Evaluation of data usability generated by wearables & IoT-enabled home use medical devices via Telehealth to identify if blockchain can solve potential challenges

by

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The student author, whose presentation of the scholarship herein was approved by the program of study committee, is solely responsible for the content of this thesis. The Graduate College will ensure this thesis is globally accessible and will not permit alterations after a degree is conferred.

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TABLE OF CONTENTS

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ABSTRACT

The adoption of blockchain shows a variety of benefits owing to an incorruptible digital ledger and a decentralized database. This has eliminated the need for a gatekeeper to oversee all associated transactions. Blockchain, the underlying technology behind bitcoin and other crypto-currencies, has found use in many industries besides finance, such as healthcare, where it has shown promise in several use-cases. Patient data is collected using a plethora of devices, such as wearables or IoT-enabled home use medical devices. These types of devices are utilized in telehealth and provide the ability to remotely monitor the patient's health condition. This requires the patient to perform measurements themselves in their home (such as vital signs), which puts the burden of reliable and precised patient exam data in the hands of the patients. The purpose of this quantitative study is to increase the understanding of what factors affect data usability generated by these devices, with the findings that the surveyed medical professionals are concerned that patients may have issues setting up the device in the home, operating the device properly (including not positioning themselves or the device correctly), the provider not knowing where the patient resides during measurement, or the patient's inability to determine when a device has malfunctioned. Upon analyzing blockchain's capabilities, it was discovered that blockchain cannot fix all identified hurdles, however, it can be used (in conjunction with smart contracts) to limit invalid data transmission to the provider. It was discussed that blockchain may also be utilized to overcome interoperability issues caused by the inability of most Electronic Medical Records (EMRs – sometimes also referred to as Electronic Health Record – EHR) to communicate and provide the patient governance of his/her own medical record. While there are interoperability issues amongst blockchain themselves, Estonia, for

instance, has harnessed the power of a single blockchain for digital security and has overcome this interoperability issue.

CHAPTER 1. INTRODUCTION

Telehealth & Remote Patient Monitoring

At the time of the last census in 2010, around 60 million of the U.S. population (19%) lived in rural areas (United States Census Bureau, 2020). Residents living in those areas are many times not able to travel to healthcare providers due to several circumstances, mainly based on economic hardships and geographical isolation. Therefore, these patients are not able to get routinely examined by a primary care or family physician and show higher "prevalence of chronic diseases such as diabetes, cancers, arthritis, and heart disease (Murray, 2006).

Telehealth has shown promise to overcome these barriers of the geographically secluded patients, allowing healthcare providers and facilities to use "electronic information and telecommunication technologies to support long-distance clinical health care, patient and professional health-related education, public health, and health administration" (Health Resources & Service Administration (HRSA).

Remote patient monitoring (RPM) is a category of telehealth and collects patient health data outside of traditional clinical settings and transmits this to the healthcare provider, enabling health care professionals to evaluate, diagnose and in some cases treat patients remotely. This patient health data, or patient-generated data, is collect via home use medical devices or wearables.

Wearables & Home Use Medical Devices

Wearables are tiny, web-enabled (or IoT - Internet of Things) computers and sensors worn on our body. These devices capture a variety of patient-generated data, such as step count,

sleep quality or heart rate to provide insight of potential health conditions, such as sleep apnea or hypertension.

This data is usually transmitted to an edge gateway which in many cases is a smartphone or tablet, and from there transferred (via different types of communication protocols, such as WIFI, bluetooth or cellular) to a healthcare provider's Electronic Medical Record (EMR) or a data warehouse where the incoming data is organized and then transported to the provider ("store-and-forward").

Telehealth Opportunities in a Changing Healthcare Environment

The vast adoption of IoT-enabled home use medical devices and wearables by patients and healthcare facilities has allowed health providers to navigate a changing reimbursement system, and at the same time shift to a value-based care system. Value-based care is a healthcare delivery model that focuses on the patient's health, d healthcare providers get paid based on the patient's health outcome. This new model will impact how physicians treat patients - less tests will be performed in the healthcare facility (physician office and/or hospital) and telehealth/RPM will allow to monitor the patient's health, and at the same time better manage patients' chronic diseases, such as sleep apnea - by monitoring sleep patterns with a Continuous Positive Airway Pressure (CPAP) device.

With the switch to this new model, \the CMS (Centers for Medicare & Medicaid Services) announced three new CPT (Current Procedure Terminology) codes for reimbursement of remotely monitoring patients via telehealth (Wicklung, 2018).

- CPT code 99453: “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; set-up and patient education on use of equipment.”
- CPT code 99454: “Remote monitoring of physiologic parameter(s) (e.g., weight, blood pressure, pulse oximetry, respiratory flow rate), initial; device(s) supply with daily recording(s) or programmed alert(s) transmission, each 30 days.”
- CPT code 99457: “Remote physiologic monitoring treatment management services, 20 minutes or more of clinical staff/physician/other qualified healthcare professional time in a calendar month requiring interactive communication with the patient/caregiver during the month.”

Home use medical devices and wearables, including health and fitness trackers, have become a major part of our lives. The research firm Berg predicts that “by 2021, there will be 50.2 million remotely monitored using connected healthcare devices, compared to 7.1 million in 2016” (Cohen, 2017). This is a compounded annual growth rate (CAGR) of 47.9%.

This trend shows that telehealth is here to stay, and the most-recent developments caused by the COVID-19 pandemic provides further opportunities for Telehealth, as many patients in rural areas are encouraged to not leave their homes amid the outbreak of this virus.

Data Usability Generated by Wearables & Home Use Medical Devices

There are a variety of usability challenges that appear when the patient or the patient’s caregiver is responsible for the device operation at his/her home. This ranges from proper device operation and ensuring that the generated data has been sent properly to the healthcare provider, to the need to set up the device correctly (if a home use medical device was provided by the

healthcare provider, such as a spirometer) at the patient's home network so the data will be transmitted reliably.

There are also safety risks to the patient if the device is not used properly. The FDA has therefore issued Human Factors guidelines describing the need to apply "Human Factors and Usability Engineering to Medical Devices" (U.S. Food & Drug Administration, 2016), such as the recommendation to add a Human Factors Use-Related Risk Analysis (URRA) validation for a Graphical User Interface (GUI) present on the screen of a wearable or home use medical device. These guidances have been released to ensure that the device interface operation by patients or their care-givers is safe for everybody involved.

Besides safety risks, inaccurate data recording can also happen when the patient is not in the proper environment during data acquisition (being stressed at work vs resting at his/her home), or if a patient is not using the device accurately since no medical professional is supervising the examination. For instance, there are many steps involved to receive an accurate as well as precised blood pressure reading, such as to have "feet flat on floor and back supported" (Muntner, 2019). During the blood pressure measurement, there will not be a medical professional in the home to remind the patient of this guidance.

Another usability issue that could have an impact on data quality is a device that requires calibration or stopped working accurately, leading to inaccurate patient data transfer, or the patient having to perform an exam and his/her home without a medical professional walking him/her through the exam.

If the device completely stops working or the exam is not performed properly, data will not be transferred. This is also true when a patient is not compliant and will not engage in the program as requested by the healthcare provider. The patient may start out motivated, but

compliance to the examination schedule will drop. With the shift to the discussed value-based care, providers need to rely on the patient's motivation to use and wear the device regularly and properly, but it can be hard for the user to build a new routine. One missing data link can lead to a miss-interpretation of the data, which can have serious consequences, ranging from impacting the patient's treatment plan to jeopardizing a patient's health in general.

Blockchain

Blockchain is an innovative technology that promises to transform many industries, including healthcare, due to its incorruptible digital ledger and decentralized database. Blockchain is secure and is used for cryptocurrencies, such as bitcoin, to perform secure payments.

In finance, each time a new transaction takes place, a new block of data is generated. Once the block is created, it is linked to the chain of previously created blocks, building an irreversible chain that becomes an immutable database. Unique to each created block is a fingerprint called "hash," which also serves as the links that holds the chain together. Since these blocks include a specific summary of the previous block in the form of the secure hash, and are structured in the form of a chain, the content of transactions cannot be manipulated and makes this tamperproof.

Microsoft (Azure) and Amazon (AWS – Amazon Web Services) have recently started to integrate blockchain infrastructure into their respective cloud platforms in order to leverage their service offerings (Ajoy, 2018). The growing popularity of these cloud platforms by healthcare and life science companies could be leveraged to store patient-generated data using blockchain as access control for these data repositories.

Do due its strong security measures and decentralized technology, Blockchain holds promise to be applied in healthcare to overcome the challenges of data usability, besides its already established benefits of keeping data secure.

This thesis investigates if blockchain can be applied to overcome the described data usability challenges of home use medical devices and wearables. This analysis will be performed through reviewing existing literature to further identify usability challenges of these devices, as well as use-cases blockchain has been used for. Additionally, a survey was administered to medical professionals in order to get quantitative feedback on their experience regarding RMP and its challenges.

CHAPTER 2. LITERATURE REVIEW

The present topic of usability challenges of data that was generated via telehealth (remote patient monitoring) and its challenges include different components and has been studied only minimally. Also, previous research on how blockchain can be applied to be used for wearables and home use medical devices is scarce.

Therefore, the literature review has been organized in different categories, with the goal to apply the key concepts of each category discussed to the overall discussion and conclusion of this thesis. This review focuses on

- Wearables & Home Use Medical Devices – Technical Solutions
- Wearables & Home Use Medical Devices - Data quality
- Wearables & Home Use Medical Devices – Generated data sets
- Wearables & Home Use Medical Devices - Motivation for use
- Wearables & Home Use Medical Devices – Usability
- Telehealth & Blockchain

Wearables & Home Use Medical Devices – Technical Solutions

In order to avoid the need for the patient to travel to a medical facility for a health check-up (in particular ECG data), Ungrean (2017) proposes an IoT system that was developed for recording the patient's ECG signals, recorded from his/her home, with the data transmitted to the medical facility. The ECG included a Bluetooth component. This enabled sending the data to an internet-enabled notebook or smartphone, which allowed data transmission to the facility for data analysis. The author states that a limitation of these data was the accurate detection of the ECG signals since the system developed as cost-effective as possible. It was also stated that a Global

System for Mobile (GSM) mobile signal would require additional components that include higher computing power, therefore, increasing cost and limitations of the devices use to connect the device to the provider.

A comparable approach by Archip (2016) examined how a modular monitoring system could be implemented to "facilitate faster and better medical interventions in emergency cases" for electrocardiogram (ECG or EKG) measurements, oxygen saturation (SpO2), temperature and movement data. The author states that the main purpose of his study is to "fill the gap in monitoring a patient's vital signs between ICU (after having undergone surgical procedures or other emergency treatments) and the actual hospital discharge." Compared to the previous study, the monitoring system for his study uses an edge gateway as the main component that is based on a Raspberry Pi B+ system. A sensor node (mobile devices equipped with wireless IEEE 802.15.4, as opposed to bluetooth) monitors the patient signal (such as ECG or SpO2) which the edge gateway collects and transmits to Android-based systems of the healthcare provider via a RESTful based web interface.

While the system performed well and provided the desired data feed error-free and without delay, it is currently only available for Android-based devices. The article states the necessity of improving data security, although overall security was not discussed in detail. Also, neither of these two articles discusses need for the user to properly use these devices, ensuring, for instance, a proper ECG signal and therefore accurate results.

Majumder (2017) lists in the article "Wearable Sensors for Remote Health Monitoring" the limitations of wearables, such as its needs to manage large amount of data collected by sensors, battery life for long-term use, low signal-to-noise ratio (SNR), or the need for a secured communication channel in order to protect sensitive personal medical data when the information

is transmitted online. Further challenges described are usability and ease of use, affordability of these devices, the need for the device to be un-obtrusive, plus the common challenge of interoperability amongst different sensors and applications. It discusses home monitoring solutions such as camera-based systems with the limitation that these systems are pricy, complex and restrict the movement of the user within a specific range, and elaborates on the gained popularity of accelerometers, gyroscopes, and magnetometers due to their limited cost and versatility.

These types of sensors may have an impact on measuring and identifying proper usability of wearables and home use medical devices while operating the device with limited training. However, small devices are low-cost devices, so many accelerometers, gyroscopes, and magnetometers may not be as accurate and precise as they should be and fail accurate position detection.

