Draft Meeting Summary
Cardiac Services Advisory Committee
January 18, 2022, 7:00pm-8:30pm
Maryland Health Care Commission (MHCC)
Virtual Meeting

Workgroup Attendees

Anna Aycock
Thomas Aversano, M.D.
Kristin Deely
Heather Green
Christopher Haas, D.O.
Steven Hearne, M.D.
Keith Horvath, M.D.
Jose Martin Ilao
Rawn Salenger, M.D.
Stefano Schena, M.D.
Jerome Segal, M.D.
Stuart Seides, M.D.
John Wang, M.D.
Stafford Warren, M.D.

Other Attendees

Tamara Baughman
Judith Boulay-Ganthier
Judith Breitenbach
Ronna Dixon
Debra Franckowiak
Michelle Hardester
Erica Hart
Diane Hollenbeck
Eddie Fonner
Richard Jones
Mary Maloney
Judith Peck
Jeanne Ruff
Toni Schiller
Jeff Trost, M.D.
Spencer Wildonger
Darleen Won
Mark Moffett, Ph.D.
Saleena Yedla

MHCC Staff Attendees

Eileen Fleck
Zoram Kaul, Ph.D.
Theressa Lee
Ben Steffen

Eileen Fleck noted that there was a lot of interest in the report and a couple members of the Cardiac Services Advisory Committee (CSAC) sent questions in advance of the meeting. She asked Mark Moffett to share information on his educational background and experience working with the type of data he analyzed for MHCC. Dr. Moffett noted that he has a doctorate degree in economics and did post-doctoral work in health services research at Baylor College of Medicine and the Michael DeBakey Veterans Affairs Medical Center in Houston. He has been working on health policy and health services research for about 20 years. He has largely

worked with claims data. The MHCC study was his first time analyzing data from the American College of Cardiology (ACC).

Dr. Moffett encouraged people to ask questions during his presentation. He mentioned that Dr. Aversano sent in a question asking about the interpretation of the volume effects. As an economist, Dr. Moffett sees things from an economic perspective. He appreciated receiving feedback from a clinical perspective.

Dr. Moffett explained the objectives of the study: evaluate the impact of a hospital's PCI volume of non-ST-elevated myocardial infarction (NSTEMI) and ST-elevated myocardial infarction (STEMI) on patient mortality and complication rates; and assess how the identification of outliers for acute kidney injury and mortality rates is affected by program volume and using different methods to calculate standard errors and confidence intervals for mortality and acute kidney injury rates. The three methods compared were Clopper-Pearson, Agresti-Coull and Jeffreys. The Clopper-Pearson or "exact" model is commonly used, and it is the one used by the ACC for its analysis of the CathPCI registry data.

Dr. Moffett explained that the study specifically investigated the impact of NSTEMI PCI volume on acute kidney injury and mortality rates; the impact of STEMI PCI volume on acute kidney injury and mortality rates; and whether the method chosen to calculate standard errors and confidence intervals influenced a hospital's outlier status for acute kidney injury and mortality rates.

Dr. Moffett explained that the source of data for the study was Maryland hospitals with PCI programs. These hospitals provided detailed data from the ACC's National Cardiovascular Data Registry (ACC-NCDR) for CathPCI for the calendar years 2015-2019. There are about 2,400 hospitals nationwide that submit data to the ACC-NCDR.

Dr. Moffett explained that the mortality inpatient mortality rates were determined by the discharge disposition for patients. For acute kidney injury rates, the rates were determined by criteria modified from the Acute Kidney Injury Network (AKIN) criteria for kidney injury. Patients identified as having a kidney injury were those patients who came into the hospital without the need for dialysis, but who left with a new need for dialysis post procedure, who had an absolute increase (>0.3 mg/dL) in serum creatine from pre- to post-procedure, or who had a relative increase of at least 50% in serum creatine from pre- to post-PCI.

Dr. Moffett explained the variable used to identify the NSTEMI and STEMI PCI cases for the study was PCI indication. The values in this field include: PCI for high-risk Non-STEMI or unstable angina, immediate PCI for STEMI, unstable PCI for STEMI (>12 hours from onset of symptoms), stable PCI for STEMI (>12 hours from onset of symptoms), stable PCI for STEMI (stable after successful full-dose Thrombolysis), and rescue PCI for STEMI (after failed full-dose lytics). Dr. Moffett used the same risk adjustment variables as the ACC,

for mortality risk-adjustment variables. He did not use the same risk adjustment model as the ACC though. For acute kidney injury risk-adjustment variables, he relied on the AKIN criteria. For each admission for PCI, Dr. Moffett identified whether the patient had died or had an acute kidney injury. He explained that the PCI procedure was nested within the hospital for the model to determine hospital specific effects.

