

**Percutaneous Coronary Intervention (PCI) Advisory Oversight Committee (AOC)  
 July 29, 2010, 1:00 p.m. to 4:00 p.m.  
 Location: Sacramento**

**MINUTES**

**Attendance**

**Members** Kathleen Billingsley (Chair), Stephen Arnold MD, Ralph Brindis MD, Robert Davidson MD, Mahmoud Eslami Farsani MD, George Fehrenbacher MD, William French MD, Steven Forman MD, Aditya Jain MD, Dipti Itchhaporia MD, Sushil Karmarkar MD, George Smith MD (alternate for Dr. Coleman), Rohit Sundrani MD

**Guests** Peter Baldrige, Lisa Barnes, William Bommer MD, Eric Brooks, Jennifer Cardenas, Bob Forey, Todd Gile, Carla Knight, Daryn Kumar, Zhongmin Li, Geeta Mahendra, Kim Newlin, Mary Owen, Kathryn Robidoux,

**CDPH Staff** Sam Alongi, Melissa Anastasio, Roberto Garces, Tom Rodacker, Carol Turner

Agenda Items/Discussion	Action/Follow-up
<p><b>Call to Order</b>            AOC Committee Chair Kathleen Billingsley (Chair) convened meeting.</p> <p>Chair – I want to thank the number of hospitals that applied to this program and congratulate those selected. More importantly, I want to thank many of you who as volunteers are joining this Committee. It says a lot that there is as much interest in this and that people are willing to give up their time to devote to the greater good.</p>	
<p><b>Bagley-Keene Act and Introduction Letter</b>            Peter Baldrige gave a presentation on the Bagley-Keene Act, which mandates rules of public meetings including ensuring that the public is noticed for, welcome to attend, and given opportunity to speak at meetings qualifying as public under the Act.            Mr. Baldrige’s presentation is available on PCI Pilot Program website [<a href="http://www.cdph.ca.gov/programs/LnC/Pages/PCI.aspx">http://www.cdph.ca.gov/programs/LnC/Pages/PCI.aspx</a> ]</p> <p>Smith – In regards to the requirement of public notice, for the members who are going to participate by teleconference, will CDPH staff take the responsibility of notifying the public of the teleconference location?</p> <p>Rodacker – Yes; page two of the agenda, which was posted publicly 10 days before this meeting, lists the conference call-in number and off-site location. If a Committee member wants to participate in a Committee meeting at another off-site location, that member would arrange to have a publicly accessible conference call location, which would be listed in this way.</p> <p>[Note: a member who calls in to a meeting from a non-publicly available, non-noticed site may participate in the meeting as a guest or member of the public and may not vote on topics presented during the meeting.]</p>	

<p>Chair – In terms of posting the agenda, when members have other off-site locations, those locations will be included in the agenda that is posted on the website.</p> <p>Davidson – Do we as individuals arrange for that, or can CDPH staff help with setting up a site in advance?</p> <p>Rodacker – Members should provide me with contact information of the appropriate staff persons; CDPH can work with staff to help set up those locations.</p> <p>Smith – As I understand this, a member calling in would have to go to that listed (posted to PCI website) site as individual members of the Committee?</p> <p>Rodacker – Correct.</p> <p>Baldrige – One issue I want to emphasize when forming subcommittees, it does not matter if the subcommittee consists of members of the AOC. If you set up a subcommittee consisting of a facility’s staff and it was formally organize and formally authorize by the AOC, and it consists of three or more persons, it is a Bagley-Keene subcommittee.</p> <p>Brindis – You skipped over the slides regarding closed sessions; Kathleen, as the chair, do you envision that there might be opportunities where the Committee might break out into those?</p> <p>Chair – Based upon my experience with the Healthcare Associated Infections Advisory Committee, which consists of 35 members, we have never had a closed session.</p> <p>Baldrige – Based on Bagley-Keene, special meetings, emergency meetings, and closed sessions are all limited to the discussion of specific categories of agenda items. If there is an agenda item that the AOC feels needs to be discussed in a closed session, the AOC must consult the attorney assigned to the AOC to verify the discussion qualifies.</p> <p>Billingsley – Thank you for coming and presenting this information.</p>	
<p><b>Meeting Protocols</b></p> <p>Chair – Chair reviewed the “Committee Recommendations and Guidelines” handout. Approved Committee guidelines will be posted to the PCI AOC website.</p> <p>Chair – The second page of the handout lists Tom Rodacker, PCI Project Lead, as the CDPH point person for this entire project. If you have any questions or concerns, his contact information is listed. Carol Turner, Field Operations Branch Chief, is also responsible for management of the PCI Pilot Program alongside Tom.</p>	<ul style="list-style-type: none"> <li>• Staff to update the “Committee Recommendations and Guidelines” with the approved change “Committee members may select an alternate member for themselves”.</li> </ul>

