

Low-cost teleradiology for rural ultrasound

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Abstract: In under-resourced communities, there are several preventable pregnancy complications that can lead to significant maternal or perinatal morbidity and mortality when left untreated. The lack of access to prenatal imaging is one of many factors that contribute to the greater mortality rates in such populations. Analysis of the most common complications suggest that even limited access to obstetric ultrasound imaging could have a positive impact, particularly in a rural context in which imaging can prompt transport of the patient to a capable facility.

The authors describe their work to establish and validate an obstetric care model in Uganda, and the design and for a clinical study to measure this model's efficacy in terms of improving outcomes at delivery. The central objective of this care model is to reduce mortality in remote locations by providing expectant mothers and their primary care-givers with advance notice of complications so that women at risk can be referred to appropriate care centers in time. The components of this model are described, including portable ultrasound machine, scanning protocols for clinical data acquisition by local operators, custom clinical data compression and transmission capabilities, and internet-based infrastructure for remote reading and reporting. The objectives, hypotheses, and design of the associated clinical outcomes study and progress to date are also presented.

Keywords: Healthcare access, under-resourced, ultrasound, imaging protocols, high-risk pregnancies, teleradiology

I. INTRODUCTION

Worldwide, complications of pregnancy and childbirth contribute to 358,000 maternal deaths annually, 99% of which occur in developing nations. More than 80% of mortality occurs in areas of high birthrate with limited access to healthcare, such as sub-Saharan Africa and south Asia [1]. More than half of these deaths are attributable to hemorrhage or

obstructed labor. Peripartum hemorrhage is responsible for 25% of maternal deaths. It is also a factor in fetal and neonatal deaths. Approximately 5% of pregnancies are affected by postpartum hemorrhage. Many are from uterine atony, which has several causes, including but not limited to multiple gestations, grand multiparity, and prolonged labor. At least 20-30% of maternal hemorrhage is due to abnormal placentation: placenta previa, placental abruption, and/or placenta accreta. Abnormal placentation is an even greater issue in developing nations than in developed nations because it is associated with greater parity, particularly where contraceptive services may be limited [2].

A certain number of these pregnancy complications could be precluded with the use of ultrasound as a diagnostic tool. However, under-resourced areas rarely have either ultrasound equipment or trained personnel to operate them. Because antenatal ultrasound is an obvious solution to these problems, it is not surprising that ultrasound outreach programs are plentiful in developing nations. Such programs may have limited sustainability when they involve expensive and time-consuming ongoing training of medical personnel and/or outdated ultrasound machines that are difficult to maintain and can demand considerable electrical power. These factors can become obstacles for local workers after foreign-based trainers and support personnel have left.

To the authors' knowledge, the use of volume ultrasound in prevention of maternal and fetal morbidity and mortality has no precedent in the literature, such that the only known references are the report of the authors' previous work and preliminary results from an IRB-approved study with Kamuli Mission Hospital (KMH) and from a clinical project at Nawanyago Health Center in Kamuli District, Uganda. This study is the first major clinical outcomes test of the new technique in an under-resourced country.

The long-term aim of this work is to mitigate the ultrasound imaging deficit in the most under-resourced areas of the world

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using a sustainable, low-cost technology-based solution. The proposed care model enables minimally-trained primary healthcare workers to capture and transmit ultrasound freehand sweeps of key regions of interest. An integrated exam data compression and transmission system automatically detects the available network bandwidth and appropriately adjusts the file sizes prior to transmission. These data are then uploaded to a server where they can be accessed by expert readers either locally or remotely. These readers can then review the images for key indications and transmit their findings via text message back to the rural areas via the cellular phone network, enabling medical diagnosis anywhere such a phone network is in place.

The high-level objectives of the authors' outcomes study are to test whether (1) for certain common diagnoses, operators with no technical knowledge or training will be able to acquire and transmit images that equal the utility of traditional ultrasound imaging (performed by an operator with years of training), and (2) remote obstetric ultrasound diagnoses will improve maternal and perinatal outcomes. These objectives specifically target the World Health Organization Millennium Development Goal #5, which aims to improve maternal health by reducing maternal mortality and increasing skilled care [3].

