Hybrid 30-day Risk-standardized Acute Myocardial Infarction (AMI) Mortality Measure with Electronic Health Record (EHR)-Extracted Risk Factors

Technical Report (Version 1.1)

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1. EXECUTIVE SUMMARY

Electronic health records (EHRs) offer an opportunity to advance quality measurement in hospitals. Ideally, EHRs will allow the use of detailed clinical data in performance measures, without requiring the substantial resources involved in abstracting medical records by hand. This report describes the development of a hybrid (EHR data plus claims data) measure of 30-day, all-cause, risk-standardized mortality for acute myocardial infarction (AMI) admissions. To our knowledge, this measure was the first hybrid outcome measure developed. Our objective was to build a measure that could feasibly be implemented in current EHR systems using the data elements that are routinely entered in current clinical practice.

1.1 Development of the Hybrid Measure

We developed this measure *de novo*, rather than "retooling" a previously developed measure, in order to best utilize the EHR data platform. Although the measure is intended for use with EHR data linked to claims data, we used clinical registry data for measure development, because at the time of development no multi-hospital nationally representative EHR datasets were available. We then tested the measure feasibility and data element validity further in EHR data.

As part of model development, we established a process to identify and include only those clinical variables currently feasible for use in measures. These feasibility criteria and this process for assessing reliability and validity eventually became the basis for a standard process that identified a set of core clinical data elements that can be used more broadly in risk-adjustment models across a variety of conditions.

Outcome: We developed this measure with 30-day all-cause mortality after AMI as the outcome, to align with the claims-based AMI mortality measure that is currently publicly reported.[1]

Data source: For measure development, we used ACTION Registry®–GWTG™ (AR-G), designed and maintained by the National Cardiovascular Data Registry (NCDR®), for clinical data, merged with The Centers for Medicare & Medicaid Services (CMS) claims and enrollment data to obtain the mortality outcome. The final hybrid measure is intended for use with EHR data linked to claims data.

Statistical modeling and risk adjustment:

- We developed a set of **feasibility criteria** based on input from the literature, EHR experts, and vendors, as follows:
    - Consistently obtained in the target population based on current clinical practice
    - Captured with a standard definition and recorded in a standard format
    - Entered in structured fields that are feasibly retrieved from current EHR systems

- We used these criteria to identify variables from AR-G that would be feasible for use in the final hybrid measure.

- We developed a risk-adjustment model to account for patients' clinical status upon initial presentation to the hospital. We developed the risk model for 30-day all-cause mortality using logistic regression, and estimated hospital-level 30-day all-cause risk-standardized mortality rates (RSMRs) using a hierarchical logistic regression model.

- Model development was consistent with the rationale articulated in the American Heart Association scientific statement "Standards for Statistical Models Used for Public Reporting of Health Outcomes"[2] and used to develop prior CMS mortality measures that are endorsed by the National Quality Forum (NQF) and which CMS now publicly reports on *Hospital Compare* (http://www.hospitalcompare.hhs.gov).

- The final model includes the following variables, assessed at presentation:

    - Age
    - Heart rate
    - Systolic blood pressure
    - Creatinine
    - Troponin ratio (initial troponin value / troponin upper range limit for hospital)

1.2 Core Clinical Data Elements

These data elements are a subset of the core clinical data elements subsequently developed by CORE under contract to CMS in 2013. The core clinical data elements include a patient's age and gender, a complete set of vital signs (including heart rate and systolic blood pressure), a complete blood count, and a basic chemistry panel. (Because troponin was also found to be feasible and predictive of mortality in the AMI cohort, it has been added as a measure-specific core clinical data element.)

The core clinical data elements require that the value for each variable must be the first-captured value after a patient arrives at a hospital for care. For vital signs, this value must be captured within 2 hours of arrival. For laboratory values (excluding troponin), the value must be captured within 24 hours of arrival. Troponin must be the first value and does not have a specific time window for capture. Please refer to the Core Clinical Data Elements Technical Report v1.1[3] for further details.

1.3 Testing the Hybrid Measure

- The overall performance of the model was comparable with or better than that of current publicly reported outcome measures.

- We tested for measure score validity by correlating the RSMR with that of the previously validated, publicly reported, claims-based AMI mortality measure.

In summary, we have built the first hybrid outcome measure that produces estimates of hospital RSMRs for Medicare patients with AMI based on clinical data from EHRs combined with outcomes data from the claims.

2. INTRODUCTION

2.1 Background

Since 2007, the Centers for Medicare & Medicaid Services (CMS) has publicly reported hospital 30-day risk-standardized mortality rates (RSMRs) for acute myocardial infarction (AMI).[1] This measure, developed by Yale New Haven Health Services Corporation Center for Outcomes Research and Evaluation (CORE) and endorsed by the National Quality Forum (NQF), is calculated using administrative claims data. The use of claims data allows CMS to measure and publicly report quality measures without any additional burden on hospitals for data collection.

The implementation of electronic health records (EHRs) offers an opportunity for the development of quality measures that utilize medical record data rather than, or in addition to, administrative claims, but without requiring the resources needed for manual medical record abstraction. The American Recovery and Reinvestment Act of 2009 established incentives for hospitals across the country to universally adopt EHR systems.[4] Benefits in quality improvement after the implementation of EHRs have been documented.[5] Given the current expansion of EHR implementation and the expectation that quality measures will be increasingly able to draw off the rich clinical data resources furnished by EHRs, CMS contracted with CORE to develop a hybrid outcome measure evaluating hospital 30-day mortality following admission for AMI.

2.2 Rationale for Hybrid AMI Mortality Measure

We sought to build a hybrid measure assessing quality for an important condition and outcome for which we had already developed a claims-based measure. AMI is a high-volume, high-severity, and high-cost condition: Each year, over 600,000 Americans will experience an AMI,[6] and despite impressive improvements in treatments, 30-day mortality following AMI exceeds 7%.[7] CMS pays approximately $11.7 billion annually for in-hospital costs for Medicare beneficiaries with coronary heart disease, of which AMI is a major contributor.[6] AMI is also a well-studied condition with a rich literature on important risk factors and risk models.

Finally, as mentioned previously, an AMI mortality measure developed and calculated using administrative claims data is currently publicly reported.[1] Our goal was not to simply create a crosswalk between risk-adjustment data elements in the claims-based measure and those in the EHR environment, but to develop a new measure *de novo*. The existing claims-based measure provided a similar measure as a source of comparison for our final hybrid measure. For all these reasons, AMI represents an excellent condition for which to develop a hybrid measure.

2.3 Report Update

This report has been modified from its original version for posting with the Hospital Inpatient Prospective Payment Systems 2016 Proposed Rule. The development of this hybrid hospital 30-day all-cause risk-standardized mortality measure for AMI admissions preceded the development of the core clinical data elements and in many ways provided the foundation for that work. The risk variables for the hybrid AMI mortality measure presented in this report are a subset of core clinical data elements with the exception of troponin, which is a condition-specific data element included in this measure.

In 2013, the core clinical data elements were tested and found to be predictive of mortality following admission to acute care short stay hospitals following a variety of common medical conditions including congestive heart failure; pneumonia; acute cerebrovascular disease; septicemia (except during labor); diabetes mellitus with complications; coronary atherosclerosis; and cardiac dysrhythmias. All of the core clinical data elements listed above were also statistically significant predictors of readmission in the risk-adjusted models of 30-day readmission in a hospital-wide cohort. The testing results demonstrate that the core clinical data elements enhanced the discrimination (assessed using the C-statistic) when used either in combination with or in place of administrative claims data for risk adjustment of currently reported CMS 30-day mortality and readmission outcome measures.

3. APPROACH TO *DE NOVO* DEVELOPMENT OF A HYBRID OUTCOME MEASURE

Hybrid measure development is an emerging area, and as a result, we defined new principles during the development of the AMI measure. In this section, we describe the key aspects of the approach we used to develop this *de novo* hybrid outcome measure.

3.1 *De Novo* Development

This hybrid AMI mortality measure was developed *de novo*; we did not seek to mirror a previously developed measure, but rather we made all methodology decisions and selected variables specifically for this measure. Some measures that use EHR data, or eMeasures, are "retooled" measures, developed by creating a crosswalk between clinical data elements found in the original, paper-based measure and similar elements in EHR data. However, retooling a previously developed measure risks altering the measure in the process, because the data elements in the two sources may not match precisely. Furthermore, a clinical data element that can be easily abstracted from a paper medical record may not be equally straightforward to extract from an EHR. By contrast, *de novo* development allowed us to target those data elements most reliably and feasibly extracted from EHRs. Through the process of *de novo* development of our hybrid measure we established a roadmap for future hybrid outcome measure development.

3.2 Data Source for Measure Development

Outcome measures used to profile hospitals and assess relative performance need to be risk-adjusted to provide a fair assessment of quality. Development of a risk-adjusted hybrid outcome measure, therefore, requires a data source with a broad array of clinical variables and a substantial number of hospitals for adequate risk model development.

At the time of measure development, issues of data exchange and standardization limited the ability to aggregate EHR data from multiple hospitals. Moreover, many EHR vendors and health systems that have aggregated EHR data sources were not yet able to easily extract datasets to support measure development. Therefore, we opted to use a clinical registry for measure development. Using registry data for measurement development provided variables that were collected in a standard fashion from a large number of hospitals nationally and which could be linked to patient outcomes. The variables collected by the registry included a wide array of data elements likely to be found in current EHRs. Moreover, through the process of the registry development, these variables had been thoroughly vetted to include important risk factors for AMI patients.

In order to successfully use registry data to develop a measure for the EHR environment, we developed feasibility criteria to restrict our measure variables to only those that were currently available in EHR data at the time of development, as described below.

A further advantage of using registry data was that it enabled us to test the importance of data elements that are clinically important but not feasibly extracted from many EHRs at the time of development. This testing would not have been possible in a data source limited to elements extracted from EHRs.

3.3 Establishment of Feasibility Criteria in the Current Clinical and EHR Environment

The EHR is primarily a tool for clinical practice; thus, optimal quality measures consider current clinical practice and current EHR capability to avoid any disruption of clinical care. Furthermore, if quality measures rely on actions such as filling out additional checkboxes to collect data elements that are not captured in the routine service of clinical care, there will be significant challenges to operationalizing functions across multiple health systems and vendors. **Therefore, our primary objective was to develop a measure that could be implemented without changing standard clinical practice or requiring that EHRs be adapted.**

In order to meet this goal, early in the measure development process, we developed a set of criteria to ensure all data elements used in the measure, both in cohort identification and risk adjustment, could be feasibly obtained within current clinical practice and with current EHR systems. As Meaningful Use criteria provide standards for *future* EHR implementation, and the Quality Data Model (QDM) is not limited to current EHR capability, we needed to establish stricter criteria based on current EHR capability. In a series of calls with EHR experts, we developed the following criteria to assess the feasibility of candidate model variables:

1. Consistently obtained in the target population based on current clinical practice
2. Captured with a standard definition and recorded in a standard format
3. Entered in structured fields that are feasibly retrieved from current EHR systems

The first criterion ensures that the measure will not rely on the adoption of new clinical practices, such as requiring medical staff to routinely collect a laboratory test they might not otherwise order. The second criterion confirms that data elements used in the measure have the same meaning across sites. The third aligns with our intention to build a measure that could be feasibly implemented in current EHRs without additional burden to hospitals. These three criteria were eventually used to develop the core clinical data elements.

Through discussions with the EHR experts and examination of the data, we assessed each potential candidate variable for the risk-adjustment model by these criteria. Variables satisfying all three criteria were deemed feasible for inclusion in the measure given the current EHR environment at the time of development. This process was completed early in measure development so that only feasible variables were considered for the model. Further feasibility testing using EHR data was completed in later phases of development; see the Core Clinical Data Elements Technical Report v1.1[3] for details.

3.4 Working Group and Expert Input

Development of the hybrid AMI mortality measure involved input from a number of experts, including a working group from CORE, as well as external EHR and clinical experts. The working group consisted of clinical and methodological experts with extensive experience in both performance measure development and AMI care; the group included cardiologists, health sciences researchers, and other professionals with expertise in biostatistics, measure methodology, and quality improvement (see Appendix A. Working Group Member Roster). The working group provided regular input on all measure decisions, including data source identification, cohort derivation, outcome definition, model development, and model testing. Working group meetings were typically held once per week and addressed key issues to ensure

the measure would be meaningful, useful, and well-designed.

Throughout measure development, we obtained expert and stakeholder input via discussions with EHR vendors and experts, as well as clinical experts from the National Cardiovascular Data Registry (NCDR). The EHR vendors and experts provided key input regarding appropriate data sources for model development and the appropriateness of including certain clinical variables in a hybrid measure. We solicited advice from representatives of the NCDR regarding the selected variables in the final model, the clinical value of the variables excluded from the model for measure feasibility reasons, and the overall clinical face validity of the model.

3.5 eSpecification and Testing

eSpecification is the process of converting a paper-based quality measure or implementing a measure specifically developed for EHR into a format usable in the EHR environment. This process includes encoding the measure specifications in a standard eMeasure format known as Health Quality Measures Format (HQMF).[8] eSpecification testing of the core clinical data elements will occur in 2015, which will be made publicly available prior to implementation of this measure.

4. APPLICATION OF THE METHODS

4.1 Overview

This section provides details about the development of the hospital 30-day risk-standardized hybrid AMI mortality measure, including the identification of a relevant data source for development, the cohort definition, variable selection for the risk-adjustment model, and model testing. In developing the measure we followed the standards set forth in the development of prior outcome performance measures, specifically using guidance from NQF,[9] the CMS Measures Management System, and the American Heart Association scientific statement, "Standards for Statistical Models Used for Public Reporting of Health Outcomes."[2]

4.2 Cohort

To align with the claims-based AMI mortality measure, this hybrid measure uses the same cohort and inclusion and exclusion criteria derived from International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) codes. Due to the fact that principal discharge diagnoses are not currently feasibly extracted from EHR systems, this information is most reliably obtained from the claims data. This is one of the reasons this measure is a hybrid measure. The full list of cohort codes is listed in Table 1.

