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TITLE: Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in Babies at Remote Military or Native American Health Care Facilities

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14. ABSTRACT: Our partnership of investigators from Madigan Army Medical Center at Fort Lewis, Washington, and Oregon Health & Science University in Portland, will test the hypothesis that trained primary care practitioners or nurses can, with telemedicine supervision, perform cardiac ultrasound exams on neonates at risk for heart disease, and thereby impact time to diagnosis and outcomes. This study is targeted at Military Medical Facilities within TRICARE West and Western Regional Medical Command. It will also include two large Alaska Native Health Care Centers. Echocardiography has had major impact in the management of neonates suspected of having congenital heart disease. The expensive, specialized equipment and significant expertise to adequately perform and interpret these studies usually is present only in tertiary level medical centers with a pediatric cardiologist on staff. Initial results of a National Multicenter Neonatal Telemedicine Echo Outcomes Study, developed by the Principal Investigator, suggest that telemedicine-implemented diagnosis positively affects outcomes in infants suspected of having congenital heart disease. Our partnership has trained 33 non cardiologists to perform neonatal echo and has installed a high bandwidth telecommunications link using the military version of Internet2, NIPRNET. By spring of 2007, we will be overseeing neonatal echo exams from 3 military installations in the NW and in Alaska, as well as a large Alaska Native Health Center in Anchorage. We have also arranged to upgrade the scanners used in our network to the latest architecture from Sonosite®: the fully digital phased array handheld ultrasound scanner, the MicroMaxx®.					
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Brief Synopsis:

Progress continues to be made on HS issues and connectivity. Patients are being entered in to the study. Serious heart disease has been diagnosed in two infants by remotely monitored ultrasound examinations. Newer high performance handheld ultrasound scanners are to be installed this spring.

TASK # 1**A. Installation of Sonosite Ultrasound systems****New Scanners to be installed**

All sites have functioning Sonosite SonoHeart Plus units – some are still waiting IRB clearance for use of them

We have completed negotiations with SonoSite® who will fulfill their obligation to replace the SonoHeart Elite® systems with their new Digital system the MicroMaxx® and adapt the remote control program written for this project to run on the new system. The MicroMaxx® has better color Doppler quality and the phased array as opposed to a linear curved array transducer. This allows imaging at runs at between 8.5 and 11MHZ with higher resolution and considerably improved color Doppler flow visualization. Minimal instruction will be required for our remote sites to learn how to use the system. The control philosophy is very similar but the control interface is larger and easier to use.

B. Communications Infrastructure

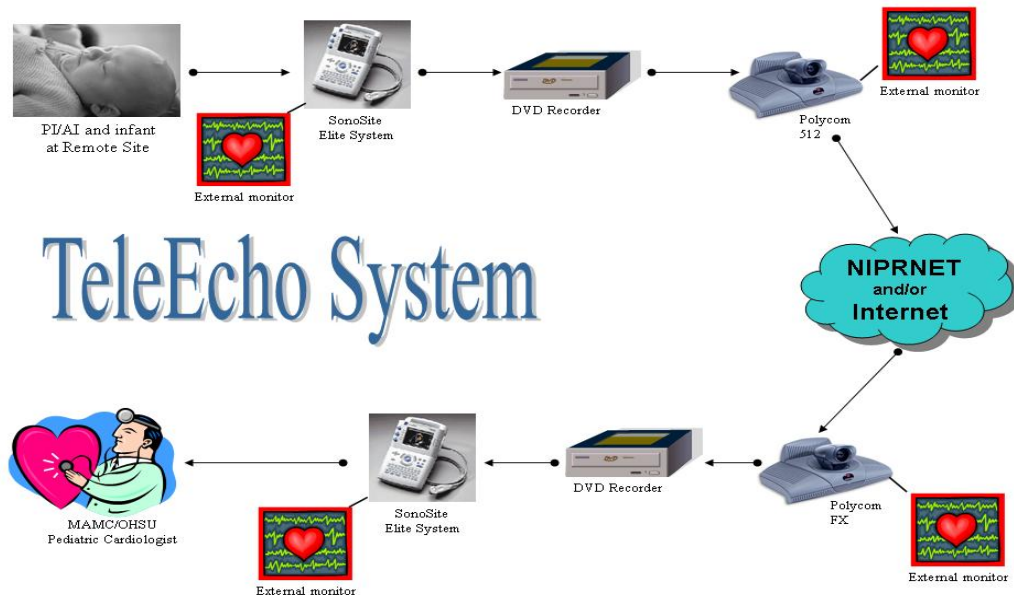
We transitioned the telecommunications to the Non-Secret IP Router Network (NIPRNET). This allows up to 712kbps bandwidth for improved visualization of cardiac images and meeting DOD and HIPAA security standards.

