BMC2 Publication Proposal Guidelines

General Principles

1. Individuals from participating centers may propose research and may request leadership roles on projects they propose, with the opportunity to serve in a leadership role if they have time, interest and willingness.

2. No one can use Consortium data for research or analytic purposes independent of the work of the Consortium (meaning that participants can't take data from the Consortium for private research or analysis without going through the Publication Committee process to get buy in from the other participants

3. Each individual participating center can use its OWN data as it sees fit, but not to actively compete in the market place (e.g., not to compare its complication rates to those of others, derived from comparative performance reports, in public settings)

Authorship Guidelines

1. Abstract Submission
    a. Data requested for abstracts will be approved based on appropriateness of request, scientific merit, timeliness of topic, availability of statistician
    b. Consortium data requests will be reviewed/approved by the BMC2 Coordinating Center[1]
2. Authorship Guidelines
    a. Eligibility for inclusion as a co-author includes active commitment to and involvement in the project as evidenced by <u>at least one</u> of the following:
        i. actively participating in discussions of the author group and substantively contributing to the development of a study project, and/or resultant analysis and interpretation of the findings
        ii. idea inception
        iii. providing scientific guidance in carrying out the project
        iv. manuscript development and review

    b. In order to meet journal requirements for restricting number of authors, we will restrict authors on each manuscript to an arbitrary limit of 10 authors. The publication committee can determine if this limit needs to be changed for specific publications.

    c. Manuscripts should be submitted for publication within 6 months of receipt of data. Rejected manuscripts should be revised and resubmitted within 1 month of rejection.

    The primary author would be expected to respond to reviewer's comments and submit an updated manuscript within 1 month of peer review.

    If the author is unable to meet these deadlines, he/she should approach the consortium Director and BMC2 Publication Committee for necessary help and guidance. Alternatively, if the author does not take this initiative, the Consortium Director, with involvement of the BMC2 Publication Committee, may do so and arrange an appropriate assignment of a primary author role in order to maintain project momentum. Whenever possible, such dialogue should include active involvement of the initial primary author.

    Costs for statistical support may be the responsibility of the primary author if manuscripts are

[1]BMC2 Vascular Surgery will have a Publication Committee comprised of physician volunteers from the consortium to review and approve proposals for statistical analysis. The BMC2 Coordinating Center will oversee this process, distributing the proposals, compiling the reviews, and communicating results to the investigators via email. The Committee will target a turnaround time of 30 days. The Coordinating Center will provide quarterly updates to the Publication Committee on the progress of approved manuscripts.

not completed in a timely manner. [Statistical consulting is estimated to cost ~$5000-15,000 per manuscript.]

d. The primary authors would not be expected to lead more than 2 active projects simultaneously from either registry (PCI, Vascular Surgery) unless pre-approved by the publication committee. Submission of a completed paper for publication would be considered end of a project for this purpose.

Analytic Memo

Study Title

Corresponding Author Name and Email

Senior Author Name and Email

Please select 1-2 other author(s) who will contribute to the project from other BMC2 member facilities. Since this is a statewide registry, the committee encourages collaboration with authors from multiple institutions and their inclusion in the Study Analysis Plan.

Research Question and Hypothesis

State the question your study will address along with your primary hypothesis.

Literature Review

Provide citations of similar research and describe what those studies have found. Then explain what is currently unknown in the literature and how this study will fill in those gaps.

Inclusion Criteria

Specify variables such as procedure types, date ranges, patient ages, etc. that will be used to select the sample.

Exclusion Criteria

List any additional criteria that will be used to exclude patients from the study. Examples are emergent procedures, death in hospital, discharge to Hospice, etc.

Primary Outcomes List one or two main outcomes of interest. Limiting the number of primary outcomes helps keep the probability of a false positive sufficiently low in the statistical analysis.

Secondary Outcomes List any other outcomes that the analysis should consider but that are not the primary focus of the manuscript.

Exposure/Treatment Variable

If the primary hypothesis relates to a group comparison, list the groups that will be compared. Otherwise enter N/A.

Covariates/Control Variables

List any variables that may be confounders that should be controlled for in the analysis. Examples are age, race, gender identity, BMI, hypertension, diabetes, etc.

Analysis Plan

Include statistical methods as well as any subgroup analyses that are intended. This section may change after a statistician has reviewed it.

Figures

Describe any desired figures. For example, “Bar chart showing frequency of dependent variable by level of treatment.”

Tables

Append shells for all anticipated tables. Repeat shells as necessary, e.g. for each outcome or subgroup analysis. See examples below.

Table 1. Demographics and Comorbidities

	Whole Sample	Treatment A	Treatment B	P-Value
Age				
Race				
White				
Black/African American				
Other				
Gender				
BMI				
Smoking Status				
Never Smoked				
Former Smoker				
Current Smoker				
Hypertension				
Hyperlipidemia				
Diabetes Mellitus				
COPD				
Afib				
Prior CABG				
Renal Failure Currently Requiring Dialysis				
Beta Blockers				
Ace Inhibitors				
ARB				
Statin				
Aspirin				

Note. Entries are means (SD), median [Interquartile Range], or frequency (%). P-values are from t-tests, Mann-Whitney test, chi-square tests, or Fisher exact tests, depending on the variable type and distribution.

Table 2. Unadjusted Differences in Outcomes

	Whole Sample	Treatment A	Treatment B	P-Value
Primary Outcome				
30-Day MACE				
Secondary Outcomes				
30-Day Mortality				
30-Day Stroke				
30-Day MI				
30-Day All Cause Readmission				

Note. Entries are frequencies (%). P-values are from chi-square tests or Fisher exact tests.

Table 3. Logistic regression results for MACE.

	Odds Ratio	95% Confidence Interval	P-value

Treatment = Treatment B
Age
Race = Black/African American
Race = Other
Black/African American
Other
Gender
BMI
Smoking Status
Never Smoked
Former Smoker
Current Smoker
Hypertension
Hyperlipidemia
Diabetes Mellitus
COPD
Afib
Prior CABG
Renal Failure Currently Requiring Dialysis
Beta Blockers
Ace Inhibitors
ARB
Statin
Aspirin

Note. Reference category for race is white, reference category for gender is male, and reference category for smoking status is never smoked.