

Award Number: W81XWH-06-2-0061

TITLE: Pacific Pediatric Advanced Care Initiative

PRINCIPAL INVESTIGATOR: Lawrence Burgess, MD

CONTRACTING ORGANIZATION:

University of Hawaii
Honolulu, HI 96822

REPORT DATE: October 2009

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel
Command

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

Form Approved
OMB No. 0704-0188

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) €F€F€-2009		2. REPORT TYPE Annual		3. DATES COVERED (From - To) 11 Sept 2008- 10 Sept 2009	
4. TITLE AND SUBTITLE Pacific Pediatric Advanced Care Initiative				5a. CONTRACT NUMBER Á	
				5b. GRANT NUMBER ÛÎFVÛÖÈ€NÈGÈ€€NFÁ	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S) Lawrence Burgess, M.D. Mark Ogino, M.D. Kathleen Connolly				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) University of Hawaii Honolulu, HI 96813				8. PERFORMING ORGANIZATION REPORT NUMBER	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research Fort Detrick, MD 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 N/A					
14. ABSTRACT The Pacific Pediatric Advanced Care Initiative establishes an advanced care Center with ECLS support in Hawaii to support the Pacific Rim. The Center will advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center will be established and evaluated through existing guidelines for clinical care and education and training. The initial research foci for the Center will be the following: 1. basic science research in ECMO, 2. development of manikin-based, simulation technologies as applied to the ECLS curriculum, 3. develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.					
15. SUBJECT TERMS Extracorporeal Life Support (ECLS), Extracorporeal Membrane Oxygenation (ECMO), Simulation, Manikin, Training, Education, Pediatric Intensive Care, Continuing Medical Education (CME) Continuing Education Unit (CEU), Septic shock, pig model, blood substitute					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT UU	18. NUMBER OF PAGES 214	19a. NAME OF RESPONSIBLE PERSON USAMRMC
a. REPORT U	b. ABSTRACT U	c. THIS PAGE U			19b. TELEPHONE NUMBER (include area code)

Table of Contents

	<u>Page</u>
Cover.....	1
SF 298.....	2
Introduction.....	4
Body.....	5 - 16
Key Research Accomplishments.....	17
Reportable Outcomes.....	18
Conclusions.....	19
References.....	20
Appendices List.....	21
Appendices.....	22 - 214

Introduction

The Pacific Pediatric Advanced Care Initiative has established an advanced care center with ECLS support in Hawaii to support the Pacific Rim. The Center's goal is to advance the science of Pediatric Advanced Care through new basic science and simulation research, while providing advanced care to patients, and improving the education and training of Department of Defense (DOD) Health Care providers. The Center is evaluated through existing guidelines for clinical care and education and training. The major research foci for the Center includes: 1. basic science research in ECMO, and 2. development and evaluation of simulation technologies as applied to pre-ECLS and ECLS curricula. This initiative is a joint venture between Tripler Army Medical Center (TAMC), Kapi'olani Medical Center for Women and Children (KMCWC), Kaiser Permanente Hawaii, University of Hawaii (UH), and the University of Pittsburgh Medical Center (UPMC). The objectives are as follows:

1. Establish a new Center for extracorporeal life support (ECLS) in Hawaii. Ongoing clinical review of results will be conducted to ensure that patient care meets national ECLS benchmarks. ECLS is established and proven standard-of-care technology, which provides advanced levels of care to Pediatric patients with life-threatening, potentially reversible cardiorespiratory failure. In preplanning, it was determined by the consortium that this program would be housed at Kapi'olani Medical Center for Women and Children and jointly staffed by physicians from Tripler, Kaiser, and Kapi'olani.
2. Name a national advisory board. This will function as an oversight panel, and will be instrumental in providing the clinical and educational experts that will help to review the administrative, clinical and educational programs to insure the Center is meeting national guidelines and benchmarks.
3. Develop a basic science research program for the Center. The first study will evaluate the utility of ECMO for management of severe septic shock in a porcine model, and whether the utilization of blood substitutes would impact results. Hormonal and physiologic parameters will be measured, combined with qualitative histologic analyses of end organs. The program will advance the science of ECLS, while providing the groundwork for future Center studies.
4. Develop a manikin-based simulator training curriculum to supplement to traditional training. This training curriculum serves multiple levels of health care providers to include physicians, nurses, perfusionists, and respiratory therapists. Following didactic education, skill acquisition rates of defined tasks and infant simulator survival will be compared both with and without manikin training.
5. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data. Patient physiologic variables are affected by pharmacologic and ECMO pump settings. Connecting these interactions through a computer simulation model will provide a valuable training resource for ECMO centers with small case numbers. ECMOjo will be refined using a heuristic evaluation model. Following prototype finalization, scenario-based curriculum will be evaluated on its ability for providers to acquire ECMO skills.

Body

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

a. Establish ECLS Hanuola Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula.

a.1. ECMO Cases

Currently, case load for the civilian sector has averaged five to six cases annually, with the Center expected to grow to 12 cases per year over the next three years. Since the opening of the Hanuola ECMO Center, there have been 47 ECMO consults (25 consults in 2008, 22 consults in 2009), with 12 patients being treated with ECMO (five patients in 2008, five patients in 2009). This number is in accordance to our estimated patient load since the development of the Center occupied the majority of the initial funding year.

The caseload at the Hanuola Center falls within the range of average cases for ECMO centers across the US. According to the ELSO database, of the 96 centers that reported patients in 1997, the average number of patients per center was nine (Roy, 2000). Within the last 20 years, there has been significant advancements for the treatment of neonates with respiratory failure, therefore the number of respiratory patients needing ECMO is going down. However, the need for cardiac patients is going up. Larger ECMO centers that offer comprehensive pediatric cardiac programs and adult ECMO services tend to treat more patients due to the availability of cardiac resources. For example, UPMC averages around 40-50 cases per year. Currently Hawaii has a limited pediatric cardiac program, no transplant or complex repair services, and no formal program that offers ECMO to adults. These factors exasperate the need for a successful ECMO transport program.

a.2. Policies and Procedures

The Hanuola Center has worked closely to integrate with several departments and programs at KMCWC. These include the blood bank, blood utilization committee, clinical laboratories, operating room, central supply, pharmacy, respiratory care, Neonatal Intensive Care Unit (NICU) nursing, Pediatric Intensive Care Unit (PICU) nursing, Risk Management and the Pediatric Executive Committee.

The development of policies and procedures with other supporting clinical departments has been completed and currently is being reviewed and updated (see Appendix A.1). This document clarifies the following: preparation for potential ECMO candidates; preparation for identified ECMO candidates; and guidelines for nursing, respiratory, surgical, pharmacy and blood bank teams. The policy also includes emergency procedures and the general guidelines and theory of ECMO.

a.3. ECMO Transport

During the first year of the Hanuola Center, the need for air and ground ECMO transport systems became a priority due to the unique clinical circumstances of the Hawaii medical community. In order to develop an ECMO transport system extensive planning and coordination of experienced personnel is necessary. Appendix A.2 is a detailed description of the ECMO transport system, which includes equipment needs and quotes. This document was submitted to Tripler to request additional funding.

The nature of transporting pediatric ECMO patients is often associated with severe instability and possible cardiac arrest. Thus, collaboration with AirMed International and Elliott Aviation has been initiated to design and build the ECMO Transport Platform (ETP). AirMed Hawaii is a provider of air ambulance services for Hawaii and Elliott Aviation is multi-service firm with extensive engineering experience in the development of specialty equipment for aircrafts. A review of progress was presented at the Advisory Board meeting in January 2009 (see Appendix D.2 for update). In August 2009, after three workshops with team members in January, May and August, the Hanuola center signed off on the final design. Appendix A.3 are minutes from the meeting with Elliot Aviation, where a mockup of the transport system was demonstrated and discussed. Elliott is now in the process of building the unit and submitting the final analysis to the Federal Aviation Administration (FAA) for certification. This design will be classified as a Supplemental Type Certificate (STC) with the FAA and will be approved for its engineering and airworthiness. Completion of the transport system is estimated to be in the early second quarter of 2010. Hanuola and Kapiolani transport team members have begun writing the protocols and procedures manual for ECMO transport and will initiate team training through drills and practice in the animal lab.

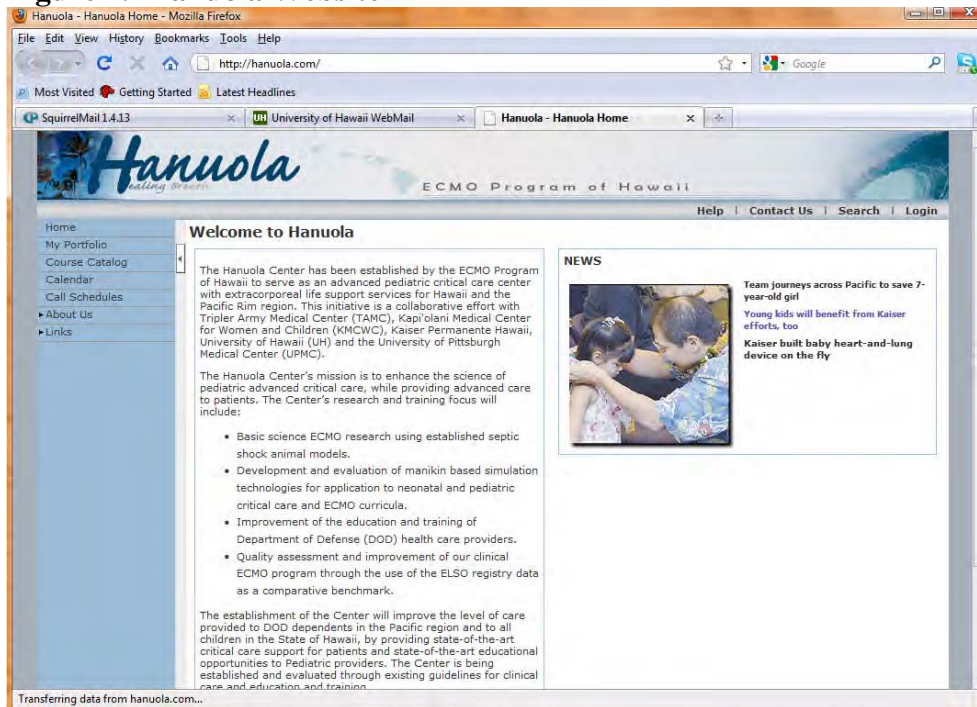
a.4. Credentialing

As part of a functioning ECLS Center, proper credentialing is necessary for management of the ECMO program. A number of physicians have been granted privileges to provide routine and emergency clinical care for infant patients on ECLS. This includes 12 Neonatal physicians and 6 Pediatric Critical Care physicians. Eight physicians have been granted privileges to independently select appropriate patients for ECLS, to oversee cannulation and decannulation procedures and participate in daily and emergency management. The ECMO training course has been developed at the Hanuola Center to accommodate the credentialing process.

a.5. Website

In addition to the clinical services provided by the Hanuola Center, a website has been developed to provide information to physicians, patients, families and the general public about ECMO and the Center (see Figure 1). This website serves as a portal to the Hanuola ECMO Training courses, training manual and lectures. The online website course titled *Assessment and Intervention for Pediatric Patients in Emergency Situations*, which had been approved for Continuing Medical Education (CME) credit, is also a part of this website (see Task 3 for details).

Figure 1. Hanuola Website



b. Conduct ongoing training, including didactic, wet labs, and animal labs based on well-established models.

The current animal lab training course outline is included as Appendix B.1. The competencies and skills checklists are attached in Appendix B.2 – B.4. Appendix B.5 is results from a course evaluation conducted in 2009. Overall, the evaluation results indicate that the speakers and course objectives were rated with scores of 3.9 or higher (maximum score 4.0). Also, several positive comments were included. For example “I have a better understanding of the different types of ECMO –VA vs VV. I also have a better understanding on what needs to be done to prepare a patient for ECMO.”, “Dr. Ogino simplifies difficult to understand concepts. Excellent job.”, and “I now feel more competent and a little more comfortable with being able to care for a patient on ECMO.”

c. Conduct ongoing evaluation of clinical results against national benchmarks using established methodology.

The Extracorporeal Life Support Organization (ELSO) was established in 1989. The organization oversees and maintains the registry, promotes education and training materials in support of ECLS, and stimulates ongoing research (ELSO, 2005). One of the major functions of the ELSO is to maintain a Registry comprised of all known cases in which ECLS was performed (ELSO 2008). Aggregate data serves as national benchmarks and are evaluated to enhance extracorporeal support technology and the technique of ECLS. New in 2009, the influenza A (H1N1) virus registry was developed to collect data on pediatric and adult patients requiring ECLS support for H1N1 related disease.

The Hanuola ECMO Center will continue to submit detailed data to the ELSO registry through the data forms. The registry returns twice-yearly reports to the Center that can be used to help evaluate results. Appendix C.1—Center Specific Summary 176, July, 2009, is the most recent ELSO data summary report for the Hanuola Center. The report has detailed information on the number of cases, description of case and outcomes.

In addition to submitting data to the ELSO registry, the Hanuola Center presents case reviews to the Advisory Board for discussion. Quarterly teleconferences are held to review the Center's interim progress, and an annual meeting is held in Honolulu to provide a comprehensive review of the Center's mission. The 2009 annual meeting was held in January followed by 1 subsequent quarterly meeting held in June (see Appendices D.1 – D.7 for agenda, minutes and presentation slides). Clinical cases are presented to mainland clinical experts to ensure that the Center is meeting expected clinical procedures and outcomes.

d. Name and convene a National Advisory Board for Center review as part of an annual review meeting.

As part of the Hanuola Center, a National Advisory Board was selected. In 2009, one additional member was added to the Board, Donald McCurnin, MD. Dr. McCurnin brings over a decade of experience in ECMO. He previously served and taught ECMO at Wilford Hall Medical Center. The current membership includes:

- Devn Cornish, MD – Vice Chairman of Faculty Development in Pediatrics, Emory University Medical School
- Denise Suttner, MD – Director, San Diego Regional ECMO Program.
- John Lin, MD – Pediatric Intensivist, Brooke Army Medical Center
- Michael Heard, RN –Egleston Children's Hospital at Emory University
- William Harris, CCP – Ochsner Clinic, New Orleans
- Melissa McNeil, MD – Education Advisor, University of Pittsburg Medical Center
- Donald McCurnin, MD (*new*) – ECMO Program Director , University of Texas Southwestern Medical Center

For this reporting year, there have been two Advisory Board teleconference meetings held (see Appendices D.6 and D.7 for meeting minutes/slides). The annual Advisory Board meeting was held in Honolulu 16-18th January 2009 (see Appendices D.1 – D.5 for agenda, minutes and presentation slides). Also this year, the Board forwarded a letter of commendation of the Hanuola ECMO Program to the Department of Defense leadership, as well as, to Senator Daniel Inouye (see Appendix D.8).

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

a. Renovate animal operating suite, to be scheduled around training and research

Thus far, renovation design consultants have proposed blue prints for animal lab operating suite renovation. Until renovation is completed, ECMO training and research procedures are being performed in a shared operating suite, and being scheduled around other TAMC research projects.

b. Conduct Center's first basic science research protocol after appropriate IRB approvals

The ECMO team of investigators and technical staff at Tripler are running ECMO experiments independent of clinical perfusionists, and the expertise of lab staff as perfusionists is firmly established. The research project of putting the septic shock hypotensive pigs on ECMO and examining blood flow distribution to different organ beds is fully underway.

We are testing the hypothesis that ECMO is an effective therapy for tissue preservation and maintenance of organ function in a porcine model of endotoxin-induced septic shock. The specific aims of the study are being addressed as follows:

Aim 1: To characterize the cardiovascular and endocrine responses to ECMO after establishment of endotoxin-induced septic shock

We continue to examine the effect of ECMO on microcirculatory blood flow in normoxia and during endotoxemia-induced hypotension in year 3. Specifically, we have found in control animals, mean arterial pressure (MAP) and total systemic carbon monoxide (CO) were maintained by ECMO in all three periods. Endotoxin caused a 40% decrease in MAP, CO, and oxygen delivery compared to baseline ($p < 0.05$). During endotoxin, ECMO was able to prevent further deterioration of MAP but did not fully return CO to baseline levels. Severe pulmonary hypertension caused by endotoxin was reversed with ECMO, and there were no significant differences in brain blood flow to all brain regions, nor any differences in oxygen consumption or extraction. In both control and endotoxic animals, ECMO caused a decrease in vasopressin, cortisol, adrenocorticotropic hormone (ACTH) and dopamine which could be attributed to a dilutional effect caused by endogenous hormone production not adjusting to the incorporation of a large circuit volume during ECMO. However, not all hormones decreased. The endotoxin-induced drop in MAP increased renin, which was reversed with ECMO treatment. Interestingly, aldosterone levels did not decrease, and sodium levels tended to increase with ECMO in either control or endotoxic animals.

Results indicate that ECMO is able to maintain blood flow to vital organs and reverse pulmonary hypertension and hypoxemia during endotoxic shock. ECMO causes similar endogenous hormonal profile shifts in both control and endotoxin conditions. Although a dilutional effect on hormone levels is evident during ECMO, the renin aldosterone system is still able to respond to shock, and results in increased plasma sodium levels.

We more closely examined the effects of ECMO on vasopressin. Vasopressin (VP) plays a vital role in regulating MAP and regional blood flow in hypotensive disorders, but whether endogenous VP levels can be sustained during ECMO is unclear. In 11 anesthetized cardiac catheterized piglets that were put on veno-arterial ECMO, either during control or endotoxin-induced septic shock states, ECMO blood flow was delivered to maintain MAP at baseline levels. Plasma VP (pVP) was compared before and after stabilization on ECMO for 2 hours. ECMO caused pVP to drop by 30% ($p < 0.01$) in both control and septic shock conditions. This drop may be due to the ECMO circuit adding to total circulating volume without additional release of VP. To test whether right atrial pressure (RAP) influence on VP release may be disrupted during ECMO due to partial cardiac bypass of blood flow, the relationship between pVP and hemodynamics during control was examined with stepwise regression. Pre-ECMO, pVP negatively correlated with RAP and heart rate ($r = 0.83$, $p < 0.05$), but not MAP. In contrast,

during ECMO, this pVP relationship with RAP was lost, but a strong positive correlation ($r=0.76$, $p<0.05$) between pVP and MAP became evident. Results indicate that during ECMO, low pressure atrial baroreceptors no longer regulate VP release, but VP control of MAP is maintained.

Hence, despite maintenance of hemodynamic stability, changes in endocrine regulation of cardiovascular and fluid balance appears to occur with ECMO and should be monitored to reduce morbidity outcomes.

Aim 2: To compare ECMO delivery effectiveness of blood substitutes versus donor whole blood, on redistribution of perfusion to vital organs and tissue preservation in the face of endotoxin-induced septic shock

We have maintained the pig well with the use of donor whole blood used to prime the circuit. We are having trouble arranging a source of artificial oxygen carrier (AOC) and may have to drop this part of the project.

Aim 3: To evaluate whether ECMO prevents multi-system organ failure in septic shock, by examining organ function of the lungs and the kidneys, the organs most likely to fail in sepsis.

The hemodynamic, respiratory, renal, and endocrine parameters are in the process of being analyzed. We have begun to examine the effect of ECMO on both lung function and reperfusion effects on histology. Regional blood flow distribution during endotoxin-induced hypotension and renal output before and after ECMO are being evaluated.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

a. Develop simulation software and curriculum in conjunction with the infant patient simulator to serve as training adjuncts to animal and wet-lab training.

a.1. Hanuola ECMO Training Course

The Hanuola Center has completed the *Hanuola ECMO Training Course*; a comprehensive, traditional classroom-based ECMO training course for physicians, nurses, respiratory therapists, perfusionists or other health care professionals interested in understanding the concepts of extracorporeal membrane oxygenation. To provide an easily accessible web-based platform to improve pediatric care, this course has been converted to an online format which is available on the Center's training website.

This year, a program for reviewing competency was required since the first members of the ECMO team were trained two years ago. This was completed in a three hour didactic classroom session reviewing ECMO physiology, management and equipment, followed by a one hour hands on simulation session that reviewed emergency procedures. Participants were required to perform a return demonstration and complete a written test. CEUs were provided. Forty eight bedside clinicians were recertified during these sessions, which were offered four times in 2009. In addition to the recertification course, two introductory ECMO courses were conducted. One eight hour classroom day, this was followed by a three hour animal lab. Thirty-four bedside

clinicians completed the Hanuola ECMO course for the bedside clinician with 11 CEUs awarded.

Figure 2. PICU Mock ECMO Simulation Training 30 March 2009



a.2. Critical Care Curriculum for Austere Environments

The Center has completed the *Pediatric Critical Care Curriculum for Austere Environments* that integrates manikin-based simulation (see Figure 3). This curriculum provides as an online resource for multiple levels of health care providers without specific specialty training in the care of critically ill pediatric patients. Learning objectives and simulation scenarios are included. Curriculum content and evaluative tools are posted on the Center's training web site. The Center will also work to integrate the curriculum with the online knowledge platforms maintained by the various branches of the military.

Figure 3. Assessment and Intervention for Pediatric Patients in Emergency Situations (AI PED EM)



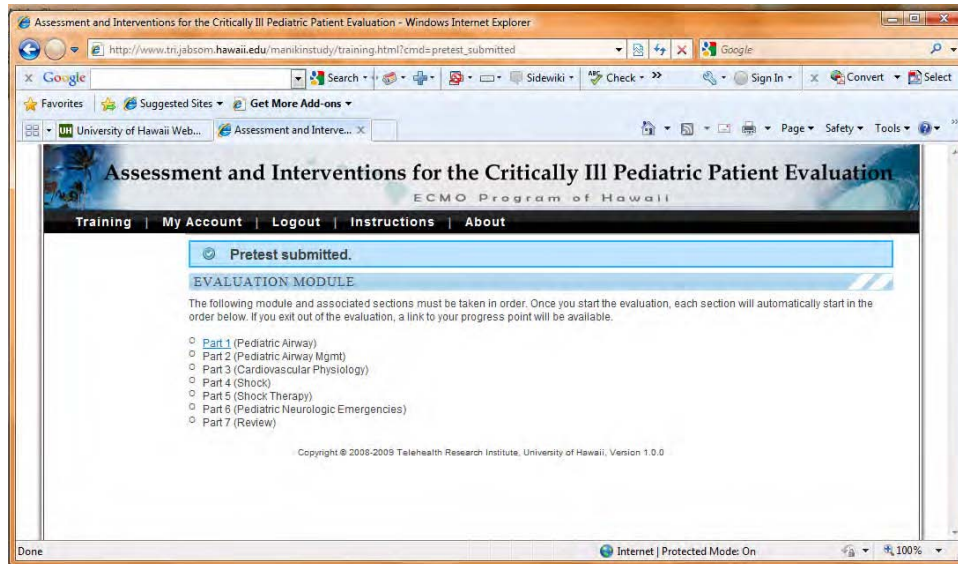
b. Evaluate the simulation curriculum.

Assessment and Intervention for Pediatric Patients in Emergency Situations

To evaluate the simulation curriculum, the Center developed the *Assessment and Intervention for Pediatric Patients in Emergency Situations* simulation-based training curriculum. Topics covered include pediatric airway anatomy and physiology, recognition of the pediatric patient in respiratory distress and respiratory failure, and shock. Neurologic emergencies and treatment options in pediatric patients are also discussed. Appendix E.1 is instructions on how to create an account for the course and how to view course material.

Currently we have 13 participants that have completed the evaluation, seven additional will be recruited next quarter. UPMC has also obtained IRB approval and has been added as an additional test center.

Figure 4. Assessment and Intervention for Pediatric Patients in Emergency Situation Online Curriculum Website



Task 4. To develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.

a. Develop simulation model

The test model has been built by a development team from JABSOM's Telehealth Research Institute's SimTiki Center. The source and build files are available via SourceForge.net under the project "ECMOjo". Validation of ECMOjo is being planned for later this year at various ECMO Training Centers across the United States. The training tutorials are currently under development and will be ready next quarter. Appendix F.1 is a poster abstract introducing the ECMOjo program, titled "Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training." This abstract was accepted for poster presentation at the Society for Simulation in Healthcare, 2009 conference.

Figures 5-7 are screen shots of the current version of ECMOjo.

Figure 5. Main Screen. Interactive GUI screen where all ECMO components can be selected and adjusted.

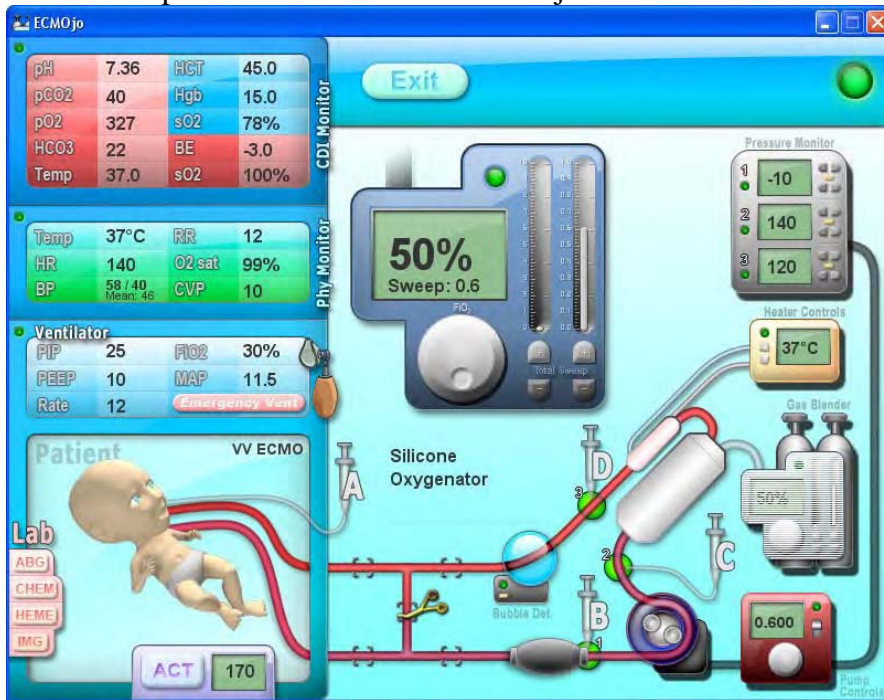


Figure 6. Tutorial Mode. The tutorial mode provides a guided Interface to explain ECMOjo and the ECMO circuit.

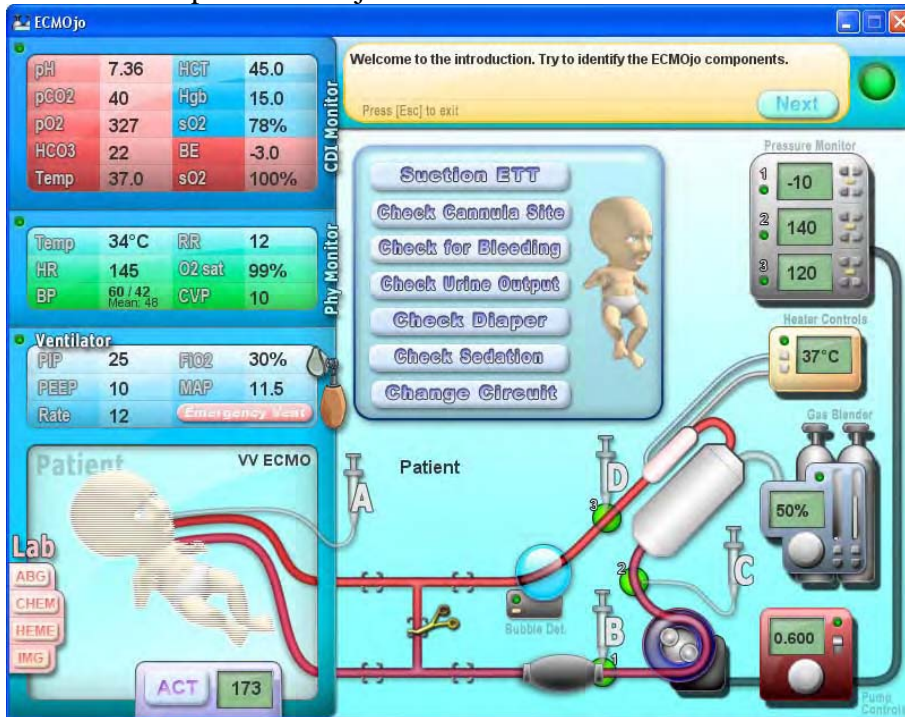


Figure 7. Menu Screen. The menu screen provides a total of over 25 tutorials and scenarios to train ECMO students and practitioners.



The screenshots below depicts the website created for the ECMOjo simulator. The website is hosted on SourceForge.net where the source code of ECMOjo is made available as open source using the BSD License. The website contains ECMOjo information and application download. See figure 8 for details.

Figure 8. ECMOjo Web Site. Contains download file and information.



b. ECMOjo scenario-based curriculum evaluation

Five ECMOjo scenarios have been developed and programmed into the computer simulation model. The scenarios are being updated as needed to correspond with refinements being made to the various ECMOjo physiological values. Heuristic expert testing has been conducted with five usability experts. Subsequent prototype improvements were incorporated based on their feedback. Results from the Heuristic Evaluation demonstrated a score of ≥ 4 for all target usability items, which exceeds the minimum standard usability required based on usability standards (see Appendix F.2 for charts of results).

A total of 18 ECMOjo training tutorials have been created for the validation study of ECMOjo:

- ❖ Circuit Check
- ❖ 5% Terror Time: Accidental Arterial Decannulation
- ❖ 5% Terror Time: Large Blood Loss from Circuit
- ❖ 5% Terror Time: Pump Failure
- ❖ 5% Terror Time: Air in Arterial Limb of Circuit
- ❖ Sweep Gases 1
- ❖ Sweep Gases 2
- ❖ Temperature Control
- ❖ VA ECMO Pump Flow
- ❖ VV ECMO Pump Flow
- ❖ Circuit Failure
- ❖ Air in the Venous Limb
- ❖ Oxygenator Failure
- ❖ Oxygenator Rupture
- ❖ High Pre-Membrane Pressure
- ❖ Negative Venous Pressure
- ❖ High Post-Membrane Pressure
- ❖ ECMOisms

The tutorials created match the classroom based curriculum as well as text book learning materials. An ECMOjo pilot training will be conducted at Children's Hospital of Pittsburgh of UPMC. Final prototype development will be completed and ECMOjo validation assessments will be conducted with multiple center participation during the next quarter. The Hawaii Consortium for Continuing Medical Education has approved this curriculum for up to 6.0 American Medical Association (AMA) Physician's Recognition Award (PRA) Category 1 Credits (see Appendix F.3 for approval letter.).

Key Research Accomplishments

Task 1. To establish a new Hawaii-Pacific Rim extracorporeal life support (ECLS) Center, which provides advanced levels of care to Pediatric patients with life-threatening cardiorespiratory failure; to evaluate the Center's effectiveness in attaining clinical results that meet national ECLS benchmarks.

- Training manual developed for Hanuola ECMO Center. Ongoing revisions are being made to the original Training Manual developed in 2007. Hardcopy and electronic versions are available.
- ECMO Training Course–The course has been revised to provide review and maintenance of skills.
- Hanuola ECMO Transport system has been designed and is in the process of FAA certification
- Hanuola ECMO Program's National Advisory Board
 - New members includes:
 - Donald McCurrnin, ECMO Program Director , University of Texas Southwestern Medical Center
 - National Advisory Board meetings are held to review clinical program on a quarterly basis through teleconferences, and with a yearly on-site visit and review.

Task 2. To conduct basic science research to advance scientific knowledge in ECLS.

- Experiments are underway.

Task 3. To develop manikin-based simulation training for the ECLS training curriculum, as a supplement to traditional ECLS training.

- An in house simulation for ECMO skills has been developed.

Task 4. To develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.

Virtual ECMO Circuit Simulator and curriculum for the simulator have been developed through collaboration with ELSO centers. The following have been accomplished.

- Development of ECMOjo, a simulator and trainer for extracorporeal membrane oxygenation.
- Conducted two iterations of a heuristic expert evaluation of ECMOjo.
- Conducted one iteration of a heuristic user evaluation of ECMOjo.
- Integration of training tutorials and training scenarios into ECMOjo.
- Setup a project at SourceForge.net to make ECMOjo available via Open Source for ECMO practitioners worldwide. ECMOjo is available via BSD License.
- Development of a web site for ECMOjo to make the software application and source code available online for ECMO practitioners and other interested parties.
<http://ecmojo.sourceforge.net>
- Preparation of ECMOjo for an upcoming validation study of the simulator at collaborating ELSO centers.

Reportable Outcomes

- Abstract Presentations:
 - *Hanuola ECMO Transport Project*, Presentation by Kristin Costales, January 2009, ECMO Advisory Board Meeting, Honolulu, Hawaii
 - *Anticoagulation Strategies for Pediatric Patients on ECMO*. Wacker, Erin L.; Maul, Timothy M.; and Wearden, Peter D. Presentation by Kent Kelly, January 2009, ECMO Advisory Board Meeting, Honolulu, Hawaii
 - *Correlations and Linear Regressions for Coagulation Times and Heparin Dosing*. Maul, Timothy M.; Wacker, Erin L. Wacker; Kelly, Kent; Morell, Victor O; and Wearden, Peter D. Presentation by Kent Kelly, January 2009, ECMO Advisory Board Meeting, Honolulu, Hawaii
 - *Pediatric Critical Care Curriculum for Austere Environments*. Naclerio, Anne and Hamilton, Melinda F. Presentation by Melinda Hamilton, January 2009, ECMO Advisory Board Meeting, Honolulu, Hawaii
 - *Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training*, L. Y. Tanaka, M. T. Ogino, C. Aschwanden¹, K. Costales, L. Burgess, Society for Simulation in Healthcare, 2009, Poster Abstract
- ECMO Physician Credentialing
- ELSO activity
 - *ELSO Training Manual* – CoEditor—Dr. Mark Ogino
 - *ELSO Committee on Logistics and Education*
- Data submitted to ELSO registry
- The animal model for endotoxin-induced septic shock using a pediatric piglet model is currently conducting ongoing experiments
- Design, engineering, and construction of ECMO Transport Sled designed specifically for air and ground transport of patients on ECLS support.
- Development of ECMOjo, a simulator and trainer for extracorporeal membrane oxygenation including integration of tutorials and scenarios, experiments are currently being performed
- Development of an open source website for ECMOjo: <http://ecmojo.sourceforge.net>

Conclusions

The Hanuola (ECMO) Center has been successfully established at Kapi'olani Medical Center for Women and Children. The following are a summary of activities thus far:

- Policies and procedures with other supporting clinical departments have been integrated into the program.
- An advisory board has been named and meetings have been convened to help in the development and evaluation of the Hanuola Center. There was one new member added in 2009.
- ECMO patients are currently being treated and consulted, 22 consulted and 7 treated in 2009.
- An ECMO transport system has been designed and is in the process of certification.
- In 2009, the website was updated and to include new course information for the *Pediatric Critical Care Curriculum for Austere Environments*.
- Experiments are underway for the basic science research program.
- Construction of the ECMO Transport Sled engineered specifically for patient on ECLS has been completed.
- ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data has been developed and made available online for ECMO practitioners worldwide.

The establishment of the Hanuola Center has significantly improved the level of care provided to DOD dependents in the Pacific region and to all children in the State of Hawaii. The Hanuola Center is now providing state-of-the-art critical care support for patients and state-of-the-art educational opportunities to pediatric providers, which is bringing the standard of care for pediatric patients in Hawaii to an equal footing with patients on the U.S. mainland. Recently, the Hanuola ECMO program has been in active discussion with the Hawaii medical community to increase awareness and forge partnerships to develop an H1N1 preparedness plan for the State of Hawaii and its dependants based on national recommendations. This includes organizations such as Blood Bank of Hawaii, the ELSO community and Department of Health.

References

- DeVita MA, Schaefer J, Lutz J, et al. Improving medical emergency team (MET) performance using a novel curriculum and a computerized human patient simulator. *Qual Saf Health Care*. 2005;14(5):326-31.
- ELSO Guidelines for Training and Continuing Education of ECMO Specialists. Extracorporeal Life Support Organization (ELSO), February 2005.
- ELSO registry page: <http://www.else.med.umich.edu/Registry.htm>, accessed December 19, 2005.
- Laerdal. SimBaby. <http://www.laerdal.com/simbaby/> . Last Accessed October 19, 2007.
- Martin GS, Mannino DM, Eaton S, and Moss M. The epidemiology of sepsis in the United States from 1979 through 2000. *N Engl J Med* 2003; 348(16): 1546-1554.
- Martin GS, Mannino DM, and Moss M. The effect of age on the development and outcome of adult sepsis. *Crit Care Med* 2006; 34:15-21.
- Roy B, Rycus P, Conrad S, Clark R. The Changing Demographics of Neonatal Extracorporeal Membrane Oxygenation Patients Reported to the Extracorporeal Life Support Organization (ELSO) Registry. *Pediatrics*. December 2000;106(6):1334.

