RESEARCH INFORMATICS: AN INTRODUCTION AND IMPLEMENTATION SCIENCE

Tsung-Ting (Tim) Kuo

HOUSEKEEPING

- Assignments are due 11:59pm on Tuesdays

PollEv.com/renawu484

OBJECTIVES

Cover core thematic issues in Clinical Research Informatics (CRI)

Define the field of implementation science and how it integrates in CRI

Explore models and frameworks for implementation science

Introduce study designs for implementation science

CURRENT NIH DEFINITION OF CLINICAL RESEARCH

Human subjects research that is:

1. **Patient-oriented research**. *Research conducted with human subjects (or on material of human origin, such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that use human tissues that cannot be linked to a living individual. This definition includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, or (d) development of new technologies.*

2. **Epidemiologic and behavioral studies**.

3. **Outcomes research and health services research**.

Reference: https://orwh.od.nih.gov/toolkit/nih-policies-inclusion/definitions

CLINICAL RESEARCH INFORMATICS (CRI)

" the intersection of biomedical informatics and clinical research"

However, there are several *"emerging domains of CRI that impede its development as a cohesive and distinct discipline"*

We will introduce 12 aspects today

Reference: https://doi.org/10.1197/jamia.M3005

1. RESEARCH PLANNING AND CONDUCT

Lack of explicit and effective connections between CRI platforms and capabilities, and the planning or execution of clinical research efforts, were lacking if not nonexistent.
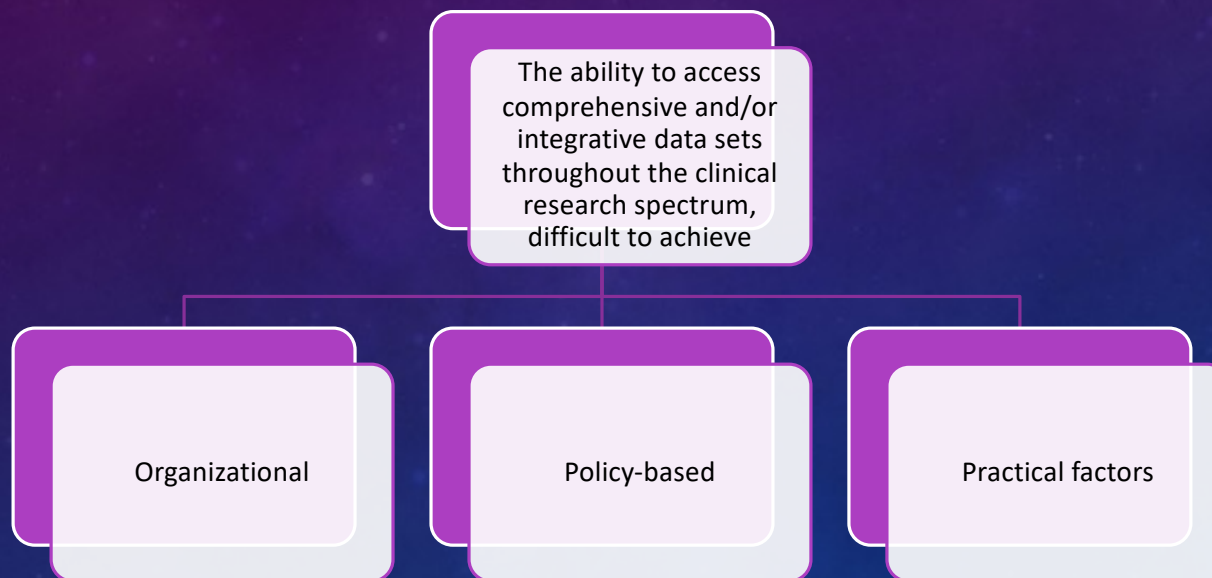
A primary impediment to the realization of the potential benefits in terms of research productivity or capacity afforded by CRI methods and tools.

1. RESEARCH PLANNING AND CONDUCT

"... the issue is that the tools are cumbersome and poorly integrated with the workflow of patient care, and so you can't recruit either the investigators or the patient"

2. DATA ACCESS, INTEGRATION, AND ANALYSIS

The ability to access comprehensive and/or integrative data sets throughout the clinical research spectrum, difficult to achieve

Organizational

Policy-based

Practical factors

2. DATA ACCESS, INTEGRATION, AND ANALYSIS

"the interface between the electronic medical record and the clinical research is critical"

3. EDUCATIONAL NEEDS

Major need to educate:

- Informaticians
- Clinical research investigators/staff
- Senior leadership concerning the theory and practice of CRI

3. EDUCATIONAL NEEDS

Necessary to ensure appropriate:

- Expectation management
- Adoption/use of CRI related methods or tools
- Allocation of appropriate resources to accomplish organizational aims

3. EDUCATIONAL NEEDS

"… it might be worth considering what is the training required, because it is a tremendous leap for a Data Base Administrator (DBA) to understand the regulations for running a clinical trial. It is a tremendous leap for an electronic health records guy. Chief Informatics Officers (CIOs) and academic centers do not get it. No offense. This is a big leap here."

4. FISCAL AND ADMINISTRATIVE ISSUES

The inability to overcome billing compliance issues (e.g., disambiguation of standard-of-care v. research related billable activities in an automated manner)—which are perceived as a primary motivator for the adoption of CRI platforms in many large organizations;

A lack of consistent funding mechanisms for persistent CRI infrastructure (e.g., beyond episodic grant funding mechanisms)

The absence of demonstrable Return On Investment (ROI) or alternative fiscal models that may serve to justify the support of CRI platforms at the organizational level.

