APPENDIX C: HOSPITAL RESPONSES

Each of the hospitals included in the CCORP 2003-2004 report was provided with a preliminary report containing the risk-adjustment model and outcome results and allowed a 60-day review period for submitting statements to OSHPD. Letters were received from two hospitals and they are included in this appendix. The hospital comments have been summarized into the following categories:

1. Risk-adjustment methodology

Comment:

One hospital raised concerns regarding the methodology used for risk adjustment. The hospital listed cases where the death of the patient was attributed to the presence of end-stage lung disease, end-stage renal disease, and end-stage ischemic cardiomyopathy combined with congestive heart failure. According to the hospital, these patients did not die as a result of the CABG surgery.

Response:

The CCORP report uses a risk-adjustment methodology that takes into account the preoperative risk factors reflecting severity of illness and risk of mortality for each patient. The presence of end-stage lung disease, renal disease, or congestive heart failure is captured by risk factors such as chronic lung disease, creatinine level, and congestive heart failure. Although not all possible risk factors can be included in the model, CCORP includes the risk factors that are included by STS and other similar programs. The CCORP risk model provides appropriate adjustments to hospitals that treat severely ill patients.

2. Operative mortality

Comment:

A hospital raised concerns about the CCORP definition of mortality. The author noted that this definition of mortality penalizes hospitals that do not transfer their CABG surgery patients to other facilities after 30 days. Patients who are transferred to another facility and expire after 30 days are not counted as deaths, whereas patients who are not transferred and expire after 30 days are counted as deaths.

Response:

CCORP uses operative mortality (patient death occurring in the hospital after CABG surgery, regardless of the length of stay or death occurring anywhere after hospital discharge, but within 30 days of the CABG surgery) as the outcome measure. Patient death is confirmed by linking CCORP data with the state death file provided by the California Department of Health Services. If a patient is transferred to another institution and dies there within 30 days after the surgery, the death is captured by this linkage. Using operative mortality helps avoid some potential "gaming" of outcomes through discharge practices though patients who are transferred 30 days after the operation and die in other facilities are not included in the mortality count. While

another measure could be used, CCORP decided to align its quality measure with the National Society for Thoracic Surgery (STS) which also uses operative mortality as their primary outcome measure for CABG quality reporting.

3. Consistency in coding

Comment:

Another concern was raised about the variation in coding of the risk factors, which can affect the validity of risk-adjusted results. Specifically, overstating the risk profiles of patients may provide an unfair advantage to some hospitals. In addition, the hospital mentioned that potentially difficult-to-measure risk factors not included in the current model may increase or decrease a patient's risk of an adverse outcome.

Response:

When this program first began, all hospital staff involved in abstracting surgical data were offered in-person instruction by the CCORP consulting cardiologist and training videos of these sessions were later distributed. Hospitals were also provided with a data abstractor's manual that clearly defines the data elements and the coding structure. For difficult to code elements, CCORP offers further information on the OSHPD Web site and refers unique cases to the consulting cardiologist. CCORP data for 2003 and 2004 were also subjected to medical chart review. The primary candidates for data audit were hospitals and surgeons identified as outliers on a preliminary basis, near outliers, or hospitals/surgeons with apparent over-reporting or under-reporting of risk factors. Audit data replaced the data submitted from the hospitals. The medical chart review, along with other analyses and data quality reports ensures the fairness of risk factor coding across hospitals. Information about the medical chart audit process is provided in Section III.

4. Combining years of data

Comment:

A hospital expressed concern about reporting separate results for individual years and combined years. The hospital believes caution should be used in interpretation of the mortality statistics.

Response:

CCORP reported hospital level data for 2003-2004 combined and 2004 separately in this report. The combined year data allows for direct comparison to the 2003-2004 surgeon level results. The two-year combined results are statistically more stable than the results from a single year of data, especially for lower volume hospitals. However, the 2004 data allows readers to see the most current performance and to observe any changes from the 2003 hospital level results previously reported.

5. Use of the Internal Mammary Artery (IMA)

Comment:

One hospital commented on the absence of consensus on what constitutes an unacceptably low level of IMA usage. However, the hospital does recognize the current endorsement, by groups like Leapfrog, National Quality Forum, Society for Thoracic Surgeons and programs like CCORP in regard to the importance of IMA usage for CABG surgeries. This hospital also stated that during the past 18 months IMA usage for CABG surgeries at their facility has significantly increased.

