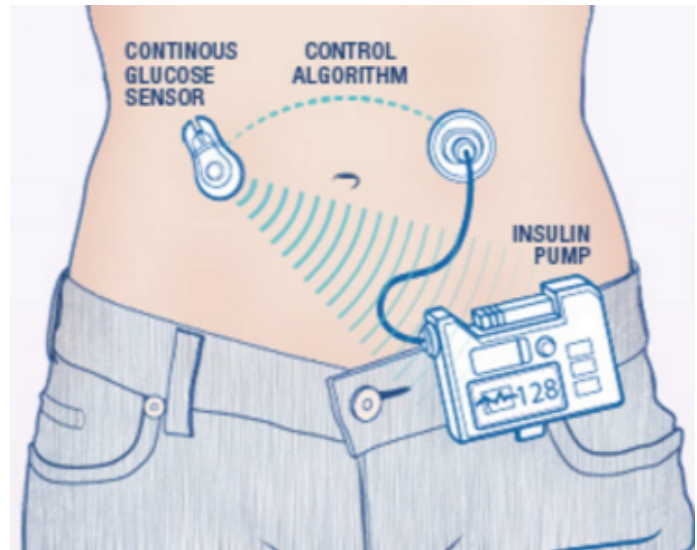


Supplemental Material: A. Briefing sheets shared with participants and used in role-playing game.

Artificial Pancreas

The human pancreas naturally supplies a low, continuous rate of insulin, known as basal or background insulin. In patients with diabetes, the body's ability to produce or respond to insulin is impaired.

According to the U. S. Centers for Disease Control and Prevention, approximately 5% of people with diabetes have type 1 diabetes. Also known as juvenile diabetes, type 1 diabetes is typically diagnosed in children and young adults. Because the pancreas does not make insulin in people with type 1 diabetes, patients have to consistently monitor their glucose levels throughout the day and have insulin therapy through injection with a syringe, an insulin pen or insulin pump to avoid becoming hyperglycemic (high glucose levels). In addition, management of type 1 diabetes includes following a plan for healthy eating and physical activity.



An “artificial pancreas,” is a technology intended to adjust insulin levels with little or no input from the patient. It works by measuring glucose levels every five minutes and automatically administering or withholding insulin. The system includes a sensor that attaches to the body to measure glucose levels under the skin, an insulin pump strapped to the body, and an infusion patch connected to the pump with a catheter that delivers insulin. While the device automatically adjusts insulin levels, patients need to manually request insulin doses after eating meals with substantial carbohydrates.

Medtronic's MiniMed 670G hybrid closed loop system, automated insulin delivery device for type 1 diabetes, was approved by the FDA on September 28, 2016 for people 14 years of age and older. Since this is a closed loop system, only the patient will have access to the information. Other companies are developing similar systems, and there is active research both in academia and industry on improving the efficacy of these systems.

Some known risks and limitations of the device include: hypoglycemia (dangerously low blood glucose due to over-infusion of insulin), hyperglycemia, as well as skin irritation or redness around the device's infusion patch. Medtronic's version of this device is unsafe for use in children 6 years of age or younger and in patients who require less than eight units of insulin per day.

What questions does this technology raise for your character?

Technology Enabled Medical Precision Observation (TEMPO) to Monitor the Risk of Falls

Annually, over 18,000 elderly adults die from falls or fall-related injuries. With a growing elderly population, 25% of US healthcare costs will be allocated to medical care for the elderly. Of that total an estimated \$8.37 billion will be spent on treatment for debilitating falls. Lethal falls are caused by



postural imbalances and movement impairments that result from nerve degeneration.

Postural imbalances are traditionally monitored through clinical observations, questionnaires, and validated functional tests. Current monitoring systems are time consuming, require the presence of trained medical staff, or can be inaccurate to the extent that they rely on patient's memory to avoid behavior that leads to harmful falls.

Technology-Enabled Medical Precision Observation (TEMPO) is a device that can be worn on various parts of the body and uses microelectromechanical systems (MEMS) based sensors, data processing and storage, and wireless communication to measure movements associated with daily activities. ASSIST researchers are working to create ultra-low-power electronics and energy harvesters that would allow the TEMPO device to be self-powered.

TEMPO is capable of motion-capture of up to six degrees of freedom, allowing healthcare professionals to remotely monitor the motion and activity of elderly, independent living patients to predict and prevent falls. In this way, data would be transmitted from the wearable device to a healthcare database and periodically reviewed by physicians who are responsible for monitoring patients. This technology can also be applied to monitor the health of patients with cerebral palsy, Parkinson's disease and multiple sclerosis, all of which affect patients' movements.

What questions does this technology raise for your character?

Gait Tracker Shoe for Accurate Step-by-step Determination of Gait Parameters

The Gait Tracker shoe provides insight into the variability of specific gait patterns associated with frequent injuries in the lower extremities of adolescents and with syndromes that affect the elderly. In plain terms, this device monitors the movement of the patient as they walk and tracks fluctuations in their gait. One goal of the Gait Tracker is to assess the progress made during a lower extremity injury recovery process in adolescent patients. Another goal is to predict the early symptoms of strokes and alert the user to seek immediate medical attention. It may also prove useful in the detection of degenerative diseases, such as Parkinson's, in elderly patients sooner than current clinical methods allow.



The Gait Tracker integrates a low-power and ultra-lightweight inertial measurement unit (IMU) into the shoe soles. When the user wears the Gait Tracker shoe, the IMU in the sole records the gait-related inertial movements and transmits them, wirelessly, to an aggregator via a Bluetooth Low-Energy (BLE) device. After receiving data, an algorithm (software on the aggregator) identifies gait phases and calculates the gait to detect any irregularities in an individual's stride.

The Gait Tracker provides unobtrusive, continuous, and accurate step-by-step measurement of an individual's gait. A prototype device is being used to collect data and is in the process of being improved for further model validation and other tests to improve the design. Moving forward, a smartphone app will be developed to support out-of-lab gait monitoring.

The primary limitations and concerns of this device include size and power consumption. The limited space available in the shoe sole restricts the physical circuit board size as well as the size of the power supply. These two design challenges are the research team's current focus. Additionally, in an effort to minimize the cost of the device, components are all commercial off-the shelf products, however cost remains an issue.

It is not clear yet whether the Gait Tracker has the power to act as a stand-alone diagnostic medical device, since it may prove useful to predict early onset of a stroke. It is also unclear where the data will be stored, what exact data will be stored (i.e. GPS location, movement, force, etc.), and who has access to that data.

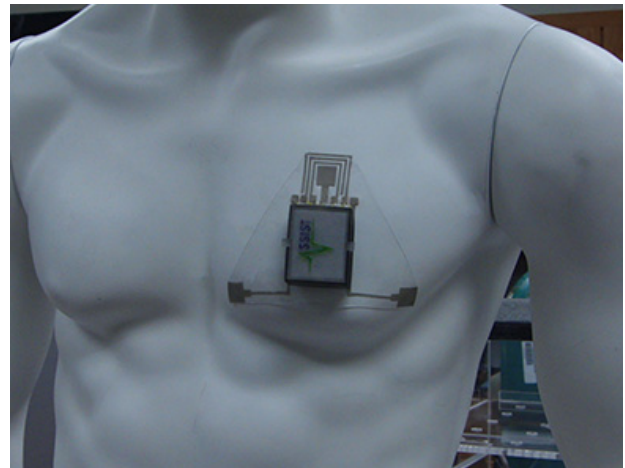
What questions does this technology raise for your character?

Health and Environmental Tracker (HET) for Patients with Asthma

The Health and Environmental Tracker (HET) is composed of a suite of new sensor devices and was developed by researchers at ASSIST. This wearable device is a system of sensors that monitors a user's environment, heart rate and other physical attributes in order to identify conditions that cause an asthma attack. The hope is to one day be able to predict conditions that spark an asthma attack and alert the user in time to prevent it from happening.

According to the U.S. Centers for Disease Control and Prevention, asthma affects more than 24 million people in the United States. Asthma patients currently rely on inhalers to deal with their symptoms, which can include often-debilitating asthma attacks. The goal is to design a wearable device that tracks the patient's wellness and provides them with information that helps to predict asthma attacks. This would allow users to take steps to prevent the onset of asthmatic responses to the environment by providing advance warning of when they enter an environment that may trigger an asthma attack. This would allow the patient to change their activities or move out of that environment.

The HET consists of a patch that adheres to the chest, a wristband, and external self-powered spirometer that the patient breathes into several times a day to measure lung function. The spirometer feeds lung function data into the system, which is then processed. This device demonstrates power consumption levels that are in the sub-milliwatt levels by using nano-enabled novel sensor technologies, resulting in a long battery life (which means it needs to be charged less often).



This device is currently in the prototype stage, and data collection is underway to validate the underlying models and inform subsequent designs. Researchers began testing the HET on a small user population in the summer of 2016.

What questions does this technology raise for your character?

Wearable Sensor for On-patient and Long-Term EKG and EMG Monitoring

ASSIST researchers have developed a wearable sensor capable of detecting electrophysiological signals such as electrocardiography (EKG) or electromyography (EMG). These detection methods are typically only used in a hospital setting to monitor the electrical activity of a patient's heart and muscles, respectively. Traditional sensors use "wet electrodes" that improve the strength of the electrical signal through an electrolytic gel placed between the sensor and the patient's skin. However, they are not ideal for long-term monitoring because the conductive gel dries out, the patient's skin can become irritated, and the sensor's accuracy is reduced.



Researchers used silver nanowires to create highly conductive and elastic conductors. The technology consists of nanowires integrated into a stretchable polymer that is placed into contact with the patient's skin in the form of a wristband. The stretchable nanowire polymer conforms to the patient's skin, providing even and accurate sensing even when the patient is in motion. Additionally, the nanowires are highly conductive, which is how they are able to maintain high signal quality without the use of wet electrodes.

The goal for this technology is to offer higher quality EKG and EMG data collection while also ensuring efficacy, efficiency, and portability for the patient. Data transmission would occur between patient and doctor through this device. It remains unclear how the data is transmitted, where data is stored, who has access to it, and whether this method will be used to diagnose patients for a particular condition.

Some limitations of this technology include that this device is still in its preliminary stages of development and is costly to manufacture. It is also unclear of the market size for this particular device.

What questions does this technology raise for your character?

Supplemental Material: B. Character cards. These card were used during the role-playing game. Note: the color of the card was associated with one group at each table.

