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Lindsay Berkowitz April 2nd, 2025

Safe+natal Sierra Leone: Opportunities and Challenges in Co-Designing a Maternal and Neonatal Health Intervention.

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Abstract

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Maternal health is a prominent focus of global health efforts in low- and middle-income countries (LMICs). Healthcare settings in LMICs often pose unique challenges such as limited resources, lack of highly skilled healthcare workers, and existing infrastructure that is not conducive to interventions that may be successful in high-income countries. Additionally, current interventions on the market often only target one or two aspects/stages of the pregnancy-related continuum of care. New approaches in maternal healthcare such as mobile health (mHealth) technology and co-design are needed to address these gaps to combat high rates of maternal and neonatal mortality. Safe+natal is a low-cost, low-tech maternal and neonatal monitoring kit that includes a mobile-phone programmed with an app to walk healthcare providers through pregnancy-related scenarios. The safe+natal pilot study uses the principles of co-design to actively engage end-users in the intervention design process while considering the cultural context of the intended use site.

The aim of this thesis is to analyze the challenges and realities of conducting the safe+natal pilot study in Sierra Leone to better understand the opportunities for this intervention in LMICS, as well as potential challenges and barriers to success. Sierra Leone, a country in West Africa, has one of the highest rates of maternal mortality in Sub-Saharan Africa and is currently serving as the most recent pilot study site for safe+natal. Through analysis of training assessments conducted on community health workers (CHWs) and first-hand interview and meeting data with the Sierra Leone co-design team, my thesis will help inform future pilots of safe+natal and improve upon the co-design process to impact scalability of the intervention and bolster use of mHealth for global maternal health.

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1. Background

1.1 Introduction

Maternal and neonatal health have long been a focus of global health efforts and the targets of technology-based interventions to reduce rates of mortality, especially in low-and middle-income countries (LMICs). Historically, these interventions have often been designed independently in high-income countries, and subsequently brought into LMIC communities, where they are studied for a brief period. This "one-size-fits-all" approach to global health fails to consider cultural context & preferences and local determinants of health, which are integral to establishing an effective health intervention. Additionally, after the pilot study concludes, the community is often left without continuous follow-up or evaluation to ensure the intervention achieves its clinical targets and is fully adopted into routine utilization. Newer methods of design, such as co-design, have risen in popularity to involve the end-users of these interventions in the design process, with more attention given to the needs of the specific community.

Safe+natal is a co-designed global maternal health intervention that incorporates a low-cost neonatal monitoring kit and smartphone app to help community health workers (CHWs) detect maternal and neonatal danger signs during and after pregnancy. If danger signs are detected, the CHW can then refer the patient to higher levels of care such as regional hospitals. Safe+natal has piloted in several sites after starting in rural Guatemala, and more recently has expanded to new pilot sites in Latin America and Africa. The pilot is currently in its preliminary stages in Sierra Leone (SL), which includes co-design of the app and workflow, training end-users on using the toolkit, and planning for dataflow and analysis.

The aim of this thesis is to assess the successes and challenges of the safe+natal pilot study's initial stages in Sierra Leone in order to inform future safe+natal studies and understand

the effectiveness and scalability of the co-design process in designing maternal mobile health (mHealth) interventions. In order to evaluate the current study in Sierra Leone, I will explore first-hand interview data from team members based in Emory and Sierra Leone, observational notes from weekly team meetings, and end-user training assessment outcomes. This information will help shape the future of safe+natal as well as contribute insights on the co-design process of an mHealth intervention as a potential new direction for global maternal health.

1.2 Global Maternal and Neonatal Health and Mortality

The United Nations' Sustainable Development Goals address maternal and neonatal health and mortality in goals 3.1: by 2030, reduce the global maternal mortality ratio to less than 70 per 100,000 live births, and 3.2: by 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-5 mortality to at least as low as 25 per 1,000 live births (United Nations, n.d.). However, even with the progress made through efforts to achieve these goals, maternal and neonatal mortality remain at staggering rates. In 2020, over 275,000 maternal deaths were recorded, with over 95% of those deaths occurring in low and lower-middle income countries (WHO, 2024). 70% of global maternal deaths occurred in Sub-Saharan Africa alone (WHO, 2024). Maternal deaths are defined as, "the death of a woman while pregnant or within 42 days of termination of pregnancy, from any cause related to or aggravated by the pregnancy or its management but not from accidental or incidental causes" (WHO, 2010). Maternal mortality can be measured in a number of ways, including the maternal mortality ratio, which is the number of maternal deaths per 100,000 live births during the same time period, or

the maternal mortality rate, which is the amount of maternal deaths per 100,000 women of reproductive age during a given time period (WHO, 2010).

Maternal mortality usually occurs because of complications during pregnancy or childbirth, many of which are treatable and preventable with the proper resources and care. The leading causes of maternal mortality, which account for about 70% of deaths, include severe bleeding/hemorrhage, infections, pre-eclampsia and eclampsia (seizures as a result of high blood pressure), complications from delivery, and unsafe abortion (Say et al., 2014). Severe bleeding, infections, pre-eclampsia, and eclampsia are all highly understood in terms of disease mechanism and are therefore treatable through the administration of drugs like oxytocics to reduce bleeding and magnesium sulfate to treat preeclampsia, as well as through proper hygiene and monitoring of danger signs in the mother and baby (WHO, 2024).

The main focus of the UN's Sustainable Development Goals thus far has been hemorrhage management, and attention has been given to the ability of global healthcare systems to address this issue. However, less effort was given to the multi-faceted causes of maternal mortality such as complications from hypertensive disorders and complications associated with non-communicable diseases including obesity, diabetes, and heart disease (Moyer et al., 2023). Even if healthcare facilities are equipped to manage hemorrhage, these more complex issues require additional capabilities, staff, and resources, which are less accessible in rural and low/middle income communities.

Even though many of the leading causes of maternal mortality are highly treatable and preventable, there are numerous factors that contribute to the inaccessibility of these services. Firstly, social determinants of health including race and ethnicity, access to education, language and cultural barriers, geographical barriers, and income can increase risk of complications or

lack of access. Even though many global health interventions for maternal health exist, they more often address acute biomedical causes of pregnancy complications, rather than underlying societal causes of poor health, lack of access to healthcare, or high rates of unwanted pregnancy (Souza et al., 2024). To truly impact global health, these underlying causes of disease and poor health outcomes must be addressed. Even if there is access to healthcare, quality healthcare systems can be difficult to achieve because of overall poor quality of care, understaffed and overworked facilities, supply shortages, undertrained workers, etc. Finally, women may be hesitant to seek care based on the gender inequalities experienced in their community or because of extenuating circumstances like political instability, health system fragility, and humanitarian crises (WHO, 2024). If the healthcare system in a country or community is already unstable, measures to ensure adequate maternal health may be overlooked in favor of other widespread health concerns.

1.3 Mobile Health Technology

Mobile Health, or mHealth, refers to the use of technology and/or wireless devices in healthcare (Agarwal et al., 2016). mHealth has gained popularity in the past 20 years for use in global health through the use of smartphones, patient monitoring devices, tablets, and mobile applications (Holcomb et al., 2014). Mobile healthcare devices offer particular advantages for health interventions in low- and middle-income countries, where standard health interventions may be ineffective due to limitations on resources and healthcare personnel (Kayingo, 2012). Wireless mobile networks, upon which mHealth devices often operate, require less extensive and less costly infrastructure compared to traditional land-line networks, making them ideal in poor and rural areas. Additionally, mobile technology can be leveraged by both providers and patients,

and can aid in the training and decision-making process for health workers as well as provide accessible, on-demand health information to patients (Rotheram-Borus et al., 2012).

1.3.1 Rationale for use of mHealth technology

The rise of mHealth technologies reflects the widespread penetration of mobile cell-phone and network use around the world, providing a valuable tool to be used in healthcare in rural and low-income countries (Tamrat and Kachnowski, 2012). A review by Tigest Tamrat and Stan Kachnowski found four main ideas referenced in 34 articles regarding how mHealth can benefit maternal and neonatal global health: emergency medical response, point-of-care, health promotion, and data collection and management (Tamrat and Kachnowski, 2012). In acute maternal or neonatal health crises, mHealth can reduce the amount of time it takes for a referral to occur or healthcare resources and data to be accessed by integrating mobile devices with proper training needed to identify and respond to the situation (Tamrat and Kachnowski, 2012). One major challenge for healthcare systems in LMICs and rural communities is lack of healthcare workers, especially those who are highly trained. Mobile health devices can be used to improve and expand the capabilities of available health workers by connecting them to specialists located in different places, so they can care for the women and babies in their community without having to train additional workers (Tamrat and Kachnowski, 2012). mHealth aids in data collection as well by streamlining the process and syncing data in one place (Tamrat and Kachnowski, 2012).

Although mHealth has been utilized extensively in LMICs for global health interventions, they have seen little success because they often fail to take into account the resource constraints and cultural context within the community and healthcare system they are intended for (Wallis et al., 2017). Specific barriers to mHealth's success include a failure to meet regulatory standards

and protect sensitive health information of users, lack of reliable internet connection or electricity and the potential complexity of the technology that could make the end-user experience more difficult (Wallis et al., 2017). The use of resources to support the integration of mHealth into LMICs is necessary to address these considerations and build an intervention that complements and integrates into the existing infrastructure (Clifford, 2016). The use of mHealth interventions in LMICs is promising in terms of improving medical decision making and expanding the capabilities of healthcare workers if barriers like lack of infrastructure, cost, and integration into the healthcare system can be overcome (Clifford, 2016).

1.3.2 Main approaches to mHealth

Mobile health technology provides technology-based opportunities to streamline healthcare services and connect people and resources that are located far away from each other, helping reduce the burden put on healthcare workers. mHealth technology is still a growing field, but its main approaches currently used today include telemedicine, remote sensing, patient reminders/updates, data collection, and mobile applications.

Telemedicine has gained traction as new technological advances have reduced costs, complicated infrastructure, and issues with connectivity that were previously inhibiting its widespread success (Zajtchuk & Gilbert, 1999). The capacity of telemedicine is increasing each year as technology improves and the need for rapid health communication and remote care grows (Waller & Stotler, 2018). Telemedicine can be thought of in terms of its functionality, application, and technology. The functionality of telemedicine is manifested in the ways it helps care for patients, such as with diagnosis, consultation, or monitoring (Waller & Stotler, 2018). The applications of telemedicine can be reduced further in terms of the field of medicine in which it is used such as telepsychiatry, the type of disease treated, like tele-diabetes, the site of

care, or the modality in which care is provided, such as physical therapy (Waller & Stotler, 2018). The technology aspect of telemedicine refers to the components necessary for its function, such as network, connectivity, and synchronicity (Waller & Stotler, 2018). Telemedicine's potential impact derives from its ability to transform the way typical healthcare is performed; by connecting patients and providers regardless of physical distance and connecting resources all over the world to each other (Zajtchuk & Gilbert, 1999).

Remote sensing involves gathering medical and psychological information from patients via mobile devices and wearable sensors rather than requiring the patient to provide the data themselves (Bidargaddi, et al., 2024). This data is more accurate than self-reporting and can also be collected continuously in real-world settings (Bidargaddi et al., 2024). Remote sensing can be used to monitor a variety of conditions including heart disease by measuring heart rate, diabetes by measuring glucose levels, general vital signs monitoring, and mental health/cognition through tracking emotional states and aiding in medication compliance, especially for those who are memory-impaired (El-Rashidy et al., 2021).

Additional approaches to mHealth include patient reminders/updates and data collection. Patient reminders leverage the widespread penetration and highly transportable nature of mobile cell-phone use, which people usually bring with them everywhere they go. This allows for mHealth interventions to reach people/patients wherever and whenever, which is especially valuable for low income and/or low-resource settings where healthcare facilities may be located far distances from cities where people live (Free et al., 2013). Additionally, data collection can help healthcare providers input patient data as well as access data from elsewhere to gain knowledge of a patient's prior medical history or even learn from other providers and specialists who are more highly skilled (Free et al., 2013). Electronic data collection has proven to be

effective in high-income, high-resource countries, but there is potential for even greater impact in less developed countries where electronic data collection is not the standard (Clifford et al., 2008).

1.3.3 Mobile internet usage

Mobile internet use has gained traction across the world over the past 25 years and Sub-Saharan Africa has seen a similar increase in use because countries are able to bypass the usual infrastructure development needed for traditional wired telecoms. According to GSMA, a non-profit organization that oversees global mobile connectivity and fosters innovation and sustainable practices in the industry, mobile subscribers in Sub-Saharan Africa reached 489 million in 2022, with projections for this number to increase by almost 30% by 2030 (GSMA, 2023). Additionally, in West Africa, 51% of people were connected to iPhones, with 60% connected to 3G network and 20% connected to 4G (GSMA, 2023). Prior to 2022, Sierra Leone had lower than average rates of mobile internet subscribers for the region (24%), but it did expand 4G network coverage between 2018 and 2019 (GSMA, 2019). However, by 2022 30% of the population was using the internet on any device, including a computer, mobile phone, or personal digital assistant and 98% of people had mobile cellular subscriptions (World Bank, 2024). Vulnerable groups such as women, people living in rural areas, and those with low-income make up the majority of the 280 million non-internet users in West Africa, calling for additional attention given to how coverage can be extended economically and politically (GSMA, 2019).

Although some mobile phones, such as iPhones, remain high cost, many Android devices, like the device used in the safe+natal toolkit, are much lower cost, which allows for greater diffusion and easier adoption around the world. The smartphone utilized in safe+natal

allows for internet connection, delivery of health information, image and data capture, calling, and communication with additional providers to aid the decision-making process (safe+natal, 2019). Additionally, by automatically submitting referrals when a danger sign is detected in a pregnant woman or fetus, the app simplifies the referral process for healthcare providers.

