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Impact of Cardiac Cath Lab Organization on Process and Outcome Quality: A Case Study

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Abstract.

Quality improvement must balance two conflicting objectives: process conformance and process re-engineering. Healthcare facility organization structure may favor one approach over the other. We examined whether cardiac cath labs that are *open* [permitting operators to work at other sites] or *closed* achieve faster door-to-balloon times [D2B] and lower in-hospital mortality. We used retrospective secondary data from the Massachusetts Department of Public Health on all 30,903 cath lab visits involving a percutaneous coronary intervention [PCI] in 4/1/03-12/31/04. Patient-level models were estimated for in-hospital mortality in all patients, and for D2B time in ST-segment elevation myocardial infarction [STEMI] patients, accounting for patient risk, hospital and operator PCI procedural volume.

The parameters of interest were the effects of a lab's closed status or the by the mean number of labs where an open lab's operators worked across. In unadjusted analyses, the patients of closed labs had lower in-hospital mortality (1.0% vs. 1.7%, P<.001), and their STEMI patients had longer median D2B times (96 vs. 73 minutes, P<.001). The more open a lab, the faster were D2B times and the higher the proportions of patients meeting D2b thresholds (trend, P<.001). Procedural experience was not consistently related to mortality outcomes. In adjusted analyses, STEMI patients of closed labs had lower odds of timely PCI <30 min (P<.05) and <60 min (P<.01); the more open a lab, the better the odds (all, P<.001). In hierarchical mixed models, STEMI patients continued to have lower odds of PCI <30 min (P=0.064) and <60 min (P<.05) the more open their labs were.

Patients of closed and less open cath labs in Massachusetts were less likely to receive timely PCI, but not more or less likely to die in hospital. Hospital and operator PCI experience was inconsistently associated with D2B times. This case study's findings support a broader search for the success factors of PCI quality beyond experience or site processes towards aspects of a lab's organization and staffing pattern.

INTRODUCTION

What should healthcare facilities learn and how should they go about it? The CEO of one large Boston hospital regularly articulated his organization's relentless focus on learning to improve safety and quality (Levy, 2010). However, such improvement efforts face a key conflict (Tucker and Edmondson, 2002). Hospitals must learn to standardize as much as possible to avoid variability. Yet on the other hand, they must intervene, address root causes and invent new approaches. The two goals thus trade-off conformance against experimenting and re-engineering.

Recognizing this paradox, organizations balance perfecting existing practices with learning new practices (March, 1991; Raisch et al., 2009). Binding constraints on time, human capital, financial capital and other resources, may cause the trade-off between conflicting learning objectives to be reflected in resource allocation and structure decisions. For example, some organizational designs should be better suited to one or the other learning objective (March and Simon, 1958; Williamson, 1991). In practice, healthcare organizations with similar objectives may reach divergent designs (Alexander et al., 1996; Burns and Thorpe, 1997).

In this case study, we explore the relationship between one aspect of organizational structure – physician staffing practices – and performance in cardiac catheterization laboratories [cath labs] performing percutaneous coronary interventions [PCI]. In cardiac care, the performance imperative is to reduce variability and improve the end outcome (Krumholz et al., 2007; Krumholz et al., 2008; Shailja et al., 2009). Outcome measurement (Douglas and Brindis, 2006) and process improvement are important precursors (Werner and Bradlow, 2006) of improved patient outcomes (Dehmer et al., 2004; Rathore et al., 2009).

Such collaborative process design efforts and inter-disciplinary team work have been shown to improve door-to-balloon [D2B] times (Bradley et al., 2006; Bradley et al., 2007) and

enhance evidence-based discharge therapy (Bradley et al., 2001). Much prior quantitative research has also focused on independent attributes of cardiologists (Artis et al., 2006) or hospitals (McNamara et al., 2006), especially in terms of procedural experience and its benefits (Smith et al., 2006) and how different combinations of operator experience or hospital experience might affect PCI outcomes (Ryan, 1995; Vakili and Brown, 2003). Surveys and other qualitative work such as case studies have also attempted to isolate the key factors that allow some hospitals to succeed in collaborative process design efforts and inter-disciplinary team work (Bradley et al., 2006; Bradley et al., 2007).

Yet to our knowledge, no prior research has examined the key organizational structure feature of whether the lab is 'open' or 'closed', and whether its cardiologists 'roam' or not. Anecdotally, a closed lab in which all operators only perform in that lab is thought to be the more effective model in producing quality outcomes. We review the clinical, management science and organizational literature and develop hypotheses for which design form is expected to be best suited to which type of organizational learning.

We test these hypotheses in a case study of all cath labs in Massachusetts using rich, clinically audited chart data of all PCI lab visits that occurred in every adult admission in Massachusetts between 4/1/2003 and 12/31/2004. Given the small, short panel, we aim to initiate a discussion in the field on an important, under-studied determinant of health care outcomes.

BACKGROUND

In this section we sketch a conceptual model (Figure 1) relating decisions on organization design and physician staffing practices with hospital performance. We summarize the key constructs and then develop our hypotheses.

PCI procedural and process success

Successful PCI (Smith et al., 2005) is defined in angiographic, procedural (no major in-hospital clinical complications) and clinical ways (persistent relief of signs and symptoms of myocardial ischemia for at least 6 months). One key procedural outcome is in-hospital *mortality* (Masoudi, 2007; Krumholz et al., 2008) which averages less than 1.5% in registry studies, and near 5% in ST-segment elevation myocardial infarction [STEMI] patients (Peterson et al., 2010). Procedural success in PCI is thought to be related to process success, in particular *rapid intervention* in STEMI patients following onset of symptoms (Brodie et al., 2001; McNamara et al., 2006).

Organizational capabilities and type of learning required

The interventional cardiologist develops *individual expertise* and works in concert with other physicians and multiple other front-line staff inside and outside the lab. A successful lab must therefore *coordinate internally* (e.g. scheduling, training, operational checklists) and also *coordinate externally* across the lab/hospital organizational boundaries. Collaborative efforts to enhance evidence-based processes of care improve outcomes in cath labs (Bradley et al., 2001; Bradley et al., 2006; Bradley et al., 2007) as well as intensive care (Gawande, 2007), and critical care (Hales and Pronovost, 2006).

To improve on PCI procedural and process measures labs may learn on two separate dimensions. One dimension reduces systematic variability by ensuring conformance to documented processes and roles documented in best practice guidelines. The other deliberately increases systematic variability by allowing and encouraging re-design of sub-optimal processes, roles and responsibilities. These dimensions may conflict, since ensuring conformance to a flawed process is as poor an organizational behavior as allowing tinkering with an optimized

process. Analogously, patching or papering over a broken system (Tucker and Edmondson, 2002) is a much more short-term solution than deep problem solving involving root cause analysis (McDuffie, 1997; Repenning and Sterman, 2002).

Interaction of PCI objectives, capabilities and organizational learning

Given the multi-factorial etiology underlying an unsuccessful procedure or adverse in-hospital clinical event, we conjectured that improving PCI in-hospital mortality would require all of the labs capabilities and both forms of learning. However, for the reduction of D2B times, we conjectured that the key capabilities were more likely to be external coordination between the lab and emergency department, and internal coordination within the lab (e.g. on-call staffing) rather than individual clinical expertise.[1] We postulated that the type of learning required for D2B reduction would tend more towards process conformance rather than reconfiguration.

Cath lab staffing practices

Cath lab physician staffing practices vary along a continuum from 'open' to 'closed' labs in which all physician operators are restricted to working just at that site. In an open lab, individual operators may rotate through one or more labs.

There is no guidance on how such differences in staffing practices might affect lab capabilities, moderate the lab's ability to learn, or ultimately affect PCI success. Organizational research on the impact of employee turnover suggests new employees allow the influx of new knowledge into an organization, particularly valuable when knowledge is not well-codified (March, 1991; Dokko and Rosenkopf, 2010; Pierce and Snyder, 2008). Work across multiple locations may thus allow physicians to acquire experience that benefits their patients at other

hospitals although there is no strong empirical evidence for (Huckman and Pisano, 2006) and scattered evidence against this (Carey et al., 2008).

