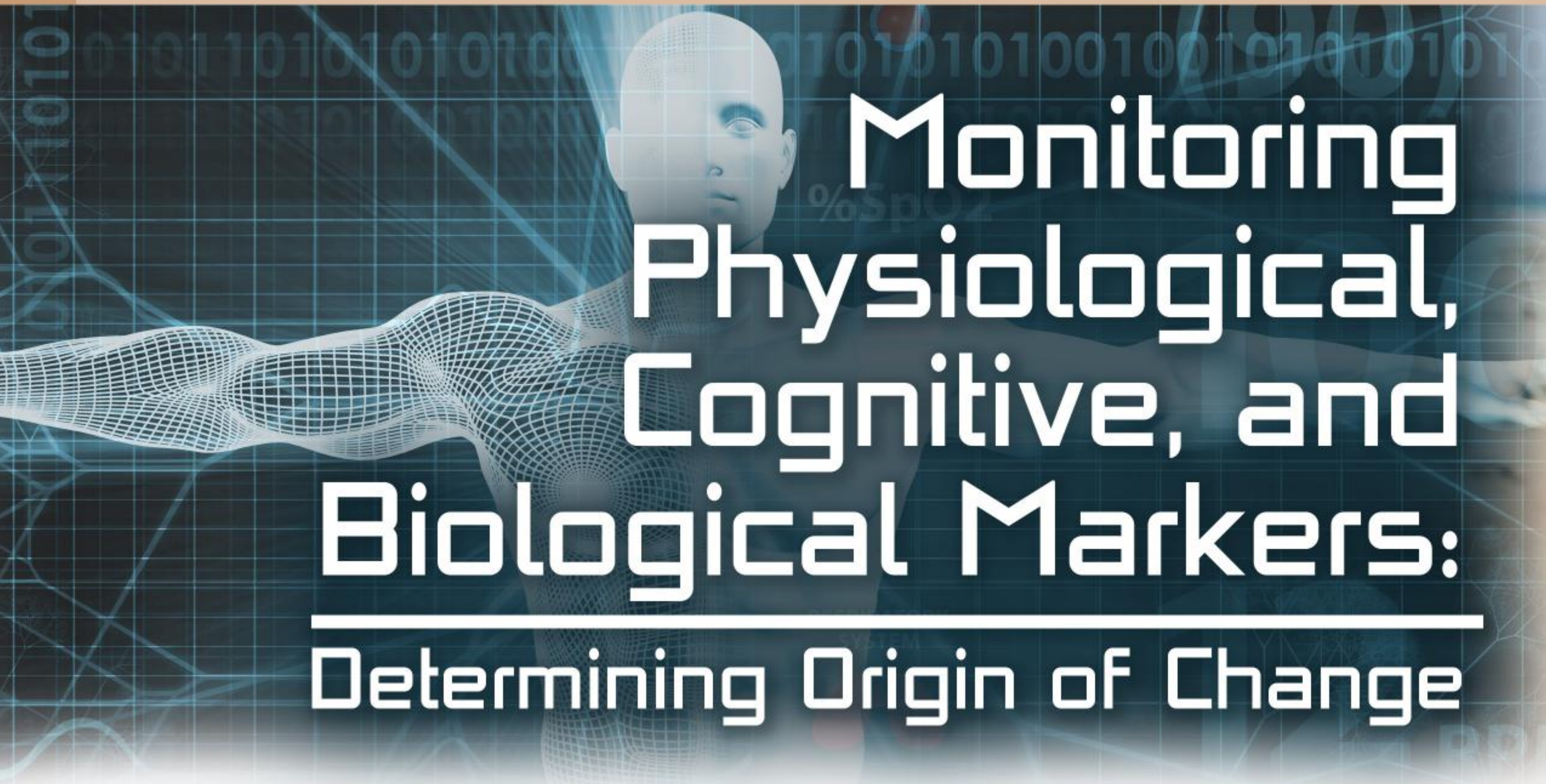

Monitoring Physiological, Cognitive, and Biological Markers:

Determining Origin of Change

Glory Emmanuel-Aviña, Ph.D.

