

**Percutaneous Coronary Intervention Advisory Oversight Committee Meeting  
 October 4, 2012, Sacramento, California  
 09:30 a.m. to 4:00 p.m.**

**Attendance**

**Members** Anthony Way, MD, Chair; French, William, M.D.; 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** Tanuj Patel, MBBS; William Bommer, MD; Zhongmin Li, PhD; Geeta Mahendra, MS; Suresh Ram, MBBS; Laurie Vazquez, ANP

**Facilitators** Teresa Fleege; Sheila Fleege

Agenda Items/Discussion	Action/ Follow-up
<p><b>Call to Order and Introductions:</b>  <b>09:36</b>            PCI AOC Chair Anthony Way (Chair) convened the meeting with introductions in the room and on the conference line. Hoag Medical Center with no attendance.</p> <p><b>Approval of Minutes:</b></p> <ul style="list-style-type: none"> <li>• No Changes</li> </ul> <p><b>Motion to approve January 19, 2012 as written</b></p> <ul style="list-style-type: none"> <li>➤ Motion— George Smith, M.D.</li> <li>➤ Second— Aditya Jain, M.D.</li> <li>➤ Motion passed as written by unanimous vote</li> </ul> <p><b>Public Comment</b></p> <ul style="list-style-type: none"> <li>• None</li> </ul>	
<p><b>Old Business</b></p>	
<p>Dr. Bommer – Welcome remarks. Thank you very much we appreciate everyone’s participation. 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. Clarification: Dr. Arnold’s replacement will not be allowed to vote in his absence. I will mention the slide numbers for easy reference for those who are on remote conference line. Recognized members from UC Davis Coordinating Center, the Pilot-Hospital Interventionalists, Pilot Hospital Coders, CDPH and AOC members were announced.</p> <p>Dr. Bommer – Enrollment update: First year on left column and second year on right column. What we have listed is STEMI, NSTEMI, Unstable Angina, Stable Angina, No Sxs, no angina, Sx unlikely to be ischemia. First year of trial we hoped to get 1200 patients we had 1273 patients, year two of the trial that just finished it went up to 1328 total patients. It will be posted on the website if you want to come back and look at it. Moving on to slide seven, we saw the enrollment and the enrollment is a little over 100 patients each month. There is a cycle variation in the enrollment numbers. It goes up and it goes down, if you can figure out what</p>	

this represents then let us know, but I can tell you there is a variation and it is about 100 and it can go as high as 140 per month and as low as 80 a month. We will take suggestions to what this actually correlates with.

Dr. Smith – It could be random behavior

Dr. Bommer – It is not seemingly related to the moon or the tilt of the earth. Next slide is Total Enrollment Per Month by individual hospital sites. Shown here are the three highest volume hospitals and again and you can see a variation in each of these hospitals and it is not necessarily correlated, some might be low while others might be high at that time. The three lower volume hospitals are again cyclical and marked variation in the number of enrollees per month each of those hospitals go through. Slide ten actually gives us some numbers, initially the program hoped for about 200 patients per year and about 36 primary PCIs per hospital site, so looking at the individual hospitals listed on the left hand side and we are going to look at the total PCIs for each hospital. Again our target for the first year was about 200 and it ranges from about 97 to 390 cases. The primary PCIs shown in the next column to the right from 2010 to 2011 which is the first year of the program which ranged from 22 to 114, we hoped to get a minimum of 36 that was targeted at that time. The two columns to the right now reflect this last year or the second year of enrollment. You can see for hospital number one, it is about the same number of total patients that were done 390 to 389, hospital number two went down slightly, 280-272, hospital number three 161 to 125, hospital number four 97 to 134, hospital number five 156 to 174, and hospital number six, 189 to 234. The primary PCIs are shown on the far column to the right and you can see Primary PCIs went from about 27 up to 114 for the six hospitals that were studied in year two of the trial. Year two of the trial shows an increase in the cases and some slight increases in primary PCIs. Slide number eleven shows a breakdown for each of the hospitals, and again year one is the left column and year two is the column on the right. On slide 12 we have hospital number two, again showing a slight decrease in the STEMIs from year one on the left to year two on the right. The overall number of cases also went down slightly. Classification of NSTEMI, unstable angina, stable angina is shown for each of those areas, again with a slight drop in the number of PCIs enrolled. Slide number 13 is the next one that we have for hospital number three. This shows for STEMIs a slight drop in STEMIs that was encountered. There was a significant drop in the total number of PCIs that was done. Basically, NSTEMIs went down 45% or so, unstable angina went down, and a slight drop in stable angina as well. Hospital number three did see a significant drop in the enrollment of those patients from 161 down to 125 a year in the second year. Hospital number four is shown on slide number 14 of your set. What we can see is a slight increase in hospital number four. Hospital number four was initially our lowest volume hospital. They have now come up significantly. There were 97 total procedures in the first year and now 134 in the second year. There has been a nice significant increase in the volume for hospital number four. All of their volumes have essentially come up as we look at each of the classifications for admitting diagnosis for hospital number four. The next slide number 15 outlines hospital number five. Hospital number five had a mild increase in the number of enrolled patients from 156 to 174 with slight increases in each of the categories that was seen there, especially in unstable angina where it went up by a factor of 100%. Moderate increases in hospital number five. Hospital number six shows an increase in volume from 189 in the first year to 234 patients enrolled in year number two on the right. Exactly the same number of STEMIs, 114, so they do receive a fair number of STEMIs. If you look at hospital number six you can see that their largest group of PCIs is actually STEMIs by literally a 2:1 margin in that case. This is clearly a STEMI receiving center that is providing service for primary PCIs in that community.

Dr. French: The other number that we do not assess too often is the floor of opening the PCI lab was to do at least 400 cases a year. None of these six hospitals actually reached that goal.

Dr. Bommer: Correct. In other words, at some point in some of the publications the recommendations were 200 cases a year. None of our hospitals have really achieved it. That is a big number to achieve. You are correct that our volumes are not exceeding 400 as a floor. Nor do I envision since we now have two years of enrollment here that they're actually going to grow to that number. For the reason that in the State of California we are pretty well pegged at 50,000 PCIs per year total. That is not growing, it is staying very stable at that point. I would predict, Bill, that these numbers probably are not going to change dramatically at this point in time but hover up and down around the numbers that we have shown. They have actually stayed pretty close between year one and year two.

Dr. Fehrenbacher: What percentage of hospitals in California do 400 PCIs per year?

Dr. Bommer: We are going to show you in a minute that data if you could wait about four or five slides and I will discuss that.

Dr. Jain: There are some patients who come with syncope and have non-sustained VT. If you cath them and they have a severe lesion in the proximal LAD how do you code them? There is no angina, there are symptoms likely to be ischemic, but there is no category for that to code them correctly.

Dr. Bommer: I think you go back and look at the history. If it seems like there was something that was an ischemic symptom we code for that. If they came in with just syncope then it could be symptoms unlikely to be angina, but you take them to the lab, you find severe disease and you fix them at that point. That is allowed. If you look at the numbers we do have for each of the hospitals anywhere from zero to four or five patients each year enrolled in a situation where they really didn't have symptoms but it was felt that they clearly qualified for PCI at that time.

Dr. Jain: So the symptoms that are unlikely to be ischemic you put in that category?

Dr. Bommer: I think if you talk to the patient it is up to the clinician to decide whether that was an ischemic symptom that they had. If you had syncope and you thought it was an arrhythmia, ventricular tachycardia, then it is up to the clinician whether you think the V-tach is coming from ischemia. If you thought the V-tach was a different problem, that is a Channelopathy or something like that, then it would not qualify as ischemic related.

Dr. Jain: So it is ischemic but the problem is that when look for the category to fit in, there is no angina but the category is only for stable angina, Class 1, 2, 3, 4 symptoms, unlikely to be ischemic or if we go back to no symptoms, no angina, symptoms are unlikely to be ischemic. There are no symptoms likely to be ischemic.

Dr. Way: Why don't you just call it angina?

Dr. Jain: That is what I was saying, but the patient has no chest pain.

Dr. Bommer: Well, you can obviously call it no symptoms, no angina. But, in this particular case the patient had syncope. If you think the syncope was angina leading to sudden death then you could call it unstable angina. They went down at rest at that point in time so that would be an unstable thing. It does not matter to us. You can also put it as symptoms unlikely to be ischemic. If they had an arrhythmia that was not related to ischemia you could classify them as that.

Dr. Jain: That is what I did, but I was wondering.

Dr. Ram: Just as a note, the definition actually creates symptoms to be defined, so you get a good history and find out if the patient had any symptoms up to 1 week prior to that, would that fit into one of the diagnoses?

Dr. Jain: But not unstable angina. That's a nonsustained VT.

Dr. Forman: If you expand the angina to anginal equivalent then VT is an anginal equivalent. The same thing happens if you have a congestive heart failure patient come in. They are not having chest pain, they are short of breath. They have an EF of 45%, you cath them and then they have coronary disease. You fix it, well was the shortness of breath the CHF vs. angina and I think, just go anginal equivalent in your head and say, well okay it was angina.

Dr. Itchaporria: I signed in, but I never got a chance to announce myself. I have been listening; I just have not

had a chance to say something.

Dr. Bommer: So the point was brought up if there is a question then in which slot do they go into. Actually it does not make that big of difference in the data set. If you believe that they had symptoms that were ischemic that led to whatever their symptoms was, then I think you could list them as unstable angina at that point in time.

Dr. Fehrenbacher: There seems to be a fear of putting a patient into the symptoms unlikely to be ischemic because there is this fear that somehow you will be caught doing something inappropriate with this AUC (appropriate use criteria). As Dr. Smith just mentioned, there are always going to be a few patients that are a little funny. They're preoperative patients who are having a high risk surgery that you might stent in spite of no symptoms but a positive stress test or a positive FFR. There are some patients who are staged. If you stage them 15 days after your STEMI then they will be patients with symptoms unlikely to be ischemic. If you said you meant 13 days they fall into the Class 4 angina category. Unless those numbers of symptoms unlikely to be ischemic are very large, focusing on them really does not mean much.

Dr. Bommer: I'm sure we will always find some patients that don't fit in the boxes of coding that we have. That's the difficulty with the digital coding system where you have to get everybody in a particular box. Obviously, there are people that fall outside of those boxes. I think the clinician is asked to do your best effort at trying to assign them and we will go with that.

Dr. Fehrenbacher: The AUC criteria are a good try, but they aren't perfect.

Dr. Bommer: The performance level on the AUC is not 100%. The performance level is literally 60% of the patients if they meet that. That is what the national averages are at this time. Obviously, not every patient is going to fit into one of these slots and you make the best effort that you can to make that assumption. We're not necessarily questioning you on that particular assignment. Moving on, we are now back to slide 17 which is the website update. Our Velo server was upgraded in August to a new server so it's a dedicated server for that. The only thing I'd mention for the coders is when you're on that site you need to actually hit the logout button, not the little X at the top. If you hit the X on the top it will leave it open at that point in time. Please hit exit button to officially logout on your website when you interact with it. We took the first year and a half and we completely reviewed it, audited it, and had a data lock down, which means we finalized all of those. We are not changing that data. That was done on September 13, 2012. We do have to report an outage for the network. There was a network problem at UC Davis. On September 26, 2012 we lost our website for four hours and then it finally had to be rebooted and brought back on four hours later. So, there was a downtime there. Otherwise, the website is open 24 hours a day for the last two years. The number of down time is relatively small if you look at the overall time. Hopefully, this never happens again. It never happens with the State of California, correct? Slide number 18 is next. You've seen this before. To reiterate, the process that goes through after the PCI. What you see on the left-hand corner, there is a considerable process that takes place with both the data that comes in through the website. There are multiple audits and reviews, queries go back and forth. There is an iterative process that takes literally weeks if not months to go through, going back and forth. Obviously, when we come up with queries we don't expect those to be answered that same day. It sometimes takes a week or so for the coder to go through it. They put down answers then we review it again. There are multiple weeks that go into this iterative process for the data that is coming off of the computer. For the in-hospital audits, we have to select randomly which those patients are, send an auditor out there. They have to make an appointment to meet with the coders, review the data, bring it back. That may initiate queries as well. Those queries then go back to the other hospital for answers and then we try to resolve all of those issues before we can get to what I will call data lock down. Once we get data lock down that we have agreed on all of them, including the angiographic reviews, which sometimes require the interventionalist to come back and look at those angios. At that point, that information is released to Dr. Li. It then goes from the Velo server and the Xcelera server goes to the SAS computer that we have. The analysis is done on the SAS computer at that time for the final data analysis that you will be seeing today. All of this iterative process

literally takes months to go back and forth, the multiple exchanges that take place, including the fact that there has to be travel involved in some of these audits. Next on slide number 19 these are things that we check for the offsite audit. This means we are looking at the data set that comes in on the website. We look for completeness, consistency, and to make sure the definitions are in compliance with the NCDR. We use the exact NCDR data set and we use very exact definitions. Everyone here agrees that it's not perfect but it's the best data set registry that we have nationally. It represents a significant improvement over other registries that were available in PCI. So, we do follow those exact NCDR definitions. Slide 20 shows you the onsite audits. By onsite, I mean we send someone out to each individual hospital. They sit down there in the record department or cath department, they get copies of the angio films, and they actually review charts. They review charts to make sure the data in the registry data set actually correlates with what we find in the review at the hospital site.

Question: Is this a physician that is going out and nurses?

Dr. Bommer: The individuals who are doing the audits are a nurse practitioner, Laurie, Dr. Ram, and it will be Dr. Patel. So it is a nurse practitioner or a physician who are doing the audits at that time. The internal audits are done by a physician as well. The angio audits are done by interventionalists who have experience in intervention. Yes, so it's physicians with the exception of one nurse practitioner who do the audits. Onsite audits are done onsite at the hospitals so they have to travel to those locations and do them. Here is a list of the onsite audits we've done as of the end of year two. For the first two years of data we had 562 procedures that were audited at those hospitals. Each of those audits takes one day or one-half day to go through a couple of patients at that hospital and ferret out all of that information. Those are the onsite audits. The angio audits are actually done by capturing a CD or a DVD with the information at the participating hospital. The auditor brings them back and then we load them onto a HIPAA compliant Xcelera server at UC Davis. Then they are available for review with password and coding to get access to those. Those are only available to the angio auditors that are on the trial. We look for diagnostic information on there as well, as you can see I have shown before. Certainly we look at that diagnostic information and make sure it has been coded correctly on the registry data set. Slide 22 shows you additional things that we look for on the PCI audit. The segment number is important, the amount, FFR information which we're starting to receive. Pre procedure TIMI flow, lesion length and thrombus present are important because they do affect the risk model that we will talk about. This shows lesion complexity on slide 23. I highlight the bottom square which is the high C complex lesion. These are the specific things we look at. I bring this up because this is the most frequent change we find when we audit the angiograms. We're changing either up scaling to a C lesion or downgrading to a less than C, that is an A or B lesion. A high complexity, or C lesion, has to have one of these five features. That is, it has to have a length of the plaque, or the lesion longer than 2 cm, excessive tortuosity, extreme angulation which is more than 90 degrees, total occlusion for more than three months or bridging collaterals, inability to protect major side branches, or degenerated vein graft with friable lesions. If it doesn't have one of those five markers it cannot be classified as a complex lesion. We review the films. If it doesn't meet those criteria we have to downgrade it from a C lesion to a less than C lesion. We go over that with the interventionalist and with the coders, etc. We go back and forth on that. There are nuances of it. We're certainly willing if it's close to that we're not going to argue a lot, but if it really is a simple lesion we just cannot classify it as a high C complex lesion. As you will see in the audits, this is one of the frequent things that gets changed in the audit process. Additionally, on slide 24 of your slide pack, angiographic information is reviewed for bifurcation lesion guide wire across the lesion, the guidewire comes down there and that does count as a procedure at that point in time if you cross the lesion. The device is used and an ejection fraction if it happens to be on the angio.

