

**Draft Meeting Summary
Cardiac Surgery Advisory Committee Meeting
Tuesday January 23, 2018
7:00 p.m. - 9:00 p.m.
MHCC, 4160 Patterson Avenue, Baltimore, MD 21215**

Work Group Member Attendees:

Jamie Brown, M.D. (Phone)
Blair Eig, M.D. (Phone)
Steven Hearne, M.D. (Phone)
Paul Massimiano, M.D.
Richard Pomerantz, M.D.
James Recabo, M.D. (Phone)
James Ridge, M.B.A., B.S.N., R.N. (Phone)
Rawn Salenger, M.D.
Jerry Segal, M.D.
Stuart Seides, M.D. (Phone)
John Wang, M.D.
Stafford Warren, M.D.

Commission Staff Attendees:

Eileen Fleck
Ose Emasealu
Ben Steffen
Suellen Wideman

Other Attendees:

Diane Alejo

Introductions and Meeting Overview

Eileen Fleck welcomed members of the Cardiac Surgery Advisory Committee (CSAC) and all attendees introduced themselves. She stated that no one proposed changes to the draft summary of the last CSAC meeting that was held on November 30, 2017. She proposed for it to be finalized, and all CSAC members agreed.

Revision of Standards for Evaluation of Certificates of Ongoing Performance for PCI Services –Staff Recommended Changes

Ms. Fleck explained that the revision of the performance metric for percutaneous coronary intervention (PCI) programs is needed because of the difficulty of getting timely information for calculating the performance measure exactly as described in the regulations for Certificate of Ongoing Performance reviews. The proposed measure refers to use of either the national or statewide risk adjusted averages for elective PCI cases based on in-hospital mortality instead of the all-cause 30 day mortality. Feedback from the last CSAC meeting indicated that using in-hospital mortality would be acceptable. She noted that the use of statewide all-cause 30-day mortality was originally proposed by the clinical advisory group formed to provide input on the development of new regulations for cardiac surgery and PCI services. She explained that if the statewide average is not available within 12 months of the end of a reporting period, then the national average will be used as the performance metric. Richard Pomerantz, M.D., noted that

many hospitals participate in the American College of Cardiology's (ACC) National Cardiovascular Data Registry (NCDR) and receive reports on in-hospital mortality that is described in terms of percentile rankings. He inquired about the source of the data, and he also asked for an explanation of the 95% confidence interval. Ms. Fleck responded that the data used to calculate the performance measure are the data that hospitals already report to the ACC NCDR. She added that the confidence intervals will be used to describe the level of precision for the statistics generated. Ben Steffen clarified that the 95th percentile will be roughly equivalent to two standard deviations away from the mean, if the distribution is assumed to be normal. Staff Warren commented that an important point is that the national average will be used if the statewide average is not available on a timely basis.

John Wang, M.D. expressed concern that if the mortality statistic is based on a statewide average, it may be difficult to interpret hospital performance because of the relatively small number of hospitals. If all hospitals are underperforming, it may not be obvious. He added that the task of computing a statewide average may not yield the benefit of better data inferences and asked why the Maryland Health Care Commission (MHCC) proposes to embark on this level of granularity when the national average is already publicly available. Rawn Salenger, M.D., agreed. Mr. Steffen explained that if the hospital performance distribution in the state is not similar to the national average, it may be of benefit to calculate the statewide average. He agreed however that this cannot be determined at this meeting since the relationship between the statewide average and national average is unknown.

Dr. Pomerantz asserted that with a larger number of hospitals, it is less likely to run into statistical flukes. He added that the risk adjusted mortality rates are not perfect measures primarily, and it makes more sense to use a measure with a large number of hospitals as the base population. Staff Warren, M.D. agreed. He also noted that although there were over 11,000 PCI procedures in Maryland hospitals last year, he still supports using the national average. Dr. Salenger asked if MHCC is more interested in outliers. Ms. Fleck responded that the performance measure was designed to capture outliers. Dr. Salenger commented that the national average would be better for capturing outliers. Ms. Fleck explained that part of the issue is that the current regulations refer to the statewide average, based on the recommendations of the Clinical Advisory Group (CAG), and she wanted to be consistent with the CAG's recommendations to the extent feasible. As a point of comparison, she noted, with respect to cardiac surgery, that the STS is not willing to share the national average, but it was willing to share the statewide average if all hospitals signed off on it. Ms. Fleck added that the American College of Cardiology has stated that using the national average for public reporting by MHCC would be acceptable. Mr. Steffen stated that all comments by CSAC members will be reviewed by MHCC staff. He noted that taking a parsimonious approach has some advantages.

