

**Percutaneous Coronary Intervention Advisory Oversight Committee (PCI-AOC)**

December 11, 2014 @ 2 – 4 p.m.

California Department of Public Health (CDPH)  
1615 Capitol Mall, 95814  
CDPH Building 173, Rooms 665 & 666

Facilitators: Dr. Anthony Way and Dr. William Bommer

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**Roll Call – Gladys Glaude**

The following individuals were present via conference call at the time of roll call:

**Committee Members**

- George Fehrenbacher
- Aditya Jain
- Sushil Karmarkar
- Stephen Arnold
- Rohit Sundrani
- William French
- Robert Davidson
- Dipti Itchhaporia

**Other Individuals**

- Suresh Ram
- Robert Forey
- John Kass (Clovis Community Medical Center)
- [Missing name] Swanson
- Renee Parlier (Los Alamitos)
- Cathy Major (Hoag Hospital)
- Amie Selda (St. Rose Hospital)
- Dani Bennett (Kaiser Walnut Creek)
- Edie Jonas (Sutter Roseville)

**1. Welcome and Introductions – Dr. Anthony Way**

Dr. Way confirmed there is a quorum of committee members present.

The meeting was converted to conference call because of the weather. Everyone should have a copy of the agenda that was sent out.

## **2. Minutes of August 21, 2014 Meeting – Dr. Anthony Way**

The August 21, 2014 minutes were available on screen and basically documented Dr. Bommer's presentation. Dr. Way asked for acceptance of the minutes as provided.

- [Unknown] moved to accept the minutes.
- Dr. Sundrani seconded the motion.
- Gladys Glaude completed a roll call of the eight AOC members who all approved the minutes.
- There were no comments from offsite participants regarding the minutes.

## **3. PCI CAMPOS Data Update – Dr. William Bommer**

Dr. Bommer presented the 4 Year PCI CAMPOS data with a slide presentation.

### **a. 4 Year PCI CAMPOS Data**

Dr. Bommer welcomed everyone to the meeting.

- This is an especially important meeting because this represents literally the four-year completion of the PCI CAMPOS program for the trial program of offsite PCI in the state of California.
- We are going to be presenting the four-year information at this time.

Coordinating Center (slide 2)

- I wanted to spend a couple minutes initially thanking everyone for their tremendous commitment to this program.
- 100 individuals participated on this team and that total commitment to the program and to the team approach is what has lead to completion of this program.
- This is a list of coordinating center members who provided coordination and analysis.

Pilot-Hospital Interventionalists (slide 3)

- We would not be here today if these interventionalists were not available 24 hours a day, seven days a week to perform these STEMI procedures on these patients to improve their chance of surviving myocardial infarction as well as to perform needed PCIs on the patients electively at each of the six offsite hospitals.

Pilot-Hospital Coders (slide 4)

- This list really emphasizes the important aspect of coders.
- All of the information that comes into our data set is provided by these hospital coders at the pilot hospitals. We want to thank each of them for their commitment over the last four years in getting all of this data in.
- They've been outstanding in their efforts to try to ensure complete and accurate data in our data set.

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### CDPH and AOC members (slide 5)

- We want to thank Dr. Way for his commitment over the last three years on this project and sticking with it as well as the rest of the CDPH administration and the AOC members both from the pilot hospitals as well as those that were not actually involved in the program but committed themselves to be oversight members for this very important program.
- George Smith was with us for most of the time and is no longer with us and we will miss him as well as his enthusiasm and commitment to the PCI CAMPOS program.
- Dr. Fehrenbacher thanked Dr. Bommer for his tremendous commitment and meticulous dedication to getting this data together.

### Total Enrollment (slide six)

- We were able to enroll over 5,000 patients, actually five zero five one, in the total program.
- For first and second years we achieved our goal, which was at least 1,200 patients each year. In year three we dip below that a little at 1172 but we came back up in year four at 1,278 and overall we did average more than 1,200 patients each year with a total of 5,051.
- The most common diagnosis for people having PCI in our program was STEMI with 1,600, followed next by NSTEMIs, then unstable angina, then stable angina.

### Total Enrollment Per Month (slide 7)

- Shows the variability over time in the enrollment in the PCI CAMPOS program. There is a variation here. It is as low as 84 per month and as high as 137 per month.
- There is an up and down pattern here. I'm not sure exactly what it relates to, but it is continued during the duration of this study over the four-year period.

### Monthly Enrollment: Hospitals (slide 8)

- This shows individual hospital enrollment variability over the four-year duration of the trial. There is a variation in each of the hospitals there. It makes a very pretty picture.
- In general, when our largest enrolling hospital was higher, we peaked for the total enrollment but each of the hospitals contributed to that.
- There is again a pattern here but I'm not sure exactly what the cause of that pattern is.

### STEMI Enrollment Year 1-4 (slide 9)

- Our goal was to get about 36 STEMIs per year per hospital as a minimum.
- For almost every hospital with a few exceptions and for most of the four years we were able to achieve 36 STEMIs per year per hospital, with a few exceptions shown here.