Henry Lee



Age: 8 months
Sex: Male
Ethnicity: Mixed (White and Korean)
Hometown: San Fransisco, California
Occupation: Newborn

Henry is a healthy infant, but his parents are not wealthy and must rely upon public clinics for neonatal care. His grandparents used to take care of him a couple of times a week, but recently his grandmother suffered a bad fall, so they aren't able to help out as much as they used to. Henry's parents are faced with caring for an infant and their elderly parents.

Special rules: After introducing himself, Henry can only ask questions.

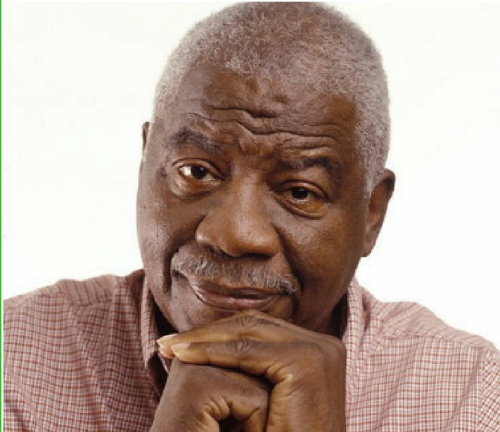
Marcus Henderson



Age: 33
Sex: Male
Ethnicity: Black
Hometown: Washington, D.C.
Occupation: Speaker/ Patient Activist

At 17, Marcus was diagnosed with a rare genetic disease. He has been working with a nonprofit organization that aims to promote research on treating rare conditions, and works to advocate for the rights of those patients. He works at the Mission House in DC. He's all for technology that will help patients, but is concerned about issues of informed consent, comfort and autonomy. He doesn't want patients to be coerced into using technology they don't understand just because they are dependent upon others for care.

Nolan Thompson



Age: 59
Sex: Male
Ethnicity: Black
Hometown: Baltimore, Maryland
Occupation: V.A. Hospital, Administrator

Nolan is interested in deploying this wireless technology to veterans that are over eighty years of age and living at the VA-Hospital. He is considering many of the data security issues and working to understand how third-party verification protocols can be integrated into the device's design. He is also concerned about how some of the patients will respond to the new technology.

Vincent Castillo



Age: 34
Sex: Male
Race/Ethnicity: Hispanic
Hometown: Houston, Texas
Occupation: Medical Device Technician

Vincent used to work at a large hospital that maintained databases. Recently, he was offered a job to work for a start up company that wants him to be an on-call technician to handle the operations of in-home wireless medical devices. He would be responsible for trouble-shooting data transfer issues with clients.

Paul Brewer



Age: 23
Sex: Male
Race/Ethnicity: White
Hometown: Cincinnati, Ohio
Occupation: Unemployed

A recent college graduate, Paul did well in school but was unable to find a job after graduation and is burdened with a significant amount of student debt. He lives at home with his parents and relies on their health insurance. He thinks this new tech is pretty cool, but is a little skeptical that older folks will ever "get it". He thinks the younger generation may have to make some decisions for them, or else simplify the explanations enough for the choices to be understandable.

Carol Lyon



Age: 85
Sex: Female
Ethnicity: White
Hometown: Wilmington, Delaware
Occupation: Retired

Carol has recently been diagnosed with early stage Alzheimer's. She requires full time care, and lives in an assisted living facility. She is still thinking clearly now, but she needs to make a few decisions now for her future self. Does she want to consent to using this technology? She isn't quite sure what it does, and doesn't really like the idea of wearing something medical all the time. Also, will she even remember what it is they are using on her a year from now?

Barbara Holmes



Age: 63
Sex: Female
Race/Ethnicity: White
Hometown: Frederickburg, Maryland
Occupation: CEO of large pharmaceutical company

Barbara is Carol Lyon's daughter. With her considerable medical expertise, Barbara feels qualified and justified in making health decisions for her aging mother, but Carol can be stubborn and uncooperative. Barbara thinks this technology is an excellent idea, and it would give her considerable peace of mind to know that her mother was well cared for even if Barbara can't be there herself. She plans to tell the assisted living facility to go ahead and use the technology even if her mother says no.

Li Jun



Age: 19
Sex: Female
Race/Ethnicity: Asian (Chinese)
Hometown: Beijing, China
Occupation: College student

Born and raised in China, Li Jun is living in the US while she completes her undergraduate degrees (she is double majoring in economics and international affairs). Jun comes from a culture with a strong traditional of caring for the elderly. She thinks this tech might help do just that, but she worries that caring for the elderly is losing the human touch. Although she also would like to have an App that gives her data about her grandparents health back in China.

William Hoffstader



Age: 5
Sex: Male
Ethnicity: White
Hometown: Weston, Massachusetts
Occupation: Private preschool student

Will suffers from type-1 diabetes, but receives excellent medical care. His parents are very loving, but can be a bit overprotective. They want the best and newest treatments for Will, and do not think any level of risk to him is acceptable. Will fears the needles and finger pricks, not to mention the constant monitoring of his overbearing father. His day is a stay-at-home parent who watches Will ceaselessly. Will wants to go and play and be a regular kid.

Special Rule: After introducing himself, Will can only ask questions.

Susan Lischner



Age: 31
Sex: Female
Ethnicity: White
Hometown: Seattle, Washington
Occupation: Programmer

Susan is pregnant, and will need to take off work soon. She is concerned that the short (three month) paid leave her firm provides will not be enough time off. She also has a strong family network; her mother is currently in town and will be staying for a few weeks after her delivery to help out. This will be Susan's first child. Recently she has been suffering from some minor health problems and was frustrated at how few options there were for pregnant women to receive treatment, as so many devices are not tested on or approved for pregnant women.

Sharon Fleming



Age: 46
Sex: Female
Race/Ethnicity: White
Hometown: Chicago, Illinois
Occupation: Biomedical Researcher, Assistant professor

The risks of this new technology seem low to Sharon, and she's really interested in all of the great data it could generate. Since the benefits seem to outweigh the potential risks, in her opinion, it's a great thing to be using in her research. She is working to actively recruit children ages 6-13 for a 5-year study of this device to better understand its effects in younger children.

Lisa Johnson



Age: 43
Sex: Female
Race/Ethnicity: Black
Hometown: Houston, Texas
Occupation: Entrepreneur (CEO of tech startup)

Lisa currently leads a successful IT company and is looking to expand into medical applications. She is confident and a risk-taker. She believes risks are a necessary part of life – you won't get ahead if you aren't willing to take them. She is health conscious herself and knows a lot of people are into personal data collection nowadays. Lisa thinks this tech could be a big seller for patients with type-II diabetes and help them manage their disease.

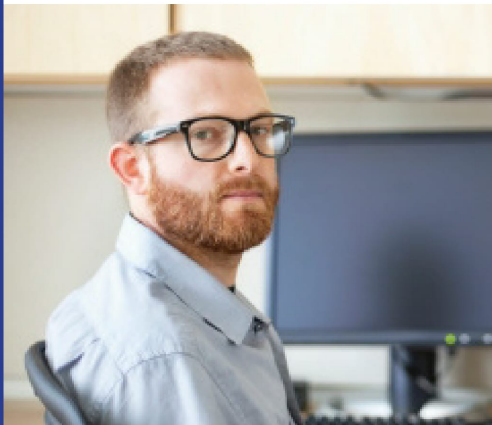
Gael Ramos



Age: 50
Sex: Male
Race/Ethnicity: Hispanic
Hometown: Albuquerque, New Mexico
Occupation: Manager (manages the factory where Rosa works)

Gael is hardworking, good with people and very safety conscious. He manages the factory where Rosa works and he oversees safety and compliance. He believes the best way to avoid risk is to have good practices in place. If something bad happens, it is usually because the accident was preceded by an unsafe act or a mechanical or physical hazard (domino effect). At the same time, he is under pressure from the executive leadership team to increase production volumes to meet demands.

Simon McCallum



Age: 41
Sex: Male
Race/Ethnicity: White
Hometown: Salt Lake City, Utah
Occupation: Health Insurance Actuary

Simon believes people should be responsible for their own welfare. He is married with two young children and thinks that risk is calculable. He knows there is no such thing as 100% safety. Accidents result when inadequate barriers are put in place to prevent it from happening. He is working to evaluate the liability and safety concerns for this new device for the insurance organization.

Rosa Morales



Age: 27
Sex: Female
Race/Ethnicity: Hispanic
Hometown: Ciudad Juarez, Mexico
Occupation: Factory worker

Rosa is an undocumented immigrant who works for low pay in Albuquerque. The factory she works for produces materials commonly used in medical devices. Rosa will take big risks (like coming to the US) for the good of her family, but wants to work in a safe job. She will do what she has to do, and is accustomed to living with uncertainty, but will only do risky things if there's a good reason for it. She is skeptical that her friends or family members may ever benefit from this high-cost technology.

Albert "Al" Miller



Age: 75
Sex: Male
Ethnicity: White
Hometown: Allegheny, Pennsylvania
Occupation: Retired (Army Veteran and former steel worker)

Al is diabetic. He lives alone and moved to a rural community after the death of his wife. He generally distrusts the government overreaching their boundaries. No way Al is letting anyone put technology on or in him. Who knows what it could do or who's controlling it? What if it shocks him? Al goes to the doctor if he's feeling sick and if the home remedies his wife used to use don't work. He gets medicine, he feels better, and that's it. There's no need for more invasive medical technology, especially if there's nothing wrong with him in the first place.

Amy Sherwood



Age: 41
Sex: Female
Ethnicity: White
Hometown: Durham, North Carolina
Occupation: Unemployed (full-time caregiver)

Though she had originally planned on returning to work after the birth of her second child, as she had with her first, she decided to stay at home after her son, Logan, (now 9 years old) was diagnosed with Type-1 diabetes. She highly values her son's health and doesn't want anyone to treat him as a research subject. She does want to keep him healthy, however, and the doctors are telling her about a trial program that may afford her son more freedom. She thinks the sensors could let doctors know what his body is doing.

Chelsea Thomas



Age: 9
Sex: Female
Ethnicity: Black
Hometown: Buffalo, New York
Occupation: Homeschooled

Chelsea was diagnosed with a heart condition as a young child. Currently she is stable, but she is behind in school and still suffers health complications. Her parents think this device would cut down on the hospital visits. While Chelsea received treatment in the hospital, the monitors constantly reported her heart rate and other important numbers to the doctors. This device could be useful to help monitor her and alert her parents to issues as soon as possible. Special rule: After introducing herself, Chelsea can only ask questions.

