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FIT FOR USE ASSESSMENT OF BIOZEN AS A BIOMETRIC SENSOR CONCENTRATOR FOR REMOTE PATIENT MONITORING

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FIT FOR USE ASSESSMENT OF BIOZEN AS A BIOMETRIC SENSOR CONCENTRATOR FOR REMOTE PATIENT MONITORING

by

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March 2023

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In recent years, COVID-19 highlighted the importance of virtual health solutions with regard to improving patient health and conserving valuable hospital resources. Currently, the Defense Health Agency (DHA) does not own a remote patient-monitoring solution and relies on external commercial entities to provide the application and services. This could potentially lead to the DHA not retaining complete data ownership when patient data would reside on or traverse through commercial remote patient-monitoring solutions. This thesis evaluates BioZen, a DHA-owned biomedical sensor concentrator designed to run on a mobile phone, as a remote patient-monitoring tool. From this analysis, several key measures of effectiveness and measures of performance for remote patient-monitoring tools are identified and operationalized to measure the overall value BioZen brings to the DHA. Based on this research, it was found that the current build of BioZen, 2.0.0, is unable to meet any of the measures outlined in the study as a remote patient-monitoring tool. A future build of BioZen, or any remote patient-monitoring tool, could then be assessed using the measures of effectiveness and measures of performance within this study to determine the overall value brought to the DHA.

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TABLE OF CONTENTS

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LIST OF FIGURES

LIST OF TABLES

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LIST OF ACRONYMS AND ABBREVIATIONS

ADC	Analog to Digital Converters
AFib	Atrial Fibrillation
ARFL	Air Force Research Laboratory
ATAK	Android Team Awareness Kit
BAMC	Brooke Army Medical Center
BATDOK	Battlefield Assisted Trauma Distributed Observation Kit
BLE	Bluetooth Low Energy
COTS	Commercial Off The Shelf
CRPM	COVID-19 Remote Patient-Monitoring Program
DCOE	Diabetes Center of Excellence
DHA	Defense Health Agency
DOD	Department of Defense
DREAM	Diabetes Remote Electronic Assisted Monitoring Program
DRG	Diagnosis Related Group
ECoG	Electrocorticography
ED	Emergency Department
EEG	Electroencephalogram
HER	Electronic Health Record
EKG	Electrocardiogram
GLWACH	General Leonard Wood Army Community Hospital
GSR	Galvanic Skin Response
ICU	Intensive Care Unit
IEC	International Electrotechnical Commission
IEEE	Institute of Electrical and Electronics Engineers
IoT	Internet of Things
ISM	Industrial, Scientific, and Medical (bands)
ISO	International Organization for Standardization
ISSA	Interservice Support Agreement
IT	Information Technology
JTCCN	Joint Tele-Critical Care Network

LFP	Local Field Potential
LoRa	Long Range radio
LPWAN	Low Power Wide Area Network protocols
MEP	Mobile Enterprise Platform
MHS	Military Health System
MOE	Measure of Effectiveness
MOP	Measure of Performance
MTF	Medical Treatment Facility
NARA	National Archives and Records Administration
NASA	National Space and Aeronautics Agency
NDAA	National Defense Authorization Act
NETCCN	National Emergency Tele-Critical Care Network
NFC	Near Field Communications
NPS	Naval Postgraduate School
PAN	Personal Area Network
PHI	Protected Health Information
PII	Personally Identifiable Information
PPG	Photoplethysmogram
QR	Quick Response
RPM	Remote Patient Monitoring
RTM	Requirements Traceability Matrix
SDD	Solutions Delivery Division
SE	Systems Engineering
SOI	System of Interest
SpO2	Spot Oxygen Saturation
STARPHAC	Space Technology Applied to Rural Papago Advance Health Care
TCC	Tele-Critical Care
TMDS	Theatre Medical Data Store
VH	Virtual Health
VMC	Virtual Medical Center
WAN	Wireless Area Network
WBASN	Wireless Body Area Sensor Networks

Wi-Fi	Wireless Fidelity
WMT	Web and Mobile Technology
WPAN	Wireless Personal Area Networks
XML	Extensible Markup Language

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I, Asa Schaefer, would like to thank God for the blessings he has shown to my family. I would also like to thank my beautiful wife, Erica, for all the long days, long nights, early mornings, deployments, moves, and PCS-related career reboots over the past 13 years. Your loving support has meant more than words can say.

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I. INTRODUCTION

A. BACKGROUND

It is the responsibility of the Military Health System (MHS) to serve 9.6 million beneficiaries around the world (Military Health System [MHS], 2023). With hundreds of clinics and Military Treatment Facilities (MTFs) worldwide, all operating on a budget, maximizing efficiency in the provision of healthcare is crucial. The number of inpatient beds that are available to patients who are checking into a clinic or hospital are finite for that facility, and once all a facilities inpatient beds are filled, the next patient who comes to that facility requiring hospitalization will be sent along to the next available bed in a different facility, potentially at a severely increased cost to the MHS. Efficiency can be found in many places. The Internet of Things (IoT) can be described as devices, sensors, appliances, smart watches or other wearable technology, and industrial controllers. These "things" are not cell phones, tablets, computers, or laptops, but they are all connected to a network. IoT devices grew from 3.6 billion connected devices in 2015 to 14.4 billion in 2022 with projections towards 27 billion in 2025; their ubiquity provides unparalleled opportunities for integrating remote health care to patients (Hasan, 2022).

Consider the transformative ability for a patient to leverage IoT wearable sensors to monitor their own biometric readings on a mobile device in their home, reducing the need for a patient to travel to a clinic which, in turn, reduces the burden to the healthcare system where an appointment, medical clerk, outpatient clinic room and technician would previously have been needed to capture the same information. Shift this vignette to a COVID-19 patient who has been treated in the Emergency Room, has received pain medication, and will need to have their blood oxygen level monitored. The ability to leverage IoT sensors to monitor biometric readings on a cell phone in the patient's home would reduce the need to admit them to the hospital for monitoring, which in turn results in more inpatient beds available for use.

The Defense Health Agency (DHA) leverages their Mobile Enterprise Platform (MEP) to develop proof of concept modules, apps, and capabilities for mobile devices,

with the intent of evolving them into fully developed applications fit for meaningful consumption (Defense Health Agency [DHA], 2021). The MEP is intended to utilize mobile phones, tablets, and IoT devices to provide health care and resources to patients. One of the most promising of the MEP apps is a biomedical sensor concentrating app called BioZen.

BioZen was developed in 2014 as a mobile application within the MEP. The app leverages commercial off-the-shelf (COTS) biometric sensors to collect sensor data, providing the capability to utilize mobile and IoT devices to track patients' vital signs and brainwaves to assist in relaxation and healthy living. The data collected by BioZen is stored on a device where it can be analyzed by the user or a medical professional to provide a real time health status. BioZen is designed to be a stand-alone application that connects to the Zephyr BioHarness, Neurosky Electroencephalogram (EEG) headset, and the Shimmer brand sensors through the Bluetooth Personal Area Network (PAN) protocol.

B. PROBLEM STATEMENT

BioZen was matured to from a minimum viable product app released in 2014 to BioZen 2.0.0 in 2019 but has not had a significant release since then. Because of this, the biosensors BioZen is compatible with are outdated and may not leverage the latest PAN technology standards (DHA, 2014). There are many private companies who are leveraging the innovations found in smartwatches and other wearable technology to integrate them into health monitoring applications to provide the user with health metrics. As of January 2023, the DHA only owns one such application for their patients, which is BioZen. The DHA recognizes the potential improvements in patient safety delivered by remote health applications powered by wireless peripheral measurement devices (GovEvents, n.d.). There is a practical opportunity here to leverage wearable technology for providing both the patient and medical professional vital data history which has the potential to increase the chance to identify adverse health conditions as early as possible. Therefore, a systematic evaluation and a gap analysis need to be executed on the current proof of concept deployment of BioZen to provide recommendations on key areas of improvement.

C. PURPOSE STATEMENT

The purpose of this research is to evaluate BioZen by utilizing a Systems Engineering (SE) approach to determine if it provides value as a remote monitoring tool for the DHA. The researchers will identify the expected stakeholder requirements for BioZen and mature them into Measures of Effectiveness (MOEs). The achievement of each MOE will then be described in a technical manner by a set of Measures of Performance (MOPs). These MOPs will then be quantitatively evaluated within the context of a remote patient-monitoring use case to evaluate the effectiveness of BioZen. Finally, the results of the evaluation will be analyzed to determine the degree at which BioZen provides value to the DHA. This report will provide guidance in the re-development of BioZen as an existing Department of Defense (DOD) technical capability with the aim of becoming a foundational study for the requirements and features needed in future IoT medical remote patient-monitoring (RPM) tools from the DHA.

D. BENEFITS OF RESEARCH

The proliferation of wearable technology such as smartwatches, fitness monitors, and rings opens a door into new innovations in remote monitoring within the realm of tele-medicine to improve upon patient safety and health. The benefits of tele-health became apparent in recent years during the COVID-19 pandemic. Elham Monaghesh and Alireza Hajizadeh concluded in their 2020 study that telehealth prevented further morbidities during the pandemic by reducing the physical exposure of patients to high-risk areas such as hospitals. They went on to say that telehealth should be used by providers to conduct telehealth visits, triaging, and verification of a patient's vitals through self-monitoring tools at home. Additionally, the study recommended that telehealth play a bigger role in healthcare and stated that future research is needed to utilize telehealth in critical health areas, specifically high-risk patients and patients who are unable to visit a provider in person. The COVID-19 pandemic has shown that telehealth is an invaluable tool that must be integrated into healthcare. It is imperative that DOD leverages wearable technology and smart devices to bring the quality of health care found in an MTF to the patient's phone.

E. RESEARCH QUESTIONS

This thesis aims at evaluating BioZen by answering the following questions:

1. What biomedical monitoring capabilities must an effective remote patient-monitoring tool have?
2. How does BioZen work as a remote patient-monitoring tool, considering its original use case?
3. How does BioZen work as a patient self-monitoring tool, considering a range of alternate use cases?
4. What are the gaps between BioZen as it is and current technology and/or technical standards?
5. What are possible future efforts to address these gaps?

II. LITERATURE REVIEW

A. TELEHEALTH VIGNETTE

The following vignette serves to provide the reader with a common use case for BioZen to serve as context for the rest of this study.

Imagine a Tricare-eligible retired veteran in their 80s, living in Shell, a rural town located in northwestern Wyoming. This veteran has high blood pressure and a heart condition that requires daily monitoring to ensure their health does not deteriorate. They have a commercial blood pressure monitor and a heart rate monitor at home that was bought at the local drug store. To keep track of their health the veteran writes down their blood pressure and heart rate each morning right when they wake up. Every month they visit their Primary Care Provider at a clinic in Worland, about an hour away. The physician looks at the veteran's recorded vitals and verifies by checking their vitals with the clinic's equipment. Additionally, the veteran undergoes an Electrocardiogram (EKG) measurement of his heart to look for signs of atrial fibrillation, a common indicator of a heart attack. Based on the results of the checkup, the veteran's medication is adjusted, and any mitigating treatment is prescribed by the physician. This cycle repeats every month, and it is anticipated the appointments will become more frequent as the veteran approaches their 90s.

To make this monthly appointment means the veteran must drive about a two-hour round trip on a two-lane road with multiple hazards including wildlife, weather, and objects on the road. This takes an immense amount of energy for the aging veteran, as they have already had an accident due to driving while drowsy. During the winter months the road may become closed, and Shell becomes cut off from the surrounding towns. The roads may be closed for a month or more, preventing the veteran from attending their appointments at their clinic. This poses two risks to the veteran's health. First, the physician cannot verify the veteran's vitals, take EKG measurements, and adjust the treatment plan accordingly. The veteran can provide some of this information over the phone, some of the recorded vital metrics in the veteran's handwritten log may be unreadable or inaccurate. The second

risk is the inability to take an EKG. The heart rate monitor cannot produce an EKG and is not designed to detect an atrial fibrillation. This puts the veteran at risk by being unable to detect if his heart condition is deteriorating. This makes receiving the necessary treatment or guidance from the physician difficult or impossible, as the medical professional must accept the risk of providing care based on incomplete information. Should the medical professional make decision based on incomplete information and make an incorrect choice, the result could be catastrophic.

There must be a better way in monitoring the health of remote patients by giving them the ability to self-monitor their critical vital signs and having that information be authentic and accurate for medical personnel. In cases like this, medical grade equipment is not an option. First, the veteran cannot afford the medical grade equipment used for vital sign measurement. Second, that equipment must be regularly maintained by qualified technicians, which is not feasible for a remote location like Shell. The only equipment the veteran has access to and can afford are internet services, medical devices found at the local drug stores, and popular wearable IoT devices that can be purchased from the internet. Therefore, the product used by the medical professional must be of a similar price point and usability.

B. REVIEW OF THE LITERATURE STRUCTURE

The researchers organized the review of the literature in accordance with the literature review map in Figure 1. The map breaks down the review into four major threads: DOD's strategic focus on telehealth, remote care, physiological telemetry, and sensor networks and interoperability. Each thread was reviewed in depth to discover what is known and addressed in the problem space.

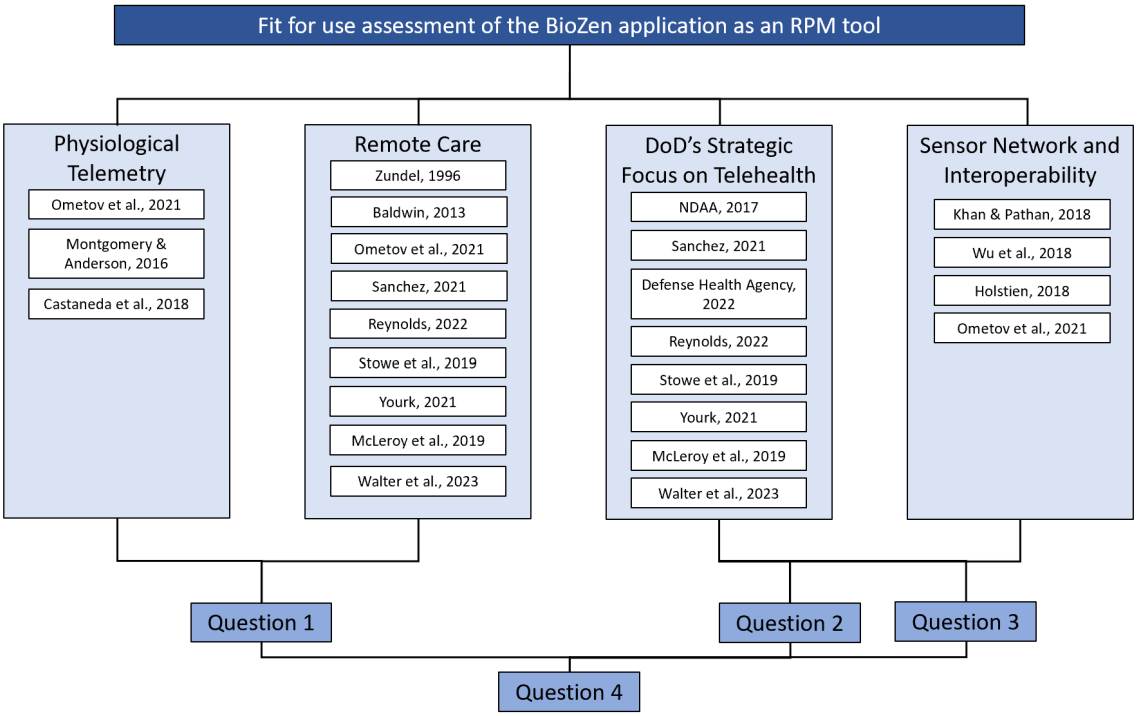

Figure 1. Literature Map

Physiological telemetry is addressed by investigating which health metrics are critical, how electronics changed the way these metrics are measured, and how state of the art wearable sensors is implemented to measure health metrics. In the remote care thread, the researchers examine how providers historically cared for remote patients, how the telecommunications impacted the level of care in the 20th century and investigate the current state of telehealth and how the COVID-19 pandemic impacted telehealth practices. Next, the focus of telehealth within the DOD is explored to identify the policies and strategic value a biomedical application is expected to provide. National Defense Authorization Act (NDAA) of 2017, existing DHA telehealth programs, and the impact these programs have on the quality of care, to help identify the specific requirements and capabilities that a mobile health application must have within the DOD. Finally, the authors reviewed recently proposed sensor network topologies for remote patient-monitoring applications, common wireless technologies implemented in sensor networks, and any interoperability concerns within these networks. Upon reviewing all threads of literature,

the review ends with a summary of each thread and discusses what has not been addressed within the problem space.