Many communities have an interest in quantifying human performance, as the monitoring of physiological data helps to inform physical fitness performance, medical assessments, mental health, rehabilitation, and educational methods. The Department of Defense (DoD) may also benefit from real-time physiological monitoring. According to the Defense Science and Technology 2016 Human Systems Roadmap, the deployment of wearable sensor technology is a key mission area for protecting warfighters from threats in the environment. Both high-resolution, wearable kinematic sensors and real-time algorithm development are near and mid-term goals to aid warfighter performance [1].

Chemical and biological agent use has grown since 9/11 and remains a known threat to military forces [2], and the use of wearable technologies to analyze human behavior in real time could help to differentiate between fatigue and exposure to chemical and biological agents. Wearables, such as a wirelessly-connected ring, have been made to detect chemical and biological agents [3], but these devices detect threats present in a liquid or vapor phase. By equipping a group with wearable devices that monitor specific biomarkers, military analysts and decision-makers can track both an individual warfighter's health and monitor for group-level physiological responses that may indicate possible chem-bio exposure. Although wearable fitness devices can be used for real-time health monitoring, research is needed to understand what biomarkers would be indicative of individual health versus threat exposure.

Currently, physiological data is the primary source for quantifying human performance. Through human-subject studies, individuals can be instrumented with wearable fitness devices capable of measuring physiological markers such as heart rate, cadence, breathing rate, etc. Statistical models then analyze this data to connect physiological markers to performance.

Monitoring neurocognition and blood chemistry provides other datasets that could serve as early indicators of health, performance, fatigue, and exposure. However, the technology for quantifying cognitive ability and blood markers are not as advanced as physiological, wearable devices. Neurocognitive data, which quantifies brain activity engaged during physical movement, is indirectly measured through cognitive tasks before and after, or periodically during, an activity. Therefore, it is difficult to develop a device that can measure neurocognitive activity in non-laboratory environments.

As far as we know, there is no adequate device to quantify neurocognition in real time or while performing a physically engaging activity. While blood composition is a measure of human performance, it is collected through invasive procedures (e.g., blood draws) and must also be analyzed post-activity. However, biomarkers have been non-invasively and passively measured through wearable, microneedle patches, which lightly penetrate the surface of the skin.

Dermal interstitial fluid (ISF), for example, can be drawn by microneedles and have been found to measure biomarkers that are usually measured through blood draws. Identifying additional data streams that measure human performance in real time and quantifying them through advanced wearable technology may allow us to both anticipate as well as make decisions about health in extreme environments.

By quantifying attributes of physical fatigue, we can differentiate physiological responses from chemical and biological threats. This is important because military personnel are often subject to high-consequence, extreme environments where physical abilities are challenged. Additionally, they may be vulnerable to biological threats in austere environments.

Although real-time monitoring of data collected from wearable technologies may help to monitor personnel behavior during a mission, analysts must be able to differentiate

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between individual health events (e.g., heat stroke, hyponatremia, dehydration, altitude sickness) and exposure to chem-bio agents (e.g., anthrax, sarin, hydrogen cyanide).

Research studies funded by government agencies that serve the DoD are examining chem-bio threats from various perspectives. Some projects study the threat agents themselves to determine how they work. Other studies examine how animals react to such agents, how to protect and defend against these agents, or the impact of attacks on large populations.

A critical body of research uses human-subjects research to study how chem-bio agents may be detected in humans. A subset of that research focuses on wearable technologies. Specifically, the Defense Threat Reduction Agency (DTRA) is funding research projects that investigate how wearable technologies may be used to detect exposure, one of which is led by the author, the Wearables at the Canyon for Health (WATCH) project.