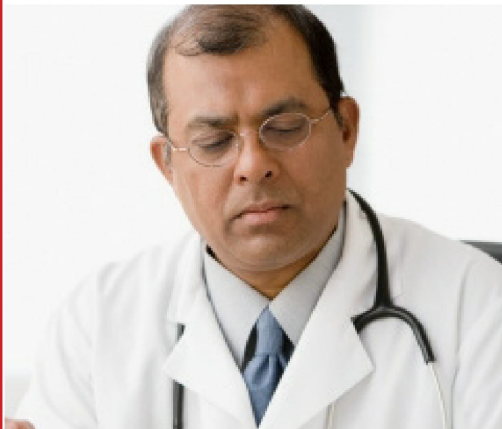
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Vinay Malhotra



Age: 53
Sex: Male
Race/Ethnicity: Asian (Indian)
Hometown: Bangalore, India
Occupation: Physician

Born in India, Vinay came to the US as a young man and has established a well-respected medical practice in Florida. He also works in a research hospital and occasionally teaches classes at the medical school. He finds the US system of medical care inefficient and believes that data from wearable sensors networks could help him diagnose patients more effectively. He also thinks this data should be made public in some way, to promote new discoveries. Vinay's daughter runs on the track team Michelle coaches.

Michelle Sanchez



Age: 56
Sex: Female
Race/Ethnicity: Hispanic
Hometown: Pensacola, Florida
Occupation: High school coach

Michelle had complications from sports injuries when she played in college, and thinks sensors and other monitoring medical devices may have aided her recovery. She thinks this device might help her keep her players healthier and to train them better, especially in the heat of the summer when elevated heart rates can indicate over-heating. She is interested in looking at data from her players in real time, and making coaching decisions accordingly. Vinay's daughter runs on the track team Michelle coaches.

Anton Moretti



Age: 29
Sex: Male
Race/Ethnicity: White (Italian-American)
Hometown: Philadelphia, Pennsylvania
Occupation: Police Officer

Anton is well versed in the challenges of security. He is charged with protecting the people of his city, yet must occasionally violate their privacy – by entering a home or vehicle, searching a computer, or gathering a lot of personal information about them. Anton believes health information like medical records should be kept private unless there is due cause to investigate them, but that public behavior doesn't need to be protected because it's already public. His father died of a heart attack and while Anton shows no signs of heart disease, he is interested in using this device

Scott Campbell



Age: 58
Sex: Male
Race/Ethnicity: White
Hometown: Cheyenne, Wyoming
Occupation: Janitor/handyman

Scott worked as a deliveryman for many years until he developed back pain and took a less physically demanding job as a janitor. He earns extra money performing odd repair jobs for friends and neighbors. He has only high school education, but pretty handy with basic electrical wiring and things. Helped his niece set up the Nightscout system to monitor her diabetic daughter's blood sugar levels while she (the daughter) is in school and feels good about that system.

Robert Hudson



Age: 86
Sex: Male
Ethnicity: White
Hometown: Newark, New Jersey
Occupation: Cashier

Robert is an ex-con and served a nine-year prison sentence for a non-violent drug offense in his 30's. Because of the lost income and subsequent difficulty finding well-paying work, he has been unable to retire. Robert is concerned about the use of such devices on vulnerable populations, such as prisoners, even those that may benefit from increased health monitoring. However, he thinks it might be okay as long as the collected data was anonymous and used in research.

Sofia Flores



Age: 13
Sex: Female
Ethnicity: Hispanic
Hometown: Tempe, Arizona
Occupation: Public school student

Classes in her school are overcrowded, but she attends an after-school program for science and technology. She is very interested in how science can help make people's lives better. She wants to know how this new tech works! Her grandmother suffered a heart attack last year and only survived because a family member rushed her to the hospital. Sofia wonders how the data could be shared with doctors in time to save people's lives.

Marcus Henderson



Age: 33
Sex: Male
Ethnicity: Black
Hometown: Washington, D.C.
Occupation: Speaker/ Patient Activist

At 17, Marcus was diagnosed with a rare heart disease. He has been working with a nonprofit organization that aims to promote research on treating rare conditions, and works to advocate for the rights of those patients. He works at the Mission House in DC. He's all for technology that will help patients, but is concerned about how the technology will produce and transfer data. What happens to the data between the patient and the doctor? Who is responsible for protecting against hackers and the like?

Susan Lischner



Age: 31
Sex: Female
Ethnicity: White
Hometown: Seattle, Washington
Occupation: Programmer

Susan is pregnant, and will need to take leave from work soon. She is concerned that the short (three-month) paid leave her firm offers will not be enough time off. She also has a strong family network; her mother is currently in town and will be staying for a few weeks after her delivery to help out. This will be Susan's first child. Recently she has been suffering from an irregular heartbeat and was frustrated at how few options there were for pregnant women to receive treatment. She hates going into the hospital and fears catching a bacterial infection. She is wondering if this device will be approved for pregnant women.

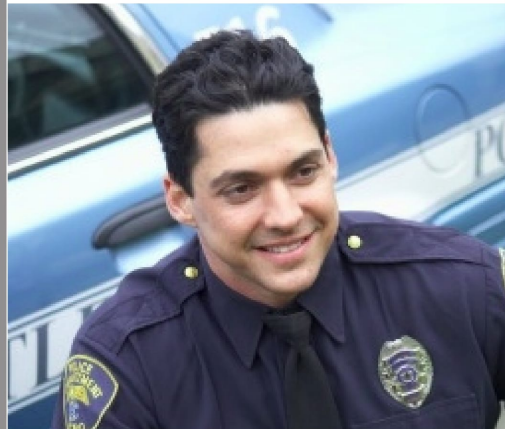
Barbara Holmes



Age: 58
Sex: Female
Race/Ethnicity: White
Hometown: Frederickburg, Maryland
Occupation: CEO of large pharmaceutical company

She is Al's daughter. With her considerable medical expertise, Barbara feels qualified and justified in making health decisions for her aging father, but Al can be stubborn and uncooperative. Barbara thinks this technology is an excellent idea, and it would give her considerable peace of mind to know that her father was well cared for during his recovery from a recent car accident. She plans to tell the doctors to go ahead and use the tech even if her father says no.

Anton Moretti



Age: 29
Sex: Male
Race/Ethnicity: White (Italian-American)
Hometown: Philadelphia, Pennsylvania
Occupation: Police Officer

Anton is well versed in the challenges of balancing privacy and security. He is charged with protecting the people of his city, yet must occasionally violate their privacy – by entering a home or vehicle, searching a computer, or simply gathering a lot of personal information about them. Anton believes health information like medical records should be kept private unless there is due cause to investigate them, but that public behavior doesn't need to be protected because it's already public.

Albert "Al" Miller



Age: 78
Sex: Male
Ethnicity: White
Hometown: Allegheny, Pennsylvania
Occupation: Retired (Army Veteran and former steel worker)

Al lives alone and moved to a rural community after the death of his wife. He generally distrusts the government overreaching their boundaries. No way Al is letting anyone put technology on or in him. Who knows what is could do or who's controlling it? What if it shocks him? Al goes to the doctor if he's feeling sick and if the home remedies his wife used to use don't work. He gets medicine, he feels better, and that's it. There's no need for more invasive medical technology, especially if there's nothing wrong with him in the first place. He was recently in a car accident and needs to rehab his legs or risk being confined to a wheelchair in a few years.

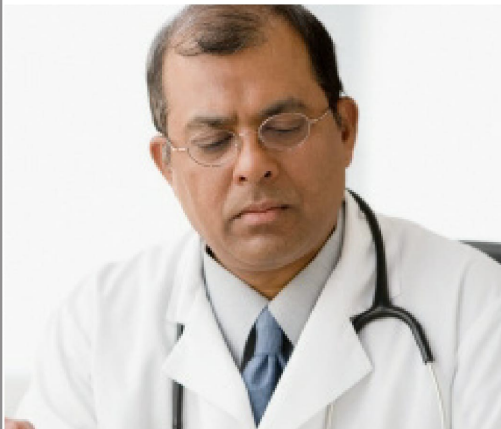
Amy Sherwood



Age: 38
Sex: Female
Ethnicity: White
Hometown: Durham, North Carolina
Occupation: Unemployed (full-time caregiver)

Though she had originally planned on returning to work after the birth of her second child, as she had with her first, she decided to stay at home after her newborn son, Logan, (now 2 years old) was diagnosed with Down Syndrome. She highly values her son's privacy and doesn't want anyone to treat him as a research subject. She does want to keep him healthy, however, and these sensors could let doctors know what his body is doing, especially since Logan cannot always articulate how he is feeling.

Vinay Malhotra



Age: 53
Sex: Male
Race/Ethnicity: Asian (Indian)
Hometown: Bangalore, India
Occupation: Physician

Born in India, Vinay came to the US as a young man and has established a well-respected medical practice in Florida. He also works in a research hospital and occasionally teaches classes at the medical school. He finds the US system of medical care inefficient and believes that data from wearable sensors networks could help him diagnose patients more effectively. He also thinks this data should be made public in some way, to promote new discoveries. Vinay's daughter runs on the track team Michelle coaches.

Michelle Sanchez



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Sex: Female
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Hometown: Pensacola, Florida
Occupation: High school coach

Michelle had complications from sports injuries when she played in college, and thinks sensors and other monitoring medical devices may have aided her recovery. She thinks this device might help her train her track athletes to run more efficiently. She is interested in looking at data from her players in real time, and making coaching and training suggestions accordingly. Vinay's daughter runs on the track team Michelle coaches. She is interested in using this technology to help runners perfect their stride length.

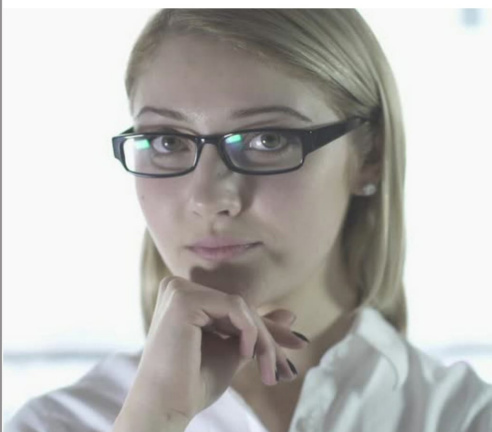
Lena Murphy



Age: 41
Sex: Female
Ethnicity: White
Hometown: Lansing, Michigan
Occupation: Operations Manager

Lena is a no-nonsense manager. She likes rules and procedures and keeps everything in order. She also values efficiency, and is interested in the gains in productivity that might be seen if some of her employees could benefit from these new technologies. However she is distrustful of new things, particularly concerning medicine, which she thinks isn't something we should experiment with too much.

