CHAPTER 9

Body-Worn, Ambient, and Consumer Sensing for Health Applications

There has been increasing momentum, particularly in the last decade, for new healthcare sensing and monitoring devices, driven in part by advances in sensor and sensor system technologies, which are delivering greater capabilities at economically viable costs. Moreover, global demographics are driving a significant rethink in the way we deliver healthcare. The cost of healthcare will continue to rise unabated, to economically unaffordable levels, unless we change our current approach. Technology affords greater flexibility in clinical protocols and enables the new consumer healthcare market. Sensing and sensor technologies play a key role at the center of healthcare innovation, and will continue to enable that innovation into the future as they integrate with a range of other information and communications technologies (ICT) to deliver exciting new capabilities.

As new sensing technologies, such as microelectromechanical systems (MEMS), biochemical, and immunological sensors continue to emerge, their proliferation into healthcare will continue to accelerate. Sensing will enable regular or continuous monitoring of health status, which will in turn enable the delivery of new proactive models of care. In the longer term, patient outcomes should improve, because issues will be identified earlier, when interventions can be more effective and less costly. Continuous monitoring solutions have already emerged in the telehealth space for monitoring chronic conditions, such as chronic obstructive pulmonary disease (COPD), congestive heart failure (CHF), and diabetes. Such monitoring provides continuous observation of disease state, which is valuable for anticipating and avoiding the physical and financial cost of acute episodes. Treating patients after an acute episode—which is the current reactive model of care—can result in catastrophic and irreversible changes in a person's health and well-being and lead to accelerated decline. Over time, sensing will also be applied to screening the general population as part of national healthcare programs to improve public health. Individuals, particularly the increasing number of "worried well" individuals (those who are healthy but are worried about becoming ill and seek reassurance by visiting their doctor, testing themselves, or taking medication when there is no medical reason to do so), are also likely to utilize sensing technology to proactively monitor and maintain their own health.

As pervasive sensing becomes the norm in healthcare, it will significantly increase our knowledge about disease risk and the effectiveness of interventions. Existing technology-based solutions are currently helping us to better understand the aging process, including identifying early signs of cognitive decline, frailty, motor and neurological issues. Sensor technologies enable a fresh look at healthcare at the individual level by building a detailed understanding of changes in a person's health status. This data provides the early warning signs for issues that most affect health and well-being.

Changing the Way We Do Healthcare

Currently, healthcare is delivered using a doctor-centric model. While this model was appropriate for its time, it is not be scalable into the future. The world's population is getting older. In 2010, there were approximately 0.5 billion people over the age of 65; this is projected to increase to over 1.5 billion by 2050 (Suzman et al., 2011), due to increases

in life expectancy. The prevalence of lifestyle diseases, like hypertension, diabetes, and obesity, are also increasing significantly. Consequently, the amount of money spent on healthcare continues to rise and is fast approaching the point where western economies can no longer afford healthcare. In 2010, the US spent a total of 2.6 trillion US dollars (17.92 percent of GDP) on healthcare, as shown in Figure 9-1. This contrasts worryingly with 5.2 percent of GDP spent on healthcare in 1960. The Congressional Budget Office has estimated that healthcare spending will reach 25 percent of GDP by 2025, 37 percent by 2050 and 49 percent of GDP by 2082, if healthcare spending continues to follow current trends (Fodeman et al., 2010).

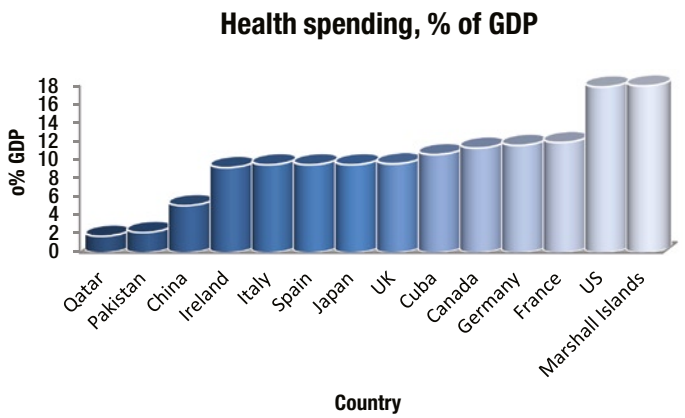

Figure 9-1. *Expenditure on healthcare in 2010 as percentage of GDP (source: WHO)*

Demands on healthcare resources will continue to grow: the longer we live, the higher the incidence of age-associated chronic diseases such as COPD and cognitive decline. Scientific advances will allow conditions such as cancer, previously considered to be acute or terminal, to be treated as chronic diseases instead. Without changes to the way healthcare is delivered, some 25 percent of a typical western country's population may have to be involved in healthcare delivery by 2040 (Vavilis et al., 2012). Therefore, there is a pressing need to invent a different way of delivering care while reducing the already unsustainable healthcare costs that plague virtually every major Western government.

Modern lifestyles are seen to play an ever-increasing role in people's health. Non-communicable diseases such as coronary heart disease, hypertension, diabetes, and some cancers (such as lung cancer) have clinically proven correlations with lifestyle choices. These "lifestyle diseases" are becoming the most significant causes of death (Colvin, 2012). Factors that influence lifestyle diseases include sedentary lifestyles, obesity, stress, high fat/sugar/salt/processed meal diets, cigarette smoking, and high levels of alcohol consumption. People are looking to technology, primarily in the area of activity monitoring, to provide more awareness of our sedentary lifestyles. Sensing technologies and supporting software can be used to encourage people to develop habits that predispose them to better health in later adult life (Corocoto, 2011). A wide variety of products, including Nike Fuel and Fitbit, already aim to make people more active, and provide mechanisms to keep them engaged in fitness over the longer term. We discuss the sports and recreational sensing area in more detail in Chapter 10.

Incidences of disease, whether lifestyle-related or due to aging, are forcing us to look at the way we currently deliver healthcare, and to consider how it should be done in the future. Modifying the healthcare delivery model will embrace a multi-faceted approach and require changes such as the following:

- Using screening and assessment technology in home and community settings to reduce pressure on hospitals.
- Moving from a reactive model to a preventative model.
- Personalizing healthcare to individuals, including risk factor identification, preventative intervention, and treatment.

- Involving individuals to a greater extent in monitoring and maintaining their health and wellness.
- Using technology to enable better management of clinical workloads and to allow health professionals to prioritize the patients of greatest need.

However, healthcare is an extremely conservative market in terms of ICT adoption, especially when it comes to large-scale systematic change. It is also a market that requires equipment to be proven and certified before adoption, which translates into a long process for new products coming to market (the regulation and certification process is discussed in Chapter 6). Finally, it is an industry that demands a lot from suppliers, including the ability to provide product liability in key healthcare situations.

The healthcare management business has long been an activity-driven or fee-for-service model that incentivizes activity over outcome (Chase, 2012). As the costs of hospital admissions continue to grow rapidly, a new emphasis on patient outcomes has started to emerge (Porter, 2010). Governments (Scher, 2011) and the private insurance industry are now starting to focus on the quality of patient outcomes, with hospitals not being reimbursed for patients who are readmitted within a specified period for the same problem. Sensing will play an important role in realizing this new model of care by providing quantitative measures of patient status in the clinical environment prior to discharge, and in the home after discharge. Insurance companies are also getting more interested in sensing, which can be used in the home to maintain the health and wellness of patients on a longitudinal basis, thus preventing or minimizing costly hospital admissions for acute events.

In the longer term, the use of health-related sensor data by insurance companies and similar organizations will undoubtedly raise significant social debate. Insurance companies already use sophisticated statistical models to estimate the future risk of clients based on their previous medical history and that of their families. The increasing availability of sensor data, especially genetic information, has the potential to quantify the impact of an individual's genetics and behavioral risks. In principle, certain individuals could have premiums that are prohibitively expensive, or they could even become uninsurable. There is likely to be significant resistance ethically to using genetic factors to load insurance premiums, especially on the basis that people can't do anything about the DNA-related risks they inherited from their parents. The real battle to be fought is likely to be related to modifiable behavior, for example, compliance with therapeutic regimes. If someone's behavior negatively impacts the predicted cost, should others bear the burden through higher premiums? Sensed information will be central to this debate as it will enable behavior and compliance to be tracked.

With the availability of over-the-counter (OTC) diagnostic tests, direct-to-consumer genetic testing kits, physiological monitoring sensors, and fertility monitoring, there is a rapidly growing online trend toward the phenomenon of the "quantified self" and "life-logging." Individuals may be driven by various motivations, such as endeavoring to stimulate discussion, seeking a cure, or experimenting with preventative measures for a known disease risk. They may choose to share this information socially, either in person or through online forums. These individuals are highly motivated to understand what the data is telling them and to utilize the data to improve their health outcomes. Part of that process is changing the conversation with an individual's doctor, as outlined in Chapter 7. The extent of these data-driven discussions is somewhat limited. In areas such as fertility, the use of sensor data is becoming the norm, and is seen by the both the patient and clinicians as adding significant value to the consultation process. However, it will take time before the use of personal sensing information provided by individuals will be accepted in the clinical community. Issues such as data quality, duty of care, and relevance must be addressed to gain acceptance. Still, the first tentative steps in shifting this dynamic have started, driven in part by the use of sensors.

Healthcare is on the cusp of a significant change in the way we understand and treat disease in individuals. We are beginning to move away from empirical, "population-based" medicine to precise, "personalized" medicine. Driven by advances in "omic" technologies—namely genomics, transcriptomics, proteomics, and metabolomics—disease pathology is now starting to be defined at a molecular level. This molecular-level classification will mean that the optimum treatment can be selected according to the both the molecular behavior of the disease and the DNA of the individual. Sensing will play a key role in personalized medicine. Companion tests, based on biosensors, will determine if a patient can benefit from a genetically targeted drug treatment. And sensors will monitor the patient during the course of the treatment (for example, monitoring biochemical by-products associated with a drug's targeted metabolic pathway). There is significant potential to radically alter our approach to disease diagnosis, prognosis, and therapeutic interventions over the coming decades.

Sensing Context in Health Applications

Context plays an important role in determining the value of sensor data. For example, some sensor readings, taken in isolation, can have limitations. These limitations can be addressed at least in part by collecting supporting contextual information. What was the person doing when the measurement was collected? Where was she located? What were the local environmental conditions that could influence the measurement? Contextual information is particularly important when capturing physiological measurements, such as activity levels prior to heart rate measurements. Context can typically be gleaned using additional sensors, accelerometers, for example, to determine if the person is moving when a physiological measurement is taken.

Qualitative approaches, such as weekly health questionnaires, can also prove useful. This is commonly used in chronic disease management systems. However, the quality of self-reported information is dependent on the accuracy of response by the patient, which is difficult to determine. When collecting contextual data to support a clinical sensor reading or observation, it is also important to ensure that any data has the appropriate temporal resolution and spatial characteristics. If not matched correctly, additional information can add ambiguity rather than clarity. Contextual sensing information can generally be used in three ways:

- The most common approach is for a clinician to manually review the contextual sensor information on an ad hoc basis to support the interpretation process.
- Alternatively, contextual information can be overlaid with the sensor measurements of interest in the same graphical representation or in an adjacently chart. This overlapping of data visually can be very helpful in the interpretative process.
- Finally, the most sophisticated approach is the intelligent and automated fusion of contextual data with the data source of interest. Algorithmic data fusion can be very useful in reducing the dimensionality of data and inferring higher-level information. It can also be useful to determine whether the context of measurement is valid based on a defined measurement protocol.

Context can also play an important role in determining the security, privacy, performance, and accessibility requirements of sensor networks. This continues to be an area of active research, exemplified by new solutions such as AlarmNet from the University of Virginia (Stankovic et al., 2011).

Sensors can also be used to provide context to the success or failure of a treatment protocol. By knowing what happens between outpatient visits, a clinician can optimize an existing treatment protocol or develop a new protocol. Data from ambient and body-worn sensors can also be combined with context-detection algorithms to generate support messages. Such messages are generated at appropriate times to support a patient on a specific treatment protocol, for example to prompt to take medication, remind about exercise, or advise about the consumption of food and drink.