### Hospital 1 Enrollment (slide 10)

- For each of the four years they achieved more than 200 enrollments per year, which was the minimum goal in each of the hospitals. In the last year they achieved over 403, or double that in year four.

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- Hospital one enrolled mostly patients who had stable angina, followed by unstable angina, followed by NSTEMI, and then STEMI. So this was mostly an elective population and their total enrollment was 1,554 patients.

### Hospital 2 Enrollment (slide 11)

- Hospital number two achieved greater than 200 in all four years.
- The most prevalent diagnosis was STEMI (399), followed by NSTEMI, then unstable angina.

### Hospital 3 Enrollment (slide 12)

- Hospital number three was not able to achieve our goal of 200 procedures per year for any of the four years. They ranged from 99 to 161 for each of the four years with a total enrollment of 485.
- Their largest population was seen in STEMI at 222, followed by NSTEMIs, and then unstable angina.

### Hospital 4 Enrollment (slide 13)

- Hospital number four did not achieve the goal of the minimum 200 procedures per year in any year. They ranged from 86 to 134 with a total of 447 patients.
- The most prevalent diagnosis was NSTEMI at 168 and then STEMI, then unstable angina.

### Hospital 5 Enrollment (slide 14)

- Hospital five did not achieve the goal of 200 patients in any year. It ranged from 139 to 174 for a total of 643.
- The most prevalent diagnosis was NSTEMI at 223, followed by STEMI, then unstable angina.

### Hospital 6 Enrollment (slide 15)

- Hospital six achieved our goal of 200 in years two and four, but not in one and three, for a total of 804 patients.
- The most common presentation at this hospital was STEMI at 450, followed by NSTEMI, and then unstable angina.

### Website Update (slide 16)

- The data for the entire website for the four years is completed and all of the entries have been locked down for final statistical analysis.
- Hospitals that are still enrolling patients through 12/31/14.
- Velos upgraded their system and after the upgrade the browsers that worked perfectly on the new Velos upgrade were Firefox and Google Chrome. Some of the Internet Explorer versions had compatibility issues.

### Website Data Entry (slide 17)

- Shows the process of the data collection and analysis for PCI CAMPOS.

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- We stored all of the data on Velos servers here at the University of California. We stored all of the angiograms on an Xcelera server. All of the statistical analysis was done on a separate S-A-S “SAS” computer.

### Initial Central Audit (slide 18)

- We did a central audit on each of the 5,051 patients enrolled in this trial which included a review of all the data fields and completeness check before this data was accepted and locked down.

### Pilot-side Audits (slide 19)

- Approximately 10% of all cases were randomly audited as well as every complication (approximately 10%) for a total of just over 20% (1,059 patients) at pilot hospitals.
- A physician or a nurse practitioner reviewed the data. They went over the records at the hospital and brought back the angiograms which were then reviewed both visually as well as with quantitative analysis for the angiographic information.

### Angiographic Audit: Diagnostic (slide 20)

- On the angiographic audit we did review a lot of things including the use of balloon pump, the anatomy on the coronaries to see if that correlated with what was entered into the database for each of the lesions for coronary stenosis in which PCI was attempted.

### Angiographic Audit: PCI (slide 21)

- Additional angiographic audit information was obtained including the percent stenosis of each lesion immediately prior to and following PCI at the pilot hospitals, whether or not IVUS or FFR was used in those individuals, pre-procedure TIMI flow, and post-procedure TIMI flow, as well as lesion complexity and presence of thrombus.

### Lesion Complexity (slide 22)

- Lesion complexity came up fairly often in our analysis initially and then seemed to improve as we went through the study.
- A lesion could not be classified or accepted as a high C lesion unless it met the criteria of the definition shown in red here.
- This was initially often a contested area and we did use and have feedback to each of the sites both to the angiographic individual as well as the coders when we disagreed with this and eventually we achieved agreement with each of the hospitals.
- In addition to those angiographic findings we did identify bifurcation lesions, which were included as well as the device deployed and did look for complications on the PCI and confirmed the LV ejection fraction.

### Angiographic Audit: QCA (slide 24)

- We also looked at selected cases with coronary quantitative analysis. Whenever the angiographic review did not agree with the actual entered lesion severity or lesion

length we performed quantitative coronary angiography. From this we were able to give a quantitative number for both the percent diameter narrowing, or stenosis, as well as length of the obstruction and this information was provided back to the individual operator when we had initial disagreement over both lesion severity as well as lesion length.

Angiographic Audit: QCA (slide 25)

- We did look at side branch diameter with quantitative angiography, and if you'll remember that a lesion cannot be called a bifurcation lesion unless there is a large side branch which is in general greater than one and a half millimeters and this lesion which is shown here would be a small side branch and not a significant side branch at 1.36 millimeters diameter.

Protocol Violations (slide 26)

- In the last year we found no operator violations of the initially outlined protocol.