4. FISCAL AND ADMINISTRATIVE ISSUES

"….struggling with the appropriateness of tracking research costs and research charges and making sure that we are compliant with that and what is research and what is not. So, there is a whole other set of business processes on the investigator's side that need to be somehow linked and coordinated with processes on the study side"

5. REGULATORY AND POLICY ISSUES

Considerations

- Seen as confusing, misunderstood, and often contradictory.

- Conflict between the regulatory frameworks faced by the clinical and translational sciences and public or governmental demand for safer or more effective therapies

- Due to the desire to systematically protect patient privacy and confidentiality that often constrains the ability to apply informatics techniques to develop and evaluate novel therapies or otherwise conduct clinical research

5. REGULATORY AND POLICY ISSUES

"overly conservative or incorrect interpretations of a regulation can become an inadvertent impediment to clinical research"

6. LEADERSHIP AND COORDINATION

Current state of coordination of current national, regional, and local-scale CRI research programs which appear to be focusing on the same essential aims

Policy and fiscal barriers that prevented coordination—thus exacerbating this particular problem

6. LEADERSHIP AND COORDINATION D

"absent leadership from CRI sitting at the table in the Regent's meeting and at the Hospital board meeting and in the corridors of the Capitol, there is little hope of the software developer curing the problem"

7. RECRUITMENT ISSUES

Well validated approaches and associated informatics platforms designed to improve subject recruitment to clinical trials have been developed

(However,) the ability to readily adopt and deploy such tools and approaches in "real world" setting is impeded by both a lack of applicable standards and a set of policy-based barriers surrounding the use of clinical data to enable such applications

7. RECRUITMENT ISSUES

"They try to target as best they can but there is under-performance that causes them to have to do rescues mid-way through. They have to close down sites, start up new sites. They cannot get a good handle on how to predict or estimate, or enhance and augment recruitment"

8. SCOPE OF CRI

CRI and its definition was still very ambiguous and often misunderstood? As an outgrowth of this finding, the definition of CRI presented in our results was developed and validated

Clinical research (superset) vs.

Clinical trials (subset)

8. SCOPE OF CRI

"(We should) expand our vision from clinical trials to encompass all of clinical research, because I think this is going to be critical as we move forward. It is not just the trials. It is the outcomes, the biomarkers. It is the epidemiology studies."

9. SOCIO-ORGANIZATIONAL ISSUES

Local policy-based objections

Need for greater integration between institutional clinical, research, and educational mission areas

Lack of sufficient resources as needed to implement robust CRI research, development, and support efforts

9. SOCIO-ORGANIZATIONAL ISSUES

"one of the biggest challenges coming is actually integrating the research mission into the academic health care environment and ensuring that (removal of) these barriers that we have to data and systems and use of them for research is able to happen"

10. STANDARDS

greatly impeded by both the large number of competing standards available to select from

absence of appropriate standards or approaches capable of supporting information exchange between the basic science, clinical research, and clinical practice domains

11. WORKFLOW

01
Lack of integration with existing or optimized clinical research workflows, thus impeding their adoption

02
Need increased focus on the development and validation of workflow optimization and informatics intervention strategies for the clinical research domain

03
Workflow issues arose in the context of the intersection of clinical research activities and clinical care

12. INNOVATION AND INVESTIGATION

Understanding of the essential or high priority scientific problems and research foci needed to advance the discipline of CRI is lacking

"Research-on-research" to advance the discipline

Need for greater coordination across national research efforts and funding agencies to catalyze and support the definition of key CRI research problems and corresponding research agendas

12. INNOVATION AND INVESTIGATION

"Academic promotion committees do not require or reward data sharing or data standardization efforts"

POTENTIAL DIRECTIONS

a. There is a critical need for the development of targeted policy and/or research agendas, driven by the CRI Community, to inform the structure and function of research programs and funding mechanisms at all levels

b. Trusted and widely accessible mechanisms for the sharing of knowledge, best practices, and technologies targeting the theory and application of CRI must be established

c. Greater advocacy for the rationalization of regulatory frameworks with clinical research informatics as a key component for consideration alongside clinical and public health concerns must be established

d. Professional organizations, such as AMIA, should play a role to help overcome certain CRI challenges and catalyze the development of broad CRI solutions by bringing together key stakeholders and serving as impartial, coordinating entities

