Statistical Analysis Plan

The information included in this Statistical Analysis Plan supersedes analytic considerations embedded within the study protocol.

TRIAL FULL TITLE	Academic Center Database Assessment of Patients with Acute Coronary Syndrome Managed With Percutaneous Coronary Intervention and Treated with Clopidogrel or Prasugrel (H7T-US-B020)
SAP VERSION	1.0
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1 Table of Contents

2 Abbreviations and Definitions

AE	Adverse Event
ACS	Acute Coronary Syndrome
CRF	Case Report Form
ARC	Academic Research Consortium
DRG	Diagnosis-related group
IMP	Investigational Medical Product
IRB	Institutional Review Board
MACE	Major Adverse Cardiac Events (All cause death or hospitalization for myocardial infarction, stroke, or unplanned revascularization)
MI or AMI	Acute Myocardial Infarction
MSSM	Mount Sinai School of Medicine
NSTEMI	Non-ST elevation myocardial infarction
PCI	Percutaneous Coronary Intervention
SAP	Statistical Analysis Plan
SD	Standard Deviation
STEMI	ST elevation MI
TIA	Transient Ischemic Attack

3 Introduction

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 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 are few observational studies that directly compare outcomes between prasugrel and clopidogrel for ischemic and bleeding events. The TRANSLATE-ACS registry was 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 evaluated the comparative effectiveness and safety of prasugrel compared with clopidogrel in the usual care environment (Wang et al. 2014). However, as long-term follow-up was prospectively collected, patient informed consent was required that limited the ability to collect data on all MI patients managed with a PCI. Therefore, there are a large number of eligible patients who were not 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. 2014). 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. 2014). However, analyses conducted in payer databases provide less clinical detail than registries (for example, the ACC National Cardiovascular Data Registry [NCDR] CathPCI Registry®) or prospective observational studies. For instance, pre-existing conditions (prior to the index admission) may be missed. Consequently, 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 from 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 clinical results. Study B020 will utilize pooled databases from academic institutions, where clinical data is routinely collected on all patients undergoing PCI both during and after the index hospitalization, to compare clinical and economic outcomes between clopidogrel and prasugrel. This approach will provide a more appropriately designed baseline characteristic collection to adjust for known patient characteristic differences between prasugrel and clopidogrel treatment groups 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, such as those with unstable angina, 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 pre-specified time window for capturing prior events. The centers participating in this study have also followed these patients post-hospitalization as part of the on-going evaluation of their results.

4 Study Objectives and Endpoints

To describe and compare the clinical and angiographic profiles of ACS patients managed with percutaneous coronary intervention with stent implantation and treated with prasugrel or clopidogrel.

4.1 Primary Objectives

To compare major adverse cardiac event (MACE) outcomes (the composite occurrence of all-cause death, MI, stroke, or unplanned coronary revascularization) within 90 days of index PCI in patients with ACS treated with prasugrel or clopidogrel.

4.2 Secondary Objectives

1. To examine the following clinical outcomes for ACS patients managed with PCI initiating treatment with prasugrel versus those initiating treatment with clopidogrel:
    a. To describe differences in the demographic, clinical, and angiographic profiles. To compare the composite MACE endpoint within 30, 180, and 365 days following index PCI.
    b. To compare the individual components of the MACE endpoint (all-cause death, MI, stroke, and unplanned revascularization) within 30, 90, 180, and 365 days following index PCI.
2. To compare all in and out of hospital bleeding events within 30, 90, 180 and 365 days from index PCI. To compare bleeding-related rehospitalizations within 30, 90, 180, and 365 days from index hospital discharge with prasugrel versus clopidogrel
3. To compare post-procedural (in-hospital) MACE and bleeding events.
4. To compare Academic Research Consortium (ARC) defined definite/probable stent thrombosis at 30, 90, 180, and 365 days following index PCI with prasugrel versus clopidogrel.
5. To compare MACE and bleeding events at 30, 90, 180 and 365 days following index PCI 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 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. Presence or absence of Diabetes mellitus
4. NSTEMI/unstable angina (UA)
5. STEMI
6. Gender
7. Presence or absence of multivessel disease
8. Presence or absence of chronic kidney disease, defined as an estimated glomerular filtration rate < 60 ml/min/1.73m^2

