Chapter 7 Consumer Initiated Health Attitude

Consumer attitudes about their healthcare are beginning to shift. I will discuss the rapid adoption of mobile health apps and devices and the role of cloud computing in healthcare. I will discuss the advent of self diagnosis, its risks and rewards.

The only healthcare products or services my 89 year old mother used were the ones her doctor told her she needed. Her attitude was seeking healthcare products or services was not her responsibility. It was the doctor's responsibility. Among her generation, doctors were revered and never were challenged or even questioned. Mom would see the doctor, the doctor would prescribe healthcare products or services, the healthcare providers would deliver the products and services, and someone either public or private would pay for them. That was how it was. As pointed out in Chapter 3, the model is unaffordable. An affordable healthcare model will require a health attitude change on the part of consumers, providers, and payers.

Consumers

The generations following Mom see their health responsibility quite differently and with a proactive attitude. They not only don't wait for providers to tell them what to do, but also tell healthcare providers what they want. Jeff Munn wrote in "Looking Beyond Health Reform: The Future of Consumer-Focused Health Care" a consumer-driven model for healthcare products is here to stay and will increase dramatically in the years ahead.[i] Consumer expectations for healthcare are changing.

The types of services demanded by patients follow a pattern similar to Maslow's hierarchy of needs. These include following a progression including physiological, safety, love and belonging, esteem, and self-actualization.[ii] Similarly, there is a range of needs in healthcare. If there is an emergency, then consumers expect the ER to have the necessary services. If a surgical procedure is recommended, then consumers expect high quality service with a good outcome. In the future, consumers will expect genetic analysis including a projection of disease that is likely to develop and what to do to prevent it.

Many hospitals already do an excellent job of providing high quality emergency and surgical services and meeting the needs of consumers. The providers may receive high ratings for what they deliver, but consumers will expect more. Genetic research is being done by major hospitals in search of certain cancer cures. Consumers will expect genetic analysis as a routine part of their care, not just for research. President Obama's 2015 call for 1 million volunteers to have their genes sequenced is just the beginning.

The Joint Center for Cancer Precision Medicine, a collaborative initiative among Dana-Farber Cancer Institute, Brigham and Women's Hospital, Boston Children's Hospital, and the Broad Institute of MIT and Harvard are developing a new way of practicing cancer medicine. Rather than treating all patients with a particular type of

cancer in the same way, the scientists at the new center study the DNA, RNA, and protein from individual biopsy samples to determine how cancers will respond to typical cancer drugs physicians prescribed.[iii] Some patients may respond very well to a certain cancer drug while others may respond poorly. By knowing which response a patient may have, the pain and suffering of side effects can be avoided when the genetic analysis suggests the drug would provide no benefit to the patient.

The Joint Center is deploying state-of-the-art capabilities including "DNA sequencing and other tumor molecular profiling technologies, pathology, radiology, surgery, computational interpretation, and new tumor model systems, which are not available at most hospitals."[iv] The genetic analysis performed at the center is utilizing the skills of biologists, bioinformaticians, and software engineers to develop new algorithms for processing and interpreting the gene sequencing data with the goal of directly applying the results to individual patients. While what Dana-Farber is doing may sound more like research than patient care, it will not be long before patients will expect such interventions. Providers will develop such capabilities as a competitive differentiator in their market.[v]

Healthcare Information

People's attitudes on healthcare are shifting and they are accepting more responsibility for their health. People also are collecting data related to their health. A study about migraine headaches published in *Neurology* more than a dozen years ago established the principle that keeping notes on one's health is a good tool for improving it.[vi] Tracking one's health today is becoming a part of our daily lives.

The Pew Research Center's Internet & American Life Project performs surveys to study the evolution of the Internet, how Americans use the Internet, and how their online activities affect their lives.[vii] In a January 2013 report, "Tracking for Health", Pew Research said that 69% of adults keep track of at least one health indicator. The survey of 3,014 adults indicated 60% tracked weight, diet, or exercise. Thirty-three percent tracked blood pressure, sleep patterns, headaches, or other healthcare indicators. Twelve percent tracked a health indicator for a loved one.

Exercise Tracking

One of the easiest health related measurements to track is the number of steps taken while walking or miles run. For athletes tracking may be essential for training, but exercise is important for everyone. Mechanical pedometers have been around for many years. The advent of electronic accelerometers silently and accurately counting each step we take and each stair we climb can be embedded in very small devices. Fitbit and Jawbone devices have made tracking really simple. A device in your pocket, clipped to your clothing, or worn on your wrist can count each step and report the results to your smartphone. The smartphone then updates the results in your fitness database in the cloud. Users can set goals, join groups, share their results, and receive email awards and motivational messages.

