

Multicenter Perioperative Outcomes Group (MPOG)
PCRC Meeting Notes – Monday,

Attendees: P=Present; A=Absent; X=Expected Absence

Active PIs		In Progress PIs Continued	
A	Kenneth Abbey, MD - OHSU	P	Leif Seiger, MD – Cleveland Clinic
A	Michael Avidan, MD - Wash U	A	Robert Schonberger, MD – Yale
P	Michael Aziz, MD - OHSU	P	Scott Springman, MD – Wisconsin
P	S. Patrick Bender, MD - Vermont		Wilton van Klei, MD – Utrecht
P	Mitchell Berman, MD - Columbia	Chairs	
P	Daniel Biggs, MD – Oklahoma	A	David Adams, MD - Vermont
P	Kaiser Conn (Research) - Oklahoma	A	Wolfgang Buhre, MD - Utrecht
A	Marcel Durieux, MD, PhD- Virginia	A	David Brown, MD – Cleveland Clinic
P	Jerry Epps, MD - Tennessee	A	Michael Cahalan, MD - Utah
P	Jesse Ehrenfeld, MD - Vanderbilt	P	Jerry Epps, MD – Tennessee
P	Ana Fernandez-Bustamente, MD - Colorado	A	Alex Evers, MD – Wash U
P	Alexander Friend, MD –Vermont	A	Jane Fitch, MD – Oklahoma
A	Daniel Helsten, MD – Wash U	A	Hugh Hemmings, Jr., MD, PhD, FRCA - Cornell
A	Sandra Holtzclaw, MD - Vanderbilt	A	Thomas Henthorn, MD –Colorado
P	Leslie Jameson, MD - Colorado	A	Roberta Hines, MD, FANZA - Yale
P	Sachin Kheterpal, MD - Michigan	A	Jeffrey Kirsch, MD - OHSU
P	Fabian Kooij, MD – AMC Amsterdam	A	G. Burkhard Mackensen, MD, PhD – U of Wash
A	Philip Lirk, MD – AMC Amsterdam	A	Mervyn Maze, MD - UCSF
A	Timothy Morey, MD - Florida	A	Timothy Morey, MD - UCSF
X	Nathan Pace, MD – Utah	A	Marco Navetta, MD – Santa Barbara Cottage
P	William Paganelli, MD – Vermont	A	Robert Pearce, MD, PhD - Wisconsin
A	Stephen Robinson, MD - OHSU	A	Howard Schapiro, MD - Vermont
P	Gabe Tharp, MD, PhD - Vermont	A	Wolfgang Schlack, MD - AMC
P	Jonathan Wanderer, MD - Vanderbilt	P	Kevin Tremper, PhD, MD - Michigan
A	Kevin Wethington, MD - Utah	A	Warren Sandberg, MD, PhD – Vanderbilt
In-Progress PIs		A	Howard Schapiro, MD - Vermont
A	Maged Argalious, MD – Cleveland Clinic	A	George Rich, MD – Virginia
P	Brian Bateman, MD - MGH	A	Wilton van Klei, MD – Utrecht
P	Jurgen de Graaf, MD - Utrecht	A	Jeanine Wiener-Kronish, MD- MGH
A	Matthias Eikermann, MD - MGH	A	Margaret Wood, MD - Columbia
A	Peter Fleishut, MD – Weill-Cornell	MPOG	
A	Bassam Kadry, MD - Stanford	A	Mark Dehring
A	Karen Nanji, MD, MPH – MGH	P	Tory Lacca, MBA
A	Bala Nair, PhD – U of Washington	P	Michelle Morris, MS
A	Marco Navetta, MD – Santa Barbara Cottage	P	Amy Shanks, MS, PhDc
P	W. Pasma - Utrecht	A	Tyler Tremper
A	David Robinowitz, MD - UCSF	P	John Vandervest

Ground Rules for PCRC:

1. Each protocol must have specific testable hypothesis with data available in MPOG data structure
2. People requesting specific data elements must also supply that data type to MPOG. If you don't submit that data type currently, then you can't get that type of data type out. However, if you have a co-investigator from another site that does supply that data, then you can ask for that type of data. The reason is so someone on the research team understands the limitations of each data element being requested and used
3. To ensure that there is not a lack of clarity about what the status of the proposal is, each proposal will get the following overall decision at the end of each presentation and discussion
 - a. Accept with minimal or no changes required
 - b. Accept with major changes required
 - c. Revise and reconsider at future meeting
 - d. Reject
4. Meeting will be recorded to be shared later with members of MPOG via the MPOG website. There were no objections to this via the members that were on the call.

