

A Proposed Set of Standard Implementation Outcome Measures for HIV Interventions to Develop Generalizable Knowledge from Local Knowledge

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ISC³I Webinar
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Agenda

- Brief background on ISC³I
- Implementation Outcomes Coordination
- Crosswalk of HIV Implementation Outcomes
- Synthetic Examples in HIV

Learning Objectives

- Describe how different implementation outcomes may be critical at different stages of implementation research
- Use the HIV implementation outcomes tool to help identify and operationalize outcomes in current EHE projects



The Three Cs

Context Behind ISC³I



Ending the HIV Epidemic

A PLAN FOR AMERICA

GOAL:

75%
reduction in new
HIV infections
by 2025
and at least
90%
reduction
by 2030.

Ending the HIV Epidemic: A Plan for America

HHS is proposing a once-in-a-generation opportunity to eliminate new HIV infections in our nation. The multi-year program will infuse 48 counties, Washington, D.C., San Juan, Puerto Rico, as well as 7 states that have a substantial rural HIV burden with the additional expertise, technology, and resources needed to end the HIV epidemic in the United States. Our four strategies – diagnose, treat, protect, and respond – will be implemented across the entire U.S. within 10 years.



Diagnose all people with HIV as early as possible.

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



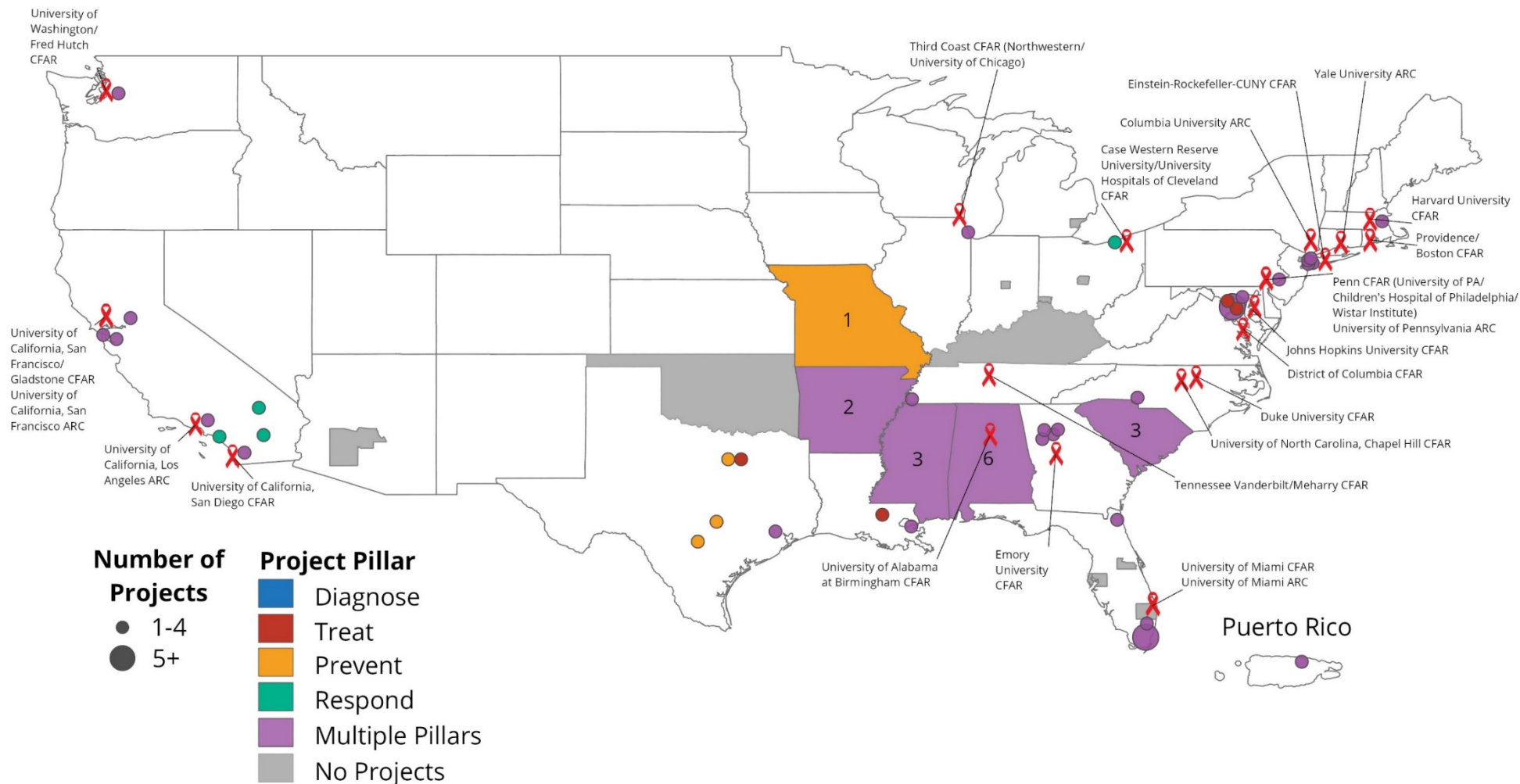
Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

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



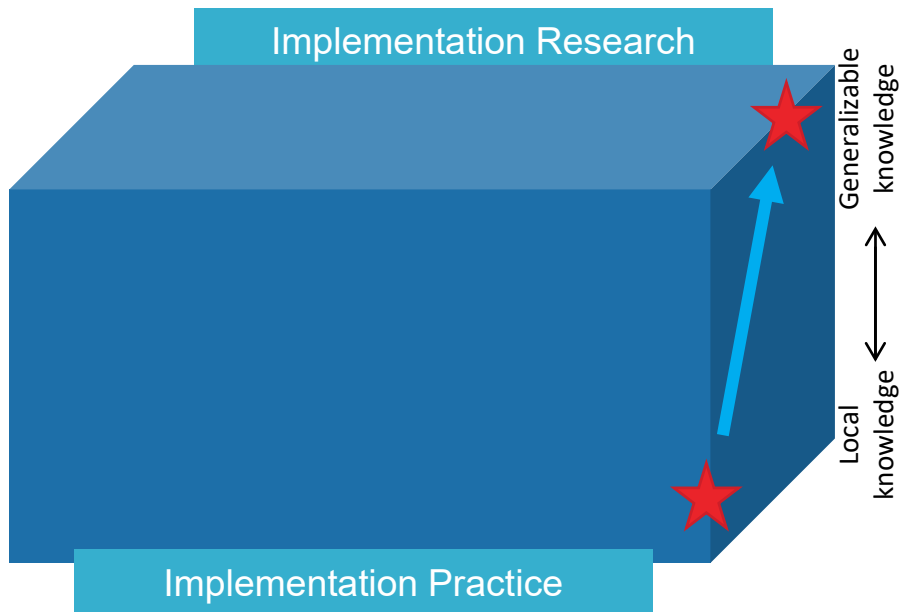


65 Planning Projects in EHE Year 1





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- 1. Support high-quality implementation science** in funded *Ending the HIV Epidemic* projects by providing technical assistance from experts on IS designs, frameworks, strategies, measures, and outcomes.
- 2. Create opportunities to develop generalizable knowledge from local knowledge** by encouraging the use of shared frameworks and harmonized measures, synthesizing data across projects, and encouraging cross-project collaboration.





