

**Percutaneous Coronary Intervention Advisory Oversight Committee Meeting  
January 20<sup>th</sup>, Sacramento, California  
10:00 a.m. to 3:00 p.m.**

**Attendance**

**Members** Anthony Way, MD, Chair; Stephen Arnold, MD; Ralph Brindis, MD; Robert Davidson, MD; Mahmoud Eslami Farsani, MD; George Fehrenbacher, MD; William French, MD; Steven Forman, MD; Dipti Itchhaporia, MD; Aditya Jain, MD; Sushil Karmarkar, MD; George Smith, MD; Rohit Sundrani, MD

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

**Staff** Sam Alongi; Roberto Garces; David Gioia

| Agenda Items/Discussion   | Action/Follow-up |
|---|------------------|
| <p><b>Call to Order and Introductions:</b><br/>PCI AOC Chair Anthony Way (Chair) convened the meeting with introductions in the room and on the conference line.</p> <p><b>Approval of Minutes:</b></p> <ul style="list-style-type: none"> <li>• There was a request to have minutes sent out with meeting packet.</li> <li>• Page 7, minor correction. The document states "standard IRV"; replace with "standard IRB" representing 'Institutional Review Board'.</li> <li>• Page 12, correction. The document states "acute left frontal"; replace with "left bundle".</li> </ul> <p><b>Motion to approve August 19th, 2010 PCI minutes as corrected.</b></p> <ul style="list-style-type: none"> <li>➤ Motion—Forman</li> <li>➤ Second—Karmarkar</li> <li>➤ Motion Passed by unanimous vote</li> </ul>  |                  |
| <p><b>Old Business:</b><br/>Brindis – In previous meetings we discussed how, or if, we would be collecting cost data; has a decision been made on that issue?</p> <p>Bommer - The question was raised related to cost of the procedure which we had talked about before. As we discussed it was difficult to pinpoint costs of this procedure done at an off-site hospital as opposed to on-site because of the many intangibles, such as personnel and transportation. At the end of the August meeting the decision was that if the AOC wants us (UCD) to collect the cost of the patient transfers, that element could be added up or categorized. Fields for cost of transportation or ambulance could be added and that data identified. All facilities have different accounting systems, so tracking this to the level of incurred costs would be difficult. But UCD is willing to look at that if the AOC decides as a group to include that information. It would require a sit-down between UCD and the AOC to determine cost markers that will go onto forms for the coders. The coders are the ones who will be asking how to get the</p> |                  |

cost information.

French - All we really need is an average cost per hospital per transfer. We don't need data on every transfer in order to determine average costs.

**University of California Update - Bommer**

For the remote sites, please refer to the slides listed on the website; these slides were also emailed to you. We will go through those slides in order.

(Slide 1 displayed)

I would like to welcome all of the sites. It is important to have your participation. I would like to thank everyone here for attending today in Sacramento. It helps to have input from all of the people here who are experts in their fields. I would especially like to thank Dr. Anthony Way for stepping in to take over the leadership role for this study.

French – Dr. Way, could we hear about your background?

Chair - I am a Chief Medical Consultant. I am a Urologist by training. I am a retired annuitant, which means I came back to work half time. I was with the state for ten years and then retired for a few years. I have been back with CDPH for three months.

French – Thank you.

Bommer - I would also like to acknowledge the team that does the work in this study process. Geeta Mahendra is here, who does the statistical preparation of the data. Dr. Li is here, who reviews all of the statistics as they come out. Laurie Vazquez is one of our auditors. And Dr. Melanie Aryana has put in remarkable time and energy on this project.

I want to acknowledge as well the interventionalists who are on-call for these procedures who may have to come in at 3:00 a.m. and return for their normal work at 7:00 a.m.

Lastly, I would like to thank the coders who abstract the data into 240 fields and do a phenomenal job getting all the data right. These staff spend many hours entering data and digging back through the medical records to make sure the data is entered correctly.

French - I would like to comment on the pilot hospital interventionalists slide. I noticed that one hospital only has one interventionalist and another only has two. That doesn't seem like a viable model. Did participation in this study hinge on a certain number of interventionalists on staff for the program?

Bommer – There was no minimum or maximum number required for participation in the study.

French - It seems to be very difficult to have one person on every night.

Fehrenbacher - I would like to comment on that as I am that "one person".

There are other interventionalists who don't have the volume to do the elective cases. They work at adjacent hospitals and they cover me for STEMI and I do the elective cases when they are up. So this slide is somewhat misleading.

Arnold - I would second that. I am from Doctors; there are two of us who are CAMPOS ready, and four of us that do STEMIs.

Bommer - The next slide is entitled "Enrollment Update". This is the enrollment update for the cases that were done in the study's first five months, which was the period from August 1 through December 31, 2010.

(Refers to statistics listed on slide for 481 patients enrolled in the PCI campus program)

Enrollment update on the next page is listed for each hospital. Hospitals are listed as 1-6.

Case number for August 1 through December 31, 2010.

Hospital 1 had 153 cases;  
Hospital 2 had 93 cases;  
Hospital 3 had 73 cases;  
Hospital 4 had 34 cases;  
Hospital 5 had 55 cases; and,  
Hospital 6 had 73 cases.

Primary PCI's are also listed and range from 49 down to nine. The target for the study—per Senate Bill 891—is to achieve about 100 PCIs every six months or 200 per year per site. To date the study has not met the hoped-for volume, which would have been about 85 PCIs over five months; we are hoping to get all of these hospitals up to that level going forward.

(Reviews enrollment statistics for each hospital contained in the slides)

Fehrenbacher - Are patients counted twice if in that period of time they get another PCI? Is each separate instance considered one patient?

Bommer - They are counted twice if there are two procedures, if they have to leave the lab to come back on a separate occasion. This is a very small number.

Brindis - I found this data fascinating. If you look at the NCDR data, patients who come to the lab for STEMI, non-NSTEMI or unstable angina, it is about 75 to 80 percent, which for this study, other than Hospital 6, mirrors the experience we are having in this program. I mention that because the Courage trial claimed 80 percent for all angioplasties and/or unstable angina, which is *not* the experience in the registry and mirrors nicely the data we have here.

French - When I see that term "no symptoms, no angina", maybe we need to look at that a little more. One hospital is very high there, and just what is that group of patients?

Bommer - That data comes from a check-off box on the NCDR database with a listing of a variety of symptoms including 'STEMI', 'non-STEMI' and 'no symptoms'. If the dictation does not list any symptoms for the patient, the coder is under the opinion that they should check that box. It is small in our group but I would expect the same in the NCDR database.

Brindis - If I remember correctly, it's actually a little higher in the NCDR database, particularly with the elderly.

French - It does seem high. Regarding the target PCI numbers, it seems that the numbers we would expect to get would be about 100 per month, this is adequate?

Bommer - If you look at the entire group, we are close to being at 100 per month. That is because one of the hospitals has enrolled at double the rate or higher. If the sum of the hospitals has low numbers, it will be difficult statistically to give you the numbers to evaluate.

French - And we have one that has low numbers, Hospital 4.

