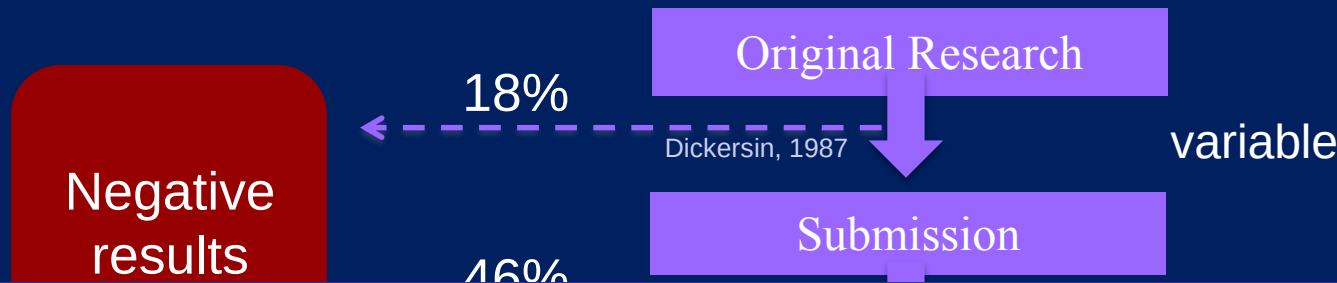


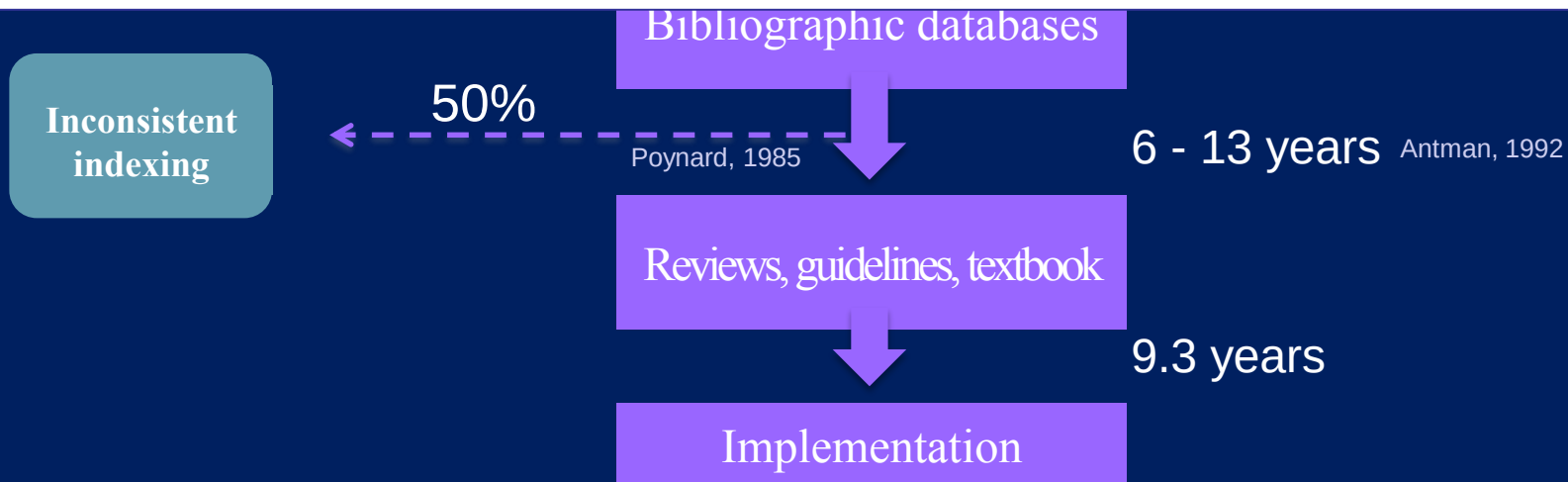
Implementation Science: Setting the Context

David Chambers, DPhil
Deputy Director for Implementation Science
Division of Cancer Control and Population Sciences, NCI
Implementation of Genomic Medicine Workshop 2015
November 19, 2015

“PUBLICATION PATHWAY” Balas & Boren, 2000



It takes 17 years to turn 14 percent of original research to the benefit of patient care



We assume... “If you build it...”