Dr. Forman: If you advance the wire and never get across the lesion does that count as an angioplasty or does that not count as an angioplasty?

Dr. Bommer: If you introduce the wire with the intent to do PCI into a native coronary artery then that counts.

Dr. Forman: Okay, I would agree with you. I just have been told that that does not count as angioplasty if you don't cross the lesion.

Dr. Bommer: Now if it's an FFR catheter then you're allowed to go in, measure that and get out of the lesion without counting it as a PCI. If you introduce a wire for the intent for treatment and you can't get it across the lesion that becomes an unsuccessful PCI.

Dr. Forman: So if you try to cross a total lesion with an FFR wire and you fail, it's not an angioplasty, is that what you are saying?

Dr. Bommer: If your intent was to measure FFR as a diagnosis then you're correct, it would not count. But if your intent was to get around the system by trying to force an FFR catheter through there to open up the vessel then we would say your intent was to open it up and it would count as a PCI.

Dr. Jain: Heavy calcification for some reason is not considered high risk. If there is a lot of calcification proximal to the lesion it does make the lesion a high risk.

Dr. Bommer: You are correct. There are other things that increase the risk of procedures that are not classified here. The reason we stick with the NCDR data is that ultimately we will be getting the California data under the same NCDR entrance requirements, hopefully, so we want to keep "apples to apples" as close as we can. You are correct that that may be a problem and you may have to use a Roto cutter or something else in that case. That certainly would increase, to some extent, the risk in that particular case. We cannot recognize it for the purposes of this study because we do not have that coding. Slide 24, those additional things are looked at under the angiogram. Now onto slide 25 we have this data on monitoring of the program from both our data set on the registry vs. our onsite audits, which are done at the hospital. I thought that it would be useful to compare the two and see how much onsite auditing adds to this review process in looking at the data. We are now going to compare offsite auditing, which is what is available to NCDR or any site where they have a protocol of the data coming in and algorithms to go through to make sure it is complete and adequate data vs. where we actually have somebody going to the hospital and reviewing the angiographic films. This is a much more intensive onsite audit. Is there a difference in what we pick up between the two? The objective was to compare our offsite data valuation with the physician going over the chart, etc. vs. onsite monitoring where one of our auditors shows up at the hospital and we look at the actual hospital records, cath records, charts, etc. and the angiogram. At the time we had 1800 PCIs, we look at 500 of those as a selected sample for that. Those were the first year ones that we had. We looked at registry field review, which is the 200 field reviews with algorithms and a physician reviewing them which is called offsite vs. onsite which is in-hospital records examination, review of images, and interventional angio recordings. We looked at all 240 fields in the NCDR data set that we used, PCI cath version 4.4. We do the audit and we find a change that we change a field. We record those changes as miscoding. That is, a code was entered into the field and in the end after going through out iterative process, getting back to the coders and the hospitals, they said yes it is correct that was an error in that change, and then the audit was right in that particular case and these are called miscodes. If the miscode affects one of the variables that we have arrived at in our multivariate risk adjustment model then they are labeled as mis-risk. That is, this coding change actually affects the expected risk of this particular procedure. That is, it is altering the risk. It is either up coding the risk or down coding the risk for that particular patient. This variable is an important variable because it actually affects the projected or expected risk of that patient. It will be listed as a mis-risk in that situation. Going to slide 26, what you can see is of the 500 total audits that were done we found about 40% of them, or about half, were listed as mis-code. When we evaluated those they were listed as mis-codes in the total audits. That could be either onsite or offsite. We found of the mis-codes about 15% were actually mis-risks. In other words, of those changes about 15% actually affected the risk assessment for that particular patient. You can see most of the cases here are one or two mis-codes per patient record that we're arriving at. There is a very small number that had more mis-codes. Mostly, this is one or two coding errors per patient chart that we're finding in about 45% of those individuals. Those were total audits. If we look at the

onsite audits, meaning we are in the hospital for these, you can see that we reviewed about 118 onsite audits at that time. In about 110 of those cases there was a mis-coding. Our onsite auditors are much more likely to pick up a change in the data set because they are actually reviewing the charts. They have obviously a lot more information to compare with our registry information. We found that about 90-95% of our onsite audits actually come up with a mis-coding error where we change and agree at the end of the process that there was a change in that coding. Now, of the onsite audits you can see about 40% of those involve mis-risk. In other words, the onsite audit detects a change in the registry that actually affects the expected projected risk for that particular patient procedure. So, about 35-40% of those onsite changes actually affect an important variable that is affecting the risk of that particular patient. If you look at those you can see the numbers that are shown here, the numbers that were detected, the most likely that is coming out as mis-risk is usually one or two items of those 35-40% of charts were identified as changing the risk profile for that particular patient.

Dr. Smith: Doesn't that figure really disturb you? It shocks me.

Dr. Bommer: We are going to have that discussion in a minute. Let me present everything first and then we will have that discussion. Slide 28 is going to tell us what kind of mis-risk assessments are there for our total audit. On slide number 28 I have the total amount of audits and these represent the total number of changes that affect risk. Again there were about 110 that were mis-risk. Of those 110 what type of fields were being altered? You can see the number one field that is being altered is actually lesion complexity. You can see that the total number of changes for lesion complexity was about 34 or so. Of those, we then assessed whether the change actually led to the error that was the mis-risk. Was it up coding of risk or a down coding of risk? You can see in red that most of the changes we found in lesion complexity were an initial up coding of the risk, which is it was called a high C complexity. When we reviewed it with angiography and got back to the interventionalist, it was then downgraded to yes we all agree this is no longer a high C lesion, it's a less than C lesion. So, the initial mis-risk was an up coding in that particular case for lesion complexity. You can see that in a few cases we upgraded it so the initial problem of mis-risk was a down coding for lesion complexity. But almost all of those 80% were up codes at the initial data entry at that time. The other registries that listed up or down codings are shown here. You can see it is pretty much a mix. Thrombus present or not. CAD presentation we altered. Pre-procedure TIMI flow was changed, etc. All of those were fairly low percentages of actual changes so most of the up coding was achieved in C lesion complexity. If you look at the up and down here, and you balance them out, I will go back to the first part of the column, you can see that the up coding red for total number of lesions on the left of the slide, the second column, and the down coding pretty much balances each other out. The fact is it looks like the up coding for PCI complexity seems to balance the down coding errors where something was missed, like thrombus in the vessel, TIMI flow, heart failure in the presentation, etc. It is interesting that there are a significant number of errors. It looks like the up codes and the down codes are roughly equal in that population. Our most frequent up code error is in PCI complexity. There is a whole litany of down code ones, heart failure, intra-aortic balloon pump. They got missed at the initial data entry that our auditor picked up and then wound up changing it.

Dr. Fehrenbacher: This is very similar to the Massachusetts data in which up code balanced out the down code.

Dr. Bommer: Slide 29. These are the onsite audits, mis-risks. These are the ones picked up just onsite. You can see that a total of 82 mis-risks were picked up. Again, you can see that about 36 of those were up codes initially in error and about 38 of them were down codes in error initially. They really balanced each other out on the up codes and the down codes. You can see again the pattern is exactly the same. The most likely up code error was PCI lesion complexity shown there. Literally 95% of the up codes are coming from lesion complexity at that time. The down codes which are shown here as the further ones coming across here, again carry the spectrum of thrombus present which was initially missed, CAD presentation where we changed the CAD presentation, TIMI flow, cardiogenic shock that was missed, heart failure, and ejection fraction that was initially missed. In one case birth date was off. Birth date changed the age of the patient. Age is a risk factor in our adjusted risk. We were not able to identify birth date other than being onsite where we could actually

check that from the records at that time. Again, a balance here, but you can see a significant number of mis-risks are actually calculating that from this data on slide 29. Slide 30 is going to summarize this for us, both in mis-codes and the mis-risk that were achieved. You can see for our offsite rate, this is not total but just the offsite initial audit of the registry data; we were able to detect 0.7 mis-codes per patient. For the onsite rate we were able to detect an average of 4.5 mis-codes per patient record. For the very important mis-risk, because this is affecting our risk projection for these patients, you can see the rate is pretty low at 0.05 per offsite evaluation. So, fairly low chance of discovering mis-risk on that. The reason is we are not reviewing angios, we are not reviewing patient data from the chart at the hospital. On the other hand, onsite data detected 0.7 mis-risk per patient. A significant number much higher for onsite. This makes sense because you are looking at the patient's chart, you have access to data, you don't on the registry. You are looking at the angiograms. Without that it is just the registry coding for that and we have no way to verify for that. What we can see is for mis-codes there is a six-fold increase when comparing offsite monitoring vs. onsite monitoring. For mis-risk, the important one that really affects the mortality projections from these patients is about a 14-fold increase. That is, the onsite rate has a more than 10 times higher chance of detecting a mis-risk in that patient population. There is a fairly significant number of mis-risks that are picked up. In summary, on slide 31 for this, you can see that onsite monitoring. . .

10: 31 a.m. EMERGENCY HAS BEEN REPORTED, BUILDING EVACUATED

11:46 a.m. MEETING RESUMED/ROLL CALL AFTER FIRE DRILL

Dr. Bommer: So here at CDPH we were able to schedule our exercise break during the day. We hope that at the remote sites you also got equivalent exercise as well. We are now ready to do. We are now on slide 31. We started on that but we will resume on slide 31 on your slide set. Again, this just shows that onsite monitoring detects more mis-codes with an odds ratio of 6.4:1, six times more miscodes, and 14 times more mis-risk compared to our offsite monitoring of the registry data for PCI. The up vs. down code rates are relatively similar. We then concluded that onsite auditing data entry medical records and imaging does improve coding and the accuracy of risk adjusted outcomes for these cardiac interventions. So that concludes the coding part. Slide 32 talks about protocol violations. In general, we find that the protocols are followed very well by all of the hospitals. There were a few protocol violations that we will bring up. There are three cases in which the angio films have disappeared, meaning when we go to the site and do an audit there is no angiographic evidence of that. So we cannot really review the angios because the site does not have access to them or they have been erased. We have notified the pilot hospitals to please make sure you save the angio before entering more patients that erase it or whatever is required at your site. Hopefully that corrective action is under way. There was one case in which an unapproved interventionalist did an urgent case. As you know, at the last meeting we said that unapproved interventionalist could do emergency STEMI PCIs but we did not want them to do elective or urgent ones in that case. So, that site has again been notified and correction of that action is under way.

Dr. Sundrani: I got this questionnaire and if you guys are wondering we are the site where we got this questionnaire about the unapproved interventionalist doing the PCI. As I had said before, I reviewed all of the records. This gentleman came in with an ST elevation MI the day before, had acute stent thrombus of the LAD, and the interventionalist on call who is a non-approved PCI guy did the ST elevation MI the day before and just did some export suction of that thrombus and got the flow back. The patient was looking more shocky and he did not want to cause more emboli distally so brought him back the next day and ballooned him and put a stent in. So the question was, I think the intervention the next day, the guy had come in with an ST elevation MI with an ICU and a balloon pump. So I do not know. I would like to get the feedback of the other members. I do not recall the definitions. I thought this was part of the same ST elevation MI with which he had come in with the day before and the intervention wasn't finished.

Dr. Bommer: Technically when we look at the NCDR definitions, the first one was a STEMI, so that qualified as emergency PCI, so the first day intervention was allowed. However, when the patient is put into the

hospital and then brought back on an urgent basis but not an emergency basis, then technically based on the agreement we had at the last meeting that should be done by an approved interventionalist in the program. In that particular case, I would say if that happens again I would ask that unapproved interventionalist to just say "Gee can you join me in the lab? I've got to take somebody back that I had in yesterday but I'm not approved. It's a second scheduled procedure or urgent in that case, can you join me on that?"

Dr. Fehrenbacher: I believe what we did was we defined an emergency as any case that would bump out the day. So it does not have to be a STEMI, it can be a case.

Dr. Sundrani: This guy with the balloon pump was having chest pain in the ICU.

Dr. Fehrenbacher: That becomes an emergency.

Dr. Sundrani: Completely not resolved and you look at the interventionalist who comes in with an ST elevation MI, does a fabulous job but not an approved PCI guy. He says now I have taken care of the emergency, I need to call somebody else to bail me out?

Dr. Bommer: No, the second case, if in fact the patient was crashing on balloon pump . . .

Dr. Sundrani: No, he was not crashing. He was still having some chest discomfort but he wasn't crashing. He was on the balloon pump.

Dr. Bommer: So the decision has to be made, is this an emergency where he comes to the lab and as George said you take somebody off the table to put this guy into the lab or you bump somebody from the schedule as an emergency. Or was it just they brought him back the next day because he was not doing well?

Dr. Sundrani: No it was not somebody to be bumped. That is very true.