C. PHYSIOLOGICAL TELEMETRY

The following section investigates the history of physiological metrics and telemetry. The history of vital signs are discussed along with how they were measured, the tools used, and the evolution of these tools and measurement methods over time.

1. Vital Signs and Early Measurement

Since the earliest recorded civilizations, humans have been monitoring their health. This could be checking a patients' temperature by putting a hand on their forehead or checking if an unconscious person is still alive by feeling their pulse and checking for respiration. Observing vital signs are a tried-and-true method to check if someone is alive and healthy. The word vital comes for the Latin word "vitalis" meaning "pertaining to life," which is fitting because humans must exhibit these signs to be considered living (Fronning, 2021). A human found with no heart rate, cold temperature, or not breathing, is dead or is close to death. Medical personnel from all cultures utilize these three vital signs to provide a generic snapshot of a person's health.

It was not until 1625 when the monitoring of vital signs started to be studied and standardized in an objective manner. It was that year Santorio and Galileo published their findings on how to measure a person's temperature with a thermometer and pulse with a pendulum (University of Virginia, 2007). Their research provided an accurate and objective way that these two vital signs could be measured in a repeatable manner and compared with others. This provided the framework for temperature and heart rate to become the first and second standardized vital sign measurements. Santorio's and Galileo's findings were largely ignored until 1707 when Floyer published his scientific paper on the "Pulse Watch," a portable hand clock he developed for use in the survey of various peoples' pulse rates (Sarah, 2018). After he published his results, heart rate became the first measurable vital sign among medical professionals.

Respiratory rate and temperature soon followed heart rate as the second and third measurable vital sign measurement in 1852. During that year, Ludwig Taube successfully plotted the course of a fever (Fronning, 2021). Throughout his study he used a thermometer to take temperatures, collected pulse rates, and added respiratory rates in his observations (Matthews, 2022). His report, along with improvements to clocks and thermometers, furthered the validity of temperature and pulse rate as vital signs. Through his work, respiratory rate became the third measurable vital sign.

Blood pressure, the fourth vital sign, only became measurable within the last 150 years. In 1881 Samuel Siegfried Karl Ritter von Basch developed the first Sphygmomanometer, a blood pressure measurement device (Booth, 1977). It was further improved upon in 1869 when Scipione Riva-Rocci added the cuff, making it the device we recognized today (Booth, 1977). This invention made it possible to measure blood pressure in a systematic manner, enabling blood pressure to be the fourth measurable vital sign.

These four vital signs are the traditional four that are universally acknowledged by the medical community (Sapra et al., 2022). There have been attempts at adding additional vital signs to help measure a patients' health. The two well-known examples are pain and exercise. In the mid-1990s, Dr. James Campbell of the American Pain Society advocated pain to be used as a fifth vital sign (Humble, 2014). Pain is subjective to the patient and accurately measuring pain on a scale is relative to the patients' tolerance, causing the American Medical Association to urge medical professionals to stop using pain as a vital sign (Sieben, 2021). There has been some criticism of the use of the pain scale as having contributed to the oxycontin epidemic of the late 1990s and early 2000s by encouraging medical professionals to over-prescribe pain medication to treat the pain vital sign (Humble, 2014). The other vital sign, exercise, began to be measured in 2009 at Kaiser Permanente in southern California (Sieben, 2021). Due to the subjective nature of what exercise is to the individual, it is difficult to conduct a quick objective measurement of exercise when a patient arrives at the healthcare facility (Sieben, 2021). Intense exercise to one individual may be light exercise to another depending on the type of exercise and how physically fit the patient is. About 80% of U.S. adults do not meet the Department of Health and Human Services' exercise guidelines of 150 minutes a week of moderate walking and

two days a week of muscle strengthening exercises (Lobelo et al., 2018). However, the lack of evidence does not make this 80% of the population any less alive. If we are to take the definition of a "vital sign" as an indicator of life, a patient may very well live for years without exercising and may be in pain. However, if a patient exhibits no pulse, respiratory rate, temperature, or blood pressure, that patient is or will be dead within a matter of minutes.

2. Computers and Sensors

Throughout the 20th century, medical devices became increasingly portable and robust by transitioning from analog devices to digital. Ambrose Fleming invented the first vacuum tube in 1904 and the design was later improved upon by Lee De Forest in 1906 (National MagLab, n.d.). The vacuum tube allowed current to be switched on and off and amplified, thus being accredited as starting the electronics profession (Macksey & Woodhouse, 1991). As technology progressed in the 20th century, William Shockley's team at Bell Laboratories announced the development of the solid-state transistor in 1951 (Riordan, 2022). This allowed electronic devices to become smaller, portable, and cheaper to manufacture. Solid state electronics allowed previously expensive and temperamental analog to digital converters (ADCs) to become commercially available (Smith, 2021). ADCs allow analog measurements to be encoded into a digital representation, typically into binary code that can be read and manipulated by computers. This allowed medical devices to become smaller, more accurate, and opened more medical metrics that could be measured.

With the development of ADCs, medical devices that were once analog became more capable and accurate. The analog Aneroid Sphygmomanometer with the mechanical gauge is prone to miscalibration if subjected to physical forces and requires a stethoscope to complete a measurement (Wayback Machine, 2015). Digital sphygmomanometers can measure and store blood pressure measurements and be easily calibrated. Additionally, some come in integrated packages found in most doctor offices that can measure pulse rate, pulse oximetry, blood pressure, and temperature at the same time.

The ability to integrate semiconductors and ADCs into medical equipment opened new opportunities to accurately measure additional metrics such as EKG, EEG, and pulse oximetry. EKG, EEG, and oximetry were all developed and measured at the beginning of the century. At the time, these devices were bulky and could give inaccurate readings. The analog oximeter was developed in the 1940s, but had to be calibrated and the lamp light adjusted to receive relevant readings (Millikan, 1942). The first digital oximeter was developed in 1974 by Dr. Takuo Aoyagi with the use of semi-conductors and digital circuits (Bhattacharya, 2020). This device can instantly calculate spot oxygen saturation (SpO2) using the onboard circuitry to do the necessary calculations and became the first commercially available pulse oximeter. EKG and EEG measurement devices also improved in a similar manner: semiconductors can shrink these devices and make them more accurate.

3. IoT Wearable Devices

As devices shrunk and became "smarter" by using onboard electronics to process data, a new class of IoT devices were developed called Wearables. Wearable devices are small electronic, mobile, or computer devices with wireless capability that can be worn on the body (Ometov et al., 2021). One could argue that the first wearable could have appeared in the 13th century with the development of glasses to improve a person's vision (Ometov et al., 2021), however it is hard to pinpoint the exact origin of modern-day wearable devices. It has been argued that the introduction of the FitBit in 2007 was the first widely accepted activity tracker (Ometov et al., 2021). In 2009 Samsung followed up with their first smartwatch, and then Apple unveiled their Apple Watch in 2015 (Ometov et al., 2021). The market is now saturated with wearable devices that can measure biological functions, act as a communication device, or track geographic position (Ometov et al., 2021). It is expected that wearable devices will only become increasingly available to the public and play greater roles in our lives. The sheer velocity at which new wearables are developed and inserted into that market makes a general survey of current technology obsolete before it is even published (Montgomery & Anderson, 2016). However, there have been attempts at classifying the general types of wearable technologies (Ometov et al., 2021).

Ometov et al. classified current wearable technology into four categories: Device type, Application, Placement, and Power Usage. Their survey focused on wearable technology in general, while Montgomery and Anderson focused on biosensor technology. Since this research is focused on wearable technology to measure biometrics it is appropriate to explore the classification proposed by Montgomery and Anderson, which classifies devices as invasive or non-invasive, and wired or wireless as shown in Figure 2.

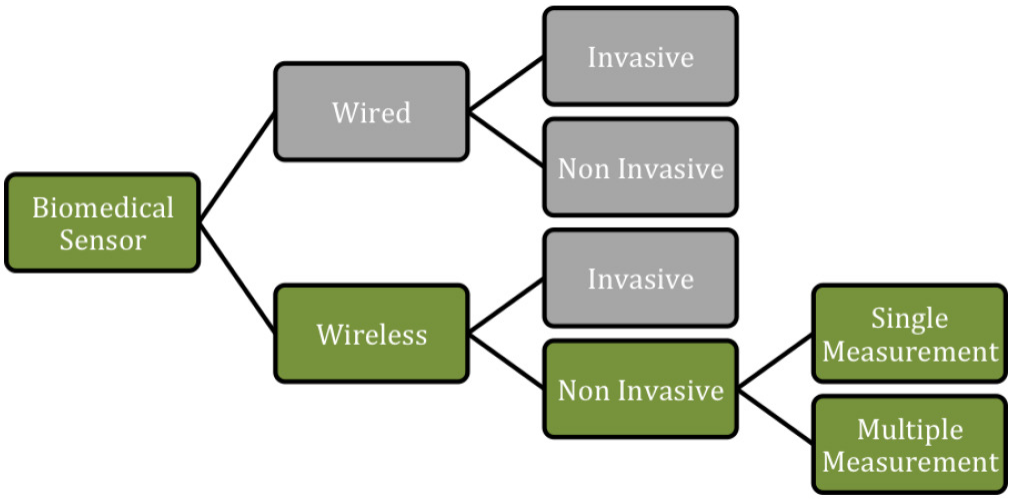

Figure 2. Classification Mapping of Biomedical Sensors. Source: Montgomery and Anderson (2016).

Invasive devices are devices that are inserted into the human body. An example of this includes the real time glucose monitoring device shown in Figure 3, which utilizes an insertable needle to monitor blood sugar levels.

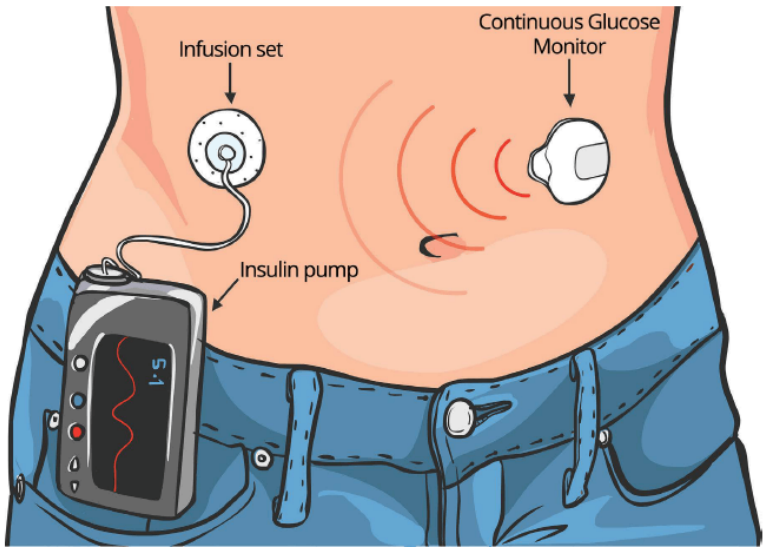

Figure 3. Example of Continuous Invasive Glucose Monitoring. Source: UMass Chan Medical School (2016).

Electrocorticography (ECoG) and Local Field Potential (LFP) chips that are inserted into key positions in the brain to measure activity are considered invasive devices as shown in Figure 4.

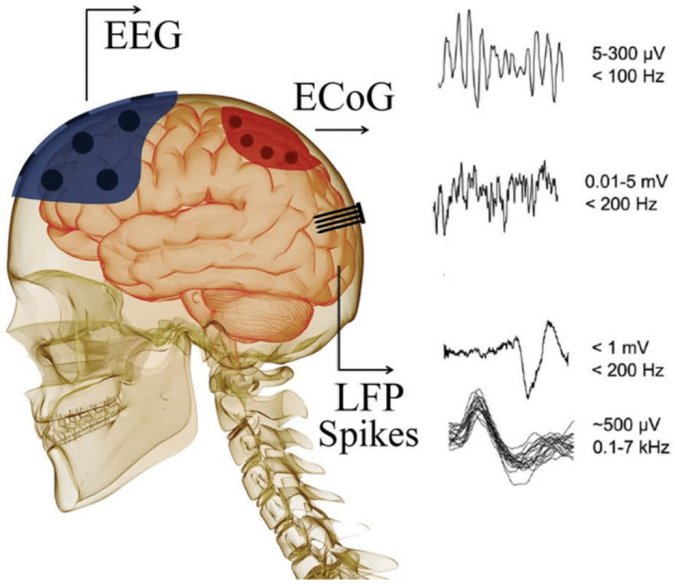

Figure 4. Example of EEG, ECoG, and LFP Sensors. Source: Fattahi et al. (2014).

There are smart pills shown in Figure 5 that can be swallowed and are typically called ingestible, which can also be considered an invasive device (Ometov et al., 2021). However, invasive devices are far less readily available than non-invasive devices.

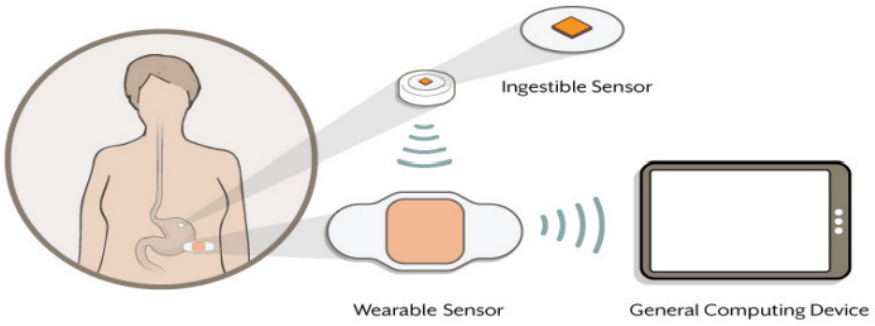

Figure 5. Example of Ingestible Sensor Pill. Source: Committee for Medicinal Products for Human Use (2016).

Non-invasive devices are devices that reside on the surface of the body or worn on the person without physically penetrating the body. EEG sensors are placed on top of the scalp and does not require surgery to attach, making it a non-invasive way to measure brain activity. Other wearable sensors such as smart watches, worn heart rate monitors, and finger clip pulse oximeters shown in Figure 6 are further examples of non-invasive wearable technology.

Pulse Oximeter Zephyr Bioharness

Figure 6. Examples of Non-Invasive Wearable Sensors.

Wearable biosensors can be further defined by weather the wearable device is a dedicated sensor that measures a single biometric or has a one or more sensors that can measure multiple biometrics. Smartwatches are great examples of a multiple measurement device as they contain multiple sensors which work together to measure multiple biometrics Wearable heart rate monitors and EEG devices are examples of dedicated wearable technologies that are designed to measure a single biometric.

Most wearable devices use electric current and/or light to measure vital signs. Wearable devices can have metal contacts that physically touch the skin that uses electric current to measure the galvanic skin response (GSR), pulse, or produce an EKG. Others have LED lights that shine onto skin to produce a photoplethysmogram (PPG) that can determine pulse rate, blood pressure, or most commonly a user's pulse oximetry.

Research is being conducted on the use of wearable biosensors for less invasive and simpler collection of vital sign measurements. PPG is becoming extremely popular due to the simple operation, ease of use, and cost effectiveness of the technology (Castaneda et al., 2018). PPG can measure pulse rate, pulse oximetry (respiratory rate), and blood pressure without the use of a cuff, effectively providing three out of the four vital signs. EEG measurement is another rapidly developing area of wearable devices. There are commercially available headsets and bands that claim to measure EEG of the user. Research into EEG monitoring is intensifying to identify the mental state of the user in

helping to treat or diagnose mental disorders (Chandra et al., 2017). Due to the decreasing cost and non-invasiveness of EEG headsets, this technology is poised to proliferate the wearable biosensor market and potentially aid in the identification, diagnosis, and treatment of many mental disorders.

Currently there is no convenient and popular commercial solution to measure core body temperature. There are commercial non-invasive solutions for monitoring core body temperature on the market, but they are targeted towards industrial use and are not yet convenient or popular (Thermal Hyperformance, 2021). These solutions either utilize sticky patches that attach to the abdomen or armpit or use an earplug that is a thermometer. The more popular form factors of wearables like smartwatches, bands, and rings are unable to accurately measure body temperature due to their location on the body and only measure the skin temperature at that location (Chang, 2021). Fortunately, core temperature typically does not need to be measured on a consistent basis: when a patient feels ill, a common thermometer will usually be fine.

D. REMOTE CARE AND MONITORING

This Section details the history of telehealth and the art of providing care to patients in remote environments utilizing telecommunications technology. The impacts of the telephone, radio, and the internet on healthcare throughout the 20th century are explored.

