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Vitals E-Medic Plus: An Open-Source Hardware (OSH) Derived Work Medical Device for A Cloud-based Patient Monitoring System

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Abstract. This paper deals with the development of Vitals E-Medic Plus--an Open-source Hardware (OSH) derived work medical device built for a Cloud-based Patient Monitoring System. Vitals E-Medic Plus comprises two sets of open-source medical sensors: (1) open-source medical sensors for a patient's vital sign monitoring and (2) open-source medical sensors for medical diagnostic tests.

Vitals E-Medic Plus, medical sensors for patient's vital sign monitoring include temperature, blood pressure, arterial oxygen saturation (SP02), heart and pulse rate, and respiratory rate. In contrast, open-source medical sensors for medical diagnostic tests include sensors for Capillary Blood Glucose (using glucometer), Electromyography (EMG), and Electrocardiogram (ECG/EKG).

The two sets of open-source medical sensors were collectively organized and attached to an open-source Bio-Shield Platform atop NodeMCU System-on-chip module.

Vitals E-Medic Plus device was developed under an Iterative Prototyping Engineering Design Methodology and employed Iterative Software Development Methodology for its software development. This device was tested and evaluated by Barangay Health Workers from the Philippines based on its efficiency, effectiveness, and reliability in gathering vital signs and diagnosing diabetes and heart diseases from a sizeable collection of patients during a one-day medical mission.

One of the significant limitations of this device is, Vitals E-Medic Plus does not have any medical certifications. Thus, it cannot be used as a medical tool for monitoring critical patients who require accurate and precise monitoring or those whose medical condition must be measured accurately and precisely for an undisclosed professional medical diagnosis.

Keywords: Open-source hardware, OSH, OSH derived work medical device, open-source medical sensors, open-source technology

1. Introduction

Marsch et al. in the journal: "The role of technology in healthcare innovation: A commentary," imposed that Information and Communication Technologies are impacting all industries, perhaps none more so than in medical research and development wherein it offers the opportunity for tremendous technological growth in healthcare (Marsch & Gustafson, 2013). For example, smartphones and tablets are starting to change the conventional medical monitoring and recording systems wherein patients are now given the option of being subjected to the full consultation in the solitude of their own homes and are no longer confined to hospitals (Sorwar, Ali, Islam, & Miah, 2016). In medical research, researchers can now map the entire human genome or integrate bionics as human anatomical parts (Savage et al., 2018). With the aid of Health Informatics tools (computers, medical software, and information and communication system), healthcare and medical research have now gone further as far as technology is concerned (Househ, Alshammari, Almutairi, Jamal, & Alshoaib, 2015). However, note that it is innovation and human ingenuity that powers medical technological progress. It is represented by innovative medical devices that balance healthcare costs and health care quality (Omachonu, 2010).

The World Health Organization (WHO) recognizes that innovative medical devices are essential in delivering health care by improving the health condition of an individual or the population. One of WHO's strategic objectives is to ensure improved access, quality, and use of medical devices (Øvretveit & Klazinga, 2008). With the absence of innovative medical devices, routine medical procedures would be absurd (Moorman, 2010). In connection with this, the Government of the Netherlands requested the World Health Organization to launch the Priority Medical Devices (PMD) project to determine whether medical devices currently on the global market are meeting the needs of healthcare providers and patients throughout the world. If not, PMD will propose a remedial action based on sound research (World Health Organization, 2010). The PMD study report recommends how the plan to improve the appropriate medical devices access could be constructed—by applying the crucial four components: Availability, Accessibility, Appropriateness, and Affordability (Hansen et al., 2010). This initiative influences everything starting from developing a kit containing affordable and straightforward technologies for measuring blood cholesterol levels, blood pressure, and blood glucose, which could assess cardiovascular risk, up to developing a portable medical devices. With the ongoing rushing pace advancement in information and communication technologies that are exerting profound changes in healthcare, innovative medical devices is bringing us closer to the World Health Organization's definition of health—that is, "Health is the state of complete mental, physical and social well-being. It does not merely connote the absence of disease and illness" (World Health Organization, 2006).

"Also, thanks to the mass adoption of so-called open-source licenses"- (Aufieri, Picone, & Paolillo, 2015).