IoT-enabled medical devices (including home use medical devices) can benefit the Original Equipment Manufacturer (OEM) of the device, service organizations (if different than the OEM) or the healthcare provider. CFE Media (2016) describes how OEMs benefit from embedded device sensors once the device sold, starting with new sales activities, better targeted customer service and more effective new product development initiates as there is more data of devices in the field available. “Increase first-time fix rates and grow service margins” is one of those newly added capabilities that is beneficial for all stakeholders involved: OEMs, service organizations and the customer/end-user as the system. Conditions can be set up that trigger an alert with the service team, should there be an issue. It would practically enable the service person to address the issue (with the majority being done remotely) before the end-user gets stuck with a non-functioning device, which would be challenging given the purpose of these

devices in a home setting. Another capability described is to "provide additional insight and advice for equipment end users" (CFE Media, 2016), which will allow the device to provide tailored advice to the end-user. The article does not elaborate on the type of advice, but it seems possible to learn from end-user behaviors (common errors, what works and what doesn't) based on the massively data sets collected. Finally, it mentions "ensure machines are used equally," (CFE Media, 2016), warranting that devices are used equally and determines utilization rates for all systems available in a healthcare setting. Some devices may have been "barely used while other devices are consistently over-used.

Wearables & Home Use Medical Devices - Data Quality

Proper device operation and the overall impact of the environment has been studied by Bitterman (2011). He describes the ramification of test results due to the patient's environment and the patient's skill-set to operate a test (compared to a qualified operator). The author also highlights the importance of the test location and states that hospital environments are "standardized, well regulated, accessible settings operating under close professional supervision and strict regulations" (Bitterman, 2011). Each patient's home is unique and not a healthcare setting. This uncontrolled environment may restrict appropriate testing and will possibly influence accuracy and precision. Therefore, Bitterman (2011) believes that the home environment needs to be well defined to avoid errors and achieve accurate and precise results. This will, in turn, motivate more users to become committed of remote services, focusing on the importance of patient motivation to run tests as demanded by the provider. One aspect missing is the need for the medical staff to educate and train the patient in a non-intimating way and create a self-executing mechanism that will trigger inappropriate usage. This could be a

notification when an out-of-range data set is detected, or if the device has not been used for a while due to lag of patient motivation.

While wearable technology is getting increasingly popular for "monitoring training, recovery and health, there is not much data available regarding the validity and reliability of this generated data" (Düking, 2017). Düking provides recommendations of how such evaluations could be established, such as including access to raw data to increase confidence in the data acquisition and that all sensor interoperate properly. He also stresses the need to describe the life of a wearable, which is dictated in large by its sensors. These can "deteriorate or wear out" and are usually not routinely tested. One important aspect to data reliability is the need to use wearables properly (and therefore it becomes a usability concern). The devices are designed many times to be used for specific body regions, which is not always clearly indicated, or there is not always confidence that the device was positioned correctly. This is especially challenging since these devices are used by "nonprofessionals." He recommends for manufacturers to clearly state how and where to position these devices, how to best reproduce the data and describe potential interference caused by other wearables in close proximity to one another.

Wearables & Home Use Medical Devices – Generated Data Sets

A big impact on data usability is the way the incoming patient-generated data is handled and parsed into dedicated databases, whether it is merged directly into dedicated EMR fields, a cloud-based solution or a proprietary database that would forward the information to an EMR ("store-and-forward"), or if it is stored permanently in other data repositories.

Davidson (2013) researched clinicians' (medical personnel) acceptability of parsing this incoming data directly in the EMR. For this qualitative research, the researcher interviewed 20

clinicians with the results that while these professionals would welcome the opportunity to review relevant patient data directly in the EMR, they are concerned on additional "workload" and "safety" (Davidson, 2013), the potential of errors being induced due to this massive amount of data, as well as the potential for this to disrupt the office's workflows - should integration be not successful at times. The article also states that devices allowing direct EMR data integration are growing in the marketplace. Additional open questions are how to "summarize the data" (such as by using filters so clinicians can select the displayed data) and how to ensure that data reliability and quality is being considered. One respondent mentioned in the interview "all of a sudden you've got a reading which makes no clinical sense. If you could somehow remove that or put it there but not actually making it count with a reason for it… you can't delete them, you just have to put a comment on it" (Davidson, 2016). Resolution suggestions for this topic included the need for good training on how to use the equipment and use proper test assessment techniques (which will be achieved with the newly introduced CPT codes as discussed in the introduction).

Prabhu (2016) discusses the value of patient data generated at home via a telehealth model and claims that this "could be the source of medical breakthroughs and effective treatment." He lists telehealth advantages over conventional care, such as not being able to "minimize or exaggerate symptoms or constantly neglecting needed follow up visits" (Prabhu, 2016). He reports that a study with 24 recently discharged heart-failure patients were divided in 2 groups where 12 patients received telehealth follow up care, and the other 12 patients received standard care. In the latter group, seven patients were readmitted within six months, whereas in the telehealth group, it was only one patient. Prabhu then moves on to explaining that this type of care would be specifically beneficial for healthcare providers that are participating in pay-for-

performance compensations as part of a value-based care system. Engaging patients in a telehealth program makes monitoring the patient more efficient and will be more effective, also financially, than conventional standard office care. His concerns are aligned with those studied in this research – data has to be usable, meaning, it needs to be interoperable and integrate into the physician's workflow so the data can be accessed if needed. This could mean EMR integration, or a proprietary database. He also lists security and ongoing device maintenance (device calibrations) as potential problems.

Wearables & Home Use Medical Devices - Motivation for Use

Patient motivation, or patient adherence to running tests as requested and described by the healthcare provider is crucial to accurately monitor the patient's health conditions. Is there a method that would increase patient motivation, increase available data points and reduce the need to travel to a medical facility to monitor the health condition? Sen (2014) investigates patient engagement among populations with high rates of non-adherence in the patient's home by offering a daily financial incentive. The daily use of three home-monitoring devices during a three-month test period was evaluated, including a three-month follow-up period. Devices used during his study were devices allowing "self-monitoring of blood glucose, blood pressure, and weight among patients with uncontrolled diabetes" (Sen, 2014). The device the participants received automatically transmitted the results to a website after each use (once daily). Also, the patient was asked to confirm successful data transmission. Upon study evaluation, the researchers found that the group's participation with a financial incentive was higher than the control group, and after the three-month period, the group's adherence with the incentive remained higher compared to the control group. As major limitations, the research mentioned

that all participants came from a single primary care office, limiting this research for a certain geographical research only. Also, the incentive payout was only designed for three months, and may have not been long enough to develop a new habit amongst the study participants. Finally, one would believe that this could work in a research setting, but introducing financial incentives, including its payouts, is challenging in a real-life environment, where patients are needed to travel large distances without the ability to collect the incentives in person, or for the facility to mail checks to the patients on a regular basis.

While Sen evaluated if financial incentives can increase motivation, Asimakopoulos (2016) evaluated the main driver of device-usage motivation. 34 global participants were asked to report their motivation level twice per week over a period of four weeks to determine what aspects drove their motivation to use these devices (in this study the participants used either a Fitbit or Jawbone fitness tracker). The questions the participants had to answer where as follows: "reasons for wanting/using an activity tracker, reasons for choosing their specific one, physical activity habits and transport regime, activity tracking and barriers, motivation or demotivation concerning sustained use, needs and desires, impact of content that prompts motivational behavior, and finally support for a personalized UX" (Asimakopoulos, 2016).

The researcher states that all users are devoted users to their device, defining this as "intrinsic motivation for use" (Asimakopoulos, 2016) with some participants stating they use the device regularly due to incentives offered by their employer. The results reveal that UX (User Experience) has a direct impact on motivation, with the main drivers being data (movement, sleep statistics), gamification (monitoring real-time tracking) and the design of the solution.

When tracking usage compliance or motivation over time of a new device, it is crucial to consider the impact of the novelty effect. The novelty effect is defined as the "tendency for

performance to initially improve when new technology is instituted, not because of any actual improvement in learning or achievement, but in response to increased interest in the new technology" (Ngai, 2018). This includes curiosity about new physical activity data, and the technology itself. Shin (2018) reports qualitative as well as quantitative research findings of a total of 23 Fitbit users who used their device between 60 and 1073 days. The users' log revealed two stages: the novelty period and the long-term use period. Based on the study results, the novelty period ended after approximately three months, with 14 participants continuing the device beyond those three months, driven by "personal motivation, social motivation, and gaming motivation" (Shin, 2018).

Gouveia (2015) evaluated compliance to using a health tracker as well over a 10-month period with a total of 256 participants. These participants were asked to download an application used for various interactions with the device, such as setting and updating personal goals. After the ten-month period, the user had to delete the app. The author reports that 66% interacted with the app longer than two days, 38% longer than a week and only 14% longer than two weeks. As limitations of this study, the author points out that an app had to be used and reports that "app acquisition in general is highly exploratory, with only 69% of all apps being kept for longer than two weeks after downloading" (Gouveia, 2015), and he adds that for health-related apps it is even less with 1%.

Wearables & Home Use Medical Devices – Usability

To find out users' preferences and perception on wearable usability, Jia (2018) tested seven fitness trackers with 388 participants for 30 days each, and surveyed the participant afterwards with a survey, inquiring on usability of the wearable and user preferences. For the

most popular preference for health management features, heart rate monitoring (4.73 highest number of top user selections), daily step-count (4.45), and fitness tracking (4.18) received the most selections, ECG monitoring (4.16) following closely. For the usability evaluation, product design was rated from 3.57 to 4.00 (points on Likert scale), followed by durability (3.63–4.26) and ease of use (3.70–3.90). While these results do not provide more input on data usability, it shows that ECG monitoring is important to users, to some most important, and this is one of these features that requires exact instructions and proper usability to get accurate and precised results. It also shows the usability preferences to be the actual looks of the device, but also highlights that ease-of-use is important to the participants.

Olmos (2014) focused on remote monitoring patients that suffer under Reflex syncope, which is "the most common cause of syncope" (Olmos, 2014). He discusses the challenges of using Holter systems for remote monitoring such health conditions or using an implantable monitor. Both types, however, pose challenges regarding application duration or the need for invasive procedures to implant monitoring device. In his study, a wireless, non-invasive remote monitoring technology was tested. The wearable was implanted in a garment, enabling monitoring the patient while the shirt was worn. The mean age of the patient population was 46 years, 31 subjects were tested. The study compared the results of the wearable with the results of a conventional monitoring system. The results showed an excellent correlation of a Holter system with conventional ECG monitoring solutions for patients with reflex syncope. The study describes that this wearable includes a 3-axis accelerometer, allowing better monitoring of the patient's position in real time, which will help in determining proper usability as well. While the researcher doesn't mention any limitations of this study, the author left out mentioning the need to build in thresholds of certain positions that would allude to improper use of the wearable

(wrong size, not wearing properly) and alert the physician of potentially unreliable results due to incorrect use of the equipment, as detected by the accelerometer.

Telehealth & Blockchain

This section will evaluate blockchain's capabilities of providing an alternative that could aid in overcoming data usability challenges of wearables and home use medical devices. The most viable option identified is in conjunction with blockchain-based smart contracts. A smart contract is a protocol that is added to a blockchain (such as Ethereum) and executes commands according to the originator's determination and a certain condition. In a smart contract approach, an expected value of a patient weight, for instance, could be recorded. Upon data receipt, the program validates the data value, such as weight, and automatically self-executes data transmission. This technology would address some of the mentioned usability challenges and was investigated by Griggs (2018).

The author created a system where sensors of a wearable (or as referred to in the publication as "Wireless Body Area Networks (WBANs)") communicate via blockchain's smart contracts in order to record events via a transactions log between the wearable and the healthcare provider, with the ability to forward the data to a designated EMR database. This set up allows monitoring the patient's device usage and enables to pre-set certain values, in the range those are expected. Amongst receiving out-of-range values or "unusual activity" (Griggs, 2018) the system would then notify the user or healthcare providers. The data coming from the wearable is sent to a master "smart device" (usually a smart computing device, such as phone or tablet) that serves as the edge gateway for collecting and formatting the raw data. Matching and formatting data coming from different vendors can be challenging and may require adding interfacing

communication protocols, which can be seen as limitation. This, however, is not mentioned in the article. As largest challenges in this setup, the authors list "maintaining security at every individual node" as largest challenge, especially, when data transfer is achieved via an open channel (such as a patient's WIFI). Finally, the system also lags of real-time data transfer, as it takes a short amount of time to verify each next block before data transfer.

Boulos (2018) moves on to explain geospatially-enabled blockchain solutions, having the potential of "not just record an entry's specific time, but also require and validate its associated proof of location, thus facilitating the accurate spatiotemporal mapping of physical world events" (Boulos, 2018). Using geospatially-enabled blockchain opens up new opportunities for remote monitoring and researching the affect a certain location (such as work, location during family activities, doctor's office waiting room) would have while a wearable is recording a user's heart rate, for instance. This will aid in answering the question "will utilization of a wearable or IoT-enabled in home medical device affect the results due to not using it properly while at work, or skew the results since the user is sitting in a doctor's waiting room, waiting for an upcoming physical?" The researcher also lists interoperability and blockchain's security as challenge and questions the adoption of blockchain due to the strict privacy rules under GDPR (General Data Protection Regulation) within the European Union.

