Portable Antenatal Ultrasound Platform for Village Midwives

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ABSTRACT

Ultrasound imaging is an effective tool for identifying maternal mortality risk factors. Unfortunately, ultrasound is nearly absent in many rural healthcare facilities in developing regions due to the high costs of both equipment and required training. To leverage existing healthcare systems commonly found in these contexts, we have focused our efforts on increasing the diagnostic capabilities of midwives – often central medical figures in rural and low-income communities. We have designed and built a low-cost portable ultrasound device consisting of a USB ultrasound probe and a touchscreen netbook for a total cost of around USD3500. Compared to currently available ultrasound devices, we simplified the user interface while maintaining functionality to allow midwives to detect three common obstetrical conditions: placenta previa, multiple gestations, and breech presentation. To evaluate our solution, we tested the accuracy of ultrasound measurements, image quality, and whether midwives could use ultrasound. Testing performed by nine clinicians indicated our device would be appropriate for identifying the three conditions. Our modular design approach allows for easy modification, and the device is designed to utilize existing local healthcare resources in order to create a sustainable solution that does not depend on continuous foreign assistance.

Categories and Subject Descriptors

H.5.m [**Information Interfaces and Presentation (e.g., HCI)**]: Miscellaneous

General Terms

Design, Human Factors, Human-Computer Interaction

Keywords

Maternal mortality, ICTD, ultrasound, medical device design, midwives, HCI, mobile diagnostic devices

1. INTRODUCTION

Maternal mortality rates in the developing world are unacceptably high. World Health Organization (WHO) estimates for 2008 indicate that women in developing regions had an estimated 1 in 120 chance of maternal death in their lifetime, compared to 1 in 4300 for developed regions [34]. Many of these deaths are preventable if potential pregnancy complications are detected early, allowing mothers to seek proper medical care at appropriate facilities. Women in developing regions of sub-Saharan Africa have an estimated lifetime maternal death risk of 1 in 31. In Chad and Somalia, the estimated maternal death risk is even higher with 1 in 14 women dying from a maternal complication, in contrast with Greece where this rate is 1 in 31,800 [34]. We aim to lower maternal mortality in developing regions by designing a portable ultrasound system that indigenous midwives can use to diagnose potential complications and subsequently refer women with high risk conditions to appropriate medical facilities for delivery.

Ultrasound is a common imaging modality for obstetrical (OB) evaluation and has proven an effective and safe means of identifying some of the most prevalent maternal and neonatal mortality risk factors [20]. In decades of use, diagnostic ultrasound has not been shown to cause adverse health affects which makes it ideal for widespread deployment [25]. We seek to enable midwives with limited ultrasound training to quickly learn to operate ultrasound equipment and to effectively diagnose high risk obstetrical conditions such as multiple gestations, breech presentation, and placenta previa. These three conditions are difficult to diagnose accurately with typical exams lacking in the use of ultrasound. A simple and portable device will enable midwives to diagnose potential problems in rural clinics or in a patient's home. If mothers have knowledge of potential complications prior to birth, they will be empowered to make educated choices about where they deliver their baby instead of discovering these conditions at the time of birth when changing plans is most difficult and time-sensitive. It is often challenging for women to travel to distant healthcare facilities to receive ultrasound examinations as travel can be prohibitively expensive.

By focusing on the needs and behaviors of midwives and patients, we believe low-cost portable ultrasound will increase the effectiveness of and demand for antenatal care in rural health centers thereby improving the use of limited medical resources through more accurate referrals.

While manufacturers have expanded their product lines to include portable and less expensive ultrasound machines, such equipment is scarce in rural developing regions. Some may argue that slow adoption is due only to equipment costs; however, we argue that in addition to price, the complexity of the user interface is also a problem. To increase ultrasound adoption rates in developing regions we postulate that a redesign is needed that focuses on three goals: streamlining functionality, simplifying the UI, and reducing the cost of this diagnostic tool. Our project dismisses the idea that more technical functionality is necessarily better, and instead simplifies the ultrasound device in order to reduce training costs. Additionally, we minimize system price by applying a modular design approach that uses off-the-shelf components including a USB ultrasound probe and a commodity netbook computer. By reducing the cost of these two components, sensor and computer, we aim to increase the use of ultrasound for antenatal evaluation in the developing world.

2. RELATED WORK

The domain of portable ultrasound is being explored by a variety of projects in developing regions. Many manufacturers, including SonoSite, GE, Siemens, and Philips are making portable ultrasound machines with costs ranging between $20,000-$75,000. Of these full featured ultrasound machines, GE's LOGIQ Book XP is the cheapest costing around $20,000. Additionally, a new class of mobile ultrasounds machines are emerging (e.g. GE's VScan, Siemens P10) that cost between $7000-$9000. However, these small devices only have a 3-inch screen size (sub-optimal for performing obstetrical diagnostics), a battery life of only 1-2 hours, and no network connectivity. SonoSite's NanoMaxx ($16,000) has a reasonable screen size, but a battery life of only 2 hours, no network connectivity, and currently lacks measurement capabilities that are essential for dating fetuses.