Compassionate Use Criteria (slide 27)

- This was introduced just after the first year of the program because we found a relatively high mortality with compassionate use and we were attempting to consider risk adjustment for this.
- Compassionate use criteria as defined by us, and agreed upon in other national studies, included coma on presentation, ventricular assist device prior to PCI, and CPR at start of procedure.
- This additional question was added to our NCDR database beginning July 1<sup>st</sup> 2011 and was present for the last three years and one month of the study.

Compassionate Use (slide 28)

- Shows our additional questions added to the NCDR database for looking for compassionate use: coma, CPR, and coronary bypass or LV assist device.

Compassionate Use Criteria (slide 29)

- Summarizes our compassionate use in this pilot group from the six hospitals over the three years and one month of the duration that we had it.
- A total of just over 3,800 patients had this question answered for them.
- 55 individuals, a little over 1%, met criteria for compassionate use. The most frequent reason was coma at 53 of those individuals, followed by CPR for 15 of those individuals. If they had both CPR and coma then that only gave them one compassionate use so that patient then qualified for whether they had one or the other or both.

Compassionate Use (slide 30)

- Shows the difference in results for STEMIs with and without compassionate use criteria.
- Individuals had a 54.5% rate mortality if they met the criteria for compassionate use. STEMI patients who did not meet those criteria had a tenfold lower mortality rate at

5.3% versus the 54%. In our group of patients, meeting the compassionate use criteria would increase the mortality by a factor of 10. That was a huge factor; in fact the most significant factor influencing mortality in our patient population.

- NCDR does not collect this data and does not have numbers to compare with however we do have a study done in Massachusetts that showed comparable evidence of mortality and risk from the compassionate use criteria. They had mortality somewhat higher at 69.8% and an overall STEMI mortality of 4.5%, again showing a greater than tenfold increase in mortality when compassionate use was seen either in Massachusetts or in California in the pilot program studies.
- Compassionate use does and continues to remain our highest risk factor for mortality in our patients who are having STEMI PCIs.

What is the purpose of quality measurement (slide 31)

- Shows some of our quality measurements and we have the advantage here of a very detailed database. We have a clinical data set from PCI CAMPOS, NCDR California, and NCDR US. We used all of those clinical databases as well as comparison with benchmarks of NCDR US results.

Quality Metrics I Post-Operative Medicine Use (slide 32)

- This is post-op medicine use; these are some of the metrics that we looked at.
  - Aspirin prescribed at discharge in the pilot trial was seen in 98.7%, which was well within the benchmarks of NCDR US numbers (97-99%).
  - P2Y12 inhibitor or Thienopyridine use was seen in 93.5% of our pilot discharge patients. This was below the benchmarks for NCDR US of 98.6 to 100% in that population. So we did dip for the use of discharge P2Y12 inhibitors or Thienopyridines or at least the documentation of that in our PCI pilot patients.
  - Statins was achieved in 97.2% and this was again within the benchmarks of US NCDR data (91-98%).

Quality Metrics II (slide 33)

- 59% of all patients who had elective PCI in the PCI CAMPOS population had an abnormal stress test or imaging test prior to getting an elective PCI. For PCI electives, almost two thirds of them had a positive stress test before achieving that. This was within the benchmark for 25 to 75 percentile of US NCDR, meaning that the majority of our patients for elective PCI had the PCI after a having positive stress test, or had a positive FFR at the time of their procedure.
- Only a small number of patients in the trial, 35 out of 40 individuals, had abnormal FFRs for a small number of individuals in the neighborhood of less than 1% actually. We actually had FFRs performed in our trials and most of the patients had SPECT imaging as well as standard exercise testing or stress echo.

Quality Metrics III (slide 34)

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- The median time of door to PCI for our STEMI patients is 65 minutes. This was literally within the benchmarks 25-75 percentile for NCDR nationally, which is 66-54. We had a 65-minute door-to-balloon time roughly and this was close to the NCDR US number. 92.7% of our individuals received their PCI within 90 minutes for door-to-balloon time and that was similar to NCDR at 94% and within the benchmarks of 25-75 percentile nationally.
- The number that required emergency CABG in the PCI CAMPOS group was 0.3%. Very close to prior published numbers of 0.3% as well and within the benchmark of 25-75 percentile for US national, although the US national average or mean was lower at 0.1%.

### Quality Metrics IV (slide 35)

- The total stroke rate was 0.3%, within the benchmarks for NCDR 0.3-0%.
- The composite of death, emergency CABG, and stroke was seen in 2.9% of the PCI CAMPOS patients of all comers. This was within the benchmark 25-75 percentile for NCDR US national numbers, slightly higher than average for the US at 2.6% but within the 25-75 percentile benchmark for this composite outcome.
- The median post-procedure length of stay was actually a little bit under too for this, which was well within the guidelines or within the benchmarks for NCDR and a US rate of 2.6.
- The post-procedure length of stay with no STEMI was approximately again one day and there is no national data on that, so the length of stays for these pilot hospitals was very good and was as good as or better as national.
- Whether we measured Creatinine before and after PCI, this was measured before and after PCI in our population in 93.9% of the individuals and you can see that that falls within the benchmark for individuals in the NCDR and was slightly higher than the NCDR rates. That's the assessment of Creatinine or renal function.
- In transfusion of whole blood or RBCs our total transfusion rate was 3%. This was outside of the 25-75 percentile benchmarks for NCDR and above the benchmark NCDR average of 1.2. This was an outlier from the benchmarks and that was in increased rate of transfusion for patients in the PCI CAMPOS program.

