Ischemic Stroke Outcomes Validation Study in California, 2006-2009

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I. EXECUTIVE SUMMARY

Background and Aims

Acute ischemic (a blocked artery in the brain) and hemorrhagic stroke (bleeding into the brain caused by a ruptured blood vessel) consistently rank among the top causes of mortality in California and are responsible for approximately 50,000 hospitalizations annually. Unlike many other prevalent acute medical conditions, stroke is associated with significant morbidity and mortality. Stroke outcomes are severe. For ischemic strokes, timely interventions have the potential to reverse the damage, reduce morbidity, and improve quality of life for survivors. The natural history of ischemic stroke and avenues for acute intervention, post-acute treatment, and recovery are keys towards assessing the quality of care delivered to stroke patients. The prevalence of stroke, the severity of stroke outcomes, and the potential for improving ischemic stroke care are driving factors for the Office of Statewide Health Planning and Development (OSHPD) to develop validated outcome measures for monitoring ischemic stroke care in California hospitals.

In order to accomplish this goal, OSHPD contracted with the University of California, Los Angeles to perform the Stroke Outcomes and Validation Study (SOVS), a statewide effort to establish meaningful, validated outcome measures of ischemic stroke for patients treated in California general acute care hospitals. The overarching goals of the OSHPD SOVS are to:

1. Establish the validity of diagnoses and procedures coded in OSHPD's Patient Discharge Database (PDD) related to the occurrence, severity, treatment, and outcomes of stroke.
2. Examine variation in key acute and hospital-based post-acute process measures of care quality, and establish their link to mortality, the principal outcome measure.
3. Examine the use of and variation in Do Not Resuscitate (DNR) orders for stroke patients.

4. Create analytic models to predict stroke mortality that can be used for ranking hospitals using PDD records, with an emphasis on identifying whether variation in hospital ranking is attributable to key process of care measures or to patient severity measures that are not currently captured in the PDD.

Identification of Key Processes of Care, Important Outcomes, and Independent Predictors of Outcomes

An extensive literature review from 2003 to the present on stroke processes of care measures, outcomes of ischemic stroke, and independent predictors of stroke outcomes was conducted. Eighty-four important outcomes of ischemic stroke were identified along with 15 consensus and/or evidence-based process of care quality indicators, quality measures, and care guidelines. A stroke clinical advisory panel, composed of six neurologists, reviewed the findings and recommended 26 revised measures across 16 domains of care. The panel emphasized the importance of end-of-life care and treatment intensity preferences.

Validation Study

During the validation portion of the SOVS, a goal of 1,000 unique "index" ischemic stroke cases were to be identified from 39 participating general acute care hospitals 1) to reabstract discharge records to validate data reported in the PDD and 2) to abstract detailed clinical information for validating risk-adjustment approaches and determining appropriateness and completeness of care in this sample. Patient cases selected for abstraction consisted of adults with a primary diagnosis of ischemic stroke who received acute level of care between December 2006 and November 2007, the most current data available at the beginning of the study.

A chart abstraction instrument was developed consisting of a Health Information Technician (HIT) Module for reabstracting PDD measures, and four clinical modules – an admission module

(including assessment of stroke severity), a discharge module, a tPA Module (to focus on appropriate receipt of thrombolytic therapy), and a Treatment Intensity Preferences (TIP) module to capture information on end-of-life decision making, treatment preferences, and withdrawal of care. Development and pilot testing of the abstraction instrument were performed using records from ischemic stroke cases treated at the two UCLA hospitals.

Validation Results

Interrater reliability assessment of the abstraction tool using 131 doubly abstracted charts showed excellent agreement for clinical abstractors and HIT abstractors for most co-morbid illnesses, a subset of acute inpatient complications, and receipt of tPA. Good agreement was noted on a retrospective assessment of the National Institutes of Health (NIH) Stroke Severity Scale, identification of acute brain imaging, and completion of early DNR orders.

Validation of PDD-derived measures in the statewide sample of 981 confirmed acute ischemic stroke cases demonstrated very good to excellent agreement for reporting of co-morbid illnesses and certain acute patient complications (pneumonia and urinary tract infections), but worse agreement for other less common complications (e.g., venous thromboembolic disease and pressure ulcers). Assessment of condition present on admission (CPOA) modifiers was consistent for most chronic conditions, but inconsistent for acute conditions, such as pneumonia and urinary tract infection, preventing determination of specific inpatient complications, since identification depends upon accurate knowledge of CPOA. Among procedures, administration of thrombolytics is well reported, but other procedures, especially critical brain imaging studies expected to be completed for all patients, are not. Early DNR orders (in the first 24 hours), a separate field reported in the PDD, are reported with fair agreement, but worse than might otherwise be expected for such an important aspect of care.

Using the validation data, we performed predictive modeling of patient outcomes (30-day mortality, inpatient mortality, and readmission) in order to examine the explanatory power of clinical measures found in the medical charts, some of which have been proposed to be included in the PDD (admission vital signs and lab results) and others which are likely to be predictive of patient outcome (e.g., stroke severity at admission and functional status at discharge). Three sets of models were created, called *limited models* (PDD-derived measures plus Census-derived measures at the zip code level), *intermediate models* (limited model variables plus vital signs and laboratory values), and *full models* (intermediate model variables plus additional clinical measures not yet proposed to be reported by hospitals). Because lab data were available in 643 of the 981 validation set abstractions, full analyses were performed on these data, and analyses excluding lab values were performed in the full set. A quality of care score (Quality Score) based on percent adherence to expert consensus quality of care indicators, a general proxy for care quality, was included in regression analyses to demonstrate a link between processes of care and patient outcomes, one of the goals of the validation study. Model results were tested for predictive power and cross-measure consistency.

Using the validation data, regression modeling of outcomes showed reasonable to excellent results for model estimation for mortality outcomes, but less so for readmission. Clinical data (vital signs and labs) were important for improving model performance, but inclusion of a stroke severity measure (NIH Stroke Scale – NIHSS) had the largest impact. Additional knowledge of function at discharge (as measured by ambulatory status) adds little information to the 30-day mortality model when one accounts for admission severity as measured by the NIHSS. In sensitivity analyses, we examined the relationship between quality and mortality. In both unadjusted and multivariate adjusted comparisons, increases in the derived Quality Score were

associated with better patient outcomes. These findings validate the use of risk-adjusted mortality outcomes as markers of underlying care quality. Ignoring CPOA flags, cause-specific complications (such as pneumonia) show good model fit, but hospital complications cannot be separated from presenting illnesses. Regression estimates using the limited model are good despite the lack of clinical measures, giving greater confidence for using existing data for overall stroke predictive modeling and hospital ranking.

Statewide Results

A statewide cohort of all incident ischemic stroke patients admitted between December 2006 and November 2009 was identified. Limited models examined in the validation set were applied to outcomes (inpatient mortality, 30-day mortality, 30-day readmission) in the statewide cohort. Similar logistic regression model performance was seen on the larger cohort with very good predictive performance for mortality models and less so for the readmission models. Hospital rankings based upon different mortality measures vary and readmission measures are discordant from mortality, highlighting the need to prospectively decide the measures with the greatest consensus validity for assessing the quality of stroke care.

The addition of clinical measures in the validation data set – especially stroke severity and functional status at discharge as measured by patient mobility – provided the greatest improvement to model performance. Proposed changes to the PDD (adding lab data and vital signs) improved model fit, but to a lesser degree. In the absence of implementing stroke-specific measures, the addition of general clinical measures would improve model performance. Unlike earlier hospital outcome reports, it is now possible to directly identify individuals transferred from outside emergency departments, an important improvement for the generalizability and

validity of these results at a time when acute stroke care initiatives are focusing on regional stroke referral centers.

Recommendations

Choice of outcome measures

- Use 30-day mortality outcomes, which overcome potential biases in relying upon inpatient deaths, which are biased by a hospital's ability to transfer patients
- Consider 30-day readmission as an alternative measure of outcome
- Report use of thrombolytics in stroke patients relative to the state average and to other benchmarks (e.g., top 10% in the state); could be added to the annual hospital utilization file
- Consider reporting percentage of patients with early DNR among patients dying within 30 days; could be added to the annual hospital utilization file
- Replace the current stroke outcome measure reported by OSHPD (adapted from Agency for Healthcare Research and Quality: Inpatient Quality Indicator) with the acute ischemic stroke measure

Data Improvement for Risk Adjustment

- Institute planned general data improvement efforts with the addition of clinical and laboratory data because these measures have significant explanatory power
- Request reporting of a prospectively measured stroke severity score
- Consider adding a measure of functional status at discharge

- Incorporate OSHPD Emergency Department Data (EDD) records to identify ED transfers into all hospital outcomes reporting for acute conditions because the source of admission variable in the PDD does not capture all ED transfers.

- Develop and disseminate training materials on the use of CPOA qualifiers to hospitals and their staff in order to improve the distinction between pre-existing or concurrent acute conditions versus hospital complications.

Regulatory Authority to Assess Care Beyond Outcomes

- Expand the scope of the outcomes reporting program to include measurement of clinical care – processes of care and their indications – and the ability to audit such measures.

Ongoing Validation of California Hospital Stroke Outcomes

- Build a relationship with the American Stroke Association and American Heart Association (ASA-AHA) "Get with the Guidelines" program to link OSHPD data with their ongoing quality improvement program data. Although not a random sample of hospitals, it may prove to be a cost effective approach and could serve as a template for a new approach to outcomes reporting by OSHPD.

II. INTRODUCTION

Stroke is highly prevalent in California with roughly 50,000 hospitalizations per year. Approximately 85% of strokes are ischemic (a blocked artery in the brain) and the remainder stroke cases are hemorrhagic (bleeding into the brain caused by a ruptured vessel). Stroke outcomes are severe. Mortality is roughly 11% for ischemic stroke and 30% for hemorrhagic stroke. Among survivors, morbidity is significant – with the majority of patients admitted from home requiring discharge to institutional post-acute care (either to a nursing home or a formal rehabilitation facility). Stroke differs from other acute medical conditions in terms of the broad spectrum of presentations ranging from confusion to weakness, paralysis, loss of speech, or worse, acute treatments, residual deficits (loss of speech, paralysis, etc.), and subsequent recovery. Depending on the portion of the brain affected and the type of stroke (ischemic versus hemorrhagic), patient presentation can range from slowly developing non-specific complaints to paralysis, coma, and/or rapid death. The goals of treatment are acute reversal of a stroke in progress, which leads to an increase in recovery of function and independence and a decrease in the likelihood of post-stroke complications and prophylaxis for the prevention of recurrent stroke.

The natural history of the disease and avenues for acute intervention and post-acute treatment and recovery are keys toward assessing the quality of care delivered to stroke patients. These provide the framework for assessing patient outcomes supported by evidence-based processes of care.

Natural History

1. Symptoms may differ widely depending upon the location of the brain injury, ranging from mild motor or sensory deficits to coma. Defining and grading stroke type and severity is important.
2. Neurologic deficits generally are most severe within the first two weeks after stroke with the bulk of recovery occurring by 3 months after stroke. Defining adequately sensitive, specific, and appropriate outcomes is necessary.

Acute Stroke Care

1. For acute ischemic stroke, interventions to regain blood flow, such as tPA (the thrombolytic agent ("clot buster")) or acute cerebral angioplasty, must occur within a narrow window of opportunity (three hours with newer protocols allowing for interventions up to six hours) to reverse a stroke's effects. Patients must be evaluated first for stroke severity and type of stroke (differentiated by imaging studies). Patients at increased risk for intracranial hemorrhage or bleeding from other sites are excluded from these interventions.
2. At present, no acute interventions exist to reverse the effects of hemorrhagic stroke.

Following Patient Wishes and Avoidance of Unnecessary Care

1. Do not resuscitate (DNR) orders are intended to assist patients in avoiding unnecessary or unwanted care (e.g., cardiopulmonary resuscitation for individuals with limited prognosis) or prolonging living in unwanted health states (e.g., mechanical ventilation for individuals in coma or persistent vegetative states). DNR orders are commonly written for patients, given the devastating effects of some strokes.

2. Under certain circumstances, offering, recording, and following DNR orders are considered measures of quality of care.

3. Because patients with severe neurological injury (including brain death) can be kept alive for significant lengths of time with assistive technology (mechanical ventilation, supplemental nutrition, and hemodialysis) and intensive nursing care when they would otherwise die, DNR orders have the potential to help patients avoid these situations and thus have a large impact on utilization and time to death. There may be considerable variation in the use of DNR orders and in the application of palliative care for stroke patients.

Post-acute Care of Stroke

1. All patients are expected to be evaluated for physical therapy and occupational therapy.

2. All patients are expected to receive physical therapy and occupational therapy designed around their stroke-related deficits and concurrent needs.

3. All patients should receive preventive care for post-stroke complications arising from stroke-related deficits and other co-morbid conditions (e.g., deep vein thrombosis (DVT) and pressure ulcers due to mobility deficits and aspiration pneumonia due to swallowing deficits).

4. Patients should receive post-stroke evaluation and treatment for the secondary prevention of recurrent ischemic stroke. This includes echocardiography, carotid duplex scan, and electrocardiogram. Treatment might include anticoagulation or antithrombotic therapy, lipid lowering agents, cardioversion, and carotid endarterectomy.

Specific Aims

Currently, a number of organizations provide public reporting of stroke care quality. Nearly all report on structural measures of quality. Only the Centers for Medicare and Medicaid Services (CMS) reports on patient outcomes. The ASA-AHA "Get with the Guidelines" has voluntary reporting of processes of care, but most hospitals do not participate. Given the clear need to establish benchmarks for ischemic stroke care quality and to monitor overall stroke care, the aims of the OSHPD Stroke Outcomes and Validation Study (SOVS) are to:

1. Establish the validity of diagnoses and procedures coded in the Patient Discharge Database (PDD) related to the occurrence, severity, treatment, and outcomes of stroke.
2. Examine variation in key acute and hospital-based post-acute service availability ("structure") and receipt of recommended care ("processes of care"), and establish their link to mortality, the principal outcome measure.
3. Examine the use and variation in DNR orders for stroke patients.
4. Create analytic models to predict stroke mortality that can be used for ranking hospitals using PDD records, with an emphasis on identifying whether variation in hospital ranking is attributable to key structural or process measures or to patient severity measures that are not currently captured in the PDD.

III. LITERATURE REVIEW

In this section, we review evidence-based measures of processes of care, outcomes after ischemic stroke, and independent predictors of stroke outcomes. The overarching goals of this literature review are to provide the background to guide choices regarding chart abstraction content (e.g., which patient characteristics and care should be collected during the validation study), to select important stroke outcomes to consider for public reporting, and to determine which data elements should be included in risk-adjusted stroke outcome models.

