Keynote Address

Please submit questions for the panelists to: <u>PragClinTrialsWkshp@nih.gov</u>

Pragmatic Clinical Trials – Unique Opportunities for Disseminating, Implementing & Sustaining Evidence-Based Practices into Clinical Care

An Orientation to Dissemination, Implementation, Sustainability, De-Implementation and the Science of Making Science Matter

David Chambers, DPhil

Deputy Director for Implementation Science,

Division of Cancer Control & Population Sciences (DCCPS)

HSC Collaboratory Workshop 2017



Presentation Outline

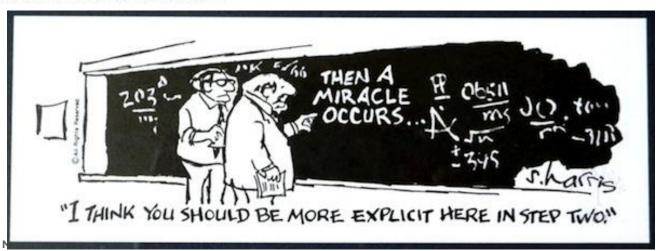
Conceptualizing the Challenge Defining Terms Opportunities and Resources Framing the Day



From Discovery to Delivery

Discovery Research						Clinical Development		
Idea/ Concept	Target molecule identification	Lead identification (non-biologics)	Lead optimization (non-biologics)	NV	Preclinical studies	Phase I Clinical pharmacology Healthy	Phase II Exploratory/ Confirmatory	Phase III Confirmator
		Lead optimization (biologics)				volunteer/ Patient	Patient	Patient
	Establishing assay system/ Target evaluation	Screening (in vitro)	Screening (in vitro) (in vivo)	Pharmacology DMPK* Pilot toxicity	Pharmacology DMPK* GLP toxicity	Pharmacokinetics Safety	Efficacy Dose regimen Dosage	Efficacy Safety

*Drug metabolism and pharmacokinetics

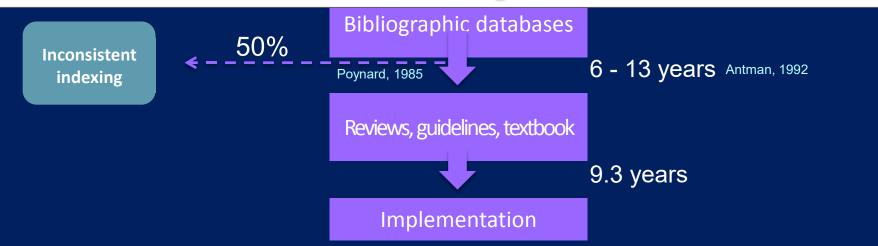


"PUBLICATION PATHWAY"

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..."





... It might take 108 years for this



An Evidence-Based Health Intervention, no matter how pragmatic the trial...

Is only so good as how and whether...

It is adopted?

Providers are trained to deliver it?

Trained providers choose to deliver it?

Eligible patients receive it?

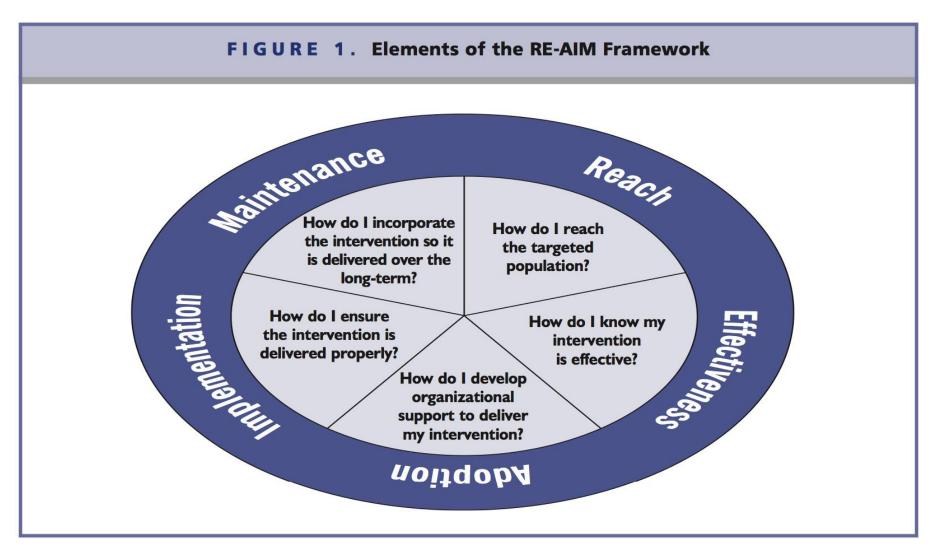
If we assume 50% threshold for each step...

