1. Retrospective Observational Research Protocol

Clinical and Economic Assessment of Patients with Acute Coronary Syndrome Managed with Percutaneous Coronary Intervention and Treated with Prasugrel or Clopidogrel using Academic Center Databases (H7T-US-B020)

☐ **Safety Objective or Measure**

X Comparative Effectiveness with LY640315

Confidential Information

Prasugrel Hydrochloride (LY640315)

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Retrospective Observational Research Protocol Electronically Signed and Approved by Lilly on approval date provided below

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3. Retrospective Observational Research Protocol

3.1. Rationale

Dual antiplatelet therapy with aspirin and a $P2Y_{12}$ adenosine diphosphate (ADP) receptor inhibitor is standard therapy for prevention of thrombotic complications of percutaneous coronary intervention (PCI). The American College of Cardiology (ACC), American Heart Association (AHA), and European Society of Cardiology (ESC) practice guidelines recommend dual antiplatelet therapy with aspirin and an ADP receptor inhibitor in patients with acute coronary syndromes (ACS), particularly among those undergoing PCI (Jneid et al. 2012; Hamm et al. 2012). Landmark studies such as CURE and CLARITY-TIMI 28 established the benefit of long-term clopidogrel for up to 1 year in subjects with ACS who undergo PCI (Mehta et al. 2001; Sabatine et al. 2005). Significant variability in the response to clopidogrel has been observed secondary to genetic polymorphisms and pharmacodynamic interactions, with some individuals having minimal inhibition of ADP-induced platelet aggregation leading to the concern that some patients may be at increased risk for thrombotic events (Mega et al. 2011; Mega et al. 2010; Mega et al. 2009).

Results from the TRITON-TIMI 38 established the superior efficacy of prasugrel in combination with aspirin over clopidogrel plus aspirin in reducing ischemic events in ACS patients managed with PCI (Wiviott et al. 2007). Compared with clopidogrel, prasugrel caused higher rates of major bleeding, particularly in patients with advanced age, low body weight, previous stroke or transient ischemic attack. Since its United States (US) approval in 2009, there is insufficient observational data that directly compares outcomes between prasugrel and clopidogrel for ischemic and bleeding events. The TRANSLATE-ACS registry is a prospective observational study of approximately 12,000 patients with myocardial infarction ([MI], ST-segment elevation myocardial infarction [STEMI] or non-ST-segment elevation myocardial infarction [NSTEMI]) managed with PCI (Chin et al. 2011). The study is evaluating the effectiveness and safety of prasugrel compared with clopidogrel in the usual care environment. However, as long-term follow-up is being prospectively collected, patient informed consent is required that limits the ability to collect data on all MI patients managed with a PCI. Therefore, there are a large number of eligible patients who will not be included in the TRANSLATE-ACS database because they either did not give consent or were discharged prior to being identified and consent obtained.

A prior comparative retrospective, observational analysis between clopidogrel and prasugrel using the Premier claims database assessed the impact of treatment group on readmission rates for MI or bleeding (Bae et al. 2012). Adjusted results showed that prasugrel was associated with significantly lower acute myocardial infarction (AMI)-related rehospitalizations compared with clopidogrel 30 and 90 days post-discharge. Additionally, adjusted results showed no significant difference in bleeding-related rehospitalization rates between prasugrel- and clopidogrel-treated patients (Bae et al. 2012). However, analyses conducted in payer databases are usually less

robust than registries (for example, the ACC National Cardiovascular Data Registry [NCDR] CathPCI Registry®) or prospective observational studies in capturing pre-existing conditions prior to the index admission, particularly if the patients were not in the plan for the particular payer at the time of the previous diagnosis. Therefore, the true baseline profile of the cohorts may be inadequately determined (for example, missing a prior MI or stroke that may have occurred more than 12 months before the index hospitalization) resulting in inadequate adjustment of the data for unmeasured differences in known confounders. Additionally, payer databases are dependent upon claims made on discharge form the hospital, and may not differentiate from the primary event or the secondary event, especially if secondary diagnoses are allowed in the definition of an outcome event.

Hence, an observational retrospective database analysis using data collected from patients and/or their medical records at the time of index hospitalization with post-hospitalization follow-up will provide important information and will allow better adjustment for baseline differences and a more accurate representation of the results. Study B020 will utilize pooled databases from academic institutions where data is routinely collected on all patients undergoing PCI both during and after the index hospitalization. With regard to clinical and economic outcomes, this approach will provide appropriately controlled baseline characteristic collection to adjust for differences in treatment groups resulting in a robust comparison of prasugrel with clopidogrel in ACS patients treated with PCI. Additionally, this study will include many of the patients who were not able to be enrolled in TRANSLATE-ACS as their data is already captured in these institutional databases. The databases from these institutions collect a large amount of data as either part of or consistent with the ACC NCDR CathPCI Registry, which includes not only clinical characteristics but also detailed procedural characteristics of patients. Additionally, as these data are entered from patient records based on the clinical evaluation, there is no prespecified time window for capturing prior events. The centers participating in this study have also followed these patients post-hospitalization as part of the ongoing evaluation of their results. The majority of the centers have also published based on results of analyses from their individual, or in some cases combined, data (Bagai et al. 2012; Hess et al. 2012; Hess et al. 2014; Mathews et al. 2012; Wang et al. 2014).

3.2. Objectives

3.2.1. Primary Objective

To compare the composite major adverse cardiac event (MACE) outcomes (all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index hospital admission in patients with ACS managed with PCI (the overall ACS/PCI population) who initiated treatment in-hospital and continued at discharge with prasugrel versus those treated with clopidogrel.

3.2.2. Secondary Objectives

1. To examine the following clinical outcomes for ACS patients managed with PCI initiating treatment with prasugrel versus those treated with clopidogrel:

a. To describe differences in the clinical and angiographic profiles of ACS patients managed with PCI treated with prasugrel versus clopidogrel
b. To compare the composite MACE endpoint at 30, 180, and 365 days following index hospital admission
c. To compare the individual components of the MACE endpoint (all-cause death, MI, stroke, and unplanned revascularization) at 30, 90, 180, and 365 days following index hospital admission
d. To compare prasugrel with clopidogrel with regard to the following non-fatal individual components of MACE at 90, 180, and 365 days following index hospital admission:
    1. new MI
    2. unplanned revascularization
    3. stroke
e. To compare all bleeding events or transfusions during index hospital
f. To compare bleeding-related rehospitalizations within 30, 90, 180, and 365 days from index hospital discharge with prasugrel compared with clopidogrel
g. To compare Academic Research Consortium (ARC) defined definite/probable stent thrombosis at 30, 90, and 365 days following index hospital admission with prasugrel versus clopidogrel
h. To compare composite MACE and bleeding events at 30, 90, 180, and 365 days following index hospital admission in the following pre-specified subgroups:
    1. ACS-PCI patients with no prior transient ischemic attack (TIA) or stroke
    2. ACS-PCI patients with no prior history of TIA or stroke and are:
        a. <75 years of age, or
        b. If ≥75 years of age, have diabetes mellitus or a history of MI
    3. Age ≥75 years
    4. Diabetes mellitus
    5. STEMI
    6. NSTEMI/unstable angina (UA)
    7. Chronic kidney disease (creatinine clearance <60 ml/min/1.73m^2
    8. Gender
    9. Prior stroke or TIA
    10. Low body weight (<60 kgs)

