

MCSQI Annual Report | 2016



Maryland Cardiac Surgery Quality Initiative

The Maryland Cardiac Surgery Quality Initiative's (MCSQI) Annual Report is a confidential report detailing the activities and achievements of MCSQI. It is intended for use by physicians, administrators, data managers and the cardiac surgery community for development and evaluation of quality improvement plans.

Calculations utilize data from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database, O/E Recalibration Coefficients from STS Reports, and apply exclusion criteria as noted in this report.

All data in this report is protected from disclosure pursuant to the provisions of Maryland statutes as may be applicable.

Unauthorized disclosure or duplication is absolutely prohibited.

Comments and questions may be directed to:

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Letter from the Chairman of the Board

Over the past several years, the Maryland cardiac surgical community has united in efforts to improve the quality of cardiac surgical care statewide. Since the formation of the Maryland Cardiac Surgery Quality Initiative (MCSQI), all ten of Maryland's cardiac surgery programs have shared data and clinical protocols with a single focus of making cardiac surgery safer for all of our patients. In working closely with the Maryland Health Care Commission (MHCC), MCSQI has become a valuable partner providing important counsel about cardiac surgery performance standards in support of the newly implemented state regulations for cardiac surgery.



John Conte, MD Johns Hopkins Hospital

During the early stages of its existence MCSQI has developed a stable governance structure and established methodologies for securely sharing data, identified organizational priorities and formulated processes for evaluating and performing research protocols using our shared state data. The group's initial quality initiatives have focused on timely extubation and blood conservation. Together members devised and have begun to implement an MCSQI best practice protocol for extubating patients within six hours of surgery. MCSQI researchers have found statistically significant variations in transfusion practices across MCSQI hospitals, which led to the group's first manuscript that was submitted for publication.

MCSQI has actively been presenting our shared data and developing a national presence. For example, MCSQI presented a poster at the STS AQO in San Antonio in October 2015. Additionally, I represented MCSQI at the STS Annual Meeting in January 2016 during a panel discussion regarding the impact of regional quality initiatives. In these ways and more, MCSQI is becoming a nationally recognized organization for clinical quality improvement.

To allow us to further our data analysis for quality initiatives and research activities we have secured the services of a biostatistician to streamline our efforts and decrease the turn around time of data analysis. We have continued to explore new quality metrics, discuss partnerships with other regional quality collaboratives and maintain a close relationship with the MHCC to drive progress and fulfill our group's vision to improve the quality and decrease the cost of cardiac surgery.

We hope this inaugural Annual Report provides useful information for your hospital's internal quality improvement efforts, and we welcome any feedback you may have. Thank you for your support and membership and I look forward to a productive year ahead.

Sincerely,

for Cal

John V. Conte, MD

MCSQI Overview

The goal of the Maryland Cardiac Surgery Quality Initiative (MCSQI) is to improve clinical quality in the state's cardiac surgery community through outcomes analysis and process improvement. MCSQI serves as a peer-to-peer value exchange whose work promotes the adoption of evidence-based best practices, ensures fair and accurate reports and enhances healthcare policies.

Our group endorses the spirit and intent of the Maryland Health Care Commission's (MHCC) legislative charge to improve oversight and maintain high performance standards in Maryland hospitals' cardiac programs.

Improve Quality and Control Costs: MCSQI members collaborate to analyze hospital processes, work to identify opportunities for improvement and help implement relevant best practice protocols.

Enhance Communications: MCSQI serves as the interface to communicate process of care information between member sites, eliminating decision making in silos and connecting clinical teams.

Inform MHCC Policy: MCSQI helps establish a voice within the state's healthcare legislation by providing MHCC committees and staff with ways to define and assess cardiac surgery performance.

Organizational Components

MCSQI is a non-profit consortium supported by all ten hospitals that perform cardiac surgery in the state of Maryland. The organization provides value to its stakeholders by improving the quality of care through data analysis and implementing best practice protocols led by the Board of Directors, Quality Committee and Research and Writing Committee.

Communications, Meetings and Outreach: MCSQI network of surgeons, data managers and clinical teams fosters statewide collaboration through in-person meetings, conference calls and site visits. Through dynamic communication MCSQI informs, motivates, builds trust and increases transparency; consequently, helping our quality improvement consortium affect meaningful organizational change.

Benchmarking and Reporting: MCSQI focuses on selecting quality indicators, establishing baseline data, designing scorecards, addressing privacy and confidentiality and using providers' commentary as context to better understand trends and variations. Data managers convene regularly to standardize coding practices, allowing for timely, sound and accurate interpretations of cardiac surgery performance reports.

Quality Improvement Agenda: MCSQI members research, identify, and replicate best practices with the goal of improving the quality of patient care across the state. Pilot programs and other 'proof-of-concept' steps are used to develop and lead initiatives for Maryland's cardiac surgery sites. Best practices and evidence-based guidelines are researched and validated before adoption.

Evaluating Impact: MCSQI adjusts its efforts to improve participants' chances for success by implementing models to evaluate hospital performance. Progress is communicated to key audiences in state government, the cardiac surgery community and other external organizations.

Informatics

MCSQI's database links clinical factors with qualitative, process-level information in order to monitor and drive quality improvements. Participants' clinical records from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database are submitted quarterly to a secure web-based system. An annual report and inter-hospital rankings are used to compare performance related to specific metrics for the group's quality initiatives.

Membership

Participation is open, voluntary and non-hierarchal. Member bylaws and committee decisions guide the group's priorities, synchronizing efforts to regularly refine the management of data.

