

California CABG Outcomes Reporting Program (CCORP)
Clinical Advisory Panel
Minutes of September 3, 2008

The meeting was held at OSHPD headquarters, 400 R Street, Sacramento, CA

Clinical Advisory Panel Members in attendance:

Robert Brook, M.D., Sc.D.
Andrew Bindman, M.D.
Ralph Brindis, M.D., F.A.C.C.
Timothy Denton, M.D., F.A.C.C.
Coyness Ennix, Jr., M.D.
Keith D. Flachsbart, M.D.
Frederick L. Grover, M.D.
James MacMillan, M.D.

Clinical Advisory Panel Member absent:

Cheryl Damberg, Ph.D.

OSHPD Staff/Consultants in attendance:

David Carlisle, OSHPD Director
John Kriege, Acting Deputy Director, Healthcare Information Division
Joseph Parker, Ph.D., HOC
Holly Hoegh, Ph.D., HOC
Robert Springborn, Ph.D., HOC
Denise O'Neill, HOC
Mary Moseley, HOC
Elizabeth Wied, OSHPD Chief Legal Counsel
Beth Herse, OSHPD Legal Counsel
Merry Holliday-Hanson, Ph.D., HOC
Brian Paciotti, Ph.D., HOC
Niya Fong, HOC
Zhongmin Li, Ph.D., HOC Consultant
Geeta Mahendra, HOC Consultant
Anthony Steimle, M.D., HOC Consultant

Members of the public present:

Ed Fonner, DrPH, Executive Director CASTS
Interested member of the public, unidentified

1. Call to Order and Introductions

In the chairperson's absence, Joseph Parker, Ph.D., Director of the Healthcare Outcomes Center, called the meeting to order at 9:30 a.m. Dr. Parker noted the public binders available for review; however, the information must not be taken from the room. All people attending the meeting introduced themselves, with one abstention. Dr. Parker also noted the absence of a court reporter, which resulted from state budget-related contract

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suspensions. He stated that an audio recording of the meeting was being made and reminded speakers to state their names before speaking to facilitate minute-taking from the session recording.

2. Approval of Minutes of July 20, 2007 Meeting

Robert Brook, M.D., chairperson, determined a quorum was present. He asked for comments or corrections to the minutes of the previous meeting. None were offered. Minutes of the previous meeting were approved by consensus.

3. Director's Report – David Carlisle, M.D.

Dr. Carlisle briefly explained the state budget crisis and remarked that OSHPD requested and received a contract suspension exemption for the UCD and Expert Cardiologist contractors for the purpose of facilitating CABG reporting. The contractors were present to assist at the meeting.

The Director also noted the success of the CCORP program, the value of additional outcomes measures to be collected, the decline in CABG surgery volume, and the increase in PCI volume. He reported that the California Health Policy and Data Advisory Commission approved OSHPD's release of eight Agency for Healthcare Research and Quality inpatient mortality indicators. One of these will be for PTCA.

In response to questions, Dr. Carlisle reported that the TAC recommended OSHPD move forward with evaluation regarding PCI as well as CABG reporting. The CAP members expressed interest and support for PCI reporting and discussed use of clinical versus administrative data.

4. Program Director's Report – Joseph Parker, Ph.D.

Dr. Parker provided an overview of the statutory requirements of the CCORP Program, with emphasis on the surgeon statement review process to be used for this meeting. He also summarized conclusions made by the panel at the one previous surgeon statement review process, which was held two years ago.

Dr. Parker summarized this year's hospital data submission process and rigorous data quality assurance activities. After a lengthy surgeon review process, five surgeons asked that their cases be reviewed by the CAP. These five surgeons submitted five statements regarding eight surgical cases.

The five statements were made anonymous and organized by an alphabetical designation "A to E". Each statement was then assigned randomly to a surgeon/non-surgeon team of panel members to take the lead in review; however, all panel members received and reviewed all five

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statements. Each statement was to be reviewed separately and a decision reached before proceeding to the next statement.

