MISHC

Michigan Structural Heart Consortium

PUBLICATION RESOURCE GUIDE

Supporting Collaboration in Quality Improvement Publications

2026

Message from our Directors

Dear Colleagues,

Thank you for your interest in advancing quality improvement for cardiovascular patients using MISHC registry data. We are committed to supporting the development and dissemination of high-quality publications that reflect thoughtful, collaborative, and data-driven improvement efforts across our consortium.

To facilitate this process, we have created this resource guide to support investigators in navigating the full lifecycle of a QI publication, from project planning and analysis to manuscript preparation and submission. In addition to offering practical tools and guidance to ensure all contributors are equipped to develop impactful, methodologically sound publications, this document also includes important information on requirements from our funder, Blue Cross Blue Shield of Michigan (BCBSM).

Successful QI projects require more than a compelling idea; they rely on strong partnerships between physicians, statisticians, and Coordinating Center staff. This guide provides a roadmap for that collaboration and outlines clear expectations for Principal Investigators (PIs) throughout the process. It is intended to promote shared accountability, transparent communication, and consistency across all registry-based publication efforts.

Before submitting a proposal, please take time to review the expectations listed in this guide. Each expectation is accompanied by a section that underscores its importance and provides resources to help you fulfill it. If you have additional questions on this process or available resources, please reach out to the MISHC Project Manager, Mary Casey at marycol@med.umich.edu.

We appreciate your ongoing contributions and look forward collaboratively to advancing meaningful improvements in cardiovascular care through high-quality, publication efforts.

Sincerely,

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MISHC Expectations for PIs

Before submitting a publication proposal, all Principal Investigators (PIs) are required to attest that they have reviewed the expectations outlined below. These expectations reflect MISHC's standards for conducting high-quality, collaborative, and ethical quality improvement (QI) publications. **PIs may have no more than two active publication projects at any given time to ensure appropriate focus, accountability, and project completion.**

Each expectation is linked to a corresponding section in this resource guide, where you will find detailed explanations, rationale, and tools to help you meet each responsibility. Please review the expectations listed and click the **[Jump to this section]** link for any areas where you would benefit from further explanation or support.

PIs are expected to…

- Understand the registry's data dictionary, available variables, and inclusion/exclusion criteria before submitting a data request. [Jump to this section]
- Develop a focused research question that addresses a clinical or operational problem. [Jump to this section]
- Think critically about their study population, the exposure being investigated, primary and secondary outcomes, and potential confounders. [Jump to this section]
- Uphold project's data integrity by engaging in transparent study design, honest data interpretation, and full disclosure of limitations. [Jump to this section]
- Collaborate with a statistician to develop a clear, well-structured analytic memo that defines the Scope of Work (SOW), aligns all collaborators, and establishes clear expectations for project milestones and timelines. [Jump to this section]
- Draft the manuscript while working closely with statisticians and co-authors to ensure accurate and ethical reporting. [Jump to this section]
    - → PIs must also ensure that the manuscript includes the BCBSM Acknowledgement and Disclosure statement.
- Comply with MISHC's requirements for Communication, Media Collaboration, and Branding Guidelines. [Jump to this section]
- Submit the manuscript, as well as coordinate necessary updates when preparing to resubmit a revised manuscript. During the initial submission, PIs must factor in time for a final review to ensure compliance with institutional and funder requirements. [Jump to this section]
    - → **Please note**: MISHC will cover up to $1,000 USD in publication costs, including fees for publishing open access; any charges beyond this amount are the responsibility of the lead author.

The MISHC Project Manager supports PIs throughout the publication process by monitoring progress from proposal through manuscript submission and acceptance, while ensuring alignment with internal timelines, milestones, and publication policies. More extensive project management support, such as coordinating complex timelines or multi-institutional collaborations, may be provided on a case-by-case basis with early planning and, when appropriate, authorship credit.

