Wearable healthcare: Lessons from the past and a peek into the future

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ABSTRACT

The market for wearable healthcare devices is one of the fastest growing markets of this decade. In this paper, we conduct a thorough review of the peer reviewed and grey literatures on wearable healthcare. Then, using SWOT analysis, we examine the market’s strengths, weaknesses, opportunities, and some of the major threats it faces. Our structured examination revealed that the primary areas of innovation in wearable healthcare include infant safety and care, elderly care, chronic disease management, military support, sports medicine, and preventive medicine. We also found that several hurdles stand in the way of the wearable market’s success; these include threats to data security and privacy, regulatory requirements, cost of system operation and management, and subpar adoption rates. Overall, our analysis revealed that significant effort is needed to address the identified technological, societal, and governmental barriers that are preventing the wearable healthcare market from reaching its full potential. Incentives by the Federal government that fuel innovation and encourage adoption by healthcare professionals and patients is deemed necessary for the wearable market’s continued growth.

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1. Introduction

Wearable technology can be traced back to the 13th century (The College of Optometrists, 2015). An English friar, Roger Bacon, is widely credited as the inventor of spectacles and the use of corrective lenses in his Opus Majus (c.1266). Several hundred years later, 17th Century French mathematician Jean Leurechon documented the first hearing aids, known as ear trumpets (van Etten, 1624). During 1887, the first glass contact lens was introduced, which fit over the entire eye (Edward Hand Medical Heritage Foundation, 2015). By the mid 20th century, advancing electronic technology rapidly produced a myriad of wearable healthcare devices. The year 1960 marked the first successful use of a long term, implantable pacemaker (Aguilina, 2006). Soft contact lenses were introduced in 1971, followed by digital hearing aids in 1987 (Hochheiser, 2013). Around the same time, insulin pumps were introduced, thanks to the research of Dean Kamen (Worcester Polytechnic Institute, 2015). The wearable sensor market in the United States (U.S.) is expected to increase to $100.35 million by 2018 (Business Wire, 2015). A study by Ipsos, an independent research company, found that nearly one in five adults in the U.S. had plans to purchase a wearable device within a year (Ipsos MediaCT, 2014). Globally, the wear

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able technology market is foreseen to grow to $5.8 billion by 2018, up from $750 million in 2012 (Transparency Market Research, 2015).

All these trends indicate that wearable technology is not only here to stay, but is also poised to surge ahead in popularity, innovativeness, and functionality. In recent years, wearable technology has rocketed into popular culture with successes in the fitness market. Products offered by Nike, Jawbone, Fitbit, and Garmin have all enjoyed great success. Technology heavy weights Apple and Microsoft have introduced the Apple Watch and Microsoft Band that not only provide the full functionality of fitness trackers (heart rate, step count, GPS, calorie tracker, sleep tracker, etc.), but can also include phone call and text messaging alerts, UV monitoring, and digital assistants. Other pharma tech companies have been experimenting with ingestible pills that can capture all sorts of biometric data. Helius by Proteus Digital Health (http://www.proteus.com/) is a consumable pill used in clinical testing to indicate if prescribed meds are taken and how patients are responding to their medications. Another example comes from a partnership between Northwestern University and the University of Illinois at Urbana Champaign, that created health monitoring crystals to track cardiovascular health and the health of a patient’s skin. Their product looks no different than a moisturizing cream that is applied to a small section of the arm or chest and requires no major behavioral changes on the part of the patient.

The popularity of this diversified technology market has also fueled the market for wearable healthcare devices. In 2012, healthcare related wearable devices reportedly accounted for 35.1% of the overall wearable technology market (Ipsos Mediact, 2014). The 2014 Consumer Electronics Show in Las Vegas, NV expanded 40 percent of exhibitor floor space to accommodate the massive number of wearable fitness devices and other digital health wearables (Faddy, 2013). Products such as glucose monitoring, contact lenses, vital sign monitoring (Shen et al., 2017), “second skin” (Yu et al., 2016), wrist bands that detect falls by elderly and automatically notify emergency services (Zhu and Cahan, 2016), and sleep monitoring pajamas for infants are all recent additions to the wearable healthcare technology market. Blood pressure monitors, electro cardiograms, body composition analysis, blood glucose meters, and even ultrasound scanners can now be connected to smartphones via apps (Pai, 2013). Life expectancy in the U.S. has increased by approximately ten years since the 1950’s, thanks to advances in healthcare (Huffington Post, 2013). This considerable increase in life expectancy results in a surge in the elderly population, and, as a result, demand for mobile healthcare has never been higher, and the elderly target consumer has never been more technologically savvy (Brandon, 2012).

In this paper, we undergo a comprehensive analysis of the wearable healthcare industry through examining its strengths, weaknesses, opportunities, and major threats that could curtail its growth. This SWOT examination uncovered the following important takeaways. First, although medical devices still make up a large chunk of the extant wearable technology market, the regulatory hurdles that inhibit adoption by healthcare professionals and consumers are likely to result in the healthcare wearable market’s slowdown in the coming years (Jeong et al., 2016; Transparency Market Research, 2015). Second, security concerns remain the most significant barrier to the growth of wearable healthcare devices because of the potentially disastrous effects of a security breach on patient safety (Davis and Khansa, 2016; Khansa and Zobel, 2014; Khansa et al., 2012, 2016). Thus, unless security and regulatory issues are properly addressed, technological innovations that increase the usability and convenience of healthcare wearables (e.g., tiny but long lasting power sources) will remain underfunded and underadopted. Lastly, before the healthcare wearable market can self sustain, considerable collaborative effort is needed on the part of industry innovators, healthcare providers, regulatory bodies, and governmental entities to resolve the lingering technological, societal, and regulatory impediments threatening the acceptance and adoption of medical wearables by healthcare professionals and consumers alike.