6. To compare the following economic outcomes (health resource utilization and costs) in ACS-PCI patients with no prior TIA or stroke and initiating treatment with prasugrel versus clopidogrel (primary economic outcomes analysis population), and the overall ACS/PCI population (economic outcomes secondary analysis population)
   a. Length of stay for index hospitalization
   b. Readmission rates for MI, bleeding, stroke, unplanned coronary revascularization, at 30, 90, 180, and 365 days following index hospital discharge
   c. Total costs for the index hospitalization
   d. Rehospitalization costs at 30, 90, 180, and 365 days following index hospital discharge

4.3 Derived variables

Both death and stent thrombosis will be classified per the ARC criteria (Cutlip et al., 2007). Myocardial Infarction will be defined per the 2007 Universal definition (Thygessen et al., 2007). Stroke will be defined as a physician-determined focal neurological deficit of cerebrovascular origin that persists for at least 24 hours. Unplanned revascularization is defined as any revascularization (PCI/CABG) that is not staged. MACE is the composite occurrence of all-cause death, stroke, MI or unplanned revascularization. Total follow-up time for all patients will be defined as time from index PCI until time of death, last contact, or 365 days whichever comes first.

5 Study Methods

5.1 Study Design

Study B020 is designed as a retrospective cohort study evaluating data for patients presenting with ACS managed with a PCI from 8 academic centers in the US from 01 January 2010 to 30 June 2013, with any follow-up data available for analysis. The centers include: Mount Sinai Medical Center, Intermountain Heart Institute, Duke University, Cleveland Clinic Foundation, University of Pittsburgh, University of Minnesota, Christiana Health Care and Aurora Research Institute. This study will evaluate the comparative effectiveness and economics of a treatment strategy initiating 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 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 PCI; 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

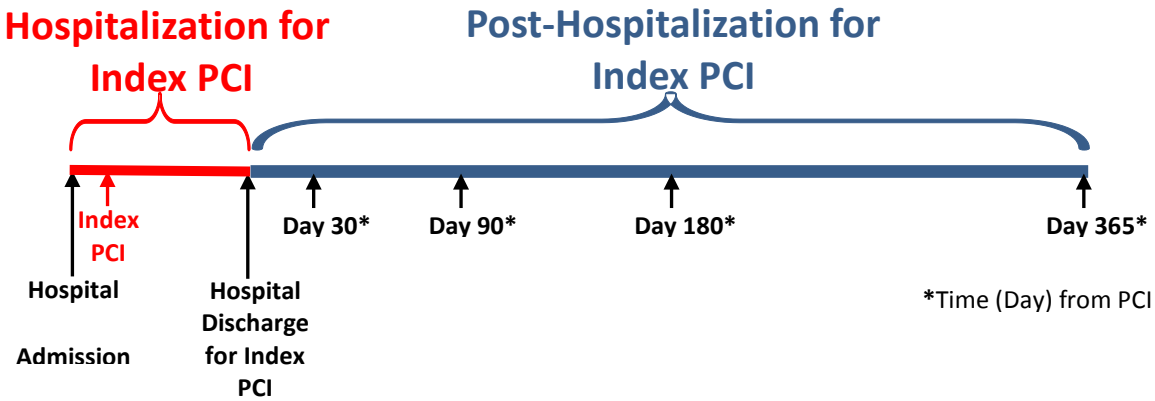

Figure 1 Study B020 design for patients with ACS managed with PCI and treated with prasugrel or clopidogrel between 01 January 2010 and 30 June 2013.

5.2 Data Source

Each of the academic centers selected to participate in Study B020 will provide 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 physician-determined diagnoses at time of hospitalization as described in Section 4.3. The index hospital data is collected at most sites according to the definitions used in CathPCI registry data collection form. 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 centers using extraction sheets with standardized definitions. Extracted data will be entered in a Core Study Dataset for data analyses.

5.3 Study Populations

Inclusion criteria:

1. At least 18 years of age at time of index PCI.
2. Diagnosed with ACS (STEMI, NSTEMI, UA) and managed by PCI with stent implantation during the index hospitalization between 01 January 2010 and 30 June 2013
3. Treatment with prasugrel or clopidogrel during index hospitalization either prior to, or during the peri-procedural period (as defined below)

Populations of Interest:

1. All ACS-PCI patients
2. ACS-PCI patients with no prior TIA or stroke
3. ACS-PCI patients with no prior history of TIA or stroke and are:
    i. $<$75 years of age, or
    ii. $\geq$75 years of age with diabetes mellitus or a prior history of MI
2. Diabetes mellitus
3. NSTEMI/UA
4. STEMI

5. Gender
6. Presence or absence of multivessel disease
7. Presence or absence of chronic kidney disease, defined as an estimated glomerular filtration rate < 60 ml/min/1.73m^2

6 Plan of Analysis

6.1 Methods

Primary Objective

The exposure groups for the primary analysis will be defined as those patients receiving prasugrel or clopidogrel at the time of PCI (i.e. loaded peri-procedurally or currently taking in the absence of a load). All patients will be assigned to one of these mutually exclusive groups irrespective of medication administered at discharge. Patients administered both medications at the time of PCI will be excluded for any comparative analyses of treatments.

