Translation of new knowledge (evidence) into clinical practice

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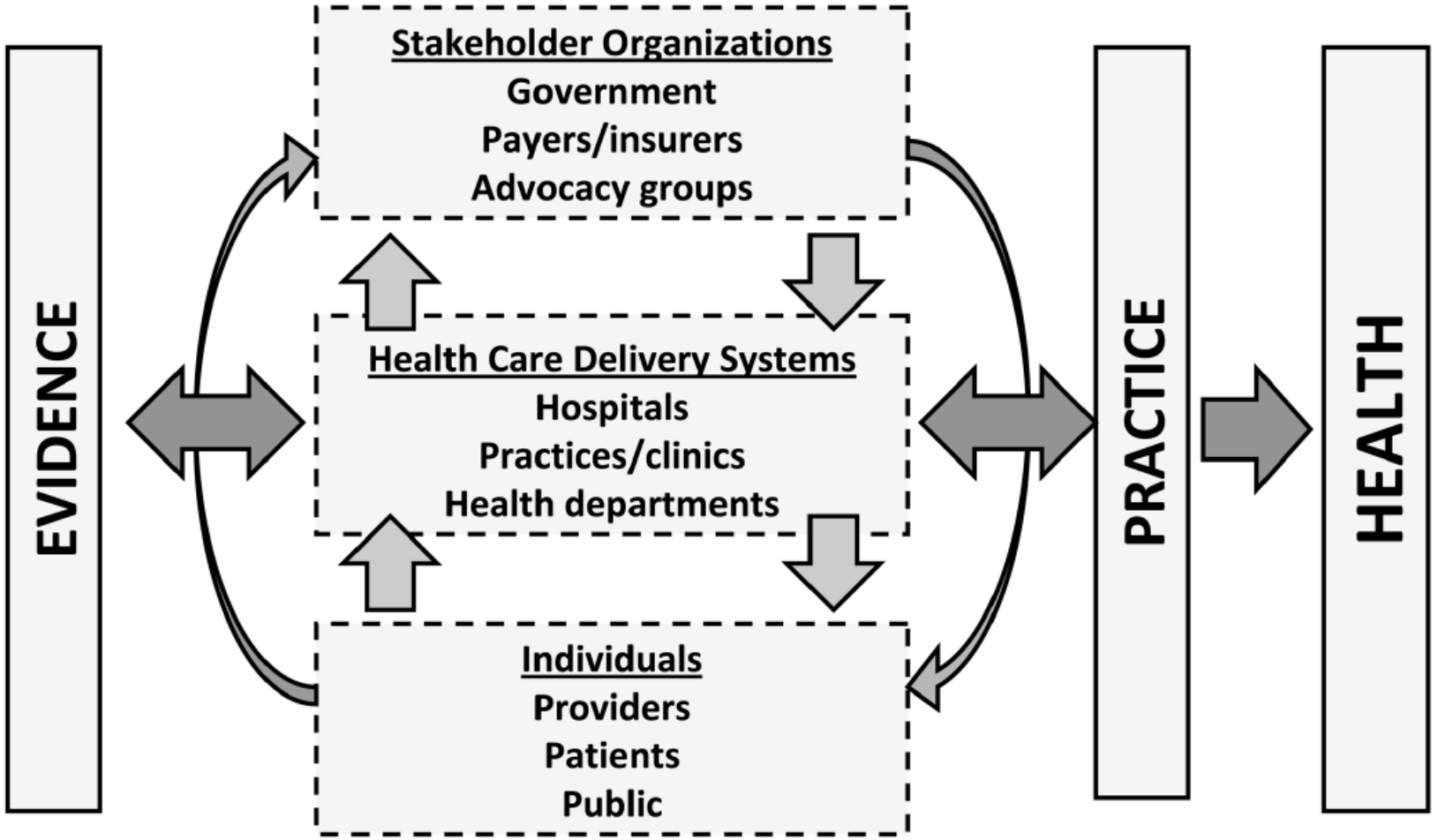
Outline

- Conceptual framework
- Evidence and type of evidence
- Evidence-practice gap
- Implementation science
- Understanding the implementation gap:
  - Cascade approach
  - RE-AIM approach to public health impact
- Understanding reasons for the implementation gap
  - Theories and models
- Implementation strategies
- Implementation research
- Mechanisms for translation of evidence into practice
- Mechanisms for translation of evidence into policy

Conceptual framework for translating evidence into practice, policy and public health improvements



Gonzales. et. al. Increasing the Translation of Evidence Into Practice, Policy, and Public Health Improvements. Acad Med. 2012 March ; 87(3): 271–278

Evidence

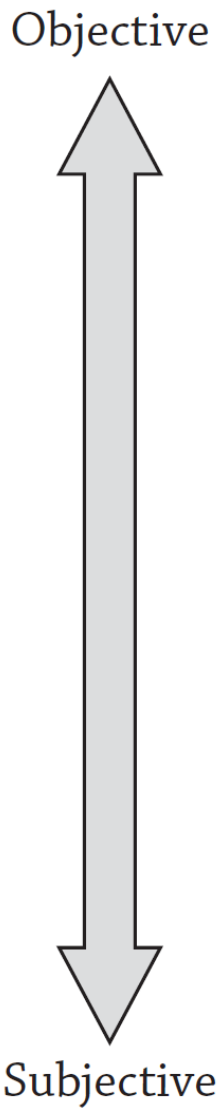
- **Evidence** is “the available body of facts or information indicating whether a belief or proposition is true or valid”.

  -(*2001. The New Oxford American Dictionary*)

- For health professional, **evidence** is some form of data- including
  - Systematic reviews, clinical trials, and other clinical
  - epidemiologic (quantitative) data,
  - results of program or policy evaluations, and
  - qualitative data - that is used in making judgments or decisions

Different forms of evidence

- Scientific literature in systematic reviews
- Scientific literature in narrative reviews
- Scientific literature in one or more journal articles
- Public health surveillance data
- Program/policy evaluations
- Qualitative data
  - –Community members
  - –Other stakeholders
- Media/marketing data
- Word of mouth
- Personal experience



Types of scientific evidence for health

Characteristic	Type One	Type Two	Type Three
Typical data/ relationship	Size and strength of preventable risk—disease relationship (measures of burden, etiologic research)	Relative effectiveness of public health intervention	Information on the adaptation and translation of an effective intervention
Common setting	Clinic or controlled community setting	Socially intact groups or community wide	Socially intact groups or community wide
Example	Smoking causes lung cancer	Price increases with a targeted media campaign reduce smoking rates	Understanding the political challenges of price increases or targeting media messages to particular audience segments
Quantity	More	Less	Less
Action	Something should be done	This particular intervention should be implemented	How an intervention should be implemented

Brownson, R.C., Baker, E.A., Deshpande, A.D. and Gillespie, K.N., 2017. *Evidence-based public health*. Oxford University Press.

Evidence-based Practice

- **Evidence- based medicine** is integrating individual clinical expertise with the best available external clinical evidence from systematic research.
- "**Evidence-based public health** is the process of integrating science-based interventions with community preferences to improve the health of populations."

(*Gibbert WS, Keating SM, Jacobs JA, et al. Training the workforce in evidence-based public health: an evaluation of impact among US and international practitioners. Prev Chronic Dis.2013;10:E148.*)

Pervasive Gap Between Knowledge and Routine Use

McGlynn et al., "The Quality of Health Care Delivered to Adults in the United States"

Daniel Prinz

November 8, 2015

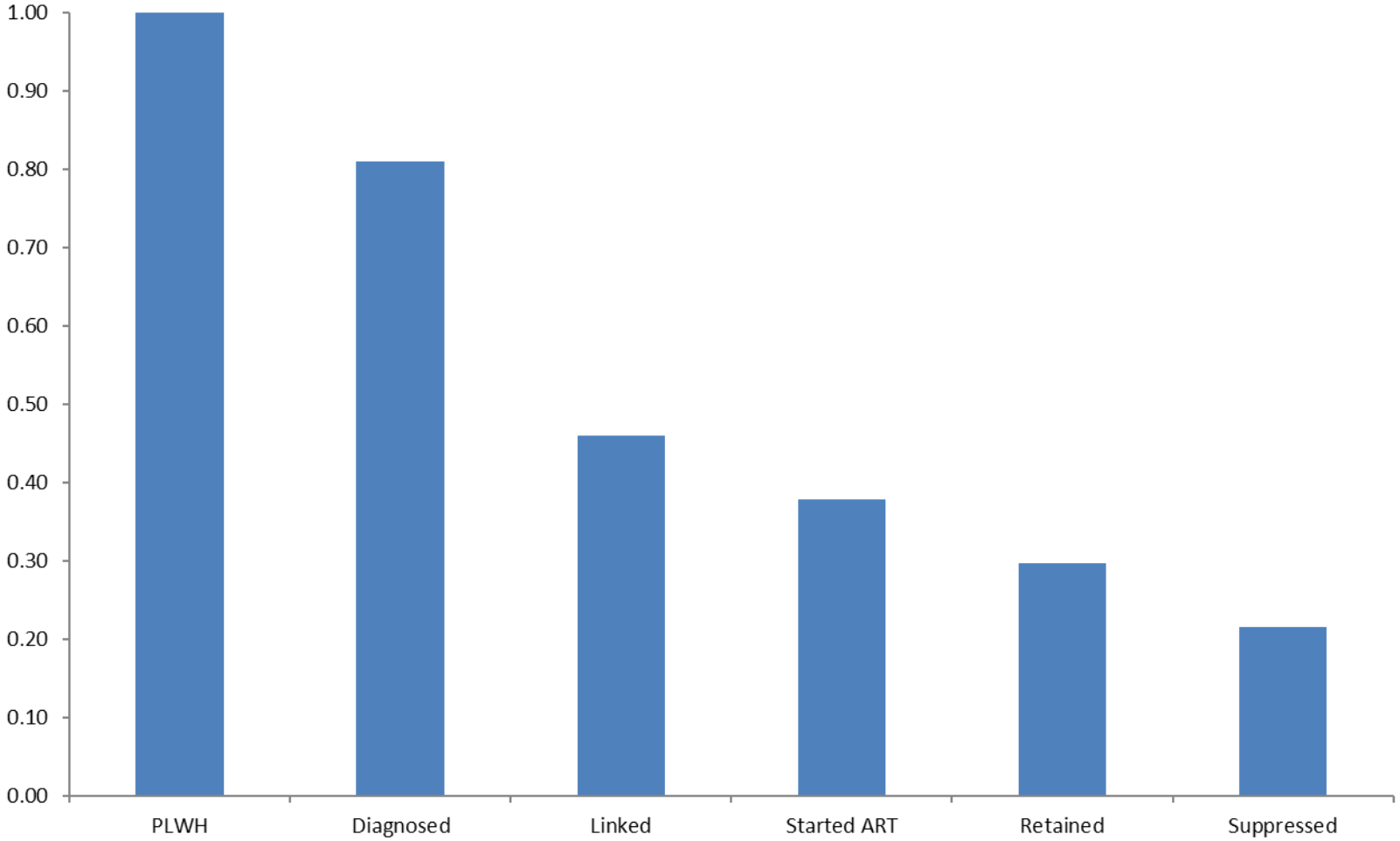
Elizabeth A. McGlynn, Steven M. Asch, John Adams, Joan Keesey, Jennifer Hicks, Alison DeCristofaro, and Eve A. Kerr, "The Quality of Health Care Delivered to Adults in the United States" *New England Journal of Medicine* 348(26):2635-2645. 2003.

