Final Report

Triage and Allocation Model for Primary PCI After STEMI

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Structured Abstract

Purpose

This project was designed to develop policy and planning options that can be used locally and nationally to regionalize emergency cardiac care.

Scope

We estimated change over 2004-2008 in the availability of PCI at US hospitals. We assessed the impact of this change in patient access to PCI over the same period. To understand the potential of EMS triage in its full context, the benefits, risks, and costs of three approaches were simulated in head-to-head comparisons: 1) EMS-based triage strategies; 2) hospital-based triage strategies; 3) expansion, construction and staffing of new hospital PCI labs.

Methods

We used drive times analysis to project the percent of the US population living within a 1-hour drive of PCI-capable hospitals and examined how this measure changed over time. We used a stratified, weighted method to arrive at a sample of 103 counties representing a variety of places in the United States with and without adequate access to PCI. For each county, we simulated heart attack to assess best strategy for increasing access to PCI and modeled county factors that are associated with three strategy groups.

Results

Approximately 251 new programs were introduced at a cost of $2-4 billion, increasing timely access to the procedure by from 79.1% to 80.9% of the population. A strategy of EMS transfer within a county is estimated to be twice as effective and up to 20% less costly than adding new PCI capability.

Key Words

Heart attack, cardiovascular disease, coronary artery disease, ST-segment myocardial infarction, access to care, percutaneous coronary intervention, thrombolytic therapy, fibrinolysis, emergency medical services, emergency medicine, drive-time analysis, simulation.

Purpose

This project was designed to develop policy and planning options that can be used locally and nationally to regionalize emergency cardiac care. Specifically, the project identified optimal strategies for increasing population access to primary percutaneous coronary interevention (PCI) in the treatment of ST segment elevation myocardial infarction (STEMI). The methodological approaches were designed to be adaptable for potential uses in local policy development in STEMI care as well as in other clinical domains.

Scope

When this Mentored Career Development Award was awarded, Dr. Thomas W. Concannon was an Assistant Professor of Medicine at Tufts Medical Center and Tufts University School of Medicine (TUSM). He was interested in the use of clinical research in health policy and planning, particularly in the care of high-cost and high-intensity patients. Dr. Concannon's career goals were to fill in knowledge gaps in the emergency management of patients with acute coronary syndromes and to develop planning tools for regionalization of cardiac care. Dr. Concannon's long-term career goals were to identify, develop, and implement optimal organizational strategies to optimize care for patients with a range of high-intensity conditions.

Ischemic heart attack, specifically ST segment elevation myocardial infarction (STEMI), is a leading cause of death and disability in the United States. A key to successful outcomes after STEMI is the earliest possible time to definitive treatment. Irreversible myocardial damage typically begins within 60 minutes of coronary occlusion and continues, on average, to approximately 5 hours. Mode of reperfusion therapy is another key determinant of outcomes. Primary percutaneous coronary intervention (PCI) has been shown to be better than thrombolytic therapy (TT) at reducing mortality, stroke, and re-infarction if it can be administered within 90 minutes of hospital arrival or no longer than 60 minutes after TT could be administered. However, PCI is available only at hospitals with cardiac catheterization labs, and TT is the standard of care in the majority of US hospitals.

To reduce time to treatment and increase the use of PCI, policymakers and practitioners have begun to consider the contribution that a regionalized emergency medical service (EMS) system could make. There is room for substantial improvement. One study on 2001 data indicated that 80% of the US population lived within a 1-hour drive of PCI facilities, but others suggest that fewer that 80% of all eligible patients with STEMI actually received PCI.

Ambulance personnel are the first point of contact for nearly half of all patients with STEMI and can play a critical role by improving triage of the patient, including selection of the destination hospital, pre-notification of expected arrival time, and expedited transport of the patient. However, improving triage in EMS is just one possible way to increase access to PCI. To understand the potential of EMS triage in its full context, the benefits, risks, and costs of three distinct approaches need to be evaluated in head-to-head comparisons: 1) EMS-based triage strategies; 2) hospital-based triage strategies; 3) expansion, construction, and staffing of new hospital PCI labs. To accomplish this, we employed powerful geographic information systems (GIS) to perform head-to-head comparisons of strategies in all three categories.

Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations).

Data

Patient data were sampled from the Atlantic Cardiovascular Patient Outcomes Research Team (C-PORT) Trial. C-PORT was a randomized controlled trial of 451 patients with STEMI conducted from July 1996 through June 1999 that compared PCI and TT at 11 community-based hospitals in Maryland and Massachusetts. Of the 451 subjects recruited into C-PORT, 408 had records containing all the clinical data needed in the mortality predictive model. Patients were probabilistically sampled from C-PORT using a uniform distribution and probabilistically assigned to Census-Block Centroids in our sample of counties using census-derived over-age-17 population densities; they were probabilistically assigned to a day of week and time of day for onset of symptoms using previously published data on the weekly and circadian patterns of heart attack onset.

American Hospital Association data from 2004 through 2008 were used to identify hospitals that had the capability to perform PCI. New PCI programs at hospitals that previously didn't have them were identified for each year from 2005 through 2008.

