

Implementation Science and You: **Real-World Applications of** Implementation Science in HIV Research

Alida Bouris, PhD Dennis Li, PhD Moira McNulty, MD **Russell Brewer, DrPH**

Implementation Science and You: Real-World Applications of Implementation Science in HIV Research

Third Coast Center for AIDS Research January 25, 2020

Alida Bouris, PhD, Dennis Li, PhD, Moira McNulty, MD, and Russell Brewer, DrPH

Objectives

 Overview of how implementation science is being utilized across diverse research projects: formative research to large, multi-site trials

 Case-based examples on how implementation science can help to achieve goals of the National Ending the HIV Epidemic Plan

• Provide examples of different implementation science consulting services available within the CFAR (illustrative, NOT exhaustive)



Implementation Science to Improve the Adoption and Sustainability of Interventions in Diverse Clinical Settings

Research Background







PhD in Social Work (Practice concentration)

- Parent-based intervention research
- Behavioral and relational theories
- Adolescent sexual health and tobacco use
- Implementing in schools and health clinics
- Pre-implementation research: intervention appropriateness, feasibility, acceptability and adoption
 - Youth and parents
 - Key stakeholders: frontline staff and providers





Third Coast Center for AIDS Research

Conceptual Model for Implementation Research



¹ Empirically supported treatments

Adapted from the Implementation Research and Practice course at Johns Hopkins Bloomberg School of Public Health



	ORCHID	Project nGage
Intervention	Implementing a Behavioral Health Screener + referral to ORCHID, an eHealth positive affect intervention (MPIs: Moskowitz & Bouris; IS Co-I: Lisa Hirschhorn)	Dyadic social network support intervention (MPIs: Bouris & Batey: IS Co-I: JD Smith)
Population	Adults living with HIV and depression	Black men living with HIV
Prior evidence	Multiple RCTs	Pilot RCT in Chicago
Design	Hybrid Type II Stepped Wedge Cluster RCT	Hybrid Type I RCT
Setting	Ryan White Health Clinics in Chicago (AFC Partner)	HIV clinics in Chicago and Alabama (FQHCs, CBOs, Academic medical center)
Effectiveness Outcomes	Improve VS, RIC and depression at clinic level	Improve VS and RIC at patient level
Implementation Focus and	Operationalize implementation facilitation strategy to link screening + referral to ORCHID	Identify clinic and geographic barriers and facilitators
Outcomes	Evaluate implementation strategy & adapt strategy for subsequent steps in trial Exploratory cost capture analysis Evaluate reach, adoption and overall implementation	Develop & evaluate implementation strategy Budget impact analysis Evaluate reach, adoption and overall implementation
Implementation FrameworksCFIR and RE-AIM, ERIC strategiesCFIR and		CFIR and RE-AIM, ERIC strategies

ORCHID: Stepped Wedge Cluster Hybrid Type II RCT

- What contextual factors will shape the adoption and implementation of a BH Screener and referral to ORCHID in 16 Ryan White clinics in Chicago?
 - Explore barriers and facilitators: staff, clinic and outer setting levels
- What are the implementation strategies that will support the adoption, sustainment and scale up of the screener and referral to ORCHID?
 - Discrete, multifaceted, and multi-level
- Mixed-methods:
 - CFIR survey and interviews with medical case managers and supervisors
 - CFIR Interviews with clients living with HIV



ORCHID: Findings to Date



ORCHID: Next Steps

- Identify relevant implementation strategies to support implementation across clinics: CFIR and ERIC (Expert Recommendations for Implementing Change)
- Utilize CFIR and clinic data to inform groupings for the cluster RCT
- Ongoing mixed-methods research to study and adapt implementation strategy
- Interviews with public health stakeholders to examine scalability to other contexts
- Examine select implementation costs: materials and human resources



Consulting Summary

- Selecting and utilizing relevant implementation science theories, models and frameworks
 - Determinant frameworks: CFIR
 - Planning and evaluation frameworks: RE-AIM
- Selecting relevant hybrid effectiveness-implementation trial designs
- Identifying implementation strategies
- Developing robust implementation and fidelity plans
- Planning for sustainability and technical assistance
- Recommend literature, online coursework, and other implementation resources and consultants





Dennis H. Li y@denhli

Assistant Professor Psychiatry and Behavioral Sciences Northwestern University







Research Background

• PhD in public health behavioral sciences

- Behavioral theories
- Intervention development
- Adolescent sexual health promotion