Forman – In the Bagley-Keene presentation Mr. Baldrige mentioned staff. At a hospital, when a team is collecting the data that requires discussions, do their discussions have to take place in a public meeting if three or more of the hospital staff is participating in that discussion?

Chair – If the AOC forms a subcommittee, that *subcommittee* must adhere to the Act. The discussions you have in your hospitals regarding the procedures of the PCI Pilot Program itself would not qualify. Subcommittees are formed by the decision of the AOC to form that subcommittee for a defined purpose, there is a beginning and end to the work they are going to do, and then it is reported back to the AOC.

Billingsley – At this time I would like to pause and allow the membership to introduce themselves. [A listing of the PCI AOC membership and members' organizations are available on the PCI website [\[http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx\]](http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx) [Introductions were made in Sacramento and on the teleconference lines]

Chair – Handout concepts are open for discussion; if any member has any questions or suggestions, your feedback is welcomed. [Chair suggested that document be edited to reflect that each member may select an alternate.]

Alongi – The second bullet under Voting Rules will be change to state that Committee members will use an alternate member; that is the wording that will be included when the Committee votes on this as a packet. If there is any discussion around the use of alternates?

Brindis – I can understand why a hospital might need to have an alternate member, but a State appointee would also have an alternate member?

Smith – I am here as an alternate member for Patrick Coleman. I might continue on since Pat couldn't come to the first meeting; I need to ask Pat to see what he wants to do. If he wants to come back on and have me be the alternate, then that's fine; if he wants me to be on the Committee instead of him, that's fine too.

Brindis – I'm an appointee from CDPH, so if CDPH wanted an alternate for me wouldn't that be your decision?

Chair – Historically CDPH has allowed Committee members to identify and nominate an alternate. You are allowed only one alternate. Committee members generally elect someone familiar with the project. So you are not bringing in someone who is not knowledgeable and wouldn't be able to provide input as you would if you were in attendance.

Rodacker – Listed in the rules the AOC is going to vote on today is a rule that the alternate needs to contact CDPH staff 14 days before the meeting.

Sundrani – The reasoning for having an alternate is that if I am unable to attend and need someone else to represent me and my organization?

Rodacker – Correct. As the minutes from all Committee meetings will be posted on the website, a selected alternate can become familiar with the process and the discussions of this body.

Itchhaporia – Those members that are part of hospitals and part of the PCI Pilot Program will find it much easier to identify alternates as other people are involved in the project. Some people on the Committee that are not participating as hospitals may find it much more of a challenge to find an alternate.

Brindis – Every hospital should have a representative at every meeting to protect their hospital's interest. As a State appointee, I'm in a different position

Smith - Do you mean the six designated hospitals or any hospital?

Brindis – The six designated hospitals.

Itchhaporia- Our facility is not one of the six designated hospitals; we're additional physician input on the AOC so it is a whole different ballgame in terms of alternates for us.

Alongi – Would it help to change the wording to “may appoint an alternate” rather than require it?

Itchhaporia – I think that would be better.

Chair – It may be beneficial to talk about attendance and participation; attendance of the member or their alternate would count for attendance; this may become important if we consider attendance rules as a condition of remaining on the AOC. Would it be the consensus of this group that alternate members be identified? I leave that to the members to give their input.

Karmarkar – The PCI Pilot Program is set to expire in 2014. I anticipate it will be successful; if it is, is one of the charges of the Committee to make a recommendation to the State that this can be disseminated to other hospitals provided they meet volume quality criteria?

Rodacker – Senate Bill 891 does expire in 2014. The AOC and CDPH will make a recommendation to the Legislature. If the Legislature does nothing with that recommendation, the Bill sunsets, the PCI Program goes away, and we go back to the way things are currently with Title 22. It would require legislative action to continue the activities set in place by the Bill.

