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WEARABLE VITAL SIGN TECHNOLOGIES AND THEIR POTENTIAL WITHIN LOW AND MIDDLE INCOME COUNTRIES

Research in Progress

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Abstract

Healthcare workers continue to operate in challenging environments when assessing and treating patients in low and middle-income countries (LMIC). These difficulties are exacerbated when it comes to the assessment of infant vital signs e.g. pulse, blood pressures. As part of the EU funded Supporting LIFE project, our aim is to develop a Mobile Health (mHealth) Android application with Wearable Vital Sign Technology (WVST) integration for infant vital sign assessment. Subsequently, the objective of this research is to conduct a state of the art review of WVST systems for infant vital sign assessment with specific focus on identifying those technologies pursuing or having recently received Food and Drug Administration (FDA) approval. With the exponential growth in mHealth solutions and the ongoing discourse on the importance of mHealth compliance with regulatory standards, this factor acted as the baseline selection criteria for the investigation. Moreover, the need for an Android compatible open API WVST further bounded the scope of this study. Our market analysis reveals that there remains a dearth of appropriate, compatible WVSTs that could be considered as possible candidates for selection as part of the Supporting LIFE mHealth solution given that most commercial WVST offerings are designed for adult use. In addition, there appears to be a paucity of empirical research on the use of WVST for capturing and monitoring the vital signs of sick children in LMIC.

Keywords: sensor technology, vital signs, Low and Middle-Income Countries (LMICs), Informatio Communication Technology for Development (ICT4D)

1 Introduction

The healthcare industry is experiencing a period of significant change. Healthcare professionals are faced with the unenviable task of improving patient outcomes while simultaneously minimising costs associated with the delivery of care. There is an urgent need to maintain and improve the availability of healthcare that is “safe, effective, patient-centred, and provides timely, efficient, and equitable care that does not vary in quality across the nation” (Park and Jayaraman, 2003, pg. 42). It is in light of these demands that the industry has increasingly sought to move patient care to the least expensive setting without compromising quality (Park and Jayaraman, 2010). In part, this is now possible thanks to improvements in portable medical devices (Chan et al., 2012). Mobile Health (mHealth) represents a seminal advancement in healthcare delivery and overcomes the previous limitations of Electronic Health (eHealth) devices which were bounded to their physical location i.e. desktop telemedicine platforms. In particular, Wearable Vital Sign Technology (WVST) systems are at the forefront of developments in mHealth.

Supporting LIFE project (http://www.supportinglife.eu/) is the development of a mobile Android application (known as SL eCCM) to help community health workers diagnose and treat potentially fatal childhood illnesses, more specifically children from 2 months to 5 years of age in Low and Middle-Income Countries (LMIC). The application digitises the widely accepted WHO/UNICEF paper based guidelines known as Community Case Management. The application promotes adherence by medical practitioners using the device by giving them an accurate support system which helps remove the possibility for human error. For children in LMICs, a wide variety of physiological variables could potentially be measured by WVSTs including the more commonly measured vital signs such as heart rate, breathing rate, temperature, as well as additional vital signs such as pulse oxygenation, capillary refill time, and blood pressure. Other key variables that could be of value to measure in such settings might include weight or other growth parameters (malnutrition). In children, several physiological variables have different normal ranges to that of adults, including weight and height, but also heart rate, breathing rate, and blood pressure (Fleming et al., 2011; WHO, 2014). Other vital signs have similar thresholds to adults, such as pulse oxygenation and temperature. Therefore systems designed for children have additional complexity of numerous thresholds for different age groups. Added to this, is the issue that several physiological variables interact, therefore WVSTs and associated Clinical Decision Support Systems (CDSS) also potentially have to consider the inclusion of such interactions in data processing and user interfaces.

A review of existing literature shows a dearth of research on sensors aimed at capturing vital signs of sick children in LMIC. In addition, commercially available WVSTs on the marketplace have predominantly been developed for adult use. Therefore, further research in this area is essential to support future sustainable development goals, whose aim it is to reduce mortality rates and promote growth and development among children under 5 years of age in developing countries (Griggs et al., 2013). The objective of this report is to conduct a state of the art of WVST systems with specific focus on those technologies pursuing or having recently received Food and Drug Administration (FDA) approval for use on children aged between 2 months and 5 years. This report is structured as follows: Section 2 describes the role mHealth, WVST sensors, and CDSS play in the diagnosis and treatment of sick children in developing countries. Section 3 describes the methodology for conducting a market analysis of sensors focused on children aged between 2 months and 5 years. Section 4 presents the findings from the market analysis and considers the findings in relation to extant literature, respectively. This report concludes with a call to action for manufacturers and academics in the WVST field.

