



Developing Access-Enhancing Injectable HIV Treatment in Diverse Health Clinics

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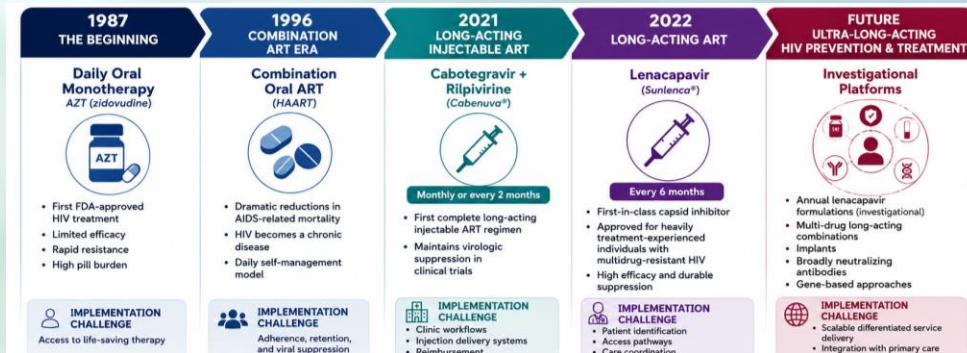
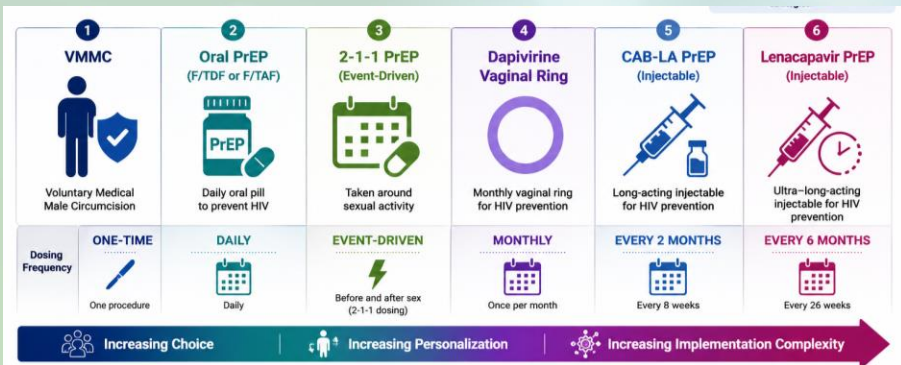
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I have no conflicts of interest.



Novel long-acting injectable methods for HIV prevention and treatment (LAI-ART)



Source: 1. Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. ClinicaInfo.HIV.gov. Updated May 1, 2024. 2. FDA. Drug Approval History. <https://www.fda.gov> 3. ClinicalTrials.gov. LATTE-2 (NCT03635788); CAPELLA (NCT03752451). 4. Sunlenca® (lenacapavir) [Prescribing Information]. Gilead Sciences, Inc.; 2022.



How do health systems redesign workflows, staffing, reimbursements, engage patients, and monitor to support integration of long-acting HIV prevention and treatment?



HIV Evidence-Based Interventions

PrEP Interventions

Increase PrEP uptake, adherence, and persistence

- PrEP navigation
- Shared decision-making
- Mobile health tools
- Workflow redesign

Structural Interventions

Address social, economic, and system barriers

- Housing support
- Transportation assistance
- Insurance enrollment
- Stigma reduction

Linkage & Retention

Improve engagement across the HIV care continuum

- Patient navigation
- Rapid ART initiation
- Case management
- Re-engagement outreach

Medication Adherence

Support sustained viral suppression

- Adherence counseling
- Digital reminders
- Peer support
- Multi-month dispensing

