Multicenter Perioperative Outcomes Group (MPOG)
PCRC Meeting Notes – Monday, July 8, 2013

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

Active PIs		**In Progress PIs Continued**	
A	Kenneth Abbey, MD - OHSU	**A**	W. Pasma - Utrecht
P	Michael Aziz, MD - OHSU	**A**	David Robinowitz, MD - UCSF
A	Mitchell Berman, MD - Columbia	**A**	Scott Springman, MD – Wisconsin
P	Daniel Biggs, MD – Oklahoma	**A**	Wilton van Klei, MD – Utrecht
A	Robert Craft, MD –Tennessee	**Chairs**	
A	Douglas Colquhoun, MD –Virginia	A	Wolfgang Buhre, MD - Utrecht
P	Marcel Durieux, MD, PhD- Virginia	**A**	David Brown, MD – Cleveland Clinic
P	Jaime Eastman, PhD - Oregon	**A**	Michael Cahalan, MD - Utah
A	Jerry Epps, MD - Tennessee	**A**	F. Kayser Enneking, MD - Florida
A	Jesse Ehrenfeld, MD - Vanderbilt	**A**	Jerry Epps, MD – Tennessee
P	Ana Fernandez-Bustamente, MD - Colorado	**A**	Alex Evers, MD – Wash U
A	Alexander Friend, MD –Vermont	**A**	Jane Fitch, MD – Oklahoma
P	Karl Hammermeister, MD - Colorado	**A**	Thomas Henthorn, MD –Colorado
A	Sandra Holtzclaw, MD - Vanderbilt	**A**	Jeffrey Kirsch, MD - OHSU
A	Leslie Jameson, MD - Colorado	**A**	Mervyn Maze, MD - UCSF
P	Sachin Kheterpal, MD - Michigan	**A**	Marco Navetta, MD – Santa Barbara Cottage
A	Fabian Kooij, MD – AMC Amsterdam	**A**	Robert Pearce, MD, PhD - Wisconsin
A	Philip Lirk, MD – AMC Amsterdam	**A**	Howard Schapiro, MD - Vermont
P	Damon Michaels, BS - Vanderbilt	**A**	Wolfgang Schlack, MD - AMC
P	Nathan Pace, MD – Utah	**P**	Kevin Tremper, PhD, MD - Michigan
A	William Paganelli, MD – Vermont	**A**	Warren Sandberg, MD, PhD – Vanderbilt
A	Stephen Robinson, MD - OHSU	**A**	Howard Schapiro, MD - Vermont
P	Peter Schulman, MD - Oregon	**A**	George Rich, MD – Virginia
A	Kelley Smith, MD – Utah	**A**	Jeanine Wiener-Kronish, MD - MGH
A	Jonathan Wanderer, MD - Vanderbilt	A	Margaret Wood, MD - Columbia
A	Kevin Wethington, MD - Utah	**MPOG Staff**	
In-Progress PIs		A	Mark Dehring
A	Maged Argalious, MD – Cleveland Clinic	P	Nikhail Iyer
A	Michael Avidan, MD - Wash U	P	Tory Lacca, MBA
A	Brian Bateman, MD - MGH	P	Fiona Linton, MD
A	Matthias Eikermann, MD - MGH	P	Michelle Morris, MS
A	Dan Helsten, MD – Wash U	X	Amy Shanks, MS, PhDc
A	Timothy Morey, MD - Florida	A	Tyler Tremper
P	Marco Navetta, MD – Santa Barbara Cottage	A	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.

Presentation 1 - New:

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, Sachin Kheterpal, MD, MBA

Primary Institution: Oregon Health and Science University

Presented by: Drs. Aziz and Schulman

Discussion Points:

Does the presence of an implanted device increase the perioperative risk? Identify the centers that have postoperative outcomes. Extract data from the structured preoperative data. Control group will be identified.