II. STUDY METHODOLOGY

A. Overall study design

Through this study, the authors will test the health impact of the use of special ultrasound volume imaging protocols designed to allow non-physician health personnel with minimal training in ultrasound to perform basic ultrasound examinations. Up to six non-physician health workers with no prior exposure to ultrasound will be trained to perform these protocols, which do not require knowledge of internal anatomy or ultrasound physics. After completing training, these trainees will begin recruiting and examining patients at their respective clinics. At experimental sites, each eligible, consenting patient will receive an ultrasound examination using the obstetric scan protocol.

Initial reports of the use of volume imaging in ultrasound date from the late 1990s [4], and much of the original focus was on 3D display in obstetrics [5-8]. This work coincided with the development of mechanical 4D transducers that created semi-real-time spatially calibrated 3D images. As ultrasound instrumentation developed, the ability to create 3D images of larger volumes was added by allowing users to manually sweep a transducer over a large distance creating a 3D volume set of images. The development and deployment of PACS capable of displaying these sweeps as a series of images much like a CT or MRI series forms the basis of body volume imaging [9, 10], which has now become part of the standard ultrasound examination [11] because of its ability to provide much more complete organ coverage than the older "representative image" approach. The Imaging the World (ITW) protocols take advantage of the exceptional organ coverage provided by volume scanning not to further enhance diagnostic accuracy, but to provide basic diagnostic capability in a situation where the operator has minimal ultrasound knowledge. During preliminary testing, these ITW protocols have been shown to produce diagnostic quality images of multiple organs [12].

Volumetric images are sent via the internet to health worker expert ultrasound professionals at the Ernest Cook Ultrasound Research and Education Institute, Kampala, Uganda (ECUREI), and the Imaging the World Corporation (ITW), who will provide interpretations. The interpretations are made available to the local primary care provider to guide patient management. Patients recruited at the control site will not receive an ultrasound examination. Patients at both experimental and control sites are followed throughout the remainder of the pregnancy, delivery and in the postpartum period, and specific outcomes data will be gathered and used to evaluate improvements in maternal and perinatal morbidity and mortality. Data from experimental sites will be compared with contemporary and historical data from the control site to determine whether utilization of special volume ultrasound technology is an effective means of reducing pregnancy-associated maternal and perinatal morbidity and mortality.

B. Clinical site selection and historical data

The training portion of the protocol concept was tested at one study locale in July 2010. A group of volunteers traveled to Nawanyago in Kamuli District, Uganda and, under Institutional Review Board supervision, spent two days training nurse midwives in a rural health clinic to use external anatomical landmarks to obtain hundreds of obstetrical images. A team of radiologists in the US and Uganda is currently evaluating the images for key indicators, such as placental location, fetal number, and fetal presentation. Early indications show that the images are of diagnostic quality.

In order to power the statistical analysis and allow detection of a significant difference in outcomes, it is necessary to properly account for underlying trends in the outcomes variables that existed prior to the start of the study. To estimate these trends, historic clinical outcomes data will be compiled by accessing clinic logbooks that are kept at each of the clinics. These logbooks contain pooled clinical data in the form of monthly statistical reports. Data collected from these logbooks will include, but will not be limited to, the number of prenatal visits, the number of maternal admissions, and the numbers of deliveries, live births, still births, and maternal deaths. Data will be collected retrospectively at each clinic for a period of 3 years prior to the start of the current study.

In addition, an independent community of comparable size and demographic makeup to the experimental groups will be selected as a control site. The control site will remain ultrasound naïve for the course of data collection. Simultaneous enrollment of all eligible and consenting participants for the duration of the study will occur at this control site, just as with the experimental groups. Enrolled patients will be followed throughout the course of their pregnancy and childbirth. Although no recommendations for care will be made, data will be gathered for each of the previously mentioned clinical outcomes variables. Through comparison of the control site and the intervention site, it will be possible to isolate the effects of the diagnostic ultrasound protocol being tested.