Table 1. ICD-9-CM Codes for Cohort of Hybrid AMI Mortality Measure

ICD-9-CM Codes	Description
410.00	AMI (anterolateral wall) – episode of care unspecified
410.01	AMI (anterolateral wall) – initial episode of care
410.10	AMI (other anterior wall) – episode of care unspecified
410.11	AMI (other anterior wall) – initial episode of care
410.20	AMI (inferolateral wall) – episode of care unspecified
410.21	AMI (inferolateral wall) – initial episode of care
410.30	AMI (inferoposterior wall) – episode of care unspecified
410.31	AMI (inferoposterior wall) – initial episode of care
410.40	AMI (other inferior wall) – episode of care unspecified
410.41	AMI (other inferior wall) – initial episode of care
410.50	AMI (other lateral wall) – episode of care unspecified
410.51	AMI (other lateral wall) – initial episode of care
410.60	AMI (true posterior wall) – episode of care unspecified
410.61	AMI (true posterior wall) – initial episode of care
410.70	AMI (subendocardial) – episode of care unspecified
410.71	AMI (subendocardial) – initial episode of care
410.80	AMI (other specified site) – episode of care unspecified
410.81	AMI (other specified site) – initial episode of care
410.90	AMI (unspecified site) – episode of care unspecified
410.91	AMI (unspecified site) – initial episode of care

4.3 Outcome

4.3.1 30-day Mortality

As compared with in-hospital mortality, a 30-day outcome timeframe provides a standard period of assessment. Models with a fixed outcome period are preferable because they ensure hospital variation in length of stay does not affect performance and minimize any opportunity for misrepresentation (transferring of patients or other gaming mechanisms).[10] In addition, the 30-day period may be a more clinically meaningful timeframe for patients, reflecting not only the outcomes of inpatient processes of care but also the transition of care to the outpatient setting. As such, a 30-day mortality measure may stimulate better collaboration between hospitals and their surrounding medical communities aimed at reducing mortality rates. These activities may include ensuring patients are clinically ready for discharge; improving communication among providers in transitions of care; and encouraging strategies that promote disease management principles and educate patients on what symptoms to monitor, whom to contact with questions, and where and when to seek follow-up care.

Because hospitals do not routinely or comprehensively collect post-discharge mortality outcomes for their patients, the outcome will be assessed using Medicare enrollment data.

4.3.2 All-cause Mortality

We used all-cause mortality as opposed to cardiac-specific mortality for several reasons. First, from the patient perspective, death is an adverse outcome regardless of its cause. Second, different causes of death may still be directly related to the quality of care. Third, making accurate determinations of specific causes of death is difficult and prone to error, particularly if the patient dies outside of the hospital setting.

4.4 Data Sources for Measure Development

4.4.1 2009 and 2010 NCDR® ACTION Registry®–GWTG™ (AR-G) Data

While the goal of this measure is to be implemented using EHR data linked to claims data, we used NCDR registry data for measure development due to the lack of a large EHR dataset for testing. The NCDR AR-G serves as a national surveillance effort to improve the quality of care for AMI patients on a national level.[11] AR-G captures detailed data about patients aged 18 years or older undergoing management for AMI. The data include demographics, comorbid conditions, clinical status, laboratory values, diagnostic tests, management strategies adopted, complications, and outcomes. Clinical experts have extensively vetted the more than 300 data elements included in the registry. These data are collected by hospitals and submitted electronically on a quarterly basis to NCDR. The data collection form and the complete list of variables collected and submitted by hospitals can be found at http://www.ncdr.com/webncdr/ACTION/. The patient records submitted to the registry focus on acute episodes of care from admission to discharge. The NCDR did not link patient records longitudinally across episodes of care at the time of measure development.

Admissions to participating hospitals were eligible for inclusion in AR-G if admitted patients had:

1) Ischemic symptoms at rest, lasting ≥10 minutes, occurring in the 24 hours before admission, or up to 72 hours for ST segment elevated myocardial infarction (STEMI); or
2) Electrocardiogram (ECG) changes associated with STEMI (new left bundle-branch block [LBBB] or persistent STEMI ≥1 mm in two or more contiguous electrocardiographic leads); or
3) Positive cardiac markers associated with non-ST segment myocardial infarction (NSTEMI) (CK-MB or troponin I/T > local laboratory upper limit of normal values) within 24 hours after initial presentation

Of note, patients admitted for other clinical conditions but who develop qualifying symptoms for STEMI or NSTEMI during hospitalization are ineligible for inclusion in AR-G.

A wide spectrum of hospitals across the country participate in AR-G. In order to understand the characteristics of the data being used for measure development, we compared the characteristics of hospitals that participated in AR-G in 2009 with those of hospitals that did not, using data from the American Hospital Association Survey. Compared with hospitals that did not participate in AR-G, hospitals that did participate were larger (had a greater number of beds), more likely to be teaching hospitals, and more likely to have the ability to provide coronary artery bypass graft (CABG) surgery. They were also more likely to be not-for-profit rather than government or for-profit hospitals and to be located in metropolitan rather than rural areas. Hospitals that participated in AR-G were less likely to be safety net hospitals (Table 2).

In Table 2 core-based statistical areas are defined on the basis of the population contained within them: division areas have more than 2.5 million inhabitants, metro areas have 50,000 to 2.5 million inhabitants; micro areas have 10,000 to 50,000 inhabitants; and rural areas have fewer than 10,000 inhabitants. Safety net hospitals in Table 2 are defined as government hospitals or non-government hospitals with high caseload of patients insured through Medicaid.

The NCDR has implemented a Data Quality Program (DQP) to ensure that data submitted to AR-G are complete, consistent, and accurate.[12] Under the DQP, data submitted from various sites are reviewed for overall completeness, and participating hospitals are provided with a confidential analysis. Additionally, each year participating sites are randomly selected to have the quality of their data audited.

Table 2. Comparison of CMS Hospitals Participating and Not Participating in AR-G in 2009

Description	Hospitals in AR-G (N=282) %	Hospitals not in AR-G (N=3,897) %
Number of beds		
<100	6.4	46.9
100 to 300	41.8	36.9
>300	51.8	16.3
Mean (SD)	362 (234)	166 (182)
Ownership		
Government	11.4	23.3
Not-for-profit	77.0	60.5
For-profit	11.7	16.1
Region		
Associated area	0.4	1.2
New England	2.8	4.3
Middle Atlantic	6.7	9.5
South Atlantic	24.1	14.9
East North Central	20.6	15.5
East South Central	7.8	8.9
West North Central	12.1	13.5
West South Central	8.5	14.1
Mountain	6.0	7.3
Pacific	11.0	11.0
Teaching status		
Council of Teaching Hospitals	17.0	5.9
Other teaching	25.9	10.7
Non-teaching	57.1	83.4
Cardiac facility		
CABG surgery	78.7	32.3
Cath lab only	9.2	12.4
Other	12.1	55.3
Core-based statistical area		
Division	14.9	14.7
Metro	74.8	41.2
Micro	9.2	19.3
Rural	1.1	24.9
Safety Net Hospital		
No	83.7	69.3
Yes	16.3	30.7

4.4.2 2009 and 2010 Medicare Data

As stated above, we used Medicare claims data to identify patients for inclusion in the measure cohort and to determine the mortality outcome. For measure development, we specifically used 2009-2010 Medicare Part A claims and the Medicare Enrollment Database.

Part A inpatient data

Part A inpatient data include claims paid by Medicare for inpatient hospital care.

Medicare Enrollment Database (EDB)

This database contains Medicare beneficiary demographic and vital status information. These data have previously been shown to accurately reflect patient vital status.[13]

Mortality information in the Medicare EDB was linked to the Part A inpatient discharges with AMI using the unique patient identifier in the Medicare databases (health insurance claim [HIC] number).

4.5 Merged Dataset for Measure Development

For development of the model, we used discharges for AMI included in the AR-G dataset from January 1, 2009 through December 31, 2009, deterministically matched with discharges for AMI in CMS claims data from January 1, 2009 through December 31, 2009.

To derive the dataset for the deterministic match from AR-G data, AMI admissions were uniquely identified by hospital Medicare provider number (MPN), patient age, sex, admission date, and discharge date. Hospital MPNs were self-reported in the NCDR ICD Registry™ hospital profile. MPNs were manually verified through the American Hospital Association annual survey database or on the web using hospital name and address.

Similarly, we derived an appropriate cohort of discharges with AMI from the CMS dataset. We identified discharges with AMI by International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) principal discharge diagnosis code 410.xx (excluding 410.x2). We deterministically matched the derived datasets to obtain the final merged CMS-AR-G dataset. A description of each step is outlined below. Figure 1 shows the number of admissions excluded at each step.

Step 1: Preparation of datasets for deterministic matching

To derive datasets from AR-G and CMS claims data for the deterministic match, we applied a series of exclusion criteria to both datasets.* This allowed us to obtain a comparable cohort of patients within each dataset in preparation for deterministic matching. The exclusion criteria applied were:

- Age <65 years (CMS claims and AR-G data): Admissions for patients aged <65 years at the time

* These exclusion criteria are unique to the linking of the registry and claims datasets and are not the same as would be applied to the measure when implemented in EHR and claims datasets. Those exclusion criteria will be finalized once the measure can be fully tested in an EHR and claims dataset, prior to measure implementation.

of admission were excluded.
Rationale: Patients younger than 65 in the Medicare dataset represent a distinct population that qualifies for Medicare due to disability. The characteristics and outcomes of these patients may not be representative of the larger population of AMI patients.

- Admissions to hospitals with missing or duplicate MPNs (AR-G data only): Any admissions to hospitals with a missing MPN or in hospitals that shared the same MPN were excluded.
  Rationale: If the MPN is unreliable, we are unable to match patients in AR-G data to patients in CMS claims data or calculate hospital mortality rates with certainty.

- Duplicate admissions (CMS claims and AR-G data): Admissions for patients who have identical information in a single dataset indicated for age, sex, admission date, discharge date, and MPN are excluded.
  Rationale: Admissions with identical demographics are excluded to avoid making matching errors upon merging of the two datasets.

We then excluded admissions for patients in certain hospitals:

- Admissions to hospitals that did not appear in the AR-G dataset
  Rationale: Admissions to hospitals that do not submit data to AR-G would not be eligible for matching.

- Admissions occurring during quarters in which a hospital did not submit data to AR-G (CMS claims data only)
  Rationale: Admissions occurring during a quarter in which a hospital did not submit data to AR-G would not be eligible for matching. (For example, if a hospital were to start submitting data to AR-G in July, patients in CMS data admitted during January through June would be excluded.)

Step 2: Deterministic match of AR-G and CMS claims datasets

The remaining hospitalizations in both datasets were then merged using hospital MPN, patient age, sex, admission date, and discharge date as the linking fields. Admissions that did not match based on all five linking fields were excluded.

Among admissions eligible for matching in AR-G, 75% were successfully matched to CMS claims data. The observed characteristics of patients whose admissions did match were very similar to those of patients whose admissions did not match, including similar age, cardiac risk factors, and presentation heart rate and blood pressure (Table 3). Possible explanations for the failure of 25% of the admissions to match include admissions for patients ineligible for Medicare (e.g., non-U.S. citizens), admissions for patients in Medicare Advantage (not in fee-for-service Medicare) or with non-governmental insurance, and inaccuracies within the CMS or AR-G data for linking fields (e.g., substituting age for date of birth).

Among admissions eligible for matching within the CMS claims dataset, 53% were successfully matched to AR-G data. Table 4 compares matched and unmatched admissions. Although age was similar between the two groups, fewer patients with subendocardial infarctions, history of congestive heart failure, and history of other comorbidities were found in the matched cohort.

Possible explanations for mismatch include differences in selection criteria for the two databases, miscoding of principal discharge diagnoses in the CMS data, failure to include an eligible patient in AR-G, and data entry errors.

Step 3: Exclusion criteria applied to the merged dataset

After performing the deterministic match, we applied exclusion criteria to the matched cohort to derive the final cohort of patients for building the risk-adjustment model. These exclusion criteria are similar to those in the currently publicly reported claims-based AMI mortality measure at the time of measure development.[1] Prior to implementation, the hybrid measure inclusion and exclusion criteria will be updated to ensure alignment with the most recent version of the claims-based measure.

The following exclusions were applied to the merged dataset:

1) Discharged against medical advice (AMA): Admissions in which the patient was discharged AMA were removed from the matched dataset.
Rationale: Patients who leave AMA do not allow the hospital to provide the entire spectrum of necessary care for management of AMI.

2) Transfer-in admissions: Among patients transferred from one acute care institution to another, the second admission with an AMI was not eligible as an index admission. We used the CMS data to define transfers as two admissions that occur within one day of each other.
Rationale: We assign the outcome for the acute episode of care to the first admitting hospital because the first hospital initiates patient management and is responsible for any decision to transfer the patient. Therefore, the first admission in an acute episode of care is eligible to be an index admission in the measure. The second admission and any subsequent admissions in the same acute episode are excluded from the measure.

3) Admissions with missing death: Records with missing vital status were excluded.
Rationale: Records with no vital status information would prevent ascertainment of the mortality outcome.

4) Admissions with unreliable/missing data: Records with unreliable or missing data for age or sex were excluded.
Rationale: Unreliable or missing data limit the validity of the risk-adjustment model.

5) Multiple AMI admissions in 2009: We randomly selected one admission to retain and excluded the other admissions for patients in the merged AR-G-CMS dataset who had multiple admissions for AMI within the year.
Rationale: Episodes of care must be mutually independent, each with the same probability of the outcome. For patients with multiple admissions in a year, the probability of death increases with each subsequent admission, and therefore the episodes of care are not mutually independent. We therefore randomly select one admission for inclusion in the measure.

Each exclusion criterion was evaluated for EHR feasibility using the feasibility criteria detailed in Section 3.3.