2. SWOT analysis of the wearable technology market

The appendix presents technologies that are currently being offered in the wearable healthcare industry. Based on this extensive product review and careful analysis of the peer reviewed literature, we discuss below a few of the wearable healthcare industry’s strengths, weaknesses, opportunities, and threats that it faces. SWOT analysis can be used by hospitals, policy makers, entrepreneurs, and companies to prioritize initiatives, create strategies, and adjust their positions in the market. The SWOT matrix assumes strengths and weaknesses are ‘internal’ to the specific entity under study (e.g., specific industry); whereas opportunities and threats are thought of as ‘external.’

2.1. Strengths

2.1.1. Competition driven innovation

There are numerous companies entering the wearable technology industry beyond the list accumulated in the appendix. This level of competition can drive creativity and innovation forward and provide some tailored solutions to a wide array of health concerns. This competition has also generated great interest in wearable technologies by skilled professionals, entrepreneurs, and investors, which leads us to the following point.

2.1.2. Availability of capital

Investment from corporations, angel investors, crowdfunding, and governmental grants have allowed startup companies, research organizations, hospitals, and inventors to hire skilled employees, acquire resources, and market their creations.

Qualcomm (https://www.qualcomm.com/), a company that creates foundational technologies for mobile devices, offers a TriCorder XPrize, awarding a total of $10 million to the best of three innovating teams. The stipulation is that the product must meet 15 health related requirements. This example is one of the many competitions that allow other entrants to find additional investors (Kosir, 2015b).

2.1.3. Synchronization with pervasive smartphones

Over 25% of the population already uses some form of activity tracking device (Tudela, 2014). Meanwhile, smartphones and smartwatches are continuously getting cheaper and prevalent in today’s economy. With the fall of Nike’s Fuelband from the market because of its inability to synchronize with other trackers, software applications, and mobile apps, the developer side of the industry has made a conscious effort to allow communications between systems. The release of the Apple iWatch and corresponding iHealth application made this effort even more dramatic. The iWatch quickly became the most popular smartwatch on the market, and its platform created an industry data sharing standard. Popular brands such as Polo Ralph Lauren, Nike, Adidas, and Under Armour are all integrating sensors into their products for athletes to track their movements and vitals, and improve their performances.

2.2. Weaknesses

2.2.1. Competition

Despite its ability to drive innovation, competition can cause less resilient startups to fall apart before they have a chance to market their products. The competition for talent alone allows wealthier companies to scoop up essential personnel from smaller companies, and in the process get a hold of their trade secrets and abilities to create new technologies. Numerous companies imply a large number of methods for data collection, different user interaction profiles, less integration between systems, and greater switching costs and learning curves for users on the consumer and healthcare provider ends.

2.2.2. Interference

Gordon E. Moore, co-founder of Intel Corporation, once postulated that “processing power doubles about every 18 months especially relative to cost or size” (Moore, 2015). This concept, now commonly referred to as Moore’s Law, has held true. As processors shrink in size and grow in power, wearable healthcare devices become smaller, lighter, and more capable. A wireless body area network (WBAN) is a sensor network that enables various medical sensors located inside or outside the human body to communicate seamlessly with one another, and integrate automatically with existing devices, such as smartphones (IEEE, 2015a, 2015b). However, as with any network, interference with other devices must be addressed, with the added challenge that the network (a person) is continuously on the move (i.e., mobile) (Darwish and Hassanien, 2011). Standing too close to a speaker, microwave oven, radio transmitter, or another WBAN could cause interference in the form of ‘network noise,’ data loss, or unwanted system resets.

Interference with other WBANs is of particular concern. Since WBANs share the same frequency ranges and communication protocols, network saturation can also be an issue. Consider two people traveling on a bus, each with a WBAN of wearable devices. Their close physical proximity would cause an overlap in the communication range of their WBANs. The 802.15.6 standard includes integrated mechanisms to prevent cross chatter and minimize interference in scenarios such as this (IEEE, 2015a). WBANs are time synchronized with the hub. A synchronization frame, called a beacon, is transmitted by the hub to the nodes to facilitate network management (IEEE, 2015a). The frame includes an indicator field that signals whether beacon shifting is enabled or disabled. When enabled, the beacon shifting index determines a time offset based on a beacon shifting sequence algorithm, and the beacon shifting sequence phase field is incremented by one (value of 0-15). This creates a repeating beacon sequence shifting pattern, unique to that time source, ergo that WBAN. Beacons also include a channel hop state indicator field and a next channel hop value. This defines a list of “8 bit encoded channels in the operating band in the order of their selection by a hub as the operating channel” (IEEE, 2015a).

2.2.3. Lack of interoperability and standardization

Related to the problem of interference discussed previously, interoperability remains one of the main concerns. According to the Pew Research Center, seven out of ten activity tracker users track some health activity; however, only 1 in 10 shares it with their healthcare provider (Fox and Duggan, 2013). Hospital IT systems and data tracking are behind many software companies because of the lack of investment in data collection and strict regulatory requirements for data security and consumer privacy. Drew Schiller, CEO of Validic, a healthcare IT provider in the U.S., believes interoperability could save $30 billion a year in medical costs in the U.S. alone (Schiller, 2015).

