NEW ENGLAND HIV IMPLEMENTATION SCIENCE NETWORK

WORK GROUP MEETINGS AND WORKSHOPS - Friday, February 27, 2015 Sturbridge, Massachusetts

Overview of Implementation Science Frameworks with Examples
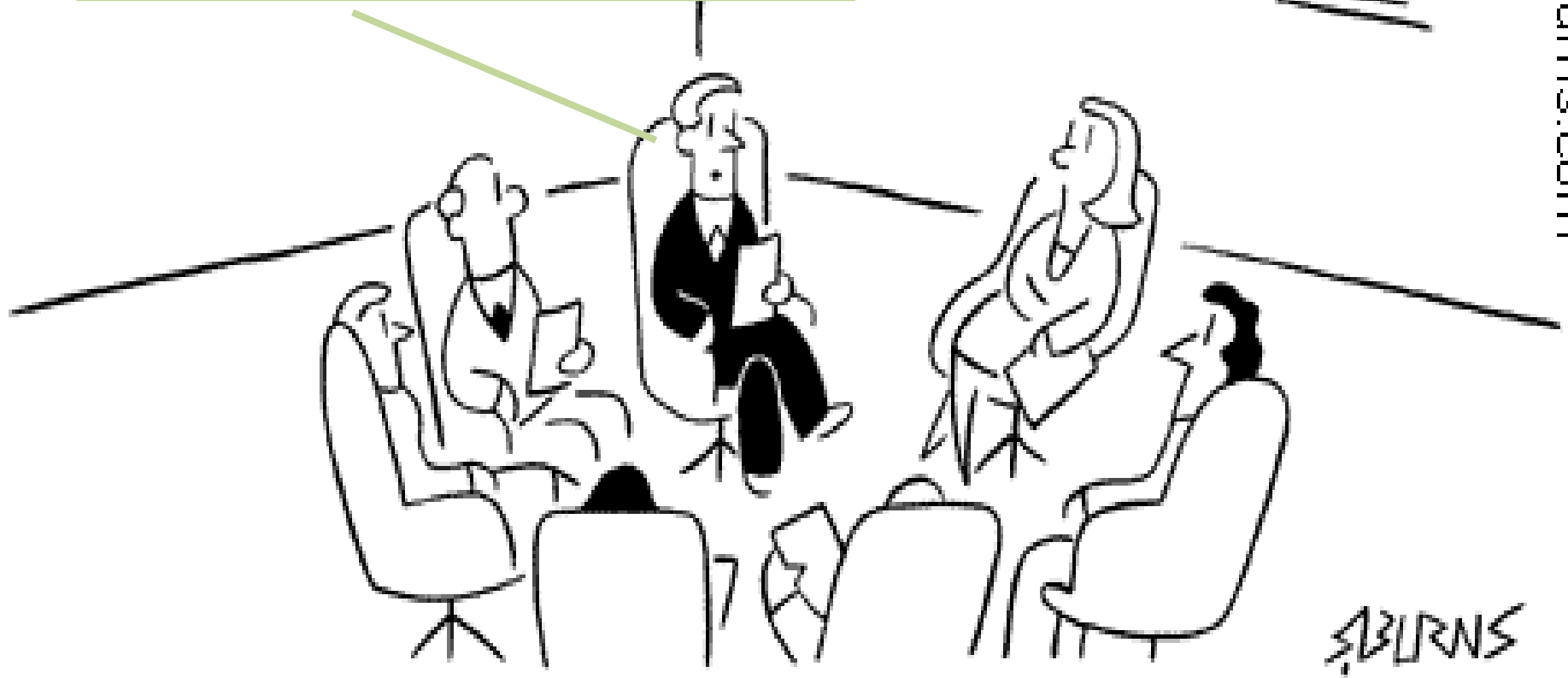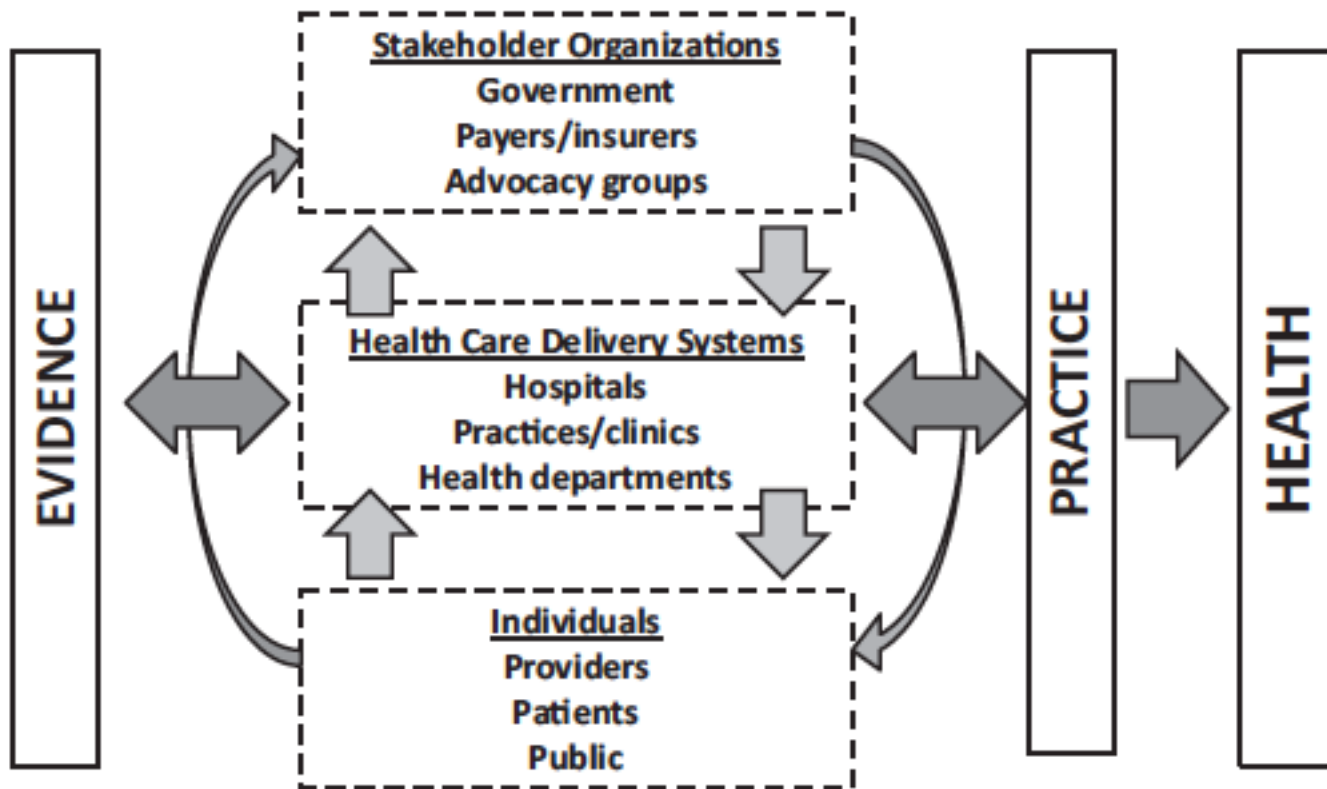
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EVIDENCE

