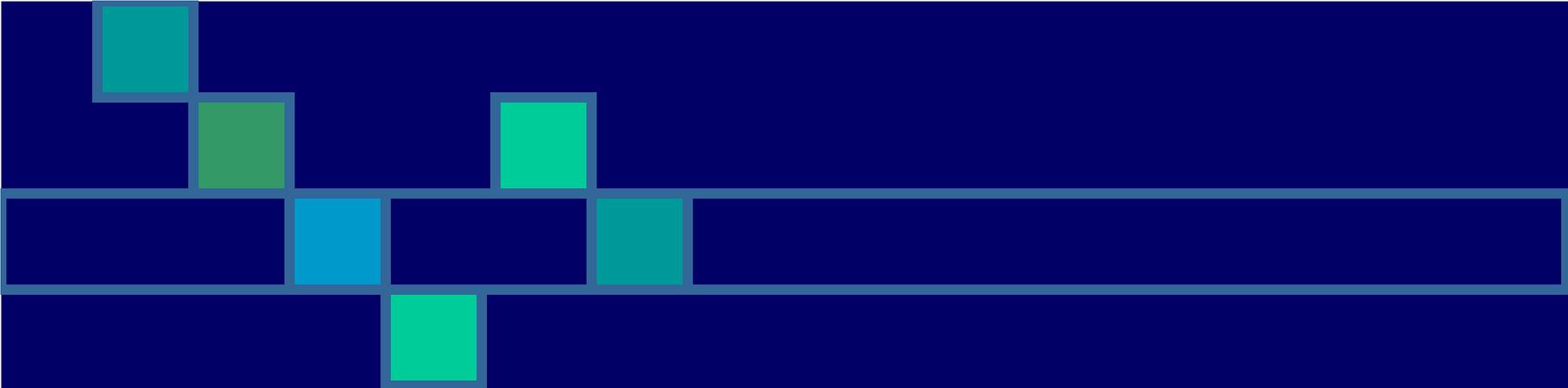


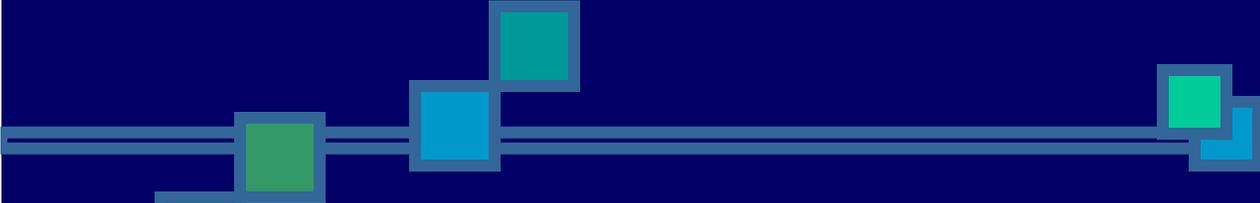
PCI-CAMPOS: Advisory Oversight Committee Draft Presentation

William Bommer MD
Melanie Aryana MD

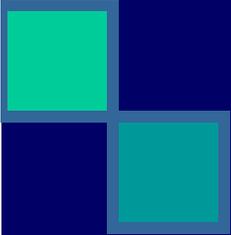
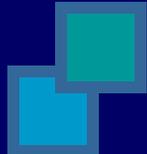
1

- 
- Currently hospitals in California without on-site cardiac surgery are limited to performing certain diagnostic and unscheduled interventional procedures

- 
- Senate Bill 891 authorizes six acute care hospitals that are licensed to provide emergent PCIs to perform scheduled, elective primary PCI for eligible patients

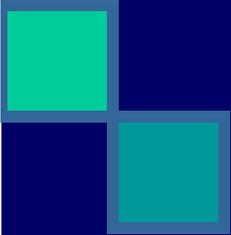
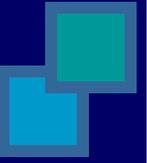


Pilot-Hospitals

- 
- Clovis Community Hospital
 - Doctors Medical Center-San Pablo
 - Kaiser Walnut Creek
 - Los Alamitos Hospital
 - St. Rose Medical Center
 - Sutter Roseville Medical Center
- 

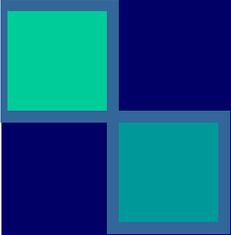
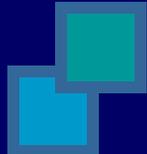


Calif. Dep. of Public Health (CDPH)

- 
- CDPH was mandated by the legislature to establish the PCI California Monitored Pilot with Offsite Surgery
 - After termination of the pilot program CDPH will make recommendations to the California Legislature about the future of offsite elective PCI in California
- 

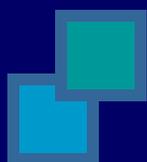


Advisory Oversight Committee (AOC)

- 
- One interventionalist from each pilot hospital, equal number of cardiologists from non-pilot hospitals, one representative from the CDPH
 - Oversee and monitor the pilot program
 - Make recommendations to the CDPH concerning the pilot program
- 

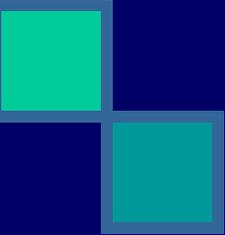


University of California, Davis

- Provides services to CDPH including IRB, consent, and transfer agreement review, pilot hospital training, website data collection and storage, auditing, risk modeling, and statistical analysis throughout the term of the project
- 

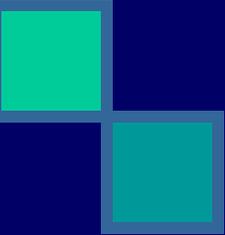


Pilot Hospitals' obligations

- 
- As of August 1, 2010 each pilot hospital will begin performing ≥ 200 primary and elective PCI procedures annually (including 36 primary PCIs) for the following three years in eligible patients
 - Pilot Hospitals will comply with all requirements of the California Department of Public Health and Senate Bill 891 when performing PCIs
- 

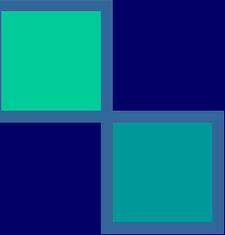


Facility Requirements I

- 
- Each facility has the capacity to perform ≥ 200 primary and elective PCIs annually
 - Facility performs ≥ 36 primary PCIs annually
 - On-call schedule with operation of the cath lab 24 hours per day, 365 days per year
 - Performs primary PCI as the treatment of choice for STEMI
- 

