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The Pacific Pediatr	ic Advanced Care	Initiative establishes	an advanced care	Center with E0	CLS
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Pediatric Advanced Care through new basic science and simulation research, while providing					
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simulation technologies as applied to the EULS curriculum, 3. develop EUMOjo, a					
computer simulation model for patient physiologic variables and ECMO pump biomechanical data.					
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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 into the future. Since the opening of the Hanuola ECMO Center, there have been 68 ECMO consults (25 consults in 2008, 22 consults in 2009, 21 consults in 2010), with 18 patients being treated with ECMO (five patients in 2008, five patients in 2009, eight patients in 2010). 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). See Appendix A.9 for ELSO results for the Hanuola Center.

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 during this reporting period; and monthly ECMO meeting have been scheduled to facilitate ongoing discussion of patient debriefs, system review and educational updates.

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. 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 Sled (ETS).

During this reporting period, Elliott Aviation began construction of the ECMO Transport Sled in mid December 2009 to facilitate the FAA approval process. Construction is at Elliott's expense. The sled was completed in early 2010, whereby Federal Aviation Administration (FAA) approval was sought. The FAA has determined that the ETS will not need a Supplemental Type Certificate to clear it for flight; only the medical base in the aircraft will need a modification of its Certificate in order to transport the ETS. The ETS received structural substantiation for the Hawker Beechjet 400A aircraft from the FAA in March 2010. The paperwork (form 8110-3) is

on file with Elliott Aviation and Hanuola. Transport Protocols have been developed based on existing KMCWC Transport Protocols. Equipment and Supply checklists have been completed as well as power and weight charts.

A funding request for the ETS construction and purchase was submitted to Tripler Army Medical Center and the request has been approved. However, we will not know if TAMC can fund the ETS till 30 June 2011. This is after a determination of funding availability has been made at the Army AMEDD Strategic Technology Clinical Policy Council Meeting held in San Antonio, TX. Unless we hear otherwise, we have reserved funding for the construction. If funding is approved prior to the end date of this contract, the reserved funds will be used to purchase additional ECMO equipment and backup supplies in support of the Center.

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. During this funding year, all pediatric intensive care unit physicians and staff have been certified, and certification of all pediatric surgeons for Level 2 credentials has been completed.

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. This website serves as a portal to the Hanuola ECMO Training courses, training manual and lectures. During this funding period, the website has been updated with staff list and contact information and Hanuola Training Course lectures. The transfer of the website administration to Kapi'olani is in process.

b. Conduct ongoing training, including didactic, wet labs, and animal labs based on wellestablished models.

During this funding period, quarterly refreshers, 4 hours each, to maintain ECMO competency for nurses, respiratory therapists and other ancillary staff members who have already completed the ECMO training course have been completed. Dates of the courses were on 29 September 2009, 2 November 2009 and 3 November 2009. A total of 48 participants completed competency review. A second ECMO training course was completed on 14 and 15 October 2009. Students included 24 participants; five of these participants were Adult Intensive Care RNs attending from Kaiser.

An animal training lab was held on October 15, 2009 for 12 participants for clinical training. Another animal training lab was held on 12 May 2010, again for 12 participants for clinical training. Training labs emphasize routine and emergent clinical skills with emphasis on communication. Participants include physicians, nurses, respiratory specialists and perfusionists. Outline objectives and specific curriculum have been completed for future ECMO Training Courses and clinical lab training. TAMC Lab technicians are now able to operate ECMO system independently without perfusion support.

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.

The Hanuola ECMO Center has continued to submit detailed data to the ELSO registry through the data forms (See Appendix A.9).

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. 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, we have used the advisory committee for their expert consultation on a case by case basis. At the end of this reporting period, the Advisory board has been closed out. As is standard practice in the ELSO community, Hanuola will seek expert consultation from established ECMO centers and ELSO community experts via personal contact and the ECLS network, as needed on a case by case basis.

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

A dedicated animal operating suite at Tripler Army Medical Center Department of Clinical Investigation for ECMO research studies has been established. An ECMO System is made available to University of Hawaii Clinical Training Wet Labs and the Pediatric ECMO Hanuola Center at Kapiolani Medical Center for Women and Children on an as needed basis.

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

The research project of putting the septic shock hypotensive pigs on ECMO and examining blood flow distribution to different organ beds is currently in the data analysis phase. All experiments have been completed and data is currently being analyzed and manuscripts are being drafted.

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

In this study we tested 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. Endotoxic shock was induced, and hormonal and physiologic parameters prior to ECMO and during ECMO therapy were compared. The original objectives of this study have been addressed and preliminary analysis suggests that this project may yield clinically relevant data that supports clinical guidelines for the use of Extracorporeal Membrane Oxygenation in the treatment of septic shock.

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 endotoxininduced septic shock

In the intial proposal, we had wanted to examine some of the side effects of the use of blood substitutes such as hemodilution and methemoglobinemia, and whether such conditions during septic shock, when the body is already compromised and struggling to maintain vital organ perfusion, can be tolerated. However, we were unable to obtain a source of artificial oxygen carrier (AOC), as vendors of such products had gone into bankruptcy, and so AOCs were no longer on the market. Thus we had to drop this part of the project. This part of the project was instead replaced by a more in depth look at the effect of ECMO on cardiovascular regulating hormones and the outcomes of shifts in microcirculatory flows as described above.

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.

Based on the dilutional effect of ECMO on circulating hormone levels, we hypothesized that ECMO will not restore urine output in endotoxic shock despite cardiac stabilization and

maintenance of blood flow to the kidneys, as ECMO simultaneously reduces endogenous vasopressin levels which are needed to modulate local perfusion pressure and renal filtration. Preliminary results indicate that ECMO may interfere with the autoregulation ability of the kidneys to provide adequate pressure to restore filtration and urine flow in endotoxic shock.

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, the course has been converted to an online format which is available on the Center's training website. Competency learning modules have been developed to maintain ECMO competency for nurses, respiratory therapists and physicians who have already completed the ECMO training course. On 11 and 12 May 2010, an ECMO training course was held using the web-based curriculum and high fidelity manikin simulation. And again on 26 and 27 July2010, a perfusion competency course using the same format was completed.

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. 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 patents.

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.

Thus far we have 22 participants that have completed the evaluation, with an additional three more participants lined up for the study. Data is currently being examined for integrity and preparation for data analysis. See Figures 1 and 2 below for the manikin study setup.



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

ECMOjo scenario-based curriculum evaluation

Validation of ECMOjo has been completed at various ECMO Training Centers across the United States. Centers include: Rady Children's Hospital, San Diego, Children's National Medical Center, University of Pittsburgh Medical Center, Wilford Hall Medical Center, Arkansas Children's Hospital, Children's Healthcare of Atlanta, University of Iowa, Mayo Clinic, Lutheran General, and Children's Hospital of Philadelphia. A total of 51 medical professionals were enrolled to participate in an ECMO skills acquisition study. Subjects were randomized into two groups, one group doing conventional classroom learning and the other training on ECMOjo over the same period. Both groups were assessed using three wet-lab scenarios after their training, with wet-lab results compared between groups. Data has been collected and results of the study are currently being analyzed. Figures 3 and 4 display screenshots of the current version of ECMOjo.

User-based evaluations were also conducted to obtain feedback on the fidelity of the system. See Appendix B.1 for example of feedback.



Figure 3 - Interactive GUI screen

Figure 4 – Scenario Selection Screen

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 is ongoing to provide review and maintenance of skills.
- Hanuola ECMO Transport system has been designed and has obtained FAA certification

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

- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamineresistant vasodilatory septic shock has been developed.
- Using a piglet model of vasodilatory endotoxin-induced septic shock, we have characterized the cardiovascular and endocrine responses to ECMO.

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

- Web platform has been created and course content has been loaded
- The following website contains the online learning portion and related quizzes <u>http://www.tri.jabsom.hawaii.edu/manikinstudy/login.html</u>
- The following website contains the simulation portion and related quizzes for the study <u>http://simtiki.simmedical.com/apps/courses/courseview.asp?course_id=6277</u>
- Evaluation of the simulation curriculum, *Assessment and Intervention for Pediatric Patients in Emergency Situations*, is under way.

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

- The development of ECMOjo, a simulator and trainer for extracorporeal membrane oxygenation, has been completed.
- Validation study has been completed.
- Project software has been updated at SourceForge.net and is available as Open Source for ECMO practitioners worldwide. http://ecmojo.sourceforge.net

Reportable Outcomes

- Abstracts, Presentations, Publications:
 - Ogino MT. ECMO Training Using Simulation. The 26th Annual Children's National Medical Center Symposium on ECMO & Advanced Therapies for Respiratory Failure, Keystone CO. Feb 2010.
 - Tanaka LY, Aschwanden C, Burgess L, Ogino MT. Computer-Based Simulation for Extracorporeal Membrane Oxygenation (ECMO) Skills Training. International Medical Simulation in Healthcare, Phoenix, AZ. Jan 2010. 5
 - Tabak BD, Tanaka LY, Mahnke CB, Elliott CL, Costales KG, Ogino MT. Echo for ECMO: Guiding Avalon Catheter Placement for VV ECMO. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. (platform presentation)
 - Costales KC, Tanaka TY, Kilcommons MM, Takenaka WS, Sommer-Candelario SA, Ogino MT. Santa's Got a Brand New Sled. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. (platform presentation) Appendix A.1.
 - Costales KC, Kilcommons MM, Takenaka WS, Ogino MT. ECMO Transport Across the Pacific: A Case Report. Poster presentation. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010. Appendix A.2
 - Tabak BD, Tanaka LY, Mannke CB, Elliott CL, Costales KC, Ogino MT. Echocardiographic Evaluation of the Avalon Elite Bi-caval Dual Lumen Catheter in Neonatal and Pediatric VV ECMO. ECMO and the Advanced Therapies for Respiratory Failure, Keystone, CO. Feb 2010.
 - L. Y. Tanaka, M. T. Ogino, C. Aschwanden, K. G. Costales and L. Burgess. Computer-Based Simulation Application for Extracorporeal Membrane Oxygenation (ECMO) Skills Training Poster presentation. 10th Annual International Meeting on Simulation in Healthcare (IMSH), Phoenix, Arizona, January 23-27, 2010
 - Uyehara CFT, Batts SG, Kinnison MW, McEntire SP, Sato AK, Ichimura WM, Hashiro GM, and Hernandez CA. Vasopressin Regulation During Extracorporeal Membrane Oxygenation (ECMO) in a Pig Model of Septic Shock. FASEB J. 23: 605.1, 2009.
 - Cardiovascular Hormonal Responses and Microcirculatory Flow During ECMO Treatment in a Piglet Model of Endotoxic Shock. Catherine F T Uyehara, Sherreen G Batts, Thornton S Mu, Sarah L Lentz-Kapua, Martin W Kinnison, Aileen K Sato, Wayne M Ichimura, and Claudia A Hernandez. Presented at The Department of Defense Peer Reviewed Medical Research Program Military Health Research Forum, Kansas City Missouri, August 2009. (Hosted by The U.S. Army Medical Research and Materiel Command.)
 - The animal study task has been successfully used to provide research opportunities for military Graduate Medical Education trainees, and to develop research interests of residents and staff of Tripler Army Medical Center's Department of Surgery. Results were presented by military GME trainees at the following:
 - Podium presentation at AAP national convention Perinatal Section Washington, D.C. Platform session October 2009

