

Special Issue

NEWSLETTER



IEEE

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Special Issue on:
**Consumer Technology
meets
Health Care**



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Editor's Comment:

Dear Reader,

This newsletter is special, as it is the first special issue of the IEEE Life Sciences Community. In our special issues, we focus on one specific topic at hand. These topics are in the scope of the life sciences and of great interest to our community.

The first special issue is dedicated to the topic "*Consumer Technology Meets Health Care*". Presenting a variation of articles about digital health with consumer technology and its functionality, challenges and comparisons to medical devices and aspects of privacy and cybersecurity.

For this issue, we invited two guest editors, Nahum Gershon and Michael Ackermann, who took over the role in conceptualizing, gathering of content and implementing the

special issue, together with author from the areas of consumer technology and life sciences.

We hope that this special issue will provide an overview and ideas about consumer technology and health care to you.

If you have an idea for a special issue in the life sciences community we would like to encourage you to get in contact.

Enjoy reading!

Editorial Contact: editorlsc@ieee.org

Tobias Cibis,
Editor in Chief,
Life Sciences Technical Community,
t.cibis@ieee.org



Guest Editor's Comment:

Consumer Technology Meets Health Care - Promises and Challenges

Mobile health technology has come a long way since the days when devices were often untested, had a small number of capabilities and were of questionable quality. Current and future mobile devices are expected to revolutionize health care through their use in mobile health. Mobile health technology enables patients in remote places and the inner city to get the health care they quickly need. It also enables everybody to get at home treatment without visiting a health practitioner. This will lead to fewer in-office visits and shorter hospital stays as a patient's treatment and rehabilitation can be monitored from home by the physician or practitioner. As an added benefit, data concerning the encounter will be captured and included in the patient's medical record automatically. This disruptive technology promises to revolutionize the existing model of the interaction of patients with the healthcare system.

As in any emerging field, there are challenges. Can the accuracy of medical sensors be maintained in a non-medical environment? Can patients be taught to properly replace their worn sensors? Can one sensor do the job or will a system of sensors be needed? How often should the device provide a warning without inappropriately interrupting the patients' life and work, causing anxiety and confusion?

Will these devices affect the quality of the human interaction of the patients with their health providers? What are the cyber security (personal and national) and privacy and legal issues associated with these devices? How are devices and systems that function accurately and efficiently across diverse populations (e.g., gender, physical or social qualities, income) and locations designed? These are some of the topics and questions that are discussed in this Special Issue on "Consumer Technology Meets Health Care - Promises and Challenges" of the Newsletter of the IEEE Life Sciences Technical Community (LSTC).

In this issue we convened experts from health, consumer technology, medical instrumentation, telemedicine, engineering, science, and other areas to discuss the present and the future of using consumer technology in health care and ways to address the various issues with the use of these technologies.

Nahum Gershon

Guest Editor,
Schmooz.org
schmooz@mac.com



Michael Ackermann,

Guest Editor
Teaching & Technology
Innovators
mjackermn@ieee.org



Digital Health: Still finding Its Way

by Robert Jarrin

A former factory worker suffers from chronic obstructive pulmonary disease (COPD). Her day begins the night before as she periodically coughs during her futile attempt at restful sleep. She typically awakes exhausted, cranky, and unprepared for the day ahead. Her lungs, ravaged through years of occupational exposure to smoke, dust, and chemicals, are severely restricted because of inflammation and lung damage. Her COPD is being treated by different specialists through a variety of medical solutions that provide therapy, oxygen, and non-invasive ventilation. One such device is a mobile sensor that works with her inhaler to coordinate reminders, track dosage, provide local environmental information, and communicates her adherence and progress to a care team. Her ventilator, durable medical equipment, is modern and has mobile connectivity to deliver her data to a cloud-based online patient monitoring system that serves as a repository for diagnostic, prescription, and therapy information. Once per week a respiratory therapist or physician may access and monitor the data for clinical insights, to change settings on the device, or to intervene if she becomes non-compliant.

Across town from her lives a middle-aged former competitive athlete who recently was diagnosed with mild hypertension, high cholesterol, and insomnia. He sought medical attention after experiencing frequent palpitations and light-headedness. Given family history, weight, and an otherwise healthy diet, his general practitioner ruled out a serious condition. However, he made note of a higher than average blood pressure and suggested the man buy a few consumer medical devices to watch his heart. The man, being technologically curious purchased a personal medical-grade EKG and a blood pressure watch. The wafer-thin EKG served to quickly rule out atrial fibrillation but instead helped him discover harmless premature

atrial contractions. The blood pressure watch provides ongoing oscillometric measurements using an inflatable cuff built into the watch band to take random clinically accurate blood pressure readings. It also provides contextual data on sleep to analyze his lack of rest and how it may affect his heart health. He shares this information with a cardiologist in hopes of determining whether he needs medications and what may be affecting his blood pressure.

A few miles away from the man, a woman struggles to start her morning. She suffers from a genetic autoimmune disorder that has caused hypothyroidism further triggering depression. Over time she's also become obese. Fearing an onset of co-morbidities, a savvy and proactive clinician in her healthcare plan helps to enroll her in a national Type 2 Diabetes prevention change program where an applied health signals company may provide her with a suite of digital tools for self-monitoring (mobile apps, an online dashboard, digital medical grade weight scale, and an activity tracker). She would also have access to an interactive online community and an expert coach that could regularly check in on her. Both the online community and her coach could provide an alternative mechanism for coping as she struggles through her journey.

Outside her home, sitting on a school bus in morning traffic is a ten-year-old boy who suffers from Type 1 diabetes and wears a continuous glucose monitor (CGM). Every few minutes the device measures his blood sugar. He carries a smartphone that displays the medical information but just as importantly submits the data into the cloud where his parents (or his pediatricians if necessary), can follow his condition as needed. Until recently, only the boy could track the information on his device – whether a sudden rise or fall in his blood sugar – because most of these devices did not communicate with the

cloud. And let's face it, he's still a kid who occasionally indulges in a tasty treat, or worse, skips a meal. After years of worrying and struggling to keep their son close at hand, a new CGM provides his family with the peace of mind they've wanted all his life: the ability to track his condition remotely.