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IMPLEMENTATION
SCIENCE

IMPLEMENTATION

Implementation science is the study of methods to promote the adoption and integration of evidence-based practices, interventions, and policies into routine health care and public health settings to improve the impact on population health.
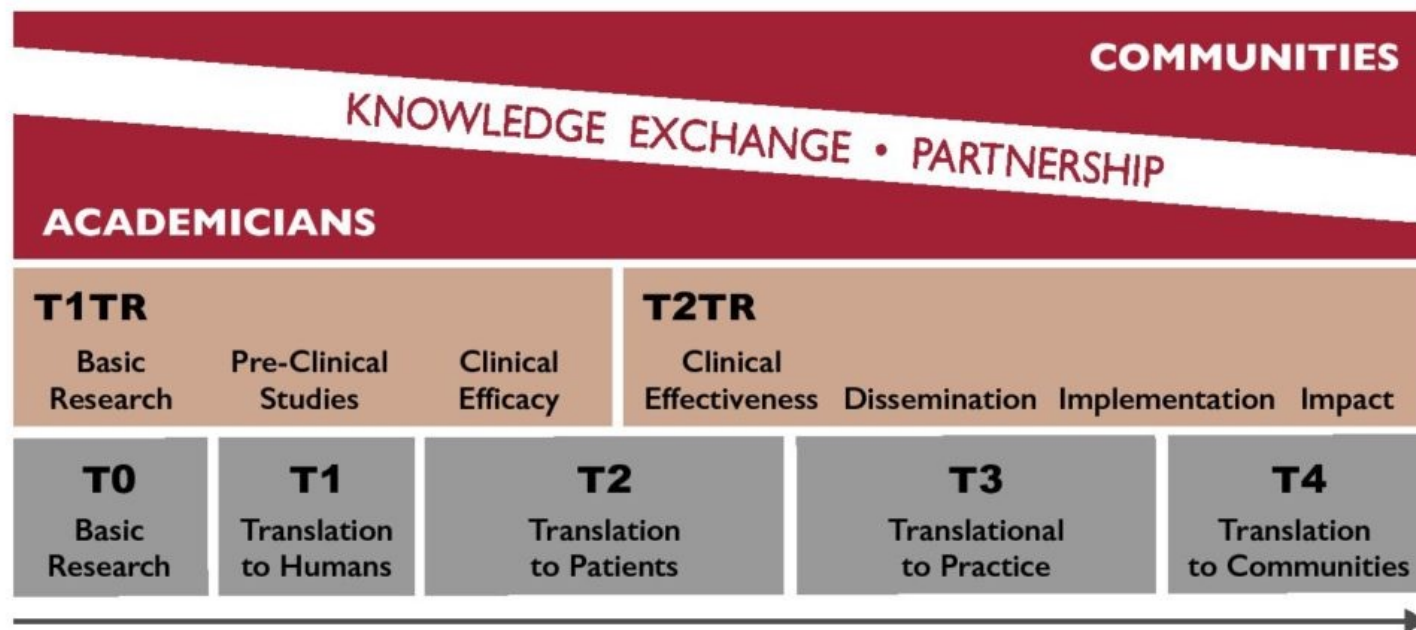
U.S. Department of Health & Human Services | National Institutes of Health
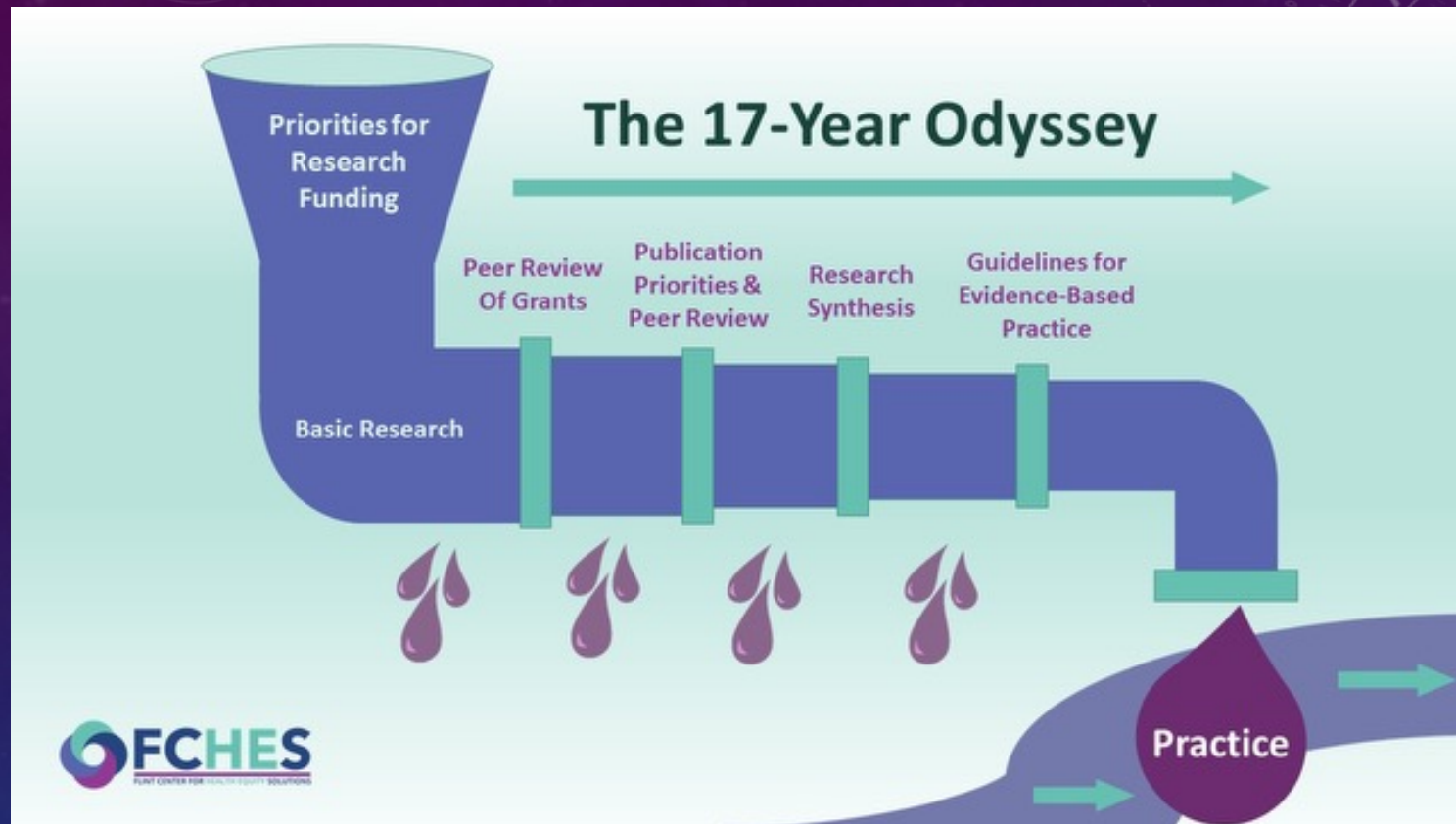
Implementation Science at a Glance

A Guide for Cancer Control Practitioners

"It takes **17 years** to turn **14% of original research into services** that are routinely provided in community service settings."

