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Clinician attitudes, opinions and practice patterns regarding inotrope use for cardiac surgery in the USA: a multicentre mixed methods study protocol

Michael R Mathis ,[1] Kamolnat Mirizzi ,[1] Courtney J Burns,[1] Allison M Janda ,[1] Graciela Mentz,[1] Keith D Aaronson,[2] Zhenke Wu,[3] Donald S Likosky,[4] Francis D Pagani,[4] Sachin Kheterpal,[1] Kamrouz Ghadimi,[5] Milisa Manojlovich,[6] Timothy Guetterman [7]

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For numbered affiliations see end of article.

Correspondence to
Dr Michael R Mathis;
mathism@med.umich.edu

ABSTRACT

Introduction Cardiac inotrope medications administered to cardiac surgical patients carry steep risk–benefit trade-offs, yet wide inter-institutional variation exists in inotrope practices. Despite known wide variation in use of any inotrope for cardiac surgery, limited multicentre data exist regarding determinants of inotrope selection and time course for use. Additionally, the reasons that underpin how clinicians decide on inotrope usage and the factors that influence inotrope practice change are not well understood.

Methods and analysis This is an investigator-initiated, multicentre mixed methods study. Quantitative data will include electronic health records from an observational cohort of adult cardiac procedures within the Multicenter Perioperative Outcomes Group (MPOG) database, comprising cardiac surgical procedures from over 30 US academic and community hospitals. Additional quantitative data will be collected via surveys of clinicians involved in inotrope decision-making, contacted through an existing multicentre research and quality improvement infrastructure with engaged clinician representatives participating across MPOG hospitals. Qualitative data will be collected from open-ended questions within surveys, as well as semi-structured interviews with surveyed clinicians, sampled across approximately six institutions selected for diversity of settings and inotrope practices. An explanatory sequential mixed methods design will merge quantitative and qualitative data to develop meta-inferences explaining inotrope practices, as guided by an existing framework for characterising clinical practice variation and levers for practice change.

Ethics and dissemination The study is approved by the institutional review board at the University of Michigan Medical School (HUM00245353). Findings will be disseminated through peer-reviewed journals, conference proceedings and quality improvement forums. The study began in February 2025 and will continue until 2028.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The use of validated multicentre electronic health record data across over 30 US-based academic and community hospitals increases the range of clinical contexts and practice patterns considered.
⇒ Inotrope choice and timing during the course of a cardiac surgical hospitalisation will be examined in association with patient-level, clinician-level and institution-level factors, allowing for previously understudied variation attribution.
⇒ Purposive sampling for surveys and semi-structured interviews recruits clinicians across a diverse range of backgrounds and inotrope practice patterns, enabling a more comprehensive understanding of inotrope decision-making and barriers to practice change.
⇒ The mixed methods design provides plans to enhance trustworthiness within qualitative analyses, including mediated allocation concealment, member checking and regular examinations of the analysis audit trail.
⇒ It is possible that survey and interview responses will be limited; in this event, existing clinical quality collaboratives contributing perioperative data and receiving monthly quality improvement feedback may be leveraged to increase participation beyond the institution-based purposive sampling.

INTRODUCTION

Inotrope practice variation in cardiac surgery

Cardiac inotrope medications are commonly used to augment heart contractility for the over one million patients recovering from cardiac surgical procedures annually.[1] Whereas inotrope-augmented contractility improves haemodynamics in up to 80% of patients recovering from cardiac surgery,[2] uptake across institutions is variable due to

conflicting data on the ability of inotropes to improve clinical outcomes. Inotropes can, at times, be life-saving for cardiac surgical patients; however, inotrope usage during and after cardiac surgery may contribute to unintended consequences, such as malignant arrhythmia[3 4] or myocardial injury when used in excess,[3 4] and are associated with increased mortality, length of stay and healthcare expenditures. However, the scope of inotrope practice variation in the setting of such risk–benefit tradeoffs remains poorly understood.

