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Trust and Rigor: When Community Engaged Research Meets Randomized Controlled Trials

NCHATS Webinar
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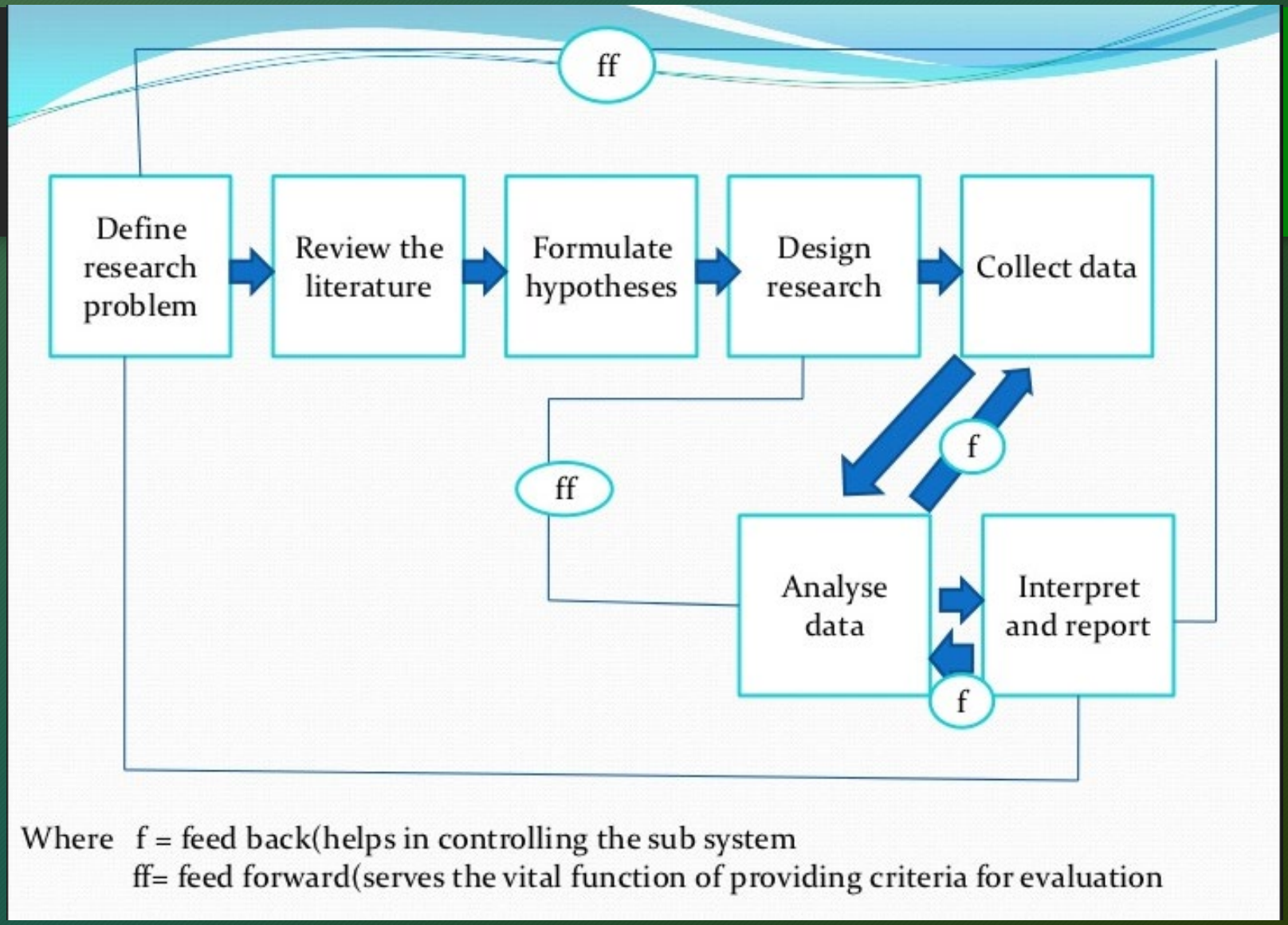


Goals of this webinar

To equip you to: Conduct meaningful and rigorous community-engaged randomized controlled trials.



The Research Process



- CBPR Defined:

- W.K Kellogg- Community Health Scholars Program

- A collaborative approach to research that equitably involves all partners in the research process and recognizes the unique strengths that each brings. CBPR begins with a research topic of importance to the community and has the aim of combining knowledge with action and achieving social change.

- CBPR involves community partners at all stages of the research process.

- Roots: 1940 Social and Political Movements
- Kurt Lewin Action Research
- Supported by Dr. Paulo Freire in the 1970s



