Long Acting Injectables - Learning as We Go: An Implementation Science Agenda

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Adherence 2023 • June 11-13 • Puerto Rico

Imagine if…

- A life-saving drug existed
- Optimal use requires careful evaluation and monitoring
- Risk of morbidity/mortality without monitoring

And there was a plan for implementation that involved

Organization	Patient
Personnel	Selection/Enrollment
Supervision	Education
Care coordination	Therapy Initiation
Communication/Documentation	Therapy Management
Lab Monitoring	Management of Complications

Consensus Guidelines for Coordinated Outpatient Oral Anticoagulation Therapy Management, *Annals Pharmaco Ther* 1997

The $1,000,000 questions

How do we support

Provider offer

Patient uptake and adherence

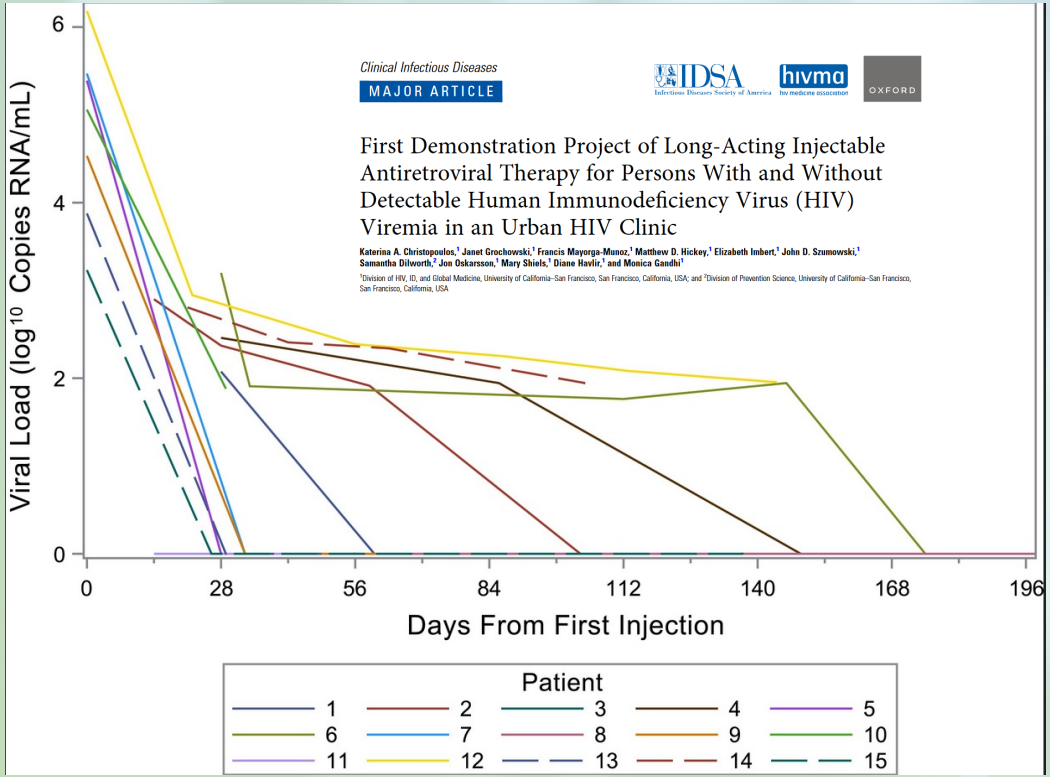
Clinical Systems

- Procurement
- Giving of Injections
- Tracking, Monitoring, and Discontinuing

How can implementation science help us?

