Department of Cardiothoracic & Vascular Surgery
McGovern Medical School / The University of Texas Health Science Center at Houston

Learning Health System - Considerations for Implementation

Charles C. Miller, III, PhD
Professor, Associate Dean, Associate VP
Department of Cardiothoracic and Vascular Surgery
McGovern Medical School / The University of Texas
Science Center at Houston
Memorial Hermann Heart & Vascular Institute

Disclosure

- IRB panel chair
- Associate VP / Clinical Research

Learning Health System

- Does not mean "teaching hospital" – not about medical education
- Take in the sense of "machine learning" – the health system is the learning machine
- Definition controversy – ascending sophistication
  - EHR scraping and dashboards
  - Application of AI to EHR data
  - Embedded CER trials

Learning Health System

- IOM/NAM definition

"knowledge generation is so embedded into the core of the practice of medicine that it is a natural outgrowth and product of the healthcare delivery process and leads to continual improvement in care."

- ICRLHC definition

To the extent feasible, every patient should be in a trial – *comparative effectiveness should be usual care*

Learning Healthcare System

Less than than 20% of current practice is supported by strong (level 1 or 2) evidence

Even where strong evidence supports practice guidelines, these are followed less than 50% of the time on average

Scientific American, March 2011

Comparative Effectiveness

Comparative effectiveness – AHRQ

Comparative effectiveness research is designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different treatment options.

For our purposes – treatments that are in current use

Comparative Effectiveness

Should trauma patients without a flail segment get rib fixation?

Should FEVAR get CSF drainage?

Does increasing MAP in the trauma bay improve SCI outcomes?

Treatment depends on where you go, or maybe even who is on call

These can be addressed in CER trials

7 Steps - AHRQ

1. Identify new & emerging treatments
2. Review & synthesize available research
3. Identify research needs and gaps
4. Develop new evidence (trials)
5. Train and develop clinical investigators
6. Translate and disseminate findings
7. Public engagement and awareness

Learning Healthcare System

- Ethics question

If comparative effectiveness trials are baked into the ordinary practice of medicine, what risks or burdens *above and beyond* those experienced in conventional medical practice are imposed by the conduct of these trials?

What should we protect from?

"…the relevant counterfactual for randomized trials without consent is not a trial with consent—rather, it is the roll out of one approach or the other, with neither consent nor rigorous evaluation."

Asch 2020