

PCI-CAMPOS Advisory Oversight Committee

January 17th, 2013

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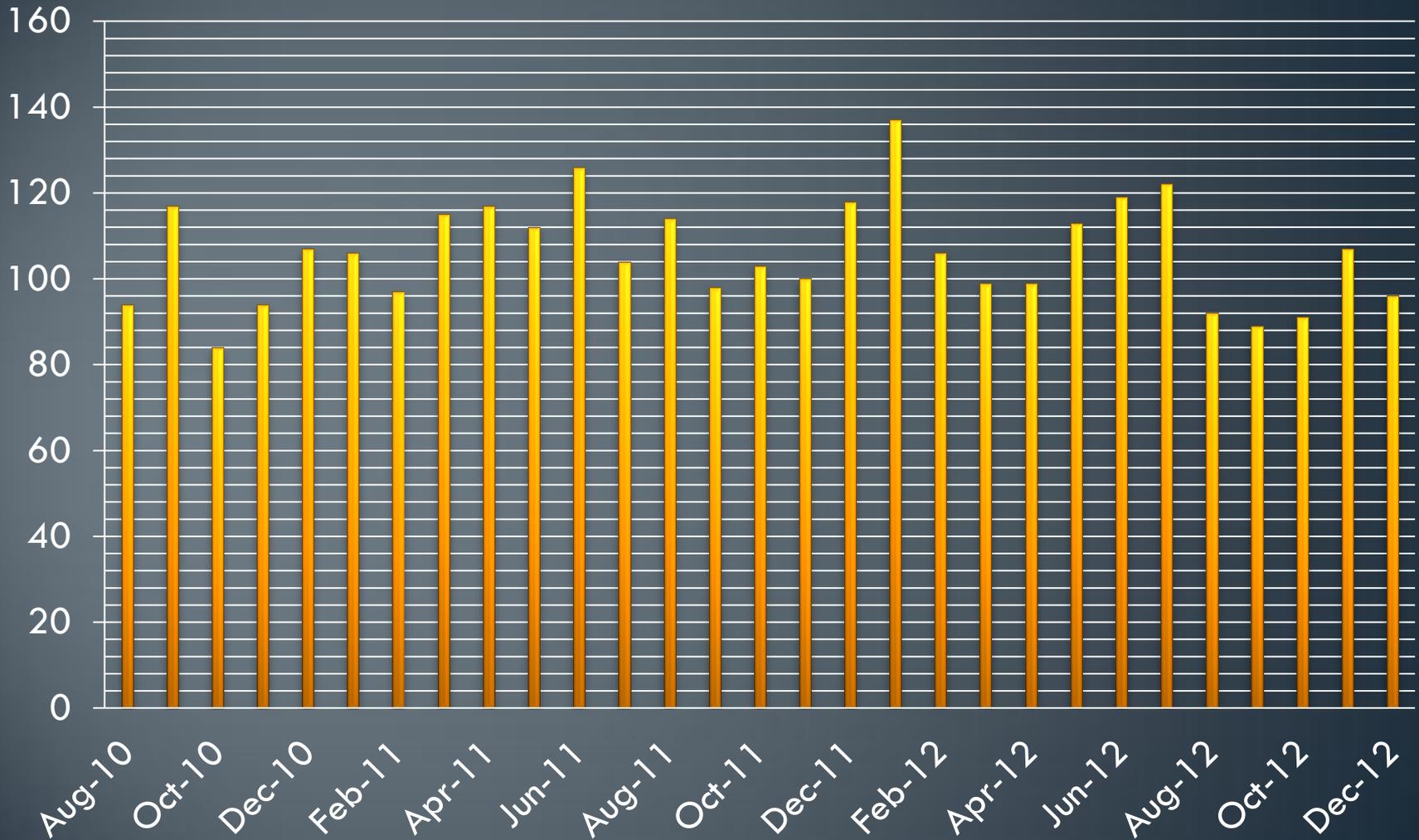
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Total Enrollment

PCI CAMPOS	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	436	401	144	981
NSTEMI	322	365	132	819
Unstable Angina	269	326	132	727
Stable Angina	199	174	54	427
No symptoms, No Angina	46	53	12	111
Symptoms Unlikely to be Ischemic	1	9	1	11
Total	1273	1328	475	3076

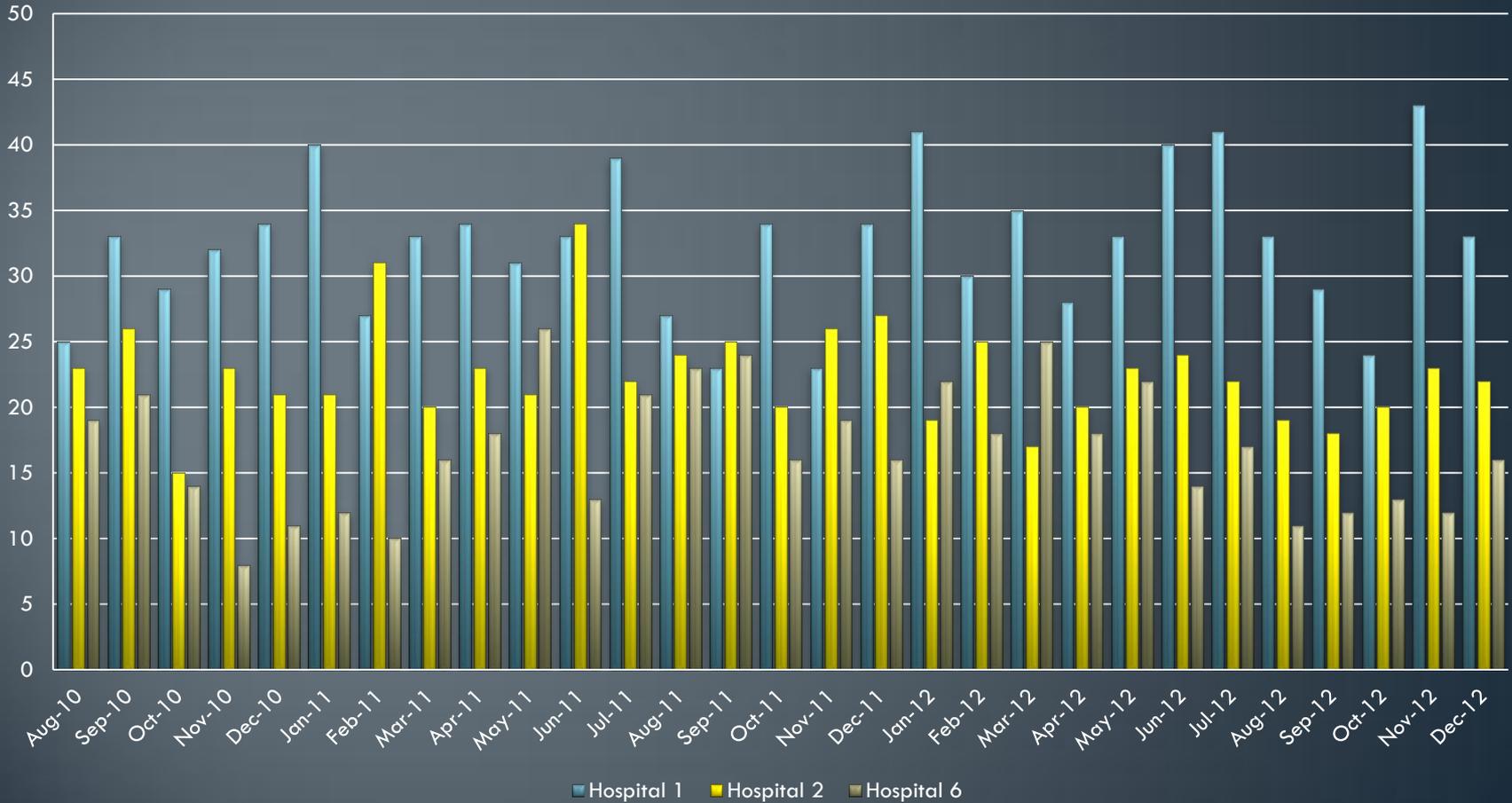
Total Enrollment Per Month

(*08/01/2012-12/31/2012 preliminary)



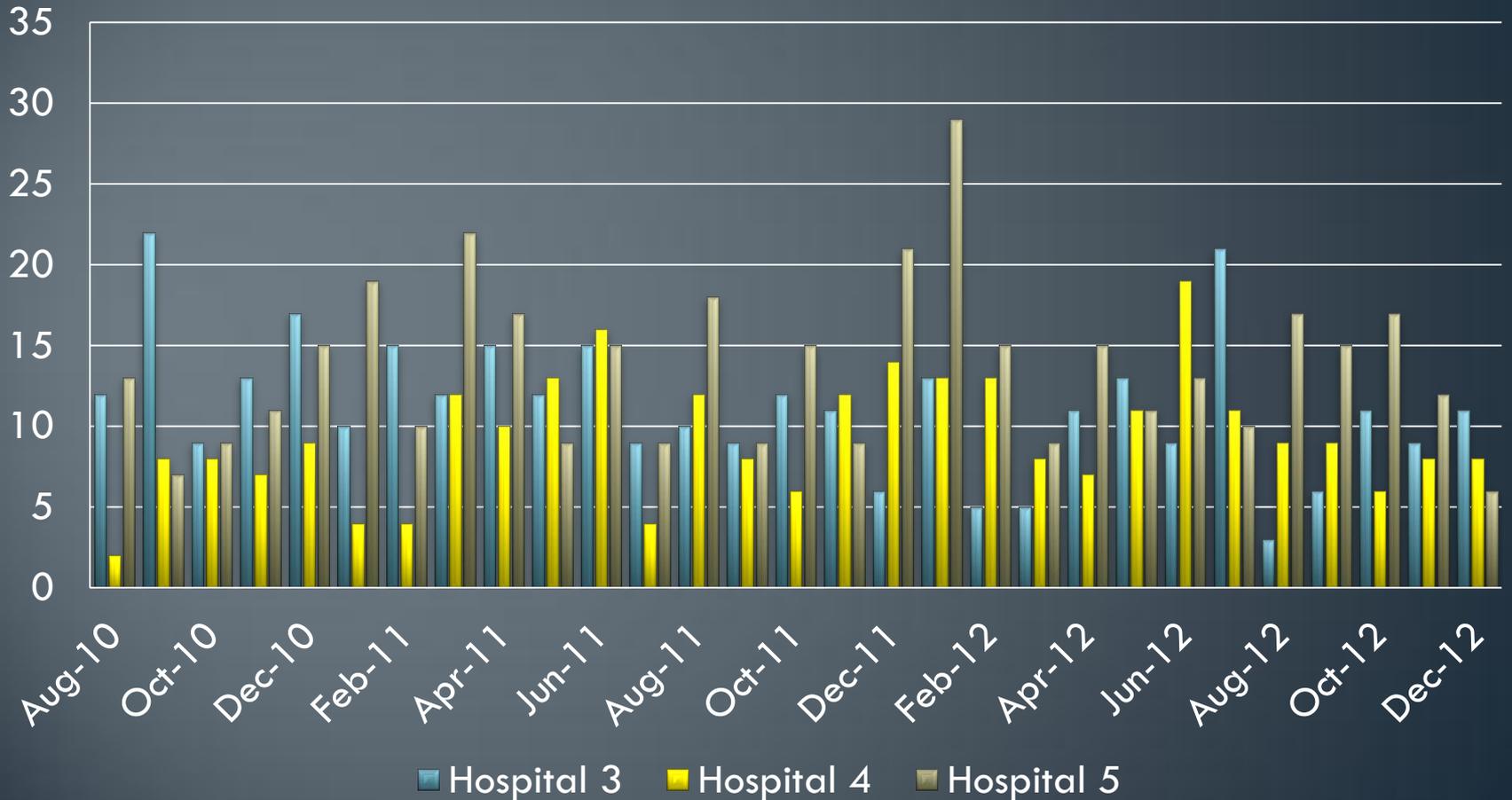
Monthly Enrollment: Hospitals 1, 2 & 6

(*08/01/2012-12/31/2012 preliminary)



Monthly Enrollment: Hospitals 3, 4 & 5

(*08/01/2012-12/31/2012 preliminary)



STEMI Enrollment Year 1, 2 & 3*

Site	Year 1		Year 2		Year 3 (*preliminary)	
	Total PCIs 08/01/2010- 07/31/2011	STEMI's 08/01/2010- 07/31/2011	Total PCIs 08/01/2011- 07/31/2012	STEMI's 08/01/2011- 07/31/2012	Total PCIs 08/01/2012- 12/31/2012	STEMI's 08/01/2012- 12/31/2012
Pilot-Hospital 1	390	73	389	56	162	29
Pilot-Hospital 2	280	108	272	86	102	37
Pilot Hospital 3	161	69	125	62	40	12
Pilot-Hospital 4	97	22	134	29	40	12
Pilot Hospital 5	156	49	174	54	67	17
Pilot-Hospital 6	189	115	234	114	64	37

Hospital 1 Enrollment

Hospital 1	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	73	56	29	158
NSTEMI	106	97	49	252
Unstable Angina	91	117	46	254
Stable Angina	97	91	33	221
No Sxs, No Angina	23	25	5	53
Sxs Unlikely to be Ischemic	0	3	0	3
Total Procedures	390	389	162	941

