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

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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

<table>
<thead>
<tr>
<th>Organization</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel</td>
<td>Selection/Enrollment</td>
</tr>
<tr>
<td>Supervision</td>
<td>Education</td>
</tr>
<tr>
<td>Care coordination</td>
<td>Therapy Initiation</td>
</tr>
<tr>
<td>Communication/Documentation</td>
<td>Therapy Management</td>
</tr>
<tr>
<td>Lab Monitoring</td>
<td>Management of Complications</td>
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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

<table>
<thead>
<tr>
<th>Suppressed</th>
<th>Retained</th>
<th>Not Retained</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quality of life</td>
<td>Likely little benefit</td>
</tr>
<tr>
<td></td>
<td>Increased volume of clinic visits</td>
<td></td>
</tr>
<tr>
<td>Not Suppressed</td>
<td>Clear Potential for High Impact</td>
<td>May not be retained in clinic but retained in a relationship with providers</td>
</tr>
<tr>
<td></td>
<td>Can use strategies to shift people to the “retained” category</td>
<td></td>
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</table>

Move to out of clinic injections
## Pre-Implementation Qualitative Findings

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

Adapted from Woodward et. al 2021
MOTIVATION

To view as viable option, need a system for logistics and clinical review

Desire to use to treat those with viral non-suppression

Confidence bolstered by successful cases

OPPORTUNITY

Environmental Restructuring - restructuring of care

Enablement - Goal Setting

Modelling - Demonstration of Successful Outcomes

Implementation Strategy

Pharmacy team procures, schedules, tracks; multidisciplinary team meetings

Treatment of patients with detectable viral load allowed

Feedback on outcomes

COM-B Domain

Implementation Determinant

Intervention Function

Mapping Provider Barriers to Implementation Strategies

#ADHERENCE2023
Mapping Patient Barriers to Implementation Strategies

**CAPABILITY**
- Retained with provider but not clinic
- Uncertainty about treatment effectiveness
- Viral suppression on oral ART not possible

**MOTIVATION**
- Environmental restructuring
- Persuasion - feedback
- Enablement - reducing barriers to initiation

**OPPORTUNITY**
- Field injections
- Feedback on viral load measurements
- Direct-to-inject for those with viremia
# Mapping Other Barriers to Key Strategies

<table>
<thead>
<tr>
<th>Domain</th>
<th>Barrier</th>
<th>Implementation Strategy</th>
<th>Ward 86 Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Characteristics of the Innovation</td>
<td>Complexity</td>
<td>Implementation blueprint</td>
<td>Clinical protocol</td>
</tr>
<tr>
<td></td>
<td>Trialability</td>
<td>Small tests of change</td>
<td>Pilot phase</td>
</tr>
<tr>
<td>Inner Context</td>
<td>Available Resources</td>
<td>Access/leverage funding</td>
<td>Pharmacy technician</td>
</tr>
<tr>
<td></td>
<td>IT Infrastructure</td>
<td>Develop and implement tools for quality monitoring</td>
<td>Electronic medical record reports</td>
</tr>
</tbody>
</table>
Mapping Facilitators to Key Strategies

Domain

- Inner Context
  - Clinical Encounter

Facilitator

- Culture
- Infrastructure
- Strong-patient provider relationships

Implementation Strategy

- Repurpose systems

Ward 86 Strategy

- Existing nurse for drop-in injections
- Existing drop-in low barrier model of care
- Small incentives
- Case managers
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

<table>
<thead>
<tr>
<th>Facilitator</th>
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<tbody>
<tr>
<td>Medicaid expansion state, municipal program for uninsured</td>
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<tr>
<td>Quick adoption by all public formularies (Medicaid, Medicare, ADAP)</td>
</tr>
<tr>
<td>No formulary requirement for pre-existing viral suppression</td>
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<tr>
<td>No prior authorization (and appeals) process</td>
</tr>
<tr>
<td>Pharmacy rather than a medical benefit</td>
</tr>
<tr>
<td>No need for billing and reimbursement monitoring</td>
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<tr>
<td>Hospital pharmacy designated as a specialty pharmacy</td>
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<tr>
<td>Identification of foundations that can cover (rare) co-pays</td>
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<tr>
<td>No loss of 340B revenue (reimbursement less than common oral ART)</td>
</tr>
</tbody>
</table>
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
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