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October 17, 2013

Eileen Fleck
Chief, Acute Care Policy and Planning
Maryland Health Care Commission
4160 Patterson Avenue
Baltimore, MD 21215

**Re: State Health Plan for Facilities and Services: Specialized Cardiovascular Service
COMAR 10.24.17**

Dear Ms. Fleck,

I am grateful for the opportunity to comment on the Maryland Health Care Commission's (MHCC) State Health plan for Facilities and Services: Cardiac Surgery and Percutaneous Coronary Intervention Services. I congratulate you and the MHCC on your excellent work to assure the highest quality and access to cardiovascular services for the people in the state of Maryland.

I am a Professor of Cardiac Surgery and serve as Chief of the Division of Cardiac Surgery at the University of Maryland. I was honored to have served on the Clinical Advisory Group to the MHCC. I serve as the Chair of the Access and Publications Taskforce of the Society of Thoracic Surgeons Adult Cardiac Database (STS ACSD) and have authored over 100 peer-reviewed manuscripts, with a focus on the field of heart valve surgery. The faculty of the University of Maryland's Division of Cardiac Surgery provides cardiac surgery to the citizens of the State of Maryland at the University of Maryland Medical Center, an 800 bed quaternary care hospital in downtown Baltimore, as well as at the University of Maryland St. Joseph Medical Center, a 263 bed hospital in Towson. The Division of Cardiac Surgery educates medical students, residents, and fellows. We are one of 24 integrated cardiothoracic ACGME-approved training programs in the country. My comments on the draft include the following:

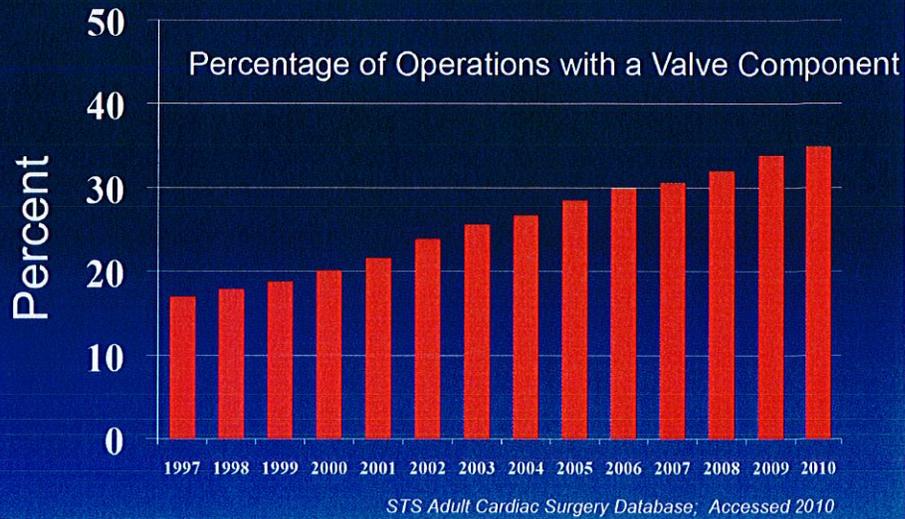
1. Volume-outcome relationship. While the document focuses on the volume-outcome relationship for CABG, it is important to recognize that the field of cardiac surgery has evolved over time. Heart valve surgery constitutes a growing percentage of adult cardiac operations. Data from the STS ACSD demonstrates that heart valve surgery presently makes up more than 1/3rd of cardiac operations. At our institution (UMMC) heart valve surgery constitutes almost 60 % of adult cardiac operations (Figure 1), with a ratio of valve to CABG operations in Q2 2013 of 1.44:



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Valve Disease: A Growing Component of Cardiac Surgical Practice



There is a clear and very important relationship between volumes and outcomes in heart valve surgery. Our group examined the relationship between center volume and outcomes in mitral valve surgery and found a striking relationship between

center volume and risk adjusted mortality as well as repair rates (a key quality indicator in mitral valve surgery). Among 13,614 elective mitral valve operations, mitral repair rates were nearly twice

as high in high volume compared to low volume hospitals (Figure 2). In addition, risk adjusted mortality was half (OR 0.48) in high volume compared to low volume hospitals (*Circulation*. 2007; 115:881-887). (Table)