Hospital 2 Enrollment

Hospital 2	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	108	86	37	231
NSTEMI	61	97	26	184
Unstable Angina	72	73	29	174
Stable Angina	28	11	7	46
No Sxs, No Angina	11	5	3	19
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	280	272	102	654

Hospital 3 Enrollment

Hospital 3	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	69	62	12	143
NSTEMI	40	25	10	75
Unstable Angina	37	24	15	76
Stable Angina	12	10	1	23
No Sxs, No Angina	3	4	1	8
Sxs Unlikely to be Ischemic	0	0	1	1
Total Procedures	161	125	40	326

Hospital 4 Enrollment

Hospital 4	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	22	29	12	63
NSTEMI	32	47	15	94
Unstable Angina	19	33	11	63
Stable Angina	19	10	1	30
No Sxs, No Angina	4	9	1	14
Sxs Unlikely to be Ischemic	1	6	0	7
Total Procedures	97	134	40	271

Hospital 5 Enrollment

Hospital 5	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Totals
STEMI	49	54	17	120
NSTEMI	47	49	20	116
Unstable Angina	25	46	21	92
Stable Angina	30	16	7	53
No Sxs, No Angina	5	9	2	16
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	156	174	67	397

Hospital 6 Enrollment

Hospital 6	Year 1 08/01/2010- 07/31/2011	Year 2 08/01/2011- 07/31/2012	Year 3 (*preliminary) 08/01/2012- 12/31/2012	Total
STEMI	115	114	37	266
NSTEMI	36	50	12	98
Unstable Angina	25	33	10	68
Stable Angina	13	36	5	54
No Sxs, No Angina	0	1	0	1
Sxs Unlikely to be Ischemic	0	0	0	0
Total Procedures	189	234	64	487

Website Update

- Log in – log out issue: must click “log out” button not the “x” .
- Data complete and locked down for all patients
 - 08/01/2010-07/31/2012
- No down time since last AOC

PCI

Website Data Entry

Central Audit 100%

Pilot-site audit 20%

Random 10% of all cases, all complications, all deaths

Initial Data Audit

Query/Review #1

Query/Review #2

Final Data Audit

Final Query

Data Lock-down

Data Analysis

In-hospital Audit

In-hospital Audit Report

Query

DVD

Angio Audit

Angio Query/Review

Consensus/Committee

Statistical Analysis

Initial Central Audit*

(08/01/2010-12/31/2012**)

Pilot Site	Procedures Audited
Hospital 1	929
Hospital 2	645
Hospital 3	322
Hospital 4	271
Hospital 5	396
Hospital 6	487
Total	3050

- Completeness check
- Internal consistency (arrival date/procedure date, CHF, troponin/MI, PCI-status, CABG/graft, CTO/STEMI, appropriate meds)
- NCDR® definitions compliance

*Audits performed on database entries

**Includes preliminary data

Pilot-site Audits*

(08/01/2010-12/31/2012**)

Pilot Site	Procedures Audited
Hospital 1	171
Hospital 2	152
Hospital 3	67
Hospital 4	63
Hospital 5	85
Hospital 6	145
Total	683

*Audits performed in-hospital plus angio film review

**Includes preliminary data

Angiographic Audit: Diagnostic

- IABP or other mechanical ventricular support
- Diagnostic cath (and/or left heart cath) done
- Diagnostic cath status (elective, urgent, emergent, salvage)
- Coronary anatomy: % stenosis in ≥ 2 mm vessels and grafts
 - LM
 - Prox. LAD
 - Mid/Distal LAD, diag. branches
 - CIRC, OMs, LPDA, LPL branches
 - RCA, RPDA, RPL, AM branches
 - Ramus

Angiographic Audit: PCI

- Segment number of PCI coronary artery
- Culprit Lesion,
- Stenosis immediately prior to RX
 - If 100%: CTO
 - If 40-70%: IVUS
 - If 40-70%: FFR
 - If Yes: Ratio
- Pre-procedure TIMI Flow
- Prev. treated lesion
- Lesion in graft
- Lesion complexity
- Lesion length
- Thrombus present

Lesion Complexity

Non-High/Non-C Lesion	<p>Non-high/non-C lesions are considered Type A or B lesions. They can be characterized as follows:</p> <p>Low Risk or Type A lesions: Discrete (<10 mm length) Concentric Readily accessible Non-angulated segment <45 degrees Smooth contour Little or no calcification Less than totally occlusive Not ostial in location No major branch involvement Absence of thrombus</p> <p>Medium Risk (Type B1) lesions: Tubular (10-20 mm length) Eccentric Moderate tortuosity of proximal segment Moderately angulated segment, 45-90 degrees Irregular contour Moderate to heavy calcification Ostial in location Bifurcation lesions requiring double guidewires Some thrombus present Total occlusion <3 months old</p> <p>Medium Risk (Type B2 lesions): Two or more "B" characteristics.</p>
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High/C Lesion	<p>Descriptions of a High Lesion Risk (C Lesion): Diffuse (length > 2cm) Excessive tortuosity of proximal segment Extremely angulated segments > 90 degrees Total occlusions > 3 months old and/or bridging collaterals Inability to protect major side branches Degenerated vein grafts with friable lesions</p>
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*NCDR® CathPCI Registry® v4.4 Coder's Data Dictionary, © 2008, American College of Cardiology Foundation

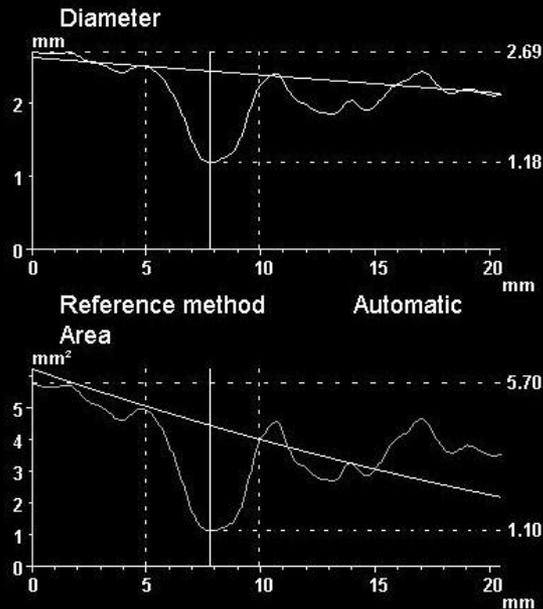
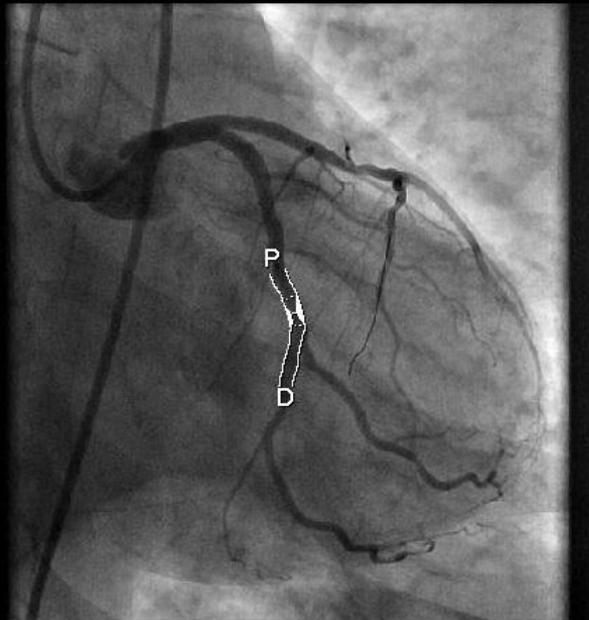
Angiographic Audit: PCI

- Bifurcation lesion
- Guidewire across lesion
- Stenosis post-procedure
- Post-procedure TIMI flow
- Device deployed
- Intracoronary devices used
- PCI complication: Significant dissection or perforation
- LVEF (if documented)

- Quantitative Coronary Analysis (QCA-Xcelera R3.1L1, 3.1.1.422-2009)

Angiographic Audit: QCA

Automatic Reference Obstruction Analysis



Stenosis	(%)
%Diameter	52
%Area(circ)	77

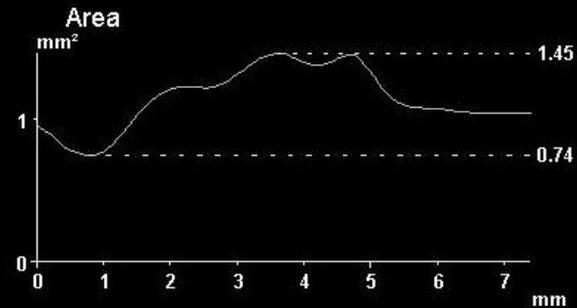
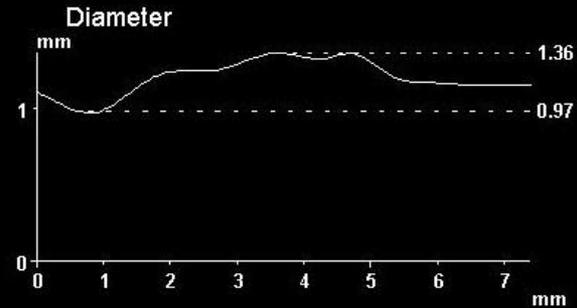
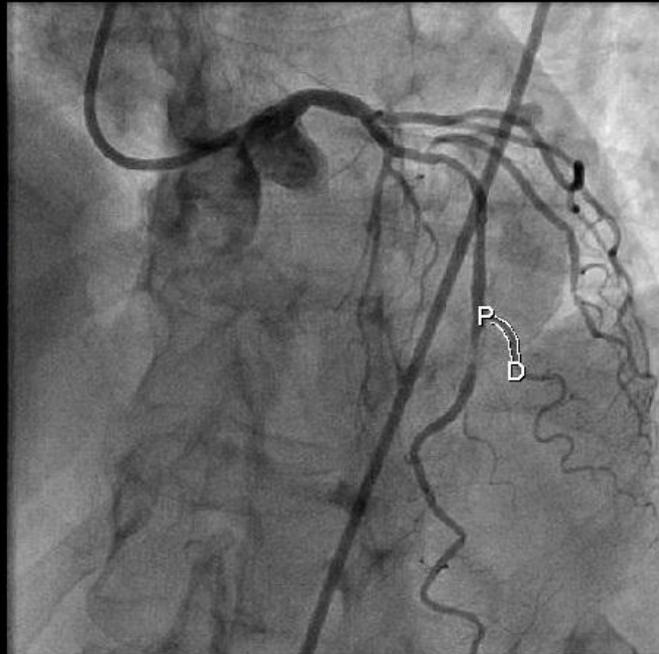
Obstruction Segment

	Diameter (mm)	Area(circ) (mm²)
Lesion	1.18	1.10
Ref	2.45	4.70
Mean	1.74	2.55
Res. prox.	4.96 mm	
Obstruction Length	4.96 mm	
Plaque A	3.31 mm	
Plaque Symmetry	0.61	

Series - Frame 1 / 1
 Rot / Ang -6.95 ; -26.09 °
 Segment Name
 Study
 Intervention
 Cal factor 0.2043 mm/pix
 Cal object 6.00 French Catheter

Angiographic Audit: QCA

Total Analyzed Segment



	Diameter (mm)	Area(circ) (mm ²)
Min	0.97	0.74
Max	1.36	1.45
Mean	1.20	1.14
Sdev	0.11	0.21

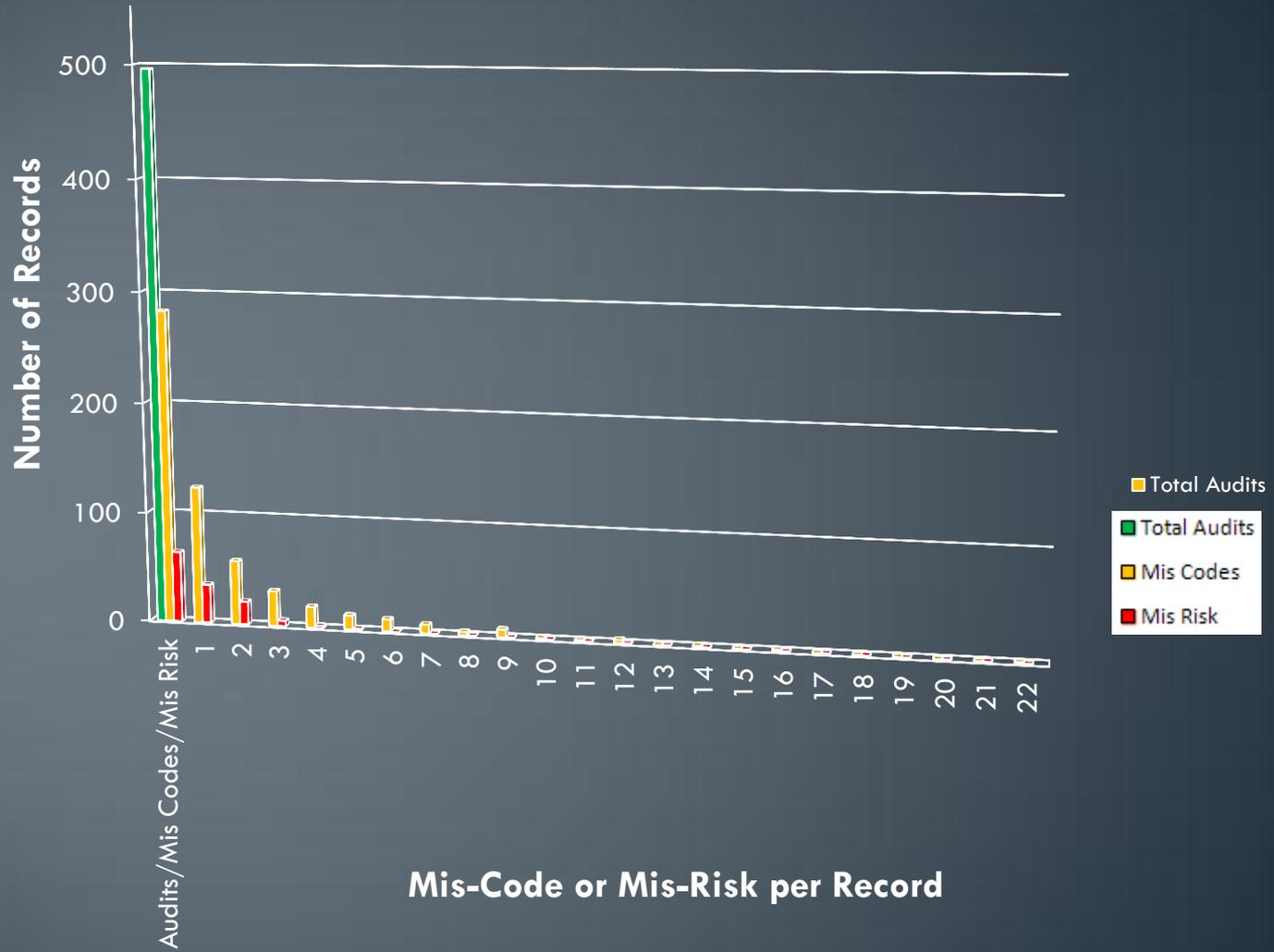
Series - Frame 1 / 1
 Rot / Ang 24.80 ; 28.43 °
 Segment Name
 Study
 Intervention
 Cal factor 0.1904 mm/pix
 Cal object 6.00 French Catheter