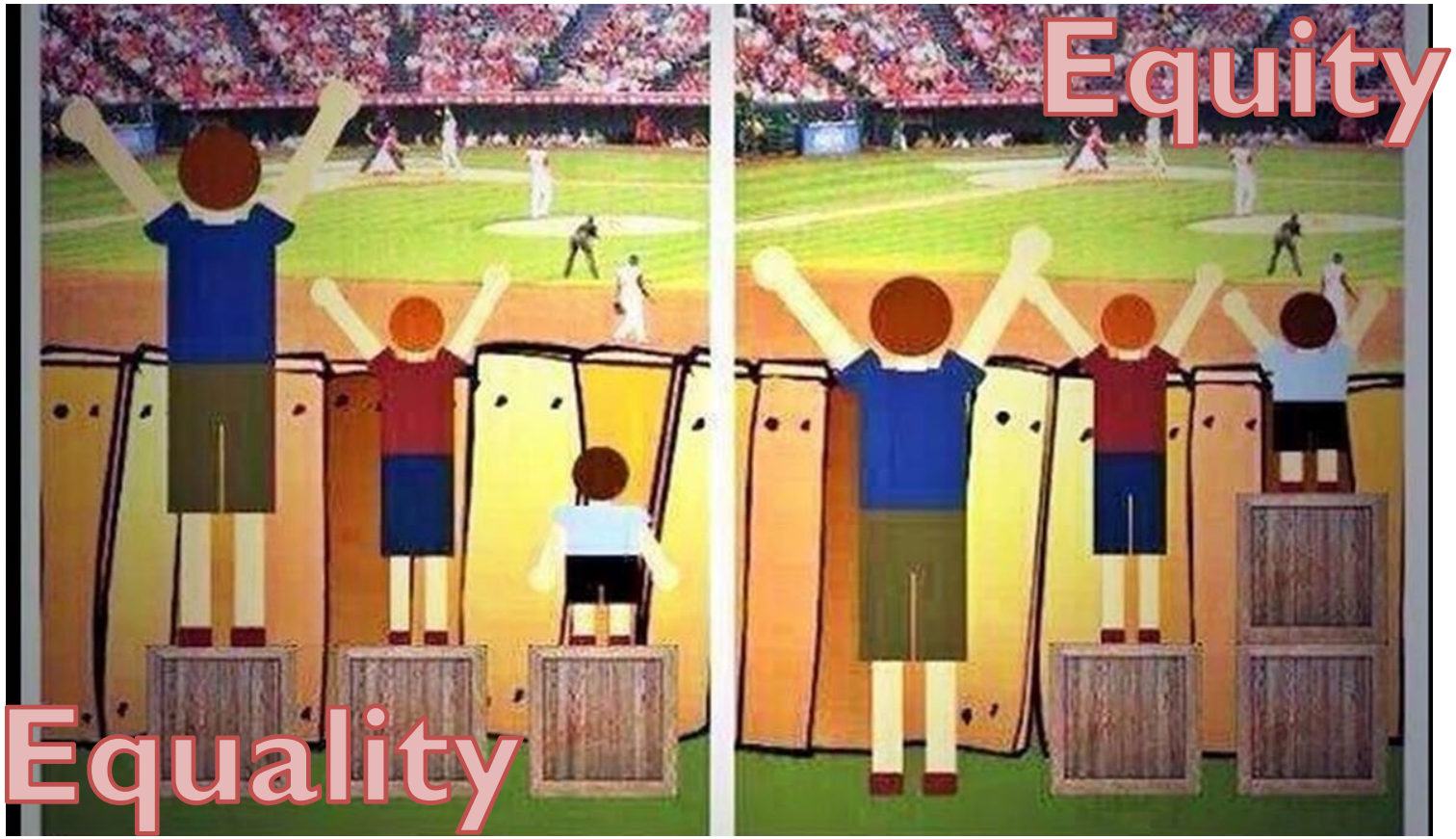
CBPR Principles

Key Principles

Developing community-based partnerships that are successful in creating relationships and research initiatives that are locally relevant take time and patience. A number of authors have advanced principles for CBPR. Drawing on over a decade of experience, Barbara Israel and her colleagues have identified eight key principles of CBPR that support successful research partnerships and are widely cited.

These include:

- Recognizes community as a unit of identity
- Builds on strengths and resources within the community
- Facilitates collaborative partnerships in all phases of the research
- Integrates knowledge and action for mutual benefit of all partners
- Promotes a co-learning and empowering process that attends to social inequalities
- Involves a cyclical and iterative process
- Addresses health from both positive and ecological perspectives
- Disseminates findings and knowledge gained to all partners



Benefits of CBPR

- Increases accurate and culturally sensitive interpretation of findings
- Facilitates effective dissemination of findings to impact public health and policy
- Increases translation of evidence-based research into sustainable community change
- Provides resources and benefits to communities
- Joins partners with diverse expertise
- Increases research trust
- Provides equity, not equality
  - The people who need to be heard the most gets a louder voice

Community-Engaged Research

For academic health sciences investigators, community-engaged research is appealing for several reasons. By engaging with communities —whether through schools, non-profit organizations or religious institutions, community or private clinics— researchers may be able to:

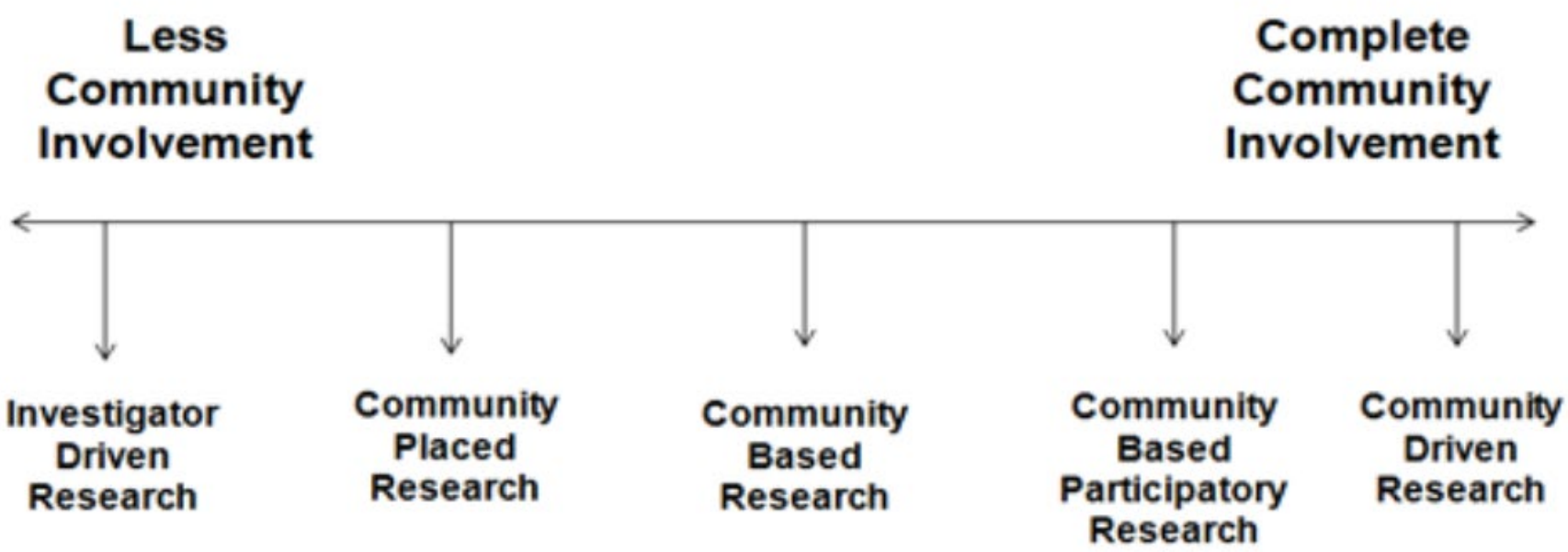
- incorporate critical insights into their research questions or interpretation of their data;
- conduct research that can translate more easily to real world settings and impact health;
- design more culturally- and language-appropriate interventions;
- include populations that have been understudied and are not adequately represented in current data about a health problem, treatment or intervention;
- increase the size of participant recruitment pools or make participant enrollment more efficient.



