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MODIFICATION OF OBSTETRICAL SURVEILLANCE SYSTEMS FOR EFFECTIVE PATIENT MANAGEMENT AND HOME-CARE OF AT-RISK PREGNANCY

The paper presents some aspects of telemedical fetal monitoring where the biomedical signals are acquired remotely at patient's home and wirelessly transmitted to the central computer through the GSM network and Internet. Signals are acquired during the monitoring sessions, and along with analysis results, they create uniform data structure describing the medical history of patient since the first monitoring to the labour. The proposed structure of database was based on the currently used in centralized monitoring systems, and extended by information essential for remote monitoring purposes. Internet-based telemedical systems allow for remote access to collected data, however, it is necessary to secure the database against unauthorized access to patient's personal data and medical history. The proposed structure of database records allows for easy searching and viewing of patient data forms and monitoring traces. These features cause that the database constitutes valuable research material, which enables to relate parameters of particular monitoring records, acquired during pregnancy, to the real fetal outcome.

1. INTRODUCTION

Cardiotocography (CTG) is a method widely used for fetal monitoring, which enables evaluation of the fetal condition during pregnancy and in labour. It relies on the analysis of the fetal heart rate (FHR) patterns in relation to maternal uterine contractile activity and fetal movements. The normal heart activity indicates the adequacy of fetal oxygenation and correct functioning of central nervous system. The most popular method of FHR signal acquisition is the Doppler ultrasound technique basing on monitoring of mechanical activity of the fetal heart. In traditional cardiotocography the signals recorded and processed by the fetal monitor are presented as printed waveforms. Their visual evaluation is subjective and considerably depends on the experience and knowledge of clinicians. The required objectivity and reproducibility of CTG records interpretation has been achieved by the use of computer-aided monitoring systems. Automated analysis allows for more accurate evaluation of the recorded trace aimed at the analysis of instantaneous fetal heart rate variability. Online detection of alerting situation helps the clinicians to make immediate and appropriate decisions.

In medical centres, a need for simultaneous monitoring of many patients caused the development of centralized fetal monitoring systems [6]. Such system comprises a number of bedside monitoring devices connected to central computer, where acquired signals are displayed, analyzed and archived. Electronic recording of CTG signals made the use of thermal printers unnecessary, at the same time simplifying archiving process. Thanks to these features centralized monitoring systems are becoming a standard approach in fetal surveillance. Further development of monitoring systems leads to remote devices, allowing to carry on the monitoring session at patient's home [3][8]. The use of telemedicine has been increasing worldwide in the last few years. Among the wide range of innovative technology solutions for healthcare, the telemonitoring is one of the most significant [7].

2. TELEMONITORING

In case of high-risk and post-term pregnancies the cyclic monitoring sessions for follow-up the fetal development process should be carried out periodically. So far continuous medical care always requires a hospitalization of pregnant woman even if there is no direct risk for fetal health. It results in high cost of longer hospital stay and discomfort for a patient. For that reason the optimal solution seems to be a remote fetal monitoring at patient's home [4][9]. High cost of the fetal monitor and long time of its usage by the patient limit the possibility of providing each patient with a personal monitor. Reducing the costs, a member of the patient's care team with a fetal monitor and PDA computer could visit patients being appointed to be monitored according to a fixed schedule. However, in case of large clinical centres, some logistic problems should be solved [5]. Taking into account home addresses of the patients and their preferences as for monitoring time, the surveillance centre operator should optimize the schedule from logistic point of view.

We proposed the structure of telemedical system incorporating two ways of connecting the fetal monitoring devices to central monitoring station: directly in hospital and remotely – allowing to carry on the monitoring session at patient's home (Fig. 1). All the monitoring records are stored in system database, regardless of where they were recorded - at hospital or at patient's home. The successive monitoring records create uniform data structure describing a medical history of patient since the first monitoring session to the labour.

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The Mobile Instrumentation (MI) comprises a standard portable fetal monitor and PDA device or tablet PC for acquiring CTG signals and control of the monitoring process. Additionally the built–in GSM module assures the wireless communication with Surveillance Centre (SC) through the WAN network. An additional Workstation can be connected to the system, allowing for access to database regardless of currently running sessions. The access to database is also possible using appointed computers in local network (e.g. in physicians offices) as well as wireless PDA terminals [1]. Moreover, the information stored in the archive can be accessed from outside the hospital via internet.