Updates on Data Abstraction

- All data from previous PCRC approvals have at least had preliminary data sent to them for review
- When cleaning data, participants will see other projects cleaning processes as well
- We do not separate it out that only certain people, can see specific projects
- As the groups gets larger, we will have to limit who can access the data
- Question: At this point, are people uncomfortable that other sites can access the data from a specific ACRC? Should we increase our efforts to have only specific people have access to the data they are involved with or is everyone comfortable with the waiting until ASA 2014?
 - Is there any issues with the IRB since it is a limited dataset?
 - No there are no regulatory issues by the letter of the law. The current DUA's allow this
 - From the spirit of the rule, we should minimize those that have access to specific tables and that we can track who is accessing each column
 - The group agrees that this is ok to have accomplished by ASA 2014
- We will develop specifications that will include full audit trailing at the user level and send out to the MPOG group for approval

Presentation 1

Title: Variation and Trends of Intraoperative Tidal Volume Habits

Proposed Authors: S. Patrick Bender, Sachin Kheterpal, William Paganelli, Lyle Gerety, David Adams, Ian Black, William Tharp, Amy Odefrey

Primary Institution: Vermont

Presented by: S. Patrick Bender

Discussion Points:

- Initial vent settings due to manufacturer defaults are what is primarily used unless the institution has changed them.
 - The hope is to have the default settings changed
- Each site will complete a data collection instrument that will tell what the standard vent settings are and the particular room and machine that are used. This will need to be completed by each OR at each site.
 - The PI will develop this
- Is the concept of a 5 minute median starting when you see a positive vent setting?
What do we used to define initial vent behavior?
 - Hesitant to use more than 5 minutes. Most people will decrease the TV within 5-10 minutes if needed
 - It depends if the AIMS takes the data every minute from the anesthesia machine. One site does not have this automatic feed and have to manually enter it. Therefore, this may not be reliable data?

- Perhaps look at if the vent settings do change, and if so when it changes and what it changes to?
- Why do we want to compare early versus overall? Clinical decision making causes the settings to change
 - The PI will be ok to comparing initial settings to early on settings?
 - Perhaps compare the default setting to the median?
- What have people done in the past? Did you take the median value and chose that?
 - Yes they used the median value throughout the entire case. The mean and median were different so the median was chose.
 - Once site thought to use the time point after the neuromuscular blockade was used but that did not work so they chose the median used as well
- So then we would compare initial versus overall and forget the early? Early is too big of a time period defined as 60 minutes.
 - We need to do initial since that is the PI's primary hypothesis
 - From overall, we would do a median setting throughout the entire case
- This is assuming q1minute data that is electronically entered and not clinician entered
 - Any unique issues to detecting vent start at each site?
 - Can we define zero time-point as when we see a vent setting? Trying to determine bag mask vent versus ventilator being used
 - One site used the first vent setting rate with a previous study
 - For initial period, vent rate set and vent rate measured are the same and that will be defined as the zero-time point?
 - When you have the first vent rate set, can this be the zero time-point?
 - Yes we can try that way
 - Some machines send out vent rate settings even when vent is on standby mode. Need to further investigate this issue
- Trends by quarter of year (or quarter) to see if TV have gotten smaller or more consistent? Any concerns about this?
 - Year is a large chunk, perhaps try quarter or year or every 6 months
- Regression analysis, predict from a linear regression or logistic regression?
 - Once concern is that each factor will be significant on a linear function
 - Isn't the core purpose to see who gets the bigger TV and therefore a logistic regression would be feasible?
 - The PI isn't sure how to define it if isn't a Boolean concept
- Could you state that the literature recommends a specific value, and this is the frequency that this is occurring?
 - Patients need different settings based on pathology. How are we going to pick one number that separates good from bad?
 - However, you aren't saying what is good versus bad but how many patients are given a specific amount because we don't know who will have a negative outcome?

- Boolean concepts are easier to understand than linear functions
 - The PI will consider a Boolean concept
- Can you do this based on height?
 - This is from IBW derived from height
- Should we look at provider difference?
 - Does anyone think this should not be done?
 - What happens when providers are switched at the end of the day?
 - For those cases, we only look at initial
- There is another group doing a similar study where there will be some overlap in the data that will be used. For transparency, we need to include that some of this data may be included in a separate dataset.
 - Moving forward, each PI should disclose that these data may be used in a separate manuscript as well

Institution	Vote
Academic Medical Center (AMC), Amsterdam	Accept and represent
Columbia	Accept with Moderate Revisions
Oklahoma University Medical Center	Accept with Moderate Revisions
Oregon Health Science University	Abstain
University of Colorado	Accept with Moderate Revisions
University of Florida	Not on call
University of Michigan	Accept with Moderate Revisions
University of Tennessee	Accept with Moderate Revisions
University of Vermont	PI
University of Utah	Not on call
University of Virginia	Not on call
Vanderbilt	Accept and represent
Washington University	Not on call