2. To compare the following economic outcomes (health resource utilization and costs) in patients treated with prasugrel versus clopidogrel for ACS patients with no prior TIA or stroke and managed with PCI (primary economic outcomes analysis population), and the overall ACS/PCI population (economic outcomes analysis subgroup):
    a. Length of stay for index hospitalization
    b. Readmission rates for MI, bleeding, stroke, unplanned coronary revascularization, or stent thrombosis at 30, 90, 180, and 365 days following index hospital discharge

c. Health resource costs at 30, 90, 180, and 365 days following index hospital discharge
d. Lost productivity due to cardiovascular death

3.2.3. Hypotheses

1. Prasugrel use will be associated with a significantly lower adjusted rate of MACE compared with clopidogrel at 90 days following index hospital admission for the index PCI among patients with ACS who undergo PCI (the overall ACS/PCI population)
2. Prasugrel use will be associated with a significantly lower adjusted rate of health resource utilization compared with clopidogrel at 30 days from index hospital discharge among all patients with ACS who undergo PCI and those without a prior TIA or stroke.

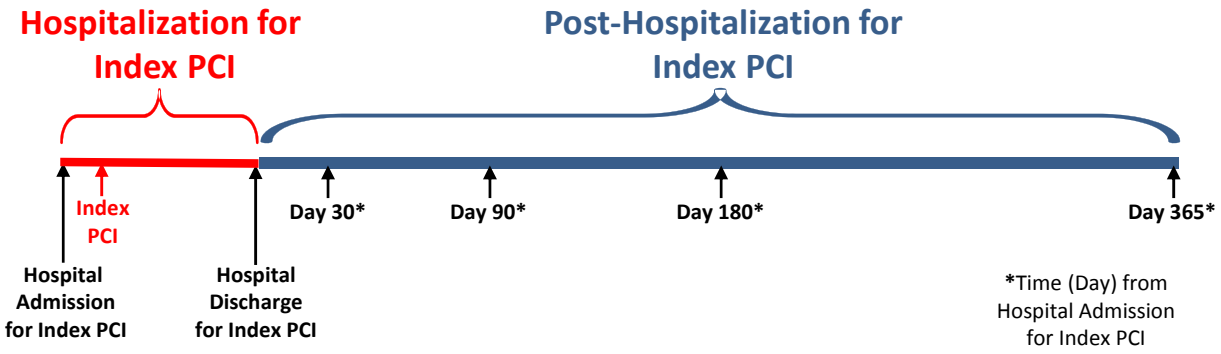
3.3. Research Design

3.3.1. Study Design

Study B020 is designed as a retrospective cohort study evaluating data for patients presenting with ACS managed with a PCI from 6 to 12 academic centers in the US from 01 January 2010 to 30 June 2013, with any follow-up data available for analysis. This study will evaluate the comparative effectiveness and economics of prasugrel relative to clopidogrel in approximately 8,600 patients (minimum 4,300 receiving prasugrel) in a usual care environment from academic centers in the US. These academic centers maintain institutional databases related to baseline characteristics, procedural characteristics and clinical and economic outcomes during and following index hospitalization of patients with ACS undergoing PCI.

The participating academic centers will run a query in their ACS-PCI database to identify all patients who received prasugrel or clopidogrel between 01 January 2010 and 30 June 2013. The study period was selected based on the approval and steady availability of prasugrel in the US market at the end of 2009 and by the need for a study with a minimum 90-day follow-up in this population. The primary endpoint of the study will be at 90 days from index hospital admission; at this point in therapy, the adherence rate is expected to continue to be high while the switching rate is expected to be low (≤10%).

Figure 1 illustrates the study time periods.



Abbreviations: ACS = acute coronary syndromes; PCI = percutaneous coronary intervention.

Figure 1. **Study B020 design for patients with ACS managed with PCI and treated with prasugrel or clopidogrel between 01 January 2010 and 30 June 2013.**

3.3.2. Data Source

Each of the academic centers selected to participate in Study B020 provided information on the patterns of antiplatelet use for ACS patients undergoing PCI and specifically their volumes for the period from 01 January 2010 to 30 June 2013 through a site selection questionnaire. Each of the participating centers maintains high quality institutional databases of both in-hospital and post-discharge follow-up events. The data in these sets are derived primarily from the NCDR CathPCI database while the post-discharge follow-up data is simple physician-determined diagnoses at time of hospitalization. The index hospital data is collected at most sites according to the definitions used in CathPCI. No adjudication of the data will be performed. These databases do not typically include prescriptions, adherence, or outpatient encounters. This project will extract data from the participating ARC data sets using standardized extraction sheets with standardized definitions. Extracted data will be entered in a Core Study Dataset for data analyses.

3.3.3. Study Populations

Inclusion criteria: Adult patients:

1. At least 18 years of age
2. Diagnosed with ACS (STEMI, NSTEMI, UA) and managed by PCI during index hospitalization between 01 January 2010 and 30 June 2013
3. Initiated use of prasugrel or clopidogrel during index hospitalization either prior to, during, or in the peri-procedural period (as defined below) of the index PCI and were discharged on the same medication as initiated during the peri-procedural period. Patients initiated on 1 agent prior to PCI and then switched to the other agent in the peri-procedural period (prior to, during, or ≤3 hours post-procedure) will also be eligible for analysis.

Subgroups of interest:

1. ACS-PCI patients with no prior TIA or stroke
2. ACS-PCI patients with no prior history of TIA or stroke and are:
    a. <75 years of age, or
    b. If ≥75 years of age, have diabetes mellitus or a prior history of MI
3. Age ≥75 years
4. Diabetes mellitus
5. STEMI
6. NSTEMI/UA
7. Chronic kidney disease (creatinine clearance <60 ml/min/1.73m^2)
8. Gender
9. Prior TIA or stroke
10. Low body weight (<60 kgs)

3.3.4. Variables

The primary dependent variable will be MACE (composite of all-cause death, non-fatal MI, stroke or unplanned coronary revascularization) through 90 days from hospital admission for the index PCI. Secondary dependent clinical and economic variables will include components of MACE, bleeding, rehospitalizations for relevant CV events and associated DRG costs, and index hospital length of stay. Other clinical and economic variables of interest will be defined in the Statistical Analysis Plan (SAP). The primary independent variable will be treatment cohort (prasugrel versus clopidogrel) and other independent variables (covariates) will include baseline demographic and clinical characteristics, and baseline treatment utilization.

The variables and their definitions collected for the analysis dataset are listed in Attachment 1.