Brian Mustanski, PhD
Co-Director



Implementation Science
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Nanette Benbow, MAS
Co-Director



C Hendricks Brown, PhD



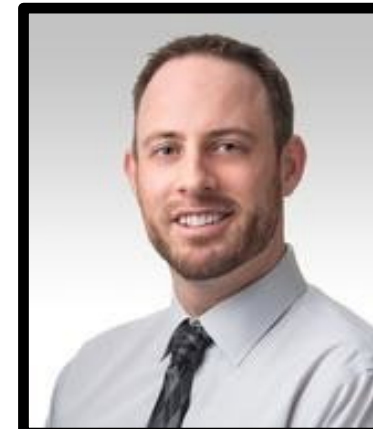
Brennan Keiser, MSW



Melissa Mongrella, MHS



Dennis Li, PhD MPH



JD Smith, PhD



Juan Villamar, MSED



Outcomes Coordination

Knowing Where You Are Going Is the First Step to Getting There



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Implementation Outcomes

- The effects of deliberate and purposive actions to implement new treatments, practices, and services (Proctor et al., 2011)
- Three functions:
 - Indicators of implementation success (e.g., reach)
 - Proximal indicators of implementation processes (e.g., adoption)
 - Intermediate outcomes relative to service system and clinical outcomes

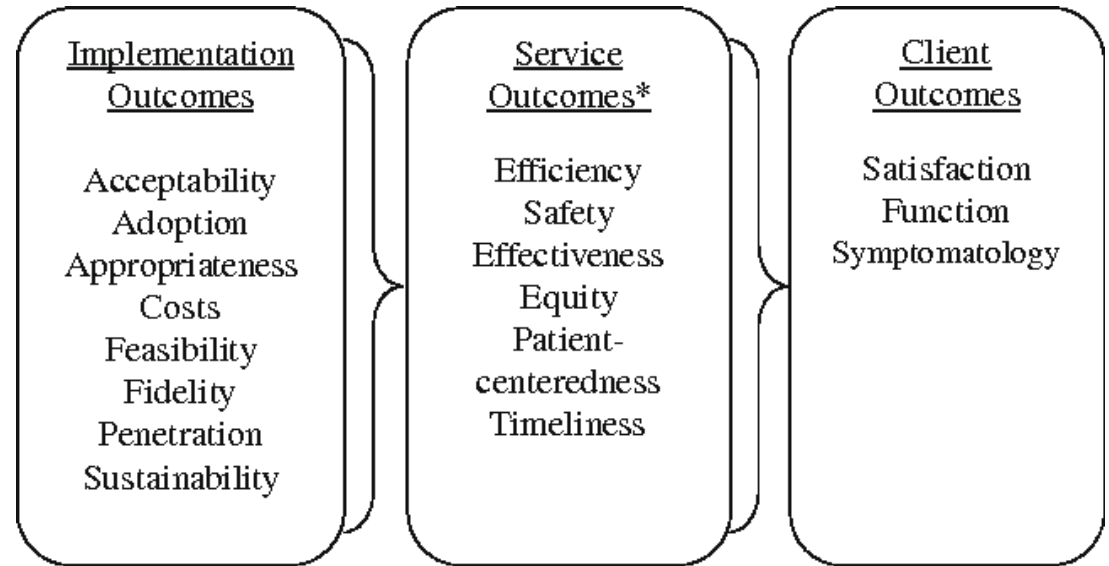


Implementation Outcomes Frameworks

RE-AIM (Glasgow et al.)



Proctor et al.



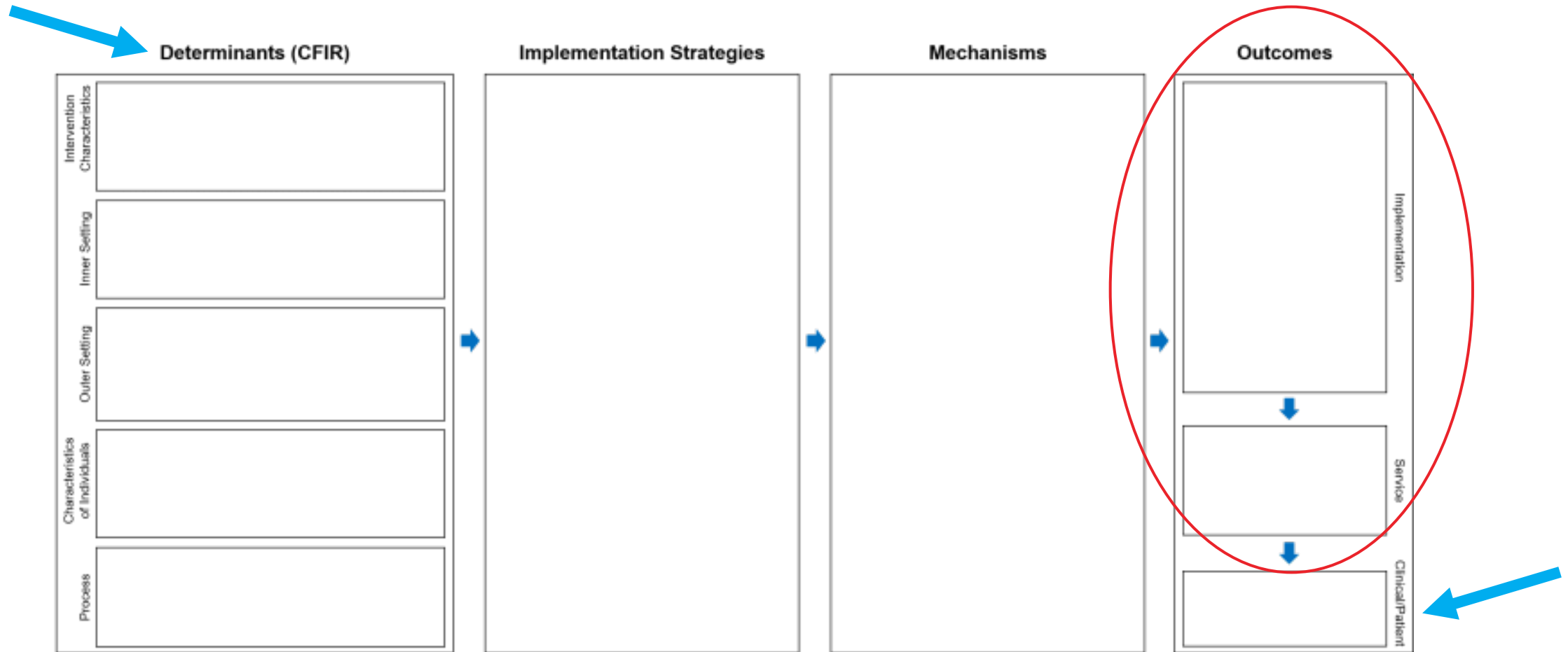
*TOM Standards of Care

Cross-Walk of Proctor and RE-AIM Outcomes

From Glasgow, 2019 ISC³I Summit

D&I Outcome	Level of Analysis	Theoretical Basis (RE-AIM)
Reach	Individual	RE-AIM
Acceptability	Individual	RE-AIM: implicit; needed for Reach
Appropriateness	Individual, Organization, Policy	
Feasibility	Individual, Organization, Policy	
Adoption	Individual, Organization, Policy	RE-AIM
Fidelity	Individual	RE-AIM: part of implementation
Cost	Individual, Organization, Policy	RE-AIM: part of implementation
Penetration	Organization, Policy	RE-AIM: necessary for reach
Sustainability	Organization, Policy	RE-AIM: maintenance