The USB ultrasound probe used in our platform is a commercialization of Richard et al's previous work with USB ultrasound probes [26]. This research featured 5MHz, 7.5MHz, and 12.5MHz ultrasound probes with suggested uses in ophthalmic, rectal, vaginal, and veterinary applications. The paper did not explore pregnancy applications beyond viewing yolk sacs very early in the first trimester with an endovaginal probe. Although an endovaginal probe can be used in the first trimester to identify potential complications, its lack of depth penetration limits use later in pregnancy. Obstetrical evaluations require a lower frequency transabdominal probe (3.5MHz) to enable deeper penetration of the larger second and third trimester uterus. Additionally, researchers at Washington University in St. Louis have connected the USB ultrasound probe to a Windows mobile phone [21]. However, it's not clear that doing obstetrical ultrasound on a smart phone is desirable because of limited screen space, limited processing (~3 frames per second), and limited battery/power. Companies like Laborie [19] and Direct Medical Systems [4] market USB transducers with custom software; however, these packages are not designed for users with minimal ultrasound training.

Imaging the World has a goal to create portable and cheap ultrasound systems for the developing world; however, they rely on remote radiologists volunteering their time to diagnose conditions [14]. We believe that midwives should be viewed as more than just ultrasound operators because with training they can diagnose basic conditions accurately. Using local healthcare workers reduces the dependence on external or foreign assistance.

A portable ultrasound machine (SonoSite Titan) was introduced to the Lugufu refugee camp in the Kigoma District, Tanzania, to assess the feasibility of ultrasound in a low-resource setting. Over a four-day period a group of four physicians and six clinical officers were intensively trained to use ultrasound for a variety of conditions including: trauma, renal ultrasound, pregnancy evaluation, echocardiography, ultrasound guided procedures, etc. Over a two-year deployment period the medical staff in the camp performed 547 ultrasound scans on 460 patients. The results showed that ultrasound was useful for female pelvic and obstetrical issues as 46% of the scans were of the female pelvis including half of these directly related to pregnancies [1]. This work demonstrates that ultrasound can be useful in a rural developing world setting; however, it does not address how successful health workers with abbreviated ultrasound training, such as midwives, would be in using a relatively complex ultrasound system.

Partners in Health deployed portable ultrasound machines (SonoSite MicroMaxx) at two hospitals in Eastern Province, Rwanda. Interested physicians took a nine-week training program and afterwards conducted 245 ultrasound scans over 11 weeks, of which 169 were females and 44% were pregnant. At one of the hospitals the sonographers' images were independently evaluated to verify ultrasound interpretation. There was a 97% agreement between the Rwandese physicians' diagnosis and an ultrasound-trained physician who was blinded to the local diagnosis. Additionally, 43% of all patients scanned had their patient management plan changed based on the scans [27]. This demonstrates that ultrasound can be an effective healthcare tool in the developing world. However, this work focused on training physicians and not other healthcare workers such as midwives. Another study in Ghana used a portable ultrasound machine (GE LOGIQ Book XP) to demonstrate it could enhance patient care. The study consisted of a two-week period during which a radiologist transported a portable ultrasound machine to four locations: a rural clinic, an urban clinic, and two hospitals [28]. The paper discusses the usefulness of ultrasound but leaves incorporating ultrasound into the medical practices of developing countries as a challenge. Another study of a remote clinic in Mexico discussed the results of cardiologists using a hand-carried cardiac ultrasound device (Philips OptiGo) for a week to diagnose 90% (113 out of 126) of the patients, thereby making conventional echocardiography unnecessary [18]. This work showed that ultrasound can be an important diagnostic tool in reducing the number of referrals to higher-end facilities; as with the other work described above, the device was operated by cardiologists, not a health worker with abbreviated training. Additionally, researchers in South Africa showed that ultrasound scans reduced the number of referrals to a regional center by studying 3009 women in an economically disadvantaged urban area who sought antenatal care at two Midwife Obstetric Units [10]. While this work was done in an urban setting, the fact that ultrasound improved accuracy of referrals shows that our approach is viable.

3. BACKGROUND

As the previous section makes clear, the use of ultrasound technology has the potential to help reduce maternal death rates in rural developing regions; however, because of limited numbers of highly trained medical personnel and high ultrasound prices it is not widely used. Most maternal and neonatal deaths occur during labor, delivery, and immediately postpartum, so care should focus on the intrapartum (labor and delivery) period [7]. However, pregnant women in developing countries frequently give birth at home, limiting their ability to receive adequate obstetrical care if needed. For this work, we initially focus on Uganda where 58% of deliveries occur at home [33] and an estimated 6,300 women die each year from maternal-related complications [34]. The Ugandan government supports using portable ultrasound units to help combat maternal mortality [17] and has agreed to the UN Millennium Development Goals to reduce maternal mortality rates by three-quarters between 1990 and 2015 [23]. Overall, it is estimated that only 5% of all births in Uganda occur in facilities with emergency obstetrical care [23]; the expected percentage is at least 15% [30]. Similarly, Caesarean sections should account for between 5% to 15% of all expected births in a typical population [30], but in Uganda only 1% of births are Caesarean deliveries [23], possibly indicating that pregnancy conditions are not being properly detected in time to take precautions. Our work targets rural areas, where 89% of births in Uganda occur, and only 37% of those births are attended by a skilled birth attendant [33].

Our goal is to improve pregnancy outcomes by enabling midwives to detect potentially dangerous conditions well before a woman goes into labor and thus refer high risk pregnancies to clinic settings equipped with appropriate medical equipment and staffed by medical professionals. While the platform we have developed aims to diagnose conditions that can be resolved at healthcare facilities, some mothers may be unable to afford giving birth in these facilities. This work does not address problems associated with providing affordable treatment; we instead focus on improving the accuracy of the referral process so that limited available medical resources can be applied effectively by correctly identifying women who need hospital-level medical attention.