Understanding the determinants of inotrope practice variation stratified across patients, clinicians and institutions remains an important area of investigation. On the one hand, certain perioperative practice patterns may reflect a targeted patient-centred approach through institutional precision health initiatives. On the other hand, observed variability in perioperative practices may reflect disparities in health outcomes driven by social or structural factors (eg, patient demographics, clinician training or hospital geography),[5] which can lead to guideline discordant care.[6] To inform an optimal strategy for addressing inotrope practice variation, important steps are to (1) quantify the degree to which such variation is attributable to patient-level, clinician-level or institution-level factors; (2) describe clinician perspectives driving practice variation; and (3) characterise barriers and facilitators to practice change.[7 8]

Current knowledge gaps and rationale for the study

Whereas prior work suggests that variation in cardiac inotrope use can in part be explained by institution-level and clinician-level factors in addition to patient factors,[9] the specific selection of individual inotrope medications, each with varying biologic mechanisms and unique physiologic effects, remains understudied. Furthermore, data are lacking on multicentre variation in the timing of inotrope initiation for cardiac surgery during critical phases of care, including initiation and separation from cardiopulmonary bypass as well as transport to the intensive care unit (ICU). Beyond a lack of granular data on inotrope practice patterns surrounding cardiac surgery, local structural factors and clinician attitudes and opinions influencing inotrope use also remain incompletely understood. To date, studies of inotropes have failed to achieve consensus regarding best practices among clinicians commonly administering such medications, due to a lack of consideration for (1) specific reasoning in inotrope choices and timing of use and (2) strategies to address local institutional barriers or facilitators to change.

This large, extramurally funded mixed methods study aims to advance the science underlying inotropic use within the setting of cardiac surgery. Specifically, this study will: (1) characterise cardiac inotrope practice variation via an analysis of granular, multicentre perioperative electronic health record (EHR) data, (2) contextualise quantitative findings through analyses of surveys and qualitative interviews with clinicians focusing on their attitudes and opinions towards inotrope use; and (3) integrate the quantitative and qualitative findings via mixed methods meta-inferences to address key barriers and facilitators to practice change.

METHODS AND ANALYSIS

Overview

The proposed study will follow an explanatory mixed methods design[10] involving integrated quantitative and qualitative phases of research. This US-based study seeks to advance insight into (1) determinants of observed multicentre practice variation regarding inotrope use in the setting of cardiac surgery, (2) clinician attitudes and opinions towards their use and (3) barriers and facilitators to practice change. The study will be conducted in three phases.

In the first phase, patient-level, clinician-level and institution-level variation in inotrope choice and timing will be quantified through the analyses of multicentre perioperative EHR data from cardiac surgical procedures. In the second phase, surveys of clinicians involved in inotrope intraoperative decision-making will characterise attitudes and opinions towards inotrope use, as well as perceptions of barriers and facilitators to practice change. In the third phase, a purposeful sample of survey respondents will be invited to participate in semi-structured interviews to provide critical contextual information (ie, reasons for individual inotrope decisions and variation). Across all three phases, quantitative and qualitative results from a deductive thematic analysis will be integrated through mixed methods analysis and interpretation (figure 1).

Theoretical framework

The theoretical framework for this study is adapted from a previously published framework characterising clinical practice variation (figure 2) as well as barriers and facilitators to practice change (figure 3).[11 12] The framework provides a lens through which cardiac surgery inotrope practice variation may be analysed.[9] Through this framework, clinical variation can be analysed across domains of *capacity* (ie, a clinician's ability to provide care as intended, and how decisions are enabled and supported), *agency* (ie, clinician motivations to pursue specific approaches to patient care, and whose needs and expectations drive clinical decisions) and *evidence* (ie, the degree to which clinician decisions align with an existing knowledge base). Within each domain, variation can additionally be parsed as potentially warranted vs unwarranted. The extent to which clinical variation is warranted is difficult to determine with quantitative data alone; however, insight may be gained from contextualising quantitative findings with qualitative data.[11 13 14] Further, levers for clinical practice change to address unnecessary variation can be analysed across a range of strategies targeting individual clinicians and institutions, as demonstrated in figure 3.