3.4. Plan of Analysis

3.4.1. Methods

Analyses comparing outcomes of interest between prasugrel and clopidogrel groups will be conducted unadjusted and adjusted (using inverse probability weight [IPW] method) for demographic, clinical, and procedural differences as described below. The primary comparison will be between patients treated with prasugrel versus clopidogrel in an intention-to-treat (ITT) fashion, after adjustment for demographic, clinical, and procedural differences as described below. The primary endpoint of interest is the first occurrence of MACE within 90 days from hospital admission for the index PCI. For the primary outcome of interest, the crude unadjusted 90-day rates of MACE will be calculated for each group using the Kaplan-Meier method, also including index hospital events. Crude rates will be compared between groups using the log-rank test (Kalbfleisch et al. 1980; Prentice et al. 1978).

For descriptive purposes, baseline clinical (including laboratory evaluations) and demographic and procedural characteristics will be compared between groups using student's t-test and chi-square test for continuous and categorical variables, respectively.

In-hospital (that is, post-procedural) outcomes will be assessed by comparing the proportion of post-procedural events between prasugrel and clopidogrel groups. These binary proportion comparisons will be performed using a Chi-square test between groups.

Total follow-up for each patient in Study B020 will be defined as time until death, last follow-up or 365 days following hospital admission for the index PCI, whichever comes first. To evaluate the associations between treatment group (prasugrel versus clopidogrel) and dependent outcomes, hazard ratios will be calculated using Cox proportional hazards regression. Median event free survival time will also be reported. In addition to age, gender and race, any baseline demographic, clinical, or procedural characteristic demonstrating a significant ($p < 0.1$) difference between groups will be included in the multivariable model. The model will also include other covariates that might be pertinent to the clinical outcome even if there are no significant differences in this cohort (for example, diabetes mellitus [DM], smoking status, etc.). Using these candidate covariates, a final multivariate model will be generated using a stepwise selection procedure to ensure model parsimony. The primary exposure of interest (prasugrel versus clopidogrel) will be forced in this final model.

As a separate sensitivity analysis, IPW will be used to adjust the selection bias for the treatment allocation. The propensity score will be generated using a non-parsimonious logistic regression model with the dependent variable as prasugrel versus clopidogrel treatment. From this model, each patient will be ascribed a predicted probability that reflects the propensity to have received prasugrel or clopidogrel at discharge. Inverse probability weights will be derived for all observations using the propensity scores, and then regression analyses will be repeated using these weights.

The primary analysis will include the overall ACS/PCI population. All analyses will be repeated in the all subgroups listed in Section 3.3.3.

3.4.2. Economic Outcomes Analyses

3.4.2.1. Unadjusted Outcomes Analyses

Data will be gathered on all patients in the study concerning their index and follow-up hospitalizations for MI, stroke, repeat unplanned coronary revascularization and stent thrombosis. The frequency of PCI and/or coronary artery bypass graft (CABG) procedures during these hospitalizations will be captured. The proportion of patients with follow-up hospitalization for these diagnoses will be compared between prasugrel and clopidogrel groups using Chi-square tests. The crude unadjusted rates will be calculated for each group using the Kaplan-Meier method and compared using the log-rank test.

All hospitalizations (except for bleeding-related hospitalizations) will be assigned a DRG based on the diagnoses of interest without knowledge of the patient's treatment assignment. The DRGs will be converted to direct medical costs for hospitalization based on Medicare Part A reimbursement. Bleeding-related rehospitalization costs will not be included in this specific analysis as the specific DRG related to this type of admission cannot be determined in this dataset. An additional cost for physicians will be estimated using the Resource-Based Relative

Value Scale (RBRVS) and the Medicare payment schedule. When a hospitalization includes more than 1 event, the highest paying DRG will be used.

Total direct medical costs for the index hospitalization and subsequent hospitalizations will be totaled. Indirect costs (lost productivity) due to premature CV death will be calculated. Hospital length of stay will be calculated as the number of days from hospital admission to discharge. The difference in mean costs (direct and indirect), length of stay, and other continuous resource utilization outcomes (for example, counts of CV-related hospitalizations per patient) between treatment groups will be calculated using t-tests. Exact tests, bootstrapping and/or nonparametric tests will be used as appropriate.

In Study B020, clinical outcomes are measured by days from index hospital admission whereas health economic outcomes are measured by days from index hospital discharge.

3.4.2.2. Adjusted Outcomes Analyses

To examine the associations between treatment group (prasugrel versus clopidogrel) and dependent categorical resource use outcomes (for example, rehospitalizations for CV events), hazard ratios will be calculated using Cox proportional hazards regression. Models will be constructed as described previously in Section 3.4.1.

For analyses of costs, length of stay, and other continuous economic outcomes, IPW will be used. Each patient who received prasugrel or clopidogrel will be weighted by the inverse of the probability of receiving prasugrel. The propensity score and inverse probability weights will be derived as described previously in Section 3.4.1.

Due to the unknown distribution of continuous economic outcomes and the skewness of the data (especially direct and indirect costs), the comparison of continuous outcomes between cohorts will be conducted using non-parametric bootstrapping on IPW adjusted differences in means costs. A 95% confidence interval for the IPW-adjusted cost in both groups and difference in mean costs between the groups will be obtained based on percentiles of the bootstrap distribution. The primary independent variable will be treatment cohort (prasugrel versus clopidogrel) and other independent variables (covariates) will include baseline demographic and clinical characteristics, and baseline treatment utilization.

Differences in healthcare resource utilization and related costs between patients treated with prasugrel versus clopidogrel will be assessed for 1) the ACS-PCI subgroup with no prior stroke or TIA (primary economic outcomes analysis population) and 2) the overall ACS-PCI population (economic outcomes analysis subgroup), and additional subgroups may be considered. As a separate sensitivity analysis, a Generalized Linear Model (with gamma specification and log link function) will be used to model costs between treatment groups. The primary independent variable will be treatment cohort (prasugrel versus clopidogrel) and other independent variables (covariates) will include baseline demographic and clinical characteristics, and baseline treatment utilization.

3.4.3. Bias Adjustment

Based on prior studies (Bae et al. 2012; Wang et al. 2013), significant differences in baseline and other characteristics between groups are expected. Therefore, 2 types of statistical procedures will be performed to account for such bias; these include multivariate and inverse propensity weighting.

3.4.4. Subgroups

Associations for the primary MACE outcome will be examined in the pre-defined clinical subgroups of interest as described in Section 3.3.3. Stratum-specific hazard ratios will be calculated within each subgroup using Cox proportional hazards regression. Formal interaction testing will be performed between the main effects of subgroup (yes/no) and treatment allocation (prasugrel versus clopidogrel) on the MACE endpoint. Interaction terms with p-value <0.05 will be considered significant.

3.4.5. Multiplicity

The primary endpoint of interest in the present study is 90-day MACE, for which a Type I error rate of 0.05 will be used. All other endpoints are secondary and therefore no multiplicity adjustments will be performed.

3.4.6. Missing Data

It is anticipated that the amount of missing data will be minimal in the present study as sites are specifically asked to ensure that the data elements being requested are available. In the instance that baseline clinical or procedural data are missing, data will be imputed with values using multiple imputations with the mi command in Stata. Missing outcome data will not be imputed.

3.4.7. Robustness

The primary analysis will involve multivariate Cox proportional hazards regression as described above. The analysis will incorporate a step-wise selection procedure to generate a parsimonious model with selected covariates. Several sensitivity analyses will be performed to ensure that the primary findings are robust. First, select covariates will be selected using different approaches (forward and backward selection) to assess whether or not the association for the primary variable of interest changes substantially. Second, all analyses will be repeated in an IPW-adjusted cohort.