The Health Information Technology for Economic and Clinical Health (HITECH) act has helped drive the standardization of healthcare data terminology and encourage system interoperability (Davis and Khansa, 2016). This is vital to the widespread implementation and success of the wearable healthcare technology. If WBANs cannot interact with traditional healthcare databases and electronic health record (EHR) systems, their functionality is significantly restricted. For example, consider a wearable cardiac monitoring device for a patient suffering from intermittent heart palpitations. In order for the data produced by this device to be useful to care providers, it must be in a usable format, it needs to be accessible to the care provider, and it needs to be generated from a regulated and reliable source. Data standardization will ensure that these conditions are met. If wearable healthcare devices use data formats that can be assimilated into the providers’ systems, care
can extend outside of medical facilities and reach patients nearly anywhere. Data standardization includes several subcategories. First, common terminology and syntax must be established. The National Library of Medicine, part of the National Institutes of Health, has developed a number of health data standards (National Library of Medicine, 2015). They have come up with a list of standardized terminology and Common Data Elements (CDEs) for 11 different categories to date. Second, data exchange and storage methodologies must be standardized. Data formats, communication protocols, and user interfaces vary greatly between different healthcare agencies and equipment vendors. Something as simple as a difference in the data type of a single database column could cause a significant obstacle when sharing data between systems. If data is not stored in identical formats while being transmitted from one organization to another, then the exchange interface needs to be capable of detecting and interpreting the differences.

2.2.4. Power consumption

Another major challenge hindering the success of the wearable healthcare technology market is a physical barrier. No matter how minuscule, electronic devices, for the most part, require a power source. Ironically, as devices become smaller, it often is more challenging to provide long lasting, reliable power. Many wearable devices use lithium ion batteries. For devices with low power density requirements, these batteries work well and are available in paper thin strips and pin sized cylinders (Energy Harvesting Journal, 2014). For devices with moderate to high power density requirements, however, these batteries do not have enough energy density to support long battery life (Anthony, 2013). To help offset this problem, devices have become much more power efficient. Lower processor power requirements and communication protocols that consume less energy have helped devices continue to get smaller, regardless of battery limitations. For implantable devices, a new source of power is needed. Wireless charging and body heat fueled micro generators are two examples of alternate energy sources that are under investigation for wearable technology (Hannan et al., 2014).

2.3. Opportunities

2.3.1. Infant safety and health tracking

Baby health tracking has opportunities to prevent many serious issues and ease parents’ fears. Pregnant mothers may be able to wear an ultrasound type device to measure vitals and check for health issues in their baby before birth. Also, as an infant or toddler, vaccines or allergy medications could be easily administered through wearable patches or sleeves rather than going to a clinic for an injection. The ability to detect asthma attacks, seizures, breathing troubles and more could save many lives in the U.S. and abroad.

The next generation of baby monitors is significantly different from traditional “listening” devices. In the early 1930s, baby monitors did not exist. After the kidnapping of Charles and Anne Lindbergh’s 20 month old baby in 1932, infant safety moved to the forefront of nearly every American’s mind (FBI, 2015). The president of Zenith, Eugene F. McDonald Jr., asked his engineers to help him develop a system that would allow him to monitor his daughter’s room. The result was a two piece product that was commercially manufactured and that consisted of The Guardian Ear, a transmitter for the child’s room, and the ‘Radio Nurse,’ a receiver for the parent’s room (Onion, 2013). The product did not have much success, likely because it shared common frequency ranges with other devices and often picked up other broadcasts. The concept, however, eventually developed into what is now known as a common baby monitor. The next generation of baby monitors will be wearable devices. Intel has partnered with a company called Rest Devices to produce the Mimo Baby, a “smart onesie” (Glatter, 2014). The garment features two green sensor strips across the chest that monitor respiratory rate. Powered by a secure digital card sized Intel processor, the garment also features a removable turtle shaped device that attaches to the front. The removable portion monitors activity level, heart rate, and body temperature.

Sproutling is a product designed by former Apple and Google engineers, in collaboration with pediatricians (Paul, 2014). It is similar to a fitness tracker for adults: A sensor attached to a band is worn around the infant’s ankle. Similar to an adult fitness band, the device has a charger station and an accompanying app. The sensor detects heart rate, skin temperature, motion, and body position. The sensor itself is encapsulated in medical grade silicon, and has a unique kidney bean shape to lower the risk of choking if swallowed. The bands are washable and come in three sizes to grow with the infant. The charging station has multiple environmental sensors that can detect light and noise levels, as well as humidity and temperature. Both devices transmit data to the smartphone app which “learns” the infant’s habits over time. With extended use, the app will attempt to predict sleep habits, optimal noise, light, temperature and humidity conditions, and provide more accurate data about fluctuations in body temperature, heart rate, and respiration. The demand was so high for this product at launch that all units were sold out in the pre order phase, months before the product was released (Sproutling.com, 2015).

Besides offering convenience and peace of mind to parents, these next generation baby monitors may help prevent the third leading cause of infant death in the U.S., namely, sudden infant death syndrome (SIDS). Since about 1990, SIDS has been declining in the U.S. (CDC, 2012). The mortality rate of infants due to SIDS has dropped approximately by half in the past 15 years, thanks to awareness campaigns on risk factors, such as second hand smoke, sleeping positions, immunizations, and bedding (Safe to Sleep, 2013). SIDS is most likely to occur between the hours of midnight and 9:00AM, typically while parents are sleeping, with no noise or evidence of a struggle (Gilbert Barness et al., 2013). Real time vital sign monitoring would alert parents immediately of any sudden changes in their infant’s heart rate, respiration, or temperature (Fernandes et al., 2016). This may allow for faster response and medical attention, possibly reducing infant mortality rates. A wearable infant device called the Owlet is marketed as a “smart sock” (Rosenberg et al., 2016). It resembles a slipper and
has all of the sensors of the Sproutling, but with added oxygen level monitoring and a “roll over” alert (Kühlmann et al., 2016). This product was designed specifically to reduce the risks of SIDS (Owlet, 2015). The device can also function independently of the app, with light and sound alerts on the base station. Data from the sensors can also be accessed via a cloud-based web app.