Researchers are investigating multiple ways that wearables may be used to detect chem-bio exposure. One approach is to quantify physiological, cognitive, and biological markers to evaluate human performance and physical fatigue in extreme environments. Another method is to collect physiological data on individuals who are sick with common health ailments (e.g., influenza, common cold) and determine how wearable technology data differentiates between healthy and sick individuals. Researchers are also testing how ISF, which is extracted from a simple wearable microneedle patch on the surface of the skin, can replace invasive and static blood draws so that biomarker data can be continuously collected and analyzed.

This article presents WATCH project methodologies and findings of human-subjects research that can be applied to high-consequence scenarios where chem-bio threats are prevalent. First, recent research in wearable technologies related to sensor development, smart clothing, and data management is presented. Then human-subjects research regarding how wearable technologies can be applied to chem-bio threat detection is examined. Finally, the need to expand human-subjects research in wearable technologies and how such R&D will continue to serve the DoD is discussed.

Wearable Technology Research for the DoD

Physiological Monitoring

Wearable sensors through fitness devices are the most common way to obtain physiological data. However, challenges arise when attempting to use these commercially available wearables for consistent medical monitoring. Proper fit of the device to avoid chafing and/or inhibition of movement, a robust signal, battery life, valid data, longevity of the device, and robustness in harsh environmental conditions are just a few of these challenges. Attempts have been made to improve form, fit, and function of devices by reducing size and improving design and materials used [4]. For example, pulse rate is a physiological marker that sheds light on work load. Photoplethysmography (PPG) pulses, which access oxygen saturation, can be assessed through pulse oximeters.

Pulse oximeters are small, wearable, pulse rate sensors, which use infrared light-emitting diodes (LEDs) and photodetectors to create a simple, reliable, low-cost way to noninvasively monitor pulse rate [5]. Skin-worn, temporary tattoos may also soon provide real-time non-invasive analysis of key electrolytes and metabolites. In addition, they may also be used to measure physiological markers, such as heart rate, electroencephalogram (EEG), and electrocardiogram (ECG), that are usually captured through bulky or uncomfortable devices [6, 7].

Furthermore, different approaches may be used to improve battery life, such as minimizing power consumption by using electrocardiographic waveforms to turn devices on and off to save battery power [8] and harvesting human and ambient energy sources using electromagnetic generators [9].

Figure 1. Hikers are asked to complete a short cognitive battery before, during, and after the hike and wear a suite of fitness, wearable devices. (Source: Sandia National Laboratories)

Smart Clothing

Smart clothing is an attractive alternative to wearables because they are easily worn, making them more integrated with human activity. Electronic textiles (e-textiles) are fabrics with electronics and interconnections either woven into them or embedded in the fibers themselves. E-textile fabrics can detect the activity and physiological status of the user. Different types of e-textiles present trade-offs between flexibility, ergonomics, low power consumption, integration, and autonomy [10]. Although smart clothing is a step forward for ease of use and integration with individual users, there are challenges with fit and flexibility. For example, with silicone-based, LED clothing, there is an intrinsic stiffness of inorganic semiconductors, which makes them uncomfortable to wear. Innovative methodologies are being researched to address this, including the fabrication of thin and flexible emitting fabric that utilizes organic light-emitting diodes [11].

Neurocognitive Data

Neurocognitive data, which is cognitive function while performing and completing a task, is of increasing interest. Neurocognitive monitoring examines an individual's ability to make decisions, remember information, maintain alertness, and respond to threatening stimuli. This is important for military settings since sleep, focused attention, decision-making, and other cognitive activities are tasked in high-consequence mission contexts [12]. Impaired cognitive function could be an earlier indicator of health decline, both for physical fatigue and chem-bio exposure. If we could measure neurocognitive data well, it would help to better quantify human performance. If we could measure neurocognitive data in real time, it could serve as an early predictor of performance decline. Currently, neurocognitive processes are best quantified in highly controlled laboratory settings. Wearable neurocognitive monitors are not suited for activities that require heavy movement and are usually limited to stationary tasks [13]. Neurocognition can also be measured before and after an activity by, for example, having an individual complete a cognitive task that measures focused attention pre- and post-hike, but this does not quantify brain activity during physical exhaustion or chem-bio exposure.

