Challenges Associated with the use of Smartwatches for out of Clinic Blood Pressure Monitoring Among Expectant Mothers in a Developing Country: A Case Study of Nakuru County Kenya

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ABSTRACT

Pre-eclampsia is a leading cause of maternal mortality globally and more so in developing countries. The condition, if detected early, can be prevented to avert death and suffering. This early detection has become easier with the development of devices such as smartwatches with BP sensors which have enhanced the practice of Ambulatory Blood Pressure Monitoring (ABPM) and Home Blood Pressure Monitoring (HBPM). However, most of these devices and monitoring practices have not been widely adopted in developing countries due to the high cost of devices and the lack of institutionalization of the ABPM and HBPM in healthcare systems. This study sought to examine the use of low-cost smartwatches, a mobile application, and a support system for the implementation of ABPM and HBPM among expectant mothers in Nakuru county, Kenya. A total of 34 expectant mothers were involved in the study over 8 months. A total of 967 readings were collected with only 3 out of the 34 mothers managing to take at least 71 readings during the period of the study. The study established that the use of low specification phones that were incompatible with the mobile application, failure of the smartwatches to work appropriately, difficulties in getting mothers who met the inclusion criteria under 20 weeks' gestation, poor adherence to the data collection and loss of the devices negatively impacted the quality and consistency of BP monitoring among the expectant mothers. The study therefore recommends the use of more robust devices such as cuff BP readers and the inclusion of community health volunteers in the early identification of pregnant mothers from the community and subsequent follow-up for ABPM and HBPM.

Keywords: Ambulatory blood pressure monitoring, Blood Pressure, Cuff BP Reader, Home Blood Pressure Monitoring, Pre-eclampsia, Smartwatch.

I. INTRODUCTION

Pre-eclampsia is a pregnancy complication characterized by persistent high BP and the presence of proteins in urine. It usually begins after 20 weeks of pregnancy in women whose blood pressure (BP) has been normal. If left untreated it will progress to eclampsia that is often fatal to both mother and baby (Macdonald-Wallis et al., 2015) The condition remains a significant public health problem for both the developed and developing countries contributing to both maternal morbidity and mortality globally (McClure & Goldenberg, 2009) (Shah et al., 2009). However, the impact of the disease is felt more severely in developing countries where unlike other causes of mortality, medical intervention may be ineffective due to late presentation (Prakash et al., 2010). The problem is confounded by continuous mystery of the etiology and unpredictable nature of the disease (Jido & Yakasai, 2013). The first sign of pre-eclampsia is a BP reading exceeding 140/90 in two or more occasions, at least four hours apart at 20 or more week's gestation (Mammaro et al., 2009).

Traditionally, BP has been measured in medical facilities that have the advantage of very accurate devices and qualified personnel for the task. On the flip side these measurements require patients to visit the facilities and are prone to white coat syndrome; high blood pressure readings caused by among other things, anxiety about the results and by just being in a medical facility. The White coat syndrome eventually leads to white coat hypertension, a diagnosis of hypertension influenced by the syndrome (Cleveland Clinic, 2023b). A different but related condition is that of masked hypertension; where the BP is normal while in a medical facility but elevated elsewhere (Cleveland Clinic, 2023a). This has been noted to be caused by reactions to stress, behavioral factors such as smoking, alcohol use, use of contraceptives in women, and sedentary habits (Papadopoulos & Makris, 2007).

The alternative to BP monitoring in a medical facility is doing so from home, or away from the facility. There is a growing body of evidence supporting the practice as it has been shown to lead to enhanced diagnosis and better prediction of cardiovascular risk. The practice has also been found to be more participatory, cheaper, easier to undertake given the increased availability of devices that can be used in out of clinic setups (George & MacDonald, 2015) (Drawz et al., 2012). These devices are readily available in the market and use a variety of non-intrusive 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 Smart watch (Omron, 2023) and a combination of optical sensors and clinically validated software algorithms as is the case with a number of smart watches such as the one developed by Aktiia (2023) and Bpro by Med*Tach* Inc (2023). These devices are not only able to take readings and generate alarms but are also capable of transmitting the data to other devices such as mobile phones for use in further analysis using machine learning techniques among others.