Stakeholder Organizations
Government
Payers/insurers
Advocacy groups

Health Care Delivery Systems
Hospitals
Practices/clinics
Health departments

Individuals
Providers
Patients
Public

PRACTICE

HEALTH

Standard Implementation Outcomes

- Acceptability
- Adoption
- Appropriateness
- Feasibility
- Fidelity
- Implementation cost
- Penetration
- Sustainability
- Effectiveness (Hybrid Designs)

Why consider implemenatation frameworks?

- "Conceptual models, frameworks, and systems can play a critical role in anchoring a research study theoretically by portraying the key variables and relationships to be tested.

- in a review of 235 implementation studies, less than 25% of the studies employed theory in any way, and only 6% were explicitly theory-based.

- Given the confusion surrounding definitions and terminology within the still evolving field of dissemination and implementation [research], grant proposals need to employ consistent language, clear definitions for constructs, and the most valid and reliable measures.

- Proposal writers should be cautioned that the theory or conceptual model used to frame the study must be used within the application. A mere mention will not suffice."

Theories, models, frameworks

- Systematic method for studying implementation phenomenon:
  - Identifying
  - Understanding
  - Operationalizing
  - Evaluating
- Examples
  - RE-AIM
  - Getting to Outcomes (GTO)
  - PRISM (Practical Robust Implementation Sustainability Model)
  - PRECEDE-PROCEED
    - (**P**redisposing, **R**einforcing and **E**nabling **C**onstructs in **E**ducational **D**iagnosis and **E**valuation- **P**olicy, **R**egulatory, and **O**rganizational **C**onstructs in **E**ducational and **E**nvironmental **D**evelopment)
  - PARiHS – (Promoting Action on Research Implementation in Health Services)
  - CFIR (Consolidated Framework for Implementation Research)
  - Hybrid Designs

RE-AIM

- RE-AIM - Consists of five elements, or dimensions, that relate health behavior interventions:
  - Reach the target population
  - Efficacy or effectiveness
  - Adoption by target settings or institutions
  - Implementation - consistency of delivery of intervention
  - Maintenance of intervention effects in individuals and populations over time

Reach

The absolute number, proportion, and representativeness of individuals who participate in a given program

Effectiveness

The impact of an intervention on important outcomes. This includes potential negative effects, quality of life, and costs.

Adoption

The absolute number, proportion, and representativeness of settings and staff who are willing to offer a program.

Implementation

At the setting level, implementation refers to how well intervention in provided. This includes consistency of delivery as intended and the time and cost of the program.

Maintenance

The extent to which a program or policy becomes part of the routine organizational practices and policies. Within the RE-AIM framework, maintenance also applies at the individual level.

RE-AIM - NIAID

- The objective of this proposal is to determine if home sputum collection, supported by targeted, mobile-phone health (mHealth) messages and incentives, is an effective and scalable solution for overcoming barriers to implementing contact investigation.
  - Household-randomized, controlled trial in five rural Ugandan communities
  - Comparing two approaches to evaluation of at-risk contacts
    - referral to clinics for TB testing (standard approach) vs. home sputum collection supported by mHealth interventions.
- Use the **RE-AIM** framework to assess the patient and public-health impact of these interventions, using pre-specified measures of their reach, effectiveness, adoption, implementation, and maintenance.
  - Determine if mHealth-facilitated home sputum collection increases rates of TB and **HIV** diagnosis and clinic follow-up (reach), TB treatment initiation (effectiveness), and completion (maintenance), as compared to standard contact investigation.
  - Use quantitative and qualitative methods to evaluate the internal effectiveness and fidelity of the component interventions across different sites (adoption).
  - Use economic and epidemic modeling to estimate the costs and epidemiological impact of this intervention (implementation).

RE-AIM - NIDA

- Purpose is to provide multisystem data to evaluate the implementation of **ART for all HIV+** and help determine the most efficient use of available resources for achieving the policy goal. The design and methods are informed by the **ecological systems model**, while the **RE-AIM** model guides the overall assessment of the implementation of the new policy.

- The study aims are:
  - 1) to assess durable viral suppression within 12 months of diagnosis among a) STD clinic cohort (N = 300) with problem substance use, and b) all new HIV diagnoses in NYC occurring during the project funding period (N=approximately 3,400/year);
  - 2) to assess key indicators along the HIV treatment cascade among the STD clinic cohort as the percentage who (a) link to HIV care; (b) receive a recommendation to initiate ART; (c) initiate ART treatment; and (d) adhere to ART treatment;
  - 3) to assess multisystem predictors of durable viral load suppression and other HIV treatment cascade indicators among the STD clinic cohort and cohort of all new HIV diagnoses in NYC, to include individual (e.g., race/ethnicity, substance use) and geospatial factors (e.g., socioeconomic conditions, social disorder, social cohesion, and spatial access to HIV-related healthcare);
  - 4) to describe and contextualize quantitative outcomes in Aims 1-3 using STD cohort qualitative data;
  - 5) to describe the adoption, implementation, and maintenance of HIV treatment policies among HIV primary care providers

RE-AIM - NCI

- Propose a two- phase cluster-randomized trial of implementation strategies for cervical cancer prevention in western Kenya.