- Determine antecedents
- Identify determinants (barriers and facilitators)
- Gives us a common language for the types of strategies that can help address barriers
- Reminds us that *specific* strategies are context dependent and may not work in all settings
- Process attends to evidence, context, and facilitation

Ward 86 CAB/RPV-LA Implementation: A Case Study



High rates of success in an underserved, publically insured population

Successful treatment of those with detectable viremia due to oral adherence challenges

Implementation Starts With Equity

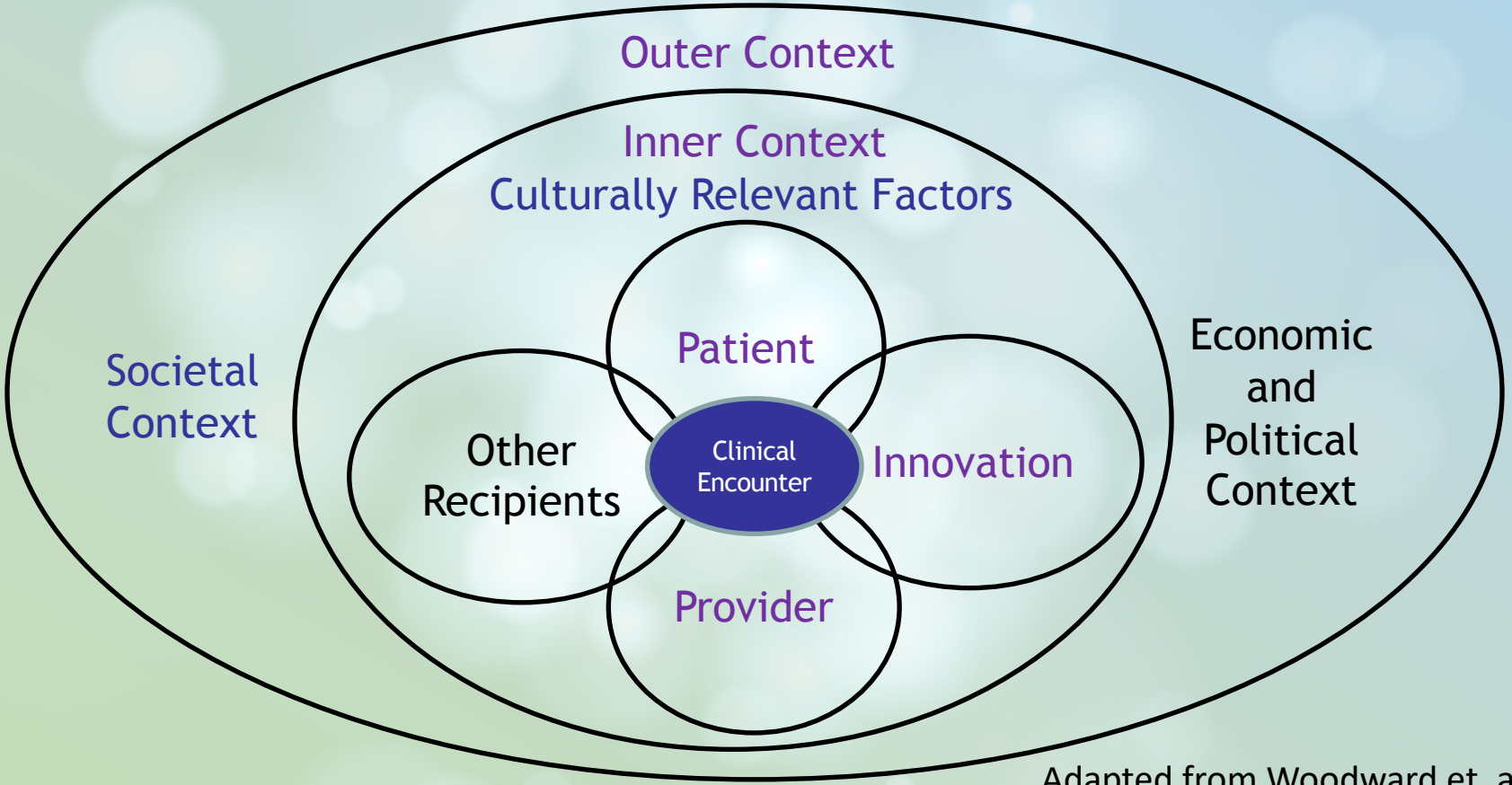
	Retained	Not Retained
Suppressed	Quality of life Increased volume of clinic visits	Likely little benefit
Not Suppressed	Clear Potential for High Impact	May not be retained in clinic but retained in a relationship with providers Can use strategies to shift people to the "retained" category

