California CABG Outcomes Reporting Program (CCORP)
Clinical Advisory Panel
Minutes of June 1, 2010

The meeting was held at OSHPD Headquarters, 400 R Street, Sacramento, California

Clinical Advisory Panel Members in attendance:

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<tr>
<th>Robert Brook, M.D., Sc.D, chair</th>
<th>Fredrick Grover, M.D.</th>
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<tr>
<td>Timothy Denton, M.D. FACC</td>
<td>Coyness Ennix, Jr., M.D.</td>
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<td>James MacMillan, M.D.</td>
<td>Keith Flachsbart, M.D.</td>
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Clinical Advisory Panel Members absent:

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<tr>
<th>Cheryl Damberg, Ph.D.</th>
<th>Andrew Bindman, M.D.</th>
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<td>Ralph Brindis, M.D., FACC</td>
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OSHPD Staff/Consultants in attendance:

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<tr>
<th>David M. Carlisle, M.D., Ph.D., OSHPD Director</th>
<th>Ron Spingarn, Deputy Director, Healthcare Information Division</th>
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<tr>
<td>Joseph Parker, Ph.D., Healthcare Outcomes Center Manager</td>
<td>Holly Hoegh, Ph.D., Healthcare Outcomes Center</td>
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<td>Mary Moseley, M.A., Healthcare Outcomes Center</td>
<td>Denise O’Neill, Healthcare Outcomes Center</td>
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<td>Robert Springborn, Ph.D., Healthcare Outcomes Center</td>
<td>Merry Holliday-Hanson, Ph.D., Healthcare Outcomes Center</td>
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<tr>
<td>Niya Fong, Healthcare Outcomes Center</td>
<td>Sanaa Shabbir, M.P.H, Cal EIS Fellow, Healthcare Outcomes Center Contractor</td>
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<tr>
<td>Anna Li, Healthcare Outcomes Center Student Assistant</td>
<td>Alex Salvador, Healthcare Outcomes Center Student Assistant</td>
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<tr>
<td>Elizabeth Wied, OSHPD Chief Counsel</td>
<td>Beth Herse, OSHPD Sr. Legal Counsel</td>
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<tr>
<td>Zhongmin Li, Ph.D., UCD, Healthcare Outcomes Center Contractor</td>
<td>Geeta Mahendra, UCD, Healthcare Outcomes Center Contractor</td>
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<td>James Marcin, M.D., UCD, Healthcare Outcomes Center Contractor</td>
<td>Beate Danielsen, Ph.D., UCD, Healthcare Outcomes Center Contractor</td>
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<tr>
<td>Dominique Ritley, MPH, UCD, Healthcare Outcomes Center Contractor</td>
<td>Anthony Steimle, M.D., Healthcare Outcomes Center Cardiology Consultant</td>
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Members of the Public and Others present:

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<tr>
<th>Sandra Bauer, CHPDAC</th>
<th>Edwin Fonner, Dr.PH, California STS</th>
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<tr>
<td>Sherry Arabel, Sutter Health</td>
<td>Junaid Khan, M.D., Sutter Health</td>
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<td>Steve Rossiter, M.D.</td>
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1. Call to Order and Introductions

Fred Grover, M.D., acting Chairperson, called the meeting to order at 9:32 a.m. A quorum of members was present. Introductions were made. (Chairperson Robert Brook, M.D. arrived later.)

2. Approval of Minutes of the November 10, 2009 Meeting

The minutes of the November 2009 meeting were approved.

3. Director’s Report – David Carlisle, M.D., Ph.D., OSHPD Director

Dr. Carlisle noted challenges for state government continue. Although OSHPD programs are not directly affected by State General Fund budget deficits, OSHPD staff members are. Employees continue with three furloughs each month through the end of June. According to the Governor’s May Budget Revision, furloughs would end but be replaced by an almost 15% salary reduction this coming fiscal year. This year will be an especially long process reaching a signed state budget.

