California Coronary Artery Bypass Graft (CABG)
Outcomes Reporting Program (CCORP)
Clinical Advisory Panel
Minutes of November 4, 2021 Meeting

Meeting was held via webinar

Clinical Advisory Panel Members present:

Ralph Brindis, M.D., MPH, FACC, Chair	Maribeth Shannon, M.S.
James MacMillan, M.D.	Richard Shemin, M.D.
Gordon L. Fung, M.D., Ph.D.	J. Nilas Young, M.D.
Cheryl Damberg, Ph.D.	Hon Lee, M.D.
Rita F. Redberg, M.D.	

HCAI Staff and Others present:

Elizabeth Landsberg, HCAI Director	Chris Krawczyk, Ph.D., Healthcare Analytics Branch Manager
Michael Valle, Information Services Division Deputy Director	Holly Hoegh, Ph.D., Healthcare Analytics Branch
James Yi, Staff Counsel	William Bommer, M.D. UC Davis

1. Call to Order, Welcome and Meeting Minutes

Ralph Brindis, M.D., Chairperson, called the meeting to order at 8:38 a.m. A quorum was present to conduct business.

Dr. Shemin made the motion to approve minutes from the April 7, 2021 meeting. Dr. Fung seconded the motion. The motion was unanimously approved.

2. HCAI Director's Office Report – Elizabeth Landsberg, Director, Department of Health Care Access and Information

Director Landsberg thanked everyone. She shared that with Governor Newsom signing of the budget and trailer bills, OSHPD has been recast as the Department of Health Care Access and Information (HCAI). The new department retains all of the existing programs and functions, but optimizes the workforce development programs. The Director outlined the workforce changes and noted, of particular interest to this group, the changes that advance cardiovascular outcomes reporting.

3. HCAI Healthcare Analytics Branch Update – Christopher Krawczyk, Ph.D., Chief Analytics Officer

Dr. Krawczyk provided a summary of work in the Healthcare Analytics Branch (HAB). He shared recent releases of the 2019 Inpatient Mortality Indicators and the 2018-2019 CCORP Hospital Report. He thanked the CAP for their leadership and guidance in that effort. Dr. Krawczyk shared HAB's goal to generationally move towards more comprehensive use of the data available within HCAI. He noted some exciting products recently released and others that are on the horizon. Recent topics of interest include social determinants of health, persons experiencing homelessness, and aging. A regulations package to add patient address to the administrative data is moving forward, so there is opportunity to bring in some of the other indices, related social determinants of health at a more refined geographic level that will further enhance opportunity within that topic area. He next highlighted a series of five visualizations related to persons experiencing homelessness and efforts to incorporate this measure into other products.

Dr. Krawczyk shared HAB's efforts to bring data linkage efforts onshore, which includes linking the administrative data to the vitals stats death and birth data. There has been success using machine learning for death data linkage. HAB is working with other partners on methods for the birth linkage.

In the area of outreach and engagement, HAB has successfully completed its third cohort of interviews which included a sampling of consumer groups. HAB also participated in a webinar collaboratively hosted by the California ACC and the California STS related to cardiovascular outcomes reporting at HCAI.

HAB is increasingly involved with the Healthcare Payments Data Program and is now working with preliminary files from data partners, such as CMS. Work is also ongoing in the areas of workforce and financial data.

4. Chair's Report, Ralph Brindis, M.D., M.P.H., F.A.C.C.

Dr. Brindis shared his recent trip to Arlington Cemetery for a memorial for Dr. Phil Lee who was the Health, Education and Welfare (HEW) Secretary in the Johnson administration, the Assistant Health and Human Services (HHS) Secretary in the Clinton administration, and a Chancellor at UCSF. Dr. Lee was a passionate advocate for social justice and health.

Dr. Brindis next honored the CAP for their efforts to improve California CABG quality within the confines of that statute. He noted the addition of the internal mammary artery (IMA) usage in the hospital reports, which markedly increased the IMA use variation in the state substantially improving potential long term clinical outcomes for California CABG patients. In earlier years a number of California hospitals were using IMAs less than 30 percent of the time. That low IMA usage has now been substantially improved through HCAI public reporting along with education

by STS. The CAP also approved excluding salvage patients from hospital and surgeon outcomes minimizing the chance surgeon avoidance of taking on these highest risk patients who have the most to benefit by emergent CABG. In addition, the CAP help institute public reporting of hospital post-op stroke and 30-day readmission rates.