Move to out of clinic injections

Pre-Implementation Qualitative Findings

Providers	Patients with Viremia	Nursing/Pharmacy Staff
Measured enthusiasm	Trusting relationship with clinic and providers "this is like my second home"	Strong commitment to making it happen – "we will find a way"
Can we use in those who need it the most?	Varying levels of enthusiasm, but generally open to the possibility	Acknowledge need to tailor service to patient needs
Need clear plan for all the logistics	Relief from having to be responsible for adherence	Need standardized decision-making
Providers too busy to handle these logistics	Sounds like a reward for being a "good" patient who takes oral ART	Want ongoing clinical input from physicians
Responsibility of clinic to ensure continued delivery		"Start small"

CFIR – Accounting for Health Equity

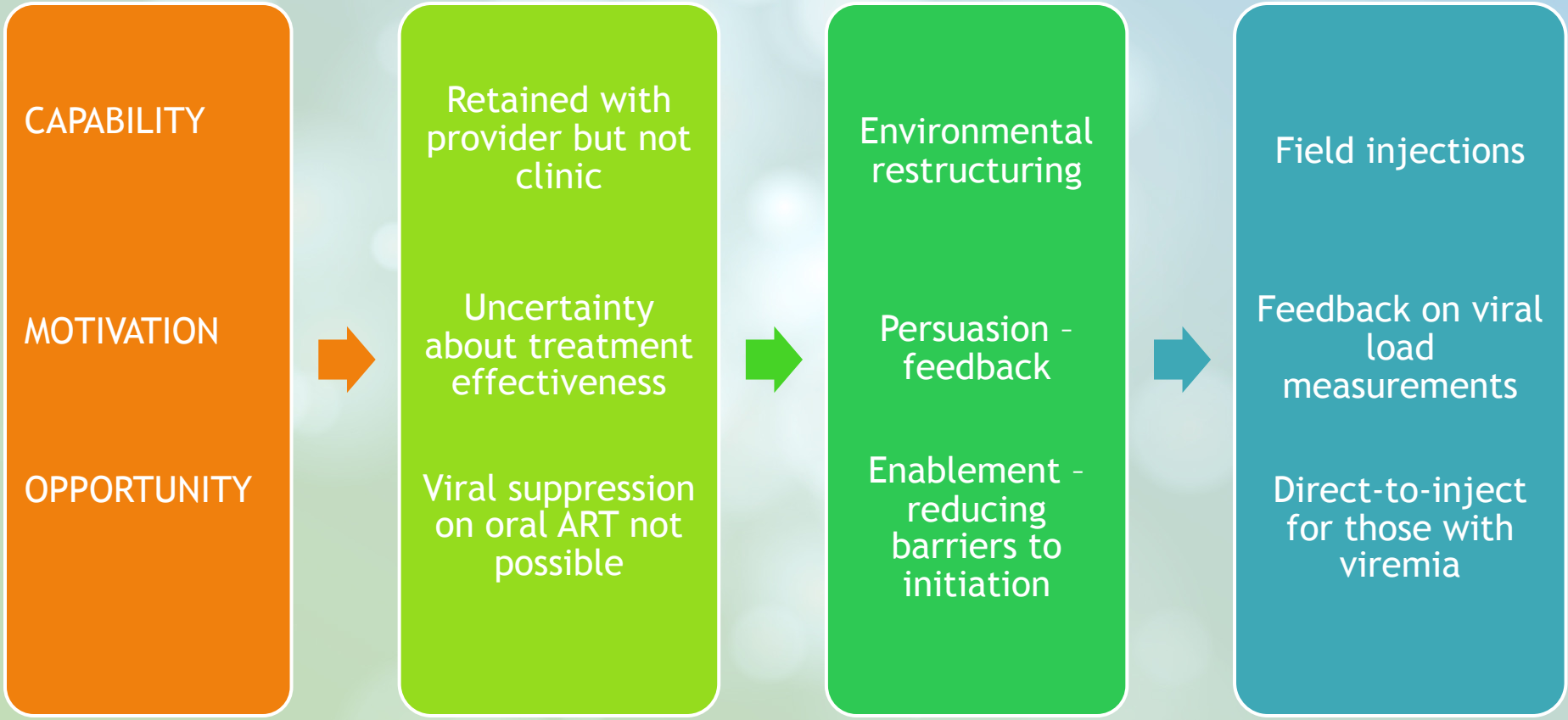


Adapted from Woodward et. al 2021

Mapping Provider Barriers to Implementation Strategies

COM-B Domain	Implementation Determinant	Intervention Function	Implementation Strategy
MOTIVATION	To view as viable option, need a system for logistics and clinical review	Environmental Restructuring – restructuring of care	Pharmacy team procures, schedules, tracks; multidisciplinary team meetings
OPPORTUNITY	Desire to use to treat those with viral non-suppression	Enablement – Goal Setting	Treatment of patients with detectable viral load allowed
	Confidence bolstered by successful cases	Modelling – Demonstration of Successful Outcomes	Feedback on outcomes

Mapping Patient Barriers to Implementation Strategies



Mapping Other Barriers to Key Strategies

Domain	Barrier	Implementation Strategy	Ward 86 Strategy
Characteristics of the Innovation	Complexity	Implementation blueprint	Clinical protocol
	Trialability	Small tests of change	Pilot phase
Inner Context	Available Resources	Access/leverage funding	Pharmacy technician
	IT Infrastructure	Develop and implement tools for quality monitoring	Electronic medical record reports

Mapping Facilitators to Key Strategies

Domain	Facilitator	Implementation Strategy	Ward 86 Strategy
Inner Context	Culture		Existing nurse for drop-in injections
	Infrastructure	Repurpose systems	Existing drop-in low barrier model of care
			Small incentives
			Case managers
Clinical Encounter	Strong-patient provider relationships		

Why Has It Worked?

- Letting go of assumptions about who will adhere
