

# ***Community Research Perspectives on Implementation Science***

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The Institute for  
Community Research

# Implementation Science Defined

Study of the process and outcomes of implementing a (tested or previously untested) approach to reduce or eliminate a problem in a **real-world context**.

That is, the study of what happens, how and why when intervention programs, devices, or medicines are **implemented** in the real world.

# Community Need for Implementation Science

- Reduce the gap between evidence-based “best practice,” derived through scientific methods, and real world practice in order to improve health or other outcomes
- Achieve the intended benefit of public health research funds used to develop and test innovative programs, drugs and medical devices to improve public health
- Recognition that real world contexts are complex and require deeper understanding when replicating evidence-based interventions or rolling out new medications and protocols

# Sources of the gap between evidence-based best practices and real world implementation of those practices

- Little involvement of communities in the original development and testing of EB programs, medicines, and devices
- Community skepticism/mistrust of scientists who have paid little attention to community issues while conducting research (or worse)
- Typical research design used to test programs, devices and medications—RCT—creates a condition that is NOT replicable in any community and generally minimizes the importance of contextual (as compared to individual) variation
- Time lag: years (decades) needed to go from concept to EB product; communities need results and solutions now

# Case Example: Microbicides Development

- Phased randomized controlled trials have generated a large number of formulations/delivery methods that appear safe and potentially efficacious (pre-clinical, Phase I and Phase II trials)
- Most are failing in Phase III “efficacy” trials because of apparent challenges with usage (“adherence”)
- Phase IV is typically the stage of development for understanding “effectiveness” in real world conditions
- “Acceptability” of product characteristics are studied concurrent with Phase II/III trials; but little is known about multilevel context factors (personal, interpersonal, cultural, contextual) that shape consumers “actual use”

# What can implementation science provide to increase EB practice in the community?

- Opportunities for community engagement in the research process
- Deeper understanding of what happens when practices developed in controlled settings meet the real world with community variations and complexity
- Opportunities for scientists to engage in and develop alternative research designs, models, measures and methods to complement RCT to generate valid, reliable, and supportable evidence of whether outcomes hold true when replicated in the real world

# What is needed in implementation science from a community standpoint?

**Community/Researcher partnerships** that involve regular ongoing community partners' presence, engagement, and feedback:

- **Resource sharing** and full integration of community stakeholders/actors in the implementation study from concept planning through study completion
- **Shared responsibilities** for conducting the research in the real world “trial”
- **Bidirectional input** from researchers and community partners during the implementation trial process

# What is needed in implementation science from a community standpoint?

## Understanding the community context:

- Observation and other in-depth examination of the real-world variation, situations, dynamic forces that support or interfere with the new approach
- Use the strength of fully integrated qualitative/quantitative methodology to understand contextual features, dynamics, and change processes over time
- Elicit multiple stakeholder perspectives, which may be contradictory
- Assess “organizational readiness” – examination of the characteristics and dynamics within the organizations that will be responsible for implementing the new program/product

# Challenges in Implementation Science: Clash or Synthesis?

- **Fidelity/Fit:** the conundrum of balancing rigorous adherence to the original prototype (tested in variously controlled settings) with the structural/cultural contextual realities of the implementation setting or situation
- **Practical considerations:** almost always fewer resources (less money, staff capacity, flexibility) to implement the program/product in the real world than there was in the original trial
- **Competing interests:** different stakeholders wanting resources, directional/administrative control, flexibility, the option to reject the model/product, etc.
- **Sustainability:** the never ending struggle to support programs that work and with limited resources in different community contexts and organizations over time

