Multicenter Perioperative Outcomes Group (MPOG)
PCRC Meeting Notes – Monday, February 13, 2017

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

P	Ben Abdullah (Wash U)	**P**	Bhiken Naik (Virginia)
P	Michael Avidan (Wash U)	**P**	Nathan Pace (Utah)
P	Joshua Berris (Beaumont)	**P**	William Paganelli (Vermont)
P	Dan Biggs (Oklahoma)	**P**	Wietze Pasma (Utrecht)
P	Michael Burns (Michigan)	**P**	Karen Posner (Washington)
P	Ruth Cassidy (Michigan)	**P**	Leif Saager (Michigan)
P	Ken Cummings (Cleveland Clinic)	**P**	Rob Sanders (Wisconsin)
P	Alex Evers (Wash U)	**P**	Robert Schoenberger (Yale)
P	William Hightower (Henry Ford)	**P**	Nirav Shah (Michigan)
P	Shelley Housey (Michigan)	**P**	Amy Shanks (Michigan)
P	Ken Johnson (Utah)	**P**	Anshuman Sharma (Wash U)
P	Sachin Kheterpal (Michigan)	**P**	Ami Stuart (Utah)
P	Kai Kuck (Utah)	**P**	Allie Thompson (Michigan)
P	Tory Lacca (Michigan)	**P**	Kevin Tremper (Michigan)
P	Kamal Maheshwari (Cleveland Clinic)	**P**	John Vandervest (Michigan)
P	Sean Mackey (Stanford)	**P**	Jonathan Wanderer (Vanderbilt)
P	Michael Mathis (Michigan)	**P**	Troy Wildes (Wash U)

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.

EOS Presentations:

Joint EOS-4, 9 & 10. Postoperative pain profiles, analgesic use and transition to opioid misuse and chronic pain

Presenter: Kai Kuck (Utah)

- Are you quantifying pain expectations as part of the study? Would be helpful to understand whether what happens matches what people expect to happen with regard to pain.
    - Excellent idea to include pain expectations; will consider revising survey to include

- Postoperative follow up success rate might be optimistic; unclear from proposal how to treat missing data if there is not a good post-operative response rate
    - Issue about whether there is a difference in drop out between those who develop pain vs. those who do not, or is there dropout across the entire group? Plan to compare baseline characteristics to determine differences.
    - There will be no imputation of outcome data

- Special issues in Anesthesiology and A&A on opioid use indicate this is a "hot topic"; great timeliness; should keep this in mind when considering this proposal

- This project provides the opportunity to use newer statistical techniques and improved covariate selection.

- Opportunity for anesthesiologists to investigate influence on patient outcome on opioid use and patient pain; perioperative surgical home – what we do in the operating room may modify the post-operative course; example of how anesthesiologists can improve care to impact patient outcomes

- How are you defining "chronic pain" primary outcome at 1 and 3 months - is it any opioid consumption at 3 months or daily opioid consumption? Also, what if someone had a subsequent surgery within that time frame, which explains the opioid use?
    - Should be able to tease out subsequent surgeries; chronic pain use is defined as continuously using opioids at 3 months; will identify potential source of pain at 3 months as well

- Great that patient-perspective outcomes are included in proposal (pain, sleep, depression, etc.); may want to consider adding in outcome of return of "function" (perhaps "return to work")

EOS-11. Pragmatic evaluation of neurologic, cardiopulmonary, and infectious complications after major surgery

Presenter: Sachin Kheterpal (Michigan)

- Unclear on the precision medicine device mentioned in pre-op description of proposal
    - NIH is using this device for the precision medicine study population; validated device

- This proposal requires the collection of a large amount of data and seems incremental over already collected datasets (NSQIP); how groundbreaking is this data?
    - No individual outcomes are groundbreaking, but novelty is the intermediate measurements prior to the outcome; intermediate measurements (spirometry, meaningful measures of oxygen, etc.) are more valuable and help explain why outcomes may occur; not just outcome but full pathophysiology view

- IRB concern over using devices or taking measurements since previous IRB encounter considered these as interventional and NOT observational
    - Previously UM IRB granted waiver of informed consent as standard of care and not an intervention (BIS); Spirometer is FDA approved medical device; there may be variation among IRBs with which deem this observational and waiver of written consent; verbal informed consent will most likely be required

- Although this proposal looks "daunting" we do not full understand what is happening to patients in the immediate perioperative period that may mitigate outcomes; no other datasets are helping to answer this missing puzzle piece

- Consider baseline cognitive testing (clock)

- Would be helpful to have dictionary of baseline characteristics that we think people are collecting

- Consider including grip strength measure devices, which can give a good indication of patient frailty

- Another advantage of this project is that it spans several domains and this project invites collaboration between multiple investigators and multiple projects; delve into each organ system with separate project and different coinvestigators to lead; lends itself to multiple focused downstream projects

- Some institutions may not be able to participate due to lack of research infrastructure

- Since you are including emergency surgeries, consider keeping in baseline neurologic assessment

- Selection bias - how do we select the patients?
    - Plan is to approach all eligible patients each day; assume a 50% consent rate (even though see higher consent rates for other studies); may be selection bias in who consents but not who is eligible
    - Inpatient criterion limits eligible study population

EOS-19. Variations and outcomes in heart failure medication management for non-cardiac surgery

Presenter: Michael Avidan (Michigan)

- Has appendix 2 questionnaire been pre-tested since it will be administered to the patients and there are a lot of medication classes listed on there that patients may not be familiar with
    - No formal testing of questionnaire, but research personnel will provide list of generic and trade-name examples for each of the main medication categories; this is also a good opportunity to test patient's literacy for what medications they are on and whether they know what the medications are for (comparing to anesthesiologist H&P)

- Please provide more detail on statistical analysis; requires large number of participants; may require epic rebuild to infrastructure to participate
    - Can assess comfort by site on imbedding the elements in H&P or can put the burden more on the research personnel if sites are not comfortable doing that; keep in mind that this would not be a permanent change but rather a change for 2-4 weeks only
    - Ideally target 10 patients for prevalence sample and specifically target the known perioperative heart failure group; ensure that all known heart failure patients are interviewed based on pre-screen by research personnel conducted the prior day
    - We are not just targeting patients with HF diagnosis, but rather patients that may not have the overt diagnosis but have features of heart failure and are on medications related to it

- Will study personnel flag patients as being in the prevalence vs. known HF sample?
    - Yes, patients will be flagged