Handley et al., 2010 Community Engaged Research Guide www.ctsl.ucsf.edu/research/community

Community Engaged Research Continuum

(clinical & social/behavioral)



RTRN is supported by grant number U54MD008149 from the National Institute on Minority Health and Health Disparities, National Institutes of Health.

The Continuum of Community Engagement in Research: A Roadmap for Understanding and Assessing Progress

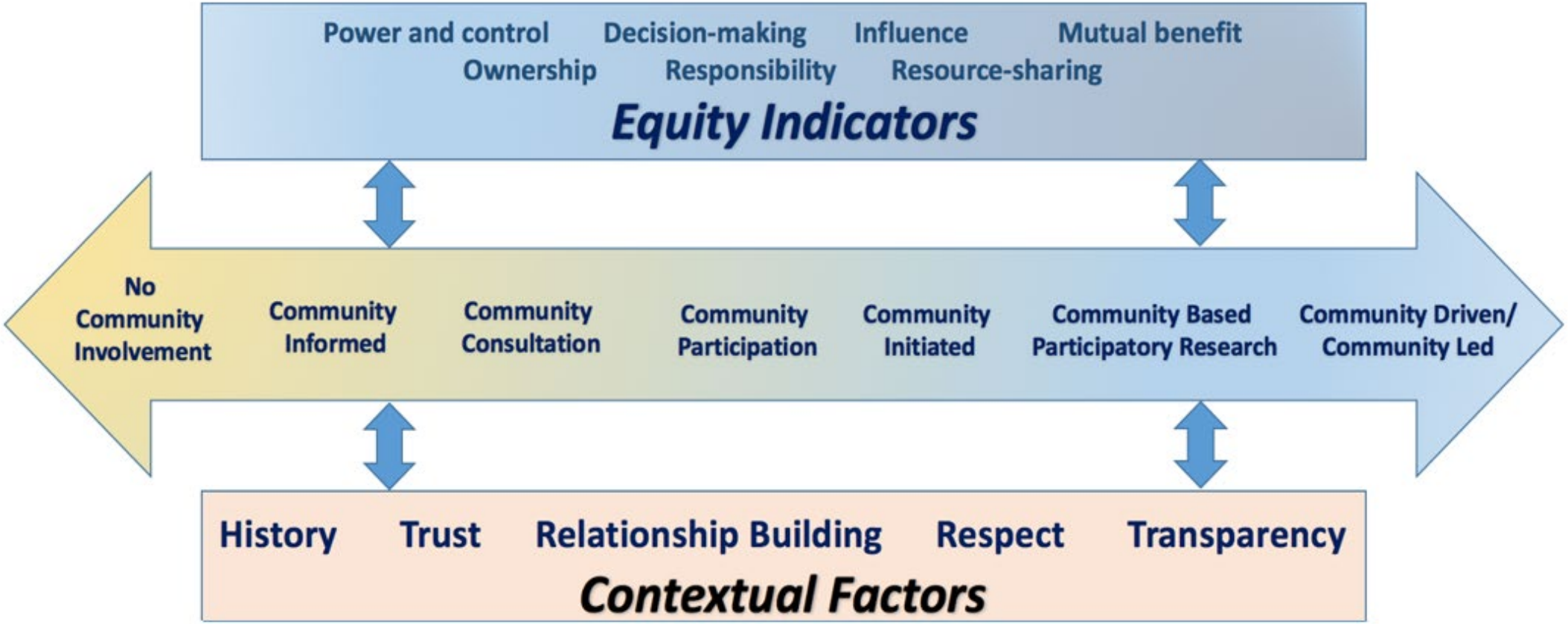
Kent D. Key, Debra Furr-Holden, E. Yvonne Lewis, Rebecca Cunningham, Marc A. Zimmerman, Vicki Johnson-Lawrence, Suzanne Selig



