Multicenter Perioperative Outcomes Group (MPOG) and Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) Protocol

Project Summary

The Multicenter Perioperative Outcomes Group (MPOG) is a consortium of anesthesiology departments of academic medical centers with electronic perioperative information systems. The purpose of MPOG is to allow multi-institutional collaboration for the purpose of accelerating outcomes research in perioperative medicine. The Anesthesiology Performance Improvement and Reporting Exchange (ASPIRE) is the quality arm of MPOG and is focused on using data to assess variation in practice, identify local/regional best practices, measure process adherence and patient outcomes, create programs for quality improvement, and enable collaboration among anesthesiologists, surgeons, and CRNAs. ASPIRE will also develop research topics which will lead to quality assurance research projects.

MPOG was developed so that institutions across the globe can join together to pool their electronic perioperative data into a common research database. These limited datasets (only date-of-service will be uploaded into the repository) are used for clinical outcomes and quality assurance research purposes by the members of participating institutions. The database will also include administrative information and outcomes data. The MPOG Coordinating Center, housed at the University of Michigan, receives and merges the limited dataset into one centralized data repository.

This protocol describes University of Michigan's role as a performance site and Coordinating Center for MPOG. As a performance site, the University of Michigan uploads a limited dataset from our anesthesia electronic information systems to the MPOG Coordinating Center repository (HUM00024166). MPOG has a Perioperative Clinical Research Committee (PCRC) which is comprised of members of institutions who are contributing data. The PCRC serves as the publication committee of MPOG responsible for reviewing, refining, and modifying any research proposals and manuscripts created by researchers at active/contributing institutions. All proposed research studies using data from the central MPOG database must pass a peer-review process by the PCRC prior to submission for publication.

Patients included will be from all age groups and all medical conditions. There are no exclusions. All data are scrubbed for any identifiable information prior to sending to MPOG central repository for merging into a MPOG database. There are no patient identifiers stored in the MPOG central repository and no members of the research team will ever have access to identifiers. Automated database extraction process is performed on secure UMHS servers. The only PHI element collected will be date-of-service.

Background

The traditional prospective, randomized controlled trial (RCT) is a mainstay of medical research. However, although RCTs are regarding as the gold standard of medical research, there are many clinical conundrums that cannot be effectively addressed by a prospective RCT. Observational studies are often the only option for research into

- Infrequent adverse events associated with a medication
- Emergency operations challenging conventional consent and randomization systems
- Generic medications without a reliable pharmaceutical funding sources
- Safety studies of medical procedures
- Ethnic and racial groups that are not appropriately represented in prospective RCTs
- Rare perioperative events
- Efficacy and safety of a treatment once applied to a broad patient population as opposed to specifically targeted group in an RCT

For these and many other clinical questions, the only practical research structure is a large observational dataset based upon existing information system data elements. By combining point-of-care clinical information systems with clinical registries, financial data, laboratory information systems, radiology information systems, administrative datasets, and scheduling datasets, one can address previously unanswerable clinical questions. Though causality cannot be concluded, these hypothesis generating studies are crucial to the advancement of clinical science.

Specifically, the field of perioperative medicine has witnessed a major improvement in safety over the last few decades. As a result, many of the morbidity endpoints (death, myocardial infarction, pulmonary complications, nerve injury) previously followed are now occurring with a frequency far too low (< 1%) for prospective enrollment in controlled trials. However, the importance of these morbidity endpoints cannot be diminished for the patients and families experiencing them. Alternative study techniques must be used to continue the necessary improvements in patient safety and satisfaction.

Recent literature has demonstrated the value of large dataset research in altering clinical practice. The widespread use of beta blockers for moderate risk patients and the routine use of aprotinin for cardiac surgery have both been called into question as a result of large clinical dataset research. These landmark hypothesis generating studies then led to large RCT that eventually identified an unacceptable risk profile for certain patients, leading to major changes in the perioperative use of these drugs.

Objective

To identify the perioperative adverse events, and changes in resource utilization associated with variation in perioperative management. Create quality measures focusing on quality improvement and as a result will include quality focused research.