C. Technical infrastructure

A hardware reference system has been developed and tested at the University of Vermont, Fletcher Allen Health Care with

the support of industrial partners (GE Healthcare and Philips Healthcare). This system currently comprises a laptop ultrasound system and a low-power netbook computer-based local storage and transmission server connected to the ultrasound system via wireless Ethernet, and to the remote imaging collaboration server (Datarealm Services, Inc., Phoenix, AZ) via either a cellular modem or other internet connection, e.g. satellite. The large volume of image data contained in volume imaging must be highly compressed for transmission over slow and sometimes unreliable connections in developing countries. A method for doing this has been developed and successfully tested using data from the existing IRB-approved study [13].

D. Patient recruitment

Patient enrollment in the study will occur at each of the three health centers and continue throughout the study period. Health workers and patients are recruited by word of mouth in each locale by talking to the community and pregnant mothers who present at the clinics. The following criteria will be applied:

a) Inclusion criteria: All female patients presenting at the study sites within the study period, who are 16 years and older, who are assumed or proven to be pregnant, and who are willing to give informed consent will be enrolled.

b) Exclusion criteria: Patients not meeting the inclusion criteria, or who are in an unstable medical condition (unless ultrasound is necessary to define treatment) will be excluded from the study. Patients with conditions requiring emergency attention as determined by the attending clinical officer or physician will also be excluded from enrollment. Emergencies are conditions that require urgent medical or/surgical intervention, like severe bleeding from orifices, coma or other deranged levels of consciousness.

c) Withdrawal or Discontinuation Criteria: Any health worker trainee may withdraw at any point. A health worker trainee may be asked to withdraw if he or she is physically unable to perform the maneuvers required to scan patients (for example hand arthritis preventing a person from gripping the ultrasound transducer). If a person withdraws, another person from a “reserve” pool of health workers, if available, will be brought into the study. Any patient may, as is normally the case, refuse participation in any part of this study, including the diagnostic test (the scan).

E. Examiner Training:

Local health personnel at each of the experimental clinics will undergo on-site training if they have not previously been trained to administer volume protocol ultrasound scans. The complete training sessions will last as long as needed for the examiner to become comfortable performing the scan.

Training will involve both didactic modules for the fundamentals of ultrasound, as well as hands-on training to learn how to generate images with the protocol. The training will be conducted by experienced project personnel from ITW and from ECUREI as has been done in past ITW studies. The trainees will pair off and one trainee will act as examiner and the other will act as the “patient” during the training process. This allows the trainees to experience what having an ultrasound scan is like as well as learning how to perform a simplified volume ultrasound scan. Typically at least four practice scans of each type of scan are required to gain some proficiency. The time required for this phase will be recorded by the ITW trainer performing the training. The training will include some physics and training on data security and patient confidentiality as well as how to receive reports and act upon results. Following completion of the training program, nurse midwives will begin generating images at their clinic according to the study protocol, when indicated by clinical history, signs and symptoms. Much of the training will be conducted by ECUREI trainers who have undergone a “train the trainers” course by ITW staff. This approach is aimed at building capacity within Uganda for this new type of ultrasound training.

F. Scanning Protocols and Image Acquisition:

Because the ITW model is implemented in Nawanyago as a proof of concept, all patients attending antenatal visits at the health center are offered ultrasound scans, once per trimester, aiming for 10-12 weeks, 18-22 weeks, and 34-36 weeks. Ultrasound may be recommended by the nurse midwife at any time based on clinical signs and symptoms. Patient data, including clinical presentation and history, is entered into the data field in the ultrasound machine. All patients are given individual ITW numbers that allow confidentiality to be maintained during image transmission, clinical data collection, and outcomes analysis.

The ITW obstetric protocol incorporates six 3-D volume sweeps over the pregnant abdomen (e.g. Fig. 1). These sweeps (cine loops) can be learned by an untrained person with limited knowledge of internal anatomy in a few hours. The protocol is designed to evaluate basic but potentially life-saving findings: to confirm intrauterine pregnancy, to assess fetal number, fetal presentation, placenta position, and amniotic fluid volume, and to look for a pelvic mass. A low-frequency curved transducer is used to obtain sweeps with the pregnant patient in a supine position, having a full bladder. The ultrasound machine has been configured by the manufacturer and ITW experts to provide three presets for three body mass index (BMI) categories, (small, medium, and large) and the operator needs only to choose one of the presets based on known BMI. Often, the BMI correlates to the gestational age (e.g. large for third trimester).