2.3.2. Care for the elderly

With the aging of the baby boomer population, wearables can lower the number of visits elderly people may need to make to the doctor’s office and lower the costs and waiting times as a result (Khosravi and Ghapanchi, 2016). Khosravi and Ghapanchi (2016)’s systematic review identified eight conditions that drive the use of wearable devices in the elderly population, namely, “dependent living, fall risk, chronic disease, dementia, social isolation, depression, poor well-being, and poor medication management” (p. 17). Perhaps one of the more well-known wearable healthcare technologies is a medical alert device. Usually worn as a necklace or bracelet, these devices started out as simple “call buttons” that would alert a monitoring station if the wearer pressed them; for example, in the event that the wearer fell and could not get back up, or if he or she were experiencing symptoms of cardiac arrest (Harada et al., 2013). The main problems with these devices were that they had limited range and the wearer still had to manually trigger the alarm. If a fall occurred and the wearer hit his or her head and became unconscious, the device would be of no use. Modern systems now include much longer ranges, longer battery life, automatic fall detection, are water proof for use in showers or baths, and are even often linked to phone systems to allow for two way voice communication (Top Consumer Reviews, 2015). An example is a shoe tracker that can monitor Alzheimer’s patients, so they do not wander too far away from their facility and forget where they are (Constantini, 2014).

Fitness trackers have also found a surprising niche market among senior citizens. As the population ages, there is demand for devices that improve quality of living, increase autonomy for seniors, and delay the negative effects of aging (Yusif et al., 2016). Physical mobility is one of the most important facets of meeting these demands (Mischke, 2011). Fitness trackers encourage activity and include alarms that can be set to notify wearers when they have been stationary for a pre-determined period. The very nature of wearing a device that monitors and tracks movement encourages the wearer to be more proactive about increasing his or her activity level. Overall, wearable devices that encourage the elderly to remain independent and active have been better received by older adults than “gerontechnologies” that are specifically targeting their age group and that frequently contain stigmatizing features (Yusif et al., 2016). Furthermore, it has been reported that the elderly tend not to be reassured by the level of service of wearable healthcare, although they seem to appreciate the convenience and usefulness of the actual technology (Lee et al., 2017).

2.3.3. Health monitoring (e.g., chronic illness)

People at high levels of health risk can be tracked in the comfort of their homes. Whether they suffer from epilepsy, the risk of falls, heart disease, or breathing problems, patients can track their health data and communicate with their doctors remotely. Wearable technology can also be used in emergency situations where the technology can be scanned by doctors to find out if the patient has allergies to certain medications, especially when the patient is unconscious. The technology can detect emergency health conditions such as a heart attack or stroke and warn caregivers and emergency personnel.

Particularly, individuals suffering from chronic diseases may benefit the most from healthcare wearables (Milani and Lavie, 2015; Milani et al., 2016). A continuous glucose monitor is an excellent example benefiting patients with diabetes, one of the most insidious chronic illnesses worldwide (Despommier, 2013; Khansa et al., 2016). Blood glucose monitoring, vital to the health of a patient with diabetes, started in the mid 1960’s with a product called Dexcom (Mendoza, 2006). Before that time, glucose levels were measured via urine samples. With the Dexcom test, a drop of blood was applied to a paper strip which changed to a gradient of blue based on the glucose level of the blood sample. The blood was wiped off and the test administrator had to wait 60 seconds for a chemical reaction to occur. The strip then had to be manually compared to a chart to determine the approximate value. For obvious reasons, this method was not very accurate, especially if the person administering the test did so only occasionally. At a later time, the Ames Company developed a product called the Ames Reflectance Meter (A.R.M.) which reflected a beam of light off the blue strip (Mendoza, 2006). The reflected light passed through a photoelectric cell and moved a needle to give the user a more accurate reading. Since the light meter was much more sensitive than a human eye, it could provide a more accurate and consistent reading. Although an improvement over the strips alone, the A.R.M. device was heavy, bulky, and expensive. For patients with diabetes who needed to test blood glucose levels multiple times a day, this device was still impractical. Through the 1970s and 1980s, several competing blood glucose monitoring devices were introduced; each smaller, more accurate, and more cost-effective than the earlier ones. In 1987, the OneTouch meter was introduced (Clarke and Foster, 2012). It required the smallest blood sample yet, and the blood was applied to a strip that was already inserted into the meter. This feature led it to be marketed as a “second generation” blood glucose monitoring system or BGMS (Salam et al., 2016). The device also had an automatic timer and would display results to the user in 45 seconds. No washing or blotting was necessary, and the relatively sealed system added to the device’s accuracy. It was also one of the smallest and lightest models introduced at that time. By the 1980s, some blood glucose monitors offered applications that could be loaded on personal computers to store and track test data (Clarke and Foster, 2012). BGMS continued to improve: They were now lighter, faster, had longer battery life, required an extremely small blood sample, and had the capability to store more results. For patients with diabetes, however, using a BGMS required multiple finger pricks a day, which necessitated that the patient remember to administer the test at appropriate times; besides, administering the test could be awkward or embarrassing in certain settings. Continuous glucose monitoring sys
tems attempt to address these issues. Early continuous monitoring systems used tiny catheters that were inserted under the skin. They still required a conventional finger prick twice a day to calibrate. Several new methods for continuously monitoring blood glucose levels have been introduced since. The GlucoWatch G2 Biographer resembles a wristwatch and uses a biosensor, rather than a pin prick, to monitor glucose (FDA, 2013). Meanwhile, Google has been developing a contact lens that detects changes in glucose levels through tears (Hernandez, 2015).