Segment length 7.39 mm
 Contour corrected 0.00 % left
 0.00 % right
 0.00 % total

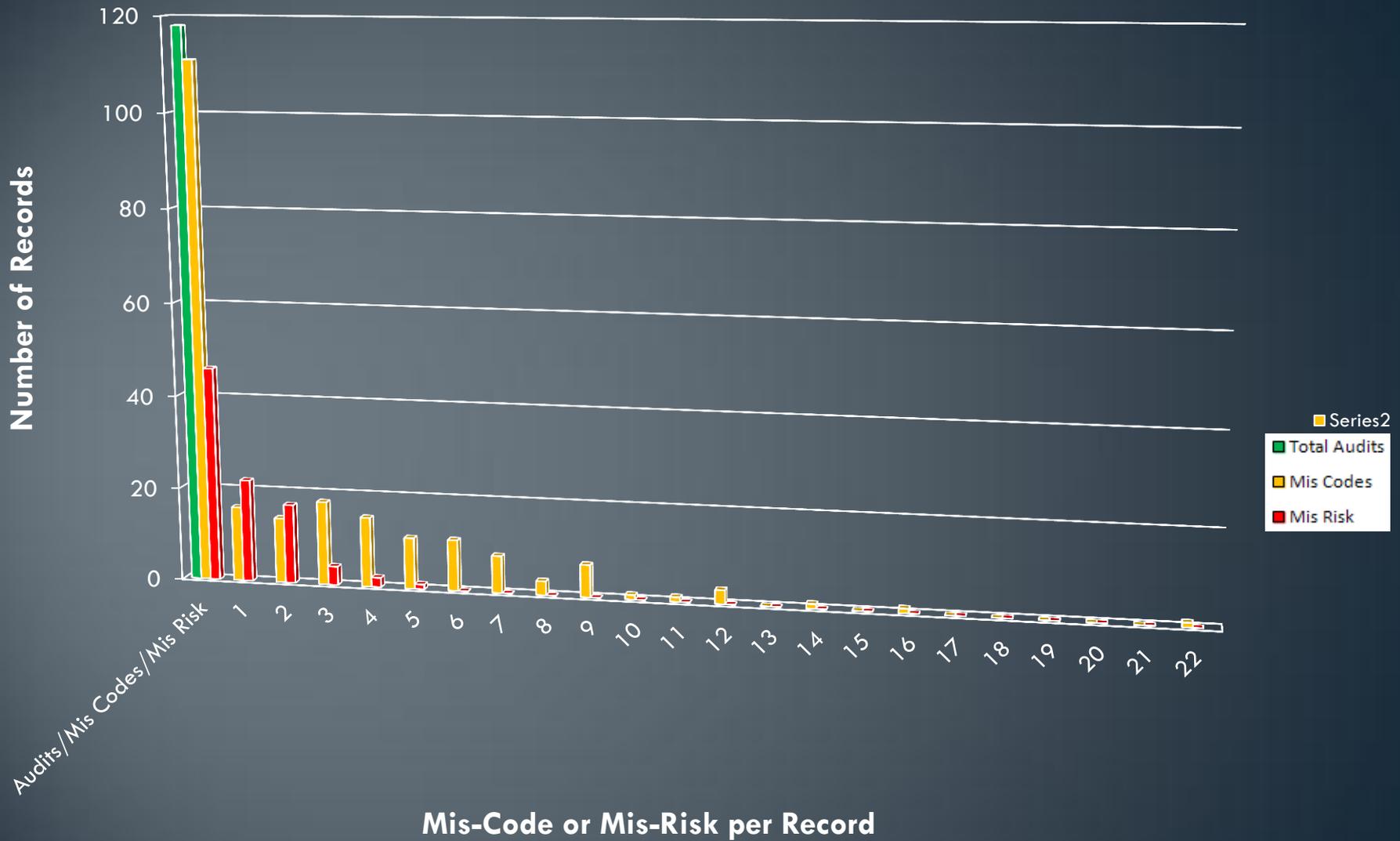
Central versus Pilot-site monitoring

- Objective: To compare **Central** versus **Pilot-site** monitoring of PCI CAMPOS registry data.
- Methods: 500/1800 PCI procedures were reviewed by both **Central** (registry field review) and **Pilot-site** (hospital, imaging, and intervention angio recording) audits. The registry contained 240 PCI fields (NCDR[®] : CathPCI Registry[®] v4.3+).
- The audit affected changes in data fields were recorded as **mis-codes**. The audit changes that altered the earlier multivariate risk adjustment model were recorded as **mis-risks**.

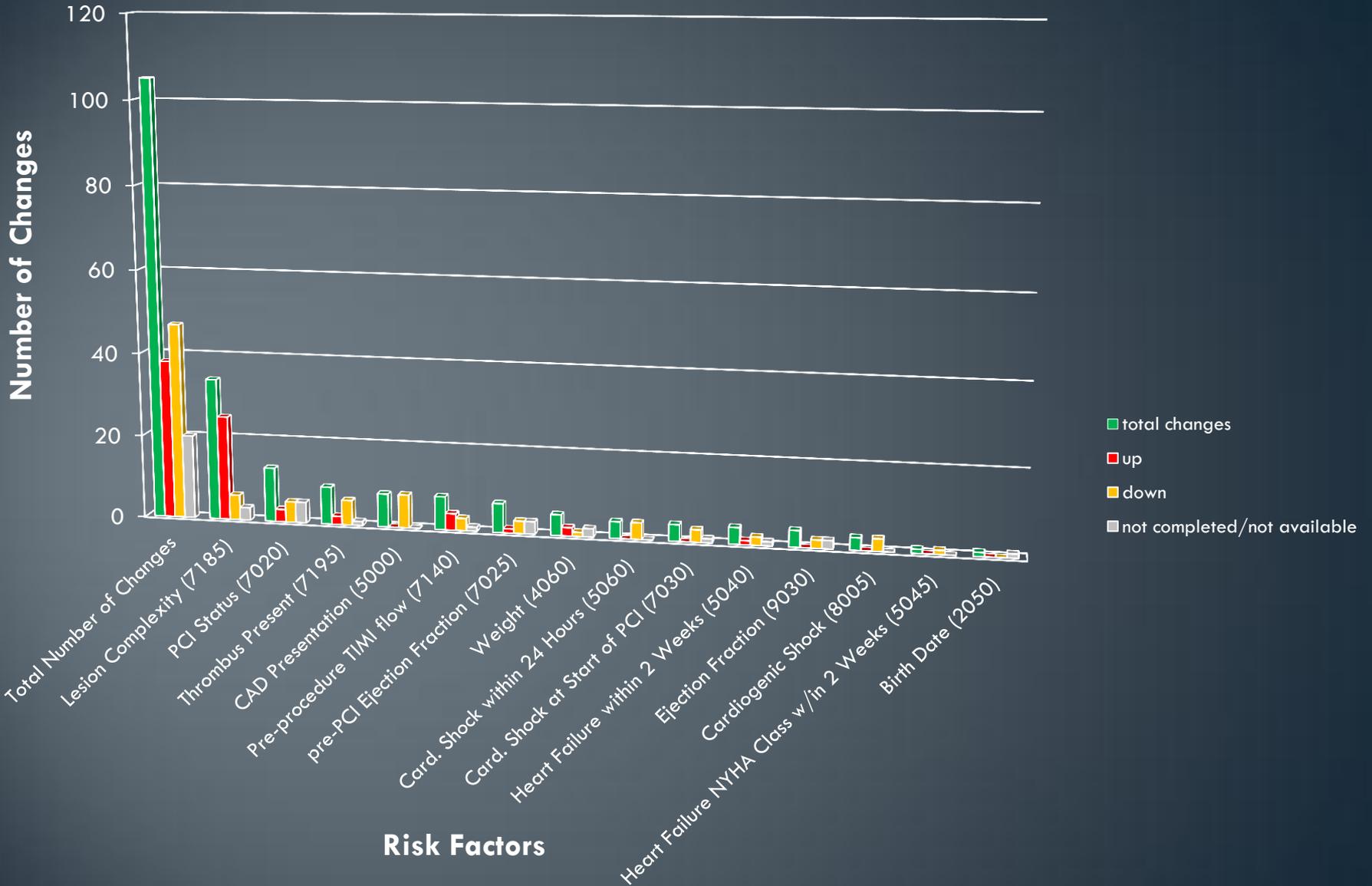
Total Audits



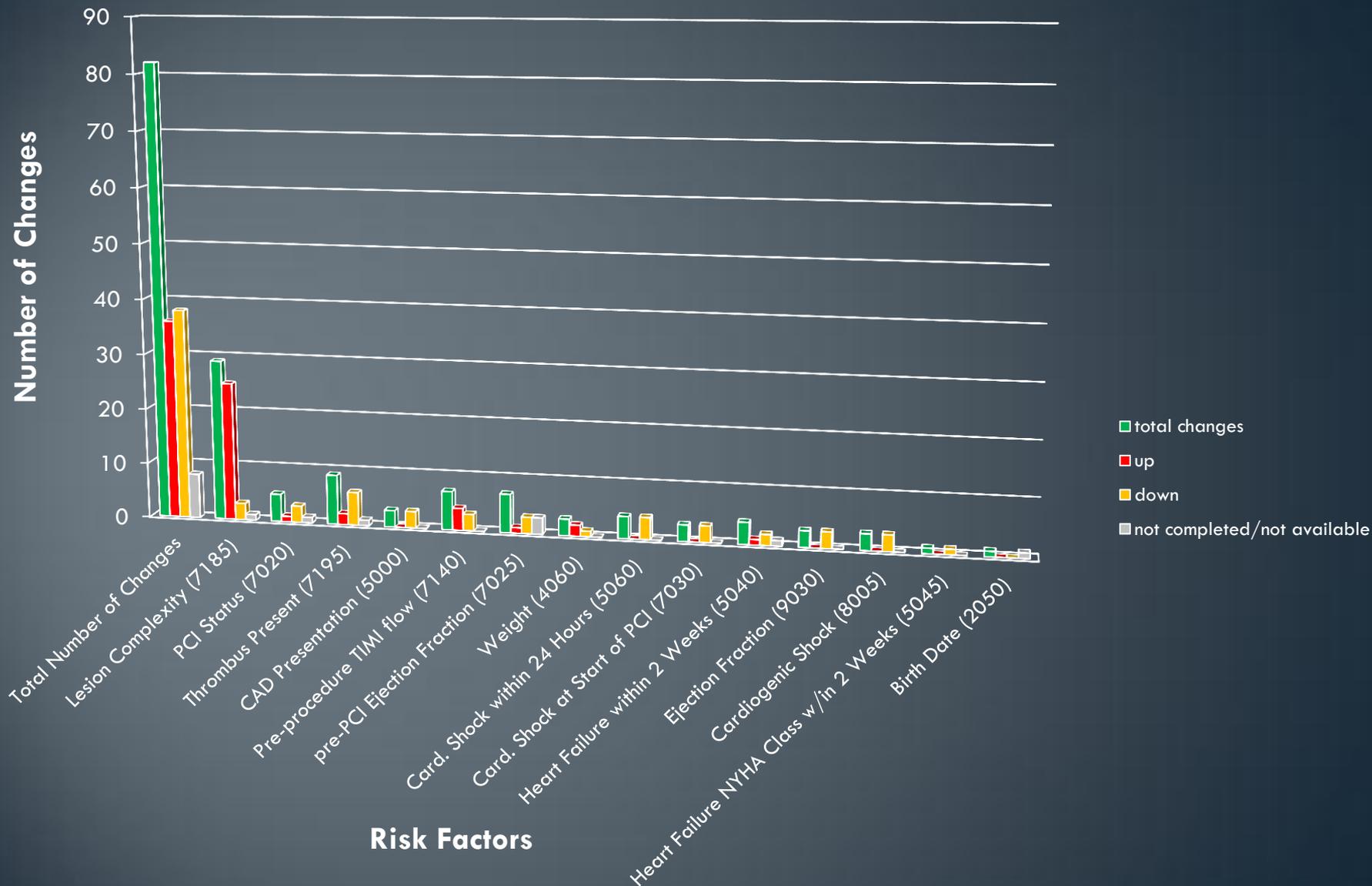
Pilot-site Audits



Total Audits- Mis-risk



Pilot-site Audits - Mis-Risk



Audit: Mis-code and Mis-risk

		Central Rate	Pilot-site Rate
PCI	Mis-codes/pt	0.7	4.5
PCI	Mis-risk/pt	0.05	0.7

Central versus Pilot-site monitoring Conclusions:

- **Pilot-site** Monitoring detects more PCI **mis-codes(OR 6.4)** and **mis-risks(OR 14)** compared to **Central** Monitoring of Registry Data for PCI.
- The up versus down rates for PCI **Mis-codes** and **Mis-risks** are similar.
- **Pilot-site** auditing of data entry, medical records, and imaging improves coding and the accuracy of risk adjusted outcomes for these cardiac interventions.