Working with Registry Data for QI Publications

Registry data serves as a powerful tool for quality improvement publications, offering real-world insights into patient care and outcomes. However, because registries are designed for benchmarking and performance improvement rather than traditional research, data may have limitations such as missing variables, inconsistent reporting, or selection bias. Understanding how to navigate these challenges ensures that research questions are feasible, data is appropriately analyzed, and findings are accurately interpreted.

MISHC Expectation

PIs are expected to understand the registry's data dictionary, available variables, and inclusion/exclusion criteria before submitting a data request. They should ensure their proposal aligns with the registry's capabilities and the available data.

Key considerations for MISHC data are the following:

1. All analyses are retrospective. Variable definitions may or may not match the study's goals.
2. Data are observational. Any association between an exposure and outcomes may be due to confounding factors, and it may not be possible to control for all confounders.
3. Missing values are present for many measures. For example, lab results may not be available for some subjects, and loss-to-follow-up results in a reduced sample size for 30-day and 1-year outcomes.
4. Selection bias can influence results. MISHC only collects data on patients who undergo procedures. It is not possible to compare patients in the MISHC database with subjects who are not admitted.

Observations are not independent. Hospital-level effects may influence outcomes beyond individual traits, and analyses should account for the clustering of patients within sites.

Resources	**What You'll Learn and Why it Matters**
MISHC Data Dictionaries • TVT V3 TAVR Data Collection Form • TMVR V3 Data Collection Form	A detailed list of data variables, including definitions, timing of variable collection, and permissible values, to help determine feasibility, spot missing data risks, and lift exact variable names straight into your protocol.
Quality Improvement vs. Clinical Research	Clear information describing the many similarities and differences between QI studies and clinical research.
AHRQ "Registries for Evaluating Patient Outcomes – User's Guide," Chapter 22 • Section 1: Introduction	Information on quality improvement registries: purposes, data quality, analytic pitfalls, strategies for causal inference, and common limitations.

• Section 8: Analytical Considerations • Section 10: Use of QI Registry Data for Research Studies • Section 11: Limitations of Current QI Registries	Sections on analytical considerations and using QI data for publications translate registry quirks into practical study tactics.

Conceptualizing a Quality Improvement Study

QI publications aim to drive measurable improvements in clinical care and patient outcomes. Unlike traditional clinical research, QI studies often involve iterative testing and real-world implementation. A well-defined research question, guided by QI frameworks such as STROBE or SQUIRE 2.0, ensures that studies are methodologically sound and clinically meaningful.

MISHC Expectation

PIs are expected to develop a focused research question that addresses a clinical or operational problem. They are encouraged to use established QI frameworks and work collaboratively with statisticians and co-authors to refine their study design and outcome measures.

Resources	What You'll Learn and Why it Matters
Developing a Research Question U-M Library Guide	Step-by-step primer on turning clinical hunches into answerable questions; includes searchable databases, sample questions, and worksheets.
What is your research question? An introduction to the PICOT format for clinicians	Short article that breaks down the Population Intervention Comparator Outcome Time (PICOT) formula with real world MSK examples.
Revised Standards for Quality Improvement Reporting Excellence	Authoritative checklist (18 items) for planning and reporting QI work—from rationale and context to sustainability and limitations.
Strengthening the Reporting of Observational Studies in Epidemiology (STROBE): explanation and elaboration	Detailed guidance and examples for each of the 22 STROBE items covering cohort, case–control, and cross-sectional studies.
STROBE Checklists	Ready to use tick box forms (separate versions for cohort, case–control, cross sectional) summarizing every reporting item.

Planning the Analysis

A well-structured analysis plan is critical for producing reliable, interpretable results. Determining inclusion/exclusion criteria, handling missing data, and selecting appropriate statistical methods in advance help ensure the integrity of the study. Understanding how to work with registry data for QI publications, paired with early and ongoing team collaboration, allows for refinement of methods and identification of potential biases.