2.3.4. Military and law enforcement
Military, law enforcement, emergency medical services, and firefighters could all benefit from vital tracking during emergencies or ‘a mission gone wrong.’ If a military or police officer on patrol is injured but cannot verbally connect with their base, the monitors could continuously send vital signs to the base instead to notify emergency response personnel. In the case of wildlife or mountain rescues, a wearable could provide emergency warmth or cooling, and air inflation, track stress levels, and send out a GPS location to emergency personnel (e.g., Krishnan and Kannan, 2016). Also, wearables could be used in the training of military and law enforcement personnel to track their vitals, reduce injury, and help them control their stress. They could also assist in simulations of emergency situations, thus speeding training time and making it more realistic.

Research and development of military related wearable technology have focused on two primary areas, namely, augmented reality devices and vital signs monitoring for combat troops (Kurillo et al., 2016). Sandia National Laboratories, a division of a major contractor with the Department of Defense, Lockheed Martin, has been developing a tiny biosensor to detect hydration and electrolyte levels for military personnel in field and combat conditions (Comstock, 2014). The device uses tiny subcutaneous needles to measure interstitial fluid. The needles are so small that they are almost undetectable by the wearer. As a wrist worn device, it offers truly continuous, passive, and noninvasive monitoring. This type of sensor has tremendous potential in other applications, such as for athletes. The researchers also believe that the device could be further developed to monitor the level of electrolytes in the wearer and help keep it within normal range (Comstock, 2014). The tiny needles that detect electrolyte levels could be used as transport for the exact electrolytes needed. This type of continuous monitoring and automatic administration of treatment is similar to the result achieved by the continuous BGMS mentioned previously.

2.3.5. Sports medicine
The criteria that wearable sensors must meet for athletes are similar to those of the military. Wearable devices must monitor vital signs, hydration, fatigue, and physical exertion. In 2013 a biosensor was tested on humans that measured lactic acid levels in perspiration in real time. The device looks similar to a temporary tattoo (Jia et al., 2013). Lactate forms when an athlete’s muscles require more energy than the body is able to supply. The body “shifts to anaerobic metabolism, producing lactic acid and lactate” (ACS.org, 2013; Jia et al., 2013). This shift only provides a temporary boost because lactate builds up in the body, causing extreme fatigue to a point where suddenly an athlete cannot continue. The sensor would warn the athlete or trainer before this point, and allow for temporary rest and recovery. The device is also useful for tracking historical stamina and fitness during training and actual performance. Electrode stimulation, heat, cold, or massagers can aid in muscle recovery, prevent blood sitting in the legs when someone is bedridden, improve muscle performance, and reduce recovery time post surgery.

2.3.6. Preventive medicine
Wearables can track sun exposure to remind the wearer about applying sunscreen. In addition, they can warn of over training, improve sleep, and measure nutritional deficiencies. In sports such as football, wearable sensors can be inserted in pads and helmets to prevent heat strokes and concussions. Major League Baseball pitchers and hitters could make use of sensors on their sleeves and hands to monitor stress on their joints. In the general population, back pain alone accounts for 149 million missed days of work and, according to the CDC in 2010, is the second leading reason for doctor visits (behind respiratory illness). (PainDoctor, 2016) This type of tracking can prevent back, shoulder, hip, and knee injuries and potentially reduce the need for expensive surgeries.

2.3.7. Integration and EHR implementation opportunities
The emergence of wearable technologies and their use in medical practice may assist hospitals in their tracking of at-risk patients and monitoring of staff movement and flow in each hospital shift. In a Bloomberg News interview, Florida Hospital Celebration Health Director, Ashley Simmons, shared how they used wearable technology to track their care team and reduce patient wait times in the ER (Bloomberg, 2016). In the same Bloomberg interview, Ashley Simmons indicated that system management costs more than the software and technology themselves, but it aided the hospital in optimally allocating staff time to better serve patients, while also attending to other duties. It could also make physicians and nurses safer by measuring their energy levels so they can avoid slips while providing care. The software communication methods used by these wearable technologies, if effectively integrated with current EHR systems, and can make them more efficient and user friendly.
2.3.8. Research benefits

In the medical research field, doctors, nutritionists, and other researchers are constantly attempting to gather more data on their subjects and monitor their compliance with study requirements. Wearables allow researchers to gather continuous and unbiased data on any number of bodily metrics and signal to the research subjects when it is time to eat or take a pill. One example is the researcher whom one of the authors interviewed for this research at a university in the Southwest U.S. (The University and the researcher are purposefully anonymized). The researcher studies the impact of dark chocolate on the human body. Part of her data collection consisted of operating a $100,000 DEXA machine for which she had to take a class and pass a test. Further, her university had to pay for a license indicating they would follow the rule of having devices with radiation on their campus (Anonymous Researcher, 2016). Because of the cost of the DEXA machine and the lengthy approval process, only a maximum of 800 individual scans are possible per year. In the case of her study, each research participant had to be scanned up to four times, meaning she could only conduct the study with a maximum of 200 participants in one year if the machine were to run full time (Anonymous Researcher, 2016).

2.4. Threats

2.4.1. Security and privacy

Data security is always a concern for any networked technology. Striking a balance between data availability and confidentiality has been a challenge for the information technology (IT) community since before the advent of the Internet. When applied to medical devices, patient privacy and, even more critically, patient safety are at stake. A diabetic security researcher named Jay Radcliffe successfully hacked an insulin pump and then shared his findings on the vulnerability he discovered at the Black Hat computer security conference in Las Vegas, NV in 2011 (Associated Press, 2011). Mr. Radcliffe found that not only was he able to remotely control the insulin pump from up to 200 feet away, but he was also able to manipulate a wireless blood glucose monitoring device. By broadcasting data with a stronger signal than the actual monitoring device used, he could orchestrate an attack in the middle or replay attacks and display false readings. These two findings have grave implications. First, they demonstrate the possibility of hacking an insulin pump to administer a potentially lethal dose; and second, they prove the possibility of projecting false blood glucose monitor readings, potentially preventing a vital insulin dose from being administered.