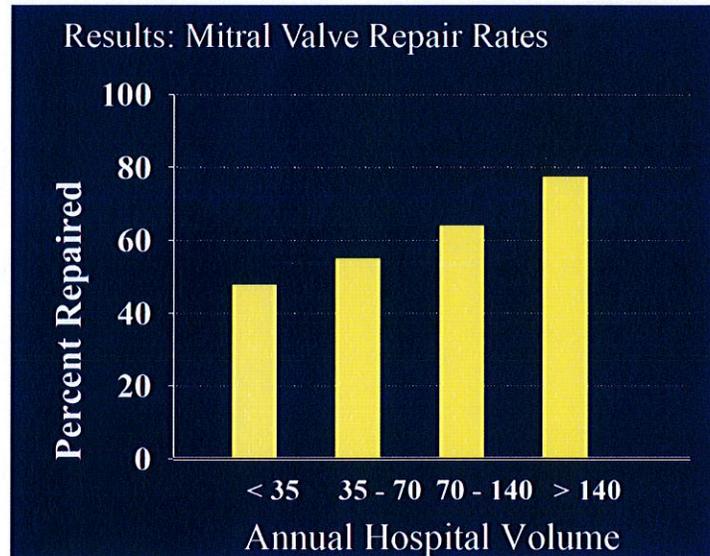
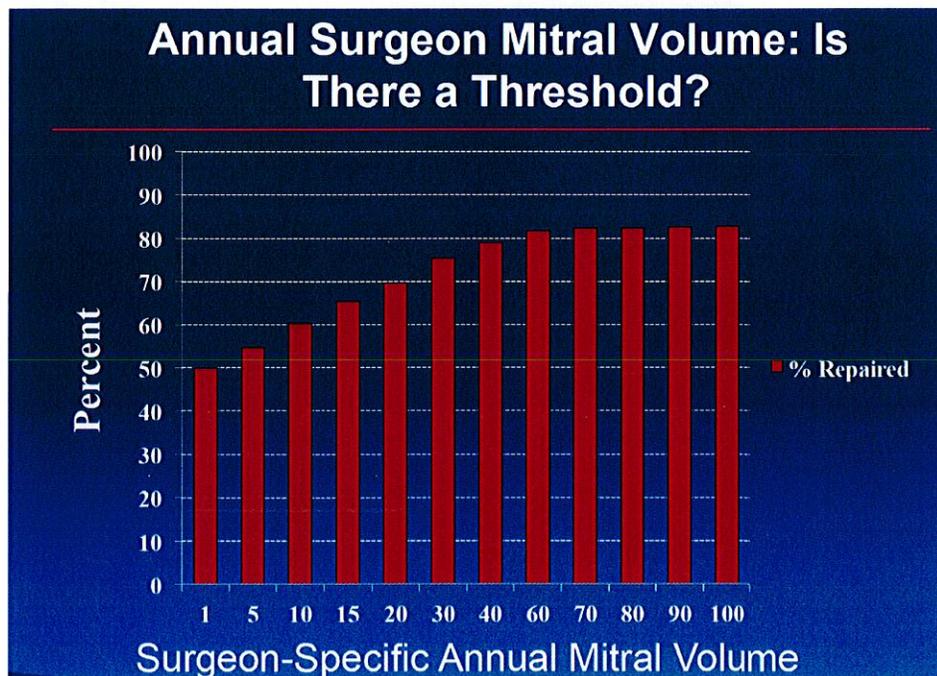
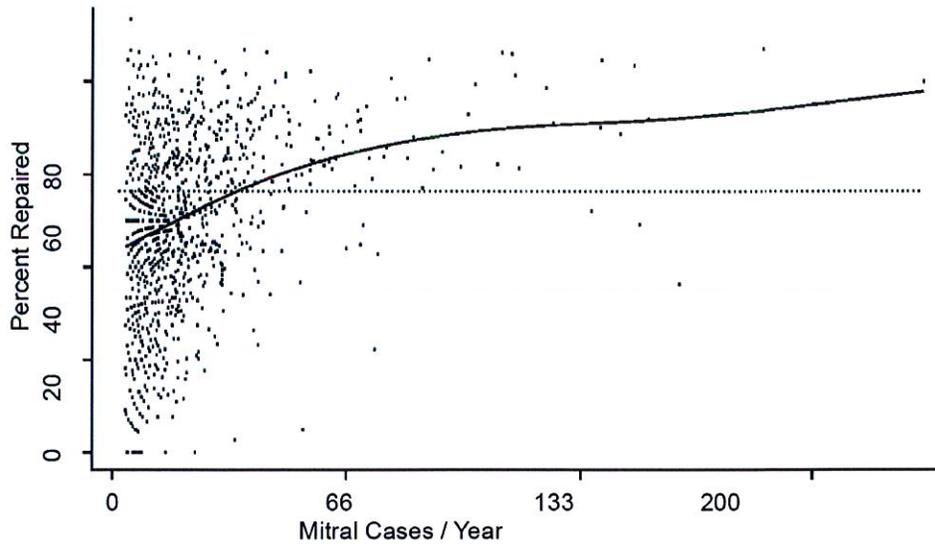


