Percutaneous Coronary Intervention (PCI) Advisory Oversight Committee (AOC)
August 19, 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, George Fehrenbacher MD, William French MD, Fischer (alternate for Dr. Forman), Aditya Jain MD, Dipti Itchhaporia MD, Sushil Karmarkar MD, George Smith MD (alternate for Dr. Coleman), Rohit Sundrani MD

Guests Melanie Aryana, William Bommer MD, Eric Brooks, Kapinga Brown, Linda Campbell, Bob Forey, Michele Golden, Edie Jonas, Linda Kerns, Maureen Kochin, Zhongmin Li, Mary Owen, Kathryn Robidoux, Kathy Trost

Staff Sam Alongi, Roberto Garces, David Gioia, Tom Rodacker, Carol Turner

Agenda Items/Discussion	Action/Follow-up
Call to Order PCI AOC Committee Chair Kathleen Billingsley (Chair) convened meeting. Chair - Thank you for everyone who has participated both as Committee members as well as pilot hospitals and staff and other interested physicians and other parties. We greatly appreciate your participation in this pilot program and with this PCI Advisory Oversight Committee. Hopefully you have all had a chance to review the minutes; the floor is open to any recommended changes or clarifications at this time. **Motion (Arnold) – Move to accept July 29, 2010 PCI AOC meeting minutes as distributed on the PCI website.** **Second—Karmarkar** **Discussion – no further discussion.** **Roll Vote – Motion Passed Unanimously.**	CDPH PCI staff to post approved July 29, 2010 meeting minutes to website as "final".
Tracking Costs of Study Chair – At the July meeting, this group had a preliminary discussion of how we are going to track the costs associated with the study patients. The language on SB 891 states that the report to be prepared at the end of the study period, with the input of UC Davis (UCD) of the data, and review by CDPH and the AOC, shall include a comparison of elective PCI performed in connection with the elective PCI pilot program and the elective PCI performed in hospital with onsite cardiac surgery. The language does *not* specifically require pilot hospitals to track the costs of individual cases in order to meet this requirement.	UCD to collect the cost data on patients referred for emergency surgery from elective PCI sites and benchmarking that with NCDR data.

CDPH recommends that the AOC work with UCD on an alternative means to meet this reporting requirement. There may be a research or report option on aggregate data, something that could be included in the report, but not necessarily the cost of each individual patient. CDPH requests that a review of alternate methods of cost tracking be presented at the next PCI AOC meeting on December 2nd. Brindis - Question regarding what the intent is and whether we have the means to meet the intent. It is not possible, no matter how the data is tracked, to come up with anything close to a cost assessment, given that there are so many variables. There is major concern as to how to approach this properly. Arnold - Does NCDR look at cost at all? Is there any kind of measure there which would be useful as a comparison? Brindis - NCDR does not. Medicare tracks cost but in a different manner; that program looks at customary costs against what they actually pay. Looking at the case cost doesn't say anything about the *cost effectiveness* in a given system of patients, waiting or sitting in a hospital, transfer costs by ambulances, etc. Bommer - To track costs in a system like this would be many more times complex than tracking the data itself. It's an enormous undertaking that neither the study nor the hospitals have the facilities to do in that interpretation of the bill. Tracking the costs of the individual patient who had to be transported for emergency surgery could conceivably be done, because we could identify an outside agency or ambulance cost, but those are only maybe one in any three hundred individuals. That data would probably not add anything to the study. In a technical way it would comply with the law but UCD would not be behind it because it could be misleading. Anything more than that is a huge undertaking none of us are prepared to do. Fehrenbacher - The intent was an afterthought. SB 891 was constructed around the clinical aspects of care rather than the cost issues. The intent of the bill was 99 percent intended to compare medical quality and not cost. Karmarkar - The State wants to compare the cost savings if those are realized doing PCI at a facility that has no surgery backup as compared to the costs of transferring patients to another hospital. The program could track those patients who are admitted to the pilot sites who otherwise would have been transferred to another facility. Now (in the study) those patients get the PCI at the same facility. Second, patients are usually transferred days later, and the discharge process typically wastes a day, so the assumption could be made that the study protocol saves by having the PCI in the same hospital. That might meet what the lawmakers were intending to show. Brindis - The answer will be different depending on what kind of medical	

system you are in, for example, if there are more elective cases coming in from home. The intent of the law was to assess this. Bill's (Bommer) suggestion may meet the legal objective but is not of comparative value.