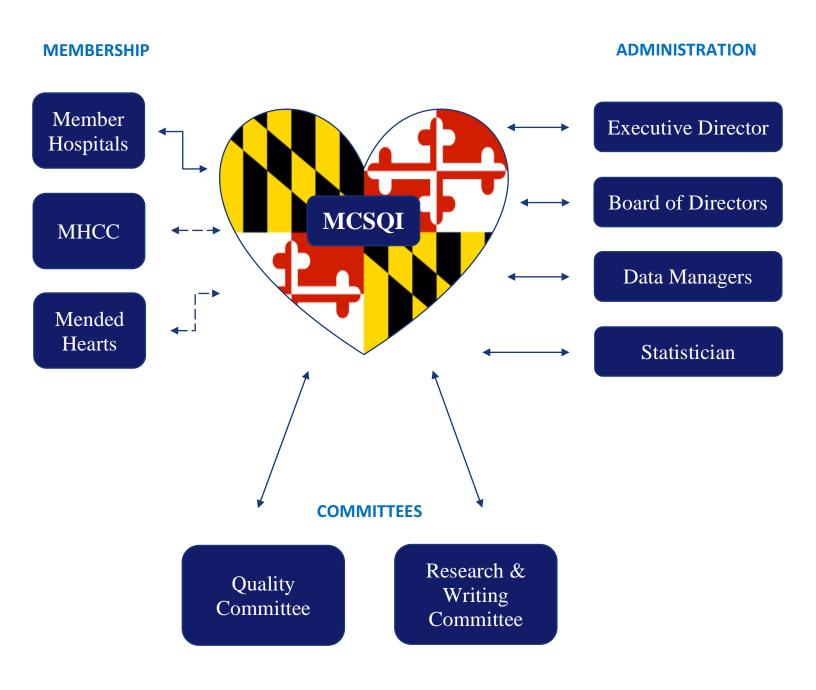
Effective Governance: The Board of Directors represent participants' interests, and developed a governance structure, set dues and adopted bylaws. MCSQI encourages broad participation among its member provider organizations and surgical practices.

Operational Capacity: In conjunction with the Board of Directors and other group members, the Executive Director manages the organization by facilitating development, setting agendas, encouraging participation, focusing discussion on key issues, helping the group reach consensus and solving problems.

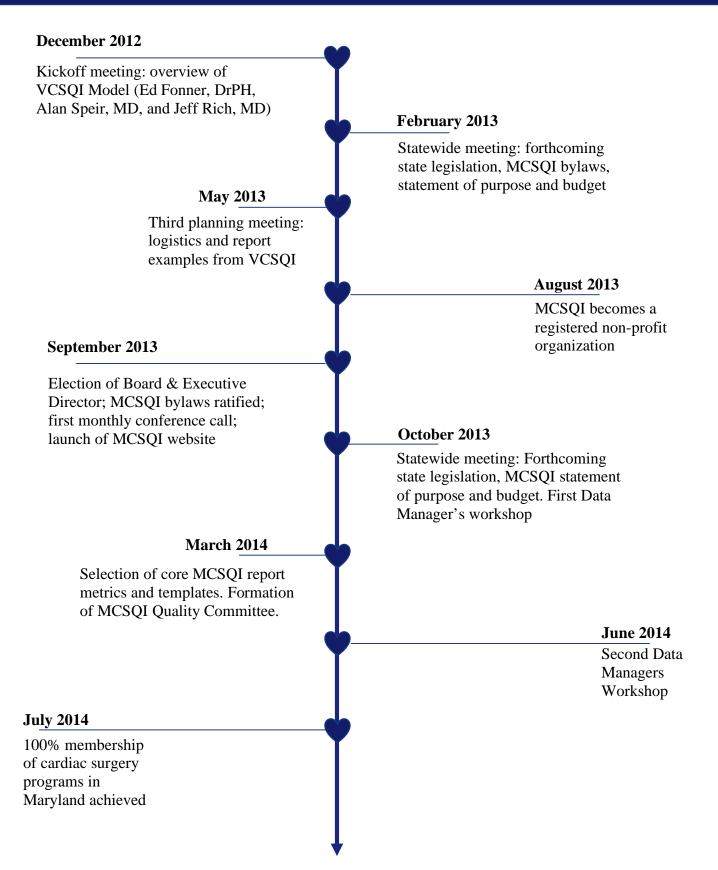
Summary

Since 2013, MCSQI has brought surgeons, data managers and hospital administrators together to compare data, share best practices, perform outcome analyses and implement process improvements. MCSQI is becoming a trusted, credible leader building a culture of continuous quality improvement in the cardiac surgery community. Benefits include reduced costs, enhanced clinical effectiveness, increased accountability, fewer regional variations and stronger alliances between heart team members.

