Low-cost blood pressure monitor device for developing countries

Arteta C[*1,2], Domingos JS[*1,2], Pimentel MAF[*1,2], Santos MD[*1,2], Chiffot C[2], Springer D[2], Raghu A[2], Clifford GD[2]

*These authors had equal contributions for this paper
[1] Centre for Doctoral Training in Healthcare Innovation, Dept. of Engineering Science, University of Oxford, Oxford, UK
[2] Institute of Biomedical Engineering, Dept. of Engineering Science, University of Oxford, Oxford, UK
{carlos.arteta, domingos.domingos, marco.pimentel, mauro.santos, gari.clifford}@eng.ox.ac.uk

Abstract. Taking the Blood Pressure (BP) with a traditional sphygmomanometer requires a trained user. In developed countries, patients who need to monitor their BP at home usually acquire an electronic BP device with an automatic inflate/deflate cycle that determines the BP through the oscillometric method. For patients in resource constrained regions automated BP measurement devices are scarce because supply channels are limited and relative costs are high. Consequently, routine screening for and monitoring of hypertension is not common place. In this project we aim to offer an alternative strategy to measure BP and Heart Rate (HR) in developing countries. Given that mobile phones are becoming increasingly available and affordable in these regions, we designed a system that comprises low-cost peripherals with minimal electronics, offloading the main processing to the phone. A simple pressure sensor passes information to the mobile phone and the oscillometric method is used to determine BP and HR. Data are then transmitted to a central medical record to reduce errors in time stamping and information loss.

Key words: Blood pressure, developing countries, electronic medical records, heart rate, hypertension, low-cost medical devices, mHealth, resource-constrained healthcare, signal processing.

1. Introduction

Globally, hypertension is a major chronic, non-communicable disease and a leading cause of death and disability in economically developing countries [1]. Hypertension, a sustained elevated blood pressure[1] (BP), is a dangerous medical condition that stresses the heart and promotes vascular weakness and scaring, making blood vessels more prone to rupture [2]. Uncontrolled and untreated hypertension increases the risk of coronary arteries damage, heart attack, stroke, kidney disease, eye damage and is responsible for other conditions such as pre-eclampsia. Most of these problems can be found in developing countries and are a serious economic burden [1,3,4].

Kearney et al. [5] predicted that by 2025 the number of adult individuals with hypertension will approximately be 1.56 billion, or 29% of the world's adult population. Developing nations represent approximately 1.15 billion of this statistic, contributing to almost three-quarters of the world's hypertension population by 2025 [5]. Kearney et al.'s findings also indicate a higher prevalence of hypertension in developed countries (37.3%) than in developing ones (22.9%). However, given the much larger population of developing countries, the absolute number of patients affected by hypertension is considerably larger and is likely to grow with less healthy lifestyle changes characteristic of urbanization [5].

Barriers to the treatment of hypertension include i) lack of detailed data on an individual's BP readings over time, ii) poor infrastructure to deliver information and medication, iii) lack of training in how and when to take reliable BP readings, and iv) lack of financial resources [6,7]. It may be suggested that manual readings are sufficient and an automated device is not needed. However, it is known that manual recording of data is error-prone and leads to even well-trained clinical staff can overestimate blood pressure or miss critical BP-related events [8,9]. In particular, lack of data leads to low hypertension awareness rates [10,11] in developing nations and therefore a screening for hypertension and the measurement of BP is therefore of critical importance in developing countries.

Nevertheless, current BP electronic devices that enable automatic BP measurements are expensive for the developing countries and also they can only store a small number of BP readings. In developed countries, easy-to-use, one button click, and clinically validated electronic BP devices can be found for the upper-arm, with automatic cuff inflation/deflation cycle for about €20. These are very useful to monitor BP and heart rate (HR) at home and doctor office visits (although the patient must remember to accurately record all readings, which is unlikely since even trained professionals introduce systematic biases [8,9]). More advanced and expensive devices allow the setting of alarm reminders to take BP measurements, save up to 120 readings, download readings to a Personal Computer (PC) through a USB cable or Bluetooth, indicate irregular heartbeat or hypertension, and even associate measures with different

[1] Generally, a systolic pressure consistently above 140mmHg and/or a diastolic pressure consistently over 85mmHg, although definitions vary with age, gender, other disease factors and measurement location on the body.

patient profiles, composed mostly by basic information such as name, gender and birth date. Such devices range in price from €40 to €150 depending on the number of features, accuracy of the measurement and quality of the hardware.

