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Development of a Novel Integrated Portal and Draping System Using Intraoperative Simulation

Presenting Author: Neil G Feinglass MD FCCP FASE

Co-Authors: Kenneth Dye CVPA, Timothy S.J. Shine MD
Mayo Clinic Florida Departments of Anesthesiology and Cardiothoracic Surgery
4500 San Pablo Rd. Jacksonville, Florida.

Background Introduction: National Guidelines and Databases have recently been developed to monitor hospital outcomes and care. One aspect of this oversight, Surgical Hospital Infections is a benchmark that most hospital QA measures are easily tracking. With this new benchmark, other parallel changes in surgical procedures such as the integration of Surgical Ultrasound and other useful electronic technology (Radioactive Marker Wands etc.) have been incorporated. All of these critical pieces of electronic technology mandate the problematic use of electrical tethers to supply electricity and directional activity from their CPU's (Central Processing Units). This equipment has in the past required sterile sheathing that originates from the (CPU) and extends to the patient onto the operative field potentially contaminating the sterile surgical field. Our Institution and Inventors have Co- developed a novel design into the standard surgical draping systems such that common procedures may utilize this needed technology and route the non-sterile electronic tethers through the "portals" to maintain absolute surgical and procedural sterility. This concept to was carried out using benefits of medical simulation. This abstract identifies the methods used to improve design efficiencies prior to use on live patients.

Methods: True mocked-up Simulation of Mayo Clinic Cardiac Operating Rooms was configured. OR table, Simulated patient, Anesthesia workspace with Echo Machine (Sonosite Corp) and Anesthesia Machine (Draeger Corp.) and EMR (Cerner Corp). The Patient was draped in a sterile fashion with modified cardiac surgical draping system with novel portal integrated into the draping system. The Portal was folded and in retracted state ready for sterile deployment. The standard surface ultrasound probe with electronic tether was placed into the portal from the non-sterile side of the draping system(Anesthesiologist side) and introduced into the portal orifice. The probe was then dressed for common use by the surgical team (sterile) and extended for measurement relative to the anatomic surgical position. Length from the sternum to ankle was determined. Probe retraction and re-use was determined as were position to surgical field when NOT in use. Speed and efficiency of usage was appreciated as were locations of the portal

Results: The Simulation of the operating room proved invaluable to the design and usage of this new draping system. Location of the portal design, length of the electrical tether and total sterility of the process was appreciated. The novel design of this technology portal appears to enhance sterility of the surgical field when tethered electronic surface ultrasound probes are utilized during cardiac surgery as would be used in Epi-aortic scanning, or imaging of anatomic structures from thorax to lower extremity. The mock drape setup Increased rate of deployment

of the device. Re-usability throughout the procedure was unique with full maintenance of the sterile field.

Conclusion: Our data simulation demonstrates that novel innovation design plus realistic simulation can rapidly move the process of product refinement to a heightened level. New questions arise and earlier issues are efficiently answered through this simulation. Realistic simulation is important not just for training and safety drills but rapid development of intellectual property.

References: 1.Fakih MG, et al. Increase in the rate of sternal surgical site infection after coronary artery bypass graft: a marker of higher severity of illness. Infection Control Hospital Epidemiology, May 2007.
2. Fowler VG, et al. Surgery for coronary artery disease, clinical predictors of major infections after cardiac surgery. American Heart Association, Inc. 2005.

Control center to Simulation Center

Simulation Mannequin anatomically correct

Surgical team orientation with proper instrumentation and orientation for Simulation.

Improving Pulse Oximetry Pitch Perception with Multisensory Perceptual Traning

Presenting Author: Joseph J. Schlesinger, MD, Vanderbilt University Medical Center

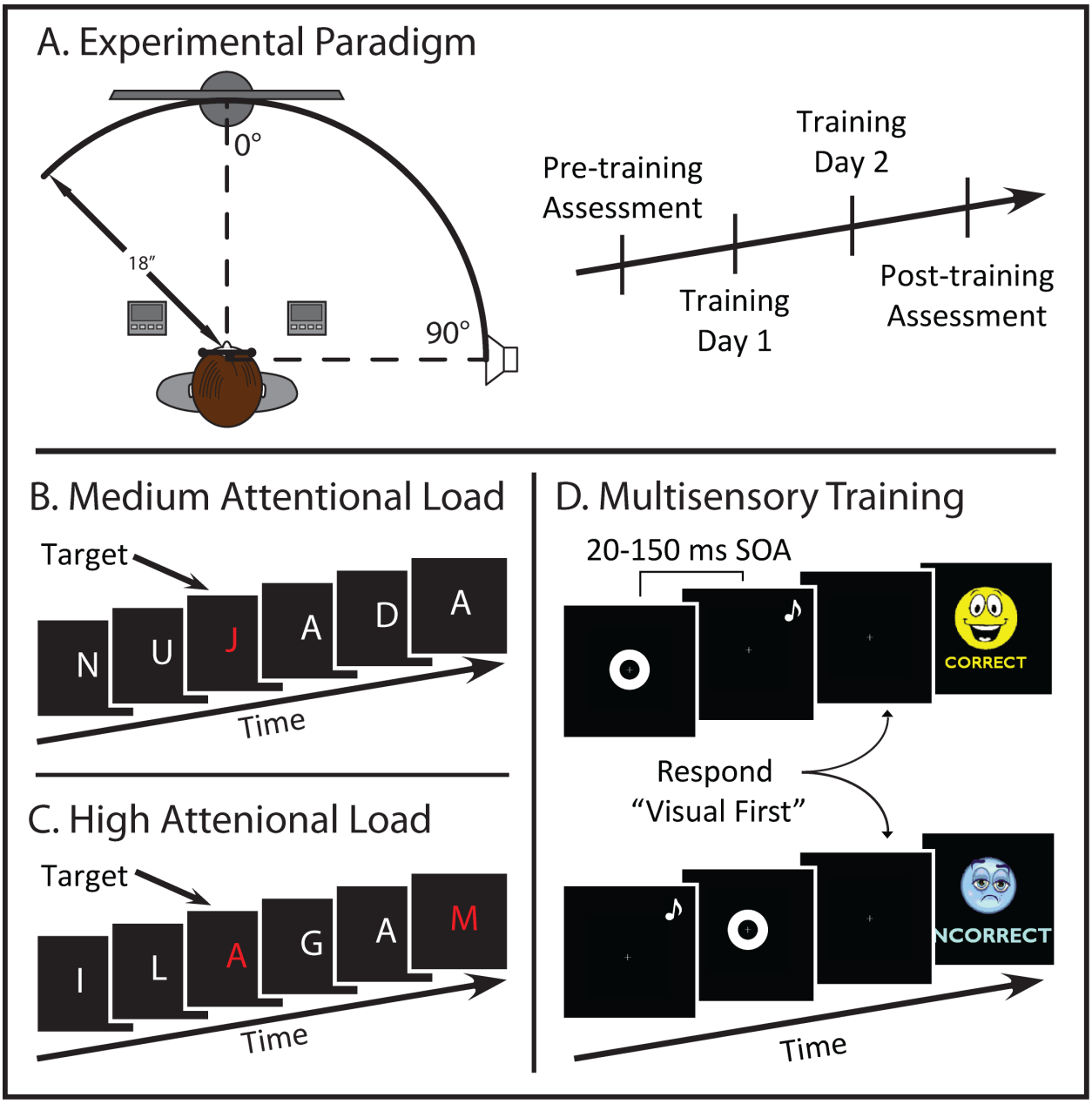
Co-Authors: Ryan Stevenson, PhD, Vanderbilt University Medical Center; Mark Wallace, PhD, Vanderbilt University Medical Center

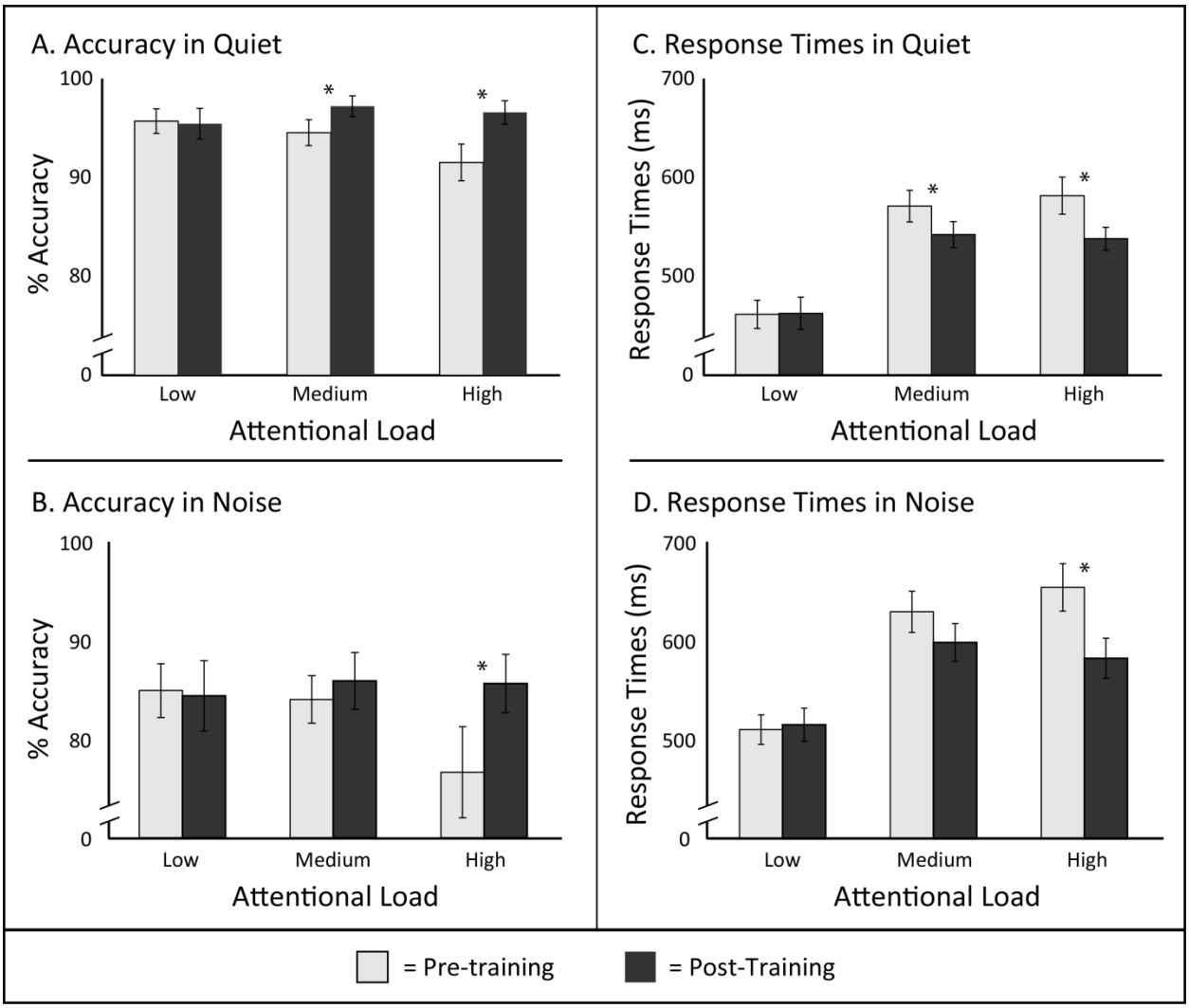
Background/Introduction: The pulse oximeter is a critical monitor in anesthesia practice that is thought to have improved patient safety. However, attention to the monitor is compromised by noise and other competing factors. Most negative patient outcomes in anesthesia result from a series of small errors, and as such, improving anesthesiologists' performance with pulse oximetry may translate into improved patient outcomes. Here, we aimed to improve the ability of anesthesiologists to monitor arterial oxygen saturation via pulse oximetry through a multisensory (i.e., audiovisual) training process.

Methods: Fifteen residents' abilities to detect auditory changes in pulse oximetry were measured before and after a multisensory perceptual-training paradigm, which incorporates the ability to judge whether audio and visual stimuli are presented synchronously or asynchronously. Accuracy and response times in detecting changes on the monitor were measured under three levels of attentional load and with and without operating room background noise. The only post-training assessment occurred less than 48 hours after training.

Results: In the condition most similar to operating room (noisy and attentionally demanding), anesthesiology residents showed an average 9% increase in accuracy of pulse oximetry pitch change detection and 11% decrease in response times following training. Fourteen of fifteen residents improved in their multisensory perceptual ability after training.

Conclusion: Multisensory training represents a novel means to improve the performance of detecting changes in the pulse oximeter. Increasing the performance of anesthesiologists has the ability to greatly improve patient monitoring and outcomes by preventing small errors; errors that have the potential to cascade into adverse outcomes. Our work builds a foundation for examining patient outcomes as related to anesthesia education and training.


A. Experimental Paradigm
0°
18"
90°
Pre-training Assessment
Training Day 1
Training Day 2
Post-training Assessment
B. Medium Attentional Load
Target
N
U
J
A
D
A
Time
C. High Attenional Load
Target
I
L
A
G
A
M
Time
D. Multisensory Training
20-150 ms SOA
CORRECT
Respond "Visual First"
NCORRECT
Time


A. Accuracy in Quiet
% Accuracy
100
90
80
0
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Medium
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Attentional Load
*
*
C. Response Times in Quiet
Response Times (ms)
700
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0
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Medium
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Attentional Load
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B. Accuracy in Noise
% Accuracy
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90
80
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D. Response Times in Noise
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700
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*
= Pre-training
= Post-Training

Wavelet Analysis of Biosignals: From Pretty Pictures to Product

Presenting Author: Paul S. Addison, PhD, Covidien Respiratory & Monitoring Solutions, Edinburgh, Scotland, UK

Introduction: The determination of a clinically useful physiological parameter is a distinctly non-trivial task. Aside from the core algorithm at the heart of the parameter (e.g. the ratio of ratio for pulse oximetry, the determination of cyclical modulation for respiration rate, the modulation strength for fluid responsiveness), a sophisticated algorithmic infrastructure is required. This takes the raw biosignal, processes it, presents it to the core algorithm, then applies further processing to the output in order to produce a value with the integrity necessary for display on the screen of a medical monitoring device [1]. This infrastructure generally includes a number of pre-processing and post-processing code modules, as well as alarm management systems, hardware interface routines (including signal acquisition processes), and often involves thousands of lines of computer code. These advanced filtering and logical decision making processes are inherent in all monitoring devices. However, the genesis of a new parameter often involves a "softer" side of signal processing where the tools involved need to inform the researcher at the conceptual level.

Method: A technique employed by the author involves decomposing the signal in order to decouple the various underlying components (including: cardiac pulse, respiratory modulations, movement artifact, blood pressure effects, vasomotion effects and electronic noise). Often these constituent elements involve a complex super-positioning within the signal not amenable to traditional filtering. A method providing strong decoupling should ideally render hidden signal information visible to the naked eye. Although a number of tools exist to perform signal decomposition, including the short time Fourier transform, phase space representations, principle and independent component analysis, the author has found the continuous wavelet transform (CWT) optimal in this regard [2].

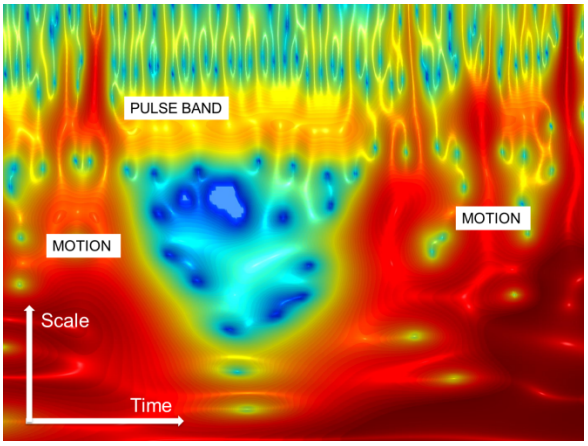


Figure 1: Wavelet Transform Modulus of a Noisy Neonatal Signal

Figure 1 contains a wavelet transform modulus representation (a scalogram) of a photoplethysmogram ('pleth') acquired from a neonate. The pulse band present in the top portion of the plot (yellow) corresponds to the cardiac pulse components of the original signal. Motion manifests itself as dominant (red) structures within the time-scale plot. The decoupling of this noisy signal in this way allows a rapid comprehension of the temporally complex interaction of signal components and aids the formation of signal processing options for attacking the problem at hand. From figure 1, we can clearly see that extraction of the pulse information should be

possible from this noisy signal: useful for the determination of both pulse rate and oxygen saturation [3], and, with further sophisticated processing, respiration rate [1].

Results: The wavelet transform visualization tool was critical in driving the success of the commercial pleth-based Respiration Rate algorithm developed by the author and colleagues (RRV.1.0, Covidien, Boulder, CO, USA). The method provided crucial insights into the multiple respiratory modulations contained in the pleth waveform (baseline modulation, cardiac pulse amplitude and frequency modulations [1]). Elements of the advanced wavelet-based signal processing were, in fact, incorporated within the final algorithm.

Conclusion: The continuous wavelet transform is well known to be a powerful tool used in the development of signal processing strategies for optimizing information. It is an integral part of numerous signal processing algorithms, finding use across disciplines in, for example, the analysis of geophysical flows, astronomical time series, engineering vibration signals, financial indices, etc. [2]. In the medical arena it has found particular use in the analysis of many biosignals [4], including: the ECG [5], EEG, photoplethysmogram [1,3], phonocardiogram, electromyogram, blood pressure signal, upper airway sounds, etc. Here, however, the author promotes its "upstream" use as a soft tool to aid the comprehension of biosignals, where it may provide a particular useful technique for initiating and driving the development of physiological parameters by providing rapid visualization of the underlying components of the signal. The method aids comprehension of the signal characteristics; provides insight into the feasibility of the underlying task; and, facilitates the development of signal processing strategies for attacking the problem to be solved.

References:

[1] Addison PS, Watson JN, Mestek ML, Mecca RS. Developing an algorithm for pulse oximetry derived respiratory rate (RR_{oxi}): a healthy volunteer study. J. Clin. Mon. Comp., 2012, Vol.26, 45-51.

[2] 'The Illustrated Wavelet Transform Handbook: Applications in Science, Engineering, Medicine and Finance', P.S. Addison, Taylor and Francis, 2002.

[3] 'A Novel Time-Frequency-based 3-D Lissajous Figure Method and its Application to the Determination of Oxygen Saturation from the Photoplethysmogram', PS Addison and JN Watson, Measurement Science and Technology, 2004, Vol.15(11), L15-L18.

[4] 'Wavelet Analysis of the ECG: A Review', PS Addison, Physiological Measurement, 2005, Vol.26, R155-199.

[5] 'Time--frequency Analysis of Biosignals', Addison, P.S., Walker, J., Guido, R.C., IEEE Engineering in Medicine and Biology Magazine, September-October 2009, Vol.28, pp14-29. [Guest Editor. Special Issue on Wavelets.]

Preoperative Type and Screen Testing for Elective Surgery: Using a Data Warehouse to Identify Workflow Process Errors

Presenting Author: Spencer T. Jennings[1]

Co-Authors: Jonathan P. Wanderer, M.D., M. Phil[1], Jesse M. Ehrenfeld, M.D., M.P.H[1,2,3]
[1]Vanderbilt University Medical Center, Department of Anesthesiology, Nashville, TN
[2]Vanderbilt University Medical Center, Department of Surgery, Nashville, TN
[3]Vanderbilt University Medical Center, Department of Biomedical Informatics, Nashville, TN

Introduction: Prior to elective surgery, type and screen testing is performed when blood loss that may necessitate transfusion is expected during surgery. While several methodologies for determining when type and screen testing should be ordered have been described, limited data is available that evaluate an existing, implemented system. The purpose of this study is to quantify the existing issue related to ordering a type and screen test with an existing institutional protocol, in order to understand how the integration of decision support software can assist providers in making decisions and eliminating errors.

Methods: Using data from Vanderbilt University Medical Center's Perioperative Data Warehouse, anesthetic records from non-inpatient surgeries were identified between 1/2012 and 6/2013. Using data from our institution's SOFT database, these records were cross-referenced with all type and screen tests performed during this time period. We quantified the following process errors: 1) type and screen tests that expired and were not redrawn for surgery, 2) extended type and screen tests (up to 14 days) were ordered but expired prior to surgery, 3) standard (3 days) type and screen tests that expired when an extended type and screen would have not expired, 4) multiple type and screen tests with overlapping expiration dates, and 5) type and screen tests ordered after surgical incision. To further explore process error type 3, where a 3-day type and screen test expired yet a 14-day type and screen test would have been sufficient, we performed an analysis by surgical service.

Results: We identified 16,887 non-inpatient procedures which were associated with type and screen tests. Of these, 8% of tests (1,333) expired before surgery and were not redrawn, 2% of tests (334) were redrawn on the date of surgery because a 14-day sample expired, 5% of tests (892) were redrawn because a 3-day type and screen test expired when date of surgery was between 4 and 14 days, 5% (863) had a valid type and screen test on file yet another one was ordered on the day of surgery, and 3% of tests (464) were ordered after the time of incision. During an analysis of the cases where a 3-day type and screen test was ordered and expired but the date of surgery was between 4 and 14 days, the surgical services most associated with these tests were Adult Cardiac, Thoracic, Vascular Surgery, and Liver Transplant.

Discussion: We identified five types of process errors that occur for blood type and screen tests ordered for elective surgery. These process errors occur relatively frequently. Integration of a decision support software system into the Vanderbilt Outpatient Order Management (VOOM)

system during the ordering process may be useful in decreasing the frequency of these occurrences. This might reduce the number of redundant tests that the Blood bank performs by improving ordering practices in the surgical clinics.

Respiratory Heat Loss as a Physiologic Variable: A New Patient Monitor (VQ_m)

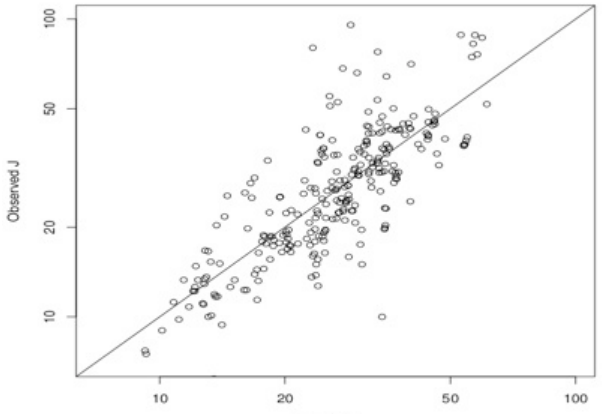
Authors: D. John Doyle MD PhD, Cleveland Clinic; Igor Brodkin MD, Vancouver General Hospital; Neal Fleming MD PhD, UC Davis Medical Center; Andreas Thierbach MD, Klinikum Idar-Oberstein GmbH

Introduction: Although the theoretical benefit of optimizing ventilation–perfusion (V/Q) matching in critically ill patients is clear, bedside devices for real-time V/Q monitoring do not yet exist. We describe one proposed approach to this challenge, based on respiratory enthalpy analysis.

Hypothesis: Currently, V/Q assessment remains indirect , relying on physical examination, ventilation parameters, arterial blood gas analysis and lung imaging. It is our hypothesis that the measurement of respiration-related transpulmonary water movement via its effect on inspired gas enthalpy might lead to a new method for evaluating V/Q. During positive pressure ventilation, evaporation from pulmonary structures results in heat transfer in relation to: [1] the volume of effective (matched to perfusion) alveolar ventilation in each breath, [2] the respiratory rate, [3] the humidity of the delivered gases and [4] the difference between the temperature of the delivered gases and body core temperature.

Background: Previous studies have used dynamic changes in exhalation enthalpy to characterize lung and cardiac function but the clinical utility of exhalation enthalpy as a surrogate of V/Q has not been explored. The main source of heat in exhaled gases (exhalation enthalpy) is the ventilated lung alveoli that are perfused with blood at body temperature. The conducting airways (tracheo-bronchial tree) of the lungs serve to minimize the loss of this heat to the environment. General principles of pulmonary thermodynamics are well understood but the idea of employing enthalpy analysis of exhaled gases for clinical purposes has remained unimplemented until now.

Description: Known as the VQ_m™ system, it consists of hardware configured to calculate inhaled and exhaled gas enthalpy from measurements of gas volumes, temperature and relative humidity over each respiratory cycle. This yields an index (VQ_i= heat loss (J/min) / body surface area (m^2)) which we hypothesize will be of clinical value as a volumetric V/Q surrogate ("effective alveolar ventilation") that is independent of pulse oximetry or capnographic monitoring.



Results: Following IRB approvals, 288 VQm™ measurements were made in 47 ASA 1-2 patients in 3 institutions. Respiratory enthalpy was directly measured using VQm™.

Multivariate regression analysis was used to create the "best fit" predictive model for the observed respiratory enthalpy using the following variables: sex, age, height, weight, inhaled minute enthalpy, minute volume, tidal volume, respiratory rate and minimum inhaled humidity. The response variable, minute respiratory heat loss, was computed. The mean observed inhaled/exhaled enthalpy was 7.2±1.7/ 29.7±15.6 Joules/min. The observed vs. fitted (final model) respiratory enthalpy values are shown.

Cardiac Output Measurements Using NonInvasive Photoacoustic Measurements of Indicator Dilution Signals

Presenting Author: Youzhi Li, PhD, R&MS, Covidien.

Co-Authors: Clark Baker, Darshan Iyer, PhD, Qiaojian Huang, PhD, Ulf Borg, R&MS, Covidien, Boulder, CO.

Introduction: Cardiac output (CO)[1] is an important established physiological parameter that enables physicians to optimize fluid and drug interventions in hemodynamically unstable, critically ill patients, in order to improve patient outcomes. Conventional technologies for measuring cardiac output involve using indicator dilution (ID) techniques[2] and require highly invasive pulmonary or femoral arterial catheterization. There is an increasing need for noninvasive devices[3] for assessing hemodynamic status in critically ill patients.

In this abstract, we describe a noninvasive cardiac output measurement technique afforded by the emerging noninvasive photoacoustic technology[4]. In this technique, a small bolus of room temperature isotonic saline is injected quickly into the central circulation of a patient as an indicator, which induces a transient hemodilution effect. A photoacoustic sensor equipped with a single flat ultrasound sensor is placed downstream over a tissue bed with a superficial artery. The sensor noninvasively measures the hemodilution effect from the artery and its nearby vein as the indicator travels across the sensor site. As the indicator is washed out of the circulation, a hemodilution (indicator dilution) curve is noninvasively obtained, and then used to derive hemodynamic parameters, such as cardiac output.

Methods: With AUCC approval, 5 swine with weights ranging from 24.7 to 28.8 Kg were used to demonstrate the feasibility of this new technology. Each swine was anesthetized and intubated with an appropriately sized ETT. The spleen was removed. A 9F double lumen central venous catheter (CVC) was placed in the Internal Jugular Vein (IJV) and advanced to the superior vena cava, and a 5F single lumen PiCCO thermodilution catheter was placed in a femoral artery. 15 ml room temperature saline was then injected through the CVC to verify that an ID curve could be measured by the PiCCO system. The PiCCO thermo-dilution CO measurements were used as the reference. The swine remained anesthetized and ventilated during the experiments. Incision times, closure times, and durations of operative interventions were recorded.

After the animal was prepared, photoacoustic CO experiments were performed to measure the cardiac output of the animal. During the experiments, CO was manipulated by creating a series of "hemorrhagic shocks"[5] by gradually removing blood through the CVC, thereby decreasing the mean arterial blood pressure by 10 mm Hg over a period of 2-5 min in each step. After each reduction of blood pressure, a stabilization period was allowed, for the animal's CO to reach a

steady state. The steady state was assumed when the continuous CO measured with the PiCCO reference becomes stable. CO measurements were performed before the initial CO manipulation and at each steady state. At each steady state, three boluses of 15 cc isotonic saline were injected sequentially at ~1 minute intervals through the CVC, and the CO of the animal was simultaneously measured by the reference PiCCO thermo-dilution technique and the photoacoustic CO system. The photoacoustic CO measurements were obtained with empirical regression analysis with PiCCO thermo-dilution measurements as the references.

Results: The figures below show results for photoacoustic CO estimates from the pool of 5 swine with leave-one-out analysis. The correlation with r^2 of 0.746 between the photoacoustic CO estimates and the PiCCO system over a range of CO from 1 – 6 l/min has been demonstrated as shown in Fig. 1. Figure 2 is the Bland-Altman analysis demonstrating a bias of -0.05 L/min and precision of 0.50 L/min.

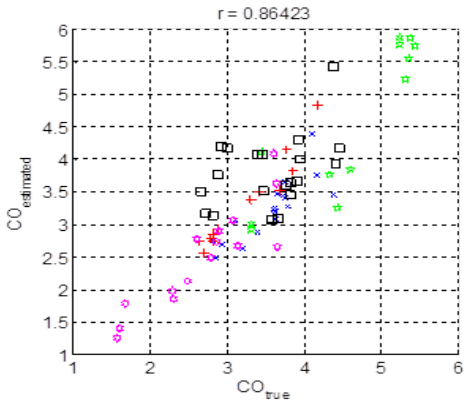


Figure 1. PA CO estimates vs. Reference Device.

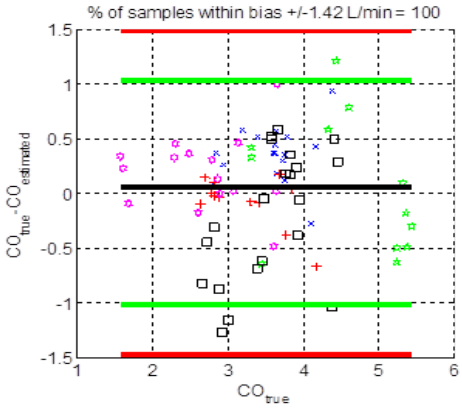


Figure 2. Bland-Altman Plot, PA CO vs. Reference Device

Conclusion: We verified with *in vivo* study on pig hemorrhagic shock model that noninvasive measurements of an indicator dilution curve with a simple photoacoustic sensor allow successful cardiac output estimation with accuracy comparable with that of an established reference.[6] The present technology does not require differentiating the indicator dilution signals from an artery or a vein. This breakthrough overcomes a major obstacle in the clinical translation of the photoacoustic indicator dilution technology.

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[1] M. Pinsky, "Goal-directed therapy: optimizing fluid management in your patient", www.initiatives-patientsafety.org, (2010); M. Cannesson, etc., "Hemodynamic monitoring and management in patients undergoing high risk surgery: a survey among North American and European anesthesiologists", *Critical Care* 2011, **15**: R197

[2] P. Meier, etc., "On the theory of the indicator-dilution method for measurement of blood flow and volume", *J. Appl. Physiology* 1954, **6:** 731-744; R. Weisel, etc., "Measurement of cardiac output by thermodilution", *N. Engl. J. Med.* 1975, **292**: 682-684.

[3] S. Benington, etc., "Emerging trends in minimally invasive hemodanynamic monitoring and optimization of fluid therapy", *Eur. J. Anaesthesiol.* 2009, **26**: 893-905; P. Marik, "Noninvasive cardiac output monitors: a state of the art review", *J Cardiothorac Vasc Anesth.* 2013, **27**:121-34.

[4] R. Esenaliev, etc., "Continuous, noninvasive monitoring of total hemoglobin concentration by an optoacoustic technique", *Appl. Opt.* 2004, **43**: 3401-3407; D. Graham-Rowe, "Sounding out photons", *Nat. Photonics* 2009, **3**: 123-125.

[5] Vrancken, etc, "Cardiac output measurement with transpulmonary ultrasound dilution is feasible in the presence of a left-to-right shunt: a validation study in lambs", BJA **108**, 409-16 (2012); de Boode, etc, "Cardiac output measurement using a modified carbon dioxide Fick method: a validation study in ventilated lambs", Ped. Res **61**, 279 (2007). W. De Boode, etc., "Cardiac output measurement using a modified carbon dioxide Fick method: a validation study in ventilated lambs", *Pediatric Research* 2007, **61**: 279-283.

[6] E. Segal, etc., "Transpulmonary thermodilution cardiac output measurement using the axillary artery in critically ill patients", *J Clin Anesth* 2002, **14**:210-213; L. Critchley, etc., "A meta-analysis of studies using bias and precision statistics to compare cardiac output measurement techniques", *J. Clin. Monit.* 1999, **15**: 85-91.

Accuracy of Continuous Non-Invasive Hemoglobin Monitoring: A Systematic Review and Meta Analysis

Presenting Author: Maxime Cannesson, MD, PhD, University of California-Irvine

Background: Non-invasive hemoglobin (Hb) monitoring devices are available in the clinical setting but their accuracy and precision against central laboratory Hb measurements have not been evaluated in a systematic review and meta-analysis.

Methods: We conducted a comprehensive search of the medical literature (2005 to August 2013) with PubMed, Web of Science and the Cochrane Library, reviewed references of retrieved articles, and contacted manufactures to identify studies assessing the accuracy of non-invasive Hb monitoring against central laboratory Hb measurements. Two independent reviewers assessed the quality of studies using recommendations for reporting guidelines and quality criteria for method comparison studies. Pooled bias and standard deviation (SD) (95% limits of agreement) across studies were calculated using the random-effects model. Heterogeneity was assessed using the I^2 statistic.

Results: A total of 32 studies (4,425 subjects, median sample size of 44, ranged from 10 to 569 patients per study) were included in this meta-analysis. The overall pooled random-effects bias (non-invasive – central laboratory) and SD were 0.10±1.37 g/dl (−2.59 to 2.80 g/dl, I^2=95.9% for bias and 95.0% for SD). In subgroup analysis, pooled bias and SD were 0.39±1.32 g/dl (−2.21 to 2.98 g/dl, I^2=93.0%, 71.4%) in 13 studies conducted in the perioperative setting and were −0.51±1.59 g/dl (−3.63 to 2.62 g/dl, I^2=83.7%, 96.4%) in 5 studies performed in the intensive care unit setting.

Conclusions: Although the bias between non-invasive Hb and central laboratory measurements were small, the wide limits of agreement mean clinicians should be cautious when making clinical decisions based on these devices.

Enhanced Measurement of Respiratory Modulations Using A Flexible Pulse Oximeter Probe

Presenting Author: Paul S. Addison, PhD, Covidien Respiratory & Monitoring Solutions, Edinburgh, Scotland, UK

Co-Author: James N. Watson, PhD, Technical Fellow. Covidien Respiratory & Monitoring Solutions, Edinburgh, Scotland, UK

Introduction: The calculation of respiratory rate (RR) from a pulse oximeter signal (the photoplethysmogram or 'pleth') has received much attention over recent years. Numerous groups have demonstrated that evaluating the respiratory-related fluctuations from the PPG signal is technically attainable approach to obtaining RR [1-5]. Recently, an algorithm to derive RR from the pleth was described by our group [6]. The algorithm has the necessary filtering, logic and decision making processes required to provide a fully-automated technology capable of coping with the extremes of data characteristics in the clinical environment; and ultimately provide a robust, clinically useful number for display. Here we describe research work undertaken to investigate the enhancement of the detection of respiratory activity through modifications to the design of the pulse oximeter probe.

Method: We constructed a flexible probe which allows for motion due to respiratory activity at certain body sites to enhance the respiration component contained within the pleth signal. A simple flexible probe was constructed for the experiment by cutting a standard forehead probe (Nellcor Max-Fast, Covidien, Boulder, CO) between the emitter and photodetector while leaving the wiring intact. This allowed the emitter and photodetector to move relative to each other when adhered to the skin surface and, consequently, body surfaces that move in phase with respiration to enhance the respiratory element of the pleth signal [7].

Results: Figure 1 shows a wavelet transform scalogram [8] computed from a pleth taken at a finger site. Figures 2 and 3 show the corresponding scalograms for a flexible and non-flexible probe placed at a site on the chest wall. The signals were acquired during a test where the subject breathed at a constant rate of 18 bpm. At around 120 seconds, the subject breathed against a flow resistor which increased his respiratory effort. The increase in effort is just discernible in the breathing band from the finger probe (Figure 1). The flexible probe exhibits a strong band all the way across the scalogram (Figure 2) and does not differentiate the effort increase well. Figure 3 shows the scalogram for a non-flexible probe during the same experiment and highlights a distinct change in breathing band energy at 120 seconds. It is noticeable that the pre-effort band contains much less relative energy than that corresponding to the flexible probe shown in Figure 2.

Conclusion: The flexible probe design appears to provide strong breathing band at lower efforts and may offer an enhancement for capturing strong respiration components at respiratory lower efforts.

References:

1. Nilsson L., Johansson A., Kalman S. "Respiration can be monitored by photoplethysmography with high sensitivity and specificity regardless of anaesthesia and ventilatory mode". Acta Anaesthesiol. Scand., 2005; 49: 1157-62
2. Leonard P.A., Clifton D., Addison P.S., Watson J.N., Beattie T. "An automated algorithm for determining respiratory rate by photoplethysmogram in children". Acta Paediatr, 2006; 95: 1124-8
3. Shelley K.H., Awad A.A., Stout R.G., Silverman D.G. "The use of joint time frequency analysis to quantify the effect of ventilation on the pulse oximeter waveform". J Clin. Monit. Comput., 2006; 20: 81-7
4. Karlan W., Raman S., Ansermino R.J., Dumont G.A.,'Multiparamter Respiratory Rate Estimation from the Photoplethysmogram', IEEE Trans. Biomed. Eng., 2013; 60: 1946-1953.
5. Lazaro J., Gil E., Bailon R., Minchole A., Laguna P., 'Deriving Respiration from Photoplethysmographic Pulse Width', Med. Biol. Eng. Comput., 2013; 51: 233-242.
6. Addison P.S., Watson J.N., Mestek M.L., Mecca R.S. "Developing an algorithm for pulse oximetry derived respiratory rate (RR_{oxi}): a healthy volunteer study". J. Clin. Monit.. Comput., 2012; 26: 45-51.
7. Addison P.S., Watson J.N., Ochs J. P., Neitenbach A-M., &. Mestek M.L, 'Flexible Pulse Oximeter Probe Design for Monitoring Respiration Parameters: A Feasibility Demonstration'; IAMPOV Symposium, Yale University, New Haven, CT, 29 June – 1 July 2012, Program Syllabus, 40-41.
8. Addison P.S., 'The Illustrated Wavelet Transform Handbook: Applications in Science, Engineering, Medicine and Finance', Taylor and Francis, 2002.

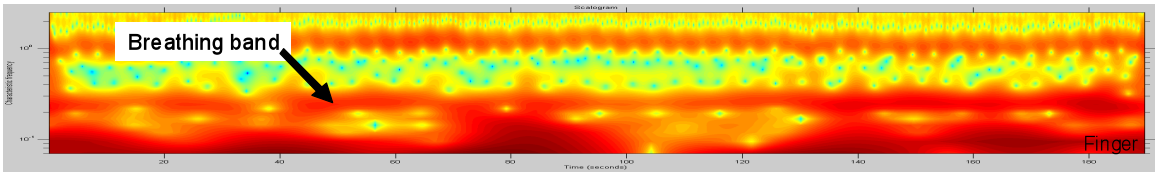


FIG.1: A signal and its scalogram obtained from a finger probe.

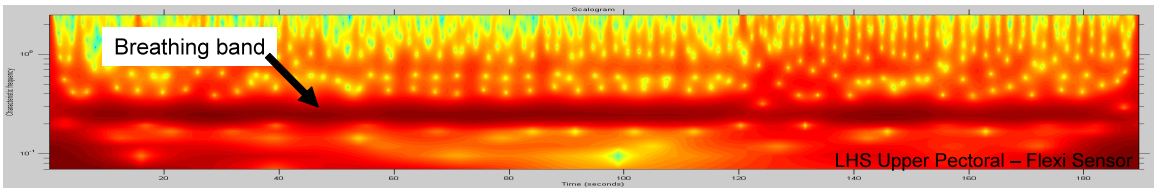


FIG.2: A signal and its scalogram obtained from a flexible probe placed on the chest.

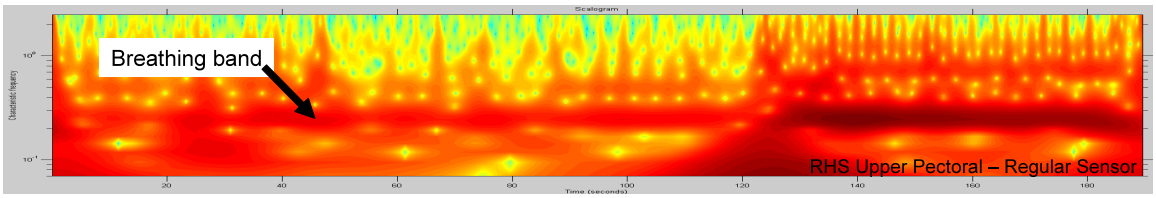


FIG.3: A signal and its scalogram obtained from a non-flexible probe placed on the chest.

Effective Alerts: Can a Single Index Alarm Reduce Alarm Fatigue?

Presenting Author: Michal Ronen, PhD, Covidien

Co-Authors: Keren Davidpur, BS, Covidien, Joshua Colman, MS, Covidien

Introduction: Physiologic monitor alarms are designed for high sensitivity, not to miss a true significant event. Single parameter thresholds are used, and the alarm is set off when a parameter's value goes beyond the set-point. This results in low positive predictive value of the alarms, i.e., high rate of clinically insignificant alarms, which lead to desensitization[1-3].
IPI (Integrated Pulmonary Index), is a single index, incorporating four parameters, $EtCO_2$, RR, SpO_2 and PR[4]. IPI ranges 1-10 and reflects the patient's pulmonary-ventilatory status and is FDA cleared. The IPI alerts when certain thresholds related to the four parameters are crossed.
In this study IPI alerts were compared to single parameter alarms and pre-defined clinically significant events based on published literature.

Methods: Data collected from 9 hospitals in different clinical environments (GI, Trauma, Pain management, ICU, Labor and Sedation, all adult cases) was used to support our analysis, with a total of 413 cases, 3507 hours. Alarm occurrences were calculated using each parameter default alarm set-point as follows: $EtCO_2$ High - 60mmHg, $EtCO_2$ Low - 15 mmHg, RR High - 30 BPM, RR Low - 8 BPM, SpO_2 88%, all lasting at least 15sec; and apnea events lasting 30sec. IPI alerts occurrences were defined as an IPI score of 4 with a duration of at least 15sec.The alerts were compared to gold-standards of clinically significant events (Table 1). Alarms and events were identified and sensitivity and positive predictive value were calculated, by detecting co-occurrences of alerts and clinically significant event.

