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Correlation Of Hospital Pci Process Measures And Association With 30-Day Risk Standardized Outcomes

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Abstract

CORRELATION OF HOSPITAL PCI PROCESS MEASURES AND ASSOCIATION WITH 30-DAY RISK-STANDARDIZED OUTCOMES.

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Over the past decade, there has been an explosion of interest in measuring and reporting the quality of care delivered to patients undergoing percutaneous coronary intervention (PCI), with the newest performance metrics just released in December 2013. One aspect of quality measurement that remains poorly understood is the nature of the relationship between individual PCI process measures as well as between process and outcomes measures such as risk-standardized 30-day mortality (RSMR) and readmission rates (RSRR). While process and outcomes measures represent potentially important metrics of hospital quality, no study has examined whether these two are measuring distinct or overlapping domains of hospital quality or whether there is an association between the newly issued and previously existing set of process measures.

We performed a cross-sectional analysis using data from the National Cardiovascular Data Registry's (NCDR) CathPCI registry. We identified 1,219,544 patients across 1,331 catheterization centers that had a procedure from January 1, 2010 to December 30, 2011. We utilized generalized linear modeling to estimate hospital performance on individual and composite process measures and generated pair-wide correlations between each set of process metrics. We also performed correlation analyses to calculate the association between hospital performance on process metrics and hospital performance on outcome metrics. We found strong correlations between medication-specific process measures ($p < 0.01$), and the overall composite measure was significantly correlated with most other process measures, particularly referral to cardiac rehab ($p < 0.01$). Hospital performance on the new emerging process measures was lower than on existing ones, and there was little correlation in hospital performance between these two sets. The composite measure was correlated with hospital-specific 30-day RSRR for all patients and RSMR for NSTEMI patients (p value < 0.05), but the association was modest, explaining at most 6.6% of the variation in hospital-level outcome metrics. These results suggest that hospital-level performance on both individual and composite PCI process measures explain only a small percentage of the hospital variations in outcomes for PCI patients. Additional efforts are needed to better characterize how hospitals can utilize these two perhaps distinct markers of quality to improve hospital performance.

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Introduction

Overview

An estimated 26.5 million or 11% of U.S. adults have coronary artery disease (CAD), and CAD remains the most common cause of death at over 600,000 Americans per year. Around 715,000 myocardial infarctions happen on an annual basis with roughly four million hospital admissions every year due to heart disease [1, 2]. Percutaneous coronary intervention (PCI) has emerged within the past three decades as the preferred method in the U.S. to treat both stable coronary artery disease and acute coronary syndromes. The prevalence of PCI has risen dramatically within the past few decades: from 1987 to 2004, the number of PCI procedures rose over 300%. Currently, PCI is one of the most commonly performed procedures in the U.S. with over 650,000 patients undergoing PCI each year [3].

Given the rise in prevalence of PCI procedures, there has been a correspondent increase in interest within the past decade in measuring and reporting the quality of care delivered to PCI patients. Quality of care is commonly defined by performance on specific measures that have been shown to reduce patient mortality or morbidity. Hospital performance on these metrics has been made largely available by Medicare and other large health care organizations as a method to provide patients, providers, and healthcare administrators objective markers of healthcare quality [4]. Several national organizations including the American College of Cardiology (ACC) and National Quality Forum (NQF) have focused on developing and endorsing respectively, sets of PCI process measures as benchmarks for hospital quality, with the most recent guidelines released within the past three months [5].

However, there have been numerous studies in recent years that have shown that high performance on process metrics does not lead to better patient outcomes as measured by 30-day risk-standardized patient mortality and readmissions [6-7]. Despite improvements in hospital performance on current PCI process metrics, there still remains a large variation in patient outcomes

after PCI [8-9]. The significance of these process and outcome measures will continue to grow as the performance on these metrics are becoming more readily available to patients and having increasing financial consequences.

Despite an explosion of literature on PCI process and outcome measures, there remains little understanding on the correlation of hospital performance on existing and emerging PCI process measures as well as between individual process measures. Perhaps more importantly, from a patient's perspective, very little information exists on whether a hospital's performance on PCI process metrics is predictive of its performance on patient outcomes. Our study will be the first to characterize the correlations among the existing and recently released PCI process metrics. Our analyses will also describe the degree to which hospital performance on process measures can explain hospital variations in PCI 30-day risk-standardized patient mortality and readmission rates.

Importance and definition of quality

As this thesis will focus heavily on the framework of quality and specifically PCI quality, it is necessary to begin by providing a precise definition for "quality" in a healthcare setting. We use the definition of quality established by the Institute of Medicine: "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" [10]. A similar definition is in use by the U.S. Agency for HealthCare Research and Quality (AHRQ), which states "quality health care means doing the right thing at the right time in the right way for the right person and having the best results possible" [11]. In a more practical context, one can define poor quality as too little care (e.g. "not performing an indicated test"), too much care (e.g. "overprescribing medications that contain significant side effects"), or the wrong care (e.g. "misdiagnosing complaints and performing misguided procedures").

It is well established that even though the United States vastly outspends any other country in healthcare dollars as a gross product and per capita, the U.S. does not have superior outcomes in

comparison to other industrialized countries [12]. In fact, the U.S. ranks among the lower third in life expectancy at birth and the worst in a study of 19 countries on mortality from preventable conditions including stroke, heart disease, and diabetes [13-14]. Specifically for PCI, despite the U.S. having by far the highest revascularization rates by percentage and volume, our patient outcomes are no better than many other developed countries [15]. As a result, within the last two decades, there has been an increasing focus on the factors that affect the quality of patient care administered throughout hospitals in the U.S. [16-17].

The emphasis on quality has not been limited to just academic literature. Hospitals throughout the nation spend considerable resources to be included in media rankings, such as the "Top American Hospitals" published by U.S. News every year [18]. Similarly, many websites are now generating revenue by providing information to patients about different metrics of quality for hospitals [19]. Both healthcare systems and the media are increasingly viewing patients as consumers that have a wide variety of hospitals to choose from for their care, with many hospitals now utilizing the topic of quality as a recruiting and marketing strategy to increase their patient volume for financial incentives.

The U.S. government has also made significant advancements in the past two decades in creating an infrastructure that allows for better public reporting of quality metrics and also standardization of quality of care throughout hospitals in the U.S. Beginning in 2001, the Bush administration in conjunction with Health and Human Services began a Hospital Quality Initiative from which the current Hospital Compare database and website was designed. Hospital Compare is a consumer-oriented website that allows patients to see how well hospitals provide recommended and appropriate care to patients [4]. Since its inception, an increasing number of metrics and outcomes have been available for patients to view. For instance, in 2005, the first set of "core" metrics on heart failure, surgical care, acute myocardial infarction (AMI), and pneumonia were added. Then, in 2008, Medicare data in addition to results from the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey became accessible, with the latter

providing a systematic approach to capturing patients' perceptions of their clinical care. Finally, in the latter half of 2013, PCI outcomes including readmissions data became publically available on Hospital Compare [4]. This focus on public reporting of quality metrics is not only on a national level but also on a state-wide level with many states undergoing similar quality improvement projects for their individual healthcare systems [20-21].

Theory of quality

From a conceptual standpoint, quality can be best understood by the Donabedian model which is the most commonly accepted framework for understanding quality of care in a clinical setting [22-24]. This model can be used as a foundation to understand the current concepts of measuring PCI quality. The paradigm is separated into the three categories of structure, process, and outcomes with structures affecting processes and processes affecting outcomes in a linear fashion. Structural definitions of quality refer to the infrastructure of the healthcare system (e.g., are there enough hospital beds for a patient population). Process qualities refer to the clinical interactions between a patient and doctor (e.g., with no other contraindication, was a PCI patient with hyperlipidemia started on appropriate therapy). Outcomes refer to changes in patients' overall health status (e.g, did the patient experience any complications or was unnecessarily readmitted after PCI) [22-24].

In this model, the unidirectional aspect of quality signifies that patient outcomes are a direct consequence of high process quality which itself depends on sound structural healthcare components [24]. For example, for an AMI patient, a facility must have the basic equipment and personnel available for an interventional cardiologist to practice the level of care to reduce any bleeding or other complications after the procedure. Although the structural components of the model are the most identifiable, studies have shown that numerous structural qualities including net profit, bed size, number of high-technology services offered, and teaching status have limited effect on patient outcomes [25]. Moreover, as upgrading facilities can be a costly endeavor,

financial constraints have also been a limiting barrier to change. On the other hand, many researchers, including Donabedian himself, believe that the measurement of process quality is nearly equivalent to the measurement of all healthcare quality as processes contain all acts of healthcare (e.g. "diagnosing, treating, and preventing") [22-23]. Hence, most of the focus historically in quality improvement research has been on the processes aspect with the assumption that given adequate resources, patient outcomes should be positive as a result of strong process qualities. Researchers have generally preferred to study process measures over outcome metrics as process metrics are a more discrete measure of clinical care and do not require the post-discharge follow-up that outcome measures do. In particular, much attention has been placed on the aspect of process quality termed technical process quality, which refers to whether the proper care was administered skillfully and whether the correct choices were made in the diagnosis and treatment of a patient [24]. The latter aspect (making the correct choices) generally can be assessed through appropriateness and adherence to professional standards.

This conceptual background is crucial to our discussion of PCI quality. In an effort to distinguish optimal medical systems that perform high PCI care, the emphasis on public reporting of both appropriate usage and performance on specific PCI process metrics have skyrocketed within the past decade. The rationale for this focus is simple: it enables patients and providers to have a framework to characterize the quality of care delivered by PCI hospitals. Implicit in this effort is the assumption that these measures will motivate providers and facilities to improve their performance on these metrics. In accordance with the model above, the general supposition is that performance on these process measures should and would lead to better PCI patient outcomes. However, recent studies have shown a lack of association between performance on process measure qualities and patient outcomes for AMI [6-7], although this relationship remains unknown for PCI. Therefore, in light of the emphasis on public reporting of such process metrics, one large component of our study is to better characterize the relationship between process qualities and patient outcomes for PCI.

Process measures and the emergence of outcome metrics

As we alluded to earlier in this introduction, past efforts to measure healthcare quality have largely focused on process of care measures. The focus on process measures as opposed to outcome measures (such as mortality rates) has been attributed to the challenges associated with measuring outcomes. These challenges include low event rates, difficulty to risk-adjust for differences in case mix, and difficulty in collecting post-discharge data [16-17]. Process measures, on the other hand, are under better control by providers as most are for in-hospital patients, are simpler to benchmark, require a shorter time-frame for assessment, and provide easier and clearer opportunities for improvement [16-17, 26]. The main drawback to process measures is that one cannot create measures for *every* service a hospital or clinician provides. Hence, process measures become indicative of quality in two specific but indirect methods. The first is that because process measures are generally evidence-based, they provide a direct indicator for whether the appropriate and necessary care was provided to the patient. The implicit assumption is that proper performance of a process measure will be linked to better patient outcomes because of correct, evidence-based patient care. For instance, multiple randomized controlled trials have shown that beta-blockers improve clinical outcomes for ST-elevation myocardial infarction (STEMI) patients through a variety of different mechanisms [27]. If providers prescribe STEMI patients a beta-blocker (provided they do not have a contraindication), then the pharmacological mechanisms of the prescription medication will lead to better outcomes. The second mechanism that process measures have historically been linked to quality is by serving as a quality indicator [23]. Using the same analogy, if a hospital is diligent about providing all their appropriate STEMI patients with beta-blocker therapy then there is another implicit assumption that the hospital will also be diligent in providing other proper services to ensure a patient has a rapid and safe discharge.

The fundamental importance of process measures has been recognized by both governmental agencies and leading healthcare organizations. Centers for Medicare and Medicaid

Services (CMS), the Joint Commission on Accreditation of Healthcare Organizations (JCHAO), and NQF all endorse their own independent as well as joint process measures for common medical conditions, such as acute myocardial infarction and congestive heart failure (CHF), as well as most procedures including surgical operations [28-30]. For many of these process measures, there has been a prompt response from the medical community to incorporate them into their clinical practice, with many of the improvements driven by the public reporting of performance on these metrics. For example, observational studies have shown that door-to-balloon (DTB) times of under ninety minutes was linked to better patient outcomes for all-cause mortality [31]. DTB times less than ninety minutes subsequently was adopted as a hospital process measure, and from 2005 to 2010, DTB times nationally decreased from a median time of 96 minutes to 64 minutes [32].