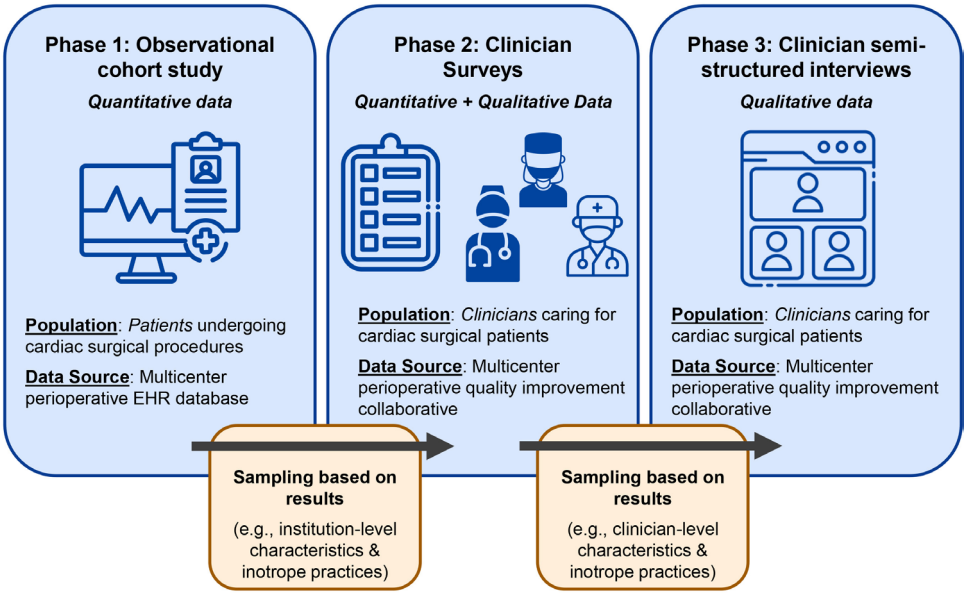

Figure 1 Flow diagram of all phases within the proposed study. EHR, electronic health record.

Phase I: observational cohort study

Approach

In phase I, an observational cohort study will be conducted with the goal of identifying patient-level, clinician-level and institution-level phenotypes associated with variation in inotrope choice and timing during cardiac surgery. Quantitative data will be extracted from the Multicenter Perioperative Outcomes Group (MPOG) EHR database. As pertaining to cardiac surgical patients, the MPOG dataset consists of over 30 US academic and community hospitals and contains granular inotrope choice and timing data. Methods for local EHR acquisition, validation and transfer to the data coordinating centre have been previously described.[15 16]

The primary categorical outcomes will be primary infusion *choice* (ie, the specific inotrope used) during or immediately following cardiac surgery and the *timing* of inotrope initiation. *Choice* of inotrope use is defined as an infusion of epinephrine, milrinone, dobutamine, dopamine or no inotrope used; these categories were selected based on the predominant MPOG-wide use rates (up to 42%) observed among cardiac surgeries.[9] The *timing* of inotrope initiation is defined as whether the selected inotrope was initiated pre-cardiopulmonary bypass, post bypass or during the early postoperative ICU period. Covariates related to inotrope administration will be defined a priori, specifically: preoperative patient comorbidities and surgical characteristics, clinician characteristics (eg, primary attending anaesthetist and surgeon, annual cardiac surgical case volume) and institution characteristics (eg, medical school affiliation, geographic region, annual cardiac surgical case volume).