1. Early Care

The earliest known "telehealth" innovation dated back to the Bubonic plague that ravaged Europe in the 14th century. Information about the bubonic plague was transmitted great distance bonfires (Zundel, 1996). The next big innovation was the incorporation of the telegraph in battlefield medical during the American Civil War (Zundel, 1996). The telegraph was critical as it enabled military physicians to order medical supplies and transmit casualty reports to ensure they could deliver the appropriate level of care (Sigmund Software, 2020).

Next, the development of telephone had an immense impact on medical care. Physicians were one of the first major occupational groups to widely adopt the telephone

to enhance their levels of care (Zundel, 1996). The telephone remained the telehealth technology of choice by physicians for decades and still true as of this day (Zundel, 1996). The invention of the telephone and the installation of the telephone network spurred a renewed interest in encoding and transmitting medical information over great distances. Willem Einthoven, who invented the first EKG in 1902, published his paper describing how he recorded and sent an EKG measurement over the phone lines in 1905 (Lemelson-MIT Program, n.d.).

The next great contributor to telehealth was the invention and widespread adoption of the radio. Radio enabled medical care to be extended into remote areas that did not have preexisting communications infrastructure such as telephone or telegraph lines. Alaska and Australia were some of the first to use radio to deliver telehealth to remote communities (Zundel, 1996). The contributions of radio to wartime medical are widely known as the ability to call in medical evacuations and receive medical support saved countless lives.

In the 1950s, advances in closed circuit television were being applied to telehealth. In 1955, the Nebraska Psychiatric Institute provided remote psychiatric care to patients located at Norfolk State Hospital, which was located 112 miles away (Sigmund Software, 2020). A closed-circuit television link was setup between the two locations where professionals at the institute could provide services to patients who were located at the hospital. This was an interactive link analogous to video calls we make today and allowed for effective consultations over a great distance.

2. Advances in Telecommunication

The telephone and radio remained the backbone of telehealth for decades until the United States and the Soviet Union entered the space race. The National Space and Aeronautics Agency (NASA) had to ensure the health and welfare of their astronauts as they traveled into space. NASA developed innovative biomedical telemetry systems to remotely monitor the astronauts' vital signs for the duration of the space mission (Zundel, 1996). This also led to efforts to diagnose and treat astronauts remotely if one fell ill or became injured. NASA continued to lead the charge in telehealth well into the 1970s with the implementation of the Space Technology Applied to Rural Papago Advance Health

Care (STARPHAC) program. The STARPHAC program took the lessons and technology developed from implementing telehealth throughout the space race and applied them to a terrestrial setting from 1973 to 1977 (Baldwin, 2013). The program aimed at implementing telehealth solutions to the remote population in southern Arizona, such as the Mobile Health Units pictured in Figure 7. STARPHAC was a massive undertaking involving multiple private and governmental agencies exploring the feasibility of using technology to deliver healthcare to remote locations (Baldwin, 2013). Since STARPHAC, NASA applied the lessons they learned in telehealth to provide support for the 1985 Mexico City earthquake and the 1988 Armenia earthquake to provide critical telehealth services to critical patients in disaster areas (Baldwin, 2013).

Figure 7. Exterior of a Mobile Health Unit. Source: Freiburger et al. (2007).

The telephone still reigned as the telehealth technology of choice for care givers throughout the 90s (VandenBos & Williams, 2000). The advent of the internet radically changed the telehealth landscape. However, email correspondence slowly became adopted as an accepted medium to conduct remote correspondence and care (Powell et al., 2003). Along with email, the internet became an easily accessible repository of a wealth of health information that could be used for general patient and professional education. The internet was a huge step in connecting a medical professional's care to a patient's home. Since then, telehealth has exploded within the last decade with web-based health applications,

implementation of IoTs enabled devices, and the challenges brought on by the COVID-19 pandemic.

3. Current State of Telehealth

Web-based health applications are becoming increasingly popular as the internet becomes even more prolific. Web-based video conferencing is a powerful tool where a user only needs an internet enabled device, a web cam, and internet access to have a virtual visit with their provider. DOD uses MHS Video Connect, which allows patients to virtually visit their healthcare provider from anywhere in the world (MHS, n.d.). Fort Leonard Wood also utilized video conferencing technology in their Tele-Critical Care (TCC) setup with great success as staff at remote MTFs could receive real time instructions from professional intensivists to care for patients (McLeroy et al., 2019).

Web based portals to access, manage, and communicate information between patient and providers are being widely adopted. MHS GENESIS is the current Electronic Health Record (EHR) used by the MHS (MHS, 2022). MHS GENESIS' patient portal is accessed via a web browser on a patient's device which allows scheduling, secure messaging, and management of medical information for the patient and provider. Web based tools like MHS GENESIS' portal allow the patient to play an active role in their healthcare by communicating with their provider and improving the quality of care they receive without having to step into the provider's office.

The integration of IoT devices within telehealth enables the improved collection of data and empowers patients to take charge of their health. Wearable IoT devices are increasingly incorporating biomedical sensors that can measure heart rate, blood pressure, EEG, and other biometrics that provide instant feedback on the user's health. The Apple Watch was developed in response to Steve Job's frustrations in sharing accurate biometric data with providers (Ometov et al., 2021). The Apple watch can monitor the user for signs of an atrial fibrillation (AFib) and warn the user when it occurs. The watch links into the Apple Health mobile application to log biometric history and share that information with the user's provider if necessary (Apple, n.d.).

The COVID-19 pandemic ushered in renewed interest into telehealth. Hospitals and MTFs quickly became overcrowded with COVID-19 patients and resources were stretched thin. New programs were initiated to keep quarantined but stable patients at home while only admitting critically ill patients into the MTFs. Studies were quickly done to determine the effectiveness of an RPM solution would have on COVID-19 patient outcomes. It was found that implementing an RPM solution to combat the COVID-19 pandemic contributed to reduced hospital stays, reduced mortality rates, and improved symptom management while keeping the patient quarantined at their home (Crotty et al., 2022). Similar outcomes were observed when Brooke Army Medical Center (BAMC) rolled out their COVID-19 Remote Monitoring Program (CRMP) program to combat the influx of COVID-19 patients into their facility (Sanchez, 2021). The COVID-19 pandemic framed how critical telehealth can be in providing quality healthcare to patients at home by integrating IoT devices, web-based tools, and the sharing of real time medical information.

E. DEPARTMENT OF DEFENSE'S STRATEGIC FOCUS ON TELEHEALTH

The application of technology to healthcare has the potential to be transformative. Institutional change to bring telehealth services to the healthcare system began in 2016 with congressional mandates to the NDAA, and have been matured in the MHS through a Virtual Health (VH) strategic plan and the DHA's Virtual Health Center

1. National Defense Authorization Act of 2017

In 2016 Congress passed the which outlined the appropriations for military activities within the DOD. Specifically, NDAA 2017 §718(a) stated that DOD must incorporate telehealth services and mobile health applications:

- to improve access to primary care, urgent care, behavioral health care, and specialty care;
- to perform health assessments;
- to provide diagnoses, interventions, and supervision;
- to monitor individual health outcomes of covered beneficiaries with chronic diseases or conditions;
- to improve communication between health care providers and patients; and

- to reduce health care costs for covered beneficiaries and the Department of Defense. (National Defense Authorization Act of Fiscal Year 2017, 2016, §718(a))

The NDAA of 2017 further stipulates that the types of telehealth which must be incorporated should allow health care providers, through video, telephone, tablet, or home health monitoring devices:

- to assess and evaluate disease signs and symptoms;
- to diagnose diseases;
- to supervise treatments; and
- to monitor health outcomes. (National Defense Authorization Act of Fiscal Year 2017, 2016, §718(a))

This NDAA mandated a foundation for the DHA to explore the use of telehealth within the DOD and MHS. It directed the DOD, and thus the DHA, to investigate and ultimately incorporate telehealth services with the MHS. The objectives were to lower costs for both the patient and DOD, provide better access to care, and help provide monitoring to patients while reducing hospital visits.

In a 2022 presentation to the Defense Health Board, Nathan Reynolds explained that the DHA developed the 2018 MHS VH Strategic Plan in response to the NDAA of 2017. This plan was developed within the DHA's strategic goal to achieve the Quadruple Aim: Better care, better health, and lower cost to increase readiness as shown in Figure 8.

Figure 8. The Quadruple Aim. Source: DHA (2022).

In Nathan Reynolds' 2022 presentation, *Defense Health Agency (DHA) Update on Virtual Health (VH) for Defense Health Board*, he quoted the *2018 VH Strategic Plan's* definition of VH as "the use of telecommunications and information technologies to provide health assessment, treatment, diagnosis, intervention, consultation, supervision, education, and information across distances" (Reynolds, 2022, slide 3). To achieve the Quadruple Aim, the VH plan consolidated separate VH programs that existed within the MHS into one DHA VH approach. This allowed the standardization of VH across the MHS to eliminate redundant efforts and to streamline the implementation of telehealth services. The DHA organized the VH program into three different capabilities which are Patient to Provider, Provider to Provider, and Complex Real-time Monitoring (Reynolds, 2022). Patient to Provider capabilities include the ability to conduct care over telephone, video, and asynchronous messaging through web portals such as MHS GENESIS. Provider to Provider capabilities allow providers to communicate and project their expertise using telecommunication technology. Lastly, Complex, Real-time Monitoring includes technology that allows providers to remotely monitor patients through capabilities like TCC and RPM.

Complex Real-time Monitoring is receiving the most focus from the DHA due to its' ability to reduce cost, mortality rates, and provide better care. Implementation of TCC is a current priority within the VH Strategic Plan (Reynolds, 2022). The focus is "to expand TCC capabilities to operational environments to provide expertise at the point of injury, during enroute care, and higher care echelons via synchronous audio video communications, advanced monitoring, decision support tools and care coordination throughout the continuum of care" (Reynolds, 2022). The ability to project the expertise of critical care intensivist providers to areas that lack qualified personnel proves invaluable in saving lives while supporting the Quadruple Aim. After studying TCC, Reynolds found that it reduces costs, mortality rate, and improves overall quality of care. Instead of hiring qualified intensive care specialists or flying them out to remote locations it is more cost effective to extend their expertise to a MTF virtually to conduct care (Reynolds, 2022).

While TCC provides much needed care for in-patients in an Intensive Care Unit (ICU), RPM is used to provide care in an outpatient setting and is used for patients who

are not critically injured but have chronic conditions that requires consistent attention from specialist providers (Reynolds, 2022). RPM extends the care a patient would receive at the MTF and brings it into their residence. Like TCC, RPM involves connecting the patient to a provider remotely to monitor a condition or disease and provide recommendations for treatment. However, unlike MHS Video Connect or telephone visits, RPM involves the ability for the patient to transmit their vital signs and other biometrics in real time to the provider, setting RPM apart from other forms of VH. This allows the provider to view the status of the patient and adjust the course of treatment based on a more quantifiable and accurate assessment. This capability proves critical in use cases where the patient is unable to visit the MTF to record vital signs and have a provider assess their condition.

2. MTF Programs and Approach to VH

Over the last few years, the Virtual Medical Center (VMC) and several MTFs have developed many RPM and TCC programs to provide continuous remote care for patients. The three main programs that will be discussed are the Diabetes Remote Electronic Assisted Monitoring Program (DREAM), CRMP, and the Joint Tele-Critical Care Network (JTCCN) (Reynolds, 2022). Each program was developed to address how to extend care to those who are unable to visit their provider or need frequent routine appointments to monitor their chronic condition. Patients who are enrolled in these programs must be referred by their Primary Care Provider (Reynolds, 2022).

a. Diabetes Remote Electronic Assisted Monitoring Program

DREAM was initiated in February 2019 to assist diabetes patients and remotely monitor their blood sugar levels (Newman, 2021). Lori Newman wrote how the DREAM program works in their 2021 article. Newman explains the program started as a joint venture between VMC and the Diabetes Center of Excellence (DCOE) in San Antonio, Texas, to determine if implementing an RPM program could improve quality of care to patients with chronic conditions and operate in an enterprise architecture while reducing overall costs. In their presentation, *Remote Health Monitoring: Past, Present, and Future*, Jennifer Stowe, Daniel York, Jeanette Little, and Holly Pavliscsak presented in 2019 the details of the DREAM program. They explained that providers referred type two diabetes

patients into this program to help manage their condition, patients received Bluetooth enabled wireless biomedical sensors that connected through the m.Care telehealth platform which had been installed on the patient's personal smartphone. Once the patient has the software installed and the biosensors were connected the provider and nurses could monitor blood sugar levels and other vitals remotely. By using this information, providers could remotely guide the patient in treatment options and adjust the insulin dosage to meet the patients' evolving condition (Newman, 2021).

In the 2019 presentation by Stowe et al., they state that the DREAM program significantly reduced the number of visits to the MTF while providing quality care to the patients. In their presentation, they showed that each patient spent about 5.1 months in the program and were able to manage their type 2 diabetes on their own after they completed the program. They commented that patients noted the additional real time support enabled them to consistently administer insulin doses and report those numbers up to their provider. The authors also went on to say providers who had this real time monitoring capability of the program were able to adjust insulin doses and identify any acute issues such as hypoglycemia and intervene quickly and accurately, without having the patient visit the MTF.

The DREAM program has some limitations. Stowe et al. identified issues with Wireless Fidelity (Wi-Fi), Bluetooth glucose meter issues, and funding for telehealth. They explained that the issues with Wi-Fi and Bluetooth sensors stemmed from incompatibility with certain smartphones the patients had in their possession. Stowe et al. identified a major limitation for this program is that patients must have their own smartphone which is Bluetooth enabled and have internet connectivity to be referred.

Due to its success, the DREAM program branched into several other RPM programs which monitor chronic conditions such as high blood pressure, as well as assisting in maintaining healthy lifestyles. Stowe et al. explained the blood pressure monitoring branch is eligible to those who are diagnosed with hypertension to help control their blood pressure. The Healthy Lifestyle Branch is intended to use remote monitoring tools "to assist units and service members who may need physical fitness remediation, dietary parameters, and activity-oversight in order to preserve the fighting strength" and to

"support military dependents in maintaining and/or attaining a healthy lifestyle" (Stowe et al., 2019). Although this lifestyle program does not monitor a chronic condition, it is currently investigating the effectiveness of an RPM program in assisting patients with general lifestyle concerns.

b. COVID-19 Remote Patient-monitoring Program

The COVID-19 Remote Monitoring Program (CRMP) was created in 2020 by VMC and BAMC to remotely monitor a COVID-19 patient's symptoms while keeping them quarantined at home (Yourk, 2021). At the height of the pandemic, it became critical to keep patients that were COVID-19 positive out of the MTFs to keep both patients and doctors safe while containing the spread of the virus (Sanchez, 2021). To limit the amount of physical interaction between providers and patients and still provide quality care to those in quarantine, BAMC and the VMC started the CRMP program (Yourk, 2021). This program was designed for high risk COVID-19 patients that had mild to moderate symptoms and were quarantined at home. Under this program, the MTF would send the patient a kit that included a network hub, tablet computer, arm band monitor, wireless blood pressure monitor, temperature sensor, and a spirometer (Sanchez, 2021). A patient would wear all the biomedical sensors and wirelessly connect them to the tablet. The tablet would then connect back to the provider using the provided network hub. This setup allowed a team of providers to monitor numerous at-risk COVID-19 patients from a central location. These providers would continuously assess the patient's condition and could communicate with them through the tablet by utilizing either chat or video. If a patient's condition became critical, the providers could send an emergency team out to the patient's location with no action required by the patient (Sanchez, 2021). These programs enabled MTFs to effectively quarantine COVID-19 patients and only conduct physical care with patients that required intensive care.