Recent evidence has suggested, however, that positive hospital performance in process factors may not be correlated with outcome metrics such as risk-standardized mortality rates [6, 16, 33]. The most likely mechanism for this discrepancy is because process measures only capture a small facet of factors that affect patient care, and other unmeasured quality-improving processes can often play a significant role (e.g., nursing staff or social support) [34-35]. Furthermore, the inclusion and exclusion criteria for a specific process metric may only allow a small minority of patients to qualify for that condition [36]. While process measures convey important information about the quality of healthcare delivered, there are associated opportunity costs of focusing on only a small aspect of the healthcare delivery spectrum. Thus, there is growing concern that process measures may not always be reliable indicators of outcome metrics, and recent literature has focused on outcome metrics such as 30-day risk-standardized mortality rates (RSMR) and risk-standardized readmissions rates (RSRR) as separate but equally important markers of hospital and clinical quality [37]. In other words, in reference to our previous example on STEMI patients and beta-blockers, a hospital that performs well on prescribing beta-blockers to patients may not necessarily have the appropriate axillary staff and services to ensure safe discharges of patients.

Outcome measures have now been incorporated by CMS and other national organizations such as JCAHO as a quality metric because they are thought to fairly account for the end result of patient care and can provide a broad, holistic view of the care [38-39]. Using medical records as validation, studies have also objectively established the use of outcome metrics such as 30-day risk-adjusted mortality as a reliable marker for hospital performance [40]. It is worthy to note that mortality has historically been the standard outcome metric; 30-day readmissions has also been recently emphasized by Medicare as a quality measure that represents an adverse and often preventable event for hospitals [41]. In addition, studies have shown that improvements in either clinical treatment or behavioral intervention can result in a significant drop in readmissions, resulting in substantial savings for society and protecting patients from unnecessary admissions [42]. Because of the increasingly recognized importance of readmissions as an outcome measure, Hospital Compare of CMS in 2009 began publicly reporting 30-day RSRR for AMI, CHF, and pneumonia [43]. This information provides patients with data on hospital-level performance on three common conditions that are often the focus of outcomes studies because they have been shown to be some of the most frequent diagnoses that account for 30-day readmissions. From a hospital perspective, Medicare has modified their payment scale to include readmissions as part of the reimbursement scale, sparking a large national effort across all medical centers to institute strategies to reduce readmissions for these conditions [41].

Therefore, in our study, when analyzing hospital quality we will include data on performance of hospitals on both PCI process and outcome measures. In regards to the outcome measures, we will be considering mortality and readmissions as separate outcomes. There are several reasons for this distinction. A recent study has shown that hospital performance on 30-day RSMR was not correlated with performance on 30-day RSRR for AMI and pneumonia and only modestly associated in CHF [44]. The study emphasizes that 30-day RSRR and RSMR may be qualifying two different aspects of hospital quality. Mortality rates can be indicative of the systematic ability to provide early and efficacious interventions whereas readmission rates may

symbolize hospital support on transitions of care, patient education, and discharge planning. Hence, by incorporating both outcome metrics into our analyses, we can better discriminate between different aspects of hospital-level services. Furthermore, we will focus our study on patients of percutaneous coronary interventions because although it is a commonly performed procedure, it has one of the highest rates of 30-day risk-standardized readmissions and only recently has had its outcome metrics publically available [9].

PCI process and outcome metrics

Although PCI has emerged as a less invasive and potentially cost-effective procedure to treat CAD in comparison to coronary artery bypass grafts (CABG), it remains a procedure with substantial variation in quality [9]. A recent study has shown that even though PCI readmissions are generally an unplanned event, approximately one in every seven Medicare beneficiaries will be readmitted to a hospital within thirty days after a PCI procedure. There is also substantial variation across hospitals in readmission rates, with one study calculating a range from 0-100% and the mean (SD) at 15.5% (10.6%) [9]. This study further found that PCI readmissions are associated with a higher level of all-cause 30-day mortality compared to those not readmitted (3.6% vs 0.6%), and 27.5% of patients readmitted received another revascularization procedure (PCI 25.8%, CABG 1.7%) [9]. The Medicare Payment Advisory Committee (MedPAC) noted that 10% of patients had unplanned readmissions within two weeks after PCI and has estimated the cost of these readmissions to our healthcare system to be 360 million dollars [45].

Many studies have tried to establish different variables to help explain the variance in PCI outcomes. Some research has looked at peri-procedural decisions such as differences in bare-metal or drug-eluting stents for saphenous vein grafts [46]. Other studies have examined clinical presentations and demographic variables and their association with PCI outcomes. For instance, one study found that gender was an independent predictor of PCI outcomes with women experiencing higher all-cause mortality and complications after PCI [47]. A clinical study in 2002

found that renal insufficiency was independently linked to cardiac events and mortality and a similar finding was established for patients with diabetes [48-49]. Others have examined the role of prescription medications before, during, and after PCI [50-52]. Finally, some researchers have examined systematic contributions to PCI outcomes, most notably DTB times of less than ninety minutes [31-32].

This entire set of research has generated a group of widely endorsed process measures that include the following: therapy with aspirin, statins, and thienopyridines (P2Y12 inhibitors) in patients with no contraindications at discharge, door-to-balloon time under ninety minutes, and referral to cardiac rehabilitation for eligible patients. The ACC and NQF have also endorsed the medication-specific criteria as process measures indicative of hospital performance [53]. The ACC has supported the public reporting of these process measures and created the National Cardiovascular Database Registry (NCDR) in 1998 with the intent to develop a standardized national database that would allow for the characterization of PCI and cardiac catheterization patients' clinical profiles and outcomes [54]. NCDR has taken the lead in quality measurement and has developed a portfolio of measures within the CathPCI Registry that includes not only the above process measures but also more recently, outcomes metrics. The impact of public reporting has given researchers and hospitals tangible goals to improve hospital performance on these metrics in an effort to improve the quality of patient care [55-56].

The list of existing process measures was recently expanded in December 2013 to include additional performance measures to highlight additional evidence-based practices that has emerged in the past few years. In addition to the process measures described above, the new guidelines, which are endorsed by the Physician Consortium for Performance Improvement (PCPI), American Heart Association (AHA), Society for Cardiovascular Angiography and Interventions (SCAI), the American Medication Association (AMA), ACC, and AQF, include the following: comprehensive documentation of the indications for PCI, an appropriate reason for elective PCI, evaluation of the individual's ability to receive dual-antiplatelet therapy before the procedure, the use of embolic

protection devices to treat saphenous vein bypass graft disease, documentation of the contrast dose used in the procedure, participation in a regional or national PCI registry, the average annual volume of PCIs performed by the physician over the past two years, and the average annual volume of PCIs performed by a hospital over the past year [5]. The establishment of these new performance measures is notable for several reasons. First, they are the first set of guidelines in the cardiovascular literature to include appropriateness of usage as a specific metric. Second, they consider the influence of pre-procedural, peri-procedural, and post-procedural factors that may affect patient short-term and longitudinal outcomes. As these guidelines have just been released, no study has examined hospital performance on these new measures or the correlation of hospital performance between these new metrics and existing measures. Finally, while these new guidelines are contributing to the growth of PCI quality assessment, little information is known about whether hospital performance on these metrics are in fact predictive of hospital performance on patient outcomes of PCI patients.

Hospital-level quality

One aspect of quality measurement that remains poorly understood is the nature of the relationship between hospitals' performance on PCI process measures and their performance on outcomes measures such as 30-day mortality and readmissions. Both types of measures represent potentially important assays of hospital quality, but it is unclear whether they are measuring overlapping or distinct domains of hospital quality. On the one hand, existing PCI process measures are evidence based and scientifically valid, and it would be reasonable to assume that observed variation in these measures would be directly associated with variations in patient outcomes (for example, a patient who was not discharged on appropriate antiplatelet therapy may be more likely to be readmitted due to a thrombotic event). It would also be justifiable to assume that existing PCI process measures can indirectly serve as a surrogate marker for the overall quality of care delivered within the hospital. One example would be the proportion of patients referred for cardiac rehab; the

rates of referral may not impact short-term risk of mortality and readmission but might be a marker for the quality of the discharge process and the transition from the inpatient to the outpatient settings.

On the other hand, there are reasons to believe that a hospital's performance on core process measures may not be associated with its performance on outcomes measures. Many of the process measures are close to being topped out, with relatively little variation across process measures [57]. It is increasingly understood that although process measures remain evidence-based and clinically important, they likely capture only a fraction of the multitude of factors that influence patient outcomes. Chen and colleagues demonstrated recently that hospitals that performed well on publically reported outcome measures for AMI, CHF, and pneumonia did not have better survival rates for in-hospital cardiac arrest patients [58]. In contrast, Amarasingham and colleagues have shown that hospitals that utilized electronic medical records were associated with fewer complications, lower costs, and lower mortality rates [59]. Other studies have demonstrated that more effective discharge planning can lead to significant drops in readmission rates [60]. Using data from an Internet hospital survey, Bradley and colleagues recently showed that partnering with community physician groups and local hospitals, arranging appropriate follow-up care before discharge, and assigning nurses for medication reconciliation are all effective strategies a hospital can use to lower its readmission rates [61]. None of these practices are included in the core process measures. It is therefore becoming increasingly clear that numerous factors can play a role and be markers for hospital quality. The focus of this thesis is to tackle the question of whether hospital quality as assessed by its performance on existing and emerging PCI process metrics is associated with 30-day hospital outcome measures such as 30-day mortality and readmissions rates.

Past studies have begun answering this question for acute myocardial infarction (AMI) patients. For example, studies have noted that there is an inverse relationship between hospital performance on core process metrics for AMI, CHF, and pneumonia and risk-adjusted mortality rates for those three conditions [62]. Furthermore, Peterson and colleagues found a close

association between in-hospital process measures and mortality of patients with acute coronary syndromes. Their study showed that a rise in adherence to a composite process measure was associated with an equivalent decline in in-hospital mortality [63]. In contrast, Bradley and colleagues found that hospital performance was well correlated between process measures but explained relatively little of the between hospital variation in 30-day mortality rates in patients with AMI. Bradley and colleagues attributed the difference in their results to Peterson's by noting that their sample included patients that were transferred out, a group that is known to be healthier than those who remain in one location [33]. Werner and Bradlow showed on a hospital-level that hospital performance on core metrics for AMI, heart failure, and pneumonia was modestly correlated with risk-adjusted mortality [6]. These same authors have found that variations in mortality rates across hospitals are much larger than what would be expected from differences in process measures performance [16]. Nevertheless, they have noted that recent efforts have been made in hospitals to improve their performance on these core metrics and this has been associated with an improvement in all outcome metrics though it is unknown if it is a casual link [55]. Other studies have tried to identify high-performing hospitals to serve as models for quality improvement, but many have noted that hospitals in the top quintile of one quality indicator are often in the bottom quintile of another. In one particular study by Shwartz and colleagues, they analyzed over a thousand hospitals on five measures—adherence to processes of care, 30-day readmission rates, in-hospital mortality, patient satisfaction, and efficiency—and found very modest correlations between them [26]. Therefore, there is ample evidence to suggest that for AMI patients, hospital performance on core quality metrics is unfortunately only modestly correlated with performance on outcome metrics.

However, there remains little information on patients specifically undergoing PCI; this dearth of knowledge is particularly pertinent as PCI outcome metrics such as readmissions have just been recently made publicly available. In one of the few available studies, Yeh and colleagues examined data from Massachusetts and found that on a patient level, including evidence-based

discharge medications did not substantially improve the discrimination of a model predicting an individual patient's risk of readmission [8].

Study objectives

Despite the current emphasis on PCI outcomes measures as a reflection of hospital quality and the attention on hospital accordance with core process measures, there exists no study that has determined the relationship between these two sets of quality metrics. It is crucial to underscore that our paper will not be focusing on measuring the outcomes of the process metrics individually (patient level) but rather together (hospital level) as a marker or surrogate of hospital quality. For example, while other studies have answered whether variations in hospital outcome metrics can be explained by patients receiving statins or aspirin upon discharge [50], our study will focus on whether hospitals' performance on the metric of prescribing aspirin upon discharge is associated with that hospitals' performance on various outcome metrics. Hence, our study will hopefully establish whether hospital quality as determined by their performance on process metrics is an overlapping or distinct domain from hospital quality defined by outcome metrics.