MISHC Expectation

PIs are expected to think critically about their study population, the exposure being investigated, primary and secondary outcomes, and potential confounders. Additionally, PIs are expected to remain engaged with the MISHC statistical team to refine the methodology outlined in the analytical memo.

Resources	What You'll Learn and Why it Matters
MISHC Data Dictionaries • TVT V3 TAVR Data Collection Form • TMVR V3 Data Collection Form	A detailed list of data variables available to our PIs to help determine feasibility, spot missing data risks, and lift exact variable names straight into your protocol.
Quality Measures: Types, Selection, and Application in Health Care Quality Improvement Projects	An overview of structure, process, and outcome measures, that explains criteria for choosing valid, reliable indicators, and offers step-by-step guidance on aligning each measure with project aims, data sources, and analytic plans.

Ensuring Integrity and Transparency

Ensuring study integrity is critical to producing meaningful, reproducible, and ethical quality improvement (QI) publications. Questionable research practices (QRPs) such as selective reporting, p-hacking, or failing to properly disclose data limitations, can distort findings, mislead the medical community, and hinder patient care improvements. Adhering to ethical practices strengthens the credibility of QI work, fosters trust among collaborators, and upholds MISHC's commitment to high-quality QI publications.

MISHC Expectation

PIs are expected to uphold project data integrity by engaging in transparent study design, honest data interpretation, and full disclosure of limitations. They should collaborate with statisticians to ensure appropriate analysis methods, report all relevant findings (even if results are not statistically significant), and avoid post-hoc changes to study aims or hypotheses without justification.

Certain steps can be followed to minimize the risk of QRPs.

1. The study design – including specification of the exposure, outcomes, confounders, and statistical tests – should be designated in advance and followed exactly. Any deviations from the analysis plan that are made after looking at the results will increase the risk of false positives (i.e. saying something is significant when it is not) and greatly reduce the likelihood that the findings will replicate in a future study.
2. Post hoc changes to the study design that nonetheless proceed must be reported as deviations from the study protocol in any abstract and publication. Failure to report is considered unethical and bad science.
3. Have one (not more than two) primary outcomes. Running additional statistical tests increases the risk of a false positive finding. An adjustment for multiple comparisons needs to be made to the cut-off for statistical significance if there is more than one primary outcome. For example, a more stringent $p < 0.025$ may be required instead of the default $p < 0.05$.
4. Additional outcomes of interest can be listed as secondary, though some restraint in the number of these measures should again be exercised. Depending on the reviewer, secondary outcomes may or may not require an adjustment for multiple comparisons.
5. Any remaining outcomes can be listed as exploratory. No adjustments need to be made, but the understanding is that these tests are not rigorous.

Resources	**What You'll Learn and Why it Matters**
HARKing, Cherry-Picking, P-Hacking, Fishing Expeditions, and Data Dredging and Mining as Questionable Research Practices	A description of common analytical shortcuts, how they slip into study design, and the biases they introduce.

The Extent and Consequences of P-Hacking in Science	A large-scale empirical assessment demonstrating the prevalence of p-hacking across disciplines and quantifying its inflationary effect on false positive rates.

Developing an Analytic Memo

A well-structured analytical memo serves as the foundation for a successful project by clearly outlining the study's objectives, methodology, and expected analyses. Crafted in collaboration with the statistician, the analytic memo functions as an invitation for co-authors within the consortium, helping to build a strong, multidisciplinary publication team.

The analytical memo is the foundation of the Scope of Work (SOW), a document that ensures alignment among collaborators, lists key milestones and anticipated timeline, and maintains transparency throughout the publication process. The Scope of Work must be reviewed and approved by the MISHC Statistician for feasibility, impact, and alignment with registry goals before granting approval to proceed. A well-defined memo prevents scope creep, reduces the risk of unnecessary rework, and keeps the project timeline on track.

MISHC Expectation

PIs are expected to partner with a statistician to co-develop a clear and well-structured analytical memo to be used in defining the Scope of Work (SOW) and ensuring alignment among all collaborators. PIs should be prepared to revise the memo based on feedback from statisticians, co-authors, or committee members before finalizing the SOW.

