Draft Meeting Summary
Cardiac Services Advisory Committee (CSAC)
Thursday, May 11, 2023, 7:00pm-9:00pm
Maryland Health Care Commission (MHCC)
4160 Patterson Avenue, Baltimore, MD 21215

Committee Member Attendees
Anuj Gupta, M.D. (online)
Christopher Haas, D.O. (online)
Heather Green, R.N. (online)
Jerome Segal, M.D. (online)
John Wang, M.D.
Josemartin Ilao, M.Ed.
Keith Horvath, M.D. (online)
Liza Vizcarrondo (online)
Matthew Voss, M.D. (online)
Rawn Salenger, M.D.
Stafford Warren, M.D.
Stuart Seides, M.D. (online)
Thomas Aversano, M.D. (online)

Other Attendees
Bernadette Hawkins (online)
Diane Alejo (online)
Judith Breitenbach (online)
Julie Miller, M.D.
Katie Hall (online)
Michael Chen, M.D. (online)
Ronna Dixon (online)
Tamara Baughman (online)
Terri Haber (online)
Toni Schiller (online)

MHCC Staff Attendees
Ben Steffen, Executive Director
Eileen Fleck, Chief, Acute Care Policy and Planning
Katie Neral, Program Manager, Acute Care Policy and Planning
Olubulola Alonge, M.D., Program Manager, Acute Care Policy and Planning

The meeting was called to order at 7:04pm. After introductions from those in the room, welcome remarks were provided by Ben Steffen followed by introductions of those in attendance online. Eileen Fleck indicated that there was a change to the roster due to a retirement at Sinai; Dr. Henry Sun now represents the hospital for CSAC, but he was unable to be in attendance. Ms. Fleck asked members to let her know if any additional changes to the roster are needed. She also asked if there were any changes or corrections to the meeting summary for May 17, 2022. The meeting summary was then finalized with no changes.

Next, Ms. Fleck introduced Katie Neral to present the overview results of the mandatory external review of PCI cases. She indicated that while there are slides to go along with the presentation, all information presented is also in the handout provided.

Results of External Reviews of Percutaneous Coronary Intervention (PCI) Cases

Ms. Neral asked committee members to refer to the handout that provided an overview of the *Summary of Annual Results of External Review of PCI Cases by Calendar Year*. She then briefly summarized the regulations governing the external reviews in COMAR 10.24.17. Ms.

Neral next explained MHCC's approach to data analysis for 2018 through 2022 and presented an overview of the information collected from 22 of the 23 hospitals in Maryland that provide primary and elective PCI services. She noted one correction to the handout, stating that reports from 20 hospitals were reviewed for 2020, rather than 19. Ms. Neral also noted that for 2021, currently just over half of the hospitals have submitted external review reports.

Ms. Neral explained that while the data on the external reviews of elective PCI cases shows a decrease in number of cases and lesions reviewed in 2020, this may be attributed to the postponement of elective PCI cases during the early COVID-19 pandemic. Caution should also be used when interpreting the data from 2021, as many reports have yet to be received from hospitals. Regarding patient outcomes, the results are consistent and good. Across the state, there is roughly a 95% success rate in treating lesions. Among cases reviewed, complications varied from approximately 5% to 7%. Across the period reviewed, alternate therapy was discussed more often, when appropriate, in recent years. A decrease was seen in the percentage of cases where alternate therapy should have been discussed, but was not, dropping from 54.1% to 35.9%. Additionally, those cases rated as rarely appropriate continue to be less than 1%.

Ms. Neral explained that there are three categories for evaluating the appropriateness of cases: angiographic, clinical, and ACC/AHA appropriateness criteria. She also explained that when a case is rated rarely appropriate, a second reviewer looks at the case. If there is disagreement between the two reviewers, a third reviewer looks at the case as well. According to the data, at least 78% of those cases rated as rarely appropriate had additional reviews conducted. At times it was not clear from the reports provided whether the additional reviews had been completed.

Stuart Seides, M.D. noted that the number of cases deemed less than appropriate was very small, which is good to see, however, he wanted to know if there was a concentration of cases at any one hospital. Ms. Neral responded that the cases were randomly distributed across hospitals.

