

**Percutaneous Coronary Intervention Advisory Oversight Committee
Meeting
January 19, 2012, Sacramento, California
09:30 a.m. to 2:30 p.m.**

Attendance

Members Anthony Way, MD, Chair; Stephen Arnold, MD; Ralph Brindis, MD; George Fehrenbacher, MD; Steven Forman, MD; Dipti Itchhaporia, MD; Aditya Jain, MD; Sushil Karmarkar, MD; George Smith, MD; Rohit Sundrani, MD, Robert Davidson, M.D.

UC Davis Melanie Aryana, MD; William Bommer, MD; Zhongmin Li, PhD; Geeta Mahendra; Suresh Ram, MBBS; Laurie Vazquez, ANP

Facilitators Teresa Fleege; Patrick Fleege

Agenda Items/Discussion	Action/Follow-up
<p>Call to Order and Introductions: PCI AOC Chair Anthony Way (Chair) convened the meeting with introductions in the room and on the conference line.</p> <p>Approval of Minutes:</p> <ul style="list-style-type: none"> • No Changes <p>Motion to approve June 23, 2011 as written</p> <ul style="list-style-type: none"> ➤ Motion— Karmarkar ➤ Second—Forman ➤ Motion passed as written by unanimous vote <p>Public Comment</p> <ul style="list-style-type: none"> • None 	
<p>Old Business</p> <p>Dr. Forman: One of the important things we discussed was whether the hospitals would be asked to share in the NCDR database, splitting the \$50,000 that it would cost. What has happened since then?</p> <p>Dr. Bommer: Actually, I have a slide on that if we want to go through it during the presentation. If we could defer it to that point, we could do the discussion on the NCDR after our first presentation. It is included in my presentation. That being the minutes approved, we're going to public comment. So, if there are any members of the public here at this meeting or at our remote sites from the public who are not on the AOC who would like to make a comment, the phone is open for you now. No comments, so we will move to the second item of business, which is old business. This relates to inquiry response, which is attached and I'll turn that over to Dr. Way because a letter was sent out for the CDPH that was discussed at the last meeting about a specific case and we have that response. Dr. Way will present it.</p>	

Dr. Way: At the last meeting, as you may recall, there was a discussion about the interpretation of a particular case and so I drafted a letter to the individuals involved and they asked for a response and I ran the response back through our legal consultants in order to redact it so that it would not conflict with the HIPAA regulations. I think key part of it is that the person responding stated that at no time was this case not recorded as a failed PCI. I think there was a discussion about the misidentification of the procedure done. So, the first responder said at no time was this case not recorded as a failed PCI. In the last AOC meeting during the presentation of the case, there was an impression that it was not recorded as a failed PCI which was certainly not true, leading to a somewhat irrelevant discussion of the case. Taking this at the writer's word, I think the matter is ended to the satisfaction of the state of California. Is there any discussion on that?

Dr. Forman: Did we actually verify that it was true? Obviously, the initial impression was that it was written as though it was just a cardio catheterization without an angioplasty.

Dr. Way: I don't have the resources to go and verify. I accept the person who wrote the letter at their word.

Dr. Bommer: We obviously discussed this and in fact I showed this film at the last AOC meeting and the question was that we basically saw a wire across the lesion and therefore qualified as a PCI. Because it was not a successful PCI, it qualified as a failed PCI. We communicated that with the actual hospital and they agreed to change the coding to reflect that at that point in time. We have verified the angiograms. The AOC has seen the angiograms for it and so that's as close verification as we can have to a hospital site inspection or of the data of the medical records as well as a review of the angiograms. The coders of the hospital agree with this in how it has been coded. This letter was a follow up to that and if this is acceptable to the AOC, then that would be fine with us.

Dr. Way: The writer of the letter said, "After recommendations from UC Davis, we have amended the field to PCI without planned CABG." Any further discussion? If not, I'd like to mention that Dr. Fehrenbacher is here.

Dr. Bommer: I believe that closes that issue for old business, but it also opens it for public comment, so if there is anyone here from the public or from our remote sites that would like to comment on that, this is your time to speak. Hearing nothing from the outside sites or here on location, we will end the public comment and move onto the next item of business.

Dr. Bommer – Welcome remarks. Thank you very much. I want to welcome everyone here who is at our site for coming today as well as those who are coming to us through the telephone connection. First of all, as we get started I'd like to congratulate everyone who has taken part in this program because we are now at what I would call our half birthday. I will refer to the number on each page so as to not get lost during discussion.

The next item of business that we have is the presentation that I hope you have access to from the remote sites, which is called PCI CAMPOS oversight committee on January 19th and it is a set of sixty-four slides that we will be going through. As part of the presentation, I will be presenting the first twenty-six slides. Dr. Li, the next twenty slides. Dr. Aryana, the next twenty and I will finish with the final three. Although we are going

to make a relatively straight presentation, I would say that because it's so long, if you have questions that you would like to ask on any slide, please feel free to interrupt and we will take both AOC questions as well as public questions to facilitate it because I think it's only fair. To hold questions for two hours is a difficult situation and I would rather discuss the issues while the slides are up at that time. So, that being the case, we are about to start on presenting it. If you have access to it from the remote sites, we are going to slide one of the slide deck. We are half way through the program; a year and a half in. About eighteen-hundred patients enrolled in the PCI CAMPOS program. Number one, congratulations to everyone who has taken part of that; the hospitals and all of the agencies who have participated. I think it's important to thank all the people who have worked tirelessly on the project. On the first slide, I have listed the individuals at UC Davis who contribute to this sometimes working up to eighteen hours a day to get all of the materials processed and through and reviewed the angiograms, etc. We review a lot of angiograms. For those individuals who are working their daily lives and then on the side contributing to this project, I want to thank all of those individuals. On the next slide, I'm on slide three, are the hospital interventionalists. These individuals don't sleep at night and are ready for any intervention at any hour of the night. We have a great group of interventionalists who are working and on call 24/7 to service the PCIs that are done emergently in the program. Those interventionalists, some of them sitting around the table here, are really dedicated to provide this service, not only to their patients, but to the PCI program. We want to thank each and everyone one of those interventionalists for that commitment. I have also listed the hospital coders on slide four. These coders work in the background and they take all of the notes that we sloppily write or some of the things that we don't enter all the data and they go and collect the necessary data to enter into the database which is essential. 100% accuracy is depending on these coders doing the best job they can to gather that data and put into the website for the PCI CAMPOS program, so we would like to thank all the coders for their tremendous effort.

CONFERENCE CALL SYSTEM GOES DOWN THEN RECONNECTED

Dr. Bommer: Summarizes and reviews previous slides for remote sites.

Dr. Bommer: On slide five, what we have here is the total enrollment per month for the program. What you can see here is that I have listed on slide five is the yellow line. The yellow line is actually our target goal that each month that we would enter a minimum of one-hundred subjects or patients into the program. You can see that we're very close to achieving that goal on most months and we slightly get over it on several months. We have been able to achieve our target goal of a minimum of a hundred per month in the overall program. As we go through here, our volume stays about the same. It's roughly one-hundred PCIs per month in the program. Moving onto slide six. What we can see for slide six is individual hospitals and we picked here initially the higher volume hospitals. Hospital number one, two, and six, you can see the yellow line again lists the minimum number that we would like for each hospital to achieve our target goal, which is 16.6 cases per month. You can see that two of the hospitals are well above it and the third hospital is a little bit above it, so these three hospitals are doing well in their volume for the PCI recruitment over the first seventeen months of the program. The next slide shows the three hospitals that have lower volumes. Again, the yellow line is the target and you can see that occasionally they do hit the target for many months. However, during the seventeen months they are below target at that point; as low as 50% or less of the target goal at that time. We do have some hospitals that have not made what was originally our goal which was to get to two-hundred patients per year, per pilot hospital. Moving onto slide eight, we'll have enrollment and it just looks at the distribution of the enrollment of the first year, or twelve months. You can see that the biggest enrollment in the first year was in the classification of stable angina? After that it was then NSTEMIs, followed by unstable angina and then STEMIs after that. That

