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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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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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STATEMENT OF WORK

The tasks in this project involve:

1. Installation of ultrasound scanning and telemedicine network equipment, set-up and testing of website for data entry

Equipment would be ordered from SonoSite and Polycom for the major equipment and other vendors for videotape recorders and monitors by OHSU staff, as defined in the Year 1 budget. Website would be live as of March 1, 2003.

Polycoms would be shipped to the Centers where local staff working with our MAMC and OHSU Telecommunications staff would connect them and program them. Two-way communications would be established between each hospital and MAMC and OHSU Polycoms during the first quarter of 2003. SonoSite will complete their project and load the new remote instrument control software in the third quarter of 2003.

2. Training of staff and beginning entry of patients into the study

Our administrators working with those at Madigan Army Medical Center would begin a survey of dates for the first training sessions at MAMC. POCs at the Military and Native Alaskan Health Care Centers would select those individuals to travel to each of the two sessions – presumably to be held in February 2003. Travel would be arranged for the network trainees by MAMC staff. MAMC staff would then visit sites. The visiting pediatric Cardiologist from MAMC would declare each site “on line” at his discretion after the visit.

Each site would be given a roster listing for the next 90 days of the physician(s) available to supervise their echos for each 24hour period and the contact numbers at MAMC or OHSU. This schedule would be updated 30 days before the start of each subsequent 90-day period.

3. Web-based data entry and selection of historical controls

The research nurses from OHSU or the Study coordinator for each site would also go on the initial site visit with the intention of walking the local staff through the aspects of Website data entry. Dr. Grigsby from Colorado working with Sahn and Webb would finalize the website for data entry. It would be anticipated that all sites would be “on line”, the website up, and data being entered by April 1, 2003.

Beginning with data entry of study patients, the staff for the Lead Agent would begin to identify the concurrent controls from Fort Polk and Fort Campbell. In February 2004, they will begin the pull of the historical match data. Summer 2004 site visits would again be made to assist local staff in cleaning up any data entry forms and identify and enter historical match data that might be lacking.

In April 2005, a GLS 212 IP SAT satellite communication system will be installed at Elmendorf AFB Hospital and for a period of 6 months, KU band will be used to send data to OHSU (only) so the trans-satellite performance of the telemedicine consultation can be compared to the Polycom results.

4. Data review

In May, 2004, the core group, Sahn, Grigsby, Webb, Carter, Puntel, Kinney and their auxiliary staff as necessary would meet at MAMC to go over progress to date, review initial experiences, and Web entries to date. In September 2004 the Core group meeting would be followed in the same location by a total network meeting and initial data review. Representatives from the outlying centers would be encouraged to attend as possible.

5. Data analysis

Periodic core group meetings would be implemented for data analysis. Periodic meetings of the entire Network will also occur as shown on the Timeline, Page 27.

6. Program evaluation

At the end of the study, equipment would remain in the outreach center and they would be free to use it as their medical staffs determined. They would also be free to seek their own telemedicine contacts for continued endeavors or to re-enroll staff with continuations or additional studies developed by the OHSU partnership.

TASK #1

A. Installation of Sonosite Ultrasound Systems

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

- Madigan is up and running on both NIPRNET and MEDNET. As soon as all sites have registered with United States Army Medical Information Technology Center (USAMITC), access to the NIPRNET will be removed.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.

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

- Bassett is up and running on both NIPRNET and MEDNET. As soon as all sites have registered with USAMITC, access to the NIPRNET will be removed.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.

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

- Weed is up and running on both NIPRNET and MEDNET. As soon as all sites have registered with USAMITC, access to the NIPRNET will be removed.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Alaska Native Medical Center is up and running with an active IP (Internet Protocol) connection. Once the system at ANMC has registered with the outside gatekeeper at USAMITC, the connection between the non-DoD facility and Madigan will be re-established.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.

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 Polycm 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. Since the MEDNET is an approved VTC network for the DoD, it should speed up connectivity approvals with the Air Force.

- The older SonoSite ultrasound system has not been exchanged for the newer all digital MicroMaxx. The swap out will occur once the Air Force solves the connectivity issue.

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

- Oak Harbor is up and running with an active IP (Internet Protocol) connection. Once the system at Oak Harbor has registered with the outside gatekeeper at USAMITC, the connection to Madigan will be re-established.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.