2 Theoretical Grounding

2.1 EHealth

The application of IT in the healthcare domain (commonly referred to as electronic or eHealth) has received a lot of attention over the last decade. The eHealth phenomenon rose from the introduction of governmental incentives/programs (Bardhan and Thouin, 2013) and attempts at reducing the rising costs of healthcare (Heart et al., 2011). The delivery of healthcare services has evolved from using paper-based approaches to stationary desktop IT right through to mobile health (mHealth). A review of the literature reveals that mHealth initiatives in developing countries range from disease surveillance and control, emergency response systems, human resource coordination, management and supervision, m-learning to health services monitoring and reporting (Mechael, 2010). Yet, the impact of mHealth has yet to be fully realised (Black et al., 2011; Payton et al., 2011), primarily in LMIC (Avergou, 2008; Varshney 2011) and more specifically in the area of Wearable Vital Sign Sensor systems (Yetisen, 2014).

Information and Communication Technology for Development (ICT4D or ICT4Dev) is a global initiative which seeks to generate sustainable development among LMIC through the effective utilisation of Information Communication Technology (ICT) (Unwin, 2008). ICT4D has a wide scope encompassing the use of ICT solutions in areas such as healthcare, education, and gender equality; however, the overall objective remains to foster economic and socio-economic growth in marginalised communities across the world (Heeks, 2008; Unwin, 2008). In particular, the Supporting LIFE project embodies the goals of ICT4D 2.0 in seeking to utilise mobile ICT solutions to address the healthcare challenges present in low resource communities. According to Heeks (2008, pg. 28) mobile telephony “already reaches out to more than half the African population” and therefore the author recommends that future efforts in the area of ICT4D should focus on mobile technology platforms rather than the prior emphasis on desktop PC based solutions, which have failed to gain traction in low resource communities. From the perspective of the Supporting LIFE (SL) project, ICT4D offers a model for deploying ICT solutions in developing nations and provides useful examples of how ICT can address healthcare challenges present in developing nations (Unwin, 2008). For low resource settings in particular, it is critical to be able to demonstrate improvements in patient outcomes, given the severe resource limitations and the competing demands on limited healthcare budgets. On the other hand, the severe health workforce shortages in many LMICs may provide a greater incentive in attempting to partially attenuate such shortages using WVST systems and CDSS.

2.2 An Overview of Wearable Vital Sign Technology (WVST) Systems

Wearable Vital Sign Technology (WVST) systems are a type of mHealth platform that allow a patient’s “physiological functions, daily activities, and individual behaviours” to be monitored unobtrusively and in an ambulatory setting (Chan et al., 2012, pg. 139). WVST can also interface with centralised Information Systems (IS) to overcome the hardware limitations of WVST devices and extend the processing capabilities available to stakeholders (Hanson et al., 2009). In turn, the decision making processes of medical practitioners can be supported by the sophisticated data analytic functionality afforded by IS solutions such as CDSS (Chan et al., 2012; Hanson et al., 2009). WVST and CDSS potentially enable major improvements in preventative health through proactive monitoring of patient data and early warning of complications or deteriorations, with the potential to then reduce costs and improve clinical outcomes (Yuce, 2010). For instance, sensor technology can continuously monitor a patient’s physiological parameters and alert stakeholders (e.g. caregivers, patient, their family, researchers, General Practitioners, doctors, nurses, caregivers, medical centres, emergency services, and other health practitioners) to the presence of worsening status, before further deterioration and the need for emergency care. WVST could consist of a solitary, multi-parameter body area sensor solution or suite of compatible solutions which measure key vital signs. WVST biosensors can take several forms such as a wearable patch sensors, smart clothing, portable accessories (jewellery), implantable devices, in vivo sensors and swallowable capsules (Chan et al., 2012). These sensors are then connected to a Central Processing Unit (CPU) e.g. smartphone, using short range communication standards such as Bluetooth or Zigbee, with the central processing unit acting as a hub where data is gathered and stored (Cao et al., 2009, Montón et al., 2008). The quantitative data recorded is aggregated and transferred in real time or intermittently from the CPU to a centralised IS using short or long range communication standards.