Results: IPI sensitivity is 0.999 for clinically significant events (Table 2), for the additional events, hypercapnia and hypocapnia, IPI sensitivity is 0.99. Single parameter alarms had a sensitivity of 1 for all events. The number of IPI alerts is close to one third of the number of the single parameters alarms (Table 3), and the positive predictive value for clinically significant events is 0.16 compared to 0.06 for the single parameters alarms.

Conclusions: IPI alarms are more effective than those of the single parameters. The number of alarms was reduced significantly by 66% without losing sensitivity (0.999 vs. 1). Hence it can be used safely and may reduce alarms fatigue and the desensitization effect.

References:

1. Cvach M. Monitor alarm fatigue: an integrative review. Biomed Instrum Technol. 2012 Jul-Aug;46(4):268-77. doi: 10.2345/0899-8205-46.4.268
2. Lawless ST. Crying wolf: False alarms in a pediatric intensive care unit. Crit Care Med, 1994; 22(6):981-985.
3. Korniewicz DM et al. A national online survey on the effectiveness of clinical alarms. Am J Crit Care,2008; 17(1):36-41.
4. Taft A, et al. A Novel Integrated Pulmonary Index (IPI) Quantifies Heart Rate, Etco2, Respiratory Rate and Spo2% presented at the Annual meeting of the American Society of Anesthesiologists, 2008

Table 1: Definitions of clinically significant events

Clinically Significant Events	*Lasting at least 15sec*
Central or obstructive apnea	$EtCO_2$ = 0 mmHg , RR = 0 BPM
Bradypneic hypoventilation with hypoxia	$EtCO_2$ >60 mmHg, RR <5 BPM, SpO_2 <88%
Hypopneic hypoventilation with hypoxia	$EtCO_2$ <20 mmHg, RR <5 BPM, SpO_2 <88%
Hypoxia	SpO_2<88%, any $EtCO_2$ and RR values
Also significant	*Lasting at least 60sec*
Hypercapnia	$EtCO_2$>60mmHg
Hypocapnia	$EtCO_2$<20mmHg and RR<5 BPM

Table 2: Alarms occurrences per clinically significant event

Event	***# of occurrences***	***# of single alarms at event (%)***	***# of IPI alarms at event (%)***
Apnea	1118	1118 (100)	1118 (100)
Bradypneic Hypoventilation with Hypoxia	11	11 (100)	11 (100)
Hypopneic Hypoventilation with Hypoxia	144	144 (100)	144 (100)

Hypoxia	1633	1633 (100)	1631 (99.9)
All events *	2647	**2647 (100)**	**2645 (99.9)**

Table 3: Events occurrences per alarms

Alarm	***# of occurrences***	***# of Clinically significant Events alarmed (%)***	***# of All Events alarmed (%)***
High $EtCO_2$	3066	947 (31)	947 (31)
Low $EtCO_2$	765	131 (17)	179 (23)
High RR	24985	671 (30)	672 (30)
Low RR	3321	851(26)	871(26)
SpO_2	3293	1268 (39)	1274 (39)
***All single parameter alarms**	**31669**	**1851 (6)**	**1898 (6)**
IPI	10627	1752 (16)	1826 (17)

* With no overlaps

Earlier Detection of Desaturation from the Nasal Ala

Presenting Author: Huwei Tan, Ph.D.[1]
Co-authors: Richard J. Melker, M.S., M.D., Ph.D.[2], Mark J. Rice, M.D.[2], Donn M. Dennis, M.D.[2], Timothy E. Morey, M.D.[2], Bryan R. Dollinger[3], Judith Wishin, RN[2].
[1] Xhale Assurance, Glastonbury, CT, [2]University of Florida College of Medicine, Gainesville, FL, USA, [3]University of Florida, Gainesville, FL, USA

Background: We recently reported disordered breathing patterns during monitored anesthesia care (MAC) similar to abnormal sleep[1]. We now report earlier desaturation detection from the nasal alae than from finger sites and additive non-physiologic delays from oximeters. These data should be applicable to all healthcare settings.

Methods: With IRB approval, 80 subjects of variable skin tone (28 male/52 female, ages 19-65 years [mean=46]) who presented for extremity surgery at an ambulatory surgical center (Florida Surgical Center, Gainesville, FL) enrolled and completed the study without incident. Surgical duration averaged 73 min (range 16-189). Alar oximetry sensors were placed on both nasal alae and a finger sensor was placed adjacent to the site chosen by the anesthesia provider (41 cases). Either identical pulse oximeters (PO_1) were used to record from the two ala and finger (n=9) or an alternative oximeter (PO_2) was substituted on one ala (n=32). Raw rather than processed data was collected from PO_1. Data using an ear sensor in lieu of the second alar sensor are not reported (n=39). Simultaneous finger oximetry data was collected from an anesthesia monitor (PO_3) (n=80). Following regional or local anesthesia, the MAC technique was at the discretion of the care team. All subjects received supplemental oxygen. Mini-desaturation (mDesat) was defined as a decrease of >3% from baseline S_pO_2. Desaturation (Desat) was defined as a decrease in S_pO_2 ≥10% from baseline.

Results: mDsats were observed in 36 subjects (38%), (mean=4; range=1-41). Desats (≥10% of baseline) were present in 15 subjects (19%) (mean=1.6; range=1-5). Statistics (SigmaPlot, San Jose, CA) are summarized in the Table. Desaturation was detected on average 9 sec sooner from the ala than the finger with an identical oximeter (PO_1) (physiologic delay) and PO_2 averaged 7 sec slower than PO_1 (device delay). A combination of physiologic and device delays results in an average 14 sec delay with PO_3 at the finger compared to PO_1 at the ala. Differences in time to desaturation were not due to data collection protocols.

Conclusions: We demonstrate faster response to desaturation during MAC by monitoring at the nasal ala rather than a digit (physiologic delay). Further, pulse oximeters can add additional delays (device delay) resulting in a significant lag in detection of desaturation. Similar findings should be expected when monitoring patients in other healthcare environments and longer delays are likely with poor peripheral perfusion and/or movement.

Table

	PO_1ala v. PO_1 finger (sec)	PO_1 ala v. PO_2 ala (sec)	PO_1 ala v. PO_3 finger (sec)
Mean	8.571	6.917	14.105
Std. Dev.	8.483	7.960	11.546
95% Confidence Interval (CI)	3.861	5.057	5.565
99% Confidence Interval (CI)	5.267	7.137	7.625

Reference: Morey TE, Cohen SF, Rice MJ, Dennis DM, Melker RJ, Disordered Breathing Detected during Ambulatory Surgery Using an Alar Sensor. Presented at the American Society of Anesthesiologist 2013 Annual Meeting. October, 2013.

Development and Implementation of a Process within an Anesthesia Information Management System (AIMS) to Record Intraoperative Complications

Presenting Authors: Jon Zhou, MD; Richard H. Epstein, MD; David M. Gratch, DO
Department of Anesthesiology, Thomas Jefferson University Hospital and Jefferson Medical College, Philadelphia PA

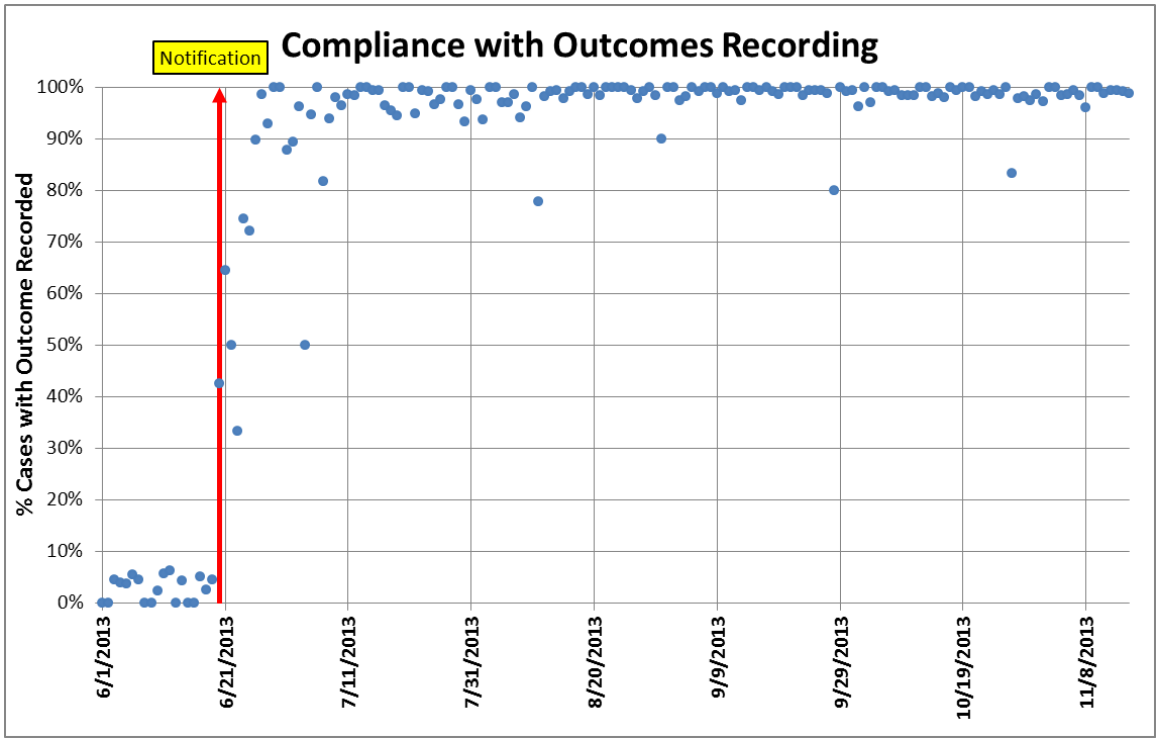
Introduction: Intraoperative anesthesia-°©-related complications have been studied extensively in an effort to improve patient safety. The National Healthcare Quality Reports estimated the incidence of anesthesia complications to be 0.724 per 1,000 surgical discharges in adults in the US in 2003.1 Most studies have focused on anesthesia related deaths and contributing factors, but there are few data on intraoperative complications with less serious morbidity. Our goal was to develop a process in our AIMS that would result in a systematic, prospective recording of intraoperative complications that would have a high rate of completion by anesthesia providers.

Methods: Since implementation in 2005, our AIMS has had a function to record perioperative complications ("Outcomes") from an extensive list of options (207 items in 11 categories). However, its use was not emphasized and complications were rarely entered. As part of a department initiative to track intraoperative adverse events, the list was reorganized to make item selection easier. The department's policy was changed to require recording an outcome on all cases, including the absence of any complications. During a one-°©-week period at the end of June, 2013, the new policy was announced at a faculty meeting, presented at Grand Rounds, and communicated via email to all anesthesia providers with instructions on how to complete outcomes entry. It was emphasized that these outcomes would not be printed on patients' anesthesia record, and that they were to select any relevant complications (whether or not attributable to anesthesia). We stressed the need to avoid writing any editorial or potentially inflammatory comments in the "Remarks" field. If appropriate, a comment was to be charted as an "Event" so that it would display on the patient record. Providers finishing cases were sent a text message reminder to their pagers 30 minutes after their cases ended if they had not yet made an outcome entry. Also, daily at 6 AM, a secure email was sent to the identified provider if an outcome from the prior day was still absent, requesting completion. The chief quality officer (DMG) received a report each morning listing complications from the previous day. We determined the percentage compliance ± SEM of outcome entry by batched means (N=20 one-°©-week bins). Reported complications were analyzed similarly (N=5 four-°©-week bins). Free text remarks were examined to determine the need to refine our outcomes list, or to provide additional education about data entry completion.

Results: Very high compliance with intraoperative outcomes reporting was achieved rapidly following notification about the new process (Figure), and has been maintained for 7 months (97.9% ± 0.4%). (Outlier points after 7/1/2013 were on weekends.) Since

7/1/2013, the incidence of patients with at least 1 reported intraoperative complication was 1.16% ± 0.4%. From the free text analysis, we added 3 items to our list. Remarks were devoid of potentially inflammatory language. Since implementation, we have not identified any cases for presentation at morbidity and mortality conference that were missed by our tracking system.

Discussion: We achieved our objective to develop an effective system to record intraoperative complications. The complication rate was low; thus, a larger sample size is needed for reliable estimates of individual complications. A limitation of our process is that this is a self-°©-reporting system, so some complications may be missing. However, the absence of intraoperative complications reported to us outside the system suggests that major complications are being identified. Another limitation is that we are not currently capturing postoperative complications with our system. Given our low baseline rate of complication entry, we question the validity of compiling multi-°©-institutional morbidity data without knowing how effectively complications are being captured by the contributing facilities. 1 Agency for Healthcare Research and Quality. National Healthcare Quality Report. December, 2003. Available at http://archive.ahrq.gov/qual/nhqr03/nhqr2003.pdf Last accessed December 9, 2013



A Survey of Resident Educational Technology Preferences from 374 Anesthesiology Residents

Presenting Author: Lynn K. Ngai, BS, University of Southern California, Stanford AIM Lab

Co-Authors: Reuben L. Eng, MD, FRCPC, Stanford AIM Lab, Matthew J. Erlendson, BA, Yale University, Stanford AIM Lab, Larry F. Chu, MD, MS, Director, Stanford AIM Lab

Background: The majority of current residents are millennial learners, incorporating new technologies and fast, mobile delivery of information. They have been accustomed to mobile, online learning from grade school through medical school, expecting similarly sophisticated teaching modalities in residency. To keep up, residency programs should aim to understand the extent to which residents depend on such information technology, with the goal of incorporating new technologies to support graduate medical education at their own institutions.

Methods: Stanford IRB approval was obtained to distribute the survey to anesthesiology residents from 19 residency programs around the US. Surveys were distributed one year apart, from May 12 to November 17, 2012, and from July 1 to July 31, 2013 (Table 1).

Results: *Anesthesia Residents are Knowledgeable and Experienced Tech Users*
Out of 374 respondents, only 1 resident described him or herself as being a "complete computer novice." Most were "knowledgeable" to "very knowledgeable" about computers and some were self-proclaimed "powerusers." During medical school, most used online courses, lectures, quizzes, discussion forums, and videos to supplement classroom learning (Table 1).

Anesthesia Residents Prefer Multimedia/ Online Approaches to Learning
To learn a new clinical procedure, both intraoperative teaching by an attending and online procedural demonstration video were rated as desirable modalities in 90% of residents. Mobile device-based short topic reviews and group studying were desirable in 50% (Fig 1A). Most residents would consult a textbook if faced with a clinical question, followed by Google, a faculty member, a peer expert, Wikipedia, and Open Anesthesia (Fig 1B).

Anesthesia Residents Report Mobile Technologies Are Useful in Education; Ownership Surges
More than 90% agreed that using mobile technologies is moderately to very important for learning anesthesia, enabling opportunities for learning to occur more frequently, in the OR, and outside of the hospital. More than 80% agreed that a mobile device would enhance his or her ability to learn anesthesia in a meaningful way, with 77% agreeing that mobile devices are under-utilized in anesthesia education. The majority thought that using a tablet computer (i.e. iPad) would enhance their learning. From 2012 to 2013, resident ownership of iPads surged from 33.0% to 134.0% (Fig 1C).

Anesthesia Residents are Content Consumers, Not Content Creators
44% claimed that they were inactive social media users or merely spectators, 42% agreed that

they connect with others in social media, 11% were collectors or critics of social media, and only 3% considered themselves creators of social media content (Fig 1D).

Conclusion: Residents are high-tech adapters, with the majority owning multiple mobile devices— iPad ownership and usage more than tripled amongst our study populations over one year alone. Furthermore, about as many anesthesiology residents prefer online teaching videos as intraoperative teaching by an attending. Residents' swift adaptability to new technologies superimposed on their growing online learning preferences provides an untapped opportunity for resident teaching. Educational technology modalities such as online teaching videos are scalable and could serve as a primer or introduction to in-person/ intraoperative teaching. And, although residents are knowledgeable, experienced, and early adopters of technology, the majority are not content producers themselves, relying on already uploaded and established information online. Residency programs have the opportunity to create and provide this online content as part of their curriculum, to accommodate to their residents' mobile, on-the-go learning styles, and to enhance their residents' educational experience with new technological modalities.

Table 1: Demographic Characteristics of Participating Residents

	2012 Cohort	2013 Cohort
Total Number of Students	176	198
Gender		
Male	103 (58.5%)	115 (58.1%)
Female	73 (41.5%)	83 (41.9%)
Average Age (years)	30.6	28.9
Training Year		
Intern	19 (10.8%)	0
CA-1	56 (31.8%)	198 (100%)
CA-2	56 (31.8%)	0
CA-3	37 (21.0%)	0
Did not report	8 (4.5%)	0
Location of Current Training		
East	56 (31.8%)	110 (55.6%)
Midwest	0	7 (3.5%)
South	33 (18.8%)	25 (12.6%)
West	60 (34.1%)	56 (28.3%)
Other/ Non-United States	27 (15.3%)	0
Location of Medical School		
East	71 (40.3%)	80 (40.4%)
Midwest	24 (13.6%)	37 (18.7%)
South	34 (19.3%)	35 (17.7%)
West	29 (16.5%)	30 (15.2%)
Other/ Non-United States	18 (10.2%)	16 (8.1%)
Learning Technologies Employed During Medical School		
Online course through platforms such as Moodle, BlackBoard, or Sakai	124 (70.5%)	109 (55.1%)
Online lectures	135 (76.7%)	140 (70.7%)
Online quizzes	145 (82.4%)	141 (71.2%)
Online web pages to supplement classroom learning	149 (84.7%)	141 (71.2%)
Online videos to supplement classroom learning	128 (72.7%)	135 (68.2%)
Online discussion forums to supplement classroom interactions	95 (54.0%)	89 (44.9%)

Figure 1A: Percentage of Residents Ranking Various Modalities as Desirable for Learning a New Clinical Procedure

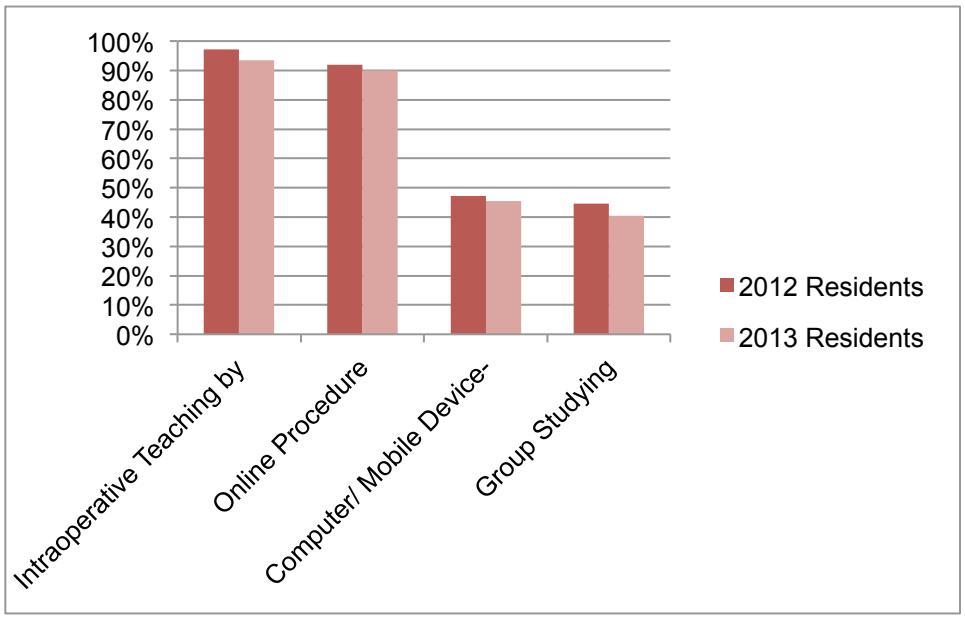


Figure 1B: First-Line Resources Residents Seek To Answer a Clinical Question

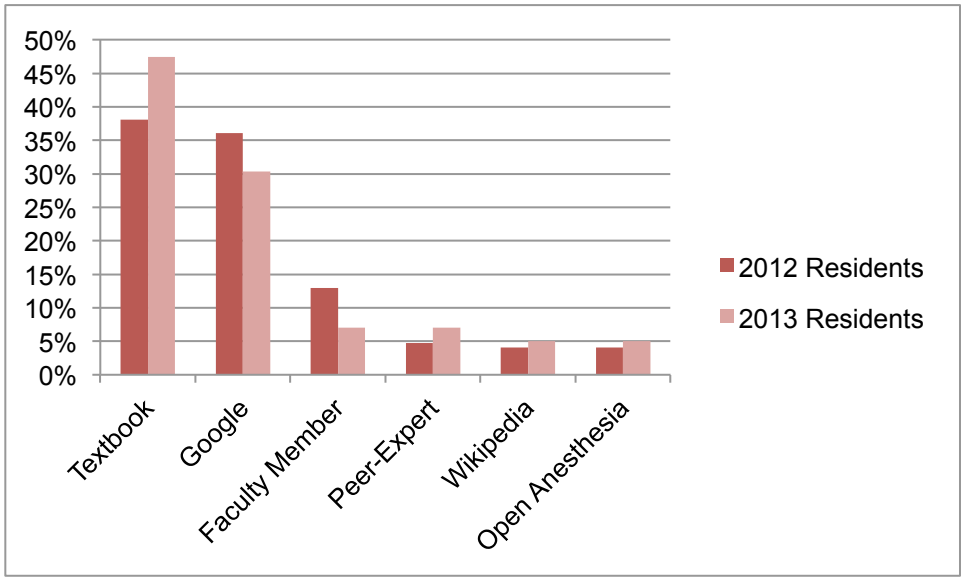


Figure 1C: Number of Devices Owned by Residents

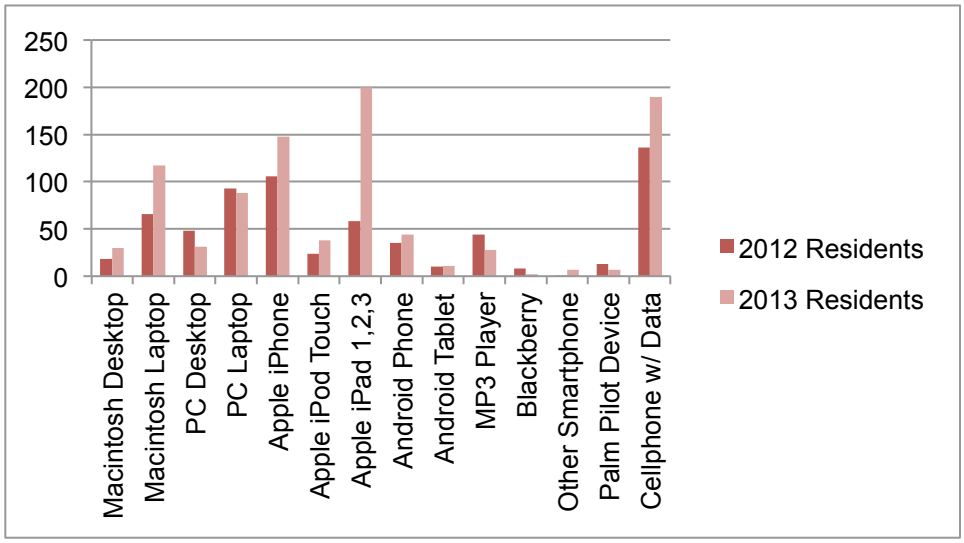
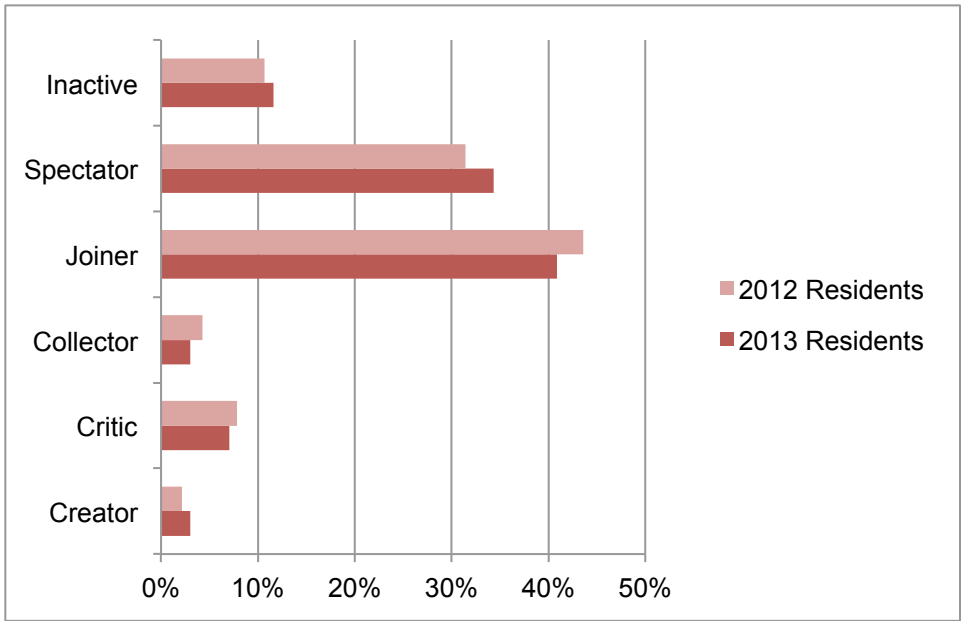


Figure 1D: Residents' Self-Described Social Media User Profiles



Reduction of Fresh Gas Flow During Administration of Volatile Anesthetic Agents via Monthly Individualized E-Mail Feedback

Presenting Authors: Neil Patel MD;1 David Maguire MD;1 Franklin Dexter MD, PhD;2 Richard H. Epstein MD;1 1Department of Anesthesiology, Thomas Jefferson University Hospital and Jefferson Medical College, Philadelphia, PA 2Department of Anesthesia, University of Iowa, Iowa City, IA

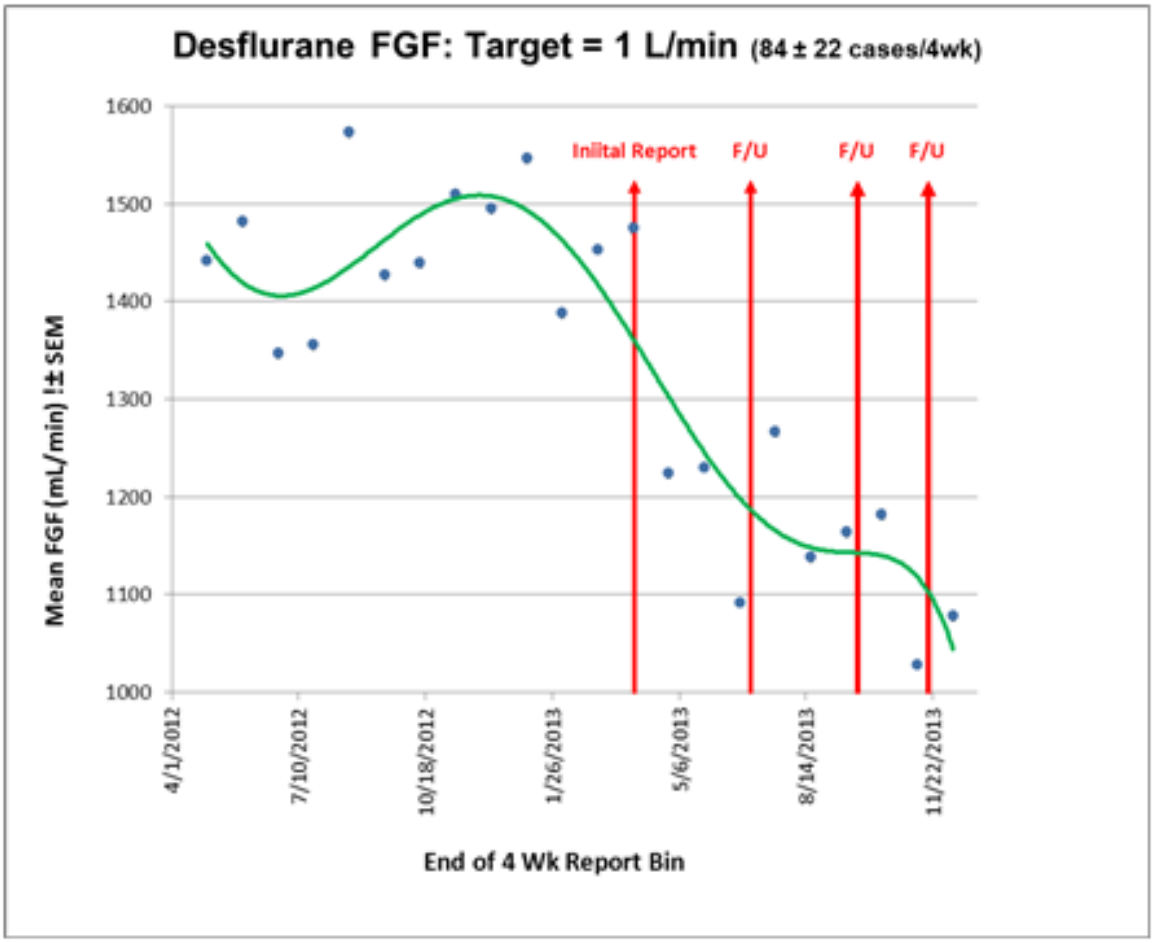
Introduction: Reducing excessive fresh gas flow (FGF) during general anesthesia is a simple strategy to lower the cost of administering inhalational agents. Atmospheric venting of such ozone-depleting gases and subsequent greenhouse gas effects are also of concern. Nair et al. recently showed that real-time feedback from their Smart Anesthesia Messenger™ system reduced FGF during surgery.i For sevoflurane (SEV) and isoflurane (ISO), but not for desflurane (DES), FGF rates increased when decision support system (DSS) messages were suppressed, and decreased when the DSS was reactivated. Although we have a similar DSS connected to our anesthesia information management system (AIMS), our approach to changing behavior is first to attempt personalized e-Mail feedback before adding real-time messages, since such messages are potentially disruptive, challenging to maintain over generations of AIMS, and may be subject to future FDA regulation. Implementing a DSS is a non-trivial task, and access to real-time monitoring data is difficult within many commercial, enterprise-wide AIMS. Not only is database reporting by e-Mail easier to implement, it provides a scalable solution. We hypothesized that a personalized feedback system, with reports delivered intermittently via e-Mail, would result in a reduction in FGF.

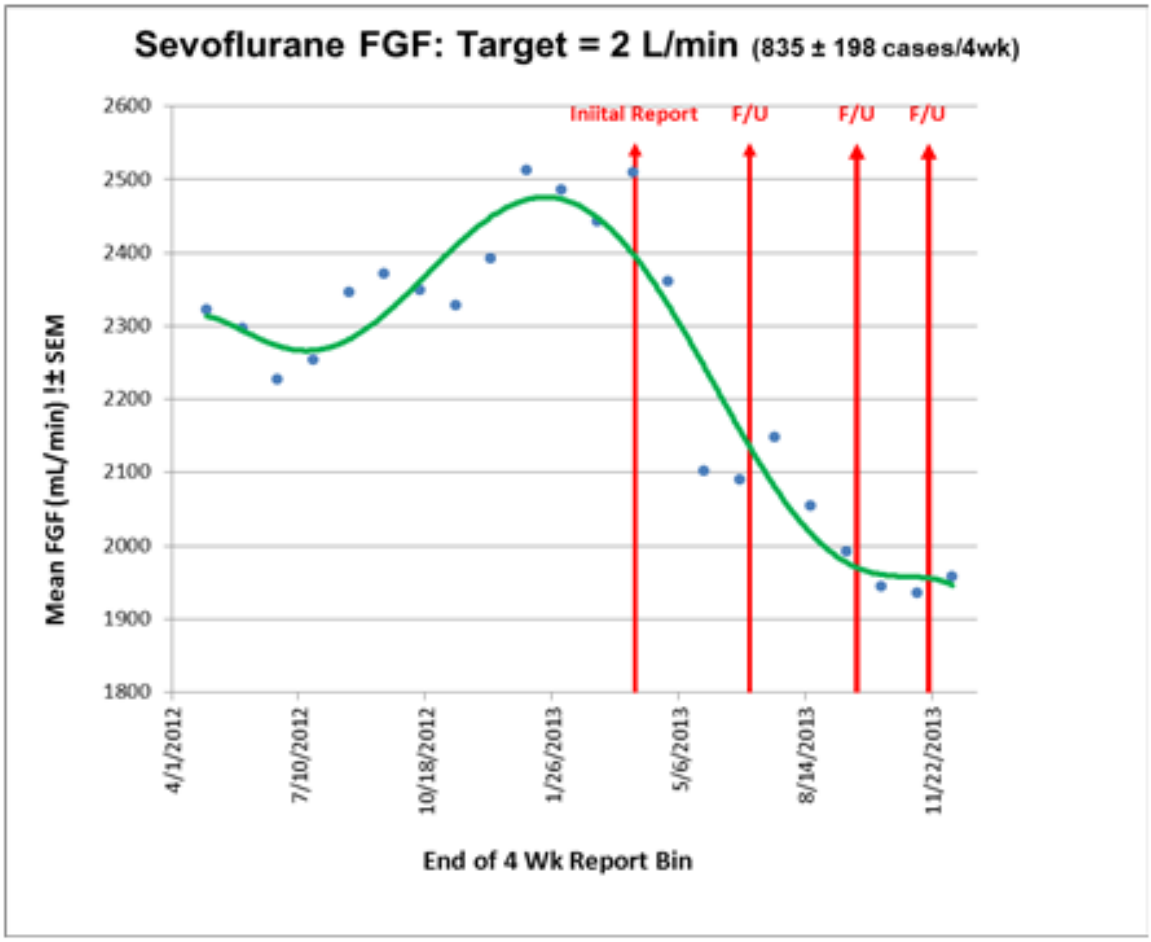
Methods: This quality improvement project was considered exempt from IRB review. Cases were included if done with a laryngeal mask airway or tracheal tube and an inhalational agent. Cardiopulmonary bypass cases were excluded, as were cases where multiple volatile agents were given. The timestamps of measurements, volatile agent, and FGF were retrieved from our AIMS from surgery begin to end for cases where this interval was ³15 min. We presented the program as an environmental initiative, with cost savings as a secondary benefit. In April 2013, each anesthesia provider was e-Mailed a report describing his or her FGF for each agent over the prior 12 months, along with an explanation of the goal to reduce mean FGF for ISO and DES to 1.0 l/min and SEV to 2.0 l/min. Providers' reports included cases where they were the sole provider. Anesthesiologists' reports included cases where they were the sole supervisor. Individualized reports for each agent (with n ³ 10 cases) over the previous 12 weeks were e-Mailed on Jul 1, Sep 4, Sep 23, and Oct 21, 2013. Data are presented as the mean FGF ± standard error (SEM), calculated using the method of batched means and 4-week bins. Comparisons to baseline used the two sided unpaired Student t-test. Results for ISO are not reported, as mean use is less than 1 case per day.

Results: During the baseline period, the FGF was 1.46 ± 0.02 l/min for DES (N = 64.8 ± 4.5 cases per bin) and 2.37 ± 0.03 l/min for SEV (N = 881.5 ± 23.1 cases per bin). The FGF

decreased compared to baseline over the last 5 4-week intervals to 1.12 ± 0.03 l/min for DES (P < 10-6) and 1.98 ± 0.02 l/min for SEV (P < 10-6). SEV and DES FGF rates were correlated, with R = 0.89 (P < 10-6), suggesting that the reductions were related to the e-Mail intervention, and were not simply random events.

Discussion: Personalized e-Mail notifications reduced the SEV FGF to below our target of 2.0 l/min, but the DES FGF remains slightly above our target of 1.0 l/min. Additional reporting periods will be required to determine if the SEV FGF benefit is sustained, with data collection and personalized e-Mails ongoing. i Nair BG et al. Anesthesiology. 2013; 18:874-84




Sevoflurane FGF: Target = 2 L/min (835 ± 198 cases/4wk)
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Assessing Impact of Fatty Meal on Vasodilating Ability of Microcirculation

Presenting Author: Siqin Nie M.D.[1], Department of Anesthesiology[1], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC

Co-Authors: Daniel Tran M.D.[2], Siqin Nie M.D.[1], I-Hsun Liang, M.D.[2], Megan Wenner, Ph.D.[3], Nina Stachenfeld, Ph.D.[3], Tyler Silverman, D.P.M.[4], David G. Silverman, M.D.[2]: Department of Anesthesiology[1], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC; Department of Anesthesiology[2] and The John B. Pierce Laboratory – Physiology[3], Yale University School of Medicine, and Department of Podiatry[4], Cambridge Health Alliance, Boston MA

Background/Introduction: In an attempt to impact cardiovascular disease and its consequences, anesthesiologists have applied their interest and expertise in cardiovascular monitoring to nonoperative settings. This has prompted the present assessment of the impact of a high-fat (HF) meal on endothelial function. Chronic lipid administration in patients with underlying cardiovascular disease leads to worsening morbidity. In a recent study (ASA 2013;#3215) we showed that, after a high-fat (HF) meal, healthy subjects had reduced at rest laser Doppler (LD) measurements of microcirculatory flow. The present study sought to determine if the difference persisted in response to vasoactive challenges, i.e., 1) local application of transdermal nitroglycerin (NTG), an inducer of endothelial-independent vasodilation; 2) changes in endothelial function as measured by flow-mediated dilation (FMD) secondary to occlusion-induced endothelium-dependent nitric oxide release.

Methods: With IRB approval, 14 healthy volunteers were studied, in a crossover design, after a HF meal (75 grams) and an equi-caloric low-fat (LF) meal. On each day, subject underwent FMD and NTG. After 15 minutes of supine rest, a baseline longitudinal image of the brachial artery diameter and blood flow velocity was recorded using the LOGIQ-e imaging system (General Electric Healthcare, Wauwatosa, WI). Forearm ischemia was then induced by rapidly inflating a blood pressure cuff distal to the olecranon process to 200 mmHg for 5 minutes. Brachial artery diameter was measured 15 seconds prior to cuff deflation and continuously thereafter for 2 minutes. The percentage change in brachial artery diameter from cuff release to peak diameter was determined. One hour later a 1x1 cm NTG patch was placed on the forehead. LD flowmetry measurements of height (volts) and peak area (volt·sec) were collected continuously at 10 Hz until a peak was obtained (<20 min); drug-induced increases in perfusion were determined. LF and HF differences were analyzed with paired t-test.

Results: While there was a trend towards decreased FMD readings after HF (LF-HF=1.842±6.3), this was not significant. Responses to NTG were similar after each meal (p=NS) (Fig 1).

Conclusion: The findings suggest that, although an HF meal may slightly compromise baseline flow (ASA 2013;#3215), the difference is overcome by a vasoactive challenge. The lack of a significant difference in the present study may be attributable, in part, to the high variability

associated with FMD and LD. Responses may be different in patients with compromised vasculature.

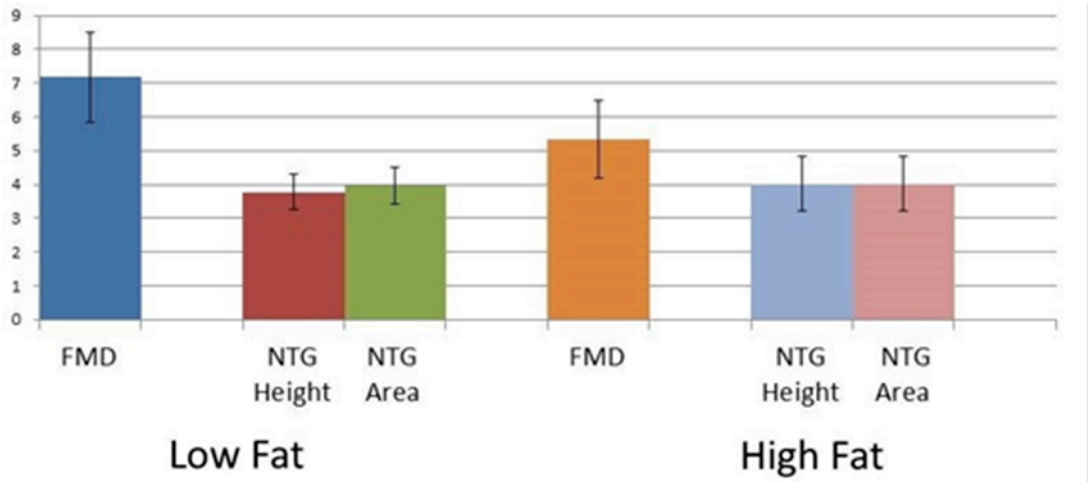


Figure 1

Monitoring Arterial and Venous Volume Response to Release of Lower Body Negative Pressure (LBNP) Using Photoplethysmograph (PPG)

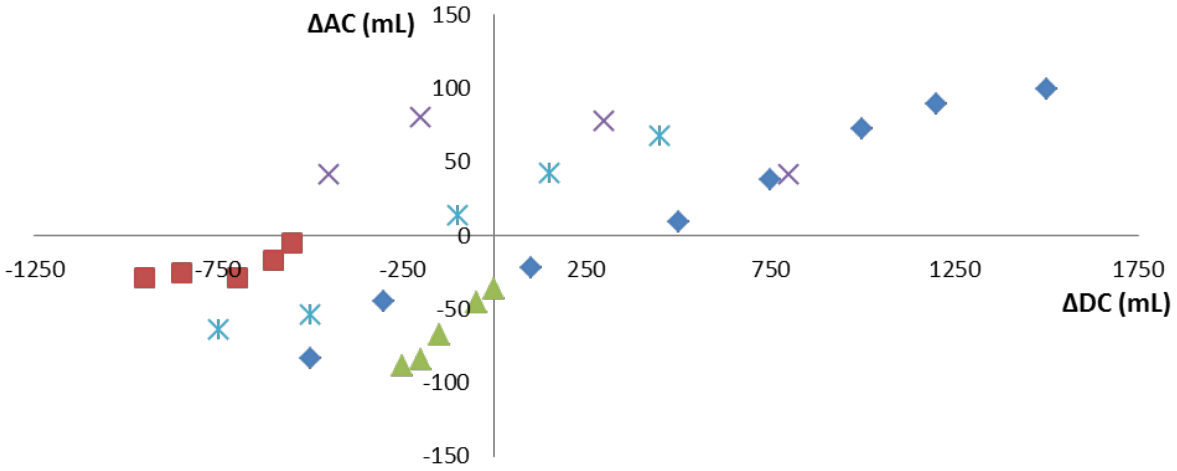
Presenting Author: Vicki Bing, B.S., Department of Anesthesiology, Yale University School of Medicine

Co-Authors: I-Hsun Liang, M.D.[1], Siqin Nie, M.D[2]., Aymen Alian, M.D.[1], Kirk Shelley, M.D., Ph.D.[1], Nina Stachenfeld, Ph.D.[3], David G. Silverman, M.D.[1], Department of Anesthesiology[1], Yale University School of Medicine; Department of Anesthesiology[2], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC; and The John B. Pierce Laboratory – Physiology[3], Yale University School of Medicine

Introduction: Recent research in monitoring aims to the return to the roots of the PPG and extract volumetric information from its waveform. Previous studies from our laboratory have shown that a voltage to volume conversion based upon pulsatile volume at rest allows volume monitoring using PPG.[1] The current study aims to further extract arterial and venous circulatory volume components from PPG via simulated volume loading of 0.75-2L upon release of LBNP.