Appendices

- A. Task 1.a. Establish ECLS Center at Kapi'olani Medical Center for Women and Children using well-established clinical and referral guidelines, and training curricula**
 - Appendix A.1. ECMO Policy and Procedures
 - Appendix A.2. ECMO Transport Sled Proposal
 - Appendix A.3. ECMO Transport Meeting – Elliott Aviation
- B. Task 1.b. Conduct ongoing training, including didactic, wet labs, and animal labs based on well-established models**
 - Appendix B.1. ECMO Lab Competency Course Outline, August 2009
 - Appendix B.2. ECMO Lab Competency Skills, August 2009
 - Appendix B.3. ECMO Lab Equipment Drill Checklist
 - Appendix B.4. ECMO Lab Emergency Skill Checklist
 - Appendix B.5. ECMO Training Course Evaluation 2009
- C. Task 1.c. Conduct ongoing evaluation of clinical results against national benchmarks using established methodology**
 - Appendix C.1. Hanuola – ECLS Registry Report – July 2009
- D. Task 1.d. Name and convene a national advisory board for Center review as part of an annual review meeting**
 - Appendix D.1. Advisory Committee Annual Meeting 2009 – Agenda
 - Appendix D.2. Advisory Committee Annual Meeting 2009 – Meeting Minutes
 - Appendix D.3. Advisory Committee Annual Meeting 2009 – Slides, Anticoagulation Strategies
 - Appendix D.4. Advisory Committee Annual Meeting 2009 – Slides, Coagulation Times and Heparin Dosing
 - Appendix D.5. Advisory Committee Annual Meeting 2009 – Slides, Pediatric Care Curriculum
 - Appendix D.6. Advisory Committee Meeting Minutes – 16 June 2009 – Minutes
 - Appendix D.7. Advisory Committee Meeting Minutes – 23 October 2008
 - Appendix D.8. National Advisory Board Commendation of ECMO Program Letter
- E. Task 3.a. Develop simulation software and curriculum in conjunction with the infant patient simulator to serve as training adjuncts to animal and wet-lab training**
 - Appendix E.1. How to Participate Flyer
- F. Task 4. Develop ECMOjo, a computer simulation model for patient physiologic variables and ECMO pump biomechanical data.**
 - Appendix F.1. Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training – Poster Abstract
 - Appendix F.2. Usability Experiment Results
 - Appendix F.3. Approval letter for CME credit

Appendix A.1

ECMO Policy and Procedures



Policy Name: Extracorporeal Membrane Oxygenation (ECMO) Protocol
Department: Neonatal Intensive Care Unit/Pediatric Intensive Care Unit
Effective Date:
Revised Date:
Replaces:

Policy & Procedure

The reader is cautioned to refer to the Central Policy Database for the most current version of this document and not rely on any printed version.

Approval Signature: _____
Name: Sharon Tourville, RN, MSN, CNA, BC **Title:** Vice President, Patient Services

Approval Signature: _____
Name: Mavis Nikaido, RNC, BSN **Title:** Director, Pediatric Critical Care

Approval Signature: _____
Name: Kenneth Ash, M.D. **Title:** Medical Director, Transport Services

Approval Signature: _____
Name: Charles Neal, MD **Title:** Clinical Director, NSCU

Approval Signature: _____
Name: Rupert Chang, MD **Title:** Medical Director, PICU

Approval Signature: _____
Name: Mark T. Ogino, MD **Title:** Medical Director, ECMO Program

Policy Reference

This protocol is written in accordance with the policy number 6630-03-W on Extracorporeal Membrane Oxygenation. Participating disciplines or departments with their own established protocols shall use this protocol in conjunction with theirs.

Equipment and Supplies

Equipment is described in general terms, as most of the essential equipment is supplied by the ECMO specialist (perfusionist).

- ECMO cannulae, as specified by neonatologist and/or surgeon (to be brought by OR team)
- ECMO circuit, with applicable flow, saturation, pressure
- ACT analyzer
- ECMO pump, centrifugal type or roller head type
- Oxygenator and sweep gases (O₂, CO₂)
- Heat exchanger and heater
- Special pharmaceuticals: THAM, code drugs (epinephrine 1:1000, atropine, calcium), heparin, albumin 5%

- Bedside ice chest maintained at 1 to 6 degrees Centigrade for blood products (temperature must be monitored q 4 hours)
- 2 suction set-ups—1 for OR team and 1 for airway management
- Procedure spot light
- Rectal temp probe and cable box from ECMO Nursing cart

Procedures

Protocol—Preparation: prior to arrival or verification of potential ECMO candidate:

The following preparations should be done as soon as an infant is **considered** a candidate for ECMO by the Neonatologist or ECMO MD:

- | | |
|---|--|
| ECMO MD
or
Neonataolog
ist | <ol style="list-style-type: none"> 1. Notify ECMO Team members 2. Assure consult note is completed 3. Assure attending is notified 4. Assign Pre- ECMO orders to assess inclusion/exclusion criteria |
| Charge
Nurse or
designee | <ol style="list-style-type: none"> 1. Notify supervisor of anticipated admission. 2. Assure ECMO team has been notified 3. Initiate preparation of the environment of care, including moving and/or reassigning patients as necessary. 4. Assign qualified ECMO RN |
| Charge
Nurse or
designee | <ol style="list-style-type: none"> 5. Prepare bedside set-up: <ul style="list-style-type: none"> • Place all non-ECMO equipment (ventilator, IV pump, etc.) on the left side of the patient. This allows the right side to be dedicated to the ECMO pump and circuit. • Two pulse oximeters for pre/post ductal sat. If applicable • Two Phillips monitors set on "big numerics": one on left side of warmer and one to the right, next to ECMO circuit. • Two syringe pumps on ECMO circuit pole • Six syringe pumps and two three-channel pumps on poles placed on left side of warmer. 6. Place infant on designated ECMO bed with bed scale and film tray: use a large-bed open warmer (Ohio) with the infant placed with head towards center of room. |

**Ward
Clerk or
Designee**

1. Use Call List and notify ECMO Team of potential candidate.

Script for 1st call:

Please call the following people on the **Heads Up** list:

Please say: This is a Head's Up call.

Tell the person where you're calling from.

There's a potential patient to go on ECMO.

The patient's name, age, wt and diagnosis.

Please explain that this call is only a **Heads Up Call**

2. Arrange, if required, STAT Exams immediately upon arrival of patient.

- Head ultrasound (HUS)
- Echocardiogram (echo)
- Chest x-ray (CXR)

**Respiratory
Therapy**

1. Anticipate and set up for high frequency ventilation with inhaled nitric oxide.
2. Have ordered ventilator available at bedside.

RN

1. Obtain PRE- ECMO labs (as listed in the Physician's Orders) for potential ECMO candidate:
 - If patient already in NICU, obtain labs as soon as the patient is identified as a candidate.
 - For potential ECMO candidate arriving via transport, obtain initial labs **prior to** moving infant out of transport isolette.
 - Initial labs to include Neoprotocol, Newborn screen, I-STAT ABG, iCa, RT lactate, CBC, renal panel, osm, PT, PTT, Fib, D-dimer and methemoglobin for an infant on nitric oxide.

Perfusionist

1. ECMO circuit preparation

Preparation for identified ECMO candidate:

The following preparations are done after the ECMO MD has **confirmed** that the infant is an appropriate candidate for ECMO.

- | | |
|-------------------------------------|---|
| ECMO MD | <ol style="list-style-type: none">1. Notify Pediatric/Cardiac Surgeon2. Arrange for Cardiologist to be present during cannulation3. Notify Attending or Intensivist of ECMO patient activation4. Assure Pre-ECMO orders are completed (MD Checklist)5. Assign ECMO Cannulation order set6. Spot the monitor |
| Charge Nurse
or designee | <ol style="list-style-type: none">1. Activate the ECMO team call-list per ECMO MD order using ECMO Team call list.
<i>Script for 2nd call:</i>
Please call everyone on the call list with the actual ACTIVATION:
Please say: This is an Activation call.
Tell them where you're calling from.
There is a patient to go on ECMO.
The patient's name, age, wt and diagnosis.
Explain any other pertinent information.
Repeat that this is an ECMO Activation.2. Anticipate arrival of essential team members (perfusionist, surgeon) within 30 minutes.3. Assure 2:1 ECMO qualified nursing staff |

4. Notify Blood Bank to prepare the following blood products:

NSCU :

- 2 units of fresh CMV negative or leukocyte reduced, irradiated PRBCs for Prime
- 1 random unit of CMV negative or leukocyte reduced, irradiated platelets for transfusion immediately after cannulation
- 1 pedi unit of FFP for transfusion immediately after cannulation
- 2 neonatal CMV negative or leukocyte reduced, irradiated PRBC units and 1 pedi pack of FFP in a cooler in at the bedside at all times while on ECMO.

3. Check all blood products with 2 RNs

4. Check and record blood cooler temperature Q 4 hours (Maintain temp between 1 to 6 degrees C.)

5. Verify preparation of the environment of care, including moving and/or reassigning patients as necessary

6. Assure various ancillary services per call list have been notified with CRC, unit secretary and/ clinical coordinator.

7. if prime meds arrive per translogic system deliver to perfusion

Perfusion

1. Assure prime meds are ordered with ECMO MD

2. Notify charge nurse or clinical coordinator if additional medications or supplies are required.

3. If circuit prime is STAT blood for prime may be ordered via the translogic system

4. Perfusionist to add the following to each of the unit of PRBC (total 2 units):

- 50 to 100 ml THAM
- 40 ml 25% albumin
- 100 units heparin
- 300 mg calcium gluconate

Nursing Team—Pre-Cannulation

ECMO

**Caregiver
RN**

1. Refer to Cannulation Checklist for Bedside RN

2. Obtain chest X-ray plate: Place x-ray plate under patient prior o cannulation if warmer does not have under warmer tray.

ECMO

**Caregiver
RN**

3. Prepare a thick neck roll (2 blankets) for surgeon to place to hyperextend neck.

4. Assure invasive nursing procedures completed: The ECMO patient must have certain invasive procedures performed in order to have appropriate monitoring devices available during ECMO, as specified by the Neonatologist. There is a high risk of hemorrhage if these procedures are done after patient is heparinized. The procedures include, but are not limited to:
 - Foley catheterization
 - Peripheral IV access
 - Arterial access
 - NG/OG placement
 - Rectal temperature probe
5. Assure emergency resuscitation medications and volume expanders are labeled and ready at the bedside:
 - Current Code sheet printed at bedside
 - Three (3) rounds of code drugs (EPI, Calcium Chloride, Sodium Bicarbonate)
 - Three (3) rounds of 20ml/kg of NS flushes, drawn up and labeled
 - NS flushes (no heparin flushes)
6. Rectal temperature probe Position monitor so the Perfusionist has a good visual of the HR, Sat, BP and core temp.
7. Additional bolus sedation & paralytic meds at the bedside **before** the cannulation procedure begins.
8. Have 2 extra suction canisters set up for OR team prior to sterile drape
9. Move ECG leads to lower chest for surgical scrub
10. Ensure ETT secure prior to sterile draping
11. Cooler with blood products is ordered and at the bedside
12. Platelets ordered and on unit in Styrofoam box
13. Assure Heparin Bolus is at bedside from pharmacy. Double check dose with 2 RNs. Hold until surgeon verbally orders it to be given via the patient IV.
14. Prepare IV ports:
 - Identify IV ports (UVC, Femoral venous line, other central venous lines, or PIV) for easy access to push meds or administer volume.
 - Attach an extension tubing with a stopcock to the port.
 - Identify access for blood draws (UAC or peripheral arterial line).
 - Arrange lines for easy accessibility when patient is draped.
15. Provide hat and mask for personnel in ECMO cannulation area
16. Close unit to as indicated per unit procedure protocol

**Charge
Nurse**

Nursing Team—During and Immediately Post Cannulation

ECMO
Caregiver
RN

1. Upon order of the surgeon or ECMO MD:
 - Sedation/analgesia followed by neuromuscular blockade (patient must be *completely* paralyzed to prevent spontaneous inspiration with potential for air embolus)
 - Administration of heparin loading dose via a PIV as surgeon cannulates vessel. (50 units/kg bolus)
 - Anything else specific to the patient
2. Monitor and record vital signs during surgical procedure
 - Record VS at least q 5 minutes during cannulation.

ECMO
Caregiver
RN

3. Anticipate need for platelet transfusion immediately after initiation of bypass due to adhesion of platelets to circuit surface. Administer 1-2 units of platelets immediately after connected to ECMO circuit.
4. After starting infant on the ECMO pump, switch supportive drips to circuit tubing.
 - Use fresh syringes (prepared by Pharmacy) and tubing-stopcock manifold.
 - Have lines primed and running, with a non-heparinized carrier fluid running into most distal stopcock.
 - Simultaneously turn on new drips while discontinuing the first set running into the patient.
5. Carefully titrate drips to maintain desired blood pressure. **Avoid hypertension by weaning drips as ordered. This may need to be done rapidly upon initiation of Venoarterial (VA) ECMO.**
6. Treat hypotension with volume as ordered.
 - Keep 5% albumin and Normal Saline bolus at bedside and available at all times.
7. Double check with another RN heparin solution for heparin drip for perfusion
8. Assist perfusion for setting up heparin drip

Nursing Team—Post Cannulation and Ongoing During ECMO

ECMO
Caregiver
RN

1. Maintain already-established vascular access.
 - No invasive procedures while on heparin anticoagulation.
 - No invasive device removal (e.g., clotted catheters, chest tubes) Unless ECMO MD order
 - No heparin flushes
 - No Heparin flushes for peripheral or umbilical arterial lines

**ECMO
Caregiver
RN**

2. Guard against trauma to skin or mucous membranes:
 - Measure ETT Suction Catheter and place at safe suctioning distance at bedside.
 - No nasal or oral suctioning without ECMO MD order
 - Note cannula site and dressing every hour. Chart every 4 hours/prn
 - Note cannula distance from insertions site and measure q12h
3. Manage fluid and electrolyte balance. The following may be administered through the circuit:
 - PRBCs, FFP, other volume expanders (administer over 1 hour)
 - (Note: it is preferable to administer all IV fluids, blood products and medications directly to the baby if IV access available) This will be ECMO MD and perfusion discretion

Note: Platelets and cryoprecipitate may *not* be given via the ECMO circuit.
4. Follow lab results closely, especially platelets, hematocrit, and blood gas. Communicate results to perfusionist.
5. Follow MD orders for parameters for B/P, urine output, and blood products administer. (See physician ECMO initial and daily orders).
6. Administer platelets through IV access in the baby as ordered. Platelets should preferably be administered when ACT is high. Communicate with perfusionist (heparin drip may need to be adjusted).
7. Obtain daily labs (as listed in Physician's orders). All lab works (except for patient blood gases) to be drawn via ECMO circuit.

Note: To obtain 100% O₂ challenge test, O₂ on the ventilator is increased to 100% for 10 minutes; note and record arterial saturation and then draw patient ABG.

8. Collaborate closely with perfusionist for ACT/heparinization management.
 - Obtain heparin drip from pharmacist.
 - Communicate to perfusionist about administration of volume expanders and blood products, urine output, or changes in sedation or paralysis medications, as these could affect ACT.
9. Monitor VS and O₂ sats continuously and record hourly.
 - Utilize arterial transduced wave pressures—no cuff pressures while patient is heparinized, unless specifically indicated for loss of functioning arterial line.
 - If cuff BP is indicated, place cuff on leg not utilized for O₂ sat monitoring.
 - Communicate with perfusionist, who can assist in managing temperature and blood pressure

**ECMO
Caregiver
RN**

10. Monitor for bleeding and keep accurate account of any significant blood loss:

- Neuro checks (pupil checks q 4 hours)
- Hemodynamic changes
- Bulging fontanel (head circumference daily)
- Distended abdomen
- Blood in stool, urine
- Bleeding from mouth ETT or IV sites

Notify MD of unusual excessive oozing at the cannula site. If a sudden massive bleeding occurs at the cannula site, immediately measure cannula position and notify ECMO MD and surgeon STAT for possible imminent decannulation.

11. Keep very accurate I&O

- Communicate hourly with perfusionist.
- Include weighed blood loss from oozing at cannula sites.
- Inform ECMO MD and perfusion of significant decrease in urine output.

12. Administer other medications as ordered, including:

- Antibiotics
- Corneal lubrication if paralyzed
- Bactroban to cannula site.

13. Provide assessment and protection for skin:

- Passive ROM Q shift
- Linen change with ECMO MD order only

14. Maintain safe head position: Once infant is on ECMO, keep the head and neck in a neutral position to prevent possible facial palsy or compression of jugular vein.

**ECMO
Caregiver
RN**

15. Support family in their emotional and spiritual concerns.

- Arrange for social services and Psych CNS consult as appropriate.
- Provides education, gives handbook and facilitates answering the family's questions.

16. Manage ongoing safety of patient

- Measure cannula at shift change with other RN caregiver; and document position
- Assure bed is not raised or lowered. Place sign on bed.
- Assure code sheet and code drugs are at bedside as indicated by patient condition and ECMO MD order
- Verify contents of bedside cooler and complete log sheet
- In conjunction with the unit secretary ensure that blood cooler temp is maintained at 1-6 degrees centigrade
- Nursing to document in EMR q 4

Nursing Team—Weaning

- | | |
|-------------------------------------|--|
| ECMO
Caregiver
Nurse | <ol style="list-style-type: none">1. Refer to ECMO Weaning, Trialing off and Decannulation Checklist2. Assess O₂ saturation and ETCO₂ during any weaning attempts and during the clamping of the ECMO circuits.3. When patient is ready to come off ECMO, transfer all IV fluids and medications (except heparin infusion) to infant from the circuit.4. Assure that ventilatory settings are increased as ordered by RT.5. Obtain 2 ABGs from patient (at 10 min and 20 min during trial off bypass). |
|-------------------------------------|--|

Note: obtain ABGs before perfusionist flashes the bridge.

Nursing Team - Decannulation

- | | |
|-------------------------------------|---|
| ECMO
Caregiver
Nurse | <ol style="list-style-type: none">1. Collaborate with OR team during decannulation to maintain a safe and sterile surgical environment.<ul style="list-style-type: none">• Have 3 rounds of code drugs drawn up and labeled (per MD discretion).2. Assure availability of blood products as specified by ECMO MD.<ul style="list-style-type: none">• Two (2) pedi units PRBCs• Two (2) pedi units FFP |
| ECMO
Caregiver
RN | <ol style="list-style-type: none">3. Keep one of patient's IVs within easy access during sterile draped procedure.4. Assure arterial lab draw access obtainable during sterile drape procedure.5. Administer sedation, analgesia, muscle relaxation as ordered by ECMO MD or surgeon to keep patient completely paralyzed during decannulation.<ul style="list-style-type: none">• Assure that ventilatory settings are increased as ordered with paralysis.6. Obtain ABG before infant is off bypass. |

Nursing Team - Post Decannulation

- | | |
|-------------------------------------|---|
| ECMO
Caregiver
Nurse | <ol style="list-style-type: none">1. Observe for bleeding after decannulation.2. Obtain ABG and CXR. |
|-------------------------------------|---|

3. Obtain patient ACT 2 hours off ECMO.
 - The heparin should be cleared by 6 hours.
4. Necessary invasive procedures may be resumed 2 hours off ECMO (cuff BP, rectal temp, OGT/NGT).
 - In extreme needs, venipuncture (IV) may be permitted with ECMO MD order
 - Obtain other lab work and diagnostic tests as ordered.
5. Follow MD parameters for Hct, platelet, B/P, O2 sat, urine output.
6. Avoid stress and unnecessary stimulation for first 24 hours, as patient is at risk for return of pulmonary hypertension:
No bathing, linen change, or unnecessary handling of infant.
7. Notify Blood Bank and STAT Lab that patient is off ECMO.
8. Post ECMO RNs, ongoing responsibilities:
 - Observe cannula site(s) for signs of infection.
 - Apply antibiotic ointment and change dressing as ordered.
 - Maintain neutral head position for 24 hours.

Respiratory Team – Pre- Cannulation

**Respiratory
Therapist**

1. Call in additional RT support. One designated RT for the ECMO patient. One designated RT for the RT labs.
2. Collaborate with surgeon and perfusionist for placement of equipment around the bed. All equipment must be on left side of patient.
3. Set up conventional ventilator behind warmer if requested by ECMO MD for use following cannulation
4. Assure secure airway:
 - The ECMO patient will be totally draped during the critical cannulation procedure, and the ETT will not be visible.
 - It is critical that the airway be well secured before cannulation is started.
 - Check for connection of ambu bag to nitric oxide as applicable.
5. Assure availability and safety of ambu bag/ neo puff:
 - The ambu bag must be readily available, but placed well away from the surgical field, as it can be a fire/explosion hazard with use of surgical bovie.
 - Do not place ambu bag under sterile drapes.
 - If requested by surgeon, don sterile gown and begin INO ambu bagging or neo puff during surgical procedure. This may require an extension on bagging unit to be out of surgical field

- Designated Respiratory Therapist for RT labs**
6. RN will release slips required for PRN RT labs for the prime
 7. Label as Prime 1, Prime 2, etc.

Respiratory Team - During and Immediately Post Cannulation

- ECMO RT Bedside RT**
1. After cannulation, maintain ongoing lung ventilation in collaboration with the neonatologist.
 - Wean ventilator settings as able to promote lung rest.
 - When determined by neonatologist, place patient on conventional ventilation with INO.
 - Wean INO as ordered.
 2. Perform minimal and safe endotracheal suctioning in collaboration with nursing.
 - Safe suctioning refers to not passing the catheter farther than the tip of the endotracheal tube.
 - The safe suction distance should be posted at the bedside.
 3. Maintain stand-by equipment for high-frequency oscillatory ventilation and inhaled nitric oxide (INO).
 4. Provide emergency ventilator settings for patient.
 - Assure emergency vent settings are taped to ventilator in the event bypass must be discontinued suddenly.
 - Verify settings daily with MD orders and change as indicated.
- Designated Respiratory Therapist for RT labs**
5. Run patient RT labs, gases and pre and post membrane circuit gases frequently as ordered for first few hours of ECMO
 6. Coordinate with perfusion to run RT indicated lab studies as required.
 7. If new MD order is necessary, or missing slip is required collaborate with ECMO RN

Respiratory Team - Decannulation

- Respiratory Therapist**
8. Collaborate with nurse, perfusionist, and ECMO MD during weaning attempts and when patient is taken off ECMO.
 - Monitor ABG's closely to insure that ventilator settings are sufficient to provide appropriate support.
 9. Refer to Weaning, Trialing off and Decannulation Checklist

Surgical Team - Cannulation

- Surgical Team**
1. Assure with ECMO MD pre-cannulation care is complete
 2. Bring all OR equipment to bedside and set up sterile environment. Monitor activity around designated sterile area to assure anyone in the vicinity has appropriate OR attire.
 3. Follow own applicable protocols.
 4. Set up bedside equipment as needed to facilitate aseptic surgical activities (suction, lighting, bovie, etc).
 5. Assure Procedure Verification and Time out has been completed

6. Collaborate with other members of the ECMO team to assure good outcome from cannulation surgery.
7. Repeat process during any catheter repositioning procedures and for decannulation.

ECMO Specialist –Cannulation

- | | |
|---------------------|--|
| Perfusionist | <ol style="list-style-type: none"> 1. Set up and manage ECMO pump and circuit. Collaborate with charge nurse or clinical coordinator to obtain blood and additives for priming the circuit. 2. Prime circuit with prepared blood per own protocol. Assure heparin, albumin, and THAM are added to blood and mixed prior to addition of calcium gluconate. 3. Collaborate with charge nurse and RN caregiver and ECMO MD to assure completion of all pre-ECMO tasks. 4. Operate and maintain ECMO pump and circuit throughout the therapy according to own protocols. Check circuit and cannulae hourly for security, clots and air bubbles. 5. Obtain pre and post-membrane blood samples at designated routine times, and as needed. 6. Run bedside ACT tests within 5 minutes of initial heparin bolus, at the initiation of bypass and every 15 minutes until stable. 7. Manage heparinization in response to ongoing ACT results. Adjust heparin drip and collaborate with nursing in order to maintain ACT as ordered. 8. Manipulate flow or sweep gas in response to lab results to achieve desired results. 9. Trouble-shoot pump and circuit as needed. |
| Perfusionist | <ol style="list-style-type: none"> 10. Administer volume, blood products (except platelets and cryoprecipitate), and medications (as drawn up by nurse) via the ECMO circuit as ordered. Draw labs from circuit as ordered. 11. Maintain security of cannulae at all times, is responsible for cannulae during any position change of patient. |

Pharmacy

- | | |
|-------------------|--|
| Pharmacist | <ol style="list-style-type: none"> 1. Prepare and deliver ordered medications: <ul style="list-style-type: none"> • Cardiovascular support infusions (e.g., dopamine, dobutamine, epinephrine) • Analgesia, sedation, and muscle relaxant infusions • Medications for the circuit prime as ordered • Heparin bolus 50units/kg • Send to unit commercially prepared 250ml bag of 25,000 units heparin in 250ml 0.45% NS (100 units per ml) |
|-------------------|--|

Blood Bank

- Blood Bank**
2. Prepare blood products as ordered
 3. Notifies Blood bank of Hawaii of ECMO patient status
 4. Assure blood available as ordered
 - 1 unit PRBC on hold in blood bank at all times while on ECMO
 - 2 random units in blood bank at all times while on ECMO
 - Call NSCU once daily in am following ECMO patient rounds for consultation of anticipated additional blood products.
 - Prepares new cooler for change out and verifies blood products as needed daily
 - Collaborates with ECMO RN to clarify prn blood product orders

Emergency Protocols

Emergency situations may call for immediate discontinuation of ECMO. Situations that may require immediate removal from bypass include:

- Power and back-up battery failure
- Air in the arterial system,
- Tubing rupture
- Accidental decannulation.

Certain other situations will be handled as deemed appropriate by perfusionist and/or MD.

These include:

- Clots in the circuit
- Cannula placement problems
- Oxygenator failure

- Cracks in connectors
- Pump or heat exchanger malfunction
- Restrictive sutures
- Other mechanical problems.

Anticipatory preparation

- Perfusionist and RN** 1. At the beginning of each shift, or as time permits, review collaborative roles and check emergency supplies and equipment together.

Power failure

- Perfusionist** 1. Hand crank pump. Patient may not need to come off bypass if this is adequate.

Air in arterial side of circuit or tubing rupture

The following steps are performed in rapid sequence, or simultaneously if possible:

- Perfusionist /RN** 1. Clamp arterial line first.
(Note: this clamping sequence is specific for centrifugal type of ECMO pump, but reversed for roller clamp type of pump.)
2. Clamp venous line.
3. Open bridge
(Steps 2 & 3 can be interchanged)
- Perfusionist** 4. Remove gas source from membrane and turn off pump.
- RT** 5. Increase ventilator settings or provide hand ventilation at emergency settings posted on ventilator.
- RN** 6. Move all infusions to the patient (if patient has been on bypass for greater than 15 min).
- Perfusionist** 7. Decrease heater settings if blood is warmer than 36.5°C.
- RN or designee** 8. Notify MD and other support STAT.
- RN** 9. Support infant as needed until MD arrives. Remember that the circuit provides a reservoir of blood if transfusion is needed.

Accidental decannulation

- RN** 1. Apply direct pressure immediately.

- | | |
|-----------------------------|--|
| Perfusionist
/RN | 2. Come off bypass as above. |
| RT | 3. Hand ventilate until ventilator is adjusted to emergency settings. Have Ward Clerk STAT page RT to NICU. |
| RN | 4. Give volume as appropriate.
Remember that the circuit provides a reservoir of blood if transfusion is needed. |
| RN or
designee | 5. Page neonatologist and surgeon STAT. OR team to be called by neonatologist or surgeon. |
| RN | 6. Transfer all IV fluids or drips to the infant. |
| Perfusionist
/RN | 7. Continue monitoring ACT every 15 minutes from infant and circuit. |

ECMO CIRCUIT EMERGENCIES

There are several circuit emergencies that will require the patient to be removed from bypass. Under controlled circumstances, the bedside RN's sole responsibility is to maintain the patient. (THIS IS A CODE SITUATION.) The Perfusionist will manage the circuit emergency.

Under some circumstances the RN may be required to monitor the ECMO circuit for very brief periods of time. During these periods an RN may be required to remove the patient from bypass in the event of a circuit emergency. This technique will be taught in depth in a skills lab. The following are general emergencies that may occur with the nursing interventions described based on the presence of the Perfusionist at the bedside.

CIRCUIT EMERGENCIES	NURSING INTERVENTION(S)
1. Circuit Emergency requiring off bypass	
A Perfusionist at bedside	1 Call ECMO MD, Intensivist, Respiratory Therapist
	2 Bag patient at emergency vent settings until Respiratory Care can intervene.
	3 Administer any code drugs, volume as required
	4 Obtain one unit of PRBCs from Blood Bank.
	5 If chest compressions are required, use extreme caution due to heparinization.
B Perfusionist NOT at bedside - one of the following occur:	1 Turn off pump
1. Circuit blood leak	2 Remove patient from bypass.
2. Accidental decannulation	3 Initiate code sequence as noted above (1A). <u>DO NOT</u> attempt to manage the circuit emergency.
3. Pump failure	
4. Air emboli	
2. Circuit Blood Leak: Blood leaking, spraying from circuit	1 Major blood loss - Is perfusionist at bedside? yes - perform 1A no - perform 1B
	2 Slow dripping of blood loss - Is perfusionist at bedside? yes - perform 1A no - perform 1B
3. Accidental Decannulation: Excessive blood loss at cannulation site, inability to achieve flow, patient decompensation	1 Is the Perfusionist at bedside? yes - perform 1A no - perform 1B
	2 Apply pressure to cannula site.
	3 Call surgery stat.
4. Pump Failure: No flow, patient decompensation, power loss, pump failure	1 Is the Perfusionist at bedside? yes - perform 1A no - perform 1B
5. Air Emboli: Air bubble noted infusing into patient cannula	1 Is the Perfusionist at bedside. yes - perform 1A no - perform 1B

Guidelines

Principles and theory of ECMO

Extracorporeal Life Support grew out of the development of heart-lung bypass machines used in cardiac surgery in the mid 20th century. Advances during the 1960s and 70s led to introduction and success in the neonatal population.

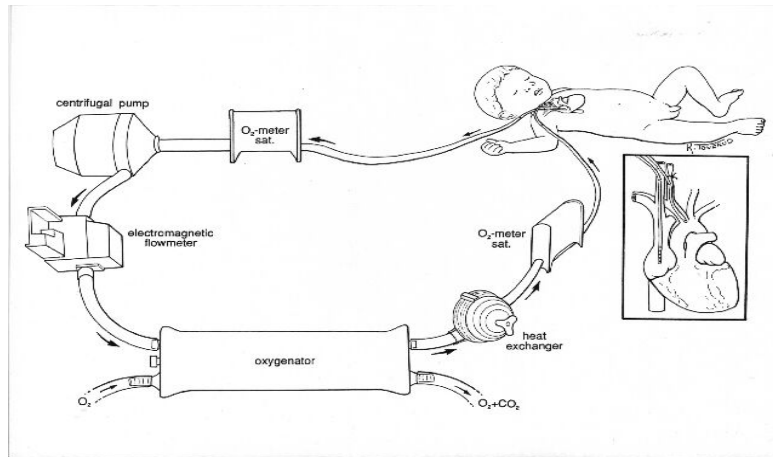
ECMO has 2 main components. It substitutes for the lungs in providing gas exchange, and it is also capable of augmenting the pumping function of the heart. It is used mainly for rescue of patients who would otherwise die from cardiopulmonary failure. These patients have conditions that are refractory to maximal medical management, including high-frequency ventilation and inhaled nitric oxide. Conditions potentially benefiting from ECMO include:

- Persistent Pulmonary Hypertension of the Newborn (PPHN), in which the pulmonary vasculature fails to dilate in transition to extrauterine life
- Meconium Aspiration Syndrome, in which the damage done by aspiration of meconium is so severe as to cause extreme ventilation-perfusion mismatch that causes or exacerbates PPHN
- Septic shock, in which multi-organ systems failure overwhelms the ability of the cardiopulmonary system to supply oxygen to the tissues of the body
- Respiratory Distress Syndrome (RDS), in which the lack of surfactant leads to hypoxia that triggers pulmonary vasoconstriction and pulmonary hypertension
- Congenital Diaphragmatic Hernia, in which the lung parenchyma was inhibited from developing *in utero* due to protrusion of abdominal contents into the chest cavity

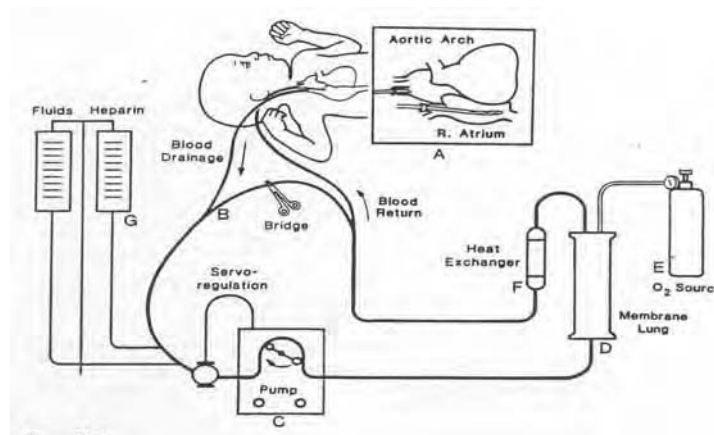
Venoarterial (VA) ECMO

Requires cannulation of right carotid artery and right jugular vein. Blood flows from venous cannula through pump and membrane oxygenator, and back through arterial cannula.

Indicated when left ventricular failure is present or patient is not a candidate for VV ECMO due to vessel size. More appropriate for long-term support, or for support of blood pressure.



Centrifugal pump ECMO circuit



Roller head pump circuit

Advantages of VA ECMO

- Excellent gas exchange and rapid stabilization
- Good cardiovascular support can be achieved, hypotension is not a complication
- Venous saturations can be used to monitor the patient

Disadvantages of VA ECMO

- Ligation of the carotid artery
- Alteration of pulsatile flow patterns created by non-pulsatile pump—may have deleterious effects on kidneys or brain
- Particles or air in the system go into the arterial side of the circuit, leading to potential systemic/cerebral emboli
- Reduced pulmonary blood flow
- Lower myocardial oxygen delivery

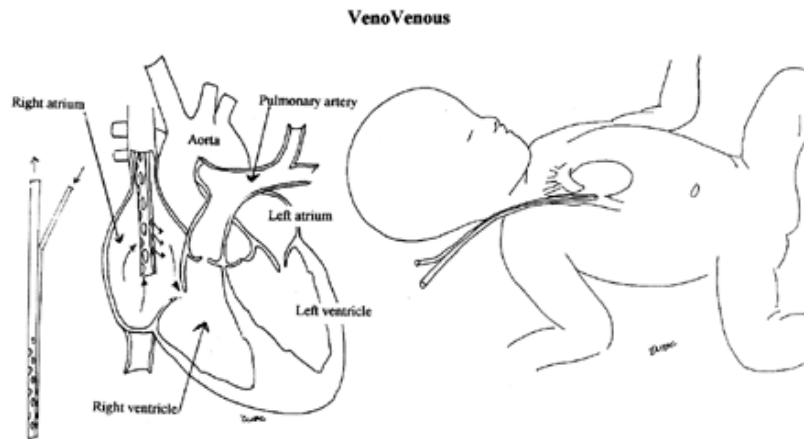
Venovenous (VV) ECMO

Usually uses a single double-lumen cannula in the jugular vein, or may involve cannulation of right jugular vein and femoral vein (see diagram).

Indicated when respiratory support is the primary goal of therapy, and heart functioning and blood pressure are not a problem.

As VV is somewhat less efficient at oxygenation than VA ECMO, the patient may require more ventilator support with higher PEEP.

VV ECMO may be changed to VA ECMO if necessary to support cardiac output and oxygenation.