Mackey (2020) evaluated if blockchain can help overcome challenges in the Japanese healthcare system caused by an aging population. These challenges include "increase in national public health spending, higher demand for health care services, acute need for long-term care, shortage of health care workers, and disparities between health care access in rural versus urban areas" (Mackey, 2020). The author focuses on several blockchain use-cases, such as "Blockchain-Based Medical Record Systems" (Mackey, 2020) and highlights the growing use

and demand of IoT-enabled devices in telehealth due this aging population and a shortage of healthcare workers. And since "92% of adults report they own a mobile device" (Mackey, 2020) this could be viable solution, however, since this technology relies on the patient's device (such as phone or tablet) as edge gateway to transmit the data to the healthcare provider, the risk of data breaches or device failure can't be underestimated, but could, however, be alleviated with blockchain. This would give the patient the control over his/her data. This added layer would provide additional security, would allow data integrity (a blockchain is append only, meaning, once a block has been added it cannot be altered - blocks can only be added) and provides additional benefits, such as the ability to reimburse with cryptocurrency, or create a connection to the EMR to monitor its transactions. The author stated as limitations that different types of blockchains could limit interoperability and therefore patient data exchange.

"Management of consent and access to healthcare data has attracted the greatest attention as a potential target for blockchain-based applications" states Leeming (2019) as he analyses a Personalized Health Record (PHR) blockchain that aids in overcoming the current challenges of accessing personal health data, exchanging health data with other stakeholders as well as providing consent to this data. To better understand its value, Lemming reviewed common features and traits of blockchain-based PHR applications, such as "health data is not stored in the chain" or "enabling telehealth" (Leeming, 2019). He discusses the fact that it would not make sense to store a full set of health data on the blockchain due to high cost incurred by cryptographically encrypting the data or covering the token costs for decentralized data storage (deepening on the consensus algorithm used). It would rather encode the health data and points to the full medical record, including patient consent to access data provided by the blockchain. The author furthermore discusses concerns over the data quality generated by "commercial

fitness trackers and unvalidated health apps" as well as integration of the data and points out that a blockchain can interoperate more effectively with different health trackers than EMRs. It can can effectively achieve this via smart contracts, connecting these data sets via their APIs to produce a comprehensive record.

Shubbar (2017) focuses on remotely monitoring patients for women who undergo breast cancer treatment and the impact telehealth can have. The author discusses the benefits and different types of telehealth and proposes a model that is used to monitor ultrasound images taken in remote locations and transferred to the physician using blockchain. With remote monitoring and blockchain integration, the author refers to "a truly accurate representation of the problem, by providing an integrity check on the images of the patient" (Shubbar, 2017). He also discusses EMRs and the common problem for the patient's health record, including images to be scattered across different health networks. He also elaborates on the system's ability to define "interoperability techniques that would coordinate data management and exchange" (Shubbar, 2017) when the need occurs to share data and manage authentication. Blockchain is introduced in order to address these interoperability challenges and integrity of the image files. This also includes smart contracts that will allow a patient to have access to his or her record and enables communication and data sharing between the patient and the provider.

While this seems a feasible solution, one of blockchain's limitation is its ability to share large datasets, and although ultrasound generates data sets smaller compared to magnetic resonance imaging (MRI) or computed tomography (CT), ultrasound image files could be too large to be handled by a blockchain, depending on the number of images sent. The author claims that the main benefit of applying the exchange of ultrasound breast imaging is "a truly accurate representation of the problem, by providing an integrity check on the images of the patient"

(Shubbar, 2017). However, the problem is believed to be more on the image exchange itself. Images are usually not stored in EMRs and cannot be shared unless they are locally stored in a non-proprietary picture archiving communication system (PACS), which typically is only the case when different providers use the same PACS vendor.

Literature Review Summary

All reviewed articles reveal valuable insight with each category including a potential solution to overcome the challenges with the generated data of home use medical devices and wearables. They also provide critical thinking considerations for implementing blockchain as resolution.

Prabhu (2016) praises telehealth and claims that this "could be the source of medical breakthroughs and effective treatment." He lists advantages over conventional care, and reports on one study showing significantly lower re-admissions after heart-failure patients are discharged and then remotely monitored. He also connects the benefits of lower cost and more effective patient monitoring with an overall financial benefit for the provider due to larger payments if enrolled in a "pay-for-performance" model as part of value-based care.

In terms of reliability of remotely monitoring patients and comparing results of a portable device with a conventional ECG, Olmos (2014) reports an excellent correlation of a Holter system with traditional ECG monitoring solutions. An important step and the big challenge compared to a conventional exam is the data transfer to the provider once the test has been completed.

In order for the data to be transferred securely and completely to the healthcare facility, several factors have to be considered and available, with the main ones being a solid IT

connection in the patient's home, an edge gateway that collects all generated data and transmits this information, and a reliably functioning device with enough battery life, high signal-to-noise ratio (SNR) with the potential impact of sensor interferences with other sensors in close proximity. Ungrean (2018) suggests the use of cellular signal in a gateway. While most of the time mobile phones or tablets are used as edge gateways due to its ability to store apps of the accompanied device and are connected (and therefore suitable to transfer the data), a potential solution by Archip (2016) to demand patients to stay at their home during tests is to provide a stationary edge gateway with the device. Bitterman (2011) proposes telehealth as risk regarding quality of the data, as hospitals are "standardized, well regulated, accessible settings operating under close professional supervision," and the remote testing should be administered in a similar setting. There are several other factors that could improve data acquisition and therefore usability. Düking (2016) suggests for the vendor to provide the facility access to raw data to make sure there aren't any interoperability issues with sensors in close proximity, resulting in a low SNR (Majumder, 2017) and to also clearly state the life and expectations of the product since these delicate sensors wear out easily. Düking (2016), CFE Media (2016) and Davidson (2013) also stress the importance of the vendor providing sufficient training as the devices are designed many times to be worn on specific body regions, such as the electrodes of a Holter monitor. With ECG monitoring having been identified by Jia (2018) as a top four feature set of a health tracker, it is crucial for the design to be fail-safe. If the electrodes are not positioned as intended, results accuracy and precision will suffer. Olmost (2014) points out that a 3-axis accelerometer will assist the user in better positioning and better patient position monitoring in real time (Olmos, 2014) to overcome such positioning issue.

To generate accurate data, it is also important for the device to function reliably, and with that for the user and/or patient to identify improper functionality. Adequate training is one aspect, but there were several other initiatives discussed that vendors can implement in order to provide peace-of-mind for the user. CFE Media (2016) suggests that devices will be able to predict failure due to the big data sets collected. It will also help the facility to run utilization rates and don't wear out one device while a different version of the same device is locked away in a drawer on a different floor.

One of the challenges in telehealth could also be the patients' compliance in adhering to the physicians' protocols and run all tests as requested. Both Shin (2018) and Gouveia (2015) report a decrease in device usage after only a short time. While Sen (2014) reports that financial incentives had a positive impact on compliance, Shin (2018) explains the concept of the novelty effect, which will drive compliance but only lasts for about three months. He and Asimakopoulos (2016) report, however, that personal motivation and gamification lead some participants to use the device longer. It is crucial, however, that the devices provide a solid UX approach (Asimakopoulos, 2016), an intuitive user interface and an attractive design (Jia, 2018), without the need to log in daily to the device app to record usage. This will detract user experience and decrease motivation (Gouveia, 2015).

This summary shows that there are many solutions to identified challenges of data usability in telehealth, and particular in RPM. The preferred alternative would be a solution that would fix all these described challenges, therefore, blockchain articles in telehealth have been reviewed as well to identify potential resolution opportunities.

Griggs (2018) and Mackey (2020) both discuss very similar and viable solutions that could serve as the leg work to overcome potential data usability issues. In this solution, a user's

wearable and/or home use medical device communicate with one another via a blockchain's smart contract and the user's phone/tablet as edge gateway, with the ability to forward the designated data to an EMR. Since this could be the ground-work for a valid concept, this will be discussed further in the Discussion section. Reported drawbacks are slow data transmission speeds (due to the time it takes in the chain for miners to complete the "transaction") and interoperability issues. Mackey (2020) moves on and adds that if this is to be implemented on a national level, it would require for each user and facility to participate in the same blockchain.

A great add-on to overcome the issue of proper patient location during the measurement, Boulos (2018) proposes a geospatially-enabled blockchain solutions, with the potential to validate the patient's location via smart contracts.

A common concept for blockchain application in healthcare is its ability to provide consent and access rights to providers, insurers or other stakeholders by the patient, who should be the owner of his/her own health record. Leeming (2019) describes efforts to utilize a Personalized Health Record (PHR) blockchain to manage patient consent and access to healthcare data, but blockchain interoperability problems and high cost to pay miners are identified downsides.

Instead of using data of wearables, Shubbar (2017) describes a method to create an image exchange on a blockchain, with the same limitations as mentioned above, plus the fact that one block of a chain can only hold a limited amount of data (currently around 2MB) and image files may exceed this limit, depending on the imaging modality.

CHAPTER 3. METHODOLOGY

After receiving IRB approval (see Appendix C - IRB Approval Letter), quantitative research was performed by using a survey instrument administered via Qualtrics totaling of 17 questions. During the Spring 2020 semester, the survey was sent to U.S. nursing managers, a consultant at a large U.S. health information technology solutions company as well as an online research community, which ensured confidentiality and the proper U.S. audience for a small fee. Eligibility criteria included being above 18 and being exposed to telehealth/RPM for a minimum of 1 year.

Due to the outbreak of COVID-19, and the fact that most medical professionals working in telehealth were either taking care of patients or were involved in other essential services that indirectly impacted the life of many, this alternative route of utilizing an online research community had to be taken in order to get timely results of the necessary target audience.

The survey included questions to gain a better understanding of RPM programs and the objectives of facilities engaging in RPM, such as reduced hospital stay and therefore less incurred cost, reduced hospital stay and therefore less potential for hospital acquired infections or increased patient health data (since patient is constantly monitored). It also addressed if RPM could limit hypertension, diabetes, sleep apnea, chronic obstructive pulmonary disease (COPD), or congestive heart failure.

An important factor that affects data usability is patient compliance to such program and if compliance and patient motivation can be increased by incentivizing the patient for participation. The instrument contained questions regarding patient compliance as well as concerns the survey's target audience had about RPM patient participation, such as patients' data

privacy concerns, the patient not being able to set up device to his/her home's IT system, or receiving inaccurate results as the patient may not be able properly use the device consistently.

Data accuracy could be impacted by RPM, and participants were asked to rate their concern for patients not being in the proper environment, and therefore the potential of the results not being precised (e.g., measurements intermittently taken at work or taken at home while resting), patients not operating equipment correctly, or the potential of a device malfunction while the test is performed remotely, vs at the healthcare facility.

The participants were also surveyed how incoming data is managed (for instance, a data warehouse collects the data and then forwards this to an EMR) and were asked what their three main challenges are with an RPM model.

Finally, the survey was set up to gauge the participants' knowledge on blockchain. If there is existing knowledge on this topic, the respondent was asked if they have seen blockchain applied in the healthcare environment.

To focus on answering the research questions, specific survey items were chosen that directly relate to the research questions, which states as follows:

- Does the data collected in telehealth by RPM programs pose usability challenges to healthcare facilities?
- If so, what are these main challenges with RPM programs and the data collected?
- Can blockchain be implemented to overcome these challenges?

During the process of creating the survey instrument, the following six hypotheses were created to state the assumption of the research outcomes –

- H_1: The patients will not have the necessary IT knowledge to connect the home use medical device to his/her home network

- H_2: The healthcare provider's IT uptime is spotty, which will lead data usability problems as not all data will be received or may be delayed
- H_3: The patient or the patient's caregiver was not properly trained on how to use the equipment. Therefore, the device will not be operated correctly at home when there is no supervision by the medical professional
- H_4: Since the patient will not be at the facility's location (either as in-patient or in ambulatory care), the location of the patient during a test at home is unknown, which may affect the precision of the results and therefore skew the data
- H_5: The device may malfunction or stop operating, which will make acquired data inaccurate, or perhaps there will not be any data recorded as the patient may not know whether the device recorded any data or not
- H_6: The patient will be compliant to the program at first and follow the schedule appropriately, but the motivation will temper off and the patient's engagement will decrease. Therefore, there will not be the amount of data available that the clinician was hoping for in order to accurately follow the patient's health condition.