Figure 1. Derivation of Cohort for Model Development

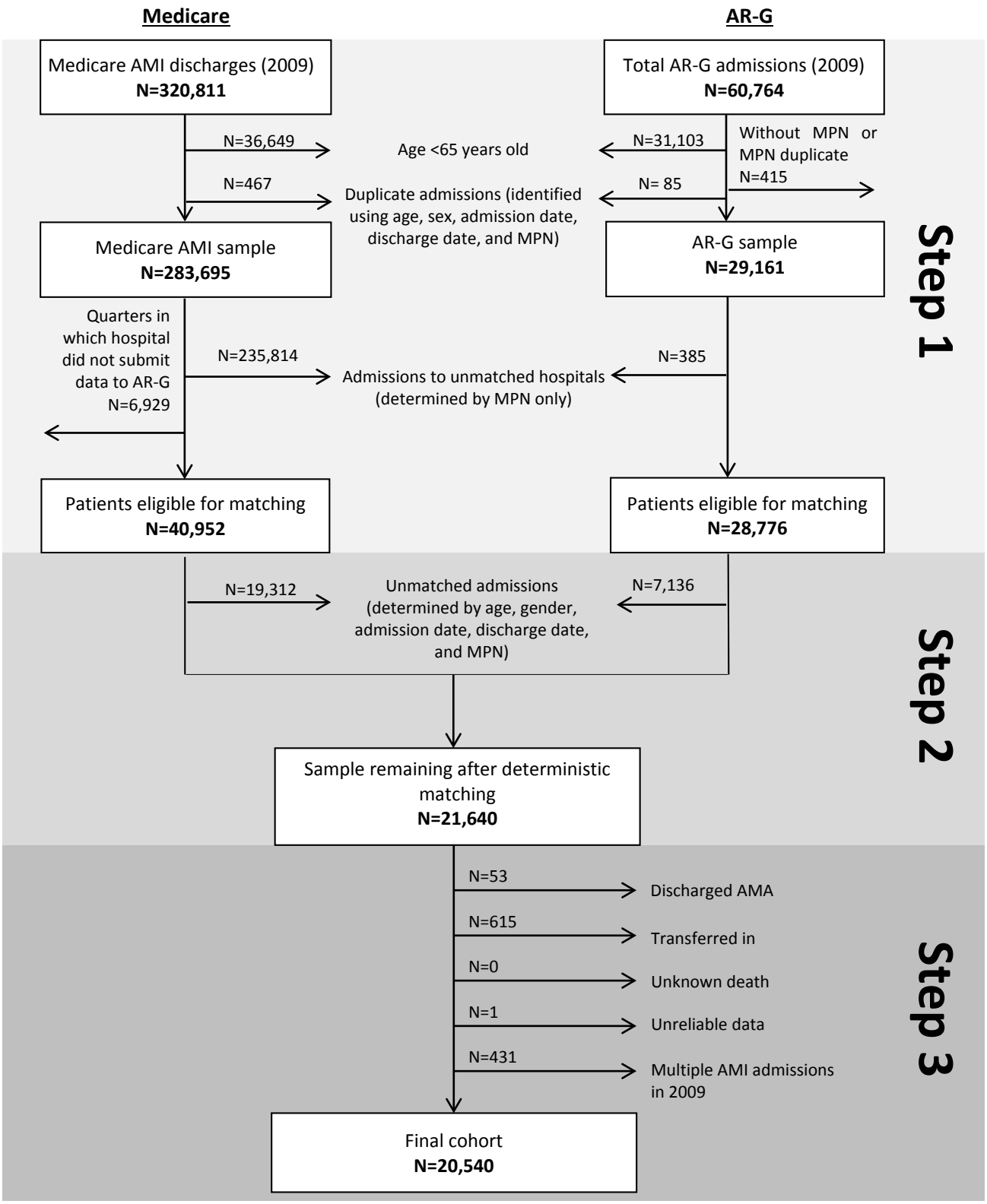


Table 3. Selected Patient Characteristics and Outcomes in AR-G Data for Patients Unmatched and Matched to CMS Data

Description	Unmatched (N=7,136) %	Matched (N=21,640) %
Demographics		
Age (y): Mean (SD)	76.2 (8.3)	77.0 (8.1)
Female	41.87	44.6
Race - White	84.9	90.3
Race - Black or African-American	8.9	6.8
Race - Other	12.9	8.4
History and Risk Factors		
Weight (kg): Mean (SD)	79.6 (20.1)	79.5 (20.0)
Current/Recent Smoker (w/in 1 year)	16.5	15.7
Hypertension	80.7	80.1
Dyslipidemia	62.8	62.9
Currently on Dialysis	3.2	2.5
Chronic Lung Disease	19.7	17.7
Diabetes Mellitus	37.2	34.5
Prior MI	29.5	27.9
Prior Heart Failure	20.2	18.4
Prior PCI	24.8	23.7
Prior CABG	19.9	20.1
Cerebrovascular Disease	17.7	17.6
Prior Stroke	12.0	11.4
Peripheral Arterial Disease	13.7	14.1
Cardiac Status on First Medical Contact		
STEMI or STEMI Equivalent	28.1	32.3
Heart Failure	24.1	23.1
Cardiogenic Shock	4.9	4.7
Heart Rate (beat/min): Mean (SD)	87.1 (25.7)	85.0 (24.3)
Systolic Blood Pressure (mm Hg): Mean (SD)	143.1 (34.7)	143.3 (33.6)
Baseline Creatinine (mg/dL): Mean (SD)	1.4 (1.1)	1.4 (1.0)
Baseline CrCl derived from Crockroft-Gault formula (mL/min): Mean (SD)	58.4 (29.5)	57.9 (30.2)
Baseline Hemoglobin (g/dL): Mean (SD)	13.0 (2.1)	13.1 (2.0)
Baseline Troponin Ratio (×ULN): Mean (SD)	33.0 (200.5)	45.7 (292.9)

Table 4. Selected Patient Characteristics and Outcomes in CMS Data for Patients Unmatched and Matched to AR-G Data

Description	Unmatched (N=19,312) %	Matched (N=21,640) %
Demographics		
Age: Mean (SD)	78.2 (8.2)	77.0 (8.0)
Female	48.3	44.6
Principal discharge diagnosis		
410.0 (Anterolateral wall)	1.2	2.5
410.1 (Other anterior wall)	5.6	9.7
410.2 (Inferolateral)	1.0	2.3
410.3 (Inferoposterior)	0.7	1.5
410.4 (Other inferior)	6.4	14.2
410.5 (Other lateral)	0.8	1.5
410.6 (Posterior)	0.3	0.5
410.7 (Subendocardial)	78.8	63.8
410.8 (Other)	0.6	0.5
410.9 (Unspecified)	4.6	3.5
History and Risk Factors		
Percutaneous intervention	8.8	9.8
CABG surgery	5.5	5.7
Congestive heart failure	31.1	21.4
AMI	27.2	13.8
Unstable angina	17.1	10.7
Anterior myocardial infarction	6.8	12.2
Other location of myocardial infarction	9.1	20.0
Chronic atherosclerosis	79.4	84.0
Cardio-respiratory failure and shock	10.1	6.7
Valvular or rheumatic heart disease	25.3	21.0
Comorbidity		
Hypertension	80.5	79.1
Stroke	6.9	4.9
Cerebrovascular disease	16.8	14.7
Renal failure	22.4	16.5
Chronic obstructive pulmonary disease	26.8	22.2
Pneumonia	23.2	16.1
Diabetes and DM complications	42.1	38.7
Protein-calorie malnutrition	5.3	3.5
Dementia and senility	15.4	11.3
Hemiplegia, paralysis, functional disability	5.4	4.0
Vascular or circulatory disease	22.3	19.1
Metastatic cancer and acute leukemia	3.7	2.9
Trauma	24.1	20.8
Major psych disorders	5.4	4.3
Liver and biliary disease	1.1	0.6

4.6 Model Development

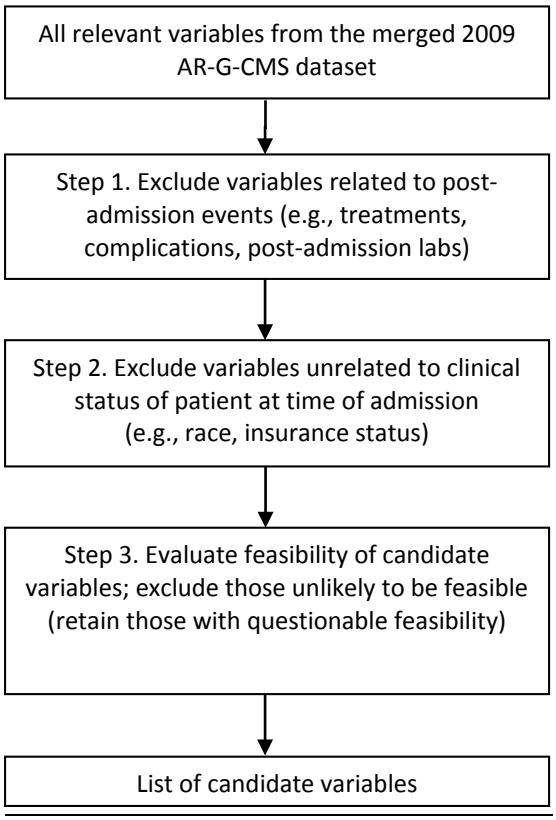
4.6.1 Candidate Risk-adjustment Variables

We sought to develop a model that included key variables that are clinically relevant, demonstrate a strong statistical association with 30-day mortality, and are feasible for use in a hybrid measure. Although EHRs likely will ultimately link across clinical episodes of care and contain historical patient data, given the EHR environment at the time of measure development and inability to reliably obtain data from the outpatient setting prior to admission, we only considered for inclusion in the measure variables that would be available and consistently collected at presentation to the hospital. This is similar to the approach used for the core clinical data elements.

To select candidate variables, the members of the working group reviewed the entire list of variables in the AR-G registry database. (The complete list of variables can be found at: http://www.ncdr.com/WebNCDR/Action/Elements.aspx.) These variables have undergone extensive vetting by clinical and methodological experts during development of the AR-G registry.[11,14] To identify clinically meaningful variables to review for the candidate variable selection process, we excluded variables that were not relevant or not suitable for use in risk adjustment (such as patient name, physician name, etc.). In addition, we combined certain variables to derive other clinically meaningful variables; for example, we derived body mass index (BMI) from height and weight.

We applied a series of exclusion criteria to the remaining 193 variables to obtain a list of candidate variables for building the model. Refer to Figure 2 for the variable selection strategy. Refer to Appendix B for a list of variables excluded at each step.

Figure 2. Candidate Variable Selection Process Flow Chart



Step 1: Exclusion of variables related to post-admission events

We excluded all variables pertaining to post-admission events such as treatments, complications, and post-admission labs. This resulted in the exclusion of 121 variables.

Step 2: Exclusion of variables unrelated to the clinical status of the patient at the time of admission

Next, we excluded remaining variables that were unrelated to the clinical status of the patient at the time of admission, such as insurance status, patient ZIP code, means of transfer to the first facility, race, etc. This resulted in the exclusion of an additional 30 variables.

Step 3. Exclusion of variables not feasible for use in an hybrid measure

As described in Section 3.3, we sought to develop a measure that was feasible for use in current EHR systems at the time of development. We developed the following criteria to assess feasibility of candidate variables that were later used to develop the core clinical data elements:

1. Consistently obtained in the target population based on current clinical practice
2. Captured with a standard definition and recorded in a standard format
3. Entered in structured fields that are feasibly retrieved from current EHR systems

Through discussions with the EHR experts and examination of the data, we assessed each variable by these criteria. Variables satisfying all three criteria were deemed feasible for use in this hybrid measure given the current EHR environment (Table 5).

Variables clearly not fulfilling one or more of the criteria were deemed not feasible for use in this hybrid measure given the current EHR environment. For example, brain natriuretic peptide (BNP) is not consistently obtained for patients with AMI. Thus, although when it is obtained BNP is captured using a standard definition, recorded in a standard format, and entered in a structured field, BNP was not considered feasible for this measure. As another example, heart failure on presentation is consistently obtained in patients with AMI; however, the definition of what constitutes heart failure varies among providers. As a final example, ECGs are consistently obtained in patients with AMI but are not entered in a structured field that is feasibly retrieved from current EHR systems.

In some cases, our review determined that certain variables questionably fulfilled one or more criteria and were thus deemed "questionably feasible" in the current EHR environment. For example, it is unclear how frequently history of peripheral arterial disease is captured using a standard definition or recorded in structured fields in current EHRs. To maximize inclusiveness at this stage, we retained the candidate variables deemed "questionably feasible" in the candidate variable selection process.

After these three steps were applied, 22 variables remained candidates for inclusion in the final model (see Table 6).

Table 5. Feasibility of Candidate Variables

Variable	Consistently obtained in target population based on current clinical practice	Captured with a standard definition and recorded in a standard format	Entered in structured fields that are feasibly retrieved from current EHR systems
1. Candidate variables deemed to fulfill all three criteria required for feasibility			
Age	✓	✓	✓
Sex	✓	✓	✓
Heart Rate at First Medical Contact (bpm)	✓	✓	✓
Systolic Blood Pressure at First Medical Contact (mm Hg)	✓	✓	✓
Body Mass Index (BMI) (kg/m^2)	✓	✓	✓
Initial Troponin Ratio	✓	✓	✓
Initial Creatinine Clearance (mL/min)	✓	✓	✓
Initial Creatinine Value (mg/dL)	✓	✓	✓
Initial Hemoglobin Value (g/dL)	✓	✓	✓
2. Candidate variables deemed to have questionable feasibility in current EHR environment			
History of Hypertension (No/Yes)	✓	✓	?
History of Dyslipidemia (No/Yes)	✓	✓	?
Currently on Dialysis (No/Yes)	✓	✓	?
History of Chronic Lung Disease (No/Yes)	✓	✓	?
History of Diabetes Mellitus (No/Yes)	✓	✓	?
Prior MI (No/Yes)	✓	✓	?
Prior Stroke (No/Yes)	✓	?	?
History of Peripheral Arterial Disease (No/Yes)	✓	?	?
Prior Percutaneous Coronary Intervention (No/Yes)	✓	?	?
Prior CABG (No/Yes)	✓	?	?
Prior Heart Failure (No/Yes)	✓	?	?
Current/Recent Smoker (w/in 1 year) (No/Yes)	✓	?	?
Atrial Fibrillation or Flutter in the Past 2 Weeks (No/Yes)	?	?	?