After analyzing bids for commercial lines, costs were deemed too excessive for the grant. Even given the fact Yukon would be on a separate intra-Alaska network. Considering the high annual cost for Madigan alone, over \$8,000, we returned to the prior discussion of using the Military NIPR network.

In December 2004, work began towards authorization to use the NIPRNET, an existing communication infrastructure within the DOD. A major benefit to utilizing the NIPRNET is sustainability. All remote MTFs in the study can easily establish point-to-point connections with MAMC or OHSU at no additional cost to the grant.

Before a site can connect to the NIPRNET, each TeleEcho System will need to undergo a DITSCAP or DOD Information Technology Security Certification and Accreditation Process. A System Security Authorization Agreement (SSAA) was drafted for the process and adapted for every site. MAMC's TeleEcho System received Interim Authority to Operate (IATO) on 23 August 2005 and Bassett Army Community Hospital (BACH) was activated on 20 January 2006.

Utilizing the military's existing network infrastructure and security and provide lower cost secure and HIPAA compliant communication and the flexibility of this approach ensures growth potential if the TeleEcho System becomes standard of care within the DOD health care system



TASK 2

Training

An update on individuals trained, to perform echocardiograms on newborn infants; number of days, and the dates of training.

Summary February 2004 – 2006:

- o 14 TeleEcho Training Seminars
- o 28 days of training
- o 27 Providers trained to perform supervised echocardiograms
- o CME Credits Offered: 154
- o CME Credits Assigned: 154

14 Category-1 CME credits were offered for each trainee attending the TeleEcho Training Seminar held 15 October 2005 – 16 October 2006.

Learning objectives

1. Understand physical basis of ultrasonography: - 2D & Doppler
2. Competence performing complete transthoracic echocardiogram: 2D, Doppler, and M-mode
3. Understand common congenital cardiac defects in clinical presentation and echocardiography.
4. TeleEcho System familiarization, data collection & informed consent process.
5. Clinical management of congenital cardiac lesions.
6. CITI – The Protection of Human Research Subject Training.

- February 21 – February 28, 2004
CPT Ronald Wells, MD, BACH

- March 24 – March 25, 2004
LCDR Andrea Donalty, MD, NHOH
- March 29 – March 31, 2004
CPT Athena Stoyas, MD, WACH
- April 10 – April 12, 2004
Dr. Michael Engel, ANMC
Dr. Calle Gonzales, ANMC
Dr. Haitham Salman, ANMC
- April 17 – April 19, 2004
CDR Karie Andersen, MD, NHB
LCDR Rose Dieffenbach, MD, NHB
- September 29 – September 30, 2004
CPT Robert Warner, MD, WACH
- December 9 – December 10, 2004
MAJ Donald Lane, MD, 3MDG
COL David Estroff, MD, MAMC
CPT Katy Gibson, MD, MAMC (Resident)
- December 14 – December 15, 2004
CDR Victoria Crescenzi, MD, NHB
CPT Katy Gibson, MD, MAMC (Resident)
- January 11 – January 12, 2005
MAJ Nola McManus, MD, 3MDG
MAJ John Harvey, MD, MAMC
- March 14 – March 15, 2005
LCDR Christopher Westbrook, MD, NHB
CDR Ronald Dommermuth, MD, NHB
Dr Daisuke Kobayashi
- May 17 – May 18, 2005
Cathy Binder, NP, BACH
- October 20 – October 21, 2005
CPT Reaches Richards, MD, WACH
CPT Rebecca Garfinkle, MD, BACH
LT David Eigner, MD, MAMC (Resident)
- January 24 – January 25, 2006

MAJ Laura Peterson, MD, 3MDG

- August 15 – August 16, 2006
CPT Steven Jay, MD, BACH
LT Bonnie Geneman, MD, MAMC (Resident)
LT Damien Powell, MD, MAMC (Resident)

TASK 3

Web based entry of patient exams

A full update on the status of all Human Subjects protocols and our qualifications to run interact with each base.