In the review of process of care measures, we identified 15 consensus and/or evidence-based process of care quality indicators, quality measures, and care guidelines in the English language literature since 2003. These include measures for acute treatment of stroke, acute rehab for stroke, and secondary prevention of stroke. We assembled a summary of high evidence measures from across these references plus measures with lesser evidence that is part of the AHA-ASA "Get with the Guidelines" campaign. In the review of stroke outcomes, 84 important outcomes of ischemic stroke were identified, including functional recovery (or decline) and complications (including death). For each outcome, we attempted to identify evidence-based independent predictors from 71 published articles dating back to 1996.

Methods for Process of Care Measures

We searched the literature for process of care measures from 2003 to present with a focus on published guidelines and documents in English with specific recommendations on the management of patients with ischemic stroke. We selected the most current guidelines with specific evidence-based, graded recommendation for physicians about ischemic stroke treatment that was sponsored by a governmental or nonprofit organization. Because grades of evidence and levels of recommendations vary from guideline to guideline, we created a standardized

unified scale (Appendix A: Table A-1) by mapping and reclassifying the existing scales of various guidelines (Appendix A: Table A-2). All measures were categorized by broad topic (e.g., thrombolytic therapy) and sub-topic area (e.g., time to presentation) in order to facilitate the review and summarization of these measures across sets (Appendix A: Table A-3).

After standardizing the evidence and recommendations across the fifteen references (10 references with guidelines and five references with quality indicators for acute stroke care), we retained the 131 (out of 628) measures for which there was the highest level of evidence (Level A in Appendix A: Table A-1) and for which the expert consensus was that either the intervention was useful, effective, and otherwise should be done (Grade 1 in Appendix A: Table A-1) or that the intervention was not useful, ineffective, potentially dangerous and should otherwise be avoided (Grade 3 in Appendix A: Table A-1). The 131 process measures considered after exclusions (Appendix A: Table A-4) were primarily for evidence-based recommended care (Grade 1) rather than care to be avoided (Grade 3). Measures were combined if they were substantially the same. A total of 29 overall unduplicated process-of-care measures were reported in at least three of the 15 consensus documents. These measures were reviewed by a stroke clinical advisory panel consisting of four stroke neurologists and two general neurologists. Seven measures were rejected and two others were combined leaving 21 evidence-based process of care measures from the review. The panel proposed adding five measures that did not meet the original criteria inclusion (see section on advisory panel recommendations for more detail), but which were deemed critical (hypoxia) or which are currently in widespread use (through the "Get with the Guidelines" initiative).

Stroke Outcomes

The review for stroke outcomes and predictors of stoke outcomes was restricted to research articles of adult stroke patients (18+ years old) written in English since 1983. Eligible studies had at least 100 patients who were assessed within 7 days of stroke onset and followed up for up to 12 months. We excluded studies that included patients with transient ischemic attacks (symptoms lasting less than 24 hours),which had only hemorrhagic stroke patients, focused on inpatient rehabilitation settings, or studied outcomes beyond 12 months. For each included study, rates for each outcome were identified for short-term (1 month), intermediate-term (3 months), or long-term (12 months) timeframes (Appendix B). A range of values is presented when results were available from multiple studies.

Despite the large amount of research performed in stroke, there are relatively few outcomes with consistent and in-depth evidence to support use in quality reporting**.** Importantly, current routinely collected data have the potential for capturing most of these outcomes, excluding patient function. The review identified the following consensus outcomes:

- Mortality (1-, 3-, & 12-month)
- Poor Functional Outcome / Incomplete Functional Recovery
- Complications: dysphagia, pneumonia, dehydration, depression, falls, and urinary tract infection
- Stroke recurrence
- All-cause hospital readmission

The review and summary of significant independent predictors of outcomes were restricted to those studies that performed multivariate analyses of independent predictors on the outcome of

patients with stroke and reported risk estimates. Although many studies provide univariate or bivariate associations among various outcome risk factors and stroke outcomes, these unadjusted risk estimates are potentially misleading without accounting for other contributing factors. Multivariate risk-adjusted estimates were included if they reached a minimum significance of $P < 0.05$.

Predictors of Outcomes

Summary results of stroke outcomes with statistically significant risk-adjusted predictors are presented for each time frame of interest (< 1 month, 3 months, and 12 months) (Appendix C: Table C-1). Available multivariate statistics – odds ratios, risk ratios, relative risks, hazard ratios, and relative hazards – were abstracted. Studies that did not report risk estimates or regression coefficients were excluded. Predictors of post-stroke function and mortality are well studied. Few studies have been performed for other outcomes. A number of function measures have been widely used: mortality, Glasgow Outcome Scale (GOS), Barthel Index (BI), and modified Rankin Scale (mRS) (Appendix A: Table A-5).

IV. STROKE CLINICAL ADVISORY PANEL – RECOMMENDATIONS

A stroke clinical advisory panel consisting of four stroke neurologists and two general neurologists was convened to review the results of the literature review and to make recommendations regarding 1) the data elements to be abstracted from charts for the validation study and 2) choice of outcomes and risk-adjustment strategies. In addition to the standard validation and outcomes modeling issues, the panel identified End-of-Life and treatment intensity preferences as especially important areas to focus on for this patient population. The findings of the panel are summarized in Table 1.

Table 1: Summary of Advisory Panel Recommendations

1. **Revise identified evidence-based process of care measures**
   - Of the twenty-nine candidate measures, rejected seven measures, created a combined measure from two existing measures, and added five measures to yield twenty-six process-of-care measures across sixteen domains of care.
2. **Consider post-discharge proxy measures of function**
   - Consider discharge to home as proxy for ambulatory at discharge
   - Discharge to home within 14 to 21 days of acute strokes
3. **Modify hospital sample selection and recruitment**
   - Include designated stroke referral centers
   - Involve hospital stroke providers to improve recruitment
4. **Focus on clinical measures for risk adjusted outcome models**
   - Risk adjustment is a major concern
   - Use NIH Stroke Scale (or similar measure)
   - Consider combining NIHSS plus a simpler scale (e.g., function at discharge) for predictive modeling
   - Ideally, include pre-morbid disability or pre-event status/function (e.g., pre-stroke Rankin Scale).
5. **Drill down on treatment intensity preferences**
   - Identify appropriate levels of care given end-of-life decision making
   - Selection criteria for patient outcomes should include consideration of choices regarding comfort care, intensity of care, withdrawal of care and deaths that occur after withdrawal of care, and withholding supplementation nutrition (e.g., stopping or not initiating enteral or perenteral nutrition).
6. **Use a theoretical framework for the validation study**
   - Affirm the validity of creating risk-adjusted outcomes by demonstrating a relationship between measured patient care and risk-adjusted outcomes
   - Identify treatment in a dedicated stroke unit directly or via proxy measures (e.g., seen by a neurologist, cardiac monitoring within 24 hours, etc.)

The advisory panel had a number of practical suggestions. Changes to evidence-based measures proposed were based primarily on using expert knowledge to ensure that measures conformed to current nationally collected data and measures that are considered important, but for which no experimental studies have been performed since non-receipt of particular care falls outside of the standard of care (e.g., treatment of hypoxemia). The panel recommended the use of internal champions (neurologist and stroke providers) to improve voluntary participation in the validation study. Use of direct and proxy measures to determine stroke severity and patient function (pre-stroke, post-stroke, and post-discharge) was recommended for risk-adjustment. Because of the prevalence of poor outcomes, discerning treatment choices driven by end-of-life considerations from complications of appropriate care was deemed important. Finally, demonstrating a relationship between measures of good care to risk-adjusted patient outcomes was given high emphasis as public reporting on unavoidably bad patient outcomes would not be worthwhile.

V. IDENTIFICATION OF STROKE CASES FROM THE PATIENT DISCHARGE DATABASE

Overview

The overall goal of the validation portion of SOVS was to select a set of 1,000 index ischemic stroke cases of interest from a sample of hospitals to review, compare with routinely collected information, and develop risk adjusted outcome models with the most complete clinical information available. Generating the sampling framework for individual cases in the SOVS was a multi-step process that required creating selection criteria for index ischemic stroke cases, identifying hospitals admitting acute ischemic stroke patients, excluding hospitals that were not general acute care facilities, identifying a pool of hospitals willing to participate in SOVS, and selecting the hospitals that would have charts abstracted in the validation portion of the study. In the end, we selected 39 hospitals to participate in the validation study, including the two UCLA hospitals where the pilot data abstractions were performed. The chart validation was complicated by the fact that the current interpretation of statutes does not support the regulatory authority of OSHPD to require hospital participation for the clinical data abstraction. The sampling framework and results are described below.

Definition of Ischemic Stroke Cases and Treating Hospitals

Index ischemic stroke admissions were defined as acute ischemic strokes in adults occurring in the community (including institutional residential care facilities). For the purposes of identifying index (first) admissions for acute ischemic stroke from the OSHPD PDD, the following criteria were employed:

Inclusion Criteria

- Primary diagnosis with ICD9-CM codes reporting ischemic stroke:

43301	occlusion and stenosis of basilar artery with cerebral infarction
43311	occlusion and stenosis of carotid artery with cerebral infarction
43321	occlusion and stenosis of vertebral artery with cerebral infarction
43331	occlusion and stenosis of multiple and bilateral precerebral arteries with cerebral infarction
43381	occlusion and stenosis of other specified precerebral artery with cerebral infarction
43391	occlusion and stenosis of unspecified precerebral artery with cerebral infarction
43400	cerebral thrombosis without mention of cerebral infarction
43401	cerebral thrombosis with cerebral infarction
43411	cerebral embolism with cerebral infarction
43491	cerebral artery occlusion unspecified with cerebral infarction
436	acute, but ill-defined, cerebrovascular disease

- Acute level of care

Exclusion Criteria

- Evidence of prior ischemic or hemorrhagic stroke (ICD9 codes 430, 431, and 432, within 180 days of the stroke admission.

- Transfer from within the hospital or from another acute care hospital (hospital-to-hospital transfer).

- Patient less than 18 years of age.

- Treatment at a hospital other than a general acute care hospital. Excluded hospitals include hospitals without emergency rooms, Children's hospitals, and chronic care (ventilator) facilities. Hospitals were identified prospectively based upon OSHPD annual financial data.

Acute Episode of Care, Outcomes, and Prior Stroke History (and other acute care)

Acute strokes that result in care at multiple inpatient facilities require greater scrutiny, but are not necessarily excluded from consideration. In fact, for assessing care, a complete acute inpatient episode of care is appropriate. Because of the increasing importance of stroke referral centers, many patients may be transferred from the emergency department of one hospital to that of a secondary hospital. For all patients, we define the following periods of care and evaluation:

1. The index hospitalization – defined as the acute hospitalization for ischemic stroke that meets the previously defined inclusion and exclusion criteria.
2. The acute episode of care – defined as the index hospitalization plus transfers from an outside emergency department and transfers to outside hospitals for acute care.
    - Emergency department encounters may occur on the same day or on the day before the date of admission.
    - Acute inpatient transfers have date of admission equal to the date of discharge (from the prior stroke hospitalization). Patients may have more than two consecutive stroke hospitalizations.
3. Look back window for stroke history and prior admissions – all hospitalizations and ED encounters two years prior to the index hospitalization.
4. Look forward window for post-discharge outcomes – all hospitalizations, ED encounters, and deaths occurring up to one year after discharge.

Figure 1. Relationship of Index Hospitalization to Acute Episode of Care, Prior Stroke History, and Post-Stroke Outcomes

Prior Stroke History	Acute Episode of Care			Outcomes
Two-year look-back window	Acute ED encounter for stroke	Index hospitalization for stroke	Acute inpatient transfers (any diagnosis)	Post-discharge outcomes (all-cause and cause-Specific)
	Not resulting in admission at this hospital	1st ischemic stroke admit with 90 day look-back	Continuous acute level inpatient care	Readmission, ED visits, and Deaths

Prior stroke history, illness-specific measures (stroke severity, co-morbidity), and post-stroke complications are defined in greater detail in Chapter XIII. Please see Appendix D (Tables D-1 and D-2) for stroke outcome codes, predictors, processes of care, and codes for emergency department to hospital transfer patients.

VI. CREATION OF THE OVERALL ISCHEMIC STROKE COHORT AND VALIDATION SAMPLE

The index case identification from the previous section was used to identify all stroke cases occurring between January 1, 2006 and December 31, 2009. For PDD and model validation, we abstracted a sample of cases occurring between December 1, 2006 and November 30, 2007 (see next section for more detail on the validation sample). For analytic modeling, we examined the most recent three year period for which data were available (December 1, 2006 to November 30, 2009), for which 30-day mortality could be defined and for which a two-year look back was possible (including records from the EDD). The goal validation sample was to consist of 1,000 ischemic stroke patients admitted to 39 hospitals between December 1, 2006 and November 30, 2007.

The state Death Statistical Master File data allowed for evaluating 30-day mortality rates for all patients admitted during this period. The total number of potential ischemic stroke patients was 35,763 at 347 facilities. After exclusions 1, 2, and 3, there were a total of 32,553 ischemic stroke patients treated at 336 facilities. Consideration of facility type led to a final sample of 32,228 patients with primary diagnosis of ischemic stroke at 327 hospitals.

VII. CANDIDATE VALIDATION – ISCHEMIC STROKE CASES AND HOSPITAL RECRUITMENT

Recruitment of General Acute Care Hospitals with Ischemic Stroke Cases

All 327 hospitals with any potential ischemic stroke cases were solicited for participation via letter and email to hospital chief executive officers and quality directors. From these, 145 (41%) hospitals expressed interest in participation and 39 hospitals were eventually selected for the study.

For each stroke hospital, we calculated the total number of stroke cases, the unadjusted 30-day mortality, the unadjusted inpatient mortality, and the use of tPA, the thrombolytic agent ("clot buster") that is administered to eligible patients in the first few hours after symptoms begin to dissolve the offending clots. In general, the larger hospitals tended to have lower mortality rates. The smallest hospitals had significant variation in performance.

The validation sample of hospitals was selected to assure an adequate representation of all types of hospitals based upon stroke case volume and unadjusted 30-day mortality. Hospitals were categorized by case volume quartile and mortality quintile. Potential hospitals were randomly identified from within each volume quartile and mortality quintile. This random assignment was then superimposed upon the pool of 140 hospitals willing to participate, creating a well-distributed sample of hospitals by size and mortality rate. In the final sample, every volume quartile – mortality quintile had at least one hospital and most had at least two hospitals.

Characteristics of ischemic stroke patients seen in the 39 hospitals in the SOVS validation sample were similar to stroke patients from all California hospitals, including the use of tPA (Table 2). An examination of the sampling frame demonstrated that the SOVS sample included an excellent distribution of hospitals by size and performance as measured by 30-day mortality.