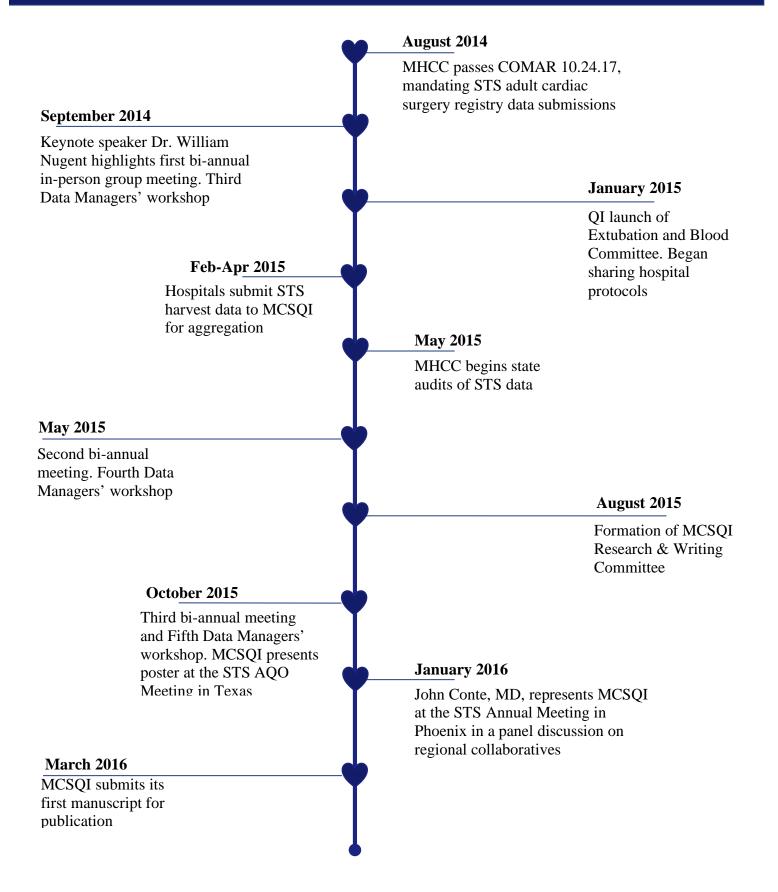
Organizational Model



Milestones



Milestones



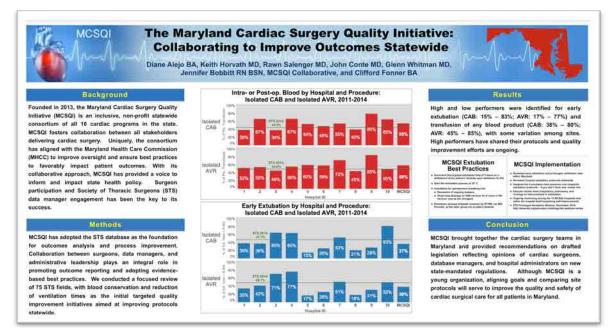
Quality Committee

The Quality Committee, formally established in March 2014, is tasked with managing MCSQI's quality improvement agenda. Membership is comprised of clinicians at all ten MCSQI hospitals, including: surgeons, data managers, intensivists, pulmonologists, nurse practitioners and members of the Cardiovascular team.

After a survey of quality improvement topics, members chose blood conservation and timely extubation as MCSQI's inaugural initiatives. The Quality Committee examined clinical data from the STS registry correlating hospitals' results against qualitative information from transfusion to extubation protocols through monthly conference calls. A subcommittee formed to analyze top performers' guidelines and craft a set of MCSQI best practice recommendations with the goal of increasing the proportion of cases extubated in less than six hours in Q4 of 2015. The MCSQI average across all ten centers has improved since implementation of this best practice protocol.

In the blood conservation subcommittee, analysis of transfusion rates by hospital, procedure type and pre-operative hematocrit levels yielded significant questions about transfusion practices across MCSQI centers. A study coordinated by the Research & Writing Committee yielded statistically significant differences between hospitals after adjusting for risk. Going forward, members will continue to analyze sites' transfusion practices and work towards generating a comprehensive list of best practice guidelines with the hopes of reducing transfusion rates statewide.

Co-chairs Diane Alejo and Dr. Keith Horvath have been vital to the committee's continued progress. Thirty-day readmissions and atrial fibrillation have been suggested as possible future projects, and group members will continue collaborating to affect positive across the continuum of cardiac surgical care.



First MCSQI abstract/poster presented at the STS Advances in Quality and Outcomes meeting in San Antonio, Texas in October 2015

Research and Writing Committee

In August 2015, the MCSQI Board of Directors voted to formally establish a committee tasked with overseeing and developing a research and publication process. This Research and Writing Committee officially reviews and approves all proposals for publication, decides upon a process for project initiation and develops and submits proposals for approval.

The Research and Writing Committee members convened and agreed upon MCSQI's first research project in October 2015, which was an analysis of inter-center differences in blood product utilization. MCSQI hired Dr. Elena Blasco-Colmenares as the group's statistician. Dr. Blasco-Colmenares brings over twenty-five years of experience as a cardiac surgeon, epidemiologist and biostatistician to the MCSQI research team.

MCSQI members submitted a manuscript to the Annals of Thoracic Surgery detailing variation in transfusion practices across Maryland hospitals after multiple rounds of review with the Research and Writing Committee in March 2016. The manuscript was recently accepted for publication.

Most recently in April 2016, the MCSQI Research and Writing Committee members discussed three new proposals: examining the underlying reasons for prolonged ventilation, analysis of a new STS data field on whether or not surgeons discussed STS risk scores with their patients pre-operatively and a follow-up project examining post-operative outcomes versus blood product usage. Going forward MCSQI members are excited for the opportunity to impact quality improvement and research on a regional and national level.

Data Managers

MCSQI's STS data managers, chaired by Jennifer Bobbitt, are fundamental to the group's operations and help to standardize database definitions and ensure consistent measurements across MCSQI's ten member hospitals. Data managers convene at bi-annual workshops to review scenarios of challenging cases and stay up-to-date with the latest documentation from the STS. Surgeons have also participated in these workshops, most recently with Dr. Paul Massimiano of Washington Adventist Hospital who presented his recommendations for abstracting data from surgeons' operative notes on MAZE procedures.

At the STS Advances in Quality and Outcomes (AQO) meeting in October 2015, MCSQI data managers presented a poster describing the group's quality improvement efforts to date. Preliminary results on early extubation and blood transfusion were included in the study along with an overview of the MCSQI model.

Data managers have also developed a comprehensive set of data quality reports utilizing consistency checks from the STS and the Michigan Society of Thoracic and Cardiovascular Surgeons. In conjunction with the MHCC audits of sites' STS harvest data, our data managers are armed with high quality, defensible data to assist with the accurate measurement of clinical quality metrics.