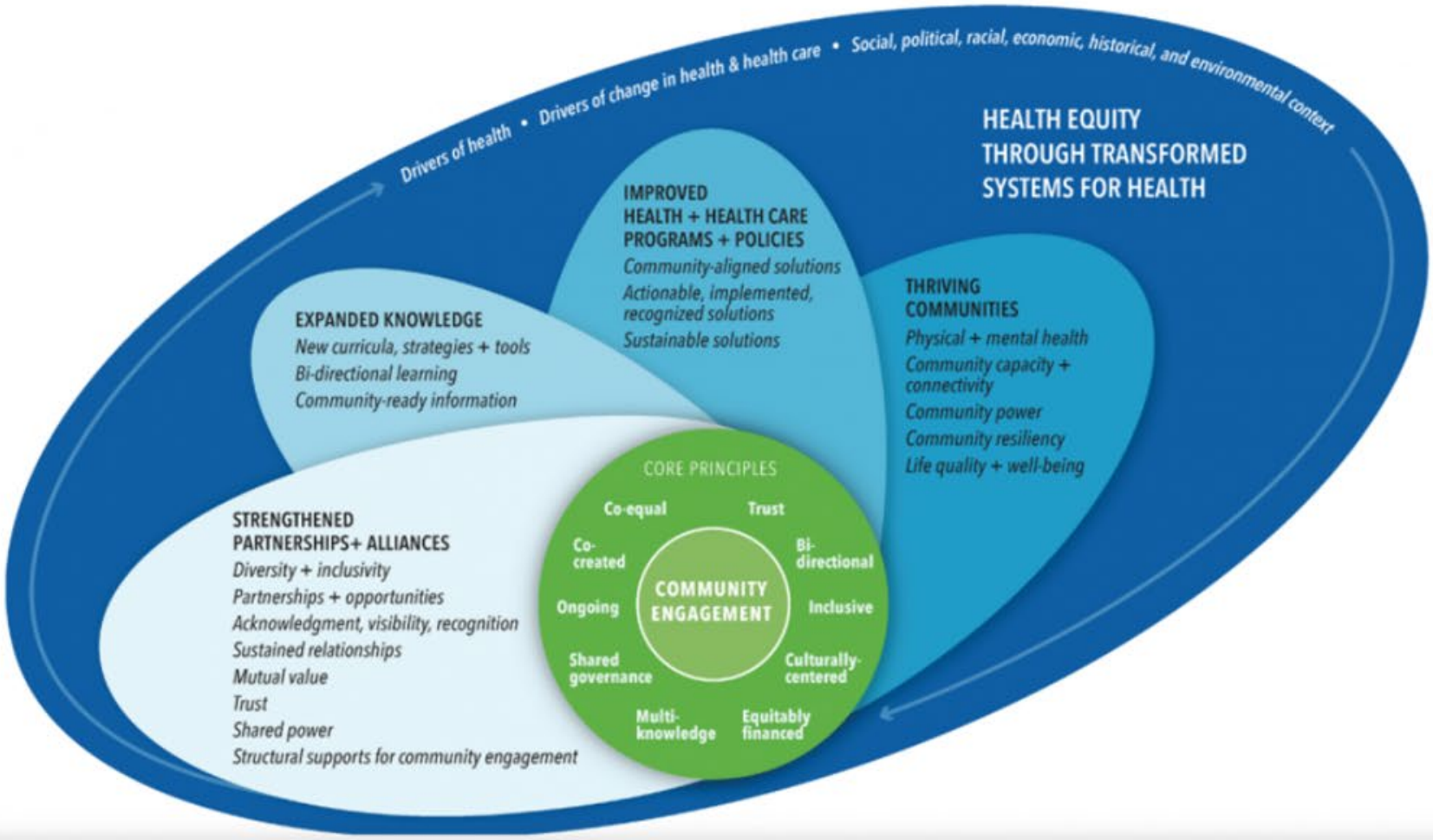
Progress in Community Health Partnerships: Research, Education, and Action, Volume 13, Issue 4, Winter 2019, pp. 427-434 (Article)

Published by Johns Hopkins University Press
DOI: https://doi.org/10.1353/cpr.2019.0064

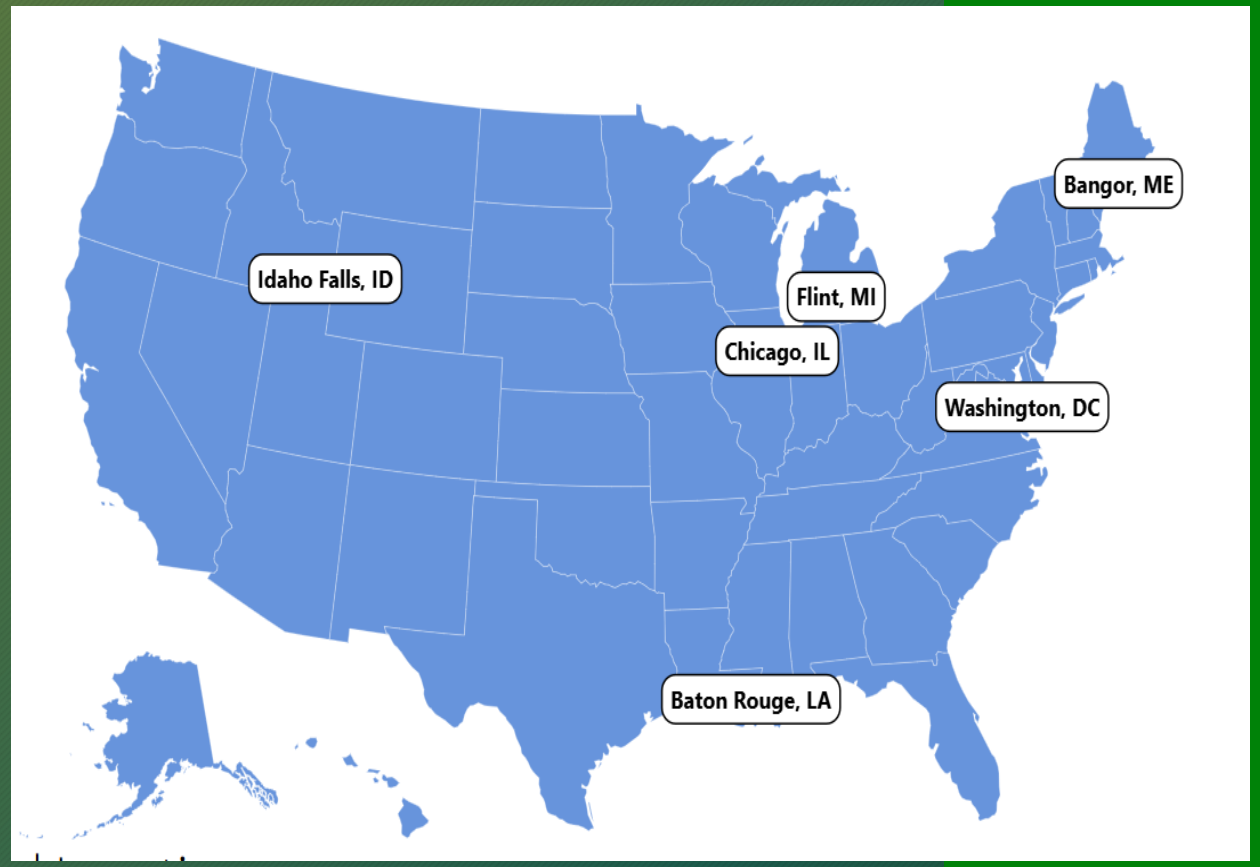
Figure 1. Continuum of Community Engagement in Research

