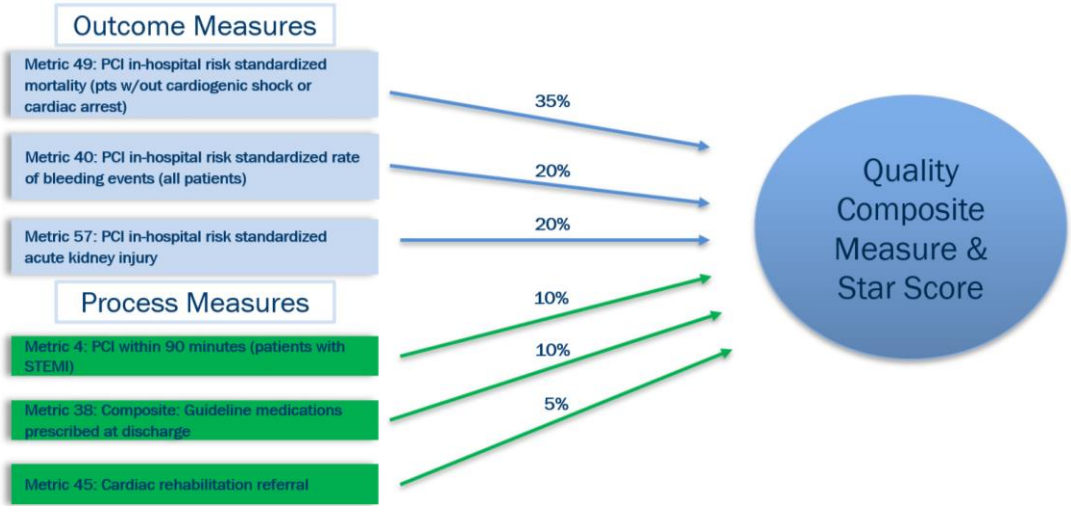
Measure #4580 Tables and Figures Contents

1.18a Attach Measure Score Calculation

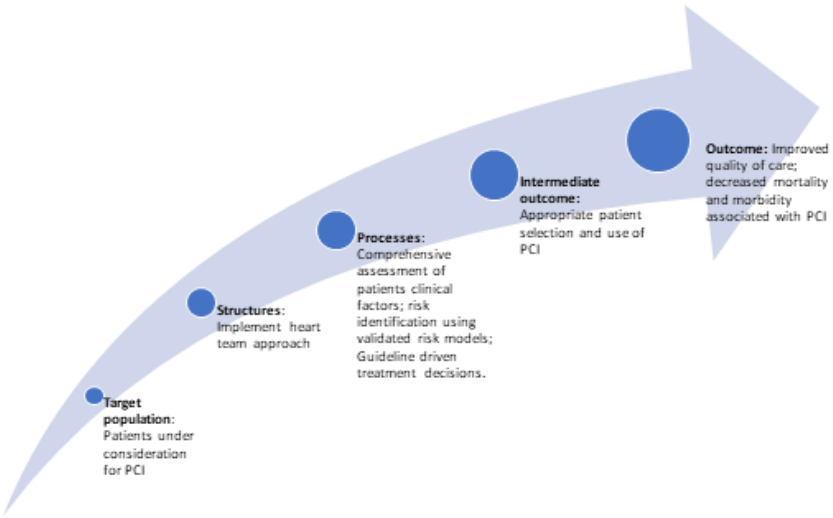
Figure 1



2.1 Attach Logic Model

Figure 2

Implementing structures (e.g., the heart team approach), effective processes such as comprehensive, personalized risk assessment and treatment decisions based on clinical evidence paired with the individual patient's risk factors and choice can lead to appropriate patient selection and use of PCI and decreased mortality and morbidity in the PCI patient population. The evidence to support this logic model is outlined in Section 2.2.



2.4 Performance Gap

A significant performance gap continues to exist in the quality care for patients undergoing a PCI.

The tables and figures below illustrate the distribution of the PCI Quality of Care Composite by two time periods of observation: 2022 (Table 1) and 2021 (Table 2). Included is the model performance for both 2021 and 2022 calendar years.

As illustrated in Table 1, with the more contemporaneous data, the median composite score was 84.20% with an interquartile range of 80.74% and 87.44%. The minimum and maximum values were 49.77% and 95.63%, respectively, **suggesting a wide gap in performance**. The distribution was left skewed such as that the majority of hospitals scored between 80% to 100% on the PCI Quality of Care Composite measure, illustrating significant room for improvement, especially for the 800 hospitals that were below the median performance.

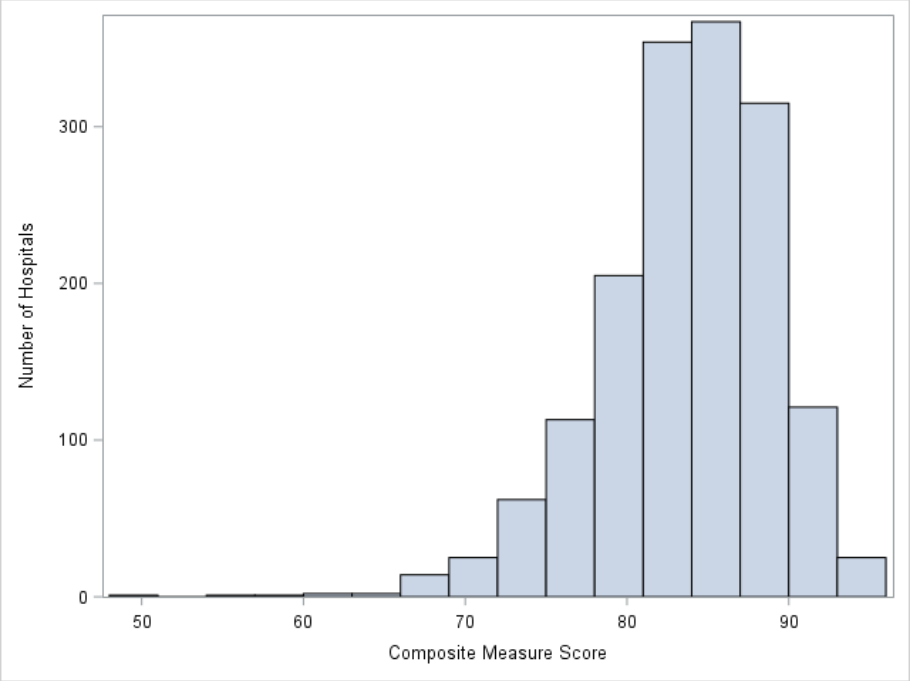
Overall

Table 1. Distribution of Hospital Composite Score (2022)

Description	Composite Measure Score
N	1608

Mean	83.63
Std Deviation	5.36
100% Max	95.63
99%	93.58
95%	90.98
90%	89.81
75% Q3	87.44
50% Median	84.20
25% Q1	80.74
10%	76.80
5%	73.60
1%	68.36
0% Min	49.77

Figure 3: Distribution of Composite Measure scores (2022)



In 2021, the median composite score in 2022 was 85.33% with an interquartile range of 80.99% and 88.40%. The distribution was similar across both years of observation.

Table 2. Distribution of Hospital Composite Score (2021)

Description	Composite Measure Score
N	1583
Mean	84.37
Std Deviation	5.63
100% Max	96.79
99%	94.58
95%	91.85
90%	90.57
75% Q3	88.40
50% Median	85.33
25% Q1	80.99
10%	76.81
5%	74.50
1%	66.24
0% Min	55.00

Figure 4: Distribution of Composite Measure scores (2021)

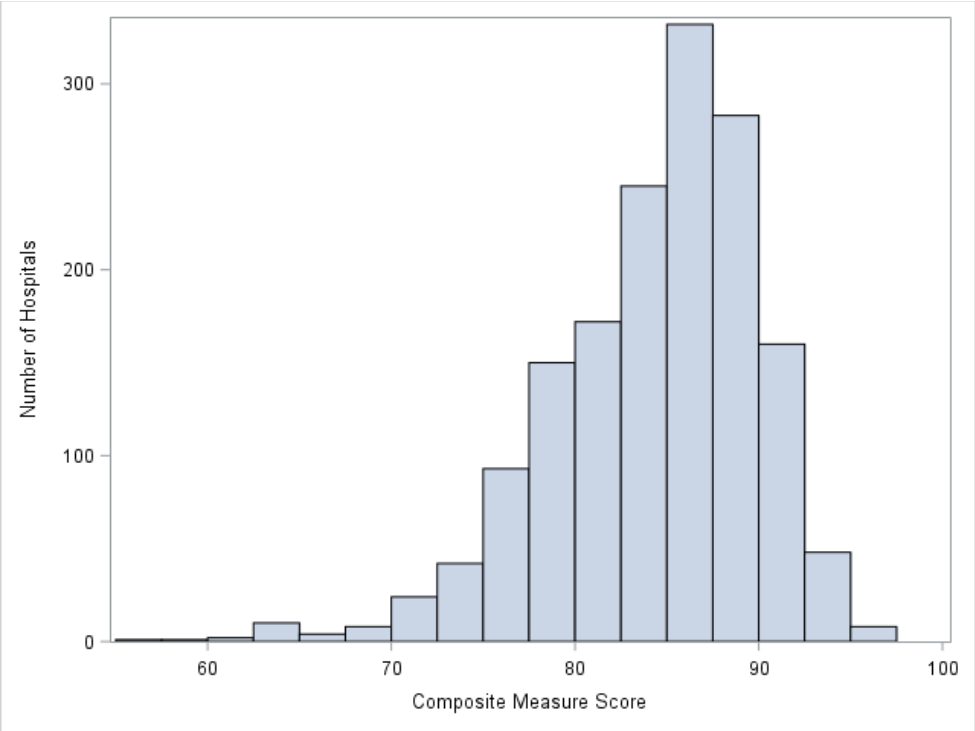


Table 3:

Below depicts a distribution of hospital performance scores (using 2022 data) into deciles.

Description	Overall	Min	Decile 1	Decile 2	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10	Max
Mean Composite Score	83.63	49.77	72.76	78.29	80.67	82.25	83.57	84.84	86.19	87.43	88.83	91.47	95.63
Entities	1608	1	160	161	161	161	161	161	161	161	161	160	1

4.1.3 Characteristics of Measured Entities

The overall measured entities, following the application of exclusion criteria, were as follow (defined in Table 4 &5):

Table 4. Entities Evaluated by Level of Analysis (2022 Data)

Level of Analysis	Variable	Data Source	Number
Patient	Patient Hospital Stay	NCDR CathPCI Registry	641,629
Hospital	Facilities	NCDR CathPCI Registry	1,608

Table 5. Entities Evaluated by Level of Analysis (2021 Data)

Level of Analysis	Variable	Data Source	Number
Patient	Patient Hospital Stay	NCDR CathPCI Registry	655,804
Hospital	Facilities	NCDR CathPCI Registry	1,583

We did not use a sample of data for this measure; rather, we include all available data meeting inclusion criteria. Please refer to Table 6 and 7 for a description of hospital characteristics.

Table 6. Hospital Characteristics for 2022 Data

Characteristics	Number of Patients	%
Participant Census Region	*	*
Midwest Region	169143	24.56
Northeast Region	121804	17.69
South Region	289362	42.01
West Region	108411	15.74
Hospital Location	*	*
Rural	95494	13.87
Suburban	236544	34.35
Urban	356658	51.79
Participant Type	*	*
Government	9075	1.32
Private/Community	600910	87.25
University	78622	11.42
Certified Bed Number: Mean, SD	434.37	269.99
Public Hospital	*	*
No	383813	55.73
Yes	304796	44.26
Hospital Volume: Mean (SD)	717.80	498.84

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Table 7. Hospital Characteristics for 2021 Data

Characteristics	Number of Patients	%
Participant Census Region	*	*
Midwest Region	177514	25.24
Northeast Region	120744	17.17
South Region	293557	41.75
West Region	111360	15.84
Hospital Location	*	*

Rural	99108	14.09
Suburban	239198	34.02
Urban	364869	51.89
Participant Type	*	*
Government	9017	1.28
Private/Community	613073	87.19
University	81085	11.53
Certified Bed Number: Mean, SD	435.49	274.50
Public Hospital	*	*
No	389790	55.43
Yes	313269	44.55
Teaching Hospital	*	*
No	336766	47.89
Yes	366409	52.11
Hospital Volume: Mean (SD)	747.01	530.01

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The tables below (8 & 9) illustrate the development of the study sample (denominator) as exclusions were applied by number of patients and facilities. The majorities of patients and facilities excluded were due to being outside of the measurement period and for not coded as PCI procedures. There were no exclusions related to sample size.

Table 8. Measure Exclusions (2022 Data)

Exclusions	Number of Patients	% of Patients	# of facilities	% of facilities
Initial Sample	5,194,148	*	1833	*
Discharges not between 01/01/2022 and 12/31/2022	4210214	81.06	148	8.07
Remaining	983934	*	1685	*
Without PCI	336491	34.20	16	0.95
Remaining	647443	*	1669	*
Not first PCI during the stay	0	0.00	0	0.00
Remaining	647443	*	1669	*
Not all 6 metrics reported	5814	0.90	61	3.65
Study Cohort	641629	*	1608	*

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Table 9. Measure Exclusions (2021 Data)

Exclusions	Number of Patients	% of Patients	# of facilities	% of facilities
Initial Sample	5194148	*	1833	*
Discharges not between 01/01/2021 and 12/31/2021	4162510	80.14	155	8.46

Remaining	1031638	*	1678	*
Without PCI	370394	35.90	16	0.95
Remaining	661244	*	1662	*
Not first PCI during the stay	0	0.00	0	0.00
Remaining	661244	*	1662	*
Not all 6 metrics reported	5440	0.82	79	4.75
Study Cohort	655804	*	1583	*

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4.1.4 Characteristics of Units of the Eligible Population

The tables provided below (10 & 11) illustrate the demographic, clinical history, and clinical indicators of patients at the time of procedure in the PCI Quality of Care composite measure. Considering the 2022 data, the mean age was 67.2 years (SD: 11.7 years), the majority were male (69.4%), and the majority were white (83.3%). In terms of clinical history, a high proportion of patients had diabetes (42.0%) and underwent a prior PCI procedure (39.3%). Clinical instability was noted to be urgent in 37.3% of patients and elective in 40.3% of patients.

Table 10. Baseline characteristics of patients (2022 Data)

Description	Total # of Patients	% of Patients
ALL	688720	100.00
Demographics	*	*
Age: Mean (SD)	67.15	11.67
Female	210688	30.59
Race	*	*
White	573874	83.32
Black	58798	8.54
Other	56048	8.14
History and Risk Factors	*	*
Cerebrovascular disease	104201	15.13
Peripheral Arterial Disease	78775	11.44
Chronic Lung disease	106693	15.49
Prior MI	187402	27.21
Previous PCI	270427	39.27
Diabetes	289316	42.01
CKD	*	*
0<=GFR<15 or dialysis	25842	3.75
15<=GFR<29	17712	2.57
30<=GFR<45	58960	8.56
45<=GFR<60	112449	16.33
GFR>60	459903	66.78
Other	13854	2.01
CSHAScale	*	*
None (1 to 4)	522788	75.91
Intermediate (5 or 6)	133164	19.33

Severe (7 to 9)	31342	4.55
Aortic Stenosis	17450	2.53
Ejection fraction percentage	*	*
Unknown	189532	27.52
Mean (SD)	50.92	13.32
Systolic Blood Pressure	*	*
NA or Missing	3992	0.58
Mean, SD	148.83	26.57
STEMI	120970	17.56
Clinical Instability	*	*
Elective PCI and No CI	277430	40.28
Urgent PCI and No CI	256909	37.30
Emergency PCI and No CI	105926	15.38
CI	47235	6.86
Other	1220	0.18
NYHA Class	*	*
Class IV	19036	2.76
Class I/II/III	170954	24.82
No CHF	498730	72.41
In-stent thrombosis	2168	0.31
Highest risk lesion -- Segment category	*	*
Other	129409	18.79
pRCA/mLAD/pCIRC	380840	55.30
pLAD	147967	21.48
Left Main	30504	4.43
Number of diseased vessels	*	*
0	3656	0.53
1	360014	52.27
2	202996	29.47
3	119163	17.30
Chronic total occlusion	28906	4.20
Surgical Turndown	28850	4.19

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Table 11. Baseline characteristics of patients (2021 Data)

Description	Total # of Patients	% of Patients
ALL	703175	100.00
Demographics	*	*
Age: Mean (SD)	66.90	11.73
Female	215509	30.65
Race	*	*
White	588554	83.70
Black	60217	8.56
Other	54404	7.74
History and Risk Factors	*	*
Cerebrovascular disease	105314	14.98
Peripheral Arterial Disease	82069	11.67

Chronic Lung disease	109642	15.59
Prior MI	191956	27.30
Previous PCI	279410	39.74
Diabetes	294586	41.89
CKD	*	*
0<=GFR<15 or dialysis	26632	3.79
15<=GFR<29	18309	2.60
30<=GFR<45	60120	8.55
45<=GFR<60	114373	16.27
GFR>60	469434	66.76
Other	14307	2.03
CSHAScale	*	*
None (1 to 4)	539727	76.76
Intermediate (5 or 6)	131231	18.66
Severe (7 to 9)	30404	4.32
Aortic Stenosis	17379	2.47
Ejection fraction percentage	*	*
Unknown	182904	26.01
Mean (SD)	51.02	13.30
Systolic Blood Pressure	*	*
NA or Missing	3732	0.53
Mean, SD	148.63	26.59
STEMI	123262	17.53
Clinical Instability	*	*
Elective PCI and No CI	279611	39.76
Urgent PCI and No CI	264514	37.62
Emergency PCI and No CI	109337	15.55
CI	48401	6.88
Other	1312	0.19
NYHA class	*	*
Class IV	21050	2.99
Class I/II/III	168279	23.93
No CHF	513846	73.08
In-stent thrombosis	2229	0.32
Highest risk lesion -- Segment category	*	*
Other	131812	18.75
pRCA/mLAD/pCIRC	392076	55.76
pLAD	149538	21.27
Left Main	29749	4.23
Number of diseased vessels	*	*
0	3627	0.52
1	364306	51.81
2	208400	29.64
3	123616	17.58
Chronic total occlusion	29549	4.20
Surgical Turndown	27214	3.87

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4.2.2 Method(s) of Reliability Testing

Assessment of reliability of the data collection at the patient level

This composite measure involves the data collection of 108 data elements. The numerator, denominator and exclusion criteria are listed above for each component measure in section "Numerator Details", "Denominator Details", and "Denominator Exclusions Details". The registry data dictionary is also attached to this application and can be used to crosswalk Table 12 with the data elements listed in the above sections for full transparency. The 108 data elements are listed in Table 12. We provide audit results from two years of registry audits, 2022 and 2021. There are two columns within Table 12 labelled Agreement rate. This column indicates how closely the audited data was consistent with the original submitted data.

In total, the composite measure requires 108 unique data elements from the CathPCI registry, 85% (92 data elements) of these data elements have recently been included in data audits. The remaining 15% (16 data elements) will be included in next year's audit program. The reliability results from the audit indicate consistency and reliability for the significant portion of data elements used in the measure. For the few data elements that do not have high agreement rates, we will focus on including these data elements in education initiatives for improving the accuracy of data collection for our participating hospitals. We anticipate the consistency of data capture will improve over time as focused education efforts are made towards that goal. We have successfully achieved this goal for other measures in the past.

Steps used reliability testing of data at the patient level

For the audit of 2022 data, eight hospitals from the pool of 100 audited hospitals were randomly selected to ensure that the auditors were abstracting the data consistently. Five records from each of the selected facilities for a total of 40 records were evaluated. The audit vendor assigned the records from each facility to another nurse for re-abstraction of data. The re-assignment was such that each nurse was represented at least one in the inter-rater reliability assessment audit (IRRA) on either the original abstraction or the re-abstraction. The IRRA involved both new and experienced nurses responsible for data abstraction. The datasets from the two auditors were then compared to detect if there was miscoding or a need to re-train the auditors.

Statistical analysis used

Agreement rate can be interpreted as follows based on the data assessed:

- Exceeds Expectations: agreement rate ≥ 93%
- Meets Expectation: agreement rate 85% - 93%
- Needs Improvements: agreement rate < 85%

A 95% confidence interval was calculated for each PABAK statistic to reflect sampling error and indicate a range of plausible values for the PABAK statistic for discrete variables.

General interpretation of the PABAK statistic is similar to the KAPPA.

PABAK score:	Interpretation
0.00	Poor agreement
0.01-0.20	Slight agreement

0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-1.00	Almost perfect agreement

Pearson correlation coefficients were calculated for continuous variables. These results are listed in bold and italicized.

Pearson Correlation Coefficient	**Interpretation**
0.70 - 1.0	Strong linear relationship
0.50 - 0.70	Moderate linear relationship
0.30 - .50	Fair linear relationship
< 0.30	Poor linear relationship

To assess reliability of the composite, we examined the extent to which one time period of evaluation (2021) compared to a different time period of evaluation (2022). That is, we took a 'test-retest' approach in which hospital performance is measured using 2021 data, then again measured using 2022 data, and calculated the agreement of the two resulting performance measures across hospitals. As a metric of agreement, we calculated the intra-class correlation coefficient.

We used test-retest reliability for the PCI Quality of Care Composite as it is an assessment of the stability and consistency of a measurement over time, mitigating the impact of random measurement errors. Through using this split-sample approach, we could average a series of reliability estimates calculated from many resamples of the data without replacement to obtain a more stable reliability estimate. (1)

1. Nieser, K. J., & Harris, A. H. (2024). Split-sample reliability estimation in health care quality measurement: Once is not enough. Health Services Research. doi: https://doi.org/10.1111/1475-6773.14310

4.2.3 Reliability Testing Results

The results from the third-party reliability testing are included in Table 12.

(Separate attachment)

4.3.3 Method(s) of Validity Testing

Patient and/or encounter level validity testing

One hundred randomly selected hospitals were chosen to participate in an audit of the 2022 CathPCI Registry data, this was repeated for 2021 data. Sites with a minimum of ten baseline records during the audit period were selected were randomly selected for abstraction. Trained nurse auditors re-abstracted preselected data elements from the medical record and these results were compared against the original registry data submitted for that procedure.

Agreement rate can be interpreted as follows based on the data assessed:

- Exceeds Expectations: agreement rate ≥ 93%
- Meets Expectation: agreement rate 85% - 93%
- Needs Improvements: agreement rate < 85%

A 95% confidence interval was calculated for each PABAK statistic to reflect sampling error and indicate a range of plausible values for the PABAK statistic. General interpretation of the PABAK statistic is similar to the KAPPA:

PABAK Interpretations:	
0.00	Poor agreement
0.01-0.20	Slight agreement
0.21-0.40	Fair agreement
0.41-0.60	Moderate agreement
0.61-0.80	Substantial agreement
0.81-1.00	Almost perfect agreement

Pearson Correlation Coefficients were also calculated for continuous variables.

Pearson Correlation Coefficient	**Interpretation**
0.70 - 1.0	Strong linear relationship
0.50 - 0.70	Moderate linear relationship
0.30 - .50	Fair linear relationship
< 0.30	Poor linear relationship

Face validity testing

Each measure submitted to a consensus-based entity for public reported from by the ACC undergoes extensive discussion and review. This composite measure was created by a joint effort between NCDR's Public Reporting Advisory Group (PRAG) and NCDR's Measure and Reporting Methodology (MRM) committee. As part of the development process the MRM met to discuss each decision within the development process. This included discussing the merits of each proposed component measure. The members voted and reached consensus to include the six included. MRM also reviewed the specific weighting for the component measures and reviewed results on P score thresholds would affect the overall star scoring. These star rating distributions were discussed by the MRM until the final proposed measure received unanimous approval. After voting, the measure goes through a 30-day public comment period. The responses are available if requested. Once the public comment period is completed, any comments are discussed by MRM and voted on once again. If the committee passes the measure, it is recommended for review by the Clinical Science and Quality Committee (CSQC). This committee voted to approve this measure for implementation in the CathPCI registry and for use in public reporting. Throughout the process, the CathPCI Registry Steering Committee provided strategic direction for the registry and ensuring that this measure submitted for endorsement meets key criterion such as reliability, feasibility, and that there is compelling

evidence base behind the development and implementation of this measure. A summary of this process is below.

- CathPCI registry steering committee provides strategic direction for future registry measures based on current evidence.
- NCDR Measures and Reporting Methodology committee creates a measure development plan.
- Yale Center for Outcomes Research and Evaluation (CORE) conducts analysis using past NCDR data.
- MRM reviews the results of the analysis and votes to approve or to run further analysis.
- 30-day public comment period is opened after MRM approval.
- Comments are reviewed by the MRM and, if necessary, the measure is changed in response to feedback. If no changes, this measure is considered approved by the MRM.
- The NCDR CSQC provides final review of the measure. The committee voted to approve this measure for implementation as a test metric for 1 year and then review the data.

In summary, face validity testing was accomplished by expert consensus, measure development that is led by those that will be measured (cardiologists), extensive committee review and comments from the public.

MRM: The Measure and Reporting Methodology committee is a designated set of experts that oversees this application. Prior to submission, it ensures there is variation in care, disparities data, and that the measure is a true reflection of quality care at a particular site and can also be used to improve quality. This committee made up of physicians with a background in measure development and statistics and, most importantly, made up of those that will directly be measured.

CSQC: NCDR Clinical Science and Quality is an ACC leadership committee that serves as the primary resource for crosscutting scientific and quality of care methodological issues. This committee ensures the metrics are consistent across registries. They also reviewed and approved the methodology and results of this measure.