Methods: Data were extracted from retrospective LBNP studies on five healthy volunteers with IRB approval. Stroke volumes (SV) were estimated by echocardiography, when available. All PPG waveforms were analyzed in ADInstruments LabChart. AC and DC were found before and during LBNP by averaging at least 75 and 10 beats, respectively. The release segment (from LBNP off to maximum PPG value) was roughly divided into 4-8 successive phases. AC and DC of each phase were found by averaging 10-12 beats. ΔAC and ΔDC from baseline were calculated for each phase and converted to a volume using AC at rest; $\Delta AC = (AC_{recovery\ phase\ x} - AC_{at\ rest})/(AC_{at\ rest}/SV_{at\ rest})$; $\Delta DC = (DC_{recovery\ phase\ x} - DC_{at\ rest})/(AC_{at\ rest}/SV_{at\ rest})$.

Results: ΔAC and ΔDC during maximum LBNP and LBNP release (Graph 1) are consistent with literature values. Overshoot of volume return may be attributable to vasodilation and splanchnic vasculature mobilization. ΔDC/ΔAC ratio tends to be smallest initially and greatest at the end of volume resuscitation. Distortions in the relationship were accompanied by abrupt hypotension and bradycardia.



Graph 1. Changes in AC and DC from baseline during release of LBNP in five healthy subjects.

Conclusion: PPG may be used as a noninvasive monitor of arterial and venous volume status, which can be useful in assessing response to fluid resuscitation. Moreover, the evidence of Frank-Starling relationship between AC (arterial) and DC (venous) may shed light on physiologic processes and warrants further study.

Reference: ASA 2013; #A3102

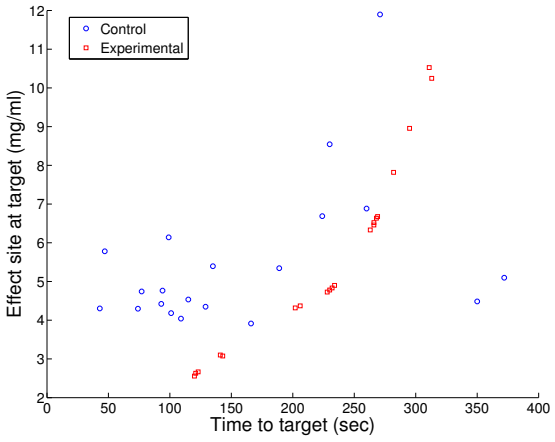
A Randomized Controlled Trial of Probability Ramp Control of Propofol for Esophagogastroduodenoscopy

Presenting Author: Jeff E Mandel MD MS, Perelman School of Medicine, Univ of Pennsylvania

Co-Author: Elie Sarraf MDCM, Perelman School of Medicine, Univ of Pennsylvania

Background: Endoscopic sedation requires titration of propofol to an endpoint of deep sedation with minimum overshoot. This is typically accomplished by intermittent boluses of propofol followed by an infusion to maintain the desired state. Patients vary in pharmacokinetics and pharmacodynamics, and proper timing of incremental doses is required to assure a steady increase in drug concentration and observation is required to determine when an adequate dose has been given. Probability Ramp Control (PRC) is decision support software that simplifies and standardizes this approach by providing the clinician with a simple infusion sequence that gradually increases the propofol until the desired endpoint is achieved. Our hypothesis was that PRC could deliver sedation that was substantially equivalent to that delivered by experienced practitioners with a reduction in the need for intervention in the control process.

Methods: With IRB approval and informed consent, 40 patients scheduled for elective diagnostic esophagogastroduodenoscopy were enrolled in a randomized open label study. Depth of sedation was assessed by SEDLine PSI. Patients were judged adequately sedated when a Robertazzi nasopharyngeal airway could be passed without purposeful response. In the control arm, a CRNA titrated propofol to this endpoint then selected an infusion rate, providing additional propofol as deemed necessary, with propofol administration was logged by an investigator. In the experimental arm PRC was employed to achieve sedation and determine the maintenance infusion. Deviation from the initially specified infusion rate and time to target identification were assessed.



Results: The two groups were similar in age, weight, and procedure duration, as were total propofol dose, estimated effect-site concentration at loss of responsiveness, estimate peak effect-site concentration, and average PSI score. Time to tolerance of airway placement was lower in control. Adjustments to control were required in 20/20 control and 2/20 experimental patients. In the experimental group, 5 patients achieved adequate sedation at target levels below 4 µg/ml, while in control, no patients were identified at this low a target.
Conclusions - Faced with an equivalent cohort of patients and procedure durations, PRC administered a similar dose of propofol to that of CRNAs, yielding similar effect-site concentrations and PSI values. It was able to do so with fewer alterations in propofol dosing during the procedure and was able to identify patients requiring lower maintenance doses of

propofol than control. PRC shows promise in altering manpower requirements in endoscopic sedation.

References:

Mandel JE, and Sarraf E. The variability of response to propofol is reduced when a clinical observation is incorporated in the control: a simulation study. Anesth Analg. 2012;114:1221-9.

Development, Evaluation, and Validation of a Rating Instrument for Multiple Categories of Medical Equipment (DEVICE) Study: Preliminary Results

Presenting Author: Thomas D. Looke MD, PhD, Florida Hospital, Orlando Florida

Co-Authors*: Michelle Dolske, PhD and Julie Pepe, PhD*

Background: As technology improves, physicians and other health care workers employ increasingly complex medical devices in the conduct of their daily activities. The Food and Drug Administration (FDA) expects manufacturers to apply human factors and usability engineering principles to optimize medical device design, but there are no guidelines or published studies to tell hospitals how to incorporate end-users in a rigorous fashion to help guide purchasing decisions. Including all stakeholders in the medical device purchasing process is an important finding of human factor research (Ref 1). However, the end-user, as one of the key stakeholders, is often not included on purchasing teams and poorly utilized as a source of safety and usability experience (Ref 2). There are two stages to development of a useful questionnaire: Design and Validation. We report here our design methodology and preliminary statistical results. Validation testing of our proposed questionnaire is ongoing.

Methods: We adopted a classical questionnaire design approach (see Table 1) as described by Devellis (Ref 3): **Construct**: We chose a modular structure describing medical devices by their features (see table 1) allowing our questionnaire to be easily customized. **Item Pool**: Generated first by the authors and expanded with input from a 12-member expert panel of anesthesiologists, an initial 160-question pool was divided into 9 dimensions (see Table 1). **Measurement format**: Medical devices are "sold" with a performance expectation, so we chose to employ a 5 point (Likert) "expectation" scale to allow users to compare actual device performance to the "expected" performance. **Initial Expert Review**: We invited 48 anesthesiologists and CRNAs (content experts) to evaluate the initial 160-question pool. Each expert rated one of 12 commonly used medical devices which were chosen to assure all device features and questionnaire dimensions were represented in the initial review. Along with the device rating, we asked the experts to rate and comment on the survey questions themselves.

Results: We correlated expert device rating results within each dimension using statistical software and marked all groups of questions with correlation values >0.90 (redundant items). We reviewed the expert comments for each redundant item and eliminated 18 questions to yield a final test questionnaire with 142 questions. Factor analysis verified item cohesion and independence of each dimension. Each of the 142 questions was then entered into a Device-Feature Matrix (Figure 1) to facilitate questionnaire customization.

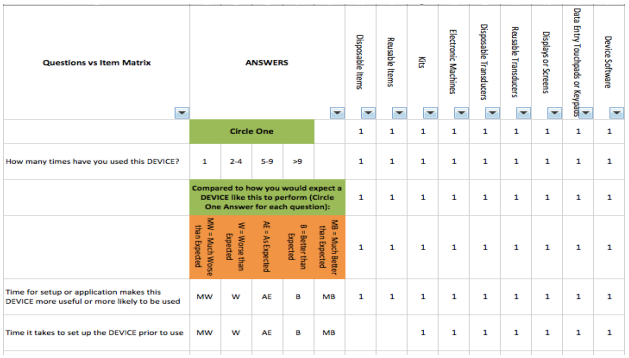
Conclusion: We report the first effort to develop a generic and useful tool to allow end-users to judge new medical devices and significantly and objectively impact hospital and department purchasing decisions. The tool is customizable to the complexity of the medical device. The large set of questions resulting from our design process is currently being tested and optimized for reliability, validity, and utility.

References: 1. Nielsen J. Usability Engineering. San Diego: Morgan Kaufmann; 1993. **2.** Johnson TR et. al., The Role of Patient Safety in the Device Purchasing Process. Found in: Advances in Patient Safety: From Research to Implementation (Henriksen K et al., editors) Rockville (MD): Agency for Healthcare Research and Quality (US); 2005 Feb. Available from: http://www.ncbi.nlm.nih.gov/books/NBK20452/ **3.** DeVellis, Robert F. Scale Development: Theory and Applications, 3rd edition, 2012.

Table 1. Questionnaire Design and Development Details

Study Issue	Details
Classical Design Steps	1. Identify a construct 2. Generate an item pool 3. Determine measurement format 4. Conduct initial expert review
Medical Device Features	1. Disposable items 2. Reusable items 3. Kits 4. Electronic Machines 5. Disposable Transducers 6. Reusable Transducers 7. Displays or Screens 8. Data Entry Touchpads or Keypads 9. Device Software
Questionnaire Dimensions	1. Ease of use 2. Device construction 3. Kit components 4. Performance 5. User interface 6. Storage-integration-interoperability 7. Safety 8. Universality-cost-value 9. Head-to-head comparison

Figure 1. First 3 Questions of Device-Feature Matrix



Questions vs Item Matrix	ANSWERS					Disposable Items	Reusable Items	Kits	Electronic Machines	Disposable Transducers	Reusable Transducers	Displays or Screens	Data Entry Touchpads or Keypads	Device Software
	Circle One					1	1	1	1	1	1	1	1	1
How many times have you used this DEVICE?	1	2-4	5-9	>9		1	1	1	1	1	1	1	1	1
	Compared to how you would expect a DEVICE like this to perform (Circle One Answer for each question):					1	1	1	1	1	1	1	1	1
	MW - Much Worse than Expected	W - Worse than Expected	AE - As Expected	B - Better than Expected	MB - Much Better than Expected	1	1	1	1	1	1	1	1	1
Time for setup or application makes this DEVICE more useful or more likely to be used	MW	W	AE	B	MB	1	1	1	1	1	1	1	1	1
Time it takes to set up the DEVICE prior to use	MW	W	AE	B	MB			1	1	1	1	1	1	1

Automated Triggering of NIBP Measurements Using Oximetry Data

Presenting Author: James N Watson[1], Ph.D., Technical Fellow, Covidien Respiratory & Monitoring Solutions, Edinburgh, Scotland, UK

Co-Authors: Rakesh Sethi[1], MSc; Graeme Lyon[1], MEng and Sergio D. Bergese[2], MD.
[1] Covidien, Respiratory and Monitoring Solutions;
[2] Departments of Anesthesiology and Neurological Surgery, The Ohio State University

Introduction: It has been widely reported that high blood pressure variability (BPV) may be correlated with patient complications and the literature has provided evidence for the prognostic significance of awake systolic BPV [1]. There is also a desire to respond to significant changes in BP in a timely fashion in order to optimize the treatment of patient conditions [2]. The objective of this work is to investigate a patient safety tool that aids in the identification of changes in hemodynamic status between timed cuff inflations, and triggers a new NIBP measurement when appropriate, using standard oximetry data.

Methods: The algorithm is designed to issue a trigger command to an NIBP cuff when the hemodynamic status of a patient has changed. To achieve this proposed objective, the device monitors a series of metrics (HR, % modulation, pulse statistics) derived from the pulse oximeter signal and compares them with reference values, obtained at the previous cuff measurement time These deviations from the reference values are compared with a series of thresholds which, in turn, determines whether to trigger a measurement request or not.

With institutional review board approval and written informed consent, physiologic data obtained from 31 subjects was analyzed to test the feasibility of this device (ASA III/IV; ICU: 5, OR: 26). No specific disease states or pathophysiologic conditions were targeted during enrollment. Pulse oximeter trace sections were divided into pairs with a 'truth' for mean arterial pressure changes between pairs being derived from peripheral arterial line data. To determine the sensitivity and specificity of the method in identifying pressure changes of various degrees a Receiver Operator Characteristics (ROC) analysis was performed.

Results: During periods of no motion, a sensitivity of greater than 95% in identifying pressure changes larger than 30mmHg was achieved at a specificity of 90%. The full ROC curve analysis is presented in Figure 1 for various sensitivity/ specificity pairs over three blood pressure changes (10, 20 and 30mm/Hg).

Conclusion: Automated triggering may enhance the functionality and clinical utility of currently available NIBP devices. In this feasibility experiment the blood pressure trend is more accurately captured and significant changes in blood pressure more quickly identified than when using timed pressure measurements alone ($p < 0.05$).

References

[1] Mena L, Pintos S, Queipo NV, Aizpúrua JA, Maestre G, Sulbarán T. A reliable index for the prognostic significance of blood pressure variability. J Hypertens. 2005 Mar;23(3):505-11.

[2] Monk,TG. Anesthetic management and one-year mortality after noncardiac surgery. Anesth Analg. 2005 Jan;100(1):4-10.

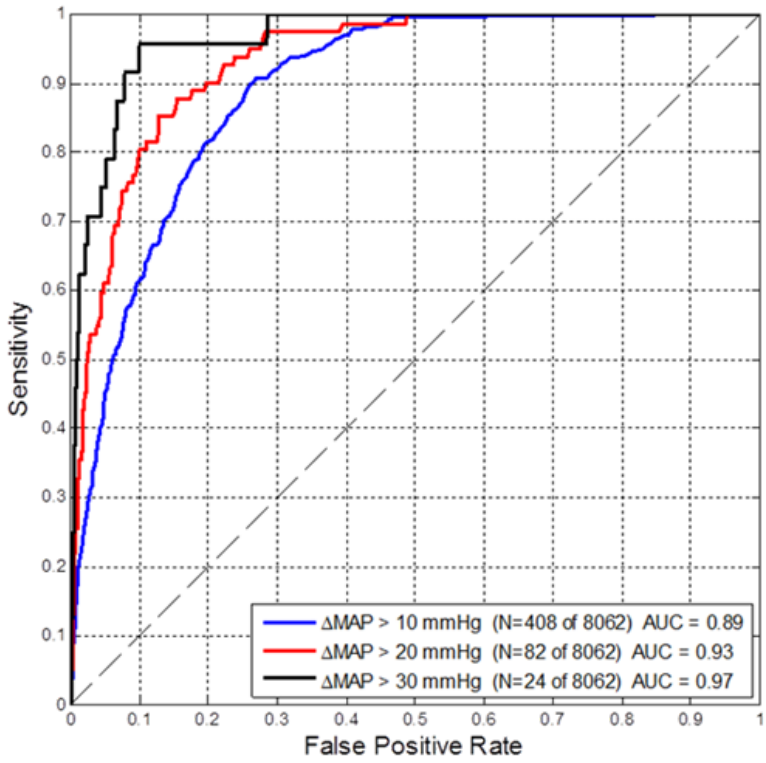


Figure 1. A ROC curve reflecting system efficacy in identifying pressure changes from an in-hospital data set (ICU and OR patients).

Closed-Loop Testing of Pulse Oximeters During Subject Motion

Presenting Author: James N Watson[1], Ph.D., Technical Fellow, Covidien Respiratory & Monitoring Solutions, Edinburgh, Scotland, UK

Co-Authors: Rakesh Sethi[1], B.Sc., B.Eng., Graeme Lyon[1], M.Eng., Yu-Jung Pinto[1], M.Sc., Paul D Mannheimer[2] Ph.D., Michael Luna-Victoria[1], R.T., B.Eng., Keith Batchelder[1], Ph.D., Scott Kelley[1], M.D.

[1] Covidien, Respiratory and Monitoring Solutions;
[2] Mannheimer Consultancy, California, USA;

Introduction: Recent changes to the international standard for oximeter safety and testing recommend the disclosure of measurements that indicate the degree of artifact created when evaluating performance during motion [1]. These recommendations have been incorporated into recently published FDA guidance [2]. We describe a new test methodology that provides a chain of evidence designed to illustrate protocol compliance (through pressure pad logging and video), the degree of induced signal artifact (through metric disclosure), and system performance (through results analysis). We further present the results when a popular pulse oximeter device (N600x, Covidien, Boulder, USA) is tested using this procedure.

Methods: Motions including tapping and rubbing were generated with amplitudes of 1-2 cm and random intermittency (frequencies of 1-4 Hz). Each subject was instructed to move their fingers such that a consistent area of effect was maintained on a calibrated pressure pad. The instructor had real time feedback from the pad and video to aid coaching. The pad and video information was recorded and subsequently used to exclude subject data not consistent with protocol compliance. The finger movements were videoed next to a visible cue and displayed to the subjects to facilitate protocol compliance by closing the feedback loop identified by Shang et al. [3].

With IRB and informed consent, seventeen healthy, adult, volunteer, subjects were enrolled (age: 31.6 ± 6.5 years; 7 female / 10 male; Pigmentation: 2 dark, 2 olive and 13 light). An invasive blood hypoxia study during motion was conducted according to EN ISO 80601-2-61:2011 [1]. The reported SpO_2 and pulse rates were collected from the units under test: Nellcor N-600x monitors (comprising the Nell-1 OEM board). These data were compared to reference-standard measurements of blood SaO_2 (by CO-Oximeter) and heart rate (by ECG) during motion conditions. Performance was evaluated using paired observations from the N-600x monitor and the reference over an SaO_2 range of 70% to 100%. System accuracies were calculated as Accuracy Root Mean Square (A_{RMS}) and the existence of a significant noise component was shown through percent modulation signal metrics, as recommended in [1].

Results: Fourteen subjects provided motion consistent within the protocol requirements and were included in the study analysis. Three were excluded, having too few points of contact with the pressure mat for more than 25% of the motion time of the study. Signal percent

modulation was statistically greater (*P<0.05* Wilcoxon Rank sum) and 1.80 times larger during motion periods compared to quiescent periods. The A_{RMS} for SpO_2 was 1.53% (N = 1240; range: 70 to 98.4%) and pulse rate was 1.64% (N = 1300; range: 47 to 102 beats per minute) during motion.

Conclusion: Novel monitoring equipment has been used to close a previously highlighted feedback loop [1]. It has further illustrated protocol compliance and ensured statistically significant artifact has been added during motion testing. Across the SaO_2 saturation range of 70 to 100%, these results indicate the N600x monitor provides accuracy better than 2% for both SpO_2 and pulse rate during the quantified motion conditions described.

References

[1] EN ISO 80601-2-61:2011 Particular requirements for basic safety and essential performance of pulse oximeter equipment.
[2] Pulse Oximeters - Premarket Notification Submissions [510(k)s] Guidance for Industry and Food and Drug Administration Staff, Food and Drug Administration, 2013.
[3] Shang AB, Kozikowski RT, Winslow AW and Weininger S, Development of a Standardized Method for Motion Testing in Pulse Oximeters; Anesth Analg; 2007; 105(6); pp S66-105

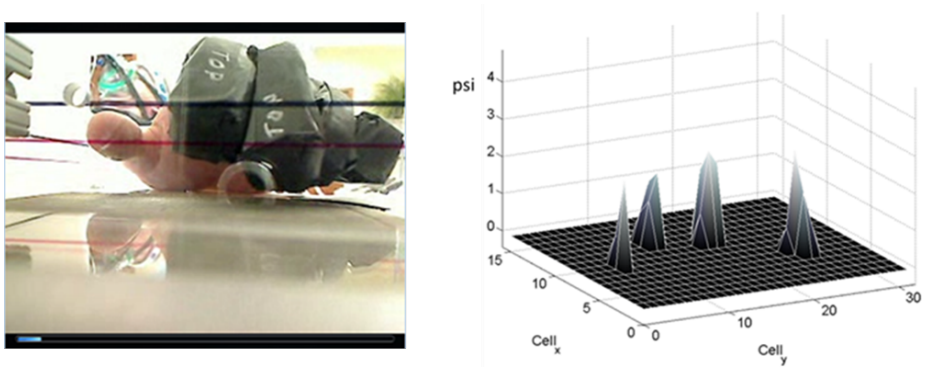


Figure 1: Sample video still (left) and pressure pad (right) data as used to ensure protocol compliance

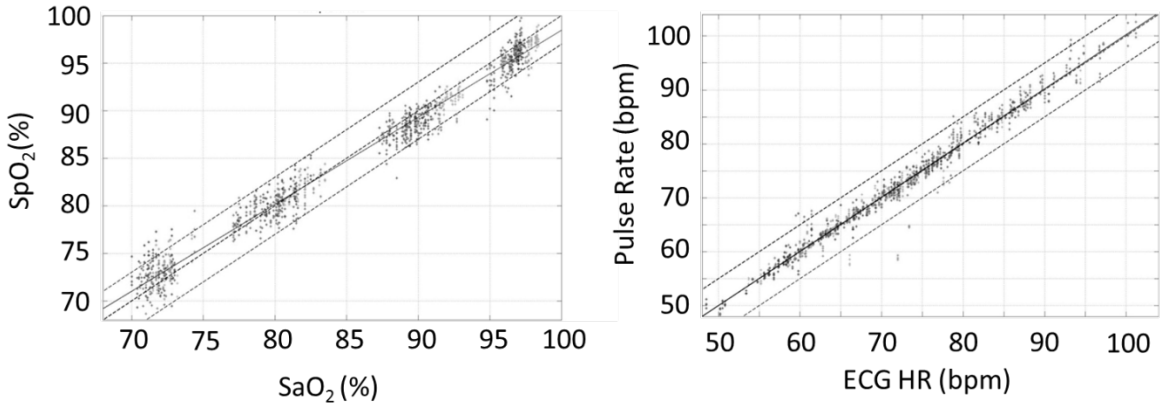


Figure 1: Correlation Plot for SpO_2 (left) and pulse rate (right) - All Data

The EEG Spectrogram as a Real Time Monitor of Anesthetic Depth for Individual Patients

Presenting Author: Christopher Scheib, MD, Hefner VAMC

Background: At a previous meeting of the Society for Technology in Anesthesia, this investigator reported that there is a consistent progression in the shape of the EEG spectrum as the concentration of a halogenated anesthetic agent is changed across its clinically useful range. The concept that it is easier to appreciate these changes when the EEG spectra are displayed as a log-log graph (power vs. frequency) instead of the conventional log-linear graph was also introduced at that time. Here we report an extension of this evaluation to include propofol based (TIVA) anesthetics and compare their spectral progression with that of halogenated agents. Also, efficient methods to track changes in an EEG spectrum during surgery and methods to compare one EEG spectrum to several simultaneously are demonstrated.

Method: The raw EEG data from 25 patients anesthetized with halogenated agents and 25 patients anesthetized with propofol had been previously obtained with an IRB approved protocol. In the previous investigation the EEG spectra were created with a Matlab program which did not enable the user to superimpose two spectra easily. Since then a program was written which runs through the data of an entire recorded case at an accelerated speed displaying the EEG spectra and any selected second spectra for comparison. This makes it easy to evaluate changes in the EEG spectra over the duration of the recorded anesthetic. The program enables the user to stop and save EEG spectra which can be displayed for comparison or imported into an Excel spreadsheet. Excel is used to simultaneously compare all of the spectra in a series. This data is being archived to create a library of reference spectra for all anesthetic agents and all demographic groups of patients to be used in a method of EEG based intra-operative monitoring.

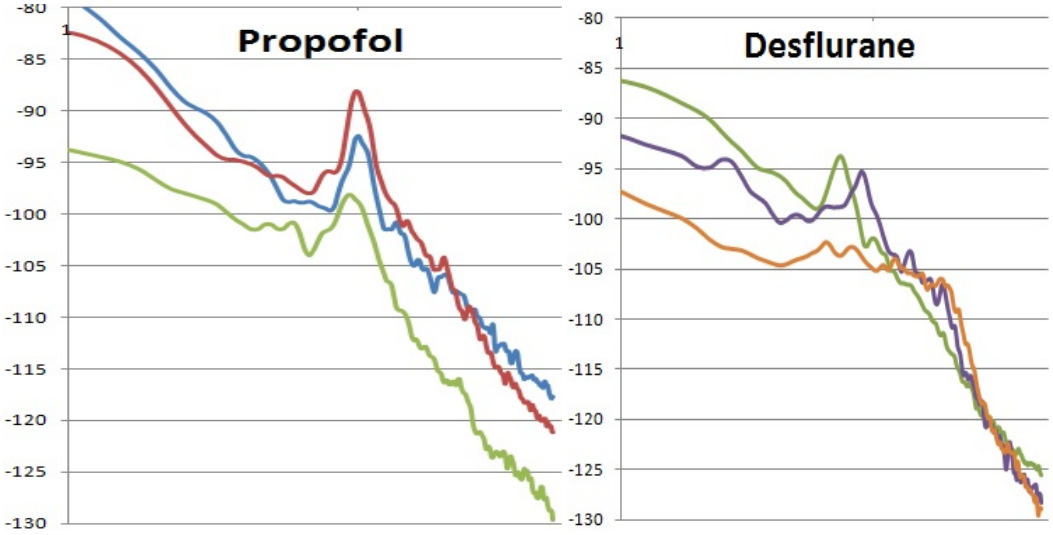
Results: There are separate and distinct pathways of progression of the spectra for halogenated agents versus propofol based anesthesia. However the two paths intersect at approximately one MAC with a single pattern for the EEG spectrum for both types of anesthetics at that point. The level of analgesia (opioids or regional anesthesia) can have a profound effect on the progression of EEG spectra, especially at lower concentrations of anesthetic agents.

Conclusions: The two different pathways of EEG spectral progression cast doubt on the concept that one EEG analysis algorithm can be accurate for both propofol and halogenated agents or that an EEG based index measures the "hypnotic effect" of anesthetics.

Establishing the pattern of progression of EEG spectra makes it possible to use the EEG spectra to monitor and titrate the level of anesthesia for individual patients. Using this method, after anesthesia is established the current EEG spectrum can be compared to the spectra in a library of spectra from similar patients with the same agents. This will result in an estimate of the point in the progression. Because there is variability between patients, accuracy is improved by increasing or decreasing the concentration and comparing with the previous spectra and the collection of spectra. After the EEG spectra at two or three levels of agent concentration are evaluated it is clear where the

patient is in the progression.

At lower levels of anesthesia the effectiveness of analgesia can be evaluated by observing whether or not the administration of additional opioid changes the EEG spectral pattern toward one associated with a deeper level of anesthesia.



ALERTSTATS™: An Anonymous, Provider-Specific, Quality Metric Feedback System

Presenting Author: James Szocik, MD, University of Michigan Medical School

Co-authors: Kevin Tremper, PhD, MD, University of Michigan Medical School

Background/Introduction: To improve a departments' overall quality of care each clinical provider must improve their individual care. For provider to modify their care to adhere to guidelines, they must have clear and agreed upon metrics and optimally an alerting system that warns them when they are approaching the range of concern. Finally, a user specific feedback system, which would allow providers to see their care relative to their peers, would complete the quality improvement cycle. Recently, a multifunction, icon-based alert display was developed at the University of Michigan (AlertWatch™), which receives data from the physiologic monitor, the AIMS, history and physical data, and the laboratories. To provide individual specific feedback on care a series of metrics, which are associated with alerts, are presented on a display. The following is a description of this system: AlertStats™.

Methods: Quality metrics were developed for the following parameters: glycemic control, blood pressure, transfusion management, postoperative pain, postoperative temperature, and weight not entered. Two levels of management/treatment were assessed for glucose, blood pressure, hematocrit and pain score. An exclusion criterion for each parameter was developed to minimize the effect of outlier patients or treatments. A weekly query was run on the database, and a display generated for each provider showing their performance relative to the whole.

Results: Figure 1 shows a single parameter (glucose >200 ml/dl, treated or not) using absolute number of occurrences. Figure 2. Shows the same parameter using percentage. Note the shift in the provider's location on the "bad" to "good" axis. Figure 3 shows the same information as figure 1, the absolute number of treatment against the opportunities to treat. Note the provider who had the same absolute number of untreated glucose, but missed treating all potential ones. Lastly figure 4 shows a single provider over time. These outputs are available for all the quality metrics listed.

Conclusion: This system has been recently initiated at the University of Michigan. The effect on outlier improvement in care has not assessed to date. Further studies will be required to determine if providing this individual feedback will improve each provider's performance in compliance with quality metrics and therefore improve the overall department's metrics and hopefully postoperative outcomes measures.

Figure 1.

Operations with glucose readings over 200 not treated with insulin
(July 01, 2012 to November 30, 2013)

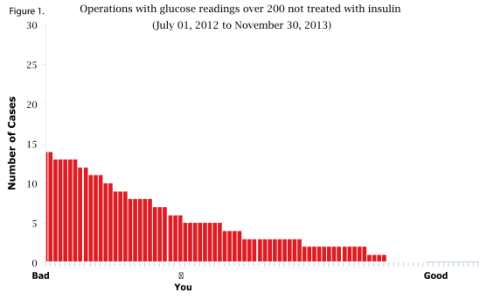


Figure 2.

Percentage of operations with glucose readings over 200 not treated with insulin
(July 01, 2012 to November 30, 2013)

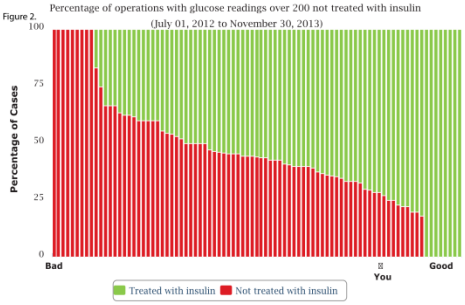


Figure 3.

Operations with glucose readings over 200 not treated with insulin
(July 01, 2012 to November 30, 2013)

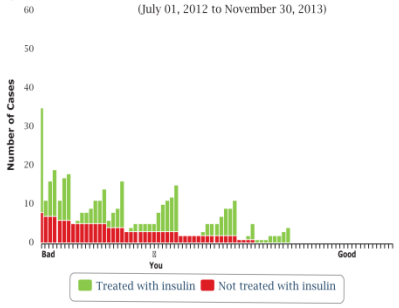
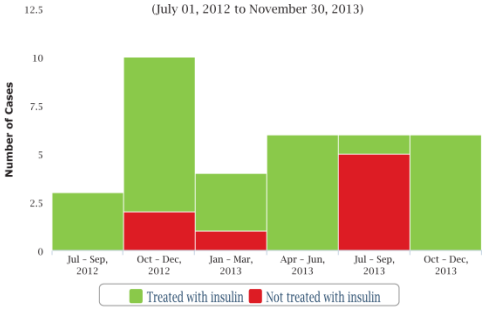


Figure 4.

Operations with glucose readings over 200 not treated with insulin
(July 01, 2012 to November 30, 2013)



Development of a Student-Faculty Matching Algorithm for Preceptorship Placement

Presenting Authors: Shane Cory Selig, Michaelene Johnson, B.S., Jonathan P. Wanderer, M.D., M.Phil., Jesse M. Ehrenfeld, M.D., M.P.H.

Introduction: Increasingly, medical schools, nursing schools, and residency training programs need to assign trainees to clinical placements, which is essentially a one-way matching problem. This requires assignment of a student with a faculty preceptor and clinic site. Placement characteristics which may warrant consideration include clinic specialty as well as clinic location. At Vanderbilt, our first year medical students need placement into a longitudinal clerkship experience. In order to accommodate the preferences of the medical students being paired, and the needs of the clinic sites being assigned, we set out to develop a methodology to facilitate student-faculty matching. Our goal, therefore, was to create an automated algorithm, which could produce a near ideal assignment, quickly and efficiently.

Methods: At the time that we wrote our algorithm, the faculty preceptors had one of three types of clinics: internal medicine, pediatrics, and surgery. These preceptors were both on and off campus. The incoming medical students were asked to fill out a Research Electronic Data Capture (REDCap) survey indicating their preference of clinic, and whether or not they could travel off campus. In order to create the matches, we generated a "Satisfaction Score." An individual student's Satisfaction Score was assigned based on the rank of their assignment. If a student got their first choice, their Satisfaction Score was zero. If they got their second choice, their Satisfaction Score was one, and so on. The overall Satisfaction Score for any given assignment was the sum of all of the individual students' Satisfaction Score. The closer to zero the Satisfaction Score was the better the assignment was. We then mapped every possible type of assignment involving either a direct assignment, or an assignment involving a single reassignment. We identified six assignment types. When making our assignments, our first goal was to make the lowest an assignment with the lowest possible Satisfaction Score. Given multiple possible assignments with the same Satisfaction Score, our goal was to then make the assignment that had the most students with the highest assignment. Additionally, since our dataset contained students who could travel and students who could not travel, we first assigned students who could travel to Preceptors with remote locations then assigned all students to Preceptors on campus. This was to offset the increased probability that students who could travel got their first choice, by also making it more likely that they had to travel to their Preceptor.

Results: Running the algorithm on our SQL server, we were able to make all the assignment, for ninety-two students in an efficient time period. We ran the algorithm on the data set one thousand times, each time randomizing student assignments, each resulting in the same Satisfaction Score. A manual review of five of these trials found no

better assignment. Additionally, thirteen additional trials were done with different datasets, three of which had no biases in the data, the remaining ten with varying biases. The manual review of the assignments for those datasets also showed no better assignment available.

Conclusions: We have developed a simplified approach to solving the one-way match problem. Our algorithm can be easily run on any computer, and will efficiently make assignments, while minimizing additional workload on the administrative staff, and maximizes the fairness and effectiveness of the assignments. Additionally, we have found that use of our algorithm can be expanded beyond its initial use for other, preference based, one-sided matching scenarios. We are now working to code this into a desktop program.

Using Routinely Collected Physiologic Vital Signs for Surgical and Anesthesiology Quality improvement Projects

Authors: Matthias Görges, PhD[1], J Mark Ansermino, MBBCh, FRCPC[2], and Simon Whyte, MBBS FRCA[2]
1) Electrical and Computer Engineering Department, 2) Department of Anesthesiology, Pharmacology & Therapeutics;
The University of British Columbia, Vancouver, Canada

Background: Current perioperative monitoring systems produce, and potentially store, a huge amount of largely unused data. The American College of Surgeons Pediatric National Surgical Quality Improvement Program (P-NSQIP), collects approximately 120 variables, which are used to measure and improve the quality of surgical care using risk-adjusted comparisons with other institutions [1]. However, none of these variables reflects intraoperative physiology. We identified three undesirable intraoperative physiologic changes as candidates for addition to P-NSQIP data collection: hypothermia, hypoxemia, and hypotension. We report our method of abstracting information, identifying true episodes of undesirable vital signs changes, and using this data to provide additional variables, which can be used in investigating surgical outcomes.

Methods: At BC Children's Hospital vital signs and full resolution waveforms are collected continuously from the Datex AS/3 patient monitoring system (GE Canada, Mississauga, ON) using a custom data collection application that does not contain any patient identifiers. We extracted trends with a time resolution of 0.1 Hz. We used algorithms to identify episodes of hypotension, hypothermia and hypoxemia, and the percentage of case duration spent in each condition (Figure 1). Rules are based on physiology for hypoxemia (inflection point at 93 %), and on literature for hypothermia [2] and hypotension [3]. To include this data in our institution's P-NSQIP modeling efforts, we needed to re-identify the data, which we did by matching its date and time of collection, and its operating room source, to P-NSQIP cases (Figure 2). Case-matched data were then verified manually to remove artifacts not automatically detected, and to exclude episodes of expected deviations from "normal" vital signs, such as deliberate hypoxia in neonates to avoid oxygen toxicity, and submitted back to the reviewers.

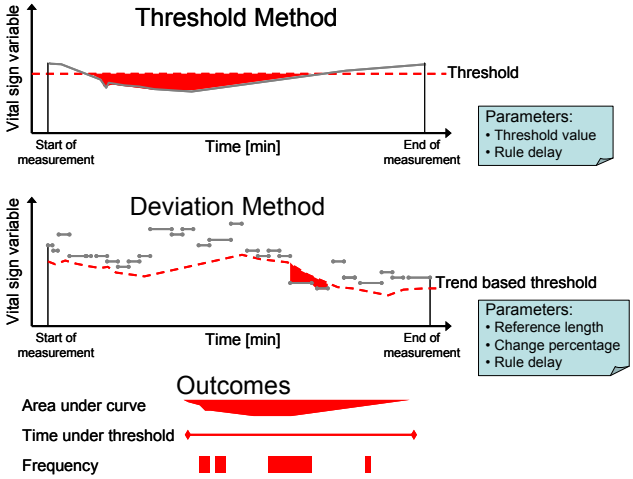


Figure 1: Comparison of threshold and deviation based methods for identifying undesired vital sign changes.

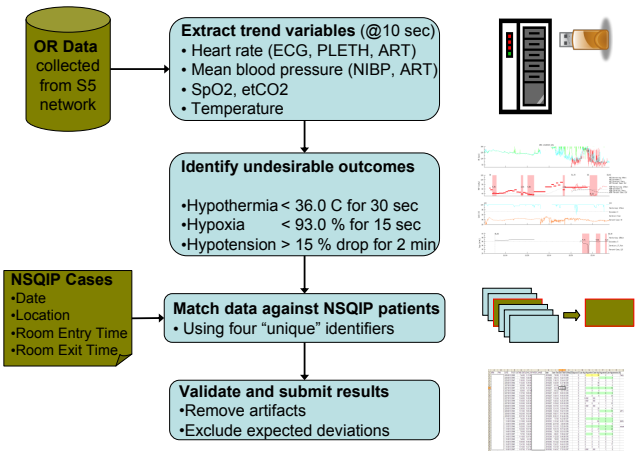


Figure 2: Overview of data extraction process for NSQIP

Results: During the last 23 months our case-matching rate was 89.3%. Reasons for failures in matching cases included blank times in the data requests; missing data due to monitoring

network problems; and new anesthesia machine trials. Hypoxemia occurred in 21.8% of 2517 cases; hypothermia in 40.6% of 2049 cases, where temperature was recorded; and hypotension in 56% of 2422 cases.

Conclusion: The described approach for using vital signs deviations, extracted from routinely collected data, for quality improvement was found to be a feasible and reliable method. Future work includes expanding this approach to other areas, such as investigating vital signs changes after induction of anesthesia in neonates.

References: [1] J Pediatr Surg 2011; 46:115–21; [2] Infect Control Hosp Epidemiol 2011; 32:603–10; [3] Proc Am Soc Anes Ann Mtg. 2010; A940

Robust Closed-loop Control of Anesthesia in Adults Undergoing Elective Surgery

Authors: A Umedaly[1], N West[1], K van Heusden[2], M Görges[2], CL Petersen[1], GA Dumont[2], JM Ansermino[1], RN Merchant[1]

[1]Department of Anesthesiology, Pharmacology & Therapeutics; [2]Electrical and Computer Engineering Department

The University of British Columbia, Vancouver, Canada

Background: Closed loop control of total intravenous anesthesia involves the continuous adjustment of drug infusion rates according to measured clinical effect [1]. Depth of Hypnosis (DoH) measures, such as the WAV_{CNS} index [2], can provide feedback suitable for closed loop control. A study that will culminate in the design of a robustly tuned controller automatically determining propofol and remifentanil infusion rates is currently ongoing. In the first phase of this study, propofol infusion was controlled by the closed-loop system while remifentanil was administered using a target controlled infusion (TCI)[3]. Collected data is then used to model the effects of varying remifentanil utilisation on the EEG and design an automated remifentanil infusion controller. In the second phase, remifentanil will be automatically titrated to counteract brief disturbances in the WAV_{CNS} that are assumed to be a result of nociceptive stimulation. Propofol will continue to be used to achieve the overall DoH setpoint. The data reported summarises the initial phase.

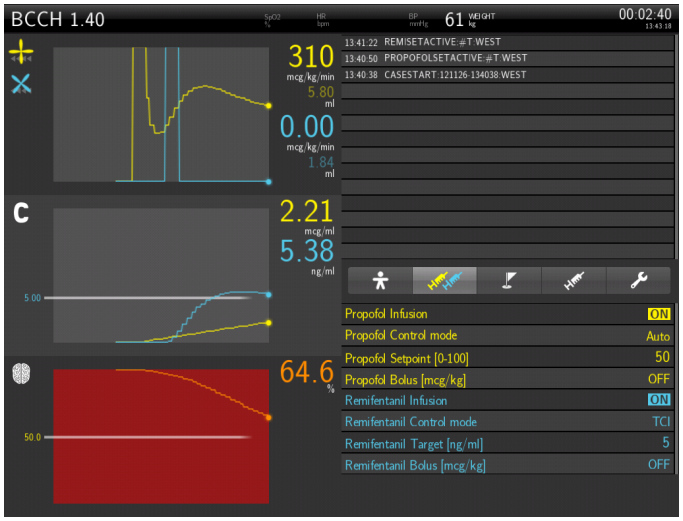


Figure 1: Main screen of controller user-interface

Methods: With both Health Canada and REB approval and written informed consent, ASA I-III adults, requiring general anesthesia for a wide variety of elective surgical procedures (expected to last ≥ 1hr) were enrolled in the study. The WAV_{CNS} was used to provide continuous feedback to the control system for induction and maintenance of anesthesia with propofol. An initial WAV_{CNS} setpoint of 50 was used in all cases. Remifentanil was administered according to an effect side target [3] specified by the clinician throughout induction and maintenance of anesthesia. Changes to the WAV_{CNS} setpoint and remifentanil target as well as bolus dosing of both drugs were permitted by the system (Figure 1).