Developing a better understanding of the association between PCI process and outcomes measures is important from several perspectives. With increasing public data about hospital performance available to patients, it is important to elucidate whether hospital performance on core PCI metrics can help patients locate hospitals that have the best outcomes. In other words, if a patient was researching a catheterization site for his elective PCI, can a hospital's performance on clinical process measures be indicative of whether or not he would need to be readmitted or suffer life-threatening complications after the procedure? Furthermore, understanding the association between these two sets of quality metrics can help hospital administrators and policymakers target their attention and resources to identifying quality care for one of the most commonly performed procedures in the U.S. From an administrative standpoint, improved characterization of process metrics can not only aid a hospital executive in understanding how his hospital is performing on

the emerging PCI measures in comparison with existing ones but also demonstrate where efforts and resources could best be utilized to improve patient outcomes. Furthermore, from a policy standpoint, better understanding of this relationship between current process metrics and outcomes can help direct what additional policies or process metrics are necessary to drive an improvement in patient outcomes for PCI. If, as we hypothesize, these measures are only modestly correlated, understanding the different factors that affect hospital performance on outcome metrics is crucial for hospitals striving to improve their outcomes as well as patients looking to receive care with the best outcomes.

Specific Hypothesis and Aims

Specific hypothesis:

The overarching goals of this project are to a) examine the correlation among hospitals between existing and emerging hospital process measures for patients undergoing percutaneous coronary intervention (PCI) and b) to assess the degree to which hospitals' performance on these process measures are associated with the hospitals' 30-day risk-standardized 30-day readmission rates (RSRRs) and risk-standardized 30-day mortality rates (RSMRs) for patients undergoing PCI.

We hypothesize that existing and proposed PCI process measures are strongly correlated with one another, but hospital performance on these measures will be only modestly correlated with PCI outcomes measures.

Specific aims:

Aim 1: To examine the correlation between hospitals' performance on existing NCDR-endorsed PCI process measures and emerging PCI metrics

Aim 2: To determine the association between hospitals' performance on PCI process measures for patients undergoing PCI and risk standardized 30-day readmission rates

Aim 3: To determine the association between hospitals' performance on PCI process metrics for patients undergoing PCI and risk-standardized 30-day mortality rates for both ST-elevation myocardial infarction (STEMI) and non-ST-elevation myocardial infarction (NSTEMI) patients

Methods

Study design and population

We performed a cross-sectional analysis of all hospitals in the CathPCI registry that reported at least 25 PCI procedures from January 1, 2010 to December 30, 2011. This time period reflects the populations for whom information about both 30-day readmission and mortality rates among Medicare beneficiaries is available using direct patient identifiers, including name, date of birth, and social security numbers. Developed by the ACC in 1998, the CathPCI registry is the oldest subset of the National Cardiovascular Data Registry (NCDR) and is the largest clinical registry of elective and emergent PCIs in the world with representation of more than 1600 hospitals and cardiac catheterization sites. The registry collects standardized data on patient demographics, procedural, and clinical variables and peri-procedural and in-hospital outcomes [54]. The registry also contains data metrics that provide information on national appropriate usage of PCI in various hospitals [64]. The data completeness of the CathPCI registry is over 95%, and the data quality of the registry has been extensively published in prior literature [65-66]. For this study, we used version 4 of the CathPCI registry data collection form as it contains the elements necessary to calculate appropriate usage and correlates with the time frame of our study sample.

No patients who underwent PCI in this time period were excluded from the analyses if they had their procedure performed at a cardiac catheterization center with over 25 documented PCI procedures within our study period. However, we did not consider information from subsequent PCI procedures if more than one PCI procedure was performed during a single hospital stay.

This study was conceptualized by the first author of this manuscript and later designed together by the first and senior author of this paper. This project was completed with the approval of the CathPCI registry after a proposal submission to the registry written by the first and senior author. These authors were also responsible for defining the variables and methodologies to the statisticians who subsequently performed the statistical analyses in this manuscript. The authors of

this paper then jointly completed the interpretation and analysis of the data. All of the data analyses were performed and the study design formulated at the Center of Outcomes Research and Evaluation at the Yale University School of Medicine. The Yale University Human Investigations Committee approved analyses of this limited NCDR data set.

Process and Outcome Measures

Our first aim focused on hospital performance on current NCDR-endorsed and emerging NCDR process measures for PCI. As mentioned previously, current NCDR-endorsed process measures include aspirin at discharge, thienopyridines at discharge, statins at discharge, door-to-balloon time under ninety minutes for patients presenting to the ED and door-to-balloon times under one hundred twenty minutes for patients being transferred from another acute care facility, and referral to cardiac rehabilitation after PCI. For emerging process measures recently approved by the PCPI in December 2013, we were able to include the following using the data elements in the registry: comprehensive indications for PCI, documentation for PCI appropriateness use criteria (AUC), documentation of contrast dose, and use of embolic protection devices in saphenous vein bypass grafts. Other recently approved metrics did not have the needed data variables in the registry for us to calculate. These metrics included the following: pre-procedural renal assessment (GFR calculation), pre-procedural evaluation for patient's ability to tolerate and adhere to dual antiplatelet therapy, documentation of radiation dose delivered during procedure, average annual volume of PCIs performed by practicing physician over the past two years, and average annual volume of PCIs performed by the hospital over the past calendar year.

For each of the process measures, we identified whether patients were eligible for each individual metric and aggregated patient-level results to calculate the hospital performance in the indicated performance measure. Measure-specific inclusion and exclusion criteria were applied to each case to ensure that the population used to define performance was appropriate. For instance, for the discharge medications, we excluded patients who were transferred or had a contraindication

to the medication. For the door-to-balloon time under ninety minutes, we excluded patients who were transferred from another institution because the upstream data before transfer was often not captured in the registry. Furthermore, for the appropriate indications for PCI process measure, we classified a procedure as indicated based on nationally established guidelines and algorithms that were defined using registry variables [64]. The proportion of appropriate PCIs was calculated at the hospital-level rather than on the individual patient-level which the rest of the process metrics was calculated on. Hence, the proportion of appropriate PCIs was not calculated in the overall composite measure.

We calculated hospital-specific risk standardized 30-day readmission and mortality rates in a manner consistent with NQF-approved mortality and readmission measures. Specifically, there are two models we used to calculate hospital risk-standardized 30-day mortality: one for patients with STEMI or cardiogenic shock, and one for patients without STEMI and without cardiogenic shock [67]. Both models use hierarchical logistic regression which takes into account clustering of patients within hospitals. The models use various clinical characteristics of patients as adjustment variables, allowing us to identify the independent effect of process measures on hospital-specific mortality rates. Two models were used for RSMR because the different clinical features of the patients amount to different adjustments being necessary. Both of the models have high discrimination, and the *c* statistics for the STEMI and NSTEMI models are 0.83 and 0.82 [67]. The model used for hospital-specific RSRR was developed in 2009 between researchers at Yale and the CathPCI registry. This NQF-endorsed model has excellent correlation between expected and observed readmissions (correlation coefficient $r = 0.99$) and good patient-level discrimination. The *c* statistic for this model is 0.66 [68].

Statistical Analysis

We estimated performance for each hospital using a separate hierarchical generalized linear model (HGLM) for each of our process measures. This method allowed us to estimate rates for

hospitals that accounts for clustering of patients within hospitals and reflects the differences in precision of estimates due to the varying numbers of patients treated at each hospital. Crude rates, defined as the number of times a specific process measure was performed on a patient over the total number of eligible patients at that hospital, were also calculated for all process measures. Additional sensitivity analyses revealed that our HGLM estimated rates matched very well with our crude rates.

For our first aim, we used the hospital performance estimates for each process measure to calculate a set of pair-wise correlations. Because different numbers of patients have eligibility for the process measures at each hospital, analyses was weighted by the total number of patients from that hospital who were included in the calculation of the specific process measure. For each correlation, we tested the null hypothesis that there is no correlation between measures, adjusting *p* values for multiple comparisons. In addition, we calculated the Cronbach alpha coefficient for the process measures and assessed the item-scale correlation for each measure. The Cronbach alpha is an indicator of internal consistency and the item-scale correlation was used to measure the correlation of the process measure with the rest of the scale if the original process metric is removed.

We also created a composite measure that was defined as the total number of process measures patients received over the total number of eligible performance measures for patients treated at that hospital. This method is consistent with prior studies and allows for more variance in hospital performance on core process metrics [33]. In secondary analyses, we restricted the composite measure to only current process metrics (excluding emerging ones) as well as to only medication-specific process measures (current NQF-endorsed ones). These composite measures were also included in our linear modeling analyses and crude rate calculations.

For our second and third aims, we used correlation analyses to determine the association of hospital risk-standardized 30-day mortality and readmission rates with corresponding hospital composite score estimates of process measures. Again, we repeated our analyses with the composite

measure restricted to only current process measures and then medication-specific metrics. We also calculated correlation coefficients and the proportion of the hospital-specific variation in risk-standardized mortality rates explained as indicators of the strength of the associations. This variation is the square of the correlation coefficient and is calculated out of 100.

We also performed several secondary analyses to assess the robustness of our primary analyses. First, sensitivity analyses was performed that included hospital characteristics such as geographical location, profit status, and teaching status. Second, we restricted the calculation of hospital process measure performance to Medicare beneficiaries included in the calculation of corresponding outcomes measures. Lastly, we repeated all analyses using crude process measures rates instead of ones calculated from our linear models.

Analyses were conducted using SAS version 9.1 (SAS Institute, Cary, NC). All reported p values are reported as 2-sided with significance at $p < 0.05$.

Results

Sample descriptives

The total number of patients that was admitted during our study's time period and satisfied our methodological criteria was 1,219,544 patients with 1,268,860 PCI procedures with some patients receiving more than one procedure over the course of several visits. These patients were distributed over the 1,331 hospitals in the CathPCI registry that reported over 25 cases during our study period. Hospital rates for each of the current NCDR-endorsed process measures, emerging process measures, and composite measure in addition to 30-day RSMR (for STEMI patients), 30-day RSMR (for non-STEMI patients), and 30-day RSRR are shown in Table 1.

Table 1: Hospital performance in 2010-2011 on current endorsed process measures, emerging process measures, and 30-day mortality and readmission rates*

Variable	N	Mean	SD	25th percentile	Median	75th percentile
Aspirin at discharge	1288	96.8	3.6	96.0	97.9	99.0
Thienopyridines at discharge	1285	98.0	2.8	97.6	98.8	99.4
Statin at discharge	1288	89.8	7.2	86.8	91.4	94.7
Proportion DTB time <90 minutes	1134	77.5	11.1	71.2	78.9	85.1
Referral to cardiac rehab	1291	53.8	35.1	18.4	60.7	87.2
Documentation of Contrast Dose	1291	99.7	0.9	99.7	100.0	100.0
Use of embolic device	775	20.7	18.5	3.6	16.5	33.9
Documentation of AUC eligibility	1156	62.5	16.8	51.1	64.3	75.0
Proportion Of Appropriate PCIs Performed**	1156	29.2	16.8	17.5	26.3	37.8
Overall Proportion Of Process Measures Met	1291	85.2	7.6	78.5	86.4	91.8
Risk Standardized Readmission Rate	1076	11.9	1.3	11.1	11.8	12.7
Risk-Standardized Mortality Rate (STEMI)	743	12.3	2.0	10.9	12.1	13.4
Risk-Standardized Mortality Rate (NSTEMI)	1059	1.8	0.4	1.6	1.7	2.0

* Hospitals were only considered eligible if they had more than 25 patients for each of the individual process measures
**Proportion of appropriate PCIs performed was not included in the overall proportion of process measures met

Descriptive histograms for each of the individual process measures are given in the supplementary materials section of the paper. Results from restricting the total composite measure to only the current NCDR-endorsed process measures along with further restricting the composite measure to only current medication process measures (aspirin at discharge, thienopyridines at discharge, and statins at discharge) are shown in Table 2.