Ms. Fleck noted that the performance standard for primary PCI programs will change to be consistent with the decision on the performance standard for elective PCI programs. She explained that the issue is the same, and the discussion does not need to be repeated.

Next, Ms. Fleck addressed the issue of hospital reporting when PCI services are not available, either unexpectedly or expectedly. Dr. Segal commented that a lack of service availability is not rare. Ms. Fleck clarified that the draft language pertains to when no services are

available for anyone, not a situation where demand exceeds capacity. Dr. Wang explained that although many hospitals have safeguards in the event that a patient cannot be accommodated, it is not uncommon for this to happen due to circumstances beyond the control of the hospital. Even if a hospital has two cardiac catheterization laboratories, there usually will only be one interventionalist during many hours of the day. It would be expensive to have two interventionalists on standby doing nothing. Dr. Wang asked how often and for how long it is acceptable for PCI services to be unavailable. He commented that zero hours is unrealistic.

Ms. Fleck responded to Dr. Wang's question by stating that MHCC is concerned about outliers, where PCI services are unavailable beyond the typical experience of peer hospitals. She explained that the purpose of the standard is to encourage programs to focus on system improvements. Mr. Steffen agreed that the goal is to find programs that have significant differences in availability of PCI services compared to other hospitals. Mr. Steffen also commented that MHCC staff expected that the Maryland Institute for Emergency Medical Services Systems (MIEMSS) would be aware of when services are not available and would not transport a patient to a hospital, but that is not always the case. Dr. Segal asked how MHCC staff will know what improvements are needed if the cause of PCI service disruption is not known. There are legitimate reasons why PCI services may not be available. Dr. Wang agreed with Dr. Segal. He noted that two physicians are on-call to cover two hospitals in the Baltimore area, even though the number of times that one physician cannot handle both hospitals may be less than five times in a year. Dr. Wang commented that sometimes a patient is diverted because, in the physician's judgement, the patient would be better served by another hospital, such as Johns Hopkins Hospital or the University of Maryland. Dr. Salenger responded that in the scenario described, the services were not unavailable, so the reporting requirement would not be triggered, even though a patient was diverted to another location. Dr. Salenger and James Ridge commented that the standard as written makes it seem like there is zero tolerance for PCI services being unavailable. Mr. Ridge noted that weather can be an issue at his hospital in the winter. Dr. Warren commented that the consequences are not spelled out in the regulations.

Dr. Warren asked, what the consequences will be for a hospital, as a result of the proposed collection and use of the data. Ms. Fleck responded that MHCC will inquire about the details of reported situations, and a clinical expert will advise whether a hospital's performance is acceptable or not. She added that the outcome could be a recommendation for systems improvement. Dr. Wang expressed concern that the standard may put undue pressure on hospitals to ensure that they comply with regulatory time limits at the expense of optimal patient care. We would not want someone rushing another surgery or delaying patient care until a physician is available, rather than transferring a patient. Mr. Steffen responded that MHCC staff will need to review the language used in the regulation. If defined clearly, there should not be much reporting, but if it is vague, as it seems to be now, then it may be problematic. Ms. Fleck encouraged CSAC members to provide additional feedback via email, if they have suggestions for changing the standard.

Discussion of Feedback on ICD-10 Codes to Count for Volume

Ms. Fleck commented that a lot of progress has been made on categorizing the codes, even though it may not feel that way. She reviewed the general conclusions that had been reached. For example, if a procedure is defined as cardiac surgery then generally it should count for volume,

but there are some exceptions. She mentioned that for trauma cases there should be exceptions. She noted that in some cases the consensus on a code changed, and one of the handouts captures a lot of the history and discussion of some of the codes. She also noted that there seems to be confusion about procedures that are described as “percutaneous endoscopic.” She has heard that some of those procedures do not exist, and there seem to be differing opinions on how to handle that situation.

