Digital Health: Should We Be Concerned?

John Mandrola, MD

BAPTIST HEALTH LOUISVILLE, LOUISVILLE, KENTUCKY

ABSTRACT: Type "health and fitness apps" into any search engine, and thousands of options will appear—so many, in fact, that people can now measure their own heart rate, sleep habits, and dozens of other health parameters that once required a doctor's visit. While anecdotes of a personal health device capturing early signs of disease may garner media attention, the increasing quantification of human physiology can have downsides.

In essence, the enhanced ability to assess surrogate measures of health, such as temperature, minute-to-minute blood pressure, and genomics, are an expansion of anticipatory health—that is, an attempt to detect and avoid events that might happen in the future. While patients used to seek out doctors when they were sick, digital tools will send increasing numbers of people to their physicians before they are sick. In a Cartesian model of the human body, wherein one system could potentially be fixed independent of another system, having more data may be beneficial. The human body, however, is far more complex than any Cartesian model could explain. This article explores the limitations of digital devices to improve health.

INTRODUCTION

Digital health devices have given people more options for assessing health parameters that were either previously unknown or measured by a physician. Should we be concerned about digital health? Yes, I believe we should be very concerned.

Health needs no modifier. In his wonderfully contrarian book, *The Death of Humane Medicine*, the late Dr. Petr Skrabanek wrote my two favorite sentences on true health[1]:

Healthy people do not think of health.

The pursuit of health is a symptom of unhealth.

Before I present the empirical reasons to be cautious about digital health, first consider your thoughts when you meet a 95-year-old woman who was admitted to a hospital after living five decades without seeing a doctor. Do you think she has lived this long because of luck…or because she did not interact with the healthcare system? I will make the case that the latter notion is not foolhardy. And this is why modifying health with the word digital is concerning.

CAVEATS AND BACKGROUND

Being cautious about the digitizing of health does not make one a Luddite. Recall that the Luddites did not revolt against the machines; they busted the machines in protest against unfair labor practices. Similarly, the problem with digital health is not the technology; it is the misthink that would lazily equate technology to health. Today there are many examples of beneficial digital technology: remote monitoring of cardiac devices may detect lead malfunctions before a catastrophe; point-of-care ultrasound has transformed the physical exam by allowing visual inspection of organs; and telehealth brings medical care to those geographically distant from medical centers. The common theme in all of these examples is that technology is being used to help people who have a problem and are asking for our help. This is the antithesis of anticipatory medicine,[2] which, according to Dr. H. Gilbert Welch, is the prescribing of medication and/or screenings to detect and avoid events that might happen in the future. Anticipatory medicine is central to much of consumer-driven digital health. Alas, the incentive inherent in a profit-driven healthcare sector is to find more customers, and a system that treats only those with complaints limits the number of potential customers.

Enter medicalization, in which human conditions and problems such as menopause or sleep disorders come to be defined and treated as medical conditions. Through good intentions, wishful thinking, and vested interests, there are now numerous ways to be unwell. While disease expansion has occurred in many conditions (think hypertension, type 2 diabetes, mood disorders, atherosclerosis via the coronary artery calcium score), few examples highlight the power of digital health to medicalize more than the smartwatch. In times past, the diagnosis of atrial fibrillation (AF) most often required symptoms, a trip to the doctor, and an electrocardiogram. Now, a smartwatch allows the diagnosis of minutes of subclinical AF, which may or may not be important to treat.

THE EMPIRICAL CASE AGAINST DIGITAL HEALTH

Observational Evidence

The epidemiology of longevity is not kind to digital health. A review of longevity data from the Centers for Disease Control and Prevention (CDC) shows that the age of death for any gender or race category has not increased since 2006 (Figure 1).[3] Some categories even show a decline in longevity. Thus, the digital revolution of the last decade has had no effect on human longevity. That same CDC data does, however, find that while deaths from cardiovascular disease and cancers have declined modestly, the numbers of people living with chronic conditions, dementia, and frailty has increased. Is this a positive? How does digital health reduce human suffering at end of life?