Results: Results are reported as median (interquartile range). Forty-five adults age 63 (49-69) years and body mass index (BMI) 27.7 (25.1-30.2) were enrolled. Length of time required to complete induction (WAV_{CNS} below 60 maintained for 30 seconds) was 3.8 (3.3-4.7) mins. Required induction dosage of propofol was 1.5 (1.1-1.9) mg/kg, which corresponds to a calculated effect-site concentration [4] of 4.6 (3.9-5.8) mg/ml at the end of induction. Propofol utilisation during the maintenance phase of anesthesia was 117.0 (90.3-146.6) µg/kg/min. Remifentanil utilisation during maintenance was 0.10 (0.08-0.14) µg/kg/min. WAV_{CNS} during the maintenance phase remained within 10 units of the specified setpoint for 85% of the time (72%-91%).

Conclusion: These results suggest that closed-loop control of propofol with a stable background infusion of remifentanil is feasible for induction and maintenance of total intravenous anesthesia in adults undergoing a wide variety of elective surgical procedures. Additional research will be required to demonstrate the benefit of automatically adjusting the remifentanil infusion rate.

References:

[1] Anesth Analg. 2013;117(5):1130-8. [2] J Clin Monit Comput. 2011;25(1):81-7. [3] Anesthesiology. 1997;86(1):24-33. [4] Anesthesiology. 1998;88(5):1170-82.

Disordered Spontaneous Breathing Patterns Detected Using an ALAR Sensor

Presenting Author: Richard Melker, M.D. Ph. D.1,2

Coauthors: Sean Cohen, B.S.2, Timothy Morey, M.D.1, Mark Rice, M.D.1, Donn Dennis, M.D.1,2, Richard Melker, M.D.,Ph.D.1,2.
1Anesthesiology, University of Florida College of Medicine, Gainesville, FL, USA,
2Assurance Biosense, Inc., Glastonbury, CT, USA.

Introduction: The nasal ala represents an attractive site for monitoring because it can provide respiratory rate (RR), respiratory effort (RE) and respiratory patterns in addition to oxygen saturation (SpO_2), and heart rate (HR) during spontaneous breathing. We hypothesized that during monitored anesthesia care (MAC) these patterns would include normal (N), obstructive (O) and ataxic (AT) breathing as well as hypopnea (H), bradypnea (B), and apnea (A).

Methods: With IRB approval, 81 consecutive subjects of variable skin tone (29 male/52 female, aged 46.33 years (19-65) presenting for extremity surgery at an ambulatory surgical center (Florida Surgical Center, Gainesville, FL) were enrolled and completed the study without incident. Surgical duration was a mean of 71 (16-223) minutes and included procedures of the finger (n=30), hand (n=7), wrist (n=34), elbow (n=9). An alar sensor containing a thermistor (Assurance Biosense, Glastonbury, CT, USA) was placed on either nasal ala. High-resolution data was collected. Following regional or local anesthesia, the MAC technique was at the discretion of the care team typically consisting of balanced anesthesia (e.g., midazolam, fentanyl, and propofol). All subjects received supplemental oxygen. A proprietary algorithm calculated SpO_2, HR, RR, RE, N, H, B, A, O and AT breathing patterns from the thermistor and PPG signals. Mini-desaturation was defined as a decrease of >3% or more from baseline SpO_2. Desaturation was defined as $SpO_2 \leq 90\%$. Hypopnea was defined as a progressive decline in the thermistor signal over several breaths leading to apnea, defined as the cessation of breathing for 10 seconds or greater. Ataxic breathing ("the atrial fibrillation of breathing") was defined as an abnormal pattern which included hypopnea, bradypnea, changing respiratory rate and apnea. Partial airway obstruction produced a "sawtooth" (snoring) PPG pattern confirmed by physical examination. Complete obstruction was defined as apnea detected by thermistor but continued respiratory efforts detected by PPG, usually leading to an arousal. Central apneas (no attempts to breath) were also detected.

Results: In these spontaneously breathing surgical patients, mini-desaturations were observed in 36 subjects (44.4%) with a mean of 4.8 (1-41) mini-desaturations/hour. Desaturations ($SpO_2 \leq 90\%$) were present in 15 (18.5%) subjects. Also, 25 (30.9%) subjects experienced apnea of greater than 30 seconds with the maximal duration being 90 seconds. Examining the airflow patterns, 46 (56.8%) subjects developed hypopnea. 29 (35.8%) patients exhibited periods of ataxic breathing and 51 (63.0%)

patients exhibited partial airway obstruction by PPG waveforms. A pattern indicative of obstructive apnea was detected in 39 (48.1%) of patients, 25 (30.9%) of whom had arousals.

Conclusions: The nasal alar probe may not only be useful to monitor SpO_2 and heart rate, but also to provide insight into the presence of apnea and other abnormal breathing patterns in spontaneously breath patients undergoing MAC.

Constrained Model Predictive Control of Propofol in Adults: A Simulation Study

Authors: Sara Khosravi[1], MASc, Guy A Dumont[1, 2], PhD, J Mark Ansermino[2], MBBCh, FRCPC,
[1] Electrical & Computer, Engineering Department, [2]Anesthesiology, Pharmacology & Therapeutics Department, University of British Columbia, Vancouver, Canada

Background: An advantage of model predictive control (MPC) in closed-loop control of anesthesia is its ability to handle constraints on drug infusion rates and drug concentrations while controlling both hypnosis and analgesia. At high plasma concentrations (>10µg/ml), propofol may significantly decrease arterial blood pressure, an effect more evident in elderly [1],[2] while concentrations less than 1.6µg/ml are associated with awakening from anesthesia [3]. In this study, a constrained MPC is designed for closed-loop control of hypnosis with propofol.

Methods: A nominal model was constructed based on 44 models, identified from 18-60 yr adults with an ASA status of I or II [4]. The mean (SD) age and weight were 36(12) yr and 80(14) kg. The controller was tuned to provide adequate and stable depth of hypnosis during simulated induction and maintenance of anesthesia, with a set-point overshoot of less than 5% and an initial rise time of 5 minutes [4]. The WAV_{cns} index by NeuroSENSE monitor (NeuroWave Systems Inc., Cleveland Heights, USA) was considered as the clinical endpoint. A 60-minute surgical procedure was simulated for the complete set assuming an infusion of 10 mg/ml propofol. For all patients, a hypothetical surgical stimulus was fixed to start 20min after the beginning of the simulation. The following constraints (safety bounds) on the infusion rate (u), predicted propofol plasma concentration (C_p) and effect-site concentration (C_e) were defined:

$$0ml/h \le u \le 600ml/hr,\ 1.5\mu g/ml \le C_p \le 10\mu g/ml \text{ and } 1.5\mu g/ml \le C_e \le 8\mu g/ml.$$

Results: Simulated induction of anesthesia (WAV_{cns}<60) was completed in an average (SD) of 2.8min (0.9) with set-point overshoot (WAV_{cns}<50) of 3.6%(7.3), (Figure1). Results obtained with an unconstrained MPC emphasizes the importance of the concentration constraints, as it shows that without them, 40% of patients would reach C_p > 10µg/ml during induction of anesthesia, (Figure 2)

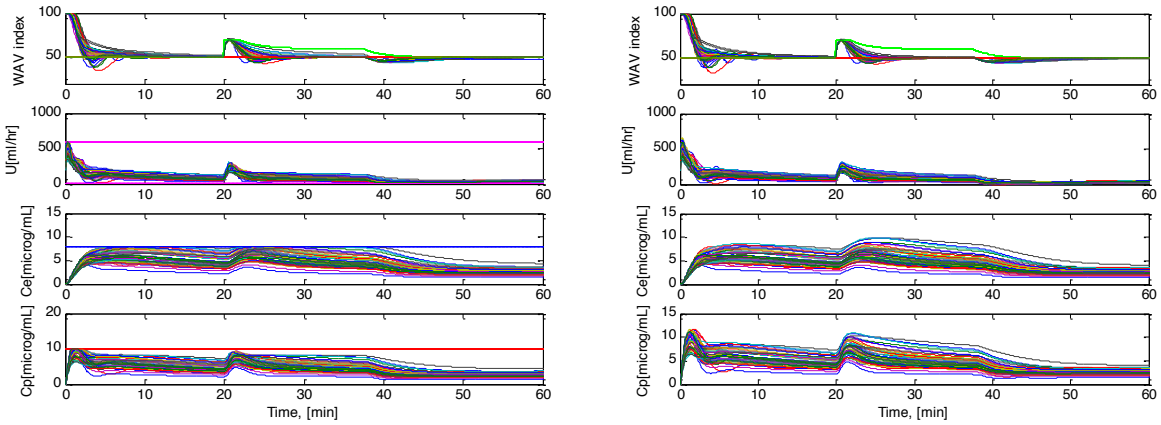


Figure 1. Constrained closed-loop MPC response of 44 patients. Figure 2. Unconstrained closed-loop MPC response of 44 patients

Conclusions: Evaluation of the proposed MPC controller during simulated induction and maintenance of anesthesia shows that the design specifications are satisfied. The proposed constrained control strategy can reduce the risk of under- or overdosing for most patients by providing controller enforced safety bounds. Future work includes extending the proposed method to multivariable control of hypnosis and analgesia.

[1] Vuyk, J, et al, Anesthesiology. 1997; 87(6):1549-62. [2] Kazama, T, et al, Anesthesiology. 1999; 90(6):1517-27. [3] Kazama, T, et al, Anesthesiology. 1998; 88(4):928-34. [4] Dumont, G A, et al., *Int.l Journal of Adaptive Control and Signal Processing*. 2009; 23: 435–454.

Information Needs for the OR and PACU Electronic Medical Record

Presenting Author: Marc Ellsworth, MD, Mayo Clinic, Rochester, MN

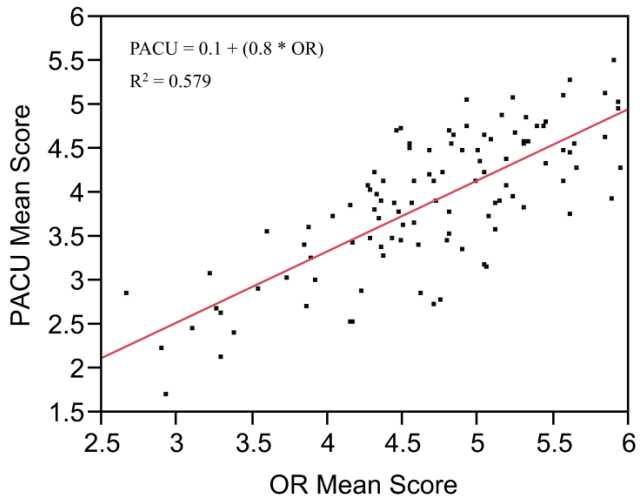
Co-Authors: Vitaly Herasevich, MD, PhD, Brian Pickering, MB, BCh, James Hebl, MD, Michael Brown, MD, Mayo Clinic, Rochester, MN

Background: The amount of daily clinical information that anesthesia providers encounter creates an environment for information overload and medical error. Patient-centered EMR platforms are a way to curb this overload and improve patient safety. In an effort to create more efficient OR and PACU EMR viewer platforms, we aimed to better understand clinical information needs among anesthesia providers. Similar methods used for creation of a novel EMR platform in our institution's ICUs was shown to improve performance and decrease errors of cognition.

Methods: A web-based survey to evaluate 75 clinical data items displayed in our current EMR was created and distributed to all anesthesia providers (attendings, resident/fellows, CRNA/SRNAs) at our institution. Participants were asked to rate the importance of each of the 75 data items in helping them make routine clinical decisions in the OR and PACU settings independently.

Results: There were 107 completed survey responses with distribution throughout the 4 clinical roles. 84% of the data items had ratings that fell within the top 2 quartiles in the OR setting compared to only 65% in the PACU. Thirty of the 75 items (40%) received an *essential* rating by more than half of the respondents for the OR setting as opposed to only 19 of the 75 items (25%) in the PACU. Only 1 item (admission source) was rated by more than 20% of respondents as *not needed* in the OR compared to 20 data items (27%) in the PACU. A bivariate fit model (Figure) comparing each respondent's overall rating of all data items in the OR versus PACU setting showed overall lower rating of data item importance in the PACU setting compared to the OR.

Conclusion: When surveyed, anesthesia providers demonstrated a larger need for EMR data to help guide clinical decision making in the OR as compared to the PACU. When creating EMR platforms for these settings it is important to understand and include data items providers deem the most clinically useful. Minimizing the less relevant data items helps prevent information overload and reduces the risk for medical errors. Future development of novel OR and PACU EMR interfaces should incorporate such concepts.


PACU = 0.1 + (0.8 * OR)
R2 = 0.579
PACU Mean Score
OR Mean Score
6
5.5
5
4.5
4
3.5
3
2.5
2
1.5
2.5
3
3.5
4
4.5
5
5.5
6

Comparison of Motion Artifact Response in Three Mobile Pulse Oximeters

Authors: Christian L Petersen[1], Heng Gan[1], Matthias Görges[2], J Mark Ansermino[1] and Guy A Dumont[2]
Departments of Anesthesiology, Pharmacology & Therapeutics[1], and Electrical and Computer Engineering[2], The University of British Columbia, Vancouver, Canada

Introduction: Low-cost smartphone-based medical devices, e.g. mobile pulse oximeters, hold great promise as diagnostic tools in low- and middle-income countries [1]. The artifact rejection capability of mobile oximeters is a key aspect of their performance, as their main users are likely inexperienced healthcare workers unfamiliar with plethysmography. We investigate the motion response of three models, the Nonin Xpod, the Masimo OEM inline module, and an Audio Phone Oximeter prototype [2], all interfaced to Apple iPod Touch devices.

Method: With research ethics board approval and written informed consent, 14 subjects were recruited and fitted with pairs of the three pulse oximeter models (6 devices in total), one set on each hand. The subjects were placed inside a hypoxia chamber where the inspired oxygen was gradually decreased, and asked to perform a standardized motion protocol with the dominant hand; the non-dominant hand remaining immobile. The oxygen saturation of the subjects typically varied between 100% and 75% during the hypoxic exposure. Data from all six mobile oximeters was collected and synchronized against a common time server. The motion intervals were extracted, resulting in 133,117 motion/non-motion paired readings sampled at 1 Hz.

Results: The paired readings were binned into three oxygen saturation ranges based on the non-motion values: 100-93%, 92-85% and <85%. Each bin was analyzed for motion-induced bias (Fig.1) and percentage of valid readings during motion (Fig.2), corrected for spurious fallout in the non-motion measurements. All devices exhibited a positive change in motion bias at lower saturations. The change was about 3% for Masimo and Nonin, and 12% for the Audio oximeter. The Masimo device had the biggest percentage of valid measurements during motion, about 85%-87%, while the Nonin and Audio oximeters were comparable at 60-75%.

Conclusion: The motion response during 37 cumulative hours of mobile oximeter readings was analyzed. Compared to the Audio oximeter, both Nonin and Masimo had relatively small motion-induced bias because of advanced motion rejection algorithms. The difference is more evident at lower oxygen saturations. More work is needed to improve artifact rejection in the Audio oximeter by identifying the types of motion that have greatest impact on performance and developing algorithms to filter the true signal from the motion artifact.

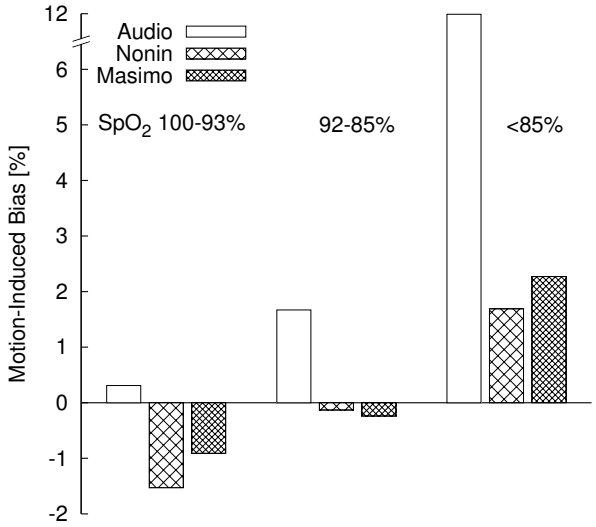


Fig. 1: Motion-induced bias

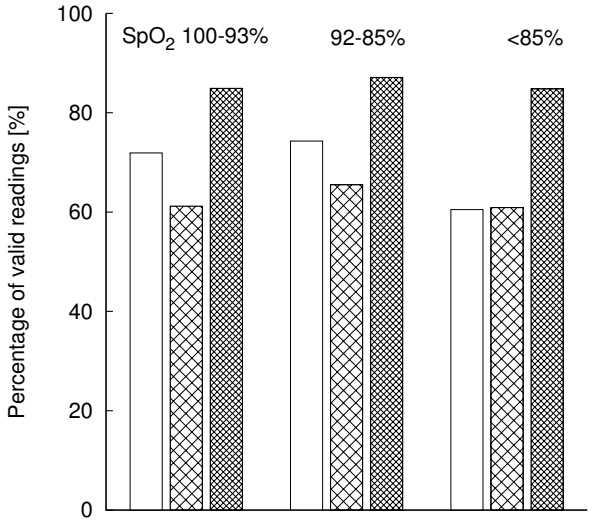


Fig. 2: Valid readings during motion

[1] The United Nations Foundation, and Vodafone Partnership. mHealth for Development: The Opportunity of Mobile Technology for Healthcare in the Developing World. 2009.
[2] Petersen, C.L.; Gan, H.; MacInnis, M.J.; Dumont, G.A.; Ansermino, J.M. Ultra-Low-Cost Clinical Pulse Oximetry. Conf Proc IEEE Eng Med Biol Soc.;2013:2874-7

iSwirl: Self-affine Visualization of PPG and ECG Waveforms

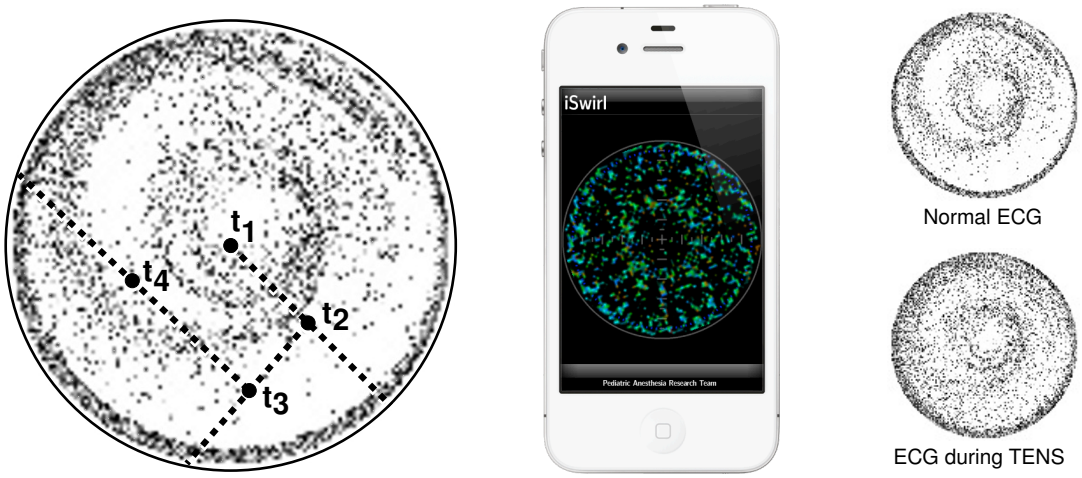
Authors: Christian L Petersen[1], J Mark Ansermino[1] and Guy A Dumont[2]
Departments of Anesthesiology, Pharmacology & Therapeutics[1], and Electrical and Computer Engineering[2], The University of British Columbia, Vancouver, Canada

Introduction: Physiological waveforms such as the photoplethysmogram (PPG) or electrocardiogram (ECG) exhibit complex non-linear phenomena [1]. This complexity is often ignored in conventional analysis, where time or frequency domain filtering is used to extract simple numeric trends. We present an alternative method of analysis where a set of contracting transformations form a self-affine set with a 2D attractor. We investigate the effect of nociception on ECG attractor patterns, and implement a smartphone application for visualization of the PPG attractor, *iSwirl*.

Method: We consider a unit disk, map the current waveform value (256Hz ECG / 65Hz PPG) to its periphery with a cosine transform, and plot a point midway between the previous point (initially the center of the disk) and the periphery location. The resulting cloud of points encodes the history of the driving waveform and lies on the attractor of its self-affine set. The patterns have a "swirly" appearance determined by the unfiltered self-similar structure (Fig. 1 (a)).

Results: An iOS application visualizing real-time PPG waveforms from a Nonin XPod and Audio Phone Oximeter [2] was developed. The visual feedback was augmented by color-coding of the patterns and rotating them in proportion to heart rate, thereby further strengthening the swirling perception (Fig. 1(b)). Preliminary tests revealed significant inter-person variations in these patterns, suggesting that subtle differences in the shape of the PPG wave exist. Applying the visualization to ECG waveforms obtained during anesthesia (with ethics board approval and written informed consent) in a related study revealed a delocalization in the attractor pattern during periods of Transcutaneous Electrical Nerve Stimulation (TENS) (Fig 1(c)).

Conclusion: We have developed a new method of visualizing complex structure in physiological waveforms to complement conventional analysis. Its apparent sensitivity to both inter- and intra-patient variability may offer a new way of detecting subtle physiological anomalies and/or events that might otherwise go undetected. More work is needed to investigate the nature of the attractor patterns and their relation to physiological state.



(a) (b) (c)

Figure 1: a) ECG attractor and set; b) iSwirl PPG visual; c) ECG attractor during TENS.

[1] Eberhart, R.C. Chaos theory for the biomedical Engineer. IEEE Eng Med Biol Mag **8** (1989) p. 41.
[2] Petersen, C.L.; Gan, H.; MacInnis, M.J.; Dumont, G.A.; Ansermino, J.M. Ultra-Low-Cost Clinical Pulse Oximetry. Conf Proc IEEE Eng Med Biol Soc.;2013:2874-7

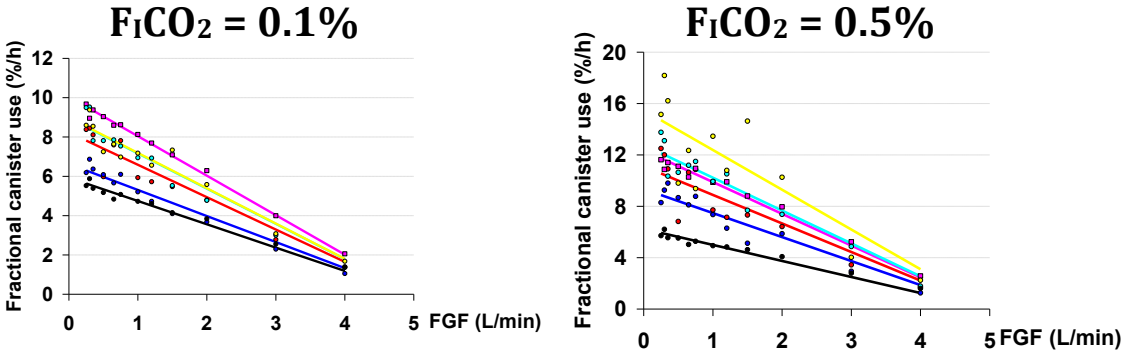
In Vitro Canister Life of CO_s Absorber Prepacks with Different Fresh Gas Flows with the Aisys Anesthesia Machine

Presenting Author: Jan FA Hendrickx, MD, PhD, OLV Hospital, Aalst Belgium
Co-Authors: *Lemmens H, MD, PhD, Stanford University, CA; De Hert S, MD, PhD, Gent University, Belgium; De Wolf AM, MD, Northwestern University, Chicago, IL*

Introduction: Low fresh gas flows (FGF) reduce inhaled anesthetic and carrier gas waste, but increase CO_2 absorbent use. The performance of CO_2 absorbents remains poorly studied, especially in a setting that resembles clinical practice. We measured canister life of prepacks of 6 brands over a wide FGF range. Because circuit configuration affects the rebreathing characteristics and thus performance, only those that fitted on 1 particular anesthesia machine were studied.

Methods: Via a CO_2 flow meter (MEDEC, Aalst, Belgium; accuracy of 3.7 mL/min), 160 mL/min CO_2 flowed into the tip of a 2L breathing bag that was ventilated with an Aisys® machine (GE, Madison , WI) using controlled mechanical ventilation (tidal volume 500 mL, rate 10/min, I:E 1:1). For each brand (see Figure 1), canister life was determined for 12 canisters (all of the same lot), each of which was assigned to 1 of 12 different FGFs that ranged from 0.25 to 4 L/min O_2/air (see X-axis in Figure 1). For each FGF, we measured the time until the inspired CO_2 (F_ICO_2) reached either 0.1% or 0.5%. To facilitate comparison between the canisters and to easily calculate costs, this duration was converted into how much of one canister was used per hour (expressed as % of 1 canister/h); this so-called "fractional canister usage" or FCU was calculated for both F_ICO_2 thresholds. E.g., if it took 8h to F_ICO_2 = 0.1%, FCU was 12.5 %. Because this FGF-FCU relationship turned out to be linear, performance of each brand (for each F_ICO_2 threshold) could be described by a linear fit.

Results:



Product	F_ICO_2 = 0.1%	F_ICO_2 = 0.5%
Amsorb (Armstrong, yellow)	FCU = -3.096*FGF + 15.48	FCU = -1.797*FGF+8.987
LoFloSorb (Intersurgical, light blue)	FCU = -2.557*FGF + 12.78	FCU = -1.791*FGF+8.954
Medisorb (GE, red)	FCU = -2.223*FGF + 11.11	FCU = -1.648*FGF+8.231
Medisorb EF (GE, pink)	FCU = -2.472*FGF + 12.36	FCU = -2.009*FGF+10.05
Spherasorb (Intersurgical, dark blue)	FCU = -1.868*FGF + 9.342	FCU = -1.326*FGF+6.631
Spiralith (Micropore, black)	FCU = -1.249*FGF + 6.243	FCU = -1.186*FGF+5.931

Conclusion: The only LiOH based product, SpiraLith®, has the longest canister life and produces no compound A nor CO (1). Of the $Ca(OH)_2$ based canisters, those without NaOH (Amsorb, LoFloSorb) are less efficient but do not produce compound A nor CO.

References: (1) ASA 2010 Abstract 1693

Cost Benefit of a Home-Made Computerized Anesthesia Record System in the Electronic Health Recorder

Presenting Author: Philippe Dony MD, Affiliation

Co-Authors: Jean Boogaerts MD,DSc, PhD,Jean Pirson MD, Sophie Brichard, Guy Haller MD, MSC, PhD

Introduction: Anesthesia information management systems (AIMS) are being increasingly used in the operating room to document anesthesia care. The database structure influences both the amount of information gathered and the ease of analysis. These factors determine the value of AIMS to record useful administrative patient/procedure related information and to monitor the quality of care provided.. Currently computarized AIMS have limited pre and postoperative database fields which limit their usefulness as overall patient management monitoring systems. The reason is that AIMS are usually independent of the rest of the patient's medical record because they are developed by separate commercial partners with little knowledge on interoperability issues with the rest of the hospital computerized system. To avoid this problem, we developed in our hospital, a home-made AIMS database as an integral part of patient's electronic medical record. The system includes all aspects of anesthesia care and allows also the storage and analysis of pre and postoperative data. The aim of this study was to assess the cost-benefit of developing such a device, compared to commercially available AIMS

Methods: Our department hired an anesthesiologist with both field and computer expertise to create a full AIMS. This AIMS has been integrated into the hospital electronic patient record with the help of the medical informatics department. The financial impact was measured and compared with a commercially available system. We assessed altogether direct, indirect costs and intangible costs. Direct and indirect cost included: salaries of the physician and technicians, equipment, computer maintenance; Intangible costs: loss of productivity of the physician and time required for interaction with other hospital partners. We also performed a secondary cost-benefit analysis: net cost and benefits of the strategy were compared to a commercially available system. Net costs, net benefits, and cost/benefit ratio are used to identify the true value of the new system.

Results: We did not encounter major problems during the introduction phase of our AIMS, specially regarding staff adjustment with the new system and particularly online documentation of vital signs. The integration of our AIMS into the hospital electronic patients' medical record allowed us to integrate full patient information to our anaesthesia system. We were subsequently able to monitor treatment control, audit quality of care and perform full, cost of care calculation. Figure 1 displays the net cost comparison between our home-made AIMS and an unnamed commercial device chosen randomly. Wee used compared the cost per unit for the commercial device and

the overall development and implementation charges (direct/indirect and intangible costs) for the home made device. The price of the commercial system remained constant at $ 7080. The home-made AIMS cost were dependent of the number of operating rooms equipped and was higher than the commercial device below 10 units (cut-off). Considering the 50 units required for the full equipment of the hospital operating theatres, the cost of the home-made system was 54% lower than the commercial AIMS. (see Table 1 and Fig 1)

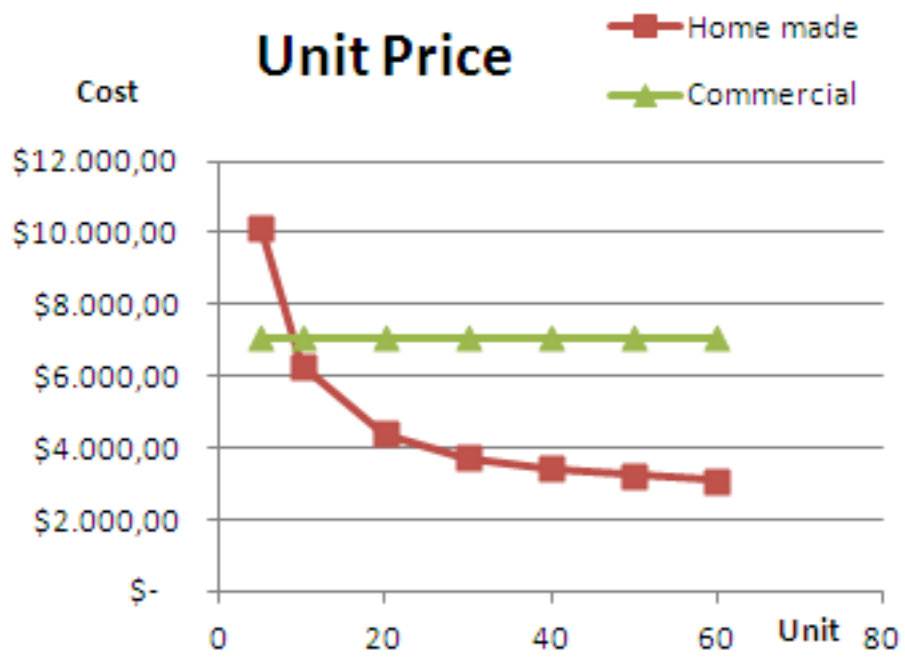
Conclusion: A home-made AIMS created to address all information requirements for anaesthesia care and also medical research can result in substantial cost-savings for our hospital (50 equipped units). Return on investment for the development of a home made solution can become advantageous for institutions with more than 10 operating rooms.

References: Ehrenfeld JM, Rehman MA. J Clin Monit Comput. 2011 Feb;25(1):71-9 Trentman TLet al. J Clin Monit Comput. 2011 Apr;25(2):129-35 Chau A, Ehrenfeld JM. Anesthesiol Clin. 2011 Mar;29(1):57-69 Stabile M, Cooper L. Can J Anaesth. 2013 Feb;60(2):119-26 Sinclair DR. J Clin Anesth. 2012 Nov;24(7):603-4

Tableau 1 The net cost comparaison

Units	Home Made	Commercial	Reduction
5	$ 10.127,24	$ 7.079,42	-43%
10	$ 6.297,74	$ 7.079,42	11%
20	$ 4.382,99	$ 7.079,42	38%
30	$ 3.744,75	$ 7.079,42	47%
40	$ 3.425,62	$ 7.079,42	52%
50	$ 3.234,15	$ 7.079,42	54%
60	$ 3.106,50	$ 7.079,42	56%

Figure 1 Comparaison home made vs commercial AIMS


Unit Price
Home made
Commercial
Cost
$12.000,00
$10.000,00
$8.000,00
$6.000,00
$4.000,00
$2.000,00
$-
0
20
40
60
Unit
80

The Portable Operating Room Tracker (telePORT) - Analysis of system usage and identification of areas for improvement

Authors: Matthias Görges[1], Peter Baxter[2], Trevor Coelho[2], Patricia Thomas[2], Christian L Petersen[3], Guy A Dumont[1], and J Mark Ansermino[3]
1) Electrical and Computer Engineering Department, University of British Columbia
2) Pediatric Anesthesia Department, BC Children's Hospital
3) Department of Anesthesiology, Pharmacology & Therapeutics; University of British Columbia, Vancouver, Canada

Background: telePORT, the remote Portable Operating Room Tracker, was developed by the Pediatric Anesthesia Research Team at BC Children's Hospital to improve information exchange, and simplify communication between anesthesia team members[1]. It combines a real-time feed of waveforms and vital signs from the operating rooms with messaging and paging functionality. The Anesthesia Department's anesthesia assistants, with whom it was developed, have used it over the last two years. This study evaluates the system usage, collected over the last 11 months, and identifies areas for improvement.

Methods: Time stamped data of user logins, logouts, and disconnects (loss of client connection for 60 seconds); navigated screens (see Figure 1); message receiver and recipients, and pages received were recorded in CSV format from the VitalNode server. Data were parsed using Matlab (The MathWorks, Natick, MA), and plotted for analysis. Additionally, feedback from the anesthesia assistants regarding the frequent disconnects was verbally collected.

Results: Battery usage was used as a surrogate for device usage and was shown to be highest between 11-15h on weekdays (see Figure 2). The most frequently used screens were Messaging (30%), followed by Overview (20%), Pages/Alerts (19%), and Waveforms (14%). The majority of pages were received between 8-10h and 11-14h, averaging 5.3 per day. Few messages were exchanged, averaging 1.1 messages per day. The majority of messages were exchanged between five pairs of the nine users, with one

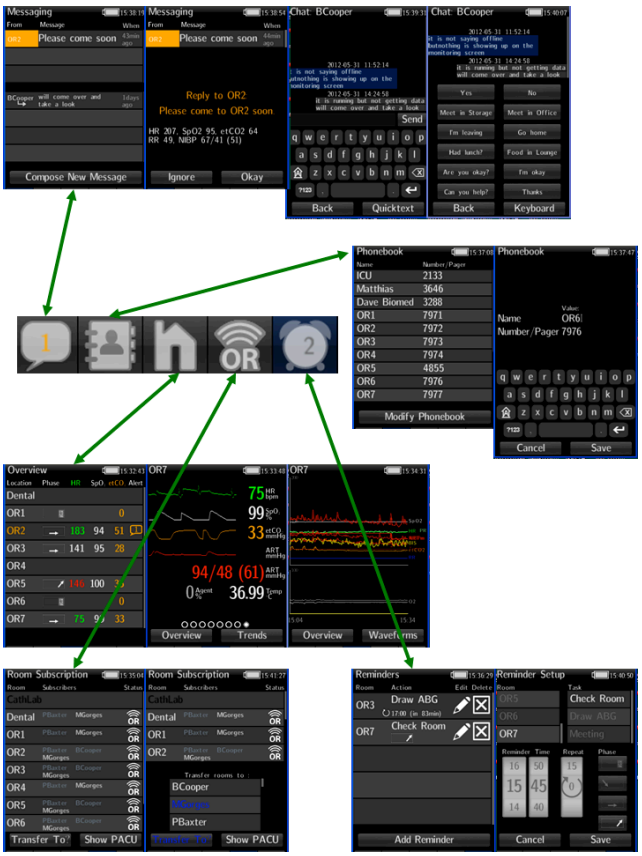


Figure 1: Navigation through the telePORT application. The navigation bar is surrounded by the messaging features at the top of the figure, the phonebook to the right and overview/waveform screens to the left of the center, and room subscription and reminders setup at the bottom.

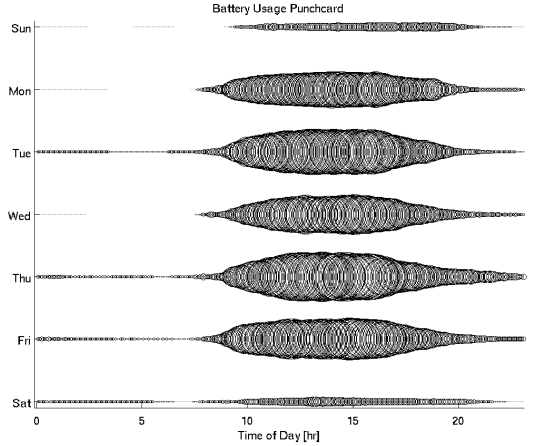


Figure 2: telePORT battery usage plot. The circles are proportional to the number of samples in a 1min segment

user being responsible for 80% of these messages. The main area of complaint was devices dropping from the network instead seamlessly switching between access points. This is supported by data showing a median of 7 (IQR 2-14) disconnects per day.

Conclusion: telePORT utilization was found to be higher on the request (paging) functionality than when being used to exchange information between team members. Data indicate that passive OR monitoring is frequently used. A search for the cause in intermittent loss of wireless connectivity, to facilitate improved reliance on the system, is currently ongoing.

References: [1] Anesth Analg. 2011;113(2S):53.

STARTPrep: A 12-Month Multi-Institutional Online Preparatory Course for the American Board of Anesthesiology Part 1 Basic Examination

Presenting Author: Reuben Eng, MD, FRCPC, Stanford University School of Medicine

Co-Authors: Sanford E. Roberts, BA, Stanford University School of Medicine. Will Grove, BS, Stanford University School of Medicine. Lynn Ngai, BS, University of Southern California. Jeffrey Bartsch, BA, University of Colorado School of Medicine. Andrea J. Fuller, MD, University of Colorado School of Medicine. Larry F Chu, MD, MS, Stanford University School of Medicine.

Introduction: STARTPrep is a 12-month online curriculum that prepares residents for the American Board of Anesthesiology (ABA) Part I Basic Examination (ABA exam) through daily learning activities. It uses open-source learning management system (LMS) tools to deploy individualized learning, feedback-corrective procedures and formative knowledge assessments. The primary outcome is student self-assessed feeling of preparedness for the ABA exam. Secondary outcomes include the ABA exam result, self-reported stress levels, and analysis of course participation activity. This is the preliminary analysis for the first month of the course.

Methods: A human subjects protocol (#27444) was obtained through the Stanford IRB. 204 post-graduate year (PGY)-2 residents from 13 institutions were voluntarily enrolled. Performance was blinded to home institutions. Daily lessons consisted of a brief teaching text followed by a quiz; lessons were written and edited by faculty members from every institution. Monthly comprehensive assessments (MCA's) were administered, and qualitative feedback from students was periodically solicited. The Moodle LMS was used to build the course. Data were analyzed using SPSS 22 (IBM, Armonk, NY).

Results:

Demographics of Learners

The demographics of institutions and residents are shown in Table 1. 52% of participants were male and 48% female. The largest program had 28 CA-1 residents and the smallest program 5 CA-1 residents. The majority of learners were from the Northeast region of the US.

Self-Reported Feeling of Preparedness and Stress Levels

At the beginning of the course, the vast majority of students felt unprepared for the ABA exam (Table 2), 33% felt they would definitely not pass it at that time, and 55% had stress levels of 6 or higher (out of 10) about it.

Course Performance and Participation

On-schedule participation (OSP) was defined as completion of a lesson on the day of its publication. A Q-Q plot showed that the data was skewed, thus necessitating non-parametric analyses. On average, 44% of students maintained OSP, and this was significantly different between sites ($p<0.001$) according to Kruskal-Wallis test calculation. Calculation of Spearmen's rho (2-tailed sigma = 0.280) did not reveal a statistically significant correlation between a student's rate of OSP and MCA performance. The mean MCA grades by institution are shown in Figure 2, and rates of MCA completion by institution are listed in Table 3; the Kruskal-Wallis test did not reveal a statistically significant relationship between these two variables ($p=0.265$).

Conclusion: STARTPrep is a novel, online, high-stakes exam preparatory course that is unique for the large number of participating institutions and geographic distribution of its students. Our initial results show that the vast majority of students feel unprepared for the ABA exam and have significant levels of stress. Remarkably, many students maintain OSP rates greater than 50% during this daily course. The overall mean MCA score of 69.8% suggests that knowledge retention occurs between the time of the lesson and MCA since students must score 100% on post-lesson quizzes. No significant correlation was found between student OSP rate and MCA performance, and students taking the MCA had similar outcomes regardless of home institution. Future work will present effects of this course on the defined outcome measures.

Table 1. Demographics for STARTPrep institutions and residents

Geographic Distribution of Institutions	
Region	*Number of Participating Institutions*
Northeast	6
Midwest	1
South	3
West	3
Number of STARTPrep Students per Institution	
Institution Number	*Number of Students*
1	28
2	8
3	7
4	23
5	26
6	11
7	5
8	21
9	15
10	16
11	8
12	17
13	19
Total	204
Student Gender Distribution	
Gender	*N (%)*
Male	107 (52)
Female	97 (48)

Table 2. Self-reported Feeling of Preparedness and Questions

Q1: How prepared would you feel if you had to take the ABA written exam tomorrow ? (Scale of 0-10, 0 = completely unprepared, 10 = extremely prepared)

Q*	0	1	2	3	4	5	6	7	8	9	10
Q1	45%	28%	13%	8%	0%	1%	2%	1%	0%	0%	0%

Q2: If you had to take the ABA written exam tomorrow what do you think your chances of passing would be? (Scale of 0-100%, 0% = would definitely NOT pass, 100% = would definitely pass)

Q*	0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
Q2	33%	31%	17%	9%	3%	3%	1%	1%	1%	1%	1%

Q3. On a scale of 0-10, with 0 being absolutely no stress and 10 the most stress imaginable, what has been your average stress level OVER THE PAST MONTH?