There are various ways to measure neurocognitive activity. Portable, wearable eye trackers have the potential to measure this activity via gaze location, blink rate, and/or pupil dilation. Similarly, portable, reduced-electrode EEG devices may provide insight into brain function. Eye trackers are often used to gain insight into underlying mental processes, such as attention, situational awareness, cognitive load, and behavior-directed intentions [14-16]. Much like the wearable technologies field, eye tracking research is on the rise, with lightweight, increasingly portable machines becoming more accessible and numerous than ever before (e.g., eye tracking "glasses"). Portable EEG machines that are quick to set up and have a reduced number of electrodes are now readily available. In relatively uncontrolled settings, these machines are best used for determining general alertness or activity (e.g., the ratio of alpha- to beta-band activity), which has been linked to fatigue during intense activity in laboratory environments [17]. However, EEG studies are limited to controlled environments because of the delicateness of the equipment, the consequence of sweat on device fit, and overall discomfort of device when moving around.

Advances are being made to enable EEG for more active behaviors [18], but this technology is not yet mature for intense activity, such as hiking or running. Transcranial direct-current stimulation (tDCS) is another neurocognitive application that has been linked to improvements in working memory capacity [19]. Application of tDCS as part of a wearable device in extreme settings could have positive effects, but the research in this area is both sparse and difficult to conduct without proper technology development.

Human-subjects Research for Wearable Technologies

By studying hikers in an environment with significant changes in temperature and altitude, the WATCH study is creating a dataset that measures cognitive and physiological markers that could help predict performance decrement from physical stress. WATCH collects data from hikers hiking from the Grand Canyon's South Rim to its North Rim. These hikers each wear multiple wearable, commercial-off-the-shelf (COT), fitness devices provided by the research team to monitor their physical activity [20, 21]. Cognitive data is also collected by requiring hikers to complete a 5-10 minute cognitive battery every 5 miles during the hike. Data is collected from two different cohorts: civilian volunteers and military personnel. The purpose of this study is to identify physiological and cognitive markers most relevant to health and task performance and to assess which COT wearable devices are best for such measurement in extreme environments.

It also focuses on developing statistical models to identify markers that are the most predictive of benign versus traumatic health events. This study is funded by DTRA's Chemical and Biological Technologies department. Below are figures that show data collection at the Grand Canyon trailhead with human subjects as well as data from fitness devices illustrating how heart rate can be displayed for individuals wearing multiple fitness devices.

Another study conducted by the Naval Warfare Center [22] examines how sleep patterns, heart rates, respiration rate, and body temperature are disrupted by bodily infection or other altered health statuses. These disruptions are also present for military personnel in a mission context. This project aims to collect wearable device data from individuals to establish baseline physiological parameters for healthy individuals when they are normally functioning and when they are exposed to common infections (cold, flu, etc.). The goal is to develop an early warning system that monitors physiological endpoints using state-of-the-art COT biomonitoring devices that correlate the data with actual health status and medical readiness. Devices test for personal identifiable information (PII) security, performance, robustness, data security controls, and reliability in monitoring and recording physiological parameters of interest. In addition, statistical algorithms have been developed using programming languages to analyze subject time-series data. The algorithms monitor sleep, heart rate (from inter-beat-intervals), and diurnal patterns in order to establish baselines in the dataset.