Beth Stanley



Age: 36
Sex: Female
Race/Ethnicity: White
Hometown: Milwaukee, Wisconsin
Occupation: Nurse-practitioner

Beth loves her patients and is passionate about preventative care. She is concerned about the use of wireless medical devices and patients performing self-diagnosis, and this diminishing their quality of care. She wants to see her patients routinely and not rely upon data that she is not confident in.

Scott Campbell



Age: 58
Sex: Male
Race/Ethnicity: White
Hometown: Cheyenne, Wyoming
Occupation: Janitor/handyman

Scott worked as a deliveryman for many years until he developed back pain and suffered a leg injury. He took a less physically demanding job as a janitor and earns extra money performing odd repair jobs for friends and neighbors. Scott has a high school education, but pretty handy with basic electrical wiring and things. He wonders how this device would have helped his recovery, but it also concerned about data privacy and hearing about all the hacks affecting banks and the election.

Paul Brewer



Age: 23
Sex: Male
Race/Ethnicity: White
Hometown: Cincinnati, Ohio
Occupation: Unemployed

A recent college graduate, Paul did well in school but was unable to find a job after graduation and is burdened with a significant amount of student debt. He lives at home with his parents and relies on their health insurance. He thinks this new tech is pretty cool, but is a little skeptical that older folks will ever "get it". He thinks the younger generation may have to make some decisions for them, or else simplify the explanations enough for the choices to be understandable.

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Hometown: Washington, D.C.
Occupation: Speaker/ Patient Activist

At 17, Marcus was diagnosed with a rare genetic disease. He has been working with a nonprofit organization that aims to promote research on treating rare conditions, and works to advocate for the rights of those patients. Works at the Mission House in DC. He's all for technology that will help patients, but is concerned about how these technologies will be distributed and produced. What happens if it fails? Who is responsible for recalls and the like?

Sharon Fleming



Age: 46
Sex: Female
Race/Ethnicity: White
Hometown: Chicago, Illinois
Occupation: Biomedical Researcher, Assistant professor

The risks of this new technology seem low to Sharon, and she's really interested in all of the great data it could generate. Since the benefits seem to outweigh the potential risks, in her opinion, it's a great thing to be using in her research. She is working to actively recruit participants at a local prison to better reduce healthcare costs for the state's correctional facilities.

Gael Ramos



Age: 50
Sex: Male
Race/Ethnicity: Hispanic
Hometown: Albuquerque, New Mexico
Occupation: Factory Manager

Gael manages the factory where Rosa works and oversees safety and compliance. He believes the best way to avoid risk is to have good practices in place. If something bad happens, it is usually because the accident was preceded by an unsafe act or a mechanical or physical hazard (domino effect). He has a family history of asthma and wonders how someone would know if something was wrong with the device. And while he understands that asthma attacks are a medical emergency, he is not sure if he should allow his employees wear air monitoring sensors in the workplace.

Chelsea Harding



Age: 50
Sex: Female
Ethnicity: White
Hometown: Boston, Massachusetts
Occupation: Investor/Venture Capitalist

Chelsea made her fortune in the early 1990s with smart investments in fiber optics. She cashed out before the tech bubble collapsed. She is interested in investing in this technology, but is concerned that it is risky or might not pass regulatory review. Chelsea wants to know how the regulatory pathway might be eased if the device can be slightly redesigned.

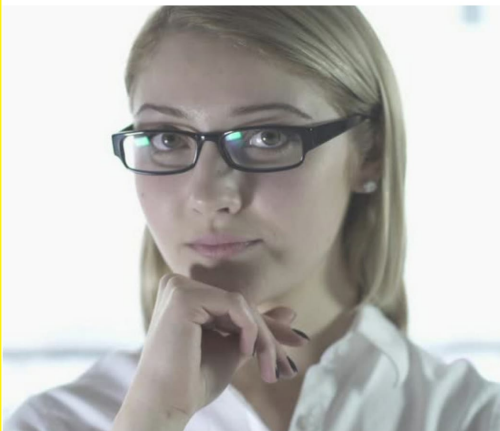
Horace Green



Age: 66
Sex: Male
Race/Ethnicity: White
Hometown: Gary, Indiana
Occupation: Regulatory Affairs Officer

Horace is considering an opportunity that his company might make an investment in that fall within the definition of "at-home" wireless technologies. It's his job to address how the company will handle liability concerns for diagnosing patients without the consultation of a licensed medical doctor. Since this is not a diagnostic device, he is worried about a few things. One thing is how can the company "prove" the device prevented an asthma attack or worse, if the patient suffers an attack how will the company know if the device failed or if the patient failed to yield to the warning signs emitted by the device?

Beth Stanley



Age: 36
Sex: Female
Race/Ethnicity: White
Hometown: Milwaukee, Wisconsin
Occupation: Nurse-practitioner

Beth loves her patients and is passionate about preventative care. She is concerned about the use of wireless medical devices and patients performing self-diagnosis, and this diminishing their quality of care. She also wonders how it will affect their insurance claims. If the patient could have responded to the device's alerts, but didn't, then is the patient responsible for the asthma attack and therefore the insurance company won't cover the medical costs?

Scott Campbell



Age: 58
Sex: Male
Race/Ethnicity: White
Hometown: Cheyenne, Wyoming
Occupation: Janitor/handyman

Scott worked as a deliveryman for many years until he developed asthma and took a less physically demanding job as a janitor. He earns extra money performing odd repair jobs for friends and neighbors. Scott has a high school education, but pretty handy with basic electrical wiring and things. He helps his niece, who also suffers from asthma, and often takes her home from school if she is not feeling well or struggling in her breathing. He is not always sure that asthma is what is making his niece want to leave school.

Lena Murphy



Age: 41

Sex: Female

Ethnicity: White

Hometown: Lansing, Michigan

Occupation: Operations Manager

Lena is a no-nonsense manager. She likes rules and procedures and keeps everything in order. She also values efficiency, and is interested in the gains in productivity that might be seen if some of her employees could benefit from these new technologies. However she is distrustful of how employees wearing the HET will be monitoring the workplace environment. She thinks this isn't something the company executives will allow, as it might expose them to increased liability if employees can demonstrate that the facility is causing their asthma attacks.

Supplemental Material: C. Character Statements

Character	Hopes	Concerns	Additional Issues
Chelsea Thomas		is this something a child can wear? - will I take it off if its not comfortable. Why would anyone else care about my data?	Will my data help Susan? Do I need to wear it every where I go?
Amy Sherwood	Help his son participate in sports- because it will show he was fine at the proper moment (who will know about his data) -One time Fee	Serious concern- limit on how its used- how it should be shared- Only to help his son- not the betterment of technology -Costs- 100 dollars	mis-use of data Who decided what gets used. How do we keep it restricted- groups use it for what they say for. He can learn with the device to self adjust what to do.
Vinery Malhotra	Data should be more public- Increase transparency- search for patterns- inefficiency. Patients need to come in for readings- can monitor people from the computer- helpful- "rounds" without patient having to come in	Patients don't do things he tells them anyway? - Wants to know that it is still installed- -Can I trust the information coming into me.	Will this effect my job?
Michelle Sanchez	Be the end user- monitor heart rate If I let the government---	Need to know who this data belongs too. What if devices come off. Will it be easy?	make sure they are not over heating during practice
Anton Moretti/	Only the bear minimum shared- With appropriate controls allow data Could help to prove your innocence -college sports-	Not everyone has the best mind intent	Can the data found- (very simple data) can help to back up data for stories.
Scott Campbell	Don't want a new job- just want it to work. - Busy life- cant afford to take time off to repair it.	Don't want government intervention? Can I fix/repair the device my self? sustainability of device - how long will it work?	
Marcus Henderson	People who do data analysis- just tell me what to do- will be more useful (don't mind if it is sent to others however would want to know where its doing)	Technology will produce a lot of technology that can be shared with others There is going to be a lot of data- how will we maintain confidentiality- monitoring people.	Tell me whom I am helping with my data.

Susan Lischner	Move science forward- If others shared data that I would know whats wrong with me. I hope that others data will help me. Decrease the amount of days of maternity leave before pregnancy.	Not a lot known about about heart condition. Will i be ok to wear this with my pregnancy.	The device should have a way if its charged/ is it being worn. How much will you be willing to pay?
Maria Suarez	Be respectful of one another and drive a civil dialogue on the issues.		
Robert Hudson	Helps in college athletics Helps to prevents student althea of harm.	Sit want my job- don't want to lose it Betterment of society Do I need to accept technology as source of medicare. Not clear what people will do with data-manipulative reasons? How transparent is transparent.	Should be up to the individual if they would like to participate

Character	Hopes	Concerns	Additional Issues
Chelsea Thomas (9)	It will help other children, then willing to help? Wants to be able to do things other kids can do.	What are side effects? What kinds of side effects are there?	Recalls- what happens if there's a recall
Amy Sherwood Mother of 2,	Hopes to give son freedom in his life	Concern about side effects- how much work he needs How technology is going to affect children when they're wearing it?	If there was a recall, we would want to be notified by the company. would have to find a new solution Risks are unacceptable
Lisa Johnson, CEO of Tech Startup in Texas	Like to know more about devices in reactive mode- are they in time, or too late	Can it work in a predictive mode? in order to be early and on time Is there an override? How do they accept those? Where is the control? How long would this reservoir take? Might be limiting in the workplace Why is this so big?	Recall- push vs. pull, would want to be called personally, I don't want to go through hoops You'll hear from my lawyer What makes one worse? What's the scale to tell how much risk is
Randy Facilitator from Boston, MA	Aiming to drive a conversation that is civil and can get at the issues		
Sharon Biomed researcher	Understand side effects on patients under 14 How this could be brought to	Control Has that been affective	Recall- should be gathering as much pre-market data as possible Surveillance