Bommer - As you noted, Hospital 4 saw 34 patients.

French - Is there a reason for that low number? Did they start late?

Bommer - There are multiple reasons. UCD will meet with that hospital next week to talk to the emergency room staff and ambulance people as well as the interventionalists to see if there is anything that can be done to enhance that enrollment. The outcome of that meeting will be reported back to the AOC.

Itchhaporia - Do the physicians ever look at what was coded? It seems that the numbers are not so large; the physicians could have a meeting to review the coding. It would be interesting to see whether the physicians believe the coding accurately represents the experience.

Arnold - At our facility, we do not leave the lab until the NCDR data is filled out by the physician, at least on paper.

Forman - Every time we do a case, the question is "What is the angina class for the two weeks prior to the angioplasty". If somebody comes in with a STEMI, their class was 'no symptoms' until the event, but we need a number so what number should we put down? We may put '4' but it isn't really '4', it is a STEMI. I don't know if those numbers are actually consistent with the symptoms presented by the patients.

Itchhaporia - That example would appear to be a good opportunity for the study to inject a clarification, and review the coding with the physicians. These questions will continue to come up; it is important for the physicians to see how these are coded.

Bommer - We follow the NCDR guidelines, which provide definitions for all of the boxes on the form. When someone asks us a question, we refer to

that definition in the NCDR guidelines. We eventually want to be comparing our data to NCDR data statewide and nationally so we want to be consistent in our use and application of those definitions.

Aryana: Regarding the NCDR check box as it relates to the presenting symptoms; a lot of these patients have staged PCIs, that is, they came in for a second procedure.

Bommer - So the answer would be if someone came in and had a PCI for an acute MI and the physician fixed the right, but there is a significant LAD lesion and a plan to bring the patient back three weeks later to do the second one, they have had three weeks of no symptoms, but it was decided that the first diagnostic case of their acute MI that they wanted to do both lesions.

Karmarkar - It is not unusual for a patient to have their pre-transplant evaluation and many times you find a lesion and you know that without doing anything about that lesion, they are not going to have the renal transplant. They may not have any symptoms or Ischemia.

Bommer - This brings up a lot of interesting interpretations of appropriateness, and I have some case example slides to review toward the end of the slideshow, to determine whether we want to expand on that. We can, if the AOC wants, send these back to the coders and send them out to the physicians to check whether the patient was really asymptomatic or the symptoms were unlikely to be ischemic. As Melanie (Aryana) said, the coders already do that, but if we want to send them back a second time to ask that question, that can be done if the AOC deems it an appropriate step in the process.

Eslami - There was only one patient so far out of the total study to which this applies?

Bommer – Yes. Zero for all the other hospitals.

Aryana - I would like to clarify the general classification of two weeks, if a patient comes in with a STEMI, this includes the event itself.

Bommer - The STEMI should be chest pain at least. So they would not be asymptomatic even though they were asymptomatic until an hour before.

Fehrenbacher – So, if a patient has a staged PCI, and the second stage occurs 15 days after the original STEMI, then that patient is moved into a different category.

Bommer - Correct. We follow the rules.

Bommer – I have an update on the software being used for the study. We had to go live in a crash program because UCD didn't have approval to proceed with the study until less than a month before the study launch date. The study started on August 1<sup>st</sup>, and it took a little longer to figure out the bugs because there wasn't time to run a pilot program.

The coders identified some issues that were resolved in September.

- Issued a data lockdown feature- once UCD has verified and audited the data, the data is locked down so that it cannot be changed for the remainder of the term. That allows us to have stable data for analysis.
- An intermittent log-on block was corrected-this issue was occurring in one of the load balancing servers at UCD. That has been resolved as well.
- UCD is working on a lesion counter.
- An issue with definition pop-ups disappearing was resolved in January 2011.
- An automatic logout function will be implemented. If someone is not typing on a keyboard, they will be logged off.
- An audio warning regarding logout function is being considered.

Other than that, the software seems to work very well.

We have worked on a flow sheet of the process that we follow.

(Displays sheet)

The process is as follows:

Coders enter the data from what the interventionalists have given them. From that data entry site, 10 percent of the cases are randomly selected for an on-site audit. Those are audited at the hospital by an auditor.

One hundred percent of all cases do go to UCD for a data audit. There are boxes on almost every patient that end up getting changed. Issues are reviewed with the coders for correction.

In the final data audit, a physician reviews each field again. Once that is completed successfully, the data goes through lockdown.

UCD provides its own data analysis on the Velos system; each hospital can do their own searches or report generation for CQI purposes. Note that the hospitals do not have access to data from the other hospitals, only the data from their own facility.

All the content is stored on load balancing servers; in case there is a heavy load on one of the servers, it can be redistributed to the other.

On-site audits are done to ensure that the data in the charts is consistent to the data that was entered into the NCDR database. At the hospital, an audit report is generated. That information comes back to the coders, and if the changes are agreed upon, the information is processed into the final audit. The auditors bring back a DVD with the angiograms; that information is reviewed by two interventionalists. If the interventionalists find a question that affects risk adjustment, it is sent back to the hospital to review the findings. If there is disagreement with the hospital interventionalists, it goes to committee vote and consensus determines how to code the lesion or question. That is then entered into the database and goes into data lockdown.

All statistical analysis is done on SAS. All the angiograms are stored on an Excelera server that allows us to review them at any point. All the data and work is password protected through the PCI-CAMPOS site.

Brindis - Is there a minimum audit percentage, particularly for the hospital that only has 38 cases?

Bommer - We are auditing those at a random 10 percent level. It comes out to one in ten over the total sites. The number at that hospital was probably four. Audit percentages could be upped if the AOC so requests.

Sundrani – What benefit would there be to justify more audits at a low volume site?

Brindis - My issue is that if you have a decent volume, 10 percent makes sense, but if you have a low volume, you are only auditing four cases which could affect you either positively or negatively.

Fehrenbacher - Who is on the consensus committee; has it been used?

Bommer - The committee has not been used for consensus because there has not been an issue sent up. Up to now, there has been agreement of the two reviewers. The committee would be the two interventionalists reviewing the case with a third from the pool of four interventionalists at UCD.

We have the ability, should the AOC find it worthwhile, to take every appeal in front of the AOC. Because of Bagley-Keene, we would lose some patient confidentiality at that point, because it is difficult to discuss in detail some patient cases without some identification information. That would be a significant barrier to overcome. Ideally, there would be a subcommittee from the AOC, but that would still be subject to Bagley-Keene. If you can come up with a proposal, we can review it with legal counsel.

French - That would be important to do. If we are going to do 10 percent of the cases, are we going to meet twice a year or four times per year?

Bommer - In the Bill and the protocol, there is no set time to meet, but we are obliged to give quarterly reports to the CDPH and there are requirements for the AOC meeting. We will look them up. I think it is at least every six months.

French - For 10 percent review it seems at least a minimum of ten cases reviewed in each facility per quarter would make sense.

Bommer - That would require the AOC to make a motion on that.

Arnold - Is there some equivalent of a closed session that the committee can enter to review individual cases in confidentiality?

Bommer - We would need to have counsel address that.

