Landscape of NIH-funded HIV Implementation Research

Preliminary Results of a Scoping Review

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Acknowledgements

• J.D. Smith
• Nanette Benbow
• Carlos Gallo
• Hendricks Brown
• Juan Villamar
• Krystal Baker
• Miriam Rafferty
• Lisa Hirschhorn
• Gregory Phillips
• Michelle Birkett
• Dennis Li
• Moira McNulty
• Stef Baral
• Amrita Rao
Funding Acknowledgments

• **NIDA:** Center for Prevention Implementation Methodology for Drug Abuse and HIV Ce-PIM (P30DA027828, Brown & Mustanski Co-Directors)

• **NIMH/NIDA:** Implementation Research Institute (IRI; R25MH080916, Proctor PI)

• **NIAID:** Third Coast Center for AIDS Research (P30AI117943, D’Aquila PI)
Purpose of Scoping Review & Definitions

• Identify the proportion and characteristics of HIV-related implementation research studies funded by NIH since 2013

• Definitions:
  - HIV-related: Studies that measure an HIV outcome related to the Prevention or Care continuum indicators (including PrEP-awareness, linkage, retention, adherence; and HIV risk reduction.
  - Implementation-related research: Studies that evaluate the use of strategies to integrate interventions into real-world settings to improve patient outcomes (NIH, 2013). *Also included pre-implementation research.
Records identified through NIH RePORTER search (March 2018) (n = 12,660)

Records after duplicates removed (n = 4,630)

Records screened electronically (n = 4,630)

Records excluded* (n = 3,786)

Records excluded (n = 124)

Project Descriptions screened manually (n = 844)

Excluded:
Not IR, Not HIV (n = 139)
Yes IR, not HIV (n = 46)
Not IR, Yes HIV (n = 332)

Project Descriptions reviewed for eligibility (n = 720)
100% Double Coded

Studies included in qualitative synthesis (n = 202)

Total HIV studies = 534

38% (Pre)Implementation Research (IR)

*Basic science or did not have at least one IR and HIV intervention word
<table>
<thead>
<tr>
<th>Funding Institute/Center</th>
<th>N</th>
<th>%</th>
</tr>
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<tbody>
<tr>
<td>CGH</td>
<td>9</td>
<td>4.6%</td>
</tr>
<tr>
<td>NCHHSTP</td>
<td>6</td>
<td>3.1%</td>
</tr>
<tr>
<td>NIAAA</td>
<td>6</td>
<td>3.1%</td>
</tr>
<tr>
<td>NIAID</td>
<td>23</td>
<td>11.7%</td>
</tr>
<tr>
<td>NICHD</td>
<td>17</td>
<td>8.6%</td>
</tr>
<tr>
<td>NIDA</td>
<td>50</td>
<td>25.4%</td>
</tr>
<tr>
<td>NIMH</td>
<td>68</td>
<td>34.5%</td>
</tr>
<tr>
<td>Other/Unknown</td>
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<td>11.4%</td>
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<table>
<thead>
<tr>
<th>Grant Mechanism</th>
<th>N</th>
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<tbody>
<tr>
<td>R01</td>
<td>84</td>
<td>41.6%</td>
</tr>
<tr>
<td>R21</td>
<td>36</td>
<td>17.8%</td>
</tr>
<tr>
<td>R34</td>
<td>23</td>
<td>11.4%</td>
</tr>
<tr>
<td>K-Series</td>
<td>18</td>
<td>8.9%</td>
</tr>
<tr>
<td>U-Series</td>
<td>25</td>
<td>12.4%</td>
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</table>

<table>
<thead>
<tr>
<th>Study Start Date</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>25</td>
<td>12.4%</td>
</tr>
<tr>
<td>2014</td>
<td>37</td>
<td>18.3%</td>
</tr>
<tr>
<td>2015</td>
<td>45</td>
<td>22.3%</td>
</tr>
<tr>
<td>2016</td>
<td>47</td>
<td>22.8%</td>
</tr>
<tr>
<td>2017</td>
<td>45</td>
<td>22.3%</td>
</tr>
<tr>
<td>2018</td>
<td>3</td>
<td>1.5%</td>
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</table>