Dr. Bommer: In this particular situation it just happens to be classified as urgent. In that case, I would suggest in the future, based on the AOC decision at the last meeting, that we have an approved interventionalist involved in that second procedure. The likely thing would be ask "can somebody join me on this case; I'm going to take him back to the lab." That would be the way I think it should be handled. The number of protocol violations are very small. I am mentioning it because this is part of our report, that's all. The third item or case here related to an individual who apparently was not in the IRB approved list of individuals who could have an IRB procedure. We notified that pilot site as well as the PI. That happens to be a qualification of an individual who came in who may not be IRB approved as a patient at that particular site. If the individual was a prisoner and the IRB did not allow enrollment on an IRB protocol of a prisoner. Slide 33 is what we introduced last year. Because of our concern we're taking patients to the cath lab that were very very high risk. The NCDR data set really did not allow us to fully adjust for that excess risk at that time. So we came up with criteria that were parallel with the Massachusetts criteria for compassionate use. It includes three things: coma on presentation, use of initial ventricular assist device (that is not a balloon pump, that is an LV assist device), or CPR at the start of the procedure when they get to the PCI lab. We in fact began entering those additional codes and we modified the NCDR data set for that beginning July 1, 2011. The next slide shows just how we did that. We actually modified the NCDR data set and added additional fields to reflect that. This is just a screen print from that. Did your patient have compassionate use? Then it specifies what qualified that patient for compassionate use criteria? Slide 35 shows the results for basically one year of recording compassionate use. During that year period, July 1, 2011 to July 31, 2012, basically one year and one month you can see we had 1400 patients enrolled in the total trial. The compassionate use section, which is an additional 4 or 5 questions at the end, was actually correctly addressed in almost all of those individuals, all but about 19 in 1413 patients in column two for each of the hospitals. Patients who met compassionate use criteria, a total of 16 in the third column were identified in that year of operation. We had

literally a little over 1% of our patients met compassionate use criteria, which is not totally different from Massachusetts, where I think it was 1.7% of their population. The individual criteria of coma was the most common compassionate use criteria seen in 15 individuals. We have it listed for each of the hospitals. A handful at each hospital literally. LV assist device was only seen in one patient out of the 1400. CPR at presentation was seen in four individuals.

Dr. Stern: How do you define an LV assist device, is that including intraaortic balloon pump?

Dr. Bommer: No it does not include intraaortic balloon. LV assist device is pretty much a pump, either Impella, HeartWare or Heartmate pump that is used. Or it could be ECMO that is used. So what you can see is cardiopulmonary bypass, ECMO or peripheral VAD device is listed in that column. There was only one in the entire cohort of patients for one year who had an LV assist device. I think you are familiar; there are not a lot of patients that you really put that in first before they come to the lab. But, there were a total of 16 patients who met compassionate use. Slide 36 is shown next. What I show here first is the Massachusetts data in the first two columns. This represents basically STEMI procedure success which was about 94%. Under compassionate use if they met one of those three criteria, that success rate dropped down to 79%. The mortality in the STEMI patient population in Massachusetts was 4.5% in the bottom left box; however, if they met one of the compassionate use criteria that mortality rose from 4.5% up to 69.8%. So a tremendous increase of literally 15-fold increase in mortality in Massachusetts. The PCI-CAMPOS data is shown to the right of that in the right two columns. Again, our overall STEMI success rate to make it comparable was 89.7% success rate. In our compassionate use group it dropped as well to 59.1%, somewhat lower than the Massachusetts success numbers. For mortality, if we look at our STEMI mortality at 5.44%, that went up 10-fold to 56.25% if they met the criteria for compassionate use in the far right lower box. Similar to Massachusetts, we have lower success rate and major high mortality in those individuals associated with compassionate use. Again, I think this reflects the reason for including compassionate use as one of the markers or criteria that we use in our system. Slide 37 is going to present some basic statistics. Dr. Li went over these but I am going to go over a couple and then turn it over to Dr. Li. In the basic statistics on slide 37 you can see up until September 19<sup>th</sup>, which was just two weeks ago, we had enrolled 2,727 individuals in the PCI-CAMPOS program. We are getting to a relatively good-sized number now at 2,700 patients. We have complete data, which is all the fields are marked, on 2,702 individuals. We break it up here for year 2010, 2011 and 2012. You can say, why don't you just show first year, second year. That's because what we will be comparing with this down the line is PDD data, (patient discharge data). Our patient discharge data is calendar year. I wanted to keep this as close as we could to the comparison which is patient discharge data. Patient discharge data will be a separate number for 2010, 2011 and 2012. We have it broken out here. You can see we did almost 500 cases in 2010, 1,300 in the year 2011, and so far in 2012 we have done about 897 cases. Overall, of all the PCI cases, in hospital mortality was 2.15% of those 2,700 patients. In 2010, the mortality was 2.02%, 2011 it slightly went up to 2.29%, 2012 so far it is slightly down at 2.01% for the three-year transition that we see. Our hospital observed mortality, that is for our individual hospitals, varies between 0.42 and 3.92% overall, for the entire period of time that we are looking at. You can see in 2010 the variability from the lowest risk to the highest risk which was 0 to 8.2%. In 2011 it was 0.79 to 4.65%. In 2012 it was 0 to 2.91%. We do have the variability from one hospital to another over the three years that we have looked at enrolling for overall mortality. If we look at the next slide 38 this now looks at the distribution of volume in the PCI-CAMPOS data set. For the calendar year of 2011 you can see on the left bars we have a hospital that is performing approximately 90, that is the lower left bar, and to the right we have a hospital that is performing about 270. Those are our low and high volume hospitals. The other four hospitals lie in the middle between 150 and 210 cases that we see there. We can see the mean number that we have of cases is 176 per hospital. Median is 163 PCIs per hospital in our program. The range is from the lowest at 90 to 296 which is our highest volume hospital. The individual quartiles are shown to the right. You can see they range from 296 at the highest volume to 90 being the lowest volume. We have 25, 50, and 75% quartiles there as well so you can come out with that information. You can see mostly we average between 160 to 176 hospitals.

Dr. Smith: Can you go back two slides and ask you one quick question? When you are comparing Massachusetts and California data, you listed the California overall mortality data for PCI as 4.5%. So this is considerably lower?

Dr. Bommer: I will go back two slides. We are going back to slide number 36. I explained but I will go over it again. For PCI-CAMPOS, what I have coded here to make it similar to Massachusetts. Remember Massachusetts is STEMI and cardiogenic shock. To get close to that, rather than to put our elective mortality in here, I elected to look and post only our STEMI mortality to show that it is comparable to the STEMI plus shock number for Massachusetts.

Richard Stern: As long as we have gone back to compassionate use, I have a question about that. The CPR definition at the onset of PCI is that prior to being on the cath table, how do you define that?

Dr. Bommer: It usually is at the start of the procedure you are doing CPR. So typically if somebody comes in whom either arrests on the table before you start the procedure or they come in under CPR and you say okay I'm going to go in radial or femoral while you are doing CPR. So it does not mean CPR in the ER, they were resuscitated, and then they send them down to the cath lab. That does not qualify. Okay, I am advancing back to what will be slide 39. Slide 39 addresses one of the questions that Bill French had earlier. It looks at the same volume distribution for the patient discharge data non-pilot. These are the rest of the California hospitals not in the pilot program and what their volumes are. As you can see for PCI-CAMPOS we were clustered around 163 to 176 for the middle or average. You can see for the rest of California the mean is slightly higher. There are 302 cases for the mean for the rest of the hospitals in California. The median is higher at 249. These numbers for median and mean are both higher for the rest of California. Now, if we look at the distribution there, you can see that this pretty much peaks or clusters around 200. So whereas PCI-CAMPOS was clustered around 160 to 170, the rest of California is clustered more around 200 or slightly above 200 at that point. So the PCI-CAMPOS volume is median and mean lower than the overall population spread for California. As you can see, the range is from 1 to 1659. There is a tremendous range in the other hospitals in California outside of the pilot program. To the right of that bar chart you can see the quartiles that are shown as well. You can see the highest volume in California for this same period of time. We matched time exactly, 2011 with 659 cases. The lowest volume was one case. If you want to know what the quartiles are, the 25% quartile is 131, the 50% median was 249, and the 75% quartile was 383 for that group. You can see that these are the numbers. The rest of California in general is a little higher volume than is the PCI-CAMPOS program.

Dr. Fehrenbacher: That means 75% of California hospitals don't meet the 400 criteria. Is that essentially what that means?

Dr. Li: Yes, about 30 hospitals will be doing more than 400 cases.

Dr. Bommer: In the end, here is that 151 hospitals that are being looked at. You can see that most of them do cluster around 200. If you had to pick a number it is a little bit above 200 where they cluster around. If we look at 400 and out you can average these out. Above 400 it is a relatively small amount of California which is above 400 at that point. Slide 40 looks at patient care mix. There was some interest early on the patient care mix of our patients on the PCI-CAMPOS vs. those in the PDD distribution for the rest of California. What this slide will summarize for you is it is a very similar case mix for both groups. If we start on slide 40 the columns to the left, look at the ratio of STEMI to non-STEMI. The STEMI to non-STEMI ratio is shown there. It is about 1.5 for the non-pilot hospitals. If we look at the patient discharge data, of our same six pilot hospitals it is about the same, 1.65. If we look at our data set, which is completely owned by PCI-CAMPOS and run by us, it is slightly different at 1.47. You can say why are those not identical. Well, because there are two separate collections of data for that. There are two separate filings. The patient discharge data set does have some variations associated with it. And, part of that is classification. If in the patient discharge data they were classified as STEMI but our coders here did not call it a STEMI, they said non-STEMI, that would

alter that. If we audited the records and perhaps changed it from STEMI to non-STEMI that occurs after the PDD data collection. We would change it in our data set, it would not get changed in PDD. So, since these are two different data sets with two different collections harvesting and review sets it makes sense that there is going to be some variation. But you can see that statistically there is no real difference in the data set patient case mix for the rest of California vs. PCI-CAMPOS. We are seeing the same types of patients that the rest of California is seeing if we look at STEMI to non-STEMI ratio. If we look at unstable angina to stable angina ratio, again similar numbers are seen. If we look at all patient discharge data or if we look at our PCI-CAMPOS data and again, although there are variations between PCI-CAMPOS and the PDD pilot set there is no statistical difference between those. Our case mix appears similar to the rest of California and that would make sense, we are not seeing different patients.

Dr. Jain: Why do we take a ratio and not each separately?

Dr. Bommer: It was suggested before that someone wanted to see the case mix ratio and that was a way of looking at it. We are following what was voted on, or suggested, at an earlier AOC meeting. We would be happy to look at anything you want but this was based on the suggestion from a prior meeting. Again, I will just briefly show on slide 41 CAD presentation is the definition. That may a little bit different in our data set than in the patient discharge data, which is a different type of coding so that may alter it somewhat. As you can see, if someone comes back to the cath lab the CAD presentation in our definition is based on the highest level of CAD presentation prior to the subsequent procedure. There are different ways of perhaps coding this. But, again no difference in our patient data mix and I don't foresee that we will continue to detect that. Slide number 42 looks at hospital observed mortality by MI type. This breaks it down into three classes, that is STEMI or STEMI excluded as well as the total PCI in the third column. Now what you can see for STEMI, the first column, again we are always going to report the patient discharge data for California on top followed by the pilot hospitals through the same data set followed lastly by in the bottom row is PCI-CAMPOS data. For STEMI we have in California a 5.08 mortality rate for the year in question, 2011. For our pilot hospitals it is similar, 5.24%, and in our own data set it's very similar at 5.44%. No significant difference between any of those numbers. If we look at STEMI excluded, now we would expect our risk to go down at that point in time. Indeed, it does go down for California in general, 4.08%. It goes down for the PDD pilot program to 2.97% mortality. In our data set again we are using slightly different definitions of STEMI excluded in these groups and it stays low at 1.5% for STEMI excluded using the NCDR definitions. The definitions for NCDR and PCI-CAMPOS are shown. PDD has different discharge data sets and so they do vary somewhat. The third column looks at total PCIs. You can see for California in general all comers PCIs the mortality for that year was 3.02%, for the PDD same collection process for pilot hospitals it was 2.66%, and for the PCI-CAMPOS data set it was 2.55%. Again, there is no statistical difference between California vs. pilot no matter how we in fact measure that.

Question: Back on slide 40 you have the ratio STEMI to non-STEMI on CAMPOS of 1.47. When I look at the numbers that you gave earlier the ratio I come up with is 1.2. I was just wondering what the difference in that might be?

Dr. Bommer: Well, we can go back and look at those numbers. In general, we did not see a difference. We got some of these numbers just recently; we haven't gone through all of them. Over the last two years we have seen no real difference in case mix here. I think the question was: Are the PCI-CAMPOS hospitals seeing sicker patients or easier patients? Really, probably no different than the rest of what California is seeing.

Comment: I think I am comparing slide six with the slide number 40. Slide six has the actual numbers but those are study years whereas slide 40 is calendar years.

Dr. Bommer: The reason we went with the calendar is that is what the PDD data is assembled on, a calendar year so we tried to do that. Throughout this presentation you will see different numbers and different

inclusion dates based on what the analysis is that we are doing. I apologize that we have our system that is on off calendar year, that is, it is August 1<sup>st</sup> to July 31<sup>st</sup>. The PDD data is January 1<sup>st</sup> to December 31<sup>st</sup>. To try to give you similar numbers we have tried to in fact balance out a different set of data for each analysis. So there will be differences in mortality that you can pick up. That is because patients including or not including based on our cutoff point.

Dr. Fehrenbacher: I would be interested in seeing the STEMI ratio to elective outpatient procedures.

Dr. Bommer: Alright, we can include that in our analysis so can you repeat that for the record.

Dr. Fehrenbacher: I would be interested in seeing the STEMI ratio to elective outpatient procedure.

Dr. Bommer: Dr. Fehrenbacher will receive his wish. If there is something specific that you want to define we can put it through.

Dr. Bommer: Slide 43 this is hospital observed mortality for STEMI excluded. In this particular case we have taken the STEMIs out of the mix. We are just looking at NSTEMIs or we are looking at patients who did not have an NSTEMI or a STEMI, that is no myocardial infarction, no MI. These are the lower risk patients. If you look at the first column here for NSTEMIs you can see that in the first column on the left PDD data for California is 1.86%.

Dr. Bommer: If you can keep your cell phone away from the speaker, step back from the speaker and mute we would appreciate it. Thank you very much. So again on slide 43, this is STEMI excluded, so it should be a lower risk group. You can see for NSTEMI here the California data was 1.86%. For the pilot hospitals using the same collection process it was 1.89%, so very similar. For our PCI-CAMPOS data it was a little bit higher, 3.69. We are going back and trying to re-verify that number because it was a little bit higher, but there was not a statistical difference between those for NSTEMIs. For the column to the right, which is no myocardial infarction, this is really amazing that in the California PDD data if you did not have a STEMI or NSTEMI then you basically had no mortality. If you look at the PDD data for the same group of patients no mortality for that year. So this is an exceptional year. Individuals who came in electively for their PCI left without a mortality. We are rechecking that right now but the two times we looked at our data through two different assays it was 0% mortality for no myocardial infarction. Just showing you that it appears that an elective PCI in California is a relatively safe procedure.

Dr. Fehrenbacher: I find that hard to believe.

Dr. Bommer: So do I, that's why we're going back and talking to PDD.

Dr. Fehrenbacher: So in the PDD data is there myocardial infarction associated with a patient's outcome and then therefore they are coded afterwards. They have an MI secondary to a misadventure and then it's coded afterwards as a myocardial infarction? Do you understand what I am saying?

Dr. Li: Actually in the PDD everything is coded with the ICD-9 code, diagnosis code. But in California we also have to check whether or not the condition was present at admission.