Gioia - There really isn't any sort of catch-all exemptions to Bagley-Keene. There are specific exemptions that allow closed sessions, but none that apply for this AOC.

Karmarkar - There are many ways of looking at 10 percent. One is 10 percent for each hospital which may treat smaller hospitals fairly or unfairly. Or it could be 10 percent for the pool of all hospitals, randomly generated.

Brindis - If the minimum desired number for a site in a year is 200 cases, the minimum number audited per site should be 20 per year.

Arnold - Having a base number for each institution is an important oversight function of the AOC.

Bommer - The coordinating group is willing to do the minimum number, twenty is not a problem to do, and then 10 percent overall. On the part of statistical analysis, the more numbers, the more robust the process becomes.

Sundrani - The 200 cases was the expected number of cases for study Year 2, not Year 1, if I read the document correctly. On the comment of reviewing 20 cases for a low volume center, I think that the reason to review 10 percent of the cases was because of the amount of effort UCD would expend. If 20 cases per center is chosen, I have no objection. You can review all of the cases; I don't understand the thinking behind doing more cases at a low volume center. You are welcome to, but I don't understand the reason for it. I would think higher volume centers that have higher risk patients would require higher numbers.

Bommer - The more numbers, the lower sampling error.

Jain - At least 20 cases should be reviewed at each hospital.

Eslami - The rule of 10 percent minimum should be in place for each of the hospitals, not for the study as a whole.

Forman - Since UCD is doing the audit. I am not sure why any of us would care how much work UCD is going to do, assuming we are entering the data the way we are supposed to. I think 20 cases or 10 percent, whichever is larger, makes sense.

Way - We want maximum data, but there may be cost constraints.

Bommer - When we went through the bidding, it was determined that the mark for reimbursement would be based on the total number of patients receiving PCIs, of which UCD was expected to perform audits on a randomly selected 10 percent. If the proposal is to significantly change the number of audits, there might have to be some renegotiation.

Way - You all know the state of the state's finances; it is unlikely that any additional money would be available.

Itchhaporia - Do you want to say "20" or "20 or 10, whichever is higher".

Brindis - The minimum volume would be 20, so a center with over 200 would be 10 percent to meet the criteria.

Fehrenbacher - Would UCD require extra money in that case?

Bommer - We would hope that every hospital would be at 200 by Year 2, and at that level the finances for the audits are covered.

Alongi - A reminder to the Committee that a motion is not binding, so you can request whatever you like at this point.

- **Motion to audit a minimum of twenty cases per hospital, or 10 percent, whichever is higher.**
  - Motion—Brindis
  - Second—Forman
  - Motion Passed

Bommer - Moving to the initial data audit slide: 100 percent of the charts are audited for completeness and internal consistency. We review the PCI status, and would check for someone with no symptoms. We go through NCDR definitions and have thoroughly reviewed these with the coders.

The next slide is an example of an unstable angina case. We go through a series of checks within the document, and if we see an issue, we send out a query. (Reviews slide example details)

The third example of audit; this is the listing of the best estimate of coronary anatomy for each of the vessels in the diagnostic cath. It is a digital number of the severity of the stenosis. The degree of stenosis cannot be guessed at by the interpreter. Now, we all agree that a 30 percent lesion to one interventionalist might be 40 percent to another, but for the example I'd like you each to pick a number.

Karmarkar - We have a few interventionalists at our facility. We have no issue entering the percentages, but it seems silly to call it a "0 percent stenosis". Can we call it "normal" or do you require the number?

Bommer - For the coders, it is actually better to put "0 percent". We know that is more work on your part, but it makes coding less ambiguous.

When we started out we had non-standardized definitions for what patients were eligible for the study. Here is another data audit and the definitions in the NCDR database. I showed on the slides the definitions of "elective". If the procedure has to be done in this hospitalization, you have to move up to "urgent" or "emergent".

Jain - If the patient comes in with cardiac arrest, and we have to use CPR, and we are able to get blood pressure, and then the EKG shows ST elevation, but the patient had a cardiac arrest and then had a PCI done, how do we report that?

Aryana - Emergency means that you would cancel any other case to go directly to the cath lab. Salvage means it is a last resort and a high risk patient where you cannot predict the outcome.

Jain - You may not know if they are going to wake up. How do you code it?

Bommer - You can code for cardiogenic shock, and if they are in CPR, you can be talking about salvage at that point in time.

Aryana (Reads passage from NCDR regarding cardiogenic shock)

Bommer - Every one of these questions is answered by the NCDR; it really does provide an answer for almost every situation. It does take some time to work through it.

Fehrenbacher - I think the question is surrounding the level of severity that moves a patient from emergency to salvage and there are a number of patients who are extremely high risk who might not be considered salvage but their mortality may even be equal to the salvage patients.

Bommer - There are nuanced situations, but the purpose of any database is to put strict definitions on to accurately accumulate and analyze the data. We can't differentiate 10 minutes of CPR or 40 minutes of CPR. They may fall up or down, but on average, if you have 200 cases per year, they balance out.

Brindis - We wrestle with this at the NCDR. I concur with the comments. In Massachusetts, every case gets audited and most get down-coded, not up-coded. The coding variance didn't have that much of an effect on the evaluation of the quality of the hospital.

Vazquez - In terms of thinking about the gray areas, hopefully it will come through in factors such as whether they went into cardiogenic shock during the PCI. Have all the interventionalists had the opportunity to review these manuals; is that something offered by NCDR?

Bommer – Since it is the best we have now, I suggest continuing with it.

The next slide is an example of some of the questions that got asked to the coders on certain issues. We kept track of how often we made a change to a record, and you can see of the six hospitals, almost on every file we have a question that leads to a change. In almost every case the change is agreed upon. Our initial audit rate of 100 percent of cases will continue because of the frequency of changes.

(Displays additional slides regarding number of procedures audited and examples of audit questions asked regarding data, angiograms and coronary anatomy)

This represents 66 audits out of 481 patients and we have additional audits scheduled, so we are meeting the 10 percent requirement.

We are trying to identify high-risk lesions versus low-risk lesions, and

those carry a risk adjustment with them. Lesion length is also important.

(Additional slide information and examples of angiograms and poll of committee regarding how they would code the results)

A 10 percent residual would be considered a successful PCI for post-procedure of a stenosis. Less than 20 percent is considered the threshold for a successful PCI. Once stenting became available, the current standards from ACC, HAI and SCAI standards show zero to 19.9 percent as successful in the guidelines.

French - I don't think you have to cut it that close. Twenty percent would be considered successful.

Bommer – Not to the letter of the guidelines. So to follow the guidelines, we are using 19.9 percent.

Brindis - It may influence how cardiologists report those lesions.

Bommer - In the example we are looking at, there was a disagreement as to whether there was 30 percent residual or 40 percent, and they settled on 35 percent residual.

AOC consensus poll: AOC agreed on 35 percent residual stenosis.

Fehrenbacher - That scrutiny will sometimes change operator strategies. They might try to stent the artery when their gut feeling was not to stent, to achieve a successful end result. When in actuality if the patient's chest pain went away and there were other reasons not to stent the patient, that might have been the right choice.

