Innovative Framework Requirements for Remote Maternal and Fetal Health Monitoring in Low Resource Settings: Mobile Phones & Medical Devices

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Abstract

Technological advancement is changing the face of remote fetal monitoring in pregnant women. This has also seen a number of proprietary applications and standards evolving to integrated standards where various remote monitoring applications communicate with each other beyond boundaries. This is anticipated to improve access to patient information, individual health monitoring, reduce errors and increase evidence-based care delivery and continuous flow of healthcare information, in and out of the remote, marginalized communities. This paper describes FHR monitoring techniques in brief as well as various interferences which affect FECG when using these techniques for remote fetal heart rate monitoring. This paper further recommends a standard framework for remote fetal health monitoring and explains in details the requirements for the proposed framework.

Keywords: *FECG, FHR, Healthcare Information, Low Resource Setting, Mobile Applications*

1. Introduction

The Fetal electrocardiogram (FECG) signal contains potentially precise information that could assist clinicians in making more accurate and timely decisions during pregnancy. The condition of the fetus such as fetal life, fetal development, fetal maturity, and existence of fetal distress or congenital heart disease, is mainly determined through various features of FECG such as heart rate, waveform, and dynamic behavior [1]. As the fetus responds to different conditions, the fetal heart rate also changes. Electronic fetal monitoring can be invasive or non-invasive. Invasive, uses electrocardiogram (ECG) signal obtained from an internal scalp electrode. Although, this method is widely used in health industry to examine the condition of the fetus because of its accuracy, it has its flaws and it is a potential risk to the fetus as well [1]. Additionally, they are non-invasive methods which are conducted external, they exists examples such as intrauterine ECG (IuECG) which uses intrauterine electrodes that come into contact with the fetal skin [2]. The main disadvantage of this method is that it contains both maternal and fetal components. As a result, different signal processing algorithms are required to detect and separate fetal signals from the composite abdominal signals.

2. FHR Monitoring Methods

FECG signal is a function of time and is describable in terms of its amplitude, frequency, and phase, where it is used to give electrical representation of FHR to obtain the vital information about the condition of the fetus during pregnancy from the recordings on the mother's body surface [3]. It lies in the range from 1.3 to 3.5 Hz and it is generally weaker by less than 20% of the mother ECG [4]. It resembles the adult ECG, containing the same basic waveforms including:

- P wave, which occurs at the beginning of the aerial contraction.
- QRS complex, which is reliable due to the size of the R wave and it is basically associated with the contraction of the ventricles.
- T wave, which follows each heart contraction and corresponds to the re-polarization phase.

In analysis of the FECG signals, things of interest are the shape, size, and duration of individual and groups of FECG waveforms together with the various ratios relating these quantities to each other. Vital information concerning the condition of the heartbeat, is then determined through R–R interval which leads to the heart beat frequency. Figure 1 below, shows the key features: the PQRST complex.

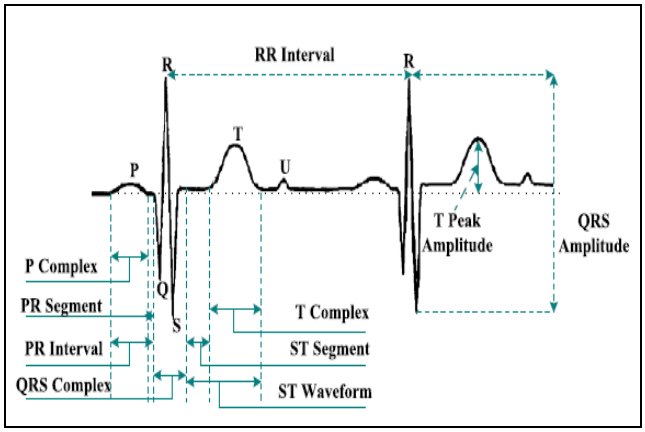

Figure 1: Key features of FECG: the PQRST complex.