Postdoc in SGM health

- eHealth HIV prevention
- Implementation science
 - TIDIRH fellow
- Implementation science team scientist
 - IS in HIV
 - IS technical assistance and training



iCHAMP\$5: <u>CHoosing And Maintaining effective</u> <u>Programs for Sex education in Schools</u>

• Over 50 curriculumbased teen pregnancy prevention programs designated as effective/promising (c. 2009)

> Evidence-based programs

Implementation gap

- 94% of middle/high schools in Texas were not using EBPs or any program at all
- Despite 4th highest teen birth rate in the US

•Understand barriers, facilitators, and process of adopting and implementing EBPs

• Develop imp strategies to support use of EBPs in schools

> Research study (PI: Peskin)



iCHAMP\$5: <u>CH</u>oosing <u>And</u> <u>Maintaining</u> effective <u>Programs for</u> <u>Sex</u> education in <u>Schools</u>

- Conducted key informant interviews with school health stakeholders
- Developed the CHAMPSS
 process model
- Using intervention mapping, designed an online decisionsupport system and toolbox





iCHAMP\$5: <u>CH</u>oosing <u>And</u> <u>Maintaining</u> effective <u>Programs for</u> <u>Sex</u> education in <u>Schools</u>

- Conducted key informant interviews with school health stakeholders
- Developed the CHAMPSS
 process model
- Using intervention mapping, designed a web-based toolkit and decision-support system







Highlights: process models, intervention/implementation mapping

Hybrid effectiveness–implementation trials of **eHealth** HIV prevention interventions for A/MSM

	SMART	Keep It Up! 3.0
Intervention	Stepped-care suite of 3 adapted EBIs (2 self-paced, 1 coach-based)	Self-paced, multimedia EBI
Population	Adolescent MSM aged 13–18	Young MSM aged 18–29(34)
Prior data	2 CDC EBIs & 1 promising program effective in young adults	Multiple effectiveness trials and service implementations
Research aims (PI: Mustanski)	 Test effectiveness of SMART Explore barriers/facilitators to future implementation (Hybrid Type 1) 	 Compare CBO delivery of KIU to direct-to-consumer approach Check if still effective (Hybrid Type 3)
Design	Sequential, multiple-assignment randomized trial	Cluster (county)-randomized trial







Hybrid effectiveness–implementation trials of **eHealth** HIV prevention interventions for A/MSM

- Implementation and data collection ongoing
- Lessons learned/findings so far:
 - Using intervention mapping to adapt/update eHealth interventions
 - Implementation considerations when designing eHealth/mHealth interventions
 - Monitoring client acceptability over time via multiple methods/media
 - Barriers/facilitators to implementing eHealth HIV prevention interventions in CBOs (using CFIR)



<u>Highlights</u>: hybrid designs, eHealth implementation







Implementation Science Coordination, Consultation, & Collaboration Initiative

Background: National EHE Plan

• 65 NIH-funded supplement projects in Y1



• 34 projects in Y2

ISC³I Aims & Activities

- 1. Support high-quality implementation science in funded EHE projects...
 - Online community of practice
 - Individual coaching/technical assistance
 - Virtual "fishbowl" peer feedback sessions
 - Webinars
- 2. Create opportunities to develop generalizable knowledge from local knowledge...
 - Data harmonization and collection
 - Synthesizing data across projects
 - Encouraging cross-project collaboration