Bommer - I appreciate that, but we have to follow the NCDR definitions.

Fehrenbacher - There was a recent patient in our facility who came in with a trauma and an ST elevation infarction and had lacerated their spleen and was bleeding. Those kinds of patients are difficult to understand what to do with; it may not be wise to put a stent in that patient.

French - We can live with the unusual exceptions; the criteria are clear.

Fehrenbacher - My original comment was that the operator may change the outcome or procedure based on the end score. I don't disagree that in most cases this wouldn't be an issue.

Eslami - This is a good example because this is an example where the operator felt that this is a lesion less than 10 percent and by definition decided not to stent. But I think 99 percent of cardiologists would have stented because of the way the patient presented. The treatment based on the interventionalist's interpretation of the residual angiographic findings which was less than 20 percent.

Jain - Did the patient have to come back?

Bommer - We only follow the patients until they discharge from the

hospital, so we know that they were discharged alive.

Here is an example of a pre-PCI patient. Looking at this, would you consider this a high complexity lesion or not? High C means it is extremely angulated, calcified, tortuous, or a lesion length greater than two centimeters in length.

(Displays example for discussion)

Bommer - The two interventionalists reviewed it and determined that although you could consider it one lesion, this is *not* a High C risk because it is really about eight millimeters in length when you measure it.

Fehrenbacher - The rules say that if this is a twenty millimeter or longer lesion that it is a high risk. That is what the ACC has defined. Although we think clinically this would not be a high risk, it is a long lesion. This is like the definitions in NCDR. There are exact definitions.

Bommer - Based on the definitions, how would you rate this lesion?

Eslami - If you are strictly following the definitions, I think this is two separate lesions. One is the proximal lesion, then a healthy segment which angiographically looks fine, and then the second lesion.

Bommer - The stent was 20 millimeters.

Jain - We cannot see if there was calcium here.

Bommer - There was no calcium. I have not shown it here. The key here is whether you would determine that you would feel comfortable putting a stent in this situation.

AOC consensus poll: AOC agreed that it was a non-high/non-C lesion.

Bommer - For study participants, there were 15 rules that had to be followed for eligibility. We spent a lot of time with the interventionalists and tested them to be sure everybody understood the new rules for eligibility, which are *not* the same rules as those used for general interventions. The rules in this Bill include identifying high patient risk.

(Displays slide regarding patient risk)

You cannot enroll patients who are high clinical risk and high lesion risk at the same time; they are not eligible. Of the 481 patients, 100 percent met the criteria. The interventionalists did not miss one overlap or ineligibility.

The second thing in looking at PCI success rate is post-procedure stenosis rate of less than 20 percent. The ones that were successful were 93.9 percent. This is a high level of success for the interventionalists.

In addition we looked at TIMI-3 flow status and it was 96.6 percent. Both of these features and eligibility were very high.

Brindis - And this was for how many cases?

Bommer - There were 481 cases, with complete data entry for 463. For 66 of the cases, angiograms were reviewed with the two interventionalists.

Overall mortality was 1.94 percent; there were nine deaths in that group. The observed hospital mortality ranged from 0 to 8.7 percent. Dr. Li is here to discuss the statistics.

Li -All the data analysis is based on the 463 complete cases.

(Displays PCI Volume Chart)

We have big variations among the hospitals. The minimum was 33 complete cases. The highest was 150.

(Displays Mortality Rates Distribution)

This is the hospital mortality rates distribution. We have six hospitals with a mean of 1.85 percent. Three had 0 and one had 8.7 percent.

(Displays Patient Discharge Data)

There are over 400 hospitals in California, but only about 150 are doing PCI's. We have 120 hospitals doing CABG, so this data covers 30 additional hospitals doing non-elective PCIs. On average, for 2009, for the whole year, the mean per hospital was 329 cases, but the variation was huge. One hospital did one case and one did 1,700. The mean for 2010 is about the same after six months of data.

For 154 non-pilot hospitals, mortality average for 2009 was 2.19 percent, with variation from 0 to 25 percent. The distribution for 2010 looks the same, but the overall mortality is going down. For 2010, it has gone down to 2.04 percent, and the variation range is 0 to 11 percent.

Overall, a third are STEMI, close to a third are non-STEMI and 'other' is a little over a third, with 1.94 percent mortality rate observed.

Non-pilot hospitals had 4.3 percent mortality. Pilot hospitals had 1.99 percent deaths; this is with 95 percent confidence.

French - The non-STEMI/STEMI rate at the PCI-CAMPOS hospitals are way up. We only have 2 percent STEMI mortality and 4 percent non-STEMI. That is clinically significant with 400 patients. We have to understand those numbers much more clearly.

Li - We don't have the NCDR data yet, so we can only use our pilot data. Looking at risk factors, 35.8 percent were over 70 years of age. The mortality rate for the older group was 3 percent compared to 1.35 percent for the younger group.

When considering multivariate risk factors, we have found five risk factors that are significant predictors. (Displays and reviews patient risk factor statistics). Using the full model all of the risk factors in the ten unvaried risk factors, mortality prediction is 92 percent.

We predict mortality rates for hospitals. For Hospital 6, their observed mortality is 8.7 percent but our predicted mortality is 6.1 percent. That

means their case mix is pretty high and they handle a lot of sick patients.

Brindis - This was the hospital that had the high STEMI rate? (Yes)

Li - Then the risk adjusted mortality rate (RAMR) uses the observed mortality and expected mortality times the state average. For Hospital 6 even though observed was 8.7 percent, their RAMR is adjusted down to 2.76 percent. That is the point estimate and we have to be very conservative. 95 percent confidence interval for this high observed mortality hospital is between 1.01 percent to 5.99 percent. This confidence level covers the pilot hospital average. This hospital may perform as safe as the pilot average; there is no statistical difference. The same logic is used—in reverse—for the 0 percent mortality hospital; statistically this hospital's performance is no different.

In comparing pilot hospital data to PDD (Patient Discharge Data) statewide, with some pilot hospitals there was not a significant difference in terms of mortality. With the RAMR there are no outlier hospitals so far.

Karmarker - I want to thank the state for all of the hard work. Having said that, I would like to know the STEMI / non-STEMI mix at the non-pilot sites, because at the pilot sites if you combine STEMI and non-STEMI it is close to 60 percent which is high risk to begin with, and yet the mortality rate is no different than the non-pilot hospitals which I assume have less STEMI and non-STEMI and more electives.

Bommer - We will get you that information. Clearly, about 30 of the hospitals are only doing STEMI because they don't have surgery onsite and that is the only thing they are allowed to do. The other 120 hospitals are your larger hospitals that have cardiac surgery on-site and it is a mix across the board of elective and non-elective.

Fehrenbacher - I am curious about the non-STEMI patient deaths. Are these patients who were extraordinarily sick patients who didn't have a STEMI or were they less sick patients with a higher mortality?

Brindis - There were four non-STEMI deaths. Were these people in shock but simply didn't have a STEMI?