Summary of Human Subject Protocol:

- o 6 sites with full IRB approval: MAMC, WACH, BACH, ANMC, 3MDG, BJACH
- o 2 sites with tentative IRB approval: NHB, NHOH
- o 1 site for resubmission: Blanchfield
- o 1 site on hold: YKHC

Madigan Army Medical Center (MAMC), Ft. Lewis, WA

- Annual Continuing Review of protocol. Approved: 24 January 2006.
- Changes to staff over 2006. COL (RET) Edward Carter, MD services as a consultant for the study were no longer required. A MOR was submitted to remove Dr Carter as an Associate Investigator and approved. IRB approval letter dated 19 January 2006.
- CITI - The Protection in Human Research Subjects Training is current for all investigators and staff.
- Curriculum Vitae are current for all investigators and staff.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Amendment #4 to Cooperative Research and Development Agreement (CRDA) between the Clinical Investigation Regulatory Office (CIRO) and TRUE Research Foundation, Control No.-0310-T-C746, submitted 19 December 2006. Amendment #4 covered changes to CRDA affecting type and cost of equipment due to ultrasonic equipment exchange.
- MAMC began enrolling subjects on 20 January 2006. A total of 13 subjects were consented in 2006 from Bassett Army Community Hospital.
- During 2006, a total of 15 subjects were enrolled as training model volunteers.
- Madigan's TeleEcho System is completely set up and ready to receive.

Bassett Army Community Hospital (BACH), Ft Wainwright, AK

- Annual Continuing Review of protocol. Approved: 24 January 2006. A separate protocol is unnecessary as BACH is under MAMC command and covered by MAMC IRB. BACH has our most currently approved consent form available for use.
- Changes to staff over 2006. CPT Rebecca Wells, MD changed duty stations and left the study. CPT Steven Jay, MD took over as PI. A MOR with the staff update was submitted to Chair, MAMC IRB and approved on 20 September 2006.

- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- The TeleEcho System is complete and connected. NIPRNET connection authorized and active.
- A total of 13 subjects were consented in 2006 from Bassett Army Community Hospital. No SAE to report.
- In 2006, follow-up conventional echocardiography was performed on 9 consented subjects by COL James, B. Kinney, MD during outpatient cardiac clinics held at Bassett.

Weed Army Community Hospital (WACH), Ft. Irwin, CA

- Annual Continuing Review of protocol. Approved: 24 January 2006. A separate protocol is unnecessary as WACH is under MAMC command and covered by MAMC IRB. WACH has our most currently approved consent form available for use.
- Changes to staff over 2006. Major Thomas E Byrne, MD assigned as site Medical Monitor for the TeleEcho Protocol at Weed. Effective 18 January 2006.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Weed received all necessary components for the TeleEcho System. TeleEcho System has been partially assembled.
- NIPRNET connection authorized and awaiting final connection to TeleEcho System.
- Once the TeleEcho System is fully assembled and tested and investigators receive refresher training, WACH will be ready to enroll subjects. Anticipated date: May 31, 2007.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Annual Continuing Review of site-specific protocol. Approved: 11 April 2006.
- No changes to staff in 2006.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- ANMC site-specific protocol submitted to HSRRB for final review and approval. Due to lengthy delays by HSRRB, the file was reassigned in September 2006. HSRRB review almost complete.
- ANMC received all necessary components for the TeleEcho System. TeleEcho System has been assembled and has active IP (Internet Protocol) connection. IP connection tested at 512kbps on 9 November 2006. Great audio and visual transmission.
- ANMC will be ready to enroll subjects once final HSRRB approval has been granted and investigators receive refresher training. Anticipated date: Summer 2007.