In IT security, risk is often calculated using the formula Risk = Threat × Vulnerability × Impact (Jacobsson et al., 2016; Harris, 2010). In other words, vulnerabilities are only one part of the equation; a valid threat must also exist, and its impact must be significant to pose a risk. Obviously, any threat to the safety of human life would have a disastrous impact if realized, and the threat of a given vulnerability being exploited is very real as well. During the first half of 2015 alone, two major data breaches affecting health insurers Anthem and Premera Blue Cross compromised the data of over 90 million people (McCue, 2015). The black market value of stolen health credentials can sell for $10 each, or about 10–20 times the price of a stolen credit card number (Hummer and Finkle, 2014). Hackers are actively seeking new ways to steal data and identities. The new attack vector of WBANs needs robust security to safeguard the user. The 802.15.6 standard (IEEE, 2015a, 2015b) also includes guidance for authentication and encryption of WBAN data transmissions. Security levels are broken down into three categories: Level 0 Unsecured, Level 1 Authentication Only, and Level 2 Authentication and Encryption. The standard requires Advanced Encryption Standard (AES) with 128 bit keys for Level 2 transmissions. Authentication is accomplished via cipher based message authentication code (CMAC). Wearable healthcare technology should comply with IEEE 802.15.6 2012 standards and meet Level 2 security criteria, at a minimum.

2.4.2. Regulatory compliance

Medical devices must acquire approval from the Food and Drug Administration (FDA) before doctors start prescribing them unequivocally. Without such approval, there may also be a stigma attached to the devices that make doctors and patients question their reliability. The framework for FDA approval is sometimes too challenging for smaller IT companies to navigate, and too expensive for large companies to readily adopt. In fact, despite being leaders in wearable consumer technology, it was not until 2014 that corporate giants Samsung and Apple announced plans to venture into the healthcare sector (MDDI, 2014).

Further, since wearable technology is a convergence of research and development from multiple sectors, companies that develop these devices are now facing new challenges related to having to develop user-centric interfaces and meet new security requirements. Layered security is always the best approach to safeguard systems and data, but it is nevertheless more complicated with WBANs. For example, physical security measures, such as locks, Faraday cages, and security guards, can be implemented for a server room in a hospital. None of these controls apply to devices that are carried on someone’s person. A next generation firewall can be a daunting challenge for a hacker attempting to gain unauthorized access to a traditional LAN, but this measure is not practical for a WBAN. In contrast, companies that have long developed consumer electronics and mobile devices are much better equipped to handle user interface and security concerns.

The challenge for these companies remains regulatory compliance (Barick et al., 2016). Laws such as Health Insurance Portability and Accountability Act (HIPAA) and HITECH heavily regulate how healthcare records are handled, transmitted, and stored. Like the FDA approval process, HIPAA regulations make prescribing and providing wearable technology and monitoring devices difficult. When healthcare providers supply a device, they are legally obligated to keep patient data secure which may limit many patient benefits such as viewing their health information on their smartphones. Also, many of the
devices synchronize to a smartphone or transmitter device using Bluetooth Technologies. Bluetooth, unfortunately, is one of the least secure forms of electronic communication, and any Bluetooth device nearby could connect to a Bluetooth receiver and potentially steal information. Oftentimes Bluetooth requires a physical proximity; however, Bluetooth range boosters are now incredibly popular tools for hackers.

2.4.3. Cost of system operation and management

Many of the consumer directed products are priced between $200 and $400, which puts these devices out of reach for many low income families when there are no clear, immediate benefits. Most devices are not medical in nature, and many medical insurers will not pick up the costs unless there is a direct medical need or a prescription by a doctor. The costs of managing these systems by healthcare IT professionals may also scare hospitals from investing directly in implementation.

2.4.4. Wearable healthcare adoption challenges

With change comes the fear of the unknown and doctors may be uncomfortable putting more information in the hands of patients when there is so much misinformation already coming into their practices. The traditional routine of meeting with patients regularly may make the care seem impersonal and robotic. Many doctors entered the profession to help people, and they may fear that the wearables make patients feel like a group of numbers rather than people with needs.

Further, like any new application or purchase, there comes the risk of patients not using the device or information to its full capabilities. It is a reason so many weight machines and elliptical sit dormant in rooms and basements across America and why diets are started and stopped over and over again with limited or no weight loss results. When it comes to wearable technology, one third of users stop using their device after six months (Constantini, 2014). This could be because these devices have served their purpose of inducing the desirable change in user behavior, or users have grown bored and stopped making them part of their daily lives.

3. Main takeaways from SWOT analysis

3.1. Wearable healthcare device market growth

Although medical devices still make up over 35% of the current wearable IT market, their stake is forecasted to shrink in coming years (Transparency Market Research, 2015). This is mainly due to the explosive growth in other areas, such as smart watches, active baby monitors, and fitness trackers, rather than because of a stagnation or decrease in the demand for or innovation in medical devices. Wearable healthcare devices, and especially implantable medical devices, are still projected to grow at a rate of 300-500% by 2018.

3.2. Solutions for chronic illnesses

Two of the most intriguing products that our survey revealed are the aforementioned contact lenses under development by Google, and a "temporary tattoo" that is being tested by scientists at the University of California, San Diego. The tattoo is designed to be worn for a day and contains a tiny sensor that detects changes in glucose levels (Wasserman, 2015). The researchers plan to use Bluetooth to transmit data directly to the wearer's healthcare provider or to a cell phone app. The concept of a WBAN of medical devices that are linked to a smartphone is a feasible healthcare option for other chronic illnesses as well.