Advantages of VV ECMO

- Spares carotid artery
- Infusion of possible emboli into the pulmonary, rather than systemic/cerebral circulation
- Perfusion of pulmonary vascular bed with oxygenated blood, possibly allowing a more rapid fall in pulmonary vascular resistance
- Perfusion of coronary arteries with oxygenated blood, supporting improvement in myocardial function
- Maintenance of pulsatile blood flow and improved myocardial oxygen delivery

Disadvantages of VV ECMO

- No direct cardiac support
- Partial recirculation requiring higher pump flow rate
- Lower systemic PO₂ due to mixing with deoxygenated blood
- Prone to mechanical problems (kinking, hemolysis)
- Potential for hypotension

Potential problems and complications with ECMO

Problem or Symptom	Likely Cause	Corrective Action
Hypotension	Hypovolemia due to overt or occult bleeding; leaky capillaries	Transfuse, give volume, increase flow
	Hypocalcemia (from large amounts of citrated blood)	Give calcium
	Myocardial failure	Inotropic drugs, increase flow VV to VA conversion
	Inadequate venous return (check for s/sx hypovolemia)	Check for kinking, occlusion, or obstruction by suture, or cannula malposition (per CXR). Give volume. Consider pneumothorax or cardiac tamponade. Decrease flow.
	Hemo- or pneumothorax, Hemo- or pneumopericardium	Check CXR

	Shunting in circuit—blood not returning to patient	Check for leaks, check for loose bridge clamps
--	--	--

Problem or Symptom	Likely Cause	Corrective Action
Hypertension	Response to oxygen and volume (overcorrection)	Slow rate of flow, decrease volume from circuit
	Improving from hypotension	Wean inotropes
	Inadequate sedation, or too rapid weaning meds after prolonged sedation	Assess and correct sedation, pain
Hypoxia, falling O2 saturation	Inadequate flow	Increase flow, check for loose bridge clamps, occlusion
	Excessive recirculation (VV ECMO)	Check catheter position and adjust if necessary; possibly decrease flow; consider change to VA ECMO
	Oxygenator failure, no gas flow to membrane	Check transmembrane pressures, check gas flow
	Atelectasis (usually a high PEEP is maintained during ECMO)	Increase PEEP, FiO2
	Miscellaneous	Check Hct. Assess for PDA. Assess for seizure activity.
Hemolysis (visible blood in	Catheter kinking	Check catheter

urine, ETT, mouth)	Tight suture	Check sutures
	High flow through narrow catheter lumen (especially with VV ECMO). Potential clots in circuit.	Decrease flow. Assess for clots in circuit—may need to change circuit or oxygenator.
High system pressure	Catheter kinking or obstruction	Check catheter, clamps, and sutures
	Malposition of cannula	Check CXR
	High flow	Check chart to see if excessive; decrease flow until problem resolved

Problem or Symptom	Likely Cause	Corrective Action
Hemorrhage (intracranial, intrapleural, GI, etc)	Heparinization status; platelet destruction	Frequent neuro assessments and daily neuro ultrasound
		Minimize barotrauma from vent settings. Minimize barotrauma from pleuravac suction (set at 10 cm H ₂ O)
		Avoid any violation of skin or mucous membrane integrity (venipuncture, injections, rectal thermometer, insertion of chest tube (or any other surgical incision) unless done using a bovie to cut and cauterize.

Clots	Disseminated intravascular coagulation from overwhelming sepsis, prolonged hypoxia and acidosis; possibly related to changing of a circuit part or clots in the circuit	Consider changing entire oxygenator or circuit. Investigate potential causes of DIC.
Fluid imbalance, renal failure	Leaky capillaries, third spacing of fluids. Kidneys may be overwhelmed by plasma free hemoglobin.	Diuretics, hemofiltration
Mechanical complication: circuit disconnect, leakage, air bubble	Accidental disconnect	Manage as an emergency (see 3.11 Emergency Protocols above). Call for extra help. Bag with 100% O ₂ and nitric oxide (if ordered) until vent settings are changed. If cannula has slipped out, apply pressure to cannula site. Be prepared to administer blood or volume.

Weaning

Weaning involves a slow decrease in total ECMO flow over time. As the blood flow is re-directed to the lungs, the ventilator settings will be changed to take over supporting the patient.

VV ECMO can usually be weaned more quickly than VA ECMO.

- The 100% Oxygen Challenge is done daily to assess functioning of the lungs
- A “trial off” ECMO support, with only minimal flow through the oxygenator (VA ECMO) or elimination of gas exchange function (VV ECMO), is called “idling.” This is the last test prior to decannulation. During the “trial off” ventilator settings, pressors and other supports can be fine-tuned.

Decannulation

Decannulation is a sterile surgical procedure with only slightly less risk than initial cannulation.

The Heart Team is reactivated to create a sterile surgical environment, and all the precautions

and concerns of the first surgical procedure also apply to the decannulation. Following

decannulation, risk of bleeding continues until the heparin has cleared the system (about 6

hours). For patients with a history of pulmonary hypertension, there is a risk of recurrence for

the first 12 to 24 hours

Abbreviation List

ABG	arterial blood gas or gases
ACT	activated clotting time
ALT	alanine aminotransferase
Ambu bag	manual ventilation device
AST	aspartate aminotransferase (SGOT)
B/P	Blood Pressure
BB	blow-by
BP	Blood Pressure
BUN	blood urea nitrogen
C	Celsius / centigrade
Ca	calcium
CBC	complete blood cell count
CK	creatinine kinase
Cl	chloride
CMV	cytomegalic virus
Cr	creatinine

CSD	Central Supply Department
CVL	central venous line
CXR	chest xray
DC	discontinue
DI	Diagnostic Imaging
DIC	disseminated intravascular coagulation
diff	differential
echo	echocardiogram
ECMO	extracorporeal membrane oxygenation
ESD	Environmental Services Department
ETCO2	end tidal carbon dioxide
ETT	endotracheal tube
FFP	fresh frozen plasma
Fib	fibrillation
FiO2	fractional inspired oxygen
GI	gastrointestinal
Glu	glucose
HCO3	bicarbonate
Hct	hematocrit
HFOV	high frequency oscillator ventilator/ventilation
HR	heart rate
HUS	head ultrasound
I&O	intake and output
iCa	ionized calcium
INO	inhaled nitric oxide
IV	intravenous
kg	kilogram
Lab	Laboratory
lytes	electrolytes
MAX	maximum
MD	medical doctor
Mg	magnesium
min	minute(s)
ml	milliliter
MOA	Moanalua
Na	sodium
neuro	neurological
NG	nasogastric
NGT	nasogastric tube
NICU	Neonatal Intensive Care Unit
NS	normal saline
O2	oxygen
OG	orogastric
OGT	orogastric tube
OR	Operating Room
osm	osmolality
PDA	patent ductus arteriosus
pedi	pediatric

PEEP	positive end-expiratory pressure
pH	hydrogen ion concentration
PIV	peripheral intravenous
PO ₂	pressure of oxygen
PO ₄	phosphorus
PPHN	persistent pulmonary hypertension of the newborn
PRBC	packed red blood cells
PRN	as required
Psych CNS	Psychiatric Clinical Nurse Specialist
PT	prothrombin time
PTT	partial thromboplastin time
PVC	premature ventricular contractions
Q or q	every
R/O-IVH	rule out intraventricular hemorrhage
RDS	Respiratory Distress Syndrome
RN	registered nurse
ROM Q	range of motion every
RT	respiratory therapy
S/sx	signs and symptoms
sat	saturation
SG	specific gravity
SpO ₂	oxygen saturation
STAT	now or immediately
T/D bili	total/direct bilirubin
Temp	temperature
THAM	thromethamine
TPN	total parenteral nutrition
UAC	umbilical artery catheter
UVC	umbilical venous catheter
VA	venoarterial
VS	vital signs
VV	venovenous

References:

- Children Healthcare of Atlanta at Emory University, 2004. "ECMO Specialist Training Manual." Atlanta, Georgia.
- Van Meurs, K., MD (Editor), 1999. "ECMO Specialist Training Manual (2nd Ed.). Extracorporeal Life Support Organization.
- Carriedo, H., MD, & Deming, D., MD, 2003. Therapeutic techniques: Neonatal ECMO. *NeoReviews*, Vol 4, No 8, p. e212-214.

Review and Approval

Authors/ Owners:	Dr. Mark Ogino MD, ECMO Program Medical Director Nelody Kilcommons, ECMO Program Clinical Coordinator Kristen Costales, ECMO Program Perfusion Coordinator
Endorsements:	
Approval:	

Appendix A.2

ECMO Transport Sled Proposal

Tripler Army Medical Center

ECMO Transport Sled Proposal

March 10, 2009



Table of Contents

Funding Request

Hawaii Mobile ECMO Equipment List

Vendor Quotes

Schedule A – Elliott Aviation	ETS Platform & ETS Spares Package
Schedule B – Levitronix	CentriMag System
Schedule C – Spectrum Medical	M3 Monitor
Schedule D - BBraun	Perfusor Space Infusion Device
Schedule E – Cardinal Health	Medsystem III DLE Multi-channel Infusion Pump
Schedule F – Pulmonetic Systems	LTV 1200 ventilator
Schedule G – Stryker	Power Pro IT Ambulance Cot
Schedule H – Abbott Laboratories	i-Stat 1 Analyzer
Schedule I – Terumo	Sechrist Air/Oxygen Blender
Schedule J – Medtronic	Pressure Display Box
Schedule K – Phillips Medical	IntelliVue MP2 Monitor
Schedule L – Cincinnati Sub Zero	Micro-Temp LT heater
Schedule M – International Biomed	Lifepoint Clipdeck
Schedule N – Thomas EMS	ALS Ultra Roller Pack, ALS Ultra, Aeromed Advanced
Schedule O – International Biomed	Cable Management Bag/Neonatal Respiratory Bag
Schedule P – Pelican Products	1620 Case

Funding Request: Construction of ECMO Transport Sled and ECMO Transport Equipment

Background

The Pacific Pediatric Advanced Care Initiative, through prior Department of Defense funding, has established an advanced Pediatric care center with Extra-Corporeal Life Support (ECLS) in Hawaii to support the Pacific Rim. The Center's goal is to advance the science of Pediatric Advanced Care through innovative research, to improve the education and training of Department of Defense (DOD) Health Care providers, and to provide advanced medical care to neonatal and pediatric patients using ECLS technologies.

This initiative is a joint venture between Tripler Army Medical Center (TAMC), Kapi'olani Medical Center for Women and Children (KMCWC), Kaiser Permanente Hawaii, University of Hawaii (UH), and the University of Pittsburgh Medical Center (UPMC). Tripler has contributed medical expertise, transport experience, animal research facilities and training facilities. Kapi'olani is the clinical center with the state's largest Pediatric and Neonatal Intensive Care Units, and also shares its clinical expertise with the program. The Medical Director of the program is provided through Kaiser. University of Hawaii and University of Pittsburgh have been instrumental in supporting the clinical research interests of the Center.

Clinical Program

ECLS employs a bedside heart-lung bypass system for critically-ill neonates and children in respiratory or combined respiratory/cardiac failure. ECLS allows extracorporeal membrane oxygenation (ECMO) and systemic circulatory support while the patient's condition improves, allowing for recovery, if possible, or until another therapy can be initiated. Although this is considered to be standard-of-care for carefully selected patients, it is high risk, with mortality ranging from 23% to 62% depending on the underlying diagnoses (Conrad et al, 2005).

Since the establishment of the Hanuola program at Kapi'olani Medical Center in July 2007, the Center has received 30 consults. ECLS support has been provided to 18 patients since the beginning of the ECMO program in Hawaii. Neonatal patients account for 80% of the cases. The Hanuola ECMO Program outcomes match or surpass the outcomes from a comparative set of patients in the Extracorporeal Life Support Organization's (ELSO) ECMO registry.

Respiratory failure is the primary diagnostic category in the referral population; however, there have been four patients with a primary cardiac diagnosis.

A challenge for the health care system in Hawaii has been to provide comprehensive cardiac services for the Pediatric population due to the limited availability of resources and subspecialty expertise. Prior to the availability of ECLS services in Hawaii, many of these patients died prior to their transfer to a Continental United States tertiary Pediatric Center. Fortunately, today, ECMO can be utilized to stabilize these patients until they reach a mainland Pediatric Referral Center for advanced cardiac interventions. Our second challenge is to transport these patients on ECMO to the continental United States. The established civilian ECMO Transport services (Univ of Arkansas, Univ of Michigan) do not have the capability to transport across the Pacific Ocean. For these emergency situations, the USAF Wilford Hall ECMO Transport unit has assisted with the emergency transfer. One of the four patients that required transport to a mainland facility was a Department of Defense dependent.

The proposed expansion of the program to retrieve ECMO patients at outside facilities and the increasing need to transfer patients on ECLS to mainland centers, make a Hawaii Mobile ECMO Transport Program a necessity. Due to our program's strong collaboration between DOD and civilian partners, an ECMO Transport unit is being designed to utilize the currently available commercial ambulance aircraft in Hawaii. AirMed International is a corporation with aircraft stationed throughout the United States, Asia, and Europe. This organization has been approved to land at military installations and provides emergency medical transports for the DOD.

The urgency in the development of an ECMO Transport Program in Hawaii is heightened with the interim reduction in neonatal services at Wilford Hall Medical Center, as Wilford Hall and Brooke Army Medical Center consolidate services between institutions. The reassignment and retirement of the ECMO Transport Unit's personnel will reduce the availability of the team for civilian humanitarian causes. Without the WHMC ECMO Team, Hawaii will be left with no options for ECMO transport. Hence, the development and opening of our ECMO Transport program is essential to ensure full medical and surgical Pediatric services to DOD dependent and civilian patients of the Pacific Rim.

Funding Request

We are working with AirMed International, the contracted air transport unit, to design our ECMO transport unit. Engineering consultants and manufacturing has been with Elliott Aviation, a firm experienced with air ambulance construction and FAA regulations. The start up funding has been through our initial grant funds.

This funding request is for the construction of the ECMO Transport Sled and the necessary equipment to complete the ECMO Transport Unit. The requested equipment is listed in Table One, with descriptions and equipment cost quotes. Recent equipment quotes have also been attached.

HAWAII MOBILE ECMO EQUIPMENT LIST

Please see attached vendor quotes for ordering and contact information for all equipment listed below. Note quantities listed in the spreadsheet.

For questions regarding the equipment or quotes please contact: Kristen Costales, ECMO Perfusion Coordinator, 808-228-6693, Kristen.Costales@kapiolani.org

Vendor	Product Name	Part Number (s)	Description	Quantity	Total Price
Elliott Aviation	ECMO Transport Platform	ETS Platform	A platform designed and tested to safely transport an ECMO patient and all necessary equipment on an ambulance or aircraft.	1	\$ 117,887.50
Elliott Aviation	ECMO Transport Spares Package	ETS Spares Package	Equipment needed for the ECMO Platform in the event of damage or preventative maintenance.	1	\$ 30,026.25
Levitronix	CentriMag System	201-90155, 201-90211, 201-50112, 201-50111, 201-30102, 8 Levitronix pumps	A pump that drives the rotational movement of the disposable pump head which drives blood through the tubing, ECMO components, and returns the blood to the patient. Includes a back-up manual pump for emergencies.	1	\$ 31,500.00
Spectrum Medical	M3 Monitor	3005-001-010, 3003-001-020, 3003-001-021, H9XLM, H7XLH	Monitor that displays the blood flow to the patient from the ECMO circuit, the percentage of blood saturated with oxygen, and the red blood cell mass. This monitor gives an instantaneous readout of values that allow an assessment of the ECMO circuit function.	1	\$ 54,755.00
B Braun	Perfusor Space Infusion Device	8713030U, 8713112A, 8713130, 8713133, 8713170, 8713180, DLSYRTR1, OTDLSP	A pump used to deliver intra-venous medications to neonatal patients. Higher accuracy at low infusion rates used in the neonatal population.	8	\$ 36,773.90
Cardinal Health	MedSystem III DLE Multi-Channel Infusion Pump	2865B, 143553, 2860729	A pump used to deliver intra-venous medications to pediatric patients.	3	\$ 12,302.58
Pulmonetic Systems	LTV 1200 ventilator	18888-001, 17650-001, 10611, 19222-001, 19102-001, 19444-001, 10823X10, 10822X10	A portable ventilator that provides respiratory support (oxygen and artificial breaths) to a patient who cannot breathe on their own.	1	\$ 17,469.35
Stryker	Power Pro IT Ambulance Cot	651000000(M)	Heavy-duty, hydraulic ambulance gurney used to support and transport the patient on the mobile ECMO platform.	1	\$ 13,697.50
Abbott Laboratories	i-Stat 1 Analyzer	06F16-10, 06F11-01, 06F23-91	A portable analyzer that tests and reports a patient blood gases (heart and lung function) and blood coagulation factors (blood clotting functions). Includes a Quality Assurance electronic simulator and a portable printer to ensure accurate test results.	2	\$ 10,820.56
Terumo	Sechrist Air/Oxygen Blender	164235, 814475	Medical gas blender that permits adjustments in oxygen and air to the oxygenator.	1	\$ 2,564.25
Medtronic	Pressure Display Box	66000	A monitor that measures the pressures within the ECMO circuit which assists with monitoring of oxygenator function.	2	\$ 1,590.00
Philips Medical	IntelliVue MP2 monitor	M8102A, B22, E20, E23, E26, M1669A, M1671A, M1599B, 989803, M1597B, 21082A, M1837A	A monitor that displays the patient's vital signs including blood pressure, heart rate, EKG, temperature, and respiratory rate.	1	\$ 5,372.06
Cincinnati Sub Zero	Micro-Temp LT heater	88116	Heating unit that rewarms the blood to body temperature before the blood is returned to the patient. It can also be used to cool the blood to treat patients with head injury.	1	\$ 455.00
International Biomedical	Lifeport Clipdeck	7319992	A mounting bracket that attaches and secures the ECMO Platform to the Stryker gurney.	1	\$ 1,100.00
Thomas EMS	ALS Ultra Roller, Red	TTR156	Packs used to organize and protect equipment and supplies needed during transport of the patient.	1	\$ 475.00
Thomas EMS	ALS Ultra, Red	TT156	Packs used to organize and protect equipment and supplies needed during transport of the patient.	1	\$ 475.00
Thomas EMS	Aeromed Advanced, Red	TT886	Packs used to organize and protect equipment and supplies needed during transport of the patient.	1	\$ 199.99
International Biomedical	Cable Management Bag	7312900	Packs used to organize and protect equipment and supplies needed during transport of the patient.	1	\$ 153.00
International Biomedical	Neonatal Respiratory Bag	7312902	Packs used to organize and protect equipment and supplies needed during transport of the patient.	1	\$ 166.00
Pelican Products	1620 Case	1620	Unbreakable and watertight case used to transport electronic equipment.	1	\$ 245.78

TOTAL	\$ 338,028.72
--------------	----------------------

Schedule A

Elliott Aviation

ETS Platform
ETS Spares Package



SPECIFICATION FOR

***Tripler Army Medical
Center/Hanuola ECMO Program of
Hawaii***

c/o AirMed Int'l

Skip Pieplow

February 16, 2009

Presented by: Ken Chitty
EA-5471
Elliott Aviation, Inc.
Quad City Airport
P.O. Box 100
Moline, IL 61266-0100
PHONE: 309.799.3183 FAX: 309.799.2015

TABLE OF CONTENTS

1	INTERIOR	3
1.1	ECMO Transport Platform (Purchase Price).....	3
1.2	ECMO Transport Spares Package	3
2	APPENDIX A: GENERAL TERMS AND CONDITIONS	4
3	APPENDIX B: LIMITED WARRANTY	5
4	PRICE SUMMARY	6
5	ADDENDUM	6

1 INTERIOR

1.1 ECMO Transport Platform (Purchase Price)

Price Includes the following:

Shipping Container
Bed Pad
External Battery Pack.

Retail Price	\$115,400.00*
Estimated sales tax.	\$ 2,487.50
TOTAL	\$117,887.50

*Price does not include any medical equipment.

Note: A Lear aircraft, in air ambulance configuration, would need to be available for fitting of ramp. This aircraft would need to be provided by AirMed and/or Kapiolani.

1.2 ECMO Transport Spares Package

Price Includes the following:

3 each Oxygen Bottles, E3, Aluminum
1 each air delivery panel
2 each latch plate assemblies
1 each restraints for heater
1 set of restraints hardware
2 each check valves
3 each air bottles, medical, aluminum
1 each external battery pack
2 each electrical chords
1 each restraints for control box
1 set of hinges for each door hinged
1 set of slides for Oxygenator
1 each Oxygen delivery panel
1 set each, slides for control box
2 each bed pads
1 each child restraints
1 set of Oxygen lines
2 sets each, slides for IV pumps
2 each spare poles for external mounting
1 each shipping container
1 set of adult restraints
1 set of air lines

Retail Price	\$28,260.00
Estimated sales tax.	\$ 1,766.25
TOTAL	\$30,026.25

2 APPENDIX A: GENERAL TERMS AND CONDITIONS

General Terms & Conditions

1. Any work required that is not part of a proposal or changes to the proposed work scope, will be performed at the current labor rate and may extend the downtime.
2. Downtime stated in proposals is based upon a timely availability and receipt of required materials.
3. Work will be performed at one of Elliott Aviation's four facilities based on the work scope and available manpower.
4. All freight charges are the responsibility of the Customer and will be charged in addition to any proposed pricing.
5. Contract cancellation is subject to restocking/penalty charges. This includes charges for work performed.

Liability

1. DELAYS. Any completion or promised date stated in any document or otherwise quoted to Customer is merely an estimated completion date and is not guaranteed. In no event shall Company incur or be liable or responsible for any consequential or other damages for nonperformance of or delay in the work, including that directly or indirectly resulting from acts of God, or the adoption or enactment of any law, regulation, ruling or order directly or indirectly interfering with or rendering more burdensome the work, or non-availability of parts, materials, or components from suppliers, delays in transportation, strikes or other causes beyond Company's reasonable control and without additional cost or expense to Company.
2. CUSTOMER AND COMPANY RESPONSIBILITIES FOR CLAIMS. Customer is responsible for any and all claims arising out of any (i) loss of or damage to Customer's aircraft or equipment, including the work accomplished on the aircraft or equipment; and (ii) loss, damage, injury, death or other liability resulting from any reasons or cause, including, without limitation, during all flight operations of the aircraft (whether or not conducted by or participated in by Company) (Customer Responsibility Claims). Customer agrees that it will protect, defend and hold harmless Company, its employees and agents (including legal fees), from and against all Customer Responsibility Claims.

Company agrees that it will protect, defend and hold Customer harmless for loss or damage to the aircraft while in Company's Possession and occurring while it is not in flight, providing such loss or damage to the aircraft is solely, directly and proximately caused by the negligence of Company (including legal fees and expenses). Upon request, Customer shall furnish evidence of ground and in-flight hull and liability insurance in a form satisfactory to Company (Company Responsibility Claims).

Payment Terms

All pricing is in U.S. Dollars. Payment in full, including any additional amounts associated with Discrepancies or additional work, will be due upon completion of the work and prior to release of aircraft, unless other prior arrangements have been established and approved. Acceptable methods of payment include: pre-approved company check, wire transfer, cash or major credit card. Any credit card fees will be the responsibility of the Customer. Progress payments will be established for projects in excess of \$400,000 quoted value, 25% due upon acceptance of the proposal (this will be considered as your deposit), 25% due upon input of the aircraft to our shop, another 25% due at the approximate 50% completion point and the remainder due prior to release of the aircraft. All work scopes less than \$400,000 quoted value will require payment of 30% of the quoted value upon acceptance of the proposal and the remainder due prior to release of the aircraft. Deposits become non-refundable 30 days prior to the agreed upon input date and will be retained by Elliott Aviation as liquidated damages in the event the project is cancelled.

Sales Tax

Customer is responsible for all sales, use, manufacturer's, occupation, excise, or any other similar or other taxes, fees, duties, tariffs or charges assessed or imposed by any governmental authority in any way related to the work performed by Company ("taxes"). Company's prices and charges do not include such taxes. Customer agrees to pay or reimburse Company for any such taxes paid by Company on behalf of Customer. Customer agrees to defend and protect Company from and against any claims for such taxes. If applicable, Customer shall furnish acceptable certificates or affidavits of exemption from any such taxes or charges.

Customer's Inspection/Claims

Customer shall inspect the aircraft or repaired part immediately upon return thereof and shall within ten (10) days thereafter notify Company in writing of any claims of incomplete or unacceptable work. The failure of Customer to notify Company of any such claims within said ten (10) day period shall constitute an irrevocable acceptance of the aircraft and all work and an admission by Customer that the work fully complies with all agreed terms, specifications, and conditions.

Applicable Law

The rights and obligations of Company and Customer shall be governed and determined by the laws of the State of Iowa and, to the extent applicable, the lien laws of any other jurisdiction in which the work is performed. Customer hereby submits to the exclusive jurisdiction and service of process of the courts of the State of Iowa and such other jurisdictions in which the work is

Tripler Army Medical Center/Hanuola ECMO Program of Hawaii

EA-5471

performed (including federal courts within said states) with respect to any dispute arising out of or in any way related to this Work Authorization, and the work to be performed and payments due there under.

Warranty and Disclaimers

The currently effective "Statement of Warranty" of the Company in effect as of the date of this Work Authorization shall govern the work. A copy has been provided to Customer or will be provided to Customer upon request. THE STATEMENT OF WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER EXPRESS AND IMPLIED WARRANTIES WHATSOEVER, INCLUDING, BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR PARTICULAR PURPOSE.

Limitations of Liability

IN NO EVENT SHALL COMPANY BE LIABLE FOR ANY LOSS OF USE OF THE AIRCRAFT OR LOSS OF PROFITS, OR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES OR LOSSES, INCLUDING, WITHOUT LIMITATION, ANY LOSS OR DAMAGE TO THE AIRCRAFT RESULTING FROM ANY FAILURE OR REFUSAL TO PERFORM CUSTOMARY RECOMMENDED OR REQUIRED STORAGE AND MAINTENANCE PROCEDURES ON ANY AIRCRAFT REMAINING OR HELD ON THE COMPANY'S PREMISES, UNLESS SPECIFICALLY AGREED IN WRITING. IN NO EVENT SHALL ANY ACTION BE COMMENCED AGAINST COMPANY MORE THAN ONE YEAR AFTER THE CAUSE OF ACTION WITH RESPECT TO WHICH THE CLAIM IS MADE HAS ACCRUED.

3 APPENDIX B: LIMITED WARRANTY

This Limited Warranty is provided by Elliott Aviation, Inc. ("Elliott Aviation") pursuant to Elliott Aviation's Aircraft Work Authorization and associated Specifications for Refurbishments (the "Specifications").

1. Limited Warranty. Elliott Aviation warrants its workmanship and services (the "Work") to conform to the specifications, plans and drawings set forth in the Specifications, and to be free from defects in workmanship according to current industry standards, subject to the terms and conditions set forth below.
2. Scope of Warranty. This warranty and the liability of Elliott Aviation for breach of warranty shall be limited to correcting or repairing such portions of the Work that is not in accordance with the Aircraft Work Authorization or Specifications. Elliott Aviation warrants only that the Work shall be free from defects under normal aircraft use. Elliott Aviation's obligations under this Warranty, and Owner's exclusive remedy, shall be limited solely to the repair, or replacement, at Seller's election, of any workmanship which is determined to be defective under normal use and service within the earliest to occur of three hundred (300) hours of aircraft operation or one (1) year after completion of the Work (the "Warranty Period").
3. Conditions of Warranty. Elliott Aviation's obligation to provide Warranty services hereunder shall be contingent upon satisfaction of the following conditions. Failure of Owner to comply with any of the conditions specified in this paragraph 3 shall relieve Elliott Aviation of any obligations hereunder:

- (a) Claim Period. Owner shall give Elliott Aviation written notice of any claim of a defective or nonconforming condition ("Warranty Claim") within the Warranty Period;
- (b) Notice of a Claim. To assert a Warranty Claim, Owner shall notify Elliott Aviation in writing within thirty (30) days after Owner has actual or constructive notice of such alleged Warranty Claim. All Warranty Claims shall be sent to the Elliott Aviation Facility where the work was performed.

Elliott Aviation, Quad City Airport, Moline, Illinois 61265, Attention: Chief Inspector.
Elliott Aviation, P.O. Box 35250, Des Moines, Iowa 50321, Attention: Chief Inspector.
Elliott Aviation, 3636 Wilbur Plaza, Omaha, Nebraska 68110, Attention: Chief Inspector.
Elliott Aviation, 13801 Pioneer Trail, Eden Prairie, Minnesota 55347, Attention: Chief Inspector.

All claims shall include the following information:

- (i) Date services were performed; and
 - (ii) Detailed explanation of the nature of the claim, and the date of detection.
- (c) Care and Maintenance. Customer shall comply in all material respects with the conditions of the respective applicable manufacturer's warranty, including without limitation recommended care, cleaning and maintenance requirements.
 - (d) Inspection. Elliott Aviation shall have a full and complete opportunity to inspect any alleged defect or nonconforming work, and review any records concerning the alleged defect prior to performance of any repairs. Owner agrees to deliver its Aircraft to Elliott Aviation's closest service facility at Owner's costs, in order to facilitate such inspection.

Tripler Army Medical Center/Hanuola ECMO Program of Hawaii

- (e) Repairs. If Elliott Aviation determines that the defective or nonconforming work is shown to be due to a breach of the above warranty, and not due to any extraneous cause, including but not limited to misuse by customer or any third party, failure to perform recommended maintenance, or effects of the environment (wind, water, corrosion, etc), then Elliott Aviation shall repair the defective work.
4. Exclusive Remedy. THE LIMITED WARRANTY PROVIDED HEREIN IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, REGARDING THE QUALITY AND/OR THE PERFORMANCE OF THE SERVICES. EXCEPT AS EXPRESSLY PROVIDED IN THIS LIMITED WARRANTY, ELLIOTT AVIATION MAKES NO WARRANTIES OF ANY KIND RELATING TO THE SERVICES PERFORMED, AND ELLIOTT AVIATION DISCLAIMS ALL WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTY OF MERCHANTABILITY, THE IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE.
- ELLIOTT AVIATION'S ENTIRE LIABILITY RELATING IN ANY MANNER TO THIS LIMITED WARRANTY SHALL BE LIMITED EXCLUSIVELY TO REPAIRING THE SERVICES DETERMINED TO BE DEFECTIVE AND THE REIMBURSEMENT OF REASONABLE LABOR COSTS TO THE EXTENT PROVIDED IN THIS LIMITED WARRANTY.
- ELLIOTT AVIATION SHALL IN NO EVENT BE LIABLE TO OWNER, OR TO ANY PERSON CLAIMING THROUGH OWNER, WHETHER IN CONTRACT, TORT, OR STRICT PRODUCT LIABILITY, FOR INDIRECT, SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES, LOSS OF PROFITS, LOSS OF USE, DEMURRAGE, OR PENALTIES, ARISING FROM ANY CAUSE WHATSOEVER.
5. Third Party Warranty. No warranty is given with respect to parts and/or materials not manufactured by Elliott Aviation. However Elliott Aviation will pass on any warranty from its vendors in favor of Elliott Aviation and/or its customers.
6. Assignment. This Limited Warranty is given only to the Owner of the Aircraft when services are performed, and may not be transferred or assigned by Owner to any subsequent owner.
7. Applicable Law; Jurisdiction. This Limited Warranty shall be governed by and construed in accordance with the internal laws of the State of Iowa without regard to the principles of conflicts of law. The exclusive forum for any action to enforce the terms of this warranty shall be the Iowa District Court in and for Scott County, Iowa.
8. Limitation of Action. No action at law or in equity shall be maintained by Owner against Elliott Aviation for Elliott Aviation's alleged breach of this Warranty and/or violation of any federal or state law now in effect or hereafter enacted with respect to any obligation or duty incurred hereunder by Elliott Aviation, unless (i) Owner notifies Elliott Aviation in writing at the address specified in this Agreement within thirty (30) days from the date of such alleged breach or violation, and provided Elliott Aviation does not remedy or correct the breach or violation within sixty (60) days from the receipt of the notice; and (ii) such action at law or equity is commenced by Owner within one (1) year from the completion of the Work, unless extended by ninety (90) days to allow for notice to Elliott Aviation and its response as provided by this paragraph.
9. Entire Agreement. This Limited Warranty constitutes the entire agreement between Elliott Aviation and Owner concerning the subject matter hereof, and supersedes all prior or contemporaneous agreements or warranties between the parties concerning the subject matter hereof.

4 PRICE SUMMARY

Interior Section 1.1	\$115,400	Decline _____	Accept _____
Interior Section 1.2	\$ 28,260	Decline _____	Accept _____

5 ADDENDUM

Except as modified herein, all remaining Terms and Conditions are unchanged and in full force and effect.

Elliott Aviation, Inc.

Ken Chitty

Project Manager

February 16, 2009

Tripler Army Medical Center/Hanuola ECMO Program of Hawaii co AirMed Int'l – Skip Pieplow

Signature _____

Title _____

Date _____

Tripler Army Medical Center/Hanuola ECMO Program of Hawaii

EA-5471

Schedule B

Levitronix

CentriMag System

Levitronix LLC
 45 First Avenue
 Waltham, MA 02451 USA

Phone (781) 622-5070
 Fax (781) 622-5090



From Farzad Parsaie
 Direct line (781) 622-5075
 Direct fax (781) 622-5090
 E-mail fparsaie@levitronix.com
 Date 05 March 2009
 Your ref NA
 Valid Until **05 April 2009**

QUOTE FOR:

Kristen Costales CCP
 Tripler Army Medical Center
 Hanuola ECMO Program of Hawaii
 1 Jarrett White Road
 Tripler AMC, Hawaii 96859

Quote No. OF 09-0305a

Pos	Amount	Unit	Article	Unit Price	Extension
1	1	Set	CentriMag Hardware	\$30,000	\$30,000
Consists of:					
201-90155 1 set CentriMag Primary Hardware (CPB) (Each set consists of one Primary Console, one Motor, one 45° Motor Bracket)					
201-90211 1 set CentriMag Back-Up Hardware (CPB) (Each set consists of one Back-Up Console, two Standard-Capacity Battery Modules & one Motor)					
2	8	Ea	Levitronix pump	NA	No-Charge
3	1	Ea	201-50112 45° Motor Bracket	\$150	No-Charge
4	1	Ea	201-50111 Transport Platform	\$250	No-Charge
5	1	Ea	201-30102 Pediatric Flow Probe	\$1,500	\$1,500
Total (excl. tax, packing and freight charge)					USD 31,500

Remark 1: Prices offered are valid for 30 days.

Remark 2: Hardware prices include one year standard warranty.

Remark 3: All items listed above are exclusively for CPB use of the CentriMag System consistent with the approved labeling.

Bank: Bank of America, ABA: 0260-0959-3, SWIFT: BOFAUS3N, Account: 0095 1029 2809

Schedule C

Spectrum Medical

M3 Monitor



February 6, 2009

Expires in 30 Days

Tripler Army Medical Center
Hanuola ECMO Program of Hawaii
1 Jarrett White Road
Tripler AMC, HI 96859
Attn: Kristen Costales, CCP

Dear Kristen,

Per your request, here is a System M quote:

The M3 is the state of the art, continuous, **NON-INVASIVE** monitoring of arterial and venous blood gas saturation, hematocrit, and flow. NO CALIBRATION is needed therefore giving the caregiver absolute accurate readings to initiate protocol without worry of drift.

The M3 dual size set can be purchased for the discounted price of \$54,755.00 each (the list price is \$66,149.00). The M3 includes the parameters of SaO2, SvO2, hematocrit/hemoglobin and flow with one probe each per system. This price will include a five-year manufacturer's warranty and software upgrades as needed. *Spectrum Medical, Inc. will provide **free shipping** upon receipt of purchase order.*

Part Number	Description	Quantity	Unit Price	Price
3005-001-010	M3 Monitor	1	49,950.00	\$49,950.00
3003-001-020	3/8 x 3/32 Hematocrit Sensor	1	0.00	Included
3003-001-021	1/4 x 3/32 Hematocrit Sensor	1	1,805.00	\$1,805.00
H9XLM	3/8 x 3/32 Flow Sensor	1	0.00	Included
H7XLH	1/4 x 3/32 Flow Sensor	1	3,000.00	\$3,000.00
TOTAL				\$54,755.00

System M Technology is evolving rapidly. We anticipate "VIPER" (Variable Input, Patient Electronic Record) and other parameters within the upcoming months. If you decide to upgrade a purchased unit within 12 months, 75% of capital will be applied to the upgrade. If upgrading within 12-24 months, 50% of original capital will be applied to the purchase.

Thank you for your interest in the System M for bettering patient outcomes. Please direct me on how you would like to proceed.

Sincerely,

Matthew C. Story

Matthew C. Story
Sales Manager

Spectrum Medical, Inc.
Cell: (404) 354-2676
Office: (800) 265-2331
Fax: (803) 545-4881
1225 Laurel Street, Suite 427
Columbia, South Carolina 29201
Matthew.Story@spectrummedical.com



Schedule D

BBraun

Perfusor Space Infusion Device



Tripler Army Medical Center
 Hanuola ECMO Program of Hawaii
 Honolulu, HI
 March 9, 2009

Perfusor® Space Infusion Device

B. Braun Medical Inc. is pleased to offer Tripler Army Medical Center the option to purchase the Perfusor® Space Infusion Device. Purchases of infusion devices and related disposables by Tripler Army Medical Center are subject to the terms and conditions of the purchasing agreement currently in effect between Military Dapa and B. Braun related to such products ("B. Braun/Military Dapa Agreement").

Outright Purchase

Quantity	Catalog Number	Description	Proposed Price per each	Extended Price
8	8713030U	Perfusor™ Space Infusion Devices	\$3,015.08	\$24,120.64
4	8713112A	Power Cords	\$75.38	\$301.52
4	8713130	Pole Clamp	\$150.75	\$603.00
3	8713133	Combi-leads	\$150.75	\$452.25
1	8713170	Battery Charger	\$145.73	\$145.73
2	8713180	Extra Batteries	\$75.38	\$150.76

*Above pricing is based upon the B. Braun/Military Dapa Agreement. To be entitled to the pricing, Tripler Army Medical Center must be a Military Dapa member in good standing at time of purchase and must have fulfilled all requirements of such membership. Terms for Capital Equipment are FOB Origin, Net 30 Days. All pricing is exclusive of any Extended Warranty, applicable taxes and freight charges. Any customization for Products/Services or Accessories not quoted in this proposal, will be made available at an additional charge. All transactions are pending credit approval

Infusomat™ Space Infusion Device Warranties:

B. Braun's standard product warranty is one (1) year from date of shipment. A copy of our Product Warranty is included with our proposal, and includes the terms of our warranty. In addition, B. Braun offers the following additional warranty program, which is described in the Extended Warranty Program Agreement included with our proposal.