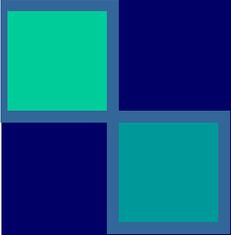
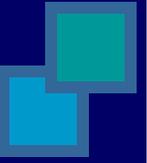


Facility Requirements II

- 
- Tracks door-to-balloon time with a goal of ≤ 90 minutes and reviews outlier cases
 - Permits interventionists who meet specific requirements to perform elective PCI under the pilot program
 - Sufficient staffing capacity in the ICU to provide post-treatment care for patients undergoing elective PCI
- 

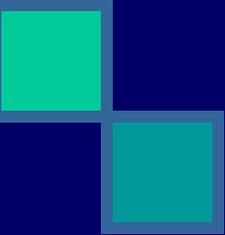


Facility Requirements III

- 
- Full support from hospital administration in fulfilling the necessary institutional requirements (e.g. respiratory care and blood banking)
 - Pilot Hospital IRB approval of participation in the pilot program and the pilot-hospital's informed consent
- 



Facility Requirements IV

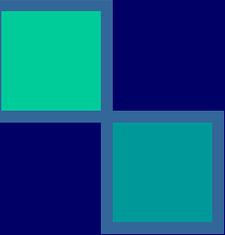


Transfer agreement

- Written transfer agreements for the emergency transfer of patients to on-site hospitals
 - Transfer protocols have to be tested at least twice a year
 - PCI to onsite door – 60 minutes
 - PCI to onsite bypass – 120 minutes
- 

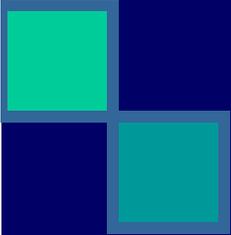
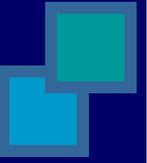


Facility Requirements V

- 
- Rigorous hospital data collection, outcomes analysis, benchmarking, QI, and formalized periodic case review
 - Participates in the NCDR
 - Rigorous case selection for patients undergoing elective PCI
- 

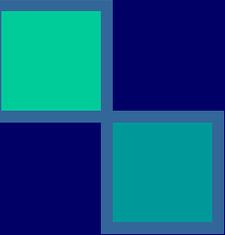


Requirements for Off-Site Surgical Backup I

- 
- Interventional Cardiologists establish a working relationship with cardiac surgeons at the receiving facility
 - Cardiac surgeon must have privileges at the receiving facility to allow review of treatment options as time allows
 - Cardiac surgeon and receiving hospital agree to provide cardiac surgical backup for urgent cases at all hours and for elective cases at mutually agreed hours
- 

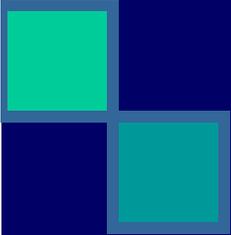
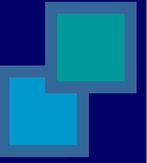


Requirements for Off-Site Surgical Backup II

- 
- Surgeon and receiving facility assure that patient will be accepted based on medical condition, capacity of surgeons to provide services at the time of request and availability of resources. If this cannot be assured before starting an elective procedure, the case should not be done at the time
- 

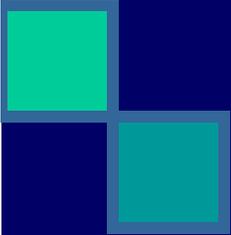
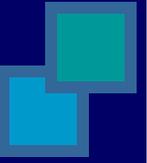


Requirements for Off-Site Surgical Backup III

- 
- Interventional cardiologist must review with the surgeon the immediate needs and status of any patient transferred for urgent surgery
 - Hospital administrators from both facilities endorse transfer agreement
 - Transferring and receiving facility establish a rigorous protocol for the rapid transfer of patients, including the proper personnel with appropriate experience
- 

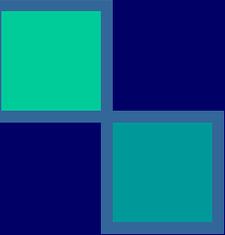


Requirements for Off-Site Surgical Backup IV

- 
- Transport provider is available to begin transport within 20 minutes of the request and provide vehicle/helicopter with necessary life sustaining equipment including IABP and monitoring capability
 - Transferring physician obtains consent for surgery from patient or appropriate surrogate
- 

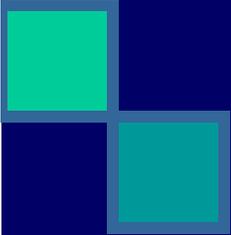
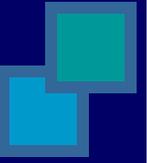


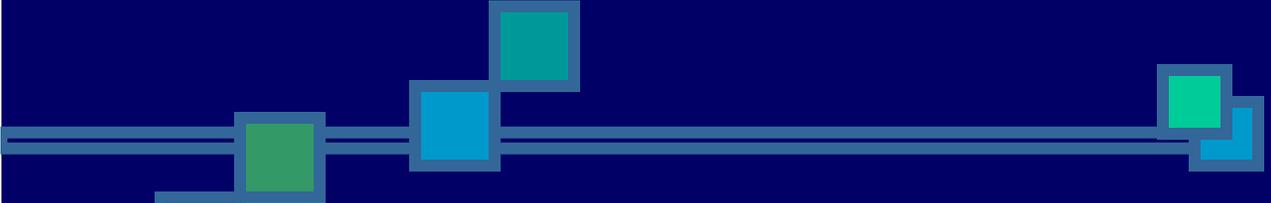
Requirements for Off-Site Surgical Backup V

- 
- Initial informed consent for PCI discloses that procedure is being done without onsite-surgical backup and acknowledges possibility of risks related to transfer. The consent process should include the risk of urgent surgery ($\sim 0.3\%$) and state that a written plan for transfer exists
- 

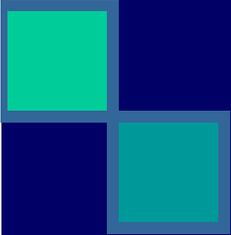
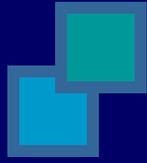


Requirements for Off-Site Surgical Backup VI

- 
- As part of the local continuous quality improvement program, the pilot hospital will review all patients transferred for emergency surgery including the final outcome and identification of any improvement opportunities
- 

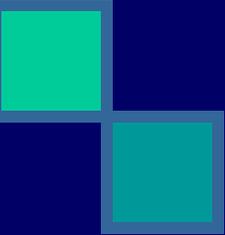


Operator Requirements I

- 
- Perform ≥ 100 PCI procedures/year, including at least 18 primary PCIs/year
 - Lifetime experience of ≥ 500 PCIs as primary operator
 - Complication rates and outcomes equivalent or superior to national benchmarks established by the ACC
- 