Electronic BP devices with all the features described above would also have an impact in developing countries, but may never be widely available at a reasonable price for the average person. However, much of the hardware needed for an automated BP measurement is already in most people's pocket and the extra hardware needed could be manufactured for less than €5. According to the International Telecommunication Union, mobile cellular subscriptions have been increasing significantly over the last decade, particularly in developing countries [12]. When compared to developed countries the trend is towards a much bigger growth in mobile phone subscriptions in developing nations [12]. It is increasingly rare that someone does not have access to a personal or at least family-owned mobile phone. Since poor supply-chains (for both hardware and information) are one of the biggest issues in medical device distribution and training, the mobile phone (one of the few products to solve these issues) provides an enormous potential.

The mobile phone provides the hardware and software required to extract the features from vital signals, calculate and display the results and automatically save them to a database (either locally or remotely). Moreover, it can provide the user (and health worker) with advice on usage, quality and decision support. By off-loading the analysis to a software application running on the phone, it is possible to provide software (and even firmware) updates to the system without having to ship the device or need specialist knowledge. This would allow continual improvement of the system, and optimization for specific communities, such as the hypertense, which is a known issue with BP measurement devices. The mobile platform would also allow for the automatic synchronisation of the BP readings with other data in an electronic medical record (EMR) saved remotely in a server. Such data could then be shared with authorized specialists, providing a permanent monitoring service, and an auditing path to improve the system.

There are many different non-invasive BP measurement methods currently used in BP monitoring: the oscillometric method, the palpation method, the auscultatory method, the unloading plethysmographic method, the volume-oscillometric method, the volume-compensation method, the arterial tonometry method, etc [13-15]. The most widely used automatic method in commercial BP monitoring nowadays is the oscillometric method [13-15]. This method measures the systolic blood pressure (SBP) and diastolic blood pressure (DBP) in the arterial system by recording the pulsatile changes in pressure that are caused by the flow of blood through an artery that is restricted by an occluding cuff. At the start of a measurement, the cuff (which is usually around the subject's upper arm) is inflated to a pressure that completely occludes the underlying artery (generally about 240 mmHg or 20 mmHg higher than the last systolic reading). The occluding cuff pressure is then gradually reduced from above SBP to below DBP and the actual values of the SBP and DBP can be determined from the oscillation in the air pressure of the arm cuff [13-15].

In this paper we present and pre-validate a low-cost easy-to-use BP monitor device for developing countries running on a mobile phone through the use of a typical and widely available cuff. The solution does not require the presence of trained personnel to take BP measurements, and allows for storage of medical data without transcription errors or other common human mistakes.

2. Methods

In the device described in this paper, the manometer is removed from a traditional sphygmomanometer and its air tube is connected to a pressure sensor integrated in a low-cost hardware. The cuff and tubing taken from the traditional sphygmomanometer costs around €3 and is widely available in many settings. It is also easily replaced by comparable materials. The hardware is connected to a mobile phone using an USB cable so that power is supplied from the phone, no wireless transmission chips are needed (which would quadruple the system cost) and data pairing between the hardware and the phone is instant, secure and trivial. Pumping is performed manually so that there is no significant power drain, or heavy pumps. The application in the mobile phone allows the user to measure BP and HR and then save it to the device database and synchronize it with the patient EMR.