These additional analyses are meant to be confirmatory (that is, yield approximately the same answer) to the primary analysis.

3.4.8. Sample Size and Power Considerations

Study B020 is designed to assess the difference in MACE associated with prasugrel versus clopidogrel in patients presenting with ACS managed with a PCI from academic centers in the US from 01 January 2010 to 30 June 2013. Data from the Premier study and from TRANSLATE-ACS have suggested that the MACE rate at 90 days will be approximately 8.0%. Using 8.0% as the control rate, it is expected that the relative reduction with prasugrel will be

20% lower than with clopidogrel (hazard ratio 0.80). To achieve 80% power with an alpha of 0.05, and factoring in a 10% patient drop-out, at least 4,303 patients on prasugrel and clopidogrel need to be enrolled, yielding a minimum enrollment of 8,606 patients. If it is necessary to extend the window of time beyond 30 June 2013 in order to enroll an adequate number of patients, no protocol amendment will be required.

3.4.9. Study Limitations

- Data on mortality is partially provided by the Social Security Death Index (SSDI) and data for patients with a mortality record in the SSDI may not be current.
- As the databases are based on a large convenience sample, a limitation of its interpretation is that the results may not be generalizable to other populations. As these centers are select centers providing tertiary care in most instances, the data may not be generalizable to overall care in the US.
- In this database, there are limited/no data that can address known treatment switches to another oral antiplatelet ([OAP]; for example, clopidogrel). Given data from another database (Wang et al. 2013), it is expected that switching during the 90-day window will be less than 15%. However, due to the ITT approach planned for Study B020, outcomes assessed beyond 90 days may be biased towards the null if moderate/high rates of medication switching and discontinuation should occur.
- Several potential unmeasured confounders such as medication adherence and persistence are not available for analysis.
- Data entry (coding) errors may exist at the site of care resulting in initial misclassification of patients or, subsequently, misclassification of patient outcome. Medicare derived costs for DRGs will be included in the cost analyses; these may not represent actual costs incurred by patients in the database.
- While the ITT approach (primary analysis strategy) will attribute outcomes to the index therapy, patients whose outcomes are unknown at time of switching or discontinuation will be censored as true outpatient treatment adherence, persistence, or appropriate drug use will be unknown. Implications of this censoring (that is, assuming that none of those censored patients experience the target outcome after discontinuation or switching) on event rates and study power are unknown.
- The databases used in this study are maintained at academic centers, which are frequently tertiary care centers. It is possible that the loss of patient follow-up may be underestimated as it may not be known to these centers if a patient has an event and is hospitalized at another center.

3.5. Management and Reporting of Adverse Events

During the course of retrospective observational research, information pertaining to adverse reactions (ARs) will not be discovered as the study does not involve identifiable patient data associated with a Lilly drug. The data in this study is only being analyzed in aggregate, study data sets do not include safety measures, and there will be no medical chart review or review of free text data fields. Patient level data from the database will not be transferred to Lilly and/or Daiichi Sankyo Incorporated (DSI).

3.6. Product Complaints

During the course of retrospective observational research, information pertaining to product complaints will not be discovered as the study does not involve identifiable patient data associated with a Lilly drug.

3.7. Ethical Review and Regulatory Considerations

Observational studies will be submitted to ethical review boards (ERBs) for approval whenever required by local law. Regulatory authorities will be notified and approval sought as required by local laws and regulations. Progress reports will be submitted to ERBs and regulatory authorities as required by local laws and regulations.

This study will be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with good clinical practices and applicable US laws and regulations, as appropriate.

3.8. Dissemination Plans

At least 2 abstract submissions are planned for immediate dissemination at a national congress with the appropriate audience: (1) focused on the clinical endpoints; and, (2) focused on the economic endpoints. Manuscripts reporting the primary clinical outcomes and the primary economic outcomes are planned.

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Attachment 1. Data Fields and Descriptions/Definitions

Data Field Term	VALUE	Description/Definition
Patient ID	#######	Patient ID for terms of this dataset (assigned after data consolidation, deidentified)
Date of Index PCI	DDMMYYYY	Actual date of procedure
Date of admission	DDMMYYYY	Actual date of admission associated with index event
Date of discharge	DDMMYYYY	Actual date of discharge associated with index event
Date of birth	DDMMYYYY	Date patient was born
Weight (Kg)	## in kilograms	Indicate the patient's weight in kilograms
Gender	0=male, 1=female	Indicate patient's gender
Height (cm)	### in cms	Indicate patient's height in cm
Hispanic	0=no, 1=yes	Hispanic or Latino Ethnicity: A person of Cuban, Mexican, Puerto Rican, Cuban, South or Central American, or other Spanish culture or origin, regardless of race. The term, "Spanish origin," can be used in addition to "Hispanic or Latino."
Black/African American	0=no, 1=yes	Black/African American (Race): Having origins in any of the black racial groups of Africa. Terms such as "Haitian" or "Negro" can be used in addition to "Black or African American."
White	0=no, 1=yes	White (Race): Having origins in any of the original peoples of Europe, the Middle East, or North Africa
Diabetes at baseline	0=no, 1=yes	Indicate if the patient has a history of diabetes mellitus regardless of duration of disease or need for antidiabetic agents. Supporting Definitions: Diabetes Mellitus: Diabetes mellitus is diagnosed by a physician or can be defined as a fasting blood sugar greater than 7 mmol/l or 126 mg/dL. It does not include gestational diabetes.

Data Field Term	VALUE	Description/Definition
Insulin-requiring diabetes at baseline	0=no, 1=yes	Indicate if patient currently using insulin (Y/N) Target Value: The value on arrival at this facility Selections: Supporting Definitions: (none) Note(s): Patients placed on a pre-procedure diabetic pathway of insulin drip after arrival but were not on insulin therapy (treated by diet or oral method) are not coded as insulin treatment. If a patient had a pancreatic transplant, code "other", since the insulin from the new pancreas is not exogenous insulin.
Hypertension	0=no, 1=yes	Hypertension is defined by any one of the following: • History of hypertension diagnosed and treated with medication, diet and/or exercise • Prior documentation of blood pressure greater than 140 mm Hg systolic and/or 90 mm Hg diastolic for patients without diabetes or chronic kidney disease, or prior documentation of blood pressure greater than130 mm Hg systolic and/or 80 mm Hg diastolic on at least two occasions for patients with diabetes or chronic kidney disease • Currently on pharmacologic therapy for treatment of hypertension.
Hypercholesterolemia	0=no, 1=yes	Indicate if the patient has a history of dyslipidemia diagnosed and/or treated by a physician. Target Value: Any occurrence between birth and arrival at this facility Dyslipidemia: National Cholesterol Education Program criteria include documentation of the following: A. Total cholesterol greater than 200 mg/dL (5.18 mmol/l); or B. Low-density lipoprotein (LDL) greater than or equal to 130 mg/dL (3.37 mmol/l); or, C. High-density lipoprotein (HDL) less than 40 mg/dL (1.04 mmol/l). For patients with known coronary artery disease, treatment is initiated if LDL is greater than 100 mg/dL (2.59mmol/l), and this would qualify as hypercholesterolemia
Serum creatinine	in mg/dl	Pre-procedure value