Pervasive Gap Between Knowledge and Routine Use

Variable	No. Indicators	No. Eligible	No. Times Indicator Eligibility	**Percentage of Recommended Care Received**
Overall care	439	6712	98,649	**54.9 (54.3–55.5)**
Type of care				
Preventive	38	6711	55,268	54.9 (54.2–55.6)
Acute	153	2318	19,815	53.5 (52.0–55.0)
Chronic	248	3387	23,566	56.1 (55.0–57.3)
Function				
Screening	41	6711	39,486	52.2 (51.3–53.2)
Diagnosis	178	6217	29,679	55.7 (54.5–56.8)
Treatment	173	6707	23,019	57.5 (56.5–58.4)
Follow-up	47	2413	6,465	58.5 (56.6–60.4)

McGlynn NEJM 348;26, 2003

The Global HIV Treatment Cascade



Science to Address the Gap

- *A lot of money are spent on research and clinical service delivery and community health programs.*
- *However, relatively little is spent on, or known about, how best to ensure that the lessons learned from research are relevant to, and, inform and improve the quality of health, delivery of services and the utilization and sustainability of evidence-based tools and approaches.*
- *Closing the gap between research and clinical and community practice through scientific inquiry is both a complex challenge and an absolute necessity.*

What is this science?

- Implementation research
- Dissemination and implementation research
- **Implementation science**
- Program science
- Delivery science
- Knowledge translation
- Mode 2 knowledge
- T-2, T-3

Understand the Nature of the Gap

Theoretical

"Evidence"

"Knowledge"

"Research findings"

Practiced

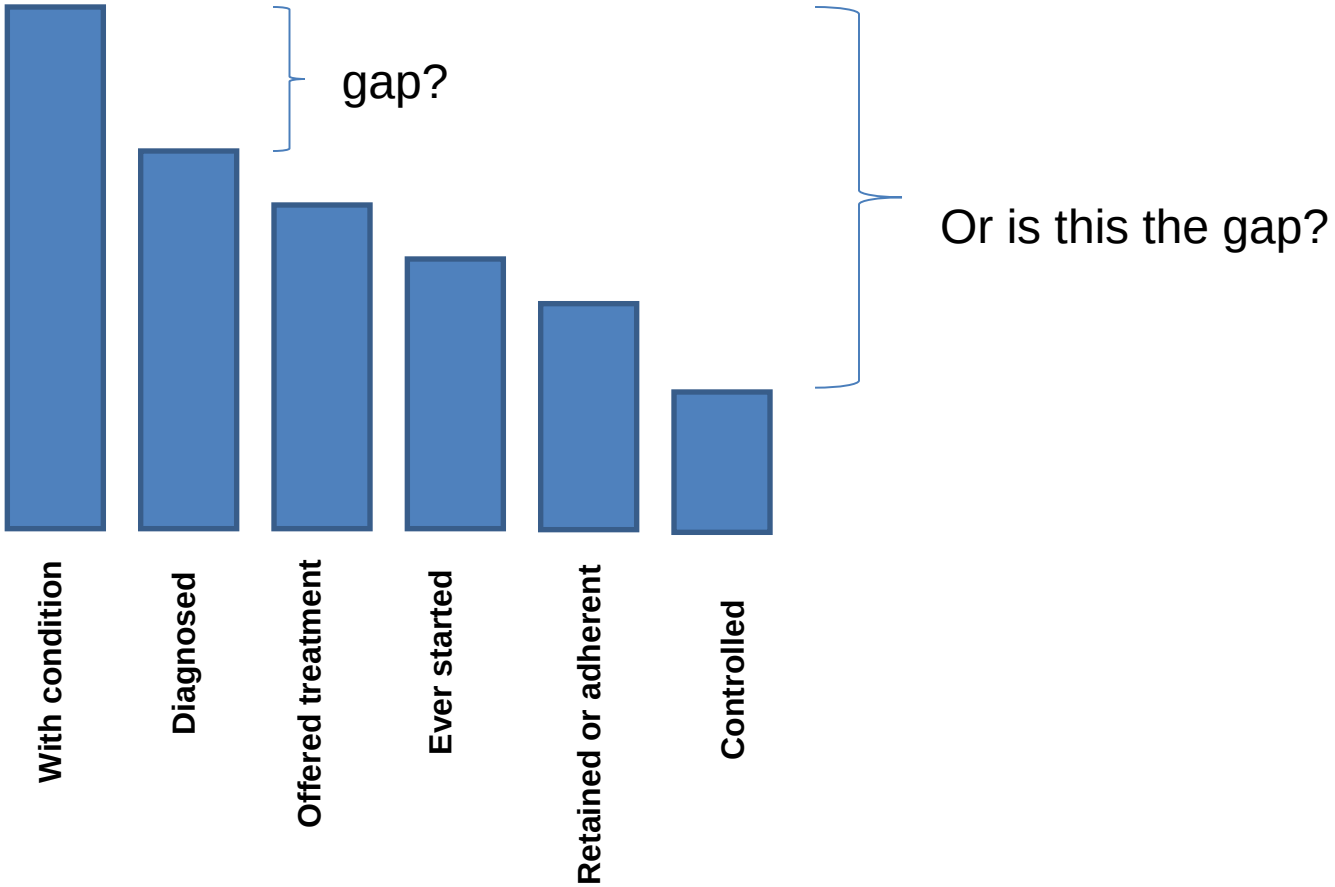
"Use"

"Delivery"

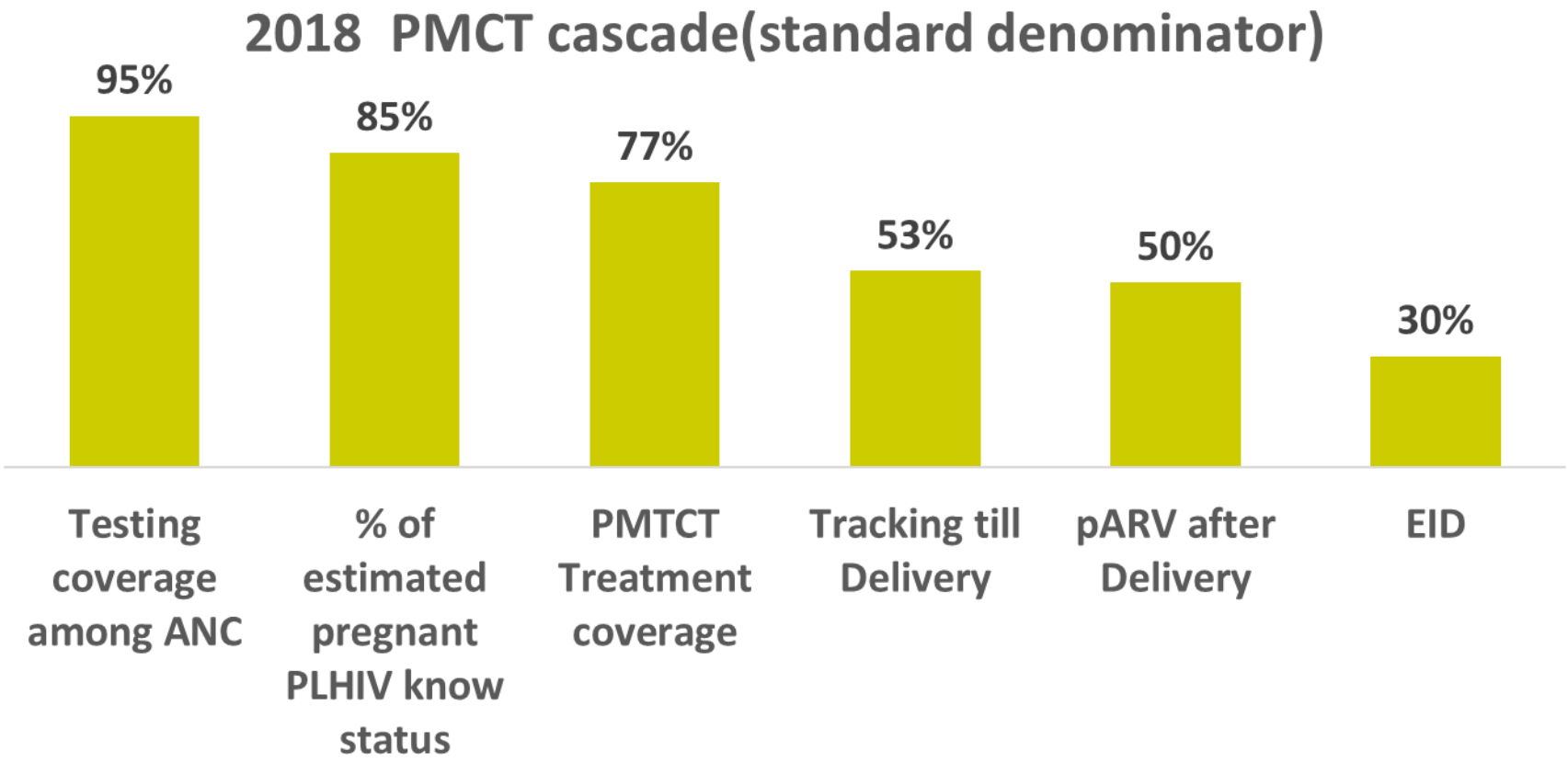
"Practice"