- Occurs in context of a patient-provider relationship
- Individualized plans for adherence
- Leveraging of existing drop-in infrastructure
- Positive feedback loop occurs upon achieving viral suppression – for both patients and providers

"I see a psychiatrist once a week, my therapist once a week. I take much less pills. I take my bipolar medication, sleeping medication, but no more HIV meds. My stomach is much, much better. I stopped drinking. I broke up with this relationship I'm forming different habits. You know, I go AA Meetings, I go support groups. It did take lots of anxiety away. Lots of anxiety…I'm not worried about dying. You know, it's more hopeful about my future. There's less stress. I stress people out lesser. So, I think the impact is huge.

-51-year-old gay white man

Facilitators at the Outer Context Level
Medicaid expansion state, municipal program for uninsured
Quick adoption by all public formularies (Medicaid, Medicare, ADAP)
No formulary requirement for pre-existing viral suppression
No prior authorization (and appeals) process
Pharmacy rather than a medical benefit
No need for billing and reimbursement monitoring
Hospital pharmacy designated as a specialty pharmacy
Identification of foundations that can cover (rare) co-pays
No loss of 340B revenue (reimbursement less than common oral ART)

Priority Issues

- Main barriers to implementation are primarily *outer context*
  - Payer issues are an urgent need
  - Guidelines advise against use in those who are not virally suppressed
- Technical assistance needed for the *inner context*
  - Securing additional resources
  - Reproducible tools for tracking and monitoring

Where are there implementation science gaps?

- Relative weight of barriers and facilitators on their own and together
- Temporal nature – this first, then that
- Unpacking causal relationships – what leads to what?
- Fitting of qualitative data into a framework gives you lists but not a story
- Role of advocacy not addressed

Acknowledgments

Ward 86 long-acting team, especially Monica Gandhi, Janet Grochowski, Francis Mayorga-Munoz, Jon Oskarsson, Matt Hickey, Elizabeth Imbert

MODERN ART (R01 MH123396) – Jonathan Colasanti, Lauren Collins, Moira McNulty, Liz Montgomery, Kim Koester, Mallory Johnson, Xavier Erguera, Manami Diaz-Tsuzuki, Sam Dilworth, Mollie Smith, Kaylin Dance

Funders: NIMH, UCSF Academic Senate