### Quality Metrics V (slide 36)

- A very small number of our individuals had IVUS, 5.9%.
- A small number had FFR, that is 12.8% of our individuals who had a 40-70% lesion, that is an intermediate lesion, about 12.8% had FFR to determine whether this was significant stenosis or not.
- 73.3% of all individuals in PCI CAMPOS had post-procedure biomarkers assessed. This was somewhat better than national, which was at 27% nationally. It ranged in the hospitals from anywhere from a low of 14% assessment of biomarkers to as high as 90% assessment or 95% assessment of biomarkers. Using that biomarker data, we can see that post-procedure myocardial infarction which is sometimes controversial following PCI was seen in 7.6% in the bottom row of the individuals in the PCI CAMPOS program. Now, for populations in the NCDR that the benchmarks are given there that measure

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less than 90% which would have been our population here, then the benchmark goal was 0-1.4% and we exceeded that benchmark at 7.6% of post-procedure myocardial infarction. For hospitals that measured more than that, that is more than 90%, we also exceeded those benchmarks, which were 0-4.1%. So we did show a higher proportion of patients who had a quote post-procedure myocardial infarction, usually documented by biomarkers.

### PCI Success (slide 37)

- Shows PCI success rate and we can see we have a total of 5,051 patients and some patients had more than one PCI done and that total number of PCIs was 6,909. For most of the patients a guide wire was passed, but not all.
- Post-procedure success is shown on the fourth line and 92.4% of all individuals in the PCI CAMPOS program had successful PCI, defined by a less than 20% residual stenosis, treatment of their coronary lesion.
- 95% of the individual in the PCI CAMPOS program has TIMI 3 flow at the conclusion of their PCI procedure.
- 89.8% of the PCI CAMPOS population had a combination of both residual stenosis of less than 20% and TIMI 3 flow, which would be graded as successful PCI in many programs and papers.

### Quality Metrics: Definitions (slide 38)

- For Thienopyridines it could be any agent that is a P2Y12 inhibitor, including the Thienopyridines, but we also accepted Ticagrelor as well for that or Ticlopidine if that was given.
- The stress testing as we said was an abnormal stress test divided by the number of elective PCIs in those individuals so STEMI and NSTEMI were excluded from that patient population.

### Quality Metrics: Definitions (slide 39)

- Gives our definitions of door-to-balloon time basically and emergency CABG and those are listed here just so anyone who is reviewing these slides can go back and check just to see what the criteria of definitions of each of those entities was.

### Quality Metrics: Definitions (slide 40)

- Post-procedure stroke is shown there. The composite, in this case we're using the composite of death, emergency CABG, or stroke were added after the beginning of the study when we saw that that was being used in the most of the PCI trials that were being reported.
- Length of stay is shown there in days.
- Creatinine definition is shown there as well.

### Quality Metrics: Definitions (slide 41)

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- Talks about transfusion of whole blood cells. We have a higher transfusion rate, and this is the definition. It's the proportion of PCI procedures with transfusion that were received. This is patients with a pre-procedure hemoglobin greater than eight who did not go to CABG but who received whole blood or packed red blood cell transfusions. That was about 3% in our population and somewhat higher than the national numbers.
- For post-procedure myocardial infarction, we had a higher rate of that and it was the number who were biomarker positive divided by, or post-procedure myocardial infarction, divided by the number of patients who had elective PCIs in that case. We did not include STEMI and did not include NSTEMIs in that patient population, just elective patients who were evaluated.

### Transfer Costs (slide 42)

- One of the original legislative edicts from 891 was to talk about or evaluate cost. There was no easy way to compare cost before or after this program at any of the hospitals and cost analysis is extremely complex, however we did list the cost of transfer for patients who required transfer for CABG at each of the hospitals.
- Hospital one is was about \$1,000. Hospital two it was about \$2,700. Hospital three was around \$1,000 as well as hospital number four. Hospital number five went up to \$2,000 for the ambulance transfer. Hospital six was \$1,000. So between \$1,000 and \$2,700 was the cost of transfer.