<<FIGURE 1 ABOUT HERE>>

However, in open labs with many roaming cardiologists the operational complexity of the lab may increase. Coordination of tasks, technology and workers may suffer if familiarity with other team members is lower (Huckman, Staats and Upton, 2009). Familiarity with co-workers is an in important driver of psychological safety, so knowledge sharing may also be reduced (Siemsen et al., 2009). Similarly, coordination may suffer if there is decreased familiarity with organizational routines (Nelson and Winter, 1982) which embed knowledge of how to perform a task into codified repositories (Cohen and Levinthal 1990). For example, in settings such as front-line retailing where operations require high process conformance, employee turnover negatively impacts firm performance (Ton and Huckman, 2008).

Hypotheses

In line with prior research into the effect of human resources practices on industrial production (Ichniowski et al., 1997), we hypothesized that lab organization and design differences would support or obstruct the hospital's different PCI objectives. In particular, we conjectured that open labs would be more likely to facilitate the transfer of new ideas and the development of new individual expertise originating in other labs, while closed labs would be more likely to achieve high levels of process conformance and have enhanced coordination within and without the lab.

Based on our discussion of the different capabilities and types of learning required for achievement of the two PCI quality objectives of lowering mortality and hastening interventions, we therefore expected to observe the following:

***H_1**: In-hospital PCI mortality will not differ by physician staffing practices.*

***H_{2a}**: Door-to-balloon times will be faster in closed labs than in open labs.*

***H_{2b}**: Door-to-balloon times will be faster in less open labs than in more open labs.*

ANALYTICAL STRATEGY

Patient population

Our case study data were obtained from the Massachusetts Department of Public Health,[2] and included all 30,903 distinct visits to a cath lab for a percutaneous coronary intervention performed during 29,808 distinct admissions on 26,397 distinct patients aged 18 years or older in Massachusetts state-regulated acute care hospitals between April 1, 2003 and December 31, 2004.[3] Mass-DAC, the administrator of the data, collects and audits the data using ACC-NCDR version 2.0 and 3.0 forms.

Dependent Variables

We measured *intervention timeliness* for STEMI patients for their first lab visit during their admission, using the continuous variable of D2B in minutes or dichotomous indicators of D2B

time <30, <60 or <90 minutes.[4] We included incoming transfer patients and perform additional sensitivity analyses to understand the impact of differences in the proportion of transfer patients at a lab (Nallamothu et al., 2007).All patients had *in-hospital mortality* measured.

Control Variables

We extracted 38 demographic, pre-visit co-morbidities, clinical factors and angiographic covariates (Peterson et al., 2010; Douglas et al., 2009; Anderson et al., 2007), and year of admission. The Mass-DAC data were highly complete. We set all missing binary elements in the patient's past medical history to 'no' or 'not present'. We used single imputation methods to impute values for BMI, using the gender-specific median. We employed a different approach for missing values of ejection fraction (Peterson et al., 2010).[5] We validated discrimination of this data in a conventional logistic regression on in-hospital death (see Supplementary Material), and found a C-index of 0.93 in line with other recent investigations using ACC-NCDR data (Peterson et al., 2010). All control variables are used in all models.

Statistical Analyses

The central hypotheses of this study posit different procedural and process outcomes for different patients based on the closed/open staffing characteristics of the cath lab in which they underwent PCI. To operationalize this, we specified a multivariate adjusted logistic relationship between the focal independent variables $STAFFING_i$ and the dependent variable y_i for each patient indexed i, receiving PCI at cath lab h, performed by operator c:

$$y^*_{ich} = \alpha + \beta\, STAFFING_i + \gamma_1 X_i + \gamma_2 X_c + \gamma_3 X_h + \delta_{\cdot} + \varepsilon_i\,; \qquad \varepsilon_i \sim \Lambda(0, \pi^2/3)$$

$$Pr\{y_{ich} = 1 \mid covariates\} = Pr\{ y^*_{ich} > 0\} = \alpha + \beta\, STAFFING_i + \gamma_1 X_i + \gamma_2 X_c + \gamma_3 X_h + \delta_t)$$

We controlled for independent patient X_i risk factors at the time of admission, described further below. We also controlled for operator X_c and cath lab X_h factors such as number of operators practicing at the lab and individual procedural experience that might moderate the relationship of interest (Silber et al., 2010). To compute these, we used the stabilized average monthly PCI caseload observed over operator or lab panel participation.

The *STAFFING* variables were defined in two ways and used in separate analyses. First, we constructed a binary indicator for closed labs by identifying labs in which all their operators were observed to work only at that lab during the case study period. Second, since most labs were open and differed in the extent to which they were open, we also constructed a continuous measure at the lab level which represented the average number of hospitals at which a lab's operators worked to capture the extent of openness of most of the labs. Individual operators worked up to a total of 5 labs. Aggregated at the cath lab level, the continuous measure of lab openness ranged from 1 (i.e. closed) through 2.5 in our data.

We expect correlation of outcomes within operators or labs, and specify robust standard errors in conventional logistic regressions allowing for this clustering by operators or by labs. In hierarchical mixed models we separately add random effects at the operator or lab level entering the procedural volume covariates and *STAFFING* variables as fixed effects and adding random intercepts for the cath labs (Peterson et al., 2004; Austin et al., 2004; Silber et al., 2010).[6]

We used two-tailed tests of significance throughout, made no correction for multiple comparisons (Rothman, 1990) and considered $P<0.05$ to be statistically significant. The health system institutional review board at [the authors' institution] approved this study.

FINDINGS

The 14 non-pilot hospitals examined in this case study had a mean monthly PCI procedural volume of 104.5 (range 29.6 – 172.9), while the 128 PCI operators studied had a mean monthly PCI procedural volume (including at pilot program hospitals) of 12.4 (range 1.0 – 49.6).[7] We report the distribution of procedural volume in detail in the Supplemental Material and show the absence of a consistent relationship of lab and operator procedural experience with process and procedural outcomes. There is substantial crossing of operators with hospitals: 38 of the 128 operators worked across 2 or more sites. A large number of hospitals have multiple distinct operators on site over the course of the study: 9 hospitals have more than 10 distinct operators performing PCI in their labs.

<<TABLE 1A ABOUT HERE>>

In Table 1a we describe the demographic, comorbidity, cardiac status and angiographic characteristics of the PCI patients, categorized by whether or not the lab was completely closed. In the left columns we show data on all patients, and on the right for just STEMI patients. On most clinically relevant variables, the labs differed significantly by staffing practice. Closed labs saw a higher proportion of sicker patients but had more benign angiographic features with a lower proportion of patients with SCAI IV lesions, left main disease or significant proximal left anterior descending lesions.[8]

Closed labs tended to be significantly less busy than open labs, had slightly fewer operators on service, and their operators tended to perform fewer PCI than the operators of labs which were not closed. Overall, labs that were open had operators who rotated through 1.7 labs

in total; the same statistic is by definition 1 for closed labs. Associated with the different staffing practices, the lower panel of Table 1a shows unadjusted process and procedural outcomes. Compared to open labs, closed labs had 24 minutes longer median D2B time, and a 1.7% point lower unadjusted in-hospital mortality rate. Results for STEMI patients only are similar (Table 1a, right-hand columns; see Supplementary Material for additional results).

In Table 1b we show the generally increasing and highly significant trend of longer median D2B time as the lab becomes progressively more closed, culminating in the 96 minutes time in a completely closed lab. The patients of closed labs are far more likely to fail to receive PCI within even 450 minutes (19% vs. 5.0 – 12.6% for variously open labs, trend, P<.001). Figure 2 plots these gradients for achievement of the < 30, < 60 and < 90 min thresholds, again on unadjusted measures. These unadjusted analyses thus fail to reject H1, while presenting evidence against H_{2a} and H_{2b}.

<<TABLE 1B AND FIGURE 2 ABOUT HERE>>

Adjusted Analyses

In Table 2 we report the marginal effects of the key *STAFFING* variables, controlling for patient risk (estimates suppressed) and procedural volume by operator and lab to control for possible learning or scale effects independent of lab staffing practices. In the top panels of Table 2 we show the estimates of staffing practices on D2B < 30 min, < 60 min and < 90 min. In the bottom panel we report the effect on in-hospital mortality.

In our preferred specifications accounting for likely clustering of patient-level disturbances by hospital we again find evidence against both H_{2a} and H_{2b}, but fail to reject H_1.

