Introduction to Implementation Science

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Acknowledgements

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• JD Smith
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• Jen Brown
• Dennis Li
Outline

• Basics of Implementation Science
  ▪ Definitions
  ▪ Why its needed

• Implementation Science Methods
  ▪ Frameworks, Strategies, Outcomes
    • Partnerships

Definitions

• **Implementation Science** is the study of methods to promote the integration of evidence-based interventions (EBI) into healthcare/public health practice and policy¹

  ▪ **Methods**: Frameworks, Strategies, Outcomes, Metrics/Measures, Design
    o **Frameworks** are graphical or narrative representations of the key factors, concepts, or variables that explain the phenomenon of implementation ²
    o **Implementation strategies** are methods or techniques used to enhance the adoption, implementation, and sustainability of an EBI, program or practice³

• **Implementation research** is the scientific study of the use of strategies to adopt and integrate EBIs in real-world settings to improve patient outcomes and population benefit¹

• **Implementation** is the use of strategies to adopt and integrate EBIs ¹

When defining implementation science, some very non-scientific language can be helpful...

- The intervention/practice/innovation is **THE THING**
- **Effectiveness** research looks at whether **THE THING** works
- **Implementation** research looks at how best to help people/places **DO THE THING**
- Implementation strategies are the **stuff we do** to try to help people/places **DO THE THING**
- Main implementation outcomes are **HOW MUCH** and **HOW WELL** they **DO THE THING**


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**Why do we need implementation science?**

**Charge: Ending the HIV Epidemic**

**Where We Are Now:** Estimated % of PrEP-Eligible Individuals Prescribed PrEP, US, 2017

<table>
<thead>
<tr>
<th></th>
<th>Blacks</th>
<th>Hispanics</th>
<th>Whites</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Rate</td>
<td>4.0%</td>
<td>7.2%</td>
<td>29.8%</td>
<td>12.6%</td>
</tr>
<tr>
<td><strong>2030 EHE Goal</strong></td>
<td><strong>48%</strong></td>
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</tbody>
</table>

**Increase beneficial impact of PrEP**

- Scale-out - adapt and implement EBIs across different settings and/or across different populations
- Scale-up - expand implementation of an EBI designed for one setting to other similar settings

As of November 2016, there were 45 on-going (N=30) and planned (N=15) Open Label Demonstration and Implementation Projects (a total of 6 are in the U.S.). The populations of focus include: MSM (18 projects); Adolescents (13), female sex workers (6); transgender women (5); and heterosexuals (4).

Implementation Research Has a Different Emphasis Than Other Types of Research

Effectiveness vs. Implementation

System to Support Adoption and Delivery with Fidelity

Evaluate Health Outcomes

Intervention

System to Support Adoption and Delivery with Fidelity

Evaluate Quality, Quantity, Speed of Delivery

Carries over into what to Measure, what to Model, What to Test or Evaluate

Illustrations of Implementation Research Questions

- What are the primary barriers and facilitators of implementing PrEP in Local Health Departments?
- Under what conditions does implementation of Strategy A work better, faster, more efficiently than Strategy B?
- What are the characteristics of research/service/community partnerships that are sustained over time?
- Does implementation of Strategy A or Strategy B more efficiently take PrEP to scale?

Proctor et al. 2012
PrEP Implementation Settings & Systems

PrEP implementation can take place at various levels:

- **National** - Partnerships between national funders, state and local public health departments, associations, advocacy groups, researchers, and policy experts
- **Local** – City/Statewide through public health departments, community advocates and provider partnerships
- **Clinic-based** (e.g. **STD clinics**, family planning clinics, HIV primary care, FQHCs)

![Implementation Science Tools](image)

1. **Strategies**
2. **Frameworks**
3. **Implementation Outcomes**
   - Acceptability
   - Adoption
   - Appropriateness
   - Cost
   - Feasibility
   - Fidelity
   - Penetration/Reach
   - Sustainment
4. **Service Outcomes**
   - Efficiency
   - Safety
   - Effectiveness
   - Equity
   - Patient-Centeredness
   - Timeliness
5. **Clinical Outcomes**
   - Client Symptoms
   - Client Functioning
   - Health/Disease Status
   - Quality of Life
   - Client Satisfaction