TABLE 4. Association Between Hospital Volume and Risk of Mortality Adjusted for Patient Risk Factors and Performance of Mitral Valve Repair

Annual Volume (Total Mitral Operations)	Odds Ratio (95% Confidence Interval)		
	Unadjusted	Adjusted for Patient Risk Factors Only	Adjusted for Patient Risk Factors and Repair
Volume ≤ 35	1.0	1.0	1.0
35 < Volume ≤ 70	0.70 (0.50–0.98)	0.71 (0.50–1.01)	0.75 (0.53–1.06)
70 < Volume ≤ 140	0.66 (0.46–0.95)	0.74 (0.50–1.09)	0.81 (0.55–1.19)
Volume > 140	0.40 (0.24–0.64)	0.48 (0.28–0.82)	0.56 (0.33–0.94)

More recently we examined 28,507 isolated mitral valve operations using the STS ACSD and demonstrated that repair rates (higher = better) were dramatically influenced by individual surgeon volume, with a threshold of 40 mitral valve operations/year. (*Annals of Thoracic Surgery*. 2010; 90:1904-12). (Figure 3 and 4)

Surgeon Predictors of Mitral Repair



Others have reported a similar relationship for aortic valve surgery, with evidence of increased adherence to guideline recommendations for valvular prosthesis choice in elderly patients.

(Hospital volume and selection of valve type in older patients undergoing aortic valve replacement surgery in the United States) (*Circulation* 2005 May 3; 111(17):2178-82) and a strong association between hospital volume and outcomes among patients undergoing aortic valve replacement (Aortic Valve Replacement: Using a Statewide Cardiac Surgical Database Identifies a Procedural Volume Hinge Point) (*Ann Thorac Surg.* 2013 Aug 30. pii: S0003-4975(13)01283-6). In this study from the Michigan Society of Thoracic Surgeons Quality Collaborative Initiative, the authors demonstrated a “hinge point” of approximately 100 cases/year, above which outcomes were significantly better. (Figure 5)

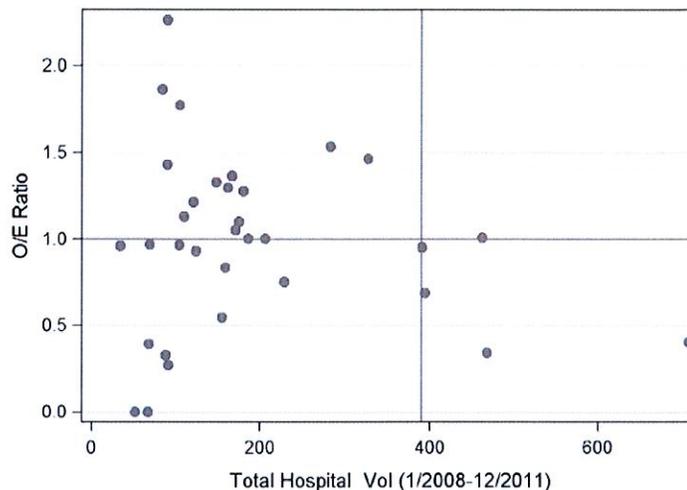


Fig 1. Scatter plot of observed to expected (O/E) ratio for early mortality versus hospital aortic valve replacement (AVR) volume. This plot shows the O/E for mortality as a function of individual hospital volume for all 33 hospitals performing AVR or AVR/CABG in Michigan. It is clearly evident that beyond 390 procedures (vertical line), the O/E falls to less than 1 for all higher volume hospitals, thus suggesting a hinge point for a volume-outcome relationship. (CABG = coronary artery bypass grafting.)