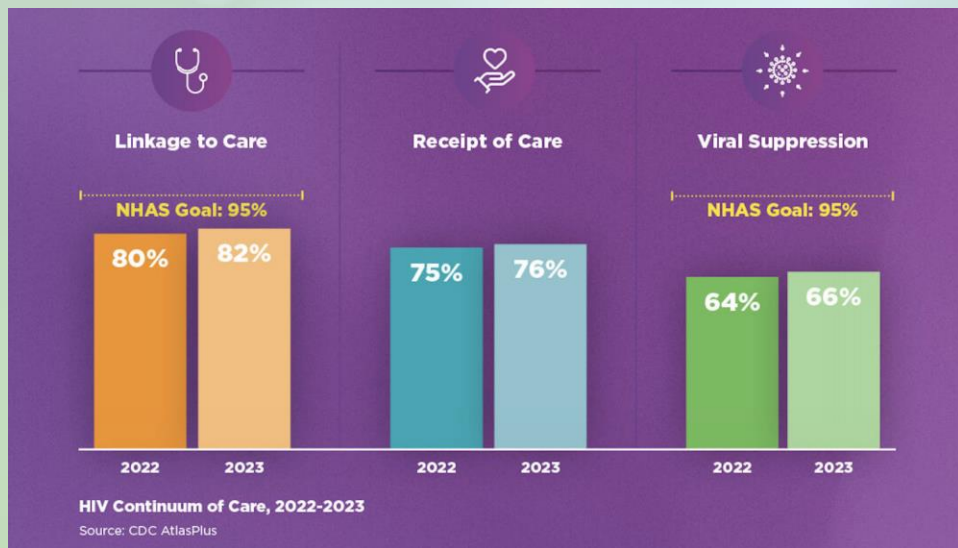
Risk Reduction

Reduce HIV acquisition and transmission risk

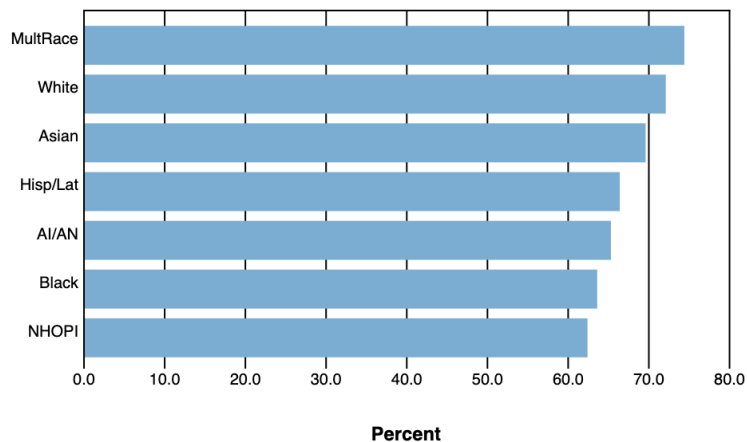
- Behavioral interventions
- Condom promotion
- Harm reduction services
- Community programs



Achievement Gaps in Ending the Epidemic Care Continuum



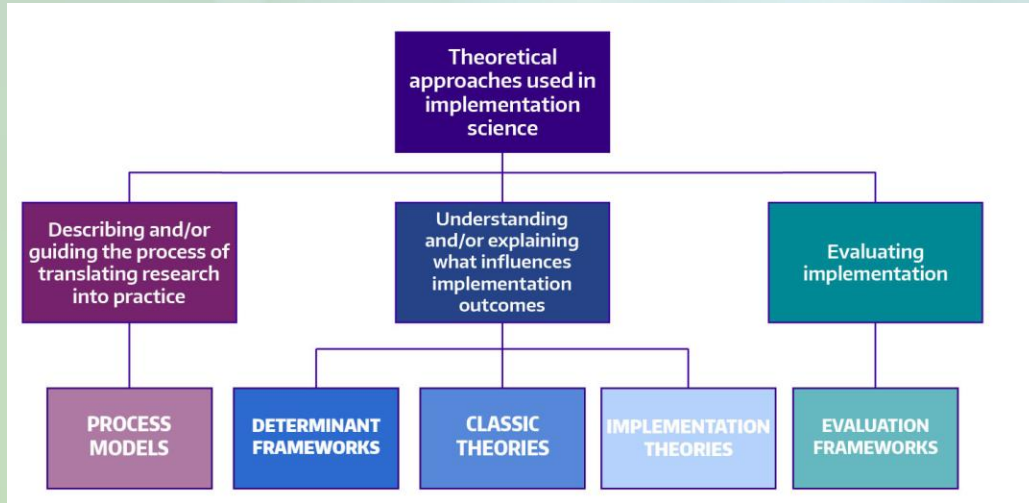
HIV viral suppression | 2023 | Ages 13 years and older | All races/ethnicities
| Both sexes | All transmission categories | United States



Source: CDC AtlasPlus. Data for 2025 are preliminary and based on data received by CDC as of December 2025.



