

The Intersection between Precision Medicine and Implementation Science

Precision Medicine and Population Health (PMPH) Interest Group

Session Logistics

- Questions are encouraged. You may submit your questions at any time during the presentation. Type your question in the Q&A feature on the right of the interface and press submit.
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Session Logistics

- Introduction

- Dr. Muin Khoury (@DrKhouryCDC)

Director, Office of Public Health Genomics, CDC

Senior Advisor, Division of Cancer Control & Population Sciences, NCI, NIH

- Presentations

- Dr. David Chambers (@NCIDACHambers)

Deputy Director for Implementation Science, Division of Cancer Control & Population Sciences

- Dr. Geoffrey Ginsburg (@PersonalizedMed)

Professor of Medicine, Pathology, and Biomedical Engineering, Duke University

- Questions

The Intersection between Precision Medicine and Implementation Science

David Chambers, DPhil

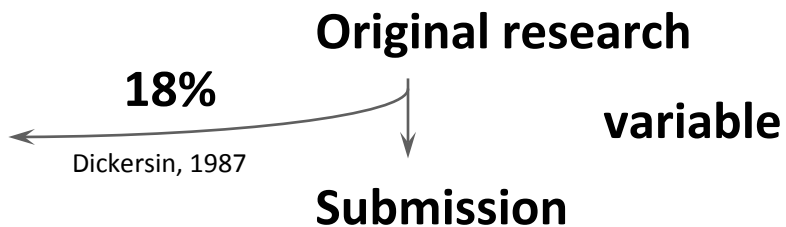
Deputy Director for Implementation Science,
Division of Cancer Control & Population Sciences (DCCPS)

Session Outline

- A Brief Orientation to Implementation Science
- Considering Implementation Science within Precision Medicine?
- Challenging Existing Assumptions



Negative results



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



Inconsistent indexing

Poynard, 1985

Reviews, guidelines, textbook



9.3 years

Implementation

“PUBLICATION PATHWAY”

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: $.5 * .5 * .5 * .5 = 6\%$ benefit

