

Award Number: DAMD17-03-1-0109

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

PRINCIPAL INVESTIGATOR: David J. Sahn, M.D.
COL James Kinney, M.D.
LTC Robert Puntel, M.D.

CONTRACTING ORGANIZATION: Oregon Health & Science University
Portland, OR 97239

REPORT DATE: March 2009

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE			<i>Form Approved</i> <i>OMB No. 0704-0188</i>		
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE (DD-MM-YYYY) 01-03-2009		2. REPORT TYPE Final Addendum		3. DATES COVERED (From - To) 15 Aug 2008 - 14 Feb 2009	
4. TITLE AND SUBTITLE Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in Babies at Remote Military or Native American Health Care Facilities			5a. CONTRACT NUMBER		
			5b. GRANT NUMBER DAMD17-03-1-0109		
			5c. PROGRAM ELEMENT NUMBER		
6. AUTHOR(S) David J. Sahn, M.D.; COL James Kinney, M.D.; LTC Robert Puntel, M.D. E-Mail: sahd@ohsu.edu			5d. PROJECT NUMBER		
			5e. TASK NUMBER		
			5f. WORK UNIT NUMBER		
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Oregon Health & Science University Portland, OR 97239			8. PERFORMING ORGANIZATION REPORT NUMBER		
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012			10. SPONSOR/MONITOR'S ACRONYM(S)		
			11. SPONSOR/MONITOR'S REPORT NUMBER(S)		
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT Our partnership of investigators from Madigan Army Medical Center at Fort Lewis, Washington, and Oregon Health & Science University in Portland, is testing 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 Medial 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 37 non cardiologists to perform neonatal echo and has installed a high bandwidth telecommunications link using the military version of Internet2, NIPRNET. As of the end of 2008, we have been 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 upgraded the scanners used in our network to the latest architecture from Sonosite®: the fully digital phased array handheld ultrasound scanner, the MicroMaxx®, and implemented the capability of having the supervising expert run the scanner remotely via IP connection.					
15. SUBJECT TERMS Echocardiography; Ultrasound; Telemedicine; Neonates; Congenital Heart Disease; Outcomes					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
U	U	U	UU	17	USAMRMC

Table of Contents

	<u>Page</u>
Introduction.....	4
Body.....	4
Key Research Accomplishments.....	13
Reportable Outcomes.....	13
Conclusion.....	15
References.....	15
Appendices.....	16

Summarized Progress:

As of 12/31/2008: A total of 82 consented subjects to date. Including 63 subjects enrolled at MAMC for training purposes, and 18 subjects consented to TeleEcho at Bassett Army Community Hospital and 1 subject enrolled at Naval Hospital Oak Harbor. Col James B. Kinney, MD conducted four outpatient cardiac clinics at Bassett Army Community Hospital in 2008. Three 3-month follow-ups were accomplished during the clinics. Cardiac abnormalities such as PFO, PPS, VSD, coarctation and Tetralogy were recognized by TeleEcho and confirmed 100% with follow-up conventional echocardiography. The patients diagnosed with coarctation and Tetralogy underwent heart surgery and are doing well.

We held 5 TeleEcho Training Sessions in 2008, training 8 providers and awarding 84 category-1 AMA 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 have converted 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 2009 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.

1. 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 during 22 January 2008 IRB meeting. Next continuing review in January 2009.
- No changes to staff in 2008.
- 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 18 subjects have been enrolled from Bassett Army Community Hospital.
- One subject was enrolled from Naval Hospital Oak Harbor.
- 2008, 15 subjects were enrolled as training model volunteers.

- Madigan's TeleEcho System is certified and registered on the USAMITC Bridge and fully operational. The transition took longer than anticipated causing 3 months lapse in data collection.