Specific Aims

1. To aggregate patient data enabling investigation of infrequent adverse events, patient conditions, and operations
2. To allow our institution to gain access to a large, international limited dataset necessary for observational and quality research
3. To combine detailed physiologic data and anesthesiology interventions with long term outcomes recorded in surgical outcomes, administrative, and financial databases

Investigator Expertise

Dr. Kheterpal is a Professor in the Department of Anesthesiology with expertise in perioperative clinical outcomes research. He has served as a systems designer, database architect, and data warehouse architect for over 15 years, creating a deep information technology and clinical informatics

knowledgebase. He has previously used retrospective analysis of clinical documentation databases to publish studies in leading peer-reviewed anesthesiology journals. In addition, he has served as a representative to the anesthesia patient safety foundation.

Dr. Shah is an assistant professor in the Department of Anesthesiology with expertise in medical informatics and quality. He is the Director of Informatics and Systems Integration for the Department of Anesthesiology and the University of Michigan Health System. He has served as a systems designer, database architect both in industry and at academic institution for over 10 years. He brings a technical and medical background that will help to integrate the software and analytic system.

Inclusion/Exclusion Criteria

As a participating site, all adult and pediatric patients undergoing perioperative services at the Michigan Medicine are included. There are no exclusion criteria.

Methodology[1]

The perioperative clinical information system, several UMHS surgical outcome databases, laboratory data, administrative data, and financial data are merged together by data analysts at our institution. The original data already exists in clinical or administrative information systems and was collected by clinical providers and administrative processes as part of routine care. The clinical care delivered and documentation will remain unchanged. The standard data extract and submission do not involve a review of individual patient records for additional data items.

Data Acquisition and Standardization

After anesthetic case data are extracted from the source system, data are integrated with other data sources including institutional research repositories, case data that may also be available from outcome registries (such as an extract of data captured by that site as part of participation in the National Surgical Quality Improvement Project [NSQIP] or Society of Thoracic Surgeons General Thoracic Surgery Database [STS-GTSD]), and other clinical, laboratory, or administrative systems. Data are matched at the participating site based on locally held unique identifiers (such as Medical Record Number or Social Security Number). The unique identifiers are removed before transmission to the Coordinating Center.

Once extracted from the local electronic health record (EHR), perioperative data are mapped to MPOG-developed standardized, semantically interoperable concepts before submission to the central repository. MPOG embraces standardized definitions where available, such as the use of ICD-10 diagnosis codes or Association of Anesthesia Clinical Directors (AACD) anesthesia events, but these are supplemented by an MPOG-specific set of data elements.

Data Validation

Once the mapping process is completed—and before centralized database transmission—data from participating sites are assessed for completeness and accuracy. Our Data Diagnostics tool facilitates the assessment—identifying specific deficiencies across data category, institution, and time domains. MPOG requires a clinically trained site representative to review and attest to data accuracy before each data transmission to the central repository. At the Coordinating Center, the MPOG Director reviews the initial data upload (including the Data Diagnostics information) before it is integrated into the main MPOG database. Participating MPOG sites perform a manual review of a random sample of cases recorded

within the local database before transmission to the centralized database, because some errors may escape detection when assessed at an aggregate level.

In rare situations, research investigators using the centralized or performance site database may observe a rare clinical event that requires additional data extraction. Every case in the centralized repository and at each performance site will have a distinct patient system number (that is randomly generated) that is NOT a patient identifier. This system number is NOT related to or derived from any PHI (ie, name, reg num, DOB, etc). The centralized MPOG repository has no way of using this random system number to link to any patient identifiers. If a rare clinical event that requires additional data extraction is observed, this non-PHI system number will be provided to a performance site. Technical staff at the performance site can access their own source databases in an attempt to link the system number to PHI. This linkage exists in the source clinical information system, not in any research database proposed by this project. If they choose to, the performance site may use this system number to extract and provide additional de-identified clinical data to the Coordinating Center investigators. No patient contact will occur. All additional data extracted would be from existing clinical and administrative data sources.

Removal of Identifiers and Data Transmission

A limited data set is first created locally by removing selected PHI via a customized "scrubbing" tool (leaving only dates and extremes of age) and then transmitted to a centralized MPOG database. The scrubbing tool additionally removes common names that may be entered in the free text. Several dictionaries are preloaded into the scrubbing application including the most common first and last names from the US Census Bureau and the Systematized Nomenclature of Medicine (SNOMED) dictionary to identify health care terminology that should remain with the transfer. Sites may add additional information to be scrubbed such as names, initials, or internal identifiers assigned to providers. All text is examined and passed through the scrubbing utility before upload.