Naval Hospital Bremerton (NHB), Bremerton, WA

- The TeleEcho System at Bremerton is fully assembled and in place.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- Once the system at Bremerton has registered with the outside gatekeeper at USAMITC, the connection to Madigan will be established and testing can begin.

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

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

B. Communications Infrastructure

Due to the security environment in the Army, all VTC over IP are in process of removal from the NIPRNET. United States Army Medical Information Technology Center (USAMITC) now provides the infrastructure for a single Army medical network (MEDNET) operating environment that enables corporate information sharing and centralized management. The creation of MEDNET or USAMITC Video Network Center bridge allows for a secure and efficient means of providing channels for video teleconferencing for DoD and non-DoD facilities.

We are currently in transition of moving our communication infrastructure from the NIPRNET to the MEDNET. The necessary hardware is already in place at the Army facilities. Non-Army facilities will be able to connect by registering their IP addresses with the outside gatekeeper at USAMITC. Once registered, the firewall will allow calls between the approved and authorized systems.

Technical delays and difficulties are expected to decrease with the additional support from the experienced staff at USAMITC. Utilizing the Army's MEDNET infrastructure and security will ensure continued stability, sustainability, and viability.

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 – June 2008:

- 18 TeleEcho Training Seminars
- 36 days of training
- 34 Providers trained to perform supervised echocardiograms
- CME Credits Offered: 224
- CME Credits Assigned: 224

14 Category-1 CME credits were offered for each trainee attending the TeleEcho Training Seminar held October 2005-September 2006 and October 2007 – September 2008.

Learning Objectives

Initial training for pediatricians, family physicians or nurse practitioners for the Tele-ECHO project. This is held at Madigan Army Medical Center in the clinic and the NICU.

Learning objectives:

1. Learners will understand the physical basis of ultrasonography including 2-dimensional imaging and Doppler ultrasound utilizing both, the portable SonoSite ultrasound machine as well as standard ATL or HP echocardiography machines.
 2. Learners will learn and demonstrate competence in performing the complete transthoracic echocardiogram with practice and demonstration on consented infants at Madigan AMC to include 2-dimensional views, color and spectral Doppler interrogation, and m-mode echocardiography.
 3. Learners will discuss and demonstrate understanding of common congenital cardiac defects and their appearance on echocardiography as well as their clinical presentation using live patients as available, as well as internet, text, slides, and videotaped cases.
 4. Learners will discuss and demonstrate understanding of the clinical management of congenital cardiac lesions.
 5. Learners will review Human Subject issues and consenting families, as well as data entry, internet systems for data collection, and the equipment used to transmit and record the tele-echo images.
 6. Learners will demonstrate competence with Protection of Human Research Subjects by completing CITI online training before attending training.
 7. Learners will demonstrate proficiency by performing satisfactorily a minimum of 5 echocardiograms only with verbal guidance from the instructor.
-
- 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 15 – March 16, 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)
- December 18 – December 19, 2007
LCDR Jeff Martens, MD, NHB
Dr Ruth Faircloth, MD, MAMC (Resident)
- January 14 – January 15, 2008
CPT Peter Vickerman, MD, BACH
Dr Lauren Gist, MD, NHB
- April 8 – April 9, 2008
LCDR Jeff McClellen, MD, NHB
CPT Dr Johnson Isaac, MD, MAMC
- May 6 – May 7, 2008
CPT Rebeckah Burns, MD, BACH

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:

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

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

- Annual Continuing Review of protocol. Approved: 14 January 2007 and 22 January 2008.
- No changes to staff in 2007.
- 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.
- A total of 17 subjects have been enrolled from Bassett Army Community Hospital.
- During 2007, 4 subjects were enrolled as training model volunteers.
- To date in 2008, 10 subjects were enrolled as training model volunteers.
- Madigan's TeleEcho System is fully operational. The conversion from NIPERNET to MEDNET should be seamless to the end user with no loss of connectivity.