Variable	Consistently obtained in target population based on current clinical practice	Captured with a standard definition and recorded in a standard format	Entered in structured fields that are feasibly retrieved from current EHR systems
3. Candidate variables deemed not feasible for use in hybrid measures given current EHR environment			
ST Segment Elevated Myocardial Infarction (STEMI) or STEMI Equivalent (No/Yes)	✓	×	×
ECG Findings for STEMI Equivalent (Selections: ST Elevation; LBBB; Isolated Posterior MI)	✓	×	×
Other ECG Findings (Selections: New or Presumed New ST Depression, New or Presumed New T-Wave Inversion, Transient ST Elevation Lasting <20 Minutes, None)	✓	×	×
Heart Failure at First Medical Contact (No/Yes)	✓	×	×
Cardiogenic Shock at First Medical Contact (No/Yes)	✓	×	×
Diabetes Therapy (Selections: None, Diet, Oral, Insulin, Other)	×	×	×
Most Recent Percutaneous Coronary Intervention Date	×	×	×
Most Recent CABG Date	×	×	×
Brain Natriuretic Peptide (BNP) (pg/mL)	×	✓	✓
Initial N-Terminal –proBNP Value (pg/mL)	×	✓	✓
History of Cerebrovascular disease (No/Yes) (Includes history of stroke, transient ischemic attack, >79% occlusion by imaging, or prior carotid artery surgery or intervention)	×	×	×
Initial CK-MB Value	×	✓	✓
Initial CK-MB ULN	×	✓	✓
Initial Hemoglobin A1c Value	×	✓	✓
INR Value	×	✓	✓
Total Cholesterol (mg/dL)	×	✓	✓
HDL Cholesterol (mg/dL)	×	✓	✓
LDL Cholesterol (mg/dL)	×	✓	✓
Triglycerides (mg/dL)	×	✓	✓

Table 6. Model Candidate Variables

Description
Demographics
Age
Sex
Cardiac Status On First Medical Contact
Heart Rate at First Medical Contact (bpm)
Systolic Blood Pressure at First Medical Contact (mm Hg)
History and Risk Factors
BMI
Current/Recent Smoker (w/in 1 year) (No/Yes) *Questionably feasible*
History of Hypertension (No/Yes) *Questionably feasible*
History of Dyslipidemia (No/Yes) *Questionably feasible*
Currently on Dialysis (No/Yes) *Questionably feasible*
History of Chronic Lung Disease (No/Yes) *Questionably feasible*
History of Diabetes Mellitus (No/Yes) *Questionably feasible*
Prior MI (No/Yes) *Questionably feasible*
Prior Heart Failure (No/Yes) *Questionably feasible*
Prior PCI (No/Yes) *Questionably feasible*
Prior CABG (No/Yes) *Questionably feasible*
Atrial Fibrillation or Flutter Past 2 Weeks (No/Yes) *Questionably feasible*
Prior Stroke (No/Yes) *Questionably feasible*
History of Peripheral Arterial Disease (No/Yes) *Questionably feasible*
Laboratory Results
Initial Creatinine Value (mg/dL)
Initial Hemoglobin Value (g/dL)
Troponin Ratio (ng/mL)
Creatinine Clearance (mL/min)

4.6.2 Selection of Final Risk-adjustment Variables

We examined distributions of the 22 candidate variables in the merged CMS-AR-G measure cohort. For missing "Yes/No" categorical variables, we assumed a "No" response. For all continuous variables, to reduce the effect of spurious outliers, we transformed extreme values by replacing them with a value at the outer limit of a designated range by a process called Winsorization.[15,16] All continuous variables were initially Winsorized to the 1st and 99th percentiles (that is, values less than the 1st percentile were assigned to the value of the 1st percentile, and values greater than the 99th percentile were assigned to the value of the 99th percentile). The variables were then plotted against 30-day mortality rates and further Winsorized as appropriate to the clinically meaningful values or derived as simple regression splines (see Appendix B. Variables Excluded at Each Step of Variable Selection). For missing values for BMI, we imputed sex-specific median values. For all other continuous variables, we imputed the median value of the entire group.[17]

After Winsorization of the continuous variables, with the pre-selected candidate variables and the outcome of 30-day mortality, we performed a bootstrap simulation with 1,000 iterations by allowing patients to be selected repeatedly. In each iteration, a bootstrap data sample was constructed and a logistic regression model with stepwise selection (entry variables with $p<0.05$; retained variables with $p<0.01$) was performed over all the candidate variables. Lastly, we summarized the model information of all 1,000 iterations on the following: number and frequency of times that a variable is selected (e.g., 70% would mean that the candidate variable was selected as significant at $p<0.05$ in 70% of the iterations), minimum, maximum, and the range of the standardized coefficient for a selected variable. We also assessed the direction and magnitude of the distribution of regression coefficients.

The working group reviewed the results of the bootstrap simulation and decided to retain all risk-adjustment variables above a 90% cutoff (i.e., the variables were selected as significant at $p<0.05$ in 90% of the iterations), which was thought to demonstrate a consistently strong association with mortality. All variables selected less than 90% of the time in 1,000 iterations were excluded except heart rate <70 bpm, which was included based on integrity of a variable, as its counterpart, heart rate >70 bpm, remained in the model. The resulting preliminary risk-adjustment model consisted of nine variables, including five variables deemed feasible for use in this measure and four variables with questionable feasibility.

To create a model with increased usability while retaining excellent model performance, we tested the performance of the model without those variables considered to be questionably feasible and compared it with that of the model containing the variables considered to be questionably feasible. Based on the results of that testing, the final parsimonious risk-adjustment model consisted of five variables collected on arrival at the hospital that were clinically relevant and deemed to be hybrid measure-feasible (see Table 7).

Four of the five final risk-adjustment variables – age, heart rate, systolic blood pressure, and creatinine – are also included in the core clinical data elements. After the initial development of this measure, further testing during the development of the core clinical data elements added a restriction around the timeframe for capture of each of these data elements to ensure that they reflect the patient's status upon arrival at the hospital and not the quality of care delivered. Therefore, in the current hybrid measure V1.1, vital signs must be first captured within 2 hours and laboratory test results, including troponin, must be captured within 24 hours of arrival at the hospital. For more information on this testing, please refer to the Core Clinical Data Elements Technical Report – Version 1.1[3].

Table 7. Description of Preliminary and Final Risk-adjustment Models

Data Elements	Preliminary model *(Contains variables with questionable feasibility)*	Final model *(Contains only variables deemed feasible)*
Age (years)	✓	✓
Heart Rate: HR<70 (bpm)	✓	✓
Heart Rate: HR>=70 (bpm)	✓	✓
Systolic Blood Pressure (mm Hg)	✓	✓
Creatinine (mg/dL)	✓	✓
Troponin Ratio (ng/mL) (per 10 units)	✓	✓
History of Dyslipidemia (No/Yes)	✓	--
Prior PCI (No/Yes)	✓	--
Prior Heart Failure (No/Yes)	✓	--
Prior Stroke (No/Yes)	✓	--

4.7 Statistical Approach to Model Development

4.7.1 Logistic Regression Model and Hierarchical Logistic Regression Model

For model development and calculation of the hospital RSMR, we estimated two types of regression models using the combined CMS-AR-G dataset. First, we fit a generalized logistic regression model linking the outcome to the risk factors.[18] Let Y_{ij} denote the outcome (equal to 1 if patient dies within 30 days, zero otherwise) for the *jth* patient who presented with an AMI at the *ith* hospital; $\mathbf{Z}_{ij}$ denotes a set of risk factors based on the administrative data. Let *I* denote the total number of hospitals and n_i the number of index admissions to hospital *i*. We assume the outcome is related linearly to the covariates via a known linked function, *h*, where

$$\text{LRM} \qquad h(Y_{ij}) = \alpha + \beta\mathbf{Z}_{ij} \qquad (1)$$

and $\mathbf{Z}_{ij} = (Z_{1ij}, Z_{2ij}, \ldots, Z_{pij})$ is a set of *p* patient-specific covariates. In our case, *h* = the logit link, which is the logistic regression model.

To account for the natural clustering of observations within hospitals, we estimated a hierarchical logistic regression model that links the risk factors to the same outcome and a hospital-specific random effect,

$$h(Y_{ij}) = \alpha_i + \beta\mathbf{Z}_{ij} \qquad (2)$$

$$\alpha_i = \mu + \omega_i; \quad \omega_i \sim N(0, \tau^2) \qquad (3)$$

where *h* = the logit link, α_i represents the hospital-specific intercept, $\mathbf{Z}_{ij}$ is defined as above, μ *is* the adjusted average outcome over all hospitals in the sample, and τ^2 is the between-hospital variance component.[19] This model separates within-hospital variation from between-hospital variation. Both hierarchical logistic regression models and logistic regression models were estimated using the SAS software system (GLIMMIX and LOGISTIC procedures, respectively).

We first fit the logistic regression model described in Equation (1) using the logit link for the model

development and model performance.

Having identified the covariates that remained, we next fit the hierarchical logistic regression models described in Equations (2) and (3), again using the logit link function:

$$\text{Logit } (P(Y_{ij} = 1)) = \alpha_i + \beta \mathbf{Z}_{ij}$$

$$\alpha_i = \mu + \omega_i; \ \omega_i \sim N(0, \tau^2)$$

where $\mathbf{Z}_{ij}$ consisted of the covariates retained in the logistic regression model. As before, $Y_{ij} = 1$ if patient *j* treated at hospital *i* had the event; 0 otherwise.

4.7.2 Calculation of Hospital-Specific RSMRs

With the hierarchical logistic regression model, we calculated hospital-specific RSMRs. These rates were calculated as the ratio of predicted to expected mortality, multiplied by the overall unadjusted mortality rate. The expected number of deaths in each hospital was estimated using its patient mix and the average hospital-specific intercept. The predicted number of deaths in each hospital was estimated given the same patient mix but an estimated hospital-specific intercept. Operationally, the expected number of deaths for each hospital was obtained by regressing the risk factors on the mortality outcome using all hospitals in our sample, applying the subsequent estimated regression coefficients to the patient characteristics observed in the hospital, adding the average of the hospital-specific intercepts, transforming, and then summing over all patients in the hospital to get a value. This is a form of indirect standardization. The predicted hospital outcome is the number of deaths in the specific hospital estimated given its performance and case mix. Operationally, this was accomplished by estimating a hospital-specific intercept that herein represents baseline mortality risk within the hospital, applying the estimated regression coefficients to the patient characteristics in the hospital, transforming, and then summing over all patients in the hospital to get a value.

Using the set of risk factors in the logistic regression model, we fitted the hierarchical generalized logistic regression models defined by Equations (2) and (3) and estimated the corresponding parameters. We calculated a standardized outcome, s_i, for each hospital by computing the ratio of the predicted to expected mean outcomes, multiplied by the unadjusted mean mortality rate. Specifically, we calculated:

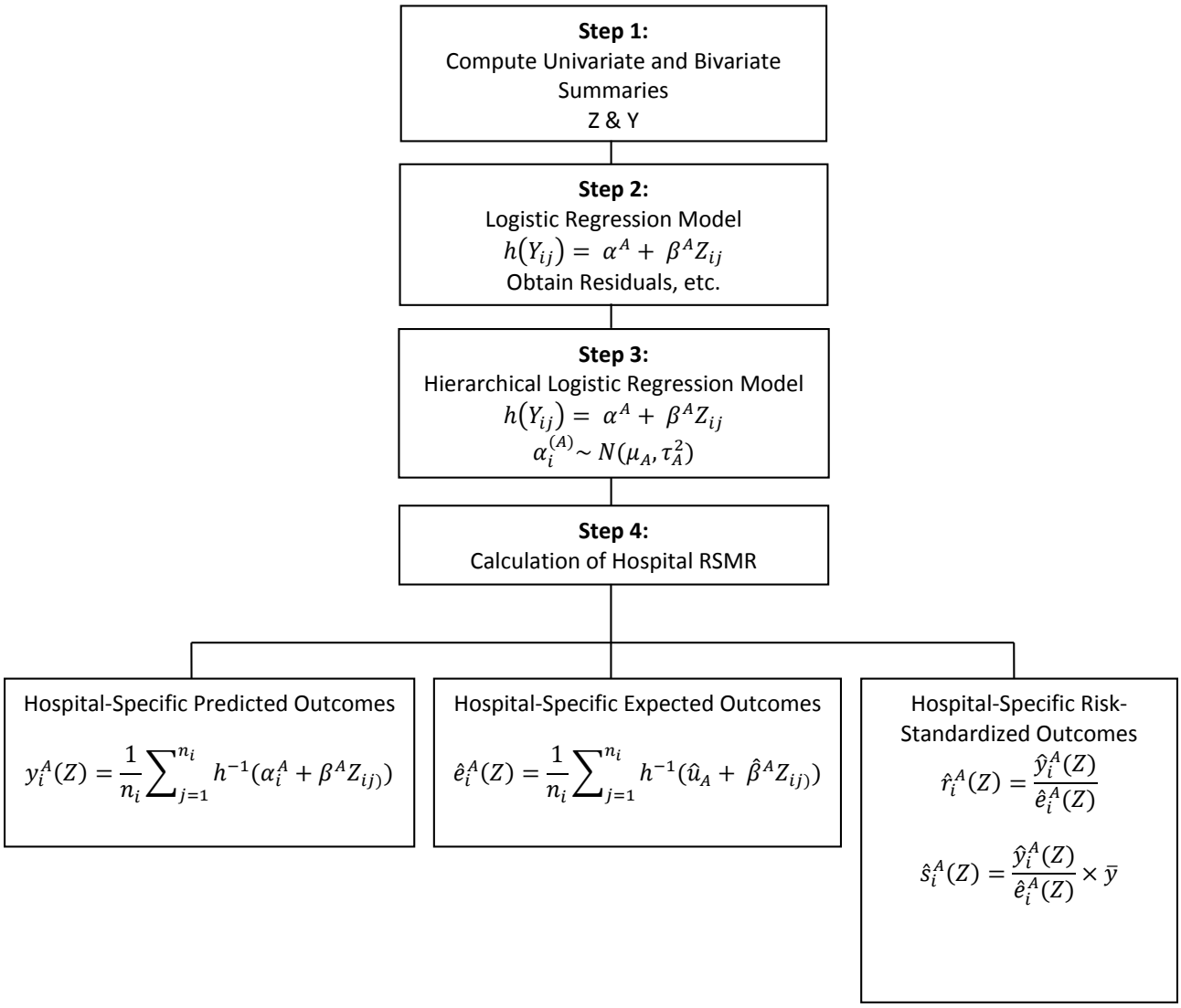
Predicted $$\hat{y}_{ij}(Z) = h^{-1}(\hat{\alpha}_i + \hat{\beta}\mathbf{Z}_{ij}) \quad (4)$$

Expected $$\hat{e}_{ij}(Z) = h^{-1}(\hat{\mu} + \hat{\beta}\mathbf{Z}_{ij}) \quad (5)$$

$$\hat{s}_i(Z) = \frac{\sum_{j=1}^{n_i} \hat{y}_{ij}(Z)}{\sum_{j=1}^{n_i} \hat{e}_{ij}(Z)} \times \bar{y} \quad (6)$$

See Figure 3 for analysis steps. If more (fewer) cases than "expected" have the outcome in a hospital, then the hospital risk-standardized outcome will be higher (lower) than the unadjusted average.