The below list depicts all survey items that are mostly related to the research questions and are used to test if the hypotheses above are supported. These core questions are listed below and are followed by a ranking to show how closely each item is correlated to the research question, with 1 being the lowest correlation and 5 the highest –

- Patients are only motivated at the beginning of the RPM program, then device usage and motivation temper off slowly (4)

- Could you please rate each of the listed concerns below about patients participating in your RPM program? Patient is not able to handle device setup to his/her home's IT system (5)
- Could you please rate each of the listed concerns below about patients participating in your RPM program? Results may be skewed results the patient won't be able to properly use the device consistently (4)
- Please let us know if you agree with the following statement: The generated data of the equipment are NOT always transferred to us - please provide further information of an instance when the generated data wasn't transferred (4)
- Could you share with us what your main concern is regarding the accuracy of the generated data in the patient's home? Patients aren't always in the right environment so test results are not precised (e.g., measurements taken at work may be different than measurements taken at home while resting) (5)
- Could you share with us what your main concern is regarding the accuracy of the generated data in the patient's home? The device could be malfunctioning or completely stop working (5)
- Please let us know briefly how the incoming data is managed (for instance, a data warehouse collects the data and then forwards this to the EHR (2)

Note - Data usability challenges caused by interoperability issues among out-of-network EMRs and health information exchanges (HIE) have not been addressed in this thesis. These are challenges that healthcare vendors have been attempting to solve, including large corporations. Out of scope were also ergonomics referring to comfort levels when the device is worn, and

ethical topics regarding Health Insurance Portability and Accountability Act (HIPAA) privacy rights.

CHAPTER 4. RESULTS

A total of 35 participants completed or partially completed the survey. Of those 35 participants, the responses collected of 14 participants were eliminated due to inadequate answers provided, showing that there was little to no background in telehealth and RPM.

Table 1 illustrates the participants' mean age of 41.9 years (SD = 10.4) and the mean experience in their current role of 9 years (SD = 4.3). 14 participants were female, 7 were male. Of the 21 completed surveys, the following lists the role of each participant and the sample size of each in parenthesis –

- Nurse (5)
- Nurse Practitioner (3)
- Physician (6)
- Physician Assistant (2)
- Certified Nursing Assistant (1)
- Manager (4 - Clinical team manager, Psychologist, Vice President for a Telemedicine Network, one manager did not mention the type of managing role)

Table 1. Research Participants and Demographics

Role	N	Mean Age	Age SD	Mean Work Experience	Work Experience SD
Nurse	5	39.5	10	11.1	3.1
Nurse Practitioner	3	42.8	15.3	6.4	3.8
Physician	6	41.2	9.8	8.8	5.1
Physician Assistant	2	34.5	7.1	5.3	4.6
Certified Nursing Assistant	1	29.5	0	8.6	0
Manager	4	52	5	10.8	4.8
Total	**21**	**41.9**	**10.4**	**9**	**4.3**

Managers had the highest mean age of 52 years and the second most experience of 10.8 years, close to Nurses, who had a little more experience with 11.1 years and a mean age of 39.5 years. The age of all Managers was closely aligned with a SD = 5, while for the work experience, it was the Nurses who had a low diversity in age (SD = 3.1). The age diversity of Nurse Practitioner was high with a (SD = 15.3), with a low diversity in work experience (SD = 3.1).

Figure 1 summarizes all identified six close-ended core questions of what could be causing data usability challenges when patients or their caregivers independently perform medical tests at their homes and/or away from the healthcare facility in a remote location. The questions shaded in blue are agree/disagree questions, and the questions in blue/yellow/orange asked the participants whether they had concerns about the given statement.

To get a better visual whether the stated hypotheses is supported or rejected, each of the specified hypothesis will be listed below in bold and followed by the corresponding question results.

H_1: The patients will not have the necessary IT knowledge to connect the wearable or home use medical device to his/her home network

Only 5% (one respondent) don't have concerns that patients are able to set up the device properly in their home environment, meaning, 95% show concerns that the patient may not be able to manage all necessary IT steps for the device to transmit data successfully to the healthcare provider. Therefore, this can be considered a major challenge in an RPM program.

H_2: The healthcare provider's IT uptime is spotty, which will lead data usability problems as not all data will be received or may be delayed

An unreliable network at the healthcare provider facility would mean no incoming data or delayed incoming data. There is a disagreement that the generated data is not always transferred properly to the facility due to an unreliable network. Of 18 respondents, 12 respondents (66.7%) do not agree that data transfer to their facility is an issue. Of all respondents that did agree, meaning, they believe that data is not always transferred correctly, the mean working experience in their role is 5.7 years (SD = 3.0), and 75% of those respondents are physicians (with four out of six physicians in total that participated in the survey). This implies that physicians desire more data to aid in the patient's treatment and may not be fully on-board with RPM being a viable alternative to standard visit at the physician's office. For these six participants that agreed with this statement, five of those also agreed with the statement that compliance to device usage tempers off slowly after initiation of the program, with four being physicians, also suggesting that these personas desire more health data. Also, all respondents that agree with this statement raised concerns over the fact that patients will not be able to set up the device at his/her home IT network properly.

H_3: The patient or the patient's caregiver was not properly trained on how to use the equipment. Therefore, the device will not be operated correctly at home when there's no supervision by the medical professional

When it comes to actual usability of the home use medical device or wearable during RPM at home, (compared to having a test performed at the healthcare facility), the majority of respondents (70%) had some concern about device operation without medical personnel supervision, while 30% (six respondents) did not see an issue with the patient running a test the proper way in his/her home. While in the healthcare facility, the patient may be instructed to sit in a chair with both arms rested on an arm rest and having both feed on the floor during a blood

pressure measurement, the patient may complete this measurement while driving home from work or while working.

H_4: Since the patient will not be at the facility's location (either as in-patient or in ambulatory care), the location of the patient during a test at home is unknown, which may affect the precision of the results and therefore skew the data

55.6% (ten respondents) stated that they have concerns that data may be skewed since the patient may not be in the proper environment during a test procedure. An equal 22.2% (four respondents) mentioned that they have a big concern (four respondents) or have no concerns about this (four respondents). All respondents without concerns have a mean age of 44.5 years, the highest of all questions. All respondents that did not think this was a big concern (three respondents) are female, and also disagreed that the generated data of the equipment is not always transferred to the facility. All concerned respondents (four respondents) also had concerns about the patient being able to properly set the device in his/her home and agreed that not all generated equipment data is transferred properly to the facility. This suggests either limited trust in the patient's technical knowledge or speaking from experience about the patient's confidence level to manage exams such as vital sings independently in a remote location. When taking a closer look, it becomes apparent that these respondents are all in direct patient contact (two physicians, one nurse, one nurse practitioner), implying that patients may share their concerns about managing exams autonomously directly with them.

H_5: The device may malfunction or stops operating, which will make acquired inaccurate, or perhaps there will not be any data recorded as the patient may not know whether the device recorded any data or not

These results were similar to the question that attempted to identify existing concerns that the medical device or wearable could be malfunctioning. While 16.7% had no concerns, a total of 83.3% had concerns around this statement. If a home use medical device or wearable does not operate the way it should, or is not calibrated correctly, incomplete data may be transmitted, or the data will be inaccurate, with the medical professionals not knowing whether the patient's condition changed, or the device may need to be re-calibrated or serviced.

H_6: The patient will be compliant to the program at first and follow the schedule appropriately, but the motivation will temper off and the patient's engagement will decrease, and therefore there will not the amount of data available that the clinician was hoping for in order to accurately follow the patient's health condition

The majority (60%, 12 respondents) of all respondents agree that device compliance to remote monitoring adherence will drop, but 40% (eight respondents) disagreed, highlighting that there still seems high device usage compliance and more patients comply to such program than originally thought. The mean work experience of all the respondents that disagreed to this statement is with 12.4 years (SD = 5.5) the highest for all questions. This experience and patient knowledge strengthen this argument and underlines the fact that patients are indeed compliant, which could also be a strong vehicle for the earlier-discussed value-based care system.

The CPT codes introduced with this value-based care initiative can help motivate the patient by the medical professional, as a more compliant patient behavior and better health outcome will increase the facility's compensation within this new pay-for-performance payment system. And with IoT-enabled home medical devices, such as CPAP device, many insurers monitor device usage and limit pay if compliance drops.

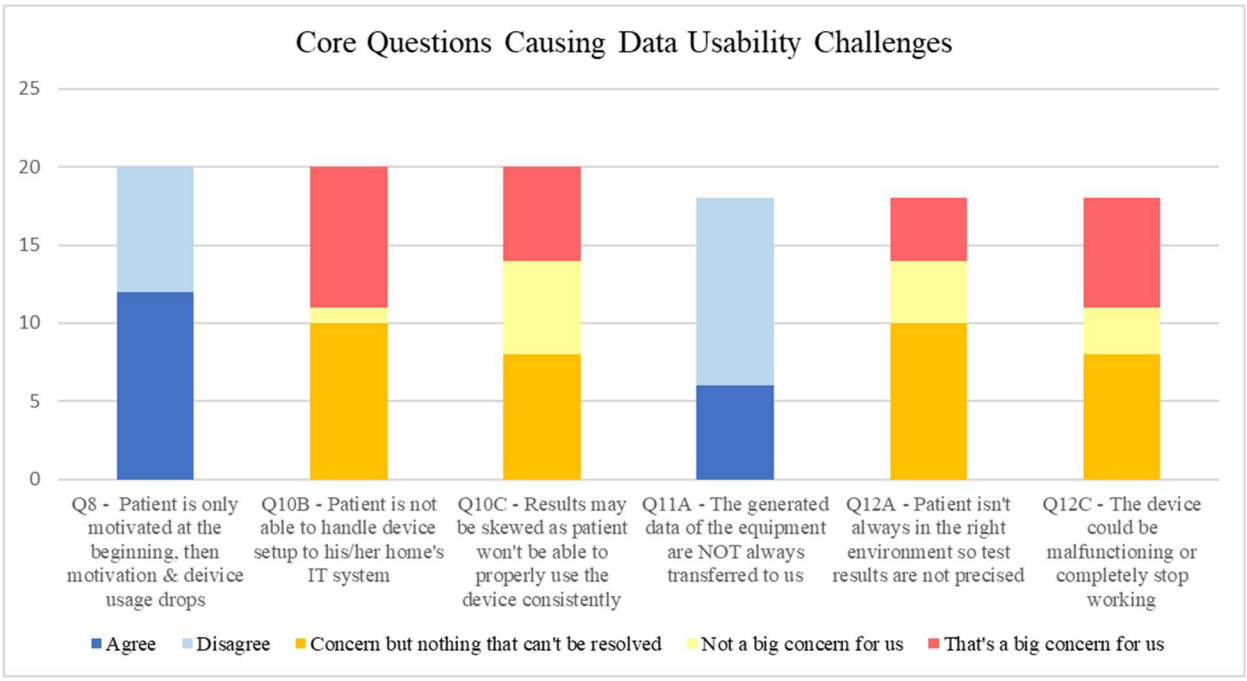

Figure 1. Summary of Identified Six Core Questions

Appendix B ("Summary of Core Questions Results") summarizes all core questions that could cause data usability challenges. The tables include the sample size n for each question, responses for each age range and range of working experience, as well as mean age, mean experience in current position, and SD of each question for age and experience in current position. For all questions that had "Concern but nothing that can't be resolved," "Not a big concern for us" or "That's a big concern for us" as an answer options, the total concern was calculated and included in these tables ("That's a big concern for us" + "Concern but nothing that can't be resolved").

The seventh and final identified core question was an open-ended question that inquired about how the incoming data is managed. This question is not matched with a hypothesis. It was, however, identified as a core question to identify if there is a usability issue caused by massive data and therefore data fatigue by the medical professional. A total of 18 participant

responded. 1 participant responded as N/A, and 3 responses were eliminated as the responses were unclear or participants just stated "use secure process" or "data is confidential." This leaves a total of 14 valid responses. The responses were categorized and evaluated, as shown below in Table 2.

Table 2. Categorized Responses for Seventh Core Survey Question

Directly to Cloud	21.4%
Local Database	57.1%
Used for Research & Managed Locally	7.1%
EMR Directly	14.3%

Of all respondents that indicated that the incoming data is going through a cloud service or a local database first ("store-and-forward"), it is unclear whether the data stays in this proprietary and therefore siloed database, or if the data is forwarded to an EMR application afterwards. Of the three respondents (21.4%) whose answer matched the "Directly to Cloud" category, two indicated that the data is forwarded to the EMR afterwards. For the local database category (57.1%), one respondent stated that this is forwarded to the EMR. This shows that most facilities collect the incoming patient-generated data by a local database or cloud service first, with most cloud services being able to directly forward the data to the most common EMR system without further software tools or additional necessary hardware. Amazon, for instance, advertises "AWS Healthcare Competency Partners" on their website that are able to build "solutions for healthcare payers and providers that securely store, process, transmit, and analyze clinical information" (Amazon Web Services, 2020).

Table 2 also shows that only 7.1% of all incoming data is not parsed into an EMR system and will stay in a proprietary repository for further research, with all other data eventually being parsed into an EMR application.