# Case Example – RAP to RAP-Clinic

## Translation of an Effective Network/Peer Harm Reduction Intervention for Drug Users

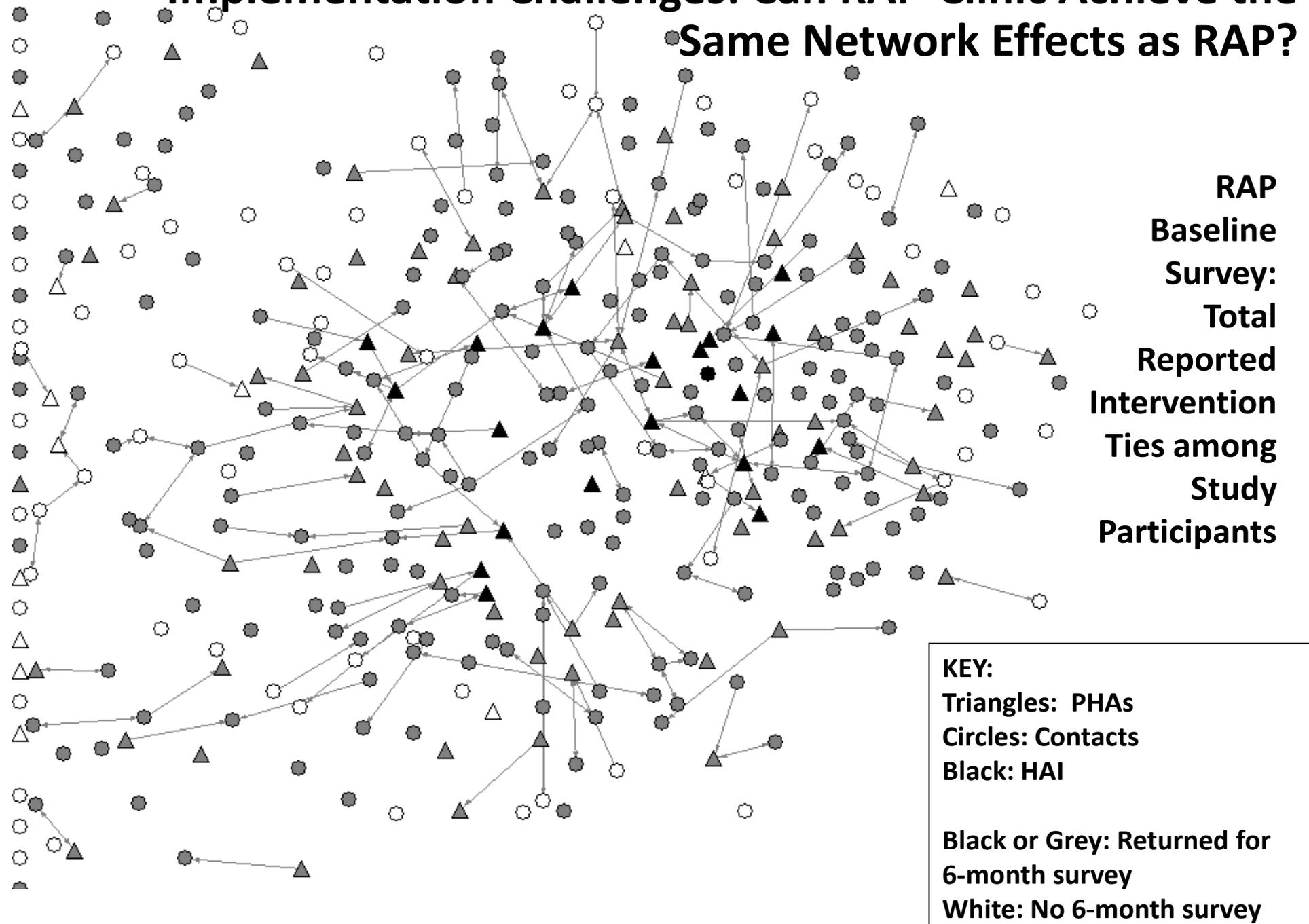
The **Risk Avoidance Partnership (RAP)** was designed to train **active** drug users as **Peer Health Advocates (PHAs)** to disseminate HIV prevention intervention through personal and community drug-user networks and to high-risk drug-use sites in Hartford.

**RAP-Clinic** is designed to train **in-treatment** clinic patients as PHAs to disseminate HIV prevention intervention through personal and community drug-user networks in their communities.

