Frost & Sullivan

The Future of Patient Monitoring – Impact of Mobile Cardiac Telemetry

Frost Perspective

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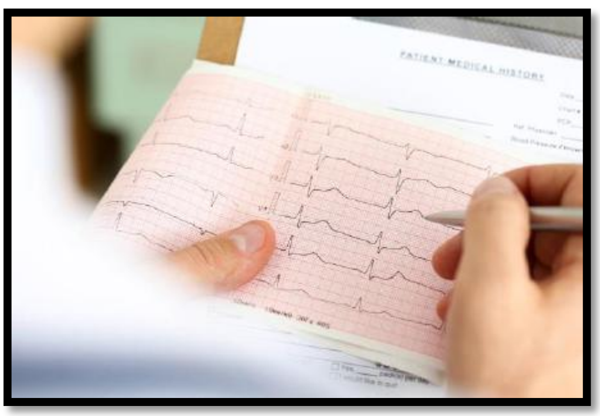
Introduction

Roman Legions over 2,000 years ago made provisions for their infantry wounded in battle to be treated and monitored by care givers. At the time, simple observation and palpitation for a heartbeat was the extent of available clinical resources. It was these keen senses of observation through trained eyes and skilled hands that led to an eventual application of dressings and organic ointments to heal blunt trauma and reduce the pain and suffering. Modern day physicians and ancillary staff still depend on this inherent developed human skill of observation to gauge a clinical response by evaluating the presence and physiological efficacy of a heart rate. Yet, in the 21st century, state-of-the-art technology is making every attempt to supersede this human first-hand observation with electronic physiological monitors designed to alert and even predict imminent cardiac impairment or heart failure.

How did we get here? And what current patient monitoring technology provides the best clinical data for diagnosing and predicting cardiac rhythm anomalies? Last, when does technology exceed its value in patient monitoring? And when does medical training and clinical instinct take over?



Early Cardiac Warning Systems

The nexus of technology and the ability to capture the electrical activity of a human heart came to fruition in the early 1950s with the introduction of a cathode ray tube (CRT). Capturing the electrical synapse of cardiac activity and representing it on a monitor as a PQRST electrocardiogram (ECG) introduced a new science of interpreting this sinus curve. The ability to visualize and quantify cardiac waves introduced a means to diagnose and catalog a number of physiological nuances related to a cardiac rhythm. Early on, this new-found clinical tool was limited to measuring slow heart rate (bradycardia) or an accelerated rate (tachycardia) used almost exclusively in surgical settings.

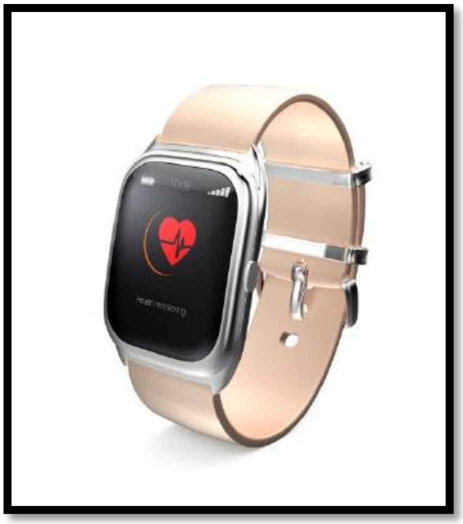
By the mid and late 1950s, cardiac monitoring industry pioneers saw the potential for creating products that capitalized on ECG technology. By aligning science and biomedical engineering, providers and nurses could monitor patients that had left the operating room (OR). Early experimentation by companies such as Birtcher, Burdick, Dallons, Air Shields, and Electrodyne began to offer such cardiac medical devices and monitors as pacemakers, defibrillators, and many physiologic-monitoring systems. Not surprisingly, ECG monitors rapidly became a standard bedside modality for monitoring and measuring cardiac rhythms.

At the same time, Litton Systems offered a telemetry system that engaged standard radio technology using FM frequency band transmission to project and display cardiac electric activity. Litton's Vector Guardian System, a subsidiary of United Aircraft boasted telemetry, was the very same technology used in space flight by NASA to monitor an astronaut's physiologic responses to space travel. However, it was not until the 1970s when sophisticated presentation of cardiac waveforms in required specificity could be used to diagnose common arrhythmia disorders such as atrial fibrillation or AF. The science that enabled this utilized a combination of digital converters and a new field of capturing data and saving it with on-board memory (RAM) embedded in computers.

Personal computers or PCs armed with a data storage capability for digital data paved the way for many technical advancements in patient monitoring for the remainder of the 20th century. Biomedical engineering and enhanced memory storage capabilities driven by software written to analyze digital cardiac activity resulted in many sophisticated bedside patient monitoring stand-alone systems. Some were equipped and engineered to be complete with prediction algorithms and programmable alarms. The discussion of each of these advances is beyond the scope of this *Frost Perspective*. Frost & Sullivan will be authoring a comprehensive study on the Future of Patient Monitoring in late 2017.