Reference: https://flintcenter.org/our-cores/dissemination-and-implementation-science-core/

HISTORIC EXAMPLES OF SLOW IMPLEMENTATION

MODERN ERA: TOBACCO

The US Smoking Rate is at an All-Time Low
Cigarette smoking among US adults

Data source: https://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/ (US CDC)
ChartYourWorld.org

TABLE 3—Odds of Receiving Medication for Other Conditions Relative to That for Tobacco Use: National Ambulatory Medical Care Survey, 2005–2007
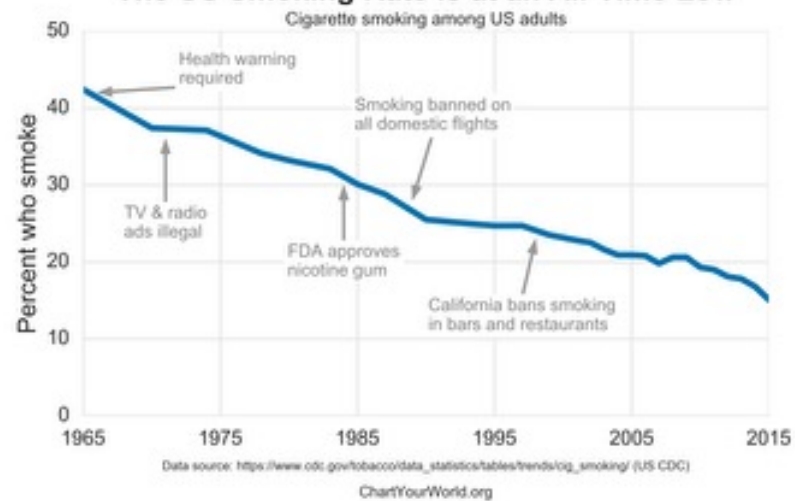
Condition	Visits Receiving Condition-Specific Medication, %	OR (95% CI)	AOR[a] (95% CI)
Hypertension	57.4	29.2 (24.8, 34.4)	32.8 (27.2, 39.5)
Diabetes	46.2	18.7 (15.5, 22.5)	20.9 (16.9, 25.8)
Hyperlipidemia	47.1	19.3 (16.0, 23.3)	16.5 (13.5, 20.1)
Asthma	42.4	16.1 (13.2, 19.7)	22.1 (17.4, 28.1)
Depression	53.3	22.9 (19.2, 27.4)	24.0 (20.0, 28.7)
Tobacco use	4.4	1.0 (Ref)	1.0 (Ref)

more likely to receive a medication for that condition

Note. AOR = adjusted odds ratio; CI = confidence interval; OR = odds ratio.
[a]Variables included in the model were age, gender, race, ethnicity, expected source of payment, type of patient (new or established), type of physician specialty (medical, surgical, primary), and provision of counseling (except for depression).