Figure 3. Analysis Steps



4.8 Model Testing

This section describes testing performed using the AR-G registry data to assess the reliability and validity of the risk-adjustment model.

4.8.1 Reliability

Reliability of data elements

Further testing of the reliability of the EHR data elements using an EHR data source is described in the Core Clinical Data Elements Technical Report v1.1.[3]

4.8.2 Validity

Model validation

To assess the validity of the model, we constructed a dataset as described in Section 4.5, except using hospital discharges from the AR-G registry and Medicare claims files from January 1, 2010 through December 31, 2010 (as opposed to 2009 for the derivation cohort). A validation model was created using the same five final model risk-adjustment variables. Summary characteristics were compared for the 2009 and 2010 models (see Section 5.3.1). We also examined the temporal variation of the odds ratios and 95% confidence intervals of the model variables in the 2009 dataset compared to the 2010 dataset.

Validity of measure score

To assess the validity of the measure score, we applied the model in the publicly reported claims-based AMI mortality measure to the study sample and calculated hospital RSMRs. Then we calculated the weighted Pearson correlation between the hospital RSMR based on the claims-based model and the hospital RSMR based on our final model.

The publicly reported claims-based AMI mortality measure was also previously validated with a comprehensive medical record model from an earlier time period. Specifically, claims-based model validation was conducted by building comparable models using abstracted medical record data for risk adjustment using Cooperative Cardiovascular Project data. When both models were applied to the same patient population, the hospital risk-standardized rates estimated using the claims-based risk-adjustment models had a high level of agreement with the results based on the medical record model, thus supporting the use of the claims-based model for public reporting (see Section 5.3.2).[20] This indicates that the claims-based AMI mortality model is suitable for validation of the measure score of the current model.

4.8.3 Disparities Assessment

We conducted analyses to explore disparities in AMI mortality by socioeconomic status (SES) and race at the hospital level. We used Medicaid eligibility status as identified in the Medicare EDB as a proxy for SES. This approach is consistent with prior research as well as NQF recommendations.[21] Hospitals were categorized into quintiles based on their proportion of patients eligible for both Medicaid and Medicare (dual-eligible patients). Similar analyses were conducted for the proportion of African-American patients in hospitals.

4.8.4 Sensitivity Analysis – Assessment of Variables Deemed Clinically Relevant but Not Feasible

Individual variables' feasibility may change over time, particularly with increasing adoption of and improving technology in EHRs. For the current measure, clinical experts assessed the clinical importance of those variables deemed not currently feasible for use in hybrid measures. Although not feasible for inclusion in the current model, these variables may warrant additional consideration for future models as EHRs evolve.

5. RESULTS

5.1 Preliminary Model (Containing Variables with Questionable Feasibility)

5.1.1 Logistic Regression

The preliminary logistic regression model performed very well, with a C-statistic of 0.79 and an adjusted R-square of 0.22. The variable descriptions, estimates, and standard errors for the logistic regression model are shown in Table 8.

Table 8. Preliminary Model: Logistic Regression Results (N=20,540 patients)

Description	Estimate	SE	Chi Sq	Pr>Chi Sq	OR	95% CI
Feasible Data Elements						
Intercept	-5.29	0.349	229	0.00	--	--
Age (per year)	0.06	0.003	351	0.00	1.06	1.05, 1.07
Heart Rate: HR<70 (per bpm)	-0.06	0.040	2	0.17	0.94	0.87, 1.03
Heart Rate: HR>=70 (per bpm)	0.14	0.010	124	0.00	1.15	1.12, 1.18
Systolic Blood Pressure (per mm Hg)	-0.25	0.010	545	0.00	0.78	0.76, 0.80
Troponin Ratio (ng/mL) (per 10 units)	0.11	0.001	107	0.00	1.12	1.10, 1.15
Creatinine (per mg/dL)	0.63	0.038	282	0.00	1.88	1.75, 2.02
Questionably Feasible Data Elements						
History of Dyslipidemia (No/Yes)	-0.29	0.051	32	0.00	0.75	0.68, 0.83
Prior PCI (No/Yes)	-0.27	0.064	17	0.00	0.77	0.68, 0.87
Prior Heart Failure (No/Yes)	0.45	0.057	62	0.00	1.56	1.40, 1.74
Prior Stroke (No/Yes)	0.30	0.068	19	0.00	1.35	1.18, 1.55

5.2 Final Model (Containing only Feasible Variables)

5.2.1 Logistic Regression

The final logistic regression model performed very well, with a C-statistic of 0.78 and an adjusted R-square of 0.20. The variable descriptions, estimates, and standard errors for the logistic regression model using the final model are shown in Table 9.

Table 9. Final Model: Logistic Regression Results (N=20,540 patients)

Description	Estimate	SE	Chi Sq	Pr>Chi Sq	OR	95% CI
Intercept	-6.045	0.342	312	0.000	--	--
Age (years)	0.063	0.003	453	0.000	1.07	1.06, 1.07
Heart Rate: HR<70 (bpm)	-0.051	0.042	2	0.217	0.95	0.88, 1.03
Heart Rate: HR>=70 (bpm)	0.150	0.013	140	0.000	1.16	1.13, 1.19
Systolic Blood Pressure (mm Hg)	-0.249	0.011	555	0.000	0.78	0.76, 0.77
Troponin Ratio (ng/mL) (per 10 units)	0.118	0.011	117	0.000	1.13	1.10, 1.15
Creatinine (mg/dL)	0.671	0.037	336	0.000	1.96	1.82, 2.10

5.2.2 Hierarchical Logistic Regression Model

In the final hierarchical logistic regression model, the estimated between-hospital variance in the log-odds of mortality was 0.0248 (standard error=0.0143). This result implies that the odds of mortality for a high-mortality hospital (+1 standard deviation) were 1.37 times those for a low-mortality hospital (-1 standard deviation). There were 280 hospitals with between-hospital variance=0.0248, standard error=0.0143. Model variable descriptions, estimates, standard errors, and odds ratios are shown in Table 10.

Table 10. Final Model: Hierarchical Logistic Regression Model Results (N=20,540 patients)

Description	Estimate	SE	T Value	Pr > |t|	OR	95% CI
Intercept	-6.050	0.333	-18.151	0.000	--	--
Age (years)	0.063	0.003	21.826	0.000	1.07	1.06, 1.07
Heart Rate: HR<70 (bpm)	-0.050	0.040	-1.243	0.214	0.95	0.88, 1.03
Heart Rate: HR>=70 (bpm)	0.149	0.012	12.135	0.000	1.16	1.13, 1.19
Systolic Blood Pressure (mm Hg)	-0.249	0.010	-24.244	0.000	0.78	0.76, 0.80
Troponin Ratio (ng/mL) (per 10 units)	0.121	0.011	11.285	0.000	1.13	1.11, 1.15
Creatinine (mg/dL)	0.670	0.036	18.852	0.000	1.95	1.82, 2.10

5.2.3 30-day Mortality Rate Distribution

The hospital unadjusted 30-day mortality rate in 2009 data ranged from 0% to 60% across 280 hospitals with a median of 10.5% (interquartile range: 8.2%, 13.3%) (Figure 4). After adjusting for patient characteristics and clustering within hospitals, RSMRs at the hospital level were found to be more normally distributed, ranging from 9.6% to 13.1% across 280 hospitals. The median RSMR was 10.7% (interquartile range: 10.3%, 11.1%) (Figure 5).

Figure 4. Distribution of Hospital Unadjusted Mortality Rates (2009)

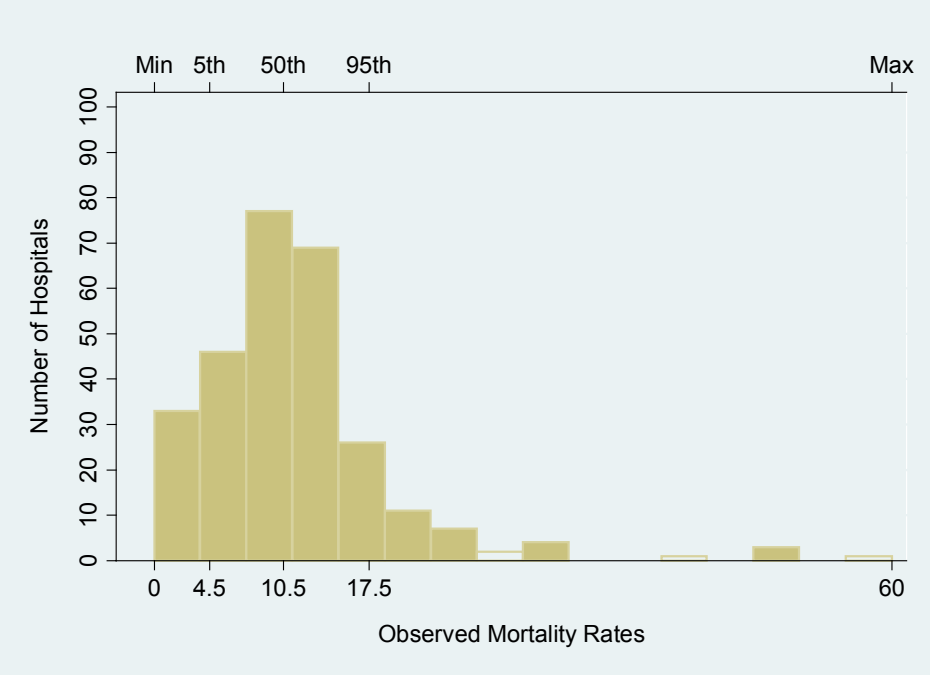
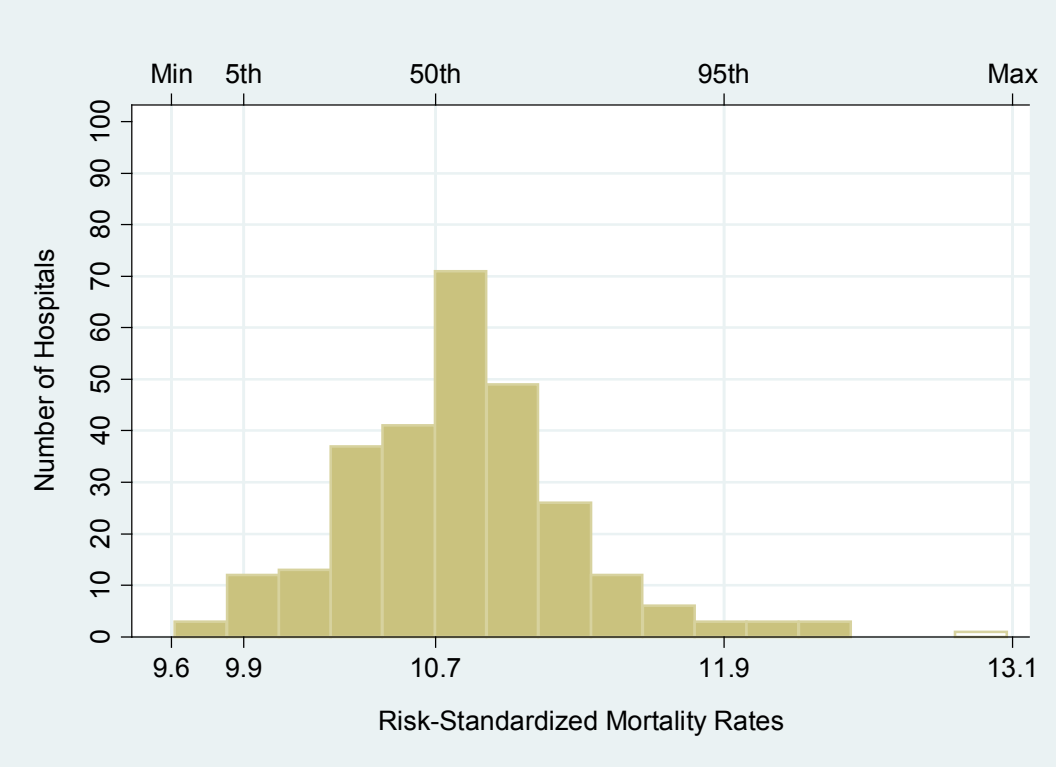


Figure 5. Distribution of Hospital Risk-standardized Mortality Rates (2009)



5.3 Model Assessment

5.3.1 Model Validation

We computed five summary statistics for assessing model performance: over-fitting indices,[†] predictive ability, area under the receiver operating characteristic (ROC) curve, distribution of residuals, and model chi-square.[‡22] The final model, originally developed with 2009 data, was validated using 2010 data. Due to the low sample size, we did not split the development sample. Model performance was similar in each dataset, with strong model discrimination and fit. Predictive ability was also similar across datasets. The C-statistic (area under the ROC curve) was 0.78 for both datasets (Table 11). We also examined the temporal variation of the odds ratios (95% confidence intervals) of the model variables. The odds ratios are consistent over the two years of data (Table 12).

Table 11. Model Performance: Results Based on the Logistic Regression Model

Indices	2009 Derivation Sample	2010 Validation Sample
Number of Admissions	20,540	34,196
Mortality Rate	10.80	10.98
Calibration	--	--
γ0, γ1	0.000, 1.000	-0.013, 0.979
Adjusted R-square	0.204	0.194
Discrimination	--	--
Predictive Ability (lowest decile %, highest decile %)	0.012, 0.375	0.012, 0.374
C-statistic	0.78	0.78
Residuals Lack of Fit (Pearson Residual Fall %)	--	--
<-2	0.015	0.000
[-2, 0)	89.187	89.019
[0, 2)	4.869	4.849
[2+	5.930	6.132
Model χ2 (number of covariates)	1880.576 (6)	3029.846 (6)

[†] Over-fitting refers to the phenomenon in which a model describes the relationship between predictive variables and outcome in the development dataset well, but fails to provide valid predictions in new patients.