Implementation Research Logic Model

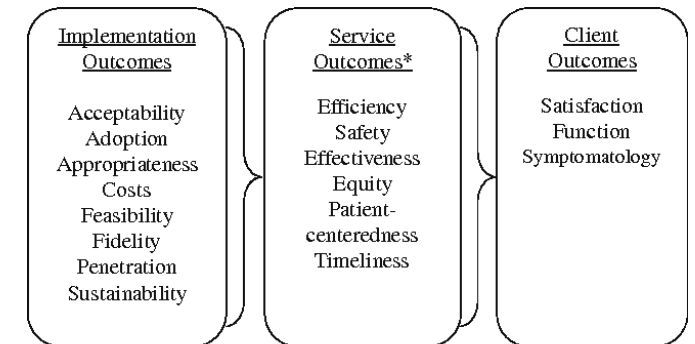


Smith, Li, & Rafferty, 2020, <https://doi.org/10.1186/s13012-020-01041-8>
<https://isc3i.isgmh.northwestern.edu/irlm/>



Foundation for Outcomes Coordination

- Used RE-AIM as the base
- Well-known framework used for over 20 years
- Has a structured, quantitative focus
 - “What does it mean to ‘employ’ the RE-AIM model?”
(Kessler et al., 2013, *Eval Health Prof*)
- Supplemented with Proctor et al. outcomes
 - i.e., acceptability, appropriateness, feasibility



*TOM Standards of Care

Initial Draft

Operationalized each construct for 8 HIV interventions

Operationalization	Lvl	PrEP	[Rapid] ART
% settings that participate based on valid denominator	Site	# clinics providing PrEP / # sites approached (and/or expected to provide)	# sites providing rapid ART / # sites approached (and/or expected to provide)
Characteristics of participating settings vs. other settings	Site	Char of sites that provide PrEP (or referral) vs. those capable that do not	Char of sites that provide rapid ART vs. those capable that do not
Setting exclusions (% or reasons)	Site	% sites that could provide PrEP (or referral) excluded	% sites that could provide rapid ART excluded
	Rschr	Reasons for excluding sites	
Use of qual methods to understand setting-level adopt	Site, Impl		
% staff invited to participate	Impl	# staff asked to provide PrEP (or referral) / # staff	# staff asked to provide rapid ART / # testing staff
Penetration (staff)	Impl	# staff providing PrEP (or referral) / # staff trained	# staff providing rapid ART / # staff trained
Characteristics of participating vs. non-participating staff	Impl	Char of staff that provide PrEP (or referral) vs. those capable that do not: e.g., role (in intervention, strategy, organization)	Char of staff that provide rapid ART vs. those capable that do not: e.g., role (in intervention, strategy, organization)
Staff exclusions (% or reasons)	Impl	% staff that could provide PrEP excluded	% staff that could provide rapid ART excluded
	Rschr	Reasons for excluding staff	
Use of qual methods to understand staff participation	Impl		

Operationalization	Level	EPIS	Molecular Cluster Response (Respond)
Acceptability of intervention	Ptp, Impl	E, I, S	N/A
Appropriateness of intervention	Ptp, Impl	S	N/A
Feasibility of the intervention	Impl		Standard.
% perfect delivery (staff fidelity to intervention)	Impl	I	% of HDs with established partnerships with local providers to whom to refer cluster participants % of HDs collaborating and seeking input from community
Cost of intervention	Ptp, Site	I	E.g., cost of MCR "team".
Adaptations made to intervention	Rschr, Impl	P, I	Standard.
Acceptability of the strategy(ies)	Ptp, Impl	E/P,	Measure using quant and/or qual methods as appropriate for research question. Timing (E vs. P) depends on focus of research and/or distinction from intervention. Repeated assessment over time/phase allows for capture of change from perceived to experienced.
Appropriateness of the strategy(ies)	Ptp, Impl	I, S	
Feasibility of the strategy(ies)	Impl		
Fidelity to strategy	Impl, Site	I	# [strategy] is delivered according to protocol or best practice / # times [strategy] is delivered Established measure of strategy fidelity, if available.
			If none available, consider pragmatic secondary indicators (e.g., monitoring electronic health records) or direct observation on a random subset of cases.
Cost of strategy	Impl, Site	I	Time-driven activity-based costing for budget impact analysis. Include staffing costs, supporting materials. Separate start-up vs. active delivery. See "cost of strategy".



Coordination Process

1. Used “What It Means to Employ RE-AIM” (Kessler et al., 2013) to generate outcomes for each type of intervention. Abstracted to a “standard approach” for IS outcomes across *most* interventions.
2. Shared outcomes with EHE projects via small group meetings and solicited feedback.
3. Presented outcomes in two meetings with CDC and HRSA EHE teams and solicited feedback.
4. Held expert consultation.
5. Consolidated feedback into revised measurement set.
6. Obtained expert panel ratings on importance/relevance of each outcome by stage of implementation research.
7. Consolidated feedback and additional ratings into revised measurement set.
8. **Make available to EHE projects.**
9. Review with NIH, CDC, and HRSA EHE teams.
10. Collaboratively publish outcome recommendations.

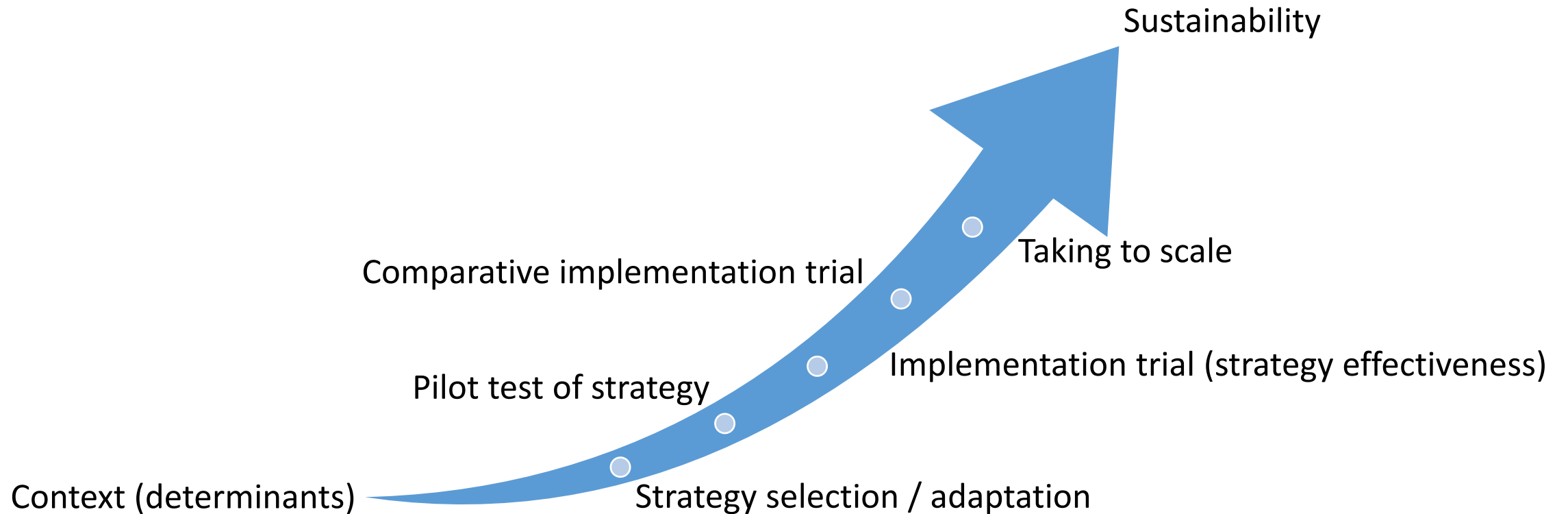


External Panel Members

- Carolyn Audet, Vanderbilt
- Ingrid Bassett, Harvard
- Larry Chang, Johns Hopkins
- Elvin Geng, Washington U.
- Vivian Go, U. of North Carolina
- Sarit Golub, Hunter College
- Lisa Hirschhorn, Northwestern
- Christopher Hoffman, Johns Hopkins
- Michael Mugavero, U. of Alabama, Birmingham
- Sheree Schwartz, Johns Hopkins
- Patrick Sullivan, Emory