![PrEP Implementation Settings & Systems](image)
PrEP Continuum of Care


PrEP Implementation Readiness in Local Health Departments (LHD)

- 500 LHDs sampled in 2015; 284 respondents
- 109 LHDs (38%) currently engaged in PrEP implementation; 81% operate an STD clinic:
  - Higher among LHDs serving a large population size (68%)
  - 45% expect to expand PrEP
- 175 LHDs (62%) not currently engaged in PrEP implementation; 58% operate STD clinic:
  - Higher among LHD serving a small (82%) or medium (68%) population size
  - 13% expect to initiate PrEP in next 4 year
  - 46% were undecided and 41% unlikely to initiate PrEP

PrEP Implementation Readiness - Among LHD currently engaged in PrEP implementation

- Referring high-risk individuals to PrEP: 75%
- Conducting community education/outreach: 50%
- Developing PrEP referral lists: 49%
- Collaborating with providers to support PrEP: 45%
- Conducting provider education/outreach: 43%
- Conducting training for health department staff: 41%
- Convening/participating in PrEP working groups: 39%
- Monitoring and evaluating PrEP uptake/impact: 13%
- Delivering PrEP at health department clinic: 10%
- Participating in demonstration projects/pilots: 8%
- Funding CBOs and agencies: 6%


Consolidated Framework for Implementation Research (CFIR)

- Characteristics of the intervention - steps required for individuals to move through PrEP Continuum
- Inner setting - factors that reflect what is happening within settings where PrEP will be implemented (e.g. staffing, policies and procedures, and organizational culture)
- Outer setting – external factors influencing implementation success (e.g. state laws dictating who can be offered PrEP (e.g. adolescents) and how it can be paid (e.g. Medicaid)
- Individuals – considers individuals involved with the intervention or the implementation process (e.g. people in need of PrEP, staff involved in PrEP outreach or delivery)
- Process – represents the combination of activities involved in planning, engaging, and executing PrEP.

Among the 62% of LHDs NOT implementing PrEP:
• Motivate the 41% not currently interested
• Help the 46% contemplating
• Support the 13% who may implement in the future

Among the 38% LHDs implementing PrEP:
• Data monitoring, metrics and feedback system improve delivery and/or sustainment of PrEP

LHD Challenges to PrEP Implementation

Unsure about what HD can or should do to support PrEP
Concern about inadequate third-party reimbursement
Concern about financial access to PrEP
Lack of health care providers willing to provide PrEP
Uncertainty about effectiveness of PrEP for prevention
Limited staff capacity to support PrEP implementation
Lack of support from health department leadership
Lack of staff awareness and knowledge about PrEP
No significant challenges

Taxonomy of Implementation Strategies

Methods or techniques used to enhance the adoption, implementation, and sustainability of an EBI, program or practice

- The stuff we do to try to help people/places DO THE THING


### Implementation Strategies in Recently Funded NIH-Grants

More than 150 discrete implementation strategies

<table>
<thead>
<tr>
<th>Strategy</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptation of intervention/tailoring strategy</td>
<td>29</td>
</tr>
<tr>
<td>Care Coordination/Care Integration</td>
<td>14</td>
</tr>
<tr>
<td>Peer-led delivery/support</td>
<td>10</td>
</tr>
<tr>
<td>Incentives</td>
<td>9</td>
</tr>
<tr>
<td>Technology-based delivery</td>
<td>6</td>
</tr>
<tr>
<td>Community-focused</td>
<td>5</td>
</tr>
<tr>
<td>Home-based delivery</td>
<td>4</td>
</tr>
<tr>
<td>Combination of EBIs</td>
<td>3</td>
</tr>
<tr>
<td>Delivery system change</td>
<td>3</td>
</tr>
<tr>
<td>Training/Coaching approach/amount</td>
<td>3</td>
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</tbody>
</table>

PrEP Implementation Activities Among Those Engaged in PrEP Implementation

Can adding support of a peer navigator improve referral rates?