Data Element:

The NCDR Data Quality Program ensures that data submitted to the NCDR are complete and validly collected. 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. Before entering the Enterprise Data Warehouse (EDW), all submissions are scored for file integrity and data completeness, receiving 1 of 3 scores that are transmitted back to facilities using a color-coding scheme. A “red light” means that a submission has failed because of file integrity problems such as excessive missing data and internally inconsistent data.

Such data are not processed or loaded into the EDW. A “yellow light” status means that a submission has passed the integrity checks but failed in completeness according to predetermined thresholds. Such data

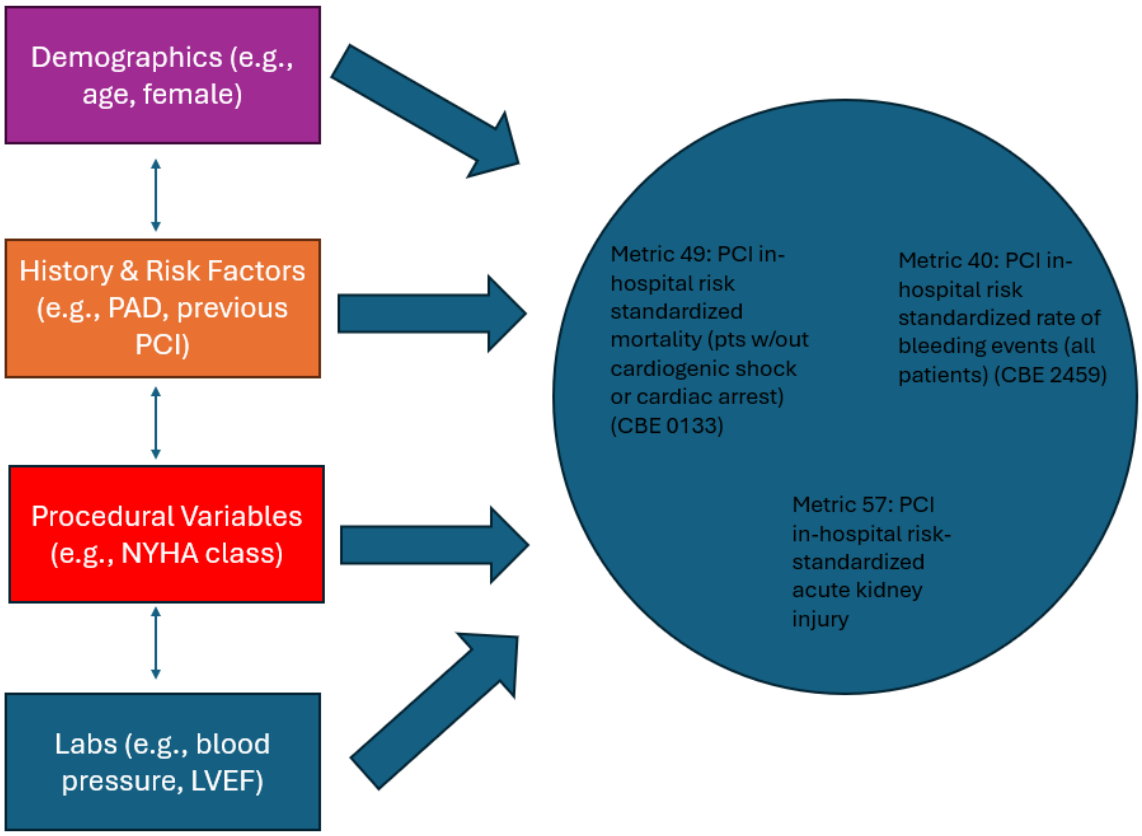
are processed and loaded into the EDW but are not included in any registry aggregate computations until corrected. Facilities are notified about data submission problems and provided an opportunity to resubmit data. Finally, a “green light” means that a submission has passed all integrity and quality checks. Such submissions are loaded to the EDW. After passing the DQR, data are loaded into a common EDW that houses data from all registries and included for all registry aggregate computations. In a secondary transaction process, data are loaded into registry-specific, dimensionally modeled data marts. A summary of the Program is noted under Table 13.

Table 13. Data Quality Program Overview

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 Data Quality Report 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.

4.4.2. Conceptual Model Rationale

Figure 5



4.4.3 Risk Factor Characteristics Across Measured Entities

The table below includes a description of hospital and patient characteristics for the mortality model For example, this illustrates the number of patients that represent diverse race/ethnicity is 21.8%.

Table 14. Selected Characteristics

Description	#	%
ALL	654127	100.00
Age>=65		
No	257090	39.30
Yes	397037	60.70
Female		
No	453631	69.35
Yes	200496	30.65
RACE		
Hispanic	46457	7.10
White non-Hispanic	511205	78.15
Black non-Hispanic	55002	8.41

Other	41463	6.34
Medicare		
No	282691	43.22
Yes	371436	56.78
Medicaid		
No	567602	86.77
Yes	86525	13.23
Dual Eligibility		
No	616215	94.20
Yes	37912	5.80
Hospital % Non-White		
Q1 (0.00% to 5.97%)	136837	20.92
Q2 (>5.97% to 14.46%)	181992	27.82
Q3 (>14.46% to 32.24%)	185208	28.31
Q4 (>32.24%)	150090	22.95
Hospital % Dual		
Q1 (0.00%)	129511	19.80
Q2 (>0.00% to 4.37%)	170869	26.12
Q3 (>4.37% to 9.60%)	192465	29.42
Q4 (>9.60%)	161282	24.66

4.4.4a Attach Risk Adjustment Modeling and/or Stratification Specifications

Table 15: Mortality model variables

Variable	***Variable Type***	***Elements***
Age Splines: Age <=45 Age >45	Number	DOB (2050) and Arrival Date/Time (3001)
Female	Boolean (yes or no)	Sex (2060)
Cerebrovascular Disease	Boolean (yes or no)	Cerebrovascular Disease (4551)
Peripheral Arterial Disease	Boolean (yes or no)	Peripheral Arterial Disease (4610)
Chronic Lung Disease	Boolean (yes or no)	Chronic Lung Disease (4576)
Prior PCI	Boolean (yes or no)	Prior PCI (4495)
Diabetes Mellitus	Boolean (yes or no)	Diabetes Mellitus (4555)
Severe Frailty	Boolean (yes or no)	CSHA Clinical Frailty Scale (4561) = one of the following: severely frail, very severely frail or terminally ill *and none* of the following:

		Cardiogenic Shock (7415), or Refractory Cardiogenic Shock (7415) or Salvage PCI (7800)
NYHA: No HF (reference) NYHA IV NYHA I, II, III	Categories	NYHA Class (4011)
CKD Stage: GFR 0-14 or dialysis GFR 15-29 GFR 30-44 GFR 45-60 Other (reference)	Categories	eGFR = 141 X min(SCr/κ, 1)^α X max(SCr /κ, 1)^(-1.209) X 0.993^Age X 1.018 [if female] X 1.159 [if Black]; κ = 0.7 (females) or 0.9 (males), α = -0.329 (females) or -0.411 (males). (2050, 3001, 2060, 2071, 6050) Currently on Dialysis (4560)
Left Ventricular Ejection Fraction (LVEF) splines: LVEF <= 55 LVEF > 55 LVEF (not measured – Imputed value)	Number for the first two and binary for the last one	Ejection Fraction (7061) ***and*** if missing then use (5116) If not measured value imputed as the median of LVEF in the stratified groups by heart failure, myocardial infarction, and shock
Systolic Blood Pressure (SBP) splines: SBP < 90 SBP 90-180 SBP > 180	Number	Systolic Blood Pressure (6016)

PCI Status and Clinical Instability	Categories	Six mutually exclusive groups: 1. Salvage PCI (7800) or Refractory Shock (7415) (excluded) 2. Cardiogenic Shock (7415) without Salvage PCI (7800) (excluded) 3. Cardiovascular instability* without shock (7415) *or* salvage PCI (7800) 4. Emergency PCI (7800) without shock or cardiac instability*(7415) 5. Urgent PCI (7800) without shock *or* cardiovascular instability* (7415) 6. Elective PCI (7800) without shock *or* cardiovascular instability* (7415), reference group 7. Other, reference group
*	*	* Cardiovascular Instability defined as 7415 = Cardiovascular Instability Type of Hemodynamic instability, or Acute Heart Failure Symptoms, or Ventricular arrhythmia; but without shock.
Aortic Stenosis	Boolean	Valvular disease stenosis type (7450) = aortic stenosis and Stenosis severity (7451) = moderate *or* severe
Surgical Turndown	Boolean	CV treatment decision (7816) = surgery not recommended
ST-segment elevation MI	Boolean	

		Percutaneous Coronary Intervention Indication (7825) = *any* of the following: STEMI - Immediate PCI for Acute STEMI, STEMI - Stable (<=12 hrs from Symptom onset), STEMI - Stable (>12 hrs from Symptom onset), STEMI - Unstable (>12hrs from Symptom onset), STEMI (after successful lytics), STEMI - Rescue (after unsuccessful lytics)
Number of diseased vessels 3 2 Other (reference)	Categories	Number of diseased vessels determined by: Native stenosis (7508) = LM >= 50% stenosis *or* LAD, CFX or RCA with one or more segments with > = 70% stenosis *or* iFR ratio <=0.8 (7513) *or* FFR ratio <=0.89 (7512) Note: Based on the criteria above, if the LM is identified as diseased and coronary dominance (7500) = Left and the RCA is identified as diseased then this is considered 3 vessel disease. If the RCA is not diseased then it is considered 2 vessel disease.
Highest Risk Lesion treated with PCI Left Main Proximal LAD Other (reference)	Categories	Left Main = Segment Number (7507) = 11a, 11b or 11c *or* Proximal Left anterior descending = Segment Number (7507) = 12
Chronic Total Occlusion	Boolean (yes or no)	Chronic Total Occlusion (8005) = Yes

In-stent Thrombosis	Boolean (yes or no)	In-stent Thrombosis (8012) within 30 days of prior PCI calculated as difference between prior PCI data (8009) and procedure data (7000)

Table 16: Model Coefficients for All PCI with No Prior Cardiac Arrest or Cardiogenic Shock

Variable	Estimate	Standard Error	T-Value	Pr > T-Value	OR	LOR	UOR
Age							
<45 yrs.	-0.0055	0.0189	-0.2890	0.7726	0.9946	0.9584	1.0321
≥45 yrs.	0.0478	0.0014	33.0445	0.0000	1.0490	1.0460	1.0520
Female	0.3190	0.0293	10.8928	0.0000	1.3758	1.2991	1.4571
Cerebrovascular disease	0.1801	0.0351	5.1239	0.0000	1.1973	1.1176	1.2827
Peripheral Arterial Disease	0.2654	0.0388	6.8349	0.0000	1.3039	1.2084	1.4071
Chronic Lung disease	0.3502	0.0341	10.2620	0.0000	1.4194	1.3275	1.5175
Previous PCI	-0.2279	0.0320	-7.1124	0.0000	0.7962	0.7477	0.8478
Diabetes	0.1240	0.0301	4.1230	0.0000	1.1321	1.0672	1.2008
CKD stage							
Stage 5 (GFR 0-14)	1.2884	0.0505	25.5241	0.0000	3.6271	3.2854	4.0043
Stage 4 (GFR 15-29)	1.1990	0.0519	23.1126	0.0000	3.3169	2.9962	3.6719
Stage 3(GFR 30-44)	0.5733	0.0428	13.3811	0.0000	1.7742	1.6313	1.9296
Stage 3a (GFR 45-60)	0.2417	0.0399	6.0566	0.0000	1.2734	1.1776	1.3770
Severe Frailty and No CA/Salvage PCI/Shock	1.2235	0.0407	30.0445	0.0000	3.3990	3.1382	3.6814
Aortic Stenosis (at least moderate)	0.3315	0.0730	4.5437	0.0000	1.3931	1.2075	1.6073
LVEF							
Not measured	0.0961	0.0406	2.3681	0.0179	1.1009	1.0167	1.1921

<55%	-0.0173	0.0016	-10.8189	0.0000	0.9828	0.9797	0.9859
≥55%	-0.0088	0.0054	-1.6290	0.1033	0.9912	0.9808	1.0018
Systolic Blood Pressure							
<90 mmHG	-0.0065	0.0056	-1.1581	0.2468	0.9935	0.9825	1.0045
90-180 mmHG	-0.0187	0.0007	-28.3523	0.0000	0.9815	0.9802	0.9827
>180 mmHg	0.0091	0.0026	3.4545	0.0006	1.0091	1.0039	1.0143
STEMI	0.8370	0.0547	15.3125	0.0000	2.3095	2.0749	2.5707
Clinical instability							
Urgent PCI without shock/CVI	1.2168	0.0548	22.2235	0.0000	3.3764	3.0328	3.7589
Emergency PCI without shock/CVI	1.8060	0.0729	24.7679	0.0000	6.0863	5.2757	7.0214
No Salvage PCI and CVI	2.2365	0.0626	35.7023	0.0000	9.3606	8.2790	10.5834
Heart failure							
NYHA class 1/2/3	0.0634	0.0386	1.6410	0.1008	1.0654	0.9878	1.1492
NYHA class 4	0.4991	0.0577	8.6484	0.0000	1.6472	1.4711	1.8445
In-stent thrombosis	0.5314	0.1461	3.6385	0.0003	1.7013	1.2778	2.2652
Highest risk lesion							
Proximal LAD vs. other	0.3193	0.0332	9.6223	0.0000	1.3761	1.2895	1.4686
Left main vs. other	0.6758	0.0507	13.3348	0.0000	1.9656	1.7798	2.1709
Number of diseased vessels							
2 vs. 1	0.2471	0.0347	7.1196	0.0000	1.2803	1.1961	1.3705
3 vs.1	0.5180	0.0373	13.8951	0.0000	1.6787	1.5604	1.8060
Chronic total occlusion	0.5264	0.0648	8.1181	0.0000	1.6928	1.4908	1.9222
Surgical Turndown	0.2403	0.0525	4.5758	0.0000	1.2716	1.1472	1.4094

*Per 10-unit increase. † Per 5-unit increase. ‡ Versus GFR >60. § versus elective PCI without shock/CI. ¶ versus no heart failure within 2 weeks. ** vs no cardiac arrest.

CVI = cardiovascular instability; CKD = chronic kidney disease; GFR = glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST- elevation myocardial

Table 17: Model variables for Bleeding

VARIABLE	*VARIABLE TYPE*	*ELEMENTS*
Observed Bleed	Boolean (yes or no)	1=Bleed, 0=No-Bleed (Definition above and in companion guide)
Predicted Bleed	Number	Predicted Probability of Bleeding in Eligible patients. Values >0, <1.
ST-segment elevation MI	Boolean (yes or no)	IF Any of these are True in 7825: • Primary PCI for Acute STEMI • STEMI - Stable (<12 hours from symptom • onset) • STEMI - Stable (>12 hours from symptom • onset) • STEMI - Unstable (>12 hours from symptom • onset) • STEMI - (After successful lytics) • STEMI - Rescue (After unsuccessful lytics)
Age <=70	Number	DOB (2050) and Arrival Date (3001): Return Age if age<=70. If age>70 return 70
Age >70	Number	DOB (2050) and Arrival Date (3001) If age<=70 return 0. If age>70 return 70-age
BMI <=30	Number	Height (6000) and Weight (6005) If BMI<=30 then return BMI. IF BMI>30 return 30
BMI >30	Number	Height (6000) and Weight (6005)If BMI<=30 then return 0. If BMI>30 return BMI-30
Female	Boolean (yes or no)	Sex (2060)
Pre-Procedure Hemoglobin <=13	Number	Pre-Procedure Hemoglobin (6030) if HGB<=13 then return HGB. If HGB>13 THEN RETURN 13
Procedure Hemoglobin >13	Number	Pre-Procedure Hemoglobin (6030) IF HGB<=13 THEN RETURN 0. IF HGB>13 then return hgb-13
Prior Percutaneous Coronary Intervention	Boolean (yes or no)	Prior Percutaneous Coronary Intervention (4495)
Mild GFR ≥ 45 – 60	Boolean (yes or no)	Pre-procedure creatinine (6050), Age (Birth Date (2050) and Arrival Date/Time (3001), sex (2060) and African race (2071)
Moderate GFR ≥ 30 - < 45	Boolean (yes or no)	Pre-procedure creatinine (6050), Age (Birth Date (2050) and Arrival Date/Time (3001), sex (2060) and African race (2071)
Renal Failure (GFR <30 or Dialysis)	Boolean (yes or no)	Pre-procedure creatinine (6050), Age (Birth Date (2050) and Arrival Date/Time (3001), sex (2060) and African race (2071) OR Currently on Dialysis (4560)
Cardiogenic Shock	Boolean (yes or no)	CV instability (7410, 7415) = cardiogenic shock or

		refractory cardiogenic shock

Table 18: Bleeding model coefficients/weights

Variable	Weight	Standard Error	Odds Ratio, 95% CI, p-value
Intercept	-0.0884	0.1258	
STEMI	0.9327	0.0196	2.54(2.45,2.64) p<.0001
dAge_LE70	0.0155	0.00128	1.02(1.01,1.02) p<.0001
dAge_GT70	0.02097	0.00154	1.02(1.02,1.02) p<.0001
dBMI_LE30	-0.04266	0.00259	0.96(0.95,0.96) p<.0001
dBMI_GT30	-0.00201	0.00183	1(0.99,1) p 0.2716
dprpci	-0.2131	0.0180	0.81(0.78,0.84) p<.0001
dCKD1	0.3346	0.0220	1.4(1.34,1.46) p<.0001
dCKD2	0.5016	0.0265	1.65(1.57,1.74) p<.0001
dCKD3	0.6309	0.0272	1.88(1.78,1.98) p<.0001
shock	1.9807	0.0240	7.25(6.91,7.6) p<.0001
dPreHGB_LE13	-0.3474	0.00606	0.71(0.7,0.71) p<.0001
dPreHGB_GT13	0.03236	0.00859	1.03(1.02,1.05) p 0.0002
female	0.4403	0.0175	1.55(1.5,1.61) p<.0001

Table 19: Model variables for acute kidney injury

AKI Model variables *Variable*	***Variable Type***	***Elements***
Age	Number	Birth date (2050) and Arrival date/time (3001)
Gender	Categorical	Sex (2060)
Hypertension	Boolean (yes or no)	4615

Cardiac Arrest and Level of Consciousness Arrest and Responsive Arrest and Non-Responsive	Categorical	Cardiac arrest: Out of healthcare facility (4630), At transferring facility (4635) or at this facility (7340) Level of consciousness is unresponsive (7810=unresponsive) Level of consciousness is all others (7810 = alert, pain, unable to assess or verbal)
Diabetes	Boolean (yes or no)	4555
Severe Frailty	Boolean (yes or no)	CHSA Clinical Frailty Scale (4561) = Severely frail, very severely frail, or terminally ill.
Heart Failure	Boolean (yes or no)	4001
Concomitant Procedures	Boolean (yes or no)	7065
eGFR	number	Age: Birth date (2050) and procedure start date/time (7000) Gender: Sex (2060) Creatinine (6050) Using AS equation MALE: GFR=min(creatinine/.9,1)**-.302 *max(creatinine/.9,1)**-1.2 *.9938**age FEMALE: GFR=min(creatinine/.7,1)**-.241 *max(creatinine/.7,1)**-1.2 *.9938**age *1.012

CKD Stage: Mild Moderate Severe	Categorical	None: GFR 60+ Mild: GFR 45-60 Mod: GFR 30-45 Severe: GFR <30
Anemia (<10g/dL)	Value	Hemoglobin (6030) <10 g/dL
Cardiovascular Instability / PCI status	Categorical	Level 1: PCI Status (7800)=salvage OR Cardiovascular instability type (7415)=refractory cardiogenic shock ELSE: Level 2: Cardiovascular instability type (7415)=Cardiogenic Shock ELSE: Level 3: Cardiovascular instability type (7415) =ALL OTHERS ELSE: Level 4: PCI Status(7800) =Emergency ELSE:

		Level 5: PCI Status (7800)= Urgent ELSE: Level 6: PCI Status (7800)=Elective
Mechanical Ventricular Support and Timing	Categorical	At Start: Timing (7424) =In place at start During: Timing (7424) =During procedure and prior to intervention
STEMI	Boolean (yes or no)	PCI indication (7825) = in Concept IDs 3137 Primary PCI for Acute STEMI 3138 STEMI - Stable (<12 hours from symptom onset) 3139 STEMI - Stable (>12 hours from symptom onset) 3140 STEMI - Unstable (>12 hours from symptom onset) 3141 STEMI - (After successful lytics) 3142 STEMI - Rescue (After unsuccessful lytics)
NSTEMI – Unstable Angina	Boolean (yes or no)	PCI indication (7825) =NSTE-ACS 3143 NSTE - ACS
PCI of Proximal LAD	Boolean (yes or no)	Segment Number(s) (8001) = Proximal LAD artery segment (pLAD) (12) Note: pLAD is equivalent to selection 12 on the CathPCI segment number diagram (Concept 2538).

Table 20: AKI model coefficients/weights

Variable	NOTE	Beta Weight	Standard Error	Odds Ratio, 95% CI, p-value
Intercept		-2.0304	0.1025	NA
Age_LE70	Min(age,70) use as continuous	0.009017	0.001145	1(1,1) P<.0001
Age_gt70	Max(0,age-70) use as continuous	0.01719	0.001428	1(1,1) P<.0001

Diabetes	1 if yes, 0 if no	0.4523	0.01593	1.57(1.52,1.62) P<.0001
Severe Frailty	1 if yes, 0 if no	0.386	0.02179	1.47(1.41,1.54) P<.0001
Heart Failure	1 if yes, 0 if no	0.6809	0.01682	1.98(1.91,2.04) P<.0001
Concomitant Procedures	1 if yes, 0 if no	0.3661	0.02047	1.44(1.39,1.5) P<.0001
CKD1	GFR >60 (1 if yes, 0 if no)	-1.5189	0.02817	0.22(0.21,0.23) P<.0001
CKD2	GFR 45-60 (1 if yes, 0 if no)	-1.053	0.02999	0.35(0.33,0.37) P<.0001
CKD3	GFR 30-45 (1 if yes, 0 if no)	-0.6344	0.0307	0.53(0.5,0.56) P<.0001
CKD4	GFR<30 (1 if yes, 0 if no)	0	0	0
Anemia		0.568	0.0223	1.76(1.69,1.84) P<.0001
Hypertension	1 if yes, 0 if no	0.247	0.015	1.28 (1.22, 1.34), p<0.001
PCI_instability_6	Level6 1 if yes, 0 if no	0	0	0
PCI_instability_5	Level5 1 if yes, 0 if no	0.6596	0.03015	1.93(1.82,2.05) P<.0001
PCI_instability_4	Level4 1 if yes, 0 if no	0.8695	0.0474	2.39(2.17,2.62) P<.0001
PCI_instability_3	Level3 1 if yes, 0 if no	0.9726	0.03305	2.64(2.48,2.82) P<.0001
PCI_instability_2	Level2 1 if yes, 0 if no	1.9795	0.04344	7.24(6.65,7.88) P<.0001
PCI_instability_1	Level1 1 if yes, 0 if no	2.2558	0.06423	9.54(8.41,10.82) P<.0001
STEMI	1 if yes, 0 if no	0.5128	0.0305	1.67(1.57,1.77) P<.0001
NSTEMI – Unstable Angina	1 if yes, 0 if no	0.27	0.02383	1.31(1.25,1.37) P<.0001
MVSupport3	MV Prior to Intervention 1 if yes, 0 if no	-0.6324	0.03562	0.53(0.5,0.57) P<.0001
MVSupport2	MV at Start1 if yes, 0 if no	-0.1609	0.07046	0.85(0.74,0.98) P0.0224
MVSupport1	None1 if yes, 0 if no	0	0	0
PCI of Proximal LAD	1 if yes, 0 if no	0.215	0.01683	1.24(1.2,1.28) P<.0001

4.4.5 Calibration and Discrimination

Mortality Example. AKI and Bleeding manuscripts are attached below.

The process for developing the model is described in section 4.4.2. above. Discrimination was assessed with the c-statistic and calibration was assessed by the slope of the predicted vs. observed risk.

The c-statistic is 0.88, which means that the probability that predicting the outcome is substantially 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).

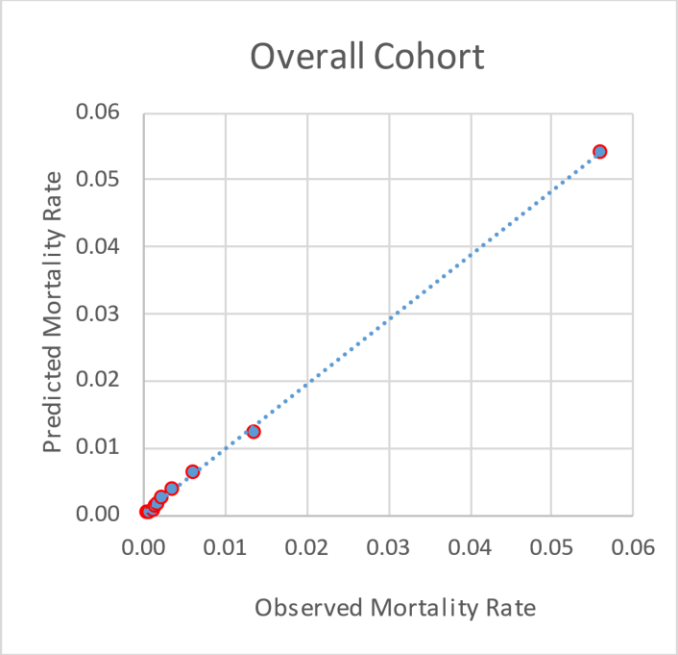
The c-statistics for the original derivation and validation cohorts, as well as clinically important subgroups are provided under Table 13.