Dr. Brindis referenced the periodic Blue-Sky discussions or directions the CAP thought HCAI and CCORP could take on in the future, including:

- PCI public reporting
- CABG and PCI one-year mortality
- Appropriateness
- Stress test data/assess appropriateness/degree of ischemia
- PCI/CABG revascularization ratio
- Reporting on isolated valves
- TAVR and percutaneous valves
- Cardiovascular surgery composite measures
- Price transparency and social determinants of health

Dr. Brindis shared the trendline for cardiovascular procedure/intervention volume over the past two decades and highlighted the significant decrease in isolated CABG and the explosive growth of TAVR since FDA approval.

Dr. Brindis announced that the STS/ACC TVT Registry has now officially launched public reporting. Hospitals had the voluntary option to be included in the public report. They needed to have three years of rolling data along with a minimum volume criteria to receive star ratings and the 30-day composite of six ordered categories: 30-day death, stroke, life-threatening bleed, kidney injury, perivalvular leak, or none.

The CAP discussed various rating systems and what consumers understand. Ms. Shannon felt many consumers are confused by confidence intervals and although color-coding is helpful, it does not show much discrimination when most hospitals in are in the middle. A display with different cardiac procedures together is helpful, where a hospital may be gray on most things but good or not good on others. Consumers are not the only audience and, arguably, probably not the primary audience. What the practitioners, hospitals, clinicians, and boards of hospitals see, results in incentives they often put in place to improve performance.

Dr. Damberg offered that a lot can be done to improve the usability of information for all audiences, not just consumers. She referenced the science on public reporting and the work of Judy Hibbard for AHRQ. She recalled that this group once discussed displaying the information in rank order, from best to worse. Consumers tend to understand this, with some definitely performing at the lower end and at the higher end. Recent work with CMS on Star Ratings found that most consumers are using an intermediary to choose a Medicare Advantage Plan.

That intermediary may reflect the information that is in the Star Ratings, but the consumers may not be aware of this.

Dr. Shemin commented that it would be ideal if every hospital in the state met a threshold of high quality so they were all indistinguishable, so consumers would never be disadvantaged by finding themselves at one hospital or another. Presenting the data does not promote a process of data sharing to achieve best practices to raise all boats up to a high level because of the competitive environment. Instead of separating hospitals, best performers could share their methodology to achieve best practice, protocols, and other things they do, so California can be a state with a high level of consistency of quality providers.

Dr. MacMillan asked if the payers are using the data to direct their patients to certain hospitals. Ms. Shannon responded that the primary incentive for a payer to contract with a hospital is still the price. To some extent they want to have a good network, but the price is the primary driver of a negotiation, unfortunately. Dr. Damberg agreed that use of this information by purchasers is relatively limited.

5. CCORP Program Update – Holly Hoegh, Ph.D.

Dr. Hoegh gave a program update. She presented the role of the CAP highlighting the areas that are new based on the statutory changes. These include recommending interventional cardiovascular procedures for public reporting and recommending data elements from databases other than STS.

The 2020 CCORP data audit is underway, with some of the audits being remote. Issues this year include getting full access to the EMRs, compliance requirements, change in hospital ownership and a hospital strike.

Dr. Hoegh shared the work of the HCAI Cal-EIS fellow on readmission related to complications of CABG surgery that shows post-op a-fib is the most common complication when a patient is readmitted after CABG. Also, not surprisingly, patients who are readmitted have a higher number of the complications, than those not readmitted. HCAI will also provide each hospital with hospital-specific results.

Regarding collaboration, in October, an informational webinar on TAVR was held with the California Chapter of the ACC. HCAI also continues to work closely with the California Cardiovascular Quality Collaborative, which is spearheaded by the California STS and the data managers.

Dr. Hoegh presented the usual slides on CABG hospital and surgeon volume. The slides showed the anticipated drop on volume for 2020. There was the expected increase overall in mortality rates, but the increase was not just overall, it was at all levels: elective, urgent, and emergent CABGs.