<p>Chair – The bill does sunset at the time designated; any further action other than the report itself would be sent to the Legislature and then become part of the legislative process.</p> <p>Davidson – Under Voting Rules, it says Committee must decide if alternate would be eligible to vote on Committee issues, could you explain how that works. Are we as a Committee supposed to vote on the eligibility of the alternate?</p> <p>Alongi – The language would be changed to state that Committee members may select an alternate member for themselves. And that alternate member would not be subject to a vote; the selection would be noticed to the Chair for approval.</p> <p><b>Motion (Forman) – Move to adopt the Committee Recommendations and Guidelines with the proposed change:</b></p> <ul style="list-style-type: none"> <li>• <b>C. Voting Rules, second bullet to read “Committee members may select an alternate member for themselves”.</b></li> </ul> <p><b>Second - Smith</b>  <b>Discussion – no further discussion</b>  <b>All ayes; Motion passed</b></p>	
<p><b>Requirements and Responsibilities of AOC/Expectations of Selected Hospitals</b>  Rodacker presented the “Duties of AOC” and “Expectations of Selected Hospitals”; handouts available on PCI AOC website:  [ <a href="http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx#meetings">http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx#meetings</a> ]</p> <p>Billingsley – SB 1301 requires hospitals to notify CDPH of an adverse event; there are 28 predefined adverse events.</p> <p>Rodacker – The one that would probably apply to a cath lab is death within 24 hours of anesthesia. Participation in this study does not preclude facilities from notifying CDPH of those events.</p> <p>Itchhaporia – What will the quarterly reports include?</p> <p>Rodacker – Patient demographic information; cath labs have already been trained in this area.</p> <p>Sundrani – How rigorous will the collection of data be.</p> <p>Rodacker – That will be covered in the presentation by UC Davis (Bommer); the cath labs received training on that as well.</p> <p>Smith – Who writes the annual reports? I assume staff will develop the reports and each Committee member signing off on it.</p> <p>Chair – The reports will be drafted by our contractor and then be reviewed</p>	<ul style="list-style-type: none"> <li>• Staff to change 5-A of the “Expectations of Selected Hospitals” handout to read “36 <b>primary</b> PCIs annually”.</li> </ul>

<p>collaboratively by the AOC and PCI staff before the final internal review process prior to being sent to the Legislature. As far as the clarifications of the AOC members' individual signatures on the reports, I will check on that.</p> <p>Smith – What responsibilities do we, as Committee members, have for the building of the report?</p> <p>Chair – From what I understand, the contractor will be collecting and summarizing the data to extrapolate that information into the report itself.</p> <p>Smith – There should be physician input from the early stages and not just as final review before the report goes to press.</p> <p>Chair – Agreed.</p> <p>Forman – What exactly will be included in the report? “Report” is a broad term; will it include interim data?</p> <p>Rodacker – Dr. Bommer’s presentation (Scope of Work by UC Davis) will present the statistics to be compiled.</p> <p>French – Are there any criteria that would prematurely terminate this study before its planned end?</p> <p>Rodacker – Other than something such as an unusual death rate, there are none that I am aware of.</p> <p>Note: “Expectations of Selected Hospitals” handout 5-A contains a typo and should read “36 <b>primary</b> PCIs annually”.</p>	
<p><b>Scope of Work-University of California, Davis (UCD)</b>  Dr. Bommer’s full presentation is available on the PCI AOC website:  <a href="http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx#meetings">http://www.cdph.ca.gov/programs/LnC/Pages/PCI-AOC.aspx#meetings</a></p> <p>Fehrenbacher –Some hospitals use their local IRB for the consent process; how will this be reconciled against the UCD IRB process for this study?</p> <p>Bommer – Each hospital will have their own IRB application with their local IRB for which consent will be approved; UCD has monitored the consent to make sure the necessary regulatory statements are in conformance with SB 891’s recommendations. UCD reviewed that for all the hospitals; all of the participating facilities’ consents now conform to those regulatory statements.</p> <p>Fehrenbacher – One of the difficulties is that because the original consent form was slightly modified, participants have had to resubmit the consent to their local IRB process.</p> <p>Bommer – The resubmission is a minor issue. The consent now reflects the fact the data has to be released to the patient; that their data does get sent</p>	

out of the hospital to a data center where UCD will analyze it, compare it statistically and do risk-modeling on that information; the data is then released to the CDPH and to this AOC to make final recommendations.