The practice of out-of-clinic BP measurement makes it possible to undertake Ambulatory Blood Pressure Monitoring (ABPM) and Home BP Measurements (HBPM). ABPM involves taking readings every 20 – 30 minutes during the day and every one hour at night. HBPM on the other hand uses the same technologies but requires readings to be taken at specific time intervals and conditions as opposed to continuously throughout the day. ABPM and HBPM are very useful for monitoring the following types of people; expectant women with hypertension, people with "borderline" hypertension, people with difficulty controlling BP with medication, people experiencing BP changes due to other medication, changes in prescription medications that may impact BP and people with fainting episodes or hypotension (low BP) (George & MacDonald, 2015), (Cleveland Clinic, 2023a).

A number of studies have been undertaken to establish the effectiveness of home BP monitoring among pregnant women. Kalafat *et al* (2018) compared Home BP Measurements (HBPM) readings with clinic recordings and established that the home readings were on average lower than the clinic readings. HBPM has also been found to reduce the number of hospital visits without compromising maternal and pregnancy outcomes according to Perry *et al* (Perry et al., 2018). ABPM has also been found to be instrumental in reducing incidences of unnecessary hospitalization among pregnant women as a result of 'white coat hypertension' diagnosis (Biswas et al., 1997). The most common approach for ABPM and HBPM is the use of devices such as cuff readers and smartwatches which are popular due to their affordability and convenience. However, there are concerns about the accuracy of ABPM and HBPM due to the lack of clinical validation of some of the devices in use as well as the nature of use by the device operators (Azizi, 2019) (Sullivan, 2020) (Hodgkinson et al., 2020). That said, most mothers in developing countries do not own BP machines for use in out of clinic settings. This lack of BP measurement devices and the need to make regular clinic visits poses a challenge in early detection of abnormal BP in mothers, which is key in determining the onset of pre-eclampsia. An alternative approach involves the use of community health volunteers or nurses who make regular visits to households to take BP readings. These volunteers or nurses are suitably trained and make use of validated devices such as sphygmomanometers or digital BP readers during their visits (Reidpath *et al.,* 2012).

The early detection of preeclampsia requires regular BP readings and monitoring among expectant mothers with a gestation of less than 20 weeks' gestation. In developing countries this exercise requires that these mothers make regular visits to the clinics for blood pressure readings to be taken. These visits are time consuming and are often not achieved due to the time and cost requirements involved. The alternative, BP measurement at home, has been found to be challenging due to lack of inclusion of the approach in the ANC care process as well as the high cost of the measurement devices. As a result, many cases of preeclampsia, which would have otherwise been detected early and managed, develop to full eclampsia leading, in some cases, to the loss of the mother and / or child. This study therefore sought to develop an affordable and convenient approach to the continuous measurement of BP in out of clinic settings as a means to achieving the early detection of abnormal blood pressure reading and possible development of preeclampsia. This study therefore sought to develop a solution integrating a smartwatch and mobile application for the collection and analysis of BP and associated activity data from expectant mothers in out of clinic settings.

II. METHODOLOGY

System Development

The system development phase of the study adopted the rapid prototyping system development approach depicted in **Error! Reference source not found.**. The approach is suitable for the development of systems where extensive stakeholder engagement is required and for scenarios where system requirements have a tendency to evolve or emerge as the development process continues (Huchthausen, 2016).