Healthcare Cost and Utilization Project State Inpatient Data (SID) files from 23 states in 2006 were used to identify hospitals that offered PCI emergently during that year. We used this file to distinguish hospitals that provided PCI on a full time, 24/7 basis from those that provided PCI on a part-time basis from 7 am to 5 pm Monday through Friday. We also used this file to validate AHA Annual Survey counts of PCI capability in 2006.

US Census data were used to identify and sample counties for the simulation (Exhibit 1A). Census data were also used to estimate centroids of Census Block Groups for simulation of location of symptom onset and to adjust multi-level, multivariate regression models with measures of area socioeconomic status (SES).

All patient, hospital, and census data were entered into a model of sampled counties that was built using ArcGIS version 9.1, Environmental Systems research Institute, Inc. (ESRI, Redlands, CA). ARC GIS StreetMap data were used to identify road networks from hospitals to block groups, to estimate the distance and transport time from location of symptom onset to arrival at a nearby hospital.

County Sample

A weighted, stratified sampling scheme from all 3,158 counties in the continental United States was used to ensure that we ran the simulation in counties of different types across the nation. Counties were first stratified into 25 groups of population x dry land area quintiles. We divided each of the 25 strata further into quartiles of PCI counts, defined as the number of hospitals within a 1-hour drive of the county's borders that are capable of delivering PCI. One of the 100 resulting strata, the lowest population x largest area stratum has a large number (50%) without PCI within 60 miles and therefore did not rank into four groups by PCI count. This resulted in the identification of 99 county strata that were eligible for sampling. We then weighted counties by the inverse of the probability nationally of being selected from a US Census region (Exhibit 1A). We thus arrived at a sample of 99 counties. Finally, we forced selection of four counties from counties corresponding to the seven largest population density metropolitan areas to arrive at a final sample of 103 counties (Exhibit 1B and 1C).

Exhibit 1. Regional Weights and Sample of US Counties

Panel A. Regional Weights

Region	Frequency	Percent
Midwest	27	27.27
Northeast	16	16.16
South	36	36.36
West	20	20.20

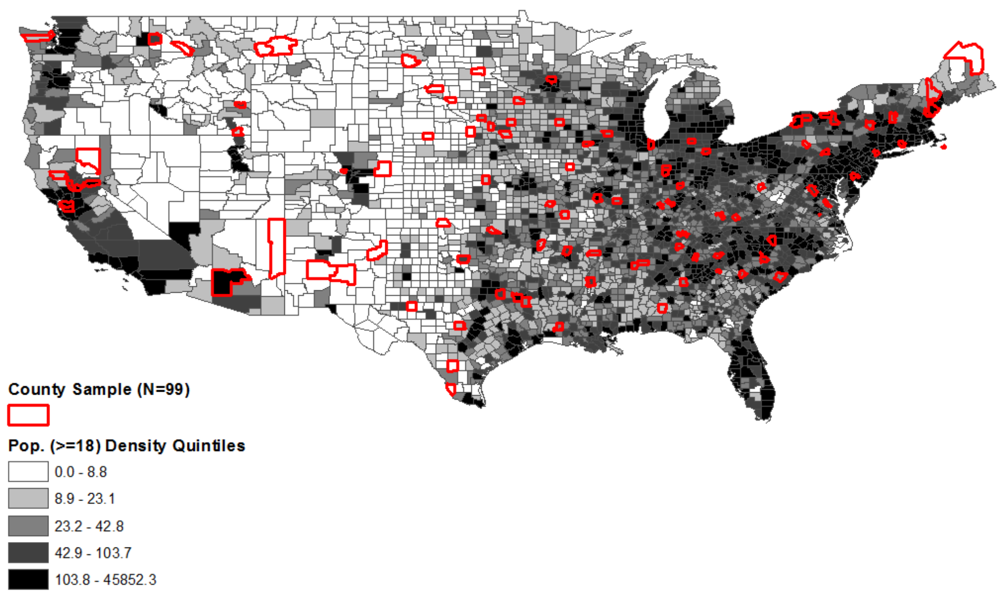
Panel B. Sample of Counties

State	County	Population >17
Alabama	Butler County	15645
Alabama	Franklin County	23578
Alabama	Randolph County	16760
Arizona	Apache County	42692
Arizona	Maricopa County	2244146
Arkansas	Faulkner County	64008
Arkansas	Franklin County	13180
Arkansas	St. Francis County	21136
California	Alameda County	1089169
California	Contra Costa County	697022
California	Glenn County	18312
California	Lassen County	26439
California	Placer County	182641
California	Sutter County	56061
Colorado	Gilpin County	3751
Colorado	Washington County	3623
Connecticut	Middlesex County	119091
Florida	Hillsborough	998948
Georgia	Clarke County	83381
Georgia	Murray County	26302
Georgia	Rabun County	11764
Idaho	Franklin County	7098
Idaho	Kootenai County	79185
Idaho	Madison County	20281
Illinois	Carroll County	12628
Illinois	Perry County	18011
Indiana	Boone County	33052
Indiana	Hendricks County	74927
Indiana	Jennings County	19929
Indiana	Lake County	354767
Indiana	Steuben County	24693
Iowa	Butler County	11571
Iowa	Cherokee County	9823
Iowa	Monona County	7693
Iowa	Muscatine County	30503
Kansas	Clay County	6622
Kentucky	Hancock County	6151
Kentucky	Meade County	18510
Kentucky	Perry County	22229