Fetal heart rate monitoring is used as a screening procedure of the fetus to detect in advance possible fetal complications that could result in irreversible damage or even fetal death during pregnancy. As a result, it has been classified that there are two methods of FHR monitoring during pregnancy and are as follows [2] [4]:

2.1 Auscultation

This method involves the listening of the fetal heart beat from the mother's abdomen using:

- An ultra-Doppler device, which is a small device that is put against mother's abdomen. This device, converts sound waves into signals of fetal heartbeat.
- A Fetoscope, which is placed into the ears of the clinicians. Fetoscope is similar to the stethoscope and it allows the heartbeat of the fetus to be clearly heard.

2.2 Electronic Fetal Monitoring

This method is the better option if abnormal patterns are found in auscultation method. It provides a continuous record of the fetal heart rate behaviour of the fetus and it uses special equipment to measure the response of the FHR to contractions of the uterus. Electronic fetal monitoring can either be:

- *Invasive (internal monitoring),* where a small plastic device is placed through the cervix and the fetal scalp electrode, used for transmitting direct information about the fetal heart rate through a wire to the fetal monitor that prints out this information, is placed just beneath the skin of the fetal scalp. As a result, this method has proven to give more clearer and consistent FHR signal because of its direct attachment to the fetus. However, there may be a slight risk of infection or cause a mark or small cut on the fetus' head.
- Non-Invasive (External monitoring), requires sensitive electrodes or devices are placed over the mother's abdomen and senses both FHR and the strength and duration of uterine contractions. The non-stress and the contraction tests are examples of non-invasive electronic fetal monitoring. Devices such as portable ultra-Doppler device and Fetoscope can be used during this method. As yet, they are no known risks of using these devices for FHR monitoring. As for this project, a portable ultra sound Doppler device would be used for FHR monitoring.

The majority of FHR analysis techniques exist, although the Doppler ultrasound and the abdominal FECG are the most viable options [2]. These two have proven to be the most reliable techniques for the monitoring of FHR. However, they have their shortfalls. For instances, a Doppler ultrasound require intermittent repositioning of the transducer and they are only suitable for use with highly trained personnel [2]. It is vastly sensitive to movement; as a result, it is inappropriate for long-term monitoring of the FHR, as it requires the patients to be bed-rested. Additionally, the detection of the fetal heart rate using the ultra-Doppler sound depends on the mechanical movement of the heart. Therefore, this method is not as accurate for beat-to-beat analysis as detection of the QRS complex. This makes Doppler devices FHR monitoring to be dependent on some form of averaging and signal processing algorithms to produce close to accurate FHR data.

In contrast, techniques using abdominal recordings have a greater prospect for long-term monitoring of FHR and also has a very low signal-to-noise ratio (SNR) because of the interference caused by MECG, electromyogram (EMG), and motion artifact in determining the FHR from the AECG signal [2]. The following section presents various signal interferences affecting remote fetal health monitoring in low resource settings.

3. Signal Detection and Extraction

When detecting FHR, two useful approaches can be taken into account and these are peak detection and a transform method [5]. The peak detection method allows a small portion of the FECG to be observed at a time and searched for the fetal R wave [5]. Results achieved, depends on the algorithm used and local SNR in the FECG portion. The varying nature of AECG signal makes the local SNR value to fluctuate about the SNR value of the entire signal and

this sometimes is smaller. As a result, some peaks are missed while applying peak detection methods to noisy FECG signals. On the other hand, the use of the transform method, a new function of one or more parameters, is generated from the historical signal [5].

A property of the entire signal is represented by each value of the new function. As a result, each value depends not on the local SNR but on the SNR of the entire signal. Therefore, when the peak detection algorithm fails to detect due to noise interferences on the FECG, a transform method might still detect the FHR. However, in non-invasive recording of the FECG, most of the signal-processing algorithms detect only the R waves. This allows the P and T waves to be left out since they are hidden. It is still possible to identify some signals within a time series which occur periodically even though hidden, through a regular transform method called Fourier transform.

Table 1 in ***Appendix A*** presents FECG signal detection, processing for extraction and separation where various methods of achieving this including their advantages and disadvantages are elaborated.