Hospital and Community-Based Sensing for Assessment and Diagnosis

Sensing is pervasive in every aspect of hospital-based care, from the simplest digital thermometer to complex laser-guided surgical tools. Imaging sensors, such as x-ray, magnetic resonance imaging (MRI), computed tomography (CT), positron emission tomography (PET), and ultrasound provide doctors with non-invasive insight into the human body and how it operates. These sensors have radically transformed diagnostic medicine. In general medicine, these images allow doctors to pinpoint areas of injury or abnormality, perform minimally invasive surgery, and evaluate the success or failure of a procedure. In obstetric care, ultrasound allows doctors to monitor the developing fetus and identify any fetal or other abnormalities that could impact the health of the mother or baby.

Complex sensing devices are used by clinical pathologists in hospital laboratories every day to perform hematology, biochemistry, immunology, histopathology, and microbiology functions. These large, non-discrete sensors require careful sample preparation by skilled professionals to ensure optimum results. Sensors also play an important role in treatment technologies. They can sense events, such as missed heartbeats, that can be acted upon by clinicians or

actuators. They can optimize drug delivery devices by identifying the optimum time to administer a drug. And they can continuously track a patient's vital signs to ensure that a treatment, such as dialysis, is delivered safely. Imaging, implantable, and drug-delivery devices are all rich sources of sensor application, worthy of entire chapters in their own right. Given our space limitations, though, this book focuses on discrete, non-invasive monitoring and assessment technologies that can, or will soon, be applied in a home or community setting.

Monitoring Vital Signs

The most familiar hospital sensors are those that measure vital signs. A patient's vital signs describe the status of their main body functions—typically body temperature, pulse rate (or heart rate), blood pressure, and respiratory rate. But other measurements may be included, depending on the context. For example, in a first-aid situation, skin, pupils, and level of consciousness are also examined. In intensive-care or post-operative units, blood pressure, heart rate, blood oxygenation, and many other variables are continuously monitored using sensing technology. In lower-dependency units, these variables are intermittently monitored by nursing staff, who manually measure these variables using portable monitors. Disposable, wearable vital sign sensors are beginning to emerge that permit personal, low-cost, continuous monitoring of vital signs for all patients, regardless of health status or location. ABI Research estimates that 5 million of these sensors will be sold by 2018 (Comstock, 2013). Similarly, sensor technologies that target both elite athletes and ordinary individuals, such as body-worn pulse-rate monitors or smart clothing with integrated sensing capabilities, are also emerging to determine performance and fitness levels (see Chapter 10).

Heart Rate

Heart rate refers to the speed of the heartbeat. It is typically measured in beats per minute. Heart rate is measured to detect bradycardia (slow heart rate), tachycardia (fast heart rate) or arrhythmia (irregular heart rate and rhythm), any of which can indicate illness. Like many vital signs, heart rate is age-dependent: an infant's heart rate is fine between 130 and 150 beats per minute, whereas an adult's should fall between 50 and 80 beats per minute. Heart rate is also highly dependent on context: it is raised following exercise and at times of stress, and the resting heart rate of an endurance athlete is much lower than a non-athlete. Given the context, neither measure would be concerning. The non-technical method to measure heart rate is to feel artery pulsations at a pulse point (such as the wrist) using the index and middle fingers. The number of pulsations is counted to find the heart rate. In a hospital setting, heart rate is measured continuously using an electrocardiograph (called an ECG or an EKG).

An ECG measures the electrical activity of the heart, using electrodes attached to the surface of the skin, filtering circuitry, and a data logger. The heart rate can be determined by measuring the interval between one R-wave and the next R-wave of the ECG signal, called the R-R interval. Variability in heart rate can also be predictive of many issues, including congestive heart failure. The timing between different points of an ECG signal (see Figure 9-2) can indicate a number of conditions, including hypocalcemia (indicated by a shortened QT interval) or coronary ischemia (indicated by flattened or inverted T waves). In a hospital setting, 12-lead ECGs are used for diagnostic purposes, and 5-lead and 3-lead ECGs are used for continuous monitoring. The number of leads describes the number of electrodes attached to the body. Each electrode is connected using cables to a data-filtering and logging circuit. Expertise is required to attach the ECG electrodes correctly and interpret the resulting ECG strip.

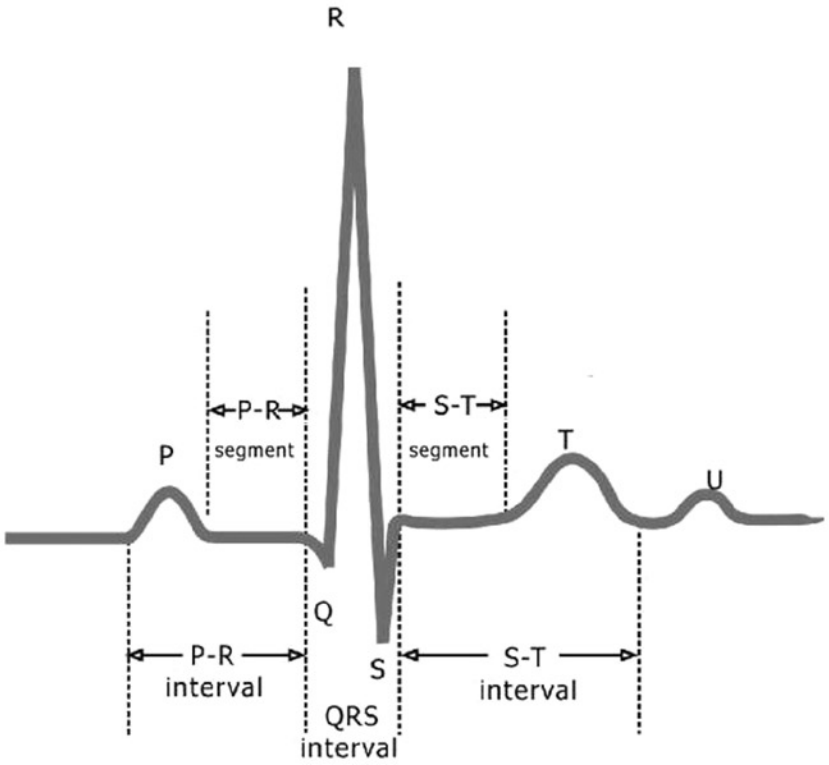

Figure 9-2. *Segment of an ECG trace, indicating the various markers and intervals of interest*

Fitness and in-home heart-rate sensors are beginning to move toward integrated wireless ECG devices, which simplify the placement of electrodes and interpretation of data. Doppler fetal monitors measure fetal heart rate using a hand-held ultrasound transducer that detects the heartbeat and produces an audible simulation of it. These devices are used by obstetric and community clinicians, but are increasingly being sold for personal use. Heart rate can also be measured using pulse oximeters or body vibrations (seismocardiography).

Blood Pressure

Blood pressure is the pressure exerted by the blood on the walls of the large arteries, such as the brachial artery in the arm. High blood pressure is a risk factor for stroke, heart attack and chronic renal failure; therefore, it is essential to not only diagnose it but also to continuously monitor the impact of treatment. Low pressure can be problematic if it results in fainting or dizziness. Blood pressure is typically described as a systolic value over a diastolic value, and is measured in millimeters of mercury (mm Hg). Systolic pressure is the peak pressure in the arteries during the cardiac cycle and the diastolic pressure is the lowest pressure at the resting phase of the cardiac cycle.

The blood pressure of a resting, healthy adult human is approximately 120 mm Hg systolic and 80 mm Hg diastolic (written as 120/80 mm Hg). Arterial blood pressure (BP) is the most accurate method to measure BP. This invasive method involves placing a cannula into a blood vessel and connecting it to an electronic pressure transducer. It is typically used only in intensive care medicine, anesthesiology, and for research purposes. Non-invasive methods are simpler and quicker and require less expertise, but are slightly less accurate. These methods measure the pressure

of an inflated cuff at the points when it just occludes blood flow (systolic pressure), and again when it just permits unrestricted flow (diastolic pressure). There are three non-invasive methods commonly used for routine examinations and monitoring or blood pressure:

- The auscultatory method requires a clinician to manually compress the artery in the upper arm using an inflatable cuff. The clinician listens to the artery using a stethoscope to recognize when the blood just begins to flow back in the artery (systolic blood pressure) and when no sound can be heard (diastolic blood pressure). The blood pressure at both of these points can be read from the mercury or aneroid manometer that is connected to the cuff. This method is considered the gold standard by many, despite its high reliance on human hearing and interpretation.
- Oscillometric methods are used in long-term measurement, home measurement, and sometimes in general practice. The equipment is functionally the same as for the auscultatory method, but with an electronic pressure sensor (transducer) fitted in the cuff to detect blood flow, instead of using the stethoscope and the expert's ear. These devices use a method, called mean arterial pressure (MAP) to calculate blood pressure. The accuracy of the algorithms can vary greatly among different devices. It is therefore essential to confirm worrying home readings with a clinician, who will have a more accurate BP device.
- Continuous noninvasive arterial pressure (CNAP) is used in research, critical care, and anesthesia to understand blood pressure at a more granular level than can be achieved using auscultatory or oscillometric methods. There are three common methods to do this: arterial tonometry is a technique for measuring blood pressure in which an array of pressure sensors is pressed against the skin over an artery. The second method, pulse transit time (PTT) is the time it takes a pulse wave to travel between two arterial sites. Blood pressure can be determined from the inverse of the PTT. In the final method, which involves clamping the finger, blood volume in the finger is measured using a light transmitter and receiver. The pressure of a finger cuff is adjusted to maintain constant blood volume in the finger. This pressure corresponds to the patient's blood pressure. CNAP methods were traditionally expensive and limited to hospital settings, but community-based PTT devices are currently available, and home-based devices, such as the Scandu Scout (www.scanadu.com), will soon be available.

While annual blood pressure measurements in a doctor's office may be appropriate for healthy young adults with no cardiovascular risk factors, there are many situations in which blood pressure requires more detailed or long-term investigation. Older adults with impaired blood pressure regulation may experience sudden drops in blood pressure when they go from sitting to standing. This is a known risk factor for falls, and can be diagnosed only using beat-to-beat CNAP techniques in a clinical setting. There are also situations in which the blood pressure reading in a doctor's office is not representative of the patient's actual blood pressure. "White coat hypertension" can cause a rise in some patients' blood pressure while they are in a clinical setting. This is a very common occurrence and may lead to clinician's prescribing blood pressure medicine to those who do not need it. Circadian variations in blood pressure can also result in incorrect prescription of medication. Some patients, who have high or normal blood pressure during the day, may have low blood pressure at night. Prescription of blood pressure-reducing medication to manage the high blood pressure measured in the doctor's office during the day could drop the patient's blood pressure to dangerously low levels overnight. Ambulatory blood pressure monitoring, using a wearable oscillatory device for a 24-hour period, is the only way to identify circadian blood pressure rhythms. As form-factor and interpretation technology evolve, it is expected that monitoring this valuable vital sign outside of a hospital setting will become increasingly smaller, cheaper, and more accurate.

Temperature

The body employs several strategies to maintain body temperature. When the body is too hot, the blood vessels in the skin dilate (expand) to carry the excess heat to the skin's surface, where it is removed through perspiration. When the body is too cold, it conserves body heat by vasoconstricting (narrowing) blood vessels to reduce blood flow to the skin and generates heat by shivering. An abnormally low (hypothermia) or high (hyperthermia) body temperature can be serious and even life threatening. Temperature sensors are therefore an essential, low-cost, reliable method to indicate health status. Body temperature can be measured in many locations on the body, including the mouth, ear, armpit, rectum, forehead, bladder, skin, and esophagus, as outlined in Table 9-1. The traditional method to measure temperature, the mercury thermometer, has been replaced by sensor-based contact and non-contact sensors. Contact temperature sensors reach thermal equilibrium with any object they are in contact with. They can measure the temperature of that object by measuring their own temperature. Noncontact temperature sensors measure radiated heat from the measured brightness or spectral radiance of an object.