Pediatrics	order		Check in to make sure device is working
Rosa Albuquerque	Availability to everyone	Expensive technology Safe words Types of management to show how well developed things are	Can't imagine that this will be available Boss should be responsible to deal in recall
Susan expecting first child soon		Has not been diagnosed Reliability Safety	If terminally ill patient- There's got to be a lot of discussion between manufacturer and FDA to get approval to take more risk and where is the line drawn?
Gael Ramos Manage factory- concerned about safety	I don't understand blood pressure- all things changing Hope that its safe	Want to make sure people can focus on what they're doing and not be distracted	Be as transparent as possible with all information "This is what happens when..." Tell people about recall and learning from it- from business perspective it can showcase leadership role and shows transparency Quality of life risk is most acceptable- playing it safe is more acceptable of over-treating and making things worse on the other end The risk of death for terminally ill is lower from the device since they're already there
Albert Miller Retired army and steel mill worker Diabetes, doesn't trust new stuff	I don't think I would need more stuff stuck in me- seems like a lot of work, so why would i do something different	Skeptical of it really working if he already has a way of taking care of	Wouldn't like companies keeping secrets If technology puts other friends in line, would want to know why in order to learn from mistakes Don't trust companies or company
Simon McCallum from Utah Concerned about new stuff, has 2 small children What are the barriers?	Regulations have been put in place and long term side effects have been tested	Still don't trust side effects for own body/children/loved ones Too often do new technologies show up with issues later How do you recruit children for studies in trials? Wouldn't want own children in the trial Effective liability and safety A lot of data needs to be in place	Medication if recall were to occur Insurance- if device is recalled Business of device and revenue- but device is way too important to keep from industry Should communicate openly Communication should be the responsibility of the company and if there is communication across the different levels it has to come from the manufacturer The risk has to be none For terminally ill, what benefits are there

Character	Hopes	Concerns	Additional Issues
Scott Campbell	Speed recovery time	Cost, affordability, data, will this raise his insurance?	Would give it a shot, but needs the data explained, people with an injury will take the “risk” if it promises improvement (esp if its low risk), needs assurances about where the data is going, where is the data being transmitted? ,
Beth Stanley	Companies might claim this could aid in predicting early onset Parkinson’s/ stroke/etc.	Device is fantasy, where’s the data coming from to support software, walk away from the device	HIPPA (!!) fundamental assumptions that the data used, created a robust sensing/software program, how can we be sure this project isn’t funded for other reasons? (i.e. Nike to make people run faster) disclosure, issues of regulation (this type of new tech is “completely unregulated”), needs concrete explanation of data proving gait is a predictor, self-diagnosis, hard to determine what tech is robust/truly useful, patient empowerment, patient support (what if something goes wrong at night?)
Al Miller (talked about PhD in self medicine wife)		“Even if I put it in my shoe, it might shock me.” Gov’t could track me, know when I am with my friends	Can’t truly anonymize anything, disclosure, need to simplify to plain language so people can understand the fine print, security of data (i.e. if it’s linked to your medical record, what if the data is hacked?)
Roberta Burfect (Facilitator)	Enables health prof to track gait, diagnose whether patients are recovering	How much space there is for this device? Power required, what happens to the data being gathered, comfortability	Issues of monitoring, question when workers don’t come back if device shows they are healthy, pain that might not show up in the data collected, why is GPS data necessary? Suspicious... elect to share data on individual basis? , appealing to altruism is met with cynicism in a privatized arena, what happens when the data is hacked? , wants an ethics review board to discuss on case by case basis , interested in the process/ discussion surrounding ethics, wants a “Gold Ethical Review Standard” for data collection
Barbara Holmes	Be at peace w/ elderly dad being monitored, ease her caretaking stress	Pushback from dad to use device	Healthcare decisions should be between doctors and patients, concerns of cyber security, doesn’t want outside issues (privacy/security) to impede tech. progress, need to bring everyone together to address these concerns as the technology goes along , how can we protect the location of Michelle’s students location data? Comfortability, doesn’t interfere in anyway with normal/daily activity
Michelle Sanchez	Help to avoid injuries in athletes	Could distort the way the athletes walk, potentially cause more harm than benefit	Important as a preventative measure, esp. in terms of adolescent growth, needs to be as light as possible, joked about aesthetics of shoes with sensors, is our health system ready to accommodate the demand of on-

			call technicians for all these wearables and health practitioners to interpret data
Lena Murphy	Help speed the recovery process for workers on leave for injury, employees who have been injured	Weight of device, will this device put more burden on the patient, increase recovery time	Could use this device as a healthcare incentive, management would not make decision of when workers should come back to work, anonymous (public data, but not linked to individual), are issues of privacy and security “show stoppers” or is there a way to get around this so as not to impede technological innovation, cost, who owns the data? , consumer vs commercial products, can establish general trends even from “garbage” data in order to refine trends and further specify
Amy Sherwood	Help daughter cope with motor difficulties, facilitate recovery	Use of data, who will have it, where it is shared, is this invasive?	What are the critical clauses/ fine print of these types of devices? Data collection, who owns it? Privacy and functionality of user, can use this to determine if someone has a disability (concerned of discrimination/segregation based on data), geographic could affect data, but is still concerned about GPS tracking, worry that it would be abused, refusal of insurance , no one ever knows the good that tech that never gets funding could have done, inferior tech sometimes gets funded bc of name brand, etc., FDA regulations is crippling, fear the limitations of “political correctness,” tension between political, social, corporate and technical sectors
Vinay Malhotra	Time between stroke and patient diagnosis, improve speed of medical care, could be good for training purposes		Having data available for research purposes to improve health of aging population (weighing detriment of privacy with well-being of country)

Character	Hopes	Concerns	Additional Issues
Henry Lee	-Can you use this device to catch neuro-degeneration early enough to prevent debilitation? Or is it just an alert after the fact?	- Are devices like this get in the way of us seeing loving faces? Because that makes me happy -If people are falling over and over again, can we find a way to let them know those places are bad and could they fix them?	
Li Jun	-Could the device 1) spot patterns and change in movements that would show risk at first sign of deviation and 2) If the device could tell us she	- Worried about bridging gap across the pacific to care for grandma - I’m worried the device is depersonalizing, I don’t want this to mean human	-I don’t think this would really make a difference for my grandma. I don’t think it would bring me much peace of mind from across the ocean, when I can’t check on her immediately. - the people nearby are the ones that

	had fallen and notify me and emergency personnel	contact is taken away from her and her care regimen	could actually help her -Data is perceived by everyone EXCEPT the person actually wearing the device, which makes it less useful. If there were more subtle enhancements besides just the medical data, I think people would wear it more
Paul Brewer	<p>-I think this is so cool, that we could wear medical stuff</p> <p>- Curious about if my parents even need this since I don't know much about their health status</p>	<p>- cost issue?</p> <p>- Is this in the home, or would they have to be in a hospital?</p> <p>- Who has to pay for it?</p> <p>- Does this increase or decrease dependence?</p> <p>- what if they trip on Muffy (the cat).</p> <p>- Maybe I can find a cheaper, practical option</p> <p>- How much do I have to know to be able to help my parents? I'm busy, I don't have time to look at all this stuff.</p> <p>- I don't even wear a watch!</p> <p>- My mom is really small and only wears delicate jewelry. She wants to look nice, and wouldn't want to wear an obvious looking device. It would have to be seamless</p> <p>- Can there be different sizes and different colors</p>	<p>-what does the device do when you fall? Is it like Life Alert?</p> <p>-Will my insurance cover that??</p> <p>- My parents aren't very good at using this technology, and I don't know if they will trust my opinion on this, and I think their friends might not like this either</p> <p>- Could this improve general health markers? People could see it earlier on, instead of only getting it when they're a fall risk They aren't falling, but this could improve their general health before that becomes an issue</p>
Vincent Castillo	<p>-I'm interesting in this device working reliably- what's missing, false positives etc...I can't run data if it isn't accurate</p>	<p>- how protected is data transfer?</p> <p>- Missing data, false positive</p> <p>- Patient compliancy, will they actually wear it?</p> <p>- Minority elders are less likely to be in trials of development and use of tech. So I'm worried that this will not get to minority/ low \$ populations that need it</p> <p>- where's the in-between data? An "almost fall" for prevention</p>	
Barbara Holmes	<p>-This seems like a no-brainer to me, why wouldn't people buy this?</p> <p>- If we can prove it works everyone will buy it</p>	<p>-Worried about my Mom, Carol, and being able to monitor her</p> <p>- Could machine learning help? You could sell the device better if it learned behavior</p>	<p>- stepped out of character, to talk about attached patch and a watch that takes all vital signs. How do you break down the barrier to actual wear ability and usability</p>

Carol Lyon	<p>My friend died from a fall in her home, and I think this could have helped her. She couldn't afford living in an assisted living facility, so this could have helped people know she had a problem early</p>	<p>I hate wearing stuff, and in a year or so I will forget what this device is because of my Alzheimer's I don't want people to know what's going on, asking me if I'm okay. False alerts mean people will be bothering me all the time. I already have a team of caregivers, why do I need this?</p>	<p>Really great at the Alzheimer's role playing!! I disagree with my daughter, I would need a lot of info to believe it worked. My girls at the facility convinced me to get an iPhone, so I would only use this tech if they used it too</p>
Nolan Thompson	<p>Integration into clinical workflows and systems</p> <p>What is the info? Is it medically relevant, actionable, etc?</p> <p>Application to a variety of conditions (vets, parkinsons, etc). Identifying subtle differences.</p>	<p>Worried about large patient pop. And monitoring We see the value and potential of TEMPO at our hospital Data security, privacy. Altering our own systems would be very expensive so integration is important Could this link with other third party services that will protect info? Protections around transmission</p>	<p>Could this reduce our costs of care? Knowledge about what Vincent talked about, understanding those key triggers that cause falls or almost falls and how we can adjust treatment based on that Is this feasible? I don't know if people will actually use it. Many of my patients feel this way.</p>

Supplemental Material: D. Identified concerns by category.