- Podium presentation at COMPRA, Bastrop, Texas November 2009
- Podium presentation at 11th Annual James W. Bass Research Symposium, 20 May 2010, Tripler AMC, HI.
- Podium presentation at 12th Annual James W. Bass Research Symposium, 19 May 2010, Tripler AMC, HI.
- Podium presentation at 29th Annual Conference of Military Perinatal Research, 6 Nov 2010, Austin, TX.
- ECMO Physician Credentialing
 - All PICU physician staff have been certified.
 - Certification all Pediatric surgeons for Level 2 credentials has been completed.
- Meetings held on 14-16 December 2009 with UPMC and Hawaii ECMO team to discuss program progress and future. The following are presentation/discussions that were held. QPR 14
 - Appendix A.3 History of the Hawaii ECMO project Overview
 - *Appendix A.4* Description of the ECMO Sled 2
 - Appendix A.5 Hanuola Website Development Overview
 - Appendix A.6 Discussion on ELSO database comparison with Hanuola data
 - Appendix A.7 Biotronics Collaboration Overview
- Data submitted to ELSO registry
- The animal model for endotoxin-induced septic shock using a pediatric piglet model has been completed and results are currently being analyzed.
- Design and engineering of the ECMO Transport Sled is complete. Construction is pending.
- Review article published in AmSECT Today, Sept/Oct edition, Appendix A.8, pg 7.

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.
- ECMO patients are currently being treated and consulted, 21 consulted and 8 treated during this reporting period.
- An ECMO transport system has been certified and will be available for use for the Center into the future.
- Animal model for ECMO treatment of bacterial endotoxin-induced catecholamineresistant vasodilatory septic shock has been developed.
- Web platform has been created for 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. Also, the *Critical Care Curriculum for Austere Environments* course is also available on the website.
- 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.

Results from the animal studies indicate that ECMO may help reduce morbidity and mortality from endotoxin-induced shock by providing cardio-respiratory support. Septic shock is a high-risk disease of infection seen in all military hospitals. Susceptibility of battlefield wounds to infections and possibilities of soldier exposure to biological warfare agents makes the treatment of septic shock a significant "military relevant disease management" concern. Guidelines for perfusion parameters and hormone replacement therapy provided by this study help clarify the role for ECMO in the treatment of septic shock in military clinical practice.

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: <u>http://www.elso.med.umich.edu/Registry.htm</u>, 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. Santa's Got a Brand New Sled – presentation
 - Appendix A.2. ECMO Transport Across the Pacific: A Case Report poster presentation
 - Appendix A.3. History of the Hawaii ECMO project Overview
 - Appendix A.4. Description of the ECMO Sled 2
 - Appendix A.5. Hanuola Website Development Overview
 - Appendix A.6. Discussion on ELSO database comparison with Hanuola data
 - Appendix A.7. Biotronics Collaboration Overview
 - Appendix A.8. Review article published in AmSECT Today, Sept/Oct edition (see pg 7).
 - Appendix A.9. ELSO Results, Hanuola Center

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

Appendix B.1. ECMOjo Evaluation 13 August 2010

Appendix A.1.

Hanuola ECMO Transport Project



Senator Daniel Inouye

"Santa's Got A Brand New Sled"

Costales KG, Takenaka WS, Kilcommons MM, Ogino MT

Hanuola ECMO Program of Hawaii Kapiolani Medical Center for Women and Children, Honolulu HI

Kristen.costales@kapiolani.org

10 ETS Design Essentials

- 1. Must accommodate all sizes of patients
- 2. Must fit into all modes of transportation without modification
- 3. ECMO circuit must be protected yet accessible
- All equipment, tubing, cables, tanks, and medical lines must fit within the footprint of the ETS platform
- 5. Must have UPS available for all vital equipment

A Year of Education

- Kapiolani ETS team meetings
- Consultations
 - University of Pittsburgh
 - Children's Hospital of Pittsburgh
- Site visits
 - Royal Children's Hospital, Melbourne
 - Wilford Hall Medical Center, San Antonio
 - Arkansas Children's Hospital, Little Rock
 - British Columbia Children's Hospital, Vancouver

AirMed International Birmingham, Alabama

- > Global medical transport company
- > Kapiolani's patient transport contractor
- > King Air, Hawker, Learjet, and Beechjet aircraft
- Site visit and initial proposal September 2008
 - Project manager assigned
 - Equipment identification and transfer
 - Elliott Aviation partnership



10 ETS Design Essentials

- 6. Must have blended gases on board
- 7. Must have ability to maintain desired patient temperature
- 8. All lines must be organized, secured, identified, protected, and easily accessible
- Equipment on ETS must be located in relation to appropriate team member's position in flight
- 10. ETS must be designed, engineered, and tested to meet FAA guidelines, standards

Elliott Aviation

- > Aviation products and services
- > Design, engineering, build, test facility
- FAA liaison
- > Site visit January 2009
 - Assembly of team members
 - First mock-up of ETS project
 - Identification of structure, equipment location, power, gas, weight
 - FAA requirements





Design and engineering team at work May 2009



Elliott Aviation Moline Illinois







Side by side with aircraft stretcher





Design

- > Total weight fully loaded 250 lbs.
- > Patient weight up to 200 lbs. on current medical base
- Engineered for weight, balance and structural integrity within the frame, medical base
- > Recessed low profile handles, 4 sides
- > LifePort footprint

Hanuola ECMO Transport System





ETS Platform Aluminum honeycomb frame







Slide out trays for accessibility



Power

- > 8.5 amp inverter in aircraft and ambulance
- > Power cords routed through relay to two external AC cords

 - RED Pump, heater, M3
 BLACK Monitors, IV and syringe pumps
- > Alternating syringe pump power switch
- > Internal battery capacity for most equipment
- > Power protocol to avoid overload
- > UPS peripheral for vital equipment

GeoData Systems UPS

- > Dual NiMH batteries
- > Lightweight, 52 lbs.
- > Temperature resistant
- > Dual 110 vAC, 375 watts output
- > 43 amp/hr capacity
- ➢ Rolling Pelican[™] case





Gas system





Gas system

- > Two aluminum E cylinders 1 air, 1 oxygen
 - Lightweight
 - 700 gaseous liters each
 - Support for transition periods
- > Internal routing of air/oxygen lines to blender and exterior connection panel
- > Exterior gas connection panel
 - Quick connects for transfer to ambulance or aircraft tanks
 Air and Oxygen flow meters

 And away we go....

Substantiation Process

- > STC (Supplemental Type Certificate)
 - Engineering package received by FAA
 - FAA issues certificate 8110-3 for airworthiness Beechjet, Hawker, King Air, Learjet
 - Completed ETS with all equipment must pass
 EMR/EMI testing for FAA
 - STC issued
 - Estimated completion March 2010



ECMO Transport Across the Pacific: A Case Report



K. G. Costales ^{1,2}, M. M. Kilcommons^{1,2}, L. Y. Tanaka^{1,2}, W. S. Takenaka¹, S. A. Sommer-Candelario¹, M. T. Ogino^{1,2,3}

Kapi'olani Medical Center for Women & Children; Honolulu, Hawai'i |² Hanuola ECMO Program; Honolulu, Hawai'i |³ University of Pennsylvania School of Medicine; Philadelphia, Pennsylvania

Introduction:

transport of a patient across the Pacific Ocean, from Honolulu, congenital cardiac surgery. We describe the first civilian air ECMO required urgent transport, on ECMO, from Hawai'i to San Diego for system was completed, we were presented with a patient who and production of a specialized ECLS transport system. Before this to develop an ECMO transport program, which includes the design prime example. The mission of the Hanuola ECMO Program of who require ECMO for complex congenital cardiac defects are a advanced medical care available in specialized hospitals. Patients distinction poses many problems for critically ill children in need of Hawai'i to San Diego, California. Hawaii is to bring ECMO to pediatric patients in the Pacific Basin and Hawai'i is the most geographically isolated land mass on Earth. This

Case Report:

surgical correction the next day and went on to recovery. team. The total transport time from door-to-door was 8 hours, with a transfer. A Hawker 800 aircraft was used to transport the 5 member respiratory therapists, physicians, BioMed staff was convened to plan arterial ECMO support. A team of critical care nurses, perfusionists, and amiodarone; however, worsening cardiac output required venofailure, and acidosis. The patient's dysrythymia stabilized on lidocaine mainland U.S., the patient developed ventricular tachycardia, renal undiagnosed supracardiac total anomalous pulmonary venous return (TAPVR). While arrangements were being made for transport to the flight time of 5 hours 37 minutes. The patient underwent successful the development of a safe and practical transport sled. AirMed International provided the air medical transportation for this transpacific A 2 month-old, 4 kilogram male presented to the PICU with an

Conclusions

Prolonged isolation from medical facilities, power limitations, and ECMO transport over the open ocean presents many interesting critical consequences. We describe our experience with these coordination between the various entities involved is essential to avoid equipment malfunction, and medical supply depletion. A high degree of times carry an increased risk for multiple patient interventions, aircraft space limitations are the most formidable. In addition, long flight challenges for both the medical team and the transport modality. challenges in our first transpacific air ECMO transport

Appendix A.2



Flight time 5 hours 37 minutes Hawaii's Geographical Isolation:



Patient and Circuit: limited supply storage, seating positions for personnel dictate roles in patient care

Ambulance Inverter: 8.3 Amps Airmed Hawker Jet Two Inverters: 8.5 Amps

E Cylinders of Oxygen (3



low fuselage clearance, gas flow pment issues: narrow



Tarmac Issues: visibility at night, weather protection

Powered Equipment	Weight Ibs	Current Draw (amps)	Battery Time (min)	
Maquet Rotaflow System	31	2	90	
Maquet Rotaflow Drive Unit	7	n/a	n/a	
Maquet Rotaflow Hand Crank	4.8	n/a	n/a	
Pulmonetic LTV 1000 Ventilator	14.5	4	60	
Pulmonetic Sprint Battery Pack LTV	4.5	n/a	300	
Propag Monitor	6.25	0.75	300	
CSZ Heater	11.4	1.75	n/a	
Alaris MedSystem III Triple Pump	5.1	0.05	360	
Medfusion Syringe Pump (9)	3.8	0.7	360	
UPS SmartPro 1200 (3)	33			
Other Equipment				
Quadrox D Oxygenator				
iStat Analyzers (2)				
Medtronic Pressure Display Box				
Sachriet Air/Ownen Blander				



Aircraft Logistics: small aircraft door, power limitations



Space Limitations: physician, perfusionist, ECMO nurse, transport nurse, RT/flight safety officer



AirMed International and the Hawker 800: Door to door coordination of aircraft, pilots, team

Working inverter, air/oxygen, door height, gurney position, skilled personnel

Ambulance Considerations:

Appendix A.3



UPMC Hawaii ECMO Meeting December 14 – 16, 2009



ECMO referrals to the mainland

- Record review 24 ECMO referrals
- 24 ECMO referrals
- 97 ECMO eligible infants (1994-2001)
- Survival
- 65% in a subgroup of babies who were transferred to the mainland for ECMO
- 80% to 95% at an ECMO center
- Morbidity
- Non ECMO survivors higher rates of
- pulmonary bleeding, IVH, oxygen at discharge

Hero

• TJ (2003)

- "Persistent Pulmonary Hypertension of the Newborn"
- Limited blood flow to the lungs with right heart failure
- Mainland ECMO center called
- Air ambulance not available for 24 hours
- Wilford Hall ECMO team contacted. USAF aircraft on east coast.

