Pricing under this program is as follows:

- The Extended Limited Warranty is \$150.00 per device per year.

This additional warranty program is offered at the time the devices are purchased. These warranty prices may increase after initial sale.



Tripler Army Medical Center
 Hanuola ECMO Program of Hawaii
 Honolulu, HI
 March 9, 2009

Drug list Editor Tier Fees

B. Braun Medical Inc. is pleased to offer Tripler Army Medical Center B Braun's Space Library Software which is required to be licensed in connection with the purchase of the Space Infusion devices. The Drug List Editor Software may be licensed from B.Braun pursuant to the terms and conditions of B.Braun's Software License and Services Agreement, a copy of which is included with this proposal.

Price List

# of devices	Catalog Number	Description	Proposed Price per each
1	DLSYRTR1	Drug Library Editor	\$9,000.00
1	OTDLSP	Space Anesthesia Drug Library*	\$2,000.00

*Drug library with 20 standard drugs and 5 custom drugs in up to 2 concentrations each. Account customizes concentrations, dose limits, bolus dosing, clinical advisories, etc. Also includes up to 4 hours of phone support from B Braun pharmacist for drug library development. B Braun downloads library to the devices. Any future changes to the library require additional fees

If the pricing under this bid response constitutes a discount or other reduction in price under Section 1128(b)(3)(A) of the Social Security Act 42 U.S.C. 1320a-7b(b)(3)(A), and 42 C.F.R. § 1001.952(h), Customer shall disclose the discount or reduction in price to the full extent required under any state or federal program which provides cost or charge based reimbursement to Customer for Products and/or services covered by this bid response. This Act requires, among other things, that Customer fully and accurately report on any claim or request for payment it submits to Medicare and Medicaid the actual purchase price paid by Customer for Products and/or services, net of any discounts, rebates or allowances provided hereunder. Customer may also be required, upon request, to provide documentation of the discount or other reduction in price to the Secretary of Health and Human Services.



Tripler Army Medical Center
Hanuola ECMO Program of Hawaii
Honolulu, HI
March 9, 2009

Thank you for your continued support of B.Braun products. We hope you find this Proposal satisfactory. Above proposal is valid for 90 days from date of issuance. We look forward to working with you.

CUSTOMER: _____
(Name of Account)

Date Signed by Customer: _____

By: _____
(Signature)

Name: _____
(Type or print name)

Title: _____
(Type or print title)

B. BRAUN MEDICAL INC.

By: _____
(Signature)

By: _____
(Signature)

Name: _____
(Type or print name)

Name: _____
(Type or print name)

Title: _____
(Type or print title)

Title: _____
(Type or print title)

Date: _____

Date: _____

Schedule E

Cardinal Health

Medsystem III DLE Multi-Channel Infusion Pump



Date: February 10, 2009

To: Kristen Costales, Tripler Army Medical Center, Hanuola ECMO Program of Hawaii

E-mail: Kristen.Costales@kapiolani.org

Per your request, please find FSS pricing below.

Model	Description	Pricing	Quantity	Total
2865B	MedSystem III® DLE Multi-Channel Infusion Pump, includes one MedSystem III Infusion Pump (with Drug List Editor and Advanced Dose Rate Calculation), and one AC Adapter.	\$3,899.90 ea.	3	\$11,699.70
143553	MSIII Protective Cases	\$137.81 ea.	3	\$413.43
2860729	Battery, Lithium, Backup	\$63.15 ea.	3	189.45

Contract: V797P-4091A
 Freight terms: FOB Destination, Freight Prepaid
 Tax: Included
 Payment terms: 1% 30 Net 31
 Directions for Use Manual: 1-DFU manual at no charge (include request on the purchase order)
 Service Manual: 2-service manuals at no charge (include request on the purchase order)
 Warranty: 12-months parts and labor

Quote valid for 90 days

Sincerely,

Sarona Sotoa
 Contract Administrator
 Clinical Technologies and Services

Schedule F

Pulmonetic Systems

LTV 1200 ventilator

February 2, 2009

Kristen Costales
Tripler Army Medical Center
Hanuola ECMO Program of Hawaii
1 Jarrett White Rd
Tripler AMC, HI 96859

Our quotation for the LTV1200 Ventilator Package utilizing GSA contract number V797P-4907a is as follows:

<u>Qty</u>	<u>Part Number</u>	<u>Product</u>	<u>Price</u>
1	#18888-001	LTV1200 Ventilator -one year standard warranty except: six months on internal battery three years on turbine -VC, PC, AC, PSV -NPPV: CPAP, Bi-Level -Internal PEEP Valve -Presets: Infant-Peds-adult	\$12545.00 ea.
1	#17650-001	Graphics Monitor Package (LTMII) -includes monitor, mounting bracket, Cabling, compact flash card & ops manual	\$3046.62 ea
1	#10611	Floor Stand W/Wheels & Oxygen Cyl Holder	\$400.39 ea
1	#19222-001	SprintPack Lithium Ion Power System -includes Power Manager & two Li batteries	\$999.00 ea
1	#19102-001	SprintPack Transport Pack	\$162.00 ea
2	#19444-001	SprintPack batteries	\$145.80 ea
1	#10823X10	Disposable Pediatric Circuit	\$85.27 ea
1	#10822X10	Disposabe Adult Circuit	\$85.27 ea

Terms: net 30 days FOB Minneapolis, MN, Prepay Freight and add

This quotation is valid through September 30, 2009. Purchase Order to be issued to Pulmonetic Systems.

Thank you for your consideration.

Michael Parker
Cell: 602-376-0182

Schedule G

Stryker

Power Pro IT Ambulance Cot

Stryker
 3800 East Centre Avenue
 Portage, MI 49002
 T: 800-669-4968

PLEASE REMIT PAYMENT TO:
Stryker Sales Corporation
PO Box 93308
Chicago, IL 60673

ESPINOZA, APRIL M
E: april.espinosa@stryker.com
 P: 602-626-5655
 F: 602-626-5657



Date : 02/06/2009		Customer Number: 0	Spec Number: 14380
Billing Address:		Shipping Address:	EndUser Address: (If Different)
Name: Tripler Army Medical Center		Name: Tripler Army Medical Center	Name:
Address: Hanuola ECMO Program of 1 Jarrett White Road Tripler AMC, HI 96859		Address: Hanuola ECMO Program of Hawaii 1 Jarrett White Road Tripler AMC, HI 96859	Address:
Contact: Kristen Costales		Contact: Kristen Costales	Contact
Phone #: 808-983-8662		Phone #: 808-983-8662	Phone #:
Email:		Email:	Email:
Fax:		Fax:	Fax:

Qty	Item No#	Name	Price	Extended Price
1	6510000000(M)	POWER PRO IT AMBULANCE COT	\$13,297.50	\$13,297.50
1	6510042000	NO ADAPTER OPTION	\$0.00	\$0.00
1	7777881669	3Yr XFrame LTD Powertrain Warr	\$0.00	\$0.00
1	6500074000	DEWALT BATTERY AND MANUAL	\$0.00	\$0.00
1	6082502010	Dual Wheel Lock Option	\$0.00	\$0.00
1	6060036017	Safety Hook, Short	\$0.00	\$0.00
1	6500070000	Domestic 110V Battery Charger	\$0.00	\$0.00
1	6510026000	Standard Components	\$0.00	\$0.00
Subtotal			\$13,297.50	\$13,297.50
Expedite cost				\$400.00
Total				\$13,697.50

All applicable Sales Tax will be calculated at time of invoicing

Comments: Wayne Takenaka			
Special Shipping Instructions: Standard shipping only: no expedite fee.			
Customer Information:			
P.O Number: _____		Signature: _____	
Title: _____		_____	
Type:	Expiration:	Security Code:	
Name On Card: _____			
CC Number: _____		CC Name: _____	

Requested Delivery Date: _____

Terms: Terms are Net 30 and FOB Origin with all costs of transportation and insurance paid by Stryker with the exception of special deliveries as requested by the customer. Such special delivery charges will be prepaid by Stryker and added to the final invoice. Order Subject to approval by Stryker Corporation. Taxes will be invoiced as a separate item when applicable. Credit cannot be allowed on returns of special or modified items.

Thank You For Your Business

Schedule H

Abbott Laboratories

i-Stat 1 Analyzer



**TRIPLER ARMY MEDICAL CENTER
Hanuola ECMO Program of Hawaii
Kristen Costales
February 14, 2009**

EQUIPMENT

List Number	Description	Each Cost	Quantity	Total Cost
06F16-10	i-Stat 1 Analyzers	\$5,037.50	2	\$10,075.00
06F11-01	Electronic Simulator	\$453.38	1	\$453.38
06F23-91	Martel Printer	\$292.18	1	\$292.18

- ❖ Prices do not include shipping, and taxes.
- ❖ Analyzers are under warranty for 1 year from date of purchase.
- ❖ Prices above are FSS prices.

Quote by:
Joni Dairiki
i-Stat Sales Representative
Abbott Laboratories Point of Care
(800)828-1181 box 222-1406
(818)340-2643

Schedule I

Terumo

Sechrist Air/Oxygen Blender



February 5, 2009

Tripler Army Medical Center,
Hanuola ECMO Program of Hawaii
1 Jarrett White Road
Tripler AMC, HI 94858

Proposal No. 210105

<u>Quantity</u>	<u>Product No.</u>	<u>Description</u>	<u>Each Price</u>	<u>Extended Price</u>
1	164235	Blender	\$2,224.62	\$2,224.62
1	814475	U.S. Hose Kit Air, O2,CO2	\$339.63	\$339.63
			TOTAL:	\$2,564.25

Estimated Shipping Costs to ship from Ann Arbor to Hawaii is \$150.00.

Warranty

Please note that this equipment comes with a warranty covering all repairs, parts and labor for the first 12 months following delivery.

Pricing

Prices contained in this proposal are valid for 60 days.

Only Terumo Cardiovascular Systems authorized Service Representatives are permitted to install electromechanical perfusion systems. The exception to this will be in regard to individual non-system items i.e.; Cooler/Heater, Centrifugal Systems, TCM II's, CDI Blood/Gas Monitoring Systems, Sternal Saws, and other ancillary equipment. If a hospital representative installs a piece of equipment, the appropriate section of the operator's manual for preparation and setup will apply.

Terumo Cardiovascular Systems Service:

Terumo CVS offers a variety of service contract options to provide just the level of coverage you want. Our experienced Field Service Technicians are able to provide full service capabilities and are on call 24 hours a day, seven days a week.

Terms

The terms of this proposal are net 30 days, F.O.B., Ann Arbor, Michigan, Freight Prepaid & Added to Invoice. (Please allow 60 days from receipt of the order to commence shipment.)

If you have any questions regarding this proposal, you may contact either of the following persons at 800-262-3304:
Steve Johnson, Terumo Cardiovascular Systems Territory Manager, extension 6017
Tara Grossheim, Contract Administrator, extension 6403

Schedule J

Medtronic

Pressure Display Box

Cardiac Surgery Pricing Proposal for Tripler Army Medctr Army Support Command



February 16, 2009



Confidentiality Clause: The terms and prices contained in this proposal shall be kept in strict confidence between Medtronic USA and employees of Tripler Army Medctr Army Support Command. If this confidentiality clause is breached, Medtronic USA reserves the right to cancel this Agreement.



Medtronic USA, Inc.
Cardiac Surgery Headquarters
7601 Northland Drive
Minneapolis, MN 55428-1088

Tel: 800.804.0789
Fax: 763.391.9285
www.medtronic.com

PURCHASE AGREEMENT

February 16, 2009

Tripler Army Medctr Army Support Command
Honolulu Tamc, HI, 96859-5000
Account Number: 1107353

Medtronic is committed to working with its customers to enable them to meet the needs of their patients. At the request of your Sales Representative, Joanne Masui, Medtronic USA is pleased to offer this Agreement for the purchase of Medtronic Cardiac Surgery products.

Terms:

- Please see attached Pricing Schedule for specific pricing.
- All Cardiac Surgery products will be sold and delivered F.O.B. shipping point, where freight will be prepaid and added to the invoice.
- Payment terms will be net 30.

- This offer will be valid for 30 days from the date shown above.

- Customer is solely responsible for properly reporting and allocating the price and any discounts received on the products purchased under this Agreement.

I sincerely hope this proposal meets your needs. If you have any questions, please feel free to contact your Medtronic Sales Representative, Joanne Masui, at 800.633.8766, or me at 800.804.0789. Thank you for your interest in Medtronic USA.

MEDTRONIC USA, INC.

Justin Shopbell
Contract Analyst
763.391.9901 (tel)
763.391.9285 (fax)
justin.d.shopbell@medtronic.com

Confidentiality Clause: The terms and prices contained in this proposal shall be kept in strict confidence between Medtronic USA and employees of Tripler Army Medctr Army Support Command. If this confidentiality clause is breached, Medtronic USA reserves the right to cancel this Agreement.



Medtronic USA, Inc.
Cardiac Surgery Headquarters
7601 Northland Drive
Minneapolis, MN 55428-1088

Tel: 800.804.0789
Fax: 763.391.9285
www.medtronic.com

February 16, 2009

PRICING SCHEDULE

Account Number: 1107353

Capital Instruments

Instrument Number	Product Description	Qty	Purchase Each Price*
66000	Pressure Display Box	2	\$795

*Title to the equipment listed above will transfer to the customer at time of sale. Purchase price includes one year parts and labor

To place your order, please call **800.854.3570**, or send Purchase Order (PO) to:
Medtronic Cardiac Surgery
ATTN: Customer Products Services
3850 Victoria Street North
Shoreview, MN 55126
FAX: 800.477.5467

Confidentiality Clause: The terms and prices contained in this proposal shall be kept in strict confidence between Medtronic USA and employees of Tripler Army Medctr Army Support Command. If this confidentiality clause is breached, Medtronic USA reserves the right to cancel this Agreement.

Schedule K

Phillips Medical

IntelliVue MP2 monitor



PHILIPS

Philips Medical Systems
 3000 Minuteman Road, MS 0400
 Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
 or
 Mail your Purchase Order To:
 Philips Medical Systems
 Order Processing MS0400
 Andover, MA 01810-1099
 (800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 1 / 6
-------------------------------------	---------------------------------	----------------------

LAST UPDATED 02/10/2009	TIME 13:21:57
-----------------------------------	-------------------------

EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION
--------------------------------------	-------------------------------------

PAYMENT TERMS
 Within 30 Days Due Net
 Subject to Credit Approval

FORMAL QUOTE

SALES REPRESENTATIVE
 Susan Nonaka-Hom PMD Phone:1-800-218-2045X
 2207
 Fax:

CUSTOMER:
 Tripler Army Medical Center
 1 Jarrett Rd Building
 TRIPLER ARMY MEDICAL HI 96859
 Customer Number: 94065620

QUOTE CONTACT
 Claudia Collins

SPECIAL COMMENTS:
 Kapiolani ECMO 1 MP2

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
10	M8102A 865040 B22	IntelliVue MP2 B22 ECG, Resp, NBP, SpO2, P+T	1	PCE		
	E20	E20 MMS Mount	1	PCE	282.00	282.00
	E23	E23 Protective Cover	1	PCE	85.00	85.00
	E26	E26 Add 2 Lithium-Ion Battery	1	PCE	319.00	319.00
		Agreement Discount			30.0 %	2,086.50-
		Price for item 10 Agreement #MV530				4,868.50
20	M1669A 989803145071	CBL 3 Lead ECG Trunk, AAMI/IEC 2.7m	1	PCE	90.00	90.00
		Agreement Discount			23.0 %	20.70-
		Price for item 20 Agreement #MV530				69.30
30	M1671A 989803145091	CBL 3 Leadset, Grabber, AAMI, ICU	1	PCE	70.00	70.00
		Agreement Discount			23.0 %	16.10-
		Price for item 30 Agreement #MV530				53.90



PHILIPS

Philips Medical Systems
 3000 Minuteman Road, MS 0400
 Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
 or
 Mail your Purchase Order To:
 Philips Medical Systems
 Order Processing MS0400
 Andover, MA 01810-1099
 (800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 2/ 6
LAST UPDATED 02/10/2009	TIME 13:21:57	
EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION	
PAYMENT TERMS Within 30 Days Due Net Subject to Credit Approval		

FORMAL QUOTE

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
40	M1599B 989803104341	Adult Pressure Interconnect Cable 3.0m Agreement Discount Price for item 40 Agreement #MV530	1	PCE	58.99 23.0 %	58.99 13.57- 45.42
50	989803 989803148221	LNC MP-10 Philips Dual Keyed Cable Agreement Discount Price for item 50 Agreement #MV530 All applicable FSS/DSCP discounts have been applied. Items identified as "Open Market" are not listed on any Government Contract for individual sale and are sold individually on an open market basis.	1	BAG	194.00 23.0 %	194.00 44.62- 149.38
60	M1597B 989803104321	Neonatal Pressure Interconnect Cable 3m Agreement Discount Price for item 60 Agreement #MV530	1	PCE	58.99 23.0 %	58.99 13.57- 45.42
70	21082A 989803100921	Long Extension Cable Agreement Discount Price for item 70 Agreement #MV530	1	PCE	36.00 23.0 %	36.00 8.28- 27.72
80	M1837A 989803105321	Esophageal/Rectal Temperature Probe Agreement Discount Price for item 80 Agreement #MV530	1	CAS	146.00 23.0 %	146.00 33.58- 112.42



PHILIPS

Philips Medical Systems
3000 Minuteman Road, MS 0400
Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
or
Mail your Purchase Order To:
Philips Medical Systems
Order Processing MS0400
Andover, MA 01810-1099
(800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 3/ 6
LAST UPDATED 02/10/2009	TIME 13:21:57	
EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION	
PAYMENT TERMS Within 30 Days Due Net Subject to Credit Approval		
FORMAL QUOTE		

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
		Total Quotation List Price				7,608.98
		Less All Applicable Discounts				2,236.92-
		Total Quotation Net Price				<u>5,372.06</u>



PHILIPS

Philips Medical Systems
3000 Minuteman Road, MS 0400
Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
or
Mail your Purchase Order To:
Philips Medical Systems
Order Processing MS0400
Andover, MA 01810-1099
(800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 4/ 6
LAST UPDATED 02/10/2009	TIME 13:21:57	
EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION	
PAYMENT TERMS Within 30 Days Due Net Subject to Credit Approval		
FORMAL QUOTE		

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
------	---------	-------------	-----	-----	----------	-------------

Philips Medical Systems North America is pleased to inform you that financing of its products and services is available to qualified applicants. To obtain more information contact Philips Medical Capital @ 866-513-4PMC.

Contract information for:VA Federal Supply Schedule

Prices quoted are subject to and reflect applicable discounts per the terms and conditions of the following contracts:
Contract #MV530 Expirations:03/31/2009
(V797P-4328a)

All applicable FSS/DSCP discounts have been applied. Items identified as Open Market are not listed on any Government Contract for individual sale and are sold individually on an open market basis.

Contract information for: DEFENSE SUPPLY SCHEDULE

Prices quoted are subject to and reflect applicable discounts per the terms and conditions of the following contracts:
Contract # MV2DR Expirations: 7/16/2007
(SP0200-02-D-8308)

Any items ordered as individual parts or supplies that are not listed on the current contract price list are sold on an open market basis. Government buyers can obtain the current contract price list by contacting Customer Service.

Philips warrants its Patient Monitoring Products against defects in material and workmanship as set forth in our Terms and Conditions for a period of 12 months from delivery.

Philips provides an Instruction for use manual in printed form. In addition, Philips provides a service guide on CD Rom.



PHILIPS

Philips Medical Systems
3000 Minuteman Road, MS 0400
Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
or
Mail your Purchase Order To:
Philips Medical Systems
Order Processing MS0400
Andover, MA 01810-1099
(800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 5/ 6
LAST UPDATED 02/10/2009	TIME 13:21:57	
EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION	
PAYMENT TERMS Within 30 Days Due Net Subject to Credit Approval		
FORMAL QUOTE		

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
------	---------	-------------	-----	-----	----------	-------------

This quotation is issued pursuant to, and any PO for the items herein will be accepted subject to the Terms of Contract# MV530If no contract is called out in the previous sentence this quotation is issued pursuant to, and any PO for the items herein will be accepted subject to the Philips Terms and Conditions of Sale posted at http://www.healthcare.philips.com/main/terms_conditions/ and the terms herein.

All work is scheduled within normal working hours;
Monday through Friday, 8 a.m. to 5 p.m. excluding Philips holidays.

All pricing is based on travel zones 1-3. For travel zones beyond 1-3, consult your Philips sales rep for alternate pricing.

It is the customers responsibility to provide Philips with the access necessary to complete the quoted work in a continuous start to finish manner.

Excessive delays and multiple visits will result in additional charges.

All prices are based upon 'adequate access' to work areas that are free from obstruction.

If it is determined, during the implementation that asbestos removal is required; Philips will suspend performance until the Customer remediates the asbestos.

Philips will work with the customers staff to reduce the downtime during the system transition.

Products are for USA end-use only. Taxes, if applicable, are not included unless noted but will be added to the invoice. The Purchase Order must reference the Quote Number and your Purchase Agreement.

Please indicate your requested delivery date and your preference, if any, to accept and pay for partial shipments. If this quote includes Value-Added Services, they may be invoiced separately. Additional sold training must be completed within twelve months of delivery/installation. System cabling, if included, is specified at the standard grade unless noted otherwise.

This quote specifically excludes Licensing & Permit Fees, Prevailing Wage Compensation and Union Labor.



PHILIPS

Philips Medical Systems
3000 Minuteman Road, MS 0400
Andover, MA 01810

Fax your Purchase Order To: 1-800-947-3299
or
Mail your Purchase Order To:
Philips Medical Systems
Order Processing MS0400
Andover, MA 01810-1099
(800) 934-7372

QUOTATION DATE 02/10/2009	QUOTE NUMBER 20386807	PAGE 6/ 6
LAST UPDATED 02/10/2009	TIME 13:21:57	
EXPIRATION DATE 04/09/2009	INCOTERMS FOB DESTINATION	
PAYMENT TERMS Within 30 Days Due Net Subject to Credit Approval		

FORMAL QUOTE

ITEM	PRODUCT	DESCRIPTION	QTY	UoM	UNIT-AMT	AMOUNT(USD)
------	---------	-------------	-----	-----	----------	-------------

This quotation is issued pursuant to, and any PO for the items herein will be accepted subject to the Terms of any current Contract with the customer. If there is no contract in place, this quotation is issued pursuant to, and any PO for the items herein will be accepted subject to the Philips Terms and Conditions of Sale posted at http://www.healthcare.philips.com/main/terms_conditions/and the terms herein.

This quotation contains confidential and proprietary information of Philips Medical Systems and is intended for use only by the customer whose name appears on this quotation. It may not be disclosed to third parties without prior written consent of Philips Medical Systems.

Schedule L

Cincinnati Sub Zero

Micro-Temp LT heater



Cincinnati Sub-Zero Products, Inc.
12011 Mosteller Road, Cincinnati, Ohio 45241 (513) 772-8810

Quote ID: 10943

Effective Date 02/02/2009 **Expire Date** 05/03/2009 **Prepared By** HAGAMAN
Sales Rep JOHN HAMILTON **FOB** DESTINATION **Ship Via** UPS PPD
Terms 0.00% / 0.00 Days, Net 30.00 Days

Bill To TRIPLER ARMY MEDICAL CENTER
ONE JARRETTE WHITE RD
CARDIOTHORACIC SURG #2C178 BLDG
HONOLULU, HI 96859 **Ship To** TRIPLER ARMY M.C.
1 JARRETTE WHITE RD.
ATTN: G1B ROOM #500
HONOLULU, HI 96859

Customer Contact

Cust ID MT0073
Name KRISTEN COSTALES **Phone** 808-228-6693
Email Kristen.costales@kapiolani.org **Fax**

Line Items

<u>Line</u>	<u>Part ID</u>	<u>Qty</u>	<u>U/M</u>	<u>Description</u>	<u>Unit Price</u>	<u>Extended Price</u>
1	88116	1	EA	MICROTEMP LT 115 VOLT	\$455.00	\$455.00
Total Quote Amount:						\$455.00

Thank you for the opportunity to quote on Cincinnati Sub-Zero Products. CSZ looks forward to supporting your patient temperature management needs. Please utilize the following information when ordering.

If unit is a demo unit currently at the facility, the serial number of the unit **MUST** be included on the Purchase Order (PO) from the customer. CSZ is not responsible for any units shipped due to omitted information on the customer's PO. Customer will be responsible for 30% restocking fee and all associated charges.

Estimated Days Lead Time After Receipt of Order: 2 weeks for equipment, or 24 hours for accessories in stock.

Customer **MUST** be current member of GPO at time of purchase. Tier level pricing subject to established parameters and may require a letter of commitment to be on file with CSZ and/or the GPO.

Please email a copy of this quote with your PO to: medicalquotes@cszinc.com **or fax to:** 513-772-9119

Schedule M

International Biomedical

Lifeport Clipdeck



Our Quotation # 006871-00

02/11/2009

P.O. BOX 143449 • AUSTIN, TX 78714-3449
8508 CROSS PARK DRIVE • AUSTIN, TX 78754-4557
PHONE: (512) 873-0033 • FAX: (512) 873-9090
www.int-bio.com • sales@int-bio.com

To :

TRIPLER ARMY MEDICAL CENTER
HANUOLA ECMO PROGRAM OF HAWAII
1 JARRATT WHITE RD G1B
HONOLULU HI 96859
United States

Quotation Valid Thru : 04/11/2009

Terms : CREDIT CARD

Attention : KRISTEN COSTALES

Phone#

Fax#

We are pleased to quote your requirements as shown below. Our company has a reputation for delivering quality products on time and we look forward to the opportunity of serving you.

Please Note: Quotes do not include sales tax and shipping charges

Item	Part / Rev / Description / Details	Quantity Quoted	Unit Price	Extended Price
001	7319992 LIFEPORT CLIPDECK	1.0000	1,100.00000	\$ 1,100.00

Total Items Price

\$ 1,100.00

Wayne Takenaka: waynet@kapiolani.org
Kristen Costales: Kristen.Costales@kapiolani.org

Please direct questions about this quotation to International Biomedical 512.873.0033 or your Sales Representative, Mike Fincher, at 512.699.1326.

*MAKE ALL PURCHASE ORDERS OUT TO INTERNATIONAL BIOMEDICAL, LTD. PLEASE REFERENCE QUOTE NUMBER ON PURCHASE ORDER.

*TO PLACE AN ORDER, PLEASE FAX THIS QUOTATION TOGETHER WITH YOUR PURCHASE ORDER TO AIRBORNE CUSTOMER SERVICE AT 512.873.9090.

*ESTIMATED DELIVERY 45 TO 60 DAYS AFTER RECEIPT OF ORDER

*UNLESS OTHERWISE SPECIFIED, ALL SALES ARE FOB FACTORY

*FREIGHT IS PREPAID AND ADDED TO THE INVOICE

WARRANTY:

Unless otherwise specified, Airborne Life Support Systems warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after the date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only. The warranty period for batteries is limited to 90 days from date of shipment.

Schedule N

Thomas EMS

ALS Ultra Roller Pack, Red

ALS Ultra, Red

Aeromed Advanced, Red

Thomas Emergency Medical Solutions

Quote

(Formerly Thomas Transport Packs)
 P.O Box 651305
 Salt Lake City, UT 84165

Date	Quote #
2/19/2009	125

Name / Address
Tripler Army Medical Center Hanuola Exmo Program of Hawaii 96859

P.O. No.	Terms	Account #	FOB
			SLC

Item	Description	Qty	Cost	Total
TTR156	ALS Ultra Roller Pack, Red	1	475.00	475.00
TT156	ALS Ultra, Red	1	475.00	475.00
TT886	Aeromed Advanced, Red	1	199.99	199.99
Freight			115.00	115.00

Total	\$1,264.99
--------------	------------

Phone #	Fax #	E-mail	Web Site
(800) 445-3640	801-2689272	silvia@thomasems.com	www.thomasems.com

Schedule O

International Biomedical

Cable Management Bag
Neonatal Respiratory Bag



Our Quotation # 006872-00

02/11/2009

P.O. BOX 143449 • AUSTIN, TX 78714-3449
8508 CROSS PARK DRIVE • AUSTIN, TX 78754-4557
PHONE: (512) 873-0033 • FAX: (512) 873-9090
www.int-bio.com • sales@int-bio.com

To :

TRIPLER ARMY MEDICAL CENTER
HANUOLA ECMO PROGRAM OF HAWAII
1 JARRATT WHITE RD G1B
HONOLULU HI 96859
United States

Quotation Valid Thru : 04/11/2009

Terms : CREDIT CARD

Attention : KRISTEN COSTALES

Phone#

Fax#

We are pleased to quote your requirements as shown below. Our company has a reputation for delivering quality products on time and we look forward to the opportunity of serving you.

Please Note: Quotes do not include sales tax and shipping charges

Item	Part / Rev / Description / Details	Quantity Quoted	Unit Price	Extended Price
001	7312900 CABLE MANAGEMENT BAG Rev B U/M EA	1.0000	153.00000	\$ 153.00
002	7312902 NEONATAL RESPIRATORY BAG Rev B U/M EA	1.0000	166.00000	\$ 166.00

Total Items Price \$ 319.00

Wayne Takenaka: waynet@kapiolani.org
Kristen Costales: Kristen.Costales@kapiolani.org

Please direct questions about this quotation to International Biomedical 512.873.0033 or your Sales Representative, Mike Fincher, at 512.699.1326.

*MAKE ALL PURCHASE ORDERS OUT TO INTERNATIONAL BIOMEDICAL, LTD. PLEASE REFERENCE QUOTE NUMBER ON PURCHASE ORDER.

*TO PLACE AN ORDER, PLEASE FAX THIS QUOTATION TOGETHER WITH YOUR PURCHASE ORDER TO AIRBORNE CUSTOMER SERVICE AT 512.873.9090.

*ESTIMATED DELIVERY 45 TO 60 DAYS AFTER RECEIPT OF ORDER

*UNLESS OTHERWISE SPECIFIED, ALL SALES ARE FOB FACTORY

*FREIGHT IS PREPAID AND ADDED TO THE INVOICE

WARRANTY:

Unless otherwise specified, Airborne Life Support Systems warrants all products of its manufacture at the time of shipment to be free from defects of material and workmanship for a period of twelve months from the date of shipment when owned by the original purchaser. Any product which is believed to be defective, if returned within twelve months after the date of shipment by the Company with freight prepaid and found by the Company's inspection to be defective within the terms of this warranty, will be repaired or replaced free of charge and shipped, freight prepaid, to any point in the United States. If inspection by the Company of any such product does not disclose any defect within the terms of this warranty, the Company's regular charges for repairs or replacement and freight shall apply. All consumable and disposable products are guaranteed to be free from defects upon shipment only. The warranty period for batteries is limited to 90 days from date of shipment.

Schedule P

Pelican Products

1620 Case

Pelican Products .US

Durability. It's in the Goods

[Home](#) [Contact](#) [Terms](#) [FAQ](#) [Tracking](#) [Shopping Cart](#) [Checkout](#) [Search](#)

Distributed by
The Rocky
Mountain Tool
Company



Pelican™ 1620 Case

Pelican's™ 1620 Case is unbreakable, watertight, dustproof, chemical resistant and corrosion proof. These are some of the features of this Pelican's™ 1620 Case that offers total protection for your equipment. It is made of Ultra High Impact structural copolymer that makes it strong and durable. Its exclusive neoprene o-ring and ABS latches seal perfectly and includes an automatic purge valve for quick equalization after changes in atmospheric pressure.

It is equipped with 2" (5 cm) hard rubber transport wheels, a retractable extension handle and multiple fold down carrying handles. Your equipment can fit into the high density foam (standard) or padded dividers (at additional cost) for total subjection and protection against impact, vibration or shock. A nameplate can be personalized (at additional cost). Retractable extension handle. Strong polyurethane wheels with stainless steel bearings.

You break it, we replace it... forever.™



Product ID: #1620

Sale Price ~~\$251.95~~ \$180.00
(Savings: \$171.95)

Pelican™ Cases

- [Micro Cases](#)
- [Small Cases](#)
- [Medium Cases](#)
- [Large Cases](#)
- [Cube Cases](#)
- [Computer Cases](#)
- [Memory Cases](#)
- [EMS Cases](#)
- [Weapon Cases](#)

Pelican™ Soft Cases

- [D'Exec Series](#)
- [Convertible Bags](#)
- [I/C Series](#)
- [Tripod/Lightstand](#)
- [RSV Series](#)

Pelican™ Flashlights

- [Small Flashlights](#)
- [Medium Flashlights](#)
- [Large Flashlights](#)
- [HeadsUP Series](#)
- [BlackKnight Series](#)
- [Recoil LED Series](#)
- [Nemo Diving Series](#)
- [Light Kits](#)
- [Night Vision](#)
- [PL Series](#)
- [Infrared Series](#)
- [Remote Area Lighting](#)

Accessories

[Pelican Head Cases](#)

Inventory Status

Black	In Stock
Desert Tan	In Stock
OD Green	In Stock
Black - No Foam	In Stock
Des/Tan - No Foam	In Stock
OD Green-No Foam	Approx. 5-7 Days
Black - w/Dividers	In Stock
Des/Tan - w/Dividers	In Stock
OD Green - w/Dividers	In Stock

Color

- Black
- Desert Tan
- OD Green
- Black - No Foam
(Subtract \$34.20)
- Des/Tan - No Foam
(Subtract \$34.20)
- ODGreen-No Foam
(Subtract \$34.20)
- Black - w/Dividers

What is Pick 'N' Pluck™ Foam?

Download Documentation

<http://www.pelicanproducts.us/p.Pelican.Case.1620.html>

2/11/2009

[Pelican Hard Case](#)
[Pelican Soft Case](#)
[Pelican Flashlights](#)

[Custom Imprinting](#)
[Unique Marine Products](#)

[Site Map](#)
[Data Sheets](#)

[Flashlight Comparison](#)
[Case Comparison](#)

Check Out



Exterior Dimensions 24.81" x 19.37" x 13.87"
(L x W x D) (63 x 49.2 x 35.2 cm)
Interior Dimensions 21.37" x 16.31" x 12.56"(54.3 x 41.4 x 31.9
(L x W x D) cm
Lid Depth 2.06" (5.2 cm)
Bottom Depth 10.50" (26.7 cm)
Total Depth 5.25" (13.3 cm)
Weight w/Foam 12.56" (31.9 cm)
Weight w/o Foam 24.47 lbs. (11.1 kg)
Buoyancy Max. 149.91 lbs. (68 kg)
Range Temperature -10 / 210° F (-23 / 99° C)
No. of Wheels 2
Colors Black, OD Green and Desert Tan
Case Certificates IP67 (1 meter submersion for 30 minutes)
MIL C-4150J
Def Stan 81-41/STANAG 4280

(Add \$116.40)

Des/Tan - w/Dividers
(Add \$116.40)

OD Green - w/Dividers
(Add \$116.40)

Qty.

- [Add to Cart](#)
- [Add To Saved Cart](#)
- [E-mail a Friend](#)

1620 Case Accessories

- 1609 - [Lid Organizer](#)
- 1621 - [6 pc. Replacement Foam Set](#)
- 1622 - [Pick 'N' Pluck™ Sections\(4\) Only](#)
- 1623 - [Replacement O-ring](#)
- 1625 - [Padded Divider Set Only](#)
- 1500D - [Peli® Desiccant \(Silica Gel\)](#)
- 1506 - [Peli® Lock](#)
- 1507 - [Peli® Quick Mounts](#)

©2008 Pelican Products . US / Quickpro Gear, LLC
50 E. 200 N. * Hyrum, UT 84319 * [Contact](#)
Today's Date is Wednesday, February 11, 2009

Pelican Products * Quickpro Gear, LLC * Blog * Quickpro, LLC * Photoburbia * Affiliated Pages

Pelican Products .US

Durability. It's in the Goods.

Distributed by
The Rocky
Mountain Tool
Company

[Home](#) [Contact](#) [Terms](#) [FAQ](#) [Tracking](#) [Shopping Cart](#) [Search](#)



This is the final step of the checkout process. Review the charges shown below and, if you are satisfied, enter your payment information in the form provided. When you are finished, click Complete Order.

Payment Information

Billing Information

Kristen Costales
Tripler Army Med Ctr
1 Jarrett White Rd
Tripler AMC , HI 96859
US
808-983-8662

Shipping Information

Kristen Costales
Tripler Army Med Ctr
1 Jarrett White Rd
Tripler AMC , HI 96859
US
808-983-8662

[Edit](#)

[Edit](#)

Pelican™ Cases

- [Micro Cases](#)
- [Small Cases](#)
- [Medium Cases](#)
- [Large Cases](#)
- [Cube Cases](#)
- [Computer Cases](#)
- [Memory Cases](#)
- [EMS Cases](#)
- [Weapon Cases](#)

Pelican™ Soft Cases

- [D'Exec Series](#)
- [Convertible Bags](#)
- [I/C Series](#)
- [Tripod/Lightstand](#)
- [RSV Series](#)

Pelican™ Flashlights

- [Small Flashlights](#)
- [Medium Flashlights](#)
- [Large Flashlights](#)
- [HeadsUP Series](#)
- [BlackKnight Series](#)
- [Recoil LED Series](#)
- [Nemo Diving Series](#)
- [Light Kits](#)
- [Night Vision](#)
- [PL Series](#)
- [Infrared Series](#)
- [Remote Area Lighting](#)

Accessories

[Pelican Head Cases](#)

Order Total

Merchandise Total:	\$180.00
Shipping:	\$65.78
Order Total:	\$245.78
Grand Total:	\$245.78

Terms and Conditions

I accept the [terms and conditions](#)

Credit Card

The information above must match that of the card holder.

