THE MECHANISM IS THE MESSAGE:
How outcomes research improves outcomes

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October 28, 2019
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Four key contentions for this talk...

• Implementation research is **pragmatic**.

• **Improving** dissemination of evidence-based interventions is the **responsibility** of the research community.

• HIV dissemination practice (and research!) is often **limited** by a focus on **only two** categories of outcomes.

• Research that supports **defining, measuring, and learning from** the **range of implementation science outcomes** will have a broader and more durable impact on EtHE.
4 Categories of Outcomes

1. Patient/Clinical Outcomes
   • How is the intervention impacting patients?

2. Implementation Outcomes
   • How (well) is the intervention being implemented?
   • What is actually happening to impact patient outcomes?

3. Proximal/Process Outcomes (Mechanisms)
   • Is the implementation strategy influencing intervention and patient outcomes through the intended pathway?

4. Service Outcomes
   • Is the implementation strategy maximizing the impact of the intervention?
Logic Model for Implementation Research

Determinants Implementation Strategies Mechanisms Outcomes

- Inner Setting
- Intervention Characteristics
- Characteristics of Individuals
- Process

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Implementation Research Example

• Collaboration with NYC DOHMH to evaluate rollout of PrEP navigation program in sexual health clinics (SHCs)

• SHC PrEP Navigation Protocol includes:
  • All SHC patients are screened for PrEP indications at triage
  • All eligible and/or interested patients are referred to PrEP Navigator
  • PrEP Navigator provides education and counseling about PrEP, including benefits/insurance navigation
  • Patients interested in PrEP are seen by SHC provider who assesses medical edibility and writes 30 day prescription
  • Navigators provide facilitated referral to clinical site for ongoing PrEP Rx and care

Is this the intervention? No!
Implementation Research Example

• Collaboration with NYC DOHMH to evaluate rollout of PrEP navigation program in sexual health clinics (SHCs)

• SHC PrEP Navigation Protocol includes:
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  • All eligible and/or interested patients are referred to PrEP Navigator
  • PrEP Navigator provides education and counseling about PrEP, including benefits/insurance navigation
  • Patients interested in PrEP are seen by SHC provider who assesses medical edibility and writes prescription
  • Navigators provide facilitated referral to clinical site for ongoing PrEP care

This is the implementation strategy
Implementation Research Example

**Evidence-Based Intervention**

Increasing the number of patients on PrEP

**Implementation Strategy**

*How (i.e., the strategy through which) we are trying to increase the number of patients on PrEP*
Traditional Evaluation Research (2 outcome categories)

**PATIENT Outcomes**

Measures the impact of the intervention on patients

- # New HIV Infections

**IMPLEMENTATION Outcomes**

Measures the impact of the implementation strategy on the intervention

- # Patients on PrEP
  - # pts who receive initial PrEP Rx at SHC
  - # pts who receive PrEP Rx at referral appointment

What is the problem with just measuring these two types of outcomes?

Implementation outcomes measure the outcome of the implementation strategy, not the strategy itself.
**A *hypothetical* tale of two clinics**

<table>
<thead>
<tr>
<th>Clinic A (150 patients)</th>
<th>Clinic B (150 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>120 (80%)</strong> given PrEP Rx @SHC</td>
<td><strong>52 (35%)</strong> given PrEP Rx @SHC</td>
</tr>
<tr>
<td><strong>42 pts (35%)</strong> attend referral appt for ongoing PrEP Rx</td>
<td><strong>42 pts (80%)</strong> attend referral appt for ongoing PrEP Rx</td>
</tr>
</tbody>
</table>

Both clinics put **28% of patients on PrEP**

- Is navigation an effective implementation strategy?
Implementation Strategies

- PrEP Navigation at SHCs
  1. Universal Screening
  2. PrEP Education
  3. Benefits Counseling
  4. Facilitated Referral

Mechanisms

How (through what mechanism) does the implementation strategy impact outcomes?

