The Leading Edge

The quantified patient of the future: Opportunities and challenges

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ABSTRACT

The healthcare system is undergoing rapid transformation as national policies increase patient access, reward positive health outcomes, and push for an end to the current era of episodic care. Advances in health sensors are rapidly moving diagnostic and monitoring capabilities into consumer products, enabling new care models. Although hospitals and health care providers have been slow to embrace novel health technologies, such innovations may help meet mounting pressure to provide timely, high quality, and low-cost care to large populations. This leading edge perspective focuses on the quantified-self movement and highlights the opportunities and challenges for patients, providers, and researchers.

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1. Introduction

The US healthcare system is undergoing rapid transformation as national policies increase patient access, encourage adoption and use of information technology, and reward value-based care. Advances in electronics and mobile communication have paved the path for consumer-oriented health solutions, commonly referred to as digital health solutions, with sophisticated diagnostic and monitoring capabilities that enable new care models outside the hospital. These advances can be leveraged to enhance the patient experience, improve population health, and reduce costs of care. This perspective will provide an introduction to health sensors and the growing quantified-self movement, outline opportunities for how these technological innovations can transform healthcare delivery, and share key challenges that must be overcome to realize their benefits.

2. The state of health sensor technologies

Health sensors are devices that enable intermittent or continuous physiologic monitoring, and are often integrated with mobile devices capable of data transmission, processing, display, and storage. These digital health innovations have contributed to the "quantified-self" movement, whose members believe that collecting and tracking detailed data on lifestyle behaviors not only helps them make better decisions, but also provides actionable insight into their personal health. Over two thirds of US adults track at least one health indicator, such as weight, food intake, exercise routine, blood pressure, or blood sugar levels, either in their heads, on paper, or with a sensor or mobile app.[1] Importantly, 46% of these quantified patients report that self-monitoring has changed their approach to maintaining their health. With over 85% of healthcare consumers owning cell phones, and 53% owning smartphones,[1] health sensors coupled with mobile communication technology allow for accurate, automated, and convenient record keeping.

The quantified-self movement and health sensors first gained footing in the fitness and wellness arena by tracking everything that could be measured by an accelerometer (a mechanical sensor).[2] Accelerometer-based sensors, which are usually worn on the wrist or clipped onto clothing, offer a quantitative assessment of a patient's physical activity level and sleep patterns, metrics that have previously been difficult or cumbersome to quantify other than by self-report. The next wave of consumer health devices are starting to offer further monitoring capabilities including body mass index, hydration, heart rate, skin temperature, electrocardiogram, and diagnostic imaging (portable smartphone-enabled otoscope, ophthalmoscope, and ultrasound).[3]

These advances are being made possible by the increasing computing power and plunging cost of electronics.[4] Future sensors

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will no longer be confined to the outside of the body; they will be ingestible, implantable, or subcutaneous.[5] The evolution of health sensors is primarily being driven by the need for passive, unobtrusive measurements and clinically meaningful assessment of human physiology. As health sensors become embedded into people's daily routines, compliance will increase, along with the value of sensor data for both the individual and the healthcare system. However, there remains a significant gap between access to information and translation of that information into actionable insights and behavior change.[6] It has been shown that behaviors can be strongly influenced by intentionally designing a "choice architecture" that influences people's decisions based on how choices are presented.[7] By providing context around many aspects of a person's health, health sensors may enable personalized, adaptive choice architectures that bring patients closer to their health goals.

3. Opportunities

Although the quantified-self movement initially gained footing in the consumer space, the ability to remotely, continuously, and quantitatively track human behavior as well as clinically relevant human physiology presents significant opportunities for various stakeholders in the healthcare ecosystem, including patients, providers, payers, and researchers.

