

LEADERSHIP CONSORTIUM FOR A VALUE & SCIENCE-DRIVEN HEALTH SYSTEM  
CLINICAL EFFECTIVENESS RESEARCH INNOVATION COLLABORATIVE

Lecture Room, National Academy of Sciences Building, 2101 Constitution Avenue NW, Washington, DC  
Thursday, 25 January 2018 – 11:00a – 12:15p

# Case Study Discussion: Learning Activities in Health Systems

Brent C. James, M.D., M.Stat



NATIONAL ACADEMY OF MEDICINE

Advising the nation/Improving health

# Disclosures

*I receive a monthly retainer from Health Catalyst  
as a part-time*

# Outline

1. **A policy** – with proper ethical oversight to embedded research
2. **A way of thinking about research**  
that fits into care delivery operations
3. **Examples of results**

# Ethical Oversight Policy for Learning Projects

- ~ **AHRQ Hasting Ethics Center grant: The Ethics of Quality Improvement**
  - published papers, a book, demonstration projects (MD Anderson Cancer Center, Intermountain Healthcare)
- ~ **Presented resulting “test” policy to SACHRP**
  - (Secretary’s Advisory Committee on Human Research Protections – oversees OHRP) **on 27 March 2008**
- ~ **Distinguishes traditional clinical research from quality improvement**
  - QI deploys evidence-based best treatment; doesn’t compare treatments
  - allows clinicians to vary based on patient need (doesn’t interrupt the ethical clinician-patient link)
- ~ **Uses a Privacy Board** (special type of an IRB established in HIPAA; structurally and functionally identical to an IRB)
  - to oversee QI projects** (off-loads regular IRBs)
  - almost always uses expedited review (with consent agenda back to the IRB/Privacy Board)
- ~ **Relies primarily on “detect controls” rather than “prevent controls”**

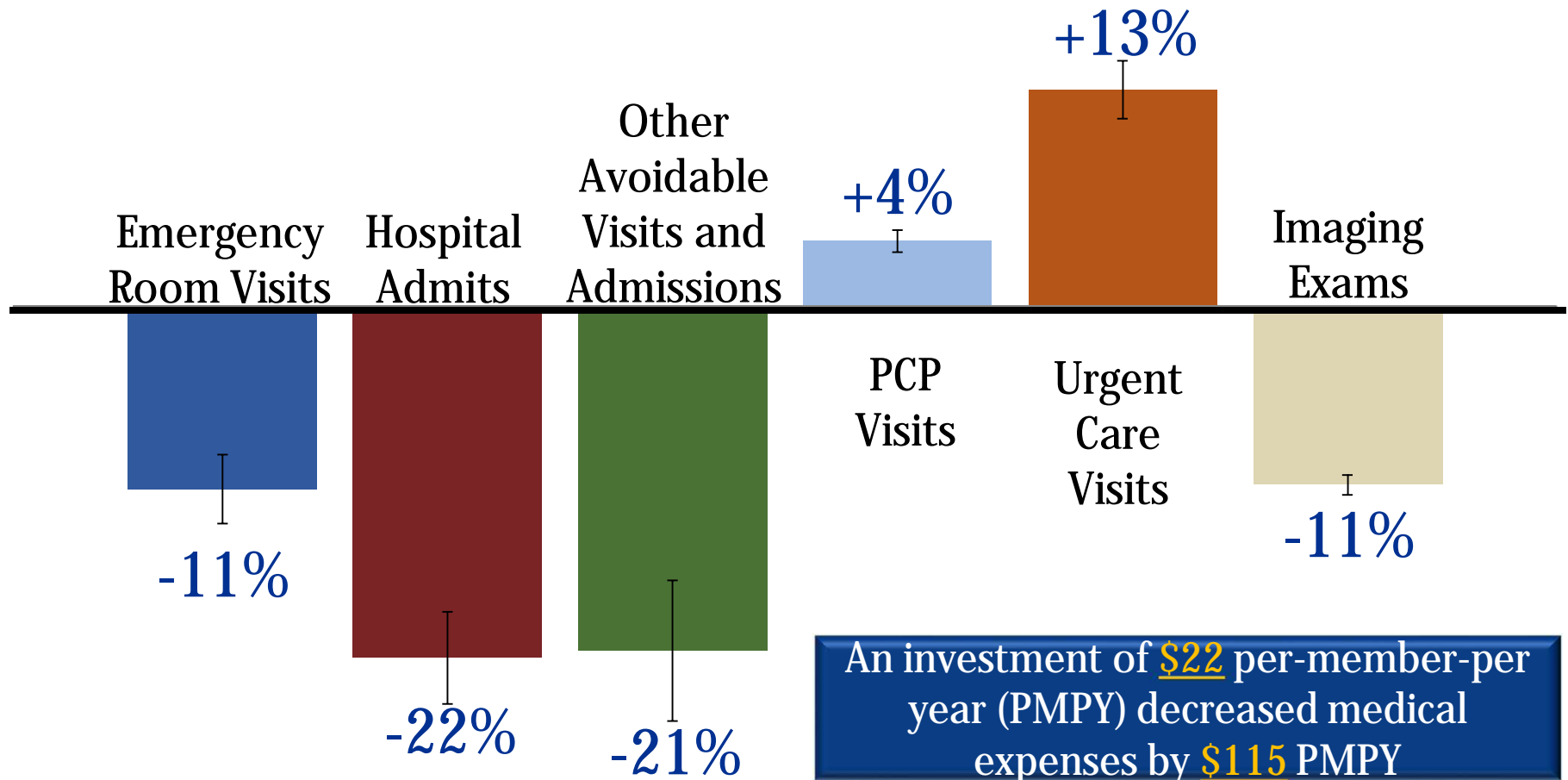
## 4 “types” of clinical learning

- 1. Rapid impact on care delivery performance** as measured in patient outcomes
  - the “best medical result at the lowest necessary cost”
  - **internally funded with “patient-care”** (operational) **dollars**
  - external grant funding, publication = “icing on the cake”
- 2. Investigator-initiated research**
  - traditional academic model
  - funded through grants
- 3. Collaborations with external investigators**
  - e.g., multi-center trials; investigators at local universities
  - requires an internal “champion”
- 4. Industry-based groups** (e.g., big pharma; device manufacturers)



# Team-Based Care

(3<sup>rd</sup> generation accountable medical home)



Reiss-Brennan B, Brunisholz KD, Dredge C, Briot P, Grazier K, Wilcox A, Savitz L, and James B. Association of integrated team-based care with health care quality, utilization, and cost. *JAMA* 2016; 316(8):826-34 (Aug 23/30).