

The Cardio-Pad™ project: progress and remaining challenges

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Low-income countries are facing a surge in the burden of cardiovascular diseases (CVDs) which, along with other non-communicable diseases, are overtaking infectious diseases as top killers in these settings (1,2). Rural populations are particularly vulnerable owing to their very limited access to either qualified health professionals or effective interventions for CVDs, notably diagnostic tools and essential medicines (3,4). Effective delivery of adequate cardiovascular care to rural populations in sub-Saharan Africa, South and East Asia should therefore be a priority for global health programs.

As acknowledged by the World Health Organization and increasingly by national health authorities, telemedicine is an important strategy to overcome the shortage of health professionals and improve delivery of health care to rural populations in low-to-middle-income countries (5). It has the potential to reduce socioeconomic disparities in the management of CVDs. Two years ago, we presented the Cardio-Pad™ (*Figure 1*), a tele-cardiology device which enables to perform electrocardiograms (ECG) in remote underserved areas and transfer the test results wirelessly to specialist physicians who can interpret them and provide assistance for cases management (6). The Cardio-Pad™ was designed and developed by Arthur Zang, a young Cameroon-based engineer, who received several awards including the 2014 Rolex Award for Enterprise (7) and the 2016 Africa Prize for engineering innovation from the Royal Academy of Engineering (8) for this invention recognized as the first medical computer tablet originating

from Africa. In this paper, we present updates on the Cardio-Pad™ initiative and some of its limitations and remaining challenges.

The technical features of the Cardio-Pad™ have been previously described (6). In brief, the Cardio-Pad™ is a touchscreen tablet whose main internal components include a Dual Core processor, a Double Data Rate Random Access Memory (DDR RAM), an internal memory for data storage, a Global System for Mobile/General Packet Radio Services (GSM/GPRS) for data transmission, a SIM card connector, GPS, Bluetooth and Wi-Fi modules, a lithium battery and two USB ports. External components include ECG electrodes and cables, and a Bluetooth sensor box which detects and digitalizes the heart signals from the electrodes connected to the patient and afterwards transfers them to the Cardio-Pad™ via Bluetooth. The Cardio-Pad™ is a multifunction cardiograph with two main functionalities: first, through the CardioPadgraph™ program, it performs a 12-lead ECG displayed on the pad; secondly, it allows transfer of patients' data via the mobile phone network using a SIM card, to a National Data Centre and then to a specialist who can interpret the data and assist in the diagnosis and management of patients. The Cardio-Pad™ can also function as a scope as it is able to perform real-time monitoring and recording of the heart's electrical activity using the CardioPadScope™ program. In the Cardio-Pad™ user guide V.1, it is claimed that the device can also perform real-time monitoring of vital parameters such as respiratory rate, blood pressure, temperature and oximetry. However,



Figure 1 The Cardio-Pad™ kit (From the Cardio-Pad user guide V.1).

no accessories are provided in the Cardio-Pad kit for the recording of these parameters, and the procedure to use the scope function is not described.

Some improvements have been made on the prototype available in 2014. First, although the autonomy of the built-in battery has not been improved, a solar panel is now provided to charge the battery using solar energy, making it more suitable for use in remote villages where there is limited electricity supply. Second, the ECG displayed on the Cardio-Pad™ can now be printed on an A4 paper compatible with all printers, and stored in patients' folders. This is an interesting feature, especially for hospitals where patients' medical information are not archived electronically. Third, according to the developer, the information recorded by a Cardio-Pad™ can now be transferred not only to another Cardio-Pad™ but also to any smartphone. Through a software that can be freely downloaded on the Cardio-Pad™ website, the smartphone can receive signals from a Cardio-Pad™, treat them and generate ECG images in various formats including JPEG. Fourth, a wireless mouse and a keyboard are now provided as backup solutions in case of damaged touchscreen or for users less comfortable with it.