"Uptake"

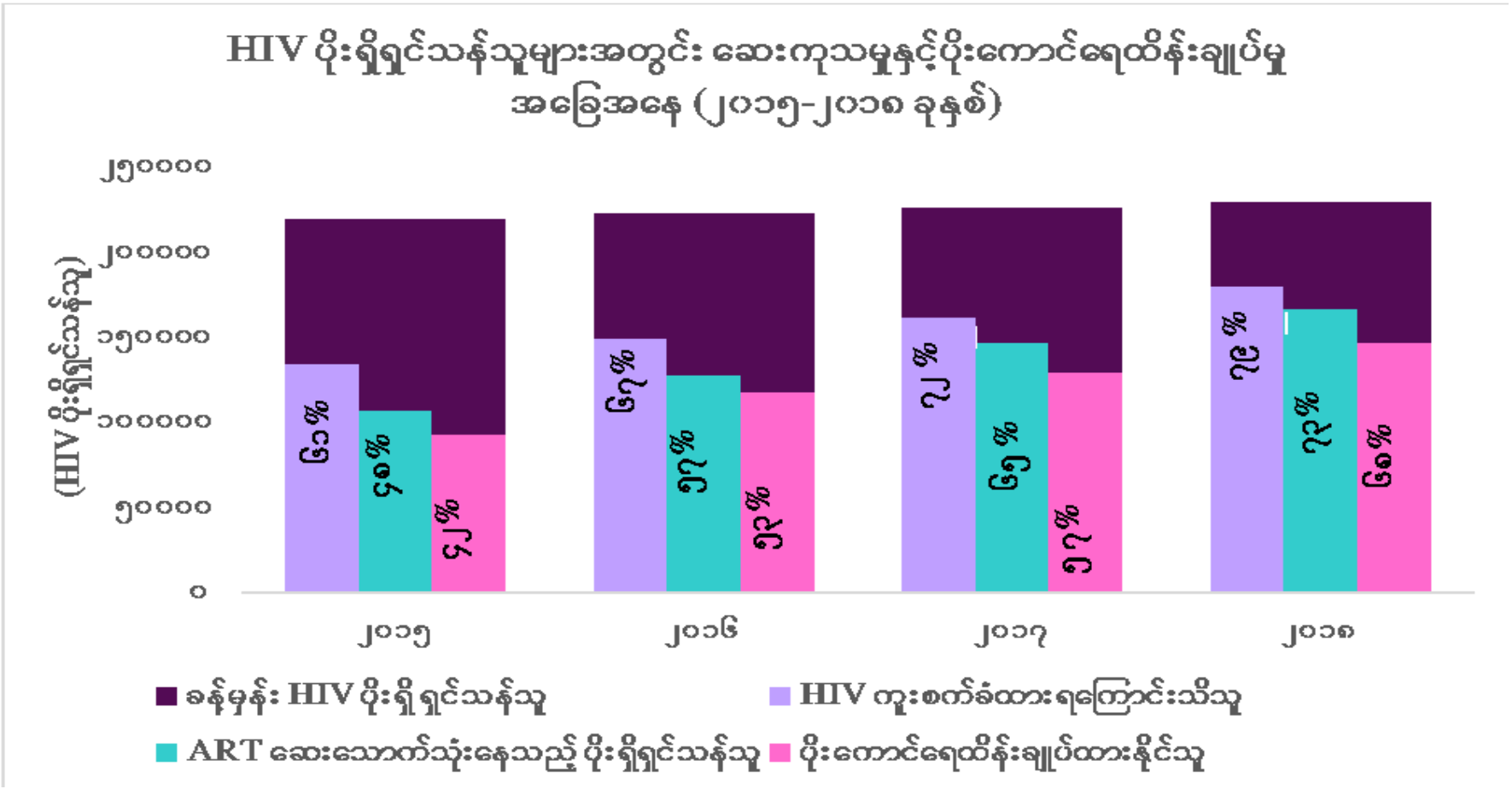
A “Cascade” Approach to Characterizing the Implementation Gap



Where we are with the 95s EMTCT cascade services in Myanmar



EMTCT=elimination of Mother-to-Child Transmission of HIV
EID=Early Infant Diagnosis of HIV


HIV ပိုးရှိရှင်သန်သူများအတွင်း ဆေးကုသမှုနှင့်ပိုးကောင်ရေထိန်းချုပ်မှု
အခြေအနေ (၂၀၁၅-၂၀၁၈ ခုနှစ်)
(HIV ပိုးရှိရှင်သန်သူ (ဦးရေခန့်မှန်း)
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ခန့်မှန်း HIV ပိုးရှိရှင်သန်သူ
HIV ကူးစက်ခံထားရကြောင်းသိသူ
ART ဆေးသောက်သုံးနေသည့် ပိုးရှိရှင်သန်သူ
ပိုးကောင်ရေထိန်းချုပ်ထားနိုင်သူ

Public Health Impact: RE-AIM

RE-AIM ELEMENT	Definition	Questions
REACH	An individual-level measure of participation (e.g., patient or employee) .	Can the practice attract large and representative percent of target population / communities?
EFFICACY	Magnitude of effect among those successfully treated	Does the practice produce large effects ?
ADOPTION	The proportion and representativeness of settings that adopt a given policy or program.	Is the practice feasible for majority of real-world settings (costs, expertise, time, resources, etc.)?
IMPLEMENTATION	The extent to which a program Is delivered as intended.	Can the program be consistently implemented across program elements, different staff, time,etc.?
MAINTENANCE	Sustainability in a given governance, policy, economic and funding context	Can the settings sustain the program over time without added resources and leadership?

Glasgow. Evaluating the Public Health Impact of Health Promotion Interventions. AJPH 1998

TABLE 1—RE-AIM Evaluation Dimensions

Dimension[a]	Level
Reach (proportion of the target population that participated in the intervention)	Individual
Efficacy (success rate if implemented as in guidelines; defined as positive outcomes minus negative outcomes)	Individual
Adoption (proportion of settings, practices, and plans that will adopt this intervention)	Organization
Implementation (extent to which the intervention is implemented as intended in the real world)	Organization
Maintenance (extent to which a program is sustained over time)	Individual and organization

[a]The product of the 5 dimensions is the public health impact score (population-based effect).

Public Health Impact: RE-AIM

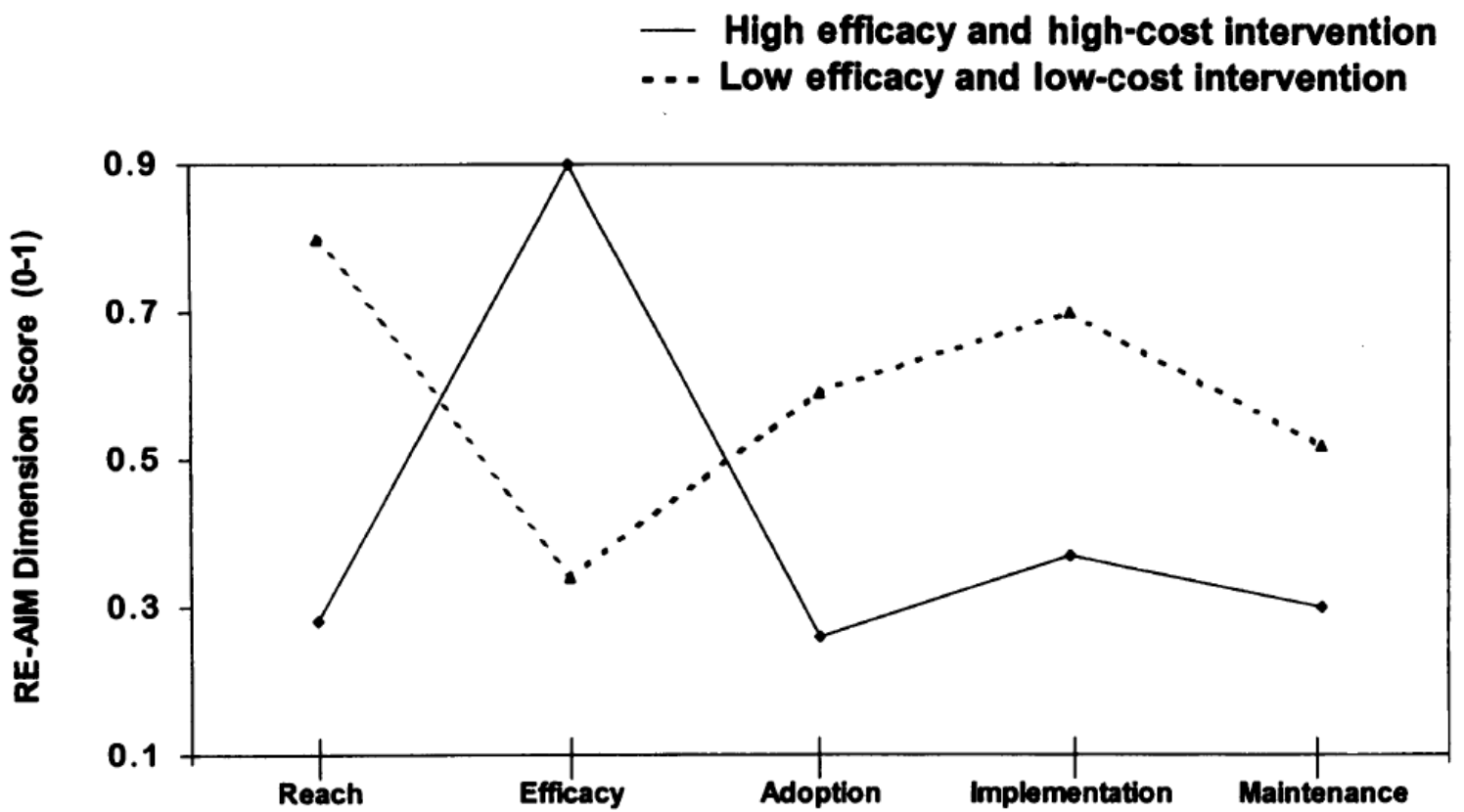

FIGURE 1—Display of 2 different intervention programs on various RE-AIM dimensions.

