

PCI-CAMPOS: Advisory Oversight
Committee 8/19/2010



William Bommer MD
Melanie Aryana MD

Consent Form

All patients who undergo a PCI have to sign a consent form

- All elective PCI patients: should sign the IRB approved elective PCI consent form
- All STEMI patients: should
 - either sign the IRB approved elective PCI consent form
 - or sign the standard consent form for primary PCI with a statement on the consent form saying that patient data will be submitted to CDPH and UC Davis

Data Collection

- **elective PCI patients:** all patients who undergo elective PCI have to be entered and submitted to UC Davis
- **STEMI patients:** all patients who undergo primary PCI have to be entered and submitted to UC Davis
- Patients with **diagnostic caths** only may or may not be entered and submitted to UC Davis

ACC-CathPCI Registry Reports

Available for individual hospitals

- ✓ Data Completeness Report
- ✓ Patient Listing
- ✓ Procedure Medication by Operator
- ✓ Discharge Medication by Operator
- ✓ Closure Methods by Operator
- ✓ Intracoronary Devices by Operator
- ✓ Intra & Post Procedure Events
- ✓ Procedure by Quarter by Operator
- ✓ Procedure by Status

ACC-CathPCI Registry Reports (cont'd)

- ✓ Procedure by Status
- ✓ Risk Factor Summary
- ✓ Risk Factor Rate by Operator
- ✓ Mortality by Operator
- ✓ Mortality by Procedure
- ✓ Length of Stay by Operator
- ✓ Length of Stay Summary

Procedure Medication by Operator

ACC - CathPCI - Procedure Meds By Operator				
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center				
Start Date : 01/01/1900				
End Date : 01/01/3000				
Operator NPI : [All]				
Procedure Medications are not collected for Diagnostic Cath Only Procedures				
As PCI Operator (PCI Only Procedures)				
Operator Name	Medication Name	Medication Count	Procedure Count	Utilization Rate
Physician A	Aspirin (any)	1	1	100.00%
	Bivalirudin	1	1	100.00%
	Aspirin (any)	1	1	100.00%
	Bivalirudin	1	1	100.00%
	Clopidogrel	1	1	100.00%
	Low Molecular Weight Heparin (any)	1	1	100.00%
Total Medications	Aspirin (any)	2	2	100.00%
	Bivalirudin	2	2	100.00%
	Clopidogrel	1	2	50.00%
	Low Molecular Weight Heparin (any)	1	2	50.00%

As Diagnostic Cath/PCI Operator (CathPCI Combination Procedures)					
Diagnostic Cath Operator Name	PCI Operator Name	Medication Name	Medication Count	Procedure Count	Utilization Rate
Physician A	Physician A	Aspirin (any)	1	1	100.00%
		Bivalirudin	1	1	100.00%
		Clopidogrel	1	1	100.00%
Physician B	Physician B	Aspirin (any)	1	1	100.00%
		Bivalirudin	1	1	100.00%
		Clopidogrel	1	1	100.00%
Physician C	Physician C	Aspirin (any)	10	11	90.91%
		Bivalirudin	9	11	81.82%
		Clopidogrel	7	11	63.64%
		GP IIb/IIIa (any)	4	11	36.36%
		Low Molecular Weight Heparin (any)	3	11	27.27%
		Prasugrel	2	11	18.18%
	Unfractionated Heparin (any)	1	11	9.09%	