Dr. Bommer: So if anyone out there knows of a patient in 2011 who came in for an elective PCI and died in California please call us right away. 1-800-PCI because we are going to be looking for that and rechecking it. At least I would suggest it is extremely low mortality. That is STEMI excluded. We are going to go on to risk adjustment. What we showed so far is overall mortality. You remember at our last meeting we elected to look at composite outcomes to look at that. Composite outcome includes death and transfer for emergency CABG at that point. We did have some transfers for that. If we look at the composite rate it was 2.6%. So it is going to be a little bit higher because it now includes those emergency transfers. We were asked by the

AOC to in fact delineate the composite death rate, death and emergent CABG. The risk factors for that and the multivariate analysis was done by Dr. Li. I am going to ask Dr. Li to stand up now and to present the risk model and the process that he went through to arrive at our risk adjustments.

Dr. Fehrenbacher: Before Dr. Li starts, I would just like to mention it is seven minutes after twelve and we can take a lunch break whenever you want. We of course had a large interruption in our time here.

Dr. Bommer: Well, it is up to the individuals here at AOC and the remote sites. Do you want to take a straw poll and see how many want to break now or how many want to continue?.

Dr. Bommer: Those in favor of a 15-minute break. So by consensus at the CDPH site we are going to take a 15-minute break. I have 12:08 so we will be back on line speaking in 15 minutes.

Dr. Davidson: I am actually sorry, I have an obligation to be teaching at UCLA this afternoon so I am probably not going to be at the rest of this meeting but I will finish looking at the slides.

Dr. Bommer: I think what I will suggest today, because we do have people who are in absence, if we take a definite vote maybe Tony could put that out on line tonight so those votes could be registered from all of the individuals.

Dr. Davidson: The slides are very nice and useful.

Dr. Fehrenbacher: Do we have any public comments so far, anybody out there?

12:17: 15-MINUTE LUNCH BREAK

12: 36: RESUME MEETING

Dr. Way: We are going to go ahead and start again. Dr. Li is going to go ahead and present now.

Dr. Li: Let's talk about the risk adjustment. This is limited to calendar 2011. Again, we took the AOC members' recommendation, not just looking at the in-patient mortality but also the emergent transport for CABG. For 2011 we had 30 cases of death and 4 emergent transport for CABG. Composite outcomes are 34. The rate observed is 2.6%. The risk factor we considered into the risk model are demography, prior PCI clinical condition, and prior PCI lesion risk. The model is a multivariable logistic regression.

Dr. Way: Do you want to give the slide number?

Dr. Li: The slide number is 45. This slide is talking about the risk factor prevalence and the relationship with the composite event. As we can see, in this table age is a significant risk factor without adjusting for other risk factors. The P-value is 0.011. P-value of less than 0.05 we consider a statistically significant risk factor. In this sense, gender, race, and BMI we did not see a significant difference. Slide 46, all the risk factors listed here are significant risk factors. So PCI status, as you can see the emergent/salvage case we had 35% of the prevalence but 5.36% of composite event. Compared to the elective urgent where we had less than 1% of composite events the P-value is less than 0.001, so it is very significant. The next one is STEMI. STEMI cases in our data set for 2011 accounts for 31.8%. The observed composite event rate is 5.01% compared to non-STEMI where we had 1.3% of composite event rate. This variable is a significant risk factor. Then we have a GFR. The stage classified as 3, 4, and 5 had a significantly higher composite event rate 4.92. Compared to stage 1 and 2 the statistics shows significant with P-value 0.0025. The last one is cardiogenic shock. We had a prevalence rate of less than 4% but the composite event rate is close to 30%. You can see the P-value is very significant. On the next slide, slide 47, the NYHA (New York Heart Association) Classification 4 we had 4.7% cases prevalence, but the mortality and emergent CABG is close to 16%. Very

significantly higher compared to NYHA Class 1, 2 and 3. Heart failure, also a very significant risk factor. The prevalence rate is 22.6% but the composite event rate is 4.58. So this is a significant risk factor. And diabetes is not. Also prior PCI.

Dr. Fehrenbacher: The P-value of 0.089, are you comparing no diabetes with non-insulin-dependent or no diabetes with insulin-dependent?

Dr. Li: This is among all three. There are multiple comparisons. It is not a contrast, this one contracted to another. Okay, next slide is 48. Among the 1, 2, 3, 4, four are risk factors CVD, peripheral artery disease, lung disease and IABP. The last two, lung disease and IABP are significant risk factors without adjusting for other risk factors. Now on slide 49 every risk factor listed here are significant risk factors. The first one is the left main stenosis. We had 2.6% of cases of a left main stenosis more than 75% stenosis but the composite event rate was up to 7.14%.

Dr. Richardson: Are these protective left mains that you are talking about or unprotected left mains, and are unprotected left mains acceptable for the protocol?

Dr. Li: This one is based on the definition from NCDR.

Dr. Bommer: Yes, they are allowed in the protocol. These could be protected or they could be unprotected.

Dr. Fehrenbacher: Unprotected left mains without an acute event are not allowed in the protocol. If you have elective cases that are unprotected left main they are not allowed to be part of the protocol.

Dr. Bommer: We have high lesion risk and we have high patient risk. You cannot be high lesion risk and high patient risk. Those are not allowed. But you can be high lesion risk in a stable patient or you can be just high patient risk in an easy lesion risk, so those are allowed. It has to be a stable left main without high lesion risk.

Dr. Li: So the LV ejection fraction, we have a little less than 6% prevalence for the PCI cases with less than 40% ejection fraction, but their composite rate is up to 9.74%. Compared to those equal or over 40% ejection fraction this is a significant risk factor here. Lesion complexity high C. We had 33.8% prevalence and with 3.83% of a composite event rate. Compared to other non-high C lesion where we had a 1.8% composite rate this risk factor is significant without adjusting for others. Thrombosis is also a significant risk factor here. We had a composite event rate 4.69 compared to 1.5, that's no thrombosis and the P-value is less than 0.0001. Pre-procedure TIMI flow of zero, we had 27.8% of prevalence but the composite event rate was up to 5.32%. Compared to the reference group with 1.38% of composite event rate this risk factor is significant. Now, when put those risk factors into a multivariate the logistic regression model, which we pick the composite event rate as the dependent variable and all the risk factors we just saw as the independent variables. We actually ran this three times. The first time we ran it was for Parsimonious Model. We identify whether or not a risk factor is really significant when adjusting for other risk factors. This model only contains significant risk factors which are six variables. Later on we select all significant risk factors in the bi-variable analysis in the prevalence table we just saw. We put them together and ran this risk model. Then later on, in step three, we considered the first one, the second one, and combined the significant risk factors plus some risk factors not statistically significant, but clinically make sense. Now we have 11 risk factors in the final model. I call this the refined model. So in this refine model we have three significant risk factors. Those significant risk factors all had an adjusted ratio of above two. They are cardiogenic shock, chronic lung disease and ejection fraction less than 40%. Why we select this model is because they have the highest discrimination power. The Parsimonious model with six significant risk factors only had statistic of 0.885 but the refined model has 0.894. I have not seen any PCI model as good as this even though we only have three significant risk factors here. For the data collaboration task we did a Hosmer-Lemeshow test which is to compare what we predicted and how many composite events we observed. The P-value larger than 0.08, that means the predicted matched what we observed. As you can see, most models have a good data collaboration test.

That is why we select the highest statistics on that refined model. Using the refined model, we computed expected mortality for each hospital. The first column is the number of hospitals, the first row shows all six pilot hospitals. For the year 2011 we had 1,309 PCI cases and the composite measure, as we saw before, it is 34. So, it turns out the observed event rate is 2.6 so this is the benchmark. Every hospital will compare to this. Now, we can see hospital one, this hospital had 378 cases and four composite events so it came up to 1.06% observed event rate. Using the model, we have an expected rate of 1.57. Risk adjusted rate is 1.76. So we calculate 95% confidence interval of this risk adjusted event rate is between 0.48 and 4.5. This confidence interval covers the overall pilot rate of 2.6%. That is why there is no difference. By the same token, we checked everybody, all six pilot hospitals. As you can see, we do not see any outliers, no better and no worse outlier when we used the PCI composite outcome measure. The next slide 53, the outcome measure is limited to STEMI excluded. For STEMI excluded, we had 900 cases for 2011. Among the 900 STEMI excluded cases we had 12 composite events. This turns out to 1.33%, much lower than all PCI cases. That means the benchmark bar is lower. For hospitals it may be a little bit harder to pass. As you can see, the first hospital, 320 cases, one composite event for STEMI excluded, an observed event rate is 0.31 and expected is 0.81. The risk adjusted is 0.5. There, 95% confidence level is between 0.01 and 2.88. They are covered the state average, 1.33, so no difference in the performance rating. However, hospital number three, they did 68 cases STEMI excluded, four composite events. The observed rate is 5.88 but the expected rate for this hospital is less than 1%. The risk adjusted rate is 9.1. The 95% confidence interval is between 2.47 and 23.24. As you can see, this is about state average, 1.33. This hospital is listed as worse outlier.

Dr. Fehrenbacher: I am sorry; I guess I do not understand the statistics here. The 95% confidence interval for risk adjusted rate for hospital three should be from 2.47 to 23.24 but 9 is between those two?

Dr. Bommer: The 1.33 is not between.

Dr. Li: This one is compared to this.

Dr. Fehrenbacher: Why is it compared to that?

Dr. Bommer: Our projection is they are statically above the average for the PCI-CAMPOS.

Dr. Fehrenbacher: Okay, I see that now, thank you.

Dr. Li: Next slide 54, we are not talking about hospitals, we are talking about the operator, so that is the physician. We have six hospitals doing the pilot PCI but we have 45 physicians doing the procedures. Instead of listing one by one, the PowerPoint would be very busy, so what I listed here is a summary. Observed event rate among 45 operators for all cases for 2011 the mean is 4.91 but the standard deviation is pretty high, 15%, so that variation is very high. As you can see, minimum is 0 but the maximum is 100. That means there is at least one physician who did one case or two cases but all had a composite event, actually one. So the expected rate for these 45 operators, the mean expected event rate is 2.72 and the standard deviation is not too high, it is 2.14. The range is as low as 0.47 and as high as 11.7. Risk adjusted rate for the 45 physicians, the mean is 3.47 a pretty large variation with a standard deviation of close to 9%. The range is between 0 for some physicians who never had a risk adjusted rate of 0 but a high of 48.87%. The volume is a bigger variation. We had one case with one physician and that one case actually had a composite event. Volume-wise, there is one physician, I think probably is a board member, and the highest of 262 cases for that year. Overall, using the state wide, remember for that year is 2.6% composite rate. We have calculated 95% confidence interval of risk adjusted rate for each of the 45 operators. Now we say two worse outliers. One outlier had a 12% for risk adjusted event rate. Another one had a 30% risk adjusted event rate. Those two physicians were identified as the worse outliers.

Dr. Fehrenbacher: Was one of those operators the one who did one case that had a complication.

Dr. Bommer: No it wasn't.

Dr. Li: Yes, but not that one, because the one case you hardly can conclude that. The statistical testing, that is why we compute 95% confidence interval. You have to do a fair amount of cases in order to be rated as worse or better. This one is for STEMI excluded. Also, for the operator. For STEMI excluded remember that number 45 is down to 36 physicians. Among the 36 physicians the mean observed event rate is 2.02. The rate is between 0 and 33%, one of the three. The mean expected rate for 36 physicians 1.84 and the range is between 0.45 and 19.68.

Question: On slides 54, it says that the median number of cases performed per physician is 11, is that correct?

Dr. Li: The question is on slide 54, volume, we are talking volume. The median is 11.

Question: Does that mean that the interventionalist performed only 11 cases?

Dr. Bommer: That means half did more than 11 and half did less than 11.

Dr. Li: Right, 50% of the 45 physicians performed more than 11 cases.

Dr. Bommer: Now realize that many of these physicians cycle into one of these hospitals for just one or two cases and do many of their cases at another hospital. So this does not reflect their overall volume, it reflects the median for them cycling into a PCI-CAMPOS hospital. That is true, we have a number of physicians of the 45 who only do a couple of cases when they are covering for STEMI coverage for that hospital.

Dr. Li: We are back to the slide 55. With 95% confidence interval we calculated for each of the 36 physicians and compared those to the statewide STEMI excluded composite event rate, which is 1.33, remember that. We found one worse outlier and this outlier had 12% of the risk adjusted event rate. The next slide 56 is talking about the relationship between total PCI volume and the composite event. On the left-hand side we have six pilot hospitals. We examined the volume-event relationship in terms of observed, expected, and risk adjusted rates. As you can see, the P-values are all larger than 0.05 so we do not see a significant relationship between volume and the composite event rate. However, we did see the coefficient is negative. Generally speaking, even though statistically it is not significant but higher volume did a better job. On the right-hand side are the 45 physicians. If you see p-values, none of them are showing significance but we see the same direction. High volume had the less observed, expected, risk adjustment composite event.

Dr. Jain: If the volume is not accurate of the operator, how can we say that this is related to the volume, the risk adjusted rate?

Dr. Bommer: This only reflects the volume at the PCI hospital. We do not track volume at other hospitals. In this analysis this only relates to within the PCI-CAMPOS data set.

Dr. Li: Does that answer your question?

Dr. Jain: Yes it does but if you are going to study the relationship of volume to the risk event rate then for this study I understand, but as a whole it does not reflect whether it is really true that volume is related to.

Dr. Li: This is a limitation of the study, I guess. We do not have the information of how many PCIs those physicians have done in other non-pilot hospitals. The next slide is 57 showing the relationship between STEMI excluded PCI volume and a composite event. As you can see, the P-values on the left-hand side for hospitals or the right-hand side for operator, none of them are significant relationships. I just wanted to

summarize what we have seen. Statistical analysis summary on slide 58: (1) in terms of case mix and observed mortality we did not see a significant difference between the PCI pilot and the PDD non-pilot hospitals. Dr. Bommer did an excellent job to present the first part of this statistic analysis, the comparison between pilot hospitals and non-pilot hospitals. (2) PCI-CAMPOS risk adjusted composite event – there is no significant outlier hospital for overall PCI composite event. Rather, we see one worse outlier hospital for STEMI excluded PCI composite event. There are two worse outlier operators for overall composite events and one worse outlier operator for STEMI excluded PCI composite event. (3) No significant relationship between hospital or physician PCI volume and the composite event. That is what we have found so far. There is the last slide 59 regarding PCI patient transfers to CABG. For the calendar year of 2011, we had 16 cases with one death.

Dr. Way: Any questions?

Question: Were any of the poor performing physicians on the overall measure, STEMI and non-STEMI cases – were any of them high volume or where they all what you would call probably low volume, say below the median?

Dr. Li: Median. They are not high volume physicians.

Question: And you say that based on all their hospital experiences, you know the total volume that they are doing, albeit even in multiple hospitals?