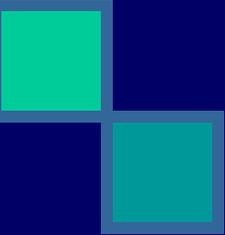


Operator Requirements II

- 
- Holds board certification by the American Board of Internal Medicine in Interventional Cardiology and Cardiovascular Diseases
 - Actively participates in the pilot hospital's quality improvement program
- 

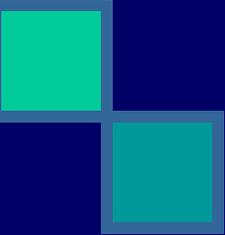


Lab Staff Requirements

- 
- Experienced nursing and technical laboratory staff with training in interventional laboratories
 - Laboratory staff has demonstrated competency treating acutely ill patients with hemodynamic and electric instability
- 



ICU Staff Requirements

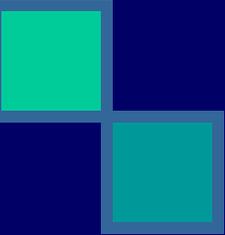


Experienced ICU nursing staff with competency in the following:

- Invasive hemodynamic monitoring
 - Temporary pacemaker operation
 - IABP management
 - Endo-tracheal intubation
 - Ventilator management at pilot site and during transfer to on-site hospital
- 



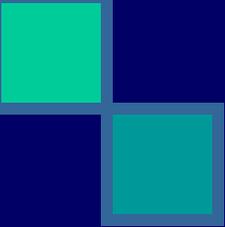
Patient Selection

- 
- Patient selection should be based on interventionalist's professional medical judgment, including the patient's risk, the patient's lesion risk, and the patient's overall health status
- 



High Risk Patient I

(expected clinical risk in case of occlusion or other serious complication caused by the PCI)



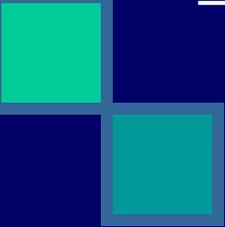
Includes but is not limited to:

- Decompensated CHF (Killip class 3) without evidence for active ischemia
 - Recent **cardiovascular** attack
 - Advanced malignancy
 - Known clotting disorders
 - LVEF ≤ 25%
- 



High Risk Patient II

(expected clinical risk in case of occlusion or other serious complication caused by the PCI)

- 
- Left main stenosis $\geq 50\%$
 - Three-vessel disease, unprotected by prior bypass surgery
 - $> 70\%$ stenosis in the proximal segment of all major epicardial coronary arteries
 - Single target lesion that jeopardizes over 50% of remaining viable myocardium
- 

High Lesion Risk I

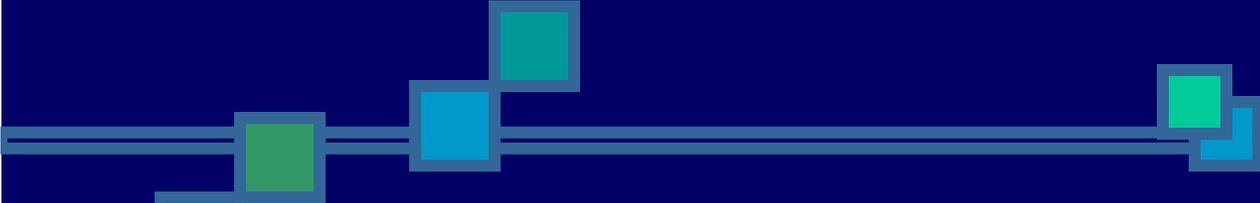
probability that the procedure will cause acute vessel occlusion or other serious complication

"High lesion risk" may include, but is not limited to lesions in open vessels with the following:

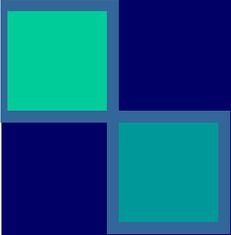
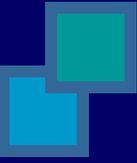
- Diffuse disease (> 2 cm in length) and excessive **tortuosity** of prox. segments
- More than moderate calcification of a stenosis or proximal segments
- Location in an extremely angulated segment (>90%)

High Lesion Risk II

- Inability to protect major side branches
- Degenerated older vein grafts with friable lesions
- Substantial thrombus in the vessel or at the lesion site
- Other features that may, in the interventionalist's judgment, impede stent deployment
- Avoid aggressive measures to open total chronic occlusion

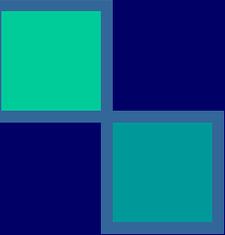


Eligible patients for elective PCI I

- 
- **High risk patient** with **high risk lesion** should **NOT** be included in the pilot program
 - **High risk patient** with a **NOT high risk lesion** may be included in the pilot program upon confirmation that a cardiac surgeon and an operating room are immediately available if necessary
- 

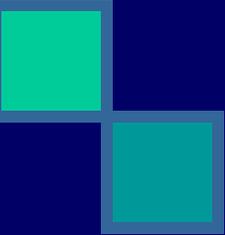


Eligible patients for elective PCI II

- 
- **NOT high-risk patient** with a **high-risk lesion** may be included in the pilot-program
 - **NOT high-risk patient** with a **NOT high risk lesion** may be included in the pilot program
- 



Reports provided by pilot-hospitals

- 
- Quarterly reports to the California Department of Public Health (CDPH) and the Advisory oversight committee (AOC)
 - Statistical data and patient information relating to the number of elective PCIs performed and the outcomes of those procedures
 - Recommendations for modifications to the pilot-program to deliver improved patient care
- 



Reports provided by UC Davis I

- Monthly reports to the CDPH on
 - Monthly mortality and complication rate at pilot-hospitals
 - Pilot-hospitals presenting late or incomplete data on a repeated basis
 - Protocol violations by pilot-hospitals and if pilot hospitals do not provide required data
 - Audit results of all fatal cases



Reports provided by UC Davis II

- Quarterly reports to the CDPH on
 - Data from interim statistical analyses
 - Adverse events including events at the original PCI facility and at centers to which these patients have been subsequently transferred
 - Details of patients transferred to cardiothoracic surgery including name, demographics, complication/reason for transfer, door-to-balloon times, time from balloon to surgery center and OR anesthesia and patients' survival at discharge
 - Primary PCI event and success rates
- 



