

**California Department of Public Health  
Question and Answer Forum  
For  
Elective PCI Pilot Program Application**

December 23, 2009

Below are CDPH responses to Elective PCI Pilot Program application questions. Most questions are listed in the order received and as close to the original format as possible. There is no ranking or priority.

Except for questions “pending answer”, no changes will be made to any question or answer once it is distributed or posted. Any revisions to questions or answers will be written as new questions. New questions will be listed as new with appropriate responses.

This posted document will be updated online weekly. For those facilities who have provided CDPH with email contact information, a copy will be emailed to you. If you have not provided CDPH with your email contact information and would like email updates, please notify Dr. Tammy Morin at [tammy.morin@cdph.ca.gov](mailto:tammy.morin@cdph.ca.gov).

**Question 1:**

How many programs are interested in becoming an Elective PCI Pilot Program pilot hospital?

**Answer 1:**

To date, we have approximately 30 facilities that have expressed an interest. Until all applications are received, however, we cannot provide more definite information.

**Question 2:**

Since one case can involve multiple procedures, when the PCI Pilot Program application uses the phrase “procedures”, does this mean “cases”?

**Answer 2:**

In general, procedures refers to cases. For instance, when questions C4 and C5 discuss “procedures”, we are looking for the actual number of cases performed. When specific types of procedures are being discussed (for instance, atherectomy procedures), we are referring specifically to that procedure. See Answers 4 and 15 for additional clarification.

**Question 3:**

The application states that hospitals that currently have cardiac surgical programs or are planning to implement one during the time of the pilot program are not eligible to apply for this PCI pilot program (page 8-9). Do you know why that decision was made?

**Answer 3:**

The goal of the study is to determine if elective PCI is as safe in a facility *with* cardiac surgery onsite as in a facility *without* cardiac surgery onsite. If a pilot hospital opens a

cardiac surgery center, then the PCI data they provide would qualify as control data, not study investigational data. The data that each pilot hospital provides will be critical to answering the questions posed by the legislature. Withdrawal of a pilot hospital, would significantly impact the study results and the costs to the other pilot hospitals.

If a facility with cardiac surgery services currently is considering closing those services, will *only* be operating their cardiac catheterization labs during the term of the study, *and* can meet the conditions of the legislation, then we could consider this special case. We have not been made aware of any facilities wishing to close their cardiac surgery services.

**Question 4:**

When the application talks about number of procedures does this mean “cases” or actual procedures, for which one case may have multiple procedures?

**Answer 4:**

In review of the literature that supports the procedure requirements, the terms “cases” and “procedures” are used interchangeably. Therefore, “procedures” refers to number of cases. If one case has multiple stents performed, we are considering that one “procedure” or “case”. If the patient returns to the cath lab during the same hospitalization and receives additional PCIs then that is an additional “procedure” or “case”. See Answers 2 and 15 for additional clarification.

**Question 5:**

We wanted to clarify the coding and billing in regards to insurers covering the patients since our hospital isn’t accredited to do elective PCI. Will this be an issue?

**Answer 5:**

CDPH is not involved in how the hospital coding, billing and payment is handled. Any facility chosen as a pilot hospital will receive an amended State of California license to perform elective PCI for the term of the pilot.

**Question 6:**

In reference to the instructions for the map, if you take a 100 mile radius around a certain point like our hospital and make a topographical map that is only 24”x24” it will be impossible to see any detail whatsoever. The hospitals would appear to be all but on top of each other. There would be no way you could see the transportation route between our facility and the transfer facility. Is there an acceptable alternative such as a larger topographical map to detail our service area, but then also have a blowup map of the area that would allow those viewing the map to see actual locations of hospitals and the routes that we would use?

**Answer 6:**

A larger map with a magnified focus area that includes the most pertinent information, would be acceptable. If the map will be very large, you may also provide it in electronic format. Please see the response to Question 7 below for additional information on topographical map requirements.

**Question 7:**

The cost of the topographical map for our region is extremely costly, as it is specified in the application. Are there any alternatives?

**Answer 7:**

CDPH did not intend for hospitals to incur significant expense to produce this map. In light of this, the requirements for Question A33, Topographical Map, have been modified as follows: "The map specifications may be reduced from a 100-mile radius to the outermost limits of the applicant's primary and secondary service areas combined ("combined service area"), provided that all cardiac surgery centers designated as receiving hospitals are included within this area. If all receiving hospitals cannot be included within the combined service areas, then the map must represent a radius equal to the distance from the applicant's hospital to the furthest receiving hospital. Note that all cardiac surgery centers in the combined service area, regardless of signed transfer agreements with the applicant hospital must be included on the map. In addition, topography needs to represent any geographic or manmade obstacles that could impede patient travel to or from the applicant hospital in the combined service area, and between the applicant hospital and any cardiac surgery center. Topographic information over and above that which addresses those issues is not necessary." All other map requirements remain the same.