Digital health has come a long way in a relatively short amount of time. Scenes like those described above are playing out every day in many corners of the world. Like these examples, there are dozens of other exciting consumer health and medical innovations that are changing the practice of medicine and transforming health care delivery. But as easy and seamless as these stories may sound, at its core, digital health is anything but easy. It requires an enormous amount of capital, clinical validity, organizational acceptance, dedication, evidence, modern infrastructure, multi-layered interoperability, sophisticated information technology, training, technical staffing, precise workflows, security protections, legal frameworks, specialized expertise, regulatory compliance, and complex business arrangements that ensure a solid return on investment and risk mitigation for all parties involved.

Consider the woman in the first example with COPD. It's not uncommon for someone with complex illness to be under the care of numerous specialists. Each separately treating and prescribing her for multiple conditions. What if each device were provided by a different supplier, using different platforms that don't share information? What if each utilized a separate EHR (Electronic Health Records) which did not have agreements in place with other EHRs for interoperability and data sharing? Each specialist would not be able to access all the information from all her devices and have only limited views of her health. What about the myriad federal regulatory documentation needed to provide coverage for her various therapies and devices (hint: it's mostly paper and not digital).

In the case of the former competitive athlete, Medicare does not reimburse for those consumer medical devices like the personal

EKG or blood pressure watch. Taking that one step further, what if his general practitioner was reluctant to utilize the information he's providing because she's worried it won't suffice coding requirements to ensure Medicare coverage and payment for her services? What if her practice did not have the ability to capture and triage any of the automated patient-generated health data that his devices provide?

Now imagine the woman who suffers from depression and obesity, wouldn't it be more efficient if her healthcare plan without the fear of privacy violations could use her anonymized data to proactively identify interventional benefits programs? The example illustrates how the woman is provided a suit of digital tools but in reality, Medicare has disallowed widespread implementation of a similar program as it further assesses the virtual format.

And finally, picture the boy who relies by the minute on a continuous blood glucose meter. The part omitted in the story is how after years of being unable to view his blood glucose data, his parents took matters into their own hands. They joined an online movement that taught them how to engineer a solution for their existing monitoring device that allowed them to constantly access his data no matter where they were. The browser-based visualization enabled them to remotely monitor their son's glucose levels. Such a case happened leading FDA (US Food and Drug Administration) to work with a [do-it-yourself](#) community for sensible collaboration.

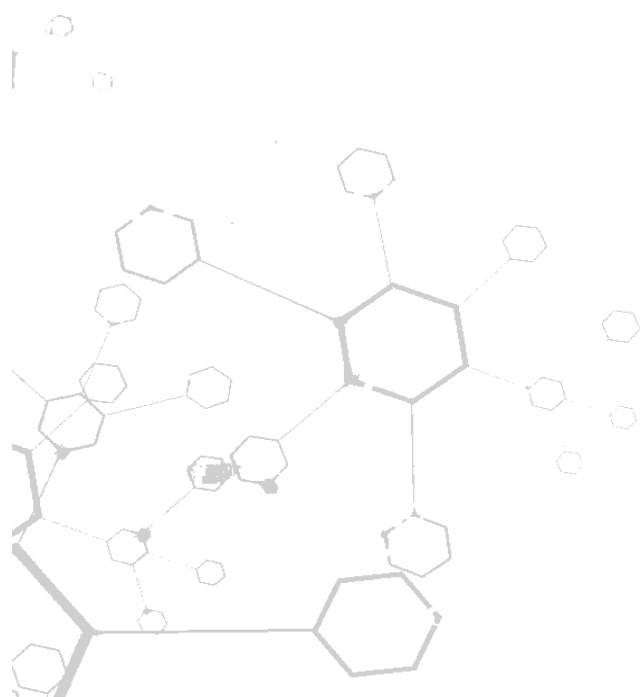
Such is the case with new technologies, industries, and sectors. Out of chaos, uncertainty, hype, and frustration – often flourishes stability. According to [Rock Health](#), \$5.5B has been invested in digital health through the first three quarters of 2019, with over \$36.3B since 2011. That's real money poured into an evolving sector. Helping to fuel that growth has been progress made by the federal government to eliminate or at least acknowledge barriers to digital health adoption. Over the past six years FDA has actively delivered regulatory clarity through dozens of guidance documents. CMS (US

Centers for Medicare & Medicaid Services) has recently provided coverage and payment for a number of services including virtual check-ins, e-Visits, and remote patient monitoring. ONC (US Office of the National Coordinator for Health Information Technology) and CMS are on the cusp of delivering final rules and clarifications concerning interoperability and data blocking. Since 2009, the US Congress has passed ARRA (US American Recovery and Reinvestment Act of 2009), MACRA (US Medicare Access and CHIP Reauthorization Act) and Cures (US 21st Century Cures Act) – each modernizing different aspects of healthcare, sometimes through technology, for decades to come. Even the unthinkable has become the actual with large retailers stepping into the digital health world with others looking to follow suit. Thus, digital health is not a cliché... it's just not easy and still finding its way.

Robert Jarrin is a strategic advisor to the Consumer Technology Association (CTA) on the regulation of digital health, and coding, coverage, and payment of digital medical services. Prior to serving CTA, Jarrin worked internationally in the mobile and wireless communications industry, eventually focusing exclusively on digital health and wireless life sciences. Jarrin has a BA in Government and Politics from the University of Maryland at College Park, and a JD from Northeastern University School of Law.



Robert Jarrin,
Strategic Advisor,
Consumer Technology
Association (CAT)[®]
Robert.jarrin@outlook.com



Consumer Health Technologies and FDA-Approved Medical Devices: A Promising Enigma

By Robert D Jensen

None of us likes to think of ourselves as “average.” However, in one way I discovered that I am, disappointingly, very much so.

Like roughly one-in-four Americans, I purchased a consumer wearable for my wrist and wore it daily thinking it would help me be healthier. I used this device to compete with others in my workplace in a “step challenge,” wore it to the gym to check my pulse, and only took it off for recharging.

Despite the auspicious start, I ultimately did what most wearable device purchasers do—I now use it far less than daily, and I’m not certain I could even find it today.