State	County	Population >17
Missouri	Knox County	3274
Missouri	Wright County	13078
Montana	Fergus County	8974
Montana	Judith Basin County	1705
Montana	Mineral County	2942
Nebraska	Antelope County	5402
Nebraska	Dixon County	4598
Nebraska	Thomas County	557
N Hampshire	Strafford County	85661
New Jersey	Bergen County	681064
New Jersey	Salem County	47835
New Mexico	Lincoln County	14997
New Mexico	Quay County	7614
New Mexico	Socorro County	12947
New York	Cayuga County	61400
New York	Erie County	719715
New York	Genesee County	44640
New York	New York	1537195
New York	Schoharie County	24013
New York	Wayne County	68050
North Carolina	Davidson County	111468
North Dakota	Grant County	2175
Ohio	Putnam County	24410
Oklahoma	Comanche County	83059
Oklahoma	Harper County	2731
Oklahoma	Pawnee County	12203
Pennsylvania	Cameron County	4510
Pennsylvania	Union County	33258
South Carolina	Edgefield County	18664
South Carolina	Lancaster County	45756
South Carolina	Williamsburg County	26556
South Dakota	Buffalo County	1192
South Dakota	Marshall County	3339
South Dakota	Sully County	1159
South Dakota	Yankton County	16085
Tennessee	Grundy County	10731
Tennessee	Putnam County	48436
Texas	Glasscock County	935
Texas	Kaufman County	50486

Louisiana	Allen Parish	19173	Texas	La Salle County	4143
Maine	Aroostook County	57218	Texas	Llano County	14333
Maine	Oxford County	41521	Texas	Rusk County	35581
Maine	York County	140469	Texas	Smith County	128208
Massachusetts	Nantucket County	7692	Texas	Zapata County	8157
Massachusetts	Suffolk (Boston)	689807	Vermont	Bennington County	28236
Michigan	Wayne (Detroit)	2061162	Virginia	Dickenson County	12776
Minnesota	Anoka County	211867	Virginia	Essex County	7698
Minnesota	Cottonwood County	9127	Virginia	Fauquier County	40344
Mississippi	Itawamba County	17257	Virginia	Colonial Heights cit	13082
Mississippi	Washington County	43144	Washington	Jefferson County	20815
Missouri	Hickory County	7158	West Virginia	Gilmer County	5708
Missouri	Jefferson County	142829			

Panel C. Unprojected Map of Sampled Counties



Access to Care

We used AHA data to identify hospitals in all 50 states and the District of Columbia that were capable of performing emergent PCI each year from 2004-2008. All hospitals were uniquely identified through their AHA identification number and located within a geographic information system (GIS) using latitude and longitude coordinates. Using longitudinal data, we identified new programs at individual hospitals. We imputed missing observations of PCI capability during the study period by carrying the last observation forward if PCI capability was in place at any time during 1994-2007 and by carrying the most recent observation backward if a hospital reported no PCI capability in 2004-2008.

To track change over time in the number of PCI programs, we estimated both relative and absolute change in the number of new PCI programs for each year after 2004, taking into account hospitals that were lost to follow-up due to closures, mergers, and survey non-response.

We updated a previously developed framework for estimating the construction, medical equipment and operations and costs of introducing a new PCI program to 2008 US dollars, using the National Income and Product Accounts (NIPA) GDP deflator. The introduction of a new PCI program may be made in hospitals with and without existing cardiac surgery programs, but access to onsite or nearby (via transfer) cardiac surgery backup is recommended or required in most places. Hospitals without onsite or nearby back-up surgery may therefore have to invest in that service along with the opening of a new PCI program. To estimate a lower and upper bounds for the cost of new PCI programs to the US healthcare system over our study period, we multiplied the unit cost for a new program developed with and without existing surgical backup.

To assess change in access to PCI, we estimated annual proportions of the population over the age of 18 living within a 60-minute drive of every PCI hospital. To do this, we followed methods described in previous work on drive times to US hospitals. We defined a "neighborhood" specific to every hospital in the US, defined as the area covered by a 60-minute drive time to the hospital from neighboring census tracts. Drive times were estimated using road network and speed limit data from ESRI's ArcGIS StreetMap dataset with the Network Analyst extension. Extra time was added to account for dispatch of the EMS vehicle (1.4 minutes for urban and suburban tracts and 2.9 minutes for rural tracts), time from EMS depot to scene (total time was multiplied by a constant of 1.6, 1.5, or 1.4 for urban, suburban, or rural tracts, respectively), and time spent on scene (13.5 minutes for urban and suburban tracts and 15.1 minutes for rural tracts). These constants were derived in a meta-analysis of empirically determined pre-hospital care times for trauma.

The population of a census tract was considered to have access to PCI if its centroid – the geographic location that represents the mean center of a polygon – lay within the hospital's neighborhood boundary. Populations in tracts covered by multiple hospitals were counted once to avoid duplication. We estimated annual and total change in the potential reach of PCI programs across the US, the four Census Regions, 50 states and the District of Columbia.