The panel could reach three possible conclusions for each case in today's review:

- A. The physician's statement reveals a flaw in the accuracy of the reported data relating to the physician that materially diminishes the validity of the report. The data for this physician shall not be included in the report until the following flaw(s) in the physician's data is corrected:
- B. The physician's statement reveals a flaw in the risk-adjustment model that materially diminishes the value of the report for all physicians. The report using this risk-adjustment model shall not be issued until the following flaw(s) is corrected:
- C. The physician's statement does not reveal a flaw in either the accuracy of the reported data relating to the physician or the risk-adjustment model. The preliminary report data for this physician shall be used.

Dr. Parker concluded that OSHPD staff will make necessary adjustments and prepare the public report after decisions are made at this meeting.

5. Review of Anonymized Individual Physician Statements and Determinations by Panel

Clarifications were sought before the review began. Dr. Brook confirmed with OSHPD attorneys that surgeons whose cases are being reviewed can comment on the case – along with any other member of the public – but cannot self-identify.

A question arose as to why only hospital comments are appended to the public reports. OSHPD legal counsel explained that hospitals do not have a statement (appeal) process as the surgeons do.

It was confirmed that definitions and explanations of Mini Maze and Full Maze are made available to surgeons via the OSHPD website, in trainings, and other communications with hospitals as well as surgeons.

The panel requested that attachments to letters and page numbering be included in CAP packets in the future.

Dr. Brook began the surgeon review process.

Statement "C" was the first randomly selected case, which was assigned to Andrew Bindman, M.D. and James MacMillan, M.D as lead discussants/reviewers. This surgeon had a performance rating of "as expected" – neither "worse than" nor "better than" in the OSHPD preliminary report. The statement included three patient deaths.

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Statement “C” - Patient #1. Patient had a left ventricular aneurysm. After case review, Drs. MacMillan and Bindman determined the surgeon did a Mini Maze, therefore, the case qualifies as isolated CABG surgery. Dr. Brook asked for a vote. MacMillan moved and Bindman seconded the motion to reject the surgeon’s claim and uphold the OSHPD decision that the case is isolated. The motion was approved unanimously. This is an isolated CABG.

Statement “C” - Patient #2. Drs. MacMillan and Bindman stated that the operative report indicates this procedure was a Mini-Maze; therefore, qualifies as an isolated CABG surgery. Dr. Brook asked for a vote. Dr. MacMillan moved and Dr. Bindman seconded the motion to reject the surgeon’s claim and uphold the OSHPD decision that the case is isolated. The motion was approved unanimously. This is an isolated CABG.

Statement “C” – Patient #3. The surgeon challenged the case because a vein was never opened. However, the surgical team did proceed with the intent to do a CABG and progressed about 45 minutes. The hospital confirmed this was a CABG. Ultimately, the patient did not have CABG surgery. Anthony Steimle, M.D. stated that induction of anesthesia is considered the starting point. Holly Hoegh, Ph.D., concurred and noted that the induction of anesthesia is considered the starting point of a surgery in our trainings for surgeons and data contacts. Dr. Brook asked for a vote. Dr. MacMillan moved and Dr. Bindman seconded the motion to reject the claim and uphold the OSHPD decision that this is an isolated CABG surgery. The motion was approved unanimously. This is an isolated CABG.

It was noted that what is and is not an isolated CABG surgery may require more discussion at a later time.

Statement “D”. The surgeon was rated “as expected” in the preliminary report. Timothy Denton, M.D. and Fred Grover, M.D. were assigned as lead discussants. Dr. Grover provided the case review for the panel members. He stated this was a high risk patient who was taken to the operating room for a CABG surgery. The surgery was completed with difficulty. Pulmonary embolus was discovered post surgery, and patient received a pulmonary embolectomy. Intent to treat was a CABG surgery. OSPHP determination was that pulmonary embolus was a result of the CABG surgery. Dr. Grover believed that the clot would not have formed during CABG. It may not have been recognized, but it was present before surgery. Dr. Denton stated that intent is one thing but a surgeon can open up the chest and find something else. Dr. MacMillan concurred that this is not a complication of CABG surgery but a diagnostic error, which may happen with pulmonary emboli. Keith Flachsart, M.D., questioned the thought pattern of the panel, which, be believed, conflicted with the reasoning on a previous case.

