Automation in clinical data collection in obstetrics - Enabling pooled IPD studies for fetal heart rate and activity monitoring

Cardiotocography is currently the standard surveillance tool during labour. For this reason, there are large cardiotography datasets available. Several studies gathering additional information of computerized CTG data aiming to improve surveillance during delivery and birth outcome are currently performed. Manual data collection and analysis takes a lot of human resources, is error-prone and study parameters can hardly be adjusted later on. Therefore, a software based approach was chosen to minimize the effort of preparation. The software called “CTG and patient information matcher” (CAPIM) collects relevant CTG signals for a specified patient dataset and under recognition of several parameters. CAPIM was tested with the patient database of Frauenklinik und Poliklinik of Technische Universität München (Munich, Germany). Further hospitals will follow. The cases received from CAPIM will be used to do feasibility studies for two innovative signal processing techniques as „phase-rectified signal averaging“ method on fetal heart rate raw data and „deceleration area“ method to improve prediction of birth outcome.

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Automation in clinical data collection in obstetrics

Enabling pooled IPD studies for fetal heart rate and activity monitoring

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Background

- Cardiotocography is currently the standard surveillance tool during labour
- Large cardiotocography dataset enables analysis of heart rate monitoring
- Studies for physiological „fetal heart rate“ are already available

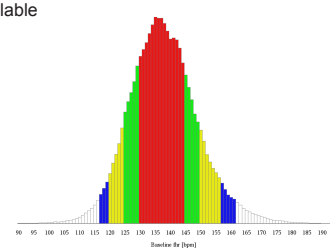

Figure 1: Histogram of baseline fetal heart rate values. Red bars show 25th to 75th percentile, red and green ones 12.5th to 87.5th percentile, red, green and yellow bars 5th to 95th percentile and all bars expect white ones display 2.5th to 97.5th percentile. According to the considered 78,852 CTG tracings the normal range of fetal heart rate is between 120 to 160 ppm. Many international guidelines define ranges of 110 to 160 bpm. [1]

- Several studies gathering additional information of computerized CTG data aiming to improve the surveillance during delivery and birth outcome are currently performed
- For clinical studies in fetal heart rate monitoring usually only a fraction of the dataset holds the study requirements.
- Data collection takes a lot of human resources
- Study parameters have to be determined in the preparation phase of the project and can hardly be adjusted later on
- Manual data analysis is error-prone
- Preparation has to be done exclusively for each problem and parameter set

Objectives

- Software based approach to minimize preparation effort
- Software will be tested with patient database of Frauenklinik und Poliklinik Technische Universität München

Method

- Selection of relevant cases and collection of relevant data in one step:
  - Umbilical arterial blood pH value < 7.1 (acidosis)
  - Only birth CTGs are relevant
  - A certain length of CTG signal is required for reliable data analysis
  - Primary caesarean sections are excluded

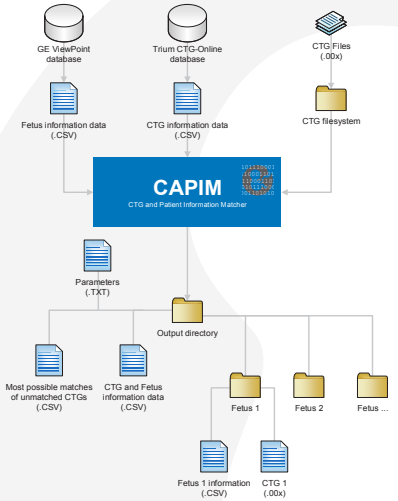

Figure 2: Information flow of „CTG And Patient Information Matcher“ (CAPIM). CAPIM gets information about fetus, all CTGs and additionally the path where the CTG-Files are stored. Furthermore a directory structure with all selected and valid CTG files and files with relevant information for further processing will be created.

