California HealthCare Foundation

Making Sense of Sensors:
How New Technologies Can Change Patient Care

February 2013

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Prepared for
California HealthCare Foundation

by
Jane Sarasohn-Kahn
THINK-Health and Health Populi blog

February 2013

About the Author

Jane Sarasohn-Kahn, MA, MHSA, is a health economist and management consultant who works with a broad range of stakeholders at the intersection of health and technology. She writes the Health Populi blog.

Author's note: Inclusion of products and suppliers in this report does not constitute an endorsement or recommendation. Organizations cited in this report were chosen as examples of sensor technology developers addressing the various segments covered. They are meant to be illustrative and not to cover the entire landscape of this young and rapidly growing market.

Acknowledgments

The author thanks the following individuals who provided their points of view on this diverse and novel landscape: Theo Ahadome, IMS Research; Yan Chow, MD, Sidney Garfield Center for Health Innovation, Kaiser Permanente; Ranjit Das, MD, Zansors; Steven Dean, Prehype, G51 Studio, and Quantified Self New York City; Stephen Ferrozco, MD, Mobiquity; Susannah Fox, Pew Internet & American Life Project; Monique Levy, Manhattan Research; Liam Quirke, IMS Research; Jody Ranck, consultant and researcher; Skylar Roebuck, Mobiquity; Juhan Sonin, MIT; Christine Sublett, health privacy and security expert; Carol Torgan, PhD, Kinetics; and, Sonny Vu, Misfit Wearables.

About the Foundation

The **California HealthCare Foundation** works as a catalyst to fulfill the promise of better health care for all Californians. We support ideas and innovations that improve quality, increase efficiency, and lower the costs of care. For more information, visit us online at www.chcf.org.

Note: As of this writing, CHCF has invested in two of the enterprises mentioned in this report: Asthmapolis and iRhythm.

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I. Introduction

"Our health care system is broken and desperately needs to change. The recent flourishing of health and fitness digital devices and apps further lays the groundwork for the big changes that are destined to occur in medicine."

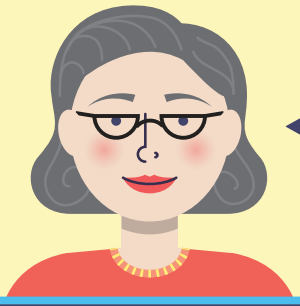
— ERIC TOPOL, MD
THE CREATIVE DESTRUCTION OF MEDICINE

When Ann R., a 65-year-old woman with congestive heart failure and diabetes, steps out of bed in the morning, her weight is recorded by a Wi-Fi-enabled sensor located under the floorboards. This is just one of several sensors that keep a close watch on Ann's health without her having to do anything at all. The data detected by all the sensors are automatically transmitted via a secure wireless connection and stored in her personal health record in a cloud-based computer server. If any of the health measurement signals falls outside of a pre-determined normal range for her, the data are transmitted to her clinician as well as to a family member designated by Ann.

This is a fictionalized scenario in the not-too-distant future illustrating how passive sensors — sensors that do not require active engagement for their use or data transmission — could proliferate in patients' daily lives to support healthy lifestyles, self-care, and more personalized medicine, yet be almost invisible to the user.

This report describes the early phase of development and adoption of passive sensors for patient care outside the hospital; it assesses the current landscape, the drivers and barriers, and the promise of these technologies.

A LOOK INTO THE FUTURE *of* HEALTH CARE



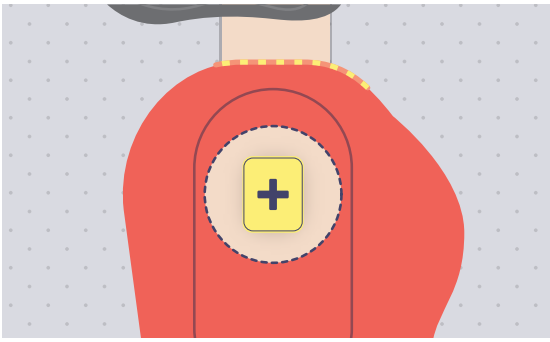
HOW PASSIVE SENSORS WILL SUPPORT PATIENT CARE OUTSIDE THE HOSPITAL

Meet Ann R. She is 65 and has congestive heart failure and diabetes. Ann is able to live safely at home thanks to sensors that monitor changes in her health without the need for frequent visits to the doctor. The data from the sensors signal her care team (clinicians and family members) when support is needed.

Let's take a look at how these sensors assist Ann without her needing to do anything.

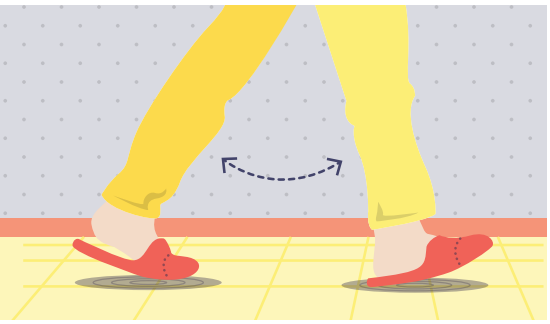
As Ann steps out of bed, her weight is recorded by a Wi-Fi-enabled sensor under her floorboards.

As she brushes her teeth, sensors in the bathroom floor mat monitor pressure points in her feet to detect early signs of ulcers.