Wearable technologies are also being used to collect biological fluids in real time, such as sweat [23] and ISF [24]. For example, microneedles are used to sample ISF for clinical monitoring and diagnosis. Although ISF can be extracted through microneedles, little is known about ISF's composition and the information it provides on human chemistry and behavior. Another study funded by DTRA develops a novel microneedle array as a wearable device to collect dermal ISF from three healthy human donors. This data is then compared with matching serum and plasma samples [25]. This study, using a shotgun quantitative proteomic approach, confirmed that ISF is highly similar to both plasma and serum. ISF was found to be highly homogeneous and nearly indistinguishable for protein diversity from serum and plasma. Additional research has found that dermal ISF possesses transcriptomic and proteomic content highly similar to serum and plasma, and, therefore, it could be a proxy for blood in health monitoring [26]. Consequently, ISF could serve as a minimally invasive alternative for blood-derived fluids with potential for real-time monitoring applications.

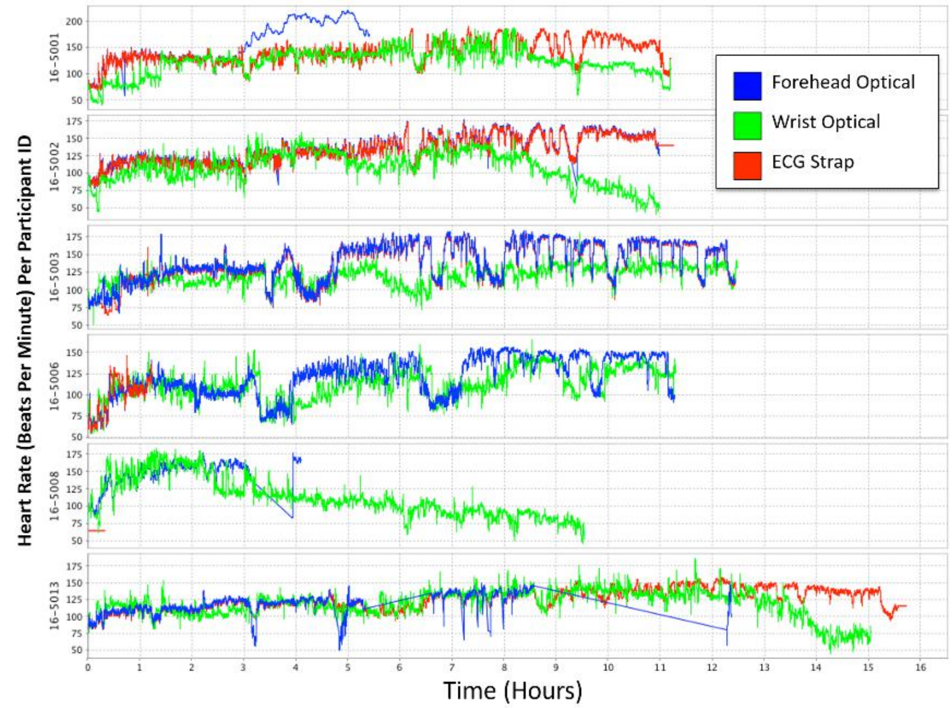

Figure 2. Parallel recordings of heart rate using 3 types of sensors on each of 6 participants. Their completion times for the hike range from 9.5 to 15.5 hours. (Source: Sandia National Laboratories)

Recommendations for Further Research

Predictive and Real-time Analytics

In addition to R&D advances, innovative statistical models must also be developed to appropriately analyze continuous, physiological data. An algorithm named Presymptomatic Agent Exposure Detection (PRESAGED) has been designed by researchers from MIT Lincoln Laboratory, the U.S. Army Medical Research Institute of Infectious Diseases, and the National Institutes of Health Integrated Research Facility. PRESAGED uses real-time physiological data to predict the probability that a person was exposed to a pathogen, such as a virus or bacteria [27].