To say that technology has been crucial in advancing healthcare is an understatement. From robotics to miniaturized smart sensors, sophisticated health technology has given clinicians more capable diagnostic and treatment tools to respond to our care needs. Other advances that are nonspecific to healthcare (e.g., predictive data analytics, continuous connectivity) continue to influence care and care models even further.

So, what do consumer technologies and medical devices mean for us as consumers/patients, the clinical caregiver community, and health technology professionals? Let’s take a pragmatic look.

The Untapped Potential of Consumer Devices

Many of us were lured by the potential of consumer lifestyle devices to improve our health—and perhaps to make a bit of a fashion statement. Surely, knowing information like the number of steps we take each day, our heart rate, and calories burned would lead us to better choices and better health.

Unfortunately, our brains don’t work that way. I once asked Neil Stroul, PhD, a psychology and leadership coach, why our team did not seem to be responding to his feedback observations. His answer: “Awareness is the carnival booby prize.”

Applied to consumer devices, this means that just because we become aware of new data does not mean we’ll meaningfully change our behaviors to achieve different, more healthy outcomes.

Research supports Dr. Stroul’s assertion. A team led by Eric Finkelstein, PhD¹ studied 800 Fitbit users in a randomized controlled trial, investigating whether the use of these devices with or without cash or charitable donation incentives would improve health outcomes (e.g., weight, blood pressure). They did not.

Another randomized trial by John M. Jakicic, PhD² and a team of investigators found that the addition of a wearable technology device did not help overweight participants more than the standard behavioral weight-loss protocols. It seems that some wearables increase our awareness, but the outcomes are not what we assumed or hoped they would be.

But, before we abandon the promise of lifestyle devices as unfulfilled, we should take a broader look into how wearable health technology and its use is evolving towards beneficial health outcomes.

Clinicians can (and sometimes are) using wearable device data to inform patient diagnosis. While this may seem odd for a lifestyle device that is not approved by the FDA (US Food and Drug Administration), in some cases a physician may decide that potentially flawed information is better than nothing.

The first of such cases involved an emergency room patient who was suspected of having a heart attack. Data was retrieved

from the patient's phone that provided clinically valuable information to the clinical team during diagnosis and treatment. The insights were more complete than what the patient could provide on their own.

Another promising area for wearable devices is the management of chronic diseases. PricewaterhouseCoopers found that 28% of us have a "healthcare, wellness, or medical app" on our mobile phones. Two-thirds of physicians said they would "prescribe an app to help patients manage chronic diseases."³

Again, while the addition of data may not be enough in and of itself, when placed in the context of a larger chronic disease management protocol, consumer apps may help patients.

FDA-Approved Medical Devices Show Remarkable Progress

A number of FDA-approved wearable and implantable devices are having a profound impact on health and are contributing to a changing health treatment model landscape. These include devices that monitor vital signs, facilitate telehealth, and even help manage attention deficit hyperactivity disorder.

I've seen the effect that these devices can have firsthand. A few years ago, some family friends discovered that their young son had diabetes. Like any parents, they were concerned about this newly discovered risk to their son's health and what his life with this disease would be like.

Today, he wears a small insulin pump with a sensor on his back that monitors his blood sugar. He gets a bolus when he needs it and his parents get all the data recorded on an iPad. He's able to have fun just like every other kid, and his parents are no longer worried. The medical device is a major part of that, allowing a child to enjoy a high-quality lifestyle.

The common denominator between these FDA-approved devices and lifestyle wearables are the sensors and, in some cases, the ability to respond based on that data. The health sector has especially benefitted from the ubiquitous miniaturization of microprocessors, improvements in connectivity, continuously dropping costs of data storage, and advanced large-scale analytics.

This has yielded several FDA-approved devices containing sensors of all kinds. They can be wearable, external ingestible, epidermal, blood sampling, or tissue embedded. Combining these developments with ever-increasing connectivity and data analytics can yield a broad range of benefits. Predictive modeling, for example, can be used to identify patient population data patterns that can be proactively applied to patient care, avoiding detrimental health consequences and improving personal health monitoring outside of traditional healthcare settings. This preventive care and the notion of "continuous" care saves on the costs of traditional clinical settings while bolstering the diagnostic information available to care providers.

Leveraging Technology Towards a Healthier Future

Medical and consumer devices, combined with an understanding of behavioral change, may help us prevent and/or treat many of the costliest chronic diseases that we're facing: cancer, heart disease, diabetes, respiratory disease, and others.

The Agency for Health Care Research and Quality (AHRQ) points to four most-influential behaviors related to these diseases: smoking, drinking, poor eating habits, and a lack of physical activity. None of the factors described by AHRQ come as a surprise. But new technology may represent a powerful tool to improve health through behavioral changes that are based on a more complete understanding of our environment.

Opportunity is growing every day with the potential for medical devices to have an even more profound influence on our personal health, the health of the population, and the healthcare of the future. While these technologies alone may fail to change health behaviors and outcomes, they can—in combination with a deeper understanding of human behavior—enable other techniques that are effective.

Behavioral change is clearly complex, as I learned after purchasing my own wearable device. But understanding it and the insights that these devices create in our environments can help inform better combinations of personal change that do lead to healthier choices and outcomes. With a groundswell of

such types of successes, we can contribute to a shift away from the treatment of disease to encouraging and enabling wellness.

Robert D. Jensen is president and CEO of AAMI, a nonprofit standards development and education organization dedicated to supporting the health community in the development, management, and use of safe and effective health technology.



Robert D. Jensen,
President and CEO,
Association for the
Advancement of Medical
Instrumentation (AAMI)
RJensen@aami.org

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No Sensor is an Island

By Dejan Milojevic

The future of using consumer devices with a variety of sensors to assist in health care is extremely promising. It may solve a plethora of complicated procedures, simplify tracking human health, consolidating all the data and deploying consistent policies across all the devices to impose the regulatory privacy compliance. These sensors may be carried by a human, deployed at spaces, such as home or work, within SmartCities and Municipalities. All the data/information may be uploaded into the Cloud (see Figure 1). However, these approaches have been discussed for decades now [1, 2, 3]. Most of the problems have been exacerbated by the lack of privacy and regulations which limited the use and sharing of data to only most conservative cases. The following two paragraphs summarize past/present and future of systems support for Smart HealthCare specifically exploring sensors. There are numerous references in support of this discussion, author chose almost a dozen of his own publications over the course of past 20 years.