Structural measures, including Joint Commission on Accreditation of Healthcare Organizations (JCAHO) stroke center certification, academic medical centers, and neurology training (residency) programs tended to be clustered in the larger hospitals in the SOVS set of hospitals as compared to all 327 stroke hospitals. Academic medical centers were identified by 1) membership in the council of teaching hospitals (requires at least three core specialty residencies) or 2) "teaching" as reported in the OSHPD annual hospital financial reports. The two definitions are substantially the same.

Table 2. Hospitals by Volume Quartile, Highest to Lowest Volume Quartiles

Volume Quartile	Variable	Overall sample				Hospitals willing to participate				Hospitals in the final sample			
		N	Mean	Min	Max	N	Mean	Min	Max	N	Mean	Min	Max
1	Case volume (n)	82	200	142	345	53	204	142	345	14	220	164	320
	30-day mortality (%)	82	11.1	3.9	23.4	53	11.3	3.9	23.4	14	10.1	3.9	16.7
	Inpatient mortality (%)	82	5.5	1.1	11.6	53	5.3	1.6	10.5	14	5.6	1.9	10.5
	Use of tPA (%)	82	4.1	0.0	13.6	53	3.8	0.0	13.6	14	5.2	0.5	13.6
2	Case volume (n)	82	124	91	156	42	121	93	156	10	118	90	153
	30-day mortality (%)	82	11.5	3.3	20.6	42	10.8	3.3	19.9	10	11.7	6.1	19.9
	Inpatient mortality (%)	82	5.5	0.7	12.7	42	5.0	1.3	11.2	10	5.3	3.2	11.2
	Use of tPA (%)	82	2.9	0.0	19.7	42	2.2	0.0	9.0	10	3.7	0.0	8.8
3	Case volume (n)	84	60	31	86	36	60	37	86	10	68	37	86
	30-day mortality (%)	82	12.3	0.0	29.2	35	11.8	2.1	22.2	10	11.5	3.5	20.9
	Inpatient mortality (%)	82	5.3	0.0	14.8	35	5.8	0.0	14.8	10	5.5	1.2	9.8
	Use of tPA (%)	82	1.7	0.0	14.1	35	2.5	0.0	14.1	10	2.7	0.0	14.1
4	Case volume (n)	80	16	1	37	15	18	3	37	7	17	3	37
	30-day mortality (%)	79	13.4	0.0	50.0	15	17.4	5.3	40.0	7	14.9	5.3	33.3
	Inpatient mortality (%)	79	5.7	0.0	50.0	15	6.1	0.0	20.0	7	4.5	0.0	12.5
	Use of tPA (%)	79	0.7	0.0	10.5	15	1.5	0.0	5.9	7	0.9	0.0	3.7

Patient Case Selection for Chart Abstraction

A total of 5,277 ischemic stroke patients were identified using the initial selection criteria previously described. After exclusions for patients with externally identified transfers from acute care hospitals (from PDD and EDD records), internally identified transfers from acute care (using the PDD source of admission variable), and those receiving carotid artery surgeries (for which ischemic stroke is both an indication for and a complication of surgery), there were 4,682 patients considered eligible for the chart abstraction study. From the pool of eligible patients, we created a sample of 1,000 patients that oversamples on deaths (22% vs. 11% overall) and receipt of tPA (14% vs. 4%). For each hospital, we selected three additional cases if patient charts could not be found (Appendix E). All charts provided by each hospital were abstracted, including these additional cases.

VIII. CHART ABSTRACTION INSTRUMENT DEVELOPMENT AND TRAINING

Overview

The chart abstraction instrument was divided into two primary sections. The first, a health information technician (HIT) module, corresponded to the data fields from the OSHPD PDD with the addition of a cover sheet to document misidentified (non-acute ischemic stroke) cases that did not require full chart review and reporting. The second, a Clinical (RN) Abstraction Instrument, was designed to assess patient illness, stroke severity, processes of care (and their appropriateness), treatment preferences, and stroke outcomes.

Instrument Development – Clinical (RN) Abstraction Instrument

The Clinical Abstraction Instrument was developed using the national Veterans Health Administration VHA Stroke Study chart abstraction tool as an initial template. The VHA tool consists of four modules – Inpatient Assessment and Management Module, NIH Stroke Scale (NIHSS) Module, Discharge Module, and a Validation (HIT) Module. The NIH Stroke Scale Module employs a previously validated retrospective data collection instrument for assessing the elements of the NIHSS.

After reviewing the VHA tool (which was applied on a single uniform electronic medical record across virtually the entire VHA system), substantial changes and reorganization of the tool were necessary to account for abstracting electronic and paper charts from many different hospitals and data sources. Physician investigators pre-pilot tested the abstraction tool using a small number of medical charts from the 50 cases that had been selected for the pilot test. For the pre-pilot test sample, we obtained hard copies of all medicals records—including all orders (handwritten and pre-printed), all consent forms signed by the patient, and all handwritten notes (including outside records that are in the charts, e.g., ambulance run sheets). Because nursing

note printouts were voluminous (up to 900 pages), only the first 72 hours and last 48 hours of nursing notes in the hospital were used. All physician notes and reports were included.

The content and format of the tool was drastically changed to improve flow of data elements to be abstracted and formatted to enhance efficiency and speed of abstraction. The clinical abstraction materials were reorganized into an Admit Module (including the NIH Stroke Scale assessment), a tPA Module, and a Discharge Module. Based on recommendations from the expert panel, a new section – Treatment Intensity Preferences Module – was developed to capture more detailed information on end-of-life decision making, treatment preferences (including withdrawal of care), and certification of brain death in comatose patients. The HIT Module was modified to reflect OSHPD rather than VHA reporting requirements.

Questions were added that allowed for opting out of abstractions if cases were not acute ischemic strokes or if the cases reflected hospital transfers. For the purposes of validation, transfer cases (from outside emergency departments) were to be excluded because documentation from outside facilities are unreliably included in hospital charts, doubling the number of charts (and hospitals) to be reviewed for these types of patients. However, from the standpoint of modeling outcomes and assessing a hospital's relative performance, transfer cases may have an important role to play, especially in the case of stroke referral centers.

IX. PILOTING THE CHART ABSTRACTION INSTRUMENT

The pilot sample was comprised of 50 ischemic stroke cases divided equally between the two UCLA hospitals (the Ronald Reagan UCLA Medical Center and the Santa Monica UCLA Medical Center). This initial sample was revised to exclude emergency department to UCLA transfers by linking the EDD to the full UCLA cohort, removing cases that were transfers and replacing them with non-transfer cases as the PDD source of admission code does not accurately code ED to hospital transfers.

The pilot abstraction showed very good agreement across many important metrics, including past medical history (co-morbidities), deaths, administration of thrombolytics, and use of DNR. We found relatively poor agreement for the NIH Stroke Scale and imaging study reporting, which led to:

- Redesign of the abstraction instrument including regrouping tests in easy to fill out abstraction tables limited to a single page rather than over many pages.
- Creation of a worksheet for abstracting the NIHSS and retraining the RN abstractors on how to use the worksheet.
- Establishment of a time frame for admission imaging studies as the potential numbers of studies are staggering, while hospitals only report a small fraction of these.

The NIHSS was re-abstracted for all of the pilot study charts. Review of inconsistency in imaging study reporting demonstrated that re-abstractions were substantially accurate, suggesting that there was a training effect on the abstractors' reliability.

X. STATEWIDE CHART ABSTRACTION AND VALIDITY OF OSHPD REPORTING

Pilot Study

During the review of the first 50 charts (Pilot Study), it was clear that nurse abstractors had to master the learning curve in order to accurately abstract data from the medical charts. Reliability significantly improved after instructions for the NIH Stroke Scale were modified, a work sheet was introduced to facilitate the abstraction process, and all abstractors were retrained. Once these issues were resolved in the pilot portion of the study, the statewide chart abstraction was initiated.

Selection of Patient Charts

As described previously, we identified and selected charts for patients with a primary diagnosis for ischemic stroke (434.xx, 436, and 437.x), treated at a general acute care hospital between December 2006 and November 2007, with exclusions for age less than 18, transfer cases, and strokes occurring due to procedures. For each hospital in the sample, three to twenty-eight charts were selected for review and abstraction, for a projected total sample of 1,000 abstracted. For each hospital, we also requested three additional charts beyond the target number in the event that a hospital was unable to locate one or more of the requested charts. Because of ongoing delays with a number of hospitals completing their Institutional Review Board (IRB) approvals and pulling charts, all requested charts were abstracted during site visits in order to ensure that the 1,000 chart goal was reached. Hospitals were able to identify medical charts by patient gender, date of birth, admission and discharge dates, and primary diagnosis.

Data Entry and Cleaning

For each chart abstraction, data were double entered into Microsoft Excel by two independent research assistants. Charts were reviewed and safely de-identified through the creation of two

crosswalks. The first crosswalk contained medical record number and chart booklet number, while the other linked booklet number with OSHPD's data. Data entry errors were compared and discrepancies were resolved.

Statewide Clinical Chart Abstraction Results

Chart abstractions were attempted on 1,052 charts (Table 3). Between a combination of stop flags in the instruments if patients met exclusions (non-acute strokes, transfers from other hospital ED or inpatient areas, or strokes occurring as complications of hospital procedures, or non-ischemic strokes), or non-completion of RN and HIT sections, a total of 981 complete primary chart abstractions were available for validation of the corresponding PDD index admissions, and 131 charts had complete reabstractions allowing for confirmation of the chart abstraction accuracy.

Table 3. Primary Chart Abstractions Completed

	N
RN Chart Abstractions to-date	1,052
HIT stop abstraction	51
ADMIT stop abstraction	8
HIT Module only	1
Completed Charts Ready to be Linked to OSHPD Data	992
Charts Not Able to be Linked	11
Total Completed Linked Abstractions	981

An error in outputting the last page of the abstraction instrument into the final document for printing led to the non-collection of lab data across the sample. After corrective measures were taken, a total of 701 unique patients had labs abstracted including 142 reabstractions (not the same records as original chart reabstractions). Among the 981 patient charts with complete RN/HIT abstractions, 643 (66%) had lab data abstracted as well.

Chart Abstraction Reliability

Chart abstraction reliability was assessed in two stages – after the initial 50 cases performed at the pilot hospitals and then at the completion of the entire chart abstraction. A total of 131

completed abstractions / reabstractions were available to assess reliability of findings. For categorical variables in both the RN and HIT sections of the chart abstraction, unweighted kappa statistics were generated. In situations where abstraction / reabstraction results have missing categories so that there are missing columns or rows in the comparison tables, a kappa statistic cannot be calculated, and we rely upon overall agreement. For continuous measures, we measure the Intraclass Correlation (ICC). Results of the ICC can be interpreted roughly analogously to the kappas, so that values above 0.5 are reasonable and above 0.6 are good. For reliability of diagnosis and procedure codes in the HIT Module, we grouped diagnoses and procedures according to the Clinical Classification System (CCS) groupings developed by the Agency for Healthcare Research and Quality (AHRQ).

In general, HIT chart abstractions were quite consistent across the 131 doubly abstracted charts; this extended across most demographic measures and for diagnoses, procedures, and condition present on admission (CPOA) measures with sufficient observations. DNR had a kappa of 0.47, reflecting moderate agreement between abstractors. Discharge location had a kappa of 0.50. Where there was 100% agreement, but no variation in the measure (e.g., scheduled / unscheduled), a kappa statistic could not be calculated using SAS.

In RN abstractions, abstractions showed moderate to excellent agreement for many measures. However, for acute complications, the only conditions with adequate observations and agreement were pneumonia, urinary tract infection, and hypoxia. Abstractors were successful in getting reasonable agreement on identifying anticoagulation in the first two days, but not in identifying other forms of VTE prophylaxis (e.g., compressive stockings, etc.). Administration of tPA showed excellent agreement, but identifying the timing of tPA was much less so. Treatment intensity preferences appear to be difficult to assess in detail. Basic items appear to be readily

captured (choice of no CPR, documenting communication of no CPR), while preferences regarding supplemental care (e.g., nutrition) are inconsistently identified. For continuous measures that may be reported to OSHPD in the future (weight, vital signs on admission), there was excellent agreement between abstractors based upon the ICC. For lab data abstracted, corresponding to potential data to be measured in the future by OSHPD, there was excellent agreement between abstractors.

Overall, results of the abstraction / reabstraction comparisons gives good confidence regarding the accuracy of measures to be used in regression modeling, as nearly all of these appear to be reliably measured.

Validation of Diagnoses, Procedures, and Condition Present on Admission

The HIT validation sample for diagnoses, procedures, and CPOA consists of data from 981 charts from 39 hospitals. In these comparisons, diagnoses and procedures are categorized according to the AHRQ single level CCS categories for diagnoses and procedures. There are 285 mutually exclusive CCS diagnostic categories (including E-codes) and 231 mutually exclusive CCS procedure categories. In other words, the AHRQ CCS software creates 285 binary variables reflecting the CCS diagnostic categories and 231 binary variables reflecting the CCS procedure categories.

Disease entities are first compared for presence or absence at any time during the hospital course, ignoring CPOA coding. This allows for an evaluation of general agreement for disease coding. Then, CPOA coding is addressed using the approach previously used by Goldman et al[1]. Among those patients where the PDD and the validation sample agree on the presence of a condition, agreement on CPOA is assessed with statistics for accuracy (overall agreement) and agreement beyond chance (kappa statistics).

Statewide HIT Validation Results – Overall Agreement on Diagnostic Categories

Results of comparisons based on agreement within CCS diagnosis categories and across all CCS diagnosis categories are shown in Appendix F (Table F-1). Overall agreement across diagnostic categories with sufficient observations is good to excellent for most of the conditions that are used in case-mix adjustment (viz. Charlson Index and Elixhauser Indicators) and for some acute conditions that might be considered as complications, such as pneumonia and urinary tract infection. Other potential complications, such as venous thromboembolic disease, did not appear to be accurately reported. Thus, certain acute conditions reported in the PDD during the index hospitalization may be helpful towards creating an in-hospital complication measure, in addition to other measures, such as all-cause mortality and all-cause readmission.

Stroke severity as measured by neurologic complications is an important predictor of patient outcome, independent of chronic conditions and acute conditions present at admission. In the current validation results, the PDD captures roughly 50% of individuals with hemiplegia with few false positives, but has a high rate of false negatives. Under-measurement of stroke severity by ICD9 diagnosis coding is problematic, but represents an area where hospitals may be able to improve capture of stroke-related disability through improved documentation as the stroke diagnosis by itself is the primary driver for hospital reimbursement without the requirement of documenting specific stroke disability.