Outcomes

- # pts on PrEP
- # pts who receive initial PrEP Rx at SHC
- # pts who receive PrEP Rx at referral appointment

# New HIV Infections
Implementation Strategies

PrEP Navigation at SHCs

1. Universal Screening
2. PrEP Education
3. Benefits Counseling
4. Facilitated Referral

Mechanisms

Proximal (Process) Outcomes

- # eligible patients identified
- perceived PrEP stigma among patients
- # patients able to pay for PrEP
- Logistical barriers to referral appointment

Outcomes

- # pts on PrEP
- # pts who receive initial PrEP Rx at SHC
- # pts who receive PrEP Rx at referral appointment

# New HIV Infections
Implementation Strategies

- PrEP Navigation at SHCs
  - 1. Universal Screening
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Mechanisms

- Proximal (Process) Outcomes
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Outcomes

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Implementation Strategies

PrEP Navigation at SHCs

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Mechanisms

Proximal (Process) Outcomes

- # eligible patients identified
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- Logistical barriers to referral appointment
- # patients able to pay for PrEP

Outcomes

- # pts on PrEP
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- # New HIV Infections
A *hypothetical* tale of two clinics

**Clinic A (150 patients)**

- *120 (80%)* given PrEP Rx @SHC
- *42 pts (35%)* attend referral appt for ongoing PrEP Rx

**Clinic B (150 patients)**

- *52 (35%)* given PrEP Rx @SHC
- *42 pts (80%)* attend referral appt for ongoing PrEP Rx

**Very successful at identifying eligible patients and reducing PrEP stigma**

**Very successful at benefits navigation and logistical support**
The Mechanism is the Message (actual data)

Not all patients got benefits counseling

PrEP Initiation by Implementation Strategy

p = .02

36% 54%
PrEP Ed only PrEP Ed + Benefits Couns

Benefits Counseling is a critical component of the Implementation Strategy
The Mechanism is the Message (actual data)

Is navigation impacting patient attitudes and motivation?

Personal PrEP Efficacy (alpha = .74)
- PrEP → control, not stigma
- PrEP will work for me
- I will be able to take PrEP

Screened: 100% N = 253
Received Navigation: 74% N = 195
Received PrEP Rx: 36.8% N = 93
The Mechanism is the Message (actual data)

- **Screened**
  - 100%
  - N = 253

- **Received Navigation**
  - 74%
  - N = 195

- **Received PrEP Rx**
  - 36.8%
  - N = 93

Personal PrEP Efficacy was **significantly higher** among patients who received navigation (p = .01)

Higher Personal PrEP Efficacy scores were associated with increased adjusted odds of PrEP Rx (p < .001)

Impacting Personal PrEP Efficacy is a critical component of the Implementation Strategy
The Mechanism is the Message

Implementation and dissemination initiatives (research or practice) must rigorously:

- Define the implementation strategy
- Specify the implementation targets (mechanisms)
- Measure these targets as process outcomes
- Analyze implementation and process outcomes along with patient outcomes

Implementation Strategies are Excipients
Implementation Strategies as “Excipients”

- **Excipients** are co-formulated with active medication for therapeutic enhancement and/or stabilization.

- All excipients must be **defined, measured and tested** to ensure:
  - Quality
  - Consistent dosage
  - Uniform distribution
Implementation Strategies as “Excipients”

Integration of PrEP services into existing clinical and community settings is the excipient through which the medication is actually delivered to highest priority populations.

- As such, these strategies must be defined, measured and tested to ensure:
  - Quality
  - Consistent dosage
  - Uniform distribution
Measuring Excipient Properties

IDEAL EXCIPIENT PROPERTIES

- STABLE AND REPRODUCIBLE
- NO UNWISHED INTERACTION (i.e., no negative impact on PrEP uptake)
- PHARMACOLOGICALLY INERT (i.e., does not induce stigma or medical mistrust)
- DESIRED FUNCTIONALITY (i.e., promotes uptake, adherence and retention)
- COST EFFECTIVE