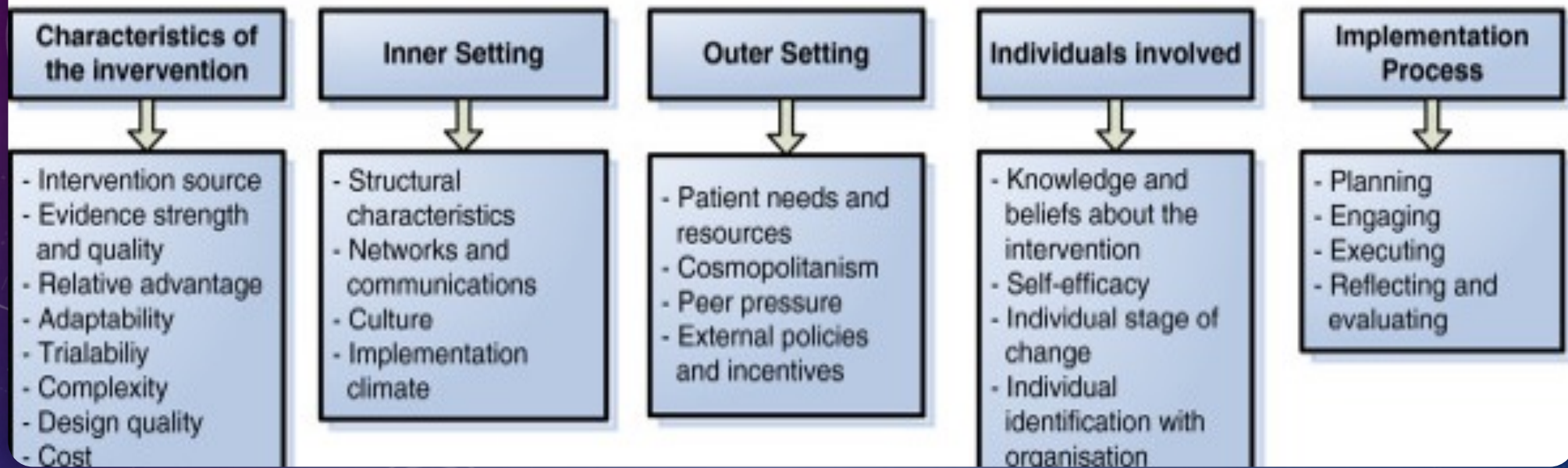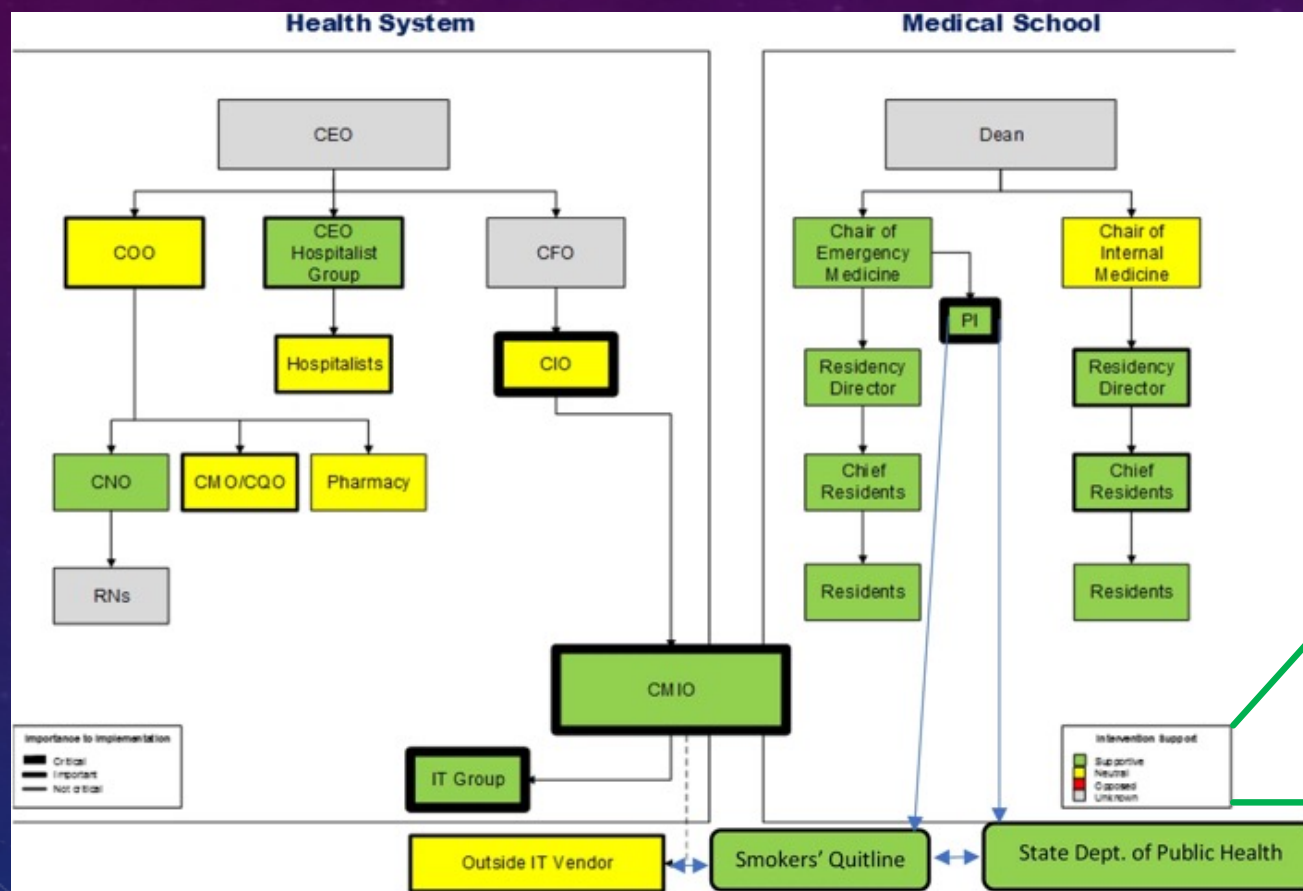*Bernstein et al., AJPH, 2013*

MODELS AND FRAMEWORKS

CONSOLIDATED FRAMEWORK FOR IMPLEMENTATION (CFIR)