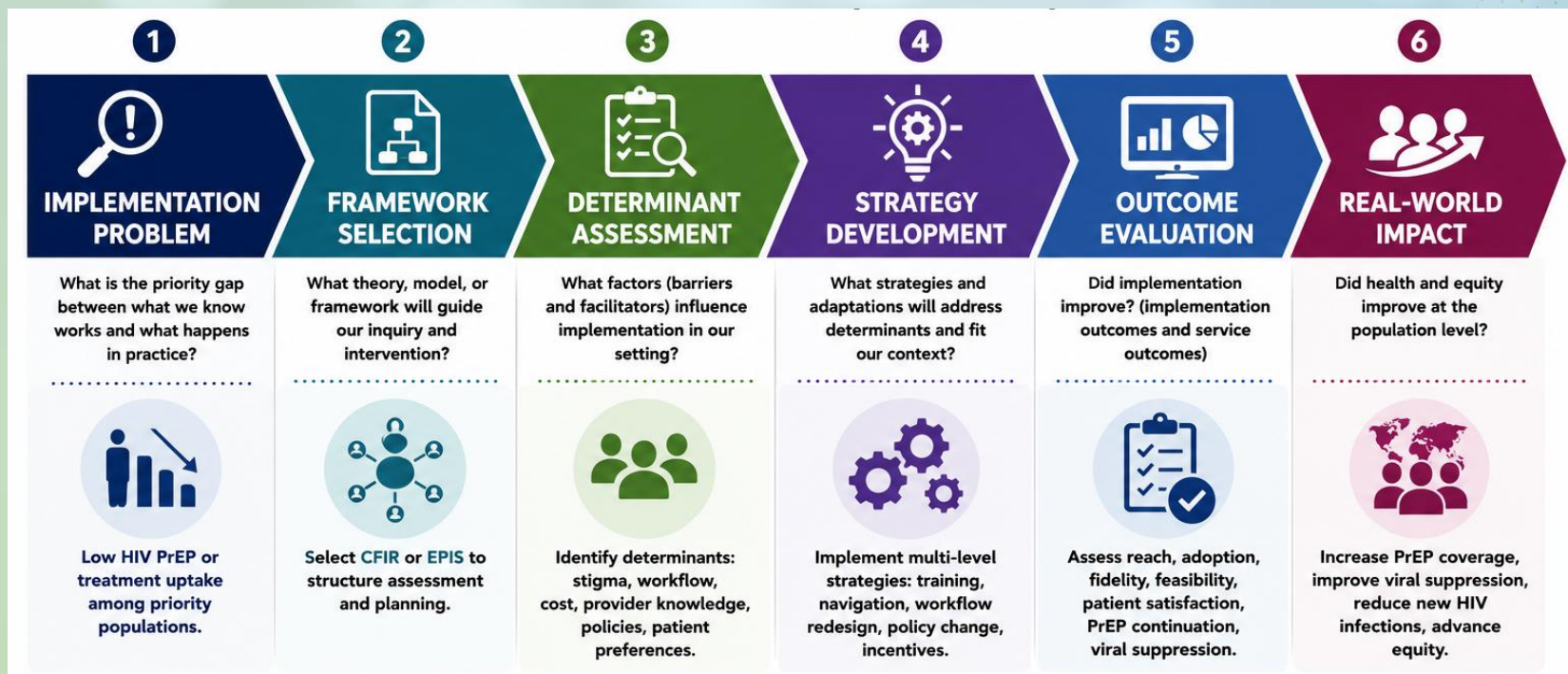
Implementation Science Theories, Models and Frameworks



- The systematic study of how to design and evaluate a set of activities to facilitate successful uptake of an evidence-based health intervention.
- Application of TMF to answer questions with real-world impact typically involves a structured process that links theory to practical implementation challenges.



Implementation Science Pathway





Implementation Science Tension

Rigor

- Internal validity
 - Strong causal inference (can examine cause-effect)
 - Control of bias and confounding
 - Standardized procedures
 - Precise measurement
- Replicability

Real-world relevance

- Responsiveness to stakeholder needs
 - Timeliness for decision-making
 - Adaptability to local contexts
- Generalizable to diverse populations and settings
- Feasibility in routine care
- Sustainability under real-world conditions



Rigor vs. Real World: Seven Key Tensions

1. Research vs Stakeholder Priorities

2. Internal vs External Validity

3. Generalizable vs Context-Specific

4. Measurement Precision vs Feasibility

5. Speed vs Certainty

6. Control vs Adaptation

7. Fidelity vs Flexibility



Defining LAI-ART Implementation Problem

1



IMPLEMENTATION PROBLEM

What is the priority gap
between what we know
works and what happens
in practice?