STS Data Managers

Executive Summary – CAB Only, 2011-2015

18%

12%

6%

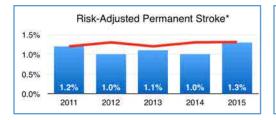
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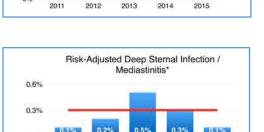
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2011









2013

2012

Risk-Adjusted Major Complications /

Operative Mortality*

13.0

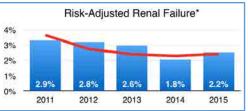
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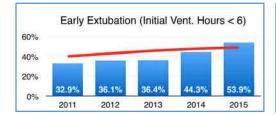
2014

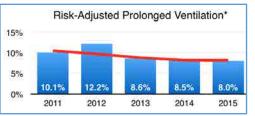
2015

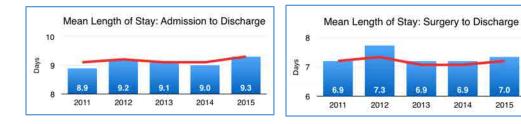
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MCSQI — STS

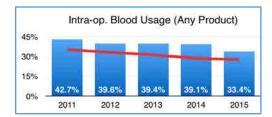


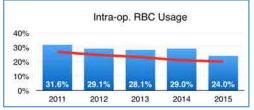
*STS Risk-adjusted Rates. These calculations involve two steps:

1. Calculation of the O/E ratio, which divides the percentage of an observed morbidity by the rate predicted by the STS risk calculator 2. Multiplication of the O/E ratio by the STS rational rate of the observed morbidity. All O/E ratios apply STS Recalibration coefficients, which normalize the national benchmark value to exactly 1.0.

Note: All Risk-adjusted Rates apply STS Recalibration coefficients from the Q4 2015 STS Reports.

Executive Summary – CAB Only, 2011-2015





32.79

2014

10.1%

2015





Table 1. NQF Measures: MCSQI

Calendar Year 2015, CAB Only Procedures unless otherwise indicated

	T	MCSQI	515
Procedure Volume	Isolated CAB	2,383	151,474
	Isolated CAB	(49.9%)	(52.9%)
	Isolated Valves	696	47,061
		(14.6%)	(16.4%)
CARACTERIA CONTRACTOR	CAB + Valve	345	24,113
	Serve Constants	(7.2%)	(8.4%)
	Other	1,353	63,501
		(28.3%)	(22.2%)
	Timing of Antibiotic Administration	99.1%	98.7%
Pre-Operative	Selection of Antibiotic Administration	99.8%	99.2%
	Duration of Prophylaxis	99.8%	98.9%
	Pre-operative Beta Blockers	97.4%	95.0%
Operative	Use of Internal Mammary Artery	99.5%	96.8%
Complications	Prolonged Ventilation O/E	0.97	1.00
	Deep Sternal Wound Infection O/E	0.56	1.00
	Stroke / Cerebrovascular Accident O/E	1.00	1.00
	Post-operative Renal Insufficiency O/E	1.02	1.00
	Surgical Re-exploration O/E	0.77	1.00
	Anti-platelet Medication at Discharge	99.5%	98.7%
Discharge	Beta Blockers at Discharge	99.6%	98.2%
	Anti-lipids at Discharge	99.1%	97,1%
	Inpatient Operative Mortality O/E/ for CAB	0.61	1.00
	Op. Mortality O/E for CAB	0.74	1.00
	Op. Mortality O/E for AV Replacement	0.77	1.00
	Op. Mortality O/E for AV Replacement + CAB	1.00	1.00
Operative Mortality	Op. Mortality O/E for MV Replacement	0.67	1.00
	Op. Mortality O/E for MV Replacement + CAB	0.92	1.00
	Op. Mortality O/E for MV Repair	2.38	1.00
	Op. Mortality O/E for MV Repair + CAB	0.35	1.00
Readmissions	30-day Readmission Rate for CAB	7.9%	10.0%

Data Quality Reports

STS Predicted Risk Elements Population: *All* Ten MCSQI Hospitals STS Major Cases, CY 2015 (N=3,524)

Data Fields with 100% Completeness		
Patient Age	Cardiac Symptoms at Surgery	
Height	Number of Diseased Vessels	
Weight	Aortic Stenosis	
Race	Mitral Stenosis	
Diabetes Control	Mitral Insufficiency	
MI: When	Tricuspid Insufficiency	
Infectios Endocarditis Type	Ejection Fraction	
Previous Valve	Incidence	
Previous PCI Interval	Status	
Cardiac Symptoms at Admission	IABP: When Inserted	

Missing Value Incidence		
Aortic Valve Insufficiency	< 0.1%	
Cardiogenic Shock	< 0.1%	
Cardiovascular Disease	0.3%	
Cerebrovascular Accident	0.2%	
Chronic Heart Failure	0.5%	
Chronic Lung Disease	2.6%	
Diabetes	0.1%	
Dialysis	0.1%	
Hypertension	0.2%	
Immunocompromise	0.2%	
Last Creatinine Level	0.1%	
NYHA Classification	0.9%	
Peripheral Vascular Disease	0.4%	
Pre-operative Atrial Fibrillation	< 0.1%	
Pre-operative Inotropes	< 0.1%	
Resuscitation	< 0.1%	
Sex	< 0.1%	

Data Specifications

• Operative Mortality O/E*: Any death during	• Inpatient Mortality O/E*: Any death during
patient hospitalization or within 30 days of	patient hospitalization
surgery	
• Prolonged Ventilation O/E*: Post-operative	Permanent Stroke O/E*: Post-operative stroke
pulmonary ventilation greater than 24 hours	that did not resolve within 24 hours
Renal Failure O/E*: Increase in post-operative	 Mediastinitis O/E*: Any post-operative deep
serum creatinine greater than 3 times	sternal wound infection or mediastinitis during
baseline, serum creatinine greater or equal to	patient hospitalization or within 30 days of
4 mg/dL, or new requirement for dialysis post-	surgery
operatively	
• Re-Operation O/E* : Return to the operating	 Morbidity/Mortality O/E*: Any patient
room for bleeding, valve dysfunction, graft	incurring operative mortality or any of the five
occlusion, or other cardiac reasons (the NQF	major morbidities listed above
definition does not include 'other non-cardiac	
reasons')	
• Readmissions within 30 Days: Any patient	Re-Operation for Bleeding: Re-exploration for
who was readmitted for inpatient stay at an	mediastinal bleeding either in the ICU or return
acute care facility within 30 days of discharge	to operating room
• Length of Stay (LOS) Admit-Discharge: Total	• Length of Stay (LOS) Surgery-Discharge: Total
number of days from patient admission to	number of days from surgery to discharge
discharge	
Post-Operative Ventilation Time: Total	• Early Extubation: Initial Ventilation Hours less
amount of time from operating room exit to	than 6; excludes patients who were extubated
initial extubation, plus any additional time	in the operating room
spent on pulmonary ventilation	
• Intra-Operative Blood Products: Any patient	• Post-Operative Blood Products: Any patient
who was transfused any time intra-operatively	who was transfused any time post-operatively
during the initial surgery.	
*The Observed-to-Expected Ratio (O/E). These	
calculations divide the percentage of an	
observed morbidity by the rate predicted by the	
STS risk calculator. All O/E ratios apply STS	
Recalibration coefficients, which normalize the	
national benchmark value to exactly 1.0.	