Stages of Implementation Research



Adapted from Smith et al., 2020, <https://doi.org/10.1007/s10461-019-02764-6>



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Rating Task

- Separately for 3 stages of IR, panelists rated agreement with our rating

Standard Construct/Metric	Pre-Implementation	PANELIST RATING	
	E.g., identifying barriers and selecting strategies		E
Acceptability of the intervention	Required	Agree with rating	Re
Appropriateness of the intervention	Required	Disagree - N/A	De
Feasibility of the intervention	Required	Agree with rating	C
Acceptability of the strategy(s)	Recommended	Disagree - Required	re
Appropriateness of the strategy(s)	Recommended	Disagree - Recommended	re
Feasibility of the strategy(s)	Recommended	Disagree - If needed	re
		Disagree - N/A	
		Eliminate measure completely	re

- Also could provide written comments

Takeaways from Panel Ratings

- Generally fair amount of consensus for most metrics.
- For those metrics where experts disagreed and provided comments, they usually made strong arguments for their points.
 - Often cited examples of studies that sit in grey area between two IR stages.
- Consider using examples to clarify additional breakdowns of IR stages:
 - Current: pre-implementation, piloting/trialing, taking to scale
 - Full: context, strategy selection/adaptation, piloting, imp trial of strategy, comparative implementation, taking to scale, sustainability
- Framing metrics in terms of research questions is useful.



Implementation Outcomes Crosswalk



Reach

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Patient	How many potential patients were reached by the intervention?	# potential patients in target health system or community eligible for the intervention --> <u>public health denominator</u>	Should reflect the scope of the project and approximate the # of patients that the intervention could potentially and feasibly touch across the entire health system or community. May use surveillance data, modeling, probability sampling, and other methods to estimate denominator.	N/A	If desired	Recommended
		# potential patients across sites eligible for the intervention --> <u>study denominator</u>	Total # of patients who could potentially and feasibly receive the intervention across sites that adopted the intervention. May be an estimate, but provide justification.	N/A	Required	Required
		# potential patients aware of the intervention	Applicability varies by intervention. May estimate via sampling.	N/A	If desired	If desired
		# potential patients offered the intervention		N/A	Required	Required
		# potential patients who initiated or were provided the intervention		N/A	Required	Required
	How representative are the patients who were reached of the population being targeted?	Characteristics of patients that receive the intervention vs. patients that do not	Use quant and/or mixed methods to compare based on individual characteristics and identified determinants (e.g., perceived risk, readiness), especially known disparities (e.g., age, race/ethnicity, insurance, gender, sex, urbanicity, transmission risk, homelessness, jail). May assess both participant and implementer perspectives.	N/A	Required	Required
		# patients excluded from receiving the intervention		N/A	Required	Required
		Reasons for excluding those patients		N/A	Required	Required
	How consistent is reach across sites, implementers, and/or strategy(s)?	Reach rates by site, by implementer, and/or by recruitment strategy(s)	Use quant or mixed methods to compare based on site and implementer characteristics and/or strategy(s) targeting reach.	N/A	Recommended	Recommended

Efficacy/Effectiveness

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Patient	How likely will patients want to engage with the intervention ?	Acceptability of the intervention	Use quant and/or mixed methods as appropriate to the intervention.	Recommended	Recommended	Recommended
		Appropriateness of the intervention	Use quant and/or mixed methods as appropriate to the intervention.	Recommended	Recommended	Recommended
	How likely will patients want to engage with the strategy(s) ?	Acceptability of the strategy(s)	Only applicable if using patient-focused strategies. Use quant and/or mixed methods.	Recommended	Recommended	Recommended
		Appropriateness of the strategy(s)	Only applicable if using patient-focused strategies. Use quant and/or mixed methods.	Recommended	Recommended	Recommended
	How well does the intervention work ?	Effect vs. a recognized clinical benchmark or public health goal	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
	(Important to collect when evidence is not yet established or intervention/ population/ setting have changed considerably.)	Effect vs. a comparator (e.g., TAU, control, alternative implementation)	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
		# patients achieving clinical milestones or demonstrating reduction in risk factors / # patients reached	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
		Time between delivering the intervention and observing a clinical effect	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
	What secondary effects , either positive or negative, does the intervention have?	Related outcomes	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
		Adverse events	Varies by intervention. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
	Are patients using the intervention enough to receive the clinical benefits? (adherence, engagement, dosage)	# patients using or adhering to the intervention as indicated / # patients reached	Definition of clinically meaningful use or adherence varies by intervention but should be clearly defined. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
	How consistent are the intervention effects for all patients?	Differential effects of the intervention by participant characteristics	Use quantitative or mixed methods. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question
		Differential adherence by patient characteristics	Use quant or mixed methods. Not needed in implementation study unless using a hybrid design.	If relevant to research question	If relevant to research question	If relevant to research question

Adoption - Site

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Site	How likely will sites want to adopt the intervention ?	Acceptability of the intervention	Acceptability of Intervention Measure (AIM), Intervention Appropriateness Measure (IAM), and Feasibility of Intervention Measure (FIM): see tab below. Use qual methods to supplement.	Required	Recommended	Recommended
		Appropriateness of the intervention		Required	Recommended	Recommended
		Feasibility of the intervention		Required	Recommended	If desired
	How likely will sites want to adopt the strategy(s) ?	Acceptability of the strategy(s)	Adapt the AIM, IAM, and FIM (see tab below). Use qual methods to supplement.	Recommended	Required	Recommended
		Appropriateness of the strategy(s)		Recommended	Required	Recommended
		Feasibility of the strategy(s)		Recommended	Required	Recommended
	How many potential sites "adopted" the intervention?	# potential sites in target health system or community eligible to provide the intervention → <u>public health denominator</u>	Total # of sites in which the intervention could be potentially and feasibly delivered across the entire health system or community. May be an estimate, but provide justification.	N/A	If desired	Recommended
		# potential sites approached to provide the intervention → <u>study denominator</u>	If the intervention is mandated or already being implemented, the # is all sites.	N/A	Required	Required
		# sites that agreed to provide the intervention	If the intervention is mandated or already being implemented, the denominator is all sites.	N/A	Recommended	Required
		# sites that began providing the intervention	If the intervention is mandated or already being implemented, the # is all sites.	N/A	Required	Required
	How quickly did potential sites adopt the intervention?	Time between approaching site 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 site and their beginning to provide the intervention		N/A	If desired	If desired
	How representative are the adopting sites of other potential sites in the target health system or community?	Characteristics of sites that agree/begin to provide the intervention vs. sites that do not	Use quant or mixed methods to compare site characteristics and determinants (e.g., capacity, organizational climate, intervention feasibility). Refer back to CFIR or other determinant frameworks.	N/A	Required	Required
		# sites excluded from providing the intervention		N/A	Recommended	Required
		Reasons why those sites are excluded		N/A	Recommended	Recommended