Dr. Brook called for comment and a vote. Dr. Bindman questioned if we are rating technical competence or diagnostic ability or both. The answer is that we can identify technical competence but have inadequate markers of appropriateness. Dr. Grover moved not to uphold the OSHPD decision for Statement “D” that the case was isolated, as this was a non-isolated CABG. Coyness Ennix, Jr., M.D., seconded the motion. There was one opposing vote, one

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abstention, and the majority supported the decision. Motion passed. This was **not** an isolated CABG.

Statement “E”. The surgeon was rated “as expected” in the preliminary report. Drs. Denton and Grover were assigned case review. The surgeon stated that the patient died six weeks after the surgery, while undergoing rehabilitation for multiple pre-existing morbidities. The surgeon felt the death was not related to the CABG surgery. There was a change of service but it did not include hospital discharge to a rehab facility, therefore the case meets the OSHPD definition of operative mortality. Dr. Brook called for a vote. Dr. Denton moved to uphold OSHPD’s decision that the case meets the definition of operative mortality and Dr. Grover seconded the motion. Passage was unanimous. The case is an isolated CABG death.

Statement “A”. The surgeon was rated “as expected” in the preliminary report. Ralph Brindis, M.D. and Coyness Ennix, M.D. were assigned to lead review of the case. Dr. Ennix explained that the surgeon proposes there is a flaw in the risk-adjustment model. The patient was treated with Trasyolol, which the surgeon believed contributed to the death. The dangers of Trasyolol were not made public before this surgery. The patient underwent a 4-way bypass. The patient had acute renal failure. Patient could not be transferred out of the hospital. A patient directive allowed relatives to cease care, and they chose to do so. Dr. Brindis stated there was a level playing field because all cardiovascular surgeons operated with lack of knowledge on the risks of this drug. Drs. Ennis and Flachsbart agreed and noted that perhaps Trasyolol should not have been used given this patient’s risk factors.

Dr. Brook called for comment and a vote. Dr. Ennix moved and Dr. Brindis seconded the motion to uphold OSHPD’s decision that the risk model is not flawed. It passed unanimously. The risk model is not flawed.

Statement “B”. The surgeon was rated “as expected” in the preliminary report. Drs Flachsbart and Brindis explained the case. The patient had Hodgkins-related radiation therapy prior to surgery. The operation went well, but the patient died two months later while still in the hospital. The hospital records are unclear regarding the cause of death. The surgeon believed the risk-adjusted results are flawed because the model doesn’t account for cardiac risk of radiation therapy. A related medical article included with the statement was not specific to acute mortality following bypass surgery.

A discussion followed regarding whether we adequately adjust for radiation. Dr. Parker noted results of a linkage to the discharge data found very few cases similar to this. Panel members stated the low numbers could be a result of hospital coding errors.

Dr. Brook called for a vote. Dr. Flachsbart moved and Dr. Brindis seconded the motion to uphold the OSHPD decision that this is an isolated CABG surgery and that the risk model is not flawed. The motion carried. The case is an isolated CABG and there is no flaw in the risk model.

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Dr. Brook asked OSHPD to keep records of radiation cases and other related areas. Currently, there is no clinical story; however, the numbers could grow if they are coded correctly at the hospitals. Dr. Grover noted an increasing number of transplant patients. There could be similar conditions small in numbers but high in death rates which might be forced into the risk adjustment model. The panel recommended OSHPD continue to capture more information regarding small numbers of cases with high death rates, to the extent coding will allow.

The panel recommended continued review of definitions for (1) issues surrounding intent-to-perform a CABG surgery (2) and induction of anesthesia as the starting point for CABG surgery. They also reiterated the need to continue to educate surgeons about the current criteria.

Dr. Brook requested continuous review of OSHPD training materials.

Dr. Brook thanked OSHPD staff. He also noted that risk models can only do so much.

Dr. Brindis asked how many statements were sent to OSHPD. Dr. Hoegh responded that eleven statements were submitted to OSHPD and five were forwarded to the panel.

6. Public Comment Period

There were no public comments.

7. Adjournment

Meeting was adjourned at 11:25 a.m.