distribution continues in the last five months that have been done from August 1st to December 31st of this year. You can see that we've enrolled 1,273 in the first year and we're at about that same pace as we continue in the last five months that we have reviewed. We are continuing at that pace of the minimum for that. Looking at slide nine, which is enrollment for each individual hospital, we can see that if we look at the hospitals, the total PCIs in the first column on the left, followed by primary PCIs in the second column. As you know, primary PCIs in the legislation, it was recommended that we do a minimum of thirty-six per hospital. You can see that five out of six hospitals have achieved the minimum in the first year of thirty-six primary PCIs, which is PCIs for STEMI that come in. One hospital is below the thirty-six at twenty-two, so it did not make it. If we look at the last five months, it looks like we're continuing at about that same rate at each of the hospitals for both primary PCIs and total PCIs. Overall, the group has made its minimum of 1,200, but we have some hospitals that are still below the volume of making two-hundred per year. One hospital is below the target of thirty-six primary PCIs per year for interventions. Slide ten breaks it down per hospital and you can see for hospital one, this is our higher volume operator with 391 procedures for the first year. You can see their population, the highest component is the NSTEMIs which is 106 for that year. They are distributed among the other indications for the other primary PCI that are shown on that slide. Slide eleven, looks at hospital number two. In this hospital, you can see the biggest contribution here is not the elective cases, but the STEMI cases. We have a variation...some hospitals big volume is in STEMIs, others are in elective NSTEMIs or in elective cases. You can see that they are continuing with that rate of STEMI in the first five months here. They made 280 procedures, so they made our minimum target goal for that. Hospital number three, shown on slide twelve, continues with this and we see more of a mixed distribution of the indications for PCI in the first year. With a total of 161 cases that we have done and because they had 69 STEMIs, they easily met our criteria for primary PCIs in the first year and they're close to meeting it already at five months into the second year. The next slide is slide thirteen and its hospital number four. Hospital number four looks at a total number of PCIs in the first year of 97 cases, so this is the lower volume hospital that we have and you can see that all of their counts are lower than in the other hospitals including their STEMI rate which was twenty-two cases at that hospital, but all of the categories are also reduced as well for that. If we look at the current five months of this year that we're operating in, those numbers are about the same as we would predict from that with the twelve STEMI cases so far, almost half way through that year. It's likely we would predict that these numbers are continuing at about the same rate that they were enrolled in during the first year. Both the overall target numbers are down, as well as the primary PCI or STEMI rate is below what was the target on the legislation. Moving now to slide number fourteen which is hospital number five. You can see that they made their STEMI or their primary PCI target at forty-nine cases. Their overall number is a little bit less at 155 from the 200 goal that we were aiming for and they are continuing at about that same rate...half of that for the last five months of this year. Moving now to slide fifteen, which is the last hospital, hospital number six. Hospital six easily made its STEMI requirements of thirty-six with over 114 primary PCIs for STEMI. Their elective volume was much less than the other hospitals and that led to a total number of 189 which was just under our goal of 200 in the first year. They are continuing at almost that identical rate for the last five months of 2011 that we have data for. That is a summary of the enrollment that we had, so we are right on for the group. Our minimum enrollments were down for some of the hospitals and we are down for one of the hospitals for the STEMI target goal that we hoped for which was 36 per year. Moving onto slide sixteen which looks at website update. You can see that we were able to complete the first year. The first year started August 1st 2010, therefore the last day was July 31st 2011. We've gone through all of that in our audit and we have locked down that data with no anticipated changes in that data set for that year. We had promised a logout warning a little earlier and it turned out to be harder for the software to be implemented for that, but it is scheduled to go in between March and April of this

upcoming year, so our deadline is 4/1/2012, when all of the coders will have the logout warning so it doesn't turn off and shutdown while they are entering data at that point. It took us a little longer to implement this than we thought because it requires all new software to handle that. But, we are talking daily with them and they have promised us that the logout will be available no later than April 1st, 2012. I'm hoping that this is not an April fool's suggestion, but we intend to commit to that.

Dr. Fehrenbacher: I was going to raise the question, should we discuss the volume requirements of the bill and the volume at each hospital now, or should we wait until the quality data is presented?

Dr. Bommer: That is up to the decision of the AOC. If the AOC wants to discuss it now, we can do that now.

Dr. Fehrenbacher: It would seem that the volume requirements are linked to quality, therefore the decision might be changed. We might make a different decision based on quality. I would suggest that we wait.

Dr. Bommer: That being that case, we will defer the discussion on volume until the end of the presentation.

Dr. Brindis: I thought I would share some interesting information that I just got yesterday for another issue actually related to competency and PCI volume related to recommendations. In the United States the NCDR hospitals have approximately 13% PCI volume of 100 or less and if you look at a volume of 200 PCIs in the nation...that would be about 32% of the hospitals are doing a volume of PCIs of 200 or less.

Dr. Bommer: I do have some information on our own volume and outcomes later on the presentation. I think we can discuss that and as we all know, and the reason I mention this, is this is what the target goals were for SCAl, which was written into the legislation that we're actually operating under so I just wanted to include those numbers. We will discuss the volume when I get to the volume qualities slide. Back to slide number sixteen, I think I was down to the automatic logout warning being implemented on April 1st. The second issue is that ecardio 2.0 individual hospital reports are available to the individual hospitals right now. If you want to print out your code and report and have them, what you need to do is go into 'my links' and that should allow you to run your own data completeness and initiate your own harvest reports that you can generate on your own. This gives each individual hospital the ability to do this analytical evaluation without coming through the coordinating center. I want to make you aware that each hospital has this capability through their 'my links' on their current website. And that was implemented July 1st, 2011 and we have actually sent in harvest reports and other things through that mechanism by the individual hospitals. The next item is server uptime. I didn't put downtime; I put uptime because I wanted to be optimistic. We are online and available 99.7% of the time. We are not perfect. We do have glitches. One of our servers went down and we ran around trying to patch those programs, but I think for most of the time, our website is open and our server is available for data entry. As you know, NCDR, we started out on what was called version 4.3 of the software. The first year and three months was actually entered under version 4.3. The NCDR then made a decision last year to upgrade to version 4.4 of the software. It sounds like an easy software update that would have no problems, but it created significant problems for us for the following reasons: When you have a data base and you want to add fields, which they did, it's nice to add the fields at the end of the data base. They scrambled the order of the data base when they did that, so it put all of the data fields out of line, which is difficult when you're downloading data and you suddenly have mixed fields and changes with that. So, it has taken us longer than we thought to merge that data together because we have to be absolutely sure that each field from version 4.3 now

matches a new field and a new number and new order in version 4.4. So, we have struggled with that, but the good news is that for the first year reporting it's all under version 4.3 so there's no problem at all and we have been going through and manually adjusting the fields in the data system to get the two to read together. Our suggestion to NCDR is when they make the next change; don't scramble the order of the fields because it is driving some of our individuals crazy trying to realign all of that data. We are currently on and have been since October on cardio version 4.4 of the NCDR system, which adds some additional information to it. Entering data has not been a problem; it's just aligning data at the end of the report time. I would just recommend for all of you that are doing harvest reports, do not mix 4.3 data with 4.4 because you will get a confusing assortment of data. Moving onto slide seventeen and this just repeats the process whereby we analyze the data, PCI is done, and it is entered into a website that is online 99% of the time. 100% of all the cases are actually audited through our central coordinating center. By looking at it, we initiate queries based on data. We go through a set of queries that results in a final audit and final queries and at that point, the data is locked down. 20% of the data is also audited on site at the hospital where we have an onsite auditor. The angiograms are also reviewed by interventionalists onsite on the server as well and angiograms go through every single view of it and we compare it with the cath record and of their medical records at the same time to make sure that they are totally compliant and that the data is accurate. If we have questions, we'll have a consensus committee for that. We'll get back queries to the individuals. I think each hospital here has had us call back and say, "We disagree" or "We want to change one of the angiographic interpretations". We have a very amicable relationship, I hope, with each site where we go back and forth. If we get eight angiographic people or interventionalists in a room to read a set of films, my guess is we'll get at least four interpretations of that as to the specific dimension or percentage of stenosis or other features. It does require a back and forth of queries and consensus until we can agree to agree on the definition that we're going to use or the description of the particular vessels. This is a somewhat time consuming process to go through this. Some of these films have fifty loops associated with them. All of the website data actually goes on a server that we have all of the statistical analysis after we get the data locked down, goes on our SAS system for analysis and all of the angiograms are held on another server, the Xcelera server, and we put all of those together to come out with the data that we have at the end, but it's a very intensive process of auditing and reviewing the data to make sure that it is as accurate as possible. Going to slide eighteen, the initial data audit set checks everything. We evaluate different comparisons, we look at NCDR definitions and we adjust those and talk to the NCDR on an almost constant basis to make sure that we are interpreting it exactly as the NCDR anticipated. There is a thick bible of NCDR definitions that we have not totally memorized, but we go through on a daily basis. Turning to slide nineteen, these are the in-hospital audits, so these are onsite at the remote hospitals and you can see that we have audited over 369 procedures onsite at the individual hospitals at this point in time, which is a 20% audit of the cases that we have so far. It's listed for each of the hospitals as well. Slide twenty shows our angiographic audit and I won't spend time on it, but just to say, we do review actually all the procedures because the angiograms hold a tremendous amount of information about how a study went down and what took place. We can see what was evaluated there and we go through details of the coronary anatomy each of the vessels and we grade each of those and make sure what's entered into the database is accurate at that point. We don't quivel if somebody says it's a 50% lesion and we think it's a 55 or a 45, if it's close we're going to be fine on that. But, if our interventionalists think that there is no way that this is a 50% lesion and it's really an 80 or a 20% lesion, then we will contest that and we will go back to the hospital interventionalist to try to get agreement on that particular situation. Slide twenty-one shows additional audit things that we go through, including data that we look at IVUS or FFR, fractional flow reserve, to make sure we have that data as well. We're asking each site that if you do FFR, make sure we get on an audit that actual data or that interpretation, because as you know an

intermediate lesion 40-70%, the decision whether it is appropriate or not, really revolves around the FFR for an intermediate lesion like that. We also look at lesion complexities. Lesion complexity turns out, when we get into risk adjustment, turns out to be a significant factor in risk adjustment for the outcome of the procedure and lesion complexity, whether it's a High C. lesion or complex lesion, is an interpretation based on the angiogram. We're very careful in looking at that because we want to make sure that each site does a fair and balanced job at assessing lesion complexity because if a hospital were just to say "all of our lesions are High C. complex", then their risk adjustment would be unfairly lowered at that point in time and give them an unfair advantage, so we want to make sure that the hospital's encoders are entering this in as accurate a way as possible. On slide twenty-two, I've got at the bottom, "What is lesion High C. risk?" This is our most common evaluation of lesion complexity that we go through in the audit and you can see to be a 'High C. lesion' "high risk" it requires that it be over 2cm in length, excessive tortuosity, angulation, total occlusion more than three months, inability to protect major side branch, or degenerated vein graphs with friable lesions. It has to meet one of those criteria to be described as a High C. grade complex lesion. If it doesn't, then we will downgrade it to a non-High C. in the data set. Slide number twenty-three shows the other things that we look at in stenosis before and after TIMI flow and any PCI complications that are there and then we reconfirm the ejection fraction that is listed there as well. So, it takes us time to go through each of those evaluations.