- Phase 1, communities will be randomized to HPV-testing in either community-health campaigns or in clinics, with standard referral for treatment of HPV+ women to government facilities. We will use the **RE-AIM** framework to assess the key outcomes; we will then work in partnership with the community to develop a strategy for enhanced linkage to care.

- Phase 2, all communities will offer community-based testing with enhanced linkage to care.

- Conducting this cluster-randomized trial will enable us to assess the proportion of women in each community who get cervical cancer screening, the gain in treatment access with enhanced linkage to care, and the cost-effectiveness of the two interventions.

- The **RE-AIM** framework will allow us to measure and refine the context-specific dimensions of the project to produce a "toolkit" for scale-up within this region and implementation into similar settings.

GETTING TO OUTCOMES (GTO)

1) **Identifying** the needs and resources
2) **Setting goals** to meet the identified needs,
3) Determining what **evidence based (EBP) or evidence-informed practices** exist to meet the needs,
4) Assessing actions that need to be taken to ensure that the EBP **fits** the organizational or community context
5) Assessing what organizational **capacities** are needed to implement the practice or program
6) Creating and implementing a **plan** to develop organizational capacities in the current organizational and environmental context
7) Conducting a **process evaluation** to determine if the program is being implemented with fidelity
8) Conducting an **outcome evaluation** to determine if the program is working and producing the desired outcomes
9) Determining, through a **continuous quality improvement process**, how the program can be improved
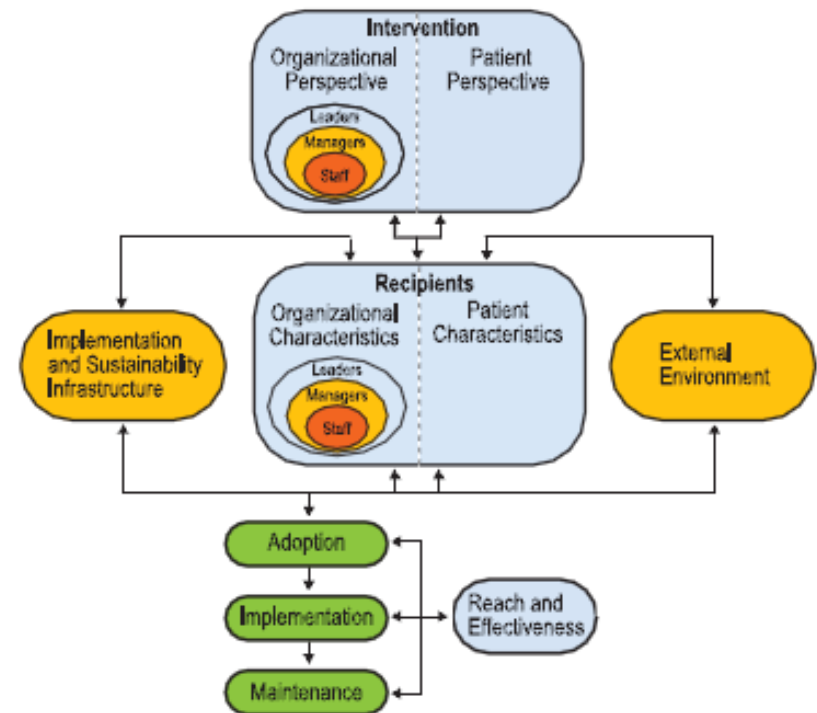10) Taking steps to ensure **sustainability** of the program

GTO- NICHD

- Use a randomized controlled design and primary data from middle school youth (N=960) and program staff from 32 cooperating Boys and Girls Clubs to assess how a capacity building intervention called Getting To Outcomes augments the quality of implementation of a research-based intervention to improve teen sexual health (Making Proud Choices, MPC).

- The study will: (1) Assess the utilization of and subsequent effects of GTO on program staff capacity to implement MPC; (2) Assess the degree to which Clubs using GTO show greater improvements in MPC fidelity than Clubs that are not using GTO; and (3) Assess the degree to which Clubs using GTO show greater improvements on teen sexual health outcomes than the comparison Clubs.