Table 21. C-Statistics Results

	Development	**Validation**
Sample, n	326,561	327,566
Mortality rate	0.8375	0.8649
Discrimination		
C-statistic	0.8851	0.8836
Adjusted R-square	0.2393	0.2329
Predictive Ability		
Lowest Decile	0.0003	0.0003
Highest Decile	0.0553	0.0567

In the development cohort, the intercept for the model was 0.0001, which was not statistically significantly different than 0. The slope of the calibration line was 1.000, which also was not significantly different than 1.0. A graphical representation of observed and predicted mortality rates across deciles of risk is shown under Figure 7.

Figure 6. Risk decile plot in the all-patients cohort excluding cardiac arrest or cardiogenic shock



4.4.5a Attach Calibration and Discrimination Testing Results

Figure 7 . Mortality model Calibration Curve

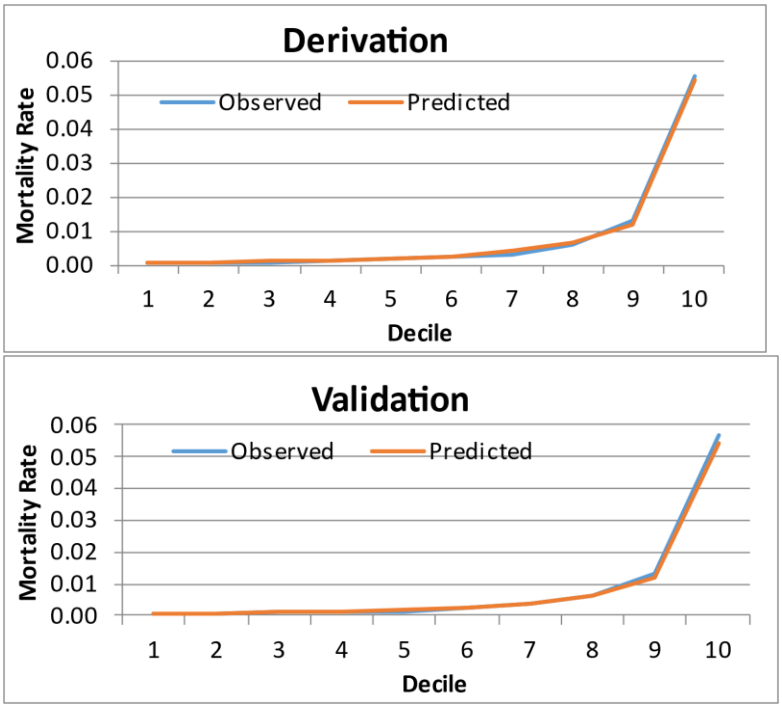


Figure 8. Adjusted Distribution of Mortality

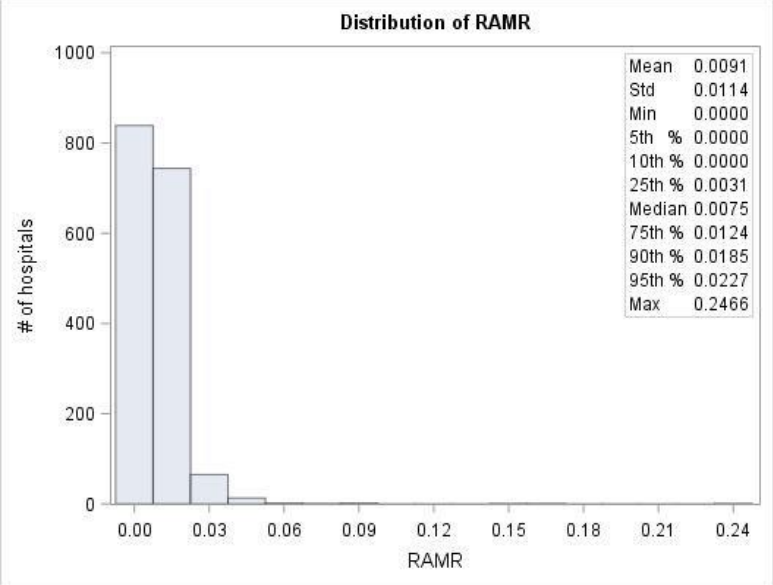


Figure 9. Distribution of Hospital Risk-Standardized Mortality Rates (excluding CA/Shock)

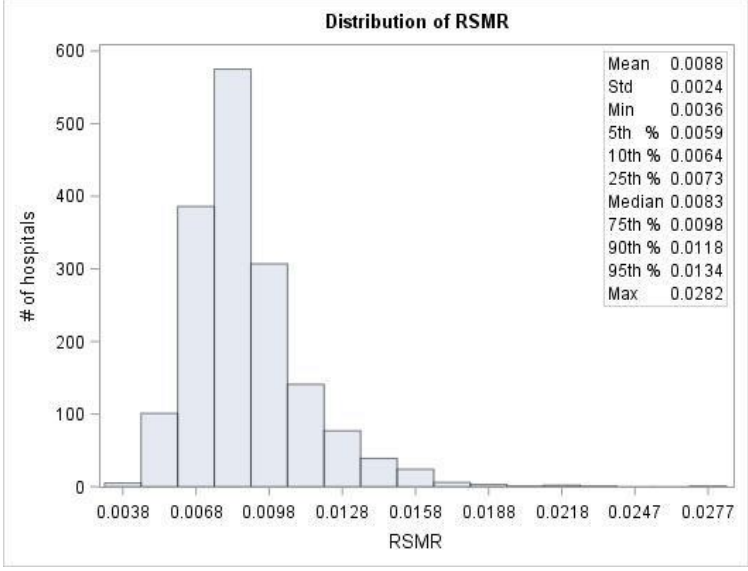
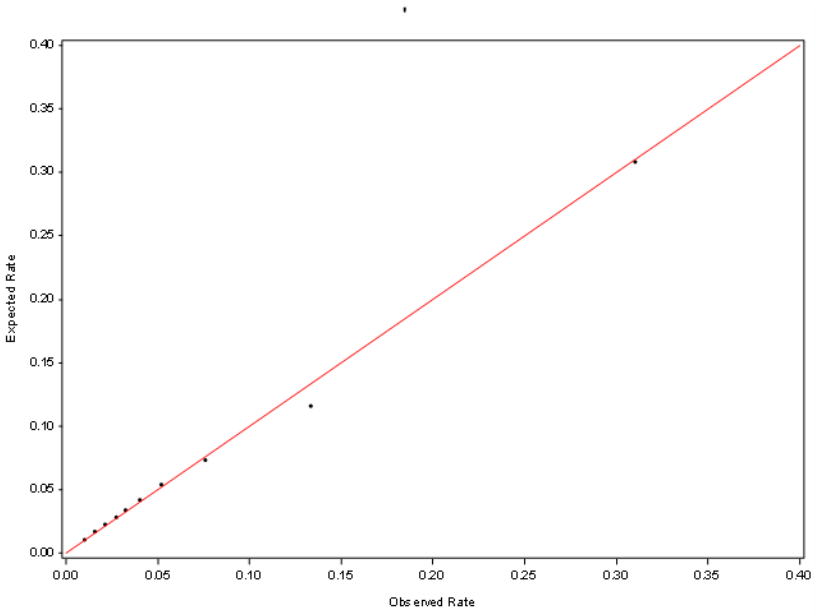


Figure 10



5.1 Contributions Towards Advancing Health Equity

We examined variation in hospital performance for the measure based on overall performance, and stratified by subgroups of age, sex, race/ethnicity, and proportion of patients insured through Medicaid to identify if there were any meaningful differences in social risk.

Age

Hospitals were stratified into quartiles by their proportion of patients over the age of 65. Hospital performance was similar across hospitals stratified by quartile based on age. The median hospital performance in the quality composite among patients aged greater than 65 years was 58.8% and ranged from 83.8 to 84.8.

Table 22. Distribution of PCI Composite Measure Score Stratified by Age at the Hospital Level (2022)

Description	%Age≥65	Quartiles of Age≥65 (%)	Quartiles of Age≥65 (%)	Quartiles of Age≥65 (%)	Quartiles of Age≥65 (%)
*	*	Q1	Q2	Q3	Q4
N	1608	402	402	402	402
Mean	0.5831	83.24	83.40	83.82	84.06
Std Deviation	0.0832	5.18	5.38	5.48	5.39
100% Max	0.8438	95.30	95.63	95.14	95.46
99%	0.7566	91.99	93.19	93.75	93.70

95%	0.7098	90.50	90.98	91.34	91.01
90%	0.6802	89.17	89.81	90.12	90.20
75% Q3	0.6373	87.03	87.26	87.60	87.75
50% Median	0.5876	83.79	83.93	84.40	84.76
25% Q1	0.5355	80.34	80.13	80.71	81.48
10%	0.4800	76.60	76.48	77.03	77.62
5%	0.4400	73.60	73.93	74.19	73.22
1%	0.3462	67.49	68.74	69.94	67.52
0% Min	0.1333	63.39	57.13	49.77	55.41

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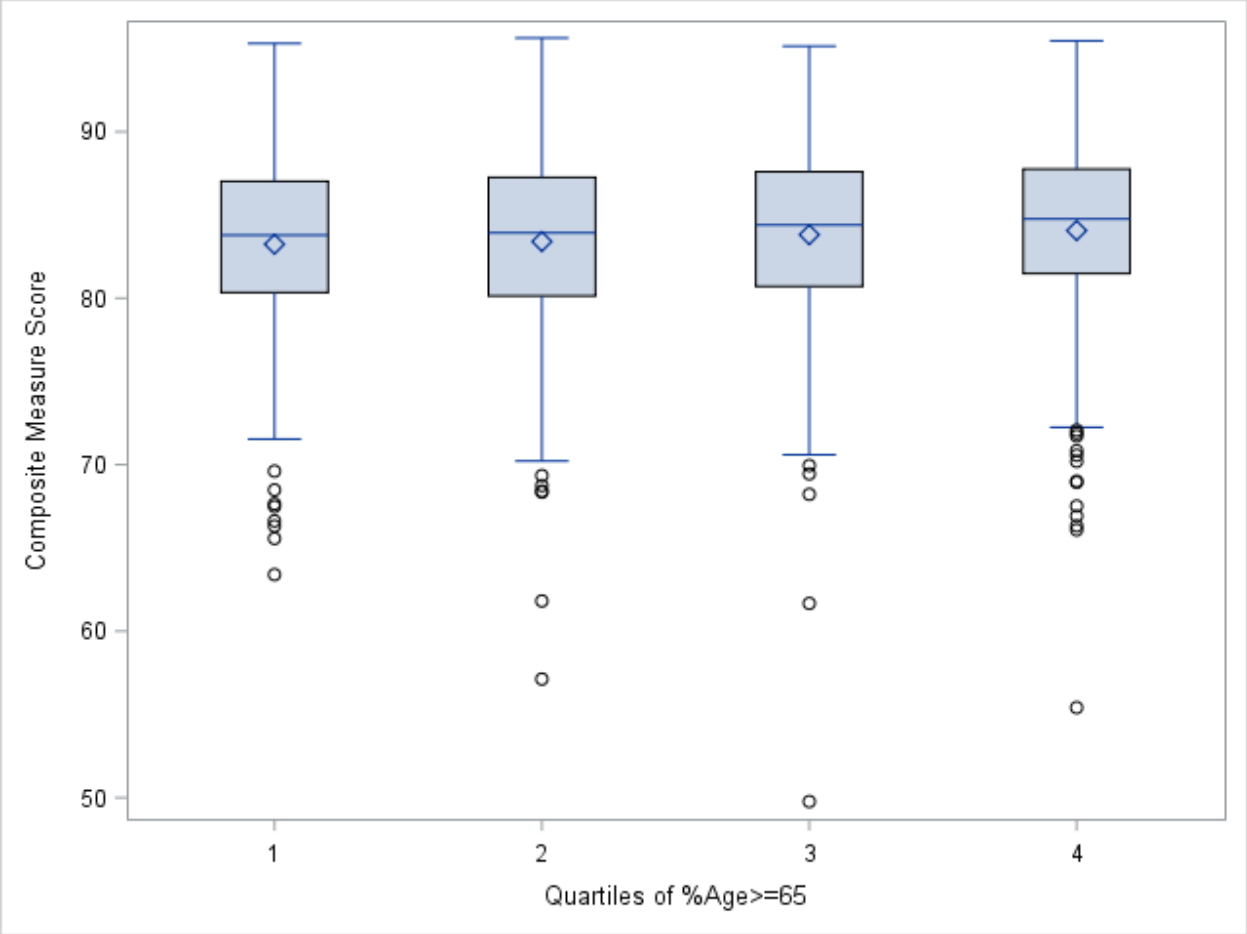
Figure 11. Distribution of PCI Composite Measure Stratified by Quartile of Hospital Percent Age ≥ 65 (2022)



Sex

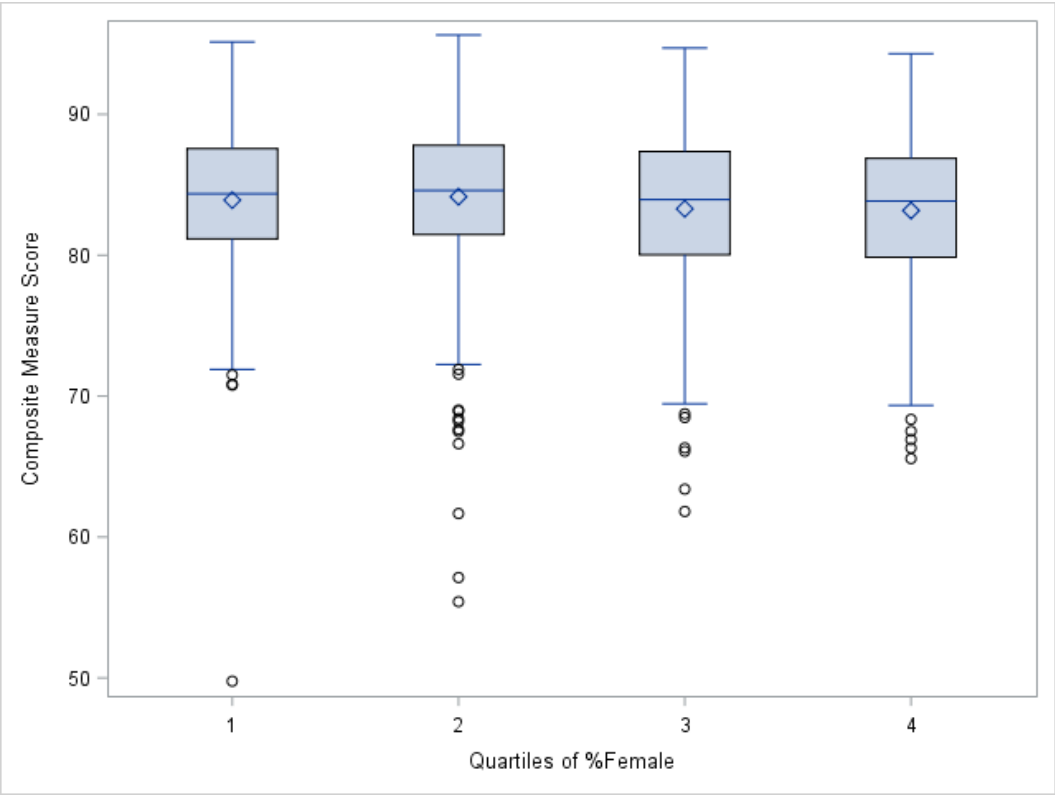
Hospitals were stratified into quartiles by their proportion of female patients. In 2022, the median performance for those hospitals with the fewest female patients (Q1) was 84.36% (IQR: 81.16% to 87.56%). Among those hospitals with the highest proportion of female patients (Q4), the median performance was 83.85% (IQR: 79.86% to 86.87%). Overall, hospitals with varying proportions of female patients perform similarly for the PCI Quality Composite Measure.

Table 23. Distribution of PCI Composite Measure Stratified by Quartiles of Sex at the Hospital-Level (2022)

Description	%Female	Quartiles, Female (%)	Quartiles, Female (%)	Quartiles, Female (%)	Quartiles, Female (%)
*	*	Q1	Q2	Q3	Q4
N	1608	402	402	402	402
Mean	0.3081	83.9111	84.1498	83.2915	83.1712
Std Deviation	0.0494	5.0412	5.5863	5.5084	5.2610
100% Max	0.6667	95.1394	95.6297	94.7037	94.3045
99%	0.4343	93.7438	93.8581	92.9238	93.1942
95%	0.3852	90.7349	91.6128	90.9149	90.6107
90%	0.3664	89.8117	90.3699	89.5556	89.4125
75% Q3	0.3362	87.5617	87.7978	87.3605	86.8736
50% Median	0.3068	84.3623	84.5947	83.9476	83.8461
25% Q1	0.2779	81.1620	81.4718	80.0363	79.8588
10%	0.2491	77.2860	77.7170	75.8562	76.1600
5%	0.2329	75.0745	74.3108	72.9624	73.2189
1%	0.2000	71.8978	67.4878	68.4861	68.3552
0% Min	0.0667	49.7664	55.4057	61.8118	65.5723

*Cells left intentionally blank

Figure 12: Distribution of PCI Composite Measure Stratified by Quartiles of Sex at the Hospital-Level (2022)



Proportion of Non-White

Hospitals (N=1,608) were stratified into quartiles by the proportion of non-White patients. In 2022, the median performance for those hospitals with the fewest non-white patients (Q1) was 84.96% (IQR: 81.44% to 87.90%). Among those hospitals with the highest proportion of non-White patients (Q4), the median performance was 83.21% (IQR: 79.53% to 86.54%).

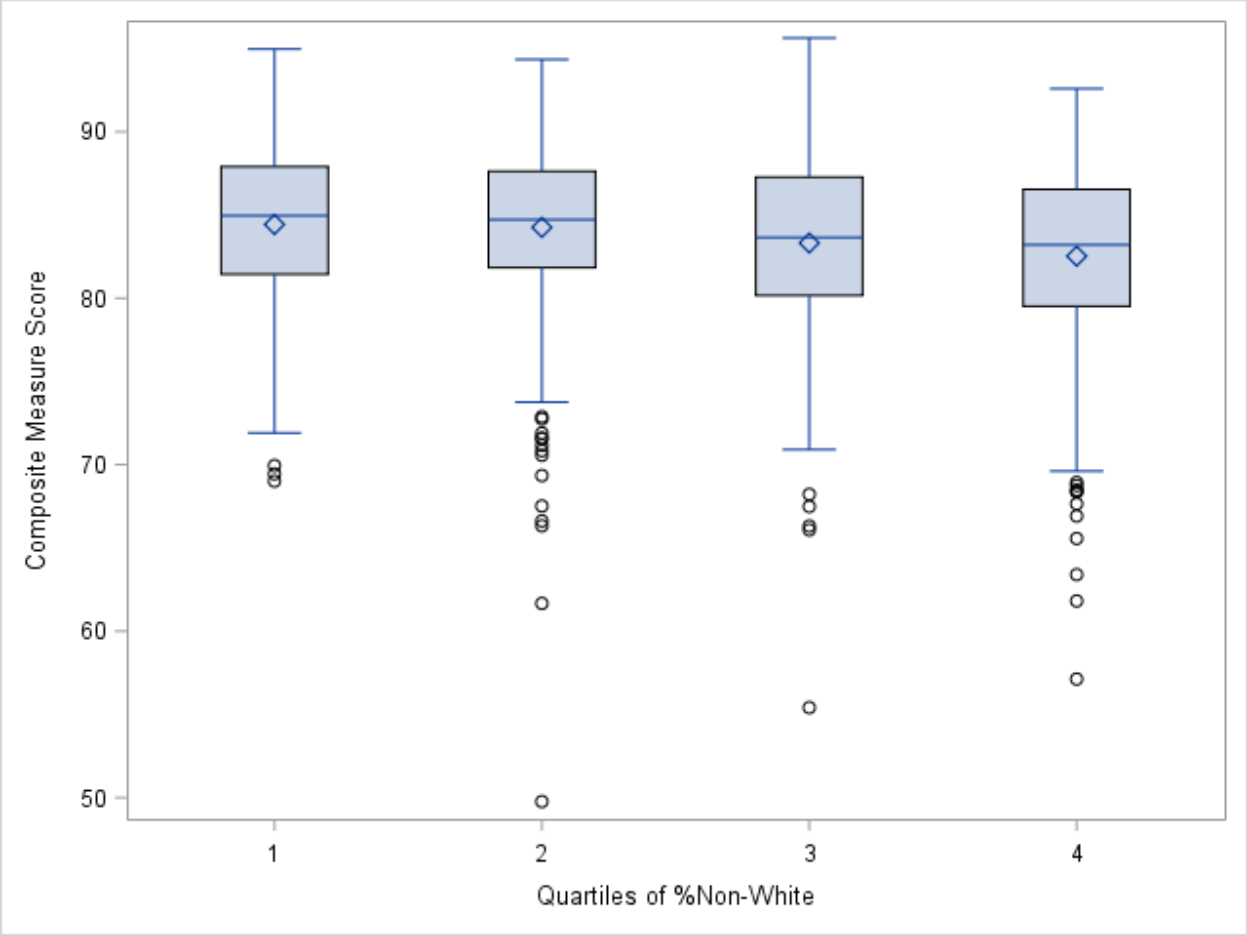
Table 24. Distribution of PCI Composite Measure Stratified by Quartile of Non-White Patients (2022)

Description	%Female	Quartiles, Female (%)	Quartiles, Female (%)	Quartiles, Female (%)	Quartiles, Female (%)
*	*	Q1	Q2	Q3	Q4
N	1608	402	402	402	402
Mean	0.1691	84.43	84.26	83.32	82.52
Std Deviation	0.1546	4.85	5.19	5.56	5.62
100% Max	0.9448	94.96	94.34	95.63	92.59

99%	0.7377	93.70	93.58	94.62	91.99
95%	0.4909	91.27	90.91	91.32	90.61
90%	0.3722	89.98	90.11	89.49	89.34
75% Q3	0.2323	87.90	87.62	87.28	86.54
50% Median	0.1223	84.96	84.72	83.65	83.21
25% Q1	0.0567	81.44	81.84	80.16	79.53
10%	0.0264	77.67	78.16	75.71	74.85
5%	0.0167	75.60	75.92	73.16	72.12
1%	0.0000	72.22	67.52	68.22	66.92
0% Min	0.0000	69.01	49.77	55.41	57.13

*Cells left intentionally blank

Figure 13: Distribution of PCI Composite Measure Stratified by Quartiles of Non-White Patients (2022)



Insurance

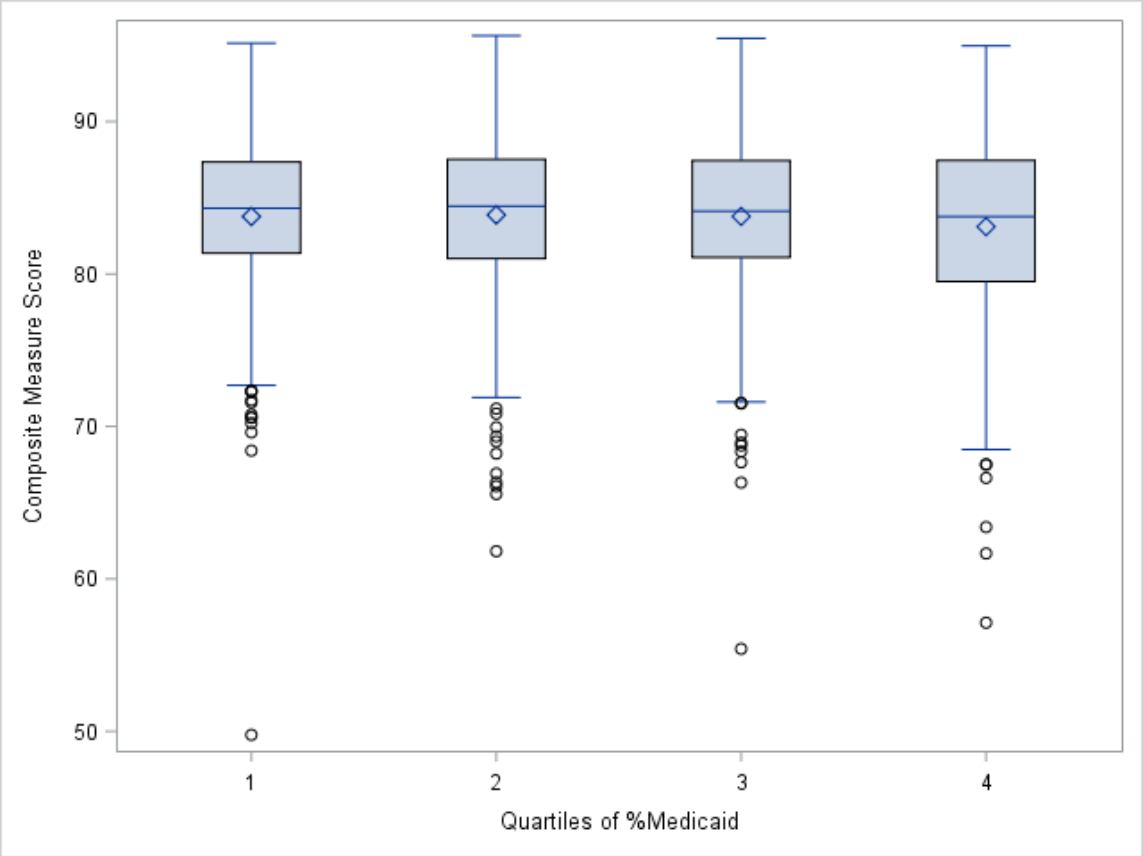
Hospitals (N=1,608) were stratified into quartiles by the proportion of Medicaid patients. In 2022, the median performance for those hospitals with the fewest Medicaid patients (Q1) was 84.31% (IQR: 81.36% to 87.35%). Among those hospitals with the highest proportion of Medicaid patients (Q4), the median performance was 83.77% (IQR: 79.50% to 87.44%) (Table 16, Figure 5).