Card Type: Card Number:

Expiration Date: Month Year Security Code:

Appendix A.3
ECMO Transport Meeting
Elliott Aviation



**PO Box 100
Moline, Illinois
61266-0100**

Kapiolani Medical Center
AirMed International
Elliott Aviation

05-18-2009

On May 14th & 15th of 2009 a meeting was held to review the mock up made for the ECMO platform being developed. The following is a review of the content of this meeting.

On May 14th the meeting started out with introductions of all who attended. Present was Ken Chitty, Ruben Segura, Rodd Caldwell, Mark Ogino, Kristen Costales, Wayne Takenaka, Skip Pieplow, and Mike Key. After the introductions Ruben gave an update to the STC progress and the processes involved getting the ETS STC approved. Next a review of Elliott Aviation was given by Ken Chitty in order for everyone to learn what Elliott Aviation is all about. A review of the quotes, payments and what to expect going forward was reviewed. A review of the ETS from the beginning, through the mock up stage and a review of the FAA presentation to be presented was given. A review of the engineering requirements discussed in the beginning was reviewed to ensure everything has been covered in respect to the ETS mock up currently. A tour of the facility was given to all who wanted to see the facility. After the tour the mock up was brought into the conference room for review. Box lunches were brought in for a working lunch as we started going through the mock up.



For the rest of the day a review of the ETP was discussed and any changes to be made to the current mock up. This was an open discussion with various Elliott employees coming in where needed to assist in there particular area of expertise.

We adjourned at 5:00 pm and scheduled to meet at 6:00 pm for dinner. At dinner we all discussed nothing in regards to the ETS after going through the system all afternoon. This was a time to just digest what was reviewed and save our thoughts until the next morning.



On May 15th we meet in the conference room at 08:30 to review the mock up and determine any changes that needed to be made. We started on the top L/H side working through to the far right. We then started on the front L/H side and worked through to the far R/H side. The first time through took several hours but flushed out a majority of the issues. Once completed through the first time we ran through the entire system once again and were able to get through it this time in a short amount of time. Box lunches were brought in and we continued working as we had lunch. It was discussed that another meeting needed to take place once all the changes established were made. Mark was given a couple of options as to when the mock up would be complete and Mark is going to let Ken Chitty know when that is. It was discussed at first that we would be able to get everything completed in one day on the next meeting but after a list of the agenda items were established the conclusions were that we would need to plan on two days for the next meeting instead. The date for this next meeting will be established once Mark determines his schedule.

After completing the discussions for the next meeting the Hawker that AirMed sent in for demonstration of the ETS going into the aircraft arrived. While the aircraft was positioned into the hanger we once again ran through the mock up and the changes to be made for Denise Treadwell and Darby with AirMed International. Once the review was completed we took the ETP to the aircraft and demonstrated it going into the aircraft. Once the ETP was in the aircraft it had considerably more room than anticipated. The ETP went into the aircraft quite easily and once on top of the medical base it fit quit well. Once everyone had an opportunity to review the platform in the aircraft the ETP was removed. Once again we met in the conference room for final discussion.



In the final discussion a review of all the medical equipment was reviewed to establish what was going to stay and what needed to be returned. A discussion of everything that needed to be an agenda item was discussed for the itinerary for the next meeting. Everyone was given one last chance to bring any issues to the table and we adjourned the meeting.

In all I believe the meeting went well. It was a relaxed atmosphere and all thoughts and ideas from everyone was welcomed and discussed. The medical practicality and the technical capabilities for this system were all discussed and a lot of issues and resolutions were determined. The fit into the aircraft went superb.

I want to thank everyone who attended for their participation as it made this meeting successful. With that in mind do not forget what Abraham Lincoln once said “Things will come to those who wait, but only what is left by those who hustle.”



The changes discussed to the mock are summarized below:

- 1) The foam pad will change from 2 inches thick to 3 inches thick.
- 2) The monitor currently mounted on the R/H side will relocate to the L/H side.
- 3) The poles for the mixer and the red monitors will relocate to the R/H side closer to where the monitor is currently.
- 4) The poles will be telescoping for multiple positions and removal.

- 5) The adult restraint will have 2 belts going across the body and have 4 point restraint.
- 6) The infant restraint will remain as is with the foam cradle to place the infant in.
- 7) The pad will have cut outs for the footman loops for the pad to sit down flat.
- 8) An IV tree will be fitted to install in the top of the telescoping poles.
- 9) On the L/H side at the top will be two footman loops for hanging medical equipment.
- 10) The air & O2 connections will move up & connections installed at the bottom for connecting to the medical base in the aircraft.
- 11) The oxygenator compartment will be 3 inches larger and everything shifting to the right by 3 inches.
- 12) Only one pump will be installed and it will be mounted on a pole so the other brand of pump could be utilized if needed.
- 13) The tray for the oxygenator will be as wide as the compartment that retains the unit.
- 14) The heater will go back further rather than being side ways with the additional room in that area.
- 15) The mixers are to stay where they are currently located.
- 16) There will be a see through door added on the R/H side of the oxygenator for retention of the circuits. This door will have 2 latch points and possibly cut out slanted at the top where the cut out is for the circuits.
- 17) The pump monitor will remain where it is currently and will remain this style unit.
- 18) The source switches will be mounted where the O2 primary & the air primary switch is to the L/H side of the switch panel. The R/H side will have the Aux O2 & Aux air switch. The center of this panel will have a rheostat for LED lighting control. It will be an off/on switch as well as variable light control.
- 19) The syringe pumps will have 8 each mounted. They will be turned the opposite way then what they were mounted for the mock up. There will be 4 rows that are double stacked. A switch will be placed between the 2nd & 3rd row. This switch will have a throw that indicates left position or right position. Left position gives the L/H 4 pumps power, from the electrical side, and the right position gives power to the R/H 4 pumps. The 4 pumps not selected will be running on internal battery power.
- 20) On the far R/H side of the platform will be mounted an electrical panel for indication of power source.(Wall outlet, base power or battery power)
- 21) Next to the pump monitor will be mounted a recessed panel where O2 & air supply levels are indicated.
- 22) 6 each recessed handles will be mounted for carrying the unit.
- 23) LED lighting will be located so each compartment has ample light.
- 24) The angles of the platform will be rounded where possible for appearance.
- 25) The R/H upper side at the top will have two cut outs for the syringe pump circuits.
- 26) The back of the unit needs to be accessible. If support structure prevents this than doors will be needed for access.
- 27) The back up battery cord will need to be hard wired to the unit and coiled on top. The receptacle will need to lock in place.



The agenda items established for the next meeting are as follows:

- 1) Discussion on the new ETP design with all the changes incorporated.
- 2) Functional test of the oxygenator and pump. (Wet Lab) Kris to bring 90 degree connectors for oxygenator, heater connectors and a filter.
- 3) Battery back up test to be performed.
- 4) Electrical circuit demonstration and explanation will be conducted.
- 5) A 12 year old dummy test will be conducted. Wayne will bring the dummy.
- 6) Determine location for non-latching foot on ETP for support.
- 7) Discuss nitric oxide use, determine feasibility.
- 8) Discuss shipping container requirements and design.

Appendix B.1

ECMO Lab Competency Course Outline August 2009



**Mandatory ECMO Review Competency
COURSE OUTLINE**

**Monday, August 31, 2009
Auditorium, KMCWC**

0745 ~ 0800	Coffee
0800 ~ 0815	Welcome So, you've been doing ECMO? ELSO Melody Kilcommons
0815-0830	Indications for ECMO Neonatal Diseases/ Pediatric Diseases Evaluation and Selection Mark Ogino
0830 ~ 0930	Physics of Extracorporeal Life Support VA & VV ECMO Mark Ogino
0930 ~ 0945	Break
0945 ~ 1015	Preparation, Initiation and Stabilization of the ECMO Patient Melody Kilcommons
1015 ~ 1030	Blood Product Administration & Documentation Melody Kilcommons
1030 ~ 1100	ECMO Management Mark Ogino
1100 ~ 1145	ECMO Equipment and the Circuit ECMO Emergencies On/Off ECMO Procedure Kris Costales Mark Ogino Melody Kilcommons
1145 ~ 1200	Post Test /Evaluation Forms

Appendix B.2
ECMO Lab Competency Skills
August 2009

ECMO Lab Training

1. Overview
 - a. Circuit
 - i. Clamps
 - ii. Alarms
 - b. Off Bypass Procedure
 - i. Turn off Pump
 - ii. Clamp off arterial line
 - iii. Clamp off venous line
 - iv. Proceed with code
 - c. Blood Products
 - i. Blood bank
 - ii. Cooler stock
 - iii. For emergencies
 1. FFP
 2. emergency PRBC unit

ECMO CIRCUIT EMERGENCIES

There are several circuit emergencies that will require the patient to be removed from bypass. Under controlled circumstances, the bedside RN's sole responsibility is to maintain the patient. (THIS IS A CODE SITUATION.) The Perfusionist will manage the circuit emergency.

Under some circumstances the RN may be required to monitor the ECMO circuit for very brief periods of time. During these periods an RN may be required to remove the patient from bypass in the event of a circuit emergency. This technique will be taught in depth in a skills lab. The following are general emergencies that may occur with the nursing interventions described based on the presence of the Perfusionist at the bedside.

CIRCUIT EMERGENCIES	NURSING INTERVENTION(S)
1. Circuit Emergency requiring off bypass	
A Perfusionist at bedside	1 Call ECMO MD, Intensivist, Respiratory Therapist 2 Bag patient at emergency vent settings until Respiratory Care can intervene. 3 Administer any code drugs, volume as required 4 Obtain one unit of PRBCs from Blood Bank. 5 If chest compressions are required, use extreme caution due to heparinization.
B Perfusionist NOT at bedside - one of the following occur: 1. Circuit blood leak 2. Accidental decannulation 3. Pump failure 4. Air emboli	1 Turn off pump 2 Remove patient from bypass. 3 Initiate code sequence as noted above (1A). <u>DO NOT</u> attempt to manage the circuit emergency.
2. Circuit Blood Leak: Blood leaking, spraying from circuit	1 Major blood loss - Is perfusionist at bedside? yes - perform 1A no - perform 1B 2 Slow dripping of blood loss - Is perfusionist at bedside? yes - perform 1A no - perform 1B
3. Accidental Decannulation: Excessive blood loss at cannulation site, inability to achieve flow, patient decompensation	1 Is the Perfusionist at bedside? yes - perform 1A no - perform 1B 2 Apply pressure to cannula site. 3 Call surgery stat.
4. Pump Failure: No flow, patient decompensation, power loss, pump failure	1 Is the Perfusionist at bedside? yes - perform 1A no - perform 1B
5. Air Emboli: Air bubble noted infusing into patient cannula	1 Is the Perfusionist at bedside. yes - perform 1A no - perform 1B

Name: _____

Date: 8-31-09

**ECMO EMERGENCY
SKILLS LAB COMPETENCY**

1.	1. Circuit Emergencies Knowledge	Knowledge/ Independently Demonstrated
A.	List the four basic emergencies that require the patient to come off bypass.	
	1. Circuit blood leak	
	2. Accidental decannulation	
	3. Pump Failure	
	4. Air Emboli	
B.	Identify when the RN should intervene with the ECMO circuit.	
C.	Perform the intervention in the event of a tubing or circuit blood leak	
D.	Perform the intervention in the event of an air emboli.	
E.	Perform the intervention in the event of an accidental decannulation.	
F.	Perform the intervention in the event of pump failure.	
G.	Describe the amount of blood to be on hold for emergencies.	
H.	Describe where clamps, volume and blood are located.	
2.	Off Bypass Procedure	
A.	Turn off Pump.	
B.	Clamp off arterial line.	
D.	Clamp off venous line.	
E.	Proceed with code situation.	

ECMO Competency Skills lab was successfully completed by _____.

Signature of Participant

ECMO Perfusion Coordinator

ECMO Clinical Coordinator

Appendix B.3

ECMO Lab Equipment Drill Checklist

Hanuola ECMO Program of Hawaii Equipment Drill Annual Competency

NAME: _____ signature: _____
TRAINER: _____ signature: _____
DATE COMPLETED: _____

THE JOSTRA HL20 HEART LUNG SYSTEM	
A.	EMERGENCY POWER PACK (E/P PACK)
	1. Demonstrate self contained cart, brakes
	2. Demonstrate connection to wall power source
	3. Demonstrate Power Supply Module <ul style="list-style-type: none"> • Demonstrate Main On/Off Switch, circuit breaker incorporated in switch
	4. Demonstrate UPS Control Module Battery Module <ul style="list-style-type: none"> • LED lights, 'ON' light • beeps when activated every 3 seconds • Alarm off button used during UPS mode (5 minutes) • battery life span 1 hour on console, and 1 hour in pump • battery life count down on CDM screen
	5. Demonstrate UPS Charging Module <ul style="list-style-type: none"> • Charging mode light • Mains OK light • UPS on light <ul style="list-style-type: none"> ◆ Lit when UPS is active
	6. Demonstrate P1 button. Explain what happens if it is on when the pump is put on or removed from console.
	7. Transducer Cable and Bubble Detector connections
	8. Demonstrate Hand Crank Storage and use
B.	Jostra Rotaflow
	1. Demonstrate pump head <ul style="list-style-type: none"> • Show mode that it is in <ul style="list-style-type: none"> ⇒ Describe different options of modes (Art. Stand alone, Free) • Explain starting alarms & how to deal with them • Explain soft alarm & why we want it on • Demonstrate turning it on. • Zero flow probe <ul style="list-style-type: none"> • Demonstrate putting the head in & where the ultrasonic cream goes • Tell what should be done if the pump flow probe does not give a reading
D.	CONTROL DECK MODULE (CDM)
	1. Demonstrate Pressure Modules - set up/location of Pressure 1, 2 and 3 <ul style="list-style-type: none"> • On Key: Safety self test • Demonstrate overriding self test if CDM is broken <ul style="list-style-type: none"> ◆ Describe CDM Screen • Alarm Override & engaged Key <ul style="list-style-type: none"> ◆ Only silences CDM, pump head will still alarm • Do not silence alarms or override while on ECMO
	2. Demonstrate Zero Procedure - Pre and Post Pressures <ul style="list-style-type: none"> • Select Pressure to calibrate • Remove dead end cap from stopcock <ul style="list-style-type: none"> • Turn stopcock off to the circuit, allow to hang naturally • Press zero key under selected pressure & Use Purple corner knob to turn setting knob to '0' • Turn stopcock open to circuit, off to air & replace dead end cap

Hanuola ECMO Program of Hawaii Equipment Drill Annual Competency

	4. Define Stop Limit (-200 to +800 range)
	<ul style="list-style-type: none"> • Pre Membrane = 350 • Post Membrane = 350 • Venous = range up to -40
	5. Demonstrate Setting Stop Limit
	<ul style="list-style-type: none"> • Push Limit Key (Toggles between High Limit & Low Limit) • Use purple cornered knob to set to desired limit
	6. Define Regulating Threshold (-200 to +800 range)
	<ul style="list-style-type: none"> • Pump automatically defines Threshold as 10% from the stop value
	9. Demonstrate Bubble Detector Module - set up/location
	<ul style="list-style-type: none"> • On/Off Key • Set Key (On back of the pump) <ul style="list-style-type: none"> ◆ Pump 1 (always) This is set up, but specialists should know it exists ◆ Bubble sensor size: 1/4 or 3/8 (The other sized shims are in the drawer of the console) ◆ Microbubble display: Yes/No (min. 300 μm) YES • Alarm On/Off Key <ul style="list-style-type: none"> ◆ Only silences CDM, pump head will still alarm • Alarm Reset Key (Push along with safety key) <ul style="list-style-type: none"> ◆ Must be pressed once air removal is complete (wait 3 seconds)
E.	MANAGEMENT OF ALARM OCCURRENCE
	1. High Pressure Pre or Post Membrane
	<ul style="list-style-type: none"> • Regulating Threshold <ul style="list-style-type: none"> ⇒ Alarm red light flashes intermittently on module with audible alarm every 3 seconds ⇒ 'Control' display on pump reads STOP Press # (1, 2, or 3) ⇒ Pump flow display amount slows to less than set flow ◆ Troubleshoot cause of increased pressure ◆ Determine need for change in limit ◆ Increase limit by +5

Hanuola ECMO Program of Hawaii Equipment Drill Annual Competency

	<ul style="list-style-type: none"> • Stop Limit
	⇒ Alarm red light displays on module with audible alarm
	⇒ Pump Display reads: Stop Pump Press # (1, or 2)
	⇒ Pump stopped
	◆ Set as an absolute for pre and post
	◆ Troubleshoot cause of increased pressure
	2. Negative Pressure Venous
	<ul style="list-style-type: none"> • Regulating Threshold
	⇒ Alarm red light flashes intermittently on module with audible alarm every 3 seconds
	⇒ 'Pump Display reads: Stop Pump Press # (3)
	⇒ Pump flow display amount slows to less than set flow
	◆ Troubleshoot cause of decreased venous return and treat
	◆ Determine need for change in limit
	◆ Decrease limit by -5, assure not approaching stop limit set
	<ul style="list-style-type: none"> • Stop Limit
	⇒ Alarm red light displays on module with audible alarm
	⇒ Pump Display reads: Stop Pump Press # (3)
	⇒ Pump stopped, flow display flashing '0.00'
	◆ Troubleshoot cause of decreased venous return and treat
	◆ Decrease flow as tolerated
	3. Bubble Detector Alarm
	⇒ Alarm red light displays on module with audible alarm
	⇒ Pump display reads: Stop Pump Bubble
	⇒ Pump stopped
	<ul style="list-style-type: none"> • Remove patient from bypass • Turn to speed control knob (flow) to zero • Remove air as per protocol • Push reset button & safety button (wait 3 seconds for it to reset) • Return patient to bypass
	4. Error Codes
	<ul style="list-style-type: none"> • Use error code guide hanging on pump to problem solve • Switch off pump, after 5 seconds switch on again • If problem persists, try a second time • If problem continues, hand crank, change out pump
F.	MANAGEMENT OF PUMP FAILURE
	⇒ '!!STOP!!' displays on pump display screen with audible alarm
	⇒ Pump display is not present
	<ul style="list-style-type: none"> • Prepare to hand crank • Switch off pump • Insert pump into hand crank • Crank flow to speed required to maintain patient status ◆ Monitor RPMs, ◆ Monitor venous pressure ◆ Monitor patient SVO2, pressure, O2 sat ◆ If hand cranking is performed erroneously counterclockwise, handle will spin freely • Prepare to change out pump as per protocol ◆ Turn of fP1 ◆ Demonstrate removal of pump console from cart

Hanuola ECMO Program of Hawaii Equipment Drill Annual Competency

THE TERUMO CDI BLOOD GAS & VENOUS SATURATION MONITOR	
	1. Function and Description
	2. Connections to circuit
	3. Calibration
THE GAS CONTROL MODULE	
	1. Function and Description
	3. Connection to membrane
	4. Connection to gas sources
	<ul style="list-style-type: none"> • blender, wall
	<ul style="list-style-type: none"> • carbon dioxide tank
THE CINNCINNATTI SUB ZERO HEATER	
	1. Function and Description
	2. Temperature Settings
	3. Alarms
	4. Connection to circuit
	5. Troubleshooting
	<ul style="list-style-type: none"> • Low or high temperature readings • Faulty temperature probe
THE ACT MACHINE	
	1. Function and Description
	2. Quality Assurance Requirements
	3. Troubleshooting
	<ul style="list-style-type: none"> • Battery on, no power loss in unit • Power loss, battery not on
THE TRANSONICS FLOWMETER AND PROBE	
	1. Function and Description
	2. Associated use with ECMO
	3. Connection to ECMO Circuit (2 sites for monitoring)
	4. Troubleshooting

Appendix B.4

ECMO Lab Emergency Skill Checklist

Hanuola ECMO Program of Hawaii Emergency Skills Annual Competency

NAME: _____ **signature:** _____

TRAINER: _____ **signature:** _____

DATE COMPLETED: _____

Initial

A. REQUIRED ELEMENTS	EDUCATOR NOTES
<ol style="list-style-type: none"> 1. Utilizes universal precautions during circuit emergencies 2. Use aseptic or sterile technique during circuit manipulations 3. Discusses “follow- up” of emergencies 4. Complete procedures within a timely manner 5. Use back up personnel as needed 	<p><i>Gloves, goggles provided, (Caps/masks/ gowns) Chloraprepl for entering ports, betadine for 60 secs, dry for cuts into tubing Primers, physicians, nurses, therapists, specialists</i></p>
B. ON AND OFF BYPASS	
<ol style="list-style-type: none"> 1. Discuss indications for turning pump flow off <i>first</i> 2. Perform Off Bypass Procedure with appropriate technique 3. Discuss indication to decrease pump flow through bridge 	<p><i>Blood out – Air in Arterial then venous Flow > 200 or pump autoregulating</i></p>
C. GAS SOURCE FAILURE	
<ol style="list-style-type: none"> 1. List causes of high pressure Clots, kinks, increased blood flow or gas flow 2. List causes of low pressure Disconnection, leak, no gas 3. Describe interventions in the event of a gas source failure Obtain tank, use room air 4. Describe the procedure for changing a carbon dioxide tank 	<p><i>What would be “known” reasons for these alarms</i></p> <p><i>Alarm off, turn off tank, move regulator, remove tubing, open Tank, Alarm on</i></p>
D. HEATER FAILURE	
<ol style="list-style-type: none"> 1. Describe interventions with a EEP alarm Check probe connection, temp set point alarm, power disruption Change out heater 2. Describe how to maintain normothermia in a patient in the event of failure 3. Describe how to change heater 	<p><i>Blankets, overbed warmer, Bair warmer blanket Hose disconnect from front, fill new heater, set point</i></p>
E. POWER FAILURE	
<ol style="list-style-type: none"> 1. Describe interventions with UPS Initiation Assures plug is secure, reposition, Disconnects unnecessary equipment 2. Perform interventions with pump failure Assure pump switch on, plug in, then turns off pump flow handcrank, watch bladder, pressures, VS, Patient Sats 3. Perform pump change out procedure (Turn off P1 first) 4. Describe interventions with the Pressure Monitor failure 5. Demonstrates override function 6. Describes changing pump to Stand Alone mode to disconnect it from the Pressure Monitor. 	<p><i>Error code review – reset vs dead What if complete power failure? Feel bladder</i></p> <p><i>Where do you get one?</i></p> <p><i>Rezeroes Pressure Monitor if/when power returned</i></p>

Hanuola ECMO Program of Hawaii
Emergency Skills Annual Competency

F. AIR IN CIRCUIT	
<p>1. Remove air from arterial side Takes pt off bypass Walks air through bridge Removes air from arterial cannula with double clamp Removes air from venous cannula with double clamp Discusses intervention in the event of air embolus</p> <p>2. Remove air from Venous side Aspirates air from venous port Push volume into circuit to replace air</p>	<p><i>(Air In/Blood Out)</i></p> <p><i>Large volume of air may need to be aspirated from the venous side</i></p> <p><i>Decides if pt can go on bypass or continue Trendelenburg, VV vs VA</i></p>
G. ROTAFLOW FAILURE	
<p>1. Performs immediate interventions If not working, problem solve first Remove from housing & put back in Decrease/stop flow to minimize blood loss Takes pt off bypass Assembles equipment and personnel Double clamps out Rotaflow, cut out both sides Attach new Rotaflow to inlet tubing Fill pump with saline Attach outlet tubing Recirculate if time allows Return to bypass</p>	<p><i>“Air in/Blood out” Emergencies</i></p> <p><i>Reasons to clamp now, watch placement, tubing space to cut.</i></p> <p><i>“Cut closest to the thing you want to get rid of”</i></p> <p><i>Always cut both sides , saves scissors from laying down</i></p> <p><i>Use a helper to hold and fill lines</i></p> <p><i>turn on pump, will need more volum to the circuit as equilibrates</i></p> <p><i>H/H, tie band,</i></p>
H. STOPCOCK CRACK	
<p>1. Perform procedure for changing a stopcock Gathers equipment, assemble and flushes new stopcock on syringe Stops pump flow Clamps pre and post stopcock Places new stopcock airlessly Removes clamps Returns flow to previous setting Follow up</p>	<p><i>If gross blood loss, decrease/stop flow to minimize</i></p> <p><i>To minimize alarms, safe environment, discuss unprotected area of circuit</i></p>

Hanuola ECMO Program of Hawaii
Emergency Skills Annual Competency

I. BRIDGE PARTS FAILURE	
<ol style="list-style-type: none"> 1. Describe assessment of parts failure <ul style="list-style-type: none"> Attempts to hand tighten, clamp tighten Differentiate between connector or bridge tubing 2. Perform procedure for changing a cracked bridge connector <ul style="list-style-type: none"> Assembles equipment, personnel Takes pt off bypass Clamps bridge and below bridge Removes old connector/places new connector airlessly Recirculates Returns pt to bypass Follow up 3. Perform procedure for changing cracked bridge tubing <ul style="list-style-type: none"> Assemble equipment Double clamp on arterial side Adjust flow if it had previously been an open bridge Remove bridge tubing Replace damaged tubing Fill with syringe for airless connection Reset the clamp for continuous open bridge Adjust flow again Follow-up 	<p><i>If gross blood loss, decrease/stop flow to minimiz</i></p> <p><i>Change entire piece-stopcock</i></p> <p><i>Clamp already present above bridge</i> <i>Watch torque</i></p> <p><i>Non emergent, no off bypass procedure</i></p>
J. CONNECTOR FAILURE	
<ol style="list-style-type: none"> 1. Discuss reasons for changing a connector 2. Perform procedure for changing a connector <ul style="list-style-type: none"> Assemble equipment, personnel Take patient off bypass Double clamps out, cuts out old Place one end of connector Fills connector and airlessly connects Remove clamps Recirculate Return patient to bypass Followup 3. Perfoms procedure for changing a connector <ul style="list-style-type: none"> Y- connector Luer vs straight connector Connector with a pressure monitor attached 	<p><i>Clotted or cracked</i></p> <p><i>Watch clamp placement, save tubing, opposite clamps act as the double, make all cuts</i> <i>Use helper, steady stream of saline</i></p> <p><i>Use only 2 clamps, put double side in first</i> <i>Always place new pigtail and stopcoc</i> <i>Override pressure module for procedure</i></p>

Hanuola ECMO Program of Hawaii

Emergency Skills Annual Competency

K. OXYGENATOR FAILURE	
<ol style="list-style-type: none"> 1. Discuss indications of failure <ul style="list-style-type: none"> Visible clot formation pre and post membrane Pre and Post membrane pressure changes Blood leaks Air rupture Blood Gas Changes Water leak 2. Discuss interventions for failure <ul style="list-style-type: none"> Notify physician In the event of patient decompensation In the event of no blood flow due to high pressures In the event of massive blood loss/air leak 3. Assemble equipment, personnel <ul style="list-style-type: none"> Take patient off bypass Detach ancillary connections to oxygenator, ie water lines, temp probe Double clamps out, cuts out old Place new oxygenator in bracket Fills connector and airlessly connects Remove clamps Recirculate Return patient to bypass Followup 	<p><i>Usually entire circuit clotted</i> ↑ transmembrane pressure – higher pre/ lower post Frank blood vs pink tinged High gas phase rupture across into blood phase CO2 clearance – 10 torr or trend, O2 350-450</p> <p>↑ vent support & take care of patient</p> <p><i>Blood prime new oxygenator for a neonate</i> Correct blood gas in new circuit if possible Watch blood temperature when going back on Remember to reconnect gas lines Reconnect pressure lines and CDI purge line May need volume to fill new oxygenator once back on</p>
L. CIRCUIT FAILURE	
<ol style="list-style-type: none"> 1. Discuss / define indications of failure <ul style="list-style-type: none"> Circuit DIC Sepsis Overwhelming clot formation 2. Discuss interventions for change <ul style="list-style-type: none"> Treat as if new on bypass procedure In sepsis 	<p>↓ platlet count, fibrinogen, unresponsive to tx, ↑ ACTs, clinically suspected sepsis or + blood cx Visible clots, requires changing multiple pieces</p> <p><i>ACTs, platelets, gases, labs</i> Ensure all fluids are attached to new circuit, new fluids for septic change outs</p>
M. ACCIDENTAL DECANNULATIONS	
<ol style="list-style-type: none"> 1. Describe symptoms of a venous decannulation <ul style="list-style-type: none"> Venous return alarm Air in venous line Blood loss at site Inability to obtain flow Visible cannula tip 2. Perform interventions for a venous decannulation <ul style="list-style-type: none"> Notifies personnel Take pt off bypass, stop flow Connects NS first to arterial side stopcock Unclamps arterial cannula, turns stopcock off to bridge Pushes volume until necessary Preserves ECMO circuit function 3. Describe symptoms of an arterial decannulation <ul style="list-style-type: none"> Blood loss at site Post Membrane pressure alarm, followed by low pressure readout Venous return alarm Vital sign changes Visible cannula tip 	<p><i>Is it a secondary cannula, can you do without it?</i> If so, how do you manage- clamp it out, put pressure on site, call for help. Treat volume needs What if cephalad is left? –Discuss no volume to this catheter due to placement in brain.</p> <p><i>Assess the situation, determine which catheter is out</i> Call for all ER volume, use saline first May place removed clamp below bridge on art side</p> <p><i>“Save the Circuit” Every 5-10 minutes, stop volume, move clamps and recirculate through the bridge.</i> Check ACT.</p> <p><i>Discuss “drain the circuit” scenario</i></p>

Hanuola ECMO Program of Hawaii Emergency Skills Annual Competency

<p>4. Perform interventions for an arterial decannulation Notifies personnel Take pt off bypass, stop flow Connects NS first to venous side stopcock Unclamps venous cannula, turns stopcock off to bridge Pushes volume until necessary Preserves ECMO circuit function</p> <p>5. Discuss interventions in returning pt to bypass Removes all air from circuit, bridge, Recirculates Returns pt to bypass Followup</p>	<p><i>Assess the situation, determine which catheter is out Call for all ER volume, use saline first May place removed clamp below bridge on art side</i></p> <p><i>“Save the Circuit” Every 5-10 minutes, stop volume, move clamps and recirculate through the bridge. Check ACT.</i></p>
N. MEGA EMERGENCY	
<p>1. Scenario: High Pre membrane pressure, regulating threshold violated Identifies correct area of circuit for troubleshooting Identifies potential causes of alarm Corrects problem and determines safety condition of circuit for patient</p> <p>2. Scenario: Low venous pressure, regulating threshold violated Identifies correct area of circuit for troubleshooting Identifies potential causes of alarm Corrects problem and determines safety condition of circuit for patient</p> <p>3. Scenario: High Post membrane pressure, regulating threshold violated Identifies correct area of circuit for troubleshooting Identifies potential causes of alarm - Corrects problem and determines safety condition of circuit for patient</p> <p>4. Scenario: Loss of Pressure Monitor module, NO COMM alarm Identifies correct area of circuit for troubleshooting Identifies potential causes of problem Corrects problem and determines safety condition of circuit for patient</p>	<p><i>Clots in oxygenator, pre membrane pigtail clotted, CVVH circuit clotted</i></p> <p><i>Volume needs, catheter kinked, erroneous alarm set point</i></p> <p><i>Catheter kinked, baby breathing, wiggling, arterial filter</i></p> <p><i>Inadvertently pushed button, component failure</i></p>

WATER LAB EMERGENCY DRILL CHECK - OFF (con't)

P:\CCS\ECMO\Education Resources\ECMO Training Manual\COURSE\Checklists\Emergency Skills Checklist.doc

Appendix B.5

ECMO Training Course Evaluation 2009

Hanuola May 2009 ECMO Training For The Bedside Clinician Evaluation Summary

Course Overview

Didactic Training at KMCWC
One 8 Hour Classroom Day

Vivarium Lab at Tripler
Two Groups of 6-7 Participants
Two –3 Hour Sessions
Hands on Practical Training Focus with didactic review
– Emergency Procedures

Participants
Fourteen Clinical Support Staff

- 1 NICU RN
- 7 PICU RN
- 2 RT
- 1 transport RT
- 2 Transport Nurses
- 1 PICU Physician

11 Continuing Educations Credits

Speakers

Mark Ogino, MD
Kristen Costales, CCP
Melody Kilcommons, RN
Len Tanaka, MD
Joan Kanemori, RN

Revisions to 2008 Training Course

- Outline changed
- Condensed Training Manual –no binder
- Tailored lectures to Hanuola Program – specific to the bedside clinician
- Updated lectures based on National/International Training Center Visits
- Partnered emergency drill procedures to increase number of participants in lab
- Test required for all participants



Day One

Wednesday, May 27, 2009

Bingham Conference Room, KMCWC

- | | |
|--------------|--|
| 0745 ~ 0800 | Coffee |
| 0800 ~ 0815 | Welcome
..... So, you think you want to do ECMO?
ELSO
Mark Ogino |
| 0815 ~ 0830 | ECMO Equipment and the Circuit
Kris Costales |
| 0830 ~ 0900 | Indications for ECMO
Neonatal Diseases
Evaluation and Selection
Mark Ogino |
| 0900 ~ 0930 | Indications for ECMO
Pediatric Diseases
Evaluation and Selection
Len Tanaka |
| 0930 ~ 0945 | Break |
| 0945 ~ 1130 | Physics of Extracorporeal Life Support
VA & VV ECMO
Recap of VV and VA ECMO
Mark Ogino |
| 1130 ~ 12:00 | Lunch |
| | Afternoon Lectures
Auditorium, KMCWC |
| 1200 ~ 1230 | ECMO Equipment and Circuit - Hands On
Kris Costales |
| 1230 ~ 1345 | Initiation and Stabilization of the ECMO Patient
ECMO Management
Mark Ogino |

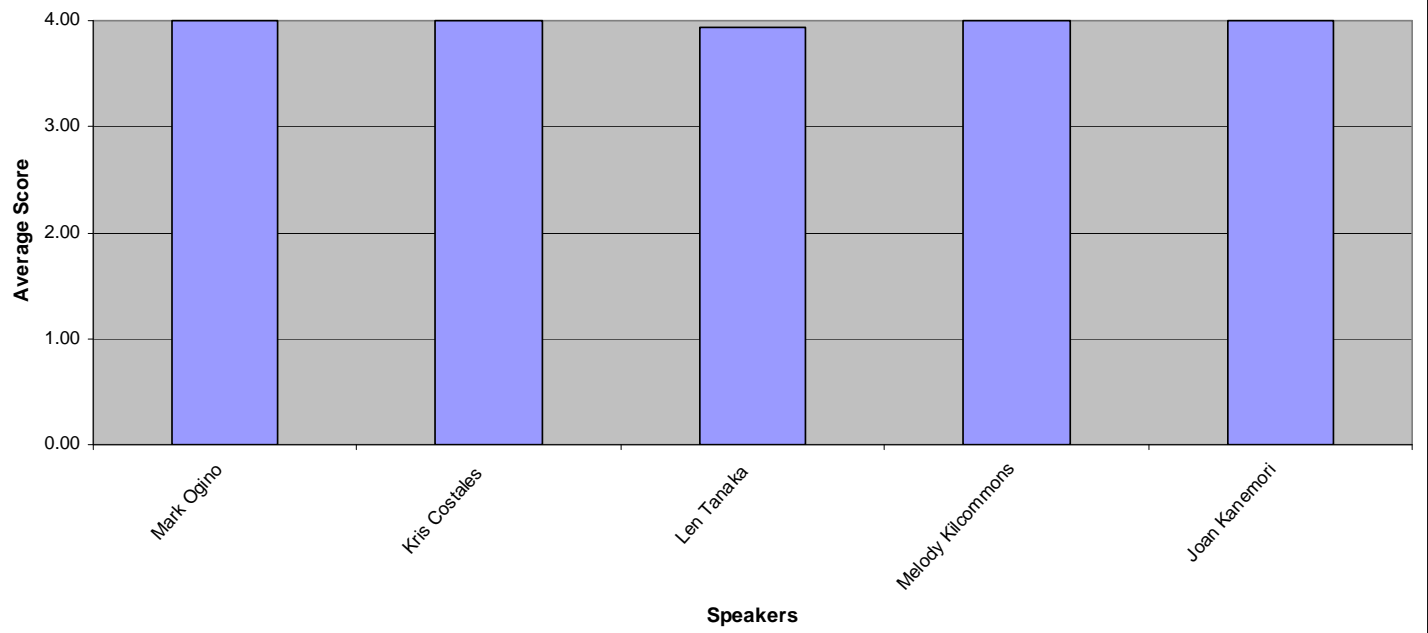
- 1345 ~ 1430 Advanced Clinical Management – cooling
Weaning, Trial off, and Decannulation
Checklists
Mark Ogino
- 1430 ~ 1445 **Break**
- 1445 ~ 1600 Bedside Care of the ECMO Patient
Melody Kilcommons
- 1600 ~1615 CRRT and ECMO
Joan Kanemori
- 1615 ~ 1645 Understanding Coagulation
Management of Hemostasis, Blood Products and ACTs
Mark Ogino
- 1645 ~ 1700 Introduction to the Vivarium Lab
Melody Kilcommons