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 or Fisher's exact 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 crude unadjusted binary proportions will be performed using a Chi-square test between groups.

The primary endpoint of interest is the first occurrence of MACE within 90 days from date of index PCI. For purposes of this primary analysis, event-free patients will be censored at 90 days or last contact, whichever comes first. 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 logrank test (Kalbfleisch et al. 1980; Prentice et al. 1978).

To evaluate the adjusted associations between treatment group (therapy initiation with prasugrel versus clopidogrel) and the primary MACE outcome, hazard ratios will be calculated using Cox proportional hazards regression that are stratified by the propensity to receive either prasugrel or clopidogrel.

Propensity scores will be calculated using a multivariable logistic regression model with the dependent outcome as treatment initiation with prasugrel (versus clopidogrel). In addition to age, and gender, this model will include all baseline covariates demonstrating significant differences ($p<0.05$) between groups. Additional variables for which there is consensus that may be related to either the outcome or exposure will also be included as covariates, even in the absence of significant baseline differences between groups. From this logistic regression model, each observation will be assigned a predicted probability for prasugrel treatment. Baseline characteristics including calculated propensity score will be reviewed to better understand the data and specified analyses plan for the outcomes (stratification, matching, IPW, and etc) will be finalized and documented prior to any actual analyses on the outcomes. The distribution of propensity scores for the entire cohort and each treatment group will be visually examined. Mutually exclusive strata will then be generated based on the propensity scores for the entire cohort, a process which will be blinded to any outcome data in order to avoid bias in selection. The number of strata and their respective cut-points will not be defined *a priori* but will be based on fulfilling the following criteria:

1. Sufficient number of strata to ensure adequate bias adjustment (i.e. at least 5 strata) [Rosenbaum et al., 1984);
2. Sufficient proportion of prasugrel and clopidogrel patients (at least 3%) within each stratum to allow reliable risk estimation [D'Agostino et al., circulation 2007];
3. Adequate balance in baseline covariates will be assessed by calculating the standardized differences between exposure groups within strata for the following variables: age, gender, serum creatinine, serum hemoglobin and prevalence of DM. A standardized difference exceeding 10% will be considered as inadequate bias adjustment..
4. Individuals with an extremely high or low propensity for prasugrel, defined as propensity scores exceeding the 95th or below the 5th percentile for the

entire cohort, may be removed from the analysis of the primary MACE endpoint (i.e. trimming).

The adjusted associations between exposure groups and the primary MACE outcome will then be calculated using Cox proportional hazards regression. This model will include the following two covariates: exposure group (prasugrel versus clopidogrel) and study center, with propensity group entered as a stratification variable.

The following sensitivity analyses for the primary MACE outcome will also be performed:

1. Covariate adjustment. Hazard ratios for the primary MACE outcome associated with prasugrel versus clopidogrel treatment will be generated using a fully-fitted Cox proportional hazards regression model. In addition to age, , gender and study center, this model will include all baseline covariates demonstrating significant differences ($p < 0.05$) between groups. Other baseline variables that may be plausibly related to the primary outcome will also be included: BMI, race, diabetes mellitus, serum creatinine, hemoglobin, prior MI, prior CHF, prior PAD, prior cerebrovascular disease, multivessel disease, CAD presentation (unstable angina vs. nstemi vs. stemi), current smoking, number of stents implanted, stent type and stent diameter (maximum). A second covariate-adjusted model will be generated using forward stepwise regression with treatment forced in first.

2. Propensity matching: A 1:1 matched cohort will be derived from the overall sample using the propensity scores as described above. Matches will be generated using nearest neighbour matching without replacement (Austin 2011).

3. Equipoise Analysis: From the overall cohort, an 'equipoise' subgroup will be derived that includes all patients with preference scores ranging between 0.4 - 0.6. These patients are assumed to have a reasonable high probability of being assigned to either treatment (Walker et al., 2013).

4. Inverse Probability Weight Analysis: Inverse probability weights (IPW) will be derived for all observations using the propensity scores. Observations with propensity scores exceeding the 95th percentile or below the 5th percentile for the

entire cohort will be excluded (trimmed) for purposes of this specific analysis. After trimming regression analyses will be performed using these weights.