(even w/perfect access/adherence/dosage/maintenance)

Impact: $.5^*.5^*.5 = 6\%$ of potential reach



Beyond efficacy/effectiveness





Current Landscape and Progress

NATIONAL CANCER INSTITUTE





- Implementation Science is the study of methods to promote the integration of research findings and evidence into healthcare policy and practice.
- Dissemination research is the scientific study of targeted distribution of information and intervention materials to a specific public health or clinical practice audience. The intent is to understand how best to spread and sustain knowledge and the associated evidence-based interventions.
- Implementation research is the scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings in order to improve patient outcomes and benefit population health.

A big tent of terms (and Circles)*

NIH NATIONAL CANCER INSTITUTE



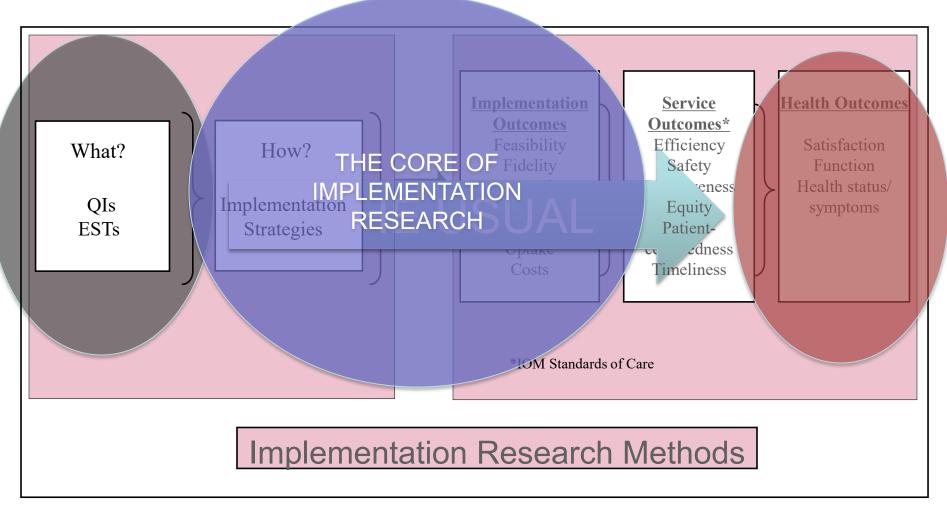
Dissemination Research

- How the "evidence" is created?
- Packaging
- Transmitting
- Receiving
- Turning Information into Action

Many of our early efforts in "translating research into practice" jumped over these steps.



Studying Implementation



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



D&I Research Studies

→NIH PARs 16-237/237/238

> 150 projects through trans-NIH D&I announcements (17 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 DevI., System Science, Genomic Medicine

Areas Ripe for Further Research

- Sustainability of EBPs in a changing context
- 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

PAR-16-238: Dissemination and Implementation Research in Health (R01)

EVENT

10th Annual Conference on the Science of Dissemination and Implementation in Health

The pre-eminent event to bridge the gap between evidence, practice, and policy in health and medicine.

Learn More

DATE & TIME

LOCATION

December 4-6, 2017

Marriott Crystal Gateway,

Quality research generates the evidence needed to optimize health and health care in the United States and elsewhere. However, the full potential of evidence can only be realized if it is effectively incorporated into health practice and policy.