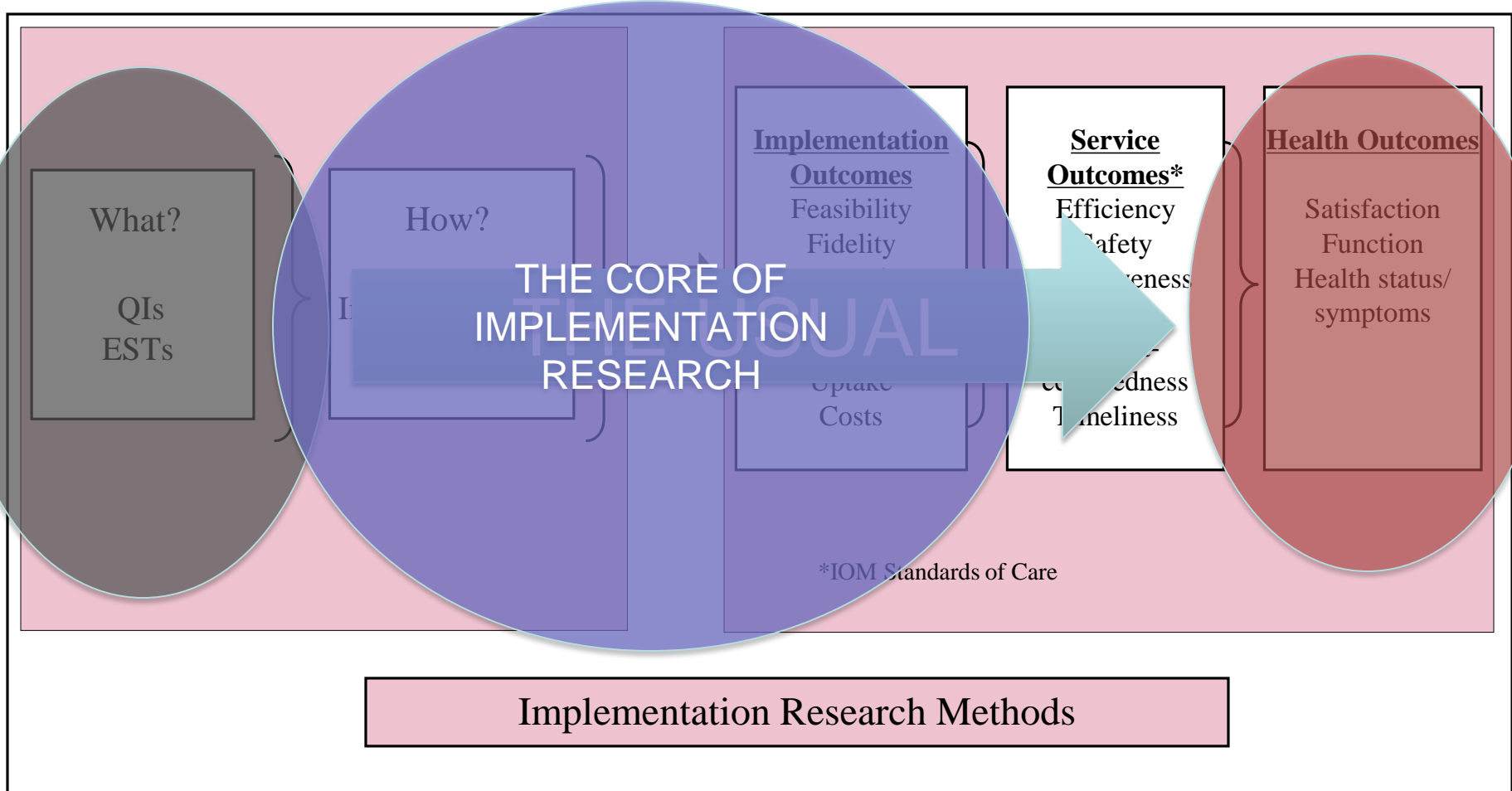
Key Terms

- **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.

Dissemination Research focuses on the process through:

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

Studying Implementation



Proctor et al, 2009, *APMH&MHSR*

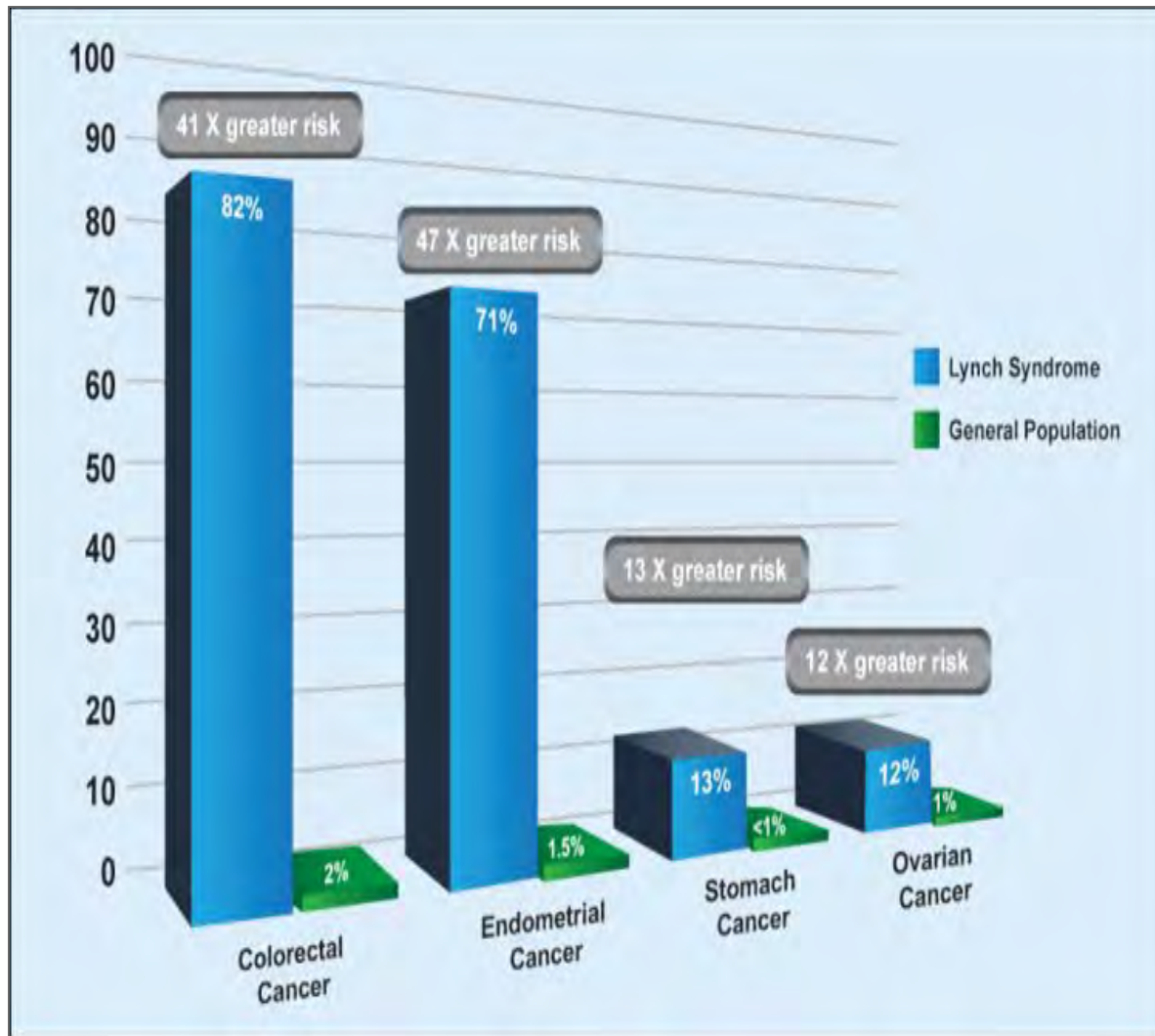
Dissemination and Implementation (D&I) Research--