Low HIV PrEP or
treatment uptake
among priority
populations.

Research Priority (Rapid Literature Synthesis):

Develop and deliver a bundle of strategies for equitable and sustainable implementation of Long-acting injectable antiretroviral therapy (LAI ART) in HIV care services across the United States (US).

- Select unique clinics at different implementation stages to produce generalizable knowledge.
- Clinical monitoring and evaluation (M&E) metrics/data to assess safe, effective and equitable delivery of LAI ART.

Real World Scenario:

- HIV treatment and care models differ.
- Staffing support for implementation and monitoring outcomes may be insufficient.
- Site or broader context-specific treatment disparities.
- Feasibility of measuring equity indicators vary.



Tension 1: Research Priorities vs. Stakeholder Priorities

Rigor:

- Focus on theoretically important questions.

Real-world relevance:

- Address problems stakeholders consider urgent.

Tension:

- Questions that are scientifically elegant may not be the ones practitioners most need answered.



Site Selection Criteria



- Geographic location (e.g., EHE jurisdiction, urban / rural)
- Type of site (e.g., FQHC, academic medical center, etc.)
- Serving underserved and marginalized populations
- Community engagement, representation of person with HIV
- Experience in convening stakeholders.
- Implementation stage of LAI-ART
- Staffing include a data specialist
- Available electronic health information infrastructure (partial or complete)



Tension # 2: Internal Validity vs. External Validity

Rigor:

- Use strict inclusion criteria and controlled settings.

Real-world relevance

- Include diverse populations and routine practice settings.

Tension:

- Studies with excellent internal validity may produce findings that are difficult to apply in everyday practice.



Tension 3: Generalizable Knowledge vs. Context-Specific Solutions

Rigor:

- Seek findings that apply broadly.

Real-world relevance:

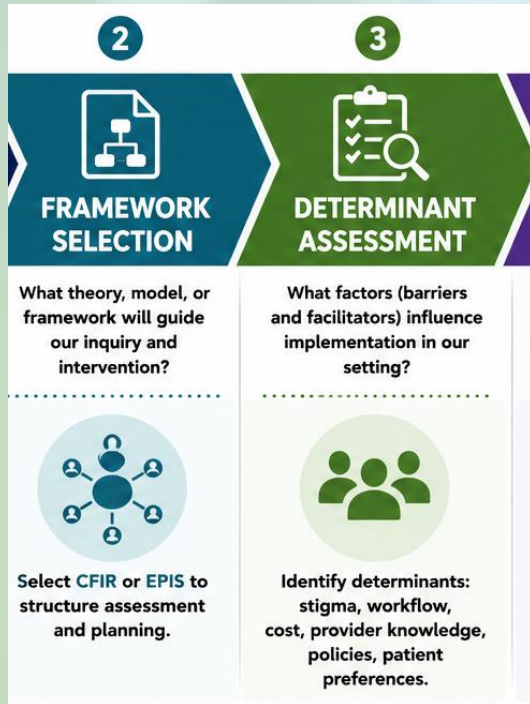
- Develop solutions tailored to specific organizations and communities.

Tension:

- What works in one setting may not work in another because implementation is highly context-dependent.