- Use of three variable selection parameter
  - **TimeToBirth:** Time frame before time of birth
  - T_{CTG_min}: Minimum duration of one CTG-slice which reaches into the Time-2Birth time frame
  - T_{SUM_min}: Minimum sum of durations of CTG-slices from one fetus which durations T_{CTG} achieve T_{CTG_min}

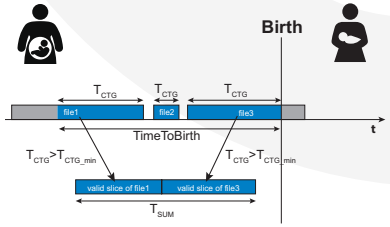

Figure 3: Representation of relevant selection parameters.

Implementation

- Software Implementation in C++
- Graphical User Interface designed with the QT-Framework
- Multi-threaded implementation
- Data visualization using QCustomPlot
- System & Unit tests using QTest
- Platform independent
- Static linking for standalone use

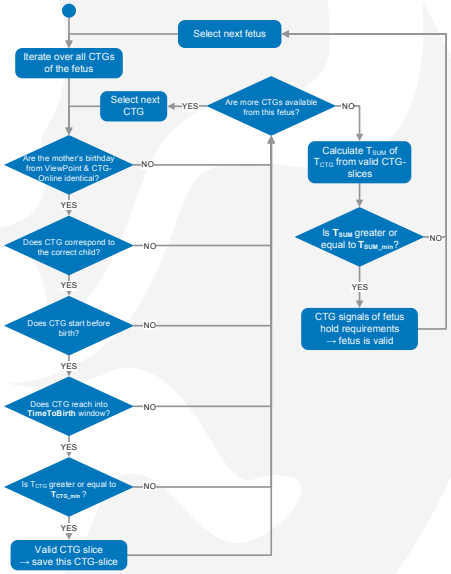

Figure 4: Flowchart of the CAPIM selection process to select only cases, which hold the defined requirements (TimeToBirth, T_{CTG_min}, T_{SUM_min}).

Results

- One execution takes less then 4 sec
- 125 - 188 valid cases (parameter depending) out of 477 possible cases between 09/2009 and 12/2015
- Directly applicable in other hospitals

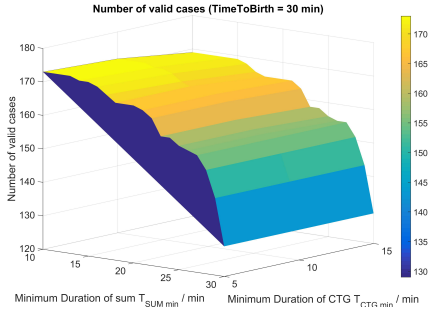

Figure 5: Result of CAPIM selection process. This plot displays the number of valid cases as a function of selection parameters T_{SUM_min} and T_{CTG_min}. Further Parameters are $pH_{umbilical}$ < 7.1 and TimeToBirth = 30 min. The dataset is from the Frauenklinik und Poliklinik, Technische Universität München, Munich, Germany. It describes the timerange between 09/2009 and 12/2015. The total number of possible cases with pH < 7.1 was n = 477. The lower number of valid cases is caused by inappropriate CTG files and/or exclusion of primary ceasarian sections.

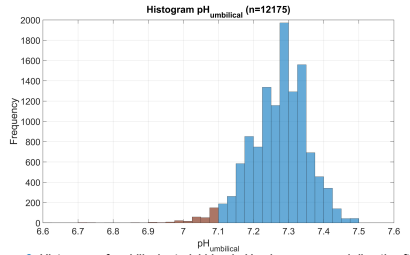

Figure 6: Histogram of umbilical arterial blood pH values measured directly after birth. The test dataset is from Frauenklinik und Poliklinik, Technische Universität München, Munich, Germany. It describes the time frame between 01/2009 and 12/2015. There were a total number of n = 12175 measurements.

Outlook to the future

- Pooled studies in cooperation with other hospitals and research centers for more resilient data and study results
- Application of innovative signal processing techniques as „phase-rectified signal averaging“ method [2] on fetal heart rate raw data and/or „deceleration area“ method [3] to improve prediction of birth outcome

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