

## Background

Since the declaration of COVID -19 as a global health emergency by the WHO in March 2020, there has been a growing burden and overloaded capacity in hospitals worldwide [1]. A systematic review by Moynihan et al. (2021) [2] confirms disruption in healthcare utilization in multiple locations by a third during the pandemic due to measures such as lockdowns, quarantine, and stay-at-home orders [3-5], especially the largest figures have been found among lower-income countries [6]. The main consequence of the reduction in healthcare access is that patients have been missed out on essential care. An early estimate by Robertson et al. (2020) has shown that the depletion of essential health interventions in maternal care and childcare would cause more than a million additional child deaths in low- and middle-income countries [7].

Among different healthcare services, prenatal care has been further detrimentally affected due to COVID-19 pandemic, where most of the clinical resources has been directed to cope with the situation leaving a huge void. Being afraid of catching the virus while visiting the hospitals, many pregnant women also choose to skip check-ups until a safer time. As a consequence, fetal health declines on a large scale which also leads to mothers' mental issues like devastation and anxiety [8]. To cope with the pandemic, there has been a growing demand and implementation of telehealth technology to help pregnant women connect with obstetricians for regular visits from afar, with a notable example in New York City [9]. However, those telehealth solutions focus solely on initiating digital conversations between pregnant women and obstetricians and have not yet incorporated any techniques to monitor fetal status continuously at home to provide on-site obstetricians with valuable information. Therefore, it is essential to develop a simple-to-implement checkup solution for pregnant women to use at home, raise people's awareness of prenatal care and release the burden on the healthcare system, especially during hard time like the COVID-19 pandemic.

Regular prenatal care is vital to reduce pregnancy complications to both mothers and fetuses and to early identify potential birth defects. In Vietnam, the rate of birth defects was reported at 6.02% [10]. Among the most common birth defects, heart defects contribute to the leading cause of birth defect-related mortality. Annually, about 1% of infants are born with some form of congenital heart disease (CHD) which originates in the early stages of pregnancy when the heart is formed (~5-week of pregnancy) and can affect any parts or functions of the myocardium [11]. Congenital heart defects account for 1 in 10 birth deaths in developed countries and 1 in 3 birth deaths worldwide [12]. Many neonates with CHDs do not show obvious symptoms, with more than 50% of affected newborns being discharged from the hospital undiagnosed. In Vietnam, the high rate of alcohol and tobacco usage and the overuse of salt daily are the leading factors to cardiovascular diseases, which also contribute to fetal heart defects [13]. Regular check-ups are essential to minimize risks of increasing fetal mortality during pregnancy and offer in-time actions in emergencies. In particular, the fetus' heart functionality checking would provide information about any abnormal cardiac development and thus is a must-have in a check-up routine.

Different techniques to examine cardiovascular health come with pros and cons. The most widely used modality to assess antepartum and intrapartum fetal wellbeing is cardiotocography (CTG). However, the current CTG machines are far too expensive and limited in availability only to hospitals and clinics. The pulse transit time-based (PTT) blood pressure measurements via electrocardiogram (ECG) and photoplethysmogram (PPG) assessment have been of great interest for more than a decade due to their low cost, portability and ease-of-use [14, 15]. However, the reliability and reproducibility of the results have raised significant concerns for the technology to be clinically used. Among many solutions to address the unmet need in assessing fetal wellbeing and monitoring fetal electrocardiogram (fECG) to derive a vital indicator for prenatal development and health status, fetal heart rate (FHR) is a promising option as it is low-cost, portable and completely non-invasive. However, after over 40 years in use, FHR monitoring technique needs upgrading to effectively improve perinatal outcomes. Currently, there is no reliable way to

assess FHR at home except with home-used consumer ultrasound Doppler fetal heart rate devices that cannot reliably detect fetal heartbeats and often cause even more alarm to the mother. The challenge is to minimize unnecessary clinical consultation while not missing the opportunity to intervene if the fetus is actually at risk, and monitoring FHR can help de-risk the situation.

