The Importance of Evidence in Digital Health

Joseph C. Kvedar, MD

Professor of Dermatology, Harvard Medical School Sr. Advisor, Center for Innovation in Digital HealthCare, MGH Immediate Past Chair, American Telemedicine Association Editor-in Chief, *npj* Digital Medicine

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.

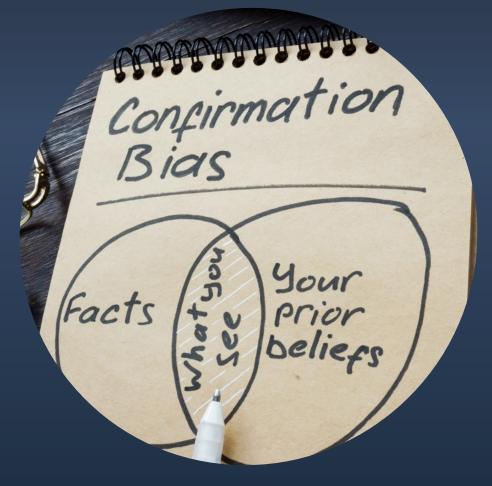
Most health-focused innovations involve efforts to improve patients' well being

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

Is video telehealth of diagnostic quality?



Original Investigation | Health Informatics

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. Demaerschalk, 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; Mekenzie 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?

npj digital medicine

www.nature.com/npjdigitalmed

BRIEF COMMUNICATION OPEN (Check for updates) The impact of expanded telehealth availability on primary care utilization

Ram A. Dixit¹, Raj M. Ratwani 💿^{1 🖂}, Jasmine A. Bishop², Kevin Schulman³, Christopher Sharp³, Kerry Palakanis⁴ 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

Source: Alemayehu et al. https://equityhealthj.biomedcentral.com/articles/10.1186/s12939-018-0748-6

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

www.nature.com/npjdigitalmed

Check for updates

EDITORIAL OPEN

npj

digital medicine

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

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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Author of Two Books: The Internet of Healthy Things • The New Mobile Age Available at Amazon.com Website: Joekvedar.com LinkedIn: @JoeKvedar Instagram: @drkvedar Twitter: @jkvedar email: jkvedar@mgb.org