Table 2: Hospital performance in 2010-2011 based upon composite measure of NCDR-endorsed process measures and ACC/AHA-endorsed process measures*

Variable	N	Mean	SD	25th percentile	Median	75th percentile
Overall proportion of total NCDR-endorsed process measures met	1291	83.8	9.9	74.6	85.8	92.6
Overall proportion of NCDR-endorsed medication process measures met	1291	94.8	4.1	93.3	95.8	97.3

* Hospitals were only considered eligible if they had more than 25 patients for each of the individual process measures

Correlation of process measures

In analysis of the process measures correlations, we found moderate to strong correlations (correlation coefficient > 0.40) across all the medications process measures, especially between aspirin and thienopyridines at discharges, which was noted to have a very strong correlation (correlation coefficient > 0.70). None of the medication process measures for medications were correlated with that hospital having an average DTB time < 90. Referral to cardiac rehab was significantly correlated with all other currently endorsed process measures (all correlation coefficients > 0.10) and had a very strong correlation with the overall composite measure (correlation coefficient > 0.90). Use of embolic devices was correlated with the medication process measures and referral to cardiac rehab but not to timely reperfusion therapy (Table 3). Documentation of AUC eligibility was strongly correlated with proportion of appropriate PCI's

performed (correlation coefficient > 0.60). The composite measure was significantly correlated to all process measures except documentation of contrast dose and proportion of appropriate PCI's (correlation coefficient > 0.15).

If the overall composite measure was restricted to only approved process measures, the composite measure was slightly weaker in correlation to all current process measures except for referral to cardiac rehab where a stronger correlation was seen (Table 4). Further restricting the overall composite measure as a marker of only the medication specific process measures yielded no change in significance (Table 5).

Table 3:
Correlation coefficients for approved and emerging hospital process measures and 30-day risk-standardized readmission rates and mortality rates* †

	Aspirin At Discharge	Thieno-Pyridines At Discharge	Statin At Discharge	Proportion DTB Time <90 mins	Referral To Cardiac Rehab	Documentation Of Contrast Dose	Use Of Embolic Device	Proportion Of PCIs AUC Eligible	Proportion Of Appropriate PCIs	Overall Proportion Of Process Measures Met
Thienopyridines at Discharge	0.713									
Statin at Discharge	0.597	0.486								
Proportion DTB Time <90 mins	0.063	0.070	0.092							
Referral To Cardiac Rehab	0.194	0.139	0.181	0.111						
Documentation Of Contrast Dose	0.033	0.023	0.000	-0.002	0.019					
Use Of Embolic Device	0.247	0.182	0.215	-0.043	0.125	-0.046				
Documentation of AUC eligibility	0.078	0.014	0.154	0.084	0.022	0.048	0.041			
Proportion Of Appropriate PCIs**	-0.007	-0.072	0.022	0.101	-0.012	-0.005	-0.025	0.650		
Overall Proportion Of Process Measures Met	0.392	0.304	0.415	0.159	0.951	0.037	0.199	0.178	0.078	
Risk-Standardized Readmission Rate	-0.120	-0.131	-0.139	-0.062	-0.100	0.007	-0.048	-0.038	0.005	-0.132
Risk-Standardized Mortality Rate (STEMI)	-0.135	-0.153	-0.116	-0.069	-0.074	-0.003	-0.013	-0.069	-0.075	-0.103
Risk-Standardized Mortality Rate (NSTEMI)	-0.223	-0.143	-0.240	0.026	-0.063	0.009	-0.134	-0.010	0.009	-0.122

* Hospitals with considered eligible only if they had more than 25 patients for each of the individual process measures
** Not included in overall composite measure
† Weighted by number of eligible patients in each hospital
Red data points indicates significance ($p < .01$) after adjusting for multiple comparisons

Table 4:
Correlation coefficients for approved hospital process measures and 30-day risk-standardized readmission rates and mortality rates* †

	Aspirin At Discharge	Thieno-Pyridines At Discharge	Statin At Discharge	Proportion DTB Time <90 mins	Referral To Cardiac Rehab	Overall Proportion Of Process Measures Met
Overall Proportion Of Process Measures Met**	0.377	0.303	0.384	0.151	0.972	
Risk-Standardized Readmission Rate	-0.120	-0.131	-0.139	-0.062	-0.100	-0.128
Risk-Standardized Mortality Rate (STEMI)	-0.135	-0.153	-0.116	-0.069	-0.074	-0.103
Risk-Standardized Mortality Rate (NSTEMI)	-0.223	-0.143	-0.240	0.026	-0.063	-0.115

* Hospitals with considered eligible only if they had more than 25 patients for each of the individual process measures
** Does not include emerging process measures
† Weighted by number of eligible patients in each hospital
Red data points indicates significance ($p < .01$) after adjusting for multiple comparisons

Table 5:
Correlation coefficients for hospital medication process measures and 30-day risk-standardized readmission rates and mortality rates* †

	Aspirin At Discharge	Thienopyridines At Discharge	Statin At Discharge	Overall Proportion Of Process Measures Met
Overall Proportion Of Process Measures Met**	0.829	0.728	0.929	
Risk-Standardized Readmission Rate	-0.120	-0.131	-0.139	-0.157
Risk-Standardized Mortality Rate (STEMI)	-0.135	-0.153	-0.116	-0.146
Risk-Standardized Mortality Rate (NSTEMI)	-0.223	-0.143	-0.240	-0.256

* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures
** Only includes hospital medication process measures
† Weighted by number of eligible patients in each hospital
Red data points indicates significance ($p < .01$) after adjusting for multiple comparisons

Item scale correlations (Table 6) for all of the process measures indicated only mediocre internal consistency ranging from 0.01 (for documentation of contrast dosage) to 0.37 (for aspirin at discharge). The raw Cronbach alpha ratio for all of the process metrics was 0.29. Further restricting the item scale correlations to only approved process measures generated a small range of correlations but no significant differences in raw values. In the approved-only process metrics set, they ranged from 0.13 (for proportion DTB time < 90 minutes) to 0.31 (aspirin at discharge). The raw Cronbach alpha for this set was 0.21. Finally, restricting the process measures to only medications (Table 8) yielded the strongest item

correlations with ranges from statin at discharge at 0.59 to aspirin at discharge at 0.69. The raw Cronbach alpha ratio for this data sample is 0.67.

Table 6:
Item-Scale Correlations for both approved and emerging process measures

Variable	N	Item-scale correlation†
Aspirin at discharge	1288	0.37
Thienopyridines at Discharge	1285	0.27
Statin at Discharge	1288	0.35
Proportion DTB Time <90 mins	1134	0.10
Referral To Cardiac Rehab	1291	0.20
Documentation Of Contrast Dose	1291	0.01
Use Of Embolic Device	775	0.17
Documentation of AUC eligibility	1156	0.08

* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures
† Item score correlation refers to the correlation of a specific item with the remaining items in a set

Table 7:
Item-Scale Correlations for all approved process measures*

Variable	N	Item-scale correlation†
Aspirin at discharge	1288	0.31
Thienopyridines at Discharge	1285	0.26
Statin at Discharge	1288	0.25
Proportion DTB Time <90 mins	1134	0.13
Referral To Cardiac Rehab	1291	0.21

* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures
† Item score correlation refers to the correlation of a specific item with the remaining items in a set

Table 8:
Item-Scale Correlations for only medication process measures*

Variable	N	Item-scale correlation†
Aspirin at discharge	1288	0.31
Thienopyridines at Discharge	1285	0.26
Statin at Discharge	1288	0.25

* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures
† Item score correlation refers to the correlation of a specific item with the remaining items in a set

Process measures and hospital-level specific outcome measures

In the initial analysis with both current and emerging process measures, the overall composite measure was modestly but statistically significant with hospital-specific RSRR (correlation coefficient > -0.132) and hospital-specific RSMR for NSTEMI patients (correlation coefficient > -0.122) but not hospital-specific RSMR for STEMI patients (Table 3). The process measures of aspirin at discharge and thienopyridines at discharge were both significantly correlated with hospital-specific RSRR, RSMR for STEMI patients, and RSMR for NSTEMI patients (correlation coefficient range from -0.12 to -0.22). Statins at discharge was found to be correlated with hospital-level RSRR and RSMR

for NSTEMI patients but not for STEMI patients. The percent variance for these process measures and the overall composite was very modest ranging from 0.0% to 1.9% for the readmissions outcome measure and 0.0% to 5.8% for 30-day mortality in STEMI and NSTEMI patients (Table 9).

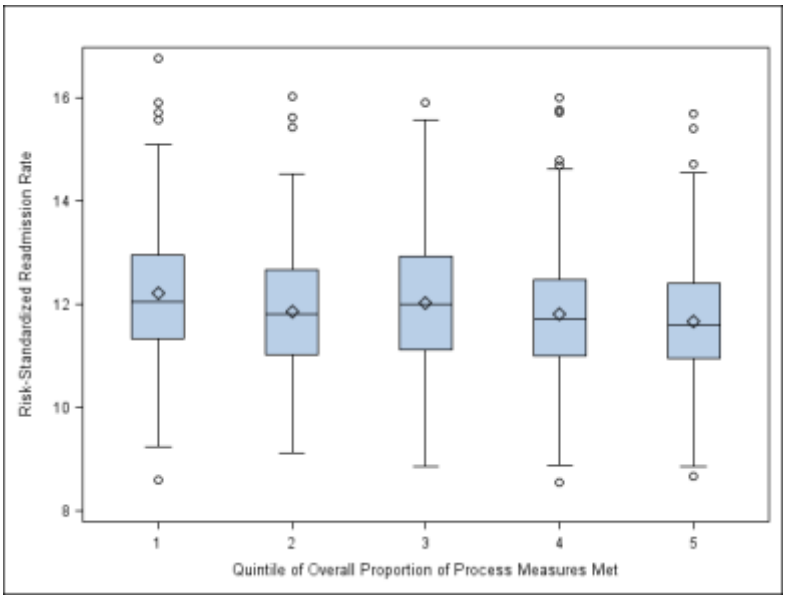
Table 9:
Percent variance in hospital-level 30-day outcome measures for both approved and emerging process measures*

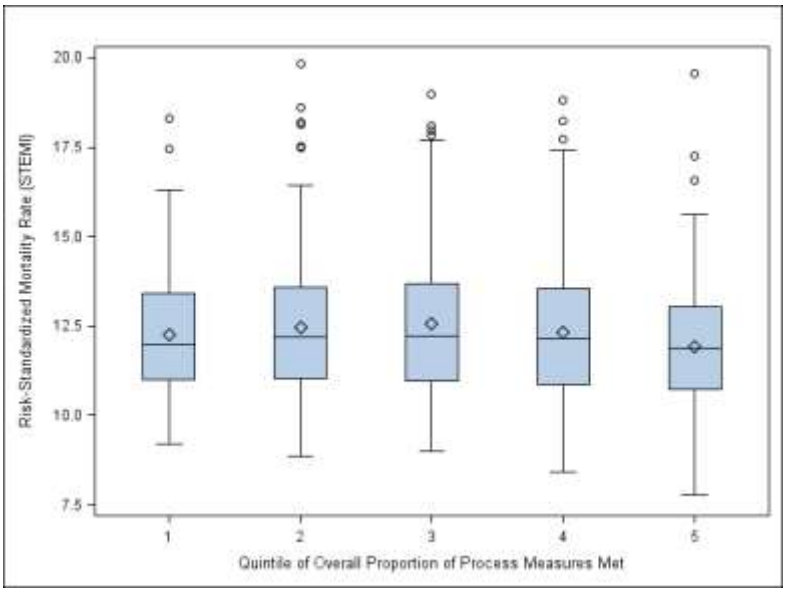
Variable	RSRR %	RSMR % (STEMI)	RSMR % (NSTEMI)
Aspirin at discharge	1.5	1.8	5.0
Thienopyridines at Discharge	1.7	2.3	2.0
Statin at Discharge	1.9	1.3	5.8
Proportion DTB Time <90 mins	0.4	0.5	0.1
Referral To Cardiac Rehab	1.0	0.6	0.4
Documentation Of Contrast Dose	0.0	0.0	0.0
Use Of Embolic Device	0.2	0.0	1.8
Documentation of AUC eligibility	0.1	0.5	0.0
Proportion Of Appropriate PCIs	0.0	0.6	0.0
Overall Proportion Of Process Measures Met	1.7	1.1	1.5

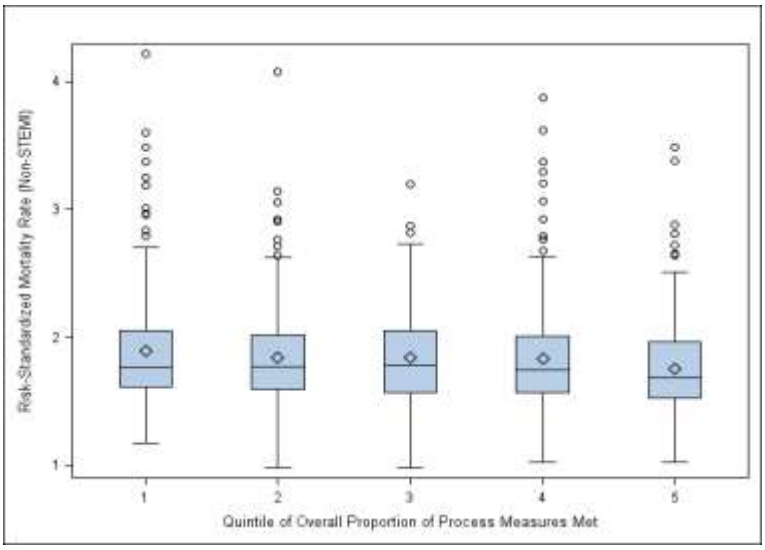
* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures

There was no significant difference across the five quintiles of hospital performance on the overall composite process measure in terms of hospital-level 30-day RSRR, RSMR for STEMI patients, and RSMR for NSTEMI patients (Figure 1).