Apple has taken exercise tracking to another level by incorporating a motion coprocessor chip in its iPhone 6 and iPhone 6 Plus. The new M8 chip continuously measures motion data using its accelerometer, compass, gyroscope, and barometer. The sensors automatically measure your steps, distance, and changes in elevation. Apple iPhones include a built-in Health app. An app is the abbreviated name for a computer software application. The Health app is a built-in companion to the calendar, messages, reminders, mail, address book, and other apps that are part of the operating system of iPhones and iPads. Third-party apps can build upon the basic measurement of steps and distance. For example, the MapMyWalk fitness app draws a map of where you walk or run. The app saves the route so you can take the same route in the future or share the route with friends. The log in MapMyWalk shows a cross-section of the elevation you encountered during the exercise. At each mile, a voice announces your distance, cumulative pace, and your split pace.

In "Exercise: Seven Benefits of Regular Physical Activity", Mayo Clinic suggests exercise is better for you than you think. It says, "From boosting your mood to improving your sex life, exercise can improve your life."[viii] Mayo Clinic outlines specific benefits saying that exercise controls weight, combats health conditions and diseases, improves mood, boosts energy, promotes better sleep, puts the spark back into your sex life, and can be fun.

Mobile Health

Although exercise is irrefutably important in our lives, mHealth can provide assistance in many more ways. As important as recording steps and miles are, they represent the tip of the iceberg of healthcare data consumers will be collecting. An explosion of healthcare related devices connected to smartphones is enabling a consumer-led revolution in healthcare. The National Institute for Health (NIH) has defined the burgeoning area as mHealth, the use of mobile and wireless devices to improve health outcomes, healthcare services, and health research.

According to the Healthcare Information and Management Systems Society, health, fitness, and technology companies are marketing more than 40,000 health-related apps. Many of these apps will work in conjunction with HealthKit, Apple's foray into the healthcare space announced as part of its newest line of iPhones. The concept behind HealthKit is to provide a repository for the storage of not only steps and miles, but sixty different types of data such as respiration rate, cholesterol, blood glucose, body temperature, weight, body mass index (BMI), oxygen saturation, sleep analysis, and nutrition. Apple has given technical details about HealthKit to app developers so they can create apps that store data in the Apple repository. For example, an app might connect a body temperature sensor via Bluetooth to the iPhone and transfer the date, time, and temperature into the HealthKit repository. A consumer may have dozens of apps that are collecting data and placing it in the iPhone or iPad Health app.

Apple's vision does not stop there. Using rigorous security techniques, the Health app can allow data to be shared with friends, family, physicians, and research databases.

The consumer will have complete control over who can see what and whether it is a one-time look or continual access. When a physician orders a lab test or imaging study, the results will be returned directly to an app on the consumer's iPhone. Consumers will be able to see statistical analysis and graphs of their health data. Apple is negotiating with major healthcare providers such as Athenahealth, Cerner, Kaiser Permanente, Mayo Clinic, and EHR providers such as Epic and Allscripts to help them use HealthKit to integrate their systems with the Health app. In effect, Apple is putting itself in the position of a conduit through which vast amounts of health data will flow between consumers, physicians, hospitals, medical device manufacturers, laboratories, and healthcare software providers.

The risk to Apple's brand is significant if security is not ironclad, but if Apple is successful, it could give them a significant advantage as the mobile device maker of choice. For consumers, it has the potential to empower them to manage their health and use the healthcare system more effectively.

Personal Supercomputers

In 1976, Seymour Cray introduced the first supercomputer, the Cray-1. The term supercomputer meant it was the most powerful computer at the time. As for the Cray-1, it was super in many respects. It cost $5-$10 million, weighed more than 5 tons, and used as much electricity as ten homes. Super as it was, the Cray-1 had no app store, could not play a song, or even make a phone call. Scientists and researchers embraced the Cray-1 because it enabled them to perform scientific simulations and explore data at a speed not previously possible. In total, the Cray-1 sold less than 100 supercomputers.