The binary indicator for a closed lab was associated with a significant reduction in the likelihood of STEMI patients receiving PCI within 30 minutes (adjusted odds ratio [OR] 0.40, P<.05) or within 60 minutes (OR 0.56, P<.01). Using a continuous measure of the extent to which a lab is open showed that a large increase by 1 in the mean number of labs that a lab's operators rotate through was associated with more than doubling of the odds of timely PCI (all, P<.001). No marginal impacts on in-hospital mortality were found. Table 2 also shows the lack of substantial impact of lab or operator procedural experience on process or mortality outcomes (see Supplementary Material for additional results).

<<TABLE 2 ABOUT HERE>>

Sensitivity Analyses

We subjected our analyses to several sets of sensitivity analyses to understand the robustness of our specification, identification and estimation strategies.

In unreported analyses, we specified a relationship between the predictors of interest and various quantiles of the D2B times for STEMI patients. Using multivariate adjusted quantile regression, a binary indicator for a closed lab was associated with an increase of 26.9 minutes in the median D2B time (P<.001), 16.1 minutes in the fastest quartile (P<.001), and 12.4 minutes in the slowest quartile of D2B times (P<.05).

Using the continuous measure of the extent of lab openness, an increase by 1 in the mean number of labs that a lab's operators rotated through was associated with a reduction in the median D2B time by 34.1 minutes, the fastest quartile by 19.6 minutes, and the slowest quartile

by 32.6 minutes (all, P<.001). These alternative specifications thus yielded results similar to the earlier logistic regressions on thresholds of D2B times.

In other unreported analyses, we specified a multivariate adjusted linear probability model for the event of in-hospital death for all admission in a non-pilot hospital. Specifying Huber-White sandwich estimated robust standard errors, a closed lab was associated with a reduction in the probability of death by 0.45% points (P<.05), while an increase by 1 in the mean number of labs that a lab's operators rotated through was associated with an increase in the probability of death by 0.42% points (P<.05). Specifying cluster-robust standard errors to account for likely clustering of patient outcomes within labs, the point estimate on closed labs remained significant at P<.05, but the estimate of an increase in openness was no longer significant at conventional levels (P=.149).

We also considered that differences in the proportion of transfer patients could confound our analyses of the impact of staffing practices. Transfer patients have a greater elapsed time from first presentation at the source hospital to cath lab procedure at the recipient hospital (Gibson et al., 2008). However, the D2B performance measure only commences on arrival at the destination hospital, by which time data acquisition and lab activation may already have occurred. Accordingly we expect and find lower D2B times for transfer patients compared to ED admissions and referrals (median 56 vs. 93 minutes, P<.001).

<<TABLE 3 ABOUT HERE>>

In our data, closed labs had significantly fewer transfer patients than open labs (51.8% vs. 56.1%, P<.05), and we were concerned that staffing variables might be spuriously correlated

with these differences. Accordingly, we re-estimated conventional logistic regressions with robust standard errors on non-transfer and transfer STEMI patients separately (Table 3) but found very similar results across the different samples.

Our identification strategy relies on cross-sectional variation in staffing variables, so is not immune to unmeasured confounding. To ascertain the sensitivity of our results to one type of time-invariant unmeasured confounding at the hospital or operator level, we specified hierarchical mixed models whose fixed part was identical to the conventional logistic models in Table 2, but adding random intercepts for the hospitals or operators (Pietz et al., 2002; Bronskill et al., 2002; Ferraris et al., 2008).

We note that the assumptions required for consistent estimation of these models may not be fully met in our data. In particular, there are not many clusters, and in one small state the patient-level disturbances may not be completely uncorrelated across hospitals.

<<TABLE 4 ABOUT HERE>>

Nevertheless, using the hierarchical models to control for such unmeasured confounding had small effects on the point estimate magnitudes, but greatly expanded the confidence intervals for the estimates of interest (Table 4). Unobserved factors that were correlated with staffing variables appear to have had independent impacts on process and procedural success. Controlling for these rendered the previously precisely estimated impacts of closed lab status insignificant, and reduces the significance level of the continuous measure of openness from P<.001 to P<.10 and P<.05 respectively for the key < 30 minute and < 60 minute thresholds.

DISCUSSION

We had expected that closed cath labs would achieve faster door-to-balloon times, while not differing on in-hospital mortality compared to open labs. These hypotheses were informed by organizational learning research in other industries, research into the types of quality improvement, and institutional detail on lab capabilities required for PCI success

Unexpectedly, our process success hypothesis was rejected. Rather than achieving faster D2B times, closed labs had worse intervention timeliness. This result was confirmed when using a continuous measure of openness. We found a gradient in which more open labs had faster D2B times than less open labs. In-hospital mortality did not differ meaningfully or consistently with staffing practices, supporting our procedural success hypothesis.

To explicate these results, we return to the conceptual model of Figure 1. With respect to achieving faster D2B times, we had argued that the team capabilities of coordination within and beyond the boundaries of the lab would be more important that individual expertise, and that the type of learning which seeks to reduce variability would be more important than that which supports experimentation. Closed labs – in our judgment – would have supported those capabilities and that type of learning and would thus drive process success.

Our failure to find empirical support for this could be due to limitations in our data and analytical strategy discussed below. Alternatively, one or more of the following three explanations may underlie our unexpected results. First, the assumed development of individual expertise that may result from operator rotation through other clinical settings may be more important than we had thought. Second, the assumed lack of familiarity with lab knowledge and hospital staff among operators in open labs may not be sufficiently adverse to affect coordination capabilities.

Third, if it is more important to intervene and change a flawed process than to ensure conformance with it, then an open lab with physicians who work at other labs, have a wider set of comparators, and have less institutional pressure to conform with an existing practice may do better than closed labs. Any of these possible explanations – if supported by additional studies – have clear implications for quality improvement.

In our ancillary results we failed to find consistent evidence procedural volume effects. Similar non-linearity in relationships between volumes and process compliance has been found more generally (Williams et al., 2008), as has heterogeneity in outcomes among cath labs of similar size, suggesting that site volume alone is an insufficient proxy for quality (Epstein et al., 2004). Since some of these strategies involve discrete events such as having an attending cardiologist on site at all times (Bradley et al., 2006), continuous relationships between procedural volumes and outcomes are less likely to be identified in quantitative analyses.

Limitations

Our case study has a number of important limitations. Most fundamentally, validity is restricted to one small state over a short period. Second, our data did not permit evaluation of clinical success such as follow-up for revascularization for restenosis, or longer-term mortality and major morbidity endpoints. Third, we have made a number of key assumptions in specifying the relationship between key predictors and outcomes, in our identification strategy, and in our modes of inference. We acknowledge that each has drawbacks, but undertook a number of sensitivity analyses to ascertain robustness of results to some of these assumptions.

We did not control for possible reverse causation or other time-varying unmeasured confounding. If patients are preferentially drawn to particular sites or operators based on

(unobserved) factors that are correlated with provider quality or ability then our results would be biased. However, we judged it less likely that patients or emergency medical services transports are systematically aware of door-to-balloon times, for example, and do or can use such information to make decisions about site options.

Of equal concern, if cath lab staffing practices are a response to existing process problems, then a closed lab could be a *consequence* instead of a cause of performance. The consistent 'dose response' gradient seen with the continuous measure of openness mitigates this concern somewhat: it seems unlikely that lab and hospital management as well as lab operators could coordinate on and calibrate the degree of openness of their lab with its particular performance level. However in a dataset which lacks exogenous sources of changes in lab staffing patterns and lacks plausibly exogenous measures of procedural experience, we are not able to rule out omitted variable biases.

Fourth, we do not know how long elapsed between the patient's first onset of symptoms and arrival at the door (Brodie et al., 2001). While there is a well-established direct link between improved D2B and survival (McNamara et al., 2006), we observed little correlation in our data. It is thus possible that some patients of labs with lengthier D2B times may not be 'penalized' for this since they present *outside* myocardial preservation windows. Finally, we did not have data on other members of the care team on the emergency department to lab pathway or on members of intersecting processes of care.

Conclusions

Our case study within one small state over a short period of time nevertheless raises important and novel questions about the relationship between an under-examined lab organizational design

feature and PCI success. Most research in this field has focused on the impact of lab and operator experience, on processes of care and on conformance of practice with evidence-based clinical guidelines (Smith et al., 2006). The present study supports the recent call for qualitative analyses to investigate complex relationships that are not completely amenable to quantitative analysis alone (Curry et al., 2009) but may be discovered through surveys (Krumholz et al., 2009; Bradley et al., 2005; Bradley et al., 2006), and case studies (Pisano et al., 2001).

