

The Research Process

Developing a PCRC Presentation

Allison Janda, MD

Clinical Lecturer

University of Michigan

Outline

- PCRC website
- Pre-PCRC process
- Writing a proposal
- Designing a query & using DataDirect
- Submitting & presenting your proposal

PCRC Online Resources

- Overview at: <https://mpog.org/pcrc/>



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MULTICENTER PERIOPERATIVE
OUTCOMES GROUP

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Perioperative Clinical Research Committee (PCRC)

The research committee coordinates the clinical research efforts of MPOG, by reviewing all submitted research proposals and tracking the progress of ongoing research projects. The committee ensures the appropriateness of the clinical research conducted within MPOG and the use of MPOG resources. Only colleagues from active MPOG sites can submit a research proposal to the PCRC for review and it is the responsibility of the MPOG site's Principal Investigator (PI) to review all proposals before submission to the PCRC.

The following steps outline the process for submitting a research proposal:

- STEP 1: BEFORE YOU BEGIN
- STEP 2: DETERMINE FEASIBILITY
- STEP 3: WRITE RESEARCH PROJECT SPECIFIC IRB AND DRAFT PCRC PROPOSAL
- STEP 4: DATA QUERY SPECIFICATION
- STEP 5: ESTIMATE MPOG COHORT SAMPLE SIZE / REFINE INCLUSION AND EXCLUSIONS
- STEP 6: INSTITUTIONAL PI PREVIEW AND TEST DATA DOWNLOAD
- STEP 7: SUBMIT PROPOSAL TO COORDINATING CENTER
- STEP 8: PCRC REVIEW

*Some steps completed concurrently

Importance of the “Pre” PCRC Process

- **Before you begin:**
 - DataDirect Security Checklist and Authorization
 - Instructional Modules
- **Determine feasibility:**
 - Consult your local MPOG Site PI (research champion)
 - Is question answerable with MPOG data?
 - DataDirect for sample size estimates

Writing the PCRC Proposal

- Use the PCRC website and checklist
- Some steps done concurrently

STEP 2: DETERMINE FEASIBILITY

STEP 3: WRITE RESEARCH PROJECT SPECIFIC IRB AND DRAFT PCRC PROPOSAL
Completed Concurrently with Steps 4 and 5

After identifying a research question answerable using MPOG data, the primary author must obtain research project-specific IRB approval and draft a PCRC proposal to include the following:

- Cover sheet – one page maximum
- Full study protocol including Introduction, Methods, Statistical Analyses, and References
- Data query specification (see Step Four)
- PCRC Proposal Submission Checklist

Please note that all MPOG research projects require a separate, research project-specific IRB to allow for analysis and use of a limited dataset (containing identifiable information) for research. Language describing the use of the HIPAA-compliant MPOG external statistical server, to potential use included in the IRB, can be found in the IRB application form.

Templates for drafting the PCRC proposal are available here:

- [PCRC Proposal Template \(includes cover sheet and study protocol\)](#)
- [Data query specification create using MPOG DataDirect](#) (See Step Four)
- [PCRC Proposal Submission Checklist](#)

An example of a completed PCRC proposal is available here:

- Example PCRC Proposal
 - [Word Document](#)
 - [PDF](#)
- Example Data Query specification
 - [Word Document](#)
 - [PDF](#)

The primary author must identify an individual or a group within their institution to serve as the statistician(s) on the project. The research proposal should include a curated analytic plan that specifies the statistical techniques and methodologies for analyzing big data. These details are covered in the Cover sheet / study protocol template above.

STEP 4: DATA QUERY SPECIFICATION

STEP 5: ESTIMATE MPOG COHORT SAMPLE SIZE / REFINE INCLUSION AND EXCLUSIONS

Templates & Examples

PCRC Proposal Submission Checklist

Pre-submission preparation:

- Proposal reviewed with institution's MPOG Site PI:
- Proposal discussed with MPOG Coordinating Center member:
- Institutional IRB Complete; IRB number:
 - IRB specifies that the dataset accessed is a Limited Dataset (i.e. *NOT* de-identified)
- Cohort Sample Size Estimated using MPOG DataDirect
- Query Test data download of local data performed. If infeasible, explain:

PCRC proposal components:

Manuscript

- Cover Sheet (limit one page)
- Introduction (target 300-500 words; limit 750 words)
- Methods - including acknowledgement of appropriate guidelines for reporting (e.g. RECORD, TRIPOD, etc.)
- Proposed Statistical Analyses
- Response to Reviewers (Revisions only; PCRC recording available on PCRC website – *Current Projects*)

Query Specifications

- Data elements to determine inclusion criteria - MPOG Query ID:
- Data elements to perform analysis - MPOG Query ID:

Guidelines for Reporting

- Completed checklist from appropriate guidelines for reporting (e.g. RECORD, TRIPOD, etc.)

