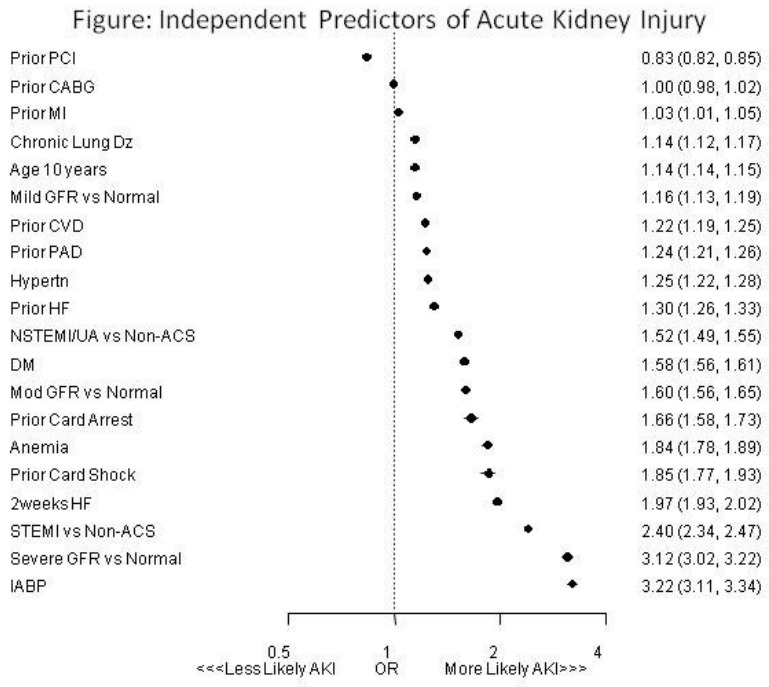
CathPCI: Acute Kidney Injury (risk-adjusted) Specifications and Testing Overview

Measure Purpose	Acute kidney injury (AKI) affects up to 15.3% of all hospitalized patients. Regardless of the underlying cause, AKI is associated with significantly increased in-hospital morbidity, mortality, and costs [J Am Soc Nephrol 21: 345–352, 2010]. Earlier studies have indicated that at least 5 % of patients who undergo cardiac catheterization experience a transient rise in the plasma creatinine concentration of more than 1.0 mg/dL due to contrast-induced renal dysfunction [Cathet Cardiovasc Diagn. 1994;31(4):316]. AKI is a serious adverse consequence of percutaneous coronary interventions (PCI) and, most importantly, is modifiable through the use of pre-procedure hydration or the avoidance of contrast (either minimization during the case or through staging of the procedure when multi-vessel revascularization is required). *Additional evidence is provided under the validity testing sections of this application.*
Numerator	Acute kidney injury -defined as Acute Kidney Injury Network (AKIN) stage 1 **or** greater or a new requirement for dialysis following PCI 1. Stage 1 is defined as an absolute increase of ≥ 0.3 mg/dL or a relative increase of 50% in serum creatinine (Cr) 2. Stage 2 is defined as an increase in serum Cr to more than 200% to 300% (>2-to 3-fold) from baseline, 3. Stage 3 is defined as increase in serum Cr to more than 300% (>3-fold) from baseline (or serum Cr of more than or equal to 4.0 mg/dl with an acute increase of at least 0.5 mg/dl. ***NOTE:*** *The AKIN criteria were created in part to be more sensitive to even small changes in creatinine. Previous epidemiologic studies have shown poor outcomes with creatinine increases as small as 0.3 mg/dl, hence the addition of the 0.3 mg/dl cut off to the AKIN stage 1 criteria. Also, the AKIN criteria for AKI are becoming the accepted standardized definition of AKI currently adopted by nephrology and critical care literature.*
Denominator	Patients 18 years of age and older with a PCI procedure performed during admission
Model Elements	
Exclusions	In the original derivation cohort of 1,245,089 PCI procedures, 24,517 (2.0%) were on dialysis, 32,999 (2.6%) had more than one PCI in the same hospitalization, and 239,025 (19.0%) did not

	have both creatinine values available with which to ascertain whether or not AKI had occurred. The only exclusions from this model were those that were already on dialysis (~2.0% of all PCIs), those undergoing multiple PCI procedures within the same admission (<3% of PCI patients), those without both a pre- and post-procedure creatinine (19% of cases), and same stay discharges (<4% of all cases). While the failure to collect pre- and post-procedure creatinine levels is common, it is also possible that it could be incorporated into a separate quality measure that may, or may not be bundled with this one. It is very rare to not collect a pre-procedural estimate of renal function as part of routine care and, despite the potential gaming that could be done by sites by selectively not assessing a post-procedure creatinine value, we have documented marked variability across sites in the rate of AKI and given the opportunities to avoid it, believe that it remains a very powerful too for QA/QI. Patients with same -day discharges often do not have a post-procedural creatinine assessed. Moreover, we anticipate that changes in Medicare reimburse policies and recently documented patient preferences for same-day discharge (Kim M, Muntner P, Sharma S, et al. Assessing Patient-Reported Outcomes and Preferences for Same-Day Discharge After Percutaneous Coronary Intervention: Results From a Pilot Randomized, Controlled Trial. *Circulation: Cardiovascular Quality and Outcomes* 2013; 6(2): 186-92) will lead to an increasing proportion of patients being discharged on the same day of their procedure. Such patients are the lowest risk for peri-procedural outcomes and are at a lower risk for AKI. Given the absence of a post-discharge creatinine, the selection preference of discharging only the lowest-risk patients on the day of their procedure, and the anticipated growing population of these patients, we felt it was best to exclude them from the performance measure. NCDR does not believe that the exclusions have any major impact on the validity, accuracy or interpretability of the risk-adjusted acute kidney injury outcome measure. The biggest threat is the large group of patients without pre- and post-creatinine values available. Clinically, however, this most often occurs in those who are elective outpatients and at lower risk for AKI. Nevertheless, reporting of the proportion of patients without a post-procedure creatinine level available, and their distribution across hospitals, could improve future acquisition of this important variable.
Demonstrated Opportunity for Improvement	Number of patients: 658096 Number of PCI procedures per hospital volume: 0-10: 49 hospitals 11-200: 49 hospitals 201-400: 49 hospitals 401-600: 263 hospitals 601-1000: 239 hospitals 1001-2000: 128 hospitals 2001+: 19 hospitals Data range date: 2012QTR1-2012QTR4. Unadjusted rate quantities: Mean: 6.7% Stddev: .03.3% Quartile 1: 4.7% Quartile 3: 8.4% Deciles of acute kidney injury adjusted rates: 1: 5.7% 2: 6.1% 3: 6.4%