Beyond The Test Itself...

- Even if genetic testing can identify optimal treatment for a specific illness or reduce risk for health problems, if:
- Only half of insurers choose to provide them
- Half of those systems choose to train clinicians to prescribe it
- Half of the clinicians at those systems prescribe it
- Half of their patients get tested:

(Assuming perfect access/testing/follow-up)

Impact: $.5 \times .5 \times .5 \times .5 = 6\%$ benefit

Evidence-based Classification of Genomic Applications in Practice

Green

- FDA label requires use of test to inform choice or dose of a drug
- CMS covers testing
- Clinical practice guideline based on systematic review supports testing

Tier 1

Yellow

- FDA label mentions biomarker*
- CMS coverage with evidence development
- Clinical practice guideline, not based on systematic review, supports use of test
- Clinical practice guideline finds insufficient evidence but does not discourage use of test
- Systematic review, without clinical practice guideline, supports use of test
- Systematic review finds insufficient evidence but does not discourage use of test
- Clinical practice guideline recommends dosage adjustment, but does not address testing

Tier 2

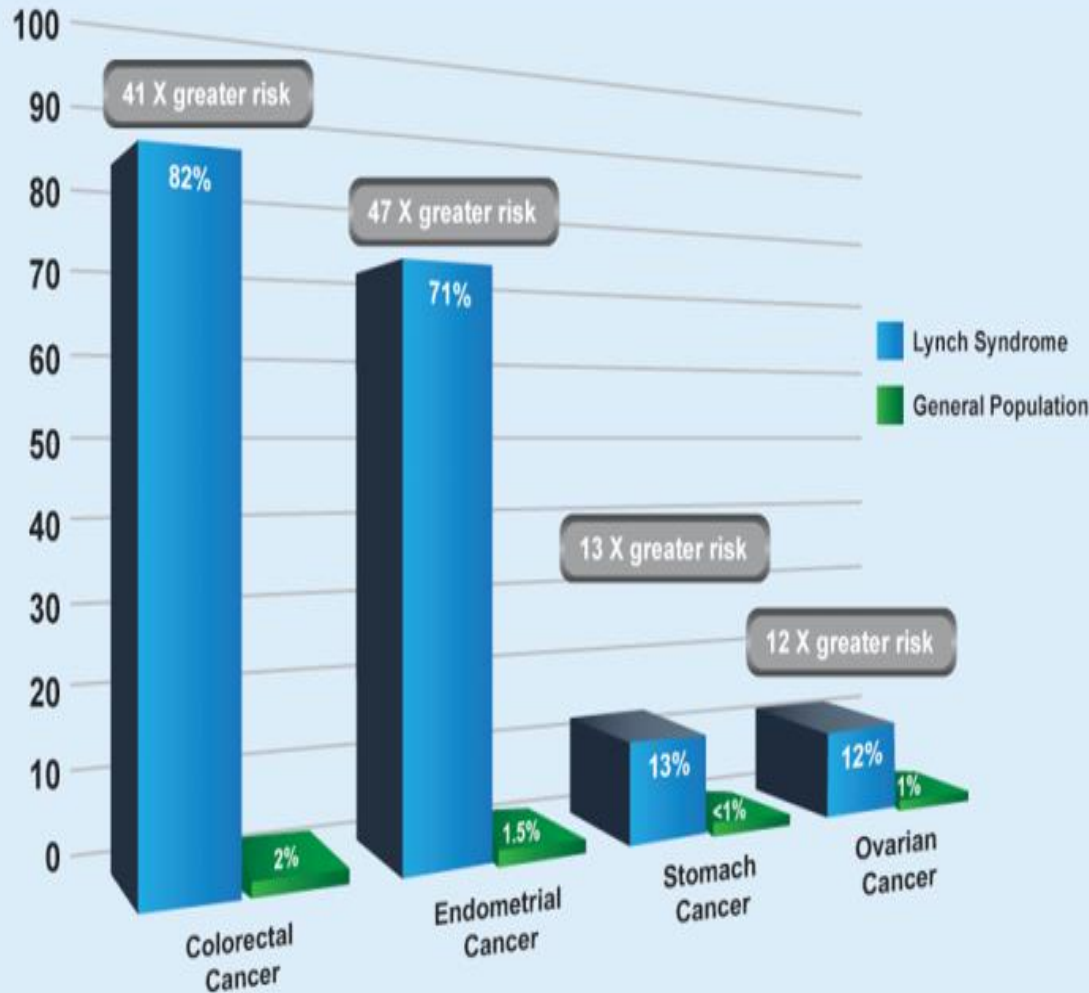
Red

- FDA label cautions against use
- CMS decision against coverage
- Clinical practice guideline recommends against use of test
- Clinical practice guideline finds insufficient evidence and discourages use of test
- Systematic review recommends against use
- Systematic review finds insufficient evidence and discourages use
- Evidence available only from published studies without systematic reviews, clinical practice guidelines, FDA label or CMS labels coverage decision

Tier 3

| *Can be reassigned to Green or Red if one or more conditions in these categories apply

Example: Lynch Syndrome



Sample IS Challenges:

- ID of Lynch Syndrome within CRC pop
- Family member scale-up
- Implementing screening/monitoring/

Example Two: BRCA1/2

Chances of Developing Breast Cancer by Age 70



People now **have the option of knowing** if they are **more likely** to develop breast cancers.

Source:

See the references section of <http://www.cancer.gov/cancertopics/factsheet/Risk/BRCA>



Sample IS Challenges:

- ID of BRCA1/2 at pop level
- Family member scale-up
- Implementing screening/monitoring/pre-emptive Tx

Example Three: PMI

THE PRECISION MEDICINE INITIATIVE®



WHAT IS IT?

Precision medicine is an emerging approach for disease prevention and treatment that takes into account people's individual variations in genes, environment, and lifestyle.

The Precision Medicine Initiative* will generate the scientific evidence needed to **move the concept of precision medicine into clinical practice.**

WHY NOW?

The **time is right** because of:

Sequencing of the human genome	Improved technologies for biomedical analysis	New tools for using large datasets
		