Table 9-1. *Current Temperature Sensing Methods in Humans*

Location	Sensor	Advantages	Disadvantages
Rectal temperature probe	Flexible catheter with thermistor on top or mercury thermometer	Accurate measure of core temperature	Slow to change Slightly higher (up to 0.3 °C) than other measures Potential to spread contaminants Potential to perforate rectum
Oral thermometer	Mercury thermometer or digital thermometer	Easily accessible Less prone to operator error Quickly reflects changes in core body temperature	Influenced by the ingestion of food or drink and by mouth breathing
Axillary (armpit) thermometer	Mercury thermometer or digital thermometer	Easily accessible Repeatable temperature measurements without significant discomfort	Time needed to record the temperature (3-4 minutes)
Esophageal temperature	Flexible thermistor-type probe	Accurate and precise estimate of core temperature	Invasive (only used during anesthesia) Placement too close to trachea could result in lower readings
Pulmonary temperature	Thermistor	Gold standard temperature	Invasive (restricted to critically ill patients who already have a pulmonary artery catheter)
Bladder temperature	Thermistor-tipped catheter	Correlates highly with rectal, esophageal, and pulmonary arterial temperatures	Invasive (only suitable for those requiring bladder catheter) Accuracy dependent on urinary output
Tympanic temperature (contact)	Small thermocouples or thermistor probes	Considered gold standard due to proximity to hypothalamus	Difficult to position correctly without otoscope Inaccurate if incorrectly positioned Risk of perforation and bleeding of eardrum

(*continued*)

Table 9-1. (*continued*)

Location	Sensor	Advantages	Disadvantages
Tympanic temperature (non-contact)	IR emission detectors (thermopile sensor or pyrosensor)	Reasonable estimate of core temperature within 1-2 seconds Suitable for awake patients	
Temporal artery (head) thermometry	IR emission detectors	Easily accessible Poses no risk of injury for the patient	Measuring temperature at head, which is not the same as core temperature (algorithm required to compensate)
Skin thermometry	Thermocouples or liquid crystals enclosed in adhesive pads	Safe Accurate to +/- 0.1 °C Useful for screening older children	Difficult to interpret Not reflective of core temperature
Pacifier thermometry	Thermocouple inserted in heat conductive nipple of pacifier	Accurate Convenient Non-distressing for babies	
Ingestible thermometry	Quartz crystal temperature sensor	Direct measure of core temperature	Currently expensive Works only for 1–2 days

Respiratory Rate

Respiratory rate is the number of breaths taken in one minute. Like heart rate, normal respiratory rate depends on several factors, including age, emotional state (for example, crying or agitation) and sleeping. Abnormally high respiratory rate is called tachypnea. Abnormally low respiratory rate is called bradypnea. Tachypnea can be caused by something as simple as exercise, or as serious as carbon monoxide poisoning. Bradypnea can indicate issues such as damage to heart tissue or high blood pressure. Respiratory rate is most commonly used to diagnose pauses, shallow or infrequent breathing during sleep, a condition known as sleep apnea. This condition affects both adults and children and can result in daytime sleepiness, as well as attention and memory issues. Sufferers are typically unaware that they have the condition, and require technology to detect and monitor the extent of the condition (see Chapter 10). Sleep apnea can be diagnosed during an overnight sleep study in a hospital sleep lab, during which respiration, brainwaves, muscle movement and eye movement are monitored. Inability to breathe without life support machines is one of the three key indicators of brain death (the others are being in a coma and having no brainstem reflexes). Naturally, the criteria for detecting apnea in this situation are more stringent.

The non-technical method of measuring respiration rate is to count the number of times the chest rises and falls during a fixed period. This method is prone to error. Chest straps and smart clothing can measure respiration by measuring changes in tension on the fabric as the chest expands and contracts. Contact and non-contact acoustic and optical methods have also been developed to measure respiration. Pressure-sensitive mattresses have been used to measure the respiration rate of sleeping babies or at-risk adults. These sensors detect respiration by measuring changes in pressure on the mattress as the monitored person inhales and exhales. Contactless bedside sensors, such as the SleepMinder from BiancaMed (biancamed.com), enable hospital-grade respiration-sensing in the comfort of the patient's own home. In a hospital setting, respiration rate can be derived from an existing ECG signal or from the electrodes used to measure ECG.

Blood Oxygenation

The body needs a certain level of oxygen in the blood circulating to cells and tissues in order to function correctly. When the oxygen level falls below a certain point (hypoxia), a person may experience shortness of breath. The amount of oxygen traveling in an artery can be measured by testing a sample of blood from an artery. It can also be estimated non-invasively using a pulse oximeter, a small device that clips on the finger, earlobe or across a baby's foot. Pulse oximetry is a non-invasive method for monitoring a patient's O_2 saturation. It is used throughout the healthcare domain, particularly for assessing patients with respiratory complaints or in respiratory-related procedures. Normal pulse oximeter readings range from 95 to 100 percent. Values under 90 percent are considered low.

Transmissive pulse oximeters measure the saturation of oxygen in the blood, which is a proxy measure of blood oxygen levels. They operate by passing light of two wavelengths from one side of the clip, through the patient, to a photodetector on the other side of the clip. The pulsing arterial flow can be determined by measuring the changing absorbance at each of the wavelengths. This method can be used to measure both oxygenated and deoxygenated hemoglobin at the peripherals. Reflectance pulse oximetry can be used on the feet, forehead, and chest. In this method, the detector lies adjacent to the light source on a flat surface such as the forehead. A number of situations can cause an erroneous SpO_2 reading, especially with the use of transmission probes. These include skin pigment, nail polish, motion, ambient or excessive light, hypoperfusion, cardiac arrest, hypoxia, malposition of the probe, and intravenous dyes. These variables must be considered and blood tests should be used to confirm hypoxia if an erroneous pulse oxygenation reading is suspected.

Community-Based Sensing

As mentioned, shifting demographic patterns are making the current reactive models of care unsustainable and compel several dramatic changes in the way healthcare is delivered. First, healthcare must become proactive and predictive to prevent costly acute health episodes. Second, healthcare must become individualized, rather than population-based, to ensure the optimum treatment is delivered. Third, the delivery of care must be decentralized from hospitals to the community and the home. Technology will play a key role in all these shifts. The first and second healthcare model shifts will be discussed later in this chapter, and this section will discuss the current and future state of community-based sensing.

Community care refers to the general practice doctor, the clinic, and nursing services in a community. In most Western countries, doctors and community clinics are the first point of contact with the healthcare system for normally healthy people. Community doctors and clinics provide routine medical services. They also act as triage services that refer those requiring further care to specialist clinics in hospitals. Community-based nursing provides hospice and long term care for people in their own homes. Nursing services can be privately or publically funded and the level of care provided is dependent on the patient's condition and the payer's resources.

A typical consultation with a community doctor lasts approximately 10 minutes, during which the doctor must listen to and record patient history, measure vital signs, and make a diagnosis. Given the time constraint, technology must be quick and easy to use. Currently, the only technology in a typical doctor's office is an electronic health record (EHR) system, a digital thermometer, a digital blood pressure cuff, and various disposable test kits. This is very much in keeping with the reactive diagnostic model of care. Technology can be used more holistically to improve the quality and throughput of community care services:

- Technology can be used in the home, in the form of clinical applications and self-care diagnostic kits to capture vital signs and other biomedical metrics. Such data can be shared with a doctor in person or using teleconsultation, to make a diagnosis. In the future, diagnosis may even be automated, thus removing the need to visit the doctor for simple illness, such as colds, flu, earache, and the like. These technologies are discussed later in this chapter.
- In the doctor's office, point-of-care tests can reduce the time to diagnosis by eliminating the need to send samples away to be tested. Automated testing, such as with blood pressure cuffs and digital thermometers, allow the doctor to take a patient history while a measurement is being taken.

- The doctor's office also has a role in reducing the burden on hospitals. The falling cost of sensor technology permits many hospital out-patient services, such as blood-coagulation monitoring, to be carried out in the community. The community practice could also be a point of contact for attaching and removing diagnostic devices, such as Holter monitors and ambulatory blood pressure monitors. Data from these devices could be shared with hospital-based specialists using secure data-sharing techniques, and face-to-face hospital visits can be arranged, if required.
- Sensor and non-sensor technologies, including electronic health records, can give patients ownership of their own health. Patients will be able to shop around for a doctor, as they can move their complete patient histories and sensor data between doctors. Patients will also be able to acquire healthcare services from retail health clinics. Such clinics can provide health services in nontraditional environments, like pharmacies, big box stores, and other non-medical locations
- Community doctors are expected to be experts in many disciplines and to keep up to date with continually changing illnesses, diagnostic methods, and treatments. Analyzing multiple sensor and non-sensor inputs and cross-referencing these inputs against specific criteria to derive a result are tasks ideally suited to computers. Community doctors could leverage these devices to diagnose an illness, thus freeing them to elicit the appropriate information, provide care, and deliver diagnoses.
- Community nurses visit patients in their own homes to provide care and monitor their health status. A community nurse carries lightweight vital sign monitors to determine the patient's weight, heart rate and blood pressure. Many of these measurements can currently be taken with home-based clinical devices or telemonitoring devices without the presence of a nurse. This allows community nurses to optimize their schedules to visit those most in need of care first, and eliminate visits to check that people are well.
- Community-based nurses provide hospice and long-term care to a very small number of patients. The technology used in these situations varies according to the patient's condition. A patient requiring dialysis, but who is too ill to travel, may have a hospital-quality dialysis machine in their home. On the other hand, a nurse caring for someone following a fall may not use any technology at all.

Home-Based Clinical Applications

Home healthcare delivery has been an area of significant effort over the last decade, both from commercial and research perspectives. This work has primarily focused on chronic disease management for conditions such as COPD, CHF, and diabetes. However, the initial focus has expanded to include additional areas, such as post-operative care, stroke rehabilitation, and well-being monitoring and alerting (with, for example, body-worn fall detectors). Clinical-grade sensing plays an important role in delivering reliable physiological and biometric monitoring of patients.

Clinically oriented home-care technologies can be classified into two groups: patient monitoring sensors and patient mobility sensors, as shown in Table 9-2. Patient monitoring sensors measure the physiological and biometric attributes of an individual and store or react to the data, as required by a supporting application. This form of sensing requires either direct contact with a human body or the collection of a sample, such as blood, for testing. Patient motion sensors, such as passive infrared (PIR) motion sensors (which can detect an individual entering or exiting a room) and pedometers (which count steps taken) observe actions. Behavioral patterns can be inferred from this data, and abnormal patterns can be used to trigger an alert. Mobility data can be sensed through direct contact with the human body, as for example, with a pedometer; or by using ambient sensors, such as PIRs, attached to the subject's environment. Wearable motion sensors are in direct contact with the person and can therefore accurately measure

the motion of that person regardless of location or the presence of others. Ambient solutions are ideal for situations in which the person may forget to attach a sensor, or attach it incorrectly. However, ambient sensors are mounted in fixed locations and can't sense a person if that person is in a different location.