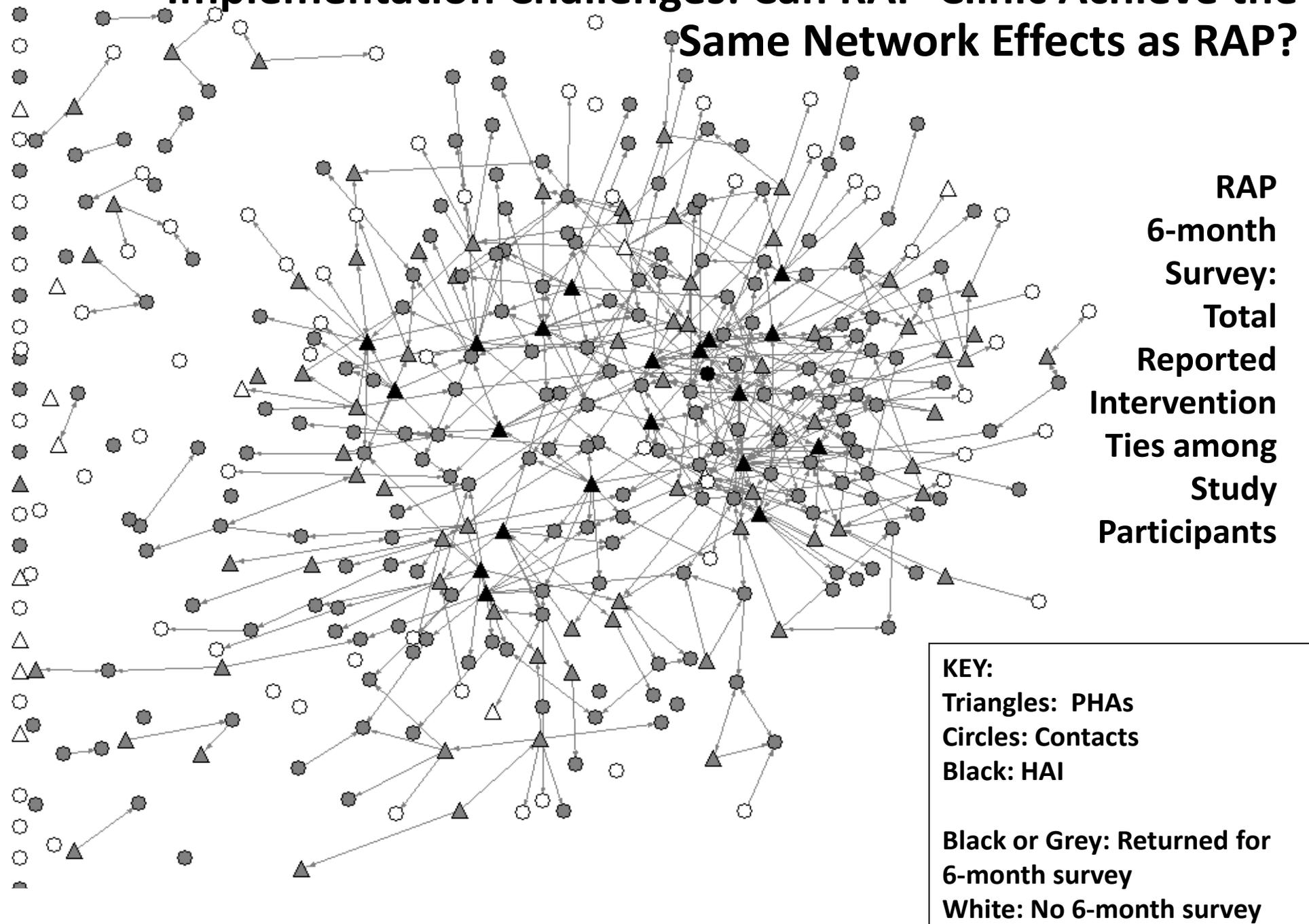
# RAP Mixed Methods Multilevel Observational Process/Outcome Evaluation Design

- PHA and Contact (limit 2-3 per PHA) individual-level risk and harm reduction attitude and behavior changes (pre/post survey: baseline, 6-month)
- Diffusion of intervention effects and practices: PHA and Contact network-level risk/prevention behavior changes (pre/post ego-network survey; macro-network linkages)
- PHA 10-session training process and impacts on trainees (session observations, in-depth interviews of PHAs, community observations)
- Community impacts: changes in “high risk sites” (community observations, in-depth interviews of drug users)