Open-source software is computer software at which the source code is made available to different users (either for software or programming modifications). Open-source software usually does not demand a license fee (O'Neill, 2012). Open-source software development has currently achieved significant interest because of various successful primary open-source projects. The open-source method offers a unique combination of advantages, including reducing costs and faster innovation. Open-source innovation is not limited to file sharing, web servers, and operating systems. Open-source has been expected to be equivalently beneficial and applicable in the medical domain as well. Open-source licenses are conceived to allow everyone to use, copy, modify and freely redistribute, under refined terms and conditions, a piece of software and its source code (Olson [1961-], Bennett, & Morgan, 1998).

"And the world is not dealing with the Open-source software alone"- (Carillo & Okoli, 2008).

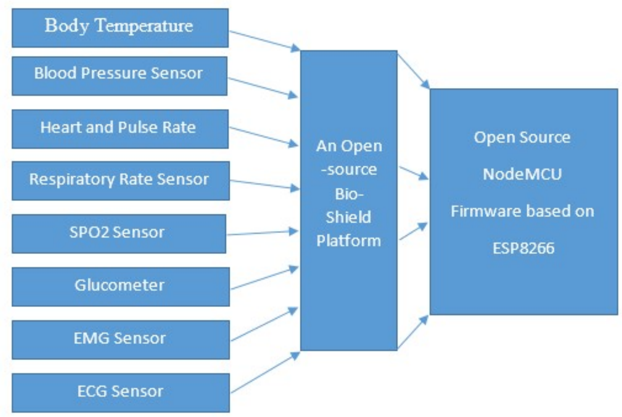
The open-source philosophy, which was adopted for software licenses, was later found in the hardware field. By definition, Open-source hardware is a hardware (electrical device or an electrical component) whose engineering and electrical design is made available publicly so that anyone can study, modify, distribute, create, and sell the output without paying royalties or fees ("Definition (English) – Open-source Hardware Association," 2018). Open-source hardware has become prevalent because of its excellent performance despite its low price, and because of its users' size guaranteed reliability (Lewandowski, 2015). The massive adoption of open-source hardware resulted in the development of low-cost, versatile products (e.g., Arduino, an open-source microcontroller) that inspire different uses and applications. Moreover, with the diffusion of three-dimensional (3D) printing, which contributes to the fostering of the "maker movement," the number of an innovative community of inventors increased rapidly (Gupta, Nowatzki, Gangadhar, & Sankaralingam, 2014).

One of the countless reasons people open-source their hardware is to allow the development of derivatives or Open-Source Hardware (OSH) Derived Works (Moritz, Redlich, Grames, & Wulfsberg, 2016). Open-Source Hardware Derived Works is the developed output product of market-released open-source hardware (Gibb, 2014). People build derivative hardware for either personalized or economic value, either for medical research, health, wellness, environment, calamity response, or system implementation (Ferdinand & Meyer, 2017).

In general, the development of Vitals E-Medic Plus was made possible because of the combination of the following occurrence: (1)Integration of Information and Communication Technology in healthcare research; (2) Medical technological progress; (3) Initiative from WHO to improve the appropriate medical devices access; (4)Adoption of open-source software; (5) Adoption of open-source hardware; and (6) Advancement of Open-Source Hardware Derived Works

2. Materials and Methods

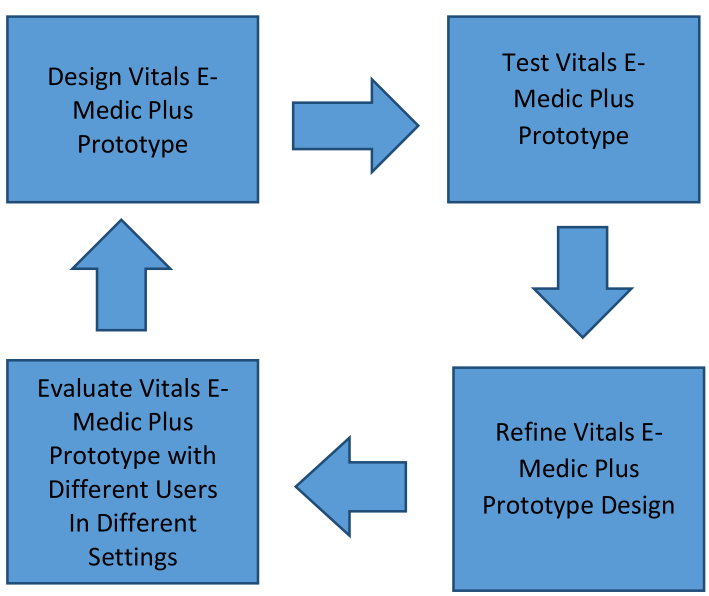
The figure below displays the block diagram of Vitals E-Medic Plus which is An Open-Source Hardware (OSH) Derived Work Medical Device for A Cloud-based Patient Monitoring System.