Karmarkar - By looking at the patients in the six pilot hospitals who would normally have been transferred , we can look at that data as it would be applicable to any hospital.

Sundrani – I agree with tracking the transfer patients which also will serve the intent. There may be a way to get some data for the other patients but to meet the intent of the law, tracking the transfer patients would be enough.

Additional points:

- How to compare the costs without a previous baseline?
- How to assess the cost savings?
- Possibility to form a subcommittee to talk with Centers for Medicare and Medicaid Service (CMS) to see if there is a way to track costs at a higher level to reflect the number of admissions and costs.
- There may be some CMS data for comparison.

French – This would provide the comparison of those who have transferred versus those who have not. There will also be surrogate costs regarding patient stay duration.

Chair - Is the recommendation to review the UCD data, which would be the number of days per patient, because the study will be tracking the patient transfers.

Bommer – UCD envisions that most of these hospitals will be doing most of the PCIs on site at the hospital. There is no randomization to it. Most will be done at the hospital and not transferred.

Motion (Brindis) - Move to 1. collect the cost data on patients who are transferred for cardiac surgeries and 2. form a subcommittee, in a partnership with UCD, to analyze surrogate issues of cost effectiveness as a potential deliverable.

Second-[Member]

Discussion

Chair - Who would take the lead on the subcommittee?

Brindis - First this Committee needs to ask UCD for their collaboration with the funding that they have in the project. Then it would go to a vote to find out if this group is willing to take on that responsibility.

Karmarkar - Is it possible to take this back to lawmakers who worked on the

bill and find out what they were looking for?

Chair - We normally don't go back to the lawmakers. They may no longer be involved in the legislature. We could talk to our personal counsel.

Bommer - The motion is on the floor to approve of the subcommittee. I would be happy to advise that committee. The current contract with CDPH and UCD does not entail tracking costs.

Chair - Can the subcommittee communicate via email or via conference calls?

Gioia - A communication from one member to another is not a violation of the open meetings act but serial emails between members would need to be discussed in open meeting.

Brindis - Rescinds motion to form subcommittee if it cannot be managed through email. I would also note that due to the legal complexities, it is highly unlikely that this Committee will be able to perform any work through subcommittees.

Motion rescinded.

[Member] - Point of clarification: Costs would be tracked for patients who were having a PCI at the offsite hospital, got into trouble and a decision was made to transfer them for urgent or emergency surgery at the surgical hospital. An ambulance would be called to move the patient.

Arnold - So we are measuring the cost of a failure. The comparator would be the percentage of patients who have emergency surgery in general with the NCDR registry with onsite surgery with the computed costs and that would be the comparator.

Further clarification/issues regarding comparative data:

- Compare those patients participating in the study and end up having emergency surgery as a numerator and denominator for offsite and compare that with what happens for the NCDR registry
- Wait for the NCDR data to come to us, then can provide that as comparison data
- No current financial comparison data collected
- Data is still compromised because the population at onsite surgery having angioplasty will differ from the elective population centers
- Rate of emergency offsite is lower than onsite

Motion (Brindis) – Move to collect the cost data on patients referred for emergency surgery from elective PCI sites and benchmarking that with NCDR data.

