The development of an obstetric tele-monitoring system*

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Abstract— Fetal growth restriction and preterm uterine contractions can turn a normal pregnancy into a problematic one. In previous work, we have developed a system for electrophysiological measurement of fetal heart rate (fHR), fetal electrocardiogram (fECG) and (premature) uterine contractions to enable early detection of foetal problems. In this work we have expanded this system into a tele-monitoring system for measurement at home. In order to permit home monitoring, the communication chain of the data has to be designed such that home-measured signals (fHR, fECG, uterine activities) are available in the hospital in real-time. Furthermore, the data must be transferred wirelessly to any location (worldwide) for interpretation by gynaecologists. A web application helps the gynaecologist or midwife to access the signals everywhere, provided that internet access is available. We developed a webserver as the heart of the entire system; it manages the patient database, transforms the signals in a graphical representation similar to that of the cardiotocography and manages the data communication with the proper data security policy. This tele-monitoring system can be used also during home deliveries enabling prompt transfer and proper intervention in the hospital when complications occur.

I. INTRODUCTION

There is a strong need for pregnancy monitoring systems due to the high percentage of complicated pregnancies. Ten to twenty percent of all pregnancies are complicated by preterm delivery, fetal hypoxia, fetal growth restriction or hypertension [1]. Unfortunately, the Peristat rapport shows the percentage of new-born mortality and morbidity to be relatively high even in developed countries such as the Netherlands [2]. High-risk pregnancies are usually monitored in the hospital whereby the patient needs to stay for days and sometimes even weeks. This is expensive and, moreover, the pregnant woman is isolated from her own environment.

During delivery at home, the midwife nowadays has almost no diagnostic tool to monitor the delivery (only a Doppler probe to hear the fetal heart rate is available). If complications occur, she has to refer the woman to the hospital. Subsequently the gynaecologist loses additional, critical time by a baseline measurement of the fetal and maternal condition.

Comfortable continuous monitoring would be desirable in a home setting, but the monitoring devices used nowadays are not suitable to be used at home for a long period: their use needs always professional help (midwife or nurse) to initiate and often adjust the measurement. Moreover, the measurements are only offline available and the obstetrician can see the measurement only at a later moment in the hospital. Another limitation of the available measurement devices such as the CTG (cardiotocograph) is in that their sensitivity and specificity are too low for accurate diagnosis [3]. A better measurement can be achieved only with invasive options (scalp electrode, intra-uterine pressure catheter, and fetal blood sampling) [4].

For all these reasons, a better and more comfortable measurement system is needed. Our objective is to use non-invasive electrophysiological measurements to enable comfortable home measurements and to achieve enough sensitivity for reliable diagnosis of pregnancy problems. Currently, no obstetric electrophysiological measurement system with telemonitoring is widely available.

The fECG system [6] developed by Nemo Healthcare (Eindhoven, The Netherlands) has the potential to improve fetal monitoring in a home delivery setting, as the adopted electrodes and the measurement device are far less expensive than common CTG devices, more patient-friendly, and require nearly no adjustment during the measurement. We have therefore chosen this system for the measurement and data acquisition in our study. We developed a method to

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transfer the signals wirelessly to any location for interpretation by gynaecologists. Moreover the augmented foetal ECG analysis implemented on the retrieved signals, will offer new possibilities for better diagnostics.

II. METHODS AND MATERIALS

Ideally, the optimal workflow should include the home measured patients in the obstetric data management system of the hospital and should keep the patient data in one environment, the EHR (electronic health record) system. One restriction we had to deal with was the “demilitarized” zone (DMZ) in a typical hospital, which is made to protect the hospital’s network from external attacks. Data from outside come in the DMZ through an internet server, an application database server, and through the communication platform Cloverleaf. At every step the data is controlled and authorized to go ahead. If necessary the data is blocked before it reaches the hospital network.

This construction is required in the hospital for every application that needs external access from internet. In this project, this was a too expensive solution to demonstrate our proof of concept. Therefore, we placed the webserver outside the hospital environment.