Figure 1:
Rapid Prototyping
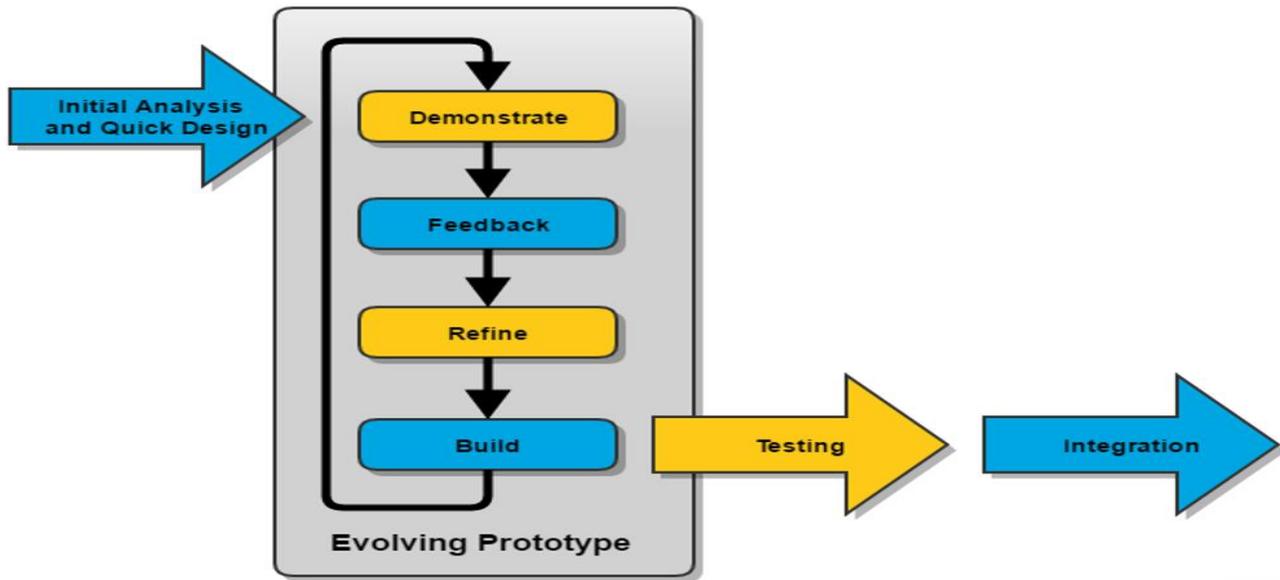
Suitable smart watches capable of taking BP measurements and transmitting them via Bluetooth were identified. An Android mobile application was developed to receive these readings, to collect data (*age, weight, height and other health conditions*) about the mother and their activities (*sleep, exercise, chores*), to analyze the readings and to send alerts to the mother if high blood pressure readings are detected. The data collected was then transmitted and stored in a cloud-based database from where it was accessible for further analysis. The system architecture is presented in figure 2 below:

Figure 2:

System Architecture Integrating a Smart Watch, Mobile Application and Cloud Application for BP Measurement and Analysis Adopted From Mueni, Thiga And Muchiri (2018)
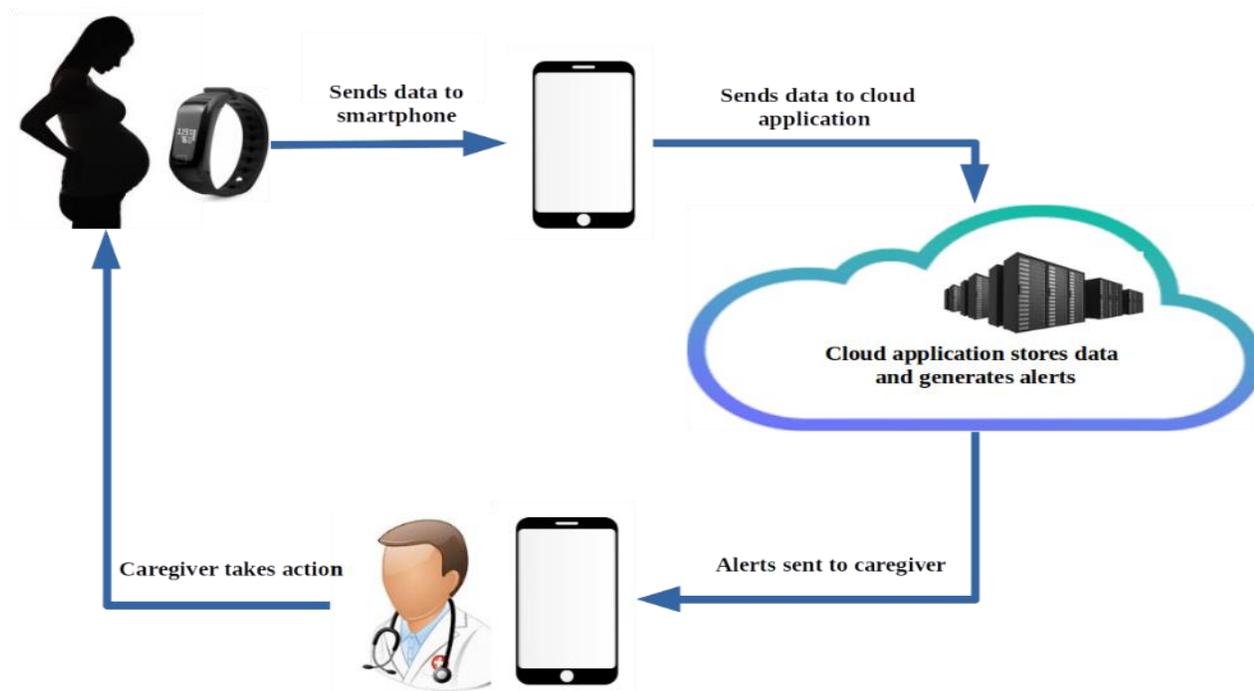
System Testing

Method: This phase of the study adopted a prospective longitudinal study design where a chort of mothers were identified, recruited and observed (Caruana et al., 2015) between February and October 2022.

