

How Can Wearable Technology Play a Role in the Monitoring and Prevention of Birthing Complications?

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In Australia, 1 in 135 pregnancies that reach the third trimester result in a stillbirth (Robertson, 2022). Despite the resources allocated to improving fetal monitoring, the rate of stillbirths in Australia has remained effectively unchanged for over 20 years. Fetal movements (FM) and fetal heart rate (FHR) are important factors in the assessment of fetal health. However, there are currently no reliable methods to monitor fetal wellbeing outside clinical environments. The Stillbirth Centre of Research Excellence (2020) estimates between 20% to 30% of stillbirths may be preventable, with early detection of fetal abnormalities being a major driver for successful outcomes.

This report investigates how wearable technology can improve at-home fetal monitoring during prenatal development, to prevent stillbirths and other birthing complications. An extensive literature review, two rounds of primary research and product benchmarking were undertaken to provide a context to patient behaviors, technological capabilities, ethical considerations and antenatal protocols. Meaningful insights validated the need for a wearable fetal monitoring device to prevent negative birthing outcomes. Furthermore, design implications were derived, forming a robust building block for the upcoming development phase.

Abstract

Introduction

Prenatal care, also known as antenatal care, refers to the medical practice associated with, monitoring and treating women throughout the duration of pregnancy (Queensland Health, 2020). This specific practice is a subspeciality of obstetric medicine (Queensland Health, 2020). The primary purpose of prenatal visits is to monitor fetal development and maternal health outcomes for high risk patients, prevent stillbirths and other adverse birth outcomes such as congenital abnormalities, maternal-fetal hemorrhage and placental dysfunction (Liang et al., 2021).

Primary fetal wellbeing is measured by interpreting patterns relating to fetal heart rate (FHR) and fetal movement (FM). These measurements are assessed with cardiotocography (CTG) and ultrasound technology and results are interpreted by clinicians (Liang et al., 2021). Research shows that decreased fetal movement (DFM) is strongly correlated with impending fetal compromise (Zhao et al., 2019; Delay et al., 2021; Somathilake et al., 2022). It is suggested that up to 30% of stillbirths are preceded by DFM and therefore play a crucial role in prompting emergency intervention (Zhao et al., 2019). While one third of stillbirths are attributed to unknown causes, The Stillbirth Centre of Research Excellence (2020) estimates between 20 to 30% of stillbirths may be preventable, with early DFM detection being a major driver for successful outcomes.

Despite the resources allocated to improving fetal monitoring, the rate of stillbirths in Australia has remained effectively unchanged for over 20 years (Australian Bureau of Statistics, 2022). It is also reported that rates of stillbirth are marginally higher among rural communities due to decreased accessibility to antenatal resources (Australian Institute of Health and

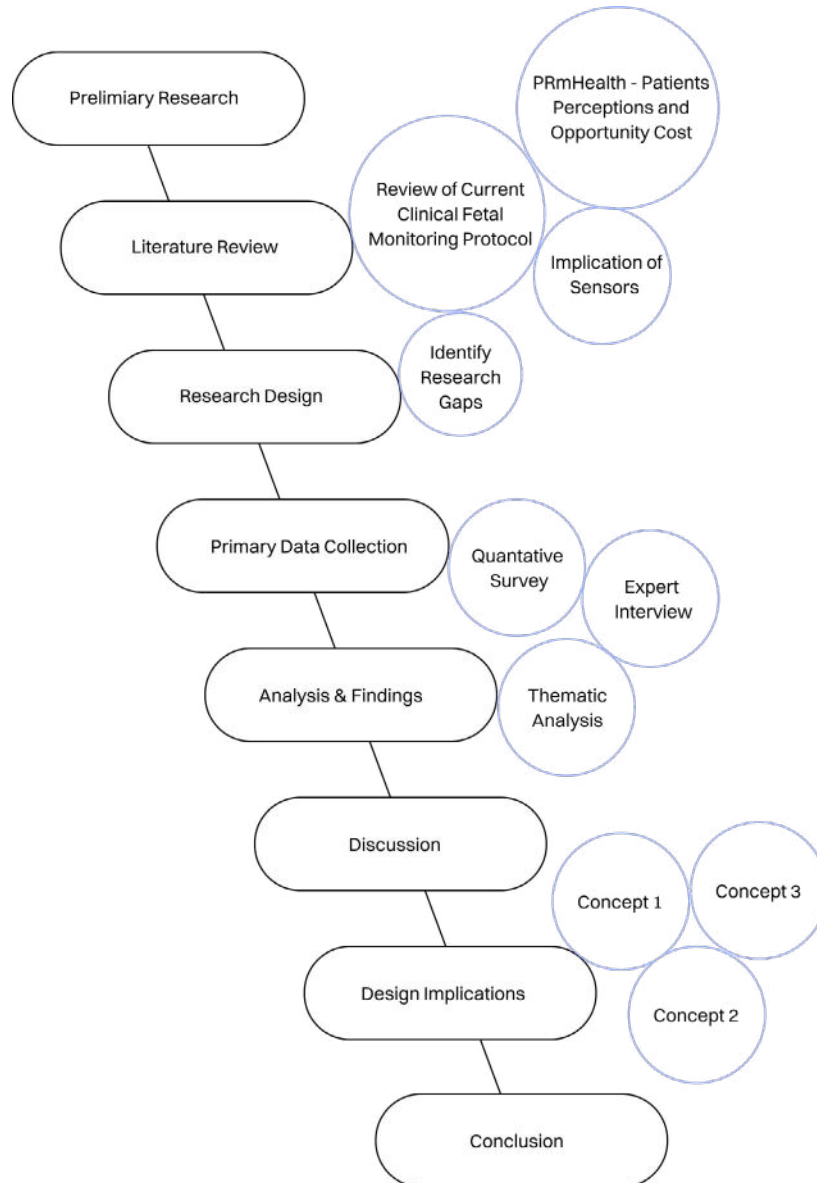
Welfare, 2018). Limitations to improving this metric are attributed to the infrequent nature of antenatal care sessions, required clinical interpretation of ultrasonic and CTG readings, and a lack of meaningful at-home monitoring protocols (Australian Institute of Health and Welfare, 2018).

The current standard at-home protocol for tracking fetal movement, known as 'kick counting', is outlined by The Stillbirth Centre of Research Excellence's Safer Baby Bundle (2020). It encourages pregnant mothers in their third trimester to self-report their baby's kicks in order to detect possible DFM. This can instantiate a degree of anxiety in pregnant mothers due to ambiguity, stress and cognitive load (Winje et al., 2012). One study by Winje et al., (2012) of 320 women tested the relationship between maternal perceived DFM and placental dysfunction. It found pregnant mothers' perception of DFM did not predict situations of clinically observable fetal compromise, suggesting that 'kick counting' provides limited, if not, zero utility to overall prevention (Winje et al., 2012). This relationship is explored further within the following literature review.

This project aims to address the antiquated at-home protocol of fetal monitoring and limitations of antenatal care by exploring innovations in continuous, at-home, non-invasive, wearable fetal monitoring.

In recent years, the market for wearables has accelerated substantially with rapid diffusion of wearable technology seen particularly within the industries of health and fitness (Liu et al., 2020). While the healthcare system, as a whole, lags behind this trend, the overall technological and social landscape is primed for opportunity and innovation (Liu et al., 2020).

Figure 1 Report Structure and Outline



Literature Review

The following literature review systematically takes a lens to the crucial themes that underpin a holistic knowledge base required to move further in the research process. Significance of various fetal health indicators, analysis of available sensory technology and clinical and user implications are among the primary topics of review.

Review of Current Clinical Fetal Monitoring Protocols

Current antenatal care guidelines outlined by Queensland Health (2020) provide a framework for assessing fetal health in the third trimester (28+ weeks of gestation). Fetal wellbeing can first be assessed by conducting a Non-Stress Test (NST). This involves a clinician using a doppler ultrasound device to measure Fetal Heart Rate (FHR) over a 40 minute time frame to determine an appropriate number of FHR accelerations (Afriat & Kopel, 2007). If the fetus does not meet the criteria of two FHR acceleration periods ≥ 15 bpm that are longer than 15 seconds in duration, the outcome is defined as non-reactive. A non-reactive NST outcome is, on its own, indeterminate of fetal wellbeing however, it constitutes further Biophysical Profile examination (Afriat & Kopel, 2007).

A Biophysical Profile (BPP) is a non-invasive diagnostic framework that uses ultrasound to assess discrete parameters of fetal movement, fetal tone, fetal breathing, and amniotic fluid volume within a 30 minute monitoring period (Afriat & Kopel, 2007). It should also be noted that there are numerous maternal factors that may influence how these results present such as BMI, blood pressure, pre-existing conditions and other high risk factors (Centre of Research Excellence in Stillbirth, 2019).

Queensland Health's Guidelines (2020) provide a comprehensive evidence based approach to

monitoring and diagnostic protocols. It is evident that the detection of DFM is paramount to assessing fetal wellbeing and furthermore, the synergistic effect of monitoring other vitals gives the ability to understand fetal wellbeing better.

Despite this, there is still no universal definition of DFM as it is highly dependent on individual pregnancy factors; however, perceived awareness of less than 10 movements over the duration of 2 hours is widely considered cause for review by a care provider (Queensland Health. 2020).

The second element of fetal wellbeing, and perhaps the most important, is patient awareness and education. In Australia, the Stillbirth Center of Research Excellence (2019) proposed Safer Baby Bundle outlines awareness of DFM as one of the main pillars responsible for preventing stillbirths however, it isn't evident that information regarding correct at-home monitoring is easily accessible or non-ambiguous.

A study by Saastad., et al (2010), investigated the implementation of uniform and standardized information on fetal movement in a Norwegian pregnant population. The sample cohort of over 20,000 participants across 14 hospitals were given information brochures prior to their third trimester that outlined relevant at-home procedures for detecting DFM, based on medical consensus. The results after intervention showed a 30% decrease in the rate of stillbirths. While the nature of the study presents some limitations due to statistical efficacy, this is still a significant reduction. Additionally, over 1 in 4 patients in the previous cohort indicated that their healthcare provider had not provided them with any information on the importance of monitoring DFM (Saastad et al., 2010).

This research was pivotal in validating the importance of standardized and mandated dissemination of quality information surrounding at-home detection of fetal movement during antenatal consultations. The UK has since launched a similar initiative that achieves the

same objectives and has also seen positive results, with a marginal reduction in stillbirths from their 2016 AFFIRM Trial (Camacho et al., 2017).

The Implications of Sensors

Methods of capturing continuous fetal movement data from a wearable device have yet to be commercialised. While wearable technology has been broadly adopted in other domains such as fitness and health, the application for at-home pregnancy monitoring is dependent on sophisticated application of sensor technology and meaningful signal processing algorithms.

Various cohorts have experimented with novel approaches to sensor technology and signal processing algorithms, and validated their results using clinical benchmarking. Their findings are as follows:

Lai et al., (2018) conducted a test that used multiple acoustic sensors to detect fetal movements on 44 women and compared the test results with concurrent ultrasound readings. Aided by the use of a reference accelerometer, which was primarily used to detect signal noise from maternal movements, fetal movements were able to be detected to a high degree of accuracy. While this method validates the application of acoustic sensors in combination with accelerometers, the results show significant errors in detecting smaller fetal movements.

Somathilake et al., (2022) proposed the use of a single IMU accelerometer, placed on the patient's abdomen. While the results outperformed traditional methods of FM tracking, the inability to effectively filter maternal movement patterns from the FM signals ultimately hindered success. In other research, the use of multiple IMU accelerometers placed strategically on the abdomen was found to detect FM to a 90% accuracy in a static environment when validated with clinical benchmarking (Du et al., 2021).

Contrary to the findings of Du et al., (2021), Altini et al., (2017) tested the use of multiple accelerometers and concluded that increasing accelerometers on the abdomen does not increase overall detection accuracy when used in combination with a wearable EMG sensor. The study also highlighted the fact that a movable device would improve accuracy as it the location of the baby's kicks could be better targeted.

