A 24-hour ambulatory blood pressure monitoring system for preeclampsia management in antenatal care

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\begin{abstract}

The burden of preeclampsia has been a major concern worldwide both in developed and developing countries, making its prevention and management a major concern. Although motherhood is a fulfilling experience in society, it is connected to ill-health in some women, leading to maternal morbidity and mortality. The United Nations' Sustainable Development Goal (SDG) 3 aims to reduce the global maternal mortality ratio to less than 70 per 100,000 live births. These deaths are caused by among other things, the emergence of conditions such as preeclampsia during pregnancy. Therefore, this study sought to implement a 24-hour ambulatory blood pressure monitoring solution for preeclampsia management, using a smartwatch in conjunction with a mobile and cloud-based application. Upon blood pressure readings from the expectant mother, an alert is sent to the assigned caregiver in order to initiate quick action. The researchers adopted a rapid prototyping approach in the implementation of the 24-hour ambulatory blood pressure monitoring system. An experimental design was adopted in the study to evaluate whether the system functionalities performed as expected. The system, which was evaluated in the context of a sample of 30 expectant mothers from two level 5 hospitals in Kenya, has been able to read blood pressure from expectant mothers' smartwatches. The real-time data is then sent to the caregivers' smartphone, as well as an alert. The solution has shown great potential for actual adoption in healthcare systems in developing countries, given its simplicity and affordability.

\end{abstract}

\section{Introduction}

Women's health is well-thought-out as a public health concern that influences personal wellbeing and societal development. According to the World Health Organization (WHO), approximately 830 women die daily from preventable causes related to pregnancy and childbirth, and up to 99\% of these deaths occur in developing countries among women living in rural areas and in poorer communities \cite{1}. The United Nations' Sustainable Development Goal (SDG) number 3, focusing on good health and well-being, also notes that maternal mortality levels are currently 14 times higher in developing countries as compared to other regions of the world \cite{2}. These unacceptably high number of deaths are caused by complications such as: severe bleeding mostly after childbirth, infections after childbirth, unsafe abortions, and high blood pressure (preeclampsia and eclampsia) during pregnancy \cite{2}. Preeclampsia, in particular, has been found to not only lead to maternal but also foetal mortality, intrauterine growth restriction, and preterm birth \cite{3}.

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hypertension and protein in the urine, a mother can have signs such as persistent headaches, blurred vision or sensitivity to light, and abdominal pain.

In a study carried out regarding the prevalence of preeclampsia among pregnant women in the University of Calabar Teaching Hospital, Calabar, it showed a rising trend in the incidence of preeclampsia over recent years, with overall prevalence being 1.2%. A little less than half of the women were nulliparous and the majority had caesarean delivery. In the study, preeclampsia was associated with iatrogenic preterm deliveries in a third of the women, while a generational hypertension condition was reported to be the underlying risk factor in a number of pregnant women. It was concluded that there is an intensifying trend in the prevalence of preeclampsia in that study area, therefore emphasizing the need to strengthen utilization of antenatal care to pregnant mothers in detecting and managing a preeclampsia condition early in advance.

While there is no cure for the preeclampsia condition other than the birth of the baby, early detection during antenatal clinic attendance contributes greatly to its management and the subsequent prevention of adverse effects [2]. However, attendance of antenatal care clinics by mothers in most Low and Middle-Income Countries (LMIC) is not a universal practice, leading to the continued prevalence and mortality associated with preeclampsia [3]. The detection and management of Preeclampsia for better treatment and control is greatly enhanced through frequent blood pressure measurement [6]. In pregnancy, these frequent measurements can be achieved during Antenatal care visits whereby expectant mothers are expected to attend ANC for a minimum of four visits.

The World Health Organization (WHO) recommends a minimum of four antenatal care (ANC) visits [7]. The WHO pictures a world where every expectant woman receives quality care throughout the pregnancy period. Antenatal care in the period of a positive pregnancy provides a platform for important healthcare function, such as health promotion, screening and diagnosis, and disease prevention, for which effective implementation of ANC visits can save and improve lives. The ANC practice also provides the opportunity to communicate with and to support women, families, and communities at a critical time in the course of a woman’s life. However, global estimates indicate that only about half of all expectant women receive this recommended amount of care [8].