Sample Size: A Non-randomized control group design was used in this study. A total of 34 pregnant mothers (Sample size calculated using General Linear Multivariate Power and Sample Size (GLIMMPSE) at or before 20-week gestation were included in this study.

Sampling: Purposive homogenous sampling was used to sample the mothers during the first antenatal clinic visit for the index pregnancy. The mothers were told about the study and those who consented to participate in the study were contacted at 20 weeks' gestation. Mothers who come f-or the first antenatal visit after 20 weeks and those with a history of hypertension were excluded. Participation in the study was voluntary and participants were allowed to withdraw at any point they wished to do so. The data collected from the participants was de-identified.

Study Location: The mothers were recruited from the ministry of health antenatal clinics located at Kabarak Univeristy health center, Ol-Rongai dispensary, Mangu dispensary, Rajuera dispensary and Imani Clinic. The localities of these health facilities is largely low income and rural with moderate to poor internet and phone network coverage.

BP and Activity Data Collection: Participating mothers were trained on the use of the smartwatch and blood pressure monitoring application. Thereafter the application was installed on their phones and they were issued with a smartwatch. The application was configured to automatically collect blood pressure

data at intervals of 1 hour. In addition, whenever a BP reading was taken then the mother was prompted to share additional details about their physical activity and emotional state at the time of the reading.

III. RESULTS

The Blood Pressure Monitoring Solution

The blood pressure monitoring solution used in the study comprised of a mobile application for the mothers and a smartwatch for taking the BP readings. The smartwatch selected for BP data collection was a fitness tracker with Bluetooth 4.0 connectivity, a Photoplethysmography (PPG) heart rate sensor, an Electrocardiogram (ECG) sensor, 0.96 display and chipset NFR52832. It is presented in **Error! Reference source not found.**.

Figure 3:

Smartwatch with PPG and ECG Sensor

The activity and mood data were collected on the mobile application. The application setup is depicted in Figure 3 while the BP and activity data collection are depicted in Figure 4. The mobile application was connected to a smartwatch via Bluetooth for the collection of BP readings.

Participant Recruitment

A total of 34 mothers were recruited for the study. The mean age for the mothers was 26 years ($\pm$5.5). Over half of the participants 56% (19/34) were not first-time mothers. The mean gestation in weeks for the mothers was 14 ($\pm$4.9). The majority 61% (21/34) of the mothers had attained high school qualification and most of them were married 79% (27/34). Figure 1 below depict a summary of maternal demographics.

Table 1:

Maternal Demographic Characteristics

Mother's demographics(n=34)		Mean (SD) and frequencies (%)
Mean age (years)		26 ($\pm$5.5)
Parity	Parity 0	15 (44%)
	Parity 1	11 (32%)
	Parity >1	8 (24%)
	Miscarriage /abortion	6 (18%)
	Gestation in weeks	14 ($\pm$4.9).
Education level	Master's level	1 (3%)
	Bachelor's level	12 (35%)
	High school and below	21 (67)
Marital Status	Married	27 (79%)
	Other	7 (21%)
Employment	Formal employment	29 (85%)
	other	5 (15%)

Figure 3:

BP Application Settings

| Application Login | Application settings | Skin tone Settings | BP Reading Frequency | Next of Kin Details |

Figure 4:

BP and Activity Data Collection

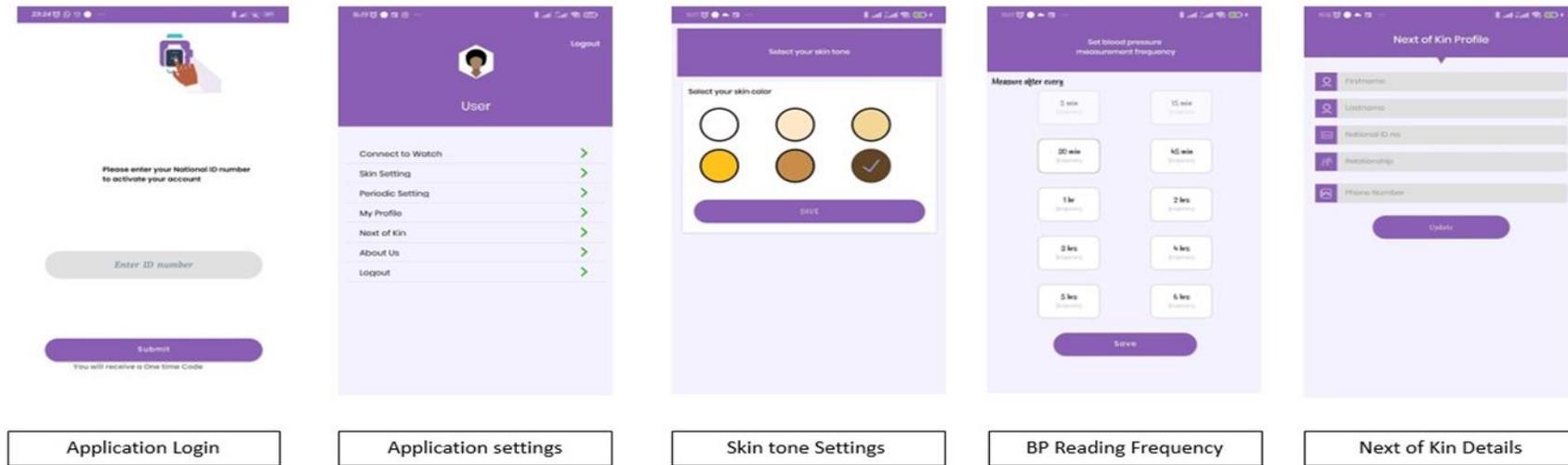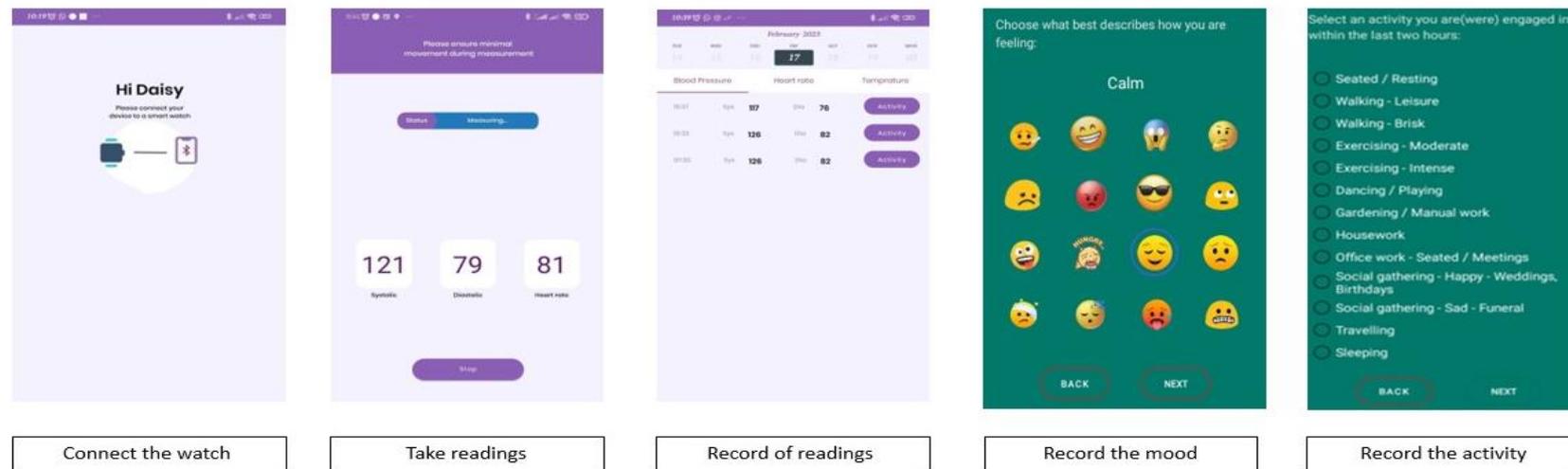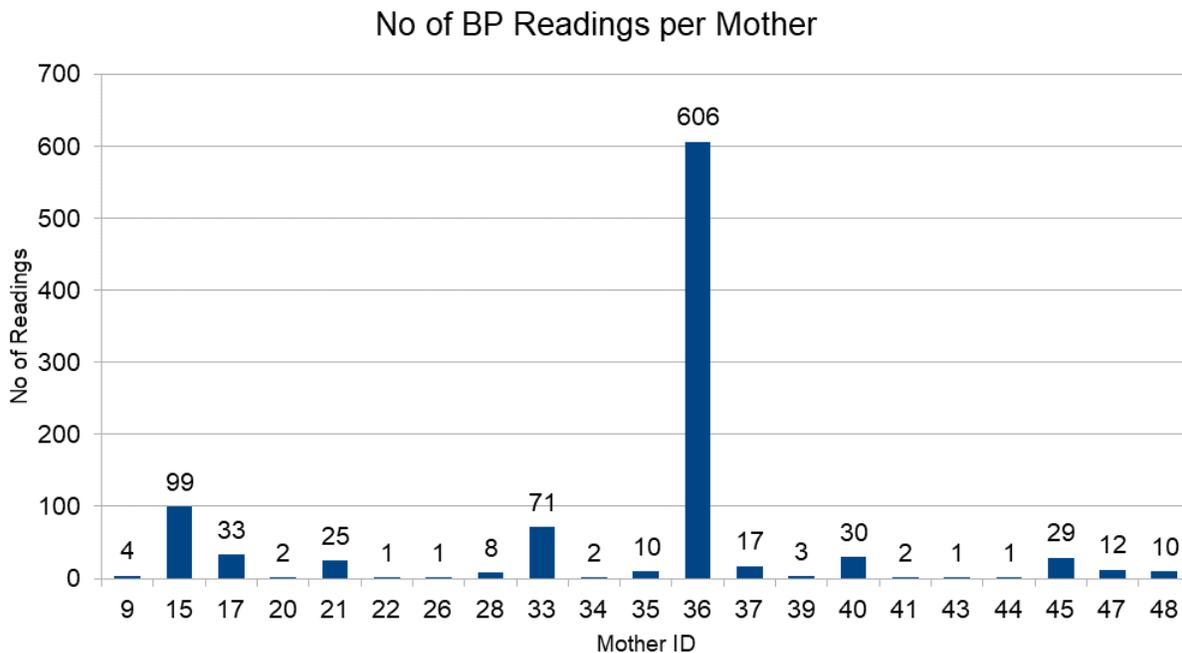| Connect the watch | Take readings | Record of readings | Record the mood | Record the activity |