PRISM: Practical, Robust Implementation and Sustainability Model

- 4 Domains:
  - Intervention Design
  - Recipients
  - External Environment
  - Implementation & Sustainability Infrastructure

The Practical, Robust Implementation and Sustainability Model (PRISM)

See references: Feldstein & Glasgow, 2008

PRISM- NICHD

- Informed by Social Action Theory, (SAT); and the prism (Practical, Robust Implementation and Sustainability Model) theoretical framework, VUKA is a cartoon-based intervention developed with intensive input from South African investigators, graphic artists, medical staff, adult caregivers and HIV+ adolescents.

- We propose a full-scale RCT to examine the effectiveness, implementation, and integration processes associated with VUKA with a sample of 360 HIV+ early adolescents (9 to 14 years of age) registered at 4 publicly financed pediatric HIV clinics in KwaZulu Natal. Youth and their family members will be randomly assigned to one of two study conditions: 1) VUKA or; 2) standard of care.
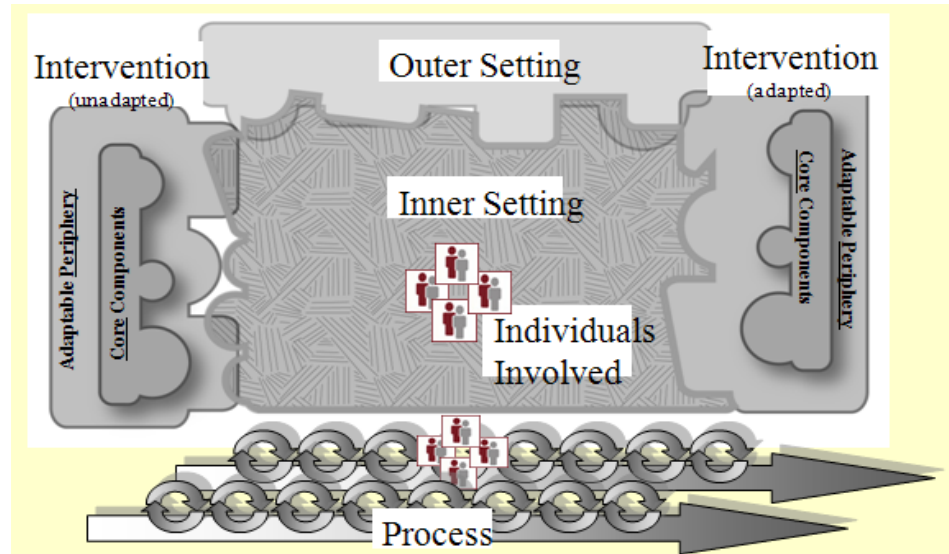
Consolidated Framework For Implementation Research (CFIR)

- A pragmatic structure for approaching complex, interacting, multi-level, and transient states of constructs in the real world by embracing, consolidating, and unifying key constructs from published implementation theories

Consolidated Framework For Implementation Research (CFIR)

- 5 major domains:
  - Intervention characteristics (8 constructs)
    - Evidence strength, quality
  - Outer setting (4 constructs)
    - Patient needs, resources
  - Inner setting (12 constructs)
    - Culture, leadership engagement
  - Characteristics of the individuals involved (5 constructs)
  - Process of implementation (8 constructs)
    - Plan, evaluate, reflect

CFIR - NIDA

- We propose a multi-stakeholder Research Center to promote EBPs addressing challenges in juvenile probationers' linkage to behavioral health services. We are guided by the **CFIR** to support acceptability, feasibility, and sustainability.
  - Aim 1 - measure current system capacity in 4 NY counties to (a) identify behavioral health needs and HIV risks in justice-involved youths, and (b) link identified youths to appropriate services. Reviewing what is learned from Aim 1 activities will likely identify service gaps.
  - Aim 2 (Connect Plus Implementation), we will build upon Aim 1 findings to implement a Continuum of Care approach to delivery of behavioral health care in the same counties. Implementing the Continuum approach will likely require enhancing procedures for both identification and linkage across service sectors. We adapt those activities and employ CFIR-informed change process components that include an interlocking set of meeting venues, Quality Assurance activities and a Learning Collaborative to set goals, monitor progress, and address identified barriers, thereby promoting uptake of Connect Plus elements.

