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INTERIM ASSESSMENT:
Current Understanding of the Feasibility of the 3-D Ultrasound Volume Dataset Capture and Evaluation

Testing Feasibility of 3-D Ultrasound Data Acquisition and Reliability of Data Retrieval from Stored 3-D Images

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There are several issues being explored by this 3-D pilot study, including whether the data can be collected, stored, transmitted, and analyzed at a central facility. This document provides a brief summary of what we know to date. The discussion of our understanding of these issues is organized by several questions as stated below.

Question 1:

Can sonographers visualize and obtain a volume measurement, using their 3-D ultrasound machines, of the fetal head, heart, kidneys, adrenal glands, lungs, pancreas, liver, upper arms, and thighs?

Current Understanding:

Sonographers trained in fetal assessment should be able to perform 3-D volume acquisitions following approximately 4 hours of training that is based on a detailed protocol. The specific technical instructions are being developed, without cost to EPA or RTI, by Dr. Chan at the Naval Hospital in San Diego. It is the belief among all physicians contacted, including Dr. Chan, Masedonia, Pretorius, Lee, Trevett, and Murtha, that given a brief training and a clear protocol almost anyone can obtain the 3D volume datasets. There is also consensus that the pancreas will not able to be measured and the adrenal glands may be difficult.

There seems to be agreement between physicians that a 3-D volume dataset on a 1st trimester fetus should take at most 2 minutes. For the second and third trimester fetuses, estimates range from 3 minutes to 15 minutes. The longer time is necessary because unlike the 1st trimester fetus that can be visualized usually in one view and therefore one volume, the larger 2nd and 3rd trimester fetuses require a volume of the head, and then

another of the torso, and at least one more to obtain the lower extremities. Dr. Pretorious found that it look 9 volumes for a 2nd trimester fetus and 11 volumes for the 3rd trimester fetus. The amount of time it takes to obtain the volume of images appears to be associated with the experience of the sonographer. As experience increases the number of minutes needed to obtain the volume dataset decreases. It is unclear if there is any association between the number of volumes needed and the experience or knowledge of the sonographer.

Dr. Masedonia believes an experienced, specially trained, 3-D sonographer is needed to manipulate the 3D volume datasets to determine organ volume measurements. Other physicians including Dr. Chan, Pretorius, and Lee believe that with a detailed protocol almost any sonographer can determine organ volume measurements. Therefore, with no cost to EPA or RTI, Dr. Chan is creating a detailed procedure to determine each organ's volume measurement that will be used to create a 3D Organ Volume Measurement Protocol by the August 25 deadline.

Question 2:

Can "raw" 3-D data be saved, transferred, and stored at a central facility without losing the quality of the images/data?

Current Understanding:

Yes, we believe the 3-D data can be saved, transferred, and stored at a central facility without losing the quality of the images/data. The data will not be compressed or otherwise manipulated. Therefore, the integrity of the data will be maintained, and we have no concerns about the quality of the images degrading during transfer and storage. The pilot will confirm this understanding.

According to physicians who have obtained volumes for fetuses in the 1st, 2nd, and 3rd trimesters, the file containing the volumes will range in size from 50 Mb - 170 Mb. The transfer of files of these sizes presents a challenge we will discuss more fully in the Final

Interim Report. The technology is changing quickly and we expect there will be appropriate compression techniques available in the next 1 to 3 years.

The attached spreadsheet is a working document providing information on the various transfer methods we investigated, (e.g., CD/DVD, Internet (via DSL, Cable, T1, T3, >T3, Dedicated T1, Internet2, and FTP)). The spreadsheet will be expanded to include notes for a non-technical reader on the advantages and disadvantages of each transfer method, and then it will be included in the Final Interim Report.

We are confident we will be able, in the Final Interim Report, to recommend a transfer method that will allow the data to be securely and reliably transferred from the medical facility to the central facility.

Question 3a:

Can the stored "raw" 3-D data be brought back into software that will allow an ultrasound interpreter (sonographer or MD) to view, manipulate, and determine volumes of organs?

Current Understanding:

Yes, the "raw" data, otherwise referred to as the 3-D volume dataset, can be brought back into software to view, manipulate, and determine organ volume measurements. The volume of images will appear just as clear, and have all of the manipulation ability, as on the ultrasound machine during the exam. GE has a desktop (proprietary) software that enables an ultrasound interpreter (sonographer or MD) to view and manipulate the 3-D volume dataset. Philips has its own proprietary software that according to Dr. Pretorius and another physician testing the machine is not able to reliably determine organ volume measurements. Therefore, to determine organ volume measurements from a 3D volume dataset created on a Philips iu22, the central facility would need to bring up the dataset on a Philips iu22 machine.

Dr. Macedonia believes that an evaluation of the 3-D volume dataset at a central facility is analogous to evaluating MRI images, which once obtained, can be manipulated/sliced to view and measure structures and organs. This opinion is shared by the representatives at GE and Philips and physicians involved in organ volume measurements including Dr. Pretorius, Lee, Chan, and Abramowicz.