In his 2021 MHS article, Daniel Yourk stated that the CRMP program was an overall success by saving patient bed days and reducing costs associated with care, but within limitations to enrollment and equipment. He explained that in February 2021, the CRMP enrolled 98 patients, 61 of which the CRMP limited bed days. Yourk says that the

ability to monitor these 98 patients' COVID-19 symptoms saved on average about 180 patient bed days, which amounts to over $908,000 in estimated savings for the DHA. There were 26 patients who were referred to the MTF for higher levels of care; and when discharged, 19 of those patients requested to be re-enrolled in the program, marking a shift in acceptance to telehealth programs (Yourk, 2021). Yourk also noted that providers felt more comfortable sending patients home while saving bed space for those who needed higher levels of care. The CRMP has some drawbacks compared to other RPM programs. The MTF purchases, maintains, and ships all the equipment needed to the patient. This creates an additional cost to the MTF when offering this program. Additionally, this program is not open to all patients. Providers must evaluate patients first and enroll them into the CRMP if the provides deems the program necessary for the patient.

c. Joint Tele-Critical Care Network

The MHS uses JTCCN to extend critical care intensivist expertise to remote MTF ICUs that lack the resources to deliver critical care. In his 2022 presentation, Reynolds stated that the JTCCN has critical intensivist staff at operation centers, called hubs, that connect to remote MTFs, called spokes, which lack full time critical care staff. The hub centers can integrate with the spoke sites through various network solutions to monitor real time patient vitals, labs, EHRs, progress notes, and communicate with the local bedside staff ("Tele-critical care will play increased COVID-19 response role in 2021," 2021). Reynolds identified the JTCCN aims at increasing the volume, acuity, and complexity of care remote MTFs can deliver while streamlining best practices and reducing costs. He told the Defense Health Board that as of February 2022 the MHS had three hubs that served a total of fifteen spoke sites, with a total of 88 beds with an expected addition of six hubs connected to 44 spokes to host 440 beds in the future (Reynolds, 2022, Slide 8).

In March 2020, the DHA launched the National Emergency Tele-Critical Care Network (NETCCN), a lightweight and rapid deployable version of JTCCN. NETCCN is intended for use by civilian institutions that need to expand their capacity to deliver care to critically ill patients during disasters or local emergencies ("Tele-critical care will play increased COVID-19 response role in 2021," 2021). In their article from 2021, the MHS

described how the NETCCN helped a civilian agency during the pandemic. The article explained in August 2020, the civilian based Guam Memorial Hospital could not handle the increase in COVID-19 patients, doubling their normal patient volume. They go on to say Guam Memorial Hospital reached out to the Federal Emergency Management Agency for assistance, after which the DHA delivered a NETCCN solution to Guam Memorial Hospital within 72 hours. The article concluded that at the peak of the surge over the course of one month, the NETCCN supported 64 physician calls, 473 patient ICU days, and handled 14 cardiac arrests.

JTCCN has some limitations. JTCCN is not deployed to operational environments where Service Members are deployed (Reynolds, 2022). Additionally, the JTCCN experiences trouble in interfacing with the EHR. As of 2022 JTCCN is being overhauled with a new user interface system and analytics to enable it to integrate within the EHR and standardize medical processes (Reynolds, 2022).

3. Patient and Provider Utilization of VH Capabilities

VH programs provide many benefits including reducing cost, recovery time, hospital stays, and improving the quality of care. The first is the increased amount of care a provider can administer while simultaneously reducing cost. The General Leonard Wood Army Community Hospital (GLWACH) started a TCC program in 2013 to address the lack of board-certified critical care physicians on their staff and to reduce the cost associated with sending patients out to qualified physicians (McLeroy et al., 2019). GLWACH's TCC program significantly increased the amount of care they could provide while simultaneously reducing purchased care costs by up to 30% (McLeroy et al., 2019). Second, the program limited the number of patients admitted to the MTF, thereby increasing the availability of care to high acuity patients. The CRMP program was able to conserve the limited bed capacity while still delivering quality real time care to patients at home (Sanchez, 2021). Third is that RPM programs like the CRMP allows providers to feel confident they can send patients home and know they can still deliver quality care remotely while reserving limited bed space for those who are the most acutely ill. This eliminates the stress of deciding which patients to turn away if resources are limited

(Yourk, 2021). Lastly, VH programs such as DREAM can increase the care receive by chronically ill patients. Instead of wasting precious time and money traveling to and from frequent appointments, patients can receive care they need through their phone and rest assured knowing their providers are in touch with their needs through the real time monitoring solution (Newman, 2021).

There are several limitations that were noted in the utilization of VH programs in regard to mobile device compatibility, increased equipment costs, and connection issues. Most of these are technical in nature, usually involving incompatibility with software and hardware. The first difficulty is acquiring the necessary equipment which is interoperable with the MTF's Information Technology (IT) network. The DHA funded the CRMP program's kits which were delivered to the patients through the mail (Sanchez, 2021). This increases the cost to the DHA but the equipment could be configured appropriately before being delivered to the patient. This ensures the RPM solution will work and is compatible with the MTF's IT enterprise systems. In contrast to this, DREAM provided the glucose monitors and necessary sensors, but the patient had to own a compatible smartphone with internet access to qualify for the program (Stowe et al., 2019). This decreases the cost to the DHA, but reduces the pool of eligible patients and leads to complications concerning compatibility with wireless technology and platforms (Stowe et al., 2019). The second hurdle is bandwidth and connection technology issues. DREAM had challenges with patients' Wi-Fi or phone not being able to support the equipment issued to them (Stowe et al., 2019). Third is data ownership and security. Providers need assurance that a patient's medical data is protected from the point of measurement to the provider.

F. SENSOR NETWORKS AND INTEROPERABILITY

There are numerous wireless architectures that have been proposed to support wearables and IOT devices. The following Section identifies several foundational architectures currently used to support wearable devices, specifically in the realm of healthcare.

1. Wireless Wearable Sensor Architectures

There are many architectures for wearable wireless sensors that have been tested or proposed. Many of these architectures use standard protocols such as the popular BLE, Zigbee, or Long Range Radio (LoRa) protocols.

a. Wireless Body Area Sensor Networks

In 2018, Rahat Kahn and Al-Sakib Pathan described a Wireless Body Area Sensor Networks (WBASN) as a network that connects different networks and devices together that are worn on or inserted into the body. They proposed the following architecture for a healthcare monitoring solution shown in Figure 9.

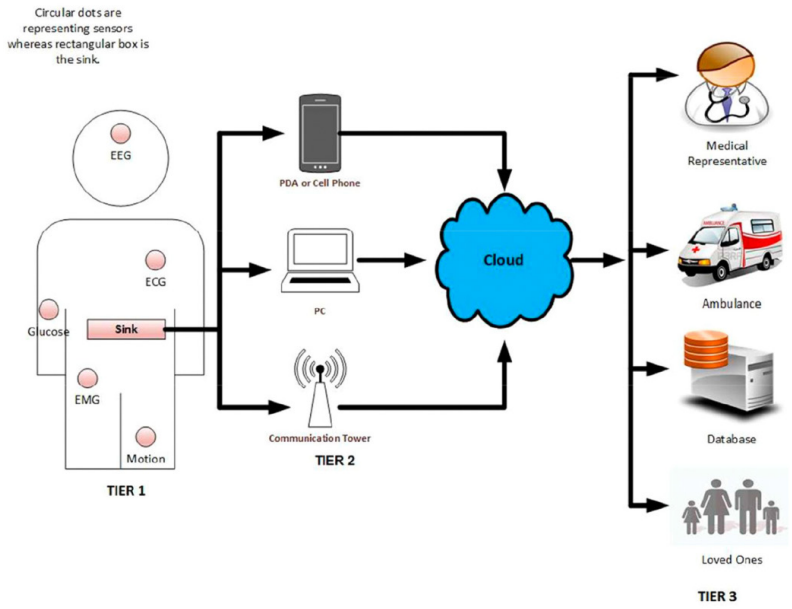

Figure 9. Wireless Body Area Sensor Network Communication Architecture
Source: Khan and Pathan (2018).

Kahn and Pathan discussed that the WBASN is divided into three tiers of communication: intra, inter, and beyond Body Area Sensor Network. The first tier is composed of a sink, otherwise known as a sensor concentrator. Tier two acts as an intermediary between the sink and the health networks of tier three. They explain these

tiers are needed due to the relatively short range the wireless technologies wearable sensors utilize: just two meters may cause a sensor to disconnect. Therefore, a sink is needed on the body that is within range of the wearable sensors but has enough power to connect to distant access points at. (Khan & Pathan, 2018).

b. Self-Powered LoRa IoT Sensor Network

WE-Safe, a self-powered, many-to-one, wearable sensor network based on LoRa technology, was proposed by Fan Wu, Jean-Michel Redoute, and Mehmet Yuce in 2018 to address the high power consumption that plagues current IoT wireless networks. Their We-Safe network utilized custom wearable sensors that could recharge through a small attached solar panel. These sensors measured environmental conditions such as temperature, humidity, and carbon dioxide concentrations (Wu et al., 2018). Their network architecture is shown in Figure 10.

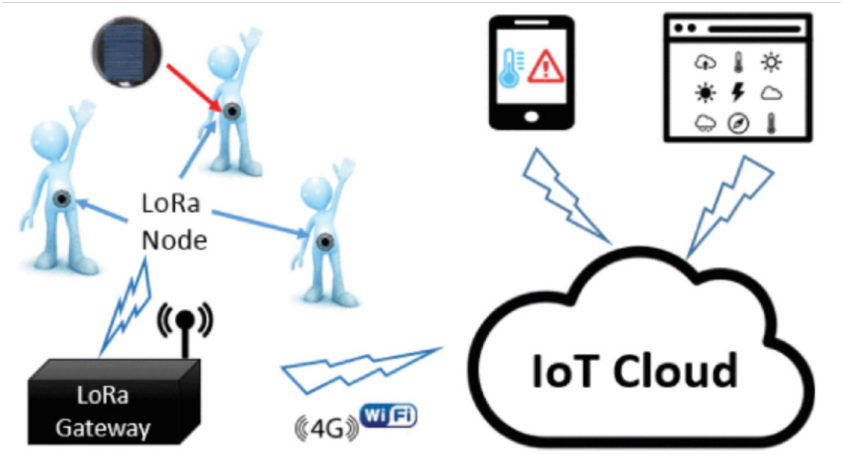

Figure 10. We-Safe Sensor Network. Source: Wu et al. (2018).

By utilizing LoRa for a wireless technology Wu, Redoute, and Yuce were able to reduce the power requirements and extend the range of the wearable sensor to 520 meters. The wearable sensors from multiple individuals connected to a LoRa gateway which then aggregated the sensor data and exported it into the cloud (Wu et al., 2018). This eliminated the need for the individual to carry a dedicated sensor concentrator and reduced power consumption within the sensor network.

2. Wireless Technologies

There are several protocols and standards that support wearable devices. Most common are Near Field Communication (NFC), Bluetooth Low Energy (BLE), Wi-Fi, ZigBee, and Low Power Wide Area Network protocols (LPWAN). (Ometov et al., 2021). These protocols are based on the Institute of Electrical and Electronics Engineers (IEEE) 802.15.4 standard, which standardizes wireless personal area networks (WPANs) at the physical and data link layers, except for Bluetooth (Institute for Electrical and Electronics Engineers [IEEE], 2020). Most protocols that support wireless wearable devices use the unlicensed Industrial, Scientific, and Medical (ISM) bands. The ISM bands are utilized by many organizations, devices, and the IEEE 802.11 standard, which may cause congestion in critical environments (Portmann & Pirzada, 2008).

Other waveforms and protocols have been tested to transmit medical data collected by biomedical sensors. One such protocol is the proprietary LoRaWAN (LoRa), a low power wide area network modulation technique. LoRa uses the frequencies 433 MHz and 868 MHz and has a bit rate of .03 to 50 Kbps to achieve low power/high range transmissions (LoRa Alliance, n.d.). LoRa has been utilized to transmit biomedical sensor data from the point of collection to a receiver and is shown to have exceptional battery life and longer range compared to ZigBee, Wi-Fi, and BLE protocols (Jain et al., 2020). Figure 11 compares the most common wireless technologies used in wearable devices.

	Communication technology	Topology	Frequency bands	Range	Data rate	Power profile
Short-range	RFID	P2P	125–134 kHz, 13.56 MHz, 860–960 MHz	Up to 100 m	Varies with frequency	Very Low
	NFC	P2P	13.56 MHz	<0.2 m	Up to 424 kbps	Very Low
	BLE (IEEE 802.15.1)	P2P, mesh, star	2.4–2.48 GHz	Up to 100 m	Up to 24 Mbps	Low
	Zigbee (IEEE 802.15.4)	P2P, mesh, star	868–868.6 MHz, 902–928 MHz, 2.4–2.49 GHz	Up to 100 m	Varies with frequency	Very Low
	Wi-Fi (IEEE 802.11a/b/g/n)	D2D, mesh, star	2.4–2.48 GHz, 4.9–5.8 GHz	20-250 m	2-600 Mbps	Medium
	Wi-Fi 5 (IEEE 802.11ac)	D2D, mesh, star	4.9–5.8 GHz	Up to 70 m	Up to 3.5 Gbps	High
	Wi-Fi 6 (IEEE 802.11ax)	D2D, mesh, star	1–6 GHz	Up to 120 m	Up to 9.6 Gbps	High
	WiGig (IEEE 802.11ad/ay)	D2D, mesh, star	57–70 GHz	10–100 m	Up to 20 Gbps	Very High
	VLC (IEEE 802.15.7)	D2D, mesh, star	400–800 THz	Up to 100 m	Varies with frequency	Very High
Long-range	NB-IoT	Star-of-star	LTE frequency bands	Up to 15 km	Up to 250 kbps	Low
	LTE-M	D2D, Star-of-star	LTE frequency bands	Up to 10 km	Up to 1 Mbps	Low
	LoRa	Star	867–869 MHz	Up to 50 km	50 kbps	Very Low
	Sigfox	Star	868–878.6 MHz	Up to 50 km	100 bps	Very Low

Figure 11. Wireless Technologies Comparison for Wearable Communication. Source: Ometov et al. (2021).

3. Interoperability

A remote medical application and supporting sensors must be interoperable within the greater health IT infrastructure and support a data format that is easily transferred to other facilities and personnel. Unfortunately, most COTS sensor vendors require the use of proprietary applications to interface with the sensor and extract data. This presents multiple problems with data ownership, security, and interoperability with third party applications. A secure remote medical application must be able to: a) directly interface with a commercial sensor without an intermediary application, b) convert the sensor data into a common data format, and c) populate the data into the greater health IT infrastructure while retaining complete ownership of the medical data. The Air Force Research Laboratory (ARFL) developed the Battlefield Assisted Trauma Distributed Observation Kit (BATDOK) as a solution to this problem.

BATDOK is a real time networked patient-monitoring tool that utilized commercial wearable biomedical sensors in an operational environment (Holstien, 2017). It is designed to run on a mobile device using Android Team Awareness Kit (ATAK) as a plugin. BATDOK digitizes many traditional forms like the Combat Casualty Card and transmits information to medics through the tactical network.

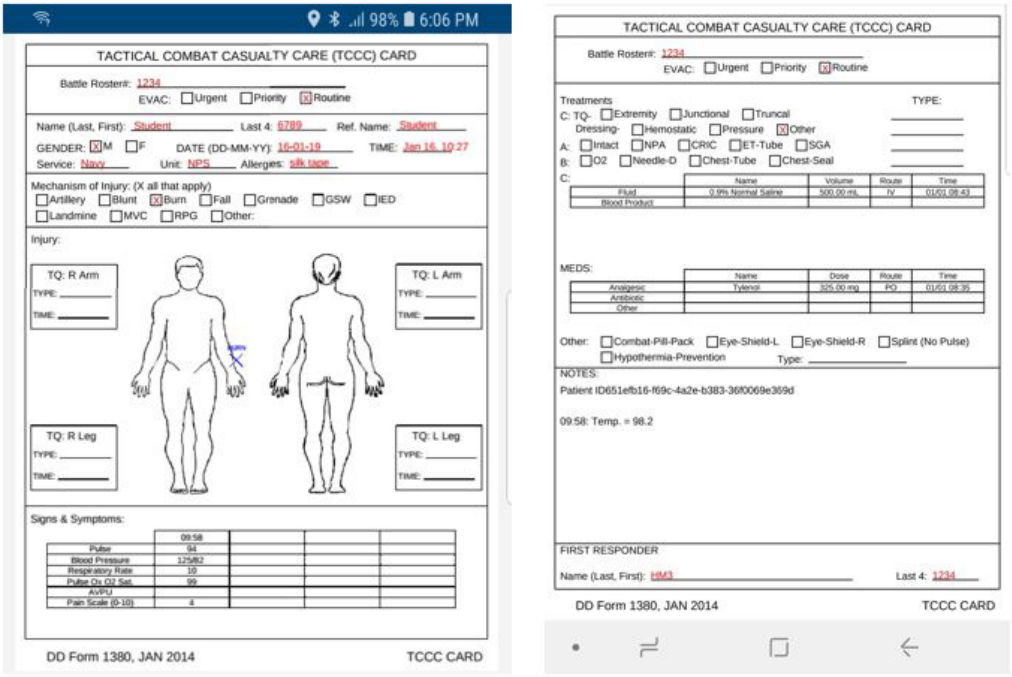

Figure 12. Screenshot of DD Form 1380 from BATDOK.
Source: Smith (2019).