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

- Annual Continuing Review of protocol. Approved during 22 January 2008 IRB meeting. Next continuing review in January 2009. 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 remained at Bassett as a civilian physician. He transferred to 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. Dr Steven Jay is due refresher training in 2009.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- CPT Peter Vickerman received initial TeleEcho Training on January 14-15, 2008. CPT Rebeckah Burns received initial TeleEcho Training on May 6-7, 2008.
- Bassett's TeleEcho System is certified and registered on the USAMITC Bridge and fully operational.
- BACH is currently enrolling subjects. Due to deployments causing physician shortage, 5 subjects were consented in 2008 from Bassett Army Community Hospital. No SAE to report.
- Three month follow-up conventional echocardiography was performed on 3 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 during 22 January 2008 IRB meeting. Next continuing review in January 2009. 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 2008.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators. Dr Peaches Richards and Dr Thomas Byrne are due CITI refresher training in 2009.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- Weed's TeleEcho System is certified and registered on the USAMITC Bridge and fully operational.
- Dr Ronald Williams and Margaret Williams, PNP, received TeleEcho Training at Madigan before transferring to WACH. Once they have completed CITI training, they will be officially added to the study in 2009.
- WACH is ready to enroll subjects.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Annual Continuing Review of site-specific protocol. Alaska Area IRB approved during 29 July 2008 IRB meeting. Alaska Native Tribal Health Consortium (ANTHC) approved 5 December 2008. Next continuing review in June 2009.
- ANMC site-specific protocol was reviewed and approved by HRPO as of 1 November 2007; however, it was suspended until ANTHC approved the protocol as per Alaska Area IRB requirements. ANTHC approved protocol on 5 December 2008.
- No changes to staff in 2008.
- CITI - The Protection in Human Research Subjects Training: Dr Engel and Dr Gonzales due refresher training.
- Curriculum Vitae are current for all site investigators.
- Drs Sahn, Puntel, & Kinney privileges are current.
- The TeleEcho System at ANMC is certified and registered on the USAMITC Bridge through the USAMITC outside gatekeeper. It is fully operational with an active IP address.
- Dr Michael Engel and Dr Calle Gonzales received TeleEcho Refresher training on 20 August 2008.
- ANMC is ready to enroll subjects.

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

- Annual Continuing Review of site-specific protocol. Approved on 1 May 2008.
- Changes to staff in 2008. Dr Laura Peterson was discharged from the Air Force but did not notify our office. We are working with Dr Heather Jones, the site medical monitor, in recruiting a new PI. The change in staff will be updated to IRB and HRPO in 2009.
- CITI - The Protection in Human Research Subjects Training is now an annual event for the Air Force. The Medical Monitor completed CITI training on 28 May 2008. 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 and continuing reviews were submitted to HRPO for final review and approval.
- 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 a new Principal Investigator is recruited and trained, final HRPO approval has been granted, and connectivity to the MEDNET is finalized. Anticipated date: Summer 2009.

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

- Annual Continuing Review of site-specific protocol for NHOH reviewed and ICD approved by Naval Medical Center San Diego (NMCS D) IRB on 23 September 2008; however, they are withholding the approval letter until Dr Dorey speaks to the IRB during the January 14, 2009 IRB meeting.
- Annual Continuing Review for site-specific satellite package for NHB was reviewed by NMCS D during the December 2008 IRB meeting. The IRB tabled the review and requested a physician be assigned to the study as medical monitor. CAPT Robert Martin has accepted the position and will be submitted to the IRB for review during the January IRB meeting.
- 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 (MCHJ-131-04) expired. MCHJ-120-08 supersedes MCHJ-131-04. Effective period 25 November 2008 – 24 November 2013.
- Memorandum of Understanding between Madigan Army Medical Center and Naval Hospital Oak Harbor (MCHJ-130-04) effective 27 October 2006 – 26 October 2009. Due to the many delays in receiving the Bremerton MOU renewal, we will begin the MOU renewal process for Oak Harbor in February 2009.
- DoD Assurance for Naval Hospital Oak Harbor, DoD N40027, renewed. Expires 30 January 2010.
- Changes to Staff in 2008 at Bremerton. CDR Dommermuth moved from the role of medical monitor to Associate Investigator (AI). Deborah Hill was going to be the new medical monitor but NMCS D IRB rejected the change. CAPT Robert Martin will join the study as medical monitor. LCDR Jeffrey Martens and Dr Lauren Gist will join the study as AIs at Bremerton. New changes anticipate approval in January 2009.
- Changes to staff in 2008 at Oak Harbor. LCDR Andrea Donalty and LCDR Chadley Huebner were removed as Investigators at Oak Harbor due to leaving the facility. LCDR Harlan Dorey was added as Principal Investigator. All documents were submitted to NMCS D IRB for review and approved during the September IRB meeting; however, the IRB approval letter is being withheld until LCDR Dorey calls in to the January 2009 IRB meeting to speak to the IRB board.
- 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 at Bremerton is fully operational.
- Once the system at Bremerton has registered with the outside gatekeeper at USAMITC, the connection to Madigan will be established and testing can begin; however, since the Navy sites do not have a MEDNET node they will run a straight IP (Internet Protocol) connection via the Bridge.
- 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 new medical monitor is approved and their system has been registered and certified with USAMITC's outside gatekeeper. Anticipated date: February 2009.