Discussion:

- Dr. Schulman has done a literature search and has only found one other study.
- Would like to determine if a person with a device become harder to manage or potentially has a higher rate of mortality
- Will this be impactful?
- Do we need to do a more descriptive paper first to see what the rate of cases that have problems with the device?
- Dr. Pace: Identify the patients with the device. Do a pilot study to see if you can correctly identify or classify patients. Dr. Pace is suggesting a more descriptive paper.
- Drs. Biggs & Fernadez-Bustamente: Dr. Fernandez-Bustemente: I feel we have enough documentation at Colorado. Although, they may be missing a small portion of them. Dr. Biggs: We record it to an extent that it will be valid.
- Dr. Trempmer: If there is a history of arrhythmia, will it be picked up by the ROC curve? Will it be difficult to match?.
- Dr. Schulman: In the existing literature, there are currently two advisories. One published by HRS and one by ASA. Those advisories recommend a high level of management during the perioperative period. The presumption is that those patients have a higher risk. Currently, there is no evidence in the literature about the actual perioperative risk. There have been case reports and a couple of small studies. There was a nine year retrospective review in India that they found that the presence of a

pacemaker was a higher rate of post-operative mortality. At this time, there have been no multicenter studies looking at this

- Dr. Fernandez-Bustamente: Is there different consideration between having a pacemaker and cardiac comorbidity?
    - Dr. Schulman: We will tease out the difference between pace makers and fibulators. We plan to have two subsets of patients.
    - Mike Aziz: Since the device is a marker for a potential higher risk, can we use it as a marker.
- Dr. Kheterpal: There is a potential for four different manuscripts.
    - Manuscript 1: Unadjusted analysis across three groups (no device,/pacer combo, pacer only) showing unadjusted primary outcome rates (simple, no matching, not case control, just chi-square/anova)
    - Manuscript 2: Case-control analysis matching on 'sick hearts' knowing treatment bias leftover with comparison across three groups
    - Manuscript 3: Descriptive intraoperative challenges of devices
    - Manuscript 4: Robust risk adjustment across all cardiac risk factors for intraoperative management
- Dr. Tremper: Suggests to publish both #1 and #2.
- Dr. Biggs: Is there enough data?
    - Check with other sites to see if they have the data.
    - Need to see if there is postop data and then the ability to match the Master Death File
- The group is supportive of manuscript #2
    - Exact definition of comorbitities and talking to Vermont and Tennessee to check the validity of their data.
    - Define the 'sick heart'

Institution	**Vote**
Academic Medical Center (AMC), Amsterdam	**Not in attendance**
Columbia	**Not in attendance**
Oklahoma University Medical Center	**Revise and re-present**
Oregon Health Science University	**n/a**
University of Colorado	**Revise and re-present**
University of Michigan	**Revise and re-present**
University of Tennessee	**Not in attendance**
University of Vermont	**Not in attendance**
University of Utah	**Revise and re-present**
University of Virginia	**Revise and re-present**
Vanderbilt	**Not in attendance**

Final – Revise and re-present

Presentation 2 – Re-presenting:

Title: Impact of deviations of intraoperative blood pressure on adverse outcomes in thoracic surgical patients: A report from the Multicenter Perioperative Outcomes Group

Proposed Authors: Michael R. Bronsert, PhD, MS, Jules Lin, MD, Sachin Kheterpal, MD, MBA, Leslie C. Jameson, MD, Elizabeth Juarez-Colunga, PhD, Karl E. Hammermeister, MD, William G. Henderson, MPH, PhD, on behalf of the Multicenter Perioperative Outcomes Group (MPOG) Perioperative Clinical Research Committee

Primary Institution: University of Colorado

Presented by: Robert A. Meguid, MD, MPH

Discussion Points:

- Outstanding Concerns:
    - Lack of patient specific concepts around baseline blood pressure in thoracic surgery patients that do not have cardiopulmonary bypass looking at blood pressre variation and if they lead to adverse events.
        - Clarifying an overlap with U of Tennessee regarding cardiac patients. Can it be expanded to all patient and define blood pressure
        - Using population definition of normotension using standard definitions of a population cohort vs. using patient definitions.
    - This project may have overlap with the Tennessee project and determine if one combined project is necessary or if we can divide into two projects and specifically state that in a publication
        - Drs. Kheterpal, Craft, Epps, Meguid and Tremper decided there is no overlap with the two manuscripts and they will remain focused on their original ideas. We will revisit a larger study at a later date.
- Dr. Meguid: Responses to previous feedback:
    - Methodology to determine a normal blood pressure. There is variability of patients who have hypertension at normal baseline. To account for that we have revised our methodology. 1.b.i Determine individual patient baseline blood pressures using data in preop to determine the individual blood pressure and this will help us to compare their interoperative deviation.
    - Using preop H&P text based data to do the risk adjustment.
    - We have not seen the actual data and at this time we are unaware of the limitation of the data. We will utilize the data given to maximize identity of preoperative co-morbidities.
    - Outcomes have remained the same.
- Dr. Pace: Section 1.ii: There are a number of summary measures. This suggests that you can have models of each as the appropriate way to describe the blood pressure variability. How can infrences can be made with so many models. Is there a potential to remove the models we do not like and kick them out of the study.

- Bill: Doing a similar project and in section 1.b.ii: That was the initial approach to the analysis and we have learned to pare down the study and we are looking at hypotensive study like in 1.b.i: We will take Section 1.b.ii out of the proposal.
    - Do we have a preference for either a correction for multiple testing vs. effect size testing? No suggestions or anything in the surgical literature. The appeal to the different approaches is there will not be a lot of difference in the methodology. It is critical to translate the results to be clinically significant. It will be interesting to see if the results have a large variation. It is good to compare, but have full disclosure of the models, so the reviewers can see how we came to the conclusion or corrected for multiple testing or effect size measure.

Institution	Vote
Academic Medical Center (AMC), Amsterdam	**Not in attendance**
Columbia	**Not in attendance**
Oklahoma University Medical Center	**Accept with minor revision**
Oregon Health Science University	**Accept with minor revision**
University of Colorado	**n/a**
University of Michigan	**Accept with minor revision**
University of Tennessee	**Not in attendance**
University of Vermont	**Not in attendance**
University of Utah	**Accept with minor revision**
University of Virginia	**Accept with minor revision**
Vanderbilt	**Not in attendance**

Final decision – Accept with minor revisions

Presentation 3 – New Proposal:

Title: National trends in intraoperative red blood cell transfusion practice: a report from the Multicenter Perioperative Outcomes Group

Proposed Authors: Fiona Linton, MBBCh, Paul Picton, MD, Elizabeth Jewell MS, Michelle Morris MS, Other collaborators, Sachin Kheterpal, MD

Primary Institution: University of Michigan

Presented by: Fiona Linton, MBBCh

Discussion Points:

- Working on this proposal for some time. Dr. Picton from the University of Michigan is a second author. We welcome collaborators from other institutions. Knowledge of transfusion volumes.