**Transverse Center Pelvis
Midline (Pelvic Bone to Breast Bone)
Notch towards Patient's Right**

Figure 1. One example of the free-hand sweeps defined by the ITW protocol for obstetrical imaging.

Three transverse (transducer notch to the patient's right) sweeps are obtained from the pubic bone to the level of the breast bone, one midline, one to the right of midline, and one to the left of midline, arcing the transducer at either end of the sweep. Sweeps are acquired at 3-4 cm per second with each sweep no longer than 10 seconds to maintain diagnostic quality during compression for transfer. Subsequently, longitudinal (notch toward the patient's chin) sweeps are generated, the first one low just above the pelvic bone, angled toward the pelvic bone, from the left hip to the right hip; the second is obtained in the same manner at the level of the umbilicus; a third longitudinal sweep is generated in the same fashion just below the breast bone.

Images are saved as volume sweeps that are then sent via a wireless router to a netbook/laptop computer. Custom-built compression software in the laptop is used to compress the images for transmission over a regular cellular telephone network (MTN modem inserted into the USB port of the laptop). The images are then sent to a secure server where they are decompressed and sent to the secure distributed client of the picture archiving and communications system on the internet.

As stated above, enrolled patients who have met the selection criteria will continue to receive the normal level of care, with the addition of ultrasound imaging. Initial ultrasound exams will be performed for all participants at the first visit to establish intrauterine gestation and assess for multiples. This first visit will generally occur during the first trimester of pregnancy. Subsequent ultrasound exams will be performed during the second trimester if indicated, or if an earlier scan was not performed. Third trimester scans will be performed on all participants for fetal and placenta positioning as well as amniotic fluid volume. Each study participant will receive these imaging tests regardless of their risk of pregnancy complications. The nurse or midwife health worker will perform each transabdominal ultrasound according to the protocol described above. At each ultrasound visit, other health indicators will be assessed and reported using the standard form.

G. Image Interpretation

As shown in the schematic in Fig. 2, once a volume scan is completed on an enrolled patient, it is sent in compressed format over the internet to an internationally accessible secure server. Qualified ultrasound experts in Uganda and the USA who have undergone a selection process, including credentials verification, will have access to the server's images (e.g. Fig. 3) using an electronic database (peerVue, Sarasota, FL).

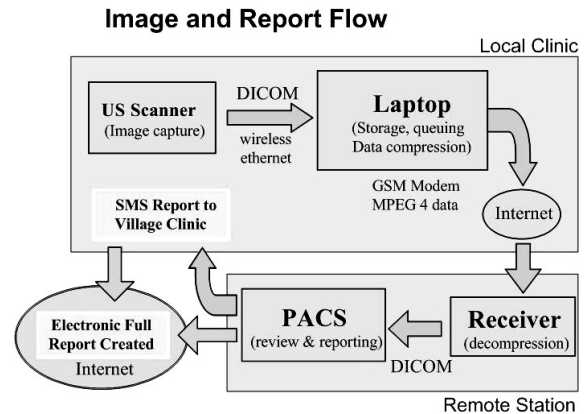


Figure 2. A schematic of the information flow among the centers involved. Exam data from rural clinics is compressed and transmitted to a remote PACS, via which remote readers can review them and report their findings to the rural clinic and the regional referral hospital.

The interpretation will be recorded using a specially designed structured reporting form within this database. A simplified version of the finalized report will automatically be sent to the nurse midwife at the clinic as a text message to the cell phone. The full report can be made available on-line or sent as an email for electronic access by the nurse midwife or KMH. Image data and results data will be kept secure on the ITW server behind firewalls with password protection.

H. Recommending care:

As described above, interpretations of ultrasound images rendered by volunteer radiologists in Uganda and the USA will be communicated to the patient in the form of clinical recommendations from the nurse midwife to the patient, often necessary after consulting with the doctor at KMH (e.g. a diagnosis of placenta previa may be communicated to the patient with a recommendation for transfer to a regional hospital). These recommendations will be passed on to the patient during the same visit in case of emergencies or at a follow-up visit for routine exams. All mothers will be encouraged to have their labor attended by a skilled practitioner at the clinic. Adherence to these recommendations will be tracked.