In spite of these troubles, OSHPD programs are doing well. The department is involved in a variety of health care reform activities including a task force coordinated by the Health and Human Services Agency. OSHPD is also charged with a major workforce component of health care reform.

4. CCORP Program Update – Holly Hoegh, Ph.D., CCORP Director

Dr. Hoegh reviewed the statutory role of the panel: recommendation of data elements, review and approval of risk adjustment models, review of physician statements, and consultation on report materials. At today’s meeting the panel will review a risk adjustment model and consult on report materials. At the next meeting, the panel will review surgeon statements.

Dr. Hoegh presented slides which demonstrated the decline in isolated CABG, fairly stable numbers for non-isolated surgery, and PCI leveling after a brief decline. Dr. Parker noted that inpatient mortality rates for PCI and CABG are converging. In general, mortality rates are dropping and the other states that produce reports also note this trend.

The 2007 public report is still under administrative review. The report contains hospital level mortality rates; for the first time, post-operative stroke rates; IMA utilization results; volume/outcomes relationship, for which an association was found; a section on CABG and PCI volumes; and letters from hospitals.
A timeline for the 2007-2008 hospital and surgeon level report was shown. The surgeon appeals meeting will be in September or October after surgeons have had the opportunity to review and appeal their results.

Dr. Hoegh summarized the status of the 2008 CCORP data, including highlights of the audit and linkage to the state death file. For 2009 data, CCORP has moved to online reporting, which has proven faster and easier data submission for hospitals, increased data security, and allowed for immediate editing of data at the time it is submitted. The 2009 data submission process is almost complete.

The new data submission process changes the point in time when the surgeon certifies his/her data. Formerly, the certifications were completed when the data was initially submitted. Now, surgeon certification occurs after data corrections have been made.

The 2009 CCORP data will be linked to patient discharge data later in the summer and the audit may be able to start earlier than in the past.

Dr. Hoegh presented CABG volume and related statistics at six month intervals. Isolated CABG volume continues to decrease, while non-isolated CABG volume remains stable.

In the future, CCORP will explore hospital readmissions in conjunction with length of stay and admissions to emergency rooms. CCORP will also compare hospital outcomes using STS Operative Mortality and 30-day mortality. Operative mortality is impacted when hospitals cannot transfer patients to other, more appropriate facilities. In these instances, patients may die in the hospitals months after the operations. CCORP will also continue to develop risk models for additional complications.

During a discussion, the speed of acquiring death data was discussed. Further evaluation of death data from the Social Security Index and the California Department of Public Health will be done. Research should include analysis of out-of-state death numbers that are picked up by the more exhaustive Death Stat Master File in comparison to data available from the “monthlies”. The panel would like Californians to receive public outcomes reports using more current data.

5. Results of the 2008 CCORP Audit – Beate Danielsen, Ph.D., UCD

Dr. Danielsen presented the results of the 2008 CCORP audit. The goal of the audit was to determine quality of hospital data coding and assure data quality issues did not affect hospital or surgeon ratings.

Hospitals reported 18,042 CABG surgeries for 120 hospitals and 264 surgeons. A total of 2,338 isolated and 255 non-isolated CABG cases in 36 hospitals were chosen for audit. The hospital audit selection process was based on identification of outlier or near outlier status for hospitals or surgeons, hospitals with substantial coding problems, and hospitals chosen at random but proportional to size. Hospital cases were selected proportional to
isolated CABG volume with 60 and 140 primary isolated CABG cases and up to 10% non-isolated CABG’s chosen per hospital, making sure cases per surgeon were selected equitably. Case selection also included all in-hospital deaths and all salvage cases. The audit includes oversampling of deaths and severely ill patients. If primary cases were not found or found to be non-isolated, sets of secondary cases were chosen.

Thirty-three isolated CABGs in CCORP data were found to be non-isolated in the audit. Fifteen non-isolated CABGs in CCORP data were considered isolated in the audit. Disposition at discharge was always coded correctly. Gender, prior cardiac surgery, prior PCI, and cerebrovascular disease were all coded very well.