Stafford Warren, M.D. questioned why the external review results are so delayed and if this process can be sped up. He wondered whether the holdup is in the review process itself or if the delay is with the hospitals. Mr. Steffen noted that the same question has been posed by Commissioners. Ms. Fleck stated that staffing constraints during the pandemic and late submissions have been reported as reasons for this and, therefore, MHCC has not pushed timely submissions.

John Wang, M.D. commented that the group should not underestimate the constraints on the workforce over the past three years. The human factor in these reviews requires that the reviews be completed off-hours in between clinical work. Julie Miller, M.D. commented that the issue is multifactorial for the Maryland Academic Consortium for PCI Appropriateness and Quality (MACPAQ)[1]; both staffing constraints and staffing changes can affect the process. Additional reviews for rarely appropriate cases also can cause delays because until the review of all cases is complete, a hospital's report cannot be finalized.

[1] MACPAQ is one of two organizations that is used by most Maryland hospitals to complete the required external reviews of elective PCI cases.

Josemartin Ilao, M.Ed. asked what type or size of the facilities have not yet submitted reports. Ms. Neral responded that two out of three of the hospitals that have yet to submit reports for 2021 are large volume hospitals. Ms. Fleck reminded the group that half of the hospitals still need to submit some review reports for 2021.

Liza Vizcarrondo inquired if Holy Cross Hospital was included in the summary of external reviews of PCI cases provided. Ms. Fleck responded that Holy Cross is the one PCI program that performs only primary PCI. Therefore, it is exempt from the mandated external review requirement that applies only to elective PCI programs.

Dr. Warren pointed out that having less than 1% of cases rated as rarely appropriate is very good. He also noted that the decrease seen in the percentage of cases where alternative therapy was not discussed and should have been discussed may be indicative of a learning benefit from completing external reviews. Dr. Wang agreed with that point and stated that this decline may show an improvement in documentation, more than anything else. Additionally, he commented that the normal value for rarely appropriate cases should be less than 1%, but higher than zero. Maryland may not be able to improve upon this data point, as there will always be situations that are rarely appropriate according to clinical guidelines and ACC criteria.

Christopher Hass, D.O. asked about the definition used for complications and if it is possible to tease out major versus minor complications. The most important question, according to Dr. Warren, might be what percentage of complications were based on creatinine kinase (CK) rises. Ms. Fleck stated that in some cases MHCC staff has more information, but this is an area where MHCC staff could likely get more information if requested. Dr. Wang reported that MACPAQ tracks complications analogous to the American College of Cardiology's National Cardiovascular Data Registry (NCDR).

Mr. Ilao asked if patients ever push for a PCI when it may not be the most appropriate treatment. Dr. Wang responded by stating this is a situation that physicians face every day. It is the physician's job to explain why PCI may not be the most appropriate treatment decision. However, the interventionalist will take a patient's preference into account if it is grey area, as to what treatment is acceptable.

Matthew Voss, M.D. agreed that less than 1% of cases being rarely appropriate is great. He asked if the data from external reviews of elective PCI cases has led to disciplinary actions for individual physicians and if MHCC staff thinks that these reviews will continue into the foreseeable future. Ms. Fleck responded that MHCC staff are focused on data at the program level, and usually do not know whether a hospital has taken disciplinary action on a specific physician. However, MHCC staff asks about external reviews at the time of the Certificate of Ongoing Performance, so it is possible that staff may become aware of disciplinary actions through that process.

Mr. Steffen stated that internal discussions are taking place regarding the state of quality reviews and reporting. It is appropriate to begin talking about how quality reporting should evolve. Dr. Voss added that all hospitals with PCI programs participate in the NCDR for CathPCI, which is very helpful in guiding quality. He expressed that the external review reports are helpful to read

and have led to better documentation, but he questioned the value of the labor-intensive reviews. Ms. Fleck explained that MHCC staff reviews the NCDR CathPCI data, and a hospital's performance is a trigger for focused reviews.

Dr. Wang stated that the NCDR CathPCI registry has become incredibly robust, having grown to more than 500 data points per patient, including appropriate use criteria, which may be worth looking at. It also includes a very detailed section about appropriateness for Acute Coronary Syndrome (ACS) cases and non-ACS cases. Dr. Haas stated that Maryland's results from the overview of the external review of elective PCI cases shows that interventionalists in Maryland perform strongly and provide quality services. He agreed that we now need to figure out how to adapt and have a mission moving forward.