Dr. Arnold: Does the presence of thrombosis make it High C.?

Dr. Bommer: Thrombosis is an independent question and you can see that thrombosis does not appear on this slide for High C. Thrombosis by itself is another indicator for higher risk and Dr. Li will show you data that thrombosis does increase the risk if it is present. The composite outcome is higher, meaning higher event rate in patients that have thrombosis detected.

Dr. Fehrenbacher: I think we've discussed this before, but the problem with this classification is that it's an old classification. Ten or fifteen years ago, related to the balloon era and things have changed, unfortunately.

Dr. Bommer: Correct. But, this is the NCDR definition and at the beginning we sat out saying that we would follow NCDR definitions so that everyone was at least on the same track. At the June meeting, we presented the information or the reason for adding compassionate use criteria. As of July 1st, 2011, we have entered into our data set compassionate use criteria. If someone has coma on presentation, ventricular assist device, CPR at the start of the procedure, then they qualify as compassionate use criteria and as of July 1st, 2011, we have included that data in our data set. That is not yet in the NCDR data set at this time. We have asked the NCDR to add that to their data set and hopefully that will be available in the future, but for the present time we are collecting it on our own. Slide twenty-five shows a page from a set of fields from our actual website when you log on and you can see that in a typical website mode, we are asking these questions: "yes or no" "did the patient meet compassionate use criteria?" So, I want to just reaffirm with each of the remote hospitals that if you do get one of those compassionate use criteria met, make sure that's entered into the data field because that has an enormous implication for risk adjustment. As we remember before the Massachusetts compassionate use criteria, identified PCI individuals who had a 70% mortality before hospital discharge, there is nothing else in our dataset that puts it up to a 70% mortality. We want to make sure that if a patient comes in who is high risk, that people won't walk away from that patient just because they're afraid, in fact to enroll them in the system and none of the other risk adjusters really get up to 70% risk.

Dr. Brindis: Remind me that you audit any record that is listed as compassionate use by

design.

Dr. Bommer: We will do that, yes. We will include that. We certainly audit every complication and every death and we can audit every compassionate use if the AOC wants us to do that. I would say that I don't think we need a motion for that. On consensus, we will say that we will audit every compassionate use.

Question: Do you know what the volume is of compassionate use?

Dr. Aryana: We don't have a volume number on it yet because we just started in July entering it, but as far as I have seen, but there is not a lot of data on it.

Dr. Bommer: We have six hospitals here and I would say there is a handful. It's not a big number, it's a handful.

Joe Parker: I was just wondering what led you to include the use of EAD as an inclusion criteria for compassionate use.

Dr. Bommer: Well, you are right, that is a process because any of us could decide to put in a ventricular assist device and that automatically qualifies somebody as high risk. You could game the system by putting in ventricular assist devices in half your patients, but our hope is that clinicians won't do that. It's so involved to put in a ventricular assist device...this is not intra-aortic balloon, this is ventricular assist. It's a big stage...you have to have basically a surgeon there to almost put those in. Now, they can be put in remotely by a non-surgeon, but you're going on cardio pulmonary bypass, so it's a big step. Most hospitals don't have this facility to do it because it's such a big step that they have to go through so many consents to get it. The real reason we did was because we have data from the state of Massachusetts where they looked at the entire state and they included these exact criteria and we had that data set. At least starting out, it gave us a starting point when we used this data. That's the real reason we went with it. We went with existing data sets so we could match up and compare.

Comment: These are basically done on patients who would be dead in minutes without it, so you're dealing with somebody who has the same risk profile as someone who has undergone CPR. Very few places do this. The only hospitals that do this are ones that have cardiac transplant capabilities.

Dr. Bommer: My guess is we will probably have not one patient entered in ventricular assist device at any of the remote hospitals, but I can take a poll of the interventionalists here at the six hospitals.

Dr. Fehrenbacher: We have the IMPELLA device at our hospital and we have trained on it. We have not used it. I agree that it is going to be quite rare and I think that we have it because we do a lot of STEMIs for our county and we want the ability for that STEMI that is moribund, but perhaps could be salvaged.

Dr. Sundrani: We don't have IMPELLA here at Clovis. I don't think that it will be an issue here at Clovis here at all.

Dr. Bommer: Thank you Joe for that comment, but so far at zero and we anticipated it'll be less than five through the entire program. Again, it was the Massachusetts data so I would have some comparison. I am now on slide twenty-six and this just summarizes where we are at this point in January of 2012. As of December 31st, we have received 1,820 for our PCIs in our six centers, so we're right at the halfway mark for that. We have complete data that is all of the complete data 1,774 patients. As you know, we still have angiograms to come in and other things to check, so it's not totally complete, so we're trying to get all of that complete data. For the first year of operation of PCI

CAMPOS, August 1, 2010 to July 31, 2011 there were a total of 1,273 patients or PCI procedures enrolled. This is actually the number of PCIs. If a patient had two PCIs on different dates, it would qualify as two, not one. So, this is not patient number, but PCI number. In the last five months, up until December 31st, there were an additional 501 patients enrolled in PCIs in our PCI CAMPOS program which is looking at a hundred a month which is right on this rate here. So, we're continuing right with that volume. Looking at year two, which will predicted be about 1,200 cases per year in year two as well. The in hospital mortality, that is before discharging those individuals, was a total of the 1,273 patients was 39 died and for the first year it was 28 deaths. 28 deaths in the first year being a 2.2% mortality overall. In the last five months, another 11 patients died and for that period of time, it again comes out to be 2.2%. So, our hospital mortality for the eighteen months, which is shown here at 39 deaths, is 2.2%. For each of the breakdown, the first year and the last five months, it also comes to 2.2%. In hospital mortality for PCIs all comers, that is STEMIs, primary PCIs, and electives combined, is 2.2%. The hospital observed range for mortality is shown here in the first year. The mortality was as low as zero at one of our hospitals and as high as 4.76%. In the last five months, the lowest hospital mortality was zero and the highest was 4.12%. This is the mortality that we have seen for the overall program at 2.2% observed mortality without risk adjustment at that time. At this point, I would like to turn it over to Dr. Li who is going to present additional statistical information on the program and I just want to tell you as we go through the slides, I have color coded these a little bit to keep it simple. If the code is in blue, that is a PCI CAMPOS patient that is enrolled in blue text. If the background is blue, that is a data analysis done through the PCI data set. If the code supposed to be orange or golden, that is the rest of California, so think of California gold for the rest of California. The light blue here again is the PCI CAMPOS information that is there. If the background is green, it means we are using data from the patient discharge information that is generated through OSHPD? I want to thank OSHPD for coming today and providing that. The OSHPD data allows us to look at the rest of California. Initially we were hoping to get the NCDR data and directly compare our NCDR data set with NCDR data from the other ninety hospitals in California that collect NCDR data. We'll talk about that at the end, the process of getting that, which is still ongoing. For the current period of time, our best comparison for PCI CAMPOS data for our six hospitals is going to be through a collection facilitated by OSHPD through the patient discharge data set and that is going to be coded background green. Dr. Li will now present our information on volume and we will talk about risk adjustment models that he will go through.

Dr. Li: Slide twenty-seven. This slide presents the PCI composite total PCI volume for the first full year. We have a maximum of one hospital at 391 cases and we have a lower hospital with 100 cases. For the first full year, we have 212 cases a year. Next slide, slide twenty-eight, this one is eleven months, not a full year, but from the PDD, non-pilot hospital...151. The maximum one hospital did is over 1,500 cases, but we also have the one hospital with only one case. With the one case, the variations are very huge. I didn't put a statistic test over there for volume, but I can tell you the volume was compared to the eleven months of non-pilot hospital from PDD compared to our composite data is no significant difference in terms of volume. One slide twenty-nine, that is a comparison. Background is green because the data source are from PDD. The first row is 151. The non-pilot hospital for eleven months, they have a STEMI: NSTEMI ratio of 1.2 to 4. Another case indicator is a non-stable angina to stable angina ratio. From eleven months of non-pilot hospital, we have a 3.76 and on the PDD we also have a 2.53 for pilot hospital. So, the P value also shows a non-significant difference between these two. Compared to composite data, we also did a ratio where some case mixed, very similar, the test also shows not to be significant to PDD, non-pilot hospital. Next slide talks about the observed mortality between non-pilot hospitals to the pilot hospital. For STEMI mortality for non-pilot hospital for first eleven months, we have a 5.32 with 95 confidence interval between 4.5-6.1 On the same data source for PDD

pilot hospital six who have a 3.15 for STEMI mortality rate and 95 confidence between 0-7.2, but the statistical testing shows no significant difference because the variation weighed in on each group. Also, we tested the non-pilot hospital from PDD to PCI composite, so the STEMI mortality rate for composite data 3.67, but also testing shows no significance compared to non-pilot hospitals. The mortality rate from PDD, non-pilot hospital, eleven months, is a little less than 2%, 1.98%. From pilot hospital, from PDD source, we had a 1.76. From the composite data, we had a 1.68, so that's very similar. We also compared this to the non-pilot hospital in PDD. There's no significant difference. Overall, PCI mortality for non-pilot hospital PDD, it's 2.83%. From pilot hospital, 2.29% from PDD data source and 2.26% from the composite data, so very similar. We can see that there is no significant difference when we compare to non-pilot hospitals. Next one is we go into the STEMI excluded. We further take a look at either non STEMIs or others...No MI. No MI means unstable angina, stable angina, and so on. I find something interesting. First of all, for using the PDD data source, we have very similar, we have no differences whatsoever compared to non-pilot hospital. For example, non STEMI, 1.8% death from non-pilot hospital. Then, we have PDD six pilot hospital 1.64, so the P value is .87, no significance. We take a look, the composite data, we have 3.74%. It's on the margin if we use this one compared to the non STEMI in the PDD data source. There is close to .05. However, then, we take a look at others... No MI. Actually from composite data, we have zero deaths. We have five hundred cases there and zero died. I think some deaths probably move to here.