UI (User Interface), personalization, and functional ensemble are the core functions to enable better use of sensors, i.e. customizing and personalizing general sensors to individuals, how sensors interact with users and the environment and how they form a coherent ensemble of devices [4]. There was a lot of progress lately with wearables and sensors in the phones, however this still remains one of the most important areas to enable adoption. Because wearables using sensors are very limited in

resources, various operations needs to be **offloaded** [5], this is the simplest problem nowadays as phones and ambient servers are becoming more and more powerful devices. However, a **standardized way** [6] of doing this is still an open problem. **Security and privacy** [7] continue to be the biggest challenge, as well as the **Platforms** [8] that support them. Because these devices are very brittle, they can frequently break and new models of **servicing** them and prior to that

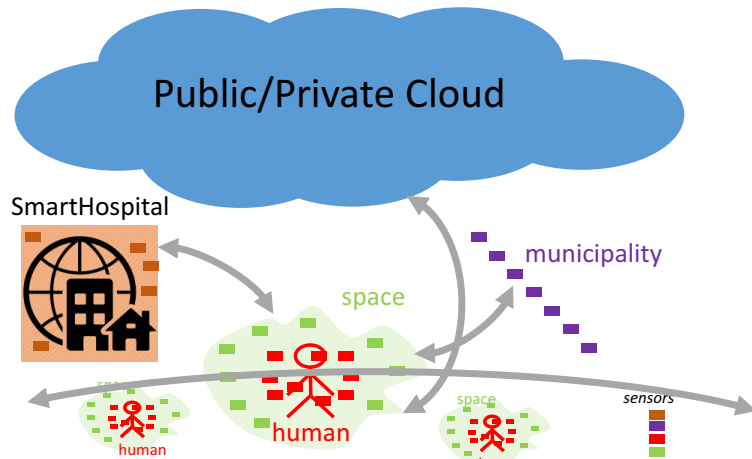


Figure 1. Sensors are deployed everywhere. On and around the user and his spaces, in municipalities, SmartCities and Smart Hospitals, etc. Models are deployed and information and models are moved from Edge to Cloud (North-South, as well as across edges (East-West) and across other entities, such as municipalities and Smart[Towns, Hospitals].

making them more **robust** at scale are required [9]. Finally, some means of **communication with the Cloud** (either direct or through proxy) is necessary [10]. How will situation change in the future? In terms of **UIs**, sensors will have to be integrated with new display technologies, e.g., AR/VR (Augmented Reality/Virtual Reality), with technologies such as machine learning, robots, and drones, and with a multitude of sensors outside, on the skin and inside the body [11]. **Offloading** will take place in terms of model offloading to execute a degree of training at the edge using deep learning accelerators. New ways of

standardization are primarily based on working code, as an evolution of open source with the introduction of Open Neural Network Exchange (ONNX) format and a benchmark for measuring machine-learning performance (MLPerf). **Security and privacy** will continue to be a major issue, but they will be assisted with active security prevention and sensors built into human bodies [11]. New **platforms** will migrate towards AI/ML/DL (Artificial Intelligence/Machine Learning/Deep Learning) platforms, running in public and private Clouds. Most **servicing/support** will be based on over provisioning and decommissioning systems once a large % of the deployed infrastructure (sensors, compute, storage) are dysfunctional. Finally, 5G will dramatically help in connectivity, but local communication networks will still dominate due to the cost and accessibility.

In summary, a very interesting and promising times are in front of us that will finally enable democratization of HealthCare. This will be accomplished by delivery at home with remote access to professionals who can assist, track and facilitate non-routine activities. Systems software will transform into AI-driven, solving some old obstacles but also introducing new ones. Issues such as bias, personalization, customization will continue to be among the top of challenges. While promising, at least a decade plus is required for this to become mainstream.

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Dejan Milojicic is a distinguished technologist at Hewlett Packard Labs, Palo Alto, CA (1998-) leading system software teams over 4 continents and projects with budgets of hundred US\$M. He has published 2 books and over 200 papers; he has 47 granted patents and 133 patent applications. He is an IEEE Fellow (2010), ACM Distinguished Engineer (2008) and member of HKN and USENIX. As president of the IEEE Computer Society (2014), he started Tech Trends, the top viewed CS news. As the IEEE Industry Engagement Committee Chair, he started IEEE Infrastructure Conference



Dejan Milojicic,
Distinguished Technologist
Hewlett Packard Labs
dejan.milojicic@hpe.com

Functional or Fictional

By Nima Taherinejad

Designing healthcare devices has always been very challenging, which -partly- stems from their interdisciplinary nature, bringing engineers and physicians together for a close -or an entangled- collaboration. Good communication between the two groups could largely reduce the difficulty: Engineers would understand the problem better and do their best to solve it; physicians would understand better what a device is capable of doing and what the limits (requiring complementary actions) are. Physicians would have an extensive knowledge about the physiology and nature of the problem that they could communicate to engineers. Engineers, on the other hand, would know in advance the (expected) operational and environmental conditions of the device and could take them into account at design time. However, the emergence of wearable devices has been a game changer in many aspects.

Maybe one of the most important changes has been bringing healthcare devices outside medical facilities and putting them in the hands of people at large, mostly with no medical training or knowledge. This has many consequences; for example, consumers have (usually and unrealistically) high and ever-increasing expectations from these devices. On the other hand, they use them or would like to use them in their daily life, i.e., in uncontrolled and unpredictable environments and operational conditions for the device, which makes the design even harder¹. We have studied and discussed issues such as dealing with low quality data or wearing the device improperly in [8], or the movement artifacts intrinsic to wearable devices in [9].

However, once we surpass these technical challenges, we may face another challenge; medical studies have been traditionally conducted under controlled conditions, partly because there were no tools available to conduct them otherwise. What we know from those studies may or may not be applicable to the uncontrolled environments of our daily lives and activities. However, wearable healthcare devices enable physicians to study people in unprecedented ways and build a new body of knowledge. But, this might take a long time to accomplish and consumers are somewhat impatient expecting more immediate answers.

