Keeping Labor Safe LLC
The Fetal Reserve Index (FRI) EFM and EMR Data Collection: Summer 2024
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The Need:

Childbirth should be a time of great joy, but it can also be perilous. Electronic fetal monitoring (EFM) has been used in labor for >50 years to predict and prevent compromised babies who can have neurodevelopmental delays including cerebral palsy. Unfortunately, EFM has performed poorly – missing as much as 50% of problematic cases. As a result, medical liability costs around labor have reached $40 Billion per year in the USA. Outcomes have been substantially worse in minority populations. Our goal is to greatly improve the performance of EFMs. To that end, we have developed a very disruptive technology called the Fetal Reserve Index (FRI). The FRI provides earlier and improved assessment of clinical risk to prevent damage rather than react to it. We need to move the FRI into a deployable platform for clinical introduction, refinement, and world-wide implementation. We need help to create the app for clinical implementation. With this project we are ultimately looking for electronic download of fetal monitoring data and risk factor data collected from current models of Electronic Health Record platforms (EPIC, Cerner). These data are input through your custom-built API into the FRI Algorithm. Once data are input, the diagnostic output will be returned to the user's device and displayed in an easy-to-read visual format. To this point, 300 test cases have been used to calibrate the Algorithm/Application.

Company Background:

Keeping Labor Safe, LLC (KLS), is a start- up medical technology company, developing technology and software that will make labor and delivery (L&D) and immediate postpartum care (L&D/PC) safer for mother and newborn infant. Our team is primarily comprised of medical professionals who have spent our careers working in maternity hospitals in Detroit, Chicago, Augusta, Dayton, Philadelphia and New York City where we have seen firsthand the need to make childbirth safer for all parties involved. We have developed the Fetal Reserve Index (FRI) a contextualized, quantitative metric to identify distressed fetuses earlier in the course of developing compromise. Earlier identification potentiates earlier intervention to help produce better medical outcomes for mother, fetus, and baby. We have multiple papers and patents and have developed the computer algorithm to "read" the tracing and produce a quantitative score.

The Project:

1) **Have the program able to accept the data in Excel.**
    a. **Produce a Tracing**
    b. **Compute the Score**

2) Interface the web Application with the:
    a. Voice Recognition Development
    b. Wifi/Bluetooth Development

3) Create an API that connects the FRI software to an EFM.
    a. Record the tracing.
    b. Compute the Score
    c. General Electric Healthcare (Novii Wireless Patch System, Corometrics 250CX Series, Corometrics 170 etc.)
    d. Phillips Healthcare (Avalon Series) Electronic Fetal Monitors (EFM's)

4) Connect the Software to an Electronics Medical Records (EMR) provider:
    a. Look into using: HL7 Software: http://www.hl7.org/about/index.cfm?ref=nav
    b. The Cerner App Store: https://code.cerner.com/apps
    c. EPIC Interoperability Guide: https://open.epic.com/

5) Add features and capabilities listed in "Application Requirements" below to the web app created by the CS Mines Summer 2023 and Fall 2023 field sessions. This will turn the Fetal Reserve Index algorithm into an Intelligent

Cloud Platform and Bedside Web Application. Currently the application has 3 user types (Administration, Clinical, and Decision Support) and will work on the current releases of the major web browsers.

Application Requirements:

- Refactoring the code to make it easy to internationalize the product.
- Dynamically update on-screen reporting as data is input.
- Standardized Reports
- Fluid Graph with Trendline
- Front End Improvements
    - Improve the design
    - Improve the Intuitiveness
    - Add reports
- Reset/Forgot Password capabilities
- Data input through intuitive UI
    - Live/Manual/Automated Input of EFM Data
    - Live/Manual/Automated Input of EHR/Risk Factor Data
    - Live/Manual/Automated Input of Notable Events
- Drop Down Menu for Maternal, Obstetrical and Fetal Risk Factors
- UI automatically prompts for inputs at predetermined and variable intervals
- Dynamically update on-screen reporting as data is input
- Multiple Concurrent viewing capabilities: Real Time Sharing of Data
- Remote Administrative access for diagnostic support
- HIPAA compliant
- Built to allow expansion

Technologies and Desired Skills:

- Python (Python Flask, Micro framework)
- General Front End Development: React
- WebSocket
- REST API
- SQL Database
- JavaScript, TypeScript
- HTML/CSS
- Others as appropriate
- C++
- Cloud Architecture

Fetal Heart Monitor Data Capture:

- Fetal Heart Rate
- Accelerations
- Decelerations
- Variability
- Uterine Activity

Sample Data:

Each row represents 1 minute of case data for a particular patient and a particular metric. The two main metrics included are UA (Uterine Activity) and FHR (Fetal Heart Rate).

We would like to see the following data being input:

- EFM/UA Data

- Nursing Data Entry

With the following diagnostic report:
- Risk Factor Scoring

Column	Data Type	Size	Required	Notes
Prop_0	DateTime		Y	Timestamp for the beginning of the minute that the record represents
Prop_1	String	128	Y	Metric (UA, HR, HR2, etc)
Prop_2	String		Y	Metric Source (external, TOCO, IUP)
Prop_3	Numeric	11,6	Y	Metric value for the first quarter second of the minute
Prop_4	Numeric	11,6	Y	Metric value for the second quarter second of the minute
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.				
Prop_242	Numeric	11,6	Y	Metric value for the final quarter second of the minute

EFM/UA Data Sheet
Each row represents a measurement of HR and UA values at a specific point in time. Based on existing sample data, we would expect this to be every quarter second.

Column	Data Type	Size	Required	Notes
PATIENT_ID	String	128	Y	Unique ID representing a patient (mother)
HR	INT	128	Y	HR Value (BPM)
UA	INT		Y	UA Value (mmHg)
DATE_TIME	DateTime		Y	Timestamp when these values were recorded

Nursing Entry Data Sheet
Each row represents a measurement recorded by a nurse (coming from Epic or other EMR) that will be ingested and could have an impact on FRI calculation.

Column	Data Type	Size	Required	Notes
PATIENT_ID	String	128	Y	Unique ID representing a patient (mother)
MEASUREMENT_TYPE	String	256	Y	Type of measurement recorded (ex: cervical dilation, Pitocin, FHR variability, etc)
DATA	String	500	Y	Measurement Value (generic string)
DATE_TIME	DateTime		Y	Timestamp when these values were recorded

Preferred Team Size: 4-5 Students

Preferred Work Location: Remote
- Meeting regularly via Zoom

Intellectual Property: All intellectual property developed as part of this project will be owned by Keeping Labor Safe, LLC.

NDA: Signed NDA will be required