Dr. Bommer: If I could just interrupt for just ten seconds here, what you'll see is and what should be explained to you is that the data acquisition in the patient discharge data set and PCI CAMPOS are different. What I've got at the bottom of the slide that I've put in is the difference for that if you can look at it. PCI CAMPOS, the definition here we pick, or have to do from the NCDR data set of CAD presentation. That's an actual field...field 5,000. The CAD presentation where the coder checks off what their presentation is. The PDD data, however, is generated from a different data set where they're looking at ICD 9 codes. The ICD 9 codes for those are shown on the bottom there that they're using that data. It is a understanding that a hospital coder who is doing the discharge summary, codes different ICD 9 codes than the other coder who is working on a different data set, entering data into the NCDR fields system. The difference is, they're different coders and they're different systems, so we can expect some variation based on just how they're going to code. They're not going to code identical. As Dr. Li pointed out, you can see we actually shifted patients from one of these events here probably, or two wound up over here that lowered the event rate for the no MI classification, but it raised it for this overall. It's probably best if we're going to compare apples to apples and if we're comparing apples to apples, then stay within the green comparison here because this is by the same ICD 9 code collection and the same coders. This is a different set of coders and a different data system. We show it so that you see the full information here, but it's probably best not to carefully or to compare these exactly because there's going to be differences based on the coding and the coders that are using different systems.

Dr. Li: Another reason I put this chart here, I'm trying to convince the AOC board that if we can, we better to get NCDR data, so we do apple to apple comparison here. If you simply just use our clinical registry data to compare non clinical registry data, there is no apple to apple comparison.

Question: Is it really fair to even calculate a P value for the CAMPOS dated to the PDD pilot, non-pilot data? Why are you even calculating the number if it is two separate data sets, it would seem me that the numbers should not even be calculated.

Dr. Li: They appear because the program calculates it automatically, but I should take it out. Good point. Now, let's move to the risk adjustment and we are going to focus on

the first full year. If you remember the last AOC meeting, Dr. Fehrenbacher made a very important point: The risk adjustment should not just be for mortality, but also we should include emergent CABG. Using all along approach, we enclosed hospital death, that's 28, and also another case for transfers for emergent CABG as the outcome measure. If the patient dies in the hospital or is transferred for emergent CABG, we will take a look, this is a composite event. We'll calculate hospital of observed event rate so we found a 2.83%. The risk factor we're going to use included three categories: Demographic (age, sex, and so on), and also we have included prior PCI and clinical conditions. Also, we have a lesion risk as the risk factor. The model is a multi-variable logistic regression model because the dependent variable here is a binary. Yes or no. Event or non-event. I'm on slide number thirty-three. This shows risk factor prevalence from the data and the composite event. The first row shows the age group. We have 2/3 of the patient less than or equal to seventy years old and 1/3 or more is seventy years old. For those less than seventy years old or less or equal, had less than 2% event rate compared to patient over seventy years old, 3.9%. The bi-variable varied test shows a significant difference. I don't want to read all of this information, but you can see from the P value, gender, race, body mass index, is not a significant risk factor. Next slide...all these four risk factors are significant risk factors. They are PCI status compared to emergent salvage to elective urgent. We have a very significant situation for emergent salvage, we had 5.7% of event rate for the elective and urgent, we have less than 1%. STEMI is significant. GFR is also significant. Cardiogenic shock, very significant. Even though we have 3.4% of patients had a cardiogenic shock, but their event rate is one fourth.

Dr. Bommer: All of these composite events will be death and or emergency coronary artery bypass. Emergency bypass.

Dr. Li: Here is the catch. Only count once. We are so far away that we don't have any patient that transferred for emergent CABG and death, but if we have that case, only count once. We don't count double. I'm on slide thirty-five. NYHA Class four is a significant risk factor as well as heart failure. Diabetes, this one variable changed if you remember the last presentation when we have less than a thousand cases, but here it's not.

Dr. Bommer: Just to clarify, on the listing, we have two sets of question. One is, What is New York Heart Association Class? There's a separate question on the NCDR data set saying, Was there a history of prior heart failure within two weeks before admission? You click yes or no. He's just looking at both sets of those questions.

Dr. Li: We also take a look at the prior PCI and this variable looked like not significant risk factor because you can see this composite event rate is almost the same.

REMOTE SITES HAVING DIFFICULTY CONNECTING, RECONNECTED

Dr. Li: I'm on slide number thirty-four. There was a question raised by when people see the significant risk factor regarding the GFR. How we got the GFR, the formula is called the GFR MDRD. You can find this formula from the internet, go to the Google and you can find the following risk factor in the formula. They are including the creatinine level, pre procedure and involve the sex, race, as well as age. I move onto next slide thirty-five. We talk about the NYHA as a significant risk factor as well as the heart failure in terms of a history. There was a question raised on the meeting on regarding what is the difference. One if the New York Heart Association. You're rating by the class 1, 2, 3, and 4. Another is talking about the heart failure in the history prior procedure. This two risk factor from the bi-varied analysis shows both significant risk factors. Diabetes as well as prior PCI, not a significant risk factor. I'm on the slide thirty-six. PAD peripheral artery disease, this too didn't show a significant risk factors, but the chronic lung disease

as well as intra-aortic balloon pump are significant risk factors. The last row, IABP, we have 4% of patients in this category, but we had a 26.76% of composite event rate, which is very significant. The slide number thirty-seven, the first one we classified as over 75% stenosis, but 2.6% of patients had more than 75% of stenosis in the left main but they had 6.5%. Probably the case number is so low that this risk factor does not show as an individual significant risk factor. We have more than 5%, less than 40% ejection fraction, but have 8% of composite event rate. Compared to 2.3% for ejection, more than 40%, that's a significant individual risk factor. We also take a look at the lesions. Lesion complexity, High C. lesion, has about 1/3 the patient with 4.6% of a composite event rate, which is significant compared to non-High C. lesion which is 1.6% composite event rate. Thrombosis had a slight less than 1/3 of patient with a 4.7% event rate compared to patient without thrombosis, 1.7%. The last risk factor we look at is pre procedural TIMI flow. TIMI flow zero, we have less than 30% patient, but close to 6% of composite event rate, which is significant compared to others 1, 2, and 3. The prevalence and the composite rate by using a bi-varied analysis give us clue for develop the multi-varied risk model. We use that information and we develop this model and we actually had several model develop. The first one we use as Parsimonious Model, which only shows significant risk factor when we enter all the individual risk factors. Then we also only develop model that only include those significant risk factors when we do the bi-varied analysis. Finally, we combine the information, we developed the model, we include all the risk factors that clinical make sense, but also have some important risk factor even though they are not statistically significant. On slide thirty-eight, I call this a full model. This full model has eleven risk factors. If you see the individual significant risk factor we just present, you can see there is thirteen significant risk factors, but I reduced to eleven because the thrombosis in this multi-varied risk model showed as a contra intuitive so there must be a multi-colinarity, so I took that risk factor out. Another one is STEMI. Maybe some other risk factor already showed a significant. Those two significant risk factors got kicked out, so now we have eleven risk factors in the full risk model and four show the predictor significant. Three of these four had a ratio of less than two. Emergent salvage PCI status, CLD (chronic lung disease), and IABP. Only the age is a significant risk factor by the less than two. That's the final model I present here. On slide thirty-nine, as I mentioned before, we had a parsimonious model which only contains the four significant risk factors and that one we had a .85 statistics, that measure how good in terms of discrimination or predictivity. I look at other states like in New York, their full model is actually .85. So, very aligned with other published clinical registries. Hospitals test data calibration and we compare predicated composite event with observed composite event, how close they are. If they are very close or the same, the P value will be larger than .05 and that means that we don't have any data collaboration problem here. For the full model, we include some risk factor beyond these four significant risk factors. We improved statistics, that's the discrimination power, but also we showed no significant difference from the P value on the hospital test. The predicted composite event is the same as the observed composite event. Using that model, we run the risk adjust results by hospital. On the slide forty, we show the detailed information by each hospital. We have a total on the first hospital on the total for composite for the first full year, 1,273 cases, 36 composite event, 28 deaths, and 8 emergent CABG. Overall, we have 2.83%. This will serve as a ruler, so everybody will compare to here. For the first hospital, we did 391 cases, 7 event, we have observed the event rate 1.79. We used that model, so calculate the hospital expected event rate is 1.9. Risk adjusted event rate is 2.66. But, this is a point estimate so we need to consider the bi-chance so we calculate using 95% confidence interval for this risk adjusted event rate and it turns out to be 1.07-5.49. This range covers the overall 2.83%. This hospital compared to the ruler, no significant difference.