<table>
<thead>
<tr>
<th>Study Section</th>
<th>N</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Behavioral and Social Consequences of HIV/AIDS</td>
<td>38</td>
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<tr>
<td>Behavioral and Social Science Approaches to Preventing HIV/AIDS</td>
<td>39</td>
<td>19.5%</td>
</tr>
<tr>
<td>Special Emphasis Panel</td>
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<td>58.5%</td>
</tr>
<tr>
<td>Other</td>
<td>8</td>
<td>3.0%</td>
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</table>
Primary Study Populations*

- General Population
- Women
- Adolescent/Young Adults
- MSM
- African American
- PWID
- Substance User
- Newborn/Pediatric
- Incarcerated/Post-release
- Sex Worker
- Transgender
- Latino

*Populations not mutually exclusive
Population Characteristics

Primary Study Populations*

- General Population
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- Sex Worker
- Transgender
- Latino

HIV Status

- Negative: 28%
- Both: 27%
- Positive: 32%
- Not specified: 13%

US = 51%
International = 49%

*Populations not mutually exclusive
## Steps Along the Continuum

### Only One Step (57%)

<table>
<thead>
<tr>
<th>Continuum Step</th>
<th>%</th>
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</thead>
<tbody>
<tr>
<td>Prevention</td>
<td>61%</td>
</tr>
<tr>
<td>HIV Testing</td>
<td>11%</td>
</tr>
<tr>
<td>Linkage</td>
<td>0%</td>
</tr>
<tr>
<td>Re-Engagement</td>
<td>3%</td>
</tr>
<tr>
<td>Retention</td>
<td>6%</td>
</tr>
<tr>
<td>ART</td>
<td>19%</td>
</tr>
<tr>
<td>Viral Suppression</td>
<td>1%</td>
</tr>
</tbody>
</table>

### More Than One Step (43%)

- Prevention+HIV testing
- Prevention+Testing+Linkage
- Prevention+Testing+Linkage+Retention+ART
- Prevention+Testing+ART
- Prevention+Retention+ART
- Prevention+ART
- Testing+Linkage
- Testing+Linkage+Retention
- Testing+Linkage+ART
- Linkage+Retention
- Linkage+Retention+ART
- Retention+ART
- Retention+Viral Suppression
- All
Selected Interventions by Delivery Method

- PrEP (N=37)
- Risk Reduction (N=21)
- HIV Testing Only (N=15)
- HIV Testing/Linkage (N=20)
- HIV Care Retention/Adherence (N=11)
- Retention (N=7)
- ART Initiation/Adherence (N=16)
- Combination Prevention (N=13)
- Integrated Services (N=10)

- In-person
- Self-administered/In-home
- Social Media
- eHealth/mHealth
- Not specified/NA
Inclusive View of Implementation Research

- **NIH Definition**: IR evaluates the use of strategies to integrate interventions into real-world settings to improve patient outcomes.

- Also included **pre**-implementation research:
  - Research to understand implementation processes and barriers/facilitators
  - Research on the feasibility, acceptability of novel strategies
  - Formative research to develop novel strategies
  - Adapting an evidence-based intervention (application of a strategy)
  - Modeling that has the potential to inform IR
Implementation Science: An Introductory Workshop for Researchers, Clinicians, Policy Makers and Community Members

Could a program work?

Making a program work

Does a program work?

Effectiveness studies

Efficacy studies

Could a program work?

Preintervention

Exploration

Preparation

Implementation

Implementation Research

Sustainment

Implementation Practice

Real-world relevance

Time

Brown et al., 2017

Traditional Translational Pipeline

Local knowledge

Generalizable knowledge
Pre- and Implementation Research
Study Type/Aim

- Impact of Implementation Strategy(s) (28%)
- Barriers/Facilitators (10%)
- Development or adaptation of Implementation Strategy(s) (9%)
- Comparative implementation (12%)
- Adaptation of an intervention (14%)
- Feasibility/Acceptability of Implementation Strategy(s) (5%)
- Impact of adapted intervention (22%)
# Implementation Research Framework, Model or Theory

<table>
<thead>
<tr>
<th>Model/Methodology</th>
<th>N</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adapt-ITT</td>
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<td>2.5</td>
</tr>
<tr>
<td>Consolidated Framework for IR (CFIR)</td>
<td>5</td>
<td>2.5</td>
</tr>
<tr>
<td>RE-AIM</td>
<td>5</td>
<td>2.5</td>
</tr>
<tr>
<td>Implementation Framework (not specified)</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>PRECEDE/PRECEDE-PROCEED</td>
<td>3</td>
<td>1.5</td>
</tr>
<tr>
<td>Diffusion of Innovation</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>PARIHS</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>EPIS</td>
<td>2</td>
<td>1.0</td>
</tr>
<tr>
<td>Note stated</td>
<td>174</td>
<td>87.0</td>
</tr>
</tbody>
</table>

Note: The Note stated includes all other frameworks, models, or theories not specified in the table.