The panel discussed the effects of the pandemic on volume and mortality. Dr. Hoegh added that there will extra attention given to the 2020 risk models and that the 2020 outcomes report will exclude any patient with COVID prior to hospitalization, in the hospital prior to surgery, after surgery, and within 30 days. Dr. Wang has looked at in-hospital mortality and stroke rates for 2019 patients and the 2020 patients by COVID status. She looked at the comorbidities and found the COVID patients have higher rates of hypertension, chronic lung disease and CHF.

Dr. Brindis asked for the next meeting to have the comparable STS data and Dr. Hoegh responded that the team would try, but that there has been trouble getting volume and mortality information from STS.

Dr. Hoegh presented PCI volume and mortality information and noted that Dr. Bommer would be presenting on PCI later in the meeting. She also presented the trendline for cardiovascular procedures over time and emphasized the increase over time in TAVR even for the year 2020. Dr. Hoegh presented the comparison to other state's reports and noted that New Jersey did recently put out and update, but no state has out 2020 data yet.

Dr. Shemin asked about Michigan and Washington State and possible other states with public reporting that may be useful to add to our reports for analysis and review. Dr. Hoegh replied that the team would research this and Dr. Krawczyk added that some of those states may have voluntary participation efforts that focus on on quality improvement. Dr. Brindis added that the Michigan program, which is funded by Blue Cross/Blue Shield, is a huge quality improvement initiative, but it is not a mandated state program. The Washington State program is similar. Dr. Shemin noted that these states may have insights into quality improvement and sharing of best practices of data, which has not traditionally been part of what we do. Dr. Brindis agreed and responded that Michigan has quality improvement initiatives and meetings to share best practices. California has been working to emulate this. Dr. Krawczyk expanded on this. Pre-COVID, there were discussions around learning from other states and developing collaborative opportunities between data organizations, surgeons, and cardiologists. HCAI is working to determine if they have the authority to facilitate such a group or if another organization should facilitate and HCAI just participate as a data organization. Dr. Shemin reminded the group of the UC system which includes five sites from Sacramento to San Diego meets on an every-other-week basis looking at data and for best practices and trying to ensure high levels of consistency. Dr. Hoegh wrapped up the presentation by thanking the HCAI team.

6. Update on the Elective PCI Program - William Bommer, M.D., UCDMC

Dr. Bommer next gave an update on the California Elective PCI Program. This program evolved through a number of trials, guidelines, and finally legislation. The trials started out as non-randomized trials that showed non-inferiority of PCIs in hospitals without onsite surgery. Randomized trials followed which confirmed that there was no difference between offsite hospitals performing PCI and hospitals with onsite surgery. Legislation in California first created

a pilot program which led to the establishment of the California Elective PCI Program in 2014 administered by the California Department of Public Health and their contractor, UC Davis.

Currently 23 hospitals are certified in the program with 6 more in process. Each year certified hospitals' PCI data is shared with HCAI from the National Cardiovascular Data Registry (NCDR). HCAI creates reports of outcomes and metrics. Based on these reports, UC Davis holds selective consultations for hospitals as needed to determine what needs to be done or changed to improve their performance. Every three years there is a recertification process. UC Davis uses three sets of evaluations: review of HCAI reported outcomes, review of California Cardiac Surgery Intervention Project (CCSIP) which includes 30-day mortality and Multiple Adverse Cardiovascular and Cerebral Events (MACE) and MACE 90-day measures and metrics on PCI performance from the NCDR. In addition, every recertification requires an onsite site hospital review. At this time 11 hospitals have gone through this process and been recertified.

Dr. Bommer shared the HCAI public report and highlighted the volume and risk-adjusted outcomes for the certified hospitals compared to California for all PCIs and elective PCIs on mortality and stroke. The report also shows at transfers for emergent CABG. He also provided risk model and performance outcome details. The main finding is that offsite PCI performance and clinical outcomes is comparable to onsite PCI performance and clinical outcomes in California. He noted that MACE events in general do increase from discharge out to 90 days, so it may be reasonable to include data for PCI outcomes beyond hospital discharge to obtain a more complete picture of PCI performance. The UC Davis team is also evaluating ways to work with California non- Elective PCI Program hospitals that have opportunities to improve their performance. Dr. Bommer added that CMS began reimbursement for ambulatory surgery center PCIs in 2020 and is anticipating California will looking at that in the future.