Second – [Member] **Discussion – no further discussion** **Roll Vote – Motion Passed Unanimously.** Public Comment - None. Chair - Second topic introduced - the tracking of ECI patients post discharge. This is a requirement of the bill. SB 891 states that the selected hospitals are required to have onsite rigorous data collection, outcomes analysis, quality improvement and formalized periodic case review. When CDPH conducted the pilot hospital onsite visits, the need to track patients who are transferred was emphasized. These patients must be reported by the pilot hospitals to UCD using the software provided by the hospitals. UCD will track and report these patient transfers. Open for discussion regarding responsibility for hospital and contractor. Smith – For clarification, is this referring to post-discharge or *post-transfer?* Bommer - Only the transferred patients will be tracked, up until the point of discharge from the secondary facility. Chair – As an example: if a patient goes from hospital A to hospital B, then the pilot hospital that transferred the patient is responsible for obtaining the status of the patient at discharge. Bommer – UCD has implemented on the database a second set of questions for those patients who are emergency transfers for cardiac bypass surgery, including their outcome and other data with twenty additional fields to answer. This is in the production software that all the hospitals have available. UCD will report back that information to the AOC. Jain – I agree with this process. Public Comment - None. **Standardization of Transfer Protocols** Chair – SB 891 requires standardized transfer protocols. Do all pilot hospitals have to have the same transfer protocols. Rodacker - There is a confusion between the transfer protocol and transfer requirement. There is no requirement for a standardized protocol. Different hospitals have different protocols. UCD is asking for a copy of the transfer protocols in place at each of the hospitals. Arnold - It is within the purview of this committee to review any transfer protocols or questions related to its efficiency should questions come up.	

Jain - If hospitals report late or refuse transfers, how are they held accountable? Fehrenbacher - That lies in the transfer agreement that was signed ahead of time. That stipulates that there will be no refusals if it is an appropriate medical decision. The AOC should look at those agreements. Jain - What if the surgeon still refuses? Conclusion - As long as the patient is transferred, any medical decisions that follow are up to the receiving hospital. There has to be a surgeon available to handle the transfer. Bommer - This pilot program will assess whether emergency transfers improve or impact the quality of care and the safety and efficacy of the PCI care. Each hospital has a transfer agreement that the patients can be transferred quickly. If the agreement is followed there should not be a problem. If they are *not* followed, CDPH could get involved with the hospital. In addition, the bill asks for a transfer protocol. This is merely a listing of: what are the events, who are the contact people, to allow for an efficient transfer. UCD is asking for the written protocol so that all the stakeholders know ahead of time what the responsibility is and the timeframe. The bill asked that the transfer protocol be tested at least once or twice per year even if there are no transfers, so that when there is a transfer it is done quickly and efficiently. Karmarkar - This deals with primarily daytime elective PCI, which is different than a patient who becomes unstable in the middle of the night and that may not be part of the pilot program. **Questions/Issues needing clarification:** • High risk patients versus low risk patients • Tracking surgical care and transfers of STEMI patients versus elective patients and timing of transfers • Obligation of receiving hospital to accept transfers not falling into certain guidelines • Delaying surgery for unstable patients • Whether intent of SB 891 is to increase onsite elective care or to also increase onsite STEMI care; SB 891 frequently refers to “elective PCI care” • Tracking both STEMI and elective transfers • Davidson - Second hospital may choose a percutaneous or alternate treatment or no treatment at all • Other types of cardiac surgeries can be tracked, such as valve replacements, only if they are transferred emergently (related to the	