Only after completion of validation procedures and the use of the scrubbing tool does the option of transferring case-level data to the MPOG Coordinating Center become available. Data are transferred into an encrypted repository, checked for validity, and integrated into the MPOG Coordinating Center database. A database table containing patient identifiers and unique case-linking information remains stored at the local site and is not transmitted to the MPOG Coordinating Center.

Automated Handling

Once data are transmitted and integrated into the MPOG Coordinating Center database, the data are available for use within research and quality improvement projects. As specific to the needs of a project, data are subject to focused examination to ensure appropriate values are included.

Data Use

All research projects using MPOG data sets must obtain project-specific IRB approval. Additionally, a detailed proposal must be presented through the monthly MPOG Perioperative Research Committee (PCRC), comprised of MPOG active site principal investigators, site chairs/heads of practice, statisticians, and other interested research faculty. The committee critically reviews and amends the proposal, and subsequently votes to accept, require revisions, or reject the proposal. Before accessing data, research

project proposals are prospectively registered and tracked on the MPOG website which remains accessible to members.

Figure 1 provides an overview of the flow of information through the MPOG consortium, outlining the process of data acquisition at the point of care, importing of data into local and central data registries, and finally, curation of data for research and quality improvement measures.

Statistical Design

A variety of statistical techniques often used for large dataset research will be used. Each approved research question may use distinct techniques, so it is beyond the scope of this document to prospectively delineate a complete statistical plan. Logistic regression modeling (GEE and standard), propensity score matching, cox proportional hazard modeling, and basic univariate comparisons are a few of the many techniques that will be used. Descriptive and inferential statistical techniques will be employed.

Risks

Clinical/Physical/psychological/social/reputation/financial Risk (No risk)

There will be no care interventions, no process changes, no documentation changes, and no alterations to a patient's clinical experience. Providers will not experience any changes in their roles, responsibilities, or care. A limited dataset will be extracted months AFTER the clinical care episode is complete. The database servers employed are not production servers and no application performance changes will be experienced

Privacy Risk (Rarely likelihood of risk)

Theoretically, since patient data is being extracted, there exists a non-zero privacy risk. However, since the data extraction process is automated and the data structures involved separate patient identifiers from the data being extracted, the likelihood is extremely rare. Patient identifiers (DOB, Name, MRN, Insurance account numbers, SSN) are NOT stored or transmitted at any point during the data extraction or transmittal process.