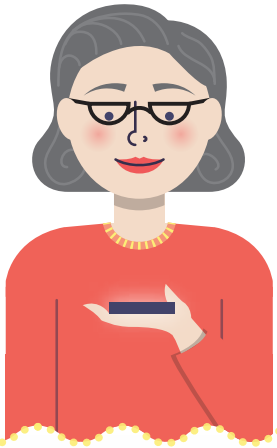
A patch on her arm monitors important signals such as:

- Heart rate
- Blood pressure
- Blood-oxygen level
- Glucose level



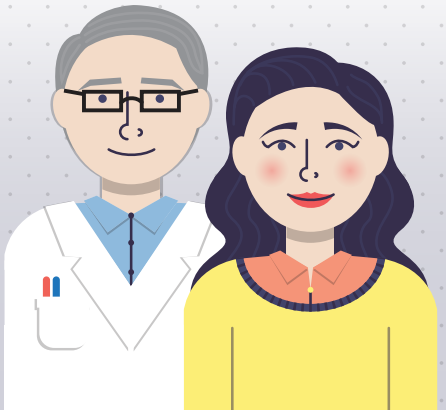
Sensors in the floor and along the wall register her gait to assess risk of falling.

Her diuretic medication contains a tiny sensor that signals her arm patch that she has ingested the pill.



The signals detected by all sensors are automatically transmitted via a secure wireless connection and stored in Ann's personal health record. She can see the data and allow others to access it.

If any of the health measurement signals fall outside of a pre-determined normal range for Ann, the data are transmitted to her doctor and her daughter.



This scenario will be achievable in the near future. Patients will be able to receive more personalized support from their care teams and live healthier lives on their own.

II. Background

While medical devices incorporating sensors have been a vital part of hospital-based care for many years, they have not been widely used by patients and providers to support care outside of the hospital. There are many reasons why sensors have been under-utilized including lack of simplicity, cumbersome design, cost, and lack of positive incentives in the health care system. As of 2013, these problems are being addressed in ways that may help set the stage for growth: Deloitte predicts a US market for wireless health monitoring devices of $22 billion by 2015.[1]

On the technology front, sensors are becoming cheaper, smaller, and more accessible. Wireless communication standards (such as 3G, 4G, Wi-Fi, Bluetooth, and Zigbee) allow sensors on or around patients to securely transmit data without any wires or cables, greatly improving patient mobility and sensor utility. Advances in material science are creating novel textiles for wearable sensors. At the same time, significant increases in computing power are enabling automatic analysis of sensor data, while the advent of networking and cloud computing allows users to store and access data from almost anywhere. The recent emergence of low-power computing used in laptops, tablets, smartphones, and other mobile devices provides numerous platforms for sensors.

On the payment side, models that reward providers for positive patient outcomes rather than volume (e.g., number of visits or procedures) and impose penalties for readmission of patients to the hospital within 30 days of discharge for specific conditions are helping drive adoption of sensors by clinicians and health systems. In addition, a growing cadre of patients wants to play a more participatory role in their health care.

All of these developments are causing sensors to rapidly evolve along a continuum, moving from the more traditional standard sensors to partially passive sensors, to passive sensors:

- Standard sensors require the patient to actively engage with the device, which collects and stores data; the patient must participate in the transmission of the data to another person or location, such as a physician, notepad, or computer. An example would be a standard glucose meter where a patient must submit a blood sample and manually log the reading in a journal, computer, or smartphone.
- Partially passive sensors automate a portion of the process. Patients need to actively engage with the device or actively transmit the collected data, but not both. An example would be a glucose meter with a built-in wireless connection, where a patient submits a blood sample, but the reading can be automatically sent to a mobile phone, computer, or personal health record in the cloud.
- Passive sensors require no patient participation. An example is a glucose-monitoring patch, worn by the patient, which constantly monitors their glucose levels and automatically transmits the data to a mobile phone, computer, or personal health record in the cloud.

The most fully passive sensors can provide constant connectivity, track and record a person's vital signs or other measures over time, and operate in ways that are undetectable by the user.

III. Integrated and Passive Sensors

Sensors are employed along a continuum of wellness to illness, from sports and fitness tracking to chronic disease management. Some enable medical tracking that had typically been performed in an inpatient setting but can now be done at home. Numerous types of sensors are being deployed, including:

- Blood-sampling sensors (e.g., a glucose meter that requires a blood sample)
- Tissue-embedded sensors (e.g., a pacemaker or implantable cardio defibrillator)
- Ingestible sensors (i.e., embedded in a pill and eventually dissolved)
- Epidermal sensors (e.g., "smart skin," via a patch or digital tattoo)
- Wearables, embedded in clothing or in accessories such as jewelry
- External sensors that connect to the body (e.g., a blood-pressure cuff or pulse oximeter)

In the following discussion, sensors are classified by their capabilities in tracking and monitoring health: sensing emotion, position, motion, ingestion, for diabetes, and for disease management and readmission prevention.

From Quantified Self and Fitness…

Some of the first consumer adopters of sensors for health are people who self-track their fitness and exercise. As early as 2008, members of Quantified Self (QS) — an online and in-person collaboration of self-trackers — began using sensors to monitor their vital signs and other measures.

Since then, self-tracking has started to go mainstream and the sensors are evolving from standard to partially passive and passive models. About 69% of US adults are tracking at least one health indicator, and about 20% of these people are currently using some form of technology.[2] Some 60 million sports, fitness, and health-monitoring devices with wireless technology are expected to be sold to consumers between 2010 and 2015. Large retail stores, such as Best Buy and Target, allocate increasing shelf space for these devices. The fastest-growing fitness applications are projected to be heart-rate monitors, sports watches, and running speed/distance monitors.[3]

The advent of the smartphone has further enabled consumers to track many aspects of their lives, from food consumption and exercise to daily hydration and hours and quality of sleep. According to IMS Research, two in three people who own a smartphone and exercise at least once a week are interested in purchasing sensors to monitor performance. The sports and fitness devices most commonly owned by consumers include heart-rate monitors, cycling computers, and global positioning system (GPS) watches.[4] One in three US consumers plans to buy a digital fitness technology in 2013, according to the Consumer Electronics Association.[5]