Fast-forward 39 years from the introduction of the Cray-1 to Apple's iPhone 5S and iPhone 6 Plus. These devices are more than 100 times more powerful than the Cray-1 in every respect, and hundreds of millions of people around the world carry them in their pocket or purse. The iPhone 6 may make the S in 5S stand for slowpoke. The iPhone 5S has a processing chip called the A7 that set a new level of performance. The iPhone 6 has a new chip called the A8 that includes more than two billion transistors and even is faster. In addition to the Apple A7 supercomputer chip, the iPhone 5S includes a second chip called the M7, and the iPhone 6 and 6 Plus have an M8. The M stands for motion and the chip is able to determine if you are moving, how fast you are moving, your latitude and longitude, direction of travel, your pace, and the barometric pressure to determine your altitude. The iPhones and iPads we take for granted are truly supercomputers. I call them personal supercomputers and will take the liberty to label them as PSCs.

Apple is not the only manufacturer of PSCs, but the company focus on healthcare and the introduction of the HealthKit are particularly relevant to *Health Attitude*. We will see an amazing growth of apps to take advantage of the iPhone's features and performance. IBM and Apple have announced a strategic partnership to focus on healthcare and other important industry segments. Analysts expect IBM will develop over 100 apps focused on healthcare.

PSC Apps and Devices

The availability of mHealth apps can help consumers to proactively manage their health and wellness. The mHealth apps can promote healthy living, and gain access to a plethora of useful information whenever they want and on whatever device they want to use to retrieve it. Innovators are developing new mHealth apps and devices at a frenetic pace. Consumers have a healthy attitude about adopting them. According to industry estimates cited by the FDA, 500 million smartphone users worldwide will be using a healthcare application in 2015, and by 2018, 50% of the more than 3.4 billion smartphone and tablet users including healthcare professionals, consumers, and patients, will have downloaded mobile health applications.[ix] As consumers adopt mHealth devices, they will be performing tests at a much lower cost than traditional laboratories.

The term regulation is anathema to many technology innovators who fear the bureaucrats will inhibit getting new ideas to market. When it comes to healthcare, regulation is a different story. The FDA sees the widespread adoption and use of mobile technologies as creating new ways to improve health and the delivery of healthcare services. The key to determining if a smartphone app or attachment should be subject to regulation is based on whether or not they are classified as devices. The FDA defines a medical device as one used as an accessory to a regulated medical device, or that transforms a mobile platform into a regulated medical device. Through 2013, the FDA has approved more than 100 such devices, and as of the middle of September 2014, the agency approved 23 additional devices.[x] The paragraphs that follow describe some mHealth apps and devices, some of which are not approved by the FDA.

AliveCor. The AliveCor is an FDA approved heart monitor which attaches to the back of an iPhone. The consumer simply holds two fingers from each hand on the back of the iPhone, and in 30 seconds, the AliveCor device takes the equivalent of a single-lead electrocardiogram (ECG). The device saves the ECG data in the iPhone and the app allows the consumer to annotate, store, display, and share the ECG data with a doctor. AliveCor claims clinical studies demonstrated the AliveCor Heart Monitor's accuracy to be comparable to readings from Lead 1 of standard ECG machines, but at a fraction of the cost.[xi] The ease of use and lack of potentially irritating sensors attached to the skin will be appealing to consumers. AliveCor received FDA approval in September 2014 to extend the basic ECG to detect atrial fibrillation, a condition presenting a major risk for stroke.

Dr. Eric Topol, author of *The Creative Destruction of Medicine: How The Digital Revolution Will Create Better Health Care*, said that 75% of monitoring performed in the doctor's office or hospital could be eliminated with smartphone devices such as the AliveCor Heart Monitor.[xii] Steven G. Burrill said that the rapid growth of such devices might bend the healthcare cost curve favorably.[xiii]

The CellScope Oto. My four children and six grandchildren's ear infections required many hours in the doctor's offices. Ear infection, or otitis media, is the most common diagnosis in preschoolers and affects 75% of children by age six. In the United

States, the disease results in 30 million physician visits per year.[xiv] The doctor visit and follow-up care add billions of dollars to the cost of healthcare.

Enter the CellScope Oto, a new consumer device turning an iPhone into an ear-inspecting otoscope.[xv] A simple clip-on attachment puts a scope over the iPhone's camera lens and enables it to take pictures of a child's ear canal. The accompanying app magnifies the image and sends it to a pediatrician who can study it remotely. Taking pictures daily could allow the physician to monitor progress and potentially avoid unnecessary antibiotics, which could help reduce cost and the risk of antibiotic resistance. With the power of the PSC, the analysis of the photo will ultimately be done in the smartphone with the diagnosis merely corroborated with the doctor. Parents will save many trips to the doctor's office.