### Summary I (slide 43)

- For some of the information you see blanks. At the time two and a half weeks ago when we sent out this data to comply with Bagley-Keene [Open Meeting Act] this data was not yet available. I will provide it verbally to fill in the blanks so you have those for discussion.
- We enrolled a total of 5,051 patients over the four years of the program.
- The volume for each of the hospitals ranged from 86 to 403 per year over the four-year period so quite a variation, a factor of over four in the hospital enrollment for each year.
- Our current NCDR California enrollment, which we used as the comparative group here, is currently 202,483 for four years. So that next line has over 202,000 enrolled 7/1/10 to 6/30/14 from the California database which is obtained from the NCDR from the hospitals that had onsite surgery that were then used to compare for PCI CAMPOS.
- PCI CAMPOS STEMI incidence of 32.4% that is true, was again still higher than the NCDR STEMI incidence, which was 18%. We have more STEMI patients (32%) versus the rest of California, which has STEMI incidence at 18% in their PCI population.
- Compassionate use designation raises CAMPOS STEMI mortality from 5.3% tenfold up to 54.5% and this is comparable to Massachusetts which also had a tenfold or greater increase in mortality when they included compassionate use criteria.

### Summary II (slide 44)

- For the California multivariate risk model we looked at all California offsite patients compared with all California onsite patients. We have over 5,000 offsite patients and

over 202,000 onsite patients in this risk model right now. We identified 33 variables in the multivariate analysis and used this for risk adjustment. We achieved a C-statistic of 0.893 which is very good showing that we have a very good way of predicting risk in this particular patient population and we achieved a high degree of risk prediction with our risk model.

- Line number two looks at risk-adjusted overall composite event rate for PCI CAMPOS in blue versus the rest of California in orange. The mortality or overall composite even rate was 1.94% for PCI CAMPOS and higher, 2.5%, for the rest of California. PCI CAMPOS achieved a lower risk-adjusted overall composite event rate compared to the rest of California. The P value for this is not significant even though we were lower for PCI CAMPOS, it was not enough to be statistically significantly different.
- The third line is STEMI-excluded so these are the more elective cases. The number for PCI CAMPOS in blue was 1.16%. It was again higher for NCDR California at 1.46%. PCI CAMPOS was lower overall composite event rate and was lower for STEMI excluded as well compared to the rest of California. This was not statistically significant by P value.
- Line four on your list is risk-adjusted overall composite event outliers. We found that one hospital was a better outlier, that is better than expected compared to the other hospitals. There were no worse hospitals. So no outliers for worse. One hospital was better than expected of the six PCI CAMPOS hospitals.
- For the next line, which is the NCDR California hospitals, there were 120 California NCDR hospitals with onsite surgery. Eight were better and 11 were worse than expected.
- The next line is CAMPOS operators. We had 53 PCI CAMPOS operators. One was better than expected. None were worse than expected.
- The next line is risk-adjusted STEMI-excluded composite event outliers. Of the six pilot hospitals there were no outliers for STEMI excluded. For the 120 NCDR California hospitals, there were seven better hospitals than expected and seven worse than expected.
- For the next line, for the 46 CAMPOS operators there were no outliers. For these elective patients, because these are STEMI excluded, we did continue to show, which we showed at year three, of the California onsite surgery hospitals there were seven that were worse than expected and those are continuing from year three also present in the four-year data that we show. There were no worse outliers for any of the PCI CAMPOS hospitals, either operators or hospitals, overall or STEMI excluded.

#### Summary III (slide 45)

- What we see is the success rate, which is shown here for post-procedure stenosis <20% residual stenosis was achieved in 92.4%.
- TIMI 3 flow was achieved in 95.2% and the combination of <20% stenosis and TIMI 3 flow was seen in 89.8% of the PCI CAMPOS population.
- The next line is talking about hospital volume variation. We've had discussions on this before and that relates to some recommendations on minimum volume for PCI and the question of if volumes are low does that increase mortality in that population. We looked at that for California and the total population. We combined both the PCI volume

for PCI CAMPOS as well as the offsite hospitals. We have a total of 207,000 PCIs in this database and we looked at a relationship between hospital and operator volume for overall patients and we did not see a hospital volume population relationship. However, when we excluded STEMI patients, that is the elective patients, there was a small signal suggesting that there was a reverse correlation in the situation where higher volume hospitals appeared to have lower composite event rates for this, suggesting that volume did play a small role in this situation and hospitals at low volume were associated with a higher event rate in this PCI population of the entire state of California. And this signal has also been occasionally reported in other publications.

- The last line here is PCI Quality Metrics and looks at some of the additional metrics we monitored.
  - First of all, for aspirin use, Statins, stress testing, emergency CABG, door-to-balloon time, stroke rate, composite event rate, and pre and post Creatinine measurement, we were within the NCDR benchmarks of 25-75 percentile for each of those.
  - Our length of stay was actually better than the 90<sup>th</sup> percentile or shorter time than the NCDR.
  - For the P2Y12 inhibitor use we were between 10 and 25<sup>th</sup> percentile. So we were not 25-75 percentile for the P2Y12 inhibitor use on discharge.
  - For transfusion and biomarker myocardial infarction we were below or outside of the 10<sup>th</sup> percentile for that, for both transfusion use as well as biomarker myocardial infarction. We were outside of the 10<sup>th</sup> percentile benchmark.