MAXIMIZES POSITIVE IMPACT of the intervention

Pharmaceutical Excipient

Implementation Excipient
### Implementation Strategies

- **PrEP Navigation at SHCs**
  - 1. Universal Screening
  - 2. PrEP Education
  - 3. Benefits Counseling
  - 4. Facilitated Referral

### Mechanisms

- # eligible patients identified
- perceived PrEP stigma among patients
- # patients able to pay for PrEP
- Logistical barriers to referral appointment

### Outcomes

- # pts on PrEP
- # pts given PrEP Rx
- # pts given PrEP referral
- # pts who attend PrEP referral appointment

### Does the implementation strategy maximize the impact of the intervention?

- # New HIV Infections

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*SHCs: Sexual Health Clinics*
PrEP Navigation at SHCs

1. Universal Screening
2. PrEP Education
3. Benefits Counseling
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Equity:

Is the # of patients on PrEP equitably distributed?

# New HIV Infections
Examining Equity (national data)

New HIV Infections in U.S. by race/ethnicity

- Black: 44%
- Hispanic/Latinx: 27%
- Asian: 3%
- White: 23%
- Multiracial/Other: 2%

PrEP Prescriptions in U.S. by race/ethnicity

- White: 74%
- Black: 10%
- Hispanic/Latinx: 12%
- Asian: 4%
- Multiracial/Other: 3%
Examining Equity (impact of SHC Navigation)

New HIV Infections in NYC by race/ethnicity:
- Black: 19%
- Hispanic/Latinx: 37%
- White: 38%
- Multiracial/Other: 6%

SHC PrEP Initiates by race/ethnicity:
- Black: 27%
- Hispanic/Latinx: 33%
- White: 29%
- Multiracial/Other: 11%

Borges et al., National HIV Prevention Conference, 2018
### Outcomes

- # pts on PrEP
- # pts given PrEP Rx
- # pts given PrEP referral
- # pts who attend PrEP referral appointment

### Mechanisms

- # eligible patients identified
- perceived PrEP stigma among patients
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### Implementation Strategies

- **PrEP Navigation at SHCs**
  1. Universal Screening
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### Efficiency: How much resources does it take to get a pt on PrEP?

- # New HIV Infections
### Implementation Strategies

**PrEP Navigation at SHCs**

1. Universal Screening
2. PrEP Education
3. Benefits Counseling
4. Facilitated Referral

### Mechanisms

- Eligible patients identified
- Perceived PrEP stigma among patients
- Patients able to pay for PrEP
- Logistical barriers to referral appointment

### Outcomes

- # pts on PrEP
- # pts given PrEP Rx
- # pts given PrEP referral
- # pts who attend PrEP referral appointment

### Service

- Implementation rates by race or gender
- Time/effort per new pt on PrEP

### Patient

- # New HIV Infections
Implications for Enhancing Impact of EtHE Initiatives

1. Support for **delivery of proven interventions** as well as **research to identify new implementation strategies** must include:
   - Specification, measurement and evaluation of **implementation strategies as excipients**
   - A focus not only on patient-level and implementation-level outcomes, but on **mechanism/process outcomes and service outcomes** (i.e., equity & efficiency)

2. **New interventions or implementation strategies** must be focused on **enhancing service outcomes**
THANK YOU!

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Outcomes

What are we trying to achieve? (i.e., through what intervention) are we trying to achieve patient outcomes?

Does the implementation strategy maximize the impact of the intervention?

What are we trying to achieve?

Mechanisms

How is the implementation strategy going to facilitate implementation outcomes?

Why do we think that’s going to work?

Implementation Strategies

What strategy are we using to accomplish the implementation outcomes (i.e. deliver the intervention)?

What specific actions comprise this implementation strategy?
Intervention “Specification”

**EQUITY**

Does the strategy achieve goals equitably?  
If not, where is the intervention failing?

**STRATEGY**

*What are we doing with clients to accomplish these outcomes?*

**MECHANISM**

*How (through what process) will the strategy achieve this goal?*

**GOALS**

*What are we trying to achieve with clients?*

**JUSTIFICATION**

Why do we think this is going to work?
4 Categories of Outcomes

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