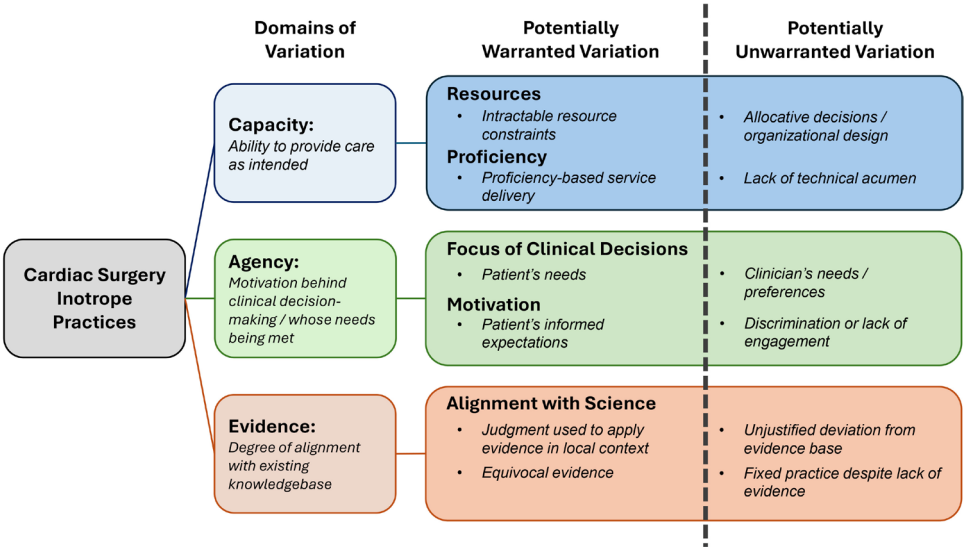

Figure 2 Theoretical framework: domains of inotrope clinical practice variation. Extended from the clinical practice variation framework proposed by Sutherland and Levesque.[11]

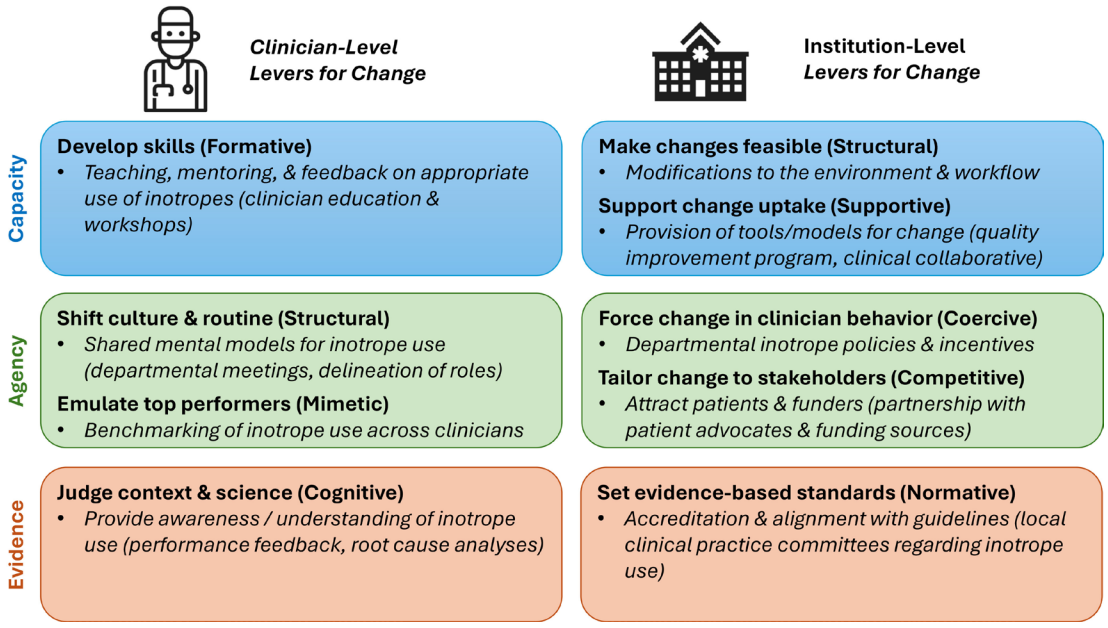

Figure 3 Theoretical framework: addressing barriers and facilitators for inotrope practice change. Extended from the levers for change framework proposed by Levesque and Sutherland.[12]

Study population

Adult cardiac surgical procedures with cardiopulmonary bypass performed at US institutions participating in MPOG from 1 January 2014 to 1 February 2022 will be used. Inclusion will be limited to common open cardiac surgical procedures, including coronary artery bypass, valve and aortic procedures performed in isolation or combination.

Analytical plan

SAS V.9.4 will be used as the analytical software. Descriptive statistics such as per-case rates of inotrope infusion choice and timing or temporal trends across case years may be examined. Variance in choice and timing may be assessed with variance partition coefficients or median ORs between clinicians and institutions.[17] A generalised linear mixed model with random intercepts will be used to evaluate relationships between patient-level, clinician-level and institution-level factors associated with variations in categorical inotrope choice and timing.