Another important aspect that has changed by the emergence of wearable healthcare devices is the need for a deep involvement of people at large in the design procedure. This requires more communication with more parties and with more clarity, some of which might not be as easy or as straightforward as one would assume and it sometimes goes completely unacknowledged. For example, we witness everyday traditional teams of engineers, or engineers and physicians, designing wearable healthcare devices. Their main concern is, naturally, the quality of the device in terms of accuracy of measuring what they intend to monitor. Better designs may consider some extra aspects such as battery lifetime to ensure that the users could wear the device for a long enough period of time, which is necessary for monitoring them during the daily or targeted activity period. Moreover, there are not many designs that emphatically consider the ease of use, being it the interface or the physical use (the ease of wearing the device in a daily setup). For

¹ In my previous article for IEEE LifeSciences [1], I briefly reviewed some of the challenges related to these two issues and some solutions, such as described in references [2]-[5], that computational self-awareness provides. For a sneak peek to

computational self-awareness check ref. [6], or [7] for a bit more information on the topic, especially in resource constrained systems (which wearable healthcare systems are).

instance, a device designed for the elderly who have not grown up in the digital age may require a much more intuitive and simpler interface than what a teenager or a young child nowadays is used to handle. Another example is a mouthpiece to monitor breath rate, which may be acceptable for a hospitalized patient but is not practical for an athlete wearing one during sport activities. That aside, there are even a much smaller number of devices that consider issues such as the social stigma of using the wearable device that they are designing. Smartwatches that symbolize wearable devices nowadays are considered very “cool” to wear but that does not apply to all wearable devices. Would an epilepsy patient be willing to wear an EEG cap or a headset continuously during their daily activities to monitor seizures? Due to the way many of them currently look like, the answer is more often no than yes. Some people may not like to wear them even for shorter periods, even in a socially safe environment, because it stirs negative feelings in them. Therefore, even if they are functional, they may be as good as fictional, ending up on a shelf rather than being worn by the consumer. However, if it looked and felt like a fashionable baseball cap, things would be considerably different and its reception could improve. Therefore, it is extremely crucial to involve another group in the design of wearable healthcare devices - fashion designers. Wearable healthcare devices need to be comfortable and look good. It is reasonable to involve another group too - social scientists. If a major reason for not using a certain wearable healthcare device is social stigma, shouldn't we study this aspect and see what elements create them or how could they be addressed? Monitoring some parameters may strictly require access to body parts, which may be impossible or very hard to be easily hidden inside a socially acceptable piece of clothes or accessory. Prescription glasses are a good example of that type of wearable healthcare devices. They came with a social stigma and it took us centuries to be able to come up with a hidden “cool” solution, aka contact lenses. It took us even longer to come up with a “cure”, i.e., surgery. However, the social stigma of wearing glasses was dealt with differently. That is, not by changing the wearable device,

rather by changing the culture (and stigma) around it. This reduced the stigma such that nowadays we can say it has disappeared. Admittedly, there are still people who wear contact lenses only due to social stigma but they are a small portion of all who need vision correction. What could we learn from those experiences and how could we apply them to designing new wearable healthcare devices that might face social stigma?

Therefore, we need to note that designing wearable healthcare devices is much more complicated than ever and even though it may appear to be similar to designing medical devices it is significantly different. To make sure that a wearable healthcare device will not be fictional, it does not suffice anymore to ensure that it is functional. Designing such devices requires a much deeper involvement of a larger group of stakeholders; consumers, fashion designers, and social scientists on top of the traditionally involved group of engineers and physicians. This, of course, makes the design procedure more interdisciplinary and more challenging; however, ignoring this need may lead to the result of a great many hours of effort sitting on a shelf collecting dust.

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Nima TaheriNejad (UBC'2015) works at the TU Wien (formerly known also as Vienna University of Technology), Vienna, Austria, in the role of Universität atassistent. His current areas of research include computational self-awareness for cyber-physical systems, wearable healthcare, embedded systems, and social robotics. Dr. TaheriNejad has co-organized conferences, special issues and workshops in the areas of wearable healthcare and computational self-awareness.

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Nima Taherinejad,
Institute of Computer
Technology,
TU Wien Austria
nima.taherinejad@tuwien.ac.at

Integrating Consumer Health with Smart Devices: A need to Weave Privacy and Cybersecurity into the Technology Fabric

By Kevin Littlefield

Patients are becoming more involved in managing their personal health with the assistance of consumer health products that augment personal healthcare management capabilities. Consumer health technology have expanded from personal fitness tracking to now include a broader set of capabilities which include weight scales, imaging devices, glucose meters, electrocardiogram solutions, diagnostic tools and others that integrate these peripherals with mobile and smart home devices allowing interaction with remote physicians. The Internet of Things (IoT) has come to home healthcare driven by consumer demand, however cybersecurity and privacy controls remain discretionary by product manufacturers and patients themselves. Technology convergence may expose and amplify risks that have already been seen in non-health related smart devices. While integration and interoperability may improve the healthcare landscape by facilitating access to health resources and compelling patient involvement in healthcare management, challenges remain. Patient treatment courses are driven by the data, and should that data be altered by malicious actors, misdiagnosis or improper treatments may undermine patient safety.

Consumer healthcare technology plays a role in bridging a healthcare accessibility gap. According to a Pew Research Center report, 96% of Americans have a cell phone, with 81% owning a smart phone deviceⁱ. National Public Radio and Edison Research recently released a report

showing 53 million Americans own a smart speaker device, with ownership rates nearly doubling between 2017 and 2018ⁱⁱ. The nation's rollout of 5G telecommunications technology promises to extend high speed Internet access, which may further catalyze the home use of IoT across the U.S. These factors set a foundation for rapid telehealth adoption.

While patients have embraced healthcare and IoT technologies, and Internet providers, consumer electronics manufacturers and software developers strive to meet the demand, privacy and cybersecurity for consumers has lagged. Healthcare regulation has been focused on healthcare delivery organizations, insurers and their business associates. The US Food and Drug Administration (FDA) has been vocal on securing medical devices used in hospitals. But attention to consumer healthcare products has been discretionary.