(Fig. 5)

In summary, modern cardiac surgery continues to evolve and in many centers heart valve surgery is more commonly performed than CABG. There is clear evidence that there is a strong center-volume outcome relationship for heart valve surgery, and that there is as well a surgeon volume-outcome relationship as well. Based on the above information for aortic valve surgery, if one assumes that AVRs make up 20 % of a hospital’s cardiac surgery volume, and then a threshold exists at a total program volume of 500 cases. The cardiac surgery program at UMMC has recognized this relationship and has embraced subspecialization within the practice of cardiac surgery. For example, our mitral valve repair program has evolved into a high-volume, two-surgeon practice, with operative mortality rates ranked in the 99th percentile across the country in the most recent STS ACSD report, and with repair rates for degenerative mitral valve disease almost 100%. An additional benefit of maintaining high volume heart surgery centers is that robust volumes support training of cardiothoracic residents. The University of Maryland and Johns Hopkins Hospital are committed to training the next generation of heart surgeons, and it is essential to maintain volumes to afford a high-quality training experience. We know that a number of our trainees will in the future provide safe, high-quality cardiac surgery services to the citizens of the State of Maryland.

There is growing recognition of the value of a multidisciplinary “heart team” approach to patients with cardiac disease affords optimal care for patients (Holmes DR, Rich JB, Zoghbi WA, Mack MJ). The Heart Team of Cardiovascular Care. *Journal of the American College of Cardiology* 61 ;(9) 903;

2013). This has been embraced by the CMS, which has promulgated minimum hospital volume requirements for the establishment of a transcatheter aortic valve implantation (TAVI) program. These include:

- ≥ 50 total AVR in the previous year prior to TAVR, including ≥ 10 high-risk patients, and;
 - a. ≥ 2 physicians with cardiac surgery privileges, and;
 - b. ≥ 1000 catheterizations per year, including ≥ 400 percutaneous coronary interventions (PCIs) per year.

(Decision Memo for Transcatheter Aortic Valve Replacement (TAVR) (CAG-00430N)) accessed at <http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=257&ver=4&NcaName=Transcatheter+Aortic+Valve+Replacement+%28TAVR%29&bc=ACAAAAAIAAAA&>

The cost to establish a new cardiac surgery program is a minimum of \$ 5,000,000 (R. Prager, University of Michigan, personal communication). The cost of establishing a new program and the negative dilutional impact on quality of care for our patients should be carefully considered.

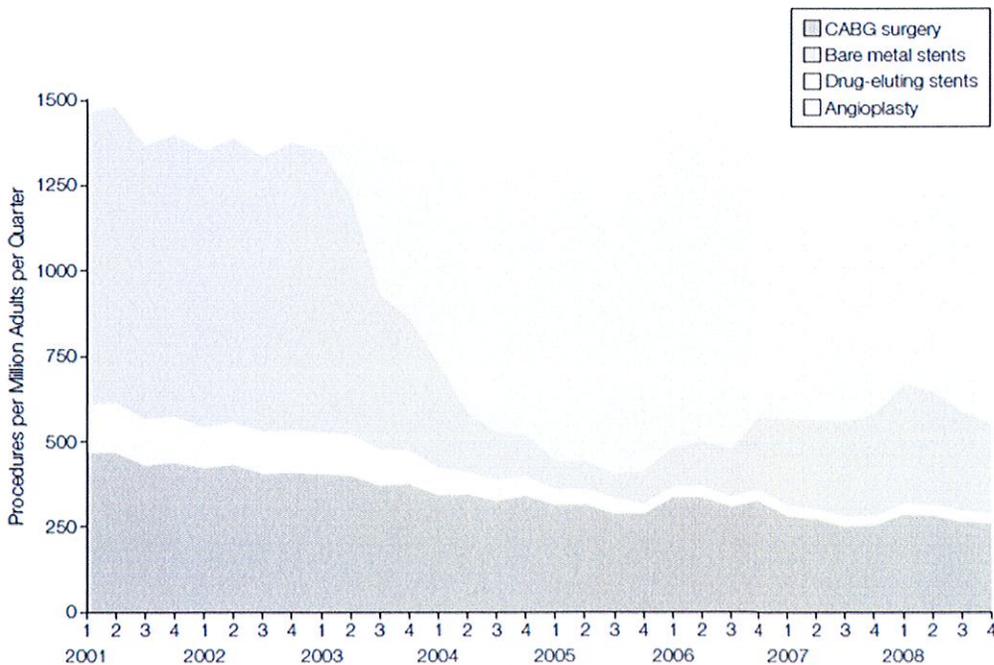
2. Heart Surgery Volume Trends in Maryland and the United States