PCI). This can be accommodated by changing slightly the twenty fields in the software to include those secondary surgical procedures • Each case will be reviewed by the audit nurse to add additional fields and descriptors Public Comment: None.	
Patient Selection Criteria Chair – Moving on to UCD and a discussion of study issues, including patient selection criteria. Thank you Dr. Bommer for being here. Bommer - Introduction of slides (slides are available on the PCI website). Consent Form - all patients who have PCI must sign a consent form. Elective patients must sign the one approved through the local IRB process. STEMI patients can either sign the IRB consent form or the standard consent form with the addendum that this information will be submitted to UCD and CDPH. French - Question regarding STEMI patients consent form and differences in consent between facilities; highlight aspects that are different between each site. Further discussion regarding exceptions and differences between patients, such as STEMI patients giving verbal consent rather than written consent. Sundrani - When an ambulance arrives, consent is often signed when the ED doctor discusses the situation with the cardiologist in the emergency room. That would be normal practice. It would be easy to add the extra line that states that “data will be collected for CDPH”. Fischer – Our facility has been doing angioplasties for years here but there is a protocol in place that if someone is a true STEMI they will be taken directly to the lab. If they stabilize and are pain free, we can stop and transfer them, and that has been the protocol for years. The concern now is that if a similar patient comes in, they become an "elective" patient, but experience shows that 20 to 30 percent of the STEMI patients, after they “cool off”, can be transferred to a different facility to meet their criteria. There is a twelve page informed consent; that cannot work with a STEMI. Bommer - You have two options. You can do the standard IRV, or for those patients you are describing, you can do as you are doing today and get a verbal consent or written consent, and add that the data will be sent to CDPH and UCD. Fischer - If the patient is pain-free, and I would normally stop (the intervention), now what will be the protocol? Bommer - The option would be to open the vessel at that point and time.	CDPH OLS to recommend to Committee whether certain issues, particularly those involving specific patients, can be discussed in closed session.

Fischer - The vessel is already open.

Bommer - But you can proceed with the PCI at that point and time. That's the intent of SB 891: to offer the PCI at the most convenient time for the patient to help or improve their health.

Fischer - So that patient will no longer be transferred. So obviously the patient will not have signed a standard twelve page form.

Bommer - You can verbally talk it over or talk it over with relatives if they are sedated. In a STEMI there is obviously no time to sit and read twelve pages of text.

Data consent - All patients have to be entered into the data set for collecting that information. For STEMI patients, they also have to be entered. You can do that at your hospital, but UCD needs all the PCI patients entered. UCD wants to track STEMI and non-STEMI elective patients to see if the intent of the law is being followed, which is to improve services both for elective PCI and STEMI. Patients who have diagnostic caths only, that is, no PCI, could be entered in the database if the Committee chooses, or if the facilities want to report those by a different system, you do not have to report those to UCD. They do have to be reported to NCDR. UCD is tracking the PCI patients only.

Fischer - We try to record everything.

Karmarkar - The data for the pilot patients will first go to UCD.

Bommer - All PCI data is monitored here. If the patient has a diagnostic cath and did not get a PCI, UCD is not required to record that. If the hospital wants to track that, UCD can accede to that requirement and make that change.

Karmarkar - Some patients may be counted twice.

Bommer - Regarding Dr. Karmarkar's question, there was a separate NCDR data entry to be compatible with the rest of your healthcare system. You can harvest your data for whatever data collections you need to, and you would submit quarterly or however you do it. UCD will *not* send in duplicate data to NCDR. For those hospitals who want to submit all their data to UCD, we will offer you the capability of doing a harvest to get that information for review and transfer by your hospital's request into NCDR.

Clarification: A guide wire across a lesion would be considered a PCI.

Bommer - If the wire is not put in an attempt to open a vessel, if you only do an FFR, that is a diagnostic cath. If the wire is put in an attempt to open a vessel, that is considered a PCI. It has to be a catheter or wire that is put in