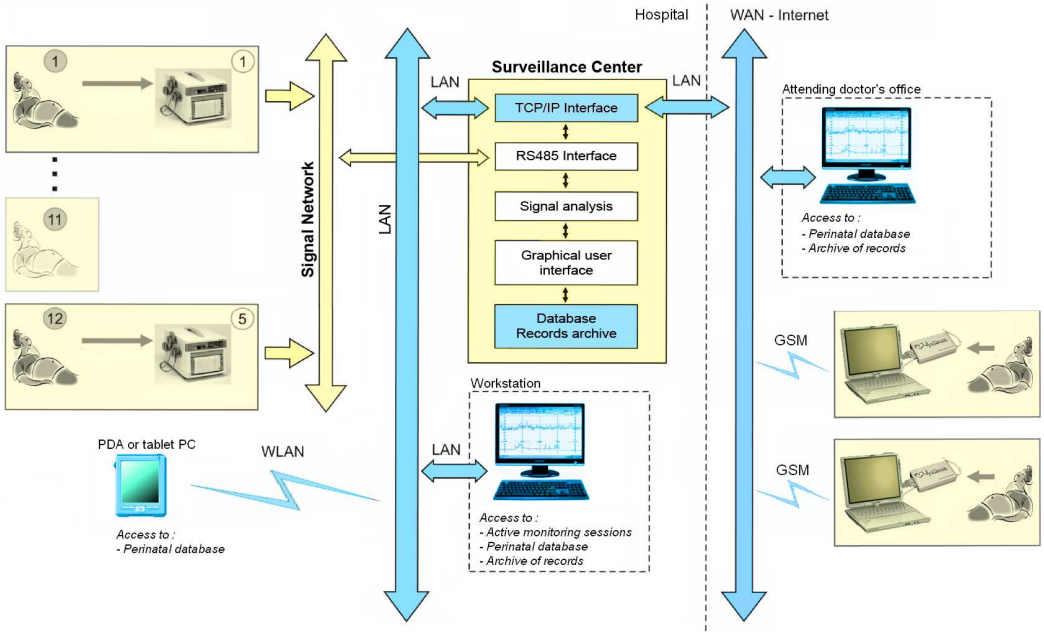

Fig. 1. A structure of centralized fetal monitoring system incorporating remote devices as well as classic bedside monitors located in hospital

3. SURVEILLANCE CENTER

Surveillance Centre is equipped with two displays, one for presentation of traces from monitors within the hospital, and the other for signals from Mobile Instrumentations. It allows for simultaneous presentation of traces from up to 24 bedside monitors and 8 MI's. This limit concerns only the number of simultaneously performed recordings. Since a communication channel is dynamically assigned at the time of logging in to the system, the total number of remote monitors used in the system can exceed eight. Every Mobile Instrumentation can be used for successive monitoring of many patients, so the established maximum value of eight remote communication channels seems to be sufficient. Since the external channels are assumed to work in on-line mode, the monitoring session at patient's home will be carried out in real-time. If a continuous data transmission is assured, the monitoring will run in the same way as it is usually carried on in hospital. The main tasks of SC are: the analysis of incoming data, dynamic presentation of traces along with their analysis results and data storing. The quantitative parameters describing acquired signals are used to detect alerting situations. The form of information displayed by the system should not affect the interpretation of CTG trace. Since in classic cardiotocography signals are visualized as waveforms printed on thermosensitive paper, the display provides the same graphic forms with regard to quality, aspect ratio and waveforms flowing.

Stationary bedside monitors are connected to the system using interface units, translating device's communication protocol to protocol established in the monitoring system. In case of remote monitors the function of interface is fulfilled by a tablet PC or PDA, equipped with GSM module for wireless access to the Internet. The Surveillance Centre includes TCP/IP interface allowing to communicate with Mobile Instrumentation via internet.

4. SIGNAL ANALYSIS

The system allows to relate accelerations to fetal movements and decelerations to uterine contractions. It also evaluates long-term and short-term FHR variability and calculates a series of quantitative indices. The FHR baseline and the acceleration/deceleration episodes along with short-term variability indices are the most clinically important features of the FHR which enable fetal state assessment.