Sample IS Challenges

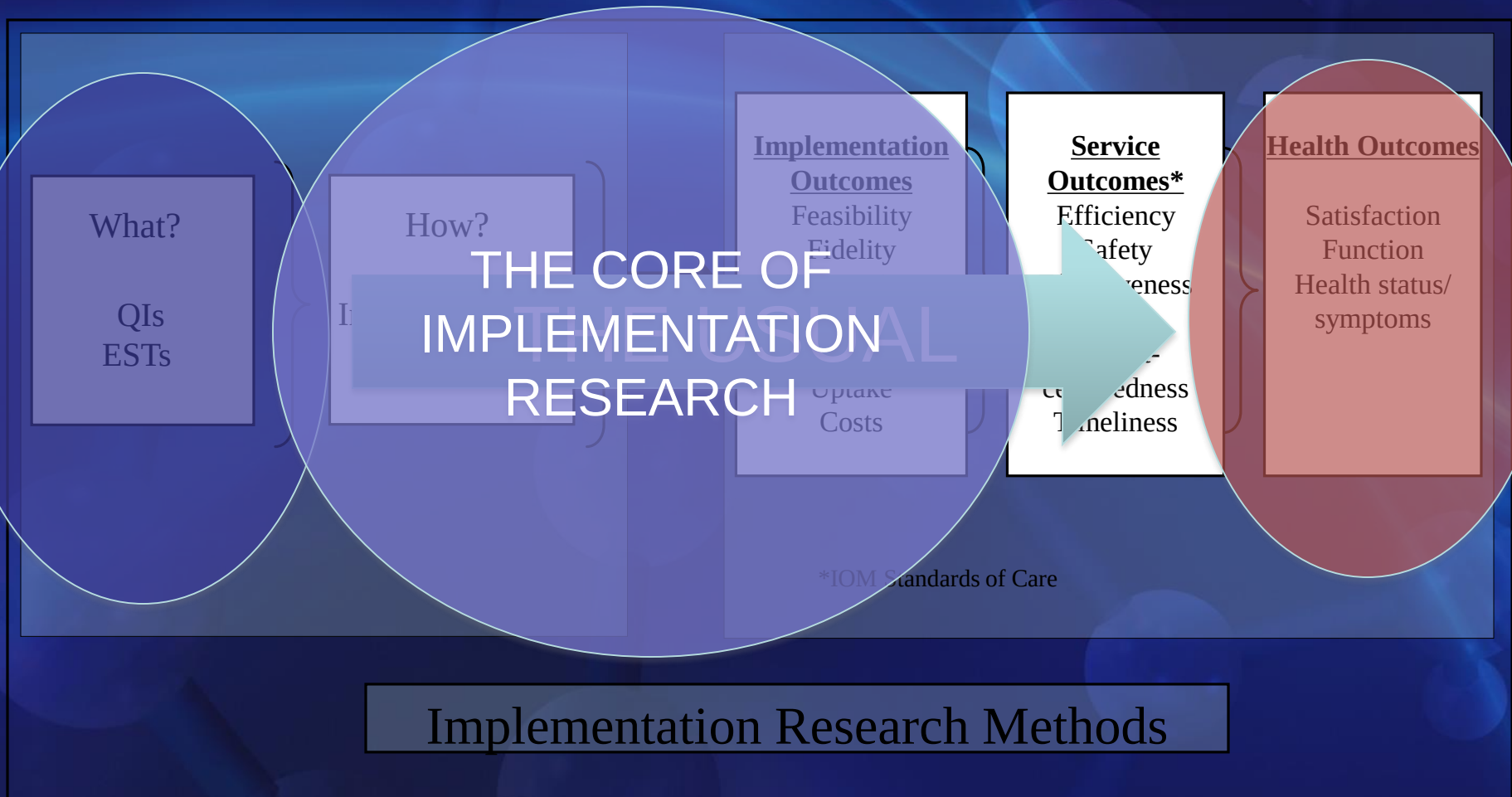
- How does clinical practice incorporate PMI findings?
- How do you implement evidence that will be evolving?
- How do you train and support the workforce?
- What services will be covered/paid for?

Dissemination and Implementation Research

- **Dissemination is** “the targeted distribution of information and intervention materials to a specific public health or clinical practice audience.”
- **Implementation is** “the use of strategies to adopt and integrate evidence-based health interventions and change practice patterns within specific settings.”