Figure 1: Box-whisker plots of risk-standardized 30-day all-cause readmission rates, mortality rates for STEMI patients, and mortality rates for NSTEMI patients based on hospital performance on an overall composite measure of current and emerging process measures by quintiles







The overall composite measure was subsequently restricted to only current process measures and there was again a modest but statistically significant correlation with hospital-specific 30-day RSRR (correlation coefficient > -0.128) and hospital-specific 30-day RSMR for NSTEMI patients (correlation coefficient > -0.115) but not hospital-specific 30-day RSMR for STEMI patients (Table 4). Further restricting the composite measure to only medication-specific process measures resulted in a stronger and significant correlation across all three outcome variables with the correlation coefficient ranging from -0.146 for hospital-specific 30-day RSMR to -0.256 for hospital-specific RSMR for NSTEMI patients (Table 5). Although there was a slight increase in the percent variance for the medication-specific composite measure (range from 2.1% to 6.7%), both of the restricted composite measures only slightly explained the variation in hospital-level 30-day risk standardized outcomes (Table 10).

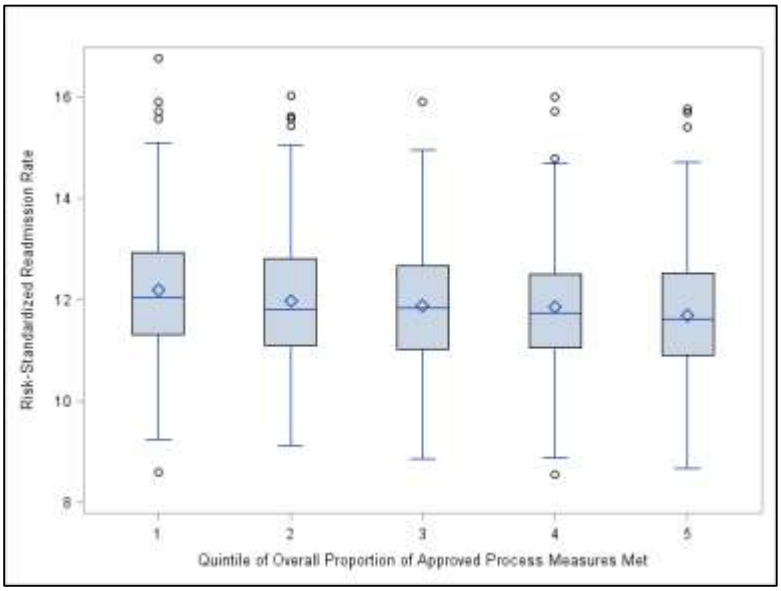
Table 10:
Percent variance in hospital-level 30-day outcome measures for composite measure of only approved process measures and medication-specific process measures*

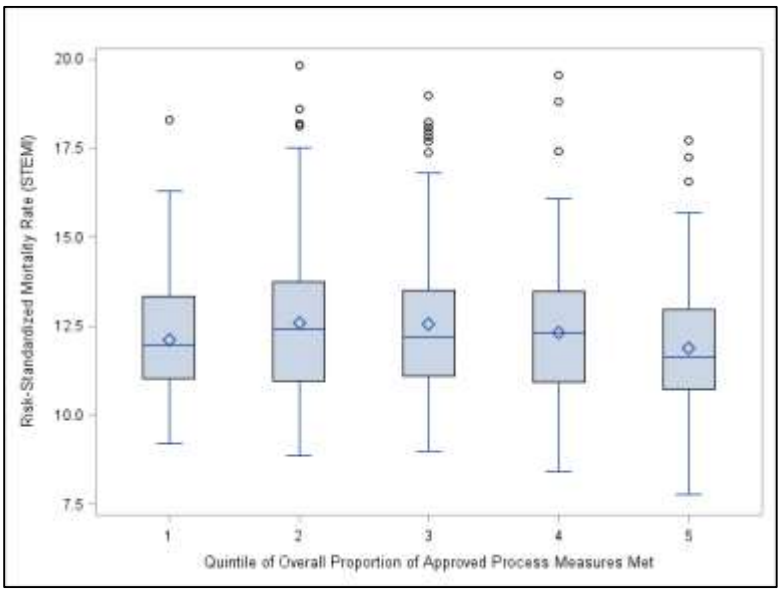
Variable	RSRR %	RSMR % (STEMI)	RSMR % (NSTEMI)
Overall Proportion Of Process Measures Met (Current process measures)	1.6	1.1	1.3
Overall Proportion Of Process Measures Met (Medication-specific)	2.5	2.1	6.6

* Hospitals were considered eligible only if they had more than 25 patients for each of the individual process measures

There was again only no significant differences across the five quintiles of hospital performance on the overall composite measures, for current metrics and medication-specific metrics, in terms of hospital-level 30-day RSRR, RSMR for STEMI patients, and RSMR for NSTEMI patients (Figure 2 and 3).

Figure 2: Box-whisker plots of risk-standardized 30-day all-cause readmission rates, mortality rates for STEMI patients, and mortality rates for NSTEMI patients based on hospital performance on an overall composite measure of current process measures by quintiles





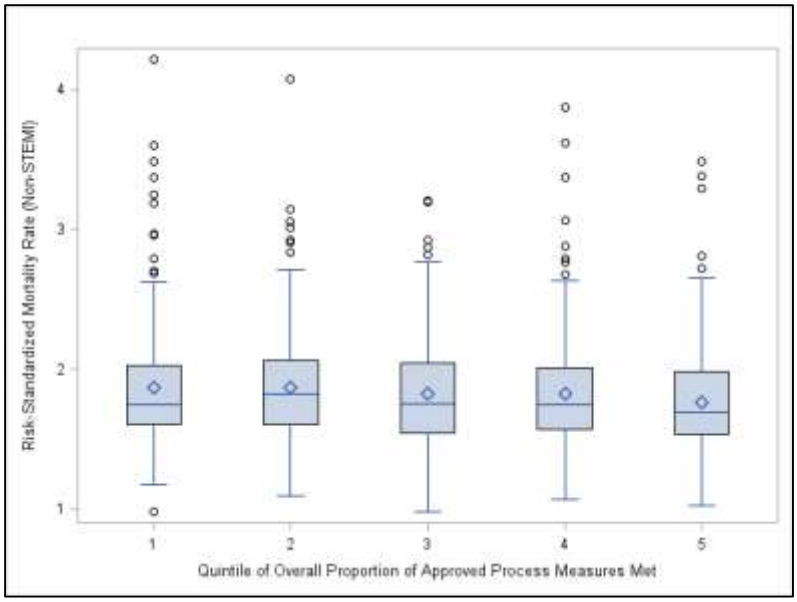
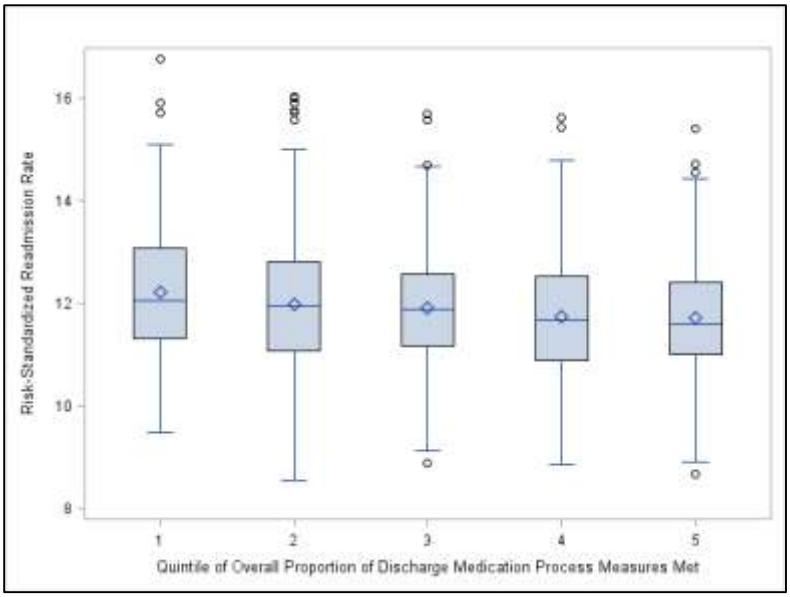
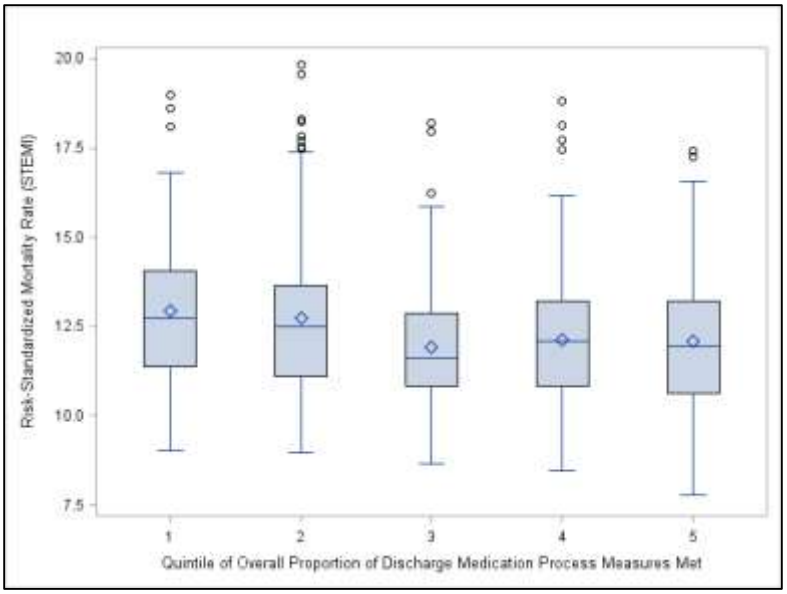
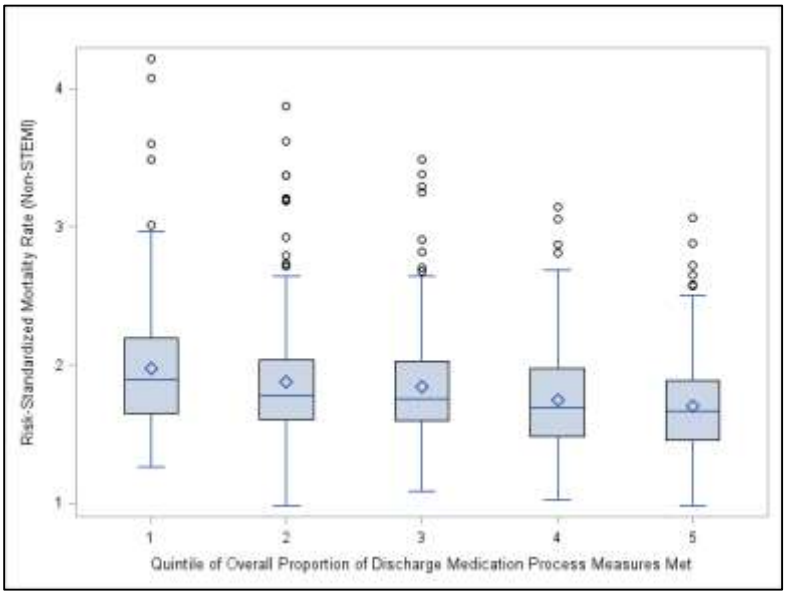


Figure 3: Box-whisker plots of risk-standardized 30-day all-cause readmission rates, mortality rates for STEMI patients, and mortality rates for NSTEMI patients based on hospital performance on an overall composite measure of medication-specific process measures by quintiles







Sensitivity analyses

Secondary analyses showed that hospital characteristics were not independently associated with any of the process measures or outcome measures. In restricting the calculation of hospital process measures to only Medicare beneficiaries, we saw no changes in the corresponding outcome measures. Secondary analyses also showed close agreement between crude process measure rates and values from our linear models.