- Theories, empirical findings, and methods from a variety of fields:
 - information science, clinical decision-making, organizational and management theory, economics, individual and systems-level behavioral change, public health, business and public administration, statistics, anthropology, learning theory, engineering, and marketing.
- **Collaboration with stakeholders** from multiple practice settings, consumers of services and their families/social networks.
- **Rigorous and relevant methodological approaches** (e.g. observational, experimental, quasi-experimental, and simulation modeling)
- Studies of dissemination or implementation strategies should build knowledge both on the **overall effectiveness of the strategies**, as well as **"how and why"** they work (e.g. mechs, moderators, mediators)

Current Funding Announcements

- NIH: PAR-16-237; 13-238;13-236 (R03, R01, R21)
- NCI leads (16 ICs total, including FIC, NIMH, NHLBI, NHGRI, as well as OBSSR)
- Organizes the D&I research agenda across NIH
- >150 grants funded through NIH since 2006
- 2010 CSR standing review committee
- Modal Grant—Randomized trial of an implementation strategy for an effective intervention (where we've been)

Example: Lynch Syndrome

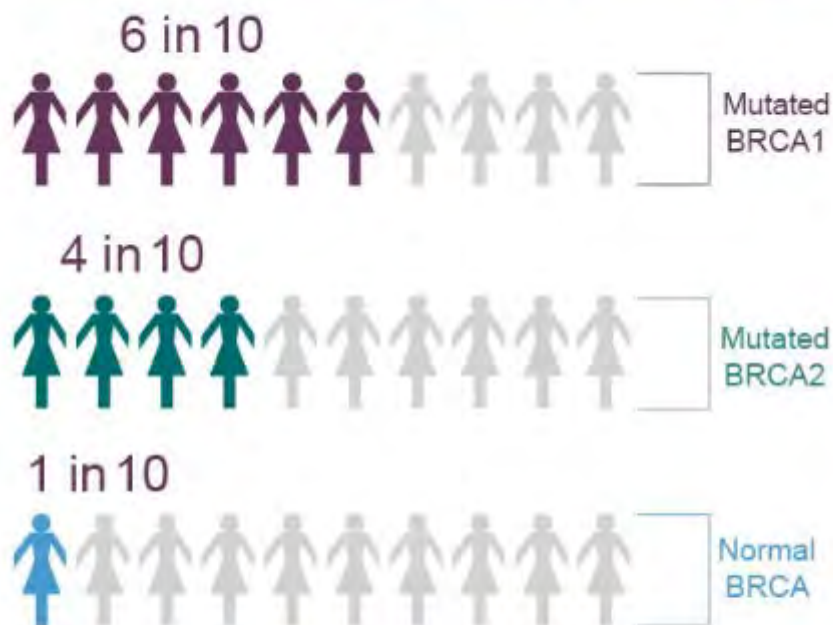


Sample IS Challenges:

- 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
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Icons: A person with a DNA helix, a laptop with a graph, and a cloud with binary code.