Maryland Health Care Commission (MHCC) Alliance

07/11/2012	The General Assembly of Maryland passes House Bill 1141, MHCC – Cardiac Surgery and PCI Services that established a new legal framework for the oversight of percutaneous coronary intervention (PCI) services and cardiac surgery. A Clinical Advisory Group comprised of 26 cardiac experts was tasked with providing input to MHCC on standards for the establishment of cardiac surgery and PCI programs and ongoing performance standards for existing and new programs.
06/20/2013	After eight meetings, the Clinical Advisory Group releases their final report, recommending procedure volume and quality measurement standards for both PCI and cardiac surgery programs.
10/21/2013	MCSQI sends a formal letter to MHCC advocating removal of the requirement for external review of cardiac surgery cases from the proposed regulations of COMAR 10.24.17. MCSQI also asked for clarification on several sections of the regulations where the exact intent of oversight was unclear. (Letter 1)
06/23/2014	MCSQI meeting with Eileen Fleck to discuss the STS data collection and reporting processes: data abstraction and harvest, procedure type categorization, risk-adjustment calculations, NQF measures and STS Star ratings.
06/30/2014	With regards to MHCC's proposal to obtain reports and patient-level metrics from the Society of Thoracic Surgeons (STS), MCSQI sends a formal letter to MHCC providing a detailed explanation of the STS database, their risk-adjustment methodology and quarterly reporting processes. (Letter 2)
08/18/2014	MHCC approves COMAR 10.24.17, the State Health Plan for Facilities and Services: Specialized Health Care Services – Cardiac Surgery and Percutaneous Coronary Intervention Services. This legislation implemented the new state regulations, which formally establishes standards for the performance of cardiac surgery programs. Procedure volume requirements and quality measures are specified to maintain certificates of ongoing performance. It also details a process of focused reviews if programs do not meet particular benchmarks. MHCC requires STS data.
05/13/2015	The MHCC Advisory Committee addresses the list of ICD-9 codes constituting cardiac surgery procedures that count toward COMAR 10.24.17's minimum volume requirements for cardiac surgery programs.
11/09/2015	MHCC passes an update to COMAR 10.24.17 with a revised list of ICD-9 procedure codes for cardiac surgery cases.
11/18/2015	MCSQI writes a letter to MHCC with recommended changes to the list of ICD-9 codes, recommending that cardiac surgery cases must fulfill two of the four following criteria: 1) an incision into the chest, 2) direct contact with the heart, 3) use of cardiopulmonary bypass, and 4) operation on the thoracic aorta and/or great vessels. (Letter 3)
12/16/2015	MHCC presents the results of the initial data quality audits of STS data. Overall, MCSQI hospitals performed very well on the audits with greater than 90% agreement for the state on the data elements impacting the STS risk adjustment model.
03/02/2016	MCSQI sends a formal letter to MHCC with updates to the ICD-9 procedure code list, comments for each procedure code that was updated or changed and a conversion chart for all possible equivalents in the ICD-10 procedure code list. (Letter 4)
04/12/2016	MHCC sends applications for Certificates of Ongoing Performance to all ten MCSQI hospitals. Programs are tasked with documenting their quality assurance standards to fulfill requirements of COMAR 10.24.17.
Source: <u>http://ml</u>	ncc.maryland.gov

MCSQI Correspondence to MHCC – Letter #1

October 21, 2013

To: Acute Care Policy & Planning, Maryland Health Care Commission From: The Maryland Cardiac Surgery Quality Initiative Subject: Comment on Proposed State Health Plan for Specialized Cardiovascular Services

The Maryland Cardiac Surgery Quality Initiative (MCSQI) is a voluntary statewide nonprofit organization established by members of the cardiac surgery practices in Maryland. Our group consists of a consortium of surgeons, cardiologists, database managers, hospital administrators and other healthcare professionals associated with the practice of cardiac surgery. MCSQI's Statement of Purpose document is attached for your reference. Our group strongly supports efforts to ensure quality and appropriateness for all procedures performed by cardiologists and cardiac surgeons. At a recent Board of Directors meeting, the group extensively reviewed the proposed regulations on cardiac surgery. This correspondence constitutes our response to the proposed regulations of the MHCC's State Health Plan.

MCSQI was formed independent of the recent MHCC activity with a goal of reviewing individual program data and identifying and sharing best practices in an effort to improve the quality and reduce the cost of cardiac surgery throughout the State of Maryland. MCSQI is well positioned to conduct both internal and external review of cardiac surgery services, delivery, and outcomes. The group is prepared to report annually on the results of this review process. MCSQI has a formal governance structure, a Quality Committee, and is patterned after successful analogous organizations in other states for process measures and quality improvement. It is supported by the administration of cardiac surgery programs across the state.