3.3. WBAN communication security

Our research revealed that many of the controls that security professionals rely upon to apply "defense in depth" are not possible or practical for WBANs. The risk is also greater for wearable healthcare technology. If a fitness tracker is hacked, it could as a worst case scenario result in identity theft. Meanwhile, if a wearable healthcare device were to be hacked, it could lead to patient death (Associated Press, 2011). Security must be intrinsic to the design of wearable healthcare devices. Further, wireless communication standards must include robust encryption standards. As such, security remains the most significant barrier to the growth of the wearable healthcare market.

3.4. Power sources

It seems that many advances in technology are slowed or even prevented by the limitations of available power sources. Wearable devices have shrunk to the microscopic level now, and finding ways to provide them with power is a challenge. The issue is twofold for wearable technology: First, finding power sources with enough energy density to last more than a few days or even hours; and second, finding power sources that can be scaled down to near microscopic levels for implantable devices. One fascinating technology that is being developed is a new type of lithium ion battery by researchers at the University of Illinois at Urbana Champaign. Their battery is about 2000 times more powerful that other lithium ion versions.
It also can be recharged in about a second. Unlike a typically solid, two dimensional graphite anode and a lithium salt cathode, the new battery has a porous, three dimensional anode and cathode. This creates a massive surface area that allows for more chemical reactions to occur in a given space, thereby providing an immense boost to power output and charging speed. Another avenue for powering wearable technology is through avoiding the need for batteries altogether, and, instead, relying on renewable energy. Researchers at the Korean Advanced Institute of Science and Technology (KAIST) have developed an incredibly thin thermoelectric power generator, printed on a transparent fabric (Phone Arena, 2014). It converts body heat into a usable power source, and according to KAIST, it produces about 10 times the energy output of earlier devices using similar technology. Although still not ready for commercial production and widespread use, the research is promising.

4. Conclusion

The wearable technology industry is young and unpredictable: it came from a natural progression of popular mobile technologies enabled by creative and technologically savvy engineers, programmers, and designers and supported with a tremendous amount of capital and consumer demand. This industry is a creation of the free market that could have profound benefits to the healthcare community if implemented correctly. Wearable technology is poised to explode in the next decade. The move to EHR systems in the healthcare industry is propelling data standardization and interoperability, both key to the success of wearable healthcare devices. Data security and privacy will continue to pose challenges for developers (Cheng and Mitomo, 2017; Li et al., 2016), but industry standards and governmental regulations can help ensure control measures are built in and enforced. Power sources are another barrier to the advancement of wearable technology, but several promising research projects may provide new avenues to power wearable devices in the near future.

Swelling consumer demand for wearables will likely encourage more companies to pursue the development of wearable healthcare devices. The emergence of wearables and medical tracking devices may be arriving at the right time, especially given the largest retirement age population in U.S. history and the higher than ever patient expectations for better healthcare. It would take tremendous efforts and considerable capital for wearables to adapt culturally, operationally, and legally at community, state, and federal levels to implement the technologies quickly and train skilled workers who can manage the systems and data. The federal government could play a vital role in fueling further innovation in wearable healthcare technologies, much as the HITECH Act incentivized the adoption of EHR systems.

Appendix: Overview of wearable healthcare products

The wearable technology industry has several unique target demographics that are within the entire spectrum of total health. We will cover products that mostly benefit those considered in peak condition such as athletes, military, and emergency personnel in training, products to help those who may have some ailments or health risks such as back pain or high blood pressure, and products for those who are at greater health risks such as the elderly and infants.

Athlete and activity devices

**LumoBodyTech:** Lumo offers several products such as the Lumo Run and Lumo Lift that offer shorts, capris, and sensors for measuring run cadence, ground contact time, pelvic rotation, stride length, posture coaching, and more. They have several options for sensors and offer discounts for teams, offices, and family tracking. Website: lumobodytech.com

**Hexoskin:** Hexoskin Smart Shirts are compression shirts for men and women that collect heart rate, breathing, and movement data. The shirts are connected to popular smartphone apps for customers and athletes to track and improve their performance. Website: hexoskin.com

**OMSIGNAL:** OMSignal develops body scanning technologies and provides them to other clothing brands such as Polo Ralph Lauren and debuted the smart shirts that track biometrics at the U.S. Open in 2015. They also sell shirts and their newest product is a bra that measures distances run, breathing rates and heart rate, and recovery. Website: omsignal.com

**Athos:** Athos is based on medical technology that measures muscle effort, heart rate and breathing and uses the app to help exercise and avoid injury. Website: liveathos.com

**Sensoria:** Sensoria Running Socks measure pace, distance, time, and running style through measuring pressure from the user's foot. Website: sensoriafitness.com

**Samsung:** Samsung offers several wearable technology products including the NFC Suite that allows users to unlock their phone, swap business cards, and set gadgets to office and driving modes; a Body Compass workout shirt that measures bio-metrics; and a golf shirt that tracks UV ratings and weather. Website: samsung.com/us

**Thin Ice Smart Vest:** The Thin Ice Smart Vest 2.0 is on Kickstarter and claims to be able to cool the body throughout the day to allow brown fat (essential fat) to actively burn white fat (nonessential fat) so the wearer can burn calories at all times and lose weight. Website: https://www.wearable.com/smart-clothing/thin-ice-system-weight-loss-clothing-line-2710

**Heddoko:** This company makes a shirt that they describe as a "wearable motion capture for ergonomics and sports." They claim it to be "a[n] injury prevention solution with fully integrated sensors that capture your every move in 3D." Website: heddoko.com
Clothing+: Clothing+ has offices in Finland and Hong Kong. It has become a go-to supplier for athletic apparel companies. It has contracted its total Heart Rate Monitoring (HRM) devices with Adidas, Under Armour, and Garmin. **Website:** clothingplus.com ( Sawh, 2016)