If achievable, taking BP readings at medical facilities during ANC visits remains the most viable and practical approach for detecting and monitoring preeclampsia. However, BP readings taken at medical facilities are not always reliable due to challenges occasioned by white coat, masked or nocturnal hypertension. In the case of white coat hypertension, BP readings taken at a medical facility are higher than levels when the patient is at home [9]. In the case of masked hypertension, readings taken at a medical facility are lower than levels recorded outside the medical facility [10]. On the other hand, nocturnal hypertension occurs when the blood pressure levels do not fall by > 10% as is expected during sleep [11].

Taking these challenges into account and given the fact that blood pressure is a continuous value with natural variations throughout the day, repeated measurements over time are generally more accurate in establishing a diagnosis of hypertension [12]. One of the recommended approaches to achieve these repeated measurements is the 24-hour Ambulatory Blood Pressure Monitoring (ABPM) approach [13]. The 24-hour ABPM is a method that makes use of a variety of devices such as one that is worn on the upper arm to take BP measurements every 20–30 min over a 24-hour period. The monitoring is best done during a typical working day, and a patient is also required to keep a diary or log of their activities, wake and sleep times, time of medication administration, meals and any occurrence of symptoms during the monitoring period [9].

However, as much as ABPM has been found to be very useful in the detection and management of hypertension, the method and devices used presently have been associated with sleep disturbances, discomfort, and restrictions in daily activities [14–17]. Pressure due to repeated inflation of the cuff has been found to cause soreness in the upper arm, while sleep time BP readings interfere with sleep. The cuff has also been found to irritate the skin and cause a mild rash on the user’s arm [12].

The challenges associated with the use of devices that cause inconvenience, discomfort, and harm have been addressed in the recent past through the development of smart blood pressure monitors. These devices that are now readily available on the market use a variety of nonintrusive methods such as a cuff that inflates slightly to measure systolic and diastolic pressure via the oscillometric method, as is the case with the Omron Smartwatch [18] and using a combination of optical sensors and clinically validated software algorithms as is the case with a number of smartwatches such as the that developed by Ref. [19] and Bpro by Ref. [20]. In this research, the F1 Smart Bracelet developed by Ref. [21] was used to collect the blood pressure readings from the expectant mother.

The Kenya Health and Demographic Survey 2014 notes that while 96% of women in Kenya receive antenatal care, only 58% of them make the recommended four or more ANC visits during their pregnancy. Of these, only 61% deliver in a health facility. The lack of consistent ANC attendance and home births has previously been associated with maternal mortality, which according to the report stands at 362 deaths per 100,000 live births in Kenya as of 2014 [22]. The causes of maternal deaths in Kenya are no different from global trends and also include obstructed labour, complications of unsafe abortion, infections, haemorrhage, and high blood pressure [23].

Hypertensive disorders in Kenya have been found to account for 16% of maternal deaths compared to the global average of 14%. The level in high income countries is much lower than the global average, with the disorder contributing to only 4.8% of maternal deaths in countries such as the United States of America. According to Ref. [24], early detection and management make all the difference in the prevalence levels for preeclampsia. This early management of the condition, however, remains a major challenge in developing countries, given the fact that many expectant mothers do not attend antenatal clinics, and even those who attend do not do so consistently and to the level required. This has been attributed to cultural beliefs, poverty, low levels of education, economic hardships and in some cases, the lack of medical facilities in some rural settings [25].

In recent times, there have been technological improvements that make the Internet of Things a reality, such as wireless communications, low power processors, and electronic devices. With visualization of IoT, every single entity on Earth can be identified, addressable, controlled, and monitored via the Internet. The wide dissemination of IoT paradigm has shown its potential to produce a considerable impact in the daily lives of human beings, which has been increasingly employed in applications from several real-world domains, such as domotics, ambient assisted living (AAL), energy, transportation, and environmental and urban monitoring [26].

In the health sector, remote monitoring to patients incorporates digital mobile applications that involve the provision of care to patients in terms of medical conditions that can be supervised, frequency to be supervised and whether they should be supervised in real-time or periodically. Remote supervision is the supervision of a medical task from a remote setting, giving a diagnosis to the patient without the patient being present physically. When medical monitoring is complete, guidance on whether the patient requires immediate attention by the doctor is released through a monitoring device. According to Ref. [27], remote patient monitoring technologies are safer and more effective in monitoring of health and safety among older adults, and control visits to hospitals with the objective of addressing cost, decongestion issues, geographic challenges, geriatric conditions, and lack of mobility.