After reviewing the seven identified core questions, it becomes evident that the strongest agreement occurs for patients having a difficult time setting up the patient-data-generated device at their home. This is followed by the fact that the device could be malfunctioning, and the patient may not be in the right environment during the test to ensure precise results. Table 3 takes a closer look at all previously listed hypotheses and whether these are supported or rejected. Each hypothesis is paired with the applicable question(s).

Table 3. All Hypotheses Indicating Support or Rejection, Paired with Applicable Question(s)

Hypothesis #	Hypothesis	Applicable Statement	Supported	Rejected	Reasoning
1	The patient's will not have the necessary IT knowledge to connect the home use medical device to his/her home network	Patient is not able to handle device setup to his/her home's IT system	**X**		95% Concerned
2	The healthcare provider's IT uptime is spotty, which will lead data usability problems as not all data will be received or may be delayed	The generated data of the equipment are NOT always transferred to us		**X**	66.7% Disagree
3	The patient or the patient's caregiver was not properly trained on how to use the equipment. Therefore, the device will not be operated correctly at home when there's no supervision by the medical professional	The results may be not be accurate as the patient or caregiver won't be able properly use the device consistently	**X**		70% Concerned

Table 3 Continued

Hypothesis #	Hypothesis	Applicable Statement	Supported	Rejected	Reasoning
4	Since the patient will not be at the facility's location (either as in-patient or in ambulatory care), the location of the patient during a medical exam at home is unknown, which will affect the precision of the results and therefore skew the data	Patient isn't always in the right environment, so test results are not precised	**X**		77.8% Concerned
5	The device may malfunction or stops operating, which will make acquired data inaccurate, or perhaps there will not be any data recorded as the patient may not know whether the device recorded any data or not	The device could be malfunctioning or completely stop working	**X**		83.3% Concerned
6	The patient will be compliant to the program at first and follow the schedule appropriately, but the motivation will temper off and the patient's engagement will decrease, and therefore there will not the amount of data available that the clinician was hoping for in order to accurately follow the patient's health condition	Patient is only motivated at the beginning, then motivation & device usage drops		**X**	40% Disagree

The driver of data usability and data accuracy is clearly the incoming data, and inaccurate data transmitted is caused by the aforementioned factors that support the hypothesis.

Table 4 below illustrates the driver that causes the inaccurate/limited data (all supported hypotheses), categorized by source, as well as a resolution suggestion (first without blockchain implementation) on how these challenges can be overcome.

Table 4. Driver Causing Inaccurate/Limited Data of all Supported Hypothesis, Categorized by Source and Resolution Suggestion

Source	Driver Causing Inaccurate/Limited Data	Resolution Suggestion
Patient	Patient isn't always in the same environment, so test results are not precised	Adding a GPS sensor to a device would enable location tracking and therefore ensure the patient is in the proper environment during the test. While many wearables have this included, this is not standard for home use medical devices - Instead of using a phone/tablet as edge gateway, the device could come with its own gateway that requires to be set up in the patient's home. This would ensure data transmission only when the patient is performing a test in her/her home
	Results may be skewed as patient or caregiver won't be able to properly use the device consistently	- User errors are addressed by new FDA guidelines and the need to submit a usability validation study to get the device registered, including a URRA for the user interface, if applicable. These only address home use medical devices as not all patient-generated data devices require FDA approval - Newly established CPT codes 99453, 99454 & 99457 will provide payment for providers to work with patients on setting up device, provide patient education on use of equipment, and allow a 20-min check in time of the clinicians with the patient and/or caregiver - Many devices have integrated sensors (such as an accelerometer or gyroscope) that senses the proper position of the device or the body part attached to the device during the test. The device will alert the user if the device is not properly positioned (such as wrist blood pressure monitor and its sensing of correct arm position while the cuff inflates)
	Patient is not able to handle device setup to his/her home's IT system	The majority of wearables and home use medical devices, especially the ones communicating with a phone/tablet as edge gateway, are very user-friendly to set up and many times provide a setup via the phone/tablet app with very simple and few steps involved

Table 4 Continued

Source	Driver Causing Inaccurate/Limited Data	Resolution Suggestion
Device	Device malfunction	- Machine Learning (ML) paired with AI (Artificial Intelligence) will make devices more reliable, will predict failure and notify user of potential issues in advance - There is a fine line between device malfunction and user errors. Therefore, device manufacturers attempt to correct this with IoT-enabled devices that are connected to the manufacturer, which allows them to verify proper usage and functionality, and attempts to provide distinction between device malfunction or device is not properly used (such as an X-ray image that looks grainy – this could be a device malfunction, or bad patient positioning by the X-ray Technologist)

After reviewing the above table, it becomes evident that a large majority of the identified factors that cause data usably issues (and with that inaccurate data) are caused the patient, and that stakeholders in this field are confident and comfortable with their IT infrastructure as well as other factors that are not influenced by a human. Therefore, there is a strong likelihood for an increase in RPM data quality in the future once patients and their caregivers accept this shift to the value-based care system and this telehealth model.

CHAPTER 5. DISCUSSION

Blockchain Application to Resole Usability Challenges

As the results section and the literature review suggest, there are many solutions identified to resolve challenges of data usability in telehealth. Many of those suggested technologies (such as ML, location sensing or predictive maintenance), however, are still in its infancy.

The preferred alternative would be "a one solution fits all" approach. One single solution that could be implemented to fix these described challenges. One technology that could show potential in alleviating these depicted challenges is blockchain, in particular blockchain in conjunction with smart contracts. While not a solution to solve all problems, it has potential to make the data exchange not only more secure, but also improve data quality.

The below flow-charts (Figures 2 – 5) illustrate the driver causing inaccurate/limited data (grey hexagon shape), the identified ("conventional") resolution solutions, as well as the benefit a blockchain would have on the identified driver that cases inaccurate data

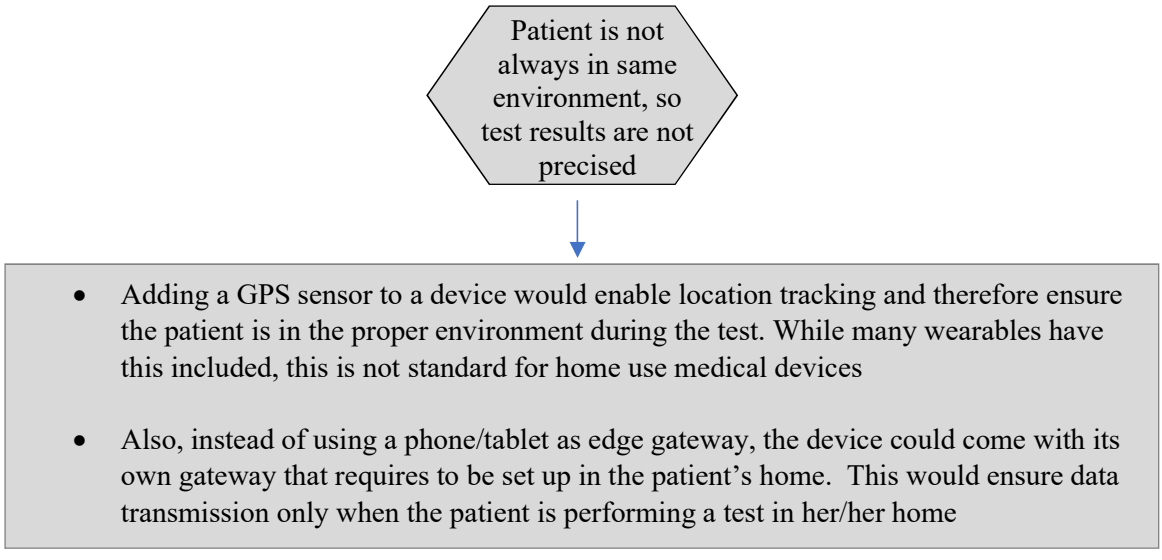

Figure 2. Resolution Solutions for "Patients aren't Always in the right Environment so Test Results are not precised"

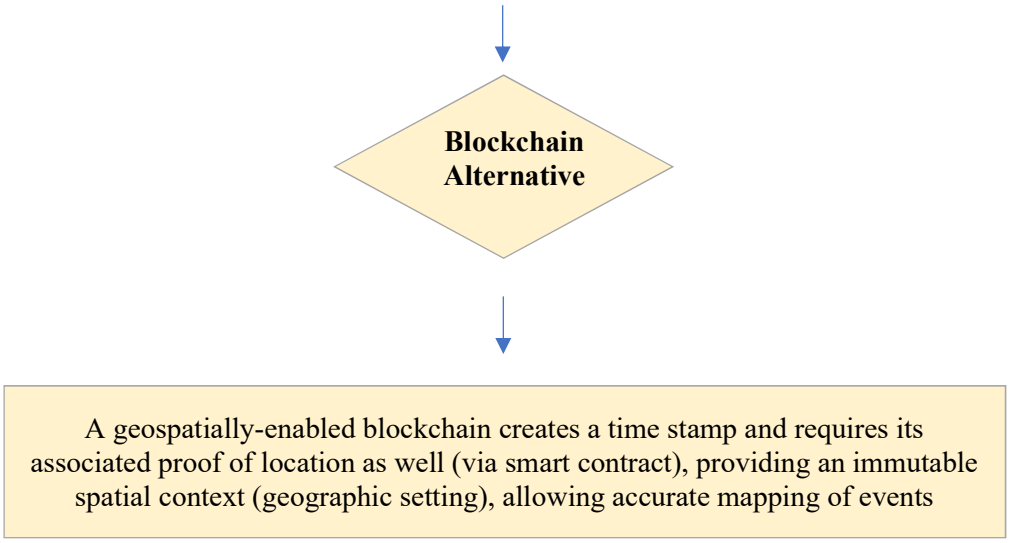

Figure 2 Continued

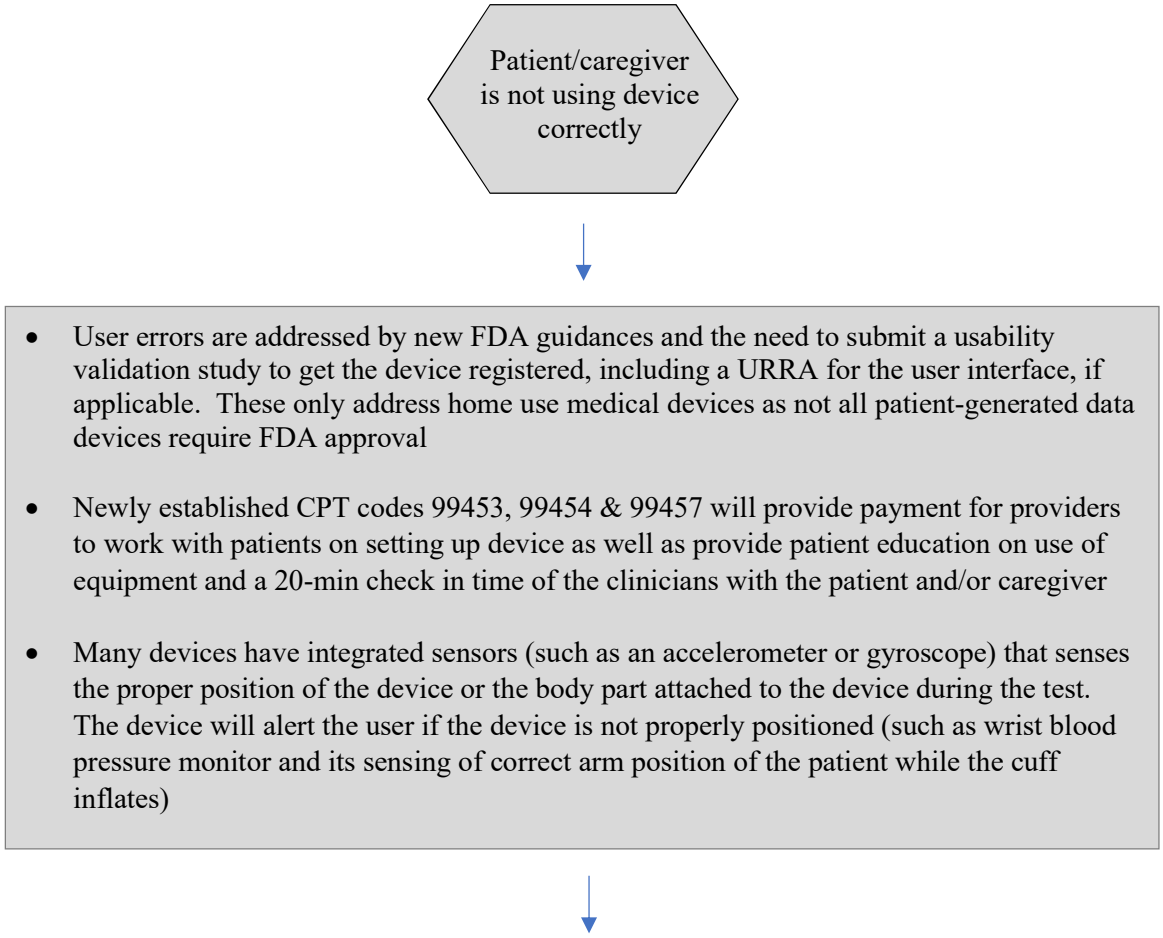

Figure 3. Resolution Solutions for "The results may be not be accurate as the patient or caregiver won't be able properly use the device consistently"