- The TeleEcho System at Oak Harbor is fully operational.
- LCDR Andrea Donalty, MD received TeleEcho Refresher training on 21 May 2008.
- LCDR Harlan Dorey received initial TeleEcho Training on December 9-10, 2008.
- NHOH is currently enrolling subjects. One subject was consented in 2008 from Naval Hospital Oak Harbor. No SAE to report.

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 for May 2008 IRB meeting. Awaiting approval letter from BAMC IRB.
- Changes to staff in 2008. 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 on 6 May 2008.
- CITI - The Protection in Human Research Subjects Training is current for all site investigators.
- 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 BAMC IRB continuing review approval letter before issuing their approval.

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

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

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

Summary February 2004 – December 2008:

- 20 TeleEcho Training Seminars
- 40 days of training
- 37 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 through 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 McClellan, MD, NHB
CPT Dr Johnson Isaac, MD, MAMC

- May 6 – May 7, 2008
CPT Rebeckah Burns, MD, BACH
- September 11, 2008
Dr Ronald Williams, MD, MAMC (PCS to WACH)
Margaret Williams, PNP, MAMC (PCS to WACH)
- December 9 – December 10, 2008
LCDR Harlan Dorey, MD, NHOH

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

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

- Madigan is certified and registered on the United States Army Medical Information Technology Center (USAMITC) Bridge. 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.
- Test calls demonstrate very good audio and video quality.

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

- Bassett is certified and registered on the USAMITC Bridge.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- Test calls demonstrate very good audio and video quality.

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

- Weed is certified and registered on the USAMITC Bridge.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- A test call utilizing the USAMITC Bridge will be conducted in January 2009.

Alaska Native Medical Center (ANMC), Anchorage, AK

- Alaska Native Medical Center is certified and registered on the USAMITC Bridge through the USAMITC outside gatekeeper. Routing the call through the USAMITC Bridge slows the transmission speed considerably. Until this issue is resolved, ANMC will continue to keep their IP (Internet Protocol) connection active.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- ANMC plans to upgrade, at their expense, their Polycom 512 to a Polycom VSX7000. The VSX7000 port settings allow for 100FULL vs. 10FULL allowing for increase video quality.

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. 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 certified and registered on the USAMITC Bridge; however, the Navy sites do not have a MEDNET node and run a straight IP (Internet Protocol) connection via the Bridge.
- The older SonoSite ultrasound system has been exchanged for the newer all digital MicroMaxx.
- Test calls demonstrate very good audio and video quality.

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; however, since the Navy sites do not have a MEDNET node they will run a straight IP (Internet Protocol) connection via the Bridge.

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

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

4. 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. The transition took longer than anticipated causing 3 months lapse in data collection.

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.

5. 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.

6. 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 using the TeleEcho System. 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. COL Robert Puntel, MD reading pediatric cardiologist 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.

In November 2008, a 2 day old male at Bassett Army Community Hospital in Fairbanks, AK was diagnosed with a Tetralogy variant, VSD with overriding aorta and pulmonary atresia using the TeleEcho System. The infant was asymptomatic and in process of being discharged when the Principal Investigator at Bassett recognized a murmur and requested a TeleEcho before sending the infant home over a long holiday weekend. COL James Kinney, MD reading pediatric cardiologist at Madigan quickly recognized a VSD with overriding aorta suggesting a Tetralogy variant; pulmonary arteries were not identified. He recommended follow up immediately with Dr Wellman at Providence in Anchorage and emergent catheterization. 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 the patient to additional exposure to x-ray and MRI.

7. 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.