Table 25. Distribution of PCI Composite Measure Stratified by Quartile of Medicaid (2022)

Description	% Medicaid	Quartile, Medicaid (%)	Quartile, Medicaid (%)	Quartile, Medicaid (%)	Quartile, Medicaid (%)
*	*	Q1	Q2	Q3	Q4
N	1608	402	402	402	402
Mean	0.0603	83.77	83.88	83.78	83.10
Std Deviation	0.0562	5.23	5.24	5.23	5.73
100% Max	0.5435	95.14	95.63	95.46	94.96
99%	0.2752	93.57	93.70	93.58	92.99
95%	0.1638	90.96	91.61	90.81	90.75
90%	0.1280	89.83	89.71	89.72	89.74
75% Q3	0.0838	87.35	87.52	87.44	87.44
50% Median	0.0452	84.31	84.45	84.12	83.77
25% Q1	0.0220	81.36	81.01	81.08	79.50
10%	0.0080	76.92	77.55	77.37	75.56
5%	0.0018	73.75	75.07	73.60	72.88
1%	0.0000	70.57	66.92	68.74	67.49
0% Min	0.0000	49.77	61.81	55.41	57.13

*Cells left intentionally blank

Figure 14: Distribution of PCI Composite Measure Stratified by Quartile of Medicaid (2022)



7.1 Supplemental Attachment

For guidelines released prior to 2015:

ACCF/AHA guideline methodology categorizes indications as class I, II, or III on the basis of a multifactorial assessment of risk and expected efficacy viewed in the context of current knowledge and the relative strength of this knowledge. These classes summarize the recommendations for procedures or treatments as follows and noted in the table below:

Classification Types:

Class I: Conditions for which there is evidence and/or general agreement that a given procedure or treatment is useful and effective.

Class II: Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of a procedure or treatment.

- IIa: Weight of evidence/opinion is in favor of usefulness/efficacy
- IIb: Usefulness/efficacy is less well established by evidence/opinion.

Class III: Conditions for which there is evidence and/or general agreement that the procedure/treatment is not useful/effective and in some cases may be harmful.

- No Benefit- Procedure/Test not helpful or Treatment w/o established proven benefit
- Harm- Procedure/Test leads to excess cost w/o benefit or is harmful, and or Treatment is harmful

Additional detail regarding the classification of recommendation and level of evidence is provided in the following figure.

Figure 15

Applying Class of Recommendation and Level of Evidence to Clinical Strategies, Interventions, Treatments, or Diagnostic Testing in Patient Care (Updated May 2019)*

CLASS (STRENGTH) OF RECOMMENDATION	
CLASS 1 (STRONG)	**Benefit >>> Risk**
Suggested phrases for writing recommendations: • Is recommended • Is indicated/useful/effective/beneficial • Should be performed/administered/other • Comparative-Effectiveness Phrases†: - Treatment/strategy A is recommended/indicated in preference to treatment B - Treatment A should be chosen over treatment B	
CLASS 2a (MODERATE)	**Benefit >> Risk**
Suggested phrases for writing recommendations: • Is reasonable • Can be useful/effective/beneficial • Comparative-Effectiveness Phrases†: - Treatment/strategy A is probably recommended/indicated in preference to treatment B - It is reasonable to choose treatment A over treatment B	
CLASS 2b (WEAK)	**Benefit ≥ Risk**
Suggested phrases for writing recommendations: • May/might be reasonable • May/might be considered • Usefulness/effectiveness is unknown/unclear/uncertain or not well- established	
CLASS 3: No Benefit (MODERATE) (Generally, LOE A or B use only)	**Benefit = Risk**
Suggested phrases for writing recommendations: • Is not recommended • Is not indicated/useful/effective/beneficial • Should not be performed/administered/other	
CLASS 3: Harm (STRONG)	**Risk > Benefit**
Suggested phrases for writing recommendations: • Potentially harmful • Causes harm • Associated with excess morbidity/mortality • Should not be performed/administered/other	

LEVEL (QUALITY) OF EVIDENCE‡	
LEVEL A	
• High-quality evidence‡ from more than 1 RCT • Meta-analyses of high-quality RCTs • One or more RCTs corroborated by high-quality registry studies	
LEVEL B-R	**(Randomized)**
• Moderate-quality evidence‡ from 1 or more RCTs • Meta-analyses of moderate-quality RCTs	
LEVEL B-NR	**(Nonrandomized)**
• Moderate-quality evidence‡ from 1 or more well-designed, well- executed nonrandomized studies, observational studies, or registry studies • Meta-analyses of such studies	
LEVEL C-LD	**(Limited Data)**
• Randomized or nonrandomized observational or registry studies with limitations of design or execution • Meta-analyses of such studies • Physiological or mechanistic studies in human subjects	
LEVEL C-EO	**(Expert Opinion)**
• Consensus of expert opinion based on clinical experience	

COR and LOE are determined independently (any COR may be paired with any LOE).

A recommendation with LOE C does not imply that the recommendation is weak. Many important clinical questions addressed in guidelines do not lend themselves to clinical trials. Although RCTs are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

* The outcome or result of the intervention should be specified (an improved clinical outcome or increased diagnostic accuracy or incremental prognostic information).

† For comparative-effectiveness recommendations (COR 1 and 2a; LOE A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

‡ The method of assessing quality is evolving, including the application of standardized, widely-used, and preferably validated evidence grading tools; and for systematic reviews, the incorporation of an Evidence Review Committee.

COR indicates Class of Recommendation; EO, expert opinion; LD, limited data; LOE, Level of Evidence; NR, nonrandomized; R, randomized; and RCT, randomized controlled trial.

For guidelines released from 2015 forward:

In 2015, the ACC and AHA updated Classes of Recommendation (COR) and Levels of Evidence (LOE) in an effort to align patient care with scientific evidence.

The COR reflects the magnitude of benefit over risk and corresponds to the strength of the recommendation. Class I recommendations are strong and indicate that the treatment, procedure, or intervention is useful and effective and should be performed or administered for most patients under most circumstances. Class II recommendations are weaker, denoting a lower degree of benefit in proportion to risk. Benefit is generally greater for Class IIa (moderate) recommendations and smaller for Class IIb (weak) recommendations, for which benefit only marginally exceeds risk. A COR of IIb suggests that implementation should be selective and based on careful consideration of individual patient factors and, for invasive procedures, available expertise. Class III is assigned when actions are specifically not recommended, either because studies have found no evidence of benefit or because the intervention causes harm.

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NEW RESEARCH PAPER

CORONARY

Contemporary Methods for Predicting Acute Kidney Injury After Coronary Intervention

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ABSTRACT

BACKGROUND Acute kidney injury (AKI) is the most common complication after percutaneous coronary intervention (PCI). Accurately estimating patients' risks not only creates a means of benchmarking performance but can also be used prospectively to inform practice.

OBJECTIVES The authors sought to update the 2014 National Cardiovascular Data Registry (NCDR) AKI risk model to provide contemporary estimates of AKI risk after PCI to further improve care.

METHODS Using the NCDR CathPCI Registry, we identified all 2020 PCIs, excluding those on dialysis or lacking post-procedural creatinine. The cohort was randomly split into a 70% derivation cohort and a 30% validation cohort, and logistic regression models were built to predict AKI (an absolute increase of 0.3 mg/dL in creatinine or a 50% increase from preprocedure baseline) and AKI requiring dialysis. Bedside risk scores were created to facilitate prospective use in clinical care, along with threshold contrast doses to reduce AKI. We tested model calibration and discrimination in the validation cohort.

RESULTS Among 455,806 PCI procedures, the median age was 67 years (IQR: 58.0-75.0 years), 68.8% were men, and 86.8% were White. The incidence of AKI and new dialysis was 7.2% and 0.7%, respectively. Baseline renal function and variables associated with clinical instability were the strongest predictors of AKI. The final AKI model included 13 variables, with a C-statistic of 0.798 and excellent calibration (intercept = −0.03 and slope = 0.97) in the validation cohort.

CONCLUSIONS The updated NCDR AKI risk model further refines AKI prediction after PCI, facilitating enhanced clinical care, benchmarking, and quality improvement. (J Am Coll Cardiol Intv 2023;16:2294–2305) © 2023 by the American College of Cardiology Foundation.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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Acute kidney Injury (AKI) is the most common complication after percutaneous coronary intervention (PCI) and is associated with periprocedural mortality, myocardial infarction, bleeding, and persistent renal impairment.[1-3] Importantly, it can be reduced with clinical interventions such as adequate hydration.[4,5] A cornerstone of quality improvement is to measure, benchmark, and develop strategies to improve outcomes; thus, risk-adjusted AKI rates serve as an important measure of PCI quality.

The vast majority of U.S. hospitals rely on the American College of Cardiology, through its National Cardiovascular Data Registry (NCDR), to provide risk-adjusted estimates of their AKI rates as a measure of PCI safety. Adequately risk adjusting AKI outcomes is critical so that hospitals with different distributions of patients can fairly compare their performance. The last AKI risk prediction model was developed and published nearly a decade ago,[6] and changes in the demographics and management of PCI warrant updating the model, particularly considering a recent revision to the NCDR data collection forms. This update ensures that validated models can be used to risk stratify patients for risk mitigation strategies and to accurately gauge the safety and quality of care. Accordingly, we used the NCDR CathPCI Registry to determine the current rates of AKI and to develop a contemporary AKI risk prediction model in patients undergoing PCI.

METHODS

DATA SOURCE. For this study, we leveraged the NCDR CathPCI Registry, a national clinical registry program of the American College of Cardiology with partnering support from the Society of Cardiovascular Angiography and Interventions.[7] The registry has been previously described.[8] Briefly, CathPCI prospectively collects data on patient characteristics, clinical status, angiographic and procedural details, and in-hospital outcomes among patients receiving PCI from more than 1,600 sites across the United States. Participating institutions enter data locally using standardized data definitions, which then undergo validation and auditing for accuracy and completeness.[9] The study was approved by Saint Luke's Hospital's Institutional Review Board, which waived the requirement for informed consent because the study involved deidentified data.

STUDY POPULATION. Among 693,026 unique PCI procedures from January 1, 2020, to December 31, 2020, we excluded 23,798 subsequent PCIs within a single admission and 195,310 patients without postprocedure creatinine, 126,297 (65%) of whom were discharged on the same day of their PCI. We also excluded 18,142 patients who were receiving dialysis before PCI. This resulted in a final sample of 455,806 procedures (Figure 1). The sample population was subsequently randomly divided into a 70% derivation cohort (n = 319,609) and a 30% validation cohort (n = 136,197).

STUDY OUTCOMES. AKI was defined according to the Kidney Disease Improving Global Outcomes and Acute Kidney Injury Network definitions as an absolute increase in serum creatinine of 0.3 mg/dL within 48 hours of the procedure or a relative increase of serum creatinine of 50% within 7 days of the PCI.[10,11] The writing group chose this definition to be consistent with past NCDR AKI risk prediction models,[6] to use a sensitive definition given the priority of maximizing procedural safety, and the known association of this magnitude of creatinine elevation with other adverse clinical events, including myocardial infarction, bleeding and death.[1,3] A second model was developed to predict new-onset dialysis, which was defined as any new occurrence of conventional dialysis or continuous renal replacement therapy during the hospitalization.

VARIABLE SELECTION. To select candidate variables, the writing group began with the variables from the prior AKI risk model and then screened the new version 5 NCDR CathPCI data set for additional variables univariately associated with AKI or deemed clinically important. How to handle variables determined by physician discretion, particularly relating to the use of mechanical circulatory support (MCS), was vigorously debated. Generally, process of care and physician-determined variables are not included in models used for risk adjustment. Although MCS use could be a marker of illness severity among patients at high risk for AKI, there is substantial variability in the use of these devices.[12] Exploratory analyses found a significantly higher rate of AKI when MCS was used that could not be fully attenuated with other markers of clinical instability. Thus, a compromise to include MCS before or at the start of the procedure but not after PCI was begun was agreed on.

A few combination variables were included to align with the recently published risk-adjusted mortality model.[13] For example, a combined variable of frailty and shock was included because patients with cardiogenic shock are often coded as frail.[14] Thus, the effect of frailty is only assigned in the absence of shock, a salvage procedure, or cardiac arrest.

ABBREVIATIONS AND ACRONYMS

AKI = acute kidney injury

GFR = glomerular filtration rate

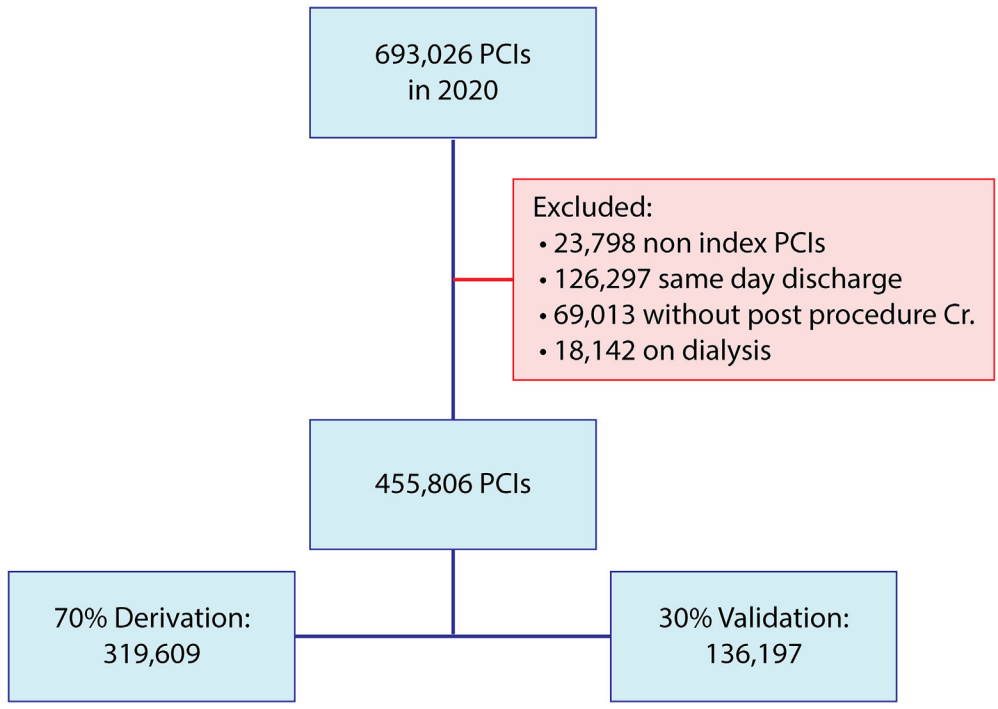
MCS = mechanical circulatory support

NCDR = National Cardiovascular Data Registry

PCI = percutaneous coronary intervention

STEMI = ST-segment elevation myocardial infarction

FIGURE 1 Study Population Consort Diagram



Cr = creatinine; PCI = percutaneous coronary intervention.

Given that preprocedural kidney function is traditionally the strongest predictor of AKI, a detailed analysis as to how best to estimate the glomerular filtration rate (GFR) was undertaken. Previous risk prediction models used a GFR equation that included a coefficient for race that assigns a higher GFR to Black patients.[15,16] Thus, the group used the prior AKI risk model to explore the predicted vs the observed AKI rates in Black patients with 4 alternative estimates of GFR and ultimately selected an updated Chronic Kidney Disease Epidemiology Collaboration equation that excludes the race term and recalibrates the age and sex coefficients to estimate GFR.[17]

Missing data on candidate variables was very low; the variable with the highest frequency of missingness was preprocedure hemoglobin (missing in 0.68%). Other variables were missing data in fewer than 0.1% of cases. Where missing, we assumed these variables were missing completely at random and imputed categoric variables into the most frequently observed category and continuous variables as sex-specific median values.

STATISTICAL ANALYSIS. We summarized categorical variables by frequencies and percentages and compared them using chi-square tests. We summarized continuous variables by medians or means and compared them using Wilcoxon rank sum tests or Student's *t*-tests, respectively. We plotted continuous variables graphically with AKI and tested for nonlinear associations using restricted cubic splines for age, body mass index, and systolic blood pressure.

Using the full list of candidate variables, we created a hierarchical logistic regression model to predict AKI with hospital as a random effect to account for the clustering of patients within hospitals. To support prospective clinical use, we minimized the number of variables required by developing a model that retained 95% of the predicted ability of the initial model, as recommended by Harrell.[18] We then

developed a simplified preprocedure risk prediction score that could be used prospectively at the bedside. For the preprocedure risk prediction score, we did not include MCS or proximal left anterior descending artery disease because these may not be known before the start of PCI. Regression coefficients for each variable were then assigned an integer weighted by their OR. This approach was repeated for the outcome of AKI requiring dialysis initiation.

Although there are conflicting data on whether the administration of iso-osmolar and low-osmolar contrast induces AKI,[19,20] there is evidence suggesting higher volumes of contrast are independently associated with AKI, and strategies to mitigate contrast use may reduce the AKI rate.[21,22] Thus, to further improve the utility of the bedside score and assist in efforts to reduce radiocontrast use in clinical practice, we added the amount of radiocontrast used to the model and back calculated the amount that would reduce the risk of AKI by 10% and 15%. This would allow providers to calculate the risk of AKI before the procedure and to establish a "safe contrast limit" at the bedside to achieve their quality improvement goals. As done in prior work,[23] we restricted these calculations to those with >7% risk of AKI (the median AKI risk), representing the top 50% of risk, and those with the lowest number needed to treat to reduce AKI. In a retrospective analysis, patients who received radiocontrast below this patient-centered threshold had lower rates of AKI than patients who received a contrast volume <2 times their estimated GFR, which is a threshold often used in practice.[24] Such an approach to reducing contrast could also potentially reduce the aversion to performing cardiac catheterization in patients with chronic kidney disease, including the elderly, for whom the benefits of PCI may be greatest.[25-27]

To assess model performance, we calculated each model's calibration and discrimination. We used C-statistics to compare discrimination among models. To assess calibration, we rank ordered patients from lowest to highest predicted decile of AKI risk and compared predicted with observed AKI rates within each risk category and calculated the intercept and slope of this relationship and compared these with the ideal values of 0.0 and 1.0, respectively. Model performance was further assessed in clinically important subgroups of patients with ST-segment elevation myocardial infarction (STEMI), shock, and cardiac arrest. As a sensitivity analysis, we repeated validation in patients treated from the second quarter of 2021 to the second quarter of 2022 to ensure the

TABLE 1 Baseline Characteristics of Derivation and Validation Cohorts

		Derivation	
	Total (N = 455,806)	Validation (n = 136,197)	Derivation (n = 319,609)
Acute kidney injury	32,760 (7.2)	9,838 (7.2)	22922 (7.2)
Age, y	67.0 (58.0-75.0)	67.0 (58.0-75.0)	67.0 (58.0-75.0)
Male	313,403 (68.8)	93,551 (68.7)	219,852 (68.8)
White	383,861 (86.8)	114,815 (86.9)	269,046 (86.8)
Black	38,925 (8.8)	11,583 (8.8)	27,342 (8.8)
Body mass index	29.2 (25.7-33.5)	29.3 (25.8-33.6)	29.2 (25.7-33.5)
Hypertension	378,566 (83.1)	113,087 (83.0)	265,479 (83.1)
Dyslipidemia	347,771 (76.3)	103,882 (76.3)	243,889 (76.3)
Prior myocardial infarction	121,991 (26.8)	36,403 (26.7)	85,588 (26.8)
Prior PCI	168,470 (37.0)	50,258 (36.9)	118,212 (37.0)
Prior CABG	67,248 (14.8)	19,825 (14.6)	47,423 (14.8)
Peripheral arterial disease	49,803 (10.9)	14,765 (10.8)	35,038 (11.0)
Chronic lung disease	73,416 (16.1)	21,995 (16.1)	51,421 (16.1)
Anemia (hemoglobin <10 g/dL)	29,078 (6.4)	8,595 (6.3)	20,483 (6.4)
Cerebrovascular disease	66,231 (14.5)	19,603 (14.4)	46,628 (14.6)
Everyday smoker	100,642 (22.1)	30,104 (22.1)	70,538 (22.1)
Diabetes mellitus	184,657 (40.5)	55,207 (40.5)	129,450 (40.5)
Frailty			
1 Not frail	147,078 (32.4)	44,126 (32.5)	102,952 (32.3)
2 Intermediate frailty	248,663 (54.7)	74,116 (54.6)	174,547 (54.8)
3 Severe frailty	58,830 (12.9)	17,565 (12.9)	41,265 (12.9)
PCI status			
1 Elective	119,245 (26.2)	35,545 (26.1)	83,700 (26.2)
2 Urgent	225,321 (49.4)	67,318 (49.4)	158,003 (49.4)
3 Emergent	109,196 (24.0)	32,712 (24.0)	76,484 (23.9)
4 Salvage	1,911 (0.4)	574 (0.4)	1,337 (0.4)
Heart failure	117,466 (25.8)	35,228 (25.9)	82,238 (25.7)
NYHA functional class			
1	34,898 (29.8)	10,532 (30.0)	24,366 (29.7)
2	31,702 (27.1)	9,466 (27.0)	22,236 (27.1)
3	34,535 (29.5)	10,371 (29.5)	24,164 (29.5)
4	15,931 (13.6)	4,739 (13.5)	11,192 (13.7)
Concomitant procedure	51,709 (11.3)	15,466 (11.4)	36,243 (11.3)
Radial access	232,209 (50.9)	69,551 (51.1)	162,658 (50.9)
Shock	13,759 (3.0)	4,124 (3.0)	9,635 (3.0)
Arrest	15,354 (3.4)	4,696 (3.4)	10,658 (3.3)
Postarrest level of consciousness			
Pain	456 (3.0)	140 (3.0)	316 (3.0)
Unresponsive	3,779 (25.0)	1,199 (26.0)	2,580 (24.6)
Verbal	597 (4.0)	185 (4.0)	412 (3.9)
Alert	6,994 (46.4)	2,114 (45.8)	4,880 (46.6)
Unable to assess	3,263 (21.6)	975 (21.1)	2,288 (21.8)
Chronic kidney disease			
GFR >60	331,178 (72.7)	98,899 (72.6)	232,279 (72.7)
GFR 60-45	76,093 (16.7)	22,859 (16.8)	53,234 (16.7)
GFR 45-30	36,096 (7.9)	10,702 (7.9)	25,394 (7.9)
GFR <30	12,439 (2.7)	3,737 (2.7)	8,702 (2.7)
Indication: ACS ≤24 h	188,935 (41.5)	56,368 (41.4)	132,567 (41.5)
Indication: ACS >24 h	109,066 (23.9)	32,742 (24.0)	76,324 (23.9)
Cardiovascular instability	138,261 (30.3)	41,516 (30.5)	96,745 (30.3)

Continued on the next page

TABLE 1 Continued

	Total (N = 455,806)	Derivation	
		Validation (n = 136,197)	Derivation (n = 319,609)
Mechanical circulatory support	18,847 (4.1)	5,708 (4.2)	13,139 (4.1)
Intra-aortic balloon pump	9,204 (2.0)	2,799 (2.1)	6,405 (2.0)
Extracorporeal membrane oxygenation	399 (0.1)	124 (0.1)	275 (0.1)
Tandem heart	37 (0.0)	10 (0.0)	27 (0.0)
Impella (Abiomed) left ventricle support	8,535 (1.9)	2,570 (1.9)	5,965 (1.9)
MCS present before the start of the procedure	2,315 (0.5)	724 (0.5)	1,591 (0.5)
MCS placed during the procedure before PCI	9,007 (2.0)	2,700 (2.0)	6,307 (2.0)
MCS placed after the PCI	7,478 (1.6)	2,270 (1.7)	5,208 (1.6)
NSTEMI/unstable angina	205,373 (45.1)	61,211 (44.9)	144,162 (45.1)
STEMI	103,603 (22.7)	31,115 (22.8)	72,488 (22.7)
Chronic total occlusion	17,987 (3.9)	5,316 (3.9)	12,671 (4.0)
Left main PCI	19,323 (4.2)	5,741 (4.2)	13,582 (4.2)
Proximal left anterior descending PCI	110,276 (24.2)	33,017 (24.2)	77,259 (24.2)
Surgery consult	24,329 (5.3)	7281 (5.3%)	17,048 (5.3)
Surgery not recommended	17,848 (3.9)	5,308 (3.9)	12,540 (3.9)

Values are n (%) or median (IQR). The patient sample was randomly split into a 70% derivation cohort and 30% validation cohort for model development and testing.

ACS = acute coronary syndrome; CABG = coronary artery bypass graft; GFR = glomerular filtration rate; MCS = mechanical circulatory support; NSTEMI = non-ST-segment elevation myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction.

model generalizability was not hindered by changes in patients and practices during the height of the coronavirus disease-2019 pandemic.

All tests were 2-tailed with an alpha level set at 0.05. We performed all statistical analyses with the SAS 9.4 (SAS Institute) and R (R Foundation for Statistical Computing) programs.