We have proposed a novel solution of monitoring FHR through continuous fetal ECG measured on non-contact electrodes. Under our close collaborator – Dr. Cao's work at UC Irvine, a prototype system has been developed and tested on human subjects initially proving the concept of the method where fECG signal can be obtained continuously in a stable manner while the device is safe and comfortable to use for mothers thanks to its non-contact nature [16-18]. The project was successfully granted Vingroup Innovation Fund (~USD 240,000) to develop the system for pre-clinical trial, with the original purpose of helping pregnant women in remote areas. With the pandemic pushing away many pregnant women even in urban regions from regular check-ups, our system is realized to be capable of providing a new complex telehealth environment engaging a network of multiple pregnant women and professional obstetricians to perform "tele-check-ups", optimizing the check-up routines and minimizing the pandemic effect on prenatal care. In this research, we focus on a novel, cost-effective ambulatory technique that can continuously monitor fetal heartbeat and the development of fetal heart throughout pregnancy at home, thus aiming at reducing the rate of perinatal mortality and heart defects in Vietnam.

Developing from the initial phase of the above-mentioned project, this work aims to elevate the implementation of the system in a developing country setting and assess the feasibility of the system in remote prenatal care. In this current COVID-19 pandemic, we believe that our proposed system could contribute to the attempt to improve the well-being of pregnant women. With potential support from PEER program, the first workstrand will focus on deepening different influences of COVID-19 in antenatal care in Vietnam. Besides, it also helps to understand of the need of the users – pregnant women – in order to provide appropriate inputs to develop a more comprehensive system. A survey will be carried out to capture aspirations, expectations and needs from pregnant women's perspectives on crucial elements in the assessment of fetus wellbeing. In the second workstrand, the research will run a pilot trial after incorporating evidence-based inputs from the first workstrand in the first version of the system. This trial will be designed to evaluate whether a larger definitive trial is worthwhile and feasible. This trial is planned to be carried out in Vietnam, with a different targeted group of users compared to the study in Irvine, CA, USA. With a focus on a developing country setting, the group of interest in this study involves women who are from different regions including remote areas, who may be vulnerable due to economic situations and disabilities.

## Project objectives

### **Aim 1: Identify antenatal common mental disorders and contacts in the COVID-19 context, thereby identifying their needs for telehealthcare**

This objective is to answer the three research questions:

1. What are common mental disorders among pregnant mothers?
2. How antenatal contacts are influenced during the COVID-19?
3. What do mothers expect for a home-based fetal/maternal ECG monitoring system?

A cross-sectional study will be conducted among pregnant mothers who visit the Hanoi Obstetrics and Gynecology hospital for antenatal contact. We estimated a sample size of about 500 mothers who can be reached within 2 months in the hospital.

### **Aim 2: Assess the feasibility of a home-based fetal/maternal ECG monitoring system.**

Collaborating with our USG partner, the University of California – Irvine (UCI), we will further develop the home-based fetal monitoring system. Moreover, we will conduct a clinical trial to assess its feasibility, including 1) the system's performance compared with standard medical device in terms of accuracy of FHR detection, sensitivity and specificity; 2) the acceptance of new technologies by pregnant women as well as attitude for telemedicine approaches in obstetrics. This aim would provide valuable feedbacks for the system as the attempt of enhancing the capability of telehealthcare, addressing the unmet need in healthcare; especially, during COVID-19 pandemic.

## Research plan

**Aim1: Identify antenatal common mental disorders and contacts in the COVID-19 context, thereby identifying their needs for telehealthcare. (3580 chars)**

**Study design:** Cross-sectional study

**Study population:**

Pregnant mothers who visit the Hanoi Obstetrics and Gynecology hospital for antenatal contacts. Inclusion criteria include age over 18 years old and not a high-risk pregnancy defined by obstetrics.

**Study setting:**

The Hanoi Obstetrics and Gynecology hospital is a specialist hospital in obstetrics and gynecology in the northern region and is mainly for people who are living in the city. There are about 44,000 deliveries per year which allow the study to obtain a sufficient sample size within the timeline of the project.

**Data collection:**

Outcomes of interest include antenatal common mental disorders, fear of COVID-19 scales, number of antenatal contacts missed due to COVID-19, and their need for telehealthcare. Antenatal common mental disorders will be assessed using the Edinburgh Depression Scale which has been validated [19] and used in previous studies [20-24]. Fear of COVID-19 scales (FCoV-19S) will be adapted from the previous study in Vietnam [25]. Mothers' need for check-up telehealthcare explores their perspective on the development of a prospective check-up telehealthcare. The sample of questionnaire is in Appendix.

Other independent variables will be collected which include demographic characteristics (e.g. age, education, occupation, income, and marital status), current stressful or adverse life events, reproductive history (e.g. gravidity, parity, abortion/miscarriage), current pregnancy, illnesses during pregnancy, mental health history, and suspected COVID-19 symptoms. Those variables are selected from previous studies in Vietnam on antenatal mental disorders [21, 24-26] and systematic review [27-29].