Final Decision: Accept with Moderate Revisions

Presentation 2

Title: Comparison of the characteristics and perioperative outcomes of patients with a formal diagnosis, preoperative bedside diagnosis or without a diagnosis of obstructive sleep apnea

Proposed Authors: Anna Fernandez-Bustamente, MD, PhD; Ken Bullard, BS; Leslie Jameson, MD, others as appropriate

Primary Institution: Colorado

Presented by: Leslie Jameson, MD

Discussion Points:

- This study has been completed at Colorado but previous work was completed on those with difficult mask ventilation. They would now like to do this on the MPOG dataset
- The PI realizes that not every site has PACU data
- Goal: To establish that we can do a bedside diagnosis for OSA that is as accurate as a formal diagnosis with formal PSG
- Making the leap that bedside and formal diagnoses are the same and therefore treat the bedside patients with a CPAP is a large leap. Instead, the PI is trying to state if there was a bedside diagnosis, then treat accordingly in the peri-operative period, not to state that the patient does not need a formal PSG later on.
 - These bedside patients, then need to be sent for a follow-up
- Who has STOP-BANG in there preop?
 - UM does not, we have a subjective thick neck
- Is the PI ok with something similar to STOP-BANG or do you need exact STOP-BANG?
 - Some of the variables are there and can be abstracted
 - No, the PI's do not have a problem with a similar representative of the variables
- How long in PACU are you looking for desaturation?
 - Until the patient leaves
 - One site would be missing some of that data
- What STOP-BANG are you looking for?
 - 4 or more covariates is the criteria requested
- Is hypertension subjective or a documented?
 - If we can get that they have treated hypertension that would be helpful
- PACU data, how many sites have saturation data there? Also, may not have the treatment that occurred.
 - The PI realizes this is a limitation
- UM has PACU data that is put into MPOG. No other site currently does
 - Tennessee does not have the ability to get the data into MPOG but will in the future but does have STOP-BANG
 - Vanderbilt has PACU data
 - U of Colorado has PACU data
 - U of Vermont has PACU data

- Amsterdam has PACU data
- Is it possible to get PACU data from other mechanisms?
 - Yes it is technically possible but it is recommended that the data goes into MPOG and that if you request data to be abstracted, you need to put the data into the MPOG database
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Institution	Vote
Academic Medical Center (AMC), Amsterdam	Not contributing data – no vote
Columbia	Not contributing data – no vote
Oklahoma University Medical Center	Not contributing data – no vote
Oregon Health Science University	Not contributing data – no vote
University of Colorado	Not contributing data – no vote
University of Florida	Not contributing data – no vote
University of Michigan	Accept with moderate revisions
University of Tennessee	Not contributing data – no vote
University of Vermont	Accept with moderate revisions
University of Utah	Not contributing data – no vote
University of Virginia	Not contributing data – no vote
Vanderbilt	Accept with moderate revisions
Washington University	Not contributing data – no vote

Final Decision: Accept with moderate revisions

Presentation 3 - Representation

Title: Perioperative Outcomes of Patients with Cardiac Implantable Electronic Devices

Proposed Authors: Peter Schulman, MD; Margaret Kathleen Menzel, MD; Michael Aziz, MD; Marc Rozner, PhD, MD; Jamie Eastman, PhD, MPH; Sachin Kheterpal, MD, MBA

Primary Institution: Oregon

Presented by: Peter Schulman, MD

Discussion Points:

- Hypothesis: CIED is an independent marker for increased perioperative risk
- Primary outcome: major adverse cardiac event meaning death or MI within 7 postoperative days
- Secondary outcome: MI or death with 30 days postoperatively
- Discussion last time centered around if this was the correct research hypothesis to be asked and the PI has determined that is the question that they would like to answer. Also what is the proper methodology to do this? The PI has decided to do propensity score matching
- Today would like to discuss if propensity score matching is the best way or how the matching should be done?
 - Do the propensity score matching and report the results for submission since if you do both, then you it appears that you are “fishing”
- Last time they presented, the co-morbidities were discussed and this proposal has a weaned down version
 - Should we use a subjective documentation of renal function rather than the actual lab value?
 - Some patients will be lost without a preoperative creatinine
 - The PI’s like the idea of just using the actual creatinine values and not the subjective documentation

Institution	Vote
Academic Medical Center (AMC), Amsterdam	Accept with Minor
Columbia	Not contributing data – no vote
Oklahoma University Medical Center	Accept with Minor
Oregon Health Science University	Accept with Minor
University of Colorado	Accept with Minor
University of Florida	Not contributing data – no vote
University of Michigan	Accept with Minor
University of Tennessee	Accept with Minor

University of Vermont	Accept with Minor
University of Utah	Not contributing data – no vote
University of Virginia	Not contributing data – no vote
Vanderbilt	Accept with Minor
Washington University	Not contributing data – no vote

Final Decision: Accept with Minor Revisions