1.4 Safe+natal

1.4.1 Background of safe+natal

The safe+natal toolkit was first piloted in Guatemala in partnership with Wuqu' Kawoq/Maya Health Alliance, a nonprofit healthcare system based in rural Guatemala (Juarez et al., 2020). The aim of the study was to address high rates of maternal mortality in indigenous Mayan populations in Guatemala by addressing the continuum of care for maternal and perinatal health among Traditional Birth Attendants (TBAs) and higher forms of care (Martinez et al., 2018). The intervention of interest was the safe+natal toolkit, which harnesses a low-cost mobile smartphone device to increase referrals between TBAs and other healthcare providers (Martinez et al. 2018). The randomized control trial recruited 44 midwives/TBAs in rural Guatemala, with 23 receiving the mHealth intervention immediately, and 21 receiving it after 6 months (Martinez et al., 2018). The kit was implemented into the pre-existing, community-based healthcare system and resulted in a significant increase in referrals for emergency maternal and perinatal complications (Martinez et al., 2018). Ultimately, 80% of midwives passed their training evaluation on the first try and 98% after a second attempt, there was increased detection of complications including hypertensive disorders, and a significant increase was made in completed referral rates (Martinez et al., 2018). The feasibility of implementing mHealth technology for TBAs, but limited scope of this paper offers room for future research to build

upon, which has called for the expansion of safe+natal to several other sites, including Tanzania (Pemba), and, as this thesis will discuss, Sierra Leone.

Table 1 depicts the outcome measures that the pilot projects for the Sierra Leone site. The pilot targets three major stakeholders: pregnant women, healthcare providers, and the health system in general. For pregnant women, safe+natal hopes to increase attendance of antenatal care (ANC) visits and improve patient satisfaction. Healthcare providers are projected to improve their capabilities by using the safe+natal kit, which improves their knowledge of antenatal danger signs, how to complete the referral process, and how to use the kit regularly. Improvements to Sierra Leone's healthcare system are projected to include an increase in completed referrals, ANC visit attendance, and overall reductions to severe maternal and neonatal complications and mortality.

Table 1: Outcome Measures (anticipated change; data source)

Pregnant women	Health care providers	Health system
• *Increased early ANC attendance.* 20% increase in initiation of ANC at ≤ 20 weeks gestation. • *Increased ANC attendance.* 30% increase in ANC attendance; MOH data. • *Patient satisfaction.* 75% of users report satisfaction with the nafe+natal toolkit/CHW ANC; endpoint survey and interviews.	• Practical evaluation on use of the safe+natal toolkit. 90% first-time pass-rate; study training evaluation. • *Knowledge of key antenatal danger signs.* 10% increase; study training evaluation. • Knowledge of appropriate triage/referral processes. 25% increase; study training evaluation. • *Regular toolkit usage*. 75% of users with weekly use; in-app heuristics. • *User satisfaction measures.* 75% of users report satisfaction with the toolkit; Endpoint surveys & interviews.	• Percentage of pregnant women engaging in antenatal care. 10% increase; MOH data. • Completed referrals for facility-based care for at risk pregnant women. 25% increase; in-app data + MOH data. • *Reduction of severe maternal and neonatal outcomes* (9). 20% decrease; MOH data. • Reduction of maternal and neonatal mortality. 10% decrease; MOH Data.

1.4.2 The safe+natal toolkit materials and set up

The safe+natal maternal and neonatal monitoring kit consists of a mobile phone, a one-dimensional Doppler ultrasonic transducer, a blood pressure monitor, a recording cable, an audio cable, a small speaker, and aqueous gel. In total, the materials cost about $200. The mobile

phone is pre-programmed with the safe+natal app, which allows the user to register new patients, choose the appropriate scenario (antenatal, during labor, or postpartum), record data, and identify danger signs from a list based on the World Health Organization's standards. After choosing the applicable scenario, the app walks the community health worker through the visit step-by-step and allows for them to record whether or not various danger signs are present. The app will automatically refer the patient to higher forms of care if any danger signs are identified, blood pressure is too high or low, or the baby's heart rate deviates the determined threshold. The app uses SMS, voice, and Wi-Fi data connectivity messaging systems to deliver referrals. After concluding the visit, the CHW can upload the data to the open-access electronic medical record system through the app, so that the patient data is recorded, protected, and able to be accessed regionally if needed.

The other components of the kit are used to record data such as blood pressure and fetal heart rate. The recording cable is plugged into both the phone and the speaker and the audio cable is connected to the speaker and the Doppler, so that the speaker can pick up the baby's heartbeat from the Doppler and the phone can record the sound. The aqueous gel is applied to the patient's belly and comes in contact with the Doppler to aid in ease of movement and listening to the heartbeat. Finally, the blood pressure monitor is used to measure the mother's blood pressure, which is then manually recorded on the phone. See Figure 1 for the individual toolkit components.

Figure 1: The toolkit components used during the safe+natal training.

1.4.3 Evidence for the use of safe+natal to detect danger signs in mother and fetus

The safe+natal toolkit streamlines the process of maternal and neonatal health visits before, during, and after labor by implementing non-invasive, low-cost technologies to detect potential danger signs, including maternal hypertension and preeclampsia, and low fetal birth weight. The 1-D Doppler ultrasound within the kit can be leveraged to detect multiple danger signs, negating the need for additional tools that could increase cost or complexity of use. Several studies have been conducted to assess the effectiveness of the Doppler on assisting community health workers and detecting potential pregnancy complications.

As mentioned earlier, preeclampsia and high blood pressure are two of the most common danger signs in pregnant women and can lead to complications including both maternal and neonatal mortality (Katebi and Clifford, 2022). Traditionally, an arm-cuff is used to measure

blood pressure, but these devices can be difficult to use correctly by CHWs with little training, or could cause pain or discomfort to the patient (Katebi and Clifford, 2022). Along with detecting fetal heart rate, the 1-D Doppler ultrasound in the toolkit was found to provide an accurate measurement of maternal hypertension by calling upon a hierarchical attention network to "model time dependencies in fetal 1D-DUS signal and capture the variability of the cardiac activity" (Katebi and Clifford, 2022). The ultrasound offers a non-invasive technique to determine potential cases of high blood pressure via fetal heart rate, as well as minimizes user-error and the amount of equipment needed.

A different study explored the use of automated image transcription via LCD localization from AI-transcription and found greater accuracy in blood pressure measurement when using an automated model (Katebi et al., 2023 a). In addition to improving accuracy, using an AI-trained model offers potential reductions in human-error through manual entry, as well as improved decision-making by healthcare workers who can rely on the automatic measurements to guide their visits (Katebi et al., 2023 a).

Fetal growth restriction (FGR), or preterm birth, is a condition that can cause low-birth weight and a subsequent increase in likelihood of mortality or long-term health complications for the neonate. The safe+natal Doppler uses a model of deep learning via a hierarchical attention network to provide an estimate of FGR. (Katebi et al., 2023 b). The deep sequence learning model processes typical measurements of fetal cardiac activity through various developmental stages to determine gestational age (Katebi et al., 2023 b). Traditional technologies to determine gestational age can be extremely difficult to access, so the safe+natal Doppler and learning model could offer a lower-cost, more accessible option.

Finally, an improvement study was conducted at the site in Guatemala to address specific concerns of midwives and found that the pilot was well-adopted by end-users and increased maternal and neonatal referral rates (Juarez et al., 2020). The changes included additional training on neonatal outcomes and triage, and modifications to the app-interface to facilitate ease of identifying danger signs and determining birth weight (Juarez et al., 2020). By working with the end-users to establish these areas of concern, they were able to improve the intervention in a way that made it easier to use by CHWs in LMICs.

1.4.4 Safe+natal in comparison to other mHealth Maternal Health interventions

Similar maternal and neonatal interventions on the market tend to focus on only one or two approaches to improving maternal healthcare. One review of nineteen maternal health interventions in LMICs found that the interventions studied had different primary focuses: data collection (n=5), decision support and provider-to-provider communications (n=6), appointment reminders (n=3), appointment reminders *and* health promotion (n=4), and clinical management (n=1) (Colaci et al., 2016). The studies focused on data collection and decision support/provider-to-provider communication were interventions geared toward midwives, CHWs, and TBAs, while appointment reminders, health promotion, and clinical management were targeted in interventions geared towards clients/patients (Colaci et al., 2016). Many of the studies used mobile cell-phones and SMS messaging to send reminders. Several incorporated health promotion techniques and other training methods to support decision making for healthcare workers (Colaci et al., 2016).

The safe+natal intervention is unique because it combines many of the functions listed above, while other interventions focus only on one or two. The app allows for data collection and step-by-step guidance for multiple types of pregnancy-related visits and also provides immediate,

automatic referrals to higher forms of care if danger signs are detected. The other technology in the kit, including the 1-D Doppler and arm-pressure cuff, are easy to use and serve multiple purposes as well by using machine learning to detect abnormalities in the maternal and fetal heart rate recordings and determining gestational age. The design principles used to develop the pilot study for each safe+natal site offers another layer of potential success of the intervention, because it is better tailored to the community using it, which could help improve adoption and integration into the current workflow.

1.5 Sierra Leone

The global maternal and neonatal health crisis extends to Sierra Leone, a low-income country in West Africa with a population of 9.1 million, where maternal mortality rates are among the highest in the world. Maternal mortality has consistently been a top health concern in Sierra Leone, with a maternal mortality ratio of 435 deaths per 100,000 live births (WHO, n.d. a). Among other social determinants of health and factors such as a low literacy rate (43.2%), large rural population (56%), low life expectancy at birth (52.2 years), and a high total fertility rate (3.71 children/woman), Sierra Leone also faced a civil war in the 1990s, which has led to a slow political and economic recovery (WHO, n.d. a). The Ebola outbreak in 2014 exposed the flaws in the country's health care system, including a significant lack of trained personnel to deliver care. High turnover, coupled with low wages and failure to advance careers, has left Sierra Leone with wide gaps in capacity when it comes to maternal and neonatal health care (WHO, n.d. a). Poverty, lack of clean water and sanitation, poor nutrition, low access to high quality health care services, and female genitalia mutilation also contribute to the high mortality rates for mothers and neonates (WHO, n.d. b).

Sierra Leone is sectioned into five regions, which divide further into sixteen districts. The healthcare system is divided into three tiers, creating a distinction between community-based care (tier one) and higher forms of facility-based care (tiers two/three). Tier one consists of peripheral health units (PHUs) which have both local health facilities that act as maternal and child health posts and larger health centers with greater capabilities, but serve a larger population (Gabani et al., 2024). Regional and district-specific hospitals make up the second tier of the healthcare system and the third tier includes larger hospitals (Gabani et al., 2024). Community health workers include doctors and nurses employed within hospitals and health facilities, skilled birth attendants, and midwives, however the density of health workers is only 0.34/1000 (WHO, 2023). Additionally, even though a majority of the population lives in rural areas, only 30% of healthcare workers work rurally (WHO, n.d. a).

The Ministry of Health and Sanitation plays an important administrative role by setting health guidelines, but it has little compatibility with the outlying healthcare system. Attempts to increase usage of the healthcare system have included a move towards universal healthcare coverage, however hospital and health facility stays still require individuals to pay out of pocket for any supplies used or procedures performed (Willott et al., 2021).

Maternal mortality in Sierra Leone is primarily due to the following adverse health outcomes: obstetric hemorrhage (46%), hypertension (22%), obstructed labor (21%), and sepsis (11%), but indirect factors such as malaria, anemia, and malnutrition contribute as well (Gborie, 2017). Over 80% of reported maternal deaths occur in health facilities, 14.1% occur at the community level and about 4% while being transported (Gborie, 2017). The Sierra Leone National Reproductive, Maternal, Newborn, Child, and Adolescent Health Strategy report indicates various structural concerns that may contribute to these rates. At the hospital level,

maternal mortality may be a result of a lack of supplies or quality supplies, low personnel numbers, low-skill levels in health workers, or the lack of referrals or inadequate referrals from community-based health facilities to hospitals (Gborie, 2017). Inability to identify danger signs, issues with transportation, and preference towards TBAs may prevent successful maternal care at the community level (Gborie, 2017).

1.5.1 Sierra Leone's current efforts to improve maternal and neonatal health

Expanding access to maternal healthcare has been at the forefront of efforts to reduce Sierra Leone's staggering maternal and neonatal mortality rates. In 2010, the government began a program called the Free Healthcare Initiative (FHCI) to reduce the barrier of cost for healthcare, specifically for pregnant women and mothers (Sharkey et al., 2017). However, utilization of this initiative was hindered by indirect costs such as transportation and "unofficial" payment to delivery nurses, preference towards using regional medical practices over healthcare facilities, as well as the inability to efficiently and safely access facilities for delivery, even if they were used for antenatal care (ANC) visits (Sharkey et al., 2017).

More recent efforts to combat maternal mortality include a pilot study program called 2YoungLives that trains women to mentor pregnant adolescents in Sierra Leone, supporting and guiding the girls on healthy behaviors to reduce their potential for a maternal related death or complications (Turienzo et al., 2024). A different intervention, called CRADLE, incorporates blood pressure and pulse measurements with a warning system and training component, and piloted in Sierra Leone to determine its efficacy in integrating with the current standard of maternal healthcare (Ridout et al., 2023). Another resource similar to safe+natal is Baby Checker, which uses a smartphone to detect potential pregnancy risks using AI-based technology to perform similar measurements as an ultrasound device ("BabyChecker," 2024). Baby Checker

also focuses on expanding capabilities through point-of-care solutions and is used in Sierra Leone as well Zambia, Kenya, and Honduras ("BabyChecker," 2024).

Neonatal mortality and deaths under age of 5 are also an area of concern. As of 2022, the neonatal mortality rate, measured as the number of deaths per 1,000 live births between ages of 0 days to 27 days old, was 30.8 in Sierra Leone (WHO, n.d. b). This decreased from 32.0 in 2020 and significantly from 40.1 in 2010, however it is still higher than the global average in 2022 which was 17.3 (WHO, n.d. b). The under-5 mortality rate, which is measured as probability of death under the age of 5 for 1,000 live births, was 100.8 in 2022 for Sierra Leone, whereas the world average was 37.0 in 2022 (WHO, n.d. c).