To assess the hospital-, neighborhood-, and state-level factors that are associated with the decision to adopt PCI, we estimated a series of discrete-time hazard models on hospitals that did and did not adopt PCI after 2004. Hospital-level covariates were time-varying and lagged two years to account for elapsed time from the decision to adopt PCI and the appearance of a lab in the AHA survey. In the event that a new hospital entered the dataset, current year values were used in place of nonexistent lagged data. Univariate models were used to identify candidate covariates from AHA-, Census-, and AHPA-derived variables. Independent variables that were moderately strongly associated ($p<0.10$) with new PCI adoption in univariate models were selected for inclusion in the initial multivariate models.

We estimated two models with alternative measures of neighborhood competition. In model 3.1, we measured duplication of PCI with a time-varying and 2-year lagged indicator for the presence of another PCI program within the hospital's neighborhood (Duplication Model). In model 3.2, we measured concentration of market share with a time-varying and two-year lagged modified HHI (Concentration Model). We assumed proportional hazards and estimated three sequential equations for each model, with hospital covariates alone, hospital + neighborhood covariates, and hospital + neighborhood + state covariates.

We assessed deviations from the assumption of proportional hazards by graphing the hazard function over time and by testing the significance of independent variable interactions with time.

Simulation Model

The project that formed the core of this award was designed to estimate the relative benefits, risks and costs of several regional planning strategies for emergency care of patients with STEMI, grouped in three categories: 1) emergency medical service (EMS)-based triage strategies; 2) hospital-based triage strategies; 3) expansion, construction, and staffing of new hospital PCI labs. The full range of possible strategies is described in Exhibit 2.

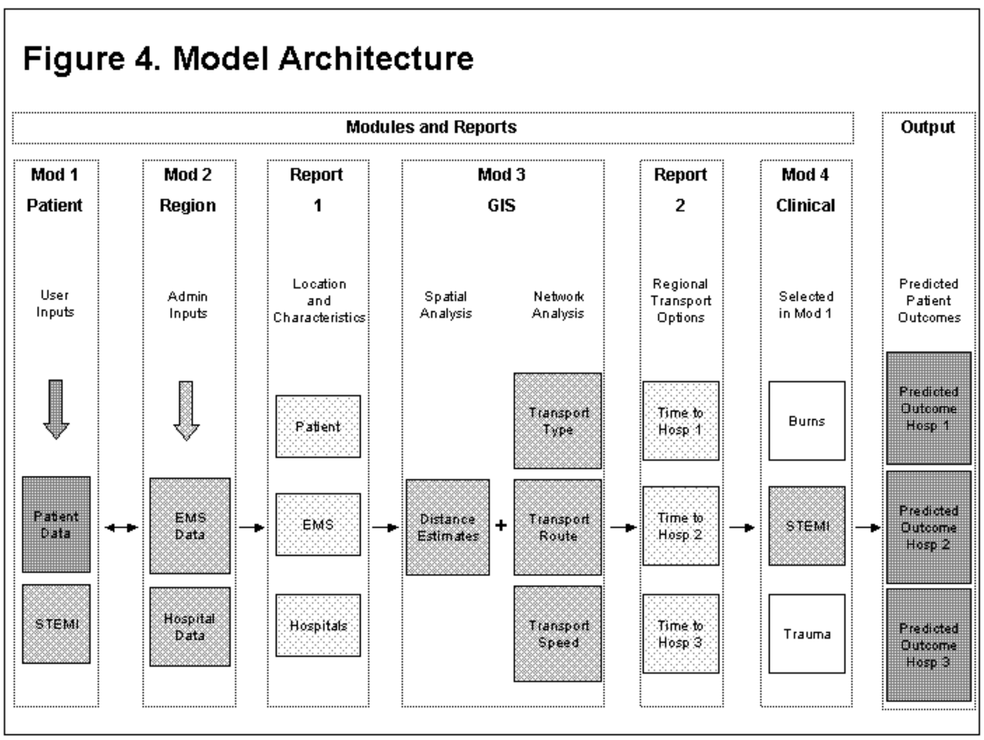
Exhibit 2. Baseline and Alternative Strategies for Increasing Access to PCI

Category and Name		Description
Baseline	Closest Hospital	Patients are transported to the closest emergency-capable hospital and treated with locally available therapy – PCI if available and TT if not.
Alternatives		
1. EMS Triage		
	Universal PCI	Patients are transported to the closest PCI-capable hospital and treated with PCI.
	Targeted PCI – benefit rule	Patients are evaluated by EMS and transported to a PCI capable hospital only if the expected benefit exceeds the expected risk of delay after bypass of a TT hospital.
	Targeted PCI – delay rule	Patients are evaluated by EMS and transported to a PCI capable hospital only if the expected delay is less than 60 minutes after bypass of a TT hospital.
2. Hospital Triage		
	Universal Transfer	Patients are transported to the closest hospital and treated with PCI if available and transferred to another hospital for PCI if not.
	Targeted Transfer – benefit rule	Patients are transported to the closest hospital and treated with PCI if available and, if not, transferred for PCI only if the expected benefit exceeds the expected risk of delay.
	Targeted Transfer – delay rule	Patients are transported to the closest hospital and treated with PCI if available and, if not, transferred for PCI if the expected delay is less than 60 minutes.
3. Hospital Expansion		
	New staff – Full time	An existing part-time PCI lab is newly staffed to operate 24/7.
	New lab and staff – Part time	A new lab is constructed and staffed to operate part time.
	New lab and staff – Full time	A new lab is constructed and staffed to operate 24/7.