Protocol Violations/Issues

- 3 cases in which IRB vulnerable population patients were enrolled in the study.
 - Pilot site and CDPH notified
 - Pilot site will review cases with local IRB

Compassionate Use Criteria

- Coma on presentation
- Use of ventricular assist device prior to PCI
- CPR at start of procedure
- Entered for procedures that were performed as of 07/01/2011-present

Compassionate Use

File Edit View Favorites Tools Help

Patient Form

Current Page: Patient Form

velos

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: 654321 Age: 90 years Gender: Pat.Name: test formtwo Org: PCI-Training

NO

Did the patient meet compassionate use criteria? Yes No

Was the patient in a coma (Glasgow <7) on presentation? Yes No

Was cardiopulmonary bypass (CPB), extracorporeal membrane oxygenation (ECMO), or percutaneous ventricular assist device (PVAD) begun before PCI? Yes No

Was patient receiving CPR at the start of PCI? Yes No

Current User: Melanie Aryana

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

Form Status* Work In Progress e-Signature * Submit

Form Version Number: 5

Compassionate Use Criteria

07/01/2011-12/31/2012*

	Total entered	CU section Completed	Pt met CU criteria	Coma	CPB/ECMO/PV AD	CPR
Site 1	590	589	1	1	0	1
Site 2	397	397	7	6	1	4
Site 3	172	172	2	1	0	0
Site 4	178	178	1	1	0	0
Site 5	250	246	5	5	0	1
Site 6	320	319	5	5	0	2
	1907	1901	21	19	1	8

*Includes preliminary data

Compassionate use (07/01/2011-12/31/2012*)

Massachusetts**

PCI-CAMPOS***

	Total	CU	Total	CU
Procedure success	94.2%	79.2%	86.7%	47.6%
Mortality	4.5%	69.8%	4.8%	61.9%

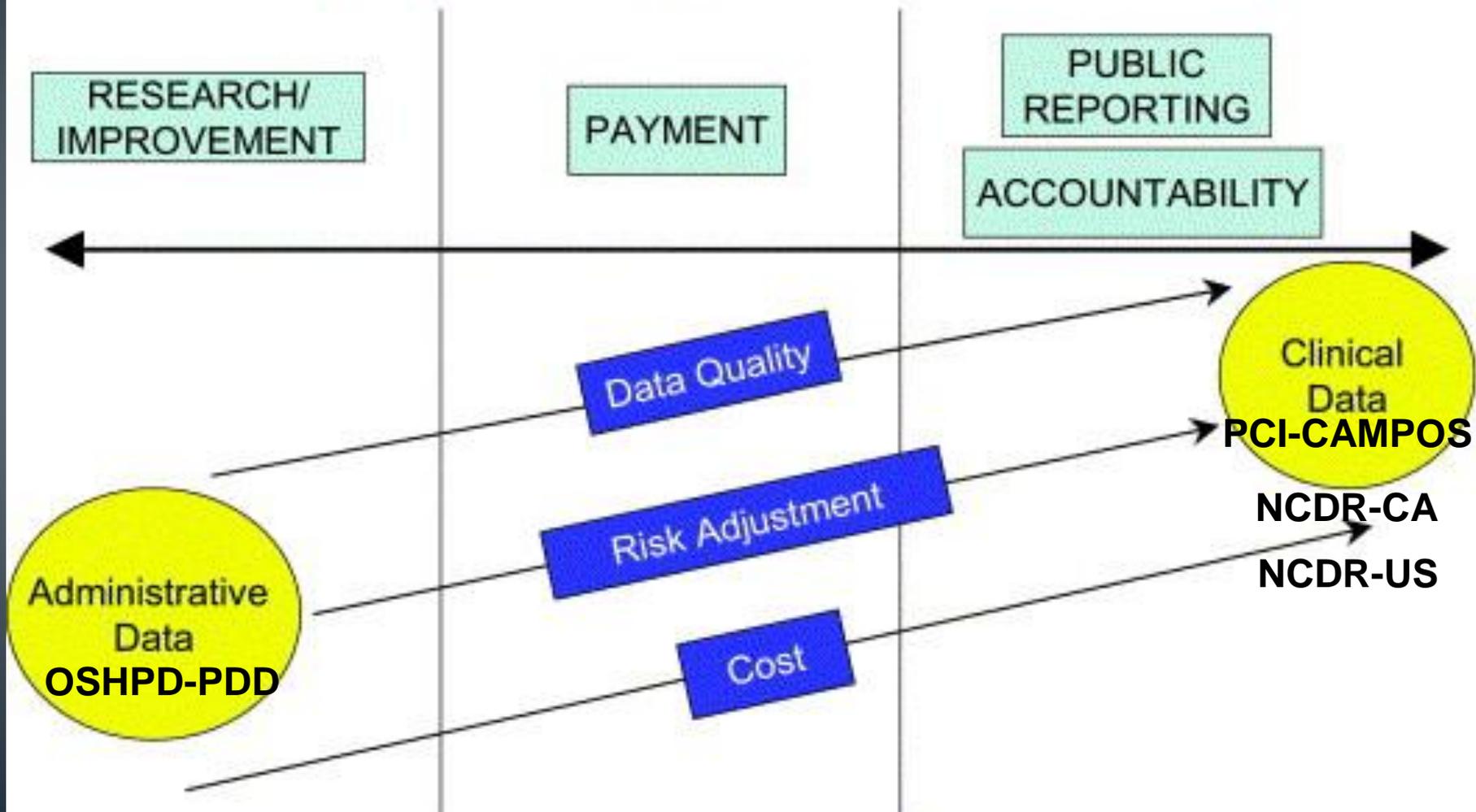
*Includes preliminary data

**Resnic et al., J Am Coll Cardiol 2011; 57(8), 904-11 (STEMI or shock)

***PCI CAMPOS (Total= STEMI, CU= Coma, LV assist, CPR)

What is the purpose of quality measurement?

The stakes get higher as the purpose moves towards accountability



California PCI Study Population

- **122 California Hospitals**
- **NCDR[®]-CA: 24 months (07/01/2010-06/30/2012)**
 - **Hospitals: 116**
 - **Operators: Unknown**
 - **Completed PCI: 99,332**
 - **STEMI: 17,577 (17.7%)**
- **PCI-CAMPOS: 24 months (08/01/2010-07/31/2012)**
 - **Hospitals: 6**
 - **Operators: 47**
 - **Completed PCI: 2,601**
 - **STEMI: 837 (32.2%)**

Comparisons in Case Profile:

NCDR[®]-CA < CAMPOS

Risk Factor	NCDR [®] -CA (N=99,332)	CAMPOS (N=2,601)	p-value
STEMI	17.7%	32.2%	<.0001
Caucasian	68.3%	72.4%	<.0001
Emergent PCI	19.7%	35.4%	<.0001
Recent smoker	19.6%	22.1%	0.002
Dyslipidemia	78.5%	83.5%	<.0001
Family CAD history	17.4%	19.0%	0.037
NYHA IV	3.7%	5.0%	0.001
Heart failure	12.8%	23.3%	<.0001
Chronic lung disease	11.7%	13.8%	0.001
Cardiogenic shock	3.0%	3.7%	0.022
Thrombosis	17.3%	31.4%	<0.0001
TIMI-0	21.1%	28.9%	<0.0001
RCA/RPDA/RPL/AM stenosis, Mean (SD)	58.0% (40.3%)	60.0% (39.5%)	0.016

Comparisons in Case Profile:

NCDR[®]-CA > CAMPOS

Risk Factor	NCDR [®] -CA (N=99,332)	CAMPOS (N=2,601)	p-value
Hypertension	81.3%	78.5%	0.001
Diabetes	38.1%	32.9%	<.0001
Prior MI	28.0%	26.2%	0.047
Prior valve surgery	1.6%	1.0%	0.009
Prior PCI	36.8%	28.7%	<.0001
Prior CABG	16.5%	12.0%	<0.0001
Dialysis	3.9%	2.0%	<0.0001
GFR stage 3-5	27.5%	25.2%	0.010
Left Main stenosis>75%	3.5%	2.6%	0.009
Ejection fraction<40%	8.6%	5.7%	<0.0001
High/C lesion	55.9%	34.1%	<0.0001

Comparisons in Case Profile: NCDR[®]-CA vs. CAMPOS

Risk Factor	NCDR [®] -CA (N=99,332)	CAMPOS (N=2,601)	p-value
Age>70	37.9%	37.3%	0.567
Female	30.3%	30.5%	0.793
BMI, Mean (SD)	29.1 (7.7)	29.3 (6.8)	0.232
CVD	11.3%	11.0%	0.570
Peripheral arterial disease	11.3%	10.3%	0.142
ProxLAD stenosis, Mean (SD)	36.9% (39.8%)	36.1% (38.2%)	0.311
IABP	3.3%	3.8%	0.134

*No significant difference between NCDR[®]-CA & CAMPOS

Observed Outcome Statistics

- **Composite Outcome : In-hospital death or emergent CABG**
 - **NCDR[®]-CA: 1,989 (2.00%)**
 - **CAMPOS: 65 (2.50%)**
 - **P-value: 0.075**

- **In-hospital mortality:**
 - **NCDR[®]-CA: 1,734 (1.75%)**
 - **CAMPOS: 56 (2.15%)**
 - **P-value: 0.118**

- **Emergent CABG:**
 - **NCDR[®]-CA: 289 (0.29%)**
 - **CAMPOS: 9 (0.35%)**
 - **P-value: <0.0001**

Comparisons in Other Observed Outcomes: NCDR[®]-CA vs. CAMPOS

Risk Factor	NCDR [®] -CA (N=99,332)	CAMPOS (N=2,601)	p-value
MI biomarkers	2.66%	3.38%	0.0234
Cardiogenic shock	1.25%	3.31%	<0.0001
Heart failure	1.02%	1.92%	<0.0001
CVD/Stroke	0.26%	0.27%	0.918
Hemorrhagic stroke	0.04%	0.04%	0.9251
Tamponade	0.13%	0.08%	0.4848
New required dialysis	0.38%	0.50%	0.3456
Other vascular complications	0.40%	0.27%	0.2894
RBC/Whole blood transfusion	3.27%	3.69%	0.2364
Bleeding within 72 hrs	1.51%	4.42%	<0.0001
Bleeding at access site	0.38%	0.46%	0.4983
Hematoma at access site	0.62%	1.31%	<0.0001
Hematoma Size>5cm	0.27%	0.50%	0.0002
Retroperitoneal bleeding	0.19%	0.08%	0.1954
GI bleeding	0.29%	0.50%	0.0471
GU bleeding	0.07%	0.19%	0.0164
Other (suspected) bleeding	0.29%	2.42%	<0.0001

Risk adjustment:

07/01/2010-07/31/2012

- Number of cases used: **101,933**
- Observed composite events: **2,054 (2.02%)**
- Risk factors:
 - Demographics
 - Prior PCI clinical conditions
 - Prior PCI lesion risk
- Bivariate analysis
- Multivariable logistic regression models
 - Parsimonious model
 - Refined model