Implementation Science Coordination, Consultation, & Collaboration Initiative

Implement. Research Logic Model

Implement. Outcomes Crosswalk



				Importa	ance by Stage of R	esearch
Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Implementation Preparation	Piloting Strategy	Bringing to Scale
Implementer	How likely will implementers want to adopt the intervention ?	Acceptability of the intervention		Required	Recommended	Recommended
		Appropriateness of the intervention	AIM, IAM, and FIM (see tab below).	Required	Recommended	Recommended
		Feasibility of the intervention	ose qualmetrious to supplement.	Required	If desired	If desired
	How likely will implementers want to adopt the strategy(s)?	Acceptability of the strategy(s)	Adapt the AIM, IAM, and FIM (see tab below).	Recommended	Required	Recommended
		Appropriateness of the strategy(s)		Recommended	Required	Recommended
		Feasibility of the strategy(s)	ose quarmetrious to supplement.	Recommended	Required	Recommended
	How many potential implementers "adopted" the intervention?	# potential implementers in sites eligible to provide/support the intervention -> <u>public</u> <u>health denominator</u>	Total # of implementers across alls ites who could potentially and feasibly deliver the intervention. Differentiate between different levels or roles (e.g., supervisors, frontline staff). May be an estimate, but provide justification.	N/A	If desired	Recommended
		# implementers approached to provide/support the intervention> <u>study</u> <u>denominator</u>	Differentiate between different levels or roles (e.g., supervisors, frontline staff). If the intervention is mandated or already being implemented, the denominator is all implementers.	N/A	Required	Required
		# implementers that agreed to provide/support the intervention	If the intervention is mandated or already being implemented, the # is all implementers.	N/A	Recommended	Required
		# implementers that began providing/supporting the intervention	If the intervention is mandated or already being implemented, the # is all implementers.	N/A	Required	Required
	How quickly did potential implementers adopt the intervention?	Time between approaching implementer and their agreeing to provide the intervention	May use additional, more specific milestones, e.g., Stages of Implementation Completion (SIC; see tab below). May not be applicable if intervention is mandated or already being implemented.	N/A	If desired	If desired
		Time between approaching implementer and their beginning to provide/support the intervention		N/A	If desired	If desired
	How representative are the adopting implementers of other potential implementers in each site?	Characteristics of implementers that agree/begin to provide/support the intervention vs. implementers that do not	Use quant or mixed methods to compare based on implementer characteristics and determinants (e.g., attitudes). Refer back to CFIR or other determinant frameworks.	N/A	Recommended	Required
		# implementers excluded from providing/supporting the intervention		N/A	Recommended	Recommended
		Reasons why those implementers are excluded		N/A	Recommended	Recommended



<u>Highlights</u>: implementation logic model, operationalizing implementation outcomes

Third Coast Center for AIDS Research

Summary of my experience and skills

- Selecting appropriate IS theories, models, frameworks
- Intervention/implementation mapping
- eHealth interventions
- Hybrid effectiveness-implementation designs
- Consolidated framework for implementation research
- Implementation research logic model
- Operationalizing implementation outcomes
- Linking to other resources, articles, methods



PrEP Persistence and Implementation

Moira McNulty, MD, MS



Background

- Clinical training in Infectious Diseases
 HIV and PrEP care
- Master of Public Health Sciences
 - Epidemiology
 - Health services research
- Training in Implementation Science
 - TIDIRH Fellow



Assistant Professor of Medicine Section of Infectious Diseases University of Chicago







Third Coast Center for AIDS Research



• Effectiveness of HIV pre-exposure prophylaxis (PrEP) depends on starting it, but also adherence and staying on PrEP





PrEP Persistence Interventions

 As PrEP service delivery matures, more interventions are being developed around persistence

Examples:

- Home or pharmacy HIV and STI testing to minimize clinical visits
- Electronic or text messaging boosters for adherence (developed for antiretroviral therapy for HIV)
- Alternative dosing strategies (long-acting injectable PrEP or PrEP on-demand for MSM)
- PrEP navigation/retention initiatives
- What is persistence and how do you monitor it?



Publication	Location	PrEP Persistence	Definition
Hevey, AIDS Educ and Prev 2018	Milwaukee, WI	81%	Semi-annual follow-up visits; Quarterly HIV tests
Hojilla, AIDS and Behavior 2018	San Francisco, CA	79% at 7m; 62% at 13m	Loss to follow-up
Montgomery, PLOS One 2016	Providence, RI	70% at 6m	Quarterly visits at 3 or 6 months
Marcus, JAIDS 2016	Northern CA	70% (mean f/u 0.9 yrs)	Medication Possession Ratio (MPR >80%
Krakower, JIAS 2019	Boston, MA	64% (median f/u 1.2 yrs)	7-day discontinuation
Chan, JIAS 2019	ri, ms, mo	60% at 6m	Quarterly visits at 3 or 6 months
Van Epps, JAIDS 2018	US (VA)	56% at 12m	PDC >80% over first 12 months
Rusie, CID 2018	Chicago, IL	43% at 12m	Quarterly PrEP visits over first 12 months
Zucker, JAIDS 2019	New York, NY	42% at 6m	Quarterly visits
Dombrowski, STD 2018	Seattle/King Co, WA	40% at 12m	Patient reported discontinuation of lost
Spinelli, OFID 2019	San Francisco, CA	38% (median f/u 1 year)	Discontinuation (<90 days PrEP/quarter)

SMITS INFALDS RESEARCE IN CHICAGO Courtesy of Al Liu, Maria Pyra

PrEP Persistence Interventions

- To have an effective intervention for persistence, need to know how to measure the outcome
 - Are they taking PrEP and if so, how consistently?
 - Are they staying in PrEP care?
- Ideally consistent measures across different programs/settings

Implementation	
Implement the Intervention	
Activate Implementation Teams	
Monitor Progress	