The Table demonstrates total adult cardiac surgery volumes by center in Maryland for the last three fiscal years. (Figure 6)

Provider	FY11	FY12	FY13	FY12-13		FY11-13	
	Actual	Actual	Actual	Net Change	% Change	Net Change	% Change
JOHNS HOPKINS	850	829	989	160	19.3%	139	16.4%
UMMC	726	726	715	-11	-1.5%	-11	-1.5%
UNION MEMORIAL	639	566	545	-21	-3.7%	-94	-14.7%
PENINSULA REGIONAL	407	395	347	-48	-12.2%	-60	-14.7%
WASHINGTON ADVENTIST	345	309	327	18	5.8%	-18	-5.2%
SINAI	334	280	321	41	14.6%	-13	-3.9%
UM SJMC	435	290	244	-46	-15.9%	-191	-43.9%
SUBURBAN	217	239	215	-24	-10.0%	-2	-0.9%
SACRED HEART	262	189	198	9	4.8%	-64	-24.4%
Other Providers	39	10	26	16	160.0%	-13	-33.3%
Total	4,254	3,833	3,927	94	2.5%	-327	-7.7%

Source: HSCRC non-confidential discharge data

(Fig. 6)



This demonstrates a decline in heart surgery volumes of 8.3 % over the last three years. This is consistent with the national data, including a JAMA publication demonstrating the ongoing decline in CABG volumes over the last decade (JAMA. 2011 May 4; 305(17): 1769-1176). (Fig. 7)

We examined overall cardiac surgery volumes using the STS ACSD and demonstrated a similar sharp decline in heart surgery volumes over a recent three-year period. There was a 10.4 % decline in volumes comparing calendar year 2011 with 2009. In summary, heart surgery volumes continue to decline at a rate of 3 - 4 % per year in both Maryland and in the United States. (Fig. 7)

Procedure	Surgery Year		
	2009	2010	2011
Isolated Coronary Artery Bypass (CABG) Procedures	149,897	141,484	129,102
Isolated Aortic Valve Replacement (AVR) Procedures	21,966	22,896	24,322
Isolated Mitral Valve Replacement (MVR) Procedures	4,718	4,834	5,042
Isolated AVR + CABG Procedures	16,952	16,350	15,824
Isolated MVR + CABG Procedures	2,296	2,147	1,986
Isolated Mitral Valve Repair Procedures	6,109	6,514	6,716
Isolated Mitral Valve Repair + CABG Procedures	4,414	4,262	3,892
Total Procedural Volume	206,352	198,487	186,884

Source: STS ACSD

(Fig. 7)

3. How will the MHCC perform audits on 5 percent of submitted data?
4. How does the MHCC define “compliance with all standards for a certificate of ongoing performance”?
5. In considering the impact of a new cardiac surgery program, the document states that “an applicant must demonstrate that other providers of cardiac surgery in the health planning region or an adjacent health planning region will not be negatively affected to a degree that will:
 - (a) Compromise the financial viability of the cardiac surgery services at an affected hospital; or
 - (b) Result in an existing cardiac surgery program with an overlapping service area dropping below an annual volume of 200 cardiac surgery cases; or
 - (c) Result in the loss of additional volume at an existing cardiac surgery program that has an annual volume of less than 200 cardiac surgery cases and that has an overlapping service area.”

Suggest changing (b) to read: *Result in an existing cardiac surgery program surgery in the health planning region or an adjacent health planning region with an overlapping service area dropping below an annual volume of 200 cardiac surgery cases*

6. The report recommends that the hospital must “develop a formal, regularly scheduled (meetings every other month) cardiac surgery case reviews that requires attendance by physicians, nurses, and technicians who care for cardiac surgery patients.” This is already performed at the University of Maryland Medical Center in our peer-reviewed monthly morbidity and mortality conference.