Common limitations to sensor based testing

The primary limitations are ubiquitous among the majority of the aforementioned cohorts. The nature of the studies are conducted in a relatively static environment. No study has been conducted where the subject was able to be completely mobile over 24 hours as tests were done in a clinical environment. Some maternal movement patterns were tested among subjects however, in these instances, FM from devices were only able to be benchmarked with maternal perceptions

Figure 2 Types of FM sensors used in studies



Note From: Liang, S., Peng, J., & Xu, Y. (2021). Passive fetal movement signal detection system based on Intelligent Sensing Technology. *Journal of Healthcare Engineering*, 2021, 1-11. <https://doi.org/10.1155/2021/1745292>

rather than ultrasound readings. Because of this, the classification and duration of fetal kicks was unable to be determined within a reasonable confidence interval.

In response to this problem, Ghosh et al., (2020) developed a novel fetal movement simulator in order to construct a more precise and controlled method of testing different sensors within a static environment. Their testing determined that piezoelectric diaphragms and acoustic sensors were able to detect weaker fetal movement displacements of 0.5mm while accelerometers were capable of detecting 1.5mm displacements. This distinction seems irrelevant as either of these displacement thresholds should capture FM after 30 weeks gestation (Du et al., 2021). Furthermore, the piezoelectric and acoustic sensors were more prone to signal corruption and therefore Ghosh et al., (2020) recommends combining sensor hardware to achieve detection accuracy.

PRmHealth — Patient Perception and Opportunity Cost

Pregnancy related mobile health (PRmHealth) is an area that is lagging behind compared to other areas of eHealth. It is currently unclear how pregnant patients would engage with interventions in this domain or how they may impact routine obstetric care protocols. Various studies have investigated pregnant patients' relationships to adjacent mHealth interventions. Their findings help accumulate a perspective on the perceived benefits and shortcomings of PRmHealth as it relates to this project.

Analysis of the literature relating to PRmhealth during pregnancy reveals some recurring themes that help to quantify general attitudes towards PRmHealth technology. (Heuvel et al., 2018; Runkle et al., 2019). These insights include:

- Women universally opted to use Google as a first resort for information relating to pregnancy but criticized its ability to provide overall reassurance (Heuvel et al., 2018).
- Heuvel et al., (2018) Found the majority of patients are comfortable with sharing their health data with tech carriers and clinicians if it helps produce improved health outcomes, although a significant number of participants have privacy concerns. This ran contrary to Runkle et al., (2019) who's study cohort expressed no privacy concerns when surveyed about wearing a pregnancy tracking device.
- There is a need for user friendly and more personalised technology (Heuvel et al., 2018; Runkle et al., 2019).
- Patient and care provider satisfaction with eHealth interventions rates are generally good, with rates up to 95% (Heuvel et al., 2018). General satisfaction is also reported among other literature (Runkle et al., 2019).
- Evidence based features are highly valued.
- Use of the KickCount App was associated with better birth outcomes (Buckingham-Schutt et al., 2022).

Segers et al., (2021) further explores the ethical implications of PRmHealth interventions and argues that data backed benefits to neonatal outcomes must outweigh the possible cognitive load of constant at-home pregnancy tracking. Furthermore Segers et al., (2021) challenges the merit of PRmHealth applications and asserts that further study is necessary to determine the true opportunity cost to mothers citing that PRmHealth too heavily impacts pregnant women's personal lives and that it problematically increases prenatal responsibilities (Segers et al., 2021)

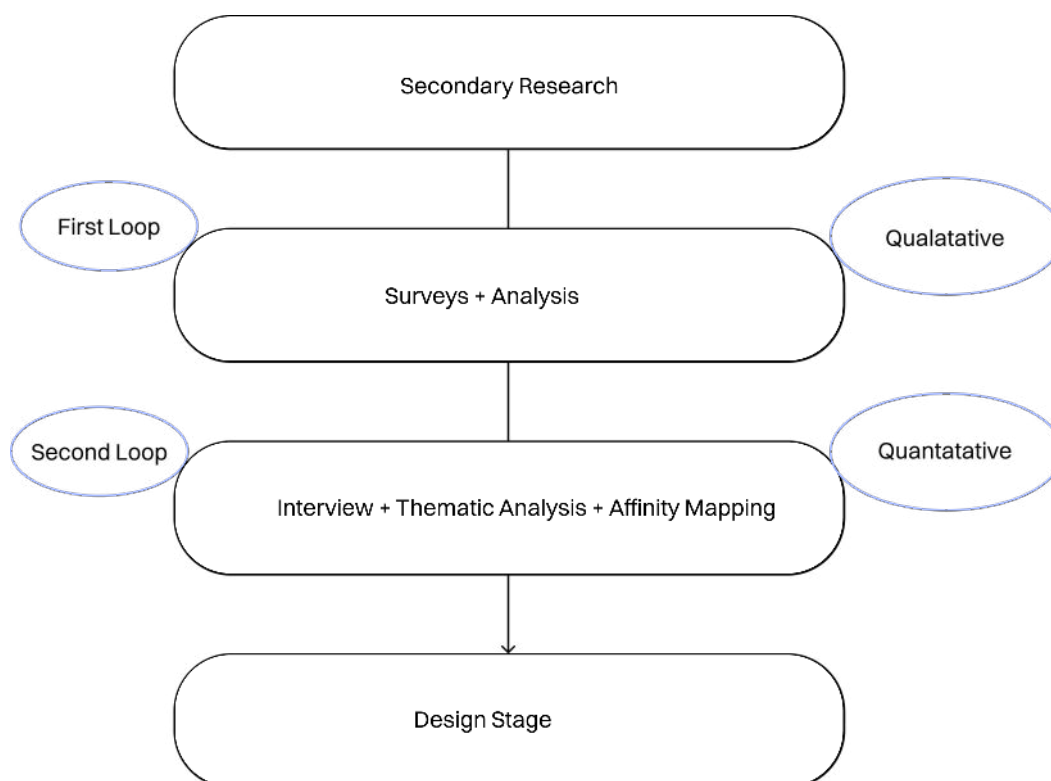
Research Gaps to Investigate in Primary Research

- Further detail on the nuances of population-wide third trimester fetal behavior to gauge design implications.
- Expert guidance to better understand complex anatomical factors that may influence the design of a wearable.
- How well do mothers understand the importance of tracking fetal movements?
- What are the current challenges relating to at home FM tracking?
- How would extra health data affect the workflow in an antenatal clinic and how would continuous monitoring data improve practices?
- Would continuous FM monitoring provide peace of mind to mothers or create more anxiety?
- What behaviors are mothers currently undertaking in the final trimester to monitor fetal health/movements?
- What are the potential negative aspects allowing patients to have unvetted access to their babies raw health data?
- What are Patient and Healthcare Providers attitudes towards novel PRmHealth wearables for FM monitoring?

Research Design

In order to address research gaps identified post literature review, primary research methods were deployed in a systematic action loop in order to gain ongoing and meaningful insights into the topic area.

Figure 3 Primary Research Structure Overview



Survey (First Round)

The first collection method was a survey developed to target mothers in the community that had given birth to a child within the last 24 months. This criteria was implemented to ensure that answers were uncorrupted by memory gaps of the participants. The survey consisted of 15 questions and took approximately 2 to 3 minutes to complete. The convenience sample consisted of 17 participants. Survey questions were structured to collect quantitative data that would easily translate to meaningful insights once reviewed.

Results and insights from this patient survey were used to inform interview design in phase 2.

Some of the research questions that the survey aims to address are:

- How well do mothers understand the importance of tracking fetal movements?
- What are the current challenges relating to at home FM tracking?
- Would Continuous FM monitoring provide peace of mind to mothers or create more anxiety?
- What behaviors are mothers currently undertaking in the final trimester to monitor fetal health/movements?
- What are Patient attitudes towards novel PRmHealth wearables for FM monitoring?

This survey is the first collection round of primary research. Once data was collected, the insights and results were used to inform interview questions intended for the second collection round (expert interview).

Expert Interview (Second Round)

The second collection round consisted of a long form semi structured interview. The participant, who will remain anonymous, is a Senior Midwife with over 30 years experience in the field. They are also involved in reviewing every stillbirth case that occurs within their hospital.

The interview was conducted in person and was intended to provide qualitative data that both validates finding from the literature review and also addresses the identified research gaps.

It should also be noted that when dealing with such complex anatomical subject matter it is highly useful to confirm understanding of the topic at large. This cannot be understated as it is crucial to avoid surface level understanding of a topic that requires a high degree of empathy and specific knowledge. Secondary to these objectives, it was crucial to create an interview environment where the subject was able to expand and elaborate on the topics in an unstructured manner. This is important to ensure that all insights and possible research blindspots may be captured.

Analysis & Findings

Quantitative Research

Loop 1 - Survey of Recently Pregnant Mothers

The results of the mothers survey illuminated many aspects of patient behavior in the third trimester that are areas of concern. It should also be noted that some respondents indicated that they have given birth over 24 months ago. These results were still included in the analysis as they were still within a reasonable time frame.

Data Validation

It should be noted that only one participant indicated that they did not track fetal movements during their pregnancy. This participant indicated they were 45+ years old. Their responses were omitted from questions regarding fetal movements so as to not corrupt the data.

Significant Raw Data Results

Figure 4 shows the FM tracking habits of participants in their third trimester. Firstly it can be observed that over 35% of participants indicated that they recorded FM less once per day. Furthermore 29% of this group either never tracked FM movements or did so only once per week. The variance of answers also suggests that there is no uniformity to standard tracking procedure, as hypothesized.

Figure 5 shows that 76.5% of participants experienced an instance where they were unsure if they should be concerned about their baby's movements. This figure may be under inflated due to the small number of participants who rarely counted FM in the third trimester.

Figure 4 Results Regarding Participants Fetal Tracking Habits

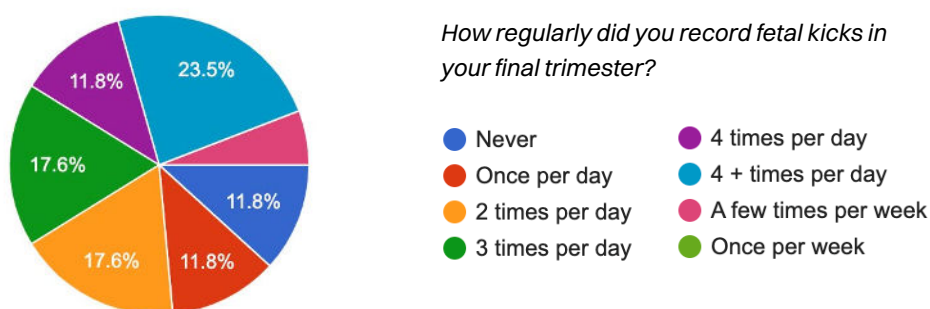
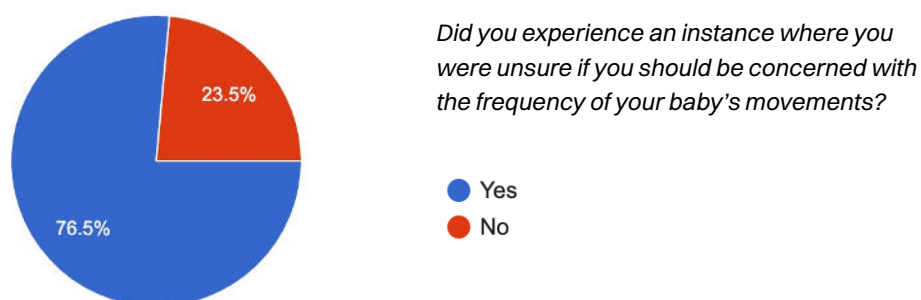


Figure 5 Results Regarding Maternal Concern Over Fetal Movements



Significant Quantitative Relationships

The following survey analysis deploys the use of alluvial plots to better segment the responses and help understand how they relate to other variables (Peterson, 2020).

Results indicated that 47% of mothers experienced an episode of DFM during their final trimester that did not precede an unscheduled visit to an antenatal clinic. This is significant as it does not reflect an appropriate response to DFM. Two alluvial plots were created to further segment the responses to this question to better understand why a large cohort of women may be skipping out on crucial health measures.