Statewide HIT Validation Results – Condition Present on Admission within Diagnostic Categories

In general, CPOA is coded as “YES” quite often, making overall comparisons difficult as there is little variation in the gold standard. Nevertheless, from the standpoint of overall agreement, most of the CPOA measures do have quite good agreement. Among items noted as potential areas to be used as measures for complication (pneumonia and urinary tract infection),

there was generally worse agreement for CPOA for these measures, as measured by both overall agreement and by the kappa statistic (Appendix F: Table F-2). Variation in CPOA may be limited in this particular group of patients given the nature of their disease and protocols in place for discharge to post-acute care prior to the development and/or recognition of acute complications. CPOA findings in the stroke population appear to be worse than that found in a recent study of patients with AMI, CHF, angioplasty, and pneumonia reported by Goldman et al.[1] This inconsistency may be explained in part by the difference in disease processes and the existence of substantial co-morbid illnesses in these patients, which could mask overlapping occurrence of in-hospital diagnoses.

Statewide HIT Validation Results – Overall Agreement on Procedure Categories

Among procedures, there was generally poor agreement overall and across individual CCS categories with the exception of category 231 ("Other therapeutic procedures"), which primarily consist of thrombolytics (Appendix F: Table F-3). A direct comparison of thrombolytics (top of the table) with category 231 shows even better agreement than might be assumed from category 231 primarily because this category is a combination of multiple different infusions, rather than just thrombolytic administration. In contrast, many expected imaging procedures, such as CT scans of the head (category 177), brain MRI (category 198), carotid ultrasound (category 192), and echocardiograms (category 193) show excellent specificity, but extremely poor sensitivity, missing most performed procedures. This is not surprising – outside of thrombolytics, most procedures for ischemic stroke patients occur outside of the operating room and do not require a physician to be present to determine and initiate therapy. The apparent excellent reporting of thrombolytic administration in these patients suggests that this measure in particular might be

used for the measurement of quality or benchmarking in the hospitalized ischemic stroke population.

Do Not Resuscitate orders written in the first 24 hours is a data element that hospitals are required to report to OSHPD for records in the PDD. This definition corresponds roughly to Early DNR orders, which are defined as occurring within the first two days (forty-eight hours) after admission. This is the single end-of-life care decision making process that is collected in these data. In general, there is fair agreement across hospitals for DNR reporting (overall agreement 86% with a kappa statistic of 0.53), worse than might otherwise be expected for such an important set of decisions.

Agreement between Nurse-Abstracted Clinical Measures and Measures Derived from the PDD

Much of the information for proposed predictive modeling of ischemic stroke patient outcomes corresponds to information collected in the Admit Module of the SOVS clinical abstraction tool. Comparison of a number of corresponding measures (demographics, health habits, co-morbid conditions, pre-existing acute conditions, and possible hospital complications) were made between abstracted measures from the validation set and potentially corresponding measures derived from the PDD (using condition present on admission flags). In general, there is excellent agreement for demographic information, good agreement for chronic co-morbid illnesses (diabetes) versus prior acute illnesses (acute myocardial infarction), and generally poor agreement for identification of inpatient complications (refer to Appendix G). As with the HIT-PDD validation, the nurses tended to identify pneumonia and urinary tract infections as acute complications, which in general were identified as present on admission in the PDD.

Use of Do Not Resuscitate in the PDD and its Association with Treatment Intensity Preferences and End of Life Decision Making

In the Admission Module of the chart abstraction instrument, we abstracted elements of DNR orders, including CPR, occurring within the first two calendar days as well as subsequent changes in these elements. Identifying DNR orders within the first twenty-four hours is potentially challenging because not every order in the chart is timed and dated, leaving only date of order (or physician note) as evidence of these orders. Thus, we allowed for DNR in the two calendar days as a compromise.

Comparing DNR to findings from the Treatment Intensity Preferences (TIP) Module does elicit underlying elements contributing to reporting of DNR. We compared mean responses in the TIP Module to (1) PDD-reported DNR choice, (2) choice of "No CPR" as abstracted in the TIP Module, (3) choice of "No Mechanical Ventilation (NOMV) as abstracted in the TIP Module, and (4) Inpatient Death (Appendix H: Tables H-1 through H-4).

DNR is consistent with the "No CPR" measure (Appendix H: Table H-2). Patients with DNR are more likely to have accompanying NOMV orders, subsequent (and earlier) changes in treatment intensity, requests for palliative care consultation, and progression to death (as measured by both inpatient death and death at 30 days). DNR was associated with much higher death rates in the hospital and within 30 days of admission. Because treatment intensity preferences such as supplemental feeding, antibiotic use, etc. were uncommonly and unreliably reported, we do not report on these here. Thus, only "No CPR" and NOMV are elements of the TIP Module that are reasonably abstracted.

Comparison to "No CPR" and to NOMV as reported by the abstractors results in a stronger relationship between initial and subsequent treatment intensity choices and patient outcomes

(Appendix H: Tables H-2 and H-3). Among those without an initial "No CPR" order, 4% have a subsequent discussion for change in CPR orders. NOMV is highly correlated with "No CPR" orders and occurred in roughly 1/3 of patients with "No CPR" orders. Palliative care consultations were more common in the "No CPR" group. Changes in TIP occur earlier in the "No CPR" group compared to those patients without these orders (as measured by follow-up discussions on CPR or mechanical ventilation orders and ordering palliative care consultations). Decision making in the NOMV group is substantially similar to the larger "No CPR" orders group (Appendix H: Table H-3).

Patients with "No CPR" orders had much higher rates of mortality than those without these orders. Of interest, 40% of deaths among these patients occurred outside of the index hospital, presumably occurring at home or in a sub-acute or hospice setting. Patients who die in the hospital tended to receive palliative care decisions later than the overall group of patients that chose lower intensity of care early (as measured by DNR or DNI orders, as shown in Appendix H (Table H-2 and Table H-4)).

In summary, the PDD DNR variable is a reasonable approximation for the identifiable "No CPR" orders identified in the SOVS chart abstraction. Substituent elements of DNR orders reliably identified from charts include "No CPR" and NOMV (in a select subset of the "No CPR" patients). Subsequent care and decision making identified in the TIP Module is consistent with initial decisions regarding DNR, but do not increase the accuracy of identifying DNR patients or how best to subset these patients from outcome analyses.

Geocoding of Patient Address

During the chart abstraction, HIT abstractors completed a separate stand-alone abstraction sheet with the study chart ID and the patient address. The list of patient addresses was geocoded according to Census 2000 and Census 2010 geographic areas plus best estimated longitude and latitude using the University of Southern California's Geographic Information Systems (GIS) Lab online geocoding service: https://webgis.usc.edu/Default.aspx, which provides free, limited geocoding.

From the 981 completed ischemic stroke abstractions, 865 patients had a street address reported, 25 patients had a P.O. Box reported, and 91 patients had no address reported found in the chart data. In initial geocoding efforts, 760 out of the 865 street addresses could be geocoded to Census 2000 blocks and tracts. Clerical review of the 105 unmatched records revealed 53 additional records with typographical errors in the street addresses, 37 addresses which appeared to be correct and 15 addresses which could not be located. Thirty-nine of the 53 additional records could be geocoded. In the final geocoding, 790 out of the 865 records were geocoded to Census 2000 tracts. Among records with a post address, 831/890 (93%) had a zip code that matched the patient residence zip code reported in the PDD. Among those not matching, 30 matched on the first three digits and 2 matched on the last three digits. Nearly all of the remainder appear to be completely unmatched.

Comparison of Census tract-level measures to Census Zip Code Tabulation Area (ZCTA) measures

A comparison of proxy measures based upon census tract versus the Census-equivalent zip code level measure, the zip code tabulation area (ZCTA) shows very good average agreement

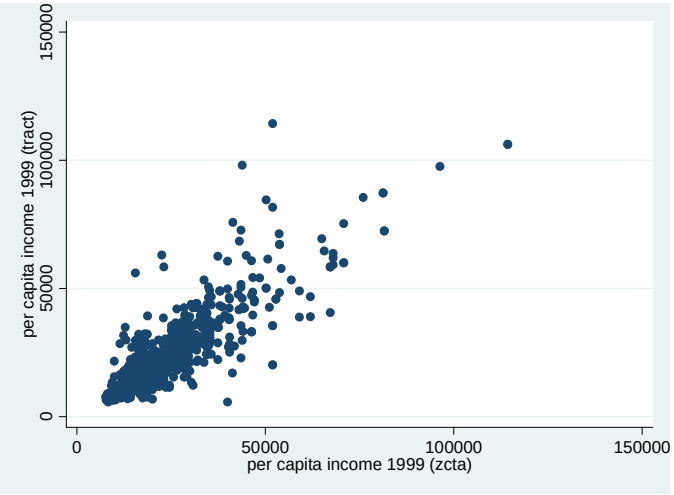
(Appendix I). By definition, the more granular census tract measures have greater variation when compared to the ZCTA-based measures.

Table 4: Comparison of Census Tract vs. ZCTA Measures (N=748)

Variable	Census Tract				ZCTA				r
	Mean	Std. Dev.	Min	Max	Mean	Std. Dev.	Min	Max	
Census 2000 Measures									
% Non-English Speakers	9.6	11.4	0.0	60.0	10.0	9.6	0.0	57.1	0.80
Per Capita Income ($)	26,287	15,049	5,725	114,318	25,946	13,381	7,632	114,359	0.83
% Income < 200% Poverty	28.3	19.4	2.6	86.9	29.0	16.4	3.4	83.9	0.78
% No High School Degree	20.6	16.6	0.7	78.2	20.7	14.1	0.9	74.9	0.81
% Rural Residence	0.0	0.2	0.0	1.0	0.0	0.1	0.0	1.0	0.51
Calculated Distance									
Distance - residence to stroke hospital (miles)	6.9	17.1	0.0	337	7.8	17.1	0.1	337	0.92

Graphical comparison of measures demonstrates the degree of agreement in ZCTA versus tract-level measures in the validation set. For example, income shows quite good general agreement, with a correlation of 0.83 and graphically good agreement (Figure 2).

Figure 2: Comparison of Income, ZCTA vs Tract

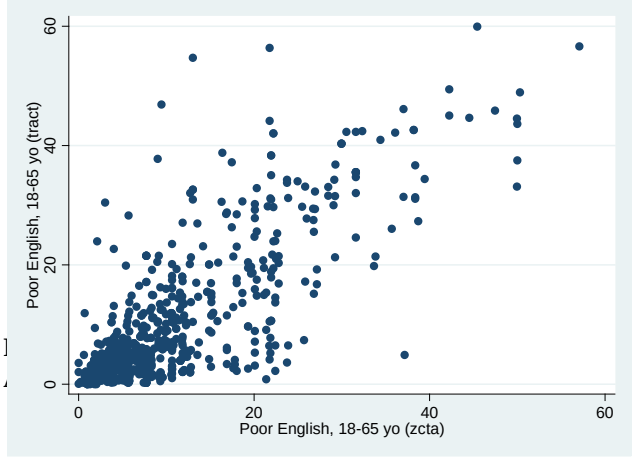


For language fluency, agreement is reasonable, but there is a lot more scatter around the diagonal (tract=zcta). This is less apparent when comparing just correlation coefficients between income and language fluency (Figure 3).

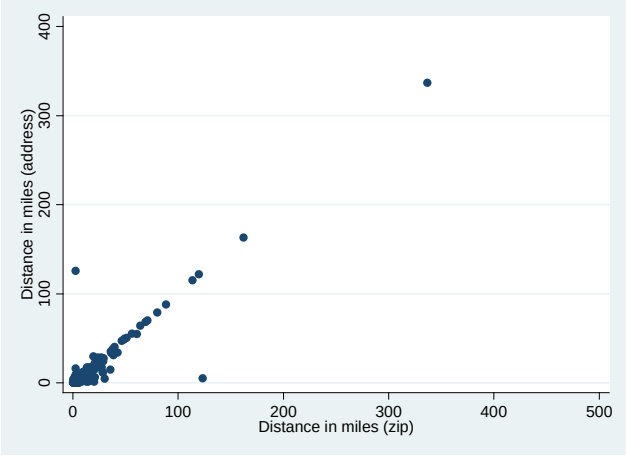
Figure 3: Comparison of Language Fluency in Adults, Tract versus ZCTA

Agreement for binary variable where rural buildings comprise more than 40% of structures is roughly 50%, primarily due to the grouping of the small number of records where patients were reported coming from rural areas (as designated by tract) with more urban tracts that together make up larger geographic entities.

Finally, straight line distance between residence and hospital is well approximated by simple zip code to zip code centroid estimates with correlation coefficient of 0.92 (Figure 4). Graphical comparison also points out what appear to be two outlier measures, which may occur with incorrect reporting of city or zip code in portions of these.



In practice, using straight line distance in regression analyses to predict patient outcomes is problematic because of patient selection biases (e.g., choice of hospital and patient outcome are linked through unmeasured severity). Alternative distance measures (e.g., distance to closest hospital or distance to closest high volume stroke hospital) are more clearly interpretable as proxy measures of local availability of hospital care or expert stroke care without the inherent biases accompanying actual choice of hospital.



Impact of Census and Distance Measures on Analysis Results (Validation Sample)

Comparison of selected regression estimates for predicting inpatient death demonstrates a small improvement in model performance (measured by increase in the model log likelihood ratio) with minimal changes in regression coefficients, except for rural residence, which changes quite a bit due primarily to the relatively large changes (19 to 11 patients classified as living in a rural area) in classification of rural areas when moving from Census tract to ZCTA (Table 5). In this example, distance to closest treating hospitals is based upon distance between zip code centroid coordinates.

Table 5: Selected Regression Coefficients Predicting Inpatient Death in the Validation Sample

	Census Tract Level Measures				Zip Code Level Measures			
Variables	**OR**	**95% CI**		**P>|z|**	**OR**	**95% CI**		**P>|z|**
%Non-English Speaking	1.02	0.97	1.07	0.44	1.03	0.97	1.10	0.28
% Income <200% Poverty	0.99	0.96	1.01	0.32	0.98	0.95	1.01	0.20
Rural	0.37	0.02	5.90	0.48	3.92	0.28	55.01	0.31
Distance to High Volume Hospital	0.99	0.96	1.03	0.77	0.99	0.96	1.03	0.64
Distance to Medium Volume Hospital	0.97	0.90	1.04	0.39	0.97	0.90	1.04	0.41
Distance to Low Volume Hospital	1.00	0.94	1.08	0.93	0.99	0.92	1.07	0.84
Number of obs	640				Number of obs	640		
LR chi2(58)	119.36				LR chi2(58)	118.55		
Prob > chi2	0.00				Prob > chi2	0.00		
Pseudo R2	0.28				Pseudo R2	0.2763		

Geocoding Conclusions

This limited examination of variability and inclusion of geocoded measures into outcomes analyses shows only a limited impact of these measures on regression estimates. Significance of estimates and their explanatory power (e.g., how much of model variance that the measures account for) are dependent upon the outcome chosen. Because of the number of uses for these proxy measures both for predicting and planning, this particular evaluation is limited. Nevertheless, internal consistency of measures across geographic entities is reassuring, and the predictive power of more granular measures should not be discounted.