[‡] Chi-square – A test of statistical significance usually employed for categorical data to determine whether there is a good fit between the observed data and expected values; i.e., whether the differences between observed and expected values are attributable to true differences in characteristics or instead are the result of chance variation. The formula for computing the chi-square is as follows:

$$\sum \frac{(O-E)^2}{E}$$

where O = observed value
E = expected value, and
degrees of freedom (df) = (rows-1)(columns-1)

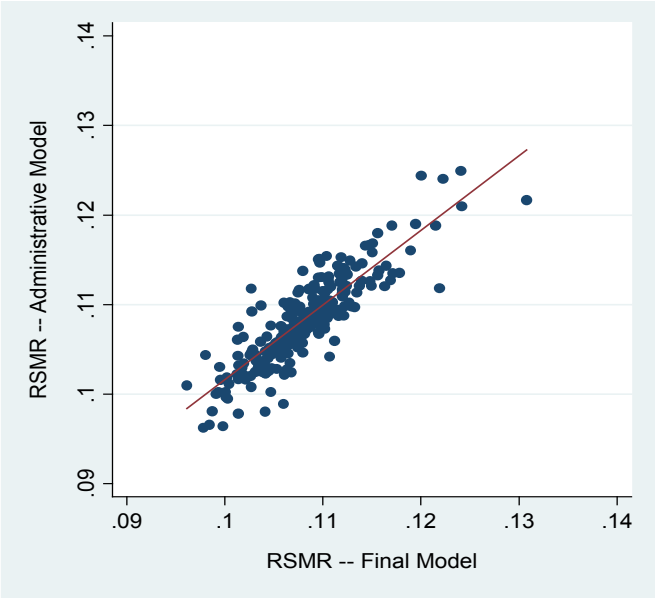
Table 12. Final Model Odds Ratios by Dataset

Description	2009 Development Sample	2010 Validation Sample
Age (years)	1.07 (1.06, 1.07)	1.07 (1.06, 1.07)
Heart Rate: HR<70 (bpm)	0.95 (0.88, 1.03)	0.99 (0.93, 1.05)
Heart Rate: HR>=70 (bpm)	1.16 (1.13, 1.19)	1.14 (1.12, 1.17)
Systolic Blood Pressure (mm Hg)	0.78 (0.76, 0.77)	0.78 (0.76, 0.79)
Troponin Ratio (ng/mL) (per 10 units)	1.13 (1.10, 1.15)	1.12 (1.10, 1.14)
Creatinine (mg/dL)	1.96 (1.82, 2.10)	1.85 (1.75, 1.95)

5.3.2 Measure Score Validity Testing Results

We calculated the correlation of the RSMR from our final model with that of the previously validated, publicly reported, claims-based AMI mortality measure, using data from 2009. The correlation coefficient of 0.86 demonstrates excellent correlation (Figure 6).

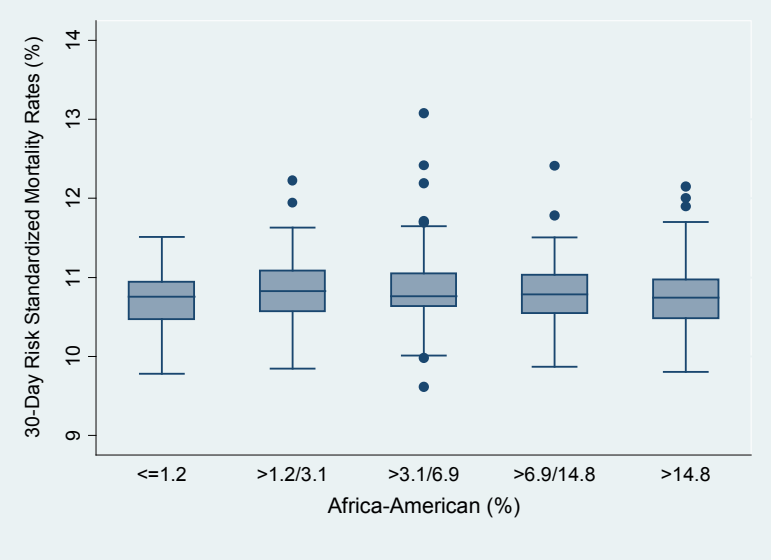
Figure 6. Correlation of RSMR based on the Currently Proposed Final Model with RSMR based on the Previously Developed, Publicly Reported, Claims-Based AMI Mortality Measure (Hospital Volume-weighted Pearson Correlation Coefficient=0.86)



5.3.3 Disparities Assessment

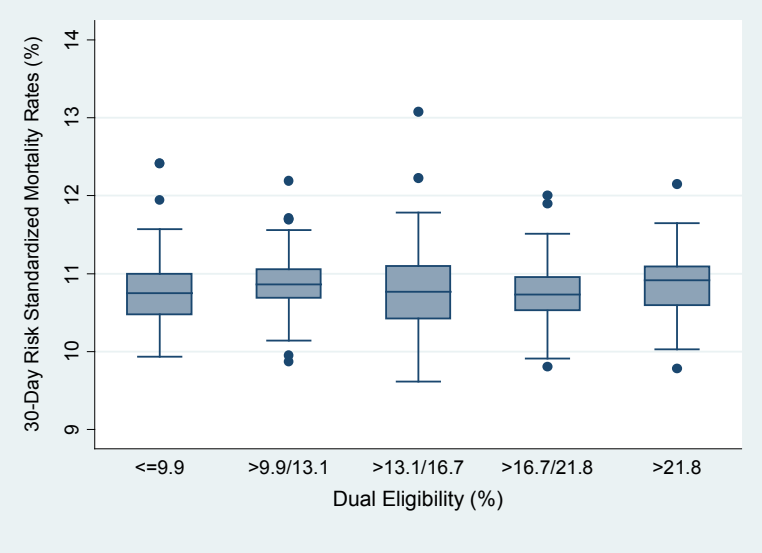
RSMRs in the 2009 data were consistent across quintiles of hospitals based on the hospital proportion of African-American patients. Thus, hospitals with high proportions of African-American patients generally performed as well on the measure as hospitals with lower proportions of African-American patients (Figure 7).

Figure 7. Hospital RSMR (2009) by Proportion of African-American Patients



Similarly, RSMRs in 2009 data were consistent across quintiles of hospitals based on the hospital proportion of dual eligible patients. This analysis suggests that that many hospitals with a high proportion of dual eligible patients performed well on the measure (Figure 8).

Figure 8. Hospital RSMR (2009) by Proportion of Dual Eligible Patients



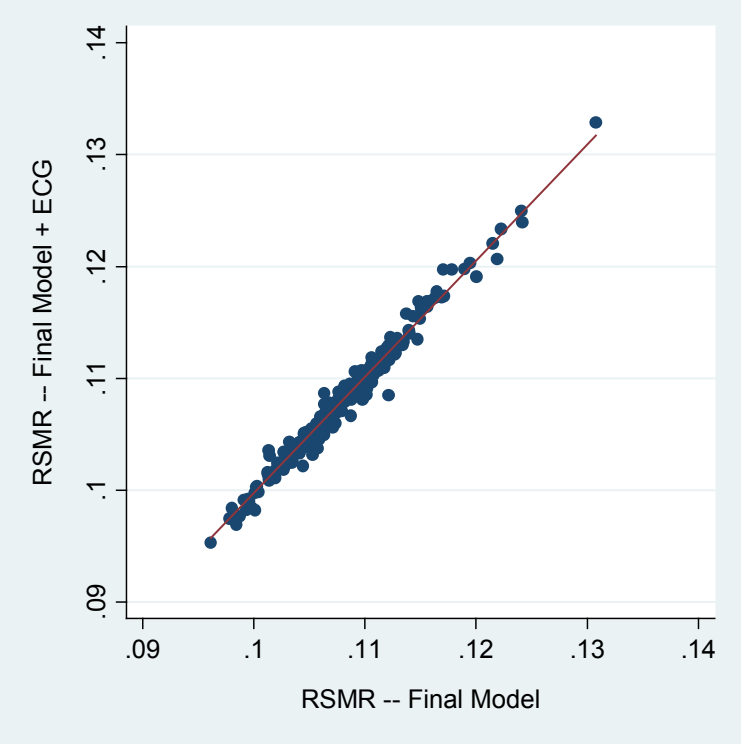
5.3.4 Sensitivity Analysis – Assessment of Variables Deemed Clinically Relevant but Not Feasible for Use in hybrid measures

Clinical experts identified three variables – STEMI on the ECG, heart failure on admission, and cardiogenic shock on admission – as clinically important despite not being feasible for use in a hybrid measure given the current EHR environment.

STEMI is identified on the ECG on presentation. While an ECG is consistently obtained on presentation in the target population based on current clinical practice, the results are not reliably recorded in a standard format nor entered in structured fields that are feasibly retrieved from current EHR systems. However, within the AR-G dataset, the ECG results are recorded in a standard format and entered in structured fields. Thus, although ECG findings did not meet the hybrid measure feasibility criteria, we were able to evaluate the effect of including this variable in the model.

The addition of ECG results to the final model in the 2009 data only increased the C-statistic from 0.78 to 0.80. This increase suggests that future models may be improved if the ECG results become more feasible (e.g., was captured in a structured format within EHRs); however, the resulting improvement in model performance will likely be modest. In addition, the correlation of RSMRs between the final model and the final model with ECG results was 0.989 (Figure 9). This high correlation confirms the low likelihood of substantial improvement in the measure with the addition of ECG results.

Figure 9. Correlation between RSMR based on the Final Model and RSMR based on the Final Model plus ECG Results (Hospital Volume-weighted Correlation Coefficient=0.989)



Heart failure on admission and cardiogenic shock on admission are also consistently obtained in current clinical practice. However, definitions of these variables are inconsistent, and their reliability is limited;[23,24] thus, the criteria for being captured in a standard format and entered in structured fields are not met. Given this questionable reliability of the data elements, assessment of the incremental value of including these variables would not be appropriate.

6. SUMMARY STATEMENT

We developed a hybrid hospital-level 30-day all-cause risk-standardized mortality measure for AMI admissions. This measure was developed *de novo* using clinical registry data through a deliberate process to select only those variables feasible for use in a hybrid claims/EHR measure.

- The measure was developed using clinical registry data from the NCDR AR-G merged with Medicare claims data. The measure was developed with extensive input from clinical, EHR, and methodological experts with knowledge and experience relevant to quality measurement of AMI.
- The cohort consists of hospitalizations for patients admitted to short-term acute care hospitals with a principal diagnosis of AMI.
- The outcome is all-cause mortality within 30 days of admission.
- In the model, we included only those risk-adjustment variables deemed currently feasible by meeting all three of the following requirements:
    - Consistently obtained in the target population based on current clinical practice
    - Captured with a standard definition and recorded in a standard format
    - Entered in structured fields that are feasibly retrieved from current EHR systems
- The hierarchical modeling accounts for hospital case mix, hospital sample size, and the clustering of patients within hospitals, thereby making the measure suitable for public reporting.
- The final model consists of five clinical variables that are present on admission and feasible for use in a hybrid measure. Four of these are a subset of the core clinical data elements. Troponin is an AMI-specific core clinical data element:
    - Age
    - Heart rate
    - Systolic blood pressure
    - Creatinine
    - Troponin ratio
- Of note, three variables that did not meet the feasibility requirements were identified to be particularly important to the clinical community – ST segment elevation myocardial infarction on the ECG, presence of heart failure, and presence of cardiogenic shock, all on admission. The clinical importance of these variables may warrant efforts to improve their EHR feasibility for consideration in future models.
- The final model performed very well, with a C-statistic of 0.78. In addition, we confirmed measure score validity by testing the correlation of RSMR from our final model with that of the previously validated, publicly reported, claims-based AMI mortality measure. The correlation coefficient of 0.86 demonstrated excellent correlation.

In summary, we have built a hybrid outcome measure that produces estimates of hospital risk-standardized mortality rates using data from the EHR and Medicare administrative claims for patients with AMI. The hybrid measure is consistent with the consensus standards for publicly reported outcome measures, is parsimonious in risk adjustment, and performs well compared with the previously validated, publicly reported, claims-based AMI mortality measure.

7. REFERENCES

1. Bernheim S, Wang Y, Grady J, et al. *2011 Measures Maintenance Technical Report: Acute Myocardial Infarction, Heart Failure, and Pneumonia 30-day Risk-Standardized Mortality Measures.* 2011.
2. Krumholz HM, Brindis RG, Brush JE, et al. Standards for Statistical Models Used for Public Reporting of Health Outcomes: An American Heart Association Scientific Statement From the Quality of Care and Outcomes Research Interdisciplinary Writing Group: Cosponsored by the Council on Epidemiology and Prevention and the Stroke Council Endorsed by the American College of Cardiology Foundation. *Circulation.* January 24, 2006 2006;113(3):456-462.
3. Dorsey K, Wang Y, Zhang W, et al. *2013 Core Clinical Data Elements Technical Report (Version 1.1).* 2015.
4. American Recovery and Reinvestment Act of 2009, (2009).
5. Chaudhry B, Wang J, Wu S, et al. Systematic Review: Impact of Health Information Technology on Quality, Efficiency, and Costs of Medical Care. *Annals of Internal Medicine.* 2006;144(10):742-752.
6. Roger VL GA, Lloyd-Jones DM, et al. Heart Disease and Stroke Statistics--2012 Update: A Report From the American Heart Association. . *Circulation.* 2012;125(1):e2-e220.
7. Yeh RW, Sidney S, Chandra M, Sorel M, Selby JV, Go AS. Population Trends in the Incidence and Outcomes of Acute Myocardial Infarction. *New England Journal of Medicine.* 2010;362(23):2155-2165.
8. (HL7) HLSI. HL7 Standards Product Brief - HL7 Version 3 Standard: Representation of the Health Quality Measure Format (eMeasure) DSTU, Release 2. 2015; http://www.hl7.org/.
9. Forum NQ. *National voluntary consensus standards for patient outcomes, first report for phases 1 and 2: A consensus report.* 2010.
10. Drye E, Normand SLT, Wang Y, et al. Comparison of Hospital Risk-Standardized Mortality Rates using In-hospital and 30-Day Models: Implications for Hospital Profiling. *Ann Intern Med.* Jan 3 2012;156(1 Pt 1):19-26.
11. Peterson ED, Roe MT, Chen AY, et al. The NCDR ACTION Registry–GWTG: transforming contemporary acute myocardial infarction clinical care. *Heart.* November 1, 2010 2010;96(22):1798-1802.
12. Messenger JC, Ho KKL, Young CH, et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: The NCDR Data Quality Program in 2012. *Journal of the American College of Cardiology.* 10/16/ 2012;60(16):1484-1488.
13. Fleming C, Fisher E, Chang C, Bubolz T, Malenka D. Studying outcomes and hospital utilization in the elderly. The advantages of a merged data base for Medicare and Veterans Affairs hospitals. *Medical care.* 05 1992;30(5):377-391.
14. Peterson ED, Roe MT, Rumsfeld JS, et al. A Call to ACTION (Acute Coronary Treatment and Intervention Outcomes Network): A National Effort to Promote Timely Clinical Feedback and Support Continuous Quality Improvement for Acute Myocardial Infarction. *Circulation: Cardiovascular Quality and Outcomes.* September 1, 2009 2009;2(5):491-499.
15. Dixon WJ, Yuen KK. Trimming and winsorization: A review. *Statistische Hefte.* 1974/06/01 1974;15(2-3):157-170.
16. Altenburg HP. Estimation of Radioimmunoassay Data Using Robust Nonlinear Regression Methods. In: Dodge Y, Whittaker J, eds. *Computational Statistics*: Physica-Verlag HD; 1992:367-372.
17. Chin CT, Chen AY, Wang TY, et al. Risk adjustment for in-hospital mortality of contemporary patients with acute myocardial infarction: The Acute Coronary Treatment and Intervention