Referrals for hospital level medical attention are often necessary because midwives in Uganda have a wide range of skills and may be able to diagnose pregnancy complications, but do not treat them directly. The term "midwife" can be applied to women coming from very different educational backgrounds and training levels. For example, Registered Midwives spend at least 52 weeks training in Midwifery, whereas an Enrolled Comprehensive Nurse may spend only 7-8 weeks training in Midwifery. Both programs are considered Midwifery programs, but the training emphasis and length is drastically different between the two. What all midwife training programs have in common, however, is that training in using ultrasound is mostly negligible or non-existent [22].

Our work centers on a device that will allow midwives of all training levels to detect multiple gestations, breech presentation, and placenta previa in order to make simple referral decisions. Multiple gestations often result in premature birth and complicated deliveries, and ultrasound is vital in verifying the presence of more than one fetus [6]. Ultrasound also makes it possible to determine the orientation of the fetus [12], enabling detection of breech presentation. In these cases, the risk of neonatal mortality doubles for vaginal delivery as opposed to Caesarean section [8]. Another complication, placenta previa, is a condition in which the placenta partially or completely covers the cervix and can cause severe hemorrhaging at birth. There are clinical risk factors that make placenta previa more likely, but only ultrasound can provide placental localization in order to confirm the presence of this complication [5]. By providing improved diagnostic services, ultrasound exams may encourage women to be more proactive about seeking the recommended four antenatal care visits.

It is important to note that complications caused by these conditions can be reduced if they are detected with obstetrical ultrasound earlier in pregnancy, before the onset of labor, allowing mothers to make informed decisions about delivery location. As the first stage of this project, the University of Washington's Radiology department conducted an informal survey with seven Ugandan obstetrician opinion leaders regarding anticipated survival rates based upon delivery location and whether the mother suffered from any of these three conditions. The survey found that the obstetricians estimated substantial increases in survival rates if pregnant women exhibiting these conditions delivered in a health care facility, estimating on average that survival rates in a hospital (as opposed to a rural village) would increase from 43% to 97% for breech presentation, from 51% to 94% for multiple gestations, and from 17% to 86% for placenta previa [Personal communication: Babagamura J. and Nathan, R., Survey of Ugandan obstetric opinion makers on maternal mortality risk. 2009]. Based on these findings, the University of Washington started a collaboration with the Ernest Cook Ultrasound Research and Education Institute (ECUREI) in a pilot program to study the effects of midwife usage of ultrasound. Initially, the study planned to use 9 donated GE LOGIQ Book XP portable ultrasound units; however, midwife training became a challenge, partly because midwives found the LOGIQ Book difficult to use. As a result, we turned our efforts to addressing the need for either more time devoted to training or a simpler interface that would allow for a shorter training period. Consequently, our prototype eliminates advanced features not necessary for basic obstetrical diagnoses with the goal of reducing the time necessary to acquire the skills to conduct an effective and accurate ultrasound exam.

4. ULTRASOUND PLATFORM

Ultrasound technology has the ability to detect a plethora of medical conditions; therefore, most portable ultrasound manufacturers assume that full functionality is necessary for the device to be effective and marketable – a reasonable assumption in the more industrialized nations. However, creating a generic ultrasound solution that will work for a wide variety of situations, cost constraints, user skill levels, and scalability needs is challenging. In a resource-constrained environment it is somewhat unreasonable to expect users to adapt to a highly complex pre-existing device that does not meet their primary needs. Factors such as ease of use, portability, replacement costs, and durability are important and may dominate purchasing decisions. The variety of requirements makes it difficult to build one system to adequately cover under-served populations of the developing world; thus, our focus is on making a platform that can be targeted to the specific needs of different medical programs.

To achieve this goal, we created a platform consisting of three separate modules: the ultrasound hardware and processing software, the application's UI, and the computing device. This modular design is uncommon as most ultrasound vendors sell proprietary hardware as an all-in-one unit that does not allow for customization. An important advantage of the modular approach is that it allows UI designers to focus on a highly specific set of tasks, permitting the elimination of confusing options and controls. In this way, separate customized interfaces can easily be created to support a wide variety of specific ultrasound use cases. By allowing the components to be used interchangeably via well-documented APIs, this platform approach will help to drive down the cost by making it easier for designers to focus on their area of expertise. For example, ultrasound manufacturers can limit their costs by focusing on producing proprietary transducers and take advantage of the various open source UIs available.

We envision a platform enabling medical organizations to choose their ultrasound vendor based on their requirements separately from choosing the computing hardware that will host that transducer. Separate modules for the UI, ultrasound transducer, and computing device also allow for faster design iterations and make it easier to replace probes as they become obsolete since the interface can remain the same as the technology improves. If part of the UI is inadequate, it can be easily modified and/or replaced to suit the organization's needs without having to buy an entirely new ultrasound machine (e.g., switching electronic medical record systems, adding a new measurement feature). The modular design approach allows organizations to adjust their platform costs based on their requirements. For example, a netbook might be durable enough for a clinic setting but a ruggedized laptop may be required for driving on rough roads in remote areas.

4.1 Design Considerations

To inform our design choices, we conducted research involving ultrasound technologists, instructors, radiologists, and Ugandan midwives who helped us develop an OB exam workflow that would allow people with limited training to acquire and optimize ultrasound images. The interface of the LOGIQ Book (used in the midwife ultrasound pilot program) shown in Figure 1 is complex because it is designed to support many advanced features for different types of ultrasound exams. Complexities include over 40 additional buttons (not including the keyboard), the variety of input interface types (e.g. parallel sliders, dials, buttons, and the keyboard), and difficulties in transitioning between the digital exam record and specific exam tasks.