Q*	0	1	2	3	4	5	6	7	8	9	10
Q3	4%	1%	7%	9%	13%	11%	15%	17%	14%	7%	2%

Table 3. Mean scores, by institution, for monthly cumulative assessment (MCA)

Institution Number	**Number of Residents Completing MCA (%)**	**Mean Score (Standard Deviation)**
1	12 (43)	71.1 (6.8)
2	3 (38)	68.0 (3.2)
3	4 (57)	69.3 (3.6)
4	16 (70)	71.6 (5.5)
5	20 (77)	71.2 (4.6)
6	7 (64)	66.7 (6.6)
7	0 (0)	N/A
8	13 (62)	71.9 (7.0)
9	7 (47)	73.7 (5.3)
10	13 (81)	72.3 (5.7)
11	2 (25)	66.5 (1.7)
12	5 (28)	63.2 (26.1)
13	8 (42)	58.8 (20.5)
Overall	110 (54)	69.8 (9.7)

Application of Python to AIMS Data to Analyze Intraoperative Hypotension Through Pediatric Blood Pressure Curves

Presenting Authors: Deepthi Shashidhar[1], Lin Mingzhe[1]

Co-Authors: Deepthi Shashidhar[1], Lin Mingzhe[1], Radoslav Ivanov[1], Insup Lee[1], PhD, Arul Lingappan[2], MD, Mohamed A. Rehman[2], MD, Jorge A. Galvez[2], MD, Pablo Laje[2], MD, Alan W. Flake[2], MD, Allan F. Simpao[2], MD

1. University of Pennsylvania, Computer and Information Science, Philadelphia, PA
2. Perelman School of Medicine at the University of Pennsylvania and the Children's Hospital of Philadelphia, Philadelphia, PA

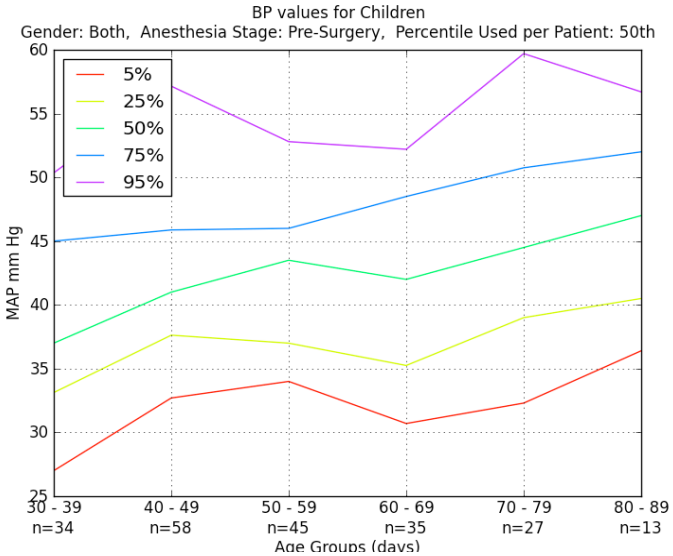
Introduction: Previous studies have shown significant variability in the definition of intraoperative hypotension (IOH) among pediatric anesthesiologists. There is scant data regarding thresholds for IOH in children less than 1 year of age. We used anesthesia information management systems (AIMS) data to develop reference values for normal perioperative blood pressures (BPs) and IOH in the infant population. Manipulating large data sets such as AIMS vital sign data can be challenging, thus we developed custom software in Python to organize the data, parse the files, perform the appropriate calculations, and output the information in graphical form.

Methods: Using AIMS data, SBP values were obtained for 215 infants between 30 to 90 days of age undergoing thoracic surgery from 3/18/2005 through 7/10/2012. The raw data was first put through a specialized parser (written in Python), which associated each BP value with a specific patient and time period during anesthesia. A custom data analysis library (Pandas) was used to perform further calculations. The multiple values per patient per time period were condensed, either by taking the 5th percentile, to look at hypotensive values, or the 50th percentile, to look at mean values, resulting in each patient having only one BP value per time period. The BP values were then grouped by relevant factors, which, for this study's purposes, were age, time period during anesthesia, sex, and type of surgery. This data was then plotted, and the resulting graph shows, for a specific time period, sex, and surgery type, the five percentile values (5th, 25th, 50th, 75th, and 95th) for each of six different age groups. To ensure that each age group had a sufficient number of patients, only data from children ages 30 days to 90 days were used.

Results: In general, SBP values at each percentile gradually increase as a patient's age increases from 30-39 days to 80-89 days. Figure 1 depicts one example of our results, which consists of graphical representations of the data described above.

Discussion: While there are many confounding factors (e.g. patient gender, height, and weight, co-morbidities, techniques of anesthetic induction and maintenance, and intraoperative blood loss), the above data serve as a starting point for reference values for normal BP values under anesthesia and establishing thresholds for the definition of IOH. Either the 5^{th} or 25^{th} percentile lines could potentially serve as a threshold to define IOH, although it could be argued that the 50^{th} percentile line could be a reasonable cutoff for IOH based on the fact that average SBPs are 20-30% lower than values established for the general infant population in the non-operative setting. We plan to develop a broader set of reference values for normal blood pressures under anesthesia and threshold for IOH, irrespective of the type of surgery. These can be used to ascertain the relationship of IOH to morbidity and mortality in the perioperative period and beyond.

Figure 1. (Mean arterial pressures pre-surgical incision and post-intubation, both genders, all cases, 50th percentile BP)



An Ultraportable Fluid-Cooling Device for the Pre-Hospital Care Environment

Presenting Author: Barrett Larson, MD, Department of Anesthesiology, Stanford University School of Medicine

Co-Author: Ben Lubkin, BS, Department of Engineering, Stanford University

Background/Introduction: Each year, over 300,000 people in the United States will experience an out-of-hospital cardiac arrest. To prevent devastating and potentially permanent neurologic injury following a cardiac arrest, the standard of care is to quickly induce therapeutic hypothermia (TH) in these patients. Recent studies have demonstrated that early initiation of TH in the pre-hospital care environment improves neurologic outcomes. The pre-hospital care environment is not particularly well suited for fluid cooling given the relative inaccessibility of electrical power outlets, space constraints, and the need for ultra-portability. Given the limitations that exist within this clinical setting, fluid cooling is often not available or is inadequately performed.

Methods: We developed an ultraportable fluid-cooling device that controls the temperature of intravenous fluid via endothermic chemical reactions. The device connects in-line with standard IV infusion sets and can be activated on demand. The device requires no electrical power. We demonstrated clinical feasibility of the device by measuring fluid outflow temperature as a function of time.

Results: Upon activation, the device was able to cool intravenous fluid to a target temperature of $4^{\circ}C$ within 30 seconds. The device maintained a target fluid outflow temperature between 4° -$8^{\circ}C$ for 37 minutes, at flow rates up to 60cc/min.

Conclusion: We successfully developed a chemically-based fluid cooling device. The ultraportable nature of the system could potentially facilitate the induction of therapeutic hypothermia in the pre-hospital care setting. Given that the device doesn't need to be plugged in, fluid cooling can be provided continuously throughout the resuscitation effort. Furthermore, the system may be useful in remote locations, third world hospitals, or any location where electricity may not be readily available or where ultra-portability is desired. Future work will aim to improve the performance, efficiency and usability of the system.

Criteria for Airway Difficulty Classification: A Survey of Clinical Practice in the U.S. and Canada

Presenting Author: Jesse Ehrenfeld, MD, MPH, Departments of Anesthesiology, Surgery, and Biomedical Informatics, Vanderbilt University Medical Center

Co-Authors: Madeleine Hebert, Department of Anesthesiology, Vanderbilt University Medical Center; Douglas Hester, MD, Department of Anesthesiology, Vanderbilt University Medical Center

Introduction: "Difficult airway" is a common label used by clinicians to categorize patient airway management; however, it currently has no standardized definition. It is poorly or incompletely defined in the literature, with the American Society of Anesthesiologists' definition neither widely accepted nor broadly explanatory. The lack of a standard definition is problematic when trying to communicate within anesthesia information management systems (AIMS). Specifically, while we would like to automatically flag patients as a "difficult airway" to facilitate communication among downstream providers, we are hindered by the vagueness of the term. We therefore surveyed clinicians at academic institutions across the United States and Canada for their definitions of a "difficult airway" and their criteria for classifying an airway management scenario as such. Our goal is to use this data to program our AIMS.

Methods: We designed a survey to assess physicians' definitions of the term "difficult airway" and their interpretations of airway difficulty in clinical scenarios. The three primary components assessed were ease of mask ventilation, vocal cord grade view, and ease of endotracheal intubation. REDCap (Research Electronic Data Capture) was used to administer the web-based survey. The survey also asked about their interpretation of the term "difficult laryngoscopy." The survey was first validated with pilot respondents, and was then emailed to all 133 anesthesiology residency training programs in the United States and all 17 in Canada.

Results: 630 survey responses were collected from 125 institutions (83% institution response rate). For scenarios in which only one difficult component was involved, 38% of respondents reported "difficult airway" when the component was impossible mask, 50% when it was a Grade IV view, and 70% when it was ≥4 attempts or ≥10 minutes to intubate (Table 1). With any 2 of these components, 88-95% found the airway "difficult." All respondents classified an airway as "difficult" when the scenario involved all 3 components (impossible mask, Grade IV view, and ≥ 4 attempts or ≥10 minutes to intubate). For consideration of a difficult laryngoscopy, 31% would classify it as a difficult intubation after 2 attempts to place the tube, and 59% after 3 attempts. The amount of time taken to intubate before considered "difficult" was 1-3 minutes for 27%, 4-6 minutes for 44%, 7-9 minutes for 5%, and 10 or more minutes for 24%.

Conclusion: Survey responses indicated that there is wide variability in operational definitions of "difficult airway" among practicing anesthesiologists, but some common ideas are shared. "Difficult intubation" appeared to be the strongest predictor of a "difficult airway." A time-dependent and attempts-to-intubate-dependent definition of difficulty did not appear sufficient. Factors such as mask ventilation, visualization, time, and intubation attempts should be taken into consideration when designing a standardized system of airway difficulty classification in order for the term "difficult airway" to have strong diagnostic power. We are now planning to use this information to provide clinical decision support within our AIMS.

References: 1. 2003 Practice Guidelines by the American Society of Anesthesiologists Task Force on Management of the Difficult Airway 2. Adnet et al., 1997. The intubation difficulty scale (IDS): proposal and evaluation of a new score characterizing the complexity of endotracheal intubation

Table 1 This table indicates survey responses to questions in which respondents rated airway management scenarios as either a "difficult airway" or not.

	1 difficult component			2 difficult components			3 difficult components
Scenario:	1	2	3	4	5	6	7
Component:							
Impossible mask	X			X	X		X
Grade IV view		X		X		X	X
≥4 attempts or ≥10 min to intubate			X		X	X	X
Reported "difficult airway"	38%	50%	70%	88%	94%	95%	100%

An Automated Case Cancellation Review System for Enhancing Systems-Based Practice in Anesthesia Residency Training

Presenting Author: Jonathan Wanderer, MD, M. Phil, Department of Anesthesiology, Vanderbilt University Medical Center

Co-Authors: Blake Thompson, Jesse M. Ehrenfeld, MD, MPH, and Matthew McEvoy, MD, Department of Anesthesiology, Vanderbilt University Medical Center

Introduction: Cancelled surgical cases can negatively impact patient satisfaction, hospital resources, and surgical training.1 At Vanderbilt University Medical Center, the Vanderbilt Preoperative Evaluation Clinic (VPEC) provides evaluations and consultation services to surgical patients in an effort to ensure patient safety, prevent delays, and reduce cancellations. Despite this effort, cancellations still occur. We developed a system to support systems-based practice for anesthesiology residents through structured case cancellation review. This automated system informs VPEC residents of cases that were cancelled on the previous business day and provides a framework for performing reviews.

Methods: We created a SharePoint-based website that provides a view of a SQL Server database of case cancellations with access restricted to anesthesiology residents, VPEC staff and clinical leadership. An automated process runs each workday that identifies cases cancelled during the previous business day. These cases are added to the case cancellation database and an automated email with the cancellation list is sent to the resident scheduled in VPEC. This email contains a link that directs the resident to our case cancellation website. From there, the resident answers a list of questions pertaining to the cancelled case assessing the presence of proper documentation, the reason why the case was cancelled, who was responsible for the cancellation, and how it might have been prevented (Figure 1). The residents' analyses are reviewed by the anesthesiologist assigned to VPEC. In addition, these data are used to populate a Tableau-based case cancellation dashboard that is available to our clinical leadership (Figure 2). This dashboard provides case cancellation trends over time as well as the granular detail on a per-case basis as provided by anesthesia residents.

Results and Conclusion: The result of this project is a comprehensive system for resident-led case cancellation review that allows for these cases to be easily reviewed with an anesthesiologist. This system has incorporated systems-based practice into the daily routine of our preoperative clinic. By linking the data input in the SharePoint site to a SQL Server database, we have created a system that builds a rich longitudinal data set for analysis, will drive continuous quality improvement projects and provides an executive-level dashboard of case cancellations.

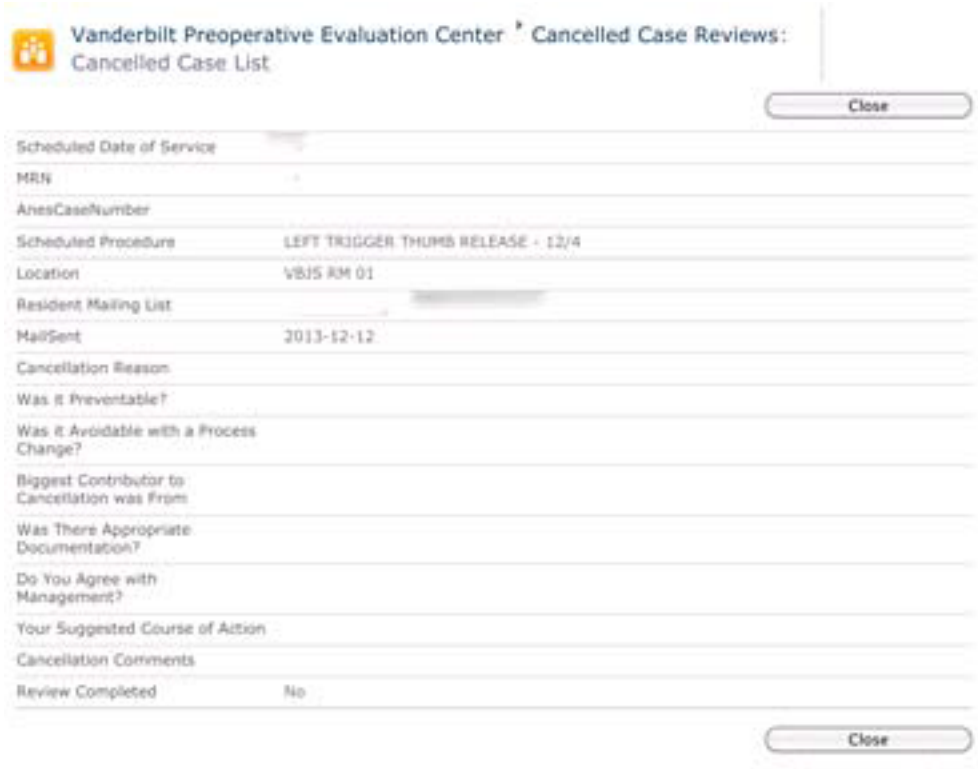


Figure 1: View of case cancellation details.

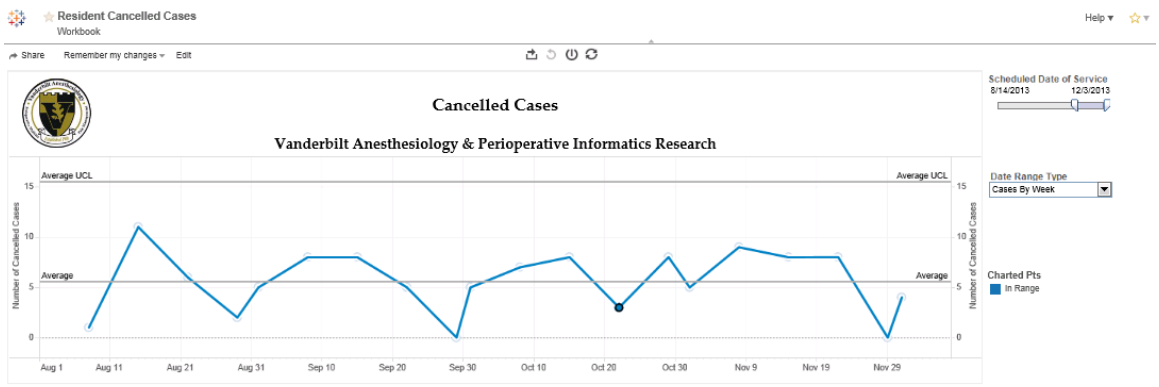


Figure 2: View of case cancellation dashboard.

References 1. Knox M, Myers E, Hurley M. The impact of pre-operative assessment clinics on elective surgical case cancellations. Surgeon 2009; 7(2): p. 76-8.

A Visual Analytics Antibiogram Dashboard as Part of a Comprehensive Approach to Perioperative Antibiotic Administration

Authors: Luis M. Ahumada, MSCS,[a] Allan F. Simpao, MD,[c] Jorge A. Galvez, MD,[c] Mohamed A. Rehman, MD,[c] Jeffrey Gerber, MD, PhD,[b] John Martin, MBA,[a] Beatriz Larru, MD,[b] Kaede Oda, MD, MSc,[b] Telene Metjian, PharmD,[d] Bimal Desai, MD, MBI[b]

[a] The Children's Hospital of Philadelphia Data Analytics and Enterprise Reporting Group, Philadelphia, PA;
[b] The Children's Hospital of Philadelphia Department of Pediatrics;
[c] The Children's Hospital of Philadelphia Department of Anesthesiology and Critical Care Medicine, Section on Biomedical Informatics
[b] The Children's Hospital of Philadelphia Department of Pharmacy Services

Background: Many hospitals routinely perform antimicrobial susceptibility testing for bacterial pathogens; the results are often organized into a summary table, or antibiogram, which may be used by clinicians as a reference guide to antimicrobial resistance patterns. Antibiograms lend information that can be used to raise awareness of resistance problems, support the use of optimal empiric therapy, and identify opportunities to reduce inappropriate antibiotic usage. At many hospitals, antibiograms are static documents that are generated from laboratory data and distributed to house staff once per year. Pediatric anesthesiologists are often tasked with administering perioperative antibiotics either for prophylaxis or to treat an active systemic infection.

Objectives: To develop a secure, Web-based, institution-specific, user-friendly visual analytics antibiogram dashboard using EHR data in near real-time that can be accessed in the operating room setting using the anesthesia information management system computer workstation.

Methods: We created a visual analytics antibiogram dashboard using both SQL queries of our EHR database and enterprise analytical software to track bacterial pathogens and their antimicrobial sensitivity at The Children's Hospital of Philadelphia. The antibiogram dashboard provides a user interface to explore our hospital's laboratory EHR data in near-real time and facilitates the rapid assessment of susceptibilities and resistances of microorganisms of interest to various antibiotics.

Results: A visual analytics antibiogram dashboard specific to our institution was designed and implemented as described in the methods. The dashboard allows the user to display up-to-date, hospital-specific antibiotic sensitivity data for a particular organism using a variety of filters and drop down menus.

Conclusion: Pediatric anesthesiologists are often given the task of administering perioperative antibiotic prophylaxis. While infectious disease specialists usually guide the antibiotic choices and dosages, there remains a dearth of information at the time of antibiotic administration in the operating room regarding the susceptibility of organisms to the chosen antibiotic

medication. This data and dashboard will be an integral part of a project to optimize perioperative antibiotic treatment based on our hospital's EHR data.

Detecting Sleep Apnea Events in Children Using the "Phone Oximeter"

Presenting Author: Ainara Garde1, PhD

Co-Authors: Parastoo Dehkordi1, PhD student, David Wensley3, MD, J M. Ansermino2, MBBCH, Guy A. Dumont1, PhD. 1Department of Electrical and Computer Engineering, The University of British Columbia 2Department of Anesthesiology, Pharmacology and Therapeutics, The University of British Columbia 3Division of Critical Care, BC Children's Hospital

Introduction: Approximately 2% of children [1] and 2.5%-6% of adolescents are affected by obstructive sleep apnea (OSA) [2]. OSA poses a serious threat to the healthy growth and development of these children [3]. Polysomnography (PSG), the gold standard for diagnosis of OSA, is highly resource intensive and is confined to overnight sleep laboratories. The Phone Oximeter (Figure 1) is a mobile device that integrates a pulse oximeter with a cell phone, providing blood oxygen saturation (SpO_2) and signal of changes in blood volume (PPG). Although SpO_2 pattern characterization has been successfully applied to identify subjects with significant OSA [4], some proportion of OSA events occur in the absence of SpO_2 desaturation. The aim of this project is to combine SpO_2 characterization and Heart Rate Variability (HRV) to identify events with OSA using the Phone Oximeter.

Methods: After REB approval and written informed consent/assent, overnight pulse oximetry data was collected using the Phone Oximeter, simultaneous to standard PSG from 160 children visiting the sleep laboratory at BC Children's hospital. The sleep technician scored all OSA events with and without desaturation. The proposed algorithm characterizes SpO_2 pattern [4] and estimates HRV from the PPG (based on pulse to pulse [PP] analysis) [5], both in time-frequency domain, using a 1-min sliding window (no overlap). Based on OSA scores, each 1-min window was labeled as: OSA with desaturation, OSA without desaturation or non-OSA. The statistically significant parameters extracted from SpO_2 and HRV analysis, were used to automatically identify OSA events through logistic regression using 10-fold cross validation.

Results: In total, we have 30,995 minutes, 3,606 with OSA (2,269 with desaturation and 1,337 without) and 27,389 without OSA. Regarding HRV analysis, OSA events showed statistically significantly higher normalized power at low frequency (95% CI, -0.18 to -0.17), lower normalized power at high frequency (95% CI, 0.18 to 0.19), lower mean of PP intervals (95% CI, 0.06 to 0.07), higher standard deviation of PP intervals (95% CI, -0.040 to -0.037) and higher root mean square of the difference of successive PP intervals (95% CI, -0.03 to -0.026). With regard to SpO_2 characterization in the time domain, OSA events presented statistically significantly greater SpO_2 variability through standard deviation (95% CI, -0.8 to -0.6) and lower mean and median values of SpO_2 (95% CI, 0.7 to 0.9). Spectral analysis of SpO_2 showed higher normalized power at low frequencies in OSA events (95% CI, -0.06 to -0.05). An accuracy of 81%,

sensitivity of 82% and specificity of 80% were obtained identifying OSA events (with and without desaturation) through logistic regression using 18 significant features extracted from SpO2 and HRV analysis.

Conclusion: The combination of SpO2 and HRV characterization extracted from pulse oximetry could improve the sensitivity of the Phone Oximeter in detecting OSA events. This provides the potential for the Phone Oximeter to be used as an OSA screening tool, providing a portable, inhome device, with the capability of monitoring patients over multiple nights. At-home screening will result in less sleep disturbance, facilitate a more natural sleep pattern and prevent unnecessary burden to both families and the health system. References: [1] J. Pediatr., 2003, 142,(4), 83–389 [2] Sleep, 2006, 29, 1135–1142. [3] Pediatrics, 2012, 30 (3), 576–84. [4] In Proc. IEEE-EMBC, 2013, 2531–2534. [5] In Proc IEEE-EMBC, 2013, 6563–6566.

Figure 1: The Phone Oximeter

Perioperative Glycemic Control with the aid of AlertWatch System

Presenting Author: Subramanian Sathishkumar, MBBS, Department of Anesthesiology, University of Michigan, Ann Arbor.

Co-Authors: Sachin Kheterpal MD, Michelle Morris MS, Kevin K Tremper MD*, and Satya Krishna Ramachandran, MD Department of Anesthesiology, University of Michigan, Ann Arbor.

Background: Perioperative hyperglycemia is associated with increased hospital length of stay, morbidity, and 30-day mortality after non-cardiac general surgery.[1] Currently there is no clear evidence on the thresholds for treating blood glucose (BG) during the perioperative period.[2] BG levels above 200 mg/dL are associated with significant increases in 30-day mortality, with a dose-dependent further increase at higher BG values.[1] On the other hand, overzealous treatment may result in hypoglycemia which may increase risk of adverse outcome. Treatment thresholds for hyperglycemia have not been defined as a standard of care, and little is known of the inter-individual variability in the intraoperative management of hyperglycemia during non-cardiac surgery. We tested the hypothesis that real-time visual notification of recent BG values would modify therapeutic thresholds for treatment of intraoperative hyperglycemia.

Methods: AlertWatch (AW) is a secondary patient monitor for use in hospital operating rooms and ICUs. The AW system pulls historical patient data (risk factors, lab results) from multiple networked IT systems and combines it with the patient's live physiologic data to display them for the clinician. After Institutional Review Board approval, we extracted data from the electronic medical record to evaluate the usage of AW and the relationship between usage and in monitoring BG and initiation of appropriate treatment. AW usage was captured by presence of concurrent access of the AW system, which requires secure login. Two thresholds for hyperglycemia were defined as any point-of-care, ABG or laboratory BG value ≥200 mg/dL, and ≥250 mg/dL Treatment was identified by searching the EMR for use of insulin. Significant hypoglycemia was defined as BG value ≤70 mg/dL. The study outcome, appropriate BG treatment, was defined as documentation of insulin use in response to preoperative (day of surgery) or intraoperative hyperglycemia. Since the AW system was accessed randomly during ~50% of all anesthetics, we compared the study outcome occurrence during contemporaneous anesthetics between 5/1/2012 and 10/31/2013. We also evaluated the frequency of post-insulin BG check among all patients who were treated intraoperatively. Differences in study outcomes between the AW and no-AW groups were analyzed using Pearson Chi-square tests and p-value of <0.05 was considered significant.

Results: The AW system was accessed intraoperatively during 10135 (51%) of 19978 adult (≥18 years) patients who underwent anesthesia care during the study period. Of these patients, 1451 (7.3%) had BG ≥200 mg/dL, and 647 (3.2%) had BG ≥250 mg/dL. Use of AW was associated with a 14% increase in the rate of insulin treatment of BG ≥200 mg/dL (p=0.039), and a 22% increase in the rate of insulin

treatment of BG ≥250 mg/dL (p=0.02). The frequency of hypoglycemia was 332 (3.3%) with AW and 302 (3.1%) in controls.

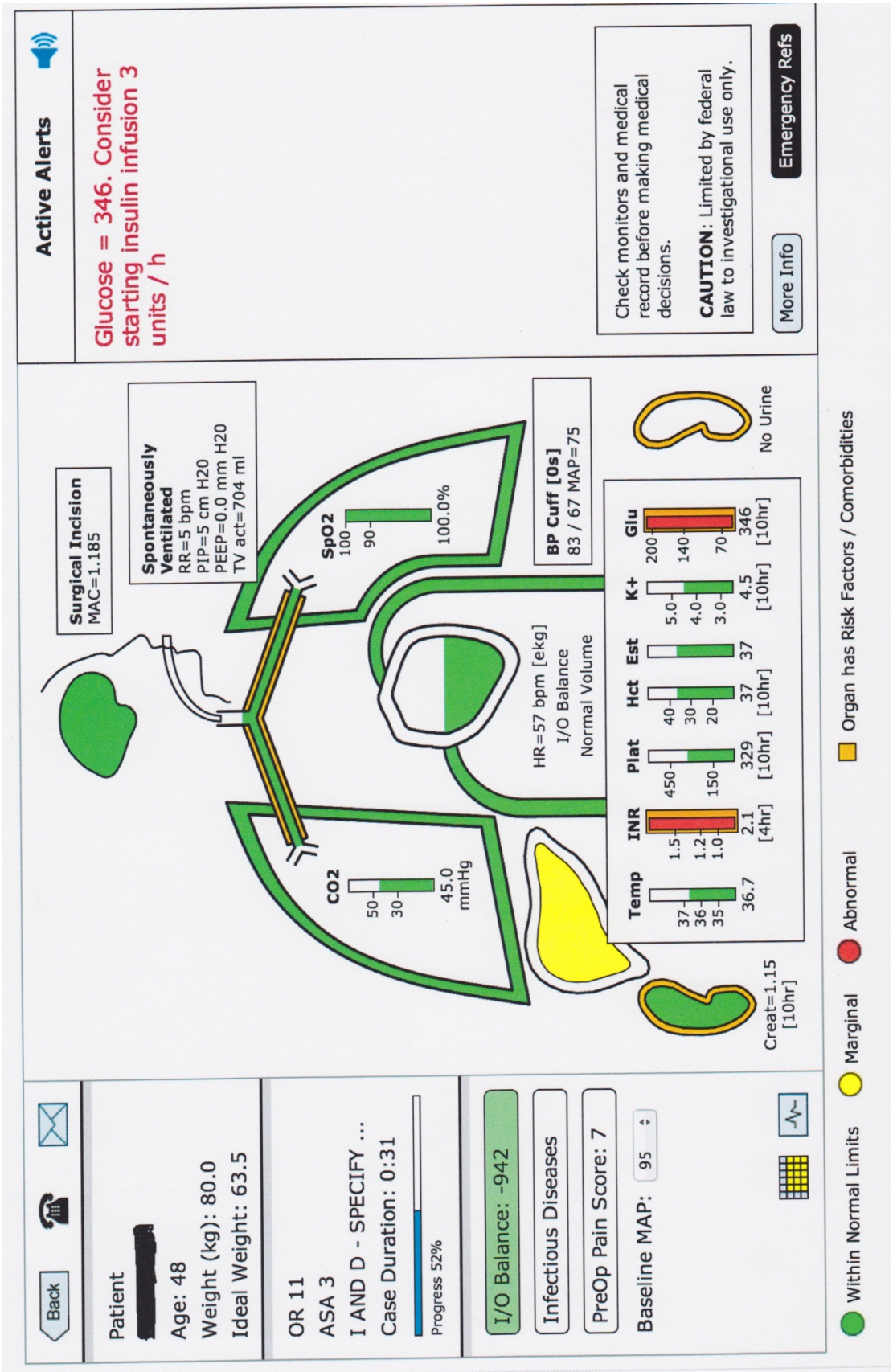
Conclusion: The use of AW technology is associated with reduced variability in the management of perioperative hyperglycemia and thereby, it may contribute to improved patient outcomes. The positive behavioral response seen with use of the AW system suggests that it may perform as an effective tool in implementation of tighter intraoperative glycemic control. The lack of difference in incidence of hypoglycemia is supportive of the safety of the AW system.

References:

1. Prevalence and clinical outcome of hyperglycemia in the perioperative period after non cardiac surgery: Diabetes care, volume 33, number 8, august 2010.
2. Perioperative Glycemic control: Anesthesiology, V110, No 2, Feb 2009.
3. Grant Kruger, Kevin Tremper, Computers in Anesthesia, Advanced integrated real-time clinical displays, Information Technology Applied to Anesthesiology: September 2011,Volume 29,number 3
4. http://www.alertwatch.com

*Has an equity interest in AW

Alert-Watch System display:



The Evaluation of a Non-Invasive Respiratory Volume Monitor in Surgical Patients Undergoing Elective Surgery under General Anesthesia

Authors: Christopher Voscopoulos, MD, C. Marshall MacNabb, MS, Jordan Brayanov, PhD, Jenny Freeman, MD, Lizeng Qin, MD, Edward George, MD, PhD.

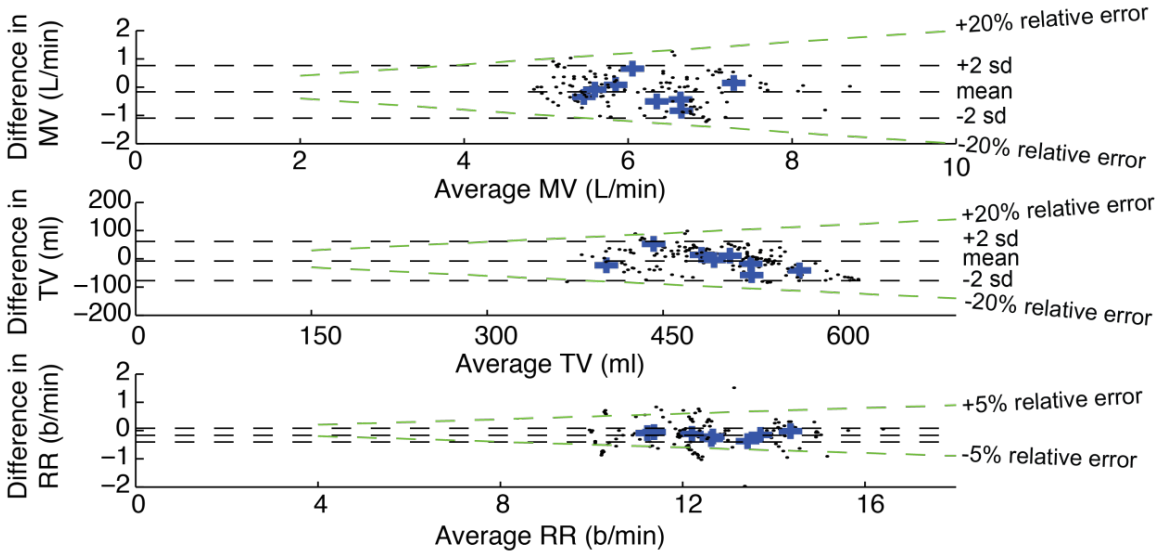
Introduction: Continuous monitoring of respiratory activity is important for identifying and predicting high-risk situations, making appropriate monitoring techniques potentially life-saving. Mechanical ventilation is an essential support therapy to maintain adequate gas exchange during general anesthesia for surgery. However, there is accumulating evidence from both experimental and clinical studies that mechanical ventilation may potentially aggravate or even initiate lung injury. Until recently there was no technology that non-invasively measured the adequacy of ventilation, especially in patients with healthy lung in the post-surgical context. Respiratory assessment is important during post-operative care when the surgical patient has been extubated and is no longer supported on a ventilator. During this recovery phase, respiratory depression and subsequent adverse outcomes can arise due to residual anesthetics and/or opioid administration, especially in at risk patients. A novel, non-invasive Respiratory Volume Monitor (RVM) has been developed that provides continuous real-time measurements of minute ventilation (MV), tidal volume (TV), and respiratory rate (RR). This study correlated RVM measurements of MV, TV and RR to ventilator measurements during general anesthesia in elective orthopedic patients.

Methods: Respiratory traces were collected from 8 patients (5 female and 3 male, mean age of 62.1± 8.2 years; mean BMI of 28.8±5.8) undergoing elective joint replacement surgery with general anesthesia from a bio-impedance RVM system (ExSpiron, Respiratory Motion, Waltham, MA) via an electrode PadSet placed on the patients thorax after obtaining written informed consent. Data (MV, TV and RR) were continuously gathered from the RVM as well as from the anesthesia ventilator during the entire surgical procedure (operating procedure time varied between 1-5 hours for the patient's studied). RVM data were compared to ventilator data and bias, precision and accuracy were calculated.

Results: Measurement error analysis of the data from the 8 subjects studied is shown in Bland-Altman plots of MV, TV and RR (Figure 1, A-C, respectively). Each data point was computed as the average for a single subject. The abscissa is computed as the average between the two devices, whereas the y-axis is the difference between the ventilator and the RVM. The middle black dashed line shows the average difference for each parameter. The upper and lower dashed black lines depict the 95% prediction interval (±2SD). The green dashed lines contain the region of space where relative error is ±20% for MV and TV and ±5% for RR. The average MV difference between the RV and ventilator is -0.17L/min with bias -2.4 (-17 to 12%, 95% CI); precision 6.0% (±8.5%, 95% CI), accuracy 8.8% (±15%, 95% CI). The average TV difference was -8.1 ml with bias 1.2% (-15 to 13%, 95% CI); precision 6.9% (±9.4%, 95% CI); accuracy 9.1% (±15%, 95%

CI). The average RR difference was 0.17 breaths/minute with bias -1.3% (-3.1 to 0.5%, 95% CI); precision 3.5% (±6.5%, 95% CI) and accuracy 3.7% (±6.7%, 95% CI).

Conclusions: The RVM measurements of RR had a bias of -1.3 and measurements of MV and TV have a relative error of <10% (8.8% and 9.1%, respectively) while RR had a relative error of <5% (3.7%) in ventilated patients undergoing elective surgery. This study comparing the RVM to the ventilator supports previous results comparing the accuracy of the RVM to a spirometer. These results confirm the accuracy of the device and provides the foundation for use in the assessment of respiratory status in non-intubated patients, allowing providers to have real-time measurements of MV, TV and RR that can lead to therapeutic interventions, improve patient safety and decrease healthcare costs.



A New Monitoring Display Improves Intraoperative Hemodynamic Management: Alert Watch

Presenting Authors: Amy Shanks, MS, PhD (candidate) University of Michigan Medical School

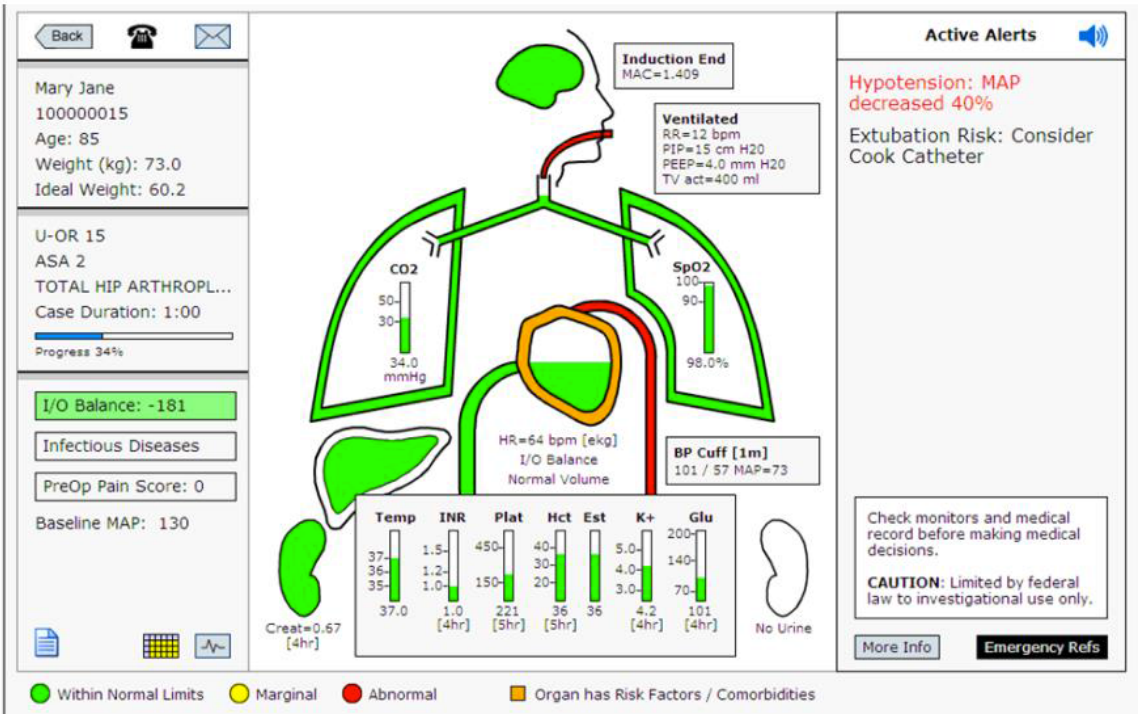
Co-Authors: Sachin Kheterpal, MD, MBA, and Kevin K. Tremper, PhD, MD, University of Michigan Medical School

Introduction: In the operating room, the anesthesiologist is responsible for assimilating the wide range of real-time second-to-second physiologic monitor data, clinical observations, and patient history and physical information. The sheer volume of data and the frequency of artifact signals can overwhelm sustained vigilance of practicing clinicians and has been documented as a major patient safety issue. AlertWatch™ (AW) is a web-based multifunction display which receives, integrates, and presents data from physiologic monitors, electronic health records, and laboratory systems to provide evidence-based alerts. The display is comprised of readily identifiable icons of human organs, whose colors change as measured and calculated parameters go from normal to marginal to abnormal risk-adjusted ranges (Figure 1). AW includes real-time alerts for more than 30 intraoperative processes of care, ranging from hemodynamics to ventilator strategy and malignant hyperthermia. We hypothesized that the use of AW would improve the intraoperative hemodynamic management across a broad range of surgical procedures and patients.

Methods: AW was implemented as a supplementary screen on May 1, 2012 in the adult operating rooms at the University of Michigan Health System. After implementation, individual clinical providers could voluntarily choose to use AW during their case. No additional clinical care protocols were instituted, publicized, or recommended. For blood pressure management, the aortic arch represents the mean arterial pressure (MAP) and changes color to yellow when the MAP drops 30% below the patient's preoperative baseline and changes to red when it drops to 40% of the patient's preoperative baseline. Simultaneous with the color change, there is a three tone audible alert which decreases from high to low pitch. This tone repeats every minute until the blood pressure increases above the 40% drop. For this analysis, all cases that were 60 minutes or greater in length were included; outpatient and cardiothoracic procedures were excluded from this analysis. Data were analyzed in two ways. First, two analysis groups were studied from 5/1/2012 to 11/1/2013: a case was considered "AW-assisted" if it was used for 75% or more of the intraoperative case duration versus "control" if it was used for less than 75% of the case duration. Second, historical controls for 17 months prior to the implementation of AW were compared against "AW-assisted" cases. A sensitivity analysis was also performed comparing "AW-assisted" cases to controls were AW was not used at all during the case (0% of duration).
The primary outcome was hypotension, defined as the percentage of case duration with a MAP below 60 mmHg or 55 mmHg. The secondary outcomes included

myocardial ischemia (MI) defined as a postoperative troponin ≥ 0.30 within seven days of the operation. Acute kidney injury (AKI) was defined using the most recent preoperative and peak postoperative serum creatinine within seven days. We used the KDIGO staging criteria (stage 1 = 1.5 x baseline or 0.3 mg/dl increase, stage 2 = 2.0 x baseline). SPSS version 21 and tests appropriate for observed normalcy were used for the analysis.