# Implementation Challenges: Can RAP-Clinic Achieve the Same Network Effects as RAP?



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# Original Study Findings Supporting RAP to RAP-Clinic Potential Benefits

- **PHA *motivations* to be peer health advocates:**
  - cut down or abstained from their own drug use: high PHA entry into drug treatment while continuing PHA work
  - enjoyed public recognition and praise for their PHA work
  - saw it as a stepping stone for future employment, with project staff as role models  
(efficacy, fit, sustainability)
- **Sites selected for RAP interventions:** streets, parking lots, shelters, soup kitchens, abandoned buildings, laundromat, restaurant, personal apartments (reach, fit, sustainability)
- **Staff identified “role change” in PHAs:** PHA-recognized need to act responsibly as model to peers; peers’ recognition of them as source of prevention/health information/materials (efficacy, fit)

# Rationale for Implementing RAP in Methadone Clinics

- Drug treatment clinics have ready access and maintain involvement with drug users (reach, fit, sustainability)
- Drug treatment clinics often build trusting positive relationships with drug users around health (efficacy, sustainability)
- Drug treatment itself has HIV/hepatitis/STD risk reduction benefits (efficacy)
- HIV prevention interventions in drug treatment programs are additionally beneficial over treatment alone, given high attrition, drug-use relapse and ongoing exposure to HIV risk from engaging in risky behaviors (efficacy, reach)

# RAP-Clinic Research Questions

- How might the following affect the RAP implementation process and outcomes when conducted with clinic patients:
  - treatment clinic organizational characteristics (e.g., “organizational readiness for change”)
  - clinic staff characteristics (capacity, attitudes, availability)
  - clinic patients’ relations to their drug using peers and the community setting (networks)
  - community characteristics (resources, population density, drug use and service locations, patient geographic distribution)
- How must RAP be modified to “fit” clinic settings while maintaining essential core components (“fidelity”) to make it efficacious for clinic patient PHAs to reach and affect the not-in-treatment drug-using community?

# RAP-Clinic Implementation Partnership: Institute for Community Research and Hartford Dispensary

- **Shared resources, responsibilities and input:** ICR grant with HD subcontract to conduct the translational pilot (current R34) and the full intervention trial (planned R01)
- **Formative examination of organizational characteristics and community context** of selected clinics (surveys, observations, in-depth interviews, community mapping):
  - Bristol Clinic
  - Hartford Main Street Clinic
  - Hartford Weston Street Clinic
  - Manchester Clinic
  - New Britain Clinic
  - Windham/Willimantic Clinic
- **Pilot of RAP-Clinic** in the Hartford clinics

# Implementation Challenges: Understanding Organizational Context

## Organizational Readiness for Change Survey

Treatment Staff Version (TCU ORC-S)

- **Motivation for Change**
  - Program needs; Training needs; Pressures for change
- **Resources**
  - Offices; Staffing; Training; Equipment; Internet
- **Staff Attributes**
  - Growth; Efficacy; Influence; Theoretical orientation; Adaptability
- **Organizational Climate**
  - Mission; Cohesion; Autonomy; Communication; Stress; Change
- **Training Exposure and Utilization**
  - Training satisfaction; Training exposure; Training utilization (individual); Training utilization (program-level)

Based on self-reports by staff/supervisors

# Supplementary Information from Clinic Staff and Patient In-Depth Interviews

- Attitudes toward harm reduction and belief in the congruence of RAP with clinic policies and regulations
- Ability and willingness to administer and implement all program requirements, including to partner with RAP trainees in community outreach intervention sessions
- Expectations about the potential of clinic patients to be peer interventionists
- Potential for allocation of resources (time, expertise, appropriate space, materials) to the RAP intervention effort
- Expectations of RAP-Clinic success or failure
- Community characteristics that might affect where PHA-trainees can practice outreach intervention

# RAP-Clinic Implementation Measurement Challenges: Clinic Patient Networks

- Will clinic patient PHA ego-networks include links to not-in-treatment drug users, their contact target population? (actual reach)
- Can and will clinic patient PHAs use those links to deliver intervention? (actual reach)
- Identifying macro-network linkages from ego-network data may be more challenging without adequate drug-user community observations to confirm linkages (measuring reach)