5. A sensitivity analysis for the primary MACE outcome will be performed by defining exposure groups as those patients receiving the same medication at the time of PCI and at discharge. For purposes of this sensitivity analysis, dependent outcome will be restricted to out-of hospital MACE and will exclude those patients with in-hospital death.

Secondary Objectives

Analyses for the secondary clinical outcomes, including subgroups, will be performed using propensity score with stratification as outlined above with covariate adjustment as a sensitivity analysis.

Note: Section 6.2 Economic Outcomes Analyses (including Sections 6.2.1 Unadjusted Outcomes Analyses and 6.2.2 Adjusted Outcomes Analyses) will be contained in ***Addendum 1: Economic Outcomes Analyses.*** References in the economic section will be added to reference list along with Addendum 1.

6.2 Economic Outcomes Analyses

6.2.1 Unadjusted Outcomes Analyses

6.2.2 Adjusted Outcomes Analyses

6.3 Bias Adjustment

Based on prior studies (Bae et al. 2014; Wang et al. 2014), significant differences in baseline and other characteristics between groups are expected. Therefore, propensity score methodology will be implemented to account for underlying bias

6.4 Populations of Interest

Associations for the primary MACE outcome will be examined in the pre-defined clinical subgroups of interest as described in Section 5.3. Stratum-specific hazard

ratios will be calculated within each subgroup using Cox proportional hazards regression with propensity score stratification. Formal interaction testing will be performed between the main effects of subgroup (yes/no) and treatment allocation (prasugrel versus clopidogrel) on the primary MACE endpoint. Interaction terms with p-value <0.05 will be considered significant.

6.5 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.

6.6 Missing Data

We anticipate that the amount of missing data will be minimal in the present study as we are specifically asking sites to ensure that the data elements being requested are available.

In the instance that baseline clinical or procedural data are missing we will impute values using multiple imputation.

Missing outcome data will not be imputed.

In case the academic centers selected provide data sets where some units have incomplete observations we will use multiple imputation [Rubin (1987)] and we will perform the analysis under the assumption of data missing at random.

6.7 Robustness

The primary analysis will involve Cox proportional hazards regression as described above with stratification by propensity strata. Multiple secondary analyses will be performed as described above to examine the overall consistency of our primary findings.

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

6.8 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 sample size 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.

7 General Considerations

7.1 Multi-center Studies

Data will be gathered on all patients in the study concerning their index and follow-up hospitalizations for acute myocardial infarction, stroke, repeat unplanned coronary revascularization, and stent thrombosis. All hospitalizations will be assigned a DRG based on these diagnoses. When a hospitalization includes more than one event, the highest paying DRG will be used. Total hospitalization costs and hospitalization costs after the index hospitalization will be totaled. The difference in

mean hospital costs by treatment are will be assessed and the 95% CI (confidence interval) assessed by bootstrap analysis.

Data will be gathered on all patients in the study that meet the inclusion criteria in between January 1ST, 2010 to June 30TH, 2013.

Each center will provide events according to the following rules:

- Patient level data. In case of a subject undergoing multiple procedures within the time frame of the study we will abstract relevant clinical, demographic and procedural details from the first procedure only
- In case of multiple events of a given type only the first event will be reported for purposes of survival analyses.

Detailed technical instructions will be provided to each site in order to extract the relevant data from each database prior to exporting to the data coordinating center.

8 Summary of Study Data

All summary tables will be organized in columns for each treatment (Prasugrel/Clopidogrel) and overall and will be annotated with the total population size relevant to that table/treatment, including any missing observations.

Total, mean, SD (standard deviation), median, min, and max will be specified for continuous data frequency and percentage (based on the non-missing sample size) of observed levels will be reported for all categorical data.

8.1 Demographic and Baseline Variables

For each center the variables listed in the table in the section 12 Listing of Tables, Listings, and Figures will be considered as demographic or baseline variables.

8.2 Concurrent Illnesses and Medical Conditions

Concurrent Illnesses and Medical Conditions will be collected as baseline Variables according to the table section 12 Listing of Tables, Listings, and Figures.

8.3 Prior and Concurrent Medications

Prior and Concurrent medications will be collected as:

- medication at admission
- medication at discharge
- procedural medication;

As described in detail in section 12 Listing of Tables, Listings, and Figures.

9 Figures

Kaplan-Meier survival curves will be used to assess the effect of antiplatelet use for ACS patients undergoing PCI, at 90 days and 1 year for:

- MACE
- All-cause death
- Myocardial infarction
- Unplanned Revascularization
- Any Bleeding
- Stroke

As described in the table Figure section 12 Listing of Tables, Listings and Figures.

