Key Ingredients of Implementation Science

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HIV DIAGNOSES IN THE U.S.

New HIV Infections by Race and Transmission Group, U.S. 2014-2018

- HIV incidence remained relatively stable in 2018 as compared with 2014

- In 2018, 37,968 people received an HIV diagnosis in the U.S.

■ 2014 ■ 2018

CDC, Estimated HIV Incidence and Prevalence in the United States 2014–2018, 2020

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ENDING THE HIV EPIDEMIC

- GOAL: reduce the number of new HIV infections in the U.S. by at least 90% by 2030 with the goal of decreasing the number of new HIV infections to fewer than 3,000/year

Diagnose all people with HIV as early as possible.

Treat people with HIV rapidly and effectively to reach sustained viral suppression.

Prevent new HIV transmissions by using proven interventions, including pre-exposure prophylaxis (PrEP) and syringe services programs (SSPs).

Respond quickly to potential HIV outbreaks to get needed prevention and treatment services to people who need them.

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SAN DIEGO COUNTY INDICATORS

Diagnoses

Diagnoses is the number of people with HIV diagnosed in a given year confirmed by laboratory or clinical evidence.

2019-2020: Prelim. as of Sept 2020

Linked to HIV medical care

Linkage to HIV medical care is the percentage of people diagnosed with HIV in a given year who have received medical care for their HIV infection within one month of diagnosis.

2019-2020: Prelim. as of Sept 2020

https://ahead.hiv.gov/locations/san-diego-county

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DEFINING IMPLEMENTATION SCIENCE

- *"Each year, billions of U.S. tax dollars are spent on research and hundreds of billions are spent on delivery of health services in clinical and community settings. However, little is spent on research to understand how best to ensure that the lessons learned from research are relevant to inform and improve the […] delivery of services and utilization […] of evidence-based tools and approaches."* NIH PAR-18-017
  - 18 of 27 NIH institutes participate in this dissemination and implementation PAR

- **Implementation science:** "The scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services."
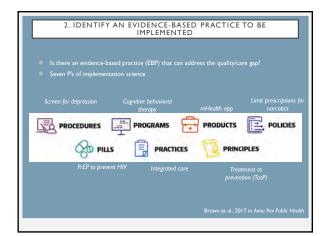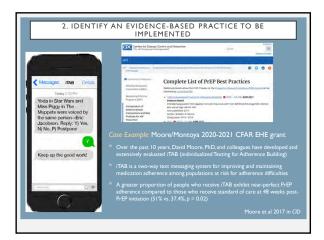
Eccles et al 2006 in *Implementation Sci*

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KEY INGREDIENTS OF IMPLEMENTATION SCIENCE

1. Address a quality/care gap
2. Identify an evidence-based practice (EBP) to be implemented
3. Use a conceptual model/framework to guide research
4. Understand stakeholder priorities and their engagement in implementation
5. Assess readiness to adopt the evidence-based practice
6. Define implementation strategy/strategies with conceptual justification
7. Apply team science
8. Develop an approach that is feasible
9. Consider pragmatic measures
10. Leverage healthcare policies

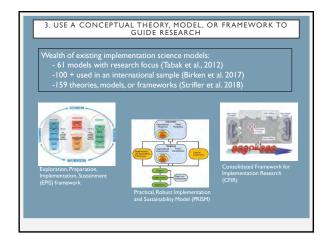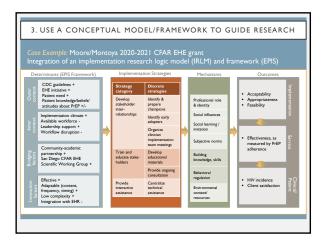Proctor et al., 2012 in *Implementation Science*

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1. ADDRESS A QUALITY/CARE GAP

- Is there evidence that a quality gap or care gap exists?
  - Demonstrate
    - variability in quality of care
    - implementation related gap
- *Case Example:* Moore/Montoya 2020-2021 CFAR EHE grant "Exploring and preparing for implementation of an individualized text messaging PrEP adherence intervention in a community setting"
  - Since 2014, the CDC has recommended PrEP for HIV prevention
  - HIV epidemic can be mitigated if people remain adherent to PrEP
  - 96% protection against HIV infection by taking ≥4 doses TDF/FTC per week (TFV-DP intracellular concentrations ≥719 fmol/punch)
  - Suboptimal adherence significantly impacts effectiveness of PrEP

Grant et al 2010 in *N Engl J Med*
Anderson et al 2012 in *Sci Transl Med*

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2. IDENTIFY AN EVIDENCE-BASED PRACTICE TO BE IMPLEMENTED

- Is there an evidence-based practice (EBP) that can address the quality/care gap?
- Seven P's of implementation science