Our method consists of the following components (see fig.1): the Nemo Healthcare system, the webserver, and the web application.

- **Nemo Healthcare system.** The compact electrode patch of the Nemo Healthcare system is able to collect the electrophysiological signals (fetal heart rate, maternal heart rate, uterine contraction and fetal ECG). The compact hardware unit of the Nemo Healthcare system can acquire these signals together with identification keys and time stamps, and organizes them in files according to a predefined protocol. The wireless data transfer option of the Nemo Healthcare system transmits these files every 7.5 s to the webserver using the standard http communication protocol via Wi-Fi or 3G/4G. Each file can use a data format that contains one device-related key, 30 date/time stamp with year, month, day, hour, minutes, seconds and milliseconds, 30 EHG (electrical hysterogram) values [7], 30 fHR (foetal heart rate) values, 30 mHR (maternal heart rate) for the “CTG file”. Similarly the “AVFECG file” (average foetal ECG) can contain one device-related key, 225 date/timestamp with year, month, day hour, minutes, seconds and milliseconds, and 225 values per ECG lead (up to three independent leads). The 500 Hz sample frequency is sufficient to accurately rebuild the original foetal ECG signals. The chosen data format is not standard, but offers the possibility to show the signals with sufficient diagnostic information. The standard format will play a role only when the raw fECG will be transmitted.

- **The webservice.** The webservice is the heart of the entire system: it manages the patient database, transforms the signals in a graphical representation similar to the cardiotocography, and manages the data communication with the proper data security policy. The webserver is designed in a standard language such as PHP (PHP: Hypertext Preprocessor). The connection between the Nemo Healthcare system and the webserver has to be verified by authentication. The webserver recognises only specific file names previously defined. Only after approval the files are posted by the database. The values of the posted files are then reorganised and saved by the right database tables.

Fig.1: Schematic of the design of the communication chain. The Nemo Healthcare system, used by the patient at home, transmits via Wi-Fi the acquired and analysed signals to a webserver. At the hospital, the gynecologist can retrieve this measurement with a dedicated web application. A graphical user interface allows real time visualization of the acquired signals’ traces.
Web application. The functionalities of the web application should be developed to fit the workflow of the gynaecologist and midwives in the hospital. This application will use an authentication and rights policy to make its use protected from external malware actions. Register and login functions for the user (gynaecologist, midwife and administrator) are possible only with the use of a valid username, user email and user password (passwordhash, an encryption of the password, is here applied). The authorised user (gynaecologist, midwife) can see his/her patients and their data only. The authorised administrator can only manage the devices present at the hospital.

Insert new patients, edit existing patients, discharge patient from the patients’ list are the functions for the patients database management. Each patient receives a unique device identified by the serial number of the Nemo Healthcare system currently in use. The management of the measurements of a specific patient is possible by selecting a patient from the list and choose one of her old measurements or the live measurement. The graphical interface shows the signals stored in the database or the real-time measurements. The mapping of the signals will follow the standard cardiotocography representation with above the fetal heart rate and underneath the contraction activity. The patient’s identification key (name or hospital ID) will always be shown to avoid undesired patient identification mistakes.

The fHR and contractions activity are displayed in a 15-minute window. With the scrolling function it is possible to make measurement longer timeframe visible. For fHR values bigger than 180bpm and less than 100bpm, a warning sign is generated (the screen becomes red). The web application named OTS (obstetric tele-monitoring system) is built in PHP Storm, a framework based on the Model-Control-View architecture. The design of the web application is such that at the hospital or everywhere else the gynaecologists can see and interpret the signals via a Personal Computer or mobile device such as a tablet or a smart phone. The graphical representation will use a buffer construction to smoothly show the real time signals in blocks of 7.5s. Each signals block is first saved in a buffer. The graphical interface draws the values saved in this buffer one by one. The system is structured in order to allow an expansion with inclusion of additional relevant signals such as maternal blood pressure and saturation from another devices.