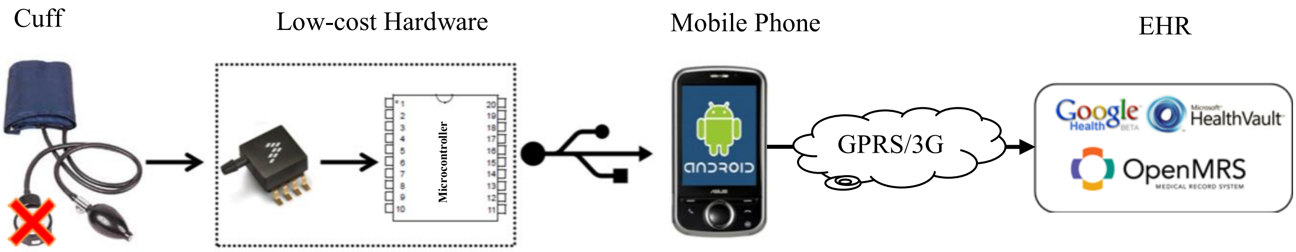

Fig. 1. Overview of the system. Note that the manometer is removed as the phone now calculates the pressure from the output of the pressure transducer.

2.1. Low-cost Hardware

In order to minimise the size and cost of the BP device, the peripheral hardware design contains just enough elements to transmit the pressure signal to a mobile phone for the digital signal processing. The circuit schematic is shown in Fig. 2.

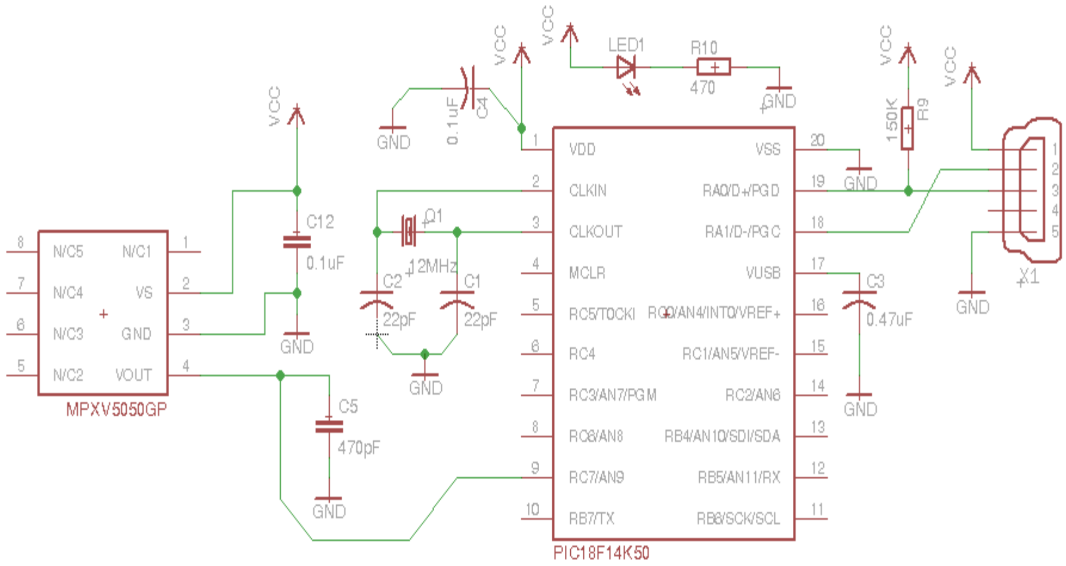

Fig. 2. Hardware schematic for the mobile peripheral in the BP device.

As is common for electronic BP devices, the air pressure in the inflatable cuff is converted into an analogue electric signal by a pressure sensor (located on the far left of Fig. 2). The transducer used in the device presented in this work is the MPXV5050GP from Freescale Semiconductors [16], an on-chip integrated and temperature-compensated pressure sensor. The analogue output signal from the sensor is sampled at 100Hz with a 10-bit resolution (0.29 mmHg per bit) using a PIC18F14K50 from Microchip [17]. The data containing discrete pressure values is sent to the mobile phone through USB, made simple by the USB 2.0 module integrated in the chosen microcontroller. In order to communicate with the peripheral, the mobile phone must support the USB 'On-the-Go' supplement of the USB 2.0 standard, which allows the phone to act as a USB Host to the external device. Furthermore, when using this feature, the peripheral can be powered from the mobile phone.