QUERI Roadmap for Implementation and Quality

Background

- 2 EHE jurisdictions:
- Cook County
 - Howard Brown Health
 - >6000 PrEP starts

Ending the Epidemic (EHE) Phase 1 Jurisdictions: 48 high burden counties, D.C., San Juan, P.R., and 7 states with a high rural burden



Source: KFF analysis of EHE jurisdictions: https://files.hiv.gov/s3fs-public/ending-the-hiv-epidemic-fiver.pdf

- Missouri
 - Washington University
 in Saint Louis
 - ~500 PrEP starts





Aims

- 1. Develop and refine metrics of PrEP persistence for surveillance and evaluation (i.e., progress towards Getting to Zero targets) that are feasible and informative for health departments and low-resourced clinics.
- 2. Use the EPIS framework to plan implementation of successful PrEP persistence interventions for at-risk populations across highly impacted Midwest jurisdictions.



Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.





Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.



Metric	Definition	Measures	Benefits / Limitations		
Total PrEP Time (TPT)	Months from 1 st prescription thru end of last supply	Duration of PrEP use	Relatively easy to calculate / Includes gaps in PrEP use		
Medication Rx Ratio	Total # pills/TPT in days; capped at 100%	Adherence over duration of PrEP use			
Proportion Days Covered	For each of the 1 st 6 months, ≥85% days are covered by PrEP prescriptions	Effective adherence over time	Measurement period and adherence level can be adjusted (57%, ~ 4/7 doses/week vs 85%, ~ 6/7 doses)/week) / More complex to calculate		
Quarterly Retention in Care	Total # quarters with an HIV test/TPT in quarters	Retention rate	Relatively easy to calculate, specific timepoints can be adjusted / Does not indicate adherence		

Third Coast Center for AIDS Research

Third * Coast * CFAR *

Aims

- 1. Develop and refine metrics of PrEP persistence for surveillance and evaluation (i.e., progress towards Getting to Zero targets) that are feasible and informative for health departments and low-resourced clinics.
- 2. Use the EPIS framework to plan implementation of successful PrEP persistence interventions for at-risk populations across highly impacted Midwest jurisdictions.



Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.





Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.



Exploration, Preparation, Implementation, Sustainment (EPIS) Framework





Third Coast Center for AIDS Research





Survey Results

- Electronic survey administered over email to organizations that offer PrEP
- 26 organizations participated
 - 14 in Cook County, IL
 - 12 in Missouri
- Average of 222 current clients on PrEP (range 3-1900)





Survey Results – Interventions for PrEP Persistence

- Does your organization have active efforts, protocols, or programs to improve retention in PrEP care?
 - Yes: 70.8%
 - No: 25 %
 - Not sure: 4.2%
- Does your organization have active efforts, protocols, or programs to improve adherence to PrEP?
 - Yes: 62.5%
 - No: 33.3%
 - Not sure: 4.2%



Survey Results – Monitoring the PrEP Continuum

- 70.8% reported collecting data on PrEP initiation
- 41.7% on retention
- 37.5% on missed visits
- 37.5% on prescription refills
- 29.2% on HIV positivity among persons ever prescribed PrEP
- 75% of responders indicated they would like to implement or expand interventions that address PrEP retention and adherence for their clients



Survey Results – Barriers

What do you perceive to be barriers to collecting data related to PrEP adherence and retention?





Next Steps: Implementation Strategies

A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project

Byron J Powell ⊡, Thomas J Waltz, Matthew J Chinman, Laura J Damschroder, Jeffrey L Smith, Monica M Matthieu, Enola K Proctor & JoAnn E Kirchner

Implementation Science 10, Article number: 21 (2015) | Cite this article

- Needs assessment
- Program champion/ leadership buy-in
- Education/training
- Refining and automating data collection
 - IT/Clinical Informatics support
- Technical assistance
 - Toolkit development

- Conduct local needs
 assessment
- Identify and prepare champions
- Conduct ongoing training
- Develop educational materials
- Use data experts
- Provide local technical assistance
- Provide ongoing consultation
 Third Coast Center for AIDS Research

Areas of Experience

- Selecting implementation frameworks, models, theories
- Determinants (i.e. facilitators and barriers)
- Implementation strategies
- Implementation study design (hybrid implementationeffectiveness studies)
- Qualitative methods



Using Implementation Science (IS) to enhance HIV and PrEP care



IS Background

2018-2019

- NIDA-funded diversity supplement via NIDAfunded Center for Prevention Implementation Methodology (CEPIM) for Drug Abuse and HIV
- Intersections between HIV and criminal justice involvement (CJI) among BMSM