Table 9-2. *Sensors for Home Use in Clinical Applications*

Patient Monitoring	Measurand	Patient Mobility	Measurand
IR thermometer	Body temperature	Radio frequency identification (RFID)	Object interaction—activities of daily living
Lung function - Spirometer - Peak flow meter	FVC (forced vital capacity), FEV (forced expiratory volume), PEF (peak expiratory flow)	Pressure sensors	Bed occupancy
Pulse oximeters	Blood oxygenation	Accelerometers	Acceleration—falls detection Limb movement—rehabilitation Step counting—pedometer
Blood pressure	Systolic/diastolic	Gyroscopes	Angular velocity—falls detection Limb movement—rehabilitation
ECG	Electrical activity of the heart	Magnetometers	Body position—falls detection
Glucometer	Blood-glucose levels		
Body fat analyzer	Percentage body fat	PIR	Room occupancy
Weighing scales	Weight		
Hemoglobin Photometer	Hemoglobin concentration—measurement of anemia		
PT/INR meters	Prothrombin time (PT) and its derived measures of prothrombin ratio (PR) and international normalized ratio (INR); Long-term use by warfarin users		
Nebulizers/Drug delivery aerosols	Inhalation patterns Drug delivery via controlled aerosols		

The focus on developing telehealth with clinical-grade sensing has been driven by the expected benefits these technologies could provide in terms of support and supervision, without requiring a clinical professional to be present. This in turn would lessen healthcare costs for both providers and individuals by reducing the time associated with in-person consultations, redundant doctor's visits, and providing early detection and reaction to adverse health events. Additionally, sensor technologies may also have the ability to notify caregivers to changes in behavior patterns or physical state that may go unreported or unnoticed by the patient but that may represent early warning signs of an impending health event. Despite the expected benefits, remote patient monitoring through telehealth remains an area of continuing debate. Studies show inconsistent results in patient benefits, expected cost savings, and so forth. For example, some studies have shown measurable improvements in patient outcomes (Miguel et al., 2013); others have been neutral (Cox et al., 2012); while others reported no meaningful impact (Cartwright et al., 2013). The area of telehealth is still relatively immature and will continue to evolve over the next decade. As we embrace and better understand personalized medicine, knowledge of how and which patients will benefit from this technology will improve. So will our understanding of when it is not appropriate for an individual. Realization of the actual benefits will also require structural changes within the healthcare domain. With a data-driven approach to remote patient

monitoring, it will take time to realize the benefits and to identify weakness in the granularity, scope and context of patient measurements. Despite the on-going debates on telehealth, its use is projected to increase six-fold to 1.8 million by 2017. In 2012, it was estimated that, globally, 308,000 patients with chronic disease utilized telehealth solutions. These were primarily post-acute patients who had been discharged from hospitals to their own homes. The expected rise in telehealth users by 2017 will be driven by the following factors:

- Government health bodies, who want to reduce readmission rates after hospital discharge.
- Provider-driven demand to improve the quality of patient care.
- Insurance companies, who want to reduce the cost of care.
- Patient-driven demand, as patients slowly embrace the concept of personal monitoring stemming from the increasing penetration of personal-fitness sensing devices (InMedica, 2013).

The availability of affordable, clinical-grade sensing for home use continues to grow. An important enabler has been the continued miniaturization and decreased power consumption of MEMs sensing devices, coupled with the integration of either wired or wireless standards-based interfaces. MEMs-based pressure sensors, for example, can be found in a variety of blood pressure monitors. They are also found in applications that require drug absorption by inhaling aerosols through positive-pressure ventilation. Delivery aerosols are increasingly being used for the treatment of cancers, AIDS, diabetes, and asthma in home environments. The key to successful operation of these devices is the ability of the MEMS pressure sensors to detect inhalation pressures as low as 0.018 psi and to accurately and rapidly switch the delivery mechanism on and off in response. In addition, MEMS pressure sensors can be used to sense the person's inhalation patterns and in turn adjust the pattern of delivery to maximize the benefit.

Body-temperature sensing is another area that has benefitted from the availability of low cost and accurate infrared sensors. The most common form of this sensor is the tympanic ear thermometers, shown Figure 9-3. These sensors work on the principle that the eardrum emits infrared radiation. Using an algorithm, the amount of received IR radiation is converted into a temperature that can be displayed via a digital display. This form of temperature sensing has proven very popular due to its ease of use, relatively low cost, and accurate results.

Figure 9-3. *Tympanic thermometer*

Chronic Disease Management

Until now, telehealth has primarily focused on chronic disease management. Chronic diseases, such as diabetes, heart disease, COPD, and asthma account for 70 to 80 percent of healthcare expenditure. The costs of these diseases is projected to reach USD 4.3 trillion by 2023 (Versel, 2012). Chronic diseases cause around 70 percent of deaths each year in the United States, with about 133 million Americans (approximately 1 in 2 adults) living with at least one chronic illness (NCCDPHP, 2009). The majority of patients who had telehealth systems deployed in their homes

suffered acute symptoms requiring hospitalization and were subsequently released after stabilization of their condition. CHF is currently the dominant condition in telehealth deployments, followed by COPD. However, it is projected that diabetes will replace COPD as the second largest grouping of telehealth users. In-home telemonitoring of diabetes will support a more structured approach to monitoring and data management. Caregivers and patients can access the data any time and any place across a variety of devices, including smartphones. They can access historical data to better understand how lifestyle choices are positively or negatively influencing the readings, in an effort to better manage their condition (Mearian, 2013).

From a sensing perspective, there are a number of challenges with chronic disease management. The sensors must be able to monitor the vital signs of the patient dependably and with a high degree of precision. Measurements must be transmitted reliably on a wired or wireless connection. There should be fully traceability of the sensor readings from the source of measurement to the point of storage. The sensors should be low-powered, and must be capable of running for months or years with standard alkaline batteries. While using rechargeable batteries is possible, it adds a layer of complexity that is undesirable given the target population. These characteristics are currently fulfilled by standard semi-mobile, discrete sensors currently found in clinical environments. Many of the clinical sensors used for chronic-disease monitoring require the patient to actively engage with the device during the measurement process and in some cases to log the data to a recording device, such as a smartphone (as with diabetes measurements).

The emergence of smaller, cheaper sensors and smartphone technology is already beginning to provide new, more flexible telehealth solutions for chronic-disease management. Emerging trends in this domain include the following:

- Smart clothing solutions, which enable simple and accurate continuous monitoring of biometric parameters. For example, the EU Chronius project has developed a smart t-shirt to monitor patients with COPD and chronic kidney disease (CKD). This t-shirt features heart-, respiration-, and activity-monitoring sensors, which are connected to a smartphone for data aggregation, processing, and transmission. The system has been successfully demonstrated in two trials with COPD and CKD patients in Spain and the UK (Pasolini, 2012).

- Intelligent, disposable sensor patches, such as the prototype developed by Sano Intelligence that sticks to the skin and continuously monitors blood parameters for seven days. This patch eliminates the need for blood tests by measuring parameters, such as glucose and potassium levels, that would usually require a full blood panel to obtain. The data is wirelessly transmitted to a smartphone for analysis, long-term monitoring, and alert detection (Schwartz, 2012). A number of continuous glucose monitors (CGM) are now commercially available, such as the Medronics Guardian REAL-Time CGM System and the Dexcom SEVEN Plus. Additionally, the Freestyle Navigator from Abbot Diagnostics was launched in 2009. However, the product was withdrawn from the US market in 2010 due to reported issues with an inconsistent supply chain, according to Abbot. The product continues to be sold in seven countries outside the US (Gilles, 2011). CGM systems are more expensive than conventional glucose monitoring, costing in the region of $1,000 to $2,000 USD for measurement units plus the additional monthly cost of sensors that may run to a couple of hundred dollars. These are not intended for day-to-day monitoring or long-term self-care, but to track trends in blood-sugar levels. The data should be used by the patient's health care team to modify the treatment plan when necessary to better optimize glucose control (WebMD, 2012). The CGM device is regarded as a niche market; however, in Europe and the US, the market for the devices is growing at a significant pace and is estimated to reach several hundred million dollars by 2018 (SBWire, 2013).

- Sensing new measurands, as demonstrated by Podimetrics, a startup company that focuses on the complications of diabetes rather than blood sugar measurement. The Podimetrics insole technology will detect the beginning of diabetic foot ulcers, which are a leading cause of lower-limb amputations. The sensor insole is placed in the patient's shoe and collects data about blood flow in their feet. This data is transmitted to a cloud-based service for processing. Alerts on potential issues are sent to both the individual and their clinician (Podimetrics, 2013).

Investigative and Episodic Monitoring

This type of sensing is designed to capture specific physiological (blood pressure, EKG/ECG) or biochemical parameters (blood-glucose level) for defined periods of time. It is used for investigative purposes, to track the progress of a disease, or to monitor recovery from a specific health event. In the cardiovascular monitoring domain, Holter monitors (or ambulatory electrocardiography devices) have been commonly used for diagnostic purposes, particularly for individuals with arrhythmias and older adults presenting with possible cardiogenic syncope (blackouts due to irregular heart rates). The monitors usually provide the ECG signals in two or three channels, via electrodes attached to the chest area. The aggregation unit (or monitor) records the ECG signal and stores it in flash memory for analysis after the monitoring period. Many Holter monitors also feature a "patient button" that enables the patient to mark the recording by pressing the button at significant points, such as feeling unwell, being dizzy or short of breath, taking medication, and so on. This allows doctors to quickly identify these areas of interest when analyzing the signal. Normal monitoring periods are 24 to 48 hours. While the form factor of the Holter monitor is relatively compact (approximately the size of a smartphone) and it can be worn around the neck using a lanyard or placed in a shirt pocket, it is still somewhat inconvenient.

The next generations of cardiac monitors are based on the concept of epidermal sensing in a patch-type configuration (a "smart band-aid"). Corventis has developed a mobile cardiac telemetry system called Nuvant, which features a single patch that can measure heart rate, respiratory rate, temperature, motion, and interstitial fluid levels around the heart. The patch has a Bluetooth radio that connects to gateway for transmission to a monitoring center for arrhythmia detection. The sensor can also be used to monitor COPD patients, due to its ability to measure interstitial fluid levels. Similarly, the zensor product offering from Intelesens provides vital signs monitoring, as shown in Figure 9-4. This compact patch device provides integrated data capture, from a diagnostic-grade, 3-lead ECG; and integrated data processing that can detect arrhythmias. Data is wirelessly transmitted via Wi-Fi to a remote database. A key feature of the Intelesens system is the biocompatibility capabilities of the patch, which allows patients to wear it for up to seven days before changing (Intelesens, 2013).

Figure 9-4. *The Intelesens zensor provides ambulatory vital-signs monitoring (with permission from intelesens)*

Sphygmomanometers are increasingly being used as a noninvasive method of obtaining ambulatory blood pressure (ABPM) readings over a 24- or 48-hour period, in a patient's own home. Many studies have demonstrated that blood pressure measured over a 24-hour period gives a more accurate reflection of blood pressure than one-off measures in a clinical setting. Apart from the detection of hyper and hypo tension, ABPM can also be used to detect organ damage, such as left ventricular hypertrophy, episodic dysfunction, and autonomic dysfunction (Rull, 2010). There are two techniques for measuring ambulatory blood pressure: intermittent measurement over 24 hours, and continuous waveform analysis. The original devices were large, cumbersome, and difficult to wear, particularly for older adults, but current devices are similar in size to an EKG/ECG Holter monitor with an arm cuff. Many now feature Bluetooth connectivity for data transfer after the monitoring period. More recently, a number of devices that can measure blood pressure from the wrist have appeared on the market. Some studies report that the accuracy of the readings is comparable to those obtained with upper-arm ambulatory monitoring (Uen et al., 2009). However wrist blood-pressure measurement is controversial and is not currently recommended by the European Society of Hypertension or the American Heart Association. Certain issues related to these devices have the potential to cause inaccuracies, such as incorrect position in relation to the heart and measurement of BP in two arteries—radial and ulnar, and peripheral pulse wave distortion (Parati et al., 2010) (Anderson, 2010).

Mobility and Behavioral Monitoring

The concept of ubiquitous sensing is based on distributed and networked sensors that monitor user activities while remaining transparent to the users (Ning, 2013). For behavioral monitoring, wireless sensors and other methods such as RFID are used to detect interactions between humans and their environment. Behavioral monitoring has garnered attention due to its potential for providing clinicians and care givers with an unbiased view of patients in their home environments on a longitudinal basis. Behavioral information could allow a clinician to determine if an individual is capable of living independently by tracking his ability to complete the activities of daily life (ADLs). This data could also be used to identify early signs of diseases, such as dementia or diabetes, through changes in behavior patterns. Reliable and accurate behavioral information will allow family doctors or public health professionals to ask questions informed about the patient's recent history, thus optimizing patient visits. Sensors can also be used to enable supporting technologies. For example, PIR sensors deployed in a kitchen environment can detect when the person is there; and RFID tags and readers can identify what objects they are using. The data can be used to actuate cues (audio, video, or visual) to support users through each step in a task such as preparing a meal (Stanley et al., 2011).

Another approach to behavioral monitoring that does not require the installation of application-specific sensors is based around the use of smart meter data. The data can be used to identify patterns such as cooking, sleeping, when the home is unoccupied, and so forth. The ability to detect these events has the potential for smart meters to act as basic wellness monitors, particularly for older adults. As smart meters become more ubiquitous over the next five years there is significant potential to exploit the data for wide-scale behavioral monitoring applications (Lisovich et al., 2010). However, issues such as privacy, data protection, and the like will need to be addressed before such capabilities can be rolled out (McKenna et al., 2012).