Discharge Medication by Operator

ACC - CathPCI - Discharge Meds By Operator				
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center				
Start Date : 01/01/1900				
End Date : 01/01/3000				
Operator NPI : [All]				
As Diagnostic Cath Operator (Diagnostic Cath Only Procedures)				
Operator Name	Medication Name	Medication Count	Procedure Count	Utilization Rate
As PCI Operator (PCI Only Procedures)				
Operator Name	Medication Name	Medication Count	Procedure Count	Utilization Rate
Physician A	ACE Inhibitor (any)	1	1	100.00%
	Aspirin (any)	1	1	100.00%
	Beta Blocker (any)	1	1	100.00%
	Clopidogrel	1	1	100.00%
	Non-StatIn (any)	1	1	100.00%
	ACE Inhibitor (any)	1	1	100.00%
	Aspirin (any)	1	1	100.00%
	Clopidogrel	1	1	100.00%
	StatIn (any)	1	1	100.00%
	Total Medications	ACE Inhibitor (any)	2	2
	Aspirin (any)	2	2	100.00%
	Beta Blocker (any)	1	2	50.00%
	Clopidogrel	2	2	100.00%
	Non-StatIn (any)	1	2	50.00%
	StatIn (any)	1	2	50.00%

As Diagnostic Cath/PCI Operator (CathPCI Combination Procedures)					
Diagnostic Cath Operator Name	PCI Operator Name	Medication Name	Medication Count	Procedure Count	Utilization Rate
Physician A	Physician A	Aspirin (any)	1	1	100.00%
		Beta Blocker (any)	1	1	100.00%
		Clopidogrel	1	1	100.00%
		StatIn (any)	1	1	100.00%
Physician B	Physician B	ACE Inhibitor (any)	1	1	100.00%
		Aspirin (any)	1	1	100.00%
		Beta Blocker (any)	1	1	100.00%
		Clopidogrel	1	1	100.00%
Physician C	Physician C	StatIn (any)	1	1	100.00%
		ACE Inhibitor (any)	4	11	36.36%
		Aspirin (any)	6	11	54.55%
		Beta Blocker (any)	6	11	54.55%
		Clopidogrel	5	11	45.45%
		Prasugrel	1	11	9.09%
		StatIn (any)	5	11	45.45%

Closure Methods by Operator

ACC - CathPCI - Closure Methods By Operator					
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center					
Start Date : 01/01/1900					
End Date : 01/01/3000					
Operator NPI : [All]					
AS Diagnostic Cath Operator (Diagnostic Cath Only Procedures)					
Operator Name	Device Name	Device Count	Procedure Count	Utilization Rate	
As PCI Operator (PCI Only Procedures)					
Operator Name	Device Name	Device Count	Procedure Count	Utilization Rate	
Physician A	Manual Compression	1	1	100.00%	
	Angio-Seal VIP	1	1	100.00%	
Total Closure Devices	Angio-Seal VIP	1	2	50.00%	
	Manual Compression	1	2	50.00%	
As Diagnostic Cath/PCI Operator (CathPCI Combination Procedures)					
Diagnostic Cath Operator Name	PCI Operator Name	Device Name	Device Count	Procedure Count	Utilization Rate
Physician A	Physician A	Angio-Seal VIP	1	1	100.00%
Physician B	Physician B	Angio-Seal	1	11	9.09%
		Angio-Seal STS	1	11	9.09%
		Angio-Seal VIP	6	11	54.55%
		Manual Compression	3	11	27.27%
Physician C	Physician C	Angio-Seal VIP	1	1	100.00%
Physician D	Physician D	Manual Compression	1	2	50.00%
Physician E	Physician E	Angio-Seal VIP	3	4	75.00%
		Mechanical Compression	1	4	25.00%