Screen for depression	*Cognitive behavioral therapy*	*mHealth app*	*Limit prescriptions for narcotics*
PROCEDURES	PROGRAMS	PRODUCTS	POLICIES

PILLS	PRACTICES	PRINCIPLES
PrEP to prevent HIV	*Integrated care*	*Treatment as prevention (TasP)*

Brown et al., 2017 in *Annu Rev Public Health*

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2. IDENTIFY AN EVIDENCE-BASED PRACTICE TO BE IMPLEMENTED

Complete List of PrEP Best Practices

Case Example: Moore/Montoya 2020-2021 CFAR EHE grant

- Over the past 10 years, David Moore, PhD, and colleagues have developed and extensively evaluated iTAB (individualized Texting for Adherence Building)
- iTAB is a two-way text messaging system for improving and maintaining medication adherence among populations at risk for adherence difficulties
- A greater proportion of people who receive iTAB exhibit near-perfect PrEP adherence compared to those who receive standard of care at 48 weeks post-PrEP initiation (51% vs. 37.4%, *p* = 0.02)
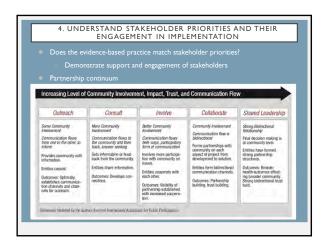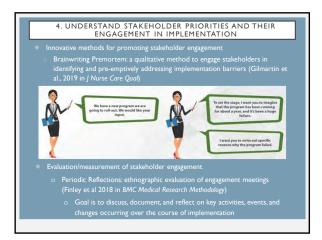
Moore et al 2017 in *CID*

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3. USE A CONCEPTUAL MODEL/FRAMEWORK TO GUIDE RESEARCH

- Is the research guided by a conceptual model/framework?
  - Demonstrate rationale for selecting and using a specific implementation science model/framework
    - Process Models: goal is to describe and/or guide the research-to-practice process (does not predict or analyze what factors influence outcomes)
    - Determinant Frameworks: goal is to understand and explain what influences implementation outcomes
    - Evaluation Frameworks: goal is to evaluate implementation
  - Consider how implementation science model/framework will be used throughout the approach, methods, and analyses

Nilsen (2015) in *Implementation Science*

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3. USE A CONCEPTUAL THEORY, MODEL, OR FRAMEWORK TO GUIDE RESEARCH

Wealth of existing implementation science models:
- 61 models with research focus (Tabak et al., 2012)
- 100 + used in an international sample (Birken et al. 2017)
- 159 theories, models, or frameworks (Strifler et al. 2018)

Exploration, Preparation, Implementation, Sustainment (EPIS) framework

Practical, Robust Implementation and Sustainability Model (PRISM)

Consolidated Framework for Implementation Research (CFIR)

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3. USE A CONCEPTUAL MODEL/FRAMEWORK TO GUIDE RESEARCH

Case Example: Moore/Montoya 2020-2021 CFAR EHE grant
Integration of an implementation research logic model (IRLM) and framework (EPIS)

Determinants (EPIS Framework)	Implementation Strategies		Mechanisms	Outcomes	
Outer context: CDC guidelines + EHE initiative + Patient need + Patient knowledge/beliefs/ attitudes about PrEP +/-	**Strategy category**	**Discrete strategies**	Professional role & identity	• Acceptability • Appropriateness • Feasibility	Implementation
	Develop stakeholder inter-relationships	Identify & prepare champions	Social influences		
Inner context: Implementation climate + Available workforce - Leadership support + Workflow disruption -		Identify early adopters	Social learning / imitation		
		Organize clinician implementation team meetings	Subjective norms	• Effectiveness, as measured by PrEP adherence	Service
Bridging factors: Community-academic partnership + San Diego CFAR EHE Scientific Working Group +	Train and educate stake-holders	Develop educational materials	Building knowledge, skills		
		Provide ongoing consultation	Behavioral regulation		
Innovation factors: Effective + Adaptable (content, frequency, timing) + Low complexity + Integration with EHR -	Provide interactive assistance	Centralize technical assistance	Environmental context/ resources	• HIV incidence • Client satisfaction	Clinical/ Patient

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4. UNDERSTAND STAKEHOLDER PRIORITIES AND THEIR ENGAGEMENT IN IMPLEMENTATION

- Does the evidence-based practice match stakeholder priorities?
  - Demonstrate support and engagement of stakeholders
- Partnership continuum

Increasing Level of Community Involvement, Impact, Trust, and Communication Flow →

Outreach	Consult	Involve	Collaborate	Shared Leadership
Some Community Involvement	More Community Involvement	Better Community Involvement	Community Involvement	Strong Bidirectional Relationship
Communication flows from one to the other, to inform.	Communication flows to the community and then back, answer seeking	Communication flows both ways, participatory form of communication	Communication flow is bidirectional	Final decision making is at community level.
Provides community with information.	Gets information or feedback from the community.	Involves more participation with community on issues.	Forms partnerships with community on each aspect of project from development to solution.	Entities have formed strong partnership structures.
Entities coexist.	Entities share information.	Entities cooperate with each other.	Entities form bidirectional communication channels.	Outcomes: Broader health outcomes affecting broader community. Strong bidirectional trust built.
Outcomes: Optimally, establishes communication channels and channels for outreach.	Outcomes: Develops connections.	Outcomes: Visibility of partnership established with increased cooperation.	Outcomes: Partnership building, trust building.	