Figure 6 demonstrates that women who did not visit an antenatal clinic or hospital in the event of DFM had

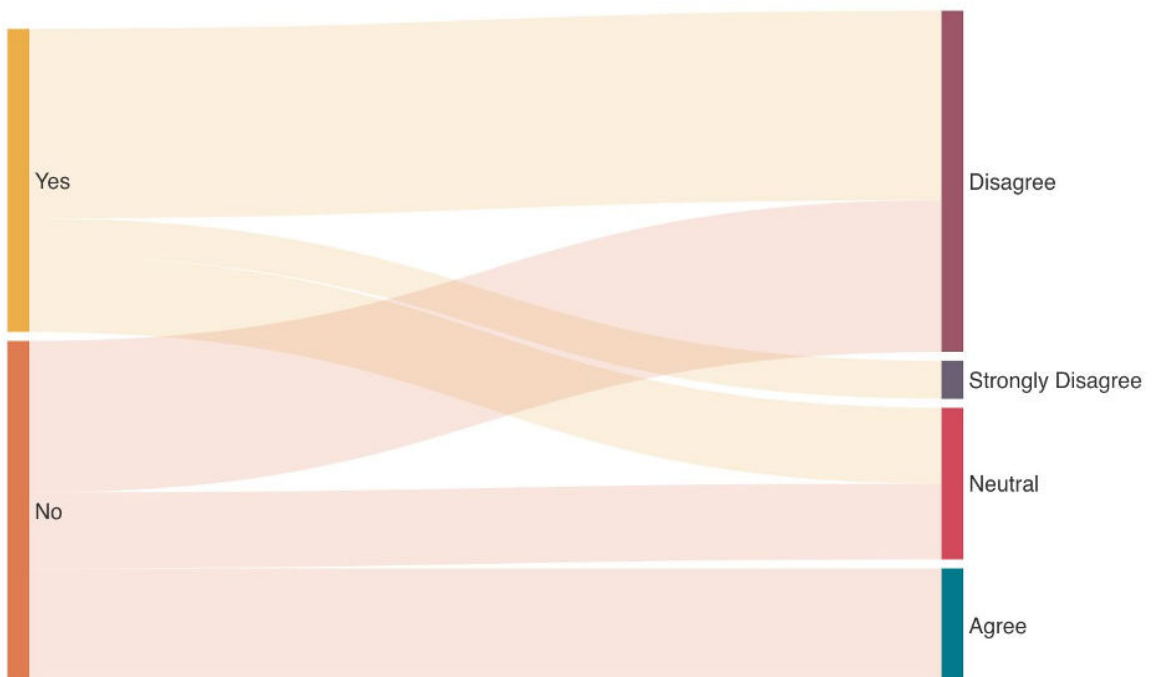
difficulty finding clear information that those who did visit an antenatal clinic in the event of DFM.

Figure 7 further reveals that women who did not visit an antenatal clinic or hospital in the event of DFM had the most difficulty identifying DFM compared to those who found it easier to detect DFM.

Insights from Figure 6 & Figure 7 suggest ambiguity surrounding correct information and difficulty tracking DFM significantly affected the participants probability of self admitting to a clinic in the event of DFM. This relationship is potentially concerning and is dissected in length in the second round of qualitative interviews.

Figure 6 Alluvial Plot 1

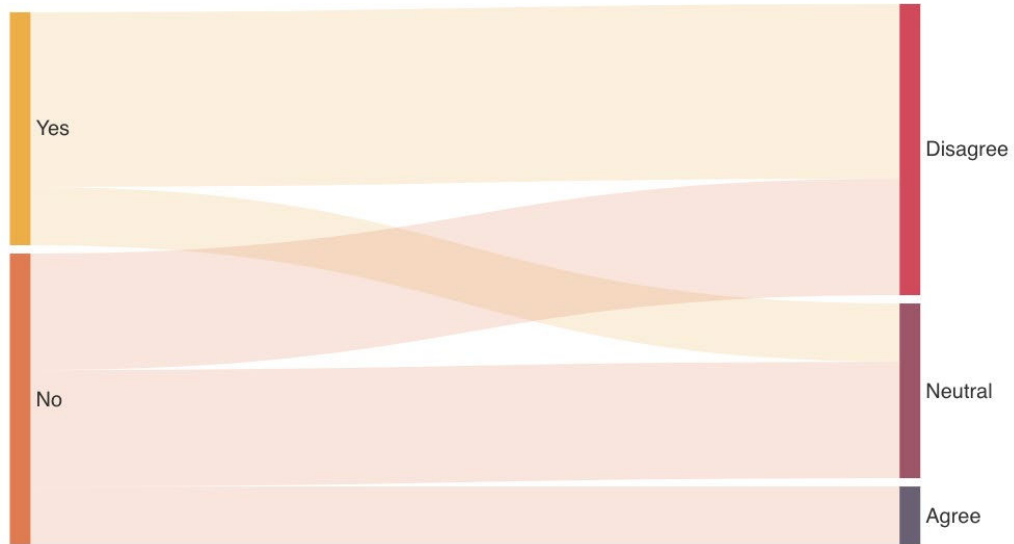
Did you experience an instance of decreased fetal movements (DFM) during your last trimester that did NOT result in an unscheduled antenatal/hospital visit?



I found it easy to find clear information about the 'normal' number of fetal movements.

Figure 7 Alluvial Plot 2

Did you experience an instance of decreased fetal movements (DFM) during your last trimester that did NOT result in an unscheduled antenatal/hospital visit?



Identifying decreased fetal movements was easy.

Relationship Between Technology Interventions and Perceived Anxiety

77% of respondents indicated that they experienced increased levels of anxiety during their pregnancy. Because of this, it is important to ensure that the design of a device does not inadvertently increase anxiety for mothers in an already difficult time.

When asked how continuous accurate 24/7 information on fetal movements would most likely to affect their state of mind, 77% of respondents indicated that it would provide peace of mind and decrease stress.

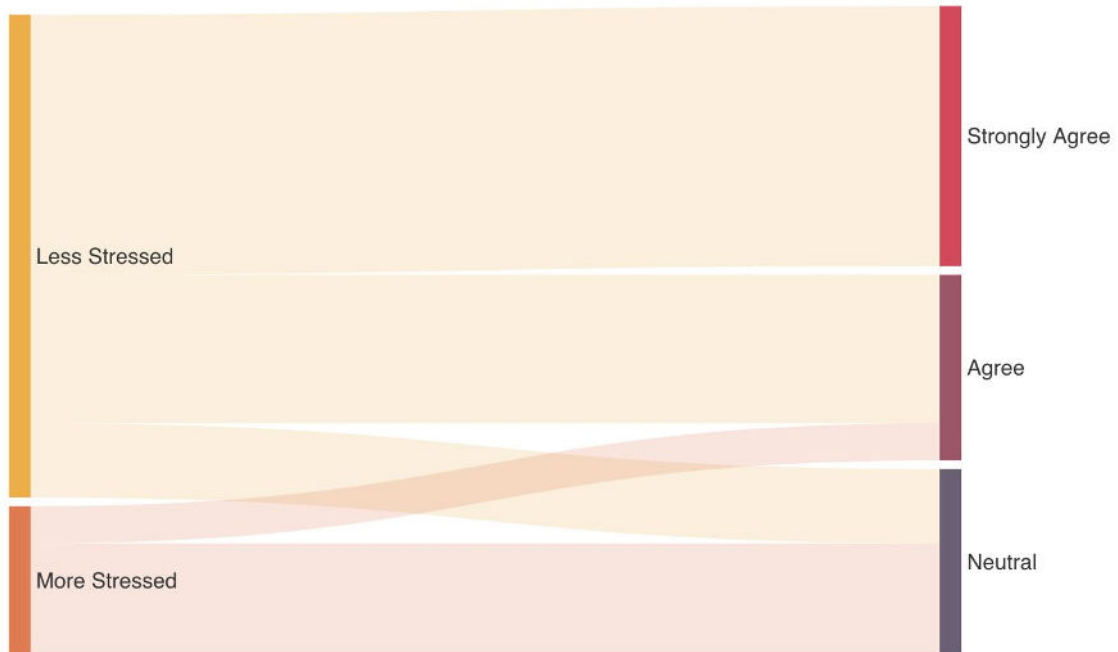
Figure 8 compares these results with respondent's attitudes and beliefs surrounding the importance of tracking fetal movements. It was found that those who understood the merit of tracking kicks (DFM) were

much more likely to experience decreased anxiety and peace of mind from continuous fetal monitoring. These results also corroborate findings from Figure 6 and 7 demonstrating an awareness gap in patient at home tracking procedure.

Full survey data can be found in Appendix 1.

Figure 8 Alluvial Plot 3

How would having continuous 24/7 information on your baby's movements most likely affect your state of mind in your final trimester?



Kick counting is important to the ensuring the health of a fetus

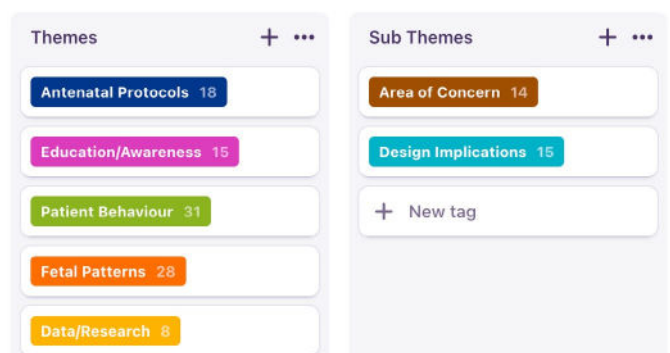
Qualitative Research Loop 2 - Interview with Senior Midwife

In order to corroborate key findings from the previous quantitative survey, an extensive semi structured interview was conducted. Thematic analysis was conducted using the program Dovetail to gain meaningful data insights.

Figure 9 shows the themes and the relevant sub-themes. In this analysis the sub-themes were used in combination with main theme tags to identify when the subject made direct comment to an area of concern or made a statement relating to design implications.

Using these codes, an initial affinity map was created made to consolidate interview insights. This is shown in Appendix 2.

Figure 9 Interview Themes and Sub-Themes



In conjunction to this, a Radar Plot (Figure 10) was created to show the frequency of each theme. From this plot it can be observed that the dominant themes are Patient Behavior, Fetal Patterns and Education & Awareness.

graph. This is shown in Figure 10. It can be observed that “Design Implications’ and ‘Areas of Concern’ re-occur in the domain of Patient Behaviors. It is also evident that there is a high concentration of Areas of Concern relating to Education & Awareness.