with the intent of opening that vessel. This is the definition in the NCDR database; UCD will use those same definitions. You do have the ability to put the FFR data into the database. If you only do an angiographic film and an FFR, it qualifies as a cath but not a PCI. Karmarkar - Is it something that should be submitted? Bommer - Those are the rules that are being used in all of the hundred and thirty hospitals that are currently doing PCI with onsite surgery. UCD will use the same criteria for onsite and offsite, to avoid introducing a bias into the data set. Brindis - The NCDR does not require all diagnostic catheterizations to be entered in onsite surgical programs. People didn't want to put in the cost of tracking the caths. Bommer - UCD can record the FFR information if the hospital includes this information. Bommer - Reporting - There are sixteen standard or canned reports available for each hospital for each monthly or quarterly report. Each hospital has access to only their hospital data. (Lists report types listed in the presentation). You can select for date range and other filters. (Review of slides regarding closure methods, discharge medication) You can identify reports by operator. We look at intracoronary devices by operator. You can see a listing that is updated as each device comes out once included in the NCDR database. You can report on operator preferences. (Further review of report options and patient conditions/parameters/risk factors/length of stay parameters) UCD can do a composite of all the six hospitals, for each of the sixteen reports. Each hospital can use its own report internally. Regarding length of stay, patients are generally coming in right before the procedures and leave the following day. The STEMI patients are the exception. UCD submitted about fifty changes for the software team; the system will be fine tuned in two or three weeks, but you can use this reporting right now for your own hospital. The identified aggregate data is only available to UCD; UCD will then provide the de-identified data to CDPH and the AOC. There will not be individual operator or patient identification distributed. Question regarding adjudication:	

Bommer - If there is disagreement between individual operator and the final decision in the central data committee that would get flagged to the AOC for final adjudication. Karmarkar - Will we differentiate between STEMI mortality and elective PCI mortality? Bommer - UCD will be reporting by STEMI, urgent status mortality, elective, etc. There are actually over a thousand reports available if you want to customize your own reports and select the fields and queries. This is just general reporting, it is not risk adjusted. The final report that will be produced quarterly and annually will be a sophisticated risk adjusted model, including all the risk factor adjustments for each operator, hospital and procedure. That is done on a *SAS* program set and requires a lot of information. It will not be available monthly, but potentially quarterly and certainly annually to the AOC. Individual hospitals can do running twelve month reports. Question regarding why diagnostics are included if they won't be reported consistently. Bommer - Some hospitals asked to put in diagnostic cases in order to use one set of software if they already need to use it for the PCIs. If it makes it easier UCD would make that available. You just need to communicate that to the coders at the individual hospitals. French - Question regarding bias. Bommer – It is not possible to eliminate all biases because this is not a random trial. There is no question that this study will result in doing PCIs on a somewhat lower risk population than a hospital for surgery would be doing, because patients who are high risk clinical and have a high risk lesion are being excluded. Very likely the study is targeting a lower risk group. Introduction on patient selection slide: Bommer - UCD made slight changes in this high patient risk table. Recent cerebra vascular attack is listed. Otherwise these are the same high risk criteria used last time and outlined in the bill. (Refers to ten high risk criteria on slide). Note - high lesion risk requires you to have both a long lesion greater than two centimeters and excessive tortuosity of the proximal lesions. One or the other does not include high lesion risk based on the bill language. (Other risk criteria noted)	

Based on the motion made by Dr. Smith made during the last AOC meeting UCD did change the “90 %” to “90 degree angulation” in that segment and that is based on the AOC decision. Importantly, any feature that in the operator's judgment impedes stint deployment, so at any time the operator can back out of the PCI at any time. Sundrani - If the operator decides not to proceed, are we tracking those patients who do not go through PCI? Are we supposed to track them as a private hospital or not? Bommer - The bill does not require us to track those patients but if you choose to track them in the diagnostic set, UCD can do that. In summary, this is the sheet the operators will have for inclusion criteria. If you have both high patient risk and high lesion risk you cannot include that patient in the trial. You can select one or more of the patient risks, and if it is low lesion risk, you can proceed with PCI. There will be risk adjustment done for every hospital, so risk adjustment modeling will allow us to compare as best we can in a non randomized trial. (Reviews red light / green light slide inclusion criteria) **Expectations of Pilot hospitals:** • Inclusion and exclusion criteria needs to be followed • The Pilot hospital should be enrolling two hundred patients by the end of year two, of which thirty six should be primary PCIs • We are asking the Pilot hospitals to facilitate Pilot nurse access to the medical record system and angiographic recording **Timeline Update:** • AOC first meeting 7/29/10 • IRB approval of the consent forms; one hospital resubmitted with a small change • Central IRB approval for data collection • The official Pilot start date was 8/1/2010 • Production software was online by 8/2/2010 • Coder testing was completed at 8/2/2010 • Operator testing for interventionalists has been completed at five of the hospitals; one hospital has yet to be completed • Tested exclusion and inclusion criteria • Transfer protocols received from two hospitals • Enrollment as of August 18 was 36 patients, 67 percent were elective PCIs, 33 percent were STEMI • Some report formats have been reviewed and can be customized based on AOC input • Motion approved for handling cost tracking	