Data Field Term	VALUE	Description/Definition
Serum hemoglobin	in g/dl	Pre-procedure value
Troponin		Pre-procedure value
CK-MB baseline	ng/ml	Pre-procedure value
Peak serum creatinine	in mg/dl	highest value; leave missing if not drawn
Nadir hemoglobin	in g/dl	lowest within 72 hours;. leave missing if not drawn
Peak CK-MB	ng/ml	highest 6-24 hours; leave missing if not drawn
Peak Troponin		highest 6-24 hours; leave missing if not drawn
Smoking	0=no, 1=yes	Indicate if the patient has smoked cigarettes anytime during the year prior to arrival Coding Instructions: at your facility. Target Value: Any occurrence between 1 year prior to arrival at this facility and arrival at this facility
Family history of CAD	0=no, 1=yes	Family Hx Premature CAD Direct Relatives: Family history includes any direct blood relatives (parents, siblings, children) who have had any of the following diagnosed at age less than 55 years for male relatives or less than 65 years for female relatives: A. Angina B. Acute myocardial infarction C. Sudden cardiac death without obvious cause D. Coronary artery bypass graft surgery E. Percutaneous coronary intervention
Previous MI	0=no, 1=yes	Indicate if the patient has had at least one documented previous myocardial Coding Instructions: infarction. Target Value: Any occurrence between birth and arrival at this facility. Note(s): Code 'No' if the patient's only MI occurred at the transferring facility. Admit Source (3010) must be "Transfer in from another acute care facility." MI: A myocardial infarction is evidenced by any of the following: A. A rise and fall of cardiac biomarkers (preferably troponin) with at least one of the values in the abnormal range for that laboratory [typically above the 99th percentile of the upper reference

Data Field Term	VALUE	Description/Definition
		limit (URL) for normal subjects] together with at least one of the following manifestations of myocardial ischemia: a. Ischemic symptoms b. b. ECG changes indicative of new ischemia (new ST-T changes, new left bundle branch block, or loss of R wave voltage). c. Development of pathological Q waves in 2 or more contiguous leads in the ECG (or equivalent findings for true posterior MI). d. Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality. e. Documentation in the medical record of the diagnosis of acute myocardial infarction based on the cardiac biomarker pattern in the absence of any items enumerated in a-d due to conditions that may mask their appearance (for example, peri-operative infarct when the patient cannot report ischemic symptoms; baseline left bundle branch block or ventricular pacing). B. ECG changes associated with prior myocardial infarction can include the following (with or without prior symptoms): a. Any Q-wave in leads V2-V3 >=0.02 seconds or QS complex in leads V2 and V3 b. Q-wave >=0.03 seconds and >=0.1 mV deep or QS complex in leads I, II, aVL, aVF, or V4-V6 in any two leads of a contiguous lead grouping (I, aVL, V6; V4-V6; II, III, and aVF). c. R-wave >=0.04 seconds in V1-V2 and R/S >=1 with a concordant positive T-wave in the absence of a conduction defect. C. Imaging evidence of a region with new loss of viable myocardium at rest in the absence of a non-ischemic cause. This can be manifest as: a. Echocardiographic, CT, MR,

Data Field Term	VALUE	Description/Definition
		ventriculographic or nuclear imaging evidence of left ventricular thinning or scarring and failure to contract appropriately (i.e., hypokinesis, akinesis, or dyskinesis). b. Fixed (non-reversible) perfusion defects on nuclear radioisotope imaging (for example, MIBI, thallium). D. Medical records documentation of prior myocardial infarction.
Previous PCI	0=no, 1=yes	Indicate if the patient had a previous percutaneous coronary intervention. Target Value: Any occurrence between birth and arrival at this facility Note(s): Timeframe does NOT include PCIs performed after arrival. PCI: Percutaneous coronary intervention (PCI) is the placement of an angioplasty guide wire, balloon, or other device (for example, stent, atherectomy, brachytherapy, or thrombectomy catheter) into a native coronary artery or coronary artery bypass graft for the purpose of mechanical coronary revascularization.
Previous CABG	0=no, 1=yes	Indicate if the patient had a previous coronary artery bypass graft (CABG) surgery. Target Value: Any occurrence between birth and arrival at this facility Note(s): Timeframe does NOT include CABG performed after arrival.
Prior CHF	0=no, 1=yes	Indicate if there is a previous history of heart failure. Target Value: Any occurrence between birth and arrival at this facility. Note(s): A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure described as unusual dyspnea on light exertion, recurrent dyspnea occurring in the supine position, fluid retention; or the description of rales, jugular venous distension, pulmonary edema on physical exam, or pulmonary edema on chest x-ray. A low ejection fraction alone, without clinical evidence of heart failure does not qualify as heart

Data Field Term	VALUE	Description/Definition
		failure.
Prior PAD	0=no, 1=yes	Indicate if the patient has a history of peripheral arterial disease (PAD) (includes upper and lower extremity, renal, mesenteric, and abdominal aortic systems). Supporting Definitions: PAD: Peripheral arterial disease can include: A. Claudication, either with exertion or at rest. B. Amputation for arterial vascular insufficiency. C. Vascular reconstruction, bypass surgery, or percutaneous intervention to the extremities (excluding dialysis fistulas and vein stripping). D. Documented aortic aneurysm with or without repair. E. Positive non-invasive test (for example, ankle brachial index <=0.9); ultrasound, magnetic resonance, computed tomography, or angiographic imaging of > 50% diameter stenosis in any peripheral artery (for example, renal, subclavian, femoral, iliac). For purposes of the Registry, peripheral arterial disease excludes disease in the carotid and cerebrovascular arteries.

Data Field Term	VALUE	Description/Definition
Prior Cerebrovascular Disease	0=no, 1=yes	Indicate if the patient has a history of cerebrovascular Coding Instructions: disease. Target Value: Any occurrence between birth and arrival at this facility Cerebrovascular Disease documented by any one of the following: A. Cerebrovascular Accident (CVA): Patient has a history of stroke, i.e., loss of neurological function with residual symptoms at least 24 hrs after onset, presumed to be from vascular etiology. B. Transient Ischemic Attack (TIA): Patient has a history of loss of neurological function that was abrupt in onset but with complete return of function within 24 hrs, presumed to be due to vascular etiology C. Non-invasive/invasive carotid test with > 79% occlusion. D. Previous carotid artery surgery/intervention for carotid artery stenosis. This does not include neurological disease processes such as metabolic and/or anoxic ischemic encephalopathy.
Left ventricular ejection fraction (%)	## %	If only a range is reported, report the median of the range (i.e.50-55%, is reported as 53%). If only a descriptive value is reported (i.e.normal), enter the corresponding percentage value from the list below: Normal = 60% Good function = 50% Mildly reduced = 45% Fair function = 40% Moderately reduced = 30% Poor function = 25% Severely reduced = 20% The Left Ventricular Ejection Fraction can be assessed via invasive (i.e. LV gram) or non-invasive (i.e. Echo, MR, CT or Nuclear) testing. If an ejection fraction is not measured during this admission and prior to the PCI, and their clinical status has not changed, it is acceptable to code an ejection fraction

