PCRC Meeting Notes – Jan 13, 2012

Attendees

Vermont – Bill Paganelli and Alex Friend

MGH – Ed Bittner

Columbia – Mitch Berman not on call. Will listen to audio recording later

Tennessee – Jerry Epps and Robert Craft

Michigan – Sachin Kheterpal, Kevin Tremper, Amy Shanks, Tory Lacca, Krishna Ramachandran (Guest), Milo Engoren(Guest)

Colorado – Leslie Jameson is not on call. Will listen to audio recording later

Oregon – Ken Abbey and Mike Aziz

Guest sites – Santa Barbara Cottage hospital – might join in

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.

General Questions and Discussion Elements:

1. Who decides the answer to if a proposal is approved?
    a. MPOG by-laws state that each institution gets one vote, not one vote per person. Therefore each site must agree on the final conclusion to a single vote
2. If PCRC is reviewing a protocol that is getting data that only a few sites contribute, do only those contributing sites vote or every site?
    a. Primary voters are those sites contributing the data. However, we ask that all sites still give constructive feedback to the overall research proposal.
3. Is anybody uncomfortable with an open vote on proposals while we are still a family of 7?
    a. No one spoke that there were uncomfortable. However, in a year or two we may need to have an editorial board to serve as a review board down the road.

Presentations:

Title: Infusion Pump Alarm Limits Determined from EMR Usage Data
Proposed Authors: Leon Freudzon, MD[1], Shuang Wang, PhD[2] and Sachin Kheterpal, MD, MBA Mitchell Berman, MD, MPH[3],
Primary institution: Columbia University

- Sachin Kheterpal presented the research protocol for Mitch Berman who is on vacation

Discussion points

- Report EMR limits for each infusion by site
  - Picis makes a recommended limit but it's not binding.
  - First author needs to see the limits from each site to reflect different practice around the parameters.
  - Look at hand entered comments for all infusions within the AIMS
- Do we need to be concerned that some limits have changed over time since 2004? For example, Dex was used conservative with upper limits and now it's gone up in the years since. The ranges have changed over the interval of MPOG data that can be accessed.
  - Descriptive analysis to look year by year first to see what is happening. May not need data from 2004. May only need two years of data
  - Dose changes have changed from 2004 to current. The suggestion to look over time year by year for descriptive perspectives was proposed
  - Focus on contemporary data only from 2010-2011 was suggested
- Center effects? Should we look by institution? Would that add to scientific value?
  - Several MPOG members thought this would be interesting. Potentially even look at it by region of the United States.
  - Start with descriptive or exploratory analysis to see if there is significant variation between institution or region
- Any other drugs we should be looking at? Suggestions included;
  - Vasoactive agents
  - Neuromuscular blockade
  - Chose things that people don't tend to use as much in daily practice because they are not as familiar with the dosing
- Impact of study on the Anesthesiology community
  - PCRC group thinks it will have a moderate impact and serve as brief communication in A&A
- Look at outcomes within NSQIP
  - Consensus was not make this project that complicated
  - However, the need to determine threshold for dangerous alarms was discussed and felt a reasonable suggestion

<u>Voting</u>
Oregon: Accept with minor revisions
Vermont: Accept with minor revisions
MGH: Accept with minor revisions
Michigan: Accept with minor revisions
Tennessee: Accept with minor revisions
Status: Accept with minor revisions

[1] Resident
[2] Statistician, Mailman School of Public Health, Columbia University
[3] Attending Physician

Title: Predictors of perioperative pulmonary complications in non-cardiac surgeries
Proposed authors: Ken Abbey, MD, JD, Jeffrey Kirsch, MD, Stephen Robinson, MD, Brett Shepard, MD, Darrell Campbell, PhD, MD, Kevin K. Tremper, MD, PhD, Sachin Kheterpal, MD, MBA
Primary Institution: OHSU

- Ken Abbey presented the study to PCRC

Discussion Points

- How many MPOG sites will be obtaining NSQIP quickly?
    - Currently MPOG has a very small subset of all the cases with NSQIP data. MPOG will have approximately 17,000 from Michigan and OHSU. Columbia should be submitting NSQIP data in the coming months
- Preoperative covariates is NOT the focus of this project. However, we must control for them. OHSU is really interested in what is happening in the OR.
- Worry that there may not be enough cases to speak about cases in the low-risk quartile because there may not be enough events
- In addition, since this study using NSQIP data, the surgeons will also vote on this as well as those are giving NSQIP data to MPOG
- Should we focus on a particular patient population?
    - Describe variability in a patient population and just do a descriptive analysis first across a couple institutions or several institutions.
    - We can do this without NSQIP so we have more patients and more institutions. As we identify variability, then we could go onto NSQIP outcomes or billing data outcomes
        - The PCRC group voted for yes, this was a good idea and can answer the question "What people really do?"
- Are there outcomes that we can use that don't require NSQIP data? How do we get reliable and useful outcomes without NSQIP data?
    - Could go after a billing code data abstraction but that is 8-12 months down the road
        - Use billing codes for hospital discharge with pulmonary complications
- Should we look at post-op complication form for immediate postop complications?
    - Some sites have this type of reporting
    - People are concerned with under reporting and not every site have great post-op visits rates
- Should we break up into this proposal into separate papers?
    - Look at variability first
- If plan on using ICD-9 codes to obtain a large sample size, should we just wait for those codes to become available in MPOG? What is the best use of research time?
    - No definitive conclusion was decided
- Should the focus just be on high risk patients?
    - If we do that now, we may not have the power
    - If we look at high risk patients and use a smaller subset, then it probably makes more sense to wait
- Low and medium risk patients may be hard to find rare events
- Ken Abbey thoughts on how to move forward
    - Combine risk stratified (high risk group) and do an initial paper that looks at variability and treatment for intraoperative management
    - Do second paper with outcome data with ICD-9 codes
- How to identify high-risk patients?