Glasgow. Evaluating the Public Health Impact of Health Promotion Interventions. AJPH 1998

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Understand Reasons for the Gap

"…the study of the processes and variables which determine/influence the adoption of health promotion and disease prevention-related knowledge."

Eliot 2003

Case Study: Pre-exposure Prophylaxis for HIV Prevention

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 30, 2010 VOL. 363 NO. 27

Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men

Robert M. Grant, M.D., M.P.H., Javier R. Lama, M.D., M.P.H., Peter L. Anderson, Pharm.D., Vanessa McMahan, B.S., Albert Y. Liu, M.D., M.P.H., Lorena Vargas, Pedro Goicochea, M.Sc., Martín Casapía, M.D., M.P.H., Juan Vicente Guanira-Carranza, M.D., M.P.H., Maria E. Ramirez-Cardich, M.D., Orlando Montoya-Herrera, M.Sc., Telmo Fernández, M.D., Valdilea G. Veloso, M.D., Ph.D., Susan P. Buchbinder, M.D., Suwat Chariyalertsak, M.D., Dr.P.H., Mauro Schechter, M.D., Ph.D., Linda-Gail Bekker, M.B., Ch.B., Ph.D., Kenneth H. Mayer, M.D., Esper Georges Kallás, M.D., Ph.D., K. Rivet Amico, Ph.D., Kathleen Mulligan, Ph.D., Lane R. Bushman, B.Chem., Robert J. Hance, A.A., Carmela Ganoza, M.D., Patricia Defechereux, Ph.D., Brian Postle, B.S., Furong Wang, M.D., J. Jeff McConnell, M.A., Jia-Hua Zheng, Ph.D., Jeanny Lee, B.S., James F. Rooney, M.D., Howard S. Jaffe, M.D., Ana I. Martinez, R.Ph., David N. Burns, M.D., M.P.H., and David V. Glidden, Ph.D., for the iPrEx Study Team*

ABSTRACT

BACKGROUND

Antiretroviral chemoprophylaxis before exposure is a promising approach for the prevention of human immunodeficiency virus (HIV) acquisition.

METHODS

We randomly assigned 2499 HIV-seronegative men or transgender women who have sex with men to receive a combination of two oral antiretroviral drugs, emtricitabine and tenofovir disoproxil fumarate (FTC–TDF), or placebo once daily. All subjects received HIV testing, risk-reduction counseling, condoms, and management of sexually transmitted infections.

RESULTS

The study subjects were followed for 3324 person-years (median, 1.2 years; maximum, 2.8 years). Of these subjects, 10 were found to have been infected with HIV at enrollment, and 100 became infected during follow-up (36 in the FTC–TDF group and 64 in the placebo group), indicating a 44% reduction in the incidence of HIV (95% confidence interval, 15 to 63; P=0.005). In the FTC–TDF group, the study drug was detected in 22 of 43 of seronegative subjects (51%) and in 3 of 34 HIV-infected subjects (9%) (P<0.001). Nausea was reported more frequently during the first 4 weeks in the FTC–TDF group than in the placebo group (P<0.001). The two groups had similar rates of serious adverse events (P=0.57).

CONCLUSIONS

Oral FTC–TDF provided protection against the acquisition of HIV infection among the subjects. Detectable blood levels strongly correlated with the prophylactic effect. (Funded by the National Institutes of Health and the Bill and Melinda Gates Foundation; ClinicalTrials.gov number, NCT00458393.)

The authors' affiliations are listed in the Appendix. Address reprint requests to Dr. Grant at the J. David Gladstone Institutes, University of California at San Francisco, 1650 Owens St., San Francisco, CA, 94158, or at robert.grant@ucsf.edu.

*Other members of the Preexposure Prophylaxis Initiative (iPrEx) study team are listed in the Supplementary Appendix, available at NEJM.org.

This article (10.1056/NEJMoa1011205) was published on November 23, 2010, and updated on December 1, 2010, at NEJM.org.

N Engl J Med 2010;363:2587-99.

- PrEP is highly efficacious
  - 95% if highly adherent, up to 50% with moderate adherence
- PrEP is underused
  - 1,230,000 persons in US eligible for PrEP (MMWR 11/27/15)
- PrEP uptake is far from optimal

"Why do these Gaps Exist?" Theory-Based Approach

Why is there a gap between evidence and practice?

Consult frameworks and theories in implementation science

Consult relevant frameworks and theories in a particular area of social science or psychology

Peruse primary literature to sharpen your understanding of the problem

Apply your own contextual knowledge, local network, consult stakeholders to further shape your diagnosis

Invest in a formulation of a diagnosis

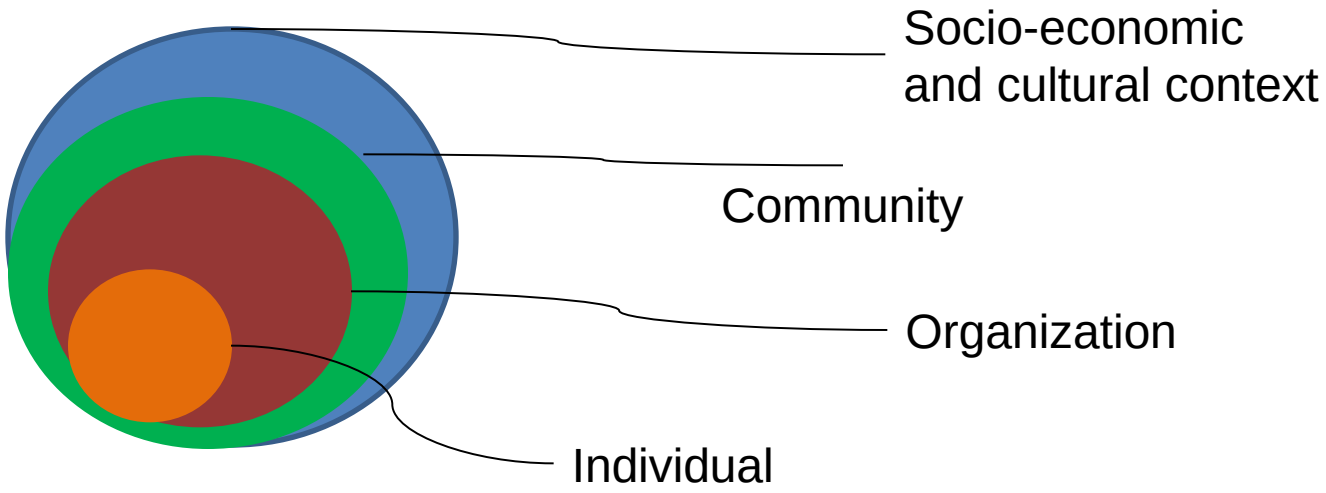
Propose research which is embedded in existing discourse; builds on what is known; adds to body of knowledge

Understand Reasons for the Gap

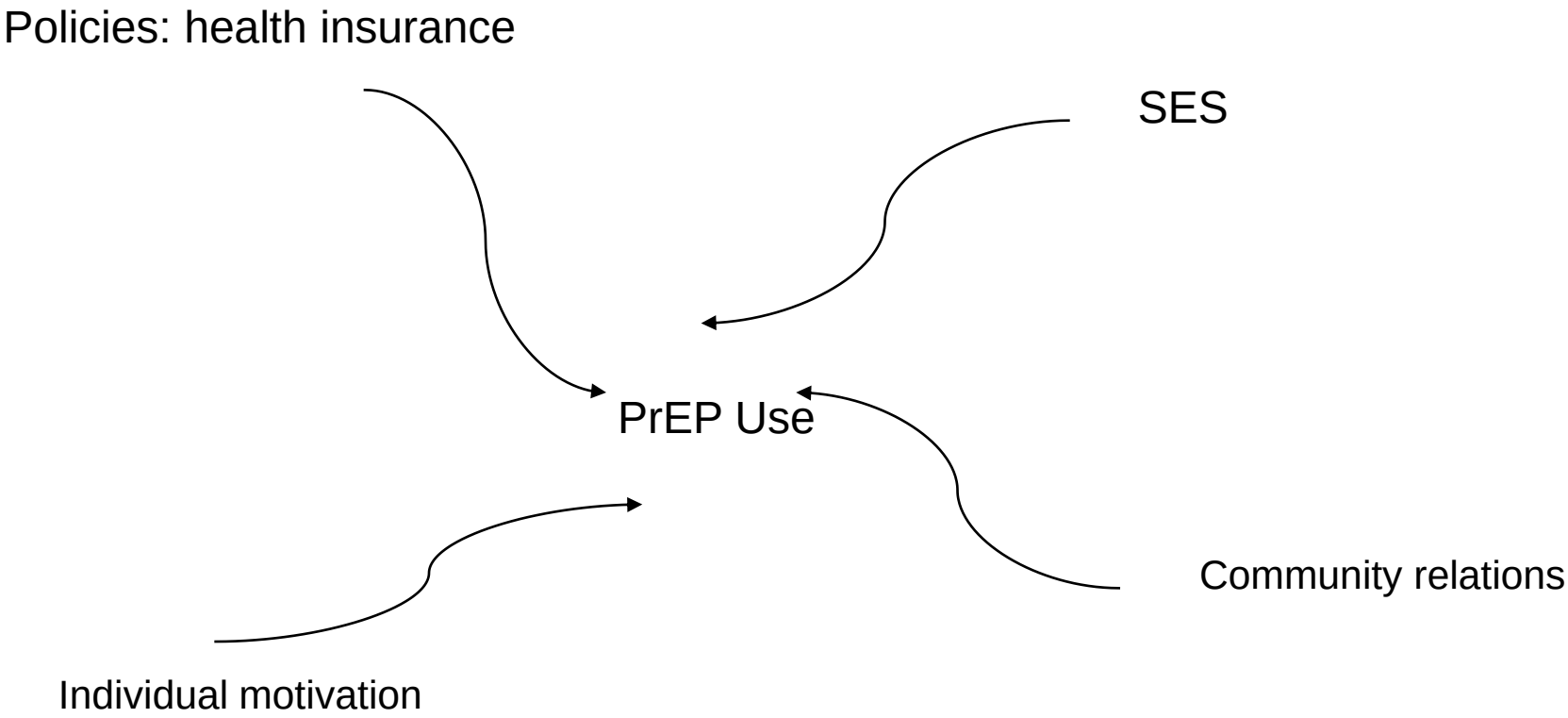
- Use theory when you seek to understand the reasons for a gap between evidence and practice
  - Socio-ecological models
  -Diffusion of innovation
  -COM-B
  -Health belief models
  -Theory of Change **PRECEDE**
  -CFIR (Consolidated Framework for Implementation Research)