By default all the threshold values for detection of events in CTG signals has been established in the system in accordance with FIGO (International Federation of Obstetrics and Gynaecology) guidelines [2]. The acceleration is recognized if the increase in FHR above the baseline is of 15 bpm or more, and lasting 15 s or more. Deceleration is an episode of slowing of the fetal heart rate below the baseline level of more than 15 bpm and lasting minimum of 10 s. A different set of threshold parameters defines the normal physiological range of signal features. Any exceeding of these values during the monitoring session results in warning, which informs the SC operator about occurrence of abnormal signal characteristics. An information concerning the reason of alarm raising is displayed on the screen of SC, and stored in the database.

Regardless of FIGO guidelines a given hospital may use different practice concerning evaluation of cardiotocographic records. Also the same CTG record may be interpreted differently if patient was monitored on the labour ward, than on the pregnancy pathology ward. For that reason the thresholds of automated analysis together with criteria for detection of events in CTG signal and for evaluation of so called non-stress test may be adjusted by the system administrator.

a)

Patient details
Surname: **X...X** First name: **X...X**
Date of birth: **XX.XX.XX** ID number: **XXXX/XX**

MONAKO – Perinatal database
Monitoring Log
Printed: 2009.05.07

Date and time of recording: 2009.04.12 12:29 Duration: **2h 23min**
Pregnancy duration: **34** weeks, by: **US**
Diagnosis: **G1P1 Hbd 34 Hydrorrhea praecox**
Administered drugs, comments: 1. **14:00 - Aminophyllinum 450mg i.m**
Attending physician: **Mark Apple**
CTG monitoring supervised by: **John Pear** X PDA Client: **Mary L**
Position of patient: **Semi-Fowler** X Client Number: **X...**
Monitor type: **FM 20** X Phone: **1234567**
Location of monitoring: **Labor Room**
Event marker button: **Yes**
Fetal movements perceived by mother: **Yes**
Time passed after last meal: **3h 30min** * Telemetry: **No**
Comments to each hour of recording: **No** * Admitted to hospita
Ward stay: **10** days * Blood test: Ht
Limited physical activity: **Yes** Hb
Body temperature: **36.5** ^{0}C RBC
Heart rate: **78** bpm
Blood pressure: Systolic: **128** mmHg; Diastolic: **85** mmHg
Drugs of current intake: 1. **Sefril** Dose: **1.0 every 8 hours** Rou

X fields existing only in case of telemonitoring session
* fields existing if monitoring session is carried out in hospital

b)

Patient details
Surname: **X...X** First name: **X...X**
Date of birth: **XX.XX.XX** Identification number: **XXXX/XX**

KOMPOR – Perinatal database
Newborn Data
Printed: 94.09.14

Baby identification: **256** Date of birth: **94.07.02** Sex: **M**
Birth weight: **3450** g Length: **54** cm Pregnancy duration: **41** weeks
Apgar 1 minute: **9** Percentiles: **75** % Head circumference: **35** cm
5 minute: **10**
10 minute: **10**
Intrauterine death: **No**
Delivered by: **Mary Orange** Date when stated: –
Perinatal death: –
Attending physician: **John Watermelon**
Newborn resuscitation required: **No**
Visual placenta evaluation: **Normal**
Congenital malformations: **None**
Acid-base balance pH:
Umbilical artery: **7.31** pH
Umbilical vein: – pH

Blood gas analysis:	Venous	Arterial
pO_2	–	**15.0** mmHg
pCO_2	–	**50.3** mmHg
HCO_3^-	–	**25.6** mmol/l
BE	–	**–3.4** mmol/l

Neonatal Intensive Care Unit admission: **No**
Prolongated neonatal ward stay (>24 h): **No**
Newborn condition when discharged: **Perfect**
Newborn death: **No** Days of life: –
Cause of death: –

Fig. 2. Two completed forms describing results of a single monitoring session (a) and newborn state assessed just after delivery (b)

4.1. NON-STRESS TEST

Since the home monitoring sessions have to be previously appointed and their duration is strictly defined, the session usually consists in performing standard non-stress test. The test works well as a screening procedure, since it allows to confirm the fetal well-being with high likelihood. According to FIGO guidelines for the use of fetal monitoring, the test is usually performed over 20 minutes of trace recording with detailed signal analysis together with a final qualitative evaluation. The automatic NST evaluation comprises two blocks: classification and inference. The former relies on assigning a value of a given parameter to a class according to variable discriminant subranges, and then on assigning a logical value to this parameter. The latter leads to transforming the set of logical values into a test result using fixed rules. Antenatal FHR patterns are divided into three classes: „normal", „suspicious" or „pathological", representing the fetal state. If the test is nonreactive or the obtained traces are in other way alarming, the operator is obliged to take the suitable reaction. The decision of hospitalization of a given patient can be taken after consultation with the doctor on duty. In some questionable cases there is also possibility to consult with patient's attending doctor, who can access the monitoring results using Internet connection and assess the risk of fetal distress.