Cholesterol Application for Rapid Diagnostics. Some apps can take photos to a new level and leverage the power of the mobile PSC. A team of engineers at Cornell University has developed the smartphone Cholesterol Application for Rapid Diagnostics (SmartCARD).[xvi] A consumer can extract a single drop of blood and place it onto a small paper strip whey they then insert the strip into a slot in the SmartCARD attachment to the iPhone. The camera takes a photo of the strip and the PSC performs a colorimetric analysis displaying your cholesterol level in a matter of seconds. Not only could such an mHealth device and app save millions of dollars of laboratory blood tests, but they also could enable a consumer to better manage their cholesterol level and determine the effectiveness of dietary changes. A more frequent test, rather than as part of an annual medical examination, could enable better cholesterol management by the consumer. The new app is not yet commercially available but, when it is, it will probably include the differentiation between "good" and "bad" lipids, just like the labs do.

Propeller. More than 50 million people are affected by either asthma or chronic obstructive pulmonary disease. Many of those affected use inhalers when they experience symptoms resulting in swollen airways making it difficult to breathe. The propeller device is a sensor, which connects to a smart inhaler. The inhaler reports the latitude and longitude at the time of an inhalation.[xvii] The FDA approved the Propeller inhaler in September 2014 for both diseases.

Propeller Health worked with data scientists from IBM to collect data from consumers with asthma. The data was supplemented with data about weather and air quality. This allowed researchers and IBM to develop maps of where the conditions are most hazardous for asthma patients so they can avoid such locations.

Lumoback. I met Dr. Charles Wang, a young physician with an MBA who has a great vision for using mobile technology to address back pain at the Demo conference in San Jose. Dr. Wang developed a concept to use a stick-on sensor similar to a Band-Aid you place on your back. The sensor can tell when you are following good posture or when you are slouching. The sensor sends data to your mobile phone and an app alerts you to your bad posture and keeps track of your habits. The theory is looking at the data

with your app will lead you to more healthy habits and less back pain. The FDA approved device lists for $149.

Cue. Since the iPhone has the power of a supercomputer, it is going to be the host for a wide range of healthcare related consumer devices and related apps. One of the latest comes from a San Diego startup named Cue. The company has developed a compact, consumer-oriented device which can detect five biological conditions at a molecular level. This is not a fitness tracker. To the contrary, the compact and simplistic looking device is a mini-laboratory that has been years in the making. With a simple nasal swab and insertion into the Cue device, the biological data is transferred to your iPhone and then compared with data from the Cue cloud to determine recommended dietary or other actions.[xviii]

When Cue launches in summer 2015, it will have five tests available:

1. Inflammation: The cue can detect the level of C-reactive protein, a commonly used marker of inflammation. Based on the level of the marker, a consumer may get suggestions on how to optimize workouts, speed up recovery, and maintain a healthy heart.

2. Vitamin D: Vitamin D, often called the "sunshine vitamin", is a hormone produced by the body when the skin absorbs sunlight. Cue suggestions might include spending more or less time in the sun to achieve well-balanced health.

3. Fertility: Cue says that tracking the detected level of Luteinizing Hormone is the best tool to determine the ideal time to conceive a child. The device helps women track the hormone level as an indicator of fertility trends, and Cue can recommend food choices that are claimed to support fertility. Cue will provide alerts when the hormone level is at an optimum time for conception.

4. Influenza: Cue detection of flu can find an early warning that can enable you to see a doctor early and get an appropriate treatment alert.

5. Testosterone: Testosterone is an essential hormone for health and well-being as well as the prevention of osteoporosis.[xix] Cue claims its recommendations can help you plan exercise, training, and diet that can boost your natural testosterone levels.

In 2015, the Cue device is expected to retail for $199. It is considered a "consumer health product" at this stage, but the company is hoping for an FDA approval so that it can join the growing list of consumer medical devices.

World's Smartest Thermometer. Kinsa has received FDA approval for an innovative thermometer they call the world's smartest. The thin and flexible device plugs into the audio jack of an iPhone or Android smartphone. The senor end of the thermometer can be used orally, under the arm, or rectally. The engaging screen from the

app may make it easier to take the temperature of a fidgety and sick child. Like other mHealth apps, the device information is recorded in the smartphone, and in the case of the iPhone, in the Health app. When you are at the pediatrician's office, you can tell him or her exactly when and how your child's symptoms began by pulling out your phone. The app accommodates individual profiles for each family member and tracks illness history. The Kinsa thermometer became available in 2014 for $29.99.