Assessing Determinants of LAI-ART

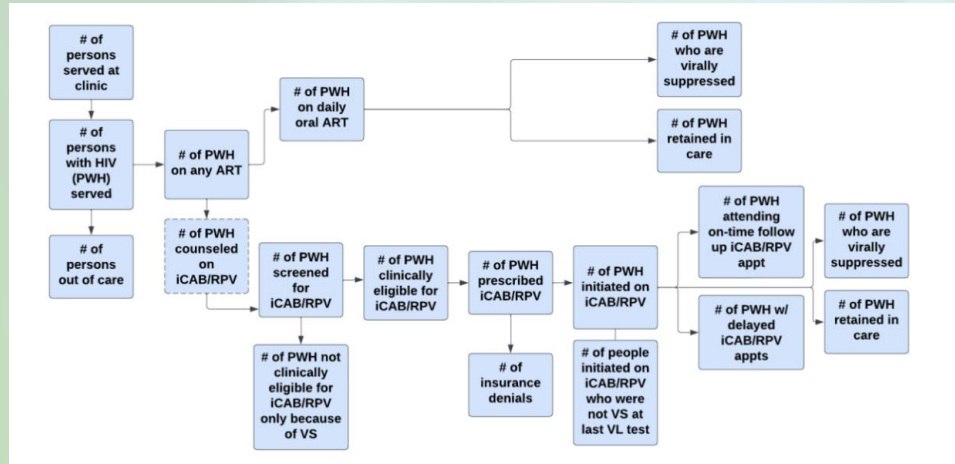


- Behavioral theories, several models and frameworks.
 - CFIR, RE-AIM, EPIS, Proctor outcomes, Diffusion of Innovations
- Rapid assessment of initial barriers and facilitators through stakeholder interviews, site-specific needs assessment.
 - Prioritized marginalized populations (unstably housed, younger PWH, substance use disorders)
 - Financing gaps, coverage, prior approval,
 - Education and counseling
 - workflow



Co-Creation of LAI-ART Clinical Cascade

Harmonized Clinical Cascade



- What is the model of HIV care - clinical workflow?
- How is current ART care monitored and evaluated (M&E)?
- How will LAI-ART change the workflow and M&E?
- How are routine M&E data used for reports (i.e. to funders, regulatory agencies etc)?
- How will the introduction of LAI-ART change reporting?



Measuring Disparities in LAI-ART

Clinical Cascade: EHR

- Which populations experience disparities that will be addressed with LAI-ART?
- Are the data on those populations accessible and available?
- Which steps in the cascade are critical for addressing disparity the clinic population?

Equity metrics reported by all sites
Age
Gender
Ethnicity
Race
HIV related behaviors

Variable	S1	S2	S3*	S4*	S5	S6	S7	S8
Employment								
Housing status								
Poverty level								
Immigration status								
Primary language								
History of incarceration								
Other HIV-related SDoH reported quantitatively								