Whether and how lab structure and staffing patterns affect process and procedural success will require much further research to definitively answer. Such future research must continue to seek those factors that characterize all successful hospitals, without allowing the many differences across hospitals to obscure what can, in fact, be done to improve patient care.

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Disclosures

The Confidential Data Officer of the Privacy and Data Access Office at the Massachusetts Department of Public Health, and anonymous other reviewers within the Department and/or Mass-DAC reviewed and approved this draft before submission for compliance with all provisions of the authors' data use agreement. There was no editorial review nor any influence on the decision to submit. No other disclosures reported.

ENDNOTES

[1] For example, angiographic and procedural success *after* balloon insertion cannot causally be related to the length of pathway between ambulance, emergency department and lab.

[2] The Confidential Data Officer of the Privacy and Data Access Office at the Massachusetts Department of Public Health, and anonymous other reviewers within the Department and/or Mass-DAC reviewed compliance with all provisions of the authors' data use agreement. There was neither editorial review nor any influence on the decision to submit.

[3] We excluded all 353 patient records belonging to 7 community hospitals with pilot programs.

[4] Subsequent lab visits during admission were excluded as D2B coding was inconsistent.

[5] We stratified the lab visits by history of congestive heart failure, prior myocardial infarction, pre-procedural cardiogenic shock and STEMI. For each of the 16 combinations of these 4 binary elements we calculated the median ejection fraction and used this to impute missing values of ejection fraction for records in each stratum.

[6] We used likelihood ratio χ squared tests to understand whether adding the controls for hospital-level clustering added explanatory power to the model beyond conventional logistic regression. All likelihood ratio tests for reported models were significant at $P<.001$.

[7] Mean panel participation by physicians was 17.4 months; 81 were observed in all 21 months.

[8] We used non-parametric Kruskal-Wallis tests for continuous variables and χ squared tests to examine differences in categorical variables and in tests for independence between rows and columns in tables with categorical variables.

Figure 1: Conceptual Model

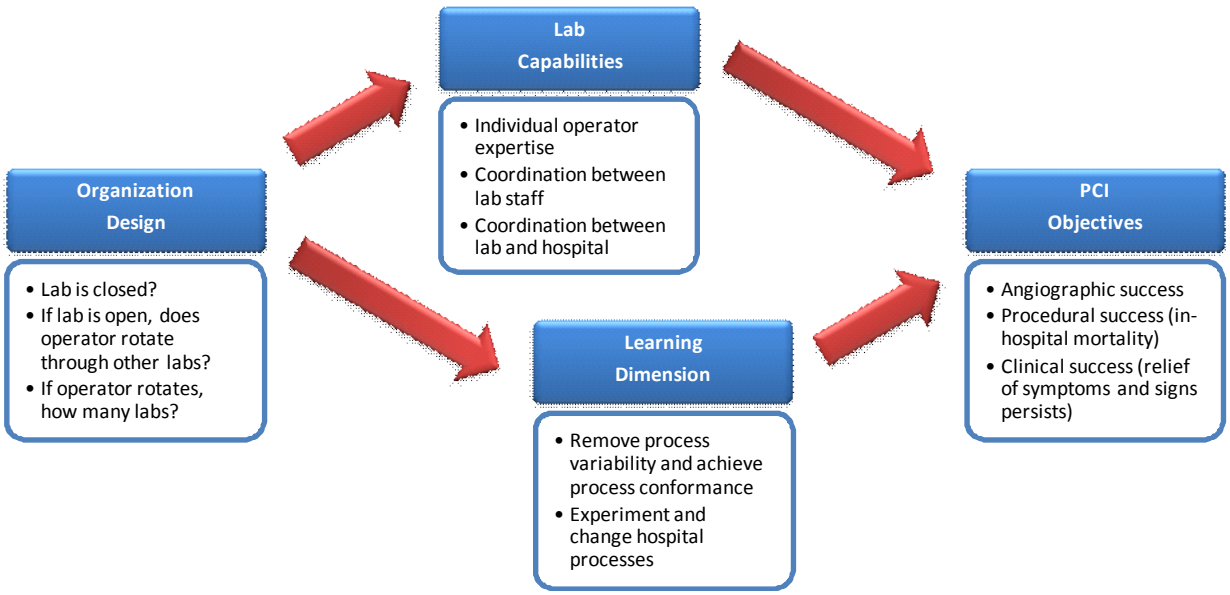

Table 1a: Summary statistics for all and STEMI patients, by open/closed lab

	All PCI recipients				STEMI only			
	Open	Closed	All labs		Open	Closed	All labs	
PCI, cases	27,159	3,391	30,550		4,231	778	5,009	
of which first lab visit in admission	26,165	3,292	29,457		3,941	733	4,674	
Age, yr, median	65.0	64.0	65.0	***	61.0	60.0	61.0	*
Female	31.4	31.7	31.5		30.0	29.1	29.8	
Caucasian	90.3	88.9	90.1	**	88.9	85.1	88.3	**
BMI, value, median	28.2	28.4	28.3		27.6	27.8	27.6	
CHF, current	10.7	7.7	10.4	***	10.1	10.4	10.2	
CHF, past	12.2	7.2	11.7	***	6.4	4.1	6.0	*
DM, no insulin	19.8	18.9	19.7		13.5	14.5	13.7	
DM, insulin	10.5	8.4	10.3	***	5.7	6.2	5.8	
CRF, past dialysis	1.6	1.7	1.6		0.9	0.6	0.9	
CRF, past, no dialysis	5.6	3.9	5.4	***	3.3	2.2	3.2	¶
Chronic lung disease	11.2	11.4	11.2		9.3	10.0	9.4	
Cerebrovascular disease	9.2	9.7	9.2		6.2	7.2	6.4	
Peripheral vascular disease	14.3	9.8	13.8	***	7.3	4.9	7.0	*
MI, past, > 7 days ago	31.6	32.5	31.7		17.2	19.9	17.6	¶
Lipidemia, treated	68.4	57.3	67.2	***	39.7	32.9	38.6	***
Prior PCI	32.2	26.0	31.5	***	15.4	12.7	15.0	¶
Prior CABG	16.5	12.4	16.0	***	4.7	4.1	4.6	
Prior valve surgery	1.1	0.7	1.0	*	0.4	0.4	0.4	
ACS Class 4	31.9	48.2	33.7	***	76.9	89.9	78.9	***
STEMI	15.6	22.9	16.4	***				
IABP on lab arrival	0.5	0.6	0.5		1.4	1.3	1.3	
CP bypass on lab arrival	0.5	0.2	0.5	**	1.5	0.1	1.3	**
Cardiogenic shock at PCI	1.8	1.7	1.8		8.5	5.9	8.1	*
Urgent PCI	39.9	32.3	39.0	***	16.7	21.9	17.5	**
Emergent PCI	15.6	20.6	16.2	***	76.9	72.4	76.2	**
Salvage PCI	0.2	0.0	0.2	**	1.2	0.0	1.0	**
Highest SCAI lesion risk IV	11.1	8.4	10.8	***	31.1	19.2	29.2	***
LVEF, fraction, median	55.0	55.0	55.0		50.0	50.0	50.0	
Left main disease	7.1	3.9	6.8	***	4.3	3.6	4.2	
Significant pLAD stenosis	34.6	26.9	33.7	***	33.5	26.6	32.4	***
Hospital monthly PCI cases, median	149.6	117.3	148.1	***	148.1	117.3	148.1	***
Number of operators at site, median	12.0	10.0	11.0	***	11.0	10.0	11.0	***
Operator monthly PCI cases, median	18.1	14.5	16.5	***	17.9	14.1	16.1	***
Mean # sites their operators work across	1.7	1.0	1.6	***	1.7	1.0	1.6	***
Door to balloon time†, minutes, median	72.7	96.0	76.5	***	72.2	96.0	76.0	***
D2B threshold								
< 30 min	2.0	1.2	2.0	**	13.6	5.3	12.3	***
< 60 min	6.3	6.1	6.3		42.0	27.4	39.7	***
< 90 min	8.9	10.5	9.1	**	59.1	47.1	57.2	***
In-hospital mortality	1.7	1.0	1.6	**	5.7	2.4	5.2	***

Patient-weighted means in % unless otherwise indicated. Excludes 355 records at 7 pilot hospitals with PCI-only STEMI programs. Comparison of open and closed lab statistics significant at (***) <.001, (**) <.01, (*) <.05 and (¶) <.10 *p*-values. (†) All door-to-balloon times and thresholds restricted to first lab visit during admission.