On behalf of the proposed team of investigators, I attest to having completed the above required steps prior to scheduling a PCRC review.

Name: Date:

Role (e.g. first author, PCRC presenter, site PI/RC):

Example PCRC Proposal

- Complete each section
- Commonly overlooked areas:
 - Power analysis
 - Handling of missing or invalid data
 - Preliminary data
- Involve a statistician at your institution

PCRC Proposal Cover Sheet

Title of Study or Project:	Multicenter Review of Practice Patterns Regarding Benzodiazepine Use in Cardiac Surgery
Primary Institution:	University of Michigan
Principal Investigator:	Allison Janda, MD
Co-Investigators:	Allison Janda, MD; Jessica Spence, MD; Timur Dubovoy, MD; Emilie Belley-Côté, MD PhD; Graciela Mentz, PhD; Sachin Kheterpal, MD, MBA; Michael Mathis, MD
Statisticians:	Graciela Mentz, PhD
Type of Study:	<input checked="" type="checkbox"/> Retrospective Observational
IRB Number and Status:	HUM00167369 / approved
Hypotheses/Aims:	We propose to explore data from cardiac surgical patients meeting inclusion criteria, to describe benzodiazepine use during cardiac surgery across MPOG centers. We aim to identify patient factors associated with benzodiazepine use and further describe the timing of administration. We hypothesize that patient, provider, and institutional factors are independently associated with benzodiazepine use during cardiac surgery.
Number of Patients/Participants:	Based on the availability of pertinent perioperative data, we expect approximately 5,000 patients to be included at the University of Michigan, and 60,000 in MPOG.
Power Analysis:	Sample size for this descriptive study are based on the accuracy of the overall estimates of benzodiazepine administration. It was determined that if the true population level use of benzodiazepines ranges between 70% and 90%, we will need a sample between 1,536 to 3,585 patients to estimate descriptive statistics with a precision of 3%.
Proposed statistical test/analysis:	We will produce descriptive statistics including: histograms, mean/median, standard deviation/interquartile ranges, percentiles and Q-Q plots.
Resources (Brief summary of resources for data collection, personnel, financial):	Data collection will include MPOG database queries performed via IT support. Statistical analysis will be conducted by Anesthesiology Department staff in consultation with Graciela Mentz; and in discussion with all co-investigators. Financial support as per the University of Michigan Department of Anesthesiology, NIH-NIGMS, Grant T32GM103730-06; NIH-NHLBI, Grant 1K01HL141701-02, Bethesda, MD

Example Data Query Specification

- **Inclusion criteria** clearly outlined
- **Exposure variables, covariates** and **exclusions** in separate table
- Date ranges or time periods for hemodynamic data or labs
- Programmers provide raw data, your research team curates

Sample Query Specification PCRC 0096 – Inclusion Criteria

Variable Name	Definition	Data Format	Data Source / ID	Notes
DOS	Date of Surgery/Procedure/Service	Mo/Day/Year	Phenotype: Surgery Start Date/Time	Include: Surgery performed between January 1, 2014 and August 1, 2019
Age	Age in years	Num	Phenotype: Age (Years)	Include: >=18
MPOG_Institution_ID	MPOG Institution ID	Num	Phenotype: Institution	Recode MPOG institution ID into a fake institution ID
Cardiac_cases	Cardiac cases	Num	Phenotype: Cardiac	Include: o Cardiac – Anesthesia CPT Codes 00550, 00560, 00561, 00562, 00563, 00567, 00580