■ **Note** Smart meters are generally electric, but they can be water or gas meters as well. They have embedded intelligence that enables them to record consumption of electric energy at defined intervals (say, every 5 minutes) and communicate that information back to the energy supplier for monitoring and billing purposes. Many smart meters can also communicate wirelessly with a home display unit that allows the home owner to monitor energy consumption in near real-time.

A significant downside to this type of sensing is the loss of privacy. Other sensing systems, such as those used for chronic-disease management, provide information on health status, which, of course, does raise some privacy considerations. But that is not as invasive as tracking the number of times you go to the toilet during the night or

whether you decided to stay in bed until the afternoon. It therefore important that such sensing systems are deployed on a voluntary basis and that access to the data is strictly controlled and managed. Of course, loss of privacy has to be offset against the potential loss of independence and the financial cost that a move to an assisted-living community would bring. For many, the controlled loss of privacy is a price worth paying to remain in their own home.

A significant number of small-scale demonstrations of assisted-living technology solutions incorporating wireless sensors in the research domain have been carried out. But large-scale, longitudinal studies with numbers in the high hundreds or thousands have not been realized to date. The barriers to achieving large deployments are a complex mixture of the technical and financial, as well as organizational structures and medical conservatism. One key limitation that must be addressed is that of electronic health records (EHRs) for patients. These are critical in connecting assisted-living data sets to the traditional hospital and community records. An integrated view of these diverse data sets is vital in establishing a complete picture of a patient's healthcare at any moment in time. Only then can the health delivery strategy ensure maximum patient benefit. There are number issues associated with the use of EHR's. Key among them is the issue of who owns the data (Stafford, 2010). We need answers to questions such as:

- Does the patient, the doctor, or the hospital own the data?
- Who has the right to access the data? Do insurance companies and national health authorities?
- Can the records be moved from one hospital to another, from one country to another?
- What types of data should be stored and in what formats? Are the records interoperable between access systems?

These are challenging questions that will require answers before EHRs can become more ubiquitous. Population-level data that can be harvested for EHRs has the potential to deliver enormous benefits, particularly in the areas of personal healthcare. Organization such as the European Alliance for Personalized Medicine are working with policy makers to develop regulatory frameworks to enable researchers and doctors to realize the value of these records when they are eventually fully implemented and are accessible on both a national and cross-border basis (euapm.eu).

For assisted-living technologies to succeed in the long term, they must demonstrate an ability to drive a "closed-loop" system. Closed-loop means data extracted from the home environment drives an appropriate response from a clinical decision support system, which results in improvements in well-being, patient outcome, and cost reduction. That goal is very much a work in progress and will take many years of trial and error to realize tangible, quantifiable, and sustainable benefits.

Apart from activity-tracking, other types of applications include fall detection, medications tracking, physical activity, and social engagement. Fall detection, through the use of body-worn sensors, is a well-established market. Initial fall-detection products relied on a single sensing modality, such a triaxial accelerometer. They suffered from high false-positive rates due to poor selectivity, for example, difficulty in distinguishing between sitting down rapidly and falling on the floor. Current products employ a multisensory approach, with some combination of accelerometers, gyroscopes and magnetometers, to reduce the false-positive rate. Some devices also feature mobile phone network connectivity to automatically alert a call center when a fall occurs. This feature is particularly useful if the fall results in a loss of consciousness. The use of walking aids, such as canes and walking frames, is common among older adults and has attracted the attention of researchers. The addition of inertial sensors to walking frames has been reported in the literature with a high degree of sensitivity and specificity for key gait characteristics, such as heel strike and toe events. Poor stability of the walker likely indicates poor stability of the subject (Alwan, 2009).

Mobility-tracking is starting to play a role in dementia care. GPS tags worn by patients allow caregivers to track their location via a web-based application, if required. In 2012, the GPS smart shoe from GTX Corp was launched; it tracks patients who wander away from the confines of their home. These devices are not only useful to caregivers but can be beneficial in supporting the patients themselves. The systems can be used to define areas within which the patient should remain, and trigger alarms when the patient leaves this area. This form of monitoring can allow sufferers increased levels of freedom, mobility, and independence.

Mobility monitoring can also play a role in post-surgery support. Body-worn sensor solutions, containing inertial and/or physiological sensors can be useful in helping to quantify recovery status. Continuous in-home behavioral data is more useful than one-off measures in a clinic, where patients may "put on a performance" for the doctor that does not give a true reflection of their progress. Mobility-sensing is useful, whether the person's mobility is impaired, is recovering, or has returned to normal. It can be used to quantify whether the patient has returned to normal patterns of walking, sleeping, exercise, and so forth. Abnormal activity patterns may indicate issues with the recovery process. The e-AR sensor was developed by Imperial College London to assess postoperative gait impairment. The sensor module contains a triaxial accelerometer, weighs only 7.4g, and is worn on the ear. It is used for functional recovery monitoring in patients in their own homes (Atallah et al., 2013). Other approaches include balance and stability monitoring using pressure-sensitive floor sensors (Taylor et al., 2012); and mobility trend monitoring using ultrasonic sensors to monitor bed exits or sit-to-stand transitions (Pouliot et al., 2012).

Biomechanical Rehabilitation

The use of body-worn sensors for in-home rehabilitation is an emerging healthcare application domain (Patel et al., 2012). These virtual reality applications typically consist of body-worn sensors, interactive software, and real-time representations of the patient. This modern approach to rehabilitation is fun for the patient and has psychological as well as physical benefits. Providing biofeedback to the patient is both a motivation and a reward for the user, and encourages compliance with the program. As well as monitoring biomechanical performance during the virtual reality session, sensing can also be used to quantify activity levels, rate of recovery, and physiological well-being outside of the sessions. This provides a more holistic view of the patient's status and can be used to detect potential complications at an early stage. Demand for these types of sensor applications will increase over time with the increase in global aging and obesity. Sensor-based rehabilitation is typically used in the following situations:

- Monitoring post-operative recovery, such as range of motion, following a joint replacement.
- Monitoring patient performance and progress in a rehabilitation program; for example, a post-stroke or post-fall program.

Post-operative applications are typically based on one or more inertial body-worn sensors:

- The Telefonica "Rehabitic" product uses SHIMMER inertial sensors to enable knee-replacement patients to perform their post-operative rehabilitation regimes in the comfort of their own home. The patient simply attaches the SHIMMER sensors to both sides of the affected knee. The sensor data is transferred wirelessly to an application on a touch screen PC that visually instructs the patients through a predefined therapy session. Visual feedback is provided to the patient in the form of an onscreen avatar, which displays the movement in real-time and indicates performance against targets. Clinicians can remotely follow the therapy sessions in real time or review the data offline (Smith, 2012).
- Smart Step, from Canadian company Motion Health, is an inertial sensor unit that is worn on the ankle to monitor and provide guided therapy sessions after orthopedic surgery. The sensor unit can provide auditory feedback, based on the identification of correct or incorrect gait patterns. It is also used in stroke rehabilitation and diseases such as Parkinson's (Motion Health, 2013).

Approximately 16 million first-time strokes occur annually on a global basis, resulting in 5.7 million deaths (Carlo, 2009). In the US, it is estimated that 795,000 people experience a stroke annually, at an estimated cost of USD 38.6B (CDCP, 2013). Stroke is the leading cause of long-term disability, with about half of stroke survivors being left with some degree of physical or cognitive impairment. The use of sensors for home-based stroke rehabilitation has been an area of research in both in academia and industry for many years. Efforts have focused on the use of

body-worn inertial sensors both for upper (Chee Kian et al., 2010) and lower limb rehabilitation. Recent research efforts have included sensing technologies, such as flex sensor and force sensitive resistors that have the potential to be integrated into clothing (Bin Ambar et al., 2012):

- The Philips Research Stroke Rehab Exerciser coaches the patient through a series of prescribed exercises using a touch-screen PC. Body-worn wireless inertial sensors record patient movement and stream the data to the PC. Data is analyzed for deviations from a required movement target and feedback is provided to the patient. A physiotherapist can also review the patient remotely and update the targets for the exercise program.
- A recent development in stroke rehabilitation is based around the availability of low-cost games platforms, which integrate inertial sensors in the controller. Studies have shown that game-based therapies are enjoyable and comparable in delivering patient improvement to conventional therapy without any significant safety risks (Joo et al., 2010).

Aggregation and Management

As outlined in Table 9-2, there are a variety of sensing options to monitor patient health and activities in the home. These sensors can be used in discrete, standalone devices with no external connectivity, as well as in connected devices. Connected sensor devices are linked into a larger patient care system using wired (USB, for example) or wireless (Bluetooth, Wi-Fi, or Zigbee) interfaces. These care systems typically consist of an in-home aggregator, which can process, display, contextualize, and securely transfer the sensor data and other qualitative data to a remote back end, for clinical access and review. The architecture of a patient-care system is shown in Figure 9-5. These multifunctional aggregation devices were initially customized personal computers, such as the Care Innovations Guide and Bosch Health Buddy System; or customized set-top boxes for use with a television, such as Motiva from Philips Healthcare. More recently, product software elements (such as the Care Innovations Guide) have been decoupled from the custom hardware, allowing them to run on standard, off-the-shelf laptops or tablets. In this mode, the patient management software takes complete control of the computing device, thus preventing any accidental or intentional user modifications to the software. This gives the end user or care provider the freedom to repurpose unused computing devices as health aggregators, or to select new form factors, such as smartphones or tablets, as they become available. The emergence of health communication standards, such as Continua, guarantees that any compliant sensor device can be seamlessly interchanged with another sensor of the same type.

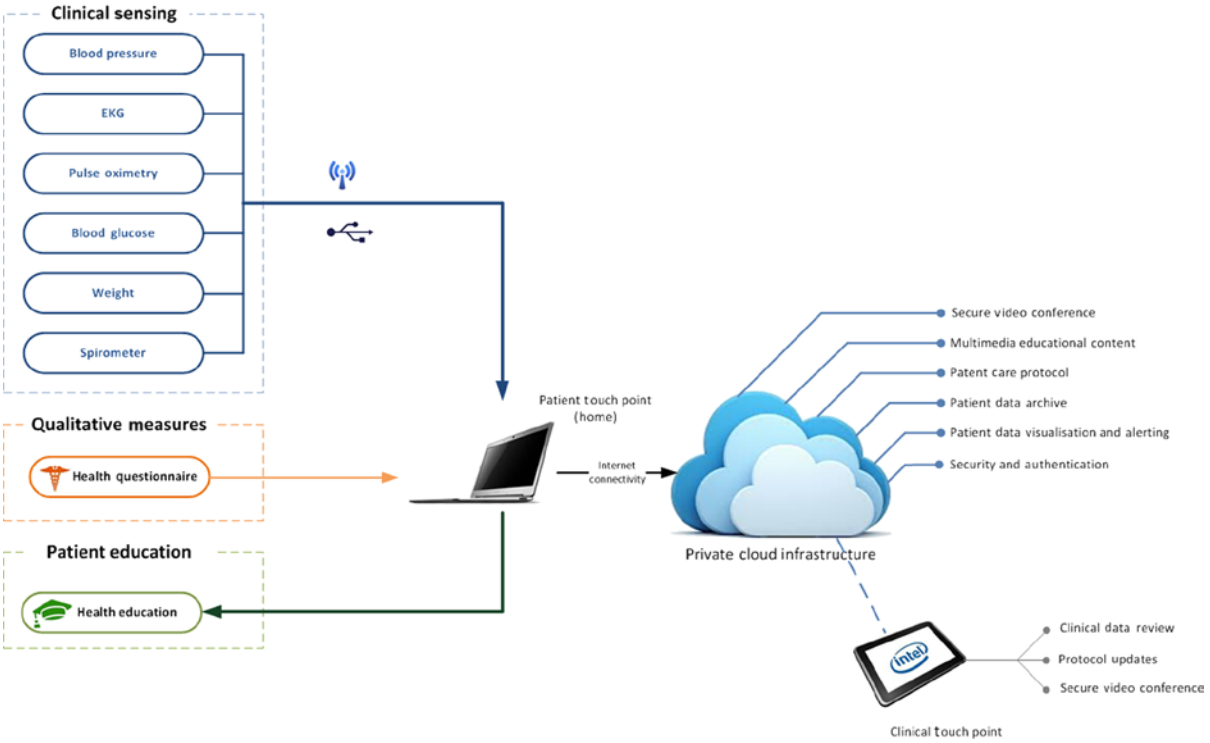

Figure 9-5. *Architecture of home-based chronic-disease management system*

Qualcomm has developed a different approach to the aggregation of clinical sensor data. Its 2net Hub is a stationary telehealth hub or gateway that plugs into an electric socket. The device incorporates Bluetooth, ANT+, Wi-Fi, and USB connectivity and can communicate wirelessly with clinical sensors and other peripherals. The hub also features cellular connectivity, allowing it to transmit data to the 2net Platform, a cloud-based system. The 2net Platform provides interoperability with different medical devices and applications. It also enables end-to-end wireless connectivity for sensors and medical devices, and provides secure access to biometric data for patients and their physicians. A 2net gateway for embedded form factors can be directly built into a clinical sensor. Additionally, a software module is available for mobile devices, such as smartphones and tablets, to serve as gateways to the 2net Platform. When combined, the 2net gateways and 2net Platform provide building blocks that allow companies to build home health-monitoring services without having to deal with major integration and data management tasks. Similarly, Verizon has collaborated with Entra Health Systems to develop its own cloud-based platform that facilitates the connection of medical devices to a common diagnostic database (Fitchard, 2011).