RESULTS

PATIENT CHARACTERISTICS. From January 1, 2020, to December 31, 2020, 455,806 PCIs were included in our final cohort, 319,609 in the derivation cohort and 136,197 in the validation cohort. The baseline demographic and clinical features of the 2 cohorts are presented in Table 1. The median (IQR) age of our sample was 67.0 years (IQR: 58.0-75.0 years); 68.8% were men, 86.8% were White, and 8.8% were Black. Cardiovascular risk factors were common, with 83% having hypertension, 76% dyslipidemia, and 41% diabetes. Non–ST-segment elevation myocardial infarction or unstable angina was the presenting condition for 45% of patients, and 22.7% presented with STEMI. AKI occurred in 32,760 (7.2%) patients after PCI, and AKI requiring dialysis occurred in 0.7% of patients. Unadjusted rates of AKI in several prespecified subgroups included 9.8% in patients with diabetes, 10.3% in patients with STEMI, 7.7% in patients with non–ST-segment elevation myocardial infarction or UA, 39.3% in patients with shock, and 26.7% after cardiac arrest.

THE AKI MODEL. The working group initially selected 26 candidate variables for the full logistic regression model for AKI. The full 26-variable AKI model was able to discriminate AKI with a C-statistic of 0.801 in the derivation cohort and 0.798 in the validation cohort (Supplemental Table 1). Model calibration was excellent with an intercept of −0.036 and slope of 0.977 (Figure 2). We reduced the model to 13 variables that retained >95% of the explanatory power of the full model (Table 2). Age, body mass index, and systolic blood pressure had nonlinear associations with AKI, resulting in the inclusion of spline terms for these characteristics.

The strongest predictors of AKI were the clinical severity of patients at the time of PCI (salvage procedures [OR: 9.54; 95% CI: 8.41-10.82], shock [OR: 7.24; 95% CI: 6.65-7.88], and unresponsive cardiac arrest [OR: 3.85; 95% CI: 3.48-4.25]) and the presence of pre-existing severe chronic kidney disease with a GFR <30 (OR: 4.57; 95% CI: 4.32-4.83). The reduced 13-variable model also had excellent discrimination (C-statistic = 0.797 in the derivation cohort and 0.794 in the validation cohort) and calibration (intercept = −0.032 and slope = 0.979) (Table 3). The simplified model for bedside use with integer scores (Figure 3) had similar discrimination with a C-statistic of 0.793. In our sensitivity analysis validating the model on patients from the second quarter of 2021 to the second quarter of 2022, the C-statistic was 0.794 with a calibration intercept of −.018 and slope of 0.973, demonstrating the robust performance of the model. Table 4 provides contrast limits as a function of AKI risk from the simplified bedside risk model.

THE NEW-ONSET DIALYSIS RISK MODEL. The model for AKI requiring dialysis also initially contained 26 variables (Supplemental Table 1). The strongest predictors of a new need for dialysis were GFR <30 (OR: 16.95; 95% CI: 14.76-19.46) and clinical urgency (salvage procedure [OR: 15.21; 95% CI: 10.91-21.22] and shock [OR: 11.04; 95% CI: 8.22-14.84]). Model reduction identified 11 variables that accounted for

95% of the predicted variance of the full model (Table 2). The full and reduced dialysis models had excellent discrimination (C-statistics = 0.925 and 0.918, respectively) and calibration in the validation cohort.

Because of the excellent performance of both the AKI and AKI requiring dialysis reduced models even in relevant prespecified subgroups (Table 5), the writing group decided to use these as the final models for benchmarking and quality improvement.

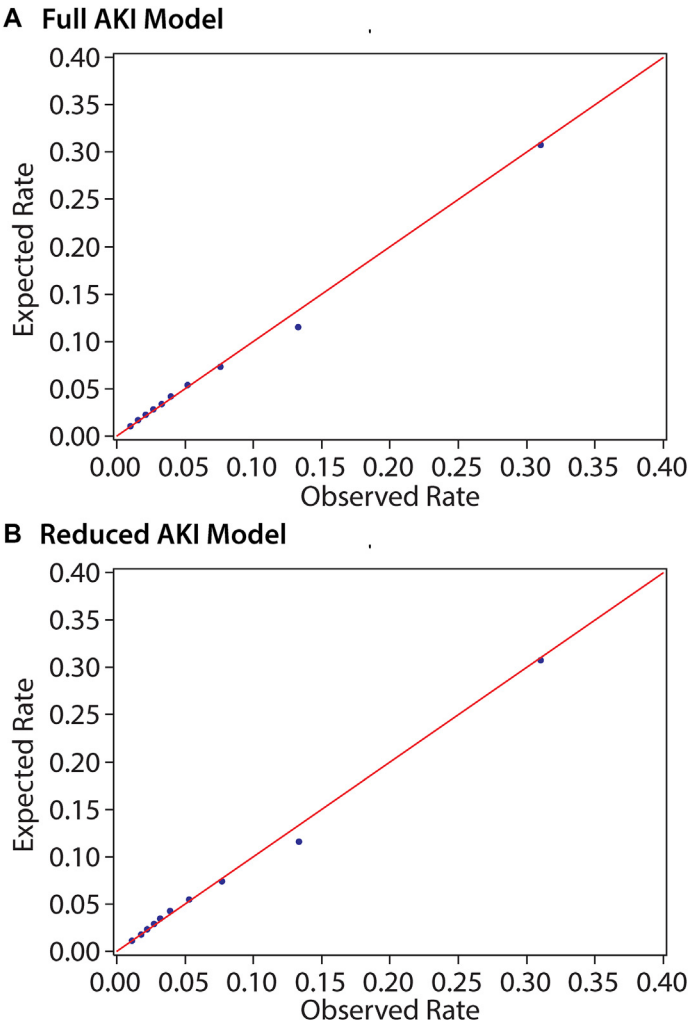
DISCUSSION

AKI RATES AND PREDICTION. Understanding patients' risks for AKI and dialysis can help inform patients of these risks before PCI and enable providers to identify patients who may benefit from risk mitigation strategies. These models also serve to update the NCDR's ability to benchmark PCI quality and safety. Using the largest database of patients undergoing PCI in the United States, we determined contemporary rates of AKI and created a cache of AKI risk prediction models to support quality assessment, quality improvement, and bedside care. AKI continues to be the most common complication after PCI, occurring in association with 7.2% of procedures. Despite current knowledge regarding AKI incidence, prognostic importance, and risk mitigation strategies, these rates of AKI are unchanged from a decade ago when the previous NCDR AKI risk prediction model was created.[1] This underscores the need for further efforts to mitigate the risk of AKI and improve the safety of PCI.

The current models have better discrimination than the prior NCDR risk model (C-statistic = 0.79 vs 0.71), primarily because of the expanded data collection in version 5 of the CathPCI data collection form. Specifically, the new data elements for responsive and nonresponsive cardiac arrest, frailty, cardiovascular instability, and shock were independently associated with AKI risk and suggest that the increased burden of collecting these data may be offset by their value in better estimating risk, particularly if used to prospectively improve care (Central Illustration). We laud the effort, time, and resources committed by the over 1,600 sites participating in the CathPCI Registry to make these advances in science possible and hope that the improved ability to stratify risk can reward this commitment. We elected to focus on the reduced 13-variable model, given the comparability in discrimination and calibration compared with a 26-variable model (Table 3, Supplemental Table 1), to decrease the burden of collecting data in future case report forms. Although other contemporary AKI risk models exist, they were either developed and validated within a single center, questioning generalizability,[28] or used machine learning models that do not lend themselves to prospective scoring for bedside use without sophisticated technology.[29]

KEY VARIABLES. This model is also the first to use a race agnostic equation for GFR estimation.

FIGURE 2 Calibration of the Full and Reduced Model AKI Models



Calibration curves for **(A)** the full acute kidney injury (AKI) model and **(B)** the reduced AKI model. These curves have observed rates on the x-axis and expected rates of AKI on the y-axis. For both the full and reduced models, the intercept is close to 0, and the slope is close to 1, indicating excellent calibration.

TABLE 2 Reduced AKI and New-Onset Dialysis Models

AKI				Dialysis			
Observations	Label	OR for AKI (95% CI)	*P* Value	Observations	Label	OR for Dialysis (95% CI)	*P* Value
1	Age +10, for age ≤70	1.09 (1.07-1.12)	<0.0001	1	Age +10, for age ≤70	1 (0.93-1.07)	0.9949
2	Age +10, for age >70	1.19 (1.15-1.22)	<0.0001	2	Age +10, for age >70	0.74 (0.68-0.82)	<0.0001
3	Hypertension	1.28 (1.22-1.34)	<0.0001	3	Male vs female	1.44 (1.3-1.59)	<0.0001
4	Anemia (hemoglobin <10 g/dL)	1.76 (1.69-1.84)	<0.0001	4	Anemia (hemoglobin <10 g/dL)	1.9 (1.69-2.14)	<0.0001
5	Diabetes	1.57 (1.52-1.62)	<0.0001	5	Diabetes	1.45 (1.31-1.6)	<0.0001
6	Severe frail vs not severe (no shock/arrest/salvage)	1.47 (1.41-1.54)	<0.0001	6	Severe frail vs not severe (no shock/arrest/salvage)	1.97 (1.73-2.24)	<0.0001
7	History of heart failure	1.98 (1.91-2.04)	<0.0001	7	History of heart failure	1.94 (1.75-2.16)	<0.0001
8	Any concomitant procedure	1.44 (1.39-1.5)	<0.0001	8	Any concomitant procedure	1.85 (1.66-2.05)	<0.0001
9	Arrest: responsive vs none	2.05 (1.92-2.19)	<0.0001	9	CKD: GFR 60-45 vs GFR >60	2.4 (2.08-2.76)	<0.0001
10	Arrest: nonresponsive vs none	3.85 (3.48-4.25)	<0.0001	10	CKD: GFR 45-30 vs GFR >60	4.57 (3.96-5.27)	<0.0001
11	CKD: GFR 60-45 vs GFR >60	1.59 (1.53-1.66)	<0.0001	11	CKD: GFR <30 vs GFR >60	17.23 (15.05-19.73)	<0.0001
12	CKD: GFR 45-30 vs GFR >60	2.42 (2.32-2.53)	<0.0001	12	Salvage/refractory vs elective	44.78 (33.04-60.7)	<0.0001
13	CKD: GFR <30 vs GFR >60	4.57 (4.32-4.83)	<0.0001	13	Shock (not salvage or refractory) vs elective	23.21 (17.56-30.69)	<0.0001
14	Salvage/refractory vs elective	9.54 (8.41-10.82)	<0.0001	14	Other cardiovascular instability vs elective	4.4 (3.36-5.75)	<0.0001
15	Shock (not salvage or refractory) vs elective	7.24 (6.65-7.88)	<0.0001	15	Emergent vs elective	3.1 (2.16-4.45)	<0.0001
16	Other cardiovascular instability vs elective	2.64 (2.48-2.82)	<0.0001	16	Urgent vs elective	1.98 (1.51-2.59)	<0.0001
17	Emergent vs elective	2.39 (2.17-2.62)	<0.0001	17	STEMI vs no ACS	2.1 (1.74-2.53)	<0.0001
18	Urgent vs elective	1.93 (1.82-2.05)	<0.0001	18	NSTEMI/UA vs no ACS	1.5 (1.27-1.78)	<0.0001
19	STEMI vs no ACS	1.67 (1.57-1.77)	<0.0001	19	Proximal LAD PCI	1.48 (1.35-1.64)	<0.0001
20	NSTEMI/UA vs no ACS	1.31 (1.25-1.37)	<0.0001				
21	MCS at start vs none	1.6 (1.41-1.82)	<0.0001				
22	MCS before intervention vs none	1.88 (1.76-2.02)	<0.0001				
23	Proximal LAD PCI	1.24 (1.2-1.28)	<0.0001				

The left side of the table shows the reduced AKI model, and the right side of the table shows the reduced dialysis model. Because their performance was similar to the full model, the writing group opted to use the reduced models for benchmarking and quality.

AKI = acute kidney injury; CKD = chronic kidney disease; LAD = left anterior descending artery; UA = unstable angina; other abbreviations as in Table 1.

TABLE 3 Reduced AKI and New-Onset Dialysis Models

	Discrimination (95% CI)		Calibration	
Models	Derivation	Validation	Intercept	Slope
AKI models				
Full	0.801 (0.797-0.805)	0.798 (0.793-0.803)	−0.036	0.977
Reduced	0.797 (0.792-0.782)	0.794 (0.790-0.799)	−0.032	0.979
Bedside	0.793 (0.790-0.796)	0.793 (0.789-0.796)	−0.197	0.957
Dialysis models				
Full	0.932 (0.926-0.937)	0.925 (0.916-0.935)	0.016	0.995
Reduced	0.925 (0.920-0.930)	0.918 (0.908-0.927)	0.006	0.994
Bedside	0.922 (0.917-0.927)	0.916 (0.906-0.925)	−0.348	1.010

Summary of model performance measures for the AKI and dialysis models.

AKI = acute kidney injury.

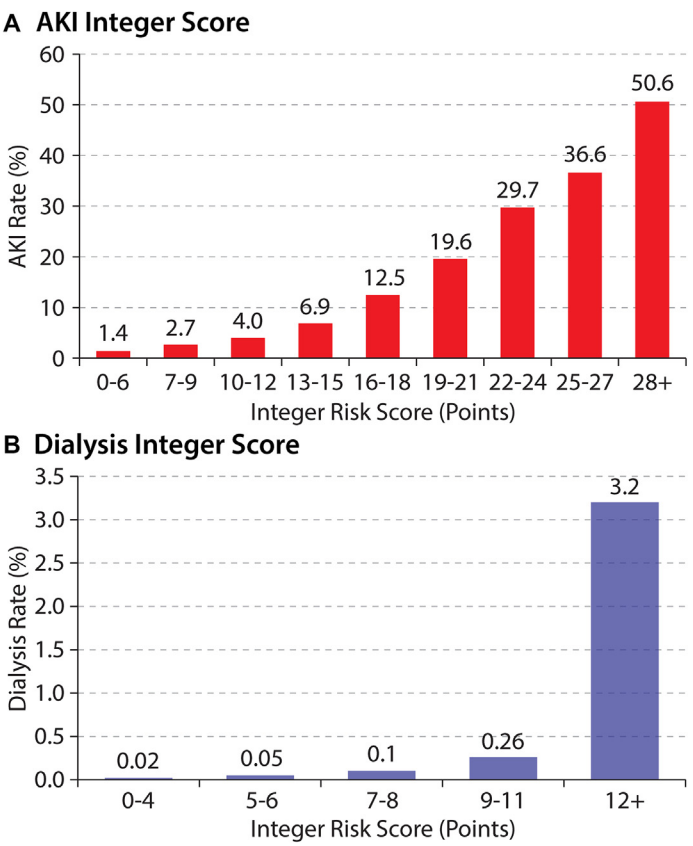
Preprocedural GFR is the most important predictor of AKI in the absence of salvage or shock. Thus, accurate estimates of GFR are critical to understanding AKI risk because direct measurement of renal function with iothalamate clearance is cumbersome and impractical. Although previous GFR estimates relied on a race term, this has been a subject of significant debate, and leading societies now recommend the use of race agnostic GFR equations.[17] This recommendation was further substantiated by our work, which found that GFR equations that include a race term underestimate AKI risk in Black patients and could contribute to an excess of AKI in this population. The more accurate estimation of AKI risk in Black patients with the current model can avoid inadvertently

higher observed than expected rates of AKI in hospitals that treat predominantly Black patients. It can also support better tailoring risk mitigation strategies, such as decreasing contrast volume or staging complex procedures, more appropriately for Black patients.

The writing group spent considerable time discussing whether the inclusion of MCS within the model was appropriate. In our analysis, MCS was significantly associated with AKI, even after adjusting for markers of clinical instability. This may suggest that there are signs of clinical deterioration physicians are appreciating, prompting MCS placement, that are not captured by other elements in the CathPCI data collection form. Alternatively, it is also possible that the MCS devices themselves contribute to the development of AKI, although a mechanism for this is not clear and will require future research to define.[12,30] Because it is unclear whether MCS is a marker or a mediator of AKI, the working group elected to include MCS present before or at the start of the procedure, which was consistent with the previous NCDR AKI risk prediction model that included intra-aortic balloon pump at the start of the procedure. By excluding subsequent use of MCS devices during the procedure, we also avoided inadvertently masking the AKI risk associated with complications of an unsuccessful PCI warranting the need for MCS.

BEDSIDE APPLICATION. Prospective use of the bedside model is an important opportunity to further improve PCI quality and decrease AKI incidence. As previously noted, AKI rates have remained unchanged since the last risk model was created a decade ago. Prospective use of the AKI bedside model to guide hydration, decisions to stage procedures and consider contrast thresholds has the potential to reduce AKI. Although questions remain regarding the role of radiocontrast media volume in the development of AKI, which would lessen the importance of limiting contrast,[19] efforts to limit radiocontrast administration demonstrate that volume reductions are feasible and have been associated with decreased AKI rates in higher-risk patients undergoing PCI.[21,22] We provide radiocontrast limits based on a patient's AKI risk that, in a retrospective NCDR study, were associated with lower AKI rates than the commonly used 2 or 3 times estimated GFR volume limits.[23] Subsequently, a study in *JAMA* demonstrated that prospective implementation of these risk-based contrast limits and hydration protocols was associated with reduced AKI rates in a multicenter stepped-wedge design compared with usual care (OR: 0.72; 95% CI: 0.56-0.93).[31] Future prospective studies should aim to illuminate whether risk-based contrast limits confer a benefit over traditional GFR-based contrast limits in reducing AKI.

FIGURE 3 Bedside Risk Scores and Event Rates



Validation of the integer risk score for both **(A)** acute kidney injury (AKI) and **(B)** dialysis. This demonstrates that as the risk score increased, the observed event rates increased.

STUDY LIMITATIONS. First, serum creatinine after contrast administration often peaks 2 to 5 days after PCI. However, the median length of stay for our sample was 2 days. Thus, there may be patients who develop AKI after discharge who would not be captured. However, if this were the case, the rate of AKI (7.2%) in our cohort would be lower than those of cohorts that have serial serum creatinine measurements, but instead we found similar rates of AKI (7%-9%).[1,32-34] Second, there are invasive hemodynamic parameters such as left ventricular end-diastolic pressure[35] and periprocedural practices

TABLE 4 Bedside Risk Score With Contrast Media Volume Thresholds

Condition	Points
Age <60, y	0
Age 60-69, y	1
Age 70-79, y	2
Age 80+, y	3
Hypertension	1
Hgb <10 g/dL	3
Diabetes	3
Severe frailty	2
History of heart failure	4
Concomitant procedure	2
Responsive cardiac arrest	4
Nonresponsive cardiac arrest	8
CKD: GFR 60-45	3
CKD: GFR 45-30	5
CKD: GFR <30	9
STEMI	3
NSTEMI/unstable angina	1
Salvage/refractory shock	14
Shock	12
Other cardiovascular instability	6
Emergent	5
Urgent	4

Score	AKI Risk (%)
0-6	1.40
7-9	2.70
10-12	4.00
13-15	6.90
16-18	12.50
19-21	19.60
22-24	29.70
25-27	36.60
28+	50.60

	Volume Threshold (mL)	
Preprocedure Risk (%)	10% Risk Reduction	15% Risk Reduction
7	97.2	71.7
8	94.9	69.3
9	90.6	64.8
10	86.8	60.7
11	83.2	56.9
12	79.9	53.3
13	76.7	49.9
14	73.8	46.6
15	70.9	43.5

This demonstrates how the bedside risk score is calculated and a way to practically apply this information by setting radiocontrast volume thresholds to decrease risk. The **top panel** shows the risk score variables and the corresponding points for each component present. The **middle panel** converts a total risk score to the risk of an AKI. The **bottom panel** shows the contrast threshold that theoretically could be used to decrease the risk of AKI by 10% and 15%.

Hgb = hemoglobin; other abbreviations as in Tables 1 and 2.

TABLE 5 Subgroup Model Discrimination Using the Reduced Model

Subgroup	C-Statistic (95% CI)	Brier Score
Age ≥65	0.791 (0.785-0.793)	0.068
Age <65 y	0.791 (0.783-0.801)	0.044
Shock	0.665 (0.652-0.685)	0.218
Arrest	0.761 (0.746-0.776)	0.161
STEMI	0.797 (0.787-0.807)	0.078
Male	0.797 (0.791-0.804)	0.053
Female	0.784 (0.786-0.792)	0.070
No ACS, shock, or arrest	0.763 (0.751-0.775)	0.035

Model performance in important prespecified subgroups is generally preserved, although there is a decrement in performance in patients presenting with shock.

Abbreviations as in Table 1.

such as hydration that are associated with AKI development[4] that are not captured by the CathPCI Registry. Although the inclusion of hydration could potentially improve the performance of the model, we would not want to include such information in a risk model so that preventative efforts would be adjusted out of the AKI estimates and diminish recognition of the beneficial steps taken by some hospitals to reduce AKI.

CONCLUSIONS

We present the rates of AKI after PCI in a large U.S.-based contemporary cohort and have developed new more accurate AKI risk prediction models based on the increased granularity of the version 5 CathPCI data set. Our models use the new race agnostic GFR equation, which will lead to better risk prediction and improvement in disparate outcomes for Black patients. Furthermore, we have transformed this model into a bedside tool that can generate safe contrast thresholds to support sites seeking to proactively reduce the rates of AKI at their institutions. Ultimately, these AKI risk prediction tools will drive improved quality assessment and can support quality improvement.

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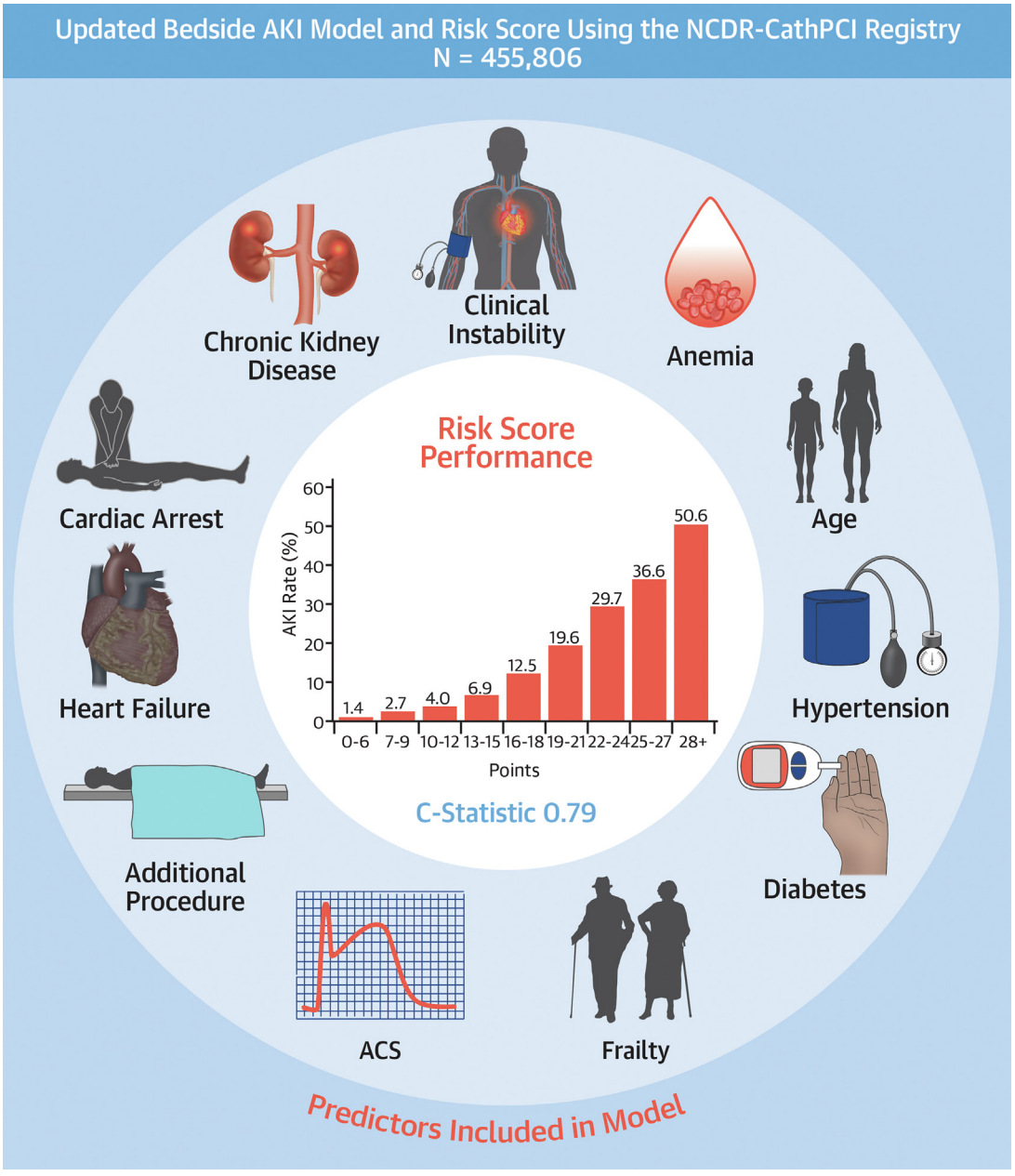
CENTRAL ILLUSTRATION New Bedside Acute Kidney Injury Model



Uzendu A, et al. J Am Coll Cardiol Intv. 2023;16(18):2294-2305.

This demonstrates the new bedside acute kidney injury (AKI) model with its predictor variables and key performance metrics. Along the circle are individual predictors of AKI included in the model. The center of the figure displays performance demonstrating the C-statistic = 0.79 and AKI rates with increasing integer scores. ACS = acute coronary syndrome; NCDR = National Cardiovascular Data Registry.