Dr. Moffett separately analyzed STEMI and NSTEMI PCI volumes. For one analysis, he categorized cases into one of two categories (high volume/low volume) based on median counts of PCI procedures from calendar years 2015 to 2019. For a second analysis, he categorized cases into one of three categories (low volume/medium volume/high volume) based on median counts of PCI procedures from calendar years 2015 to 2019. Josemartin Ilao asked how the statistical analyses accounted for the complexity of cases. He asked if more difficult cases were likely to be handled by larger hospitals, then would it affect the results for low-volume hospitals. He wanted to know if that possibility had been accounted for in the analysis. Dr. Moffett explained that this was factored in by looking at the other sources of patient complications. At the patient level, prior PCI status was known and whether a patient had a prior CABG or a number of other procedures. If those patients went to the higher volume hospital, that would be directly controlled for by the patient's level of severity.

Thomas Aversano, M.D. suggested that Mr. Ilao may be asking whether there are unmeasured, potential, complicating factors that are not included among the adjustment factors for the model. For example, he suggested that complexity of the angiography (type of lesion) may be an important factor. Mr. Ilao agreed that he is concerned that complex cases could be typically sent to a high-volume program, complicating the analysis. Dr. Moffett agreed that it was a possibility, but he was unsure as to what extent. Dr. Moffett noted that part of issue raised by Dr. Aversano could be addressed by looking at the cases where the source of admission was another acute care facility. He noted that the analysis was based only on where the procedure was performed and controlling for the patient level of severity. Unmeasured or unobserved severity may not have been fully adjusted.

Mr. Ilao expressed approval that the analysis accounted for when a patient came from another acute care program. However, a CSAC member and Dr. Moffett noted that Mr. Ilao was mistaken. Dr. Moffett stated that the goal was to control for other factors that affect volume. It has been suggested to the ACC that it adjust for volume, but the ACC does not. The purpose of his analysis was to see whether hospital volume itself is a predictive factor. Dr. Moffett noted that in the data analyzed for the period from 2015 through the first quarter of 2018, the source of admission was either the emergency department, another acute care facility or other; the "other" category was not specifically defined. Dr. Moffett again noted that source of admission was not considered in his analysis.

Dr. Moffett shared the results of his analysis of the NSTEMI cases, including analysis of whether significant differences exist for demographic variables and clinical measures when

the data is categorized by PCI volume levels. Rawn Salenger, M.D. asked for clarification on the results shown on Slide 12. He asked whether for hypertension, the results show that among PCI patients at low volume centers 81% had hypertension and among PCI patients at the high-volume centers 85% had hypertension. Dr. Moffett stated that Dr. Salenger's interpretation was correct. Dr. Moffett also noted that the difference is statistically significant, but he is not qualified to say whether clinically significant.

Dr. Moffett next explained the incremental effects of increasing NSTEMI PCI volume on both mortality rates and acute kidney injury rates. He explained that the incremental effect refers to whether there is a difference with moving from a low to medium volume hospital and then from a medium to a high volume hospital. He noted that the results reflect an odds ratio comparison. He noted that generally if the lower limit and upper limit of the confidence interval were less than one, it would mean lower mortality and if greater than one, it would suggested increased mortality.

He noted that his analysis shows that NSTEMI PCI volume does not have a strong effect on the mortality and acute kidney injury rates. John Wang, M.D commented that although the results were not statistically significant, the trend suggests lower mortality rates in higher volume centers, but that is not the case with the acute kidney rates. Dr. Moffett agreed; he added that he would not be surprised if the ACC found a volume effect for mortality rates in its much larger data set.

Dr. Wang asked what the impetus was to perform this study. Mr. Steffen responded that MHCC wanted to look at the results in Maryland in a more systematic way, reviewing all the programs at the same time. Mr. Steffen explained that about a year ago, MHCC issued a bid board notice. MHCC staff had a few concerns, but mostly MHCC staff had a desire to look at this information from a different perspective and to move beyond the program-by-program review of results. Dr. Wang commented that using mortality as an end point makes sense, but renal failure rates may not be the best choice. Sometimes the change in creatinine reaches the threshold that defines kidney injury (an absolute increase of $\geq$0.3 mg/dL in serum creatinine) but it is of no clinical significance. He suggested that may be why the analysis shows a trend in higher volume centers doing better with mortality rates, but not renal failure rates. He suggested analyzing vascular complications or another complication may be more valuable.