Adoption - Implementer

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Implementer	How likely will implementers want to adopt the intervention?	Acceptability of the intervention	AIM, IAM, and FIM (see tab below). Use qual methods to supplement.	Required	Recommended	Recommended
		Appropriateness of the intervention		Required	Recommended	Recommended
		Feasibility of the intervention		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). Use qual methods to supplement.	Recommended	Required	Recommended
		Appropriateness of the strategy(s)		Recommended	Required	Recommended
		Feasibility of the strategy(s)		Recommended	Required	Recommended
	How many potential implementers "adopted" the intervention?	# potential implementers in sites eligible to provide/support the intervention --> <u>public health denominator</u>	Total # of implementers across all sites 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 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

Implementation

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Site + Implementer	How quickly is the intervention being delivered to eligible patients?	Time between assessing patient for eligibility and delivering the intervention		N/A	Recommended	Recommended
	How closely is the intervention delivered as designed? (fidelity to the intervention)	Completeness of intervention delivery: # times an adequate amount of the intervention is delivered / # times the intervention is delivered	Use quant measures (e.g., checklist, number of sessions, engagement metrics) as appropriate to the type of intervention to determine "adequate" completion (e.g., delivery as planned, delivery to a certain level). May use randomly selected proportion of cases as estimate. May not be applicable if delivery is automated.	N/A	Required	Required
		Quality of intervention delivery	Use quant or mixed methods (e.g., coding of recordings) as appropriate to the type of intervention. May use randomly selected proportion of cases as estimate. May not be applicable if delivery is automated.	N/A	Required	Required
		Adaptations made to the intervention , the reasons, and the results	Specify adaptations made using the Framework for Reporting Adaptations and Modifications to Evidence-based interventions (FRAME; see tab below)	N/A	Required	Required
	How closely is the strategy(s) delivered as designed? (fidelity to the strategy)	Completeness of strategy(s) delivery: # times an adequate amount of the strategy is delivered / # times the strategy is delivered	Use quant measures (e.g., checklist, number of sessions, engagement metrics) as appropriate to the type and level of strategy(s). May use randomly selected proportion of cases as estimate. May not be applicable if delivery is automated.	N/A	Required	Required
		Quality of strategy(s) delivery	Use quant or mixed methods (e.g., coding of recordings) as appropriate to the type and level of strategy(s). May use randomly selected proportion of cases as estimate.	N/A	Required	Required
		Adaptations made to the strategy(s) , the reasons, and the results	Specify adaptations made using the Proctor et al. strategy specifications (see tab below).	N/A	Required	Required
	How much does it cost to deliver the intervention (intervention + strategies)?	Cost of intervention: Total \$ amount for intervention materials and <i>required</i> resources	Cost of interventions materials, typically absent delivery mechanism unless an essential component of intervention effect. If applicable, may differentiate reimbursable vs. non-reimbursable costs and/or include administrative and reporting requirement burden. Staffing costs may be included if intervention is primarily based around staff interaction (e.g., linkage), can only be delivered by a specialist (e.g., licensed drug counselor), and is not part of the strategy being studied. For eHealth, include license and subscription fees.	N/A	Recommended	If desired
		Cost of strategy(s): Total \$ amount for the implementation strategy(s)	Use time-driven activity-based costing for budget impact analysis. Include staffing and supporting materials. Separate start-up vs. active delivery.	N/A	Recommended	Recommended
	How consistent is implementation across sites, implementers, and/or strategy(s)?	Differential fidelity and delivery rates, by site, by implementer, and/or by strategy(s)	Use quant or mixed methods to compare how site characteristics and identified determinants differ between high- and low-fidelity implementers. Identify explanatory relations between determinants and outcomes (e.g., quality audit). Refer back to CFIR or other determinant frameworks.	N/A	Recommended	Required

Maintenance

Lvl	Question	Standard Construct/Metric	General Considerations or Procedures	Importance by Stage of Research		
				Implementation Preparation	Piloting Strategy	Bringing to Scale
Site + Implementer	Is delivery of the intervention and strategy(s) being sustained over time?	# sites continuing to deliver the intervention after X time / # sites that began implementing	X time varies by intervention.	N/A	Recommended	Recommended
		Program/clinical sustainability assessment tool : https://www.sustaintool.org/	Select domains of the CSAT (staff & leadership, stakeholders, readiness, workflow integration, implementation & training, monitoring & evaluation, outcomes & effectiveness) and/or PSAT (environmental support, funding stability, partnerships, capacity, evaluation, adaptation, communications, strategic planning) as applicable to the setting and intervention (see tab below).	N/A	Recommended	Recommended
Implementer	Are fidelity to intervention delivery and the strategy(s) being sustained at acceptable levels over time?	Completeness of intervention delivery and strategy(s) sustained X time	Use the same methods as in the "Implementation" domain. X time varies by intervention.	N/A	Recommended	Recommended
		Quality of intervention delivery and strategy(s) sustained X time	Use the same methods as in the "Implementation" domain. X time varies by intervention.	N/A	Recommended	Recommended
		Adaptations made over time to intervention or strategy(s)	Running list of adaptations by date, specified using the same methods as in the "Implementation" domain.	N/A	Recommended	Recommended
Patient	Are the intervention effects being sustained over time?	Primary outcome sustained for $\geq X$ time after achieving intervention effect	Use the same methods as in the "Effectiveness" domain. X time varies by intervention.	If relevant to research question	If relevant to research question	If relevant to research question
		Related outcomes sustained for $\geq X$ time post-intervention	Use the same methods as in the "Effectiveness" domain. X time varies by intervention.	If relevant to research question	If relevant to research question	If relevant to research question
		Robustness (differential effects of the intervention) across subgroups over time	Use the same methods as in the "Effectiveness" domain.	If relevant to research question	If relevant to research question	If relevant to research question
		Long-term attrition (differential adherence) across subgroups over time	Use the same methods as in the "Effectiveness" domain.	If relevant to research question	If relevant to research question	If relevant to research question

By the Numbers

	Implementation Preparation	Piloting	Bringing to Scale
Required	6	23	22
Recommended	10	26	28
If desired	0	9	8
N/A	42	0	0
If relevant	13	13	13
Total	71	71	71



Using the Crosswalk

Selecting and Operationalizing Outcomes for Different Pillars and Stages



Synthetic Example 1: Pilot Test of Strategy



Diagnose all people with HIV as early as possible.

Routine HIV testing among people with SUD

High-Risk Population

- The high-risk practices of sharing needles, syringes, and other drug injection equipment (e.g., cookers) are common among PWID.
- PWID may also engage in risky sexual behaviors
- Social and economic factors limit access to HIV prevention and treatment services among PWID
- PWID may face stigma and discrimination

OF THE 38,739 HIV DIAGNOSES IN THE UNITED STATES (US)
AND DEPENDENT AREAS IN 2017:

1 IN 10 (3,641) WERE
AMONG PWID*

2,625 WERE
AMONG MEN WHO
INJECT DRUGS*

1,016 WERE AMONG
WOMEN WHO
INJECT DRUGS

* Includes infections attributed to male-to-male sexual contact *and* injection drug use (men who reported both risk factors).