For every sampled county, we identified all hospitals lying within a 1-hour drive time of county borders. StreetMap USA, a component of ArcGIS v 9.2, automates spatial and network analyses along roadways by speed limits. Speed was adjusted to account for rush hour, with weekday slowdowns of 20% during the hours of 7-9 am and 4-6 pm, and 10% during the hours of 6-7 am, 9-10 am, 3-4 pm, and 6-7 pm. For each individual patient, located probabilistically at a Census Block Group centroid, distance measures to every hospital and every dispatch location were computed in a spatial analysis. Measures of distance from every Centroid to any hospital within a 2-hour travel time were saved in look-up tables, to allow for quick estimation of time from 9-1-1 activation to hospital arrival. In this way, EMS response and transport options were modeled for each individual patient under varying assumptions.

Model architecture is presented in Exhibit 3. The simulation is designed in modules so that future code can be updated to account for patient (Module 1), region (Module 2), strategy (GIS Module 3), or clinical (Module 4) changes to the simulation without disrupting the entire simulation structure. For instance, for each patient who lives closest to a hospital without an operating PCI lab, the STEMI model in Module 4 uses a previously published clinical predictive instrument, the PCI-TPI, to predict whether it is better to transport to that hospital and deliver TT as quickly as possible, or to a more distant hospital and treat with delayed PCI. This tradeoff is not the same for every patient. This clinical module could be replaced in future iterations with new clinical predictive instruments for patients with STEMI, burns, or trauma.

Exhibit 3 Simulation Model Architecture



The primary analyses compare event rates of patients with ST-elevation myocardial infarction under the different strategies. Linear regression models test for differences in strategies across counties.

For example, differences in the effectiveness of strategies between PCI-access quintiles are tested with with the model $\log(OR) = \alpha_0 + \alpha_1 Q + \varepsilon$, in which Q is a vector representing the county quintile and OR is the odds ratio between two strategies. In addition to the global test of association, pairwise comparisons are made between the quintiles using the Tukey test to adjust for multiple comparisons. Additional county-level variables are included in the model as covariates. A limited number of interactions between county variables and the quintiles will be included to investigate the consistency of the results across potentially different spatial patterns. The intra-class correlation coefficient is used to summarize the extent of variability between quartiles compared to the variability between counties within a quintile.

Multiple regression models are used to investigate differences between the treatment strategies across continuous measures of county characteristics. For example, the model $\log(OR) = \alpha_0 + \alpha_1 A + \varepsilon$, in which A is the percent of the population within 1 hour of a PCI-capable hospital in a given county, will be used to test for a linear association with strategy effectiveness.

Analyses are weighted to account for stratified sampling.

Results

Access to Care

Two papers were completed showing a substantial growth in the number of hospitals that introduced a new PCI program between 2004 and 2008. In 2004, 1,524 (33.5%) of 4,544 acute care hospitals in the 50 states and the District of Columbia were capable of performing adult interventional PCI. Four years later, 1,739 (37.1%) of 4,686 acute care hospitals were capable of performing the procedure. After accounting for hospital closures and mergers, this represented 251 new interventional PCI programs and a 16.5% total growth in the number of PCI capable hospitals. Both the relative and absolute annual rates of growth in PCI capability declined over time from a high of 5.5% relative growth in 2005 (absolute increase of 84 hospitals or 1.8%) to a low of 2.7% in 2008 (absolute increase of 46 or 1.0%) and averaged 3.9% relative annual growth over the 4 years.

Our estimate of the 2008 per-program cost of introducing a new PCI program was \$7,810,892 if backup for surgical revascularization already existed onsite and \$16,410,201 if it did not. The total cost for 251 new PCI programs under these two scenarios would therefore be more than \$1.9B if all 251 hospitals already had cardiac surgery programs in place and \$4.1B if none of them did. This calculation suggests the total cost of new PCI programs during our study period was \$2-4 billion.

Our analyses showed that access to PCI grew by a small margin over the period, from 79.1% of the population in 2004 to 80.9% in 2008. Access to PCI-capable hospitals varied by region, and these relationships did not change substantially over time. Access was highest in the Northeast (87.4% in 2004 and 88.5% in 2008) and lowest in the South (74.4% in 2004 and 76.8% in 2008). Of populations living within 60 minutes of a PCI capable hospital, the estimated elapsed time from 9-1-1 call to arrival at the closest of those hospitals decreased from a national median of 26.1 minutes in 2004 (inter-quartile range [IQR] 21.5 to 34.6) to 25.7 minutes in 2008 (IQR 21.2 to 33.8), a drop of 24 seconds for the typical patient.

We found that several factors are associated with the decision to introduce a new PCI program. Hospitals are more likely to adopt PCI if they are newly opened, larger (i.e., had higher expenditures and more hospital beds), own other expensive medical technology, and if PCI is already offered in the neighborhood.