Table 1b: Door-to-balloon statistics for STEMI patients, by degrees of openness

	Extent of openness (mean number of sites that a lab's operators rotate through)						
	2.50-2.00	1.99-1.75	1.74-1.50	1.49-1.25	1.24-1.01	1 (Closed)	Trend
Mean openness, #	2.13	1.91	1.66	1.39	1.18	1	
Cases, #	820	523	1,550	782	235	727	
D2B, minutes, median	63.7	70.0	65.3	94.0	91.5	96.0	***
D2B threshold, %							
< 30 min	14.0	17.6	16.0	8.4	4.2	5.3	***
< 60 min	45.9	47.1	46.4	30.8	24.6	27.4	***
< 90 min	68.9	61.3	60.7	47.6	47.9	47.1	***
> 450 min	5.4	5.0	12.6	8.7	5.9	19.0	***

Patient-weighted statistics, includes only STEMI patients at non-pilot hospitals on their first lab visit during an admission for PCI. (***) indicates tests for trend across D2B statistics significant at *p*-value <.001.

Figure 2: Gradient of door-to-balloon statistics by degrees of openness

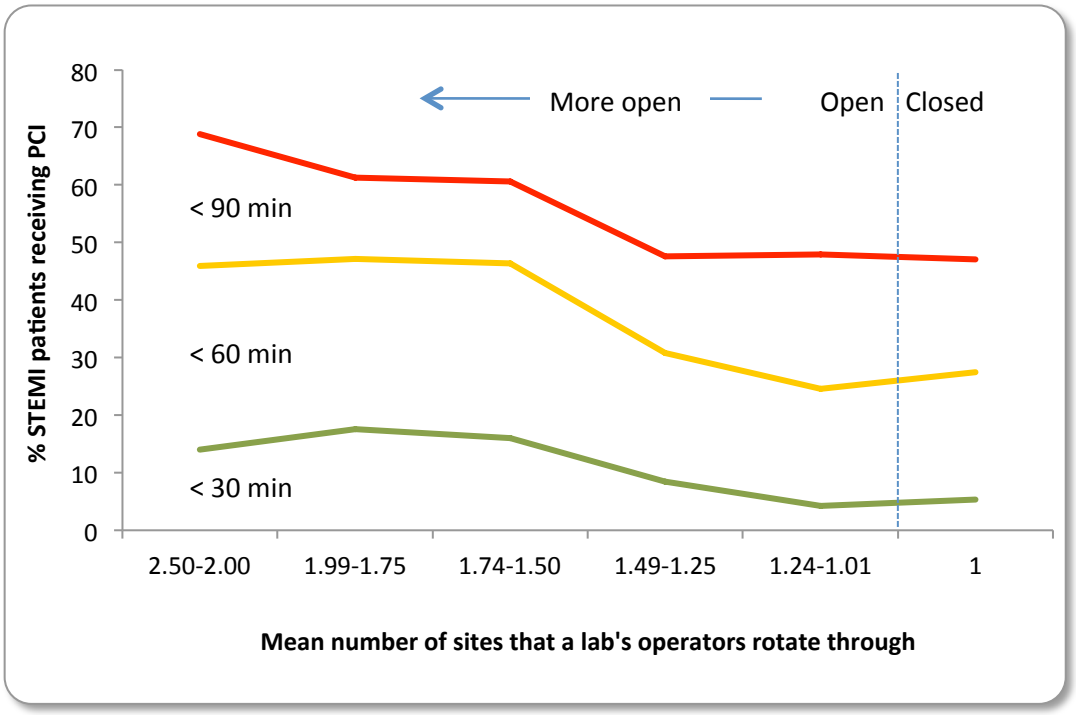

Table 2: Conventional logistic regression on binary and continuous staffing variables

	Conventional logistic regression			
	Binary measure of closed lab		Cts measure of open lab	
	Robust s.e., clustered by operator	Robust s.e., clustered by hospital	Robust s.e., clustered by operator	Robust s.e., clustered by hospital
STEMI only, D2B < 30 min				
Hospital PCI, monthly cases	1.01 ** (1.00-1.01)	1.01 (1.00-1.01)	1.01 *** (1.00-1.01)	1.01 * (1.01-1.02)
Operator PCI, monthly cases	0.97 ** (0.96-0.99)	0.97 * (0.95-1.00)	0.98 * (0.96-1.00)	0.98 ¶ (0.95-1.00)
Lab is closed	0.40 *** (0.24-0.65)	0.40 * (0.19-0.82)		
Mean number of sites that operators at lab rotate through			3.40 *** (2.17-5.34)	3.40 *** (1.78-6.52)
< 60 min				
Hospital PCI, monthly cases	1.00 * (1.00-1.01)	1.00 (1.00-1.01)	1.01 *** (1.00-1.01)	1.01 * (1.00-1.01)
Operator PCI, monthly cases	0.99 * (0.98-1.00)	0.99 ¶ (0.97-1.00)	0.99 ** (0.98-1.00)	0.99 * (0.98-1.00)
Lab is closed	0.56 *** (0.42-0.73)	0.56 ** (0.36-0.86)		
Mean number of sites that operators at lab rotate through			2.63 *** (2.00-3.45)	2.63 *** (1.70-4.05)
< 90 min				
Hospital PCI, monthly cases	1.00 (1.00-1.00)	1.00 (0.99-1.01)	1.00 (1.00-1.00)	1.00 (1.00-1.01)
Operator PCI, monthly cases	1.00 (0.99-1.01)	1.00 (0.98-1.01)	1.00 (0.99-1.00)	1.00 (0.99-1.01)
Lab is closed	0.66 * (0.47-0.92)	0.66 (0.35-1.26)		
Mean number of sites that operators at lab rotate through			2.34 *** (1.71-3.20)	2.34 *** (1.38-3.98)
All patients, died in-hospital				
Hospital PCI, monthly cases	1.00 (1.00-1.00)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	1.00 (1.00-1.00)
Operator PCI, monthly cases	1.00 (0.98-1.01)	1.00 (0.98-1.01)	1.00 (0.98-1.02)	1.00 (0.98-1.02)
Lab is closed	0.65 (0.36-1.17)	0.65 ¶ (0.42-1.03)		
Mean number of sites that operators at lab rotate through			1.40 (0.90-2.19)	1.40 (0.88-2.24)

Conventional logistic regression with multivariate adjusted odds ratios (95% CI), significantly different from 1 at p values of (***) <.001, (**) <.01, (*) <.05, and (¶) <.10.. Controls (see Table 1) suppressed.

Table 3: Inclusion and exclusion of transfer-in patients

	Conventional logistic regression with robust s.e.					
	Binary measure of closed lab			Cts measure of open lab		
	All STEMI	Transfer only	Non-transfer only	All STEMI	Transfer only	Non-transfer only
STEMI only, D2B < 30 min						
Lab is closed	0.40 *** (0.28-0.56)	0.41 *** (0.28-0.61)	0.33 * (0.14-0.77)			
Mean number of sites that operators at lab rotate through				3.40 *** (2.54-4.55)	3.19 *** (2.25-4.52)	4.80 *** (2.48-9.49)
< 60 min						
Lab is closed	0.56 *** (0.46-0.67)	0.62 *** (0.49-0.80)	0.45 *** (0.32-0.64)			
Mean number of sites that operators at lab rotate through				2.63 *** (2.20-3.14)	2.49 *** (1.94-3.19)	3.05 *** (2.26-4.13)
< 90 min						
Lab is closed	0.66 *** (0.55-0.79)	0.69 ** (0.54-0.89)	0.67 ** (0.52-0.86)			
Mean number of sites that operators at lab rotate through				2.34 *** (1.97-2.78)	2.67 *** (2.06-3.45)	2.00 *** (1.57-2.54)

Conventional logistic regression with multivariate adjusted odds ratios (95% CI), significantly different from 1 at p values of (***) <.001, (**) <.01, and (*) <.05. Controls and procedural experience covariates suppressed. STEMI patients with first lab visit during PCI admission at non-pilot hospital.