Results of Bivariate Analysis

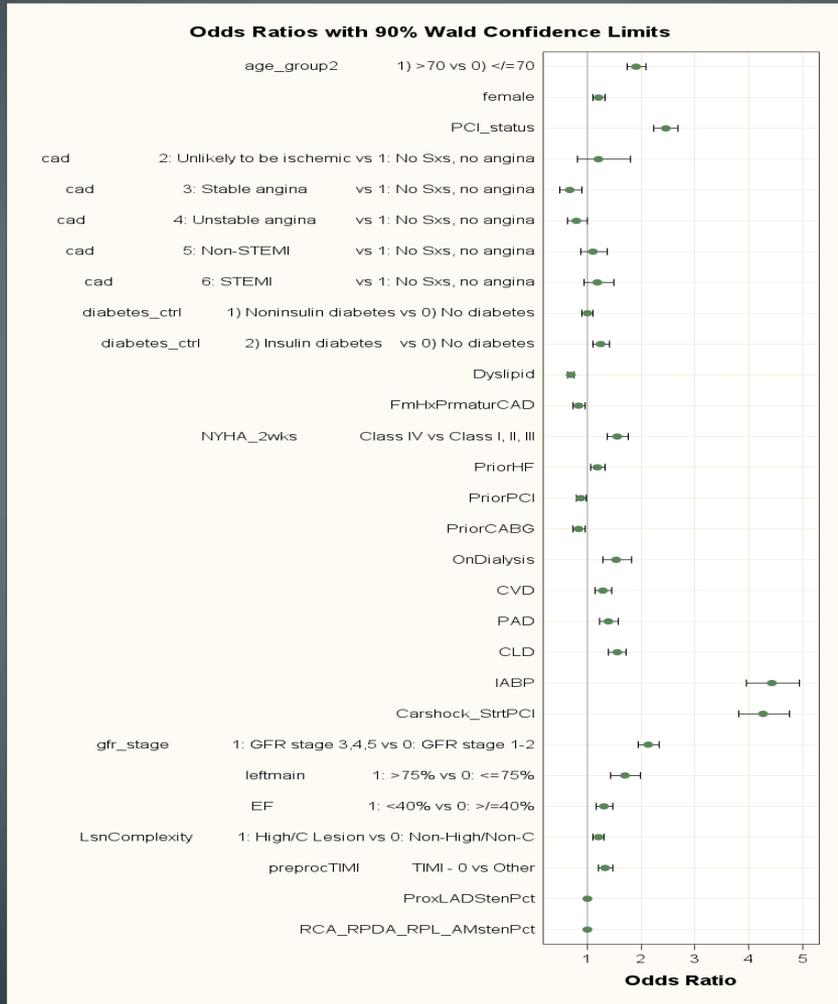
Significant variables (p<0.05): n=22	
Age	IABP
female	Cardiogenic shock
BMI<18.5	GFR stage
PCI status	Left main stenosis
CAD	Ejection fraction
Insulin Diabetes	Lesion complexity
NYHA IV	Thrombosis
Prior HF	PrePCI TIMI
Dialysis	ProxLAD stenosis
CVD	RCA/RPDA/RPL/AM stenosis
PAD	
CLD	

Results of Bivariate Analysis

Insignificant variables ($p < 0.05$): n=4
Race
Recent smoker
Prior valve surgery
Pilot status

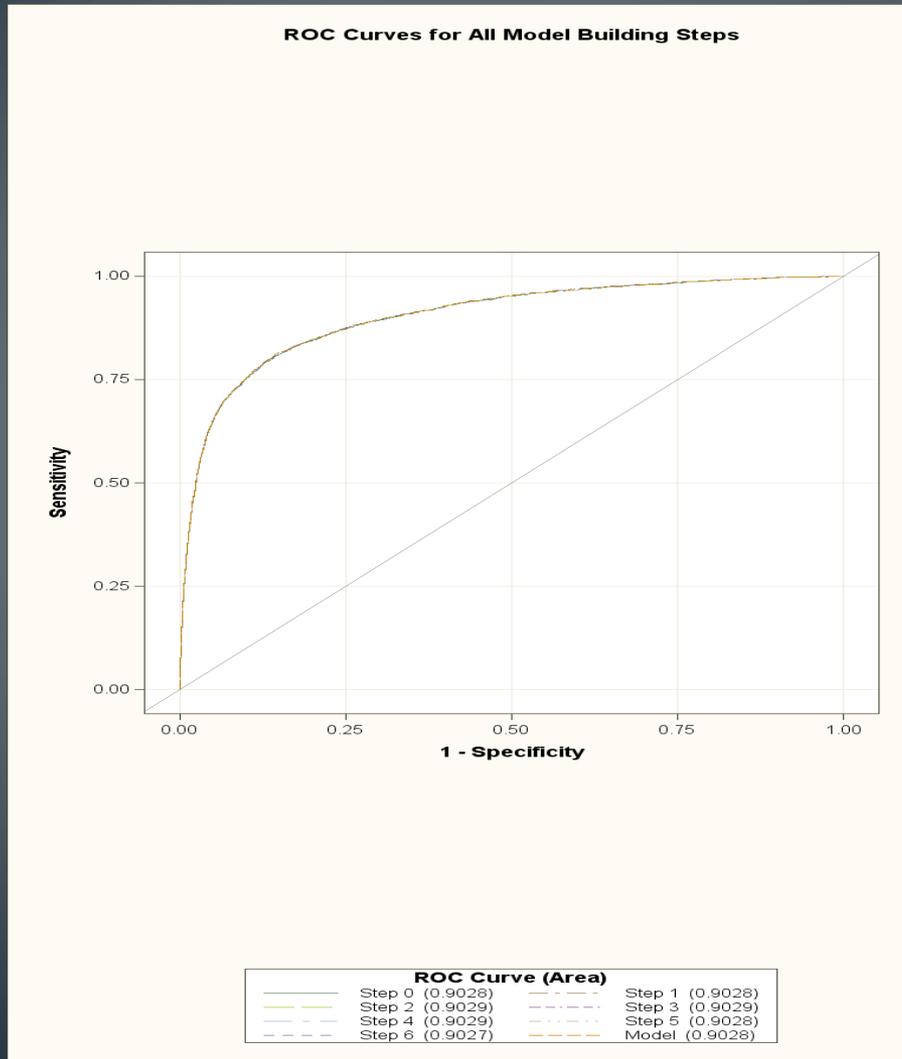
Significant but “protective/counterintuitive” Variables ($p < 0.05$): n=6
Hypertension
Dyslipidemia
Family CAD history
Prior MI
Prior PCI
Prior CABG

Multivariable Logistic Regression Model for Composite Event



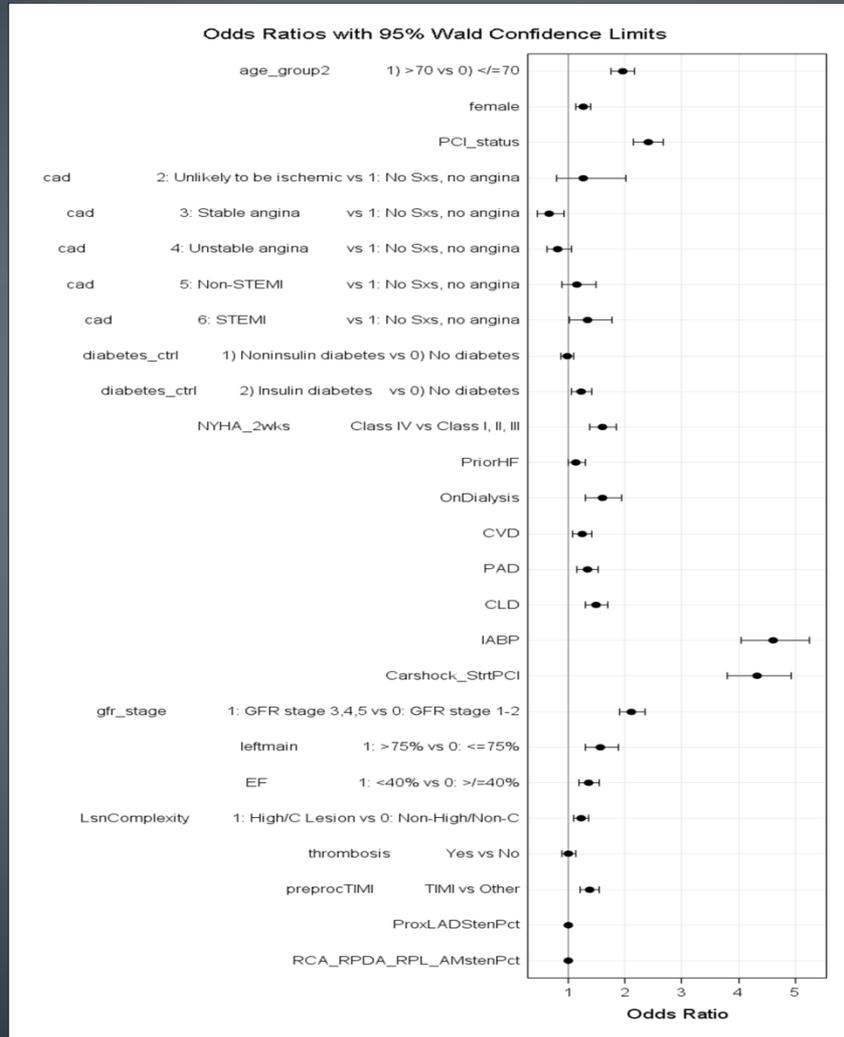
- Candidate RFs: 32
- Parsimony via backward selection at $\alpha=0.1$
- **24 sig. risk factors remain**
- 4 sig. but counterintuitive predictors:
 - Dyslipidemia
 - Family CAD history
 - Prior PCI
 - Prior CABG

Multivariable Logistic Regression Model for Composite Event



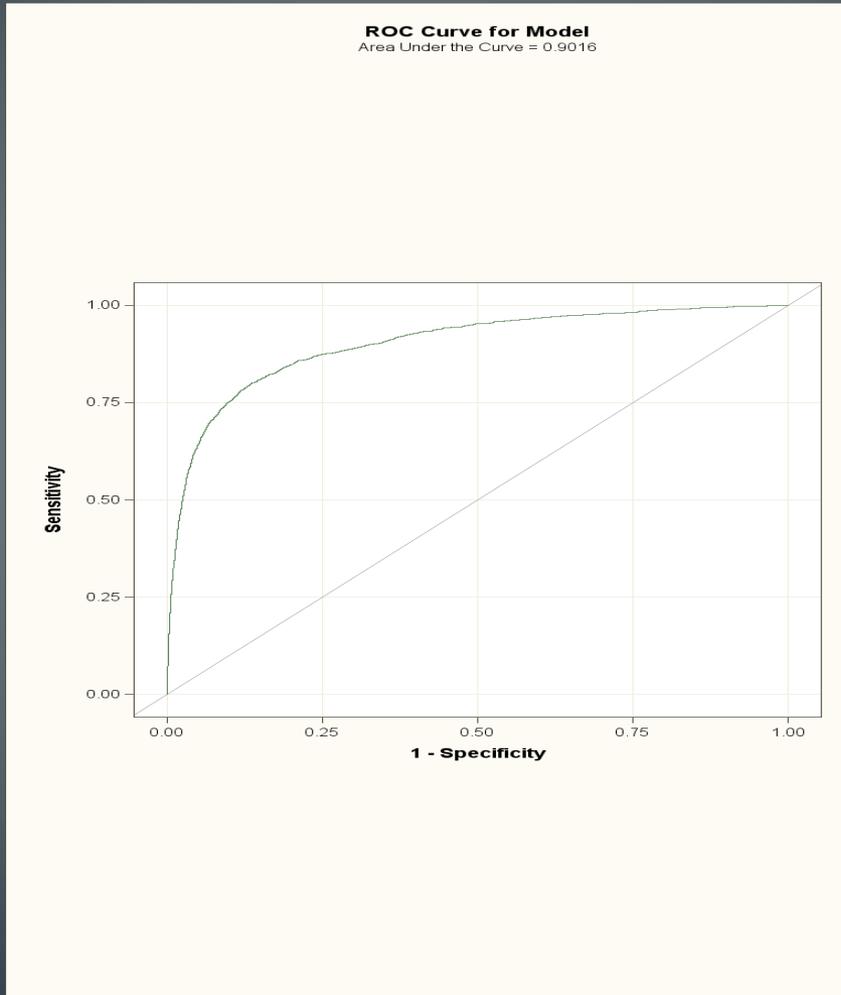
- Parsimonious Model:
 - 24 sig. risk factors
 - C-statistic= 0.903
 - Hosmer-Lemeshow test: p-value <0.0001
- Using NCDR[®]-CA data only (N=99,332):
 - Results in a very similar model (c=0.903)

Multivariable Logistic Regression Model for Composite Event



- Refined model:
 - Removed 4 counterintuitive risk factors
 - Added Thrombosis
 - 21 risk factors
- AOR > 2.0 predictors:
 - PCI status
 - IABP
 - Cardiogenic shock
 - GFR stage 3-5

Multivariable Logistic Regression Model for Composite Event



- Refined Model: 21 variables
 - C-statistic = 0.902
 - Hosmer-Lemeshow test:
 - p-value < 0.0001
 - Calibration analysis by risk group (deciles):



Deciles Calibration Test

Decile	Cases	Observed events	Predicted event	Difference	95%CI of predicted events
1	10202	11	10.1	-0.9	(3.9, 16.4)
2	10194	12	17.0	5.0	(8.9, 25.0)
3	10196	24	25.2	1.2	(15.3, 35.0)
4	10180	21	34.1	13.1	(22.7, 45.6)
5	10191	34	45.9	11.9	(32.6, 59.2)
6	10196	51	64.0	13.0	(48.3, 79.7)
7	10193	83	96.2	13.2	(77.0, 115.4)
8	10194	95	142.8	47.8	(119.4, 166.2)
9	10194	219	233.3	14.3	(203.4, 263.3)
10	10193	1504	1385.4	-118.6	(1312.5, 1458.4)
Total	101,933	2054	2054.0	0	

- Two risk groups (deciles 4 and 8) fall below the expected range.
- Another one risk group (decile10) falls above the expected range.
- Overall there were no systematic underestimates or overestimates of event at extreme.