Phase II: clinician survey

Approach

In phase II, a web-based survey (Qualtrics, Provo, Utah, USA) will be developed and administered to clinicians involved in cardiac inotrope decision-making. Clinicians will be contacted via email using an existing contact network within MPOG as currently used for distribution of personalised performance feedback.

The survey introduction will contain key information about the study and an indicator of consent to proceed. Survey questions are anticipated to contain items including Likert scales, multiple choice, rankings and open-ended questions addressing cardiac surgery inotrope use and perceived barriers and facilitators to practice change. Survey content will be developed by research team members with clinical domain expertise in cardiac inotrope use, as guided by existing literature and variation factors from figure 2 and phase I results. As no validated instrument currently exists, case vignettes will be designed to simulate the clinical decision-making process and assess participant attitudes and opinions while providing face validity.[18] Prior to broad dissemination, the surveys will be piloted and iteratively enhanced through feedback from clinical domain experts.[19] Survey participant characteristics and demographic information will also be collected. Findings will inform purposive sampling, semi-structured interview questions and preliminary coding in phase III.

Study population

Survey data will be collected from clinicians involved in inotrope decision-making during cardiac surgeries and in the postoperative period. Clinicians will include cardiac surgeons, anaesthetists, critical care physicians, nurses and cardiologists across multiple institutions. Institutions will be identified and selected in order to capture diversity in characteristics such as geographic location, affiliation (ie, academic, community) and case volume, as well as diversity in inotrope practices as determined from phase I.[20] While a priori survey sample sizes that mitigate bias are difficult to justify, an estimated 7–15 complete surveys per survey item are anticipated for consistently providing descriptive statistics, and validation practices (eg, assessing convergent validity across items) can further inform an empirical subject-to-item ratio.[21 22] Survey invitations and participation reminders will be distributed via email to local practice leads for respective distribution. By engaging local practice leads in survey distribution,

survey response rates will be enhanced while ensuring the communication of research rationale and assurance of anonymity between clinicians and research team members.

Analytical plan

Survey response rates will be described using frequencies, percentages and item non-responses. Data visualisations (eg, bar plots, histograms) will be generated to identify response patterns. Descriptive statistics will be calculated for participant demographics, clinician roles, experience level and Likert scale responses. Additionally, coefficient alpha and factor analysis will determine reliability and construct validity, respectively. Response trends that suggest variation in inotrope use at the clinician and institution levels will be identified via the descriptive statistics and be considered for purposive sampling in phase III.

Phase III: clinician semi-structured interviews

Approach

Following surveys, an explanatory qualitative semistructured interview phase will be conducted. Semi-structured interviews lasting approximately 1 hour will be held virtually via Zoom (Zoom Workplace, San Jose, California, USA). At least one research team member with clinical expertise will be present to conduct interviews. An interview guide will be developed and piloted with clinical domain experts iteratively for content refinement.[23] The content may include open-ended questions, prompts to consider inotrope decision-making scenarios familiar to each interviewee's current clinical practices, probes and follow-up questions. Prompts to consider familiar scenarios will allow researchers to probe decision-making within institution-specific and context-specific settings. Probes will address categories within the clinical variation theoretical framework (figure 2; ie, *evidence, agency, capacity*) as well as perceived influences on decision-making and barriers and facilitators to practice change (figure 3). Follow-up questions will assess decision-making processes and relevant sources of information. Factors emerging as key points of consideration guiding inotrope use may be probed absent the use of emphasis or leading questions. Interviews with identifiers removed will be transcribed using a transcription service compliant with handling of protected health information (Landmark Associates, Phoenix, Arizona, USA). The study team will verify up to 10% of the transcripts by comparing transcripts with audio recordings and making appropriate corrections.