#### PCI-CAMPOS Plans (slide 46)

- We will send out the completed slides now that we have the data and we will post them to the CDPH the website and make sure those go out individually to each of the members of the AOC committee.
- Those are still in process but we have pretty good confirmation that they are accurate the numbers that I just gave you. We do not have the final statistical computation back at this time. It's still in process. The completed data only got to us several weeks ago and it has not yet finished the entire SAS computer run. We should have those very shortly.
- SB 357 was the extension for this year. It ends as of midnight on 12/31/2014 and we will no longer be enrolling patients in either the original pilot or the extension after midnight on 12/31/14.
- SB 906 was passed and signed by the governor and currently allows the six pilot hospitals to continue performing elective PCI as a certified hospital beginning January 1<sup>st</sup> 2015. They are allowed to perform those PCIs until January 1<sup>st</sup>, 2016. However, after January 1<sup>st</sup>, 2016, they have to have or be renewed as a certified hospital to be considered under the elective PCI program under the new language of SB 906.

That concludes the presentation. The presentation is now open to questions both from the advisory oversight committee and anyone offsite and then after that we will open it up to public questions or comment about the PCI CAMPOS data.

b. Questions from AOC Members

Dr. Sundrani: A couple questions for us. Do we have to worry about January 1<sup>st</sup>, 2015, or do we have time as a valid PCI hospital to go from January 1<sup>st</sup>, 2015 for the application? That's the number one question. The second question is, we have had trouble with our volume and so we have to meet that 200 PCI as for the bill that would mean that we have to add more interventionalists and if we have to do that for 2016, how do we do that?

Dr. Bommer: To answer specifically the questions related to the application process to become a certified hospital, I'd like to refer that to Dr. Way because CDPH will be making the final decision as to what the process for application will be as well as any protocol they are going to follow on that.

Dr. Way: We are working very diligently to get everything set up. Drop-dead date for us is January 1<sup>st</sup> but I'm not certain we're going to have application available for people to fill out until a week to a month after that particular date. All pilot hospitals have one year in order to reach that, to get the application and fill it out and get it approved.

As far as the volume that was mentioned, I don't know that it's actually listed in the senate bill. I have the bill in front of me but I can't extrapolate out of it immediately. So perhaps it would be best to pose that as an email question to me directly and I can get back to you on that.

Dr. Bommer: To answer that question, currently the recommendations that hospitals that are full-service labs (performing both STEMIs and elective cases but do not have surgery on site), then the recommendation is for hospitals that perform less than 200 cases annually, they must have stringent systems and process protocols with close monitoring of clinical outcomes and additional strategies that promote adequate operator and cath lab staff experience through collaborative relationships with larger volume facilities both physicians and staff should have opportunity to work at high volume centers to enhance their skills, the continued operation of laboratories performing less than 200 procedures annually that are not serving isolated or underserved populations should be questioned and any laboratory that cannot maintain satisfactory outcomes should be closed.

In the application process you'll see definitions and descriptions that you enter as to whether you qualify as serving an underserved population or rural area. Those are defined in there as well. So you can see that hospitals that are under 200 will need to meet extra criteria that they have stringent criteria for quality that is ongoing and there will be questioning of any hospital that does not serve an underserved population or area that continues to maintain itself under 200 annual volume and any hospital that does not meet adequate satisfactory outcomes there will be potentially a recommendation for closure of that hospital. So those will continue to be in there. I

don't want to define anything more than that at this time because those will be probably outlined in your application process.

Dr. Sundrani: About the second question for operators to get in for next year. For 2016, how do I add more operators into the program for 2016?

Dr. Bommer: Great questions, as you know, since we're no longer under the pilot program you can, as of December 31<sup>st</sup> this year, drop the requirement for a lifetime of 500 cases. In this situation the lifetime disappears at that time and operators after December 31<sup>st</sup> will need to be credentialed by your own hospital in whatever their criteria are for volume. As we go forward for pilot programs, not for pilot programs but the elective offsite programs after this interim year then there will be recommendations that operators perform at least 11 primary PCIs a year for that and ideally they should be operating only at hospitals that are doing more than 200 elective PCIs per year and more than 36 primary PCIs at that hospital. So we'll still probably continue the 36 primary PCIs per year but all of the hospitals in general have been able to meet that and if an operator is going to be listed as a primary STEMI operator, they should try to achieve 11 primary PCIs a year averaged over two years.

Dr. Sundrani: Thank you for answering that Dr. Bommer.

Dr. Fehrenbacher: I have a quick question. We can now notify our IRB (institutional review board) that the project will terminate December 31<sup>st</sup>? Is that correct?

Dr. Bommer: The pilot program terminates midnight 12/31/14.

Dr. Fehrenbacher: Okay. Thank you.

Dr. Jain: The criteria for interventions for elective PCI would that be 11 primary PCIs or any other volume or any other criteria that each hospital should think about in your opinion? I'm talking about other operators who are not in the pilot right now at these six hospitals. If they want to be a part of the, if they are interested in doing elective PCIs, then I know we'll be setting up our own criteria at each hospital, but is there any minimum requirement that is there or can we do what we feel is best for the hospital.

