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

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

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

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.

Special Lecture:

Title: Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

Presenter: Dr. Jesse Ehrenfeld - Vanderbilt

- Dr. Ehrenfeld presented De-Identification – see Appendix A.
- We need to come up with a more robust free text scrubber. The committee is very supportive of this project.
- Dr. Kheterpal. The current scrubber is not designed to deal with dictations, but to deal with Anesthesia notes.
  - In the future we will import admission notes, radiology notes, etc. This may potentially cause problems with the de-identification of the data. If we have a valid alternative that is not the MPOG scrubber then we will be supportive of implementing it to MPOG.
- Dr. Biggs: When I was validating data for Dr. Aziz's study I came across staff PHI.
  - Dr. Kheterpal: We will worry about patient PHI first and then after we have that under control we will work on the staff identification.
- Dr. Aziz: I understanding the presentation goals. My question is that if our IRB is fine with what we are doing, then why does Vanderbilt care what we do with our data?
  - Dr. Ehrenfeld. The purpose of the presentation is that if when you are reviewing any data from Vanderbilt and you come across a breech, you need to report this to Vanderbilt.
  - Ultimately, the goal is to document the De-identification process and potentially lead to some changes in the legal documentation (DUA).
- Dr. Kheterpal action items:
  - Dig into documentation with Dr. Ehrenfeld, look at the missed items and how to integrate the software.
  - Come up with a disclosure plan.
  - We want to make significant progress by the ASA Annual Meeting.

- Dr. Pace: If you identify aspects that change the DUA are we going to be making addendums to the all the DUAs?
  - Dr. Kheterpal: We will look into this information.
  - Dr. Pace: It makes sense that all the MPOG sites should follow the same process. If this is a problem, then we need an MPOG wide solution.
- Dr. Kheterpal: We will look into this and work with our lawyer at the University of Michigan. After we determine the best course of action, each institution will be contacted and given assistance with the new documentation and process. The goal is to have consistency. We want to self-police the process to ensure that we do not make any mistakes that will potentially bring harsher regulations from the government.
- Dr. Ehrenfeld: I have been in talks key members in Washington in attempts to make the process easier for groups like MPOG and to ensure there will be better language in the policies. He will keep the group informed of his continued efforts.
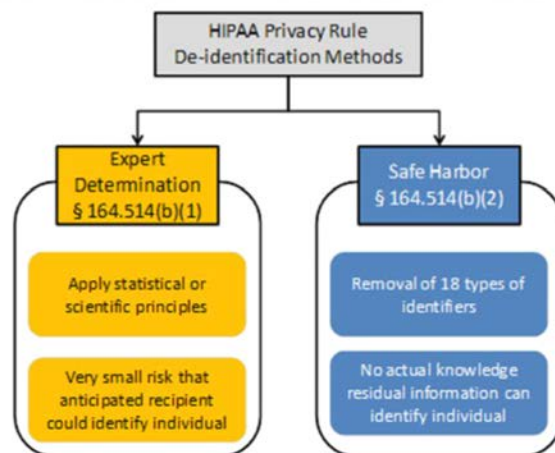
Updates and Annual Meeting Overview:
- Difficult Mask Ventilation: Best abstract and the paper was accepted and will be published in the December Anesthesiology. A link has been added to the website for the location of the poster presentation at the ASA Meeting.
- Dr. Aziz is working with sites to manually review the concepts for the DL project in order to turn it into a manuscript.
- We are aware that the data extraction is becoming a rate limiting step. We appreciate your patience. We knew the first few projects would be more difficult, but we are happy with the results so far and are working out the bugs.
- Scientific Advisory Board (SAB), we wanted to invite individuals who are not anesthesiologists to be on the board. For the first SAB, Dr. Kheterpal has invited several members to participate. Going forward we will have elections and input from the Executive Committee. The first group has been invited and have accepted:
  - Francois de Brantes, Executive Director for the Health Care incentives Improvement Institute, he will provide the payer perspective.
  - Paul Taheri, MD, MBA, Deputy Dean and Chief Executive Officer of Yale Medical Group. He is the head of faculty group practice at Yale. He is a national leader who is respected for thinking outside the box.
  - Sachin Jain, MD, MBA, Chief Medical Information and Innovation Officer for Merck. He will bring the industry perspective to the group. Dr. Jain will not be available for the SAB meeting in San Francisco, but we will be asking Thomas Tsang, MD, Global Director for Health Information Partnerships, Business Development and Strategy at Merck to attend for Dr. Jain.
  - Michael O'Reilly, MD, MS, Vice President for Medical Technology for Apple Corporation. He used to be a faculty on staff at the University of Michigan and went to Massimo Corporation and now works as a VP for Apple.
- As we move forward in the coming years, we would like to receive your input and suggestions for members to the SAB.