Study population

On completing the web-based survey in phase II, respondents will be presented with an invitation to participate in a semi-structured interview aimed at further exploring the reasoning and context of survey responses. Participants across the same range of clinical roles (ie, cardiac surgeons, anaesthetists, critical care physicians, nurses and cardiologists) will be sampled; a formal target sample size will be estimated using principles of information power.[24] Roughly six institutions will be sampled for diversity across geographic location, affiliation (ie, academic, community) and case volume/complexity. Maximal variation purposive sampling based on survey results will seek to screen and recruit participants representing diversity across clinician self-reported years of training, role and inotrope use patterns.[20 25] Mediated allocation concealment, in which participant traits and selection criteria are blinded to qualitative interview leads, will be applied to reduce interviewer bias and promote the neutral framing of interview questions.[26] Selection criteria will be managed by research team members with clinical domain expertise.

Analytical plan

Interviews will be analysed using deductive thematic analysis based on the theoretical frameworks (figures 2 and 3) and prominent factors driving variation discovered in phases I and II.[27] Analysis will occur concurrently with data collection in order to determine the point of data saturation and so that insights from earlier data inform subsequent data collection and analysis.[28] Themes driving inotrope use, reasoning and decision-making and barriers and facilitators to practice change will be developed from the data. An initial set of codes will be developed prior to analysis, per the deductive approach. A coding manual will be developed beginning with at least two researchers coding a subset of initial interviews. Discrepancies between coders will be collaboratively resolved through discussion; audits and reviews for consistency will continue as remaining interviews are coded.[25 29] NVivo software (Lumivero; Denver, Colorado, USA) will be used. The initial codebook is expected to evolve over time as new codes and themes are created and merged during the iterative qualitative analysis process. Codebook evolution will be tracked in a detailed audit trail. Study team members with both qualitative and clinical expertise will regularly meet to examine patterns among codes and to develop themes from the codes, leveraging strengths towards enhancing mixed methods integration and engagement with data.[26]

Mixed methods integration

An explanatory sequential mixed methods study design will be used with integration occurring in phase III during sampling (connecting), data collection (building, explaining) and analysis (merging) phases.[10 30] In sampling, the survey quantitative results will inform purposive sampling to capture a plurality of inotrope practice patterns.[13 20 31] In data collection, the survey and EHR quantitative results will be used to inform the development of qualitative semi-structured interview questions and probes. The qualitative interviews are intended to elicit underpinning themes and reasoning behind the quantitative results. In qualitative analysis, a deductive analysis approach will be used, with initial codes extracted from the guiding theoretical framework and quantitative

results. Joint displays will be used as a visual technique to enable merging the resulting qualitative themes with the quantitative findings to develop meta-inferences explaining inotrope practice variation and characterising specific levers for change.[32–34]

The trustworthiness (ie, credibility, dependability and confirmability, and transferability) of the qualitative analysis will be enhanced in several ways.[10 25 26 29] Specifically, credibility may be enhanced with peer debriefing, purposive sampling intended to capture diversity and plurality in data, member checking via participant feedback and cross-referencing interpretations with raw data. Dependability and confirmability may be enhanced through the sharing and internal audits of process notes and coding manuals between research members with a range of clinical and qualitative methods expertise. Finally, the judgement of transferability may be supported by thorough and detailed methods and analysis reporting.

Patient and public involvement

As this study focuses on clinicians and their attitudes and opinions towards inotrope use (an aspect of clinical care not routinely discussed with patients undergoing cardiac surgical procedures), there are no plans to engage patients in this research. To the extent that clinicians involved in inotrope decision-making are the subjects studied in the research protocol, findings will be disseminated to clinician subjects and colleagues via (1) journal publications and conference proceedings and (2) recurring web meetings for the MPOG Cardiac Surgery Quality Improvement Subcommittee, comprised of clinical practice champions across sites participating in MPOG. Throughout the conduct of the study, research team members will participate in partnerships with Blue Cross Blue Shield of Michigan/Blue Care Network as part of the Blue Cross Blue Shield of Michigan/Blue Care Network Value Partnerships programme. Results will be disseminated to these bodies, which impact health policy decisions directed to consumers.