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

- Annual Continuing Review of protocol. Approved: 27 January 2007 and 22 January 2008. 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. Dr Steven Jay separated from the Army but will remain at Bassett as a civilian physician through the summer of 2008. He decided to move into the medical monitor position. Dr CPT Rebeckah Burns, MD and CPT Peter Vickerman, MD joined the study in early 2008. CPT Burns assumed the role of PI and CPT Vickerman assumed the role of AI. A MOR with staff updates was submitted to Chair, MAMC IRB on 13 May 2008.
- CPT Peter Vickerman, MD deployed for Iraq with an anticipated return date of May 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.
- Bassett's TeleEcho System is fully operational. The conversion from NIPERNET to MEDNET should be seamless to the end user with no loss of connectivity.
- Due to physician turnover, only 1 subject was consented in 2007 from Bassett Army Community Hospital. No SAE to report.
- Three subjects have been consented to date in 2008 from Bassett Army Community Hospital. No SAE to report.
- 2007 to date, follow-up conventional echocardiography was performed on 6 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: 27 January 2007 and 22 January 2008. 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.
- No changes to staff in 2007.
- 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.
- Bassett's TeleEcho System is fully operational. The conversion from NIPERNET to MEDNET should be seamless to the end user with no loss of connectivity.
- MAJ Peaches Richards, MD received TeleEcho Refresher training on 21 November 2007.
- WACH is ready to enroll subjects.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Annual Continuing Review of site-specific protocol. Approved: 31 July 2007.
- Changes to staff in 2007. Haitham Salman is no longer at ANMC.
- 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 was reviewed and approved by HRPO as of 1 November 2007.
- The TeleEcho System at ANMC is fully operational with an active IP address. They are in process of registering with the Army's gatekeeper to remain in communication after the conversion to MEDNET.
- Enrollment of subjects can begin once refresher training is completed. Madigan is working with site investigators to schedule refresher training. Anticipated date: June 2008.

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

- Annual Continuing Review of site-specific protocol. Reviewed: 2 June 2008. IRB is withholding approval letter until site PI completes CITI training.
- No changes to staff in 2007.
- CITI - The Protection in Human Research Subjects Training is now an annual event for the Air Force. The Medical Monitor has completed CITI training and the PI is expected to complete training soon.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- 3MDG site-specific protocol submitted to HRPO for final review and approval. HRPO is waiting for the IRB continuing review to complete before issuing their approval as well.
- 3MDG received all necessary components for the TeleEcho System; however they will not be upgraded to the MicroMaxx until connections have been authorized.
- Connectivity with 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. The MEDNET should offer an acceptable solution to keep the TeleEcho System off the Air Force network.

- 3MDG will be ready to enroll subjects once final HRPO approval has been granted, connectivity to the MEDNET is finalized, and investigators receive refresher training. Anticipated date: Summer 2008.

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

- Annual Continuing Review of site-specific protocol for NHOH and satellite package for NHB. Approved: 12 December 2007.
- 3-Party Cooperative Research & Development Agreement (CRDA) between Naval Hospital Oak Harbor / Naval Hospital Bremerton and TRUE Research Foundation and Oregon Health & Science University current and in place.
- The first Memorandum of Understanding (MOU) between Madigan Army Medical Center and Naval Hospital Bremerton (MCSJ-131-04) has expired. The MOU renewal (MCHJ-120-08) is awaiting signatures and will be effective for 5 years.
- Memorandum of Understanding between Madigan Army Medical Center and Naval Hospital Oak Harbor (MCSJ-130-04) effective 1 August 2006 – 1 August 2009.
- DoD Assurance for Naval Hospital Oak Harbor, DoD N40027, renewed. Expires 30 January 2010.
- Changes to Staff in 2007 at Bremerton. CDR Westbrook had a change of duty station and is no longer at Bremerton. Dr CDR Charles Blackadar is no longer at Bremerton. LCDR Jeffrey Martens, LCDR Jeff McClellan, and Dr Lauren Gist joined the study as Associate Investigators (AI) at Bremerton. CDR Dommermuth moved from the role of medical monitor to AI. Deborah Hill is the new medical monitor.
- No changes to staff in 2007 at Oak Harbor.
- 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.
- Site-specific protocol for NHOH and satellite package for NHB was reviewed and approved by HRPO as of 16 November 2007.
- The TeleEcho System at Bremerton is fully operational.
- Bremerton has authorization to connect via IP for test calls.
- 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 the MOU is renewed and connectivity is approved. Anticipated date: June 2008.
- The TeleEcho System at Oak Harbor is fully operational.
- LCDR Andrea Donalty, MD received TeleEcho Refresher training on 21 May 2008.
- Oak Harbor is authorized to enroll subjects.