Dr. Brindis thanked Dr. Bommer for his leadership, work, and oversight of the California Elective PCI Program for the State of California. Dr. Shemin noted the volume of PCIs performed in the state and asked about the ability to expand reporting to include all PCI hospitals. Dr. Bommer responded that perhaps beyond TAVR, reporting could expand to include all PCI hospitals.

Dr. Young asked if more Elective PCI Program hospitals are anticipated. Dr. Bommer felt the offsite program will peak out in the thirties. Dr. Brindis asked how many California PCI programs are not participating in the NCDR. Dr. Bommer responded that this is hard to track, but believes it is around 15 or 16 low elective PCI volume hospitals. There are between 133 and 138 hospitals in the NCDR depending on the year.

7. Revisions to the California Health Safety Code related to Cardiovascular Outcomes Reporting - Christopher Krawczyk, PhD, HCAI

Dr. Krawczyk reminded the CAP of the trailer bill language that included improvements and enhancements to current programs and created new opportunities to meet the needs of the changing healthcare environment. The trailer bill language went forward added flexibility for

reporting cardiovascular measures, was developed based on previous CAP discussions and on engagement with stakeholders and partners, including collaboration with the California chapter of the American College of Cardiology (CA ACC). The trailer bill language emerged as AB 133. The final language allows for flexibility in administering the cardiovascular reporting program in collaboration with the CAP and specifically allows for HCAI to publish risk-adjusted performance reporting for CABG, TAVR and additional interventional cardiovascular procedures which would need recommendation from the CAP and would be limited to one new procedure every three years.

Additional components of the statute allow for flexibility on the level of reporting beyond hospital and give HCAI the authority to collect or acquire additional data from hospitals or from registries where hospitals submit data, such as the STS/ACC TVT Registry for TAVR data. Finally the statute expands the membership of CAP to ensure members have the expertise in any new procedure for public reporting.

Dr. Krawczyk referenced the Blue Sky discussions noted earlier by Dr. Brindis, other stakeholders engagement and the slide showing the vast increase in TAVR volume which led to the decision that TAVR would be a good measure for public reporting.
He shared a timeline and the steps that would be necessary to move forward with TAVR reporting. These include development of a regulations package, stakeholder outreach, and contracting with NCDR for the TVT Registry data.

The revised statute allows for flexibility on the level of reporting to include reports at the provider group or individual physician level in addition to the hospital level. Prior statutory language required physician level reporting for CABG, which included an appeals process and final CAP review if necessary. The revised statute also includes an appeals process for any reporting at the individual physician or provider level and that may require review by the CAP.

The revised statute retained the language that allows HCAI to audit data. HCAI currently audits the CABG data that hospitals submit directly to the department. For future data acquired from registries, there will be more operational discussions about the ability to audit that data.

Dr. Krawczyk commented that HCAI plans to stay budget neutral when implementing TAVR reporting by utilizing existing resources and emerging technologies. There are costs for the data, but some current programmatic costs savings will help to remain budget neutral.

Dr. Krawczyk noted that hospitals will have to authorize NCDR to share their TVT Registry data with HCAI. If mandatory, versus voluntary reporting is recommended, a rulemaking process will be needed which could extend the timeline for the first report.

The CAP next discussed whether the next CABG report should include surgeon level results for 2019-2020 data. Regarding the resources needed for surgeon level reporting, Dr. Hoegh shared that it does not add a significant additional workload, but if discontinued, some resource saving

would occur every other year. If provider level reporting was initiated, additional resources would be need initially, but over time it would likely be similar to surgeon level reporting.

The CAP discussed provider group level reporting. Dr. Krawczyk shared that this recommendation came from that stakeholder feedback. The statistical concern is with wide confidence intervals and smaller numbers at the surgeon level. Folding results up into provider group would have less influence of small numbers. Counter to that, a particular provider moving in one direction or another in terms of performance might be masked.