Mr. Steffen provided an overview on the need for categorizing the ICD-10 codes and cautioned that each code has to be considered prudently because it will affect which surgeries may be done in Maryland hospitals. He commented that the more exceptions to rules that are included, the more difficult it will be to explain to others. Dr. Salenger stated that it will be better to keep the rules for categorizing the ICD-10 codes simple. He mentioned that heart transplants and ECMO could be excluded, but any other procedures could be counted for volume. Stuart Seides, M.D. commented that, as he has noted before, the cases that count for volume are based on the volume quality relationship. In order for that approach to be reasonable, the cases counted need to be cases that hone skills for doing cardiac surgery. He mentioned, for example, that TAVR by the femoral route has been excluded, not because it does not require skill or is not dangerous, but because it does not contribute to the skills a surgeon and team need to perform open cardiac surgery. He noted that, for those reasons, he would count transplants, but maybe not ECMO. Dr. Salenger agreed with those points.

Dr. Salenger reminded the group that the criteria for cardiac surgery was previously agreed to be at least two of the following: incision on the chest, use of cardiopulmonary bypass, operation on the heart, or operation on great vessels. He commented that when two of those criteria are met, then it will be honing a surgeon’s skills. He noted that heart transplants are regulated separately and are excluded for that reason, and a lot of ECMO is done peripherally and he expects more of it will be done that way in the future in the cardiac catheterization laboratory. Dr. Salenger added that the majority of cardiac surgery cases done are coronary artery bypass, aortic valve replacement, mitral valve procedures, and other aortic valve procedures. The other procedures will be performed infrequently and will not have much impact on the number of cases for programs, but they will complicate meetings and result in a lot of discussion. Dr. Seides agreed with those points.

Paul Massimiano, M.D. commented that the terminology used is difficult. He asked CSAC members to turn to page 7 of the handout with codes for discussion and read the description of one code, “bypass coronary artery, two sites from aorta with synthetic substitute, percutaneous endoscopic approach.” Dr. Massimiano noted that including the word “percutaneous” is a misnomer. Washington Adventist recommended counting for volume because it is bypass surgery. Others agreed that the use of the word “percutaneous” is confusing. Ms. Fleck asked Diane Alejo, from Johns Hopkins Hospital, who works closely with Stefano Schena, M.D., if she could comment on the feedback from Johns Hopkins Hospital. In his view, the procedure would not be done percutaneously, and he would have preferred to mark as “not applicable.” Dr. Warren commented that theoretically all surgery is “percutaneous,” but it is not used in that way.

Dr. Salenger stated that after reviewing the codes, it was his opinion that all the procedures coded as percutaneous endoscopic were cardiac surgery while the procedures that are only

percutaneous, were not. All agreed. Dr. Salenger commented that it was probably difficult for Dr. Schena to jump into the process when other members have been reviewing the codes over a couple of years, and while Dr. Schena's approach is reasonable, it results in some pragmatic problems. Ms. Fleck commented that she believes that people are in agreement in spite of putting down different answers on some of the codes. Ms. Fleck then proposed reviewing the codes together. She noted that some other codes should be discussed that are not on the list of codes to be discussed that touch on the same issue just discussed, specifically some of the codes assigned to Western Maryland Health System that are described as "percutaneous endoscopic."

Ms. Fleck next reviewed the handout with the list of codes for discussion. For codes corresponding to 35.05, Ms. Fleck noted that the written feedback was mixed. There was consensus that the corresponding ICD-10 codes for 35.05 should not be defined as cardiac surgery or count for volume. For 35.55, it was agreed that it is cardiac surgery and should count for volume. For 35.61, it was agreed that the four corresponding ICD-10 codes that are all percutaneous should not be defined as cardiac surgery or count for volume. For 35.62, when the approach is percutaneous, the ICD-10 code should not be defined as cardiac surgery or count for volume. In general, it was agreed that for open procedures and percutaneous endoscopic procedures, the ICD-10 code should be defined as cardiac surgery and count for volume; for percutaneous procedures, it should not be defined as cardiac surgery or count for volume. Ms. Fleck noted that for 35.92, 35.94, and 35.95 all corresponding ICD-10 codes were labeled as cardiac surgery and count for volume. For 36.10, 36.11, 36.12, 36.13, 36.14, 36.15, 36.16, 36.17, 36.19, 36.20, and 37.41, all of the corresponding ICD-10 codes listed for discussion are "percutaneous endoscopic" and it was agreed that all should be labeled as cardiac surgery and count for volume.