Response:

According to the STS, the internal mammary artery confers long-term graft patency and improves patient survival as compared to surgical revascularization with venous conduits alone. Despite these advantages there is great variability in its application. The main goal of public reporting of IMA usage rates is to encourage hospitals and surgeons to consider the IMA when appropriate. Absent clinical consensus on what constitutes an unacceptably low level of IMA usage, this report adopted a statistical one. CCORP encourages all hospitals and surgeons to make efforts to increase IMA usage rates.

The hospital letters received in response to this report follow.





August 29, 2006

Holly Hoegh, Ph.D. Manager, Clinical Data Programs Office of Statewide Health Planning and Development 818 K Street, Room 200 Sacramento, CA 95814

Dear Dr. Hoegh,

St. Jude Medical Center (SJMC) is one of Orange County's most respected hospitals, which ensures our patients receive superior care at every step, including expert physicians, advanced practice nurses, a state-of-the-art intensive care unit, and comprehensive rehabilitation programs.

St. Jude Medical Center appreciates the efforts of the California CABG Outcomes Reporting Program (CCORP) and the opportunity to respond with comment regarding the results of Internal Mammary Artery (IMA) usage in this most recent report.

As stated in the section of this year's CCORP report, <u>Use of Internal Mammary Artery in CABG Surgery as a Process Measure of Quality</u>, there is an "Absent consensus on what constitutes an unacceptably low level of IMA usage". However, St. Jude Medical Center recognizes the current endorsement of the California CABG Outcomes Reporting Program (CCORP), the Leapfrog Group, the National Quality Forum, and the Society of Thoracic Surgeons in regards to the importance of IMA usage for the CABG patient.

Appreciating that our facility's use of internal mammary artery use in CABG surgery could be higher and our commitment to continuous quality improvement, St. Jude Medical Center has implemented processes which detail the importance of considering IMA usage for patients undergoing CABG surgery. During the past 18 months, our facility's IMA usage for patients has significantly increased. Referring to the most recent Society of Thoracic Surgeons (STS) National Database Report - Spring 2006, our facility's IMA usage was 92.2% for 2005. In addition, review of more recent internal data shows that IMA usage for St. Jude Medical Center is 93.1% for January through June 2006.

St. Jude Medical Center is dedicated to continually improving the health and quality of life of people in the communities we serve through our core values of dignity, service, excellence and justice. We look forward to our continued participation in the California CABG Outcomes Reporting Program (CCORP).

Thank you for the opportunity to respond to the 2003-2004 California CABG Outcomes Reporting Program (CCORP) Report.

Best regards,

Doreen L. Dann

Executive Vice President and Chief Operating Officer



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August 31, 2006

Holly Hoegh, Ph.D. Manager, Clinical Data Programs Office of Statewide Health Planning and Development 818 K Street, Room 200 Sacramento, CA 95814

Re: 2003-2004 California CABG Outcomes Reporting Program Report

Dear Ms. Hoegh,

The Division of Cardiothoracic Surgery at the University of California, San Francisco was one of the first groups to provide open-heart surgery in the state of California. The Division, along with the UCSF Medical Center are committed to providing excellence in all aspects of cardiovascular care. Surgery for coronary artery disease is no exception.

The UCSF Medical Center has participated in the state reporting of coronary artery surgery since 1999. As you know, only a minority of cardiac surgery practices reported on a voluntary basis at that time. In the 3 voluntary public reports issued by CCMRP from 1999 through 2002, UCSF consistently scored "as expected" for risk adjusted mortality in coronary artery surgery. In 2003, state law mandated public reporting of coronary artery surgery results for all centers providing this service. Again, in the 2003 public report, the UCSF Medical Center scored "as expected". The 2003-2004 California CABG Outcomes Reporting Program (CCORP) Preliminary Report will be made public shortly. In that report, the UCSF Medical Center along with one of its cardiac surgeons will be listed as "worst than expected" for risk adjusted coronary artery bypass graft mortality. We believe that this designation is not an accurate reflection of the excellence of care here at UCSF for the following reasons:

The CCORP risk stratification methodology cannot adequately capture the
risk profile of some of our patients. This is exemplified by one patient at
UCSF who underwent coronary bypass surgery who had end stage lung
disease. This patient was on the waiting list for lung transplantation. The
patient recovered uneventfully from his coronary bypass procedure and
was discharged home. Unfortunately, the patient developed progression
of his severe underlying lung disease and refused further care. He expired
of complications related to his underlying end stage lung disease.