XI. PREDICTIVE MODELING – CONCEPTUAL MODEL, PREDICTORS AND OUTCOMES

The index ischemic stroke hospitalization is identified using a primary diagnosis of ischemic stroke with exclusions for age, complication from an acute procedure, transfer (i.e., that the stroke occurred during the earlier hospitalization or that the initial contact should be credited to the earlier hospitalization), and stroke within 180 days. The index hospitalization is distinguished from the acute care episode, which may include ED and acute care hospital transfers (Figure 5).

Figure 5. Relationship between Index Hospitalization and Acute Episode of Care, Patient Transfers, Past Hospitalizations, and Post-Discharge Outcomes

Stroke history	**Acute Episode of Care**			**Outcomes**
Two-year look-back window	Acute ED encounter for stroke	**Index hospitalization for stroke**	Acute inpatient transfers (any diagnosis)	Post-discharge outcomes (all-cause and cause-specific)
	Not resulting in admission at this hospital	1st ischemic stroke admit with 180 day look-back	Continuous acute level inpatient care	Readmission, ED visits, and Deaths

For all patients, we defined the following periods of care and evaluation:

1. **The index hospitalization for stroke** – defined as the acute hospitalization for ischemic stroke that meets the previously defined inclusion and exclusion criteria.

2. **The acute episode of care** – defined as the index hospitalization plus transfers from an outside emergency department and transfers to outside hospitals for acute care.

   - **Emergency department encounters** may occur on the same day or on the day before the date of admission.

- **Acute inpatient transfers** have date of admission equal to the date of discharge (from the prior stroke hospitalization). Patients may have more than two consecutive stroke hospitalizations.

3. **Two year look back window for stroke history and prior admissions** – all admissions and ED encounters two years prior to the index hospitalization.

4. **Up to one year look forward window for post-discharge outcomes** – all admissions, ED encounters, and deaths occurring up to one year after discharge.

Outcomes

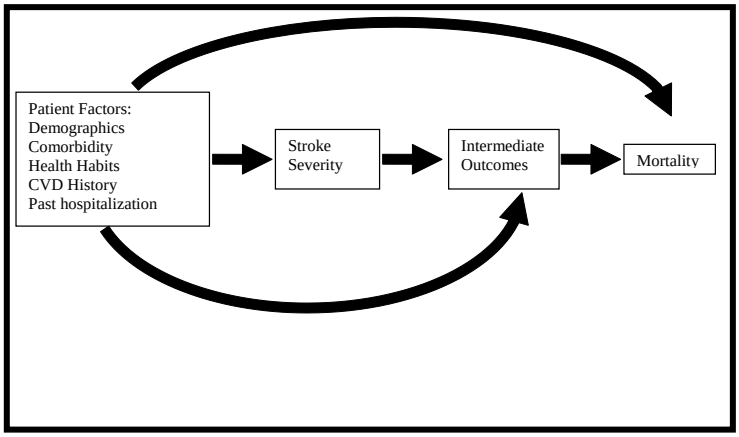
In the construction of the stroke cohort and chart sampling, we identified mortality (inpatient and 30-day) and administration of tPA during the acute hospitalization. The literature review identified a number of potential alternative outcome measures that might be used for public reporting (Table 6). Certain measures identified in the literature review and by the advisory panel are not measurable (e.g., functional recovery and recovery of independence) or are not reliably measured (e.g., venothromboembolic disease and pressure ulcer). Because reliable cause-specific outcomes were uncommon, it was felt that in the modeling of patient outcomes the focus should be given to all-cause outcomes (mortality and readmission).

Table 6: Outcome Measures Considered
All Cause Mortality • 30-day mortality (from date of admission) • one year mortality (from date of admission) • 30-day mortality after discharge • one year mortality after discharge • inpatient mortality **All Cause Readmission after stroke** • 30-day readmission • one year readmission **All Cause Outcomes** • 30-day readmission, ED visit, or death • one year readmission, ED visit, or death **Medical complications after stroke** • during the index hospitalization (in-hospital complications) • all hospital visits 30 days after discharge (cause-specific readmissions or deaths)

Predictors of Outcome

The relationship of patient-related factors to stroke outcomes is shown in Figure 6. Patient factors influence intermediate outcomes and mortality. Stroke severity – neurologic signs, symptoms, and disability due to the acute stroke is an intermediate outcome of stroke. In a reduced model, it is a predictor of other outcomes. Thus, in the context of regression modeling, we used both patient factors and stroke severity to predict mortality and other patient outcomes. These factors are outlined below in more detail.

Figure 6. Conceptual Model of Stroke Outcomes



1. **Risk factors** predicting complications after stroke, including hemorrhagic transformation measured during the index hospitalization

- (1) evidence-based disease measures related to patient stroke outcomes
- (2) other co-morbid disease measures that predict mortality in the general hospitalized patient population
- (3) Patient demographics, including indirect measures of socioeconomic status based upon Census measures and travel distance to closest high volume stroke hospitals (a measure of access to stroke specialty care)
- (4) Health habits (smoking and alcohol use)

2. **Stroke Severity** – Neurologic signs, symptoms, and disability due to stroke

- Elements that are prospectively part of the NIHSS and stroke disability that is not part of the NIHSS, such as seizure disorder
- Severity measured during the index hospitalization and the entire acute care stay (including prior ED encounters and later transfer hospitalizations)
- In the stroke validation set, elements of disease severity and function include the NIHSS, patient function (mobility) at discharge, admission vital signs, and lab results

3. **Stroke type and history of cerebrovascular disease (CVD)**

- Prior strokes are defined as: (1) ischemic, (2) hemorrhagic, (3) unknown, and (4) total
- Occurrence of temporary ischemic attacks (TIAs)
- Measured during the index hospitalization and prior hospitalizations (within two years of the index hospitalization) and any prior emergency department visits

4. **Admission history**

- Creation of longitudinal record that includes admission and transfer dates for all admits in the care episode, including emergency department visits.
- Variables: facility, admit type (inpatient versus emergency department visit), and dates of admission and discharge, length of stay (LOS) (each hospital) and total LOS
- Source of admission from a nursing home or other long term care facility

5. Quality of Care

- In the validation data the large number of quality indicators allows for creation of a quality of care index, a measure for better care.

Model Specification

Patient outcomes are modeled according to a reduced form model that includes **Stroke Severity** as a predictor rather than as an outcome. Although successful receipt of thrombolytics is a predictor of improved outcome among eligible patients, there is likely selection bias, so this process of care was excluded from final models. A functional relationship can be imagined between predictors and patient outcome:

Patient Outcome = Function (Patient Demographics, Stroke Severity, Co-morbid Illness, Prior Cerebrovascular Disease History, Patient Health Habits, Quality of Care, ED Transfer, Hospital Transfer)

Measures of socioeconomic status are not directly measured in the PDD, but indirect measures based upon U.S. Census results by zip code (or census tract, if available) can be linked to the data. Because arrival time to a hospital is critical towards initiating treatment and because treatment in a hospital where there is experience in acute (administering thrombolytics) and post-acute (rehab) stroke care, distance to the closest high volume (or otherwise determined specialty) stroke center is a good proxy for access to specialty stroke care. Distance from patient home to hospital is likely confounded. Excluded from predictive modeling are end-of-life care decisions (early DNR) that are highly correlated with patient outcomes

Model Predictors

A summary of model predictors and source of the patient level data is shown below (Table 7). Excluded from the table are proxy measures based upon the U.S. Census (linked in the

validation set by Census Tract and in the full cohort by Zip Code), hospital structural measures, and any other area-wide (supply) measures that may be used for predictive modeling of patient outcomes, but which are typically excluded from predictive modeling for quality of care purposes.

Table 7. Patient-Level Predictors of Outcomes and Source of Information					
Measure	**Past Admits**	**ED**	**Index Admit**	**Transfer Hospital**	**Excluded from Models**
Demographics					
Age at index admission			X		
Gender			X		
Combined race/ethnicity			X		
Source of admission			X		
Patient zip code of residence (for multilevel modeling)			X		X
Centroid distance to index hospital (by zip)			X		X
Centroid distance to ED (if first part of encounter; by zip)		X			X
Centroid distance to closest low/medium/high volume hospital (by zip)			X		
Stroke Severity *** source applicable only for admissions with short length of stays for which credit was given to the transfer hospital**					
Dysphasia (difficulty with language)		X	X	*	
Aphasia		X	X	*	
Dysarthria (inability to articulate)		X	X	*	
Dysphagia		X	X	*	
Facial palsy		X	X	*	
Hemiplegia/Hemiparesis		X	X	*	
Other paralysis		X	X	*	
Hemineglect		X	X	*	
Vision loss		X	X	*	
Apraxia		X	X	*	
Ataxia		X	X	*	
Decreased consciousness, altered mental status, coma		X	X	*	
Seizure or seizure disorder		X	X	*	
Paralysis (in any combination)		X	X	*	
Conjugate deviation of eyes		X	X	*	
Tube feeding (enteral nutrition)		X	X	*	
Perenteral nutrition		X	X	*	
Any other post-stroke disability		X	X	*	
Large vessel pre-cerebral atherosclerosis		X	X	*	
Other cerebral ischemic signs or symptoms		X	X	*	
Large vessel pre-cerebral atherosclerosis		X	X	X	
Specific evidence-based measures influencing post-stroke outcomes					
Admission glucose (for a 100mg/dl increment in glucose) (elevated glucose)		X	X	X	

Table 7. Patient-Level Predictors of Outcomes and Source of Information					
Measure	**Past Admits**	**ED**	**Index Admit**	**Transfer Hospital**	**Excluded from Models**
Acute myocardial infarction		X	X	X	
Left sided valvular heart disease		X	X	X	
Right sided valvular heart disease		X	X	X	
Atrial fibrillation		X	X	X	
Other cardiac arrhythmias		X	X	X	
Systolic heart failure		X	X	X	
History of CHF (left heart failure, cardiomyopathy)		X	X	X	
Any Ischemic Heart Disease: Coronary artery disease, angina, acute myocardial infarction, prior myocardial infarction		X	X	X	
Hyperlipidemia		X	X	X	
Dementia or Alzheimer's Disease		X	X	X	
Low platelet count		X	X	X	
Bleeding Disorders (excluding platelet disorders)		X	X	X	
Anticoagulation		X	X	X	
Hypercoagulable state		X	X	X	
Falls		X	X		
Elixhauser Co-morbidity Indicators					
Congestive heart failure		X	X	X	
Valvular disease		X	X	X	
Pulmonary circulation disorder		X	X	X	
Peripheral vascular disorder		X	X	X	
Hypertension, uncomplicated		X	X	X	
Hypertension, complicated		X	X	X	
Chronic pulmonary disease		X	X	X	
Diabetes without chronic complications		X	X	X	
Diabetes with chronic complications		X	X	X	
Hypothyroidism		X	X	X	
Renal failure		X	X	X	
Liver disease		X	X	X	
Chronic peptic ulcer disease (includes bleeding only if obstruction is also present)		X	X	X	
HIV and AIDS		X	X	X	
Lymphoma		X	X	X	
Metastatic cancer		X	X	X	
Solid tumor without metastasis		X	X	X	
Rheumatoid arthritis/collagen vascular diseases		X	X	X	

Table 7. Patient-Level Predictors of Outcomes and Source of Information					
Measure	**Past Admits**	**ED**	**Index Admit**	**Transfer Hospital**	**Excluded from Models**
Obesity		X	X	X	
Weight loss		X	X	X	
Fluid and electrolyte disorders		X	X	X	
Blood loss anemia		X	X	X	
Deficiency anemias		X	X	X	
Alcohol abuse		X	X	X	
Drug abuse		X	X	X	
Psychoses		X	X	X	
Depression		X	X	X	
Other Health Habits					
Smoker, current		X	X	X	
Cerebrovascular disease history					
Recurrent strokes	X				
Former TIA	X				
TIA (resolved)	X				
Other factors during the initial admission period					
Fever (48 h)		X	X		
Do Not Resuscitate Order in First 24 hours			X		
Past hospitalization					
Any hospitalization in past year	X				
Transfer Indicators					
Transfer from ED		X			
Any transfers to another hospital for acute care				X	
Number of transfers to another hospital for acute care				X	X
Thrombolytic therapy during the initial presentation					
tPA and other thrombolytic procedures (ED or hosp rec)		X	X		X

*** For patients who transfer between hospitals, source applicable only for admissions with short length of stays for which credit was given to the transfer hospital**

XII. PREDICTIVE MODELING – VALIDATION

In preparation for modeling patient outcomes for the entire stroke sample (2006 to 2009), we examined predictive modeling using the validation sample of stroke patients (n=981). The goals of this portion of the study were to examine the explanatory power of measures to be found in the medical charts, some of which have been proposed to be included in the PDD (admission vital signs and lab results) and others which are likely to be predictive of patient outcome (e.g., stroke severity at admission and functional status at discharge if alive). We refer to these models as the **limited model** (PDD-derived measures plus census-derived measures at the zip code level), **intermediate models** (limited model variables plus vital signs and laboratory values), and **full models** (intermediate model variables plus additional clinical measures not yet proposed to be reported by hospitals). There are more than one version of the intermediate and full models because of differences in outcome modeling and availability of lab data in the validation set.

We model inpatient death, 30-day death (from admission), and 30-day readmission (with censoring for death) accounting for the PDD-derived measures shown in Table 7 plus additional measures from the validation data set for the intermediate and full models. Because lab data were available in 643 of the 981 validation set abstractions, analyses were performed on the entire set (not including lab measures in regressions) and limiting regression models to those observations with lab measures. Because of the large number of independent variables in these models, we also attempted to create more parsimonious models using stepwise regression for the limited model before adding chart abstraction measures to avoid potential over-fitting of the data.

Finally, we also examined the role of quality of care in predicting patient outcomes. As described in the literature review, we identified 26 quality-of-care measures relevant to the care of stroke patients during the inpatient stay. For each patient, we calculated a quality of care

score (Quality Score) equal to the number of recommended processes of care received divided by the total number of eligible processes of care. The total number of eligible processes of care varies by patient. The Quality Score can be interpreted as a general proxy for care quality since it is assumed (and hoped) that measurable quality is associated with unmeasured recommended and appropriate care. For example, patients who die in the hospital will not be eligible for quality of care measures related to patient discharge. The Quality Score was included in regression analyses to demonstrate a link between processes of care and patient outcomes, one of the goals of the validation study.

Results of these models are compared across a number of measures. Global measures of goodness of fit (R-squared and log-likelihood) and local measures (z-score and p-values for included measures) were examined across the models. Finally, we examined goodness of fit within models by comparing model performance in predicting actual events using the C-statistic, allowing for dynamic comparison depending upon cutoff thresholds for classifying predicted probabilities.