In a meeting with Dr. Gregory Burnett and Capt Stephen Cunningham, the BATDOK program managers, on November 17, 2022, they described how BATDOK operated. ARFL designed BATDOK to be interoperable with many COTS sensors and integrate the collected data into the tactical network for situational awareness while retaining complete ownership of the medical data. To do this, they said the sensor vendor provides BATDOK with a plugin that can interface with the connected sensor. BATDOK then encapsulates the sensor data. They went on to say that once the data is received by BATDOK, it uses Extensible Markup Language (XML) to reencode the sensor data into common data formats in the form of records as shown in Figure 12 (G. Burnett and S. Cunningham, lead engineer and program manager, interview with authors, November 17, 2022). These records can then be distributed within the network and medical community.

In the meeting Dr. Burnett and Capt Cunningham discussed that BATDOK can use any sensor which currently has a plugin loaded. Plugins can either be loaded directly to the program using a USB cable or downloaded wirelessly and do not send any data to the

sensor vendor. They said these vendor plugins allow BATDOK to interpret the biometric data from the sensors without the use of a proprietary application from the vendor while maintaining ownership of the medical data from the point of capture. Dr. Cunningham also stated that BATDOK also uses standard quick response (QR) codes to encode and transmit medical records from the tactical environment into the Theatre Medical Data Store (TMDS) for population into the EHR. The methods used by BATDOK show it is possible to have a vendor independent patient-monitoring application which can translate individual sensor data into a universal format all while remaining secure. This allows for ubiquitous data sharing and the flexibility to adapt to future wearable technologies.

G. SUMMARY

1. What Is Known

In this review, the authors investigated four threads of literature within the problem space: DOD's strategic focus on telehealth, remote care, physiological telemetry, and sensor networks and interoperability. Each were examined to address any gaps within the research questions proposed in Chapter I:

1. What biomedical monitoring capabilities must an effective remote patient-monitoring tool have?
2. How does BioZen work as a remote patient-monitoring tool, considering its original use case?
3. How does BioZen work as a patient self-monitoring tool, considering a range of alternate use cases?
4. What are the gaps between BioZen as it is and current technology and/or technical standards and what are possible future efforts to address these gaps?

In investigating Question 1, several capabilities an RPM tool must be identified. An RPM tool must allow medical professionals to track patient metrics in real time. These metrics must include the four vital signs: Respiratory rate, heart rate, temperature, and blood pressure. Additionally, the tool must allow medical professionals to give guidance

to patients through the tool by either utilizing chat, text, or video. It was found that RPM tools are valuable in reducing patient bed days, out-patient deferrals, out-patient encounters, and admissions. Several required technical capabilities were identified such as compatibility with COTS hardware and MHS health information systems, BLE equipment, and encryption of medical information. Lastly, there were administrative, organizational, and legal requirements identified for an RPM tool. These centered on DOD ownership of the data from the point of collection to the point of storage on the cloud and minimizing the storage of patient data on non-DOD managed cloud environments.

Current and historical RPM tools were reviewed based on their intended use cases to provide insight into Question 2. It was found there are two main categories of use cases for RPM tools: in-hospital use and home use. In-hospital RPM involves connecting a patient admitted to a hospital to remote medical specialists the host hospital lacks, such as in GLWACH's TCC program and STARPHAC. In home use involves connecting medical professionals to a patient at home for continuous monitoring of health metrics, as seen in the CRMP and DREAM programs. Both serve to connect a patient in a remote environment to medical professionals or resources to monitor and treat chronic conditions or contagious illnesses. These use cases aimed at providing treatment while preserving hospital bed space, improve doctor-patient safety, and reduce the need for multiple routine hospital visits.

Several alternate use cases were also evaluated to provide context into Question 3. Use cases such as healthy lifestyle management and self-monitoring using RPM tools are gaining traction. These use cases are aimed at prevention of chronic diseases and improving a patient's overall health. In the case of DREAM, several spinoff RPM programs were developed including the healthy lifestyle branch and blood pressure monitoring.

2. Current Issues

Several limitations were identified within the problem space upon the conclusion of the review. First, in respect to Question 1, interoperability continues to be an issue with RPM programs utilizing COTS sensors, software, and equipment. As discussed, most of these are technical in nature involving compatibility between devices. It is difficult to

integrate commercial devices and programs into an RPM solution that is interoperable with the secure network of EHR. In addition to utilizing COTS devices, data ownership continues to be an issue due to the proliferation of proprietary applications vendors require users to download to interface with the device. BATDOK does solve this issue by being strictly government developed, owned, and operated. It is necessary to point out that BATDOK is designed to work in a secured tactical network and is not available to the public. Solutions that are available to dependents, such as CRMP and DREAM, rely on use commercially available software and therefore struggle to retain data ownership. Next, there are current gaps in use cases providing context for Questions two and three. These RPM solutions are specifically targeted to small populations of patients and not for general use. BATDOK is used for operational forces, CRMP is for enrolled COVID-19 patients, and DREAM is explicitly for diabetic patients. The MHS currently does not have a generic RPM solution for beneficiaries that is able to provide a real time view of a patient's health to the provider that while providing a secure connection to the EHR.

III. RESEARCH DESIGN

BioZen is a DHA-owned mobile application capable of using COTS sensors to collect biometric data on heart rate, respiratory rate, and brainwave activity (Web and Mobile Technology [WMT], 2022). This study is focused on evaluating the BioZen application as-is with the intent to discern what value the application has to the DHA and military health clients and its potential to augment the MHS provision of VH. Through this study, we have defined value measures to optimize the military healthcare system through executing RPM, value measures of satisfaction for members who use the application, and value measures for the DHA of having the right information at the right place at the right time (DHA, 2022). A SE approach has been selected, based on technical processes from the International Organization for Standardization (ISO)/ International Electrotechnical Commission (IEC)/IEEE 15288:2015 common framework for the Concept and Development stages of the life cycle processes for systems. The selected framework allowed researchers to sufficiently evaluate the current prototype of BioZen by defining stakeholder needs, system requirements, system architecture, and design definitions to develop measures of effectiveness and performances. The analysis was then reviewed to generate possible use cases for BioZen and to provide any findings and recommendations to the DHA.

A. OVERVIEW

The proposed evaluation was carried out by utilizing the following technical processes from ISO/IEC/IEEE 15288:2015:

6.4.2 Stakeholder Needs and Requirements Definition process

6.4.3 System Requirements Definition process

6.4.4 Architecture Definition process

6.4.5 Design Definition process

6.4.6 System Analysis process

These processes encompass the Concept life cycle stage and the first half of the Development life cycle stage of a system as defined in ISO/IEC/IEEE TR 24748-1 Systems and software engineering – Life cycle management (Walden et al., 2015). The Concept stage consists of modifying an existing System of Interest (SOI); identifying, analyzing, and defining stakeholder needs and requirements; exploratory research, and testing of critical element prototypes (Walden et al., 2015, pg.29). Since BioZen is a minimum viable product, the Concept stage was completed to fully evaluate BioZen's compliance with the original stakeholder requirements as stipulated by the DHA. Researchers then completed the evaluation of BioZen by conducting specific technical processes under the Development stage.

Once the system requirements were refined, they were used to propose a system architecture and design. The stage ended when the system production, implementation, and validation requirements were defined. The evaluation of BioZen in the development stage will only include the system requirements and design definition. The use cases and recommendations from this study will be provided to the DHA to guide the completion of the remaining technical processes for the development BioZen. Note that the very first technical process, IEEE 15288 6.4.1 Business or Mission Analysis process, has been omitted from the research framework. This process has already been completed by the DHA by defining the problem domain, identifying stakeholders, and defining the business requirements per the Interservice Support Agreement (ISSA) between the DHA and the Naval Postgraduate School (NPS). Research has been conducted in three phases: identifying requirements, design definition, and system analysis.

B. PHASE I: IDENTIFYING REQUIREMENTS

This phase answered research Question 1 where researchers reviewed past research, technologies, and stakeholder needs to complete the stakeholder requirements, system requirements, and the architecture definition processes. The purpose of this phase was to increase the researchers' understanding of the problem space to include technical aspects and current architectures, and to guide the development of system requirements. In this phase the researchers met with DHA stakeholders to develop operational use cases which

identify operational environments and incorporate SOI capabilities. These and other stakeholder requirements were then used to develop operational indicators of success for BioZen in the form of MOEs (Walden et al., 2015, pg.54). The identified requirements and MOEs then became the foundation to develop technical system requirements for BioZen in the form of MOPs (Walden et al., 2015, pg.57). Phase I ended once the literature had been sufficiently reviewed, MOEs, and MOPs had been defined.

C. PHASE II: DESIGN DEFINITION

This phase answered research Questions 2 and 3 where researchers conducted the Design Definition process. The purpose of this phase was to evaluate the design of BioZen. The researchers departed from the original ISO/IEC/IEEE 15288:2015 design definition technical process by evaluating the current design of BioZen instead of defining a new design for BioZen. In accordance with the ISSA between DHA and NPS, DHA was interested in the technical capabilities of the current design of BioZen to identify any misalignments with stakeholder requirements. Because of this, the researchers modified the design definition process to evaluate the current design of BioZen and compare it to the developed MOEs, MOPs, and architecture to identify any misalignments. Phase II ended when the current design of BioZen was evaluated.

D. PHASE III: SYSTEM ANALYSIS

System Analysis consisted of the quantitative assessment of BioZen as-is based on the identified MOEs, MOPs, architecture, and design characteristics. The purpose of this phase was to evaluate BioZen's fitness for use as intended and produce the main deliverable of this thesis: the Chapter IV analysis. An effectiveness analysis was conducted on BioZen as outlined in Chapter IV, which evaluated what value BioZen brings to its users and the DHA and how effective BioZen is as a self-monitoring tool. In addition, this analysis was compared to the original stakeholder requirements as defined by the DHA to identify any gaps or misalignments and provide recommendations. Lastly, the researchers explored suitable use cases for BioZen based on the results of the system analysis. Phase III ends when the analysis report is completed and use cases are explored.

E. PROPOSED DATA ANALYSIS METHODS

Data was gathered through interviews and personal communications with selected individuals from the DHA and through scholarly review of pertinent literature. The interview data is purely technical in nature and no Personally Identifiable Information (PII), Protected Health Information (PHI), or other identifiable information was collected. Expected qualitative data collected from the interviews include technical specifications, application architecture, and current and planned capabilities of BioZen.

The following list includes the proposed metrics to be measured, their units, and the proposed method in which each metric was measured. For these measurements, the maximum desired value will be known as the metric's objective and the minimum desired value will be known as the metric's threshold:

1. Bed Days saved per month: Bed days saved is the avoided occupancy of an inpatient hospital/clinic bed.
2. Prevented Admissions per month: Prevented Admissions is the total number of inpatient admissions, over 30 days, that can be avoided because of the use of a VH RPM solution to monitor patients at home.
3. Prevented Outpatient Deferrals: The use of existing VH programs within the MHS augmented remote patient-monitoring to simulate TCC capability in any clinic to reduce outpatient deferral to network.
4. Outpatient Encounters avoided per month: An Outpatient Encounter is said to be avoided when an outpatient encounter that would have taken place in the clinic is not scheduled because of the use of a VH RPM solution to monitor patients at home allows collection of required biometric data.
5. Biometric signals measured: Biometric signals measured refers to the types of biometric signals reported with clinically significant specificity. i.e. EKG, EEG, SpO2.
6. Successful utilization per month: Rate expressed as the number of patients in a 30-day period at a specific location who did use a VH solution to avoid

an admission or an outpatient medical visit as a function of the total number of patients in that same period who could have used a VH solution to avoid an inpatient admission or an outpatient medical visit.

F. SCOPE AND LIMITATIONS

This thesis considered COTS biomedical sensors with the DHA developed BioZen mobile phone application. The scope of this thesis does not include any experimentation involving connecting to a LAN or Wide Area Network (WAN). Currently, any experimentation involving networking beyond the local device is not possible and could be considered for future research.

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IV. STAKEHOLDER ANALYSIS

This chapter outlines the identification and documentation of BioZen's stakeholders and further refinement of stakeholder wants and needs into a requirements traceability matrix of BioZen.

A. STAKEHOLDER IDENTIFICATION AND ANALYSIS

To fully investigate BioZen and identify the overall effects it was trying to achieve within the MHS, the stakeholders were identified and their wants, needs, and constraints documented. This data is used in Section IV to assist in identifying the overall effect BioZen is trying to achieve and support the development of MOEs and MOPs presented in Chapter V.

1. Identification

The first step in stakeholder analysis was to identify who the major stakeholders of BioZen were. The first identified stakeholder was the patient, or the user of BioZen. The user is a major stakeholder as they are the ultimate consumer of BioZen services. BioZen must ultimately be engineered to be easy for users to understand and provide features that they find desirable. If BioZen cannot do this well or failed to create any sort of value to the user, then the application would never be adopted and see widespread use. One of the reasons why CRMP was successful is that it addressed the needs of the user by including instant messaging with nurses and providers to ensure the user felt safe and taken care of (Sanchez, 2021). This was why it was imperative that the user is listed as one of the major stakeholders and their needs identified.

The second identified stakeholder was the medical professional interacting with the user through BioZen. The medical professional must be able to use BioZen with confidence when interacting with users and reviewing health metrics. BioZen must be able to provide relevant features and information to the medical professional to provide increased value to care through its use. Therefore, the medical professional is a critical stakeholder to address and ensure their needs are met.

The next identified stakeholder was the Solutions Delivery Division (SDD) Web Mobile Technology (WMT) team. WMT are the primary developers of BioZen and are responsible for the development, maintenance, and deployment of the application on the MEP. They are the primary stakeholders for BioZen and their constraints, needs, and wants must be accounted for throughout BioZen's life cycle.

The last major stakeholder was the DHA's VMC. The VMC was identified as a stakeholder by conducting a review of the literature in Chapter II. The VMC oversees all the VH and RPM programs within the DHA and has extensive experience and expertise in this area. If an RPM application were to integrate within the greater DHA health infrastructure, the VMC would champion or sponsor the WMT project in deploying and maintaining BioZen as an RPM tool. It was important to list the VMC as a stakeholder as they oversee all VH programs within the DHA.

2. Stakeholder Analysis

To conduct the stakeholder analysis, the WMT and the Director of the VMC were contacted to provide their wants and needs for BioZen. The medical professional and user's wants and needs were determined from the insights gained through the review of the literature in Chapter II. Table 1 shows identified stakeholders for BioZen along with their wants, needs, concerns, and barriers.

Table 1. Stakeholder Analysis Table

Stakeholder	Want/Need	Concern or Barrier
Solutions Delivery Division Web and Mobile Technology	• Cloud Based • Programmable Web Application • GSPAN • Integrate with COTS sensors • Measure EEG • Ability to start, stop, save and share current data as a session • Historic Analysis of current session against prior sessions • Bluetooth 5.0 connectivity • Retain Data Ownership • Quickly integrate with new sensors • PYTHON Preffered • Amazon Web Services • Separate Provider / User Dashboards to BioZen • App Platform Agnostic i.e. Android, IOS, Windows	• User Acceptance • Data Security • Interoperability • Patch Management • Time between Major Updates • Sensor / Cloud / Vendor alignment compatability • Limiting Sensor Choice based on supported protocol(s) • Integrity of sensor data as it moves through the pipeline • BioSensors as a Cyber Attack Vector • Internet Connectivity
VMC	• Integrate with Electronic Health Record • DoD Owned Cloud Storage	• Privacy • Clincian Acceptance • Time to learn another new system • Loss of function if there is no internet
Medical Professional	• Measure accurate metrics • View Published Sessions • Communicate Generic Alerts to user through app • Receive Alerts for sensor readings ouside of set parameters	• Ease of Use • Specificity of Biometric Data
User	• Ability to start, stop, save current data as a session • Ability to share session data with provider Continuously measure a Biometric	• The ability to connect to DoD health resources and/or education through App • Internet Connectivity Age of Personal Mobile Device

Being the primary developers of the application, the WMT team has the most needs and concerns relating to BioZen. Overall, the table shows their needs revolve around cyber

security, interoperability, cloud integration, and data ownership. This was in line with the VMC's primary concern of compatibility with the EHR and data ownership.

The medical professional and the user needs focus more on functionality and accuracy of data in a mobile biomedical application such as BioZen. Medical professionals must be able to easily access and view patient data within BioZen and have the confidence that said data was accurate and reliable. Users also desire compatibility with their personally owned devices and medical equipment as indicated from the incompatibility issues users experienced from the DREAM program (Stowe et al., 2019).