Pacific Pediatric Advanced Care Initiative

- 1. Establish an ECMO center
- 2. Conduct basic science ECMO research
- 3. Develop simulation training for ECMO curriculum

<section-header><section-header><image><image><image>







Establish a Hawaii-Pacific Rim ECMO center



- Establish ECMO center to support Department of Defense (DOD) and civilian neonatal and pediatric populations
- Develop second DOD ECMO transport program
- 18

















Pacific Pediatric Advanced Care Initiative

- 1. Establish an ECMO center
- 2. Conduct basic science ECMO research
- 3. Develop simulation training for ECMO curriculum

TAMC Department of Clinical Investigation





Pacific Pediatric Advanced Care Initiative

- 1. Establish an ECMO center
- 2. Conduct basic science ECMO research
- 3. Develop simulation training for ECMO curriculum

30





National and International Recognition

ELSO

- Steering Committee Member, Extracorporeal Life Support Organization
- Co-editor, ELSO Training Manual

SEECMO

- 2010, Iowa City: Simulation

Other

- Royal Children's Hospital, Melbourne Australia

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"We are in the business of hope" ³

Appendix A.4



















Solutions

> Power

- 8.5 amp inverter in aircraft and ambulance
- Battery capacity for all vital equipment
- UPS peripheral for equipment without batteries
- Power cords routed through relay to two ETS AC cords
- Develop power protocol to avoid overload

Solutions

⊳ Gas

- Two aluminum E cylinders 1 air, 1 oxygen
 Lightweight
 - 700 gaseous liters each
 - Support for transition periods
- Oxygen shared with ventilator and blender
- Built-in panel with gas connections
 Quick connects for transfer to ambulance or
 - Oxygen flow meter for hand bagging

Substantiation Process

- Elliott Aviation to begin build of ETS December 1, 2009
- Completion set for mid-January 2010
- Final drawings and data from engineer to be sent to FAA

Substantiation Process

> STC (Supplemental Type Certificate)

- Final engineering package received by FAA
- FAA issues certificate 8110-3 for aircraft category – first Beechjet, followed by Hawker, King Air, Learjet
- Completed ETS with all equipment must pass EMR/EMI testing for FAA
- STC issued, owned by Hanuola
- Estimated completion February/March 2010





Costs

- > Engineering, Design, FAA Approval Process
- Funding: DoD grant
- Construction
- ECMO Transport Platform \$118,000
- Spare Parts \$34,000
- Equipment \$212,000
- Additional aircraft STC \$5000 each
- Funding: Partial funding DoD Grant External Funding Sources

Policy and Procedure

- Build off of existing KMCWC Transport Protocols
- > Checklists completed
 - Equipment
 - Supplies
 - Guidelines for preparation and execution
 - Power and weight chart

Appendix A.5













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Tedatric Intervent, ND Pediatric Intervent	Provent Chrone Care, List Province St. Hennede, HL 9625 Phone: Care Care Care Care Care Care Care Care
John (Jaime) Harrington, 50 Pediatris Intensivist	Pediatric Critical Care, 1319 Fanatava II, Hyndula, HC 96828 Phone: (Dis 100 902) Care (P Email: (harrington®kapadasi.org
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-	Colonel Mark Thompson, ND Chief, Pediatrics	Dept. of Pediatrics, 1 Jarrett White Rid., Tripler Army Hedical Center, Hunalulu, HI 96059 Phone: The Book 103: 6027 0 Crisell Mark, Thempson than Lamc, amedid, army, mil
_	LTE Sarah Lentz-Kapua, ND Chief of Newborn Special Care Services	Division of Neonatology, 3Jarrett White Rd., Trigher Army Medical Center, Honolubu, HJ 96859 Phone: Section 433-6701 O Emulti associated benz September James, amedid, army, mil
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	UNIVERSITY OF PITTSBURGH MEDI	ICAL CENTER
-	Ralph Caputo VP Dusiness Development, Biotronics	1370 Beulah Rd, Pettsburgh, PA 15235 Phone

Additions

- Tyree, Puapong, Woo, Feng, Xonis, Oliveras, Kabbur, Level one ECMO
- David Palmer, Kent Kelly, Brad Kuch
- · Link to Advisory Board Letter
- Group to UPMC
- Advisory Board
- Ogino @ CHOP









































Appendix A.6



Hanuola ECM July 2007 to Novembe	IO Patients er 2009
Neonatal Respiratory	8
Neonatal Cardiac	1
Pediatric Respiratory	4
Pediatric Cardiac	2
Pediatric ECPR	1
Total ECMO Patients	16

OVERALL OUTCOM	AES:	
Neonatal Respiratory	ECLS	
	<u>Hanuola</u>	ELSO Database
Total Number		
Patients	8	4661
Survived ECLS	75%	67%
Survived to		
discharge	75%	* /

OVERALL OUTCOMES:				
Neonata	i Respiratory Rui	ns By Diagnos	IS	
		<u>Hanuola</u>	ELSO Database	
PPHN	# of patients	2	848	
	% survived	50%	76%	
CDH	# of patients	1	1497	
	% survived	100%	45%	
Sepsis	# of patients	2	249	
•	% survived	50%	71%	





OVERALL OUTCOM Pediatric Respiratory	MES: ECLS	
	<u>Hanuola</u>	ELSO Database
Total Number Patients	4	4005
Survived ECLS	75%	64%
Survived to discharge	50%	*
* 5 year data not available		

		Hanuola	ELSO Database
Viral			
Pneumonia	# of patients	3	213
	% survived	67%	68%
Other	# of patients	1	775
	% survived	100%	50%

OVERALL OUTCOMI Pediatric Cardiac ECLS	ES: 31 days to < 1	year
	<u>Hanuola</u>	ELSO Database
Total Number Patients	1	954
Survived ECLS	1/1 = 100%	455/954 = 48%
Survived to Discharge	*	*
* 5 year data not available/disch	arge status pendin	g

OVERALL OUTCOM Cardiac ECLS: Congenita 31 days to < 1year	ES: al Diagnosis by	Age Group
	<u>Hanuola</u>	ELSO Database
Other	1	221
Survived ECLS	1/1 = 100%	111/221 = 50%
Survived to Discharge	*	*
* 5 year data not available		





OVERALL OUTCOMES: Neonatal & Pediatric Cardiac ECLS: All Age Groups							
	<u>Hanuola</u>	ELSO Database					
Total Number Patients	3	4186					
Survived ECLS	3/3 = 100%	44%					
Survived to Discharge	*2/3 = 50%	*					
* 5 year data not available/disch	arge status pendi	ng					

OVERALL OUTCO Pediatric ECPR	DMES:	
	<u>Hanuola</u>	ELSO Database
Total Number Patients	1	832
Survived ECLS	0%	52%
Survived to discharge	0%	39%

Total Referrals							
					-		
	<u>NICU</u>	<u>PICU</u>	<u>TOTAL</u>	<u>ECMO</u>			
200	73	2	5	2			
200	89	10	19	4			
200	96	9	15	10			







Appendix A.7





Hanuola and BioTronics "Our common goals"

- BioTronics, Inc.
 - University of Pittsburgh Medical Center
 - Service lines
 - Personnel and activity
 - Our programs
 - Solutions



Our Community Presence

- 52,000 Employees •
- \$7.5B in Assets \$7.7B in Revenue
- 20 Hospitals operating nearly 4200 beds
- 43 Regional Cancer Locations More than 400 Service Locations
- 188,000 admissions
- 1.4M lives covered in Insurance Division products \$169M Charity Care
- \$99M Community Health Programs and Donations
- \$250M Support for Research and Education
- \$24M Taxes and Voluntary Contributions

BioTronics Service Lines



Overview

- 65 personnel: certified perfusionists and autotransfusion specialists
- · Average of 10+ years experience
- · Service area:
 - Western Pennsylvania
 - Eastern Ohio
 - Northern West Virginia - Baltimore Washington area
 - Western Maryland area



Perfusion Activity

- 5,000+ open-heart procedures
- 7,500+ autotransfusions
- Platelet gel therapy
- 150+ chemoperfusion procedures





- 625+ intra-aortic balloon
- Transport services
- Perioperative services
- Consultation services



Our Programs

een PMC Presbyterian PMC Phadyside PMC Pasavant PMC Mercy Ifferson, PA Biblio, PA estmoreland, PA uBois, PA estmoreland, PA uBois, PA ttaburgh VA, PA ashington, PA timity, OH yrum Northside, OH yrum Northside, OH yrum Northside, OH yrum Northside, OH prombal, Hawati hemo Perfusion PINC Southaide PINC Southaide PINC Shanarot PINC Shanarot PINC Harmarville PINC Harmarville PINC Magee PINC Northwest Ion General, PA Marten, PA ameson, PA tercy Jeannette, PA ameson, PA tercy Jeannette, PA xoela Latrobe, PA xoela Latrobe, PA Perioperativ

Salem, OH East Ohio, OH East Ohio, OH Davis Memorial, WV United Health, WV Davis Memorial, WV VA, Clarksburg, WV Weirton, WV Reynolds, WV Garrett, MD Doctors, MD South Maryland, MD Franklin Square, MD Sibley, DC

Perfusion Services

- Personnel
- Supplies
- Equipment





Hanuola ECMO 2010 and Beyond

- Local and National ECMO experience
- Kapi'olani agreement
- Stae of Hawaii H1N1 strategic plan
 - Perfusionists
 - ECMO SpecialistsEducation
- BioTronics arrangements



UPMC Children's ECMO Experience







UPMC BioTronics Agreement

- Leadership
- Quality assurance
- Monitoring
- On-call coverage
- Transport services
- Training
- Consultation



Hawaii Personnel

Primary Perfusionists

Kristen Costales, CCP Eugene Garrett, CCP Pete May, CCP Mark Yanogacio, CCP Shilpa Nair, CCP Brian Costales, CCP

Relief Perfusionists Thomas Hogan, CCP Lisa Hogan, CCP Kent Kelly, CCP Don Koch, CCP Don Maloney, CCP Elizabeth O'Malley, CP

Relief Perfusionists

Thomas Hogan, CCP Lisa Hogan, CCP Kent Kelly, CCP Don Koch, CCP Don Maloney, CCP Elizabeth O'Malley, CP

Local Perfusion Acitivity

- Kapi'olani Medical Center for Women and Children
- Queens Medical Center
- Kuakini Medical Center
- Kaiser Medical Center
- Staub Hospital
- Hawaii Medical Center
- Tripler Army Medical Center



Relationships

- Quality
- Service
- Fiscal responsibility





www.biotronics.com

BioTronics, Inc. 1370 Beulah Road Pittsburgh, Pennsylvania

888-881-5218











Appendix A.8

CALENDAR OF EVENTS

September 10-12, 2010 – Team SUNY 2010, SUNY Upstate Medical University, Syracuse, NY. For more information and online registration, please visit www.ec.upstate.edu/ chp/cp/TeamSUNY/home.html

September 18-19, 2010 – North Carolina Society of Perfusionists Fall Meeting, Hilton Garden Inn at Southpoint, Durham, NC. For more information, visit http:// ncperfusion.org

October 1, 2010 – Call for Abstracts opens for the 49th International Conference, April 13-16, 2011, New Orleans, LA. Visit www. amsect.org for more info.