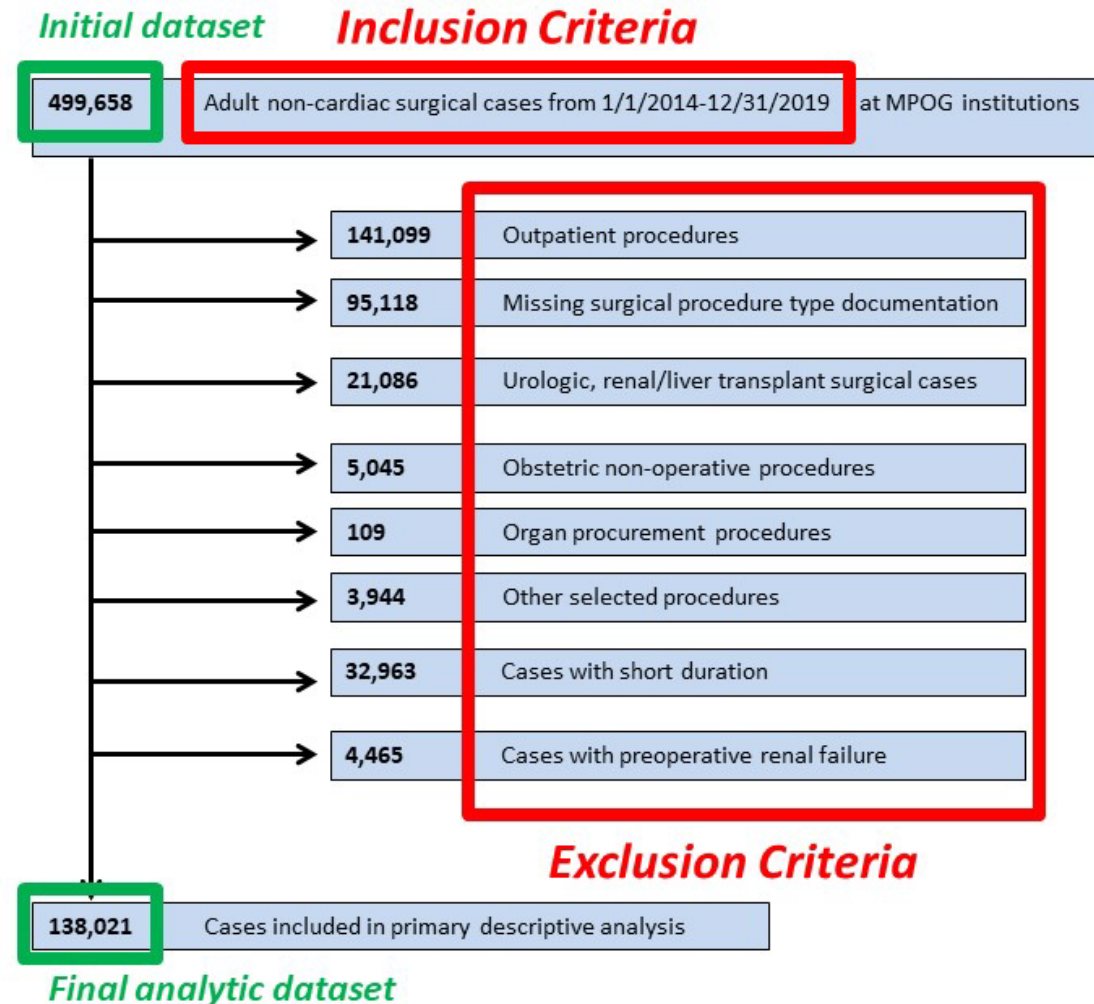
Sample Query Specification PCRC 0096 – Exposure Variables, Covariates, Exclusion Criteria, and Outcomes

Variable Name	Definition	Data Format	Data Source / ID	Notes
DOS	Date of Surgery/Procedure/Service	Mo/Day/Year	Phenotype: Surgery Start Date/Time	Include: Surgery performed between January 1, 2014 and August 1, 2019
Age	Age in years	Num	Phenotype: Age (Years)	Valid range: 18-120
Sex	Sex	Num	Phenotype: Sex	Sex
Race	Patient Race	Num	Phenotype: Race	Race
Actual_Procedure_Text	Procedure name (performed, not scheduled)	Character	Phenotype: Procedure Text	Actual_Procedure_Text
Charge_Capture_Primary_Diagnosis_Code	ICD-9/ICD-10 Code	Num	All ICD diagnosis codes	Charge_Capture_Primary_Diagnosis_Code
MPOG_Patient_ID	MPOG Patient ID Number	Char		MPOG_Patient_ID
MPOG_Case_ID	MPOG Case ID Number	Char		MPOG_Case_ID
MPOG_Institution_ID	MPOG Institution ID	Num	Phenotype: Institution	MPOG_Institution_ID

Created by Allison Janda, last updated 01/13/2020

Data Query Planning

- **Inclusions:** used to define your starting dataset
- **Exclusions:** applied by study team after data cleaning, to define final analytic dataset