In order to derive better insights into the dominant themes, the sub themes were plotted on the same

Figure 10 Radar Plot of Key Themes

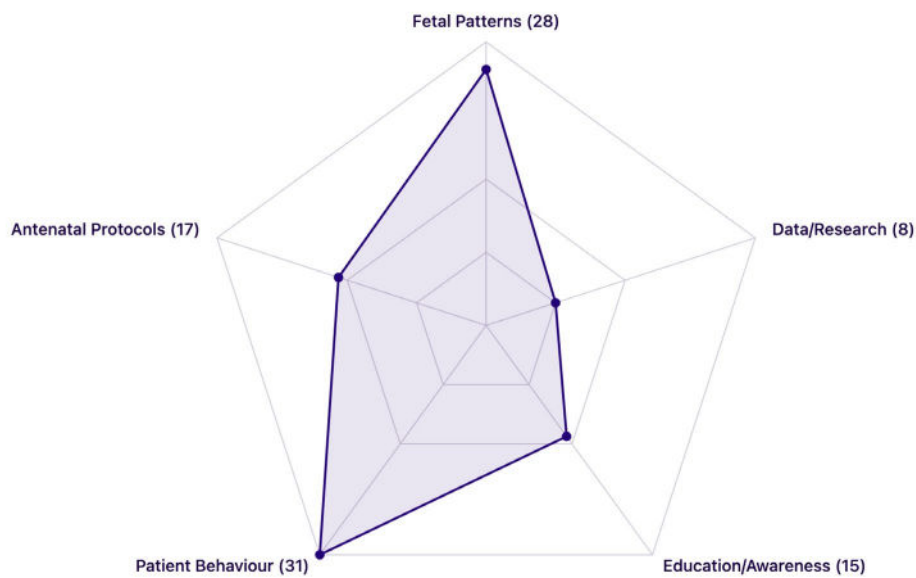
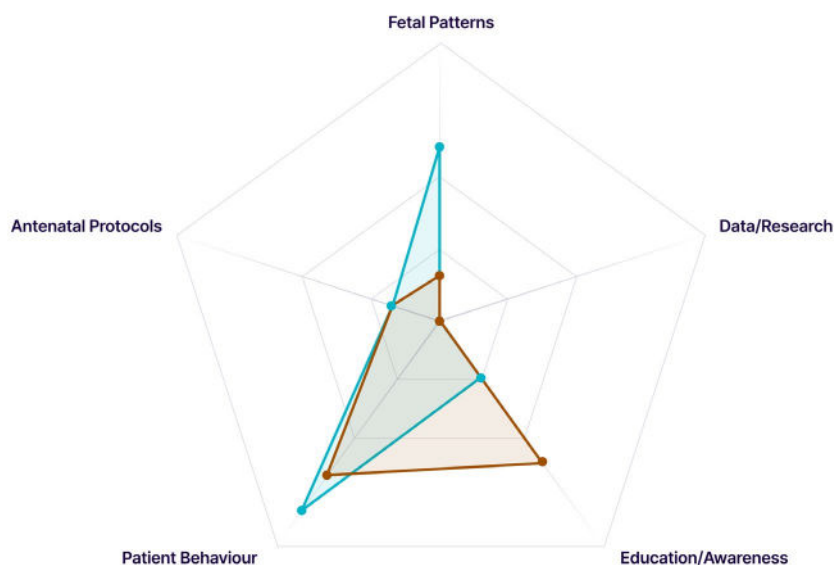


Figure 11 Radar Plot of Sub Themes as they Relate to Main Themes



Consolidating Qualitative and Quantitative Findings

Findings from the survey (Figure 6 & Figure 7) suggested that a lack of awareness and tracking simplicity surrounding DFM was a likely cause of lack of antenatal attendance. These findings were detailed to the interviewee who expressed deep concern. Figure 12 and Figure 13 shows their comments surrounding the findings.

Other key insights as they relate to the research gaps are found in Appendix 2. Further inquiry into their significance will be uncovered in the discussion section.

Figure 12 Key Interview Excerpt

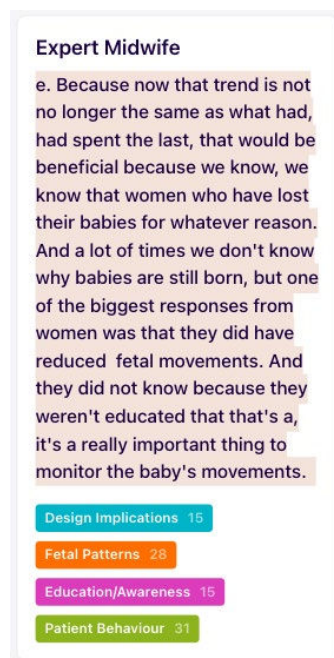
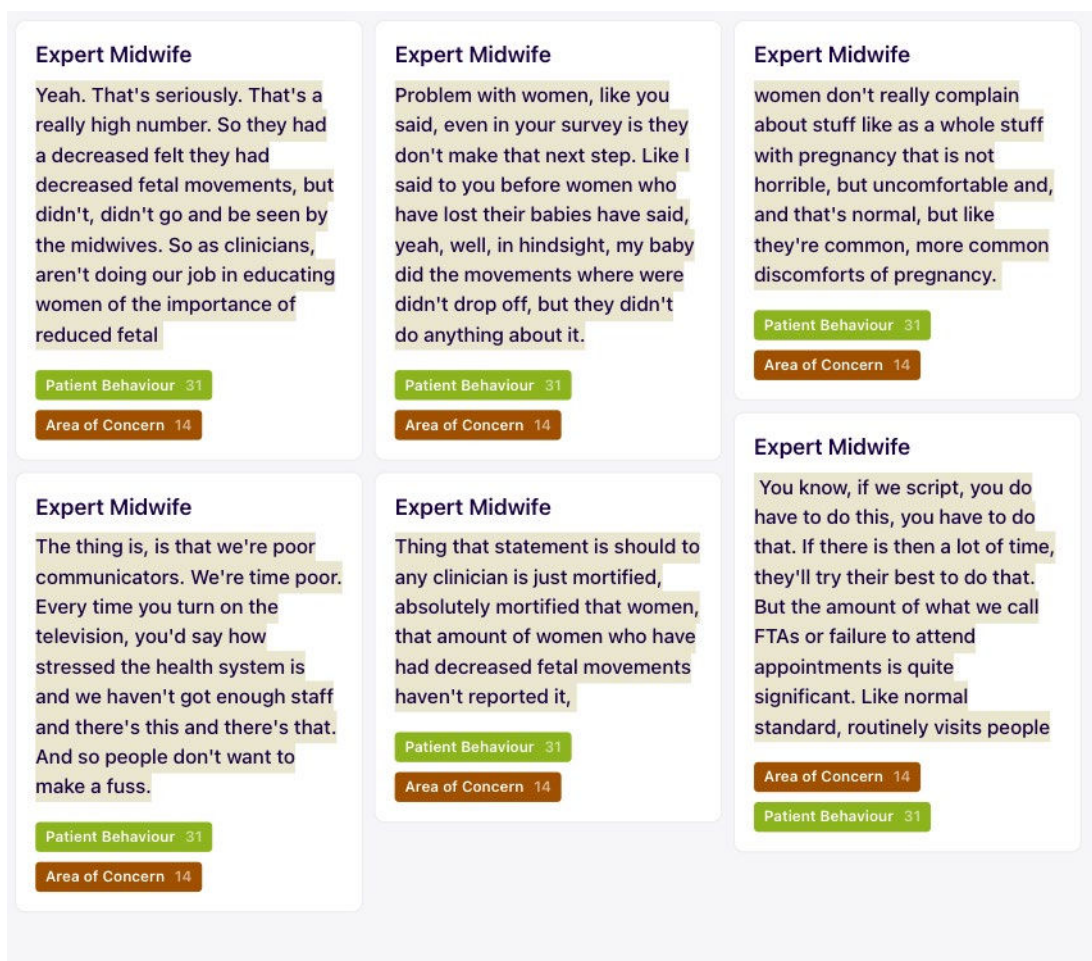


Figure 14 Interview Responses Surrounding Patient Behaviour + Areas of Concern



Discussion & Design Implications

After conducting primary research with both mothers and experts in the field of midwifery, the majority of the research gaps were able to be addressed. Additionally, new information was unearthed which further contextualised the design problem.

Nuances of anatomical fetal wellbeing in the third trimester and key health metrics

Understanding the biological and anatomical complexities of third trimester pregnancies is a non-trivial task that requires thorough investigation through different modalities.

Analysis of similar products on the market, and much of the relevant literature, profess merits of fetal heart rate (FHR) monitoring technology in addition to fetal movement (FM) monitoring. Despite this, there are a number of conflicting publications regarding the adoption of FHR as a valid metric for at-home fetal monitoring. Primary research interview analysis pertaining to themes of 'fetal patterns' and 'antenatal protocols' were able to conclude with confidence that FHR data is not sufficient to detect impending fetal compromise. Conversely, it is the unanimous opinion of the academic literature and interview subject that high quality tracking of FM is determinate of better birthing outcomes.

Additionally, the interview was able to corroborate information and reveal that fetal movement patterns in the third trimester vary substantially between each pregnancy, however each baby's movement patterns are unique and routinely repetitive on a daily basis. It was found that fetal movement patterns behave almost entirely independently of maternal behaviors. These nuances are imperative insights as they qualify the trackability of the fetal movements and reinforce the important patterns needed to inform realistic design outcomes.

The Education and Awareness Gap

Initiatives in Norway and the UK succeeded in decreasing the rate of stillbirths by a significant amount by providing better patient information surrounding the importance of tracking DFM (Saastad et al., 2010). This suggests that a lack of awareness surrounding the importance of DFM may be a contributing factor to negative birthing outcomes. The patient survey found that 47% of patients were failing to self admit to an antenatal clinic when they detected DFM. From those participants, a majority of them indicated difficulties tracking DFM and understanding its importance in fetal wellbeing. These findings were deemed highly concerning by the expert interviewee who also suggested that some women's reluctance to contact an antenatal clinic is due to a perceived belief that they might be a hindrance to the healthcare system.

This claim was investigated as part of the research gap of addressing the perceived friction to the clinical workflow.

It was found through the interview process that all hospitals are equipped with a 24/7 Maternity Assessment Unit (MAU) which is solely equipped to screen calls from concerned mothers. Furthermore, midwives are urged to encourage patients to call the clinic even if unsure about their baby so they can be assessed over the phone and prompted to go to hospital if required. Despite this, it is clear from all methods of research that an estimated 20-40% of pregnant women are failing to contact the MAU in instances of concern. Furthermore, the interviewee states that access to large quantities of continuous FM data would make a substantial impact on improving clinical outcomes.

This insight is key in reframing the problem statement from, "how might a wearable fetal monitoring device detect DFM" to "how might a wearable fetal monitoring device increase patient-clinic communication in instances where fetal health is in question". These two statements are both in service of the overall objective

of reducing preventable stillbirths; however, the latter provides more context to the issue and implies different design implications.

While precision accuracy detecting DFM tracking is difficult to achieve, the level of accuracy of these tests unanimously outperformed maternal perceptions of DFM in all studies. It can confidently be stated that this is sufficient to ensure better birthing outcomes when paired with good design.

Ethical Considerations and Opportunity Cost

A research gap relating to the ethics of PRmHealth wearables was identified post literature review as it was not clear if they would create a net positive utility to already potentially anxious mothers (Heuvel et al., 2018; Runkle et al., 2019). 76% of survey respondents indicated that wearing a FM tacking device during the third trimester would lower their anxiety. The majority of respondents who responded otherwise indicated that they did not believe tracking FM to be an important part of fetal wellbeing. This suggests they do not understand the benefits of a wearable device and real statistics surrounding perceived benefit may be higher.

Other ethical concerns were raised by the interviewee involving patient access to data. The interviewee revealed situations where hand held doppler devices were used by women to track (FHR) at home. This resulted in situations where FHR data was misinterpreted to give a false sense of fetal well-being when in fact emergency attention was required. This theme was largely absent from the literature however it is important to note this as an ethical concern during the design process.

Technology Benchmarking

The literature review found that there are numerous sensor configurations that succeed in tracking FM to a high degree of accuracy. While these experiments were mostly constrained to a static clinical environment, they serve as a proof of concept for future development.

Design Implications

- The device should track fetal movement patterns to a higher degree of accuracy than maternal perception. Outperforming maternal perceived movements is more important than absolute accuracy.
- Device must make detecting DFM easy.
- The device should be able to be worn 24/7
- The device should aim to reduce the cognitive load and lower anxiety for the mothers.
- A combination of sensors consisting of accelerometers, piezoelectric diaphragm sensors, acoustic sensors and EMG sensors to derive fetal movements.
- The device should intrinsically lower the barriers of communication between patient and healthcare provider.
- The device should enhance the emotional connection between mother and baby
- The device should not provide the patient with the health data that has potential to be misinterpreted. Decisions surrounding health data access should be carefully considered in order to decrease anxiety and decision fatigue
- Use of the device should be overseen by a midwife or healthcare professional in the final trimester.
- In the presence of DFM the device should prompt patients to contact their relevant Maternity Assessment Unit.
- FM data should be made available to antenatal staff members as it can help in assessment of fetal wellbeing.