10 Reporting Conventions

P-values $\geq$0.001 will be reported to 3 decimal places; p-values less than 0.001 will be reported as "<0.001". The mean, standard deviation, and any other statistics other than quantiles will be reported to one decimal place greater than the original data. Quantiles, such as median, or minimum and maximum will use the same number of decimal places as the original data. Estimated parameters, not on the same scale as raw observations (e.g. regression coefficients) will be reported to 3 significant figures.

11 References

Austin P.C. An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies. Multivariate behavioural Research. 2011. 46: p. 399-424.

Bae et al. Curr Med Res Opin. 2014 Nov; 30(11):2207-16. doi: 10.1185/03007995.2014.941055. Epub 2014 Jul 18.

Bagai A, Peterson ED, Honeycutt E, Effron MB, Cohen DJ, Goodman SG, Anstrom K, Gupta A, Messenger JC, Wang TY. In-Hospital Switching of ADP Receptor Inhibitors in Myocardial Infarction Patients Treated with Percutaneous Coronary Intervention: Insights from the TRANSLATE-ACS Study: Abstract 15573. Circulation. 2012;126(21) S.

Bernstein EM and Putnam FW. Development, reliability, and validity of a dissociation scale. J Nerv Ment Dis, 1986. 174(12): p. 727-3

Chin CT, et al. Treatment with adenosine diphosphate receptor inhibitors-longitudinal assessment of treatment patterns and events after acute coronary syndrome (TRANSLATE-ACS) study design: expanding the paradigm of longitudinal observational research. Am Heart J, 2011. 162(5): p. 844-51.

Cutlip CE et al., Clinical end points in coronary stent trials: a case for standardized definitions. Circulation, 2007 115(17): 2344-51.

D'Agostino RB. Propensity Scores in Cardiovascular Research. Circulation. 2007; 115:2340-2343.

Hamm CW et al. [ESC guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation. The Task Force for the management of acute coronary syndromes (ACS) in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC)]. G Ital Cardiol (Rome), 2012. 13(3): p. 171-228.

Hess CN, Wang TY, Kaltenbach L, Honeycutt E, Messenger JC, Smith WT, Zettler ME, Effron MB, Henry TD, Peterson ED, Fonarow GC. Unplanned 30-Day Readmission Risk Among Patients with Acute Myocardial Infarction: A Report from TRANSLATE-ACS: Abstract 14371. Circulation. 2012:126(21) S.

Hess CN, McCoy LA, Duggirala HJ, Tavris DR, O'Callaghan K, Douglas PS, Peterson ED, Wang TY. Sex-based differences in outcomes after percutaneous coronary intervention for acute myocardial infarction: a report from TRANSLATE-ACS. J Am Heart Assoc. 2014:3(1):e000523.

Jneid H et al. 2012 ACCF/AHA focused update of the guideline for the management of patients with unstable angina/Non-ST-elevation myocardial infarction (updating the 2007 guideline and replacing the 2011 focused update): a report of the American College of Cardiology Foundation/American Heart Association Task Force on practice guidelines. Circulation, 2012. 126(7): p. 875-910.

Kalbfleisch JD, Ross LP, The statistical analysis of failure time data. New York: John Wiley & Sons, 1980: p. 321 p.

Mega, JL et al. Dosing clopidogrel based on CYP2C19 genotype and the effect on platelet reactivity in patients with stable cardiovascular disease. JAMA : the journal of the American Medical Association, 2011. 306(20): p. 2221-8.

Mega JL et al. Reduced-function CYP2C19 genotype and risk of adverse clinical outcomes among patients treated with clopidogrel predominantly for PCI: a meta-analysis. JAMA : the journal of the American Medical Association, 2010. 304(16): p. 1821-30.

Mega JL et al. Cytochrome p-450 polymorphisms and response to clopidogrel. The New England journal of medicine, 2009. 360(4): p. 354-62.

Mehta SR et al. Effects of pretreatment with clopidogrel and aspirin followed by long-term therapy in patients undergoing percutaneous coronary intervention: the PCI-CURE study. Lancet, 2001. 358(9281): p. 527-33.

Mathews R, Wang TY, Honeycutt E, Henry TD, Chang M, Fonarow GC, Peterson ED. Persistence of Secondary Prevention Medications after Acute Myocardial Infarction: Insights from the TRANSLATE-ACS Study: Abstract 13160. Circulation. 2012:126(21) S.