Resources	What You'll Learn and Why it Matters
Analytic Memo template	Provides a structured format for outlining the key analytic details of your project, clarifying variables, cohorts, and planned analyses.
Scope of Work (SOW) template	Helps define roles, deliverables, timelines, and resource needs at the outset of a project, setting shared expectations and reducing confusion throughout collaboration.

Writing a Quality Improvement Manuscript

Writing a high-quality manuscript means ensuring that all major conclusions are well-supported by the analysis, that figures and tables are complete and correctly labeled, and that narrative descriptions align with the statistical findings and provide meaningful context for interpretation. Attention to detail at this stage is essential to maintain integrity and transparency and ensure the study's impact is clearly conveyed.

Managing version control and communicating regularly with co-authors and the MISHC Coordinating Center helps avoid confusion, ensures consistency across drafts, and prevents delays. To meet MISHC's funder requirements and ensure consistency with consortium expectations, the Coordinating Center must review the manuscript prior to journal submission. Please plan accordingly and allow sufficient time for this review, especially when working toward submission deadlines.

Publication author teams must include all four MISHC Directors. Physician co-authors must be Structural Heart Cardiologists or Cardiac Surgeons, or trainees in these specialties, or have documented project involvement in accordance with ICMJE requirements.

MISHC Expectation

PIs are expected to draft the manuscript while working closely with statisticians and co-authors to ensure accurate and ethical reporting.

PIs must also ensure that the manuscript includes the **BCBSM Acknowledgement and Disclosure** statement:

> *Support for MISHC is provided by Blue Cross Blue Shield of Michigan (BCBSM) and Blue Care Network as part of the BCBSM Value Partnerships program. Although BCBSM and MISHC work collaboratively, the opinions, beliefs and viewpoints expressed by the authors do not necessarily reflect the opinions, beliefs, and viewpoints of BCBSM or any of its employees. Further, BCBSM does not have access to MISHC data, and all patient episodes occurring at engaged hospitals are included in the data registries, regardless of payer.*
>
> *(Statement updated 6/25/2024)*

Resources	What You'll Find and Why it Matters
Key Strategies to Publishing Your Quality Improvement Work	A concise playbook that demystifies QI publication hurdles: selecting the right journal, matching your work to SQUIRE, and navigating reviewer critiques.

Writing a better research paper: Advice for young authors	Bite sized wisdom on crafting clear titles, logical flow, and compelling discussion, distilled from an editor's viewpoint.
Manage Citations with Zotero, Mendeley, and EndNote UM LibGuide	Side-by-side tutorials, comparison tables, and plugin links that get you from blank library to perfectly formatted references in minutes, saving hours at submission time.
Defining the Role of Authors and Contributors (ICJME)	Gold standard criteria clarifying who qualifies for authorship and what contributions merit acknowledgment, protecting integrity and preventing disputes.

Collaboration and Communication

Clear and consistent communication ensures smooth collaboration between co-authors, statisticians, and the Coordinating Center throughout the publication process. Proper acknowledgment of funding sources and adherence to branding guidelines maintain the integrity of published work and align with the expectations of our funding partners. Following these requirements enhances the visibility and credibility of MISHC-supported publications while ensuring compliance with institutional and funder policies.

MISHC Expectation

PIs are expected to comply with MISHC's requirements for Communication, Media Collaboration, and Branding Guidelines.

Communication: PIs are expected to respond to requests for information from the MISHC Communications Specialist and Project Manager, providing timely communication on:

- Notifications of significant project delays
- Status changes (journal submissions, rejections, requests for revisions, notification of acceptance).
- Name of journal/meeting where manuscript or abstract was submitted.
- Upcoming presentations

Media Collaboration: PIs are expected to notify MISHC of any media inquiries following a presentation or publication to ensure alignment on messaging and ensure collaborators receive the necessary support to optimize communication efforts. Both specialized media training and communication support are available. Please review the MISHC Media Policy or more information and full details on MISHC media use expectations.