Table 4: Hierarchical mixed model regressions on binary and continuous staffing variables

	Hierarchical logistic regression			
	Binary measure of closed lab		Cts measure of open lab	
	Random effects for operator	Random effects for hospital	Random effects for operator	Random effects for hospital
STEMI only, D2B < 30 min				
Hospital PCI, monthly cases	1.01 ** (1.00-1.01)	1.01 (1.00-1.02)	1.01 *** (1.00-1.01)	1.01 (1.00-1.02)
Operator PCI, monthly cases	0.98 (0.96-1.01)	1.00 (0.98-1.02)	0.98 (0.96-1.01)	1.00 (0.98-1.02)
Lab is closed	0.45 * (0.24-0.84)	0.74 (0.17-3.23)		
Mean number of sites that operators at lab rotate through			3.64 *** (2.20-6.02)	2.90 ¶ (0.94-8.94)
< 60 min				
Hospital PCI, monthly cases	1.01 *** (1.00-1.01)	1.00 (1.00-1.01)	1.01 *** (1.00-1.01)	1.00 (1.00-1.01)
Operator PCI, monthly cases	0.99 (0.97-1.00)	1.00 (0.99-1.01)	0.99 (0.98-1.01)	1.00 (0.99-1.01)
Lab is closed	0.58 ** (0.40-0.85)	0.74 (0.28-1.97)		
Mean number of sites that operators at lab rotate through			2.83 *** (2.12-3.79)	2.38 * (1.16-4.88)
< 90 min				
Hospital PCI, monthly cases	1.00 * (1.00-1.01)	1.00	1.00 *** (1.00-1.01)	1.00 (0.99-1.01)
Operator PCI, monthly cases	1.00 (0.98-1.01)	1.01 ** (1.00-1.02)	1.00 (0.98-1.01)	1.01 * (1.00-1.02)
Lab is closed	0.68 ¶ (0,45-1.03)	1.10 (0.38-3.15)		
Mean number of sites that operators at lab rotate through			2.59 *** (1.88-3.56)	1.83 (0.79-4.26)
All patients, died in-hospital				
Hospital PCI, monthly cases	1.00 (1.00-1.00)	1.00 (1.00-1.00)	1.00 (1.00-1.00)	1.00 (1.00-1.00)
Operator PCI, monthly cases	1.00 (0.99-1.02)	1.00 (0.98-1.01)	1.01 (0.99-1.02)	1.00 (0.98-1.01)
Lab is closed	0.60 * (0.37-0.96)	0.66 (0.37-1.15)		
Mean number of sites that operators at lab rotate through			1.47 * (1.00-2.17)	1.37 (0.85-2.20)

Hierarchical mixed models with multi-variate adjusted odds ratios (95% CI), significantly different from 1 at p values of (***) <.001, (**) <.01, (*) <.05, and (¶) <.10. Controls (see Table 1), variance of random effects suppressed. All likelihood ratio tests against conventional logit significant at p <.01.

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SUPPLEMENTAL MATERIAL

Appendix 1: Risk model

Appendix 2: Lab visits by year by hospital

Appendices 3-6: Procedural volume detail

Appendix 7: Unadjusted D2B times for STEMI patients, by hospital and operator volume

Appendix 8: Unadjusted D2B times for STEMI patients, by hospital and operator volume

Appendix 9: Door-to-balloon times, D2B thresholds, and in-hospital mortality performance

Appendix 10: Door-to-balloon interval detail in STEMI patients

Appendix 1: Risk model for calculated expected mortality

	Logit regression on in-hospital mortality		
	OR	95% CI	
Age, yr	1.052	(1.042-1.063)	*
Female, %	1.175	(0.946-1.458)	
Caucasian, %	0.813	(0.587-1.125)	
BMI, value	0.986	(0.967-1.005)	
CHF, current, %	1.538	(1.190-1.988)	†
CHF, past, %	1.068	(0.797-1.430)	
DM, no insulin, %	1.327	(1.016-1.733)	‡
DM, insulin, %	1.787	(1.300-2.457)	*
CRF, past dialysis, %	2.505	(1.484-4.227)	†
CRF, past, no dialysis, %	1.983	(1.458-2.696)	*
Chronic lung disease, %	1.634	(1.256-2.125)	*
Cerebrovascular disease, %	1.232	(0.923-1.644)	
Peripheral vascular disease, %	1.267	(0.969-1.656)	
MI, past, > 7 days ago, %	1.141	(0.881-1.476)	
Lipidemia, treated, %	0.613	(0.482-0.779)	*
Lipidemia, untreated, %	0.552	(0.369-0.827)	†
Prior PCI, %	0.926	(0.709-1.209)	
Prior CABG, %	0.770	(0.560-1.059)	
Prior valve surgery, %	2.599	(1.309-5.163)	†
ACS Class 1, %	2.740	(1.029-7.296)	‡
ACS Class 2, %	0.701	(0.286-1.717)	
ACS Class 3, %	0.929	(0.605-1.428)	
ACS Class 4, %	1.250	(0.824-1.896)	
IABP on lab arrival, %	1.375	(0.764-2.473)	
CP bypass on lab arrival, %	3.684	(2.068-6.563)	*
LVEF, value	0.979	(0.970-0.989)	*
Left main disease, %	1.652	(1.218-2.240)	†
Significant pLAD stenosis, %	1.242	(1.004-1.536)	
Cardiogenic shock at PCI, %	8.189	(6.152-10.90)	*
Urgent PCI, %	2.719	(1.821-4.060)	*
Emergent PCI, %	6.668	(4.312-10.31)	*
Salvage PCI, %	44.99	(20.37-99.36)	*
Highest SCAI lesion risk II %	1.516	(1.127-2.041)	†
Highest SCAI lesion risk III, %	2.252	(1.635-3.103)	*
Highest SCAI lesion risk IV, %	2.408	(1.803-3.217)	*
Admitted 2004, %	0.934	(0.759-1.150)	

N = 30545 PCI lab visits, excluding pilot program labs.

Pseudo-R2 = 36.2%; C-index = 0.928

* P <0.001

† P <0.01

‡ P <0.05

Appendix 2: Cath lab procedural volume, number of operators and mean number of labs where their operators worked

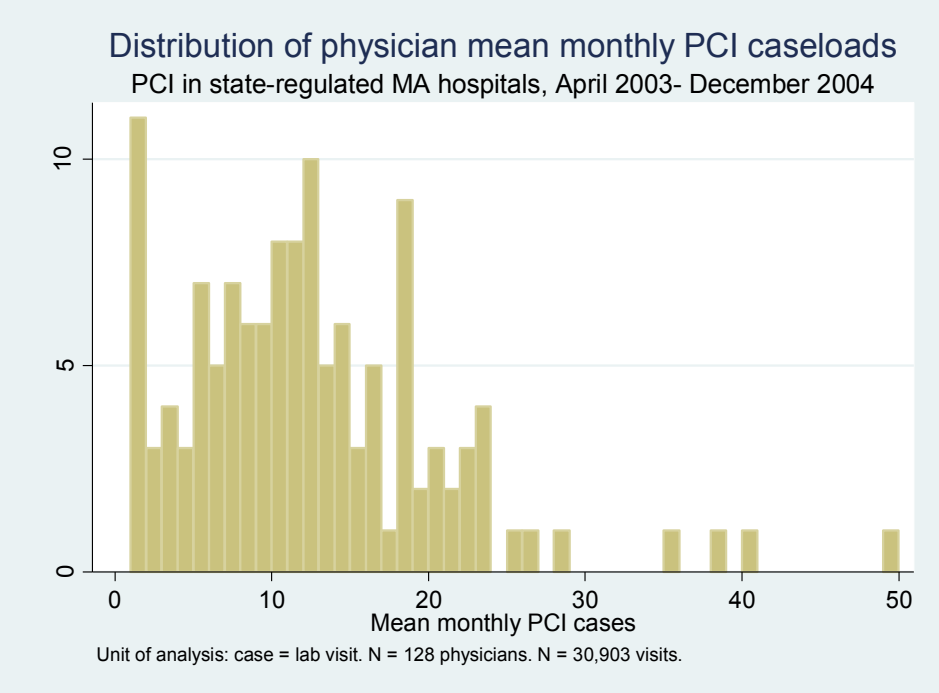
Hospital	4/1-12/31/2003	1/1-12/131/2004‡	Total Lab PCI visits*	Number of operators by site	Average number of sites that operators worked at
A	1,476	2,157	3,633	9	1.4
B	1,561	2,032	3,593	16	1.6
C	1,667	1,864	3,531	23	1.7
D	1,352	1,791	3,143	18	1.7
E	1,351	1,765	3,116	11	1.9
F	1,128	1,393	2,521	13	1.3
G	1,045	1,421	2,466	10	1.0
H	600	1,011	1,611	12	2.1
I	609	896	1,505	4	2.0
J	620	862	1,482	9	1.7
K	672	760	1,432	11	2.4
L	501	677	1,178	11	1.2
M	392	533	925	4	1.0
N	50	364	414	4	2.0
	13,024	17,526	30,550	11.1	1.6
Pilot-hospital†					
O	38	54	92	7	2.7
P	42	43	85	2	3.0
Q	36	41	77	3	3.0
R	3	35	38	5	2.6
S	0	26	26	6	2.7
T	0	19	19	2	3.0
U	0	16	16	2	3.0
	119	234	353	3.9	2.9

(*) Admissions comprise 1 or more cath lab visits.