The Smartphone as a Healthcare Platform

Smartphones are commonly used as sensor aggregation platforms for wellness applications, as discussed in Chapter 10. This functionality is now being extended into the healthcare domain for the provision of in-home health monitoring services. Smartphone apps have a number of common components: wired or wireless interfacing to a health sensing device, and facilities for data storage, analysis, and display, as well as data forwarding to a clinician or a server.

As discussed in Chapter 4, smartphones enjoy many advantages over custom aggregators. Many, if not most, people already own a smartphone, so the patient only pays for the health sensor device and any cloud-based data services. Smartphones inherently feature Internet connectivity, processing, and display capabilities, and they can interface to internal and external sensors to provide contextual data for health related data measures. Sensor and contextual data can be archived locally on the smartphone, on a cloud-based service, or shared with family, friends, or clinicians. Individuals can use the software application to see micro and macro trends in their health readings.

Initially, customized healthcare apps were developed to interface to individual devices, but there is an increasing trend towards apps, such as the ZephyrLIFT app (www.zephyr-technology.com), that interface to multiple sensor devices. Similarly, sensor manufacturers are opening their communication interfaces to external app developers, providing consumers with a choice of free or paid apps for their health sensor devices. Healthcare apps are most commonly found in the following domains, although this list is likely to change as both health sensors and smartphones continue to evolve:

- *Blood pressure monitoring*: iHealth Labs, for example, has an innovative range of product offerings for blood pressure monitoring using a smartphone or tablet. One option is the wireless blood pressuremonitor that is placed around the upper arm. Data from the cuff is streamed wirelessly to the patient's iPhone running iHealth's mobile app, as shown in Figure 9-6 (a). The app displays your current systolic and diastolic readings, heart rate, pulse wave, and measurement time. The app also lets users compare daily results against their historical averages, as well as World Health Organization (WHO) classifications to provide context for the readings. There is also an integrated cloud service, where the user's data can be backed up and stored securely, giving the user access to his data regardless of location.

  Another option is a wrist cuff with wireless connectivity to a smartphone running the iHealth app as shown in Figure 9-6 (b). The cuff unit also features a motion sensor to improve the accuracy of the measurements by detecting the optimal wrist position, which helps users take a more accurate blood pressure reading. There is also an upper arm cuff that connects to a blood pressure dock as shown in Figure 9-6 (c). An iOS-based device (smartphone or tablet) is then connected to the dock, turning the device into a blood pressure monitor. Similar blood pressure dock and smartphone combinations are available from companies such as Withings and Verdian Healthcare. Blood pressure monitoring is one of the application domains that benefits from the contextual data provided by smartphones, as taking a blood-pressure reading immediately following strenuous activity, for example, will result in misleading data.

Figure 9-6. *Blood pressure cuffs with smartphone and tablet connectivity (image used with permission from iHealth Labs)*

- *Heart rate monitoring:* The ZephyrLIFE iOS app, for example, provides data processing and remote data transmission services. The app interfaces to the Zephyr BioPatch module over Bluetooth to provide heart monitoring measurements, including heart rate, R-R interval, respiration rate, and EKG/ECG. The app can also interface wirelessly to other medical devices, including pulse oximeters, weighing scales, blood pressure cuffs and glucometers. The Zephyr

BioPatch differs from basic heart rate sensors, used in fitness applications, in the number and quality of the cardiovascular parameters it provides. It is likely that smartphone apps and external, health-grade cardiovascular sensors will replace the discrete Holter monitor devices as diagnostic devices in the near future.

- *Diabetes monitoring:* Smartphones are ideal for diabetes management, which requires frequent entry of both diary and sensor-based information, display of micro and macro trends, and data aggregation for sharing with clinicians. Various hardware solutions have been proposed for monitoring blood-glucose levels using a smartphone. These include manually entering glucometer readings into an app, connecting standard glucometers to a smartphone using the Glooko MeterSync Cable, creating smartphone glucometer accessory devices, such as the Sanofi iBGStar, or creating a smartphone device with integrated glucometer functionality, such as the LifeWatch V smartphone. The apps associated with these hardware interfaces feature the data storage, analysis, display, and data-sharing capabilities previously described for other apps.

Home health monitoring is an exciting use of smartphone technology, and the practice will keep on growing as the computational capabilities of smartphones continue to increase, external sensors become increasingly easy to integrate, the performance and range of on-board sensors and sensor hubs grow, and the capabilities of mobile networks continue to develop.

Self-care Diagnostic Test Kits

As we have already discussed, individuals have a growing interest in proactively managing their own health. This is leading to increased adoption of self-care diagnostic test kits for home use. Various motivations drive the utilization of test kits, including self-empowerment of individuals, convenience, privacy, anonymity, the "worried well" effect, and financial considerations. A proactive consumer philosophy has developed over the last few decades and is now percolating into the personal health domain, driven in part by easier access to test kits that are available off-the-shelf at pharmacies and online. In-home diagnostic test kits have been available for less than four decades. In 1977, the first over-the-counter early-pregnancy test appeared. At the time, there was significant professional and public controversy surrounding the test (Pray, 2010). Many were concerned about potential societal impacts, particularly on younger women. That discussion has now been largely confined to the history books and has moved on to debates about the availability of tests for disease, infection, and blood chemistry.

As the popularity and general availability of self-care health test kits have grown, voices of concern or even alarm have increased. If used correctly, FDA-approved test kits should be as accurate as a laboratory tests, which are conducted under controlled conditions. However, the manner in which the test is performed at home can vary significantly, due to poor instructions related to sample collection and data interpretation. This variability can result in misleading readings, false positives (such as for the prostate specific antigen, or PSA), and give a false sense of security (for example, with a colon cancer screening). Experts argue that home tests can often be a waste of money. Clinicians will most likely repeat the tests an individual has carried out at home once they present themselves at the doctor's office (NHS, 2011).

Cholesterol-level kits are among the most popular home test kits currently on the market. However, results vary significantly, especially if subjects are not fasting when they take the test. Another common problem is poor adherence to the sampling instructions. In cholesterol testing, people tend to squeeze or "milk" a finger to get blood onto the test strip or into the well, which may affect the accuracy of the results.

In some circumstances, the scientific value of particular tests is highly debatable. Food allergies may cause life-threatening shock reactions, such as severe breathlessness and tongue swelling, while symptoms of food intolerances range from mild discomfort to diarrhea. An allergic food reaction results in an immunological response in the form of IgE antibody production. Food allergy test kits are designed to detect and quantify this antibody-based immunological response. Some experts argue that these results are questionable and are often dependent on the intensity of the allergic reaction. Food intolerance test kits are also available, which apply the same immunological

response principle to identify food intolerances, although food intolerance does not elicit a full-blown allergic reaction. There is little or no scientific support for this form of testing. A simple trial and error approach with the suspected foods is the normal course of action prescribed by most experts for identification of food intolerance.

Home testing suffers from a lack of legislation and corresponding regulation, as discussed in Chapter 6. In the US, only some tests have FDA clearance. Some tests can be certified by other professional bodies. For example, cholesterol tests can be certified by the Cholesterol Reference Method Laboratory Network (CRMLN). Other tests have no certification or peer-reviewed science to back them up. The lack of regulation and consistent quality assurance will continue to bring confusion and uncertainty to the area of home monitoring for many years to come. In the interim, some de facto certification of tests will occur on an ad-hoc basis or through utilization of crowd-sourced determination of efficacy.

Some experts believe that affordable tests don't provide enough information to be truly useful. Others think this is a limited and somewhat vested view by the medical establishment. As we head down the road of patient-centric healthcare, it can be argued that considerations valued by patients, such as convenience and privacy, will gain greater weight—especially when it comes to people having basic access to healthcare. The value of any testing, despite potential flaws, has to be weighed against no testing and no understanding of potential risks (Carrell, 2012).

There are three sensing techniques commonly used for home testing kits:

- Enzymatic/immunological assays
- Enzymatic test strips (Clinistrip)
- Chromatic wet chemistry

Enzymatic/Immunological Assays

The immunoassays used in home test kits are based around the enzyme-linked immunosorbent assay (ELISA) The test uses antibodies and color change to identify the presence of a substance in a liquid sample (blood, urine, or saliva). Monoclonal antibodies, which are single-specificity antibodies, are typically used in these tests. The substance to be detected is usually an antigen, which evokes the response of one or more antibodies. In a direct immunological assay, an antigen that has been coated to the "wells" in a plastic well plate (also known as a microtiter plate, a flat plate with one or more depressions, or "wells," that can act as small test tubes) is detected by an antibody that has been directly conjugated (attached) to an enzyme (such as horseradish peroxidase (HRPO), urease, or alkaline phosphatase (AP)). This can also be reversed, with an antibody is coated to the "wells" in the plate and a labeled antigen used for detection. When the enzyme-labeled conjugated antibody is added to the sample, the test antigen reacts and prevents the antibody from binding to the antigen on the solid phase—the walls of the well. The added antigen in the sample (liquid phase) and solid phase antigen compete for the labeled antibody. The higher the concentration of the liquid-phase antigen, the greater the competition between the two phases. Unbound antigen and antibody enzyme conjugate is removed in a washing step. Upon the addition of the enzyme substrate, the intensity of color is inversely proportional to the concentration of antigen of interest in the sample (BIO-RAD, 2013). Chemiluminescent or fluorescent signals are alternative optical approaches to determining antigen concentrations, but are generally unsuitable for home use, due to the cost of detectors. Variations on the direct ELISA approach include Indirect Elisa, Sandwich Elisa (as shown in Figure 9-7) and Competition or Inhibition ELISA. This form of sensing is highly sensitive, with typical detection ranges of 0.01 to 0.1ng, with sensitivities of 99.7 percent (Jordan, 2005).