BP and Activity Data Collection

A total of 967 BP readings were collected over the data collection period between 2022-02-28 and 2022-10-15. The corresponding activities and moods were recorded for 74 (7.6%) of the BP readings.

Figure 5:

BP Readings Per Mother

The average number of readings was 46, min 1, max 606. Only three (8.8%) mothers took readings above the mean.

Challenges Encountered During the Out of Clinic Blood Pressure Monitoring Among Expectant Mothers

A number of challenges were observed during the data collection. These are broadly categorized around the mobile application, the smartwatch, recruitment and general technological issues as follows:

Mobile application challenges

a. *Installation:* Some of the expectant mothers did not have enough storage on their devices: This made the installation process take long. This is because they first had to delete data or other applications from their phones for the BP monitoring application to be installed.

b. *Power:* During the use of the BP monitoring application the phone battery drained faster than usual since the users had to turn on both Bluetooth (BT) and location, (to properly connect to the smartwatch). As a result, they needed to charge their smartphones more often than they normally would. Turning on Battery Saving Mode inhibited the BP monitoring application from accessing the smartwatch which contributed to the inconsistency of data collection from the mothers.

c. *Incompatibility:* While some smartphones were excellent when paired with the BP monitoring application, some of the smartphones did poorly. Even though the application was able to install, some challenges emerged thereafter. Some phones, especially ones with the older versions of Android, were not able to configure the settings accordingly, an example being the Periodic Settings which enables the user to set a consistent interval for the BP and heart rate readings. Another example is the Skin Setting page that enabled the users to input their skin color. If not set properly like it was for some of the smartphones, the smartwatch was not able to read the BP and heart rate of the user.

d. *Bugs:* For most phones, the history page took more than 10 seconds to load and sometimes lead to a crash of the application. This therefore discouraged users from updating some of the important information needed such as mood and activity. There was also an issue of the readings taking place on the smartwatch but BP monitoring application not recording them.

Smartwatch challenges

a. *Connection:* The connectivity between the two devices was problematic in some cases. This was due to reasons such as the user being away from the smartphone for a long period of time. This forced some users to manually collect BP and heart rate data.

b. *Malfunction:* After a few weeks of use, a few smartwatches stopped working. This was due to the quality of the smartwatch.

c. *Power:* Some participants found it difficult to charge the smartwatch so they would stay a few days without charging the device until they reached out to the researchers, or the researchers reached out to them.

d. *Notifications:* The smartwatch vibrated whenever the user's temperature was high. This in turn discouraged the users from wearing the watch at night because the vibrations would wake them up. The watch also vibrated for other reasons besides temperature.

e. *Mode:* When the watch went to sports mode due to a user's touch by mistake, they found it difficult to go back to the home page. The data was then not collected because the watch was in another mode.

f. *Loss and damage*: Some participants lost the smartwatches through theft, or damaged them while doing chores. Their mobile phones were also lost through theft in some cases.