Data available for everyone



Data available with varying levels of completeness or quality



Collected but not accessible

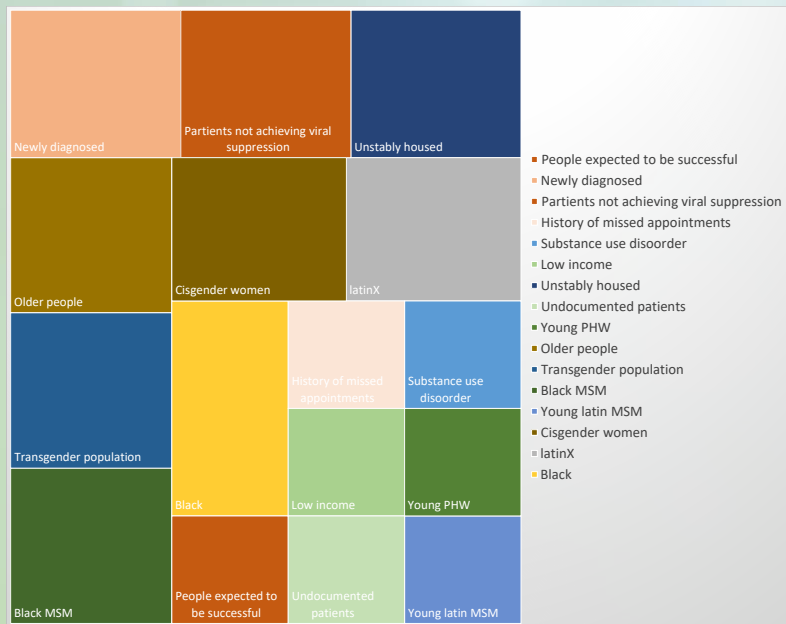


Data not available

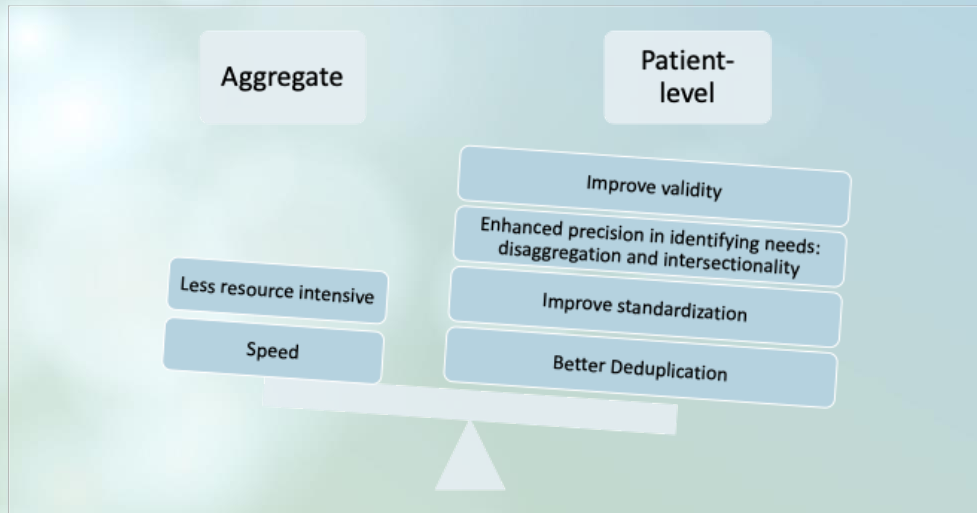


Measuring disparities

Intersectional identities



Individual-level data monitoring





Tension # 4: Measurement Precision vs. Feasibility

Rigor:

- Collect extensive, validated data using multiple instruments.

Real-world relevance:

- Minimize burden on participants and organizations.

Tension:

- Busy healthcare settings often cannot sustain intensive data collection protocols.

Tension 5: Speed vs. Scientific Certainty

#GCRNINJUN2026



Rigor:

- Conduct lengthy studies with extensive review and analysis.

Real-world relevance:

- Provide timely answers to decision-makers.

Tension:

- Health systems and policymakers often need evidence quickly, while rigorous research takes time.



Selecting Strategies for LAI-ART

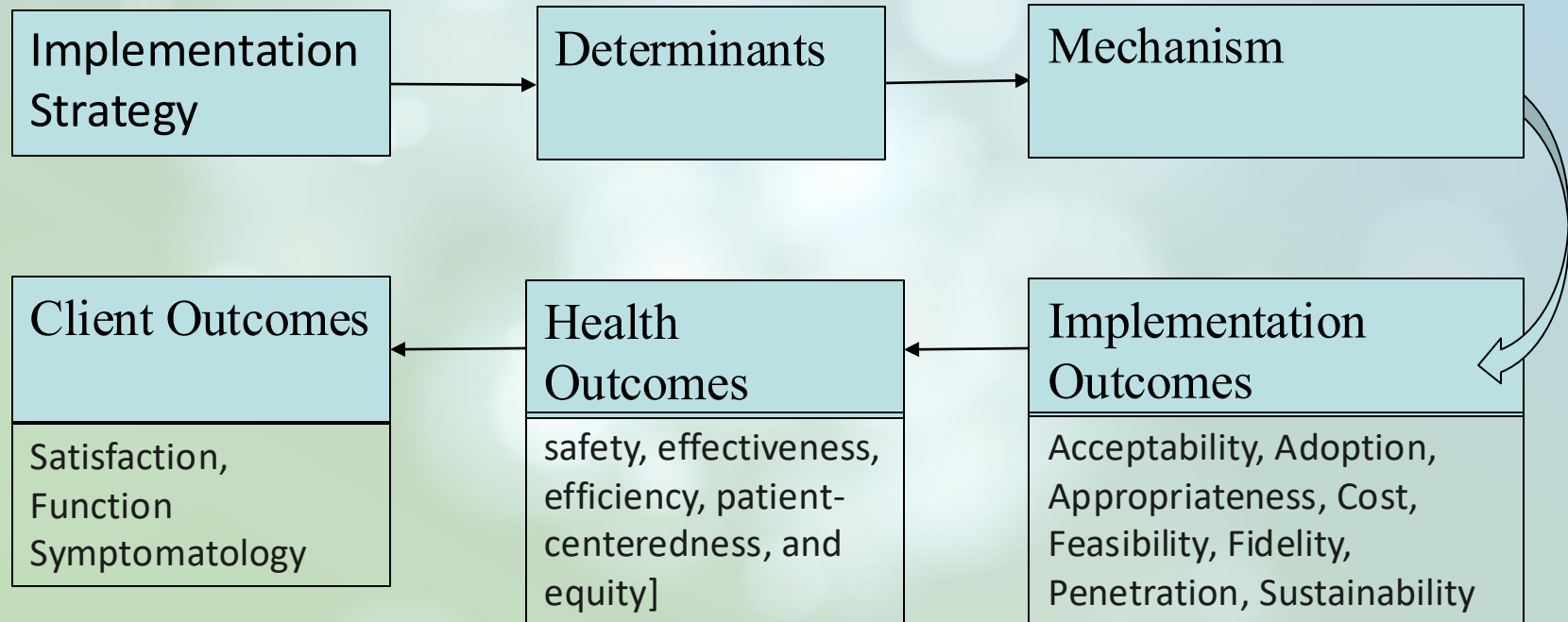
Select and streamline strategies based on common determinants across sites. Strategies from some site may not be selected or measured.