Sundrani - In the participating hospitals, there are the interventionists who have qualified through the criteria and have been set as the interventionists who will be performing these elective PCI procedures. Out of those 36 PCIs, there may be other interventionists at the participating hospitals who will be performing those PCIs, as they have privileges and have been doing these procedures for years. Do those numbers count towards the 36 PCIs and 200 PCIs requirements?

Bommer – That is a good question for the AOC to deliberate. For the purposes of training for the hospital, UCD would recommend counting those as part of the primary PCI count since that cath lab is encountering all those patients as well.

Fehrenbacher – The original bill required each individual (interventionist) who participated to have done 18 PCIs; you could do 18 primary PCIs per year, a total of 100 cases, and be doing all the elective procedures at the hospital while somebody else can do the other 18 or more.

Sundrani – In Fresno, Clovis, there are four hospitals; I am an interventionist at all four hospitals. Three of them have CABG at site; however one, Clovis Hospital, does not. Out of the 60 ST-Elevation PCIs I perform each year, maybe only six to eight are done at Clovis Hospital. At the facility, which is a Pilot hospital, do the interventionists who are also doing ST-Elevation PCIs there be considered as part of the 36?

Bommer - I would recommend you would count all of them; the AOC can make a motion to decide that at the end of this presentation whether to include those or not.

Karmarkar – Nationwide STEMI incidence is going down. At Kaiser Permanente, our STEMI incidence is 50% lower than it was a decade ago. I am not sure we can meet 18 STEMIs per individual per year going forward the next three years. Are we going to terminate a program or an individual if they do not meet the criteria of 18 STEMIs per year?

Bommer – It is a very good point to discuss; it is part of the business of the AOC to make decisions on that. If the AOC does decide to change something that is currently on the bill, then that would require considerations with the legal department to decide if there are any alterations in that bill language that can be legitimately accepted by the AOC.

Rodacker – The Senate Bill answers that; it says clearly that to participate, eligible hospitals shall perform 36; it does *not* specify that any individual

perform 36.

Forman – The Bill does say that the individual does 18 but it doesn't say at the Pilot hospital.

Rodacker – As part of the qualification, CDPH considered *total* volume.

Davidson – What was the basis for setting up the criteria of the number of primary PCIs?

Fehrenbacher – That came directly out of the SCAI guidelines. The first attempt with the Legislature was rejected; the second focused on the SCAI guidelines and was successful.

Karmarker – How do we incorporate new hires or transfers?

Rodacker – That is addressed in the Senate Bill; if an interventionist needs to meet the requirements, notify the audit nurse or CDPH.

Arnold – PCI to onsite bypass of 120 minutes is a good goal. However, there may be cases where the operating room (OR) is not kept open all the time for an emergency PCI. How would this issue be addressed?

Bommer – For regular patients, 120 minutes is the goal we try to achieve. For patients that are high-risk for PCI, the requirement is that you call the receiving hospital notifying them of the need for an OR to be open and a surgeon available before starting a case that is high-risk.

Jain – How do you hold the receiving hospital to meet the standards of the Program?

Bommer – There is an agreement that has to be signed between the PCI Pilot hospital and the receiving hospital requiring them to comply with the standards. We are receiving those contracts right now.

Sundrani – If a low-risk PCI develops complications, what happens if the receiving hospital OR cannot get the patient to surgery within 120 minutes?

Bommer – Ideally, the goal is for you to work with the receiving hospital to get the patient in the operating room within the 120 minutes.

[A. Bommer suggested that the PCI AOC recommend interpreting the wording under High Risk Patient I “90%” to mean 90°, as it reads in SCAI guidelines which guided development of SB 891.

B. Bommer suggested that the PCI AOC recommend interpreting the wording under High Risk Lesion I “cardiovascular” to mean cerebrovascular, as it reads in SCAI guidelines which guided development of SB 891.]

Fehrenbacher – This (in regards to 90° vs 90%) is taken word for word from the SCAI guidelines. The intent of the bill was essentially to verbatim have the SCAI guidelines in there. If there are any questions about the wording or a misspelling, my recommendation is to go back to the SCAI guidelines.