Results: A total of 35,612 cases were included in the primary analysis: 7,391 "AW-assisted" cases, 11,315 parallel controls, and 16,906 historical controls. "AW-assisted" cases exhibited significantly less percentage of the case with MAP below 60 mmHg (median 2.13 IQ range [0-6.7] vs 2.33 [0-7.6] parallel control; 2.13 [0-6.7] vs 2.62 [0 – 8.0] historical control) and 55 mmHg (0 [0-2.08] vs 0 [0 – 2.43] parallel control; 0 [0-2.1] vs 0-2.6] historical control) all p-value < 0.01). In addition, in the parallel control period there was a statistically significant lower incidence of MI for "AW-assisted" versus control cases, 0.7% versus 1.0% (p = 0.0025). There was no difference in AKI in this group. In the historical control analysis, both Stage 1 and 2 AKI were significantly less common in the AW-assisted group (stage 1: 12.5% vs 14.8%; stage 2: 1.6% vs 2.5%), p-value < 0.001. MI demonstrated a lower incidence in AW cases when compared against the historical controls but it did not reach statistical significance, 0.7% versus 0.9% (p = 0.141). The sensitivity analysis demonstrated the same findings for hemodynamic control but did not reach statistical significance for MI or AKI.



Conclusion: Our findings suggest that the use of an integrated display that alerts providers to moderate relative hypotension is associated with a decrease in the incidence of moderate and severe absolute hypotension. We also observed a

decreased incidence of myocardial ischemia and acute kidney injury. Caution should be noted when interpreting these results. First, this is an observational study so it cannot causality; second, the historical controls have the bias of time while the parallel controls are subject to treatment or selection bias by the provider choosing to use AW. In spite of these limitations it appears this type of display may allow for improved management and postoperative outcomes.

Monitoring Hypnotic Effect with qCON During General Anaesthesia

Presenting Author: Ms. Patricia Pineda, Dept ESAII, Centre for Biomedical Engineering Research, UPC BarcelonaTech, Spain

Co-Authors: Dr. Erik Weber Jensen, Dept ESAII, Centre for Biomedical Engineering Research, UPC BarcelonaTech, Spain Prof José Fernando Valencia, Universidad de San Buenaventura, Electronic Engineering Dpt., Cali(Colombia) Mr. Mathieu Jospin, Dept ESAII, Centre for Biomedical Engineering Research, UPC BarcelonaTech, Spain

Introduction: In recent year anesthetic monitoring has been in progress by improving mathematical methods applied to the different monitors. One of the fields that are currently being studied is monitoring anesthetic depth. These monitors help the anesthesiologist to tailor the anesthetics to the patient requirements. The electroencephalogram (EEG) is a direct measure of brain activity and from the EEG signal recorded a measure of hypnotic effect can be developed.
In the present study, the qCON (Quantium Medical, Spain) monitor was used, which defines the qCON index of hypnotic effect. The qCON index is based on the combination of different frequency bands, which are fed into an Adaptive Neuro Fuzzy Inference System (ANFIS) which generates the output on a 0-99 scale.
The objective of the present work was to analyze EEG recorded from patients undergoing surgery under general anaesthesia to find a specific indicator of hypnotic effects.

Methods: After Ethics Committee approval, data was recorded from 60 patients scheduled for general anaesthesia with propofol and remifentanil, using TCI. Response to noxious stimulation was recorded. The patients were classified as movers or non-movers and the mean value for the qCON were calculated over the 1 min period after the stimulus. The qCON was compared with the BIS, and the linear correlation coefficient was calculated. A Students t-test (paired) was used to test for significance, at $p<0.05$.

Results: The R2 between qCON and Bis was 0.85. The qCON were able to detect the response to noxious stimuli for LMA, tracheal intubation, laryngoscopy and suture ($p<0.05$) but not to incision. During the general anaesthesia (Ce propofol>2µg/ml Ce remi > 2ng/ml) the mean value for qCON was 45(8).

Conclusion: During general anaesthesia with propofol and remifentanil, in this study, the qCON was able to detect loss of consciousness and movement as a response to noxious stimulation. During general anaesthesia qCON decreased to values in the 40-60 range.

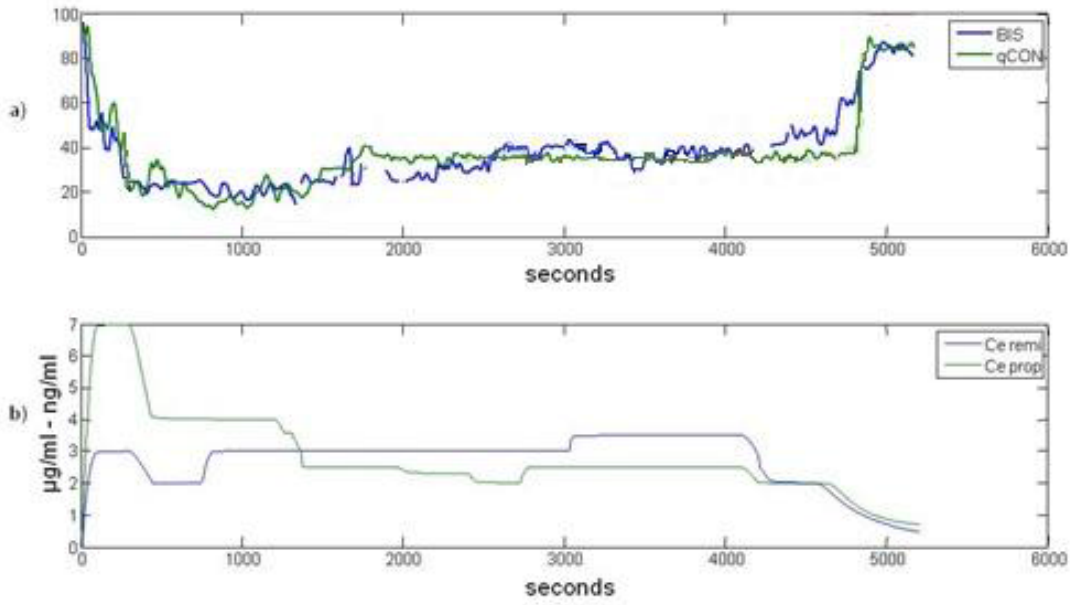


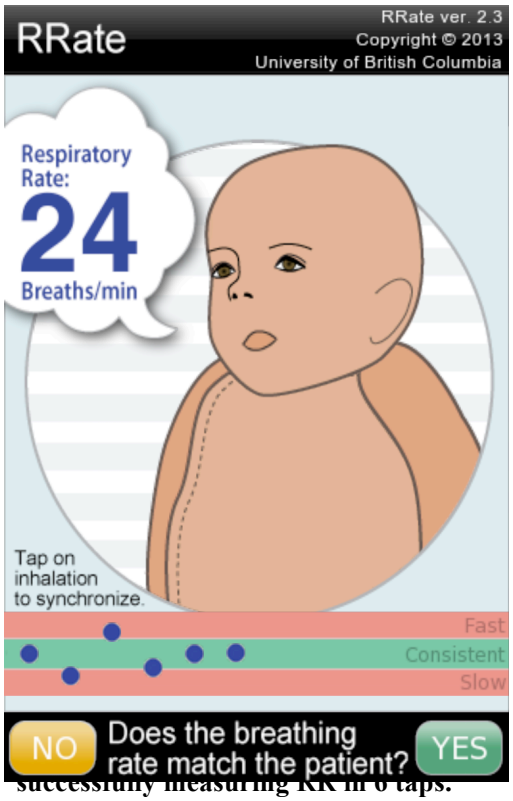
Figure 1: Panel (a) shows the tracing of the EEG derived parameters; qCON (green line) and Bis (blue line). Panel (b) shows the time course of predicted effect-site concentration of propofol and remifentanil for this particular patient.

The Design of a Respiratory Rate Mobile Application

Authors: Dustin Dunsmuir[*], Walter Karlen[†], Heng Gan[*], Michelle Chiu[#], Christian L Petersen[*], Guy A Dumont[†], J Mark Ansermino[*]Departments of [*]Anesthesiology, Pharmacology & Therapeutics and [†]Electrical and Computer Engineering, and [#]Faculty of Medicine, The University of British Columbia, Vancouver, Canada

Introduction: Respiratory rate (RR) is an essential vital sign, yet its manual assessment is often inaccurate[1]. The recommended method for measuring RR is counting the number of breaths in a minute. In a busy clinical setting, this is a significant period of time to be focused on counting breaths. Any disruption means the minute must be restarted. We have designed a smartphone application, called *RRate*, to provide a more efficient measurement of RR with clinically acceptable accuracy for the diagnosis of fast breathing in children. The user taps the touch screen of the phone each time the patient inhales and the RR is calculated iteratively from tap intervals. If the taps are sufficiently consistent, the RR is displayed.

Methods: Two iterative processes were involved in the *RRate* development: the user interface design and the optimization of the tap consistency algorithm. *RRate* requires a minimum number of taps **n** that are timed within a maximum deviation percent **c** from the median between-taps time interval. The RR calculation considers the **n-1** time intervals between the most recent **n** taps. The median of these time intervals **M** is calculated and a consistency range defined as **M** ± (**c** * **M**). If all n-1 intervals are within the consistency range, the animation is displayed and the RR of **60/M** breaths per minute is shown. If this test fails, more taps are recorded.



successfully measuring RR in 6 taps.

The user interface consists of the following elements: 1) *The touch screen* where the user taps each time the patient inhales; 2) *Audio feedback* to the user when they are observing the patient's breathing. *RRate* emits a breathing sound upon each tap. Chimes sound when the tap consistency algorithm has been satisfied and a RR is successfully calculated. After the chimes, *RRate* continues to emit breathing sounds at the calculated RR; 3) *An animation* of a breathing baby is displayed once the RR is calculated, breathing at the calculated RR (Figure 1). The user can compare the *RRate* animation and breathing sounds to the patient's breathing to confirm that the correct rate has been obtained; and 4) *A visualization* of the timing of the taps (Figure 1) that provides feedback on why the tapping was rejected or accepted. Each tap is a blue circle that is either consistent with the median of the most recent taps (green zone) or too fast or too slow (red zones).

We performed a study with 30 adult subjects using *RRate* to measure the RR of children in 10 standard videos. RRate was configured to accept taps for a minute. The collected data was used to determine the optimal choice of the **n** and **c** parameters.

Results: The choice of **n** = 5 taps and consistency **c** = 13% provided the best trade-off between efficiency and accuracy, yielding a mean time to complete of 9.9 seconds and a normalized root mean square error of 5.6%. This corresponds to 2.2 breaths/min at a RR of 40 breaths/min[2], the threshold for fast breathing in children

[1] P.B. Lovett, et al., "The vexatious vital: Neither clinical measurements by nurses nor an electronic monitor provides accurate measurements of respiratory rate in triage", *Annals of Emergency Medicine*, 2005; 45:1 68–76.
[2] W. Karlen, H. Gan, et al., "Improving the accuracy and efficiency of respiratory rate measurements in children using mobile devices", *PLOS ONE*, Submitted November 19, 2013.
[3] World Health Organization (WHO), "Pocket Book of Hospital Care for Children: Guidelines for the Management of Common Illnesses with Limited Resources", *WHO*, Geneva, 2005.

aged 1 to 5 years[3]. This study also provided valuable feedback on the user interface. The *RRate* audio was modified to its current form based on this feedback. We also added the ability to synchronize the phase of the animation to the patient's inhalation by tapping on the animation.

Conclusion: *RRate* is a simple application for efficient and accurate measurement of RR. It is available for free download on the global Google and Apple stores. It provides acceptable RR results 6 times faster than the current practice of minute-long counting. In the future, *RRate* will be used within more complex applications to aid the diagnosis and management of childhood pneumonia.

Randomized Controlled Comparison of IV Catheter with Coiled Tip Guidewire and Conventional Peripheral IV Catheter

Presenting Author: Bette K. Idemoto, PhD RN, UHCMC

Co-Author: James R. Rowbottom, MD, UHCMC

Introduction: Intravenous therapy is a frequent treatment modality (90%) for hospitalized patients. However, this modality can be associated with pain/discomfort and risk of phlebitis/infections; therefore, first attempt success and dwell time for IV catheters are important outcomes. Currently first attempt success averages 40%, complications occur 47% and IVs dwell time average is 44 hrs. Multiple attempts at insertion, multiple IVs during each admission result in poor patient and clinician satisfaction as well as unnecessary costs. A new peripheral catheter technology that uses a proprietary coiled tip guidewire design previously seen only in central lines is now available (AccuCath™). This prospective study compared AccuCath™ and conventional IV catheters in adult patients. Outcomes that were evaluated included: higher rate of successful placement on first attempt, higher rate completion of therapy, fewer complications, longer dwell times, increased patient and clinician satisfaction and lower overall costs of therapy than conventional IV catheters. With INS (Infusion Nursing Society) standards now stating IVs can dwell until complication there is significant opportunity to improve patient outcomes with guidewire technology that offers greater first attempt success and longer dwell time with AccuCath™.

Methods: Industry and Hospital IRB approval were obtained prior to beginning the study. Adult Medical-Surgical patients who required a non-emergent IV catheter were enrolled and consented. The SICU and telemetry step-down were initially the sites, but the study was expanded with IRB approval to include all of Medical-Surgical adult patients. Randomized enrollment was ensured with sealed envelopes, opened once patient consent was obtained. Study forms were completed by the RN after insertion. The study was conducted over four months with a total of 248 patients (AccuCath™ 123, conventional 125). Data was collected using a standardized instrument. Outcomes were assessed using parametric and non-parametric tests.

Results/Analysis: The study included 248 patients total: 123 AccuCath™; 125 Conventional IVs. First attempt success was 88.6% with AccuCath™ compared to 43.2% with Conventional ($p=<0.001$ Fisher's exact). Complications including infiltration, phlebitis, occlusion, infection occurred only 8% of the time with AccuCath™ and 52% with Conventional ($p=<0.001$ Fisher's exact). Dwell time significantly improved with AccuCath™ at mean of 4.39 days compared to Conventional IVs at 1.46 days ($p=<0.001$ Fisher's exact). Completion of therapy (IVs in place until no longer needed) was 89% with AccuCath compared to Conventional at 34% ($p=<0.001$ Two-sided Fisher's exact). Patient satisfaction with IV insertion for AccuCath™ using a 5 point Likert Scale scored a mean of 4.6 compared to Conventional at 3.06 ($p=0.001$ Two-sided *t* test). Patient comfort rating of procedure for AccuCath™ was 4.2 compared to Conventional IVs at 2.9 ($p=0.001$ Two-sided *t* test). Patient satisfaction with overall performance scored 4.8 with

AccuCath compared to 2.8 with Conventional (*p=0.001* Two-sided *t* test). Overall clinician satisfaction for AccuCath using a 5 point Likert scale scored a mean of 4.5. Cost savings in a Return on Investment model was also significant due to the need to start 50% fewer peripheral IVs.

Conclusion: Use of the AccuCath™ was associated with positive outcomes (first attempt success, dwell time, higher completion of therapy), fewer complications and decreased cost of therapy. This study demonstrated that the use of the AccuCath™ was feasible for hospitalized adults, associated with better outcomes without increasing overall cost of care and significantly improved patient satisfaction. Larger studies are needed to validate this technology in other populations and multiple care settings.

References (optional):

1. Barton AJ, Danek G, Johns P, Coons M. Improving patient outcomes through CQI: vascular access planning. *J Nurs Care Qual*. 1998; 13(2):77-85.
2. Danek G, Kilroy R. IV CQI Study: impact of a vascular access planning algorithm on patient outcomes. *Friday's Focus Hospital Newsletter at Shands (University of Florida)*. April 1998:1-5.
3. Santolucito JB. A retrospective evaluation of the timeliness of physician initiated PICC referrals. *JVAD*. 2001:20-26.
4. Wolosin RJ. Largest study of patient satisfaction ever conducted. *The Press Ganey Satisfaction Report*. August 2003; VII:2-4.
5. Kokotis K. Cost containment and infusion services. *J Infusion Nurs*. 2005; 28(3S):S22-S32.
6. Kokotis K. The role of the IV therapist. *JVAD.* 1999; Winter: 22-27.
7. Van Donk P, Rickard C, McGrail M, Doolan G. Routine replacement versus clinical monitoring of peripheral intravenous catheters in a regional hospital in the home program: a randomized controlled trial. *Infection Control and Hospital Epidemiology.* Sept 2009;V3(9).
8. Maki DG, Ringer M. Risk factors for infusion-related phlebitis with small peripheral venous catheters. *Annals Int Med*. 1991;114:845-854.
9. Frey AM, Schears GJ. Why are we stuck on tape and suture? *J Infusion Nursing.* 2006; 29(1):34-38.
10. Schears GJ. Summary of product trials for 10,164 patients. *J Infusion Nursing*. 2006; 29(4):225-231.
11. Spader C. IV insertion, still a special skill. *Nursing Spectrum*. Feb 2006.
12. Infusion Nursing Society (INS). Infusion nursing standards of practice. *J Infusion Nursing*. 2011;34(1S):S57.
13. Sheppard K, LeDesma M, Morris N, O'Connor K. A prospective study of two intravenous catheter securement techniques in a skilled nursing facility. *J Infusion Nursing.* 1999;22(3).

Absolute and Trend Accuracy of Masimo O_3 Regional Oximetry in Healthy Volunteers During Controlled Hypoxia

Presenting Author: Daniel Redford, MD, University of Arizona, Tucson, AZ
CoAuthors: Samantha Paidy, MD, University of Arizona, Faisal Kashif, PhD, Masimo Corporation, Irvine, CA

Introduction: Traditional patient monitoring may not detect tissue hypoxia, and typical interventions may not improve tissue oxygenation. Therefore, monitoring cerebral tissue oxygen status with regional oximetry is being increasingly utilized by anesthesiologists and perfusionists during surgery. Absolute and trend accuracy of commercially-available regional oximeters varies. The purpose of this study was to evaluate the absolute and trend accuracy of a new regional oximetry technology in healthy volunteers.

Methods: After obtaining institutional review board approval, healthy adult volunteers were consented and enrolled. A sensor connected to a prototype regional oximetry system (O_3^{TM}, Masimo®, Irvine, CA) was placed on the subject's forehead. The system uses near-infrared spectroscopy (NIRS), interrogating tissue by transmitting light of four different wavelengths through the tissue and processing the received light waveforms, in order to provide continuous measurement of regional saturation of oxygen (rSO_2). Reference blood samples were taken from both an arterial cannula placed in the radial artery and a catheter placed in the internal jugular bulb vein, obtained at baseline and after a series of increasingly hypoxic states induced by altering the inspired oxygen concentration while maintaining a normocapnic arterial pressure of carbon dioxide ($PaCO_2$) level. The rSO_2 values were compared with reference cerebral oxygen saturation ($SavO_2$), computed as $SavO_2 = 0.3\ SaO_2 + 0.7\ SjvO_2$, where SaO_2 and $SjvO_2$ represent arterial and jugular venous oxygen saturation, respectively. Absolute accuracy was assessed by calculating bias, standard deviation (SD), root mean square accuracy (A_{rms}), and limits of agreement and was displayed per Bland and Altman plotting method. Trend accuracy was assessed by calculating the A_{rms} per established method.

Results: A total of 27 subjects were enrolled. Four subjects were excluded leaving 23 subjects (age range 18 to 35 years, median 23 years) with 12 males and 11 females included. A total of 202 separate $SavO_2$ and rSO_2 comparisons were included in the analysis. A scatter plot is shown in Figure 1a. Absolute accuracy analysis yielded a bias of 0.4%, SD of 4.0%, and A_{rms} of 4.0%. The limits of agreement were 8.2% to -7.4% (Figure 1b). The trend accuracy analysis yielded an A_{rms} of 2.1%. Age, gender, and skin color did not affect the accuracy of rSO_2 measurements.

Conclusion: Valid accuracy studies of regional oximeters require precise data collection, blood sampling, and laboratory analysis methods. With the methods we used in this study, Masimo O_3 regional oximetry provides clinically acceptable absolute and trend accuracy in healthy volunteers undergoing controlled hypoxia.

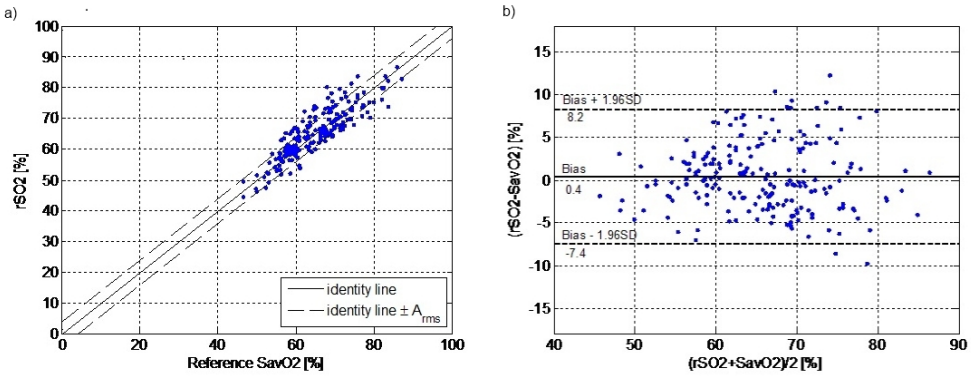


Figure 1: Scatter (a) and Bland Altman (b) plots to assess accuracy of rSO_2 against reference $SavO_2$.

Applying Google Analytics to Understand User Behavior and Smartphone Applications

Presenting Authors: Elicia C. Wartman, Jorge A. Galvez MD

Co-Authors: Allan F. Simpao MD, Jody M. Richards, Justin Lockman MD, Laura Schleelein MD, Mohammed Rehman MD

The Department of Anesthesiology and Critical Care Medicine, The Children's Hospital in Philadelphia, PA; Bioinformatics section

Introduction: Smartphone utilization has increased dramatically across healthcare settings worldwide (1). While new Applications (Apps) have the potential to reach a large user audience quickly, a major challenge that remains is the ability to obtain feedback from users to improve design. Many aspects that are determined during development, such as user interface and usage patterns, remain unknown after application deployment. We report on our experience of developing the Pedi Crisis App, a critical event algorithm app based on the Society for Pediatric Anesthesia Critical Events checklists. While developing the Pedi Crisis application, we wanted to know how, where and to what extent people were using the application. Traditionally, developers determined software use by either directly observing users or seeking user feedback via surveys. Newer methods allow the software to automatically capture user information such as flow through screens, crashes or time spent in the App. The Google Analytics (GA) platform provides one solution to this dilemma. Designers can utilize GA to gain insight into their application's usage and traffic. GA offers several out-of-the-box features such as; audience characteristics and behavior, device and operating systems, usage statistics and application performance. Our specific questions were how to monitor usage patterns (frequency of use, length of session, flow during a session) and geographic distribution of the App over time.

Methods: We gathered App usage information via Google Analytics data for the Pedi Crisis Application, from October 4, 2013 to December 11, 2013. Demographic information on App usage was obtained from the "app overview" screen (fig. 1.0). The screen-to-screen user flow was reported via the "engagement flow" section, which displayed the way users navigated the application (fig.1.3).

Results: The data shows that there have been 1,252 active users (both new and returning) and 4,140 sessions (figure 1.0). Since releasing the App on October 4, 2013, it has been used in 98 countries (fig. 1.1). We found that returning users used the application longer and viewed more screens. An average of 6.46 screens were viewed per session and the average length per session was 49 seconds (fig. 1.0). The events that were accessed most frequently were

Anaphylaxis, Tachycardia and Cardiac Arrest (figure 1.4). Most users accessed the App on an iPhone (81.96%), followed by iPad (17.42%) and iPod Touch 0.62% (fig. 1.0, 1.3).

Discussion: Mobile Apps have the potential to reach a large audience almost instantly. We were able to apply GA as a traffic monitor for our application. Most of the information we gathered would have been inaccessible to us without a tool like GA. GA has a growing set of built-in features, requiring little configuration from the user. Monitoring software utilization can be resource intensive and time consuming.(2) GA offers the advantage of being cost-effective (free for applications that have less than 10,000,000 hits per month) and is easy to use. GA also offers visualization tools that can help designers see how users interact with the application. There are Advanced Segments options that can help differentiate between types of traffic. Social reports can help designers monitor the impact of outside events such as relevant conferences or advertisements (Fig. 1.0) .Nevertheless, there are some limitations. GA only provides app download information for android based apps. However, the number of downloads is available directly from the iTunes App store for IOS apps. Another limitation is that in order for GA to collect data, the application must connect to the internet; if the target user/device is offline GA will not capture the data.

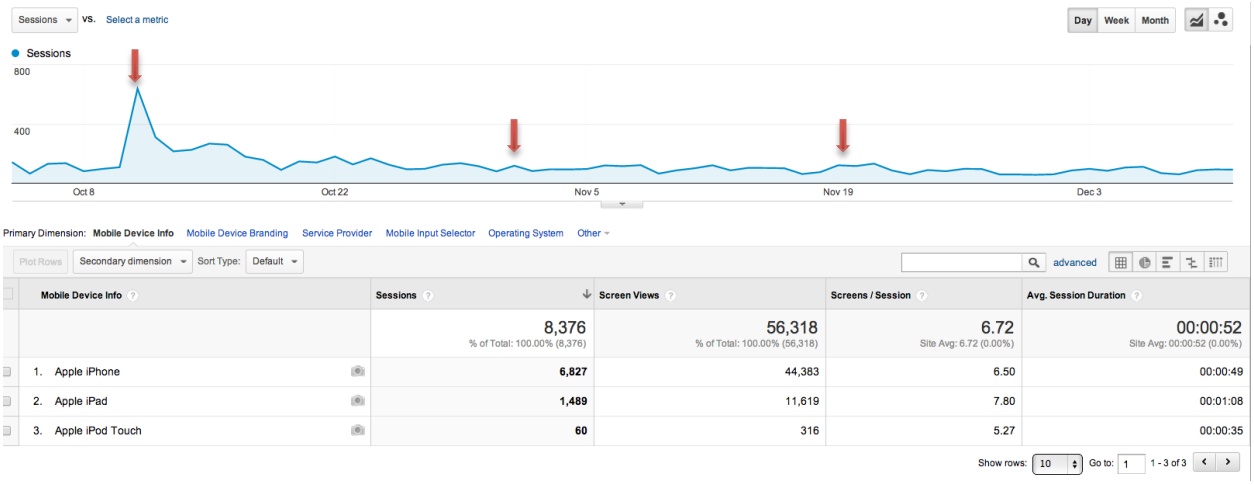


Figure 1.0. The red arrows in figure 1.0 show spikes in usage, that correspond with dates the Pedi Crisis App was promoted; e.g. the application was introduced at the SPA conference on October 11,2013.

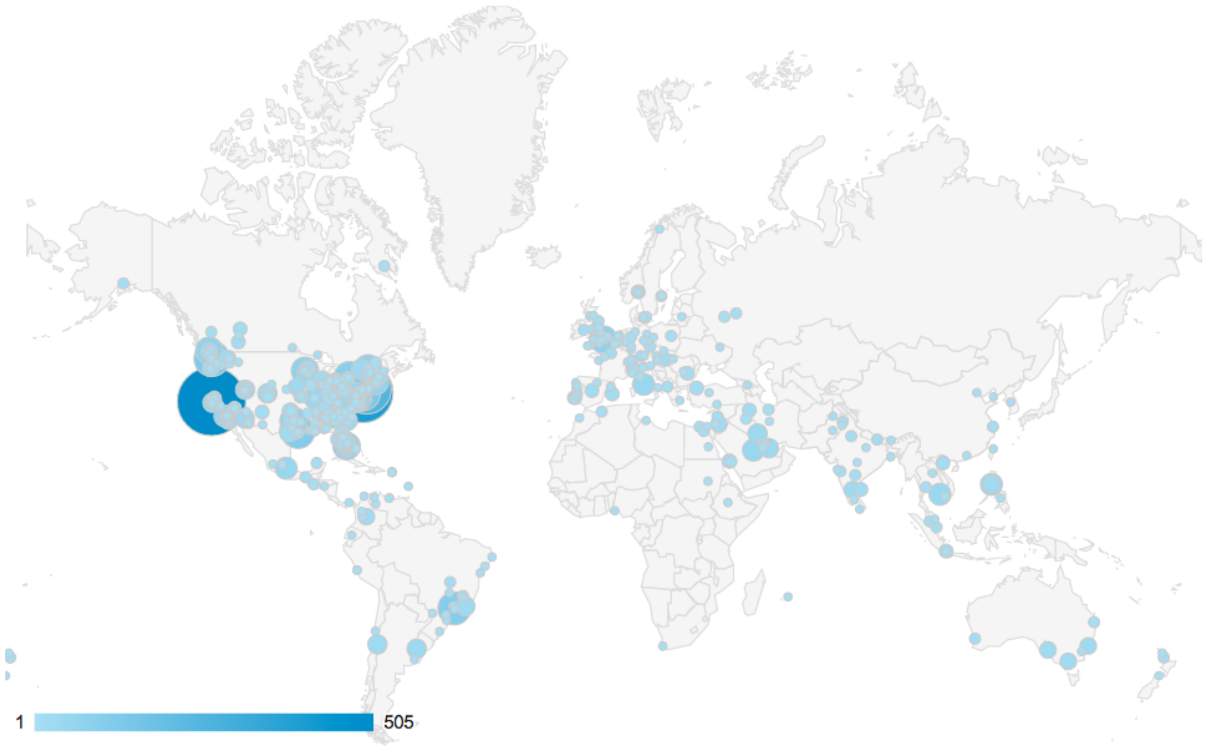


Figure 1.1

Figure 1.2

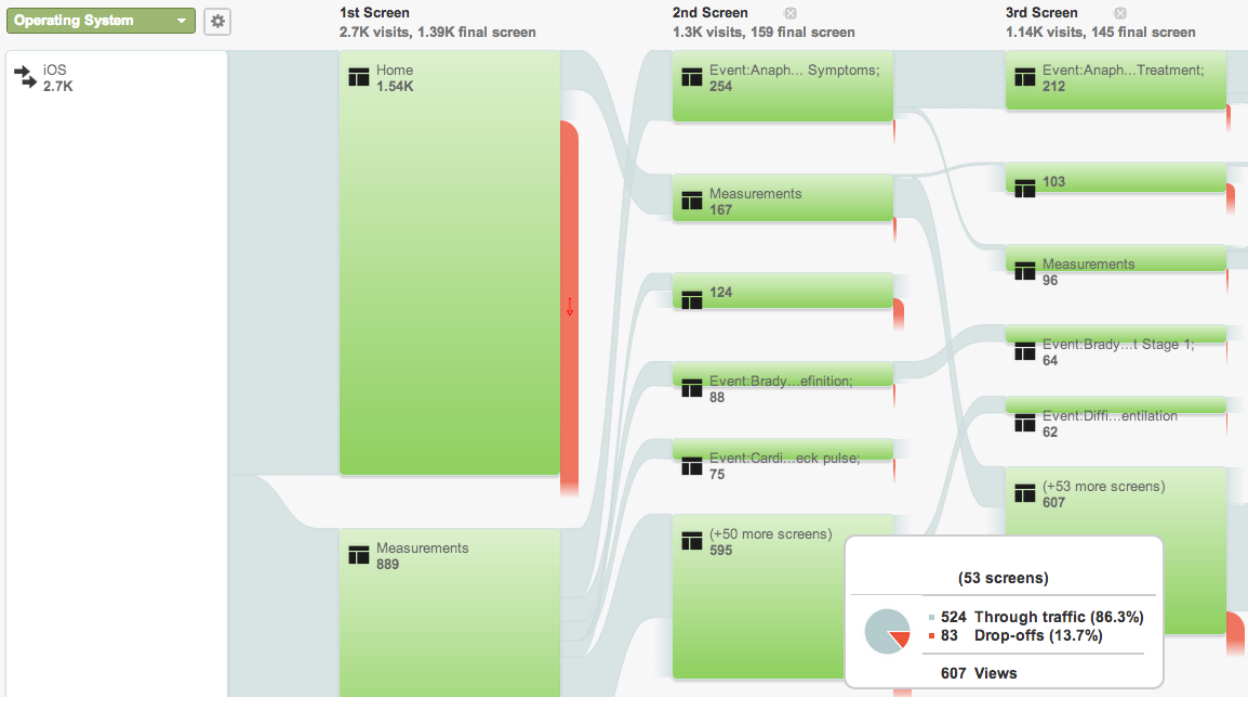


Figure 1.3

(+53 more screens) ×

607 Views 00:00:06 Avg. Time on group **83 Drop-offs**

Top screens

Screen	Views	% of traffic	Drop-off rate
Log	49	8.07%	10.2%
Event:Anaphylaxis;Step:Signs and Symptoms;	39	6.43%	12.8%
Event:Tachycardia;Step:;	36	5.93%	11.1%
Event:Cardiac Arrest;Step:Pulse present;	32	5.27%	3.13%
Event:Hypotension;Step:Systolic Blood Pressure 5% percentile;	31	5.11%	9.68%
Event:Cardiac Arrest;Step:Shockable or Non-Shockable rhythm?;	30	4.94%	10.0%
Event:Fire;Step:Fire Landing screen;	27	4.45%	22.2%
Event:Head Trauma;Step:Initial Management of Head Trauma;	27	4.45%	0.00%
Event:Hyperkalemia;Step:Emergency Treatment, Stage 1;	26	4.28%	11.5%
Event:Hyperkalemia;Step:;	22	3.62%	0.00%
Event:Venous Air Embolism;Step:Venous Air Embolism Treatment;	21	3.46%	0.00%

Figure 1.4

References:

1. Chu LF, Erlendson MJ, Sun JS, Alva HL, Clemenson AM. Mobile computing in medical education. Current Opinion in Anaesthesiology. 2012:25 (6) :699-718

2. Stone D, Jarrett C, Woodroffe M, Minocha S. User Interface Design and Evaluation. Morgan Kaufmann; Amsterdam, 2005.

Optimizing Measurement of the AC Component (Height) of the Photoplethymorgraphic (PPG) Signal

Presenting Author: Siqin Nie MD[1], Department of Anesthesiology[1], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC

Co-Authors*:* I-Hsun Liang, MD[2], Feng Dai, Ph.D[2], Nick Florio, BS[3], Vicki Bing, BS[2], Kirk H. Shelley, MD/Ph.D[2], Aymen Alian, MD[2], David G. Silverman, MD[2]
Department of Anesthesiology[1], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC; Department of Anesthesiology[2], Yale University School of Medicine, and Stony Brook University School of Medicine[3]

Introduction: The search for means to assess volume changes noninvasively has prompted renewed looks at the PPG as a monitor not only serving as the foundation for pulse oximetry but also for volume assessment. This primarily has taken the form of detailed waveform analysis, looking at oscillations in PPG waveform in association with respiration, a challenge which causes varying return of blood to the left ventricle. In addition the AC component of the PPG waveform of the forehead or ear decreases in close proportion to stroke volume (SV) as measured echocardiographically[1]. The present study was undertaken to: 1) determine the degree to which AC measurements may be altered by filtering so as to remove distortion caused by respiration and potential interference; and 2) determine whether consistency of AC measurements under baseline conditions is comparable to the consistency of echocardiographically measured SV under resting conditions.

Methods: All assessments utilized infrared reflectance PPG sensors interfaced via bridge amplifier to Power Lab data acquisition system (ADInstruments) applied to the forehead (because it is relatively immune to vasoconstrictive stimuli)[2] in six healthy volunteers with IRB approval. The mean (±SD) of AC height of 10 seconds of data was compared after five means of filtering to determine whether filtering significantly affected height determination. We then selected one of these methods for assessment of intersession consistency during total 48 sessions performed 3 to 72 hours apart in three volunteers and compared PPG intersession variability to that reported for SV variability.[3,4]

Results: Part 1: Omnibus test comparing all six groups (as well as just the five filtered groups) was significant ($p<0.0001$); $p<0.0001$ for each filtering method vs raw data except P=NS for data filtered to selectively suppress autonomic and respiratory impact (notch between 0.01 and 0.38 Hz). Among AC filtered signals, higher frequency ranges were associated with greater height determinations.

Variables	Adjusted mean (95% CI)	P-value[1]
AC height raw	0.01257 (0.007276 - 0.01786)	ref
AC height 0.5-5	0.009155 (0.003864 - 0.01445)	< 0.0001
AC height 0.5-10	0.009886 (0.004595 - 0.01518)	< 0.0001
AC height 0.5-50	0.01059 (0.005297 - 0.01588)	< 0.0001
AC height notch	0.01244 (0.007152 - 0.01773)	0.698
AC height notch<50Hz	0.01024 (0.004948 - 0.01553)	< 0.0001

Part 2: We elected 0.5 to 10 Hz filtering (so as to ensure capture of tachycardia, ectopy and/or potentially rapid microcirculatory control) while minimizing high frequency interference. Coefficient of variation (CofV) for intersession variability in our subjects was 17.3%; this was greater than the 9.2%

CofV for echocardiographic SV assessments on successive days.[3] Alternatively, 2x standard error (2xSE) in our subjects averaged 8% of mean vs. 11% in the literature.[4] Moreover, our intrasession 2xSE/Mean averaged only 3%.

Discussion: The consistency of AC height measurements of the PPG at the forehead is very encouraging. However, it is important to reach a consensus as to how to best isolate the AC signal. The choice of filtering will influence determination of AC height; while this will not affect AC consistency so long as the same filtering is used, it will affect the recommended application of AC height to calibrate the PPG signal and thus enable quantification of changes in DC as well as AC values.[5]

References:

1. Alian AA, et al. J Clin Monit Comput. 2011;25(6):377-385; **2**. Silverman DG, et al. Circulation 1994;90:23-6;
3. Hutchison SJ: Principles of Echocardiography and Intracardiac Echocardiography. Saunders 2012; **4**. Ihlen H, et al. Am J Cardiol. 1987 15;59(9):975-8; **5**. Liang I-H, ASA 2013; #A2214

Integrated Monitoring of Arterial and Venous Components of Plethysmographic Signals

Presenting Author: I-Hsun Liang, M.D. [1], Department of Anesthesiology, Yale University School of Medicine

Co-Authors: I-Hsun Liang, M.D.[1], Siqin Nie, M.D. [2], Samrawit Goshu, M.D. [1], Saeeda Qadri, M.D. [1], Nina Stachenfeld, Ph.D.[3], Aymen Alian, M.D.[1], Kirk Shelley, M.D., Ph.D.[1], David G. Silverman, M.D.[1], Department of Anesthesiology[1], Yale University School of Medicine; Department of Anesthesiology[2], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC; and The John B. Pierce Laboratory – Physiology[3], Yale University School of Medicine

Introduction: Members of our research team recently have focused on two extremes of cardiovascular monitoring, assessing the local impact of transdermal vasoactive agents [e.g. nitroglycerin (NTG) patch] and monitoring volume in the context of simulated loss with lower body negative pressure (LBNP). The extremes share a common problem – how to effectively monitor volume noninvasively. Moreover, they may share a common solution – a heretofore unreported use of the photoplethysmograph (PPG) to monitor (perhaps, even quantify) local as well systemic changes in blood volume. We previously have shown that PPG monitoring at a site relatively devoid of vasoconstrictive activity (e.g., forehead[1] and Ear[2] reveals relative degrees of pulsatile and nonpulsatile blood similar to the relationship between stroke volume (SV) and venous volume systemically and that voltage changes could be expressed as AC equivalents, i.e., in multiples of the change in voltage associated with the delivery of the SV to the given site under resting conditions.[3] We herein determine whether we can isolate changes in the AC and DC PPG components in response to the aforementioned challenges.

Methods: All studies were performed with IRB approval in healthy volunteers with surface infrared PPGs interfaced via bridge amplifier to a Power Lab data acquisition system (ADInstruments).

Part A (n=6). Two sites were studied. Site #1: Readings (10 sec) were obtained at the time of NTG application and at peak NTG effect at ~10min. ΔAC1 and ΔDC1 were determined. Site #2: On the contralateral FH, after baseline (base) readings, pressure was applied to PPG2 as per Figure 1 (so as not to disturb PPG1). The DC drop was attributable to the volume of displaced blood (DC_{blood}); as per above[3], the decline in voltage was expressed in AC equivalents. The relative changes in AC and DC were determined as ΔAC1/baseAC1 and ΔDC1/baseDC_{blood}2. Compliance was determined based upon established pressure measurements.[4,5] ΔAC1/baseAC1/65mmHg and ΔDC1/baseDC_{blood}2/17.5mmHg were compared to relative arterial and venous changes reported in response to intravascular NTG.[6,7]

Part B (n=12 in an LBNP chamber). We sought to determine if declines in AC and DC in response 75mmHg LBNP corresponded, respectively, to declines in SV and overall volume reported for comparable degrees of LBNP in the literature.[8]

Results. Part A. The NTG patch-induced ↑ in DC compliance was 2.04x > ↑in AC compliance. This did not differ significantly from the 1.8x ↑venous/↑arterial compliance ratio reported during intravascular NTG infusion (p=NS), in studies that led to the destination of NTG as primarily a venodilator.

Part B. Similar agreement with the literature was noted during LBNP: The 73.3 ± 12% ↓in AC was similar to the reported 65% ↓in SV. [8] The decline in DC of 5.4 ± 2.4 AC equivalents, corresponding to 675ml (5.4 x baseline SV of 125ml): This was within 500 to 1000ml decrease reported in the literature for comparable degrees of LBNP.

Discussion: The findings suggest a new application for PPG monitoring, wherein AC and DC measurements can be monitored and compared during myriad clinical and investigative settings. The relative individual changes and their relationships were consistent with changes in systemic arterial and venous volume reported in the literature.

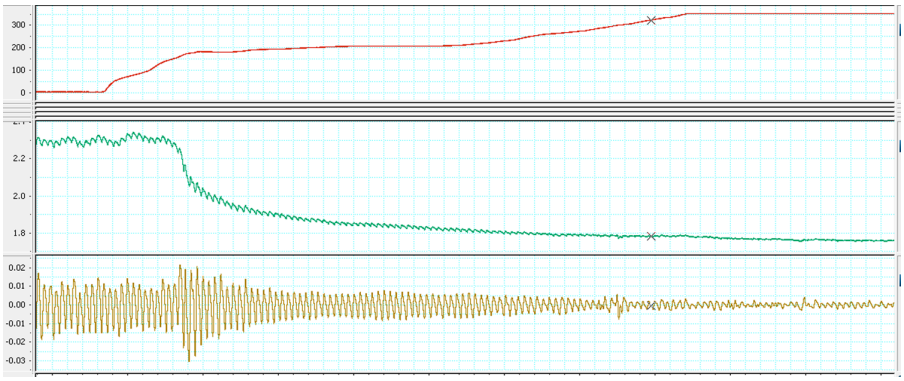


Figure 1. Application of Pressure to the PPG

Top channel: Applied pressure
Middle: Change in raw signal voltage
Bottom: Change in filtered AC component

1. Silverman DG, et al Circulation 1994;90:23-6; 2. Alian AA, et al. J Clin Monit Comput. 2011;25(6):377-385; .3. Liang I-H, ASA 2013; # A2214; 4. Best CH and Taylor: The Physiological Basis of Medicl Practice Williams & Wilkins, 1966; 5. Intaglietta el al. Microvascular Research 1970; 2:212-220; 6. Imhof PR, et al Eur. J. Clin. Pharmacol. 1980; 18:455-460; 7.Mackenzie JE, et al. Br. J. Pharmac. 1977; 60:155-160; 8. Convertino VA, et al. Autonomic Neuroscience: Basic and Clinical 2004; 111:127-134

Autocentering the PPG Waveform: Is it Worth the Price?