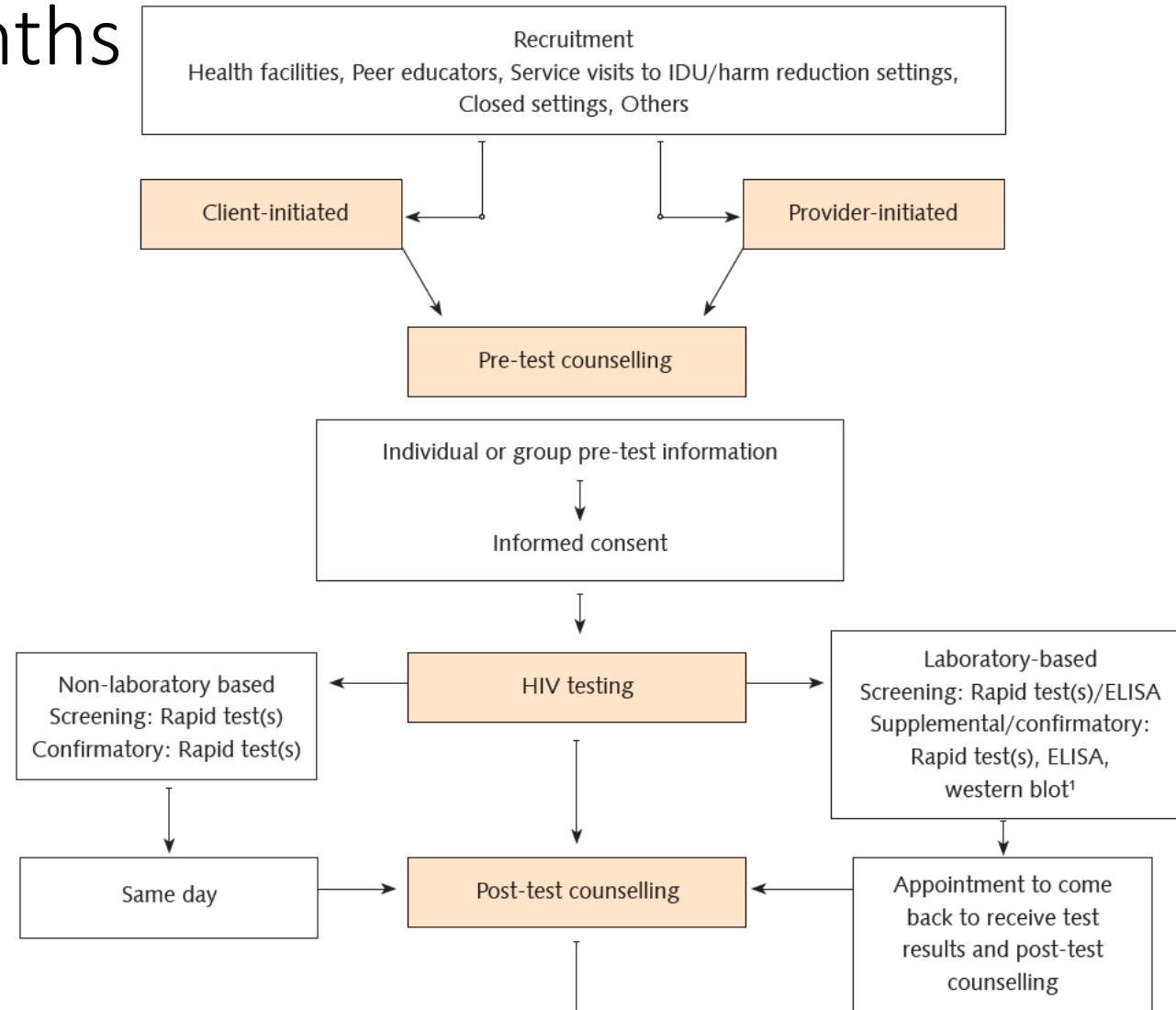
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HIV testing among those who have not been tested in prior 6-months

Evidence-based clinical intervention

- Regular HIV testing during service visits
- Substantial variation in protocols, competition for other needed services



Regular rapid testing during MAT/IDU treatment services should be high yield

Implementation gap

- Medical teams can effectively provide rapid HIV testing when patients present for treatment
- Initial/Repeat HIV testing is provided inconsistently because of competing interests during a short clinical appointment
- **Coupling rapid HIV testing with a urine drug screen** could be a bridging strategy to identify high-risk individuals to providers; it could also improve support for substance use disorder by making clients eligible for housing and other support

Implementation strategy

- Provide cheek swab along with urine screening in the bathroom before clinical visit →
 - Urine sample and swab put in cabinet for staff POC interpretation. Staff provide support for collection as requested by client. Results would be available at same time as drug result. Linkage to care for positive.



Routine HIV testing during semi-annual IDU treatment

Research questions

- Are clients willing to perform the cheek swab with fidelity?
- Are the staff willing to add this task to their activities
- Do we find undiagnosed HIV positive clients?
- Does the benefit to clients outweigh the costs to the system?

Hypothetical study design and setting

- Pilot implementation in three settings using a Interrupted time series design
- Focus on acceptability, fidelity, and context



Reach (1)

- *Outcome*: # [ppl] tested / # [ppl] in [population]
- *Required*
- Level: patients
- Answers: How many potential patients were reached by rapid HIV testing?
- Data sources: EPIC
- Considerations: Primary outcome – does rapid self testing increase testing coverage?

Reach (2)

- Outcome: Characteristics of those tested vs. those not tested
- *Required*
- Level: patients
- Answers: How representative are the patients who completed a rapid test of the target population (all new diagnoses)? Are there systematic differences?
- Data sources: EPIC
- Considerations: We are interested in whether there is a change in who is reached by rapid testing



Effectiveness

- Outcome: # positives / # tested (i.e., positivity rate)
- *Recommended*
- Level: patients
- Answers: Are we reaching these of high risk of HIV?
- Data sources: Clinical records
- Considerations: We are interested in seeing if the strategy also increases uptake of HIV treatment.

Adoption (1)

- Outcome: Acceptability, appropriateness, feasibility of the self-testing strategy
- *Required*
- Level: Providers
- Answers: Is the process acceptable, appropriate and feasible
- Data sources: Surveys w/ treatment team using adapted AIM, IAM, and FIM metrics
- Considerations: What aspects of the program cause challenges in clinical care



Adoption (2)

- Outcome: Char of participating and non-participating sites
- *Required*
- Level: Provider
- Answers: Which types of site that tests vs. those who do not adopt?
- Data sources: Qualitative interviews
- Considerations: Why do sites decide to participate, value seen in the program, how it fits into their context and service portfolios.



Implementation (1)

- Outcome: Median % fidelity across all implementers and computed at site level
- *Required*
- Level: Provider & Clinic
- Answers: How closely is the strategy delivered as designed?
- Data sources: Audit of patient testing records by provider
- Considerations: We need to determine if some systems needed to be adapted to make this strategy work



Implementation (2)

- Outcome: Time-driven activity-based costing
- *Recommended*
- Level: HDs
- Answers: How much does it cost to deliver the self-testing strategy?
- Data sources: Budget impact analysis, including staff salaries, billing codes, supplies, etc.
- Considerations: Given that self-tests would be an additional expense to the health facility, we are interested to see if adding this strategy would be cost effective at improving reach and individual outcomes.



Maintenance

- Outcome: Use of qualitative methods to understand setting/institutionalization
- *Recommended*
- Level: Clinic
- Answers: Can self-testing be sustained?
- Data sources: Interviews with providers, evidence of integration into workflow, intention to continue purchase of materials.
- Considerations: How can this be funded in the long-term?