Healthcare practitioners take a lot of time traveling between their patients and hospitals since the equipment they are using is not readily
portable. Due to time limitations, the mobile application has emanated rapidly, thus reducing these challenges as faced by healthcare practitioners. According to Ref. [28], due to the rapid use of mobile applications in healthcare, there is need to investigate the current trend toward the acceptance of those mobile health applications that are tailored towards the tracking of the patient's condition, sharing of patient information, and performing other related healthcare services. In the study the Technology Acceptance Model was applied to investigate user acceptance of mobile technology applications within the healthcare industry. The evaluation was based on a Technology Acceptance Model (TAM) to examine the system mobile tracking Model. The related constructs that were found for evaluation were: Perceived of Usefulness, Perceived Ease of Use, User Satisfaction, and Attribute of Usability, which was then modified to suit the context of the study.

The aim of our study was to implement a 24-hour ambulatory blood pressure monitoring system for expectant mothers using a smartwatch in conjunction with a mobile and cloud-based application, to help in preeclampsia management, based on an Internet of Things architecture. The authors’ motivation to begin research work related to the implementation of 24-hour ambulatory blood pressure monitoring system was related to the high mortality in expectant mothers and even long-term health complications that are being experienced in developing countries due to the preeclampsia condition. Moreover, this work was evaluated to examine whether the implemented system could perform as expected by expectant mothers in terms of content richness, perceived ease of use, perceived usefulness, and user satisfaction.

The remainder of the article is organized in the following structure. The Materials and Methods section includes the architecture used in the development of the system, and the process followed to design and implement the 24-hour ambulatory blood pressure monitoring system. In addition, the evaluation method is described as well as the conducted experiment. The Results section presents the outcomes. The Discussion section describes the significance of the results obtained, and the Conclusion section provides a summary.

2. Materials and methods

2.1. Architectural design

The architectural design process was exploratory given that there is presently no existing approach being evaluated or tested. Exploratory studies seek to look for patterns, ideas or hypothesis rather than to confirm any predetermined hypothesis [29]. This architectural design was used as a blueprint to develop the 24-hour ambulatory blood pressure monitoring system.

The system was developed on the Android platform and then connected to a Firebase cloud application. The process that was followed was a rapid prototyping technique. Rapid prototyping is a system development approach that is used to develop a proof of concept system for use in the clarification of system and user requirements [30].

2.2. Experimental design

To evaluate the performance of the 24-hour ambulatory blood pressure monitoring system, in order to examine whether the system performs as expected, an experiment was undertaken to verify system
workflows and key functionality. The target population for the study was expectant mothers who were 20 weeks pregnant and above, in two level 5 hospitals in Embu and Kiambu Counties. Level 5 hospitals were selected because most mothers go for ANC, referred to in case of a complication, and also for delivery. The choice for the pregnancy stage is because hypertension disorders are diagnosed from the second trimester of the pregnancy period. After a pilot study was undertaken from the expectant mothers, a questionnaire was administered to them so that they evaluated the performance of the system. Only 30 expectant mothers were used as the subjects of the study, with purposive sampling utilized to carry out the research.

Before the researchers engaged in data collection, approvals were received from the National Commission for Science, Technology and Innovation (NACOSTI) Kenya, County Commissioners (Embu and Kiambu counties), County Director-Education (Embu and Kiambu counties), County Director-Health (Embu and Kiambu counties), and Medical Superintendent of the two level 5 hospitals in the two counties (Embu Level 5 and Thika Level 5 hospitals). Each participant willingly gave their written informed consent to participate in the study.

Measurement in research involves devising some form of scale in the range and then mapping the properties of the objects to be measured onto this scale. In this study objective on the evaluation of the implemented 24-hour ambulatory blood pressure monitoring system, Technology Acceptance Model (TAM) indicators were used. The indicators include Content Richness (CR), Perceived Usefulness (PU), Perceived ease of use (EU), and User Satisfaction (US). Research variables were measured using Ordinal and Likert-type scales because they not only are informational, but also come handy in respondent centered studies [31]. Table 1 depicts a summary schedule of measurement scales operationalizing the study, and the items that constitute the measures used to construct the research instrument.

3. Results

3.1. 24-hour ambulatory blood pressure monitoring system architecture

The 24-hour ambulatory blood pressure monitoring system was based on Internet of Things architectures, and is comprised of the following components:

1. Users: there are two users involved in the system - the expectant mother and the caregiver.
2. F1 Smart wristwatch: It consists of an integrated chip for sensing,
recording, and displaying real-time data on the screen.