Social Acceptability	Educating end-user
Social Acceptability	Safe for Children & Pregnant women?
Social Acceptability	Convergence with other Technology
Social Acceptability	Wearability
Social Acceptability	Human contact (line between people & Tech)
Social Acceptability	Device allows participation in sports
Social Acceptability	Combining functionality (Ex: put it into a hearing aid)
Social Acceptability	Clear communication to user about issue
Social Acceptability	Can we trust?
Social Acceptability	Need for user - centered Design/Understanding the real problem?
Social Acceptability	User interface who has control me or device
Social Acceptability	Just because we can doesn't mean we should
Social Acceptability	Aggregate lots of data from large population - Advance research
Social Acceptability	Good nudges/versus bad nudges
Social Acceptability	Addressing innovation for customer/skepticism from customer
Social Acceptability	Working w/ care givers
Social Acceptability	Impact on clinical outcomes
Social Acceptability	Messy data can still be useful
Social Acceptability	Resistance by professional to adopt (risk aversion)
Social Acceptability	Affordability
Social Acceptability	Cost affordability device
Social Acceptability	Should be light weight/comfortable
Social Acceptability	user experience & user interaction
Social Acceptability	Is it better? (than human/current contact)
Social Acceptability	is it helpful?
Social Acceptability	Values (What does a fall mean?) Autonomy - safety
Social Acceptability	user dependency
Social Acceptability	Might we create dependence? (until failure)
Social Acceptability	Will insurers reimburse?
Social Acceptability	Will insurers use this to adjust rates
Social Acceptability	Liability
Social Acceptability	Self vs. Insurance paying/required?
Social Acceptability	How does it fit with/change user lifestyle?
Social Acceptability	Ease of use
Social Acceptability	Cost of device/cost of healthcare
Social Acceptability	Who owns the data
Social Acceptability	Plain language contracts
Social Acceptability	Behavior Changes
Social Acceptability	Just because we can doesn't mean we should
Social Acceptability	Cultural sensitivity
Social Acceptability	Can it be used to discriminate against me or someone else?
Social Acceptability	Social justice
Social Acceptability	user/patient empowerment
Social Acceptability	Social stigma
Social Acceptability	Stigma
Social Acceptability	impact on environment/system & individual

Safety	Concerns about the reliability of data
Safety	Reliability
Safety	Data/device reliability
Safety	reliability & Repair-ability
Safety	Cost effectiveness/accessible
Safety	is data valid?
Safety	messy data can be useful
Safety	Keep students athletes safe
Safety	working w/care givers
Safety	Ease of use
Safety	clear comment of technology issues to users
Safety	Safety & Testing in different populations
Safety	Risk should be based on users group
Safety	Reactive vs. Proactive (does it act to late?)
Ethics	Publically useful data
Ethics	Discrimination (Down's)
Privacy	Misuse of data/unintended use
Privacy	Only want data from device shared with doctor or coach. Person I know.
Privacy	Who can see/use this data? (Privacy/security)
Privacy	Appropriate process for law enforcement access to data.
Privacy	publically useful data
Privacy	Medical data surveillance
Privacy	Can we trust (e.g. The device/regulators other players)
Privacy	user control (privacy settings, etc.)
Privacy	Discrimination
Privacy	Discrimination
Privacy	Data opt-in/ opt out
Regulation	Assurance
Regulation	is it helpful?
Regulation	Clear communication to users about issues
Regulation	FDA Validation Verification
Regulation	Data & Device Reliability
Regulation	Is data valid?
Regulation	Messy Data can still be useful
Regulation	Medical data surveillance
Regulation	User/patient empowerment
Regulation	Discrimination
Regulation	Impact on Environment/system & Individual
Regulation	Who owns the data?
Regulation	Who can see/use data
Regulation	Publically useful data
Regulation	Impact on clinical outcomes
Regulation	Impact on future Research
Regulation	Liability
Regulation	Cost affordability of device
Regulation	ease of use
Regulation	Affordability

Security	Working with Care Givers
Security	Reliability
Security	UI: user interface who has control (me vs. device?)
Security	Data device reliability
Security	Medical Data Surveillance
Security	Data Transmission
Security	Who can see or use data?
Security	Could bad guys use it & how?
Why & for Whom	Raising/bringing out perspectives/biases of stakeholders
Why & for Whom	Disconnect between stakeholders? (including customers)
Why & for Whom	Mismanagement of trust
Why & for Whom	Address commitments made biyearly adopters/societal level questions
Why & for Whom	Economic survivability - selection bias of funding (public or private) against what could become major technologies
Users centered design	Integration of Technology systems integration
Users centered design	Device self monitors to be sure patient is using correctly
Users centered design	usability
Users centered design	Continuous wearability
Users centered design	Cost
Users centered design	Need to analyze data/How? Who?
Users centered design	Data from device is detailed or summarized & sent
Users centered design	User more independent - don't need to go to Dr's office
Users centered design	what is the care system
Users centered design	Meaningful & Actionable information
Users centered design	Aesthetics
Users centered design	Interoperability of data feed to human
Users centered design	if this technology becomes mainstream will I be forced to adopt it?/Opt in vs. opt out

Supplemental Material: E. Ranking of who is responsible for [privacy, patient safety, risk, regulation] across six phases of wearable device innovation. Cards that were ‘non-compliant’ and offered alternative scoring methods are highlighted yellow. Note: 1 is the highest ranking and 8 is the lowest ranking.

Privacy Set 1	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	1	2	1	1	1	1
Caregiver/nurse	2	3	4	3	4	2
Clinician/doctor	3	4	6	4	5	3
Funder	4	5	8	6	3	6
Hospital Administrator	7	6	5	5	8	5
Manufacturer	6	7	3	8	7	8
Patient/Patient Advocate	5	8	2	2	2	4
Regulator (FDA)	8	1	7	7	6	7

Privacy Set 2	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	7	1	1	1	1
Caregiver/nurse	2	1	6	6	8	4
Clinician/doctor	6	8	7	5	7	3
Funder	7	6	2	2	2	2
Hospital Administrator	3	5	5	7	6	8
Manufacturer	1	4	3	8	5	7
Patient/Patient Advocate	4	2	4	3	4	6
Regulator (FDA)	5	3	8	4	3	5

Privacy Set 3	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	7	8	8	3	1	3
Caregiver/nurse	1	1	7	1	7	1
Clinician/doctor	2	2	3	2	8	2
Funder	5	5	2	6	2	5
Hospital Administrator	3	3	6	5	6	4
Manufacturer	8	7	5	8	4	7
Patient/Patient Advocate	4	4	1	4	5	6
Regulator (FDA)	6	6	4	7	3	8

Privacy Set 4	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	7	7	3	4
Caregiver/nurse	2	5	2	3	7	3
Clinician/doctor	6	7	8	6	8	5
Funder	4	3	3	5	2	1
Hospital Administrator	5	2	4	4	6	2
Manufacturer	7	4	5	8	4	7
Patient/Patient Advocate	1	1	1	1	1	8
Regulator (FDA)	3	6	6	2	5	6

Privacy Set 5	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	8	7	1	3
Caregiver/nurse	2	2	5	3	6	2
Clinician/doctor	3	3	6	4	8	4
Funder	5	5	3	5	2	7
Hospital Administrator	4	4	4	1	5	1
Manufacturer	7	7	7	8	4	8
Patient/Patient Advocate	1	1	1	2	7	5
Regulator (FDA)	6	6	2	6	3	6

Privacy Set 6	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	1	2	4	2	2	6
Caregiver/nurse	8	8	8	8	8	7
Clinician/doctor	6	6	7	7	8	2
Funder	5	5	6	7	7	8
Hospital Administrator	7	7	8	6	6	8
Manufacturer	4	4	8	8	8	8
Patient/Patient Advocate	3	3	5	5	8	4
Regulator (FDA)	2	2	8	4	8	3

Privacy Set 7	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	5	5	5	4	6	5
Caregiver/nurse	3	3	3	3	2	3
Clinician/doctor	4	4	4	2	3	4
Funder	6	6	6	7	5	2
Hospital Administrator	7	7	7	6	8	6
Manufacturer	8	8	8	8	7	8
Patient/Patient Advocate	2	2	2	1	2	1
Regulator (FDA)	1	1	1	6	1	7

Privacy Set 8	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	+++	++	+++	+	++	+
Caregiver/nurse	+	+++	++	+	+++	+
Clinician/doctor	+	+++	+++	+	+++	+
Funder	+	+	+	+	+	+
Hospital Administrator	+	++	+	+	++	+
Manufacturer	+++	+++	+++	+++	++	+++
Patient/Patient Advocate	+	+	++	+	+	+
Regulator (FDA)	++	++	++	++	+++	+++

Patient Safety Set 1	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	2	7	1	1	1	1
Caregiver/nurse	5	2	2	3	8	4
Clinician/doctor	1	5	6	6	7	5
Funder	8	3	3	2	2	2
Hospital Administrator	4	1	4	5	3	3
Manufacturer	7	4	8	8	4	7
Patient/Patient Advocate	6	6	5	4	6	6
Regulator (FDA)	3	8	7	7	5	8

Patient Safety Set 2	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	7	8	5	4	1	3
Caregiver/nurse	5	2	6	1	7	1
Clinician/doctor	6	3	8	2	8	2
Funder	2	5	1	6	2	6
Hospital Administrator	3	4	7	3	6	5
Manufacturer	8	7	2	8	3	8
Patient/Patient Advocate	1	1	4	5	4	4
Regulator (FDA)	4	6	3	7	5	7

Patient Safety Set 3	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	7	7	4	3	3	1
Caregiver/nurse	3	3	6	6	6	7
Clinician/doctor	6	6	8	7	8	8
Funder	2	2	2	2	2	2
Hospital Administrator	4	4	7	4	7	4
Manufacturer	8	8	5	8	5	5
Patient/Patient Advocate	7	1	1	1	1	3
Regulator (FDA)	5	5	3	5	4	6

Patient Safety Set 4	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	2	3	2	2	2	3
Caregiver/nurse	3	6	5	5	8	4
Clinician/doctor	8	7	6	6	7	5
Funder	4	2	1	1	1	6
Hospital Administrator	1	5	3	4	6	1
Manufacturer	7	8	8	8	3	8
Patient/Patient Advocate	5	4	4	3	5	2
Regulator (FDA)	6	1	7	7	4	7

Patient Safety Set 5	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	3	3	3	3	3	3
Caregiver/nurse	7	7	6	6	6	6
Clinician/doctor	6	6	7	7	7	7
Funder	1	1	1	1	1	1
Hospital Administrator	5	5	5	5	5	5
Manufacturer	2	2	2	2	2	2
Patient/Patient Advocate	8	8	8	8	8	8
Regulator (FDA)	4	4	4	4	4	4

Patient Safety Set 6	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher		8	6	2		1
Caregiver/nurse		5	4	6		7
Clinician/doctor		6	3	5		8
Funder		4	5	4		2
Hospital Administrator		3	2	3		6
Manufacturer		7	7	8		4
Patient/Patient Advocate		1	1	1		3
Regulator (FDA)		2	8	7		5

Patient Safety Set 7	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	2	1	1	1
Caregiver/nurse	5	5	4	5	5	5
Clinician/doctor	6	6	5	6	7	6
Funder	4	4	1	2	2	2
Hospital Administrator	1	1	3	7	6	7
Manufacturer	2	2	8	8	8	8
Patient/Patient Advocate	7	7	6	3	4	3
Regulator (FDA)	3	3	7	4	3	4