**Medical and health-related devices**

**Clothing+:** The medical tracking devices supplied by Clothing+ include a liquid accumulation vest, chest belt, and light therapy blanket. These devices can detect posture, motion, respiration, and body temperature and store the generated data online so a patient’s physician can view them remotely. If the device suspects an arrhythmia or ischemia, it will notify the doctor automatically (medGadget Editors, 2015). **Website:** clothingplus.com

**Health Watch:** Heart Activity Shirt by Health Watch Technologies sends data to a patient’s phone and their doctors via Bluetooth. It has a twelve lead ECG and a pocket for the transmitter in the shirt. The Shirt can detect an arrhythmia or a fall and could be adapted for women who may have high risk pregnancies. The MasterCaution Device (MCD) in the shirt holds up to 72 hours of recordings (Tech Research Team, 2015). **Website:** personalhealthwatch.com

**Smart Sensing:** Smart Sensing is a company within the Citizen Sciences consortium that enables the technologies in wearable devices. It initially began with the intention of creating a more convenient method for blood pressure testing and other heart health signs. **Website:** smartsensing.fr/en (Merlien Institute, 2014)

**Xsensio:** This Swiss company is focused on running technology and “nanowearables” or tiny intelligent stamps on the skin that generate ECG readings, core body temperature, and hydration levels. It is heavily investigated in research. **Website:** xsensio.com

**Cancer Detecting Clothing:** Started by a man in Minneapolis, MN, who lost an uncle to cancer, the company created a device that is still in its early stages, but the potential is “endless” and includes the ability to detect pneumonia. **Website:** cancerdetectingclothing.com ( Kosir, 2015a)

**Health Care Originals:** Intelligent Asthma Management by Health Care Originals created an automated device for asthma monitoring and management or ADAMM. It will alert if the patient is experiencing an asthma issue, it will journal records, display treatment plans, and track information on the treating of a patient’s symptoms. It easily allows patients to view information online or on the smartphone app. **Website:** healthcareoriginals.com

**Valedo Back Therapy:** A small device attaches to a person’s lower back; users can follow a companion application on their television or mobile device that uses over fifty therapeutic exercises with video game-like interactions for back therapy. **Website:** valedotherapy.com/us_en/

**Quell Relief:** Quell Relief offers a knee brace and leg wrap type device that uses electrode pulses to aid in pain relief for over 40 hours before needing to be charged again. **Website:** quellrelief.com/

**Vital Connect:** HealthPatchMD by Vital Connect tracks heart rate, breathing, temperature, steps, and even body position to detect if a person suffers a fall. It is one of the only medical devices approved in the U.S., Canada, and Europe for use inside and outside a hospital or medical setting. **Website:** vitalconnect.com

**Chrono Therapeutics:** Smart Stop by Chrono Therapeutics aids consumers in their efforts to quit smoking. It delivers medication when a patient shows signs of being in need. **Website:** chronothera.com

**Cloud DX:** This company offers the Vitaliti Platform that looks like headphones draped around a patient’s neck to track vitals including heart rate, respiration, blood pressure, oxygen, movement, and temperature. The app can assist with information on mobility exercises, feedback on posture, and ways to eliminate stress. **Website:** http://www.clouddx.com/vitaliti.html

**Cycadia Health:** The ITBra by Cycadia Health tracks breast health and can detect cancer risks and abnormalities. It has been tested on 500 people with an 87% success rate. **Website:** cycadiahealth.com

**Abbot Diabetes Care:** Abbot has a glucose monitoring system which uses a sensor on the upper back of a patient’s arm for two weeks without the need for finger pricking. **Website:** abbotdiabetescare.com

**ISonohealth:** The ISonohealth ultrasound device attaches to the inside of a patient’s bra and uses a machine learning algorithm to scan for breast health issues in one to two to three minutes each month. **Website:** isonohealth.com

**Leaf Healthcare:** Leaf Healthcare’s Ulcer Sensor is a simple stick on device used in nursing homes and hospitals to let nurses know when patients need to turn or move to prevent ulcers and to track patients during their hospital stay. **Website:** http://www.leafhealthcare.com/

**QardioCore:** An ECG Strap and EKG monitor free from patches and wires that wrap around a user’s torso. It uses a 3 lead wireless EKG/ECG, and tracks body temperature, respiratory rate, activity rate, heart rate and HRV, and stress. **Website:** www.getqardio.com

**Empatica:** Empatica created the Embrace to monitor physiological stress, arousal, and sleep and physical activity using medical grade sensors. Most importantly it can sense a seizure or epilepsy shock when it occurs to a child or elderly person. **Website:** empatica.com/product_embrace

**Biolinq:** Biolinq, formerly known as Electrozyme, creates skin applied electrochemical sensors that look like tattoos to analyze body fluids and provide actionable health information. **Website:** biolinq.me

Baby tech

Mimo: The Mimo Smart Baby is a green turtle shaped monitor on a baby onesie that tracks sleep status, breathing, body position, and also allows for parents to listen in on their infant. Website: mimonbaby.com

My Sensible Baby: A baby vital tracker that is low energy, uses a small amount of battery, and could be used on a sock or onesie. Website: mysensiblebaby.com

MonBaby: MonBaby can track sleep patterns, positions, and orientation and forward the information to the parents’ smartphone. The circular sensor attaches to the chest of a baby onesie or shirt and can still be used as the baby grows. Website: monbaby.com/

Owlet Care: Owlet is a bootie sensor and alarm to track a baby’s heart rate, breathing, and sleep with pulse oximetry, a technology that has been used in hospitals for decades. Owlet is a collaborator on a $1.5 million grant from the National Institute of Health. Website: owletcare.com

Neopenda: Neopenda, a New York company, developed a smart baby hat to measure temperature, heart rate, respiratory rate, and blood oxygen saturation. It is designed for nurses to track up to twenty four different babies in a clinical setting with the data synced to one monitor for nurses to view. Website: neopenda.com (Kosir, 2015b)

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