Dr. Moffett presented the unadjusted STEMI PCI volume results, which showed more variance than the NSTEMI PCI volume results. Dr. Moffett noted that Dr. Aversano had pointed out than many of the low-volume hospitals were tertiary hospitals, which may be why the clinical variables did not necessarily go in the same direction as for the NSTEMI cases when hospitals are categorized by volume.

Dr. Aversano commented that there were important racial differences that were not included in the table, such as differences in African American and Hispanic proportions. He

noted that while race may be an artificial parameter, it also relates to insurance, education, economics, and a number of social determinants of health that are unaccounted for in the analysis. Dr. Moffett agreed.

Dr. Aversano also asked why race and certain other factors that were statistically significantly different in comparisons with hospitals grouped by volume were not shown in the next table on Slide 17. Dr. Moffett said that he wanted to highlight the differences in clinical severity. He agreed that Dr. Aversano was right that there are definite differences in both race and ethnicity variables. Dr. Moffett commented that social determinant indicators can be linked using zip code information. He did not do that analysis, but it could be done.

Ms. Fleck noted that MHCC staff provided AGS with the data elements needed for the analysis requested. At the time, zip code area information was not regarded as necessary. Mr. Steffen added that in rethinking this study, it would be useful to include a deprivation index measure, if the study continues going forward. Mr. Ilao asked if renal failure could be defined differently, based on symptoms, if that would be more meaningful. Dr. Aversano commented that there typically are no symptoms until someone needs dialysis.

Dr. Moffett continued his presentation. He described the incremental effect of increasing STEMI PCI volume. The study found that STEMI PCI volume, after controlling for demographic and clinical characteristics, tends to be associated with lower mortality and lower acute kidney injury rates. In comparisons of medium to high volume programs and high to low volume programs, he found lower mortality and acute kidney injury rates in higher volume programs. For a comparison of low to medium volume programs, there was not a difference. Dr. Moffett noted that this difference led him to include economies of scale may be affecting the results.

Dr. Aversano commented that eight of the 12 low volume hospitals are tertiary hospitals, and the low volume hospitals are those with the worst mortality rates. From his perspective, it seems unlikely that those hospitals have the least experienced interventionalists and least specialized nursing units and staff. The economy of scale and experience of the interventionalists are unlikely explanations for the differences in mortality and acute kidney injury rates. Unmeasured variables such as the timing of patients presenting at the hospital, symptom to presentation time, and presentation time to device time are of great interest because all are important determinants of mortality. It may also be possible to remediate those factors. Dr. Aversano noted that those things are affected by social determinants of health in some cases. For example, someone without insurance and chest pain may be reluctant to go the hospital because if that person wrong about chest pain being a heart attack, it will be very expensive. The time from symptoms to showing up at a hospital may be longer for someone without insurance.

Dr. Moffett responded that in the data he analyzed, he has the date of arrival, arrival time, procedure date, and procedure time. For some of the years, he has the onset time. He does not have the primary or secondary payers. Dr. Aversano commented that many of the hospitals that have no on-site cardiac surgery are the high-volume hospitals, so it seems there has been a movement of STEMI cases to hospitals without cardiac surgery on-site. He noted that it may be possible that the logistics for caring for STEMI patients in community hospitals without cardiac surgery on-site are better than in the tertiary hospitals. It would be important to identify that issue because it can be remediated, especially presentation to device time.

Dr. Moffett explained that one reason some of the smaller hospitals had a higher STEMI PCI volume is because they are closer to where patients have myocardial infarctions. Dr. Wang commented that volume is complicated because in hospitals with low or high volume, the same interventionalists may be operating as both hospitals. He felt the analysis reflected a simplistic view of volume.

Dr. Aversano raised the issue of how a primary PCI is counted. He asked if a patients who had been transferred from another hospital would be counted at the first or second hospital. Dr. Moffett answered that in his analysis, the PCI case would be counted at the hospital where the PCI procedure was done. Dr. Aversano commented that capturing who is a transfer patient is important because of the added time from presentation to PCI.

Dr. Wang asked how the highest mortality group for STEMI patients and the worst group as far as acute kidney injury rates compared in the lowest volume hospitals to the national benchmark. If even the worst hospital was better than the national average, then that would be great and useful to know. Dr. Moffett responded that he did not have that data and would have to look it up. Dr. Aversano again noted that from his perspective finding something that can be fixed and addressing it would be useful. He emphasized looking at timing for patients. Ms. Fleck agreed that those were good points. She noted that what sometimes happens is there can be reasons for a delay due to a patient's condition, which hospitals sometimes explain if the hospital has not met the door-to-balloon time performance metric. Those delays are considered non-system delays by the ACC. Dr. Aversano noted that the ACC accounts for those patients. Dr. Wang added that those factors are accounted for primarily at the hospital where a procedure was done. If a patient was intubated at another hospital before transfer to a second hospital that performs PCI, that would not be accounted for by the ACC.