Results

Regression modeling of outcomes using the validation data set shows reasonable to excellent results for model estimation for the selected outcomes (Appendix J: Tables J-1 through J-10). Focusing first on inpatient mortality (Appendix J: Table J-1), PDD-based predictors yield a pseudo-R^2 of 0.18, rising to 0.29 with the addition of vital signs and to 0.43 with the inclusion of the NIHSS in the models. Taken alone, the NIHSS by itself has a pseudo-R^2 of 0.22. In the subset of observations for which lab data are available, inclusion of lab data in the regression models provide a moderate improvement in model prediction for stroke outcomes (Appendix J: Table J-2). Examination of the C-statistic shows that model predictions are good with just PDD

measures (0.85) and excellent with the addition of vitals and the NIHSS (0.92). In the subset of data with admission labs, the C-statistic was even better with addition of lab results (0.94) (Appendix K).

Models predicting 30-day mortality are less predictive, but still perform moderately well with the observable information. The limited model has a pseudo-R^2 of 0.24, rising to 0.32 with the addition of the NIHSS (Appendix J: Table J-3). In the subset of observations with lab results, the full model (including lab results) has a pseudo-R^2 of 0.36 (Appendix J: Table J-4). The C-statistic for the limited model shows fair to good performance (0.80) with very good performance for the full model (excluding labs – 0.86). In the subset of data with lab results, performance is better (0.90) (Appendix K). Knowledge of function at discharge (as measured by ambulatory status) adds little information to the 30-day mortality model.

Impact of Quality of Care

In sensitivity analyses, we examined the relationship between quality and mortality. In both unadjusted and multivariate adjusted comparisons, increases in the derived Quality Score (raw pass rate for eligible processes of care) were associated with better patient outcomes (inpatient death and 30-day mortality, $P < 0.01$ for each comparison) (Appendix L-1 through L-5). This relationship remained for 30-day mortality even when inpatient deaths were excluded (Appendix M). In contrast, quality was not predictive of patient readmission. Selection effects associated with receipt of these measures may be associated with patient outcomes, potentially overstating the actual relationship between quality of care and outcomes. Nevertheless, these findings are consistent with expectations and warrant a more detailed analysis of the quality data collected in this study.

Summary

Based upon the validation data set, model performance for the two mortality outcomes appears to be reasonable within the limitations of the routinely collected inpatient data. Importantly, the addition of a limited number of clinical measures (primarily the NIHSS) results in very good to excellent model performance in the validation set. General measures (such as vital signs and admission labs) are predictive, but less important than the NIHSS. Despite these limitations, regression estimates using the limited model are good despite the lack of clinical measures, giving greater confidence for using existing data for overall stroke predictive modeling and hospital ranking.

XIII. STATEWIDE STROKE COHORT CHARACTERISTICS

After exclusions for age and inpatient transfers preceding patient stroke, the overall stroke cohort between December 2006 and 2009 totaled 104,918 individual cases. Of these, 2,884 "likely transfers" (based upon source of admission, but not evidence of preceding hospitalization in the PDD) also would be excluded based upon criteria used in other inpatient outcomes reporting. Among eligible patients, 6,098 were seen and transferred from an emergency department at a different hospital, 4,346 were transferred to another acute care hospital after the initial stroke admission, and 305 patients were both transferred from an ED to the stroke hospital and transferred to another hospital after the stroke admission. In general, patients admitted directly or through another hospital's emergency department appear to be younger (Table 8A). In contrast, hospital-to-hospital transfer patients have a greater proportion of minorities and stay in the hospital the longest.

Predictors selected for regression models are shown in Table 8B. Commonly reported stroke disabilities in the PDD used in the prediction models include hemiplegia (34.3%), aphasia (17.2%), dysarthria (15.5%), facial palsy (10.8%), and dysphagia (10%). Other measures of neurologic impact – seizures (6.2%) and altered level of consciousness (3.1%) – are reported much less commonly. Co-morbid illnesses– atrial fibrillation (24.4%), ischemic heart disease (25.7%), heart failure (15.8%), valvular heart disease (8.3%), hypertension (72.8%), hyperlipidemia (46.8%), and diabetes (30%) – are prevalent. Beyond the 90 day exclusion period, 13.9% of patients had a prior stroke up to two years before the index stroke admission, and another 6.1% had a Transient Ischemic Attack (TIA) in the same period. Patients requiring inpatient transfers from the index stroke hospital to other general acute care hospitals appear to have greater rates of stroke disability and co-morbid conditions as compared to patients not

requiring such transfers. In contrast, patients seen in the emergency department and transferred to a second hospital for inpatient stroke care appear to have similar rates of neurologic disability and co-morbid conditions as compared to patients seen and discharged from a single hospital.

Table 8A: Stroke Cohort Characteristics by Transfer Status						
	ALL	**No Transfers**	**ED Transfers**	**Transfer to Index Stroke Hospitalization**	**ED & HH Transfers**	**Likely Transfers**
N	104,918	91,285	6,098	4,346	305	2,884
DEMOGRAPHICS						
Age in Years at Admission (mean)	72.3	72.6	70.2	71.2	67.2	71.3
Age in Years at Admission (median)	75	75	72	74	69	74
AGE BREAKDOWN (%)						
18-29	0.4	0.4	0.8	0.7	2.3	0.8
30-39	1.4	1.3	2.1	1.9	3.6	1.8
40-49	5.5	5.3	7.5	5.6	9.5	6.3
50-59	12.9	12.8	15.1	13.0	13.8	13.4
60-69	18.2	18.2	18.5	19.1	21.6	17.7
70-79	24.1	24.0	23.7	26.4	25.6	24.9
80-89	28.6	28.9	25.1	26.9	20.3	27.3
90+	8.9	9.1	7.2	6.4	3.3	7.8
RACE/ETHNICITY (%)						
White	59.2	59.2	61.2	55.8	58.0	58.9
Black	10.5	10.4	10.1	11.3	11.1	11.8
Hispanic	17.5	17.3	18.1	20.5	19.0	15.9
Asian	9.5	9.7	6.7	8.4	7.5	8.3
Other/Unknown	3.4	3.3	3.9	4.0	4.3	5.2
GENDER (%)						
Male	47.1	46.6	48.9	50.0	53.8	50.9
Female	52.9	53.4	51.1	50.0	46.2	49.1
EARLY DNR ORDERS (%)						
Yes	12.4	12.4	13.0	8.5	6.6	16.7
HOSPITALIZATION						
Length of stay (Mean)	5.1	5.0	5.2	5.2	5.4	6.4
Length of stay (Median)	4	4.0	4.0	3.0	3.0	4.0
Days in episode	5.7	5.0	5.6	17.1	16.7	7.3
# hospital transfers (mean)	0	0	0	1.1	1.1	0.1
OUTCOMES						
30D mortality, no hospital death	6	6.0	6.5	5.0	5.6	6.8
30D mortality(%) index admit date	11.3	11.0	11.5	13.8	13.1	16.0
30D mortality(%) from index discharge date	12.3	11.9	12.5	15.8	13.8	17.6
30D mortality(%) from episode discharge date	12.4	11.9	12.5	18.4	16.1	17.8
Hospital mortality	5.8	5.4	5.4	11.0	9.5	10.5
30D readmission	12.7	12.5	12.4	17.3	16.1	14.1

Table 8B: Prevalence of Conditions by Transfer Status						
Parameter Name	**Overall**	**No Transfers**	**ED Transfers**	**Transfer to Index Stroke Hospitalization**	**ED & HH Transfers**	**Likely Transfers**
Facial Palsy	10.81	10.50	12.07	14.10	15.41	12.41
Dysathria	15.48	15.33	15.20	18.94	22.30	15.01
Any Post Stroke Disability	2.51	2.52	2.33	2.53	3.28	2.53
Aphasia	17.24	16.80	16.74	23.95	20.66	21.57
Hemiplegia/Hemiparesis	34.30	33.48	35.06	46.00	48.85	39.42
Other Paralysis	1.12	1.09	0.97	1.52	2.95	1.63
Hemineglect	0.70	0.66	0.90	0.81	1.64	1.49
Vision Loss	2.36	2.37	2.20	2.16	3.28	2.74
Apraxia	0.41	0.41	0.48	0.35	--	0.59
Ataxia	6.26	6.36	6.28	4.76	7.21	5.24
Decreased Consciousness	3.05	2.95	2.80	4.30	4.26	4.65
Seizure or Seizure Disorder	6.24	6.06	6.35	8.40	7.87	8.08
Conjugate Deviation of the Eye	0.04	0.04	--	0.05	--	0.07
Other Cerebral Ischemic Signs or Symptoms	1.61	1.58	1.53	2.25	2.30	1.84
Total Parenteral Nutrition (TPN)	0.41	0.38	0.33	0.87	--	0.59
Dysphagia	9.96	9.72	9.38	14.59	11.80	11.51
Admission Glucose	1.99	1.93	1.94	2.42	4.92	2.95
Acute MI	1.65	1.52	1.33	3.45	2.62	3.50
Left Sided Valvular Heart Disease	1.20	1.17	1.18	1.59	2.95	1.60
Right Sided Valvular Heart Disease	1.42	1.41	1.51	1.45	1.31	1.35
Atrial Fibrillation	24.37	24.12	22.53	28.62	25.57	29.40
Cardiac Arrest	2.42	2.24	2.66	4.28	7.21	4.16
Systemic Heart Failure	0.08	0.07	0.07	0.07	0.33	0.31
History of Congestive Heart Failure	15.81	15.57	15.40	19.58	15.74	18.45
Any Ischemic Heart Disease	25.70	25.51	24.45	29.80	25.57	28.09
Hyperlipidemia	46.82	46.73	46.49	47.17	49.18	49.69
Dementia or Alzheimer's Disease	5.76	5.87	4.95	5.20	3.28	4.96
Low Platelet Count	0.13	0.12	0.15	0.25	--	0.17
Bleeding Disorders (excluding platelet disorders)	0.46	0.43	0.44	0.92	0.98	0.52
Anticoagulation	7.01	6.93	6.59	7.66	9.84	9.12
Hypercoagulable State	0.58	0.56	0.57	0.71	1.31	0.80
Falls	3.56	3.32	6.67	3.91	5.90	3.68
Current Smoker	11.63	11.17	12.94	17.46	18.36	14.08
Recurrent Stroke	13.94	13.86	13.30	13.62	11.80	18.62
Former TIA	6.13	6.06	6.79	6.10	5.57	7.21
TIA Resolved	5.73	5.64	6.18	6.58	5.57	6.10

Table 8B: Prevalence of Conditions by Transfer Status						
Parameter Name	**Overall**	**No Transfers**	**ED Transfers**	**Transfer to Index Stroke Hospitalization**	**ED & HH Transfers**	**Likely Transfers**
Fever 48h	0.28	0.26	0.48	0.35	0.98	0.38
Valvular Disease	8.32	8.32	7.74	8.54	8.85	9.36
Pulmonary Circulation Disease	1.97	1.95	1.67	2.21	2.30	2.67
Peripheral Vascular Disease	7.79	7.67	8.46	7.75	8.20	10.06
Hypertension	72.83	72.86	71.52	74.16	68.85	73.02
Paralysis	10.17	9.83	10.72	14.01	16.39	13.21
Other Neurological Disorders	8.39	8.20	8.38	10.24	9.84	11.20
Chronic Pulmonary Disease	12.35	12.24	12.89	13.32	12.46	13.18
Diabetes without Chronic Complications	23.37	23.41	22.11	26.74	24.59	19.42
Diabetes with Chronic Complications	7.59	7.48	8.49	6.65	6.89	10.54
Hypothyroidism	12.90	13.03	12.02	11.60	8.85	13.25
Renal Failure	12.32	12.19	12.28	13.00	12.13	15.57
Liver Disease	1.32	1.29	1.69	1.15	0.98	1.63
Ulcer	0.04	0.04	0.05	0.02	--	0.03
AIDS	0.03	0.03	0.02	0.02	--	0.07
Lymphoma	0.34	0.34	0.41	0.37	0.33	0.28
Metastatic Cancer	1.20	1.20	1.13	1.36	1.31	1.35
Solid tumor without Metastasis	1.60	1.56	1.87	1.68	1.64	2.18
Rheumatoid Arthritis	2.12	2.15	1.82	1.75	2.30	2.32
Obesity	8.04	8.01	8.84	7.50	6.89	8.15
Weight Loss	2.49	2.41	2.57	3.27	3.28	3.74
Fluid and Electrolyte Disorders	17.01	16.95	14.97	20.92	22.30	16.75
Chronic Blood Loss Anemia	0.50	0.47	0.52	0.67	0.66	1.01
Deficiency Anemias	14.28	14.22	12.40	16.22	13.44	17.27
Alcohol Abuse	3.46	3.37	4.21	3.89	4.59	3.88
Drug Abuse	2.15	2.11	2.67	2.19	4.26	2.01
Psychoses	2.81	2.74	3.36	2.81	3.28	3.92
Depression	8.43	8.46	8.82	6.99	7.87	8.70

XIV. PREDICTIVE MODELING – STATEWIDE RESULTS

For each ischemic stroke index admission, a longitudinal record identified the index admission, acute care episode, prior admissions, and subsequent outcomes (death and readmission). In predictive modeling, we examined risk-adjusted mortality and hospital readmission using standard logistic regression models (inpatient death, 30-day death, 30-day readmission, and 30-day death excluding inpatient death) – the traditional approach to risk-adjustment used by OSHPD, and survival (Cox) regression models (30-day death and 30-day readmission censoring for death). Baseline models identified the index hospitalization as the source of key predictors for regression models. A number of sensitivity analyses were performed to account for the nature of the entire acute care episode (patient transfers, either from an outside Emergency Department or to another acute care hospital). Patients who transferred to the index stroke hospital due to likely complication at another acute care facility as reported in the PDD are excluded in all models. These cases typically are related to post-procedure or institutional setting strokes. Overall, a total of 3,783 (2.8 %) likely transfer stroke records were excluded from the analyses (Appendix N).

Independent predictors in multivariate risk adjusted models include patient demographics (age, gender, and race), the four categories of patient admission (the index record without any transfer, the index record with ED transfers, the index record with transfers to index stroke hospitalizations, and the index record with both ED transfers and transfers to index stroke hospitalizations), stroke severity (as measured by stroke reported disability and related conditions in the PDD), co-morbidity (Elixhauser indicators plus independent predictors identified in the literature review), health habits (smoking and alcohol use reported in the PDD), proxy measures of socioeconomic status (Census 2000 measures by zip code), and proxy

measures for access to stroke care (distances to closest high, medium, and low volume hospital treating acute stroke patients). All regressions use robust regression techniques for standard error estimates to account for clustering of observations within hospitals.

