California CABG Outcomes Reporting Program (CCORP)
Clinical Advisory Panel (CAP)
Minutes of September 18, 2015

The meeting was held at the Office of Statewide Health Planning and Development, 400 R Street, Sacramento, CA 95811

Clinical Advisory Panel Members present:

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

Clinical Advisory Panel Members absent:

OSHPD Staff and Consultants present:

Robert David, OSHPD Director	Ron Spingarn, Deputy Director, OSHPD HID
Joseph Parker, PhD, HOC	Beth Herse, Senior Staff Counsel
Holly Hoegh, PhD, HOC	Denise Stanton, Data Manager, HOC
Lisa Christensen, Contract Manager, HOC	Merry Holliday-Hanson, PhD, HOC
Robert Springborn, PhD, HOC	Ricardo Jaime, ITSD
Ying Yang, HOC	Limin Wang, HOC
Phillip Morris, HOC	Niya Fong, HOC
Zhongmin Li, PhD, UCD Contractor	Mia DeSoto, HOC
Banafsheh Sadeghi MD, PhD, UCD Contractor	Dominique Ritley, MPH, UCD Contractor
Patrick Romano, MD, UCD Contractor	Geeta Mahendra, MA, UCD Contractor
Anthony Steimle, MD, HOC Consultant	

Members of the Public present:

Joe Carey, MD, California STS	

1. Call to Order

Ralph Brindis, MD, Chairperson, called the meeting to order at 10:02 a.m. A quorum was present to conduct business.

2. Welcome and Introductions

People in attendance introduced themselves. Dr. Brindis acknowledged the contributions made to the CCORP Program by Dr. Joe Parker and Dr. Zhongmin Li, both of whom will retire at the end of this year.

3. Approval of Minutes of February 3, 2015 Meeting

The committee unanimously approved the minutes with two minor corrections. The corrections include on page 5 adding the qualifier "for aortic valve procedures" to "exclude open left atrial MAZE" and on page 6 change "atrial" to "aortic".

4. Director's Report – Robert David, Director, Office of Statewide Health Planning and Development

Robert David reported that OSHPD is working on an update of its 3-year strategic plan to ensure that the work being done is appropriate in the post-Accountable Care Act (ACA) environment. The plan should be published in January 2016, and will be presented at the next CAP meeting.

OSHPD was notified by CalPERS, the building owner, that our lease would not be renewed when our lease expires. Subsequently, OSHPD has been looking at new headquarter locations. We are in final lease negotiations with a building roughly 3 miles to the north. If all goes according to plan, OSHPD will move during the fourth quarter of 2016.

The Director called attention to OSHPD's Seismic Safety Program for Hospitals, noting that there has been an approximate 50 percent decrease in the number of hospital construction plans submitted for approval. The slowdown of large hospital construction projects are attributable to two reasons: 1) 90 percent of seismic work required by statute has been completed or is in process; and 2) the remaining facilities have until 2020 to complete their work. The ACA may also be a contributing factor to the slowdown because hospitals are changing their focus from inpatient services to outpatient services.

There are several major changes in legislative leadership: the Senate elected Jean Fuller as the new minority leader, which takes effect immediately; the Assembly chose Anthony Rendon as the new speaker and Chad Mayes as the minority leader commencing January 1, 2016. California may see more stability in leadership due to recent term limit changes; these leaders may serve until 2024.

The Director reported that OSHPD tracked about 250 bills this session and is in the process of finalizing an enrolled bill report on the handful of bills that impact OSHPD. This report, which will be sent to the

Governor's office, includes OSHPD recommendations to sign or veto each bill. A number of bills turned into two-year bills, meaning they either didn't get out of committee or the author pulled them temporarily and the legislature will reconsider them starting in January 2016. This year, the Governor called a special session about healthcare funding specific to managed care and transportation.

The Panel posed a question about CCORP funding and Dr. Parker summarized the history of the budget for the program which began in 2001 with approximately $900,000 annually with much of that allotted to contracts with an auditing firm and UC Davis

Finally, Director David will be meeting with several key Legislators to discuss some of these issues as OSHPD prepares for the second of the two-year session, beginning in January. He will provide updates at the next CAP meeting.