Synthetic Example 2: Implementation Trial

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



Health-department-based community health workers (HD-CHWs) to improve early HIV treatment initiation

Evidence-based clinical intervention

- Early HIV treatment initiation (a.k.a., rapid ART/rapid start):
 - Assessment of psychosocial barriers to treatment and adherence
 - Education on medication adherence
 - Provision of medicine
 - Follow-up

• Substantial variation in protocols nationally

Identify Rapid ART Candidates	Counseling and Education	Assess and Refer	Baseline Lab Testing	Initiate ART	Payment Assistance?	Follow-Up	Adjust ART
<p>Candidates have:</p> <ul style="list-style-type: none">• A new reactive POC HIV test result, new HIV diagnosis, acute HIV, or known HIV, <i>and</i>• No or limited prior ARV use, <i>and</i>• No medical conditions or OIs that require deferral of ART initiation	<ul style="list-style-type: none">• HIV diagnosis• Disclosure• Adherence• Side effects and management of• Management of lifelong medications	<ul style="list-style-type: none">• Health literacy• Identify and address medical and psychosocial barriers to treatment and adherence• As indicated, refer for substance use treatment, behavioral health services, housing assistance	<ul style="list-style-type: none">• Confirm HIV diagnosis• Viral load• Resistance testing• CD4 count• HAV, HBV, HCV testing• Metabolic panel• STIs• Urinalysis• Pregnancy test for individuals of childbearing potential	<ul style="list-style-type: none">• Choose a preferred regimen based on patient characteristics and preference• Initiate ART immediately—preferably on the same day—or within 96 hours• Administer the first dose on site if possible	<ul style="list-style-type: none">• Assess need for payment assistance• Refer patients with no insurance to NYS UCP• Provide resources for payment assistance	<ul style="list-style-type: none">• Contact the patient within 24 to 48 hours by phone (or other preferred method)• Assess medication tolerance and adherence• If feasible, schedule in-person visit with medical care provider within 7 days• Reinforce adherence	<ul style="list-style-type: none">• Change or adjust the initial ART regimen based on results of initial lab and resistance testing

HD-CHWs to improve early HIV treatment initiation

Implementation gap

- Medical teams can effectively provide rapid ART when patients present for treatment
- Length of time between first diagnosis and presentation for treatment is inconsistent because HIV testing does not always occur in clinics, and linkage capacity at testing sites may vary
- **Centralized community-based linkage and outreach** could be a bridging strategy to more quickly link newly diagnosed individuals to providers; it could also improve long-term adherence by better addressing psychosocial barriers

Implementation strategy

- Centralized community-based linkage and outreach → Paid, supervised community health workers based at the public health department that bridge community-based and other testing sites and clinics



HD-CHWs to improve early HIV treatment initiation

Research questions

- Does the use of HD-CHWs improve reach and delivery of rapid ART?
- Does the addition of HD-CHWs improve the effectiveness of ART to achieve viral suppression?
- Does the benefit of including HD-CHWs outweigh the costs?

Hypothetical study design and setting

- Type 3 effectiveness–implementation hybrid trial: HD-CHW model vs. regular systems of care
- Among jurisdictions/public health authorities already implementing rapid ART
- Cluster-randomization (cluster = jurisdiction) with stratification or matching on jurisdiction-level demographics and characteristics
- Within-and-between design



Reach (1)

- Outcome:
 - # new diagnoses offered rapid ART within X days / # eligible
 - # new diagnoses who initiated rapid ART / # eligible
- *Required*
- Level: patients
- Answers: How many potential patients were reached by rapid ART?
- Data sources: HD testing epi data (eHARS) and CBO testing records
- Considerations: Primary outcome – do HD-CHWs increase reach of rapid ART?

Reach (2)

- Outcome: Characteristics of patients that receive rapid ART vs. those that do not
- *Required*
- Level: patients
- Answers: How representative are the patients who received rapid ART of the target population (all new diagnoses)? Are there systematic differences?
- Data sources: HD testing epi data (eHARS) and CBO testing records
- Considerations: We are interested in whether there is a change in who is reached by rapid ART through the use of HD-CHWs.



Effectiveness

- Outcome: Differential effects of rapid ART by patient characteristics (including receipt of HD-CHW strategy)
- *Recommended*
- Level: patients
- Answers: How consistent are the intervention effects for all patients?
- Data sources: Clinical records
- Considerations: We are interested in seeing if the HD-CHW strategy also changes intervention effects of rapid ART on adherence and viral suppression.



Adoption (1)

- Outcome: Acceptability, appropriateness, feasibility of the HD-CHW strategy
- *Required*
- Level: Health department
- Answers: How likely will jurisdictions want to adopt the strategy?
- Data sources: Surveys w/ HD HIV team (e.g., director of HIV services, existing DIS staff) using adapted AIM, IAM, and FIM metrics
- Considerations: At this stage, the clinical intervention should already be acceptable, appropriate, and feasible; focus should be on strategies.



Adoption (2)

- Outcome: # HDs that agree to work with HD-CHWs / # HDs approached to use HD-CHW strategy
- *Required*
- Level: Health department
- Answers: How many potential jurisdictions adopted the strategy?
- Data sources: Study records of HDs approached and their response
- Considerations: Jurisdictions are already providing rapid ART, so adoption here is about the strategy. This uses a “study denominator” (cf. “public health denominator”) because focus is not on scale out.

Adoption (3)

- Outcome: If HDs are not approached, reasons why they were excluded
- *Required*
- Level: Health department
- Answers: How representative are the adopting implementers of other potential implementers?
- Data sources: Study records of HDs selected to approach / not approach
- Considerations: At this stage (trialing), we are trying to move towards generalizability. Knowing which HDs were systematically excluded informs external validity.



Adoption (4)

- Outcome: Characteristics of testing orgs and clinics that agree to work with HD-CHWs vs. those that do not
- *Required*
- Level: Clinics and community-based testing orgs
- Answers: How representative are the adopting implementers of other potential implementers?
- Data sources: Study-specific survey of implementer characteristics and key-informant interviews
- Considerations: This will tell us differences between teams that opt out of using HD-CHWs, which helps inform generalizability.



Implementation (1)

- Outcome: Completeness (relative to a defined protocol) and quality of HD-CHW delivery
- *Required*
- Level: HDs, clinics, community-based testing orgs
- Answers: How closely is the HD-CHW strategy delivered as designed?
- Data sources: Checklist for HD-CHW linkage steps; audit of records of CHW–patient interactions; audit of patient linkage records
- Considerations: For a complex strategy like HD-CHW linkage, it is important to operationalize fidelity in a number of different ways and triangulate findings.



Implementation (2)

- Outcome: Total \$ amount for hiring and training HD-CHWs
- *Recommended*
- Level: HDs
- Answers: How much does it cost to deliver the HD-CHW strategy?
- Data sources: Budget impact analysis, including staff salaries, billing codes, supplies, transportation, etc.
- Considerations: Given that HD-CHWs would be an additional expense to the HD, we are interested to see if adding this strategy would be cost effective at improving reach and individual outcomes.



Maintenance

- Outcome: Completeness (and quality) of rapid ART delivery and HD-CHW strategy sustained over X time
- *Recommended*
- Level: HDs, clinics, community-based testing orgs
- Answers: Are fidelity to rapid ART delivery and the HD-CHW strategy being sustained at acceptable levels over time?
- Data sources: Checklist for HD-CHW linkage steps; audit of records of CHW–patient interactions; audit of patient linkage records
- Considerations: Should the strategy be continued, the ideal would be to integrate fidelity monitoring into routine program evaluation activities at the HDs.