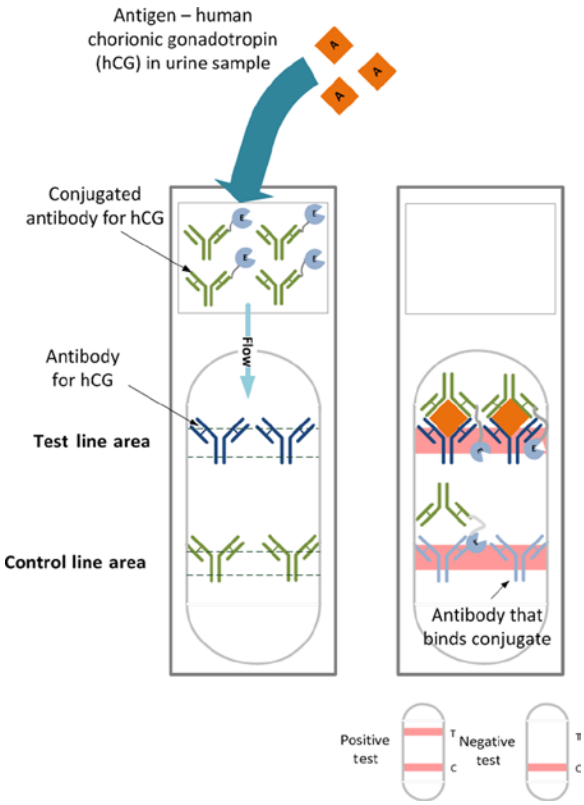

Figure 9-7. *Home pregnancy test based on a Sandwich Elisa*

Enzymatic Test Strips

Test strips or "dip sticks" are a very common approach to home test kits and are also commonly found in doctors' offices. They offer a quick and cheap mechanism to screen for a variety of conditions, and may be either biological or chemical. Clinistix sticks, which first appeared in the 1950s, are commonly used to test for the presence of glucose in urine. The sticks contain two enzymes, glucose oxidase and peroxidase, which are immobilized onto a cellulose fiber pad. The pad is fixed onto a plastic strip approximately 5 to 10mm in width and in 70 to 80mm in length. The sample is applied to the pad, where the reaction between glucose and oxygen is catalyzed by the glucose oxidase, producing gluconic acid and hydrogen peroxide. The peroxidase in turn catalyzes the reaction between the hydrogen peroxide and an indicator pigment, resulting in a visible color change. The intensity of this color change is proportional to the concentration of glucose present in the sample.

Chromatic Wet Chemistry

Chromatic wet chemistry test strips can detect a wide range of analytes in urine and saliva samples. They consist of a plastic strip approximately 5 to 10mm in width that is impregnated with various chemical compounds. The chemicals react with one or more analytes present in the sample being tested, normally producing a color change proportional to the concentration of the analyte of interest. For example, ketones in the form of acetoacetic acid and acetone in a urine sample are detected by the reaction with sodium nitroprusside, which forms a purple color, as shown in Figure 9-8 (Chronolab, 2009).

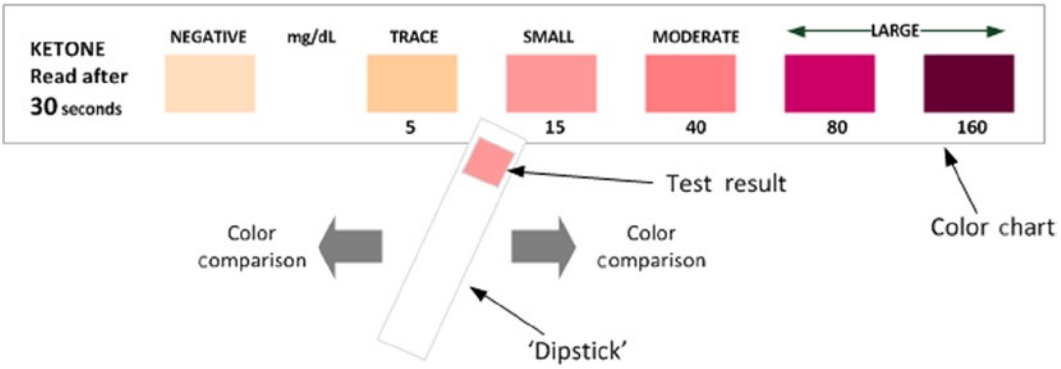

Figure 9-8. *Ketone detection in a urine sample using a dip stick*

The Home Test Market

The self-diagnostic home test-kits market is volatile and continually changing. New tests are introduced while others disappear as their efficacy or utility is disproven by the scientific community or they become outdated as the technology moves on. The market continues to grow at around 7 to 8 percent annually, with sales in 2013 expected to reach USD 5.68B. Revenues are currently dominated by pregnancy and cholesterol test kits, which account for about 85 to 90 percent of sales; however, that share will change over time as other tests gain traction among consumers (Kelleher, 2009). Table 9-3 outlines the home test kits that are currently available to consumers over the counter or via the Internet. A variety of kits also provide home sampling in which analysis is carried out by a laboratory and results are returned to the customer. Those tests are not included in Table 9-3 because they do not provide "sensing" capabilities. The FDA recently approved the first home test for the HIV, which raised significant debate about the lack of appropriate support structures and access to counseling if a positive test result occurs. Clinical support would be valuable for this and other tests, in case of false positives due to improper context.

Table 9-3. *Consumer Home Health Test Kits*

Category	Type	Condition	Description
Infection	Fungal	Yeast infection (Candidiasis)	Changes in urine pH
	Bacterial	Cystitis (Bladder) Pyelonephritis (Kidney) Helicobacter pylori (Stomach) Chlamydia	Measurement of protein, nitrites or Leukocytes (esterase) in urine—chemical reagent-based test strips with interpretation based on color intensity Immunological assay for bacterial antibodies in blood sample.
	Virus	HIV	Immunological assay for HIV antibodies in saliva.

(*continued*)

Table 9-3. (*continued*)

Category	Type	Condition	Description
Blood Chemistry	Cholesterol	Total Cholesterol Low Density Lipoprotein (LDL) High Density Lipoprotein (HDL) Triglycerides	Chromatic chemical test strips or biosensing (such as enzyme-based amperometric. sensing). Results are sensitive to the method of blood collection and fasting prior to testing.
	Ketones	Diabetic ketoacidosis	Enzyme-based colorimetric assay or chromatic chemical test strips for detection of ketones in blood (acetoacetate or beta-hydroxybutyrate) or urine (acetoacetate or acetoacetate and acetone). Ketones can indicate low or lack of insulin (diabetes), or dieting effects (as with Atkins and alcoholism).
	Hormones	Hormone insufficiency Hyper- or hypothyroidism Cushing disease Lack of libido	Chromatographic immunoassay of saliva, urine, and blood samples. Determination of estradiol (E2), progesterone (Pg), testosterone (T), DHEA-S, cortisol levels, thyroid-stimulating hormone (TSH). Serum tests are normally unable to distinguish the protein-bound (inactive form) from its free form (biologically active), thus giving only a rough estimate of hormone levels. Urine testing normally requires repeated testing over 24 hours for accurate results. Saliva tests give a better indication of bio-available or active hormones.
		Menopause	Chromatographic immunoassay measurement of follicle-stimulating hormone (FSH) in the urine. High levels of FSH can signal menopause.
	Anemia	Ferritin	Immunoassay (polyclonal antibody/streptavidin-peroxidase conjugate) determination of ferritin protein levels in blood. Ferritin is an iron storage protein and is a sensitive indicator of iron deficiency anemia.
Food and Drink	Allergies	Egg Wheat Soya Peanuts Seafood Fish Tree nuts Caffeine	Immunoassay measurement of Immunoglobulin E (IgE) antibody.
Environmental	Allergies	Cat dander Dog dander Dust mites Grass Pollen	Immunoassay for qualitative detection of IgE antibodies in whole blood due to airborne allergen response.

(*continued*)

Table 9-3. (*continued*)

Category	Type	Condition	Description
Disease	Celiac disease	Gluten	Immunoassay for IgA and/or IgG antibodies. The presence of gluten in a celiac's diet causes the body's immune system to produce antibodies that attack the lining of the small intestine.
	Colon (gastrointestinal, cancer, Crohn's)	Blood in fecal stools	Guaiac fecal occult/ hemoccult test (FOBTs)—chemical test strips for measurement of peroxidase activity Immunoassay for globins or transferrin proteins.
Fertility	Ovulation detection	Luteinizing hormone (LH)	Immunoassay with color indication for detection of elevated LH hormone in urine or blood during ovulation.
Pregnancy	Pregnancy test	Human chlorionic gonadotropin (HCG) hormone	Tests work by binding the hCG hormone in urine to a monoclonal antibody and an indicator/pigment molecule. Urine-based (HCG) hormone.
	Amniotic Leak Detector	Amniotic fluid	pH sensitivity polymer-coated polyester strip (panty liner) with color indication.
Organ Function	Prostate Disorder	PSA	Immunoenzymometric assay. PSA appears in higher concentrations in the bloodstream when the gland is enlarged or cancerous.
	Adrenal	NaCl	Titration method using with color indication at end to determine salt level in urine.
	Liver	Bilirubin, urobilinogen	Chromatic chemical reagent strip for measurement of bilirubin and urobilinogen in urine.
Drugs	Illegal	Amphetamines (speed) Barbiturates (barbs, downers, reds) Cocaine and crack Methamphetamines (ecstasy) Opiates (heroin) Phencyclidine (angel dust) Cannabis	Drug-specific chromatic chemical test strips with urine sample. Immunoassay screening tests.
	Prescription	Painkillers Antidepressants Benzodiazepines Methadone	Chromatic chemical reagent strips for measurement of Oxycodone, Oxycontin, Vicodin TCA Tricyclics (antidepressants) Tranquillizers such as diazepam, temazapam, nitrazepam, and flunitrazepam
Alcohol	Breath Urine	Ethanol	Fuel cell-based sensor. Metal oxide semiconductor sensor. Test strips—conversion of ethanol by alcohol oxidase (ALOx) in the presence of peroxidase and an indicator such as tetramethylbenzidine (TMB) to produce acetaldehyde and colored TMB (oxidized).
Smoking	Active Passive	Nicotine	Immunoassay for detection of cotinine (metabolite of nicotine) in saliva and urine.

Home Genetic Testing

One area in home diagnostic testing that has received significant attention recently is direct-to-consumer genetic testing. This form of testing currently falls outside the sensing domain, as samples are collected at home and sent to laboratories for testing using techniques such as polymerase chain reactions (PCR). However, it is a growing element of the home testing market.

Efforts to bring this form of testing into the mainstream have met with considerable opposition. For example, the planned partnership between Pathway Genomics and Walgreens to provide testing quickly drew both congressional and FDA scrutiny and resulted in the plans being dropped almost immediately (Wanner, 2012). Many in-home genetic tests lack rigorous scientific validation and fail to capture important contextual information, which is required when building a complete picture of risk (School, 2010).

However, interest among the public still remains, in particular in identifying genetic risks including Alzheimer's, diabetes, and certain forms of cancer such as breast and ovarian (based on the inherited mutation of the BRCA1 and BRCA2 genes). Tests are desired to determine if any genetic risks exist that could be passed on children, such as those causing cystic fibrosis and Tay-Sachs. Recent research has shown that a normal, healthy person has on average about 400 potentially damaging DNA variants, of which two have known disease-trait correlations. Research indicates that the actual possession of these variants is not enough to cause disease in most cases. The catalyst for disease expression remains unknown. (Xue et al., 2012). It is highly likely that factors such as lifestyle and environment are contributory influences. This area will remain hotly debated by doctors, politicians, patient advocacy groups, and individuals with specific family histories. For the moment, we are "opinion rich and information poor" in our understanding of genetic expressions and disease risk. It is likely that it will be a number of decades before we bridge the knowledge gap and realize the value of clinical genomics.

Key Drivers and Challenges

A variety of organizational, technical, and end-user challenges and drivers currently exist for successful sensor utilization in the healthcare domain. Demographic changes, technology innovation, and the cost of reactive healthcare are driving the adoption of in-home and in-community health monitoring. Yet many barriers remain, such as the organizational changes required within healthcare systems to realize the value and utility of sensor technologies. There are also key challenges to be addressed, such as usability of the sensor technology to ensure patient compliance. Despite these challenges, there is growing momentum behind the adoption of sensor technologies based on their ability to provide new and potentially lower-cost models of care. These models of care are also more adaptable to the needs and lifestyle choices of patients. We will now look at the key drivers and challenges in more detail.