Dissemination and Implementation in Health (D&I), co-hosted by the National Institutes of Health (NIH) and AcademyHealth has become the pre-eminent

event to bridge the gap between evidence, practice, and policy in health and

A decade since its inception, the Annual Conference on the Science of

10th Annual Conference on the Science of Dissemination and Implementation in Health

2017 D&I Call for Abstracts

http://www.academyhealth.org/events/site/10th-annual-conference-science-dissemination-and-implementation-health

Implementation Science Training...











Application Opens: 5 July 2016 Application Closes: 1 August 2016 11:59 PM EDT Questions? Email <u>PEER@nas.edu</u>



Participants form Bangkok 2015 Training Course present the "abc's" of implementation science. (Photo courtesy of Robert Gasior)

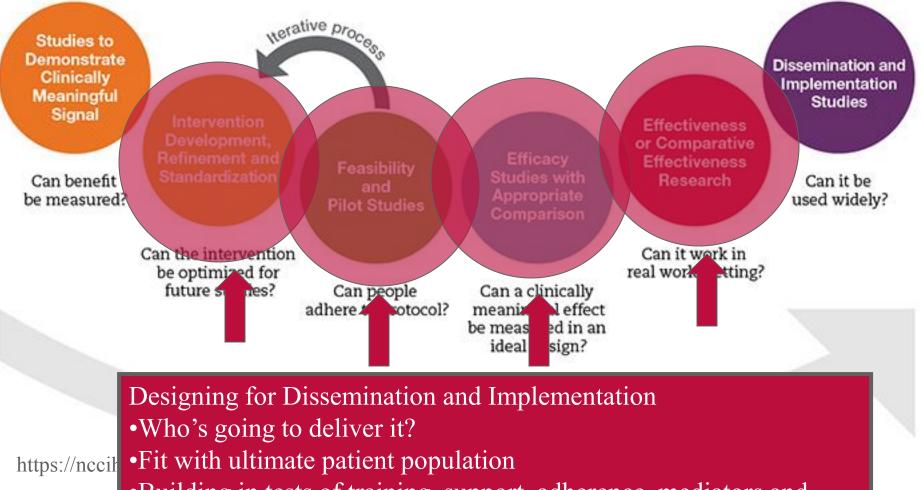


Framing the Day

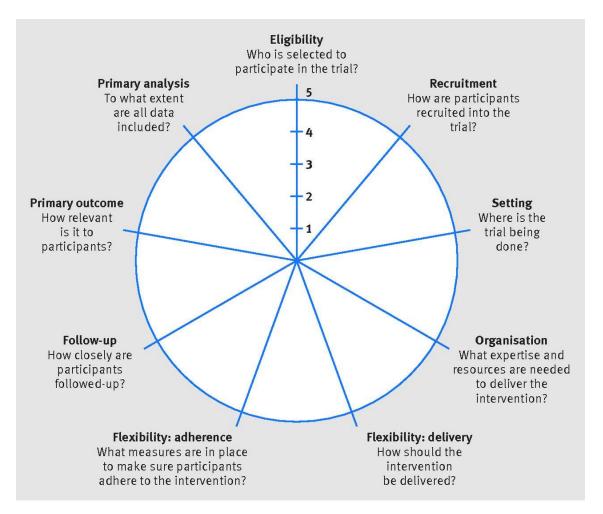
Considering Fit Between Interventions and Settings...