Risk factor coding improved in 2008. Data elements with kappa values in the range 0.6 to 0.8 are considered satisfactory, but need improvement. These included status of procedure and arrhythmia. Disappointing coding occurred for cardiogenic shock and salvage. Dr. Hoegh noted that hospitals must prove cardiogenic shock and salvage by submitting documentation starting with 2009 data collection. Timing of MI, NYHA Class IV, mitral insufficiency, and chronic lung disease continue to be the most problematic risk factors.

Discussion ensued regarding the low kappa value for immunosuppressive treatment, which is a Yes-or-No variable. Some panel members felt the problem might be the wording of the definition, which is an STS definition, or incomplete listing of medications. Dr. Parker said CCORP would look into answers for this question.

A scatter plot demonstrated quality variable coding for all hospitals. Significant hospital to hospital variation occurred. Dr. Danielsen noted that the sample is severely biased toward deceased and severely ill patients for hospitals and surgeons; therefore, results may not represent overall CCORP cases.

Key audit findings for process measures and complications varied. IMA had a high kappa value of 0.92. LAD bypassed, an exclusion criteria rather than risk factor, was undercoded by hospitals. Coding of complications remained good for post-operative stroke, prolonged ventilation, and re-op bleeding; however, poorer coding was found with many of the complication measures.

The audit findings did change pre-audit performance ratings for a few hospitals and surgeons. Most pre-audit “Worse” outliers were confirmed by the audit. For selected risk factors, coding quality from 2003 to 2008 showed improved kappa. Analysis of the physician and peer audit over-reads indicated a high validity.

The panel recommended a few changes or additions to the next audit. They would like the physicians to over-read the most complicated cases and to confirm that all physician and peer over-reads of cases be “blind” or independently over-read. The CAP also would like CCORP to follow up with deficient hospitals to strengthen reporting of specific data elements which have not been reliably coded.
Panel members complimented CCORP on the audit related research and suggested the information be published and that CCORP collaborate with other states regarding data submission and audits.

**Recommendation:** The panel recommended CCORP staff explore a complication composite measure for public reporting and/or options for such a measure, focusing on the complications that are most important, valid, and reliably coded. All measures in the index should be risk-adjusted and operative mortality may or may not be included in the index, as appropriate.

6. **Presentation on the Preliminary Findings of an Analysis of the Impact of Public Reporting of Internal Mammary Artery Utilization – Zhongmin Li, Ph.D. substitute for Ezra Amsterdam, M.D., UCD.**

Dr. Li presented Dr. Amsterdam’s work on the impact of public reporting of IMA utilization. Both STS and CCORP provide public reporting of IMA usage. The data collection eliminates prior CABG surgeries, emergent or salvage cases, cardiogenic shock, and LAD not bypassed (2008).

Analysis shows a significant increase in IMA use from 2003 to 2008. Also the variation among hospitals and surgeons has decreased significantly. There are a few, rare medical problems that make use of the IMA impossible. The UC team recommends that public reporting of IMA continue.

7. **Presentation and Discussion of Post-Operative Dialysis Requirement as a Possible New Outcome Measure – Richard White, M.D., UCD**

Dr. White presented his analysis of post-operative dialysis requirement and whether it is an appropriate outcome measure for public reporting among patients undergoing isolated CABG surgeries. At an earlier meeting, the panel expressed interest in identifying new quality measures and acute renal failure was identified as a possible reportable outcome. A problem arose in that creatinine-based measures had poor agreement in audits, so renal failure requiring dialysis seemed a better defined data element with more accuracy in data submission to CCORP.

The panel discussed the data and problems with public reporting. The numbers of patients evaluated were quite low. Reported yes/no dialysis data was, somewhat illogically, often inaccurate; perhaps timing of data reporting could account for the discrepancy. Fundamentally, to start dialysis earlier or later may or may not reflect mismanagement. The panel decided that CCORP staff could evaluate this outcome measure as part of the composite.
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8. Upcoming CCORP Hospital and Surgeon Level Report – Holly Hoegh, Ph.D.