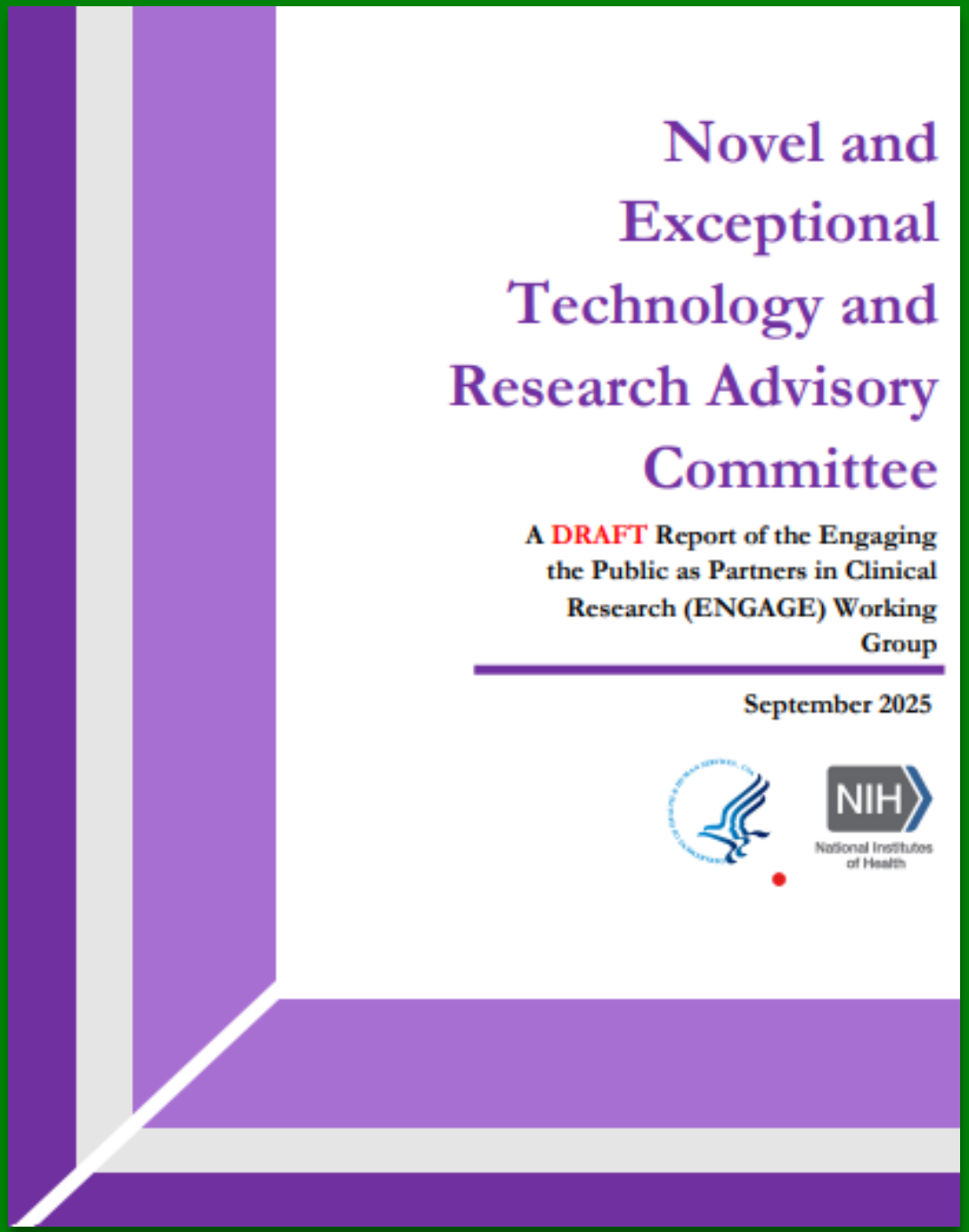


Social Determinants of Health



NIH Report on CE and Clinical Research





Framework for Clinical Research Engagement

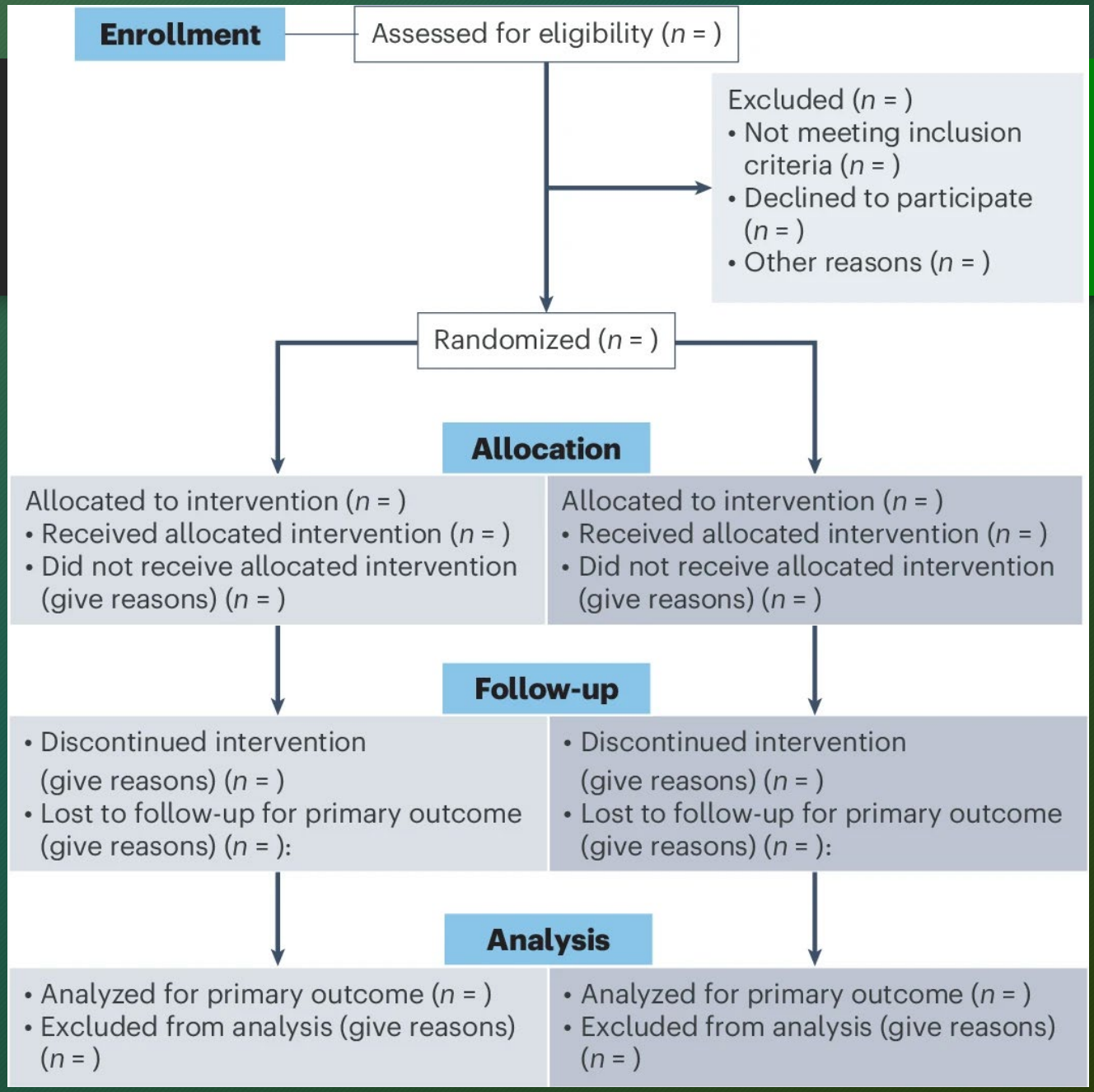


Figure 1. Framework for Clinical Research Engagement

Questions so far?



Applying community engagement to randomized controlled trials



Features of randomized controlled trials

Prospective with rigor, reproducibility, masking, randomization, standardized protocols, control condition

Open science: trial registration, protocol/statistical analysis plan, data sharing, funding/conflicts of interest

Introduction: background & rationale, specific objectives

Methods: patient/public involvement, trial design, changes to trial protocol, setting, eligibility criteria, intervention & comparator, outcomes, harms, sample size, randomization, masking, statistical methods

Results: Participant flow diagram, recruitment, intervention & comparator delivery, baseline data, numbers analyzed, outcomes and estimation, harms, ancillary analyses

Discussion: interpretation, limitations.

Continuum of community engagement in research

Community Perspective/Experience						
We do not know about this project	We may or may not be aware of this project but our information informed it	Researchers met with us to present the project and asked for our input	Researchers provided opportunities for us to participate (e.g., recruitment, community advisory board)	We told researchers what questions we need answers for	We participated in all aspects, equitably	We fully own the research
No Community Involvement	**Community Informed**	**Community Consultation**	**Community Participation**	**Community Initiated**	**Community Based Participatory Research**	**Community Driven/Lead**
We had no contact with the community	We sat in on a meeting and learned a great deal	We met with several community organizations, they shared their concerns and gave us suggestions	We have a defined role(s) for community to participate in the research	We created the research in response to community identified issue(s)/question(s)	We developed the project together with community partners	The community is in charge and we support their efforts when asked
Researcher Perspective/Experience						

Key et al., 2019. The continuum of community engagement in research: A roadmap for understanding and assessing progress. Prog Community Health Partnersh 13(4):427-434.

It’s OK to mix and match