…to Sensors for Health Care

Beyond fitness, consumers are increasingly using sensor-enabled technology to manage health issues from chronic conditions to life-threatening diseases. For example, one-third of self-trackers say their collection of data has affected a health decision, and 40% say doing so has led them to ask a doctor a new question or seek a second opinion.[6] Using sensor-based technology to monitor wellness or illness often involves monitoring health metrics in two ways:

- Episodic monitoring, for patients recording specific indicators to track the progress of disease or recovery. This could involve tracking vital signs (e.g., heart rate, temperature) and disease-specific indicators (e.g., blood-glucose level, blood pressure, EKG).
- Continuous monitoring, for patients with acute conditions who need frequent or constant monitoring of signals such as heart rate or rhythm. "Continuous" is defined based on the sampling rate acceptable for the patient's specific condition.

In both types of monitoring, an alarm can be sent to the clinicians and family when clinical readings fall outside of pre-set norms.[7]

Sensing Emotion for Mental Health Status

"There's so much sensitivity to the role that mental health plays in our health care," said Dr. Joseph Kvedar, from the Center for Connected Health at Partners HealthCare.[8] Sensors can monitor physiological responses that detect emotion and mood, such as stress and burnout in employment situations, and post-traumatic stress disorder (PTSD) in people experiencing trauma. One example is monitoring emotional states passively through facial expression (e.g., via a webcam) or a wearable sensor. Both capabilities are offered by Affectiva, a spin-off of the MIT Media Lab, whose technology has been used in autism research with children conducted at the University of Notre Dame, in child anxiety studies at Newcastle University in the UK, and sleep studies at Harvard and MIT.

Another example is the behavior analytics platform created by the start-up Ginger.io; their product uses a mobile phone app to collect both passive (from the smartphone's sensors) and active patient data (from mental health surveys), which can then be sent to the patient's clinicians. The company, which also spun out of MIT's Media Lab, incorporates algorithms that predict potential problems for each patient based on their own data.

Researchers are also exploring the human voice as a carrier of emotion that can be detected passively through sensors. In 2012, Cogito Corporation began working with the US Department of Defense to develop a smartphone product that passively monitors an individual's speech and social activity, and can signal the need for an immediate intervention to help soldiers and veterans with depression, PTSD, and mild traumatic brain injury. Cogito's platform is called "Honest Signals," reflecting CEO Joshua Feast's belief that, "an individual's 'honest signals' — the subtle, unconscious signals or behavioral markers we relay in speech" can be analyzed to identify and monitor psychological distress and trigger early intervention including suicide prevention.

Cars are also emerging as a useful platform for passive sensors that serve mental health applications. The Veterans Affairs Palo Alto Health Care System is working to address PTSD in war veterans, who as a cohort have above-average driving accident rates. In a trial, sensors were attached to the brake pedal, gas pedal, and steering wheel in veterans' cars. A monitoring belt provided by Zephyr Technology

recorded the driver's heart rate and respiration. Using the car's GPS, researchers combine the car's location with data from sensors in the car and the belt to sort out triggers to PTSD symptoms. The VA is working with Fujitsu to integrate the data through an iOS app and provide feedback to the driver. (This mobile operating system was created by Apple.)

Sensing Position for Asthma

GPS is also being deployed to help patients with asthma, which affects 25 million people in the US. Research found that over one-half of these people had attacks in the previous year and were at risk for adverse outcomes such as emergency department visits or hospitalizations.[9]

Asthmapolis developed a sensor (the Spiroscout) that wirelessly links a GPS-enabled smartphone with an anti-inflammatory medication inhaler to passively sense the time and location of inhaler use.[10] This allows the generation of a personalized map that identifies the locations where the patient wheezed or had a difficult time breathing, as well as information on the frequency of inhaler use. Data are uploaded to the user's smartphone (and to a secure record in the cloud), which delivers daily text reminders to use the inhaler. Users can opt-in to a social network with other people using Asthmapolis, and can share their data with clinicians so that medication or treatment regimens can be adjusted.

Safe Aging at Home

Jeffrey Kaye, director of the Oregon Center for Aging & Technology, believes that seniors being continuously monitored at home will be the norm in the US by 2015.[11] Steven Dean, a health technology designer and leader of Quantified Self in Manhattan, already has that vision for his mother, who lives in Las Vegas. During a visit to her retirement community, he wondered, "How can I teach Mom's environment to sense things that I can't do from afar?" Dean took the initiative to seek an answer to that question with an overarching goal of keeping his mother happy and safe in her home as long as possible.

Dean first set her up with the same type of computer he used so that they could communicate on a shared physical system. Then, back home, he began monitoring how often his mother played an online game. When he noticed that she didn't play for a few days, he called to find out if anything was wrong. He found that her new medication was causing serious insomnia; he encouraged her to consult with her doctor, who changed the medication. Dean believed that he would not have found out about the problem if he had not been monitoring her online activity. "Seniors don't want to talk about bad things," he said.

This experience led Dean to envision a dashboard that would track his mother's behavior and activities. This dashboard could be filled with data from a variety of passive sensors that would monitor activities of daily living by sensing, for example, the opening and closing of a refrigerator door or front door, or the use of the restroom. Additionally, data from sensors in the home or that are worn could monitor walking to help prevent falls, the leading cause of admission to nursing homes and assisted living facilities and a major source of morbidity and mortality for older people. In the event of a fall, a passive sensor could automatically call for help and light up an alert in the dashboard. Finally, a person's online activities could be monitored, such as playing games, communicating with friends, and viewing pictures.