October 6 - 9, 2010 – AmSECT's Perfusion Safety & Best Practices in Perfusion, Fairmont Royal York Hotel, Toronto, Ontario. For more information, visit www. amsect.org/sections/education/ Best_Practices/

October 22-24, 2010 – Autologous Blood Therapy Course, Jameson Inn Pearl, MS. For more information, contact Glenda Courtney (601) 824-3915, PRFUZN@ Bellsouth.net http://autologousbloodtherapycourse

October 29-30, 2010 – 27th Annual Scientific Meeting/Australian and New Zealand College of Perfusionists, Seaworld Resort, Gold Coast, Australia.

November 30, 2010 – Willingness to Serve applications due. Please visit http://amsect.societyhq.com/members/wtsa. iphtml to submit.

November 30, 2010 - National Award Nominations due. Visit the Members Only section at www. amsect.org.





MESSAGE FROM THE PRESIDENT

Safety and Evidence-Based Practices

By Susan J. Englert RN CNOR PBMT CCP AmSECT President

It almost goes without saying that experience and knowledge, translation in using judgment skills, and being watchful during a case are critical components for the safe delivery of extracorporeal support. Cardiopulmonary bypass, blood management, heart failure therapy and support, ECMO, and associated perfusion-directed services are lifesaving, but they also carry the potential to seriously injure or kill a patient.

The estimated risk of death or a serious injury during cardiopulmonary bypass is one in 2,500 procedures. This is 100 times greater than the risk from anesthesia. A plethora of statistical data abounds with ratios of serious injuries or deaths to cases pumped, or for certain CPB procedures done. Many states collect and publish for public consumption the CABG and mortality ratios for surgeons and hospitals. To the best of my knowledge, the specific hand of a perfusionist in contributing to these adverse medical outcomes is not recorded. It can only be guessed.

There already has been, and will continue to be, the adoption by private insurance companies, the federal Medicare program, and states the use of evidence-based medical practices and patient outcomes for the identification of medical



Susan J. Englert RN CNOR PBMT CCP

care delivery process problems. These are clinical practice factors that can be shown to contribute to the manifestations of less than optimal patient care outcomes. These activities are occurring in hospital systems, within surgical departments, and within programs, with the intent to identify and evaluate clinical practice risks and take steps to improve quality assurance. Some of this information also gets translated into uses such as identifying problem hospitals or linking, for example, Medicare hospital payment rates to a hospital's achievement of benchmark standards of care for patients as delivered by the care providers. In the case of perfusion, to the surgical team members and

Continued on page 15

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September/October Theme Article	Student View Point
Committee Spotlight	Self Quiz Answers
Feature Article	Willingness to Serve Application
Government Relations Committee	Self Quiz
Theme Article	Welcome New Members
Safety/ Best Practices Registration 💷	Award Nominations
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SEPTEMBER / OCTOBER THEME ARTICLE

Safety / Best Practices

By Nadia C. Azuero, BS CCP LP Atlanta, GA

Safety is defined as the condition of being safe: freedom from danger, risk, or injury. It also extends to technology stating, a device designed to prevent accidents, as a lock on a firearm preventing accidental firing. Perfusionists would think the second definition applies more to our profession, but personally, I believe the first one is more crucial. The second definition is the preventative measure to the first



Nadia C. Azuero BS CCP LP

one. In our profession, we have progressed in taking safety measures behind the pump to protect the patient and ourselves. Utilizing equipment like level detectors, air bubble detectors, high-pressure alarms for cardioplegia and the arterial pump, all linked to servo-regulation to the arterial pump as a safety measure to avoid pumping air or runaway pump. These methods have become standard in the industry but still the most important safety measure is the attentiveness of the perfusionist.

To parallel, the airline industry received the approval of Congress to overhaul the safety rules for pilots. This all came about after the commuter airline crash February 12, 2009 in western New York. The cause of this crash? Fatigue, something that we can all relate to, something that plagues every healthcare professional. However, this issue was addressed in 2003 and 2004 when it was reported that many residents made mistakes from excessive fatigue of 36-hour call shifts. That time has since been reduced to 30-hour shifts every other day. And while perfusion does not require such a rigorous call schedule, we have our own set of fatigue issues. I cannot speak for most of the community since every program operates differently. However, we can all assume that being understaffed for the duties required by the institution, such as ECMO and VADs, modalities that require around the clock monitoring, will deplete the staffing requirements when scheduled cases must continue. The attentiveness is definitely diminished. Another example is smaller programs of 450 cases or fewer being staffed with the bare minimum. When caseloads and emergencies get hectic, fatigue increases. Perhaps, salary requirements can be partially blamed. Since the base salaries have had to go up in recent years, that leaves fewer funds available to hire additional full time employees. The root of the issue is as personal as a program's protocols and is left for each individual Chief to decipher. However, it is a topic to be considered to meet the safety requirements of being alert during the needed hours for work.

As professionals, I would like to think that we all do our part to protect each other in times of strenuous work and long hours. However, fatigue is still an issue that needs to have an eye kept on it. Sleep deprivation, being the main culprit of fatigue, can cause drastic mistakes behind the pump that our first line of defense, safety systems, may not be linked to. Such examples can be accidentally shutting off the pump during bypass, infusing the wrong medications, over diluting, or even hypoperfusing. Knowing the signs of fatigue and allowing ourselves, as professionals, sufficient breaks, rest and recovery, can avoid all the issues mentioned above. If we can all avoid becoming a statistic, we have served our profession right. Working together as a team can help prevent many of these issues.

References:

http://www.npr.org/templates/story/story.php?storyId=128825665 http://www.thefreedictionary.com/safety http://aviationweather.gov/static/docs/forum/greenway.pdf http://www.news.harvard.edu/gazette/2006/12.14/99-fatigue.html http://www.ncbi.nlm.nih.gov/pubmed/17505227 http://www.nifc.gov/wfstar/reports/signs_of_fatigue.pdf

Membership Questions?





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COMMITTEE SPOTLIGHT: ICEBP

Each 2010 issue of AmSECT Today will highlight one of the many AmSECT committees. For this issue, the spotlight is on the International Consortium for Evidence-Based Perfusion (ICEBP).



International Consortium for Evidence-Based Perfusion (ICEBP)

It's been 11 years since the landmark report published by the Institute of Medicine (IOM) entitled "Too Err is Human." This report was the first of its kind to study the impact of inpatient hospital medical errors. The IOM concluded that nearly 98,000 patients die annually from potentially preventable medical errors, and strongly suggested that it should be classified as a national epidemic. In 2004, the HealthGrades Patient Safety in American Hospitals study calculated that the previous IOM study underestimated the incidence of patient death from medical error by 50%. Consider this: if the above-mentioned calculations are accurate, then approximately 2 million people have mistakenly died in this country at the hands of healthcare professionals since the publication of the IOM report.

Since the landmark IOM report, there has been a growing interest among many in the healthcare field in studying how other industries have tackled issues of safety and quality. For interest, there have been several comparisons drawn between healthcare and the airline industry. Many hospitals and health organizations point to the incredibly low incidence of airline tragedy, due in large part to the strict policies and procedures adopted by this industry. While many in healthcare have developed and implemented policy and procedures manuals as a way of preventing unintended errors, our industry performs poorly as compared to the airline industry. For instance, the number of estimated annual preventable patient deaths is equivalent to 390 jumbo jets full of passengers dying every year. One can't begin to imagine the negative impact on the airline industry if at least one jet is fatally crashing every day.

As perfusionists, we need to ask ourselves what we can do to improve the cardiac surgical culture of safety. We need to be receptive to breaking the mold, and carefully examining solutions for safety at the local, national and international levels. The International Consortium for Evidence-Based Perfusion (ICEBP), a committee within the American Society of ExtraCorporeal Technology, has focused their efforts on the identification and diffusion of safe practices during cardio-pulmonary bypass.

The ICEBP

Mission: The International Consortium for Evidence-Based Perfusion (ICEBP, http:// www.bestpracticeperfusion.org) is a partnership and collaboration between perfusion societies, medical societies, clinicians and industry to improve continuously the delivery of care and outcomes for our patients.

Vision: To achieve this mission, we will focus our energies in two principle areas:

Guidelines

- Review, comment, and/or endorse evidence-based guidelines concerning the practice of cardiopulmonary bypass
- Collaborate with medical societies in the development of guidelines concerning the practice of cardiopulmonary bypass Registry
- Create an international perfusion registry and facilitate its implementation
- Identify gaps between current and evidence-based clinical practice

In order to succeed, the ICEBP will foster communication amongst its membership through a web portal, scientific conference, and internal and external publications.

Guideline Writing

The mission of the Guideline Writing subcommittee is to develop evidence-based clinical practice guidelines for cardiovascular perfusion. This committee has adopted the methodology used by the American College of Cardiology/American Heart Association (www. acc.org/qualityandscience/clinical/manual/ manual_index.htm) Guideline Writing Group.

One of the obstacles discovered early was being able to manage the large volume of work and large number of workers needed to actually achieve our goals of developing guidelines fashioned on the strict ACC/AHA methodology. We needed to actually develop some tools to aid us in each facet of the work. The Flinders Medical Centre group in Australia has developed an online tool, "Guideliner" to help in this endeavor.

Simply put, "Guideliner" helps us organize the review of the abstracts and structures our paper reviews, electronically filing all of the responses enabling the final synthesis of the vast literature to be organized and structured. We are now starting to see some output from groups using "Guideliner" and this promises to be pivotal to the generation of reproducible and consistent work in the future.