3.1. Patient empowerment

Thoughtfully designed health sensor ecosystems have the potential to greatly improve patient experience, engagement, and health outcomes. At their core, these devices close the feedback loop between a patient's choices, actions, and overall health. Patients may feel more engaged in their care, as these quantitative measures can inform conversations with their providers and impact treatment plans. Similar to blood glucose tracking for diabetes management, daily monitoring of physical activity, dietary intake, and sleep hygiene, could lead to improved cardiovascular health and become a cornerstone of chronic disease management. Initial studies have shown that activity monitoring improves metabolic profiles of inactive older adults[8] and also improves time to recovery and shortens hospital stay after cardiac surgery.[9]

3.2. Redefining population medicine

Traditionally, longitudinal epidemiologic studies have relied on episodic health assessments to determine the association between risk factors with outcomes. However, emerging health sensors combined with smartphones will not only enable frequent physiological assessments in out-of-hospital environments, but also generate large streams of patient data tied to a specific time and place. The ability to analyze these data with patient consent opens the door to confirming previously established associations using massive sample sizes (e.g. resting heart rate and mortality), as well as studying complex relationships between risk factors and outcomes (e.g. resting heart rate, fitness level, cigarette use, hypertension, and mortality). Furthermore, novel associations could be used to generate new hypotheses that can then be prospectively tested in controlled cohorts. Two large population-based cohorts, the UK Biobank study (www.ukbiobank.ac.uk) and the Health eHeart study (www.health-eheartstudy.org), both of which employ digital health sensors, exemplify new models of longitudinal, observational, population studies.

3.3. Unraveling the true potential of personalized medicine

The genomic revolution has led to significant advances for diseases with simple Mendelian inheritance patterns, but has yet to deliver on its promise to explain heterogeneities in disease development, progression, and response to therapies, particularly as they relate to complex polygenic diseases. A major obstacle has been an incomplete assessment and understanding of genotype–phenotype relationships, i.e. understanding how someone's inherited genetics interacts with their environment and daily behaviors to impact health. Furthermore, current large-scale genomic studies establish genotype-phenotype correlations using phenotypes that are part of our current views of disease (e.g. one-time blood pressure, self-reported activity levels). However, there is an opportunity to explore phenotypes in much greater detail. Emerging technologies that allow us to continuously record personal biometric data (quantitative physiology: e.g. continuous blood glucose measurements) and capture patient context and symptoms (qualitative phenotype: e.g. physical activity, sleep, dietary intake, and stress), when combined with genomic information, will help us move closer to understanding physiology and response to interventions at the level of an individual, as opposed to populations.

4. Challenges: the road ahead

To realize the opportunities previously described, healthcare sensors must be widely adopted and used by both patients and health care providers, a formidable challenge given the complexity and variability of healthcare delivery. Sittig and Singh developed an eight dimensional socio-technical model that identifies factors that need to be addressed in the design, development, implementation, use and evaluation of health information technology systems, including (1) hardware and software; (2) clinical content; (3) human computer interface; (4) people; (5) workflow and communication; (6) organizational policies and procedures; (7) external rules, regulations, and pressures; and (8) system measurement and monitoring.[10] Each of these factors may help us better understand why hospitals and health care providers have been slow to embrace digital health technologies. We highlight and suggest next steps to overcome three key barriers to wide scale adoption of health sensors: external rules, regulations and pressures; workflow; and system measurement and monitoring.

4.1. External rules, regulations, and pressures: ensuring safety, accuracy, and privacy

Digital health solutions that collect physiologic and phenotypic data must be safe. The US Food and Drug Administration (FDA) will take a risk-based regulatory approach and apply regulatory oversight only "to those mobile apps that are medical devices" (or extension/accessory to a medical device) and "whose functionality could pose a risk to a patient's safety if the mobile app were to not function as intended."[11] Since health sensors measure physiologic signals and often use mobile apps for displaying and sharing the data with a provider, we anticipate the majority will have their validity and safety regulated by the FDA. For example, a mobile device with a sensor to capture electrocardiograms transforms the mobile device into a regulated medical device. However, digital health solutions often include a component of patient reported outcomes, such as food diaries or pain records, which will not be regulated by the FDA.