	No comm involvement	Comm informed	Comm consultation	Comm participation	Comm initiated	CBPR	Community driven/led
Idea to have a trial						X	
Awareness of funding opportunity		X					
Why the project matters: background & rationale							X
Trial design			X				
Setting						X	
Eligibility				X			
Interventions to test						X	
Acceptable control condition						X	
Important outcomes						X	
Recruitment						X	
Interventionists							X
Assessment of harm						X	
Analysis			X				
Interpretation						X	
Hiring				X			
Budget						X	
Letters of support							X
Disseminating results						X	

Always feed back results!

Principles to maximize partnership and rigor

1. It's OK for different projects (or components within projects) to use different parts of the engagement continuum
   - Consider situation and research question
2. PROSPECTIVE: Be extremely partnered in how the study is designed *before* you submit the application
3. Budgets, titles, and contributions reflect partnership

Misconceptions

But it's slow! It doesn't have to be

But they are not experts on X, Y, Z. Learn from each other. Biosketch tip.

This can't be done with basic science. Yes it can



FCHES

FLINT CENTER FOR HEALTH EQUITY SOLUTIONS

U54 MD011227 (2016-2021)

Community brought	Investigators brought
Knowledge of community needs and priorities Knowledge of interventions existing in community & feasibility Awareness of other clinicians/researchers doing work in the area who could help Immense social capital Ability to get wide-ranging letters of support	Awareness of funding opportunity Knowledge of how to write strong Center grants & create NIH biosketches reflecting partner expertise Knowledge of research design Collaborations with methodologists Ability to write quickly

Origin story: community-partnered faculty job interview
Structure: fast; academic and community PIs of each project; extensive partnership; $ to community partners and organizations; included multiple RCTs



MIRACLE R01 MD016003 (2020-2025)

Community brought	Investigators brought
Desire to re-provide and sustain previously successful program 2 communities created intervention materials, manuals, feasibility and effectiveness data for all 3 tested interventions Interventionists Paper-writers	Knowledge of community wishes for program/s Watched for appropriate funding opportunity announcement Methodological and statistical expertise Grant-writing & partner biosketch expertise Ability to formalize and disseminate (properly credited) intervention manuals Paper-writers