Intracoronary Devices by Operator

ACC - CathPCI - Intracoronary Devices By Operator				
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center				
Start Date : 01/01/1900				
End Date : 01/01/3000				
Operator NPI : [All]				
As PCI Operator (PCI and Combination Procedures)				
Operator Name	Device Name	Device Count	Procedure Count	Utilization Rate
	Multi-Link Vision RX Stent	1	1	100.00%
	Voyager Rx Coronary Dilation Catheter	1	1	100.00%
	Balloon from deployed stent	2	3	66.67%
	Export Catheter	2	3	66.67%
	Promus DES RX	3	3	100.00%
	VeriFLEX RE	1	3	33.33%
	Voyager Rx Coronary Dilation Catheter	3	3	100.00%
	Export Catheter	1	1	100.00%
	Promus DES RX	1	1	100.00%
	Cypher Sirolimus-eluting Stent (Rx)	1	3	33.33%
	Maverick(2) Monorail Balloon RE	2	3	66.67%
	Promus DES RX	2	3	66.67%
	Sprinter Legend - RX	1	3	33.33%
	Maverick(2) Monorail Balloon RE	3	4	75.00%
	Multi-Link Vision RX Stent	2	4	50.00%
	NC Sprinter - RX	2	4	50.00%
	Promus DES RX	3	4	75.00%
	Pronto LP	2	4	50.00%
	Quantum Maverick RE Balloon	3	4	75.00%
	Sprinter Legend - RX	1	4	25.00%
	Apex (OTW)	4	12	33.33%
	Export AP Catheter	4	12	33.33%
	Export Catheter	1	12	8.33%
	FilterWire EZ Embolic Protection System	1	12	8.33%

Total IntraCoronary Devices	Apex (OTW)	4	35	11.43%
	Apex Monorail	2	35	5.71%
	Balloon from deployed stent	2	35	5.71%
	Cypher Sirolimus-eluting Stent (Rx)	1	35	2.86%
	Driver OTW Coronary Stent	2	35	5.71%
	Endeavor Sprint - OTW	1	35	2.86%
	Endeavor Stent (OTW)	1	35	2.86%
	Export AP Catheter	4	35	11.43%
	Export Catheter	4	35	11.43%
	FilterWire EZ Embolic Protection System	1	35	2.86%
	Liberte RE Stent	1	35	2.86%
	Maverick OTW Balloon	1	35	2.86%
	Maverick(2) Monorail Balloon RE	7	35	20.00%
	Multi-Link Mini Vision OTW Stent	1	35	2.86%
	Multi-Link Mini Vision RX Stent	1	35	2.86%
	Multi-Link Vision RX Stent	3	35	8.57%
	NC Quantum Apex Monorail	3	35	8.57%
	NC Quantum Apex OTW	7	35	20.00%
	NC Sprinter - RX	4	35	11.43%
	Promus DES OTW	16	35	45.71%
	Promus DES RX	12	35	34.29%
	Pronto Extraction Catheter	1	35	2.86%
	Pronto LP	2	35	5.71%
	Quantum Maverick OTW Balloon	2	35	5.71%
	Quantum Maverick RE Balloon	4	35	11.43%
	Sprinter Balloon	1	35	2.86%
	Sprinter Legend - RX	3	35	8.57%
	Sprinter OTW	4	35	11.43%
	Stormer OTW Balloon	2	35	5.71%
	VeriFLEX OTW	1	35	2.86%
	VeriFLEX RE	2	35	5.71%

Intra & Post Procedure Events

ACC - CathPCI - Intra & Post Procedure Events

Participant ID : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center

Start Date : 01/01/1900

End Date : 01/01/3000

Event Description	Event Count	% of All Procedures	% of All Procedures With Events
Heart Failure	1	3.33%	3.33%
Cardiogenic Shock	1	3.33%	3.33%

Report Summary

Total Number of Procedures	30
Total Number of Events in all Procedures	2
Average Number of Events per Procedure	.07