DAMSCHRODER ET AL., IMPLEMENTATION SCIENCE, 2009

IMPLEMENTOME: STAKEHOLDER MAPPING

Example: "a study using clinical decision support to improve the treatment of hospitalized smokers."
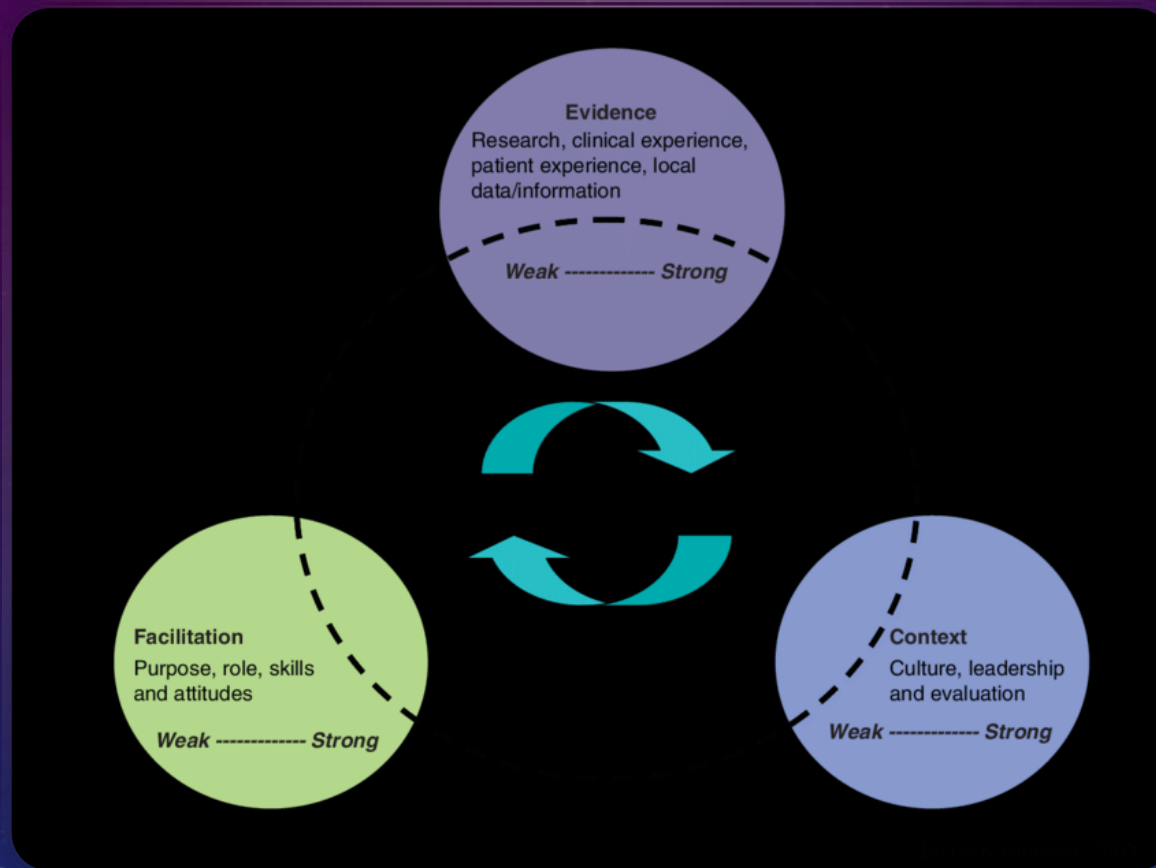
Reference: https://doi.org/10.1186/s43058-020-00030-8

REACH,
EFFECTIVENESS,
ADOPTION,
IMPLEMENTATION,
MAINTENANCE
(RE-AIM)

REACH
How do I reach those who need this intervention?

EFFECTIVNESS
How do I know my intervention is working?

ADOPTION
How do I develop organizational support to deliver my intervention?

IMPLEMENTATION
How do I ensure the intervention is delivered properly?

MAINTENANCE
How do I incorporate the intervention so it is delivered over the long-term?

RE-AIM

Reference: https://doi.org/10.3389/fpubh.2014.00143

PROMOTING ACTION ON RESEARCH IMPLEMENTATION IN HEALTH SERVICES (PARIHS)

•*Rycroft-Malone, J Nursing Care Qual, 2004*

DESIGNS IN DISSEMINATION & IMPLEMENTATION (D&I) STUDIES

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METHODOLOGIC TOOLKIT

Randomized Clinical Trials (RCTs)

Quasi-experimental designs

Hybrid designs

Mixed methods: quantitative and qualitative methods

Multimethods

Community-based participatory research (CBPR)