Reference: Modified by the authors from the International Association for Public Participation.

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7 PS TO IDENTIFY STAKEHOLDERS IN COMMUNITY-ENGAGED RESEARCH

Category	Description
Patients and the public	Current and potential consumers of patient-centered health care and population-focused public health, their caregivers, families, and patient and consumer advocacy organizations.
Providers	Individuals (e.g., nurses, physicians, mental health counselors, pharmacists, and other providers of care and support services) and organizations (e.g., hospitals, clinics, community health centers, community-based organizations, pharmacies, EMS agencies, skilled nursing facilities, schools) that provide care to patients and populations
Purchasers	Employers, the self-insured, government and other entities responsible for underwriting the costs of health care
Payers	Insurers, Medicare and Medicaid, state insurance exchanges, individuals with deductibles, and others responsible for reimbursement for interventions and episodes of care
Policy makers	The White House, Department of Health and Human Services, Congress, states, professional associations, intermediaries, and other policy-making entities
Product makers	Drug and device manufacturers
Principal investigators	Other researchers and their funders

Concannon TW, Meissner P, Grunbaum JA, et al. A new taxonomy for stakeholder engagement in patient-centered outcomes research. J Gen Intern Med. 2012;27(8):985-991. doi:10.1007/s11606-012-2037-1

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4. UNDERSTAND STAKEHOLDER PRIORITIES AND THEIR ENGAGEMENT IN IMPLEMENTATION

- Innovative methods for promoting stakeholder engagement
  - Brainwriting Premortem: a qualitative method to engage stakeholders in identifying and pre-emptively addressing implementation barriers (Gilmartin et al., 2019 in *J Nurse Care Qual*)

- We have a new program we are going to roll-out. We would like your input.
- To set the stage, I want you to imagine that the program has been running for about a year, and it's been a huge failure.
- I want you to write out specific reasons why the program failed.

- Evaluation/measurement of stakeholder engagement
  - Periodic Reflections: ethnographic evaluation of engagement meetings (Finley et al 2018 in *BMC Medical Research Methodology*)
    - Goal is to discuss, document, and reflect on key activities, events, and changes occurring over the course of implementation
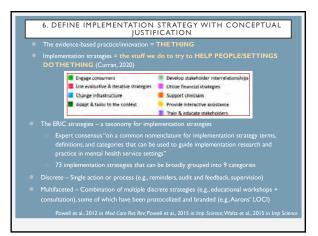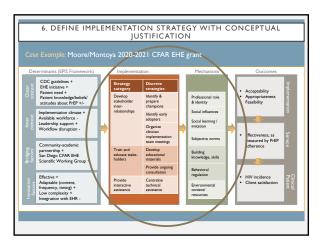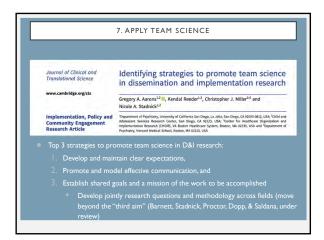
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5. ASSESS READINESS TO ADOPT THE EVIDENCE-BASED PRACTICE

- Is the specific setting ready to adopt a new evidence-based practice?
  - Demonstrate desire for change at the specific setting
- *Case Example:* Moore/Montoya 2020-2021 CFAR EHE grant
  - Identify decision-makers
  - Present business case for implementing iTAB (i.e., there's a market for it based on interviews with clients, providers, directors)
  - Understanding the role of $ - demonstrate cost-savings, identify funding to support the evidence-based practice
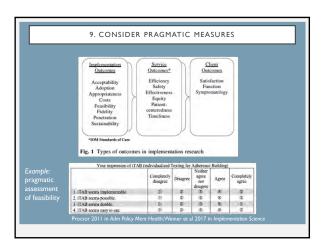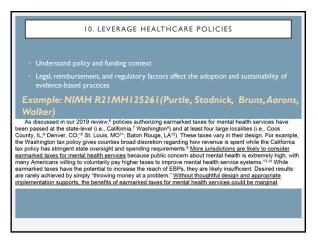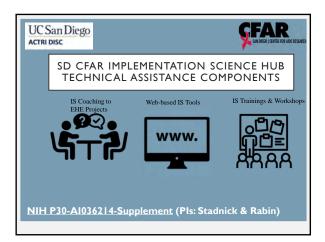
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6. DEFINE IMPLEMENTATION STRATEGY WITH CONCEPTUAL JUSTIFICATION