Results

Overall logistic regression models predicting inpatient death and death within 30 days demonstrate model performance similar to that seen in the validation set restricted to predictors only available in the PDD and other routinely collected data. Overall measures of model fit were similar to that seen in the validation set. Predictive performance for regression models for both the inpatient death and for the 30-day mortality models as measured by area under the curve (C-statistic) were good – inpatient death: 0.824; 30-day death: 0.825; and 30-day death excluding inpatient deaths: 0.820. Numerically, these results are substantially similar to what was seen in the validation data set. Because of the large number of observations in the three year cohort, many more predictors reach statistical significance than were seen in the validation set. Full model regression coefficients and risk adjusted odds ratios with confidence intervals are given below in Table 9 (validation cohort and three year statewide cohort) and by outcome in Appendix J.

Table 9: Regression Model Coefficient Estimates: 30 Day Mortality after Admission					
Parameter	**Model Estimate**	**P-value**	**OR**	**95% Confidence Interval**	
Intercept	-6.3503	<.0001			
Age in Years at Admission	0.0518	<.0001	1.05	1.05	1.06
Male	-0.0205	0.4574	0.98	0.93	1.03
Black	-0.7201	<.0001	0.49	0.44	0.55
Hispanic	-0.4289	<.0001	0.65	0.60	0.71
Asian	-0.5175	<.0001	0.60	0.52	0.68
Other Race-Ethnicity	-0.2837	<.0001	0.75	0.66	0.86
ED Transfer	0.1490	0.0154	1.16	1.03	1.31
HH Transfer	0.1396	0.1053	1.15	0.97	1.36
ED + HH Transfer	0.2062	0.3532	1.23	0.80	1.90
Nursing Source of Admit	0.5501	<.0001	1.73	1.59	1.89
Other Source of Admit	0.1212	0.2464	1.13	0.92	1.39
Distance to High Volume Hospital	0.0002	0.7005	1.00	1.00	1.00
Distance to Medium Volume Hospital	0.0011	0.3488	1.00	1.00	1.00
Distance to Low Volume Hospital	-0.0015	0.1797	1.00	1.00	1.00
Rural (≥40% of pop)	0.0262	0.6553	1.03	0.92	1.15
% <200% Poverty	-0.0032	0.0359	1.00	0.99	1.00
% College	-0.0047	0.0006	1.00	0.99	1.00
Facial Palsy	-0.0997	0.0096	0.91	0.84	0.98
Dysarthria (inability to articulate)	-0.3972	<.0001	0.67	0.63	0.72
Any Post-Stroke Disability	-0.0668	0.3633	0.94	0.81	1.08
Aphasia	0.2795	<.0001	1.32	1.25	1.40
Hemiplegia/Hemiparesis	0.5611	<.0001	1.75	1.64	1.87
Other Paralysis	0.3134	0.0035	1.37	1.11	1.69
Hemineglect	0.2902	0.0243	1.34	1.04	1.72
Vision Loss	-0.1898	0.0125	0.83	0.71	0.96
Apraxia	-0.8625	0.0007	0.42	0.26	0.70
Ataxia	-0.8910	<.0001	0.41	0.36	0.47
Decreased consciousness, altered mental status, coma	1.6092	<.0001	5.00	4.43	5.64
Seizure or seizure disorder	0.3147	<.0001	1.37	1.26	1.49
Conjugate deviation of eyes	1.2246	0.0029	3.40	1.52	7.61
Other cerebral ischemic signs or symptoms	-0.1781	0.0538	0.84	0.70	1.00
Perenteral nutrition	0.5023	0.0042	1.65	1.17	2.33
Dysphagia	0.1644	<.0001	1.18	1.09	1.28
Admission elevated glucose	0.1411	0.0963	1.15	0.98	1.36
Acute myocardial infarction	0.8083	<.0001	2.24	1.97	2.55
Left sided valvular heart disease	-0.0868	0.4649	0.92	0.73	1.16
Right sided valvular heart disease	-0.0827	0.4300	0.92	0.75	1.13
Atrial fibrillation	0.4771	<.0001	1.61	1.54	1.69
Cardiopulmonary arrest	1.7183	<.0001	5.58	4.95	6.28
Systolic heart failure	-0.0733	0.8432	0.93	0.45	1.92
History of CHF (Left heart failure, cardiomyopathy)	0.4358	<.0001	1.55	1.46	1.64
Any Ischemic heart disease: CAD, angina, AMI, prior MI	0.0650	0.0216	1.07	1.01	1.13
Hyperlipidemia	-0.4642	<.0001	0.63	0.60	0.66
Dementia or Alzheimer's disease	0.2554	<.0001	1.29	1.18	1.42
Low platelet count	0.0226	0.9476	1.02	0.52	2.01
Bleeding disorders (no platelet disorders)	0.5160	0.0010	1.68	1.23	2.28
Anticoagulation	-0.1963	<.0001	0.82	0.76	0.90

Table 9: Regression Model Coefficient Estimates: 30 Day Mortality after Admission					
Parameter	**Model Estimate**	**P-value**	**OR**	**95% Confidence Interval**	
Hypercoagulable state	0.4177	0.0164	1.52	1.08	2.14
Falls	-0.0135	0.8132	0.99	0.88	1.10
Current smoker	-0.0359	0.3614	0.97	0.89	1.04
Recurrent strokes	0.0452	0.2044	1.05	0.98	1.12
Former TIA	-0.0247	0.5623	0.98	0.90	1.06
TIA resolved	0.1595	0.0008	1.17	1.07	1.29
Fever within 48 h	0.6203	0.0002	1.86	1.34	2.58
Valvular disease	-0.0945	0.0203	0.91	0.84	0.99
Pulmonary circulation disease	-0.0353	0.6291	0.97	0.84	1.11
Peripheral vascular disease	0.1959	<.0001	1.22	1.12	1.32
Hypertension	-0.0896	0.0013	0.91	0.87	0.97
Paralysis	0.2537	<.0001	1.29	1.20	1.38
Other neurological disorders	0.0441	0.3550	1.05	0.95	1.15
Chronic pulmonary disease	0.0432	0.2228	1.04	0.97	1.12
Diabetes w/o chronic complications	0.1073	0.0003	1.11	1.05	1.18
Diabetes w/ chronic complications	0.0542	0.2635	1.06	0.96	1.16
Hypothyroidism	-0.1602	<.0001	0.85	0.80	0.91
Renal failure	0.2626	<.0001	1.30	1.21	1.40
Liver disease	0.4081	<.0001	1.50	1.23	1.85
Peptic ulcer disease with bleeding	0.4557	0.3348	1.58	0.63	3.98
Acquired immune deficiency syndrome	0.2475	0.7725	1.28	0.24	6.86
Lymphoma	0.3519	0.0386	1.42	1.02	1.99
Metastatic cancer	1.9593	<.0001	7.10	6.06	8.30
Solid tumor w/out metastasis	0.6631	<.0001	1.94	1.68	2.24
Rheumatoid arthritis/collagen vas	0.0082	0.9232	1.01	0.85	1.19
Obesity	-0.2142	0.0002	0.81	0.72	0.90
Weight loss	0.2259	0.0012	1.25	1.09	1.44
Fluid and electrolyte disorders	0.2478	<.0001	1.28	1.21	1.36
Chronic blood loss anemia	-0.0088	0.9513	0.99	0.75	1.32
Deficiency anemias	-0.0545	0.1197	0.95	0.88	1.01
Alcohol abuse	-0.0409	0.5791	0.96	0.83	1.11
Drug abuse	0.2485	0.0338	1.28	1.02	1.61
Psychoses	-0.2461	0.0010	0.78	0.68	0.91
Depression	-0.1059	0.0128	0.90	0.83	0.98

Evaluation of the predictive performance of these models demonstrates reasonably good calibration between observed and expected events. Comparing predicted events by decile of predicted probability of mortality demonstrates that the cumulative risk of events corresponds to the observed rates of death by event risk decile. In general, the model tends to under-predict events among the highest decile risk individuals and over predict for those in the lowest decile risk groups. Total numbers of predicted events are similar as expected (Table 10).

In sensitivity analyses, we find that the inclusion of CPOA flags for determining preexisting conditions for model predictions slightly worsened model performance. We also explored other model variants, including thresholds for patient outcomes depending on whether a patient is a short-stay (two days or less) and is transferred to another facility. These marginal changes do not substantively affect the model performance. However, hospital rankings (next section) can change somewhat if a hospital happens to be a major recipient of transfer patients. Accounting for ED transfers is quite important in this context, but based on prior work, only hospitals with the actual inpatient stay are ranked with regards to patient outcomes. Using two years of data for model prediction instead of the three years of data for these validation models does not substantially change point estimates for regression results, but does change the precision of these measures – fewer observations in the two year sample means fewer regressors have statistically significant risk-adjusted estimates. Use of stepwise regression does create a more parsimonious model with minimal changes in the predictive accuracy of the model as measured by the C-statistic (Appendix O: Table O-1).

Table 10: Observed Deaths by Decile of Predicted Probability of 30-day Death

group	N	Observed	Predicted	Difference	95% CI of predicted death	
1	10,202	108	78.11	-29.89	63.63	96.50
2	10,203	128	164.80	36.80	136.00	200.77
3	10,203	198	256.17	58.17	212.59	310.11
4	10,203	276	371.42	95.42	309.37	447.45
5	10,203	449	521.19	72.19	435.76	625.15
6	10,203	663	723.35	60.35	606.78	864.49
7	10,203	949	1,003.49	54.49	844.19	1,193.93
8	10,203	1,591	1,434.77	-156.23	1,210.26	1,699.17
9	10,203	2,537	2,204.57	-332.43	1,872.25	2,583.69
10	10,208	4,521	4,624.68	103.68	4,096.55	5,162.66
	102,034	**11,420**	**11,382.60**	**-37.44**		

Alternate outcomes (30-day readmission, time to readmission, and time to death) and models (survival analysis) yield complementary results to the mortality models, but have much worse

performance as measured by the C-statistic. For example, the logistic regression model predicting readmission (but not accounting for death) yields a C-statistic of 0.627 (Tables 11 and 12). The predictive performance of these models demonstrates reasonably good calibration between observed and expected events. In general, the model tends to under-predict events within the middle deciles and over predict for those in the lowest and in the highest decile risk groups. Total numbers of predicted events are similar (Table 12). These results are not dissimilar from other models that have attempted to predict readmission and which are now being used to rate hospitals in other venues, such as CMS Hospital Compare. Again, stepwise regression results in a more parsimonious model with minimal impact on model prediction (Appendix O: Table O-2).

Table 11: Regression Model Coefficient Estimates: 30 Day Readmission after Discharge					
Label	**Model Estimate**	**P-value**	**Odds Ratio**	**95% Confidence Interval**	
Intercept: readmit_30d=0	-2.6808	<.0001			
Age in Years at Admission	0.00373	<.0001	1.00	1.00	1.01
Male	0.0365	0.0641	1.04	1.00	1.08
Black	0.092	0.0053	1.10	1.03	1.17
Hispanic	0.0253	0.4005	1.03	0.97	1.09
Asian	0.019	0.6112	1.02	0.95	1.10
Other Race-Ethnicity	-0.0698	0.2325	0.93	0.83	1.05
ED transfer	0.025	0.5995	1.03	0.93	1.13
HH transfer	0.3982	<.0001	1.49	1.36	1.63
ED + HH transfer	0.3762	0.0144	1.46	1.08	1.97
Nursing Source of Admit	-0.00178	0.9682	1.00	0.92	1.09
Other Source of Admit	-0.1424	0.1089	0.87	0.73	1.03
Distance to high volume hospital (miles)	-0.00236	<.0001	1.00	1.00	1.00
Distance to medium volume hospital (miles)	-0.00037	0.744	1.00	1.00	1.00
Distance to low volume hospital (miles)	0.00267	0.0097	1.00	1.00	1.01
Rural (≥40% of pop)	-0.1001	0.0647	0.91	0.81	1.01
% Individuals w/Income <200% Poverty	0.00106	0.2181	1.00	1.00	1.00
% Adults with 4 or more yrs college	-0.00043	0.676	1.00	1.00	1.00
Facial palsy	-0.1141	0.0009	0.89	0.83	0.95
Dysarthria (inability to articulate)	-0.0525	0.0621	0.95	0.90	1.00
Any post-stroke disability	0.00569	0.9266	1.01	0.89	1.14
Aphasia	0.0327	0.236	1.03	0.98	1.09
Hemiplegia/Hemiparesis	0.0312	0.2354	1.03	0.98	1.09
Other paralysis	0.0288	0.7371	1.03	0.87	1.22
Hemineglect	-0.039	0.7339	0.96	0.77	1.20
Vision loss	0.0796	0.2128	1.08	0.96	1.23
Apraxia	-0.1238	0.4129	0.88	0.66	1.19
Ataxia	-0.0725	0.0555	0.93	0.86	1.00
Decreased consciousness, altered mental status, coma	-0.081	0.2025	0.92	0.81	1.05
Seizure or seizure disorder	0.1989	<.0001	1.22	1.13	1.32

Table 11: Regression Model Coefficient Estimates: 30 Day Readmission after Discharge					
Label	**Model Estimate**	**P-value**	**Odds Ratio**	**95% Confidence Interval**	
Conjugate deviation of eyes	-0.7427	0.3184	0.48	0.11	2.05
Other cerebral ischemic signs or symptoms	-0.0324	0.7208	0.97	0.81	1.16
Perenteral nutrition	0.1018	0.4773	1.11	0.84	1.47
Dysphagia	0.2471	<.0001	1.28	1.20	1.37
Admission elevated glucose	-0.0151	0.8229	0.99	0.86	1.12
Acute myocardial infarction	0.1501	0.0448	1.16	1.00	1.35
Left sided valvular heart disease	-0.0799	0.3836	0.92	0.77	1.11
Right sided valvular heart disease	-0.207	0.0267	0.81	0.68	0.98
Atrial fibrillation	0.1164	<.0001	1.12	1.06	1.19
Cardiopulmonary arrest	0.256	0.0005	1.29	1.12	1.49
Systolic heart failure	0.0929	0.7967	1.10	0.54	2.23
History of CHF (Left heart failure, cardiomyopathy)	0.1752	<.0001	1.19	1.13	1.26
Any Ischemic Heart Disease: CAD, angina, AMI, prior MI	0.1101	<.0001	1.12	1.07	1.17
Hyperlipidemia	-0.0936	<.0001	0.91	0.87	0.95
Dementia or Alzheimer's Disease	-0.0002	0.9958	1.00	0.93	1.08
Low platelet count	0.34	0.1317	1.41	0.90	2.19
Bleeding Disorders (no platelet disorders)	0.0501	0.7176	1.05	0.80	1.38
Anticoagulation	0.0465	0.2302	1.05	0.97	1.13
Hypercoagulable state	0.2844	0.0224	1.33	1.04	1.70
Falls	0.1225	0.0138	1.13	1.03	1.25
Current Smoker	0.0249	0.4074	1.03	0.97	1.09
Recurrent Strokes	0.0876	0.0008	1.09	1.04	1.15
Former TIA	0.157	<.0001	1.17	1.09	1.26
TIA resolved	0.2023	<.0001	1.22	1.14	1.32
Fever within 48 h	0.2779	0.1215	1.32	0.93	1.88
Valvular disease	0.0745	0.0714	1.08	0.99	1.17
Pulmonary circulation disease	0.1314	0.0717	1.14	0.99	1.32
Peripheral vascular disease	0.1048	0.001	1.11	1.04	1.18
Hypertension	0.109	<.0001	1.12	1.07	1.16
Paralysis	0.1974	<.0001	1.22	1.13	1.31
Other neurological disorders	0.0562	0.1535	1.06	0.98	1.14
Chronic pulmonary disease	0.1114	0.0001	1.12	1.06	1.18
Diabetes w/o chronic complications	0.1421	<.0001	1.15	1.10	1.21
Diabetes w/ chronic complications	0.2812	<.0001	1.33	1.23	1.43