Discussion

In a large cross-sectional analysis of PCI patients treated at 1620 hospitals, we have shown that hospital performance on existing and emerging process measures is weakly correlated with hospital performance on PCI outcome metrics, including hospitals' 30-day risk-standardized mortality and readmission rates. Although the composite process measure and several individual performance metrics were found to be associated with short-term mortality and readmissions, hospital performance on PCI-specific process metrics explained less than 10% of the variation in mortality or readmission rates. We also found that with the exception of door-to-balloon times under ninety minutes, there were strong correlations for hospital performance among the existing process measures. However, existing process measures were less strongly correlated though for the new emerging PCPI metrics recently released. These findings suggest that outcome metrics, currently endorsed PCI metrics, and the emerging measures are each capturing complimentary but not overlapping domains of quality.

At present, there is substantial variation across PCI hospitals in their 30-day risk-standardized mortality and readmission rates. Our crude all-cause mortality and readmission rates are consistent with findings from prior studies [8-9, 67]. While previous analyses have examined the association between AMI outcome metrics and AMI process measures and others have identified specific clinical profiles and risk factors of PCI patients that correlate to mortality or readmission rates, our study was the first to examine the relationship between hospital-performance on PCI process measures and PCI outcome measures [8, 33].

Our analyses revealed that the composite measure was statistically significantly correlated to both hospital-level 30-day RSRR, and RSMR for patients without STEMI and without cardiogenic shock. However, the strengths of the correlation was modest. Furthermore, there was no correlation between the composite process measure and for RSMR for STEMI patients. This finding was similar when we restricted the composite measure include only the currently approved process metrics. When we further restricted the composite measure to discharge medications, all

three outcome variables were significantly correlated. We also noted that the inclusion of the emerging process measures into the composite did not result in any significant change in the percent variance explained by the outcome measures. Our results suggest that similar to the existing process measures, the newly approved ones capture an aspect of quality that is separate and distinct from that reflected by outcome measures.

There are several possible reasons why even with the addition of new process measures, the percent variance explained of the outcome metrics is still very modest. First, many of the process measures such as statin at discharge or documentation of contrast dose are close to having a performance measure performance of 100% [33]. This finding may therefore limit the ability to discriminate hospitals on these measures. Furthermore, as discussed previously, hospitals' outcomes are influenced by many variables not captured in process measures. These include the quality of medication reconciliation, adherence to patient safety guidelines, nurse staffing levels, and availability of post-hospitalization home healthcare services [61, 69]. Similarly, process measures do not capture the quality of the transition of care from inpatient to the outpatient setting, or the effectiveness of communication with primary care providers, both of which may represent key determinants of patient outcomes [36, 65]. Many of these practices represent strategies that require collaboration beyond the walls of a hospital and effective, efficient communication between hospitals, patients, and providers. Thus, there is ample research now to suggest that to improve outcomes, hospitals will have to take ownership and ensure the quality not only of care within its facilities, but also direct social services and transitions of care that may involve family and community contributions [8, 70].

While the new PCPI performance metrics are groundbreaking in attempting to establish guidelines for appropriateness as well as markers for technical expertise, our findings suggest that these new measures continue to encapsulate only a specific and narrow domain of quality. We believe that additional sets of process measures may be needed for PCI in the future to capture a more complete picture of the services that a hospital provides, which may extend beyond the sphere

of direct clinical care. Alternatively, we appreciate that outcome measures continue to capture quality that represents all aspects of care that may be impossible to reflect in just process measures. While additional efforts to create standardized performance metrics in areas such as the transition of care, post-discharge follow-up, or behavioral modification may align with current efforts to improve overall all-cause patient outcomes, the difficulty of creating such performance measures may suggest a complimentary and important role that outcome measures play in representing quality.

Although our results do seemingly undermine the significance of process measures as a quality indicator, it is crucial to emphasize that in fact we are suggesting there are numerous advantages to public reporting of process measure performance. Public reporting of these measures can provide an actionable item for hospitals to achieve with the hope of affecting long-term outcomes for patients. Furthermore, it can provide to patients a marker of the clinical care they may receive at an institution and a source of motivation for hospitals. In addition, improvements in clinical care has been linked to public reporting and the emphasis on process measures [71]. However, as many previous researchers have noted, there is a need for additional research to identify process measures that can better explain the variations in outcome metrics [33, 72]. Defining such variables or performance metrics though may not be possible in many cases. Selecting process measures must satisfy the basic principle that the process measure is clinically meaningful, can be adjusted for patient variability, be valid and reliable, can be modified by improvements in the care delivery, and can measure the performance of healthcare providers [72]. In many cases such as the transition of care of patients, the heterogeneity of each case currently prohibits the use of standardized process measures as a quality marker. If such process measures were to be developed, then identification and implementation of these process measures can establish, a tangible link between patient end outcomes and evidence-based clinical care. Until the establishment of those process measures, however, outcome metrics provide an indirect but encompassing manner to capture quality of care in the various avenues of healthcare delivery.

Our study is also the first to identify pair-wise correlations for PCI-specific existing performance metrics. Similar to past studies of AMI patients, the medication-specific process measures had the highest-level of correlation with one other [33, 63]. When we restricted the item-scale correlations to only the three medication process measures, a much higher correlation was seen in comparison to analyses where we included all process metrics. This finding is consistent with other studies that showed medication-specific measures have a high level of internal consistency with one another [33]. Our results also indicate that hospital performance of having a DTB time less than ninety minutes was only significantly correlated with referral to cardiac rehab. This dissociation of DTB times from other process measures has been documented in literature [73]. Improvements in DTB time require a systematic shift in hospital procedures and structure that may often involve changes in how patients are triaged and transferred, assignment of new hospital floor space with the capability to quickly receive AMI patients, and designating and training the proper personnel.

Our results showed that hospital performance on referral to cardiac rehabilitation was significantly correlated with all other existing NCDR-approved measures except proportion of DTB times < 90 minutes. A robust correlation was seen between referral to cardiac rehabilitation and the overall composite measure comprising of both current and emerging process measures and discharge medications metrics. There may be several reasons for this strong correlation. As mentioned above, most of the process measures have been topped and hence very little variation exists in the top two to three quintiles of hospital performance [6, 33]. For instance, our crude rates show that the median to 75^{th} percentile for hospital performance on aspirin and thienopyridines at discharge are 97.9%-99.0% and 98.8%-99.4% respectively. These numbers suggest that hospitals and providers are performing identically well in their clinical practices to generate the high performance marks on these process measures; the lack of variation in these metrics do not provide much statistical discrimination when combined with the overall composite measures [16]. In contrast, hospital performance for referral to cardiac rehabilitation has a mean performance of

around 50% generating significantly more variation that likely contributed to the strong correlation seen with the overall composite measure. The rather low crude values for hospital performance for referral to cardiac rehab are consistent with ranges found in the literature that suggest that this specific process measure represents an area for improvement for hospital performance [74].

We found in our analyses that any variation in the overall composite measure was largely driven by referral to cardiac rehabilitation, given the very robust correlation between these two metrics. Several composite measures already exist in NQF's portfolio of endorsed measures for other areas of focus such as AMI and CHF. With an increasing number of performance metrics available to the public, NQF has considered composite measures as a mechanism to provide a valid and comprehensive picture of healthcare quality that single individual process measures cannot capture [75]. Our findings, however, suggest that a composite measure for PCI currently would be superfluous given that it would be driven largely by one individual metric.

Focusing on emerging metrics, the mean hospital performance was actually higher in the composite measure comprising of both currently approved *and* emerging metrics as opposed to the composite measure of just the existing measures. However, few of the emerging metrics were significantly correlated with the core measures with the exception of use of embolic protection devices. The results therefore indicate that hospitals are already performing well on the emerging metrics though overall performance on the current metrics is not associated with performance on the new measures. This lack of correlation between the emerging and existing metrics suggests that the emerging metrics are representative of another dimension of quality that the previous metrics was not capturing, albeit one in which there is already relatively little opportunity to improve. It is very likely that as these new recommendations become fully incorporated into hospital guidelines, the association between the current and emerging set of process measures will become stronger in the upcoming years.

. There are several limitations to our study that should be considered. The first one is that our entire patient population is from a single registry. We appreciate that these results may not be

generalizable to all PCI centers in the U.S. However, given the CathPCI registry captures over 95% of PCI procedures performed in the US, we do believe our data sample is fairly inclusive of all patient and hospital demographics and relatively free from selection biases [54]. In addition, given the restraints of the available data elements in the registry, we were not able to fully capture all of the emerging and newly PCPI approved process measures. Some of these metrics such as the average volume of patients seen by a provider or hospital may represent more systematic aspects of quality that is more represented in outcome metrics. While our results should provide a fairly accurate snapshot of hospital performance on these new metrics, it is possible that the performance on the individual metrics we studied in this analyses are not representative of hospital performance as a whole on the full portfolio of novel metrics. Furthermore, it is possible that a composite measure incorporating more of the emerging metrics may be stronger in explaining hospital-level variance in 30-day outcome measures. There are also inherent limitations associated with cross-sectional analyses. As with all observational studies, it is impossible to establish causation between our two sets of quality metrics. It is possible that hospital or patient characteristics could have served as cofounders although hospital size was weighted in our logistical regressions. Lastly, as we addressed earlier in this discussion, although the composite measure has been used in prior studies as a fair metric to judge a hospital's performance overall on process measures [33, 76], specific performance measures such as referral to cardiac rehabilitation can be a disproportional contributor to the discriminative ability of the composite measure.

In summary, hospital performance on current and emerging PCI-metrics only explain a small variation of hospital performance on outcome measures such as 30-day risk-standardized mortality and readmission rates. This fact highlights that these two sets of markers are capturing distinct components and aspects of hospital quality care. From a perspective of a PCI patient, both sets of quality metrics should be considered together in evaluating hospital quality. Additional efforts are needed to better how characterize how hospitals can utilize these two distinct markers of quality to improve hospital performance.