Dr. Shemin asked about the value add of individual provider performance. Hospitals have internal processes in place for credentialing and monitoring outcomes by all the providers for recredentialing. He noted the major aberration of 2020 surgeries where providers and hospitals may have been differentially impacted by their COVID rules and regulations. He argued that it is the responsibility of the hospital to get the best outcomes out of their providers. Dr. Lee felt that it is the culture that makes the programs focus on individual performance and that a two-year lag for specific physician performance is almost irrelevant. Hospitals have to move quickly, in real time, on the performance of any particular surgeon.

Ms. Shannon asked about the credible threat of consumer engagement. If reporting is only transparent to providers, is it as effective as if reporting is visible to the outside world? She supported having information available to consumers, even if a whole lot are not using it simply because it provides an extra level of incentive. She recommended not abandoning surgeon level CABG reporting yet but looking at volume and variation as the criteria for choosing what to report in the future.

Dr. Brindis noted that he does get asked "who is the best surgeon?" Ms. Shannon added that most consumers do not have a choice and are locked into systems and go to who their system recommends. Consumers may be out shopping for hospital systems and/or provider groups, but not individual physicians.

Dr. Damberg reminded the group that the primary purpose of this program was to provide information to consumers. People do ask who is best at performing a particular procedure, especially one as complicated CABG. There are constraints around provider networks and locked systems, but it is not universal, and there is some choice. It would be helpful to ask a broader set of stakeholders what they see as the value in physician reporting; thinking of how state dollars are best spent and with, in general, low CABG mortality rates across the board, these dollars may be better spent elsewhere.

Dr. Brindis asked about presenting only surgeon volume. He recalled the situation in New York where many low volume surgeons, who were identified as outliers, quit. This implies that some internal quality assurance mechanisms failed in some of the New York hospitals. Dr. Shemin responded that volume alone can be misleading, as some high-volume cardiac surgeons do primarily other procedures and have low volume isolated CABGs. He noted that quality cardiac

surgery is based on hospital environment, culture, intensive care teams, anesthesia teams, and everything else that leads to good outcomes. Very good technical surgeons can find themselves, if they are at a hospital without a robust infrastructure, not getting good results. The return on investment, the value in identifying best hospitals where informed decisions are made, should be where payers focus their attention. Dr. Fung concurred with hospitals working with their own quality programs to improve processes.

Dr. Damberg asked about the ability to do key informant interviews with hospitals to find out the utility of the data. Dr. Krawczyk offered that HCAI could add that topic to targeted outreach and engagement of stakeholders. One option would be to interview a sample of hospitals with different representativeness and a second option is to include people from the cardiovascular units and ask about the awareness and utility of surgeon data when we reach out to Cohort 4 hospitals.

Dr. Shemin asked if during hospital audits there could be a questionnaire offered to hospital administration to see how the data is actually used. HCAI will consider this option, however the audit often engages folks in medical records or data collection. Such a survey would need to get into the hands of the practitioners, leadership or the quality and improvement side.

Dr. Shemin noted his concerns on low volume hospitals and the resources required for surgeon-specific reporting. Dr. Hoegh outlined the extra resources required for surgeon level reporting, but noted that it is an every-other-year process, and felt the extra tasks were not overwhelming. Dr. Shemin asked about the number of practicing surgeons and Dr. Hoegh replied between 270 and 280 surgeons, with a small but varying number of outliers each year.

The CAP further discussed gathering stakeholder feedback to make an informed decision on surgeon reporting. Dr. Shemin noted 2020 was an aberrant year with COVID that may affect individuals more than hospitals and suggested tabling the physician level report. Dr. Damberg agreed and felt it would be best to wait for 2021-2022 data. Ms. Shannon asked if the data would still be collected and Dr. Hoegh confirmed the data would be collected, just not analyzed.

Dr. Damberg motioned that HCAI conduct hospital-level qualitative data collection to understand the utility of surgeon level data collection and reporting. Dr. Shemin seconded the motion. The motion was unanimously approved.

Dr. Shemin motioned that HCAI delay surgeon level reporting (not produce a 2019-2020 individual surgeon report) until further assessment. Dr. Fung seconded the motion. The motion was unanimously approved.