Dr. Wang commented that it is important to recognize limitations in data and determine if the findings indicate performance worse than the national average. He suggested even if a hospital is low volume and performing worse than the national average, not having a program at all may result in worse outcomes for patients because of longer time to get to another hospital. It is important to consider the larger consequences. Chris Haas, M.D. thanked Dr. Wang for his comments. He commented that low volume centers, like the one where he

performs PCI, are often concerned about how analyses regarding the impact of volume will be used. Low PCI volume at a hospital may be due to geography or reputation.

Dr. Haas suggested that it would be best to use national data and to compare similar programs, as determined by factors other than just volume. He also noted that time from first medical contact to PCI is a critical factor not captured by Dr. Moffett's analysis. He asked how the data and analysis is going to be used. Mr. Steffen responded that this is a work in process, and MHCC staff wanted to obtain feedback from CSAC members before presenting the report to the Commission. He noted that MHCC staff has found some suggestions to be very valuable. Additional follow-up may depend on the budget available for it. Mr. Steffen again stated that his objective with the analysis requested was to get an overall picture of the performance of Maryland hospitals.

Dr. Moffett explained the results from the analysis of three different methods to calculate confidence intervals and standard errors. He noted that the analysis showed no real difference in the NSTEMI mortality, NSTEMI acute kidney injury, STEMI mortality, and STEMI acute kidney injury rates (no outliers found).

Dr. Moffett summarized the key findings. Impacts on outcomes of care related to NSTEMI PCI volume are modest, at best, and can be explained by the variance in patient severity. Hospitals with relatively high STEMI PCI volume have lower mortality and acute kidney injury rates after controlling for demographic and clinical factors. Finally, the methods used to calculate standard errors and confidence intervals for inpatient deaths and acute kidney injury proportions do not make a substantive difference in identifying outlier hospitals for STEMI and NSTEMI PCI cases. The recommendation is to continue using the Clopper-Pearson model for future data analyses. Dr. Moffett plans to expand the limitations to include the points raised in the meeting and in email correspondence with Dr. Aversano.

Mr. Steffen reiterated that some of the suggestions received in the meeting, such as factoring in social determinants or specifically an area deprivation index, will require linking with another data system. MHCC staff will consider the suggestion related to the types of patients who arrive at tertiary hospitals. Mr. Steffen asked Dr. Wang and Dr. Aversano if they knew a different mix of patient shows up at certain locations in their respective health care systems.

Dr. Aversano suggested that the simplest thing to look at which does not require looking at a different database is incorporate the time from presentation to device time. It is not as good as looking at social determinants of health, but it would be valuable. He was not able to comment on any demographic differences. Dr. Wang reiterated that his main point is to be cautious about classifying hospitals based on PCI volume only.

Dr. Wang suggested picking one metric such as vascular complications relative to PCI volume. He again stated that comparison with national benchmarks would be helpful in determining how well the hospitals are doing in Maryland. Dr. Haas commented that factors before a patient even arrives at a hospital can be confounders. Mr. Steffen agreed with the suggestions made and stated that MHCC staff would discuss the feedback. Most importantly, MHCC staff has to look at the remaining funding to determine what is financially feasible. Mr. Steffen stated he wanted to keep the record open for further comments from CSAC members. Mr. Steffen asked Ms. Fleck is she had anything to add.

Ms. Fleck brought up that comments in the chat box expressed concern about MHCC's use of the analysis and asked to know the purpose of the study. Ms. Fleck stated that the purpose of the analysis was to look further into the methods of the ACC and determine if volume or the method used for standard error and confidence interval calculations has an effect on the conclusions drawn about a PCI program's performance. Ms. Fleck noted that a concern had been raised about whether or not there is enough distinction between the programs and whether this related to some hospitals having a low volume. The intention was not to use the analysis to question the results of a specific program. MHCC staff primarily relies on ACC reports to evaluate the performance of hospitals.

Mr. Steffen thanked everyone for attending and recognized that the CSAC has not met in about two years. He plans to create a work schedule to resurrect the work of the CSAC. Mr. Steffen encouraged members to reach out with additional comments and reiterated that information regarding the next meeting would be shared with the group.