To better understand what functionality was either useful or difficult to use, we sent paper surveys with 14 questions to Ugandan midwives participating in the ECUREI ultrasound training program. All six of the midwives who responded stated that Time Gain Control (TGC), which allows the user to adjust the gain along many different bands, was the single most challenging feature to understand and use. Additionally, four out of six midwives reported that measuring fetal anatomical structures was also difficult. Other elements of the LOGIQ Book that midwives reported to be difficult were M-Mode imaging (for monitoring fetal heartbeat using a single ultrasonic beam), color Doppler (a method of imaging using the Doppler effect to show the direction

Figure 1. The pilot training program in Uganda is currently using GE LOGIQ Book ultrasound machines, which have a complex multi-purpose interface.

of blood flow with directions being represented by colors), and the small keyboard. We also sent e-mail correspondences containing four questions regarding device-specific training issues to two ECUREI instructors. One of the instructors responded that midwives overwhelmingly found editing the OB report and saving and retrieving images to be difficult. Another instructor corroborated that TGC was difficult to teach to the midwives due to the nature of the TGC interface itself – a row of six parallel sliders. We decided that several features requiring advanced training (including TGC, color Doppler, and M-Mode imaging) were diagnostically unnecessary.

To make a solution more sustainable in light of the high cost of training, a device should be both a learning and diagnostic tool. We feel it is important to include an embedded contextual help system that will allow midwives to compare their images with those of professional ultrasound technologists, to learn ways to increase the quality of their scans, and to have easily accessible information about a variety of antenatal conditions for reference. Moreover, village midwives are more likely to be occasional users of the system and will most likely require refreshers much more often than full-time ultrasound professionals.

The LOGIQ Book lacks a contextual help system and instead provides help content within a web browser that is external to the flow of exam tasks. A robust help system, that includes video content and a variety of scaffolding options for users of different levels, can offer midwives more control over their own learning and reduce dependence on costly training programs. Additionally, the features included to support the process of image annotation allow midwives to easily and clearly communicate potential questions to others who may have more experience with ultrasound, providing midwives the opportunity to leverage the diagnostic abilities of their co-workers, supervisors, and other medical professionals.

Other important considerations are image size and a digitized exam review auto-populated with fetal measurements. An image of insufficient size is not diagnostically useful; however, choosing an appropriate screen size becomes a trade-off between portability and diagnostic effectiveness. A device that is both portable and diagnostically useful will allow midwives to perform ultrasound exams in the home instead of a healthcare facility. A digitized exam review form supports recording medical information that can help determine whether or not a woman should be referred to a hospital for birth. These measurements can also provide information about fetal growth, well-being, and gestational age. Knowledge of gestational age is critical for mothers with pregnancy complications wishing to give birth in a hospital. Especially in resource-constrained environments, where visits to referral hospitals must be planned well in advance, knowing the approximate delivery date can greatly influence the outcome of the pregnancy.

Lastly, in order for a solution to be truly sustainable it must be cost-effective. The cost of introducing ultrasound is determined by both the cost of the device itself and the cost of training required to use it successfully. By using off-the-shelf components that support fewer features, we can reduce the cost and maintenance of the device by avoiding complex all-in-one systems. In the United States, a typical ultrasound technician undergoes training for two years or more [31] which would be prohibitively expensive for Ugandan midwives. By simplifying the functionality and streamlining the workflow we can reduce the time required to learn how to use the device, thereby reducing the cost of training.

4.2 Initial Implementation

Our design priorities for the prototype implementation included adequate image quality, simplicity, low cost, portability, and creating a learning tool. Simplicity is achieved by including only essential image optimization controls, minimizing the number of components needing to be carried and powered, and streamlining the exam and data collection process. To keep costs low the platform uses the Interson SeeMore USB Ultrasound Imaging Probe [15] attached to a netbook, as shown in Figure 2. The SeeMore probe is a 3.5 MHz abdominal probe with a focus depth of 7.5 cm, making it an appropriate choice for obstetric scanning [24]. The transducer comes with an SDK for processing images. This probe has been cleared for use by the US Food & Drug Administration, has a CE mark in the European Union, and has a medical device license from Health Canada. Currently, the unit cost for a complete platform is about $3500; however, researchers at Washington University in St. Louis are working with Microsoft Research with a goal to reduce the cost of the ultrasound probe to a few hundred dollars [21]. If the price of the probe was reduced substantially it would bring down the overall platform cost to less than $1000 as the probe is the dominant cost.

To maximize portability we chose the Lenovo IdeaPad S10-3t netbook (11.5" by 8.3" by 1.2" and weighing 3.2lbs) with a 10-hour extended battery, allowing several ultrasound exams to be performed when electricity is unavailable. The GE LOGIQ Book is also portable, but almost three times the weight of ours (9.2 lb) with less battery life (4-hours). In order to provide an image size that is diagnostically useful we chose a 10" touchscreen, balancing the opposing criteria of portability and ultrasound image size. Since one hand is already dedicated to holding the ultrasound probe, the other hand can make use of the touchscreen, touch pad, or mouse to optimize the image. A variety of commodity solutions are available for charging netbooks (e.g. car