ETHICS AND DISSEMINATION

Institutional review board approval has been received (University of Michigan Medical School; HUM00245353). Reporting of quantitative findings will follow the REporting of studies Conducted using Observational Routinely collected Data extension of the STrengthening the Reporting of OBservational studies in Epidemiology guidelines. Reporting of qualitative findings will follow the COnsolidated criteria for REporting Qualitative research guidelines.[35]

Quantitative MPOG EHR data from the first study phase will be collected through data collection, validation, variable mapping and secure transfer processes that have been previously described.[15 16] To enhance rigour and reproducibility, EHR data will be processed into precomputed, publicly available, digital phenotypes (ie, standardised representations of commonly collected health data such as comorbidities, surgical procedure types and laboratory values).[36] To limit the need for additional data transfer during the study, analyses will be performed within a secure computing enclave, as supported through MPOG Data Use Agreements with each participating institution.

Additionally, quantitative and qualitative survey and interview data from the second and third study phases will be collected and analysed through secure processes compliant with health data security regulations. During the survey conduct, a landing page containing study information with acknowledgement of implied consent through participation will be displayed to all respondents. The interview interest survey following the survey will not be associated with survey responses, ensuring anonymity. Verbal informed consent will be received from all interview participants, and identifying information from interview recordings will be removed in the transcription process.

DISCUSSION

This US-based study will leverage multicentre health record, survey and interview data to precisely characterise inotrope practices and the range of nuanced contexts surrounding their administration. Via a mixed methods analysis, novel insights regarding clinician-specific and institution-specific factors driving inotrope practice variation as well as barriers and facilitators to practice change will inform the design of future research seeking to understand causal effects of inotrope use across a variety of nuanced clinical contexts. Furthermore, the integration of quantitative and qualitative findings may be used to guide quality improvement efforts seeking to optimise inotrope use through reducing unnecessary inotrope practice variation and promoting patient-centred inotrope therapies, uncovering insights relating to whether cardiac inotrope practice variation may be warranted versus unwarranted. The mixed methods research proposed includes considerations for trustworthiness (eg, mediated allocation concealment, audit and coding meetings, member checking). Regular discussions between qualitative and clinical experts on the team will enhance data integration and interpretation of findings while ensuring rigour in methods.[26 37]

To enhance the robustness of the research plan, alternative approaches have been developed to address potential limitations, if found to exist during the conduct of the study. First, the observational cohort study (phase I) and survey (phase II) may find low variation across clinicians and institutions; however, this is unlikely based on preliminary findings which support significant multicentre variation in cardiac inotrope use patterns.[9] In this event, the sampling strategy for phase II will emphasise diversity of institution-level characteristics based on judgement from clinical experts on the research team. Another limitation may be encountered if survey responses or interview recruitment are initially lower than anticipated. In this

event, local clinical leadership across institutions surveyed may be engaged to uncover and address reasons for non-responses; and the number of survey questions may be reduced, survey format and timing may be varied and survey value may be reinforced. For the interviews, clinicians who are already engaged within the MPOG Cardiac Surgery Quality Improvement Subcommittee can be invited as additional participants.[38] Finally, by nature of qualitative data analysis, transferability of results cannot be predicted; however, sufficient methodology and analytical details will be provided within all subsequent reports and publications to support judgement of transferability, according to mixed methodology best practices.

Author affiliations
[1]Department of Anesthesiology, University of Michigan Medical School, Ann Arbor, Michigan, USA
[2]Department of Internal Medicine—Cardiology, University of Michigan Medical School, Ann Arbor, Michigan, USA
[3]Department of Biostatistics, University of Michigan, Ann Arbor, Michigan, USA
[4]Department of Cardiac Surgery, University of Michigan Medical School, Ann Arbor, Michigan, USA
[5]Duke University School of Medicine, Durham, North Carolina, USA
[6]School of Nursing, University of Michigan, Ann Arbor, Michigan, USA
[7]Department of Family Medicine, University of Michigan Health System, Ann Arbor, Michigan, USA

X Michael R Mathis @Michael__Mathis

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ORCID iDs
Michael R Mathis http://orcid.org/0000-0002-9697-2212
Kamolnat Mirizzi http://orcid.org/0000-0002-9168-1360
Allison M Janda http://orcid.org/0000-0001-5080-5630
Timothy Guetterman http://orcid.org/0000-0002-0093-858X

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