Recruitment challenges

The recruitment phase of this study was faced with several challenges.

a. *Inclusion Criteria:* The inclusion criteria of 20 weeks' gestation posed a great challenge because pregnant women with a gestational age below 20 weeks hardly come to the clinic until they are sure they are pregnant or when they start to show physical signs of pregnancy.

b. *Lack of android mobile phones:* The second challenge with recruitment was that some mothers who were below 20 weeks' gestation were not in possession of an android mobile phone which was a requirement for the use of the BP monitoring application.

c. *The chosen catchment area:* The community that surrounds the public health facility identified for the study is rural in nature and geographically large. This posed a challenge because mothers preferred to go the nearest private health facilities for their health care needs instead of traveling to the selected facility that was considered far by some of the mothers.

d. *Knowledge gap on the importance of blood pressure monitoring during pregnancy:* This was also a hindrance during the recruitment process.

i. It took a long time with lengthy explanation to the mothers on the importance of continuous blood pressure measurement during pregnancy.
ii. Those that were recruited but still had some gaps in their understanding did not actively wear the provided smart watch for blood pressure measurements.
iii. Some mothers believed that by agreeing to participate in this study they would be inviting the problem of high blood pressure which they did not have initially.
iv. Myths and misinformation regarding the etiology of preeclampsia by some mothers also contributed to barriers experienced during recruitment process as some mothers voiced out how they heard from other people how the disease occurs and so they believed they cannot be affected by the same problem.

e. *Family dynamics and support system*: Some mothers who met the eligibility criteria were afraid or avoided to participate in the study due to fear of questioning and explanations to their next of kin and especially their spouses as to why they agreed to be part of the study and most importantly an explanation of where they got the smart watch from and its use and whether it was safe for the mother and the unborn baby.
f. *Need for incentives by some mothers:* This was expected by some mothers in order to effectively participate in the study. This may have been due to various factors such as lack of interest in the research study or due to financial constraints.

Adherence challenges

a) *Consistency:* Some expectant women cited domestic responsibilities, taking care of the spouse, and raising children as obstacles to poor adherence to data collection. Others claimed that their outside-the-home employment prevented them from producing data and using their smart watches. Some pregnant mothers reported that because of their schooling they did not have enough time to update the application on the collected data, some even forgot to put on the watch. Turning on Bluetooth consistently was also a problem to the users because they were not used to it, so they sometimes turned it off due to forgetfulness.
b) *Connectivity:* Some of the mothers in the study experienced network connectivity challenges. This was mostly true for those that were from remote areas where there is poor network connection. Additionally, some mothers did not know how to reboot the smart watches whenever they had experienced loss of network connection. The watches therefore were not able to connect to the smartphone application and take BP readings until they were rebooted.
c) *Relocation:* Some mothers dropped out of the study because they moved to a different location.
d) *Follow-up:* The research assistants were not able to adequately follow up the mothers. The study funds were not sufficient to allow them to follow up each mother in person at least once a week to check on them and address any challenge they would be facing.

Shared Smartphones: Some of the mothers in the study shared their mobile phones with a family member or their spouses. Sharing of a phone resulted in loss of data as well as data not being saved when the mother did not have the mobile phone.

IV. DISCUSSION

Mobile Application - The use of mobile applications in healthcare continues to increase. There are however challenges associated with their development and use. These include ensuring the privacy of patient data, keeping up with market trends, effective integration of Artificial Intelligence (AI)

and Internet of Things (IoT), big data management, user experience, interoperability with other systems, lack of ethical considerations during development and the lack of efficient payment models (Aljedaani & Babar, 2021), (Golden Edge IT Technologies, 2022), (Kapoor, 2022). However, in this study the challenges faced with respect to the mobile application were largely related to the low specification of the phones possessed by the participants. This can be attributed in part to the fact that the study took place in a rural and developing country context. These challenges associated with the low specification mobile phones are a pointer that in a developing country context, up to date technology may not be universally accessible or affordable.