Monitoring Board member or chair for trials sponsored by Bayer, Gilead, Mineralys, Palladio, and ReCor. Dr Giri has received research funds to his institution; and has served on advisory boards for Boston Scientific, Abiomed, Abbott Vascular, Inari Medical, Biosense Webster, and Recor Medical. Dr Rymer has served on the advisory board for Chiesi; has received a research grant from Chiesi; and receives research funding from Idorsia, Pfizer, and Abbott. Dr Bangalore discloses has served on the advisory board for Abbott Vascular, Boston Scientific, Amgen, Pfizer, Merck, Inari, and Truvic. Dr Wang has received research grants to the Duke Clinical Research Institute from

Abbott, AstraZeneca, Bristol Myers Squibb, Boston Scientific, Artivion (formerly Cryolife), Chiesi, Merck, Portola, and Regeneron; and has received consulting honoraria from AstraZeneca, Bristol Myers Squibb, Artivion (formerly Cryolife), CSL Behring, and Novartis. Dr Curtis has an institutional contract with the American College of Cardiology for his role as chief scientific adviser of the NCDR; and has equity in Medtronic. Dr Spertus has provided consultative services on patient-reported outcomes and evidence evaluation to Alnylam, AstraZeneca, Bayer, Merck, Janssen, Bristol Meyers Squibb, Edwards Lifesciences, Kineksia, 4DT Medical, Terumo, Cytokinetics, Imbria, and United Healthcare; holds research grants from Bristol Meyers Squibb, Abbott Vascular, and Janssen; owns the copyright to the Seattle Angina Questionnaire, Kansas City Cardiomyopathy Questionnaire, and Peripheral Artery Questionnaire; and serves on the Board of Directors for Blue Cross Blue Shield of Kansas City. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.

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PERSPECTIVES

WHAT IS KNOWN? AKI is the most common complication after PCI and can be reduced by optimizing per-procedural care. Accurately estimating AKI risk can support quality assessment and improvement.

WHAT IS NEW? Capitalizing on more refined data collection captured in the NCDR CathPCI v5 Registry, we developed updated AKI risk prediction models for benchmarking health system performance, facilitating quality improvement initiatives, and enhancing patient care.

WHAT IS NEXT? Rigorously developing, implementing, and evaluating multicenter interventions to use this AKI risk assessment to reduce AKI rates and improve the safety of PCI should be conducted.

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KEY WORDS acute kidney injury, benchmarking, contrast-induced nephropathy, coronary angiography, percutaneous coronary intervention, risk model

APPENDIX For a supplemental table, please see the online version of this paper.

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NCDR REPORT

An Updated Bleeding Model to Predict the Risk of Post-Procedure Bleeding Among Patients Undergoing Percutaneous Coronary Intervention

A Report Using an Expanded Bleeding Definition From the National Cardiovascular Data Registry CathPCI Registry

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Objectives This study sought to develop a model that predicts bleeding complications using an expanded bleeding definition among patients undergoing percutaneous coronary intervention (PCI) in contemporary clinical practice.

Background New knowledge about the importance of periprocedural bleeding combined with techniques to mitigate its occurrence and the inclusion of new data in the updated CathPCI Registry data collection forms encouraged us to develop a new bleeding definition and risk model to improve the monitoring and safety of PCI.

Methods Detailed clinical data from 1,043,759 PCI procedures at 1,142 centers from February 2008 through April 2011 participating in the CathPCI Registry were used to identify factors associated with major bleeding complications occurring within 72 h post-PCI. Risk models (full and simplified risk scores) were developed in 80% of the cohort and validated in the remaining 20%. Model discrimination and calibration were assessed in the overall population and among the following pre-specified patient subgroups: females, those older than 70 years of age, those with diabetes mellitus, those with ST-segment elevation myocardial infarction, and those who did not undergo in-hospital coronary artery bypass grafting.

Results Using the updated definition, the rate of bleeding was 5.8%. The full model included 31 variables, and the risk score had 10. The full model had similar discriminatory value across pre-specified subgroups and was well calibrated across the PCI risk spectrum.

Conclusions The updated bleeding definition identifies important post-PCI bleeding events. Risk models that use this expanded definition provide accurate estimates of post-PCI bleeding risk, thereby better informing clinical decision making and facilitating risk-adjusted provider feedback to support quality improvement. (J Am Coll Cardiol Intv 2013;6:897–904) © 2013 by the American College of Cardiology Foundation

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Bleeding complications after percutaneous coronary intervention (PCI) are common and are associated with an increased short- and long-term risk of morbidity and mortality as well as increased costs (1,2). Several bleeding avoidance strategies (BAS), such as bivalirudin, radial approach, and, in some studies, vascular closure devices, have been proposed to reduce periprocedural bleeding among higher-risk patient groups (3–6). Yet previous studies have demonstrated a "risk-treatment" paradox with respect to the use of BAS among patients undergoing PCI: BAS are used the least among patients with the highest bleeding risk (7). Among high-risk patients, such as those with ST-segment elevation myocardial infarction, some of these BAS are associated with reduced mortality (8,9), underscoring the importance of applying BAS in patients most likely to benefit. Moreover, Medicare has begun considering peri-PCI bleeding as a component of its Acute Care Episode Demonstration Project, suggesting the growing importance of bleeding as an indicator of quality.

Previous studies have identified patient factors associated with bleeding in the context of acute coronary syndrome (10,11); however, these studies used a definition of bleeding specific to the dataset in which the models were developed and did not include a broad population of patients undergoing PCI. Given the importance of PCI outcomes as performance measures and the interest in public reporting of PCI-related quality of care (12), pre-procedural identification of patients undergoing PCI who are at higher bleeding risk could support more efficient use of BAS to improve the safety of PCI. Moreover, pre-procedural identification could facilitate better patient informed consent (13) and provide risk-adjusted bleeding outcomes feedback to sites participating in quality improvement registries.

Abbreviations and Acronyms

BARC = Bleeding Academic Research Consortium

BAS = bleeding avoidance strategies

BMI = body mass index

NCDR = National Cardiovascular Data Registry

The National Cardiovascular Data Registry (NCDR) CathPCI Registry is an ongoing contemporary quality improvement registry of patients undergoing PCI in the United States. The data elements recorded in the registry undergo periodic review and are updated to support continuous quality improvement. We previously published a model predicting the risk of bleeding for patients undergoing PCI using the data elements captured in the registry (14), but the bleeding definition relied on site identification of hemorrhagic events and was restrictive compared with bleeding definitions used in other studies. For example, bleeding events were not considered complications if they were not associated with a prolonged hospital stay or a hemoglobin decrease of at least 3 g/dl. In 2009, the CathPCI Registry implemented a new data collection form with more detailed data elements associated with bleeding events to capture important complications that were not available in previous versions. Using these data elements, a new CathPCI Registry post-procedure bleeding definition was created, with which we sought to: 1) define contemporary bleeding event rates; 2) define major independent predictors of bleeding; and 3) develop and validate a full pre-procedure risk prediction model as well as a simple bedside additive risk prediction tool.

Methods

Study population. The CathPCI Registry is an initiative of the American College of Cardiology and the Society for Cardiovascular Angiography and Interventions and has been previously described (15). This registry records data on patient and hospital characteristics, clinical presentation, hospital length of stay, treatments, and in-hospital outcomes for PCI procedures from >1,000 sites across the United States. The NCDR has a comprehensive data quality program, including both data quality report specifications for data capture and transmission, and an auditing program. Dataset variables are determined and defined by physician work groups; data collection forms and dictionaries can be found on the NCDR website (http://www.ncdr.com).

For this study, we included all PCI procedures performed between February 2008 and April 2011 that had collected data using version 4 of the CathPCI Registry data collection form. Nonindex PCI procedures during the same hospitalization were excluded, as were patients who died the same day as their procedure. In addition, we excluded patients who had missing data on bleeding events and sites that reported no bleeding events (Fig. 1).

Definitions and outcomes. The primary outcome for this analysis was post-PCI bleeding. Using the updated data collection form and the desire to improve the capture of clinically important bleeding events, a panel of experts amended the definition of bleeding as any of the following occurring within 72 h after PCI or before hospital discharge (whichever occurs first): site-reported arterial access site bleeding, which may be either external or a hematoma >10 cm for femoral access, >5 cm for brachial access, or >2 cm for radial access; retroperitoneal, gastrointestinal, or genitourinary bleeding; intracranial hemorrhage; cardiac tamponade; post-procedure hemoglobin decrease of 3 g/dl in patients with a pre-procedure hemoglobin level ≤16 g/dl; or post-procedure nonbypass surgery–related blood transfusion for patients with a pre-procedure hemoglobin level ≥8 g/dl. This definition includes events such as intracranial hemorrhage, tamponade, hemoglobin decreases that account for potential hemodilution, and transfusions that account for severe anemia that were not included in the previous definition. The definitions of the other data elements are available at http://www.ncdr.com.

Statistical analysis. Categorical variables are summarized as frequencies and percentages and compared with Pearson

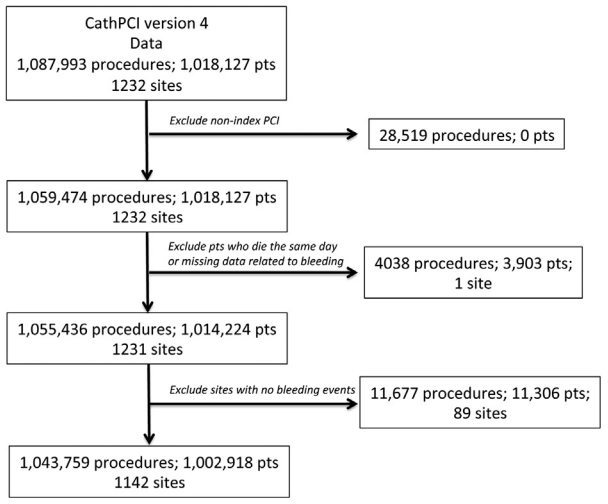

Figure 1. Study Sample Selection Flow Diagram

The initial study population through the final study population after applying exclusions. Pts = patients.

Table 1. Baseline Characteristics of the Development and Validation Samples

Characteristics	Overall (N = 1,043,759)	Development (n = 834,696)	Validation (n = 209,063)
Demographic			
Age yrs	65.0 (56.0–74.0)	64.0 (56.0–74.0)	65.0 (56.0–74.0)
Female	32.7	32.6	32.8
BMI, kg/m^2	29.1 (25.7–33.3)	29.1 (25.7–33.3)	29.1 (25.7–33.3)
Medical conditions			
Diabetes mellitus	35.9	35.9	35.9
Hypertension	81.8	81.8	81.9
Peripheral vascular disease	12.4	12.4	12.4
Chronic kidney disease	3.6	3.6	3.6
Previous PCI	40.3	40.3	40.3
Previous CABG	18.8	18.9	18.7
Median pre-procedure Hb, g/dl	13.7 (12.4–14.9)	13.7 (12.4–14.9)	13.7 (12.4–14.9)
Procedural			
Procedure status			
Elective	45.2	45.2	45.1
Urgent	37.5	37.5	37.7
Emergent	17.0	17.0	16.9
Salvage	0.3	0.3	0.3
STEMI	16.0	16.0	15.9
Lytics before PCI for STEMI	8.1	8.0	8.2
Shock	2.5	2.5	2.4
Cardiac arrest within 24 h of PCI	1.7	1.7	1.7
Hospital			
Beds	410.0 (283.0–571.0)	410.0 (283.0–571.0)	409.0 (282.0–569.0)
University hospital	11.3	11.3	11.3
Annual PCI cases	726.0 (445.1–1,177.9)	726.6 (445.1–1,183.1)	726.6 (448.0–1,177.9)

Values are median (25th–75th percentile) or %. All p values >0.05.

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

chi-square tests. Continuous variables are summarized as median (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.

The study population was randomly split into a development sample consisting of 80% of admissions and a validation sample consisting of the remaining 20% of admissions. Baseline patient characteristics and variables from diagnostic catheterization were considered candidate variables. Candidate variables had <0.5% missing data except for estimated glomerular filtration rate (7.8%), pre-procedure hemoglobin level (9.5%), and ejection fraction (29.4%). Missing values were imputed to the lower risk group for discrete variables and replaced with sex-specific medians for body mass index (BMI), sex, and renal failure/dialysis–specific medians for estimated glomerular filtration rate, median value for hemoglobin, and congestive heart failure/cardiogenic shock/previous myocardial infarction–specific medians for ejection fraction. We used logistic regression with backward selection to stay criterion of $p < 0.05$ to develop a model predicting post-PCI bleeding. Variables that showed nonlinear associations with the outcome were transformed using splines.

We developed a full post-PCI bleeding model using all potential predictive variables. We also developed a risk prediction score by taking the regression coefficients from the pre-procedure model and assigning them an integer weighted to the comparative odds ratio associated with the risk factors (16). Covariates selected for the risk score were those with a chi-square >500. An individual patient's bleeding risk score is the sum of their integer weights. Patients were defined as at low, medium, and high risk of bleeding based on the predicted risk of bleeding derived from the prediction score. Patients with a predicted risk of bleeding at or below the 25th percentile probability were considered low risk, patients with a predicted risk of bleeding between the 25th and 75th percentile probability were considered moderate risk, and patients with a predicted risk of bleeding at or above the 75th percentile probability were considered high risk.

The C-statistic was used to compare discrimination between models and in clinical subgroups of interest including patients with ST-segment elevation myocardial infarction, females, those older than 70 years of age, those

Table 2. In-hospital Bleeding Rates Overall and in Pre-specified Subgroups in the Development and Validation Samples

Group	Overall (N = 1,043,759)	Development (n = 834,696)	Validation (n = 209,063)
All patients	5.8	5.8	5.8
STEMI	14.1	14.2	14.0
Females	8.6	8.7	8.5
Age >70 yrs	7.5	7.5	7.5
Diabetes	5.9	6.0	5.9
Excluding in-hospital CABG	5.4	5.4	5.4

Values are %.
Abbreviations as in Table 1.

with diabetes mellitus, and those who did not undergo in-hospital coronary artery bypass grafting. Calibration plots were used to access goodness of fit. A p value <0.05 was considered statistically significant. All statistical tests were 2 sided. All statistical analyses were performed at the Duke Clinical Research Institute using SAS software (version 9.2, SAS Institute, Cary, North Carolina) and Stata version 11 (StataCorp LP, College Station, Texas).

Ethical considerations. The Institutional Review Board of Duke University Medical Center approved this analysis and determined that it met the definition of research not requiring informed consent.

Results

Study sample. Between February 2008 and April 2011, 1,059,474 PCI procedures were performed at 1,232 sites and had data entered into version 4 of the CathPCI Registry data collection form. After applying exclusion criteria, 1,043,759 procedures from 1,142 sites remained (Fig. 1). Table 1 displays the baseline patient, procedure, and hospital characteristics of the development and validation samples. There were 60,194 PCI procedures that had post-procedure bleeding, yielding a post-PCI bleeding event rate of 5.8%. Of these events, 32% were site-reported at a specific anatomic location, whereas 44.6% were detected due to a pre- to post-procedure hemoglobin decrease, 21.8% by a blood transfusion, 1% by cardiac tamponade, and 0.6% were intracranial hemorrhage events.

Risk factors for in-hospital bleeding. Table 2 displays the in-hospital bleeding rates for the overall development and validation samples, as well as the rates for each pre-specified subgroup within the samples. The full model, which includes 33 variables, is displayed in Table 3. The most predictive factors, according to their chi-square, were female sex followed by shock or salvage PCI. In contrast, non-insulin-requiring diabetes mellitus was the least predictive. Several variables required transformation with splines such that the relationship with bleeding changed according to knots at specific values. Pre-procedure hemoglobin value, BMI, and age all had nonlinear associations with bleeding and required transformation. Table 4 shows the bedside NCDR bleeding risk score derived from the pre-procedure

Table 3. The Full Model

Category	OR	95% CI	Chi-Square
Demographic characteristics and medical history			
Female vs. male	1.97	1.93–2.02	4,045.30
Dialysis vs. no disease	1.88	1.80–1.95	975.02
Moderate chronic kidney disease (GFR = 30–44 ml/min) vs. no disease	1.68	1.62–1.73	918.89
Previous PCI	0.74	0.72–0.76	726.13
BMI (when BMI ≤ 30 kg/m^2)*	0.96	0.96–0.97	594.60
Mild chronic kidney disease (GFR = 45–59 ml/min) vs. no disease	1.34	1.31–1.38	487.83
Heart Failure NYHA class IV within 2 weeks Heart failure NYHA class IV within 2 weeks vs. no heart failure within 2 weeks	1.63	1.56–1.70	458.03
Age (≤70 yrs)*	1.02	1.01–1.02	456.10
Chronic lung disease	1.23	1.19–1.26	241.87
Peripheral vascular disease	1.19	1.15–1.22	139.27
NYHA functional class IV HF within 2 weeks before PCI vs. NYHA functional class<IV	1.17	1.13–1.21	76.74
Cerebrovascular disease	1.13	1.10–1.16	74.81
Age (>70 yrs)*	1.01	1.00–1.01	51.20
Insulin requiring diabetes mellitus vs. no diabetes	1.09	1.06–1.13	32.29
Presenting characteristics and PCI status			
Shock within 24 h before and at start of PCI or Salvage procedure	6.02	5.67–6.39	3,511.54
Emergent procedure	2.88	2.76–3.00	2,557.14
Shock within 24 h or at start of PCI	4.39	4.13–4.66	2,334.84
Urgent procedure	1.50	1.46–1.54	948.41
Shock within 24 h and at start of PCI	5.22	4.56–5.98	571.96
Cardiac arrest within 24 h of PCI	1.75	1.66–1.83	533.55
Lytics before PCI for STEMI	1.12	1.04–1.19	10.11
Laboratory values			
Pre-PCI Hb (Hb ≤13 g/dl)*	0.80	0.79–0.81	2,300.92
Pre-PCI Hb (Hb >13 g/dl)*	1.11	1.10–1.12	621.50
Procedural characteristics			
2- or 3-vessel disease vs. no disease or 1-vessel disease	1.23	1.20–1.25	397.13
STEMI	1.45	1.40–1.50	376.49
SCAI lesion class II or III	1.25	1.22–1.28	330.45
SCAI lesion class IV	1.43	1.37–1.49	301.23
Pre-procedure TIMI flow grade = 0	1.24	1.20–1.29	151.28
Left main PCI	1.43	1.35–1.51	149.45
Subacute stent thrombosis	1.61	1.44–1.81	67.12
Proximal LAD PCI	1.10	1.07–1.12	51.43

*Variables transformed using splines
CI = confidence interval; GFR = glomerular filtration rate; HF = heart failure; LAD = left anterior descending; NYHA = New York Heart Association; OR = odds ratio; SCAI = Society for Cardiovascular Angiography and Intervention; TIMI = Thrombolysis In Myocardial Infarction; other abbreviations as in Table 1.

Table 4. NCDR CathPCI Bleeding Risk Score

Variable	Score			
STEMI	No	Yes		
	0	15		
Age, yrs	<60	60–70	71–79	≥80
	0	10	15	20
BMI	<20	20–30	31–39	≥40
	15	5	0	5
Previous PCI	No	Yes		
	10	0		
Chronic kidney disease	No	Mild	Moderate	Dialysis
	0	10	25	30
Shock	No	Yes		
	0	35		
Cardiac arrest within 24 h	No	Yes		
	0	15		
Female	No	Yes		
	0	20		
Hb	Hb <13	13 ≤Hb <15	Hb ≥15	
	5	0	10	
PCI status	Elective	Urgent	Emergency/salvage	
	0	20	40	

Abbreviations as in Table 1.

model. Using these 10 variables and the scoring system, the risk of post-PCI bleeding can be estimated by summing the point scores between 0 and 210 (Table 5, Fig. 2).

Model performance. The full bleeding risk model had good discrimination in both the development and validation samples (c-index, development sample 0.78; validation sample 0.77). Table 6 lists the c-indexes of the full model and the risk score in the overall development and validation samples, as well as in pre-specified subgroups. The c-indexes for the subgroups ranged from 0.70 to 0.78. The model calibration plot for the full model is shown in Figure 3. There was high concordance between the risk predicted by the models and the observed bleeding events. Model calibration plots for the pre-specified subgroups are shown in the Online Appendix. There was a high level of concordance among these subgroups as well.

Discussion

Bleeding remains one of the most common complications of PCI. Accordingly, as part of its quality improvement efforts, the NCDR seeks to improve its data collection and update its risk models by leveraging new data elements and improving bleeding definitions to capture a range of additional clinically important variables. These new models can be used to improve the safety of PCI by enabling the prospective identification of patients who would benefit most from BAS and by creating the infrastructure to support risk-adjusted provider feedback reports.

Table 5. Risk of Bleeding Based on Point Totals From the NCDR CathPCI Registry Bleeding Risk Score

Total Points	Risk of Bleeding, %
0	0.90
5	1.10
10	1.30
15	1.50
20	1.70
25	2.00
30	2.30
35	2.70
40	3.10
45	3.60
50	4.20
55	4.90
60	5.60
65	6.50
70	7.50
75	8.60
80	9.90
85	11.40
90	13.10
95	14.90
100	17.00
105	19.30
110	21.80
115	24.60
120	27.50
125	30.70
130	34.10
135	37.60
140	41.30
145	45.10
150	49.00
155	52.80
160	56.60
165	60.40
170	64.00
175	67.50
180	70.80
185	73.90
190	76.80
195	79.40
200	81.80
205	84.00
210	86.00

NCDR = National Cardiovascular Data Registry.

Using our updated bleeding definition, ~1 in 20 patients (5.8%) were observed to have a bleeding event. This rate is higher than previously reported (2.4%) and reflects the inclusion of bleeding complications (such as tamponade and transfusions in clinically appropriate groups) that were not included in the previous definition, but which enabled broader estimates of clinically important bleeding to be

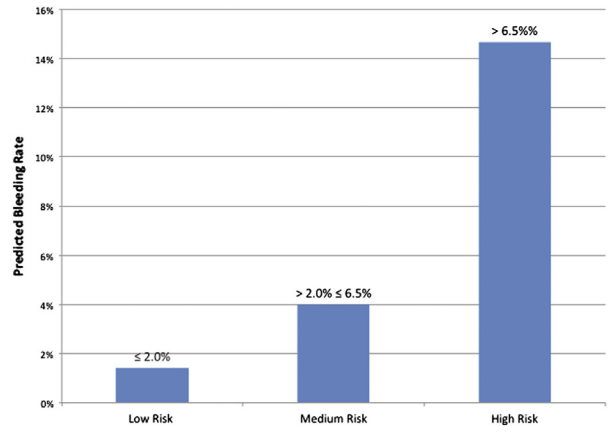

Figure 2. Risk of Post-Percutaneous Coronary Intervention Bleeding Based on the Bedside Bleeding Risk Prediction Score

The predicted risk of in-hospital bleeding among patients determined to be at low, medium, or high risk of bleeding based on the bedside bleeding risk score. Scores of ≤25 are low risk, scores 25 to 65 are medium risk, and scores >65 are high risk.

generated. The bleeding rate reported in our study is also more consistent with the rate reported in clinical trials, such as the ACUITY (Acute Catheterization and Urgent Intervention Triage Strategy) trial, where the rate of bleeding among patients treated with glycoprotein IIb/IIIa inhibitors was 5.3% to 5.7% (17).

Studies indicate that the reported rate of bleeding is highly dependent on the definition used (18); a standardized bleeding definition, called the Bleeding Academic Research Consortium (BARC) definition, was recently proposed for clinical trials of patients with acute coronary syndrome or those undergoing PCI (19). The BARC definition includes many of the elements used in the current CathPCI Registry bleeding definition, but also relies heavily on adjudication. Although the size and scope of the CathPCI Registry makes adjudication of bleeding events impractical, the new bleeding definition is consistent with the major components of the BARC definition. An ongoing randomized clinical trial, the SAFE-PCI (Study of Access site For Enhancement of PCI for Women [NCT01406236]), is using the CathPCI Registry as a platform for data collection and has BARC type 2 or greater bleeding as the primary endpoint. This study will provide estimates of the correlation between BARC-defined bleeding and the updated CathPCI Registry definition of bleeding.

Importantly, a number of patient characteristics were strongly associated with periprocedural bleeding. Many of the predictive factors that we identified have been shown in other studies to be predictive of bleeding events. For example, female sex is consistently associated with an increased risk of bleeding (20), as are other variables like age, renal function, and BMI (21). In addition to these factors, we also identified unique variables not present in other bleeding risk models, such as pre-procedure hemoglobin level, cardiac arrest, shock, and clinical status (e.g., salvage procedures). For the full model that will be used to support risk-adjusted hospital comparisons, the addition of such variables is a significant advantage over previous models that use clinical trial data where the acuity of clinical presentation is generally not as severe. The inclusion of these variables minimizes the risk that hospitals that disproportionately care for patients with these high-risk characteristics would not be unduly penalized. This model can be used to risk-adjust post-PCI bleeding rates for the centers participating in the CathPCI Registry, identify leaders and laggards, and ultimately improve the safety of PCI by encouraging the adoption of BAS at centers that have higher-than-expected risk-adjusted bleeding rates. For example, previous studies have shown substantially greater absolute risk reductions with BAS use among patients with higher bleeding risks, previously defined as >1% (14). Corresponding thresholds with the new bleeding definition would be a risk of ≤2.0% (integer score ≤25), >2.0%, ≤6.5% (integer bleeding risk score of 25 to 65), and high risk representing risks >6.5% (integer bleeding risk score >65). The use of the CathPCI Registry bleeding risk score may encourage greater adoption of bivalirudin, vascular closure devices, or radial approach among patients in these higher-risk categories. This may be

Table 6. c-Indexes of the Full Model and Risk Score Models in the Overall Dataset and in Pre-Specified Subgroups

Group	n		Full Model		Risk Score	
	Development Sample	Validation Sample	Development Sample	Validation Sample	Development Sample	Validation Sample
Overall	834,696	209,063	0.78	0.77	0.76	0.75
STEMI	133,649	33,311	0.71	0.71	0.70	0.70
Women	272,357	68,540	0.74	0.74	0.73	0.72
Age >70 yrs	275,089	69,015	0.76	0.76	0.74	0.74
Diabetes	299,402	75,003	0.78	0.78	0.76	0.76
Excluding in-hospital CABG	824,414	205,510	0.79	0.78	0.76	0.76

Abbreviations as in Table 1.