3. Stakeholder Requirements

Lastly, the stakeholders' wants and needs were transformed into a set of requirements for BioZen. To accomplish this, the authors conducted follow-up interviews and emails to refine each stakeholder's expectation, specifically with the WMT and VMC. Out of these expectations, a list of requirements was developed for BioZen. To organize the requirements in a Requirements Traceability Matrix (RTM), the authors adapted the 2018 *Stakeholder Requirements Specification* framework provided by the National Archives and Records Administration (National Archives and Records Administration [NARA], 2018). This framework categorizes stakeholder requirements into the following areas: Requirement Number, Requirement, Type, Category, and Priority. The Requirement Number is a static number that has been arbitrarily assigned to a requirement. The Requirement Number will be used to refer to the requirement in other parts of the paper. The Requirement column is a common name for the function or capability expected, and the Type and Category columns further decompose the origin of the requirement. Priority ranks the criticality of each requirement and identifies which requirements must be met to deliver BioZen. The values and definitions for Type, Category, and Priority are shown in Table 2.

Table 2. Requirements Decomposition Description. Adapted from National Archives and Records Administration (2018).

		Description
Type	Business	Business requirements define the critical activities that a project that must perform to meet the organization's objective(s) while remaining solution independent (i.e., "what the organization wants or needs to be able to do once the project is completed").
		Business requirements are included with the stakeholder requirements to provide traceability and to promote a better understanding of the stakeholder requirements by making the associated business requirements more accessible. The business requirements typically come from the project's business case.
		Note: It may not be appropriate to include the business requirements with the stakeholder requirements because of various issues, such as availability. However, it is highly recommended that they be included when possible.
	Business Rule	Criteria or condition originating from external authority that dictates a system's action or response.
	Stakeholder	Stakeholder requirements define decisions about business needs, goals, and objectives from the perspective of the stakeholders and their role in the business. Stakeholder requirements are expected to decompose the business requirements.
Category	Constraint	Constraints limit the options open to a designer of a solution by imposing immovable boundaries and limits (e.g., the system shall incorporate a legacy system element, or certain data shall be maintained in an online repository).
	Functional	Functional requirements describe the system functions or tasks to be performed.
	Non-Functional	Non-functional requirements identify operational or system properties. They define how a system should be. Information Management, Availability, Backup and Recovery, Compatibility, Maintainability, Reliability, Transferability, Performance, Capacity, Scalability, Security, Usability, and User Interface requirements are examples of this type.
	N/A	Used for Business requirements for purposes of completeness, i.e., to ensure that every requirement traces to a category. (Business requirements are not typically categorized.)
Priority	Must	Requirements that are CRITICAL to meeting the projects objectives.
	Should	Requirements that are critical and should be included if possible, but which can be excluded.
	Could	Requirements that are part of the project's scope and add or enhance project benefits.
	Would	Requirements that do not have a significant impact on project benefits or could be considered as a "would like to have"

Describes Type and Category and Priority column headers in the BioZen Requirements Traceability Matrix (Table 3).

The requirement Function is stated as "the high-level function, capability, feature or other grouping that has meaning for the stakeholders" (NARA, 2018) and is intentionally omitted by the authors. The MOEs and MOPs shown Chapter V are high level effects that are critical to the stakeholders. The authors will discuss and link each requirement to its respective MOP in Chapter V.

Using the RTM adapted from NARA as a framework, the authors organized the requirements for BioZen in Table 3.

Table 3. BioZen Requirements Traceability Matrix

REQ #	Requirement	Type	Category	Priority
RQ-01	Utilize COTS sensors	Business	Concern or Barrier	Must
RQ-02	Vendor agnostic	Business	Concern or Barrier	Must
RQ-03	Cyber Security	Business Rule	Concern or Barrier	Must
RQ-04	Retain data ownership	Business	Concern or Barrier	Must
RQ-05	Cloud based	Stakeholder	Concern or Barrier	Should
RQ-06	Utilize GSPAN	Stakeholder	Concern or Barrier	Should
RQ-07	Bluetooth enabled	Stakeholder	Concern or Barrier	Must
RQ-08	Python based	Stakeholder	Concern or Barrier	Must
RQ-09	Measure EEG	Stakeholder	Functional	Must
RQ-10	Measure EKG	Stakeholder	Functional	Must
RQ-11	Measure Respiration	Stakeholder	Functional	Must
RQ-12	Rechargeable Battery	Stakeholder	Functional	Must
RQ-13	Provider acceptance	Stakeholder	Non-Functional	Should
RQ-14	Integrate with electronic health records	Business	Concern or Barrier	Must
RQ-15	Save metrics offline	Stakeholder	Functional	Could
RQ-16	Measure Blood Oxygen	Stakeholder	Functional	Should
RQ-17	Measure accurate metrics	Stakeholder	Functional	Must
RQ-18	Ability to communicate to patient through app	Stakeholder	Functional	Could
RQ-19	Receive alerts in changes to patient health	Stakeholder	Functional	Should
RQ-20	User acceptance	Stakeholder	Non-Functional	Should
RQ-21	Ease of use	Stakeholder	Non-Functional	Should
RQ-22	See metrics in real time	Stakeholder	Functional	Must
RQ-23	Save and compare metrics	Stakeholder	Functional	Should
RQ-24	Access to health resources	Stakeholder	Functional	Could

These requirements were conceived over three months (October 2022 to December 2022) and validated by the WMT and VMC through multiple emails, interviews, and personal communications. The authors recognize that Patients and Provider requirements were not validated directly with medical professionals and their patients. However, the requirements were validated against the literature review in Chapter II and with the VMC, which has constant interaction with patients and providers within the MHS.

B. SUMMARY

In this chapter, the stakeholders were identified, their needs discovered, and the RTM for BioZen was developed. Through numerous personal communications, emails, and interviews, the authors were able to develop a comprehensive list of requirements for a future build of BioZen. This list was then validated by all stakeholders to ensure the validity of the requirement data. From there the information was utilized to discover the MOEs and MOPs for BioZen in Chapter V.

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V. ANALYSIS

This chapter analyzes BioZen within a framework of MOEs and operationalized MOPs. First, the overall effect or purpose of BioZen was determined from stakeholders and the DHA. Second, the MOEs were developed to analyze BioZen's performance. Third, the MOEs were operationalized into MOPs with measurable objectives and thresholds. Lastly, an analysis was conducted from the data in Chapters II and IV to determine the effects the BioZen application must have to be considered a successful remote patient-monitoring application as described by the NDAA 2017.

A. IDENTIFYING OVERALL EFFECT

Before any MOEs can be determined, the overall effect BioZen was intended to achieve must be identified. This section uses the stakeholder analysis provided in Chapter IV to analyze BioZen's effect it will achieve for the DHA.

The authors asked several stakeholders at WMT what overall effect BioZen was originally designed to achieve. Through several emails and interviews, WMT programmers Sven Garber and Scott Coleman stated the first concept of BioZen that came out as early as 2014 envisioned the application to be a meditation assistant. BioZen utilized Neurosky's EEG headset coupled with Zephyr's Bioharness to measure brain activity and heart rate to guide the patient through mediation sessions. The patient could review past sessions and track their progress to improve the effectiveness of their meditation. Thus, the goal of BioZen was to improve the patient's mental wellbeing and state of mind using wearable sensors and improving the outcome of each session.

Programmers at WMT wish to improve BioZen by increasing the application's capabilities, standardizing the metrics measured, and connecting BioZen into the EHR. The idea is that BioZen can be used to help patients track their overall physical health and make the data available to medical professionals to act upon that data (S. Garber, personal communication, November 2, 2022). With this future goal in mind, the authors reviewed the new *DHA FY22-26 Campaign Plan* to identify where BioZen would fit into the future vision of the DHA. The authors identified "Great Outcomes," the DHA's number one

priority in the Campaign Plan, as the primary effect BioZen would support within the DHA. To provide more specificity within supporting DHA's "Great Outcomes," the authors proposed "Improve Patient Outcomes" as the overall effect BioZen should achieve. This proposed effect is in line with BioZen's original objective and the future vision for the application: improve the patient's overall health.

B. IDENTIFYING MEASURES OF EFFECTIVENESS

With the overall effect BioZen will achieve identified, it was important to understand how to measure BioZen's impact on the overall effect. The following section will break down several MOEs that should be observed to gauge the extent to which BioZen was fulfilling its desired effect.

1. Optimize the Healthcare System through VH Execution

The DHA Campaign Plan of 2022 identifies the optimization of the healthcare system as a critical component to support the improvement of patient outcomes. The Campaign Plan goes further and identifies VH execution as a major line of effort to support optimization. Therefore, as a VH application, BioZen's first MOE was to optimize the healthcare system.

2. Provide the Right Information at the Right Place, at the Right Time, in the Right Format for the MHS

BioZen collects real-time biometric data for review by the user or medical professional. This data could assist in providing the right information, at the right time, place, and in a meaningful data format, which was another core principle within DHA's Campaign Plan. By gathering meaningful and actionable medical information for medical professionals and users, BioZen can support the goal of improving patient outcomes.

3. Achieve Patient Satisfaction

Patient satisfaction is a closely monitored metric related to the provision of care and is one of four priorities for the DHA (*Defense Health Agency Campaign Plan*, n.d.). The importance of this MOE cannot be overstated as the adoption of any RPM tool requires that the patient feels safe and comfortable with it. Because of this metric, patient

satisfaction was a critical component to any VH or RPM application as seen in the programs DHA implemented, discussed in Chapter II. The Satisfied Patients metric provides a snapshot into the value brought to patients by the application and gauges the quality of care the RPM application realistically provides.

C. IDENTIFYING MEASURES OF PERFORMANCE

MOEs by their nature can be abstract, subjective, and difficult to measure directly and objectively. Because of this, they are operationalized into MOPs that can be measured and thereby enable an objective assessment. This section deconstructs each MOE into several MOPs that can be observed and measured to quantify the effectiveness of BioZen for each MOE. The objective target measurement, at which we find maximum value, and threshold measurement, below which we find no value, are defined for each MOP to assist in determining to what extent BioZen meets or misses each MOP.

With regard to the overall effect, MOEs, and MOPs, the Value Hierarchy can be assembled for BioZen as shown in Figure 13. The Value Hierarchy is the framework used to conduct the fit for use assessment for BioZen. It uses the operationalized MOPs to measure the effectiveness of BioZen in meeting the three MOEs. How close BioZen comes to meeting these MOEs will gauge the extent to which BioZen achieves its goal of improving patient outcomes.

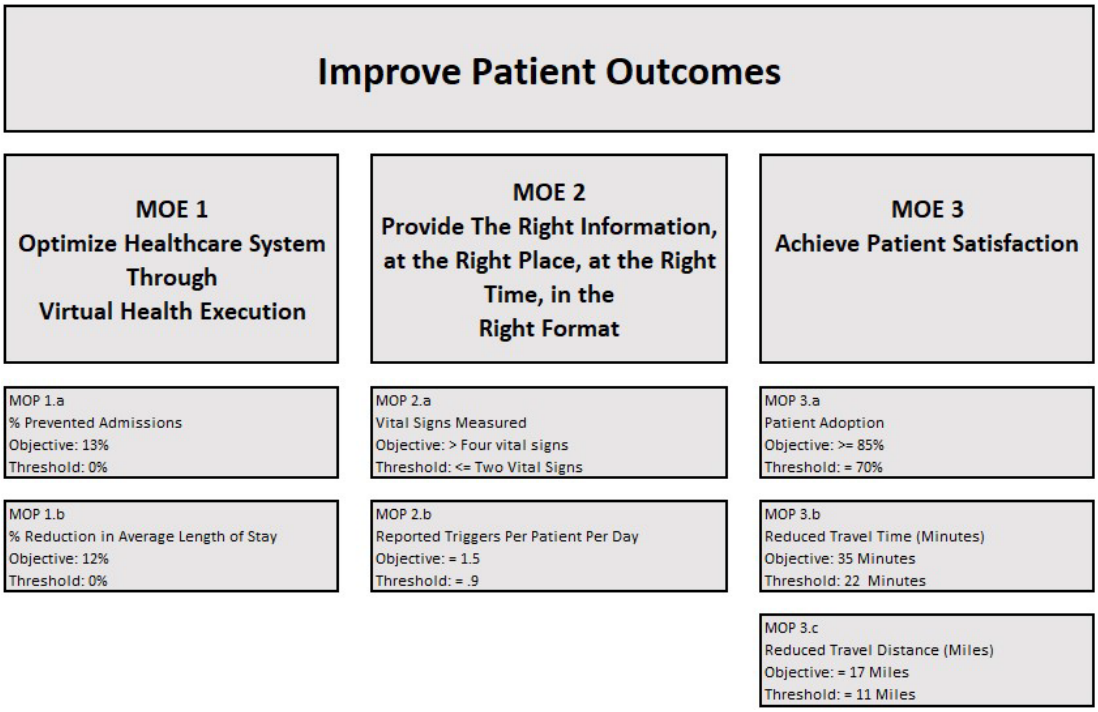


Figure 13. BioZen Value Hierarchy

1. MOE 1: Optimize the Healthcare System through VH Execution

a. MOP 1.a: Percentage of Admissions Prevented

Percentage of Admissions Prevented is a function of the total number of inpatient admissions that can be prevented because of the use of a VH RPM solution to monitor patients at home. The numerator is the number of patients sent home to use a VH RPM solution and the denominator is the total number of patients who would be admitted if no VH RPM solution was available. Percentage of Admissions Prevented is a valuable metric because hospital resources for patient care are finite. A medical facility will have a static capacity of available beds to support inpatients every day. Every patient who has been admitted uses one of the available beds from this static quantity, and once a hospital has filled its inpatient beds, it has reached capacity can no longer accept more inpatients.

Patients who could be discharged after a visit to the Emergency Department (ED) but who require continued monitoring, or outpatient encounters who would not otherwise be admitted for care, but who do require continued monitoring of one or more vital signs,

may otherwise be able to recover at home if appropriately monitored (Aalam et al., 2021). RPM applications allow for a patient to be monitored at home by a medical professional, which decreases the likelihood of future admission and potentially reduces the burden on finite resources within the healthcare system. One less patient admitted for monitoring of one or more vital signs means the hospital can admit one more acute patient who may otherwise be sent to an inpatient bed, outside of the MTF. The objective for this metric is 13%, and the threshold for this metric is zero.

b. MOP 1.b: Percent Reduction in Average Length of Stay

The length of an inpatient hospital stay can be measured in terms of bed days, defined as the number of days a patient occupies a bed in a hospital. For this MOP, a percent reduction in the length of stay is shown in Figure 14 as a function of the reduction in average length of stay for all patients with a specific Diagnosis Related Group (DRG) for a given time at an MTF. This MOP will enable the measurement of the impact of the RPM as a VH solution. Since available beds are a limited resource, any medical solution that impacts average utilization of that resource across the facility would be significant. The objective for this metric is 12%, and the threshold for this metric is zero.

Total Days = Total recorded bed days for all patients with a specific DRG
Total Patients = Total number of patients with a specific DRG being studied
Hist Average = Historical average bed days for patient with DRG of Total Patient group.

$$1 - \frac{Total\ Days}{(Total\ Patients \times Hist\ Average)} = \%\ \text{Reduction in Average Length of Stay}$$

Figure 14. Percent Reduction in Average Length of Stay Calculation

2. MOE 2: Provide the Right Information at the Right Place, at the Right Time, in the Right Format for the MHS

a. MOP 2.a: Vital Signs Measured

Vital signs measured refers to the types of vital signs reported with clinically significant specificity, i.e., heart rate, respiratory rate, blood pressure, and temperature. A

virtual health application needs to measure the appropriate metrics that will enable a medical professional to accurately assess a patient's health. The four basic vital signs of HR, Pulse/Ox, temperature, and blood pressure give a quick, general snapshot of a patient's current health status. A VH biometric monitoring solution must therefore be able to measure these metrics or at a minimum interface with wearable sensor devices that can.

This MOP is determined according to which vital signs the VH application can measure either directly or with a compatible measurement device. At a minimum, two of the four basic vital signs must be measured by the application to collect enough data and context to determine a patient's health. Therefore, the threshold for this metric is two, and the objective for this metric is four.

b. MOP 2.b: Reported Triggers Per Patient Per Day

It is imperative that an RPM application help medical professionals decide whether to intervene when a patient shows signs of a medical emergency. The data provided by an RPM application must be accurate and actionable to enable medical professionals to make educated decisions about when to intervene with a patient. The DREAM program executed this objective well as medical professionals were able to virtually manage a patient's diabetes by obtaining blood-glucose measurements and recommend adjusted insulin doses to the patient (Newman, 2021).