Procedures with Events

Total Number	30
Percentage of all Procedures	1.00%
Average Number of Events	.07

Procedure by Quarter by Operator

ACC - CathPCI - Procedure By Quarter By Operator				
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center				
Start Date : 01/01/1900				
End Date : 01/01/3000				
Operator NPI :				
As Diagnostic Cath Operator (Diagnostic Cath Only Procedures)				
Diagnostic Operator Name	Procedure	Timeframe	Procedure Count	
All Diagnostic Cath Operators	Total Procedures	->	0	
As PCI Operator (PCI Only Procedures)				
PCI Operator Name	Procedure	Timeframe	Procedure Count	
	PCI	2010Q3	1	
	PCI	2010Q3	1	
All PCI Operators	Total Procedures	->	2	
As Diagnostic Cath/PCI Operator (CathPCI Combination Procedures)				
Diagnostic Cath Operator Name	PCI Operator Name	Procedure	Timeframe	Procedure Count
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI		1
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI	2010Q3	8
		Diagnostic Cath and PCI		2
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI	2010Q3	4
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI		1
		Diagnostic Cath and PCI	2010Q3	1
		Diagnostic Cath and PCI		1

Procedure by Status

ACC - CathPCI - Procedure By Status

Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center

Start Date : 01/01/1900

End Date : 01/01/3000

Diagnostic Cath Only Procedures

Diagnostic Cath Status	Procedure Count	Percentage
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PCI Only Procedures

PCI Status	Procedure Count	Percentage
Elective	1	50.00%
Emergency	1	50.00%
All PCI Procedures	2	100.00%

CathPCI Combination Procedures

Diagnostic Cath Status	PCI Status	Procedure Count	Percentage
Elective	Elective	11	32.35%
Elective	Elective	1	2.94%
Emergency	Emergency	14	41.18%
Urgent	Elective	2	5.88%
Urgent	Urgent	6	17.65%
All CathPCI Procedures		34	100.00%

Risk Factor Summary

ACC - CathPCI - Risk Factor Summary

Participant ID : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center

Start Date : 01/01/1900

End Date : 01/01/3000

Risk Factor Description	Risk Factor Count	% of All Procedures	% of All Procedures With Risk Factors
Peripheral Arterial Disease	3	8.33%	8.33%
Hypertension	29	80.56%	80.56%
Dyslipidemia	29	80.56%	80.56%
Prior PCI	12	33.33%	33.33%
Diabetes Mellitus	14	38.89%	38.89%
Prior Heart Failure	6	16.67%	16.67%
Diabetes Therapy	1	2.78%	2.78%
Currently on Dialysis	1	2.78%	2.78%
Chronic Lung Disease	7	19.44%	19.44%
Family History of Premature CAD	6	16.67%	16.67%
Prior MI	13	36.11%	36.11%
Prior CABG	4	11.11%	11.11%
Current/Recent Smoker (w/in 1 year)	7	19.44%	19.44%

Report Summary

Total Number of Procedures	36
Total Number of Risk Factors in all Procedures	132
Average Number of Risk Factors per Procedure	3.67

Procedures with Risk Factors

Total Number	36
Percentage of all Procedures	100.00%
Average Number of Risk Factors	3.67

Risk Factor Rate by Operator

ACC - CathPCI - Risk Factor Rate By Operator					
Participant ID : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center					
Start Date : 01/01/1900					
End Date : 01/01/3000					
Operator : [All]					
Diagnostic Cath Only Procedures					
Diagnostic Operator	Risk Factor	Risk Factor Count	Procedure Count	Risk Factor Rate	
		0			
PCI Only Procedures					
PCI Operator	Risk Factor	Risk Factor Count	Procedure Count	Risk Factor Rate	
Physician A	Hypertension	1	1	100.00%	
	Dyslipidemia	1	1	100.00%	
Physician B	Hypertension	1	1	100.00%	
	Dyslipidemia	1	1	100.00%	
	Diabetes Mellitus	1	1	100.00%	
	Prior Heart Failure	1	1	100.00%	
PCI Total Risk Factors	Hypertension	2	2	100.00%	
	Dyslipidemia	2	2	100.00%	
	Diabetes Mellitus	1	2	50.00%	
	Prior Heart Failure	1	2	50.00%	
CathPCI Combination Procedures					
Diagnostic Operator	PCI Operator	Risk Factor	Risk Factor Count	Procedure Count	Risk Factor Rate
Physician A	Physician A	Hypertension	1	1	100.00%
		Dyslipidemia	1	1	100.00%
Physician B	Physician B	Hypertension	1	1	100.00%
		Dyslipidemia	1	1	100.00%
		Diabetes Mellitus	1	1	100.00%
		Prior CABG	1	1	100.00%
CathPCI Combination Total Risk Factors					
	Peripheral Arterial Disease	3	34	8.82%	
	Hypertension	27	34	79.41%	
	Dyslipidemia	27	34	79.41%	
	Prior PCI	12	34	35.29%	
	Diabetes Mellitus	13	34	38.24%	
	Prior Heart Failure	5	34	14.71%	
	Diabetes Therapy	1	34	2.94%	
	Currently on Dialysis	1	34	2.94%	
	Chronic Lung Disease	7	34	20.59%	
	Family History of Premature CAD	6	34	17.65%	
	Prior MI	13	34	38.24%	
	Prior CABG	4	34	11.76%	
	Current/Recent Smoker (win 1 year)	7	34	20.59%	