5. CCORP Program Update – Holly Hoegh, PhD, CCORP

Dr. Hoegh acknowledged CCORP and UCD staff contributions to ensuring the success of the program. She also reiterated the positive contributions of Dr. Parker, noting that when he retires, we will go through the State process to hire his replacement. She then introduced Dr. Sadeghi, who is working part-time with Dr. Li until his retirement in December. She will become the UC Davis principal investigator starting in January 2016.

Dr. Hoegh presented 2014 data on the number of hospitals performing CABG surgery. In 2013 the lowest volume hospital had a single CABG case whereas, in 2014, the lowest volume hospital had eight cases. Director David asked how a hospital could support such an expensive program with such low volume, especially in the current cost-cutting environment. Dr. Shemin noted that it could be the result of a failed Percutaneous Coronary Intervention (PCI). Dr. Hoegh stated that there may be some changes in the low volume hospitals once the new legislation is implemented.

Dr. Hoegh explained that while she normally presents trends in mortality, CABG, valve, etc., Dr. Li would be presenting that information in his presentation. Dr. Hoegh noted that no other state has published a mortality report since the last CAP meeting. A discussion ensued about the complexities of and sources of data required for comparing California mortality rates to other states. The panel recommended CCORP add the overall Society of Thoracic Surgeons (STS) numbers to the trend lines for other public reporting states for a national perspective. They also suggested CCORP investigate why California has a higher isolated CABG mortality rate than other publicly reporting states by comparing in-hospital mortality to see if there is a difference in definitions that contribute to the different mortality rates.

In addition, the panel suggested OSHPD prepare a table comparing PCI volumes and outcomes for those states that publicly report them to show the trends and relative differences. They also recommended OSHPD investigate PCI volume in low volume CABG hospitals to help discern whether these expensive CABG programs operate just to enable the PCI procedures.

The 2013 public report is being reviewed by OSHPD with a goal of releasing by the end of this year. At the panel's recommendation, CCORP tested the interaction between surgery type and cardiogenic shock for CABG + valve mortality. The interaction term was significant and it was added to the risk model.

The 2014 medical chart audit of 36 hospitals will start this month. CCORP will do site visits at some hospitals during the audits. Data collection for the last half of 2014 was a challenge due to the implementation of mid-year STS data element changes. However, the 2015 data collection has been much smoother, in part, due to bi-monthly CCORP calls with the hospitals (about a 60-70% participation rate) to help answer questions. Hospitals are also more familiar with the STS changes.

In 2014, Senate Bill 906 established a new program permitting certified hospitals to perform elective PCIs without on-site surgical back-up. Participating hospitals results will be publically reported. The law went into effect January 1, 2015, with OSHPD receiving funding to support the reporting program on July 1, 2015. Prior to the passage of this bill, six hospitals were part of an elective PCI pilot program. Study results showed no harms to permitting this procedure without on-site surgical support. Under the new law, any hospital that wishes to perform elective PCIs without surgical back-up must be certified by the California Department of Public Health. UC Davis will provide the clinical consultation during the certification process. In addition to the pilot hospitals, there are between eight and twelve hospitals currently working on an application for certification.

Approved hospitals will be required to submit their PCI data to the National Cardiovascular Data Registry (NCDR®). They will also be required to file a data release form with the American College of Cardiology Foundation (ACCF) so that their NCDR® data can be released to OSHPD. Once the data is available, CCORP will develop risk models to calculate risk-adjusted mortality, stroke and CABG rates. The program will hire two staff and contract with a health services researcher to work on this project.

Dr. Brindis asked how the program is funded. Dr. Hoegh noted that interested hospitals will pay a fee to CDPH for the application process which has been contracted out to UC Davis. OSHPD will be required to pay ACCF for the NCDR® data. OSHPD funding for data and staff was approved via the state budget process.

Dr. MacMillan asked whether there was an idea of which applicant hospitals have new PCI programs, are acting independently, or currently have small back-up programs. Dr. Parker stated that it is unclear at this time; however, CCORP might consider inviting Dr. Bommer to the next CAP meeting to present additional information about the Elective PCI Program. Panel members expressed concern about the appropriateness of PCI if there is a minimum requirement (200 PCI/facility/year) for program certification. Some postulated that hospitals may inappropriately bump up PCI rate to meet the certification criteria.