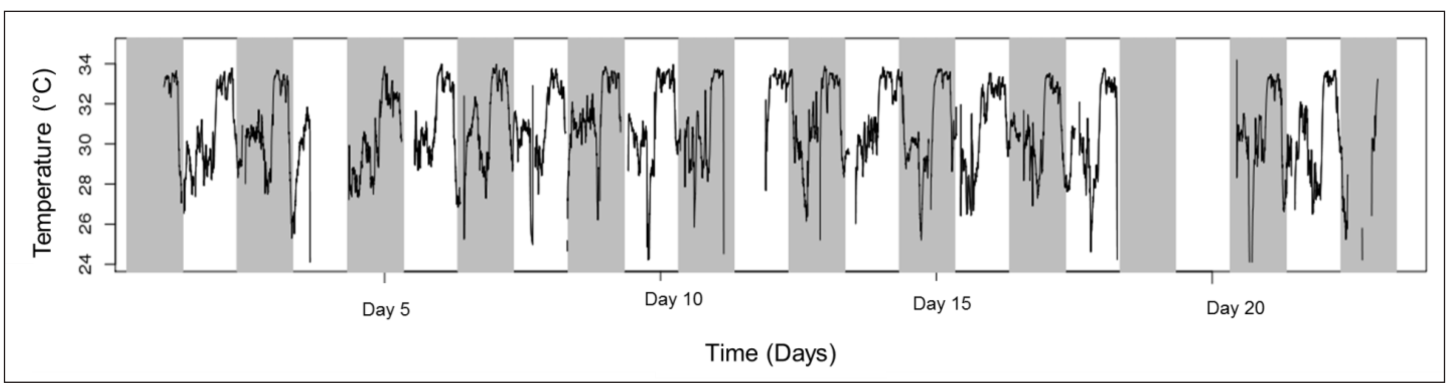

Figure 3. The Naval Warfare Center developed a statistical algorithm to identify diurnal patterns within subjects utilizing a wrist-worn COTS biomonitor. (Source: Naval Surface Warfare Center Dahlgren Division)

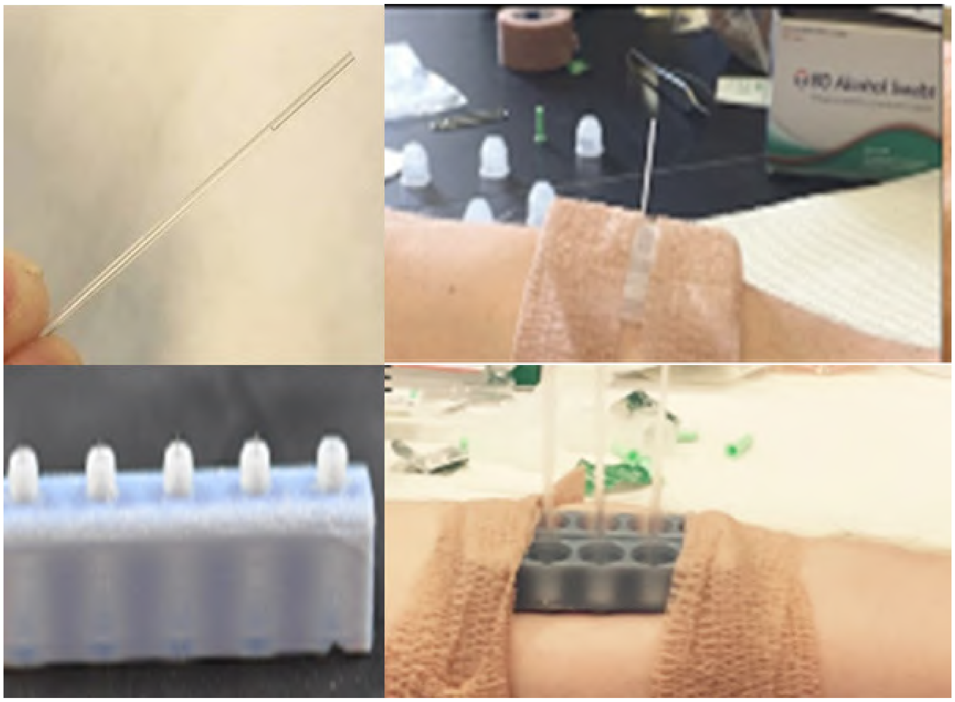

Figure 4. Development of microneedles as a wearable technology. (Source: Sandia National Laboratories)