5. DATABASE

Information concerning particular patient is collected in the whole period since registration to the system, through successive monitoring sessions, until delivery. The information contained in the database are organized in the structure of tables (Fig. 3). The information are available for the user as the forms, among which some are filled in by the staff supervising the monitoring session whereas the others are automatically filled by the system.

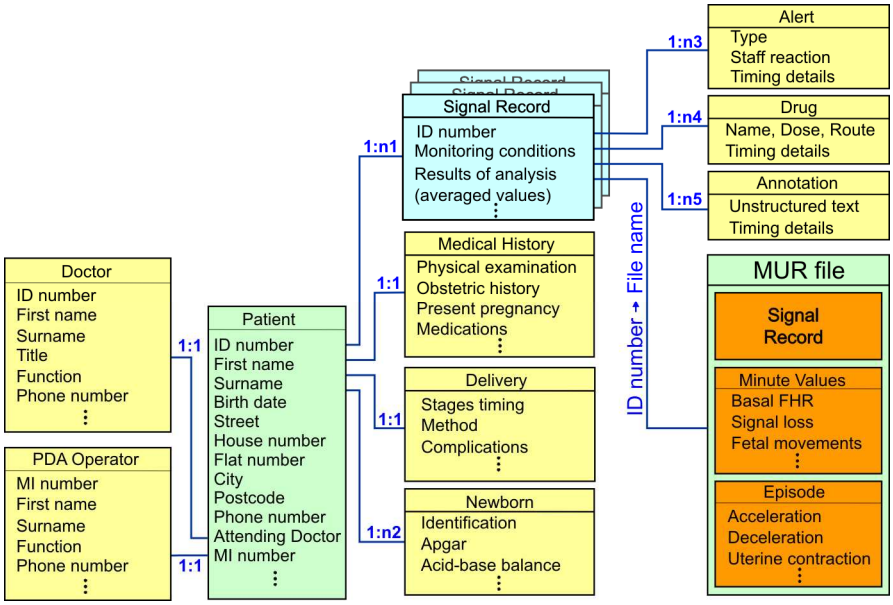

Fig. 3. Block diagram of implemented perinatal database

In the proposed telemedical system the structure of database was based on the structure used in centralized monitoring system. The differences involve extending the data structure by information necessary for telemedical systems. The basic object of the database is a patient's record. Each patient in the database is explicitly identified by the identification number, which is created automatically during registration process. At the same time a basic personal information concerning the given patient are entered to the database, allowing the operator for her identification (e.g. name, surname, personal ID). Additionally, for telemedical purposes, the patient's record was extended by fields containing address and phone number.

A single patient's record contains a number of forms describing successive monitoring sessions. Each Signal Record form is identified by the unique number, which is also used as a name of associated data file. The file is created using MUR structure (Medical Universal Record) which allows for storing acquired CTG signals together with analysis results. Three different contents are written to the MUR file. First and the most important is the full record of signals acquired during monitoring session. The next two describe the results of performed analysis. Instantaneous values of signal parameters calculated in one-minute periods are stored in the table called "Minute Values", and the events identified in the signals (e.g. accelerations, decelerations, uterine contractions) are stored in "Episodes" table. Additional information concerning each monitoring session are stored in three forms, associated with „Signal Record" form. The first form contains the list of alarming situations during the monitoring session along with their occurrence time and staff reaction. The next form contains the list of drugs given to the patient during monitoring session. Since each event is described by the doze and time of administration, the future analysis of fetal reaction to the given drug is possible. The last form keeps additional comments allowing the operator of MI to keep record of any other events, not related to previously described.

On account of telemedical system two additional tables were created in the database. The first one contains a list of attending physicians allowed to access information concerning their patients. For each patient registered in the system only one doctor from the list can be assigned at the same time and the assignment is usually done once for the whole pregnancy period. The second table contains a list of PDA operators. Each record in this table includes an ID number of specific Mobile Instrumentation and personal details of the operator. The operator must be assigned to the patient the day before the monitoring session is to be done. Basing on these assignments a monitoring schedule for each PDA operator can be generated.