Bommer - We will provide you with those numbers as well. Let me emphasize that we were not able to get the NCDR data. We went to the PDD (Patient Discharge Data). It is from the beginning of 2010 and comparing it with our end of 2010 data. At least it is from the same year. It is the best we have at the time without the NCDR data. PDD keeps fewer risk factors in line but does tell us mortality.

Jain - Do we have data on patients who came in with shock and did not get taken to the cath lab?

Bommer - We have no way to monitor those patients.

Jain - There are different practices with different physicians. I would like to know from the physicians how they would handle that. (AOC members

agree to polling to respond to this)

Poll responses-

- If there is a cardiac arrest and the patient has been resuscitated, and there is opportunity to go to the cath lab, and there is no reason to think they are neurologically impaired, then the focus would be to continue.
- We take everybody to the cath lab. We are seeing great success inducing hypothermia, taking them into the cath lab and they walk out two weeks later.
- We induce hypothermia and take them to the cath lab.
- Same, induce hypothermia and take them to the cath lab.
- Same, induce hypothermia and take them to the cath lab. We are a STEMI receiving center. The majority go to the cath lab, but some elderly patients may not.
- That is not what this project is about. Are we now asking the pilot project to take on the cardiac population as a regular standard PCI problem? I think the data is very loose and incomplete. We have to be careful in a pilot project encouraging that all the cardiac arrest patients be taken on as part of the PCI project and all the data will not be the same. (Bommer - No disagreement. I understood the question to be regarding a *STEMI patient*.)
- If they are in shock and salvageable, we do take them to the cath lab. Before this PCI project, we would have transferred all of those patients and it would have taken additional time to do that.

French - I think we need to risk stratify this and decide who is a candidate and who is not. I don't think the cardiogenic shock patients should be part of this project.

Sundrani - They are not part of the project in that way, but we have to collect the data for them. They are not getting electively enrolled but they are part of the count. We need to keep our volume count high enough to be part of the program.

French - What are we suggesting the hospitals do with those in this part of the process?

Bommer - Acceptance into the cath lab is up to the clinician and interventionalists at the receiving hospital. We are not interfering with that. If the AOC approves a motion recommending a policy or statement on that for consideration, that could be added to the current inclusion criteria. STEMI was included because we didn't want cases coded as STEMI to exclude it from the rates. The state wants a minimum of 36 primary PCI's per hospital per year, so we wanted to monitor those.

Forman - Those patients coming in STEMI are not signing consent for CAMPOS when they come in with an ST elevation MI. Even though we are collecting the data, they fall outside that scope. With the shock patients, they are not signing consent forms either. We are comparing apples to oranges.

Sundrani - This was discussed last time and my understanding was that these ST elevation MI patients would have an extra line added to the

consent, saying that the data would be collected and sent to UCD. That is how we have been handling ST elevations here.

Way - That is an agenda topic for later in today's meeting.

Bommer - Moving onto the next slide, patients who are transferred for cardiac surgery, we have the information for each of the hospitals. A small number of patients—eight—were transferred, and of those patients there was one death.

There is more detail on transferred patients on the next slide. All but one were STEMI patients. We also looked at the time of transfer. They should be transferred in an hour and a half as a goal. The times are mixed because of the varying patient condition factors. (Displays patient transfer data on individual patients)

Forman - Are those minutes or time on the clock?

Bommer - Time on the clock, which is what the staff enter.

French - For the one death, how long after the transfer did the patient die and what were the circumstances that he didn't have surgery before that?

Aryana - I can forward the AOC that information. We have the data on when the patient died and the discharge reports.

Jain - I can elaborate. The patient had come with a circumflex occlusion. The patient was transferred to the hospital for surgery. When he was reached the receiving hospital he was stable. The surgeon decided to wait until the morning. Early morning, the patient developed acute mitral regurgitation (MR) and died because of that. We need to discuss, once we pass the patient to the receiving hospital, why would they want to wait?

Bommer - Do we want to poll the panel? (AOC agrees)

Poll responses-

- It is always difficult to convince the surgeon to take a patient who is in cardiogenic shock or has a complication. A lot of surgeons like to have a cooling down period for optimally treating the patient.
- We have been pretty successful in working with surgeons on this. The ones that urgently need care are taken quickly. Once every two years there may be an argument about it. More often they would be pushed ahead of a stable patient if necessary.
- I don't think we have had a huge issue. When we push clearly about what we want, they generally go ahead.
- I have the same problem mentioned earlier with the cardiothoracic surgeons. Their data says that if they wait, they get better outcomes. My experience says that if you wait, the sicker patients die, and then you are only taking the healthier patients. I have had at least two patients that should have gone right away who died because the surgeon wanted to wait.
- Most of the surgeons will operate immediately. They are afraid of

mortality because of the outcomes reporting. They don't want to be the ones doing all the salvage cases with the high mortality rates.

- This is the usual discussion between interventionalists and surgeons. In general, the patient should be operated on. In this particular case, we don't know the details of what was going on that day, what support the surgeon thought they might have at midnight instead of six a.m. It is hard to say what should have happened without having all the details.
- It depends on your individual relationship with the surgeon. If stated the correct way and clearly, they will usually take them.
- In one case there is a STEMI transfer where the infarction has been going on a while and the surgeon is deciding what to do after assessing the patient. They might wait or take the patient. The other situation would be in the case of a cath lab mishap that was not a STEMI at the beginning, and there has been induced ischemia, they will generally operate right away.
- What was the TIMI flow on this patient? (Response—As I remember, there was no flow after the dissection in the distal vessel.) Then in this kind of patient, with ST elevation and no flow, the surgeon would take them right away.
- The key thing is that the right thing was done by the transferring hospital, and what occurred was beyond their role in the timing of surgery. That is really a separate issue. I agree that in retrospect surgery was the right thing to do.

Brindis – The point to note is that the system was working.

Bommer - Fourth on the slide is a STEMI transferred for bypass due to failed PCI. There was a 70 percent lesion after PCI. The patient was transferred for bypass because of failure of the RCA. At the receiving hospital, they decided that they could do the PCI, so they went ahead with it. There was no requirement for CABG for that patient. The transfer time was about two hours. No bypass surgery was done.

Fifth on the slide was a STEMI, an urgent transfer for CABG due to failed PCI. Surgeons decided against CABG, treated the patient and no CABG was done. Transfer happened in less than two hours.

Sixth on the slide was a STEMI. The patient was transferred for elective CABG. The second form was not filled out, so we do not have that data. We do know they were transferred for CABG.

The seventh patient was a STEMI. The RCA was stented. They planned CABG because of a high-grade lesion. They fixed the acute lesion to transfer for CABG. The patient received CABG two days later, presumably at the decision of the surgeons at the receiving hospital. The transfer happened in two hours, but that doesn't mean the patients are automatically and immediately going to the OR.

The last patient was a non-STEMI transferred for emergent CABG. There was about a 90-minute transfer time. The patient went to surgery relatively soon after the transfer.

Forman - It is important to point out that *none* of those patients were elective cases. There were 150 or so elective cases and not one required transfer for emergency CABG, which speaks well for this program.

Bommer - The non-STEMI were not necessarily included, so we would have to include that.