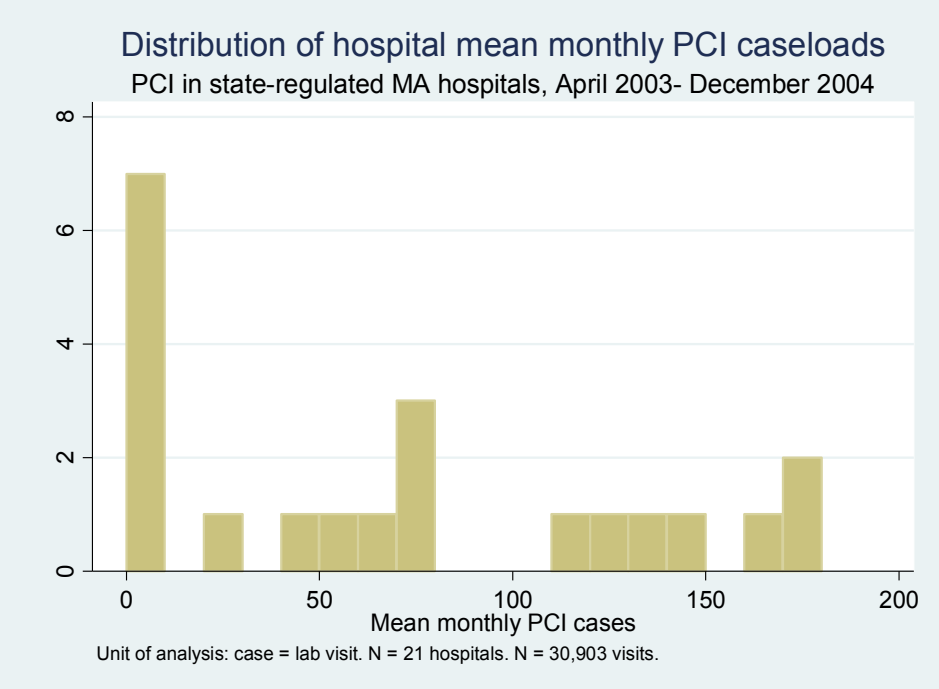
(†) For STEMI or shock only, without CABG back-up. Records excluded from all patient-level analyses, but used in computing hospital and operator procedural volume covariates.

(‡) Procedures in 2004 include 4 admissions with lab visits in early 2005.

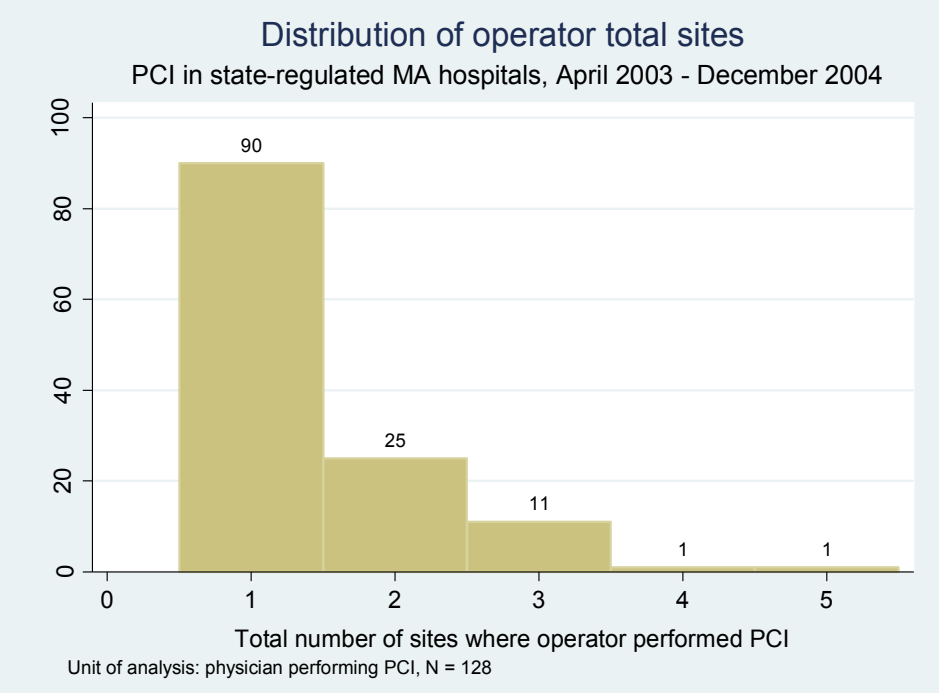
Appendix 3: Histogram of physician mean monthly caseloads



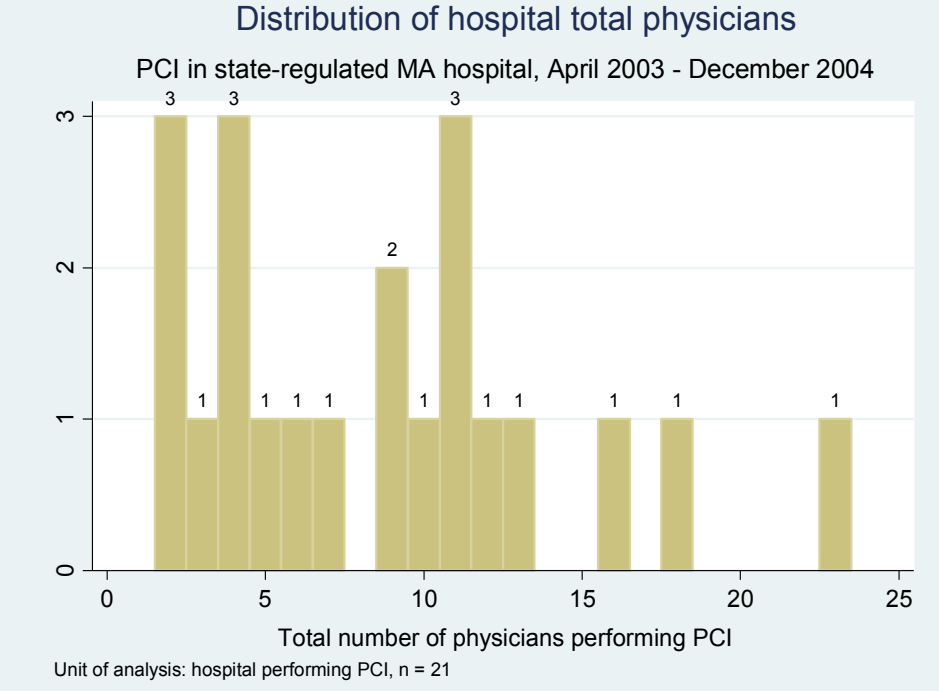
Appendix 4: Histogram of hospital mean monthly caseloads, including pilot hospitals



Appendix 5: Histogram of frequencies of hospitals/PCI operator



Appendix 6: Histogram of frequencies of PCI operators/hospital



Appendix 7: Unadjusted D2B times for STEMI patients, by hospital and operator volume

Median, minutes, STEMI, first lab visits only				
Operator PCI cases† per year‡	Hospital PCI cases† per year‡			
	< 400	400-1,199	> 1,200	Overall
< 74	nm*	69	120	80
75-149	106	70	84	80
> 150	82	67	78	75
Overall	92	68	80	76

< 30 mins, %, STEMI, first lab visits only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	17.6	2.6	12.9
75-149	0.0	13.1	10.6	11.0
> 150	8.2	10.5	13.8	12.8
Overall	4.5	12.2	12.6	12.3

< 60 mins, %, STEMI, first lab visits only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	41.2	17.9	33.9
75-149	17.6	42.7	38.1	38.6
> 150	29.5	42.1	40.5	40.7
Overall	24.1	42.2	39.2	39.7

< 90 mins, %, STEMI, first lab visits only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	59.4	35.9	52.0
75-149	37.3	59.8	53.2	54.5
> 150	59.0	67.2	56.1	59.0
Overall	49.1	64.0	54.8	57.2

(*) nm = not meaningful due to small number.