IoT devices are hackableⁱⁱⁱ. Vulnerabilities in communications protocols ranging from ZigBee, Bluetooth, and WiFi have been shown to have vulnerabilities that have allowed malicious actors to discover access passwords to home networks, compromise devices, and use devices as pivot points to launch large-scale denial of service attacks against other entities. Devices have also been found to be susceptible to high frequency audio attacks as well as line of sight attacks using lasers. While sophisticated attack vectors continuously emerge, even basic security controls such as authentication methods have not been enabled in smart speakers. These

threat types have been found in automated home technologies. The foundational technologies that enable the automated home will power consumer healthcare devices.

Consumer personal health devices coupled with telehealth improves the healthcare landscape, acting as a force multiplier especially in rural and underserved areas and potentially containing the ever-increasing cost of healthcare. However, as consumer technology enters into the healthcare delivery supply chain, the patient needs to be equipped with capabilities that have privacy and cybersecurity measures built into the fundamental technology fabric.

Kevin Littlefield is a Principal Cybersecurity Researcher and Healthcare Cyber Domain Capability Area Lead at the National Cybersecurity FFRDC within the MITRE Corporation. With over 25 years' experience in cybersecurity, Mr. Littlefield has held senior information security roles with the Brigham and

Women's Hospital and the Novartis Institutes for Biomedical Research.

¹ *Mobile Fact Sheet.* Available: <https://www.pewinternet.org/fact-sheet/mobile/>

² *The Smart Audio Report.* Available: https://www.nationalpublicmedia.com/wp-content/uploads/2019/06/The_Smart_Audio_Report_Spring_2019.pdf

³ <https://nvlpubs.nist.gov/nistpubs/ir/2019/NIST.IR.8267-draft.pdf>



Kevin Littlefield,
The MITRE
Corporation
klittlefield@mitre.org

Health Integrity by Way of Patient Ownership of Health Data Through “Wearables”

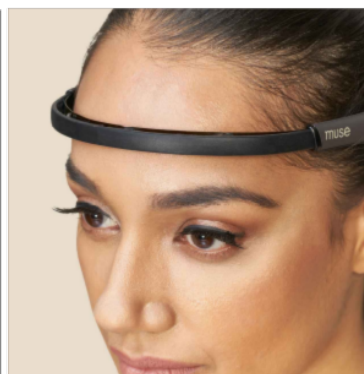
By Steve Mann

Compared with older times, records that were ordinarily kept by individuals and their extended families have now become centralized by healthcare providers, police, and other institutions. This often-centralized monitoring of individuals by doctors, hospitals, and other institutions could be called “surveillance”. Surveillance has been the default power relationship of modern medicine where institutions have been the data collectors, curators, and gatekeepers. Patients have been the observed subjects (“the surveilled”). They were sometimes even subjects of privacy-violating experiments run on their personal data without their knowledge or consent [1]. [Rosenbaum, Ron. "The great Ivy League nude posture photo scandal." *New York Times* 15 (1995): 28.]

The evolution of privacy protection in healthcare during the 1980s and 1990s did more to further institutionalize and bureaucratize personal data than to really give it or its control back to patients. Many of us were unable to get copies of, or to even see our own medical images like X-rays, in part, due to the increased bureaucracy

brought about by these more stringent “privacy” safeguards. This increased “security” often served merely to “lock down” data and further centralize its storage, thus giving even greater control of our personal data to doctors and institutions and “expert guardians”, creating an even more asymmetrical power relationship between patients and institutions. This allowed the powerful to sometimes even benefit from our data (e.g. to do “data mining” or sell it) while keeping us from accessing it freely. Data should really be the property of its subjects (patients), and that is why I introduced the concept of Subjectrights and Quantigraphic Self-Sensing (QSS) at MIT in the early 1990s [2] [Mann, Steve. “Subjectright”, *The Journal of Medical Knowledge Management*, Volume 6, Number 2, p8-9, Apr. 2001].

Right now, wearables are the “wild west” of healthcare innovation. There is a socio-political battlefield between the interests of the vulnerable (the patients) and the interests of the powerful (governments, health and insurance providers, and the multi-billion-dollar marketplace).



QSS (Quantigraphic Self-Sensing, Steve Mann, 1996

InteraXon Muse, 2019

Fig. 1 QSS (Quantigraphic Self-Sensing), now known as QS (Quantified Self) was introduced by S. Mann in the 1990s and presented to Kevin Kelly at WiReD Magazine in San Francisco in 1996 as an early prototype. Ten years ago (2009), Mann and others founded InteraXon, makers of the Muse and Muse2 brain-sensing headband that senses EEG, blood flow, head movement, etc..

But, I believe that we can cause a transition from the hypocrisy of treating personal data in a surveillant manner, toward creating systems that ensure the integrity of health data by putting its ownership into the hands of patients themselves, through Subjectrights and wearables. Wearables (including smartphones, watches, “smart clothes”, eyeglasses, etc.) have the potential to mitigate or even reverse these often-detrimental one-sided power structures. Patients now have the possibility of gathering their own data in real-time and maintaining more information about their own physical condition and behavior than going to annual visits to a doctor, hospital, or having lab tests done. Fortunately, this “wearables” trend is being combined with efforts by governments and healthcare providers to promote patient-centered care where patients can be participants in their own care and can even help invent the future of healthcare. This is called “sousveillance” (the reverse of surveillance).

Thankfully, this “sousveillance” can turn traditional healthcare inside-out, starting with a “data to the people” as its default. This can help foster integrity, human dignity, human rights, and true privacy (in contrast to institutionalized pseudo-privacy). Most importantly, wearables and sousveillance can provide us with agency over our own bodies through self-determination.

As a simple example, we're constantly recorded by surveillance cameras all around us while we've been sometimes prohibited from recording ourselves. But now, we can record our own brainwaves and actually make our biological eyes function as cameras. We call this “eye-is-a-camera” sensing the EVG (ElectroVisuoGram). The EVG is just one of many new and exciting technologies for health sousveillance from which we can search through correlated EVG and ECG (electrocardiogram) recordings to answer questions like “What is happening around me that is causing me stress, and how are various events and stimulus affecting my health and well-being?”. The EVG is a visual memory prosthetic that helps us remember exactly

what we were doing when our heartbeat went irregular. This will put an end to the hypocrisy of surveillance and its one-sided “we can watch you, but you can't watch us” gaze. Surveillance is the veillance of hypocrisy and what we need is sousveillance which is the veillance of integrity.