Community Health Workers (CHW) in LMICs could use a CDSS to analyse the physiological data recorded by a WVST and compare it against the threshold value chart for the child's age bracket (WHO, 2014). Abnormal vital sign values might indicate that the child is sick or their condition is deteriorating and they are in need of medical attention. For instance, if a child's heart rate, respiratory rate, and body temperature were above the normal threshold value for their age it is possible that the child has a fever and they may have contracted malaria (WHO, 2014). Based on the assessment of the sensor data, the child's caretaker might be advised to visit their nearest first level health facility immediately or at a later date, depending on how sick the child is. Further diagnosis of the child's condition can be carried out during a face to face consultation i.e. where a CHW checks for the three danger signs (i.e. "is the child able to drink or breastfeed, does the child vomit everything, has the child had convulsions"), and measures the child's weight against a growth chart (WHO, 2009, pg. 15).

2.3 Clinical Importance of WVST Systems for Children

WVST systems for children have several unique challenges. Vital signs are key physiological parameters that form part of both the initial assessment of children presenting with acute illness, as well as a way of monitoring their ongoing severity, response to treatment, and need for either more intensive treatments or discharge home. In the acute setting, vital signs ideally provide an objective way that should complement rather than replace more subjective clinical assessments. The interpretation of vital sign values is a critical question, even with a given threshold, as it is important to know what that means in terms of diagnosis of a clinical disease. Having a threshold that is too low risks over diagnosing i.e. incorrectly defining a child as 'unwell' (e.g. pneumonia, malaria, sepsis), whereas having a threshold that is too high risks missing children who are 'sick', hence the level of threshold and what it signifies in terms of underlying clinical disease needs to be embedded into the WVST system and CDSS. Further to this, clinical needs may vary depending on the setting, necessitating tradeoffs between sensitivity and specificity, so that in first contact settings (e.g. primary care or community clinics) there is a need to identify all children who could possibly be sick, and there is low tolerance for missing any children, to the expense of reduced specificity. In higher acute settings where the pre-test probability of serious illness is much higher, the clinical goal may switch to 'ruling in' serious illness. WVST systems and CDSS need to consider these issues to ensure that the functionality offered to practitioners meets contextual requirements. As there are very few clinical signs which individually are highly predictive of a clinical outcome (with notable exceptions), clinicians must rely on combinations of clinical signs. WVST systems and CDSS for children that use vital signs need to mirror this, in that there are few vital signs that individually are likely to be highly predictive of a particular outcome, but rather it is a combination of certain vital signs that together yield greater diagnostic value. Related to this, some vital signs change based on the level of a different one, so for example both breathing rate and particularly heart rate increase with temperature, so clinicians in the SL team have quantified this interaction (Thompson et al., 2009; Nijman et al. 2012). These two issues (using combinations of vital signs, and the interactions between vital signs) are concerns where the processing and user interface of a WVST system and CDSS can markedly facilitate the presentation of vital signs values to clinicians by using algorithms to combine vital signs (e.g. in clinical prediction rules) or to deal with their interactions.

2.4 Technical Importance of FCC/FDA Approval for Sensor Use

The widespread adoption of mobile medical devices specifically mobile applications and WVST technology has heightened the discourse vis-à-vis Federal Communications Commission (FCC)/FDA approval when considering the use of these technologies in the field. FDA approval provides a high level of assurance that the WVST system is considered safe and effective for its intended use (FDA, 2014). Given the stringent regulatory standards employed during the FDA evaluation process, approved medical devices are far less likely to cause harm to the user compared to unapproved devices. FCC approval offers assurance that a radio-frequency emitting device does not cause harmful electromagnetic interference to other radio communications (FCC, 2013). It is important that a WVST device is FCC approved to prevent the risk of harmful interference from other radio communications that are active in the surrounding environment (Cao et al., 2009; Yuce, 2010).

3 Methodology

The research objective of this report is to conduct a state of the art review of WVST systems with specific focus on those technologies approved for use on children aged between 2 months and 5 years. The review of WVSS conducted for the purpose of this paper focused solely on FDA approved and/or FCC compliant sensors which are available currently on the marketplace. As a result, any sensors currently under development or seeking approval are excluded in this study. These selection criterion align the European funded Supporting LIFE project's efforts with the World Health Organisation's (WHO) Community Case Management (CCM) guidelines (WHO, 2014). CCM specifically focuses on improving access to and efficacy of healthcare treatment for children aged between 2 months and 5 years in low resource communities (WHO, 2014). The Supporting LIFE Android application (SL eCCM) is underpinned by a CDSS, codifying the WHO's traditionally paper-based CCM guidelines in a codebase rule engine to support CHW assessment and treatment of children in Malawi, Africa. From the outset, WVST integration was identified by the SL team as an integral requirement of the SL eCCM. Subsequently, sensors were investigated to further understand how this type of technology may be used in conjunction with the mobile application to accurately capture infant vital signs e.g. heart rate, breathing rate, as per the CCM guidelines, in low resource settings.