Outcomes Network (ACTION) Registry®–Get With The Guidelines (GWTG)™ acute myocardial infarction mortality model and risk score. *American Heart Journal.* 1// 2011;161(1):113-122.e112.
18. McCullagh P, Nelder JA. *Generalized Linear Models.* Chapman and Hall; 1989.
19. Daniels MJ, Gatsonis C. Hierarchical Generalized Linear Models in the Analysis of Variations in Health Care Utilization. *Journal of the American Statistical Association.* 1999/03/01 1999;94(445):29-42.
20. Krumholz HM, Wang Y, Mattera JA, et al. An Administrative Claims Model Suitable for Profiling Hospital Performance Based on 30-Day Mortality Rates Among Patients With an Acute Myocardial Infarction. *Circulation.* April 4, 2006 2006;113(13):1683-1692.
21. Kindig D, Stoddart G. What Is Population Health? *American Journal of Public Health.* 11/15/accepted 2003;93(3):380-383.
22. Harrell FE, Jr., Shih YC. Using full probability models to compute probabilities of actual interest to decision makers. *International journal of technology assessment in health care.* Winter 2001;17(1):17-26.
23. Barringhaus KG, Zelevinsky K, Lovett A, Normand SL, Ho KK. Impact of independent data adjudication on hospital-specific estimates of risk-adjusted mortality following percutaneous coronary interventions in massachusetts. *Circulation. Cardiovascular quality and outcomes.* Jan 1 2011;4(1):92-98.
24. Curtis JP, Rathore SS, Wang Y, Chen J, Nallamothu BK, Krumholz HM. Use and effectiveness of intra-aortic balloon pumps among patients undergoing high risk percutaneous coronary intervention: insights from the National Cardiovascular Data Registry. *Circulation. Cardiovascular quality and outcomes.* Jan 2012;5(1):21-30.

8. APPENDICES

Appendix A. Working Group Member Roster

Name	Title/Affiliation
Yale-CORE Members	
Harlan Krumholz, MD, SM	Co-Lead; Cardiologist; Professor of Medicine (Cardiovascular Medicine), Yale School of Medicine
Robert McNamara, MD, MHS	Co-Lead; Cardiologist; Associate Professor of Medicine (Cardiovascular Medicine), Yale School of Medicine
Susannah Bernheim, MD, MHS	Director, Quality Measures
Lori Geary, MPH	Senior Project Manager, Quality Measures
Yongfei Wang, MS	Lead Analyst
Zhenqiu Lin, PhD	Supporting Project Analyst
Julia Montague, MPH	Project Coordinator
Purav Mody, MBBS	Research Assistant
Elizabeth Eddy, BA	Research Assistant
Amena Keshawarz, MPH	Research Assistant

Appendix B. Variables Excluded at Each Step of Variable Selection

Step 1: Exclude variables related to post-admission events

Variable category	ACTION Premier Form Variables
E. Medications	
Aspirin post admission	Aspirin in First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Aspirin at Discharge (Selections: No; Yes; Contraindicated; Blinded)
	Aspirin at Discharge - Dose
Clopidogrel post admission	Clopidogrel in First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Clopidogrel in First 24 Hours - Dose
	Clopidogrel at Discharge (Selections: No; Yes; Contraindicated; Blinded)
	Clopidogrel at Discharge - Dose
	Clopidogrel at Discharge - Recommended Duration of Therapy (months)
Ticlopidine post admission	Ticlopidine in First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Ticlopidine in First 24 Hours - Dose
	Ticlopidine at Discharge (Selections: No; Yes; Contraindicated; Blinded)
	Ticlopidine at Discharge - Dose
	Ticlopidine at Discharge - Recommended Duration of Therapy (months)
Prasugrel post admission	Prasugrel in First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Prasugrel in First 24 Hours – Dose
	Prasugrel at Discharge (Selections: No; Yes; Contraindicated; Blinded)
	Prasugrel at Discharge - Dose
	Prasugrel at Discharge - Recommended Duration of Therapy (months)
Warfarin at discharge	Warfarin at Discharge (Selections: No; Yes; Contraindicated; Blinded)
Beta blocker post admission	Beta blocker First 24 Hrs (Selections: No; Yes; Contraindicated; Blinded)
	Beta Blocker at Discharge (Selections: No; Yes; Contraindicated; Blinded)
ACE Inhibitor post admission	ACE Inhibitor First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	ACE Inhibitor at Discharge (Selections: No; Yes; Contraindicated; Blinded)
Angiotensin Receptor Blocker post admission	Angiotensin Receptor Blocker First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Angiotensin Receptor Blocker at Discharge (Selections: No; Yes; Contraindicated; Blinded)
Aldosterone Blocking post admission	Aldosterone Blocking Agent First 24 Hours (Selections: No; Yes; Contraindicated; Blinded)
	Aldosterone Blocking Agent at Discharge (Selections: No; Yes; Contraindicated; Blinded)
Statin post admission	Statin First 24 Hrs (Selections: No; Yes; Contraindicated; Blinded)
	Statin at Discharge (Selections: No; Yes; Contraindicated; Blinded)
Non-Statin Lipid-lowering Agent post admission	Non-Statin Lipid-lowering Agent First 24 Hrs (Selections: No; Yes; Contraindicated; Blinded)
	Non-Statin Lipid-lowering Agent at Discharge (Selections: No; Yes; Contraindicated; Blinded)
GP IIb/IIIa	GP IIb/IIIa Inhibitor Administered (Selections: No; Yes; Contraindicated; Blinded)
	GP IIb/IIIa Inhibitor Type (Selections: Eptifibatide; Tirofiban; Abciximab)
	GP IIb/IIIa Dose
Anticoagulants	Anticoagulants Administered (Selections: No; Yes; Contraindicated; Blinded)
Unfractionated Heparin	IV Unfractionated Heparin (No/Yes)
	Unfractionated Heparin Initial Bolus (No/Yes)

Variable category	ACTION Premier Form Variables
	Unfractionated Heparin Dose of Initial Bolus
	Unfractionated Heparin Initial Infusion (No/Yes)
	Unfractionated Heparin Dose of Initial Infusion
Enoxaparin	Enoxaparin (No/Yes)
	Enoxaparin Initial Subcutaneous Dose
	Enoxaparin Initial IV Bolus (No/Yes)
	Enoxaparin Frequency of Injections Per Day (Selections: q12h; q24h; None)
Dalteparin	Dalteparin (No/Yes)
	Dalteparin Dose
Bivalirudin	Bivalirudin (No/Yes)
Fondaparinux	Fondaparinux (No/Yes)
Argatroban	Argatroban (No/Yes)
Lepirudin	Lepirudin (No/Yes)
F. Procedures and Tests	
Positive Cardiac Markers	Positive Cardiac Markers w/in First 24 hours (No/Yes)
Non-invasive Stress Testing	Non-invasive Stress Testing (No/Yes)
LVEF	LVEF (%)
	LVEF Not Assessed (No/Yes)
Diagnostic Coronary Angiography	Diagnostic Coronary Angiography (No/Yes)
Angiography Findings	Left Main Stenosis Percent (%)
	Left Main Not Available (No/Yes)
	Proximal LAD Stenosis Percent (%)
	Proximal LAD Not Available (No/Yes)
	Mid/Distal LAD, Diag Branches Stenosis Percent (%)
	Mid/Distal LAD, Diag Branches Not Available (No/Yes)
	CIRC, OMs, LPDA and LPL Branches Stenosis Percent (%)
	CIRC, OMs, LPDA and LPL Branches Not Available (No/Yes)
	RCA, RPDA, RPL, AM Branches Stenosis Percent (%)
	RCA, RPDA, RPL, AM Branches Not Available (No/Yes)
	Ramus Stenosis Percent (%)
	Ramus Not Available (No/Yes)
Diagnostic Cath Contraindication	Diagnostic Cath Contraindication (No/Yes)
PCI	PCI (No/Yes)
	Stent(s) Placed (No/Yes)
	Bare Metal Stent Implanted (No/Yes)
	Drug Eluting Stent Implanted (No/Yes)
	Other Stents Implanted (No/Yes)
	PCI Indication (Selections: Immediate primary PCI for STEMI; Rescue PCI (after failed full-dose lytics for STEMI); PCI for NSTEMI; Stable, successful reperfusion for STEMI, or completed infarction post-STEMI; Other)
	Non-system Reason for Delay in PCI (Selections: Difficult vascular access; Cardiac arrest and/or need for intubation before PCI; Patient delays in providing consent for the procedure; Difficulty crossing the culprit lesion during the PCI procedure; Other; None)
CABG	CABG (No/Yes)

Variable category	ACTION Premier Form Variables
G. Reperfusion Strategy	
Reperfusion	Reperfusion Candidate (No/Yes)
	Primary Reason Not Indicated (Selections (~30) not listed; refer to coder's data dictionary)
Thrombolytic therapy	Thrombolytics (No/Yes)
	Strength of Thrombolytic Dose
	Type of Thrombolytics (Selections: Tenecteplase; Alteplase; Reteplase; Streptokinase; Other)
Delay in Reperfusion	Non-System Reason for Delay (No/Yes)
H. In-hospital Clinical Events	
Reinfarction	Reinfarction (No/Yes)
Cardiogenic Shock	Cardiogenic Shock (No/Yes)
Heart Failure	Heart Failure (No/Yes)
	Heart Failure Date
CVA/Stroke	CVA/Stroke (No/Yes)
	Hemorrhagic Stroke (No/Yes)
Suspected Bleeding Event	Suspected Bleeding Event (No/Yes)
	Suspected Bleeding Event Location - Access Site (No/Yes)
	Suspected Bleeding Event Location - Retroperitoneal (No/Yes)
	Suspected Bleeding Event Location - GI (No/Yes)
	Suspected Bleeding Event Location - GU (No/Yes)
	Suspected Bleeding Event Location - Other (No/Yes)
Surgical Procedure or Intervention	Surgical Procedure or Intervention Required (No/Yes)
Blood Transfusion	RBC/Whole Blood Transfusion (No/Yes)
	Transfusion Related to CABG (No/Yes)
Peak Troponin	Peak Troponin Collected (Selections: No; Yes – I; Yes – T)
	Peak Troponin Value (ng/mL)
	Peak Troponin URL (ng/mL)
Peak CK-MB	Peak CK-MB Collected (No/Yes)
	Peak CK-MB Value
	Peak CK-MB Unit (Selections: IU/L; %; (mg/mL)/IU; ng/mL)
	Peak CK-MB ULN
Peak Creatinine	Peak Creatinine Collected (No/Yes)
	Peak Creatinine Value (mg/dL)
Lowest Recorded Hemoglobin	Lowest Recorded Hemoglobin Collected (No/Yes)
	Lowest Recorded Hemoglobin Value (g/dL)
J. Discharge	
Discharge	Comfort Measures Only (No/Yes)
	Clinical Trial (No/Yes)
	Discharge Status (Selections: Alive; Deceased)
	Smoking Counseling (No/Yes)
	Dietary Modification Counseling (Selections: No; Yes; N/A)
	Exercise Counseling (Selections: No; Yes; Ineligible)
	Cardiac Rehabilitation Referral (Selections: No; Yes; Ineligible)
	Discharge Location (Selections: Home; Extended Care/Transitional Unit; Other Hospital; Nursing Home; Hospice; Other)
	Transfer Time

Variable category	ACTION Premier Form Variables
	Transfer for PCI (No/Yes)
	Transfer for CABG (No/Yes)
	Cause of Death (Selections: Cardiac; Non-Cardiac)
	Time of Death

Step 2: Exclude variables unrelated to clinical status of patient at time of admission

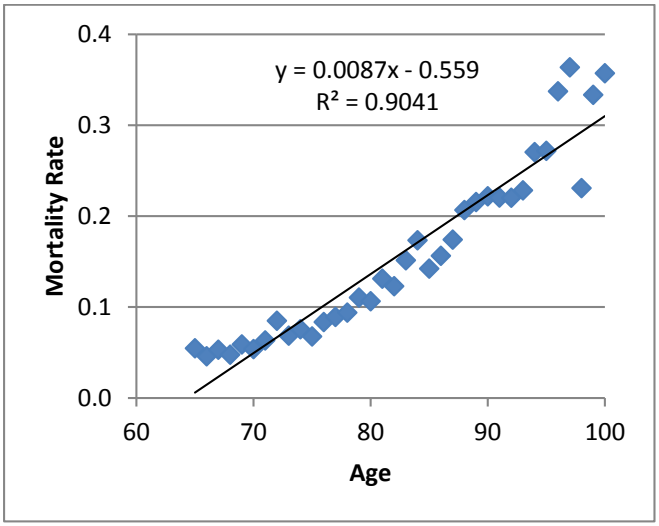
Variable category	ACTION Premier Form Variables
A. Demographics	
Race	White
	Black/African-American
	Asian
	American Indian/Alaskan Native
	Native Hawaiian/Pacific Islander
Hispano or Latino Ethnicity	Yes/No
B. Admission	
Patient Zip Code	Patient Zip Code
	Zip Code N/A
Means of Transport to First Facility/ Arrival Time	Means of transport to First Facility (Selections: Self/Family; Ambulance; Mobile ICU; Air)
	Pre-arrival First Medical Contact Time Estimated (No/Yes)
Insurance Payer	Insurance Payer - Private Health Insurance (No/Yes)
	Insurance Payer - Medicare (No/Yes)
	Insurance Payer - Medicaid (No/Yes)
	Insurance Payer - Military Health Care (No/Yes)
	Insurance Payer - State-Specific Plan (No/Yes)
	Insurance Payer - Indian Health Service
	Insurance Payer - Non-US Insurance
	Insurance Payer - None
Cocaine Use	Cocaine Use (No/Yes)
Aspirin at Home	Aspirin at Home (No/Yes)
Clopidogrel at Home	Clopidogrel at Home (No/Yes)
Ticlopidine at Home	Ticlopidine at Home (No/Yes)
Prasugrel at Home	Prasugrel at Home (No/Yes)
Warfarin at Home	Warfarin at Home (No/Yes)
Beta Blocker at Home	Beta Blocker at Home (No/Yes)
ACE Inhibitor at Home	ACE Inhibitor at Home (No/Yes)
Angiotensin Receptor Blocker at Home	Angiotensin Receptor Blocker at Home (No/Yes)
Aldosterone Blocking Agent at Home	Aldosterone Blocking Agent at Home (No/Yes)
Statin at Home	Statin at Home (No/Yes)
Non-Statin Lipid-lowering Agent at Home	Non-Statin Lipid-lowering Agent at Home (No/Yes)

Step 3: Exclude variables that are deemed not feasible

See Section 4.6.1.