Hospitals are less likely to adopt PCI if they have a higher volume of outpatient services (higher outpatient/inpatient revenue and more non-emergency outpatient visits), if they operate in a more competitive market, if they are in a neighborhood with a higher percentage of foreign-born and elderly residents, and if they are in a state that maintained laws requiring automatic review of new catheterization labs.

Operating in a state that maintains a Certificate of Need (CON) program with automatic review of catheterization labs reduces the risk of PCI adoption by approximately 40%. In no-CON states, access to PCI was extended to 1.5% of the population and the population living closest to PCI grew by 1.8%. In states maintaining CON without automatic review, these figures were 2.2% and 3.7%, respectively. In states maintaining CON with automatic review, they were 2.0% and 8.3%, respectively. Automatic review of catheterization labs seemed to result in a substantial increase to the population whose closest hospital could perform PCI.

Simulation Results

The pilot simulation was completed in Dallas County, Texas. In the base case (A), 609 (95% confidence interval: 569, 647) primary PCI procedures – representing 30.4% of all patients with STEMI – were performed annually in 14 hospitals. Roughly 250 of these were performed during weekdays at a time when elective procedures would otherwise be scheduled. With 14 PCI labs operating on 260 weekdays per year, we assumed that demand for elective PCI was already being met and that no additional elective procedures would be performed as a result of new capacity. In this context, new construction and staffing costs could not be defrayed with elective procedures.

The costs and effectiveness of each successive scenario (B-O) were compared with the base case (A). An additional 82 patients had access to PCI after construction of a new part-time lab in a hospital seeing more than 200 patients with STEMI annually (B). This scenario resulted in nearly \$4.8M additional costs over 10 years, and the additional 82 PCI procedures performed over this period saved 157.4 QALYs. The cost per QALY saved was \$30,399, well under the costs of other accepted life-saving therapies. When that same hospital built a new lab and staffed it full time (D), an additional 272 PCI treatments could be performed in a year and the cost per QALY saved dropped to \$14,765. If a new program of onsite CABG backup was needed for this new lab, costs increased to \$85,032 per QALY saved in the part-time scenario (C) and to \$31,021 in the full-time scenario (E). Building a new lab was most cost effective if it could be opened full time and if a new onsite CABG backup program was unnecessary (D).

Expansion of PCI capability in the two highest-volume hospitals that already had a part-time PCI lab in place (F) resulted in 304 additional procedures and 605.2 QALYs saved at a cost of \$10,000 per QALY saved. This expansion, involving only the additional costs of night and weekend on-call staff, was the most cost effective of hospital-based scenarios. We explored a series of combinations involving new lab construction and expansion of part-time PCI labs to full-time hours (G-N). When compared with the base case, each scenario cost less than \$100,000 per QALY saved.

Finally, we estimated the incremental costs and effectiveness of one EMS strategy for increasing access to PCI (O). For the present study, we assumed the EMS transport strategy would cost an additional \$1,000 per diverted patient. This strategy resulted in 1,391 diversions at a cost of nearly \$1.4M and a cost per QALY saved of \$506. Because it was less costly and more effective than any of the hospital-based strategies, we considered the EMS strategy to be dominant. It would no longer be the most cost-effective strategy if the average cost per diverted patient rose to more than \$19,769 (a 20-fold increase).

Alternatively, it would no longer be the most cost effective strategy if the most favorable hospital-based scenario (F) cost less than \$306,231 (a 20-fold decrease).

The results of this simulation in 103 counties are not finalized. A manuscript is in development and will be published.

Implications

Access to Care

Our studies of change in the availability of PCI have several important implications. At least three types of health system strategies are available around the US to increase access to PCI for patients with STEMI while restraining duplicative investment:

- *Voluntary interventions.* One class of strategies is the development of voluntary STEMI systems of care in local communities or in states. Known at STEMI Systems or STEMI Regional Plans, these may be defined as the systematic, iterative assessment and implementation of voluntary agreements between hospitals and emergency medical service systems that are designed to improve access to timely PCI. The largest such program in the US, the North Carolina RACE protocol, has been successful at establishing inter-hospital agreements and has shown benefit for patients with coronary artery disease (CAD). Other plans have been implemented elsewhere and have shown promising results.
- *Market-based interventions*. Market interventions such as payment reform may also help to address duplicative investments in PCI. Our results show that PCI investments are declining over time and may soon approach zero; therefore, the prime opportunity for targeted payment reform in this procedure may have passed as many as 10 years ago. There is evidence, however, of continued robust investment in PCI. If investments continue while utilization of the procedure remains flat, payment for these procedures may be reduced potentially, to discourage future investments without reducing access to the procedure. Other candidates for this kind of analysis and reform may include interventions in robotics, lasers, nuclear medicine, and radiology.
- *Regulatory interventions.* Health systems interventions do not have to be voluntary or market-based. Twenty-seven states in the US are equipped with regulatory programs that can be used to compel a formal review of hospitals that wish to open new interventional catheterization labs. Our analysis showed that hospitals in states with robust CON programs were 40% less likely introduce a new PCI program in any given year, suggesting that this policy mechanism can restrain diffusion of interventional catheterization labs. Of note, automatic review was the only non-voluntary regulation that seemed to have an inhibitory effect on the introduction of new PCI programs. Other CON mechanisms, such as review of major medical equipment (MME) and capital expenditures above specified thresholds, appeared to have no effect. Further work is needed to establish whether these review mechanism works to restrain low-value diffusion in other medical technologies.