Patient Safety Set 8	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	1	3	1	7	2	1
Caregiver/nurse	3	2	6	4	6	2
Clinician/doctor	4	7	8	5	7	6
Funder	2	4	2	1	1	3
Hospital Administrator	5	1	4	2	3	5
Manufacturer	8	6	5	8	4	8
Patient/Patient Advocate	6	5	3	3	8	4
Regulator (FDA)	8	8	7	6	5	7

Patient Safety Set 9	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	7	5	5	5	4
Caregiver/nurse	1	2	2	2	2	2
Clinician/doctor	2	3	3	3	3	3
Funder	5	6	7	7	6	5
Hospital Administrator	3	4	4	4	4	1
Manufacturer	7	8	8	8	8	8
Patient/Patient Advocate	4	1	1	1	1	6
Regulator (FDA)	6	5	6	6	7	7

Risk Set 1	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	1	3	1	4	4	5
Caregiver/nurse	2	2	4	1	3	1
Clinician/doctor	4	6	6	6	6	3
Funder	8	1	1	2	2	2
Hospital Administrator	3	7	3	3	1	6
Manufacturer	5	8	5	7	7	7
Patient/Patient Advocate	6	5	7	5	8	4
Regulator (FDA)	7	4	2	8	5	8

Risk Set 2	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	5	5	4	2	1	1
Caregiver/nurse	2	2	7	3	7	4
Clinician/doctor	3	3	8	4	8	5
Funder	7	6	1	6	2	3
Hospital Administrator	4	4	5	5	6	6
Manufacturer	8	8	2	8	4	8
Patient/Patient Advocate	1	1	6	1	5	2
Regulator (FDA)	6	7	3	7	3	7

Risk Set 3	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	7	2	6	8	8	8
Caregiver/nurse	3	7	7	7	3	5
Clinician/doctor	5	5	4	5	1	4
Funder	8	3	1	1	6	6
Hospital Administrator	6	8	8	4	4	7
Manufacturer	1	4	2	2	5	1
Patient/Patient Advocate	4	6	5	6	2	3
Regulator (FDA)	2	1	3	3	7	2

Risk Set 4	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	4	1	4	6	2	1
Caregiver/nurse	7	8	3	4	5	5
Clinician/doctor	1	6	7	3	8	8
Funder	5	2	5	8	1	2
Hospital Administrator	8	5	6	7	3	4
Manufacturer	6	3	1	1	7	3
Patient/Patient Advocate	3	7	8	5	6	7
Regulator (FDA)	2	4	2	2	4	6

Risk Set 5	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	7	6	1	4
Caregiver/nurse	3	6	6	2	8	1
Clinician/doctor	7	7	8	5	6	5
Funder	5	2	3	4	2	8
Hospital Administrator	4	5	5	3	3	6
Manufacturer	6	4	2	8	7	7
Patient/Patient Advocate	1	1	1	1	5	3
Regulator (FDA)	2	3	4	7	4	2

Risk Set 6	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	3	3	7	7	7	8
Caregiver/nurse	6	4	3	3	5	5
Clinician/doctor	5	5	4	5	6	6
Funder	8	7	5	4	3	3
Hospital Administrator	4	6	6	6	4	4
Manufacturer	2	2	2	2	2	1
Patient/Patient Advocate	7	8	8	8	8	7
Regulator (FDA)	1	1	1	1	1	2

Risk Set 7	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	6	8	8	3	8	8
Caregiver/nurse	5	3	7	2	2	1
Clinician/doctor	7	4	5	6	1	2
Funder	8	7	1	7	7	6
Hospital Administrator	2	6	4	4	5	7
Manufacturer	3	1	2	8	3	5
Patient/Patient Advocate	4	5	6	1	4	4
Regulator (FDA)	1	2	3	5	6	3

Risk Set 8	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	1	6	1	2	2	2
Caregiver/nurse	8	1	4	3	3	3
Clinician/doctor	6	7	5	4	4	4
Funder	2	3	8	1	1	1
Hospital Administrator	5	2	6	5	5	5
Manufacturer	3	5	3	8	8	8
Patient/Patient Advocate	7	8	7	6	7	7
Regulator (FDA)	4	4	2	7	6	6

Regulation Set 1	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	Yes	Diminishing role at the point	N/A	N/A	N/A	Social Science research, yes
Caregiver/nurse	N/A	N/A	N/A	N/A	Yes	Yes
Clinician/doctor	Maybe	Maybe	Yes	N/A	Yes	Yes
Funder	Maybe	Maybe	N/A	N/A	N/A	N/A
Hospital Administrator	N/A	N/A	N/A	N/A	Yes	Yes
Manufacturer	N/A	Yes	Yes - compliance	Yes 8	Yes	Yes
Patient/Patient Advocate	Maybe	Maybe	Yes - input	N/A (post)	Maybe	Yes
Regulator (FDA)	May be involved early but maybe no	Probably	Yes	Yes 7	Yes	Yes

Regulation Set 2	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	5	7	6	7	6	4
Caregiver/nurse	4	2	2	4	8	6
Clinician/doctor	7	6	7	7	8	8
Funder	3	4	4	4	8	5
Hospital Administrator	3	5	5	4	8	3
Manufacturer	7	7	8	8	8	2
Patient/Patient Advocate	1	6	5	6	8	7
Regulator (FDA)	2	5	7	6	8	1

Regulation Set 3	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	7	6	4	4	4
Caregiver/nurse	5	2	4	1	7	2
Clinician/doctor	4	8	7	3	5	6
Funder	1	1	3	5	3	3
Hospital Administrator	2	4	5	2	6	8
Manufacturer	3	5	1	8	6	8
Patient/Patient Advocate	7	6	2	6	5	5
Regulator (FDA)	6	3	8	7	4	4

Regulation Set 4	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	6	8	6		1
Caregiver/nurse	6	4	7	2		3
Clinician/doctor	6	4	7	2		4
Funder	8	8	8	8		6
Hospital Administrator	4	4	7	2		5
Manufacturer	8	8	8	8		8
Patient/Patient Advocate	6	4	7	2		2
Regulator (FDA)	8	8	8	6		7

Regulation Set 5	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	7	2	3	2
Caregiver/nurse	4	5	5	5	7	5
Clinician/doctor	6	7	6	6	8	6
Funder	7	3	2	3	1	1
Hospital Administrator	2	1	4	4	6	3
Manufacturer	1	2	1	8	4	8
Patient/Patient Advocate	5	6	3	1	5	4
Regulator (FDA)	3	4	8	7	2	7

Regulation Set 6	Phase A	Phase B	Phase C	Phase D	Phase E	Phase F
Academic researcher	8	8	7	7	1	4
Caregiver/nurse	2	2	2	2	6	6
Clinician/doctor	4	3	6	3	8	6
Funder	7	6	4	4	2	8
Hospital Administrator	3	4	8	5	7	6
Manufacturer	6	7	5	8	3	8
Patient/Patient Advocate	1	1	1	1	5	8
Regulator (FDA)	5	5	3	6	4	8

Supplemental Material: Issues, nature of the problem, negative effects, solutions, strategies, and work around.

Privacy	Nature of the problem	Negative effects (who is harmed and how)?	Solutions	Strategies	Work around
Who owns the data	Issue: One of commercial rights/ usability (i.e. public goods/services), disclosure, transparency, harm.	Privatized/public, Individual/group data, differences in platform, contract (?), (ex. You might get the results but Fitbit owns the data.)	Policies that reward transparency and maintain compliance with regulations	Shift from assumption of single owner to multiple and work to understand what that means and create shared expectations. Acknowledge ownership is multifaceted and should be reflected in consent forms and other policy documents.	Make explicit how the data captured. Be clear about who is making money from data and data is being collected and by whom, e.g. PI, doctor, data service provider, etc.
Minority rights and voice	Issue: Recognize one size does not fit all, accessibility/ affordability, etc.	Information/ideas/ potential solutions could be lost, data can be used for discrimination	Clinical studies should be designed in a way that fully encompasses age, ethnicity, etc. have an advisor/ liaison with vulnerable population from start to address those concerns	Insure testing of different populations	Bulk data, data with additional qualifiers or categories that can be used to further recognize patients
Plain Language (e.g. contracts)	Issue: “common” reading level (i.e. 4 th not 8 th). How much does the patient need to know to “sign the contract”?	Burying of facts under legal jargon, diligence issue, lawyers protecting somebody else’s interests, not those of the patients, defining what is criminal or not? When can someone prosecute/ get legally charged? (thresholds should exist to protect the individual)	Investigator/health practitioner should be aiding patient in understanding, encourage them to ask questions, ask: did you consider this? insure fair representation of both sides of the story, good and bad (list of viable options, not just pressure to sign or not, what are your options? Instead of being monolithic)	Say it simply: What are you giving away what are you taking. Could use social media to reach larger public (facebook, websites), have a shorted version with an addendum, ex. Genetics counseling (same concept could be expanded)	Very few people are capable of simplifying language to help patient understand, assumption that counselor will work in best interest of patient, this is not always the case, cultural sensitivity
Privacy of data	Issue: Who has access to it, confidentiality of data, disclosure? Privacy of others (the right of 3 rd parties)	Hacking, disclosure, how to respond in event of hacking? Cultural acceptance, issues of invasion into private spaces (i.e. bathroom, home, bank, family gatherings), self-incrimination, issues of surveillance (conflict between privacy and security of overall system)	Data use agreements, contracts, request permission, full disclosure, certificates of confidentiality, clearly define the legal liabilities/ ground (whether or not hacked data can be used to charge someone), people opt in to altruism (but how can we protect this opt in?, alert individuals if info has been breached)	Contractual agreements between parties involved (including iCloud, etc. if involved in storing the data), need to look at the underlying assumptions when it comes to the definition of privacy (this is potentially different for different cultures/places)	Federal mandates, evaluation of systems that hold data and how protection of data is insured, expectations of involved parties, what is the compromise, where is the line drawn?