The resulting peripheral device is a 39x30mm PCB potted inside a small PVC box (recycled from a typical confectionary box at no cost), with a connector for the cuff air tube and a single full size female USB socket. Since most smart phones come with a USB cable of varying connector sizes at one end, which fit the phone, and a full size male USB cable at the other, choosing a female USB socket for this board means that no extra cables need to be purchased.

2.2. Cuff Pressure Signal Processing

The oscillation waveform from one representative measurement is shown in Fig. 3. Note the resemblance to a typical oscillometric cuff measurement. The pressure in the cuff that corresponds to the point of maximum oscillation has been accepted as the mean arterial pressure (MAP) [13,14, 18,19]. In order to determine the SBP and DBP values, a height-based approach has been used: a ratio is obtained by dividing the amplitude by the maximum value [13,14]. The ratios before the maximum amplitude are used to compare a certain ratio to determine the SBP, whereas the ratios after the maximum amplitude are used to compare to another ratio to find the DBP. Some researchers and manufacturers obtain different ratios as the selection criteria: Ball-Llovera et al. [13] defines a standard for the ratios as 40% and 60%, Geddes [20] as 50% and 80% and Wang et al. [15] as 50% and 67% for the SBP and DBP respectively.

In our algorithm, the source signal is initially pre-filtered using a 5 point median filter to reduce the noise and possible motion artefacts from the signal. A 6th order Butterworth band-pass filter with cut-off frequencies of 0.5 and 5 Hz is then applied in order to obtain the oscillation waveform, the red trace in Fig. 3. This allows the determination of the MAP, SBP and DBP by using a height-based approach. Ratios of 50% and 70% out of the maximum amplitude were chosen for the SBP and DBP respectively [13]. The HR is calculated from the frequency spectrum generated via the Fast Fourier Transform (FFT) of the oscillation waveform. The frequency component with the highest magnitude corresponds to the HR.

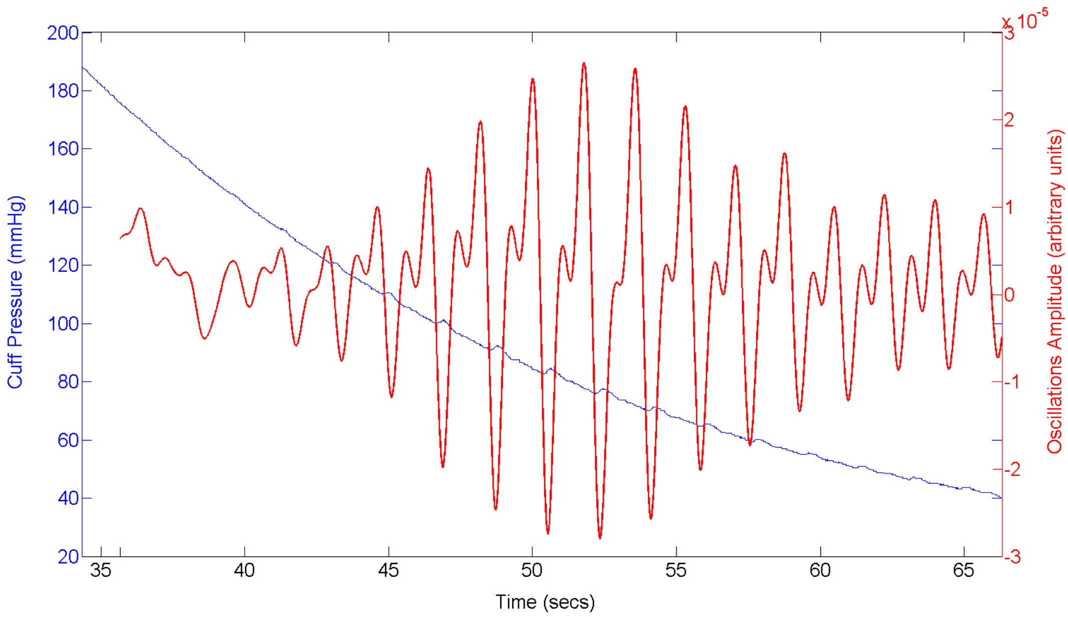

Fig. 3. Cuff pressure signal (in blue, mmHg) and oscillation waveform (in red, arbitrary units).