Origin story: Investigators saw opportunity to support goals of two communities. Community and academic contributors (equal #s) met weekly to conceptualize, enact, and problem-solve the proposal
Structure: Community Co-Is are intervention developer and interventionists; 46% of direct cost $ to partners; team representativeness
Protocol: https://pmc.ncbi.nlm.nih.gov/articles/PMC9809987/



R01 MD016003 (2020-2025)

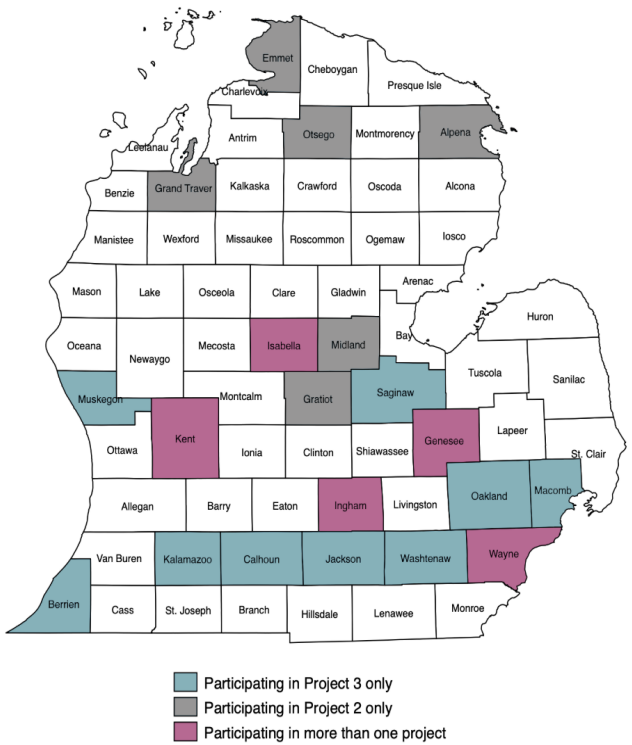
What does this look like in the grant application?

"Community"	Table D2: Role to date		Role in proposed study
AA women from target counties	Developed, implemented, and tested the level 2 intervention Informed the Level 1 intervention	Inform all intervention levels	Lead level 2 intervention
EPC staff, leaders	Co-developed the Level 1 intervention Led level 3 (AIM-CCI quality bundles) intervention development		Lead level 1 and 3 (telehealth and quality bundles) interventions
Physicians, providers, health systems	Provided input into the telehealth (level 1) and AIM-CCI quality bundle (level 3) interventions		Develop mechanisms to integrate Level 2 training into clinical practices

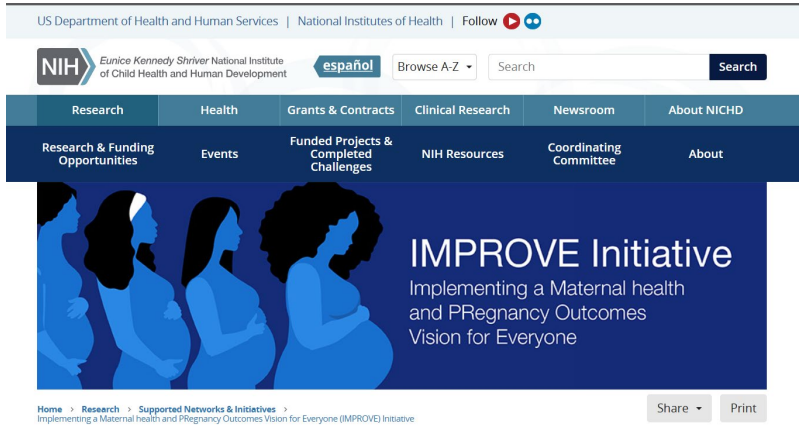
MIRACLE

Center for Maternal Health

U54 HD113291 (2023-2030)



Opportunity:



Origin story: Partners and we had been working together on >=5 related projects (building department, MIRACLE R01, evals of community programs, and digital interventions). We coalesced next steps when NIH IMPROVE Center call came out. Community, clinical, and academic partners met weekly during proposal period.

Structure: Formal community and academic PIs of the overall Center and every project/core. There are three research projects, a community partnership core, and a training core

Protocol: mimiracle.org

MIRACLE

Center for Maternal Health

U54 HD113291 (2023-2030)

Community brought	Investigators brought
Project 1: Co-developed intervention being tested, operational leadership in setting in which to test Project 2: Identified needs & priorities, “appathons” providing intervention modules for this RCT Project 3: Developed and tested guidelines being scaled in this randomized implementation trial, knowledge and data on what has worked well in previous implementation efforts Community partnership core: Decades of skill in partnership and strong community networks in maternal health Training core: Experience training community and academics in partnering together	Awareness of funding call Ability to create biosketches for partners Methodological expertise in research design, randomized trials, implementation science, statistics Knowledge of what NIH looks for in Center grants Ability to write and stitch pieces together Development of platform and structure for Project 2 intervention Co-developed Project 1 intervention Years of relationships with community partners

Mimiracle.org

THE NATIONAL CENTER FOR HEALTH AND JUSTICE INTEGRATION FOR SUICIDE PREVENTION (NCHATS)

$15.5 million NIH-funded P50 Center led by Dr. Jennifer Johnson (MSU), Dr. Brian Ahmedani (HFH), & Dr. Lauren Weinstock (Brown)

NCHATS
NATIONAL CENTER FOR HEALTH AND JUSTICE INTEGRATION FOR SUICIDE PREVENTION

PROBLEM #1 IN SUICIDE PREVENTION IS FINDING PEOPLE AT RISK FOR SUICIDE AT THE TIME THEY ARE AT RISK, ESPECIALLY THOSE NOT WELL CONNECTED TO HEALTHCARE.

WE FOUND THEM.

OUR RESEARCH HAS...

Shown that limited accessibility of community mental health and substance use services – and not violent crime rate – predict the size of county jail populations

Shown that **1 in 5 U.S. adults who die by suicide** spent at least one night in jail in the past year

Tested policies for keeping individuals with mental illness adequately treated in the community and out of jails in 950 U.S. counties, an important step for reducing mass incarceration

Identified the first evidence-based suicide prevention intervention for the 10,000,000 releases from jail each year

Published the first comprehensive list of evidence-based mental health practices for individuals involved across the criminal-legal system;

Identified that only **22-43% of counties** have each practice available anywhere in the county

BIG PROBLEM #2: HOW TO CONNECT PEOPLE TO COMMUNITY CARE?