CHAMPS, or Child Health and Mortality Prevention Surveillance, is a child mortality surveillance program run across multiple organizations whose data has helped contribute to more accurate record keeping of child mortality in Sierra Leone and other LMICs. CHAMPS operates in several districts in Sierra Leone in the Makeni region and tracks stillbirths and deaths under the age of five by utilizing resources from the Ministry of Health and other facilities that have testing equipment (CHAMPS, n.d. a). The specific region they monitor, which overlaps with the intervention sites for safe+natal, has a population of just over 160,000, a neonatal mortality rate of 39/1,000, an infant mortality rate of 92/1,000, and an under-five mortality rate of 156/1,000 (CHAMPS, n.d. a). Accurate reporting is important to understand the causes of neonatal and child deaths. In Sierra Leone, the top underlying causes of neonatal death are perinatal asphyxia (baby does not receive enough oxygen during birth), complications associated with preterm birth, and neonatal sepsis (CHAMPS, n.d. b). Obstructive labor and maternal hypertension are the leading comorbid causes of neonatal death (CHAMPS, n.d. b).

While these studies and programs are promising, additional efforts are needed to combat the maternal mortality crisis in the country, specifically targeting healthcare personnel in remote areas. For example, safe+natal could offer improvement by training healthcare workers and expanding their capabilities in delivering maternal and neonatal care, not just adding an additional device to use in healthcare settings.

1.6 The Co-Design approach

Approaches to public health interventions have typically been situated as 'top-down', utilizing a large evidence base, but little to no involvement from end-users and are based on the premise that one intervention can be applied to everyone (Lesak et al., 2019). These design processes often fail to listen to and understand the people who are directly impacted by the interventions, so gaps in research and care persist, which perpetuate the health problems that are the initial target of the intervention (McKercher, 2020). Conversely, Co-design is an approach that engages end-users actively in the conceptualization and implementation of research. The co-design approach, sometimes called co-creation or participatory research, encompasses four guiding principles: sharing power, prioritizing relationships, using participatory means, and building capacity (McKercher, 2020). Co-design and related approaches contrast with *user-centered design*, which involves the perspectives and needs of end-users, but regards them as experts/informants rather than co-creators of the intervention. Co-design requires a higher level of end-user engagement than user-centered design, but less so than *user-generated design* because there is still involvement from a non-stakeholder group in the research development and implementation (Brubaker et al., 2017). Commonly applied to fields such as global health and anthropology, the co-design approach has been harnessed to develop healthcare services, digital

health technologies, and systems of sanitation and farming, as well as to enhance value creation in business (Brubaker et al., 2017).

Co-design, as is utilized in the safe+natal project, hinges on the principles of the PRECEDE-PROCEED model developed by Lawrence Green and Marshall Krueter. PRECEDE, which stands for Predisposing, Reinforcing, and Enabling Constructs in Educational/Environmental Diagnosis and Evaluation, was developed first, in the 1970s. PRECEDE is rooted in the idea that an intervention plan should first start with an "educational diagnosis," similar to how medical diagnoses come before a doctor develops a plan for treatment (Gielen et al., 2008). The model was developed because it was believed that health education was not devoting enough attention to meeting established needs through strategically designed interventions and was focusing too much on program implementation (Gielen et al., 2008).

PROCEED stands for Policy, Regulatory, and Organizational Constructs in Educational and Environmental Development, and was created in 1991 to add emphasis on environmental factors that influence health and health behaviors to the previous model (Gielen et al., 2008). In order to devote more attention to broader determinants of health, bolstered by a simultaneous increase in the appreciation of lifestyle factors and their impact on health and related behaviors, more environmentally-minded approaches were needed in the field of healthcare intervention design (Gielen et al., 2008).

Finally, the PRECEDE-PROCEED model was revisited in 2005 and edited to address "ecological and participatory approaches" along with the growing field of genetics. This revision added four planning phases, one implementation phase, and three evaluation phases to the overall model (Gielen et al., 2008).

The Co-design Lab for Health Equity at Emory University engages the co-design process through the following steps: (1) Problem identification with local partner, (2) baseline needs assessment and local input, (3) building an existing technology for prototype, (4) refining technology based on context and local preferences, (5) end-user training, and (6) implementation and ongoing support and refining. These steps were utilized in designing the initial pilot study for safe+natal in Guatemala, and they were also adopted for the Sierra Leone study, with adaptations for the community's specific needs, as will be discussed further in later sections.

1.6.1 Benefits of Co-Design

The tailored approach of co-design elicits many benefits in the field of global health interventions and research. Co-design has been found to improve efficiency, quality of care, and cost by creating a more specific health experience that focuses on the patient (Silvola et al., 2023). By integrating both general resources and knowledge with those that are more specific to the population served, this design process can create programs that address personalized issues at the end-user level, while simultaneously improving health and clinical outcomes with large-scale resources (Silvola et al., 2023). Additionally, co-design involves the active participation of many different stakeholders, which facilitates better community participation and adoption, but requires careful consideration in order to select the correct stakeholders (Cumbula et al., 2013).

Engaging stakeholders is also critical for establishing trust in the community because it requires those making the decisions to accurately reflect the realities of the context their community is situated in and hold them accountable to those strengths and limitations to develop an intervention that truly fits the cultural context. Establishing this joint ownership builds trust between different stakeholders, including end-users, which ultimately improves utilization of the intervention and generates better health outcomes, especially among marginalized populations,

who are often overlooked by more powerful groups in the design and decision-making process (Singh et al., 2023).

In creating community ownership, for example, it is important to ensure that said ownership is meaningful and that contributions made by all stakeholders are seen in all stages of the project along with the resulting impact of the intervention, rather than just those made by the non-stakeholder group (Singh et al. 2023). Additional considerations include evaluating and refining the design process in order to better understand relationships between different stakeholder groups, organizational structures and workflow, as well as the healthcare delivery system (Silvola et al., 2023). Community-based groups and stakeholders may differ in their capacities and resources, which makes it critical to provide them with proper tools to meaningfully contribute to the design and express their thoughts and ideas (Silvola et al., 2023).

1.6.2 Challenges of Co-Design

One major challenge in using co-design principles is the possibility for the process to be both lengthy and costly in order to be effective, which can result in decreased motivation and/or engagement from stakeholders and participants (Singh et al., 2023). Additionally, power equalization is a major tenet of the co-design process, but power imbalances can persist if special consideration is not given to respecting the knowledge and contributions of non-expert stakeholders (Singh et al., 2023). Cultural barriers such as social norms and taboos, hierarchies, and politics can corrupt designs by impacting the ability for their implementation and adoption, but designs can also corrupt the community they lie in by influencing societal aspects embedded within the cultural context (Busch and Palmas, 2023). The creation of a co-design plan can also present a challenge since there is no systematic framework to guide development. This offers increased flexibility and specificity for the context in which the project will be situated, but it

could also cause discrepancies with funders/sponsors who want a regulated evidence base and could impact the ability of the study to be realistic, reproducible, and evaluated effectively (Lesak et al., 2019).

2. Methods

2.1 The safe+natal toolkit training process & quantitative data

In the initial stages of the Sierra Leone pilot study, safe+natal's two principal investigators (PIs) met with members of the CHAMPS Sierra Leone team to redevelop the safe+natal app and workflow for the study. This process included determining the highest priority changes needed to adapt safe+natal to fit within the workflow Sierra Leone's healthcare facilities, such as switching from paper intake forms to electronic records and conducting patient visits individually rather than in a group. These developmental stages occurred prior to the start of the training safe+natal toolkit training sessions and my thesis project.

The process of training community health workers to use the safe+natal device consists of two sessions each with two parts and an evaluation session (see the full outline of the training program in Appendix A). Session one is three hours in length. Part one consists of a presentation of the safe+natal toolkit materials and assembly/disassembly and review of the app and lasts one hour and ten minutes. After ensuring that there is an adequate quantity of kits and each kit has all materials, the instructor explains each component of the kit for its function and passes each item around the room. Next, the device is fully assembled and different CHWs are called upon to assist in the demonstration. Following this portion of session one, there is a break. Part two lasts one hour and fifteen minutes and involves practicing a prenatal visit scenario. The danger signs that are reviewed are seizures, bleeding, difficulty breathing, ruptured membrane, stomach pain,

blurry vision, fever, swollen feet, and headache. Each health worker has a fully constructed tool kit and a ball is thrown to different participants to demonstrate a step in the process. Additionally, the session leader demonstrates use of the ultrasound machine. Session one ends with a fifteen minute review of where the toolkits are kept in each clinic as well as time for questions and feedback from the CHWs.

Session two lasts one hour and thirty minutes. Part one of session two reviewed a visit during childbirth, including establishing danger signs including the ones identified during pregnancy and the following additional complications: unconsciousness, incorrect position of the fetus, placental implantation on the cervix, issues with the umbilical cord, placental retention in the uterus, multiple pregnancies, prolonged labor, cesarean section, abdominal pain, and dizziness. The health workers are asked how the childbirth visit process works with pre-existing protocols at their locations. Next, the training reviews a postpartum visit, including reviewing the danger signs from pregnancy as well as potential complications with the baby. The health workers are once again asked how this process is handled with pre-existing protocols at their locations, as well as the amount of supplies at their locations for emergent situations. After a break, the training reviews triage protocol, which includes health workers from each site recounting what triage protocol at their specific site entails. Finally, they go through a triage demonstration with the kit.

After both training sessions is an evaluation session, which lasts one hour and thirty minutes. First, evaluators review content by throwing a ball around the room and asking health workers for ordered protocol steps. Next, each health worker is individually evaluated on their assembly of the kit and their ability to use the kit with a practice patient for all three visit

scenarios (antenatal, during delivery with danger signs, and postpartum). Each health worker receives either a ‘yes’ or a ‘no’ on the evaluation assessment for each step of each scenario.

The training is critical for the end-users of safe+natal to learn how to properly use the kit and navigate through the app. Figures 2 and 3 depict example slides from the training course presented to the CHWs. The overall goals of safe+natal in Sierra Leone are to improve early detection of danger signs in pregnant women and their fetuses, support decision making in maternal healthcare and referrals to higher forms of care, and to bolster existing healthcare services via low-cost, but high-quality technology. In addition to providing training to the CHWs, the full kit will also be made available to the community and to healthcare facilities as well as a system to communicate patient data between remote and large-scale facilities. The clinical goals for the project were determined by the team in Sierra Leone using the WHO Safe Childbirth checklist.

Figure 2: Slide from safe+natal initial training; visual of the app interface for searching patient data.

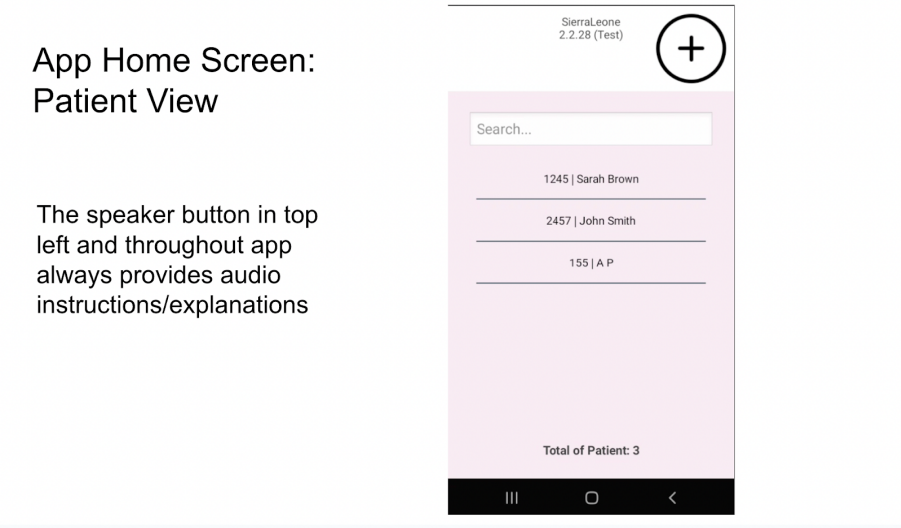
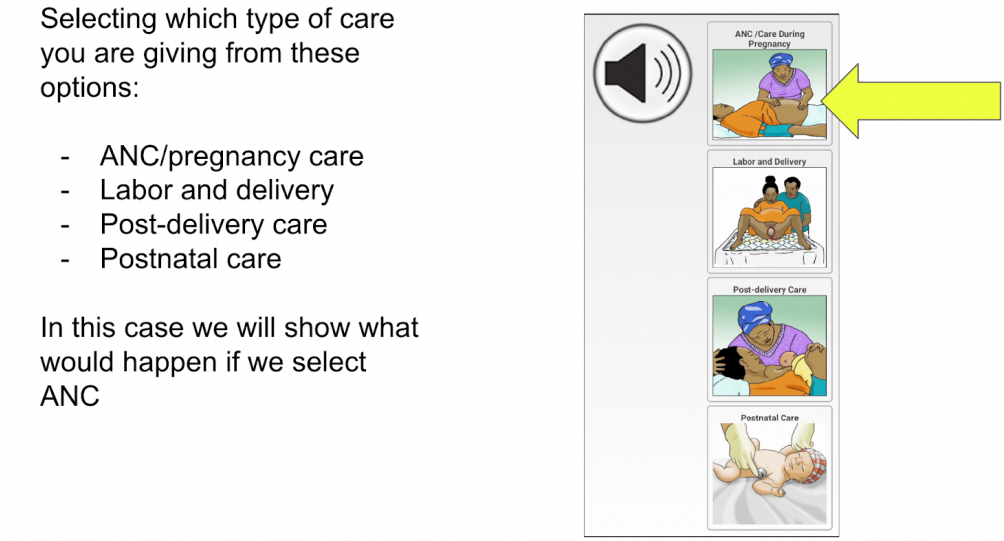


Figure 3: Slide from safe+natal training; image of app interface when the CHW selects which type of visit they are completing.



The team in Sierra Leone also decided to implement a condensed, "refresher training" to highlight the specific pain points in the initial assessment such as setting up and using the Doppler to record the fetal heartbeat and inputting data. The team was concerned that the refresher was needed because the initial training was conducted several months before and they wanted to ensure the healthcare workers remembered how to use the kit going forward. The refresher training included a document with instructions for how to conduct the training as well as a video overviewing the steps of using the kit. An individual who performed well on the training assessment was asked to demonstrate the steps of each visit scenario and the equipment in the kit was reviewed as well.