Dr. Brindis: I just want to make sure that the slides reflect an accurate definition of what an event is.

Dr. Li: It's the mortality as well as a transfer for emergent CABG.

Dr. Brindis: Might I suggest that at the bottom of the slide it defines what an event is.

Dr. Bommer: We had it on the initial ones and I agree that we'll put it on every slide so that composite is defined on every slide, but composite for this entire presentation is mortality plus emergency coronary artery bypass graph surgery.

Dr. Li: Slide forty-one. This slide shows risk adjusted results, composite event, by a hospital, but this only takes a look at STEMI excluded PCIs. For six hospitals, we have 838 cases, 14 composite events, which turns out to 1.67%. Here, I elect to point out that number three, this hospital had 91 cases, 4 events, which turns out to be 4.4%. The expected rate, using the model, is less than 1%, so that turns out to be, using all year ratio, turns out to be 8.6% risk adjusted event rate, but calculated 95% confidence which turns out to be 2.34 – 22%. Compared to 1.67 overall rate, this hospital turns out to be a worse. The other hospital didn't show a significant difference. We have this event that we checked its death and one is for emergent CABG. There is a situation I would like Dr. Bommer to talk about because once we have this result, we actually contacted this hospital.

Dr. Bommer: We actually went back and reviewed those four cases that were there and remember this category is STEMI excluded. It turns out that one of the four cases, there was three deaths and one transfer for emergency bypass, one of the cases NSTEMI excluded, it turns out the patient was admitted with a STEMI, had a PCI, then went back and stayed in the hospital, and then four days later had a second PCI. One could argue that while maybe they came in as STEMI, they should be counted as STEMI. The reason we counted it as not a STEMI on the second PCI is because we again reverted to the NCDR definition of it. I've got on slide forty-two, the description and definition by NCDR. In yellow you can see if this is a repeat visit to the cath lab during the same episode of care, code the CAD presentation based on the patient's clinical status prior to the subsequent procedure. We interpreted that to be immediately prior to the subsequent procedure. Therefore, since the patient was stable and not having chest pain, the patient did not qualify as a STEMI going into the second PCI and therefore it counted as a STEMI excluded in that definition. We checked with NCDR and that's the definition they use. In other words, if you have a patient come in with a STEMI, you can only use STEMI as the presentation for the first procedure you do. If you put them in the hospital and they are now stable, you have to count them as stable for the second procedure.

Dr. Smith: I would just point out the treachery of very little numbers in assuming something. If you look back at prior slides, there were no differences in this particular hospital, a low volume hospital, and the others only had six STEMIs that were listed. So, those six STEMIs, when counted in, made no difference. This looks like a huge difference, but there's such a number of cases in this that I think we have to be quite careful about saying, 'Well they had a much worse mortality'. All you do is you re-add six cases of STEMIs and it's no significant difference.

Dr. Bommer: This is the statistical analysis that was done that said that this was an outlier and as Dr. Li explained, the actual overall 1.6% lies outside the confidence limits for this so statistically, it kicks it out and we have to report it to the committee as this is what the statistics show.

Dr. Fehrenbacher: Sometimes, when you exclude STEMIs, you think you're getting lower risk cases and most of the time you are getting lower risk cases, but sometimes you can have very high risk cases that are circumflex occlusions, or left main occlusions, that actually do not have ST elevation and ST depression. As Dr. Smith

pointed out, when you have low numbers, and you think you're excluding high risk cases, but you actually could be including more high risk cases by having a circumflex or left main stenosis, you could be misled. I would suggest to discuss that if we're going to be concerned about a worse performance rating, statistically we should look at those cases and see if those truly were low risk cases.

Dr. Li: Continuing on, I'm on slide forty-three. This slide presents the risk adjusted total CABG composite event by an operator. At a similar table that we showed by hospital, but this is a long list. Instead of listing one by one, I have a summary table presented on this slide. We have forty-three operators on the PCI, but on average we see that 3.23% so minimum is 0 and maximum 20%. The standard deviation is huge. 95% confidence, no operators were found, all were risk adjusted composite event.

Brindis: Does this mean that the average volume of the operator is 29.6 patients? So, there are some operators that only did one patient in this entire study and there is another one operator that did 250 patients? I'm surprised at the low numbers here.

Dr. Li: This operator is defined by operator ID I didn't check the name. Next one on the slide forty-four, again we take a look, the STEMI excluded, here also there are 35 operators operating on the STEMI exclude the PCIs. The maximum was 167 cases. The observed event rate was 2.4, a huge standard deviation. Then, the expected 1.9 on average. Some operator had a very significant sick patient there.

Dr. Sundrani: We have almost nine operators and of those nine operators, eight of them probably have done 25% of the cases. Are your numbers diluted because you have divided the cases and number of operators?

Dr. Li: Here, I include all operators. They will show up in the database.

Dr. Bommer: I think that what we're showing is the average or the mean volume per operator and I should also point out that we are only tracking the PCIs done by the operator at a PCI CAMPOS hospital. Some of these operators are doing angioplasties and PCIs at four or five different hospitals. We are only able to tag or calculate this based on their volume within the PCI program. The only reason we're showing this is we just wanted to do as we got more data. We first presented hospital data, but now we have enough numbers that we could look a little bit into operator volume and operator outcomes for composite and I thought we should include this just to be monitoring it as best we can. As you can see, all of these operators, no matter what their volume, none of them lie outside the risk adjusted composite rate so all operators on this analysis at small numbers as it is still there are no outliers for this individual group which is STEMI excluded. These are the more elective cases.

Dr. Li: I'm on slide forty-five. This slide looks at the relationship between total PCI volume and a composite event. On the last slide, I looked at correlation for hospital, and then on the right hand side is by the operator. Operator, we have forty-three operators and the hospital is six hospitals. I run the correlation between observed, expected, risk adjusted, and correlates with the PCI volume. None of them showed up as a significant correlation. Even though the relationship is most of the time negative, so the higher the volume, the better the result.

Dr. Bommer: I asked Dr. Li to run this because now we have a little bit more information and I thought it was important to present to the AOC whether volume is a factor on our outcome data. This is really looking at is there an effect or correlation between the volume that either the hospital does or the operator within our system that influences their outcome. This would identify if low volume operators would have a higher mortality or a poorer outcome in the composite or whether low volume hospitals might have that

or not. If we look at that because that certainly there is some data as we look at volumes and this is one of the issues that we face in trying to encourage more volume. Is volume affecting the composite outcome that is mortality and emergency CABG? As you can see from this, look at the data...there is no relationship to the number of PCIs in individuals and their outcome and there's no relationship between the volume the hospital does and their outcomes. So, volume in the hospital is not appearing to affect the composite outcome or the mortality when we looked at that as well. It's not based on volume.

Dr. Li: Next slide is similar relationship between the STEMI excluded PCI volume and a composite event. Similar story, so we don't find any significant relationship for correlation between the volume and composite event. Now, we go to the slide forty-seven, I just want to get a little summarize the information we just presented. PCI composites vs. a PDD non-pilot hospital in terms of volume as well observed mortality, there's no significant difference so far. We have a consistent observation here. The PCI volume risk adjusted composite event, the first one we say no significant for hospitals overall for PCI composite event, but we found one was outlier hospital for STEMI excluded PCI composite event. Maybe we should have a note here. The STEMI excluded PCI does not mean they are all easy patient. I don't know what we should call it. The no outlier operator found for overall for STEMI excluded PCI composite event. Last point is no significant relationship between hospital or operator PCI volume and composite event.

Dr. Bommer: At this point I want to thank Dr. Li for that presentation. We're at a point where we're going to take our break and then Dr. Aryana will be presenting her slides. We have about fifteen to eighteen slides to go on the presentation so we could take a fifteen minute lunch so that we are able to finish on time.