NIH PAR-13-055; Adapted from Lomas (1993)

Studying Implementation



Proctor et al 2009 *Admin. & Pol. in Mental Health & Mental Health Services Research*

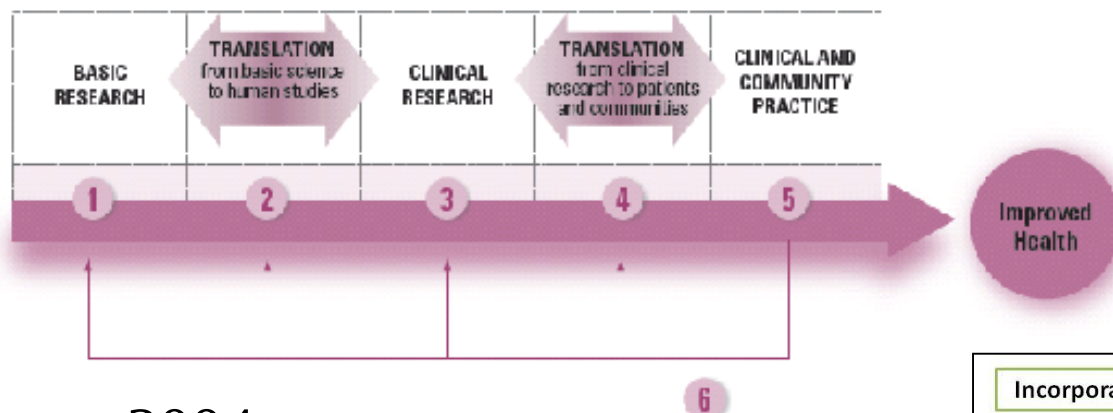
D&I Research Studies

- NIH PARs 13-054/055/056
 - > 140 projects through trans-NIH D&I announcements (16 Institutes & Centers)
- CER of implementation approaches
 - Quality Improvement, Org. Change, Provider Training and Supervision, Financing/Policy Change
- Emerging approaches
 - Learning Collaboratives, tech as D&I driver
- Methods Devl., System Science, **Genomic Medicine**