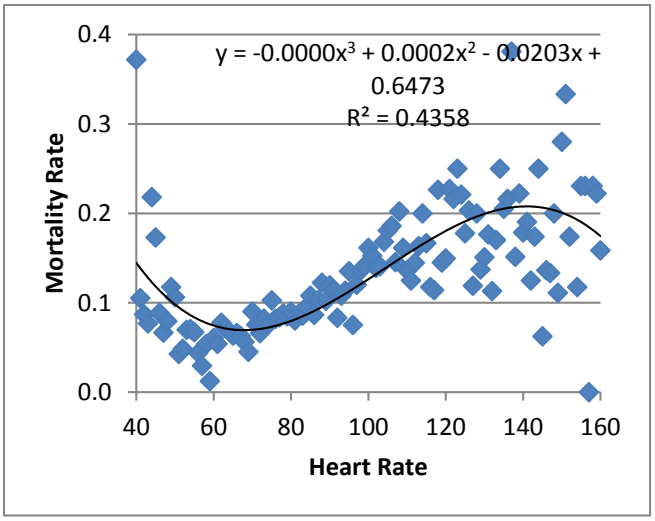
Appendix C. Approach to Defining Continuous Candidate Variables

Figure 10. Association between Age and Mortality: No Winsorization on Age



Decision: Variable to be kept unchanged.

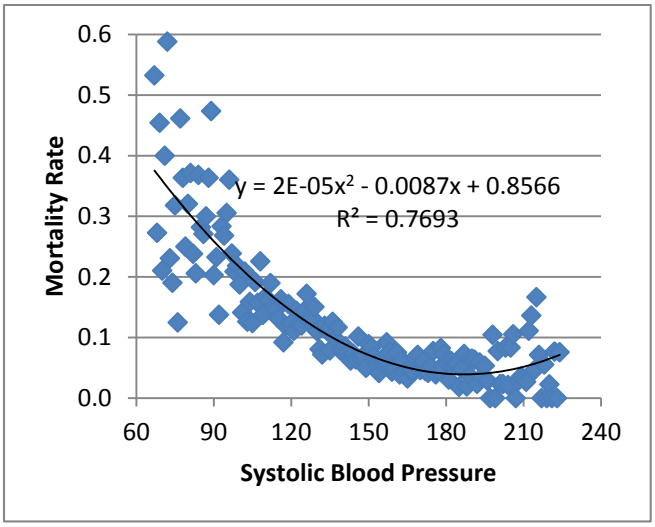
Figure 11. Association between Heart Rate and Mortality with Winsorization of Heart Rate: Low Values to 1st Percentile (40 bpm) and High Values to 99th Percentile (160 bpm)



Decision: Winsorize lower limit to 40 bpm and upper limit to 140 bpm; use splines with a knot at 70 bpm.

Rationale: Presence of a clear linear relationship between heart rate and mortality in the region 40-70 and 70-140 bpm. Thus, it is more appropriate to consider the two linear relationships separately rather than as a single linear relationship in the model. In addition, the use of splines with a knot at 70 bpm is the same approach that was used by the Duke Clinical Research Institute for their AR-G risk model.[24]

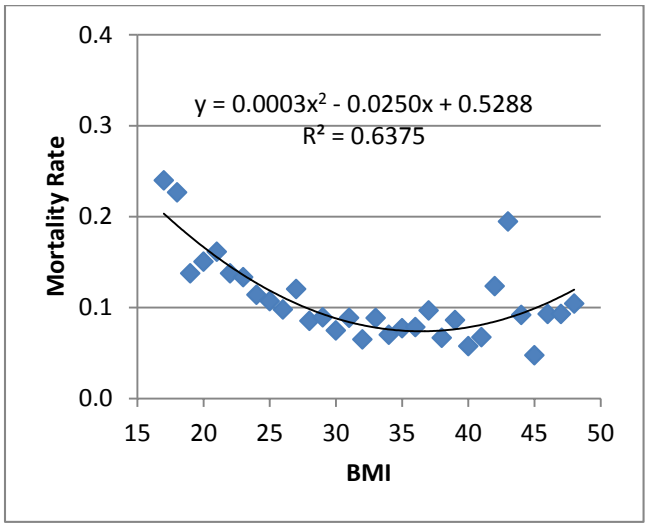
Figure 12. Association between Systolic Blood Pressure and Mortality with Winsorization of Systolic Blood Pressure: Lower Values to 1st Percentile (67 mm Hg) and Higher Values to 99th Percentile (224 mm Hg)



Decision: Winsorize lower limit to 70 mm Hg and upper limit to 150 mm Hg.

Rationale: Risk at systolic blood pressure >150 mm Hg is not clear; risk at 150 mm Hg appears to approximate risk thereafter. Although the risk between 70 mm Hg and 90 mm Hg is variable, the risk appears to decrease as the blood pressure increases. Additionally, 70 mm Hg is clinically more meaningful than 67 mm Hg (1st percentile) as the lower endpoint.

Figure 13. Association between Body Mass Index (BMI) and Mortality with Winsorization of BMI: Lower Values to 1st Percentile (16.5 kg/m²) and Upper Values to 99th Percentile (48.0 kg/m²)

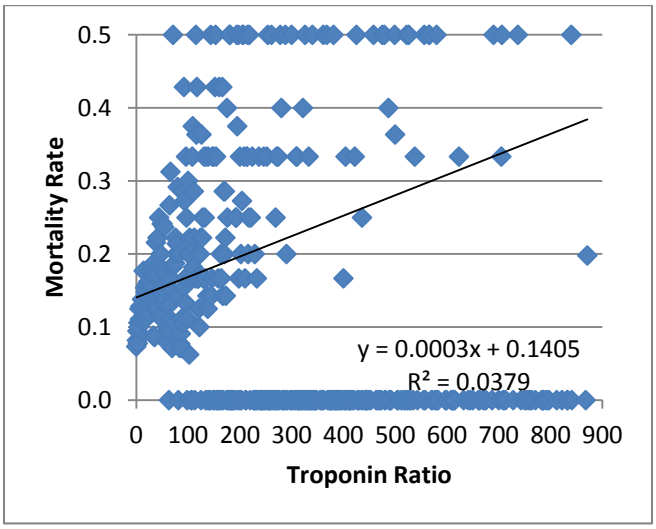


Decision: Winsorize lower limit to 18.5 kg/m² and upper limit to 30 kg/m².

Rationale: Winsorization cutpoint selected as per NCDR CathPCI mortality models. In addition, risk after

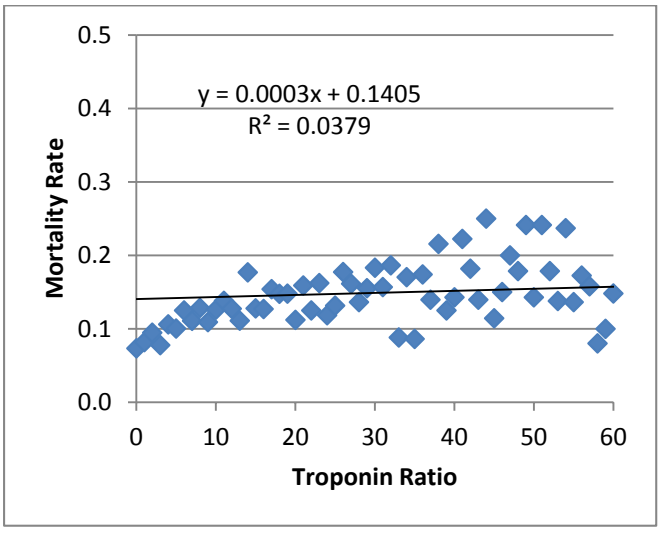
BMI 30 kg/m^2 is unclear but appears relatively constant. Decision to Winsorize the lower end point to 18.5 kg/m^2 compared with 16.5 kg/m^2 as risk appears unclear under this value and it is the lower end of the normal range (18.5-24.99) for BMI.

Figure 14. Association between Troponin Ratio and Mortality with Winsorization of Troponin Ratio: High Values to 99th Percentile (871). The 1st Percentile is 0



(Note: <10% of values were >60)

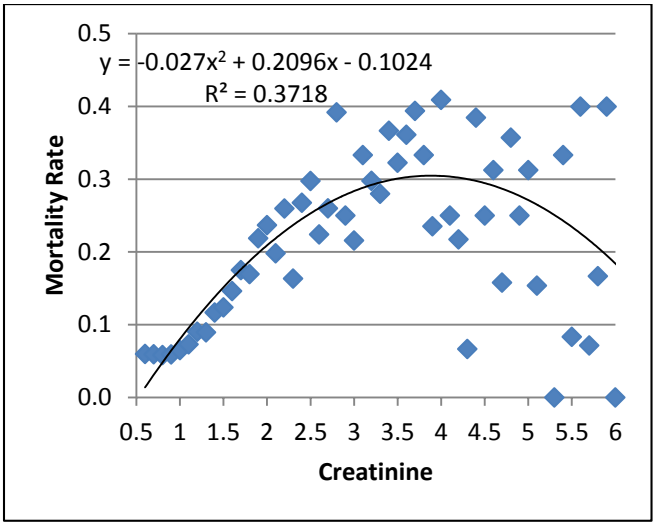
Figure 15. Association between Troponin Ratio and Mortality with Winsorization of Troponin Ratio: High Values to 99th Percentile (871). Only Range of Troponin Ratio between 0 and 60 Are Shown



Decision: Winsorize upper values to 60.

Rationale: Troponin ratio covers a large range of values from 0 to 871; however, the 90th percentile is 60. Risk above 60 is unstable and with relatively few data points.

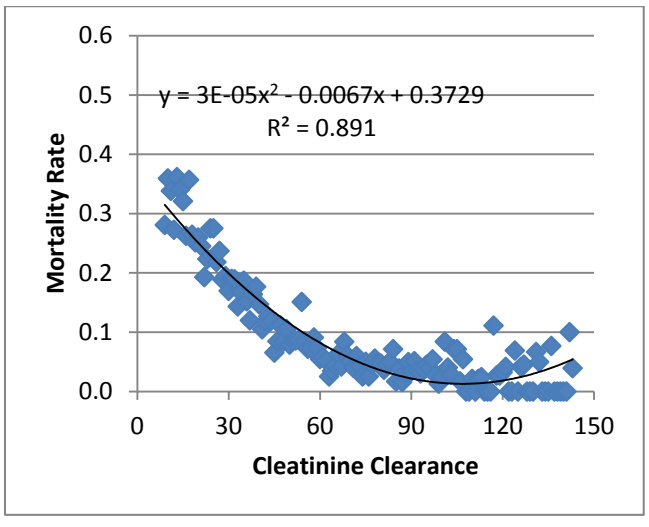
Figure 16. Association between Creatinine and Mortality with Winsorization of Creatinine: Low Values to 1st Percentile (0.6 mg/dL) and High Values to 99th Percentile (6.1 mg/dL)



Decision: Winsorize lower limit to 0.6 mg/dL and upper limit to 3 mg/dL.

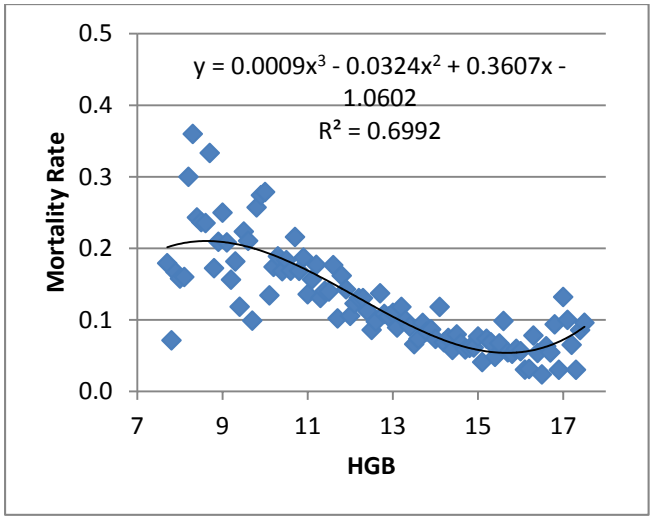
Rationale: The 95th percentile of the data points is 2.7 mg/dL and there is an increasing linear trend in risk prior to 3 mg/dL. Risk >3.0 mg/dL is unclear.

Figure 17. Association between Creatinine Clearance and Mortality with Winsorization of Creatinine Clearance: Low Values to 1st Percentile (9.1 mL/min) and High Values to 99th Percentile (142 mL/min)



Decision: Winsorize lower limit to 9.1 mL/min and upper limit to 90 mL/min.

Figure 18. Association between Hemoglobin and Mortality with Winsorization of Hemoglobin: Low Values to 1st Percentile (7.7 g/dL) and High Values to 99th Percentile (17.5 g/dL)



Decision: Winsorize lower limit to 9 g/dL and upper limit to 16 g/dL.

Rationale: Risk below and above these values is unclear.