We have now implemented remote control of the SonoSite MicroMaxx handheld system by the remote expert over IP connections and operating by a remote operating system, implemented via the Virtual User Interface PC application developed by SonoSite. Virtual User Interface allows control of all of the user accessible panel controls from the remote scanner by the expert with immediate response so that the physician or nurse performing the physical examination has only to direct the transducer while the remote supervising expert controls all other features of the examination, including turning on and off color Doppler, spectral analysis, adjustment of PRF, saving or reviewing clips.

The software has stable, consistent and fast performance over the Internet, is easy to install, easy to operate and feels truly interactive to the remote supervisor. In its first test implementations, it has optimized quality and shortened exam time substantially for neonatal tele-echocardiographic examinations.



Remote operation of the ultrasound system to optimize the echo exam and review images by videoconferencing link represents the next step in pediatric telemedicine.

8. 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.

9. References

None

APPENDIX 1

From: "Frank, Allegra K Ms True Foundation"
<Allegra.Frank@us.army.mil>
To: "Moaveni, Siamack Mr USAMMA" <Siamack.Moaveni@amedd.army.mil>
Date: 1/16/2008 5:50:26 PM
Subject: TeleEcho Project funding (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

Good afternoon Siamack. Thank you for taking a look at our program while visiting Madigan Army Medical Facility. I hope the information gathered below helps your proposal. Please feel free to contact me for any further information.

Full Protocol Title: "Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in Babies at Remote Military or Native American Health Care Facilities." Short Title "TeleEcho Project"

The TeleEcho Project is currently operating under Award No.DAMD17-03-1-0109.

Grant is scheduled to operate from 15 Feb 2003 - 14 Mar 2007.

We applied for and received a No Cost Extension to continue operating from 14 Mar 2007 - 14 Sep 2008.

Dr Sahn has confirmed that there are enough funds to continue current funding thru February 2009.

Job descriptions and CVs are available upon request.

Attached:

- Poster
- TeleEcho Project write up in the May 2007 edition of "Mountaineer"
- Grant Award
- No cost extension request
- Anticipated future operating budget

Sincerely,
Allegra K. Frank
TeleEcho Project Administrator
TRUE Research Foundation
Madigan Army Medical Center
Office/Fax (253) 968-1832
Classification: UNCLASSIFIED
Caveats: NONE

CC: "Puntel, Robert A COL MAMC" <robert.puntel@us.army.mil>, "David Sahn" <sahnd@ohsu.edu>

APPENDIX 2

Statement of Work

Continue running the Telemedicine Based Ultrasound for Detecting Neonatal Heart Disease in Babies at Remote Military or Native American Health Care Facilities program based out of Madigan Army Medical Center.

Keep all HS approvals and interorganizational agreements for networking and use of NIPRNET intact.

Maintain and upgrade or replace as necessary, video teleconferencing equipment.

Maintain and upgrade or replace as necessary, portable ultrasound systems.

Arrange follow-up and verification of patient diagnosis and status.

Maintain database of results and report them in Academic and Military literature and documents.

Expand the current program to incorporate 3 additional west coast sites and 2 more sites in Alaska – COL Puntel to determine.

Anticipated Annual Budget

GS-11/12 Salary & benefits for TeleEcho Project Administrator – Ms Allegra Frank.

Travel - \$18,000.

- Travel expenses for 5 practitioners to attend TeleEcho Training Seminar at Madigan Army Medical Center.
- Yearly CME/Conference for Administrator and 2 cardiologists.

Video teleconferencing equipment maintenance, upgrades, and new purchases - \$17,500

Portable ultrasound equipment maintenance, upgrades, and new purchases - \$45,000

Civilian Consultant services, Dr David J. Sahn - \$20,000

- Diagnosis, training, and program development.
- Recognized Regional Expert in Pediatric Cardiology with extensive experience in data collection and analysis.
- Will ensure continual verification that standard of care (SOC) is being met since Pediatricians and Family Practitioners are performing echocardiograms under supervision of Pediatric Cardiologist at MAMC, instead of echo-technicians.

Total - \$100,500 plus GS-11/12 salary & benefits

*Present inventory of equipment owned by OHSU, on permanent loan to facilities participating in TeleEcho Project.