After detection, the extraction of FECG is very important from a clinical point of view to achieve reliable fetal status results. The condition of the fetus can be determined through responses of the fetal heart to the uterine contractions [6]. However, monitoring the FECG during these contractions is a complicated task because of very poor SNR. For accurate and reliable results on the nature of the fetus, the following characteristics need to be obtained from the FECG extraction [6] [7] [8]:

- FHR
- Amplitude of the different waves
- Duration of the waves

4. Technical and Resource Requirements

4.1 Requirements at Patient Level

Remotely located patients must have some form of a monitoring apparatus. These apparatus come in different types and from different vendors exhibiting unique characteristics:

- One common one consists of a device with a central messaging station which can be connected to a mobile phone with GPRS connectivity or may have a modem built in. The clinician can leave personalized video or text messages for patients. Patients can follow prescribed precaution measures or diagnosis and also view educational material delivered as video-on-demand.
- Monitoring apparatus must allow for communication between the clinician and the patient. The key benefit of remote monitoring is the ability for patients to communicate with clinicians without having to travel long distances.
- Additionally, they are peripheral monitoring devices which are also essential in connecting with base stations so that remote connection can be possible. These peripheral devices depend on the patient's condition and they include fetal heart rate monitors, sphygmomanometers (blood pressure cuffs), pulse oximeters (measuring heart rate and blood oxygen level), scales, blood-glucose measurement, peak-airflow measurement, or wound photography using phone camera. These devices may either connect direct wirelessly to a remote server or through a Bluetooth-enabled cell phone. The cell phone will connect to a remote server through GPRS or 3G technologies depending on the type of a phone. Figure 2 below shows how these peripheral devices can be integrated to mobile phone and send data to remote clinicians for diagnosis.

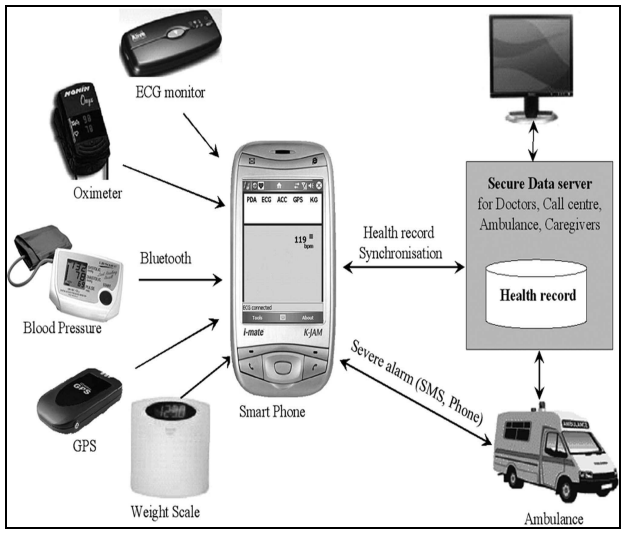

Figure 2: Peripheral devices connecting through phone

- These remote apparatus or devices must be able to send data to a remote server whether synchronous or asynchronous.
- The existence of ubiquitous and widespread of broadband connections in most areas allows for continuous monitoring of patients in remote areas by clinicians and care givers in larger hospitals.

- Finally, the usage of cost effective apparatus on patient side is emphasized so as to minimize all relevant costs.

4.2 Requirements at the Clinician Level

Clinicians have a responsibility of diagnosing whatever information they receive from patient side and offer referrals. To achieve this, the clinicians require:

- Extensively knowledge on fetal and maternal related issues.
- They need to have computer hardware and software for collecting the information from remote monitoring available so that they can make quick diagnosis of complications and decisions. In this project, a remote monitoring application using OpenMRS can reside in a centralized hospital servers where among other tasks the diagnosis is performed by specialists and decisions made as to whether the pregnant mother should be referred.
- Clinicians will view patient data via web browsers on the server or software bundled within the mobile application since they have administrator privileges.
- Again, the clinicians in large hospitals require increased bandwidth and reliable connectivity. This will facilitate in continuous monitoring of different patients at once and also improve data loss.
- Security and confidentiality of patient data is also a measure which should be given high attention. Clinicians have to make sure that patient information is secure at all times.
- Organizational investment and leadership is also another requirement at the clinician level that should be taken into consideration so as to increase productivity.
- Usage of interoperable technologies allows information flow and continuous patient care between different health providers.
- Another vital requirement is investing in training on clinicians so that they have relevant knowledge to deal with different scenarios.
- Lastly, technical expertise must be available to set up and maintain these systems.