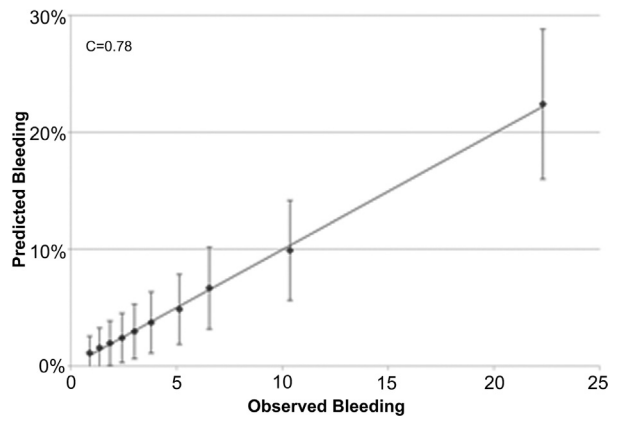

Figure 3. Model Calibration Plot for the Full Model

The observed versus the predicted bleeding rates and 95% confidence intervals for 10 equally sized risk groups.

particularly important given the interest in public reporting of PCI-related outcomes (12). The distribution of risk using the new bleeding definition potentially broadens the proportion of patients who might benefit from BAS implementation, but future comparative effectiveness studies are needed to confirm this hypothesis. The bedside risk score that we developed, using 10 key variables, has further utility by facilitating pre-procedure identification of patients at high risk of bleeding, as well as informing the consent process (13).

Study limitations. First, in many states, participation in the CathPCI Registry is voluntary; therefore, this registry may not be completely representative of all PCI procedures performed in the United States. Nevertheless, the CathPCI Registry is the largest ongoing contemporary registry of PCI and there are no a priori reasons to believe that the associations between patient characteristics and periprocedural bleeding would differ among hospitals that do and do not participate in the NCDR. Second, the new definition of bleeding still includes site-identified bleeding complication data, although these data have objective definitions, sites may vary in their threshold for reporting these events. Nevertheless, the definition now also includes blood transfusion, hemoglobin decreases, and intracranial hemorrhage, thereby making it likely to detect the most clinically significant bleeding events. The use of blood transfusion in the registry may not necessarily reflect clinical bleeding, and its use is controversial in patients with coronary artery disease. Although some may argue that other physicians involved in patient care may be ordering "unnecessary" blood transfusions, the limitation of the new definition to only include those transfusions that occur in patients with hemoglobin values >8 mg/dl is congruent with previous data showing harm from transfusions in this population (22,23).

Conclusions

Using data from the NCDR CathPCI Registry, we updated the definition of bleeding to capture hemorrhagic events previously excluded and developed and validated contemporary predictive and risk-adjustment models for post-PCI bleeding. The models had good operating characteristics in the overall dataset of patients undergoing PCI, as well as among high-risk subgroups. This model will serve as the basis for providing risk-adjusted feedback on bleeding rates for sites participating in the CathPCI Registry, and the bedside bleeding risk score can facilitate the use of BAS in patients most likely to benefit.

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Key Words: bleeding complications ■ bleeding risk models ■ percutaneous coronary intervention ■ quality improvement.

APPENDIX

For supplemental material, please see the online version of this article.

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Predicting In-Hospital Mortality in Patients Undergoing Percutaneous Coronary Intervention

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ABSTRACT

BACKGROUND Standardization of risk is critical in benchmarking and quality improvement efforts for percutaneous coronary interventions (PCIs). In 2018, the CathPCI Registry was updated to include additional variables to better classify higher-risk patients.

OBJECTIVES This study sought to develop a model for predicting in-hospital mortality risk following PCI incorporating these additional variables.

METHODS Data from 706,263 PCIs performed between July 2018 and June 2019 at 1,608 sites were used to develop and validate a new full and pre-catheterization model to predict in-hospital mortality, and a simplified bedside risk score. The sample was randomly split into a development cohort (70%, n = 495,005) and a validation cohort (30%, n = 211,258). The authors created 1,000 bootstrapped samples of the development cohort and used stepwise selection logistic regression on each sample. The final model included variables that were selected in at least 70% of the bootstrapped samples and those identified a priori due to clinical relevance.

RESULTS In-hospital mortality following PCI varied based on clinical presentation. Procedural urgency, cardiovascular instability, and level of consciousness after cardiac arrest were most predictive of in-hospital mortality. The full model performed well, with excellent discrimination (C-index: 0.943) in the validation cohort and good calibration across different clinical and procedural risk cohorts. The median hospital risk-standardized mortality rate was 1.9% and ranged from 1.1% to 3.3% (interquartile range: 1.7% to 2.1%).

CONCLUSIONS The risk of mortality following PCI can be predicted in contemporary practice by incorporating variables that reflect clinical acuity. This model, which includes data previously not captured, is a valid instrument for risk stratification and for quality improvement efforts. (J Am Coll Cardiol 2021;78:216–29) © 2021 by the American College of Cardiology Foundation.

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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

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The National Cardiovascular Data Registry (NCDR) CathPCI Registry was developed to characterize the quality of care provided to patients undergoing percutaneous coronary interventions (PCIs) (1). Risk-adjusted models allow for the consideration of patients' pre-procedural risk factors when estimating PCI-associated mortality rates, a cornerstone of quality assessment (2). The CathPCI Registry risk-adjusted mortality prediction models have been important tools used in clinical decision making, quality improvement, and research, and have potential use in public reporting programs by allowing appropriate comparison of site-specific outcomes that account for differences in case mix (3).

Prior mortality models from the registry included a full model used for risk adjustment, a pre-catheterization model developed to understand risk prior to performing diagnostic angiography, and a simplified 8-variable risk score designed to be used at the bedside (4). In 2013, these models were updated to account for patients undergoing high-risk PCI (5,6). All prior models had excellent performance in contemporary clinical practice; however, concerns were raised that the risk-adjustment models may not adequately account for risk in extreme-risk patients or lower-volume centers, and that clinicians and hospitals treating a greater number of high-risk patients may have worse risk-adjusted mortality ratings (7,8). Appropriate risk adjustment is necessary to prevent potential risk-adverse behaviors that may negatively affect patients who are at highest risk, particularly those with cardiogenic shock and cardiac arrest, who may benefit the most from revascularization (9,10).

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The CathPCI mortality risk model plays an important role as public reporting and incorporation of outcomes measures into payment programs continues to evolve in the United States. Given the impact on public perception and practice patterns, improvements in the model and evaluation of the model's performance across the spectrum of risk are paramount. The CathPCI Registry released an updated version 5 dataset in 2018, which introduced new variables including frailty, cardiovascular instability type, level of consciousness after cardiac arrest, and decision for PCI with surgical consult. We sought

ABBREVIATIONS AND ACRONYMS

ACC = American College of Cardiology

CI = confidence interval

CVI = cardiovascular instability

DCFv5 = version 5 of the CathPCI Registry data collection form

EF = ejection fraction

GFR = glomerular filtration rate

NCDR = National Cardiovascular Data Registry

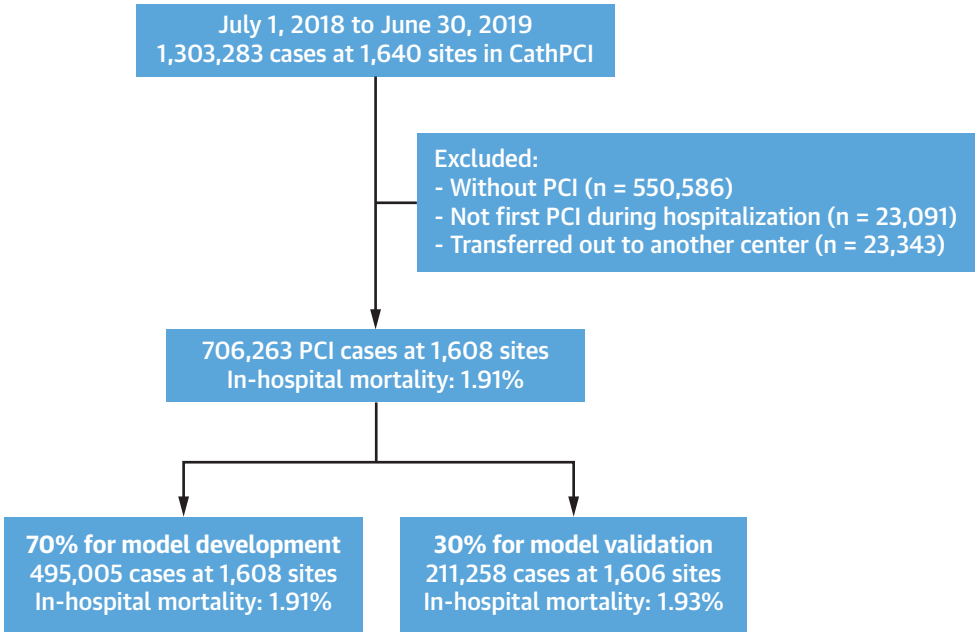
OR = odds ratio

PCI = percutaneous coronary intervention

RSMR = risk-standardized mortality rate

STEMI = ST-segment elevation myocardial infarction

FIGURE 1 Study Cohort



Between July 2018 and June 2019, 1,303,283 consecutive procedures were recorded in the National Cardiovascular Data Registry CathPCI Registry. Following exclusions, 706,263 total patients undergoing percutaneous coronary intervention (PCI) from 1,608 sites were included in the model development and validation cohorts.

TABLE 1 Patient Clinical Characteristics

	Overall (N = 706,263)	Development (n = 495,005)	Validation (n = 211,258)
Patient characteristics			
Age, yrs	66.3 ± 11.7	66.3 ± 11.7	66.3 ± 11.7
Female	30.8	30.7	30.8
Race			
White	85.0	85.0	85.0
Black	8.5	8.5	8.4
BMI, kg/m^2	30.2 ± 6.5	30.2 ± 6.5	30.2 ± 6.5
Comorbidities			
Diabetes	40.8	40.8	40.9
Cerebrovascular disease	14.3	14.3	14.3
Peripheral arterial disease	11.8	11.8	11.8
Chronic lung disease	15.7	15.7	15.6
Prior myocardial infarction	28.0	28.0	28.0
Prior PCI	41.0	41.0	41.0
Prior CABG	16.2	16.2	16.3
CKD stage			
Stage 3a (GFR 45–60 ml/min/1.73 m^2)	14.9	14.9	15.0
Stage 3b (GFR 30–45 ml/min/1.73 m^2)	7.3	7.3	7.4
Stage 4 (GFR 15–29 ml/min/1.73 m^2)	2.0	2.0	2.0
Stage 5 (GFR <15 ml/min/1.73 m^2 or dialysis)	3.5	3.5	3.5
Frailty scale			
Not frail	77.9	77.9	77.9
Intermediately frail	17.8	17.8	17.8
Severely frail	4.0	4.0	4.0
Aortic stenosis (at least moderate)	1.9	1.9	1.9
Family history of premature CAD	17.4	17.5	17.4
LVEF, %	51.5 ± 13.0	51.5 ± 13.0	51.6 ± 13.0
NYHA functional class			
IV	2.9	2.9	3.0
I/II/III	20.7	20.7	20.7
No CHF	76.4	76.4	76.3

Continued on the next page

to: 1) develop a new hierarchical mortality model that incorporates these new variables and accounts for case mix and hospital volume; 2) evaluate the performance of this new mortality model across different risk cohorts; and 3) identify unique cohorts suitable for internal quality improvement and potentially public reporting.

METHODS

DATA SOURCES. The CathPCI Registry is a national clinical registry program of the American College of Cardiology (ACC) with partnering support from the Society for Cardiovascular Angiography and Interventions. Description of the registry and the development of its risk mortality prediction models have been previously reported (4,11). The registry collects data on patient demographics, procedural and clinical characteristics, hospital characteristics, and in-hospital outcomes for PCIs from >1,600 participating hospitals in the United States. Data are monitored through a comprehensive data quality program that includes a data quality report, a set of internal quality assurance protocols, and a yearly independent auditing program (12).

STUDY POPULATION. All patients undergoing PCI at any of the 1,608 participating hospitals submitting data to the CathPCI Registry between July 2018 and June 2019 were included. Consistent with prior CathPCI mortality models, only the first procedure per admission was included, and patients were excluded if they were transferred to another facility after the index procedure. The study population was randomly allocated into a model development cohort (70% of total) and a validation cohort (30% of total).

VARIABLE DEFINITIONS. The v5 data collection form (DCFv5) integrated a series of new variables that further characterize patients' clinical status. To better characterize cardiovascular instability, new variables included ventricular arrhythmias, acute heart failure symptoms, hemodynamic instability without cardiogenic shock, cardiogenic shock, and refractory cardiogenic shock (defined as persistent hypotension despite mechanical or pharmacologic vasopressor support). A composite ordinal variable was created combining the components of cardiovascular instability with the procedural status, assigned into 6 mutually exclusive categories in decreasing order of procedural urgency and mortality risk: 1) salvage PCI or refractory shock; 2) cardiogenic shock (not refractory) without salvage; 3) cardiovascular instability [CVI] (includes hemodynamic instability, acute heart failure symptoms, and ventricular arrhythmia in the absence of shock) without salvage; 4) emergency PCI without shock or CVI; 5) urgent PCI without shock or CVI; and 6) elective PCI without shock or CVI.

The new frailty variable included in DCFv5 was based on the Canadian Study of Health and Aging clinical frailty scale (13). Patients were classified as nonfrail, intermediately frail (mild and moderate frailty), and severely frail (severe, severely frail, and terminally ill). Per the data definitions for DCFv5, frailty was based on the clinical condition prior to the start of the procedure, which could lead to patients presenting with cardiac arrest, cardiogenic shock, or salvage being coded as severely frail irrespective of their baseline status before admission. For purposes of the model, only those patients without cardiac arrest, shock, or undergoing salvage PCI were eligible to considered as severely frail and were compared with all other patients (nonsevere frailty).

A new variable that captured level of consciousness at start of PCI in patients who have suffered cardiac arrest was also incorporated. Patients were categorized as unresponsive if they were not responsive to verbal or painful stimuli or if their level of consciousness was unable to be assessed (e.g., patients who are intubated and sedated). In addition, surgical evaluation prior to PCI was also integrated as new variable. Patients were considered to be a surgical turndown in those cases in which a cardiac surgical consult was obtained before engaging in PCI but surgery was not recommended. Aortic stenosis severity as an indication for cath lab visit was also a newly collected variable. The definitions for number of diseased vessels have been updated to include not only angiographically significant stenosis, but also fractional flow reserve and instantaneous wave-free ratio values indicative of ischemia. Finally, estimated glomerular filtration rate (GFR) was calculated based on the Chronic Kidney Disease Epidemiology Collaboration equation. Chronic kidney disease was classified according to latest guideline-recommended definition: stage 3a, GFR 45 to 60 ml/min/1.73 m^2; stage 3b, GFR 30 to 44 ml/min/1.73 m^2; stage 4, GFR 15 to 29 ml/min/1.73 m^2; stage 5, GFR <15 ml/min/1.73 m^2 or dialysis (14). The full definitions of the data elements in the registry are available on the NCDR website (15).

VARIABLE SELECTION. The NCDR established a Risk Adjusted Mortality work group of ACC volunteers to oversee model development and provide input on variable selection and considerations for the model. Candidate variables were screened and selected by the workgroup based on their clinical relevance, association with outcomes from prior research, and importance in model development. For final variable selection, bootstrap analysis was performed. First, the development sample was used to create 1,000 "bootstrap" samples. For each sample, we ran a logistic regression that included the candidate variables using stepwise selection method (entry = 0.0005, exit = 0.0001). We then calculated the percentage of times each of the variables was selected in the 1,000 samples. The variables that were selected in at least 70% of bootstrap samples were then included in the final model. All clinical variables that had been identified a priori as being clinically relevant met this threshold except patients turned down for surgery. Given that this variable represents a unique population that may be clustered at certain facilities and high-risk patients with limited treatment options, it was forced into the final model.

TABLE 1 Continued

	Overall (N = 706,263)	Development (n = 495,005)	Validation (n = 211,258)
Clinical presentation			
Systolic blood pressure, mm Hg	148.0 ± 26.4	148.0 ± 26.4	148.0 ± 26.4
STEMI	16.3	16.4	16.2
Treated with thrombolytics	0.6	0.6	0.6
Clinical instability			
Salvage PCI or refractory shock	0.5	0.5	0.5
Cardiogenic shock without salvage	1.8	1.8	1.8
Cardiovascular instability without salvage	4.3	4.3	4.3
Emergency PCI without shock/CVI	14.4	14.4	14.3
Urgent PCI without shock/CVI	40.3	40.2	40.3
Elective PCI without shock/CVI	38.8	38.8	38.8
Cardiac arrest			
Responsive	1.4	1.4	1.4
Unresponsive	1.3	1.2	1.3
Surgery not recommended	3.2	3.2	3.2
Procedural characteristics			
Highest risk coronary segment treated			
Left main	3.5	3.5	3.6
Proximal LAD	20.1	20.1	20.0
Number of diseased vessels			
1	52.4	52.5	52.3
2	29.7	29.7	29.8
3	16.8	16.7	16.8
TIMI flow grade 0	15.2	15.2	15.1
Subacute in-stent thrombosis	0.3	0.3	0.3
In-stent restenosis	10.8	10.7	10.9
Chronic total occlusion treated	4.1	4.1	4.1
Bypass graft treated	5.1	5.1	5.1
Type C lesion	63.0	63.0	62.9
Bifurcation lesion	12.0	12.0	12.0

Values are mean ± SD or %.

BMI = body mass index; CABG = coronary artery bypass grafting; CAD = coronary artery disease; CHF = congestive heart failure; CKD = chronic kidney disease; CVI = cardiovascular instability; GFR = glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; STEMI = ST-segment elevation myocardial infarction; TIMI = Thrombolysis In Myocardial Infarction.

MISSING DATA. The rates of missing data were very low (<1%) for all variables, except for ejection fraction (24%) and GFR (2.5%). For cases with missing information, the following imputation rules were used: 1) for variables related to past medical history, presence of stent thrombosis, and highest-risk coronary lesion, missing data were imputed to "no"; 2) for body mass index, missing values were imputed to the sex-specific median; 3) for GFR, missing values were imputed to the sex-, prior renal failure-, and ST-segment elevation myocardial infarction (STEMI)-specific median; and 4) for ejection fraction, missing data were imputed to the strata-specific median based on a history of congestive heart failure, prior myocardial infarction, pre-procedural cardiogenic shock, and the presence of STEMI. These imputation rules have been used in prior models and have

TABLE 2 Unadjusted In-Hospital Mortality Rates (N = 706,263)

Overall population	1.91
Demographic group	
Female	2.40
Male	1.70
>70 yrs	2.71
≤70 yrs	1.43
Diabetes	2.06
No diabetes	1.82
Severely frail excluding shock/cardiac arrest/salvage	6.92
Surgery not recommended	5.11
No cardiogenic shock or cardiac arrest	0.80
MI status	
STEMI	6.56
No STEMI	1.01
STEMI without cardiac arrest/shock	2.23
Cardiac arrest	
Responsive	7.30
Unresponsive	51.7
Clinical instability status	
Salvage PCI or refractory shock	62.01
Cardiogenic shock without salvage	35.61
Cardiovascular instability without salvage	7.26
Emergency PCI without shock/CVI	2.18
Urgent PCI without shock/CVI	0.70
Elective PCI without shock/CVI	0.17

Values are %.
MI = myocardial infarction; other abbreviations as in Table 1.

generated results similar to those using multiple imputation methods (4,5).

STATISTICAL ANALYSIS. Graphical functions were evaluated for all continuous variables to test for a linear relationship with mortality. For nonlinear relationships the variable was transformed using spline functions. Extreme values for continuous variables were set to outer limits based on clinical judgment. A multivariate logistic regression model linking mortality to the selected variables was fitted. Three models were developed, including: 1) a full model that included all the candidate variables; 2) a pre-cath model that excluded the angiographic data; and 3) a simplified bedside risk score, which included a reduced number of variables that explained >90% of the risk model. The regression coefficients for these variables were converted to an integer score to create a bedside mortality risk score. To account for the natural clustering of observations within hospitals, a hierarchical logistic regression model was fitted linking mortality to the selected variables with a hospital-specific random effect. Hospital-specific risk-standardized mortality rates (RSMRs) for each hospital were calculated using the regression coefficients and estimates of the random effect of each hospital from the hierarchical model. RSMRs were obtained as the ratio of hospital-specific predicted mortality to the hospital-specific expected mortality, multiplied by the mortality rate in the study cohort. The expected number of deaths for each hospital was calculated by summing over the predicted mortality risks for all patients in the hospital using the average of all hospital-specific intercepts, and the predicted number of deaths was calculated in the same manner but using an estimated intercept that is specific for that hospital. This ratio was then multiplied by the mortality rate in the study cohort to calculate RSMRs for that particular site (16,17). The Human Investigation Committee of the Yale University School of Medicine approved the use of a limited dataset from the NCDR for research purposes without requiring informed consent because all of the data were deidentified and maintained centrally by the NCDR.

MODEL PERFORMANCE. After development, the 3 models were applied to the validation sample. Model discrimination was assessed using the C-index, and model calibration was evaluated by rank-ordering patients from lowest to highest predicted mortality and comparing predicted versus observed mortality rates within deciles of risk. In addition, discrimination and calibration were further assessed among the following cohorts: 1) all PCI patients excluding cardiogenic shock and cardiac arrest patients; 2) all PCI patients excluding STEMI patients; and 3) all STEMI patients excluding cardiogenic shock and cardiac arrest.

RESULTS

PATIENT CHARACTERISTICS. During the study period between July 2018 and June 2019, 1,303,283 consecutive procedures were recorded in the NCDR CathPCI Registry. After applying exclusion criteria, including visits not associated with a PCI (n = 550,586), 706,263 total PCI cases from 1,608 sites were included in the overall sample (Figure 1).

The clinical, demographic, and angiographic features of those patients in the development (n = 495,005) and validation (n = 211,258) cohorts were similar (Table 1). The mean patient age was 66 years, 30.8% were female, 85.0% were White, 40.8% had a history of diabetes, and 41.0% had prior PCI. Elective procedures represented 39.2% of procedures performed, while 1.3% were in patients who were unresponsive after cardiac arrest, and 0.5% were in patients with salvage PCI or refractory shock. In the overall sample, 4.0% of the patients

TABLE 3 Full and Pre-Cath Mortality Models

	Full Model			Pre-Cath Model		
	Chi-Square	OR	95% CI	Chi-Square	OR	95% CI
Intercept	152.67			136.98		
Age*						
<45 yrs	2.70	0.84	0.69–1.03	2.28	0.86	0.70–1.05
≥45 yrs	1,526.13	1.51	1.48–1.55	1,692.42	1.54	1.51–1.57
Female	271.70	1.46	1.39–1.52	210.03	1.39	1.33–1.45
Cerebrovascular disease	39.95	1.20	1.13–1.27	52.58	1.23	1.16–1.30
Peripheral arterial disease	68.75	1.29	1.22–1.37	98.82	1.36	1.28–1.44
Chronic lung disease	62.93	1.24	1.18–1.31	51.59	1.22	1.15–1.28
Prior PCI	72.25	0.81	0.77–0.85	73.95	0.81	0.77–0.85
Diabetes	32.62	1.14	1.09–1.20	56.83	1.19	1.14–1.25
CKD stage†						
Stage 3a (GFR 45–60 ml/min/1.73 m^2)	181.78	1.49	1.40–1.57	186.29	1.49	1.41–1.58
Stage 3b (GFR 30–44 ml/min/1.73 m^2)	558.65	2.15	2.02–2.29	565.32	2.15	2.02–2.29
Stage 4 (GFR 15–29 ml/min/1.73 m^2)	912.39	3.65	3.36–3.97	916.07	3.65	3.35–3.96
Stage 5 (GFR 0–14 ml/min/1.73 m^2 or dialysis)	951.47	3.53	3.26–3.82	1,000.75	3.61	3.34–3.91
Severe frailty without shock/cardiac arrest/salvage	1,021.15	3.12	2.91–3.34	1,082.36	3.20	2.99–3.43
Aortic stenosis (at least moderate)	43.20	1.52	1.34–1.72	44.01	1.52	1.34–1.72
LVEF‡						
<55%	359.29	0.90	0.89–0.91	496.82	0.88	0.87–0.89
≥55%	4.07	1.04	1.00–1.08	2.38	1.03	0.99–1.07
Not measured	76.00	1.27	1.21–1.34	74.03	1.27	1.20–1.33
Systolic blood pressure*						
<90 mm Hg	3.72	0.96	0.92–1.00	3.20	0.96	0.92–1.00
90–180 mm Hg	951.20	0.86	0.85–0.87	981.35	0.86	0.85–0.86
>180 mm Hg	23.63	1.11	1.06–1.16	22.35	1.11	1.06–1.15
STEMI	190.46	1.58	1.48–1.68	127.30	1.44	1.35–1.54
Clinical instability§						
Salvage PCI or refractory shock	4,151.99	92.77	80.83–106.47	4,509.11	108.75	94.84–124.70
Cardiogenic shock without salvage	3,909.06	41.74	37.13–46.92	4,242.80	47.87	42.61–53.78
CVI without shock/salvage	1,829.11	11.25	10.07–12.57	1,957.76	12.09	10.83–13.51
Emergency PCI without shock/CVI	1,184.62	7.68	6.84–8.62	1,284.30	8.28	7.38–9.30
Urgent PCI without shock/CVI	515.76	3.29	2.97–3.65	549.14	3.41	3.08–3.78
Heart failure‖						
NYHA functional class I/II/III	6.61	0.93	0.87–0.98	2.13	0.96	0.90–1.02
NYHA functional class IV	59.45	1.32	1.23–1.42	93.65	1.42	1.32–1.52
Cardiac arrest¶						
Responsive	193.41	1.94	1.77–2.13	190.26	1.92	1.75–2.11
Unresponsive	4,963.69	11.36	10.62–12.15	4,861.57	10.91	10.20–11.67
Surgery not recommended	22.83	1.23	1.13–1.34			
In-stent thrombosis	42.75	1.96	1.60–2.40			
Highest-risk lesion						
Proximal LAD vs. other	166.17	1.38	1.32–1.45			
Left main vs. other	246.75	1.89	1.74–2.04			
Number of diseased vessels						
2 vs. 1	111.76	1.32	1.25–1.39			
3 vs. 1	371.49	1.73	1.64–1.83			
Chronic total occlusion	43.42	1.39	1.26–1.53			

*Per 10-U increase. †Versus GFR >60 ml/min/1.73 m^2. ‡Per 5-U increase. §Versus elective PCI without shock/CVI. ‖Versus no heart failure within 2 weeks. ¶Versus no cardiac arrest.