Our findings and those from studies of other technology-intensive medicine also suggest a new priority for health services research: an urgent need to track and assess the value obtained from health system investments in medical technology. Rapid change in medical technology has been a chief suspect in the escalation of US health expenditures for decades, but its value for patient and population health has been unclear.

Health technology assessments and macroeconomic research have sought to address its role in patient and national outcomes, respectively, but the relationship between change in medical technology over time and outcomes in hospitals, accountable care organizations, and other health systems is poorly understood. Better information and methods are needed to assist decisionmakers in these settings plan for capital investments, regional partnerships, service-line offerings, and other critical health services decisions. Health services researchers could make major strides in our understanding of the effects of medical technology change in health systems, but a special focus is needed on this theme.

Regional Planning

Our primary target in the K award was to guide the implementation of regionalized PCI care. This project ambitiously addressed all available strategies for increasing access to PCI. To our knowledge, no other study has been able to include both EMS- and hospital-based strategies in head-to-head comparisons.

In this effort, we have completed a draft manuscript with recommendations planning for regional STEMI systems. Three general approaches have been put to work in developing regional systems of care, including strategies to (1) manage the number of hospitals that can provide PCI, (2) link patients to existing PCI hospitals through direct hospital transport, and (3) link patients to existing PCI hospitals through inter-hospital transfer. STEMI regional plans may include combinations and variations of these primary strategies. State and local legislation, regulation, resources, hospital capacity, EMS capacity, road and air networks, population density and demographics, and geographic features such as elevation and dry land area are relevant factors that can influence outcomes of these strategies.

To design a STEMI system that is responsive to the specific needs of a region or state, policymakers can start by launching a decision-making process that involves all relevant stakeholders, including patients, multidisciplinary clinicians, payers, EMS agencies, quality improvement organizations, outcomes experts, and others. We followed a recently developed framework for identifying stakeholders in healthcare decision making to identify individuals and organizations that should be at the planning table.

To guide policymakers and practitioners in the design and development of a STEMI regional plan, we recommend collecting data that can support the selection of strategies for increasing access to timely reperfusion and especially to PCI in the region. The three strategies that are available---manage the number of PCI hospitals, create EMS-based transport protocols, and create EMS-based transfer protocols---are potentially competing approaches; therefore, it may help to review data that can inform the selection of one strategy over the others, or in combination with them. Three kinds of information are needed: 1) information about the populations of interest, 2) information about the health systems that can be deployed to care for these populations, and 3) information about the potential consequences, or projected outcomes, of choosing one strategy over another.

The first of these information inputs has to do with the patients and populations that will be affected. A utilization review of care for patients with CAD and STEMI can be conducted to understand recent and current utilization trends of fibrinolytic therapy, PCI, and surgical revascularization. Both elective and emergency utilization might be considered. The first data inputs for a region to consider are local coronary artery disease (CAD) prevalence, STEMI incidence, and service utilization. Intermediate patient-level outcomes such as transport time, door-in-door-out (DIDO) time, transfer time, and door-to-balloon (DTB) time are critical to good outcomes and should be included.

Health insurance claims and other administrative data may be the most widely available source of this kind of information. However, clinical data contained in patient registries and in hospital patient records may also be available. Clinical and administrative data can be obtained from state health departments, the ACTION Get with the Guidelines Registry, the National Cardiovascular Data Registry (NCDR), the Healthcare Cost and Utilization Project (HCUP), Medicare, and other sources. Regions that have access to electronic data networks may want to consider building a customized report from local systems.

The second type of inputs has to do with the healthcare systems that can be deployed to care for these populations. Hospital and EMS inventories, regional characteristics, and the state and regional policy environment are all critical in this group. Baseline inventories of hospital capability and capacity are priorities for any regional plan. This includes inventories of existing PCI programs, including operating status on nights and weekends and plans for rescue revascularization. Information on existing agreements between referral and receiving hospitals are also needed. Data on healthcare systems can be obtained from the American Hospital Association Annual Survey of Hospitals, and from administrative data such as HCUP and Medicare. Prior to the development of its statewide STEMI system in North Carolina, the RACE investigators elected to conduct a locally designed survey to collect baseline data on healthcare systems.

Inventories of the EMS system are also helpful. Because EMS is highly fractured in some places and highly variable across the US, collecting data on these systems may be difficult. EMS vehicles may be located at firehouses, near to emergency departments, or in private locations. The vehicles may be equipped for basic (BLS) or advanced life support (ALS) and staffed by emergency medical technicians (EMTs) or paramedics. Many areas of the nation are served exclusively by volunteer BLS. Some regions may use fixed and rotary wing medical transport. A National Heart, Lung and Blood Institute (NHLBI) consensus document recommended widespread implementation of pre-hospital 12-lead ECGs in the EMS setting, which have been demonstrated to significantly reduce time delay to PCI treatment and have been recommended as a standard for systems of excellence. Therefore, inventories of 12-lead ECG equipment, communications resources, handoff strategies between EMS and emergency departments, and use of pre-hospital 12-leads in receiving hospitals' ED and catheterization labs, are also needed. Getting reliable data on all of these aspects of EMS systems is challenging. There is no single national source of data currently available, though the nascent National EMS Information System (NEMSIS) has made progress in some states and regions. The Atlas & Database of Air Medical Services (ADAMs) has reliable information on fixed and rotary wing systems. Regions that rely exclusively on public EMS systems typically locate EMS vehicles at firehouses and may maintain data through the Fire Department. Some state health departments maintain data on EMS systems operating in the state.