Block Diagram for Vitals E-Medic Plus

Vitals E-Medic Plus is made-up of a collection of open-source medical sensors for patient's vital sign monitoring (temperature, blood pressure, heart and pulse rate, respiratory rate, and arterial oxygen saturation (SP02)), and a medical diagnostic sensors for Capillary Blood Glucose (using glucometer), Electromyography (EMG) and Electrocardiogram (ECG/EKG). Iterative Prototyping Engineering Design Methodology which deals with processes that integrate resources (ideas, people, materials, money, etc.) and objective that contains requirements and constraints to transform concepts into a real solution to a problem (Wynn, Eckert, & Clarkson, 2007) was employed in the development of Vitals E-Medic Plus as an engineering design principle. By definition, Iterative Prototyping Engineering Design Methodology is a design methodology based on a recurrent process of prototyping, testing, analyzing, and refining of a product. Based on the knowledge collected in the testing process, the most recent iteration of design is changed and refined (Dow, Heddleston, & Klemmer, 2009). The figure below is regarded as the guideline to which detailed working engineering procedures was designated in the development of Vitals E-Medic Plus. Particular significance is placed on the iterative nature of the design approach, and that the sequence of steps must not be strict.

Vitals E-Medic Plus Design Process



Following the Iterative Prototyping Engineering Design Methodology, Vitals E-Medic Plus medical sensors were conjointly assembled using a bio-shield platform on top of a NodeMCU System-on-a-Chip development board.

NodeMCU is an embedded Lua Programming Language-based firmware for the ESP8266 WiFi SOC (System-on-a-Chip) created by a China-based company Espressif. The NodeMCU firmware is packaged to the popular NodeMCU development kit which is a ready-made open-source development board integrated with an ESP8266-12E chip ("NodeMCU Documentation," 2018). ESP8266 WiFi SoC usually contains a Power Management Circuitry, Memory (RAM), CPU, USB controller, and wireless radios (WiFi, 3G, 4G LTE).

Open-source Bio-Shield Platform was used for this study to join all the medical sensors. Bio-Shield Platform is an open-source development board platform that allows developers and researchers to build a derived work device that can perform biometric and medical applications by integrating into its circuitry the different medical sensors. The selected medical sensors to be incorporated into the Bio-Shield Platform are Body temperature, blood pressure, heart and pulse rate, respiratory rate, and arterial oxygen saturation (SP02)), and a medical diagnostic sensors for Capillary Blood Glucose (using glucometer), Electromyography (EMG) and Electrocardiogram (ECG/EKG).

For monitoring the patient's body temperature, a thermistor was packaged into a working temperature device and then integrated into the Bio-Shield Platform. The thermistor is small and extremely sensitive and based on the electrical property of changing resistance with changing temperature. Usually, their temperature range is kept well within -80 'C (-112 OF) to +150 'C (+302 OF) to retain sensitivity (Lessard, Chan, Glenn, & Schmidt, 1988). If the Thermistor is exposed to temperatures outside their normal operating range, a calibration is necessary. However, thermistors operated within their design range will have a long life and remain accurate for many years (Boano, Lasagni, Römer, & Lange, 2011).

Non-invasive blood pressure (BP) based on cuff occlusion was integrated into the Bio-Shield Platform for measuring patient's systolic (SBP) and diastolic blood pressure (DBP). It is done by modifying a traditional manual-based sphygmomanometer; specifically by removing some parts to connect to the pressure sensor. The modified sphygmomanometer was then attached to the Bio-Shied platformand programmed to output digital blood pressure reading.