Prentice RL et al. The analysis of failure times in the presence of competing risks. Biometrics, 1978. 34(4): p. 541-54.

Rosenbaum PR, Rubin DB. The central role of the propensity score in observational studies for causal effects. Biomterika. 1983; 70:41-55.

Resenbaum PR, Rubin DB. Reducing bias in observational studies using subclassification on thepropensity score. J Am Stat Assoc. 1984;79:516-524.

Rubin D B. (1987) Multiple Imputation for Nonresponse in Surveys. New York: Wiley.

Sabatine MS et al. Addition of clopidogrel to aspirin and fibrinolytic therapy for myocardial infarction with ST-segment elevation. The New England journal of medicine, 2005. 352(12): p. 1179-89.

Thygesen, K et al. Universal Definition of Myocardial Infarction. Circulation, 2007; 116:2634-53.

Walker et al. A tool for assessing the feasibility of comparative effectiveness research. Comparative Effectiveness Research 2013:3 11-20.

Wang TY, Zettler M, Effron MB, McCoy L, Anstrom K, Fonarow GC, Messenger JC, Stone G, Cohen D, Henry TD, Peterson E. Comparative effectiveness of prasugrel vs. clopidogrel among acute myocardial infarction patients treated with percutaneous coronary intervention: 30-day outcomes from the TRANSLATE-ACS observational study. J Am Coll Cardiol. 2013; 62(18_S1):B1-B1.

Wang TY, McCoy L, Henry TD, Effron MB, Messenger JC, Cohen DJ, Mark DB, Stone GW, Zettler M, Singh M, Fonarow GC, Peterson ED; TRANSLATE-ACS Study Investigators. Early Post-Discharge Bleeding and Antiplatelet Therapy Discontinuation Among Acute Myocardial Infarction Patients Treated with Percutaneous Coronary Intervention. J Am Coll Cardiol. 2014; 63(16):1700-2. [Epub ahead of print].

Wang TY. Outcomes Associated with Prasugrel vs. Clopidogrel Use Among Acute Myocardial Infarction Patients Treated with Percutaneous Coronary Intervention: 1-Year Results from the TRANSLATE-ACS Study. Abstract presented at Transcatheter Cardiovascular Therapeutics Conference: Sept 13-17, 2014; Washington DC

Wiviott SD et al. Prasugrel versus clopidogrel in patients with acute coronary syndromes. The New England journal of medicine, 2007. 357(20): p. 2001-15.

12 Listing of Tables, Listings and Figures

The following tables will be used to derive from an accompanying data set or spreadsheet that will be used to automate the aesthetic aspects of table production.

Table Listings

Number	Table Title	Summary Statistics	Formal Analysis
1	Summary of Baseline Characteristics by therapy at PCI	n, mean, SD, Median, min, max, n (%)	χ^2 test or Fisher's exact test will be performed for categorical variables as necessary and independent sample t-test continuous variables
2	Summary of Procedural Characteristics by therapy at PCI	n, mean, SD, Median, min, max, n (%)	χ^2 test or Fisher's exact test will be performed for categorical variables as necessary and independent sample t-test continuous variables
3	Procedural Events	n (%)	χ^2 test test for proportion
4	Clinical Outcomes by therapy at PCI	KM estimation [95% CI], crude HR, Propensity-adjusted HR; Covariate-adjusted HR	log-rank test, Cox model
5	Economic Outcomes by Discharge Therapy	mean, SD, Median, min, max, 95% CI for continuous variables, n (%) KM estimation [95% CI], crude HR, HR propensity score adjusted	t-tests, exact tests, and/or nonparametric tests; bootstrapping; GLM for continuous variables χ^2 test, fishers exact test, KM estimation, log rank test, Cox model for categorical variables

Figure Listings

	Title	outcome	Pop	Type of graph	Horizontal Variables	Vertical Variables	Groupings	Statistics	Facets
1	KM rates at 90 days	MACE	Full Analysis	KM	time	probability		KM Estimates	NA
1a	KM rates by Therapy at PCI at 90 days	MACE	Full Analysis	KM	time	probability	Treatment	KM Estimates	NA
2	KM rates at 1 year	MACE	Full Analysis	KM	time	probability		KM Estimates	NA
2a	KM rates by Therapy at PCI at 1 year	MACE	Full Analysis	KM	time	probability	Treatment	KM Estimates	NA

The corresponding Mock Tables are in the following section.

Table 1. Summary of Baseline Characteristics by Therapy at PCI.