3rd Medical Group (3MDG), Elmendorf AFB, AK

- Annual Continuing Review of site-specific protocol. Approved: 1 May 2006.
- Changes to staff in 2006. Major Heather Jones, MD assigned as site Medical Monitor for the TeleEcho Project at 3MDG. Effective 28 July 2006.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- 3MDG site-specific protocol submitted to HSRRB for final review and approval. Due to lengthy delays by HSRRB, the file was reassigned in September 2006. HSRRB review in progress.
- 3MDG received all necessary components for the TeleEcho System.
- NIPRNET connection at 3MDG has encountered numerous roadblocks. Including being routed all the way to HQ AF Communications Agency in Washington, D.C. After review, HQ AF Communications Agency recognized no major issues and fielded the issue back to HQ PACAF. CPT Sorrells, 3MDG CIO, still has some concerns with connecting the TeleEcho System to his network. He will work with the technical consultants and network administrators to resolve the concerns.
- 3MDG will be ready to enroll subjects once final HSRRB approval has been granted, connectivity to the NIPRNET is finalized, and investigators receive refresher training. Anticipated date: Fall 2007.

Naval Hospital Bremerton (NHB), Bremerton, WA and Oak Harbor Naval Hospital (NHOH), Oak Harbor, WA

- The site-specific protocol for NHOH and satellite package for NHB went through several IRB reviews in 2005 and 2006 before receiving tentative approval on 13 December 2006. The final rewrite was approved on 14 February 2007. Revisions included (1) Clarification of the hypothesis (2) Clarification of the statistic section of the protocol (3) Clarification that infant will be cared for according to standard of care practices (4) Addition of both parents consent in Third Party Informed Consent Document. (5) Including in the Risk section the possibility of a “false positive/negative” result with the ultrasound images. IRB official approval letter forthcoming.
- 3-Party Cooperative Research & Development Agreement (CRDA) between Naval Hospital Oak Harbor / Naval Hospital Bremerton and TRUE Research Foundation and Oregon Health & Science University finally completed & signed copy arrived at MAMC. Signatures: TRUE - 19Aug2005, OHSU - July 2005, NHB - 23 Sep 2006, NHOH - 27 Oct 2006.
- Memorandum of Understanding between Madigan Army Medical Center and Naval Hospital Bremerton (MCSJ-131-04) effective 1 September 2005 – 1 September 2007.
- Memorandum of Understanding between Madigan Army Medical Center and Naval Hospital Oak Harbor (MCSJ-130-04) effective 1 August 2006 – 1 August 2009.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- Curriculum Vitae are current for all site investigators.

- Drs Sahn, Puntel, & Kinney privileges are current.
- NHOH & NHB site-specific protocol submitted to HSRRB for final review and approval. Due to lengthy delays by HSRRB, the file was reassigned in September 2006. HSRRB review in progress.
- Bremerton received all necessary components for the TeleEcho System but the system has not been assembled while they wait for IRB approval.
- Bremerton has authorization to connect to the NIPRNET to test connections. Once IRB approval is official the TeleEcho System will be fully connected and test calls placed to MAMC.
- Dr Puntel holds monthly cardiac clinics at NHB. Local Investigators rotate during the clinic to retain proficiency performing supervised echocardiograms.
- Bremerton is ready to enroll subjects once final IRB and HSRRB approval has been granted and equipment connected and tested. Anticipated date: June 2007.
- Oak Harbor received all necessary components for the TeleEcho System and the system is assembled and ready for use once official IRB approval is granted.
- Oak Harbor will authorize local network connection to the NIPRNET once we receive full NETCOM Authorization to Operate (ATO).
- Oak Harbor is ready to enroll subjects once final IRB and HSRRB approval has been granted, TeleEcho System connection to NIPRNET, and investigators receive refresher training. Anticipated date: June 2007.

Blanchfield Army Community Hospital, Ft. Campbell, KY

- Site-specific protocol closed due to no current Principal Investigator. The original PI, Dr. Robert Moore, is no longer at Blanchfield ACH. CPT Carol J. Rowe, MD volunteered to be PI but then deployed. Once CPT Rowe meets IRB requirements and finishes CITI training, the protocol will be resubmitted to Eisenhower Army Medical Center IRB.
- Data Use Agreement and Waiver of Authorization complete and approved.
- Original protocol documents submitted to HSRRB but due to lengthy delays by HSRRB, the file is no longer current. A current site specific protocol will be submitted to the HSRRB for final approval once the PI has completed necessary requirements.