The routines used for the signal analysis process were firstly written in MATLAB, and then ported to the Java version compliant with the Dalvik Virtual Machine [21] for Android.

2.3. Software Architecture

The main requirements for the software are: i) the interface must be easy-to-use and guide the user to take high quality BP measurements; ii) the application must support different languages, especially those spoken in developing countries; and iii) the device must save BP measurements to a local database to provide review capabilities, and to a remote system to allow the back-up of data, device-independence, and sharing with a healthcare providers.

Fig. 4 shows a diagram of the application workflow and components. The main elements of our system are 1) the *help page* has simple pictograms that allow the user to learn easily how to interact with the device and take the BP in a proper way even if they are partially literate; 2) the *measure page* guides the user during the measure and shows his BP at the end of the recording; 3) the *measure list page* shows the list of measurements saved by the user and also provides a way to synchronise them with a specific EMR; 4) the *measure view page* displays the information of a specific measurement as well as a field to attach useful comments to the data; and 5) the database contains all the saved measurement information. Finally, the application allows the user to save the entire pressure signal to a file in the mobile phone. This information can then be synchronised with a database of BP signals to improve the signal processing strategies.

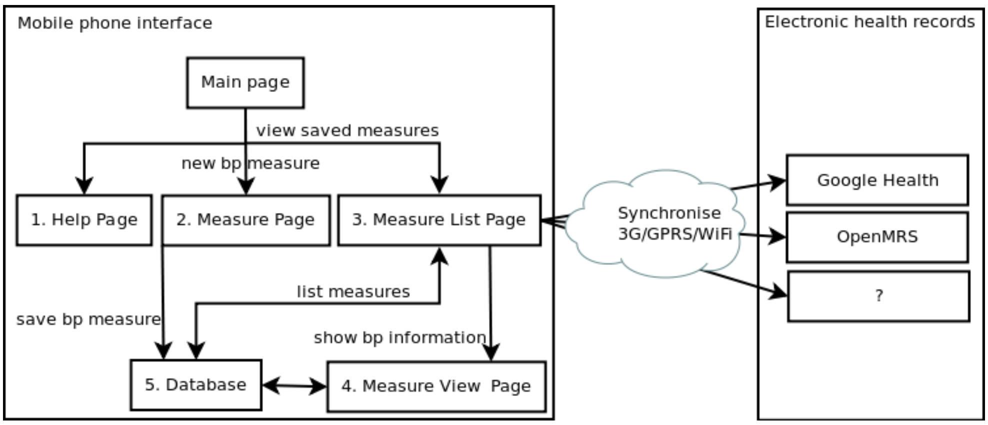

Fig. 4. Diagram of the application workflow and components. The three most commons use-cases are: 1) using help page to learn how to use the device, 2) measure the blood pressure, 3) review saved measures. The application allows easy access and intuitive use of these components. Advanced users can synchronize important measures with patients' EMRs while reviewing them in their mobile phones.

2.4. Prototype

Fig. 5 shows the experimental setup of the mobile BP measure device. The manometer is removed from a traditional sphygmomanometer and its tube connected to the pressure sensor on the PCB. The latter is encased in a free confectionary enclosure and connected to the mobile phone using a standard USB cable. The final prototype has all the characteristics described in the methods section.