Reports provided by UC Davis III

- Annual reports to the CDPH on
 - Complete data analyses, risk-adjustment modeling and compilation of patient demographic data from pilot-hospitals
 - Benchmarks for each interventionist, compared to state and national benchmarks
 - Interim reports after year 1, year 2 and a comprehensive report at the end of year 3 and submission for Peer Review Publication
- 



Reports provided by UC Davis IV

- Final report to the CDPH on
 - **Primary outcomes** – in-hospital mortality and/or need for emergent cardiac surgery
 - **Secondary outcomes** – major adverse CV events (death, q-wave MI, stroke, emergent cardiac surgery)
 - **Additional outcomes** – MI (biomarker), cardiogenic shock, heart failure, pericardial tamponade, new requirement for dialysis, vascular complication requiring repair, blood transfusions, major bleeding event within 72 hours
- 

PCI Risk- Mortality OR

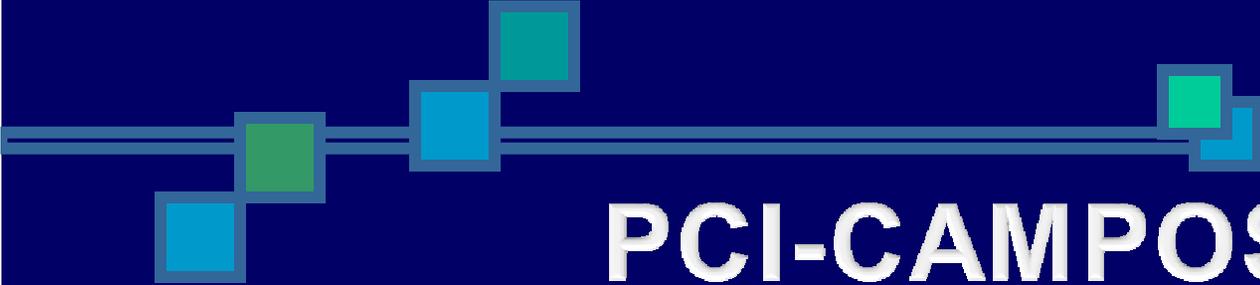
■ Salvage:	13.38	■ Prox LAD	1.97
■ Age > 80	11.25	■ SCAI III	1.87
■ Shock	8.49	■ Urgent	1.78
■ Age 70-79	6.44	■ Pre IABP	1.68
■ Emergent	5.75	■ SCAI II	1.64
■ LVEF <10%	3.93	■ Non-stent	1.64
■ Age 60-69	3.75	■ Diabetes	1.41
■ LVEF 10-19%	3.43	■ Thrombolytic	1.39
■ Renal failure	3.04	■ COPD	1.33
■ Age 50-59	2.61	■ AMI<24 hr	1.31
■ SCAT IV	2.11	■ LVEF 30-39	0.99
■ L Main	2.04	■ LVEF 40-50	0.87
■ LVEF 20-29	2.04		

35

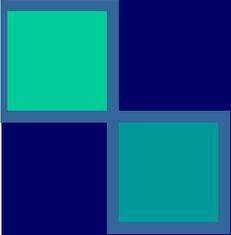
PCI Risk- Mortality OR

■ LVEF 40-50	0.87	■ LVEF 20-29*	2.04
■ LVEF 30-39	0.99	■ L Main*	2.04
■ AMI<24 hr	1.31	■ SCAI IV	2.11
■ COPD	1.33	■ Age 50-59	2.61
■ Thrombolytic	1.39	■ Renal failure	3.04
■ Diabetes	1.41	■ LVEF 10-19%*	3.43
■ Non-stent	1.64	■ Age 60-69	3.75
■ SCAI II	1.64	■ LVEF <10%*	3.93
■ Pre IABP	1.68	■ Emergent	5.75
■ Urgent	1.78	■ Age 70-79	6.44
■ SCAI III	1.87	■ Shock	8.49
■ Prox LAD	1.97	■ Age > 80	11.25
		■ Salvage	13.38

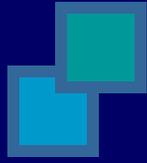
36



PCI-CAMPOS:



Website entry of 220 NCDR fields and 20 PCI-CAMPOS fields within 72 hours,
Data cleaning and lock. Transfer to SAS for statistical analysis and modeling.
10% random and complication audits including angiographic review
Comparison with California ON SITE hospitals
Uploading of quarterly harvest reports to NCDR





High Patient Risk includes, but is not limited to:

Clinical risk

- Decomp. CHF (Killip3) without evidence for active ischemia
- 3-VD unprotected by prior CABG
- recent **cardiovascular** attack
- LVEF \leq 25%
- advanced malignancy
- known clotting disorders

Myocardial risk

- left main stenosis \geq 50%
- $>$ 70% stenosis in the prox. segment of all major coronary arteries
- single target lesion that jeopardizes over 50% of remaining viable myocardium

High Lesion Risk includes, but is not limited to:

- diffuse disease ($>$ 2cm in length) and excessive tortuosity of proximal segments
 - more than moderate calcification of a stenosis or proximal segments
 - location in an extremely angulated segment (**$>$ 90 degrees**)
 - inability to protect major side branches
 - degenerated older vein grafts with friable lesions
 - substantial thrombus in the vessel or at the lesion site
 - any feature that may, in the operator's judgement, impede stent deployment
- 

California Legislature

report within 90 days after the termination of the pilot-program

CDPH

C. Turner, T. Rodacker

quarterly, annually, and final reports

UC Davis – PI, PM

W. Bommer, M. Aryana

2 interim plus one final report

AOC

Angio Review Panel

Server Website
PCI-eCardio

Statistical Analysis

Z. Li, G. Mahendra

Audit Nurse

data entry online

On-site
NCDR

Off-site
NCDR

1

2

3

4

5

6

pilot-hospitals



Welcome to Velos eResearch

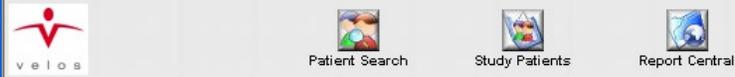
User Name

Password

Login

- User name and password are case sensitive.
- Pop-up blockers must be disabled for this application.

Ver 8.8.1 Build#524a



- Homepage
- Personalize Account
- Manage Patients
- Report Central
- Ad-Hoc Queries
- Help
- Logout

Search a Study [ADVANCED SEARCH](#) [Account Forms](#) [Edit](#)

Last Modified Studies
 You do not have access to any Study

Study Number	Study Title	Study Status
--------------	-------------	--------------

My Links	Edit

Quick Links	Edit

Message Center [Unread\(0\)](#) [Read\(0\)](#) [Acknowledgements\(0\)](#) [[Unread Messages](#)]

Name	Study	Text	Request	Permission	Snapshot
------	-------	------	---------	------------	----------

[What is a Snapshot](#) Click on to view the current study snapshot.