	4:6.7% 5(median): 6.9% 6: .7.2% 7: 7.6% 8: 8.1% 9: 8.9% This means that at the 10th percentile that 90% of hospitals demonstrated AKI rates higher than 5.7%. Although 10 percent of hospitals were able to attain such a low rate of AKI and could be a target for other hospitals to improve. A meaningful difference is one that indicates the potential for improvement in comparison to others. There are no absolute levels of AKI risk that are significant, as compared with others. The average, adjusted AKI rate was 6.5% and the upper quartile ranges from 8.2 to 20.8% of patients having AKI. Given an average PCI volume of 410 cases/hospital, this suggests between 7 and 59 patients having AKI per year among hospitals in the upper quartile as compared with the average hospital. Clinically, this is a large number of events, particularly given that there are readily applied interventions, such as hydration and contrast reduction through the avoidance of LV grams or staging of procedures, to mitigate AKI. We believe that the use of this model to identify outliers and the ability to pre-procedurally risk stratify patients and tailor therapy to risk holds great promise for improving the quality and safety of PCI. The below information below tables addresses the AKI rates for various populations that include hospital location, sex, race, gender, and insurance status, and race. **Hospital Location:** There were 66731 Rural, 156792 Suburban, and 295021 Urban patients representing these hospital locations. The AKI rates were: 6.9% 7.0%, and 7.5% respectfully (p<.001) **Teaching Hospital:** There were 261583 patients at teaching hospitals and 256961 patients at non-teaching hospitals. The teaching hospitals had a slightly higher AKI rate 7.3% vs 6.7% (p<.0001) **Gender:** There were 350962 Males and 167582 Females with Females having a significantly higher AKI rate (8.5% vs 6.3%, p<.0001). **Insurance Status:** There were 332098 patients with Private insurance, 115575 with Medicare, 19994 with Medicaid, 11761 with other insurance, and 39116 with no insurance. AKI rates were significantly different (p<.0001): 6.3%, 9.1%, 8.0%, 6.8%, and 6.3%. Medicare patients had the highest AKI rate of 9.1% but this is due to age being a strong predictor of AKI. **Race:** There were 452595 Caucasians, 42776 African Americans, and 23964 from other races. AKI rates were: 7.0%, 7.5%, 7.3% respectfully (p<.001).
Reliability Testing	We have chose to use different datasets to provide support for different aspects of the proposed measure. 1. Audit data: 01/2009-12/ 2009 has been used to support the inter-rater reliability of the application.

2. We used 985,737 consecutive PCI patients from 1253 sites participating in the NCDR CathPCI registry from 06/09–07/11 to develop, validate and define the model's performance characteristics.

3. A separate cohort of the NCDR CathPCI registry was used to validate the model, which included all data collected from 1365 hospitals in 2012 (01/2012-12/2012). These data were also used to provide test-retest reliability of the data elements for the risk model and further validate the model.

Assessment of test-retest reliability among patients undergoing 2 procedures within 2012:

Additional examination of the test-retest reliability of the key data elements used in the risk-adjustment model: At the data element level, ACCF staff evaluated the test-retest reliability by reviewing CathPCI patients who were readmitted or had a repeat procedure in 2012. This approach enabled us to examine 2 independent abstractions of data for the same patient. For certain characteristics that would not change (e.g. gender), we would expect near perfect reproducibility. For other characteristics (e.g. diabetes) we would expect that any patient diagnosed with diabetes on the first visit should also have diabetes recorded on the second visit. It is, however, clinically plausible that someone could be diagnosed with diabetes between their first and second visit, so the emergence of diabetes on the second visit is not necessarily an 'error' and no interpretation is made for these scenarios.

Patient Characteristics :

Creation of the AKI model: 1253 sites participating in the NCDR CathPCI registry from 06/09–07/11 to develop, validate and define the model's performance characteristics

For the initial derivation and validation of the AKI risk model, 985,737 consecutive PCI patients from 1253 sites undergoing PCI between 6/09-7/11 were included; a random 80% in the derivation cohort and 20% in the validation cohort. Of these, 69,667 (7.1%) PCI patients developed AKI. The table below documents very similar patient characteristics in both groups:

Patient Characteristics of the AKI Model Derivation and Validation Cohorts.

	Total	Cohorts		
	n = 985737	Validation n = 295994	Derivation n = 689743	P-Value
Demographics				
Age	64.8 ± 12.2	64.8 ± 12.2	64.8 ± 12.2	0.897
Sex Male Female	 662947 (67.3%) 322790 (32.7%)	 199173 (67.3%) 96821 (32.7%)	 463774 (67.2%) 225969 (32.8%)	0.622
Race - White	872397 (88.5%)	262085 (88.5%)	610312 (88.5%)	0.392
Race - Black or African American	77905 (7.9%)	23289 (7.9%)	54616 (7.9%)	0.397
BMI Missing	30.1 ± 11.7 1769	30.0 ± 7.9 550	30.1 ± 12.9 1219	0.438
Over 7 Days Procedure to Discharge	42224 (4.3%)	12697 (4.3%)	29527 (4.3%)	0.844
Same Day discharge	10587 (1.1%)	3170 (1.1%)	7417 (1.1%)	0.847
LOS	2.3 ± 4.5	2.3 ± 4.5	2.3 ± 4.5	0.383
Baseline CKD status				