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 HRPO but are no longer current. A current site specific protocol will be submitted to the HRPO for final approval once the new PI has completed necessary requirements.

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

- Annual Continuing Review of site-specific protocol. Approved: 6 June 2007. Annual Continuing Review for 2008 submitted and awaiting approval.
- Changes to staff. CPT Monica Mirchandani, MD is no longer at Bayne-Jones. CPT Jennifer LaBahn, MD took over as PI. A MOR with the staff update was submitted to Chair, BAMC IRB with the 2008 continuing review.
- Data Use Agreement and Waiver of Authorization complete and in place.
- BJACH site-specific protocol submitted to HRPO for final review and approval. HRPO is waiting for the IRB continuing review to complete before issuing their approval as well.

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 6/16/2008: A total of 75 consented subjects to date. Including 58 subjects enrolled at MAMC for training purposes, and 17 subjects consented to TeleEcho at Bassett Army Community Hospital. Col James B. Kinney, MD conducted outpatient cardiac clinics at Bassett Army Community Hospital in 2007 and beginning of 2008. Six 3 month follow-ups were accomplished during the clinics. Cardiac abnormalities such as PFO, VSD, ASD, and coarctation were recognized by TeleEcho and confirmed 100% with follow-up conventional echocardiography. The patient diagnosed with coarctation underwent heart surgery and is doing well.

We held 4 TeleEcho Training Sessions, training 7 providers and awarding 84 category 1 CME credits. All active sites have at least one trained provider and all the equipment necessary. Madigan, Bassett, Weed, American Native, and Oak Harbor and Bremerton received approvals to connect to local area networks and are in process of converting to the MEDNET. All sites, except Yukon, have received the necessary medical equipment for the study and equipment swap out per CRDA has been completed.

Currently Madigan, Bassett, Weed, American Native, Elmendorf, Oak Harbor, Bremerton, and Bayne-Jones have received IRB approval and continuing approval for 2008 is anticipated. Blanchfield will resubmit once a new PI completes all IRB requirements. Yukon is still on hold due to staff constraints. HRPO has reviewed and approved Madigan, Bassett, Weed, American Native, Oak Harbor, and Bremerton for enrollment. HRPO is in process of reviewing Elmendorf and Bayne-Jones.

TASK #4

Data Review

Key Research Accomplishments

In January 2008, a 3 day old male at Bassett Army Community Hospital in Fairbanks, AK was diagnosed with coarctation, transported, and underwent surgery before any serious symptoms developed. The on-call family practitioner at Bassett could not appreciate femoral pulses on the subject while in the nursery. Differential BP's showed a 20-30 point drop in BP's from upper extremity to lower extremity. The investigator could not appreciate distal pulses the morning of the TeleEcho transmission. Dr Robert Puntel at Madigan recognized a moderate

coarctation with a gradient of 35mmHg and recommended the infant transfer to Children's in Seattle for probable surgical repair within the next 24-48 hours. The infant is now doing well.

The telemedicine system has also been useful in cases that did not qualify for the study due to the subject's age or condition. Eliminating unnecessary transport from Whidbey Island to Madigan Army Medical Center and eliminating additional exposure to x-ray and MRI.

Reportable Outcomes

A software program has been developed which operates through the Polycom© units, allowing 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. The software program is expected to deploy in 2008.

New Scanners Installed

We have completed the replacement of the SonoHeart Elite® systems with the new Digital system the MicroMaxx®. The MicroMaxx® system 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. In addition, the MicroMaxx digital images transmit with higher quality resulting in a clearer image at the reading sites.

TASK #5

Data analysis

Not started

TASK #6

Program evaluation

Not started

CONCLUSION

Progress had been slowed by the multiple human subject approvals required, investigator turnover and recruitment, placement of telemedicine systems on IP and conversion to the MEDNET. 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. The swap out the Elite® systems for the new MicroMaxx® scanners is complete in all but one site that will not yet allow connectivity. This year we plan to continue enrolling subjects at all the approved sites, provide initial and refresher training to investigators at remote sites, and of course, continue to help infants in underserved regions.