122 Hospital Ratings:

All PCI Cases 07/01/2010-07/31/2012

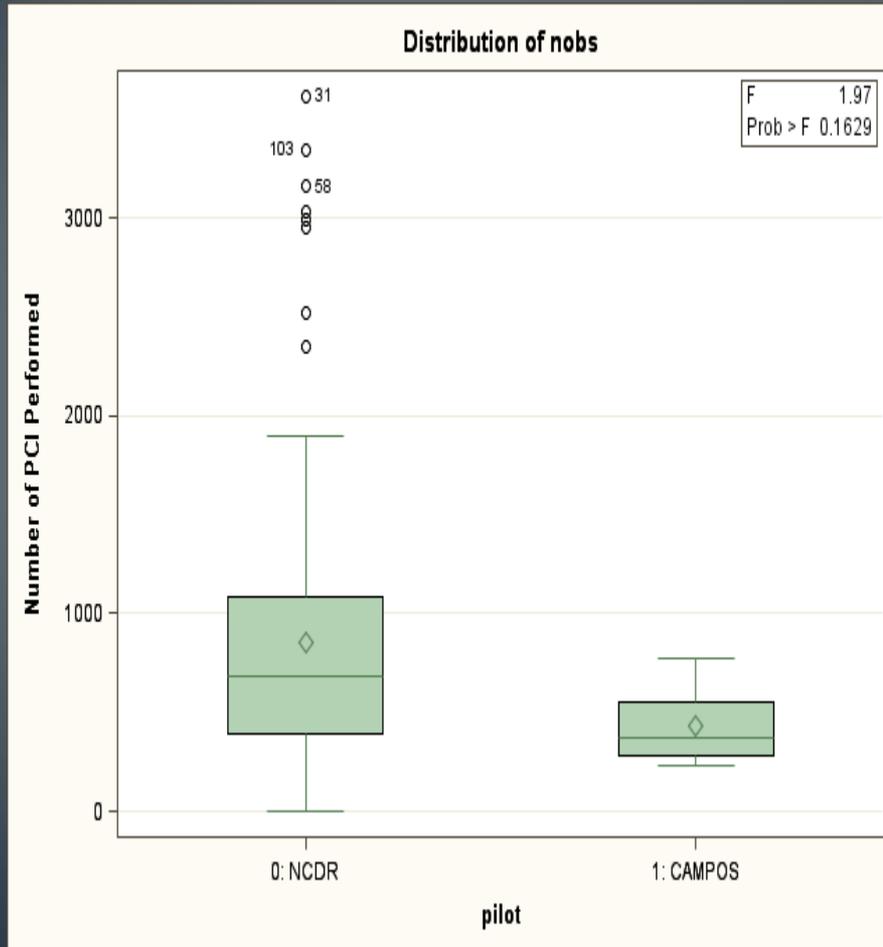
	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
NCDR[®]-CA	As Expected	105	Volume	779	592	658	1	3344
			Observed event rate	3.23	9.66	2.07	0.00	100.00
			Expected event rate	2.58	3.06	2.01	0.39	31.33
			Risk adjusted event rate	2.04	0.88	2.00	0.00	6.43
Better		4	Volume	2428	1544	2972	157	3613
			Observed event rate	1.12	0.50	1.11	0.54	1.72
			Expected event rate	2.80	2.24	2.11	0.94	6.03
			Risk adjusted event rate	1.02	0.43	1.10	0.43	1.44
Worse		7	Volume	1119	1105	649	277	3027
			Observed event rate	3.60	1.24	3.52	2.17	6.14
			Expected event rate	1.98	0.57	1.80	1.59	3.25
			Risk adjusted event rate	3.65	0.62	3.91	2.75	4.29

122 Hospital Ratings:

All PCI Cases 07/01/2010-07/31/2012

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
CAMPOS	As Expected	5	Volume	410	217	330	231	778
			Observed event rate	2.54	1.85	2.44	0.43	5.44
			Expected event rate	2.89	1.58	2.33	1.87	5.66
			Risk adjusted event rate	1.67	0.68	1.94	0.47	2.11
Better		1	Volume	552	.	552	552	552
			Observed event rate	2.17	.	2.17	2.17	2.17
			Expected event rate	3.80	.	3.80	3.80	3.80
			Risk adjusted event rate	1.15	.	1.15	1.15	1.15

Comparison in Total PCI Volume: NCDR[®]-CA vs. CAMPOS

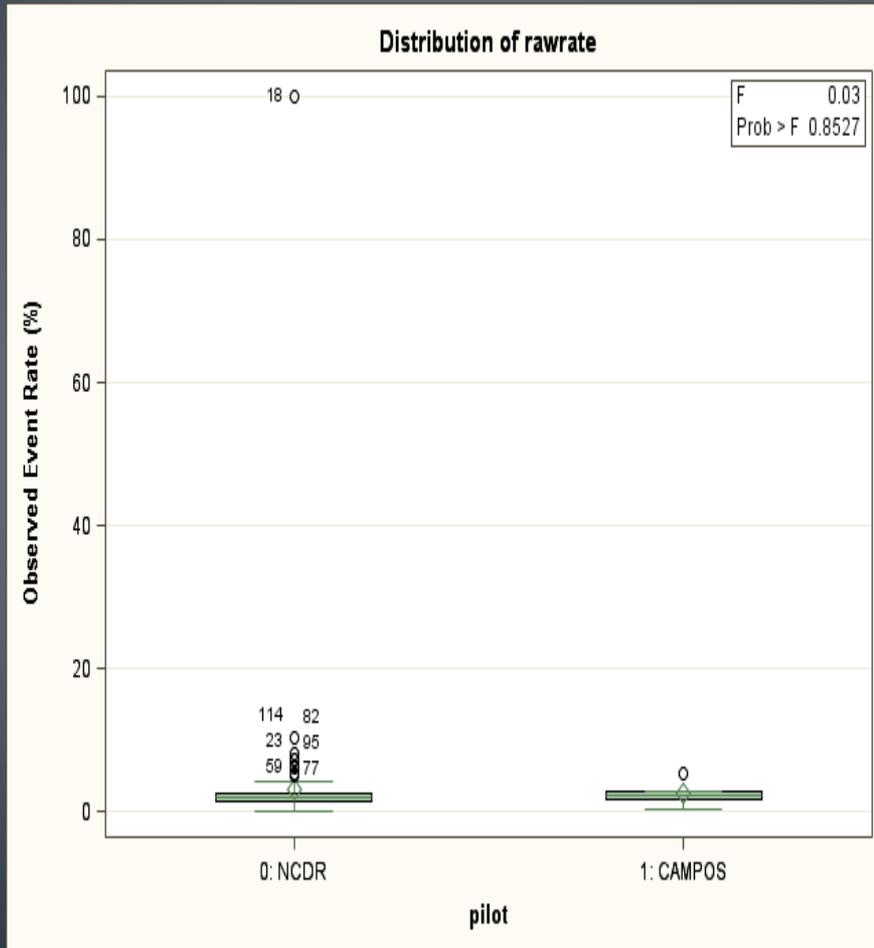


	Total PCIs LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0:NCDR [®] -CA	856	0.1629
1: CAMPOS	434	

*Least squares mean

Comparison in Observed Event Rate:

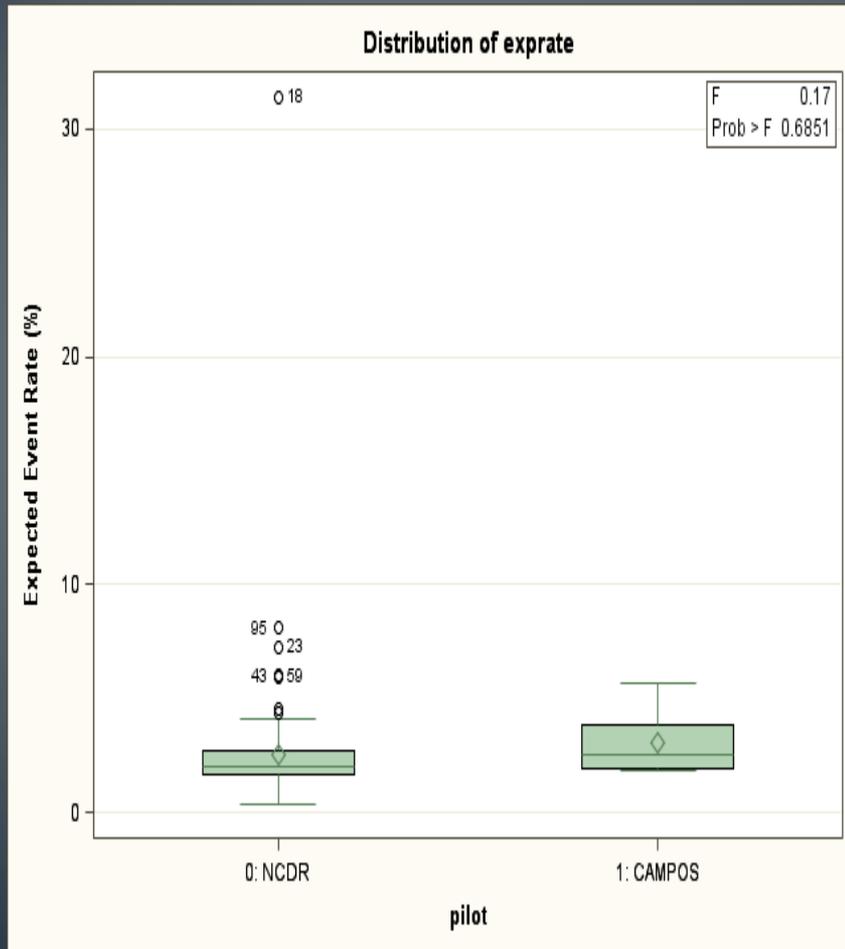
NCDR[®]-CA vs. CAMPOS



	rawrate LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	3.18	0.8527
1: CAMPOS	2.48	

*Least squares mean

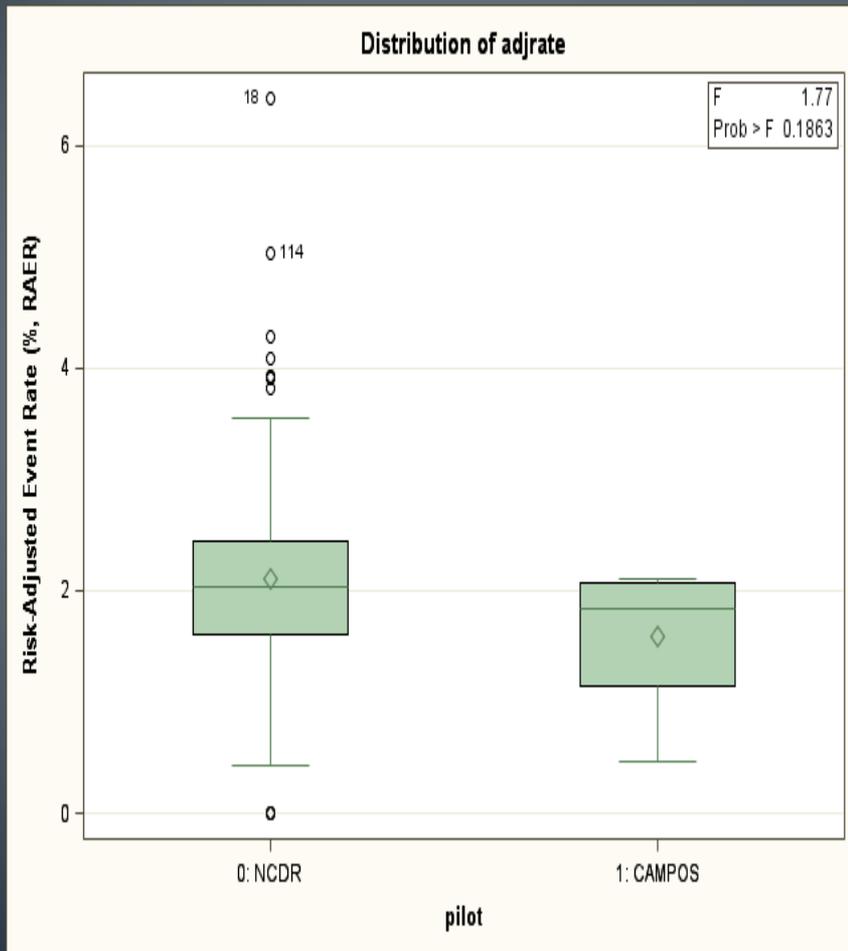
Comparison in Expected Event Rate: NCDR[®]-CA vs. CAMPOS



	exprate LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	2.55	0.6851
1: CAMPOS	3.04	

*Least squares mean

Comparison in Risk-adjusted Event Rates: NCDR[®]-CA vs. CAMPOS



	adjrate LSMEAN**	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	2.11	0.1863
1: CAMPOS	1.58	