Dean pointed out that, "This wasn't a home health-monitoring system." These are the opportunities for services to expose patterns in daily activities and behaviors versus a health care-centric event. Dean believes that this is a richer way to get into the dialogue of monitoring "without making it feel like 'Big Brother is watching.'"

In studies performed by Asthmapolis and the Centers for Disease Control, users with the Spiroscout improved control over asthma symptoms from 25% of the time to 62% of the time. Another study found that the number of people with uncontrolled asthma fell by 50% when using the Spiroscout. Asthmapolis is working with health providers to expand patients' use of the technology.

Sensing Motion for Alzheimer's

Alzheimer's impacts 5.4 million Americans and is projected to affect 16 million in 2050 as the baby boomers generation ages.[12] A study presented at the 2012 Alzheimer's Association International Conference used passive sensors to monitor a patient's gait to assess cognitive decline. Bill Thies, chief medical and scientific officer for the association, said "Monitoring deterioration and other changes in a person's gait is ideal because it doesn't require any expensive technology or take a lot of time to assess."

Continuous at-home monitoring may be a more accurate measure of gait than single tests in people with cognitive decline. "Advanced technology now allows us to measure walking speed in one's own home, derived from hundreds of walking episodes," said Dr. Lisa Silbert of the Oregon Health & Science Center. "This potentially provides a better measure that links information about real-world walking abilities and changes in brain health."[13]

Sensing Ingestion of Medications

About one-half of patients do not take medications as prescribed, and one-third of new prescriptions never get filled.[14,15] The challenge of adherence to prescription drug instructions costs $100 billion to the US health system in the form of emergency room visits and inpatient admissions, and avoidable visits to the doctor. "Directly digitizing pills in conjunction with our wireless infrastructure may prove to be the new standard for influencing medication adherence and significantly aid chronic disease management," according to Eric Topol, author of *The Creative Destruction of Medicine.*[16]

The Ingestion Event Marker (IEM), a passive ingestible sensor, is "the size of a grain of sand," according to Proteus Digital Health, the company that developed the technology. The sensor can be inserted into any product that can be orally consumed, such as medications.

The sensor is activated by fluid in the stomach (powered similar to a potato starch battery) and transmits a signal to a skin patch that logs the time the medication was taken as well as the type of medication consumed. The patch wirelessly transmits the data to a mobile device which can then send the information on to designated individuals (such as clinicians and caregivers) based on the patient's preference.

Proteus envisions that the sensor could be best used in drugs for managing chronic conditions such as diabetes, along with conditions where the timing of medications is critical, including Alzheimer's, Huntington's, and Parkinson's.

The IEM was first approved in Europe in 2011; the FDA approved the sensor for use in the US in 2012. The company is partnering with many organizations to roll out distribution of the sensor, including Lloydspharmacy in the UK, Bodymedia, Kaiser Permanente, Medtronic, Novartis, and ON Semiconductor.

Sensing for Sleep Disorders

Insufficient sleep is a public health epidemic in the US, and costs the nation $63 billion in lost productivity.[17,18] Lack of sleep is linked to motor vehicle crashes, industrial disasters, medical and other occupational errors.[19] Growing recognition of this problem has led to the development of sensor-based

devices that passively monitor sleep. They fall into a few categories for different consumer segments, from fitness/wellness to sleep apnea.

Bam Labs offers a device in the form of a pad with integrated sensors that track breathing, heart rate, and movement. The self-inflating pad is placed underneath the mattress. One of the pad's sensors monitors fluctuations in air pressure via breaths, heartbeats, and getting out of bed. Data are wirelessly transmitted to the Internet. Trends and measures (e.g., quality and duration of sleep) can then be viewed by users via mobile apps or an online portal. The technology is especially useful in preventing falls: Bam claims that facilities using the app have seen a 43% reduction in falls out of bed and an hour of daily staff time saved per bed. "What's nice is that it's unobtrusive, and doesn't medicalize a person. They can just sleep as normal, but still be monitored closely," noted Jo Sollet, a researcher in Harvard Medical School's sleep medicine division.[20]

iMPak Health developed the SleepTrak system, a credit-card sized near-field communication (NFC) device on an arm cuff that users wear. NFC is a set of standards that allow electronic devices to establish radio communication with each other by touching each other or coming close together. The device senses sleep patterns and transmits the data to the user's computer for self-tracking or to share with physicians. SleepTrak pairs with Near Field Communication-enabled phones; data are transmitted by removing the sensor and tapping it against the phone. The information can then be viewed by the user on a computer or phone, or emailed to a health provider. A more comprehensive sensor system for home use was developed by NovaSom; it includes the ability to measure breathing effort (chest strap), blood-oxygen levels, heart rate (via a finger-worn pulse oximeter), airflow, and snoring (via a breath sensor). The latest generation of NovaSom's system includes the ability to send the gathered data via a mobile phone network for same-day diagnosis.

Sensing for Diabetes

For the 26 million Americans living with diabetes, managing their illness involves many activities throughout the day: testing blood-glucose levels, checking foot health, selecting and eating the right foods, and getting exercise.[21] Good management means good glycemic control, which benefits people with either Type 1 or Type 2 diabetes.[22]

Making diabetes management a little easier are glucose sensors that are partially passive; many regular glucose-sensing devices (those that require a finger prick) are being paired with smartphones (either via a direct connection, cable, or wirelessly), which can automatically record the glucose reading. The collected data can then be charted by the patient and/or sent to clinicians for further review. One example is the iBGStar blood-glucose monitoring system, which directly attaches to an iPhone or iPod Touch. The product comes with a lancing device and test strip, which is placed into the port that attaches to the phone. A phone app records the glucose reading and allows the data to be organized with tags (e.g., pre-breakfast, post-dinner, morning, night). The app also alerts users when blood-sugar tests out of the normal range, and can be configured to share information with clinicians.