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?

Traditional Assumptions

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

How well do these relate to the implementation of precision medicine?

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



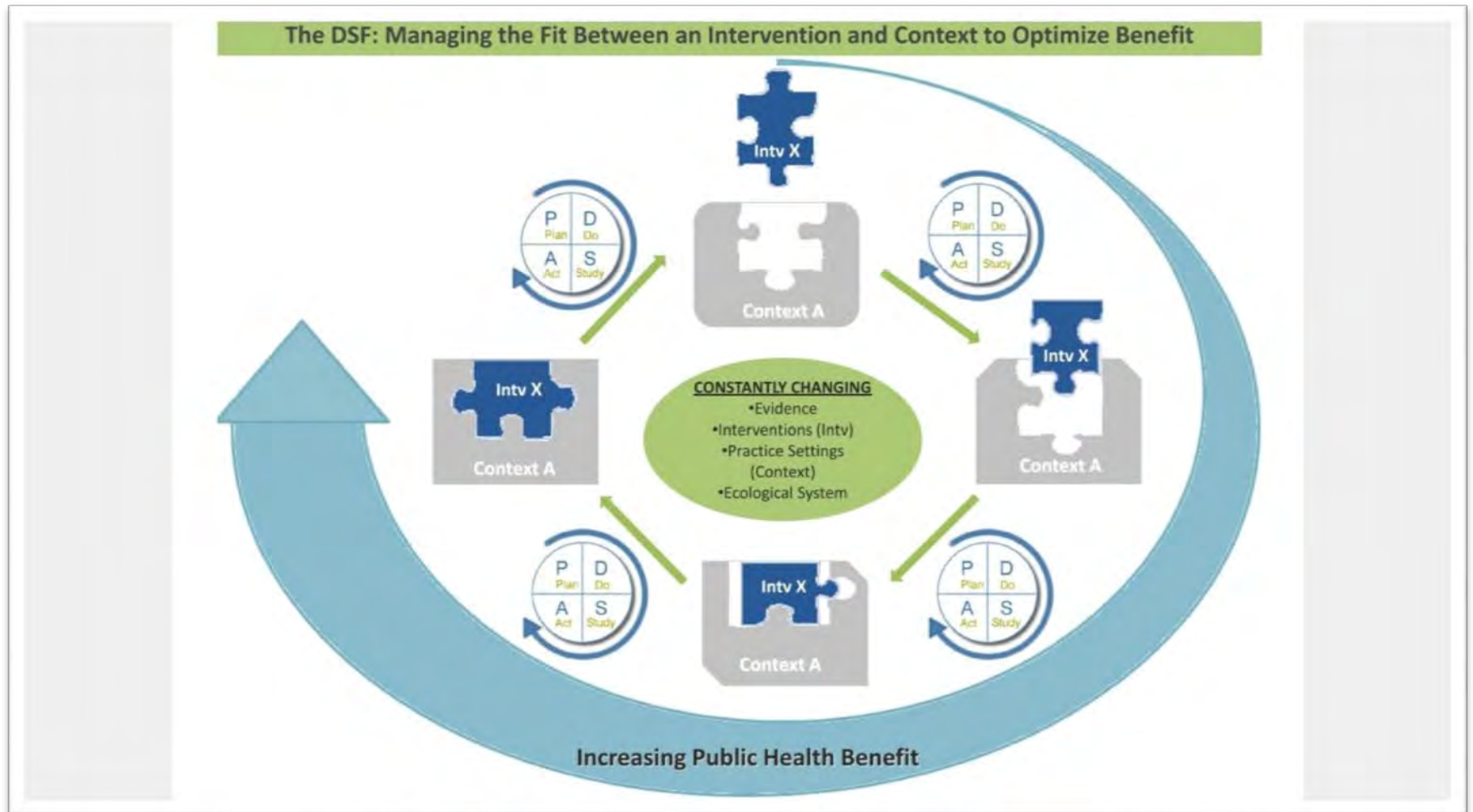
- QUESTIONS ABOUT “ACTIONABILITY”
- WHAT IS REIMBURSED?
- IS COUNSELING AVAILABLE?
- ARE EXISTING TESTS OPTIMAL?
- IS THERE A DEMAND FOR THE KNOWLEDGE?