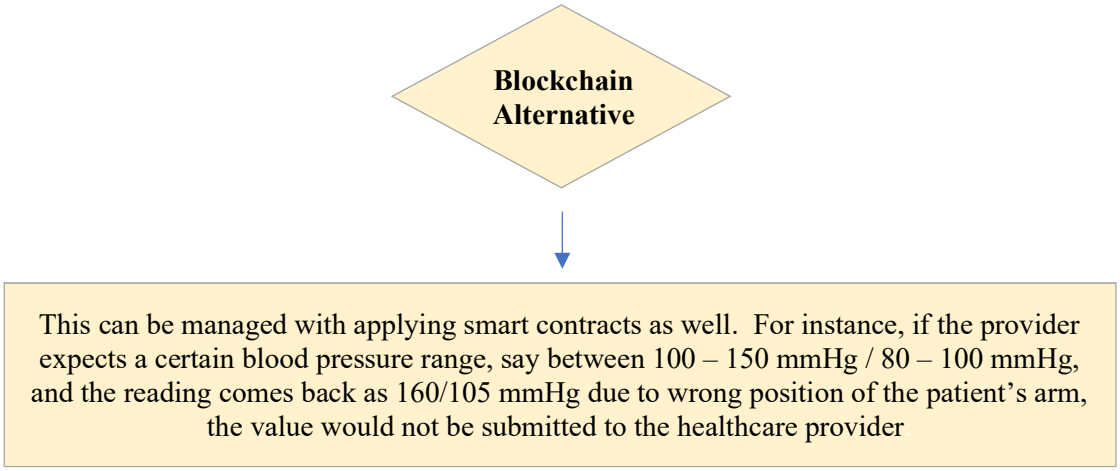

Figure 3 Continued

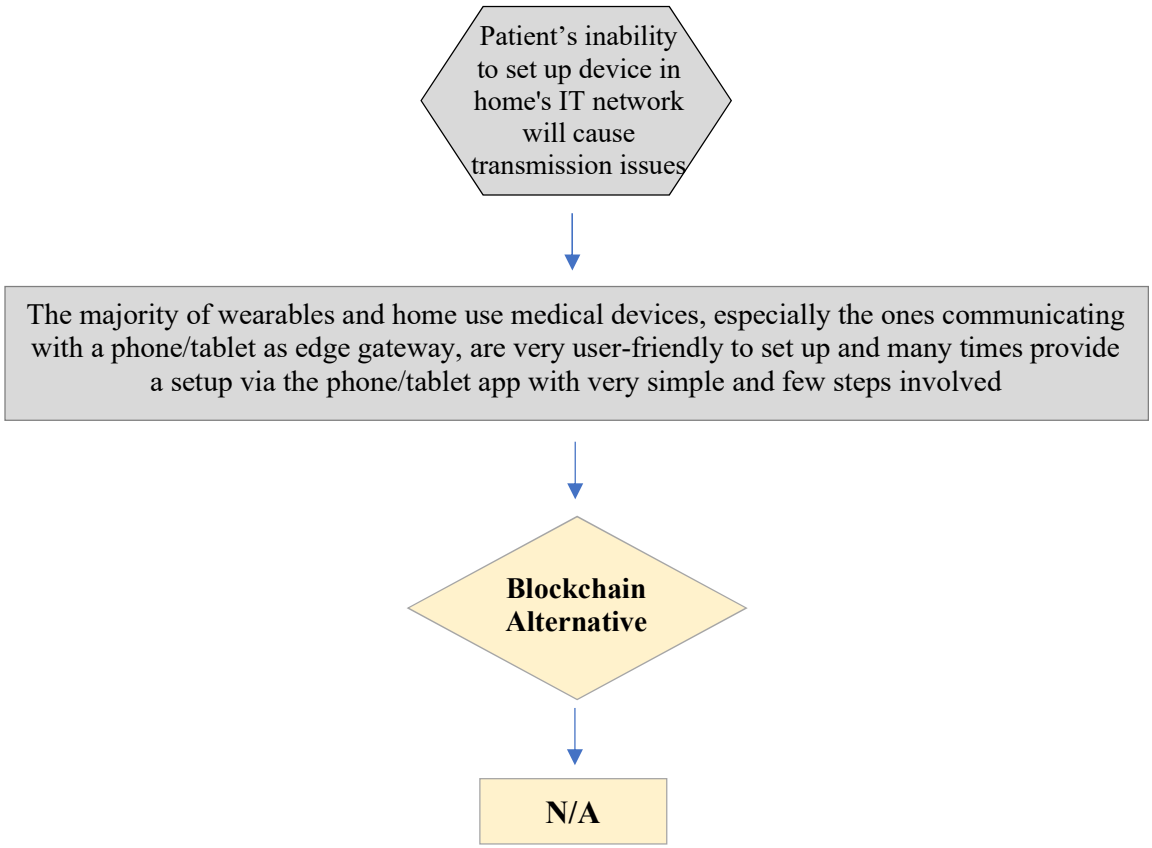

Figure 4. Resolution Suggestions for "Patient or Caregiver's Inability to set up Device in his/her Home's IT Network will cause transmission issues"

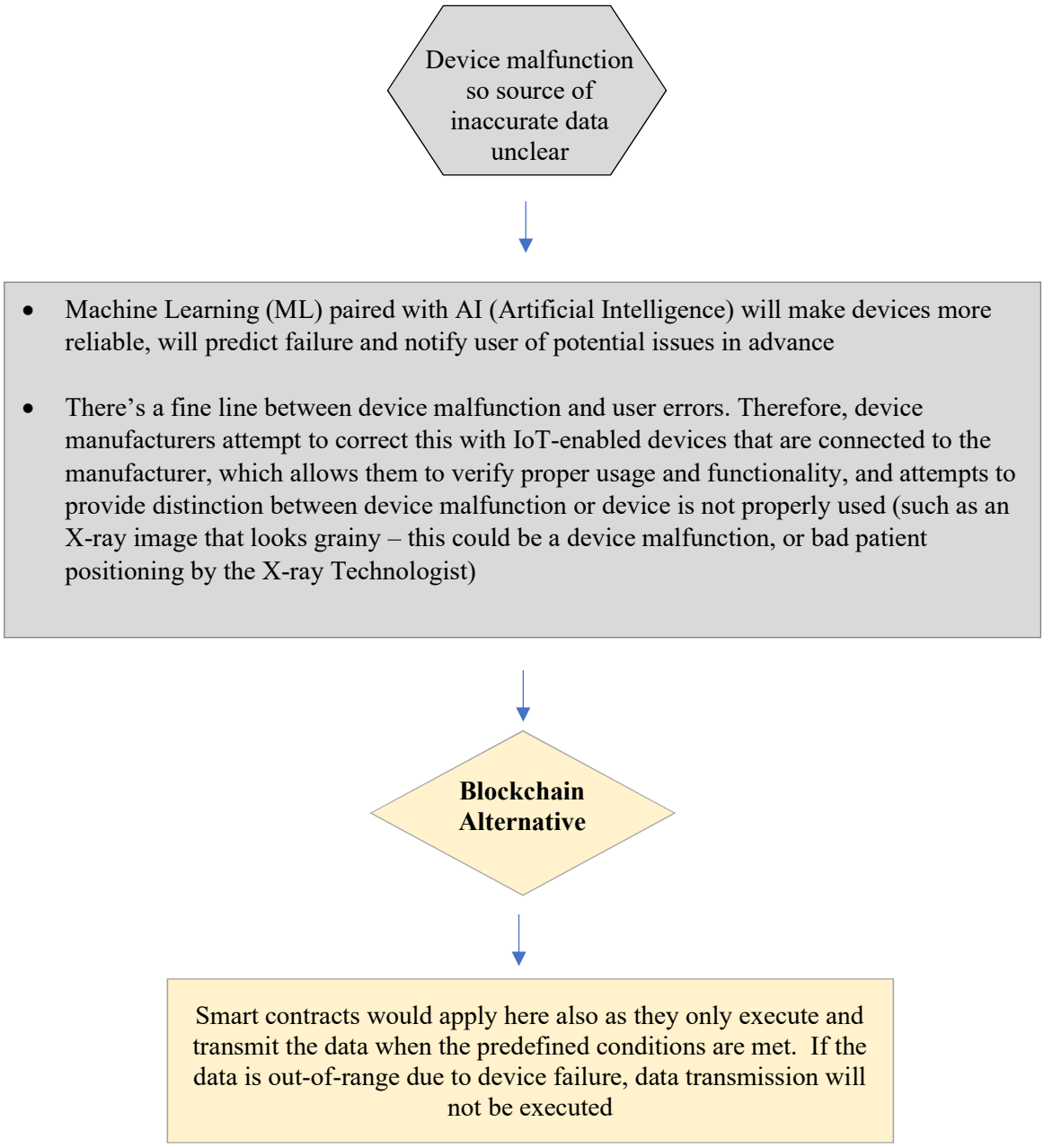

Figure 5. Resolution Suggestions for "Device Malfunction so Source of Inaccurate Data Unclear"

This analysis confirms that while blockchain will not be the cure for all, there are opportunities for this technology to solve some of the identified usability issues and prevent data to be used if invalid.

While it is crucial for innovative technology to be employed inside a wearable or home use medical device (such as the proposal for vendors to monitor image quality, for instance, in X-ray imaging and alert the facility if there is an issue with patient positioning vs instead the detector may go out) or predicting failure, blockchain can assist with resolving the identified issues once the patient has completed his/her exam and verify the data. Smart contracts could be deployed by the healthcare provider in advance to filter out-of-range test results and demand the patient to run these tests in their homes with a geospatial blockchain. Similar results achieved by smart contracts can be accomplished with logic gates that execute (and transmit data), for instance, when value A or B are met, or only A or B are true. However, using a smart contract as gate-keeper could automatically communicate out-of-range results or off-location data to everybody participating in the same blockchain.

While not in scope and not directly related to data quality that is generated by a wearable or home use medical device, another promising prospect to blockchain is the potential to overcome the issue of interoperability, a common problem in healthcare today, in which EMRs cannot communicate with other out-of-network EMRs (as mentioned for instance by Shubbar (2017), see literature review). Today it is nearly impossible for a patient to have a full medical record of all physician visits in one repository, with the patient having little to no access to their own medical records, as those are spread across different healthcare systems and providers (such as cardiologist, orthopedists, primary care physician, or even dentist or ophthalmologist). This creates data silos which can't be accessed by neither the healthcare provider nor the patient himself with the consequence that physicians won't always get a full picture of the patient's health when needed. This in turn could impact diagnosis and increase costs as tests may have to be repeated.

How can blockchain be plugged in to resolve this? Due to the fact that blockchain eliminates the central owner of a database and every node (computer in a blockchain network) has access to the full ledger, the patient could control their own data and provide consent to the healthcare providers of the patient's choice including physicians, pharmacy or insurance.

One of the limitations of blockchains, however, are limited data storage per block (around 2 MB, depending on the type of blockchain) and its slow transaction speeds due to the need to solve the consensus algorithm that is executed with every transaction. Due to this limitation, blockchain is not ideal to store a full medical record, but does lend itself to act as an access control of the actual data and points to the repository the data is stored in. There would be essentially no change to the full medical record and where it resides. But a block could be created which includes the node's encrypted information and a signed permission (consent) with the link where it is pointing to.

CHAPTER 6. CONCLUSION, LIMITATIONS, RECOMMENDATIONS

Conclusion

Blockchain technology is very promising to be applied in the healthcare field, with many identified use-cases, and with many more being investigated and developed. However, those are tested in silos by single companies and healthcare consortia, and there are currently no standards, which causes interoperability of blockchains itself with different healthcare providers running different type of blockchains by different vendors. The wide adoption of bitcoin and its blockchain, however, shows potential for a standard healthcare blockchain to be deployed.

Estonia, the "The World's Most Digital Country" (Greenwald, 2018) shows that a blockchain can be deployed successfully, as it became a digital society and utilizes blockchain to serve their state government. The country introduced a "once only" policy, which dictates that "no single piece of information should be entered twice (Heller, 2017) including eliminating the need to fill out documentation at the healthcare provider's waiting room since "physicians can access their patients' medical histories" (Heller, 2017).

Telehealth is on a similar strong growth trajectory, but compared to blockchain, it is no longer in its infancy. It is teaching patients new ways of communication with healthcare providers, and it is "no longer just a nice-to-have, but instead a must-have for patients and healthcare professionals alike' (Harpaz, 2020).