Dr. Warren commented that there are two clear advantages of external reviews of elective PCI cases; the reviews have a teaching component and operators perform better when they believe they are being observed. He thinks these two functions, regardless of the delays in obtaining the results of the external reviews, serve a good purpose. Dr. Wang agreed that the broad statement made by Dr. Warren is largely accurate; however, Dr. Wang also noted that large programs may find the mandated external review process redundant. Depending on the robustness of the hospital's internal review processes, a lack of external reviews may or may not cause quality to suffer.

Dr. Miller noted that external reviews serve a different function than the NCDR CathPCI registry. She also pointed out that smaller hospitals, which may not have many interventionalists, may get more value from the mandated external review process. The mandated external review process provides a mechanism for additional reviews and feedback to physicians. She noted that external reviews are a separate process which includes looking at angiograms, but the NCDR provides robust data in terms of complications that cannot be duplicated in the small sample of external reviews. Mr. Ilao added that he is happy to see external reviews raising the bar across all hospitals in Maryland.

Discussion of the Updated Consensus Statement from SCAI

The discussion began with Ms. Fleck stating that she has received several questions regarding intravascular lithotripsy (IVL). While this procedure is not explicitly forbidden in MHCC's regulations, hospitals have been looking for MHCC's blessing on the guidance issued by the Society for Cardiovascular Angiograms and Interventions (SCAI). She referred people to Figure 1 on page 3 of the SCAI Consensus Statement, which shows specific status and features of the case. It indicates what needs to be true in terms of the resources, support, and operators available, and whether it is okay to complete these procedures at facilities without cardiac surgery onsite. She noted that according to the regulations, extracorporeal membrane oxygenation (ECMO) and percutaneous ventricular assist devices (pVAD) procedures are defined as only appropriate at cardiac surgery centers. Hospitals should be aware when treating complicated cases, as this limits hospitals.

Multiple members asked for clarification on whether Impella devices are allowed at a non-surgery site. Ms. Fleck stated that this is her understanding, based on the ICD-10 procedure codes

in the regulations, that Impella devices could not be used at hospitals without cardiac surgery onsite.[2] Dr. Wang pointed out that there are some instances where the pVAD may save lives, if used to transfer the patient to a facility with surgery onsite. Discussion regarding the appropriate use of an Impella device ensued. It was noted that a great deal has to do with operator experience and judgment. While it may not be appropriate to use an Impella device to do high-risk PCIs at a hospital without cardiac surgery, it is good to use it for transfer patients in shock to cardiac surgery centers.

Dr. Seides commented that he agrees with other members on IVL. He suggested that it would be appropriate to adopt the criteria outlined in the SCAI document. Dr. Wang agreed that the SCAI statement is a tremendous effort and very thoughtful, but it appears that the article applies to the entire U.S. There is great variability in types of procedures completed at non-surgery centers. He referred to Table 2 on page 8 where it defines levels of hospitals and emphasized that physicians must know their institutions and the experience and resources that are available. Dr. Wang also added that IVL is safe and much safer than other calcium modifying devices. He thinks it very low risk and appropriate for operators who have the appropriate level of experience to add as a tool.

Thomas Aversano, M.D. commented that operator experience is extremely important and leads to good outcomes. The problem with potentially dangerous devices is often not the operator, but the ancillaries that offer support if a complication occurs. He cautioned the group to think about potential consequences of a complex intervention, irrespective of the volume and experience of the operator, and consider the support services available at a hospital. Ms. Fleck agreed. She also mentioned that the literature shows the need for emergency CABG is rare. Dr. Miller clarified that it is the tools that come with the surgery onsite that may be better at a larger hospital.

One CSAC member asked why non-surgery setting would take on highly complex cases. Dr. Voss responded that there are two reasons for this. One problem is that it takes time to get a patient to the tertiary center and additionally, transportation is an expense to the healthcare system. He considers IVL very low risk and something that should be added at all hospitals with PCI. For more complex interventions, Dr. Voss stated that you need a backup system if you get in trouble, and the Impella device is that backup for those patients in shock needing transfer. He added that it's a useful tool in select patients.