**Sample size and sampling:**

HSS sample size which was developed by Hanoi University of Public Health (<http://comau.tk/>) was used for sample size estimation. For pregnant women, antenatal common mental disorders symptom was 24.5% [21]. The mean of FCoV-19S was 20.1[25]. Antenatal care that was influenced by the COVID-19 was 8.1% [24]. Therefore, the sample size is estimated at 500 at 80% power and 5% level of significance for the given statistics.

**Procedure:**

Signed informed consent will be obtained from each voluntary participant at recruitment, who are free to withdraw at any time. Agreed mothers will be interviewed face to face when they visited the hospital for antenatal contact using Research Electronic Data Capture (REDCap) [30] at Hanoi University of Public Health to collect data.

### **Data analysis:**

A descriptive analysis to explore the distributions of the different variables will be carried out. We will use chi-square tests (or Fisher's exact test) for categorical variables and t-tests for continuous variables to compare the distributions of studied variables between women with and without outcomes of interest. The bivariate and multivariate logistic regression models will be used to adjust independent variables with the outcomes of interest. Significant differences are assessed at p values of  $<0.05$ . Statistical analysis will be performed using OriginLab 2019 (MA, US).

### **Caveats and alternative approaches:**

Telephone interviews or online surveys will be alternative options if the COVID-19 situation does not allow for a face-to-face interview. Interviewees will be employed outside of the hospital to ensure the will of mothers who participated in the study. They will receive training before recruitment to ensure consistency in the interview procedure and data collection process.

### **Aim 2: Assess the feasibility of a home-based fetal/maternal ECG monitoring system.**

The COVID-19 pandemic has significantly affected pregnant women in many aspects of life. In an attempt to mitigate that effect, a home-based fetal monitoring system would help pregnant women keep being informed about their unborn babies and reassure them during this pandemic. In this proposal, we plan to assess the feasibility of the system with criteria such as its performance to monitor unborn child's heart rate and the acceptance of new technologies by pregnant women as well as attitude for telemedicine approaches in obstetrics.

### **Device description:**

Collaborating with the USG partner from the University of California, Irvine (UCI), we have worked together to develop a home-based fetal monitoring system and algorithm to accurately extract fetal heartrate [16, 31-33]. The system has gone through several versions and our partner recently conducted a clinical trial with 10 pregnant subjects in UCI medical center [17]. All experiments in this study comply with protocols approved by the Institutional Review Board (IRB) committee at UC Irvine (IRB#2020-6342).

Fig. 1 illustrates the overview system and the prototype used in the current experiments (Fig. 1 in Appendix). Specifically, the abdominal ECG signals are collected by a wearable belt, and then the collected data are sent to the Android app via Bluetooth Low Energy (BLE) communication (Fig. 1a). The pre-processing and extraction algorithms are performed through the connected cloud server from the application to calculate the FHR. This information would be sent to the mother's phone and doctors for further analysis. Figure 1. b describes more detail about the belt and measurement setup with the belt to collect data. A fabric with a smiling face is used to cover whole electronic components and battery while four slits made in the back of the belt are for four electrodes to contact the abdominal area. These are safe for the expectant mom and her unborn child as the electrodes contact the abdomen through non-conductive materials. With the support from our USG partner, we would further improve it to suit Vietnamese women's body physic and carefully test the system before conducting the trial in Vietnam.

### **Study design**

This study is a prospective, open-label, comparative, multi-center study, aiming to assess the feasibility of our home-based fetal monitoring device in terms of its accuracy compare with standard measurement (i.e., cardiotocography - CTG). Besides, the study would evaluate the comfort level as well as the acceptance of new technologies by pregnant women. Regarding data collection, we plan to perform experiments in both clinics and at home. Specifically, in-clinic our proposed system and an Avalon FM-30 Fetal Monitor CTG device (Philips Healthcare, Andover, MA) will be placed on the woman's abdomen concurrently. The CTG sensors were placed close to our system. Signals were acquired and fetal and maternal heart rates were measured simultaneously using both instruments. Each recording session can be within at least 30 minutes, according to current clinical practice guidelines [34]. For recording data at home, participants will be given our system and asked to download an app on their smartphone. A research nurse shows participants how to use our system during a 5-min training session when they do record in the clinic. Participants will be sent reminders via text message, email, or phone call for the questionnaire or short conversation about users' experience with the device. From the recordings done by clinicians and from home recordings, the following outcome measures will be considered: 1) detection of FHR, 2) the number of continuous recordings longer than 10 minutes, 3) total FHR recording time, and 4) average FHR. Combining with aim 1, the follow diagram of steps being planned to conduct is summarize in Fig. 2 in Appendix.