*21 variables, OE ratio x Population rate

**Least squares mean

121 Hospital Ratings:

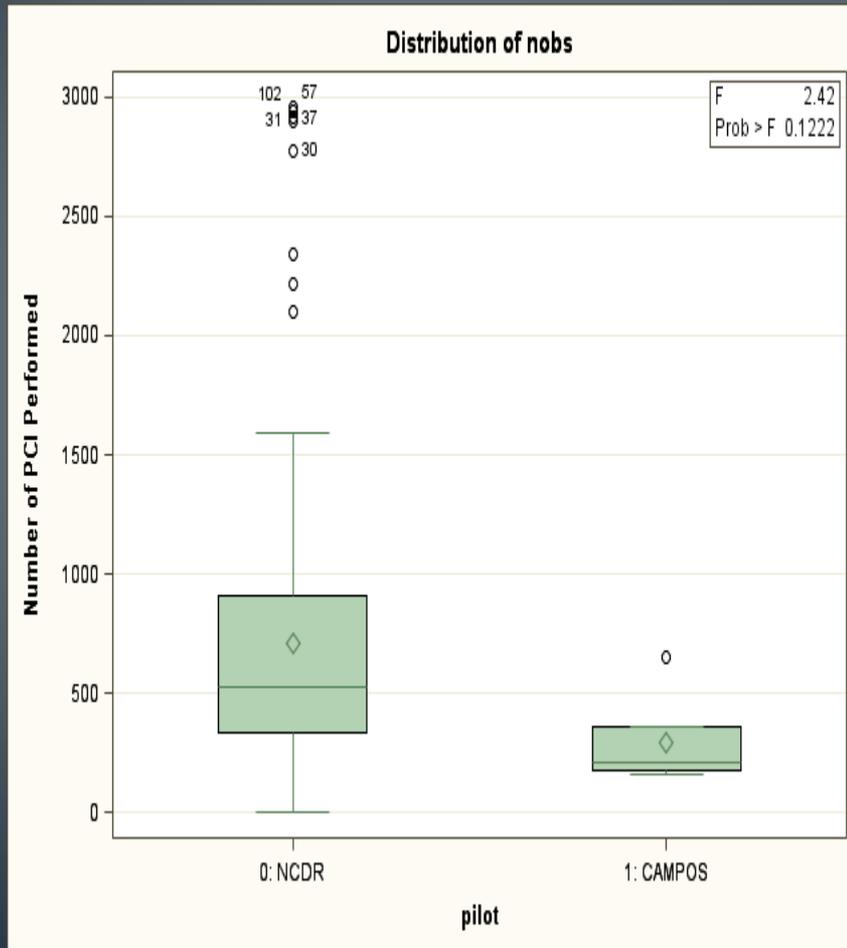
STEMI Excluded PCI Cases 07/01/2010-07/31/2012

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
NCDR[®]-CA	As Expected	106	Volume	665	562	530	1	2942
			Observed event rate	3.06	12.39	1.05	0.00	100.00
			Expected event rate	1.81	4.19	1.01	0.37	31.33
			Risk adjusted event rate	1.11	0.69	1.06	0.00	4.41
Better		4	Volume	2421	929	2847	1032	2959
			Observed event rate	0.64	0.18	0.64	0.48	0.81
			Expected event rate	1.20	0.29	1.23	0.82	1.52
			Risk adjusted event rate	0.58	0.10	0.60	0.45	0.68
Worse		5	Volume	325	122	269	219	522
			Observed event rate	3.35	0.88	3.58	1.92	4.09
			Expected event rate	1.42	0.38	1.66	0.91	1.72
			Risk adjusted event rate	2.55	0.31	2.49	2.27	3.04

121 Hospital Ratings: STEMI Excluded PCI Cases 07/01/2010-07/31/2012

	Performance rating	Number of hospitals	Measure	Mean	Std Dev	Median	Minimum	Maximum
CAMPOS	As Expected	6	Volume	294	188	211	156	649
			Observed event rate	1.28	0.91	1.10	0.00	2.56
			Expected event rate	1.38	0.74	1.17	0.78	2.68
			Risk adjusted event rate	1.15	1.15	0.78	0.00	3.33

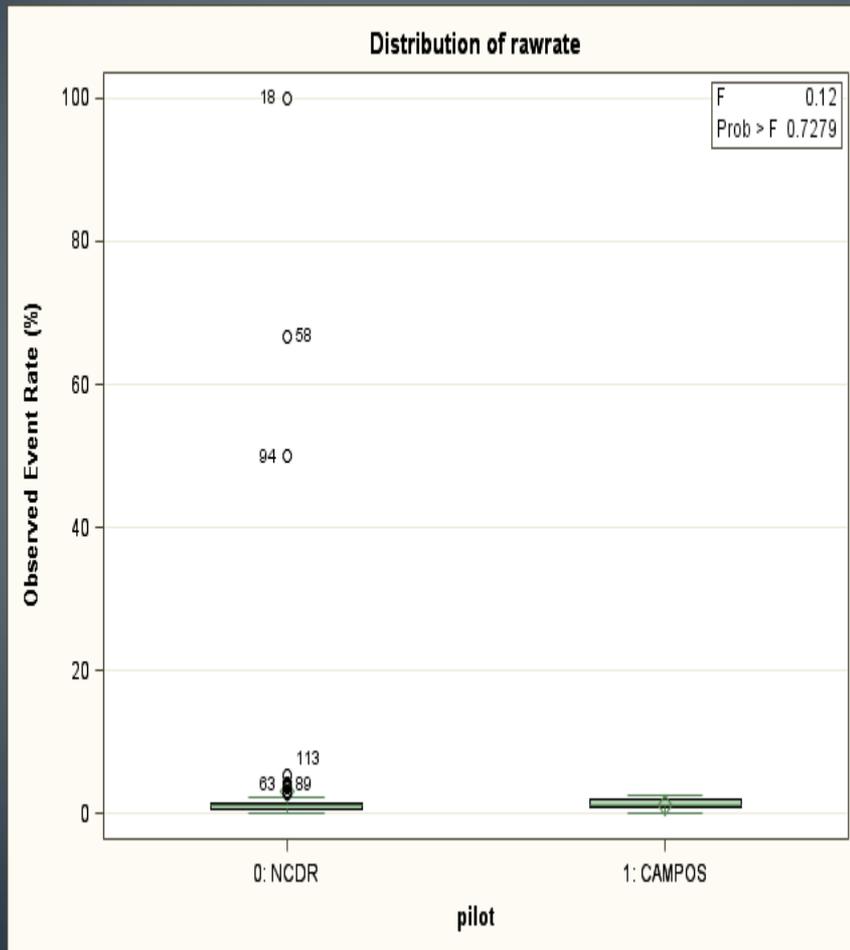
PCI Volume (STEMI Excluded): NCDR[®]-CA vs. CAMPOS



	STEMI Excluded PCIs LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	711	0.1222
1: CAMPOS	294	

*Least squares mean

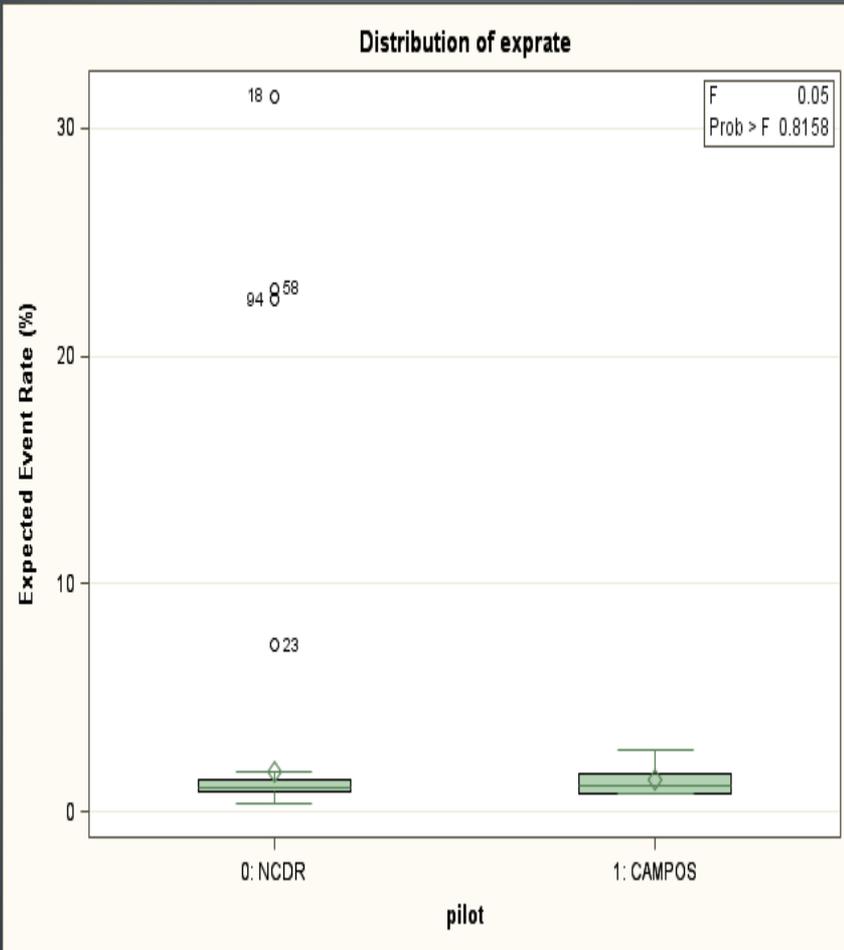
PCI Observed Event Rate (STEMI Excluded): NCDR[®]-CA vs. CAMPOS



	rawrate LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	2.98	0.7279
1: CAMPOS	1.28	

*Least squares mean

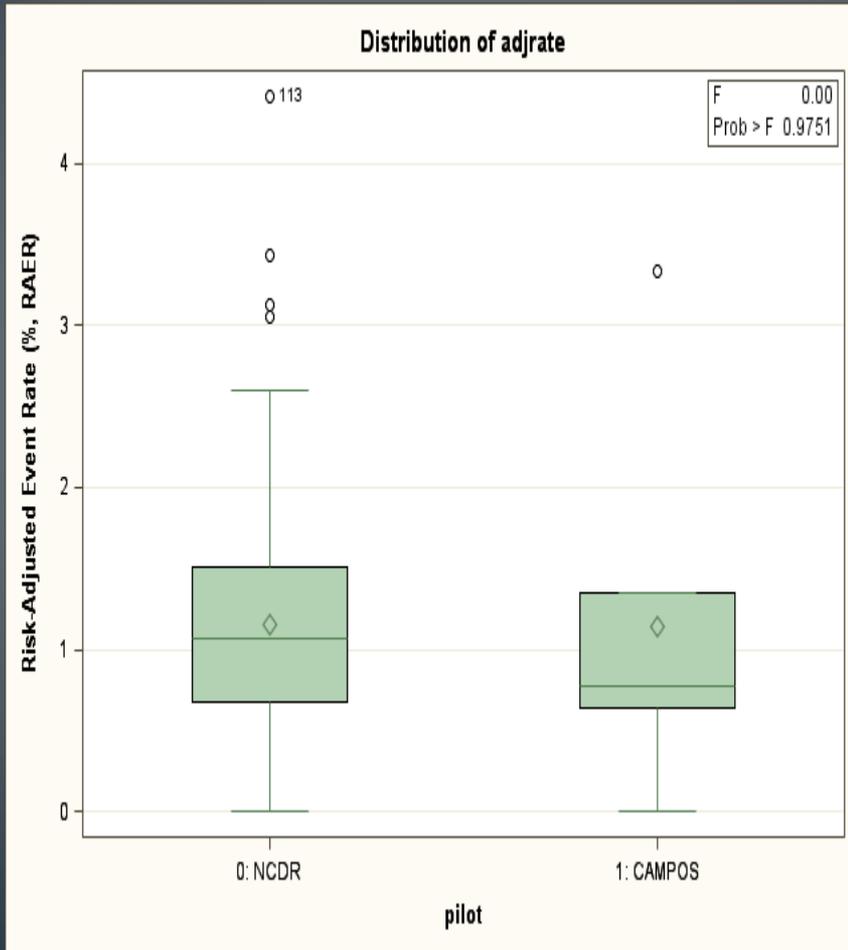
PCI Expected Event Rate (STEMI Excluded): NCDR[®]-CA vs. CAMPOS



	exprate LSMEAN*	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	1.77	0.8158
1: CAMPOS	1.38	

*Least squares mean

PCI Risk-adjusted Event Rates (STEMI Excluded): NCDR[®]-CA vs. CAMPOS



	adjrate LSMEAN**	H0:LSMean1 =LSMean2 Pr > t
0: NCDR [®] -CA	1.16	0.9751
1: CAMPOS	1.15	

*OE ratio x Population rate

**Least squares mean

CAMPOS Physician Ratings

Total PCIs 08/01/2010-07/31/2012

	Number of Operator	Measure	Mean	Std Dev	Median	Minimum	Maximum
As Expected	46	Volume	46	52	19	1	179
		Observed event rate	3.84	8.44	0.78	0.00	50.00
		Expected event rate	3.50	2.39	2.70	0.62	12.09
		Risk adjusted event rate	2.09	4.69	0.96	0.00	28.73
Better	1	Volume	491	.	491	491	491
		Observed event rate	1.83	.	1.83	1.83	1.83
		Expected event rate	3.73	.	3.73	3.73	3.73
		Risk adjusted event rate	0.99	.	0.99	0.99	0.99

CAMPOS Physician Ratings

STEMI Excluded 08/01/2010-07/31/2012

	Number of Operator	Measure	Mean	Std Dev	Median	Minimum	Maximum
As Expected	41	Volume	43	64	15	1	336
		Observed event rate	1.80	5.57	0.00	0.00	33.33
		Expected event rate	2.05	3.65	1.10	0.43	23.02
		Risk adjusted event rate	0.88	1.85	0.00	0.00	9.64