Moving towards a passive system, continuous glucose-monitoring (CGM) devices from companies such as Medtronic and Dexcom provide several hundred blood-sugar measurements every 24 hours via a sensor that is inserted under the skin; CGM can provide a more complete picture of glucose trends that can help diabetics manage their condition. A less invasive sensor — which could lead to a passive sensing system — comes from the early-stage

company Sano Intelligence. A patch on the skin monitors the blood and wirelessly transmits vital signs including glucose and potassium levels to a smartphone. Sano is looking to incorporate other measures such as electrolyte balance and kidney function into the patch.

Other researchers and companies are also working on non-invasive glucose sensing systems that may lead to passive sensing systems. At Purdue's Birck Nanotechnology Center, researchers developed a sensor that detects glucose in saliva, tears, and urine. "It's a platform that might eventually help to eliminate or reduce the frequency of using pinpricks for diabetes testing," said Jonathan Claussen, a researcher on the Purdue team.[23] Another developer, Quantum Catch, is working on a way to monitor blood glucose by measuring the interaction between light and the glucose contained in the aqueous humor of the eye, between the lens and the cornea.

Helping people with diabetes to monitor foot health is another area of sensor development, as more than 60% of non-traumatic lower-limb amputations occur in people with diabetes.[24] The start-up Podimetrics was formed by a multi-disciplinary team from MIT that developed a sensor-enabled mat for people with diabetes. When a person steps on the mat for 30 seconds, sensors collect data about blood flow and wirelessly transmit the information to a cloud-based server. If the algorithms detect a pre-ulcer, an alert is sent to the patient and physician. Because the sensing can occur while the person is conducting an activity of daily living such as tooth brushing, the monitoring can be passively included in daily life.

Sensing for Disease Management and Readmission Prevention

Sensing blood pressure, weight, pulse rate, and heart rhythm is becoming more popular at home where it can be used to help avoid hospitalization, prevent readmission for patients with chronic illnesses who were recently discharged, or for diagnostic testing. Preventing readmissions is particularly relevant as Medicare began to penalize health providers who readmit patients with congestive heart failure (CHF), acute myocardial infarction, and pneumonia within 30 days of discharge as of October 2012. About 25% of patients with CHF are readmitted to the hospital within one month of discharge.[25]

Devices that monitor blood pressure, weight, and pulse rate are becoming partially passive or passive via integration of wireless technology so that collected data can be automatically logged in a record on a smartphone or in the cloud. For example, iHealth Labs markets a wireless blood-pressure wrist monitor, weight scale, and pulse oximeter (measures pulse rate and blood-oxygen level) that transfer data to the iHealth MyVitals app on an iPad, iPhone, or iPod Touch. iHealth is working with electronic health record vendors to integrate device data into EHR systems. Traditional medical device companies such as A&D, Nonin, Omron, and others are also moving their weight scales, blood-pressure cuffs, and pulse oximeters to partially passive and passive models.

In the area of cardiology, a number of companies offer partially passive and passive sensors for monitoring and diagnosis. CardioNet and Corventis market a mobile cardiac telemetry service where a patient wears a passive sensor that can send abnormal heartbeats to a monitoring center in real time. For patients who don't need real-time monitoring, iRhythm Technologies developed the Zio Patch, a small, band-aid-like partially passive sensor that records every heartbeat.[26] It can be worn for up to

14 days; at the end of the monitoring period, the patient mails the device to iRhythm, which analyzes the data and sends a report to the physician.

Zephyr Technology, Preventice, and Corventis have taken this idea a step further; these companies have developed patches that can passively monitor heart rhythm as well as other important signals such as breathing rate, position/posture, and activity, and wirelessly transmit the data to a record in the cloud. Zephyr's technology is also used in a venture with Under Armour in their E39 biometric compression shirts for monitoring NFL athletic performance.

Further down the road are epidermal electronics; skin patches that adhere to the body without wires, pins, adhesives, or gels, which can enable comfortable, nearly invisible passive sensing of some vital signs. Researchers at the University of Illinois at Urbana-Champaign, through their company MC10, have developed sensor patches that stretch with the skin as people move in daily life. The patch sits on the skin as a temporary tattoo does via water and a peel-off backing, and in the future will be able to transmit data wirelessly.

Wearable Sensors and Design Importance

The trend toward sensors that are passive for the user has led to considerable interest in "wearables" — sensing devices that are always on, always accessible, and easily worn on the body.[27] They feature capabilities for real-time information access, data input, local storage, and collaborative communications. This technology represents a convergence of health, technology, fashion, and textiles. More consumers look to design aesthetics to translate to medical devices the way design has permeated consumer goods in retail stores like Target, and in the products of Apple.

A Pinterest board dedicated to wearable sensors [www.pinterest.com] is run by Carol Torgan, a scientist who works on mobile health development. By the end of 2012, there were more than 200 examples of wearable sensor technologies pictured on the board. The market for wearable wireless health and fitness devices is expected to reach 169.5 million units by 2017.[28] Adidas, Apple, Brenig, Google, Microsoft, Motorola, Nike, Reebok, and Under Armour (working with Zephyr Technology) are among the growing list of companies launching wearable sensor products.

In one example of wearables, Nike introduced a $300 pair of sneakers during the London Olympics. The shoes feature the Nike+ fitness tracking platform and incorporate pressure sensors in the soles in addition to triaxial (three-plane) accelerometers to track the wearer's movement. In another example, Adidas via Stella McCartney, designed a Tennis Performance Bra incorporating a miCoach heart sensor that tracks heart rate and calorie burn. The bra was priced at $70 on the Adidas website (well under the price of McCartney's own designer-labeled goods).