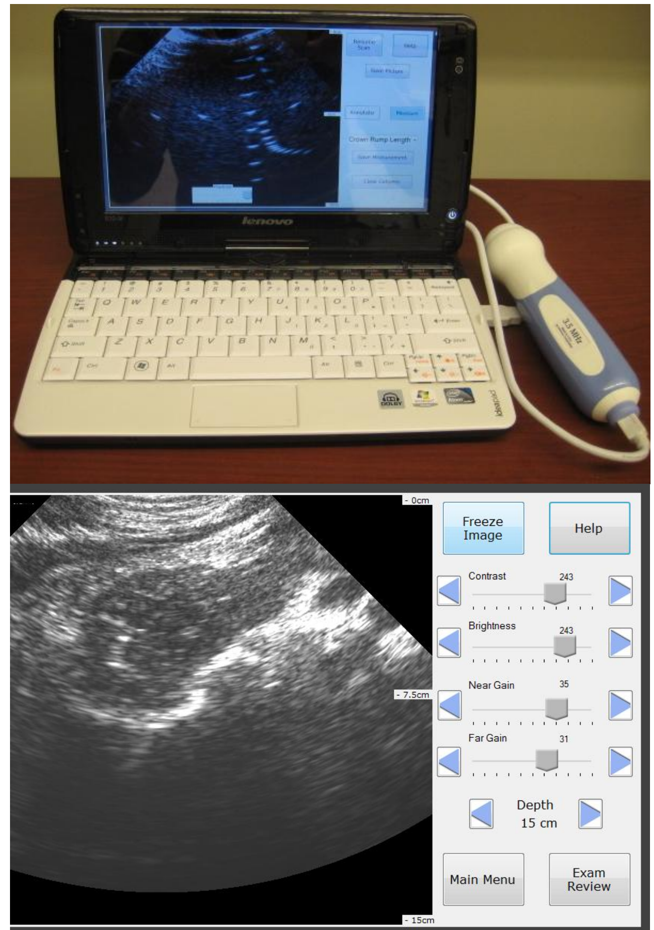

Figure 2. Prototype platform consisting of USB probe and netbook (above). Ultrasound scanning screen of the prototype simplified UI (below).

battery chargers, solar chargers, etc.) allowing the power solutions to be customized to an organization's deployment context. To provide connectivity to healthcare facilities, midwives can use a GPRS modem (USB external or internal) to transmit images, data, or send referral information, taking advantage of the established cellular infrastructure in Uganda to quickly deliver information.

The custom, open source UI is designed to allow midwives to easily obtain quality scans, know where they are in the task flow of an OB exam, and populate digital medical records as automatically as possible. By adhering to typical OB exam protocols, the design accommodates users who have performed very few ultrasound exams and shifts the cognitive burden of remembering exam components from the user to the software. By conducting observations of ultrasound exams, we discovered several controls that seemed to be frequently accessed. Our qualitative analysis of which features to include was corroborated by examining existing ultrasound platforms, all of which incorporated these controls. To remove TGC while still maintaining the ability for midwives to optimize ultrasound images, the active scanning interface shown in Figure 2 minimizes image controls by only including near gain, far gain, brightness, contrast, and depth. Near and far gain adjust the amplification of the received echoes at near and far depth, respectively. Depth adjustment controls the maximum depth penetration of the probe which can be adjusted to either 10cm, 15cm, or 20cm. Compare our scanning UI to the UI of the GE LOGIQ book seen in Figure 1. Notice that while there are over 50 physical controls (over 40 buttons plus sliders, scroll wheel, etc.), not including the keyboard, with which the user can interact on the main scanning screen of the LOGIQ book, our main scanning screen contains only nine, three of which are related to menu functions. All text displayed to the user is loaded from XML files, allowing organizations to customize instructions or language without modifying code.

The UI provides the user the ability to freeze the ultrasound image during active scanning to allow the user to measure a fetal anatomical structure. However, freezing the image at the desired moment can be challenging so cine buffering, the ability to do playback, was added to allow users to select up to 20 previous image frames. The frozen image screen includes predefined measurement options to allow midwives to measure fetal anatomical structures (e.g. femur length) and have the value automatically recorded in a digital exam record. Pointers and text annotations are also included to enable midwives to annotate images allowing effective communication of information among midwives as they consult with each other. GPRS/Internet connectivity also allows midwives to pose questions to radiologists anywhere in the world, although ideally we envision a scenario where midwives are medically autonomous.

In order to encourage medical autonomy and increase sustainability, we gathered information from ultrasound instructors and technologists to create a contextual help system for obstetrical ultrasound exams. The help system answers common questions and presents example images of anatomical structures and ultrasound scans of varying quality for reference. The sample images chosen will allow midwives to compare their scans to typical professional scans, and the associated documentation will help them increase the quality of their images. The help section opens in a separate panel allowing the user to view the help screen while actively conducting an exam.

4.3 Evaluation

To evaluate our system, we examined 1) the power and speed of our hardware selection, 2) the quality of images obtained, 3) the accuracy of measurements, and 4) whether Seattle-area midwives were able to use our system to perform tasks similar to those we envision supporting in the field.

4.3.1 Hardware Evaluation

According to the WHO guidelines for ultrasound images, a frame rate of 5-10 frames/sec is sufficient for imaging [32]. Testing of the initial implementation showed a frame rate ~13 frames/sec which is sufficient for diagnosing the three conditions of interest. Since we are currently using slightly older transducer technology, the high frame rate of a phased array transducer (these require 10-15 frames per second [32]) is unnecessary. Based on the feedback from radiologists, a higher frame rate, while not required, might make scanning easier for an operator by allowing them to more easily spot complications. The frame rate is processor-bound as the program consumes 45% of the CPU. Experiments on a more capable Windows desktop produced a 4x improvement in frame rates. Extending Moore's Law we would expect technology trends to allow a portable computing device to achieve faster frame rates in the near future. Additionally, modifying the SDK to be independent of the Windows API will improve modularity and potentially allow for higher frame rates by using a more resource efficient OS.