Data Field Term	VALUE	Description/Definition
		that was obtained prior to arrival. LVEF: The left ventricular ejection fraction is the percentage of the blood emptied from the left ventricle at the end of the contraction.
CAD Presentation	1=No sxs/no angina; 2=unlikely ischemic; 3=stable angina; 4=Unstable Angina; 5=Non-ST-elevation myocardial infarction, 6=ST-elevation myocardial infarction	Indicate the patient's coronary artery disease (CAD) presentation. Choose Coding Instructions: the worst status. Target Value: The highest value between 7 days prior to arrival and current procedure Selections. Note(s): If the patient presents with atypical symptoms of myocardial ischemia (i.e. only shortness of breath, upper abdominal pain, left arm pain, etc.) that is known and documented to be myocardial ischemia, and is considered to be an anginal equivalent, code the selection that fits their presentation. If these symptoms are not thought to be or have not been proven to be the anginal equivalent, code "Symptom unlikely to be ischemic." If this is a subsequent episode of care (within 7 days), do not code the CAD Presentation from the previous episode of care. For STEMI and NSTEMI, code the highest value within 1 week of the current procedure. If this is a repeat visit to the cath lab during the same episode of care, code the CAD presentation based on the patients clinical status prior to the subsequent procedure.Selection Text Definition 1. No symptom, no angina: No symptoms, No angina 2. Symptom unlikely to be ischemic: Pain, pressure or discomfort in the chest, neck or arms NOT clearly exertional or NOT otherwise consistent with pain or discomfort of myocardial ischemic origin. This includes

Data Field Term	VALUE	Description/Definition
		patients with non-cardiac pain (for example, pulmonary embolism, musculoskeletal, or esophageal discomfort), or cardiac pain not caused by myocardial ischemia (for example, acute pericarditis). 3. Stable angina: Angina without a change in frequency or pattern for the 6 weeks prior to this cath lab visit. Angina is controlled by rest and/or oral or transcutaneous medications 4. Unstable angina: There are three principal presentations of unstable angina: a. Rest angina (occurring at rest and prolonged, usually >20 minutes) b. New onset angina (within the past 2 months, of at least Canadian Cardiovascular Society Class III severity); or c. Increasing angina (previously diagnosed angina that has become distinctly more frequent, longer in duration, or increased by 1 or more Canadian Cardiovascular Society class to at least CCS III severity). 5. Non-STEMI: The patient was hospitalized for a non-ST elevation myocardial infarction (STEMI) as documented in the medical record. Non-STEMIs are characterized by the presence of both criteria: a. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I) exceed the upper limit of normal according to the individual hospital's laboratory parameters with a clinical presentation which is consistent or suggestive of ischemia. ECG changes and/or ischemic symptoms may or may not be present. b. Absence of ECG changes diagnostic of a STEMI (see STEMI) 6. STEMI: The patient presented with a ST elevation myocardial infarction (STEMI) or its equivalent as documented in the medical

Data Field Term	VALUE	Description/Definition
		record. STEMIs are characterized by the presence of both criteria: a) ECG evidence of STEMI: New or presumed new ST-segment elevation or new left bundle branch block not documented to be resolved within 20 minutes. ST-segment elevation is defined by new or presumed new sustained ST-segment elevation at the J-point in two contiguous electrocardiogram (ECG) leads with the cut-off points: >=0.2 mV in men or >= 0.15mV in women in leads V2-V3 and/or >= 0.1 mV in other leads and lasting greater than or equal to 20 minutes. If no exact ST-elevation measurement is recorded in the medical chart, physician's written documentation of ST-elevation or Q-waves is acceptable. a. If only one ECG is performed, then the assumption that the ST elevation persisted at least the required 20 minutes is acceptable. Left bundle branch block (LBBB) refers to new or presumed new LBBB on the initial ECG. b. Cardiac biomarkers (creatinine kinase-myocardial band, Troponin T or I)exceed the upper limit of normal according to the individual hospital's laboratory parameters a clinical presentation which is consistent or suggestive of ischemia. c. Note: For purposes of the Registry, ST elevation in the posterior chest leads (V7 through V9), or ST depression that is maximal in V1-3, without ST-segment elevation in other leads, demonstrating posterobasal myocardial infarction, is considered a STEMI equivalent and qualifies the patient for reperfusion therapy.

Data Field Term	VALUE	Description/Definition
PCI Status	1=elective; 2=urgent; 3=emergency; 4=salvage	1. Elective: The procedure can be performed on an outpatient basis or during a subsequent hospitalization without significant risk of infarction or death. For stable inpatients, the procedure is being performed during this hospitalization for convenience and ease of scheduling and NOT because the patient's clinical situation demands the procedure prior to discharge. If the diagnostic catheterization was elective and there were no complications, the PCI would also be elective. 2. Urgent: The procedure should be performed on an inpatient basis and prior to discharge because of significant concerns that there is risk of ischemia, infarction and/or death. Patients who are outpatients or in the emergency department at the time that the cardiac catheterization is requested would warrant an admission based on their clinical presentation. 3. Emergency: The procedure should be performed as soon as possible because of substantial concerns that ongoing ischemia and/or infarction could lead to death. "As soon as possible" refers to a patient who is of sufficient acuity that you would cancel a scheduled case to perform this procedure immediately in the next available room during business hours, or you would activate the on-call team were this to occur during off-hours. 4. Salvage: The procedure is a last resort. The patient is in cardiogenic shock when the PCI begins (i.e. at the time of introduction into a coronary artery or bypass graft of the first guidewire or intracoronary device for the purpose of mechanical revascularization). Within the last ten minutes prior to the start of the case or during the diagnostic portion of the case, the patient has also received chest compressions for a total of at least

Data Field Term	VALUE	Description/Definition
		sixty seconds or has been on unanticipated extracorporeal circulatory support (for example, extracorporeal mechanical oxygenation, or cardiopulmonary support). Code the best estimate of current left ventricular ejection fraction. Target Value: The last value between 6 months prior to current procedure and prior to the intervention
PCI Indication	1=Immediate PCI for STEMI; 2= PCI for STEMI, unstable > 12 hours; 3=PCI for STEMI, stable > 12 hours; 4=PCI for STEMI stable after successful lytics; 5=Rescue PCI for STEMI after failed lytics; 6=PCI for high risk NSTEMI or unstable angina; 7= Staged PCI; 8=Other	Selection Text Definition 1. Immediate PCI for STEMI: Immediate PCI for patient with STEMI (or STEMI equivalent). 2. PCI for STEMI (Unstable, >12hrs from Sx onset): PCI for STEMI (or STEMI equivalent) more than 12 hours from symptom onset with recurrent or persistent symptoms, symptoms of heart failure or ventricular arrhythmia. 3. PCI for STEMI (Stable, >12 hrs from Sx onset): Patient with STEMI (or STEMI equivalent) who is stable, and is more than 12 hours from symptom onset. The patient does not have any symptoms of recurrent or persistent ischemia, symptoms of heart failure, or electrical instability. 4. PCI for STEMI (Stable after successful full-dose Thrombolysis): PCI for STEMI (or STEMI equivalent) who is stable after receiving full dose thrombolysis. 5. Rescue PCI for STEMI (after failed full-dose lytics): Rescue PCI for STEMI (or STEMI