Reported Triggers Per Patient Per Day are measured by the number of times the system alerts medical professionals that the patient's measured biometric signal is outside of set parameters, which will better enable the medical professional to intervene accordingly. In 2023, Walter et al. published findings on a VH solution which allowed Covid-19 patients to be discharged from the ED with a hospital-supplied kit that provided RPM capabilities that enabled the patients to be monitored at home (Walter et al., 2023). Included in these findings is the metric for that system's reported triggers per day. Based on the findings from Walter et al., the objective for this metric is set to 1.5 triggers per patient per day while the threshold is set to .9 interventions per patient per day.

3. MOE 3: Achieve Patient Satisfaction

a. MOP 3.a: Patient Adoption

The rate of Patient Adoption is important because BioZen's target population is not all active-duty Military, and there are many dependents and retirees who could benefit from voluntary use of BioZen. This MOP can be measured formally as patients using RPM applications can be asked to provide feedback on their experiences while using the application. It can also be measured by directly mining data associated with utilization by users who have been signed up for a VH program. Findings from Walter et al. (2003) showed wearable adherence as being 85% for patients enrolled in their VH program. Based on Walter et al.'s findings, the objective for this metric is 85% and the threshold is 70%.

b. MOP 3.b: Reduced Travel Time (Minutes)

This MOP considers the reduction of the patient's travel time to and from the MTF by using an RPM application. As seen in multiple RPM programs, the goal is to bring quality care to patients in remote environments or within their place of residence. Instead of focusing on value brought to MTFs by reducing patient bed days or admissions, this MOP focuses on the value brought to the patient by reducing their need to travel to MTF to receive care. This is especially critical for patients who are in rural or remote locations that do not have easy access to medical facilities.

Reduced travel time is measured as minutes of round-trip travel time to and from an appointment that are avoided by using an RPM tool. In 2022, Sharma et al. pre-published a meta-analysis of telehealth data from five University of California health care systems. Sharma et al. found that patients participating in telehealth studies saved an average of 35.3 minutes of round-trip travel time per visit, with a minimum observed savings of 22.8 minutes, using telehealth services. Based on these findings, the objective for this metric is 35 minutes of travel time savings while the threshold is 22 minutes of travel savings.

c. MOP 3.c: Reduced Travel Distance (Miles)

Time savings is valuable; however, the distance a patient can travel in a set amount of time will vary based on location: 20 minutes of travel in an urban area amounts to a very

different distance than 20 minutes of travel in a rural area. Because of this difference, Travel Avoided in miles is a useful measure of satisfaction that can be applied regardless of geographic location. Sharma et al. (in press) found that the average patient avoided 17.6 miles of round-trip travel, with the minimum observed savings being 11.4 miles. Based on these findings, the objective for this metric is 17 miles and the threshold is 11 miles.

D. ASSESSMENT OF BIOZEN

This section conducts a fit for use assessment of the current deployment by conducting a comparative analysis utilizing the framework provided by the Value Hierarchy in Figure 13 within the scenario described in Chapter II. This section begins by comparing the current deployment of BioZen against each MOP within the scenario. Next, the measured MOPs will determine if each respective MOE is met. Lastly, the MOEs will be used to determine if the current deployment of BioZen meets the overall Effect identified in Chapter V.

1. MOE 1: Optimize the Healthcare System through VH Execution

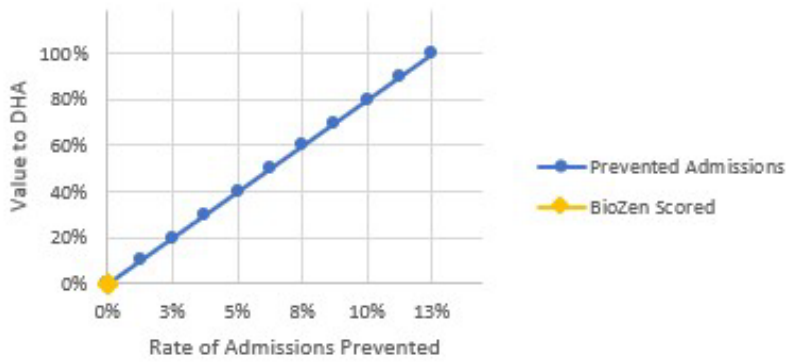
The first MOE was evaluated within our scenario by assessing if and by how much the current version of BioZen reduced patient admissions and the length of their stay. BioZen is measured on a scale ranging from 0% to 100% where the threshold for the MOP is evaluated at 0% and the objective is evaluated at 100% with a 10% reduction in the recorded value for each score aligning with a 10% reduction in the value of that score for the metric. This information is shown in Table 4.

Table 4. Healthcare Optimization Value Table

Value of Optimized Healthcare System												
Measure	Threshold	Objective	How Value is Scored									
			0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
% Of Admissions Prevented	0%	13%	0.0%	1.3%	2.6%	3.9%	5.2%	6.5%	7.8%	9.1%	10.4%	11.7%	13%
% Reduced Average Length of Stay	0%	12%	0.0%	1.2%	2.4%	3.6%	4.8%	6.0%	7.2%	8.4%	9.6%	10.8%	12%

a. MOP 1.a: Percentage of Admissions Prevented

The current build of BioZen (2.0.0) does not prevent any admissions. As a biometric monitoring tool, it is designed to provide a medical professional a review of historical data and does not provide remote monitoring by a medical professional. It does not integrate with the EHR or have any remote functions whereby a medical professional can make a clinical determination for a patient in the home. Therefore, BioZen scores a 0% in this metric and provides no value to the DHA as shown in Figure 15.

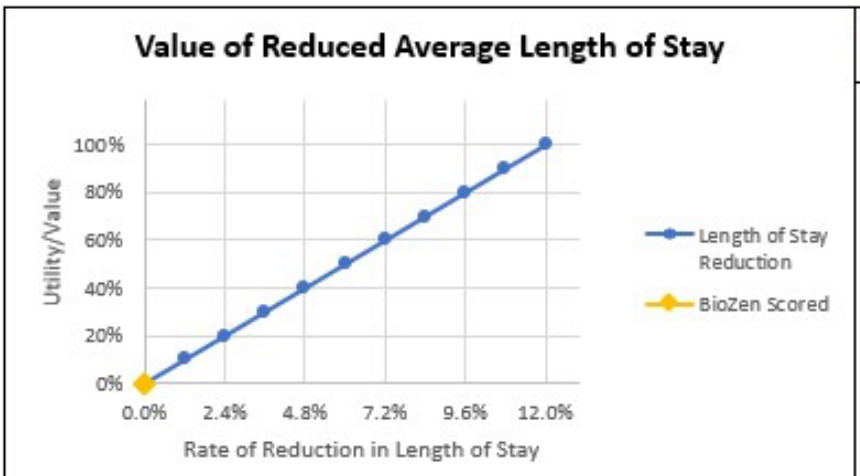


Prevented Admissions	Value to DHA
13.0%	100%
11.7%	90%
10.4%	80%
9.1%	70%
7.8%	60%
6.5%	50%
5.2%	40%
3.9%	30%
2.6%	20%
1.3%	10%
0%	0%

Figure 15. Percentage of Admissions Prevented Value Curve

b. MOP 1.b: Percent Reduction in Average Length of Stay

BioZen does not have any remote monitoring capabilities whereby a medical professional can remotely monitor a patient. Therefore, BioZen has no impact in reducing the length of a patient's stay in a facility, or bed days. This result is shown in Figure 16.



Reduced Length	Value to DHA
12.0%	100%
10.8%	90%
9.6%	80%
8.4%	70%
7.2%	60%
6.0%	50%
4.8%	40%
3.6%	30%
2.4%	20%
1.2%	10%
0%	0%

Figure 16. Percent Reduction in Average Length of Stay Value Curve

2. MOE 2: Provide the Right Information at the Right Place, at the Right Time, in the Right Format for the MHS

The second MOE is evaluated by assessing whether BioZen meets the objectives defined by MOP 2.1, Biometric Signs Measured, and MOP 2.2, Reported Triggers. This information is shown in Table 5.

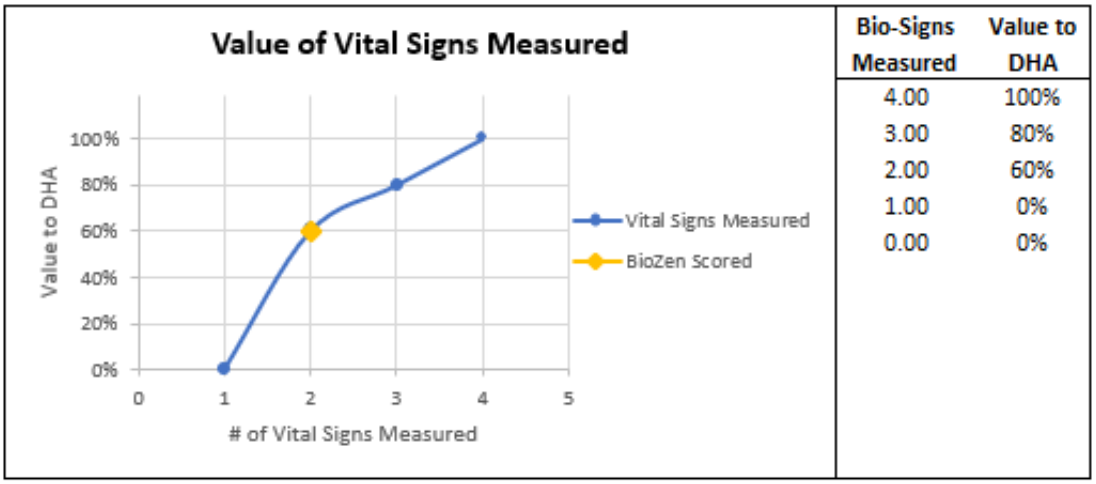
Table 5. Right Information/Place/Time/Format Value Table

Value of Providing the Right Information/Place/Time/Format												
			How Value is Scored											
Measure	Threshold	Objective	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Vital Signs Measured	2	4	0.0	0.0	0.0	0.0	0.0	0.0	2.0		3.0		4.0
Reported Triggers per patient/day	0.9	1.5	0.9	0.96	1.02	1.08	1.14	1.2	1.26	1.32	1.38	1.44	1.5

a. MOP 2.a: Vital Signs Measured

As a biometric sensor concentrator, BioZen can display the readings from any compatible wearable sensor that is connected. At the time BioZen was developed, the Zephyr BioHarness, Shimmer GSR/ECG sensors, and the Neurosky Mindset combined was able to measure core temperature, EKG or EEG, EMG, GSR, and respiratory rate.

Therefore, BioZen can measure two of the four identified vital signs and meets the objective as shown in Figure 17.

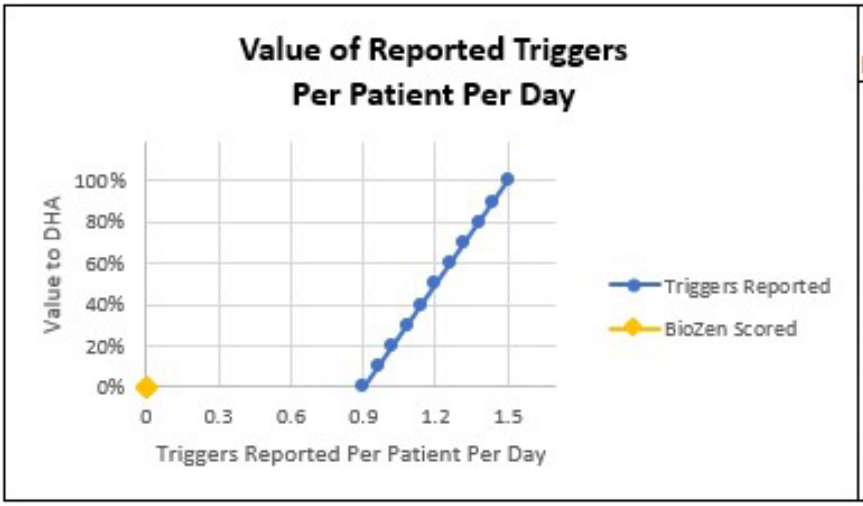


Bio-Signs Measured	Value to DHA
4.00	100%
3.00	80%
2.00	60%
1.00	0%
0.00	0%

Figure 17. Vital Signs Measured Value Curve

b. MOP 2.b: Reported Triggers Per Patient Per Day

Currently, BioZen is unable to distinguish abnormal metrics or send alerts to the user or medical professional. It is only able to display sensor readings and relies on the user to interpret sensor output. BioZen scored a zero in this metric and provides no value to the DHA as seen in Figure 18.



Triggers Measured	Value to DHA
1.5	100%
1.44	90%
1.38	80%
1.32	70%
1.26	60%
1.20	50%
1.14	40%
1.08	30%
1.02	20%
0.96	10%
0.90	0%

Figure 18. Reported Triggers Per Patient Per Day Value Curve

3. MOE 3: Achieve Patient Satisfaction

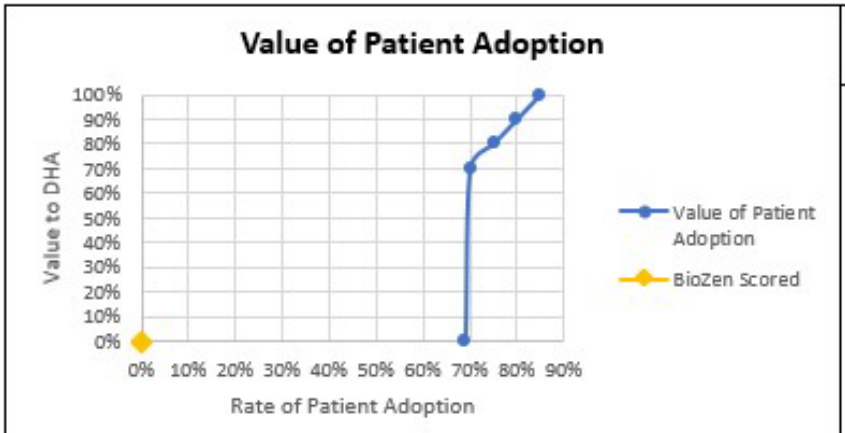
To measure the extent to which BioZen satisfies patients, the researchers applied the metrics Patient Adoption and the Reduced Travel in Time and Miles to the current deployment of BioZen. These results are shown in Table 6.

Table 6. Satisfied Patients Value Table

			Value of Achieved Patient Satisfaction										
Measure	Threshold	Objective	How Value is Scored										
			0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Patient Adoption of program	70%	85%	0%	0%	0%	0%	0%	0%	0%	75%	82%	84%	85%
Reduced Travel Time (Minutes)	22	35	22	23.3	24.6	25.9	27.2	28.5	29.8	31.1	32.4	33.7	35
Reduced Travel Distance (Miles)	11	17	11	11.6	12.2	12.8	13.4	14	14.6	15.2	15.8	16.4	17

a. MOP 3.a: Patient Adoption

The current deployment of BioZen has little to no adoption with patients. Within the MHS there are no patients utilizing BioZen for their health needs. Therefore, BioZen scores a zero in this metric as shown in Figure 19.