French - Is it possible that we could make sure these cases are reviewed angiographically?

Bommer - They all are, yes. We can bring those in for AOC review.

(Displays PCI-CAMPOS Summary 1 Slide)

There are 481 patients. The target was 500. Of those patients, 164 were STEMI, so about a third of this population were STEMI. For data completion, we have complete data entry on 463. 18 more are a work in progress and additional fields are being filled in for those patients. Of the 481 patients, audit queries were submitted for each patient. (Additional statistics displayed)

One emergency transfer fell within the two-hour window; one fell outside of the timeframe.

Aryana - I understood that the transfer was supposed to be completed within one hour.

Bommer – One hour is the goal for the hospital transfer, and to have the patient into the OR within 120 minutes total.

Poll responses regarding suggestions on maintaining short transfer times:

- Critical events training is useful, and doing that live with the other facility, timing it, and identifying systems and efficient processes has helped significantly in reducing the transfer time.
- We have a single point of contact to call who coordinates everything on the receiving side, and we arrange the ambulance. Where our issues happen is with the scheduling commitment of surgeons—and for the schedules in the actual ORs— and having a surgeon and OR available on short notice.

Bommer - With a STEMI, the transfer protocol has to be rehearsed. I like the idea that was mentioned of having a single point of contact.

Smith - The biggest hang-up at our facility has been with the ambulance. We have quick coordination with the cath lab and the OR; the problem has been with ambulance delays. We are better now for a number of reasons including using than one ambulance service, but that has been an issue up until now.

Guest question - How is the transfer time calculated?

Bommer - The clock starts with the determination is made in the cath lab that a transfer is required.

Sundrani - We have two cardiac surgical hospitals where we can take patients. In the case of emergent surgery, if one hospital may have an OR sooner but is not participating in the program at this time with the ACC registry, and the surgeon may even be the same for either hospital, what is the requirement as to where that patient is sent?

Bommer - We will check with the actual requirements in the Bill, if they actually cover that. I would think if the AOC wants to make a recommendation on that, it could.

Sundrani - In this case, they are participating in the CT surgery registry and have acceptable numbers, but the hospital hasn't invested in the time to have the cath lab data sent to the ACC registry, which does take significant time and effort.

Bommer - UCD's legal department is reviewing the Bill to look at the requirements. I don't remember seeing a requirement for the *receiving* hospital. I believe the Bill just states that you have to have met with the receiving hospital, established a protocol that you agree on, and that they are willing to accept patients on a timely basis. If you have that, you are in compliance with the PCI-CAMPOS study.

Aryana - The pilot hospital has to submit data to NCDR, but there is no such requirement for the CABG surgery department.

Bommer - So you are free to move forward if you have an agreement and protocol with the receiving facility in place.

Sundrani - In this case, we do have an agreement with both hospitals; thank you for clarifying.

Bommer - (Displays PCI-CAMPOS Summary 2 slide)

The PCI success rate was very good, at 93.9 percent showing less than 20 percent stenosis. The TIMI-3 Flow was 96.6 percent, again very good. The observed mortality was 1.94 percent. This was slightly *lower* than the patient discharge data showed for the rest of California. We cannot yet do risk adjustment analysis on the PDD data because we do not have all the fields.

As far as transfer, the emergent transfer rate was .43 percent, the urgent was .86 percent and the elective was .43 percent. This is slightly over the rates of other hospitals, but statistically insignificant.

We identified risk factors in our limited data. We don't have all of the California data, so we performed our own risk assessment model. This (slide) shows what we have found for mortality risk factors. The observed correlates very well to the predicted in terms of mortality.

French - The one that is missing that I find amazing is age.

Bommer - We don't yet have big enough numbers to support age as a factor. There was a trend suggesting age is a factor but it wasn't statistically significant.

French - Can you review the non-STEMI mortality again?

Bommer - We can look on the risk factors on the non-STEMI patients as well and come up with that separately and provide that data.

French - As well as looking at the data from the rest of the state.

Bommer - We have a limited number of risk factors available with the PDD data from the state. There are four to five that we can use.

Overall, using our own group, we were able to assess adjusted risk mortality at between 0 and 2.76 percent. There was no statistically significant difference between the hospitals in the trial.

The next slide is the NCDR agreement. We were under the understanding that if everyone joined, the six pilot hospitals plus the coordinating center, and we paid our admission fees, that they would provide us with a limited set of data from California to compare PCI-CAMPOS patients with the rest of California. They came back to us last month and said that was fine but wanted additional funding besides the admission costs, and that was \$105,000. This letter—option one—states that NCDR is willing to share a de-identified data set, which means that they take the name of the patient and change it to a numeric identifier. The physician is also de-identified and given a number instead of a name. Only NCDR keeps the code relating the patients and the physicians to their corresponding numbers.

French - They can't give you data that is not de-identified unless each of the participating hospitals formally give permission to NCDR to offer that to the state.

Bommer - Correct, and that is option two. If individual hospitals would consent to allow that data to come over without identity changes, then NCDR would do that data transfer for \$26,000. That would require *each* of the 150 hospitals to agree to send us that information to use in a confidential, HIPAA-protected manner.

Under option three, NCDR would release technical documents with updates and give us access to data files directly. The catch is that each of the hospitals would have to send us the data on their own. That would be \$1,000 per year.

When we filled out the budget a year ago, this was not part of the budget and UCD does not have the funds to cover the additional \$105,000. We had only budgeted what has already been paid to NCDR. I could make arrangements to do some cost shifting to pay for the \$26,000 option without additional funding, but if we go for option one, there would need to be additional funding.

Arnold - Is July 2009 through June 2011 enough to have a control group, or does the dataset need to cover a longer time period than that?

Bommer - UCD would work with NCDR on the timeframe. I just wanted to

put those numbers down to illustrate the options.

Regarding the funding, if a vote from the group confirms that the study can't afford the fee, with CDPH consent I can go back and see if I can negotiate a lower fee. We have a couple of NCDR Governors at this meeting, so maybe we can have some influence.

Brindis -Is the state able to make mandates regarding collection of data? Also, with option two, how do we make it of value to the hospital. If we do offer some value added, maybe the hospitals would be more inclined to agree. In the same way that we would have a benchmark report, the participating hospitals would also have the benchmark report, so that would be a mild carrot in terms of incentive to relinquish consent with de-identification of the hospital.

Down the line, there are a number of potential projects in the state of California such as merging of STS and NCDR databases. We may be able to figure out how option two could play out in combination with those other projects.

Bommer - We could make some incentives to get many of those 150 hospitals to want to consent to us seeing the data. The issue is that we might not get 100 percent unless we mandate the consent. I spoke to Dr. Way about this and said that the CDPH is the regulator for each of those hospitals. If there was an AOC recommendation to CDPH to mandate this, CDPH could possibly implement this for all the hospitals they oversee. It would mean that to have CABG at your hospital, or do PCI's, the data would have to be released to central recording, with the understanding that it will be confidential and HIPAA protected.

I would prefer something like that because it would get us 100 percent of the hospitals. If we select an option where we only get partial compliance, it creates sampling error.