The Emergence of Mobile Cardiac Telemetry (MCT)

MCT is the most recent of many new patient monitoring options. MCT devices are purposely designed as miniaturized, ergonomically friendly portable monitors. The scientific intent of MCT technology is to scan what is referred to as *beat to beat* heart rhythms for anomalies such as AF and then record those incidents. This enables physicians to better detect and manage atrial fibrillation, reducing the risk for stroke. Early detection is of critical importance in preventing AF-associated stroke activity. Data is transmitted to a 24-hour hub or monitoring epicenter using cell-phone mobile technology. The information packets are encrypted to prevent hacking and are received and evaluated by qualified cardiac-trained nurses. This application goes well



beyond earlier event monitors that capture and record arrhythmia data but do not transmit it digitally.

Some innovations in MCT are emerging with growing diagnostics as well as remote patient capabilities by creating *wearable* devices that exhibit ergonomic properties accurate enough to enable them to seamlessly fit into a broad range of daily activities. A most recent development using MCT is the creation of a one-piece device that offers a single receiver/recorder. These singular device designs are gaining popularity with researchers and physicians.

Another adaption using MCT is the Extended Holter or *patch* as it is referred to, which extends the traditional Holter harness data collection capability creating an extended or *long term* Holter device. This patch does not require wires like the Holter harness. It is made up of a two-piece technology that synchronizes data to a remote device or hub using Bluetooth technology. About the size of a large band aid, this style of CMT device adheres directly to the patient's chest.

MCT advances are also assimilating with GPS technology using accelerometer metrics. This advanced MCT application transmits data directly to the cardiologist, who then uses other digital tools and imagery to enhance cardiac diagnostic capabilities. The added GPC component allows scientists to capture geo-data, which establishes patient locations that coincide with data transmitted in real time. The accelerometer then establishes a physical activity quotient at the time of a documented cardiac event. These added features introduce a much broader array of data and evidence that assist cardiologists in learning the scope and clinical patterns of their patient's heart activity. This data can also serve to document progress in cardiac and respiratory stress and recovery following a stroke or acute myocardial infarction (AMI). In addition, this data can be captured in remote locations, allowing patients to recover at home rather than extended stays in the hospital. This criterion of cost avoidance and enhanced home health capability fits nicely in the dawning era of value-based reimbursement and alternative payment models or APMs.

It is unclear as to what extent MCT capabilities can be employed across a broad spectrum of physiological monitoring and immediate and continuous transmission of real-time data using cellular technology. More and more innovations are appearing and with them new original equipment manufacturers (OEMs) enter the medical device industry vertical seeking 510(k) approval from the Food and Drug Administration to take their new technology to market.

Introduction of a New Paradigm of Patient Monitoring

The introduction of sophisticated Bluetooth technology in a cloud configuration that employs a single ECG lead technology as a wearable device, or MCT, ushers in a new era of both cardiac diagnostic and clinical trial capability. Moreover, remote patient monitoring (RPM), so far limited to gathering physiologic measurements, has now expanded to include myriad other health indicators. These new dependent variables that conceptually encompass patient monitoring include sleep patterns, mood, diet, occupation, relationships, depression, poverty, wealth, housing, and so on. Using a data interface for these socio-economic indicators with a comprehensive population analytics platforms as found in IBM Watson, we now conceivably have an ability to write algorithms that capture the precursors of chronic and degenerative diseases. For example, by mapping electroderma and nerve synapse data over time it may be possible to predict Parkinson's disease.

Can We Predict Disease With Reliability and Validity?

This is the future of patient monitoring. Prediction. Evidence of this scientific reality can be seen in the recently revealed Verily Project Baseline methology. "Project Baseline is the quest to collect comprehensive health data and use it as a map and compass, pointing the way to disease prevention."1[1] Over 4 years, (N = 10,000) Verily is employing MCT technology using a one-lead cardiac and physical activity monitoring wearable, a sleep monitor powered again by a singlular lead sensor that captures sleep activity or how many times you are awakened during the night, and a study hub that captures this digital data and transmits it to an encrypted database.

The Verily Project Baseline is at the forefront of future patient monitoring and with it we will begin to understand the relationship of lifestyle, environment, economic strata, and intelligence to health. We will discover the intricate influencers and precursors to chronic disease to such a level to be able to predict their eventual genetic or environmental triggers. Then, we will better define true health, and better yet, learn through comprehensive patient monitoring how to maintain a healthy homeostasis with all that impacts our health.

[1] Taken directly from the Verily Project Baseline Website – https://www.projectbaseline.com