Currently, three projects are being undertaken.

- Development of Perfusion Guidelines in conjunction with the Society of Thoracic Surgeons and Society of Cardiovascular Anesthesiologists. Currently these guidelines are in their formative stage, although some sections are more developed than others.
- Update of the Ferraris Perioperative Blood Management Guidelines in conjunction with the Society of Thoracic Surgeons. This work is nearing completion, with a draft manuscript currently under review by co-authors.
- Development of the perfusion guidelines by the ICEBP, especially related to the inflammatory response. These guidelines are progressing well, with the hope of completion of all sections and a manuscript by the end of 2010.

A progress report on all these guidelines was presented at Amsect's 48th International Conference in Reno, Nevada.

Future Work: Requests for Volunteers

Although lots of work is already done, it is never complete. Therefore, the Guidelines Writing Subcommittee is seeking volunteers to help in subsequent projects. The ICEBP will provide support and resources, and you don't need to be a Guideline Specialist to enroll in this interesting endeavor. All are welcome to contribute, including students, and practicing perfusionists. Volunteering could include both short and long-term commitments.

If you're interested, please contact Rob

COMMITTEE SPOTLIGHT: ICEBP

Baker or David Fitzgerald for further assistance.

Publications from the Guideline Writing Committee

The Guideline Writing Subcommittee has recently published two pieces of work:

- An editorial on Perfusion Data in Scientific Journals: Perfusion Standards of Reporting Trials (PERFSORT) just published in *JECT* (*J Extra Corpor Technol.* 2010 Jun;42(2):101-2.)
- "Effect of the Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery Clinical Practice Guidelines of the Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists upon Clinical Practices" currently published in both JECT (J Extra Corpor Technol. 2010 Jun;42(2):114-21) and Anesthesia & Analgesia (Anesth Analg. 2010 Aug;111(2):316-23. Epub 2010 May 20).Pediatric Committee
- The Pediatric Committee has continued to develop and support its collaborative relationship with the STS Congenital Database Taskforce, Multi-Societal Database Committee for Pediatric and Congenital Heart Disease (MSDCPCHD), and the AmSECT Pediatric Committee. In 2009, the ICEBP Pediatric Subcommittee, in collaboration with the AmSECT Pediatric Committee, developed new variables and definitions for the 2010 Update (version 3.0) of the STS Congenital Database that focus on the practice of congenital and pediatric perfusion. A manuscript describing the process and resulting variables and definitions that were accepted by the STS Congenital Database Taskforce has just been published in the World Journal for Pediatric and Congenital Heart Surgery (WJPCHS). (World Journal for Pediatric and Congenital Heart Surgery April 2010 1: 34-43)
- We have worked with the editor of this journal to offer free online-access to this article. Anyone can register for free online access to Volumes 1-3 of WJPCHS at the following URL: www.sagepub.com/journalsProd-Desc.nav?prodId=Journal201975. Through the strength of the STS Congenital Database (over 90 participating congenital heart surgery centers) we hope to identify associations between congenital perfusion practice and patient outcome.

Registry Subcommittee

In the Mission and Vision statement of the ICEBP, it is mentioned that, '...to achieve the mission, an International Perfusion Registry should be created and its implementation facilitated.'

The ICEBP has designed and developed

the ICEBP International Perfusion Registry structure for collecting and analyzing data related to cardiopulmonary bypass. This registry would fill gaps in our knowledge that is not currently covered by other registries in cardiac surgery. It would serve a need to provide feedback to clinicians on the best practices in perfusion.

The first iteration of this registry focuses on the following areas:

- Patient demographics (to adjust for potential patient-level confounders)
- Compliance with published perfusion guidelines
- Cell processing and filtration
- Renal Management
- Factors that influence low Ejection Fraction among patients with normal ejection fraction

The regional cardiac surgery quality collaborative in the state of Michigan has agreed to serve as a pilot organization for this registry. The MSTCVS Quality Collaborative (www.mstcvs.org/qc) promotes and shares optimal processes of care and cardiac surgery outcomes and implements quality improvement initiatives based on regional and national data as well as clinical research and evidence based cardiac surgery practice and guidelines.

To emphasize the approach of the pilot phase (currently underway), the Executive Committee has drafted a White Paper describing the ICEBP International Perfusion Registry. It focuses on the concept, purpose, practical workout, functionality and goals of this initiative.

You can download the International Perfusion Registry White Paper on the Registry Subcommittee page (www.bestpracticeperfusion.org/sections/committees/Registry/ index.html).

Perfusion Safety & Best Practices Meeting 2010

AmSECT's Perfusion Safety & Best Practices in Perfusion 2010 marks our second venture outside of the USA, allowing us to explore the unique position of the ICEBP as a group with international expertise and participation. This year we are building on the theme initiated in New Orleans in 2009 with the union of Perfusion Safety and Best Practices through hands-on simulation training and the knowledge translation.

To Register, please visit: www.amsect.org/ sectionseducation/Best_ Practices/index.html

Date: October 6-9, 2010

Location: The venue will be Toronto, Ontario, Canada with the first two days of the conference hosted at the CAE/ Michener Centre for Advancement of Simulation Education (CASE), a unique private/public partnership between the CAE Healthcare (www.cae.com/en/healthcare/ home.asp) and Michener Institute of Applied Health Sciences (www.michener.ca/). Such a venture leverages over 60 years of best practices acquired in the aviation simulation industry with 50 years of dedicated experience in health care education. With 20,000 square feet of simulation studios, including 24 fully-functional Objective Structured Clinical Examination (OSCE) suites, the centre features flexible studio space that can be used by a variety of healthcare teams including students and practicing professionals in the disciplines of medicine, nursing, imaging, radiation, cardiovascular perfusion and many more.

Keynote Speaker: To complement our program, we are extremely fortunate to have as our keynote speaker Dr. Amitai Ziv MD MHA. Dr Ziv is a worldrenowned expert in the field of medical simulation and has been invited to give keynote talks at multiple medical conferences worldwide, as well as Grand Rounds at leading medical institutions around the world. Dr. Ziv is the Deputy Director of the Sheba Medical Center at Tel Hashomer, Israel, and is responsible for Risk Management, Quality Assurance and Medical Education. He is also founder and Director of MSR - the Israel Center for Medical Simulation. He is also the recipient of national and international awards including The 2007 Charles Bronfman Award for Humanitarian Action and The 2007 Michener Honorary Diploma of Health Science Award for leadership and commitment to the Michener Institute of Applied Health Sciences.

Rich Agenda: We are extremely proud to provide our delegates the unique opportunity to experience a dedicated high fidelity simulation environment with four concurrent simulation sessions. This opportunity, coupled with our 10 didactic sessions (focused on the perfusion safety, use of simulation, ICEBP registry and guideline development and implementation), makes this an extraordinary meeting to be savored and not missed.

Online Newsletter regarding the ICEBP

By going to the followings link, you can subscribe to the ICEBP newsletter! www.bestpracticeperfusion.org/sections/ Newsletter/index.html

We would like to thank Medtronic Inc. for their contribution of translating our latest newsletter into Spanish.



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Citations:

- Shann et al, An evidence-based review of the practice of cardiopulmonary bypass in adults: A focus on neurologic injury, glycemic control, hemodilution, and the inflammatory response; *Journal of Thoracic and Cardiovascular Surgery*, 2006;132:283-290.
 Ferraris et al, Perioperative Blood Transfusion and Blood Conservation in Cardiac Surgery: The Society of Thoracic Surgeons and The Society of Cardiovascular Anesthesiologists Clinical Practice Guideline; Annals Thoracic Surgery, 2007:83:S27-86.
 Preston et al, Clinical Gaseous Microemboli Assessment of an Oxygenator with Integral Arterial Filter in the Pediatric Population, *Journal of ExtraCorporeal Technology*, 2009; 41:226-230.
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FEATURE ARTICLE

Say "Hello" To ECMOjo

By Gary Grist RN CCP Children's Mercy Hospital and Clinics Kansas City, Missouri

Perfusion simulators for training are becoming very popular and a new Source Forge open source simulator from Hawaii is now available to anyone wishing to test their skills in using a heart/lung machine to keep a patient alive: http://ecmojo.sourceforge. net. The latest version of "ECMOjo" became available in February 2010. ECMOjo is not



Gary Grist RN CCP

a typographical error; it is a contraction of two words, ECMO and mojo (a magical charm). The program was developed by the Telehealth Research Institute at the John A. Burns School of Medicine of the University of Hawaii, under a grant from the Department of Defense. The Hanuola Center uses this and other tools to train its physicians, nurses and other personnel in the basics of ECMO. The Hanuola Center is the ECMO Program of Hawaii, which serves to provide pediatric extracorporeal life support services for Hawaii and the Pacific Rim region. The simulator was developed in cooperation with Tripler Army Medical Center, Kapi'olani Medical Center for Women and Children, Kaiser Permanente of Hawaii, the University of Hawaii and the University of Pittsburgh Medical Center. The project manager is Mark T. Ogino, MD, Hanuola ECMO Medical Director. Among many other contributors are two perfusionists who participated in the simulator's development, Kristen Costales CCP, ECMO Perfusion Coordinator and Kent Kelly CCP.

ECMOjo is an open source program, which means it is free to use online or for download under the terms of the Berkeley Software Distribution License. It is available for Windows, Macintosh, Linux and UNIX operating systems. The simulator uses a graphical interface, delightfully illustrated by artist Kaleiohu Lee.

The ECMOjo screen is divided into left and right sides. On the left, the graphic interface shows a patient (an infant) attached by blood tubing to a heart/lung (ECMO) pump on the right side.

On the left side, the patient's blood pressure, arterial blood saturation, heart rate, venous blood saturation, temperature, respiratory rate and other parameters are displayed above the patient. Modifications to the circuit cause changes to the patient values. For example, if the VA ECMO pump flow is increased, the patient's blood pressure goes up. If the sweep gas flow is reduced, the patient's pCO2 increases. If the water temperature is reduced, the patient's temperature goes down. If the pump stops altogether, the patient will rapidly decompensate in all vital areas. Lab values such as arterial blood gases, hematology (CBC & coags), electrolytes, lactate, and ACT values can be reviewed and new values obtained. These can also change with pump changes; for example, increasing acidosis and lactate values correlating to decreasing pump flow. Chest X-rays and head ultrasound images can be viewed and cardiac ECHO reports read. Ventilator parameters can be changed from rest settings to emergency settings. Another indicator shows if the patient is on venoarterial or venovenous ECMO.

Placing the cursor over the patient brings up a menu that allows the operator to suction the endotracheal tube, check the cannulae for bleeding or kinks, assess urine output, assess level of sedation and even check for a dirty diaper. A short summary of the patient's diagnosis and current status can also be viewed. During the simulations, the patient status may worsen. This is visually enhanced as the patient becomes progressively paler and

bluer. This visual change provides added urgency to each simulation.