Battery life tests showed that the netbook lasted for ~5 hours with the ultrasound probe acquiring images and with an active LCD monitor. According to a sonographer, detecting the 3 target conditions should take less than 5 minutes for a highly trained ultrasound sonographer; therefore, we estimate a midwife will take 15 minutes to complete an exam. Given our ~5 hours of battery life we expect that a midwife could complete 20 exams on a single charge which should be sufficient if she is going from home to home within a local community. While clinics may have access to power, the 5 hours of exam time on the battery should allow the clinic to operate even if the power becomes temporarily unavailable.

4.3.2 Image Quality

To obtain preliminary feedback on image quality we scanned the liver, a common organ for evaluating ultrasound depths. We used the liver of a heavy-set adult male with a history of cancer that spread to his liver. We obtained images using our prototype ultrasound device and a standard ultrasound machine from a hospital radiology department to perform a baseline comparison (shown in Figure 3). The images obtained with our prototype ultrasound system were at depths of 10cm, 15cm, and 20cm, while images obtained for baseline with the high-end ultrasound had depths of 14cm and 18cm. In both cases, the far side of the liver was viewable at approximately 17cm.

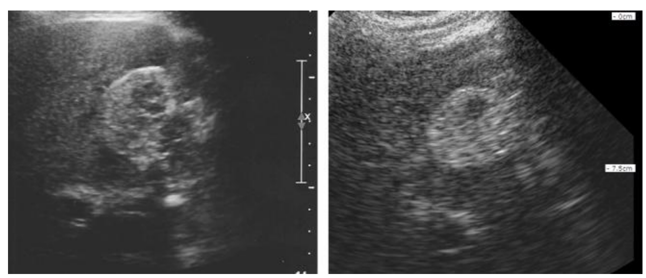

Figure 3. Image of liver obtained using standard ultrasound machine in hospital radiology departments (14cm) (left) and using our prototype (15cm) (right).

We asked nine local ultrasound clinicians (including five MDs in radiology with over 10+ years experience from two different hospitals) to evaluate our prototype. The clinicians were all given the chance to use the system in person and provide feedback. The five radiology MDs were sent a follow up survey via email including the two images of the liver shown above in Figure 3. All five were able to identify liver anomalies in the images obtained with our prototype system. We then asked, based on the quality of the liver images obtained using the prototype system, whether it would be possible to diagnose: multiple gestations, breech presentation, and placenta previa. The radiology MDs indicated that diagnosis of breech presentation was likely (5 out of 5) and multiple gestations was likely (4 out of 5) or plausible (1 out of 5). Results for diagnosis of placenta previa ranged from likely (2 out of 5), and plausible (1 out of 5), to not likely (2 out of 5). Placenta previa can be difficult to diagnose in general; however, using an endovaginal probe would allow technologists an alternative method of detecting previa. Since midwives are only triaging conditions, if the placenta cannot be found near the opening of the vagina then previa can be ruled out. Overall, clinicians indicated that it was likely that our prototype device would provide a high enough quality image to allow diagnosis of the three conditions of interest. In the process of testing our prototype ultrasound platform, a sonographer noticed a previously unknown kidney cyst on a member of our research team. Figure 4 below shows an image obtained from a 17 week fetal phantom using our system. We have now obtained Human Subjects approval to test our prototype on pregnant women, which will be the next step in our evaluation and design iterations.

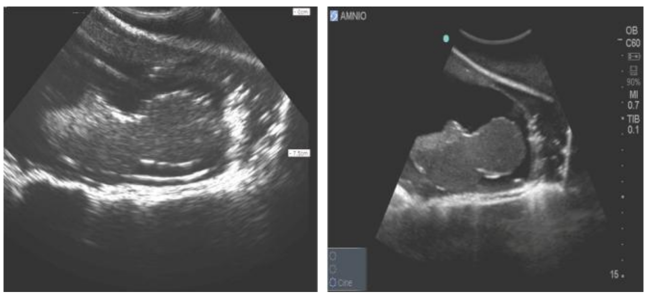

Figure 4. Image of 17 week fetal phantom obtained using our prototype (15cm) (left) and using SonoSite M turbo ultrasound machine (15cm) (right).

4.3.3 Measurement Accuracy

Biometrics are used as a measurement of fetal development, and accurate biometrics are important in determining the health of the fetus. For example, femur length of the fetus is often a parameter used to determine gestational age, which is useful for determining when birth will occur. To determine the accuracy of our measurements, we calibrated our software's measurements against known distances using an ultrasound phantom – a training device meant to simulate human tissue which is used widely in ultrasound training programs. Obtaining an accurate delivery date estimate is important when in an environment with constrained resources and where travel may be difficult and costly.

For this component of the study, we recruited fourteen participants (12 women, 2 men; lab techs, administrative assistants, medical and grad students) from a local medical school cafeteria to interact with our prototype and a training phantom. The study site was chosen for convenience and for ease of attracting people interested in helping with a medical technology project. Participants used an external mouse, the touch pad provided with the laptop, and the touchscreen monitor to measure specific distances on the training phantom. The training phantom has markers spaced 10 mm apart. Participants were asked to measure distances of 30, 50, and 70 mm using our system's software calipers. Distances were chosen to mimic expected lengths of fetal femurs at 19-36 weeks. Participants took three measurements for each distance, before switching to another input device and repeating the process. The order of input device use was randomized among participants and all measurements were timed. Participants performed the measurement study and then completed a brief survey about their computer use and which input device they preferred.