Current User:
 Melanie Aryana

 System Timezone:
 (GMT-08:00) Pacific
 Time (US and
 Canada) Tijuana



- Homepage
- Personalize Account
- Manage Patients
- Report Central
- Ad-Hoc Queries
- Help
- Logout

Demographics | Patient Profile | Protocols | Reports | Appendix

Patient ID: * 123456 [MORE PATIENT DETAILS](#)

Survival Status: * Alive Death Date: Cause: Specify:

Personal Details

First Name:

Middle Name:

Last Name:

Date of Birth *

Gender:

Marital Status:

Blood Group:

SSN Not Applicable:

SSN:

E-Mail:

Contact Information

Address 1:

Address 2:

City:

State:

County:

Zip/Postal Code:

Country:

Home Phone(s):

Work Phone(s):

Primary Ethnicity: Additional:

Primary Race: Additional:

Registration Details

Please save your changes before adding or modifying patient registration details

The Patient is registered to the following Organization(s):

[REGISTER TO A NEW ORGANIZATION](#)

Organization	Facility ID	Registration Date	Provider	Group/Department	Access
PCI-Fictitious Organization For Training	123456	07/16/2010			Granted

Other

Current User:
Melanie Aryana

System Timezone:
(GMT-08:00) Pacific
Time (US and
Canada) Tijuana


 Patient Search
  Study Patients
  Report Central

- Homepage
- Personalize Account
- Manage Patients
- Report Central
- Ad-Hoc Queries
- Help
- Logout

Demographics Patient Profile Protocols Reports Appendix

Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Jump to Form: ACC-NCDR CathPCI Registry

Open Form Name: ACC-NCDR CathPCI Registry [Printer Friendly Format](#)

American College of Cardiology (ACC) National Cardiovascular Data Registry (NCDR)

CathPCI Registry Database Data Collection Form

Velos

ACC-NCDR-CathPCI

Time Frame of Data Submission [1020](#)

Z. Administration

Participant Name [1010*](#)

Participant ID [1000*](#)

Participant NPI [1016](#)

Auxiliary 0 [1200](#) [Select Hospital](#)

A. Demographics

Auxiliary 1 [2500](#)

Auxiliary 2 [2501](#)

Current User: Melanie Aryana
System Timezone: (GMT-08:00) Pacific Time (US and Canada) Tijuana

Current Page: Patient Form


 Patient Search
  Study Patients
  Report Central

- Homepage
- Personalize Account
- Manage Patients
- Report Central
- Ad-Hoc Queries
- Help
- Logout

Demographics Patient Profile Protocols Reports Appendix

Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

A. Demographics

Auxiliary 1 ²⁵⁰⁰

Auxiliary 2 ²⁵⁰¹

White ²⁰⁷⁰ No

Black/ African American ²⁰⁷¹ No

Asian ²⁰⁷² No

American Indian or Alaskan Native ²⁰⁷³ No

Native Hawaiian or Pacific Islander ²⁰⁷⁴ No

Hispanic or Latino Ethnicity ²⁰⁷⁶ Select an Option

B. Episode of Care

Current User: Melanie Aryana

System Timezone: (GMT-08:00) Pacific Time (US and Canada) Tijuana

Arrival Date/Time ^{3000 3001*} :

Copy Data from same Arrival-Discharge

Patient Zip Code ³⁰⁰⁵

Zip Code N/A ³⁰⁰⁶ No

Admit Source ³⁰¹⁰ Select an Option

Insurance Payors

Private Health Insurance ³⁰²⁰ No

Medicare ³⁰²¹ No

Medicaid ³⁰²² No

Military Health Care ³⁰²³ No

State-Specific Plan (non-Medicaid) ³⁰²⁴ No

Indian Health Service ³⁰²⁵ No

Non-US Insurance ³⁰²⁶ No

None ³⁰²⁷ No

HIC # ³⁰³⁰



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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

C. History And Risk Factors

(On ARRIVAL TO CathPCI FACILITY)

Current/Recent Smoker (< 1 year) 4000	Select an Option	Height 4055*	<input type="text"/> (cm)
Hypertension 4005	Select an Option	Weight 4060*	<input type="text"/> (kg)
Dyslipidemia 4010	Select an Option	Currently on Dialysis 4065	Select an Option
Family History of Premature CAD 4015	Select an Option	Cerebrovascular Disease 4070	Select an Option
Prior MI 4020	Select an Option	Peripheral Arterial Disease 4075	Select an Option
Prior Heart Failure 4025	Select an Option	Chronic Lung Disease 4080	Select an Option
Prior Valve Surgery/Procedure 4030	Select an Option	Diabetes Mellitus 4085	Select an Option
Prior PCI 4035	Select an Option	=> If Yes, Diabetes Therapy 4090	Select an Option
=> If Yes, Most Recent PCI Date 4040	<input type="text"/>		
Prior CABG 4045	Select an Option		
=> If Yes, Most Recent CABG Date 4050	<input type="text"/>		

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D. Cath Lab Visit (COMPLETE FOR EACH CATH LAB VISIT)

CLINICAL EVALUATION LEADING TO THE PROCEDURE

CAD Presentation [5000](#) Select an Option

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

D. Cath Lab Visit (COMPLETE FOR EACH CATH LAB VISIT)
 CLINICAL EVALUATION LEADING TO THE PROCEDURE

CAD Presentation [5000](#)

=> If STEMI or Non-STEMI, Symptom Onset Date/Time [5005](#) [5006](#) : : **Time Estimated** [5007](#) **Time Not Available** [5008](#)

If STEMI, Thrombolytics [5010](#) **=> If Yes, Start Date/Time** [5015](#) [5016](#) :

Anginal Classification w/in 2 Weeks [5020](#)

Anti-Anginal Medication w/in 2 Weeks [5025](#)

=> If Yes, (check all that apply)

Beta Blockers [5026](#) **Calcium Channel Blockers** [5027](#) **Long Acting Nitrates** [5028](#) **Ranolazine** [5029](#) **Other** [5030](#)

Heart Failure w/in 2 Weeks [5040](#)

=> If Yes, NYHA Class w/in 2 Weeks [5045](#)

Cardiomyopathy or LV Systolic Dysfunction [5050](#)

Pre-operative Evaluation Before Non-Cardiac Surgery [5055](#)

Cardiogenic Shock w/in 24 Hours [5060](#)

Cardiac Arrest w/in 24 Hours [5065](#)