Resources for Data Query Specs

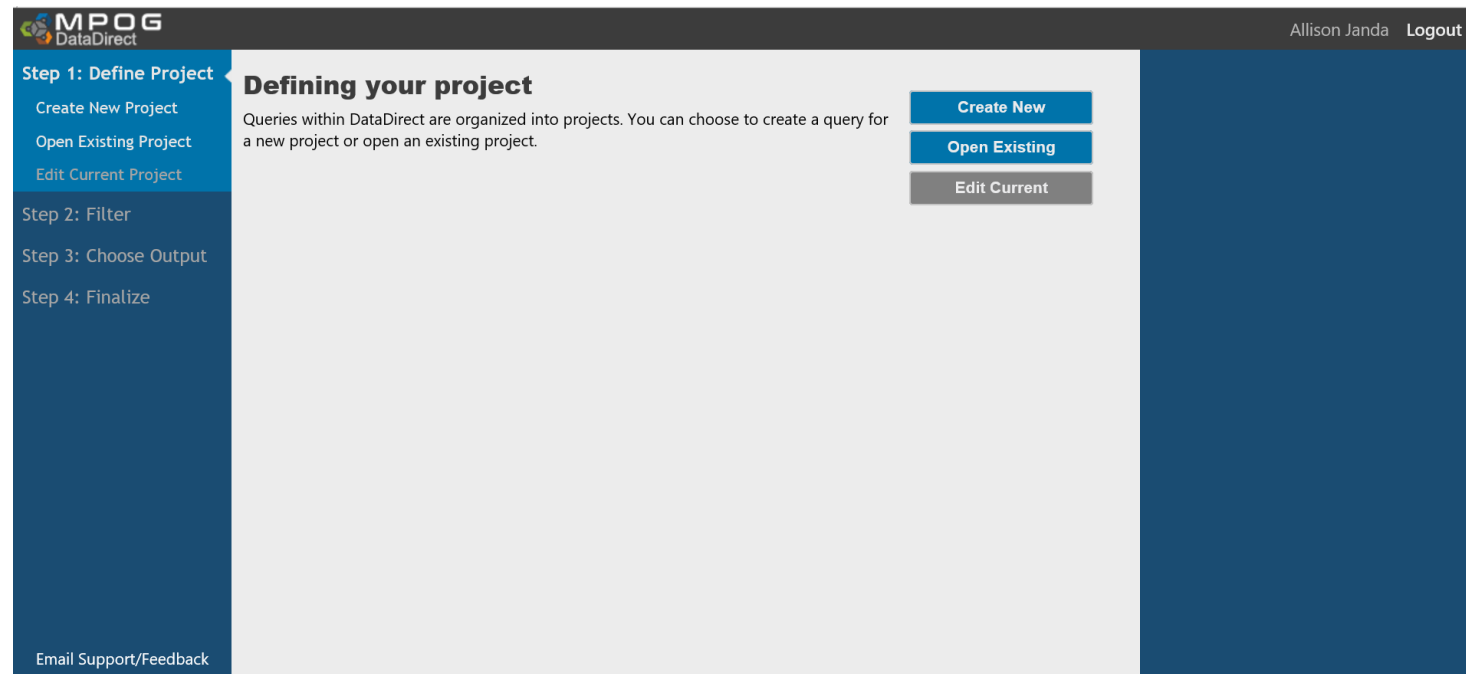
- Concept Browser
- Phenotype Browser
- DataDirect



The screenshot shows the MPOG website header and a navigation menu. The MPOG logo (Multicenter Perioperative Outcomes Group) is in the top left. The navigation bar includes links for About, Join, Research, Quality, Tools, Downloads, and Events / News. A red arrow points to the 'Tools' link. A dropdown menu is open under 'Tools', listing DataDirect, Concept Browser, Phenotype Browser, Quality Dashboards, Quality Case Reports, Provider Contacts, and MQARK. Three red arrows point to the first three items in the dropdown menu. A large banner for 'MPOG 2020 Virtual Retreat Registration is Open!' is visible in the background, with a 'REGISTER NOW' button.

DataDirect

- Intuitive, user-friendly research interface
- Review the DataDirect MPOG Instructional Module
- Take time to explore your cohort



Institutional Approval & Prelim Data Download

- Meet again with your MPOG Site PI
- Obtain IRB approval
- Download your institution's local data for preliminary analysis

Submit Proposal to Coordinating Center

- Send materials to: mpog-research@med.umich.edu
- A completed packet contains:
 - Cover sheet
 - Full study protocol including references
 - Response to reviewers (revised PCRC presentations only)
 - Data query specification
 - PCRC proposal submission checklist

PCRC Meeting Details

- PCRC meetings occur monthly on the 2nd Monday of each month
- Proposals due at least 4 weeks prior; anticipate ~2-3 month queue
- Proposal reviewed (for completeness & feasibility) by MPOG Coordinating Center
- Edits for completeness/feasibility may be needed
- 1-3 presentations per meeting; prepare a 10 minute presentation (oral or slides)

PCRC Presentation

- Moderator reviews your proposal in advance
- MPOG Coordinating Center introduces your proposal
- Project PI provides a 10 minute summary
- Moderator provides expert critique
- Floor is open to discussion/feedback from all PCRC members
- Project PI or team members respond to PCRC comments
- PCRC members vote

PCRC Outcomes

- Approve
- Approve with Revisions
 - Minor issues present
 - Submit with suggested changes and (recommended) response to reviewers
- Revise and re-present
 - Proposal warrants further revision & review to reach decision
 - Revise with suggested changes and (required) response to reviewers
 - Re-present at a future PCRC meeting
- Reject

Conclusion

- Review PCRC site: <https://mpog.org/pcrc/>
- Review additional MPOG Instructional Modules
- Examples and published MPOG manuscripts: <https://mpog.org/publications/>
- Questions?
 - mpog-research@med.umich.edu
- Thank you and we're here to help!