2.1.1 Training Participants

The participant data used for quantitative analysis in this thesis were collected by the safe+natal Sierra Leone study site in collaboration with the CHAMPS Sierra Leone team. The data included twenty-three unique participants from four different study sites who received the toolkit training and were given a skills assessment. The four sites selected for training are PHUs located in Sierra Leone's Makeni region. See T*able 2* for additional information on the intervention and control sites.

Table 2: Pilot implementation and control site demographics.

Facility	Urban/Rural	Population Size	Estimated Monthly ANC visits	Estimated Monthly births	Number of staff
Intervention Facilities					
Red Cross	Periurban	31,212	80	25	12
Makama	Urban	12,692	88	15	12
Manonkoh	Rural	4,054	75	7	3
Rokonta	Rural	4,808	55	15	2
Control facilities					
Robat	Rural	5,077	35	10	2
Polic Clinic	Urban	9,031	50	11	14
Pate Bana	Rural	5,575	40	10	3
Mabolleh	Rural	3,079	33	8	4

The individuals who were trained included ten maternal and child health aides (MCHA), seven midwives, five state-enrolled community health nurses (SECHN), and one community health officer (CHO). SECHNs are the lowest-skilled level of nurse, while MCHAs are aides trained to perform deliveries and provide maternal and child healthcare, similar to midwives, who are specifically trained for deliveries (WHO, n.d. a). CHOs are higher-level clinicians, comparable to the role of a physician assistant (WHO, n.d. a). The ages of those trained ranged

from 28 to 55 years old, with an average age of 40.2 years old. On average, the CHWs trained had been working in their roles for 6.4 years, with a range of 2 to 15 years in their role. Out of the 23 individuals who were trained, 20 live in urban communities (86.9%), while only 3 live in rural communities. Those that live in urban communities work in the urban facilities, while those who live in rural communities work in rural communities.

Two individuals repeated the assessment due to low scores, so in total, twenty-five assessments were analyzed. These data were collected in Spring of 2024. See Table 3 for additional information on the facilities where training took place and see Figures 4 and 5 of the training sessions.

Table 3: CHWs trained on safe+natal kit demographic information.

Intervention Facility	Number of CHWs Trained	Roles
Red Cross	10	5 MCHAs, 2 midwives, 3 SECHNs
Makama	10	5 MCHAs, 4 midwives, 1 SECHN
Manonkoh	1	1 midwife
Rokonta	2	1 CHO, 1 SECHN

Figure 4: CHWs at the training session.

Figure 5: CHWs at the training session.

Before conducting the training, the safe+natal study received IRB ethics approval from the Sierra Leone Ministry of Health because they are working with human subjects and private health information. For my thesis, I only worked with the safe+natal team members, and not any CHWs or patients. The Emory IRB includes approval to interview subjects, so I did not have to receive separate approval. I also took other measures, like anonymizing the interview data to protect their identities in case sensitive information was shared.

2.1.2 Quantitative Procedures: Training Assessments

The assessment that occurs at the end of each training system differs slightly between the three scenarios, but the process is the same. During the assessment, healthcare workers are asked to navigate through the steps of a given visit scenario using the toolkit, mobile phone, and app. If the individual correctly performs the task, they receive a "Yes," and if they forget how to do the task or do it incorrectly, they receive a "No." The first scenario, antenatal control, consists of 20

items. Item 14 – “the provider places the pulse oximeter on the index finger of the left arm and verifies that the pulse oximeter is working” – was omitted from the evaluation because it was not applicable due to the pulse oximeter being taken out of the kit for the Sierra Leone site. The second scenario, during delivery with presence of danger signs, consists of 20 items as well, but items 14, 15, 16, and 17 were omitted because they were not relevant for this specific site. Scenario 3, postpartum care, has ten items.

I compiled the assessment data into three tables, one for each of the visit scenarios. Within each table, each participant was listed along with their date of training, name, training site, total number of points possible, and total number of points earned. I conducted descriptive statistics by creating categorical variables from the assessment data. I counted a “Yes” on the assessment as one and a “No” as zero. The assessment data summary tables, which include each item on the checklists, are depicted in Appendix B. After compiling the data, I added the total number of ones and zeros for each item and then divided the total correct by the total number of participant evaluations (25) to determine the average correct response rate for each item. I used the total number of evaluations for this calculation rather than the number of distinct participants (23) because I wanted to include the final number of evaluations conducted. I also added the total correct responses for all items combined in both number and percentage. I repeated these two steps for all three scenarios.

I isolated items where five or greater participants received a zero to determine which were most frequently missed for each scenario. I calculated the average items correct for each scenario based on the site to determine which sites struggled more than the others. Because two of the facilities trained ten individuals and the other two only trained one or two individual(s), the resulting site averages were skewed because of that difference in number of participants.

Analyzing the assessment data was pertinent to this thesis because it helped me to assess the effects of the training program and how well the healthcare workers were able to grasp the content. If the training was ineffective, the CHWs would not know how to properly use the safe+natal kit, which is necessary for the implementation phase. Additionally, if certain sites were out-performing the others, this could illuminate specific constraints/factors that may affect the success of different sites within the same pilot study. Expanding to other safe+natal sites, the assessment data is important to use to see what parts of the training were more difficult for the CHWs to grasp, which could be modified or emphasized for future studies.

2.2 Qualitative Procedures

2.2.1 Weekly Observational Meetings with Emory & Sierra Leone Teams

Starting in August of 2024, every Wednesday morning, a thirty-plus minute meeting was held with four members of the Emory team and three members of the Sierra Leone team to discuss progress and troubleshoot issues. I took notes during each meeting to record the challenges and progress discussed.

The members of the Emory team who attended included the two principal investigators (PIs), a data analyst, and occasionally the app developer. From the Sierra Leone team, the data manager and lead trainer of the CHWs were almost always present, with the technical lead attending less frequently. The meetings usually began with one of the study coordinators overviewing what had been discussed the previous week and what the action items for that meeting consisted of. I observed the relationships between different team members and how the teams worked together, as well as what issues were brought up, how they were worked through or solved, and how long it took for an issue to be resolved.

I chose to collect observational meeting data because seeing the working relationship between the Emory and Sierra Leone teams helped me better grasp the cadence of the project and how the two sides worked together. I learned more about the way in which problems were addressed and solved and how quickly or slowly that process occurred. This was beneficial to my understanding of the co-design process and day-to-day operations of safe+natal, which ultimately will inform how the project is scaled up to other sites.

2.2.2 Semi-Structured Interviews

I conducted seven semi-structured interviews with members of both the Emory and Sierra Leone Teams working on the safe+natal pilot study. Table 4 includes additional demographic information about the individuals I interviewed and includes an 8th individual, because one of the interviews had two interviewees, both from Sierra Leone. I chose to use a semi-structured interview, which consisted of seven questions, some with one to three sub-questions. The full interview instrument is located in Appendix C. Although the interviews were all scheduled for thirty minutes, some of the interviews were as long as thirty-six minutes and others as short as eleven minutes, depending on the number of relevant questions and sub-questions as well as how descriptive the interviewee was. On average, the interviews lasted about twenty-one minutes.

Table 4: Demographics of safe+natal team members interviewed.

Location/Team	Role	Role Description	Interview ID
Emory	Principal Investigator	Co-founder of safe+natal; facilitates partnership and co-design process between the Emory & SL teams	IDIEM1
Emory	Principal Investigator	Co-founder of safe+natal; oversees development of technology and interface with teams; manages a team of engineers	IDIEM2
Emory	Data Analyst	Collects and listens to data from the Doppler recordings; assesses data quality	IDIEM3
Emory	App Developer/Coder	Manages changes of app interface and back-end structure	IDIEM4
Sierra Leone	Data Manager	Monitors data; ensures correct use of resources and kits in facilities; organizes staff	IDISL1
Sierra Leone	Technical Lead for safe+natal & Team Lead for CHAMPS	Manages communication between teams; builds project protocols and trainings; links implementation team and country's leadership	IDISL2
Sierra Leone	Team Lead for CHAMPS	Leads surveillance team for CHAMPS; direct correspondence with PIs during co-design phase; brought in other team members	IDISL3
Sierra Leone	Training Coordinator	Oversees safe+natal kit training of the CHWs	IDISL4

Interviews are a qualitative data collection method that can be conducted one-on-one or in a group and require oral questioning (Varkevisser et al., 2003). Interviews can be highly rigid, highly flexible and less-structured, or somewhere along that continuum. Rigid interviews consist of a fixed list of questions and are more often used for a large number of respondents, when the researcher has a firm understanding of the information/topic they are collecting data on, or has specific expectations about the content of responses (Varkevisser et al., 2003). Flexible interviews usually consist of general topics to discuss, rather than a set list of questions and are

used when the researcher has little knowledge about the topic or the topic is sensitive (Varkevisser et al., 2003). Semi-structured interviews rely on a preconceived interview protocol, but are monitored by the researcher and questions can be modified or redirected as they go on (Karatsareas, 2022). They can consist of closed and open-ended questions, but yes/no questions often have follow-up prompts to gather additional information (Karatsareas, 2022).

I chose to use the semi-structured interview format because the team members I interviewed had a variety of roles related to the safe+natal project that differed in their involvement along the various steps of the co-design process. A rigid interview would either have contained irrelevant questions for some of the interviewees or would have to be broad enough to encompass everyone, which may have weakened the data and resulted in responses that were less focused on my research aims. A purely flexible interview that only contained topics to discuss would have lacked the depth of specificity I was looking for and could have strayed from the themes I was focused on collecting data for.

To develop my interview instrument, I reviewed the aims of my thesis to identify the main themes I needed to learn more about from the interviews. These themes included understanding the interviewee's role in the project and co-design process, aspects that have gone well, challenges of the project, and expectations going forward. The list of questions I wrote was standard for each interview, but I included prompts within the questions to guide the team member I was interviewing further. I did not ask all of the questions for each interviewee and modified a few to adhere to the specific role of the person being interviewed. For example, if the team member had only recently joined the team, I negated the question regarding the co-design process, because they would not have been involved in that phase of the study. This occurred as

the interview went on, after gaining more insight into each team member's specific contributions to the project.

I conducted and recorded all interviews via Zoom video conferencing. I used a transcription resource called Otter.Ai to produce transcripts of each recording, which I then read through to correct any transcription errors. I reviewed the transcripts a second time in order to begin developing a qualitative data codebook.

2.2.3 Qualitative Data Codebook

I used grounded theory to develop my codebook. Grounded theory is an approach to qualitative research in which the theories that are deduced are a result of the data collected and are systematically analyzed through constant comparison and coding (Mayan, 2016). I used grounded theory because the technique elucidates social processes over a period of time or over phases and is rooted in real-world scenarios, which adheres to the boundaries of my thesis. In grounded theory, data collection and analysis happen simultaneously because the interpretations of the data arise from the data itself (Corbin and Strauss, 1990).

A codebook is used to organize qualitative data that has been collected by themes and subthemes in order to arrange the data into categories with inclusion and exclusion criteria (Creswell and Poth, 2016). The codebook I created used grounded theory because I determined my seven main categories and various subcategories from the interview data itself. The seven categories, or parent codes, are: communication, delays, design, logistics, training, motivation, and team building. After I conducted all the interviews and transcribed them, these categories became clear as recurring themes throughout the seven interviews. As I transcribed the interviews, I identified subcategories, or child codes, that branched off the parent codes by considering additional recurring topics that related to each parent code, but would also help

organize them further. Once my main themes and subthemes were determined, I defined each parent code to differentiate between data that would be included or excluded. I reviewed each interview transcript line-by-line to code the data into each parent code and child code. Because I was working with a small amount of data with only seven interviews, I chose to create the codebook by hand, rather than using software.

3. Results

3.1 Quantitative Training Assessment Results

Each CHW who was trained to use the safe+natal toolkit completed their training by taking an assessment to test their ability to use the kit for different maternal health scenarios. The data I analyzed and compiled into individual tables for each scenario with the totals and average correct responses for all participants for each item on the evaluation checklists are listed below in Appendix C. Table 5 shows the average correct for each department based on the assessment scenario.

Table 5: Average questions correct during training assessment by department.

Scenario 1: Antenatal Control				
Department:	Makama (n=11)	Manonkoh (n=1)	Red Cross (n=11)	Rokonta (n=2)
Average Correct out of 19:	16.3	19	17	19
Scenario 2: During Delivery + Presence of Danger Signs				
Average Correct out of 16:	13.9	16	14.6	16
Scenario 3: Postpartum Care				
Average Correct out of 10:	8.5	10	9.3	9.5

For scenario one, antenatal control, Makama trained eleven women who scored an average of 16.3 items correct out of 19 (85.7%). Rokonta trained two women and both scored 19 out 19. Manonkoh only trained one individual, who correctly completed 19/19 items. The Red Cross site also trained eleven women and averaged 17 items correct out of 19 (89.4%). For scenario 2, during labor with complications, Manonkoh and Rokonta each scored 16 correct out of 16. Makama averaged 13.9 out of 16 correct (86.8%). The Red Cross site scored 14.6 out of 16 (91.3%). For scenario three, postpartum care visit, Makama scored 8.5 out of 10 correct (85%). Rokonta averaged 9.5/10 (95%), while Mononkoh's trainee scored 10/10 and those trained at Red Cross on average scored 9.3 out of 10 (93%). Both Makama and Red Cross each had one participant who had to repeat the assessment because their scores the first time were too low. Makama's repeat participant scored a 10/19, 9/16, and 2/10 for scenarios one, two, and

three, respectively for the first try. For the second try, the participant scored 14/19, 11/16, and 8/10, for the three scenarios. The individual who had to repeat their test for the Red Cross initially scored 9/19, 7/16, and 9/10 for scenarios one, two, and three, respectively. On the second try, they scored 19/19, 16/16, and 10/10.