	Overall (N = XX)	Prasugrel XX (XX%)	Clopidogrel XX (XX%)	Pvalue
DEMOGRAPHICS				
Age, years				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Gender (female)	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Height (cm)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Weight (Kg)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Ethnicity		xx (x.x%)	xx (x.x%)	x.xxx
Hispanic	xx (x.x%)	xx (x.x%)	xx (x.x%)	
Non-Hispanic	xx (x.x%)	xx (x.x%)	xx (x.x%)	
Race				
African American	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
White	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Other	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Diabetes at baseline	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Insulin-requiring diabetes at baseline	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Hypertension	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Hypercholesterolemia	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Pre-Procedure Creatinine, mg/dl				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Pre-Procedure Hemoglobin, mg/dl				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	

Table 1. Summary of Baseline Characteristics by Therapy at PCI.

	Overall (N = XX)	Prasugrel XX (XX%)	Clopidogrel XX (XX%)	Pvalue
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Troponin				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Baseline CK-MB, ng/ml				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Peak serum creatinine, mg/dl				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Nadir hemoglobin, g/dl (lowest within 72 hours)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Peak CK-MB, ng/ml (highest 6-24 hours after PCI)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Peak Troponin (highest 6-24 hours after PCI)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Smoking	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
ISCHEMIC HISTORY				
Family history of CAD	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Previous MI	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Previous PCI	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx

Table 1. Summary of Baseline Characteristics by Therapy at PCI.

	Overall (N = XX)	**Prasugrel XX (XX%)**	**Clopidogrel XX (XX%)**	**Pvalue**
Previous CABG	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prior CHF	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prior PAD	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prior Cerebrovascular Disease	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Left ventricular ejection fraction (%)				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
CAD Presentation	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Non-ST-elevation myocardial infarction	xx (x.x%)	xx (x.x%)	xx (x.x%)	
ST-elevation myocardial infarction	xx (x.x%)	xx (x.x%)	xx (x.x%)	
Unstable Angina	xx (x.x%)	xx (x.x%)	xx (x.x%)	
PCI status	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
PCI Indication	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Stress or Imaging pre procedure	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
MEDICATIONS AT ADMISSION				
Beta Blocker	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Ca Channel Blocker	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Aspirin	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Clopidogrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prasugrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Ticagrelor	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Nitrate	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Ranexa	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
MEDICATIONS AT DISCHARGE				
ACE-I or ARB	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Aspirin	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Beta Blocker	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Statin	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Clopidogrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
75 mg	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
150 mg	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prasugrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
5 mg	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
10 mg	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Anticoagulant	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx

Table 2. Summary of Procedural Characteristics by Discharge Therapy.

	Overall (N = XX)	**Prasugrel XX (XX%)**	**Clopidogrel XX (XX%)**	**Pvalue**
PROCEDURAL MEDICATIONS				
Aspirin	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Fondaparinux	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
LMWH	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
UFH	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Bivalirudin	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
IIb/IIIa	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Clopidogrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Prasugrel	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
ANGIOGRAPHIC CHARACTERISTICS				
Multivessel disease	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Total stent length				x.xxx
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
At least 1 type B2/C lesion	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
At least 1 lesion with moderate/severe calcifications	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
At least 1 bifurcation lesion	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
At least one bare metal stent	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
At least one drug eluting stent (1st gen)	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
At least one drug eluting stent (2^{nd} gen)	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
PCI vessel LM	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
PCI vessel LAD	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
PCI vessel LCx	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
PCI vessel RCA	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx

Table 3. In-Hospital Post-Procedural Events by Therapy at PCI.

	Overall (N=XX)	**Prasugrel XX (XX%)**	**Clopidogrel XX (XX%)**	**Pvalue**
MI	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Cardiogenic Shock	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Heart Failure	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
CVA/Stroke	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Tamponade	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Dialysis	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Vascular Complication	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Blood Transfusion	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx
Bleeding event (72 hours)	xx (x.x%)	xx (x.x%)	xx (x.x%)	x.xxx

Table 4 In and Out of Hospital Post-Procedural Events by Therapy at PCI.

	Clopidogrel	Prasugrel	Unadjusted HR [95% CI]	Propensity adjusted HR [95% CI]	Covariate-adjusted HR [95% CI]
MACE[1]					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
Death					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
Myocardial infarction					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
Unplanned Revascularization					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
Bleeding					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
Stroke					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]

Table 4 In and Out of Hospital Post-Procedural Events by Therapy at PCI.