- The evidence-based practice/innovation = **THE THING**
- Implementation strategies = **the stuff we do to try to HELP PEOPLE/SETTINGS DO THE THING** (Curran, 2020)

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

- The ERIC strategies – a taxonomy for implementation strategies
  - Expert consensus "on a common nomenclature for implementation strategy terms, definitions, and categories that can be used to guide implementation research and practice in mental health service settings"
  - 73 implementation strategies that can be broadly grouped into 9 categories
- Discrete – Single action or process (e.g., reminders, audit and feedback, supervision)
- Multifaceted – Combination of multiple discrete strategies (e.g., educational workshops + consultation), some of which have been protocolized and branded (e.g., Aarons' LOCI)

Powell et al., 2012 in *Med Care Res Rev*; Powell et al., 2015 in *Imp Science*; Waltz et al., 2015 in *Imp Science*

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6. DEFINE IMPLEMENTATION STRATEGY WITH CONCEPTUAL JUSTIFICATION

Case Example: Moore/Montoya 2020-2021 CFAR EHE grant

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7. APPLY TEAM SCIENCE

Identifying strategies to promote team science in dissemination and implementation research

Gregory A. Aarons[1,2], Kendal Reeder[1,2], Christopher J. Miller[3,4] and Nicole A. Stadnick[1,2]

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- Top 3 strategies to promote team science in D&I research:
  1. Develop and maintain clear expectations,
  2. Promote and model effective communication, and
  3. Establish shared goals and a mission of the work to be accomplished
     - Develop jointly research questions and methodology across fields (move beyond the "third aim" (Barnett, Stadnick, Proctor, Dopp, & Saldana, under review)

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8. DEVELOP AN APPROACH THAT IS FEASIBLE

- Does the approach capture internal/external validity?

	Hybrid trial type 1	Hybrid trial type 2	Hybrid trial type 3
Aims	Primary: determine effectiveness of a clinical intervention Secondary: better understand context for implementation	Co-primary: determine effectiveness of a clinical intervention Co-primary: determine feasibility and potential utility of an implementation strategy	Primary: determine utility of an implementation strategy Secondary: assess clinical outcomes associated with implementation trial
Questions	Primary: Will a clinical intervention work in this setting/with these patients? Secondary: What are potential barriers/facilitators to an intervention's widespread implementation?	Co-primary: Will a clinical intervention work in this setting/with these patients? Co-primary: Does the implementation strategy show promise (either alone or in comparison with another strategy) in facilitating implementation of a clinical intervention?	Primary: Which implementation strategy works better in facilitating implementation of a clinical intervention? Secondary: Are clinical outcomes acceptable?

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9. CONSIDER PRAGMATIC MEASURES

- Do the methods and analysis correspond to the conceptual model?
  - Use selected theory, model, framework to inform selection of measures, data collection, analysis, and interpretation/organization of findings
  - Specify when, from whom, how, and what data will be collected
  - Consider multiple levels and the perspective of multiple stakeholders
  - Engage stakeholders in prioritizing measures
  - Choose measures that are actionable and pragmatic
  - Consider implementation and effectiveness outcomes
  - Combination of qualitative and quantitative is important

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9. CONSIDER PRAGMATIC MEASURES

Fig. 1 Types of outcomes in implementation research

Example: pragmatic assessment of feasibility

Proctor 2011 in *Adm Policy Ment Health*; Weiner et al 2017 in *Implementation Science*

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10. LEVERAGE HEALTHCARE POLICIES

- Understand policy and funding context
- Legal, reimbursement, and regulatory factors affect the adoption and sustainability of evidence-based practices

Example: NIMH R21MH125261 (Purtle, Stadnick, Bruns, Aarons, Walker)

As discussed in our 2019 review,[6] policies authorizing earmarked taxes for mental health services have been passed at the state-level (i.e., California,[7] Washington[8]) and at least four large localities (i.e., Cook County, IL;[9] Denver, CO;[10] St. Louis, MO[11]; Baton Rouge, LA[12]). These taxes vary in their design. For example, the Washington tax policy gives counties broad discretion regarding how revenue is spent while the California tax policy has stringent state oversight and spending requirements.[6] More jurisdictions are likely to consider earmarked taxes for mental health services because public concern about mental health is extremely high, with many Americans willing to voluntarily pay higher taxes to improve mental health service systems.[13,14] While earmarked taxes have the potential to increase the reach of EBPs, they are likely insufficient. Desired results are rarely achieved by simply "throwing money at a problem." Without thoughtful design and appropriate implementation supports, the benefits of earmarked taxes for mental health services could be marginal.

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