Branding Guidelines: Manuscripts, presentations, and other outputs must adhere to MISHC Brand and Style Guide, including the use of official logos, color schemes, and formatting standards where applicable. PIs should consult MISHC's branding resources to ensure compliance and seek MISHC Coordinating Center approval before submitting materials for external distribution.

Resources	What You'll find and why it matters
MISHC Brand and Style Guide	Clarification on the use of MISHC logos, color palettes, and typography.
MISHC Media Policy	Policies for conference abstracts, press releases, and social media, spelling out approval workflows, embargo expectations, and spokesperson roles.

Submitting a QI Study Manuscript

A well-prepared manuscript submission ensures that key findings are disseminated effectively, reaching the right audience and contributing to improvements in patient care. Proper submission also helps avoid unnecessary delays due to formatting issues, incomplete reporting, or failure to meet journal guidelines. Following best practices for manuscript submission enhances the likelihood of acceptance and ensures transparency in reporting methods, findings, and limitations.

MISHC recognizes the growing value and visibility of publishing in open access journals and is committed to supporting publication decisions that align with broad dissemination and accessibility goals. **To support equitable opportunities for all collaborators, MISHC will contribute up to $1,000 USD toward publication costs.** This funding may be used for traditional journal publishing fees or open access charges. We encourage investigators to consider open access options when selecting a journal, and.

MISHC Expectation

PIs are expected to submit the manuscript, as well as coordinate necessary updates when preparing to resubmit a revised manuscript. During the initial submission, we ask PIs to factor in time for MISHC's final review to ensure compliance with institutional and funder requirements.

PIs should carefully follow journal-specific author guidelines, adhere to structured reporting standards, and properly acknowledge MISHC funding and data sources. If substantial changes to the study's objectives or analysis are needed, these should be justified, documented, and discussed with co-authors before revising the manuscript direction. Upon revising and resubmitting a manuscript, PIs must communicate pertinent status updates to the Coordinating Center.

Please note: MISHC will cover up to $1,000 USD in publication costs, including fees for publishing open access; any charges beyond this amount are the responsibility of the lead author.

Resources	What You'll find and why it matters
Submission Checklist	Details the steps needed for a complete journal submission.
How to Write a Cover Letter	A guide to writing an effective cover letter with examples.

Journal Citation Reports Data *(available to U-M Collaborators only)*	Find journal information, Journal Impact Factor (JIF), Journal Citation Indicator (JCI), and other journal ranking data for 8,400+ scholarly journals
Next Steps for Revising a Journal Manuscript	Outlines a step-by-step approach to interpreting reviewer feedback, prioritizing revisions, and coordinating updates with co-authors
How to deal with revisions?	Practical guidance and tips for revising manuscripts.

Frequently Targeted Meetings and Journals

MISHC

Meeting	**Abstract Due Date** *(Estimated)*
AATS Annual Meeting	October
ACC Scientific Sessions	September
AHA Scientific Sessions	June
London Valves	October
NY Valves	April
TCT	July

Journal	**Description**
JACC	Covers all aspects of cardiovascular disease, including original investigations, experimental investigations with clear clinical relevance, state-of-the-art papers, and viewpoints.
JACC: Cardiovascular Interventions	Encompasses the entire field of interventional cardiovascular medicine: case selection and management; procedural techniques; complications of coronary intervention; catheter-based management of non-coronary arterial disease; anatomy and anatomic variants; pharmacology; and

	cardiovascular imaging and physiologic assessment.
Structural Heart	The journal covers topics such as transcatheter procedures, cardiovascular surgery, drug treatment, basic and translational science and imaging in structural heart disease and innovation (new devices, therapies and first-in-humans). Each issue contains original research, reviews, opinion pieces, editorials and images in cardiovascular disease.