Bommer – If you look at SCAI guidelines, it does say 90°; because it is in the Bill, I would recommend the AOC would agree for our interpretation that “90%” to be 90° as recommended in the literature.

Fehrenbacher – Are you going to risk-adjust for age?

Bommer – In this study, we will risk-adjust for age, yes.

Brindis – I do want to make sure everyone understands that high-risk for mortality does not translate as high-risk for emergency surgery.

Brindis – In the CABG Oversight Program, there is adjudication process if there is a disagreement with the contracting site doing the review that the Clinical Advisory Panel can be involved in. If the Pilot hospital has a disagreement with the audit, is there an adjudication process? Although I applaud the State for funding the extra cost of auditing, I wish I could say the auditing program will be concurrent with the remainder onsite programs in California.

Bommer – No; it will not be the same level of auditing and monitoring that exists in the current onsite hospitals. When this was presented to the State, the decision was made that the data entered is legitimate and robust because a recommendation is going to be made to the Legislature whether this Program continues or not. NCDR does some limited checks but not as comprehensive as ours will be. In the adjudication process, films come in under audit and get reviewed by two angioplasty professionals. If they agree this is compatible with the standard of care, then it is sent in as acceptable as the final result. If the two individuals disagree, then a third PCI angioplasty professional is called in as an oversight who reviews it with the first two. If the group cannot agree on the result, that is something that may potentially get passed to the AOC to decide if they want to have an adjudication committee.

Itchhaporia – Are the 10% audits taken at random?

Bommer – Yes; a random generated statistical program identifies what cases will be audited.

Guest – Clarification: *after* taking out the deaths and complication cases; then the rest will be randomly generated.

Bommer – Correct; the complication cases will not be randomly audited. Complications could be as high as 10% of all cases. Auditing all of these

cases in addition to the 10% randomly generated makes for a robust audit

Brindis – Are you going to ask each hospital to have a confirming mechanism that all patients who were brought into the lab were actually entered into the NCDR?

Bommer – An audit nurse will visit that hospital, checks cath lab logs, and speak directly with the hospital nurses and cath lab. If it is discovered that high-risk patients are not being reported, UCD will immediately report that to CDPH.

French – Isn't one unnecessary death too much?

Bommer – In the trial, one death will not be statistically significant. This trial needs a larger number to make a decision of whether this protocol is statistically a higher risk or not. If UCD determines during the trial that a threshold has been passed and that there is a statistical higher complication or mortality rate, that information will be immediately reported to CDPH and to the AOC.

French – I would be concerned about statistical significance verses clinical significance. One death in elective PCI patients that are low-risk would be too much.

Bommer – The reality is mortality in low-risk patients is 1 in 100.

Brindis – The diagnosis of myocardial infarctions depends on the rigor with which people draw enzymes. In the NCDR, we have data showing the higher the myocardial infarctions rates, the higher the quality of hospital care that they have. Are there criteria for the hospitals here and how will they be compared to California, where there is no standard of care in diagnosing myocardial infarctions?

Bommer – UCD will not impose troponin measurements or laboratory measurements; those are decided by the PCI physician and the hospital through their established protocols. If levels are elevated, then the study requires them to be reported just as the NCDR does. This study will mimic as close as it can the current NCDR rules and regulations for the onsite hospitals in California.

Sundrani – Is there going to be a follow-up protocol; for example, 30-day follow-up phone calls?

Bommer – We will be able to enter voluntary follow-up data but it is not required; it is not required by NCDR for the other onsite hospitals as well. There is one additional tracking; UCD intends to look at the California mortality data each year to see if there was a death that was relative within 30 days of these PCIs.

Sundrani – Can we as the PCI AOC decide we want to implement follow-up protocol for the Pilot hospitals so we can get better data?

Bommer – The AOC can make any recommendations it approves to CDPH; if CDPH wants to implement those rules and regulations on the hospitals, then they would apply. The AOC in concurrence with CDPH can make those decisions.

Davidson – The question we're addressing is whether the absence of cardiac surgery ability at a hospital is going to increase the mortality or morbidity of these cases. It is really a separate issue whether there are complications that have nothing to do whether surgical options are available at that hospital.