6. Chair's Report – Ralph Brindis, MD, Chair

Dr. Brindis reported that, in May 2015, *U.S. News and World Report*, reported process and performance measures for coronary artery bypass surgery (CABG), and gave additional stars to hospitals that are willing to share their data publicly. It is expected that in 2016, they will delve into PCI. At present, about 40% of the STS program participants share their data with *Consumer Reports*. There is consensus that hospitals are becoming more comfortable with sharing their data publicly.

He also discussed efforts in California to expand public reporting for coronary revascularization or valve surgery relative to transcatheter aortic valve replacement (TAVR). Dr. Brindis noted that TAVR is performed at 350 sites. Commercial data are available for more than 30,000 patients. A paper will be released soon that discusses one-year outcomes for TAVR.

There is a stakeholder advisory group that is pushing for public reporting using the transcatheter valve therapy (TVT) registry. Right now the registry does not have risk-adjusted mortality, but a risk-adjustment model was recently completed. The next report should contain risk-adjusted data and has the potential to be shared with the public. This model will also be used to create a clinician/patient tool that advises patients on their relative risk based on clinical descriptors. The challenge is that clinicians and patients will want to compare that with the STS risk model, but the patient populations in these risk models are quite different, therefore patients and clinicians need to be reminded that results from these two models can't be compared.

Dr. Brindis asked whether there are or will be any bills next year that are related to publicly reporting on coronary revascularization. Dr. Carey stated that Dr. Bommer has some ideas for addressing the funding issues that prevented the coronary revascularization bill from passing last year. If those can be resolved, then Dr. Bommer would be willing to go back to the legislature.

7. Statewide Trends in Revascularization Procedures – Zhongmin Li, PhD

Dr. Li used patient discharge data (the last 15 years), CCORP clinical registry data and newer OSHPD emergency department and ambulatory survey data to present changes in volume year-to-year and in-hospital mortality for isolated CABG, valve, CABG + valve, and CABG + other procedures. He also included PCI and noted that all rates were observed, not risk-adjusted.

Dr. Li explained that among surgery types, valve + CABG declined slightly while other types of surgery increased in more recent years. On-pump continues to dominate CABG and it may be important to study the impact of doing CABG off pump. Total volume of PCI's has declined but PCI for Acute Coronary Syndrome (ACS) ST segment elevation myocardial infarction (STEMI) continues to increase. TAVR volume for 2014 was two times greater than in 2011. The panel discussed various aspects of the increase in TAVR.

Mortality for most types of surgery declined with the exception of PCI, which is increasing and continues to be higher than CABG mortality. Among PCI's, mortality for patients with acute coronary syndrome (ACS) remained relatively stable, but mortality has increased for patients without ACS. Valve + CABG, and isolated valve declined by almost half over the past fifteen years. Between 2011 and 2014, mortality for TAVR procedures fell significantly while the volume of TAVR's increased. Since 2009, operative mortality rates for isolated CABG has increased slightly in recent years.

A discussion ensued about why isolated CABG mortality rates have increased slightly. Dr. Hoegh asked if it is because the patient population is sicker. Dr. Li said that he suspects that certain risk-factors, like diabetes, contribute. While index hospitals and surgeons provide good care, there is less control once a patient is discharged to rehab, home health, or another acute care facility. Payment reform may also have an impact where care is bundled by episode including post-acute care. Dr. Romano is taking the lead on an impact of public reporting project that may show, after risk-adjustment, whether this is a valid trend.

8. Proposed Change to One CCORP Clinical Data Element – Holly Hoegh, PhD

CCORP currently collects valve information under separate data elements not linked to the data element "isolated CABG". To capture the full complement of Isolated CABG, CABG+ Valve, and "other non-isolated CABG", CCORP needs to create a new data element. Dr. Hoegh engaged the panel in a discussion about changing the "ISOLATED CABG" data element. She explained that at a previous meeting, the panel approved a definition for "Isolated CABG" and a "CABG + valve". Since no STS data element for this is available, CCORP identified the CABG + Valve cohort using ICD-9 codes contained in the OSHPD Patient Discharge Data (PDD). Hospitals were provided their cohort and asked to verify cases, which proved to be very labor intensive for CCORP staff, hospital staff, and for Dr. Steimle. Hospitals sent documentation if aortic valve cases included an open MAZE, so they could be reviewed for exclusions from the public report. The process worked and CCORP obtained the cohort, but defining open MAZE was challenging.