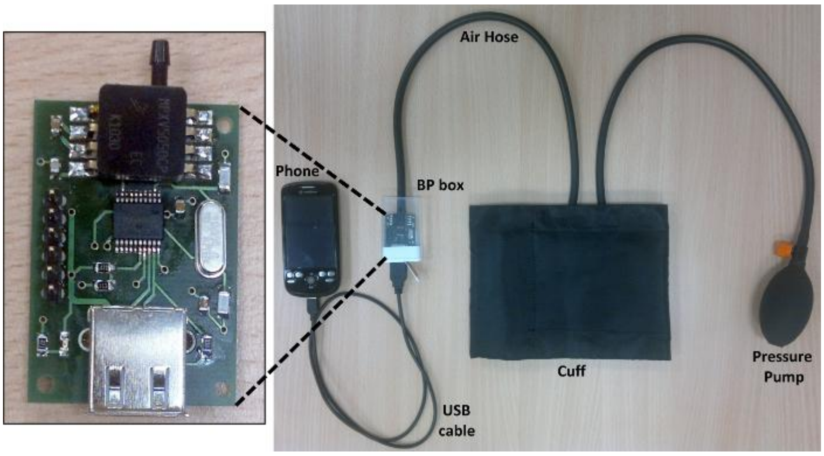

Fig. 5. Experimental setup of the mobile BP measure device. Note that the sphygmomanometer is not used. The cuff and pump were purchased with the sphygmomanometer for less than $10.

The application was implemented using Android 2.2 Software Development Kit (SDK) on an Android device that supported USB host mode. The application comprises 5 pages: *main page*, *help page*, *measure page*, *measure view page* and *measure list page*. These pages were implemented as Activity classes from the Android SDK [22]. To guide the BP measurement, the *measure page* has a chart that renders the real time pressure values coming from the cuff while the measure is being taken, suggesting that the user to pump until a pressure of 240 mmHg (or another defined limit based on historical or user-selected values) is reached and stop pumping. The device is then allowed to slowly deflate (Fig. 6). The application also identifies if the deflation was too fast to extract the oscillations from the recording. In such a case the application requests the user to repeat the measurement with a slower deflation rate. Otherwise, after the pressure drops to 30 mmHg the measurement stops, the SBP, DBP and HR are determined from the processed pressure recording and the result is shown to the user. The user can then save the measurement to the database and also create a CSV file with all the information used to derive the measurement (for debugging and development). This file is only created on the mobile phone if the micro SD card is available with sufficient free space.