Data Field Term	VALUE	Description/Definition
		equivalent) after failed full-dose lytics. 6. PCI for high risk Non-STEMI or unstable angina: Incudes patients with unstable angina or Non-STEMI who have high risk features for short-term risk of death or nonfatal MI. High risk features includes at least one of the following: a. History - accelerating tempo of ischemic symptoms in preceding 48 hours. b. Character of pain - prolonged ongoing (greater than 20 minutes) rest pain. c. Clinical findings: i. Pulmonary edema, most likely due to ischemia ii. New or worsening mitral regurgitation murmur iii. S3 or new worsening rales d) Hypotension, bradycardia, tachycardia iv. Age greater than 75 years v. ECG vi. a) Angina at rest with transient ST-segment changes greater than 0.5 mm vii. Bundle-branch block, new or presumed new viii. Sustained ventricular tachycardia ix. Cardiac markers - NSTEMI patients with elevated cardiac TnT, Tnl, or CK-MB. x. Staged PCI The second PCI of a planned, staged procedure (the first PCI could have been during a prior admission, or during this admission). xi. Other: Includes patients that don't fit into any of the above categories. This can include patients with elective or urgent status, status/post

Data Field Term	VALUE	Description/Definition
		cardiac arrest or cardiogenic shock but without ECG or biomarker evidence of acute infarction.
Stress or Imaging pre procedure	0=no, 1=yes	For any subsequent procedures during this episode of care, only code new imaging or stress test results that were performed after the previous procedure until the current procedure.
Beta Blocker on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed a beta blocker to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of a beta-blocker after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.
Ca channel blocker on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed a calcium channel blocker to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of a calcium channel blocker after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.
ASA on admission	0=no, 1=yes	Indicate if the patient is currently taking aspirin at the time of admission.

Data Field Term	VALUE	Description/Definition
Clopidogrel on admission	0=no, 1=yes	Indicate if the patient is currently taking clopidogrel at the time of admission.
Prasugrel on admission	0=no, 1=yes	Indicate if the patient is currently taking prasugrel at the time of admission.
Ticagrelor on admission	0=no, 1=yes	Indicate if the patient is currently taking ticagrelor at the time of admission.
Nitrate on admit	0=no, 1=yes	Indicate if the patient is currently taking nitrates at the time of admission.
Ranexa on admit	0=no, 1=yes	Indicate if the patient has taken or has been prescribed Ranolazine to treat anginal symptoms. Target Value: Any occurrence between 2 weeks prior to current procedure and current procedure Note(s): Code 'no' if a patient was given a sublingual, IV, or short acting formula of one of these medications. Code 'yes' if the patient was started on an oral form of Ranolzine after admission but prior to this cath lab visit. If this medication was prescribed for this patient, but you are unsure if it has been prescribed specifically to treat anginal symptoms, code 'yes'.
Procedural ASA	0=no, 1=yes	Indicate if the patient was administered aspirin at any time during index procedure
Procedural Fondaparinux	0=no, 1=yes	Indicate if the patient was administered fondaparinux at any time during index procedure
Procedural LMWH	0=no, 1=yes	Indicate if the patient was administered a low-molecular heparin at any time during index procedure
Procedural UFH	0=no, 1=yes	Indicate if the patient was administered fondaparinux at any time during index procedure
Procedural Bival	0=no, 1=yes	Indicate if the patient was administered bivalirudin at any time during index procedure
Procedural IIb/IIIa	0=no, 1=yes	Indicate if the patient was administered IIb/IIIa inhibitor at any time during index procedure
Clopidogrel loading	0=no, 1=yes	Indicate if the patient was administered a loading

Data Field Term	VALUE	Description/Definition
		dose of clopidogrel
Prasugrel loading	0=no, 1=yes	Indicate if the patient was administered a loading dose of prasugrel
Ticagrelor loading	0=no, 1=yes	Indicate if the patient was administered a loading dose of ticagrelor
Discharge ACE-I or ARB	0=no, 1=yes	At the time of discharge, was the patient prescribed an ACE-Inhibitor (or ARB)
Discharge ASA	0=no, 1=yes	At the time of discharge, was the patient prescribed aspirin
Discharge bbl	0=no, 1=yes	At the time of discharge, was the patient prescribed a beta blocker
Discharge Statin	0=no, 1=yes	At the time of discharge, was the patient prescribed a statin
Discharge Clopidogrel	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel
Discharge Clopidogrel 75 mg	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel 75mg
Discharge Clopidogrel 150 mg	0=no, 1=yes	At the time of discharge, was the patient prescribed clopidogrel 150mg
Discharge Prasugrel	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel
Discharge Prasugrel 5mg	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel 5mg
Discharge Prasugrel 10mg	0=no, 1=yes	At the time of discharge, was the patient prescribed prasugrel 10mg
Discharge Ticagrelor	0=no, 1=yes	At the time of discharge, was the patient prescribed ticagrelor
Discharge Anticoagulant	0=no, 1=yes	At the time of discharge, was the patient prescribed an anticoagulant (warfarin; LMWH; rivoraxaban)
Multivessel disease	0=no, 1=yes	Value is 1 if number of diseased vessels > 1
Number of lesions treated	##	Total number of lesions treated during the index PCI

Data Field Term	VALUE	Description/Definition
Number of stents implanted	##	Total number of stents implanted during index PCI
mean stent diameter	#.## mm	Mean diameter of all stents implanted during index PCI
Total stent length	## mm	Total length of all stents implanted during index PCI
At least 1 type B2/C lesion	0=no, 1=yes	Does patient have at least 1 type B2/C Lesion
At least 1 lesion with moderate/severe calcifications	0=no, 1=yes	Does patient have 1 lesion with moderate/severe calcifications
At least 1 bifurcation lesion	0=no, 1=yes	Does patient have at least 1 bifurcation lesion
At least one bare metal stent	0=no, 1=yes	yes if any BMS used to treat any lesion during index PCI
At least one drug eluting stent (1st gen)	0=no, 1=yes	yes if any 1st generation DES used to treat any lesion during index PCI
At least one drug eluting stent (2nd gen)	0=no, 1=yes	yes if any 2nd generation DES used to treat any lesion during index PCI
PCI vessel LM	0=no, 1=yes	PCI was performed of LM
PCI vessel LAD	0=no, 1=yes	PCI was performed of LAD
PCI vessel LCx	0=no, 1=yes	PCI was performed of LCx
PCI vessel RCA	0=no, 1=yes	PCI was performed of RCA
Post procedure MI	0=no, 1=yes	Indicate the NEW occurrence of a biomarker positive myocardial infarction after PCI. At least one determination of biomarkers obtained no sooner than 6 hours after PCI, and preferably within the interval of 6-24 hours post-PCI, should be used to make this diagnosis. Target Value: Any occurrence between start of procedure and until the next procedure or until discharge. Note(s): Q waves with absent, incomplete or inconclusive biomarkers should be considered evidence of MI and should be