On a consensus-basis the group is addressing the Maryland Health Care Commission's reporting requirements on focused reviews, data collection, quality of care, and volume standards. We are in alignment with most of the proposed requirements, but would like to express some concerns and request further clarification on the following issues:

- <u>Disclosure of Source Data</u>: Sharing identifiable patient information as part of the internal and external review processes described in Quality section 4(e) could involve the submission of a data file containing patient names or identifiers as well as clinical data relevant to the review criteria. Details of this process need further delineation. In the interest of patient confidentiality and HIPAA compliance, we urge that patient-level data not be disclosed
- <u>Risk-Adjustment:</u> The risk-adjusted mortality rates described in section 5 on Performance Standards are reliant upon ratios of observed mortalities to the number expected by the Society of Thoracic Surgeons (STS) risk prediction algorithm. Better definitions of what constitutes "exceeding the statewide average beyond an acceptable margin" and "a risk-adjusted mortality rate that is consistent

with high quality patient care" are necessary. We also feel that comparison of programs to the state average may not be sufficient. Additional benchmarking against the entire network of local peers, including highest and lowest performers, can provide a better context for quality dialogue. One of MCSQI's aims is to create an aggregate database of the hospitals' STS patient data, which would provide a more comprehensive basis for this analysis.

Appropriateness and Quality: Differences in referral, patient screening and the variety of procedures performed between interventional cardiology and cardiac surgery require nuanced evaluations of these specialties. In cardiology, PCI procedures address one disease, so analyzing the clinical films and guidelines such as the American College of Cardiology's reports are suitable to assess appropriateness of care. Patients may not be evaluated by more than one physician prior to PCI and the screening may therefore be deemed less rigorous than cardiac surgery. In the case of PCI, post hoc reviews may assess appropriateness of therapy.

Cardiac surgeons perform a wide variety of procedures to treat a wide variety of diseases. Patients are screened 100% of the time before they are referred for cardiac surgery, often multiple times, and the appropriateness of therapy has already been assessed. Measuring the overall quality of care is a much more relevant way of evaluating surgical programs.

Therefore, MCSQI recommends against the review process via random selection of five to ten percent of cases as described in Quality sections 4(b) and (c) for cardiac surgery. A random sample of only five or ten percent will leave a large margin for error, and will not necessarily pinpoint a program's higher risk cases. While defensible for PCI review, this process will yield low results for surgery cases and drive up overall costs. If the goal of the review process is focused on coronary artery bypass grafting (CABG) cases, then this needs to be explicitly stated and reviews tailored for that purpose. However, to account for the entire range of procedure types performed by cardiac surgeons, the review of summary level data will provide a better assessment of performance. The STS quarterly reports and National Quality Forum (NQF) National Voluntary Consensus Standards for Cardiac Surgery are two examples of systems that address the overall quality of hospital care. To augment these reports, similar measures could be recommended to the MHCC's Clinical Advisory Group and provided via the MCSQI database.

We support the development of the multidisciplinary "heart team" approach to discuss all treatment options available for diseases for which several therapies are available, before elective application to ensure appropriateness.

• <u>Procedure Volume</u>: In Volume Requirements section 6, please clarify what occurs when a hospital performs between 100 and 200 cases, and amend the wording in 6(a) to: "a cardiac surgery program shall *strive to* maintain an annual volume of 200 or more cases."

 <u>Flexibility for Future Procedures</u>: The methodology ultimately chosen needs to be flexible enough to ensure that appropriate evaluations occur for all current and future therapies. The use of pacemaker and automated internal cardioverter defibrillator (AICD) technologies in particular are subject to the same quality and appropriateness concerns and do not appear to be addressed by recent MHCC deliberations. Transcatheter Aortic Valve Replacement (TAVR)—with multiple different devices involved—and mitral valve interventions with devices such as the Mitra clip are in clinical trials and will likely be approved for use in the near future. Like PCI, there will be the opportunity with these therapies for self-referral and inappropriate use of expensive technologies.

MCSQI is an organization dedicated to ensuring the quality, appropriateness, and cost effectiveness of cardiac therapies in the State of Maryland. We request that the MHCC consider our comments to help ensure the optimal care of patients with heart disease now as well as in the future.

Regards and thank you for your consideration,

Clifford Edwin Fonner MCSQI Executive Director cefonner@gmail.com

(913) 909-3140

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MCSQI Correspondence to MHCC – Letter #2

June 30, 2014

Via email: paul.parker@maryland.gov Via fax: (410) 358-1311

Paul Parker

Director, Center for Health Care Facilities Planning & Development Maryland Health Care Commission

4160 Patterson Avenue

Baltimore, MD 21215-2299

RE: Comments regarding the State Health Plan for Facilities and Services: Specialized Health Care Services—Cardiac Surgery and Percutaneous Coronary Intervention Services (COMAR 10.24.17)

Dear Mr. Parker:

Thank you and your staff for working with members of the Maryland Cardiac Surgery Quality Initiative (MCSQI) to better understand the proposed regulations for cardiovascular services. We appreciate the opportunity to provide comments on the drafted legislation and hope you consider these remarks as a reflection of the opinions of cardiac surgeons, database managers, hospital administrators, and other healthcare professionals from nine hospitals across the state.

MCSQI's main concern with the proposed regulations regards the transfer of patient-level information from the Society of Thoracic Surgeons' Adult Cardiac Surgery Database (STS-ACSD) to the Maryland Health Care Commission. The drafted regulations state that the submission of this data will help ensure "complete, accurate and fair evaluation of Maryland's cardiac surgery programs." However, it is MCSQI's strongly held opinion that this goal can be accomplished much more efficiently by instead utilizing information from the STS' Quarterly Reports.

As discussed with Eileen Fleck of the MHCC at a meeting on June 23, 2014, the STS-ACSD is renowned as the preeminent clinical database and risk model nationally and internationally. Data validity is ensured by a comprehensive Quality Reporting process, that includes a data collection and entry staff, extensive clinical and scientific database expertise, multiple steps of data validation, and random auditing processes. Database functionality and risk model accuracy fundamentally depend on the size of the data source; the Duke Clinical Research Center (DCRI) is able to provide these services through their statistical expertise and the analysis of more than 4.5 million surgical records.

The methodologies surrounding risk modeling and analysis of such a large data set are of critical importance and can make the difference between accurate, actionable information and incorrect or improper data usage. Expert staff members at DCRI perform calculations on patient-level data to produce a comprehensive summary of risk factors, process measures, and post-operative outcomes across all procedure types. The STS utilizes risk prediction methodologies derived from continually evolving and validated logistic regression models to risk-adjust nine outcomes metrics, providing an objective, continuous quality improvement tool that is among the best of its kind in the world1 2 3. Both CMS and the National Quality Forum have recognized the STS-ACSD reports as national standards for evaluating the quality of cardiac surgical care.