**Motion (Smith) – Move to recommend to the CDPH that the AOC will recognize the following changes in the listed risks:**

- **Under High Risk Patient I, recent *cerebrovascular* attack instead of recent cardiovascular attack.**
- **Under High Lesion Risk I, the location in an extremely angulated segment as (*greater than 90°*) instead of (*greater than 90%*).**

**Second – Sundrani  
Discussion**

Chair – Several times during the presentation, the word 'interpretation' has been used. It is important to outline what the roles are of the administration and of the Committee. As a member of CDPH's administration, I may look at a law and decide what the definition of a particular word is, but I cannot interpret that law. CDPH cannot apply guidance and send out that guidance to hospitals instructing them to what a particular word actually means. CDPH's role is to obtain the Committee's recommendation, guidance, and feedback. As far as applying this in the real world, the Committee can make the decision of a particular word's definition but that does not mean that the law has changed.

**All ayes; Motion passed**

French – Who selected these criteria; are these included in the law?

Bommer – From SCAI recommendations; those were discussed with the Legislature and it was decided to use those previously published recommendations in the Bill.

French – So at the end of three years, hospitals will only be able to do those selected criteria?

Bommer – That is up to the AOC and CDPH to make recommendations and ultimately for the Legislature to decide. The Legislature may keep those same inclusion criteria, widen them, or narrow them at their discretion.

French – Is there any consideration, at least on the AOC's part, to leave the criteria up to the individual hospitals? Why do the criteria have to be so

stringent?

Bommer – Because it is written in the law; we cannot literally change the substance of these inclusion or exclusion criteria.

Chair – It is in the report to the Legislature in 2014 in which you, as AOC members, have this opportunity to provide your recommended path forward. The Legislature recognizes your expertise; there are people who are very serious about hearing your findings and considering your recommendations.

French – I would not have these criteria at all. I would leave it up to the local hospitals; then measure what the local hospitals are doing. These criteria tie their hands behind their backs and they can't do what my facility is doing; that seems to defeat the whole purpose.

Bommer – To reformulate those rules would mean going back to the Legislature; introducing a new Bill, having discussion, and getting it passed by the Legislature.

Fehrenbacher – The Bill was difficult to put together; there were many stakeholders. The Bill was introduced to the Legislature three years ago. What we know now may be different from what we will know two years from now and from what we knew two years ago.

[Bommer suggested that, as the Bill directs participating facilities to track costs, a consideration be given to tracking particular sets of costs associated with patients in this study. Dr. Bommer's suggestion was to track costs of those patients transferred for emergency surgery.]

Brindis – The issue of costs is much more complex than you just described. Although I congratulate the State in wanting to look at comparative effectiveness and cost efficiency, this study as we have it presently designed, is not able to do that.

Bommer- I entirely concur with Ralph (Brindis); this is an enormous process. It is an impossible task, but it is included in the legislation so it is important to consider it somehow.

**Motion (Sundrani) - Move to recommend to the CDPH to require tracking only the costs of those patients who are transferred for emergency surgery.**

**Second – Smith  
Discussion**

Brindis – In tracking transfer costs, other than to acknowledge you're giving some suggestion to meet the letter of the law, I am not sure that really answers the question about the costs of the PCI Pilot Program. I do not see its particular value.

Forman – I agree; I do not see any reason in tracking one to three patients per year, assuming the costs of the ambulance transfer, and how that is going to apply to what we are doing.

Karmarkar – I agree with leaving the costs out. Different hospitals have different contractual agreements with the hospitals accepting the patients for emergency surgery.

Jain – I agree; tracking the costs would be difficult and would not be fair.

Sundrani – I introduced the motion only to attempt to meet the intent of the law. The motion was suggested to track as little costs as you can while keeping with the wording of the law.

Bommer – That is UCD’s suggestion as well. I agree the total costs of the Pilot would be onerous to track. But because it is the letter of the law, it makes sense to do what is required in the law. This tracking would be done to be in compliance with the law; not because it is a good idea.

Karmarkar – Now that we’re here and have to track something that translates to tracking costs; why not track how many patients we would transfer to another facility for a PCI currently? For example, our facility transfers 500 patients to another facility because we cannot do elective PCIs at our hospital. So possibly 500 ambulance rides may be saved per year by keeping those patients because now they can go down to the lab.

Bommer – As far as this discussion, for the individual hospital that is a lot of monitoring that was not included at the time they signed on to participate.