**Question 8:**

Question A16 asks for administrative penalties imposed. What time frame should we consider when responding to this question? The previous year, two years or the duration of the facility's license?

**Answer 8:**

The timeframe to be considered is "ever". Since administrative penalties are relatively new concepts to public health, we don't feel this timeframe would place undo hardship on the applicants to respond.

**Question 9:**

Regarding question A17, immediate jeopardy, what timeframe should we consider when responding?

**Answer 9:**

The timeframe to be considered is "ever". Since immediate jeopardy is a relatively new concept to public health, we don't feel this timeframe would place undo hardship on the applicants to respond.

**Question 10:**

Question B7 asks if we have an "active" blood bank. Can you clarify what "active" means?

**Answer 10:**

An active blood bank means an onsite unit that has adequate blood products and laboratory services available to support the needs of your hospital's patients, and actively obtains, stores and manages those blood supplies.

**Question 11:**

Question C4 asks about "other" procedures for the treatment of patients presenting with IHD. Can you clarify if "other" refers to interventional radiology procedures?

**Answer 11:**

"Other" procedures includes any procedure done in the cardiac catheterization lab that is not 1) diagnostic as listed in Title 22 Section 70438.1 (right heart catheterization and angiography, right and left heart catheterization and angiography, left heart catheterization and angiography, coronary angiography, electrophysiology studies, myocardial biopsy) and 2) is not PCI as defined in Health and Safety Code 1256.01 as percutaneous transluminal coronary angioplasty and stent placement. If your facility performs procedures other than cardiac procedures in the cardiac cath lab, please provide details on which procedures and how those procedures will be accommodated if your facility is chosen as a pilot hospital.

**Question 12:**

Regarding Question A33 the topographic map, will a "Google map" be sufficient for this response?

**Answer 12:**

Provided the map includes the information requested in the application, the format is at the discretion of the applicant. Please see Answer 7 for additional, new information regarding the topographical map requirements.

**Question 13:**

On page 15, Section E, under the requirements for the Interventionalists, it states "performs 100 total PCI procedures/year with at least 18 of them primary PCI/year". On page 27 Appendix B, Question AB2 states "List procedure types as Diagnostic, Elective PCI or Primary PCI". Are diagnostics counted as part of the 100 total PCI procedures referenced in section E?

**Answer 13:**

No, diagnostics are not included in the PCI procedure count. See the definition of PCI in Answer 11 above and/or H&S Code 1256.01.

**Question 14:**

On page 21, Transport Service, question G9 states "transport vehicles have a high resolution digital imaging capability and intra-aortic balloon pump support". The IABP

support is clear, however what type of equipment could be in a transport vehicle that would cover the high resolution digital imaging?

**Answer 14:**

Pending response.

**Question 15:**

In the grid for part C4 (page 10), Treatment of IHD patients, we need to quantify the number of all cardiac cath procedures. A patient can have multiple procedures per CPT code per case. Does this application want the total number of patients or the total number of procedures?

**Answer 15:**

We are referring to number of “cases”. Each patient visit to the cath lab would be considered a “case”. See Answers 2 and 4 for additional clarification.

**Question 16:**

In the grid for part C4 (page 10), Treatment of IHD patients, there are lines for “total # Primary PCI performed” and “total # of PCI Performed”. Can you please clarify the difference?

**Answer 16:**

The Department is using the definition of Primary PCI as given in the ACC/AHA/SCAI 2005 Guideline Update for Percutaneous Coronary Intervention: “A clear distinction is drawn between the emergency use of PCI for patients with ST-segment elevation myocardial infarction (STEMI), termed “primary PCI,” and all other procedures, which are included under the term “elective PCI.” Therefore, total PCIs would be all PCIs. Total # of Primary PCIs” would be those PCIs that meet the definition of Primary PCI defined above. Note that total PCIs and total Primary PCIs may be the same number.

**Question 17:**

For the grid in part G1 (page 20), Patient Transfer History to Cardiac Surgery, can you clarify the difference between transferred after undergoing diagnostic cardiac cath procedure and transferred for findings on diagnostic cardiac catheterization?

**Answer17:**

“Transferred after undergoing diagnostic cardiac catheterization” was meant to be the total number of patients transferred after diagnostic cardiac catheterization for any reason. “Transferred due to adverse event from diagnostic cardiac catheterization” refers to the subset of total diagnostic cardiac catheterization patients who experienced an adverse event during or as a result of diagnostic catheterization. “Transferred due to findings on diagnostic cardiac catheterization” would be the subset of total diagnostic cardiac catheterization patients that were found to require transfer for cardiac surgery because the angiography revealed the patient would require cardiac surgery or PCI with onsite cardiac surgery was required and there was no diagnostic catheterization adverse event.

