The Importance of Evidence in Digital Health

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The fundamental **challenge**

- Markets and science move at different speeds
- Entrepreneurs are conflicted but most often want to move at the pace of the market
- Quality Clinical Research is resource intensive.
Most health-focused innovations involve efforts to improve patients' well being, i.e., lives are at stake. And...clinicians care about evidence as they make purchasing decisions.
Why can’t common sense guide us?

Cognitive biases – 162 of them!

The most common example is the placebo effect

Conflicts of interest
The dog days of summer
The Fever Tree
The goal in science is to isolate one variable and follow it over time to draw conclusions on its effect.
Ways to gather evidence (study design)

Observational studies
  regression to the mean
  learning bias
Before and after studies
Case-control studies – imperfect matching
Single-blind trials – possible study staff bias
Double-blind trials – difficult with digital interventions
Common logic traps

Correlation is not causation

Digital health interventions change subjects in multiple ways (before-after studies)

Null hypothesis, Type I (false +) and type II (false -) errors
Where are you on the evidence journey?

1. Keen observation leads to hypothesis generation
2. Hypothesis testing in small samples
3. Large-scale, randomized, controlled trials
4. Multiple studies point to same conclusion
Assessment of Clinician Diagnostic Concordance With Video Telemedicine in the Integrated Multispecialty Practice at Mayo Clinic During the Beginning of COVID-19 Pandemic From March to June 2020

Bart M. Damaerschalk, MD, MSc; Andrew Pines, MD; Richard Butterfield, BS, MA; Jack M. Haglin, MD; Tufia C. Haddad, MD; James Yiannias, MD; Christopher E. Colby, MD; Sarvam P. TerKonda, MD; Steve R. Ommen, MD; Matthew S. Bushman, BSc; Troy G. Lokken, MBA; Rebecca N. Blegen, MBA; Melendie D. Hoff, MSW; Jordan D. Coffey, MBA, MHA, MA; Greg S. Anthony, MBA, MSPH; Nan Zhang, MSc; for the Diagnostic Accuracy of Telemedicine Utilized at Mayo Clinic Alix School of Medicine Study Group Investigators
Is telehealth additive or substitutive?

**Brief Communication**

The impact of expanded telehealth availability on primary care utilization

Ram A. Dixit, Raj M. Ratwani, Jasmine A. Bishop, Kevin Schulman, Christopher Sharp, Kerry Palakanis and Ethan Booker
Barriers to high-quality clinical research in LMIC

Lack of financial and human capacity
Ethical and regulatory system obstacles
Lack of a research environment
Operational barriers
Competing demands

Possible Solutions

Capacity development

Links between research policy and practice

Emphasis on a systems approach

Source: Franzen et al. doi:10.1136/bmjopen-2016-012332
Digital Twins

Health digital twins as tools for precision medicine: Considerations for computation, implementation, and regulation

www.nature.com/npjdigitalmed
Wrapping up

Evidence gathering takes *time, costs money, and requires open-mindedness and patience*

Most other ways of looking at the world are *fraught with bias*

Industry and academia should do more *collaboratively* to bring the two worlds together

It is critical that *LMIC strengthen their capacity* to do high-quality biomedical research
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