Areas Ripe for Exploration

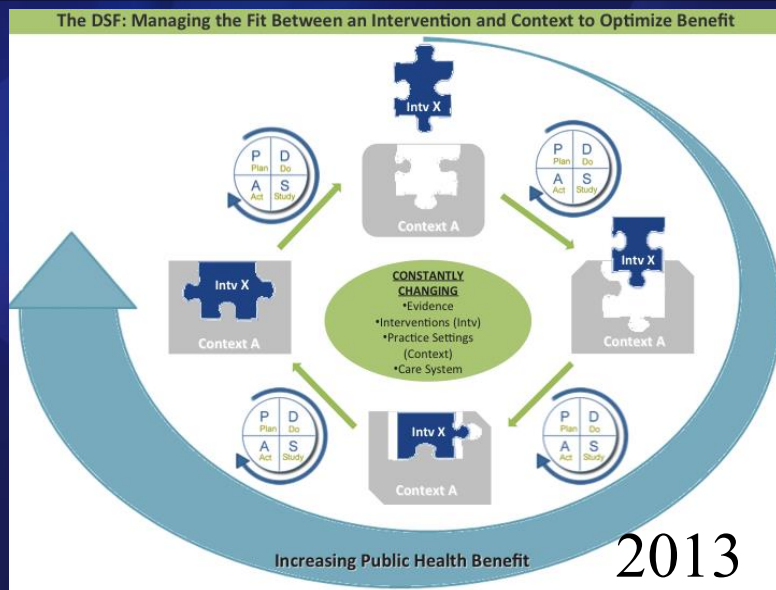
- Sustainability of EBPs in a changing context
- Adaptability/Evolution of EBPs over time
- Implementation of a set of ITVs
- Impact of dissemination strategies on practice
- Scaling up practices across health plans, systems, networks, and nations
- De-Implementation/Exnovation

The Current Paradigms for D&I Science



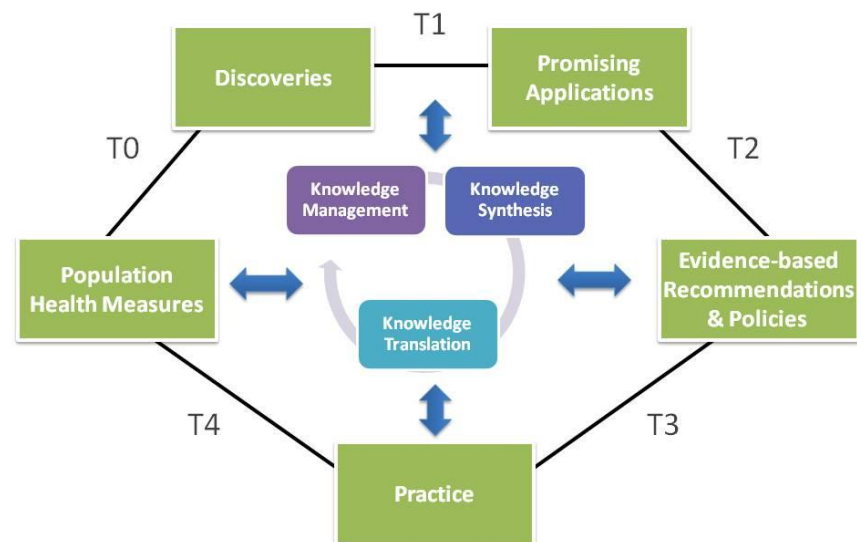
2004

2012



2013

Incorporation of Knowledge Integration into the Translation Continuum



National Cancer Institute

Growing Resources

- Training Programs (e.g. TIDIRH, IRI, MT-DIRC, KT Canada, Universities)
- Research Infrastructure (CIPRS, CPCRN, CRN, Other Centers, CTSA Cores)
- Measurement Tools (GEM-IS, SIRC, SIC, RE-AIM)
- Other relevant tools (e.g. P.L.A.N.E.T, R2R)
- The Next Generation (100s of trainees)
- Annual D&I Science Conferences
- *Implementation Science*
- Brownson, Colditz, Proctor (Eds.) *Dissemination and Implementation Research in Health*, 2012