Total PCI Volume and Composite Event

Hospital

Pearson Correlation Coefficients, N = 122 Prob > r under H0: Rho=0	
	PCI Volume
rawrate	r=-0.14724
Observed Event Rate (%)	p=0.1056
exprate	r=-0.22463
Expected Event Rate (%)	p=0.0129
adjrate	r=-0.03996
Risk-Adjusted Event Rate (% , RAER)	p=0.6621

Operator

Pearson Correlation Coefficients, N = 47 Prob > r under H0: Rho=0	
	PCI volume
rawrate	r=-0.1063
Observed Event Rate (%)	p=0.477
exprate	r=-0.1276
Expected Event Rate (%)	p=0.3927
adjrate	r=-0.05951
Risk-Adjusted Event Rate (% , RAER)	p=0.6911

* NCDR[®]-CA and CAMPOS

*PCI CAMPOS data only

PCI Volume and Composite Event (STEMI Excluded)

Hospital

Pearson Correlation Coefficients, N = 121 Prob > r under H0: Rho=0	
	PCI Volume
rawrate	r=-0.17
Observed Event Rate (%)	p=0.0623
exprate	r=-0.18499
Expected Event Rate (%)	p=0.0422
adjrate	r=-0.09628
Risk-Adjusted Event Rate (%), RAER)	p=0.2935

* NCDR[®]-CA and CAMPOS

Operator

Pearson Correlation Coefficients, N = 41 Prob > r under H0: Rho=0	
	PCI volume
rawrate	r=-0.07575
Observed Event Rate (%)	p=0.6378
exprate	r=-0.14349
Expected Event Rate (%)	p=0.3708
adjrate	r=0.10083
Risk-Adjusted Event Rate (%), RAER)	p=0.5305

*PCI CAMPOS data only

Statistical Analysis Summary

- **NCDR[®]-CA** and **CAMPOS** had different Case profiles
- Risk-adjusted composite event rate based on total PCIs:
 - Overall no significant difference between **NCDR[®]-CA** and **CAMPOS** hospitals
 - **NCDR[®]-CA** (N=116): 4 “**better**” and 7 “**worse**” outlier hospitals
 - **CAMPOS** (N=6): 1 “**better**” and no “**worse**” outlier hospitals
 - **CAMPOS** Operators (N=47): 1 “**better**” and no “**worse**” outlier

Statistical Analysis Summary

- Risk-adjusted composite event rate based on STEMI excluded PCIs:
 - Overall no significant difference between **NCDR[®]-CA** and **CAMPOS** hospitals
 - **NCDR[®]-CA** (N=115): 4 “**better**” and 5 “**worse**” outlier hospitals
 - **CAMPOS** (N=6): no outlier hospital
 - **CAMPOS** (N=41): no outlier operator
- No significant relationships between hospital/operator PCI volume and risk-adjusted composite event.

Quality Metrics I

Post-Operative Medicine Use

(08/01/2010-07/31/2012)

➤ **Aspirin** prescribed at discharge:

Pilot 99.0%

NCDR[®]-US 98.5% (96.7-99.5%)

➤ **Thienopyridine** prescribed at discharge (pts with stents):

Pilot 99.8%

NCDR[®]-US 99.3% (98.2-99.9%)

➤ **Lipid lowering agent** prescribed at discharge:

Pilot 97.1%

NCDR[®]-US 93.4% (88.6-96.5%)

Quality Metrics II (08/01/10-07/31/12)

Hospital	1	2	3	4	5	6	Total
# of Elective PCI pts. (excl. pts. with ACS)	218	52	25	42	47	49	433
Pts. who had a Stress Test, Imaging Study, or FFR	133	35	21	31	30	44	294
Stand. Exercise Stress Test +/indeterminant/total	49/11/68	2/0/2	1/0/1	0	1/2/4	0	53/13/75
Stress Echo +/indeterminant/total	1/0/1	3/0/3	7/1/8	0/1/1	4/0/4	0	15/2/17
SPECT +/indeterminant/total	56/3/69	27/0/29	11/0/12	23/5/30	19/1/22	22/6/32	158/15/194
CMR +/indeterminant/total	0	1/0/1	0	0	0	0	1/0/1
FFR (≤ 0.75 /total)	6/15	0	0	0	0	0	6/15
+stress test/# elective PCI*	98/215 44.9%	33/52 63.5%	19/25 76%	23/42 54.8%	24/47 51.1%	34/49 69.4%	231/433 53.3%

* NCDR®-US 2012Q2 : median, 25th – 75th percentile: 61.7%, 50.1 – 72.8%

Quality Metrics III (08/01/10-07/31/12)

Hospital	1	2	3	4	5	6	Total	25 th – 75 th	NCDR®-US
Median time to immediate PCI for STEMI patients (minutes)	73	60	66	69	72	64	65	55.8-67.0	61.8
Proportion of STEMI patients receiving immediate PCI within 90 minutes (%)	93.7	93.2	94	95.7	77.5	96	92	87.0-96.8	93.1
Emergency CABG (%)	0.3	0	0.4	0	0	1.4	0.3	0.0-0.4	0.1
Acute kidney injury (%)	0.8	2.5	3.3	3.5	4.4	4.9	2.7	1.6-3.1	2.3

Quality Metrics IV (08/01/10-07/31/12)

Hospital	1	2	3	4	5	6	Total	25 th – 75 th	NCDR [®] - US
Post procedure stroke (%)	0	0.2	0.4	0	0.3	0.9	0.3	0.0-0.3	0
Composite: Death, emergency CABG, stroke	1.7% 13	2.4% 13	2.8% 8	0.4% 1	3.0% 10	6.1% 26	2.7% 71	1.7-3.3	2.4
Median post-proc LOS for PCI with STEMI (days)	2	3	3	2	3	2	2.5	1.9-2.8	2.6
Median post-proc LOS for PCI with no STEMI (days)	1	1	1	1	1	2	1.1	NA	NA
Creatinine assessed pre-and post PCI (%)	96.2	98.7	89.3	88.5	94.5	77.4	92.0	75.9-93.2	87.3
Transfusion of whole blood or RBCs (%)	1.9	5.4	1.1	3.0	1.5	6.2	3.3	0.7-2.5	1.5

Quality Metrics V (08/01/10-07/31/12)

Hospital	1	2	3	4	5	6	Total	25 th – 75 th per- cen- tile	NCDR [®] - US
Intermediate stenosis lesions (40-70%): IVUS (% of patients)	7.4 (12/163)	5.3 (1/19)	0 (0/11)	19.5 (8/41)	0 (0/15)	0 (0/69)	6.6 (21/318)	NA	NA
Intermediate stenosis lesions (40-70%): FFR (% of patients)	14.1 (23/163)	5.3 (1/19)	27.3 (3/11)	9.7 (4/41)	0 (0/15)	0 (0/69)	9.7 (31/318)	NA	NA
Biomarkers assessed post procedure for elect. inpatients (%)	83.5	96.6	93.9	16.7	69.2	17.6	70.0	13.3-77.2	36.1
Post procedure MI (%)	5.4	5.1	22.6	7.7	9.5	0	6.5	≥90%: 0.3-4.7 ≤90%: 0.0-1.6	≥90%: 1.9 ≤90%: 0.3

PCI Success (08/01/10-07/31/12)

Hospital	1	2	3	4	5	6	Total
Number of patients	779	552	286	231	330	423	2601
Number of lesions treated	1288	653	352	280	403	566	3542
Guidewire across	1271	644	343	272	384	555	3469
Post procedure stenosis <20% (%)	90.4	95.7	85.8	88.9	90.8	83	89.7
Post procedure stenosis ≥20% (%)	8.2	2.9	11.6	8.2	4.5	15	8.2
Post procedure TIMI 3 (%)	94.6	94	92.3	92.5	91.8	89.6	93
<20% stenosis <u>AND</u> TIMI 3 (%)	87.6	92.2	83.2	87.9	88.3	78.4	86.7

Transfer Costs

Hospital 1: Transfers for 'emergent' CABG

Transfer 1	\$1,106
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Transfer 2	\$1,106
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Average cost per transfer	\$1,106
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Transfer Costs

Hospital 2: Transfers to 'other acute care hospital' for impella device, AVR, MVR, etc. not for CABG

Transfer 1	\$2,025
Transfer 2	\$478
Transfer 3	\$2,730
Transfer 4	\$2,730
Transfer 5	\$885
Transfer 6	\$1,685
Transfer 7	\$3,720
Average cost per transfer	\$2,036

Transfer Costs

Hospital 3: Transfer to CABG facility (10.9 miles)

Base rate \$599 plus \$20/mile = \$819

Cost per transfer to CABG hospital \$819

Transfer Costs

Hospital 4: Transfers for 'urgent' CABG

Transfer 1	\$255
Transfer 2	\$255
Transfer 3	\$515
Transfer 4	\$255
Average cost per transfer	\$320

Transfer Costs

Hospital 5: Transfers for 'urgent' CABG

Transfer 1	\$600
Transfer 2	\$888
Transfer 3	\$4,936
Transfer 4	\$2,335
Average cost per transfer	\$2,190

Transfer Costs

Hospital 6: Transfers for “emergent” CABG and “other acute care hospital”

Transfer 1	\$897
Transfer 2	\$1,036
Transfer 3	\$897
Transfer 4	\$897
Transfer 5	\$897
Transfer 6	\$870
Average cost per transfer	\$916

Summary I

- CAMPOS Enrollment: 3076 (8/1/10-12/31/12)
- CAMPOS Hospital Enrollment: 97-390/year (8/1/10-7/31/12)
- NCDR[®]-CA Enrollment: 99,332 (7/1/10-6/30/12)
- Pilot-site audits detect more mis-codes (OR 6.4) and mis-risks(OR 14) than Central audits
- CAMPOS STEMI incidence (32.2%) is greater than NCDR[®]-CA STEMI incidence (17.7%)
- Compassionate Use raises CAMPOS STEMI mortality from 4.8 to 61.9% comparable to Massachusetts

Summary II

CA Multivariate Risk Model: 21 Refined variables, C-statistic=0.902

Risk-Adjusted Overall-composite Event: no significant difference

CAMPOS 1.58%, NCDR[®]-CA 2.11% p=NS

Risk-Adjusted STEMI-excluded Composite Event: no significant difference

CAMPOS 1.15%, NCDR[®]-CA 1.16% p=NS

Risk-Adjusted Overall-composite Event Outliers:

6 CAMPOS hospitals : 1 better outlier

116 NCDR[®]-CA hospitals: 4 better and 7 worse outliers

47 CAMPOS operators: 1 better outlier

Risk-Adjusted STEMI-excluded Composite Event Outliers:

6 CAMPOS hospitals : no outliers

106 NCDR[®]-CA hospitals: 4 better and 5 worse outliers

41 CAMPOS operators: no outliers

Summary III

PCI-CAMPOS Success Rate: (08/01/2010-07/31/12)

- post-procedure stenosis <20%: 89.7%
- post-procedure TIMI 3 flow: 93.0%

NCDR[®]-US and **PCI-CAMPOS** Hospital Volume correlation: (07/01/10-07/31/12)

- No significant Composite Event to Hospital Volume correlation

PCI-CAMPOS Quality Metrics: (08/01/2010-07/31/12)

- ASA, thienopyridine, stress testing, emergent CABG, D2B, kidney injury, stroke, composite events, LOS, and pre/post creatinine are within **NCDR[®]-US** 25-75th percentile; +lipid meds and -transfusion are within 10-90th percentile; and -post proc. biomarker MI is outside the 10-90th percentile.

NCDR California PCI Dataset

ACCF NCDR[®] to create and transmit a de-identified dataset of California hospitals that does not require hospital consents, with select elements suppressed, masked, or calculated .

- UC Davis/ NCDR[®]: contract signed 06/2012
- Pilot-Hospitals: CDPH invoices sent 08/2012
- NCDR[®] Sample Data file: uploaded 08/27/2012
approved 09/21/2012
- NCDR[®]-CA Data: initial data export 10/16/2012
complete data export 12/13/2012

PCI-CAMPOS Plan: follow up

- Continue to support hospital volume: Operator survey
- Review performance variation: Notified PI's, both worse outlier operators (12.05%/30.84%) had no mortality in 2012 (35/14 procedures respectively)
- Refer outliers to local CQI: CQI reviewed and reports filed
- Review CQI implementation: Reports received
- Re-consider Public Disclosure: To be addressed at January meeting
- Obtain California NCDR® Database: Received 12/13/12
- Develop Early Publication: In-progress, outline completed
- Develop PCI CAMPOS transition plan: SB 891 Extension drafts written, awaiting approval by original author, Sponsor-CHA, Support- 6 Pilot Hospitals, CAACC, CMA, CANP representatives. To be submitted by 02/23/13

PCI-CAMPOS Analysis Plans

Review National, State, and PCI CAMPOS data on:

- Demographics
- Episode of Care (Admission, Insurance)
- History and Risk Factors
- Cath Lab Visit (Clinical, Stress, Procedure, Ventricular Support, Access)
- Diagnostic Catheterization
- Coronary Anatomy
- PCI Procedure (indication, Medications)
- Lesions, Devices, and Intra-procedure Events
- Labs
- Intra and Post procedure Events
- Discharge (Status, Medications)
- Outcomes

PCI-CAMPOS Plans

- SB 891 Extension: Submission February 23, 2013
- Hospital CQI Audit Review
- Mis-Codes/Mis-Risks: Continue to work with Velos support
- Compare PDD with NCDR data
- Submit 2 year data for publication
- Schedule next AOC meeting