I. The outcomes study objectives and hypothesis

The objectives of the study are as follows:

- Track the number of deliveries attended by skilled health care providers.
- Track the number of antenatal visits per patient at each location.

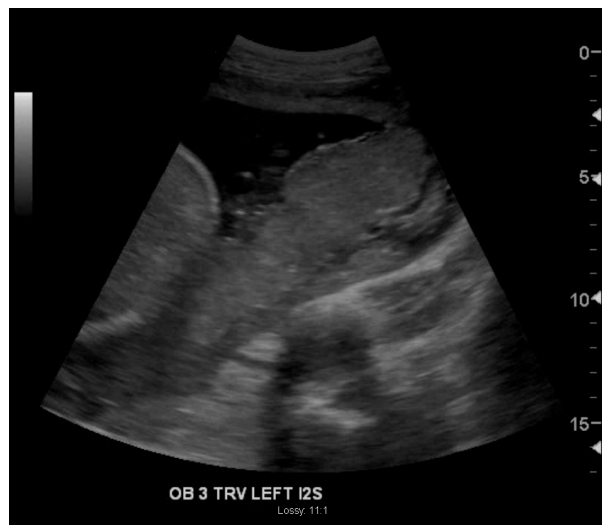


Figure 3. Representative images stored on the secure server. The images above are from a 2nd trimester fetal presentation obtained at Nawanyago Health Center, showing the fetal head (top) and the placenta (bottom).

- c) Track the number and causes of patients referrals from the clinic to a regional hospital.
- d) Track the number and causes of maternal morbidity and mortality.
- e) Track the number and causes of perinatal morbidity and mortality.
- f) Track the number and description of diagnostic findings that are identified from remote image review.
- g) Track the number and type of ultrasound findings that are associated with maternal and perinatal morbidity and mortality
- h) Track the number of ultrasound scans that resulted in a change in patient management.

i) Track the number of ultrasound scans that resulted in a patient being successfully treated.

j) Compare each of the tracked clinical outcomes between the experimental group and the control data to determine changes in outcomes that are attributable to the implementation of ultrasound technology.

k) Determine the proportion of each adverse outcome than can be prevented with the model.

The volume exam data will allow remote readers to make diagnoses (e.g. placenta previa, breech presentation, and multiple births). An analysis of preliminary data collected from pilot studies conducted in Belize in 2008 and Uganda in 2010 suggest that use of this protocol can be expected to increase diagnostic rates for important gestational conditions. It is hypothesized that the experimental sites in this study will show statistically significant improvements over the control site and, when compared to historic trends, significantly higher rates of births attended by a skilled health care worker, increased number of antenatal visits during the duration of pregnancy, and significantly decreased rates of maternal and perinatal morbidity and mortality.

J. Data analysis:

Analysis of clinical outcome data will consist of simple difference-of-means tests that detect differences between the experimental groups and the control group. There a several implementations of this type of test that can be used:

- One-sample t-test to determine if treatment groups are significantly different from some constant value [e.g. if the average infant mortality rate in Uganda is known]
- Independent sample t-test between experimental group and population [this assumes individual data from both; with this test all experimental groups would be collapsed into one]
- Paired t-test between experimental group at Time 1 versus Time 2 [e.g. before and after ultrasound diagnoses are introduced]
- ANOVA + post-hoc analysis: tests across all four groups to identify any differences among means of individual groups, and then further tests to identify the location of these differences [e.g. difference in mean infant mortality rate in the three affected health centers and then another or the broader population]

Given the data sets that this study will collect, the two analyses to be applied to test the overall hypotheses are the independent sample t-test and the ANOVA + post-hoc analysis.

III. PROGRESS TO DATE

A. Progress to date

While evaluating the training protocols and studying the quality of images captured using the ITW model, it has been observed that during a one year period there has been a 70% increase in both antenatal visits and deliveries at Nawanyago clinic compared to the corresponding period of the previous year. In addition, several patients were successfully transferred to the regional hospital, Kamuli Mission Hospital (KMH), for

surgical delivery. So far over five hundred patients have been scanned and successfully stored on a remote PACS server as part of the image quality evaluation.

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