7. The report also recommends:
- (b). The hospital shall conduct an annual external review of five percent of randomly selected cardiac surgery cases.
 - (c). The hospital shall evaluate the performance of each cardiac surgeon through an annual review of:
 - (i) At least 10 cases or 10 percent of randomly selected PCI cases performed by the cardiac surgeon, whichever is greater; or
 - (ii) If fewer than 10 cases have been performed, then all cases shall be reviewed;
 - (d) The performance review shall:
 - (i) Include a review of angiographic images; and
 - (ii) Be conducted by a reviewer who meets all standards established by the Commission to ensure consistent rigor among reviewers.
 - (e) The hospital shall provide annually, or upon request, a report to the Commission that details its quality assurance activities, including internal peer review of cases and external review of cases.

How will the external review be performed? Who will do this external review? The cost of such reviews will be high – who will pay for them? What measures of quality will be used as benchmarks? For the hospital review of individual surgeons, who will perform these reviews? Surgeons do not perform PCIs.

Some cardiac surgery patients (e.g. heart valve surgery) do not have angiographic images performed before operation. What are “standards established by the Commission to ensure consistent rigor among reviewers?”

8. On page 24, the report states: (b) A hospital with a risk-adjusted mortality rate for cardiac surgery cases that exceeds the statewide average beyond the acceptable margin of error calculated for the hospital by the Commission is subject to a focused review.

Please consider striking this language. Challenges with this approach to identifying outliers include “cardiac surgery cases” – does this include only isolated CABG? The identification of outliers is best achieved using the STS composite quality (star) rating system. 95% confidence intervals can be very wide for low-volume programs, and it is unclear what reporting period the MHCC is suggesting as a window of evaluation. The 95% confidence intervals of most cardiac surgery programs overlap widely.

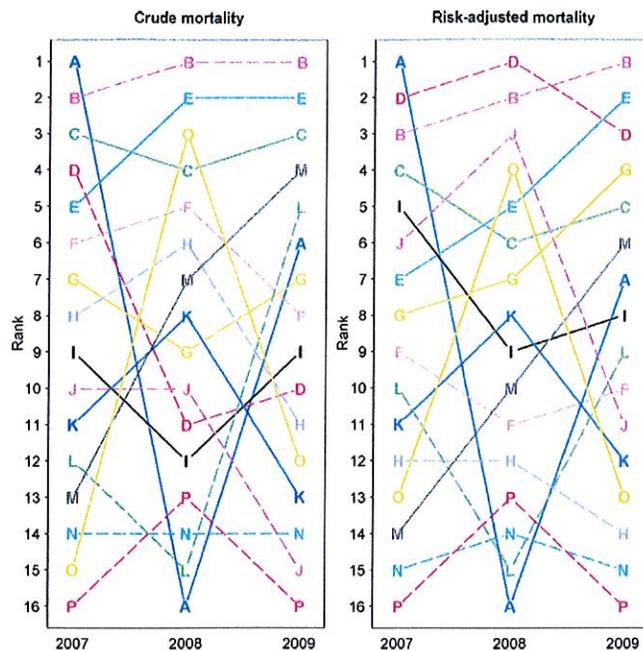


Figure 1. Ranking lists based on crude and risk-adjusted mortality rates of all 16 cardiothoracic surgery centers in The Netherlands for the years 2007, 2008, and 2009, separately. Risk-adjustment was performed using a random-effects model. Reshuffling of the ranks is seen across the years in both panels.

As consequence of this, reshuffling of ranks can be expected solely due to chance. In an analysis of cardiac surgery outcomes in the Netherlands, Siregar and colleagues examined the use of mortality rates to rank programs. They conclude that “Rankings are an imprecise statistical method to report cardiac surgery mortality rates and prone to (random) fluctuation. Hence, reshuffling of ranks can be expected solely due to chance. Therefore, we strongly discourage the use of ranking lists in the comparison of mortality rates.” (Circ Cardiovasc Qual Outcomes. 2012; 5:403-409-attached).

Furthermore, the composite score includes measures of mortality, as well as morbidity and evidence-based processes of care, thereby providing a more comprehensive assessment of quality.

Thank you for the opportunity to comment on the draft document. I look forward to working with you and your team to assure optimal performance and quality of heart surgery in the State of Maryland.

Sincerely,

James S. Gammie, M.D.