Hospital CABG + valve risk-adjusted mortality rates/ratings and mortality records were provided to hospitals for their review in advance of the public report being published.

In order to streamline the process for gathering the CABG + valve cohort, Dr. Hoegh recommended that the current data element "isolated CABG", which has two categories (yes or no), be changed to the following:

TYPE OF CABG
1. Isolated CABG
2. CABG + Valve
3. Other Non-isolated CABG

Action item: The CAP unanimously approved the data element change.

Dr. Hoegh also explained that while collecting information from the hospitals, there was confusion related to the exclusion of MAZEs and for what types of procedures, most likely the result of inconsistent definitions. The group discussed whether the same logic regarding full MAZE procedures for CABG + valve apply to isolated CABG.

Action item: The CAP unanimously approved the following exclusions and inclusions:

- **Isolated CABG** - *Exclude* any open MAZE procedure and *include* any epicardial MAZE procedure
- **CABG + Valve** - *Include* open MAZE for replacement or repair of mitral valve, exclude open MAZE for replacement of aortic valve and *include* epicardial MAZE for aortic or mitral valve.

9. Definition of Operative Mortality – Joseph Parker, PhD

Dr. Parker noted at the last meeting, the panel requested additional analysis on transfer cases, as a result of the STS changing its definition of operative mortality. The panel asked CCORP to include patients transferred to acute inpatient facilities and multiple transfer patients using 90-days post-surgery data for inpatient deaths and transfer deaths and compare these results to the current method, and within 6 months of surgery. The analysis would also include a review of the principal diagnosis of patients who were readmitted and try to capture the cause of death in an effort to understand how inpatient deaths may differ from acute transfer deaths.

He reminded the group of CCORP's current operative mortality definition and presented an analysis that looked at mortality using 90- and 180-day follow up period over three years. In addition, he showed a slide that identified the principal diagnoses for inpatient deaths after acute transfer noting that infection might be an issue and could result in readmission. Dr. Parker suggested that reducing the follow-up period for transfer patients from 180- to 90-days resulted in losing two transfer patients from the data. He further noted that reducing the patient stay follow-up period to 90 days for inpatient deaths resulted in less than one patient lost annually. Neither of these losses were significant.

He pointed out that shortening the period to 90 days for both inpatient and transfer cases, would be inconsistent with STS. However, STS has a very limited ability to track these kinds of patients. While it is unclear how hospitals will do with a new definition, it is something that CCORP can track. Changing the definition will make mortality rates non-comparable across the years, but this is something CCORP could retrospectively recalculate. Dr. Shemin inquired about whether CCORP could trend and compare the rates and a concern was expressed that this might result in confusion. The panel was generally of the opinion that it would be a positive incentive for patient care to change the window to 90-days and that there did not appear to be possible, negative, unintended consequences.

Action item: The CAP unanimously agreed to a 90-day operative mortality definition for both in-hospital and for acute care transfer cases.

10. Constructing Composite Measures for Ranking Provider Performance – Zhongmin Li, PhD

Dr. Li presented a conceptual approach for constructing a composite performance measure based on the STS composite method. He explained how the following individual measures could be weighted and combined to create a composite measure: operative mortality, post-operative stroke, 30-day readmission (all risk-adjusted), and internal mammary artery utilization (a process measure that is not risk-adjusted). The panel generally agreed that a composite measure might make it easier for consumers and stakeholders to understand and use the CABG outcomes information.

Dr. Li explained the pros and cons of using pre- or post-risk-adjustment within a composite measure. He presented Centers for Medicare and Medicaid Services (CMS) Hospital Quality Incentive Demonstration (HQID) data that showed the impact of using post-risk-adjustment, especially when trying to combine process and outcome measures. Each of the seven measures used in the CMS data were equally weighted. However, this approach favors process measures rather than the important outcome measures like mortality, for example. Despite debate over the weighting of individual measures, CMS found that using a composite measure for pay-for-performance raised overall quality ratings.

Dr. Li provided a handout identifying 11 STS quality measures which are grouped into four domains. From those domains, one summary measure is defined and a composite score is calculated. A STS-like method was employed to construct a CCORP composite score using data from the CCORP 2012 public report of CABG surgery outcomes and a correlational analysis was performed. The group discussed objective weighting and variation. Dr. Young expressed that mortality might be underweighted in a composite model and conversely process measures could be over-weighted. However, if there is less true variation within a measure, it counts less.