Stress or Imaging Studies Performed [5100](#)

[Set All Stress or Imaging Tests - NO](#)

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

MECHANICAL VENTRICULAR SUPPORT

IABP [5330](#)

=> If Yes, Timing [5335](#)

Other Mechanical Ventricular Support [5340](#)

=> If Yes, Timing [5345](#)

ARTERIAL ACCESS

Arterial Access Site [5350](#)

Closure Method Not Documented [5356](#)

Auxiliary 3 [5400](#)

Auxiliary 4 [5405](#)

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Closure Methods

[Add More Closure Method](#)

Closure Method(s) 5355	Arterial Access Closure Method Name
<input type="text"/>	<input type="text"/> Select Closure Method



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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

F. Best Estimate of Coronary Anatomy

(Complete For Each Cath Lab Visit)

Dominance [6100](#) Select an Option

Coronary Territory	Native Artery Percent Stenosis in >=2mm vessels	Grafts Supplying Coronary Territory (note 1) Percent Stenosis
Left Main	<input type="text"/> % 6110 * Not Available 6111 No	
Proximal LAD	<input type="text"/> % 6120 * Not Available 6121 No	<input type="text"/> % 6170 * Not Available 6171 No
Mid/Distal LAD, Diag Branches	<input type="text"/> % 6130 * Not Available 6131 No	<input type="text"/> % 6180 * Not Available 6181 No
CIRC, OMs, LPDA, LPL Branches	<input type="text"/> % 6140 * Not Available 6141 No	<input type="text"/> % 6190 * Not Available 6191 No
RCA, RPDA, RPL, AM Branches	<input type="text"/> % 6150 * Not Available 6151 No	<input type="text"/> % 6200 * Not Available 6201 No
Ramus	<input type="text"/> % 6160 * Not Available 6161 No	<input type="text"/> % 6210 * Not Available 6211 No

Current User:
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Time (US and
Canada) Tijuana

J. Intra and Post Procedure Events

[Set All Post Procedure Events - NO](#)

(Complete For Each Cath Lab Visit)

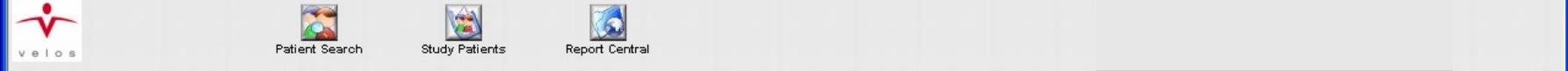
Myocardial Infarction [8000](#)
(Positive Biomarkers) Select an Option

Cardiogenic Shock [8005](#) Select an Option

Heart Failure [8010](#) Select an Option

Bleeding Event w/in 72 Hours [8050](#) Select an Option

=> If, Yes Bleeding at Access Site [8055](#) Select an Option



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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

J. Intra and Post Procedure Events

[Set All Post Procedure Events - NO](#)

(Complete For Each Cath Lab Visit)

Myocardial Infarction 8000 (Positive Biomarkers)	Select an Option	Bleeding Event w/in 72 Hours 8050	Select an Option
Cardiogenic Shock 8005	Select an Option	=> If, Yes Bleeding at Access Site 8055	Select an Option
Heart Failure 8010	Select an Option	Hematoma at Access Site 8060	Select an Option
CVA/Stroke 8015	Select an Option	=> If, Yes Hematoma Size 8061	Select an Option
=> If Yes, Hemorrhagic Stroke 8021	Select an Option	Retroperitoneal Bleeding 8070	Select an Option
Tamponade 8025	Select an Option	GI Bleed 8080	Select an Option
New Requirement for Dialysis 8030	Select an Option	GU Bleed 8090	Select an Option
Other Vascular Complications 8035	Select an Option	Other Bleed 8100	Select an Option
RBC/Whole Blood Transfusion 8040	Select an Option		
=> If Yes, Hgb Prior to Transfusion 8041*	<input type="text"/> g/dL		

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System Timezone: (GMT-08:00) Pacific Time (US and Canada) Tijuana

K. Discharge

(Complete for each Episode of Care)

CABG [9000](#) Select an Option



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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

K. Discharge

(Complete for each Episode of Care)

CABG [9000](#)

=> If, Yes CABG Status [9005](#)

=> If, Yes CABG Indication [9010](#)

=> If, Yes CABG Location [9015](#)

=> If At your facility, CABG Date/Time [9020](#) [9021](#) :

Other Major Surgery [9025](#) LVEF [9030*](#) % LVEF Not Assessed [9031](#)

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Discharge Date [9035](#)

Discharge Status [9040](#)

=> If Alive, Discharge Location [9045](#)

=> If Alive, Cardiac Rehabilitation Referral [9050](#)

=> If Deceased, Death in Lab [9055](#)

=> If Deceased, Primary Cause of Death [9060](#)

Hospital Status [9065](#)

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Discharge Medications (Prescribed At Discharge)

[Get Medications](#) [Set All Administered - NO](#)

Discharge medications are not required for patients who expired OR were discharge to 'Other acute care hospital' or 'hospice'.

Data Entry Date*

Form Status* e-Signature*

IC Device Count

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Medication Count

Cls Device Count



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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Jump to Form: ACC-NCDR CathPCI Registry - Part 2 Go

Open Form Name: ACC-NCDR CathPCI Registry - Part 2 [Printer Friendly Format](#)

Section 1

Data Entry Date*

Was the patient transferred for urgent surgery?* Yes No

- If Yes:
- 1- Please answer all questions on this form.
- If No:
- 1- Leave the rest of the questions unanswered.
 - 2- Skip to the bottom of this form.
 - 3- Change the Form Status from Work In Progress to Completed.
 - 4. Enter your eSignature.