Data Field Term	VALUE	Description/Definition
		coded as yes. In rare situations, biomarkers may not be obtained in the setting of a post-PCI acute MI (for example, sudden unexpected cardiac death without symptoms or ECG changes suggestive of ischemia, patient is transferred, or biomarkers were just not ordered). In these situations, the site may choose to report a clinically-diagnosed post-PCI myocardial infarction even in the absence of the usually required biomarker elevations. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure.
Post Procedure Cardiogenic Shock	0=no, 1=yes	Indicate if the patient had a new onset or acute recurrence of Coding Instructions: cardiogenic shock. Target Value: Any occurrence between start of procedure and until next procedure or discharge. Note(s): Transient episodes of hypotension reversed with IV fluid or atropine do not constitute cardiogenic shock. The hemodynamic compromise (with or without extraordinary supportive therapy) must persist for at least 30 minutes. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Cardiogenic shock is defined as a sustained (>30 minutes) episode of systolic blood pressure <90 mm Hg, and/or cardiac index <2.2 L/min/m2 determined to be secondary to cardiac dysfunction, and/or the requirement for parenteral inotropic or vasopressor agents or mechanical support (for example, IABP, extracorporeal circulation, ventricular assist devices) to maintain blood pressure and cardiac index above those specified levels.

Data Field Term	VALUE	Description/Definition
Post Procedure Heart Failure	0=no, 1=yes	Indicate if the patient had new onset or acute recurrence of heart failure which necessitated new or increased pharmacologic therapy. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Heart Failure: A previous hospital admission with a principal diagnosis of heart failure is considered evidence of heart failure history. Heart failure is defined as physician documentation or report of any of the following clinical symptoms of heart failure: unusual dyspnea on light exertion; recurrent dyspnea occurring in the supine position; fluid retention; the description of rales, jugular venous distension, pulmonary edema on physical exam; or pulmonary edema on chest x-ray. A previous hospital admission with principal diagnosis of heart failure is considered evidence of heart failure history. A low ejection fraction without clinical evidence of heart failure does not qualify as heart failure.
Post Procedure CVA/Stroke	0=no, 1=yes	Indicate if the patient had a cerebrovascular Coding Instructions: accident (CVA). Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): A stroke or CVA is documented by a loss of neurological function caused by an ischemic or hemorrhagic event with residual symptoms lasting at least 24 hours after onset or leading to death. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure.
Post Procedure Tamponade	0=no, 1=yes	Indicate if the patient experienced fluid in the pericardial space compromising cardiac filling and requiring intervention. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): For patients with extended hospital stays, restrict coding of post-procedure events to 30 days

Data Field Term	VALUE	Description/Definition
		after the last procedure. Tamponade should be documented by either: A. Echocardiogram showing pericardial fluid and signs of tamponade such as right heart compromise, or B. Systemic Hypotension due to pericardial fluid compromising cardiac function.
Post Procedure Dialysis	0=no, 1=yes	Indicate if the patient experienced acute or worsening renal failure necessitating Coding Instructions: renal dialysis. Target Value: Any occurrence between start of procedure and until next procedure or discharge Note(s): If a patient is on receiving continuous veno-venous hemofiltration (CVVH) as a result of renal failure (and not as treatment to remove fluid for heart failure), code yes. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure.
Post Procedure Vascular Complication	0=no, 1=yes	Indicate if the patient experienced any other vascular complications (excluding external bleeding or hematomas) at the percutaneous entry site that required treatment or intervention. Note: Code 'yes' for patients treated with IV therapy for loss of distal pulse. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Target Value: Any occurrence between start of procedure and until next procedure or discharge. Vascular complications can include, but are not limited to, access site occlusions, peripheral embolizations, dissections, pseudoaneurysms and/or AV fistulas. Any noted vascular complication must have had an intervention such as a fibrin injection, angioplasty, or surgical repair to qualify. Prolonged pressure does not qualify as an intervention, but ultrasonic guided compression after making a diagnosis of pseudoaneurysm does qualify. A retroperitoneal bleed or hematoma requiring transfusion is not a vascular complication under this data element. To qualify, this adverse outcome should be attributable

Data Field Term	VALUE	Description/Definition
		to this procedure and not related to a previous or subsequent procedure.
Post Procedure Blood Transfusion	0=no, 1=yes	Indicate if there was a transfusion(s) of either whole blood or packed red blood cells. For patients with extended hospital stays, restrict coding of post-procedure events to 30 days after the last procedure. Target Value: Any occurrence between start of procedure and until next procedure or discharge.
Units of Blood Transfused	##	Number of prbc transfused. Leave as missing if pp_trans = 0.
Post Procedure Bleeding event (72 hours)	0=no, 1=yes	Note(s): A patient who was actively bleeding with coffee ground emesis pre-procedure should not qualify as bleeding. However, a patient with peptic ulcer disease with no noted or active bleeding prior to procedure who starts bleeding after the procedure would qualify as a "yes".
Death (all)	0=no, 1=yes	Report of patient death
Death (all) date	DDMMYYYY	Date of death
Type of Death	1=cardiac, 2=noncardiac, 3= unknown	Enter type of death
Myocardial infarction	0=no, 1=yes	hospitalization for acute (spontaneous) MI after index PCI
Myocardial infarction date	DDMMYYYY	date of event
Number of acute MI hospitalization until		Total number of acute MI hospitalization from 1/1/2010 - 12/31/2012

Data Field Term	VALUE	Description/Definition
12/31/2012		
Unplanned revascularization	0=no, 1=yes	Hospitalization for unplanned revascularization with CABG or PCI after index PCI
Unplanned revascularization date	DDMMYYYY	date of event
Number of unplanned revasc hospitalization until 12/31/2012		Total number of unplanned revasc hospitalization from 1/1/2010 - 12/31/2012
Bleeding	0=no, 1=yes	Hospitalization for bleeding after index PCI
Bleeding date	DDMMYYYY	date of event
Number of bleeding hospitalization until 12/31/2012		Total number of bleeding hospitalizations from 1/1/2010 - 12/31/2012
Type of Bleeding	1=access site; 2=GI; 3=GU; 4=CNS; 5= other; 6=unknown	1)access site 2) GI 3) GU 4) CNS 5) Other 6) Unknown
Stroke	0=no, 1=yes	Was the patient diagnosed as having a stroke
Stroke date	DDMMYYYY	Date of event
Stroke type	1=ischemic; 2=hemorrhagic; 3= unknown	1) Ischemic 2) hemorrhagic
Number of stroke hospitalizations until 12/31/2012		Total number of stroke hospitalizations from 1/1/2010 - 12/31/2012
Definite/Prob ST	0=no, 1=yes	Hospitalizations for Definite/Probable Stent Thrombosis
Definite/Prob ST date	DDMMYYYY	Date of Event

Data Field Term	VALUE	Description/Definition
last follow up date	DDMMYYYY	Last date of encounter with patient