(a) 2007-2008 mortality risk model

Dr. Hoegh presented information about the operative mortality risk model and methods for generating hospital-level and surgeon-level results for the public report. The panel briefly discussed the precipitous decline in the number of CABG surgeries and speculated as to the reasons – under-use, pay related decline, other types of interventions – but the data collected through CCORP does not provide an answer.

Action: The panel approved the operative mortality risk model.

(b) 2007-2008 post operative stroke risk model

The panel discussed the risk model and methods for hospital-level reports.

Action: The panel approved the post operative inpatient stroke risk model

(c) Proposed contents of the 2007-2008 report:

Action: The panel approved:
(1.) risk-adjusted mortality rates for hospitals with one year only rates (2008), rather than two years;
(2.) hospital risk-adjusted post operative inpatient stroke results for 2007-2008;
(3.) surgeon risk-adjusted mortality results for 2007-2008;
(4.) hospital internal mammary artery utilization results for 2008; and
(5.) volume/outcomes analysis for 2008

9. Presentation and Discussion of Preliminary Proposal for a Risk-Adjusted Mortality Model and Methods for Generating Hospital Level Results for CABG+Valve – Zhongmin Li, Ph.D.

Dr. Li’s presentation provided a continuation of a discussion from the last CAP meeting. At that meeting the panel requested more research to determine if all non-isolated CABG’s reported by hospitals were really non-isolated. The panel also wanted selection of a homogenous cohort for risk-adjustment and public reporting.

The results presented used CCORP data linked to PDD data. All procedures performed on each patient were examined. From these comparisons, 284 questionable non-isolated CABG’s were identified. Further investigation established a total of 2,536 procedures performed on the 284 cases. The 10 most common procedures performed on these patients were not non-isolated procedures.

The distribution of the questionable non-isolated CABG cases occurred at 71 hospitals, more than 50% of hospitals performing CABG surgeries in California. Since a significant
number of non-isolated CABG’s appear to be isolated, UCD recommends the data verification process be changed to review all hospital reported non-isolated CABG’s for which the PDD suggests they are isolated, expanding the Data Discrepancy Report beyond checking for only death cases. CCORP staff accepted this recommendation from UCD.

Dr. Li also evaluated 2,452 procedures performed on non-valve/non-isolated CABG cases. UCD recommends excluding non-valve/non-isolated cases from public reporting as these cases are too few and too complicated to accommodate risk-adjustment.

Possible approaches for public reporting were Valve + CABG cases and Valve+CABG+Other cases. Focusing on Valve+CABG would include multiple valves and exclude salvage and tricuspid/pulmonic cases. The Valve+CABG+Other could be used by adding a dummy risk variable for other non-isolated CABG procedures. Ultimately, the UCD recommendation was to exclude Valve+CABG+Others. UCD also recommended using more than one year of data for public reporting, report risk-adjusted operative mortality, and further refine the risk model with data from multiple years.

Discussion included questions regarding the tricuspid/pulmonic valve cases, as this should be quite rare. Staff responded that CCORP would contact hospital data contacts to determine reasons these single valve procedures were performed.

Recommendation: The CAP recommended that staff present a risk-adjusted CABG+Valve only model using 2008 and 2009 data combined and present to the panel.

10. A Review of the State of Cardiac Outcomes Reporting – Dominique Ritley, MPH

The impetus for the review was an interest by the CAP in possible future directions for CCORP as well as trends in coronary revascularization.

Ms. Ritley contacted the states with heart bypass surgery public reporting programs – Massachusetts, New Jersey, New York, and Pennsylvania -- and spoke with senior managers and program officers. These individuals reported that California’s reporting program is well respected nationally.