Dr. Bommer: One of the operators was pretty close to our median for procedures within PCI. The other one was lower volume. They only came in for a limited number of cases. One operator was very close within 10-15 of our median for number. It was a median operator number, the other one was a lower volume, but again covering from another hospital.

Question: My question did not relate to the volume outcome relationship, more to the reliability of the results with low volume surgeries, that was the basis of my question.

Dr. Bommer: The median one would be more reliable.

Comment: Right, I agree.

Dr. Sundrani: What is the range of the data between the operators? For my knowledge I want to know. You said one guy did just one case but what was the highest number of cases performed by any operator? Do you know?

Dr. Bommer: 262 is the maximum and one would be the minimum.

Dr. Sundrani: 260 maximum out of the 45 operators. Do you know how many were over 100 cases?

Dr. Bommer: We showed the distribution for hospitals but we did not really show a distribution for operator. We can include that next time. But, remember for each of these operators it's only perhaps a small segment of the number of PCIs they do that we have access to their data.

Dr. Sundrani: You are exactly right because we have eight operators in my facility and most of them are at that median number. One of them is over 100 but most of them are at the median number because most of their volume is in other facilities.

Dr. Bommer: Right. We have no access in this current PCI program to access that data.

Dr. Bommer: Now the next section I am going to introduce is Dr. Suresh Ram who is going to present information that was additionally collected about things like the indications for doing the PCI, whether they have positive exercise tests, some of their testing that was done for renal and other areas as well, and some of the medicines that they were on at discharge.

Dr. Karmarkar: I have a question going back to the copy. We talked about operator volumes. When the program was launched all operators were vetted and their previous experience was reviewed in order to qualify for the PCI-CAMPOS program. Are there any thoughts or plans for continued assessment of the operators and try to get their volumes from other facilities? Maybe most of the operators have a significant volume outside the PCI-CAMPOS program, and is there any value to that?

Dr. Bommer: Dr. Karmarkar's question was how about the initial vetting. The initial vetting requires 500 lifetime cases before they be entered into the program. This is a short-term program so we have not really changed that rule so it's still 500 lifetime cases to get into it. That vetting is done mostly by the PI at each pilot hospital providing that data from the other ones. So if the PI at the hospital is satisfied that they met the 500 number, then attest to the fact that they are doing the minimum number that was required in the bill, then we accept that. We have not tried to re-audit those numbers because it would be relatively difficult to go to all of the outlying hospitals and try to come up with that information. I think it would be a really large step to undertake.

Dr. Fehrenbacher: One of the questions that I might have would be of the two individuals how many qualified for elective PCIs? That is, in order to qualified for elective PCI you have to be doing 100 per any rolling 12-month period of time. So we agreed that you can do STEMI's at an individual hospital if you did less than 100 but you couldn't do the elective cases. One of the questions I have is of the two operators were they listed as elective operators?

Dr. Bommer: One of the operators was truly listed as an elective operator.

Dr. Fehrenbacher: And the other one probably did not make the 100?

Dr. Bommer: And that individual I can tell you did more than 100 cases in a year. So they did meet those criteria.

Dr. Fehrenbacher: May I ask one other question? The other question is: We as a committee, we need to decide whether we continue with a mortality that is significantly higher for a given hospital or should we make any sort of recommendations? Should we have that discussion today? What is your recommendation?

Dr. Bommer: I would suggest we finish the data presentation and then we open it up for discussion including any potential changes you might want to make or introduce any motions. Then the motion would be open for discussion. As we talked about before, if we can't get total consensus we may want to go to a written vote that Tony could survey the members who are not here.

Dr. Fehrenbacher: I have a question about that. Can you have a vote outside the meeting that is internet based or telephone based and still comply with the Bagley-Keene.

Dr. Bommer: I think that's Dipti that is coming through, you need to mute your loudspeaker there.

Dr. Way: Well, technically we could do polling and then we could present it at the next meeting. Then that would bring it into the purview of Bagley-Keene. I think that is a good point because I do not think that should stop us now if you want to go ahead when we finish this. Don't forget you have two items.

Dr. Fehrenbacher: I have two items.

Dr. Way: Well, we ran out of time last time.

Dr. Bommer: Just so we continue at this point, Dr. Ram is going to present some information about the quality metric measured during PCI-CAMPOS.

Dr. Ram: We are on slide number 60. These are basically dealing with the quality metrics for postop medication use. Just make a note, the date ranges are changed on these slides. It is actually from August 1, 2010 to December 31, 2011 which includes all of the data that has been audited and locked down. The three medications we looked at are aspirin, the thienopyridines and lipid-lower agents. Aspirin for the pilot study came out as 91.0% which actually fell outside of the 25<sup>th</sup> to 75<sup>th</sup> percentile compared to the NCDR reports. Thienopyridines result was 99.8 which actually fall at the 75<sup>th</sup> percentile. Lipid-lowering agents were 89.1 which also fell within the range of 25<sup>th</sup> and 75<sup>th</sup> percentile. Going on to slide 61, which is Quality Methods continued, this slide involves stress testing prior to procedure in elective PCI patients. The various totals are here but the important one that we looked at was positive stress test prior to elective PCI. The total came out to 59% which fell right around the median percentile for the NCDR data. Slide 62, we looked at the median time to immediate PCI for STEMI patients and this is in minutes. As you can see, the total for all six pilot hospitals was 69 minutes which fell just outside of the 25<sup>th</sup> to 75<sup>th</sup> percentile for the NCDR data. The proportion of STEMI patients receiving immediate PCI within 90 minutes was 84.1% for all sites and that also fell outside of the 25<sup>th</sup> to 75<sup>th</sup> percentile for NCDR data. Emergency CABG was 0.4% for all six sites which was right at the 75<sup>th</sup> percentile. Acute kidney injury was 4.0% which fell outside of the 25<sup>th</sup> to 75<sup>th</sup> percentile range. Slide 63, we looked at post-procedure stroke percentages. This was 0.33% for all sites which was just outside of the 75<sup>th</sup> percentile for NCDR range. Composite events which were death, emergency CABG, and stroke, the total was 3.3% which fell just outside the 75<sup>th</sup> percentile as well. Median post-procedure length of stay for PCI with STEMI in days, the total was two days. That fell within the range for NCDR. The median post-procedure length of stay for PCI with no STEMI was one day. We do not actually have a comparison for NCDR. Creatinine assessed both pre and post PCI procedure was 93.8% which is actually a little bit outside of the 25<sup>th</sup> to 75<sup>th</sup> range but this is actually better. Transfusion of whole blood or RBCs was 3.2% which fell outside of the range for NCDR as well. Slide 64, we looked at intermediate stenosis lesions which was 40 to 70% lesions and the use of IVUS. This is 5% of patients that received and the total was 9.2. We do not have a comparison. For intermediate stenosis lesions and FFR the percentage was 10.1. We also do not have a comparison. For biomarkers assessed post-procedure for elective inpatients the percentage was 46.8 which fell within the range for NCDR. Post-procedure MI was 6.5% which fell outside of the range. Slide 65 is dealing with PCI success for patients from August 1, 2010 to December 31, 2011. The total number of patients was 1,806. The total number of lesions that were treated was 2,457. The number of lesions where the guide-wire made it across the lesion is 2,407. The important parameters here post-procedure stenosis which was less than 20%, we had 89.7% of the patient in which that was achieved. Post-procedure stenosis that was greater than or equal to 20% was 10.3%. Post-procedure TIMI flow of 3 was 93.1%. Cases in which both less than 20% stenosis and TIMI 3 flow were achieved was 87.1%. Going on to slide 66, we are now looking at the transfer costs for the pilot hospitals. Hospital one had an average cost per transfer of \$1,106.00. Hospital two had an average of \$2,036.00. Hospital three has a fixed rate and that is \$819.00. Hospital number four has an average rate of \$342.00. Hospital five has an average of \$2,190.00. Hospital six is \$925.00.

Dr. Bommer: Are there any questions on that Quality Metrics?

Dr. Forman: Can you go back to slide 61 for a second? On the bottom line you've got a total elective PCI of 305 but on the top line you've got the number of elective PCIs at 309, so they don't match. With that being said, is that a positive stress test involved in total elective PCI or any stress test involved?

Dr. Ram: Positive.

Dr. Forman: So 130 patients had no stress test prior to an elective PCI? The last row, stress test to elective PCI is only 59%, so 40% of patients have gotten an elective PCI and the study did not have a stress test at all, or had a stress test and it was negative and still got an elective PCI?

Dr. Bommer: Okay, so 179 patients had a positive stress test of the 305, they had elective PCI. So the ones that didn't have a positive test could have had a negative test or could have had no test.

Dr. Forman: Right, I just wonder what was the indication, and you probably can't answer, it is 40% of the patients had no evidence of ischemic but got an elective PCI anyway. Doesn't that seem like a large number? They are elective cases so they don't have a positive troponin, they weren't admitted with unstable angina, so they are seen in your office, you got a negative stress test and you cath them and angioplastied them?

Dr. Bommer: To answer your question, that is exactly what it is nationally because you can see that the NCDR averages 60% and we are at 59%. We're dead even with national and the range nationally is 49 to 71%.

Dr. Forman: Do you make anything out of that though?

Dr. Bommer: That we are within the benchmarks for the national number. I would expect that you are going to see those numbers ratchet up because a lot of the reimbursement is going to be based on having an abnormal stress test or FFR prior to getting an elective PCI. If you look at the benchmarks that we've been following nationally, they have been going up. So, the expectation is those would continue to go up.

Dr. Karmarkar: I share your concern. From my perspective, the five consults I saw in my office in the last week for coronary syndrome, one I admitted, four were referred for elective cath, three ended up getting PCI, and one got bypass surgery. No stress test but very compelling symptoms when I saw them for consultation. As I said, I ended up admitting one patient and did elective. So, that could be subcategory of the patients who had no positive stress but the symptoms were so compelling. Again, it could be a very small number so I don't think they are necessary all negative stress tests and still get elective PCI, some could have just very compelling symptoms. But, I understand it is a small number.

Dr. Bommer: You may realize we have actually changed the language at the ACC. This is so-called appropriate use criteria. We have actually changed that language. We used to have inappropriate and it is now appropriate, may be appropriate, and rarely appropriate in that situation to handle it. There are cases where somebody comes in and they so clearly have coronary disease you need to go the cath lab. They clearly have a lesion that needs something to be done at that point in time. So, it is understood that no one will be 100% on this. I am now on slide 72 of your slide set. The title is summary slide number 1. In summarizing this, you can see that the total enrollment was 2,601 patients in the first two years of this trial. This is the first two years of the PCI-CAMPOS, 2,600 cases were enrolled. Our minimum expected was 2,400 so we did meet the minimum number for that. Hospital enrollment varied from 97 to 390 cases per year during the first two years. There is quite a range, almost 4:1 range in enrollment between hospitals. The success rate, and by that we're going to define that by NCDR criteria, as less than 20% residual stenosis, was 89.7%. Success rate defined by TIMI 3 flow or greater was 93% post-procedure. The 2011 mortality, which is the last calendar we have to look at in total, PCI-CAMPOS mortality was 2.55% and the PDD pilot data was 2.66%. Remember, that is a calendar year, slightly different than the numbers that we showed you earlier. The PDD pilot hospitals was 2.66%, the PDD non-pilot hospitals, that is the rest of California, was slightly higher at 3.02%. You can see that our PCI-CAMPOS data and the PDD data on our same six hospitals is fairly close at 2.55 to 2.66. Remember that there are slightly different selection criteria in coding in this, and that probably explains that variation. But, either way, for 2011 it appears that we are slightly lower than the rest of the hospitals in California in the PCI-CAMPOS population overall for mortality. Summary slide number 2 which is slide 73 in your set as was discussed for the risk factor models. We came out with

significant risk factors in this population including age, presence of shock, PCI status, the GFR, New York Heart Association, congestive heart failure, chronic lung disease, intra-aortic balloon pump, TIMI flow, ejection fraction and the complexity C lesion for the anatomy. Using that stepwise three, a risk model was set up for that as explained by Dr. Li. That was very well predictive with a very high C statistic that meant that this was a very good way of predicting expected risk for this population. The 2011 total composite was higher than mortality because we now include CABG emergency at 2.6%. In that analysis there were no hospital outliers. There were two operator outliers that were mentioned previously. For the 2011 total data, the composite events, if we exclude all STEMIs, meaning these are the non-STEMIs or the elective cases, the event rate was much lower at 1.33% with one hospital and one operator outlier in that data set. The next slide number 74 looks at compassionate use. Compassionate use identification significantly raised the mortality in our group as would be expected for Massachusetts data. If someone comes in with one of the compassionate use indicators then that was 56.25% mortality in our data set for the last year when it was in operation. There was correlation but no significant correlation between composite event rate and volume number of procedures done by hospital or by operator. Again, it is not yet shown to be statistically significant for that. But, as was mentioned earlier by Dr. Li, there was a trend that higher volume operators and hospitals seem to have a somewhat lower event rate. For the PCI-CAMPOS quality metrics, we identified stress testing, emergent CABG, length of stay, creatinine and biomarkers and were all within the benchmarks that we have chosen. That is, the NCDR national 25<sup>th</sup> to 75<sup>th</sup> percentile. Some of the benchmarks were close to those benchmarks but slightly outside of those boundaries. They included the medicines that were being given including aspirin, they included door to balloon time, they included acute kidney injury, stroke, the composite of stroke, death or MI, and transfusion use in post-procedure myocardial infarction. Those parameters were perhaps close to the markers of 25<sup>th</sup> to 75<sup>th</sup> percentile but they were outside of those markers for the period of time from the beginning of the trial of 08/01/10 to the end of where we had data lock down at 12/31/11.

Dr. Forman: What criteria are you using for the post-procedure MI? Is that CPK five times normal?

Dr. Ram: It is biomarker positive so it would be, troponin, or. . .

Dr. Forman: Yes, but how much troponin elevation are you using?

Dr. Ram: Three times.

Comment: The latest guidelines suggests five times.

Dr. Bommer: The latest guidelines have changed and will be changing but we are still following the NCDR until the NCDR officially changes.

Dr. Fehrenbacher: So if it is 0.04 and it goes up to 0.15 it is a myocardial infarction?

Dr. Forman: That's my question.

Dr. Fehrenbacher: Yes, the answer is yes.

Dr. Bommer: Currently yes, but I do know we have the new guidelines. They just have not been implemented in NCDR yet.

Dr. Forman: Are you using the particular hospitals' range for upper limit of normal?

Dr. Bommer: Yes. We found one of those hospitals actually changed or corrected their range in normal so we had to go back and actually re-change some of the data. The original ones reported to us in writing turns out not to be true. That is summary number 3.

Dr. Jain: Does the volume in any way relate to this different than you see in the NCDR data that appears slightly outside the NCDR 25<sup>th</sup> to 75<sup>th</sup> percentile?