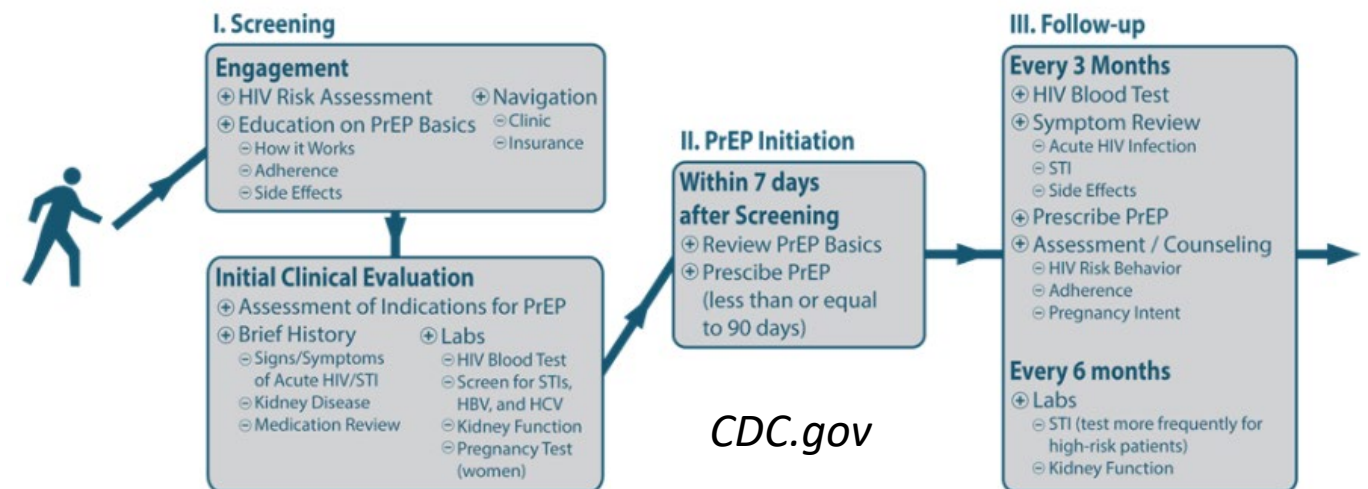
Synthetic Example 3: Taking to Scale



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

Scale a 12-month PrEP navigation intervention to all sexual health clinics in NY state

- PrEP when delivered and taken reduces sexual risk for HIV infection by up to 99%
- CDC recommends PrEP for men and women:
 - Shared injection or drug preparation equipment <6 mos.
 - Have condomless anal or vaginal sex **and/or**
 - Had a bacterial STI <6 mos.



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PrEP navigation scale-up

Evidence-based clinical intervention(s)

- PrEP
- PrEP navigation

Implementation gaps

- PrEP not reaching PrEP-eligible at-risk individuals
- Providers inconsistently trained to provide PrEP
- Bias in assessment of risk (who gets screened or who perceived to be at risk) can limit PrEP delivery
- Linkage to PrEP providers



PrEP navigation scale-up

Evidence-based clinical intervention

- PrEP navigation

Implementation strategies

- (1) training for PrEP providers to prescribe/manage PrEP
- (2) training for PrEP navigators to screen for eligibility & educate clients on PrEP benefits
- (3) universal screening for PrEP at the facility-level among SRH clients & automated referrals
- (4) PrEP navigation of clients to providers via the PrEP navigator
- (5) PrEP counseling & prescribing by the health care provider



PrEP navigation scale-up

Research questions

- To what extent can PrEP navigation be successfully scaled up across SRH clinics in NY?
- What is the impact and sustainment of these efforts?
- What factors are associated with more rapid and complete implementation of the PrEP navigation intervention?

Hypothetical study design and setting

- Follow-on to successful RCT in a small number of clinics demonstrating effectiveness and which developed an implementation plan
- All sexual health clinics in NY state offered support to scale up PrEP navigation
- Focus on understanding context of adoption and implementation (facility-level >>> patient level)



Reach (1)

- Outcome: # [ppl] engaged by navigator / # [ppl] PrEP-eligible [in NY]
- *Required*
- Level: patients
- Answers: How well did the program reach eligible individuals?
- Data sources: EMR; public health surveillance data
- Considerations: Relies on accurate understanding of estimated number of PrEP-eligible individuals in NY



Reach (2)

- Outcome: # [ppl] engaged by navigator / # [ppl] PrEP-eligible [per clinic]
- *Required*
- Level: patients
- Answers: Within the adopting sites, how many potential patients are reached by the program?
- Data sources: EMR
- Considerations: Interested in exploring heterogeneity by clinics; as well as factors (e.g. geography, patient pop size, gender/age composition) associated with higher/lower clinic reach



Effectiveness

- Outcomes:
 - # [PrEP-eligible] started PrEP/ # [PrEP-eligible]
 - # [PrEP clients] retained on PrEP [6mo.] / # [PrEP initiated 6+mos]
 - # New HIV infections
- *Recommended*
- Level: patients
- Answers: How well does the intervention work?
- Data sources: EMR; surveillance data
- Considerations: Assessed overall & by clinic; new infections overall



Adoption (1)

- Outcome: # [sites] providing navigation / # [eligible sites] in NY
- *Required*
- Level: Site [clinic]
- Answers: What is the adoption rate of the PrEP navigation intervention amongst SRH clinics?
- Data sources: PrEP service inventories; clinic surveys
- Considerations: How representative are the adopting sites among all eligible SRH clinics? We will compare sites adopting the EBI vs. not adopting based on urban vs. rural, racial composition, sex, provider characteristics



Adoption (2)

- Outcomes:
 - # [PrEP providers] newly initiating PrEP across sites
 - # [PrEP providers] currently prescribing PrEP
- *Required*
- Level: Implementer [Provider]
- Answers: How many potential implementers adopted the intervention
- Data sources: EMR prescribing records; clinic surveys
- Considerations: Also assess per potential PrEP providers; less focus on acceptability, appropriateness and feasibility



Implementation (1)

- Outcome: # universal screens completed by site / # patient visits
- *Required*
- Level: Site
- Answers: Completeness of strategies delivered
- Data sources: EMR records
- Considerations: Consider heterogeneity in performance across clinics; follow-up on # patients PrEP eligible navigated to a PrEP provider as additional outcome



Implementation (2)

- Outcome: # [providers] trained at adopting sites / # [eligible providers] at adopting sites
- *Required*
- Level: Implementer
- Answers: Completeness of strategies delivered
- Data sources: clinic surveys indicating # providers on site & # receiving training
- Considerations: Also note speed of time to implementation of intervention



Maintenance (1)

- Outcome: % [PrEP providers] that received initial PrEP training 12 mos.; 24 mos.
- *Recommended*
- Level: Implementer
- Answers: Is delivery of the intervention strategies being sustained at acceptable levels over time?
- Data sources: Annual clinic surveys
- Considerations: Overall & by site



Maintenance (2)

- Outcome: % [PrEP navigators] retained at 12-months
- *Recommended*
- Level: Implementer
- Answers: Is the delivery of the intervention sustained over time?
- Data sources: Annual clinic surveys
- Considerations: Turnover & renewed contracts are relevant. Sustained inclusion of budgeting for PrEP navigators as a signal of maintenance over time

Concluding Thoughts

Putting the Crosswalk to Use in the Real World



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Continued Development

- Living document
- Review with NIH, CDC, and HRSA EHE teams
- Make changes as we refine examples and put it to use



Accessing the Crosswalk

- Available on the ISC³I Community of Practice soon
 - isc3i.isgmh.northwestern.edu
- Publicly available following publication
- IS Hubs can use to work with currently funded EHE projects





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