On the right side of the screen is the ECMO circuit with its disposable components and hardware. The circuit can be checked or changed with the touch of a button. The pump flow can be regulated. The sweep gas FiO2 and flow can be controlled. The heater temperature can be changed or the unit replaced. The circuit pressure monitor alarm limits can be adjusted. There is a bubble detector and four interventional sites that allow the operator to administer PRBC, FFP, platelets, heparin, catecholamines, 5% albumin or sedatives.

On the top right is a timer/clock used during simulations to assess the operator's speed at solving the various problems presented in the simulations. A red light flashes and an audible alarm sounds when the infant's vital signs become abnormal. The audible alarm is unique and almost comical. It is reminiscent of the klaxon horns used in submarines ("Dive! Dive! Dive!"). Anyone in the room when the game is being played is inevitably drawn to see the cause of the strange noise.

On opening the program, the operator can choose tutorials (Overview, Introduction, Detailed and Advanced) to train in its use. The operator can also choose to use venoarterial or venovenous cannulation, a silicone or hollow fiber oxygenator, and a roller or centrifugal pump. After gaining familiarity with the fundamentals, the operator can choose from two broad categories: Scenarios and Simulations.

Scenarios are step-by-step training exercises that teach the operator about the various procedures needed to deal with circuit and/or patient problems. These include such things as routine circuit checks, coming off pump and going on pump, pump failure, air in the arterial line, circuit failure, temperature control, sweep gas control, oxygenator rupture, high system pressures, etc.

Simulations are exercises to test the operator's skill in recognizing a problem and correcting it. During the simulations a timer counts down to warn that some problem will soon develop. Once the counter reaches 'zero', another timer starts to measure the time needed for the operator to diagnose the problem and select the appropriate solution. For example, increasing system pressures might stop the pump, causing the infant's blood pressure and heart rate to fall as well as arterial desaturation. The cause might be a kinked arterial cannula, which is corrected very simply. On the other hand, the high system pressure might be caused by a developing DIC which is clotting the oxygenator and which can only be detected by a review of the hematology labs and only corrected by changing out the entire circuit. If the cause of the infant's deterioration cannot be readily determined, immediate resuscitation steps may be needed, such as infusing volume, giving catecholamines, or going to emergency ventilator settings. These may buy time until a solution can be found and the pump restarted. Other simulations might deal with equipment failure, progressive acidosis, platelet consumption, agitation, a large blood loss from an accidental arterial decannulation, or a number of other things. If the problem is diagnosed and solved before the allotted time expires, the patient survives. Otherwise, the patient expires and the operator fails the exercise.

ECMOjo is still a work in progress. There seem to be a few bugs in the system. But, the website has contact links to the Telehealth Research Institute and encourages feedback by users to help in solving these problems.

On first impression, ECMOjo seems like a quaint, fun, ECMO video game, but it is really much more sophisticated than it first appears. Even an operator with 40 years of perfusion experience and 25 years of ECMO experience (like me) can find this program quite challenging. So, say hello to ECMOjo and have some fun! You might even learn something along the way.

GOVERNEMENT RELATIONS COMMITTEE

Federal Changes in the Delivery of Health Care

By Lee Bechtel

Director, Government Relations Committee

Robert D. Longenecker BS LCP CCP Chairman, Government Relations Committee

There may be a few people in the country that don't know about the recent enactment of the comprehensive health care system reform law, otherwise known the Patient Protection and Affordable Care Act (PPACA) of 2010. This new law, to be implemented over the next few years, includes several future Medicare hospi-



Lee Bechtel

tal and cardiovascular physician payment policy changes, along with the imposition of new medical device tax on manufacturers of cardiovascular equipment and supplies used by perfusionists in the operating room.

AmSECT's Government Relations Committee is focused on perfusionist state credentialing for protection of clinical practice entry requirements to better ensure patient safety and the competent delivery of perfusion services. However, knowledge about other public policy changes that indirectly impact the profession is also valuable. Examples are the safety and effectiveness of medical devices used by perfusionists and regulated by the Food and Drug Administration (FDA), changes in Medicare CMS (Center for Medicare and Medicaid Services) coverage, and reimbursement policies impacting hospitals and physicians for providing high cost surgical procedures.

The members of the Government Relations Committee share the opinion that knowledge regarding such matters should not be excluded from a perfusionist's day-to-day clinical practice. Perfusionists grow wise in the science, techniques, and technologies in their own profession, but they need to have some fundamental understanding regarding the external governmental influences and factors impacting their work environments. These regulatory issues are important whether perfusionists are employed by hospitals, surgeon

groups, or independent contract providers of services. With this in mind, the following overview highlights some of the coming changes in Medicare payment policy. Other health care reform changes will be discussed in *AmSECT Today* with future concise GRC articles.

Medicare Bundling of Physician and Hospital CABG and Heart Valve Replacement Case Payment

In the 1990's the Medicare Participating Heart Bypass demonstration project found that bundling of hospital Diagnosis Related Group (DRG) payments and Medicare Physician Fee Schedule (PPS-Prospective Payment System for physicians) payments could reduce Medicare costs for these types of high cost cardiovascular procedures. In 2008, the Medicare Physician Advisory Committee (MEDPAC) recommended to the Congress, and the Congress approved, a two-year pilot program for these types of cases. Five hospitals were selected from different parts of the country to participate.

At these pilot project hospitals, each hospital would receive a combined payment amount that included the DRG payment amount and the



Robert D. Longenecker BS LCP CCP cardiovascular surgeon PPS payment amount. To get Medicare beneficiaries to use these hospitals, they would receive an incentive payment that could be used as they saw fit. The pilot project Medicare cost data collected showed a combined 5% cost savings reduction for CABG and heart valve cases done in these five hospitals.

In the Medicare sections of the Patient Protection and Affordable Care Act (PPACA) (PL 111-148), the CMS has been given the regulatory authority to expand the pilot program to a two-year Regional Demonstration

program starting in 2011, and authority to convert this to a national payment system in 2013 or thereafter, based on the collection of more cost and utilization data.

Two adjustments when converting to a national payment system would also come into play. First, university and teaching hospitals would be exempt from the global fee payment for hospital and physician services. Second, rural-based hospital global fee reimbursement amounts would be adjusted to reflect a surgical case index number. Under current Medicare hospital DRG payments, rural-based hospitals already receive a percentage increase from what is paid to urban hospitals to reflect the higher cost of hospital care, due to unique manpower and demographic issues in less populated areas.

"The future ain't what it used to be."

- Yogi Berra, Baseball Hall of Fame Player and Former New York Yankees Coach

Physician/Cardiovascular Surgeon Reaction

In the June 2008 report and recommendation to Congress on bundling of high cost surgical procedures, not just CABG and heart valve cases, the MEDPAC argued that even though hospital DRG payments were already a bundled payment. They felt that extending the concept to physicians would encourage doctors and hospitals to

work together to control Medicare program costs and improve patient quality of care. Of course, cardiovascular physicians and other medical specialty physicians took issue with the concept of giving hospitals too much control over physician payment rates. Sending a lump sum payment might potentially provide an incentive to skimp on medical care services to maximize hospital profits.

While these arguments were generally rejected during the Congressional and public debate over the Medicare reimbursement reforms promulgated and subsequently enacted into law, a post-passage financial analysis was performed by the CMS covering the complete range of Medicare payment system reforms. It showed that hospitals and hospital administrators will be facing tough challenges as well. Without delving into the other major payment policy changes directly impacting the financial viability of hospitals in the future, the CMS has estimated that one in six hospitals in the country (15%) could very well go bankrupt over the next ten years. For example, the hospital DRG payment rate for 2011, as now scheduled, will be further reduced by 2.9%. This reduction will be included in the bundled payment rate for the global fee paid to hospitals for high cost surgical procedures.

THEME ARTICLE

Indirect Impact on Perfusion Practice and Future Income Potential

Reimbursement changes by the Federal Government are not the only change we will see. There is a newly enacted medical device tax on manufacturers of cardiovascular equipment and supplies used by perfusionists and all other health care professionals. The Health Information Technology for Economic and Clinical Health (HITECH) enacted in 2009 mandates hospitals to have a seamless interoperable patient medical record information system by 2014 or face Medicare payment penalties. It remains to be seen how these new laws will affect perfusionists, regardless of how they are employed or conduct their clinical practices. The impact on salaries, benefits, and the ability to continue to provide innovation in the delivery of patient care are largely unknown. This is not only true of the perfusionist community, but also every other health care professional.

These changes upon us clearly demonstrate what a famous New York Yankees coach said many years ago – "The future ain't what it used to be". The health care industry in the United States is likely to be one of constant change for the foreseeable future.



"Blue to Red, Don't Run Dry, and Don't Gel"

By William Mathew Medlin RRT RCP BS CCP Savannah, GA

As a graduate of the Medical University of South Carolina, I heard the faculty members always instilling very important safety information toward our careers as skilled perfusionists. The mnemonic above is one I will never forget because it displays imperative safety information to our practice in the operating room. I always compare operating the heart-lung machine to flying an airplane and how we hold the patient's life in our hands at all times. We should always strive to be quick on our feet, ready to troubleshoot at any time.



Mat Medlin RRT BS CCP LP

A perfusionist should always perform a pre-bypass checklist and record the results. These checklists can become routine and items are often overlooked, so it is critical to perform the checklist slowly and thoroughly so no errors occur. Once cardiopulmonary bypass is initiated, there are a few safety checks to consider:

On Bypass Safety Checks

- ✓ Blood flow at proper rate
- ✓ Arterial line pressure is normal
- Oxygen started at proper flow/concentration
- ✓ Oxygen saturations normal
- Patient's MAP normal
- Temperature appropriate
- Coagulation status acceptable
- ✓ Vaporizer turned on at appropriate level

Safety Devices Checked

- Bubble Detector ON
- ✓ Level Detector ON
- Manifolds in right position
- Drugs given as required
- Oxygen analyzer ON

The best safety device available today is the perfusionist, one who is well trained, experienced, and qualified to handle routine as well as emergency situations. It is doubtful that anyone would encourage an indepth conversation with the pilot of an airplane during final approach and landing. Distracting the perfusionist with additional responsibilities and gadgets can, and has, created the same terrible results.

Always remember that patient safety is our number one priority! Perfusionists should always train themselves to 'do it the same way' every time; this way, in emergent procedures you cover all your bases. I really have a great appreciation for perfusion education, because one of the main objectives is toward perfusion safety. Now, with simulators in use, errors can virtually be eliminated.