The STS-ACSD report measures also involve calculations that incorporate data from more than 1,000 surgery practices nationwide. For instance, the STS Star Ratings compare hospitals' risk-adjusted 95% confidence intervals against national benchmarks; without the national data set or these proprietary benchmark values, it is impossible to recreate the exact metrics on the STS-ACSD reports4 5. Eileen Fleck has stated that the MHCC could:

- 1. Purchase the software from an STS approved vendor, and
- 2. Use the raw data from programs picked at any time to decide upon the need for a focused program review.

However, the members of MCSQI oppose this premise based on the intricacy of the database and its reports, and the monumental, continual efforts required to create and maintain a national registry used to monitor and improve patient care. Because of the complexity of these calculations, significant differences would exist between the STS-ACSD reports and any calculations MHCC would perform on the patient-level data. These differences in methodology and reporting could lead to inappropriate data usage, resulting in wasted time and resources for providers and ultimately harming the patient population and Maryland residents as a whole.

During the MHCC's Clinical Advisory Group meetings, the group recommended acquiring raw, patient-level data solely for interventional cardiology. The American College of Cardiology's National Cardiovascular Data Registry (ACC-NCDR) does not provide the same risk-modeled, audited, validated and composite data as does the ST-ACSD. Thus review of these cases is more appropriate, as nationally recognized standards for these cardiology procedures do not yet exist.

If the MHCC were to undertake an analysis of the patient-level STS-ACSD cases, MCSQI would question the potential validity and timeliness of such reports. What additional information would an MHCC-derived report be able to provide above and beyond the comprehensive measures that STS already provides, and at what cost to taxpayers? In an era calling for increased fiscal responsibility, we again urge MHCC to consider the time and money involved in analyzing these patient-level data and whether this constitutes a wise utilization of taxpayer resources.

For these reasons, MCSQI recommends the MHCC use the currently available STS reports in lieu of reviewing the patient-level data. A suggested compromise could involve

For these reasons, MCSQI recommends the MHCC use the currently available STS reports in lieu of reviewing the patient-level data. A suggested compromise could involve using these reports for an interim period (1-3 years) and then revisiting the prospect of patient-data calculations after MHCC is more familiar with the STS-ACSD, its quarterly reports, and the intricacy within.

Thank you for your consideration,

Clifford Edwin Fonner, MCSQI Executive Director <u>cefonner@mcsqi.org</u> (913) 909-3140

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 ² Shroyer, A.L.W., Plomondon, M.E., Grover, F.L., and Edwards, F.H. The 1996 Coronary Artery Bypass Risk Model: The Society of Thoracic Surgeons Adult Cardiac National Database. Ann Thorac Surg. 1999; 67: 1205–1208

³ Shroyer, A.L.W., Coombs, L.P., Peterson, E.D. et al. **The Society of Thoracic Surgeons: 30--Day Operative Mortality and Morbidity Risk Models.** Ann Thorac Surg. 2003; 75:1856–1864

⁴ Shahian, D.M., Edwards, F.H., Ferraris, V.A. et al. Quality Measurement in Adult Cardiac Surgery: Part 1—Conceptual Framework and Measure Selection. Ann Thorac Surg. 2007; 83:S3–S12
⁵ O'Brien, S.M., Shahian, D.M., DeLong, E.R. et al. Quality Measurement in Adult Cardiac Surgery: Part 2—Statistical Considerations in Composite Measure Scoring and Provider Rating. Ann Thorac Surg. 2007; 83:S13–S26

MCSQI Correspondence to MHCC – Letter #3

November 18, 2015

Eileen Fleck Maryland Health Care Commission 4160 Patterson Ave. Baltimore, MD 21215

Dear Ms. Fleck,

For the purpose of serving the MHCC and its Clinical Services Advisory Panel, members of the Maryland Cardiac Surgery Quality Initiative recently convened to discuss the MHCC's classification of procedures in COMAR 10.24.17. MCSQI represents all cardiac surgery programs in the state of Maryland, and our consensus opinion is that the current system classifying procedures as "Open Heart" and "Cardiac Surgery" is confusing and does not accurately reflect the clinical practice of cardiac surgery in the current era. Our goal is to work with the Maryland Health Care Commission to develop a system of classification that is accurate, representative of the current practice of cardiac surgery, and can be used by the State of Maryland to maximize safety and quality outcomes for patients in the State of Maryland. We have made the following recommendations using the International Classification of Diseases, Ninth Revision (ICD-9) codes based on the stated preference of the Maryland Health Care Commission at our previous meetings.

We advocate merging "Open Heart" and "Cardiac Surgery" procedures into one category, henceforth referred to as Cardiac Surgery. This new definition is based on an operation fulfilling at least two of the following criteria: 1) an incision into the chest, 2) direct contact with the heart, 3) use of cardiopulmonary bypass, and 4) operation on the thoracic aorta and/or great vessels. The attached table details the procedures that we recommend as Cardiac Surgery, along with a new category for cases that are not Cardiac Surgery but should only be performed at a center with cardiac surgical services available in the event an emergency operation is required.

We believe these revisions accurately represent cardiac surgery procedures in 2015 and will help ensure COMAR 10.24.17 optimizes patient safety, cost effectiveness, and appropriateness of care for heart procedures.

Thank you in advance for your consideration of our recommendations, and please let us know if there is any additional information that would assist with the State Health Plan for Cardiovascular Services.

Sincerely,

Jamie Brown, MD Chairman, MCSQI Eddie Fonner Executive Director, MCSQI

MCSQI Correspondence to MHCC – Letter #4

March 2, 2016

Eileen Fleck Maryland Health Care Commission 4160 Patterson Ave. Baltimore, MD 21215

Dear Ms. Fleck,

Based on recommendations from the MHCC at the November 18, 2015 meeting of the Cardiac Services Advisory Group, members of the Maryland Cardiac Surgery Quality Initiative have updated our list of Cardiac Surgery procedure codes for COMAR 10.24.17. We have attached three documents for your reference.