Session One: Designing for Dissemination and Implementation



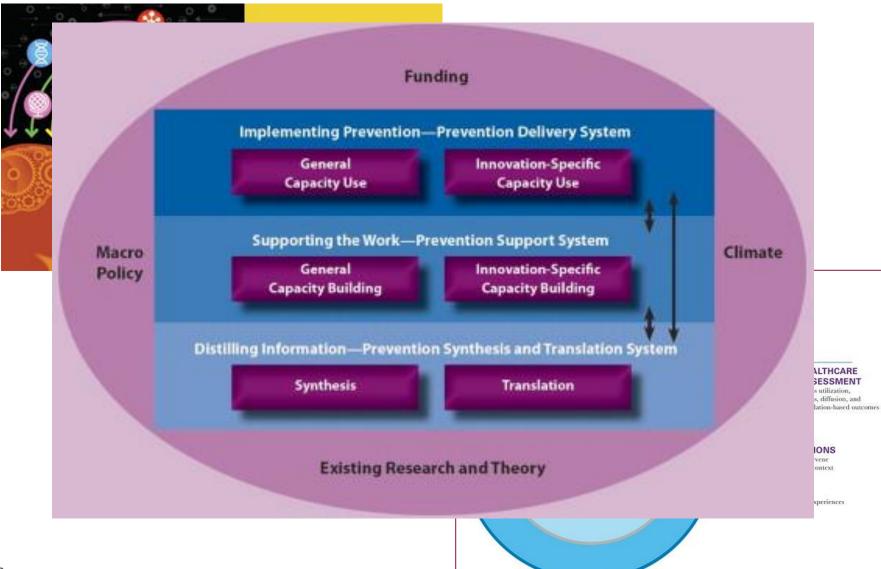
The PRECIS-2 Tool



Loudon et al, BMJ, 2015; Johnson, Neta et al, Trials, 2016

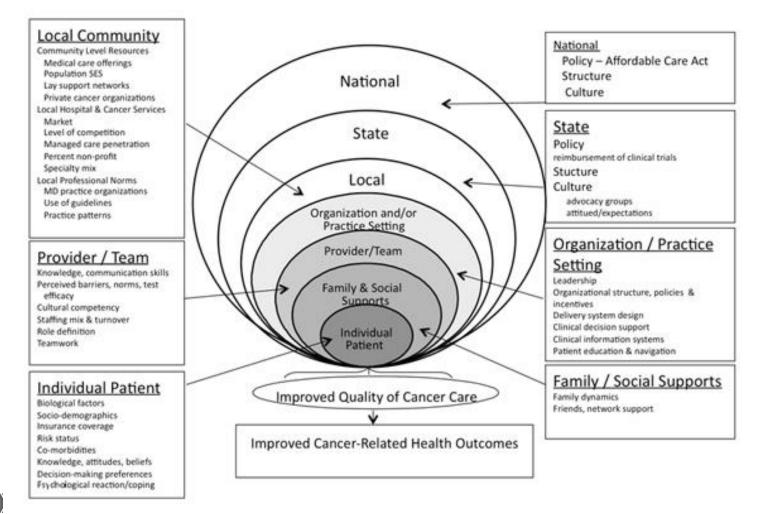


Session Two: The Importance of Partnerships

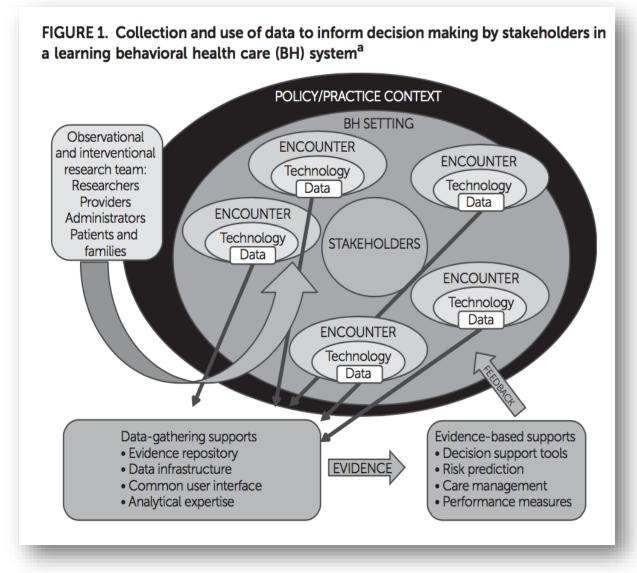


Partnerships Needed at Multiple Levels...