Dr. Bommer: We don't have that analysis. As to whether on each of those quality metrics if we're outside mean is it high volume, low volume, operator, or hospital? I don't have that analysis. That actually concludes the data presentation that we have. I have two other slides to go through. One is the NCDR. As you know, at our last meeting there was a vote taken to go ahead with acquiring the NCDR California Data Set. The progress on that is the following: We did negotiate with ACC to acquire the NDCR data set for the whole State of California of all hospitals that are currently using the PCI-CAMPOS Data Registry. Because we do not have individual hospital consents for that, we have to do it in a select way. That means we suppress certain elements, we mask or recalculate certain things. We cannot identify literally the name of the hospital or the name of the patient in that case. So we back-calculate certain ages, dates and stuff like that to make sure we are blinded to who that is. We can identify that they all come from the same hospital, we just can't tell you what that hospital is, where the zip code is, or even whether it is in northern or southern California to be appropriately blinded to that data to stay in line with the contract that NCDR has with every individual hospital. We signed the contract in June 2012. The pilot hospitals CDPH sent out invoices to the pilot hospitals to cover that \$50,000 cost. The NCDR data sample set was uploaded on the internet on 08/27/12 and a month later we were able to confirm, review that, accept that, and approve that as an acceptable transmit form for that particular data set. We expect that on 10/19/12 or in another two weeks that that California Data Set will be uploaded to the site where we can then download it at that point in time. For the first time in two years we will now have access to the NCDR clinical data set that will free us from having to rely on the patient discharge data which is a more limited administrative data set. Hopefully this gives us the very highest quality comparison, hopefully "apples to apples", at least the same type of data set for California as for us. Now, not all hospitals in California actually are in the NCDR. I think it's about 128 hospitals right now, but it's almost all of them but not 100%.

Dr. Way: Well, there are 100 in and 50 are not. So that means 1/3 are not in there.

Dr. Bommer: Yes. But they are usually the lower volume hospitals and things like that. It's the best we can do so that we can compare the same data set acquired with the same definitions. We will have that a little bit later this month. That brings us to what are our plans at this point in time. We certainly are trying to continue to work with each of the hospitals to support volume. We feel that volume is an important issue. If we're going too low of volume that will in fact jeopardize the statistics and it may jeopardize in fact the results. As we said earlier, there is a trend that lower volume might be a problem with some of these situations. We would like to continue to support hospital volume for that. There is a variation as we mentioned earlier. There are some outliers. We need to review that performance variation. We would like to get all of the hospitals for the variation to be less, meaning they are all performing more similar rather than dissimilar at that situation. We certainly are going to review with our data in our hospitals ways of trying to get the entire herd, let's say, closer together. We have referred outliers, that is both hospital and operator outliers, to the hospital CQI committee. We don't have any further way to go into the cath lab and say what happened in this case, etc. But we think it is appropriate for hospital CQI to actually review those cases and see if there was anything that could be modified for continuing quality improvement in that particular situation. It is also up to the AOC if they decide any further steps need to be taken in that direction. We will review CQI implementation. That was part of the bill that hospitals should have a CQI program. We are going to begin reviewing to make sure there is a process ongoing with each of these six hospitals for continuing CQI review and action plan. We would like to reconsider public disclosure. We talked about it last time. The reports we have given you so far are confidential to actually the identification of any operator or hospital. I think we would leave them confidential to operator but there may be a time where the AOC or the state decides that it may be reasonable to release this data for individual hospital performance. I think it is something to consider in discussions later on. We are in the process of acquiring the California NCDR Data Set and we will have in two weeks. We are looking forward to that. We want to work on, let's say, early publication so we need to

start putting together a process of developing a publication that would reflect the results of the PCI-CAMPOS program. We would like to consider the use of an AOC member, which is a member on this committee, as perhaps a reviewer for angiographic status. So we are always looking for individuals to review angios. We have 3,000 angios to review by two observers, etc. I know everybody is busy and does not have time for it, but we have identified individuals on the AOC who have said they would be willing. We would pay them to review some of those angiograms. We will bring it up as to whether a member of the AOC could serve as an angio auditor in the trial or is there a conflict of interest. The next item is talking about a transition plan for the PCI-CAMPOS Program. That relates to the following: PCI-CAMPOS Program that we know today, and by legislation, the legislation that authorizes it ends at the end of 2013. The contract between CDPH and UC Davis for enrolling patients actually ends August 1, 2013. That means for all of the hospitals that have ramped up to a value of approximately 200 patients per year with active labs, with coders intact, all in service, etc. with nurses, with labs going full tilt, technically either August 1, 2013 or at the very latest December 31, 2013 by law or by contract would now have to ramp down to zero for elective cases. And, going to zero until the report can be finalized, which is going to take several months, three months we estimate or so, as a minimum to get all that data locked down and everything else. Then go to perhaps the final report from CDPH, gets sent to the legislature, sits at the legislature, gets reviewed there. Then the legislature decides whether they want to write a new bill that would be a follow-up or not. That would have to be authored, it would have to go through committees at capital, and then following that there would be a vote. Following that there would be perhaps a signing by the governor and at the end of the year there would then be an up or down for that. We estimate that period of time at roughly 18 months but it could take 24 months for that entire process to go through. What we are looking at is a transition plan. At the end of our contract (or at the end of the statute) instead of going to zero, staying at zero for a period of time, and, if approved, it then has to ramp up to 200 again, it is going to be difficult to keep all of the staff and people on line, trained and paid to accomplish that. We are looking at a transition program. I have met with the California Hospital Association, the California American College of Cardiology, and the California Medical Association and what has been proposed is an extension of the current PCI-CAMPOS program. As it is now, it would be an extension of it for anywhere from 18-24 months or until the legislature makes their final up or down vote of whether PCI at hospitals without onsite surgery is going to be allowed, continued or modified at that point in time. To do that, I have the consensus of the groups that I have talked about for that. We have taken votes. We have legislators who are interested in authoring that in the Capitol right now. They require finishing the elections first before they can concentrate on it. That potentially could take place in November of this year to sit down and write the language for an extension bill that would cover the transition to where we go next. It would merely be an extension of the existing program as we know it now at that point. To facilitate that, we would be looking for potentially a motion to be introduced at the AOC whether AOC was in favor of continuing in that line or not. We would also be interested because I have ACC, CMA and CHA approval for that. That is my final presentation here.

Dr. Fehrenbacher: I would say that overall I think we should continue, but the question is in what form we should continue it? In August 2013 do we need to continue angiographic monitoring? Do we need to submit the NCDR reports that we currently do or should we do it through the PCI-CAMPOS process? Are we going to continue with the same level of intense statistical analysis that we are doing now or will it be a looser analysis to get us to the final product?

Dr. Way: Something that I have learned working with the state, the easier you can make it for the state to do something the better chances you will have of getting it done.

Dr. Fehrenbacher: So, before we make a motion I guess that is one of the thought processes we should go through, exactly how we would want this to continue. We could continue it exactly as we are now with the exact same analysis as we are doing now, or we could have some different requirements such as the AOC could continue to meet, it could continue to look at NCDR reports to make sure there are no outliers.

Dr. Forman: I think that probably depends on Dr. Bommer and his staff once this ends whether or not you

would be willing or able to continue to monitor the data to the same level you have been doing so far.

Dr. Bommer: The question for that is obviously (and that is why I presented some of the audit stuff) part of this process and part of the expense is those onsite audits where we're reviewing angios, we're sending people out there, etc. where we detect as high as 40% of those are different risk adjustments, etc. That is part of the process. Meetings with CHA (California Hospital Association) and others they did not feel comfortable enough to say okay, now this can be opened up for everybody. They were of the idea that they would support a bill if it continued along these lines as well as California ACC. In other words, we don't yet have enough data to say this is free for everyone to do without monitoring. They wanted to continue it with monitoring. Now the actual bill is dependent on the committee in the assembly in the State of California of writing and passing. It really is not any of us who get the vote on that actual language in the bill, but at least CHA and CACC were more inclined to say not rock the boat, lets continue it the way it was, that's the least changes because it really just extends SB 891 the way it was originally written and we're not rewriting the language for inclusion criteria, monitoring or anything else. We're just continuing it the way it was. They thought that was the simplest way, as Tony eluded to, to continuing it, we are not really changing the project in mid-course, we are continuing as it is right now.

Question: So Steve's question I think is are you and your staff willing to do that, do you have the funding to do that? That is clearly the simplest thing to do. Can you do it?

Dr. Bommer: We can clearly do that.

Dr. Way: The funding for this project has been borne entirely by the six pilot hospitals including obtaining the NCDR data. Perhaps it would be something your hospitals would like to do or not do. I suppose they could look at it as a cost benefits analysis for them because they may or may not make more money by being able to do these procedures than they would if they were not able to. I think that was probably a selling point. I do not know the details of that when they originally signed up for it. If they would be willing to agree to have the licensed fees that we charge them added to the same ratio, the same amount of money that they are getting now to support this extension, if they were allowed to do that this would again make it simple. If the legislature passes it that way and it is in the original bill that the cost would be borne by the hospitals having the licensing fees increased to cover it.

Dr. Bommer: I have talked to the CEOs of each of the six participating hospitals and I have letters from each of the six hospitals that they would be willing to continue under the current program to extend it. Each of the CEOs has agreed to do that and to continue it in the current process. I have letters from each of the six hospitals.

Dr. Forman: You mentioned the 200 cases per year, per hospital. And if you look at the list, three of the hospitals don't make the 200 per year. On previous meetings we determined that the language of the law was a little bit murky, but then it worked out that the 200 cases could be disbursed over the three years of the pilot program. Well, if you are going to extend that do the 200 cases then spread out?

Dr. Way: The way it is written in the original language at the senate bill is that by year two 200 cases per year will be the goal and will be expected of each hospital. Our attorney said, it doesn't say where in the second year. We always think at the beginning but it's not, it could be any time.

Dr. Forman: I thought we determined that it was not that we needed a total of 200 cases each year.

Dr. Way: 200 by the second year.

Dr. Bommer: By year two is what the language says.

Dr. Way: That is the way it is in the bill. That would not need to apply because this is a two-year extension. There is no reason to have a number in there.

Dr. Bommer: As far as I can see, the language would be to extend SB 891 an additional 18-24 month period, not changing anything else. As far as the enforcement of that number, that is actually up to CDPH and the AOC how they want to develop that, etc.

Dr. Way: In the original bill it says by year two they will be at 200 per year.

Dr. Bommer: So I think we could consider that a separate issue as to how you want to operate on that.

Dr. Way: But year two will be long gone.

Dr. Bommer: I have stepped back from that.

Dr. Way: I can run it by the attorney again.

Dr. Fehrenbacher: So in actuality, even if we do extend SB 891 as is, we don't have to decide now whether to continue onsite reporting or not because the original SB 891 never really talked about onsite reporting, it was something CDPH was in charge of essentially. Therefore, as far as the law goes, then we can simply say extend it and then decide later exactly the format by which we wish.

Dr. Way: I think there was a general statement that the monitoring would be done by the state.

Dr. Fehrenbacher: Right. And you contracted with UC Davis.

Dr. Way: We deferred to UC Davis to do that and so we would continue to do that.

Dr. Fehrenbacher: To monitor.

Dr. Way: Your right, that may leave an opening for changing, how do you do it, but that may disrupt your ultimate outcome and corrupt your data if you have it three years one way and two years another.

Dr. Fehrenbacher: But the report will be written at the end of three years, so at the end of three years.

Dr. Way: The end of three years is mandated in the Senate Bill so that has to be done. Doing an extension wouldn't necessarily require another report, although you think it would.

Dr. Fehrenbacher: So at the end of three years a report has to be written. That report has to be sent to the legislature and then theoretically the legislation would use that report to decide whether to permanently change the law or not.

Dr. Way: Yes, that is exactly what the law says.

Dr. Fehrenbacher: So the additional two years will really have no effect on that report.

Dr. Bommer: To answer that question, yes technically that is true. However, in the discussions with each of the groups that would support this, which are required, I should mention one other thing. To get this bill in on time so that it would have an effect August 1 or next year 2013 means to has to qualify as an urgent bill. Urgent bill requires two-thirds majority meaning that we have total bipartisan support to get this passed. CHA and CMA have advised us that they suggest and had approved that they would want to see it continued under the same monitored basis to feel sure for that to continue. Now, we can go without that but there is also a

possibility you will not accrue two-thirds of the vote of the house at that point in time and it is possible it may not get through committee if you start cutting things off of the current one. The groups that I have met with felt that they were most comfortable continuing the program as it exists now including the monitoring of it so that they could be sure that it remains safe for that period of time. We can drop that but it may drop the change that the extension bill gets passed.

Dr. Fehrenbacher: Does it have to be included in the law of the CDPH?

Dr. Bommer: No but I have to testify to them what the plans would be and if I tell them that there is no inclusion for monitoring then there may be votes in the committee that drop off.

Dr. Fehrenbacher: I am not suggesting that there would be no inclusion for monitoring but I am just talking about the letter of the law and exactly what SB 891 says.

Dr. Bommer: It is two things, letter of the law in the politics. In other words, we have to convince the committee members of both the senate and the house that this is the way to go.

Dr. Way: Since we are the people who are deciding, I would be in favor of just continuing with the way it is. As I said at the beginning, if you want something to get done you got to make it as simple as possible. Sure you have variable options but you could wind up spending years getting it done.

Dr. Jain: Dr. Bommer, we really appreciate the work that UC Davis is doing in this onsite monitoring but we are comparing data from other hospitals which don't have onsite monitoring and they are just getting the data what they want to give. Then our data is compared with their data. Do you think this will be comparable?

Dr. Bommer: Well, I can tell you that the data set that we obtained through the patient discharge data set is acquired the same for other hospitals as it is for our pilot hospitals. Joe is here and I can ask him, there should be no difference in the data that we collect from our pilot hospitals in the PDD discharge data set compared to the other California hospitals.

Joe: Well, when you say no difference that is a pretty large statement, but with regard to most of the demographic kinds of information, admission dates, discharge, patient expired, admission source discharge, destination, and those sorts of things. The patient discharge data for the State of California is one of the most widely used in the country, one of the most researched, one of the most validated data sets. We use it also to do risk adjusted outcomes recording based on only the ICD-9 data that is available and the ICD-9 procedure and diagnostic information. It is pretty good. We also run the cardiac registry also for the State of California. We do the hospital and surgeon level reporting. We routinely compare the patient discharge data to data that we get with our cardiac registry and are pretty favorable sort of comparisons there.

Dr. Bommer: The difference is it is an administrative data set so the risk analysis and adjustment that Zhongmin was able to do is really not as robust on that administrative data set as it is on a very rich NCDR data set of 240 variables vs. maybe 20 variables for discharge that they have to look at.