(†) Case = a lab visit for PCI occuring during an admission between 4/2003 and 12/2004.

(‡) Annualized = 12 x observed total cases / observed total months.

Appendix 8: Unadjusted and risk-adjusted mortality, by hospital and operator volume

Observed mortality, %, STEMI, first lab visit only				
Operator PCI cases† per year‡	Hospital PCI cases† per year‡			
	< 400	400-1,199	> 1,200	Overall
< 74	nm*	1.1	4.5	2.3
75-149	11.3	5.5	4.9	5.3
> 150	3.2	4.2	5.8	5.3
Overall	6.9	4.2	5.5	5.2

Expected mortality, %, STEMI, first lab visit only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	2.7	6.5	4.0
75-149	5.2	4.2	5.0	4.8
> 150	6.4	5.0	5.5	5.4
Overall	5.8	4.5	5.4	5.1

Risk-adjusted mortality, %, STEMI, first lab visit only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	2.2	3.6	2.7
75-149	11.3	6.7	5.0	5.7
> 150	2.6	4.4	5.5	5.1
Overall	6.6	4.8	5.3	5.2

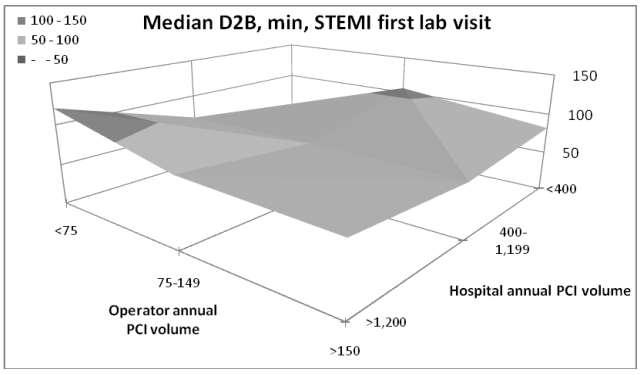
Risk-adjusted mortality, %, all patients, first lab visit only				
Operator PCI cases per year	Hospital PCI cases per year			
	< 400	400-1,199	> 1,200	Overall
< 74	nm	0.9	1.5	1.1
75-149	3.3	2.1	1.5	1.7
> 150	1.0	1.4	1.7	1.6
Overall	1.9	1.6	1.6	1.6

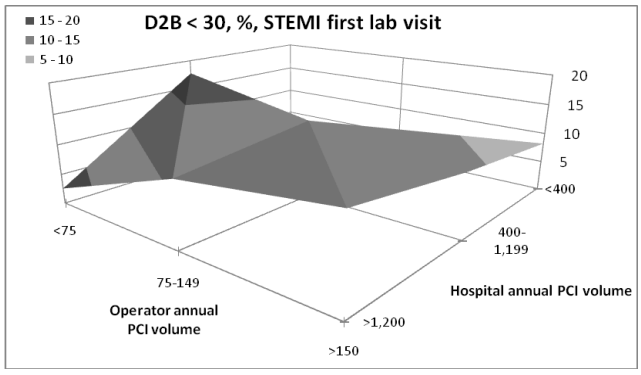
(*) nm = not meaningful due to small number.

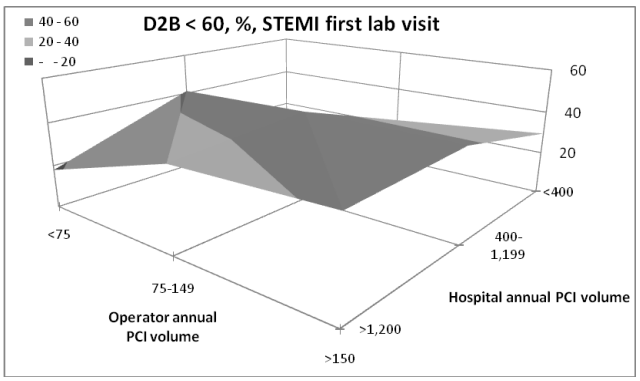
(†) Case = a lab visit for PCI occuring during an admission between 4/2003 and 12/2004.

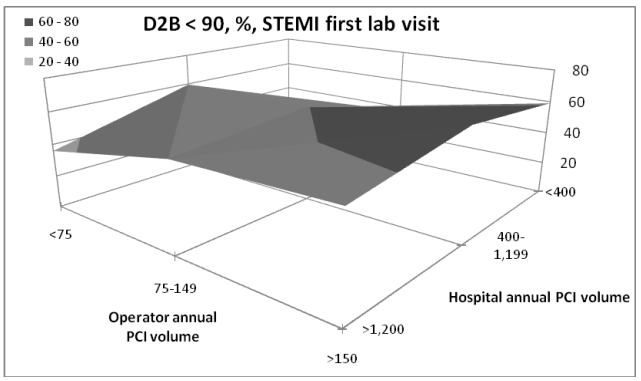
(‡) Annualized = 12 x observed total cases / observed total months.

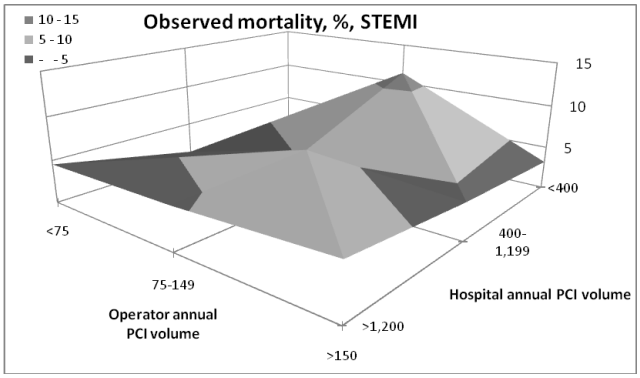
Appendix 9: Door-to-balloon times, D2B thresholds, and in-hospital mortality performance

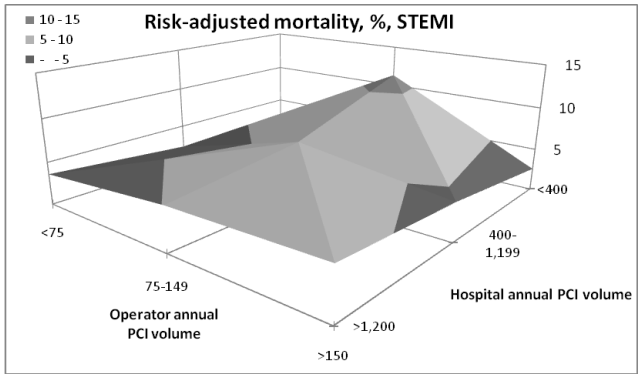












Appendix 10: Door-to-balloon interval detail in STEMI patient

	STEMI only			
	Open	Closed	All labs	
PCI, cases	4,231	778	5,009	
of which first lab visit in admission	3,941	733	4,674	
Door to balloon time†, minutes, median	72.2	96.0	76.0	***
Door to balloon time within interval, %				
? 30 min	13.9	5.3	12.5	***
31 - 60	28.8	22.1	27.7	***
61 - 90	17.5	19.7	17.8	
91 - 120	12.4	14.9	12.8	¶
121 - 150	7.0	7.0	7.0	
151 - 180	3.9	4.1	4.0	
181 - 210	2.3	2.5	2.4	
211 - 240	1.8	0.8	1.7	¶
241 - 270	1.1	0.4	1.0	¶
271 - 300	0.9	0.7	0.9	
301 - 330	0.8	1.2	0.8	
331 - 360	0.7	0.6	0.7	
361 - 390	0.2	0.1	0.2	
391 - 420	0.4	0.6	0.4	
421 - 450	0.2	0.4	0.2	
? 451 min	8.9	19.0	10.5	***

Patient-weighted means in % unless otherwise indicated. Excludes 355 records at 7 pilot hospitals with PCI-only STEMI programs. Comparison of open and closed lab statistics significant at (***) <.001, (**) <.01, (*) <.05 and (¶) <.10 *p*-values. All door-to-balloon times and thresholds restricted to first lab visit during admission.