	Clopidogrel	Prasugrel	Unadjusted HR [95% CI]	Propensity adjusted HR [95% CI]	Covariate-adjusted HR [95% CI]
Def/Probable Stent Thrombosis					
90 Day	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]
1 Year	x.xx% [x.xx%-x.xx%]	x.xx% [x.xx%-x.xx%]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]	x.xx [x.xx-x.xx]

[1]MACE is defined as all cause death, hospitalization for myocardial infarction, stroke, or unplanned revascularization.[2]HR calculated from propensity stratified model. [3]HR calculated multivariable-adjusted model.

Table 6. Healthcare Utilization and Costs by Therapy at Discharge

	Overall (N = XX)	Prasugrel XX (XX%)	Clopidogrel XX (XX%)	Pvalue
Index Hospital Length of Stay				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
Index Hospital Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	

Table 6. Healthcare Utilization and Costs by Therapy at Discharge

	Overall (N = XX)	Prasugrel XX (XX%)	Clopidogrel XX (XX%)	Pvalue
30 day Rehospitalization Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
90 day Rehospitalization Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
180 day Rehospitalization Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
1yr Rehospitalization Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	
1yr Aggregate (Index + Rehospitalization) Total Costs				
N, N Missing	xxx,x	xxx,x	xxx,x	

Table 6. Healthcare Utilization and Costs by Therapy at Discharge

	Overall (N = XX)	**Prasugrel XX (XX%)**	**Clopidogrel XX (XX%)**	**Pvalue**
Mean ± Std	x.xx ± x.xx	x.xx ± x.xx	x.xx ± x.xx	
Median	x.xx	x.xx	x.xx	
Min , Max	x.xx,x.xx	x.xx,x.xx	x.xx,x.xx	

13 Attachment 1. Data Fields and Descriptions/Definitions

	VALUE	Descriprion/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
Gender	0=male, 1=female	Indicate patient's gender
Weight (Kg)	## in Kilograms	Indicate the patient's weight in kilograms
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.

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
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 limit (URL) for normal subjects] together with at least one of the following manifestations of myocardial ischemia: a. Ischemic symptoms 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 reportischemic 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, 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 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.
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 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 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 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.
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 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 STAMI, unstable >12 hours; 3=PCI for STEMI, >12 hours; 4=PCI for STEMI stable after successful lytics; 5=Rescue PCI for STEMI after faild lytics; 6=PCI for high	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

	risk NSTEMI or unstable angina; 7=Staged PCI; 8=other	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 equivalent) after failed full-dose lytics. 6. PCI for high risk Non-STEMI or unstable angina: Includes 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 Hypotension, bradycardia, tachycardia iv. Age greater than 75 years v. ECG vi. 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, TnI, 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 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.
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 lowmolecular 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 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)
Dischage 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
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 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.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.
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 new onset or acute recurrence of 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 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 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 occurring within one year of procedure date
Death (all) date	DDMMYYYY	Date of death
Type of Death	1=cardiac; 2=noncardiac; 3=unknown	Enter type of death
Myocardial infarction within one year of procedure	0=no, 1=yes	Hospitalization for acute (spontaneous) MI within one year of index procedure date
Myocardial infarction date	DDMMYYYY	Date of event
Number of acute MI hospitalization within one year of procedure	##	Total number of acute MI hospitalization within one year of index procedure date

Unplanned revascularization within one year of procedure	0=no, 1=yes	Hospitalization for unplanned revascularization with CABG or PCI within one year of index procedure date
Unplanned revascularization date	DDMMYYYY	Date of event
Number of unplanned revascularization hospitalization within one year of procedure	##	Total number of unplanned revascularization hospitalization within one year of index procedure date
Bleeding within one year of procedure	0=no, 1=yes	Hospitalization for bleeding within one year of index procedure date
Bleeding date	DDMMYYYY	Date of event
Number of bleeding hospitalization within one year of procedure	##	Total number of bleeding hospitalizations within one year of index procedure date.
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 within one year of procedure	0=no, 1=yes	Was the patient diagnosed as having a stroke within one year of index procedure date
Stroke date	DDMMYYYY	Date of event
Stroke type	1=ischemic; 2=hemorrhagic; 3=unknown	1) Ischemic 2) Hemorrhagic
Number of stroke hospitalizations within one year of procedure	##	Total number of stroke hospitalizations within one year of index procedure date.
Definite/Probable ST	0=no, 1=yes	Hospitalizations for Definite/Probable Stent Thrombosis
Definite/Probable ST date	DDMMYYYY	Date of Event

last follow up date	DDMMYYYY	Last date of encounter with patient