		1 Normal eGFR >=60 2 Mild eGFR 45-60 3 Moderate eGFR 30-45 4 Severe eGFR <30 Missing	697800 (70.8%) 168537 (17.1%) 90356 (9.2%) 28878 (2.9%) 166	209697 (70.9%) 50550 (17.1%) 27027 (9.1%) 8665 (2.9%) 55	488103 (70.8%) 117987 (17.1%) 63329 (9.2%) 20213 (2.9%) 111	0.834
		History				
		Intra Aortic Balloon Pump Missing	25871 (2.6%) 312	7837 (2.6%) 121	18034 (2.6%) 191	0.341
		IABP_prior to procedure	2598 (0.3%)	813 (0.3%)	1785 (0.3%)	0.159
		anemia Missing	36677 (3.8%) 24292	10972 (3.8%) 7230	25705 (3.8%) 17062	0.612
		Current/Recent Smoker (w/in 1 year) Missing	275383 (28.0%) 816	82755 (28.0%) 265	192628 (27.9%) 551	0.734
		Hypertension Missing (.)	805228 (81.7%) 571	241966 (81.8%) 184	563262 (81.7%) 387	0.293
		Dyslipidemia Missing (.)	786436 (79.9%) 1149	236066 (79.8%) 332	550370 (79.9%) 817	0.610
		Family History of Premature CAD Missing (.)	240990 (24.5%) 405	72348 (24.5%) 131	168642 (24.5%) 274	0.945
		Prior MI Missing (.)	293217 (29.8%) 403	88007 (29.7%) 141	205210 (29.8%) 262	0.873
		Prior Heart Failure Missing (.)	113919 (11.6%) 669	34471 (11.7%) 204	79448 (11.5%) 465	0.069
		Prior Valve Surgery/Procedure Missing (.)	14352 (1.5%) 739	4319 (1.5%) 238	10033 (1.5%) 501	0.859
		Prior PCI Missing (.)	389191 (39.5%) 243	116970 (39.5%) 79	272221 (39.5%) 164	0.629
		Prior CABG Missing (.)	182242 (18.5%) 137	54552 (18.4%) 39	127690 (18.5%) 98	0.332
		Cerebrovascular Disease Missing (.)	120250 (12.2%) 541	36097 (12.2%) 180	84153 (12.2%) 361	0.951
		Peripheral Arterial Disease Missing (.)	120289 (12.2%) 610	36015 (12.2%) 208	84274 (12.2%) 402	0.494
		Chronic Lung Disease Missing (.)	149540 (15.2%) 608	45151 (15.3%) 206	104389 (15.1%) 402	0.124
		Diabetes Mellitus Missing (.)	352733 (35.8%) 327	105676 (35.7%) 113	247057 (35.8%) 214	0.279
		Cath Lab Visit				
		PCI Indication Immediate PCI for STEMI PCI for STEMI (Unstable, >12 hrs from Sx onset) PCI for STEMI (Stable, >12 hrs 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 Missing (.)	 138479 (14.1%) 8945 (0.9%) 6774 (0.7%) 4743 (0.5%) 4796 (0.5%) 442728 (44.9%) 73190 (7.4%) 305677 (31.0%) 405	 41375 (14.0%) 2698 (0.9%) 2037 (0.7%) 1390 (0.5%) 1421 (0.5%) 133157 (45.0%) 22011 (7.4%) 91788 (31.0%) 117	 97104 (14.1%) 6247 (0.9%) 4737 (0.7%) 3353 (0.5%) 3375 (0.5%) 309571 (44.9%) 51179 (7.4%) 213889 (31.0%) 288	0.817
		Anti-Anginal Medication w/in 2 Weeks Missing (.)	674955 (68.5%) 566	202839 (68.6%) 165	472116 (68.5%) 401	0.443

Heart Failure w/in 2 Weeks Missing (.)	99958 (10.1%) 366	30439 (10.3%) 109	69519 (10.1%) 257	0.002
Cardiomyopathy or Left Ventricular Systolic Dysfunction Missing (.)	98365 (10.0%) 227	29676 (10.0%) 69	68689 (10.0%) 158	0.307
Pre-operative Evaluation Before Non-Cardiac Surgery Missing (.)	17597 (1.8%) 409	5349 (1.8%) 129	12248 (1.8%) 280	0.280
Cardiogenic Shock w/in 24 Hours Missing (.)	18705 (1.9%) 331	5592 (1.9%) 112	13113 (1.9%) 219	0.694
Cardiac Arrest w/in 24 Hours Missing (.)	18286 (1.9%) 531	5469 (1.8%) 177	12817 (1.9%) 354	0.726
Pre-PCI Left Ventricular Ejection Fraction Missing	52.2 ± 12.6 289176	52.2 ± 12.6 86900	52.2 ± 12.6 202276	0.189
Procedure Information				
Contrast Volume Missing	198.9 ± 91.4 2911	199.0 ± 91.5 872	198.9 ± 91.3 2039	0.450

All p-values >0.05

BMI = body mass index; CABG = coronary artery bypass grafting; Hgb = hemoglobin; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction

The hospital characteristics from which the AKI risk model was developed are shown below.

AKI – Derivation/Validation set	
	Total
	n = 1253
Participant Classification	
FREE STANDING CATH LAB	1 (0.1%)
FREE STANDING CATH LAB/CLINIC	3 (0.2%)
HEALTH SYSTEM/NETWORK	54 (4.3%)
HOSPITAL	1106 (88.3%)
HOSPITAL/HEALTH NETWORK	85 (6.8%)
OTHER	3 (0.2%)
PRIVATE CV PRACTICE	1 (0.1%)
Hospital Location	
RURAL	210 (16.8%)
SUBURBAN	454 (36.2%)
URBAN	589 (47.0%)
Participant Type	
GOVERNMENT	19 (1.5%)
PRIVATE/COMMUNITY	1130 (90.2%)
UNIVERSITY	104 (8.3%)
Teaching Hospital	489 (39.0%)
Public Hospital	654 (52.2%)
Census Region	
MIDWEST REGION	373 (29.8%)
NORTHEAST REGION	166 (13.3%)
SOUTH REGION	467 (37.3%)
WEST REGION	245 (19.6%)
Missing	2

For the additional testing of predictive validity, calibration and test-retest reliability, we used 514343 patients undergoing PCI between 1/12-12/12, of whom 36241(7%) had acute kidney injury and 28,313 underwent a repeat procedure within 2012. A summary of these patients' clinical characteristics (focusing upon those that are predictor variables in the final, full model) are provided in the table below:

Patient Characteristics of NCDR PCI cases in 2012 stratified by occurrence of Acute Kidney Injury				
	Total	aki		
	n = 514343	1 n = 36241	0 n = 478102	P-Value
AKI Risk				
Predicted Risk of AKI by model	0.07271 ± 0.07000	0.14436 ± 0.13635	0.06728 ± 0.05869	< 0.001
AKI Variables				
stemi	92131 (17.9%)	9822 (27.1%)	82309 (17.2%)	< 0.001
nstemi_ua	317867 (61.8%)	21693 (59.9%)	296174 (61.9%)	< 0.001
age	65.0 ± 12.2	68.5 ± 12.4	64.7 ± 12.1	< 0.001
anemia	21243 (4.1%)	4496 (12.4%)	16747 (3.5%)	< 0.001
Intra-aortic balloon pump before procedure	1235 (0.2%)	420 (1.2%)	815 (0.2%)	< 0.001
gfri	77.7 ± 29.3	71.1 ± 53.9	78.2 ± 26.5	< 0.001
prior2weekshf	55771 (10.8%)	9667 (26.7%)	46104 (9.6%)	< 0.001
diabetes	189860 (36.9%)	18256 (50.4%)	171604 (35.9%)	< 0.001
priorhf	63329 (12.3%)	8839 (24.4%)	54490 (11.4%)	< 0.001
priorcvd	64837 (12.6%)	6945 (19.2%)	57892 (12.1%)	< 0.001
priorcardioshock	10538 (2.0%)	3610 (10.0%)	6928 (1.4%)	< 0.001
priorcardiacarrest	10965 (2.1%)	2631 (7.3%)	8334 (1.7%)	< 0.001
History				
IABP Missing (.)	12996 (2.5%) 924	4152 (11.5%) 75	8844 (1.9%) 849	< 0.001
Current/Recent Smoker (w/in 1 year) Missing (.)	143663 (28.0%) 1146	8457 (23.4%) 102	135206 (28.3%) 1044	< 0.001
Hypertension Missing (.)	421405 (82.1%) 992	31426 (86.9%) 87	389979 (81.7%) 905	< 0.001
Dyslipidemia Missing (.)	400612 (78.1%) 1303	27589 (76.4%) 112	373023 (78.2%) 1191	< 0.001
Family History of Premature CAD Missing (.)	125788 (24.5%) 990	6894 (19.1%) 84	118894 (24.9%) 906	< 0.001
Prior MI Missing (.)	155453 (30.3%) 930	11902 (32.9%) 78	143551 (30.1%) 852	< 0.001
priorhf	63329 (12.3%)	8839 (24.4%)	54490 (11.4%)	< 0.001
Prior Valve Surgery/Procedure Missing (.)	7843 (1.5%) 1109	823 (2.3%) 102	7020 (1.5%) 1007	< 0.001
Prior PCI Missing (.)	204846 (39.9%) 912	13291 (36.8%) 78	191555 (40.1%) 834	< 0.001
Prior CABG Missing (.)	92050 (17.9%) 872	7406 (20.5%) 69	84644 (17.7%) 803	< 0.001
Currently on Dialysis Missing (.)	0 (0.0%) 1294	0 (0.0%) 110	0 (0.0%) 1184	
priorcvd	64837 (12.6%)	6945 (19.2%)	57892 (12.1%)	< 0.001
Peripheral Arterial Disease Missing (.)	62900 (12.3%) 1046	6711 (18.6%) 95	56189 (11.8%) 951	< 0.001

Chronic Lung Disease Missing (.)	79608 (15.5%) 1058	7714 (21.3%) 93	71894 (15.1%) 965	< 0.001
diabetes	189860 (36.9%)	18256 (50.4%)	171604 (35.9%)	< 0.001
Cath Lab Visit				
PCI Indication Immediate PCI for STEMI PCI for STEMI (Unstable, >12 hrs from Sx onset) PCI for STEMI (Stable, >12 hrs 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 Missing (.)	 82012 (16.0%) 5174 (1.0%) 2212 (0.4%) 1877 (0.4%) 2655 (0.5%) 276396 (53.8%) 26322 (5.1%) 116781 (22.7%) 914	 8449 (23.4%) 874 (2.4%) 258 (0.7%) 147 (0.4%) 283 (0.8%) 19690 (54.4%) 1182 (3.3%) 5282 (14.6%) 76	 73563 (15.4%) 4300 (0.9%) 1954 (0.4%) 1730 (0.4%) 2372 (0.5%) 256706 (53.8%) 25140 (5.3%) 111499 (23.4%) 838	< 0.001
CAD Presentation No symptom, no angina Symptom unlikely to be ischemic Stable angina Unstable angina Non-STEMI ST-Elevation MI (STEMI) or equivalent Missing (.)	 26698 (5.2%) 11006 (2.1%) 66365 (12.9%) 199308 (38.8%) 118182 (23.0%) 91875 (17.9%) 909	 1538 (4.3%) 734 (2.0%) 2432 (6.7%) 10222 (28.3%) 11442 (31.6%) 9800 (27.1%) 73	 25160 (5.3%) 10272 (2.2%) 63933 (13.4%) 189086 (39.6%) 106740 (22.4%) 82075 (17.2%) 836	< 0.001
Anginal Classification w/in 2 Weeks No symptoms CCS I CCS II CCS III CCS IV Missing (.)	 46254 (9.0%) 16917 (3.3%) 69761 (13.6%) 184126 (35.9%) 195819 (38.2%) 1466	 3863 (10.7%) 839 (2.3%) 3275 (9.1%) 10223 (28.3%) 17924 (49.6%) 117	 42391 (8.9%) 16078 (3.4%) 66486 (13.9%) 173903 (36.5%) 177895 (37.3%) 1349	< 0.001
Anti-Anginal Medication w/in 2 Weeks Missing (.)	369428 (72.0%) 960	26665 (73.7%) 80	342763 (71.8%) 880	< 0.001
prior2weekshf	55771 (10.8%)	9667 (26.7%)	46104 (9.6%)	< 0.001
Cardiomyopathy or Left Ventricular Systolic Dysfunction Missing (.)	56130 (10.9%) 921	7102 (19.6%) 69	49028 (10.3%) 852	< 0.001
Pre-operative Evaluation Before Non-Cardiac Surgery Missing (.)	8187 (1.6%) 972	514 (1.4%) 77	7673 (1.6%) 895	0.006
priorcardioshock	10538 (2.0%)	3610 (10.0%)	6928 (1.4%)	< 0.001
priorcardiacarrest	10965 (2.1%)	2631 (7.3%)	8334 (1.7%)	< 0.001
Pre-PCI Left Ventricular Ejection Fraction Missing	52.1 ± 12.6 153853	46.3 ± 15.1 12536	52.5 ± 12.3 141317	< 0.001
Procedure Information				
Contrast Volume Missing	193.8 ± 87.4 2213	200.9 ± 97.6 174	193.2 ± 86.6 2039	< 0.001
Fluoroscopy Time Missing	15.1 ± 11.9 7990	17.4 ± 13.6 649	14.9 ± 11.7 7341	< 0.001
Outcomes				
Discharge Status Alive Deceased Missing (.)	 507175 (98.8%) 6378 (1.2%) 790	 32313 (89.3%) 3865 (10.7%) 63	 474862 (99.5%) 2513 (0.5%) 727	< 0.001