The CAP next discussed TAVR outcomes reporting. The CAP discussed and agreed to not consider individual physician TAVR reporting. Dr. Fung asked about the utility of including TAVR volume for physicians in the report. Dr. Brindis responded that it has not been decided what would be in the report.

Dr. Shemin supported hospital TAVR reporting since it has complete reporting throughout the state and nation with a common set of definitions and algorithms for analysis. It has tremendous buy-in at the individual and professional level, but recommended only including institutional volume, not individual provider volume.

Dr. Shemin motioned for public reporting of TAVR at the hospital level. Dr. Fung seconded the motion. The motion was unanimously approved.

The panel discussed the pros and cons of mandatory versus voluntary hospital reporting of TAVR data. Dr. Shemin felt there should be consistency with CABG reporting and that it should be mandatory. Ms. Shannon asked about the rulemaking process and if it would stretch out the timeline. Dr. Hoegh responded that it would not and Dr. Krawczyk added that regardless of if there is a rulemaking package there will be stakeholder engagement.

Dr. Shemin motioned for mandated reporting of TAVR data and Dr. Fung seconded the motion. The motion was unanimously approved.

8. New Membership of the Clinical Advisory Panel - Ralph Brindis, Chair

The current CAP has nine members. Three each nominated by the CA ACC, the California Medical Association (CMA), and consumer organizations. AB 133 allows the CAP membership to expand, if necessary, to have the expertise that aligns with the new procedure in HCAI reporting. If it is determined there is that need, nominations for two additional members will be submitted to HCAI by the CA ACC, with the appointment coming from the HCAI Director.

Per original statute the CAP:
- Reviews and approve the risk-adjustment methodology and model
- Review physician appeal statements and make a final determination
- Approve new or delete clinical data elements
- Advise in report structure for consumer understanding

Per AB 133
- Provide the CAP flexibility to include other health related topics in their scope
- Expand the membership of CAP to ensure members have expertise in any new recommended procedures or interventions for reporting

If they will be a new procedure reported where there is not expertise on the CAP, HCAI shall seek to appoint two new members with expertise in that procedure from a list of nominees submitted by the CA ACC. At least one-half of the appointees from the lists submitted by CA ACC and CMA and at least one appointee from the lists submitted by consumer organizations, shall be experts in collecting and reporting outcome measurements.

Dr. Brindis preferred qualities for new CAP members are:

- An interest and time to participate in 3 to 4 six-hour meetings annually and more time initially when a new interventional procedure is being considered and implemented
- An expertise in interventional cardiology
- Ideally a high-volume operator/high volume center
- An interest or expertise in CV outcomes research or at least an understanding as to statistical methods, risk adjustment, public reporting
- A consensus builder personality in addition to be being a great advocate for the interventional community and local hospitals

Dr. Lee asked about the need for additional CAP members if HCAI adds another modality. Dr. Krawczyk and Mr. Yi responded that membership is capped at 13, but changes in procedures reported and some reshuffling of the CAP should ensure there is the necessary expertise.

Regarding the decision process for nominations, Dr. Hoegh shared that historically HCAI asks for multiple nominations in order to vet and make sure there is good representation, then evaluates the nominees based on predeveloped measurable items and put forth recommendations to the HCAI Director for a final decision.

Dr. Shemin suggested collaboration with the California STS in seeking out nominations, and Dr. Fung added that it would be appropriate to add in diverse members. Dr. MacMillan shared the history of the original CAP and his efforts to ensure representation of surgeons. Dr. Brindis acknowledged Dr. MacMillan's participation in the formation of the CAP.

Dr. Damberg expressed concern about nominees understanding how information is used, not just by surgeons, but by a broader population, including consumers. Ms. Shannon felt nominees with an understanding of public reporting would be a bonus. Further discussion encouraged collaboration between the CA ACC and the California STS on the nominations.

Dr. Shemin motioned that we add two new two interventional cardiologist who have expertise in interventional approaches to structural heart disease and seek nominations from both the California ACC and the California STS. Dr. Fung seconded the motion. The motion was unanimously approved.

9. Public Comment

There was no public comment.

104. Adjourn

Dr. Brindis adjourned the meeting at 1:23 p.m.