Social Acceptability	Nature of the problem	Negative effects (who is harmed and how)?	Solutions	Strategies
Behavior Changes	<ul style="list-style-type: none"> - How the collected data is turned into information that generates behavior-changing decisions - KAP: Knowledge, then attitudes, then practice: all of these come before a behavior change - Levels to behavior change (1 getting people to actually use, and 2, altering their behaviors as they use) - When do you adopt the technology? - Behavior change goals at individual, interpersonal and societal level. - Any of wearable device requires a behavior change - At all 6 stages we ranked, behavior needs to be considered and people must be involved - We shape our tools and our tools shape us 	<ul style="list-style-type: none"> - Does the industry understand this issue at all, or understand that change is needed for these devices to be effective? - What is the motivation to <i>actually</i> change your behavior 	<ul style="list-style-type: none"> - integrate potential users at the outset and during the whole development process - This should be done both at conception (needs assessment) and during development (prototyping phase) - What is the process? If we redesign the process to start with needs, the devices function better 	<ul style="list-style-type: none"> - Beliefs, attitudes, tensions, self-efficacy are all necessary to induce behavior changes - What skills are necessary to make the behavior change happen? - Psychosocial implications - There may be wildly different devices for different people- not a one-size fits all - Maybe we should have a workshop like this for each technology with important stakeholders (patient, caregivers, community, etc) - Make end- user integrated in the process
<p>Just because we can, doesn't mean we should</p> <p>Just because we can, doesn't mean we should (continued)</p>	<ul style="list-style-type: none"> - If, we do improve the design process as discussed above, is there more of a market condition? - Does what we discussed above mean we should - Everything shouldn't be automated - We don't HAVE to automate everything, and in many cases it isn't essential - Unintended consequences and allocation of resources - Motivation - What SHOULDN'T we be doing - How much do we already rely on other systems to answer these questions 	<ul style="list-style-type: none"> - People totally unconnected to issues can invent and produce devices even if we don't need them - Whats to stop someone from creating something? Who gets to decide that? - Who loses out with funding changes (policy wise, public sector) 	<ul style="list-style-type: none"> - Incorporating public health - Ethicists should be involved and <i>not</i> only at the tail end 	<ul style="list-style-type: none"> - Build capacity to recognize unintended consequence and respond with adaptive governance measures

Social Justice	<ul style="list-style-type: none"> - Daunting task, as all of these are - How are we even reaching certain populations (minorities, low income, etc) 		<ul style="list-style-type: none"> - No solutions are fast and easy, its all cultural/ process change - Integrated funding mechanism - If the end goal is manufacturing, its more of an issue. IF we change funding, then motivations are also changed - Public health again, for environment changes (esp. for minority/low income/high risk populations) 	<ul style="list-style-type: none"> - Where there is no marketplace, how do you provide incentive? - How to ensure distribution? - Is it categorized as a consumer product or as a medical device? - Public health and personal health tension (pre-existing model of both of these, but how do we integrate into both?) - Public health approach could supersede need for these devices - How do you cure the cause (why create a device for asthma if you can eliminate what's causing the asthma) this is the public health prospective - False requirement for inclusive populations in clinical trials - And then, how do you improve access to those populations, even after you include them? - Engineering public health services? - Wireless access itself as a question
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Security	Nature of the problem- rich problem definition	Negative effects (who is harmed and how)?	Solutions	Strategies	Work around
Reliability	<p>Of what?</p> <p>How reliably can we asses and then defend security issues?</p> <p>Asses threats</p> <p>Robust</p> <p>Think about the ways it can fail/ attack</p> <p>Know what you can v. can't do- make other aware of this</p> <p>How long until it will wear out. If bombarded/ over time.</p> <p>Do I feel secure in making a decision based on this data? -is it operating the way it is designed to do so.</p> <p>Who's responsible for security?</p> <p>-Look more broadly then just if the hackers will come</p> <p>rigorous assessment</p> <p>Fixed in time assessment or other updates that changes the calculus</p> <p>Reliable security/identifying</p>	<p>-attack others</p> <p>-Risk around exposure of data</p> <p>-Not able to determine all the loop holes in wireless devices.</p> <p>-doctors spend more time on the computer submitting data then with the patient</p> <p>-is security be bleached</p> <p>-compare the usefulness of the data analytic to what is actually happening.</p> <p>-Loss of data v. stock failures (physical harm seems to effect more then data)</p> <p>-FDA looks at complete system- cant use others systems</p> <p>Pace Makers- software/security errors call for multiple updates</p>	<p>-Fails in that mode- Sent a distress mode</p> <p>-software update</p> <p>-spend money on security- engineering testing</p> <p>-Calculus between cost effectiveness and the balance of use case</p> <p>-create a new role- one who is in charge of Data safety</p> <p>-obscurity</p> <p>-Establish risk event scenarios- risk hazard analysis</p> <p>Take a scenario and give a responsive- what are the biggest risks- how would we respond (vulnerability assessment)</p>	<p>-fails in that mode- Sent a distress mode/ Design time- not an after effect (lessens risk)</p> <p>--everyone uses obscurity</p> <p>-what risks that come along with this medical device- security in charge of this</p> <p>-failure mode effective analysis (have they looked at these devises)- have they hired the right people to do so?- Hire these people</p> <p>Expanding the digital millennium copyright act- currently does not allow for the exemption of medical devices- illegal to reverse engineer - The good people out there is not aloud to do their job and look at all the concerns – This needs to change</p>	<p>-update can create more back doors.</p> <p>-The way the device works- different devices causes for different actions after- harmful more rapidly.</p>

Who can see or use data?	<ul style="list-style-type: none"> -What is valuable to you may not be valuable to someone else - A piece of innocuous data is out there that can effect ones future (job offer) - It should be up to us who we give the data 	<ul style="list-style-type: none"> -Loss of job/not hired if bad data about you get ours -Information Leakage (not always seemingly harmful) -Loss of personal independence - The DMCA - hurdles that effect the creation of medical devices 	<ul style="list-style-type: none"> -Put a risk cost and then asses - can never say that someone can't do something based off data- -Checklist for data protection-internal that the IRB uses- implementing best practiced security solutions that should be regularly used. 	Educate people on the value of data and allow them to determine its costs.	-(not always around who has the data but more about the data/if the device works)
Automation vs self control	<ul style="list-style-type: none"> -Human security interaction -gets modified over time -glucose stripes - the accuracy of those are bad but we still use them today. -relying context to the human- -worry is taken away -the costs meet the risks to continue to produce medical devices 	-acceptable inaccuracy levels	<ul style="list-style-type: none"> -make sure the operator retains context within the data and makes conscious decision based on the reading vs how they feel. - measurement context 	-create a secondary safety mechanism within the device (might cost more but might save lives)	<ul style="list-style-type: none"> -Let your brain still be your brain- always have a secondary evaluation process -some want to entirely remove human from these devices (get ride of human error)
Data Transmission	<ul style="list-style-type: none"> open wireless= least secure In place third party verify, log into system that is offline, second/third level of verification=most secure -Case by case based on risk analysis should determine how much security should go into data transfer 	<ul style="list-style-type: none"> -bluetooth- less secure but easier -deniability 	<ul style="list-style-type: none"> -guidelines to determine when to use what -thought about what frequencies are better/worse around a persons environment (where do you lead in the guideline) 		

Patient Safety	Nature of the problem	Negative effects (who is harmed and how)?	Solutions	Strategies	Work around
Data/ Device Reliability	<ul style="list-style-type: none"> Consistently functions Clinical reporting structure Whatever the technology is, the system is connected and works Systematic approach: one part cannot exist without the other Does the job it's been given As an individual piece, it must do its job Failure rates and components from an engineering perspective Accepting some failures, but minimizing others Benchmark Define failure before you can define reliability Different dimensions Defining reliability in a way it becomes absolute or scale Is there a scale of reliability or is it a black and white picture? Context is important Case by case situation- just has to meet a certain threshold What are you asking the question of reliability for? Based on what for, the answer changes 	FDA Manufacturer User/ Patient Insurance companies Health Care System	<ul style="list-style-type: none"> Put software that can check all devices across the system and calibrate what needs to be calibrated; self-test at the system level, ex/check engine, check lights, ... Reliability of individual systems- when they fail, it's known Reliability of full systems should take into accountability of all individual systems Has to be someone's responsibility assessment that keeps something running FDA will define how things run and how it's done; comes back to the manufacturer- someone has to be responsible at the system level Reliability is based on whatever the manufacturer determines what the device is based on what they know it can do System integrating data Stakeholder's aspect- FDA's responsible for safety vs. in terms of reliability (quality) it's all on the manufacturers Self-check- a dynamic way of knowing how things are performing Patient reliability- how to use, are you wearing it/using it right? User guide will account for patient reliability 	<ul style="list-style-type: none"> Articulate this ecosystem that is affected by the device What needs to be done? Who's responsible for different aspects of responsibility Be able to articulate specific strategies and other initiatives Implement certain types of safety controls What are good design practices? 	<p>Work to avoid device classification that warrants FDA review</p> <p>Have to write own guidelines, standards, safety, methods that have been used</p> <p>If the regulators are going to be slow, let's have a direct agreement with our user....</p> <p>Articulating to the FDA, why your benchmark is right and good; changing the way they operate today</p> <p>What is this product? Teach us about it? FDA writes regulations and codes</p>

<p>Safety and Testing in Different Populations Risk based on User Group</p>	<ul style="list-style-type: none"> • Algorithm is deduced from data that doesn't fully encompass larger group picture • What is concluded is not necessarily accurate • Conflict amongst where the data comes from and what it means • Can't just treat data as a bunch of numbers, it has to have some story and accountability • Understanding thresholds and diseases • There are no benchmarks; where are the guidelines for the actual tests and how to do them? • What are the expected results? • Brands now can write their own standards when developing something new 	<p>If it takes 15 years to get approved; if we're not going to use it, then why make it?</p> <p>What's the point of creating all of these wearables, if the solution is never going to be accepted?</p>	<ul style="list-style-type: none"> • Look at who is the population and what is the diversity in the population • Make sure that when testing, there's a showing of that diverse population- looks like the U.S. as a whole instead of a smaller group • Make sure "who was this tested with" is known; make sure data is transparent and not hidden • Inclusion and exclusion materials- users don't know about them currently, and don't know how to get access to that information from case studies • Building in incentives to funnel these more scientific testing initiatives to manufacturers 	<ul style="list-style-type: none"> • Start thinking of ways of getting a hold of people that are needed to be analyzed • Utilizing data correctly through the viewpoint of what you're looking for and needing to find- can always interpret and create trends of what you need to find, but how do we know it's true • What is your test method? • Making an effort to get a diverse population • Tax incentive 	<p>Private sector information: why would we share that?</p> <p>With a lot of new wearable devices have no testing guidelines; what is the test?</p> <p>And who is responsible for monitoring them through their entire cycle?</p>
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