Scot H. Merrick, M.D. Professor of Surgery Thoracic Surgery Program Director 350 Parnassus Avenue Suite 150 San Francisco, CA 94143-0118 tel: 415/353-1312 fax: 415/353-1312 A second patient underwent coronary artery bypass surgery with underlying end stage renal disease. This patient recovered uneventfully from the surgical operation and was discharged home. The patient subsequently died as a result of complications from hemodialysis, not from her cardiac disease.

A third patient who was admitted to the UCSF Medical Center with end stage ischemic cardiomyopathy and congestive heart failure. He was being considered for heart transplantation. After considerable discussion with our cardiovascular experts, coronary bypass surgery was recommended. The patient had a successful operation. However, he continued to have persistent severe heart failure postoperatively. He was placed on a ventricular assist device and was awaiting transplantation. The patient expired as a result of a stroke while on the ventricular assist device.

- 2. The CCORP reporting mechanism penalizes those hospitals that keep complicated coronary artery bypass patients within their institution for more than 30 days. Should these patients subsequently expire after 30 days, they are counted in the mortality statistics. However, if the patient is transferred to another facility at any point in time, the mortality is not noted under the CCORP Program. Again, UCSF has steadfastly maintained a dedication to uninterrupted care of heart surgery patients.
- There are significant issues with the CCORP statistical methodology. Excerpts from a statement from the Society of Thoracic Surgeons national cardiac surgery data base report is appropriate here. "The validity of risk adjusted results relies on consistent and accurate coding of risk factors and surgical outcomes. In reality, there may be some variation in the way risk factors and outcomes are coded by two different participants. If one hospital tends to overstate the risk profiles of its patients while another hospital understates the risk profiles of its patients, the hospital that overstates the risk profiles will have an unfair advantage. To minimize bias, it is essential to pay close attention to it to data definitions when coding events and risk factors." Furthermore, the STS also states "not all risk factors are captured in the model. Risk adjustment attempts to level the playing field by adjusting for risk profiles of the participant's patient population. However, there are potentially difficult to measure factors that are not included in the risk assessment model which may increase or decrease a patients' risk of an adverse outcome. For this reason, two patients having exactly the same measured risk factors prior to surgery,



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might actually have substantially different real risk. If a participant tends to treat patients that are at greater or lower risks that they might appear based on the measured risk factors, this may bias their risk-adjusted results upward or downward." As you know, CCORP performed a data audit for the 2004 report. Forty hospitals were selected, including the University of California, San Francisco. The results of that audit revealed that 10.8 % of the categorical risk factors required correction. Moreover, 4.7 % of the categorical risk factors were over coded (risk factor coded more severely by hospital than by audited data) and 4.9% of categorical risk factors were under coded. Based on these statistical limitations, we believe that great caution should be used in the interpretation of mortality statistics.

We believe that the 2003-2004 California CABG Outcomes Reporting Program Report final report is also misleading in that it includes data from both 2003 and 2004. As mentioned previously, the 2003 CCORP published report for the UCSF Medical Center shows that we had an "as expected" designation for risk stratified CABG mortality. While our risk adjusted mortality for 2004 is "worse than expected", we feel that reporting our results for both years as "worse than expected" is not appropriate.

In summary, the Division of Cardiothoracic Surgery and Medical Center at the University of California, San Francisco, is dedicated to excellence in the care of patients with cardiovascular diseases, and we do not feel that the 2003-2004 CCORP report accurately reflects our practice here at UCSF. We would like to emphasize that the 2005 CCORP Hospital Data Summary Report for the UCSF Medical Center shows an unadjusted CABG mortality of 0.8%. In addition, for the first six months of 2006, the unadjusted operative mortality for CABG was 1.4%. We believe that these results along with our past-published CABG mortality reports are a more accurate reflection of the excellence in care at UCSF.

Sincerely

Scot H. Merrick, MD Professor and Chief

Division of Cardiothoracic Surgery