3. Expectant mother’s Smartphone: after the F1 smart wristwatch reads the real-time data, the data is then sent to the mother’s smartphone that is connected to the smart band via Bluetooth connectivity. The smartphone has a blood pressure monitoring mobile application installed on it, and is developed specifically for expectant mothers.

4. Blood Pressure Monitoring Mobile Application: This mobile application consists of two modules: Expectant Mother and Caregiver modules. Expectant mother module stores details which are: Mother Name, Identification number, Mother image Date of Birth, Height in centimeters, Weight in kilograms, Pregnancy start date, expected delivery date, gestation stage in weeks, and Blood Pressure History. The Caregiver module consists of the caregiver name, medical identification number, gender, caregiver image, view list of expectant mothers, search new expectant mothers, and alerts history.

5. Cloud Data center: The mobile application is synchronized with a Firebase database that keeps all records. Data is shared for this centralized database, in which it is properly analyzed for statistics and in-depth knowledge of the level of blood pressure of the expectant mother. It has the function to check if the records of blood pressure exceed normal, and if so, an alert message is sent to the caregiver’s smartphone for further action.

6. Caregiver’s smartphone: this smartphone has also a mobile application installed in it. The caregiver can access the expectant mother’s records, as well as receiving alerts on blood pressure readings.

The components based on Internet of Things technology are depicted in Fig. 1.

The process works as follows: The smartwatch on the expectant mother’s hand takes BP readings and transmits them by Bluetooth to their phone at regular intervals. A mobile application on the mobile phone receives the BP readings as well as sending the data to the cloud application which stores it and generates alerts. The generated alerts are sent to the caregiver to take an action as needed.

3.2. Implementation of 24-hour ambulatory blood pressure monitoring system

The mobile application for the collection and analysis of the BP readings has been developed comprising of the following modules:

- User registration: The system requires the registration of expectant mothers and caregivers. For the mothers, the details required are

The coefficient models were presented to show a deeper understanding of the effect between variables.

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3. Expectant mother’s Smartphone: after the F1 smart wristwatch reads the real-time data, the data is then sent to the mother’s smartphone that is connected to the smart band via Bluetooth connectivity. The smartphone has a blood pressure monitoring mobile application installed on it, and is developed specifically for expectant mothers.

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<table>
<thead>
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<th>Variable</th>
<th>Indicator</th>
<th>Percent (%)</th>
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<td>1</td>
<td>Content Richness</td>
<td>Appropriate mobile application</td>
<td>96.7</td>
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<tr>
<td></td>
<td></td>
<td>Reliable technical assistance</td>
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<td></td>
<td></td>
<td>Timely 24-hour Ambulatory Blood monitor app</td>
<td>100.0</td>
</tr>
<tr>
<td>2</td>
<td>Perceived Usefulness</td>
<td>Useful information about the expectant mother</td>
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<tr>
<td></td>
<td></td>
<td>Follow up about expectant mother blood</td>
<td>99.9</td>
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<td></td>
<td></td>
<td>pressure condition</td>
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<td></td>
<td></td>
<td>Rapid feedback information by users</td>
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<td></td>
<td></td>
<td>Time saving</td>
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</tr>
<tr>
<td></td>
<td></td>
<td>Tracking Blood Pressure condition</td>
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<tr>
<td>3</td>
<td>Perceived Ease of Use</td>
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<td></td>
<td></td>
<td>Easy to navigate through the interface</td>
<td>93.3</td>
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<td></td>
<td></td>
<td>System is clear and understandable</td>
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<td></td>
<td></td>
<td>Easy to get skills while using system</td>
<td>89.9</td>
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<tr>
<td>4</td>
<td>User satisfaction</td>
<td>Satisfied with the system</td>
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<tr>
<td></td>
<td></td>
<td>Feeling confident with the system</td>
<td>93.4</td>
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<tr>
<td></td>
<td></td>
<td>Quick task accomplishment</td>
<td>100.0</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved quality in Healthcare clinics</td>
<td>93.3</td>
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</tbody>
</table>

The coefficient models were presented to show a deeper understanding of the effect between variables.