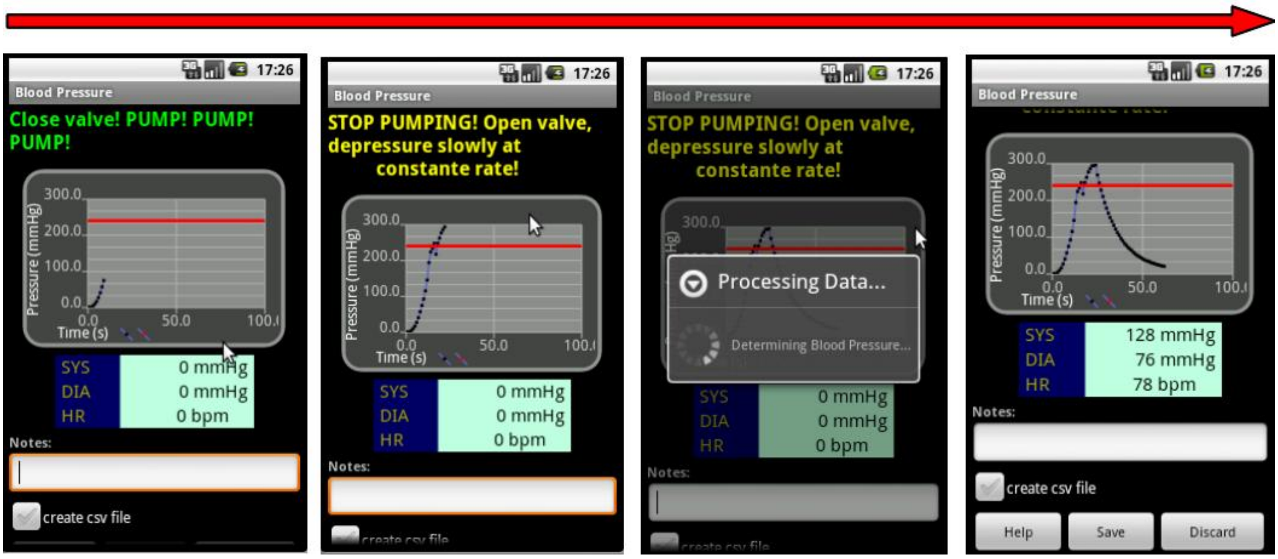

Fig. 6. Screen shots of each step of the acquisition process. Note the chart showing the real time pressure values coming from the cuff while the measurement is being taken.

The application has been translated to Portuguese, Spanish, English, French, Simplified Chinese, Arabic (Egypt) and Standard Hindi. The application, together with the PCB design, is open-source and is available from the project website hosted in Google Code [23]. Users with a QR reader can use the QR code at the end of this document to install the application in their Android devices [24].

3. Results and Validation

The prototype was used in 5 different healthy volunteers (1 female, mean age 25.0, range 24-27 years, 1 Hispanic, 3 Caucasian and 1 Afro-European) to measure SBP, DBP and HR. The automatic Boots Arm Cuff BP Monitor 5690447 (The Boots Company PLC, Nottingham, England), which is well known CE marked device, was used in order to pre-validate the BP and HR measurements.

Three measurements with both devices were taken for each subject in the following conditions: i) after lying down for 5 minutes; ii) after running for 5 minutes and iii) after inserting the right hand in a bucket of ice water for 1 minute. These measures try to simulate daily events like, a person at rest, a person after physical activity and a person undergoing a stressful condition, respectively. The measurements were performed on the left arm with the subject sitting down with the cuff at the same height as the heart, except for the first condition where the subject remained lay down. A 5-minute period was given between the readings from the two devices.

The percent difference (mean ± standard deviation) between our device and the Boots device were compared for each individual over all three types of tests and all individuals for each type of test. The results are shown in Table 1 and Table 2, respectively. The mean percent differences for all individuals over all readings were 14.5 ± 9.8 %, 5.0 ± 5.3 % and 8.1 ± 6.9 % for SBP, DBP and HR, respectively.

Table 1. Values of the mean percent difference (mean ± SD) in % for each individual over all three types of tests.

Subjects	*1*	*2*	*3*	*4*	*5*
SBP	17.3 ± 8.8	19.0 ± 11.1	5.0 ± 6.98	19.0 ± 13.7	12.2 ± 3.2
DBP	2.3 ± 0.7	3.4 ± 5.9	6.2 ± 4.9	8.0 ± 7.6	5.2 ± 6.8
HR	6.6 ± 9.2	11.8 ± 13.4	4.5 ± 2.0	9.8 ± 3.7	7.7 ± 2.0

Table 2. Values of the mean percent difference (mean ± SD) in % for all individuals for each type of test.

Test	*1*	*2*	*3*
SBP	17.2 ± 11.6	18.1 ± 10.6	8.2 ± 3.6
DBP	2.4 ± 3.7	8.4 ± 6.7	4.3 ± 3.8
HR	10.3 ± 10.2	8.4 ± 6.5	5.5 ± 2.6

5. Conclusion and Discussion

A low-cost BP monitor has been developed to function as a mHealth device for developing countries and both the hardware designs and software have been made open source (see [25]). The preliminary data showed a good agreement between the values of SBP, DBP and HR measured with a known device, with an average error of less than 20%, which is within the accuracy levels of the Boots device itself. A standard inflatable cuff and an inexpensive peripheral make use of the considerable processing power in mobile phones to digitally process the pressure signal and compute the BP and HR values using the oscillometric method. The software developed for Android powered devices allows the user to keep records of the measurements in their mobile phone and/or upload them to EMR systems such as Google Health or OpenMRS using the connectivity provided by the phone. Such an implementation would serve as an efficient platform for sampling and analysing BP data from large populations. This could subsequently be used to monitor treatments and in epidemiological studies.