Primary Cause of Death				< 0.001
Cardiac	4460 (70.1%)	2784 (72.2%)	1676 (67.0%)	
Neurologic	489 (7.7%)	208 (5.4%)	281 (11.2%)	
Renal	68 (1.1%)	60 (1.6%)	8 (0.3%)	
Vascular	71 (1.1%)	46 (1.2%)	25 (1.0%)	
Infection	164 (2.6%)	114 (3.0%)	50 (2.0%)	
Valvular	184 (2.9%)	101 (2.6%)	83 (3.3%)	
Pulmonary	366 (5.8%)	187 (4.8%)	179 (7.2%)	
Unknown	248 (3.9%)	146 (3.8%)	102 (4.1%)	
Other	309 (4.9%)	210 (5.4%)	99 (4.0%)	
Missing (.)	507984	32385	475599	
Myocardial Infarction (Biomarker Positive)	11249 (2.2%)	1354 (3.7%)	9895 (2.1%)	< 0.001
Missing (.)	942	78	864	
Cardiogenic Shock	5893 (1.1%)	2565 (7.1%)	3328 (0.7%)	< 0.001
Missing (.)	933	77	856	
Heart Failure	6419 (1.3%)	2579 (7.1%)	3840 (0.8%)	< 0.001
Missing (.)	940	77	863	
CVA/Stroke	1357 (0.3%)	471 (1.3%)	886 (0.2%)	< 0.001
Missing (.)	942	79	863	
Other Vascular Complications Requiring Treatment	2259 (0.4%)	516 (1.4%)	1743 (0.4%)	< 0.001
Missing (.)	945	78	867	
RBC/Whole Blood Transfusion	13257 (2.6%)	5549 (15.3%)	7708 (1.6%)	< 0.001
Missing (.)	948	78	870	

Continuous variables compared using Student's T-test.
Categorical variables compared using chi-square or Fisher's exact test.

The hospital characteristics from 2012 are shown below:

AKI – 2012 Data	
	Total
	n = 1367
Participant Classification	
FREE STANDING CATH LAB	1 (0.1%)
FREE STANDING CATH LAB/CLINIC	3 (0.2%)
HEALTH SYSTEM/NETWORK	60 (4.4%)
HOSPITAL	1203 (88.1%)
HOSPITAL/HEALTH NETWORK	95 (7.0%)
OTHER	3 (0.2%)
PRIVATE CV PRACTICE	1 (0.1%)
Missing	1
Hospital Location	
RURAL	249 (18.2%)
SUBURBAN	492 (36.0%)
URBAN	625 (45.8%)
Missing	1
Participant Type	
GOVERNMENT	21 (1.5%)
PRIVATE/COMMUNITY	1232 (90.2%)
UNIVERSITY	113 (8.3%)
Missing	1
Teaching Hospital	524 (38.4%)
Missing (.)	1
Public Hospital	530 (38.8%)
Missing (.)	1

Census Region	
MIDWEST REGION	395 (28.9%)
NORTHEAST REGION	182 (13.3%)
SOUTH REGION	521 (38.2%)
WEST REGION	267 (19.6%)
Missing	2

Finding no clear misclassification by test-retest reliability for any assessable risk factor being >3.0% provides strong support for the test-retest reliability of the AKI risk factors assessed.

Assessment of item-level reliability through the Audit Program:

Data elements used in the model were assessed by an audit of 25 hospitals reviewing 627 patients; this assessment was reviewed by an independent contractor hired by ACCF.

At the data elements level, ACCF staff were also able to compare the reported data with those from an independent assessment by a trained abstractor as part of an NCDR audit. Kappas and percentage agreement rates were calculated to support interpretability of these comparisons.

The National Cardiovascular Data Registry® (NCDR®) Audit Program ensures that submitted data are completely and validly collected. A summary of the Audit Program is noted below.

Methodology	• Nationwide program (i.e., all submitting participants in the United States) • Review of data submitted the previous year • Review of a subset of data elements that can rotate each year • Remote review of data combined with couple of onsite visit • Onsite visits are targeted based on the Data Outlier Program • Random selection of sites and records • Blinded data abstraction from medical charts • Inter-rater Reliability Assessment conducted to validate the audit findings • Adjudication step for participant to refute audit findings
Scope	• Review of hospital's medical records for related episodes of care • Assessment of complete submission (Comparison of two lists : hospital list of cases with specific billing codes versus NCDR submitted records)
Criteria for selecting sites/records	Remote audit : • Sites passing their quarterly DQR for 2 quarters within audited year • Sites submitting at least the number of records/sites being reviewed Onsite audit • Sites identified with an outlier and not contacted with the data outlier program
Scoring	NCDR uses a grading system for identifying the amount of agreement or matching between the data captured during the medical record review and data submitted to the NCDR.

The kappa and percentage agreement scores were computed and noted below:

CE #	Variable Name	Kappa	Levels	Agreement

2060	Sex	0.937	3	98.1
4035	Prior PCI	0.872	2	94.4
4045	Prior CABG	0.979	3	99.4
4085	Diabetes Mellitus	0.909	2	96.2
5000	CAD Presentation	0.553	6	69.1
5040	Heart Failure w/in 2 Weeks	0.512	3	92.2
5060	Cardiogenic Shock w/in 24	0.565	3	98.6
5065	Cardiac Arrest w/in 24 Hours	0.446	3	98.1
7020	PCI Status	0.563	4	95.1
7030	Cardiogenic Shock at Start of	0.401	3	97.9

Of the elements that are part of the AKI model that were evaluated in the audit, the agreement between the auditors and that reported in the data collection form exceeded 90% for all but the CAD presentation. The kappas vary, in part, because of the rarity of some of these events. Furthermore, the lowest kappas, such as heart failure and CAD presentation, are often not well documented, independent of the NCDR data collection form, in routine PCI and there may be errors made by either the abstractors, or the data collection system at the hospital.

NCDR's Data Quality Program rotates the review of all the variables in the registry. CathPCI has 263 elements which get reviewed on a 3 year rotating cycle. Unfortunately, NCDR has not audited the critical data elements required to meet this measure given the need to test for the other NQF applications which required many additional data elements. The elements for this measure are slated to be reviewed during the upcoming 2013 audit.
Collectively, we believe that the audit data and repeat procedure data strongly support the reliability of the data elements used in the model.