Wearable sensors reach beyond the wellness/fitness market segment into medical care. Aetrex, the shoe company, developed shoes with GPS technology targeting Alzheimer's patients who might wander away from home. The shoes sell at retail for $299, plus a $35 monthly service fee for tracking. Torgan expects more sensorized shoes and clothing to hit the market soon. She sees shoes as a particularly useful platform for sensors. "They don't have to withstand repeated trips through a washing machine, they offer a stable surface, and they provide a great locus for tracking movement, better than the wrist," she said. Shoes could be used for pressure sensing and gait analysis for conditions such as diabetes, Parkinson's, and dementia. Torgan stressed the importance of

user-centered design and eliminating the medical focus from the design process. "The platform should take the form the consumer wants it to be."

Sonny Vu, founder of Misfit Wearables, believes everyday wearables are ideal for this technology, in part because they eliminate having to carry anything around. "Put a sensor in a simple white t-shirt," or something everyone wears every day, such as socks or a belt, he said.

If devices flow seamlessly into daily life, people will more likely want to use them. Vu has identified three factors that can motivate people to wear sensors:

1. **Comfort:** Is the device comfortable? A good test is asking the question: "Would you wear the device if it didn't measure anything?"
2. **Utility:** Does the device do something useful for me? "Jeans can hold stuff and protect me from the elements. If they measure and give me data, too, that is also useful," Vu asserted.
3. **Invisibility:** Does the device get in the way of daily living? "Does it make you look like Tron?" If it's not going to be invisible, Vu said, then make it "precious and desirable, intentionally good-looking."

Jennifer Darmour, founder of ElectricFoxy's Pulse ring, agrees on this point. She told Co.Design, "Tracking and using your body data doesn't have to be clinical; it can be beautiful and part of your lifestyle."[29]

IV. Market Considerations and Challenges for Passive Sensing

Among the sensor innovations discussed above, a handful have found sustained commercial success. While the drivers for developing these sensors are numerous, there are also barriers that prevent them from being readily adopted and deployed in the US health system. "Today, there are solutions looking for a problem," said Dr. Yan Chow of Kaiser Permanente's Garfield Innovation Center. However, he said, from the health care perspective, there are problems looking for a solution. "The challenges are legal, regulatory, political, and medico-cultural."

Consumer/Patient Engagement

Many Americans are interested in keeping track of their health. About 60% of US adults track their weight, diet, or exercise routine — whether using technology or recording the information manually or mentally — and about one-half of these people say self-tracking has changed their overall approach to health. One-third of self-trackers say their collection of data has affected a health decision, and 40% say doing so has led them to ask a doctor a new question or seek a second opinion.[30]

Self-tracking isn't only the province of younger consumers: 50% of seniors and 57% of boomers are open to using self-monitoring and remote health-monitoring technology that sends information to doctors. Boomers view tech-enabled health products as a way to foster control and ongoing independence for themselves, especially in light of the rising incidence of chronic disease with aging, and their desire to reduce costs.[31] Over one-half of boomers show a high willingness to use in-home health-monitoring devices in tandem with the care of their primary physician.[32]

IMS Research found that people are willing to pay for sensors paired with their smartphones. Some 82% of people (polled in the US and UK) said they would spend up to $140/£90 for a smartphone-paired health/fitness sensor.[33] This is far more than the average price of $2.05 that Apple iTunes charged for health-related apps in 2012 (dropping from $2.34 in 2010).[34]

Factors including health literacy and data display are also critical to consider for consumer/patient acceptance and engagement. Only 12% of US adults have proficient health literacy, and over one-third have difficulty with common health tasks like following directions on a prescription drug label or adhering to childhood immunization schedules using a standard chart.[35] Because it is difficult for many people to use raw health data, it is important that crucial health information be presented in a way that is easily understood and actionable by the consumer. For some patients, a single number, such as the Nike+ FuelBand score, or the Zeo ZQ number, is understandable and useful. For other people, a picture or graphic might be more helpful, such as the facial scale used by patients for tracking pain.

Sensor design also impacts consumer/patient acceptance. "You need to develop an unobtrusive system," said Carol Torgan, noting that most people don't want to be defined by their health conditions. She described the response of an acquaintance who is reluctant to wear his FuelBand in public. "He said, 'I am basically advertising to the world that I am trying to lose weight.'"

Finally, there is often a mismatch between the measures that consumers (and likely patients) want to track and those that their doctors want them to track. There can be gaps in particular areas such as blood sugar, physical activity, vital signs, and weight, as shown in Figure 1. While over 60% of physicians would like to see patients track blood glucose, only 20% of consumers want to. To overcome this challenge, consumers/patients might need an incentive to adopt and sustain tracking of measures that clinicians and payers want them to monitor over time.