Note: Initial Concepts Found in Appendix 3

Conclusion

This project has addressed the antiquated at-home protocol of fetal monitoring and limitations of antenatal care by exploring innovations in continuous, at-home, non-invasive, wearable fetal monitoring. In recent years, the market for wearables has accelerated substantially with rapid diffusion of wearable technology seen particularly within the industries of health and fitness (Liu et al., 2020). While the healthcare system, as a whole, lags behind this trend, the overall technological and social landscape is primed for opportunity and innovation (Liu et al., 2020).

A review of the literature took a lens to current antenatal protocol, patient behavior and analysed the effectiveness of various sensor based technologies in tracking FM. Findings showed that accelerometers and various combinations with piezoelectric diaphragm sensors, acoustic sensors and EMG sensors are able to outperform maternal perceptions of DFM in static environments, and in many cases provide a highly accurate continuous depiction of FM.

Two rounds of primary research were deployed to answer literature gaps surrounding patient behavior and clinical implications for antenatal protocols. Insights gained from a patient survey and interview with a Senior Midwife found that up to 47% of pregnant patients experience DFM and did not contact their antenatal clinic. Further findings suggest this high number is likely attributed to lack of awareness surrounding the normal amount of fetal movements, lack of education surrounding the importance of detecting DFM, reluctance to be a burden on the healthcare system and lack of effective methods of tracking FM.

Ethical considerations were also investigated in order to understand the opportunity cost of a continuous monitoring device as a review of the literature was not conclusive regarding patient anxiety. Primary research results found that the vast majority of patients who were educated on the importance of tracking FM in the third trimester would find peace of mind having access to continuous FM data. Furthermore they would be

comfortable sharing their health data.

Overall, the insights from this report strongly validate the utility of developing a continuous fetal monitoring device and its ability to integrate easily with the current antenatal practice. Opportunities to improve FM monitoring, increase education of DFM and enhance the dialogue between patient and care provider are key themes that will guide the next phase of design and development.

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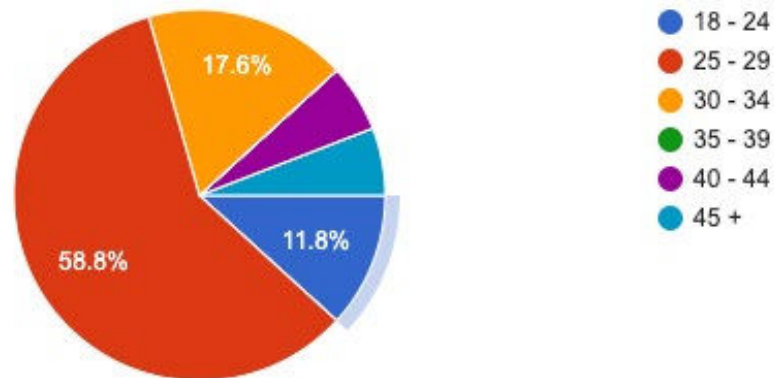
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Appendix

Appendix 1: Survey Data

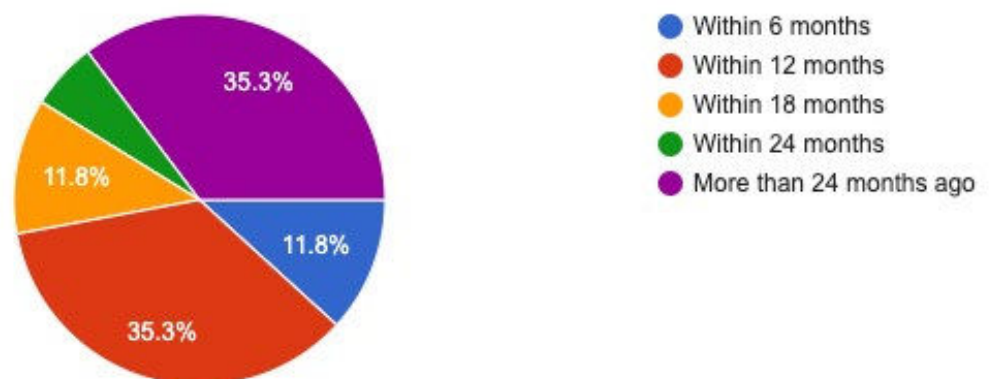
What is your age?

17 responses



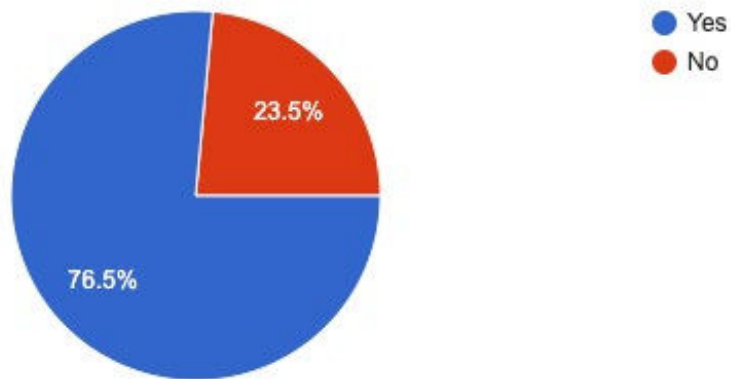
How recently did you give birth?

17 responses



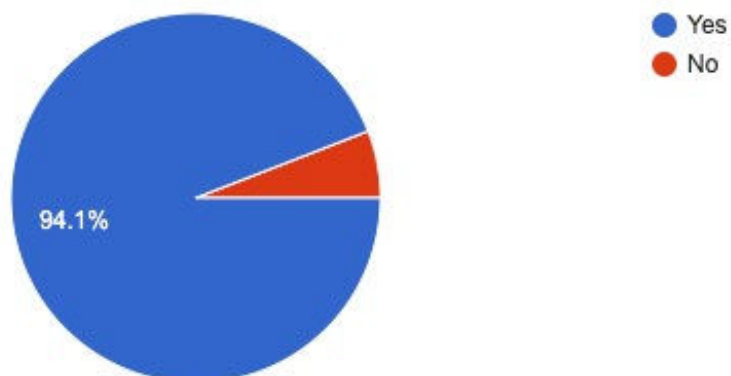
Did you experience increased levels of anxiety during pregnancy?

17 responses



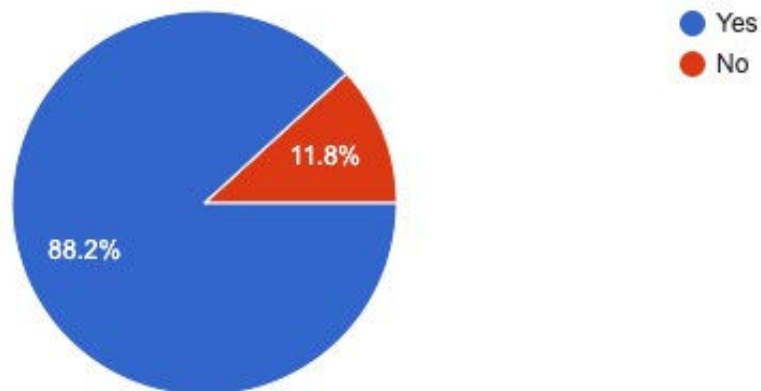
Was there instances in which you were unsure of the health of your baby during pregnancy?

17 responses



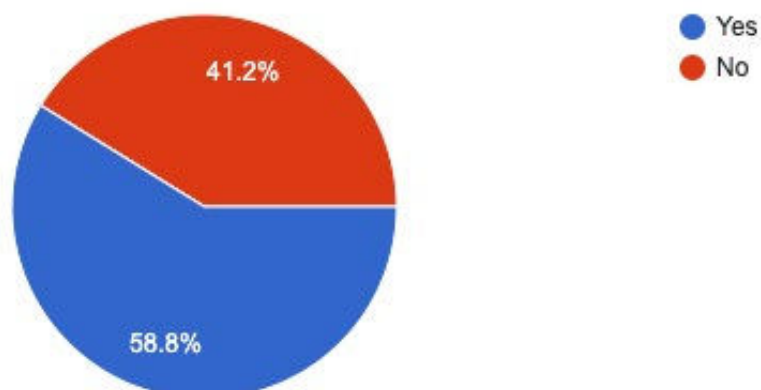
Did you track fetal movements (baby kicks) during your final stage of pregnancy ? (28 weeks and beyond)

17 responses



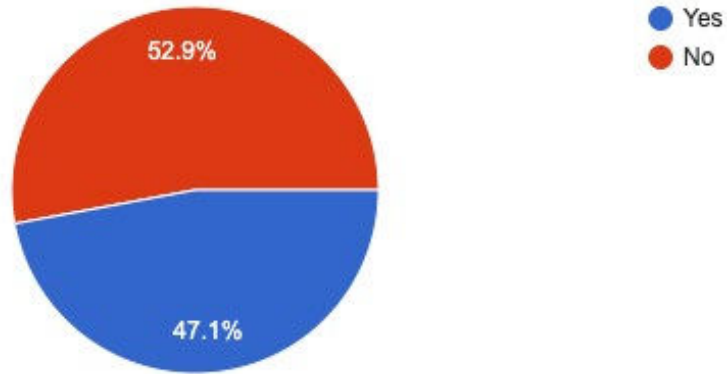
Did you experience an instance of decreased fetal movements (DFM) during your last trimester that resulted in an unscheduled antenatal/hospital visit?

17 responses



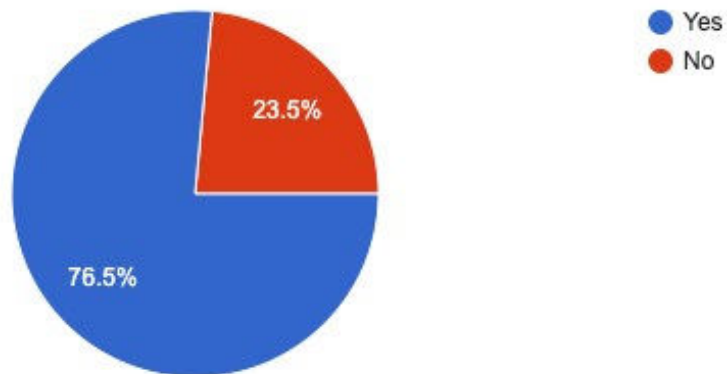
Did you experience an instance of decreased fetal movements (DFM) during your last trimester that did NOT result in an unscheduled antenatal/hospital visit?

17 responses



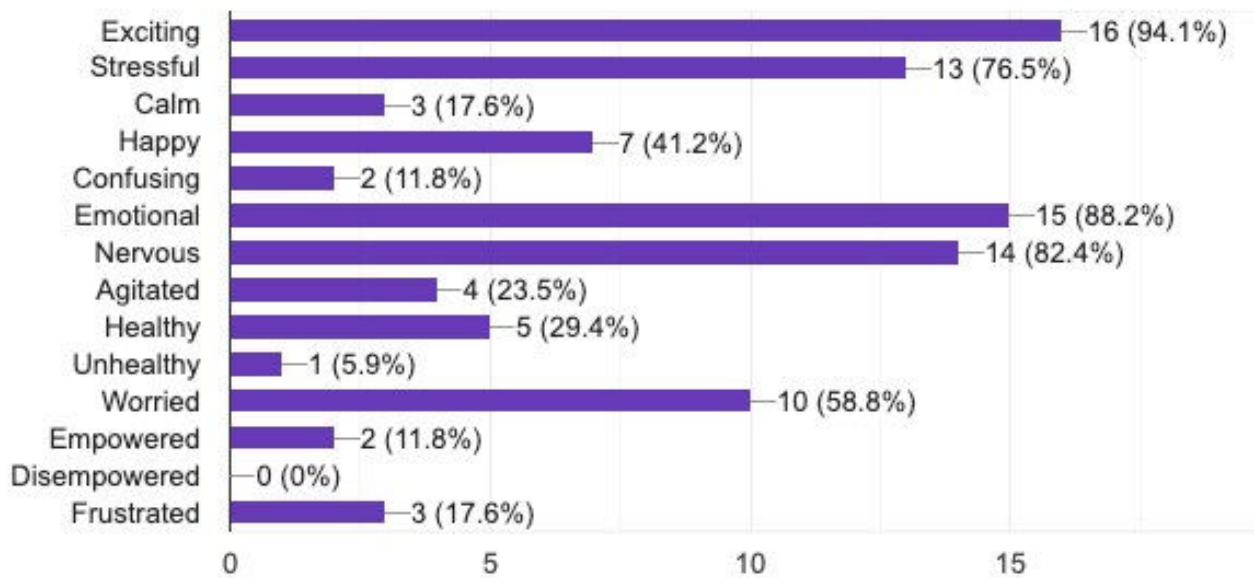
Did you experience an instance where you were unsure if you should be concerned with the frequency of your baby's movements?