- Committee can check data entry for completeness but prefer not to review quality of care issues based on input of data; that information is available to the hospitals to use that information for their own CQI

(Additional parameters reviewed regarding patient risks/infarction/NCDR criteria)

Fehrenbacher - The original definition of PCI did not include STEMI. Many emergency patients aren't STEMI but are in extremis to be treated as an emergency patient; certain conditions do not fall into STEMI but fall into a similar consent form issue where a lengthy document may not be possible to review. There is a gradation between urgent and emergency patients; the determination is dependent on multiple factors and may differ between surgeons and facilities. Classifying as STEMI and elective doesn't follow the four level classification by NCDR.

Bommer - Currently hospitals who do onsite surgery are allowed to do STEMI in their cath labs and they are also allowed to do patients who are crashing or hemodynamically unstable. In that situation you can still use your regular consent form, if you mention the data collection element.

Fehrenbacher - I just wanted to distinguish that the division of electives and STEMIs does not include all patients.

Bommer – The study is not designed to interfere with a patient who needs emergency care, it is to improve the care for non-emergent patients. Informed consent is what we are talking about. It is up to the physician to get the consent in the best way. That is between the operator and the patient.

UCD recommends that if there is time to explain consent, that the patient be informed that they are about to have a procedure done at a hospital that does not have onsite surgery, and in the event that they need surgery, they will have to be transferred. Once the patient knows and accepts that risk, that is informed consent. It protects you against a claim of informed consent, if that is written down. If you can't do it, maybe you can with the patient's family. We are not trying to interfere with that process.

Smith - If a patient has an acute left frontal branch block or an acute post infarction, and those people as far as I'm concerned are considered STEMIs.

Brindis - This raises a number of important points, which is it divides patients between STEMI and non-STEMI. We are not really talking about elective PCI, there are a number of gradations. The NCDR has risk adjustments that take all of this into account. The challenge will be in the veracity of the auditing which will be very high in this study. As demonstrated in (a study done in) Massachusetts, there is a substantial change in up-coding and down-coding.

Bommer – UCD has provided each local hospital with a set of definitions for

every one of the fields they are entering in the database. Staf spent a day with them on the site visits going over these types of questions. If you carefully read through it, it does a good job with every scenario that comes up. It is available to look up and answer your questions. UCD is offering training sessions. About 2/3 of the people trained, this was new to them. There is training, testing and sample data entry. Questions come in on a daily basis.

Karmarkar - If the Committee decides that all patients should be entered into the study, including those for diagnostic cath only and other categories, that would change the workflow and turnaround times if every patient has to be consented.

Bommer - You could modify your current consent form to include the few words that this data may be submitted to CDPH.

Jain - Age is a significant risk factor but is not listed as a risk factor. Is age risk left to the operator?

Bommer - You are correct that it is not listed as a high risk factor. It was left off of the bill. You can make your own decision that a candidate cannot be enrolled. You can set up your own criteria to be more restrictive than the current guidelines.

Sundrani – There is some concern that the Clovis Center may not meet the criteria of 36 PCIs per year; it is impossible to predict going forward. Also, we are not a receiving center; I wonder if Committee members would share which of you are receiving centers?

Bommer - Each of the hospitals should review that with CDPH if there is a concern that the facility will not meet the criteria. There will be information on the quarterly report, UCD will monitor and report to CDPH any areas of concern.