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Supplemental information

Figure 1: Distribution of hospital volumes

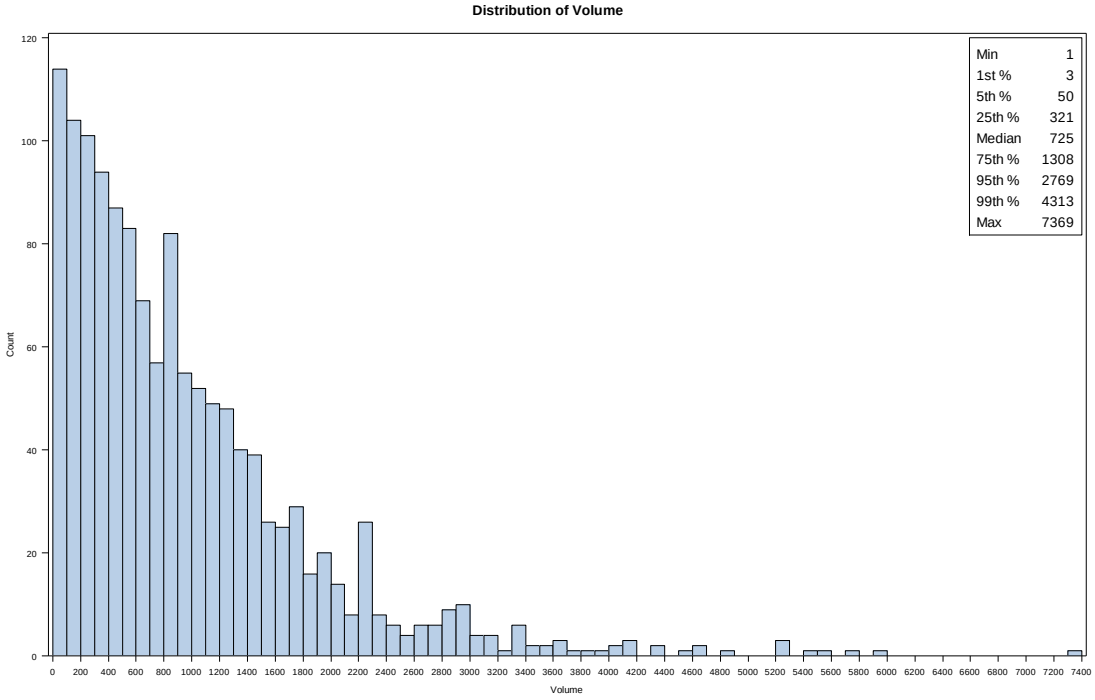

Figure 2: Histogram distribution for the process measure of aspirin at discharge

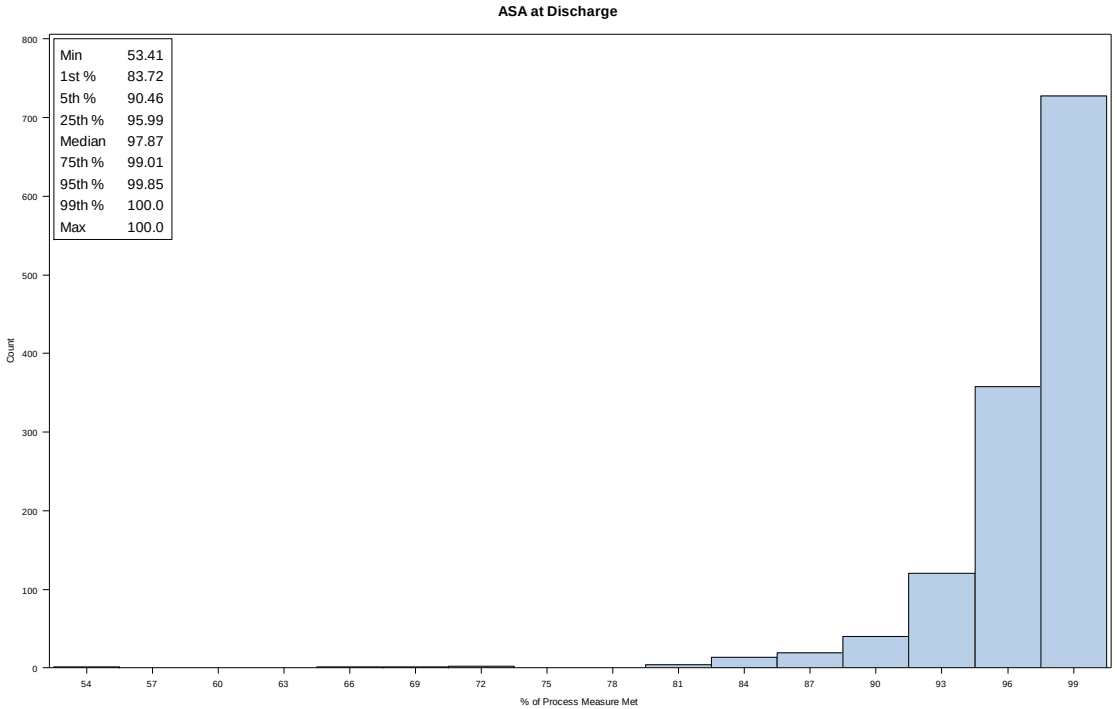

Figure 3: Histogram distribution for the process measure of thienopyridines at discharge

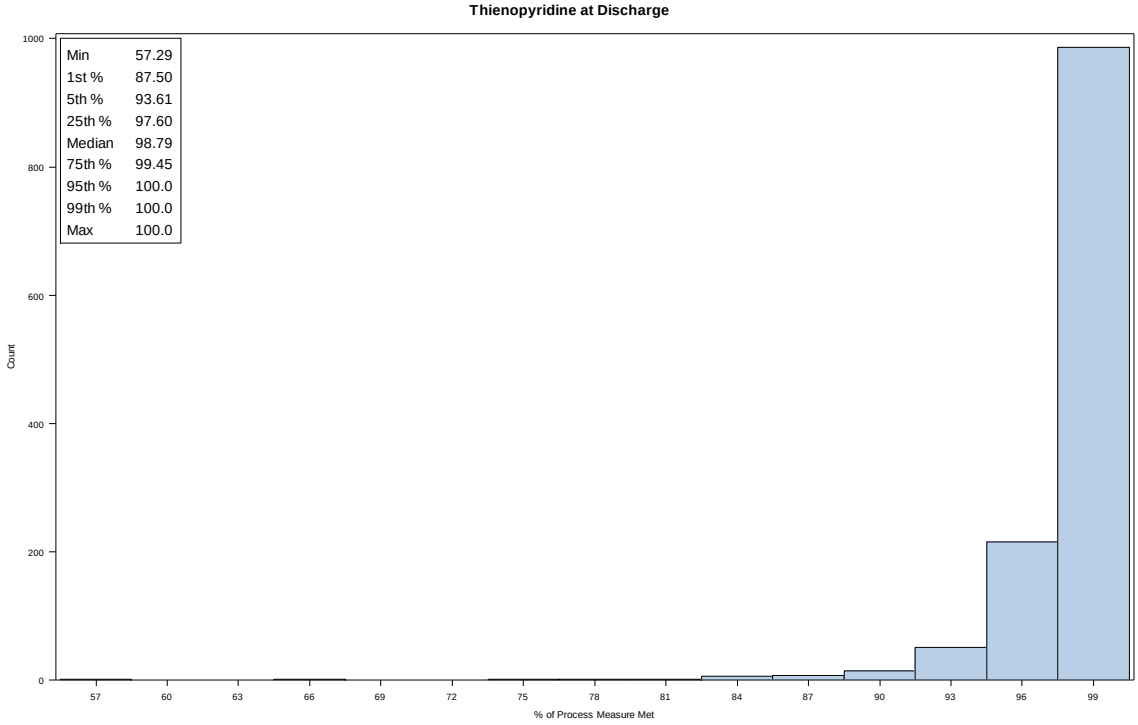

Figure 4: Histogram distribution for the process measure of statins at discharge

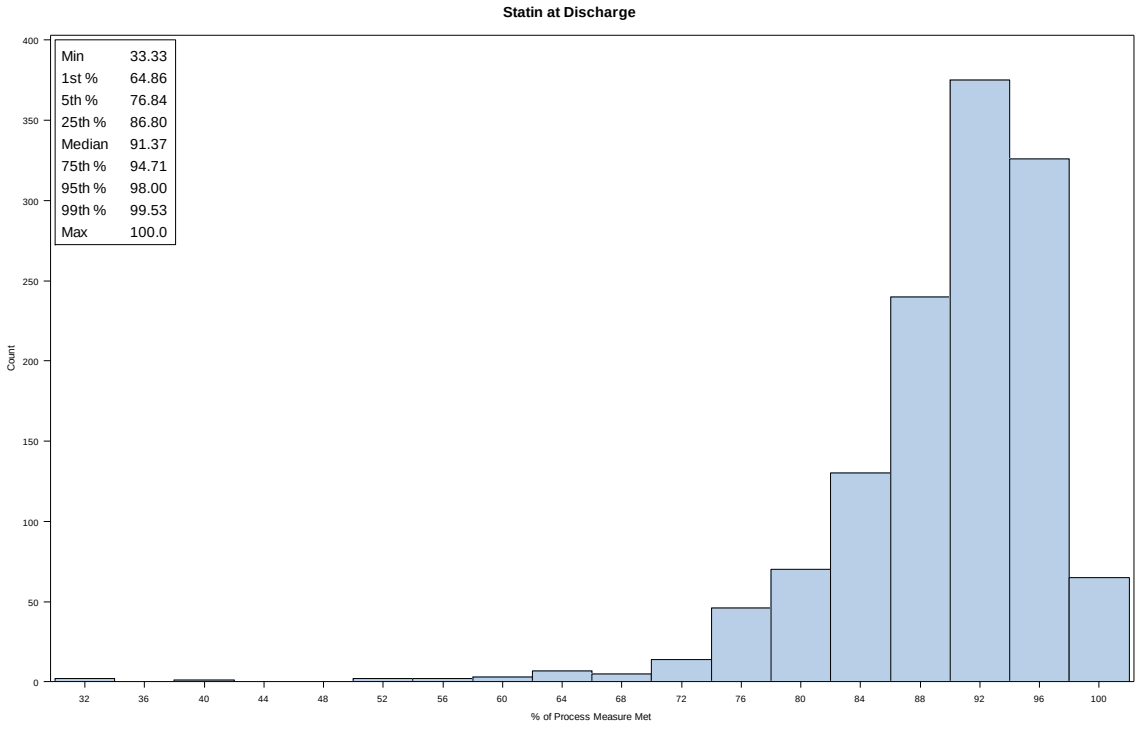

Figure 5: Histogram distribution for the process measure of proportion of DTB times < 90 mins

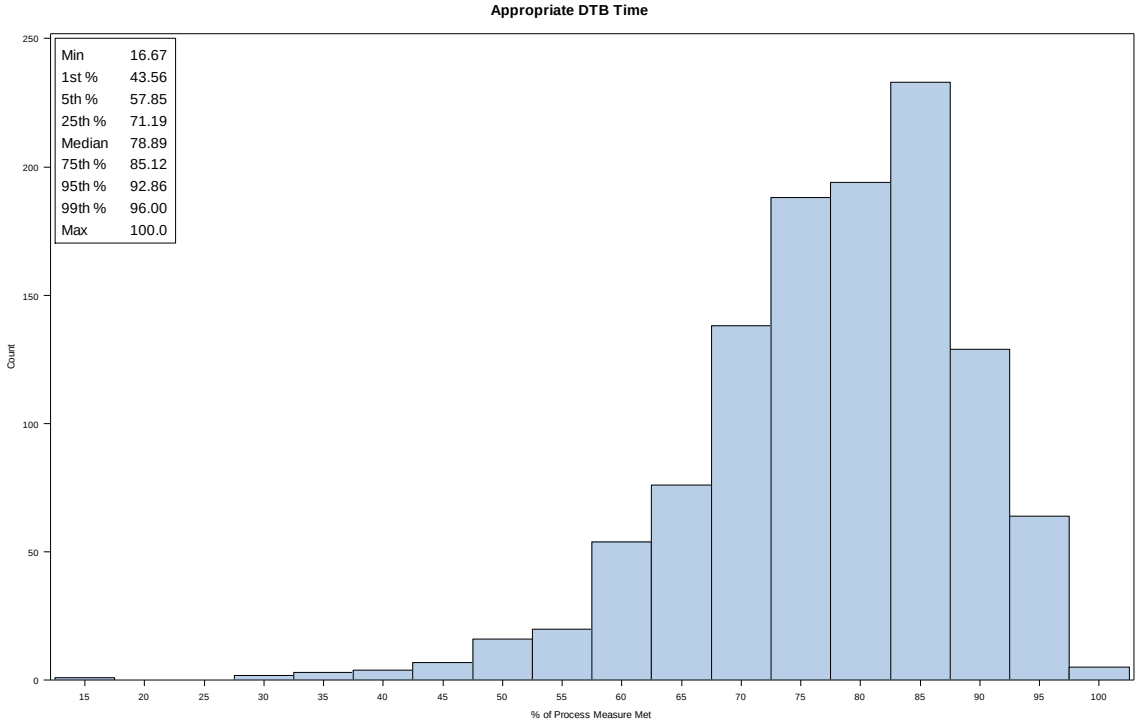

Figure 6: Histogram distribution for the process measure of referral to cardiac rehab