Dr. Aryana: I will start with an overview over the patients that have been transferred for CABG surgery. All together there were 19 patients that were transferred for CABG surgery. Every time that a patient is transferred for CABG surgery, the coders have to fill out a second form that we created and they actually fill that out for every transfer. We are on slide forty-eight. The only time this form is not filled out is when a patient needs elective CABG surgery and will have the CABG surgery at a later point in time. Every time when the patient goes from the pilot hospital directly to the CABG facility, the second form is filled out. Here, we see the emergent cases that were transferred for surgery. All together we have eight cases and one of these cases, the patient actually died and was transferred to the CABG facility, but never made it to the OR and expired before he had surgery. All together we have eight urgent cases that were transferred for surgery and three elective cases that went directly from the pilot hospital to the CABG facility to have surgery. Let me now start with the quality matrix. We looked at lipid lowering agents and I have to point out here that the numbers for the pilot hospital, the 99.7% is actually a mean and this is the range. The NCDR data, this is actually a median and this is the 75th to 25th percentile. All together, the pilot hospitals, 99.7% of the patients were discharged on aspirin and had no contra indications. We excluded all the patients who died from all these numbers. I locked all the patients down who had PCI before August 1st, 2011. Every time when a patient was discharged without aspirin, I called the coder and I asked what was going on and for most of these patients, the reason is in the discharge summary, the patient is not discharged on aspirin, but it says on the discharge summary that the patient will follow up with their doctor in the next two days and will get their final medication. This is, for the most part, the reason why we have here .3% who were not discharged on aspirin. Technically, if the patient was not discharged on that medication, we cannot record it. So, 99.7% of the patients were discharged on aspirin. 99.6% of the patients were discharged on thienopyridines, and 97% of patients were discharged on lipid lowering agents. Here, we looked first at all elective patients, meaning patients who did not have an acute coronary syndrome and

all together had 242 patients who did not have an acute coronary syndrome and I am on slide fifty right now. 242 patients who did have an acute coronary syndrome and 166 of these patients had either a stress test and imaging study or FFR done before the procedure. The hospital number one was the hospital with the most exercise stress tests and I have to say here, this is the number of positive exercise stress tests. This is the number with an indeterminant result and this is the total number. In this case, five patients actually had a negative result. We looked at standard exercise stress test. Only three hospitals did stress tests to begin with and overall 44 exercise stress tests were done. When we look at the stress echoes, the numbers here are not very large. We only had 14 stress echoes done. The first hospital didn't do stress echoes at all. The major test that was preferred by all hospitals was the SPECT. Overall, we had 110 SPECTs done. C-arm was only done by one hospital with one case and a positive result here. We also looked at FFR and I have listed here on the front the number of cases that had an FFR with less than .75. Ten cases here had a result of less than .75 in the number of 16 total cases for hospital number one. Hospital number two had one positive FFR done and hospital number three had three FFRs, one was below .75. Hospital number four did the FFR twice, but both results were negative. This is in patients who did not have acute coronary syndrome. Then we looked at the number of positive stress tests per elective PCI patients. If we look at all our hospitals, 140 positive stress tests out of the 242 patients and this puts us at 58%, which means that we are within the 25th-75th percentile of the newest number from the NCDR report from 2011 in the second quarter. The next quality matrix is the median PCI for STEMI patients. I also talked to the coders about the fact that it's very important that the information on time that they enter really is consistent with what actually happened. It's very important that if the ST elevation was not found on the first ECG, but on a subsequent ECG, that this is entered because otherwise it will result in a very high door-to-balloon time. When we ran the reports, every time we saw very long door-to-balloon time, we double checked with the coder to make sure that everything was done correctly. The median time to PCI for STEMI was overall 65 minutes, which is close to what the NCDR shows and we are actually here within the limits within the NCDR. We also looked at the proportion of STEMI patients receiving immediate PCI within 90 minutes and we have listed here the percentage. All our hospitals are above 80%. Most are above 90% and the percentiles here are 83.5-95.1. Again, we are close to what the NCDR reflects. We also looked at patients with vascular access site injury requiring treatment or major bleeding. We do a little bit worse than the NCDR here. The NCDR has a median of 1.1. We are looking here at .28. Emergency CABG, again the NCDR percentile is 0-.4. We are here at .63, so we are a little bit above the NCDR numbers. Here for acute kidney injury, the NCDR only reports results for acute kidney injury if the hospital has reported pre and post procedure creatinine for more than 90% of the PCIs. Actually, now if you look at the last row, not all of our hospitals have reported for more than 90% of their cases, pre and post procedure PCI. They have not reported the creatinine for more than 90%, so this is why I have put a couple of the numbers in parenthesis. Acute kidney injury was actually defined as the creatinine that is at post procedure, 50% higher than the pre-procedure creatinine. Here, the percentiles are 1.4 to 3 and we are actually lying in that limit, even though, like I said, not all hospitals reported the creatinine for more than 90% of their cases post procedure stroke.

Dr. Fehrenbacher: The kidney injury issue is not risk adjusted, is that correct? So, if you had a high volume, shock patients, acute MI patients, who did not get fluids beforehand, you would have a higher number as all these six hospitals.

Dr. Aryana: We did everything the way the NCDR does it in their institutional outcomes report that they sent their members. So, the post procedure stroke rate, we had two hospitals that didn't report any strokes and all the other four hospitals reported at least one stroke. We are a little bit higher than the NCDR percentiles on stroke. We also

looked at a composite of death, emergency CABG, and stroke. I have to say, the NCDR looks at a composite of death, emergency CABG, stroke, and repeated target vessel vascularization. We have no possibility to look at repeated target vessel vascularization; we cannot run that report. This is why this is missing here in the numbers that we looked at in the pilot hospitals. Overall, 3.2% of the patients fall in this category and we are slightly above the numbers of the NCDR here, but we are almost within the percentiles there. The median post procedure length of stay for PCI patients with STEMIs was three or two days on average it was two days and we are in line there with NCDR. I also listed the medium post procedure length of stay for PCI with no STEMIs and I included this because we had included it last time, but in the newest outcome report from the NCDR from 2011, they actually stopped listing this one. We're pretty consistent here with one or two days and these are the numbers from the report from the NCDR from 2010.

Dr. Bommer: The question is, do you need to keep them overnight? I'm not aware that it's a legal requirement of 891. We'll check that and run it by the CDPH to see how they interpret that, but we have not interpreted it as the patient has to stay overnight. PCI gets done and the patient I think could go home that day or the next day, depending on how we're doing it. Certainly for radial procedures, there are a lot of places that are discharging them from PCI on the same day.

Dr. Fehrenbacher: I don't remember the wording in the SB 891 that mandates overnight in the hospital.

Dr. Bommer: We have it right here and afterwards we'll sit down and go through it.

Dr. Aryana: That was the length of stay. Then the creatinine is pre or post procedure and the numbers here are a little bit higher, overall 89.2% show that the creatinine was assessed at some point in time. We also looked at transfusion of blood and there we are at 3.8% which our numbers are a little bit higher than what the NCDR shows, so we are giving a little bit more transfusions and red blood cells. Nothing is risk adjusted here. I go to slide fifty-three now. We looked again at IVUS and FFR in patients who had a stenosis between 40-70% and because we can only enter the FFR or the IVUS into the database for patients who had lesions between 40-70%. If you have a higher lesion than 70%, the field is actually greyed out and FFR and IVUS cannot be entered, even though it was done. In these cases, before when we looked at FFR, these were cases that excluded acute coronary syndrome. These cases here are all the cases that were coded as PCI status elective by the coders. I didn't enter any NCDR data here because the NCDR doesn't look at that. Three of the hospitals did IVUS. Hospital number one had 13 of 112 patients receive IVUS, number two 1 of 9, hospital number three did not do IVUS at all, hospital number four, 5 of 23 cases had IVUS. Hospital number five and six didn't do an IVUS at all. Again, if we now look at the FFR, it's a similar picture. 15 of 112 patients had an FFR. This is always IVUS and/or FFR. In the second hospital 1 of 9, in the third hospital, 2 of 9, in the fourth hospital, 2 of 23 patients, and hospital number five and six did not assess a fractional flow reserve. Then, we look at bio markers assessed post procedures for elective inpatients. This includes all patients who are not coded as elective and excludes all patients who are coded as outpatients. I have to say, bio markers here includes any kind of troponin I or T and it includes CKMB. Overall, 51.4% of the elective inpatient patients had a post procedure cardiac biomarker done and we are here within the 25-75 percentile of the NCDR. We are actually higher than the median of the NCDR. Post procedure MI is only recorded by the NCDR for hospitals that report cardiac biomarkers in more than 90% of their post PCI patients. Overall, we had 4.4% of patients who had a post procedure MI and again, like I said before, we have to take into account here those hospitals that do not report post procedure MIs, will automatically show up with a lower number here.

Dr. Bommer: Current definition is a threefold increase before to after and that's NCDR and because we're hopefully going to get NCDR data to compare it with, we have to use the same definitions. We have not included PCI in our composite outcome. It is really a matter of where you're going to draw the line. We have not included that in our outcomes.

Dr. Aryana: We are going forward to slide fifty-four now. Here, we actually looked at PCI success. PCI success is defined as a post procedure stenosis of less than 20% and a post procedure TIMI flow of 3. All together again, in the first year we had 1,273 patients. All six pilot hospitals treated at least 1,273 patients. The pilot hospitals treated 1,713 lesions and in 1,685 of these 1,713 lesions, the guide wire was across the lesion. In 91.5%, the post procedure stenosis was less than 20%. In 8.5% of the cases, the post procedure stenosis was either 20% or greater than 20%. The post procedure TIMI flow was 3 in 93.6% of all the patients. I also looked at all the procedures that had at the end, less than 20% stenosis and TIMI 3 flow and 87.4% of the PCI achieved this. I'm going to slide fifty-five now where we displayed the transfer costs. From hospital number one, the transfer costs were pending last time when we had the meeting so I would like to show this here now. Two transfers, each transfer was 1,106 all together. There are still some transfer costs pending from the last half of 2011, but hospital number two had an average cost per transfer of 1,756 dollars. Hospital number three had 819 to pay per transfer to a CABG hospital. Hospital number four paid 255 dollars for each transfer for an urgent CABG and hospital number five average out at 744 dollars per patient to transfer for urgent CABG. The last hospital, hospital number six, paid 932 dollars per transfer for emergent CABG.