*Sm*artwatch - The use of the Internet of Things (IoT) in healthcare is a growing trend. They are largely used for their ability to aid in the collection of data from persons in out of clinic settings as well as their ability to either relay or temporarily store data for further analysis. That said there are still challenges associated with their use in healthcare. These include; discomfort to users, noisy data occasioned by disruptions and transmission from one device to another, high costs associated with procuring the devices and the development of systems, high energy consumption during data collection and transmission, and privacy challenges due to low computing resources that make it difficult to employ encryption for the data (Selvaraj & Sundaravaradhan, 2019). In this study the smartwatch selected experienced failures after a short period of use. This could be attributed to the criteria for its selection, 'affordability'. With lower costs comes lower quality of the hardware and sensors.

Recruitment - The process of recruiting participants for any given study is widely acknowledged as one of the challenging facets of research. Effective recruitment and retention of study participants determines the success of participatory research and trials. Research trials that have had challenges in their recruitment process have been forced to adjust some areas such as modifying the eligibility criteria and at times extending the recruitment period in order to achieve the desired goals (Ekambareshwar et al., 2018). In research trials involving expectant mothers, recruitment process is deemed more challenging due to factors such as narrow window of eligibility to recruit and deliver the intended intervention, time constraints on expecting mothers with competing priorities, other work commitments, and responsibilities such as caring for other children and generally disinterest in research (Liu et al., 2020). In this study this challenge was addressed by identifying additional study locations in order to increase the chances of identifying mothers who met the inclusion criteria and those who were also in a position to participate by virtue of having a smartphone, a reliable internet connection and an appreciation of the need to monitor their Blood Pressure.

Adherence - Data collection challenges exist in all research works. They are associated with the locations of the study, the levels of literacy of study participants, the language used in the data collection exercise and tools, the duration of the data collection, researcher fatigue and the nature of data being collected with sensitive data being more difficult to collect (Rimando et al., 2015). This study experienced all of these challenges given that the study location was rural with the participants generally of a lower social economic status. A number of participants were not IT savvy and could not work out the connection between the smartwatch and their mobile phones. The tool used for data collection was a smartwatch and mobile phone, a combination that was both new and complicated to the participants. The collection of blood pressure data was also treated with suspicion by some potential participants and their next of kin. The duration it took to recruit

participants and the need to identify additional study locations also took its toll on the research team.

Conclusion

This study sought to develop a solution integrating a smartwatch and mobile application for the collection and analysis of BP and associated activity data from expectant mothers in out of clinic settings. The integration of a smartwatch and mobile application for BP data collection was achieved. It was able to also collect the corresponding mood and activity data. A total of 34 mothers were recruited to the study from four locations, which was three additional locations occasioned by difficulties associated with getting mothers who met the inclusion criteria of under 20 weeks' gestation with no previous history of hypertension from the first location. The data collection exercise was however faced with a myriad of challenges associated with the use of the smartwatch and mobile application, the failure of the smartwatches, loss of devices and the lack of adherence to the data collection exercise by study participants. Overall the study was not able to achieve a consistent collection of BP data from the expectant mothers but instead established key challenges that need to be addressed before the collection can succeed.

Recommendations

Application – In a developing country context, mobile phones with what may be considered 'standard' or 'up to date' specifications may not be readily available and affordable. It is therefore necessary to identify options for out of clinic BP measurements that do not require a participant to have a mobile phone. Such options may include GSM enabled BP measurement devices that can transmit the readings directly to a cloud based system. The use of community health volunteers to make regular home visits for BP data collection can also be considered.

Smartwatch – The need to balance between affordability, comfort and effectiveness requires a reconsideration on the use of smartwatches. BP cuff readers are relatively accurate and cost almost the same as smartwatches. Their downside is on aesthetics, they are larger and more bulky. However, they are likely to be more robust and not as inconveniencing if the reading frequency is not high.

Recruitment – The need to embark on the BP monitoring at 20 weeks' gestation requires that the expectant mothers attend the first ANC clinic visit on time. This continues to be a challenge which can be addressed through enhanced campaigns by healthcare providers as well as strengthening community identification of expectant mothers through initiatives such as the community health volunteer programs.

Adherence – Ensuring consistent data collection can be achieved by a combination of interventions. Sufficient health education on the importance of early detection of preeclampsia and other hypertensive complications can help in creating an appreciation for the monitoring of BP. Strengthening support systems such as next of kin and community health volunteer follow-up can also be helpful.

Acknowledgment

Conflict of Interest

Authors declare no conflict of interest.

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