Way – A statute of regulation would be the way to proceed, the way to get that 100 percent. I am happy to take this forward if the AOC so decides, but it is difficult to mandate anything without legislature passing a statute.

Brindis - My perception is that funding to do the oversight would be difficult. We can do a mandate without public reporting, so you don't have that stick, and then the state gets a free look in a HIPAA compliant de-identified capacity.

Bommer – UCD is willing to fund option two right now. But as you mentioned, it is then an unfunded mandate, and I'm not sure if that is any easier to get through, because the mandate probably has to come through CDPH.

Forman - With option two you would be transferring records that have patient demographics...

Bommer - Correct. Just as we are, it would be just like PCI-CAMPOS. NCDR would release to us information from hospitals in California that

had the same data set that you are entering for PCI-CAMPOS.

Forman - But all the patients we have are signing medical releases that say that we can release the data to UCD. Would there be an issue with individual patients having to consent to this, or has that already been covered by the release form?

Bommer - We can build that into a consent form for the 150 hospitals. To clarify, CDPH has regulatory authority to walk into any hospital at any time to review records.

French - I think mandating is how it would work best. That's what was done with the STEMI Receiving Centers, by mandate; we now have hundreds reporting data to their local EMS agencies.

Brindis - How long did that take?

French - It took about two years, but it has become so automatic that Los Angeles County decided to add on Cardiac Arrest / Hypothermia Centers to SRCs, and mandated that basically overnight. Now you cannot be an SRC without also being a Hypothermia Center in Los Angeles County.

Brindis - I just thought of option four, using the national report rather than the California report. I remember the statute talked about California, but that would be one possible recommendation. What deficiencies would you have using the national report?

Bommer - The national report is available, but not individual data.

Li - You cannot apply their data to our work. The software needs to compare the same data.

Bommer - If you don't know how much variation there is in the data coming in, you lose statistical power in just comparing the means.

Forman - Do we have a choice to not get the data from NCDR? Since you used the PDD data for this presentation, is that enough to prove what we need, or do we need the NCDR data?

Bommer - Well the advantage of the NCDR data is that the PDD data has maybe about five risk factors as opposed to 220 risk factors in the NCDR data; that allows for a more robust comparison.

Li - PDD data is not for clinical adjustment purpose.

Way - Obviously the best thing to do would be to come up with \$105,000. Whatever the AOC's recommendation, send it to me as an email; I will send the request up the chain of command.

Bommer - We will do that. Regarding the other option, if the AOC decided to divide the \$105,000 between the hospitals, that would be assessed and divided by CDPH so that each hospital would cover one-sixth of that total.

Fehrenbacher - If UCD could afford to take on \$26,000 as stated, then each hospital would then owe about \$13,000.

Bommer - We could pursue that. This whole dataset costs problem only arose three weeks ago. UCD has been working with NCDR all along and this is the first time this additional cost came up.

Fehrenbacher - What percentage of California hospitals are involved with NCDR?

Bommer - About half the hospitals.

Fehrenbacher - So the PDD data would represent California more completely. Is there a quality differential between those hospitals that participate with NCDR and those that do not?

Bommer - We don't know that answer. PDD does not give you risk adjusted mortality rates, because you don't have the risk factors. So the PDD two percent reported mortality could be higher or lower if risk adjusted. The reason for acquiring NCDR data is that it is a big data set; the risk model would have more precision, and we could then compare our smaller volume PCI-CAMPOS data to the larger volume California data. That would be the best way to risk adjust in our process.

Brindis - If you can get the state to mandate it, you would only need to pay NCDR the \$1,000.

Bommer - That involves not only having six hospitals reporting to us; now you would have 150 hospitals sending in data continuously, which means we would need to track and audit those. If we did that, I would have to hire a person to handle the calls and support. That is why UCD supports option two.

Sundrani – This is a decision of the administration and we would need to discuss it with them.

Forman - Can we work option one and two at the same time?

Bommer - We can do that. There is a cost benefit ratio when you think about what 200 PCIs generate for the hospital. I will provide the two options in an email for review.

Moving onto the next slide, there has been quite a bit of interest nationally in appropriateness criteria for PCI and for automatic implantable cardioverter defibrillators (AICD), and so forth. We do have appropriateness criteria for PCI and I have listed them here. This is on the website and has been published. There are 59 criteria for PCI. Do we want to go down that route again for appropriateness? It is in the headlines nationally and there is interest in some of the third party carriers in finding this information.

Brindis - The next iteration of the NCDR report will have benchmark reports on a hospital's appropriateness in benchmark form. We would

have that data available for these hospitals. It would be benchmarked against national data, not California data. There are actually 180 different scenarios because each has different permutations, but the appropriateness criteria document is in the process of being updated related to changes in guidelines and syntax. Most of the updates are in areas that would preclude candidates from inclusion in this program. Even using the current appropriateness model should work for this program.

Bommer - We would not look at appropriateness of PCIs that were not done, but we would look to ensure that the ones that were done met the appropriateness criteria. If they could share with us what the criteria algorithm was for selection on NCDR, we would try to mimic that in our data set to compare our PCI-CAMPOS criteria to the national appropriateness criteria.

Brindis - Intuitively appropriateness in the CAMPOS-PCI program is going to be high, because we submitted a paper about the NCDR appropriateness, looking at our last 500,000 cases. By definition, a STEMI or non-STEMI or unstable angina is appropriate.

Bommer - We don't have that many electives right now, but that may change over the years during the study. I will research criteria. I was waiting to hear from the AOC if they want to take the step into appropriateness criteria or not.

Brindis - I have to ask what it would cost the state to undertake that.

Way - CDPH would much rather see you do the other 150 hospitals, rather than opening up the complex issues of appropriateness criteria. If you could add another 150 hospitals for the same cost, that is an option.

Brindis – Ninety five of the 130 hospitals that do angioplasty in the state are in NCDR.

Forman - I would not be against the appropriateness work but we need to keep the intent of the original law on the table. The appropriateness criteria should be a secondary goal.

Sundrani - We should just stay focused on what we have at this time.

Brindis - I would agree with that. There are some interesting aspects to this, because one of the issues we have been having is in getting some centers adequate buy-in, so maybe this would influence decision making in doing angioplasty, and maybe that would be important information for us to know if that is occurring. By assessing appropriateness, you would be able to do that.

The important point is whether there is any added work on the Quality Analyst level in submitting the data, and the answer should be no.

Bommer - It should be cost-neutral since we already have coders entering every field. The only difference would be processing onsite to assess appropriateness, so it would not cost the hospitals any additional fee.

Forman - So the data is already being submitted. The NCDR has not decided whether to include it?

Brindis – That data inclusion will happen next quarter. The variables are from the appropriateness criteria document published in January last year, and the algorithms are included in version four of the NCDR.

Forman - So why take it upon ourselves to do that for these six hospitals as a separate issue if you are already going to be collecting that data?

Brindis - We are not doing that for the state.

Fehrenbacher - We will get appropriateness criteria when we get our quarterly rolling twelve-month report.