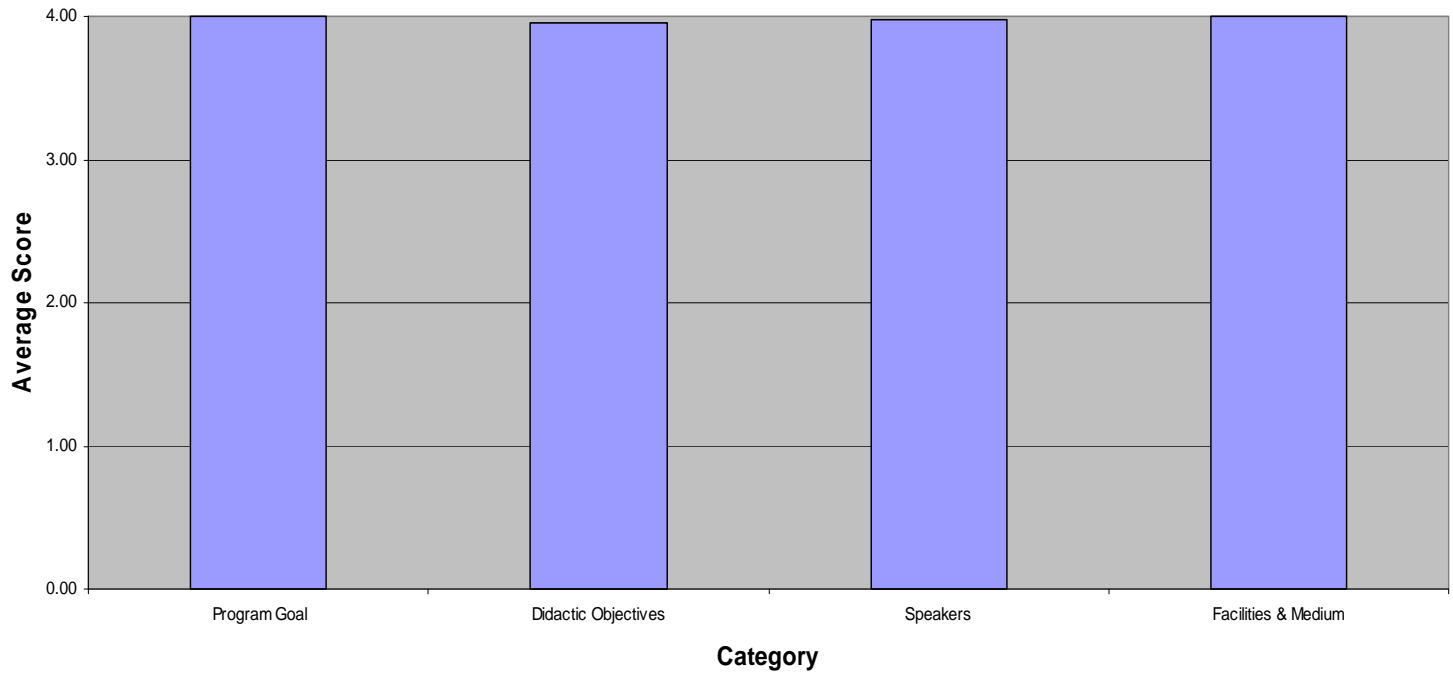
DayTwo
Thursday, May 28, 2009
Tripler Army Medical Center, Department of Clinical Investigation
Vivarium

	Group 1 (max = 6)	
1100 ~ 1200	Circuit Review VA\VV Physiology Review	Kris Costales Mark Ogino Melody Kilcommons
1200 ~ 1330	Emergency Procedures Lab Emergency Procedures Skills Evaluation	Kris Costales Mark Ogino Melody Kilcommons
1330 ~ 1400	Test and Review	
	Group 2 (max = 6)	
1400 ~ 1500	Circuit Review VA\VV Physiology Review	Kris Costales Mark Ogino Melody Kilcommons
1500 ~ 1630	Emergency Procedures Lab Emergency Procedures Skills Evaluation	Kris Costales Mark Ogino Melody Kilcommons
1630 ~ 1700	Test and Review	

Participant Speaker Evaluation
Effectiveness of Presenter?
1=very little, 2=somewhat, 3=mostly, 4=completely



Participant Evaluation Overview
How well were objectives met?
1=very little, 2=somewhat, 3=mostly, 4=completely



Objective Evaluation Questions with Responses

Program Goal	How well do the objectives below relate to the program goal? To provide healthcare professionals with cognitive and technical didactics combined with skills practice and competencies to facilitate care of the ECMO patient and management of the equipment utilized within the scope of their practice																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4.0
Obj. 1	Briefly describe Extracorporeal Membrane Oxygenation. Indicate awareness of a National Registry and Data collection process for the ECMO patient.																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 2	List the basic components of the ECMO circuit. Describe the basic physiology of the ECMO circuit																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 3	Describe the oxygenation, ventilation and blood flow management for the patient on Extracorporeal Life Support.																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 4																			
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4.0
Obj. 5	Identify the rationale for the use of radiology, laboratory, and physical assessments of the newborn in the decision process to select a candidate for ECMO																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4.0
Obj. 6	Identify the rationale for the use of radiology, laboratory, and physical assessments of the pediatric and/or adult patient in the decision process to select a candidate for ECMO																		
Scores	4	4	4	3	4	4	4	4	4	4	4	4	4	4					3.9
Obj. 7	Define the use of venoarterial ECMO and the management of the patient on VenoArterial bypass. Identify potential complications associated with VenoArterial ECMO																		
Scores	4	4	4	3	4	4	4	4	4	4	4	4	4	4					3.9
Obj. 8	Define the indications for of Venovenous ECMO and the management of the patient on Venovenous bypass. Identify potential complications associated with Venovenous bypass.																		
Scores	4	4	4	3	4	4	4	4	4	4	4	4	4	4					3.9
Obj. 9	Identify and explain the procedures and techniques used during cannulation to initiate and stabilize the ECMO patient																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4
Obj. 10	Identify role responsibilities specific to the patient requiring ECMO in the NICU or PICU. Explain importance of effective communication between staff caring for the ECMO patient.																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4
Obj. 11	Explain the expectation of the vivarium lab and reduce potential apprehension related to the vivarium lab experience.																		
Scores	4	4	4	3	4	4	4	4	4	4	4	4	4	4					3.9

Obj. 12	Interpret normal lab values for a patient with hemostasis, and those at risk for bleeding.																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 13	Explain the use of blood products, heparin and other hemostatic agents used in the management of the ECMO patient's coagulation status.																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 14	Identify system assessments specific to patients on ECMO.																		
Scores	4	4	3	4	4	4	4	4	4	4	4	4	4	3					3.9
Obj. 15	Identify the disease states that may require the pediatric patient in respiratory and/or cardiac failure to require ECMO; as well as the management of the patient on ECMO.																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4
Obj. 16	Discuss the roles and responsibilities required to care for an ECMO patient during evaluation, initiation and stabilization																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					3.9
Obj. 17	Describe the weaning process, trial off and decannulation procedures used during venoarterial and veno venous ECMO.																		
Scores	4	4	4	3	4	4	4	4	4	4	4	4	4	4					3.85
Obj. 18	Explain the clinical significance of fluid and electrolyte balance for the patient on ECMO. Identify the equipment required to hemofiltrate a patient on ECMO.																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 19	Indicate understanding of the basic principles of ECMO																		
Scores	4	4	4	3	3	4	4	4	4	4	4	4	4	4					3.9
Obj. 20	Describe the ECMO circuit equipment																		
Scores	4	4	3	3	4	4	4	4	4	4	4	4	4	3					3.8
Obj. 21	Identify emergencies that require a patient to come off bypass																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4
Obj. 22	Demonstrate/verbalize appropriate emergency actions																		
	a) When the perfusionist is at the bedside																		
	b) When the perfusionist is not at the bedside																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4
Obj. 24	Demonstrate/Verbalize Off Bypass Procedure																		
Scores	4	4	4	4	4	4	4	4	4	4	4	4	4	4					4

Comments May 2009 Course Evaluations

Comments

- I have a better understanding of the different types of ECMO –VA vs VV. I also have a better understanding on what needs to be done to prepare a patient for ECMO
- ECMO is definitely a team effort and everyone needs to work together
- Dr. Ogino simplifies difficult to understand concepts. Excellent job.
- Very educational
- Loved the scenarios. We should do this on a yearly basis.
- This would help my practice in helping with bedside RN or perfusionist duties when called upon
- As a result of this program I have a better understanding of ECMO circuitry and practices used by KMCWC
- AWESOME learning and hands on experience.
- I will be able to competently care for a patient on ECMO and will know what to expect when at the bedside. I will know what labs are required and the meds utilized with the ECMO circuit
- I now feel more competent and a little more comfortable with being able to care for a patient on ECMO
- Great Program!!! Love the short lectures with frequent breaks. Kept my attention. Thanks for all the snacks and refreshments to keep our glucose up and our brains at top function. Nice to hear some of the same info from different lectors- definitely helped me to remember important facts.
- As transport RN- we can be utilized to watch circuits/pump if extra eyes are needed. As to transporting in the future- this course is fundamental
- Kudos to everyone who has created the program. Good learning techniques/facilities. Well organized and thank you for coffee/snacks
- This is my first ECMO class before this I didn't really know anything. Today I feel I have learned a lot from this class and the training - what I did not grasp I will continue to read in the training manual.
- Help other staff in our department to understand our responsibilities. What blood gas values to look out for.
- Increased confidence in participating with the medical staff and communication!
- Great hands on experience. Helpful w/the visual learner.
- Awesome thanks
- This course will help me to better care for the ECMO patient/good to review clotting process/pathophysiology. It increased my understanding and confidence
- I have a better understanding of oxygenation and ventilation for ventilated patients, general overview. I will be better able to care for ECMO patients
- The lab experience was great to get hands on experience with real scenarios. Thank you for setting this up!
- I will use what I learned at the bedside.

- It would be great to have more lab and/or mock drills for more practice. This was great.
- This class made me less apprehensive and more comfortable in caring for the ECMO patient
- I think it was very helpful to see the ECMO equipment first and a patient on ECMO, before taking the class, it made more sense to me.
- Excellent practical/clinical approach to ECMO. Excellent speakers and effective Audio visual on Day 1. Really appreciated the snacks and drinks as well. Bingham conference room small but I prefer the table lay out rather than the auditorium. Lab was integral to the program, great compliment to the didactic sessions from day 1
- This class reinforced my knowledge of blood product administration and uses
- Direct pressure is the best response to bleeding ;)
- The whole class was well organized and I am much more comfortable with ECMO in general.
- No changes excellent

Proposed Revisions and Continued Areas of Significance for 2009

- Consider binding that reference materials as a separate bedside resource manual. (Done)
- Improve explanation of TAMC facilities and procedure for admittance to lab (Done)
- Introduce TAMC staff at beginning of each lab segment (Done)
- Prepare clinical support staff for the amount of information to be presented at the training and rationale for same. State areas of importance for each scope of practice will be emphasized and made clear upon completion of the training (Done) Role responsibilities identified
- Hanuola Team will do all lectures 2009. (Done)
- All presenters should state course objectives at beginning of slides. (in process)
- Recruitment of new presenters (Joan Kanemori)
- Mentoring and retention of current presenters (in process)
- Consider video taping lectures to update website and upload new PowerPoint slide sets. (for future)
- Continue to modify Emory's materials and revise Hanuola program based on travel to other center and course feedback (continuing process)
- Discuss whether or not to move training to KMCWC to avoid cost of transporting ECMO pump from Tripler. Difficult due to heavy booking of KMCWC auditorium. (done)
- Consider refresher course as well as training course for next year to address learning needs of those staff already trained and keep skills current. (in process)
- Continue review of VA, VV physiology at the lab (done)
- Continue animal sat probe at skills lab to reinforce learning (done)
- Continue to improve scenarios and role playing at lab (done)
- Change skills lab time allotment to 3 hours per group (done)

Appendix C.1
Hanuola ECLS Registry Report
June 2009

ECLS Registry Report

Center Specific Summary

July, 2009



Extracorporeal Life Support Organization
1327 Jones Drive, Suite 101
Ann Arbor, MI 48105

Hanuola - ECMO Program of Hawaii (176)

Overall Outcomes

	<i>Total Patients</i>	<i>Survived ECLS</i>		<i>Survived to DC or Transfer</i>	
Neonatal					
Respiratory	5	4	80%	4	80%
Cardiac	1	1	100%	1	100%
Pediatric					
Cardiac	2	2	100%	1	50%
Total	8	7	88%	6	75%

Neonatal Respiratory (0-30 days)

Neonatal Respiratory Runs by Year

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2007	2	2	110	123	1	50%
2008	2	4	159	295	2	100%
2009	1	5	66	66	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Runs by Diagnosis

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
PPHN/PFC	2	61	98	2	100%
Other	3	161	295	2	67%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Support Mode Details

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VVDL+V	2	61	98	2	100%
VV-VA	1	123	123	0	0%
VVDL	1	66	66	1	100%
VA+V	1	295	295	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Neonatal Respiratory Complications

	<i>No. Reported</i>	<i>% Reported</i>	<i>No. Survived</i>	<i>% Survived</i>
Hemorrhagic: Surgical site bleeding	1	20.0%	0	0%
Neurologic: CNS hemorrhage by US/CT	1	20.0%	1	100%
Renal: Creatinine > 3.0	1	20.0%	1	100%
Renal: CAVHD required	1	20.0%	1	100%
Cardiovascular: Inotropes on ECLS	4	80.0%	3	75%
Metabolic: Hyperbilirubinemia (> 2 direct or > 15 total)	2	40.0%	2	100%

Pediatric Respiratory (>30 days and < 18 years)

Adult Respiratory (18 years and over)

Cardiac

Cardiac Runs by Year

Age Group: 0 - 30 days

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2008	1	1	95	95	1	100%

Cardiac Runs by Year

Age Group: 1 year and < 16 years

	<i>Annual Runs</i>	<i>Cumulative Runs</i>	<i>Average Run Time</i>	<i>Longest Run Time</i>	<i>No. Survived</i>	<i>% Survived</i>
2008	1	1	108	108	0	0%
2009	1	2	105	105	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Diagnosis

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Congenital Defect	1	95	95	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Congenital Defect	1	108	108	0	0%
Cardiogenic Shock	1	105	105	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Surgical type

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Other postop, not bridged	1	95	95	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
Other postop, not bridged	2	106	108	1	50%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Congenital Diagnoses

Age Group:	0 - 30 days	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
	Other	1	95	95	1	100%

Cardiac Congenital Diagnoses

Age Group:	1 year and < 16 years	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
	Hypoplastic left heart	1	108	108	0	0%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Runs by Procedure

Age Group:	0 - 30 days	Total Runs	Avg Run Time	Longest Run Time	Survived	% Survived
	Blalock-Taussig, modified	1	95	95	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Support Mode Details

Age Group: 0 - 30 days

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VA	1	95	95	1	100%

Age Group: 1 year and < 16 years

	<i>Total Runs</i>	<i>Avg Run Time</i>	<i>Longest Run Time</i>	<i>Survived</i>	<i>% Survived</i>
VA	1	108	108	0	0%
VA+V	1	105	105	1	100%

Run time in hours. Survived = survival to discharge or transfer based on number of runs

Cardiac Complications (0-30 days)

	No. <i>Reported</i>	% <i>Reported</i>	No. <i>Survived</i>	% <i>Survived</i>
Hemorrhagic: Cannulation site bleeding	1	100.0%	1	100%
Cardiovascular: Hypertension requiring vasodilators	1	100.0%	1	100%

Cardiac Complications (1 year and < 16 years)

	No. Reported	% Reported	No. Survived	% Survived
Hemorrhagic: Cannulation site bleeding	1	50.0%	0	0%
Renal: CAVHD required	2	100.0%	1	50%
Cardiovascular: Inotropes on ECLS	2	100.0%	1	50%
Cardiovascular: Myocardial stun by echo	1	50.0%	1	100%
Metabolic: Hyperbilirubinemia (> 2 direct or > 15 total)	1	50.0%	0	0%

Appendix D.1

Advisory Committee Annual Meeting 2009

Agenda

Advisory Committee Meeting Agenda

January 16 - 18, 2009
Honolulu, Hawaii

Friday, January 16th, 2008

John A Burns School of Medicine

Medical Education Building - Access Grid Room, 2nd Floor

- ❖ 0730 – 0800 Continental Breakfast
- ❖ 0800 – 0815 Introductions
- ❖ 0815 – 0915 Program Review
 - Administrative Structure (Morton)
 - Educational Programs, including Training Program Site Visits (Kilcommons, Costales)
 - Vivarium (Lentz-Kapua)
 - Clinical Overview (Ogino)
 - 2008 Advisory Board Recommendations
- ❖ 0915 - 1015 Queen Kapiolani (Colette Higgins)
- ❖ 1015 – 1030 Break
- ❖ 1030 – 1200 Research Symposium
 - 1030 – 1100 Pediatric Critical Care Curriculum (Fiedor)
 - 1100 – 1130 Children's Hospital Pittsburgh Coagulation Study (Kelly)
 - 1130 – Noon Porcine Septic Shock Study (Uyehara)
- ❖ Noon – 1300 Lunch at JABSOM Cafeteria
- ❖ 1300 – 1400 Virtual ECMO Simulator – ECMOjo (Ogino)
- ❖ 1400 – 1500 Keynote Address ([???????](#))
- 🚪 1800 - 2200 Reception – RumFire Restaurant, Sheraton Waikiki

Saturday, January 17th, 2008

John A Burns School of Medicine

Medical Education Building - Access Grid Room, 2nd Floor

- ❖ 0730 – 0800 Continental Breakfast
- ❖ 0800 – 0930 Hanuola Confessions (Kilcommons, Costales, Ogino)
- ❖ 0930 – 1030 Case Reviews
- ❖ 1030 – 1045 Break
- ❖ 1045 – 1200 Case Reviews
- ❖ 1200 – 1300 Lunch at JABSOM
- ❖ 1300 – 1400 Final comments from Case Review
- ❖ 1400 – 1500 ECMO Transport
- ❖ 1500 – 1515 Break
- ❖ 1515 – 1530 Hanuola Clinical Program Finances (Fukumoto)
- ❖ 1530 – 1600 Hanuola: 2010 and beyond (Morton, Ogino)
- 🚪 1800 - 2100 Reception – Sheraton Waikiki Niihau Room
 - Blessing
 - Prayer Cards

Sunday, January 18th, 2008

Sheraton Waikiki Oahu Room

- ❖ 0800 – 1000 Breakfast Meeting -
 - Program summary and comments from the Advisory Committee Members

Appendix D.2
Advisory Committee Annual Meeting 2009
Meeting Minutes

Advisory Committee Meeting 2009

Friday January 16, 2009

Attendees:

Advisory Board: Denise Suttner, Bill Harris, John Lin

Invited Guests: Jeanne Braby, Scott Lawson

UPMC: Bob Hardie, Mindy Fiedor Hamilton, Leslie Anthony, Kent Kelly

Wilford Hall/DOD Partners: Don McCurnin, Melissa Tyree

KMCWC: Mavis Nikaido, Charles Neal, Laura Bonilla, Willow Morton, Bala Balaraman, Sid Johnson, Len Tanaka, Ken Nakamura, Mark Ogino, Melody Kilcommons, Sheree Kuo,

Perfusion: Shilpa Nair, Kristen Costales

JABSOM: Kathleen Kihmm-Connelly, Larry Burgess, Dolly Puchert, Chris Aschwanden, Kalei,

TAMC: Catherine Uyehara

Clinical Program Overview

[Harris] a lot of work has been done.

Site visits and Educational Overview:

[Harris] Apply for ELSO Award of Excellence.

[Braby] Need 5 patients a year minimum. Used to be on the review committee. Offered assistance if Hanuola Program decides to apply.

[Suttner] Recommends keeping a core group of ECMO MDs trained and not the entire MD group. States we have trained too many non-essential people

[Sid Johnson] Bulk of training was "ECMO awareness"

[Tyree] Simulation training is good for emergency/clinical staff/ team building. Animal lab should be used for cannulation practice and experience. Recommends one a year for cannulation, equipment selection and to train surgeons and perfusion.

[Burgess] What is your surgical support?

[Johnson] 2 surgeons, [TAMC surgeon covers week end call] one pediatric cardiac surgeon.

Percutaneous Cannulation

[Ogino] Discussed for the PICU

[Suttner] Discussed at their institution but they have not gone there yet.

[Hamilton] Attended National Simulation Conference and high fidelity simulation may be innovative enough to be utilized for cannulation training in the future.

[Nakamura] requested that on Sunday as one of its recommendations the board could formally address how many trained MDs does Hawaii need and suggestions for call structures.

[Overall] Training of a core group improves performance by increasing comfort levels and centralizes training and resources. Once core group established disseminate out to training new staff.

Transport Update

[Tyree] consider tether points for extra security for tie downs with weights

[Lin] LTV bleeds air – consider alternate ventilator- MVP 10 may require electrical and gas testing

[Harris] Who will own the design?

[Costales] Hardware owned by Kapi'olani and Hanuola. Design will be shared by Airmed and Hanuola

[Harris] UPS consider a system that will lock into the wheelbase

[Tyree] like a trailer hitch. Also might consider a generator for support for the UPS as part of the ambulance system

[?] Do you have HFOV and iNO options for transport?

[Costales] Currently for neonatal transport but not with the proposed ECMO gurney

[Braby] Make considerations for equipment changes that may occur in the future

[Lin] Do not use a triple channel pump for less than 10kg. Need syringe infusion pump capability

Pediatric Critical Care Modules

What should remain as didactic?

What should become simulation teaching?

Coagulation Study

PTT, ACT, Carmeda coated circuits discussed based on last years head bleeds. No definitive correlation.

23 ECMO patients enrolled in the UPMC study.

Hemochron junior signature ACT machine

Looked at ACT, PTT, and heparin relationship

Weak correlation between the ACT & PTT

Continuing to look at the Anti Xa and utilizing the EDAC machine (emboli detection improvement from Doppler. EDAC shows the difference between one bubble and many air bubbles). Also evaluation TEGs

Take Home Point [Kelly] POCT if you change your machine you have to change your POCT ranges. When they changed from the Hemochron to the iStat (recommended not using the iStat LR [low range] as it does not work for ECMO ranges)

ACT ranges run higher for the iStat.

[Lawson] At Duke they noticed clinically that they had a higher incidence of head bleeds in patients that had a significant event prior to ECMO. Therefore these patients were changed to the carmeda coated circuit and run without heparin. The question remains whether these patients then have a higher risk for micro-clotting in exchange for a presumed reduction in risk for head bleed.

Conclusion was that most of the members agreed that ACT range alone was not an acceptable indicator of safe and effective coagulation.

New products being engineered or soon to be released are the Bioline and the Safeline. Albumin and heparin coated products.

Waiting for TEG studies

Sepsis Module

Making progress. Hormone vasopressin research has interesting merits in clinical application as it relates to blood pressure interpretation. Connections to its application in ECMO support therapy seems somewhat questionable. Much will depend on the results that will be interpreted the upcoming year.

[Suttner] questioned the validity of extrapolating the results from the current study for its application to human use in relation to blood flows and cannula site.

EC-MOjo

[McCurnin] Explained the name of the Simulator. MOJO if you do ECMO you have to have MOJO. Reviewed the history/obstacles in choosing the name.

Everyone impressed with the graphics and capability of the Simulator. Indication for use were discussed both for developing skill sets and maintaining skill sets.

[Harris/Braby] Discussed potential of accessing some previous scenario work that they had submitted to ELSO and thought that this might be accessible and appropriate for this simulator project.

Saturday, January 17th, 2009

John A Burns School of Medicine

Medical Education Building - Access Grid Room, 2nd Floor

Attendees:

Advisory Board: Denise Suttner, Bill Harris, John Lin

Invited Guests: Jeanne Braby, Scott Lawson

UPMC: Bob Hardie, Mindy Fiedor Hamilton, Leslie Anthony, Kent Kelly

Wilford Hall/DOD Partners: Don McCurnin, Melissa Tyree

KMCWC: Karen Whiteted, Charles Neal, Laura Bonilla, Willow Morton, Bala Balaraman, Sid Johnson, Len Tanaka, Ken Nakamura, Mark Ogino, Melody Kilcommons, Sheree Kuo, Jaime Harrington, Louise Fukumoto

Perfusion: Shilpa Nair, Kristen Costales, Pete May, Mark Yanogacio

JABSOM: Kathleen Kihmm-Connelly, Larry Burgess

TAMC: Catherine Uyehara

Case Presentations

PICU Cases

Five Pediatric Cases were reviewed. This included ECMO and ECMO referral patients.

NICU Cases

Eight Neonatal Cases were reviewed. This included ECMO and ECMO referral patients.

January 17th, 2009 – Hanuola: 2010 and Beyond **Willow Morton** (*notes by Kathleen*)

1. One of the issues from last year, was the complicated consortium
 - a. Not enough of a population to sustain one entity
 - b. Hanuola captures the essence of the program
2. Strategic Planning
 - a. Success factors
 - i. Physician consortium
 - ii. Startup funding
 - iii. Jabsom leadership
 - iv. Partnerships
 - b. UPMC/Biotronics
 - i. Training and simulation development
 - ii. Perfusion services
 - iii. Technical assistance
 - iv. Administrative assistance
 - c. Tripler
 - i. Physician experts
 - ii. Animal labs
 - d. National Advisory Board
 - e. Physician Champion—Mark Ogino
3. 2010—Goal: Maximize grant resources for development to set the stage for 2010
4. Financials
 - a. 256K net revenue for ECMO Cases – estimated to date
 - b. As long as contracting arrangements do not change, Kapiolani’s maintenance should be okay
5. \$200-\$250K admin costs that need to be moved over to the hospital (previously paid off grant)
6. Ongoing contracts and relationships
 - a. Kaiser
 - b. Tripler
 - c. Jabsom – future grants in simulation
 - d. Biotronics
 - e. ECMO physicians
7. Challenges ahead
 - a. Weak economy
 - b. After grant ends, continued communication, effort and development
 - c. Maintaining excellence
 - i. Attention to clinical performance
 - ii. Scrutiny of service delivery model
 - iii. Cost of training
8. We have optimism for the future
9. Thank you

10. Comments

- a. Some clinicians do not feel the need for ECMO, Advisory Committee please address the importance and value of the program
 - i. Administration is supportive
 - ii. Professional community has concern because of the length of time that it took to get started
 - iii. Adaptation occurred without ECMO
 - iv. Clinicians are not aware or just accepted that patients were dying
- b. 2 page letter from the Board – possibly Dr. Devn Cornish
 - i. Add some cost data
 - ii. Impact of patients
 - iii. ECMO survivor day – media coverage

Advisory Recommendations: Present hard data “ECMO as Standard of Care”
Reinforce the data with saved lives, quality adjusted, Cost effectiveness of the program

Sunday, January 18th, 2009
Sheraton Waikiki Oahu Room

Attendees:

Advisory Board: Denise Suttner, Bill Harris, John Lin

Invited Guests: Jeanne Braby, Scott Lawson

UPMC: Mindy Fiedor Hamilton, Leslie Anthony, Kent Kelly

Wilford Hall/DOD Partners: Don McCurnin, Melissa Tyree

KMCWC: Mavis Nikaido, Laura Bonilla, Willow Morton, Ken Nakamura, Mark Ogino, Melody Kilcommons, Sheree Kuo,

Perfusion: Shilpa Nair, Kristen Costales

JABSOM: Larry Burgess,

[McCurnin] Fragmented organizational structure that he brought up last year has been addressed. Key players will make the program successful

Advisory Board will write the letters to assist with the underlying resistance

Everyone has been doing a lot of work and it shows

There is a very real potential that Wilford Hall will no longer be able to support Hawaii transport

[Tyree] Wilford hall may no longer be doing transport and it may not be a transport option for Hawaii.

[Lin] There may be personnel resources that Hanuola could tap into from Wilford hall and How can these be explored?

[Lin] What is the future of the advisory Board? Can we tag it onto another meeting on the mainland?

[Harris] Support will be ongoing. Advisory is committed to the program

[Dr. Burgess] Is there a small volume center consortium? Could Hanuola start up something like that and tack it onto the ELSO meetings?

[Suttner] Hawaii is self reliant and it needs to be successful as a small volume center

There is an opportunity to be transport leaders. Explore alternatives for hemofiltration

Staffing – don't have to put nursing through the complex training. Create a core MD group. You already have perfusion they are the experts and you have your MD group to manage

[May] I rely on the nurses to tell me what is happening with the baby.

[Costales] Bypass in the OR is very different than ECMO. Perfusion does not have the critical care experience that the nurses have. Nursing and perfusion have to work together.

[Braby] Managing an adult patient in the OR is a lot different than a neonate on ECMO. Perfusion aren't aware of some of the nuances that are necessary for neonatal and pediatric care.

[Kilcommons] I hesitate to limit nursing contribution to the delivery of ECMO support. Team building and collaboration has been one of our success factors. Historically we heard yesterday that there has been something missing here. I think ECMO brings practitioners the hope of practicing excellence. Practicing excellence in our critical care units is cost effective not just for the ECMO program but for the application of this knowledge for all the patients who enter the critical care units. I believe that we do not need to teach our nurses how to manage the pump, however we need to be able to look at our program and dissect the information that nurses will need in order for them to augment the role of the perfusionists who are managing the pump and the MDs who managing the pump and the patient.

[Harris] When you look at the most successful programs it is the ones who have everyone on board as part of the team that have the best programs.

[Lawson] At our institution it takes everyone nurses, RTs to make ECMO work.

[Tyree] consider cross-covering (ECMO) create a team even for pre ECMO care and management. Ensures the best preventative pre ECMO management

[Suttner] bicarb is a buffer. After 2 doses consider your indications for ECMO

[Ogino] How often do you round on your ECMO patients?

[Hamilton] 2 x a day, support staff want it.

[Lawson] consider only doing ECMO on one unit

[McCurnin] Don't be afraid to put kids on. Don't take chances by not putting them on VV doesn't sacrifice the carotid

[Suttner] differences in medical management unique management of kids in an isolated setting

[Nakamura] Can the advisory board make a recommendation for the requirement for pre ECLS management

[Burgess] change threshold for "going on"

[Suttner] don't use ECMO as a rescue use it as an avoidance of problems and optimal outcomes

[Nakamura] could give an advisory board ECMO update at grand rounds

[Lawson] commend everyone for doing the program right

Statement on the complexity of the transport system

Opportunities to break new ground

New equipment

New ELSO subgroup

Transport

Transport and simulation could be used as a conduit to financial grants

[Harris] equipment issues: for future new oxygenator Medox will tolerate lower flows may be able to get rid of our open bridge. New cannulas what should we have available. UPC battery. Make sure that email addresses of the advisory are sent to everyone so that the letters can be completed.

[Braby] provide scenarios for EC-MOjo

To Do List:

- Develop an inotrope protocol
- The Hanuola program is ready to do more ECMO. Look at your inclusion criteria not as those circling the drain but the optimal time for ECMO for the best outcomes
- Follow up outcomes for your referrals and your ECMO cases
- Consider not paralyzing patients as part of your pre-ECMO management
- Explore cannulation alternatives and venous cannulas for neck cannulation
- Explore neonatal hemofiltration options
- Consider one designated unit for ECMO
- Follow PTs

Letter by the advisory to be written to the founder of the grant (appropriations, senator, kap institution)

Letter by advisory to the hospital to address internal resistance and summarize Advisory Board evaluation and recommendations

January 17th, 2009 – Hanuola: 2010 and Beyond

Willow Morton and Louise Fukumoto

11. One of the issues from last year, was the complicated consortium
 - a. Not enough of a population to sustain one entity
 - b. Hanuola captures the essence of the program
12. Strategic Planning
 - a. Success factors
 - i. Physician consortium
 - ii. Startup funding
 - iii. JABSOM leadership



- iv. Partnerships
 - b. UPMC/Biotronics
 - i. Training and simulation development
 - ii. Perfusion services
 - iii. Technical assistance
 - iv. Administrative assistance
 - c. Tripler
 - i. Physician experts
 - ii. Animal labs
 - d. National Advisory Board
 - e. Physician Champion—Mark Ogino
13. 2010—Goal: Maximize grant resources for development to set the stage for 2010
14. Financials
- a. 256K net revenue for ECMO Cases – estimated to date
 - b. As long as contracting arrangements do not change, Kapiolani’s maintaince should be okay
15. \$200-\$250K admin costs that need to be moved over to the hospital (previously paid off grant)
16. Ongoing contracts and relationships
- a. Kaiser
 - b. Tripler
 - c. Jabsom – future grants in simulation
 - d. Biotronics
 - e. ECMO physicians
17. Challenges ahead
- a. Weak economy
 - b. After grant ends, continued communication, effort and development
 - c. Maintaining excellence
 - i. Attention to clinical performance
 - ii. Scrutiny of service delivery model
 - iii. Cost of training
18. We have optimism for the future
19. Thank you
20. Comments
- a. Some clinicians do not feel the need for ECMO, Advisory Committee please address the importance and value of the program
 - i. Administration is supportive
 - ii. Professional community has concern because of the length of time that it took to get started
 - iii. Adaptation occurred without ECMO
 - iv. Clinicians are not aware or just accepted that patients were dying
 - b. 2 page letter from the Board – possibly Dr. Devn Cornish
 - i. Add some cost data
 - ii. Impact of patients

iii. ECMO survivor day – media coverage

Appendix D.3

Advisory Committee Annual Meeting 2009

Anticoagulation Strategies

Anticoagulation Strategies for Pediatric Patients on ECMO

Erin L. Wacker^{1,2,3}, Timothy M. Maul, PhD^{1,2,3}, Peter D. Wearden, MD, PhD^{1,3}

Departments of Cardiac Surgery, Children's Hospital of UPMC¹, Bioengineering, University of Pittsburgh², and the McGowan Institute for Regenerative Medicine³, Pittsburgh, Pennsylvania, USA

Introduction

- Currently utilized anticoagulation tests may fail to provide an accurate measure of the degree anticoagulation and platelet inhibition in pediatric patients.
- This prospective study aims to determine if alternative tests demonstrate a more accurate correlation to the observed outcomes of bleeding and embolization

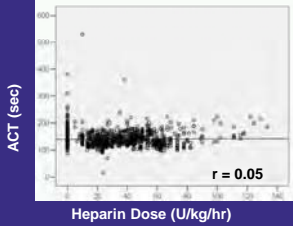
Introduction

- ACT is the most widely used standard to test for adequate anticoagulation
 - Has been shown to have weak to excellent correlations ($p=0.38-0.98$), particularly at high heparin doses^{1,2,3}
 - appears to be no correlation with plasma heparin levels for when <225 seconds⁴

1. Chan, AK. Coagulation and Fibrinolytic Profile of Pediatric Patients Undergoing Cardiopulmonary Bypass. *Thromb Haemostasis* 77: 270-7, 1997
 2. Smythe, MA. Correlation between Activated Clotting Time and Activated partial Thromboplastin Times. *Ann Pharmacother* 36: 7-11, 2002
 3. Baird CW. Anticoagulation and Pediatric Extracorporeal Membrane Oxygenation: Impact of Activated Clotting Time and Heparin Dose on Survival. *Ann Thorac Surg* 63: 912-9. discussion 919-20, 2007
 4. Orlinove V. Heparin Use in Pediatric Bypass—Empirical Regimen (ACT) vs. Heparin Concentration: A Multicenter Trial. 32: 84-88, 2000

Introduction

- A recent pilot study completed on our ECMO population confirms the lack of correlation to heparin dose



Maul, T, Wacker, E, Kelly, K, Morell, V, Wearden, P. Coagulation Times and Heparin Management for Pediatric Patients Requiring ECMO Support. Mechanical Circulatory Support Conference, 2008.

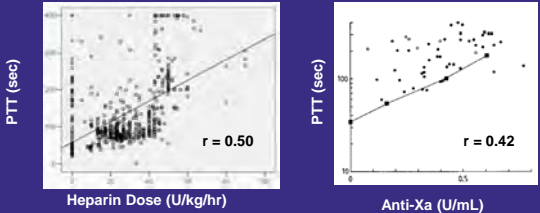
Introduction

- PTT can be used as an alternative or complimentary indicator to ACTs
 - Consistently good linear correlation to plasma levels ($r=0.76$), with heparin levels up to 2.0 units/ml¹
 - Excellent correlation between the bedside PTT and lab PTT ($r=0.89$), while the ACT did not correlate well with either the laboratory ($r=0.63$) or bedside PTT ($r=0.68$)²

1. Chan, AK. Coagulation and Fibrinolytic Profile of Pediatric Patients Undergoing Cardiopulmonary Bypass. *Thromb Haemostasis* 77: 270-7, 1997
 2. Reiner, JS. Bedside Monitoring of Heparin Therapy: Comparison of Activated Clotting Time to Activated Partial Thromboplastin Time. *Cathet Cardiovasc Diagn* 32: 49-52

Introduction

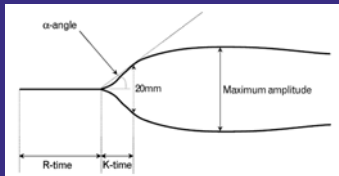
- The pilot study on our ECMO patients also confirms this (left) as well as other studies between PTT and the Anti-Xa assay (right)



RIGHT: Van den Besselaar, *Clinical Chemistry* 43: 1215-1222, 1997
 LEFT: Maul, T, Wacker, E, Kelly, K, Morell, V, Wearden, P. Coagulation Times and Heparin Management for Pediatric Patients Requiring ECMO Support. Mechanical Circulatory Support Conference, 2008.