*Implementation Science: An Introductory Workshop for Researchers, Clinicians, Policy Makers and Community Members*
Implementation Strategies

More than 150 discrete implementation strategies

• Adaptation of intervention/implementation strategies
• Care coordination/integration
• Delivery location/method/agent
• Education/Training
• Implementation facilitation/toolkit/support
• Policy
• Peer navigation/support
• To be developed
Implementation Outcomes

N = 13: Acceptability, Adoption, Appropriateness, Cost, Determinants, Fidelity, Implementation, Penetration/Reach, Process, Scalability, Speed, Sustainability/Maintenance, System Effects (Proctor et al., 2011; Glasgow et al., 1999; Saldana et al., 2013)
Study Design Type (categorized)

- RCT with Individual Participant Assignment: 43%
- Formative, Observational, Developmental, Field: 10%
- Cohort, Longitudinal, Process: 6%
- Modeling: 6%
- Within-Site: 24%
- Between-Site: 6%
- Within- and Between-Site: 6%
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IR Continuum

Pre-Implementation
- Barriers/Facilitators Only: 7%
- Developmental: 18%
- Pilot (no IR outcomes): 9%
- Pilot (with IR outcomes): 13%
- Test/Trial (no IR outcomes): 15%
- Test/Trial (with IR outcomes): 19%
- Comparative Implementation (no IR outcomes): 11%
- Comparative Implementation (with IR outcomes): 6%

Strategy Effectiveness
- Comparative Implementation: 11%

Comparative Implementation
- Comparative Implementation: 6%
Selected Interventions by IR Stage

- PrEP (N=37)
- Risk Reduction (N=21)
- HIV Testing Only (N=15)
- HIV Testing/Linkage (N=20)
- HIV Care Retention/Adherence (N=11)
- Retention (N=7)
- ART Initiation/Adherence (N=16)
- Combination Prevention (N=13)
- Integrated Services (N=10)

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

Pre-Implementation | Strategy Effectiveness | Comparative Implementation
IR Continuum by Funding Institute/Center

- Barriers/Facilitators
- Developmental
- Pilot w/o IR outcomes
- Pilot w/IR outcomes
- Test/Trial w/o IR outcomes
- Test/Trial w/IR outcomes
- Comparative Imp w/o IR outcomes
- Comparative Imp w/IR outcomes

Legend:
- CGH
- NCHHSTP
- NIAAA
- NIAID
- NICHD
- NIDA
- NIMH
- OD

Northwestern Medicine
Feinberg School of Medicine
Center for Prevention Implementation Methodology
For Drug Abuse and HIV
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IR Continuum by Funding Institute/Center

- OD (N=8)
- NIMH (N=68)
- NIDA (N=50)
- NICHD (N=16)
- NIAID (N=23)
- NIAAA (N=6)
- NCHHSTP...
- CGH (N=9)

Barriers/Facilitators
Developmental
Pilot w/o IR outcomes
Test/Trial w/o IR outcomes
Comparative Imp w/o IR outcomes
Pilot w/o IR outcomes
Test/Trial w/IR outcomes
Comparative Imp w/ IR outcomes
Limitations

• Analysis based on project descriptions
  – may not contain sufficient detail of implementation-related variables
  – Underinclusion/Underestimating

• Lack of uniformity in abstract content

• Does not reflect the universe of HIV studies
Next Steps

• Inter-coder reliability (approximately 90% for initial human-coded include/exclude)
• Review sample of excluded studies
• Further distinguishing implementation strategies and interventions
• Long form presentation of results
• Prepare for manuscript submission
Conclusions

• Implementation research is still emerging in HIV
• Large number of unlabeled/inaccurately labeled studies
• IR terms and constructs melded with HIV research
• Ample opportunities to expand IR in HIV: Only 14%!!!
  – Large proportion of studies are still pre-implementation
  – Need to collect IR outcomes – it isn’t IR if you aren’t collecting outcomes pertaining to implementation
• Need a paradigm shift in the way research is done to understand how to make effective interventions work
• Doing so will speed translation and increase reach of promising interventions to prevent and treat HIV