Dr. Bommer: I'm going to bring you now to slide number sixty-one in your slide set. We're shooting for a possible early dismissal if things go well. What I have on slide sixty-one here is a brief summary of some of the things that we have presented here. Number one, the total enrollment in the first year was 1,273 cases which were at our minimum that we were hoping to accrue during the first year, so we met our minimum target goal for total enrollment of the six hospitals. The individual hospital enrollment was 97 to 391 per year and as we've said, we've been working over the last year to try to increase the low volume and we've met with those hospitals and their staff to try to bump that up higher. Total volume as we analyze does not appear to be a variable in the outcomes. The number is not affecting the outcomes, but it is clearly affecting the robustness of which we do our statistical analysis. We have small numbers that can teeter and it's very difficult to separate out noise from true signals when you have low volumes so we're still trying to push enrollment of the lower hospitals up to at least the 200 a year number to increase the robustness of the statistical analysis that we will do and make the whole PCI CAMPOS report to the legislature more meaningful at that time. The next issue is success rate. I think we have a good success rate. Post stenosis less than 20% which means the vessel is almost entirely open at 91%. TIMI flow is a very adequate or normal or near normal in 93% of cases and that is a good reflow following the PCI, so we're seeing good flow in that open vessel. The mortality rate that I'm listing here, 2.29% in the pilot group and then 2.83 in California is from the PDD data, so it's apples to apples. I wanted to make sure that we weren't shifting from one data set to another. You can see that in the pilot hospitals, we actually have a slightly lower mortality than in the rest of California as monitored by the PDD data. I think that our overall mortality compared to California is good in the PCI CAMPOS program at one year. In our risk factor models that we've gone through, you can see that we've picked out individual or bivariate risk factors of age, shock, PCI status, GFR, New York Heart Association, heart failure, lung disease, balloon pump, TIMI flow, ejection fraction, and a type of lesion, whether it's a high risk lesion or not. These are very similar risk factors that have been used in New York and other states that have gone through it, so there really is no difference in the risk factors for PCI outcome in California versus nationally versus the other states, so we're seeing exactly the same risk factors. In multivariate analysis and stepwise progression, we came across four risk

factors and those were included into the risk adjusted model that Dr. Li has developed. Our risk model is very similar to other states, nothing unexpected that we've come up with in California, as opposed to nationally and reported in other states. The next issue is composite and we change from our death, which was recorded at the first meeting to now composite that included emergency CABG. Those are two different items. One is determined by the operator, the other is determined by the patient. As I said, those are sort of the two worst outcomes for an individual who is at a remote hospital. If in fact the procedure goes bad and they have to be transferred out to another hospital, then perhaps they would've been better off at the other hospital to start with onsite surgery. Of course, if they never leave the hospital alive, that's a bad outcome as well. As we get more data, we can include other things in composites or look at other sub groups as well, but Dr. Li is right; with the data that we have right now, we're able to do this single analysis based on the data that we have. The composite endpoint of death and emergency CABG was seen in 2.83 percent of individuals or of patients in the trial or procedures in the trial. That means that 97.2% of individuals come through their PCI without one of these bad outcomes at that time. We found that there was no variation in hospital or operator outliers in this composite. If we look at the composite of STEMI excluded and this may be the high risk stable patients, or it may be the patients who are lower risk or active as well combined...at any rate, none of them came in for a primary PCI. In that situation, you can see that it's a lower risk group because the mortality and bypass is less in that group. So, it drops from 2.8% to 1.67%. In that analysis, Dr. Li was able to identify one hospital outlier at that point where it lay beyond the expected distribution that we had for the entire group and it was outside of the confidence limits. There was one outlier where the variation was more than would be expected by chance. The next is no composite intra volume correlation and I put that in there because I wanted to see if our volume, either high or low, was influencing our outcomes. As you can see here, either operator or hospital, volume did not seem to play a role in the ultimate outcome or composite outcome in this study. Volume was not determining this. On slide sixty-two, the requirements for an interventionalist at the PCI program, these are straight from the bill, you have to perform at least 100 PCIs per year, at least 18 primary PCIs, lifetime experience 500, complication rates within national bench marks, certification is ABIM and interventional cardiology as well as participates in CQI. Those are the requirements that have for each of the interventionalists at each hospital. We do know that some of the procedures being done at some of the hospitals have been done by individuals who were not initially approved by CDPH. That's a question that I think we need to address for our AOC and it comes up to this question of title 22, what does that allow an individual to do outside of the PCI CAMPOS program? Title 22 allows you only to do diagnostic procedures in the cath lab. However, in the state of California, we know that many hospitals, without onsite surgery, are doing STEMIs in their hospital. We know that is ongoing. Many of the hospitals feel that an interventionalist that is not approved by CDPH for the PCI CAMPOS, is allowed to do STEMIs in their hospital. It's also eroded past STEMIs to where they're doing some urgent cases and some non STEMIs as well. The question comes up that CDPH has to address, is where do we draw the line where an interventionalist, non-approved, for the PCI CAMPOS program, how many procedures can they do before we have to check on them and track them down? Can they do STEMIs? That is emergency PCI for STEMI. Can they do NSTEMIs? Who are stable patients who are in the hospital for a day or two...Can they do rescue PCIs and salvage PCIs at that point in time? I wanted to bring that up for discussion. Here are the requirements for the interventionalists in the hospital and that question is really guidance for CDPH, how far away from the law and 891 do we vary in allowing interventionalists in hospitals that are not approved to do some of these procedures?

Dr. Fehrenbacher: I would like to make a motion right now to be discussed and put on the floor. We will continue with the STEMIs as we have and that is that all interventional cardiologists can perform STEMI primary PCIs just as we were doing for the first year

and a half.

Dr. Sundrani: I will second that motion

Dr. Fehrenbacher: Let me restate my motion. Any cardiologist can perform primary PCI on ST elevation, MIs, and cardiogenic shock patients regardless if they've been vetted through this AOC process or not. We can vote on this issue and discuss the non STEMI afterwards.

The motion seconded and called to a vote

The motion passes

Dr. Bommer: Can someone decide or issue or propose a motion to cover an emergency situation? Here's what we look at from our side of the coding. They're coded as either salvage, emergency, urgent, or elective. As we go down through that list, we need to decide on each of those and we decide that all interventionalists can do STEMIs or do we roll that over to all emergencies. Then the question is, do we do NSTEMIs and who can do elective ones. Maybe we should approach from the bottom one meaning electives and who can do electives.

Motion: I make the motion that any patient that comes to the emergency room or emergently or any cath that has to be done emergently, that any interventionalist privileges at that hospital should be able to do the angioplasty.

Dr. Arnold: I second that.

Motion amended: The emergencies are verifiable by the PI at each site hospital.

The motion called to a vote

The motion seconded and amendment passes

Dr. Bommer: The next in series is salvage. I would like to entertain a motion on the floor of whether we will allow the same format to go through for salvage cases or not. This is a discussion first. This is a patient that is coded as salvage. The procedure for salvage is a last resort. The patient is in cardiogenic shock when the PCI begins, i.e. at the time of introduction into a coronary artery or a bypass graph of the first guide wire or intra coronary device for the purpose of mechanical revascularization. With the last ten minutes prior to the start of the case or during the diagnostic portion of the case, the patient has also received chest compressions for a total of at least sixty seconds or has been on extra corporal support.

Dr. Arnold: Motion that salvage PTS can be performed by non-approved interventionalists.

Motion retracted

New motion: A salvage case can only be done by CAMPOS approved interventionalists that is not an emergency.

The motion is seconded and put to a vote

The motion does not pass

New motion: For a case where NCDR coding lists the patient as salvage at the PCI CAMPOS hospitals, both an approved operator and a non-approved operator would be

allowed to do that procedure.

The motion is seconded and put to a vote

The motion passes

Dr. Bommer: We will now combine urgent and elective. Those are the two other categories, together. Urgent, if you want me to read the definition, I can do it. It usually means the patient doesn't have to go directly to the cath lab, but they should go to the cath lab before going home or being discharged. An elective would be somebody who could literally go home and come back and have their PCI at a separate admission.

Dr. Fehrenbacher: I'd like to make a motion that only the approved operators may perform this category.

The motion is seconded and put to a vote

The motion passes

Dr. Bommer: We are now on slide sixty-three, moving right along. This relates to the NCDR data set that we were trying to acquire. We have an agreement between the UC Davis and NCDR to create and transmit a de-identified data set of California hospitals. There are about 91 that participate in NCDR in California. They send their information to the NCDR data set. They will de-identify it with individuals with select elements, either suppress or calculated so we cannot identify select patients or necessarily identify hospitals, but we can identify which ones come from the same operator and from the same hospital. That will be a masking. We won't know the address or name of the hospitals. In our last meeting in June, there was an approval of a motion which passed that we would proceed with acquiring this data. NCDR did reduce after negotiation from \$105,000 down to \$50,000. A motion was passed at the last meeting, introduced by Dr. Itchhaporia that would approve this for acquiring this data for the PCI CAMPOS program. We have finalized the contract with NCDR between UC Davis and NCDR to acquire this data for the PCI CAMPOS program. That was finalized in October. The current situation is we're awaiting CDPH approval to go on with this and CDPH is actually waiting funding from the pilot hospitals so it sits at this point between CDPH and the pilot hospitals as how to fund this approval.

Dr. Way: We need to draft a letter that needs to be reviewed by a legal department.