Hybrid Designs

- Testing effects of an intervention on relevant outcomes while observing and gathering information on implementation

- Dual testing of effects and implementation interventions/strategies

- Testing of an implementation strategy while observing and gathering information on the intervention's impact on relevant outcomes

Hybrid Type 1

- Testing an intervention while gathering information on its delivery during the effectiveness trial and/or on its potential for implementation in a real-world situation

- Effectiveness emphasized over implementation

Hybrid Type 2

- Simultaneous testing of a clinical intervention and an implementation intervention/strategy

- Effectiveness and implementation get equal emphasis

Hybrid Type 3

- Testing an implementation intervention/strategy while observing/gathering information on the intervention and related outcomes

- Implementation emphasized over effectiveness

Hybrid Type 1 - NIAAA

- Compare the effectiveness of home-based versus clinic-based "Healthy Choices", a brief, 4-session intervention using Motivational Enhancement Therapy (MET) to address alcohol use, medication adherence, and health outcomes in youth living with HIV (YLH).

- Healthy Choices will be tested in a "real world" clinical setting and be delivered by community health workers (CHW), who are already members of the HIV care team.
  - The study population will consist of YLH, ages 16 to 24, who are current patients at 5 ATN sites.
  - Youth will be randomized to receive Healthy Choices, 4-sessions of MET for YLH, either clinic-based or home-based delivered by the same CHW in both conditions.
  - Data collection for biological measures will be conducted through medical record extraction, and self-reported measures will occur using a brief Web-based CASI (computer-administered self-interviewing) survey on an iPad at each site.
  - All intervention sessions will be audio-recorded for MITI fidelity coding, and investigators will support local supervisors during the active intervention phase.
  - We will conduct qualitative interviews with CHWs, supervisors and organization leaders at the end of the trial to obtain critical information about barriers and facilitators of implementation.

- The proposed trial will allow us to use a **Type 1 Effectiveness-implementation hybrid design** to pilot a sustainable model of MI implementation in real-world youth care settings towards the goals of 1) examining the effectiveness, cost-effectiveness, and scalability of an efficacious behavioral intervention when delivered by CHWs in real-world adolescent HIV care settings; 2) gathering information about who responds under what contexts; and 3) increasing our understanding of the barriers and facilitators for future implementation.

Hybrid Type 2 - NIDA

- The proposed study is a Type 2 Effectiveness-Implementation Hybrid Trial.
  - Aim 1 will test the effectiveness of a motivational interviewing-based brief intervention for substance use within community- based HIV/AIDS service organizations, relative to usual care.
  - Aim 2 will test the effectiveness of adding an organizational-level implementation intervention called Implementation & Sustainment Facilitation (ISF) to the implementation strategy currently used by SAMHSA-funded Addiction Technology Treatment Centers.
  - Aim 3 will examine the incremental cost- effectiveness of the ISF implementation intervention.

Modeling/Simulation- AHRQ

- We aim to: 1) define primary models of ED **HIV** screening programs, 2) simulate baseline ED clinical operations, and 3) test and optimize the operational impact of ED **HIV** screening models on ED operations. To obtain robust estimates for simulation parameters, we will perform time-and-motion observations of ED **HIV** screening activities and usual ED operation in the absence of ED **HIV** screening in selected sites. This highly innovative project will have rapid and substantial impact by: i) guiding ED **HIV** screening implementation, ii) spurring innovation in screening program methods, and iii) demonstrating the utility of simulation for **implementation research** involving any number of healthcare initiatives including clinical practice guidelines, error prevention, and reduction of healthcare acquired infections.

Summary

- Theories, frameworks and model provide a systematic method for studying implementation by helping to identify, understand, operationalize and evaluate key phenomenon

- There are a variety of frameworks to choose from, some of which have been employed in funded research

- Hybrid designs allow for the simultaneous evaluation of effectiveness and implementation