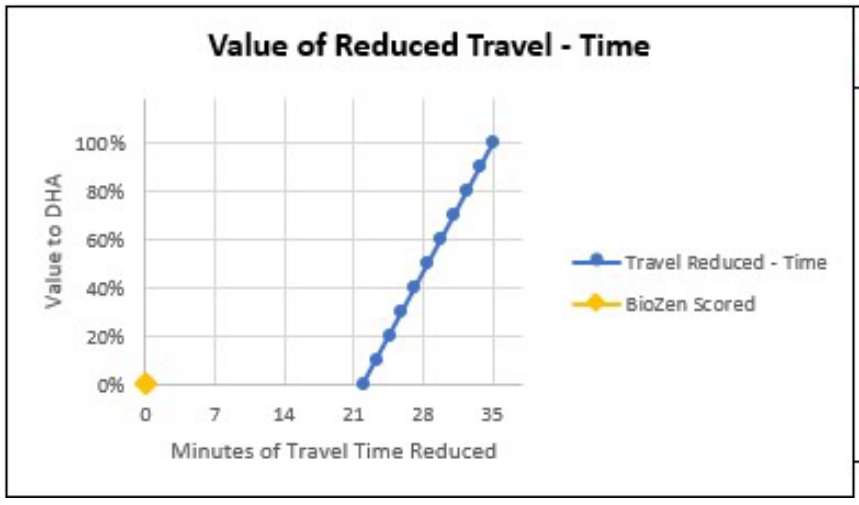


Adoption Rate	Value to DHA
85%	100%
80%	90%
75%	80%
70%	70%
69%	0%
< 69%	0%

Figure 19. Patient Adoption Value Curve

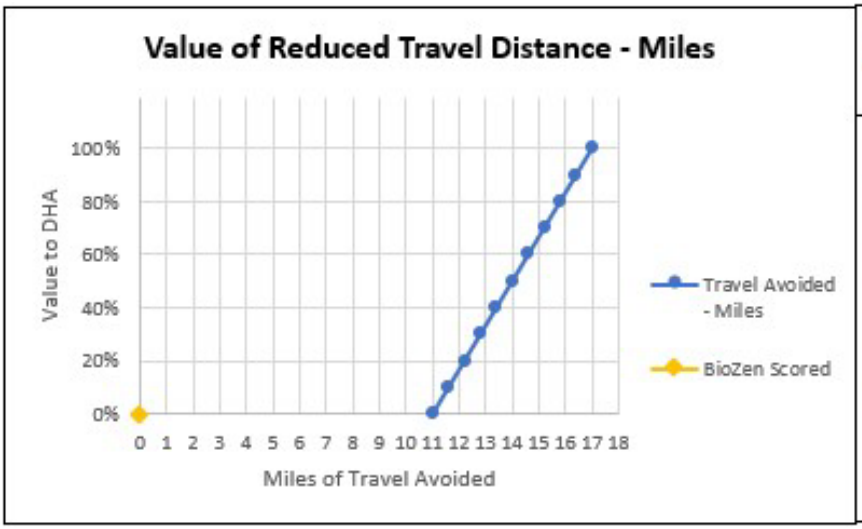
b. MOP 3.b and 3.c: Reduced Travel Time and Distance

BioZen does not possess any remote monitoring capabilities whereby a medical professional can remotely monitor a patient. A patient using BioZen must book an appointment with and travel to the medical professional so they can review the captured metrics. Therefore, BioZen does not save time or distance traveled by patients and scores a zero in both metrics. These results are shown in Figure 20 and Figure 21.



Time Reduced	Value to DHA
35.0	100%
33.70	90%
32.40	80%
31.10	70%
29.80	60%
28.50	50%
27.20	40%
25.90	30%
24.60	20%
23.30	10%
22.00	0%

Figure 20. Reduced Travel Time Value Curve



Miles Avoided	Value to DHA
17.0	100%
16.40	90%
15.80	80%
15.20	70%
14.60	60%
14.00	50%
13.40	40%
12.80	30%
12.20	20%
11.60	10%
11.00	0%

Figure 21. Reduced Travel Distance Value Curve

E. SUMMARY

This chapter analyzed BioZen within a framework of MOEs and operationalized MOPs. The overall effect of BioZen was identified as Improve Patient Outcomes. Then, the authors identified three MOEs for to measure the overall effect: Optimize the Healthcare System through VH Execution, Provide the Right Information at the Right Place, Right Time, in the Right Format for the MHS, and Achieve Patient Satisfaction. Third, the MOEs were operationalized into several MOPs with measurable objectives and thresholds based on the data from Chapters II and IV. Lastly, the authors conducted an analysis of BioZen utilizing the identified MOPs and determined that BioZen does not meet any stated objectives and provided little to no value in Improving Patient Outcomes.

VI. FINDINGS

This chapter contains a discussion of the results produced in Chapter V and answers the research questions. The discussion was organized around each MOE and reviewed BioZen's scores in each MOP. Following the discussion, the research questions were revisited and answered based on the knowledge gained throughout the study and through the evaluation of BioZen.

A. MOE 1: OPTIMIZE THE HEALTHCARE SYSTEM THROUGH VH EXECUTION

BioZen 2.0.0 scored zeros and did not meet the objective set forth in both MOPs 1.a and 1.b due to the lack of remote connection capabilities. To bring value to the DHA as a remote monitoring tool, BioZen must be able to remotely monitor patients with moderate illnesses or chronic conditions to reduce patient admissions and save bed days for the acutely ill. Successful RPM tools that brought immense value to the DHA used real time remote monitoring of a patient's metrics to prevent admissions and save bed space for the acutely ill, as can be seen with the CRMP. To do this, RPM tools share captured metrics with medical professionals over a remote connection. The medical professional would then be enabled to make a clinical decision remotely, potentially saving admissions and bed days. BioZen 2.0.0 does not support remote connections or sharing, instead saving all captured metrics locally on the host device. Medical professionals are unable to review and monitor metrics remotely while the patient remained at home. Therefore, BioZen 2.0.0 did not improve the optimization of healthcare for the DHA and provided no value because it does not meet the objectives set out for MOP 1.a and 1.b.

B. MOE 2: PROVIDE THE RIGHT INFORMATION AT THE RIGHT PLACE, AT THE RIGHT TIME, IN THE RIGHT FORMAT FOR THE MHS

BioZen 2.0.0 did not meet the objective for both MOP 2.a and MOP 2.b. BioZen could not display core temperature or blood pressure, therefore missing the objective of measuring the four vital signs set forth in MOP 2.a by two. Additionally, BioZen lacks the ability to distinguish abnormal measurements and flag them for review, receiving a score

of zero for MOP2.b. As it currently stands, BioZen 2.0.0 displays only the obtained measurements for the connected wearable sensors. It cannot process and compare obtained measurements to a set baseline. BioZen relies on the user to self-report abnormal metrics, which could be missed if not reviewed by a medical professional. It is on the user or patient to review sessions and metrics to identify whether any observed metric is abnormal. This can pose an issue for a user who is not aware of what abnormal or potentially dangerous physiological metrics are.

C. MOE 3: ACHIEVE PATIENT SATISFACTION

BioZen 2.0.0 did not meet the objectives and scored zeros for MOPs 3.a, 3.b, and 3.c. Patient adoption was extremely low to none as BioZen is not currently used within the DHA or by the public. As of January 2023, the download page for BioZen on the Google Play store shows about 10,000 downloads of BioZen since 2012 (Google, 2023). There are several reasons that explain this low adoption rate. First, it could be argued that the portfolio of compatible sensors for BioZen is small and relatively expensive for the average user. The more successful RPM programs discussed in Chapter II provided the required wearable sensors for the patient. Some programs, such as DREAM, required the patient to procure a compatible smartphone, but the program provided the rest of the equipment and sensors. Second, BioZen has not been regularly maintained or updated within the last three and a half years. The portfolio of wearable biosensors that are compatible with BioZen are now outdated as newer versions of respective devices are out on the market. These updated devices create compatibility issues with BioZen that could be potentially solved if BioZen were updated to interface with the new sensors. BioZen scored zeros for MOPs 3.b and 3.c due to the lack of any remote connection capabilities. Biometric data recorded by BioZen is stored locally on a patient's phone. Patients who utilize BioZen are forced to visit their local medical professional to share and review results. However, it is possible for a patient to screenshot their results, schedule a video appointment, send an email, or phone their medical professional to discuss the recorded results. This requires an out of band method of communication that is not consistent with RPM solutions in which results should be automatically and securely sent to a medical professional by the RPM application itself. Therefore, BioZen itself does not possess the capability to remotely communicate captured

results to a medical professional and by itself does not contribute to reduced travel time or distance.

D. RESEARCH QUESTIONS

This section answered the research questions based on the insight gained from the Literature Review and evaluation of BioZen as a remote monitoring tool. The research questions were as follows:

1. What biomedical monitoring capabilities must an effective remote patient-monitoring tool have?

A remote patient-monitoring tool must have the following capabilities to provide sufficient value to be considered effective:

- Allow medical professionals to review the captured metrics remotely in real time while also providing a real time view to the patient
- At a minimum be able to capture two of the four vital signs
- Be able to identify and flag recorded biometric readings that deviate from a clinically acceptable baseline
- Use Bluetooth 5 to connect to common and/or popular COTS wearable sensors, such as smartwatches, smart rings, wearable monitors, and headsets in a cyber secure manner
- Enable a medical professional to provide alerts or secure messages to the patient, even if that alert is simply a warning to stop current activity and call the clinic or ER.

2. How does BioZen work as an RPM tool, considering its original use case?

As a meditation assistance application, BioZen did not work as an RPM tool but as a self-assessment and monitoring tool to help improve the quality of a user's meditation session. The user connected a NeuroSky Mindset to measure their EEG and any other additional sensors such as the BioHarness to measure other desired metrics i.e., heart rate.

BioZen was not developed to integrate with any external EHR or provide remote access for monitoring.

3. How does BioZen work as a patient self-monitoring tool, considering a range of alternate use cases?

The use case used in this study evaluated BioZen as an RPM tool for a Tricare eligible Veteran with a chronic condition who has difficulties making regular appointments with the nearest clinic. For BioZen to function in this use case, it must, at a minimum, incorporate the remote monitoring capabilities described in Question 1. This would enable BioZen to meet the objectives set forth in the MOEs and MOPs proposed in this study. In meeting these objectives BioZen would enable a medical professional to remotely manage the Veteran's chronic condition.

4. What are the gaps between BioZen as it is and current technology and/or technical standards?

Several gaps were identified throughout this study. As stated, BioZen lacks the ability to share the captured biometric readings through a secure network or remote connection. In addition, BioZen is not able to interface with the more common and popular wearable devices that have dominated the wearable market since its latest release in 2017. This poses a significant barrier to BioZen being adopted by new users and limits its potential use cases. Lastly, BioZen is not compatible with the new Bluetooth 5 standard. Moving forward it is imperative that BioZen utilizes the newer Bluetooth standard to ensure the security of its connections.

5. What are possible future efforts to address these gaps?

This question is further elaborated in the conclusion of this study where the authors discuss their final recommendations ahead of the future research recommendations to address these gaps.

E. SUMMARY

In this chapter the results from the analysis were discussed and analyzed. Each MOE was investigated by analyzing the results of its respective MOPs. The current

deployment of BioZen failed to meet the minimum threshold for all the MOPs except for MOP 2.a Vital Signs Measured. The resulting discussion identified the major gaps BioZen has as an RPM tool, including inability to pass biometric data securely or remotely with medical professionals, and inability to interface with newer or more popular biometric sensors. This chapter ended with the proposed answers to the research Questions 1 to 4.

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VII. RECOMMENDATIONS AND CONCLUSIONS

This chapter provides concluding thoughts on the fit for use assessment of BioZen as an RPM tool. The chapter starts with key insights derived from this study's analysis of the Literature Review and the assessment of BioZen. Following these insights, the authors present recommendations to address the gaps found. The authors then propose potential future use cases for BioZen that will bring value to the DHA if the recommendations are followed. Last, future research opportunities and goals are presented to address the limitations or gaps this study revealed.

A. KEY INSIGHTS

The authors conclude that BioZen is not fit for use as it is currently built, and it will not provide value to the DHA under the *DHA FY22-26 Campaign Plan*. It was found that BioZen did not achieve the desired effect of Improving Patient Outcomes by its inability to meet the objectives set for all three MOEs. BioZen's overall scores are shown in Figure 22.

Measure of Evaluation - Optimized Healthcare System			
Measure of Performance	**Threshold**	**Objective**	**BioZen Score**
% Of Admissions Prevented	0%	13%	0
% Reduced Average Length of Stay	0%	12%	0

Measure of Evaluation - Providing the Right Information/Place/Time/Format			
Measure of Performance	**Threshold**	**Objective**	**BioZen Score**
Vital Signs Measured	2	4	2
Reported Triggers per patient/day	0.9	1.5	0

Measure of Evaluation - Achieved Patient Satisfaction			
Measure of Performance	**Threshold**	**Objective**	**BioZen Score**
Patient Adoption of program	0.7	0.85	0
Reduced Travel Time (Mins)	22	35	0
Reduced Travel Distance (Miles)	11	17	0

Figure 22. Fit for Use Assessment of BioZen

Additionally, the authors offer the following insights derived from the study's review of the literature and assessment of BioZen:

6. A patient-centered, government-owned RPM tool does not exist within the DHA.

This study revealed that the DHA does not have a government owned, developed, and operated RPM tool available to patients to help manage chronic conditions. BATDOK is government developed and owned, but it is designed to assess and evaluate trauma patients in a combat environment. Most of the RPM tools and programs reviewed utilized commercial solutions and external clouds, therefore jeopardizing biometric data ownership by the DHA.

7. BioZen is unable to normalize biometric data from the front end to enable big data analytics.

There are many data types and forms of biometric data. It was found that many COTS sensors required proprietary applications to access and view the captured metrics from the vendor's device. This makes it difficult to aggregate biometric data without utilizing the numerous applications, Application Programming Interfaces, and data formats. In addition, it was found that the DHA does not have an effort to normalize biometric data from wearable devices to enable the use of advanced analytics to identify baselines, trends, and anomalies.

8. The DHA does not have an RPM solution that retains data ownership from the point of collection to long-term storage.

The DHA does not have an organic RPM tool and outsources the data storage and application to commercial organizations. This arrangement prevents the DHA from retaining ownership of the collected biometric data as the data may be processed or stored in commercial clouds or proprietary systems. DHA may be exposing itself to unnecessary risk if patient data is compromised or is unrecoverable from these external systems.

B. RECOMMENDATIONS

To address the gaps identified within the key insights, and to fully answer Question 5, the authors propose the following recommendations:

1. The DHA should invest in developing an RPM tool for use by patients to manage their chronic conditions and overall health.

This tool should be developed, owned, and operated by the DHA to ensure data ownership, patient safety, and confidentiality. BATDOK is a great example of this sort of endeavor. ARFL coordinated with several wearable device vendors to provide plugins for BATDOK so it could interface with the vendors' wearable sensor without the need to download proprietary applications from the internet. The use of these plugins prevents sensitive medical data from traversing into the vendors' systems and cloud environment. The authors recommend WMT coordinate with wearable device vendors and redevelop BioZen to allow for similar vendor plugins. This change will enable BioZen to be compatible with a wider portfolio of wearable sensors while ensuring the DHA securely owns the data from the point of capture to storage.

2. The DHA and WMT must implement data normalization strategies on the biometric data being generated by RPM tools.

This study revealed that data generated from IOT wearable devices will continue to increase. The information such a massive dataset contains may prove invaluable to the DHA. It is imperative that the data generated by RPM tools is normalized in a standard data model. Normalization allows advanced analytics to be conducted on this potentially massive data set to discover health trends, anomalies, baselines, and even predictions on patient health within the MHS. BioZen may provide the opportunity for this endeavor. The authors recommend rebuilding BioZen to incorporate data normalization on captured biometrics and prepare the data for use in analytics.

3. The whole data pipeline from the point of collection to storage must be wholly owned and secured by the DHA.

The authors recommend the DHA to invest in an RPM solution wherein the data is encrypted, transmitted, and stored by the DHA or DOD owned systems. This arrangement ensures that patient data remains confidential and secure while the DHA retains complete ownership of the data. DHA control of data reduces the risk of sensitive medical data exposure by third parties and will assist in incorporating the captured medical data into an EHR such as MHS GENESIS. BioZen is potentially an excellent start in developing a DHA-owned RPM tool that retains data ownership. However, further investments into BioZen are required to achieve the goal of securing data from the point of collection to storage. These investments should focus on the plugins stated in the first recommendation and in developing remote capabilities for BioZen to enable it to securely transmit real time biometrics to medical professionals and MHS GENESIS.

C. USE CASES

If the recommendations are followed, the authors propose the following future use cases for BioZen:

- Enable sleep studies to be conducted at the patient's home through a remote connection.
- Manage chronic conditions such as diabetes, high blood pressure, and cardiovascular disease for high risk or remote patients.
- Healthy lifestyle coaching, weight loss, or physical therapy.
- Preeclampsia monitoring for beneficiaries who cannot travel to medical facilities twice per week in the last trimester of pregnancy.
- Reducing contagion risk by quarantining and monitoring sick patients at home from a remote location.
- Remote Biometric monitoring for patients as needed, in lieu of hospitalization.

D. FUTURE RESEARCH

The authors conclude that the current iteration of BioZen is ineffective at improving patient outcomes and brings no value to the DHA as an RPM tool. The authors note that this conclusion does not mean that BioZen cannot provide this value or that DHA-developed RPM tools are ineffective. On the contrary, the review of past and present RPM programs has revealed that RPM tools are effective at improving patient outcomes, reducing cost, and ultimately saving lives. With this, the authors encourage additional research into RPM tools within the DHA. The following are a few suggestions:

- Conduct stakeholder surveys of providers and beneficiaries within the DHA to identify a comprehensive list of wants and needs from an RPM solution.
- Conduct a longitudinal study of the long-term effects of RPM tools on patient outcomes and cost savings within the DHA.
- Re-evaluate a redeveloped BioZen or other DHA-developed RPM tool against the framework of MOEs and MOPs proposed in this study to determine the associated value.

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