Dr. Smith: How long does it take the regulatory agency?

Dr. Way: Six to twelve months.

Dr. Fehrenbacher: My suggestion is that we need a final decision on this six months from now. We will need final data and a final decision on how we want the law to look at the next meeting.

Dr. Way: This will require an addendum to the contract. That's the reason it takes so long.

Dr. Fehrenbacher: If we get a bill in front of the legislator next January they will take 6-9 months to debate and pass it. It won't be signed until the following year. It's a long process. It would be nice have the final data at the next meeting.

Dr. Bommer: We have a year and half to go.

Dr. Fehrenbacher: If we wait until 2014 there will a gap.

Dr. Bommer: We would like to get the data that is crucial to our evaluation of the NCDR of the six pilot hospitals to the rest of the California hospitals as soon as possible. The problem is if it's another 6-12 months before we start receiving the data. We will be long into the cycle. We have to process the information and crunch it and risk adjust it. It would be good to have the NCDR data so every analysis here included it as well.

Dr. Smith: Why do we have to have legislative approval?

Dr. Way: We need to have the letter worked out that needs to go out to the hospitals. Dr. Bommer will work out a letter with us to the six hospitals to pay 1/6 of the \$50,000. cost, attorney to review, and signed by the deputy director, payment by the six hospitals will be via an additional supplemental license fees from the six hospitals which will be notified of this additional requirement. UC Davis will pay for the data and CDPH will reimburse from the collected fees. They will wait to be paid six months. That's my understanding that by the law that is a legal process. I will review the original statute.

Dr. Bommer: We can draft the letter at the end of this meeting. The six pilot hospitals should be receiving the letter for the funding shortly.

Dr. Bommer: Slide 64 and the final slide. We are half way through the program, our plans are we want to support hospital volume, it helps gives us more information for statistical evaluation and robust study that we then can use in the presentation to the legislature for the next step. We need to bring up the numbers of the low volume hospitals.

Dr. Forman: We need to address this now as there are 3-4 hospitals that won't meet the requirement of 200 cases.

Dr. Way: Reviews statute by the second year each hospital will have 200, but the second year isn't the beginning of the year, it can be anytime of the year. The end of the year would be actually the end of year two.

Dr. Forman: 200 total by the end of year two? That would be July of this year.

Dr. Way: It's until year two period. Interpreting it broadly we have until year two.

Dr. Bommer: SCIA Guidelines are written as two hundred per year. The bill has left off the word year in the last statement they made.

Dr. Way: No, it's 200 by year two.

Dr. Bommer: That drops the numbers in half.

Dr. Sundrani: Is it possible, if you have a non-approved physician if they are proctored by an approved interventionalist?

Dr. Bommer: If you have a non-approved physician doing the procedure they are able to do it under an approved interventionalist and they should be available in the lab and can take over the case if any problems arise. That will be listed as an approved PCI. The approved operator will be listed in your data set.

Dr. Bommer: Reviewing performance variation between hospitals and operators. We will review your IRB applications. If you have submitted you may need to renew. You will need to address your policies and what you want to put on the IRB applications. I

would also like to address public disclosure; you are listed as a hospital by number. WE do know that in the state in California using the PDD data all hospitals report PCI data and you can see your hospital's mortality on the website. The question is do we want to consider adding voluntary NCDR data to that. We have talked to a number of CA hospitals some have said yes, we will provide that. The advantage is that NCDR data is risk adjusted. So it takes in to account of the acuity to a much higher level than PDD data. So it gives us a better risk adjustment because we have 220 variables versus about 10 in the patient discharge data. It offers a better risk adjustment model and gives you a better number. If the six pilot hospitals are willing to have this information available to go public on a website you will need to sign a form that will go to the California American College of Cardiology which would facilitate putting only mortality rates on the website. The next issue is developing publication we think it is worthwhile of the design and the process so far enrolled, we just have to be clear if we list individuals as co-authors that when send you a copy of the paper that it doesn't violate Bagley-Keene dispositions. We may be under restrictions of what I can share with you for publication. I wouldn't want to list you as co-authors if you can't see publication until it appeared in print. The last thing is we intend to obtain data NCDR data base from California, hopefully we will have that on site in the next six months so we can be presenting the next review with both NCDR and PDD data simultaneously so we have apples and apples versus oranges and oranges.

Dr. Fehrenbacher: The original five or six years ago, we obtained legal opinion that we did not need IRB approval for this. Before that, There were objections from the anesthesia lobby that requested IRB approval in the bill. The SB was then written such that when the ACCAHA decides that it is no longer a class 3 indication IRB approval is no longer needed. That's in the bill. As all of you know, a month or two ago, the ACCAHA task force made PCI offsite facility Class 2 therefore, the law states that IRB approval is no longer needed for this project. I'd like to make a motion that we number one acknowledge that the IRB approval is no longer needed for individual institutions, but each individual institution may continue the IRB process if they wish, or they may close it out depending on that locale. The twelve page consent form we are currently using is no longer necessary once IRB is closed out and that each individual hospital may develop its own consent form with the proviso that the information for that patient's stay must be available to the CDPH and UC Davis. That's the motion that I have on the floor any discussion?

Smith: I feel this excellent and I agree with you, but will it jeopardize the study anyway? Unable to understand mumble.

Dr. Fehrenbacher: The bill states that IRB approval is no longer needed when the indication for PCI without site surgery is no longer class 3. That's what it says it was written with the intent. I know the intent because I wrote it. The intent was that simply to at the time did not think it was experimental. We got opinions that IRB was not needed. There were physicians and lobbyists in the legislature who objected to the bill who objected as long as it was Class 3. If each individual hospital wishes to continue the IRB process then it can be left up to the individual hospital. It is my opinion that it's not necessary that it is not experimental therapy and has been deemed as Class 2 therefore is not experimental. Unfortunately our law in the state has not caught up with that and that's why we are here. I think there are problems with IRB. Continues with a patient example, a patient had received narcotics and can't get the consent form. Therefore, I believe it interferes with good patient care. Reviews motion on the floor.

Dr. Arnold: Seconds

Dr. Bommer: Can you give us the publication citation so we can put down for the new guideline. In another words we can put that into the motion. I can give it to you after the

meeting.

Dr. Arnold: Can that patient be reclassified as emergent?

Dr. Fehrenbacher: We have been through that, it is my opinion that each hospital can do what they feel is appropriate for them and their system. That is what my motion says.

Dr. Way: I'm unclear on what you are saying. I agree you don't want to jeopardize the process.

Dr. Fehrenbacher: The bill says that IRB approval is no longer necessary.

Dr. Otto: Introduced by Dr. Way as co-chief medical consultant: It's not something you can change midstream and compromise the outcome.

Dr. Fehrenbacher: The rules are quite clear in the law. The law states it is no longer needed. For us to change the rules against the law, actually I think would jeopardize the situation just as readily if we decided that it was required in spite of the law saying it is not required.

Dr. Bommer: I have the law here and I can read it. Just waiting for the citation from Dr. Fehrenbacher. He reads the law.

Dr. Fehrenbacher: The citation is from the American College of Cardiology published online November 7, 2011.

Dr. Way: Any further discussion?

Dr. Fehrenbacher: In the consent form it will be included that the data will still be available to CDPH and UC Davis. It acknowledges that the patient will be part of the study.

Dr. Bommer: Many IRBs do require even if you just collect data that you go through the IRB approval, as you are taking patient information at that time and sending it out of the hospital for a study. Any kind of study even if you are just collecting data has to go through IRB for that. Dr. Bommer reads the actual guidelines published.

Dr. Brindis: I'm not ready to vote. The IRB issue is not a trivial one. (Unable to understand discussion due to echo on phone.)

Dr. Way: Meeting will stop in two minutes.

Dr. Sundrani: I'm happy with my IRB.

Dr. Bommer: Do we have a motion to table the motion?

Dr. Brindis: I would like to make a motion to table.

Seconded

Motion: Passes

Dr. Bommer: The amendment passes

Dr. Way: The meeting is over and due to Bagley-Keene no more business can be

done.

Acronyms

ACC	American College of Cardiology
AFL	All-Facilities Letter
AOC	Advisory Oversight Committee
AVI	Audio Video Interleave
CA	California
CABG	Coronary artery bypass graft
CAMPOS	California Audit Monitored Pilot with Offsite Surgery
CDC	Centers for Disease Control and Prevention
DPH	California Department of Public Health
CMS	Centers for Medicare and Medicaid Services
CQI	Continuous quality improvement
CT surgery	Cardiothoracic surgery
EKG	Electrocardiogram
FFR	Fractional Flow Reserve
HIPAA	Federal Health Insurance Portability and Accountability Act
IRB	Institutional Review Board
MI	Myocardial Infarction
NCDR	National Cardiovascular Data Registry
Non-STEMI	Non-ST Elevation Myocardial Infarction
OLS	DPH Office of Legal Services
OSHDP	Office of Statewide Health Planning and Development
OR	Operating Room
PCI	Percutaneous Coronary Intervention
PDD	Patient Discharge Data
RCA	Right coronary artery
RAMR	Risk adjusted mortality rate
SCAI	Society for Cardiac Angiography and Interventions
STEMI	ST-Elevation Myocardial Infarction
STS	Society of Thoracic Surgeons
TIMI	Thrombolysis in Myocardial Infarction
UCD	University of California at Davis