System Usability. The real time availability of the data in the hospital during delivery at home is a challenging factor in the communication chain. In the obstetric field, a delay of maximal 1 minute is considered acceptable. There are many stages to pass before the data are made available to the gynaecologist: the data acquisition, the data transmission by a mobile device (integrated in the Nemo Healthcare system), the data processing by the webserver (such as format control and data authentication), and the web application with its graphical interface. Risk analysis shows that the use of a mobile device such as a private smart phone to receive the data and transmit them to the webserver is a high-risk factor: the patient is too involved in the control of the data streaming. She has to start up the app, to control if the communication is correct, and to stop the measurements. These actions, if performed in a wrong way, can damage or delay the measurement with undesired effects on the clinical diagnostics. By integrating these functionalities into the Nemo Healthcare system, this problem is avoided, as the patient will no longer be involved in the initialization procedure of the communication chain. In this way, the system becomes more intuitive and easy to use (plug and play) for the patient and the caregivers. In the obstetric field, 1 minute missed signal is considered acceptable. For this reason, the maximum number of data files allowed be lost in sequence during the transmission is equal to 8.

III. RESULTS

The prototype was tested with simulated signals in the form of pre-defined data files sets according to the described protocol. These files, containing all different signals (fHR, fECG, uterine contractions) from the Nemo Healthcare system, were transmitted via a laptop to the webserver. The hardware unit of the Nemo Healthcare system was replaced during the test with a laptop with Wi-Fi connection.

The webserver received correctly the signals: these are posted real time in the right tables of the database and are shown real time in the graphical interface of the web application (see Fig.2). However the design of the buffer needs to be improved: a too long delay (2 minutes delay after 20 minutes measurement) occurs after the visualization of the real time acquired signals.

The results, obtained during one hour test, show neither delay nor loss of files. The test of the functionalities implemented in the web application was successful, providing the expected results and fulfilling the defined requirements on delay and safety.
IV. DISCUSSION

This project aims to provide a proof of principle for obstetric tele-monitoring system. It offers new possibilities for comfortable, continuous, and more reliable monitoring, by letting the pregnant woman stay at home even during long term monitoring during her pregnancy. All the signals acquired at home simultaneously from different patients are available in real-time for the gynaecologist in the hospital, but also elsewhere, as long as internet access is available. When a problem in the measurements is detected, the gynaecologist can contact the patient or the midwife involved in the delivery by phone.

One restriction we had to deal with was the “demilitarized” zone in the hospital, which is made to protect the hospital’s network from extern attacks. When the webserver, the Cloverleaf server and the database server will be installed each on a separate hardware inside the hospital infrastructure, it will be possible to integrate this system in the hospital EHR. In this project, this was a too expensive solution for the proposed proof of concept. Therefore, we placed the webserver outside the hospital. The home measured data are then accessed and managed by a web application that is unfortunately completely separated from the EHR environment. The integration with the EHR is not possible as long as the system is a prototype. Therefore, our future plans include the integration of this function in the actual EHR system of the hospital.

The buffer design has to be improved: taking into account that the visualisation of the signals can easily tolerate a 15s delay (2 transmitted files), it is technically possible to show the signals without creating constructive delay as a next step. The proposed tele-monitoring system can be used also during home deliveries (common in the Netherlands). The benefits are evident. Now that the signals are already measured at home, the proper intervention can be immediately started at the hospital.

In a future scenario, we can imagine that all the home measured pregnancies and all the home deliveries will be real-time followed and monitored from a control room where the professionals will interpret the fetal and maternal signs and intervene in time if necessary.

V. CONCLUSION

We have implemented an obstetrical tele-monitoring communication protocol that allows continuous, easy measurement of key electrophysiological parameters. The general system requirements were met. In the future such a system will help to prevent or to early diagnose pregnancy problems, will help to avoid long and expensive hospitalization, and can contribute to a reduction in newborn mortality and morbidity.

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