Bayne-Jones Army Community Hospital (BJACH), Ft. Polk, LA

- Annual Continuing Review of site-specific protocol. Approved: August 2006.
- Changes to staff over 2006. MAJ Robert Crowe, MD changed duty stations and left the study. CPT Monica Mirchandani, MD took over as PI. A MOR with the staff update was submitted to Chair, BAMC IRB and approved on 6 August 2006.
- Data Use Agreement and Waiver of Authorization complete and in place.
- BJACH site-specific protocol submitted to HSRRB for final review and approval. Due to lengthy delays by HSRRB, the file was reassigned in September 2006. HSRRB review almost complete.

Yukon-Kuskokwin Health Corporation (YKHC), Bethel, AK

This facility is holding off on participating in the study due to staff constraints.



Training session:
COL Kinney helping
with a baby echo at
MAMC

An update of the infrastructure plans to bring up site connections.

Madigan Army Medical Center (MAMC), Ft. Lewis, WA

- Madigan is up and running.

Bassett Army Community Hospital (BACH), Ft. Wainwright, AK

- Bassett is up and running.

Weed Army Community Hospital (WACH), Ft. Irwin, CA

- I spoke with Dennis Clark, Network Specialist at Weed. IMD has no issues and they are a go once the investigator is ready to connect the equipment to the NIPRNET.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Initially ANMC wanted to use Internet-2 (I-2) for the TeleEcho Project. After discussing this further with investigators and IMD a decision was made to utilize standard IP at this time. If ANMC were to connect via I-2 they would only have access to 1 Pediatric Cardiologist at Oregon Health & Science University in Portland. Since Madigan does not have I-2 capability at this time, ANMC would not be able to place a call to the 2 Pediatric Cardiologists at Madigan. By using standard IP, investigators at ANMC will have access to all 3 Pediatric Cardiologists.
- Alaska Native Medical Center received all necessary components for the TeleEcho System. The System has been assembled and has active IP (Internet Protocol) connection. A test call between Madigan and the IMD department was held on 9 November 2006 to test the IP connection. The call was placed at 512kbps with better than anticipated audio and video transmission. The TeleEcho System was transferred to an examination room and Dr Engel, PI at Alaska Native, performed another test call sending ultrasound transmissions on 27 November 2006. Virtually no delay. Once the local IRB approves the new informed consent document for training volunteers, we will arrange another test call using images from an infant or small child.

3rd Medical Group (3MDG), Elmendorf AFB, AK

- 3MDG received all necessary components for the TeleEcho System. NIPRNET connection at 3MDG has encountered numerous roadblocks, including being routed all the way to HQ AF Communications Agency in Washington, D.C. After review, HQ AF Communications Agency recognized no major issues and fielded the issue back to HQ PACAF. CPT Sorrells, 3MDG CIO, has some concerns with connecting the TeleEcho System to their local area network. He explained that the Air Force network is more stringent than the Army's. His biggest concern is that 3 Polycom port ranges are flagged as potential threats according to the Air Force Approval Matrix. Two of the port requests are Yellow (medium threat) and one is Red (High threat). He will work with the technical consultants and network administrators to resolve the concerns. Additionally, CPT Sorrells explained this is a bad time for adding new systems to the network, it may take quite a bit of time.

Naval Hospital Oak Harbor (NHOH), Oak Harbor, WA

- Oak Harbor received all necessary components for the TeleEcho System and the system is assembled and ready for use once official IRB approval is granted. Nancy Peterson, Oak Harbor CIO, will authorize local network connection to the NIPRNET once we receive full NETCOM Authorization to Operate (ATO).

Naval Hospital Bremerton (NHB), Bremerton, WA

- The IMD at Bremerton is ready to connect the TeleEcho System to the NIPRNET. The equipment needs to be fully assembled and connected to the local area network. Once this is accomplished, testing can begin. Due to the lengthy approval process, investigators were waiting on final IRB approval before beginning.

Yukon-Kuskokwin Health Corporation (YKHC), Bethel, AK

- This facility is holding off on participating in the study due to staff constraints.