4.3 Requirements for provider to provider remote monitoring

Basically this type of remote monitoring would be for patients admitted in rural clinics without an intensive care unit (ICU). The only clinicians present are semi-skilled nurses or community health workers. As a result, it is necessary for remote monitoring or communication between CHW and skilled personnel or clinicians in large urban hospitals to correctly provide medication and knowledge pertaining the patient's condition. Skilled personnel monitor ICU patients' vital signs through a remote monitoring system and contact on-duty CHW. Therefore, the requirements in this scenario should be of:

- High quality and continuous
- The monitoring equipment should provide real time feedback and must be highly reliable.
- The connectivity has to be robust, with minimal delays or free disruptions and ubiquitous.

5. Data Management Considerations

To recognize the benefits of personal medical devices, a number of information management questions that providers must answer when implementing these devices is given below.

How are patients identified by personal medical devices? It is critical to determine how these devices interface with electronic health record (EHR). Identity traits should be provided by clinicians so as to ensure that the master patient index (MPI) used, correlate to the identity traits being used by the device. Once this is implemented correctly, because of slightly varying MPIs, correct data would be captured and transferred to correct individual patient record in the HER for storage.

Is the date and time synchronized by the personal medical device? Some patients using personal medical devices are always travelling or mobile. As a result, it is critical for the devices to record the date and time of the area in which the patient is located as well as the local time the data was received. This would make it easy to determine when and what information or data was captured and made available to the clinician to make clinical decisions. Such a measure is critical for legal health record perception.

Does the personal medical device provide any type of audit trail or not? Even though the primary goal of medical devices is data capturing, metadata, decision support logic and audit information must be recorded as well so as to know who captured the data and when. Decision support logic rules will determine why certain data may or may not have been transferred to the provider. Policies and measures should be implemented if ever the device does not support the capability of capturing some or all of this information.

Is authentication provided by the personal medical device? One can define authentication as a security mechanism of verifying a user's identity. Once the user is recognized as an authorized or legitimate, authentication

assigns responsibility and privilege for the user to manipulate data. If authentication is not offered by the device, it is the responsibility of the organization to ensure that data cannot be manipulated or altered once captured. This can be done through setting policies.

What are the different ways of transmitting data and when will that occur? There are two primary ways in which data can transmit from the device to the care providers:

- *Store and forward*: Data is recorded and stored within the device. It will be transmitted to the care givers when necessary. The user can do this manually after the device has maintained readings overtime. In some cases, the CHW or the application performs editing of the information based on clinical relevance and only transfer what is medically essential.
- *Streaming*: The transmission of data is done in real time that is sent immediately to a provider after being captured.

The best method of data transmission will depend largely on the individual patient scenario and capability of the specific device. However, organizations should also consider the capabilities and limitations of their own systems in terms of whether they can handle the volume of data being sent through the device.

Is privacy and security provided? Data encryption on devices and anywhere is critical because patients' information should remain confidentially always. Transmitting data over wireless requires certain security precautions being implemented to avoid data inception or phishing. As a result, various policies and measures should be implemented to ensure sufficient security (e.g., encryption) in each of the various interfaces through which data is transmitted.

Are they ways in place for destroying data in the device? There must be a plan in place to ensure that all information on the device is properly destroyed. Policies should be implemented to address the issue of data retention on the device after it has been sent to the EHR and before they can be overwritten or otherwise destroyed. Data would need to be retrieved for validation or legal reason sometimes. Therefore, the question of retention is critical.