The first document is an Excel spreadsheet containing the ICD-9 codes for our previously agreed upon Cardiac Surgery procedures as well as codes for procedures that are only safe to perform at a hospital with cardiac surgical services. We have provided commentary for all procedure codes that have been added or changed from COMAR 10.24.17 and have included these comments in a separate Word document as well. ICD-10 conversions for these ICD-9 codes are provided in an Excel document as the third attachment.

Please let us know if there is any additional information that might assist your work on the State Health Plan for Cardiovascular Services. We appreciate this opportunity to advise MHCC and look forward to continued collaboration toward improving the quality of care and helping ensure patient safety across the state of Maryland.

Sincerely,

John Conte, MD Chairman, MCSQI Eddie Fonner Executive Director, MCSQI

Abstracts, Posters and Manuscripts

The Maryland Cardiac Surgery Quality Initiative: Collaborating to Improve Outcomes Statewide. Alejo D, Horvath KA, Salenger R, Conte JV, Whitman GR, Bobbitt J, Fonner CE. Poster presented at the Society of Thoracic Surgeons Advances in Quality and Outcomes Meeting, 2015.

Variation In Red Blood Cell Transfusion Practices During Cardiac Surgery Among Centers In Maryland: Results From A State Quality Improvement Collaborative. Magruder JT, Blasco-Colmenares E, Crawford TC, Alejo D, Conte JV, Salenger R, Fonner CE, Kwon CC, Bobbitt J, Brown JM, Nelson MG, Horvath KA, Whitman GR. The Annals of Thoracic Surgery, 2016.

Are Surgeons Discussing STS Predicted Risk Scores? A Look across Maryland Hospitals. Alejo D, Bobbitt J, Costantini F, Sender D, Brogan M, Getson K, Toro A, Romine H, Hanna G, Kakellos M, Roach D, Behrens K, Fonner CE. Poster presented at the Society of Thoracic Surgeons Advances in Quality and Outcomes Meeting, 2016.

STS Data Managers & Surgeons Enhancing Quality Measurement – Statewide Review of Reasons for Prolonged Ventilation. Alejo D, Bobbitt J, Costantini F, Sender D, Brogan M, Getson K, Toro A, Romine H, Hanna G, Kakellos M, Roach D, Behrens K, Fonner CE. Poster presented at the Society of Thoracic Surgeons Advances in Quality and Outcomes Meeting, 2016.

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MCSQI Annual Report

Eddie Fonner	Development and Executive Management
Diane Alejo	Editor and Content Development
Jennifer Bobbitt	Content Advisor
Shell Singal	Operations

Calendar of Events

Spring In-Person Meeting:

April 19, 2017

Data Managers Workshop: 9:00 a.m. – 4:45 p.m. Evening Meeting: 5:00 p.m. – 8:00 p.m.

Conference Calls: 6:00 – 7:00 p.m.

Quality Committee:

November 17, 2016 December 15, 2016 January 18, 2017 February 15, 2017 March 15, 2017 May 17, 2017 June 21, 2017

Board of Directors

November 18, 2016 December 16, 2016 January 19, 2017 February 16, 2017 March 16, 2017 May 18, 2017 June 15, 2017

Links

MCSQI Website	www.mcsqi.org
Maryland Health Care Commission	https://mhcc.maryland.gov
MHCC Quality Reports	https://healthcarequality.mhcc.maryland.gov
Maryland Health Services Cost Review Commission (HSCRC)	http://www.hscrc.state.md.us
Society of Thoracic Surgeons (STS)	http://www.sts.org
STS Public Reporting	http://www.sts.org/adult-public-reporting-module
Consumer Reports	http://www.consumerreports.org/health/doctors- hospitals/surgeon-ratings/ratings-of-bypass-surgeons.htm
National Quality Forum (NQF)	http://www.qualityforum.org

Testimonials

"Following the pioneering efforts of Dr. Alfred Blalock at Johns Hopkins Hospital in the 1940's and Dr. Joseph McLaughlin at University of Maryland in the 1970's, the development of the Maryland Cardiac Surgery Quality Initiative (MCSQI) is probably the single most important advancement in the history of organization of cardiovascular medicine in the state of Maryland. The future of cardiac surgery in Maryland is dependent on statewide hospital and physician collaboration and sharing of 'best practices.' "

~Kurt Wehberg, MD; Chief, Cardiothoracic Surgery; Peninsula Regional Medical Center

"In 2013 Maryland created a statewide cardiovascular quality initiative providing a platform for in depth review of the care our patients receive who undergo heart surgery. Success of a program is measured by its outcomes. The Society of Thoracic Surgery (STS) sets the 'National' benchmarks to measure this success. The data managers in MCSQI are committed to ensuring Maryland programs succeed in data integrity, as this is the core of meaningful data. Data Managers at all ten sites in Maryland work collaboratively, review patient scenarios/data definitions, etc. to ensure STS registry data is accurate, complete, reproducible, and reflect the quality of care for patients in Maryland. The data managers play a vital role in supporting the quality improvement goals of MCSQI at a regional level and align themselves with other regional STS collaboratives at a national leve!! This collaborative and supportive approach is the key to MCSQI's success in reporting surgical outcomes among the 10 programs in our State."

~ Jennifer Bobbitt, BSN, RN; STS Cardiovascular Coordinator; Washington Adventist Hospital

"MCSQI provides the framework for an ongoing unprecedented level of collaboration between cardiac surgery programs in Maryland. By learning from experiences at other high quality programs, UM St. Joseph Medical Center has been able to augment our own quality initiatives, and ultimately improve care for our patients."

~ Rawn Salenger, MD; Assistant Professor of Surgery, Division of Cardiac Surgery; University of Maryland St. Joseph Medical Center