Table 11: Regression Model Coefficient Estimates: 30 Day Readmission after Discharge					
Label	**Model Estimate**	**P-value**	**Odds Ratio**	**95% Confidence Interval**	
Hypothyroidism	-0.0139	0.6527	0.99	0.93	1.05
Renal failure	0.3291	<.0001	1.39	1.31	1.48
Liver disease	0.3429	<.0001	1.41	1.22	1.63
Peptic ulcer disease with bleeding	-0.00372	0.9938	1.00	0.39	2.56
Acquired immune deficiency syndrome	-0.1974	0.7207	0.82	0.28	2.42
Lymphoma	0.5468	<.0001	1.73	1.35	2.21
Metastatic cancer	0.546	<.0001	1.73	1.47	2.03
Solid tumor w/out metastasis	0.2409	0.0006	1.27	1.11	1.46
Rheumatoid arthritis/collagen vas	0.1311	0.0614	1.14	0.99	1.31
Obesity	-0.0426	0.2491	0.96	0.89	1.03
Weight loss	0.3228	<.0001	1.38	1.21	1.57
Fluid and electrolyte disorders	0.1838	<.0001	1.20	1.15	1.26
Chronic blood loss anemia	0.4288	0.0001	1.54	1.23	1.91
Deficiency anemias	0.2477	<.0001	1.28	1.22	1.35
Alcohol abuse	-0.0461	0.4036	0.96	0.86	1.06
Drug abuse	0.1331	0.0559	1.14	1.00	1.31
Psychoses	0.1479	0.0067	1.16	1.04	1.29
Depression	0.0411	0.2101	1.04	0.98	1.11

Table 12: Observed Readmits by Decile of Predicted Probability of 30-day Readmits						
Group	**N**	**Observed**	**Predicted**	**Difference**	**95% CI of predicted death**	
1	9,627	681	694.68	13.68	609.89	795.49
2	9,628	741	842.06	101.06	752.81	943.16
3	9,628	848	923.40	75.40	824.24	1,035.10
4	9,628	1,025	1,004.43	-20.57	891.50	1,132.04
5	9,628	1,110	1,092.77	-17.23	964.69	1,237.80
6	9,628	1,238	1,196.47	-41.53	1,050.60	1,361.71
7	9,628	1,438	1,325.75	-112.25	1,156.32	1,518.99
8	9,628	1,592	1,500.99	-91.01	1,301.45	1,728.66
9	9,628	1,844	1,775.45	-68.55	1,531.70	2,051.74
10	9,625	2,409	2,525.06	116.06	2,158.74	2,931.57
	96,276	**12,926**	**12,881.10**	**-44.95**		

XV. PREDICTIVE MODELING – STATEWIDE RESULTS: RISK-ADJUSTED OUTCOMES AND HOSPITAL RANKINGS

Ranking Method

For each modeled outcome, overall risk-adjusted outcomes were calculated by hospital. These predicted outcomes are used in the creation of the indirectly standardized rates by hospital. The risk adjusted rate by hospital is obtained by multiplying the observed three years overall rate of California by the ratio of observed rate within each hospital divided by the predicted (risk-adjusted) rate. For the ith hospital, the standardized rate is given by:

_____

Each hospital is rank ordered by the standardized rates. A 98% confidence interval for the score is obtained by the assumption that the observed counts follow a Poisson distribution. If the entire confidence interval (both lower confidence limits and upper confidence limits) is above the state mean, the hospital is identified as a better performer; if the entire confidence interval is below the state mean, the hospital is a poor performer; and if the state mean is within the confidence interval, the hospital's risk adjusted performance is similar to the state average (The California Report on Coronary Artery Bypass Graft Surgery 2005-2006 Hospital and Surgeon Data[2]). We also checked the predictive model by the paired t-test for each model. If the observed counts are significantly different from the predictive counts, we identify the hospital as a statistical outlier from its predicted performance.

Because multiple outcomes were examined, we explored whether there is concordance in rankings despite using different outcomes. Correlation between hospital rankings were examined graphically and using the Pearson Correlation Coefficient (Appendix P). To better assess the stability of rankings, hospital rankings were categorized by quintile and then were

compared using contingency tables with kappa testing for consistency. For both graphical and tabular comparisons, we used 30-day mortality as the comparison. This type of comparison allows for a better understanding of how ranking behavior may differ between outcome measures.

Ranking Results - Agreement

Overall agreement is seen between logistic regression models predicting patient outcomes (Table 13). Predictive models of death are correlated, including different mortality-related outcomes and different modeling techniques (Logistic versus Cox). In survival models, it appears that mortality is the primary driver of this measure and hospital rankings.

Table 13: Correlation Between Patient Outcome Variables

Pearson Coefficient Prob > |r| under H0: Rho=0 # of Obs	30 Day Death	Hospital Death	30 Day Readmit	30 Day Death, No Hospital Death	30 Day Death (Cox)	30 Day Readmit (Cox)
30 Day Death	1 309	0.68404 <.0001 309	-0.12763 0.0251 308	0.67872 <.0001 309	0.40754 <.0001 308	0.47189 <.0001 308
Hospital Death	0.68404 <.0001 309	1 309	-0.02401 0.6747 308	0.04763 0.404 309	0.28302 <.0001 308	-0.02427 0.6714 308
30 Day Readmit	-0.12763 0.0251 308	-0.02401 0.6747 308	1 308	-0.10337 0.07 308	-0.08065 0.1586 307	-0.11647 0.0411 308
30 Day Death, no Hospital Death	0.67872 <.0001 309	0.04763 0.404 309	-0.10337 0.07 308	1 309	0.24704 <.0001 308	0.73931 <.0001 308
30 Day Death (Cox)	0.40754 <.0001 308	0.28302 <.0001 308	-0.08065 0.1586 307	0.24704 <.0001 308	1 308	0.46713 <.0001 307
30 Day Readmit (Cox)	0.47189 <.0001 308	-0.02427 0.6714 308	-0.11647 0.0411 308	0.73931 <.0001 308	0.46713 <.0001 307	1 308

When hospitals are compared by quintiles of hospital rankings, agreement between quintiles is centered on the diagonal rather than a random assignment of ranks (Table 14).

For example, examination of 30-day mortality from admission versus inpatient death shows clustering around the diagonal with the greatest agreement occurring at the highest and lowest quintiles (kappa = 0.29). Thus, choice of mortality outcome can move a hospital significantly between rankings, even when the choice of outcome measures is strongly related.

Table 14: Quintiles of Hospital Rankings

	Inpatient Death					
30 Day Mortality	Quintile 1	Quintile 2	Quintile 3	Quintile 4	Quintile 5	Total
Quintile 1	**33**	17	8	2	1	61
Quintile 2	11	**24**	14	11	2	62
Quintile 3	9	15	**16**	19	3	62
Quintile 4	8	4	13	**21**	16	62
Quintile 5	0	2	11	9	**40**	62
Total	61	62	62	62	62	309

Ranking Results – Hospital Rankings for Hospital and 30-day Mortality Models

After excluding hospitals with fewer than 30 observations, risk-adjusted stroke inpatient mortality rates ranged from 0.000 to 0.14 (Appendix Table Q-1). In contrast, risk-adjusted 30-day mortality outcomes range from 0.018 to 0.24. As expected, in general, 30-day mortality rates are higher than the inpatient death rates. Inpatient mortality rates appear to be biased. For most hospitals, risk-adjusted 30-day mortality is at least double versus inpatient death. Readmission models that do not account for death may generate misleading results since mortality is a more likely event than readmission, biasing measures created using logistic regression modeling. Hospital rankings for readmission are in Appendix Table Q-3.

XVI. CONCLUSIONS

Ischemic stroke is a common, severe acute illness with high short-term mortality and prolonged recovery. Patients are seen in the vast majority of acute care hospitals in California that report data to OSHPD. Thus reporting on stroke outcomes in California hospitals will reflect care delivered in most California hospitals.

Based upon inpatient, emergency department, and mortality data currently available to OSHPD, risk-adjusted mortality outcomes are feasible, reliable, and valid measures of patient outcome. Inpatient and 30-day mortality models show reasonable predictive performance. Other outcome measures appear to be less reliable or not predictable using existing data at OSHPD. From the validation portion of the work, conditions such as pneumonia, thromboembolic disease, and urinary tract infections are reliably identifiable, but the timing of these illnesses cannot reliably be distinguished as occurring before or during the acute care episode. Thus, a condition-specific inpatient complication measure cannot be recommended at this time. National stroke care recommendations are focusing on functional recovery within 90 days. Such measures of outcome are unlikely to be measured routinely in the absence of a specific funded program to do so.

Readmission models show modest fit to the data, consistent with findings found for hospital measures created by CMS. Readmission as a marker of poor care is ambiguous. Readmission may occur due to poor initial care or subsequent care, early discharge, or insufficient follow-up leading to readmission. Readmission is difficult to predict from inpatient measures. Even the addition of more detailed clinical information, as was possible in the validation data set, did not result in dramatic improvements in model fit. These findings suggest that many readmissions are sporadic (noise) or occur due to issues not captured in the initial hospitalization. Thus, hospital

quality, or at least processes of care captured in the current study, may not account for a substantial portion of hospital readmissions. Nevertheless, the endorsement of readmission at the national level compels us to consider this measure.

In the validation portion of the study, the study team demonstrated a statistically significant relationship between measured acute quality of care and patient outcomes (as measured by inpatient and 30-day mortality). Establishing the process-outcome link is important towards validating the outcome measures as reflective of care. This is critically important in the stroke domain, where stroke injury is acutely reversible in a fraction of patients, but acute complications are common.

Individual processes of care, if measured, can also be used for tracking quality. Results of the validation study show that the acute use of thrombolytics for the treatment of ischemic stroke is reliably identified in the PDD. Although indications and contraindications for administration are not available, reporting of rates of use relative to the statewide average and to a benchmark standard for expected use of thrombolytics would be informative to hospitals around the state. No other acute care process of care specific to stroke care is reliably measured in this way, even those which occur with nearly all patients, such as brain imaging, carotid artery doppler scans, echocardiograms, and speech, occupational, or physical therapies.

Do Not Resuscitate orders is a second process of care measure that could be used to track care in the stroke population. Given the mortality and morbidity associated with stroke, the use of DNR orders is important. The reporting of early DNR was reasonably reliable making their use, as with employment of thrombolytics, a potential measure of process of care for benchmarking purposes. The gold standard measures for end-of-life decision making would be evidence of discussions between providers and patients (or their surrogates) in order to make

these decisions (percentage discussing end of life care vs. percentage having DNR orders in the first 24 hours). A DNR index (% patients dying within thirty days of stroke who also have early DNR orders) would be a benchmark indication of the successful initiation of end-of-life decision making. Tracking such a measure would ensure that physicians and hospitals actively elicit patient preferences.

The addition of clinical measures in the validation data set – especially stroke severity and functional status at discharge – provided the strongest improvement to model performance. Proposed changes to the PDD (lab data and vital signs) improve model fit, but to a lesser degree. In the absence of implementing stroke-specific measures, the addition of general clinical measures would improve model performance. Unlike earlier hospital outcome reports, it is now possible to directly identify individuals transferred from outside emergency departments, an important improvement for the generalizability and validity of these results at a time when acute stroke care initiatives are focusing on regional stroke referral centers.

Geocoding address rather than relying solely upon patient zip code does improve the precision of related estimates (calculated travel distance, small area estimates of income, education, insurance, and acculturation), but does not appear to dramatically change findings at least within the validation portion of the study. The impact of such improvements in precision and granularity are likely to vary based upon the type of study performed.

XVII. RECOMMENDATIONS

Choice of Outcome Measures

- Use 30-day mortality outcomes, which overcome potential biases in relying upon inpatient deaths that are biased by a hospital's ability to transfer patients.
- Consider 30-day readmission as an alternative measure of outcome
- Report use of thrombolytics in stroke patients relative to the state average and to other benchmarks (e.g., top 10% in the state); could be added to the annual hospital utilization file
- Consider reporting percentage of patients with early DNR among patients dying within 30 days; could be added to the annual hospital utilization file
- Replace OSHPD's current stroke hospital inpatient mortality measure (AHRQ IQI) with the validated acute ischemic stroke 30-day mortality measure

Data Improvement for Risk Adjustment

- Institute planned general data improvement efforts with the addition of clinical and laboratory data because these measures have significant explanatory power
- Request reporting of a prospectively measured stroke severity score
- Consider adding a measure of functional status at discharge, which would generalize beyond stroke patients
- Incorporate EDD records to identify ED transfers into all hospital outcomes reporting for acute conditions because the source of admission variable in the PDD is inaccurate

- Develop and disseminate training materials on the use of CPOA qualifiers to hospitals and their staff in order to improve the distinction between pre-existing or concurrent acute conditions versus hospital complications.

Regulatory Authority to Assess Care Beyond Outcomes

- Expand the scope of the outcomes reporting program to include measurement of clinical care – processes of care and their indications – and the ability to audit such measures.

Ongoing Validation of California Hospital Stroke Outcomes

- Build a relationship with the ASA-AHA "Get with the Guidelines" program to link OSHPD data with their ongoing quality improvement program data. Although not a random sample of hospitals, it may prove to be a cost effective approach and could serve as a template for a new approach to outcomes reporting by OSHPD.

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[1] Goldman LE, Chu PW, Prothro C, Osmond D, Bindman A. Accuracy of Condition Present On Admission, Do Not Resuscitate, and E-Codes in California Patient Discharge Data. Sacramento: Office of Statewide Health Planning and Development; 2011.

[2] State of California, Office of Statewide Health Planning and Development. *The California Report on Coronary Artery Bypass Graft Surgery 2005-2006 Hospital and Surgeon Data*, Sacramento, CA: Office of Statewide Health Planning and Development, March 2009.