What is the contingency plan? Personal medical device, like any other technology do fail. As a result, different measures and precautions should be in place to handle these failures, particularly when the information captured on the device is a critical part of the patient's continual care. For example, when a glucose monitor fails for a patient who is a brittle diabetic, the hospital may require that patient come on site.

6. Medical Device Considerations

To determine the best and appropriate FHR monitoring device to use in low resource settings, various factors need to be considered first. These factors have been categorized as technical, operational and economic and are given in the following section.

6.1 Technical Considerations

Technical considerations are vital when one is purchasing a fetal heart rate monitoring device. One has to understand how the device works. This can viewed from the user manual. Again, the basic knowledge associated with problems of inaccuracy is required. External factors such as mechanical shock, to wear and tear of moving parts may cause inaccurate measurements. As a result, it requires strategic consideration of how to eliminate these inaccuracies e.g.

- Proprietary algorithms are used to calculate fetal heart rates and to achieve close to accurate results depending on the algorithm employed.
- Errors can also arise from the devices or the observer. Such errors can be minimized by good training and adherence to recognized protocols and procedure.
- Good equipment management can also reduce device errors in measurements.

6.2 Operational Considerations

When selecting a device, user needs have to be taken into account. It is very important to consider what the users want and expect otherwise the technology will be rejected. One has to consider various characteristics of the device such as:

- Does the device have additional features other monitoring FHR like connectivity to the printer, Bluetooth enabled or can supply software to facilitate the transfer of stored data via a USB port?
- Determine if the device has connection for mains adaptor and does it have backlight on the monitor.
- Determine if they is not unlikely of storage problem since majority of them are small and light in weight.
- Look at the servicing costs, that is determining if the supplier provides fixed servicing cost or not.
- Purchase a clinically validated device so as to have accurate and reliable results.

6.3 Economic Considerations

Users have to consider various economic related factors so as to achieve best value buying a low cost FHR monitoring device and some of these factors are as follows:

- Determine if additional accessories required to use the monitoring device are supplied at an extra cost.
- Determine if consumables such as batteries are obtained locally or the devices require special batteries that need to be imported.
- The usage of devices does require special training.
- Consider the warranty of the devices as it differs from different vendors.

6. Medical Device Considerations

The proposed framework shown in ***Appendix B*** provides an approach to efficiently manage and transfer FHR signals and XML messages by means of intelligent algorithms deployed in application. Additionally, the framework uses these algorithms also to efficiently manage media content, in the form of audio, text and image files. The efficiency provided by the proposed framework lies within the functionality of its four main components, and the interaction between these components.

7.1 Doppler Device Component

The Doppler FHR monitoring device records FHR in form of ultra sound signals which are recorded in mp4 format then converted to wave file format. The device is either Bluetooth enabled and uses JSR-82, JSR-256 or JSR-257 specification for Bluetooth connectivity or it outputs the Doppler FHR amplitude signal in waveform through the headphone jack. This unit connects the biological acquisition device to the MIDlet software running on the patient's mobile unit. The FHR monitoring devices are selected so that they would allow the proposed system to use the existing properties and functions of the medical devices and does not affect the implementation of the device. It is not required to re-engineer the medical device's embedded software to be compatible with the system.

7.2 Signal Extraction and Pre-processing Component

Doppler ultrasound signal is processed on this component. This is achieved through detection and extraction of FECG signals by using powerful and advanced methodologies and algorithms. The best algorithms in terms of low processing overhead and high accuracy would be manipulated and implemented in this application. Again, due to processor limitations on mobile phones, the raw signal would the re-sampled by setting the scale to an optimum trade-off condition – accuracy versus performance speed. Within this component, exists, a scheduling module responsible for assigning and checking which process would be executed next depending on the service requested. This component has a status converter, which checks if they is connectivity problem or good communication and the application is ready to use. It shows various device statuses in terms of online and offline statuses. After, all processing stages are complete; the application allows preliminary estimation of FHR and displays the results on the phone screen.