Forman - If it would support the final product, I would do it. If we can say that we are not only safe but 100 percent appropriate, so that the law could be changed so that we could do elective angioplasty permanently, then it makes sense to do it. But if it just adds more data, I am not clear why we are doing it for these six hospitals.

Bommer - If we process the data to do it, we would present it back to the AOC. If you keep that information for the hospitals separately, we could not report that data. If the hospitals turned that data back over to UCD, we could include it in the report.

Itchhaporia - It is not data that is required, and it is only representative of 20 percent because it is only elective PCI stable patients.

Smith - When you are dealing with small hospitals, you are dealing with 20 percent of their already small volume.

French - I would suggest appropriateness might be a better subject for year two or year three, when we have the fundamentals in place.

Brindis - I think it is another way of assessing quality. You can ask what the mission statement is for the program, and this would take it to another level of quality assurance.

Arnold - I think that the legislature wants us to come back with a cost in a center that provides it with or without backup bypass surgery, and on this there is no chance of supplying any meaningful data. This is an area we *can* supply useful data in addition to the primary data points.

Brindis - That is a good point. If the state is concerned with cost of care, which they put in the Bill, one of the cost concerns could be opening the door to sites that don't have onsite surgery, there might be a higher level of PCI appropriateness, and I don't think that is the case, but this would be ammunition to show that.

**Motion proposing the addition of an evaluation of appropriateness to PCI data submissions.**

- Motion—Arnold
- Second—Brindis
- Motion Passed

Bommer - I would like to thank everyone for coming today. That concludes my presentation. There were a couple questions from pilot hospitals if we want to enter into that.

Way - As a non-cardiologist I am very impressed by the quality and depth of the study and amazed at what has transpired. I am happy to be here. I am going to ask David Gioia to say something about Bagley-Keene.

Gioia - We talked about Bagley-Keene over the past couple of meetings. The one outstanding issue was to hold closed sessions in the meetings to discuss specific patient data. I thoroughly reviewed the exemptions, none of which would cover our situation. There really is not any catch-all that would allow us to close the meetings, so if we are going to bring up any specific data, it would have to be appropriately masked the way it has been thus far.

Way - The next item: questions from the pilot hospitals. The first question regards discharge CABG reporting at pilot and non-pilot hospitals.

Bommer - The question was whether we may be reporting more transfers out of our group than the NCDR or other groups because we have the additional transfer reporting that is not part of the NCDR information. What we have reported is deaths during hospitalization. That is the same as NCDR reporting, so even though we are transferring someone, we will always report that separately. We will be reporting deaths similar to similar. We would not add deaths that occur after the patient goes home. We would report that separately. When we get NCDR data, UCD will make sure it is comparing like data.

Forman - As far as getting the NCDR data, is there a drop-dead date where you need it at the end of the trial to process the data?

Bommer - We anticipated the NCDR data before we started the program. We would like it as soon as possible, because we would have more data for risk adjustment. This year would be the objective.

Fehrenbacher - When patients are readmitted to the hospitals, the national NCDR does not look at that or count them, but are we looking at that at the six pilot hospitals?

Bommer - We will have that data if you report it to us, but we will not use that data to compare it to NCDR. There is valuable data that we will have available that will not be part of the comparison.

Fehrenbacher - The other issue was on up-coding and down-coding. You are up-coding our data to make it more accurate. Is there up-coding in the national or California NCDR database? There is no way to audit that data.

Brindis - The first time it has ever been done was in Massachusetts where

they audited 100 percent of the charts. Sharon-Lise Norman wrote an article about that which you can review for your own interpretation of up-coding and down-coding ramifications.

Bommer - The next issue is confidentiality of patient data. For STEMI patients coming in who normally wouldn't have to have a consent signed, we are still interested in that data. If you include on your intent form that data may be released to the state, then we are covered. If you verbally tell them, given the extenuating circumstances, that would be fine as well as long as the patient is aware. If they can't be informed, you can talk to the family. If you decide not to have that consent, or a patient refuses, because the state's mandate is to follow STEMI patients, we would probably ask the state to get that information separately. The state does have the authority to go into the hospital to review patient information.

Fehrenbacher - Sometimes it is not the interventionalists or coders who are unwilling to get the consent. Sometimes it is the IRB who looks at the entire package and decides it wasn't part of the original agreement and was not necessary. There are multiple layers involved.

Bommer - I would be happy to speak with the IRBs at the hospitals, which I have already done prior to the start of the study. For an IRB, having this information looked at improves the relative safety of the patient. There is nothing here that is detrimental. The IRB folks I have talked to have agreed to it.

Arnold - It goes a little deeper in our case than the IRB. It is the core in the emergency room at the time of the STEMI. There are many things occurring around the patient at the same time. It is the ER staff obtaining the consent initially, and the ER staff wants little to do with the explanation of CAMPOS or data to Davis or anything along those lines. Our solution has been to get the patient to the cath lab, get them treated as quickly as possible and get the consent *after*, which 100 percent of the time the patients have consented.

Karmarker - I wanted to clarify the consent process. Some of the interventionists are concerned that at 2:30 a.m., getting out of bed to take care of patient, the last thing on their minds is getting consent for data. You may also get called back to back on two STEMI alerts at different hospitals, so to go back to get consent later is difficult. Are you saying that just by adding two sentences to the consent form, that is adequate, that they wouldn't have to sign a separate consent form?

Bommer - Since it is 'informed consent', it does imply that the patient or the patient surrogate is aware of the procedure you are going to do along with the risks. If in that informed or verbal consent you mention that the data will be shared with the state, then you are covered for consent.

Forman - I agree with the point of going back after the procedure to get the consent.

Karmarker - We try to do that as much as possible, going back and obtaining consent. I just wanted to confirm that adding the statement to

the standard consent form is adequate.

Bommer - For our program, yes. You may want to run it by your individual IRBs. It may not even have to go through IRB, but your hospital administration probably wants to ensure there is reasonable informed consent for patients.

Way - By Bagley-Keene, we have one minute to wrap up.

Bommer - We would like to thank everyone for their hard work and look forward to reporting back to you on our progress.

Brindis – Bill (to Bommer), as a member of the AOC I wanted to congratulate you and UCD for your hard work and diligence in helping the state and the six centers, and being able to do terrific oversight on the quality. I want to reiterate your comment that the six centers are doing very high quality work and I am proud of their representation to the state with what we can do with PCI's without onsite surgical backup.

Bommer - On behalf of the team that does all the work, thank you very much.

**Meeting Adjourned**

#### **Acronyms**

|            |   |
|------------|---|
| ACC        | American College of Cardiology                              |
| AFL        | All-Facilities Letter                                       |
| AOC        | Advisory Oversight Committee                                |
| CABG       | Coronary artery bypass graft                                |
| CAMPOS     | California Audit Monitored Pilot with Offsite Surgery       |
| CDC        | Centers for Disease Control and Prevention                  |
| CDPH       | California Department of Public Health                      |
| CMS        | Centers for Medicare and Medicaid Services                  |
| CQI        | Continuous quality improvement                              |
| CT surgery | Cadiothoracic 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        | CDPH Office of Legal Services                               |
| 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                           |