The commercialization of the Cardio-Pad started in early 2016. According to Himore Medical Equipments, the company which produces and commercializes the Cardio-Pad™, 300 pads have been produced and about 50 have been sold to date. Most of the buyers were Non-Governmental Organizations in Nepal, India, Comores Island and Gabon. The manufacturer assures that there is a close follow-up of the products delivered. Local partnerships to ensure maintenance are being put in place in high sales countries and there is even a possibility to replace

dysfunctional pads.

Despite the rapid commercialization of the Cardio-Pad™ driven by the clear potential to help improve the care of patients with CVDs in remote underserved areas in low-to-middle-income countries, several questions remain unanswered, pertaining to its reliability and cost-effectiveness as a public health intervention. Moreover, there is virtually no peer-reviewed publication to support the Cardio-Pad™ in the competition with similar technologies and devices being developed worldwide. Below are some recommendations to be considered by Himore Medical Equipments in order to ensure the success of the Cardio-Pad™.

First, there is a need to validate the Cardio-Pad™ against standard ECG devices. This should ideally be done by assessing the performance of the device in a group of healthy volunteers and publishing the results in an academic peer-reviewed biomedical journal. The results should include measures of inter-observer and intra-observer agreement (9-11); error margins for each of the multiple ECG parameters; optimal operating conditions; and quantification of the effects of some ecological or patient-related factors on the performance of the device, notably age, gender, body mass index, patient's or examiner's mobility during the recording, exercise, skin moisture, tobacco or caffeine consumption.

Second, the performance of the Cardio-Pad™ for the diagnosis of cardiac diseases should be rigorously demonstrated in the pre-hospital and intra-hospital emergency settings where such device would be the most useful especially because it could facilitate the coordination of medical decisions and interventions by allowing simultaneous real-time visualization of patients' ECGs by several teams. The priority should be given to some specific conditions such as myocardial infarction, conduction blocks, atrial fibrillation, dyskalemia, dyscalcemias, prolongation of the QT interval, and ventricular tachycardia. It should be noted that the Cardio-Pad™ is actually lagging far behind its competitors. Indeed, several other portable electronic ECG devices are being developed all around the world with promising results (12-17). Therefore, the designers of the Cardio-Pad™ should manage to catch up quickly in order to safeguard its competitiveness on the market.

Third, it is advisable that medico-economic studies are conducted to quantify the clinical and economic benefits of using the Cardio-Pad™ rather than current standard ECG devices even in rural settings with limited resources. Important items to consider include the average reduction

of time to access meaningful information, the average gain of space allowed by cloud-based archiving, the average gain of time to diagnosis and treatment which converts into reduction of disability- and quality-adjusted life years (18-20), and the average reduction of the ECG cost due to savings on printing charges.

Fourth, while implementing technical and clinical validation studies, the staff at Himore Medical Equipments should also try to enhance the safety of patients' data transfer and storage and incorporate new algorithms to assist users in the diagnostic process. Such advanced algorithms should be able to perform real-time analysis of the ECG and comparison with previous traces stored on the device or in the cloud. The safety of data transfer and storage is critical and should be taken seriously when contemplating the potential consequences of either the falsification or the deletion of patients' medical information (21,22).

As a conclusion, we would like to congratulate and encourage Arthur Zang and his team for their invention and encourage them to keep aiming high in their quest of excellence. It is indeed a great achievement to have designed the Cardio-Pad™ and constantly improved its functionalities over the years. We hope that the recommendations in this paper will help them take the necessary steps to ensure the worldwide success of the Cardio-Pad™ especially in western countries where regulations on drugs and medical devices are more coercive and companies developing rival products are thriving. They should also realize that the implementation of these recommendations will request a diversification of the staff to include experts from various domains (cardiology, public health, biostatistics, data management, cybersecurity, economics, ethics, and law) and the initiation of international collaborations with various biomedical engineering institutes around the world. We would also like to take advantage of this tribune to raise the awareness of governments in low-to-middle income countries on the need to create regulatory boards that will closely monitor and guide the progressive introduction of new medical devices in their countries so as to minimize the health risks for their populations.

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Footnote

Conflicts of Interest: The authors have no conflicts of interest to declare.

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