According to Harpaz (2020), "25% of respondents had used telehealth prior to COVID-19. 59% reported they are more likely to use telehealth services now than previously, and 33% would even leave their current physician for a provider who offered telehealth access."

While telehealth is growing in patient acceptance amidst the COVID-19 pandemic with the ability for more effective health monitoring, it is essential to the healthcare facility as well as better patient outcome secures higher compensation within the new pay-for-performance model.

Limitations

The following limitations were identified during analysis of the data received:

- Limited sample size
- Questionnaire did not ask respondents in which type of healthcare facility/area they work and what size it is (there is a difference of how incoming data is handled between research labs, small offices, large healthcare networks, or other facilities, such as mental health clinics)
- Questionnaire needs to ask more around the way incoming data is handled and its impact (for instance, does it contribute to dissatisfaction amongst medical professionals)

Recommendation for Future Work

Focusing on Human Computer Interaction and Human Factors, it is logical to continue to connect telehealth and blockchain research with the human. Future research could investigate how the human can interact and takes full advantage of a blockchain. Having discovered with this work that most of the data usability challenges are caused by the patient, future research should include the interaction of the user with blockchain in providing consent and assigning access rights of patient data to healthcare providers.

Also, a blockchain interface should be identified that depicts the workflow of a provider setting up smart contracts via an intuitive UI/UX that will eliminate the guess-work of the user.

This will be a natural next step in reviewing how blockchain can be plugged in to overcome usability challenges of data generated by wearables and home use medical devices in the field of Human Computer Interaction and Human Factors.

REFERENCES

Aditi P Sen, Taylor B Sewell, E Brooks Riley, Beth Stearman, Scarlett L Bellamy, Michelle F Hu, Yuanyuan Tao, Jingsan Zhu, James D Park, George Loewenstein. (2014). Financial Incentives for Home-Based Health Monitoring: A Randomized Controlled Trial. Journal of General Internal Medicine , 770–777.

Alexandru Archip, Nicolae Botezatu, Elena Şerban, Paul-Corneliu Herghelegiu, Andrei Zală (2016). An IoT based system for remote patient monitoring. 17th International Carpathian Control Conference (ICCC) (pp. 1-6). Tatranska Lomnica, Slovakia: IEEE.

Amazon Web Services. (2020). *Healthcare Partner Solutions*. Retrieved from AWS: https://aws.amazon.com/health/healthcare-partners/

Asimakopoulos, S., Asimakopoulos, G., & Spillers, F. (2017, March). Motivation and user engagement in fitness tracking: Heuristics for mobile healthcare wearables. In *Informatics* (Vol. 4, No. 1, p. 5). Multidisciplinary Digital Publishing Institute.

Ajoy, A. (2018, May 10). GeekWire. Retrieved from Blockchain in the cloud: Microsoft and Amazon look to democratize the distributed ledger for developers: https://www.geekwire.com/2018/blockchain-cloudmicrosoft-amazon-look-democratize-distributed-ledger-developers/

Bitterman, N. (2011). Design of medical devices—A home perspective. European Journal of Internal Medicine, 39-42.

Carmen Olmos, Eduardo Franco, Aida Suárez-Barrientos, Elena Fortuny, Agustín Martín-García, Dafne Viliani, Carlos Macaya, Leopoldo Pérez de Isla. (2014). Wearable wireless remote monitoring system: An alternative for prolonged electrocardiographic monitoring. International Journal of Cardiology, 43-44.

Centers for Disease Control and Prevention (2012). *Spirometry Quality Assurance: Common Errors and Their Impact on Test Result*. Retrieved from Department of Health and Human Services: https://www.cdc.gov/niosh/docs/2012-116/pdfs/2012-116.pdf?id=10.26616/NIOSHPUB2012116

CFE Media LLC (2016). 8 ways medical device manufacturers can use strategic IoT solutions: developments in monitoring power and performance data allow manufacturers to provide better service and preventive maintenance packages. Learn about the eight ways the Internet of Things (IoT) is transforming the way medical equipment manufacturers do business. *Control Engineering 63.1 (2016): DE1+. Business Insights: Essentials*. Web. 3 June 2020.

Cohen, J. K. (2017, February 15). 7.1M patients use remote monitoring devices, says Berg Insight report. Retrieved from Becker's Hospital Review: https://www.beckershospitalreview.com/healthcareinformation-technology/7-1m-patients-use-remote-monitoring-devicessays-berg-insight-report.html

Davidson, E., Simpson, C. R., Demiris, G., Sheikh, A., & McKinstry, B. (2013). Integrating telehealth care-generated data with the family practice electronic medical record: qualitative exploration of the views of primary care staff. *Interactive journal of medical research*, *2*(2), e29.

Düking, P., Fuss, F. K., Holmberg, H. C., & Sperlich, B. (2018). Recommendations for assessment of the reliability, sensitivity, and validity of data provided by wearable sensors designed for monitoring physical activity. *JMIR mHealth and uHealth*, *6*(4), e102.

Gouveia, R., Karapanos, E., & Hassenzahl, M. How do we engage with activity trackers. *UbiComp '15*, 07-11.

Greenwald, M. (2018, August 16). *Business Lessons From The World's Most Digital Country,*

Estonia, And The Happiest Country, Finland. Retrieved from Forbes: https://www.forbes.com/sites/michellegreenwald/2018/08/16/business-lessons-from-the worlds-most-digital-country-estonia-the-happiest-country-finland/#5de214a01935

Health Resources & Service Administration. (2019, August). *Telehealth Programs*. Retrieved from Health Resources & Services Administration : https://www.hrsa.gov/rural-health/telehealth

Harpaz, J. (2020, March 4). 5 Reasons Why Telehealth Is Here To Stay (COVID-19 And Beyond). Retrieved from Forbes.

Heller, N. (2017, December 11). Estonia, the Digital Republic. Retrieved from The New Yorker: https://www.newyorker.com/magazine/2017/12/18/estonia-the-digital-republic
Jia, Y., Wang, W., Wen, D., Liang, L., Gao, L., & Lei, J. (2018). Perceived user preferences and usability evaluation of mainstream wearable devices for health monitoring. *PeerJ*, *6*, e5350.

Ioan Ungurean, Adrian Brezulianu. (2017). An Internet of Things Framework for Remote Monitoring of the HealthCare Parameters. Advances in Electrical and Computer Engineering, 11-16.

Kristen N. Griggs, Olya Ossipova, Christopher P. Kohlios, Alessandro N. Baccarini, Emily A. Howson. (2018). Healthcare Blockchain System Using Smart Contracts for Secure Automated Remote Patient Monitoring. Journal of Medical Systems, 130.

Leeming, G., Cunningham, J., & Ainsworth, J. (2019). A ledger of me: personalizing healthcare using blockchain technology. *Frontiers in medicine*, *6*.

Maged N. Kamel Boulos, James T. Wilson. (2018). Geospatial blockchain: promises, challenges, and scenarios in health and healthcare. International Journal of Health Geographics, 17 – 25.

Mackey, T., Bekki, H., Matsuzaki, T., & Mizushima, H. (2020). Examining the Potential of Blockchain Technology to Meet the Needs of 21st-Century Japanese Health Care: Viewpoint on Use Cases and Policy. *Journal of Medical Internet Research*, *22*(1), e13649.

Muntner, P., Shimbo, D., Carey, R. M., Charleston, J. B., Gaillard, T., Misra, S., ... & Urbina, E. M. (2019). Measurement of blood pressure in humans: a scientific statement from the American Heart Association. *Hypertension*, *73*(5), e35-e66.

Murray, C. J., Kulkarni, S. C., Michaud, C., Tomijima, N., Bulzacchelli, M. T., Iandiorio, T. J., & Ezzati, M. (2006). Eight Americas: investigating mortality disparities across races, counties, and race-counties in the United States. *PLoS medicine*, *3*(9).

Ngai, J. (2018, July 16). Designing with Data. Retrieved from UX Design: https://uxdesign.cc/designing-with-data-ed721ffa008e

Prabhu, Sandesh R. "The real value of IoT at home: accurate patient data at home could be the source of medical breakthroughs and effective treatment." *Health Management Technology Sept. 2016: 17. Business Insights: Essentials*. Web. 3 June 2020.

Shin, G., Feng, Y., Jarrahi, M. H., & Gafinowitz, N. (2019). Beyond novelty effect: a mixed-methods exploration into the motivation for long-term activity tracker use. *JAMIA Open*, *2*(1), 62-72.

Shubbar, S. (2017). Ultrasound Medical Imaging Systems Using Telemedicine and Blockchain for Remote Monitoring of Responses to Neoadjuvant Chemotherapy in Women's Breast Cancer: Concept and Implementation (Electronic Thesis or Dissertation). Retrieved from https://etd.ohiolink.edu/

Sumit Majumder, Tapas Mondal, M. Jamal Deen. (2017). Wearable Sensors for Remote Health Monitoring. Sensors, 1-45.

U. S. Census Bureau (2020). How Does the Census Bureau Define Rural? Retrieved from Rural America:https://gisportal.data.census.gov/arcgis/apps/MapSeries/index.html?appid=7a41374f6b03456e9d138cb014711e01

U.S. Food & Drug Administration. (2016, February 3). Applying Human Factors and Usability Engineering to Medical Devices. Retrieved from FDA Executive Summary: https://www.fda.gov/media/80481/download

U.S. Food & Drug Administration. (2018, August 31). Home Use Devices. Retrieved from U.S Food & Drug Administration: https://www.fda.gov/medical-devices/home-health-and-consumer-devices/home-use-devices

U.S. Food & Drug Administration. (2019, 12 16). How to Determine if Your Product is a Medical Device. Retrieved from U.S Food & Drug Administration: https://www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device

Wicklund, E. (2018, November 2). CMS to Reimburse Providers for Remote Patient Monitoring Services. Retrieved from mHealth Intelligence: https://mhealthintelligence.com/news/cms-to-reimburse-providers-forremote-patient-monitoring-services

APPENDIX A. SURVEY INSTRUMENT

Start of Block: Introductions

Thanks for participating in our survey, your feedback is highly appreciated. It should not take longer than 20 min to complete. We are a research team at Iowa State University, trying to identify the challenges of managing data that is generated by wearables, in home use medical devices or other health trackers via Remote Patient Monitoring (RPM) programs. The survey results will be used to identify if adding Blockchain technology could eliminate some of these challenges. Please click the blue arrow below to get started.

End of Block: Introductions

Start of Block: Demographics

Q1 Which of the following best describes you?

- ○ I am a physician
- ○ I am a physician assistant
- ○ I am a nurse practitioner
- ○ I am a nurse
- ○ I am a manager (please specify below)

  _____

- ○ Other (please specify below)

  _____

Q2 How long have you worked in this position?

- ○ Less than 1 year
- ○ 1 - 3 years
- ○ 3.1 - 6 years
- ○ 6.1 - 11 years
- ○ 11.1 - 18 years
- ○ 18+ years

Q3 Please indicate your gender

- ○ Male
- ○ Female

Q4 What is your age range?

- Under 18
- 18 - 24
- 25 - 34
- 35 - 44
- 45 - 54
- 55 - 64
- 65 - 74
- 75 - 84
- 85 or older

End of Block: Demographics

Start of Block: Remote Patient Monitoring (RPM) Objective

Q5 To start, we'd like to find out the main objective why facilities engage in an RPM (remote patient monitoring) program. Please indicate your response for each of the statements below. If there's an important objective for an RPM program missing, please let us know under "Others

not listed."

	VERY important Objective	Important Objective	Not that important
Reduced hospital stay and therefore less incurred cost	○	○	○
Reduced hospital stay and therefore less potential for hospital acquired infections	○	○	○
Acquire more patient health data (since patient is constantly monitored)	○	○	○
Receive more accurate patient health data since patient will not develop anxiety when seeing a doctor in a health facility	○	○	○
To be recognized as "innovative" and start of the art healthcare facility	○	○	○
Others not listed (please specify below and select one of the options provided	○	○	○

Q6 How do the below patient types benefit from RPM? Please indicate your response for each of the statements below. If there's an important patient type missing, please let us know under

"Others not listed."

	Very important	Possibly	Not relevant
Postpartum patients	○	○	○
Diabetes patients	○	○	○
Patients with sleep disorders	○	○	○
COPD patients	○	○	○
Patients with congestive heart failure	○	○	○
Any patient that wants to participate	○	○	○
Others not listed (please specify below and select one of the options provided	○	○	○

End of Block: Remote Patient Monitoring (RPM) Objective

Start of Block: Patient Motivation

Q7 Please let us know if you agree with the following statement: Patients are only motivated at the beginning of the RPM program, then device usage and motivation temper off slowly.

○ Agree

○ Disagree

Q8 Please let us know if you agree with the following statement: In order to increase patient motivation, we have considered offering an incentive for the patient to stay motivated with using

the device and sending the generated data while home.