### Study population

Participants in Aim 2 would be selected from the study population recruited for Aim 1 of the study. However, to be applicable for the experiment, they need to have a singleton pregnancy between 25 to 38 weeks gestation. Exclusion criteria included the following: a pre-pregnancy body mass index of  $\geq 30$  kg/m<sup>2</sup> or  $\leq 18.5$  kg/m<sup>2</sup> [35]; multiple gestations; the presence of a fetal anomaly; an implanted electronic device (e.g., pacemaker, defibrillator); or a skin condition in the abdominal area (e.g., wound, skin rash). All patients provided written informed consent to participate in the study.

### Statistics/data analysis

Statistical analysis will be performed using OriginLab 2019 (MA, US). The agreement between the heartbeat monitor and cardiotocography was established using Bland Altman plots and 95% limits of agreement. To assess the usability and learnability of the heartbeat monitor, we will use the international medical standard System Usability Scale [36]. It is a 10-statement survey that evaluates the learnability, reliability, and usability of products. When evaluating the results, System Usability Scale raw scores are reported as means and 95% CIs and converted to a percentile rank (0–100) with a corresponding letter grade (A+ to F). We will perform subgroup analyses to evaluate the relationship between BMI, gestation, obstetric history, and placental position on outcome measures for all participants and for the subgroup of women who were 25 - 38 weeks of gestation (in which cardiotocography monitoring is typically performed). The relationship with clinical features was assessed using nonparametric tests owing to the skewed distributions (Kruskal-Wallis and Mann-Whitney U).

### Caveats and alternative approaches

In this study, we plan to conduct experiment sessions in both clinics and at home. We expect the system will be self-administered by pregnant women at home. However, if many subjects find it difficult to operate it at home, an alternative approach will be performed. Specifically, once they visit the hospital, we will ask them to stay in a private room and let them try to measure by using our device by themselves. The follow-up interview would be conducted after that. Regarding device performance, our sensors used in the device are non-contact electrodes (NCE), and being susceptible to motion artifact is the most challenging for the NCE [37]. Graphene sensors can be another alternative for the NCE.

Graphene-based textile sensors are better than wet electrodes in terms of the user experience while the signal quality is preserved [38].

## Innovation

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The proposed project seeks to investigate insight into the mental well-being of pregnant women under different influences of COVID-19 in antenatal care in Vietnam (in Aim 1). Furthermore, we first assess the feasibility of a novel fetal monitoring which provides a potential solution with a telehealthcare focus, aiming to reduce the effect of COVID-19 on pregnant women.

Traditionally, pregnant women have to visit a hospital or clinic for antenatal care, required to do basic tests to determine the unborn child's health using standard medical devices. For example, CTG systems, like those from GE, Philips, and others, cost between \$2,000 to over \$10,000; and these cannot be used outside of the hospital setting, not to mention the bulkiness and complications. In terms of fetal ECG monitoring approach, MindChild Medical has developed the *MERIDIAN M110* system which is however wire-connected, bulky, and non-mobile. The GE *Monica Novii* wireless patch system uses less bulky fECG sensors and is wireless. However, the mobile range is limited to the labor and delivery areas in the hospital. The cost of those is also at par with the traditional CTG systems. The measurement is also especially challenging for non-medical persons.

In contrast, our system can easily be programmed to provide live information of fetal well-being in a mobile, out-of-clinic setting, with more reliable ECG-based FHR data, by using non-intrusive sensors with mobile phone-based wireless transmission technology. Integrated with a cloud system and security, our system architecture, graph construction as well as security implementation shows unique innovations [16, 17]. The information obtained thereof can be related to all relevant healthcare providers and entities. With the current smart-device coverage, the implementation of fetal monitoring could be done anytime, anywhere. Additionally, a deep learning artificial intelligence (AI) model being developed to extract reliably FHR from data collected by our system would be another innovation. To our knowledge, there is currently no deep learning model for this such application. With data from multiple sensors for a long duration, the deep learning algorithms are trained with enough data points so that the signal-to-noise ratio can be significantly better than the previous works and much meaningful information can be extracted.

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