Participants ranged in age from approximately 25-55 years of age and all were moderate (16-30 hours per week) or heavy (31 or more hours per week) computer users. Most participants never (5 out of 14) or rarely (6 out of 14) used a touch screen with their finger. Most sometimes (2 out of 14) or very often (11 out of 14) used a touch pad, and sometimes (3 out of 14) or very often (9 out of 14) used a mouse. Participants judged the touch screen as very hard (4 out of 14) or moderately hard (6 out of 14) to use. The touch pad was seen as moderately easy to use (6 out of 14) or very easy to use (5 out of 14). The mouse was overall picked as the easiest to use with respondents reporting it moderately easy to use (2 out of 14) and very easy to use (12 out of 14).

In total, 9 out of 378 measurements were discarded due to participants deviating from exam instructions. For example: tick marks are present every 10 mm to assist in measurement, and some participants were approximately 10 mm off of their target distance. Given this, it is reasonable to assume that this measurement is erroneous and so it was discarded.

The mean percent errors of the measurements were 2.95%, 1.77%, and 1.95% for using the touch screen, touch pad, and mouse, respectively. We compared this to the commercial systems described in Gamba et al. [9], in particular the Advanced Technology Labs Imager 860, which had a mean percent difference of 3.32%, and concluded the measurement errors were within an acceptable range.

Users were much faster when using the mouse. On average, participants required 8104 ms to measure distances with the mouse, compared to 13445 ms for the touch pad and 12429 ms for the touchscreen. Users showed the most variance in measurement time while measuring with the touch screen, and the least with the mouse (σ = 6263 ms for the mouse, 10069 ms for the touch pad, and 12608 ms for the touch screen).

Our study had some limitations: our conditions were ideal for mouse use, in that we performed the exam on a flat, clean surface with users who are experienced with using mice. Users overwhelmingly found our touchscreen to be frustrating, and a different device with a more accurate touchscreen may give drastically different results. Despite these limitations, however, the accuracy of our device exceeds some commercial systems.

4.3.4 Evaluation with Midwives

To investigate the usability of the interface, we recruited five midwives from Seattle-area hospitals and midwifery schools. The midwives surveyed are either ultrasound nonusers who refer their patients to an ultrasound specialist when needed, or use ultrasound to perform third-trimester limited scans. Though midwives who perform these limited scans have more formal training than our target audience, their feedback provides useful information regarding exam workflow because the basic ultrasound tasks they perform are similar to the tasks we envision our device supporting in the field. Third-trimester limited scans are less comprehensive than exams performed by specialists and include tasks such as determining fetal position, placenta location, number of fetuses, and measuring the volume of amniotic fluid.

The midwives tested our device using the same ultrasound phantom that was used to investigate measurement accuracy. The phantom provided a consistent object for scanning, allowing us to compare the quality of the midwives' scans to baseline images.

The midwives were asked to complete five tasks: begin an exam and record patient data, scan at 10cm and optimize the image, measure between two pins within the phantom and store the measurement as femur length, scan and optimize the image at 20cm, and store all exam data at the end of the exam. These tasks were selected because they best represent the full functionality of our device.

All of the midwives surveyed – including three midwives who had little or no experience using an ultrasound device – were able to successfully acquire and optimize images from the phantom at various depths and take measurements between pins embedded within the phantom. One midwife, who uses ultrasound to perform third-trimester limited scans, mentioned that the included image optimization controls would be sufficient for the type of exams she performs. She also mentioned that on her machine "there are 100 controls" and that she has to actively avoid the ones she doesn't need.

While indicating that our simplifications make the device a feasible alternative to more costly and complex ultrasound machines, our usability investigation also provided important feedback for design iteration. In particular, we found that most midwives had difficulty understanding our probe's plane of imaging because its rounded top gives no cues about plane orientation. We could address this in future iterations by modifying the probe to include tactile or visual cues that communicate sound wave orientation.

5. DISCUSSION

Our ultrasound platform should enhance midwives' diagnostic abilities, especially in rural, developing world settings. The evaluation of our low-cost prototype showed that (1) it produces frame rates that surpass WHO standards; (2) clinicians report that it obtains images of a high enough quality to allow diagnosis of the three targeted conditions; and (3) the accuracy of measurements taken using our prototype is comparable to commercial systems. In addition, local midwives, including those with little or no ultrasound experience, were able to complete tasks similar to those that Ugandan midwives will perform. Additionally, our work differs from previous work by (1) shifting some responsibility from physicians (whether local or foreign) and trained ultrasound professionals to local midwives that will identify these conditions directly; (2) making difficult ultrasound concepts easier to understand and control through a custom UI; and (3) reducing costs through modularity.

Midwives mostly work in out-patient settings, making them more physically removed from other medical professionals. This distance can interfere with continuing medical education programs and quality of care assurance. Our intention is to support remote work practices of midwives by enabling them to expand their medical skills using the ultrasound unit as an educational tool. GPRS connectivity allows midwives to pose questions to fellow midwives or radiologists. Additional medical information can be provided to remote midwives via training software, helping them avoid the cost of travel. Quality of care can be monitored remotely by a local radiologist reviewing the midwives' findings. If midwives are able to diagnose conditions that could previously only be diagnosed by physically distant professionals, the community will achieve a greater degree of medical autonomy.

Enhancing midwives' ability to identify prenatal conditions also comes with the possibility of fetal sex identification, which should be considered in cultures that have a preference for male children. Researchers have suggested that the deficit in the number of female fetuses in India is most likely caused by antenatal sex determination and selective abortion [16]. In 1994, India passed a law prohibiting doctors and clinics from determining the sex of the fetus using diagnostic techniques due to traditional primogeniture [11]. A study conducted in Nigeria has also found that incorrect sex determination through ultrasound has led to domestic violence and marital conflicts [3].