A review of extant sensors was performed using criteria from Pantelopoulos and Bourbakis (2010):

1) their ability to measure multiple parameters;
2) the amount and the detail level of their provided documentation; (i.e. technical description)
3) the frequency of their citation by other projects;
4) the extent to which they utilise state-of-the-art hardware technologies; and
5) the incorporation of intelligent algorithms for feature extraction and/or decision support.

These criteria were further extended to include age suitability and disposability of the product. The age suitability criterion was added to ensure that the sensors were appropriately designed for use on children aged between 2 months and 5 years. The disposability of the product criterion examined whether WVST and its associated paraphernalia had a maximum service life and requires replacement once the serviceable life is exceeded. As SL eCCM is developed for Android, only sensors compatible with the Android operating system were selected. Currently, healthcare practitioners in LMICs often face shortages of apparatus to sufficiently deliver healthcare services at the point-of-care (Chin et al., 2007) with some healthcare equipment considered to be outdated (Yetisen, 2014). Android WVST would complement extant mHealth applications by having reliable tools readily available to the community health worker.

Despite the numerous academic endeavours which have been undertaken in the WVST system domain, there are comparatively few WVST systems available to purchase on the market. Nevertheless, seven suitable WVST systems were found and included in the market analysis. These commercial WVST products were identified from literature, Google's search engine, and the website of WVST supplier Vivonoetics (www.vivonoetics.com).

4 Findings: Market Analysis of Extant Sensors

Table 1 presents seven WVSS identified by our research team which can be utilised on children.

Product	Bio Harness	Corscience's WVSS	EQ02	BioRadio	Onyx II Model 9560	WristOx2 Model 3150	Wearable Wellness System
1. WVSS Product Information							
Age Suitability	✓	✓	✓	To be confirmed	✓	✓	✓
Citations	Science Direct: 23 Scopus: 6 PubMed: 4	Science Direct: 10 Scopus: 4 IEEE: 3	Science Direct: 9 Scopus: 5	Science Direct: 11 Scopus: 9 IEEE: 5	Science Direct: 30 Scopus: 2 IEEE: 1	None	Science Direct: 1
Compliance	FCC Compliant	FDA Compliant	FDA Compliant	FCC Compliant	FCC Compliant	FCC Compliant	×
Non-disposable	✓	✓	✓	✓	✓	✓	✓
No disposable equipment	✓		✓		✓	✓	✓
2. Sensor Measurement Functionality							
Pulse	✓	✓	✓	✓	✓	✓	✓
Respiratory rate	✓	×	✓	✓	×	×	✓
Sp02	×	✓	✓	✓	✓	✓	×
Temp	×	×	✓	✓	×	×	×
3. WVSS Hardware Specifications							
USB	✓	✓	✓	✓		✓	✓
Bluetooth	✓	✓	✓	✓	✓	✓	✓
SD Card		✓	✓				✓
On device storage capacity	500+ hours typical logging capacity	128MB RAM 256MB Flash	8GB memory gives up to 1,200 hrs.	4 GB, 8 hours recording time	Min 20 single point measure	270 hrs recording, 1080 hrs.	2GB, 432 hrs. recording time
Battery life	26 Hours per charge	4.2V DC-IN power supply. 3W power rate	48hrs battery	8 hrs. battery, 3-4 hour recharging	~ 600 spot checks on 2 AAA batteries	48 hrs. no Bluetooth, 24 hrs. Bluetooth	>24 hours recording, 10 hours Bluetooth

Corscience (2014) WVST, available at: corscience.de/en/medical-engineering/products/multiparameter.html (Accessed 2 Sept 2014)
Equivital (2014), EQ02 LifeMonitor, available at: http://www.equivital.co.uk/products/tnr/sense-and-transmit (Accessed 3 Sept 2014)
GL Neuro Tech (2014), BioRadio™, available at: glneurotech.com/bioradio/ (Accessed 3 September 2014)
Nonin (2014a), Onyx II 9560, available at: www.nonin.com/PulseOximetry/Wireless/Onyx9560 (Accessed 10 Sept 2014)
Nonin (2014b), WristOx2 3150, available at: www.nonin.com/OEMSolutions/WristOx2-Model-3150-OEM (Accessed 10 Sept 2014)
Smartex (2014), WWS, available at: www.smartex.it/index.php/en/products/wearable-wellness-system (Accessed 5 Sept 2014)
Zephyr (2014), BioHarness™ 3, available at: zephyranywhere.com/products/bioharness-3/ (Accessed 2 Sept 2014)