For Scenario 1, antenatal control, the following items were missed most frequently: Item 3 - The provider manages to enter a new patient name (20/25); Item 5 - The provider, when viewing the green and red button, understands and interprets and performs the instruction (19/25); Item 10 - The provider presses on the image of the green arrow in the boxes of the images of danger signs without much difficulty and asks her patient about these discomforts (20/25); and Item 18 - The provider places the girdle and adjusts it to the Doppler to start recording the heartbeat (15/25).

For Scenario 2, during labor with danger signs present, the items missed most frequently were: Item 8 - The provider evaluates the size of the mother's belly and presses on the correct image (20/25); and Item 19 - The provider notes the presence of a complication and steps taken (19/25).

The items most frequently missed in Scenario 3, postnatal care visit, were: Item 4 - The provider, when viewing the green and red buttons, understands and interprets and performs the instruction (20/25); Item 7 - The provider recognizes the danger sign in the newborn and presses the correct button (18/25); and Item 9 - The provider correctly describes the triage protocol for a newborn for their facility (20/25).

The health providers struggled most with identifying danger signs and using equipment such as the Doppler throughout all three scenarios, which prompted the provision of a “refresher” training that highlighted these aspects of using the safe+natal kit, which was

conducted during the Fall of 2024. The initial pass rate for all trainees was 91%, with only 2 of the 23 women who were trained having to retake the assessment, which they passed on the second try.

3.2 Observational Meeting Data

The Emory and Sierra Leone teams met every Wednesday to discuss progress and next steps for the safe+natal pilot. Throughout the semester, two major issues arose that constituted much of the efforts discussed in the weekly meetings: (1) signal quality and (2) cellular network connectivity. The signal quality refers to how clear the 1-D Doppler recordings are and if they are usable for data analysis. The Doppler uses a database of recordings to detect any abnormalities in fetal development. If too much of the recording is of low-quality, it cannot be used to measure fetal heart rate or determine whether there are any danger signs in the mother or fetus. During the first few months of the meetings, time was spent trying to determine whether signal quality issues were due to user-error, background noise, or an issue with the technology itself. If the Doppler, speaker, and cables are not set-up correctly, a high-quality recording is difficult to obtain, so emphasis was placed on ensuring the equipment worked well and that the CHWs knew how to set-up the kit correctly, which also contributed to the decision to implement the “refresher training.”

Issues surrounding cellular network connectivity were introduced later in the sequence of weekly meetings. The mobile phones in the safe+natal toolkit do not require internet connection, but do need to be able to connect to mobile cell networks in order for the app to sync patient data and send referrals via messaging to hospitals or higher forms of care when warranted. One of the Sierra Leone team members brought up the fact that some of the intervention sites are so remote

that they do not have access to any cellular networks, which requires staff members to bring the phones with them into the city after leaving the clinic sites to get network access for the referrals to go through. This requires additional steps for the healthcare workers rather than being an automatic process. Some Emory team members were surprised to hear about this so many months after the intervention facilities were chosen, however they worked with the other team members without animosity to discuss and brainstorm solutions to the problem as efficiently as possible. Additional topics discussed included confirming the type of cell-phone in the safe+natal toolkits at each facility, continuous app-redesign, and ensuring data was being recorded for the patients in each facility.

Building relationships with end-users and key stakeholders is immensely important in creating effective global health interventions. As part of collecting weekly meeting data, I observed how the relationships between the Emory and Sierra Leone teams developed over the course of the meeting period. Each meeting began with small talk regarding each other's weekends, helping build familiarity with the team's lives. This small gesture acknowledges that the team members care more about just getting their work done and that learning more about their colleagues is important. However, inconsistent internet connectivity also created challenges in community during the meetings. I also took note of how individuals spoke when problems or delays arose. Even when problems arose, no individual or team was ever blamed, rather each side took time to understand the problem and work through it rather than let it create animosity and further delays.

3.3 Qualitative Data Codebook Parent Codes

The interviews I conducted produced seven main themes, or parent codes, from which the qualitative data codebook was built off of: (1) Communication, (2) Design, (3) Delays, (4) Logistics, (5) Training, (6) Motivation, and (7) Team Building (see the full codebook outline in Appendix D).

3.3.1 Communication

Communication was a major target of concern for safe+natal team members both at Emory and in Sierra Leone. Several interviewees spoke of how communication flow was either facilitated or hindered and the impacts that had on the project. Within communication flow, one of the main challenges that was addressed was responsiveness. Several team members from Emory spoke about lack of consistent responsiveness due to external factors such as time difference, as well as internal factors such as misunderstandings regarding who was responsible for certain aspects of the project and who from Sierra Leone was designated to communicate with members at Emory. One interviewee from the Emory team said, “Yeah, probably the biggest challenge is the communication, so we never know quite who's meant to be responding to us and often have to request a few times to get something that we that we need, and it doesn't quite come through as the right thing that we need initially…” (IDIEM2). The lack of responsiveness and miscommunications from both Emory and Sierra Leone colleagues contributed to growing delays in the project and frustrations among the team.

Multiple interviewees also noted positive aspects of communication within the pilot study. One team member highlighted that they were impressed by the commitment shown by their colleagues and that communication with the Emory team has helped them build

relationships. Additionally, these challenges have forced the team to problem solve and seek alternative solutions such as reaching out in smaller groups to clarify information and objectives.

3.3.2 Delays

Team members spoke about both external and internal factors that resulted in delays of progress for the pilot study. External problems including weather, i.e. Sierra Leone's rainy season, which prohibits travel around the country, and the remote distance of facilities, which impacted their accessibility. Sierra Leone is located in a time zone that is five hours ahead of the Eastern time zone in which Emory is located, which prolonged the response time on urgent matters. In addition, political instability in the region inhibited the ability for consistent contact with remote team members. Another delay occurred with the process to get ethics approval for the IRB in Sierra Leone, which took over two years and significantly pushed back the start of the pilot. Multiple team members mentioned their surprise over how much longer the project was taking than had been expected,

> "And then we understood, because of the layers and the intricacies that we actually had to go through different approval, and that took a long time. So in the co-design phase, I think we had a snag there, because we weren't quite connecting on what was on the Emory side. So that took a long time for us to clarify" (IDISL3).

Both broader misunderstandings in terms of responsibilities as well as micro examples such as who was supposed to communicate with who allowed for such delays to persist. Within the team, the main challenges addressed by interviewees was misunderstandings regarding who was responsible for communicating with who because of the many layers of the project on both the Emory and Sierra Leone sides. With lots of revolving changes to the app, constant communication was necessary, but difficult to achieve consistently, which elicited these

delays in progress. One person suggested that there should be clarification over roles and responsibilities, with someone specifically designated to communicate on various specific matters, including problems with/changes for the app.

3.3.3 Design

Three main topics regarding design were spoken about by interviewees: (1) Co-designing the study with team members in Sierra Leone, (2) the process of building and modifying the app, and (3) how the Sierra Leone pilot study has differed from implementing safe+natal in Guatemala.

The cycle of modifying the app design was said to be rather smooth, but actually implementing it into the facilities' workflow was more challenging, as was noted with difficulties in getting IRB ethics approval and ensuring that data capture was consistent with the Ministry of Health guidelines. In Guatemala, the project had more funding and a more established reputation, which aided the co-design process. In Sierra Leone, they were able to build off the app from the Guatemala site, but the Emory team had to devote more energy into working with local researchers and healthcare workers to understand the healthcare landscape and the potential for safe+natal in the country since they were not already established there.

One of the more challenging aspects of integrating safe+natal into standard practice is that the impact of safe+natal comes from the referral process and ensuring that once danger signs are identified, that referrals to higher care are completed. Because of the lack of funding, the Sierra Leone site does not include transportation or transference of referred patients, which makes completing referrals more difficult – a stark contrast to the Guatemala site. Therefore, the health care staff are the key to ensuring follow through of the referral process.

3.3.4 Logistics

The process of building a pilot study between teams on different continents came with many logistical considerations and challenges in terms of technology, workflow, and supply chain. With regards to the use of the app itself, there were many considerations related to data entry and record keeping.

Issues with technology and staff were often addressed by interviewees. Main concerns surrounded data entry errors and uploading, which were common problems for the Guatemala site. Healthcare workers in Sierra Leone are relatively untrained, so even though the app walks them through the steps of each visit, the team mentioned that there could be errors in data entry, which would thwart correct referral of patients to higher forms of care. One interviewee commented on the logistics of staffing the project, "...So we're going to get a new person in the mix, because I want him to sort of take over the data wrangling on the Sierra Leone project…But you know, it's always, never enough. You never have enough staff working on this kind of stuff" (IDIEM2). Both lack of training/errors in data capture and the quantity of staff offer logistical challenges within the broader trajectory of the pilot study. Additionally, as mentioned earlier, cellular network access is a problem in Sierra Leone, with some of the study facilities being located very remotely and hard to access, which could further impact the ability for data to be uploaded efficiently.

Concerns regarding workflow addressed the imperative for completed referrals, which is the responsibility of the healthcare workers, since the safe+natal app itself does not do the referrals. Another logistical issue was the lack of transportation provided to help with completing referrals. When asked about the possibilities for safe+natal in Sierra Leone in the future, one team member said,

> "This project is not going to involve transportation…I was asking about, like, referral pathways, and they were like, well, tell them to go to the next facility, but it's on the patient to do so. And so I anticipate that, you know, we may not see so many completed referrals because of the barriers to transportation and transfer to facilities to hire higher level facilities" (IDIEM1).

Failure to complete referrals could undermine the potential impact of safe+natal, since they are necessary to improve maternal and neonatal health outcomes. The completion of referrals is at greater risk if the healthcare workers do not properly input data.

On a wider scale, various factors created additional roadblocks that resulted in delays in the project, such as the lack of cell network access and the rainy season, which prohibits access to a large portion of the country, including two of the largest cities, for several months of the year. Interviewees also spoke about the logistics of broader applications of safe+natal in the community, including considerations regarding how to get the data out into the community and how to receive feedback, as well as how to expand the reach of safe+natal to other countries and continents.

3.3.5 Training

The process of training nurses and health care workers took place over several months at four facilities in Sierra Leone. The main challenges identified in relation to training were lack of prior training in the nurses, difficulties navigating the phone/technology, and poor record keeping systems in the facilities. The team members in Sierra Leone were in charge of training the health care workers and worked with the Emory staff to understand the training process and timeline of the study. They also completed a "refresher" training course two months after the initial training to go over specific areas of concern, such as inputting patient data and specific danger signs to be wary of for the different types of visits.

One concern that was mentioned regarded the acceptability of the training/safe+natal kit because the members overseeing the training did not want the health care workers to view the intervention as something forcibly imposed upon them. To prevent this, the Sierra Leone team worked with the Ministry of Health, so that the nurses associated the project with the Ministry, giving it more priority and legitimacy.

Interviewees also mentioned various benefits they saw as related to training the workers. First, one person mentioned that they really enjoyed seeing the simplicity of the process and the moment that it 'clicked' for the healthcare workers being trained. They mentioned that there is great opportunity for safe+natal to improve and simplify the decision-making process in Sierra Leone's healthcare system, because it validates choices made by the health care workers. Another team member commented,

> "...Some of the training contains emergence of reflective and newborn care…So when we are teaching, we'll tell them…how to talk to the pregnant woman, how to monitor, how to weigh properly. So it's like, also like a capacity building for the healthcare workers…with that training can also help to capacitate those nurses in terms of delivering good health services" (IDISL2).

The possibility to enhance the capabilities of healthcare workers expands the possibilities of safe+natal beyond the confines of the pilot study.

3.3.6 Motivation

Most interviewees were motivated to participate and commit to the study because of their desire to help others and make a difference. Several people spoke of the joy they felt from knowing they were directly helping others. Additionally, team members addressed how safe+natal could improve existing maternal and neonatal healthcare, train healthcare workers, and reduce maternal and neonatal mortality in Sierra Leone. They also spoke positively about the

possibility of expanding safe+natal to other facilities, regions, and countries through creation of a social enterprise. Several team members mentioned how learning about new people and a new culture has enhanced their experience in the project. One team member stated their hopes for safe+natal's impact on Sierra Leone's healthcare system,

> "I think it will change the face of this whole maternal health care, or maternal mortality, to be specific, because for the ministry of Sierra Leone here, they have already, they have also implemented a system similar to safe+natal, but our own system is more than their own…so it has great improvement, because one it has early detection" (IDISL1).

Main concerns regarding motivation included fears of waning engagement due to delays in the study, assuring expectations met the project's ability to deliver, and the process of completing referrals in order to make sure safe+natal's impact is realized. These fears were addressed more often by the Emory team members, whereas the Sierra Leone members spoke more often of their positive impression of their colleagues' commitment to the project.

3.3.7 Team Building

The process of team building between Emory and Sierra Leone was difficult because of various factors that posed barriers towards forming relationships. Interviewees mentioned that the project started while the Covid-19 pandemic was still restricting travel, so there was no possibility for the team to meet all in person. One team member said,

> "Knowing that we've managed to build a team even in difficult circumstances, because we first started this when people were not traveling much still because of the pandemic, and then kind of all of these other like hurdles to get through the fact that we formed a really strong team and are like, just about to start the pilot…" (IDIEM1).

There still has not been in person contact between the Emory team and Sierra Leone team, and although this is a growing priority, it has not entirely hindered their ability to form a

team. Additionally, the project has had to work around its lack of funding because many of the individuals involved work part-time rather than full-time. Because of this, some interviewees expressed concern over the engagement of those working on the project and believed that it could be advantageous if more of the team was working full-time. Personnel changes interrupted the workflow and numerous delays have contributed to lack of full engagement in the project as well.

Both principal investigators from Emory mentioned the importance of visiting Sierra Leone in person and their desire to do so. They emphasized their longstanding history working in Guatemala, and how it has been difficult to establish the same level of trust and bonding in Sierra Leone working remotely. In response to being asked what could be improved about the co-design process for the study, IDIEM2 stated, “It's very hard to replace being in person, because it builds bonds, but it also you see things that you don't see off camera, and you see, you can see the bigger context much more quickly…People just bond much better in person” (IDIEM2). Both IDIEM1 and IDIEM2 explained their beliefs that establishing these close relationships is key to the co-design process.