CI = confidence interval; CKD = chronic kidney disease; LAD = left anterior descending artery; OR = odds ratio; other abbreviations as in Table 1.

were thought to be severely frail, but when considering only patients without cardiac arrest, salvage PCI, or shock, 2.7% were categorized as severely frail. Aortic stenosis (at least moderate) was noted as an indication for the cath lab visit in 1.9% of the patients, while 3.2% had a documentation of surgery not being recommended after a cardiac surgery consultation.

TABLE 4 CathPCI Registry Bedside Risk Score

Scoring Response Category	Points
Age	
10–19 yrs	1
20–29 yrs	2
30–39 yrs	3
40–49 yrs	4
50–59 yrs	5
60–69 yrs	6
70–79 yrs	7
80–89 yrs	8
90–99 yrs	9
≥100 yrs	10
CKD stage	
GFR >60 ml/min/1.73 m^2	0
Stage 3a (GFR 45–60 ml/min/1.73 m^2)	1
Stage 3b (GFR 30–44 ml/min/1.73 m^2)	2
Stage 4 (GFR 15–29 ml/min/1.73 m^2)	3
Stage 5 (GFR 0–14 ml/min/1.73 m^2 or dialysis)	3
Clinical instability	
Salvage PCI or refractory shock	13
Cardiogenic shock (not refractory) without salvage	11
CVI without shock/salvage	7
Emergency PCI without shock/CVI	6
Urgent PCI without shock/CVI	3
Elective PCI without shock/CVI	0
Cardiac arrest	
No	0
Responsive	1
Unresponsive	5

Total Points	In-Hospital Mortality, %
≤5	0.04
6	0.07
7	0.12
8	0.19
9	0.27
10	0.55
11	0.85
12	1.28
13	2.28
14	4.04
15	6.38
16	10.01
17	14.92
18	22.72
19	33.76
20	38.89
21	45.73
22	53.00
23	63.57
24	69.22
25	75.39
26	78.63
27	85.48
28	87.85
29	91.67

Abbreviations as in Table 1.

IN-HOSPITAL MORTALITY RATES. In-hospital mortality following PCI was 1.9% and was similar in both the development and validation cohorts. The unadjusted rates of in-hospital mortality according to clinical characteristics such as age, sex, frailty, and the presence of diabetes (Table 2). In-hospital mortality rates increased with worsening clinical instability—0.2% for elective procedures without cardiovascular instability or shock, 5.1% in whom surgery was not recommended, 51.7% for patients with cardiac arrest and unresponsiveness, and 62% in salvage PCI or refractory shock cases (Table 2).

IN-HOSPITAL MORTALITY MODEL. The full model contains 22 variables that were consistent predictors of in-hospital mortality in multiple bootstrap samples (Table 3). Procedural urgency, cardiovascular instability, age, and responsiveness following cardiac arrest were the variables most predictive of in-hospital mortality. The presence of clinical instability before PCI was a strong predictor in the multivariable model, with those patients who were the most unstable having the highest odds of mortality when compared with patients undergoing elective PCI: salvage PCI or refractory shock (odds ratio [OR]: 92.77; 95% confidence interval [CI]: 80.83 to 106.47), cardiogenic shock without salvage (OR: 41.74; 95% CI: 37.13 to 46.92), cardiac instability without shock or salvage (OR: 11.25; 95% CI: 10.07 to 12.57), emergency PCI without shock or cardiac instability (OR: 7.68; 95% CI: 6.84 to 8.62), and urgent PCI without shock or cardiac instability (OR: 3.29; 95% CI: 2.97 to 3.65). New variables associated with in-hospital mortality include unresponsiveness following cardiac arrest (OR: 11.36; 95% CI: 10.62 to 12.15); severe frailty for patients without cardiac arrest, shock, or salvage (OR: 3.12; 95% CI: 2.91 to 3.34); aortic stenosis that is at least moderate in severity (OR: 1.52; 95% CI: 1.34 to 1.72); and surgery not recommended (OR: 1.23; 95% CI: 1.13 to 1.34). The bedside risk score model contains the variables (age, chronic kidney disease, clinical instability, cardiac arrest) that had the strongest association with mortality and that in combination explained >90% of the risk model (Table 4, Supplemental Figure 1).

MODEL PERFORMANCE. The full, pre-cath, and bedside risk adjustment models performed well with excellent discrimination in the validation samples (C-indexes, full model: 0.943; pre-cath model: 0.940; bedside risk score: 0.923) (Table 5). The full model performed well in important cohorts including those undergoing PCI without cardiac arrest or shock (C-index: 0.883), all PCIs without STEMI (C-index: 0.926), and patients with STEMI

without cardiogenic shock or cardiac arrest (C-index: 0.859) (Supplemental Figure 2). The performance of the full, pre-cath, and bedside risk adjustment models in other cohorts and subgroups are shown (**Table 5**).

Most patients had a relatively low predicted risk of mortality (90% of the population had a predicted risk of mortality rate that was <1.6%). There was high concordance between model predicted risk and observed mortality in the development and validation cohorts (**Figure 2**). The model was also well calibrated across the different categories of clinical instability (Supplemental Figure 3), across prespecified cohorts (Supplemental Figure 4), and across the top quintile of predicted risk (Supplemental Figure 5). The receiver-operating characteristic curves for the full model, pre-catheterization model, and the bedside risk score are shown in Supplemental Figures 6 and 7.

RISK-STANDARDIZED MORTALITY RATES. Hospital RSMRs for the overall sample and for the cohort of patients without cardiogenic shock and cardiac arrest are shown in **Figure 3**. The median hospital RSMR in the overall sample was 1.9% (interquartile range: 1.7% to 2.1%) and in the cohort of patients without cardiogenic shock and cardiac arrest was 0.8% (interquartile range: 0.7% to 0.9%). The distribution of hospital RSMRs in the cohort of patients without STEMI and the cohort of STEMI patients without cardiogenic shock or cardiac arrest are shown in Supplemental Figure 8.

TABLE 5 Discrimination in the Full and Pre-Cath Models

		C-Index		
	Sample, n	Full Model	Pre-Cath Model	Bedside Risk Score
Development cohort	495,005	0.943	0.940	0.924
Validation cohort	211,258	0.943	0.940	0.923
Cohorts				
All PCI except cardiogenic shock/cardiac arrest	678,347	0.883	0.841	0.843
All PCI except STEMI	591,015	0.926	0.921	0.898
All STEMI except shock/cardiac arrest	98,170	0.859	0.849	0.784
Subgroups				
STEMI	115,248	0.927	0.923	0.903
Female	217,228	0.929	0.924	0.908
Male	489,035	0.949	0.946	0.933
Age >70 yrs	267,418	0.925	0.922	0.900
Age ≤70 yrs	438,845	0.952	0.950	0.935
Diabetes	288,391	0.942	0.938	0.920
Without diabetes	417,872	0.945	0.941	0.928
Cardiogenic shock/cardiac arrest	27,916	0.845	0.841	0.822

Abbreviations as in **Table 1**.

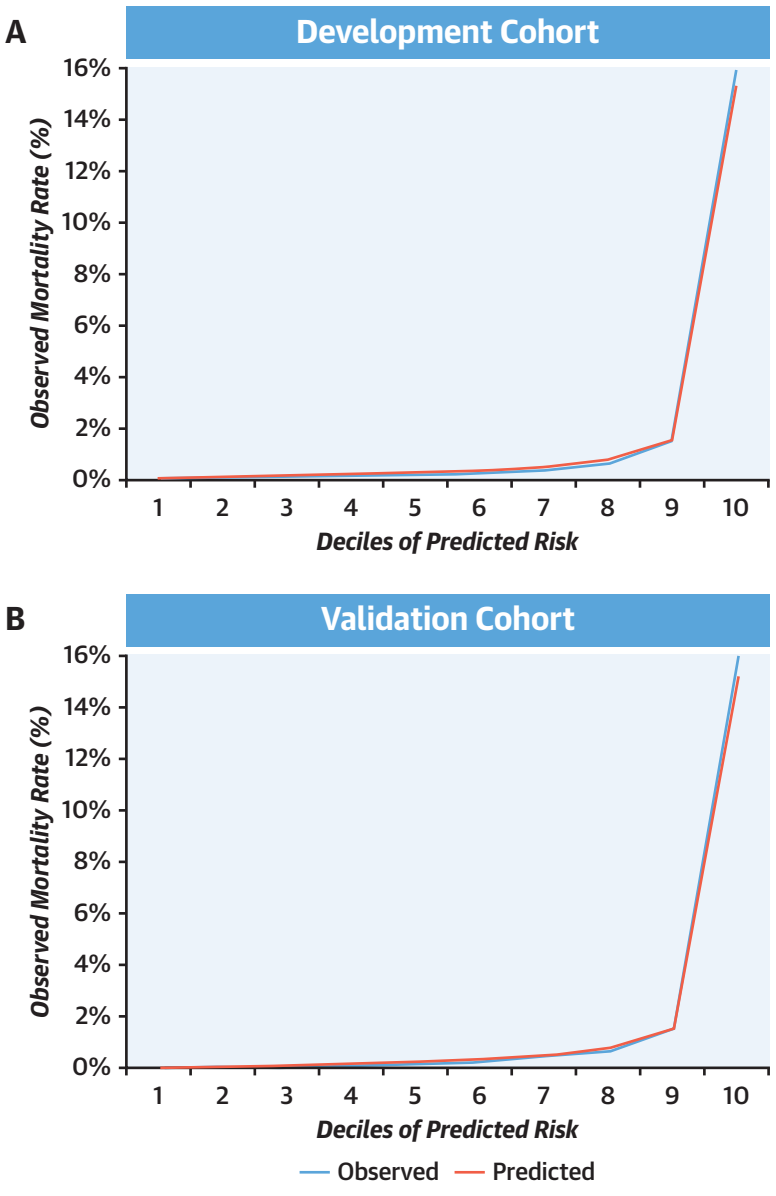
DISCUSSION

As the techniques for PCI continue to evolve, as does patient selection, it is important to continually update risk models used to benchmark health care quality. In this analysis, we found that the contemporary in-hospital mortality rate after PCI is 1.9% and increases with worsening clinical instability. Patients with cardiogenic and refractory shock, patients undergoing salvage PCI, and patients who are unresponsive after cardiac arrest account for a minority of the overall PCI population, yet these patients carry the highest risk of mortality. We found that consideration of newly captured data elements, including frailty, aortic stenosis, refractory shock, and level of consciousness after cardiac arrest, add important prognostic information when predicting the risk of in-hospital mortality for patients undergoing PCI (**Central Illustration**). Including these variables improves the discrimination from prior models and enables further stratification of risk in patients undergoing PCI.

The CathPCI Registry is the largest and most widely utilized quality improvement registry for patients undergoing PCI in the United States. The risk-adjusted mortality model was last updated in 2013 to specifically improve the ability of the model to account for patients undergoing high-risk PCI (5). Since these initial efforts to develop models that predict in-hospital risk associated with PCI, there have been considerable changes in PCI including advances in available equipment, adoption of alternative access sites, and changes in the indications and characteristics of patients who undergo PCI. Furthermore, there have also been improvements both in the methods used to appropriately model risk and in the quantity, quality, and relevance of data captured in version 5 of the CathPCI Registry. Use of hierarchical models has been shown to be more accurate and improve on classic regression models. These models allow for variations in the overall mortality rates at a specific site while at the same time standardizing the patient level factors associated with risk (16,18).

To date, risk prediction models have not included frailty in the risk assessment of patients undergoing PCI. In studies with prospective evaluation and measurement of physical frailty, more than two-thirds of patients >65 years of age undergoing PCI have some degree of frailty (19,20). After PCI, frail patients are at increased risk for hospital mortality

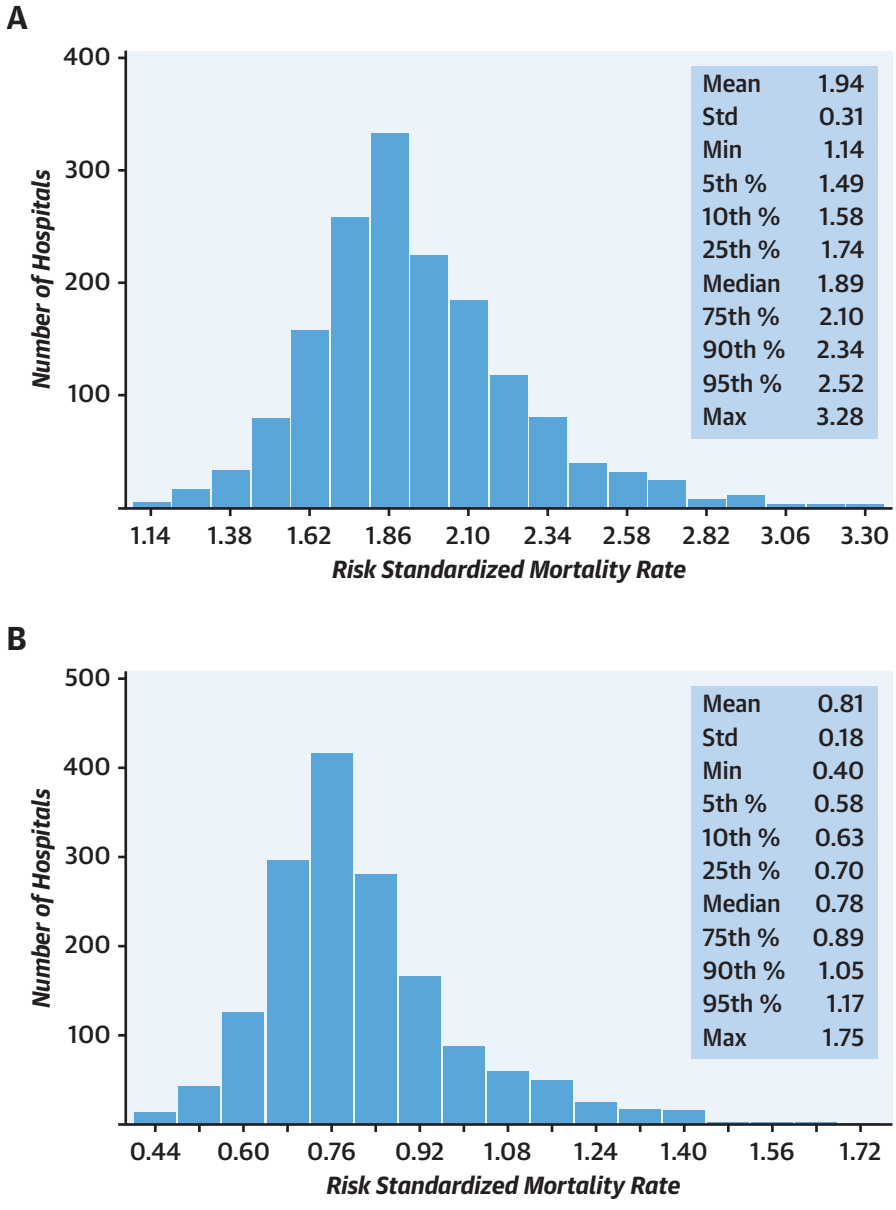
FIGURE 2 Calibration of the Full Model in the Development and Validation Cohorts



Observed versus predicted mortality estimates for each decile of predicted patient risk in the **(A)** development and **(B)** validation cohorts. There was high concordance between model predicted risk and observed mortality in the development and validation cohorts.

and cardiovascular complications, but PCI remains an important treatment option (21). Given this, CathPCI Registry began collecting outcomes on patient frailty in DCFv5, designated based on the clinical status at the time of PCI. Depending on the measurement tool, a patient's frailty status can vary over time from the baseline status before admission to the time of PCI, particularly in patients hospitalized with acute illness. For this analysis, we elected to only consider frailty for the model in those patients who did not have cardiac arrest or shock, or were undergoing salvage PCI. This was done because the current definition of frailty would be reflective of their acute illness, rather than of the patients' baseline frailty. In our multivariate model, frailty was an important predictor that improved the discriminatory ability of

FIGURE 3 Distribution of Hospital Risk-Standardized Mortality Rates



Hospital-specific risk-standardized mortality rates for **(A)** all patients cohort and **(B)** all percutaneous coronary interventions excluding the cardiogenic shock or cardiac arrest cohort, determined using the hierarchical logistic regression model.

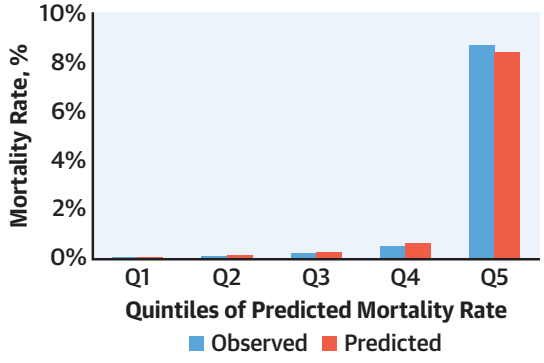
the model. Although assessment of frailty can be subjective, this model incorporates a standardized definition and is monitored by the CathPCI Registry data monitoring and audit programs.

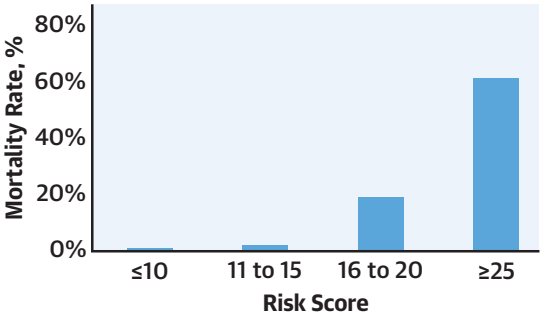
The new model also considers patient characteristics found to be predictors of particularly poor outcomes, including unresponsiveness following cardiac arrest and refractory cardiogenic shock. Inclusion of high-risk features is necessary, as public reporting of outcomes following cardiovascular procedures has become increasingly common. It is possible that public reporting can serve as a powerful driver of quality improvement for hospitals and allow patients to have more insight into the institutions in which they receive health care. Public reporting has been associated with improved PCI

CENTRAL ILLUSTRATION Predicting Mortality in Patients Undergoing PCI: Full Model and Bedside Risk Score

Predictors (Full Model)			
Age	Female	Salvage PCI or refractory shock	Number of diseased vessels
CVD	PAD	Cardiogenic shock without salvage	Highest risk lesion-Left main
CLD	CKD	CVI without shock/salvage	Highest risk lesion-Proximal LAD
Prior PCI	Diabetes	Emergency PCI without shock/CVI	CTO
Frailty	Aortic stenosis	Urgent PCI without shock/CVI	In-stent thrombosis
LVEF	SBP	Cardiac arrest - Responsive	
STEMI	Surgical turndown	Cardiac arrest - Unresponsive	

Bedside Risk Score			
Predictor	**Points**	**Predictor**	**Points**
Age (for every 10-year increase)	1	Salvage PCI or refractory shock	13
CKD stage (GFR)		Cardiogenic shock without salvage	11
Stage 3a CKD (GFR 45-60)	1	CVI without shock/salvage	7
Stage 3b CKD (GFR 30-44)	2	Emergency PCI without shock/CVI	6
Stage 4 CKD (GFR 15-29)	3	Urgent PCI without shock/CVI	3
Stage 5 CKD (GFR 0-14 or dialysis)	3	Cardiac arrest - Responsive	1
		Cardiac arrest - Unresponsive	5





Castro-Dominguez, Y.S. et al. J Am Coll Cardiol. 2021;78(3):216–29.

(Top left) Using data from the CathPCI Registry, a multivariate hierarchical logistic regression model was developed to predict in-hospital mortality of patients undergoing percutaneous coronary intervention (PCI), including new updated variables. **(Bottom left)** Observed versus predicted mortality rates for equally sized groups are shown. **(Top right)** A simplified bedside risk score included a reduced number of variables that explained >90% of the risk model. **(Bottom right)** Observed mortality rates varied substantially by risk score. CLD = chronic lung disease; CVD = cerebrovascular disease; CVI = cardiovascular instability; CKD = chronic kidney disease; GFR = glomerular filtration rate; LAD = left anterior descending; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PAD = peripheral arterial disease; SBP = systolic blood pressure; STEMI = ST-segment elevation myocardial infarction.

outcomes (22). However, studies have also suggested that public reporting may result in risk aversion by providers due to concerns that it may affect individual operator and institutional outcomes, resulting in patients who are at high risk not being offered procedures in which they could potentially benefit (7,8,23). Thus, risk prediction models, particularly those that are going to be used in public reporting, must fully account for variables associated with extreme risk and monitor for and mitigate potential to lead to risk aversion.

In this new model, inclusion of level of consciousness following cardiac arrest and refractory cardiogenic shock will allow for the accounting of these particularly high-risk features in such a way as to not penalize providers and sites from being willing to offer high-risk patients treatment. The 2013 ACC/American Heart Association guidelines recommend that immediate angiography and PCI should be considered in resuscitated out-of-hospital cardiac arrest patients whose initial electrocardiography shows STEMI (24). Although the care of patients with out-of-hospital cardiac arrest has improved over time, outcomes in this population are extremely poor, with mortality rates of approximately 50%, primarily driven by noncardiovascular sequalae (10,25). There are multiple factors that impact mortality in this high-risk cohort, including time to cardiopulmonary resuscitation, time to defibrillation, total ischemic time, and neurological status; the latter is shown to enhance mortality risk prediction when considered (26). This new model accounts for level of consciousness following cardiac arrest, which was significantly associated with mortality. We also found that further description of the persistence or "refractoriness" of the cardiogenic shock improves characterization of risk within this extreme-risk cohort. These patients also have extremely high mortality rates, which are often a reflection of the acuity of illness, rather than direct effects of the coronary intervention. Moving forward, consideration should also be given to the exclusion of patients with prior cardiac arrest or cardiogenic shock from publicly reported outcome measures (27).

Documented surgical ineligibility is associated with increased long-term mortality in patients undergoing PCI even after accounting for common risk factors. Many of these patients have higher anatomical complexity or prohibitive comorbidities, or are severely frail, and many are treated with PCI as salvage cases or compassionate use (28). Current guidelines recommended utilizing a heart team approach for handling difficult cases to ensure a multidisciplinary approach that considers a broad range of treatment options in an attempt to optimize care. For the first time, consideration of the heart team decisions will be included in the risk modeling. Patients in whom surgery was not recommended were at increased risk of mortality even after controlling for other potential confounders. Inclusion of these data will improve risk adjustment and help account for the differences in risk that is undertaken by physicians when treating these high-risk cases.

STUDY LIMITATIONS. These findings should be considered with some important limitations. First, this model has excellent discrimination and calibration in the cohorts in which it was developed and validated. However, both the development and validation cohorts were taken from the same overall dataset with variables that are specific to the CathPCI Registry. Participation in the registry is voluntary, and individual sites may participate based on external requirements; therefore, results from this model may not be generalizable to smaller or non-U.S. practices. However, it is estimated that CathPCI collects data from >90% of all PCI centers and >90% of all PCIs performed in the United States (1). The presence of a chronic total occlusion was a significant predictor of risk; however, the registry does not collect detailed angiographic or procedural variables that have been associated with higher rates of successful revascularization (29). The reasons behind the recommendation against surgery in the surgical turndown group were out of the scope for this study and should be explored in further research. Finally, although variables in the registry have clearly delineated data definitions, there may be some variation in coding across sites. To address this, the registry counts with a data quality and auditing program, which monitors for accuracy of data collected.

CONCLUSIONS

This new in-hospital mortality model incorporates contemporary variables that are reflective of clinical acuity and allows for the accurate prediction of risk of mortality following PCI. Utilization of this model, both in public reporting and in quality improvement efforts, will help standardize the assessment of risk associated with PCI both for hospitals and patients.

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PERSPECTIVES

COMPETENCY IN PATIENT CARE AND PROCEDURAL SKILLS: In patients undergoing PCI, unresponsiveness after cardiac arrest, refractory cardiogenic shock, salvage, and severe frailty are predictive of in-hospital mortality.

TRANSLATIONAL OUTLOOK: This updated risk model for in-hospital mortality in patients undergoing PCI can enhance risk stratification of patients considered for PCI, identify opportunities for quality improvement, and improve public reporting of procedural outcomes.

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KEY WORDS hierarchical logistic regression model, percutaneous coronary intervention, risk-standardized mortality rates

APPENDIX For supplemental figures, please see the online version of this paper.