Russell Brewer, DrPH, MPH

Research Associate Professor, Department of Medicine, University of Chicago

Director of Health Equity Research, Chicago Center for HIV Elimination







2020-present

TC-CFAR IS support for early stage investigators

Presentation Overview

- Implementation science lessons learned
- Describe 2 diverse implementation science studies with a snapshot of some of the findings
- Summary of my skills to support early stage investigators and/or those interested in conducting implementation science studies



Lessons from Implementation Science

- Focused on the methods and strategies that facilitate the uptake of evidencebased and/or informed practices into regular use
- Can be utilized for different settings and populations
- Context matters and qualitative methods can help broaden understanding implementation barriers and challenges
- The quality of implementation plays a significant part in improving health and wellbeing. If a program is implemented poorly or even moderately well, its goals are unlikely to be achieved, or the results will be less significant.¹
- Successful implementation requires a coordinated effort between diverse individuals and groups (e.g., researchers, clinicians, frontline staff, patients)²
- Need to document and report on adaptations made as well as the reason(s) for those adaptations
- Timely information to inform implementation and any needed adaptations



Source: 1. USDHHS. Available at https://childcareta.acf.hhs.gov/systemsbuilding/systems-guides/design-and-implementation/program-design-and-implementationoverview/importance; 2. AED. Available at https://childcareta.acf.hhs.gov/systemsbuilding/systems-guides/design-and-implementation/program-design-and-implementationoverview/importance; 2. AED. Available at https://www.aedweb.org/blogs/rachel-presskreischer1/2019/08/25/conceptual-model-of-implementation-research.

Justice PrEP (JPrEP)

Rationale

- BMSM are disproportionately impact by HIV and incarceration
- Post release period characterized as a vulnerable period of time for HIV acquisition and transmission
- Correctional settings (e.g., jails) have been identified as high priority HIV prevention settings
- Offer a unique opportunity to deliver HIV prevention interventions (e.g., conventional and nonconventional forms of PrEP)

Study Design

- Multi-method implementation science study to determine awareness, acceptability, and adoption of PrEP within jail settings
- HIV negative BMSM and stakeholders in Chicago and Baton Rouge
- Guided by the Exploration phase of EPIS
- Led by UC in collaboration with the Capitol Area Reentry Program (CARP) in Baton Rouge, Cook County Jail Infectious Disease Physician, and Chicago CJI consultant



Funding: NIMH R21MH121187-02 (PI: Brewer R) PrEP delivery systems for Black men who have sex with men (BMSM) transitioning from jail to community contexts

Preliminary Findings (Stakeholder Perspectives from Chicago, IL)

- Based on key informant discussions with criminal justice involved stakeholders
- PrEP is provided sporadically by request within Cook County Jail (CCJ)
- Opt-out HIV testing provided for women, all others have to request it within CCJ
- PrEP can be prescribed electronically within cook county system for pick up post release
- Limited time to assess and prescribe PrEP due to short-term stays (e.g., 1/3 released within 48 hours, 1/3 within 2 weeks, 1/3 within 6 weeks)
- CCJ's internal system provides discharge alert
- Champions exist CCJ



Baton Rouge Positive Pathway Study (BRPPS)

Rationale

- The Baton Rouge area has one of the highest HIV/AIDS rates in the county
- An estimated 2,000 PLWH are not receiving the full benefits of HIV care and treatment
- Community convening selected the implementation of conditional financial incentives within HIV clinics to improve HIV care outcomes

Study Background

- A multi-method implementation science study conducted in Baton Rouge, LA
- Examine acceptability, feasibility, costeffectiveness, utility, and sustainability of conditional financial incentives
- Guided by the RE-AIM framework
- Led by the Louisiana Public Health Institute in collaboration with UC, Baton Rouge HIV clinics, Policy & Research Group (PRG), and cost effectiveness consultant



BRPPS Findings

Surveys (N=11)



Qualitative interviews (N=13)

- Providers and administrators would like to sustain financial incentives, as they believed the incentives increased HIV care attendance
- Financial sustainability of the incentives will likely rely on outside funding, as the clinics have limited resources

Summary of my skills

- Proposal development
- Selecting appropriate IS theories, models, frameworks
- Implementation strategy selection
- Using qualitative research to support data collection/triangulation
- Addressing real-world implementation challenges
- Partnership development and maintenance
- Operationalizing implementation outcomes
- Connections to other resources



Request IS Consultation

Submit a service request on the CFAR website

https://www.thirdcoastcfar.org/services

or contact a research navigator cfar@northwestern.edu