4. Discussion

The aim of this thesis was to explore challenges and realities of implementing safe+natal in Sierra Leone to better understand the co-design process and, in turn, improve the scalability of the intervention. The safe+natal study seeks to address maternal health in low-and-middle income countries by training community health workers to use a maternal and neonatal monitoring kit and smartphone app that walks them through pregnancy related-visits and completes referrals to higher levels of care. By evaluating training assessment data, conducting

semi-structured interviews with Emory and Sierra Leone team members, and observing weekly meetings, I found that the main challenges regarding the study included issues with consistent communication and understanding responsibilities, timeliness of the co-design process, and lack of cell network access at remote facilities. The main opportunities I identified for the intervention included the automatic flagging of a need for referrals to higher levels of care and the possibility to expand the capabilities of healthcare workers in low-resource settings.

Although this study only addresses one study site for safe+natal, the data gathered will help inform and improve future studies on streamlining the co-design process and implementation period. On its own, safe+natal is a tool that can be used to take maternal and neonatal measurements in healthcare settings. However, its potential for broader impacts on maternal health is derived from the process of referring pregnant women to higher forms of care when danger signs are present. The key to safe+natal's success in maternal and neonatal health outcomes is in the ability for referrals to be completed. As a global health intervention, safe+natal must be integrated into normal workflow to be used consistently. The use of the co-design process within the safe+natal study has helped account for contextual factors that will help aid in integrating the intervention in Sierra Leone's existing healthcare system.

4.1 The Co-Design Process for safe+natal

The co-design approach engages end-users within the design process in meaningful ways that improve the cultural competency of the interventions that are developed. The steps of the co-design process as used by Emory University consist of the following: (1) Problem identification with local partner; (2) Baseline needs assessment and local input; (3) Building an existing technology for prototype; (4) Refining technology based on context and local preferences; (5)

End-user training; and (6) Implementation and ongoing support and refining. The interviews conducted with members of both the Emory and Sierra Leone teams and weekly observational meeting data elucidated how the co-design process was used in the safe+natal pilot for SL and where there were challenges or room for improvement in the process. For example, team members explained how CHAMPS helped highlight Sierra Leone as a prime site for the study and how their personnel contributed to the co-design process as well as the specific modifications made as a result of co-designing the intervention for this site.

4.1.1 Problem Identification with local partner

The co-design process for safe+natal began by working with teams in Sierra Leone to identify a clear and identifiable problem by which the intervention would operate. Sierra Leone's maternal mortality crisis is long standing, and gaps in their healthcare system such as the lack of highly skilled healthcare personnel and rurally located providers became especially evident after their civil war and the more recent Ebola outbreak. Therefore, the study team identified a need for an intervention which targeted this lack of healthcare resources for rural communities in Sierra Leone. One interviewee commented on how Sierra Leone was chosen as the specific study site:

> "The Gates Foundation funded consortium called CHAMPS, the childhood health and mortality project…was interested in translating this for Sub Saharan Africa, and we talked to quite a few different locations about how we would do this…the one location that was more proactive than the others was, I would say, is the group in Sierra Leone" (IDIEM2).

Partnering with other/larger organizations, like CHAMPS, expedited the co-design process by leveraging existing data and infrastructure that helped pinpoint exact locations where the need for an intervention was greatest. CHAMPS' existing child health surveillance data and

infrastructure helped immensely in selecting Sierra Leone as a target site as well as identifying the specific problem regarding maternal health. Once Sierra Leone was selected, the Emory team worked closely with CHAMPS team members to determine the specific issues that safe+natal would seek to address that were different from previous sites, including lack of network access and need for increased clinical support. Safe+natal can expand to sites where there are no existing organizations to help, but the process may take more time and energy, especially without partners on the ground to immediately begin communication and designing with. At this step of the co-design process, larger scalability is possible through establishing connections with other global health organizations that can act as a proxy in the country/site itself, especially when one of the teams is located in a different country.

4.1.2 Baseline needs assessment and local input

After determining Sierra Leone as the location for the project, the Emory team worked closely with several individuals in Sierra Leone to get IRB ethics approval, understand the healthcare system, and learn more about the cultural context in which safe+natal would be implemented (IDIEM1). At this step, the PIs for the project met with individuals from CHAMPS to conduct the baseline needs assessment and assess feasibility of necessary changes needed for this site.

One area for improvement that the teams identified was the need to more clearly structure the initial steps of the co-design process. Common concerns of end-users involved in co-creation include preparation for the design session, guidance and structure during the session, and balance of participation (Tremblay et al., 2022). One individual I interviewed on the Sierra Leone team mentioned that there were some discrepancies in understanding the scope and goals of the project in the initial co-design meetings. Specifically, the Sierra Leone team struggled to understand the

intricate bureaucratic layers on the Emory team, which in turn delayed getting ethics approval in Sierra Leone. Better preparation and a more concrete structure for these early meetings, including more a tailored introduction to the infrastructure of the teams on both sides, could help ease these concerns in end-users in future study sites as well as expedite the expansion of safe+natal. To improve the scalability of safe+natal, especially in global sites lacking organizations like CHAMPS who facilitate the beginning of the project, a clear structure can aid in establishing trust with end-users early on in the process. This strong foundation would allow subsequent co-design steps to proceed more smoothly.

4.1.3 Building an existing technology for prototype

The prototype of the safe+natal app and kit were initially built for the project's first pilot site in Guatemala. The equipment used, such as the 1-D Doppler and blood pressure cuff, were not novel technologies themselves, but using them together with the app and by implementing machine learning to increase the number of functions of the Doppler offered a more unique and efficient approach to maternal healthcare visits. In addition to using existing technology for the toolkit, the safe+natal Sierra Leone pilot was also able to build off of earlier versions of the app developed for previous study sites. During one interview, one individual commented on the importance of leveraging existing processes and structures:

> "In recent years, we've usually started with what we already have. Because if you, if you go into a community and say, 'What do you want', they'll say, 'what do you have?' And you, you try to create as little bias as possible. But if they don't have some idea of what you can do, then it's very hard for them to imagine what is feasible within the time that you have and the resources that you have" (IDIEM2).

Several team members also discussed how the pilot process for safe+natal involved building off the existing app to address the specific community needs in Sierra Leone. As the

initial prototyping step was conducted by the PIs and only a few members from the Sierra Leone team, they were able to complete the preliminary groundwork for the pilot more efficiently and effectively. Studies have found that co-design could benefit from creating a differentiated prototyping phase in which only key stakeholders are involved by increasing the efficiency of the process and ensuring that the prototype is perfected before more rigorous testing is conducted (Noorbergen et al., 2021). Separating this step from the next step, in which the technology is refined based on contextual and cultural factors, helped the team establish clear boundaries for each phase and distinguished the bulkier prototype design phases from the refining process, which could benefit other safe+natal sites.

4.1.4 Refining technology based on context and local preferences

The safe+natal app was first developed for Guatemala, and additional study sites were added afterwards, with changes depending on the specific needs of that site. Building off the existing prototype aids in expediting the ground stages of the intervention process, while also allowing enough flexibility for site-specific changes to be made. A more rigid design process would not account for cultural context and engagement of end-users/community leaders, but starting from scratch to build the technology would be inefficient and costly. Multiple team members spoke about the process of working with colleagues in Sierra Leone to identify and implement necessary modifications. Various considerations were pertinent to the Sierra Leone site, including switching from paper intake forms to digital records, teaching staff to input data on the app, and altering standard workflow from seeing patients in a large group to instead conducting individual visits. Other considerations included how to integrate safe+natal into the standard workflow of Sierra Leone healthcare facilities and working in conjunction with local infrastructure such as the Ministry of Health and CHAMPS. In regards to the process of

redesigning the app, one team member said, “I think the redesign of the app is a lot smoother than I thought. Usually that becomes problematic to come up with a new, new design, because everybody has a different protocol, but there's a lot of similarities, it seems, and enough for us to really be able to leverage what we already have” (IDIEM2). Specific changes made to the app include updating the images that include people and clothing that reflects the end-users in Sierra Leone (see Figure 6) and adding a screen with a summary of patient data including total patients submitted and how many of those were flagged for having complications (see additional images from the app interface for Sierra Leone in Appendix E). Additionally, the app includes both audio and written instructions and data collection tools because the healthcare workers at the Sierra Leone site had higher literacy levels than in the Guatemala site, where only audio was used.

Figure 6: Example of the different images for Guatemala (right) in comparison to Sierra Leone (left).

Along with modifying the app interface, attention was paid to the referral pathways and how data was collected. This is where the co-design process can specifically help tailor safe+natal to different sites given the makeup of their healthcare system in determining the referral pathways and specific preferences on how data flows. For example, in Sierra Leone, the two-level healthcare system means that referrals are made from the PHU's to the second-tier, larger hospitals. For the Guatemala site, midwives referred patients to doctors and nurses from safe+natal's partner, Maya Health Alliance/Wuqu' Kawoq, and subsequently to hospitals if further care was needed, with transportation and support from Maya Health Alliance (*Wuqu'*

Kawoq, n.d.). The Sierra Leone site does not currently have a structure in place to provide transportation for referrals, which makes the completion of referrals more difficult, since patients have to get to the hospitals themselves.

One major barrier to implementing impactful health interventions in LMICs pertains to the collection, retention, and sharing of patients' health data. When addressing health concerns in LMICs, empirical knowledge is crucial to make effective health policy decisions, yet many LMICs, including Sierra Leone, use paper intake forms to record patient data, which is less reliable and protected (Free et al., 2013). Additionally, the ability to readily share medical information within and between facilities is often lacking for paper medical records, and is made easier with electronic medical records. However, there is more discrepancy in how data is formatted and stored (Free et al., 2013). Global health efforts must trend towards culturally competent electronic medical records that can be shared across different facilities in order to increase leveraging of highly-skilled knowledge and improve access of records to inform point-of-care decision making as well as future research efforts.

In both this step and for the baseline needs assessment and local input, the Emory team was not able to meet in person with the Sierra Leone team. This was cited as a concern in two realms: communication flow and the ability to establish trust with the individuals on the ground in Sierra Leone. The lack of consistent communication contributed to overall project delays and frustrations among the groups, with some calling for the need for a specific individual to be designated for communications regarding app modifications and other time-constricted communications. However, there was never conflict among the teams and the relationships never suffered because of issues with communication. This was reflected in the interview data, but also in the weekly meetings I attended, where I could see the Emory and Sierra Leone teams directly

working with each other. Meeting every week allowed for the teams to grow more comfortable with each other and learn more about each other by sharing aspects of their life. Although the majority of the meetings were dedicated to working, they always began with the team members checking in with each other and engaging in small talk about their lives.

Establishing trust with local team members and end-users is also an integral part to the co-design process. Without creating a relationship, global health interventions may see less success because the end-users do not have as much of a stake in the success of the project. With teams that are spread between different continents and time zones, this becomes increasingly difficult to achieve, but recognizing its importance helps set the correct intentions. The project's PIs knew that building bonds is an important step in developing and implementing global health interventions because of their prior experience in Guatemala, where they had developed relationships with the local health workers over multiple decades. Translating this to different sites where that same established relationship is not available could create a roadblock in the scalability of global health interventions like safe+natal. To remedy this, the safe+natal study in Sierra Leone prioritized regular communication with members of the SL team and also demonstrated their commitment to the project, which was shared by the SL-based individuals as well.

4.1.5 End-user training

The Sierra Leone pilot is currently in the end-user training phase, which is described in detail in the methods section. Interviewees mentioned that there have been some difficulties in training because of disruption to the usual workflow and use of unfamiliar technology, although staff have been eager to implement safe+natal's use into their daily work routine.

Since implementation of the safe+natal toolkit has not yet begun, no data has been collected on the impact of safe+natal on maternal health in Sierra Leone. However, the training itself has been successful, with an initial pass rate of 91% and a final pass rate of 100% after two individuals took the training assessment a second time. Future studies will be needed to evaluate the subsequent use of the safe+natal kit once it is implemented to understand any potential issues with the training or gaps in knowledge of the CHWs.

Because of the delays experienced in the study, a “refresher training" was needed to remind the CHWs of how to use the safe+natal kit/app, especially components that were frequently missed in their assessments. The training was created quickly from existing training materials based on what was needed to be covered, specifically focusing on setting up the equipment and identifying danger signs. Going forward, having a second, supplementary training built into the study timeline may be more efficient and beneficial to increase capacity building of those who are trained.

Training the CHWs to use safe+natal increases their skills in terms of this specific intervention, but also expands their capacities more generally because they are better able to identify pregnancy-related danger signs, work through visit scenarios, and use common technology like blood pressure cuffs and Dopplers. This provides a promising new direction for maternal health, where the use of mHealth can aid in expanding skills and, thus, expand high-quality care throughout low-resource areas around the world.

4.1.6 Implementation and ongoing support and refining

Although implementation has not yet started, many team members expressed excitement over the opportunities they believe safe+natal will provide for Sierra Leone’s maternal health status,

> "I'm optimistic in terms of what will come out of that, because of what we have gone through and what we have put together, especially the forms, and then also the linkages in terms of identifying cases and referring them to the appropriate facility…so it's a pilot phase, and I know when we do that one, there's possibility for an expansion, which will be so useful" (IDISL2).

The Implementation phase was supposed to take place from April 2024 to March 2025, but various delays stalled the project's progress. The Sierra Leone pilot was initially projected to take place over twenty-four months, ending in Spring of 2025, but the process to get IRB approval in Sierra Leone took two years longer than expected and other external factors, like political unrest, and inability to reach the facilities due to weather, further delayed progress. In order to improve the co-design process and enhance scalability of safe+natal and other mHealth maternal health interventions, the process must become more efficient in navigating logistical delays. However, it must do so while still ensuring equal participation from all stakeholders in ways that meaningfully impact the resulting intervention (Pallesen et al., 2020). The key to an effective co-design process in global health is working efficiently while also carefully navigating the power dynamics that underlie these participatory relationships.