No state planned substantial revision of their reporting programs due to a decrease in CABG surgery mortality. None of the states are basing program decisions on leadership from NQF or CMS. No program planned to add or retire current quality measures and no states are considering adoption of composite measures. All states were proud of their successes reducing CABG mortality rates and the processes they use to develop public reports.

Representatives stated that public reporting has increased effective communication with hospitals, physicians, and the public. One program published peer-reviewed research and another distributed a pre-op risk assessment tool for physicians. All states report concerns about budget reductions.
On the two-to-five-year horizon, NJ would like to add readmissions and NY would add adult congenital cardiac surgery and link another registry with their data for long-term tracking. PA must undergo a major revision of data collection and analysis as a result of recent state legislation. MA would like physician-level reporting for PCI procedures. MA, NY, and PA are currently reporting PCI in-hospital mortality. MA and NJ do not report non-isolated CABG, New York is reporting non-isolated, and PA is working on it.

Ms. Ritley interviewed 17 California stakeholders about their observations and recommendations regarding CCORP. Stakeholders were payer/purchasers, researchers, consumer advocates, and providers.

Stakeholders held a very positive view of CCORP’s work. Many would like to see expansion or refocusing on PCI and valve. Stakeholders believed OSHPD should have authority to collect and publish PCI outcomes reports (currently OSHPD does not have authority). Suggestions for new quality measures included readmissions, complications of care for CABG, patient-reported functional health status, composite measure for surgical processes, appropriateness of care, track co-morbidities, track longer-term outcomes, repackage data from CMS to run NQF measures or use PDD, and report on other conditions or procedures. Additional stakeholder requests included look further at collaboration with organizations with similar interests, provide increased consumer information and health literacy, and report on shared decision making and patient experiences.

11. Presentation and Discussion of Letter from Surgeon written to Clinical Advisory Panel members

Dr. MacMillan summarized the contents of a surgeon’s letter which contained a number of observations, suggestions, and criticisms. Although some issues presented were inaccurate, the panel was both familiar and sympathetic to concerns raised by the surgeon. The panel asked Dr. Parker to draft a response letter.

In this letter the surgeon questioned a seeming conflict between STS collection of data beyond 30 days and the CCORP collection criteria. Staff and panel members stated CCORP and STS use the same operative mortality definition for public reporting. That definition includes all inpatient deaths occurring during the index admission, no matter how long they occurred after the procedure, as well as deaths occurring post-discharge within 30-days of surgery. The panel recognized that some deaths occurring after discharge could be unrelated to surgery. Such cases are infrequent and randomly distributed, so all surgeons are treated similarly.

Another issue was the definition of “salvage”. Although the surgeon would like to see the definition expanded, CCORP uses the STS definition for consistency. Each case reported as salvage receives a review of the medical records. Beginning with the 2007 public report, salvage cases are excluded from public reporting.
The surgeon suggested using GFR instead of creatinine to risk-adjust for renal failure. In the past, CCORP has compared the prognostic value of GFR versus creatinine in the risk models and found no clinically or statistically significant difference in predictive power.

The panel agreed with the surgeon that calcified aortas are a risk factor for stroke and likely death. However, no data element seems clearly useful to assess this risk in a reliable way. Without a reliable data element, implementation of such an assessment would be problematic.

The final issue concerned patients, who for religious or other reasons, refuse blood transfusions post-CABG surgery. The issue has been discussed many times in CAP meetings. Ultimately, the panel has decided not to exclude such cases. The reason is that starting a list of exclusions would create a slippery slope, compromising policy into inconsistent elements that are difficult to defend. Surgeons are encouraged to submit an appeal if a death was caused by post surgery bleeding and refusal of blood products could be argued as the primary reason. In fact, any surgeon who is not satisfied with CCORP’s response to an issue may bring actual cases for review by the panel. The identity of the surgeon is redacted to assure impartial decision-making.

12. Public Comment and Adjournment

No public comment was requested. The meeting was adjourned at 1:32 p.m.