Data Security and Privacy

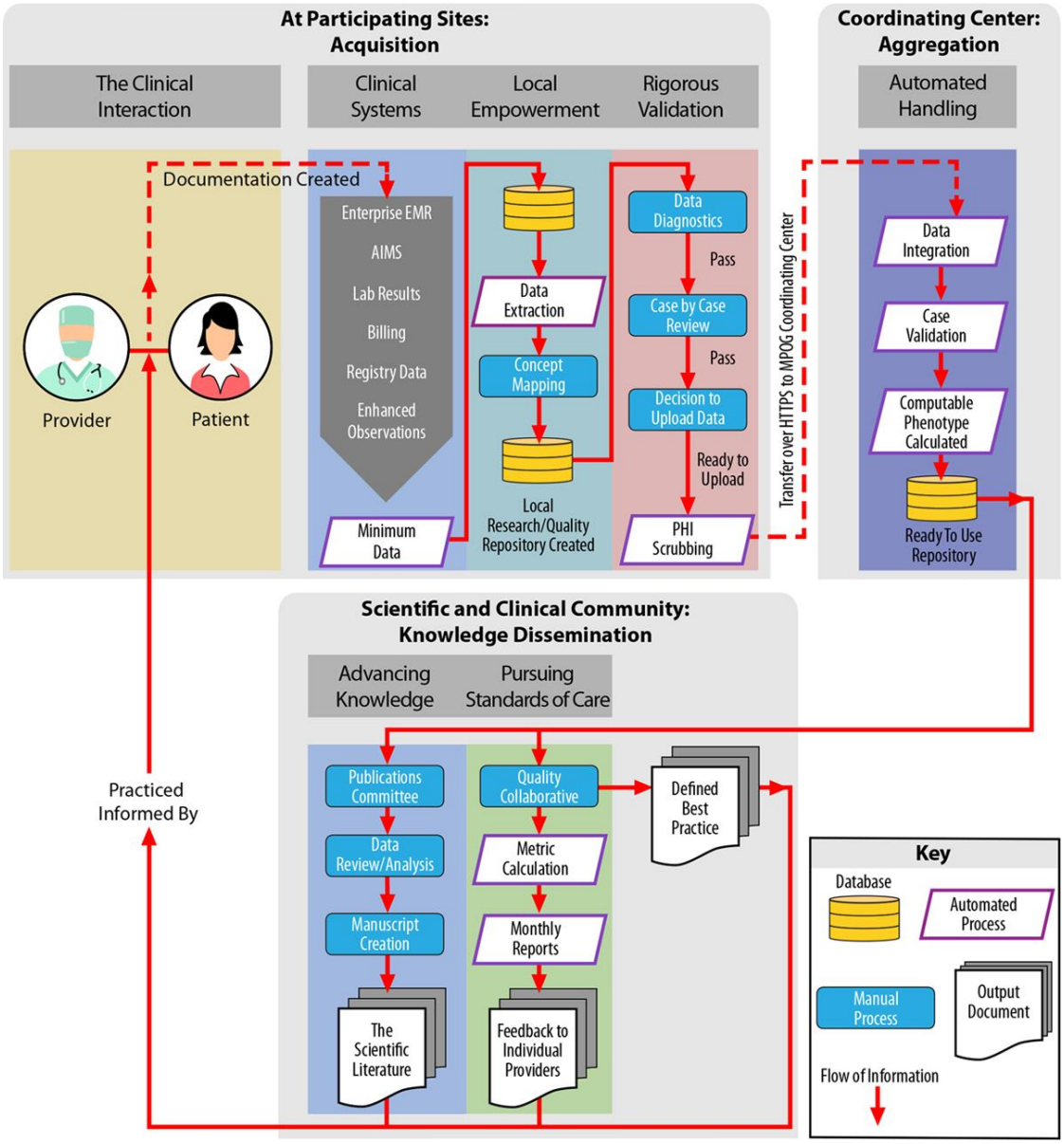
All data extraction processes are automated to eliminate the possibility of human error. No research personnel are required to 'match' or review identifiers. All database work is performed on UMHS-MCIT approved and secured servers, with multiple password security layers for access, that are physically located in the UMHS computing environment and maintained by MCIT security standards. No patient identifiers will ever be stored or transported on portable computing devices (laptops, USB drives, CD, DVD, etc) that can be lost or misplaced.

Data is encrypted using standard relational database management system storage techniques. On a regular basis (semi-annual or annual), new data will be transmitted to the coordinating center. These data will not contain any patient identifiers. The only PHI included will be date of service / surgery. The transmission will be using a secure-socket-layer / transport-layer-security encryption to ensure that data 'eavesdropping' is avoided during transmission of the data to the Coordinating Center.

Only the database mining automated processes will have visibility to the patient identifier and not the statistical team, manuscript authors, or any members of Coordinating Center. All identifiers will be destroyed prior to any members of the study team seeing the data.

An internal perioperative clinical information system number for each operation that is completely unrelated to the patient medical record number or name remains in the data extract. This system number cannot be used to ascertain any PHI regarding the patient unless the perioperative clinical system database is accessed by a database specialist. In rare cases, additional info about a patient may be requested. In that case, a separate IRB application will be submitted to link the internal system number to the perioperative clinical information system.

Figure 1.



Colquhoun DA, Shanks AM, Kapeles SR, et al. *Anesth Analg*. 2020.

References

1. Colquhoun DA, Shanks AM, Kapeles SR, Shah N, Saager L, Vaughn MT, Buehler K, Burns ML, Tremper KK, Freundlich RE, Aziz M, Kheterpal S and Mathis MR. Considerations for Integration of Perioperative Electronic Health Records Across Institutions for Research and Quality Improvement: The Approach Taken by the Multicenter Perioperative Outcomes Group. *Anesth Analg*. 2020;130:1133-1146.