HomeLink. Alere Connect, formerly known as MedApps, received FDA approval for its HomeLink, a hub that connects to blood pressure monitors, pulse oximeters, glucose meters, and weight scales via USB or Bluetooth. Both connection methods are available on nearly all personal computers. The HomeLink hub transmits the data collected from the consumer by the individual devices to an alarm center or healthcare provider using a cellular radio link.[xx] The advantage of this approach is it simplifies data transmission for consumers that may not have broadband Internet service or do not have the skills to connect the hub to a local area network in the house.

QardioArm. QardioArm is an FDA approved smart blood pressure monitor which measures your systolic/diastolic blood pressure and heart rate. The wireless monitor design makes it light, compact, and portable. In addition to blood pressure and heart rate, the device can detect an irregular heartbeat. QardioArm claims to have a proprietary relaxation function and multi-measurement averaging feature allowing greater accuracy.[xxi] The device turns on when you unwrap it and it connects to your smartphone with Bluetooth. After you put the device around your arm and press the start button, all readings are automatically recorded and uploaded to Qardio's secure cloud. You then can share your data as you see fit with your family, friends, or doctor. I anticipate Qardio will use HealthKit to develop the interface to Apple's Health app.

Otoharmonics. Otoharmonics, a startup supported by Cedars-Sinai Medical Center, received FDA clearance for an iPad and iPod Touch app which treats a medical condition called tinnitus.[xxii] Tinnitus is a condition with which I can identify because I have had it since 1985. I still remember the pleasant day in November when I was blowing leaves from my property. Ear protection was not commonplace back then. I was using a backpack-style leaf blower for more than two hours until the blower ran out of gas. At that moment I heard loud ringing in my ears like what one experiences when hearing a loud noise such as a gunshot. The ringing in both of my ears has continued 24x7 since then.

Subjective tinnitus is the perception of a sound within the ear that cannot be heard by others. Although tinnitus is usually described as 'ringing in the ears', the variety of sounds and combinations people perceive are as widespread as the condition. Some people get tinnitus from too much loud music, some from war-zone military service, and some from excessive noise in the workplace. Regardless of how it begins and what it sounds like, tinnitus can range from mildly bothersome to debilitation. There is no cure for tinnitus, but Otoharmonics has developed an mHealth app called the Levo System that may provide relief. Using an iPad app, a hearing practitioner works with you to determine the pattern of sound you experience. He or she then prepares a proprietary set of sound

patterns and puts them on an iPod Touch outfitted with custom made ear buds. You take the iPod home and sleep with the sound patterns. Feedback to the practitioner allows for incremental changes and improvements over time.

Gmate Smart Glucometer. A glucose meter, glucometer, is a medical device for determining the approximate concentration of glucose in the blood.[xxiii] The glucometer is a key element of home blood glucose monitoring for people with diabetes mellitus or hypoglycemia. The consumer places a drop of blood, obtained by pricking the skin with a lancet, on a disposable test strip the meter reads, calculates the blood glucose level, and displays the result.

New York City based medical device maker Philosys has received FDA approval for its Gmate Smart glucometer, which consumers plug into the audio jack of an iPhone and launch the Gmate Smart app. One of the advantages over the traditional glucometer is with each use of the app, the consumer can add supplementary notes to the reading such as nutrition or fitness data, or medication information. The app has a log of prior readings and can display averages over 1, 7, 14, 30, and 60-day periods. The Apple Health app will accommodate glucometer data, and it is likely Philosys will update their app with HealthKit.

Eko Devices. Connor Landsgraf, CEO of a San Francisco startup Eko Devices, believes it is time to upgrade the stethoscope, which he pointed out has not changed since the 1880s.[xxiv] He claims many physicians do not get adequate training on how to interpret the sounds they hear with a classic stethoscope. He says the result is "rampant misdiagnosis".[xxv] Eko is developing a computerized insert for stethoscopes which is not approved by the FDA. The insert will provide data from the stethoscope to a PSC, which can then analyze the data and compare it with cloud based sound patterns representing various conditions. The goal is to help physicians make data-driven decisions resulting in improved patient outcomes.

iDoc24. mHealth apps can provide standalone monitoring or testing, or experts can supplement data the apps collect. Another San Francisco startup, iDoc24, offers a dermatology app that allows patients and caregivers to send images of skin conditions to its staff of dermatologists who, for $25, will diagnose your condition and prescribe medications. Pictures of skin conditions can be submitted anonymously and iDoc24 dermatologists will respond within 24 hours.