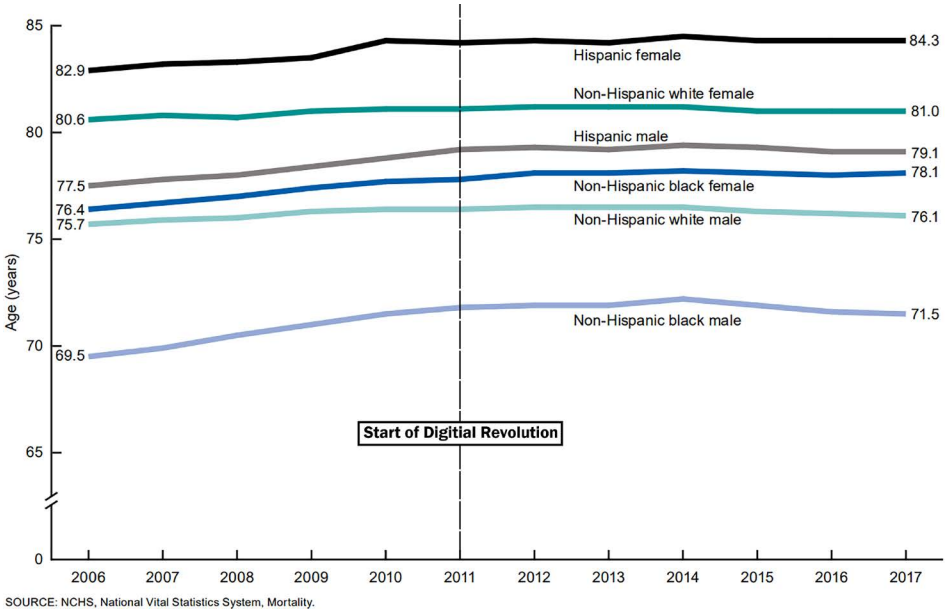

Figure 1.
Longevity rates by gender and race before and since the digital revolution. From the Centers for Disease Control and Prevention's National Vital Statistics database.[3]

Plausibility Challenges of Digital Health

Digitizing organ function might work if the Cartesian frame of the human body held true. In medical school, we learned to think of the body in systems, as if it were a machine. There was the cardiovascular system, the gastrointestinal system, the central nervous system, and so on. You fix each system, and *voilà*, the patient gets better. Wise clinicians quickly learn the folly in this way of thinking.

The failure of screening programs beautifully demonstrates the flaw of Cartesian thinking in medicine. Black et al. reviewed multiple randomized controlled trials (RCTs) of cancer screening and found that while screening programs may modestly reduce disease-specific deaths, there was no difference in all-cause mortality.[4] Why? Because the vast majority of deaths occur from non-cancer causes. Also, in a systematic review of both RCTs and meta-analyses of screening for deadly diseases, Saquib et al. found that reductions in all-cause mortality were very rare or nonexistent.[5]

Given the hundreds, maybe thousands, of ways one can die, it makes sense that detecting merely one disease will not make us live longer.

Another example of how digital health's intention to help may fall short comes from social media. In 2019, CNBC reported that Facebook planned to debut a new tool that reminds users to get regular medical checkups.[6] While that sounds smart, a Cochrane review of general health checks, including 17 trials of more than 250,000 individuals, failed to show any benefits for total, cancer-related, or cardiovascular mortality.[7]

Absence of Evidence

In 2019, Dr. Ida Sim published an exhaustive review of mobile devices and health in the *New England Journal of Medicine*.[8] The 6,100-word review included 80 references. The number of references to RCTs with outcomes was zero. While the absence of evidence does not equate to evidence of no effect, the lack of RCT-level evidence for improved health from digital technology is notable.

POTENTIAL HARMS FROM SENDING ASYMPTOMATIC PATIENTS TO THE DOCTOR?