4.2 Other Opportunities & Challenges for safe+natal

Ultimately, the goals of those working on the safe+natal project mainly center around improving the lives and health of other people. When asked about their motivation to work on the study, many of the individuals I interviewed explained that their motivation came from the prospect of helping others and improving maternal health. The data collected in this thesis emphasized the potential impact of safe+natal on the wellbeing of others through key components such as referrals and capacity building for CHWs. But challenges in completing the

referral process and generating consistent communication between teams could hinder the overall outcomes of safe+natal.

Safe+natal's use of the co-design process and mHealth technology offers insights into the future for maternal health interventions. Although safe+natal's co-design process was delayed in various parts, the overarching principles employed helped the teams build relationships with each other even when working on different continents. Using co-design will also allow for future interventions to recognize the importance of engaging end-users in the design process in order to create more tailored interventions that are cognizant of the cultural context in which they are implemented.

Additional research is needed on the implementation stages of the project to understand how the co-design process impacts adoption and utilization of the intervention. Safe+natal's Guatemala site showed promising results in terms of end-user adoption and completion of referrals. If additional sites can prove they can also integrate safe+natal into normal workflow while simultaneously catering to the specific healthcare system of the site, there will be a larger evidence base for the validity of safe+natal as a maternal health intervention, which would help expand the scale of the project.

The use of mHealth offers a new resource in the healthcare setting that can connect remote facilities to higher forms of care without additional burden placed on healthcare personnel. Mobile networks connect across the world, which bodes well for the scalability of an mHealth-based maternal health intervention like safe+natal. Currently, most mHealth devices being used in the maternal and neonatal health field center around one single use or one point in the healthcare process (Tamrat and Kachnowski, 2012). Conversely, safe+natal presents an

mHealth device that operates along the entire continuum of pregnancy-related care, which steers the future of global maternal health towards more comprehensive solutions.

Safe+natal is not alone in this new effort to address multiple aspects of maternal healthcare. Savemom and TulaSalud are two additional interventions that seek to integrate mHealth technology into the maternal health landscape along with mechanisms to connect knowledge and resources with rural populations. Savemom is an intervention based in India that incorporates a mobile phone app with wearable and regular mHealth technology to monitor a patient's health status, vital signs, and BMI, as well as portals to connect doctors and patients and sync health information (Savemom n.d.). Tula Salud's intervention functions in Guatemala and focuses on training of healthcare personnel at various levels along with surveillance measures and digital interfaces (Tula Salud n.d.). Tula Salud has built out a more intricate mobile network platform that includes modules for education and training, activities like referrals and clinical consultations, and for both community and patient health data that can be accessed by healthcare workers easily (Tula Salud n.d.). Tula Salud expands upon the capabilities of the safe+natal app, which has similar functions, but is less complex. Extensively developed programs and app interfaces like Tula Salud offer potential adaptations for additional morbidities, which is another new direction for the future of mHealth use in global health. Safe+natal's interface is advantageous in terms of usability by low-skilled healthcare workers, especially in places where there are high illiteracy rates, but the simplicity also limits the functions it performs and data it displays compared to other apps and programs on the market.

Further, my findings reveal that no one piece of the safe+natal study will generate a positive impact on maternal health alone. The most successful mHealth interventions are those that engage a multi-faceted approach, rather than just adding a technology-based tool or

cellphone into healthcare settings (Tamrat and Kachnowski, 2012). Future mHealth-based maternal health studies must consider a variety of factors and constraints that play into the provision of quality maternal healthcare including transportation, indirect costs, and level of skill in healthcare workers (Tamrat and Kachnowski, 2012). Safe+natal accounts for many of these factors by integrating health measurement tools used during pregnancy-related visits with mobile health technology that has the ability to refer patients and sync health data and a training procedure to expand the capabilities of healthcare workers. However, safe+natal is most effective when all of the components work together, so if one, such as the ability to complete referrals, is hindered, the overall success of the intervention could be diminished.

4.2.1 The Referral Process and Capacity Building for Health Workers

The interview data coupled with the weekly meetings I attended with the safe+natal Sierra Leone team illuminated the importance of referrals in the safe+natal intervention and maternal health interventions in general. The safe+natal kit itself is a valuable tool that can be utilized in low-resource settings to improve maternal healthcare. However, there are already many other similar tools on the market, including Sense4Baby, a maternal and fetal monitoring kit with wireless components, a Doppler, and connection to a health information database (Sense4Baby, n.d.). Nuvo is another wireless monitoring maternal care system that uses an app interface to present information to mothers and be viewed by physicians (Nuvo Solutions, n.d.). Safe+natal contains similar technology to these interventions, but is specifically tailored to LMICs by incorporating end-user training to increase their capabilities and referrals to higher forms of care. The potential impact of safe+natal was highlighted by one of the Emory study coordinators,

> "Yeah, I mean, I always say that the safe+natal toolkit like it's not a quick fix, it can help us identify complications. But without referral to further care, it won't do anything like it itself. It just, you know, increases diagnostic and predictive capacities…So it's really the staff that, you know, we rely on to make those referrals and then to provide, really, you know, high quality, responsive care that's taking into account the data" (IDIEM1).

For maternal health to benefit from the referral process and for safe+natal to distinguish itself from other similar programs, the toolkit must be integrated into normal workflow within the local healthcare systems in which it is implemented. This is why using co-design is imperative to create health interventions whose success spans farther than solely during the study period. By understanding the cultural and healthcare context in which the intervention is to be used, it can be better designed to integrate into the workflow, rather than act as an accessory that is not fully adopted by healthcare personnel.

Ethically, safe+natal offers a stark deviation from the historical model of global health intervention design in which researchers drop interventions into the Global South, study the effects for a period of time, and then leave the community with little to no follow-up evaluation. By using the co-design process, ethical considerations are embedded into the very values of the project ensuring equal, meaningful stake-holder participation and the creation of interventions that seek to equitably transform a community's healthcare landscape. Including end-users in the design process has aided in establishing relationships with the intervention community and has helped design a tool that will improve, but not ignore, cultural healthcare practices. Safe+natal brings attention to the need for more ethically-conscious global health interventions in the maternal health field.

Additionally, the point of the referral-making function of the safe+natal app is that it is automatic and does not require extra effort from the healthcare worker once they have identified

danger signs and input data. One major issue that came to light in the weekly meetings I attended was that some of the intervention facilities were located so remotely that the mobile phones could not connect to the cellular network until they were brought to more urban areas. The automaticity of the referral process is similarly integral to safe+natal's effect on maternal health as its adoption into normal workflow. This is one of the many unique challenges in designing health interventions for low-income, low-resource settings. Using co-design principles can help better prepare for problems that arise by actively problem solving with end-users and seeking creative thinking from those living within the constraints of the community/healthcare system (Page et al., 2016).

However, if safe+natal *can* be integrated and adopted fully, it has the potential to improve maternal health. Safe+natal has seen success in reducing maternal mortality in other sites, which bodes promising for the Sierra Leone site as well. Additionally, the intervention could increase the capabilities of healthcare workers by teaching them step by step how to walk through different types of maternal health visits and use technology such as the Doppler and blood-pressure cuff more regularly.

The pass rate of the women trained between the four departments for the Sierra Leone study was 91.3% on the first try and 100% on the second try. At the Guatemala site, the initial pass rate was 80% (safe+natal, n.d.). The number of emergency referrals in the Guatemala study increased significantly after 44 midwives were trained to use the safe+natal kit (NIH, n.d.). One study of the Guatemala site found that the midwives trained to use safe+natal successfully completed 80 referrals and the proportion of neonates who received follow-up care increased from 59% to 92% after implementation of the smart-phone device and app (Juarez et al., 2020).

Additionally, since Sierra Leone has a much larger proportion of lower-skilled healthcare workers than highly skilled, there is a great opportunity for safe+natal to improve the capacities of these CHWs, distributing high-quality care to more remote regions, rather than just in urban centers, without the need of employing or training additional staff. When expanding to additional sites, the bones of the co-design process can be the same to make the process more efficient, but the cultural specificity and engagement of end-users who have a stake in the outcome will enable the intervention to thrive in different environments.

4.2.2 Challenges in Communication and Building Relationships

Within the interview data, the major areas of concern included the flow of communication, which was hindered by external factors like network accessibility, weather, and political instability, as well as internal factors such as lack of clarity on who was responsible for said communication. The codebook also highlighted the need for establishing trust within the co-design team to help the success of the co-design process and intervention's adoption.

The lack of consistent communication and occasional miscommunications throughout the project may stem from the initial phases in which the co-design framework was employed. As mentioned earlier, one team member involved in these preliminary phases commented on difficulties in understanding the initial scope of the project and depth of responsibilities on the Emory and Sierra Leone side. Another interviewee commented on how it was unclear who was responsible for communicating with who and on what issues. Establishing these distinctions in communication channels and responsibilities is necessary for minimizing miscommunications and potential delays. One study found that in design settings with different stakeholders, establishing structured communication is necessary to ensure efforts and motivation do not waste away (Page et al., 2016). This should occur in the initial co-design steps when the problem is

identified and the baseline needs assessment occurs in order to boost confidence in the project early on.

4.2.3 Delays in the Co-design Process

In order to improve the co-design process and enhance scalability of safe+natal and other mHealth maternal health interventions, the process must become more efficient in navigating logistical delays. The Sierra Leone pilot was initially projected to take place over 24 months, with the co-design process occurring from September 2022-March 2024, training taking place in March 2024, and the intervention process from March 2024-April 2025. The co-design phase was delayed almost 2 years because of difficulties with obtaining IRB ethics approval in Sierra Leone and further delays were caused by political unrest and weather prohibiting access to some of the facilities.

For the co-design process to be effective and culturally competent, it may take longer than other design processes to produce meaningful results. Acknowledging this and accepting that there must be enough time and resources allocated to the effort will help expedite the process as much as possible (Singh et al., 2023). Putting in time and effort into the process will also show to the end-users/co-collaborators that the project is prioritized, building trust and motivation, which, again, will make the overall design process more effective and efficient (Singh et al., 2023).

5. Conclusion

The aim of this thesis was to explore the challenges and realities of the initial phases of the safe+natal pilot study in Sierra Leone. Rather than looking at the impact of the intervention, I sought to discover more about the co-design process and implications for mobile-health-based

maternal health interventions in low resource settings. Through interviews, assessment data, and weekly observational meetings, I found that the opportunities for safe+natal to improve global maternal health lie in the completion of the referral process when danger signs in the mother or fetus are detected and in the possibility for expanding the capabilities and knowledge of community health workers. The major challenges I identified in this safe+natal study include difficulties in consistent communication and building relationships with a remote team and study population as well as major delays that slowed the progress of the co-design process. In order to expand the scale of safe+natal, ensuring referrals are completed and the co-design process is refined is necessary. Further studies should evaluate the implementation and evaluation phases of safe+natal in Sierra Leone to address the intervention's impact on health outcomes.

5.1 Limitations of this research

The pilot study in Sierra Leone is still in the training phase, so implementation of the safe+natal toolkit has not yet begun. Therefore, no data has been collected on the impact of safe+natal on maternal health in Sierra Leone. The specific aim of this thesis was to explore the steps leading up to implementation and use of the mHealth intervention, including the co-design and training processes. This information is valuable to inform future safe+natal studies and mHealth maternal health interventions in general, but future studies in Sierra Leone should research the impact of safe+natal on referral rates, detection of maternal and neonatal complications, and overall maternal health in the region. mHealth's future in maternal health is promising, but currently there is a lack of high-quality research on these interventions (Colaci et al., 2016). Therefore, further high-quality research is needed to address this gap and evaluate

safe+natal's effectiveness as an mHealth maternal intervention in Sierra Leone and, more generally, for the future of similar global maternal health efforts.

One other potential limitation of this paper lies within the co-design process itself. The intention of this thesis is to help identify challenges in the co-design process in order to improve it moving forward. Since the premise of co-design is to individually tailor to the specific context in which the intervention will be used, improving the process must be done in a way that does not hinder the principles of co-design itself. Therefore, there are some limitations to how much the data from this thesis can influence the process of co-design when applying it to other situations without disregarding cultural intricacies. Regardless, there is still a great amount that the process can be improved.

5.2 Future Directions

The findings from this thesis can be used to inform future safe+natal sites on potential obstacles that may be encountered in using a co-designed, mHealth intervention to support maternal and neonatal health in LMICs. Because this thesis is site-specific, future studies should look at safe+natal across all sites to learn more about the potential for global scalability. Ultimately, safe+natal has the opportunity to increase capabilities of healthcare workers in remote, low-resource settings, enabling them to provide improved maternal healthcare and make more informed decisions.

In a broader sense, this thesis explores the potential future for global maternal health by investigating the initial phases for an intervention that uses mHealth technology and co-design principles. The ability for mHealth to connect disparate parts of the world via mobile networks expands the resources, healthcare staff, and health knowledge that is available to low- and

middle-income countries and their communities that lack these to begin with. The technology is simple to use and by designing with co-design principles, there is a higher likelihood that it will ethically fit into the normal workflow.

Ultimately, this thesis offers promising data on potential new directions for maternal health in order to achieve the United Nations' Sustainable Development Goals addressing maternal and childhood mortality. The future of maternal and perinatal health relies on novel ways to bring healthcare to underserved populations, in ways that understand the intricacies of the healthcare system and the unique cultural context, especially in relation to pregnancy, of a given community. Co-design principles and mHealth tools bolster the need for global health interventions to reach across geographical, cultural, and socioeconomic barriers to make a lasting impact on this area of healthcare where great inequities still persist.

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7. Appendices:

Appendix A: safe+natal Toolkit Training

The training plan is a strategic teaching tool that will intervene in the skills and knowledge of health providers through the use of equipment in patient visits during pregnancy, labor, and in the postpartum period. The device is a perinatal monitor set consisting of a smartphone, Doppler, pulse oximeter, and pressure monitor, all allied to a virtual intelligence system that will enable the importation and collection of prenatal health data from patients.

Evaluations will be made in both the theoretical and practical stages, and will be done in a personal, non-group manner to obtain data from each provider to assess whether they are able to properly use the perinatal monitoring equipment or need reinforcement before another assessment opportunity.