The group discussed the usefulness of reporting a composite measure and how it might be used by the consumer. Historically, consumer use of quality measures for provider selection is low, but accountable care is changing perception, and, to a degree, consumer behavior. For example, CMS instituted a series of direct consumer contacts to persuade them to move from low-performing to high-performing plans using quality information. In addition, this information is useful for provider organizations when contracting for specialists in their provider network.

The panel suggested CCORP engage STS, specifically Dr. Shahian, to learn about their experience with composite measures. The group agreed that more work needs to be done to gather information that looks at the role of composite measures and how these are influencing consumers and purchasers and requested that CCORP continue to investigate the utility and reliability of composite measures and the role composites play in influencing consumers and purchasers.

11. Mortality Profiles of High-Risk Patient Groups in CABG surgery Cohort – Joseph Parker, PhD

In response to an earlier request by the panel, Dr. Parker presented an analysis on patient outcomes for CABG patients at high-risk for death within six months of CABG surgery, using a combination of available literature and data. The intent of the analysis is to help clinicians, patients and their families understand what high-risk patients are so they can work together to make patient-centered decisions about the risks and benefits of a CABG. More specifically, Dr. Parker's presentation focused on understanding the impact of co-morbid risk-factors, especially end-stage organ failure on mid-term outcomes and how this information could be useful to patients and their physicians.

He explained that the six month period was selected because CMS provides hospice care benefits for patients with "clinical findings that support a life expectancy of six months or less." Three years of CCORP data was used including all CABGs to find high-risk cohorts including salvage and cardiogenic shock patients. CMS Hospice Primary Eligibility Criteria were adapted (to the extent possible) to identify three high-risk end-stage organ failure patient groups, using CCORP risk factors and the prognostic literature on mid-term mortality, to narrow the cohort size.

For CABG patients at high-risk for death within six months of CABG surgery, most appeared to have a poor quality of life following surgery (death or discharged to SNF). Dr. Parker noted that the data suggest that a few patient sub-groups have six-month mortality rates similar to salvage patients. "Overall" and by risk-factor patient outcomes for cardiogenic shock/salvage, renal disease, pulmonary disease and heart failure were reported. He reported that 100% of Salvage patients and 77% of Shock patients 80+years, experienced mortality or discharge to SNF within 180 days. Across all five groups, and for most sub-groups, patients who died spent the majority of their days after surgery in the hospital and also died in-hospital. Discharges to SNF were highest for those with chronic conditions: BMI<18.5, Liver Disease, and Albumin <2.5.

The group discussed the dilemma between trying to save a life versus the quality of life (data which is not collected), as well as the influence of families who tend to make decisions on behalf of the patient. However, CMS has mandated collecting 30-day, 6-month, and 1-year data related to the quality of life, which may assist patients and families who are faced with end-of-life decisions.

The panel concurred that the data revealed how emergency circumstances can result in a worse prognosis/outcome. Frequently, there is no opportunity to evaluate the patient, optimize them, and/or

get to know the family to identify what other issues or preferences exist before proceeding with surgery. There typically is not enough time to discuss life care planning and advanced directives in an emergency situation, whereas there is opportunity to discuss these things prior to elective surgery.

The group discussed whether the data might be used to publish a research article. They felt a paper would be helpful to patients and their families by informing and engaging them in available choices and the best possible care. The panel asked if OSHPD could disseminate the information and put it in a format that would educate and provide value to the consumer. Director David suggested discussing this with OSHPD's public affairs team to identify ways to position the information.

12. Discussion of Potential Agenda Topics for Next Meeting – Joseph Parker, PhD

The panel suggested that CCORP delve deeper into the mortality profiles data to identify the hospitals involved, and which of these had better than expected outcomes for high-risk CABG patients.

The panel reiterated the desire to have Dr. Bommer attend the next meeting to discuss PCIs and public reporting.

13. Public Comment

Dr. Carey reiterated the need to understand how and when to record PCIs. Dr. Brindis suggested that Dr. Bommer be invited to the next CAP meeting to discuss PCI and public reporting. It was also noted that the deadline for submitting new bills is February 2016.

14. Adjourn

Dr. Brindis adjourned the meeting at 2:40 p.m.