Table 1. Market Analysis of Extant Sensors

Our findings reveal that the marketplace to date is inundated with sensors primarily targeted for adult consumption. These sensors are deemed unsuitable for the assessment of vital signs in infants as their design is unlikely to fit properly which could lead to sensor displacement and compromised data quality (Hanson et al., 2009). Therefore, our market analysis is limited to the seven WVSS products suitable for infants aged between 2 months to 5 years. The research team first carried out a keyword search of each product name using databases such as Google Scholar and Web of Science to count the citations received by each WVST. Academic citations were investigated to determine whether the products had been used in previous studies and could be examined as part of this research. Both BioHarness and Onyx II WVST received the highest number of citations (33), while WristOx2 was the only product that had not been cited to date. An examination of product literature showed that all WVSTs with the exception of Wearable Wellness System are FCC or FDA approbed. In addition, all seven products meet the non-disposable criteria; however, Corscience's WVST and BioRadio require disposable paraphernalia. To meet the project’s objectives, sensors should be able to measure numerous parameters such as child’s heart rate (beats/min), respiratory rate (breaths/min), SpO2, and body temperature. The findings reveal that two (i.e. EQ02 and BioRadio) from the seven sensors capture all four vital sign measurements. A minimum of two vital signs are captured with pulse being consistently captured across all sensors. From the ‘hardware specification’ perspective the findings show that USB and Bluetooth connectivity are most favourable across the sensors for communicating with Android mHealth applications. EQ02 and WristOx2 offer optimal levels of on-device storage with logging times of >1,000 hours whereas BioRadio offers 8 hours; three WVSTs use a SD card slot for storage. Battery life also ranges across the devices with most sensors achieving a minimum of 24 hours of use. BioRadio is considered the poorest device in terms of battery performance with only 8 hours of battery life. Future developments of mobile-based solutions should attempt to capture all four vital signs while ensuring longevity of battery performance.

This emphasises the significant opportunity to develop a multi-vital sign WVST suitable for Android smartphone integration appropriate for use with infants and younger children. The lack of open Application Programming Interface (API), Android compatible technologies with FDA approval available specifically for the measurement of infant vital signs may be attributed to the difficulties associated with both the clinical (WHO, 2009) and technical (Hanson et al., 2009) issues in these circumstances. In addition, there is a dearth of empirical research on the use of WVST and CDSS for monitoring the vital signs of children in LMIC, an area which warrants further study to address the inherent clinical and technical challenges that may inhibit further progress in the area.

4.1 Conclusions

This paper has discussed how WVST technology and CDSS may be leveraged as a means to address the prevailing challenges related to the management of childhood illnesses in LMIC. The affordances offered by WVST and CDSS create opportunities for monitoring infant vital signs in the least expensive setting using ambulatory solutions that are highly accurate (Chan et al., 2012). This could in turn help address the goals of ICT4D by utilising the aforementioned ICT solutions to improve the standard of paediatric healthcare in developing nations. However, there remains a paucity of empirical research in the use of WVST for vital sign assessment amongst young children in low resources settings (Latré et al., 2011; Pantelopolous & Bourbakis, 2010). In addition, an investigation of the commercial WVSTs available on the marketplace suggests that that no one suitable product exists which meets the requirements of the Supporting LIFE project. Therefore, it is important to highlight the gap that currently exists in the marketplace and call on WVST producers to develop solutions which are designed specifically for usage by children aged between 2 months and 5 years to serve the needs of medical practitioners in low resource settings. To achieve this goal, partnerships could be formed between manufacturers, academics, and practitioners (i.e. CHWs, Ministries of Health) in order to identify potential issues that exist in the field and develop solutions that meet these challenges. The market analysis was conducted solely on desk research, which may be considered a limitation of this study. Further research should focus on understanding practitioner’s (both clinical and technical) unique requirements for appropriate, technically compatible WVST and CDSS solutions. Another potential limitation of this paper is that a systematic review of WVST literature was not undertaken; therefore, it may be necessary to undertake a systematic review to ensure that all relevant publications are considered as part of on-going research.

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