Summarized progress:

As of 2/28/2007: A total of 52 subjects have been consented and enrolled to date. Col James B. Kinney, MD conducted outpatient cardiac clinics at Bassett Army Community Hospital in 2006. Nine 3 month follow-ups were accomplished during the clinics. Cardiac abnormalities such as PFO, VSD, and PDA were recognized by TeleEcho and confirmed 100% with follow-up conventional echocardiography. One patient diagnosed with Tetralogy of Fallot underwent heart surgery and is doing well.

We held 2 TeleEcho Training Sessions, training 4 providers and awarding 28 category 1 CME credits. All active sites have at least one trained provider and all the equipment necessary. Madigan, Bassett, Weed, American Native, and Bremerton received approvals to connect to local area networks. The secure website and database used for data collection is ready for use. All sites, except Yukon, have received the necessary medical equipment for the study and we are making arrangements to swap out equipment per CRDA.

Currently Bassett, Weed, American Native, Elmendorf, and Bayne-Jones have received IRB approval and continuing approval for 2007 is expected. Oak Harbor and Bremerton's protocol is tentatively approved as of 2/14/2007 by Naval Medical Center San Diego. Full approval should follow quickly. Blanchfield will resubmit to the IRB once

a new PI completes all requirements. Yukon is still on hold due to staff constraints. HSRRB has begun the process of reviewing all IRB approved protocols. We await HSRRB final authorization before enrolling subjects at approved sites

Small apical muscular VSD in a newborn which was verified during a visit by COL Kinney, and then closed spontaneously.



TASK 4

Data Review

Key Research Accomplishments

CPT Ronald Wells at Basset Army Community Hospital (BACH) in Anchorage performed an unofficial exam late winter 2005. COL Kinney at MAMC taught him to perform echocardiograms in late February 2005. After he had been trained on his Sonosite©, and before his Telemedicine NIPRNET connection was activated, he performed an echo on a cyanotic newborn infant; and in discussing the echo with Col Kinney, it was confirmed that he had correctly diagnosed the baby with hemi-truncus, a complex cyanotic heart condition. The baby was promptly transferred to Anchorage for stabilization and cardiac treatment, and eventually underwent corrective surgery at Emmanuel Hospital in Portland.

The first Remote Supervision subject was enrolled in the study at Bassett Army Community Hospital on 20 January 2006. Justifying the need for remote site echocardiography, Bassett called Madigan just .50 an hour after evaluation and receiving clearance to begin subject enrollment! At 1430, Dr Garfinkle at BACH called because a 2 week old male was brought into the outpatient clinic with a loud murmur, suspected to be Pulmonic stenosis. Dr Puntel diagnosed the infant with a healthy heart, physiologic peripheral pulmonary artery stenosis and a patent foramen ovale, physiological for a newborn infant. The entire call took about 25 minutes.

Using the Tele-ECHO protocol and equipment on 8 May 2006, a 3 day old baby who had presented with a murmur in Fairbanks, Alaska was diagnosed within 5 minutes of the study as having the heart defect Tetralogy of Fallot. She was then transferred to

Madigan via Air EVAC for stabilization and within 2 days and formal final diagnoses and treatment plans were initiated. She was later referred to OHSU where she underwent cardiac surgery and had an excellent course.

In-coming echo
session from
Fairbanks



Reportable Outcomes

A software program has been developed which operates through the NIPRNET and the Polycom© units and will allow the remote supervisor to operate a number of track ball accessible adjustments on the MicroMaxx® ultrasound scanner being used to study patients at the distant site. Since this is a fully digital system, the remote control allows optimization of more controls of Doppler parameter control, color Doppler quality, and directed sampling for M-mode and spectral Doppler recordings. This feature will be transferred to the new MicroMaxx.

TASK 5

Data analysis

Not Started

TASK 6

Program evaluation

Not started

The grant is in a no-cost extension period with funds to operate for 18 months. As patient entry proceeds, data analysis and program evaluation will progress.

CONCLUSION

Progress had been slowed by the multiple human subject approvals required, the complex arrangements to avoid prohibitive costs for ISDN lines, and placement of our telemedicine system on the NIPRNET. Only YKHC in Bethel, AK awaits entrance to the study; due to their remoteness, they chose to wait until new staff arrives and can be trained. This spring we will swap out the Elite® systems for the new MicroMaxx® scanners, brush up trained individuals on the new control philosophy, and, of course, continue to help infants in underserved regions.