- Use your practiced based and contextual knowledge

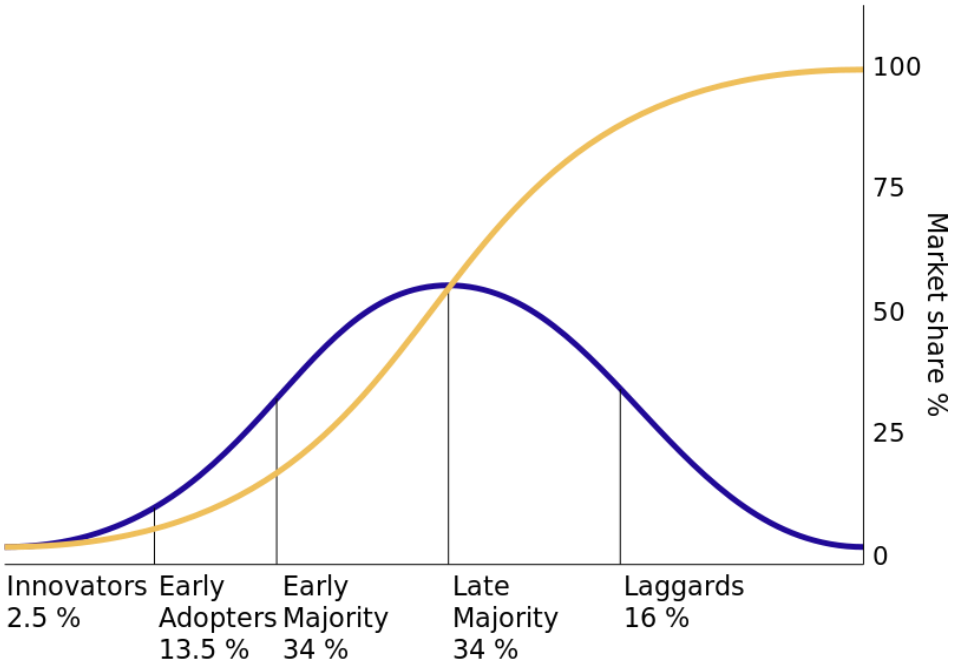
Socio-Ecological Models



Smedley BD, Institute of Medicine. Promoting Health 2000.


Policies: health insurance
SES
PrEP Use
Community relations
Individual motivation

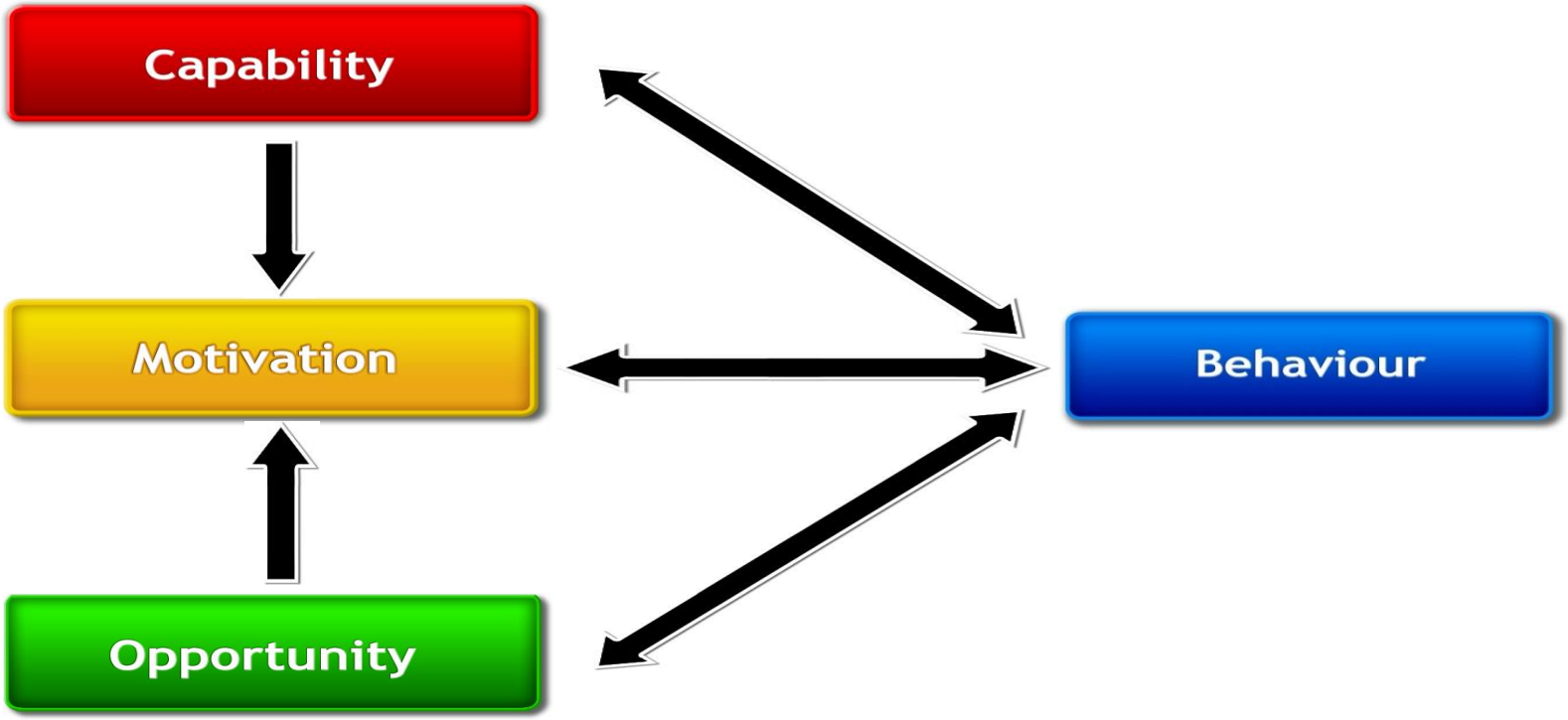
Rogers' Diffusion of Innovations



- Quantify the gap *numerically*
  - 50% of people doing X
- Quantify the gap *socio-behaviorally*
  - Innovators
  - Early adopters
  - Early majority
  - Late majority
  - Laggards