Question 3b:

Is there a standard software package that can read data obtained from different models and brands of ultrasound machines?

Current Understanding:

No. According to our contacts at GE and Philips, there is no standard software that can read 3-D volume datasets from machines other than their own. Representatives from both companies, Dr. Macedonia and Dr. Pretorius believe this will happen in the future but there is no expected date for this "generic software." Both the GE Voluson 730 and the Philips iu22 machines create datasets that can only be read on the same type of machine they were created on or by the manufacturer's proprietary software.

Question 4:

Will different sonographers at the central facility arrive at the same organ volume measurements when viewing the same raw 3-D data?

Current Understanding:

The consensus is that yes, sonographers at the central facility should be able to pull up the 3-D datasets, and using the proprietary software, determine very similar organ volume measurements. Unlike 2-D measurements, which are clearly defined and posted on the AIUM web site, standard procedures for determining organ volume measurements do not exist. Instead, there is a body of research looking at different guidelines and their associated reliability and validity. Apparently, to determine volume, each image is traced then rotated and retraced. It appears that the difference between techniques is how many trace/rotate cycles are needed and what angle of the organ to trace. Some methods, while

saving time, result in different measurements even if the same volume dataset and technique are used. To be able to analyze the inter-observer variability without the measurement technique confounding the results, it would be best to use a technique that provides the most reliable measurement in an acceptable amount of time.

There are no strong opinions among the experts we contacted on whether someone at a central facility, who is not present for the 3-D exam, will be able to determine the organ volumes as easily as someone who performed the exam. Following the same, reliable set of guidelines was mentioned as the way to achieve the greatest success at the central facility.

The quality of the 3-D volume dataset, which can be thought of as a volume of 2-D images, can be affected by anything that interferes with a clear 2-D image. This includes decreased amniotic fluid, little fluid near the area of interest, maternal obesity, stage of organ development, calcification of ribs causing shadows, or size or position of fetus. The more unclear the image, the more variability that can be expected between each central facility sonographer who try to “trace” a fuzzy image and therefore end up with different measurements.

Transmission Methods Considered for 50Mb - 170Mb 3-D Volume Datasets as of August 18, 2004

Method of Transfer	Description	Installation Time	Equipment Needed	Usual Contract Period	Speed	Remarks
CD (compact disk)	An optical digital audio disc that has a storage capacity of 650MB.	None	CDs	n/a	n/a	
DVD (digital video disk)	A DVD-ROM is like a large CD-ROM that holds data and interactive audio and video material.	None	DVDs			
DSL (digital subscriber line)	A technology that dramatically increases the digital capacity of ordinary telephone lines (the local loops) into the home or office.	30 days	Modem		DSL speeds are tied to the distance between the customer and the telco central office.	
Cable Modem	A modem used to connect a computer to a cable TV service that provides Internet access. Cable modems can dramatically increase the bandwidth between the user's computer and the Internet service provider, especially in the downlink (from ISP to user). Cable modems connect to the computer via an Ethernet port, which is an always-on connection. Ethernet is a shared medium, and the individual user's speed will vary depending on how many customers are sending or receiving data on that cable segment at the same time.	30 days	Cable modem and Ethernet card.		4.0 Mbs for downloads; slower for uploads	
FTP (file transfer protocol)	A protocol used to transfer files over a TCP/IP network (Internet, Unix, etc).	n/a	none	n/a	Depends on the speed of the connection to the Internet.	Secure.
Dedicated T1 (point-to-point)	A 1.544 Mbps point-to-point dedicated, digital circuit provided by the telephone companies. T1 lines are widely used for private networks as well as interconnections between an organization's PBX or LAN and the telco.	45-60 days if the telephone company has service at both ends.	Router at originating point (~$2,000); ~$10,000 for equipment at terminating point.	1 year	1.5 Mbs	The monthly cost is typically based on distance. Distances of a few hundred miles may cost $2,000 - $3,000 per month. Secure.
Dedicated T3 (point-to-point)	A 44.736 Mbps point-to-point dedicated line provided by the telephone companies. A T3 line provides 672 64-Kbps voice or data channels. T3 channels are widely used on the Internet.	45-60 days if the telephone company has service at both ends.	Router at originating point (~$2,000); ~$10,000 for equipment at terminating point.	1 year	4.5 Mbs	The monthly cost is typically based on distance. Distances of a few hundred miles may cost up to $100,000 per month. Secure.
T1 (point-to-minipoint)	Connection between a facility and a local Internet provider. The monthly cost is $300-$500.				1.5 Mbs	
Internet2	The second generation of the Internet, developed by a consortium of more than 200 universities, private companies and the U.S. government. It was not developed for commercial use or to replace the Internet, but is the reincarnation of it, currently intended primarily for research. Whereas the Internet was first designed to exchange text, Internet2 is designed for full-motion video and 3-D animations.					Not widely available. Organizations may require major upgrades to their networks to connect to Internet2. Hops may be Internet rather than I2; this reduces the transmission speed to Internet speeds.