Validity Testing

Systematic assessment of content validity:
Content validity of this outcome – and the specific definition used in defining AKI – was achieved by the specialized expertise of those individuals who developed this model (including nephrologists, interventional cardiologists, general cardiologists, and outcomes researchers) as well as the structured discussions that the group conducted to examine and vet the risk model. For this particular topic those individuals who were involved in identifying the key attributes and variables for this process measure were leaders and experts in the field of interventional cardiology. Serial phone calls were held to both define the eligible population and given process. These clinical leaders are noted below:

NCDR Clinical Subworkgroup ensured the measure demonstrated an opportunity for improvement, had strong clinical evidence, and was a reliable and valid measure. These members included Drs. Jeptha Curtis (Chair), Frederick Masoudi, John Rumsfeld, Issam Moussa, and David Malenka.

NCDR Scientific Quality and Oversight Committee—a committee that served as the primary resource for crosscutting scientific and quality of care methodological issues. These members included Drs. Frederick Masoudi (Chair) , David Malenka, Thomas Tsai, Matthew Reynolds, David Shahian, John Windle, Fred Resnic, John Moore, Deepak Bhatt, James Tcheng, Jeptha Curtis, Paul Chan, Matthew Roe, and John Rumsfeld.

Lastly the 16 member NCDR Management Board and 31member ACCF Board of Trustees reviewed and approved these measures for submission to NQF.

In summary, we believe that we have a valid risk-adjustment model or a clinically important (and

	modifiable) outcomes that includes numerous patient-level characteristics present prior to the treatment and that can be validly captured with the NCDR Cath/PCI registry. Evidence: A review of matched data obtained from US Medicare beneficiary claims and the US Renal Data System (USRDS) indicated that patients 67 years and older who developed acute kidney injury were 6.7 times more likely to develop end stage renal disease by two years after discharge compared with those who did not experience kidney injury [J Am Soc Nephrol. 2009;20(1):223]. A meta-analysis that included 13 cohort studies demonstrated a higher risk of developing chronic kidney disease and end stage renal disease among patients who developed AKI compared with patients who did not experience AKI [Kidney Int. 2012;81(5):442]. The validity of the AKI definition was assured by selecting the widely accepted Acute Kidney Injury Network (AKIN) definition for Stage 1 or greater injury, defined as a ≥0.3 mg/dL absolute or ≥1.5 fold relative increase in post-PCI creatinine or new initiation of dialysis. Threats to Validity: **Missing Data Bias:** Because of the large amount of data typically contained in registries, it is not feasible to meet the stringent requirements used in clinical trials. However, unlike with administrative claims data, data fields in a registry must be assessed for completeness, consistency, and accuracy to support the central activities of the registry. The NCDR Data Quality Program consists of 3 main components: data completeness, consistency, and accuracy. Completeness focuses on the proportion of missing data within fields, whereas consistency determines the extent to which logically related fields contain values consistent with other fields. Accuracy characterizes the agreement between registry data and the contents of original charts from the hospitals submitting data. The thresholds for all critical elements in a performance measure are set high to ensure data completeness and consistency for the overall calculation of the performance measure. Therefore it is unlikely missing data bias would threaten the validity properties. **Selection Bias:** Based on the entity and patient descriptive statistics, there does not appear to be certain subgroups of hospitals or patients who are excluded. Lastly, the exclusion frequencies did not appear to be unusually high.
Risk Adjustment	NCDR is proposing a risk-adjusted peri-procedural AKI outcome measure to help assess the quality and safety of PCI. However, it is noteworthy that we included age in the risk-adjustment model because even after adjusting for GFR, age is significantly associated with AKI. Importantly, if the predicted risk is to be used prospectively to improve the rates of AKI avoidance strategies, it is important that clinicians know the true expected AKI risk for each and every patient. ***Describe the conceptual/clinical and statistical methods and criteria used to select patient factors used in the statistical risk model or for stratification by risk*** There was an extensive process to develop the face and contact validity of the measure. After settling on the outcome definition and candidate variables through serial conference calls with the expert panel, categorical variables were summarized as frequencies and percentages and compared with Pearson chi-squared tests. Continuous variables were summarized as medians (interquartile range) and compared using Wilcoxon rank-sum tests. Ordinal variables were tested using a chi-square test based on the rank of the group mean score. Candidate variables included those present at the start of the PCI procedure, and not variables such as contrast load, that are under the control of the operator. The full list of candidate variables included: Age, Gender, BMI, IABP Before Procedure, baseline CKD status (mild =eGFR 45-60, moderate =30-45, severe <30

ml/min per 1.73m^2), HF within the prior 2 weeks, Diabetes, Hypertension, Prior MI, Prior HF, Prior PCI, Prior CABG, Prior CVD, Prior PAD, CLD, NSTEMI/Unstable Angina, STEMI, Prior Shock, Prior Cardiac Arrest, Anemia (Hgb<10), Multiple procedures, and Transfer-in Status. Missing categorical variables were imputed to the most common value, and missing continuous variables were imputed to relevant group-specific medians.

The study population was then randomly split into a development sample consisting of 70% of PCI procedures and a validation sample consisting of the remaining 30% of admissions. Baseline patient characteristics and variables from diagnostic catheterization were considered candidate variables. Missing values were imputed to the lower risk group for discrete variables and replaced with gender-specific medians for body mass index (BMI), gender and renal failure/dialysis-specific medians for estimated glomerular filtration rate, median value for hemoglobin, and congestive heart failure (CHF)/cardiogenic shock/prior myocardial infarction (MI)-specific medians for ejection fraction. We used logistic regression with backward selection with a 'stay' criterion of $p<0.05$ to develop a model predicting acute kidney injury . Variables that showed non-linear associations with the outcome were transformed using splines.

We developed a full post-PCI AKI model using all potential predictive variables. We then reduced the set of predictor variables by ranking variables by the strength of their association with AKI and sequentially removing the least important ones until the adjusted R^2 of the model reached 95% of the full model. We confirmed minimal loss of discriminatory power by examining the integrated discrimination improvement (IDI) and the difference in c-statistics between the full and reduced models. he IDI comparing the full to reduced AKI model was 0.0024. We also developed a risk prediction score by taking the regression coefficients from the pre-procedure model and assigning them an integer that was weighted to the comparative odds ratio associated with the risk factors. While this score is not proposed as a performance measure, we mention it here to show that a tool exists that can be used by hospitals to estimates each individual patient's AKI risk as a means with which to increase the safety of their PCI performance. Calibration plots were used to access goodness of fit. A p-value <0.05 was considered statistically significant. All statistical tests were two-sided. All statistical analyses were performed using SAS software (version 9.2, SAS Institute, Cary, NC).