17 responses



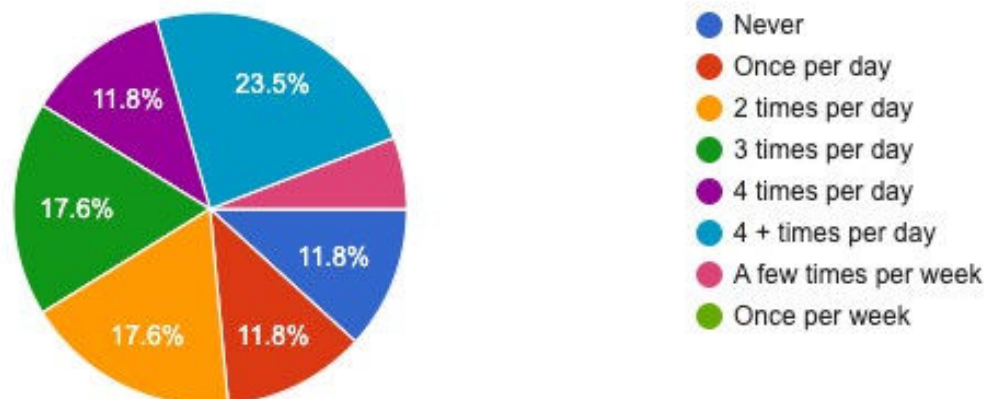
What words describe the third trimester of pregnancy? (Tick all that apply)

17 responses



How regularly did you record fetal kicks in your final trimester?

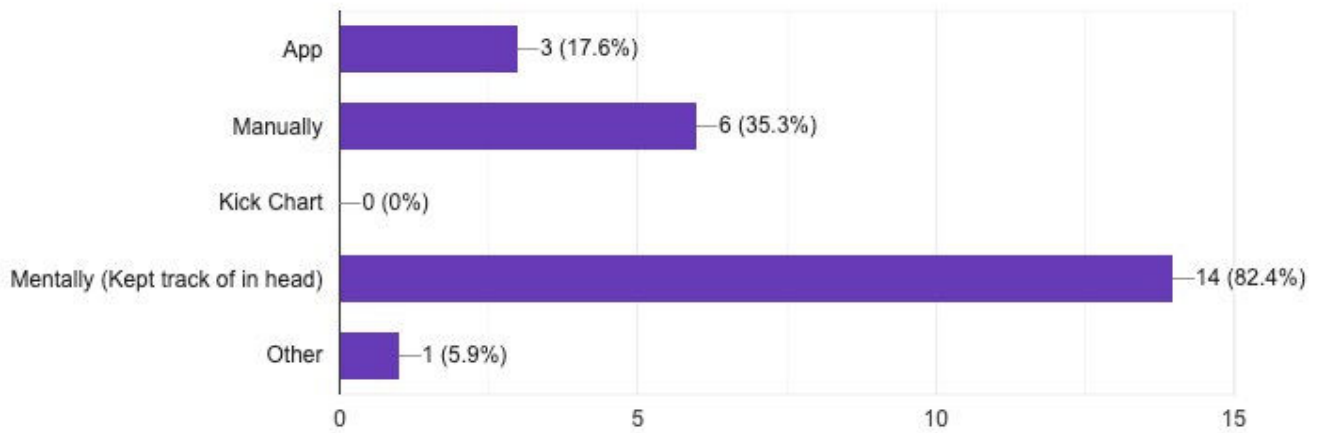
17 responses



How did you track fetal movements (baby kicks)?
(Tick all that apply)



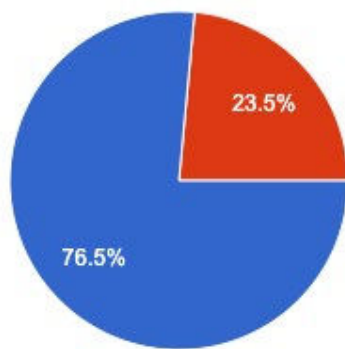
17 responses



How would having continuous 24/7 information on your baby's movements most likely affect your state of mind in your final trimester?



17 responses

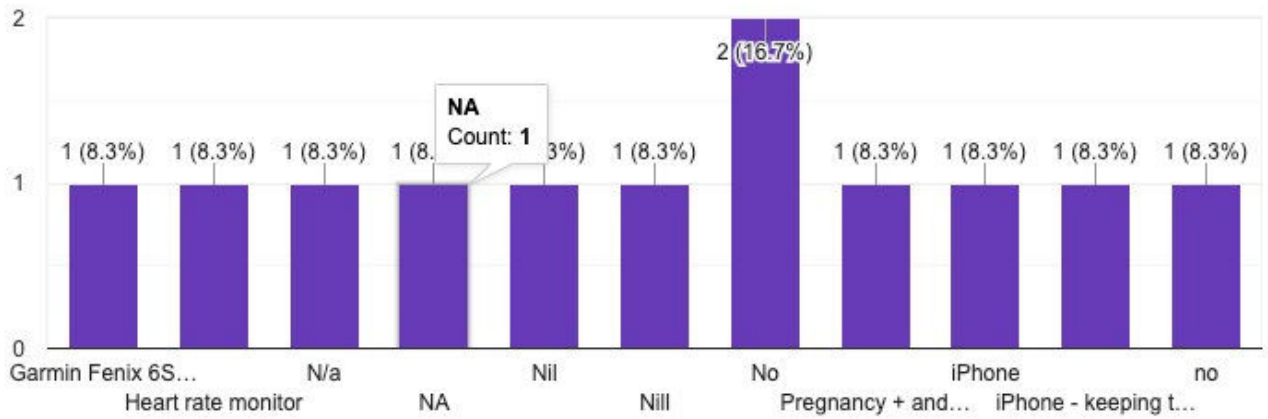


- More accurate and continuous fetal movement tracking would give me more piece of mind in relation to the safety of my baby
- More accurate and continuous fetal movement tracking would cause me to be hyper-aware and stressed.

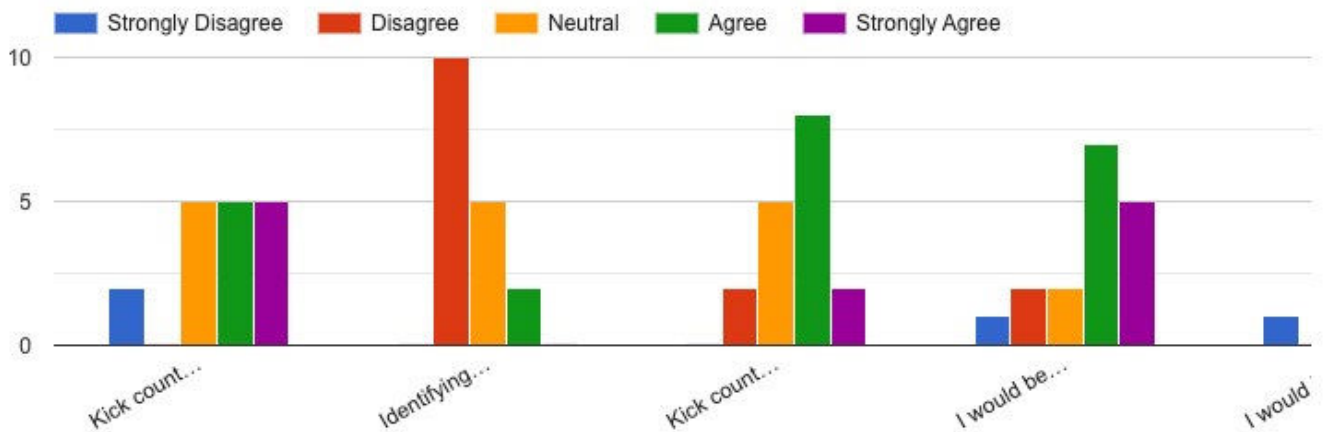
Did you use any smart devices during your pregnancy? Please list.



12 responses



Please indicate your response to the questions below with how much you agree/disagree with the statement.



Expert Midwife

there'll be a lot of education in regards to expectations of labor and preparedness for labor education around making sure patients have information in regards to a safe environment for baby to take baby home

Education/Awareness 15

Area of Concern 14

Expert Midwife

I think, I think we, we market things really poorly. Like I'm on a steering committee, which stands for it's growth and the acronym is generating research and something about obstetric outcomes

Education/Awareness 15

Area of Concern 14

Expert Midwife

Do you see any barriers to something like this being implemented? No, because it's our core business like educating women to consider their fetal movements is what we already do. We just don't do it well enough for women to actually do that on a daily basis.

Education/Awareness 15

Area of Concern 14

Expert Midwife

Okay? So two things, firstly, it's not that common. It's probably about less than 5% of pregnancies come that way. And it causes more, could potentially cause more complications because babies heads are generally the biggest part of them

Fetal Patterns 28

Expert Midwife

So most babies come head first,

Fetal Patterns 28

Expert Midwife

Fetal movements in addition to fetal heart, right. Better than fetal heart rate alone.

Fetal Patterns 28

Expert Midwife

And that heart rate alone just tells you that the babies is living. It doesn't tell you whether it's stressed or it's not stressed. So their normal baby's heart rate is anywhere between 110 and 160.

Fetal Patterns 28

Expert Midwife

So that's true. Yeah. If a baby's got lots of energy in reserve, he or she is more likely to move more if the baby's not got a lot of reservoirs and he's less likely to move, but

Fetal Patterns 28

Expert Midwife

ght. Although it is normal over for a short period of time, 30 or 40 minutes for the baby to have a sleep cycle. And so the CTG looks very different, but if it's certainly, if the, if it's a reduced variability in CTG, if that continues for an hour, two hours, then that's not normal. And that's when you would order other tests.

Fetal Patterns 28

Expert Midwife

It can have a detrimental effect because it fetal heart rate alone is not an indicator of fetal wellbeing.

Fetal Patterns 28

Expert Midwife

babies do have good hearing and they, they might get startled.

Yeah. But that's, that's a neurological response to an audio stimulus. It's not an indicator of fetal wellbeing

Fetal Patterns 28

Expert Midwife

Yeah. And that's not so surprising because there is no normal number. So one woman might have 10 kicks a day and that's normal for her. And another woman might have 50 kicks a day. So if she ended up with it is a big barrier. So if that particular woman B starts experiencing 20 kicks a day, then that's significant for her.

Fetal Patterns 28

Expert Midwife

I'd probably say 32 weeks or 28 weeks is the last trimester, 28 weeks onwards. But in regards to fetal maturity and muscle growth and development, 28 weeks is still fairly mild kind of kicks. Whereas at 32 weeks you've got a more robust fetus onboard and you know,

Fetal Patterns 28

Expert Midwife

Everybody's different. So somebody might, might move intermittently throughout the course of the day at the baby's mood just in the morning, don't move in the afternoon. So you can't like I could sit there with an ultrasound for an hour and might see no fetal movements, which is why a biophysical profiles,

Fetal Patterns 28

Expert Midwife

if you've got a BMI of 45, those women generally don't feel as good, a quality fetal movements as someone that you've got a BMI of 25. So sometimes the appliance that you've got, it's just not going to do it for you.

Fetal Patterns 28

Expert Midwife

Breached babies potentially might not have as many fetal movements because they, their legs normally like that some babies,

Fetal Patterns 28

Expert Midwife

I think the stats are reading. And you would, you would obviously know, like, I think, I think there's a 50%, 50% of stillbirths reported, decreased fetal movements, or maybe I'm getting a stat Easily, easily, easily that high, probably higher.