Dr. Jain: Our data set is double checked and triple checked because there are a number of layers that need to be checked, whereas there are other hospitals which are not a part of this study who are submitting their data and their data is not checked again for correction.

Dr. Bommer: It is not as intensely checked, right. The amount of auditing that the NCDR does is they have limited capability of doing it and they relatively rarely audit their data.

Dr. Sundrani: Do you know if out of these 150 non-pilot hospitals in California, I would presume that most of them have onsite surgery.

Dr. Bommer: 121 of them have onsite surgery, I believe.

Dr. Fehrenbacher: I think there are only 26.

Comment: 125 have onsite and 26 hospitals do STEMI only. They are not supposed to do anything but STEMIs because it is an emergency.

Dr. Sundrani: So out of the 150 we are comparing hospitals like ours to the other hospitals in that data base.

Dr. Bommer: What data base?

Dr. Sundrani: The comparison of 250 hospitals data you showed from California, the discharge data.

Dr. Bommer: Patient discharge data, we should be using about the same acquisition method for our hospitals, PCI-CAMPOS vs. theirs if we look at just the subset of patient discharge data. For the PCI-CAMPOS which is a different registry of 240 fields that is totally different from the other hospitals. However, we have about 128 hospitals in California for which we are two weeks from getting that data, which is NCDR data. Then at least the registry data and the definitions are identical for both data sets. The difference is auditing. We do auditing of 20% of our cases and they do auditing of a very small number of their cases.

Dr. Way: I would like to make a point. One of the reasons for all of this auditing and verification is that Title 22 (which is the regulation promulgated 37 years ago) prohibits therapeutic cardiac interventions in hospitals that don't have cardiac surgery, as you know. So the legislature has to be reassured because they don't know, they're not professional people; they have to be reassured that everything is okay. That is the reason that these stipulations were put in. This allows them not to have to worry about what's going on, trying to make it safe. Now, we all know, based upon what's happened here and what happens in other states, it is probably safe to do what you have been doing without all these checks and balances. We are dealing with lay people in the legislature, and I think they would want it to proceed exactly as it is.

Dr. Jain: Dr. Bommer, do you think it is worthwhile to do a study with correction and without correction of the data that is sent by the physician originally and see if there is any difference compared to the NCDR, uncorrected data? What I am saying, one is corrected and one is uncorrected data. Is it worthwhile comparing "apples to apples", if you do not correct the data that the physician has already entered?

Dr. Bommer: We can try and go back. As I said, we did identify mis-risks. Those in fact are parameters that are in our risk adjustment system. They will alter the actual risk adjustment for that. In general, it averages out but I cannot say quantitatively whether that overall there is a net up or down risk adjustment based on the uncorrected data.

Dr. Jain: Do you think it is worthwhile looking at a pilot thing to see if it makes any difference? I am just trying to see if the data that we have is really comparing "apples to apples". You are comparing us with hospitals which are not undergoing this onsite auditing. Their data is being accepted the way it is being given by the cardiologist.

Dr. Bommer: Let me remind everyone, the patient discharge data set which we had comparisons are "apples to apples". It is the same data acquisition and the same auditing of those particular individuals. We have not changed the patient discharge data set for that. That is identical and what it shows is that the PCI-CAMPOS group is, in general, very close to the rest of California and no statistical difference. That example of the same data set and the same, let's say, auditing shows no difference. To answer your questions, we would actually have to audit the 91 hospitals in California. If you are willing to do that I would be happy to go along with it.

Question: So the differences would be in the complications, like the intra-procedure complications and things like that, right? Is that in the hospital discharge data?

Dr. Bommer: There is a whole bunch of things. To extend it from six hospitals to 100 hospitals would be a relatively enormous step for this group to take.

Question: I'm just asking what the difference is in what the PCI-CAMPOS data is, is it the quality measures and the intra-procedure definitions that can make. . .

Dr. Bommer: Well, the risk adjustment, we do not have that intense or that robust risk adjustment for expected and observed rate in the PDD data that we do have in the NCDR data.

Dr. Forman: I think the data we've seen so far clearly shows that it's perfectly safe to do these procedures, yet the guidelines have changed and made this a Category 2B for doing PCI in hospitals without bypass. What I am concerned with is that if there is some way of avoiding, we're going to propose a motion to extend this for up to 24 months.

Dr. Bommer: Up to two years until the legislature makes a decision.

Dr. Forman: So the point of extending it is to give them an opportunity to correct the law. What I am concerned with to some degree is that we vote to extend this for two years the legislature then says we have two more years before we need to make a decision. So we are sitting here again in two years having to extend it. Is there any way of wording the new extension that this purely to give them an opportunity?

Comment: On an urgent basis you need two-thirds. They vote on it and they can do that right away.

Dr. Foreman: I don't want them to say we need an extra two years of data before we can make any decisions.

Dr. Bommer: The language in the bill can be that they can vote on it a week after and then it becomes law.

Dr. Fehrenbacher: I am willing to make a motion that the current program be extended with appropriate monitoring until January 1, 2015 or until the permanent law is enacted.

Dr. Smith: I second that.

Dr. Way: Wait a minute. We have to be clear about what dates the program sunsets on August 31, 2013 with 90 days allowed for the report to be delivered to the senate, which is how it is put into the bill.

Dr. Fehrenbacher: Put the CDPH can continue that until December 31, 2013.

Dr. Way: That's two years and three months.

Dr. Fehrenbacher: You could elect to continue that until December but the law states that it has to end December 31, 2013.

Dr. Way: The project ends on August 31, 2013.

Dr. Fehrenbacher: Right, but the bill says that three months later it has to end. The pilot program will be in effect until August 2013.

Dr. Fehrenbacher: DHS and the AOC may continue the program until December 31, 2013. That's what the

SB 891 says. The DHS and AOC may continue it but then it has to end December 31, 2013.

Dr. Way: So you want to make it two years. Do you want to set a date?

Dr. Fehrenbacher: Well, I guess my thought is if we give two years that should be enough time to pass the bill. If you fail the first year then you'll come back the second year.

Dr. Way: I think that's perfectly good. So you made a motion. Do you want to restate it?

Dr. Fehrenbacher: Yes, I will restate it, that the AOC recommends that the pilot program as outlined in SB 891 continue until December 31, 2015 or until a permanent bill or until the legislature passes or doesn't pass a permanent bill. So if in 2014 the legislature decides to pass a permanent bill, if we're able to muster the appropriate lobbying and we get out wording together, if they do this in 2014 then it will work. But, if we fail the first year we still have another year.

Dr. Way: You could say just extend it for two years or until the legislature decides.

Dr. Li: Can you clarify, so for this two-year extension do we allow more hospitals to be a pilot hospital?

Dr. Way: No.

Dr. Bommer: In the discussions with CMA, CHA and others I brought that up and not one of the sponsors was interested in opening this up to other hospitals until the final report for the pilot is looked at. There was really not any enthusiasm amongst the sponsors to, let's say, open this up across California because there would be very little way to monitor that situation. They felt that the report in the legislature's decision could be made just on the pilot project.

Dr. Way: There was also about a two-year runoff to get all these hospitals screened to get it down to six. I don't think we have the resources to ever do that again. We had one medical consultant full time on that for a considerable period of time.

Karmarker: I second the motion made by Dr. George Fehrenbacher.

Dr. Way: Okay, we have the motion made and seconded. Is there any further discussion on the motion? We will take a vote of the voting members of the committee. We could do it by roll call.

Roll Call Vote: Dr. Arnold and Dr. Brindis are absent. George Fehrenbacher (yes), Steve Forman (yes), William French (no answer), Dr. Itchaporla (yes), Dr. Jain (yes), Dr. Karmarkar (yes), Dr. Smith (no answer)

Dr. Way: Dr. Smith, before he left, said yes.

Roll Call Vote: Dr. Sundrani (yes), Dr. Davidson (no answer).

Dr. Way: So how many do we have?

Comment: Seven.

Dr. Way: There are 11 on the committee, I suppose that counts. So the motion is passed. I think we will send this report onto the other members to say it's passed as a majority for now.

Dr. Bommer: Okay, and just to let everyone know, this is an advisory vote which I will take to the legislators who are crafting this new bill and language just to say that the AOC supports this as well as CHA, CACC And

CMA. For that, that will be part of it. Crucial to that was thank you very much to the CEOs who wrote letters because that's also crucial to the legislatures who will be potentially crafting this new legislation.

Dr. Fehrenbacher: I wonder if you can keep the AOC members informed about the language of the bill and certainly get input, I'm certainly happy to help.

Dr. Karmarkar: Assuming that the extension is approved, will the IRB consent process undergo any changes?

Dr. Bommer: That's going to follow. That's the next session. If you want to hold on for five minutes.

Dr. Way: Are there any other questions specifically about this bill, recommendation? Dr. Fehrenbacher, you should have some slides entered into Dr. Bommer's computer if you want to present.

Dr. Fehrenbacher: Sure, I would be happy to discuss that. I think we discussed that a bit last time so we will go over the details again. There are some slides and a handout also. They are going to be short and to the point. Can I have the power guide? Basically the purpose of this is to discuss the need for local IRB approval and the language of the law in SB 891 in the pilot program. Next slide, basically page six, section 15 of SB 891 essentially says "Shall demonstrate evidence of the process for obtaining written informed consent from patients prior to ongoing elective PCI. The application shall include a copy of the eligible hospitals and informed consent form applicable to elective PCI. Evidence of IRB approval of the informed consent form will be provided as long as the ACC, AHA, SCAI guidelines categories elective PCI with offsite cardiac surgery a Class 3 indication." If you remember, years ago when this was crafted the PCI surgery offsite was considered Class 3. Recently it has been deemed Class 2B. Dr. Way had asked me to get the data for that. Next slide. For those of you who are probably not the members of the AOC, the cardiologists, but for others in the room, just to go over Class 1, 2A, 2B, 3 very quickly here. Class 1 is considered the benefits far greater than the risk, treatment should be performed. Class 2A and 2B, the benefit is greater than the risk. In 2A it means that it is reasonable to perform the procedure or administer the treatment. Class 2B would be that treatment may be considered. Class 3 has now been divided into two categories, no benefit or harm. When we started this program there was only one class 3 and simply should not be done. I was asked to get a reference for this. The reference for that is in the lower right hand corner. Next slide, in 2011 the guidelines from the American College of Cardiology, American Heart Association and the Society for Cardiac Angiography and Intervention suggested or stated that elective PCI might be considered in hospitals without onsite cardiac surgery provided that appropriate planning for program development has been accomplished and rigorous clinical and angiographic criteria are used for proper patient selection. The references for that are 352 and 354 in this body. Again, I was asked to provide those references and I have done that. Next slide shows those three references and I do not think I need to go over these. These are older references that are not as important as some of the current stuff. This is the landmark SCAI paper that actually we derived the definitions and the high patient risk and high lesion risk criteria from in this original article in 2007. There are some other studies for your amusement. Next slide. I would point out that the AHA and ACC made it a class 2B indication prior to the publication of this last article. The Seaport Trial was not included in the decision to make this a 2B indication. This is May of 2012 you can see. I am sure again all of the interventionalists have read this article. This is a randomized trial that was very expertly done. I believe there were 12,000 patients, a large number of patients randomized demonstrating a non-inferiority of PCI performed at hospitals with cardiac surgery on site with respect to mortality and major adverse cardiac events at nine months. Next slide, so at this point in time the SB 891 clearly states that when PCI with surgery offsite is non-class 3 (that is what the law said) that IRB approval of the consent form is no longer needed. I would point out that the members of the AOC that use this project use this data for quality improvement at their local hospitals, certainly I do. I would submit this to you that I believe that the IRB and the 12-page consent form is not necessary with the current law. The reason why it is overwhelming is that sometimes patients are very sick. They are having a lot of chest pain, they may not be at ST elevation myocardial infarction but then they're given narcotics for their chest pain, you can't withhold narcotics. Once you've given them narcotics then you have violated some IRB protocols by handing them a 12-page consent form after getting narcotics. We have been in violation of

that at our hospital. It seem onerous and almost disrespectful to the patient actually sometimes to have them sign a 12-page consent form when I believe that we have proven that it has been safe. And the American Heart Association and ACC have additionally stated that it is no longer Class 3. My understanding of this, it would be nice to have the AOC to endorse this, although it is not clear from legal opinion whether it is actually necessary based on the law. I think it is nice to have the AOC endorse this.

Dr. Way: I did run this by legal and the attorney said as far as she can understand this meets the letter of the law. It is no longer required, but she thought it would be wise to have a vote by this organization on removing this restriction. So would someone like to make a motion?

Question: Are you only asking for approval of written informed consent IRB approved or are you moving that the IRB will continue to approve this in the ongoing research?

Dr. Way: It would remove the need for the IRB completely.

Dr. Fehrenbacher: If you remove the written consent you have removed the IRB in my understanding of this.

Dr. Bommer: I have just one comment. This looks fine, but perhaps legal could answer on this. Due to HIPAA requirements medical record reviews are no longer exempt from IRB so we just need to make sure this is state law that this qualifies for. HIPAA is a federal law and IRB for that does say that medical record reviews are not exempt from IRB. Just to let you know, the collection of data that we do, including the audits where we have people at the individual hospitals reviewing medical records, is a medical record review. Therefore, because it involves personal identifying information (that is we see the patient's name when we do it and on the angiograms it's there) we just need to make sure even though it doesn't violate state law that it does not violate HIPAA in that situation.

Dr. Way: Concerning HIPAA, what you will have to do is send exactly what you want. We have a compliance officer and attorney who make decisions about HIPAA.

Dr. Fehrenbacher: One of the suggestions I might have to think about is that the AOC could mandate that the consent form that each hospital has provide the data to UC Davis and CDPH.

Dr. Way: Rather than try and do something, let's get clear about what we are talking about. I would say why don't you go ahead with this motion and then I will take this to the compliance officer and get back to you.

Dr. Forman: There are currently two consents. There is the 12-page but then there is still the medical release. All the records that go to UC Davis the patients have to sign a medical release form. Even the ones that are not involved in CAMPOS because they are ST elevation MI. Dr. Fehrenbacher is not talking about that consent at all. It's the 12-page consent. I have some other issues with that 12-page consent also. I've had patients have problems actually with their insurance because they signed that 12-page consent form. The insurance then assumed that this was a research trial and then refused to pay their hospital cost for the procedure because it was a research trial. That has happened on a few of my patients. I don't know if that has happened to any of the other hospitals but it is happening in our hospital. I think the patients also get the misconception that angioplasty is a non-approved procedure and that it is research that we are doing angioplasty in the first place. If this is a way of not having them to have sign it so that they don't misunderstand what is going on, I would be in favor of that also.

Dr. Bommer: To answer your question, because we are collecting information which has patient identifiers on it, to be compliant with HIPAA our IRB requires us to have our process and that's just at UC Davis covered by the IRB in that situation. We are collecting patient identifiable information. We have our own IRB that approves our process. As far as what's done at your hospital, I think that is pretty much up to you and your local IRB. If your local IRB feels that you're compatible with HIPAA and IRB by reporting that data out then

that is fine. I just would want to make sure that the study continues by collecting data.