- Referring high-risk individuals to PrEP: 75%
- Conducting community education/outreach: 50%
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Potential Strategies Along the PrEP Continuum

- Awareness
  - Outreach strategies (SNS) to potential users through PrEP ambassadors

- Uptake
  - mHealth technology for peer navigators to promote initiation/adherence
  - Identification of PrEP clients in ER
  - Provider education to increase provision of PrEP
  - Partner services actively identify PrEP candidates and linkage
  - Active referral to PrEP services

- Adherence & Retention
  - Community of Practice to assist providers w/ prescribing practices (discontinuation)
  - Appointment reminders or interactive reminder messaging
  - Consistent contact with clinic through staff / peers
### Taxonomy of Implementation Research Outcomes

**Definition:** Implementation outcomes are the effects of deliberate and purposive actions (strategies) to embed new treatments, practices, and services into real-world systems of care.


### Examples of Implementation Outcomes

- **Acceptability** – *Individual client* or *individual provider level.*
  - Perception among STD clinic providers that PrEP is effective, can be delivered in the clinic with acceptable level of complexity

- **Adoption** – *Individual provider or organization/setting.*
  - Intention to prescribe PrEP, uptake and utilization of PrEP in STD clinic;

- **Appropriateness** – *Individual client, individual provider or organization/setting.*
  - Perception that PrEP is suitable to their needs or mission; compatible with their other clinic services

- **Feasibility** – *Individual provider or organization/setting*
  - Perception that PrEP can be successfully carried out within the STD clinic

- **Fidelity** – *Individual provider*
  - Degree to which PrEP was implemented in the STD clinic as outlined in original protocol/procedures

- **Penetration/Reach** – *Organization/setting*
  - Degree of the integration of PrEP into STD clinic service, e.g. number of STD clinic providers who prescribe PrEP

Implementation Research Designs to Evaluate Impact of Strategies

- **Within-site designs** - Generally simpler designs, create *local knowledge*
  - **Post Design** - Only measure implementation outputs after a new EBP is adopted
  - **Pre-Post Design** - Compare implementation outputs before/after new strategy is used to deliver an EBP

- **Between-site designs** - Comparison of implementation strategies at the same time in different sites, *increases generalized knowledge*
  - **Novel implementation strategy vs routine practice**, different sites - can be non-randomized or randomized (reduces bias)
  - **Head-to-Head Randomized Implementation Trial** - two novel implementation strategies for the same intervention

- **Within- and between-site designs** - Roll-out designs, assign units randomly to when and what implementation strategy is used, *produces generalized knowledge*

- **Hybrid Effectiveness-Implementation Trials**, *produces generalized knowledge*

**Partnerships are central in the NIH-funded (EHE) Supplements**

- **Funding:** planning projects to form *partnerships* to address local high priorities gaps in one or more EHE pillars.

- **For whom:** *partnerships* between CFAR/ARC investigators and local jurisdictions - CBOs, local, county, and state health departments carrying out EHE-related activities.
  - *Partnerships* “will have identified and designed targeted implementation science research project”.
Partnerships in Theories, Models & Frameworks

- **EPIS Framework**
  - Aarons, Hurlburt, & Horwitz 2011

- **CFIR Framework**
  - Damschroder et al 2009

- **Glasgow, Vogt, & Boles 1999**
  - Smith & Hasan 2019

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Implementation Strategies

- **Engage consumers**
- **Use evaluative & iterative strategies**
- **Change infrastructure**
- **Adapt & tailor to the context**
- **Develop stakeholder interrelationships**
- **Utilize financial strategies**
- **Support clinicians**
- **Provide interactive assistance**
- **Train & educate stakeholders**

- Powell et al. 2015
- Waltz et al. 2015
Community-Engaged Research

- Bidirectional exchange of expertise between academics (scientific experts) & communities (local, cultural, practice, lived experience experts) to increase value of research for improving health & equity

- Broad spectrum: minimal to equal partnership in all aspects

Principles of Engagement

Summary

- What’s is implementation science?
  - A science that focuses on understanding and informing effective implementation of the many interventions we have at our disposal

- Expand use of implementation science to shorten the time between intervention development, testing and applying it in real-world settings
  - Harnessing academic/public health partnerships
  - Developing implementation research questions needed to inform and guide local implementation

- Disseminate findings on effective implementation strategies and how to apply them through the use of dissemination science

Questions

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