Perfusion Safety & Best Practices in Perfusion October 6-9, 2010

CAE Michener Simulation Centre and the Fairmont Royal York Hotel

Toronto, Ontario, Canada





Sponsored by

American Society of ExtraCorporeal Technology In joint collaboration with the

International Consortium for Evidence-Based Perfusion (ICEBP) and the Michener Institute for Applied Health Sciences and the CAE Michener Simulation Center





ICEBP's Mission is:

To continuously improve the delivery of care and outcomes for surgical patients through peer review of scientific publication by:

- DEVELOPING evidence-based guidelines for extracorporeal circulation
- PROMOTING the integration of these guidelines into clinical practice
- IDENTIFYING gaps in the medical literature
- ENCOURAGING research in areas where evidence is scarce
- EVALUATING improvement in surgical care related to the adoption of guidelines



AmSECT Today - September/October 2010



CONFERENCE REGISTRATION Perfusion Safety/Best Practices in Perfusion 2010 October 6-9, 2010

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PRESIDENT'S MESSAGE

Continued from page 1

surgeons,Evidence-based medical practice guidelines are here now, and will be even more prominent in the structure of our future health care system.

As perfusionists know, the most common contributing factors to patient safety in the performance of a CPB case are equipment malfunctions or operator error. Operator error may not just involve a single perfusionist. It can include problems that come from miscommunications between surgical team members and/or the surgeon. More often than not, despite due diligence in the conduct of a pre-bypass checklist, running calculations, and selecting equipment, every patient is their own island of yet-to-be manifested associated medical conditional influences. In other words, expected responses do not turn out as anticipated and have to be managed in order to maintain a patient within the accepted normal ranges for a number of on-pump measurements - venous drainage, blood gases, cannula disruption, occlusion of cardioplegia lines, you name it.

Attention to safety and the use of critical judgment skills in response to a patient's needs, in support of the patient's on-pump condition during a CPB case, in support of the surgeon and surgical team, to successfully get to the endpoint of having a good patient post surgical case medical outcome is the goal. Added to these influences and factors, are new challenges that arise with the incorporation of new techniques and/or devices.

In the bigger picture of delivery of quality in performing perfusion services, these safety factors and the associated patient outcomes also contribute to the use of evidence-based perfusion, or best practices. In developing the scientific sessions for its perfusion best practices symposiums, AmSECT has actively engaged the International Consortium for Evidence-Based Perfusion (ICEBP).

Safety and the performance of best practices go hand in hand with continued competency assessment, which is critical for reducing medical errors, either equipment or operator related. The beginning use of CPB simulation in a few perfusion training programs poses a tremendous advancement for the whole of the profession. Its use, in my view, has clinical practice value to currently practicing perfusionists, and not just to students. Articles about this topic appeared in the March/April and July/August editions of AmSECT Today. Clinical simulations have been used in other professional medical fields for many years. It's application to the performance of perfusion, and the techniques of this not-so-new technology, will be on display at AmSECT's upcoming Perfusion Safety/ Best Practices 2010 symposium on October 6-9, in Toronto, Ontario.

Having been a practicing perfusionist for 28 years, I am envious of the recent use of cardiovascular simulation. It was not around when I trained, which is probably why we older perfusionists have more worry wrinkles and gray hair. Nothing does better than real world experience and the knowledge translation that takes place during a case. This works well when things go right, but not so well when it comes to making splitsecond decisions to prevent serious harm to a patient. With simulation, the learning curve for students is reduced, and potential safety issues avoided as they start pumping their own cases. Consideration should be given, eventually, for voluntary simulation for perfusionists already in practice. In either case, simulation mixed with real world cases of things gone wrong, could lead to the improved delivery of perfusion services, and potentially improved CV patient medical outcomes.

Not all individual patient safety circumstances can be pre-planned and managed in advance of a case. However, attention to and effectively dealing with safety issues does contribute to the execution of perfusion best practices. The evidenced-based use of standards and guidelines in the performance of perfusion can serve individual perfusionist needs, and positively contribute to the conduct of our profession now and in the future.

UPCOMING MEETINGS



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Safety During Cardiopulmonary Bypass

By Kayla McClintock

Rush University

How do we maintain safety during cardiopulmonary bypass? Since cardiopulmonary bypass was first used in the early 1950s, there have been great attempts to ensure the patient's safety. Due to advancements in technology, the practice of perfusion and cardiopulmonary bypass have become exponentially safer. Circuits have become simpler and more safety devices have been incorporated as well. However, it is not only the pump that has improved; the profession of perfusion has also come a long way.

Perfusion first began as on-the-job training and has progressed all the way to national accreditation. Educational programs have also advanced to offering a Master's Degree in Perfusion Technology. With the new developments of



Kayla McClintock

increasing technology, it is just as important for the perfusionist to stay up-to-date as well. I feel that the expertise of the perfusionist is the most important key to cardiopulmonary bypass safety.

The heart-lung machine and the perfusionist are not the only factors in contributing to patient safety. Conduct and communication in the operating room as well as surgical technique, are also major players. It is extremely important to maintain a professional attitude in the OR and to be able to communicate promptly and effectively. Listening and being on your toes at all times can greatly contribute to patient safety from what I have seen. With technological advancements concerning the pump, there are also advances being made in surgical technique, such as the increasing popularity of minimally invasive procedures. Ultimately, these new techniques will also lead to greater patient safety.

The level detector, the bubble detector, autoclamps, pressure, temperature and gas monitors are all safety devices that I have encountered so far during my clinical rotations. They all greatly contribute to cardiopulmonary bypass safety by eliminating danger to the patient. However, it takes more than technology and safety devices to perfect the practice of perfusion. It also requires a well-educated professional to achieve maximal safety and cardiopulmonary bypass success.



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Willingness to Serve Application 2011

Volunteering is a subject of paramount importance to our organization. AmSECT is dedicated to promoting and disseminating knowledge to our peer perfusionists around the world. Without volunteer leaders, our organization cannot fulfill this mission. Volunteering requires self-sacrifice and does not return any financial gain. However, the reward for

giving back to our professional community is many-fold. AmSECT has improved itself throughout the years and continues to work with other organizations toward further progress in our industry. Without volunteers and their efforts, stagnation occurs, and this hurts us all. Please consider volunteering with AmSECT and set an example of leadership for other perfusionists and the future perfusionists of this rewarding profession we all love. As medical heath care practitioners, our number one responsibility is patient welfare; our second responsibility may be improving the community in which we practice. All new and current members are encouraged to run for offices that are currently open for AmSECT. Your example will show all how much you care and will raise the bar for AmSECT.

Volunteer Leadership Positions Available

- Director, Zone 1 Three-year term. Zone 1 includes the following states: Alaska, Arizona, California, Colorado, Hawaii, Idaho, Montana, New Mexico, Nevada, Oregon, Utah, Washington, and Wyoming. Note: Alaska residents need not apply as Alaska is already represented on the Board of Directors.
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- □ Achievement Recognition Committee Member Three-year term. Member serves as Chairman in third year of term.
- Ethics Committee Member Three-year term. Member serves as chairman in third year of term.
- □ Nominating Committee Member Three-year term. Member serves as Chairman in third year of term.

All candidates must be AmSECT members in good standing to be considered for nomination. All volunteer leadership serving on any committee, or in any office of AmSECT, will be required to complete a Conflict of Interest Disclosure.

Willingness to Serve application and attachments must be submitted no later than November 30, 2010 to earn recognition on the ballot. Questions? Contact Nominating Committee member Mat Medlin, rrtccp06@yahoo.com

Submission Instructions

Willingness to Serve Applications must be filed online at http://amsect.societyhq.com/members/wtsa. iphtml.

In an effort to assist the Nominating Committee and the membership in making the selection, all candidates must submit the following:

- Biographical statement of 150 words or fewer to include:
 - Educational background
 - Job experience
 - AmSECT experience
- □ Statement of why you are running for this position, in 150 words or fewer
- Dependence Photograph of yourself

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BEST PRACTICES & SAFETY



By Christina Burn CCP LP

- 1. More than 90 percent of allogeneic blood transfusion complications have been attributed to which of the following:
 - a. Leukocytes
 - b. Thrombocytes
 - c. Erythrocytes
 - d. Plasma
- 2. Once a person has been infected with the HIV virus, how long is the general period between inoculation and seropositivity (using traditional screening tests)?
 - a. 1 week
 - b. 3 weeks
 - c. 1 month
 - d. 6 to 12 weeks
- 3. When stored properly, how long are red blood cells safe for infusion?
 - a. Up to 21 days
 - b. Up to 30 days
 - c. Up to 42 days
 - d. Up to 56 days
- 4. If not used properly, a gas scavenging line to scavenge waste gas from a hollow-fiber membrane oxygenator could inadvertently cause back pressure into the oxygenator. Such pressure could introduce gas into the blood phase resulting in an air embolism. True or False
- 5. According to the Joint Commision's 2010 National Patient Safety Goals, which of the following is their number one goal?



b. Improve the accuracy of patient identification

Christina Burn CCP LP

- c. Improve communication among caregivers
- d. Improve safety of medication use
- 6. Which of the following would be seen if there was a leak in the gas supply line to the CPB circuit?
 - a. Bright red blood in the arterial line
 - b. Decreased CO2 levels
 - c. Decreased PaO2 levels
 - d. No change would be seen
- 7. Which of the following abbreviations is incorrect and should NOT be used while charting?
 - a. U for units
 - b. Mcg for micrograms
 - c. L for liter
 - d. % for percent
- 8. A reported advantage of a centrifugal pump vs. a roller pump is a reduced risk of passing clinically significant amounts of air into the arterial line. True or False
- 9. According to Gravlee, a minimum of how much air needs to be introduced into the circuit for a centrifugal pump to become deprimed and stop pumping?
 - a. 12 mL
 - b. 25 mL
 - c. 32 mL
 - d. 45 mL

SELF QUIZ

 A pregnant patient requiring CPB should be placed in a supine position with their left hip elevated, also known as a right lateral position.

True or False

- 11. Irreversible ischemic injury can become apparent with coronary occlusion in the working myocardium after how many minutes?
 - a. 5 min
 - b. 10 min
 - c. 20 min
 - d. 30 min
- Protein denaturation and damage to the cellular portions of blood increases with a heater-cooler water temperature above 42 °C and a temperature below 4°C.

True or False

- 13. Of all the health risks to open heart team members, which of the following is the most serious risk?
 - a. Bloodbourne pathogens
 - b. Blade cuts
 - c. Needle sticks
 - d. Back injuries

References:

AmSECT. 15 July 2010. <http://www.amsect.org>

Gravlee GP et al. *Cardiopulmonary Bypass*. 3rd ed. Philadelphia, PA: Lippincott Williams & Wilkins, 2008

International Board of Blood Management. 15 July 2010. http://www.intbbm.org/

Pall Corporation. 15 July 2010. <www.bloodtransfusion.com>

2010 AmSECT Today Themes

January/February	Extended Life Support
March/April	Adjunctive Perfusion/Ancillary Perfusion Responsibilites AmSECT International Meeting Promotion
May/June	Emerging Technologies - Pharmacology
July/August	AmSECT International Meeting Summary Blood Management
September/October	Perfusion Safety/Best Practices in Perfusion
November/December	Pediatric and Congenital Perfusion

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Tom Irwin CCP	Lexington, KY
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Teng Siew Yan	Singapore, Singapore
Eoin Coleman	Cork, Ireland

PERIOPERATIVE BLOOD MANAGEMENT CLINICIAN

Deborah Reid	Idaho	Falls,	ID
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STUDENT

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Dana Hutchison	Penrose, NC
Carrie Kovaleski	Santa Ana, CA
Marie Letourneau	Indianapolis, IN
Chelsea L. Starrett	Milwaukee, WI

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AmSECT Awards!