JUSTIFICATION:
The introduction of a mobile health system in rural areas will help monitor maternal and neonatal health through providers who are trained in the use of this system. The quality of care is expected to improve through early detection of pregnancy complications in resource-constrained contexts.

OBJECTIVES:

- Providers are expected to gain knowledge on how to implement perinatal monitoring equipment through training.
- Provide learning opportunities for new accomplishments in providing care.
- To contribute to the professional preparation of providers through this new experience.
- To make the provider feel satisfied by achieving the use of this new system.

TRAINING ACTIVITIES:

- SESSION 1, PART 1: 1) Presentation of the safe+natal toolkit; 2) How to assemble and disassemble equipment; 3) Review of the app
- SESSION 1, PART 2: Use of perinatal monitoring application for visits during a patient's pregnancy.
- SESSION 2, PART 1: Use of perinatal monitoring application for visits during childbirth and postpartum.
- SESSION 2, PART 2: Practice with patients of use of Perinatal Monitoring equipment prior to evaluation.
- EVALUATION SESSION

Session 1: 3 hours

Supplies needed: safe+natal toolkits, ball, projector for reviewing slides (if possible)

1. Presentation of safe+natal toolkit (1 hour 10 min)
    a. Supply kit list per training: ensure adequate quantity of kits
    b. Each component is explained for function and passed around the room
    c. Device assembly shown, with different community health workers being called up during demonstration
2. BREAK
3. Prenatal visit (1 hour 15 min)
    a. Each health worker has a fully set up toolkit
    b. Ball is thrown to different health workers to facilitate a step in the process
    c. Community workers should be present for learning and viewing ultrasound practice so that they are able to better communicate with patients
4. 15 minute review
    a. Where will the toolkits be kept in each clinic (urban, peri-urban, rural)?
    b. Take questions and feedback from health workers

Session 2: 1.5 hours

Supplies needed: safe+natal toolkits, projector for reviewing slides (if possible)

1. Visit during childbirth: danger signal (birthing longer than 12 hours, preeclampsia, etc) (30 min)
    a. Ask health workers how this process works with pre-existing protocols at locations
2. Visit postpartum: danger signal in infant (30 min)
    a. Ask health workers how this process works with pre-existing protocols at locations, alongside amount of supplies at locations for emergent situations
3. BREAK
4. Triage protocol (30 mins)
    a. Have health workers from each site demographic recount what triage protocol at their specific sites entail
    b. Go through triage demonstration with the kit (can also be demonstrated after break in evaluation)

Evaluation Session: 1.5 hours

Supplies needed: safe+natal toolkits, pregnant participants, evaluation forms, ball, large paper and marker pens (if possible)

1. Facilitators can review by throwing a ball around the room, asking health workers for ordered protocol steps (20 min)
2. Individual evaluation of health workers through all steps of device assembly and use with a practice patient
3. Emphasize that health workers already have a working expertise; troubleshoot foreseen challenges with safe+natal implementation

a. Can implement a game (pin the tail on the facility) for health workers to provide feedback as to specific concerns in specific environments

Appendix B: Training Assessment Data Summary Tables

*Note: Rows highlighted in green indicate frequently missed questions with 5 or more incorrect responses.

Scenario 1: Antenatal Control				
Question:	Yes	No	% Yes	% No
1: The provider manages to turn on the phone	25	0	1	0
2: The provider follows the instructions indicated in the recording by pressing on the correct image.	23	2	0.92	0.08
3: The provider manages to enter a new patient name.	20	5	0.8	0.2
4: The provider manages to complete new patient enrollment without much difficulty.	23	2	0.92	0.08
5: The provider, when viewing the green and red button, understands and interprets and performs the instruction.	19	6	0.76	0.24
6: The provider registers a new patient.	25	0	1	0
7: The provider manages to select the number of months of gestation that her patient carries.	21	4	0.84	0.16
8: The provider is able to recognize the antenatal visit and presses on the correct image.	25	0	1	0
9: The provider evaluates the size of the mother's womb and presses on the correct image.	23	2	0.92	0.08
10: The provider presses on the image of the green arrow in the boxes of the images of danger signs without much difficulty and asks her patient about these discomforts.	20	5	0.8	0.2
11:The provider correctly places the blood pressure collection equipment on the indicated arm.	25	0	1	0
12: The provider turns on the blood pressure monitor and takes the shot without much difficulty.	25	0	1	0
13: The provider checks the values shown on the blood pressure monitor screen and takes the photo with the image of the result.	24	1	0.96	0.04
15: The provider manages to connect the horn to the Doppler and turn it on.	21	4	0.8	0.2

16: The provider manages to turn on the fetal Doppler and locates the fetal heartbeat.	21	4	0.8	0.2
17: The provider uses lubricant or transducer gel to listen to the baby's heart.	25	0	1	0
18: The provider places the girdle and adjusts it to the Doppler to start recording the heartbeat.	15	10	0.6	0.4
19: The provider manages to press on the green button and record the sounds of the fetus's heart without much difficulty.	21	4	0.8	0.2
20: The provider manages to close the application and saves the computer correctly.	24	1	0.96	0.04
Total (out of 475)	425	50	0.89	0.11

**Question 14 (The provider places the pulse oximeter on the index finger of the left arm and verifies that the pulse oximeter is working) was omitted because it was not applicable due to the pulse oximeter being taken out of the kit.

Scenario 2: During delivery and there is presence of danger sign				
Question:	Yes	No	% Yes	% No
1: The provider assembles the equipment correctly.	24	1	0.96	0.04
2: The provider launches the app to begin.	23	2	0.92	0.08
3: The provider registers the patient.	24	1	0.96	0.04
4: The provider records demographic information correctly	23	2	0.92	0.08
5: The provider selects the option for during delivery.	23	2	0.92	0.08
6: The provider is able to select the number of months of gestation your patient has.	21	4	0.84	0.16
7: The provider is able to recognize the prenatal check-up visit and press on the correct image.	23	2	0.92	0.08
8: The provider evaluates the size of the mother's belly and presses on the correct image.	19	6	0.76	0.24
9: The provider is able to recognize the danger signal of delivery (prolonged labor).	21	4	0.84	0.16

10: The provider acknowledges the danger signal by pressing the correct button.	21	4	0.84	0.16
11:The provider correctly places the blood pressure equipment in the indicated arm.	24	1	0.96	0.04
12: The provider turns on the blood pressure monitor and takes the blood pressure measurement without difficulty.	25	0	1	0
13: The provider verifies the values displayed on the blood pressure monitor screen and takes the picture with the image of the result.	25	0	1	0
19:The provider notes the presence of a complication and steps taken.	20	5	0.8	0.2
19: The provider can describe the correct triage protocol for their facility.	23	2	0.92	0.08
20: The provider manages to closes the application.	23	2	0.92	0.08
Total (out of 400)	362	38	0.905	0.095

Question 14 (The provider is able to connect the speaker to the Doppler and turns on the speaker and Doppler.), Question 15 (The provider uses lubricant or transducer gel to listen to the baby's heart), Question 16 (The provider locates the fetal heartbeat, places the girdle, adjusts it to Doppler to begin recording the heartbeat), and Question 17 (The provider manages to press on the green button and record the sounds of the fetus's heart without much difficulty) were omitted.

Scenario 3: Postnatal Care				
Question:	Yes	No	% Yes	% No
1: Provider assembles equipment, turns on devices, and launches app.	25	0	1	0
2: The provider presses on the correct image for a post-natal care visit.	24	1	0.96	0.04
3: The provider manages to press on the image of the patient they have already registered.	24	1	0.96	0.04
4: The provider, when viewing the green and red buttons, understands and interprets and performs the instruction.	20	5	0.8	0.2
5: The provider is able to recognize the postnatal check-up visit and presses on the correct image.	23	2	0.92	0.08
6: The provider presses on the image of the green arrow in the boxes and asks about the warning signs of the newborn.	23	2	0.92	0.08

7: The provider recognizes the danger sign in the newborn and presses the correct button.	18	7	0.72	0.28
8: The provider continues the application after detecting danger signs.	23	2	0.92	0.08
9: The provider correctly describes the triage protocol for a newborn for their facility.	20	5	0.8	0.2
10: The provider is able to close the application and save the equipment correctly.	23	2	0.92	0.08
Total (out of 250)	223	27	0.892	0.108

Appendix C: Full Semi-Structured Interview Instrument

Safe+Natal Sierra Leone + Emory Team Member Interviews

Name:

Date & Time:

Ask if it is okay to record.

Introduce self and project for context:
My honors thesis will focus on the challenges and realities faced in the implementation of Safe+Natal using data from the Sierra Leone pilot study. This information will help inform future Safe+Natal pilot studies, as well as other global health interventions as well, on how co-design can be utilized and improved upon. Your interview data will be used to gather first-hand data on the difficulties

1. Tell me about your role in the Safe+Natal project.
    a. Prompts: What do you do day-to-day for the project? Who do you communicate/Interact with (both in SL and at Emory)? Do you work with the nurses or patients at all?

2. Walk me through the co-design process for this study.
    a.

3. Have you ever been involved in a similar project or study (global health/maternal health implementation)?
    a. How has this study differed or been similar?

4. What were your expectations going into this study?
    a. Have they been met, exceeded, or not met? Please elaborate.
    b. Have they changed since the beginning of the project?

5. What has gone well for you during this process?
    a. Prompts: What has been fun or enjoyable about the process of getting safe+natal ready for Sierra Leone?
    b. Has anything been easier than expected or gone particularly smoothly? Are there any big goals that you have already achieved?

6. What challenges have you faced?
    a. How have you addressed these challenges/overcome them?
    b. What could be better about the co-design process?

    c. What could be better about the pilot study?

7. What are your goals or expectations going forward?
    a. Prompts: What can safe+natal do for maternal care in Sierra Leone?

Appendix **D**: Qualitative Data Codebook Outline

1. Communication - Definition: Communication within and between the Emory and Sierra Leone teams; specific concerns over how communication flow was facilitated or blocked and any miscommunications that hindered progress as well as how those challenges were overcome.
    a. Facilitating Communication
    b. Miscommunications
    c. Communication flow
2. Design - Definition: Any internal (communication within and between teams, responsibilities, etc.) or external (weather, political climate, logistics, etc.) factors that impacted and slowed progress of the pilot as well as potential consequences of the delays.
    a. Workflow
    b. Iterative → Cycling through app design
3. Logistics - Definition: The process, details, and coordination of the pilot study in Sierra Leone based on using and developing the technology, how safe+natal would integrate into the current healthcare system/flow, and the available personnel & resources.
    a. Technology
    b. Workflow
    c. Supply chain
4. Delays - Definition: Any internal (communication within and between teams, responsibilities, etc.) or external (weather, political climate, logistics, etc.) factors that impacted and slowed progress of the pilot as well as potential consequences of the delays.
    a. Workflow
    b. External
        i. Location Accessibility
        ii. Remote Communication
        iii. Political and Bureaucratic
5. Training - Definition: The process of training of midwives and nurses in Sierra Leone to use the safe+natal kit; any challenges including difficulties and errors in using the technology; benefits and possible opportunities for safe+natal in Sierra Leone.
6. Motivation - Definition: What motivates the team members to work on the safe+natal pilot; how this motivation has driven the pilot and the future of maternal health in Sierra Leone; any concerns over lost motivation or engagement.
    a. Helping people
    b. Work
    c. Learning
7. Safe+natal SL Team building - Definition: Working with and building connections with team members across different states, countries, and continents; challenges in working remotely from the implementation site; positive aspects of building connection.
    a. Remote
    b. Roles
    c. Learning
    d. Commitment/fun!

Appendix E: Safe+natal App Interface Images

Figure 7: Menu to select in which country the health provider visit is occurring.

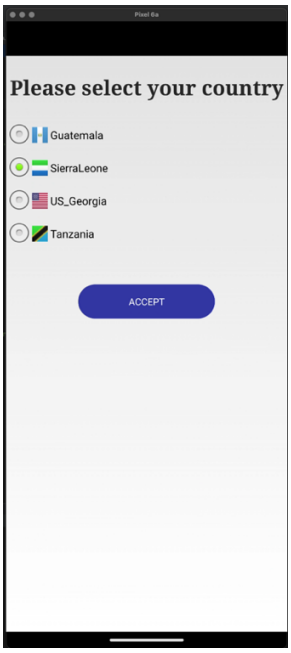


Figure 8: Menu to select patient for visit.

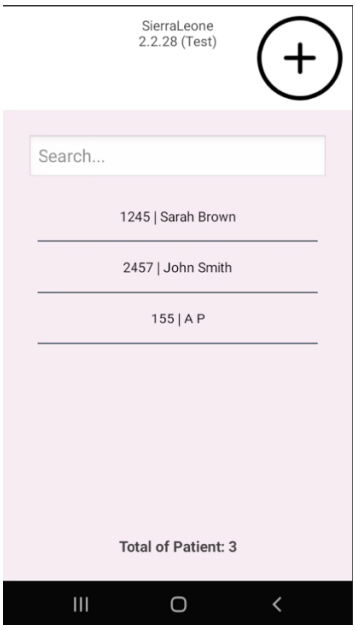
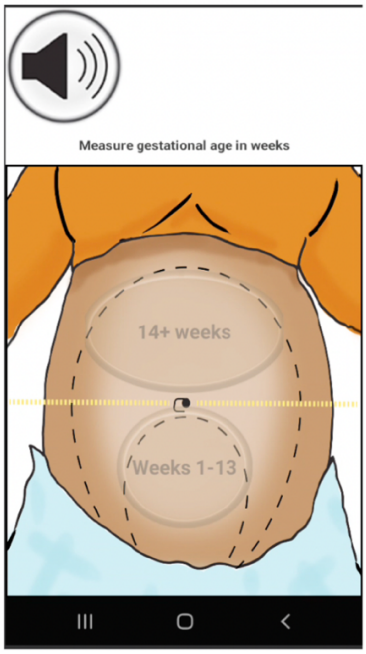


Figure 9: Screen to record presence of danger signs.

Figure 10: Directions to measure gestational age of the fetus.


Measure gestational age in weeks
14+ weeks
Weeks 1-13