Appendix A – Presentation Slides

Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule

http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/De-identification/guidance.html#protected

De-Identification Methods

Expert Determination Method

Implementation specifications: requirements for de-identification of protected health information. A covered entity may determine that health information is not individually identifiable health information only if:

(1) A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:
(i) Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and
(ii) Documents the methods and results of the analysis that justify such determination;

Safe Harbor Method

The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

1. Names
2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP code, and their equivalent geocodes, except for the initial three digits of the ZIP code if, according to the current publicly available data from the Bureau of the Census:
(1) The geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people; and
(2) The initial three digits of a ZIP code for all such geographic units containing 20,000 or fewer people is changed to 000
3. All elements of dates (except year) for dates that are directly related to an individual, including birth date, admission date, discharge date, death date, and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older

4. Telephone numbers
5. Fax numbers
6. Email addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial numbers, including license plate numbers
13. Device identifiers and serial numbers
14. Web Universal Resource Locators (URLs)
15. Internet Protocol (IP) addresses
16. Biometric identifiers, including finger and voice prints
17. Full-face photographs and any comparable images
18. Any other unique identifying number, characteristic, or code, except as permitted by paragraph (c) of this section [Paragraph (c) is presented below in the section "Re-identification"]; and

De-Identification Methods
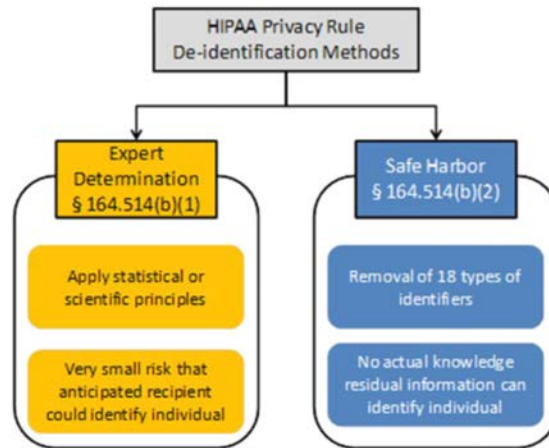
Data Scrubber Certification
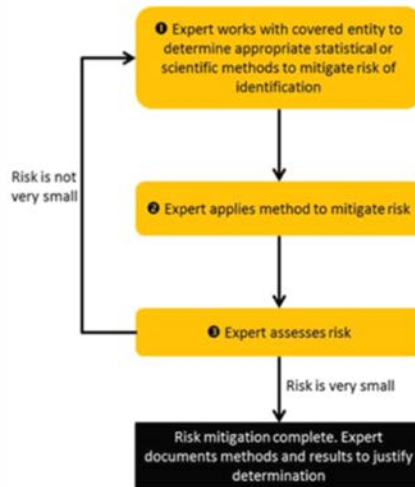
Process for expert determination of de-Identification.

✓ Must be generalizable to other Institutions!

Vanderbilt Validation Plan

After lengthy discussions with our IRB, legal counsel, privacy office, and national privacy experts, we determined that in order to contribute free text we must:

1. Modify the MPOG Data Use Agreement to make ensure we are fully compliant with legal requirements
2. Run our free text through a more robust, previously validated filter (MIST), and repeat our prior analysis to determine the amount of PHI that is slipping through
3. Fully document our de-identification process

Recommendations for MPOG Steering Committee

- Standardize the PHI filtering process at all participating institutions that are contributing free text
- Standardize the validation process for evaluating the local efficacy of the PHI filter at each institution
- When errors occur, create a detailed reporting process. This process should include complete documentation of errors and how they can be corrected in the future. This information will then be disseminated to each individual site so they can follow the corrective action plan
- Each site contributing free text should meet with their IRB, privacy office, and legal counsel to obtain approval for their individual processes

Proposed Change to Data Use Agreement

- Modify Participants Obligations:
  - require and establish clear procedures for reporting discovery or disclosure of PHI (timeframe, reporting structure, corrective action plan)
- Modify Michigan Obligations:
  - Provide to participants within 5 business days of discovery of a PHI breach:
    - the date of the breach & the date of the discovery of the breach;
    - a description of the types of unsecured PHI that were involved;
    - identification of each individual whose unsecured PHI has been, or is reasonably believed to have been, accessed, acquired, or disclosed; and
    - any other details needed to complete an assessment of the risk of harm to the individual.
  - Participant will be responsible to provide notification to individuals whose unsecured PHI has been disclosed, as well as the Secretary and the media, as required by Sec. 13402 of the HITECH Act, 42 U.S.C.A. § 17932;
  - Michigan agrees to establish procedures to investigate the breach, mitigate losses, and protect against any future breaches, and to provide a description of these procedures and the specific findings of the investigation to Participant in the time and manner reasonably requested by Participant.

Process for Correcting Errors

- Identify Error
- Completely document error
  - Type of Error
  - Number of Records affected
  - Recommended corrective action, if known at site level
  - Report error to regulatory bodies if necessary
- Report the error to MPOG
- MPOG reviews & develops a resolution to the error
- MPOG provides sites with instructions on resolution
- Sites implement resolution