Presenting Author: I-Hsun Liang, M.D.[1], Department of Anesthesiology, Yale University School of Medicine

Co-Authors: Siqin Nie, M.D.[2], Nina Stachenfeld, Ph.D.[3], Aymen Alian, M.D.[1], Kirk Shelley, M.D., Ph.D.[1], , David G. Silverman, M.D.[1], Department of Anesthesiology[1], Yale University School of Medicine; Department of Anesthesiology[2], First Affiliated Hospital of Guangzhou University of Chinese Medicine, Guangzhou, PRC; and The John B. Pierce Laboratory – Physiology[3], Yale University School of Medicine

Introduction: When the photoplethysmograph (PPG) is used for measurement of oxygen saturation and/or heart rate, clinicians commonly prefer that the pulsatile waveform be displayed. This typically is achieved with the inclusion of an auto-centering algorithm to "correct for" variations in the strength of the PPG signal as may be caused by attenuation as well as altered blood volume. Recently, there has been renewed interest in applying the PPG for volume assessment; in this setting, auto-centering could be harmful, since it would distort the raw signal.

Materials: PPG's: We compared two different PPGs on the ear: 1) Uncentered PPG (PPG1): Infrared surface reflectance sensor interfaced via bridge amplifier to PowerLab of ADInstruments (Boulder, CO). 2) Autocentered PPG (PPG2): PPG sensor of Oxypleth (Soma Technology, CT). With the appreciation of potential differences among proprietary algorithms, the Oxypleth was selected because it provided an output that could be interfaced to our data acquisition system, with the assumption that it would demonstrate values comparable to that of other auto-centered commercial devices (which remains to be confirmed).

Methods: With IRB approval, 12 healthy volunteers monitored with PPG1 and PPG2 on different ears. The subjects then underwent lower body negative pressure (LBNP) until the simulated hypovolemia attributable to venous pooling in lower extremities resulted in lightheadedness or comparable symptomatology. The DC and AC reading of PPG1 and PPG2 were compared at baseline (Pre) and at the LBNP level just prior to symptoms, which would correspond to simulated blood loss of 500 to 1000ml.[1]

Results: The AC height of PPG1 declined by 73.3 ± 12%, while PPG2 AC height declined by 53.3 ± 28%; in one subject AC of PPG2 actually increased. The inter-device difference was most dramatic with respect to DC. For PPG1 0.23V ± 0.16V ($P<0.01$) whereas for PPG2 virtually did not change 0.006V ± 0.02V ($P<0.17$).

	DC Pre of Uncentered PPG	DC LBNP of Uncentered PPG		DC Pre of Autocentered PPG	DC LBNP of Autocentered PPG		AC Pre of Uncentered PPG	AC LBNP of Uncentered PPG		AC Pre of Autocentered PPG	AC LBNP of Autocentered PPG
1	-1.2274	-1.3528		0.2529	0.2405		0.0338	0.0077		0.3968	0.1938
2	-0.5778	-0.7848		0.2535	0.2462		0.0407	0.0117		0.2969	0.1094
3	0.2541	0.1840		0.2510	0.2610		0.0231	0.0082		0.2230	0.0212
4	-0.0458	-0.6049		0.2536	0.1970		0.0630	0.0136		0.3116	0.1017
5	0.0832	-0.3057		0.2507	0.2601		0.0554	0.0065		0.1396	0.1176
6	-0.0913	-0.3108		0.2491	0.2681		0.0746	0.0181		0.3318	0.1369
7	1.0392	0.9781		0.2501	0.2099		0.0130	0.0045		0.3392	0.3685
8	0.0458	-0.2585		0.2503	0.2403		0.0917	0.0063		0.4251	0.0731
9	0.2956	0.0814		0.2466	0.2536		0.0542	0.0249		0.4939	0.1151
10	-0.7448	-1.1736		0.2491	0.2460		0.0401	0.0067		0.3648	0.0696
11	-0.1722	-0.3465		0.2513	0.2473		0.0427	0.0198		0.2093	0.1026
12	-0.4107	-0.4508		0.2596	0.2716		0.0069	0.0018		0.8102	0.4016

Discussion: Auto-centering effect of the PPG masked changes associated with blood loss. This is most dramatic for DC, but also impacted AC. Hence, clinicians and investigators must be aware the price they are paying for autocentered PPG waveforms. At the minimum an option should be available to track voltage changed in uncentered signal.

Reference:

1. Wolthuis RA et al, Avit pac Environ Med 1975; 46: 697-702

Development of a Disposable Wireless Sensor for Monitoring Patient Movement and Activity

Presenting Author: Barrett Larson, MD, Department of Anesthesiology, Stanford University School of Medicine / Leaf Healthcare

Co-Author: Daniel Shen, MS, Stanford University School of Medicine / Leaf Healthcare

Introduction: Pressure ulcers place a significant financial burden on the healthcare industry. Each year approximately 2.5 million Americans suffer from pressure ulcers and the annual cost of treating these ulcers is estimated to be as high as $11 billion. It is well established that frequent and regular patient turning is a key element to pressure ulcer prevention. The currently accepted standard of care is to turn high-risk patients at least every 2 hours, day and night. In many healthcare facilities, such a turning protocol is difficult to maintain. To address the need for improved pressure ulcer prevention methods, we developed a wireless patient monitoring system to improve both system efficiency and patient care by monitoring and coordinating patient turning. The system provides caregivers with information regarding a patient's position over time, thus enabling them to easily identify which patients are turning adequately on their own and which patients are in need of a caregiver-assisted turn.

Methods: A disposable, wireless sensor is affixed adhesively to the patient's upper torso. The sensor takes measurements of the patient's orientation and communicates this data wirelessly to a mesh network of relay antennas. The mesh network communicates data from the sensors to a server computer having an RF to USB transceiver. The network server software collects patient data from the transceiver and stores the data into an SQL database for subsequent analysis. A user-interface displays each patient's turn history and current status and also alerts staff if any patient requires a caregiver assisted turn.

Results: The monitoring system was successfully tested in a clinical environment. The sensor was used to continuously monitor and record the position/activity of over 100 patients. The user-interface was used to successfully coordinate patient turning efforts and ensure compliance with such efforts.

Conclusion: Factors that impair compliance with turning protocols include difficulty monitoring patient position, ineffective turn reminders/alerts, and sub-optimal caregiver staffing ratios. In this study, we developed a system to monitor patient turning patterns and to explore the possibility of improving turning protocols through the implementation of novel IT policies/procedures.

A Pilot Study to Measure the Impact of Blended Learning on Intern Wellness and Burnout

Presenting Author: Louise Wen, MD, Stanford University Department of Anesthesiology

Co-Authors: Emily Ratner, MD; T. Kyle Harrison, MD; Larry Chu, MD; Edward Mariano, MD; Sanford Roberts, BA; Tammy Wang, MD; Ankeet Udani, MD

Introduction: The incidence of intern burnout approaches 75% [1]. Recognition of the serious issue of intern burnout has catalyzed the development of wellness programs that have shown increases in self-reported well-being [2].

ImPRINT, a yearlong blended curriculum for interns matriculating into anesthesiology residency includes monthly courses based on the "flipped classroom." Assigned didactics are viewed from home, and classroom time is reserved for interactive discussions, part task training, and high-fidelity case simulations. We hypothesized that such a course would promote intern wellness.

Methods: After IRB approval, all anesthesiology interns were invited to participate. A learning management system (Moodle, Perth, Australia) organized the online curriculum. All interns completed a modified MBI in their first and last months of internship. Additionally, for each module, responses to the following statement were recorded: "We define wellbeing as a sense of wholeness and balance (of mind, body, and spirit) that creates an inner resilience to meet the challenges of living without being overwhelmed. On a scale of 1 to 100, please score your wellbeing at this particular moment: 100 being the most and 1 being the least."

Our primary outcome and hypothesis is that higher rates of burnout would be present at the end of intern year and that participation in ImPRINT would be a protective factor. For the primary outcome, we case matched students by gender and age. Our secondary outcome and hypothesis is that participation in the monthly modules would promote an improvement in reported well-being through facilitating a sense of community.

Normality of distribution was determined using the Kolmogorov-Smirnov test. Primary outcome data were normally distributed and were compared using Student's t test. Secondary outcome data, pre- and post- scores for each module, were compared using repeated measures ANOVA with post-hoc Tukey-Kramer multiple comparisons testing. A two-side $p<0.05$ was considered statistically- significant for all analyses.

Results: All 22 anesthesia interns consented and were enrolled in our study. For the primary outcome, a control group of 5 interns did not participate in ImPRINT (group 1) and were case-matched to the interns that did participate in ImPRINT (group 2).

Primary outcome: Mean[SD] score on modified MBI of 2.2[2.9] vs. 2.8[2.8] for groups 1 and 2, respectively (p=0.749).

Secondary outcome: Within module pre- vs. post- scores were not statistically-significant.

Post-hoc power calculation revealed that the sample size of 5 subjects per group had 6% power to detect the 0.6 difference between means at a 0.05 significance level, and a sample size of 34 per group would have been required to achieve 80% power.

Conclusion: Based on this pilot study, a blended learning curriculum did not show a significant impact on intern wellness or burnout. Scores greater than 4 on the MBI suggest a high risk of burnout and the rationale for our post-hoc power calculation. In theory, utilizing classroom time for interactive learning activities promotes socializing and peer-to-peer support. Future research should focus on disseminating a similar curriculum to other institutions and promote multi-center prospective study to further elucidate of the impact of blended learning on physician wellness.

References:

1. Ripp. Acad Med, 2011.
2. Shapiro. Acad Med, 2000.

Google Glass in the OR: Rapid Montioring of Surgical Blood Loss

Authors: Siddarth Satish, MS,[1] Chris Madison, [1] Kevin Miller, MS, [1] Yossi Weinberg,[1] Maxime Cannesson, MD, PhD [2] *

[1] Gauss Surgical, Inc.
[2] Department of Anesthesiology and Perioperative Care, UC Irvine.

Introduction: Rapid assessment of blood loss is vital in guiding intraoperative fluid management, but visual estimates by providers are demonstrably inaccurate. Recently, a mobile vision platform has been developed for photometric assessment of blood loss on sponges via an iPad interface [1]. Because the algorithmic analysis is performed on a remote server, the potential to use virtually *any* front-end device for imaging and display exists. One such device is Google Glass. As a wearable computing platform, Glass enables previously inaccessible levels of mobility and intuitive control through the use of its integrated display, camera, and speech recognition capabilities. As an egocentric vision system[2], Glass also presents interesting considerations for diagnostic image analysis (e.g., repeatibility, completeness, background variability). In this pilot study, we assessed the stability of photometric blood loss measurement from images of lap sponges captured by the Glass platform.

Methods: Synthetic whole blood (Laerdal, Inc. Stavanger, NO) was poured and dispersed onto an 18x18 surgical laparotomy sponge in a simulated operating rom environment. The user issued a vocal command to a Glass device, which initiated a 10s video recording of the sponge as it was held up by the user in an egocentric fashion. To vary background conditions, this procedure was repeated while facing a different direction. The captured videos were transmitted to a proprietary server where all 298 frames of each video were individually extracted, downsampled, and filtered to remove frames in which the sponge had not been fully raised into view. The two framesets were batch-processed using Feature Extraction Technology (FET, Gauss Surgical, Inc., Los Altos, USA), a novel image analysis platform, to measure Hb content from the image. The resulting prediction of sponge Hb mass (g) per frame was stored for analysis. Repeatability and stability of the measure was assessed across all image processing outputs from both framesets.

Results: The mean +/- SD of Hb mass on the sponge was 1.3 +/- 0.1g in the first frameset (n = 204 extracted images) and 1.4 g +/- 0.2 g in the second frameset (253 images), sampled over two different backgrounds. Across both framesets, the mean +/- SD of Hb mass was 1.3 g +/- 0.1g. The corresponding CV ratios were 4.5% (frameset 1), 11.7% (frameset 2), and 10.3% (combined), indicating low variability in the algorithm's measurement of Hb mass across variable background conditions and repeated measures.

Conclusion: Wearable computing platforms have the potential to capture valuable intraoperative image data and augment user experience. The Glass platform demonstrated

viability in imaging sponges for blood loss assessment with significant repeatibility and background invariance. Using Glass with Feature Extraction Technology may aid the user (e.g., circulating nurse) in their ability to rapidly count sponges and simultaneously assess surgical blood loss.

***** Dr. Cannesson is a scientific advisor to Gauss Surgical, Inc.

REFERENCES

[1] Holmes AA, et. al., Clinical Evaluation of a Novel System for Monitoring Surgical Hemoglobin Loss. Anesthesia & Analgesia. In Press. (2013)

[2] Fathi A, et. al., Learning to Recognize Objects in Egocentric Activities. CVPR (2011)

FIGURE 1. Image processing and FET output from frameset 1 (frame 180) of bloodied sponge images captured using Glass.

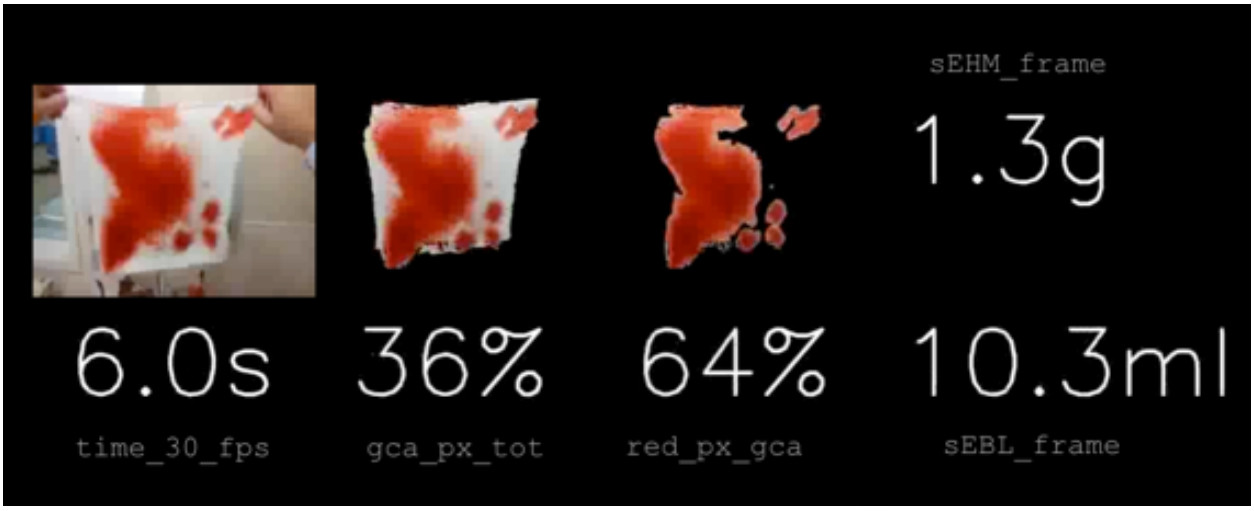
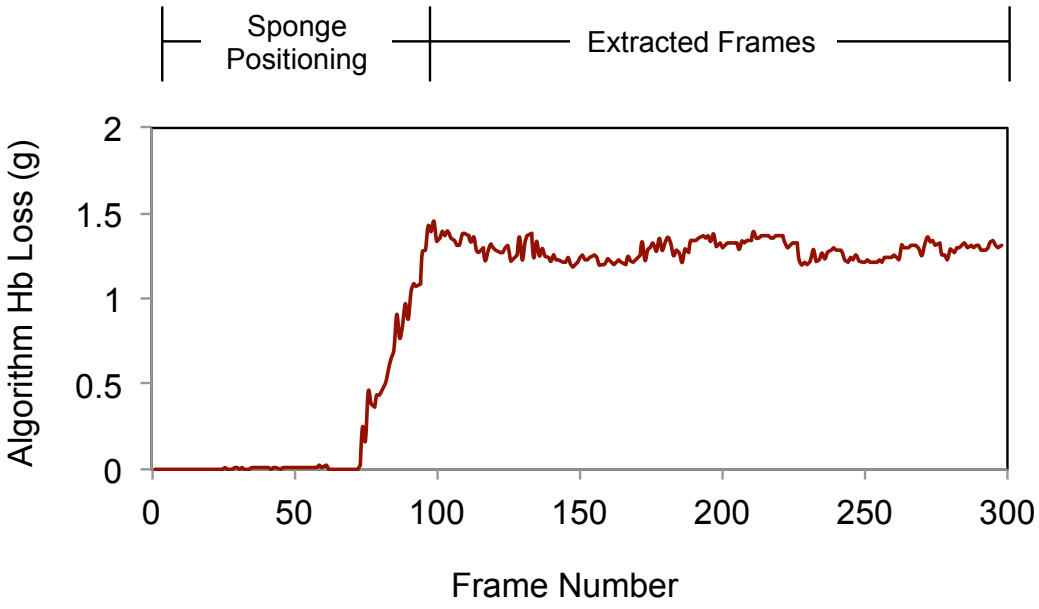


FIGURE 2. Algorithm prediction of Hb loss (g) across first frameset of images from Google Glass.


Sponge Positioning
Extracted Frames
Algorithm Hb Loss (g)
2
1.5
1
0.5
0
0
50
100
150
200
250
300
Frame Number

Closed-Loop Fluid Management in Hepatobiliary Surgical Patients

Presenting Author: Joseph Rinehart, MD, Department of Anesthesiology & Perioperative Care, UCI Medical Center, Orange, CA

Co-Authors: Trish Huynh BS, Christine Lee BS, Marc Lilot MD, Cecilia Canales MPH, and Maxime Cannesson MD, PhD
Department of Anesthesiology & Perioperative Care, UCI Medical Center, Orange, CA

Background: Dynamic parameters like stroke volume variation (SVV) have been shown to be accurate predictors of fluid responsiveness[1]. Perioperative hemodynamic optimization based on fluid management and stroke volume (SV) optimization (PGDT) has been shown to improve patient outcomes, especially for subjects undergoing moderate and high risk abdominal surgery[2]. After conducting simulation, engineering, and animal studies, we report preliminary results of a prospective, propensity-score matched clinical study between closed-loop and manually delivered PGDT.

Methods: Subjects undergoing elective open pancreatic, hepatic, or splenic procedures between January and December 2013 were recruited for this study. Inclusion criteria were Body Mass Index < 40 and cardiac output monitoring (Vigileo EV1000, Edwards Lifesciences®, Irvine CA) planned for general anesthesia with TV≥7mL/kg. Exclusion criteria were arrhythmia, valvular problems, right heart dysfunction, pulmonary hypertension, or emergency surgery. Subjects in the control group received the departmental standard PGDT protocol (crystalloid 3 ml/kg/h and additional boluses of colloids based on SVV and SV). In the closed-loop group, the closed-loop system applied the same PGDT protocol automatically under the anesthesiologist's supervision. Closed-loop patients were recruited sequentially based on availability of the study team. Hemodynamic variables analyzed were stroke volume index (SVI), cardiac index (CI), heart rate (HR), stroke volume variation (SVV), and mean arterial pressure (MAP). Outcome measures included hospital and ICU length of stay (LOS). Following recruitment, the study patients were matched to non-closed loop cases over the same time period using a propensity match that included baseline hemodynamics (listed above), surgeon, planned procedure, age, and body weight.

Results: Propensity score matching resulted in 22 study-control matched pairs. Analysis of the groups showed there were no significant differences between group baseline ages, weights, procedures, or hemodynamic values. The closed-loop group had a significantly lower end-of-case SVV (6.6 vs 11.6, CI=-6.9 to -3.1, $p<0.001$) and a significantly shorter length of ICU stay (1.27 vs. 4.52 days, CI=-4.86 to -1.62, $p<0.001$). There was no significant difference in case duration, crystalloid or colloid administration volumes, blood loss, urine output, or phenylephrine/ephedrine administration.

Conclusion: The results of this clinical use of an automated fluid management system in subjects undergoing high risk abdominal surgery shows that it can be effective in predicting fluid responsiveness. The current study shows that the application of an automated fluid management system resulted in a significant difference in outcomes in comparison to goal-directed fluid therapy alone. This further shows that the dynamic predictors involved in fluid responsiveness along with the closed-loop fluid management system can be practical in the healthcare setting.

Reproducible Research Using Software Development Methodology

Author: Patrick J. McCormick, MD, Icahn School of Medicine at Mount Sinai, New York NY

Co-Author: Matthew A. Levin, MD, Icahn School of Medicine at Mount Sinai, New York NY

Introduction: There has been a significant increase in unintentionally erroneous research results that were peer-reviewed and published. Many of these errors arose during the data analysis phase, often when researchers made mistakes with statistical analysis software.

For example, in 2011 a major paper in the journal *Hypertension* overestimated US hypertension incidence by 26 million people because of a merge error. If the authors had not reported the mistake themselves, it is unlikely that others would have discovered it.

Our hypothesis is that the application of software development techniques to large dataset research will reduce the risk of error and improve reproducibility.

Methods: For our database research projects, we instituted a set of strict controls on data, software, and manuscript generation. All specifications and software were maintained within a source control system (Subversion). The source control tree was marked with a "tag" when a manuscript revision was released. Software and specification changes were automatically circulated to our entire group for review. Large datasets were exported to a universal text format, marked with a date, and stored within our shared data repository. Each project maintained a "reproducibility" spreadsheet tracking major changes and milestones. All software used to maintain reproducibility is free, open source, and multiplatform.

Manuscript generation was performed using the R Project for Statistical Computing and the associated "knitr" package. Using "literate programming" techniques, figures and tables were generated directly from datasets.

Results: We applied our methodology to three research projects. There were two contributors for each project. The total number of source control revisions specific to each project was 71, 127, and 187 respectively. The average number of revisions per 90 days for each project was 2.91, 2.85, and 7.02. Since inception, the source control tree has had 2,672 revisions. This includes our data warehouse implementation and tools used to extract research data from anesthesia records. On some occasions, periodic code reviews revealed questions about study methodology which were resolved with improved documentation and clearer analysis scripts. These same reviews found that researchers were able to replicate each other's results despite using different computers and operating systems.

Conclusion: It is possible to institute strict controls on analytic research using careful planning, open source software, and periodic code reviews. However, taking advantage of reproducibility techniques requires a cultural shift toward the defect-reduction mindset of software engineering. The resulting research can be published with high confidence that any errors more likely due to research design and not analysis implementation.

References:

1. Shafer SL, Dexter F: Publication bias, retrospective bias, and reproducibility of significant results in observational studies. Anesth. Analg. 2012; 114:931–2

2. Sandve GK, Nekrutenko A, Taylor J, Hovig E: Ten simple rules for reproducible computational research. PLoS Comput. Biol. 2013; 9:e1003285
3. Peng RD: Reproducible research in computational science. Science 2011; 334:1226–7

Feasibility and Comparison of Variation in EKG Lead II R wave Amplitude and R:T Amplitude Ratio to Stroke Volume Variation as Dynamic Predictors of Fluid Responsiveness

Presenting Author: Christine K. Lee, BS, Department of Anesthesiology and Perioperative Care, UC Irvine

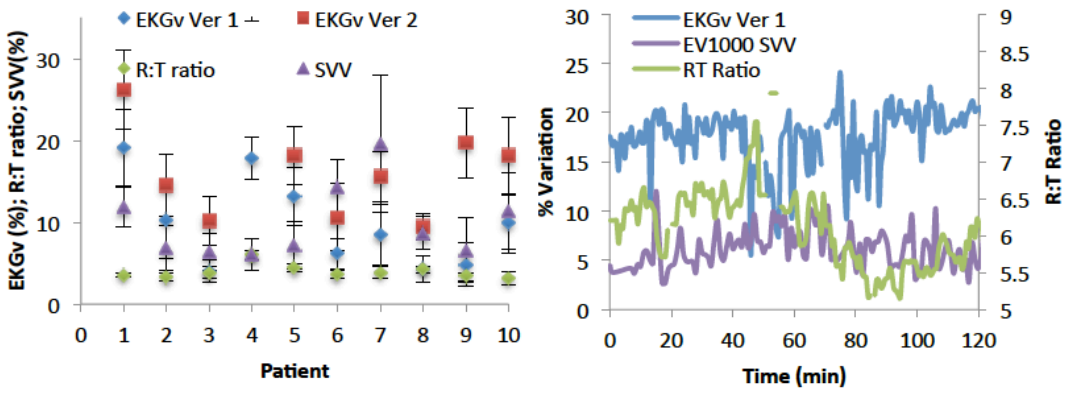
Co-Authors: Joseph Rinehart, MD and Maxime Cannesson, MD, PhD, Department of Anesthesiology and Perioperative Care, UC Irvine

Background: Studies have shown that respiratory variation in the EKG lead II R-wave amplitude (EKGv) correlates with dynamic predictors such as pulse pressure variation (PPV) and stroke volume variation (SVV) in mechanically ventilated patients under general anesthesia1 and to predict volume status2 . In addition, changes in R-to-T wave amplitude ratios (R:T) of EKG lead II have been shown to correlate with changes in cardiac output and left ventricular stroke volume during inferior vena caval occlusion during cardiac bypass surgery (PINSKY PAPER). However, to date, all calculations of lead II R and T wave amplitude variations have been done by hand. A previous study by our group has shown that there is a significant relationship between manually determined EKGv and EKGv automatically calculated by an algorithm we developed ($R2 = 0.98$, $p < 0.001$; Bias 0.17 ± 1.77%). The goal of this study was to compare EKGv calculated by this first feasibility version of our algorithm (EKGv1), and EKGv and R:T calculated by a subsequent version of the algorithm (EKGv2 and R:T) to stroke volume variation (SVV).

Methods: EKG waveforms were collected for 10 patients more than 18 years of age, with BMI < 35, undergoing mechanical ventilation and elective open abdominal surgery. Digitalized EKG waveforms were collected from the Solar 8000i anesthesia workstation (GE Healthcare, USA) at a sample rate of 240 Hz for 2 hours per patient. Stroke volume variation from the EV1000 (Edwards, USA) was collected retrospectively from the clinical database. EKG lead 2 waveforms were then analyzed offline for EKGv by Versions 1 and 2 of our algorithm (EKGv Ver 1 and EKGv Ver 2), as well as for R:T amplitude ratio (R:T). Both versions of our algorithm utilized relative slope information to identify wave peaks and baselines, defining baseline as the preceding isoelectric plateau of an R peak. EKGv Ver 2, however, identified baseline as between an R peak and a preceding T peak, where EKGv Ver 1, identified baseline by tracing backwards from an R peak. EKGv Ver 2 also filtered out "incorrect" R and T peaks and baseline as it proceeded, and thus did not filter out any EKGv's before reporting the final reported mean EKGv of a data sample (42 seconds). EKGv Ver 1, on the other hand, filtered out "incorrect" R peaks and baselines based on amplitudes calculated as well as EKGv's.

Results: Mean case EKGv Ver 1 for each patient was overall closer to mean case SVV than mean case EKGv Ver 2 (Figure 1). Patient 4's EKGv Ver 2 was > 50%, and thus not shown. In addition, it was observed during this study that qualitatively a relationship

can be seen between R:T ratio and SVV , as shown in a representative patient's continuous data (Figure 2).



Conclusion: Initial analysis indicates a better agreement between the EKGv Ver 1 and SVV than EKGv Ver 2 and SVV. However, work on analyzing the ability of EKGv to trend correctly with SVV may be more informative and will need to be done to better determine correlation. In addition, the observation of R:T ratio trending with SVV indicates that further work needs to be done to analyze this relationship.

References:

1. Cannesson et al. JCMC 2010; 24:203-207.
2. Giraud et al. JCMC 2013; 27(2): 107-11.
3. Pinsky et al. AMJC 1995; 76: 667-674.

The Case for Paramagnetic Oxygen Sensing in Anesthesia and Respiratory Therapy - A New Miniature Sensor

Presenting Author: James Hobby, Chief Technical Officer, Servomex Group

Co-Authors: Dominic Corsale and Scott Gordon, Hummingbird Sensing Technologies

Introduction: The importance of accurate measurement of oxygen in anesthesia and ventilation has been established over many years since its introduction in the late 1970's[1]. The technology that permitted its widespread adoption was based on the electrochemical oxygen sensor originally developed by Leland C. Clark[2]. Recent advances in paramagnetic technology have overcome the advantages (e.g. power and size) that electrochemical sensors once enjoyed. With the existing limitations of electrochemical sensors eliminated, paramagnetic sensors can allow for increased confidence in and less care of the oxygen sensor providing advantages to both the clinician and hospital management. Characteristics of each sensor technology affecting clinical use including predictable performance, lifetime and concerns relating to the use of hazardous substances, are addressed.

Electrochemical Oxygen Cells: Electrochemical oxygen cells operate through a process similar to that found in batteries where the oxidation of the anode by the oxygen leads to the liberation of electrons. The simplicity of this method leads to its main weaknesses that once all the active surface of the anode has oxidised, the sensor will stop working. Unfortunately the exact point at which this occurs cannot be predicted with certainty. This leads to the potential for a loss of oxygen measurement during an operation with potential risk to patient outcome. To ameliorate this situation, Respiratory Technicians increase the amount of pre-operative equipment validation needed, and the frequency with which cells are changed to greater than the manufacturer's recommendation. For example, although many manufacturers will state a two year lifetime[3], producers of anaesthesia ventilators will recommend changing the sensor more often - at annual or less periods[4]. The need for frequent sensor changes is exasperated by electrochemical sensors having a limited recommend shelf life, in some cases as short as six months[5]. Furthermore, the materials that are used in the construction of electrochemical sensors are not benign and typically contain both caustic liquids and heavy metals including Lead[6]. This leads to used electrochemical sensors being treated as hazardous waste with the end user often paying a fee for sensor disposal. Concerns about the toxicity of Lead have already led a number of jurisdictions to start prohibiting its use (e.g. Restriction of Hazardous Substances (RoHS) regulations). Although an exemption for electrochemical cells, granted within the European Union, is subject to periodic review and with the availability of RoHS compliant sensors, is not likely to persist indefinitely[7]

Paramagnetic Oxygen Sensors: An alternate technology for oxygen measurement is based on the innate and strong paramagnetism of oxygen, the property of a material which is

attracted towards a magnetic field. Various techniques are used to exploit this property of oxygen but the most common is the torsion dumbbell system. In this system the positioning of the dumbbell in a strong magnetic field gradient produces a force that varies proportionally with the oxygen concentration present. With this approach, no consumption occurs and the device will have an indefinite lifetime. While paramagnetic based sensors has been used for patient monitoring since the 1970's, their use for delivered oxygen measurement (FiO_2) has until recently, been limited by a combination of size, power consumption, interface compatibility and cost. Improvement in electronics and sensor technology over the last decade have allowed these sensors to be reduced dramatically in size, cost and power consumption, thus permitting wider use with the associated opportunities for improvements in FiO_2 monitoring and therapy.

Conclusion: With the arrival of miniature paramagnetic sensors (e.g. Paracube Micro[8]), the traditional limitations of paramagnetic oxygen sensors are no longer relevant as they provide a device of equivalent size and compatible interface as the traditional electrochemical sensor.

References

1. US Patent 4,127,121 for 'Oxygen and Anesthesia delivery and monitoring device' by Westenskow et al.
2. Some Milestones in the 50-year History of electrochemical Oxygen Sensor Development by Lembit Nei. ECS Trans. 2007 Volume 2, issue 25, 33-38
3. Maxtec (http://www.maxtec.com/resources/warrantyStatement.php)
4. GE Aespire 7900 reference manual (doc # 1009-0633-000)
5. O2 Sensor Data Sheets (http://www.alphasense.com/)
6. Material Safety Data Sheet (http://www.teledyne-ai.com/pdf/msds_sensors.pdf)
7. Directive 2011/65/EU (http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:174:0088:0110:EN:PDF)
8. Hummingbird Sensing Technology (www.hummingbirdsensing.com)

Attitudes To Alarm Fatigue and Alarm Management Tools Hospitals Want: Hospital Responses to Survey on Opioid Management

Authors: Michael Wong, JD , Physician-Patient Alliance for Health & Safety; Anuj Mabuyi, PhD, Northeastern Illinois University; Beverly Gonzalez, ScM, Johns Hopkins Bloomberg School of Public Health

Introduction: The Joint Commission 2014 national patient safety goal is being implemented and reinforces the defined problem called alarm management that is caused from clinicians experiencing alarm fatigue.

Methods: During March and April 2013, almost 200 hospitals in 40 states were surveyed about their attitudes to alarm fatigue and alarm management tools and training they would like to have.

Results: Alarm fatigue is an issue that about 90% of hospitals are concerned about. The survey results show that alarm fatigue is impacting work flow and patient safety. Although hospitals that continuously electronically monitor their patients reported experiencing a reduction in adverse events, costs, and expenditures, hospitals said that they would use more monitoring technology if alarm fatigue was not an issue. Moreover, when asked what tools that would like to have to help manage alarms better, hospitals said that would like better tools and training to tackle this issue - about 70% would like a single indicator that incorporates multiple physiological parameters (like respiratory rate, oxygenation, and end tidal C02) and approximately half would like recommendations to more easily assess patients.

An Infusion Rate Monitor for Use in Intravenous Therapy

Authors : Richard Merchant, Cody Robson, Joel Wiedman, Ryan Yee

Institutions (ALL): Royal Columbian Hospital, Faculty of Medicine, and Engineering Physics, University of British Columbia, Vancouver, BC, Canada.

Introduction: Management of intravenous fluid administration is a core anesthesia task and new parameters are constantly appearing. Liberal, restricted, and now goal-directed fluid therapy are management paradigms. Conventional fluid monitor/controller pumps are widespread but expensive, prone to alarming and failure, often difficult to program, and frequently not available. As a consequence they are little-used in routine OR management save for the control of vasoactive medications. The infusion rate monitor is device to assist clinicians in simple and routine fluid management tasks. The primary focus of this project was to design a user interface (UI) and make improvements with the acquisition of user feedback. The results observed thus far will give the direction and narrow the scope for future design changes.

Methods: The infusion monitor attaches to an unmodified drip chamber and measures the rate of infusion through an optical sensor. Once the device is calibrated in the settings menu, the device then displays in real-time the necessary IV therapy parameters. The prototype was fabricated and tested in a laboratory environment to analyze the functionality of the drip detector and UI. The device then received feedback from medical personnel and fellow engineers through a revision process. Participants were given a brief introduction, but relevant operational instructions were undisclosed, allowing for an authentic test of usability. Participants were tasked to set the parameters of the device and then run the program. While on video, they voiced their thought process and immediate concerns about the device.

Results: Measurements show that optical drip detection is 100% accurate before factoring in a UI. Due to the choice of microcontroller for this research, implementing a TFT display for a UI, decreases efficiency of drop detection to ~95%. The first revision of the device was evaluated by four different users: a university professor, and three university students. Users reported five key issues with the design: Intuitive menu navigation, menu and user-parameter selection, system responsiveness, and overall device bulkiness. The user based study for the first revision showed that 100% of users required assistance to operate the device. The second revision was then evaluated by four new users: an anesthesiologist, an industry engineer, and two university students. Users consistently reported that accuracy of the parameter selection was an issue, as was physical size of the device. Results showed that with the second revision, improvements to

software were implemented. This allowed users to successfully and independently interact with the device with no training.

Discussion: Overall, these results suggest that with further usability testing on clinicians in the field, the design features and UI can be further focused to adequately suit their needs.

The Integrated Clinical Environment (ICE) Data Logger-Opportunities and Advantages Relative to Individual Device Data Logging

Presenting Author: Michael Jaffe*, PhD; Co-Authors: David Arney*, BS, Sandy Weininger[+], PhD, Steven Dain[^], MD, Julian M. Goldman*+, MD

Massachusetts General Hospital*, Harvard Medical School[+], Boston, MA; [+]US FDA; [^]Schulich Medicine and Dentistry, Western University, London, Canada

Introduction: Medical devices have had some level of data logging capabilities for decades. The data logs are not standardized as to content or format and may include device performance metrics for technical troubleshooting and maintenance, and clinical data for patient care. These logs are downloaded as needed to perform an adverse event analysis, but even if one device log is fairly "complete", a log of the entire clinical picture including data from all devices in use at that time, is not available. For example, in typical complex clinical environments (e.g. OR, ICU, ED) the time-aligned integration of data streams from multiple devices – each with its own proprietary communication protocols and algorithms, time base, and physical interfaces – offers numerous challenges. An integrated data logging capability is needed for the entire clinical environment in which the patient is being monitored or is receiving therapy – to include logging of commands, device connection and disconnection, physiologic and technical alarms, patient physiologic data, and other device status information. [1]

The Problem: The data logging capabilities and characteristics of selected medical devices with varying capabilities – including ambulatory data loggers (e.g. digital Holter recorders), handheld monitors (e.g. combined SpO_2 and CO_2), laboratory data recorders (e.g. sleep diagnostics systems), multi-parameter respiratory monitors, multi-parameter physiologic monitoring systems, anesthesia workstations, and ventilators – vary significantly with respect to the capabilities, data formats, and bandwidth requirements. Given the wide range and differences in device output data streams and capabilities, it is daunting to try to combine measurements from devices from different manufacturers and sometimes even the same manufacturers. This is further complicated by the need for efficient mechanisms for data playback for adverse event/near-miss investigation and reporting. The ability to playback data sets does exist, but is limited in scope. For example, ambulatory ECG recording devices have developed a sophisticated suite of tools for the playback and analysis that data.

Proposed Solution: A data/patient-centric approach as defined in the ICE standard [2] will allow plug-and-play devices using data-centric protocols and an ICE data logger to work seamlessly, in an open, standardized, and time-synchronized manner, as compared to individual device-based approaches. The advantages include more efficient adverse event/near miss analysis, common terminology and time base, and improved security. Such an approach permits new opportunities for improved patient monitoring and safety. This is distinct from the capabilities of the EHR, which uses lower granularity data storage (e.g. one minute) and can fail to capture clinically significant outliers. [3]

With each device uniquely identified (e.g. FDA UDI) and data formatted in a standardized form, new opportunities for improvements in adverse event investigation will be enabled, similar to those enabled by the data recorders used in transportation and flight data recorders. Challenges with current approaches to adverse event analysis, including device location and sequestering, manual data entry, differences in clock timing, and problems with data extraction, are reduced. Debugging logs including network interactions can facilitate sophisticated debugging of device and operator interactions, which may assist with clinical event analysis. Significant work will be required to develop effective playback tools.

References:

1. Arney D, Weininger S, Whitehead SF, Goldman JM. Supporting Medical Device Adverse Event Analysis in an Interoperable Clinical Environment: Design of a Data Logging and Playback System. ICBO– Representing Adverse Events Workshop, July 26, 2011.
2. ASTM F2761-09(2013) Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model.
3. Spainhour S, Dombrowski K, Kolls B, Naglich M, Riemen K, and Olson D. Documented ICP values are not adequate for use in clinical research. ANIM Manneim (January 23-26, 2013).

OpenICE Prototype: A New, Open Interoperable Medical Device Clinical Research Platform

Presenting Author: Julian M. Goldman*^, MD

Co-Authors: David Arney*, BS; Jeffrey Plourde*, BS; *Massachusetts General Hospital, ^Harvard Medical School, Boston, MA

The MD PnP Program (http://mdpnp.org) has developed an open source implementation of the Integrated Clinical Environment (ICE) standard as described in ASTM 2761-09(2013) and made it freely available on SourceForge. The platform consists of software device adapters for medical devices (including anesthesia machines, ventilators, and patient monitors), OMG DDS standard middleware, and demonstration applications. Applications can be built on this platform to implement smart alarms, physiologic closed-loop control algorithms, data visualization, and clinical research data collection.

The ICE standard defines an architecture for building a safe patient-centric Integrated Clinical Environment. It defines roles for device adapters, a network controller that mediates traffic, a supervisor capable of hosting applications, a data logger for forensic analysis, and external interfaces to hospital resources such as an EHR, ADT, or pharmacy system.

Safe interoperability requires that participants on the network all play by the same rules. DDS was chosen as the middleware for this prototype because it supports the expression of a wide range of quality of service parameters, allowing us to experiment with a variety of clinical scenarios on the way to achieving widespread adoption.

Applications ("apps") in this implementation announce that they are interested in receiving particular pieces of data. Other network participants publish updates to data as it becomes available, and the middleware matches publishers to subscribers. Apps can publish data, so an application could, for example, receive a variety of heart rate signals from a number of medical devices and then publish a "canonical heart rate" topic. In this way, data from apps can be indistinguishable from physical medical devices, for example, enabling the development and sharing of sophisticated data processing apps that may generate data for use by other system components

Matching publishers to subscribers requires that all of the participants use a common set of terms. For this work, a subset of the ISO/IEEE 11073-10101 nomenclature was used. This allows for components (applications or devices) to be interoperable. Using this approach, it is our intent that a device manufacturer will be able to produce a device with an electronic interface that will work with any ICE application, and any ICE application will work with any device that provides the necessary data elements.

We are presenting an initial implementation here with the expectation that it will be useful to clinical researchers in its current state. We look forward to feedback, suggestions, and bug reports from the clinical research community to help with the development of future versions that will be suitable for mainstream clinical use. Updates will be available to the community via our SourceForge site (http://sourceforge.net/projects/mdpnp), and we are working on an ICE Application exchange (ICE AX) site where researchers and developers can post and download ICE applications.

We are very interested in forming a broad user/developer community by collaborating with diverse clinical research groups to inform the direction of development (http://www.mdpnp.org/Get_Engaged.html). We believe that our OpenICE implementation will reduce the time and cost of performing clinical studies, and lead to the development of an ecosystem of commercial and research interoperable apps and devices.