- ○ No, we haven't considered this
- ○ Yes, we have considered it
- ○ Yes, we have implemented incentive of some type
- ○ We had this implemented but stopped providing incentives

Q9 Could you please rate each of the listed concerns below about patients participating in your RPM program? If we missed an important concern, please let us know under "Others not listed."

	That's a big Concern for us	Concern but nothing that can't be resolved	Not a big Concern for us
Patient's concern of data privacy and security	○	○	○
Patient is not able to handle device setup to his/her home's IT system	○	○	○
Skewed results as the patient won't be able properly use the device consistently	○	○	○
Others not listed (please specify below and select one of the options provided)	○	○	○

End of Block: Patient Motivation

Start of Block: Data usability, interoperability, and security

Q10 Please let us know if you agree with the following statement: The generated data of the

equipment are NOT always transferred to us.

○ Disagree

○ Agree (please provide further information of an instance when the generated data wasn't transferred _____

Q11 Could you share with us what your main concern is regarding the accuracy of the generated data in the patient's home? If we missed an important concern about generated data accuracy, please let us know by providing details under "Others not listed."

	That's a big Concern for us	Concern but nothing that can't be resolved	Not a big concern for us
Patients aren't always in the right environment so test results are not precised (e.g., measurements taken at work may be different than measurements taken at home while resting)	○	○	○
Patients don’t operate equipment correctly	○	○	○
The device could be malfunctioning or completely stop working	○	○	○
Others not listed (please specify below and select one of the options provided)	○	○	○

Q12 Do you allow patients to use their own equipment and transfer the data that has been

generated by this device (such as an Apple Watch)?

- ○ Yes
- ○ No
- ○ We considered it but haven't done so
- ○ We have in the past but there have been too many issues (please provide short explanation below) _____

Q13 Please let us know briefly how the incoming data is managed (for instance, a data warehouse collects the data and then forwards this to the EHR)

_____

Q14 In your opinion, what percentage of patients do you believe have concerns about the data privacy?

- ○ less than 5%
- ○ 6 - 20%
- ○ 21 - 25%
- ○ 26 - 50%
- ○ 51 - 75%
- ○ 75% +

End of Block: Data usability, interoperability, and security

Start of Block: Blockchain

Q15 Have you heard of a technology called Blockchain? If so, please let us know your knowledge level by selecting one of the provided options below.

- ○ Never heard of Blockchain
- ○ Heard of Blockchain, but that's it
- ○ Little knowledge of Blockchain
- ○ Advanced knowledge of Blockchain

Q16 Have you seen Blockchain applied in the Healthcare field?

- ○ No
- ○ Yes (please provide short explanation below)

_____

End of Block: Blockchain

Start of Block: Summary of Main Challenges

Q17 Please list the 3 main challenges you have experienced with an RPM model.

- ○ Challenge 1 _____
- ○ Challenge 2 _____
- ○ Challenge 3 _____
- ○ Not Applicable/we've never used RPM

_____

End of Block: Summary of Main Challenges

APPENDIX B. SUMMARY OF CORE QUESTIONS RESULTS

	Question	%	% - Concern Combined	Experience in Current Position				Age			
				Range	Count	Mean	SD	Range	Count	Mean	SD
Q8 (n = 20) Patients are only motivated at the beginning of the RPM program, then device usage and motivation temper off slowly	Q8 - Agree			1-3'	3			25 - 34'	6		
				6.1 - 11'	7			35 - 44'	3		
				11.1 - 18'	2			45 - 54'	2		
	Sub-Total	60%			12	7.9	4.0		11	35.9	7.7
								25 - 34'	1		
	Q8 - Disagree			3.1 - 6'	2			35 - 44'	3		
				6.1 - 11'	1			45 - 54'	3		
				11.1 - 18'	3			55 - 64	2		
				18+	2						
	Sub-Total	40%			8	12.4	5.5		9	46.0	9.4
	Total				20				20		
Q10B (n = 20) Could you please rate each of the listed concerns below about patients participating in your RPM program? Patient is not able to handle device setup to his/her home's IT system	Q10B - Concern but nothing that can't be resolved	50%		1 - 3'	2			25 - 34'	6		
				6.1 - 11'	4			45 - 54'	2		
				11.1 - 18'	3			55 - 64'	2		
				18+	1						
	Sub-Total				10	10.1	5.3		10	39.5	12.7
	Q10B - Not a big concern for us	5%		3.1 - 6'	1			45 - 54'	1		
	Sub-Total				1	5.0	0.0		1	49.5	0.0
	Q10B - That's a big concern for us			1 - 3'	1			35 - 44'	6		
				3.1 - 6'	1			45 - 54'	2		
				6.1 - 11'	4			55 - 64'	1		
				11.1 - 18'	2						
				18+	1						
	Sub-Total	45%			9	9.9	5.0		9	43.9	6.9
	Total		95%		20				20		
Q10C (n = 20) Could you please rate each of the listed concerns below about patients participating in your RPM program? Skewed results as the patient won't be able to properly use the device consistently	Q10C - Concern but nothing that can't be resolved			3.1 - 6'	1			25 - 34'	3		
				6.1 - 11'	5			35 - 44'	3		
				11.1 - 18'	1			45 - 54'	1		
				18+	1			55 - 64'	1		
	Sub-Total	40%			8	10.1	4.2		8	39.5	10.0
	Q10C - Not a big concern for us	30%		1 - 3'	1			25 - 34'	2		
				3.1 - 6'	1						
				6.1 - 11'	2			35 - 44'	1		
				11.1 - 18'	2			45 - 54'	2		
					6	8.8	4.7	55 - 64	1		
	Sub-Total								6	42.8	11.1
	Q10C - That's a big cconern for us			1 - 3'	2			25 - 34'	1		
				6.1 - 11'	1			35 - 44'	2		
				11.1 - 18'	2			45 - 54'	2		
				18+	1			55 - 64'	1		
	Sub-Total	30%			6	10.1	6.5		6	44.5	9.6
	Total		70%		20				20		

Appendix B Continued

	Question	%	% - Concern Combined	Experience in Current Position				Age			
				Range	Count	Mean	SD	Range	Count	Mean	SD
Q11A (n = 18) Please let us know if you agree with the following statement: The generated data of the equipment are NOT always transferred to us	Q11A - Agree			1 - 3'	2			25 - 34	2		
				3.1 - 6'	1			35 - 44	3		
				6.1 - 11'	3			55 - 64	1		
	Sub-Total	33.3%			6	5.7	3.0		6	39.5	10.0
	Q11A - Disagree			1 - 3'	1						
				3.1 - 6'	1			25 - 34	4		
				6.1 - 11'	5			35 - 44'	3		
				11.1 - 18'	3			45 - 54'	5		
				18+	2						
	Sub-Total	66.7%			12	10.9	5.2		12	40.3	8.6
	Total				18				18		
Q12A (n = 18) Could you share with us what your main concern is regarding the accuracy of the generated data in the patient's home? Patients aren't always in the right environment so test results are not precised (e.g., measurements taken at work may be different than measurements taken at home while resting)	Q12A - Concern but nothing that can't be resolved	55.6%		1 - 3'	1			25 - 34'	3		
				6.1 - 11'	6			35 - 44	5		
				11.1 - 18'	2			45 - 54'	2		
				18+	1						
	Sub-Total				10	10.0	4.46		10	38.5	7.0
	Q12A - Not a big concern for us			3.1 - 6'	1			25 - 34'	1		
				6.1 - 11'	1			45 - 54'	3		
				11.1 - 18'	1						
				18+	1						
	Sub-Total	22.2%			4	12.0	5.53		4	44.5	8.7
	Q12A - That's a big concern for us			1 - 3'	2			25 - 34'	2		
				3.1 - 6'	1			35 - 44	1		
				6.1 - 11'	1			55 - 64'	1		
	Sub-Total	22.2%			4	4.3	2.68		4	39.5	12.3
	Total		77.8%		18				18		
Q12C (n = 18) Could you share with us what your main concern is regarding the accuracy of the generated data in the patient's home? The device could be malfunctioning or completely stop working	Q12C - Concern but nothing that can't be resolved	44.4%		6.1 - 11'	5			25 - 34	2		
				11.1 - 18'	2			35 - 44'	4		
				18+	1			45 - 54'	2		
	Sub-Total				8	11.2	3.84		8	39.5	7.1
	Q12C - Not a big concern for us	16.7%		3.1 - 6'	1			25 - 34	1		
				6.1 - 11'	1			45 - 54'	2		
				11.1 - 18'	1						
	Sub-Total				3	9.2	4.11		3	42.8	9.4
	Q12C - That's a big concern for us			1 - 3'	3			25 - 34	3		
				3.1 - 6'	1			35 - 44'	2		
				6.1 - 11'	2			45 - 54'	1		
				18+	1			55 - 64'	1		
	Sub-Total	38.9%			7	6.5	5.72		7	39.5	10.7
	Total		83.3%		18				18		

APPENDIX C. IRB APPROVAL LETTER

IOWA STATE UNIVERSITY
OF SCIENCE AND TECHNOLOGY

Institutional Review Board
Office for Responsible Research
Vice President for Research
2420 Lincoln Way, Suite 202
Ames, Iowa 50014
515 294-4566

Date: 12/11/2019

To: Steffen Baumann Richard T Stone

From: Office for Responsible Research

Title: **Design characteristics of blockchain integration to enhance usability of patient-generated data devices.**

IRB ID: **19-421**

Submission Type: Initial Submission **Exemption Date:** 12/11/2019

The project referenced above has been declared exempt from most requirements of the human subject protections regulations as described in 45 CFR 46.104 or 21 CFR 56.104 because it meets the following federal requirements for exemption:

2018 - 2 (iii): Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) when the information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a LIMITED IRB REVIEW to [determine there are adequate provisions to protect the privacy of subjects and to maintain confidentiality of the data].

The determination of exemption means that:

- **You do not need to submit an application for continuing review. Instead, you will receive a request for a brief status update every three years. The status update is intended to verify that the study is still ongoing.**
- **You must carry out the research as described in the IRB application.** Review by IRB staff is required prior to implementing modifications that may change the exempt status of the research. In general, review is required for any *modifications to the research procedures* (e.g., method of data collection, nature or scope of information to be collected, nature or duration of behavioral interventions, use of deception, etc.), any change in *privacy or confidentiality protections*, modifications that result in the *inclusion of participants from vulnerable populations*, removing plans for informing participants about the study, any *change that may increase the risk or discomfort to participants, and/or* any change such

that the revised procedures do not fall into one or more of the regulatory exemption categories. The purpose of review is to determine if the project still meets the federal criteria for exemption.

- All ***changes to key personnel*** must receive prior approval.

- **Promptly inform the IRB of any addition of or change in federal funding for this study.** Approval of the protocol referenced above applies only to funding sources that are specifically identified in the corresponding IRB application.

  Detailed information about requirements for submitting modifications for exempt research can be found on our website. For modifications that require prior approval, an amendment to the most recent IRB application must be submitted in IRBManager. A determination of exemption or approval from the IRB must be granted before implementing the proposed changes.

  Non-exempt research is subject to many regulatory requirements that must be addressed prior to implementation of the study. Conducting non-exempt research without IRB review and approval may constitute non-compliance with federal regulations and/or academic misconduct according to ISU policy.

Additionally:

- All research involving human participants must be submitted for IRB review. **Only the IRB or its designees may make the determination of exemption**, even if you conduct a study in the future that is exactly like this study.

- **Please inform the IRB if the Principal Investigator and/or Supervising Investigator end their role or involvement with the project** with sufficient time to allow an alternate PI/Supervising Investigator to assume oversight responsibility. Projects must have an eligible PI to remain open.

- **Immediately inform the IRB of** (1) **all serious and/or unexpected adverse experiences** involving risks to subjects or others; and (2) **any other unanticipated problems involving risks** to subjects or others.

- **Approval from other entities may also be needed**. For example, access to data from private records (e.g., student, medical, or employment records, etc.) that are protected by FERPA, HIPAA or other confidentiality policies requires permission from the holders of those records. Similarly, for research conducted in institutions other than ISU (e.g., schools, other colleges or universities, medical facilities, companies, etc.), investigators must obtain permission from the institution(s) as required by their policies. **An IRB determination of exemption in no way implies or guarantees that permission from these other entities will be granted**.

- Your research study may be subject to **post-approval monitoring by Iowa State University's Office for Responsible Research**. In some cases, it may also be subject to formal audit or inspection by federal agencies and study sponsors.

- Upon completion of the project, transfer of IRB oversight to another IRB, or departure of the PI and/or Supervising Investigator, please initiate a Project Closure in IRBManager to officially close the project. For information on instances when a study may be closed, please refer to the IRB Study Closure Policy.

Please don't hesitate to contact us if you have questions or concerns at 515-294-4566 or IRB@iastate.edu.