Dr. Bommer: Okay, so in the interim year, and there is a transition year, there are actually no set numbers for this transition year, that's why I said it will revert to your hospital credentialing for the next year. When go into the certified hospitals performing and the new hospitals enter the system as well as the pilot hospitals after this interim year, then there will be operator recommendations that intervention operators should perform a minimum of 50 PCIs per year averaged over two years to maintain their competency and if they do primary PCIs they should do at least 11 primary PCIs per year. The 500 lifetime [requirement] has been dropped from this and these are current requirements.

Dr. Jain: What about board certification in intervention cardiology? Would that be still there or won't be there?

Dr. Bommer: I'm going to read you exactly what that says abstracted from the 2014 SCAI/ACCF AHA recommendations from which the 906 language refers to. 906 says we should follow current ACCF/SCAI guidelines. These are the current guidelines. Operators should have ABIM board certification in interventional cardiology and maintain certification with the exception of operators who have gone through equivalent training outside the United States and are ineligible for ABIM certification and recertification exams.

Speaker: Excuse me Bill, what document are you reading from?

Dr. Bommer: Those are recommendations that have been abstracted from the 2014 SCAI/ACCF/AHA recommendations from which the 906 language refers to.

Speaker: Okay, so it's not in 906, it's a reference.

Dr. Bommer: 906 says we should follow current ACC/SCAI guidelines and those are current SCAI/ACCF/AHA guidelines.

Dr. Karmarkar: So, I may have missed out on this, but is CDPH getting the application process ready for pilot hospitals to get recertified which are currently in the pilot program or new hospitals to join the PCI program and when will we be able to get it?

Dr. Way: The application is in the process of being created. We haven't yet got sign off from legal on everything and it will probably be some time in January before it's available and it should be posted then on the CDPH website and I'm hoping I can just send it out directly to everyone who's involved in this particular process. I would like to make a few more comments on 906 when your questions from the general audience are done.

Dr. Bommer asked if there any more questions from those of the AOC related to the presentation.

Dr. Sundrani: I've looked at the Dehmer article and essentially the bill points out to it so for us to continue for 2016 we should keep that as our guideline document which has good details about the peer review process and what they would expect as well as the volume of the cath lab personnel and I guess about the numbers and all that. So essentially I think if we kind of focus on that we probably be, I don't know how it's going to work but in 2016 we should probably try and, and that includes the new consent because we will have to have another consent saying specifically, and the article does mention all that. So if we have that language then I think we probably should be okay. Is that correct?

Dr. Bommer: Correct. I believe that 906 refers to that. As I said, this year that is coming up, 2015, is an interim year without definitions of actual recommendations. Thereafter you will be complying with the recommendations of the SCAI guidelines, the most recent are the 2014 guidelines.

Dr. Bommer asked if there were any public comments or questions.

Dr. Fehrenbacher: Will the data be open specific publically displayed for each hospital without masking each hospital? Was that ever solved?

Dr. Bommer: As far as I can determine, whenever this was brought up to the AOC, there was never a total vote, there was consensus but not an agreement of all of the hospitals that the information unmasked could be released per hospital. We have listed them 1-6 but we have not identified the hospitals. When this came up at the AOC, and I know Tony addressed it, unless each of the hospitals, that is all of the six pilot hospitals, agree to release it, it cannot be released in general.

c. Public Comment

No public comment or questions.

Dr. Bommer emphasized that this is potentially the last AOC meeting thoroughly thanked the over 100 people who participated to make this a successful pilot study or trial as well as to help with the patients' care of those more than 5,000 patients who were taken care of in this study.

**4. Items for Discussion – Dr. Way**

Dr. Way gave personal thanks to Dr. Bommer and UC Davis and the members of the AOC committee for the work that they did so diligently to create this document that shows that in California we're able to do interventional cardiology without in-house cardiac surgery and go forward to allow other hospitals to participate. The amount of work that was put into this was immense and the quality of the work was outstanding.

a. Senate Bill 906 Implementation

Dr. Way discussed several SB 906 items:

- Certification in this new process will be unlimited in the number of general acute care hospitals that can apply. I think that's something to be aware of. The pilot hospitals all have one year to get this done and we've had quite a lot of inquiries from other hospitals about the process. They'll have from January 2015 to January 2016 to become certified in this process as will your hospitals that have the one year period coming up to also apply for that but will be able to be active in the interim year of 2015. Certified means that you'll be able to be eligible to participate in the program and do

interventions even if your hospital doesn't have cardiac surgery and I think everybody understands that.