Illumina DNA Chip. Illumina, Inc. is a global life sciences company with a goal to apply sequencing and array technologies to the analysis of genetic variation and function. The sequencing will make previously unimaginable studies possible. Their

ultimate goal is to make personalized medicine commonplace resulting in a transformation of healthcare.

Beginning in 1990, more than 200 scientists collaborated on a $3 billion project to sequence the roughly 3 billion bases of human DNA. Between 2002 and 2008 the cost to perform the sequencing gradually declined from $100 million to $10 million. The introduction of next generation sequencing technology in 2008 led to a plummeting of the cost over the six years until now, bringing the cost down to a few thousand dollars.[xxvi] In March 2014, Illumina claimed it had brought the cost of sequencing a human genome to $1,000, a much anticipated target predicted some years ago and now fulfilled. President Obama in 2015 funded an initiative to sequence the genes of one million people. This is a large step toward individual gene sequencing.

Now, Illumina, Inc. has laid out a vision for a consumer product. The company believes it can build a DNA chip to plug into a smartphone, bringing genetic medicine into the world of consumer mHealth. Rick Merritt at *EE Times* has been following the development closely as reported in "DNA Chip Will Plug into Handsets."[xxvii] In a recent technology forum, Mostafa Ronaghi, Illumina's Chief Technology Officer, said that Illumina's technology would make the smartphone "a molecular stethoscope".[xxviii] Ronaghi predicted that we would no longer need a primary care physician in the future because consumers will make genetic tests at home or in a clinic, and go directly to a specialist. He said this would happen in six to seven years.[xxix]

Illumina scientists and engineers are making progress toward development of an mHealth DNA chip, but considerable challenges remain. One of the biggest challenges is finding biocompatible interfaces between "wet and dry science".[xxx] The app may require as much as a half of a shot glass of blood to perform the required analysis. The app may also require more data than today's smartphones can process. At this stage, it appears that FDA approval is not imminent or that PCPs need to fear being replaced by smartphones, but the future may surprise us.

Cognoa. Some mHealth apps, such as the Kinsa thermometer, deliver results directly to the consumer. In other apps, such as the Levo iPod Touch solution for tinnitus, the results require the app plus a practitioner. A new development is the use of mHealth in combination with artificial intelligence (AI). AI is intelligence exhibited by machines or software, not by humans. Cognoa, a Palo Alto, California startup, uses AI to analyze children's behavior from a video and questionnaire provided by the parents. The company analyzes the information using algorithms that can produce a risk score for autism and other developmental issues. The diagnoses take just three days. The company says many children get diagnosed too late and miss a window of opportunity where the children could receive the greatest benefit.

Wearable Technology. The realm of technology integration into our daily lives will extend far beyond smartphones and devices. A new category of consumer technology has opened up new opportunities for wearable items including watches, glasses, and clothing. Ralph Lauren is taking the lead with a new Polo Tech t-shirt. The

shirts are interwoven with a set of sensors with close proximity to the body. The sensors can track heart rate, breathing rate, breathing depth, activity intensity, steps walked, calories burned, and heart rate variability. The data are transmitted from the shirts' sensors to a small transmitter device wearers can clip to shirt. The transmitter connects to an iPhone using a Bluetooth signal and relays the data to a Ralph Lauren iPhone app and probably to the Apple Health app.

A sub-category of wearable technology includes Band-Aid looking devices. Researchers from Northwestern University in Evanston, IL, and the University of Illinois at Urbana-Champaign have developed a wearable, wireless, skin-like device the researchers say can monitor cardiovascular and skin health 24 hours a day. The 2 inch long device is made with more than 3,500 tiny crystals organized on a thin, soft, and flexible strip consumers can attach directly to their skin. The device is nearly invisible and it stretches, twists, and compresses just like skin itself. The device monitors blood flow, temperature, and skin hydration level.

FDA Data Collection.