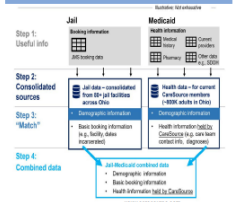


It's complicated...

3,000+ county and local jails, 18,000 police depts in the U.S.

2,500+ community mental health centers, 14,000+ addiction treatment centers, ~626 health systems in the U.S.

AN INGENIOUS SOLUTION: CARESOURCE'S JAIL MEDICAID DATA PROJECT





4 large projects + 4 pilot project

- **Includes the 2 largest randomized suicide prevention trials ever**
- **>107,000 people**
- **Methods support**

	Project 1	Project 2	Project 3	Project 4
Project Title	Syncing Screening and Services for Suicide Prevention Across Health and Jail Systems	Real-Time Managed Care Updates of Subscriber Justice-System Involvement for Suicide Prevention	Suicide Risk Identification in Jails using Data Linkage and Automation	Improving Mental Health Treatment for Individuals in Crisis Interacting with the Criminal Justice System
Lead Institutions	Henry Ford Health System & Brown University	Michigan State University & Butler Hospital	Wayne State University and Henry Ford Health System	Cambridge Health Alliance
Project Details	Identify health system affiliated individuals at the time of jail release who will be randomized to usual care vs a multi-level intervention.	Randomize ~43,000 managed care subscribers who pass through jails to receive Caring Contact (CC) letters or to Care as Usual (CAU); implement intervention and training for a subset of subscribers in contact with behavioral health agencies.	Validate suicide risk prediction model for ~6,000 individuals booked into 3 jails using jail records and historic Medicaid claims data.	Compare the effectiveness of a police department intervention and usual care on medically treated suicide behavior, ED use, jail admission, recidivism, police calls, and arrests and engagement in outpatient mental health services.

See link for talk at BoT meeting
NCHATS website at www.nchats.org
Reach us at: Contact.NCHATS@msu.edu

NATIONAL, MULTISECTORIAL EFFORT

RESEARCH AND HEALTH INSTITUTIONS

Michigan State University (MI)
Henry Ford Health (MI)
Brown University (RI)
Addiction Policy Forum (DC)
Butler Hospital (RI)
Cambridge Health Alliance (MA)
CareSource Ohio, Inc. (OH)
Columbia University (NY)
George Mason University (VA)
HealthPartners Institute (MN)
Mount Auburn Hospital (MA)
Pacific Institute for Research & Evaluation (MD)
RAND Corporation (CA)
UCLA (CA)
University of Illinois at Chicago (IL)
University of Pennsylvania (PA)
Wayne State University (MI)

PRACTICE, POLICY, AND LIVED EXPERIENCE PARTNERS

Addiction Policy Forum
Advocates for Human Potential
All Rise
American Academy of Addiction Psychiatry
American Foundation for Suicide Prevention
American Jail Association
American Probation and Parole Association
Civil Citation Network
Faces and Voices of Recovery
Franklin County Sheriff's Office
Genesee County Community Corrections
Greater Flint Health Coalition
JustLeadershipUSA
National Association of Police Organizations
National Center for State Courts
Pennsylvania Department of Corrections
Phronema
Justice Strategies
Treatment Alternatives for Safe Communities
Treatment Communities of America
YesCare

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MICHIGAN STATE UNIVERSITY

Origin story



P50 MH127512 (2022-2027)

Structure: national, 4 proposed research projects + 4 pilot projects, methods core, administrative core with national Consortium Partners. 48 investigators, 19 institutions, 21 Consortium Partner organizations. Community/clinical partners are PIs/Co-Is.

Protocol: https://nchats.org

Community brought	Investigators brought
Found and enacted a practical solution to a problem in the field that had been unsolved for decades	Recognition of how revolutionary the solution was
Were willing to conduct the n~45,000 RCT with guidance from investigators	Strong clinical suicide prevention experience
Understanding and interpretation of claims data patterns	Decades of experience working with jails and other criminal and legal systems to improve health
National network of 100+ cross-sector partnerships in opioid prevention to approach about suicide prevention & relationships with them	Evidence of intervention effectiveness and risk algorithms from previous studies
Willingness/ability to nurture partnerships for the Center	Knowledge of the literature on evidence-based suicide prevention approaches
Expertise in marketing, communications	Ability to write grants, knowledge of NIMH priorities
Interventions, settings	Methodological expertise in statistics, health economics, biomedical informatics, implementation science, research design
Opinion leaders & national network to disseminate results	Theory-based dissemination expertise

Start somewhere (my first R01)

Interpersonal psychotherapy (IPT) for major depression in state prisons

	No comm involvement	Comm informed	Comm consultation	Comm participation	Comm initiated	CBPR	Community driven/led
Idea to have a trial			X				
Awareness of funding opportunity			X				
Why the project matters: background & rationale				X			
Trial design			X				
Setting						X	
Eligibility			X				
Interventions to test		X					
Acceptable control condition			X				
Important outcomes						X	
Recruitment				X			
Interventionists				X			
Assessment of harm				X			
Analysis		X					
Interpretation			X				
Hiring						X	
Budget				X			
Letters of support				X			
Disseminating results			X				

Consider community benefit

CERB

Community Based Organization Partners (CBOP) – "home" of the Community Ethics Review Board (CERB). The purpose of the CERB is to serve as a safety net to ensure that research conducted in the community is ethically safe, morally sound, and provides equal benefit to the community.

The CERB reviews research projects to make sure that:

- The community is engaged and informed
- It will benefit from said research
- Projects are sensitive to the community's culture and needs
- Needs and concerns about research are heard and addressed
- A feedback loop is provided where research results will be disseminated to the community
- for its use and its benefit
- The community is educated about research

Questions?



nchats.org





Contact Information

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