Leslie Curry
Marcella Nunez-Smith

MIXED METHODS
in HEALTH SCIENCES
RESEARCH

A Practical Primer

1 MIXED METHODS RESEARCH SERIES

BUILDING THE TEAM: EXPERTISE

Clinical epidemiology

Biostatistics

Qualitative/mixed methods

Economics
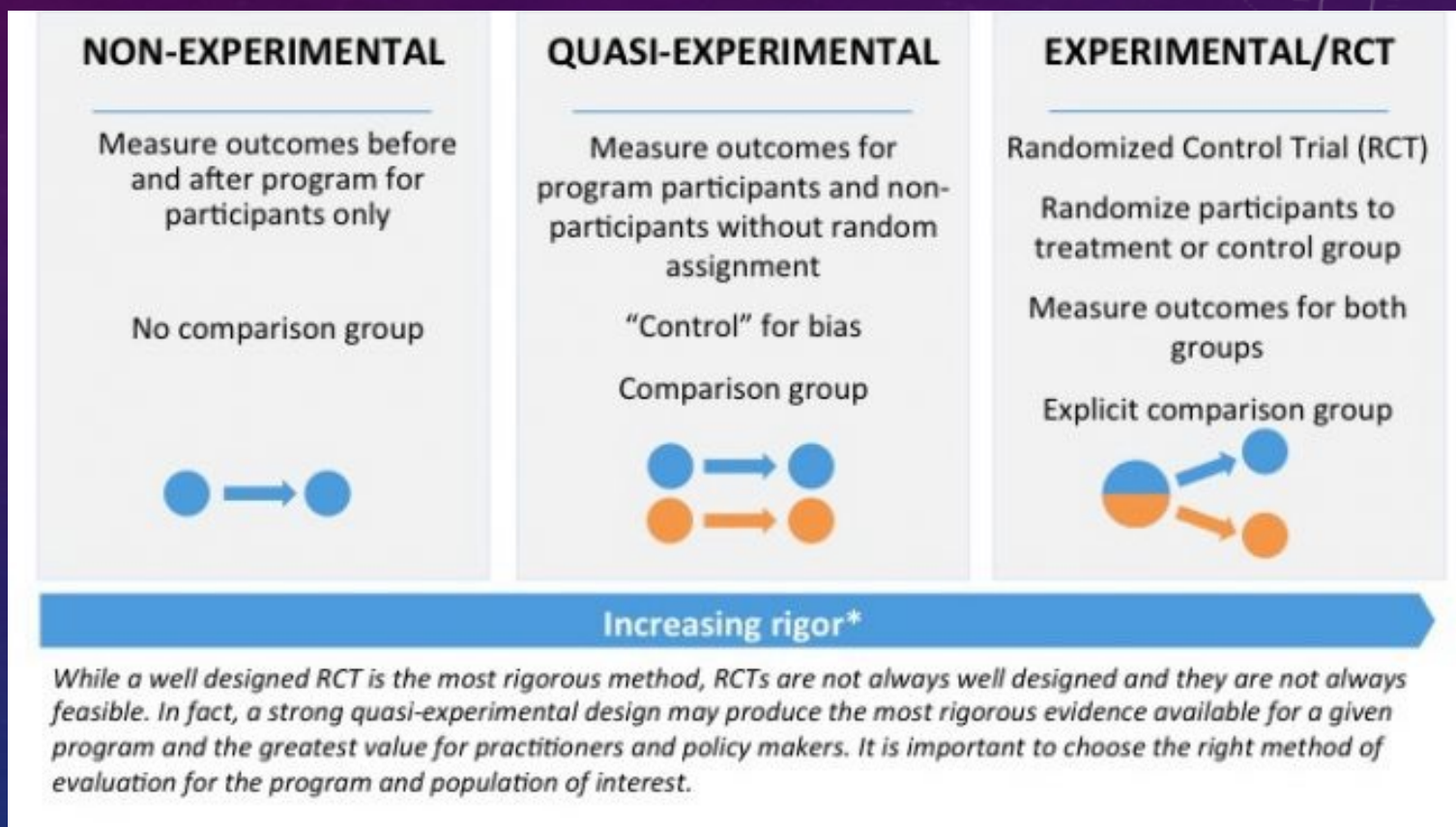
Organizational behavior

Clinical informatics

Policy

IMPLEMENTATION STRATEGIES

RCT VS QUASI-EXPERIMENTAL DESIGNS

Reference: https://publichealthnotes.com/20-differences-between-randomized-controlled-trial-rct-and-quasi-experimental-study-design/
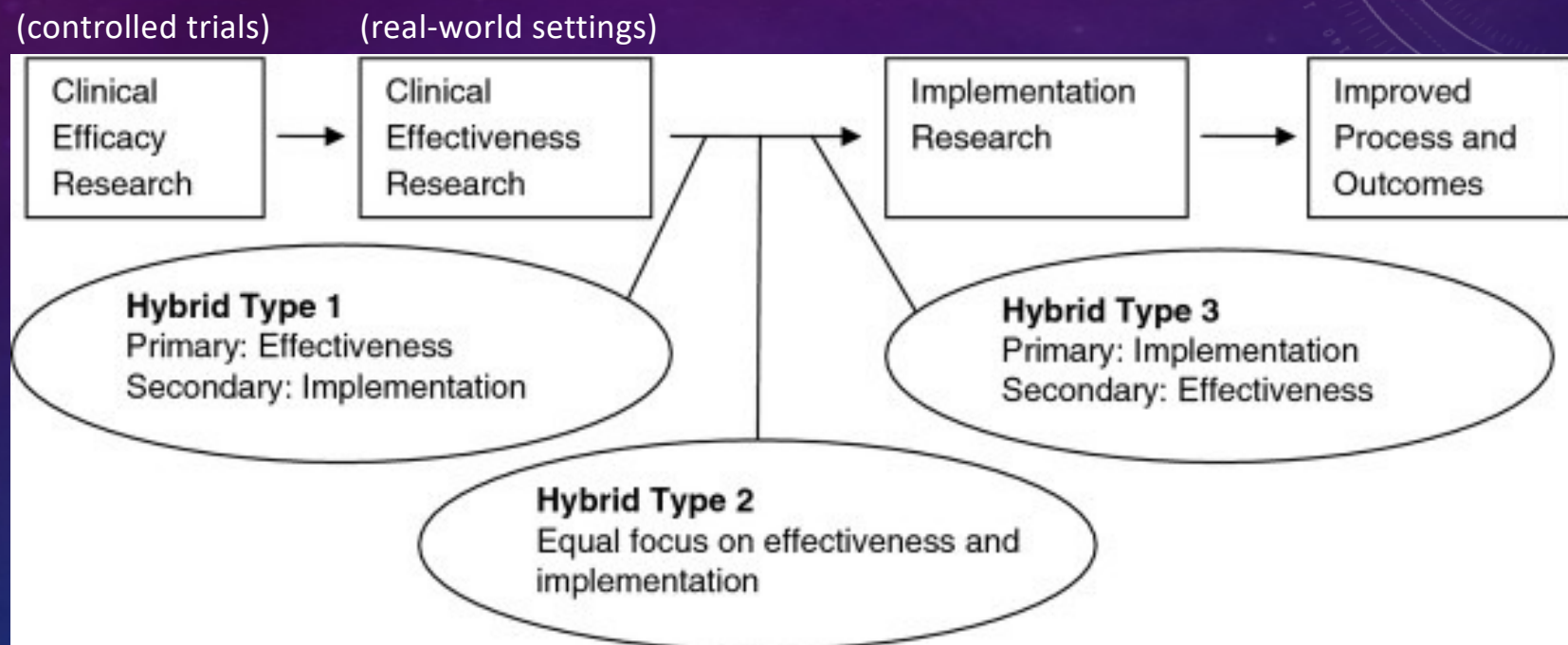
HYBRID DESIGNS