Specific Aims

- To explore the correlation between TEG parameters, plasma heparin levels and platelet activation (determined by flow cytometry)

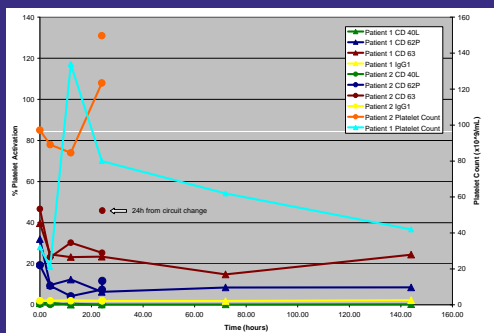


Methods

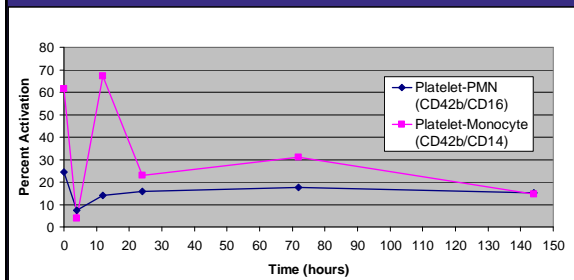
Time Points to Collect Blood: baseline, 4h, 12h, 24h, 72h, every third day

Collect	Room Temp / Ice	Test	Send to Lab (Yes/No)
1 light blue top (1.8 ml)	Room Temp	PTT/D-Dimer	Yes
1 light blue top (1.8 ml)	Room Temp	TEG	Yes
1 light blue top (1.8 ml)	Ice	AT III	Yes
1 light blue top (1.8 ml)	Ice	Anti-Xa	Yes
1 light blue top (1.8 ml)	Ice	FL.2, S100B	No
1 light blue top (1.8 ml)	Room Temp	Flow Cytometry	No
TOTAL			
6 light blue tops (10.8 ml)			

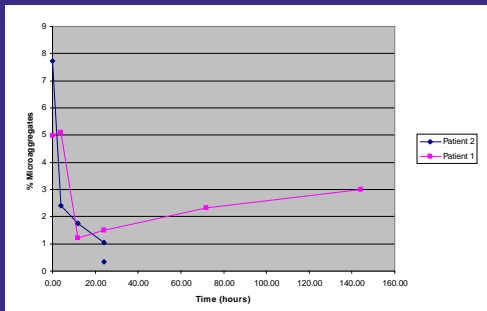
Preliminary Results: Platelet Activation



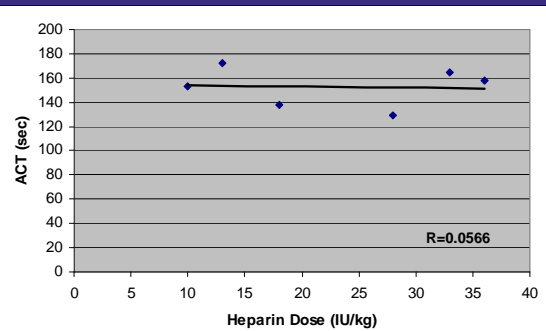
Preliminary Results: Platelet-Leukocyte Activation



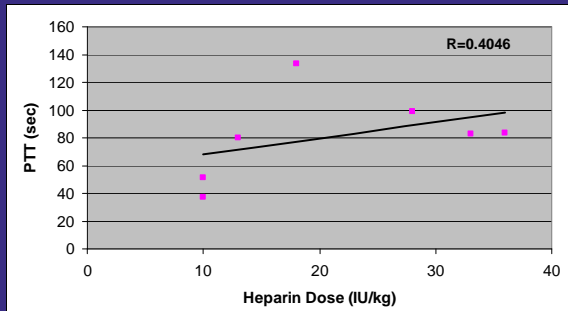
Preliminary Results: Microaggregates



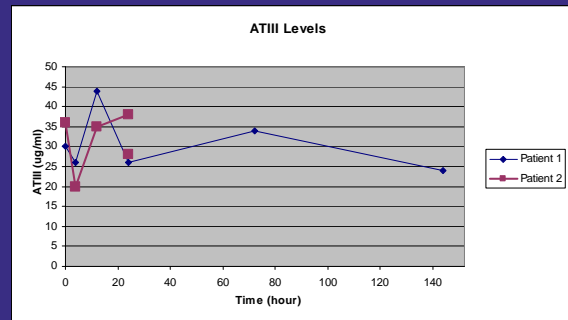
Preliminary Results: ACT



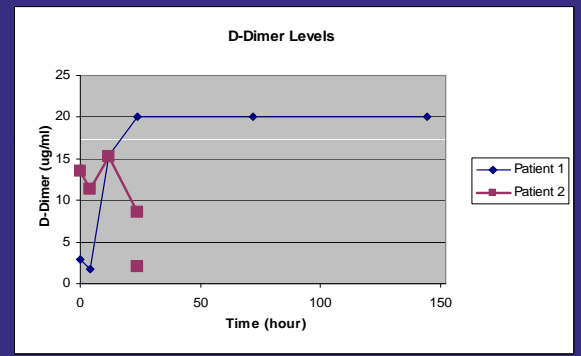
Preliminar Results: PTT



Preliminary Results: Antithrombin III



Preliminary Results: D-Dimer



Questions?

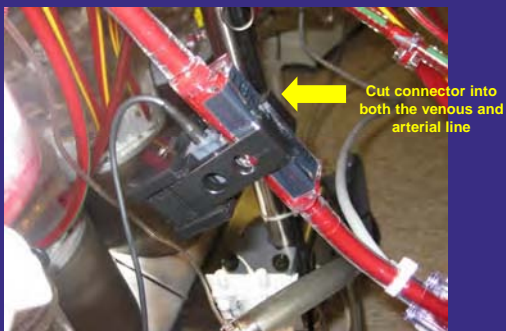
Emboli Detection and Characterization (EDAC)

Introduction

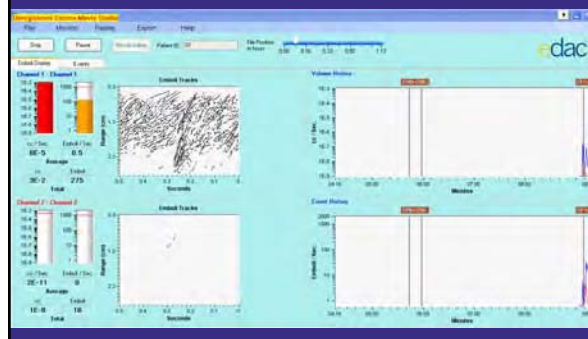
- Emboli Detection and Characterization (EDAC)
 - The EDAC system employs a series of broadband ultrasound pulses with a center frequency of 4 MHz to detect and track microemboli in CPB circuits
 - EDAC differs from narrowband ultrasound systems (ie: Doppler) which can not provide the necessary resolution to differentiate *one bubble* from *many bubbles*



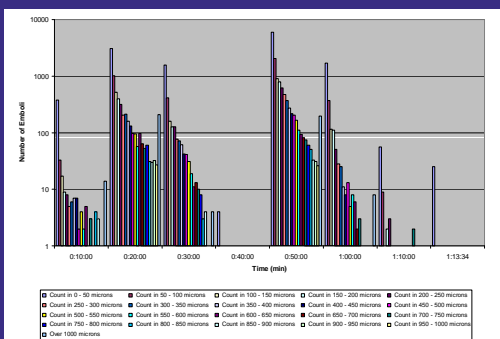
Setup



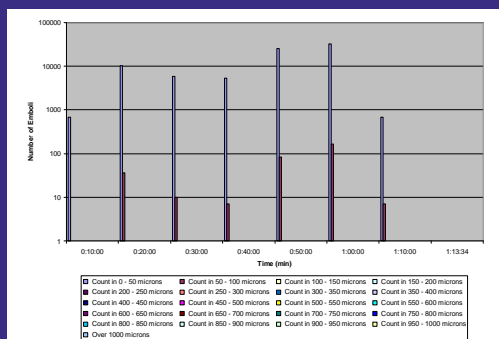
Results: CPB OR Case



EDAC Analysis - Venous



EDAC Analysis - Arterial



Appendix D.4

Advisory Committee Annual Meeting 2009

Coagulation Times and Heparin Dosing

Children's Hospital of Pittsburgh | UPMC

University of Pittsburgh School of Medicine
Bio Engineering

Correlations and Linear Regressions for Coagulation Times and Heparin Dosing

Timothy M. Maul, PhD,
Erin L. Wacker, BS, Kent, Kelly, CCP,
Victor O. Morell, MD, Peter D. Wearden, MD, PhD

Background and Purpose

- Extracorporeal membrane oxygenator (ECMO) support for pediatric cardiac surgery patients both pre- and post-operatively has provided adequate survival for congenital defects.
- Co-morbidities, including bleeding and thrombo-embolism, remain significant clinical challenges.
 - Traditionally, heparin management has been monitored with activated clotting times (ACTs).
 - For low clotting times, partial thromboplastin times (PTTs) may be more accurate.
- The purpose of this study was to analyze the relationships between heparin dosing for 23 pediatric patients on ECMO and point of care (POC) ACT and PTT values, as well as laboratory PTT values.

Methods

- POC ACTs and PTTs (Hemochron Jr.), laboratory PTTs and heparin dosing were recorded for 23 pediatric patients during ECMO support.
 - The ECMO circuit for all patients consisted of 8 feet of either 3/8" or 1/4" diameter Carmeda™ coated tubing and hollow fiber oxygenator (Medtronic).
 - Each 1/4" circuit was primed with 700mL PlasmaLyte containing 1 unit of packed RBCs, 30mL Tham and 10mL NaHCO₃ (volumes doubled for 3/8" circuits).

Methods

- Values for the first four hours of support were eliminated because they were artificially elevated from pre-operative heparin administration.
 - Also eliminated data points where circuit was changed (+2 hrs)
- Spearman's ranked correlations were performed for each coagulation test compared to heparin dosage.
- A Bland-Altman analysis was used to plot the differences between POC PTT and Laboratory PTT vs. the average between the two
 - The percentage of values that lay two standard deviations outside of these differences can indicate how well two measurements agree with each other, despite high correlation statistics

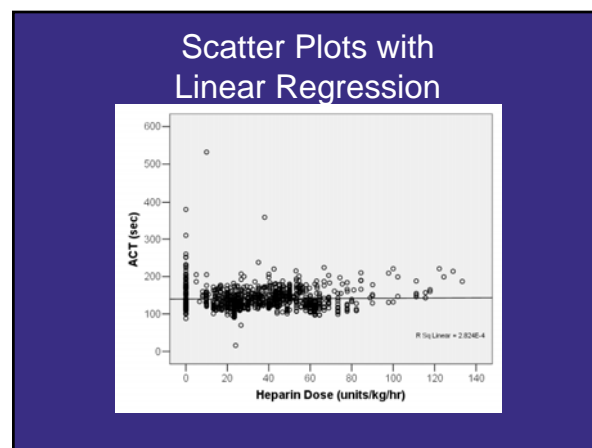
Patient Population

	Age (yr)	Wt (kg)	Run (Hrs)	ACT (sec)	PTT (sec)	Heparin (U/kg/hr)
Avg	2.9	10.8	183.2	172.9	112.8	27.5
SDEV	1.3	3.5	47.2	16.1	13.0	5.7
Count	23					

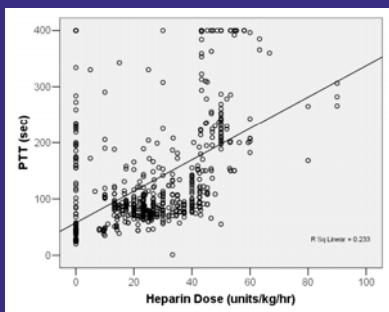
Correlation to Heparin Dose

	ACT	PTT	Lab PTT
Correlation Coefficient	0.05	0.50**	0.44**
Total samples	993	608	700

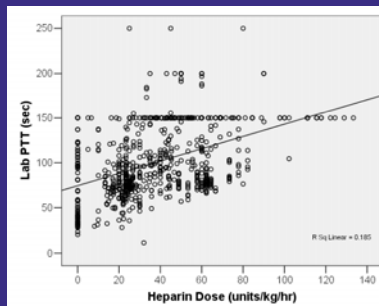
**p<0.01
Low correlation: 0-0.2
Moderate correlation: 0.4-0.8
High correlation: 0.8-1.0



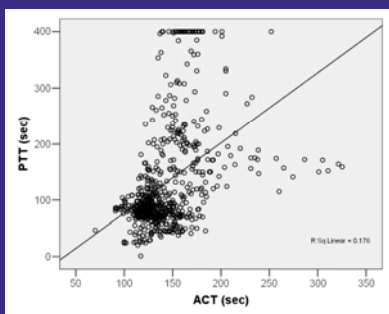
Scatter Plots with Linear Regression



Scatter Plots with Linear Regression



Scatter Plots with Linear Regression



Separating Populations: Cardiac vs. Respiratory Failure

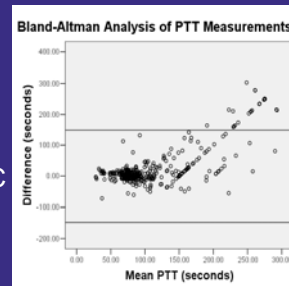
	Cardiac (n=9)	Non-Cardiac (n=14)
Age (yrs)	4 ± 7.7	2.2 ± 5.0
Weight (kg)	14.5 ± 23.5	8.5 ± 10.5
Time (hrs)	65.9 ± 38.4*	258.6 ± 265.1*
ACT (sec)	150 ± 40.4	148.1 ± 56.0
PTT (sec)	67.3 ± 42.7*	145.4 ± 99.2*
Lab PTT (sec)	94.4 ± 48.8*	104 ± 38.7*
Platelets	114.9 ± 52	112 ± 34.3
Fibrinogen	228.2 ± 39.9	171.1 ± 109
Heparin Dose (U/kg/hr)	21.4 ± 20.8*	36.7 ± 23.4*

Spearman's Correlations

	Cardiac Patients (n=9)			Non-Cardiac Patients (n=14)		
	ACT (sec)	PTT (sec)	Lab PTT (sec)	ACT (sec)	PTT (sec)	Lab PTT (sec)
Correlation Coefficient	0.53**	0.81**	0.70**	0.02	0.38**	0.35**
Total Samples	147	97	99	852	515	606

Bland-Altman Analysis

- Less than 10% of samples are 2 std dev from the average difference between the laboratory and POC systems.
- Drops to less than 1% if PTT is below 150 seconds



Appendix D.5

Advisory Committee Annual Meeting 2009

Pediatric Care Curriculum

Pediatric Critical Care Curriculum for Austere Environments

Anne Naclerio, MD, MPH, LTC USA MC
Melinda F. Hamilton, MD, MSc



Pediatric Critical Care Curriculum for Austere Environments

- **Target Audience:** Military personnel with varied medical backgrounds
- **Educational Goal:** To provide an online resource to assist in the care of critically ill pediatric patients in austere environments
- **Curriculum:**
 - Ten online modules written by leaders in the fields of pediatric critical care medicine, surgery, and pharmacy
 - Educational Reference slides with hyperlinks for quick access to formulas, guidelines, calculations

Introduction Page



PEDIATRIC CRITICAL CARE CURRICULUM FOR AUSTRERE ENVIRONMENTS (PICC/AUSTERE)

REGISTER FOR A CLASS

Upcoming Class Dates: None scheduled at this time.

Instructors: Pediatric Instructors, Anne Naclerio

Small Course Directors:

Author(s): Anne Naclerio, MD, MPH, LTC USA MC, Anne F. Hamilton, MD, MSc, James H. Hamilton, MD, MPH, LTC USA MC, Robert Clark, MD, PhD, Robert Clark, MD, PhD, Stephen Vanhook-Wagner, MD, Carol Kohnen, PhD, MD

Administrator: John Lutz

Small Course Administrator:

Description: This course provides an online, accessible web-based platform to improve the care of pediatric casualties in austere environments. Designed for the medical personnel without specialty training in the care of critically ill children. It includes:

- 10 educational reference slides
- Pediatric modules for more than 2000
- Traumatic Brain Injury
- Basic Pediatric Considerations
- Burns
- Pediatric Neurotrauma
- Drug dosing in Pediatrics
- Pediatric Trauma
- Septic Shock
- Mechanical Ventilation
- Weaning and Extubation in Children
- Organ Injury/Compartment Syndrome (in development)
- Pain, Sedation and Neuromuscular Blockade (in development)
- Small Patient (in development)
- Recognition of need for Pediatric ECMO (in development)
- Fluids, Electrolytes and Nutrition (in development)
- Hyperkalemia reference tool
- Case base scenarios (in development)
- Simulation training (in development)

Participant Material



Pediatric Critical Care Curriculum for Austere Environments

Select a module: **Course Overview**

COURSE OVERVIEW

Course Description: This course provides an online, accessible web-based platform to improve the care of pediatric casualties in austere environments. Designed for the medical personnel without specialty training in the care of critically ill children. It includes:

- 10 educational reference slides
- Pediatric modules for more than 2000
- Traumatic Brain Injury
- Basic Pediatric Considerations
- Burns
- Pediatric Neurotrauma
- Drug dosing in Pediatrics
- Pediatric Trauma
- Septic Shock
- Mechanical Ventilation
- Weaning and Extubation in Children
- Organ Injury/Compartment Syndrome (in development)
- Pain, Sedation and Neuromuscular Blockade (in development)
- Small Patient (in development)
- Recognition of need for Pediatric ECMO (in development)
- Fluids, Electrolytes and Nutrition (in development)
- Hyperkalemia reference tool
- Case base scenarios (in development)
- Simulation training (in development)

Course Authors:

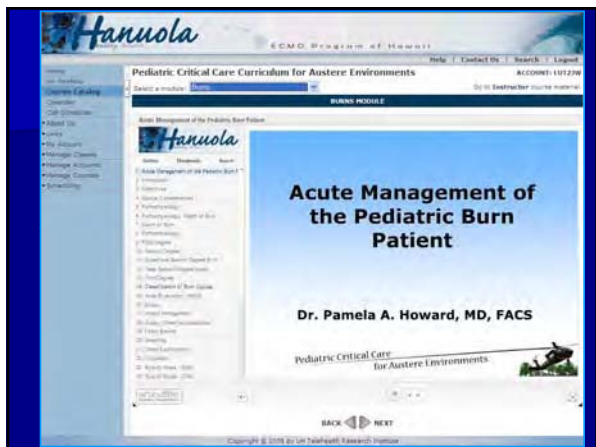
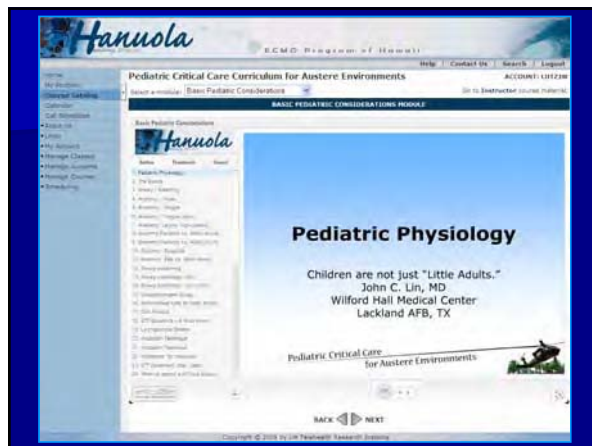
- Patrick Healey, MD, FAED
- Hans Edwards, MD
- JEDI Lutz, MD
- James H. Hamilton, MD, MPH
- Robert Clark, MD
- Kim Palmer, MD
- Robert Clark, MD
- Stephen Vanhook-Wagner, MD
- Carol Kohnen, PhD, MD

Course Co-Editors:

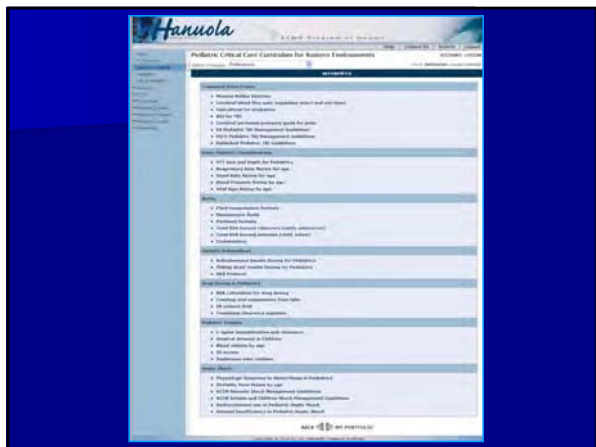
- Anne L. Naclerio, MD, MPH, LTC USA MC
- LTC USA MC, Chief, Pediatric Critical Care Medicine, Tripler Army Medical Center, Assistant Professor of Pediatric, Uniformed Services University of the Health Sciences, Director of FICM Tripler, National ECMO Program of Walter
- Pamela F. Hamilton, MD, MSc, Assistant Professor of Critical Care Medicine and Pediatrics, Department of Critical Care Medicine, University of Pittsburgh Medical Center, Director, Pediatric Simulation
- Tracy M. Brown, Pediatric for Simulation, Education and Research (PERSE) and Children's Hospital of Pittsburgh Simulation Center

Copyright © 2008 by US TeleHealth Research Institute

Example Modules



Hyperlinks



ETT placement: size / depth

Age	Age	ETT (Depth) (cm)
Newborn	3.5	3.5 (9)
3 mos	6.0	3.5 (10)
1 yr	10	4.0 (11)
2 yrs	12	4.5 (12)
Age > 2 yrs:	ETT size: 4 + age/4	ETT depth: 12 + age/2

Suction catheter French size = 2 x ETT size.

... Gets you to here ...

... and gives you choices as to where you go next ...

BACK TO REFERENCES CONTINUE TO BASIC PEDIATRIC CONSIDERATIONS MODULE

CHILD "RULE OF NINES"

AGE 1-9 YEARS AGE 9-14 YEARS AGE 10-14 YEARS

Courtesy of ASA

BACK TO REFERENCES CONTINUE TO DRUG DOSING MODULE

TRAUMATIC BRAIN INJURY - INTRACRANIAL VOLUME AND COMPLIANCE

80% 10%

Pressure (mmHg)

Δ Volume

$V_{intracranial} = V_{brain} + V_{blood} + V_{CSF} + V_{other}$

"Monroe-Kelley Doctrine" = Intracranial fixed

BACK TO REFERENCES CONTINUE TO TRAUMATIC BRAIN INJURY MODULE

SHOCK - NORMAL RESPONSE TO LOW CVP IN A PEDIATRIC PATIENT

% of Control

Heart rate

Vascular Resistance

Blood Pressure

Cardiac Output

25% 50%

% Plasma Loss

BACK TO REFERENCES CONTINUE TO SHOCK MODULE

SHOCK - NORMAL RESPONSE TO LOW CVP IN A PEDIATRIC PATIENT

% of Control

Heart rate

Vascular Resistance

Blood Pressure

Cardiac Output

25% 50%

% Plasma Loss

BACK TO REFERENCES CONTINUE TO SHOCK MODULE

Future...

- Completion of modules
- Case based scenarios to complement relevant modules
- Simulation scenarios to complement relevant modules
- End user evaluations will allow us to revise current curriculum

Assessment and Intervention for Pediatric Patients in Emergency Situations



Study Design

- Pre-test (MCQ)
- Online Powerpoint Module
- Participate in 3 of 5 scenarios with expert facilitators
 - Pediatric resuscitation skills tested via checklist
 - Recognition, assessment and treatment
- Post-test (MCQ)

Simulation Scenarios

- 5 pediatric simulation scenarios
 - Traumatic brain injury
 - Abdominal trauma
 - Burn injury
 - Blast/IED injury
 - Motor vehicle injury

Skills Checklist

- | | |
|---|---|
| <ul style="list-style-type: none"> ■ Airway and Breathing <ul style="list-style-type: none"> – Apply C-spine stabilization – Chin lift/jaw thrust – Apply hi-flow oxygen – BVM at 20-35 breaths per minute – Reassess airway | <ul style="list-style-type: none"> ■ Circulation <ul style="list-style-type: none"> – Assess femoral or brachial pulse – Ask for blood pressure – IO placed – Administer 100 cc resuscitation fluid IO push – Reassess circulation |
|---|---|

Skills Checklist

- | | |
|--|--|
| <ul style="list-style-type: none"> ■ Intubation <ul style="list-style-type: none"> – Choose 3.5 cuffed or uncuffed ETT – Choose Miller 1 or 2 blade – Choose appropriate stylet – Intubate airway – Use c-spine precautions during intubation – Verbalize need for RSI with tight-head precautions | <ul style="list-style-type: none"> ■ Disability and Exposure <ul style="list-style-type: none"> – Roll patient with C-spine precautions – Assess temperature – Identify source of ongoing blood loss (will vary scenario to scenario) – Identify correct treatment of ongoing blood loss (will vary scenario to scenario) – Reassess disability and/or exposure |
|--|--|

Facilitator Debriefing Points

- Temperature control (avoid hyper or severe hypothermia)
- Avoid hypotension
- Avoid hyper or hypoglycemia
- Avoid hypoxia
- Treat coagulopathy
- Appropriate sedation and analgesia
- Brain injury protective strategies
- Continued reassessment after interventions

Scenario Example

- Traumatic Brain Injury
 - A 3-month old infant is brought into triage after a bomb exploded in a local restaurant. The infant was thrown approximately 10 feet and cried initially but is now unresponsive and flaccid. He has blood coming from his left ear. The patient has been put on a cardiorespiratory monitor and pulse oximetry

Facilitator Information

- **Verbal information given to trainee if asked:**
 - Infant weight is 5 kg
 - No significant past medical history
 - Infant is flaccid
 - Infant is unresponsive to deep pain
 - Infant is non-verbal
 - Infant pupils are non reactive
 - Infant capillary refill is 5 seconds
 - Infant is cool with mottled extremities
 - Infant hematocrit is 18
 - Infant CBG give you pH of 7.10 and base deficit of -12
- **Facilitator information to give to trainee:**
 - When asked, infant has hematoma, abrasions to right posterior occiput

Assessment and Intervention for Pediatric Patients in Emergency Situations

- Pilot scenarios performed
- Study to occur soon...

Acknowledgements

- WISER
 - John Lutz
 - Aimee Smith
 - Max Leake
- Hawaii
 - Larry Burgess
 - Kris Hara
 - Mark Ogino
 - Many others...

Appendix D.6
Advisory Committee Meeting Minutes
16 June 2009



Advisory Board Quarterly Teleconference

June 16, 2009

Meeting Minutes

1

Roll Call

- Leslie Anthony
- Lawrence Burgess
- Kathleen Kihmm Connolly
- Devin Cornish, MD
- Kris Costales, CCP
- Melinda Fiedor Hamilton MD
- Bob Hardie
- William E. Harris, CCP LP
- Micheal Heard, RN
- Melody Kilcommons
- John Lutz
- John Lin, MD
- Pete May, CCP
- Donald McCurnin, MD
- Melissa McNeil, MD
- Willow Morton
- Anne Naclerio, MD
- Charles Neal, MD
- Mark Ogino, MD
- Denise Suttner, MD
- Len Tanaka, MD
- COL Mark Thompson, MD
- Jamie Harrington, MD
- Omar Chikovani, MD
- Laura Bonilla
- Mavis Nikaido

Meeting Minutes 1. Add Melissa Tyree to invite list for future meetings

2

Agenda

- Training Update - Kris
- Transport Update - Kris
- Hanuola 2010 and Beyond – Willow
- Clinical Case Review
 - Septic Shock
 - Pertussis Pneumonia
 - Coagulation Challenges

Meeting Minutes

3

Hanuola ECMO Training Course

- Didactic training at KMCWC May 27-28, 2009
 - One 8 hour classroom day
 - All lectures given by Hanuola personnel
- Vivarium Lab at Tripler
 - 2 groups of 6-7 participants
 - 2 three hour sessions
 - Hands-on practical session with didactic review, emergency procedures

Meeting Minutes

4

Hanuola ECMO Training Course

- 14 Clinical support staff
 - 1 NICU RN
 - 7 PICU RN
 - 2 RT
 - 1 Transport RT
 - 2 Transport RN
 - 1 PICU Physician
- 11 Continuing education credits

Meeting Minutes

5

Hanuola ECMO Training Course

- Course Revisions
 - Lectures condensed and revised
 - Training manual condensed – handouts, reference
 - Lectures handled "in house"
 - Lectures tailored to Hanuola program – specific to bedside clinician
 - Lectures updated based on clinical site visits
 - Lab participants partnered to increase class size
 - Exit test required of all participants

Meeting Minutes

6

Hanuola ECLS Transport

- Elliott Aviation May 14-15, 2009 workshop
- FAA Certification Process Review
 - STC required for platform only
 - Equipment treated as carry on baggage
 - Elliott to present overview of project to FAA
 - Design and engineering data submission to FAA
 - Last step = final design submission, no changes

Meeting Minutes

7

Hanuola ECLS Transport

- ECMO Transport Platform Review
 - Initial certification for Hawker 800, King Air C90, Learjet 36
 - ETS weight estimate = 225 lbs.
 - Initial certification for patients up to 75 lbs
 - Final patient target weight = 250 lbs
 - Compartmentalized for space and weight
 - Review of each compartment

Meeting Minutes

8

Hanuola ECLS Transport



Meeting Minutes

9

Hanuola ECLS Transport



Meeting Minutes

10

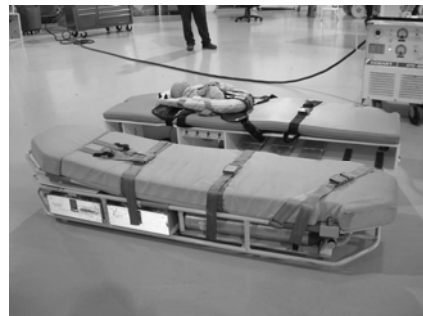
Hanuola ECLS Transport



Meeting Minutes

11

Hanuola ECLS Transport



Meeting Minutes

12

Hanuola ECLS Transport



Meeting Minutes

13

Hanuola ECLS Transport

- Final workshop scheduled for August 2009
 - Review changes made in May
 - Electrical and Gas test
 - Circuit and emergency procedure test
 - Battery test
 - Shipping container issues
 - Structural report

1. FAA requirements for vibration and EMR testing for the transport unit raised
 - will follow up with AirMed engineers on this issue
2. Battery life is shortened by altitude. Recommended air testing and establishing battery power requirements for essential equipment in flight
 - follow up with AirMed engineers and discuss need for in flight air test of batteries

Meeting Minutes

14

Hanuola ECLS Transport



Meeting Minutes

15

ECMO 2010 and Beyond

Meeting Minutes

16



KAPIOLANI
MEDICAL CENTER
FOR WOMEN & CHILDREN



An affiliate of Hawaii Pacific Health

100 YEARS of CARING for CHILDREN

Meeting Minutes

17

Sustainability planning

- Grant covers non reimbursable, non patient care expenses
- Financial planning:
 - Continuous financial monitoring for clinical care
 - Regular communication with our payers
 - Redeploy patient care fund toward program development
- Regular administrative meetings

Meeting Minutes

18

Ongoing Program Planning

- Restructured training approach for RNs and RTs for sustainability
- Increased funding for physician training at other ECMO centers
- Complete the ETS design
- Proposals submitted for sled purchase

1. Proposal for ECMO Transport Sled purchase (construction and equipment) submitted to government agency via TAMC. Funds for construction and equipment not included in original grant proposal.

Meeting Minutes

19

Hospital Budgeting

- Clinical care covered via reimbursement
- Built in administrative infrastructure and expenses (medical director, clinical coordinator, ELSO membership, etc.)
- Staff training dollars
- Biomedical preventive maintenance

Meeting Minutes

20

Ongoing Planning Contracting and Collaboration

- Kaiser—medical director and coverage
- Tripler—CRADA in place; animal labs; administrative leadership in ECMO transport program
- Biotronics—working on perfusion services contract
- Hawaii ECMO physicians group: Tripler, Kaiser and Kapiolani physicians

Meeting Minutes

1. Laura Bonilla is assuming responsibility for contracting

21

Challenges Ahead

- Maintaining communication with all the players
- ECMO physician manpower pool
- Development of transport system
- Maintaining Excellence
 - Continuous attention to clinical performance
 - Continuous scrutiny of service delivery model
 - High cost of training

Meeting Minutes

1. Advisory Board's contributions to Hanuola were acknowledged
2. Future of Advisory Board meetings discussed. Quarterly teleconferences will continue. Future of annual meeting is still being discussed.

22

Mahalo!

Research Updates

1. Assessment and Intervention for Pediatric Patients in Emergency Situations.
Recruited 17 participants. Nine participants have completed the study
Ongoing recruitment at Kapiolani and Tripler is being conducted
2. ECMO Simulator (ECMOjo)
FI Detrick and UH Exempt IRB approval obtained
Validation study sites have been recruited and IRB approvals are pending
Radiograph image library loaded
Programming continues
Ready for heuristic evaluation

Meeting Minutes

23

April to June 2009

- NICU – None
- PICU – Two cases
 - 15 mos – septic shock
 - 1 mos – pneumonia, pertussis

Meeting Minutes

24

Eric SHL

- 15 mos old
- Previously healthy with h/o a week of cold symptoms
- ER
 - Hypotensive, v-fib
- PICU
 - Hypotension (epi 0.5, norepi 1, milrinone 1)
 - Lidocaine
 - Two cardiac arrests
 - Lactate 14.3 to 18.89

Meeting Minutes

25

Eric SHL

- VA+V cannulation
 - Cardiac stun
 - CVVHDH
- Day 4
 - Milrinone only. Good EF
 - Left lung atelectasis – bronchoscope to remove secretions. Improved aeration
 - Decannulated
- Post ECMO
 - Temporary PD
- Discharged home ~ 1 month after decannulation

Meeting Minutes

1. Patient developed large hematoma at an attempted femoral catheter insertion site. Expanded in size. Concern for compartment syndrome. Lead to bronchoscopy to reexpand lungs and decannulation.
2. Team congratulated on successful run.

26

AJ: Presentation

- 4 week old
- 10 kg
- Presented to ER
 - 3 wk history of cough
 - “coughing fits” with color change
 - apneic on day of admission

Meeting Minutes

27

AJ: Presentation

- PICU
 - Pertussis immunofluorescence - negative
 - CMV to HFOV
 - Acute deterioration CO₂ 171
 - CXR “white out”

Meeting Minutes

28

AJ: ECMO Course

- VV ECMO cannulation
- Bronchoscopy for secretion removal every day to every other day.
- Day 5
 - VV+V to VA+V conversion (circuit changed)
 - CVVHD initiated for fluid removal (normal renal function)
- CVVHD filters changed daily (day 6-10)
- Day 13
 - CVVH Circuit Change

Meeting Minutes

29

AJ: ECMO Course

- Day 14
 - ECMO circuit change
 - CVVHD stopped
- Day 16
 - Hemofiltration started
- Day 18
 - Bleeding from arterial line
 - Amicar started

Meeting Minutes

30

AJ: ECMO Course

- Day 19
 - Seizures
 - Head ultrasound – *left* temporal hemorrhage
 - Review of day 15 head ultrasound revealed bleeding
 - Decannulated

POST ECMO Update

1. VasCath placed and CVVHD continued
2. SVC clot created SVC syndrome. Bedside angioplasty performed to remove clot
3. CVVHD stopped and PD initiated
4. Follow-up Head US. No extension of hemorrhage
5. Continues on HFOV and PD
6. Future of Advisory Board meetings discussed. Quarterly teleconferences

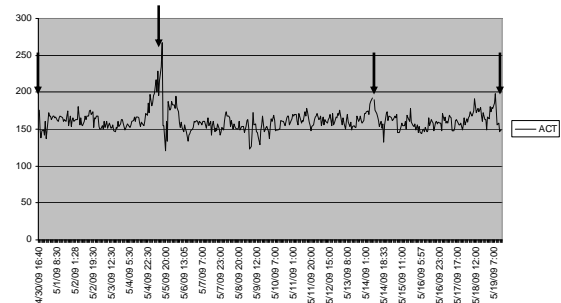
COMMENTS

1. Extremely difficult case due to underlying disease process
2. Poor prognosis. See ELSO data
3. ECMO survivors frequently have CNS morbidity (strokes) due to high white counts
4. Number of circuit changes typical for length of run
5. Coagulopathy expected for length of run and due to sepsis
6. Multiple centers collecting anticoagulation data. Await analysis of data.