Strategies may be relevant to sites at a different implementation phase.





Theory Guided Causal Pathway of Implementation Strategies



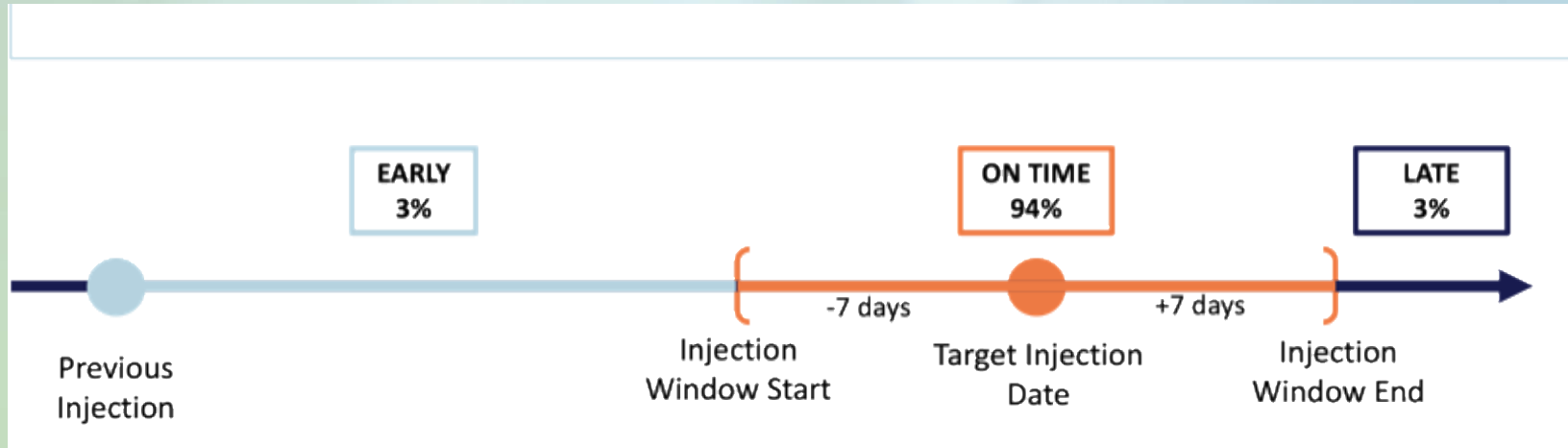


Measuring Reach

	Variable: Age	S1 N (%)	S2 N (%)	S3 N (%)	S4 N (%)	S5 N (%)	S6 N (%)	S7 N (%)	S8 N (%)
People with HIV (PWH)	Age Median, Range	28 (18, 57)	39 (18, 77)	45 (20, 91)	35 (18, 75)	55	47 (9, 80)	48 (18, 89)	35 (19, 81)
	15-19	1 (1%)	2 (0.4%)	0	3 (0.2%)	5 (0.2%)	2 (0.4%)	2 (0.1%)	3 (3%)
	20-29	51 (55%)	50 (11%)	37 (10%)	368 (22%)	112 (4%)	51 (9%)	160 (9%)	23 (23%)
	30-65	40 (44%)	383 (83%)	311 (80%)	1301 (77%)	2275 (78%)	459 (84%)	1444 (82%)	71 (70%)
	≥66	0	23 (5%)	40 (10%)	22 (1%)	508 (18%)	35 (6%)	165 (9%)	4 (4%)
PWH on any ART	Age Median, Range	28 (18, 57)	39 (18, 77)	-	-	55	47 (9, 80)	49 (18, 89)	35 (19, 81)
	15-19	1 (1%)	2 (0.4%)	-	-	4 (0.1%)	2 (0.4%)	1 (0.1%)	3 (3%)
	20-29	51 (56%)	50 (11%)	-	-	108 (4%)	48 (9%)	121 (8%)	23 (23%)
	30-65	39 (43%)	378 (83%)	-	-	2170 (79%)	446 (84%)	1253 (83%)	69 (70%)
	≥66	0	23 (5%)	-	-	472 (17%)	35 (6%)	146 (10%)	4 (4%)
PWH on iCAB/RPV¹	Age Median, Range	30 (23, 42)	36 (22, 49)	39 (24, 91)	36 (24, 65)	43	34 (31, 58)		
	15-19	0	0	0	0	0	0	0	0
	20-29	8 (50%)	1 (8%)	1 (4%)	8 (17%)	3 (6%)	0	0	0
	30-65	8 (50%)	12 (92%)	20 (87%)	39 (83%)	43 (90%)	5 (100%)	1 (100%)	0
	≥66	0	0	2 (9%)	0	2 (4%)	0	0	0