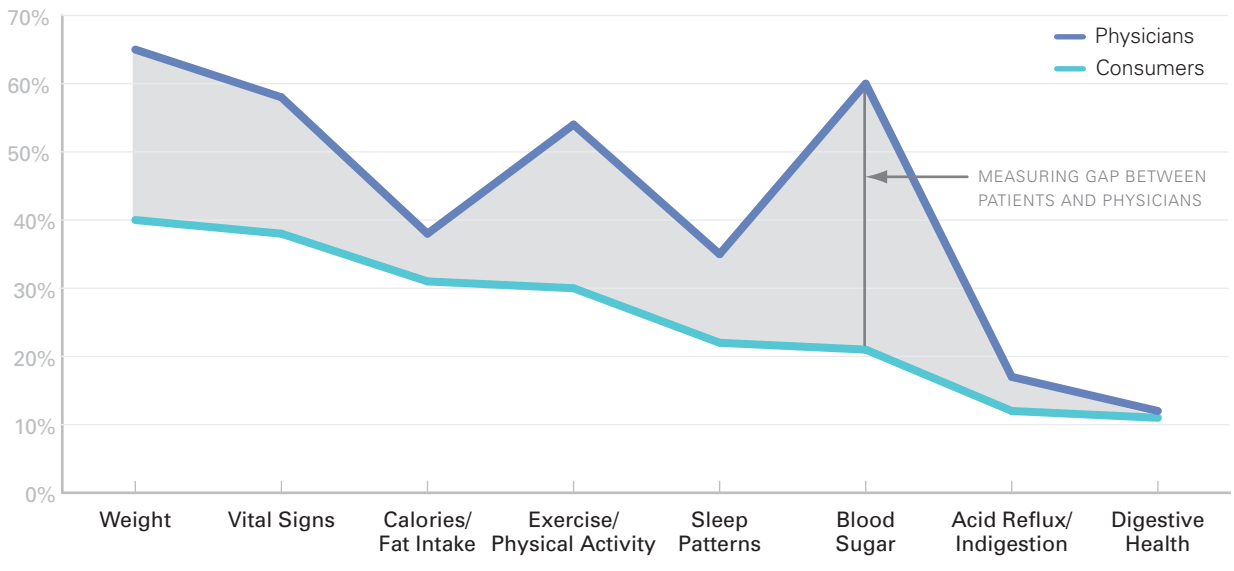
Provider Engagement

Among consumers who self-track, one-third share their information, and among those, half share it with a clinician.[36] However, it is unclear how many clinicians are ready to embrace the data flows and have electronic health records (EHR) fully capable of supporting this activity. Also, as discussed under "A Blitzkrieg of Data?" below, there is concern among providers there will be a tsunami of health data for them to analyze from all of these sensors.

Reimbursement is also a critical driver in the diffusion of technology in health care. The adoption of new funding models – in particular, value-based payment, such as paying for performance, bundled payments, and accountable care — will better align incentives between providers, consumers, and health plans for the adoption and sustained use of remote health monitoring and sensor-based technologies. Outcomes, such as preventing hospital readmissions and shortening time to return to work, provide hard-dollar justification to invest in sensor-based technologies that demonstrate cost-effectiveness.

"Providers of all stripes are now open to different models of care delivery," according to Partners HealthCare's Joseph Kvedar. "They're more likely to

Figure 1. What Health Metrics Consumers and Physicians Want to Track



Source: *Healthcare Unwired: New Business Models Delivering Care Anywhere,* PricewaterhouseCoopers, September 2010.

say, 'Okay, what we're going to do is to concentrate on doing the right thing, and because reimbursement models are changing, we have faith that going forward we will be able to figure out how to get paid for our work.'"[37]

One way that sensors may help win providers over is to enable better care for patients with chronic illness by filling in the information blanks between visits. Dr. Ranjit Das of Zansors, LLC, a company developing applications for medical sensors, noted that patients who collect objective data between office visits can engage in more meaningful conversations with their doctors. Zansors' goal is for consumers to use real-time monitoring to capture clinical events and present the information to doctors in a way that fits into their workflow through summary reports. Das pointed out the usefulness of EKG monitoring over time, rather than episodically or well after someone has chest pain. "We need to know what the heart was doing at that moment," Das said, to be able to draw clinical conclusions about whether the cardiac event was stress induced, or whether it matches up with medications at the end of a dose, for example. "Sensor data can empower physicians to better deal with the next event," Das asserted, which may obtain their engagement.

A Blitzkrieg of Data?

"Many people are seduced by the ability to sense more stuff, so we are piling on the sensing side," warned Steven Dean, a health technology designer. "It would benefit us to slow down and take smaller steps with sensing data, to work on sense-making." There needs to be a strong focus on smartly analyzing and interpreting the data that are coming from the sensors, he said.

For health providers, it's a question of workflow, and how a health data deluge from widespread adoption of sensors might negatively impact their productivity. EHR systems today don't generally accept data from the various sensors patients use or consumers' own wellness devices (e.g., a Fitbit, which measures steps, distance, calories burned, and sleep). Currently, physicians view remote monitoring data in separate applications. There are some hospitals that have been able to integrate remote data into the EHR, largely accomplished without the support of health IT suppliers.

Even if user-generated data seamlessly flows into electronic health records, there is still the worry about the sheer volume of data; for sensors to be embraced by clinicians, the algorithms designed at the back-end must be able to do some of the sense-making. For example, a clinician might prefer to be notified only during a triggering event where the sensor data for the patient is outside of a pre-determined normal range.

Privacy and Data Security

Deploying passive sensors for patients raises concerns about privacy; patients want to know who is monitoring their personal health data, and what they are doing with this information. Health privacy expert Christine Sublett said, "We need to be cognizant of collecting only the data we need. As consumers, we need to feel confident that 'my' device is tracking only those issues that it should be tracking based on my consent."

Yan Chow of the Garfield Innovation Center stressed the importance of weighing the quid pro quo — the value received for what is given up in terms of privacy. "There is value to the information," he said. "Should we monitor people at home? Privacy advocates might immediately say 'no.' But the doctor asks the patient, 'What is the tradeoff if you have to go into a nursing home?' So we might have an information market where patients are in control

and can sell their information as they need to and understand the risks in advance."