Dr. Wang asked Ms. Fleck to verify that Impella devices are currently limited by the regulations, as it really is a needed tool for some patients, especially for emergency transfer. Rawn Salenger, M.D. agreed that it seems appropriate for an Impella device to be used, especially as many sites without surgery are often the initial receiving sites for patients with acute myocardial infarction. Dr. Wang added that improvements have been made to Impella devices, which makes it less risky. Additionally, IVL has changed the paradigm of how lesions are treated across the nation. There seemed to be a consensus among CSAC members that IVL makes sense at all hospitals with PCI programs and Impella devices are safe for some uses at non-cardiac surgery sites, specifically patients in cardiogenic shock, who require transfer.

[2] Following the CSAC meeting, on May 12, 2023, Ms. Fleck updated CSAC members that she was mistaken in thinking the Impella device could not be used at all at hospitals without cardiac surgery onsite.

Dr. Salenger stated that it would be valuable to establish a registry for the patients treated with Impella for transfer to a tertiary center, to see how they do, as this is such a critical patient population. These cases may or may not be part of randomized external or internal reviews completed by hospitals.

Next, Ms. Fleck asked CSAC members to weigh in on whether MHCC staff should endorse the SCAI statement. CSAC members agreed with endorsing it. Mr. Steffen agreed that there seems to be consensus among committee members. In response to another question about use of Impella devices at hospitals without cardiac surgery on-site, Ms. Fleck reminded CSAC members that while the SCAI consensus statement had been endorsed by CSAC members, MHCC regulations restrict certain procedures to hospitals with cardiac surgery onsite. She noted that one reason for the discussion is to determine whether to recognize the expert guidelines and to make a potential change to the regulations, if needed.

Ms. Fleck stated that it would be wise to talk more about updating MHCC's regulations regarding the use of the Impella device at a future meeting.[3] She also agreed that Dr. Salenger's idea about a registry is a good one and the group should talk more about making that change in the future.

Before moving on, Dr. Wang asked for MHCC's stance on cardiac services moving to office-based locations and ambulatory surgery centers (ASCs). Mr. Steffen responded by stating that MHCC staff plans to start looking at the issue because there have been several inquiries. It would require a change in statute and regulations. While it's not currently permitted in Maryland, he has heard projections that as much as 30% of PCI services may move out of hospitals in the future. The challenge is how hospitals that currently do elective PCI would be affected.

Quality Standard for Cardiac Surgery Programs – COMAR 10.24.17.07B(4)

Ms. Fleck explained that cardiac surgery programs, unlike PCI programs, do not have an external review requirement. She asked the group to consider the following questions: (1) How often should mortality and morbidity reviews be performed and how quickly? (2) Would it be useful to have more uniformity between PCI and Cardiac Surgery programs? (3) Should hospitals have a formal policy regarding when a case should be sent for external review?

Dr. Salenger stated that the Phase of Care Mortality Analysis (POCMA) is a great tool for reviewing mortality and morbidity in cardiac surgery cases. The purpose is to identify the root causes of deaths and complications, which may not be in the operating room, but rather pre-operative or post-operative. He also noted that it would be reasonable to have guardrails around how often mortality and morbidity or peer review should be completed, and for the timeliness of these reviews. The suggestion was made to require hospitals to have a policy for when they would send a case for external review. Programs get value from looking at their own quality. Keith Horvath, M.D. also recommended that MHCC staff pay attention to STS risk calculations, and there should be concern when the observed to expected ratio is more than one.

[3] As communicated by Ms. Fleck following the CSAC meeting, the regulations allow for use of the Impella device at hospitals without cardiac surgery onsite in certain situations; a change in the regulations is not needed to allow for use of the Impella device to support patients in cardiogenic shock for transport to another facility.

CSAC members decided that a requirement of quarterly reviews, at a minimum, is reasonable for mortality and STS major morbidity. The timeliness of reviews could be quarterly as well, as a reasonable place to start.

With that, Ms. Fleck stated that the group had accomplished its goals for this meeting. For the next meeting, the use of Impella devices should be discussed and possibly site of service. The meeting was adjourned at 8:51pm.