D&I
collection, but published in an earlier issue
(DOI: <https://doi.org/10.1017/cts.2019.386>).

Introduction to the *JCTS* special issue on Dissemination and Implementation Sciences

Kathleen R. Stevens¹ and Jonathan N. Tobin^{2,3}

¹JCTS Senior Editor, Castella Endowed Distinguished Professor, School of Nursing, University of Texas Health San Antonio, San Antonio, TX, USA; ²JCTS Co-Deputy Editor, President/CEO, Clinical Directors Network, Inc. (CDN), Professor, Department of Epidemiology and Population Health, Albert Einstein College of Medicine, New York, NY, USA and ³Co-Director, Community-Engaged Research, Senior Epidemiologist and Adjunct Professor, The Rockefeller University Center for Clinical and Translational Science, New York, NY, USA

First themed issue for *JCTS*

Together with the Association for Clinical and Translational Science, the Editorial Board of the *Journal for Clinical and Translational Science (JCTS)* has worked over the past two years to raise awareness of the potential of Dissemination and Implementation (D&I) Sciences in improving population health. To that end, this is the first special issue of *JCTS* focused on these emerging scientific fields. This Special Issue has generated significant enthusiasm from those pushing systematic research to this range of the translational science spectrum, where knowledge turns into practice and benefit (hopefully). This collection identifies a body of work that advances translational science. We believe that this themed issue is an excellent vehicle for summarizing a representative selection of leading scientific work stemming from collaborations with (but not limited to) the NIH/NCATS-funded Clinical and Translational Science Award (CTSA) program. We look forward to seeing *JCTS* become a central dissemination partner for D&I Research and scientists going forward.

Definition of Dissemination, Implementation, and D&I Research

NIH defines implementation as the adoption and integration of evidence-based health interventions into clinical and community settings to improve care delivery and efficiency, patient outcomes, and individual and population health. Implementation Research is the scientific study of methods that promote systematic integration of research findings in routine care and practice. Implementation Science is a specialized field that evaluates strategies to enhance adoption of evidence-based practices into everyday care to improve health and health care. Dissemination Research is the scientific study of active and targeted distribution of information and intervention materials to a specific public health or clinical practice audience.¹ The goal of Dissemination Science is to expand our understanding of effective ways to spread knowledge of evidence-based interventions. Some studies combine both D&I while others focus on specific aspects of either one.²



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<https://www.cambridge.org/core/journals/journal-of-clinical-and-translational-science/issue/8290AE183B2BBCFED7D44950BE74E891>