Meeting Minutes

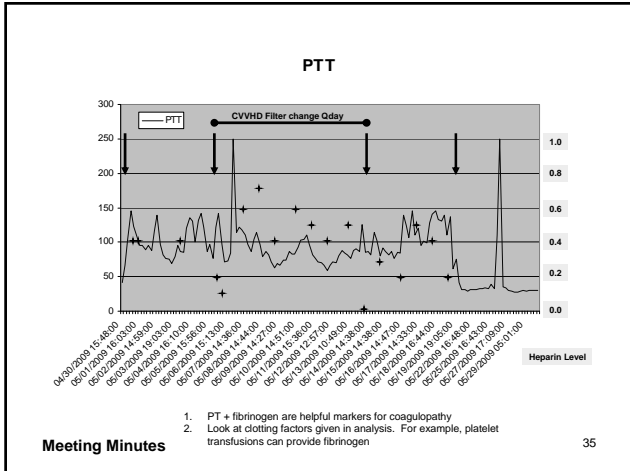
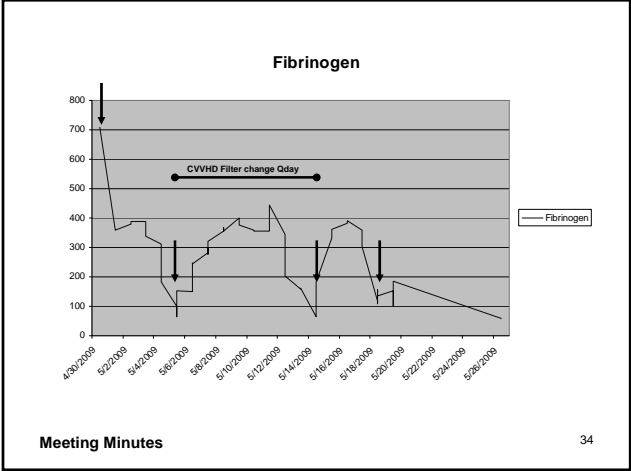
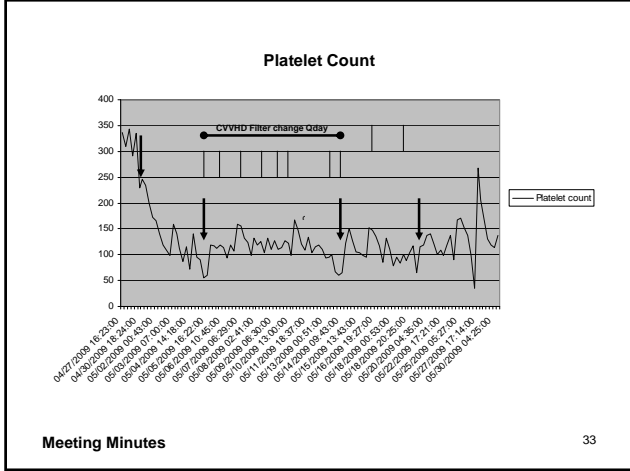
31

ACT



Meeting Minutes

32



ELSO Experience Pertussis

2000 to 2008

Meeting Minutes 36

Overall Experience

2000 to 2008

- 85 cases
 - Age (mean) = 34 days
 - Weight (mean) = 3.74 kg
- ECMO Mode
 - VA 79%
 - VV 7%
 - VV to VA 14%

Meeting Minutes

37

Overall Experience

2000 to 2008

- Indication for ECMO
 - Pulmonary 96%
 - Cardiac 3%
 - ECPR 1%
- Survival = 24%

Meeting Minutes

38

Non-survivors

2000-2008

- 65 out of 85 in registry = 76%
- Age (mean) = 32 days
- Weight (mean) = 3.58 kg
- Indications for ECMO
 - Pulmonary 95%
 - Cardiac 3%
 - ECPR 2%
- ECMO hours (mean) = 318 (13.3 days)
 - Range 8 to 1126 hrs (0.3 to 47 days)

Meeting Minutes

39

Survivors

2000-2008

- 21 out of 85 in registry = 24%
- Age (mean) = 39 days
- Weight (mean) = 4.04 kg

Meeting Minutes

40

Survivors

2000-2008

- Indications for ECMO
 - Pulmonary 95%
 - Cardiac 5%
- Mode
 - VA 90%
 - VV 5%
 - VV to VA 5%
- ECMO hours (mean) = 365 (15.2 days)
 - Range 72 to 829 hrs (3 to 35 days)

Meeting Minutes

41

VV to VA Subset

2000-2008

- 12 patients (14% of registry)
- Age (mean) = 34 days
- Weight (mean) = 3.94 kg
- ECMO hours (mean) = 360 (15 days)
- Survival
 - 1 out of 12 = 8.3%

Meeting Minutes

42

Appendix D.7
Advisory Committee Meeting Minutes
23 October 2009

Hanuola Advisory Board Teleconference

October 23rd, 2008, 10:00-1100AM HT

<i>Attended</i>	
Advisory Committee	PIs and Staff
Devn Cornish, MD Micheal Heard, RN Denise Suttner, MD Bill Harris, CCP John Lin, MD Melissa McNeil, MD - absent	Mindy Fiedor Hamilton, MD Willow Morton Mark Ogino, MD Kris Costales, CCP Melody Kilcommons, RN Ralph Caputo Leslie Anthony

1. Notes are supplement to attached slides
2. Clinical Program
 - a. Neonatal Patients – 4 consults
 - b. Pediatric Patients – 2 consults
 - c. ECMO Patient – 1 pediatric patient
 - i. Transport to Rady Children’s Hospital by Wilford Hall ECMO Team
 - ii. Surgical revision of BT shunt and decannulation
 - iii. Discharged home
3. ECMO Training Course – October 13– 17, 2008
 - a. 22 participants
 - i. Similar Format
 - ii. Several lectures modified based on center site visits experience
 - iii. Diverse group-RT to experienced Neonatologists
 - iv. Evaluation feedback positive from all participants
 - b. Animal Lab – No negative comments regarding animal use at lab
 - i. Might be related to addition of "Introduction to Vivarium Lab” Lecture
4. ECMO Training Site Visits and Collaboration
 - a. Wilford Hall Medical Center
 - i. Positive site visit with educational exchange of information
 - ii. Primary Highlight - Animal lab
 1. Protocols very beneficial
 - b. Nationwide Children’s Hospital
 - i. Primary Focus on New Training Program
 - ii. Vivarium lab
 - c. Arkansas Children’s Hospital
 - i. Primary Highlight - Simulation Lab
 - ii. Excellent experience with take home points for Hanuola Simulation lab
 - iii. Extensive information for transport project

5. Hanuola ECMO Transport
 - a. Travel to AirMed International, Birmingham, Alabama
 - i. Equipment needs identified
 - ii. AirMed and Elliot Aviation experienced with FAA approval process
 - iii. Transport sled prototype design started
 - iv. Shipment and purchasing of equipment ongoing
 - v. Ongoing discussion with engineers
 - vi. EMR Testing - Pump tested to European Standards
 1. Follow up with FAA Approval with AirMed
 2. Flight test the unit
6. ECMO Simulation Project (ECMOjo)
 - a. Overview of completed features
 - i. VA or VV
 - ii. Pump choices: Roller or Centrifugal
 - iii. Oxygenator choices: Silicon or PMP
 - iv. Ventilator choices: CMV or HFOV
 - v. Clock for real time
 - vi. Alarms for auditory stimulus
 - vii. No carbogen for sweep gases
 - viii. Interventions with blood products, inotropic agent
 - ix. Imaging screens
 - x. Laboratory data screens
 - b. Tutorials
 - i. Basic tutorial concepts
 - ii. Possibly use ECLS .net to get further input
 - c. Scenarios
 - i. Ongoing accumulation of data
 - ii. Based on the 10 key concepts from the selected training centers visited
 - iii. ECLS.net for more community input
 - d. Simulator Update Next Challenges
 - i. Programming realistic physiological variables and relationship between them
 - ii. Virtual Baby
 - iii. Implementing alarm sounds
 - iv. Developing clinical scenarios

Comments positive from advisory group members and other meeting attendees. More information and hands on opportunity with the simulator will be available at January Advisory Meeting.

7. Research Projects
 - a. Advanced Pediatric Critical Care Curriculum
 - i. Should be ready for testing very soon
 - ii. Some examples of the 5 models possible situations
 1. blunt trauma
 2. hypovolemia
 3. shock
 - iii. Dr. Larry Burgess and Kathleen Kihmm-Connolly enrolling participants
8. Porcine Septic Shock Model
 - a. Kathy Uyehara not available

9. January 2009 Advisory Board Meeting agenda reviewed.

10. No further comments. Meeting Adjourned.

Hanuola Advisory Board Teleconference

October 23, 2008

Roll Call

- Lawrence Burgess
- Ralph Caputo
- Kathleen Kihmm Connolly
- Devin Cornish, MD
- Kris Costales, CCP
- Melinda Fiedor Hamilton MD
- William E. Harris, CCP LP
- Micheal Heard, RN
- Melody Kilcommons
- John Lutz
- John Lin, MD
- Pete May, CCP
- Melissa McNeil, MD
- Willow Morton
- Anne Naclerio, MD
- Charles Neal, MD
- Mark Ogino, MD
- Denise Suttner, MD
- Len Tanaka, MD
- COL Mark Thompson, MD

Clinical Program

July to September 2008

- Neonatal Patients - 4 consults
 - 40 wk, cardiogenic shock
 - qualified, improved
 - 37 wk, MAS/PPHN
 - qualified, improved
 - 40 wk, MAS/PPHN
 - Did not qualify
 - 35 wk, CDH
 - Did not qualify

Clinical Program

July to September 2008

- Pediatric Patients - 2 consults
 - 14 yo, fresh water drowning (unwitnessed)
 - Excluded
 - 5 yo, ARDS, cardiac arrest, Rotavirus, electrolyte imbalance, renal failure
 - Qualified, improved

Clinical Program

July to September 2008

- Neonatal Patient - 1 ECLS
 - 37 week infant with TOF, severe multilevel PS, PDA
 - BT shunt placed on DOL 2
 - Acute desaturations unresponsive to medical intervention on DOL 11
 - Placed on VA ECMO support
 - Transported to Rady Children's by Wilford Hall ECMO Team



Wilford Hall Medical Center San Antonio, TX

- Attendees:
 - Mark Ogino MD, Kris Costales CCP
- Purpose:
 - Observe and interact with a well established program
 - Review ECMO transport program
- Contacts
 - Melissa Tyree, MD
 - Cheryl Collicott, Coordinator



ECMO TRAINING COURSE October 2008



Course Overview

- Didactic Training at JABSOM
 - 3 Eight Hour Classroom Days
- Vivarium Lab at Tripler
 - Three Hour Sessions
 - Hands on Practical Training Focus – Emergency procedures
- Attendees
 - 12 Clinical Support Staff (Nurses, Respiratory Care)
 - Three MLP/Nurse Practitioners
 - One Neonatal Practitioner KMCWC
 - Two Neonatal Fellows
 - Two Surgical Residents TAMC
 - One AirMed Flight Nurse
 - One Perfusionist

ECMO Training Course Site Visits

- Children's National Medical Center
- Royal Children's Hospital
- Wilford Hall Medical Center
- Nationwide Children's (Columbus OH)
- Arkansas Children's
- Vancouver Children's
- Rady Children's San Diego

Wilford Hall Medical Center San Antonio, TX

- Attendees:
 - Mark Ogino MD, Kris Costales CCP
- Purpose:
 - Observe and interact with a well established program
 - Participate in an established training course and animal lab
 - Review ECMO transport program

Nationwide Children's Hospital Columbus, OH

- Attendees:
 - Mark Ogino MD, Len Tanaka, MD, Melody Kilcommons RN
- Purpose:
 - Observe and interact with a well established program
 - Attend lectures given by Dr Giles Peek
 - Participate in a new training course and animal lab

Arkansas Children's Hospital Little Rock, AK

- Attendees:
 - Mark Ogino MD, Sheree Kuo MD, Melody Kilcommons RN, Kris Costales CCP
- Purpose:
 - Observe and interact with a well established program
 - Participate in an established training course with a high fidelity ECMO simulator
 - Review ECMO transport program

Arkansas Children's Hospital Little Rock, AK



Arkansas Children's Hospital Little Rock, AK



Hanuola ECMO Transport

- Site visit to AirMed International 9/18/2008
- Review of facilities and capabilities
- Discussion of goals, design, equipment, power
- Elliott Aviation engineering on board

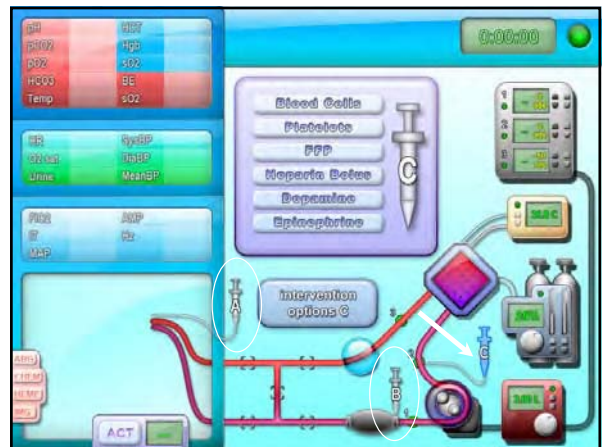
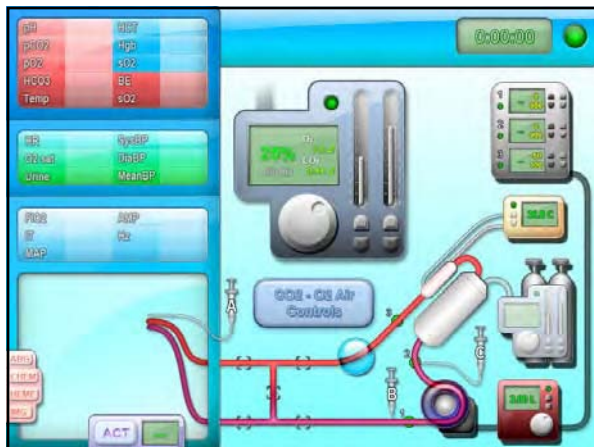
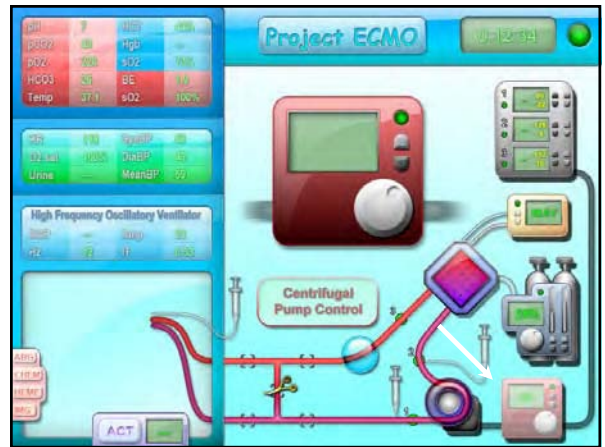
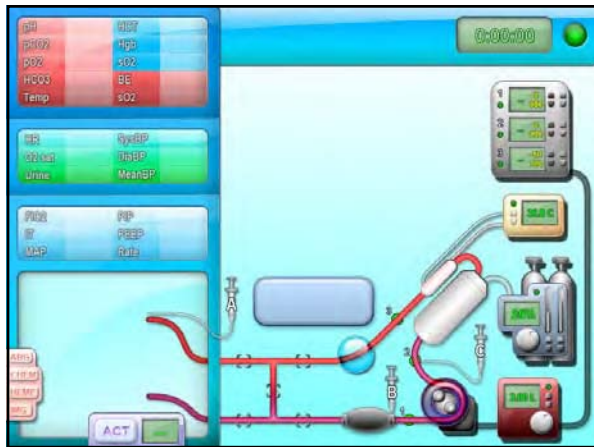
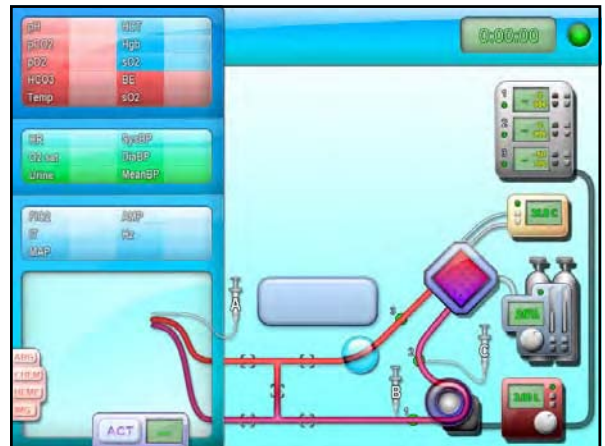
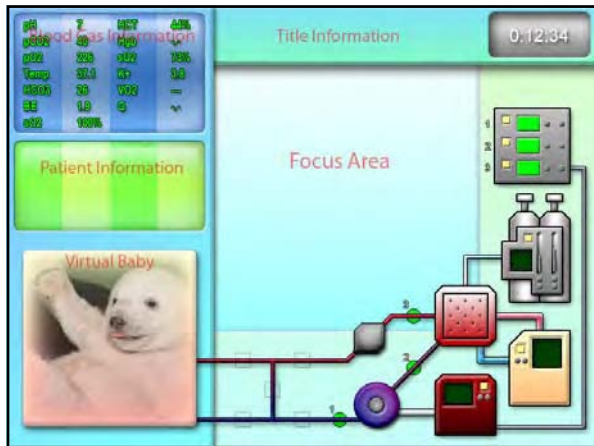
- Equipment sent for mock-up in mid October
- Begin engineering phase in November

First Mock-up pictures



ECMO Simulation Project

- Current project members
 - Dr Don McCurnin
 - Dr Mark Ogino
 - Dr Christoph Aschwanden
 - Kin Lik (Alex) Wang
 - Kaleiohu Lee (graphic artist)
- IRB approval





Tutorials

Non center specific concepts (10)

- ECMO equipment
- ECMO physiology
- Patient physiology
- Laboratory values
- Bedside care issues
- Dr Cornish's Unofficial Rules of ECMO aka "ECMOisms"
- Final selection of tutorials TBD based on ELSO community input



Scenarios

- Blood gas interpretations / management
- VA vs VV physiology
- Heparin management
- Pneumothorax physiology
- Hypovolemia
- Mechanical issues
- Additional scenarios TBD based on ELSO community input

Research Projects

- Advanced Pediatric Critical Care
- Porcine Septic Shock Model

Hanuola Annual Advisory Board Meeting

January 16 to 19, 2009
Sheraton Waikiki
Honolulu, Hawaii

Hanuola Annual Advisory Board Meeting

Friday, January 16

- Program Overview
- Research Symposium
 - Pediatric Critical Care Curriculum
 - Porcine Septic Shock
 - ECMOjo Simulation
 - CHP Coagulation Study
- Keynote Address
 - Steve Horton CCP

Hanuola Annual Advisory Board Meeting

Saturday, January 17

- Case Reviews
 - ECMO Consults
 - ECMO Patients
- ECMO Transport Program
- Clinical Program Finances
- Hanuola 2010

Hanuola Annual Advisory Board Meeting

Sunday, January 18

- Advisory Board Members
 - Review and Comments

Appendix D.8

National Advisory Board

Commendation of ECMO Program Letter

March 10, 2009

Martha Smith, FACHE
Chief Operating Officer
Kapiolani Medical Center for Women and Children
1319 Punahou Street, Executive Office
Honolulu HI 96826

RE: 2009 National Advisory Board Commendation of ECMO Program

Dear Mrs. Smith,

In 2005, the Hanuola ECMO project of Hawaii was inaugurated. This project was established to provide life saving intervention for infants and children which had not been previously available in Hawaii, but which had become the standard of care in the continental United States. The project was made possible by a Department of Defense grant which was instrumental in establishing the Pediatric Advanced Care Initiative. This project had the goals of establishing an extracorporeal life support (ECLS) center, conducting basic science research in ECLS, and developing simulation training for ECLS. To achieve these goals a remarkable collaboration was established amongst several entities including Tripler Army Medical Center, Kapiolani Medical Center for Women and Children, Kaiser Permanente Hawaii, the University of Pittsburgh Medical Center, and the University of Hawaii.

At this point, substantial progress has been made in achieving the goals set forth by the project. Under the superb leadership of the Clinical Director, Dr. Mark Ogino, an ECLS center has been established at Kapiolani Medical Center for Women and Children. After an extensive period of equipment acquisition, education and training of numerous medical personnel, the program has started and is now actively providing ECMO treatment for very critically ill infants and children.

As part of the Hanuola program, an ECMO Advisory Board was established to actively review the clinical outcomes of the program. On a quarterly basis, the Advisory Board has had teleconferences with Dr Ogino and his staff to discuss individual cases and outcomes. In addition, the Advisory Board has done an annual on-site evaluation of the program. As a result of this in-depth review process, the Advisory Board has concluded that the ECLS program at Kapiolani Medical Center is performing in a safe and highly competent manner. Given their positive outcomes, the program should feel comfortable to expand ECMO services to all neonatal and pediatric patients who meet the established criteria for ECLS support. We also recommend that the Hanuola Center apply for the distinction as an ECMO Center of Excellence. Because of this program, several infants and children have survived who would have either had to have undergone a very high risk transport to the Mainland, or who may not have survived long enough to be transported.

In addition to the success with establishing an ECLS center, there has been excellent progress in ECLS research. Under the direction of Dr. Catherine Uyehara, important research is being done to evaluate the physiologic impact of ECMO. Dr Uyehara has developed a very sophisticated porcine model of septic shock and has done some initial work on understanding the distribution of blood flow to vital organs while on ECMO. These results will clearly advance our knowledge and understanding of ECMO and help to optimize the use of this therapy.

Other progress the program has made is in the development of medical simulation training for ECMO. Dr Ogino, working in collaboration with Dr. Larry Burgess and his staff at the Telehealth Research Institute at the University of Hawaii, has developed a low-fidelity interactive computer-based simulation which has the potential to be easily distributed. This will not only benefit the Hanuola Project, but will provide essential training to ECMO centers around the world.

An additional goal of the Hanuola Program is to develop an ECMO transport system (ETS). Progress on establishing an ETS has been very substantial. Because of the unique geography of Hawaii, an ECMO transport capability is of paramount importance. ECMO transport is necessary to move ECMO patients requiring cardiac catheterization to the catheterization lab, move cardiac ECMO patients to the mainland, bring outer-island ECMO patients to Kapiolani, and bring DoD dependants in the Pacific to Kapiolani Medical Center. With the leadership and energy of Kristen Costales, the ECMO

Transport team has visited several centers around the world to learn and discuss design of ECMO transport systems. In collaboration with AirMed International, an initial prototype of an ECMO transport system has been developed. With ongoing efforts, the Hanuola project should field a state-of-the-art system that will be a valued asset in support of the Pacific Rim.

The success of the Hanuola ECMO Program of Hawaii is due to the tireless efforts of numerous people and agencies. Because of this program, very critically ill infants and children can be cared for locally without exposing them to the risk and hardship of being transported to the continental US. While this program has been very successful, it will continue to require collaboration of local institutions, and technical and infrastructure support of Kapiolani Medical Center.

As experienced ECLS professionals and members of the Advisory Board and review team, we congratulate the Hanuola ECMO Program and its sponsors and supporters, for the program's remarkable accomplishments to date. We fully endorse the program. We wish to emphasize its ongoing importance to the children of Hawaii. This is especially applicable for DoD dependents, with the interim reduction in neonatal services at Wilford Hall Medical Center, as Wilford Hall and Brooke Army Medical Center consolidate services between institutions. We express our sincere wish that mechanisms will be put in place to assure the continued availability and development of this life saving technology.

Sincerely yours,

J. Devn Cornish, MD
Professor and Vice Chair for Faculty Development
Department of Pediatrics
Emory University School of Medicine

William Harris, CCP LP FPP
Extracorporeal Technology
Chief Perfusionist
Ochsner Health System

Micheal Heard, RN
Coordinator, ECMO
and Advanced Technologies
Children's Healthcare of Atlanta

John Lin, MD
Pediatric Intensivist
USAF Wilford Hall Medical Center

Donald McCurnin, MD
Professor, Department of Pediatrics
Chief, Neonatology
University of Texas Southwestern Medical Center

Melissa McNeil, MD, MPH
Associate Chief, Section of General Medicine
Director, Comprehensive Women's Health Program
University of Pittsburgh Medical Center

Denise Suttner, MD
Director, San Diego Regional ECMO Program
Rady Children's Hospital and Health Center

Appendix E.1

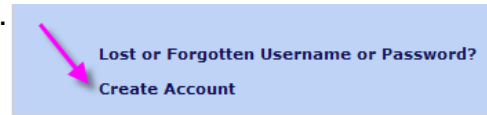
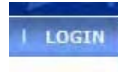
How to Participate Flyer



Participant Simtiki Help

Creating an Account

1. Simtiki.org.
2. Click Login on the top right toolbar.
3. Click Create Account in blue at the bottom.
4. Answer the questions and Submit



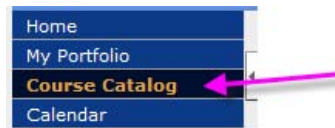
Log in

1. Simtikii.org.
2. Click Login on the top toolbar.
3. Enter username and password.

1. Register for a Course

Simtiki.org & log in

1. Click Course Catalog on left side.
2. Click on the name of your desired course
3. REGISTER FOR A CLASS. Role in Class: Participant. Preferred Class Date: choose one.
4. Submit
5. Your request for registration will be sent to the instructor or course facilitator via email.



Assessment and Intervention for Pediatric Patients in Emergency Situations (AI PED EM)

ASSESSMENT AND INTERVENTION FOR PEDIATRIC PATIENTS IN EMERGENCY SITUATIONS (AI PED EM)	
VIEW PARTICIPANT COURSE MATERIAL	2. Click for hyperlink to pre-course material
VIEW INSTRUCTOR COURSE MATERIAL	
- OR -	
REGISTER FOR A CLASS	1. Click to register for a date/time
Upcoming Class Dates:	4/20/2009, 4/20/2009, 4/20/2009, 4/20/2009, 4/20/2009, 4/21/2009, 4/21/2009, 4/21/2009, 4/21/2009, 4/23/2009, 4/23/2009
Directors:	Lawrence Burgess, Melinda Hamilton, Anne Naclerio, Mark Ogino
	Email Course Directors

2. View and Complete Pre/Post Course Material

Please complete the course material before coming to SimTiki Simulation Center if possible.

1. You may go directly to: <http://www.tri.jabsom.hawaii.edu/manikinstudy/> , or
2. Simtiki.org
3. Course Catalog
4. Assessment and Intervention for Pediatric Patients in Emergency Situations (AIPED EM)
5. View Participant Course Material
6. Click the hyperlink

Questions?

1. Click Help on the tool bar Contact Us or, Email Cami Mikami at mikamic@hawaii.edu ph: 692-1085 or Kris Hara, RRT at harakm@hawaii.edu ph: 808-692-1096, c: 228-6078

Appendix F.1

Computer-Based Simulation for Extracorporeal Membrane Oxygenation Skill Training (Poster Abstract)



 [Print this Page for Your Records](#)

[Close Window](#)

Control/Tracking Number: 10-WIP-594-SSIH

Activity: Work in Progress

Current Date/Time: 11/26/2009 2:18:04 PM

Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training

Biosketch:

Dr. Len Tanaka works in the Pediatric Intensive Care Unit at Kapiolani Medical Center for Women and Children located in Honolulu, Hawaii. He is co-director for the pediatric transport team. His research interests include pediatric transport, simulation in medical education, extracorporeal life support, and health informatics. He received his medical degree from the University of Hawaii, John A. Burns School of Medicine. He completed a Pediatric Critical Care Fellowship and a Masters degree in health informatics at the University of Texas Medical Center at Houston before joining the faculty in the Department of Pediatrics at the John A. Burns School of Medicine.

Author Block: L. Y. Tanaka¹, M. T. Ogino¹, C. Aschwanden¹, K. Costales², L. Burgess¹;

¹University of Hawaii, John A. Burns School of Medicine, Honolulu, HI, ²Hanuola ECMO Program, Honolulu, HI.

Abstract: INTRODUCTION:

ECMO is artificial pulmonary and cardiac life support to a person whose lungs and heart are severely diseased. Acquiring the skills necessary to care for patients on ECMO traditionally include a didactic course complimented with a laboratory experience. In ECMO centers where low patient volumes limit clinical case experience for training, the laboratory experience is critical. However limitations include the time for planning, class size limitations, and the cost for the animals and equipment used. We present the development of ECMOjo that functions like an ECMO pump with a simulated patient attached, where the effects of treatment can be displayed and where the relationships between pump and physiologic variables can be experienced by the learner.

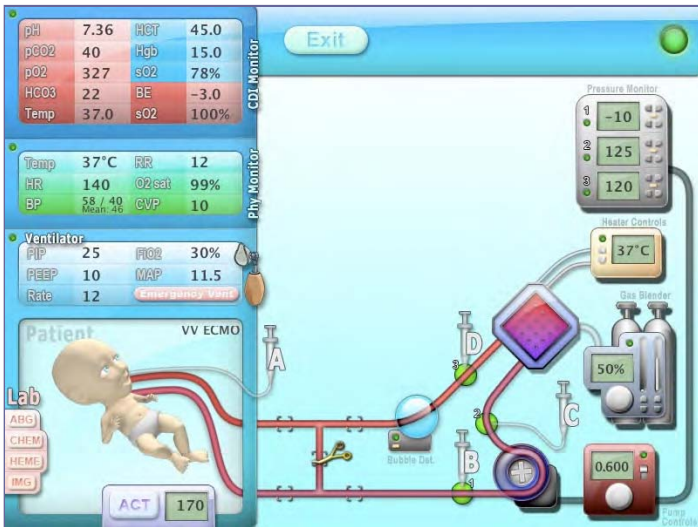
METHODS:

ECMOjo is written in Java and the source code is freely available at ecmojo.sourceforge.net under the open source Berkeley Software Distribution (BSD) License. The relationships between the extracorporeal circuit and the patient's physiologic variables are demonstrated through 22 guided tutorials. Four case-based scenarios test the achievement of cognitive and psychomotor skills. The primary hypothesis is whether ECMOjo improves the acquisition of ECMO skills over conventional classroom learning, as assessed in performance during lab testing.

We selected five sites for evaluation. A standard didactic lecture was used to compare efficacy versus ECMOjo. Students were randomly assigned to either session. We collected surveys, before and after the lab assessment. Pearson's Chi-square analysis was used to compare the ECMOjo and didactic training groups. A significance level of .05 or less was used.

RESULTS/DISCUSSION/CONCLUSIONS:

We are currently testing the inclusion of ECMOjo as part of training at various ECMO centers. This application using readily available computers of a low fidelity simulation of anatomic, physiologic, and pharmacologic processes has the potential to enhance ECMO skills training and to test decision making skills.



Author Disclosure Information: L.Y. Tanaka, None; M.T. Ogino, None; C. Aschwanden, None; K. Costales, None; L. Burgess, None.

Category (Complete): Education, competency, and assessment

Attached Files:

LYTanaka CV (PDF, 53887 bytes)

Status: Complete

Society for Simulation in Healthcare

524 Rex Rd
Tipton, MO 65081
IMSH@ssih.org

FOR TECHNICAL SUPPORT:

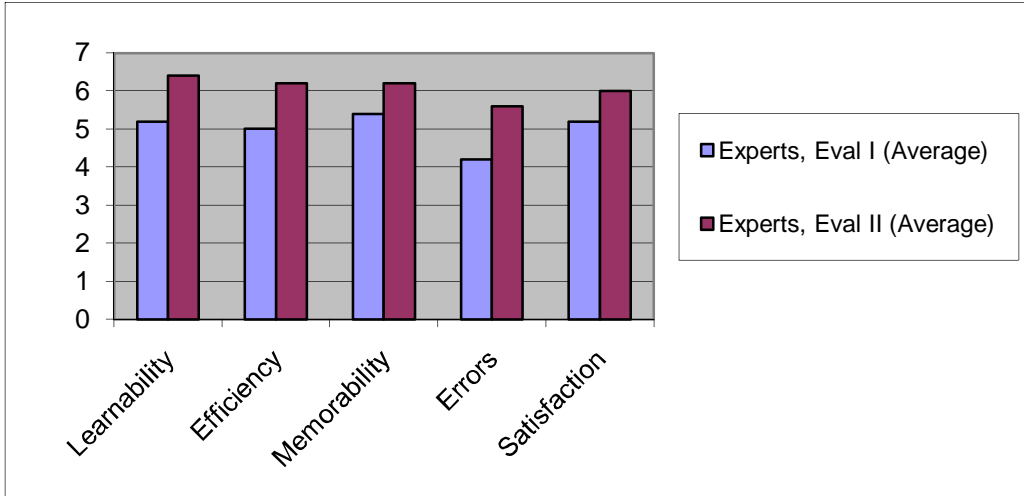
217-398-1792 (Monday through Friday 9:00 am-5:00 pm Central Standard Time)
or [OASIS Helpdesk](#)

Powered by [OASIS](#), The Online Abstract Submission and Invitation System SM
© 1996 - 2009 [Coe-Truman Technologies, Inc.](#) All rights reserved.

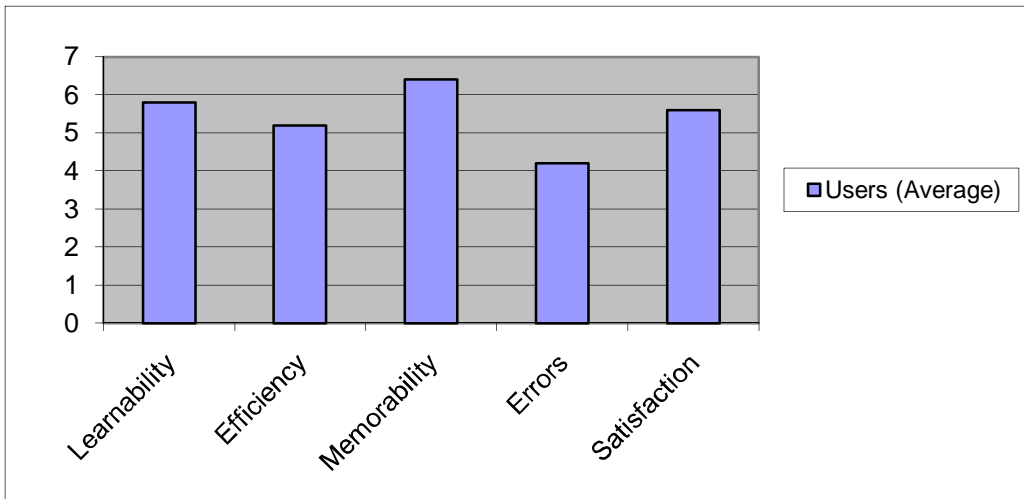
Appendix F.2

Usability Experiment Results

	Target Usability Evaluation (Appendix I)				
	Learnability	Efficiency	Memorability	Errors	Satisfaction
Experts, Eval I (Average)	5.2	5	5.4	4.2	5.2
Experts, Eval II (Average)	6.4	6.2	6.2	5.6	6



	Target Usability Evaluation (Appendix I)				
	Learnability	Efficiency	Memorability	Errors	Satisfaction
Users (Average)	5.8	5.2	6.4	4.2	5.6



Appendix F.3

Approval letter for CME credit

Hawaii Consortium for Continuing Medical Education

c/o John A. Burns School of Medicine · University of Hawai'i
651 Ilalo Street, CME/MEB · Honolulu, HI 96813-5534
Tel: 808-692-0878 · Fax: 808-692-1246 · E-mail: jwoo @hawaii.edu

July 23, 2009

Mark T. Ogino, MD
Telehealth Research Institute
651 Ilalo Street, MEB, 212
Honolulu, HI 96813
via e-mail: mtogino@hawaii.edu

Dear Dr. Ogino:

The Hawaii Consortium for Continuing Medical Education, at its meeting on July 15, 2009, took action on your request for credit designation for "Basic Extracorporeal Life Support (ECLS) & Patient Physiology on Extracorporeal Membrane Oxygenation (ECMO)". This is to let you know that the HCCME approved the request and designates this educational activity as follows:

- a) A maximum of 6.0 *AMA PRA Category 1 Credits*TM when a learner participates in:
Web or computer based self-study curriculum - ECMOjo **and** Wet Lab Program
- b) A maximum of 6.0 *AMA PRA Category 1 Credits*TM when a learner participates in:
Didactic Classroom Curriculum **and** Wet Lab Program
- c) A maximum of 2.0 *AMA PRA Category 1 Credits*TM when a learner participates in the web or computer based self-study curriculum - ECMOjo.

As the committee discussed, the effectiveness of the activity must be evaluated in terms of changes in competence (acquisition and application of new knowledge), performance, *or* patient outcomes. The plan described in the application --- if implemented appropriately --- should help you demonstrate compliance in this area.

Additionally, all print and electronic announcements need to be reviewed and approved by the HCCME prior to distribution. I am also the checklist for the post-activity report.

A representative of the HCCME will be appointed to observe the activity. We will forward the contact information at a later date.

Sincerely,


Juliana J. Woo, M.P.H.
CME Compliance & Accreditation Manager

Enc: Post-Activity Checklist
cc: Kathleen Connolly, email: kihmm@hawaii.edu

The Hawaii Consortium for Continuing Medical Education, a joint venture between the Hawaii Medical Association and the John A. Burns School of Medicine, University of Hawai'i is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.