Bivariate analyses were done to identify candidate variables that differed significantly between those with and without a clinically important AKI. Multivariable, hierarchical logistic regression analyses were then performed to retain those with a statistically significant association withAKI ($p<0.05$ for each).

Describe the method of testing/analysis used to develop and validate the adequacy of the statistical model or stratification approach:

We developed the model in the 70% derivation set and tested its discrimination and calibration (using both the Hosmer-Lemeshow test and the slope of the predicted vs. observed risk). We then replicated this in 2 separate data sets; 30% of the original sample from 6/09-7/11 and in a completely unique set of data from 2012 (see above). To address potential secular trends in AKI rates, we explored recalibrating the model with a new intercept (no change to the β-weights) each year, as was done for 2012 data.

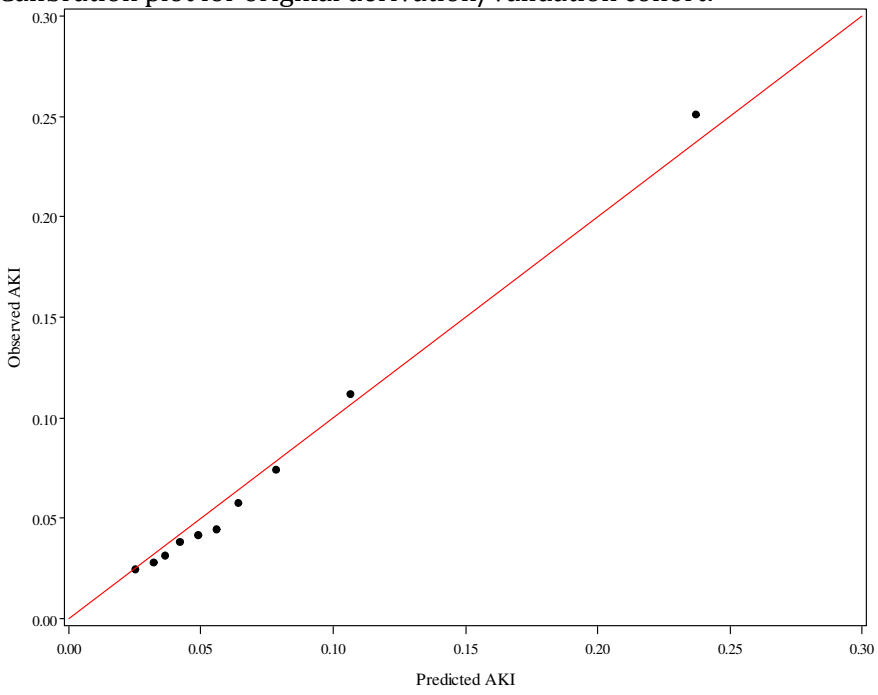
Statistical Risk Model Discrimination Statistics:

The c-statistic is 0.72, which means that the probability that predicting the outcome is better than chance. This method is used to compare the goodness of fit of logistic regression models. The range is between 0.5 to 1.0. A value of 0.5 indicates that the model is no better than chance at making a prediction of membership in a group and a value of 1.0 indicates that the model perfectly identifies those within a group and those not. Models are typically considered reasonable when

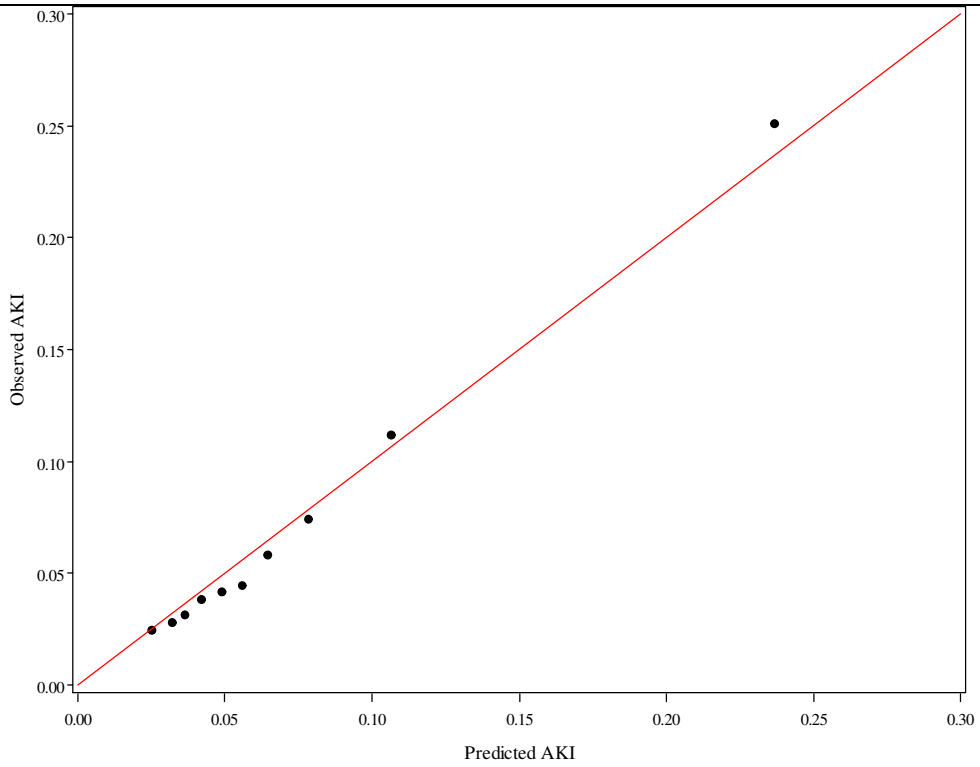
the C-statistic is higher than 0.7. (Hosmer & Lemeshow, 2000). Amongst important subgroups, the c-statistics were well preserved: STEMI (c-statistic = 0.74); Men (c-statistic = 0.71); Women (c-statistic = 0.72); Age>70 (c-statistic = 0.72) and diabetic patients (c-statistic = 0.727).

Statistical Risk Model Calibration Statistics:
Before recalibrating the model to the 2012 data the slope of the calibration line was 1.06 (p<.001) indicating that the relationship between the independent variables in our model and the AKI outcome remained consistent, and the intercept of the line was .1223 (p<..001) indicating that the AKI rate has increased since the model was developed.