There is little doubt that digital devices will send more people to their doctor. The smartwatch is a good example. In the Apple Heart study, which recruited more than 400,000 owners of a smartwatch, an irregular pulse detection was found in 0.52% of participants.[9] *Apple Insider* estimates that more than 30 million Apple watches were sold in 2019 in addition to the 22 million sold in 2018—and these are just Apple products.[10] *Reuters* reports that Garmin expected to ship nearly 125 million wearable units by the end of 2018; a conservative estimate, therefore, might be approximately 100 million products. One-half percent of that number is approximately 500,000 people who may be seeking medical consultation for suspected atrial fibrillation. And that

is an underestimate because the watch also will also detect bradycardia and premature beats.

Since arrhythmia detection is a medical test, we need to consider specificity. In an editorial in *JAMA Internal Medicine*, Andrew Foy and I calculated the risk of AF misdiagnosis from electrocardiographic screening.[11] Using numerous studies on the 12-lead electrocardiogram, which is arguably better than a smartwatch recording, we estimated a 95% specificity for detecting AF. If you apply that specificity to a population of 100 million smartwatch owners and assume a conservative estimate of AF prevalence of 1% (skewed to a young population), you will find that the number of people with AF is 0.01 × 100 million, or 1 million people. This means that the number of people without AF is 100 million minus 1 million, or 99 million. At 95% specificity, the false positive rate would be 0.05 × 99 million people, or 4.95 million people. Thus, a conservative estimate of AF prevalence in a population of smartwatch owners plus a generous estimate of specificity leads to nearly 5 million people seeking medical attention for a misdiagnosis of AF. Some of these millions of people-now-turned-patients will meet wise doctors who will reassure them without further testing. But many of these patients will experience cascades of care. Ganguli et al. recently published a survey of nearly 400 practicing US internists and found that almost all had experienced cascades of care after an incidental finding,[12] and a majority had observed harm from cascades.

Another deeply concerning area of digital health is the push towards genomics. Professor Christopher Semsarian, an expert on the genetic basis of cardiovascular disease, wrote in the *BMJ* that sequencing the genomes of people who are well and asymptomatic has great potential to do more harm than good.[13] Semsarian explained that sequencing a human genome in a healthy person can identify up to 12 potentially harmful DNA variants, and knowledge of these could induce cascade testing and the iatrogenesis that comes with it.

Polygenic risk scores look equally dubious. Despite advances in the ability to calculate polygenic risk scores for complex conditions such as coronary heart disease, a comparative study of two large cohorts found that the polygenic risk score was associated with incident coronary heart disease events but did not significantly improve discrimination, calibration, or risk reclassification compared with a pooled cohort equation using simple clinical indices.[14] To be fair, this technology is in its early phases.

PRIVACY AND RACIAL CONCERNS

In her review article, Dr. Ida Sim wrote that the US Food and Drug Administration has decided to regulate software as a medical device via a digital health software precertification program. The criteria set out for having software streamlined for review is decidedly lax: companies that demonstrate a "culture of quality and organizational excellence." Also notable was this quote: "products of pre-certified companies do not have to be associated with improved clinical outcomes before market release…."[8]

Malicious tampering of technology is concerning. Minsky et al. demonstrated the ability of an attacker to modify 3-dimensional medical imagery using deep learning.[15] The authors showed that they could inject or remove lung cancer nodules from computed tomography scans using free medical imagery downloaded from the Internet. And this manipulation easily fooled radiologists using state-of-the-art artificial intelligence.