How these technologies will be integrated into our bodies and our socio-political and economic lives will have significant implications for their invention, design, deployment, regulation, and effects on individual integrity.

Acknowledgements:

Dr. David Naylor and Dr. Joseph Ferenbok provided a great deal of useful help and discussion in this work.

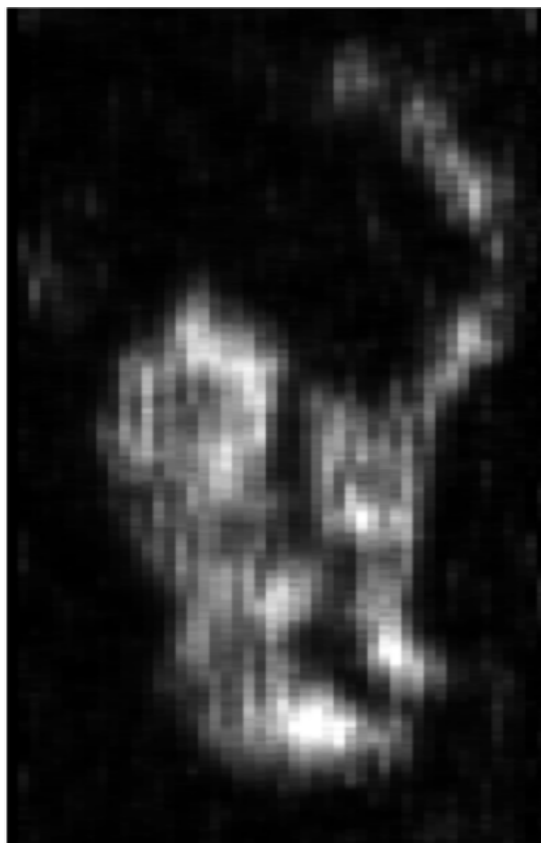
Steve Mann is often referred to as “the father of wearable computing,” in recognition of his invention of the first wearable general-purpose computer in 1981. A professor of computer engineering, he is also credited with inventing modern High Dynamic Range (HDR) imaging methods, natural user interfaces, ‘sousveillance,’ and many more techniques that seem to have come from the future.



Steve Mann,
Centre for Humanistic
Intelligence,
University of Toronto,
Canada
mann@eyetap.org



Input viewed
by subject



Output from
EEG (brainwaves)

*Fig. 2 High resolution version of Figures can be downloaded here:
World's first Quantigraphic Self-Sensing (Quantified Self) system:*

<http://wearcam.org/QSSteveMann1996.svg>

<http://wearcam.org/QSSteveMann1996.pdf>

EVG (ElectoVisuoGram):

http://wearcam.org/luke_minds_eyecam.svg

http://wearcam.org/luke_minds_eyecam.pdf

[S Mann, D Lam, KE Mathewson, J Stairs, C Pierce, J Hernandez, G Kanaan, L Piette, H Khokhar, and C Mann, "The Human Eye as a Camera", IEEE Healthcom 2019, Bogotá, Colombia]

Legal, Regulatory and Policy Challenges at the Bleeding Edge of Mobile Medicine

By Michael Aisenberg

When Massachusetts General Hospital (MGH) inaugurated its experimental remote telemedicine center at Boston's Logan Airport under a US Departments of Commerce and Health and Human Services joint grant in 1975, it was ushering in a new era of the application of Information & Communications Technology (ICT) to medical challenges. In the MGH-Logan pilot, the effort was to reduce mortality among acutely ill passengers by eliminating the "golden Hour" of ER risk in ill or injured passengers by avoiding the notorious rush hour transit time from Logan to MGH. Tele-diagnosis on site at the airport permits immediate treatment and reduces mortality. And it spawned even more imaginative approaches to linking patients to active medical professional care, spanning gaps of distance and time.

Today, the individualization and wearability of diagnostic and therapeutic ICT-enabled devices have only enhanced the physician and patient appetites for these tools. WiFi monitoring and adjustments for pacemakers, insulin pumps, home wired diagnostic devices for glucose testing and a host of sensor-delivery tools for therapies offer unprecedented accuracy, immediacy of therapeutic adjustment and associated improvements in survivability and overall quality of life.

But with these innovative applications comes increased risks. And some of these risks may be beyond the scope of present legal and policy structures to address.

However, one area of real concern today is entirely within the scope of remediation in the near term, suggesting other possible connected medical device (CMD) improvements. The concern, a procedural one, involves the inability of injured patients to sue "connected" medical device manufacturers in their state courts for injuries

or death due to claims of device failure of US Food and Drug Administration (FDA)-approved medical therapeutic technologies.

Most Internet-connected medical devices are subject to FDA review. They fall into a category of products originated in the FDA's pharmaceutical program, but now widely extended by court rulings both within the FDA to connected medical devices. The legal principle, Federal Pre-emption of Liability applies to protect device manufacturers whose products have received FDA review and approval. These manufacturers may not be sued in state courts by individuals claiming injury due to a device failure. Instead, victims or their families must first bring administrative actions against the manufacturer at the Federal agency level. This policy is not limited to just medical devices and pharmaceuticals reviewed by the FDA, it also exists for products under the jurisdiction of other Federal agencies, such as consumer products at the US Consumer Product Safety Commission (CPSC) and telecommunications devices reviewed by the US Federal Communications Commission (FCC).

And today, victims may only seek review of the devices' medical "safety and efficacy". If the device fails because of a cyber security vulnerability leading to a hack, a security weakness permitting unauthorized tampering or other threat vector not reviewed by the FDA, the victim or his/her survivors may be left without a remedy if they do not complain to the FDA first.

The Federal pre-emption concern raises three related paths to improvement that also offer good models for other connected consumer devices.

First, states could pass statutes granting **explicit jurisdiction** to their state courts over

cases involving failures of the ICT software in connected medical device products sold in their states.

Second, the FDA should be granted specific responsibility for the review of not only the medical safety and efficacy of CMD products, but their **embedded ICT software** as well, evaluating National Institute of Standards and Technology (NIST) SP 800-53-type security and privacy controls to assure the performance of their connectivity, appropriate limitations of device access and privacy of patient data collected and transmitted by the devices.