Heart Rate Monitor Interface (HRMI) was utilized for reading the patient's heart and pulse rate. HRMI is an intelligent, open-source peripheral device that converts the ECG signal from Polar Electro Heart Rate Monitor transmitters into useful heart rate data. This device implements a complex computing algorithm for an average heart rate even with noisy or sporadic data from the Polar Electro Heart Rate Monitor transmitters. HRMI computes the patient's heart rate by measuring the time interval from one heartbeat to the next as received from the Polar transmitter. The transmitter sends a pulse for each heartbeat it detects. During normal operation, the data from the Polar transmitter may contain a significant amount of false information, but corrected accordingly by the embedded system(Danjulodesigns, 2018).

The Vitals E-Medic Plus attached respiratory airflow sensor is a device used to monitor the respiratory rate of a patient based on a real-time respiration rate measurement using temperature Sensor. This device is attached to the patient's nostril where it allows the thermocouple/thermistor sensor to be placed in an optimal position to accurately detect the oral/nasal thermal airflow changes as well as the nasal air temperature. This concept is based on the journal *"Real Time Respiration Rate Measurement Using Temperature Sensor"*(Singh & Chaudhary, 2017).

Vitals E-Medic Plus utilized an open-source Pulse Oximeter for patient's arterial oxygen saturation (SP02) readings. A pulse oximeter is a non-invasive, accurate, continuous indicator of arterial oxygen saturation. It works by illuminating vascular tissue (finger, ear, etc.) using red and near-infrared light (Phillips et al., 2009). The light can be detected on the same side (reflectance mode) or the other side (transmittance mode) of the tissue by a photodetector. The output from the photodetector is converted into a voltage and then further processed producing the signal known as the photoplethysmographic signal (PPG) (Shafique & Kyriacou, 2012). The signal can be divided into a pulsatile (ac) and a relatively constant (dc) PPG component. Arterial oxygen saturation (SpO2) is then calculated using the ratios of ac and dc components of the red and infrared PPG signals ((ac/dc) /red (ac/dc)ired) and by using a calibration curve (Semiconductor Inc, 2011).

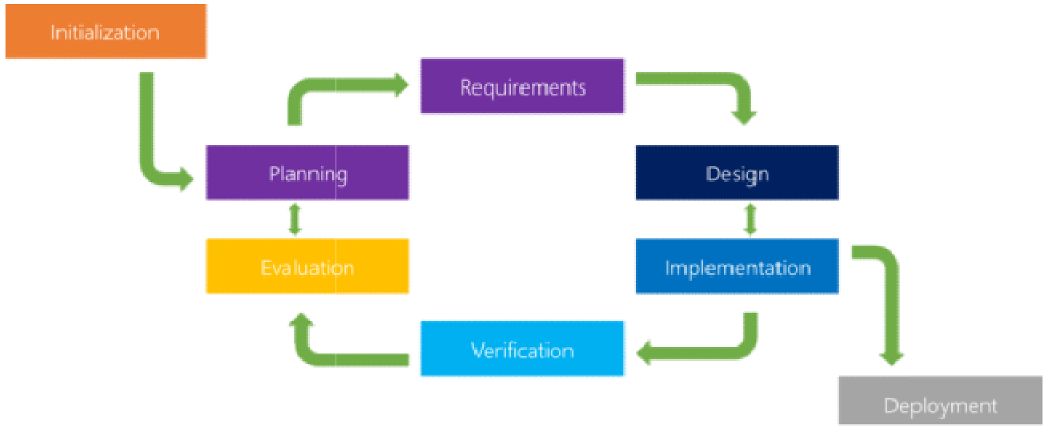
Vitals E-Medic Plus utilized an open-source Glucometer that uses ONE TOUCH ULTRA test strip. Glucose meters have two essential parts (1) an enzymatic reaction and (2) a detector. The enzyme part of the glucose meter is generally bundled in a dehydrated state at the disposable strip. Glucose in the patient's blood sample rehydrates and reacts with the enzymes to produce a product that can be detected by the Glucometer (Tonyushkina & Nichols, 2009).