Figure 1: The multilevel context of care

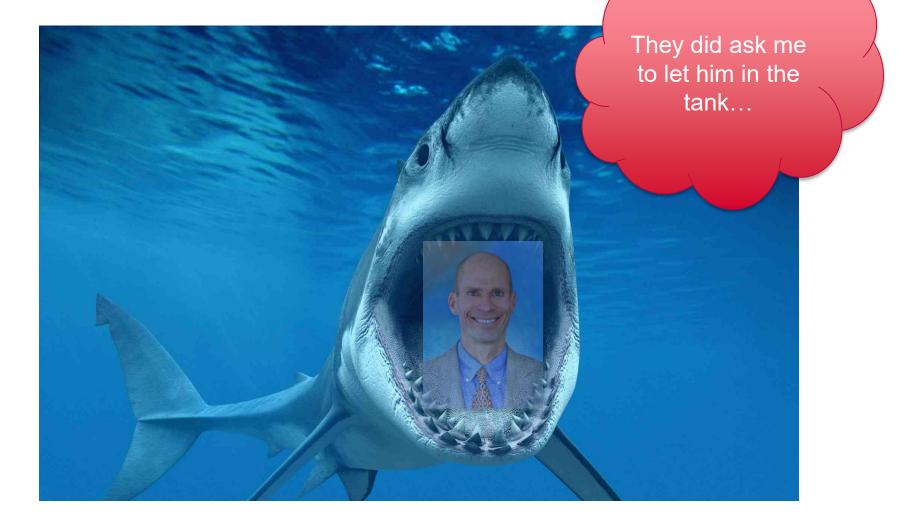


Towards a learning health care system...?



Stein, Adams, Chambers. Psychiatric Services, 2016.

Might this happen at lunch?





Session Three: Towards Sustainability?

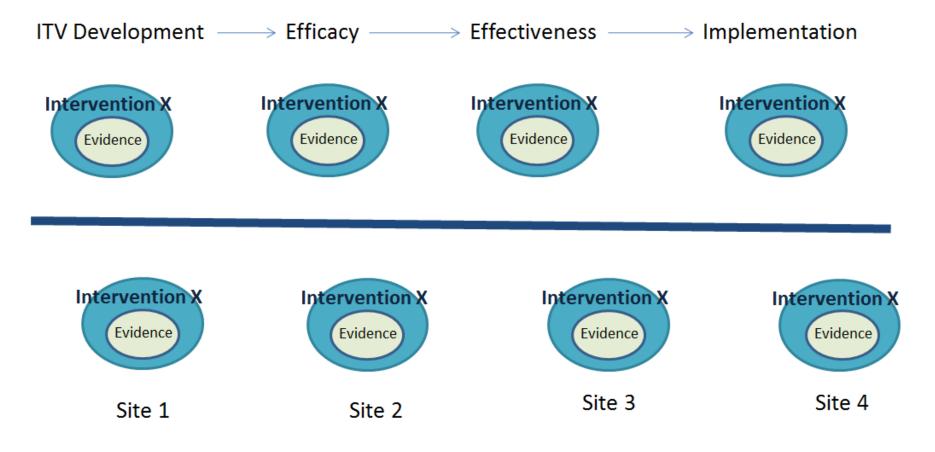
To Sustain:

- 1 to give support or relief to 2 to supply with sustenance: nourish
- 3 keep up, prolong
- 4 to support the weight of : to carry or withstand (a weight or pressure) 5 to buoy up <*sustained* by hope>
- 6 a: to bear up under *b* : suffer, undergo < *sustained* heavy losses>
- 7a : to support as true, legal, or just b: to allow or admit as valid <the court sustained the motion>

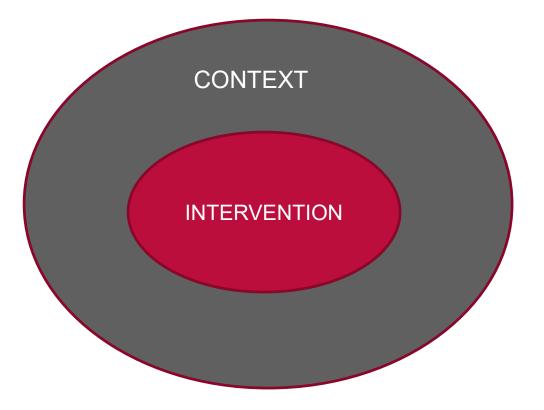
(Merriam-Webster, 2011)