MOVING BEYOND TRADITIONAL ASSUMPTIONS

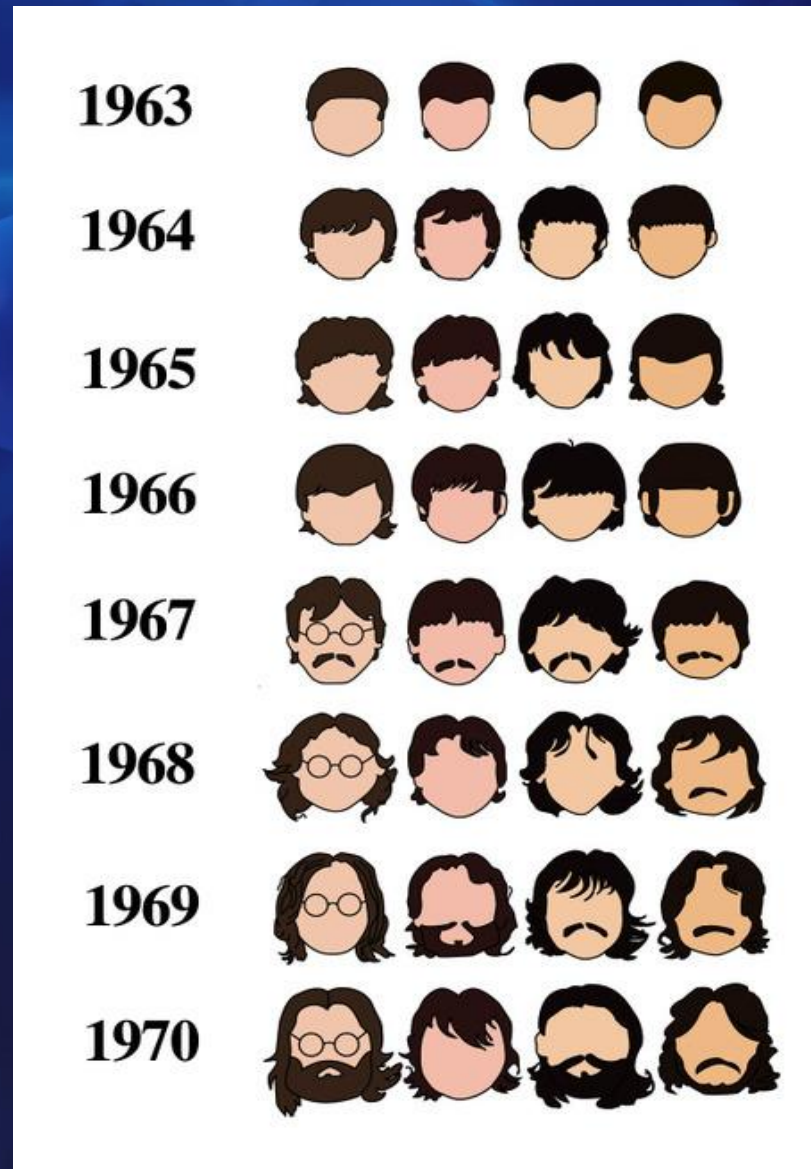
Traditional Assumptions

- EBPs are static
- System is static
- Implementation proceeds one practice or test at a time
- Consumers/Patients are homogeneous
- Choosing to not implement is irrational

Choosing not to implement is irrational... (Does it fit?)



Sustainability or Evolution?



Fidelity vs Adaptation?



The image shows the words "THANK YOU" in a bold, three-dimensional red font. The letters are thick and blocky, with a slight shadow cast beneath them on a white surface. The word "THANK" is positioned above "YOU". The entire graphic is set against a white background within a rectangular frame.

**THANK
YOU**

dchamber@mail.nih.gov
240-276-5090