Beyond privacy worries, Americans are concerned about data security; many lack trust in their personal digital health data being "locked down."[38] Personal health-monitoring data might present a concern for many potential users, especially data that uses the patient's mobile phone. These phones are "not as tightly coupled to the person as they should be," said Jacob Sorber of Dartmouth College, who believes smartphones are more subject to hacking and viruses.[39] One security solution, developed by a team at Dartmouth's Institute for Security, Technology, and Society, is a "smartwatch." It acts as a hub for health apps that would integrate on a secure platform. The watch, fitted with a mini-USB port that can accommodate external devices, is uniquely associated with a patient by electrical signals within the wrist muscles next to the device — eliminating the likelihood of data being accessed from a lost or stolen mobile phone. This and other security innovations may ease patients' potential resistance to adopting health sensors.

Health Sensor Regulation

The FDA regulates how sensor-based devices are used in a medical setting, while the FCC regulates the devices as a form of communication. In 2011, the FDA published draft guidance on the regulation of mHealth (mobile health) devices, which is relevant to sensor-based medical devices. The FDA's 2011–2015 Strategic Initiatives and recent Draft Guidance for Mobile Medical Applications reflect more vigilant commitments to consumer safety and product quality.[40]

Regulators are under pressure to maintain the balance of supporting innovation while assuring safety and effectiveness for these new sensing devices and applications. Health privacy and security expert Christine Sublett observed that, "This is the beginning of a whole new innovation, and the FDA is behind the curve. They are in the process of figuring out what guidelines manufacturers have to follow to combat the (hacking) threats out there," she said. "Most manufacturers of sensor-based medical devices are probably not going to build in the privacy and security that needs to be there because it adds complexity and may add cost as well. Most importantly," she added, "it will add time to market — and that's the big issue, if it's a matter of getting a product out in three months, versus six months." Adding time-to-market can make the difference between profitability and failure for a company, she said.

In addition to the FDA, sensor-based health devices can also be regulated by the FCC, which has set aside spectrum to support the wireless transmission of data between sensors attached to patients and medical devices. These Medical Body Area Networks (MBANs) operate over short range in hospitals, nursing homes, and in-home monitoring applications. For home monitoring, data collected can be sent to a provider via a separate broadband network.

V. Prospects for Sensor-Enabled Health

"What used to take up a building now fits in my pocket, and what fits in my pocket will fit inside a blood cell in 25 years."

— RAY KURZWEIL

Despite the various challenges, Eileen Bartholomew of the X Prize Foundation is unabashedly enthusiastic about the future of sensor technology. "You will see sensors embedded in your life — whether that is your phone, clothes, home, or car," she predicted.[41] Industry observers point to factors that appear to bode well for passive sensors in health care over the next decade: the falling price point, proliferation of practical applications, continued innovation in physical configuration (from watches to high-tech tattoos to devices that can be ingested), and continued growth of a patient cohort ready to adopt sensor-based devices. Furthermore, as value-based and accountable care payment paradigms expand in the US, aligned financial incentives should create a strong push to keep people well, more effectively manage chronic conditions, and stem hospital readmissions. Industry observers see a useful role for remote, mobile, and passive health sensing in such an environment.

In response to the perceived opportunity, a variety of players are entering the passive sensing space. These include telecommunications, networking, consumer electronics, and cable TV companies, as well as small-scale entrepreneurs growing out of technology incubators in Boston, New York, Chicago, San Francisco, and San Diego. At the same time, medical device and consumer health companies are continuing to enter the space — especially targeting large patient populations such as people with diabetes. With health sensors enabling continuous monitoring at the point-of-patient, the new medical home may end up being wherever the patient is. Such a scenario would challenge the traditional delivery system centered around the hospital, physician office, and health plan, although it remains to be seen exactly how patients (and consumers) want health sensors to fit into the larger health system picture.

The most important thing, industry observers emphasize, is that passive sensing can help close the communications loop between the patient and the clinical team, providing real-time (or near-real-time) feedback to patients. "The power of health information in the right context is a whole new paradigm," said Monique Levy of Manhattan Research. "This tends to get overshadowed by talk about Big Data.

But if we capture your personal data story with contextually relevant information, then we can push aided decisionmaking to where the patient is," she said. The ultimate goal is behavior modification.

To prevent the potential data blitzkrieg it will be necessary to determine specifically what data are required to manage a patient's conditions, which passive sensors to use for collecting these signals, and how best to intervene once a triggering event is detected. "The bottleneck is the informatics," according to Scripps Institute's Eric Topol. This is the challenge of making sense out of the patient's health signals that come from different devices – say, a wellness/fitness device and a glucose monitor. "Most of the stuff that's on the market today is one sensor with one type of analytic software that's built on top of it," Dave Marvit of Fujitsu told *Information Week*.[42] "Our vision," he said, "…is to build a platform so that all these other sensors can be integrated and you can apply analytics to the data they generate." MIT's Juhan Sonin expects that, "Early detection of chronic diseases will be as easy as carrying your cell phone in your pocket."

Larry Smarr, director of the California Institute for Telecommunications and Information Technology, also has an optimistic vision for the future of sensors in health. Writing in December 2011, he said: "People will soon be able to have their genetic code and medical imaging stored in the cloud, along with charts of vital signs and detailed nutritional analysis of everything they consume. Besides providing early detection of internal changes that could lead to disease, cloud-powered voice-recognition wellness coaches could provide continual personalized support on lifestyle choices, potentially staving off disease and making health care affordable for everyone."[43]

Before such a future can take shape, the significant practical challenges described in this report will require short-term and ongoing resolution. Among them are problems of patient engagement, provider embrace, payment issues, privacy concerns, legal and regulatory challenges, and information integration. For any of the sensor technologies to thrive in the marketplace, they will need to address these issues while helping improve patient outcomes.

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California
HealthCare
Foundation

1438 Webster Street, Suite 400
Oakland, CA 94612
tel: 510.238.1040
fax: 510.238.1388
www.chcf.org