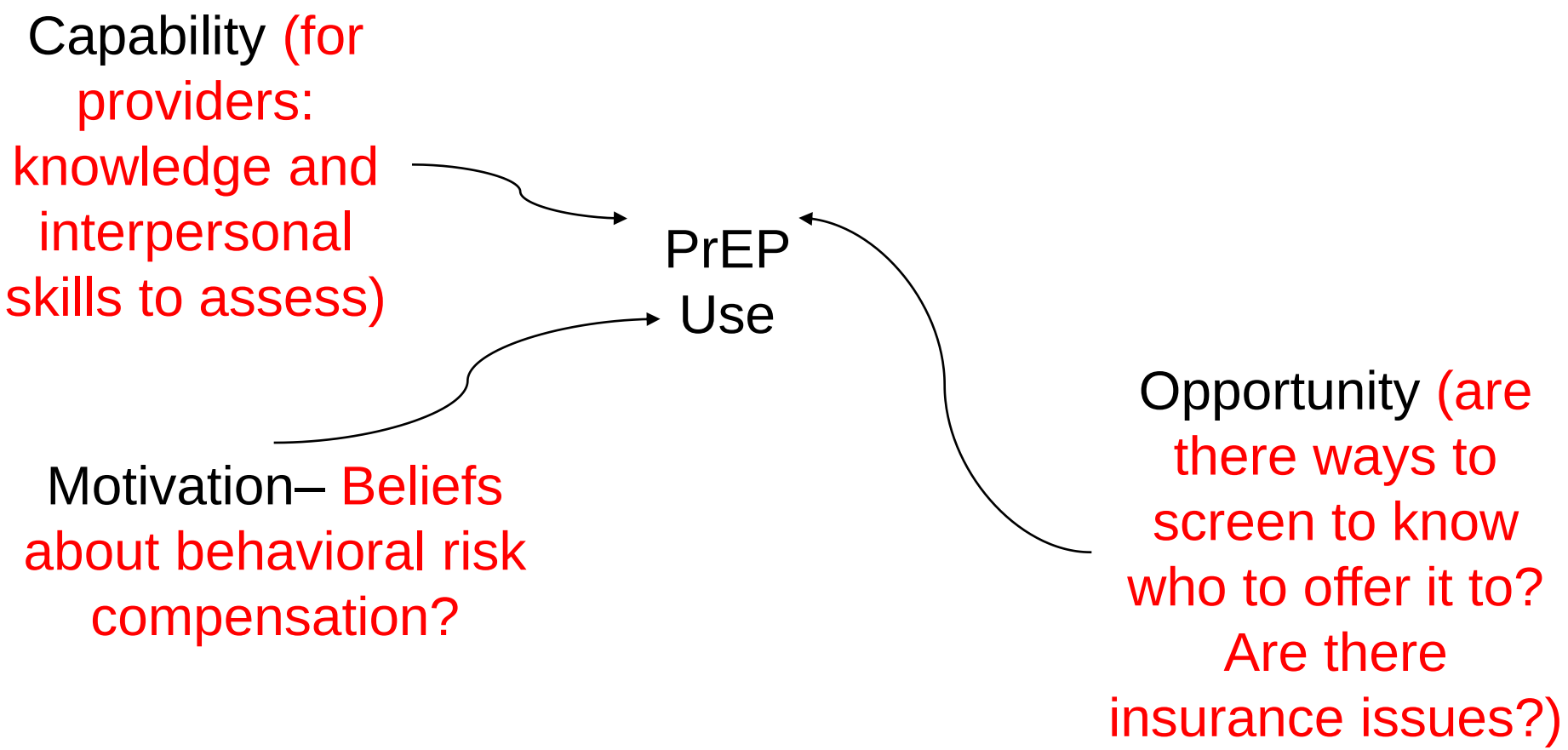
Rogers, Everett M. Diffusion of innovations. Simon and Schuster, 2010.

Elucidate and Explain: COM-B

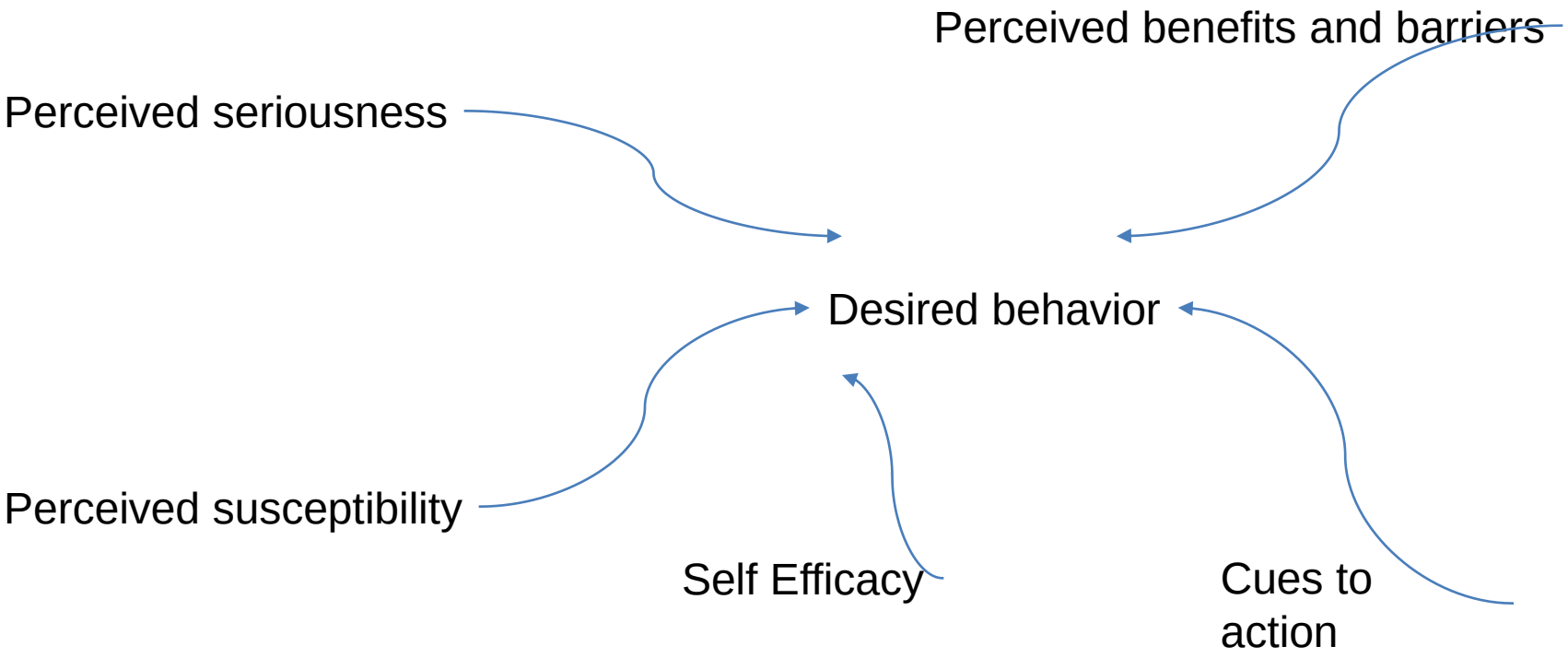


Michie et al (2011) *Implementation Science*

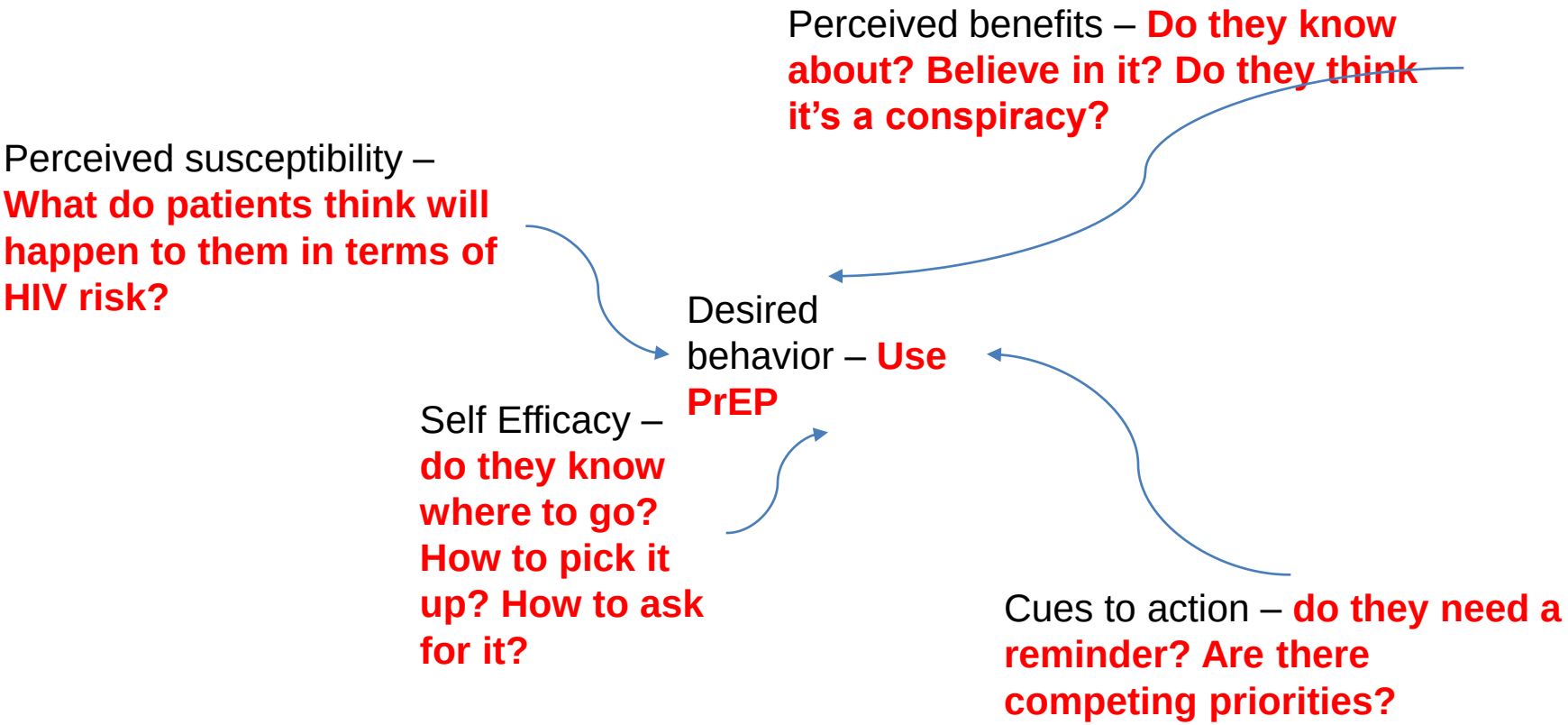
Apply COM-B to the PrEP Problem



Health Belief Model



Apply Health Belief Model to the PrEP Problem



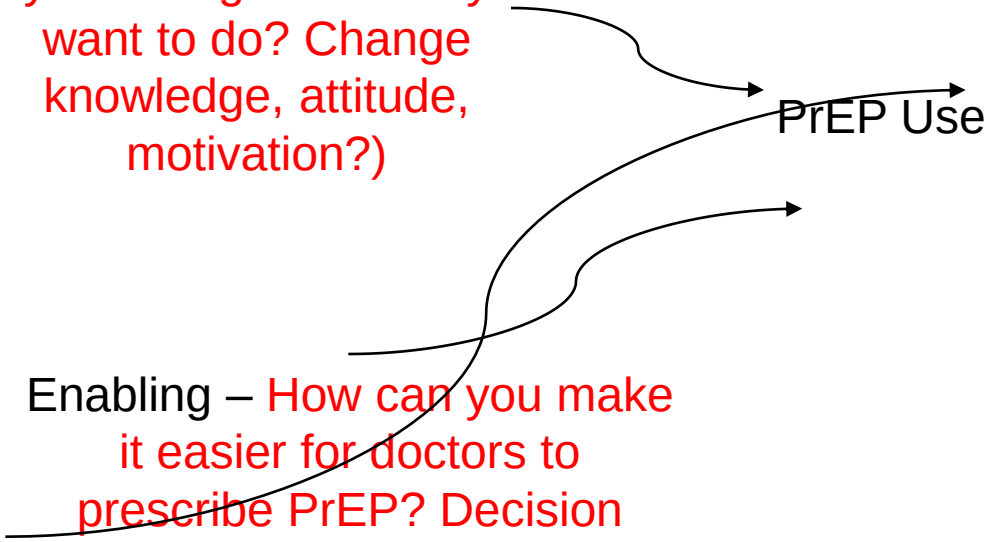
Theory of Change PRECEDE

- *Predisposing, Reinforcing and Enabling Constructs in Educational Diagnosis and Evaluation*
- **Predisposing:**
  - Knowledge or information that inclines or influences a person to a particular behavior
- **Enabling**:
  - Materials or skills that facilitate the desired behavior
- **Reinforcing**:
  - Anticipated rewards to consequences of behavior24

Green, Lawrence W., and Marshall W. Kreuter. "Health program planning: An educational and ecological approach." (2005).