Further work includes completing the validation of the device on larger populations, software improvements to support different cuff sizes and development of an Application Programming Interface (API) to provide easy integration with other applications such as SANA Mobile [26]. Calibration for different age groups hypertensive patients is also required, since standard oscillometric methods are known to lead to clinical error through under- and over-estimation of blood pressure [27-30]. We also hope to include warnings and guidelines for bradycardia, tachycardia, hypertension, hypotension and arrhythmia. However, we do not envision this system as a replacement for trained medical oversight at this stage. Therefore, integration with a medical record system shared or supported by a medically-trained worker will be important. We also anticipate integrating this system with other decision support tools such as cardiovascular risk indicators.

Earlier in this paper we noted that barriers to the treatment of hypertension, and in fact healthcare delivery in general, include -i) lack of detailed temporal data ii) poor infrastructure, iii) lack of training, and iv) lack of financial resources. The first of these barriers can be addressed by frequent measurement-taking (if a suitable device is available), and transmission of the data to a central medical record. This is only likely to happen if the individual or a close care-giver is able to take readings. Poor infrastructure can be addressed by using existing supply channels, such as Coca Cola's delivery trucks, or a more decentralised approach such as that taken by mobile phone companies. Training can be addressed by adding user-feedback and intelligent processing into the device. Our system addresses all these problems (and solutions).

An obvious criticism remains, in that Android only runs on smart phones, which are not widely available in developing countries. However, Android represents the best choice of development platform for several reasons. First, Android is constantly (and intentionally) being ported to cheaper and cheaper devices with the price point for an unlocked device dropping from several hundred dollars to under one hundred dollars in just a couple of years, with a wide variety of devices being able to run Android. Over the last year, Android adoption has increase 886%, with the closest competitor, the iPhone, increasing only by 86% [31]. Moreover, in contrast to the iPhone, which has almost saturated its markets, Android's gains have been largely in developing countries. The reasons for this are unclear, but it may be connected to the incredible potential for Android to offer a whole new market for programmers in emerging economies.

Android, being adopted by Google, has followed its philosophy of cloud data storage and analysis, moving users towards device independence, where an individual's data medical record can be stored in the cloud, and ported across several devices and shared with several users. Even when phone sharing is common (such as between families in developing countries), Android allows you to authenticate a single device with several accounts. Finally, we should note that our BP system is initially aimed at healthcare workers, where deployment of the phone is essentially a low overhead compared to the rest of the clinical trial. By the time the system has been proved to be efficacious (or not), the price point for Android phones is highly likely to have tumbled even further.

Of course, our code is basically vanilla Java and/or C, with few OS-specific tweaks, which means that cross-platform portability is technically quite simple. The issue lies purely in the way the manufacturers decide to lock down the hardware. Unfortunately most phone OS's do not allow good low level interaction with peripheral (or even built-in) sensors or devices. In particular, true USB host capacity is currently only available for mobile phones under Android (and on a limited number of iOS devices). In general there has been a move towards using Bluetooth for medical devices to interface with phones which is partly driven by the lack of USB hosting on phones, but also the natural electrical isolation wireless connections provide. However, Bluetooth requires more energy, drops packets, and can be easily 'sniffed' raising privacy concerns, and is often a suboptimal choice. Bluetooth chips also cost much more than tethered serial chips. USB tethering increases data quality and privacy, allows delivery of power in an efficient manner and prevents the phone from being plugged into the mains during medical device use (without a special power interface), thereby enhancing isolation. Of course, if the low cost pressure sensor is integrated into the phone, these issues are mute.

The final point to consider is how to deploy the non-phone hardware. Although the cuff, pump and tubing in a typical manual device cost about €3, and are easily replaced by local equipment, the electronics are not. It is therefore our intention to make the electronics available either as built-in systems for phones or as a low-cost add-on for the phone available through the same supply channels for phone accessories such as the charger, USB cables and batteries.

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