Open-source hardware board SHIELD-EKG-EMG was used which allows open-source microcontroller boards to capture Electrocardiography Electromyography signals. SHIELD-EKG-EMG converts the analog differential signal (the ECG/EMG biopotentials generated by muscles), attached to its CH1_IN+/CH1_IN- inputs, into a single stream of data as output (Olimex, 2015). The signal of this process is an analog output and has to be discretized further with an aim to give the choice of digital processing. Typically, this is done via dedicated ADC embedded in the MCU of the baseboard (like OLIMEXINO-328, OLIMEXINO-32U4, OLIMEXINO-STM32, etc.).Electromyography (EMG) which is measuring muscle activation via electric potential, has traditionally been used for medical research and diagnosis of neuromuscular disorders(Goen, 2014).

For reading the patient's Electrocardiogram (ECG/EKG), a piezoelectric transducer was utilized. This transducer picks up vibrations from the heart beats then converts them into electrical output signals. To this end, piezoelectric and signal processing techniques were employed to extract the ECG corresponding signal from the piezoelectric output voltage signal (Townsend, 2001).

For the embedded software development processes of each sensor, this study followed an iterative methodology of software development life cycle (SDLC). The adopted iterative software development process adheres to the hardware development iterative nature of the Vitals E-Medic Plus wherein it started as a single development platform(referring to Bio-Shield Platform), then progressively gainedcomplexity with the additionof each medical sensors and a broader electronic hardware setuntil the final OSH derived work medical device was completed. In the development of the embedded software for Vitals E-Medic Plus, with the iterative method, the concept of incremental development is followed generally and interchangeably.

The figure below illustrates the adopted iterative design methodology of the embedded software in Vitals E-Medic Plus.



Software Development Iterative Model
(Source: airbrake.io)

The development of Vitals E-Medic Plus and its embedded softwarebased on Iterative Model started with Planning & Requirements gathering. As with most any development project, the first step is to go through an initial planning stage.In this phase, the researchers of Vitals E-Medic Plus mapped out specification documents, established software and hardware requirements, and generally prepared the project for the upcoming phases in software and hardware life cycle. Then follows analysis & design wherein an analysis is executed to capture the relevant business requirements, Database Management System (DBMS) and data models that are necessary for the design of this project. The design stage establishes any technical requirements (languages, data layers, services, etc.) required in an analysis stage.The figure below lays out the designed system architecture of Vitals E-Medic Plus which is based on the Input, Process, and Output Conceptual Framework.