Fetal Patterns 28

Expert Midwife

Th that's important when mother sleeps, baby doesn't necessarily sleep baby sleep in utero. Usually they have about a 40, 45 minutes cycle of sleep

Fetal Patterns 28

Expert Midwife

o fetal sleep, doesn't mimic maternal sleep patterns at all.

Fetal Patterns 28

Expert Midwife

If you had sensors, if you had a device that's going around to come posteriorly, you would have your senses across. So it doesn't matter what the baby went left or right. You will still be able to pick it

Fetal Patterns 28

Expert Midwife

About 30% of the time, a third of the time, we have no idea. A lot of times it's about a third of the time I had to placental central problem

Fetal Patterns 28

Expert Midwife

CTG or a stress test is taking not just the baby's heart rate, but the pattern of the baby's heart rate period of time

Antenatal Protocols 18

Expert Midwife

Even Gympie that I'd have a unit, but they have someone on the phone that gives advice and then says, come in, come see us.

Antenatal Protocols 18

Expert Midwife

And that would be to either visit her GP who don't have CTG machines, that they only have handheld Doppler technology in their surgeries, but more probably go to their antenatal clinic for CTG. And that the CTG monitors is able to pick up five different features rather than just heart rate. No, no, these are just, this is just non-stress test stuff. So not just, we look at the heart rate, we look at the variability of the heart rate. We look at accelerations decelerations and potentially in a uterine activity. Cardiotoxic

Antenatal Protocols 18

Expert Midwife

So we've got a platform at the moment, which is a electronic, fetal monitoring. But the data from that period of time where we trust that woman or that baby automatically gets uploaded to a platform called in space. And so I've got thousands and thousands of hours of CTG tracing.

Antenatal Protocols 18

Expert Midwife

But for us, when a woman presents with decreased fetal movements and she actually, we actually go, yeah, that does sound like you've got some pretty obvious, decreased fetal movements. Why don't you come in and we'll have a look and do a monitor test of the baby and run for half an hour at CTG.

Antenatal Protocols 18

Expert Midwife

Because there will be a degree of extra workload in educating women and fixing the device to the woman, showing them how to download the app on their phone or something like that, you know, in that initial registering the device to the woman, that would be an increased workload that we currently don't do. But the rest of it is already in place.

Antenatal Protocols 18

Expert Midwife

And you can find a handheld Doppler at a chemist or online for 25 30 bucks, which is fantastic. But unless you're trained to use one, find where the heart beating is. Like I said before, you'd help take the mum's tummy. And you think, okay, that's on the left so that you put your Doppler over the sort of left lower quadrant of the mother's abdomen and you will usually get the fetal heart there, but you could inadvertently, if you're not knowing where the baby's position is, just go stick it here and get on your Doppler a heartbeat, but not necessarily the baby's.

Area of Concern 14

Fetal Patterns 28

Expert Midwife

I think what we tell our mothers is that the movements of her baby are unique to her baby. And if the pattern of that baby's movements change, then that's an indicator for her to go and make further efforts to reassure her that her baby's not compromised

Fetal Patterns 28

Antenatal Protocols 18

Expert Midwife

If she goes home then, and she presents again, two days later with a second episode of decreased fetal movements, the Queensland clinical statewide guidelines recommend we induce her. That's how serious decreased fetal movements are that we recommend induction on the second episode, even with a reassuring CTG, that's how serious it is in the third trimester, particularly after 32 weeks

Antenatal Protocols 18

Fetal Patterns 28

Expert Midwife

Yeah. So it's, it's not the number of reduction in kicks. It's the pattern that there is a reduction is more important.

Fetal Patterns 28

Design Implications 15

Expert Midwife

she's asleep and she's lying flat on her back in reduction in the blood flow through to the placenta cause the baby's weight and the placenta's weight and the uterus is weight is pushing on your abdominal aorta and therefore decreasing the amount of profusion through to the placenta.

Design Implications 15

Fetal Patterns 28

Expert Midwife

If You had a wearable device that you stayed on for a number of days, and if it automatically picked up fetal movements at whatever time in that 24 hour cycle, and then it did that again the next day, if it could recognize the pattern for that individual Fetus, and then realize that in perhaps the next day, that pattern isn't potentiall the same

Design Implications 15

Fetal Patterns 28

Expert Midwife

e. Because now that trend is not no longer the same as what had, had spent the last, that would be beneficial because we know, we know that women who have lost their babies for whatever reason. And a lot of times we don't know why babies are still born, but one of the biggest responses from women was that they did have reduced fetal movements. And they did not know because they weren't educated that that's a, it's a really important thing to monitor the baby's movements.

Design Implications 15

Fetal Patterns 28

Education/Awareness 15

Patient Behaviour 31

Expert Midwife

Yeah. That's seriously. That's a really high number. So they had a decreased felt they had decreased fetal movements, but didn't, didn't go and be seen by the midwives. So as clinicians, aren't doing our job in educating women of the importance of reduced fetal

Patient Behaviour 31

Area of Concern 14

Expert Midwife

Problem with women, like you said, even in your survey is they don't make that next step. Like I said to you before women who have lost their babies have said, yeah, well, in hindsight, my baby did the movements where were didn't drop off, but they didn't do anything about it.

Patient Behaviour 31

Area of Concern 14

Expert Midwife

women don't really complain about stuff like as a whole stuff with pregnancy that is not horrible, but uncomfortable and, and that's normal, but like they're common, more common discomforts of pregnancy.

Patient Behaviour 31

Area of Concern 14

Expert Midwife

The thing is, is that we're poor communicators. We're time poor. Every time you turn on the television, you'd say how stressed the health system is and we haven't got enough staff and there's this and there's that. And so people don't want to make a fuss.

Patient Behaviour 31

Area of Concern 14

Expert Midwife

Thing that statement is should to any clinician is just mortified, absolutely mortified that women, that amount of women who have had decreased fetal movements haven't reported it,

Patient Behaviour 31

Area of Concern 14

Expert Midwife

You know, if we script, you do have to do this, you have to do that. If there is then a lot of time, they'll try their best to do that. But the amount of what we call FTAs or failure to attend appointments is quite significant. Like normal standard, routinely visits people

Area of Concern 14

Patient Behaviour 31

Expert Midwife

That would have that data like thousands and thousands of women's data on fetal movements will be just enormous for researchers to delve into that. Yeah. If you could download that and keep it, and then analyze it

Data/Research 8

Expert Midwife

Yeah, I think it's good that there's lots of, there's starting to be a lot of money thrown at research for stillbirth, really, you know, babies die from a lot of things, but the ones that we can save and these ones, when they're telling us over a number of days or weeks that I'm not good here, I'm stuffed, I've got no energy. I've got no reserves

Data/Research 8

Expert Midwife

Data is gold. Data is gold. You have to start.

Data/Research 8

Expert Midwife

Yeah. And it's like, unless you've got the data around a certain cohort of people, for whatever reason, then you're never, ever gonna find things

Data/Research 8

Expert Midwife

Because we don't have, we don't have any quality data in regards to fetal movements. It's, it's, it's not hypothetical, but it's often retrospective and it's, you know, it's, it's, women's perceptions of what's. Right. And what's not. So how can you clearly measure that except for patents,

Data/Research 8

Expert Midwife

So if, if your device could then potentially, might be too complex, a thing to, to highlight to the mother that this baby's just had a deceleration, maybe that would encourage her more to go and seek help.

Design Implications 15

Patient Behaviour 31

Expert Midwife

And really the multiple alerts to the woman would be great if should get, you know, message on a phone to just say, call the hospital, make the call. Not just vibrate, because that's not saying it's alerting her, but she needs to be told go to hospital call a midwife now.

Patient Behaviour 31

Design Implications 15

Expert Midwife

Yeah. If it could be like a single soft stretchy band with your senses, wherever, probably mostly across the anterior portion of it, if it was waterproof, that'd be great. Like the more you take it off, the more chance of your woman's not going to put it back on again

Design Implications 15

Fetal Patterns 28

Expert Midwife

I think decreased movements in, if we can make women more aware of the importance of decreased fetal movements by simple wearable device, which will notify her when her trend becomes not abnormal, but different from previous daily trends of her own baby, that would be great.

Patient Behaviour 31

Design Implications 15

Expert Midwife

Sometimes people just don't turn because yeah, which is a problem. But for them to be able to say, well, but I've got this added thing, that'll give me reassurance that my baby's movements are good. That's a good thing. But to have to bundle up your other kids have sent her to childcare or make the appointment on a day where you have got childcare for the other people to come to hospital and then not go pay for parking and all that sort of stuff. I think the take-up would be good with women. As long as it's not restrictive, it's not in the hot sweaty area.

Patient Behaviour 31

Design Implications 15

Expert Midwife

But what I think is, should be different with yours is that it's notifies the woman. It actually sends them warning to the woman to say, your baby has reduced fetal movements from what its usual trend is. You need to do this

Fetal Patterns 28

Design Implications 15

Expert Midwife

I think I've got decreased movements that it says I do. Can you just like pull up my daughter and have a look like, you know, if it's on the server, like it's uploaded. Like it can do, if that, if your device could do that and that would be fantastic.

Antenatal Protocols 18

Design Implications 15

Expert Midwife

Can send the woman some sort of alert and, and even open her phone so that it's on the phone number for her antenatal clinic. So GP is not good enough because the GP has just got a handheld Doppler. You've got to get into the hospital where you can have one, a CTG and two an ultrasound.

Patient Behaviour 31

Design Implications 15

Expert Midwife

do you think there's any potential problems with the patient having access to the actual raw data and the trends like in the, No, not at all, because she's aware of that anyway. Usually hopefully, Well, I mean, not when your baby's kicking, like when there's she's asleep, like Yeah. I can't say there's any downside to her having that information.

Patient Behaviour 31

Expert Midwife

Yeah. I'm sure it is because women are always, when you're pregnant, you're always worried that something's not right.

Patient Behaviour 31

Expert Midwife

It's going to be, it's a fantastic opportunity. You're going to going to be great. It's free and you don't have to do anything more than make a phone call

Patient Behaviour 31

Expert Midwife

when you get to about 28, we're certainly 30 weeks. It's uncomfortable to sleep on your back. Cause this, this uterus and placenta and like a uterus is like a muscle

Patient Behaviour 31

Expert Midwife

Yeah. That's going to stop people. They're not going to sit down in their day and do a questionnaire every time that device says your trend has changed. You feel movements have changed. If you want to fill out a questionnaire. Now we just want you to call.

Patient Behaviour 31

Expert Midwife

. And so to call a health care provider and complain about decreased fetal movements, that seems like a bit of a bit pathetic. So just reinforcing to both clinicians, as well as consumers, that this is something that's really important that we need to sort of value a little bit more, you're doing the right thing by just picking up the phone and making calls. It doesn't necessarily mean like you've got to pack your bag and go into hospital, but certainly just by making a call and asking all questions around it is really, really important.

Patient Behaviour 31

Antenatal Protocols 18

Expert Midwife

Probably the more problematic until it gets streamlined.

Patient Behaviour 31

Antenatal Protocols 18

Expert Midwife

Everyone that re whose device detects a reduced movement, we'll make a phone call, but that's that's workload that's okay. But not everybody who, who makes a phone call is invited in, because then we'll go through that script of things.

Antenatal Protocols 18

Patient Behaviour 31

Expert Midwife

so they would get two phone calls a day and it was like they were being harassed. So overdoing it just in case I think consumers wouldn't go for the plus. It was at a major increase in workforce to the hospitals.

Antenatal Protocols 18

Patient Behaviour 31

Expert Midwife

We talk at them all the time, but they don't understand what we're talking about. They really don't. So we have to find a common ground and things that are user-friendly that speaking their language that go don't, you know, maybe you can do this. Maybe you can do that. Maybe you should do this. They can't make a decision. So the device has to say, but number one, we've got this fantastic opportunity for you to be involved in this data collection about your baby and your baby Alliance, so that it will be able to interpret your baby's movements and say that that's normal for you. And then if those, if that pattern changes, this device is going to alert you and tell you to call the midwife or call the clinic. And that's going to make sure that your baby's not going to get compromised over the remainder of your pregnancy.