The inclusion of ICT-related software elements in FDA structural reviews to pre- and post-market review of safety and efficacy of ICT-enabled devices should promptly become part of the agency's program, irrespective of actions taken by states to assure the availability of a state court remedy for injured patients.

And third, **continuous monitoring** of addressable wireless enabled devices should become part of device routine operating models, to assure that the wireless technological component of device operations is as free from defect or performance degradation as the therapeutic aspects of the device. The enhancement of CMD standards to assure minimum standard among commercial CMD manufacturers should promptly become an agenda item for health standards bodies addressing health care cyber standards. But similar scrutiny could also enhance the safety of unmanned vehicles by the US National Highway Traffic Safety Administration (NHTSA) and aerial devices by the FAA.

The legal and policy communities can assist in establishing best practices and contextual

considerations for the creation of standards for the burgeoning CMD product community. But, guided by medical expertise, the device vendor community must become the source of the actual effort in standards setting to assure the true "safety and efficacy" of devices relied on by health care consumers.

Michael Aisenberg is a lawyer who does policy work in support of Federal agencies' IT Security programs in the intelligence and national security communities. He is Chair of the ABA's Information Security Committee and a Member of the National Conference of Lawyers and Scientists. He has a BA from Penn and a JD from the UMaine Law School.



Michael Aisenberg,
The MITRE Corporation
maisenberg@mitre.org

Technology for the Benefit of Humanity Not Humanity for the Benefit of Technology

By Nahum Gershon

"When my kitchen sink was clogged last year, I grabbed the strainer out of the drain and placed it with my left hand above the trash can. I then banged it with the strainer upside down and this got rid of the dirt clogging the strainer. But suddenly, my Internet-connected watch tapped me on my wrist, and I got a message on my watch screen: "It looks like you have taken a hard fall". I immediately canceled the alert and did not let my watch call emergency.

This has made me think... The watch has a sensor basically occupying a point in space. The body, on the other hand, is a system that occupies more than one point in space. In spite of that, some body parameters like heart rate could be determined by measuring it at one point on the body. However, when one would like to detect a fall, one must make sure that the whole body changed height suddenly. This is not possible with certainty when only one sensor is attached to a point on the body (e.g., the left arm). More than one sensor - a few at least - distributed over the body are needed. In other words, more than one thing needs to be considered... Here, a thing is not just a sensor (like in the "Internet of Things") but also things like the situation, geometry, and other facts of life" [1].

This watch could also monitor activity, measure heart rate, perform an ECG, sense the environment (weather, noise) and it is expected that in the future it will have additional health-related capabilities. In addition to a capable watch, one could expect that we will have more wearables, sensors on our skin and implanted ones monitoring our bodies, health, and other factors. Even without commercial alerts (a looming nightmare...), this could produce a "flood" of status messages and alerts that come in

addition to many interruptions we tend to get from our cell phones and computers during the day and unfortunately at night too (emails, text messages, alerts etc.). This situation could be a problem as life and research has shown that frequent interruptions could decrease concentration and thus reduce the effectiveness of our work. They even might cause some unwelcome changes in the brain (see [2]).

Reducing the Number of Alerts. To reduce the forthcoming huge number of disruptive alerts, we should take on ourselves to design and build a system that will remove unnecessary alerts from our environment. Such a system will go over the plethora of alerts, evaluate which ones are repetitive and/or unnecessary and then "weed out" (or "sanitize") the unnecessary and the disruptive ones. It is not expected to be an easy task and even when the current expectations of AI will be fulfilled, it might not be enough...

In addition, addiction to our mobile devices and potentially to our future wearables might further disconnect us from the physical environment around us, e.g., spouse, children who need positive and constructive human parental attention that is necessary for their development, from friends and just from mere human beings in our physical vicinity. And, just imagine how hypochondriacs might become obsessed with their health-related wearables... In short, something needs to be done here.

Humans First! These cases illustrate some examples where technology developers sometimes do not consider enough the needs of humans while developing technology products. This lack of knowledge and/or concern about how people tend to conduct their lives and how communities work (and

the lack of common sense) is not just limited to wearables. This could remind us of a situation happened in the 1950s and the 1960s when urban planners were trying to design city environments composed of large areas with tall buildings sparingly distributed in a park-like environment. They thus preached to destroy older neighborhoods that were composed of buildings of a few stories high with a mix of residential and commercial entities. The famous Jane Jacobs who lived in the West Village in New York City at that time understood what makes a city livable and functional and wrote the now famous book, "The Death and Life of Great American Cities" [3]. She asserted that urban renewal practitioners did not respect the needs of city dwellers. Now, it is widely accepted that she was right.

Before designing a human environment that relies on technology, it is important to first understand how people will use it or would like to use it before developing & installing the technology. It is necessary to understand and consider all things - sensors, habits, health, and humans and community expectations, and use common sense. Technology should

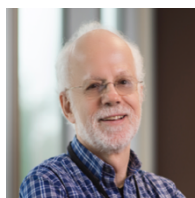
be built for the benefit of humanity, and we should not use humanity for the benefit of technology!

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[2] Adam Gazzaley and Larry D. Rosen, "The Distracted Mind: Ancient Brains in a High-Tech World", MIT Press, 2016.

[3] Jane Jacobs, "The Death and Life of Great American Cities", New York: Random House, 1961. ISBN 0-679-60047-7

Nahum Gershon focuses on social media, consumer technology, the Internet of Things, visualization, combining creative expressions with technology and real-time information delivery, presentation & interaction (including storytelling) in mobile, wearable as well as traditional devices including how they could improve both organizational environments and our personal lives. Nahum is a well-known community organizer, mentor, and communicator and is quite socially oriented. He enjoys life.



Nahum Gershon,
Schmooz.org
schmooz@mac.com



*thanks
the Guest Editors*

Nahum Gershon –

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Michael Ackerman –

received his Ph.D. from the University of North Carolina, Chapel Hill, in Biomedical Engineering. After almost 44 years he retired as the Assistant Director for High Performance Computing and Communications at the National Library of Medicine, responsible for programs in medical imaging, telemedicine and advanced networking. He originated the Visible Human Project. Dr. Ackerman is a Founding Fellow of AIMBE, and ACMI, a Fellow of ATA and a senior life member of the IEEE. He serves on the Editorial Boards of TeleMedicine and e-Health, and JAMIA.