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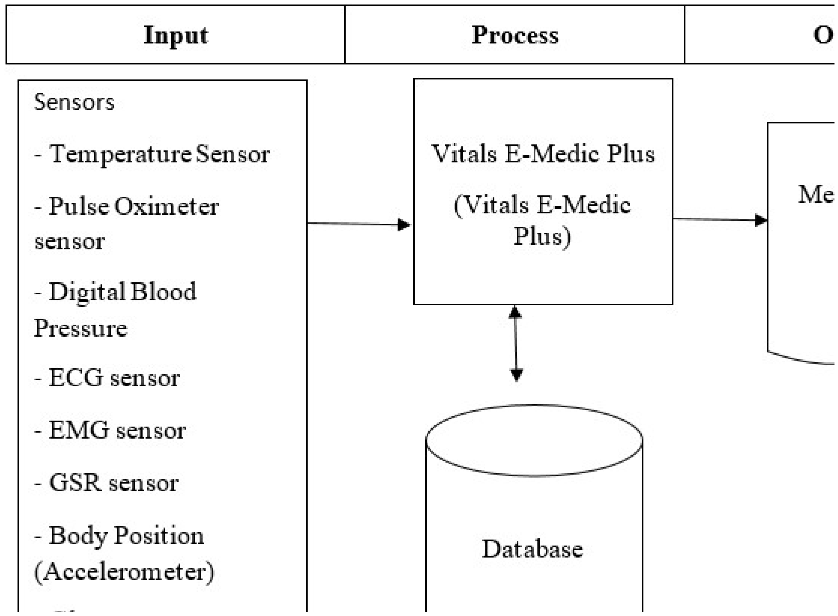
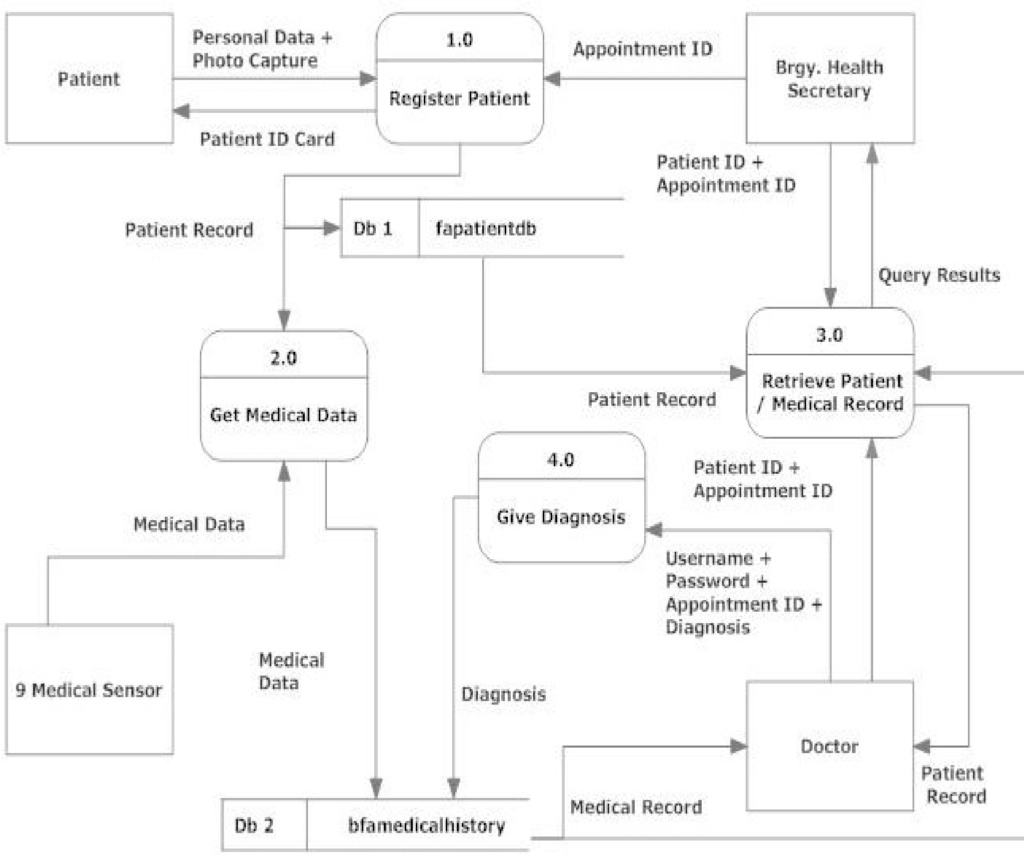


Input, Output, Process Conceptual Framework

Vitals E-Medic Plus System Software Data Flow Diagram



Vitals E-Medic Plus System Software Level 1 Data Flow Diagram

Implementation and Prototyping: With the planning and analysis out of the way, the actual implementation and coding process for Vitals E-Medic Plus began. All plan, specifications, and documents up to this point are coded and implemented into this initial iteration of the project. Below is the second phase iteration prototype of the project showing medical sensors for patient's vital sign monitoring (temperature, blood pressure, heart and pulse rate, respiratory rate, and arterial oxygen saturation (SP02)) and open-source medical sensors for medical diagnostic tests (sensors for Capillary Blood Glucose (using glucometer), Electromyography (EMG) and Electrocardiogram (ECG/EKG)).

Testing: Vitals E-Medic Plus went through a sequence of testing procedures to identify and locate any potential error bugs or issues that have popped out from the project. Every iteration product output is tested and retested accordingly. Hardware is rechecked for the efficiency, whereas the embedded software undergoes a series of programming bug tracking.