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Stress or Imaging Studies Performed [5100](#)

Select an Option

[Set All Stress or Imaging Tests - NO](#)

If Yes, Specify Test Performed:

Test Performed	Result	Risk/Extent of Ischemia
Standard Exercise Stress Test 5200 5201 5202 (w/o imaging)	Select an Option	Select an Option
Stress Echocardiogram 5210 5211 5212	Select an Option	Select an Option
Stress Testing w/SPECT MPI 5220 5221 5222	Select an Option	Select an Option
Stress Testing w/CMR 5230 5231 5232	Select an Option	Select an Option
Cardiac CTA 5240 5241	Select an Option	Select an Option
Coronary Calcium Score 5250	Select an Option	Calcium Score 5251 *

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PROCEDURE INFORMATION

Procedure Date/Time [5300](#) [5301](#)*

Input fields for date and time

PCI [5305](#)*

Select an Option

Fluoro Time/Dose [5320](#) *

Input field for minutes

OR [5321](#) *

Input field for mGy

Diagnostic Cath [5310](#)*

Select an Option

Contrast Volume [5325](#)*

Input field for volume

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velos

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Time Of Decision For Transfer For CABG Date Of Decision For Transfer For CABG Time Of Arrival At CABG Onsite Hospital Date Of Arrival At CABG Onsite Hospital

Time Of Arrival - At The Cardiac Surgery Center OR (Anesthesia Protocol) Date Of Arrival - At The Cardiac Surgery Center OR (Anesthesia Protocol) Discharge Date From The Cardiac Surgery Center

Discharge Status From The Cardiac Surgery Center Alive Dead

Post Discharge Complication Within 30 Days? Yes No

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Pat.ID: 123456 Age: 40 years Gender: Male Pat.Name: Velos Test Org: PCI-Fictitious Organization For Training

Post Discharge
Complication Within 30
Days? Yes
 No

Post Discharge Death
Within 30 Days? Yes
 No

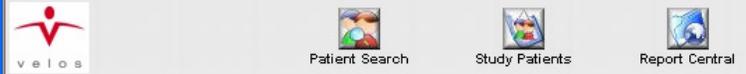
Current User:
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System Timezone:
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Form Status*
Form Version Number: 1
Work In Progress
Completed
Resubmit
Work In Progress
Incomplete

e-Signature *

Submit

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Select Report Type: Acc-Cathpci

Report

ACC - CathPCI Registry Reports

- ACC - CathPCI - Data Completeness Report
- ACC - CathPCI - Patient Listing
- ACC - CathPCI - Procedure Meds By Operator
- ACC - CathPCI - Discharge Meds By Operator
- ACC - CathPCI - Closure Methods By Operator
- ACC - CathPCI - Intracoronary Devices By Operator
- ACC - CathPCI - Procedure By Quarter By Operator
- ACC - CathPCI - Procedure By Status
- ACC - CathPCI - Data Collection Form
- ACC - CathPCI - Intra & Post Procedure Events
- ACC - CathPCI - Risk Factor Summary
- ACC - CathPCI - Risk Factor Rate By Operator

Mortality Reports

- ACC - CathPCI - Mortality by Operator
- ACC - CathPCI - Mortality by Procedure

Length of Stay Reports

- ACC - CathPCI - Length of Stay By Operator
- ACC - CathPCI - Length of Stay Summary

Available filters for this Report Type are:

Date Filter: All Year Month Date Range

[All]

Additional Filters:

Select Organization: PC-UC Davis Data Coo

Enter Participant ID

Do not display selected filters in Report Header

Do not display download options in Report Header

Display

Current User: Melanie Aryana

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Select Report Type Adverse Event

Report

Adverse Event Reports

- Adverse Events by Patient
- Adverse Event Summary

Study Specific (select one study only)

- Adverse Events by Study
- Adverse Event Tracking

Available filters for this Report Type are:

Date Filter:
All Year Month Date Range
[All]

Additional Filters:

Select Study
Select Organization
Select Patient

- Do not display selected filters in Report Header
- Do not display download options in Report Header

Display

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Download the report in: [Word Format](#) [Excel Format](#) [Printer Friendly Format](#)

ACC - CathPCI - Mortality by Operator

Site Name : PCI-UC Davis Data Coordinating Center
 Start Date : 01/01/1900
 End Date : 01/01/3000

Diagnostic Cath Only Procedures

CATH OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE
-	0	0	No Patients for this time period

PCI Only Procedures

PCI OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE
-	0	0	No Patients for this time period

CathPCI Combination Procedures

CATH OPERATOR	PCI OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE
-	-	0	0	No Patients for this time period

Summary

Description	Total
-------------	-------

Report By:Melanie Aryana

Date:07/19/2010 11:38:29

PCI- Risk Factors

- **Demographics**

- 2050 Birth Date (only year)
- 2060 Gender (?) – male, female

- **History and Risk Factors**

- 4000 Current/Recent Smoker (<1year) – Y/N
- 4005 Hypertension - Y/N
- 4010 Dyslipidemia - Y/N
- 4015 Family Hx of Premature CAD - Y/N
- 4020 Prior MI - Y/N
- 4025 Prior Heart Failure – Y/N
- 4030 Prior Valve Surgery/Procedure – Y/N
- 4035 Prior PCI - Y/N
- 4045 Prior CABG - Y/N
- 4055 Height
- 4060 Weight
- 4065 Currently on Dialysis - Y/N
- 4070 Cerebrovascular Disease - Y/N
- 4075 Peripheral Arterial Disease - Y/N
- 4080 Chronic Lung Disease - Y/N
- 4085, 4090 Diabetes mellitus – none, diet, oral medication, insulin, other