The Integrated Clinical Environment (ICE) Standards (ASTM F2761-09) - The First Ten Years

Presenting Author: Julian M. Goldman, MD*

Co-Authors: Michael B Jaffe*, PhD, David Osborn, MS[+];
Sandy Weininger, PhD[^]

* Massachusetts General Hospital, Harvard Medical School, Boston, MA;
[+] Philips Healthcare, Andover, MA; [^] U.S. Food & Drug Administration, Silver Spring, MD

Summary: The architecture and concepts embodied in the Integrated Clinical Environment (ICE) Standard (1), originated in the 2004 OR of the Future Plug-and-Play kick-off meeting (2). Development of the standard, its publication and use parallels the growth and increased levels of support of the MD PnP program's research on medical device interoperability and safe medical device/HIT system integration. Using source materials from the development of this standard from 2004-2009, the evolution of the ICE standard is chronicled from its origins to its publication as a US standard in 2009, re-approval in 2013, and its ongoing impact.

OR of the Future: Issues of medical device interoperability are apparent in the OR environment, given the range of disparate equipment used and the need to coordinate devices with clinical care. How to better address and deal with hazards caused by the absence of integration of devices and therapies was one theme of a meeting of stakeholders in 2004 (2). From this meeting came the vision described by Julian Goldman for building the foundation for medical device plug-and-play interoperability: "an architectural framework for self-configuring, self-describing devices that enable devices to be automatically configured when connecting to a network, communicating their capabilities and control information to any appropriate control application or device. Eventually, all medical devices will interconnect through standardized hardware and software."

ICE and ASTM: The initial draft was prepared by a writing group under ASTM F29 (convener Julian Goldman, recording secretary Carl F. Wallroth, and document controller Dave Osborn) during the last 5 months of 2006. This draft described requirements applicable to the basic safety and essential performance of networking components suitable for managing a network of medical devices in a medical system in support of a single patient in an integrated clinical environment. The draft established the general principles for the design, verification, and validation of a model-based integration system, including a network controller and one or more interfaces, with acceptable residual risk. Given the importance of issues being addressed by the draft standard, it was felt that this standards work should be pursued at an international level. ICE was initially proposed as a mandatory collateral standard for general standard IEC 60601-1, but was dropped at the 5th small-group group meeting in March 2007 in Cambridge, MA in favor of a standalone standard, as not all devices that would need connecting were medical electrical equipment (within the scope of IEC 60601-1).

ICE via the international route: ASTM F29, holder of the US TAG to ISO/TC 121, submitted a New Work Item Proposal (NWIP) for "ICE Part I – Network Control" to ISO TC121 SC/3 and IEC 62A in September 2007 for progression of the initial work on a global standards stage. The ballot closed December 21, 2007, and resulted in a tie vote in ISO and a majority vote but insufficient number of nominated experts in IEC, due in

part to heavy lobbying by certain manufacturers that were concerned with progressing interoperability. ASTM graciously arranged with ISO and IEC to regain responsibility for hosting the ICE standards program of work.

Concerns and New Approach: Given FDA's interest in innovation and patient safety that could result from interoperable systems, interested stakeholders met (March 2008) in an effort to discuss issues raised during the ISO balloting, establish consensus on these issues, discuss roadmaps for moving the ICE standards work forward. Difficulties in moving such a standard through an international consensus standards process were identified: SDO ownership/turf issues of a broad standard, proprietary commercial ecosystem and the associated inertia, and the lack of awareness of the development activities prior to the balloting. The ISO document was edited into ASTM format and over 160 comments from the NWIP ballot were voluntarily addressed, resulting in publication as an ASTM standard in 2009, and re-approval in 2013.

Influence: The ICE standard has strongly influencing the trajectory of medical device interoperability in the U.S. through the adoption of ICE terminology and architecture, commercialization activities, procurement language (MD FIRE) [3] supported by major hospital systems including the Dept. of Veterans Affairs, regulatory proposals for new FDA health IT-related safety regulations (e.g. FDASIA), and new standards work relating to safety aspects of medical device interoperability (e.g. AAMI/UL 2800, AAMI Interoperability Working Group). Additional standards parts, e.g. for the ICE Data Logger, are under development.

References:

1. ASTM F2761-09(2013) Medical Devices and Medical Systems – Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) – Part 1: General requirements and conceptual model.
2. Operating Room of the Future – a CIMIT/TATRC Symposium – developing a plug and play open networking standard (May 2004) http://www.mdpnp.org/uploads/May_04_MD_PnP_Meeting_Agenda.pdf
3. http://mdpnp.org/mdfire.php

ICE Data Logger Prototype

Presenting Author: Dave Arney, BS*

Co-Authors: Venkata Rentachinthala, Dennis Troup, Anand Maji, Antoine Fillinger, Lukas Diduch, Kamran Sayrafian;** Julian M. Goldman, MD*^

* Massachusetts General Hospital, ^Harvard Medical School, Boston, MA
** National Institute of Standards & Technology, Washington, DC

Medical devices are increasingly being connected together into networked systems, for example to populate the electronic health record (EHR). Problems with individual devices in such a system, or unexpected interactions between the devices, can cause system failures and may compromise patient safety. As the sophistication and integration of heterogeneous medical equipment that are running "apps" in an Integrated Clinical Environment increases in sophistication, the liability and regulatory concerns increases.

A "black box recording" that can provide forensic data logs for the analysis of these events is an important system capability. Events unrelated to device failures also require complete and accurate clinical device data to re-create the event. A Data Logger has been identified as a foundational component of an Integrated Clinical Environment (ICE) system in the ASTM F2761-09(2013) ICE standard.

An ICE system analysis and requirements collection and analysis process funded in part by awards from TATRC W81XWH-09-1-0705 and W81XWH-12-C-0154, NIH award U01EB012470 from the National Institute of Biomedical Imaging and Bioengineering and NIST award 70NANB10H258), an initial prototype Data Logger based on the ASTM F2761 standard has been developed by NIST in collaboration with the Medical Device Plug-and-Play (MD PnP) Interoperability Program team (http://mdpnp.org), and implemented based on the NIST Data Flow System II (NDFS II). Figure 1 illustrates the basic prototype architecture – NDFS II is a distributed middleware system for supporting high-bandwidth distributed applications. It enables the connections between components – in this case the Data Logger components – to be distributed across several machines. The Data Logger prototype components have been developed using C++ and the ADAPTIVE Communication Environment (ACE) open-source framework. XML has been used to transport the data between components. The MySQL database is used to store the logged data for later playback and analysis. A separate playback component has been written in Java as a web application running in the Glassfish application server.

Data Logger Module. The Data Logger is designed to log the desired clinical and non-clinical (i.e. technical) data flowing through the ICE Network Controller. It monitors the flow of information streaming from the connected medical devices, and records all required information communicated by each device or possibly by other environmental sensors (e.g. video, temperature, humidity, etc.). As an example of technical data, it can record device connect/disconnect messages through the Network Controller. Recorded data can be annotated during the logging process if necessary.

Playback Module. The playback application is an independent web application that allows display and analysis of the logged data. The playback module enables time-stamped and synchronized display of alarms and annotations along with the device/sensor data. Editing logged annotations is possible with this module. The graphical display allows zooming to adjust to the appropriate level of detail. The data that is played back is based on the patient and session ID. If already logged, a video clip associated with a particular time period in a session may also be played back when that time period is selected. Sophisticated search functionality has been provided in the playback module to allow searching for clinical or technical events of interest. For example, device/sensor data can be searched for time periods when a particular threshold is reached for a specified period of time. In addition, multiple device/sensor threshold-crossing queries may be grouped together as a single integrated query.

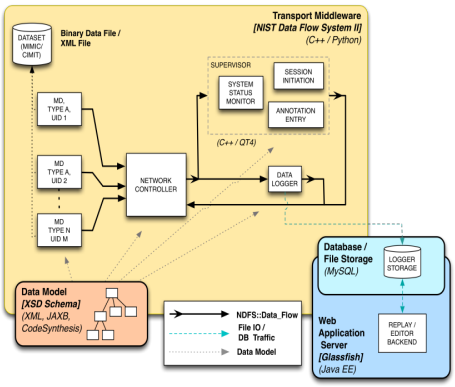


Figure 1: The ICE Data Logger & Playback Demonstration Architecture

Web-Based Clinical Scenario Repository™ (CSR™)

Presenting Author: Diego Alonso*, MS

Co-Authors: Jeffrey Plourde*, BS; Sandy Weininger, PhD˜, Julian M. Goldman*+, MD

Massachusetts General Hospital*, Harvard Medical School+, Boston, MA, US FDA˜

Summary: The Clinical Scenario Repository™ (CSR™) is a web-based tool under development by the Medical Device Plug-and-Play (MD PnP) Interoperability Program (http://mdpnp.org) to help collect data to support a learning healthcare system to improve patient safety and the quality of clinical care. The CSR is intended to enable clinicians and non-clinicians (including patient's family members) to document actual or potential adverse events, especially related to systems issues that are caused by or can be mitigated by device-integration based technology solutions. These "scenarios" will assist the healthcare community, including researchers, standards developers, regulators, and manufacturers, to solve intractable clinical system problems. Our focus is on identifying and mitigating hazardous situations related to workflow, product usability, data integration, and the lack of effective medical device-HIT system integration. Collecting better event information and proposed solutions can help identify opportunities to improve existing devices and create new, more effective healthcare delivery.

Clinical Goals: A primary motivating factor of the CSR is to collect information that is not currently collected, and by being under-reported, problems are not being solved. For example, numerous deaths and other preventable adverse events are caused by patient-controlled analgesia (PCA), but unless the infusion pump malfunctions, neither the adverse event nor suggestions for safer implementation of PCA (e.g. safety interlock with physiologic data) is reported by clinicians or patients to any identified national authority. The CSR would facilitate the reporting of this type of event to generate national data to identify and prioritize solutions. It will have a "like" function to reduce data re-entry and add a social networking aspect.

The CSR is intended to acquire de-identified data from a different perspective as compared to the traditional reporting methodology. The Medical Device Reporting (MDR) regulation (21 CFR 803.1) requires that manufacturers and health professionals "report deaths and serious injuries that (a) device has or may have caused or contributed to." These reports are used to "protect the public health by helping to ensure that devices are … safe and effective for their intended use." The adverse event reports focus on capturing and documenting the event data (e.g. date of event, date of report, description of event), details on the medical device (e.g. manufacturer, serial number) and basic patient demographics. In contrast to the MDR, the perspective of the CSR is to identify events and/or elicit ideas for system-level solutions that cross the boundaries of specific manufacturers, regulated and non-regulated products, diverse users, and practice variability.

Technical Description: The CSR, now in beta, has been designed as a flexible, scalable solution built on the Google Application Engine. The user interface is based on a tabbed design that allows easy navigation, selection and entry of information describing and documenting the

clinical scenario (scenario description, identified contributing factors, description of clinical environment and equipment used), and proposals to address this scenario through changes in workflow, environment, and equipment. The system utilizes a dynamic client-server communication mechanism to allow the user to enter the information available at the moment and to save one's progress based upon Asynchronous JavaScript and XML. Scenarios are intended to mature from initial entry as the result of collaborative interaction among users before being "approved" for general access. The database will be curated by having scenarios approved (content validated), returned to the user for additional clarification, or rejected by an administrator (administrator approval includes screening for privacy and other concerns). Additional functionality includes the ability to search data fields for keywords. To encourage collaboration, scenarios can be entered and reviewed only by registered users.

Supported by TATRC awards W81XWH-09-1-0705 and W81XWH-12-C-0154.

References

1. DeLuca LA, et al. Analysis of automated external defibrillator device failures reported to the Food and Drug Administration. Ann Emerg Med. 2012 Feb;59(2):103-11.

Impact of Incentive Spirometry (IS) Breathing on Infra Red Finger Photoplethysmographic (IR-PPG) Waveform Provided by the Sentec Digital Monitor

Presenting author: Aymen A Alian MD, Yale University School of Medicine

Co-authors: Adam J Shelley MS, Lee Hingula MD, Lila Baaklini MD,David G Silverman, MD, Kirk H Shelley MD, PhD - Yale University School of Medicine, New Haven, CT

Introduction: Pulse oximetry is the most widely used application of the optical technique photoplethysmography (PPG). It has recently been shown that pulse oximetry has potential for the assessment of fluid responsiveness during mechanical ventilation.[1] During spontaneous breathing, assessment of fluid responsiveness still continues to be a challenge as dynamic indices have been unable to detect hypovolaemia.[2] Commercially available pulse oximeters provide waveforms that are filtered (high pass) and are dynamically amplified (auto-center & auto-gain). In this study, we sought to explore changes in the raw finger PPG signal (infrared - IR) waveform provided by a SenTec® Digital Monitor (www.sentec.ch) during Incentive Spirometry (IS) breathing. This was done in the hopes of developing a better understanding of the physiology of cardiopulmonary interaction. We see this as the first step in solving the dilemma of assessment of fluid responsiveness in spontaneous breathing subjects. We assume that the less filtered IR PPG signal will reveal more of the normally filtered venous component of the PPG waveforms (DC component), and thus will allow for the comparison of the impact of the IS on both the IR-PPG waveforms and the peripheral venous pressure (PVP) waveforms. Incentive Spirometry breathing will increase the lung volume quickly. It results in a reduction in RA preload, as well as an increase in afterload of the right and left ventricle, that appear to have characteristics similar to positive pressure ventilation.[3]

Methods: With IRB approval, 11 healthy volunteers were recruited. The SenTec sensor was applied to the finger and the PVP signals were recorded from a transduced intravenous catheter at the hand at 100 Hz with GE S/5 Collect system and analyzed with LabChart 7.3.7 (ADInstruments). Each subject was asked to take deep breaths through the incentive spirometer for 12 breaths (encourage the patients to move all 3 balls). The height of both IR-PPG and PVP waveforms was measured. Data were summarized as mean ±SD and analyzed using a paired t-test. P value <0.05 were considered statistically significant.

Results: The IS breathing showed significant increase in the amplitude of the IR-PPG and PVP (8828±4098 vs.17434±9202) and (1.3±0.4 vs.4.7±2.7) respectively as shown in figure 1. The percent change of IR-PPG and PVP height increased respectively by 97%% and 269% during IS breathing respectively.

Conclusion: The cardiopulmonary interaction of IS showed significant increase in the amplitude of the IR-PPG. This confirms that the raw PPG signals reflect more of the venous component of the waveform. Figure (1-a) shows the effect of the Incentive Spirometry on the PVP waveforms with the creation of a “shock wave” down the arm that resulted in an increase in the PVP and this coincides with changes of the IR-PPG waveforms. This leads to the

intriguing potential for measurement of venous compliance via the measurement of changes in both pressure and volume of the peripheral venous system.

References:

1. Anesth. Analg. 2006; 103 1478–84
2. .Physiol. Meas. 31 (2010) 953–962
3. Sensor 2012;12 (2)2236-54

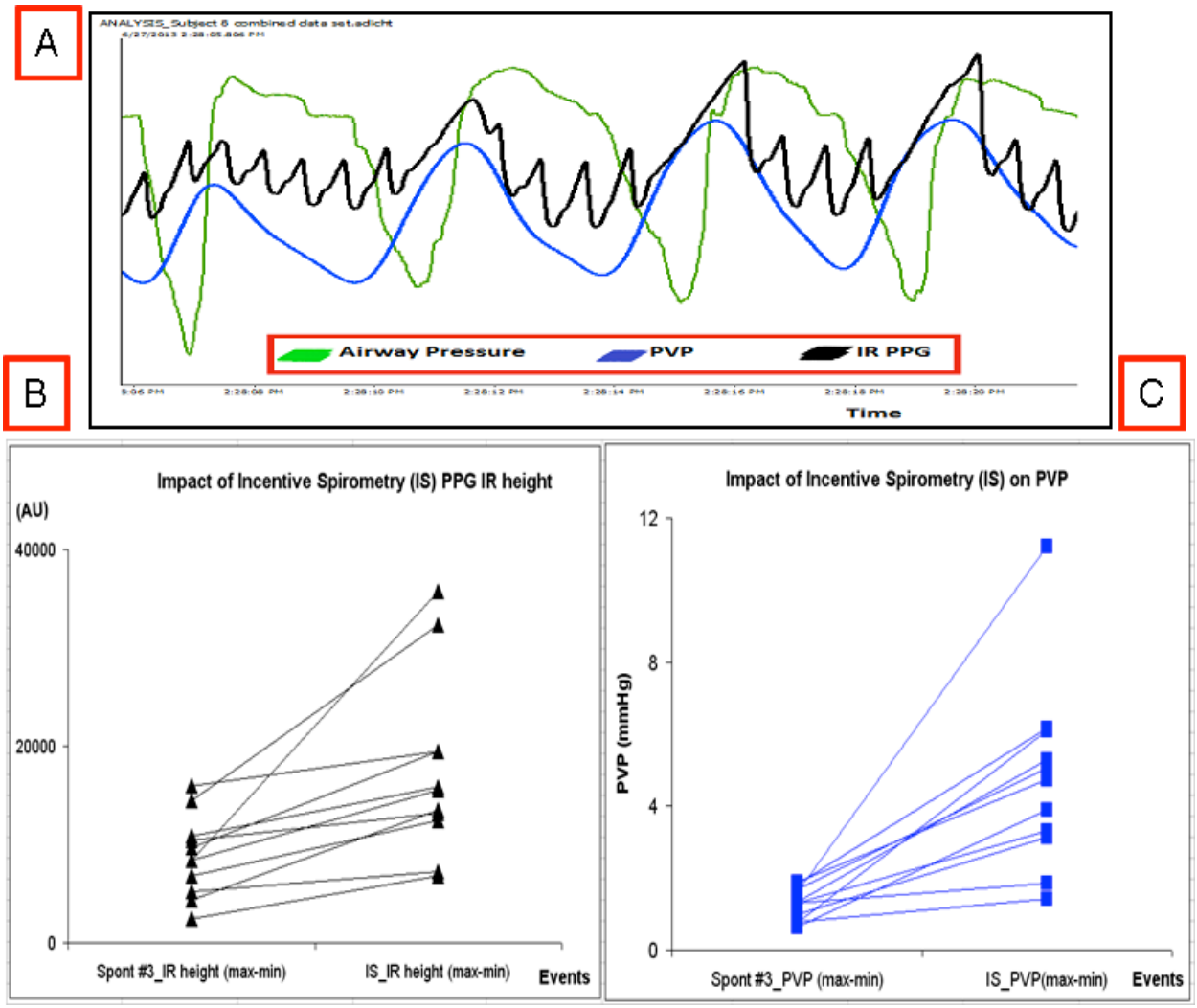


Figure (1): (A): Raw data of airway pressure, IR_PPG and peripheral venous pressure (PVP) during Incentive spirometry; notice the concordance of the increase in IR- PPG and PVP during inspiration (down deflection of the airway pressure). (B): The impact of incentive spirometry (IS) on IR-PPG. (C): The impact of IS on the on PVP.

Impact of Different Breathing Patterns on Peripheral Venous Pressure (PVP)

Presenting author: I-Hsun Liang, MD, Yale University School of Medicine

Co-authors: Siqin Nie MD, Lee Hingula MD, Adam J Shelley MS, David G Silverman, MD, Kirk H Shelley MD, PhD, Aymen A Alian MD - Yale University School of Medicine, New Haven, CT

Introduction: It has been suggested that peripherally transduced venous pressure (PVP) from a standard intravenous correlates well with central venous pressure and thus they could be used interchangeably.[1-4] The PVP is also interesting because unlike the CVP, it is independent of the direct impact of changes in thoracic pressure. Our study sought to explore the physiology of different breathing maneuvers [Muller, Valsalva and Incentive Spirometry (IS)] using the PVP waveforms. Muller maneuver consists of forced inspiratory effort against an obstructed airway. The sudden imposition of negative intrathoracic pressure leads to an abrupt decrease in left atrial volume and a decrease in left ventricular systolic performance. These changes reflected an increase in left ventricular afterload.[5] Valsalva maneuver consists of an expiratory effort against a closed glottis; the resulted increased intrathoracic pressure reduces venous return and results in a transient drop in average blood pressure and in pulse pressure.[6] Taking deep breaths through incentive spirometry will increase the lung volume quickly and results in reduction of right atrial preload as well as an increase in afterload of the right ventricle.[7]

Methods: With IRB approval, 11 healthy volunteers were recruited. Breathing pattern protocol consists of Muller breathing, Valsalva maneuver and taking deep breaths through the incentive spirometer for 12 breaths (encouraging the subjects to move 3 balls), with spontaneous breathing preceding each maneuver. PVP signals were recorded from a transduced intravenous catheter at the hand at 100 Hz with GE S/5 Collect system and analyzed with LabChart 7.3.7 (ADInstruments). Data were summarized as mean ±SD and analyzed using a paired t-test. P value <0.05 were considered statistically significant.

Results: In comparison to the preceding spontaneous breathing, Muller, Valsalva and IS breathing showed significant increase in mean PVP (3.1 mmHg ±1.4 vs.1.2±0.5), (7.1 mmHg ±3.8 vs.1.3±0.5) and (4.7 mmHg ±2.7 vs. 1.3±0.4) respectively. The percent change of PVP height were 151.8%, 446% and 254% during Muller, Valsalva and IS breathing respectively figure (1).

Conclusion: The cardiopulmonary interaction of Muller, Valsalva maneuver and IS showed significant increase in the PVP amplitude (mean venous pressure) as a result of changes in preload and/or afterload of the heart. Characterization of the changes in the morphology of the PVP waveform may yield valuable information about a patient's cardiovascular status. One advantage of the IS over the other 2 breathing maneuvers is that the breaths are standardized and therefore were similar in flow rate and depth. We were surprised to discover that IS breathing appears to create a positive pressure 'venous shockwave' that has similar characteristics to that of positive pressure ventilation.

References:
1. J Cardiothorac Vasc Anesth 2001;15:40-3
2. Acta Anesthesiol Scand 2004; 48:1101-4
3. J Clin Anesth 2005; 17:348-52
4. J Clin Anesth 2006; 18:251-5
5. Am J Cardiol. 2008;102(11):1557-61
6. J Clin Monit 1996; 12: 365–377
7. Sensor 2012;12 (2)2236-54

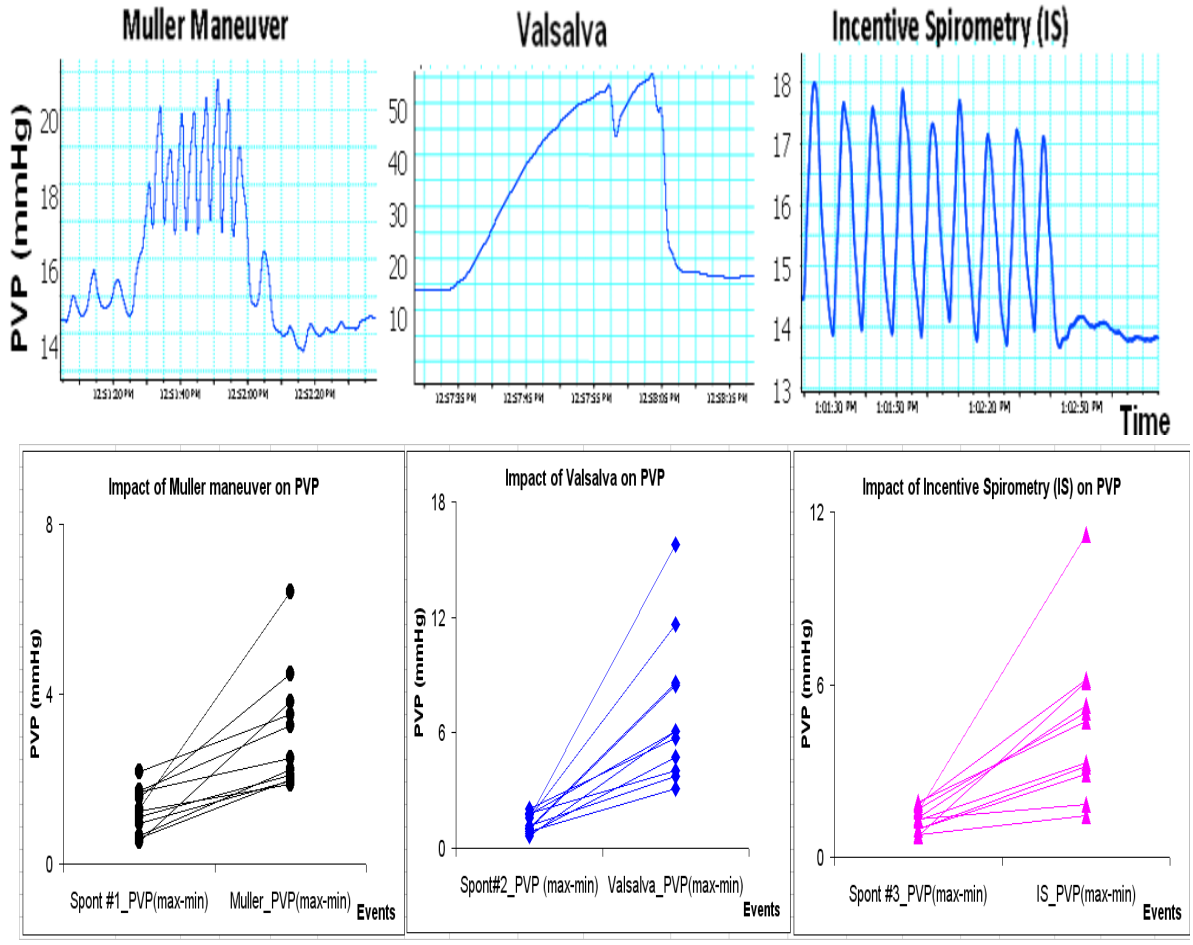


Figure (1): upper panel: An example of the peripheral venous pressure (PVP) waveform during different breathing patterns. The lower panel: graphs represent the impact of different breathing patterns on PVP

Impact of Different Breathing Patterns on Finger Photoplethysmographic (PPG) Parameters

Presenting author: Lee Hingula, MD, Yale University School of Medicine

Co-authors: Siqin Nie, MD, Lila Baaklini MD, Adam J Shelley MS, Kirk H Shelley, MD, PhD, Aymen A Alian, MD
Yale University School of Medicine, New Haven, CT

Introduction: Dynamic indices, such as ventilator induced variability of pulse oximeter PPG amplitude – pulse height, have been shown to be better predictors of fluid responsiveness than static indices such as CVP/PAWP during mechanical ventilation.[1] These dynamic indices are based upon physiological models of cardiopulmonary interaction during mechanical ventilation. During spontaneous breathing, assessment of fluid responsiveness still continues to be a challenge as these dynamic indices have been unable to detect hypovolaemia.[2] Our study sought to explore changes in the PPG waveform (height, peak area) during different respiratory maneuvers [Muller, Valsalva and Incentive Spirometry (IS)] to develop a better understanding of the cardiopulmonary interaction as a first step in solving the dilemma of assessment of fluid responsiveness with spontaneous breathing subjects. The idea of Muller is forced inspiratory effort against an obstructed airway, lung volume remains constant, so pleural pressure is decreased and this results in an increase in left ventricular afterload. This maneuver is used to mimic the obstruction in the upper airway as seen during obstructive sleep apnea.[3] Valsalva maneuver consists of an expiratory effort against a closed glottis, the resultant increased intrathoracic pressure reduces venous return and results in a transient drop in average blood pressure and in pulse pressure.[4] Arterial response during the Valsalva maneuver has been proposed as a tool for predicting fluid responsiveness in patients not on mechanical ventilatory support.[5] Taking deep breaths through (IS) will increase the lung volume quickly and results in reduction in RA preload as well as an increase in afterload of the right and left ventricle.[6]

Methods: With IRB approval, 11 healthy volunteers were recruited. Breathing pattern protocol consists of Muller breathing, Valsalva maneuver and taking deep breaths through the IS for 12 breaths (encourage the patients to move all 3 balls), spontaneous breathing preceded each maneuver. PPG signals from a Nellcor pulse oximeter (GE) were recorded at the finger at 100 Hz with GE S/5 Collect system and analyzed with LabChart 7.3.7 (ADInstruments). Data were summarized as mean ±SD and analyzed using a paired t-test. P value <0.05 were considered statistically significant.

Results: In comparison to the preceding spontaneous breathing, Muller, Valsalva and IS breathing showed significant reduction in the finger PPG amplitude – pulse height (2.65±1.81 vs.4.62±3.36), (2.27±2.33 vs. 4.17±2.33) and (2.27±1.63 vs. 4.31±2.74) respectively. The percent change of finger PPG height were 43%, 45% and 29% during Muller, Valsalva and IS breathing respectively figure (1). Finger PPG area showed significant reduction during different respiratory maneuvers in comparison to spontaneous breathing. The percent changes were 47%, 56% and 40% during Muller, Valsalva and IS breathing respectively. During Muller, Valsalva and IS breathing the finger PPG area showed significant reduction in relation to the preceding spontaneous breathing (0.76±0.53 vs.1.42±1.09), (0.55±0.44 vs.1.24±0.78) and (0.76±0.51 vs.1.27±0.84) respectively.

Conclusion: The cardiopulmonary interaction of Muller, Valsalva maneuvers, and IS showed significant reduction in the PPG amplitude and area, likely as a result of changes in preload and/or afterload of the heart. This may indicate that these maneuvers might be a useful tool in the assessment of fluid responsiveness in spontaneously breathing subjects. One advantage of the IS over the other 2 breathing maneuvers is that the breaths are standardized and therefore were similar in flow rate and depth.

References:
1. Curr Opin Crit Care 2005;11: 235–9

2. Physiol. Meas. 31 (2010) 953–962
3. Laryngoscope 2000;110:1819-23
4. J Clin Monit 1996; 12: 365–377
5. Intensive Care Med .2009, Vol. 35 Issue 1, p77-84.
6. Sensor 2012;12 (2)2236-54

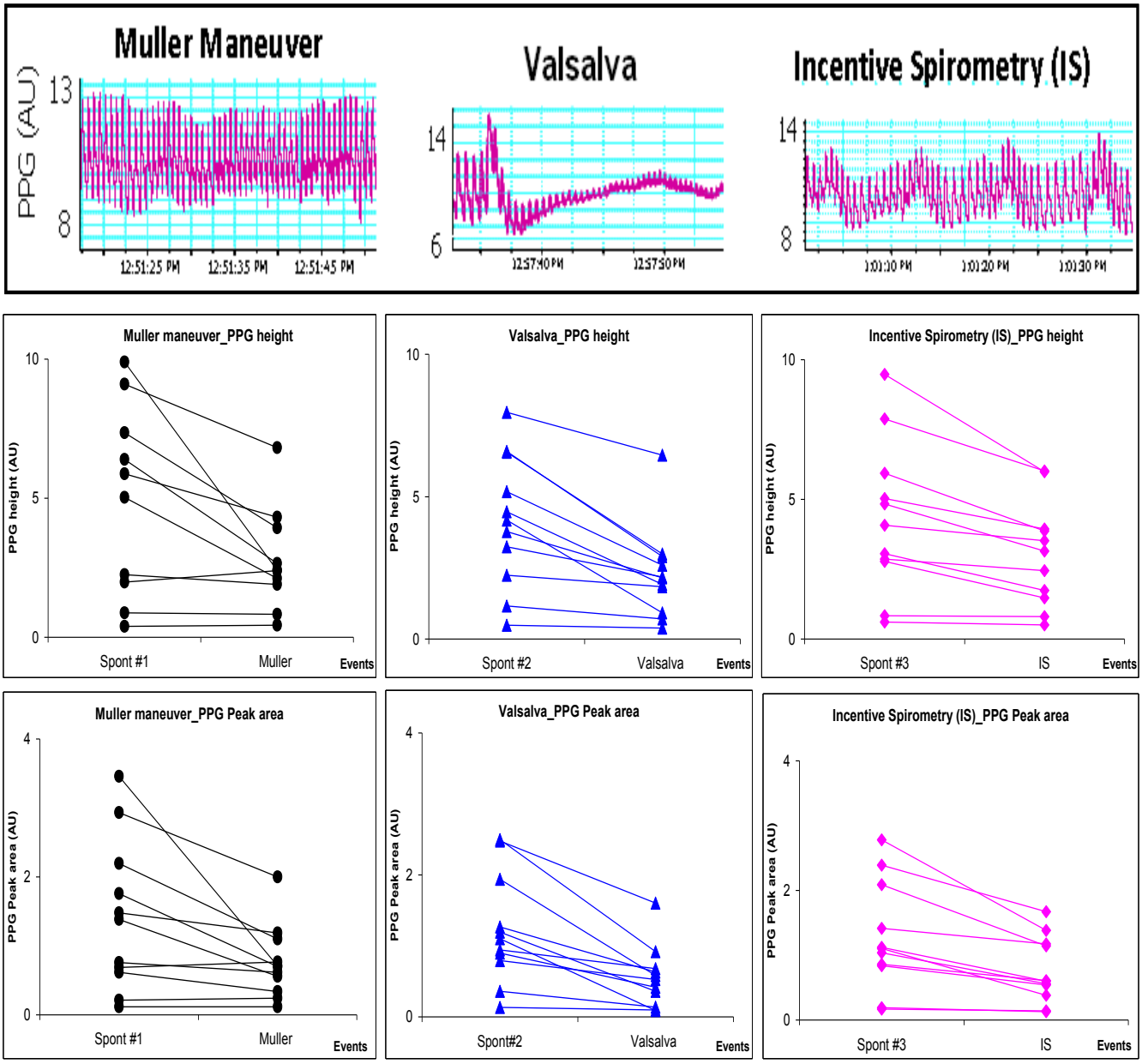


Figure (1): upper panel: the raw data of PPG signals from a Nellcor pulse oximeter during different breathing patterns. The middle panel: graphs represent the impact of different breathing patterns on the finger PPG amplitude. The lower panel: represents the impact of different breathing patterns on the finger PPG area.

Impact of Hydrostatic Pressure on Peripheral Venous Pressure Measurements

Presenting author: Terence Rafferty, MD, Yale University School of Medicine

Co-authors: Reim Alian, Kirk Shelley, MD, PhD and Aymen Alian, MD, Yale University School of Medicine

Yale University School of Medicine, New Haven, CT

Introduction: It has been suggested that changes in peripheral vein pressure (PVP) might provide a clinically meaningful estimate of fluctuations in intravascular volume (1-2). There are no available data on the impact of limb position on derived measurements. This study was performed to address this void.

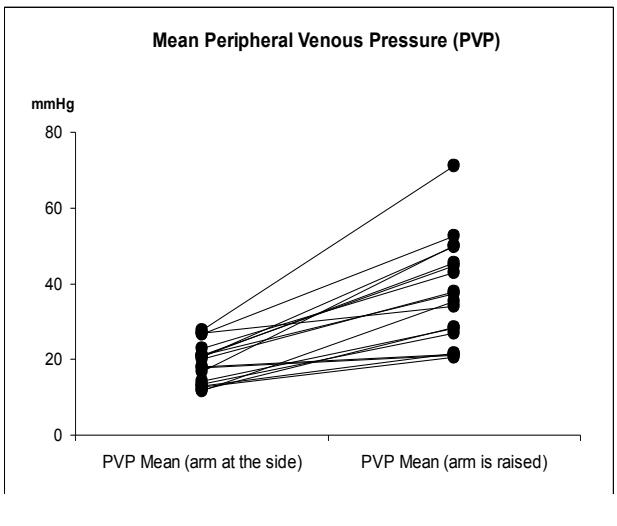
Methods: Institutional IRB criteria were fulfilled. 14 consecutive adult patients undergoing general anesthesia were included. PVP data were transduced from standard intravenous catheters inserted into the forearm/hand. Transducers were "zeroed" at the mid-axillary line with the patients supine. Pressures were measured with the arms at the side and at a ninety-degree elevation. An arterial catheter was inserted in the same side of the IV location for monitoring of blood pressure. Data are presented as mean ± SD. Statistical analyses were by paired t-test, P value <0.01 were considered statistically significant.

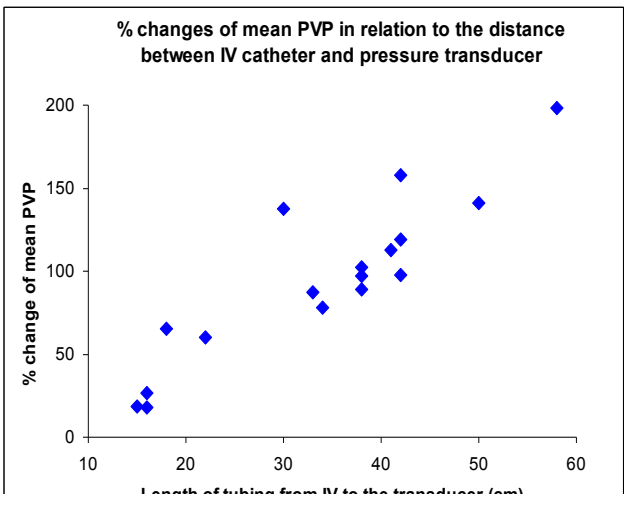
Results: Limb elevation resulted in statistically significant increase in mean PVP (18.7 ± 5.2 versus 37.2 ± 13.7 mm Hg), with percent change of 98.5% (figure 1). The height of the fluid filled pressure tubing between the Intravenous catheter site (hand or forearm) and the transducer correlated with pressure changes in PVP, (r = 0.86), as shown in (figure 2). Corresponding changes in mean arterial pressure were not significant (88 ± 13.2 versus 89.7 ± 16.4 mm Hg).

Conclusion: We have shown limb height and the specific location of the intravenous catheter have a profound impact on PVP measurements. Valid extrapolation of such data must take this hydrostatic pressure factor into account. We suggest adjustment of transducer position to the location of the intravenous catheter and "re-zeroing" at this new position as a solution to this problem.

References:

1. J CardioThor Vasc Anesth 2004; 18: 446-450
2. J Clin Anesth 2012; 24: 542-548





Blackout of All Patient Monitors in Operation Rooms

Presenting Author: Wonsik Ahn, MD, Department of anesthesiology, Seoul National University Dental Hospital, Seoul, Korea

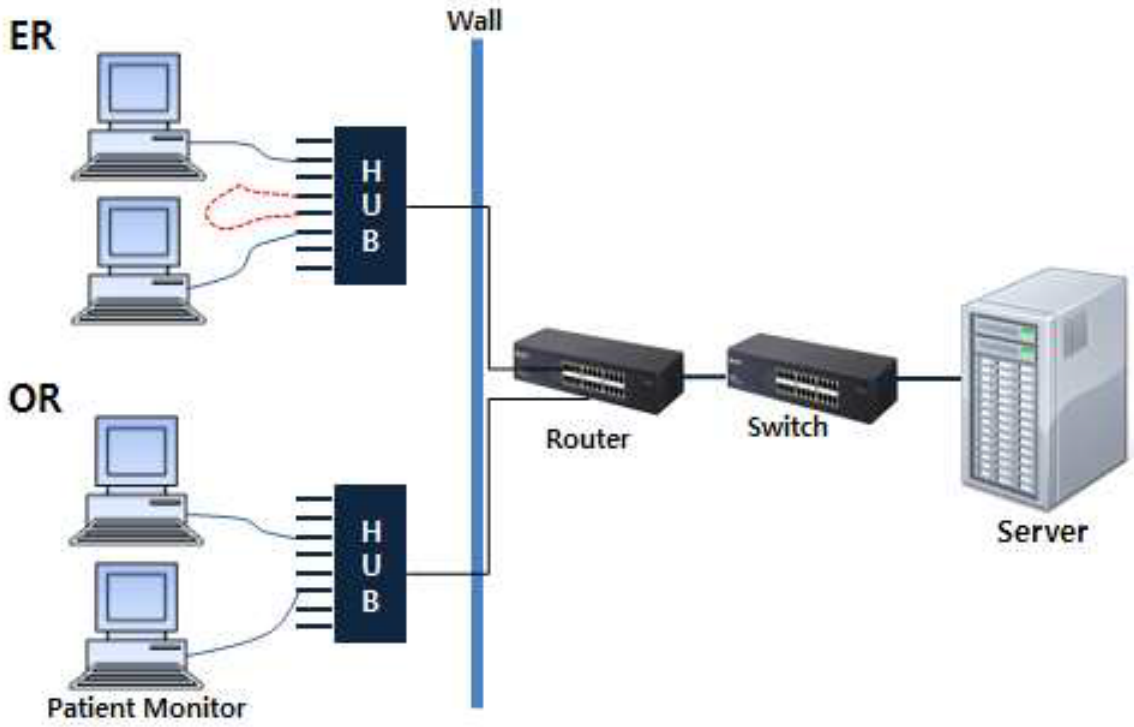
Co-authors: Sungwoo Ahn, Department of electrical engineering, Yonsei University. Young-A Kim, Department of anesthesiology, Seoul National University Dental Hospital

Background: Several medical devices in operation rooms communicate with each other for giving more information to clinicians. Adding the communicating capability should not hinder the original function of the medical devices. However, there was black-out of all of patient monitors in operation rooms (OR) due to an error in a network connection within the communication system.

Two Cases: Solar 8000M monitors (GE) communicate their information to a data storage server via a hub, a router and a switch. All patient monitors stopped displaying patients' vital signs when a hub was connected to an LAN cable to make a loop in an emergency room (Figure). The hub made a lot of packets and sent them to the data storage server. Because the data storage server could not respond packets from the patient monitors in OR, all 34 patient monitors in OR did not display anything for one hour. No patient monitor displays patients' vital signs. Vital signs displayed in the screen after we took out the LAN cables from the patient monitors. The first incident occurred in 2006, and then a second incident occurred in 2012.

Simulation: We simulated the same situation with the same kind of monitors, hubs, a router, a switch, and a data storage server. The black-out phenomenon recurred when the monitor end of a LAN cable from a hub was connected to the hub slot instead of the port of a patient monitor. Network management system confirmed that the hub made a lot of packets and sent them to the data storage server. This data surge abolished when the LAN cable was connected to the correct slot or when the hub was disconnected from the router.

Conclusion: "Risk management" is defined as "systemic application of management policies, procedures and practices to the tasks of analysing, evaluation, controlling and monitoring risk" in ISO 14971 (application of risk management to medical devices) and in IEC/TR 80001 series (risk management for IT-networks incorporating medical devices). We think that risk management of medical devices should be applied to this kind of communication systems. The Solar 8000M patient monitor (GE) should adopt a rescue algorithm when there is no response from a server for a designated duration.



<Figure> Schematic representation of an electromedical recording system. A monitor end of a LAN cable in the emergency room was connected to the hub slot instead of the port of a patient monitor (red dot line). The hub made a lot of packets and sent them to the data storage server. Because the data storage server could not respond packets from the patient monitors in OR, all patient monitors in OR did not display anything for one hour.