Evaluation: The evaluation process is the most crucial part of the entire project. Iterative model, whereby the most recently built iteration of the software, as well as all feedback from the evaluation process by the stakeholders, is drawn back to the planning, and the process repeats itself all over again. Evaluation allows the researcher, or other stakeholders, to examine the current status of the project, what can or should change, and so on. Vitals E-Medic Plus was evaluated by Barangay Health Workers from the Philippines based on its efficiency, effectiveness, and reliability in gathering vital signs, and in diagnosing diabetes and heart diseases from a sizeable collection of patients during a one-day medical mission.

3. Results and Discussion

The OSH derived-work medical device Vitals E-Medic Plus, a hardware component of a Cloud-based Patient Monitoring System, was tested and evaluated on a private medical mission event in Brgy. Sta. Filomena, District of Arevalo Iloilo City, Philippines.

A purposive sampling technique was performed based on selected respondents to evaluate the device's efficiency, effectiveness, and reliability in collecting vital signs and diagnosing diabetes and heart diseases. The validity and reliability of the data gathering tools are established to achieve the study's specific purposes. Thirty-Eight (38) served as the respondents of the survey. The research instrument was accomplished correctly through the aid of the three (3) juries.

The researchers utilized appropriate statistical tools in the data analysis phase and the weighted mean was used to arrive at a descriptive interpretation.

Based on the resulting score of the evaluated response of the barangay health workers and other respondents, the OSH derived work medical device Vitals E-Medic Plus is efficient, effective and reliable in gathering patient's vital signs and in diagnosing diabetes and heart diseases. Efficiency, effectiveness, and reliability are manifested in the survey questionnaire concerning ease of use, reliability, and stability.

The implementation and utilization of an OSH derived work medical device Vitals E-Medic Plus, is positively accepted by Brgy's patients and medical health workers. Sta. Filomena, Arevalo Iloilo City Philippines because of its efficiency, effectiveness, and reliability, in the gathering of patient's medical data; and the patients and medical health workers of Brgy. Sta. Filomena, Arevalo Iloilo City Philippines requires it.

4. Conclusion

There are countless reasons why the modern medical innovators should develop medical devices using open-sourcetechnology. For one, open-sourcehardware is more flexible andmost of the times, less expensive than the equivalent commercially produced experimental medicaldevices. Open-source’s flexibility and cost-effectiveness would further allowmedicalinnovators to explore new research interestwith lesser risk. It may increase our ability to pursue the World Health Organization’s definition of health, which embraces total well-being based on mental, physical and social wellness and not merely the absence of disease and infirmity.

Vitals E-Medic Plus which is an Open-Source Hardware (OSH) derived work medical device for A Cloud-based Patient Monitoring System is an example implementation on how open-source’s flexibility and cost-effectiveness would benefit medical researches specifically on the medical devices. Somehow this ideology will bridge the gap between availability and accessibility in the use of medical devices as based on the study by WHO (Hansen et al., 2010).

Although it can be established that there is a need for the utilization of open-source hardware in medical devices, challenges for open-source hardware in healthcare still exists. Medical devices need to be regulated and require a considerable amount of time and financial resources in medical research before it can be certified.Since Vitals E-Medic Plus lacks the necessary medical certifications, this deviceis barred for patients with the critical condition and who requires accurate and precise medical monitoring.The same is true as with those patients whose medical condition must be measured accurately and precisely for an undisclosed professional medical diagnosis.

5. Recommendation

In the course of this study, the researchers have identified some aspects that would be interesting to look further into:

- In-depth research and studies in Open-Source Hardware (OSH) derived work medical device specifically on how this device can become committed to precision and accuracy in medical data gathering andhow this device would be beneficial to the general public. Further research might focus, for example, in the usage of this device in medical missions wherein a considerable number of patients can be involved in the study.

- Further Research that could explore the application of necessary medical certifications and standard compliance to ensure that each component, the final product, the processes involved and the manner it is used, remains fit for their purpose.

- Research and studies that will develop more employment of Open-Source Hardware (OSH) derived work medical device and will perform a full cost-benefit analysis.

- Redevelop the design and integrate Wireless Technology on each medical sensors (wireless technology may use wireless radio frequency (RF) communication such as Wi-Fi, Bluetooth, and cellular/mobile phone) for a wireless transfer of patient data from the medical sensors to the Bio-Shield platform. This integration will increase patient's mobility and will shorten the time in placing all the medical sensors to the patient.

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