- Did an extensive literature review and there has not been any multicenter studies.
- Dr. Kheterpal: From a statistical perspective we want to identify if there is a significant trend and the null hypothesis is that the trends have not changes (flat line). We will be looking to see if there is a significant variation and what could be the cause. Using the Westing House Rules to see if it goes outside the variation. Main thrust of the paper will be a main trend line with several other lines to show other services.
- Dr. Pace: Concerned about refer to this as a trigger, this is an unproven influence.
    - Picton: It is not a trigger, but it is a useful variable. Trend may be useful, but we may only see a flat line because we are analyzing our worst cases.
    - KKT: Look at the lowest hemoglobin as a target. The surgical trends are changing and surgeries are getting less invasive. Possibly look at the lowest hemoglobin. Using lowest hemoglobin as target.
    - Kheterpal: We have estimated blood loss, but we are not sure how random the blood loss. The bias would be lowest intraoperative hematocrit. We are tolerating lower hemoglobins. This is the new transfusion guidelines are geared to tolerate lower hemoglobins.
    - KKT: Lowest hemoglobin for the first postoperative day. Are we allowing the patient to go through a surgery with a lower hematocrit during surgery?
- Dr. Biggs: Why look at all the years, look at 2007 and 2012 only to see if there is any change, you may not have to look at the years in between. Don't do a trend, but look at two separate times (early and late). Look at lowest hematocrit, we are doing more complex procedures now. Use this as a 'sniff test' to determine if there is a variable.
- Dr. Pace: In favor of looking for trends, because we don't know if there were variables from year to year.
    - Dr. Biggs – not opposed to trend, but to look if there was any changes at the path.
    - There are a lot of statistical techniques for handling a parametric or non-parametric bases to get an idea as to how much variance we have.
- Dr. Kheterpal: Should we be focusing on discretionary units?
- Dr. Aziz: Looking at the timing and the lowest hematoglobin during the case and whether they got a transfusion.
- Dr. Fernandez-Bustemente: Look at the instability change, this will be a bias whether you transfuse or not during the case. Threshold will be different. Known limitation – absence of hemodynamic data.
- Dr. Picton: Discretionary use will be more interesting. Will it be difficult to pull data?
    - Dr. Kheterpal – no, this will not be a problem.
    - KKT: Are you defining discretionary as one or two units? (Kheterpal – yes). Timing would be a factor also (If you get three units over a ten hour case vs. a two hour case).
- Pace: Include everything. If you are trying to describe what is going on, then you include everything.
    - Kheterpal: Plan subgroup analysis.
- Identify a separate trend of ischemic heart disease of value? It will take a lot of work to clean the data, do people think this will add value?
- Dr. Tremper: Yes, I believe this will add value because people with ischemic heart disease are more cautious. Anyone else? Ana/Aziz

- Emergency cases: Exclude or have the primary analysis exclude emergency and have the primary analysis be non-emergency and a sub analysis of the emergency cases. Would like a decision on how to handle emergency cases.
    - Concensus is to exclude the emergency cases.
- Dr. Pace: The title of the paper says national trends and so you should look at everything. If not change the title of the paper. If you are trying to describe what is going on, then include them into the paper. The title is the trends and does not exclude emergency cases.
- Should we do this for JAMA or BMJ or should we format for Anesthesiology? See what the results are and then see if they are impressive enough to submit to a higher level journal.
- Any thoughts on changes? Anything on any other blood products – no commentary for FFP, Cryo, etc. We are not reporting them and consciously looking at RBC use.
    - Dr. Aziz: Do not avoid the patients, they are relevant. Leave those patients in the analyses.

Institution	Vote
Academic Medical Center (AMC), Amsterdam	**Not on call**
Columbia	**Not on call**
Oklahoma University Medical Center	**Approve with minor revisions**
Oregon Health Science University	**Approve with minor revisions**
University of Colorado	**Approve with minor revisions**
University of Michigan	**n/a**
University of Tennessee	**Not on call**
University of Vermont	**Not on call**
University of Utah	**Approve with minor**
University of Virginia	**Approve with minor**
Vanderbilt	**Not on call**

Final Vote: Approve with minor revisions – no re-presentation.

DE-ID information will be put on a later agenda

Dr. Ehrenfeld and Damon Michael will present on de-identifying data. We will allocate 45-minutes to an hour at the next PCRC Meeting. There are conversations on making more comprehensive free-text data scrubbing. We have scrubbed the data at a local level, but there are concerns with the 'free text' areas of the database. If a name is misspelled in a free text field, it will come up. There is nothing in the policy that each site should do if they come across PHI in free text areas.

The discussion at the next meeting will be determining the best methods to scrub the data to make it a true limited dataset. We want to look at a process to report PHI that slips by the scrubbers to put a new policy in place for MPOG.