**Question 18:**

The IRB needs to approve the consent form as stated originally in Senate Bill 891. The application also states that IRB approval is needed for participation in the pilot program. Do you want the IRB to approve the general concept as outlined in H&S 1256.01, or a general statement that describes the pilot program, or more specific details regarding data collection, safety monitoring, etc.?

**Answer 18:**

For CDPH's needs, the IRB for each hospital needs to approve the pilot program in concept as detailed in H&S 1256.01 for the duration of the pilot program. Please refer to your hospital IRB policies for further information on its specific requirements.

**Question 19:**

There is a question regarding restriction of atherectomy devices. "I agree that this pilot program should not plan to use atherectomy devices on elective patients. However, I have had a couple cases where a stent can be placed in an MI patient only after a limited atherectomy...thereby converting a failed PCI in an MI patient to a successful PCI, which is potentially lifesaving. The patient that I recall was very sick, presented to the hospital in cardiogenic shock....no time for transfer to another facility for PCI. In this type of instance, will atherectomy be allowed?"

**Answer 19:**

Atherectomy increases the risk to the patient. Some types of atherectomy are higher risk than others and experience levels of the operator can increase this risk even further. Today, without cardiac surgery onsite, there is no generalized need to increase that risk to the patient, which is what will occur if CDPH permits atherectomy in this study. Atherectomy is not permitted on elective PCI patients in facilities without cardiac surgery onsite.

That said, in the event of Primary PCI, we do not want to prevent any physician from safely and successfully treating his/her patients. If a physician feels that an emergency atherectomy is the treatment required to save a patient's life, and he/she has the appropriate training and experience, then that physician has the legal right to proceed as he/she feels necessary based on his/her professional judgment acting in the best interests of the patient. CDPH would require that the atherectomy case be reported as an adverse event, as we do today for any Primary PCI done in a facility without cardiac surgery onsite.

**Question 20:**

Question AB2 (page 27) requests “lifetime interventional procedures as primary operator”. Does *lifetime* mean the following:

When the cardiologist started residency to present?

When the cardiologist was appointed to the CMC medical staff to present?

When the cardiologist obtained the privilege to present?

**Answer 20:**

Lifetime procedures would be all PCIs where the physician was the primary operator. This may include procedures from the physician’s interventional cardiology fellowship forward. Note that the physicians must be able to show convincing documentation of procedure counts, if requested.

**Question 21:**

Is the application available as a Word document?

**Answer 21:**

Unfortunately, the Word document is not available for distribution. Facilities will need to complete the paper application.

**Question 22:**

IRB approval of consent forms cannot be obtained in the timeframes requested. Is there any possibility to reconsider the application requirements?

**Answer 22:**

CDPH has extended the date for IRB approval of the pilot and consent forms to April 30, 2010. The IRB pilot program approval and IRB approved consent form must be presented to CDPH upon notification of selection on May 1, 2010. If the selected hospital cannot provide this information immediately, that hospital’s application will be deemed incomplete and the decision to select that hospital will be withdrawn.

If a hospital can meet the original deadlines, we encourage it to submit the data as originally requested in Question A32. For those hospitals unable to meet the original deadlines, CDPH requires the following in response to Question A32:

- 1) IRB meeting schedule from December 1, 2009 through April 30, 2010
- 2) draft consent form being presented to the IRB
- 3) copy of the IRB approval application and proof of its submission to the board
- 4) any other information that the applicant feels will document its efforts

Please see Answer 18 for additional information on IRB approval.

**Question 23:**

Our facility currently has all of the rooms, staff and non-payroll funding available to us to undertake the pilot were we awarded a spot in the program. As such, we have no specific business case to develop in order to assure that these resources are in place. With that understanding, would you consider an appropriate answer to A31 a detailing of the current resources, referencing how they meet the SCAI and H&S 1256.01 requirements, an appropriate response to this question?

**Answer 23:**

The purpose of the business plan is to ensure that each hospital has thoroughly evaluated its needs and requirements to safely participate in this program, has adequate funding to support the program, and management support through the term of the project. There will be costs incurred over and above an existing cath lab, for instance, staff training, supplemental license fees, etc. In addition, there should be a change in the number and types of procedures done, which may require additional staff training, additional supplies, etc. If your current business plan includes all elements necessary to support the pilot program, then please submit that evidence to us with the application.

End of December 23, 2009 Question and Answer document.