Statistical Risk Model Calibration – Risk decile plots or calibration curves:
Calibration plot for original derivation/validation cohort:

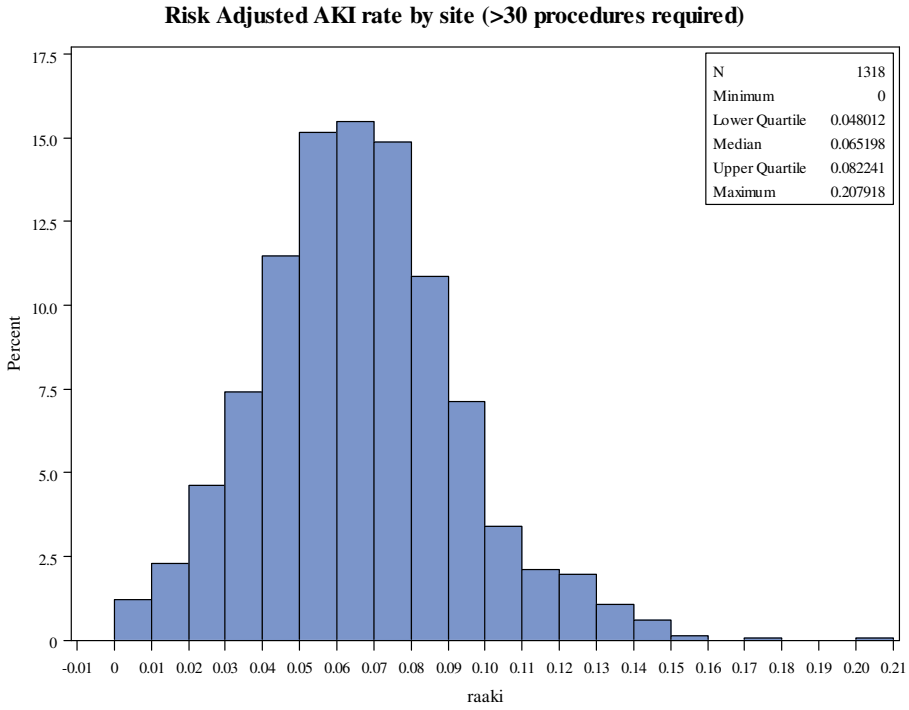


The calibration plot in the2012 sample is shown below:

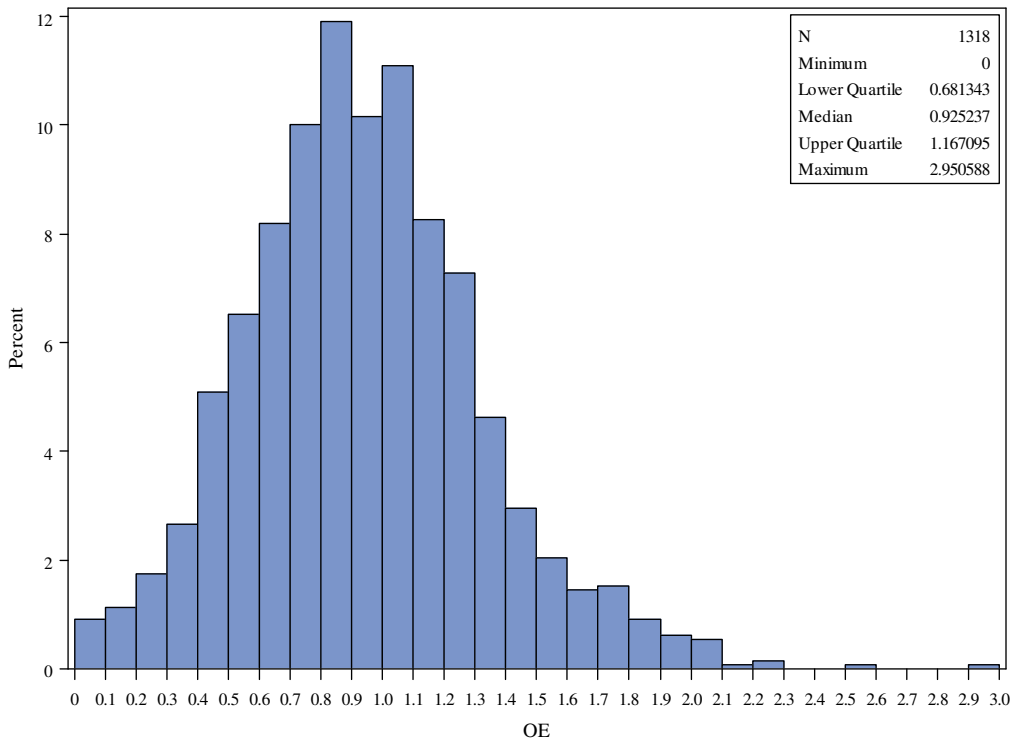


Results of Risk Stratification Analysis:

The risk stratification was able to adequately segregate deciles of risk from <5.6% to >9% at the patient level. At the hospital level, we observed a broad range of adjusted risk (0% to >20%) as shown below:



The distribution of sites' observed/expected ratios are shown below:



Interpretation of the results in terms of demonstrating adequacy of controlling for differences in patient characteristics (case mix):

We believe that our AKI model performs very well to adjust for patient characteristics present prior to the conduct of PCI and is able to discriminate well across a wide variety of important clinical subsets of patients. Moreover, there is substantial hospital variation before and after risk-adjusting for patient characteristics. The distribution of hospitals' O/E ratios show that there are some sites with excellent performance and others with AKI rates that are 80% or greater than expected. A quarter of sites have a 17-300% greater observed AKI rate than would be expected based upon patients' risk factors. These would be sites where substantial opportunities to improve patient safety likely exist. Examination of their hydration procedures and contrast doses would be ideal initial efforts to improve the safety of PCI.

A meaningful difference is one that indicates the potential for improvement in comparison to others. There are no absolute levels of AKI risk that are significant, as compared with others. The average, adjusted AKI rate was 6.5% and the upper quartile ranges from 8.2 to 20.8% of patients having AKI. Given an average PCI volume of 410 cases/hospital, this suggests between 7 and 59 extra patients having AKI per year among hospitals in the upper quartile as compared with the average hospital. Clinically, this is a large number of events, particularly given that there are readily applied interventions, such as hydration and contrast reduction through the avoidance of LV grams or staging of procedures, to mitigate AKI.

We believe that the use of this model to identify outliers and the ability to pre-procedurally risk stratify patients and tailor therapy to risk holds great promise for improving the quality and safety of PCI.