Valuing Consistency

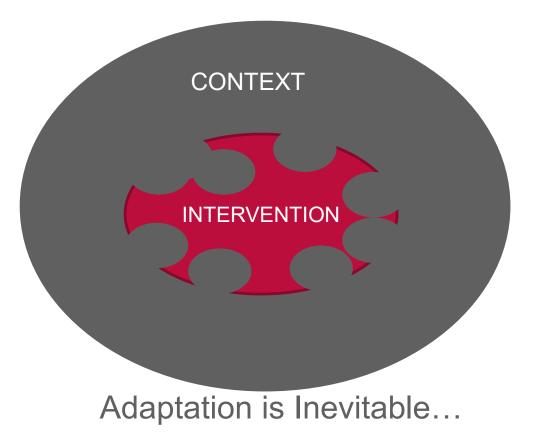


Relative Weights?



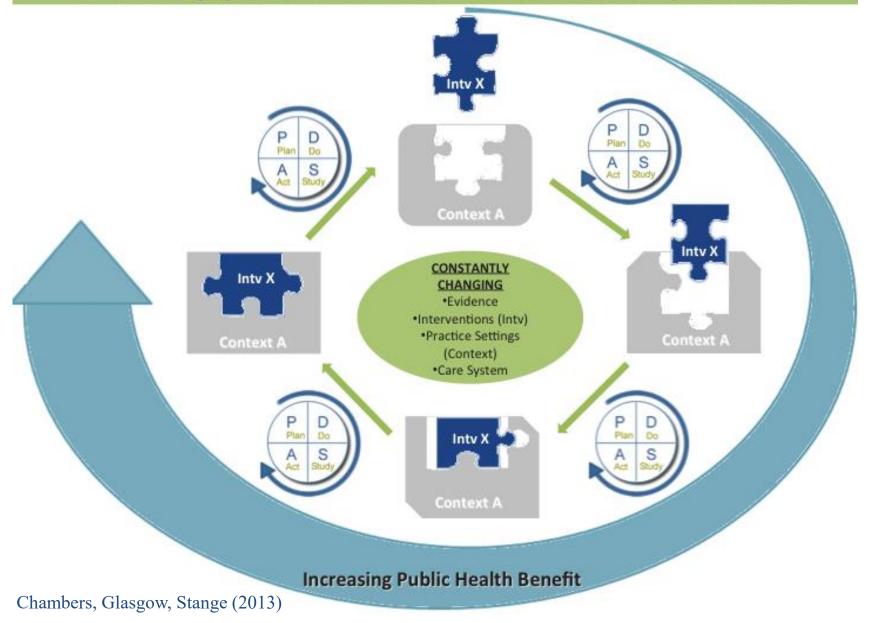


A Natural Process





The DSF: Managing the Fit Between an Intervention and Context to Optimize Benefit



Sustainability or Evolution?



- IF EVIDENCE CONTINUES TO EVOLVE, SHOULD EXISTING INTERVENTIONS BE SUSTAINED IN THE SAME FORM THAT WE'VE CREATED THEM?
- HOW DOES THE SYSTEM
 COPE WITH A DYNAMIC
 FIELD THAT IS CONSTANTLY
 CHANGING?
- WHERE DO WE GO FROM HERE?

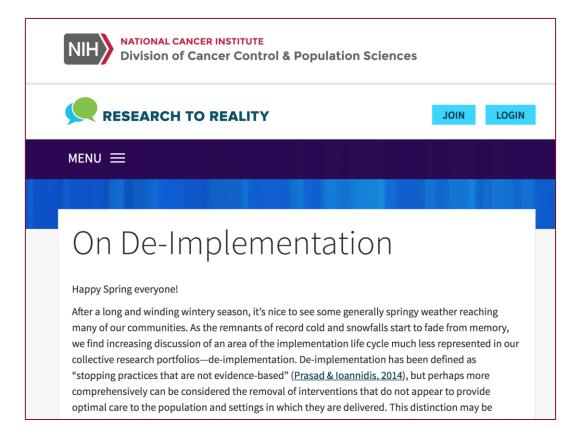
http://www.thestrut.com/2012/12/19/the-evolution-of-the-beatles-hair/

Fidelity vs Adaptation?









- Overuse of evidence-based practices
- Any use of harmful practices
- Mis-use of evidence-based practices



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