3. Expectant mother’s Smartphone: after the F1 smart wristwatch reads the real-time data, the data is then sent to the mother’s smartphone that is connected to the smart band via Bluetooth connectivity. The smartphone has a blood pressure monitoring mobile application installed on it, and is developed specifically for expectant mothers.

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<table>
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<th>Standardized Coefficients Beta</th>
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their name, Date of Birth, Height in centimeters, Weight in kilograms, Pregnancy start date, and Expected delivery date. The system automatically updates the gestation weeks of the expectant mother. For the caregiver, the details required include name, Medical ID, and Gender. This is shown in Fig. 2.

- User authentication: both caregiver and the expectant mother are required to login to the system before allowing them to access any of the system functionality. Fig. 3 shows the login user interface.
- Blood pressure data collection: The mobile application is synchronized with the smartwatch via Bluetooth in order to receive the BP readings periodically. The expectant mother can also initiate the readings using a reading initiator functionality on the mobile application. The data is displayed on the smart wrist band and also sent to the mobile application. The mother can, over time, view their history of readings of blood pressure measurements taken. The interface shown in Fig. 4 indicates the scanning process of smartwatch using the mobile application.
- Caregiver access: The caregiver can view the blood pressure readings for all the registered expectant mothers registered on the system. They also receive alerts when the patient’s blood pressure is taken. Fig. 5 shows an interface for caregiver, pop-up alert that shows the blood pressure reading.

With the use of a 24-hour ambulatory blood pressure monitoring system, the preeclampsia condition will be managed wherever caregivers have access to real-time information about expectant mother’s blood pressure condition, despite the distance. Even when the caregiver’s phone is not connected to the Internet, an alert will later pop up for the caregiver to obtain an alert when the phone later connects to the Internet. In addition, the caregiver can keep track of blood pressure readings for the expectant mother, where her history is stored in the cloud for retrieval. A mother can review the blood pressure reading at any time.

3.3. Evaluation of 24-hour ambulatory blood pressure monitoring system

The results from the questionnaires completed after the conducted experiments on the implemented 24-hour ambulatory blood pressure monitoring system are presented in Table 2 (See. Table 3).

4. Discussion

The process of implementation of a 24-hour BP ambulatory system involved the definition of system functionality, and the description of the specific components followed in transforming the architecture into a working application. The architecture incorporates four main components which include: users, smartphones, smartwatch, mobile network providers, and a cloud-based database system. The rapid prototyping approach was used in developing a functional system from the architecture depicted in Fig. 1.

Performance evaluation based on the implemented 24-hour ambulatory BP was technical. Three performance evaluation measures were adopted from Ref. [16]: profiling methodology, system responsiveness, and system error rate. It was found that the profiling methodology for the system was cost-effective, as profilers consist of open source software that enhances the development of system mobile application. Moreover, the FI smartwatch produced BP readings after 100 seconds as it was configured, thus indicating 100% response. The results were also retrieved by users without any delay since the Firebase database system used produced real-time data.

Analysis of obtained results on the evaluation of the implemented 24-hour Ambulatory Blood Pressure Monitoring system, indicated that Content richness has a slightly positive linear effect on Perceived Ease of Use, while there is a slightly negative relationship between Content Richness and Perceived usefulness. This implies that the 24-hour Ambulatory Blood Pressure Monitoring system is equipped with rich content, as expected in preeclampsia management. In addition, it implies that perceived ease of use is the key indicator to have a system perform as expected by users.

5. Conclusions

The reduction of maternal mortality as is envisaged by the SDG Number 3 will require concerted efforts by multiple stakeholders, addressing different dimensions of the challenge, and using a variety of processes and technologies. In this research, the specific challenge of preeclampsia management in antenatal care has been identified. The solution approach under investigation is the use of a smartwatch integrated with a mobile and cloud application for data collection and analysis as well as for the generation of alerts. The solution has shown great potential for actual adoption in healthcare systems in developing countries, given its simplicity and affordability due to free open source software such as Firebase and Android platforms. To reduce high maternal mortality and long-term complications to expectant mothers in developing countries, hospitals should adopt the system to assist in preeclampsia management during the antenatal care period.

The use of Internet of Things technology for health requires that the ecosystem in use be secured in order to ensure that no service disruptions occur. There is a need to carry out a study on security challenges associated with the use of Internet of Things and mobile application for Blood Pressure monitoring, and to further develop solutions for the identified challenges for a secure operation.

Conflicts of interest

None declared.

Ethical statement

None.

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