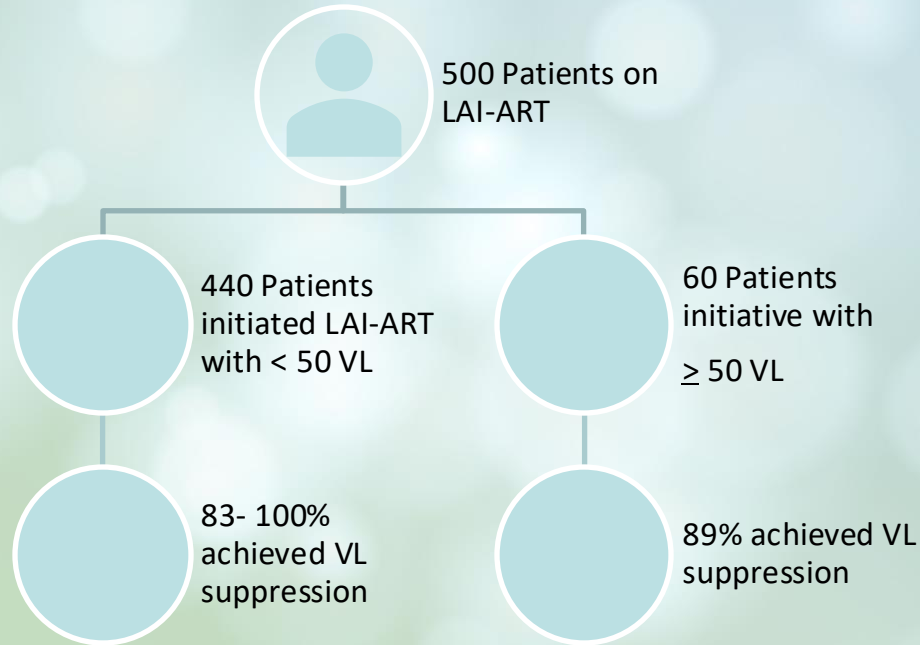


Measuring Fidelity: On-time injections among clients ever on LAI-ART





Measuring Safety and Effectiveness





Tension 6: Fidelity vs. Flexibility

Rigor:

- Ensure interventions are delivered exactly as designed.

Real-world relevance:

- Permit modifications to meet contextual needs.

Tension:

- Excessive focus on fidelity may make interventions impractical, while excessive flexibility may reduce effectiveness



Tension # 7: Control vs. Adaptation

Rigor

- Standardize intervention delivery to ensure consistency.

Real-world relevance:

- Allow adaptation to fit local workflows, culture, resources, and patient needs.

Tension:

- The more an intervention is adapted, the harder it becomes to determine exactly what caused the outcomes.



Evaluation Designs for Rigor and Real-World Relevance

- Hybrid Type 1, 2, and 3 Effectiveness-Implementation Designs.
- Stepped-Wedge Cluster Randomized Trials (SW-CRTs)
- Adaptive Implementation Designs
- Qualitative and Mixed-Methods System Dynamics
- Quasi-experimental designs (Interrupted Time Series (ITS))



Summary

- Behavioral theories with Implementation Science models and frameworks are being utilized to address the evidence-to-practice gap for long-acting prevention and treatment to achieve population impact in the US. Paucity of global health data.
- Early and continuous stakeholder engagement and innovative evaluation designs aim to address some of the tensions between rigor and real-world evidence.
- Future research is needed on effective stakeholder engagement approaches, evaluation design and analyses to achieve optimal balance between rigor and real-world relevance



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