6. ACCESS TO DATABASE

All components of the telemedical system together with information of their functionality are presented in Table 1. Additional Workstation has the same permission to access the database as the Surveillance Centre, except for observation of currently running sessions. The main advantage of the Workstation is the possibility of access to the database while some monitoring sessions are running on the screen of SC. It can be also used to create new patient records during registration process, to bring paper documentation as well as to set up the system. Within the hospital local network it is possible to preview data using computers located in doctors offices. They provide functionality of the Workstation limited to reading information only.

Table 1. Restrictions on the access to system database

	Access to patient's data forms	Access to archive of records	Filling out or modification of data forms	Printing of reports	Registering new patients	View of currently running monitoring sessions	System setup
Surveillance Center	✓	✓	✓	✓	✓	✓	✓
Workstation	✓	✓	✓	✓	✓		✓
Computer in Doctor's Office	✓	✓		✓			
Attending doctor connecting via Internet	✓	✓					
Additional PDA in local network	✓						

Telemedical system also assures the remote access to the data from outside the hospital, using a computer connected to the Internet. This solution is supposed to improve the communication between patient and her attending physician. However, in case of connection to the database which is established from outside the hospital, using the Internet, the access to information have to be restricted. Only previously registered physician can get an access to the system database. While establishing the connection, the authorization process is performed, by confirming physician's identity and his password. The restrictions are also applied to the data range available to view via Internet. The attending doctor can only access data which belong to his patients, which is marked in the patient's data form by "Attending Doctor" field.

7. CONCLUSIONS

We hope that telemedical systems for home fetal monitoring will soon become a standard in large medical centres, since the GSM-based devices are commonly available, inexpensive and allow carrying out the monitoring session everywhere within the range of GSM network. The proposed system for fetal monitoring will certainly improve patient's comfort and reduce the cost of medical care. Additionally, the proposed solutions improving the access to patient's data will make communication between the patient and her attending doctor much easier.

The structure of perinatal database allows for archiving signals, analysis results and other information concerning patient and her child, collected during pregnancy. These information, together with description of delivery and the newborn state, are stored in the hospital's archive as the patient's medical documentation.

The structure of records allows for easy searching and viewing of patient data forms as well as the monitoring traces. These features cause that the database constitutes valuable research material, allowing to relate parameters of specified monitoring records, acquired during pregnancy, to the real fetal outcome.

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BIBLIOGRAPHY

[1] CHOI J., YOO S., PARK H., A PDA-Based Mobile Clinical Information System, IEEE Trans. Inf. Technol. Biomed., Vol. 10, pp. 627-635, 2006.

[2] FIGO News: Guidelines for the use of fetal monitoring. Int. J. Gynecol. Obstet. Vol. 25, pp.159-167, 1987.

[3] HOD M., KERNER R., Telemedicine for antenatal surveillance of high-risk pregnancies with ambulatory and home fetal rate monitoring: an update, J. Perinat. Med., Vol. 31, pp. 195-200, 2003.

[4] HOROBA K., WROBEL J., ROJ D., et al.: Ensuring the real time signal transmission using GSM/Internet technology for remote fetal monitoring, in Information Technologies in Biomedicine, Editors: Pietka E., Kawa J., Advances in Soft Computing Series, Springer Verlag, pp.291-298, 2008.

[5] JASEMIAN Y., NIELSEN L.A., Design and implementation of a telemedicine system using Bluetooth protocol and GSM/GPRS network, for real time remote patient monitoring, Technol. Health Care, Vol.13, pp.199-219, 2005.
[6] JEZEWSKI J., WROBEL J., HOROBA K., et al., Centralised fetal monitoring system with hardware-based data flow control, Proc. III Conf. MEDSIP, pp. 51-54, 2006.
[7] LIN B.-S., CHOU N.-K., CHONG F.-C., RTWPMS: A Real-Time Wireless Physiological Monitoring System, IEEE Trans.Inf.Technol.Biomed. Vol. 10, pp.647-656, 2006.
[8] SALVADOR C.H., CARRASCO M.P., et al. Airmed-Cardio: A GSM and Internet Services-Based System for Out-of-Hospital Follow-Up of Cardiac Patients, IEEE Trans.Inf.Technol.Biomed. Vol. 9, pp.73-85, 2005.
[9] WROBEL J., JEZEWSKI J., MATONIA A., et al.: Telemedical system for home fetal monitoring with online analysis of bioelectrical abdominal signals, Journal of Medical Informatics and Technologies, Vol. 12, pp.91-96, 2008.