Drivers and Challenges in Healthcare Systems

Home monitoring is potentially a less-expensive way to diagnose and watch a patient than intermittent clinical assessment or reacting following a health event—the current model of care. For example, diagnosis of an irregular heart rhythm disorder is more effectively determined through continuous home monitoring rather than with numerous hospital visits or extended in-patient assessment. It is widely agreed that early detection and treatment of most diseases results in lower cost and better outcomes. The adoption of smartphones as health platforms will provide an ability to deliver continuous health monitoring, through body-worn or point-of-care sensors, or sensors integrated into the smartphone itself. This, in turn, will provide early warnings of impending critical health events, such as a heart attack or other significant disease episode. Such capabilities would allow movement toward predictive healthcare rather than the reactive healthcare that dominates the current approach. Political pressure is another key driver toward adopting new, clinically effective monitoring, diagnostic, or treatment strategies, especially if there is a significant projected economic value.

The interface between healthcare systems and technology can be challenging, and this is particularly true when introducing new technologies, new protocols, or new non-clinical settings. Home and community-based sensing promises to deliver all three of these "new" features. The healthcare professions and the healthcare industry are both

complex and conservative, however, and are often seen to be slow to embrace innovation and change. They often require expensive longitudinal, randomized control trials to prove efficacy before adopting new treatment protocols and technologies. Their cautious approach may serve to protect patients. But in many ways, preventing patients from accessing new technologies and treatments may put their health at greater risk than the technology or treatment itself.

The regulatory system, discussed in Chapter 6, also provides a barrier to getting technology to patients. While regulation is a costly, bureaucratic, time-consuming activity, it is necessary to protect vulnerable patients. An unregulated system, such as in-home test kits and mobile apps, can mislead patients with dangerous consequences. A streamlined regulation system that keeps pace with rapidly evolving technology is long overdue. Individual clinicians may also resist change as they may feel uncomfortable using and interpreting remote sensing technologies. Or they may fear these technologies could provide increased transparency into their clinical evaluations, protocol utilization, and decision-making on treatment plans.

Technology Drivers and Challenges

Sensors, especially wearable sensor devices, need to be fashionable, unobtrusive, comfortable, and wireless. The emerging range of "band-aid" sensor formats coupled with smartphones are addressing many of these requirements (Kumar et al., 2011, Whitney, 2010, Montalbano, 2013). However, the form factors of some physiological sensors, such as ambulatory blood pressure monitors, remain large and intrusive due to the physical requirements of their sensing method. Body-worn sensing solutions need to adapt to individual requirements, personal preferences, and habits. The biocompatibility of sensor materials is an important consideration. While much progress has been made at a basic material level, much work remains to fully understand the relationship between the sensor interface and the human body and skin during long term monitoring. Epidermal sensors, such as "smart skin," promise sensors that can be worn for weeks or months without any obvious impact on the skin or surrounding tissues of the patient. The implantable devices domain has already led the way with significant progress achieved to date. Most implants have already achieved a normal operational life span of 10-15 years.

There is much work to be done in breaking down the silos within the health technology industry. A lack of interoperability often exists between sensors and devices, resulting in data being transferred to separate back end systems that make it impossible or extremely inconvenient for a consumer or caregiver to manage all the available data. Initiatives such as the Continua Healthcare Alliance are helping to address many of these interoperability issues and will ultimately make remote clinical sensing more affordable and more effective.

Security and privacy issues are pervasive in many aspects of our daily lives, some of which we give higher priority over others. Healthcare is and will most likely always be one of those high-priority areas. Beyond the technical aspects of security, which depend on the weakest link in the chain (the human), attention must be paid to understanding the societal, ethnographic, and demographic impacts of sensing in healthcare. People have concerns about genetic profiling, third-party exploitation, "big brother," and so forth. These concerns must be addressed up front and policies must be developed and agreed upon before the technology becomes pervasive. Personal ownership and informed consent, which maintain the rights of individuals to privacy with respect to their health data, must be protected. However, individuals must also protect themselves. As people use sensing to obtain more and more information about their health, they should know the implications of sharing this data in an open and uncontrolled manner. Privacy must also be maintained as wireless sensor networks become more pervasive.

Consumer Drivers and Challenges

The patient acts as both a driver and inhibitor of sensor technologies. Some patients instinctively resist new technology, particularly if they feel it will result in a loss of personal contact with their clinician. Others embrace technology as they see it as a mechanism to collect the evidence for the symptoms and issues they are experiencing. Some patients may feel a sense of comfort in knowing that their vital signs are normal and someone is watching their data, while others may be motivated by a desire for the latest and coolest technology device. As with most technologies, ease of use is of critical importance. A poor experience with using a sensor, difficulty interpreting a result, or a getting a false reading may negatively impact a patient's view of the technology and prevent subsequent use.

As more technology is integrated into healthcare, the complexity of personal health data management will increase significantly. People have to become more data literate (see Chapter 5) to understand what their sensor measurements mean. They will also have to understand that an individual measurement in isolation may not necessarily reveal any great insight into their health, but can provide substantial insight if combined with other data sources. An integrated view of the data will be critical in providing context for measurements and for proving meaningful consumer benefits. A positive home test result may be misleading without supporting measurements and additional contextual information, for example. It is therefore essential to consider the end user and different contexts when designing such technology.

As new sensor technologies provide greater insights into the parameters of health, we must be careful to develop robust models of cause and effect. This is particularly true of genetic markers, which of themselves do not necessary mean someone will develop a particular disease. This is one of the key weaknesses of genetic home testing kits. Many people will never develop a particular disease, even if they have been identified as having a risk. Therefore, even if no preventive measures are taken, they would not develop the disease or condition anyway. Once identified as having a particular risk, an individual must be treated under a duty of care or they will demand some form of treatment from their doctors. That could result in greater costs and reduce the economic benefits of preventive measures. As the precision of sensor technologies and our understanding of how to piece together the various individual sources of information improve, we will have more precise tools to identify individuals who really need to and can benefit from proactive treatments.

The Future of Sensor-Based Applications for Healthcare

Current trends indicate that the future of health sensing will be a convergence of many areas—health, technology, fashion, clothing and lifestyle. As health consumerism continues to grow, people will expect their medical devices, particularly non-prescribed monitoring devices, to be aesthetically pleasing. Many healthy people want to keep track of their health status on a continuous basis through easy to use, non-intrusive, fashionable devices. This growing group of people ranges from those who proactively manage their health, to the "worried well" who are concerned about the latest health scare in the media. Patients are becoming more aware of the sensors and services that have emerged in the wellness and fitness domain. In the future, they will likely demand similar capabilities for their prescribed healthcare therapies. This will also lead to a rebalancing of the dynamic between patients and healthcare professionals. Many will view this as a positive development as it will empower individuals to have a more active role in the decision making process with respect to their health. People are becoming better educated and, as a result, are questioning and demanding more of their healthcare providers. Patients will want choices and will play a more active role in the decision-making process with respect to their health and issues associated with it.

The next decade will bring acceleration in the use of personalized medicine, as it moves toward becoming standard practice in healthcare. This will be driven by the utilization of "omics" technologies, where genomic information will be used to determine the most effective course of treatment for an individual. It will move us away from population-centered statistics, where we look at the average effect of treatment, and toward tailoring treatments and continuously modifying that treatment base on the biological data of the individual. That approach is commonly known as theranostics, which focuses on targeted drug therapies and companion diagnostic tests to advance personalized medicine. Testing forms an integral part of it, as immediate reactions to taking a new medication must be detected and the patient treatment can then be optimized based on the test results. Sensing will play a central role in this approach, ranging from determining which drug treatment will be most effective for an individual's biology, to monitoring its efficacy.

From a technology perspective, sensing will be heavily influenced by increased integration of devices through the continued evolution of MEMS. The size of sensors will continue to shrink, enabling to them to be used in form factors that match the needs and expectations of patients. New epidermal sensing technologies—such as electronic skin patches, or "smart skin," where the sensor is literally tattooed onto the patient's skin—will enable clinicians to monitor vital size in almost any location without the need for prodding or poking. This technology will form part of the new world of cyber-physical systems, where the physical world and the cyber world are connected in a seamless, natural way. Sensing platforms based on the "smart band-aid" form factor are the first significant step on this journey (Fangmin et al., 2012, Hoi-Jun et al., 2010).

There will also be exciting developments in the use of smartphones as health platforms. Their pervasiveness and familiarity will see smartphones gain greater adoption as healthcare sensing and management devices. There is already growing interest among the major smartphone players, including Samsung and Apple, and Telco providers, in delivering future devices and services. Initial product offerings will be based on a combination of existing sensors, innovative smartphones, and cloud-based software. For example, an Israeli company called LifeWatch has an Android-based smartphone product (shown in Figure 9-9) that has integrated blood glucose monitoring, EKG/ECG, body temperature, percentage body fat, blood oxygen saturation levels, and stress-level sensors. Innovative product offerings will be developed as new discrete sensors emerge and the integrated sensing capabilities of smartphones continue to evolve. These products will include apps and services to provide continuous, always-connected sensing in any location required by the lifestyle of an individual. This will in turn drive the growth of cloud services and features such as security, privacy, configurable access rights, and integrated electronic health records.

Figure 9-9. *The LifeWatch health sensing smartphone (image used with permission from LifeWatch)*

The development of new drugs is slow and costly. Still, our understanding of how diseases affect individuals at a molecular level due to subtle variations in or genetic and biochemical make-up is growing at a significant pace. This knowledge is driving requirements for many new drugs that are designed for specific genetic markers and biochemical pathways. The current models of clinical trials will have to change in order reduce costs, support assembly of cohorts with specific genetic characteristics, and expedite the output of results demonstrating efficacy. Approximately USD 25 billion is spent on trials annually in the US alone, accounting for around 60 percent of the development costs. Sensing will play a greater role in clinical trials by providing extensive quantitative measures of a subject's physiological and biochemical well-being. Data-quality issues, one of the leading issues currently in clinical trials, will be reduced by using sensors to continuously monitor and automatically report data during home monitoring. The data will be stored in electronic health records on cloud infrastructures that enable real-time demonstration of clinical effect and the identification of potential side effects. This will lead to shorter clinical trials, as substantial evidence with respect to efficacy can be demonstrated during the trial, thus expediting the licensing process. Sensor-based physiological monitoring is already an emerging reality in trials of cardiac drugs, where 24-hour continuous EKG/ECG monitoring is becoming normal practice. The increase in sensor adoption for home monitoring during clinical trials should lead the way to faster, better-characterized and a cheaper drug development process.

The use of sensing technologies is already attracting growing interest from insurance and national services providers as a means to prevent serious health events through proactive monitoring programs or for post-discharge monitoring of patients. In the US, over 30 percent of Medicare patients discharged from the hospital are readmitted with 90 days, in what is sometimes referred to as the revolving-door syndrome. There is a reassessment underway of how medical care is reimbursed with a move toward pay-for-performance. Medicare has now modified its reimbursement policy to penalize

care providers when a patient with a chronic disease is readmitted within 30 days of discharge (CMS, 2013). Sensing technologies will play a greater role in assessing the physiological and kinematic status of patients to ensure they are fit for discharge. The use of body-worn and ambient sensing to monitor a patient post discharge will become normal clinical practice. This type of monitoring will be further catalyzed as we move towards more stringent and frequent requirements on compliance reporting for patients with various disorders and conditions.

Sensing, coupled with other ICT capabilities, such as smartphones, clouding computing, and healthcare data analytics, can offer many potential benefits to society. However, the adoption of these technologies and what their data can reveal about the current or future health status of an individual will have ethical and societal aspects. These aspects must be addressed in a transparent and balanced manner to ensure trust among the monitored and the data consumer. We are on the cusp of an exciting era, where sensing, combined with other technologies, will make a meaningful impact on the health and well-being of individuals and society at large.

Summary

In this chapter we looked at how sensor technologies play a key role in the continuum of healthcare, ranging from the hospital environment, to the community, to home-based monitoring. A variety of factors—including an aging population, moving to proactive healthcare, personalized healthcare delivery, and greater involvement by patients in their health and well-being—are driving this sensor-based, proactive health monitoring approach. We reviewed how sensing is already playing an important role in chronic disease management, investigative monitoring, home rehabilitation, mobility monitoring and consumer sensing. The integration of sensor and ICT technologies into mobile form factors such as smartphones is leading to the development of a new wave of products and services. This evolution is helping to address patient expectations that technology can adapt as required to their lifestyle choices and needs. Finally, we looked at the future of sensing and how it will help deliver new models of care.

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