Despite the potential negative impacts of ultrasound technology, research demonstrates that women who see ultrasonic images of their developing fetus often become more engaged in their pregnancy [2]. Providing women with access to ultrasonic images of their fetus may motivate them to take a more active role in the progression of their pregnancy, such as visiting healthcare facilities for antenatal care or follow-up treatment. In Uganda, less than half of pregnant women receive the WHO-recommended four antenatal visits [33]. Our platform may decrease maternal and infant mortality rates even in women without serious antenatal complications simply because they will be encouraged to enter the healthcare system to receive antenatal care.

Pregnancy complications can require medical attention to remedy, but pregnancy itself is not a medical condition – it is a social, emotional, and personal experience. As such, introduction of technology to this experience should not be taken lightly and could potentially affect relationships between midwives and expectant mothers. Midwives may incur increased stress from the burden of having to reveal potentially devastating antenatal complications to the mother. Instead of being seen as bringers of new life, midwives could be seen as harbingers of bad luck and death due to their new ability to inform about fatal complications. This, in tandem with the amount of training required to operate an ultrasound device, may compel midwives to stay with more conventional methods of providing care to their patients.

Conducting an ultrasound exam could also lead to changing communication models between the midwife and mother. Because these exams require a great deal of attention and concentration, minimal face-to-face communication may occur during exams. This potential reduction of human contact may lead to a degree of sterility in the examination process and alter the behavior of midwives when interacting with expectant mothers. A study of pregnant women's attitudes to ultrasound in England revealed that a major source of patient dissatisfaction with ultrasound was a lack of communication by the operator about the process of taking the fetal images, or any failures in acquiring images [13]. A related study – conducted in a Botswana district hospital – indicated that many women who had little experience with ultrasound were fearful of the technology itself, and the fear seemed to be exacerbated by a lack of communication between the mothers and ultrasound operators. Additionally, mothers seemed to overestimate the diagnostic powers of ultrasound [29]. In light of potential negative aspects of ultrasound from the patient perspective, it is important to consider how to best support existing communication paradigms between midwives and their patients when designing an ultrasound platform.

6. FUTURE WORK

We plan to evaluate the usability and durability of our platform in Uganda. We will test our low-cost ultrasound platform as an alternative to the GE LOGIQ Book XP ultrasound machines as part of our collaboration with ECUREI in the midwife pilot program. The two units will be directly compared to determine if our solution is capable of detecting multiple gestations, breech presentation, and placenta previa with the same effectiveness as the LOGIQ Book XP ultrasound unit. We plan to measure accuracy, problems midwives encounter while using the device, and maternal and neonatal outcomes for the control group. In addition, we will perform user studies in Uganda to test the custom UI combined with the USB ultrasound transducer on different host platforms in order to provide a quantitative assessment of platform choices. Our plan is to quantify how our simplified UI increases symptom detection and decreases errors as compared to the complex UI of a proprietary system. The results of the user studies could reduce costs even further by identifying a cheaper netbook that meets midwifes' needs and streamlining the UI thereby reducing training requirements. Coupled with obtaining a cheaper probe, our goal is to eventually produce a platform that costs under USD1000.

We also plan to enhance our software to include additional functionality to assist midwives. For example, an auto-gain feature would make the system simpler to use by automatically making coarse image adjustments. Additionally, we intend to investigate adding a simple M-mode interface to enable midwives to detect fetal heartbeats. Our long-term goal is to incorporate computer vision to assist midwives in diagnosis by having the software automatically extract important information from ultrasound images. Algorithms could automatically detect features of the fetus, provide assistance/verification that the image is of high enough quality, and ensure that the operator has correctly identified relevant structures in the pregnant uterus. We imagine our device suggesting locations of specific tissues (for example, the placenta and cervix), pointing these structures out to the user and determining whether previa is present based on the placenta's distance from the cervix. In an ideal scenario, the user would no longer be required to have expert knowledge about the anatomy of the uterus. Additionally, computer vision could compare images obtained during an exam to a control set of images to detect possible complications and present the image that possibly contains a complication to the midwife to verify the possible condition exists. Finally, it could be beneficial to use computer vision to obscure the gender of the fetus, potentially avoiding problems observed elsewhere [3, 11, 16].

7. CONCLUSION

We have developed a cost-effective and easy to use ultrasound platform designed for midwives in rural developing regions. What distinguishes our approach from existing technologies is the sustainability of our platform, which is designed to enhance a midwife's ability to provide care at a cost that is more likely to fit the financial constraints of African health systems. A tailored UI fits the needs and skill level of midwives, increasing their medical expertise and autonomy. Our prototype produces frame rates that surpass WHO guidelines, obtains images of a high enough quality to diagnose the three targeted conditions, and produces measurement accuracy comparable to commercial systems. Testing performed by nine clinicians indicated our device would be appropriate for identifying our target conditions. In addition, Seattle-area midwives, including those with little or no ultrasound experience, were able to complete tasks similar to the Ugandan midwives' expected tasks. The platform's modular design allows for relative ease of specialization, improved scalability, and reduced costs. In the future, we envision NGOs and medical groups being able to download our software, buy the required off-the-shelf components, and use the training materials to deploy this new simplified system on their own. We believe our platform may decrease maternal and infant mortality rates even in women without serious antenatal complications simply because they will be encouraged to enter the healthcare system to receive antenatal care.

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