The FDA is encouraging the use of apps for data collection. During the H1N1 swine flu epidemic in 2009, some experimental drugs were used, but there was no efficient method of collecting data about adverse effects from taking the drugs. The FDA developed a smartphone app to provide reporting direct from the patient.[xxxi] Collecting data directly from the public may turn out to be a boon for public health agencies and epidemiologists. As the accountable care model rolls out, health providers are going to become very interested in learning as much as possible about the population for which they will be providing care. Gathering data from the community could help healthcare planners design appropriate clinics.

Self Diagnosis

Home monitoring of blood glucose or blood pressure is not new. Gathering such data on a regular basis can help consumers with chronic illness to manage their condition. A more recent trend is gathering data such as cholesterol or C-reactive protein, a marker for detecting inflammation, for the purpose of self diagnosing conditions such as cardiovascular disease. Another example is UMSkinCheck, a free mHealth app from the University of Michigan letting consumers perform a skin cancer self-exam. The app provides surveillance allowing users to complete and store a full body photographic library, track detected moles or lesions, download informational videos and literature, and locate a nearby skin cancer specialist.[xxxii]

Healthcare apps and devices can provide useful information for managing chronic illness or detecting a medical condition needing attention. Some physicians I know are very concerned about a trend toward self diagnosis. They are worried consumers will self diagnose and then self medicate with an ever expanding array of over the counter drugs. Some are concerned about lost revenue from profitable tests consumers can now perform on their own. The ultimate concern is a person could self treat with a fatal result. The

concern is legitimate, but the trend is likely to continue as self diagnostic technology becomes more affordable and ubiquitous. TV advertising of medical conditions and related drugs may lead consumers to unnecessarily self diagnose. Healthcare resources on the web need to put up the red flag of caution and urge consumers to take the data they gather to their doctor before making conclusions about what treatment may be needed.

Self Diagnosis with Isabel

Very few physicians would say their diagnoses are right 100% of the time. One physician told me he would feel good if he were right 75% of the time. Unfortunately, sometimes a diagnosis is seriously wrong and leads to a bad outcome. In 1999, Jason and Charlotte Maude took their 3 year old daughter, Isabel, to the local hospital where she was misdiagnosed and had nearly fatal consequences. Isabel had chicken pox, and a new set of symptoms prompted her hospital visit. A physician told Jason and Charlotte Isabel's symptoms were typical of the chicken pox from which she was suffering. Isabel was later diagnosed with serious complications of chicken pox: Toxic Shock Syndrome and Necrotizing Fasciitis. Isabel spent two months in the hospital, including a month in the pediatric ICU after experiencing multiple organ failures and cardiac arrests.[xxxiii] Isabel was brought back from the brink and is now a healthy and beautiful young woman.

Rather than suing the hospital for the diagnostic error, Jason and Charlotte formed a company, Isabel Healthcare, to develop a better way to perform diagnoses. Their initial idea was the failure in Isabel's diagnosis was the physician failed to ask the simple question of what else could this be. Isabel Healthcare's first product, Isabel, was a web based Diagnosis Checklist System designed to assist clinicians in forming a diagnosis in which they can feel confident. Isabel enhances the process of determining a diagnosis by supplementing the expertise of the clinician.[xxxiv]

Isabel Healthcare believes the most effective way for clinicians to improve the quality and speed of diagnosis is for them to develop a comprehensive list of diagnostic possibilities for a patient. The Isabel Healthcare software can be integrated with the EHR workflow of a hospital or during a consultation with the patient. The company says clinicians who 'Isabel' their patients at an early stage are able to substantially reduce clinical risk by ensuring important possible diagnoses have not been missed.

"Patients are experts on their symptoms and doctors are experts in working out their probable causes. Patients and doctors need to work together to formulate a list of possible diagnoses." said Jason Maude, Chief Executive of Isabel Healthcare.[xxxv] Some physicians cringe at the thought of self diagnosis, but others see the potential to enhance their productivity by having the patient, with Isabel Healthcare's assistance, develop a first pass at a possible illness or disease. By collaborating, a synergy can develop whereby patients and their medical providers can embark on a safe and effective treatment program. A study by Graber and Mathew published in the *Journal of General Internal Medicine* found Isabel software suggested the correct diagnosis in 48 of 50 (96%) complex cases.[xxxvi]

Isabel Healthcare software is now available as an mHealth app. Like the web based tool, the app uses a technology called differential diagnostics. After entering your age, gender, and the region of the world where you live, you enter all the symptoms you are experiencing. The Isabel app instantly returns a list of possible diagnoses from a database of more than 6,000 diseases. Self diagnosis and research by patients can be helpful. No physician can possibly read every journal article and know about every medication. As of December 31, 2013, the FDA has approved 1,453 drugs.[xxxvii]