Education/Awareness 15

Design Implications 15

Patient Behaviour 31

Expert Midwife

I think, like I said before, marketing is everything because particularly that last trimester is uncomfortable. So the device has to be seen to be not restrictive, but other than that,

Design Implications 15

Patient Behaviour 31

Education/Awareness 15

Expert Midwife

That's what this type of baby bundle is meant to do. And that, that is included at every anti-natal visit asking about fetal movements. But yeah, the number of fetal movements has got nothing to do with it. And the, the brochure that goes into the decipher baby bundle brochure that goes into the woman's record is when I first looked at it, I thought, what the hell are you asking me? And I'm a clinician.

- Area of Concern 14
- Antenatal Protocols 18
- Education/Awareness 15

Expert Midwife

that's what we're relying on. Women's perceptions of their own, fetal movements. And it's very generalized

- Patient Behaviour 31
- Data/Research 8

Expert Midwife

I, this annoys me because it's a lack of communication and a lack of education too, from clinicians to make realize, oh, that's devastating. Like how can we not pass that message onto women about how important fetal movements are when we've seen what we're seeing. And we know what we know, it's just terrible

- Education/Awareness 15
- Antenatal Protocols 18
- Area of Concern 14

Expert Midwife

Maybe the baby does actually move in the morning, but you're just not aware of it because there's too much else going on. So be interesting. Is there a, is there a pattern, like we see a picture of a CTG when we know as clinicians that's normal, we don't have that with fitting movements, but maybe, maybe women's perceptions of the period of time when the babies aren't moving is actually incorrect.

- Patient Behaviour 31
- Data/Research 8

Expert Midwife

A lot of women have really uncomfortable in the last trimester too. So they might not want to go for that, which is why marketing. It is really important. How you put it to two women that it's going to be a benefit to them. It's going to be easy. It's going to be free and it's going to be a good for your baby's health. So just those four things is like, remembering, this is so easy and it's going to be, you know, it's, it's going to be great to be able to monitor you by yourself or something on that.

- Education/Awareness 15
- Patient Behaviour 31

Expert Midwife

Women, if they feel like they are participating in the, their pregnancy, then they'll go for it

- Patient Behaviour 31
- Education/Awareness 15

Expert Midwife

Women already had in their pregnancy information, a number to call for any advice in pregnancy, back to the hospital that they intend to birth, that they already have that number. We already had the telephone advice form with the script, with all the questions on it. We have a unit set up, so it's not going to impact

- Patient Behaviour 31
- Education/Awareness 15

Expert Midwife

So if we can get a device that says to them, call him midwife now, because your movements have changed. We want clinicians want to hear that. Like we have just about every decent size maternity hospital has a maternity day assessment unit. That's separate from birth suite. It's separate from the clinic, usually sits around the clinics, which is MBA. It's a unit, it's an, it's a specific unit that we can see people during the day that aren't in labor, that aren't there for their 32 week appointment for people

- Education/Awareness 15
- Patient Behaviour 31
- Antenatal Protocols 18

Expert Midwife

But that's even more disgusting, disturbing that we've got and we've got a unit and yet we still haven't got the message to women that we can accommodate that we want to see you. If that happens to you, if you have reduced fetal movements

- Area of Concern 14
- Education/Awareness 15
- Patient Behaviour 31

Expert Midwife

So if we through this data, change our practice or our education to women, and it's got to be a good thing.

- Education/Awareness 15
- Data/Research 8

Expert Midwife

We talk about fetal movements now, every anti-natal visit because that, that brochures in, in women's charts, but over time, that's going to like your research from overseas. That'd be implemented that for a lot longer than what we have. That's going to improve outcomes. For sure.

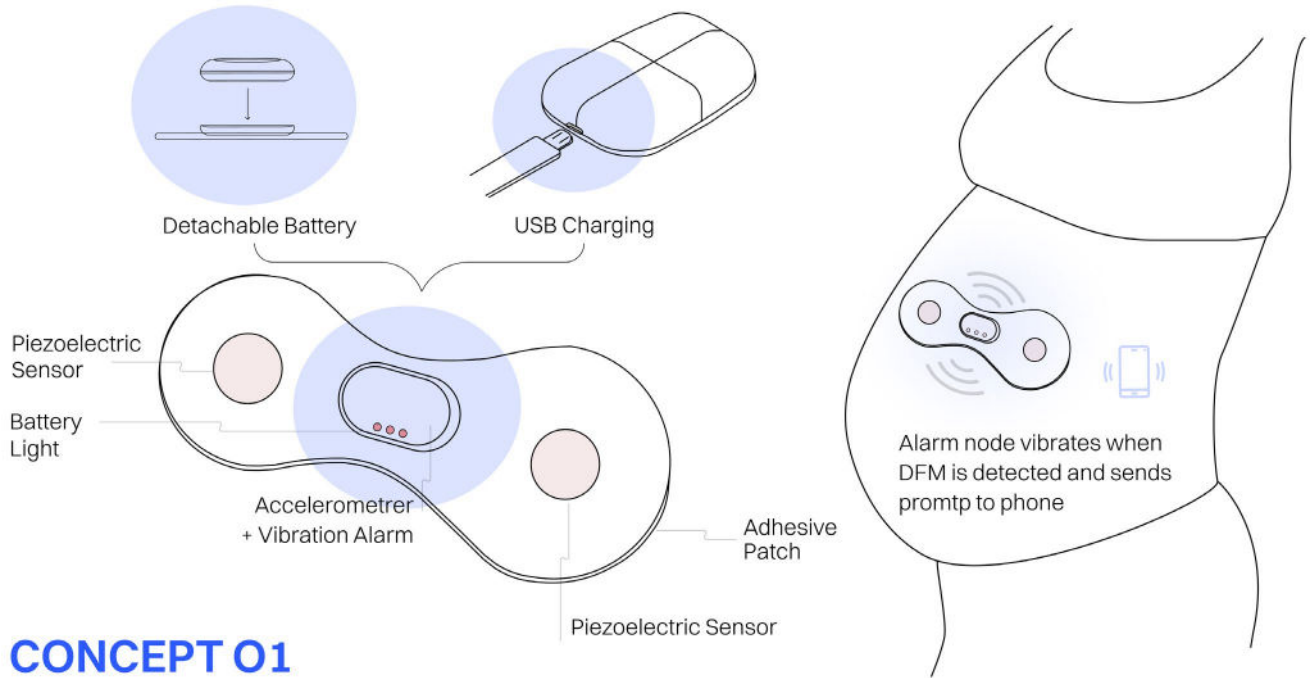
- Education/Awareness 15
- Antenatal Protocols 18

Expert Midwife

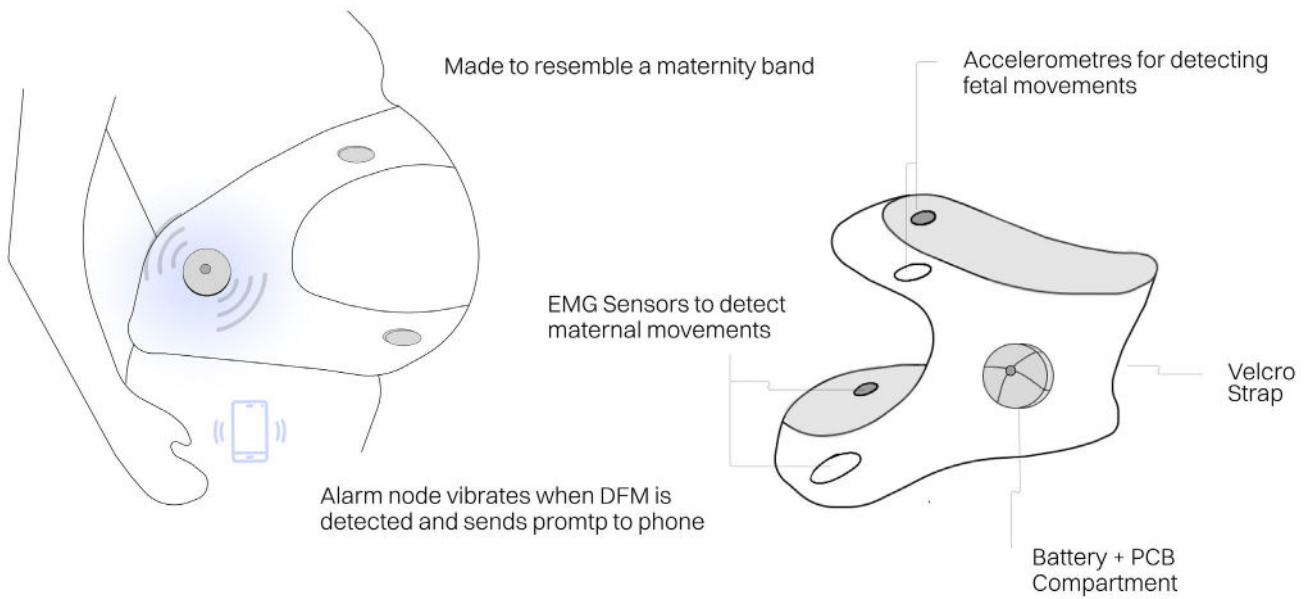
The alert or the message needs to not be a question for them, it may, it should be called the hospital that you plan the birth that not like, well, if you've movements don't get better in the next hour. It's like, yeah, if it's a choice, the consumer will opt for the easier option, which is don't call.

- Patient Behaviour 31
- Antenatal Protocols 18
- Design Implications 15

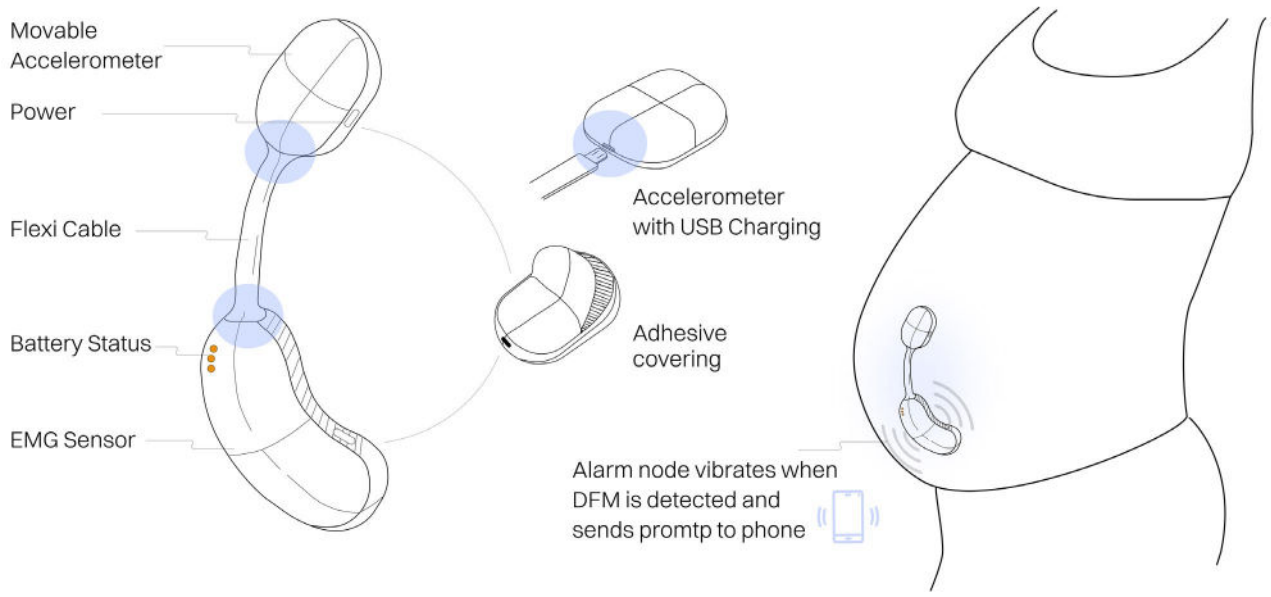
Appendix 3: Concepts



CONCEPT 01



CONCEPT 02



CONCEPT 03