Mortality by Operator

ACC - CathPCI - Mortality by Operator				
Site Name : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center				
Start Date : 01/01/1900				
End Date : 01/01/3000				
Diagnostic Cath Only Procedures				
CATH OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE	
PCI Only Procedures				
PCI OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE	
	0	1	.00%	
	0	1	.00%	
CathPCI Combination Procedures				
CATH OPERATOR	PCI OPERATOR	MORTALITY COUNT	PROCEDURES	MORTALITY RATE
		1	2	50.00%
		0	3	.00%
		0	1	.00%
		0	4	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	1	.00%
		0	2	.00%

Summary	
Description	Total
MORTALITY COUNT	1
PROCEDURE COUNT	36
PATIENT COUNT	36
MORTALITY RATE	2.78%

Mortality by Procedure

ACC - CathPCI - Mortality by Procedure

Site Name : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center

Start Date : 01/01/1900

End Date : 01/01/3000

PROCEDURE TYPE	MORTALITY COUNT	PROCEDURE COUNT	PATIENT COUNT	MORTALITY RATE
Diagnostic Cath Procedures	0	0	0	No Patients for this time period
PCI Procedures	0	2	2	.00%
CathPCI Combination Procedures	1	34	34	2.94%
All Procedures	1	36	36	2.78%

Length of Stay by Operator

ACC - CathPCI - Length of Stay By Operator					
Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center					
Start Date : 01/01/1900					
End Date : 01/01/3000					
Operator NPI : [All]					
As Diagnostic Cath Operator (Diagnostic Cath Only Procedures)					
Diagnostic Operator Name	Interval	PreOp LOS	PostOp LOS	Total LOS	
As PCI Operator (PCI Only Procedures)					
PCI Operator Name	Interval	PreOp LOS	PostOp LOS	Total LOS	
Physician A	0 Days	1	0	0	
	1 Day	0	1	1	
Physician B	0 Days	0	0	0	
	3 Days	1	1	0	
	5-7 Days	0	0	1	
Total Cases		2	2	2	
Total Length of Stay		3	4	7	
Maximum Length of Stay		3	3	6	
Minimum Length of Stay		0	0	0	
Average Length of Stay		1.5	2	3.5	
As Diagnostic Cath/PCI Operator (CathPCI Combination Procedures)					
Diagnostic Cath Operator Name	PCI Operator Name	Interval	PreOp LOS	PostOp LOS	Total LOS