- We are going to have the data collected by OSHPD. I think that's going to be an interesting process but OSHPD does data on cardiac surgeries so it's in their bailiwick and shouldn't be a problem.
- We are going to hire, contract with UC Davis and Dr. Bommer's group to continue the process for certifying eligible hospitals and eventually for recertifying all of your hospitals that were in the this original project. Dr. Bommer and UC Davis will go forward in hand with us for the next year to get this program up and running for the rest of the hospitals in the state of California that are interested in it.
- There will be supplemental licensing fees to any hospital that applies to cover the certification processes. SB 906 states that the department may charge certified hospitals a supplemental licensing fee, not to exceed the reasonable cost of the department, and the department may contract with a professional entity with medical program knowledge to meet the requirements. So it's going to be pretty much the same for the next year in particular with getting other hospitals certified and Dr. Bommer and his organization will continue their fine work in the certification process.
- I can't tell you exact date that applications will be available online or from the state of California. We should be able to get that up and running in the two few months or so at the latest which will allow your hospitals to reapply and for other hospitals to do primary application.
- The benchmarks we are going to require of your hospitals going forward and all new hospitals going forward is the benchmarks that are present in the National Cardiology databases which will make sure that going forward the quality of care being delivered will be equivalent to the quality of care that your hospitals have delivered in this past four year project.

b. PCI-AOC Going Forward

Dr. Way outlined the process for moving the PCI-AOC forward:

- SB 906 talks about the fact that we may go forward with a new AOC oversight committee. Instead of 12 members it will have five; two from the cardiology group interventionalists and two from hospitals that are not involved in this particular endeavor and then one representative from the state of California which initially anyway will be me. Sometime we have to decide on electing a new advisory oversight committee.
- I haven't got confirmation from my employer that they want to go forward with that. My feeling is they do and I think it's a good idea. But if we are going to go forward we will have to have another meeting. We have to decide on those four people.
- Then we will have meetings for that group of which any and all of you also of course would be invited. But those people would have to mandatorily be there along with Dr. Bommer and myself.

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- I also think that if we're going to do that, we ought to set up a meeting perhaps in February to flesh this out more.

### c. Public Comment

Dr. Karmarkar asked about updated slides with complete content. Dr. Bommer confirmed that the AOC members will receive the updated content and it will be posted to the CDPH website.

- We will provide you with all of those blank spots and I'll probably provide you with updated information including more data on the risk adjustment process the 33 variables, etc. It will be a much fuller analysis than we presented here and the reason for that is we literally just got the NCDR data from the rest of California. That has to go through a much longer process and was not available at the time when we had to send out those slides.

The three-year data was presented at ACC national meeting. We have submitted the data for four years to ACC in San Diego for March of next year.

As we get through the final run through of the statistical analysis of the data, we will write up a total paper that will reflect this as a manuscript and the AOC members will get that as well.

Question: We will get a risk mortality of each hospital?

Dr. Bommer: No. I can tell you that on the risk adjusted for each hospital we can provide you with that data. There were no outliers. We have done risk-adjusted analysis on your hospital. None of the pilot hospitals were outlier. Currently I'm not able to release that individual identity to you because the PCI AOC has so far decided not to release individual ID data for hospitals.

Question: In the past you sent each hospital its own data. Not everybody else's but their own data. I was talking about that.

Dr. Bommer: We'll try to do that as well.

Dani Bennett: I have a question about certification process that will start next year. I was wondering if you have any idea on how long the process will take for a facility or how you determine which facilities you should start working with first since you said there's quite a bit of interest?

Dr. Way: I'm not that far along to know yet. We'll have to wait and see. We'll try to take them in chronological order when they fill out their application and send it. But right now we don't have an application to fill out. Does that make sense?

Bennett: So I guess you'll start with whoever fills out the application first?

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Dr. Way: Yes.

Question: Any idea how long will it take to get certified from the time they fill out the application? Any idea or thoughts about that?

Dr. Way: We're going to rely on our professional entity with medical program knowledge, which would be Dr. Bommer and UC Davis so I'll defer to him.

Dr. Bommer: The anticipated application process is quite extensive and we have probably 20 to 35 pages of application. There are probably 35 appendices that go in that application process to fully comply with the ACCF/AHA/SCAI guidelines. So to fully comply with the guidelines is quite an extensive thing. I anticipate it will take several weeks to review both the digital copy of that. Plus it will require an onsite review at your actual hospital site. Filling out this application is probably take you several weeks to a month for your administrators to put everything together in the correct package. And I would say the review process will take probably a month and then it's going to be can we schedule all of the required onsite audits, which will require both the contractor for the state as well as CDPH people there as well because the hospital has to show compliance with all federal and state regulations for acute care hospitals as well and so it will be quite extensive and I would encourage hospitals that intend to apply for it, at least the pilot hospitals, to try to get their applications fully complete and in at least six months ahead of time to ensure that there's no delay.

Joe Parker: This is Joe Parker from OSHPD, just to let you know that I've been on the line and listening and that as a member of the public that will also be involved in the administration of the new bill, [call is to broken up to record comments]. I wanted to give people here an opportunity to ask me any questions if they have any.

Dr. Way: Any questions for Joe Parker from OSHPD? I guess not. I think it may be time to end the meeting.

[General thanks from the participants.]

Thank you and good night.

Adjourn: 3:54 p.m.