7.3 User Interaction Component

This component provides the basic functionality for registration, Service request and Service display. The Registration Module provides methods for collecting the information required to build the distinct User Profiles and Phone Profiles, which are stored into the central patient repository and can be accessed anywhere and anytime by authorized medical personnel. On the other hand, the Service Request Module provides generic functionality to request and invoke a Service and this is done by communicating with the backend server through the service directory and invoking the required service. The Service Viewer shows the services offered by the application, of which a patient can select from. These services are user login functionality, data uploading to a backend server, FHR monitoring and fetal activity tracking. The application is designed to provide a simple, user friendly interface with graphical instructions to allow minimum assistance and training in using the application.

7.4 Remote Server Component

This component provides restricted information to the authorized medical personnel and also for storing all biological signals from the patent's unit. For implementation purposes OpenMRS, a widely used medical records framework which is also compatible with MySQL, a relational database is preferred. OpenMRS uses JAVA which is also open source and can support open standards for medical data exchange including HL7, LOINC and IXF. An adapter in form of a web service application is required to communicate with the client application. This adapter in form of a Web service application is developed in Java and runs on the backend server to receive data from the client application and communication is either through 3G or GPRS. This component has a database and backend server engine.

The database is divided into two categories, the User Profile and the Phone Profile. The User Profile stores information about the patient, such as the unique patient ID, age, race and previous patient history record. Each User Profile is mapped onto a specific Device Profile. The Device Profile stores information about the mobile device, such as the screen dimensions and storage capacity. The database provides data from the initial Service request to the Backend Server Engine and the data utilized to categorize the files according to their respective types from the requested Service.

8. Conclusions

One way of wrapping the underlying proprietary serial protocols of the medical devices for the service user, is to implement web services. Web services support both asynchronous and synchronous (request-response or remote procedure call) based communication operations. In conclusion, for effective and efficient remote fetal monitoring the proposed framework is presented in a layered protocol view. In this layered view, the remote FHR system acts as a gateway, by translating the proprietary protocol into a web services interactions. The communication between the Doppler FHR monitoring medical device and portal is done over a secured TCP/IP connection (via SSL/TLS). This proposed framework will act as a benchmark for improving healthcare in most developing rural areas of South Africa and Africa as a whole.

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Appendix A

Table 1:Signal detection and extraction

Signal	Method	Advantage/Disadvantage
Detection	**Fourier transform**	• When the FECG is obscured by noise and the peak detection algorithm fails, a transform method might still detect the FHR proficiently • SNR is averagely high • In the case of weak signals having small duty cycle, this tool might sometimes fail to detect the average periodicity because of small correlation between the signals
	Least mean square	• Feasible for fetal heart tone signature identification and analysis in the presence of background acoustic noise
	Complex continuous wavelet transform (CCWT)	• Performs well and the accuracy of the method is high • Algorithm's parameters increase the system's efficacy • Computationally fast and excels in performance • Able to extract the MHR signal, which can be useful for parallel monitoring of the mother's health
Extraction	**Wavelet transform (WT)**	• Coherent average can get more accurate reference • Can be obtained to smooth the baseline drift • Requires only one abdominal signal for fetal QRS extraction and maternal QRS cancellation • More flexible and effective tool for FHR signals de-noising than the traditional filtering techniques
	Time–frequency analysis	• Three leads are used for FECG extraction • Spectrum produced by Wigner-Ville distribution (WVD) distribution displays very good localization properties • The main drawback of the method is the difficulty to extract the fetal R peaks in noisy background or in cases where the FECG is not distinguishable
	Artificial neural networks (ANN)	• Very fast and does not involve human efforts for categorization • Neural networks can offer the computational power of non-linear techniques • Sometimes it does not estimate the exact baseline value and its precision is limited by the number of classes
	ICA and BSS	• Relatively, SNR is high • Efficient both in batch and on-line operation modes • Fast and efficient approach for the pre-processing of multiple signals of interest • No specific prior knowledge required in order to identify components generated from different sources • Often require a large number of recorded leads to reach reliable FECG extraction

Appendix B: Proposed Framework