AmSECT National Awards Nominations Accepted Through November 30, 2010

The Awards will be presented at AmSECT's 49th International Conference, April 13-16, 2011 in New Orleans, LA. Nominations must be received by November 30, 2010, and can be submitted by visiting the home page of www.amsect.org. Nominations are accepted from members only; for UserID and password reminders, please contact liz@amsect.org.

The Gibbon Award

The award is designed to honor a candidate making a significant contribution to the cardiopulmonary discipline interrelating with the field of extracorporeal circulation.

- * The specialty of the candidate is not a criterion for the award.
- The significant contribution must be in, or relate to, the field of extracorporeal circulation.
- * The candidate may receive the award only once.
- * The award consists of a medal and a check in the amount of \$1,000.

AmSECT Award of Excellence

The Award of Excellence is presented annually to a perfusionist who demonstrates that work of excellence which best exemplifies creativity and intellectual honesty in perfusion. This award is presented for excellence in any area such as education, continuing education, research, publication or leadership.

- * The person receiving this award must be active in the field of extracorporeal technology and be a member of AmSECT.
- * No perfusionist may receive this award in two consecutive years.
- * The award consists of a plaque and a check in the amount of \$1,000.

AmSECT Perfusionist of the Year

The Perfusionist of the Year Award is presented annually to a perfusionist making significant contributions to the field of extracorporeal technology.

- * The award is presented based on a variety of reasons. Examples include excellence in the field of perfusion or extracurricular activities associated with the field of perfusion.
- * The award recipient must be active in the field of extracorporeal technology and must be a member of AmSECT.
- * No perfusionist may receive this award in two consecutive years.
- * This award is not to be presented for any one specific reason repeatedly, for there are many people in the field of extracorporeal technology making worthy contributions in a variety of areas who deserve recognition.
- * The award consists of a plaque and a check in the amount of \$1,000.



Log into the Members Section at www.amsect.org to submit your nominations

AmSECT PAST AWARD RECIPIENTS

Gibbon Award

1974	Dr. Clarence H. Dennis
1975	Dr. Charles A. Hufnagel
1976	Dr. Denton A. Cooley
1977	Dr. Clarence Crafoord
1978	Dr. John Osborne
1979	Dr. C. Walton Lillihei
1980	Dr. P. Galletti
1981	Dr. Arthur C. Beall
1982	Dr. Marian I. Ioniscu
1983	Dr. E. Coverse Pierce II
1984	Dr. Yukihiko Nose
1985	Dr. John Kirklin
1986	Dr. Norman Shumway
1987	James P. Dearing
1988	Dr. Henry Swan
1989	Dr. H. Edward Garrett
1990	Dr. Dwight C. McGoon
1991	Dr. W. Gerald Rainer
1992	Dr. Robert H. Bartlett
1993	Dr. Michael E. DeBakey
1994	LeRoy H. Ferries
1995	Bennett Mitchell
1996	Dr. Richard A. DeWall
1997	Dr. Theodor Kolobow
1998	Jeanne Lange
1999	Dr. Edward Verrier
2000	Dr. David C. Sabiston, Jr.
2001	Dr. Thomas B. Ferguson, Sr.
2002	Dr. O.H. Bud Frazier
2003	Michael W. Dunaway
2004	Dr. Robert F. Dunton
2005	Madeline M. Massengale
2006	O. Wayne Isom MD
2007	Ludwig K. von Segesser MD
2008	Gerald M. Buckberg MD
2009	Raymond Hawkins
2010	William J. DeBois CCP

Award of Excellence

1976	Jeri L. Dobbs
1977	Edward C. Berger
1978	Charles C. Reed
1979	James P. Dearing
1980	Emily Taylor
1981	Gary Reeder
1982	Mark Kurusz
1983	Jerry Richmond
1984	Munier Jallad
1985	Nancy Achorn
1986	William J. Horgan
1987	Sandra S. Witherington
1988	Jeanne Lange
1989	Rebekah Trittipoe
1990	LeRoy H. Ferries
1991	Beverly Parault
1993	Aaron Hill
1994	Phyllis Palmer Stark
1995	Alfred H. Stammers
1996	Jeff Riley
1997	Dennis Rivard
1998	Robert D. Longenecker
1999	lan R. Shearer
2000	Debbie Raymond
2001	Eric H. Jenkins
2002	Jeff Edwards
2003	Linda B. Mongero
2004	Joseph J. Deptula
2005	William E. Harris
2006	Craig Vocelka
2007	Ron Richards
2008	Paul C. Cappola
2009	David Fitzgerald
2010	Robert C. Groom



Perfusionist of the Year

4074	
1974	Madeline M. Massengale
1975	Calvin R. Scott
1976	Charles C. Reed
1977	Larry W. Cavanaugh
1978	A. Earl Lawrence
1979	Diane Clark
1980	Bob Pfefferkorn
1981	Carl L. Freytag
1982	Nancy Achorn
1983	Michael B. Hurdle
1984	Scutter Newton
1985	LeRoy H. Ferries
1986	William J. Horgan
1987	Mary Hartley Winkler
1988	Sandra S. Witherington
1989	Susan Haubert
1990	Dennis R. Williams
1991	Rebekah Trittipoe
1992	Dennis Rivard
1993	Debbie Gherlone
1994	Craig R. Vocelka
1995	Beverly Parault
1996	James Langwell
1997	Richard Burns
1998	Carl Barringer
1999	Sherry C. Faulkner
2000	Ron Richards
2001	Linda B. Mongero
2002	Gary Grist
2003	John M. Toomasian
2004	Carla Maul Williams
2005	Gary Beckman
2006	Bruce Searles
2007	Joseph J. Deptula
2008	Susan J. Englert
2009	Bryan Lich
2010	Kenneth G. Shann

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Appendix A.9

Hanuola - ECMO Program of Hawaii (176)

Unique ID	PatID	Run	Birthdate	Age	Date On	Date Off	D/C Alive
Pulmonary							
Neonatal							
1762007001	36815	1	9/14/2007 22:51	6 Days	9/20/2007 13:21	9/25/2007 16:20	False
1762007002	36944	1	10/8/2007 19:35	2 Days	10/10/2007 10:03	10/14/2007 12:00	True
1762008001	37403	1	1/4/2008 6:49	1 Days	1/5/2008 14:15	1/6/2008 14:42	True
1762008004	40359	1	11/25/2008 6:20	6 Days	12/1/2008 11:33	12/13/2008 18:21	True
1762009001	40360	1	3/2/2009 17:00	1 Days	3/3/2009 18:36	3/6/2009 12:52	True
1762009005	42413	1	9/2/2009 14:24	5 Days	9/7/2009 7:21	9/11/2009 18:21	True
1762009006	42414	1	10/3/2009 9:44	1 Days	10/4/2009 9:26	10/11/2009 13:07	True
1762009010	42418	1	11/25/2009 3:21	6 Days	12/1/2009 18:15	12/2/2009 16:14	False
1762010001	43027	1	1/19/2010 20:00	2 Days	1/21/2010 14:15	1/23/2010 12:39	True

Pediatric

1762009003	41215	1	3/29/2009 0:00	1 Months	4/30/2009 16:17	5/19/2009 16:14	False
1762009004	41321	1	6/26/1995 0:00	14 Years	7/25/2009 3:35	8/7/2009 14:46	True
1762009009	42417	1	2/29/2004 0:00	5 Years	10/29/2009 17:52	11/17/2009 3:04	False
1762010002	43299	1	8/18/2007 0:00	31 Months	3/9/2010 13:19	4/5/2010 10:15	False
Adult							

Cardiac

Neonatal							
1762008003	39181	1	7/9/2008 16:20	10 Days	7/19/2008 11:59	7/23/2008 10:00	True
Pediatric							
1762008002	37808	1	10/12/2000 0:00	7 Years	3/14/2008 2:47	3/18/2008 14:54	False
1762009002	40715	1	1/11/2008 0:00	15 Months	4/22/2009 7:31	4/26/2009 16:20	True
1762009007	42415	1	7/27/2009 0:00	3 Months	10/12/2009 9:16	10/28/2009 8:30	True
ECPR							

Pediatric

1762009008	
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42416 1

11/24/2001 0:00

Appendix B.1

ECMOjo Evaluation August 13 2010 Melody Kilcommons

Scenarios

Should we add comment if no bridge, or saline bridge, clamp arterial /clamp venous, then open bridge or add comment check your institutional guidelines? Not sure with partially open bridges, saline filled bridges and/or no bridge this is something that we should comment on or not?

Simulation 1

I think it works well. Perhaps decrease the amount of time for the scenario to start?

Simulation 2

Decannulation

Drops of blood coming from the neck

Success pathway - click baby and check for bleeding

I think there may need to be some consideration for those that think there is significant bleeding at the cannulation site, (which is what it looks like) they then clamp the circuit, go to emergency vent settings and give volume to the patient?

Can differentiate from patient bleeding and cannula site bleeding in ECMOjo?

3/5 said that they failed the first time choosing the above listed pathways instead of check for bleeding.

When you complete the scenario by checking for patient bleeding after you receive the ECMO results it makes sense and you can then pass.

Simulation 3

Feedback on this scenario was that each time you enter the scenario the labs change. I did it 7-8 times and I don't think the labs trigger the action that they should. Twice these were my labs 2 minutes into the scenario. I never gave fibrinogen or platelets.

onitor	Exit			
CDI M	Hematolog	y (Lab	
		3	2	
8	WBC	9.5	12.1	
뛷	Hgb	15.0	15.0	
÷	Hct	45.0	45.0	
	Platelets	324	327	
ā.	PT	16	14	
	PTT	103	107	
	Fibrinogen	129	131	
			•	J

If I give fibrinogen more than once, the CVP increases from 14 to 18 and an alarm goes off.

There are never clots in the circuit the circuit check is always ok.

The labs are always changing each I perform the scenario twice it worked the other 8 times the labs were not appropriate for this scenario, platelets were high normal.

When I change the circuit and one time the blood pressure was way too high and another time it was still at a mean of 28 and I had to give blood cells to get it up

The most frustrating thing about this scenario is that even after reading the ECMO results, I cannot pass this scenario. I tried over 12 times.

Participant feedback ~ No matter what they tried even after reading the ECMO results they could not illicit a "success"

Simulation 4

Good