    - Across 7 centers when the same patients with the same operations with similar preop risk factors, what's the intraop variation? Cluster at provider and center level
        - This paper would inform the second paper on variation to outcome
    - Interested in looking at DeVinci population
- As reviewer, would you publish variability of treatment without outcome data?
    - Vote for interesting from Bittner but he might want to defer to outcome data
    - Ramachandran finds variability an interesting question but worries about how it would change care
    - Suggestions for Ken Abbey to speak with Jim Blum (Michigan) as he has tried to publish similar data as well. His was accepted with single center data
- Come up with post-op complications with ICD-9 codes a year from now and not have to use NSQIP
- Is it worth effort and pulling data now to look at NSQIP outcome data to see the power and if we have enough now?

<u>Vote</u>

Michigan: Revise and reconsider (preliminarily pull the data and see how many high risk patients we have currently in MPOG)

Oregon: Revise and reconsider

Status: Revise and reconsider

Title: Predictors and outcomes of postoperative acute kidney injury after non-cardiovascular surgery

Proposed Authors: Sachin Kheterpal, MD, MBA, Milo Engoren, MD, Amy Shanks, MS, Kevin K. Tremper, PhD, MD

Primary Institution: Michigan

- Sachin Kheterpal presented the proposal

Discussion Points

- How are you going to adjust for cause and effect. For example, inotropic usage?
    - Right now just univariate associations. Currently we cannot isolate treatment bias right now using propensity scores. Sachin understands this cannot be isolated right now and is not interested in trying it right now either.
- Look at I/O
    - Make sure that you lose XXX and replace XXX quickly
    - However, how well is fluid documented?
        - Michigan – 30 minute fluid window, 5 minute drug window for documentation
        - Blood loss is documented episodically
- Thoughts are that fluids are hard to handle…should you even consider fluids?
    - Look at hourly fluid balance and look at net negative, net positive and management
        - Create an out of balance score to say how long were you out of balance and how long were you out of balance
- Generally, Sachin would like to confirm preoperative and hint at intraoperative and not focus on fluids because it opens a massive can of worms depending on specific surgery
- Sachin recommends keeping fluids out and looking at intraoperative hypotension and vasopressors. He questions to the group, would that be meaningful?
    - Epps feels fluids needs to be spoken about in the analysis and not leave them out
    - Engoren need fluid balance from OR even if it's not grossly accurate
- Sachin has discussed a fluid management chart
    - Group feels it's a good idea
    - Need to check how much blood volume is in a bag via the blood bank for each blood product type
- Sachin questioned do we still include blood as a separate concept from fluid?
    - Yes blood should be a separate component from fluid
- Blood pressure concepts and AKI: Look at absolutes and relatives
    - Yes include both absolute and relative
- Hemodynamics – Include CVPs?
    - Michigan hardly uses CVP for non-cardiac operations
    - Oregon is variable use for CVP but pretty often they do
    - Need to be careful how CVP is zeroed and drift at each institution
    - For livers, people run low CVP's
    - Engoren is worried about high CVP to reflect decrease in renal pressure
- Should we use SPV?
    - Performed and recorded manually with great variation at Michigan. Kheterpal is less trusting of SPV at Michigan and TOF ratios

- BP variability and liability
    - Kheterpal will dig into the best definitions of what is variability
    - Assess using area under the curve
- Pulse pressure

Vote

MGH: Accept with minor revisions

Vermont: Accept with minor revisions

Tennessee: Accept with minor revisions

Oregon: Accept with minor revisions

Michigan: Accept with minor revisions

Status: Accept with minor revisions

General Discussion to PCRC Process and Feedback

- Yes it was positive….. rigorous but collaborative peer review process
- Should we have intermediate data step review to see how they are going?
    - Should we update MPOG members to report what we are finding as we pull that data?
    - Some sites are interested in data updates as the process is moving along
    - Would like to have feedback about data snags and problems that have been encountered
- Once it's approved with "accept with minor revisions" then the member submits to the group again. If not problems reported within 10 days then the investigator can move forward
- Once the manuscript is done, submit to the group to answer the question "Did we answer the research hypothesis?"
    - Each group that contributed data can add to opinions
    - Ensure that MPOG approved protocol analysis is actually completed and not something different