An inventory of the road and air networks between EMS vehicle locations and the populations population they serve is also needed, as are inventories of transportation networks between populations and emergency departments. This kind of information is available in the Network Analyst extension of ArcGIS, a desktop geographic information systems (GIS). Analyses of time-sensitive emergency conditions, such as trauma, STEMI, and burns, have been completed using this or comparable information on road and air network data.

Inventories of transportation networks in a region will make it clear whether some areas are better served by hospital and EMS than others and whether proposed new EMS, hospital, or other resources can increase access or improve equity across the region.

Inventories of existing state and regional policy that could affect a STEMI regional plan are also of interest. The existence and details of state Certificate of Need (CON) programs are important if the regional plan addresses proposed changes to hospital capability. Information about existing regional plans for patients with trauma, burns, and stroke are also important as these may interact with proposed strategies in a STEMI regional plan. Detailed data on every State CON program, including contact information for local health planning offices, is presented in annual directories published by the American Health Planning Association (AHPA).

The third type of information has to do with the potential consequences or projected outcomes of choosing one strategy over others, or in combination with others. Regional planning involves the implementation of proposed system changes. Therefore, evidence about how the changes may affect patient and system outcomes can be used to inform selection of the best-fitting strategy. To forecast the potential impact on patients, hospitals, and EMS systems, one approach is to conduct a scan of lessons learned in pilot demonstrations conducted elsewhere. Another approach is to model projected outcomes using customized simulation tools. One such tool compares projected population access to PCI both before and after STEMI regionalization strategies are selected. In this approach, the population's access to reperfusion is measured using a standard drive times analysis in a geographical information system (GIS). Another approach – the Cardiac Accessibility and Remoteness Index (ARIA) – uses GIS, drive times estimates, and an index of the type and duration of projected transport to prioritize geographic areas in which system-level investments are needed. A third approach – the Triage and Allocation Model – also uses GIS, drive times analysis, clinical heart attack data, and predictive instruments to simulate patient-level outcomes before and after system interventions are implemented. Each of these forecasting models is customizable to the population and health system characteristics of small areas. As advances in computing power, GIS capability, and clinical data systems are made, the ability of health planners, policymakers, and local practitioners to use forecasting tools will continue to grow.

Recommendations

The best system for any individual region depends on many local factors and will therefore vary from place to place. This framework offers a common starting point and flexible approach that support the informed selection of STEMI system strategies. We make five recommendations to get the process started:

1. Identify and assemble stakeholders. The key stakeholders include people and organizations with a wide variety of interests in the outcomes of regionalization. We proposed using a formal stakeholder engagement framework to identify, recruit, and prepare participants in the project.
2. Collect baseline data. The key data inputs include information on the populations of interest, health system capabilities, existing handoff protocols, road and air networks, and projections of utilization and outcomes before and after utilization. We presented tools and references that can guide leaders in all of these baseline data collection activities.
3. Consider alternative strategies. To guide this process, we presented a taxonomy of potential strategies, grouped into three general approaches: strategies to (1) manage the number of hospitals that can provide PCI, (2) link patients to existing PCI hospitals through direct hospital transport, (3) link patients to existing PCI hospitals through inter-hospital transfer.

4. Project outcomes following selection and implementation of the strategies. We described three approaches that can be used to make projections: a scan of results obtained from pilot demonstrations of STEMI systems in other regions, population-level projections of access to PCI using GIS systems to estimate drive times to PCI-capable hospitals, and patient-level projections of access and outcomes after implementation of alternative system strategies.

5. Seek consensus about key features of the plan from area hospitals and EMS providers.

Despite an impressive volume of work that has been completed and published in the last decade by national advocates, innovators, and local champions of STEMI regionalization, there is still significant work left to do. A substantial amount of variation persists in the design and content of several hundred small plans across the country, and there is considerable uncertainty about the quality and impact of all of these plans. We put forth this framework and these recommendations to help policymakers and practitioners get started with a common starting point and flexible approach. Ensuring that regional plans start with a complete set of relevant stakeholders, baseline data, policy alternatives, and forecasting tools may help in the design of STEMI systems that can increase utilization of PCI after STEMI and improve outcomes for patients.

List of Publications and Products

Related Publications

1. **Concannon TW,** Griffith JL, Kent DM, Normand SL, Newhouse JP, Atkins J, Beshansky JR, Selker HP, Elapsed time in emergency medical services for patients with cardiac complaints: are some patients at greater risk for delay? Circulation: Cardiovascular Quality and Outcomes. 2(1): 9-15, Jan 2009. PMID: 20031807.
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Related Manuscripts (in preparation)

1. **Concannon TW**, Kerieakes D, Jollis J, Gaylor J, Monk L, Jacobs A, Bjerke C, Selker HP, A framework to accelerate regional planning in the care of patients with STEMI.
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