Sustainability or Evolution?



- IF PRECISION MEDICINE 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?

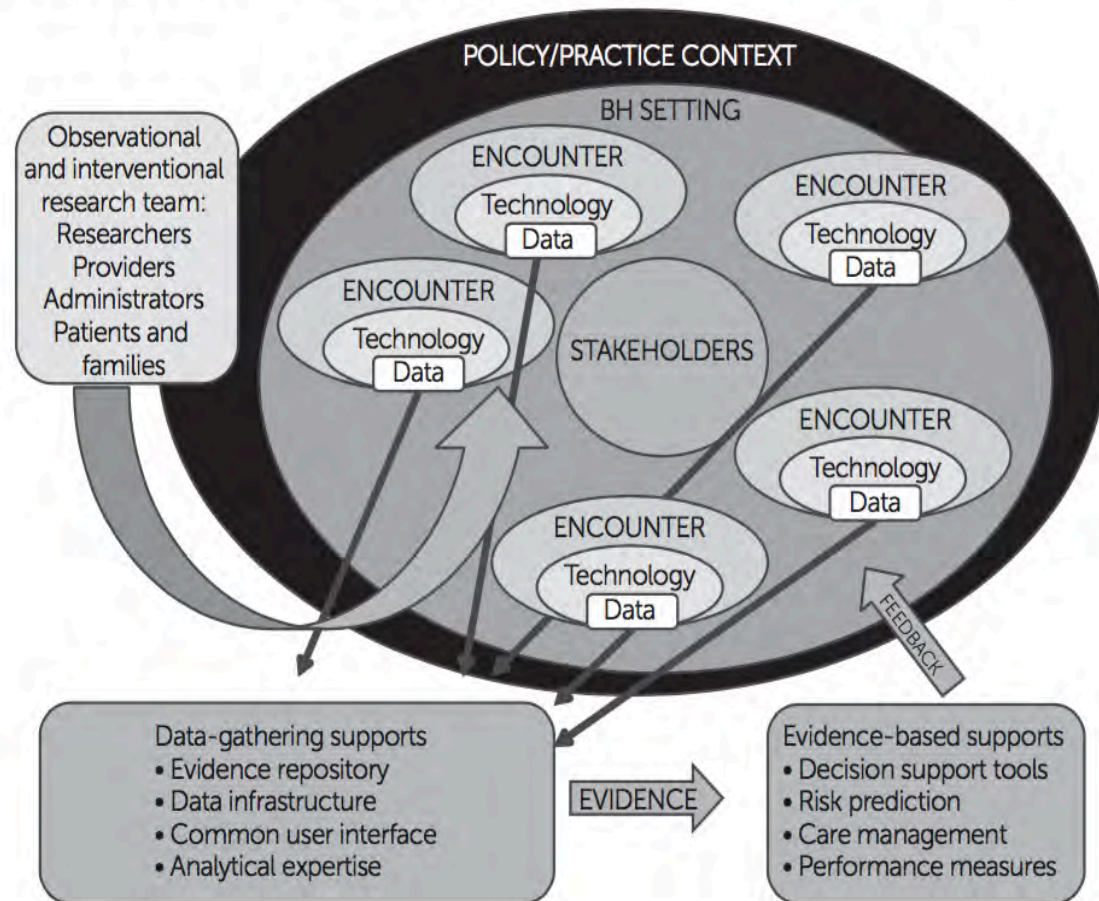
A Dynamic Approach to Sustainability...



Chambers, Stange, & Glasgow, *Implementation Science*, 2013

Enter the learning health care system...