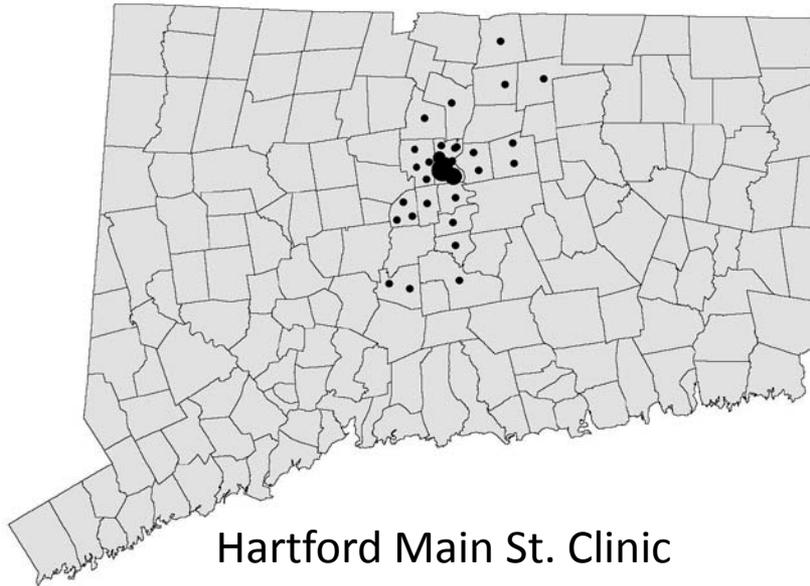
# **RAP-Clinic Implementation Measurement Challenges: Community Contexts**

- Are potential intervention delivery locations within easy access to clinic staff and patients during training? (actual feasibility)
- Where will clinic patient PHAs deliver intervention after training is completed? (actual reach)
- Can we track intervention implementation and diffusion that begins with clinic patients in town and may extend to their networks and homes outside of town? (measuring reach and efficacy)

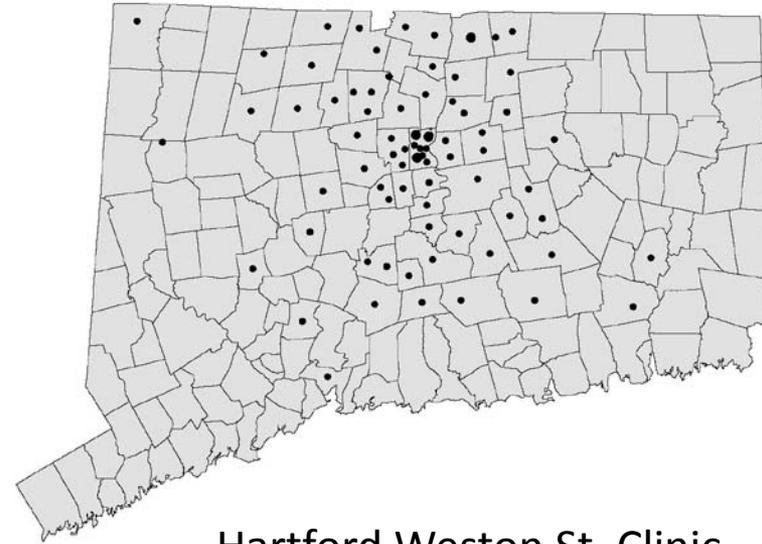
# Implementation Challenges:

## Understanding Community Context and Network Diffusion

**Zip code of Residences of Patients in Hartford Dispensary Branch Clinics**



Hartford Main St. Clinic

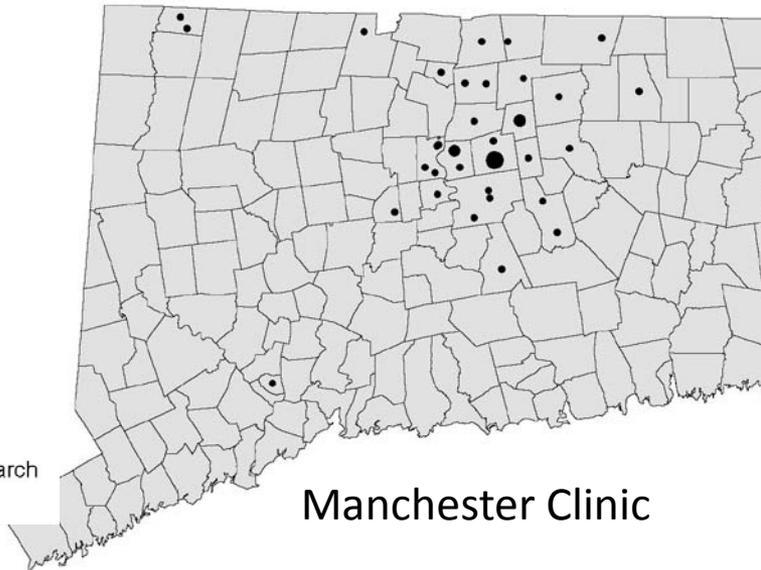


Hartford Weston St. Clinic

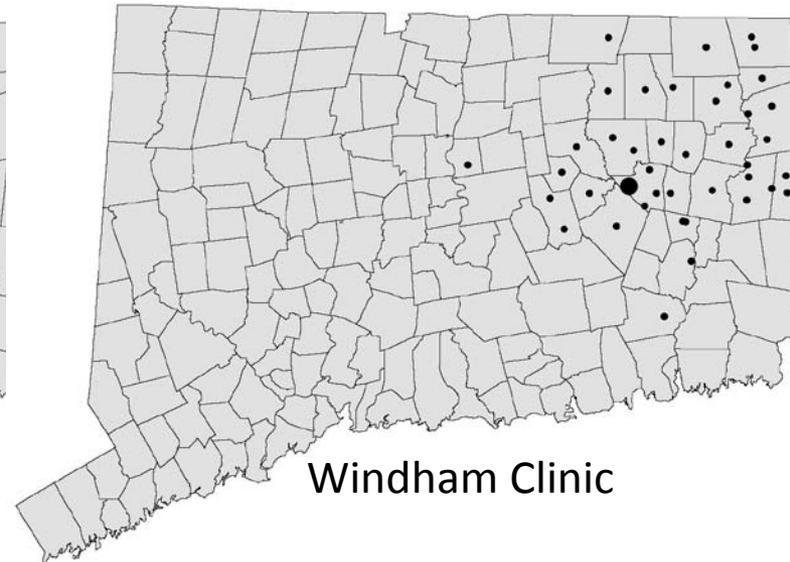
**Legend**  
**Number of Patients**

- 1 - 50
- 51 - 100
- 101 - 200
- 200 - 325

■ Town



Manchester Clinic



Windham Clinic

# **Ethical Considerations in Implementation Science for Implementers, Recipients & Other Stakeholders**

- Imbalances created by conduct of EB programs at the expense of existing programs that may have had some successful outcomes but were community developed and experientially tested
- Resource draining of the community organization during implementation trials
- Who is responsible for sustainability of interventions after the implementation trial is completed?
- Potential for unexpected iatrogenic outcomes (increased risk taking/relapse; effective product replacement; stigma, disclosure/exposure, etc.) and planning a responses to minimize these

# Ethical Considerations in Implementation Science for Implementers, Recipients & Other Stakeholders

- Community researcher dilemmas encountered during observations of real world implementation situations (cheating/misrepresentation; forced participation, iatrogenic effects, etc.)
- Informed consent for research participation may be complicated when testing EB interventions in the contexts of routine service provision or daily life
- How should community perspectives and interests (from a variety of stakeholders, particularly “consumers”) and researcher perspectives and interests be negotiated?

# Conclusions

Community engagement in implementation science improves both the quality of science (for understanding complex contexts and observing non-linear dynamic processes) and the quality of the implementation experience itself.

Implementation science offers communities the benefits of scientific rigor in assessing the values and limitations to EB interventions that have potential to contribute to improved health and well being when implemented in new contexts.

**Thank you!**