Dr. Way: I don't think this has anything to do with that. This is very simple about the necessity (because this may be considered an experimental study) to have this particular type of form signed by the patient. I will send this to the compliance officer and try to get more clarity, but I think you can go ahead and vote on this if you want.

Dr. Sundrani: I agree with all the comments made. The other form we have is just the usual form saying in the other hospital which is left heart cath possible PCI. It doesn't reflect anything about what is done differently in this hospital. I certainly not want the IRB regulations. I just don't know, maybe we have to create a different form in our facility saying this data has been collected; we are one of the six hospitals. Something that the patient would understand that there is little difference, that there is no onsite surgery vs. at other hospitals. That 13-page or 14-page form does say that but it says all the other stuff I don't want.

Dr. Ferhenbacher: At our hospital we say you have to sign for consent for emergency bypass surgery at another hospital. It's clear in the consent form that whenever you do PCI you get a preauthorization for emergency bypass surgery and our consent form says at Sutter Memorial Hospital. It is quite clear its offsite. I think that you need to set up your own consent form as appropriate. Also, the data needs to go to CDPH and UC Davis.

Dr. Karmarkar: I have a comment about the consent process and whether there is an option of the individual medical center keeping the consent form and some others opting out if you choose to base on that. First, I agree that the form is onerous; there is no question about that with the 12-page form. However, in defense of that, and I may be an outlier here, it really encourages or forces the physician to be detail oriented in terms going over the risks with the patient. It's truly an informed consent. We have had maybe a handful of patients refuse it. It does take a little longer to consent the patient but the beauty of that is the patient is fully informed of the potential risks, benefits and options. If they want they can to opt out. Because of the way our system is set up, we do get referrals from other Kaiser Permanente Medical Centers. The patients know that their options are to go to a Kaiser facility that has onsite cardiac surgery or they can go to Walnut Creek which is not an onsite cardiac facility, but here are the risks and benefits. It really encourages the physicians, forces them almost, to go over the disclosure in detail. Many of the physicians actually like the form and so do the patients. It is onerous, it does take longer. If some of us want to keep that particular form, or a variation of the form, maybe a little bit of a truncated version but just the detail oriented would we have that option?

Dr. Way: I believe you can have your patients sign whatever you want. This just removes that it is mandated, that's all.

Dr. Karmarkar: That's fair.

Dr. Way: The other option, you can keep that form but then you will be able to do prisoners, people who don't speak English, don't have the proper interpreters if it's a language that is not easily interpreted such as Spanish. We have been having problems with Romanian and other languages that are not easily interpreted in written form.

Dr. Way: So has a motion been made?

Dr. Fehrenbacher: I feel a conflict of interest to present the data and make my own motion but I can certainly do it. I would make a motion that the AOC endorses the language of the law in SB 891 that the IRB approval of the consent form we use is no longer needed.

Dr. Way: Is there a second?

Dr. Forman: I'll second.

Dr. Way: Any further discussion?

Dr. Jain: Should that be mandated but if somebody wants to do it they can still continue doing it?

Dr. Fehrenbacher: Correct. So all this says is that you don't have to use the IRB.

Dr. Way: So you want the language changed?

Dr. Jain: Yes, it should not be mandated by the law but it is up to the discretion of the performing hospital.

Dr. Way: Do you want to reinstate it so they can write it down correct?

Dr. Fehrenbacher: Yes, I will make a motion that the AOC endorses the language of SB 891 that the IRB approval of the consent form is no longer mandated but it is left up to the individual hospital.

Question: Shall I read it back?

Dr. Fehrenbacher: Sure.

Comment: That the AOC endorse the language of SB 891 that the IRB approval of the consent form is no longer mandated.

Dr. Fehrenbacher: But is left up to the discretion of each individual hospital.

Dr. Way: Any further discussion? Can we have a vote then?

Vote: Dr. Fehrenbacher (yes), Dr. Forman (yes), Dr. French (no answer), Dr. Itchaporria (no answer), Dr. Jain (yes), Dr. Karmarkar (yes), Dr. Sundrani (yes).

Dr. Way: Well, I am sorry but we only have 5 and there are 11 people on the committee.

Dr. Jain: Can I make a motion to table the issue and to bring it up again at the next AOC meeting?

Dr. Sundrani: Can they vote like we were discussing on the internet.

Dr. Way: The problem is this is ostensibly an open meeting under Bageley-Keene.

Dr. Fehrenbacher: But no discussion will be made. It will simply be a yes/no.

Dr. Way: I don't think that's going to count. So, when is our next meeting going to be? I am afraid this is going to have to be tabled to the next time we meet.

Dr. Bommer: The motion does not pass because of the lack of quorum at this time. The next issue is the next meeting. We're hoping to get this California Data Set. To me, that is the next big step that we have is to compare NCDR data across the board. The download is going to take place the end of October. I would like to wait if possible until we get that data set downloaded to make sure that it is working, etc. As far as scheduling the next meeting, I think it would be early in 2013.

Dr. Way: Well, we have to pick a date. Do we want to pick a date now? Does anybody have any

suggestions, what is early in 2013, in January?

Dr. Jain: January sounds good to me.

Dr. Way: We had our meeting two years ago in January.

Dr. Fehrenbacher: One option would be to meet and discuss the language of the extension. Would you like to do that in November or December?

Dr. Bommer: I have to have the meeting with the legislators first to see what they want and then I could report back to that. I'm not sure we need a meeting to do that. We could potentially. . .

Dr. Way: If we are not going to have any motions or do any actions the information can be sent back and forth.

Dr. Bommer: Some of our members have to fly in and it takes quite a bit of time from their schedule.

Question: If there are only one or two issues to be voted upon, is it possible to have a telephone conference to discuss the two things that are left open?

Dr. Bommer: It is possible as long as it's arranged ahead of time and there is public access to a number of sites where they can go and be present.

Dr. Way: That's really the biggest problem we have is the offsites, we had five, today we only three reported. I think some of those have actually left. To be truthful, I don't think anybody ever shows up but it is mandated or illegal to make any decisions unless we have public access.

Comment: If we have a one-hour period we might have more success for people to be present.

Comment: The CABG clinical panel is run exactly the same way because OSHPD manages it. On two occasions in the last 10 years we have met by phone, but our lawyers have made sure that each site was properly noticed and that there was public access at each site where a member was present. It has worked and sometimes we have been in the same situation as you all, critical vote, and we have gotten together just to get that stuff passed so we could move onto other things.

Dr. Way: I would say that December is a bad month, November is coming very rapidly. January is a good month. I think that if everybody could commit to being here maybe the second week in January we could get all these things taken care of. Dr. Bommer could present the NCDR data.

Dr. Fehrenbacher: I think I asked this last time, I will ask it again. Could we do the consent form at the beginning of the meeting when people are actually there as opposed to the end when everyone is gone?

Dr. Way: Actually, I put you at the front of the meeting.

Dr. Fehrenbacher: I know you did and I appreciate that. Somehow I got bumped back again. It should take five minutes only.

Dr. Way: I think we can start it as the first item of the agenda. I see no reason why not.

Dr. Bommer: So potential for that is I have a Board of Governors meeting the third week so potential would be January 17, 2013 or January 31, 2013. Now, it depends on NCDR data because NCDR harvests their data every quarter. It literally takes them a month after they harvest it to get it. If we want to look at the most

recent NCDR data, which is the 2012 data, we won't get access to that until the end of January. If you wanted to look at that very latest, that is our 2012 data with NCDR data, the earliest we could get the NCDR download would probably be the 30<sup>th</sup> of January in which case if you want to do that comparison I would say we would pick February 7<sup>th</sup> if you want to have "apples to apples" NCDR California vs. NCDR PCI-CAMPOS. If you don't want that and we ignore that then we could do January 17<sup>th</sup>.

Dr. Way: If we do January 17<sup>th</sup> you would have this data from this past year?

Dr. Bommer: Not from this past year, no. Not for 2012, because they wait to harvest that.

Dr. Way: So they only release the data once a year.

Dr. Bommer: No, four times a year it's released but it's by quarter. The problem is we'll have three quarters of the year report for them and not for us. We are just trying to line up the dates. The easiest for NCDR and us is to report calendar year because that is what they do. They do a four-quarter calendar year.

Dr. Way: Does anybody have any ideas about dates besides me?

Dr. Jain: I prefer February 17<sup>th</sup> so that we can have some meaningful description of data also.

Comment: Why don't we do January 17<sup>th</sup> where we just put a vote on a couple other issues, just my thought?

Dr. Way: Will you have your data done by then Bill, analyzed, looked at?

Dr. Bommer: We will have data. The most complete data is obviously if we wait for the harvest. The harvest for 2012 data for NCDR will literally take place and is required 90 days at the close of the year so that is not until March 1<sup>st</sup> or March 30<sup>th</sup> at that point. If you go to the end of March then we have the ability to have that downloaded data for the harvest for that year we want to compare.

Dr. Forman: We need a meeting before that regardless.

Dr. Fehrenbacher: Other issues that we do need to discuss is the outlier hospital and outlier physicians and how we going to work with that.

Dr. Bommer: We could have a meeting in January that reflects literally other items. We won't have new PDD data by that time.

Dr. Way: Originally this was supposed to meet quarterly.

Dr. Fehrenbacher: You will have 2011 NCDR data won't you?

Dr. Bommer: We will have 2011 NCDR data, yes.

Dr. Way: So next meeting will be January 17<sup>th</sup>. Is there any other further business, I guess we can't do any business.

Dr. Fehrenbacher: We can't really have a vote on anything.

Dr. Bommer: I think we can have public comment and we should open that up.

Dr. Way: Okay any public comment, please?

Dr. Fehrenbacher: I have a thought regarding the outlier hospitals. I would like to make a statement that we

don't want to punish any individual hospital or any individual operator on one hand. On the other hand, we all have an interest to make sure that this data is robust and passes muster in three years. Therefore, we have an interest to make sure that we have good outcomes at all hospitals. The question is how to review the outlier hospital and the outlier individuals. I guess one of the thoughts I might have is, should we ask the PI at that hospital to bring forth some of the issues that we can discuss? In my mind, one of the questions is can we get this better, can we improve the performance at this hospital? But, if we can't improve them in performance should this hospital be part of the pilot program?

Dr. Way: If you are talking about the one hospital that is an outlier and the two operators that are outliers, I think you are going to have to go through the local quality assurance.

Dr. Fehrenbacher: Well, the PI can do that. The PI should be part of the quality improvement process.

Dr. Way: Well, I think you have to let the hospital do it first and let their medical staff do it if it's not the individual. What you do about the hospital, you have more variation there. I don't know if we have any right to go in and look at personal data on individual physicians in a hospital setting.

Dr. Forman: The PI can review any of the cases involving CAMPOS.

Dr. Way: Yes, you can do that but if you are trying to look at credential files or. . .

Dr. Forman: Certainly the cases that caused the outlier can be reviewed. I think one of them was a physician in my hospital. The physician is actually on the STEMI call panel and not a CAMPOS physician. In our hospital there is one physician who is not involved in the pilot program. They do no elective PCIs and they did have a couple of outcomes that were less than good on STEMI patients. I reviewed those cases and they were difficult cases. I am not surprised that the outcomes weren't as good as you might want. They were not unacceptable and poor treatment. They were just bad cases. Unfortunately, the one doctor got a little bit of bad luck on his rotation. I think that is within the purview of the PI and certainly within your interventional department. If they have bad outcomes, if there is mortality from angioplasty, quality review in everybody's hospital those are going to fall out regardless.

Dr. Fehrenbacher: I am not suggesting that we engage in quality review at that hospital, which really is not our issue. The issue is whether it is a small volume hospital and the question is whether that hospital should continue in the pilot program. A small volume hospital with outlier mortality – what I am saying is that I would like our data at the end of three years to be pristine. I would like it to be equal to the PDD and the NCDR. If we can intervene early in some way to make it that way then I think that is within the purview of the AOC. It is not within the purview of the AOC to individually. . .

Dr. Sundrani: Dr. Fehrenbacher, I think the volume issue we have dealt with before. We have the least volume in the whole PCI-CAMPOS. Our data is the best data. The data is best maybe because the volume is low. I think discussion-wise most of our data comes from elective PCI. We cannot have the ambulances drive by our hospital and don't bring them here. We cannot become a destination center. I look at the data at the other hospitals and there are a lot of ST elevations which are showing up. In our place, a lot of discussions with the ambulance people here and their director, they have all failed. Dr. Bommer tried and failed. We would like to help but again I am seeing a lot of ST elevation MIs just walking away from this hospital and then go to the other hospital and the same interventionalist comes down here and then drive up there and do those cases.

Dr. Jain: Dr. Sundrani, the risk is more in STEMI cases than in elective cases actually.

Dr. Sundrani: And I completely agree. Even on that part. So I think if our data is looking the best but you can't say that the low volume is the worst data because you heard that from some part. We are the lowest

volume but our data is the best data. Maybe it is because we are not getting all the cardiogenic shock patients we should get. The ones we are getting are people that are just showing in the ED. As you know, sometimes they don't have chest pain in an ST elevation. They don't get any warning from the ambulance at all.

Dr. Fehrenbacher: We are not trying to criticize any individual. I am not even sure who the outlier was. I would like to put this on the table more generically. How can we fix this? Can we make this better?

Dr. Way: Well, you're not actually meeting as a PCI organization now so you're welcome to stay around and talk as long as you want.

Dr. Fehrenbacher: Is it over?

Dr. Way: It's over because we don't have a quorum.

Dr. Li: Next time I'm supposed to report the risk adjustment outcome using the NCDR data. NCDR, we are going to compare with onsite. Right now outcome measure is death or you weren't in transport for CABG. The onsite does not have issue right? So what is the outcome measure?

Dr. Fehrenbacher: I guess death and emergency bypass surgery whether transferred or not.

Dr. Jain: Are you talking in STEMI, non-STEMI?

Dr. Fehrenbacher: It doesn't matter.

Dr. Jain: But I think there was no difference shown in the data. All six hospitals were similar.

Dr. Bommer: I think we should just announce for those people at the remote sites that due to lack of a quorum this meeting is officially over. Some of the individuals here are going to stick around and chat and talk, etc. But we have to officially adjourn this meeting at this point in time due to lack of quorum. Everyone is welcome to stay at this time. Thank you everyone in the remote sites for being part of the program and part of today's events. We certainly appreciate your time and look forward to your continued involvement.

3:27: Meeting adjourned

## Acronyms

ACC	American College of Cardiology
AFL	All-Facilities Letter
AOC	Advisory Oversight Committee
AUC	Appropriate Use Criteria
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
OSHPD	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