Allow for simultaneous assessment of effectiveness and implementation

Need to define which (if either) is paramount

Devise study accordingly

HYBRID DESIGNS EXAMPLE: CURRAN

(controlled trials)   (real-world settings)

Curran, Medical Care, 2012

TYPICAL ENDPOINTS

Effectiveness

- Improvements in clinical markers
    - Symptom severity
    - Symptom duration
    - Mortality
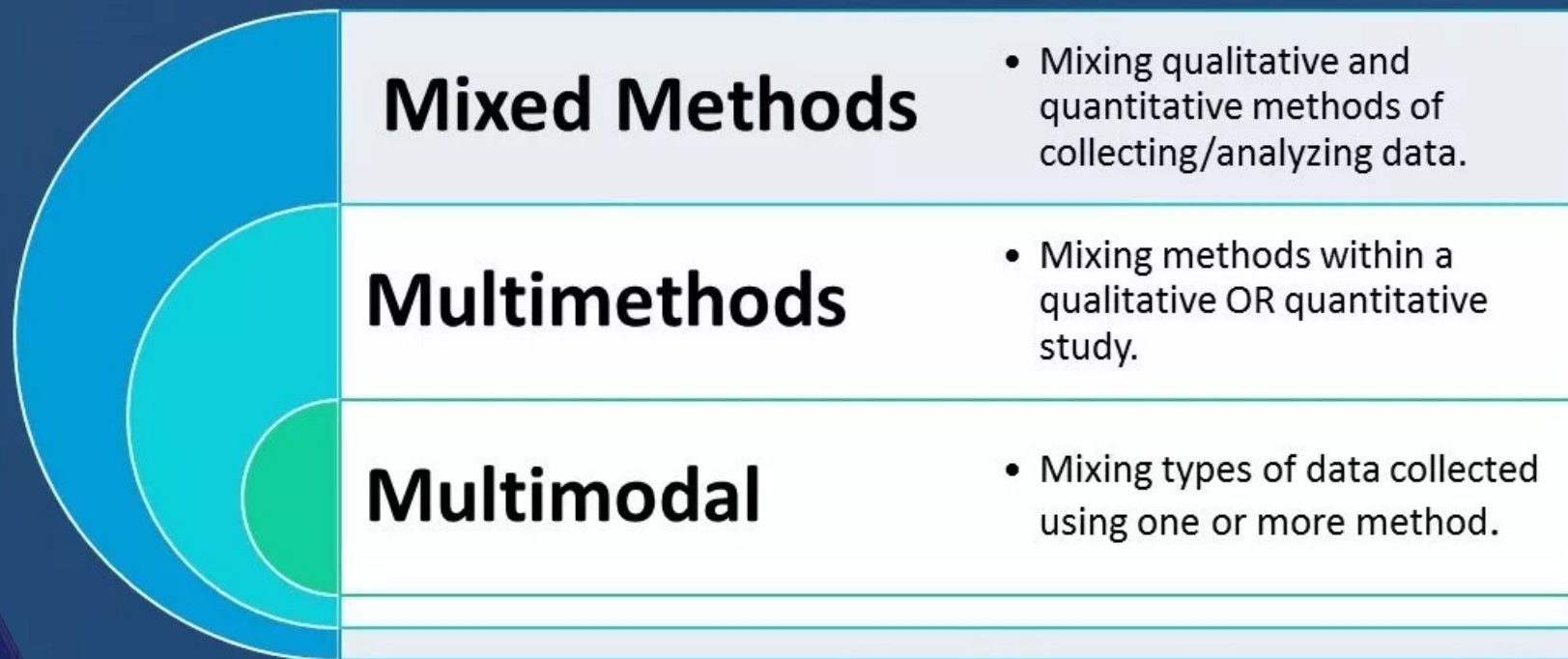   - Quality of life

Implementation

- Feasibility
- Scalability
- Acceptability
- Reach
- Adoption
- Maintenance

OTHER IMPLEMENTATION MEASURES

Implementation Outcomes	Program Outcomes	Community Outcomes	Individual Outcomes
» Acceptability	» Cost-effectiveness	» Access to care	» Longevity
» Adaptation	» Effectiveness	» Access to fresh produce	» Physical activity and fitness
» Adoption	» Equity	» Built environment	» Social connectedness
» Appropriateness	» Reach	» Disease incidence	» Quality of life
» Feasibility		» Disease prevalence	
» Fidelity		» Health disparities	
» Maintenance		» Immunization and vaccination	
» Penetration		» Walkability	
» Sustainability			

We need **mixed** modes and methods to study experiences in a **mixed-reality** world.

Mixed Methods	• Mixing qualitative and quantitative methods of collecting/analyzing data.
Multimethods	• Mixing methods within a qualitative OR quantitative study.
Multimodal	• Mixing types of data collected using one or more method.

COMMUNITY-BASED PARTICIPATORY RESEARCH (CBPR)

Reference: https://hsc.unm.edu/population-health/research-centers/center-participatory-research/cbpr-community-engagement/cbpr-model.html

THANK YOU