Apply PRECEDE to the PrEP Problem

Predisposing (for providers – how will you change what they want to do? Change knowledge, attitude, motivation?)

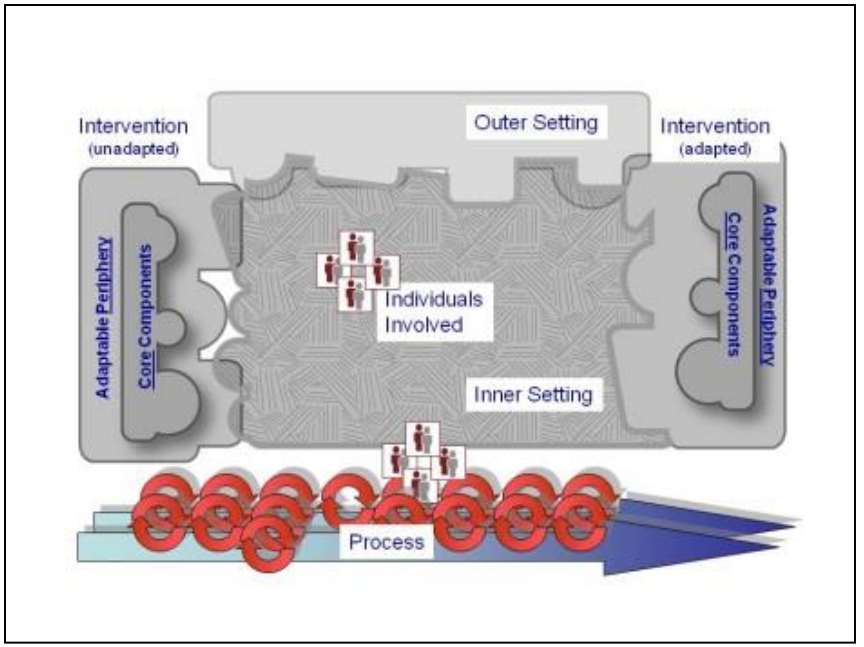


Enabling – How can you make it easier for doctors to prescribe PrEP? Decision support? Order bundles? Through an app (rather than in person?)

Reinforcing (How can you create incentives to offer PrEP? Make PrEP perscription rates reported? Dashboards?)

CFIR: Have you captured the universe of considerations?

- A “meta-theory” perhaps?
- The CFIR comprises five major domains
  - **Intervention** characteristics
  - **Outer setting**: policy, economic, political and social context
  - **Inner setting**: organizational characteristics
  - **Individuals**: actors in the system
  - **Process**: behavior change blueprint



(Damschroeder Imp Sci 2009)

Intervention Characteristics

- Intervention source
- Evidence strength perception
- Relative advantage
- Adaptability
- Trialability
- Complexity
- Design quality and packaging

Outer Setting

- Patient needs and resources
- Cosmopolitanism
- Peer pressure
- Policy environment

Inner Setting

- Structural characteristics of organization
- Networks and communications
- Culture
- Implementation climate (tension for change)
- Readiness of implementation

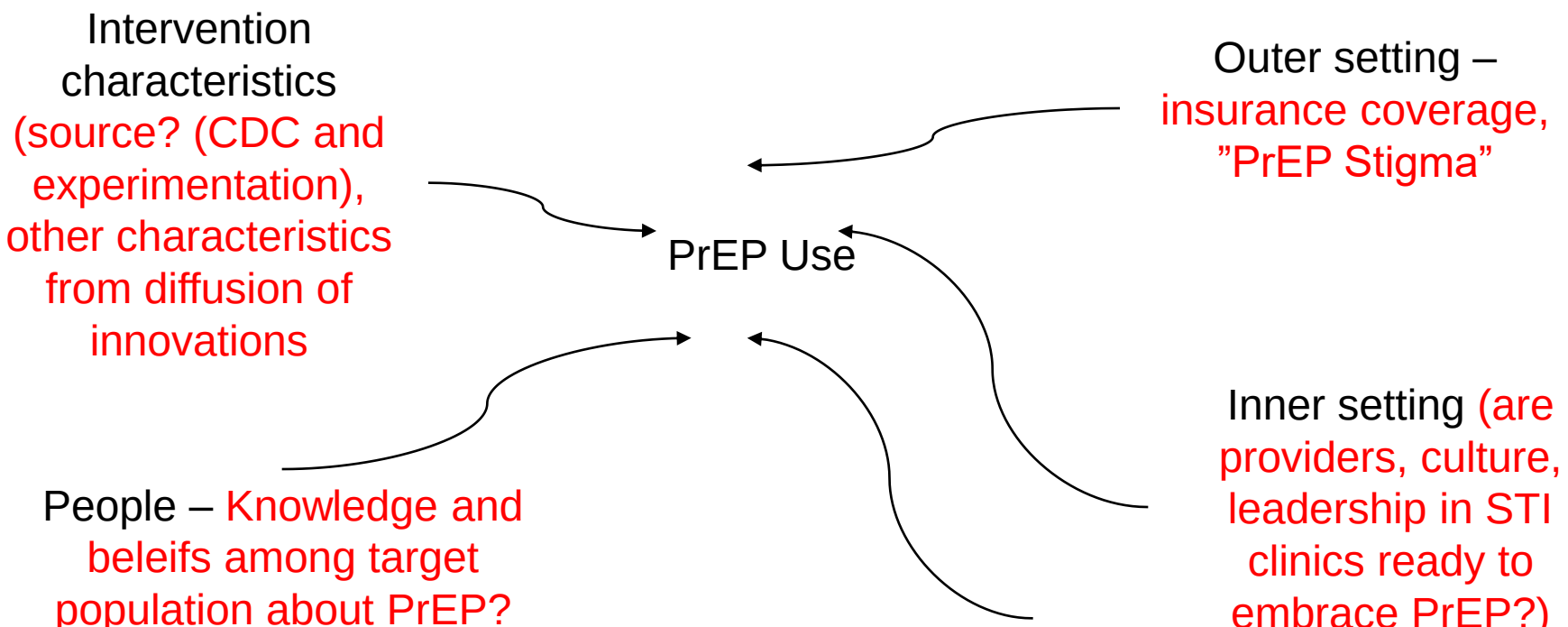
People

- Knowledge and beliefs about the intervention
- Self efficacy
- Individual stages of change
- Individual identification with the organization

Processes

- Planning
- Engaging
- External change agents
- Execution
- Reflecting and evaluating

Apply CFIR to the PrEP Problem



Implementation strategies to close the Gap

- *Systematic intervention process to adopt and integrate evidence-based healthcare innovations into usual care*

Implementation strategies to Close the Gap

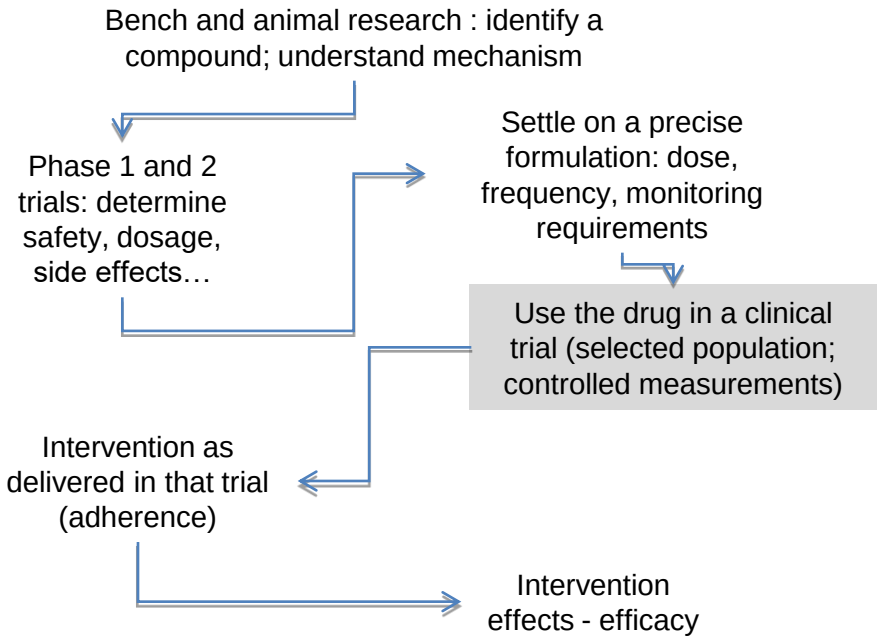
Something done to close the gap between evidence and practice