Health sensors and associated software must also protect patient's health information. The primary legislation protecting the confidentiality and security of health information, the Health

Insurance Portability and Accountability Act (HIPAA), only applies to covered entities; health care providers, health plans, and health care clearinghouses. Many sensors and mobile health apps are targeted to consumers and therefore fall outside HIPAA's jurisdiction, leaving security and privacy measures to the developers. Recent evidence finds that a minority of mobile applications have privacy policies, and that available polices were difficult to read and opaque.[12] Thoughtful oversight by independent review organizations or stronger industry monitoring (similar to post-FDA surveillance of pharmaceuticals) may be needed to ensure new sensors and medical applications are safe, accurate, and protect patient information.[13]

4.2. Workflow: integrating into the clinical workflow

Health sensors also have the potential to generate too much data and quickly overwhelm clinicians. For example, a patient checking their blood pressure twice daily as instructed might have 180 readings for their primary care provider at their three-month follow-up. Companies and service providers need to not only consider intuitive summary views of longitudinal data for healthcare providers (e.g. Holter monitor reports), but also include automated analytics that can translate information into knowledge and generate insights that can be acted upon by providers or integrated into a care management plan.

Furthermore, the health sensor data should be interoperable between vendor products, be able to integrate into the patient's electronic health record, and be easily accessible to the provider during the patient visit for active interrogation and intervention. Partners Healthcare's Center for Connected Health, for example, established a remote monitoring data repository to link home monitoring data to the patient's electronic health record (EHR) and make this data available to health care providers at the point of care.[14] More recently, large consumer technology companies like Apple, Samsung, and Google have announced platforms to aggregate data from consumer health sensors and mobile apps – HealthKit, SAMI, and Google Fit, respectively.[15] To make these data available to health care providing through existing workflows, Apple is partnering with academic medical centers and EHR vendors to integrate HealthKit data with EHRs.[16]

4.3. System measurement and monitoring: demonstrating value

The US is transitioning from a fee-for-service reimbursement model to value-based care,[17] with a focus on achieving better health outcomes at lower cost by using evidence-based practices and considering patient preferences. There is a growing literature supporting the use of health sensors and mobile communication to enable new care models and reduce costs.[9,18] The Centers for Medicare and Medicaid Services (CMS) recently expanded coverage to include remote patient monitoring and chronic care management for patients with two or more chronic diseases.[19,20] While some providers and organizations have long been using remote monitoring in their practices, this new coverage will likely spur increased adoption of health sensor technologies and mobile applications. However, remote monitoring is not valuable in all circumstances and false positive results can lead to inappropriate health care utilization.[21]

As sensor technologies evolve, we need continued rigorous evaluation in the form of prospective clinical trials to guide the appropriate use and coverage of digital health solutions, similar to the regulatory compliance and clinical evidence requirements for drugs and medical devices. Health systems, and specifically, health care providers, can play an active role in accelerating the dissemination of innovative technologies by assuming the role of early adopters and early majority[22], and working with industry to perform clinical validation.

Given regulatory and compliance requirements around safety and privacy, innovators and industry will be primarily responsible for technical validation of sensor technologies. Health care organizations and providers will play a dominant role in assessing the impact of these solutions on quality of care and health outcomes, by engaging in implementation pilots and/or well-designed clinical trials. However, full scale implementation of new technologies, without thorough information security reviews and a robust evidence base, could lead to unintended consequences in regards to safety and privacy, cost, and effectiveness. Some organizations, such as academic medical centers and large health systems, will be more interested and better resourced to validate and pilot these solutions, while others will need to wait for completion of validation trials or publication of guideline recommendations.

5. Conclusion

Rising healthcare costs, growing consumer demand, and exponential technological advancements are enabling a new era in healthcare – the era of the quantified patient. Hospitals and health care providers have been slow to embrace digital health technologies due to the fact that most solutions have not yet fulfilled all of the challenges highlighted: regulatory clearance where appropriate, integration into electronic health records and provider workflows, and demonstration of added value. Ultimately, adoption and implementation of safe, validated, and efficient health sensor technologies by care providers may help meet mounting pressure to provide timely, high quality, and low-cost care to patients, while improving their health outcomes.

Conflict of interest disclosure statement

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