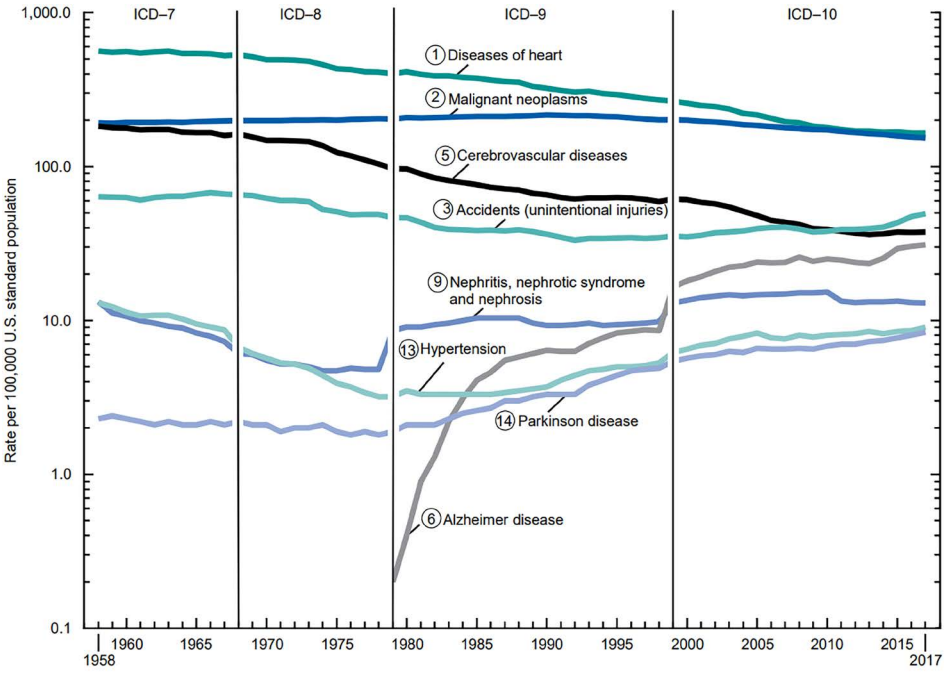

Figure 2.
Age-adjusted death rates for selected leading causes of death in the United States between 1958 and 2017. From the Centers for Disease Control and Prevention's National Vital Statistics database.[17]

"Machine learning," the authors wrote, "is very accessible to the public these days; it is almost like plug and play."

Artificial intelligence algorithms may accentuate racial biases. Obermeyer et al. studied a commercial prediction algorithm used to identify complex patients who need more support.[16] The authors found that because the algorithm predicts costs rather than illnesses, and blacks have unequal access to healthcare services, black patients received extra medical help less often than white patients.

CONCLUSION

There is much to worry about with digital health. A potentially tragic paradox of today is that improved technology may reduce death from some conditions but may also increase the numbers of older adults living with comorbid conditions (Figure 2).[17] Few advances in digital health seem targeted at the relief of suffering. Rather, most seem focused on the young and well, which raises the possibility of iatrogenesis. A society that is increasingly fearful of lurking diseases and more apt to seek out clinicians when they feel well hardly seems like a healthier one. Digital devices will surely give people more data, but that does not translate to better health.

While others may oppose this skeptical take on digital health, their view is necessarily as opinion-based as mine. This is because we have no randomized controlled trials focused on outcomes. One hopes that with time, proper trials will show that increased digitization of the human condition will help patients as much as it does doctors, hospitals, and industry.

Back to our 95-year-old woman who had not seen a doctor in decades. Indeed, it may have been more than luck that allowed her to live so long. It may have been her avoidance of the healthcare system.

Conflict of Interest Disclosure:
The author has completed and submitted the *Methodist DeBakey Cardiovascular Journal* Conflict of Interest Statement and none were reported.

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KEY POINTS

- Technology has made many aspects of healthcare better. No one is against better imaging, better catheters for procedures and improved therapeutics.
- Digital means to quantify bodily functions gives us physical data. True health, however, is much more metaphysical than physical.
- An expansion of digital technology will allow measurements of bodily function that may or may not signal impeding disease. Without knowledge of "normal," these measures may lead to cascades of medical investigation. And these cascades can lead to both direct and indirect iatrogenesis.
- Potential ways to prevent harm from expanding digital health is humility, candor and embrace of randomized clinical trials that measure hard outcomes.

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