Karmarkar - We do about two STEMIs a week for Central Contra Costa County.

Arnold - Doctors is a STEMI receiving center, same county.

Fischer - We are a receiving center for Orange County.

Jain - We have a cardiac receiving center.

Fehrenbacher - We are a receiving center in Placer county. There is no bypass program in Placer county.

Bommer - So five out of six of the pilot hospitals are receiving centers. Clovis is not but CDPH was comfortable that Clovis could provide in the

neighborhood of 36 primary PCIs per year. Sundrani – Thank you; our facility will keep trying (to become a receiving center). It is significant to know that we are the only hospital in this study that is not a receiving center. Smith - I think everyone on the Committee would favor your facility being a receiving center. Jain - Question about whether interventions can be performed by physicians who are not board certified for interventionalist cardiology. Bommer - Interventions are supposed to be handled by individuals who have a minimum number of PCIs that have been done and that are certified by internal medicine cardiology and interventional cardiology to perform those procedures, so that is itemized in the bill. Rodacker - After looking at the bill, the bill does say "*and*"; CDPH cannot argue with the letter of the law. Anyone who wants to be added as an interventionalist needs to be board certified in internal medicine, cardiovascular disease and an interventionalist. **Additional points:** • If the hospital wishes to add (a) physician(s), this can be accomplished by the hospital communicating with CDPH • Adding the diagnostic caths will add cost and work in addition to the original program data • Possibility to capture STEMI patients who are turned away because doctor refuses to perform the PCI (for any reason) • Pilot hospital rate of STEMI may be higher than in the NCDR database • All cardiologists are not a part of this PCI program and will still be transferring patients Karmarkar - Expressed concern that a large number of patients will be turned away is based on the safety of the patient. Fehrenbacher - The purpose of the study is to see if it is safe to do elective and urgent patients in receiving centers for STEMI therefore advancing tertiary care unto communities who are currently not getting tertiary care. It is not a matter of taking high or low risk patients. It is to determine if we can serve patients who are not currently being served. Bommer - If we adjudicate within a public committee, there is a legal question if we can go into closed session. If we then were to bring in case specific information, we could not avoid identifying the patient or facility.	

Can we make this a closed committee on single operator or complications? Gioia - We probably can, that will be reviewed. Given the small number of hospitals, that is an issue. The information would be protected, yes. **[Action Item: CDPH Legal to answer whether certain issues, particularly those involving specific patients, can be discussed in closed session.]** Karmarkar - If a patient is a risk case but discharged the same day, can they be included in the program? Bommer - That is up to the doctor and the facility. Public Comment - None.	
Next Meeting: Brindis - Suggested changing time of meeting to 10:00 a.m. to 1:00 p.m. to accommodate travel schedules. Membership agreed to the proposed change in meeting times. Next meeting will be on December 2nd, alternative dates and time to be polled. Unless otherwise noted, all PCI AOC meetings will be held 10:00 a.m. to 1:00 p.m. in Sacramento. Specific meeting location will be posted with the agenda at least 10 days prior to each meeting. Chair—Please forward any discussion items or questions to Tom Rodacker. Thank you for your participation. **Meeting Adjourned**	CDPH to post new agenda and draft minutes and any other attachments at least 10 days in advance of next PCI AOC meeting CDPH to schedule future AOC meetings at 10:00 a.m. to 1:00 p.m.

Acronyms

AOC	Advisory Oversight Committee
CABG	Coronary artery bypass graft
CDPH	California Department of Public Health
CMS	Centers for Medicare and Medicaid Services
CQI	Continuous quality improvement
FFR	Fractional Flow Reserve
IRB	Institutional Review Board
NCDR	National Cardiovascular Data Registry
OLS	CDPH Office of Legal Services
OR	Operating Room
PCI	Percutaneous Coronary Intervention
SCAI	Society for Cardiac Angiography and Interventions
STEMI	ST-Elevation Myocardial Infarction