CSAC members continued their review of the codes listed on the handout for discussion. For the ICD-10 codes corresponding to ICD-9 codes 37.55 and 37.60, it was agreed that certain codes should not be labeled as cardiac surgery or count for volume (02PA3QZ and 02HA3RS). Diane Alejo also explained Dr. Schena's logic for labeling one of the ICD-10 codes corresponding to 37.55 (02PA3QZ). For 37.63, it was agreed that both the open procedures and percutaneous endoscopic procedures should count for volume and be labeled as cardiac surgery, but the percutaneous procedures should not be labeled as cardiac surgery or count for volume. For 37.64, the same logic was agreed upon. For the ICD-10 codes corresponding to 37.65, it was agreed that neither code should be labeled as cardiac surgery or count for volume.

For the ICD-10 code corresponding to 37.66 (02HA3QZ), which is described as percutaneous, it was not discussed, except Dr. Salenger asked about getting clarification on the codes from the people who created them. For the ICD-10 codes corresponding to 37.68, which are described as percutaneous, it was agreed the codes should not be labeled as cardiac surgery or count for volume. The code 37.74 was not discussed, but based on the earlier discussion of counting for volume procedures labeled as cardiac surgery, Ms. Fleck concluded that the corresponding ICD-10 codes described as open procedures should count for volume. For 37.99, Ms. Fleck noted that the procedure shows up at hospitals without cardiac surgery, even when coded as an open procedure based on the corresponding ICD-10 codes. Dr. Massimiano commented that the codes should not be labeled as cardiac surgery or count for volume, and others agreed. For the ICD-10 codes corresponding to 39.0 and 39.21, Ms. Fleck noted that all the codes on the list are

percutaneous endoscopic, and CSAC members had agreed that such procedures should be labeled as cardiac surgery and count for volume. CSAC members agreed with this assessment.

Ms. Fleck next asked for feedback on the ECMO codes (39.61 and 39.65). She noted that feedback was mixed, as shown on the handout. Dr. Wang proposed that central ECMO be defined as cardiac surgery but not peripheral ECMO. Ms. Fleck asked if that was distinguished by the ICD-10 codes or whether other information is needed. Some CSAC members expressed concern about counting cases twice if 39.61 is defined as cardiac surgery. Ms. Fleck explained that discharges are counted, not procedure codes, so double counting should not be an issue. She noted that theoretically, all discharges with code 39.61 should already be counted as a result of other codes included for the same patient. CSAC members agreed that 39.61 should count as cardiac surgery and for volume, if there is no risk of double counting. A concern was raised about counting peripheral ECMO and a program having a large proportion of cases that are not really cardiac surgery. Dr. Salenger suggested revisiting 39.65 after further thought. He mentioned leaning towards not counting 39.65 as cardiac surgery and both Dr. Seides and Dr. Massimiano proposed not counting it as cardiac surgery.

Ms. Fleck stated that she wanted to review some other codes that were not included on the list of codes for discussion, and she directed CSAC members to the complete list of codes. She asked for feedback on the labeling of the ICD-10 codes corresponding to 35.31. It was agreed that for percutaneous procedures, the codes should not be defined as cardiac surgery or counted for volume and percutaneous endoscopic procedures should count for volume. Ms. Fleck stated that she would follow the agreed upon logic, and send the list out to CSAC members for review.

Ms. Fleck and Mr. Steffen thanked everyone for their participation. Mr. Steffen reminded everyone to send feedback on the changes to the regulations discussed. He added that MHCC staff will work on putting out a draft regulation that will include the codes for informal public comments. Ms. Fleck closed the meeting at 8:30pm.