PCI- Risk Factors

Cath Lab Visit

5000 CAD Presentation – no sx's, no angina; sx's unlikely to be ischemic; stable angina;

unstable angina; non-STEMI; STEMI

5020 Anginal Classification within 2 weeks – no sx's; CCS I; CCS II; CCS III; CCS IV

5040 Heart Failure within 2 weeks – none, Class I; Class II; Class III; Class IV

5050 Cardiomyopathy or LV Systolic Dysfunction – Y/N

5060 Cardiogenic Shock within 24 hours – Y/N

5065 Cardiac Arrest within 24 hours – Y/N

5305 Percutaneous Coronary Intervention (PCI) – Y/N

5330 Intra-aortic balloon pump (IABP) – Y/N

5340 Other Mechanical Ventricular Support – Y/N

Best Estimate of Coronary Anatomy

6110, 6111 Left Main – Percent Stenosis in ≥ 2 mm Vessels; not available

6120, 6121 Prox. LAD - Percent Stenosis in ≥ 2 mm Vessels; not available

PCI- Risk Factors

PCI Procedure

- 7020 PCI Status – elective; urgent; emergency; salvage
- 7025, 7026 Pre-PCI LVEF – percent of EF; not available
- 7030 Cardiogenic Shock at Start of PCI - Y/N
- 7035 PVI Indication – Immediate PVI for STEMI
 - PCI for STEMI (unstable, > 12 hours from sx onset)
 - PCI for STEMI (stable, >12 hours from sx onset)
 - PCI for STEMI (stable after successful full-dose thrombolysis)
 - Rescue PCI for STEMI (after failed full-dose lytics)
 - PCI for high-risk non-STEMI or unstable angina
 - Staged PCI
 - Other
- 34. 7040 If immediate PCI for STEMI: STEMI or Equiv. First Noted –1st or Subsequ. ECG
- 35. 7045, 7046 If subsequent ECG – Date and Time when Subsequ. ECG was recorded
- 36. 7050, 7051 If immediate PCI for STEMI: First Device Activation – Date/Time
- 37. 7055 If immediate PCI for STEMI: Transferred in for Immediate PCI for STEMI – Y/N
- 38. 7060, 7061 If yes, Date/time ED Presentation at Referring Facility
- 39. 7065 If immediate PCI for STEMI, Non-System Reason for Delay in PCI
 - Difficult vascular access
 - Patient delays in providing consent for the procedure
 - Cardiac arrest and/or need for intubation before PCI
 - Difficulty crossing the culprit lesion during the PCI procedure
 - Other
 - None
- 9500, 9510 Procedure Medication
 - Fondaparinux – Y/N/Contraindicated/Blinded
 - LMWH - Y/N/Contraindicated/Blinded
 - Unfractionated Heparin - Y/N/Contraindicated/Blinded
 - Aspirin - Y/N/Contraindicated/Blinded
 - Bivalrudin - Y/N/Contraindicated/Blinded
 - Direct Thrombin Inhibitor (other) - Y/N/Contraindicated/Blinded
 - GP IIb/IIIa - Y/N/Contraindicated/Blinded
 - Clopidogrel - Y/N/Contraindicated/Blinded
 - Ticlopidine - Y/N/Contraindicated/Blinded

PCI- Risk Factors

■ **Lesions and Devices**

- 7145 Previous treated Lesion – Y/N
- 7175 Lesion in Graft – Y/N
- 7185 Lesion Complexity – non-high/non-C; high/C
- 7190 Lesion Length – in mm
- 7195 Thrombus present – Y/N
- 7200 Bifurcation Lesion – Y/N
-
- 47. 7205 Guidewire across Lesion – Y/N
 - 48. 7210 If yes, Stenosis post Procedure – in %
 - 49. 7215 If yes, post Procedure TIMI Flow – 0; 1; 2; 3; 4
 - 50. 7220 If yes, Device(s) Deployed – Y/N

■ **Labs**

- 7315 Creatinine – in mg/dl; not drawn
- 7320 Hemoglobin – in g/dl; not drawn



PCI- Risk Factors

Lesions and Devices

7145 Previous treated Lesion – Y/N

7175 Lesion in Graft – Y/N

7185 Lesion Complexity – non-high/non-C; high/C

7190 Lesion Length – in mm

7195 Thrombus present – Y/N

7200 Bifurcation Lesion – Y/N

47. 7205 Guidewire across Lesion – Y/N

48. 7210 If yes, Stenosis post Procedure – in %

49. 7215 If yes, post Procedure TIMI Flow – 0; 1; 2; 3; 4

50. 7220 If yes, Device(s) Deployed – Y/N

Labs

7315 Creatinine – in mg/dl: not drawn

7320 Hemoglobin – in g/dl

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PCI- Risk Factors

- **Discharge**
- 9000 CABG – Y/N
- 9005 If yes, CABG status – Elective, Urgent, Emergency, Salvage
- 9010 If yes, CABG Indication – PCI Complication; PCI failure without clinical deterioration; Treatment of CAD without PCI immediately proceeding CABG; PCI/CABG hybrid procedure
- (9015) If yes, Location – Name of the hospital where CABG is performed
- 9025 Other Major Surgery – Y/N
- 9040 Discharge Status – Alive, Deceased
- 9045 If alive, Discharge Location – Home; Other acute care hospital; Hospice; Nursing home; Extended Care/TCU/rehab; Other; Left Against Medical Advice
- 9055 If deceased, Death in Lab – Y/N
- 9060 If Deceased, Primary Cause of Death – Cardiac; Neurologic; Renal; Vascular; Infection; Valvular; Pulmonary; Unknown; Other



PCI- Risk Factors

72. 9505, 9510 Discharge Medications

ACE-Inhibitor (any) - Y/N/Contraindicated/Blinded

ARB (any) - Y/N/Contraindicated/Blinded

Aspirin - Y/N/Contraindicated/Blinded

Beta Blocker - Y/N/Contraindicated/Blinded

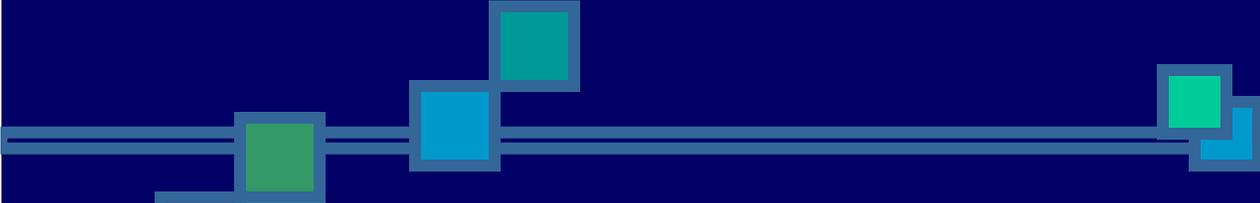
Statin - Y/N/Contraindicated/Blinded

Non-Statin - Y/N/Contraindicated/Blinded

Clopidogrel - Y/N/Contraindicated/Blinded

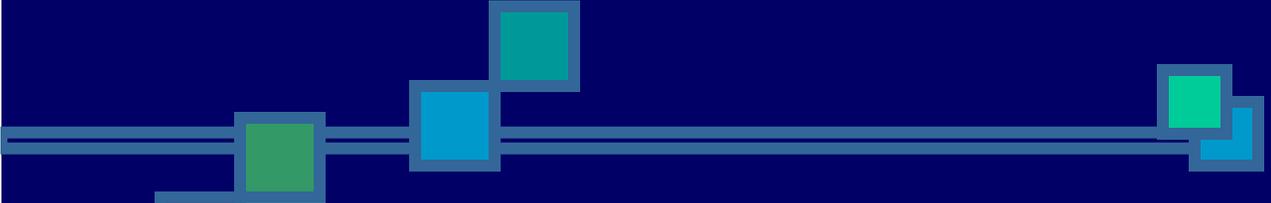
Ticlopidine - Y/N/Contraindicated/Blinded





Reports provided by CDPH

- Report to Legislature within 90 days after termination of the pilot-program including
 - Evaluation of the pilot-programs costs, safety, and quality of care
 - Comparison of elective PCI performed in connection with the pilot-program and elective PCI performed with onsite cardiac surgery
 - Recommendation on whether elective PCI without onsite cardiac surgery should be continued in California, and if so, under what conditions
- 



Reports provided by AOC

- Submit 2 reports to the CDPH during the pilot program
 - Final report at the conclusion of the pilot program, including recommendations for the continuation or termination of the pilot program
- 