Itchhaporia – We are not limited in any way on how to track the costs. We could come back in the near future after having mulled it over and discuss it at the next meeting.

Alongi – The Committee can “parking lot” any issues. There is a meeting coming up in the next few weeks; this issue does not have to be finalized by any means today.

Brindis – The complexity of cost-effectiveness is so much in that I worry that if the Committee recommends collecting this data, it will be misinterpreted by the people reviewing it.

Arnold – I recommend putting this in the parking lot; come back in a few weeks from now with everyone having thought it through.

Alongi – That would have to be acceptable to the member who made the motion and the member who seconded it.

Smith – It is acceptable.

Sundrani – It is acceptable.

**Motion is withdrawn; a discussion of tracking costs is in the parking lot for the next meeting.**

Arnold – The interventionists need to be certified for the Pilot Program that is starting in three days; is this going to happen in that time period?

Bommer – Unfortunately none of the interventionists attended the training session; tomorrow UCD will mail out a CD with 20 questions to be answered. UCD will require that to be completed in one week; the Pilot Program will go ahead and begin August 1 with the final certification taking place over the next week.

<p>Guest – Is it a shared responsibility amongst the interventionists if there are issues with cases between the hospital, the AOC, and the primary investigator at your facility. Who actually has the oversight if there are any issues with cases done by interventionists?</p> <p>Bommer – In adjudication of a particular case that was already done or selection criteria?</p> <p>Guest – The selection criteria is already set; it would be in cases they would actually do.</p> <p>Bommer – If the hospital follows selection criteria and follows the general purpose and outline of SB 891, there will be no problem. They will be audited; if there is a real high or real low complication rate then that will be noted and reported to both the AOC and CDPH. It is up to the AOC to make a recommendation to CDPH. If CDPH makes a decision prior to the end of the study, any decision they make may have consequences for it.</p> <p>Guest – Not on the hospital but on the individual? It is the physician's decision on what he/she thinks the regarding the risk.</p> <p>Bommer – How does the AOC want to play a part in this? It is anticipated that the AOC would play a key part in making those recommendations.</p> <p>Sundrani – Two questions keep coming up; the role of principal investigator versus sub-investigators has to be decided upon, and do all sub-investigators have to be certified?</p> <p>Bommer – We are asking any individual who performs an elective PCI at your Pilot hospital be certified that they understand the inclusion and exclusion risks. The test focuses on that so that they understand these are not standard risks for PCIs; the rules for SB 891 are a little bit different.</p> <p>Karmarkar- May I propose the inclusion and exclusion criteria is clearly posted in each of the cath labs?</p> <p>Bommer – The criteria will be listed on the website, in a hard-copy manual given to each hospital, on a CD given to each hospital, posted in the cath labs, and on a wallet-card given to each interventionist and each coder.</p> <p><b>Motion (Fehrenbacher) – Move to recommend to CDPH to require the primary investigator at each site with the responsibility to the local IRB ensuring protocol violations do not occur and require the primary investigators to attend the AOC meetings as an obligation to CDPH and this Committee.</b></p> <p><b>Second – Arnold</b></p> <p><b>Discussion</b></p> <p><b>All ayes; Motion passed</b></p>	
<p><b>Action Items</b></p> <p>Chair- Next meeting's agenda to include:</p> <ul style="list-style-type: none"> <li>• Discussion on whether and how to capture costs in the final report due to the Legislature in 2014.</li> </ul>	

The following items were discussed but not formally requested to be placed on a future agenda:

1. Tracking of PCI patients post-discharge
2. Standardization of transfer protocols

**Next Meetings: August 19, 2010 and November 11, 2010.**

Unless otherwise noted, all PCI AOC meetings will be held 1:00 p.m. to 4:00 p.m. in Sacramento.

Chair—Please forward any discussion items or questions to Tom Rodacker. Thank you for your participation.

**Meeting Adjourned**

**Acronyms**

AOC	Advisory Oversight Committee
CABG	Coronary artery bypass graft
CDPH	California Department of Public Health
IRB	Institutional Review Board
NCDR	National Cardiovascular Data Registry
OR	Operating Room
PCI	Percutaneous Coronary Intervention
SCAI	Society for Cardiac Angiography and Interventions
STEMI	ST-Elevation Myocardial Infarction