To date, this algorithm has been tested on datasets acquired from non-human primates. To test algorithms such as PRESAGED, datasets that quantify human performance under physical health events must be compared to datasets that quantify human performance under chemical/biological events.

However, we must first be able to clearly differentiate between markers of health decline in extreme environments and markers stemming from chem-bio exposure. Confirmatory and exploratory statistical analyses will help differentiate between health decline and exposure. The objective of confirmatory analyses is to validate how physiological, cognitive, and biological markers quantify health and fatigue in extreme environments using datasets created from human-subjects. Confirmatory statistical methodology will emphasize robustness and interpretability. We propose using a derived variable analysis [28] to build summary measures from the longitudinal data collected through human-subjects studies.

Machine learning strategies can be used to build models with complex interactions between variables. Features can also be used that can be reliably constructed outside the environment of the original study for predictive purposes. In current datasets, we propose to first use derived variable analysis to generate features from the device data and then traditional machine learning methods, such as support vector machine or neural nets, to build the predictive model and validate the model using cross-validation. We will then move toward real-time data processing. Further statistical analyses need to be developed from predictive models to rapidly and accurately fuse and assess incoming data streams.

Security Considerations

The goal is for wearable technologies to equip military personnel and DoD decision-makers with information about personal health as well as the possibility of chemical, biological, and radiological exposures [29]. However, in order to operationalize real-time data, security protocols to keep data secure must be implemented. This is evidenced by the January 2018 event in which it was discovered that location information obtained from wearable fitness watches and GPS tracking applications was being released through GPS tracking app Strava [30].

As there is a movement to integrate patient wearable data with electronic medical records, personal health records, patient portals, and clinical data repositories [31], this data must be securely transmitted. Innovative methods are being developed to prevent the exploitation of sensitive user data. One recent study determined and presented techniques that allow an adversary to extract data from smartwatches, including text messages, contact information, and biomedical data [32]. Overall, the type of data being collected by wearable devices, the way the data is being extracted and released, the information that can be deduced from the data, and who should and should have access to this information are all critical questions that should inform data management. Although an infrastructure must be created to protect data extraction and communication, this is a complex challenge. Specifically, it is difficult to create solutions for extracting device data in extreme environments, especially where there are limited network sources. It is even more difficult to protect data so that it is only accessible by a subgroup of users once it has been extracted. There is currently very limited open source literature regarding potential solutions. Most solutions are based on devices that use privacy-preserving data aggregation in cloud-assisted wireless wearable communication, but tactics include: secure multiparty computation, fully homomorphic encryption, and the one-way (trapdoor) function [33].

Conclusion

The use of wearable technologies presents an opportunity to enhance human performance. These devices are being further developed to enhance performance functions ranging from those used by individuals personally monitoring their health to military personnel monitoring their environment. However, challenges remain regarding the use of wearables for physiological monitoring in military contexts. Devices must obtain valid, useful data and remain powered for long periods of time. They must be robust enough to withstand extreme environments, multiple types of terrains, temperature swings, and variable climates. They must also enhance human performance without added distraction, weight, or discomfort, and acquired data must be securely monitored and stored.

Current research projects funded by DoD agencies are generating datasets that quantify the effects of physical and cognitive fatigue as well as biological responses when exposed to common infections. Researchers are exploring how to make wearable technologies that can continuously collect biological data related to human performance. This research will assist in the development of enhanced wearables technologies that may be used by DoD to determine the origin of change in physiological, cognitive, or biological markers.

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