- Evidence-based **clinical intervention** might be **dolutegravir and Truvada for HIV infection** (non-toxic, potent)

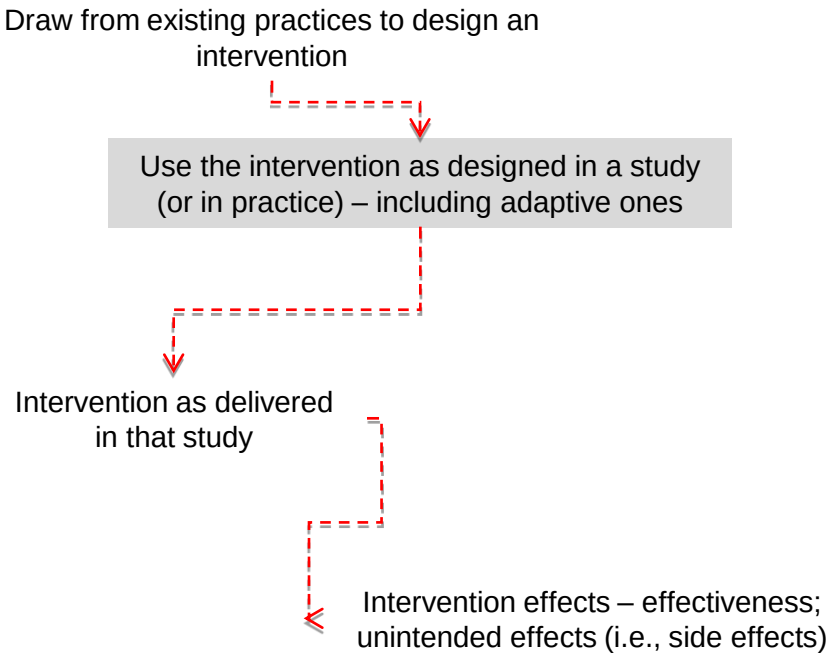
- An "**implementation strategies/intervention**" might be **adherence counseling using motivational interviewing techniques to increase adherence to that medication**

Why are Implementation Interventions Tricky?

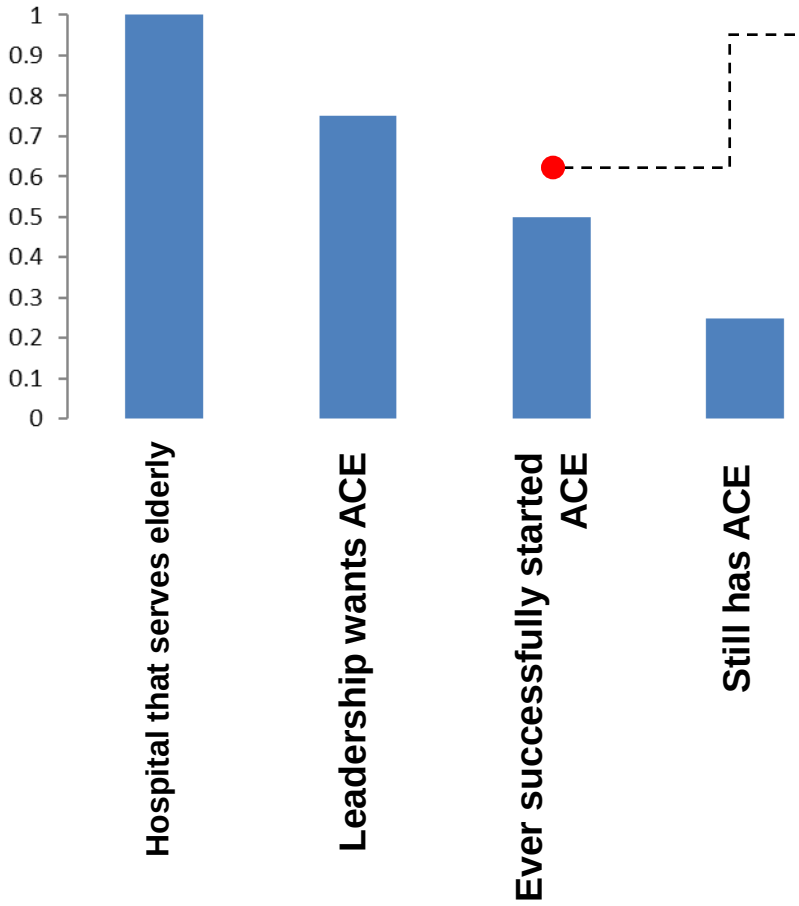
Clinical/Public Health Intervention (often a pharmacologic intervention)



Implementation Strategy (often a behavioral intervention)



From Gap, to Gap Analysis, to Implementation Intervention



We have identified a gap and analyzed the reasons for it…

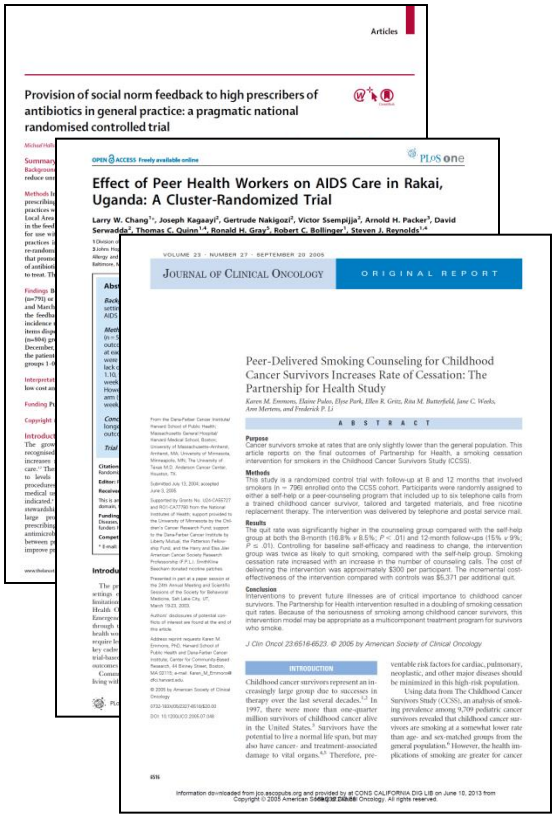
You want to change the <u>behavior</u> of the health system, organization, health care worker, patient or community to close that gap

An approach to conceptualize the interventions or strategies to close this gap

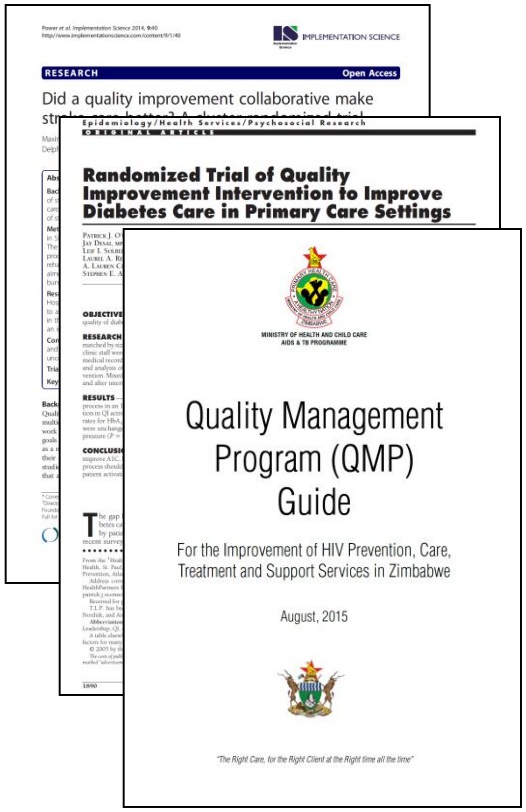
Implementation strategies/Interventions: Examples…

Incentives

Social Networks



Quality Improvement



Implementation strategies/Interventions: Examples…

- Patient behavior change
- Community behavior change
- Health care provider behaviour change
- Organizational behavior change
- Others changes such as political commitment, cultural change, financial system change, laws and governance change

Implementation research

*"**Implementation research** is:*

-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, Implementation Science, 2007

Implementation research designs

- No “study designs” specific to implementation science
- Any study design to develop and test implementation strategies
- Observational
  - Clinic or community based observational cohorts
  - Natural experiments
    - Regression discontinuity, difference in difference, and instruments
- Experimental
  - Implementation studies
  - Hybrid studies
  - Pragmatic randomized trials
  - Stepped wedge trials
- Qualitative work
- Economic study designs

Implementation research key variables

- Behaviors of healthcare professionals and support staff
- Culture/context of healthcare organizations
- Healthcare consumers and family members
- Policymakers

Implementation research key study pops

- Healthcare professionals and support staff
- Healthcare organizations/health care programs
- Healthcare consumers and family members
- Policymakers

Implementation outcomes

- Distinct from clinical outcomes

- an effective Intervention, poorly implemented
- an ineffective treatment, successfully implemented

  - **Acceptability**
  - **Adoption**
  - **Appropriateness**
  - **Costs**
  - **Feasibility**
  - **Fidelity**
  - **Penetration**
  - **Sustainability**

Mechanisms for translation of evidence into practice

- Establishing a **permanent, built-in mechanism** to relay relevant findings of research to decision / policy makers / programme managers / public health workers.
- Restructuring or forming pro-active **research utilization committees** as change agents in the **research institutions** and **ministries of health**.
- **Making the research based recommendations as simple and practical as possible** taking into account the existing system of the health care system
- Developing **a validation system for research findings** of national and regional significance.
- Making **research journals that contain functional research projects easily accessible to health professionals** in order to create a research-friendly atmosphere.

M Htwe, SP Jost Promoting the application of research findings in health development. Regional Health Forum, 1997

Strategies for translation of evidence to policy

- Influencing Policy Through Participatory Research
- Communicating with Policymakers (eg. policy briefs)
- Stakeholders and Information Brokers in the Policy Process
- Reaching Policymakers through the Media
- Funding to Translate Research into Policy