There is a broader set of issues with regard to diagnosis in general. For almost every set of symptoms there will be a long list of potential diagnoses. A balance needs to be reached between identifying all possible diagnoses and diagnoses that should be explored. As in the case of Isabel Maude, a patient may have a rare condition that can only be diagnosed with expensive or potentially dangerous testing. Dr. Dempsey Springfield, an Orthopedic Surgeon in Boston, MA said, "The physician must weigh the relative risks and benefits of ruling a particular diagnosis in or out. The most experienced physicians select those diagnoses with the most likelihood of being accurate plus those if missed would have the most severe consequence, and pursue them first." As the practice of medicine has become more sophisticated, patients have increased their expectations. Physicians feel the pressure to determine the right diagnosis quickly and therefore broaden the list of diagnoses to exclude. Dr. Springfield added, " Thirty years ago a physician could be very thorough and still not do excessive testing. Today, the amount of testing and number of diagnoses to be excluded, if one is to be completely thorough, has expanded dramatically." If a patient comes to a physician with their own list of potential diagnoses and the odds of their likelihood, the patient and physician will have to decide how many to investigate. Physicians carry a large responsibility amidst complex situations and high expectations. Dr. Springfield said, "One of the reasons it is called the practice of medicine is the physician is always learning and improving their diagnostic skills."

A *Wall Street Journal* article, "A Better Online Diagnosis Before the Doctor Visit", cited a survey by Philips North America of more than 1,000 people about their use of online diagnostic tools. More than 40% said they were comfortable using websites to check their own symptoms. One fourth said they used self diagnostic tools as often as they visit their doctor. About the same number said they used online tools instead of visiting their doctor.[xxxviii] I believe self diagnosis is here to stay.

Sequencing the Baby's Genome

The ultimate self diagnosis may come from our genes. The dramatic reduction in the cost of gene sequencing is similar to Gordon Moore's iconic observation computing power tends to double and its price falls in half every 2 years.[xxxix] This has held true for nearly 50 years with only minor revision.[xl] Does this mean all of us will be sequencing our genomes? Yes, that is likely, and some will push the envelope even further. Razib Khan decided to sequence the genome of his unborn son, who was later born in early June 2014 in California. In "How a Geneticist Sequenced His Unborn Son's Genome, Using Do-It-Yourself Biology Tools", Khan said that he believes our genetic data and

that of our unborn children belong to us.[xli] Physicians and policymakers will not necessarily agree, and many debates will be ignited in the months and years ahead.

Khan said that his son turned out to be a "normal kid".[xlii] He used publicly available analytics tools to study the 43 gigabytes about his unborn son's genome. Fortunately, he found nothing alarming or even unusual. But, what if he had found some disturbing news such as his son would be born with some disability or with a likelihood of some future fatal disease? What actions would he and his wife decide to take and what ethical issues would arise? I don't think we know even a small fraction of the issues ahead. However, some things are certain. The price of sequencing will continue to decline and the availability of big data about our children and us will be commonplace.

On January 30, 2015, President Obama announced a precision medicine initiative to greatly expand the potential of sequencing the human genome.[xliii] Precision medicine, also known as personalized or individualized medicine, may lead to identifying defects earlier in our lives and provide solutions to correct them before they become life threatening. The government initiative plans to include collecting genetic information from one million people and use big data and analytics to develop cures. Nancy A. Brown, Chief Executive Officer of the American Heart Association, said that patients with heart disease, like those with cancer, could benefit from precision medicine. *The New York Times* reported that her organization is building a database that can help develop treatments for heart failure and drugs to lower high blood pressure.[xliv] Her organization is compiling a database of genetic information. She said the data could help doctors tailor treatments for heart failure or abnormal heart rhythms, or find the right combination of drugs to lower high blood pressure.

Summary

The Internet and the web have empowered consumers for more than 20 years. mHealth has provided even more empowerment to patients in a short time through the powers of the PSC, which I described as personal supercomputers. The number of devices and apps are exploding onto the healthcare scene. The FDA has approved more than 150 apps and devices through September of 2014. The pace will likely accelerate. Self-monitoring and self diagnosis are here to stay. Although some providers are not comfortable with consumer technology for self diagnosis, the new technologies surely will lead to a new model for collaboration between patient and physician. A key element of collaboration in healthcare is the electronic health record.

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