Length of Stay Summary

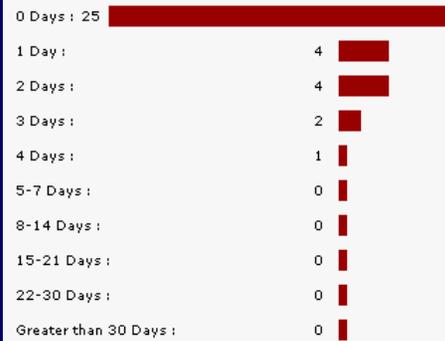
ACC - CathPCI - Length of Stay Summary

Organization : PCI-Clovis Community Hospital,PCI-Doctors Medical Center,PCI-Kaiser Foundation Hospital Walnut Creek,PCI-Los Alamitos Medical Center,PCI-St. Rose Hospital,PCI-Sutter Roseville Medical Center

Start Date : 01/01/1900

End Date : 01/01/3000

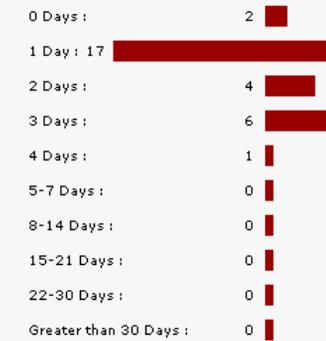
By Preop



By IntraOp



By Postop



INTERVAL	PREOP LOS	POSTOP LOS	TOTAL LOS
0 Days	25	2	2
1 Day	4	17	12
2 Days	4	4	5
3 Days	2	6	7
4 Days	1	1	2
5-7 Days	0	0	2
8-14 Days	0	0	0
15-21 Days	0	0	0
22-30 Days	0	0	0
Greater than 30 Days	0	0	0

LENGTH OF STAY SUMMARY	PREOP	POSTOP	TOTAL OP
Total Cases	36	36	36
Length of Stay Summary	22		
Maximum Length of Stay	4	4	6
Minimum Length of Stay	0	0	0
Average Length of Stay	.611		

Study Protocols: Patient Selection

High Patient Risk

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 cerebrovascular 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

Study Protocols: Patient Selection

High Lesion Risk

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 judgment, impede stent deployment

Patient Selection: Inclusion Criteria

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 cerebrovascular 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

OR

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 judgment, impede stent deployment

BUT NOT BOTH

Patient Selection: Inclusion Criteria

A high risk patient with a high risk lesion shall NOT be included in the study.

A high risk patient with a not high risk lesion may be included in the pilot-program upon confirmation that a cardiac surgeon and OR are immediately available if necessary.

A not high risk patient with a high risk lesion may be included in the pilot-program.

A not high risk patient with a not high risk lesion may be included in the pilot-program

A patient with either two criteria for “High Risk Patient” OR two criteria for “High Risk Lesion” can be enrolled in the study. However, the operator MAY decide NOT to perform any PCI at the Off-site hospital.

Expectations of Pilot-Hospitals

- Follow the inclusion and exclusion criteria for patient enrollment
- Enroll at least 200 patients by year 2 (36 primary PCIs)
- Facilitate audit nurse access to medical records and angiographic recordings

Timeline Update

- First AOC meeting 7/29/2010
- Local IRB approval of consent forms
 - 5 hospitals completed
 - 1 hospital submitted
- Central IRB approval of data collection and storage completed
- Official Pilot Start Date 8/1/2010
- Production Software online 8/2/2010
- Coder Testing Completion 8/10/2010
- Operator Testing Completion: 5 hospitals
- Transfer Protocols Receipt: 2 hospitals

New Business Proposals

- Quarterly report formats
- Costs Tracking
- Data entry checking for completeness only
- NCDR definition of emergent / urgent / elective procedures

<i>Selection Text</i>	<i>Definition</i>
Elective	The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge.
Urgent	The procedure is being performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation.
Emergency	The procedure is being performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on call team were this to occur during off-hours.
Salvage	The procedure is a last resort. The patient is in cardiogenic shock at the start of the procedure. Within the last ten minutes prior to the start of the procedure the patient has also received chest compressions for a total of at least sixty seconds or has been on unanticipated extracorporeal circulatory support (e.g. extracorporeal membrane oxygenation, cardiopulmonary support)