Keeping Labor Safe LLC The Fetal Reserve Index (FRI)-EFM and EMR Data Collection Fall 2022 Dr. Mark I Evans MD OB/GYN Gregory F. Ryan MBA

The Need:

Childbirth should be a time of great joy, but it can also be perilous. Electronic fetal monitoring (EFM) has been used 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. We have developed a very disruptive technology called the Fetal Reserve Index (FRI) to provide improved and earlier 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.

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, Ohio, 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) to identify distressed fetuses earlier in the course of developing compromise and to allow for 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:

Contains 2 main parts:

- Create an API that will extract the required FRI data from General Electric Healthcare (Novii Wireless Patch System, Corometrics 250CX Series, Corometrics 170 etc.) or Philips Healthcare (Avalon Series) Electronic Fetal Monitors (EFM's) at the standard rate of 4 times per second.
- 2) Extract the Risk Factor Data from Epic and/or Cerner Systems Electronic Medical Records Software (EMR/EHR) and automatically input the desired data into the FRI web application.

With this project we seek to develop an electronic download of EFM data (GE, Philips) and the risk factor data residing in current models of Electronic Health Record platforms (EPIC, Cerner). All data is then input into the FRI Algorithm residing on the custom-built web application created in the Summer 2022 session. Once data are inputed, the 8 factors received will produce our Fetal Reserve Index (FRI) diagnostic output that will be returned to the user's device and displayed in an easy-to-read visual format.

Application Requirements:

- Dynamically update on-screen reporting as data is input
- HIPAA compliant

Technologies, Desired Skills or ability to learn:

- MUMPS (Massachusetts General Hospital Utility Multi-Programming System)
- Cache [1]
- CCL (Cerner Command Language) https://en.wikipedia.org/wiki/Cerner CCL
- SQL
- Potential Wireless Telemetry
- Potential Bluetooth
- Epic Share Everywhere

- CommonWell Health Alliance Interoperability Software standard for electronic health records
- Client Server architecture
- Cloud based architecture
- Others as appropriate

Fetal Heart Monitor Data Capture:

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

Electronic Medical Records Risk Factor Data Capture:

We are looking to obtain three categories of Risk Factor Data: Maternal, Obstetrical and Fetal Risk Factors.

Maternal Risk Factors include:

- Decreased Cardiac Output
- Hypertension (chronic and pregnancy induced)
- SLE
- Oxygen Carrying Capacity
- Pulmonary Disorders (asthma etc.)
- Infection (chronic and acute)
- Malabsorption (poor weight gain)
- Endocrine (diabetes and thyroid)
- Advanced Maternal Age
- Smoking
- Drug Abuse/Addiction
- Obesity (BMI > 35)
- Short Stature ($\leq 5'2''$)

Obstetrical Risk Factors:

- IUGR/Macrosomia
- Oligohydramnios
- Polyhydramnios
- Bleeding and abruption
- Previous Cesarean delivery
- Placental and umbilical cord anomalies
- Rupture of membranes (PPROM, SROM, AROM)
- Dystocia (protraction and arrest of disorders of labor)
- Malpresentation

Fetal Risk Factors:

- Abnormal dopplers/BPP
- Genetic Disorders
- Fetal Arrythmia
- Meconium passage
- Chorioamnionitis
- Second stage of labor (pushing)
- Amnioinfusion

- Discontinuation of Pitocin due to fetal intolerance
- Conversion patterns (acute prolonged tachycardia: >170 beats per minute)
- Bradycardia (<100 beats per minute)
- Ominous Overshoots
- Missing important data in labor (e.g. lack of EFM in 2nd stage)

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