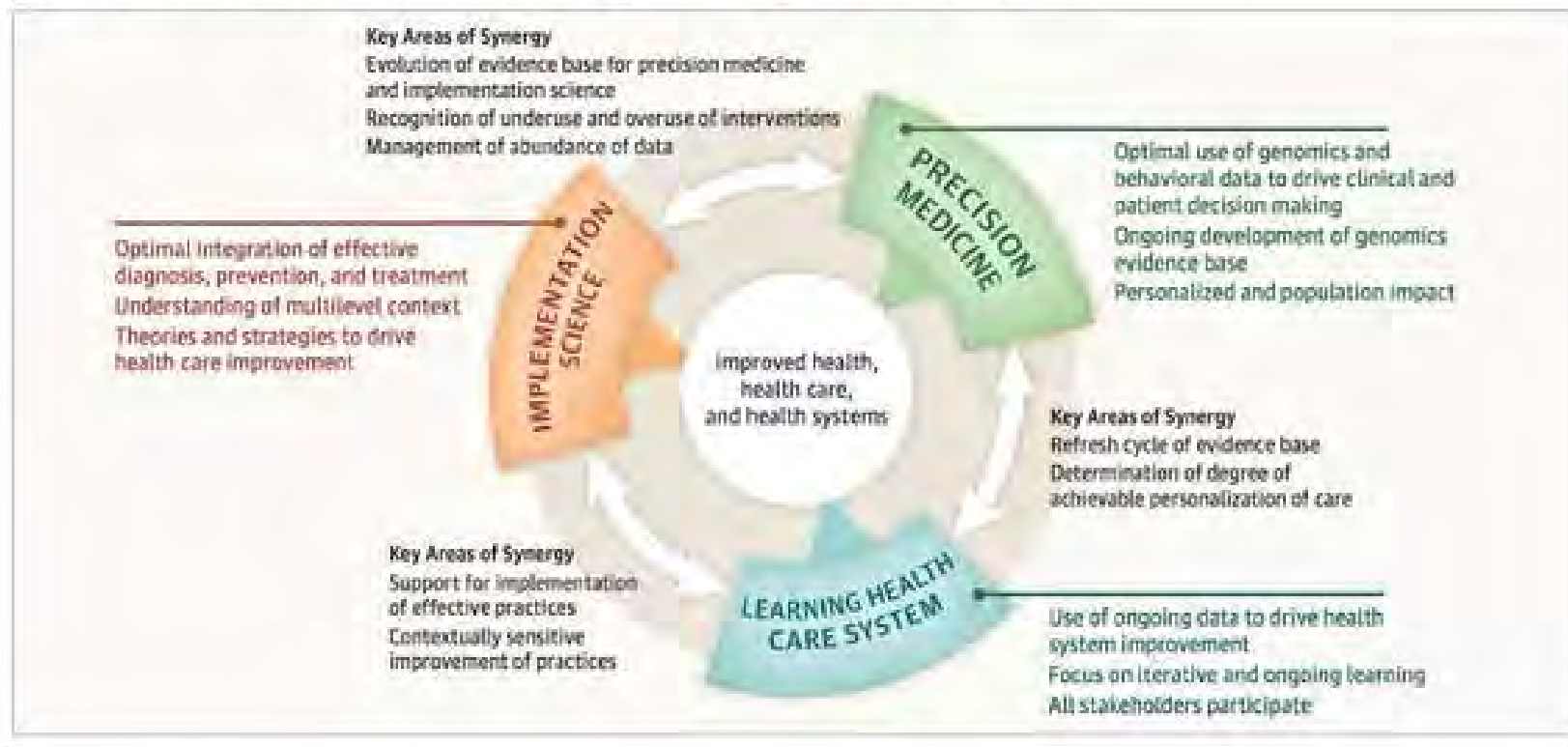
FIGURE 1. Collection and use of data to inform decision making by stakeholders in a learning behavioral health care (BH) system^a



Stein, Adams, Chambers. *Psychiatric Services*, 2016.

Hope for the future...

Figure. Contributions of Implementation Science, Learning Health Care System, and Precision Medicine



Charlton DA, Farris WS, Khoury MJ. *Collaborative of Implementation Science, Precision Medicine, and the Learning Health Care System*. <https://doi.org/10.1093/monographs/monograph-10>

Guiding Principles for IS & PM...

- First, context matters and is multilevel.
- Second, it's not just whether a practice works, but whether that practice can be delivered in many real-world settings.
- Third, there are effective strategies to implement evidence-based practices.
- Fourth, implementation science is a team sport. Partnerships needed with a range of stakeholders, including patients, clinicians, administrators, researchers, and policy makers.

**THANK
YOU**

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