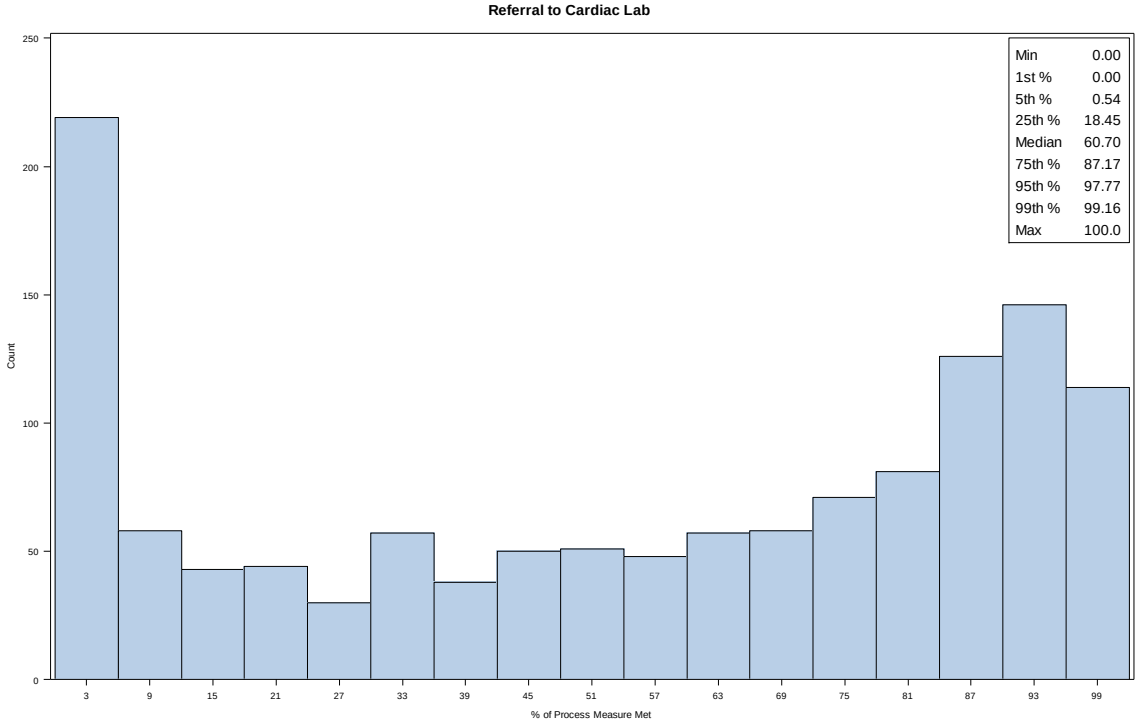

Figure 7: Histogram distribution the process measure of documentation of contrast dosage

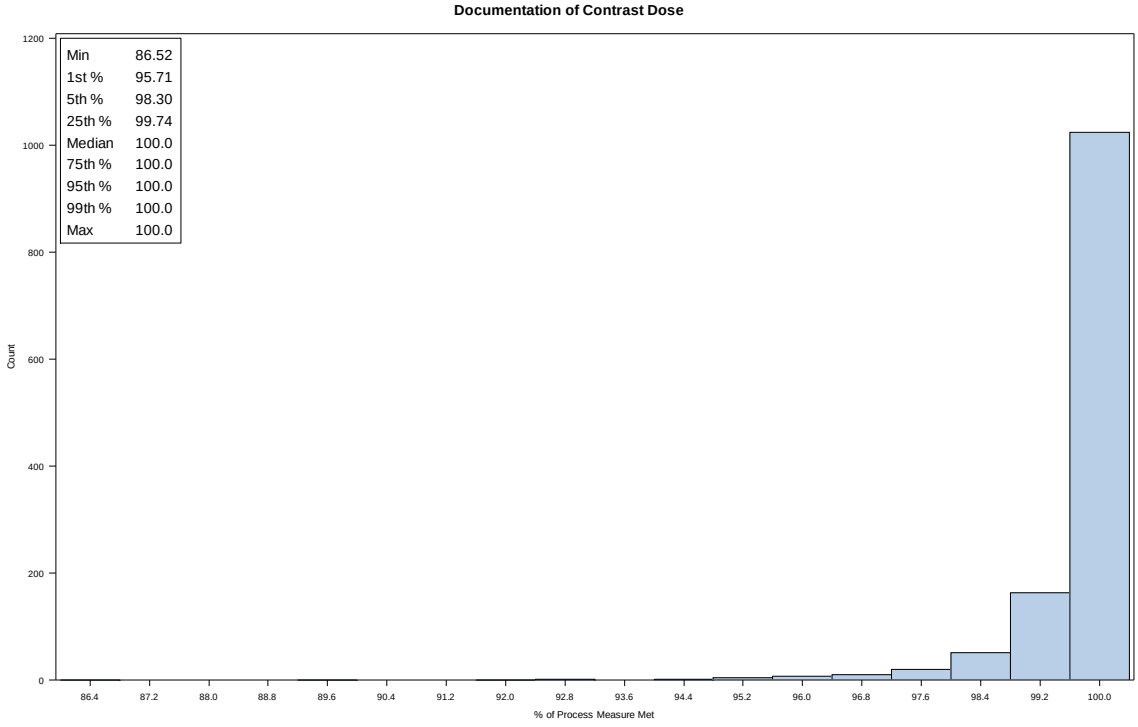

Figure 8: Histogram distribution for the process measure of use of an embolic protection device

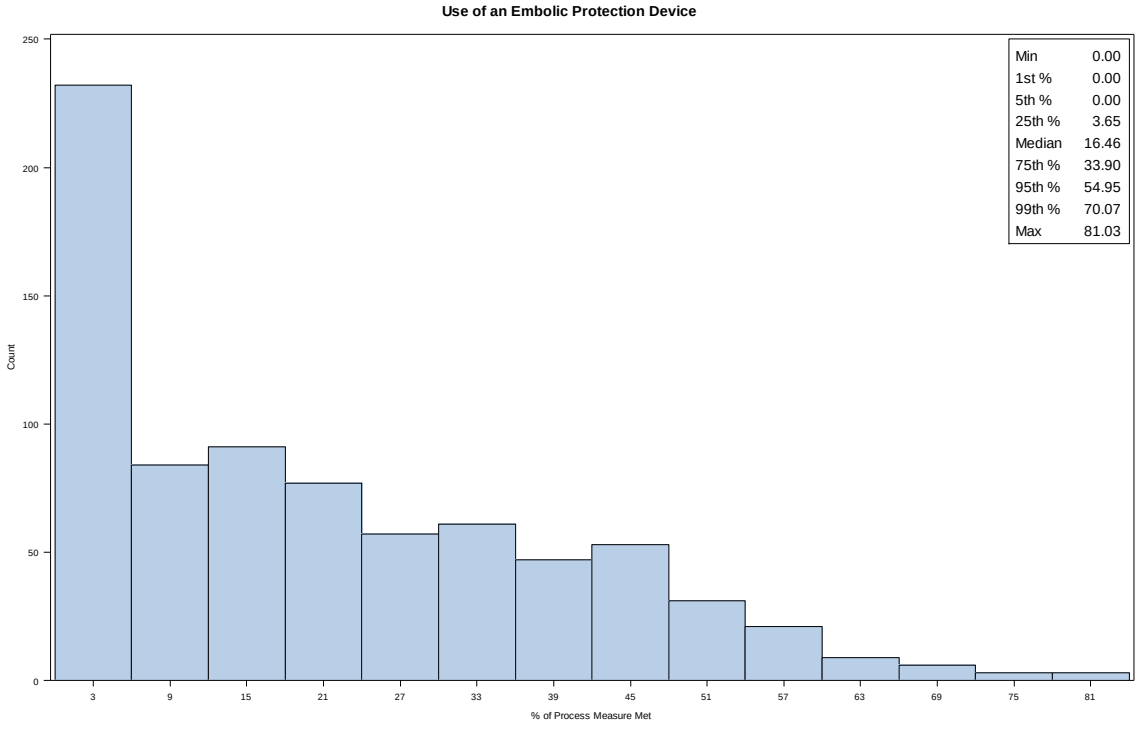

Figure 9: Histogram distribution of proportion of PCIs considered AUC eligible

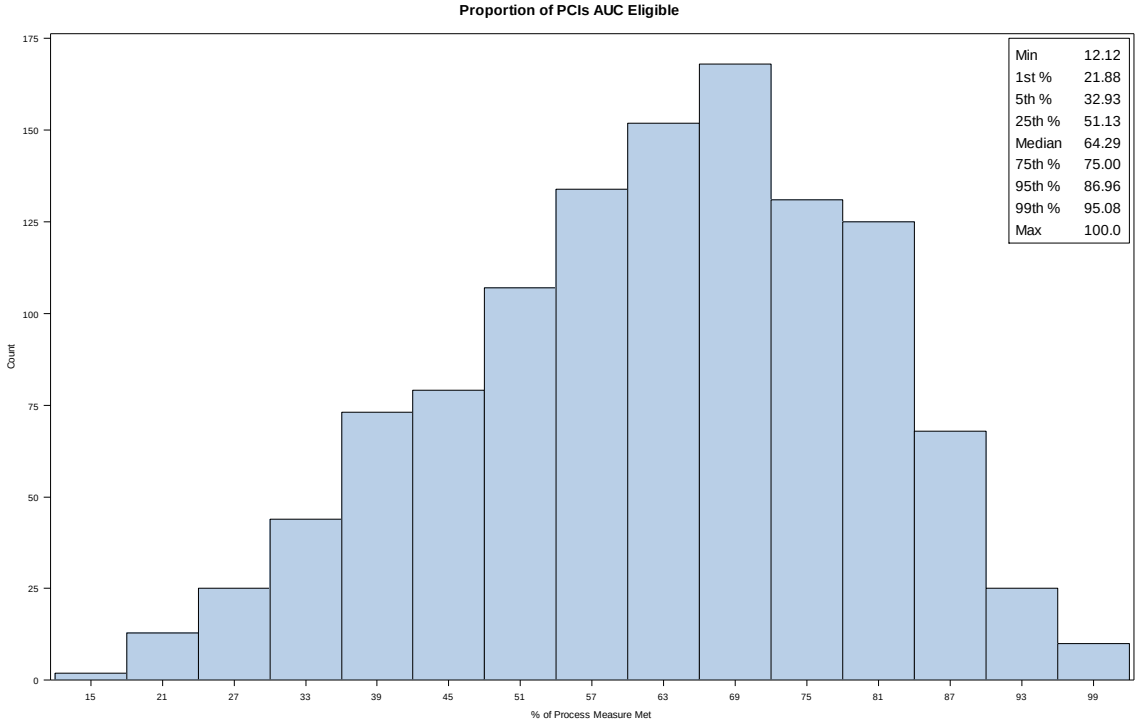

Figure 10: Histogram distribution of proportions of PCIs consider appropriate

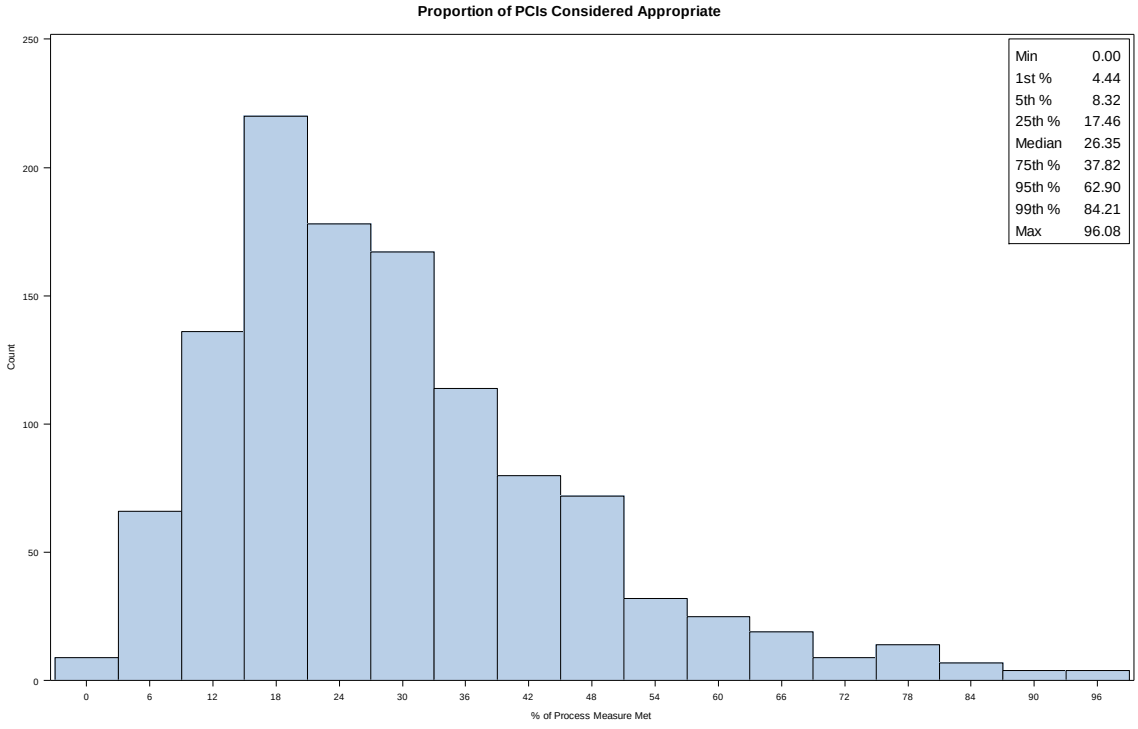

Figure 10: Histogram distribution of overall proportion of process measures met